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Besani et al describe the role and function of a paediatric psycho-oncology service. The team dealt with 316 referrals over a 32 months period.

CHARACTERISTICS OF CENTENARIANS IN THE IRISH HIP FRACTURE DATABASE

Hogan et al describe 57 patients aged over 100 years with a hip fracture. 52 were women. 88% per cent were discharged alive. The fractures were due to low velocity trauma, indicating underlying osteoporosis.

<u>CUTANEOUS MELANOMA AND SENTINEL LYMPH NODE BIOPSY; AN EPIDEMIOLOGY STUDY OF POPULATION LEVEL DATA</u>

Scanlon et al report on 13,302 cases with melanoma over a 20 year period. The overall survival rate was 65.4% in men, and 75.1% in women.

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GUIDELINES FOR THE USE OF THE ATTEND ANYWHERE PLATFORM FOR TELECOMMUNICATIONS WITHIN THE PAIN SERVICE

Skelly and O'Connor propose guidelines on how a Health Care Worker (HCW) might consider approaching a virtual consultation when initiating and safely executing a patient encounter on Attend Anywhere, in a secure and efficient manner.

A STUDY OF GP WORKLOAD AND SATISFACTION

Say et al have analysed the GP workload. GPs manage 1.76 items per consultation. The greater the number of items, the less likely that they can be managed at the same consultation.

ASSESSMENT OF LAYPERSON KNOWLEDGE OF AED USE IN SPORTS CLUBS

Ryan et al assessed a lay group's knowledge of AEDs. There were 142 participants. Following a teaching session, 77% stated that they would use an AED, compared with 20% before the session.

A SURVEY OF LATENT TUBERCULOSIS SCREENING AND TREATMENT PRACTICES IN A TERTIARY CENTRE

O'Connell et al address the issue of latent tuberculosis infection (LTBI). LTBI is a persistent immune response without active signs of infection. The authors urge better access to LTBI tests, TB specialist services, and the use of Rifampicin regimens.

A COMPARISON OF COMMUNITY-ACQUIRED AND HOSPITAL-ACQUIRED HYPERNATRAEMIA IN ACUTELY ADMITTED PATIENTS

Brennan et al report on community and hospital acquired hypernatraemia. Patients with community acquired hypernatraemia are more likely to be in nursing homes, to have dementia, and reduced mobility.

A 10-YEAR AUDIT OF PENILE PROSTHESIS INSERTION

Looney et al describe a series of 111 penile prostheses in 96 patients. Among 71 patients who responded to a questionnaire, 61 patients were satisfied with the device.

ORIGINAL PAPERS (Continued)

PLACENTAL SWAB IN SUPPORTING DIAGNOSIS OF VERTICAL TRANSMISSION IN SARS-COV-2 POSITIVE MOTHERS

Sweeney et al review the evidence regarding the possibility of fetal vertical transmission in COVID-19 positive pregnant mothers by diagnosing through placental swabs. 17 placentas tested positive for SARS-CoV-2 out of a total of 184 tested (9%). Of these 17, 7 cases of SARS-CoV-2 were identified in the maternal, neonatal and placental tissue.

PERSPECTIVES OF INTERSTITIAL LUNG DISEASE PATIENTS AND CARERS DURING COVID-19

Cassidy et al have reviewed the issue of Covid-19 and interstitial lung disease. There were 111 patients and 59 caregivers. 32% of patients and 42% of caregivers expressed extreme worry.

COVID-19 PANDEMIC AND MATERNAL PERSPECTIVES

Janjua et al surveyed 223 pregnant and postpartum women about pregnancy and Covid infection. 63% were concerned about infection, 42% were upset about isolation, and 75% were dissatisfied about the hospital visiting restrictions.

IMPACT OF A NATIONAL LOCKDOWN ON CYCLING INJURIES

Foley et al report on cycling accidents in relation to the pandemic. There was a clear drop in the number of cycle-car collisions. During the lock down there were only 8 cases, the pre-lockdown period there were 26 cases, and in a control period in 2019 there were 43 cases.

IMPACT OF COVID-19 LOCKDOWN RESTRICTIONS: AMBIENT NO2 AND ASTHMA HOSPITAL ADMISSIONS

Quintyne et al report that the environment nitrogen dioxide (NO2) concentration decreased during the pandemic traffic restrictions. The concentrations in Cork decreased from 12 to 11ug/m3, in Dublin from 25ug/m3 to 17ug/m3, in Meath from 23ug/m3 to 21ug/m3. The authors also noted a reduction in asthma hospital admissions.

ORIGINAL PAPERS (Continued)

A COMPARISON OF THE PERFORMANCE OF SARS-COV-2 ANTIBODY ASSAYS IN HEALTHCARE WORKERS WITH COVID-19

Kerr et al have compared a number of SARS-CoV-2 antibody assays. The lab-based Abbot diagnostics had the best positive and negative predictive values. The POC Nal von Minden Gm and Biozek also performed well.

SHORT REPORTS

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DEPARTMENT

McGirr et al found that among 669 paediatric scheduled appointments, 127 (27%) of children were overweight. This finding was only communicated to the GP in half of the cases. The authors discuss how matters can be improved.

CRISIS PRESENTATIONS OF CHILDREN AND ADOLESCENTS WITH NEURODEVELOPMENTAL DISORDERS

Orji and Sharkey describe the care pathway for 72 children with neurodevelopmental delay who had a crisis presentation. Autistic spectrum disorders accounted for 93% of cases.

CASE REPORTS

WHISPERING TUBERCULOSIS

Nafisee et al describe a case of laryngeal tuberculosis with dysphonia.

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Issue: Ir Med J; Vol 114; No. 7; P398

Nurse-to-Patient Ratios are Important for Best Patient Care

J.F.A. Murphy - Editor of the Irish Medical Journal

Florence Nightingale stated that the introduction of trained nurses leads to a reduction in the number of hospital deaths. In addition to her nursing expertise, she used her statistical skills to save the lives of the soldiers in the Crimean war. With her polar area diagram, she graphically demonstrated the decrease in preventable deaths between 1855 and 1856 following the introduction of sweeping changes in nursing care¹. Her use of infographics was revolutionary at the time. Her call to action was that if we have evidence and fail to act, we are going backwards. Her data overturned the entrenched military belief that soldiers died from wounds rather than unsanitary hospitals. She is considered to be the founder of modern nursing.

In the modern era there is universal acceptance that good nursing care is critically important in making sick patients better. The importance of a competent, confident, and credentialled nurse has never been more crucial². Nurses comprise more than 50% of the skilled healthcare workforce, 90% being women.

What is exceptional in nursing is the nature of the work: the continuous and intimate association with pain and not infrequent contact with death³. It has previously been stated that hospitals are held together, glued together, and enabled to function by the nurses.

The key role played by the nursing profession during the Covid pandemic is a testament to their skilled care of ill patients. However, there is still an active debate about how many nurses a ward or a hospital need in order to achieve the best patient outcomes. Despite the many discussions, policy tools to achieve safe nursing levels have rarely been implemented.

In an important paper, McHugh et al⁴ have measured the impact of setting minimum nurse-to-patient ratios in selected hospitals in Queensland, Australia. The instruction was that the nurse-to-patient ratios on morning and afternoon shifts be no lower than 1:4 and on night shifts no lower than 1:7. The directive applied to medical-surgical wards rather than ICUs and labour wards which have more concentrated staffing ratios.

Patient clinical data and outcomes were collected at 2 time points. Baseline data was recorded May 1st to 31st, 2016. The results data was collected May 1st to 31st, 2018 two years post-implementation. It was an ambitious undertaking. There were 27 intervention hospitals and 28 comparison hospitals. There were 142,986 patients in the intervention hospitals, and 88,916 patients in the comparison hospitals were assessed at baseline. Subsequently, 160,167 patients in the intervention hospitals and 97,086 patients in the comparison hospitals were assessed in the post-implementation phase.

The main finding was that the minimum nurse-to-patient ratio introduced in the intervention hospitals reduced the 30-day mortality (OR 0.89). Secondly, the hospital length of stay decreased in both groups but was greater in the intervention hospitals (OR 0.95). Thirdly, the hospital readmission rates increased over time in the comparison hospitals (OR 1.06) but not in the intervention hospitals (OR 1.0).

The average number of nurses per patient in the comparison hospital was 6.13 at baseline and 5.96 at 2 years. In the intervention hospitals the number of nurses per patient was 4.85 at baseline, and 4.37 at 2 years.

The cost savings due to reduced length of stay and readmissions was more than twice the costs of the extra staff required to comply with the policy.

The study had an inbuilt flexibility. When a nurse had to take a break, others could provide cover. An individual nurse could have more or fewer patients so long as the average number did not exceed the ratio limits. This removed any sense of rigidity that would make the directive unworkable.

It is an important paper. Most previous studies on nurse-to-patient ratios have been cross-sectional. Also, the few longitudinal studies were small, retrospective, and relied on administrative data which tends to overestimate staffing by the inclusion of non-clinical nurses. The authors emphasise that that the investment in additional nurses provides a worthwhile return for patients.

This isn't the first study that has shown the relationship between nursing numbers and better patient outcomes. Needham et al⁵ reported that a higher nurse-to-patient ratio resulted in lower rates of pneumonia, urinary tract infection, shock, upper gastrointestinal bleeds, sepsis, and deep vein thrombosis.

Aiken et al⁶ found that each additional patient added to a nurse's workload was associated with 7% higher odds of a patient dying within 30 days of admission. On the other hand, for every 10% increase in nurses, there a 7% decline in mortality.

These findings are understandable in that nurses play an essential role in ensuring patient safety. They monitor for clinical deterioration and detect errors and near misses. They are efficient at analysing care processes and weaknesses in health care systems.

The years 2020-21 have been designated by WHO as the International Year of the Nurse and Midwife⁷. There are a number of goals; encourage greater investment in nursing, recruit more nurses in leadership roles, give nurses a more prominent voice in health policy making, encourage the sharing of best nursing practices and to conduct research in the areas that nurses have the most impact.

One of the recurring concerns throughout all the nursing literature are challenges around recruitment and retention. It has been pointed out that nursing is a very stressful job with a very flat career path⁸. One of the solutions is to develop and expand senior clinical grades such as advanced nurse practitioners (ANPs) and clinical nurse specialists (CNS). There are clear differences between the 2 roles⁹. The ANPs are more generalists and are to be found in areas such as emergency medicine, oncology, cardiology, or neonatal intensive care. The CNSs are usually defined by a specific disease diabetes, stroke, renal disease, or heart failure. A specialist implies a greater depth of knowledge within a specific clinical area, while a generalist requires a greater breath of clinical knowledge. There is invariably some overlap between the two roles.

The conclusions are intuitive. Having sufficient nurses with manageable workloads is very important for good patient care and best outcomes.

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Supporting Breastfeeding: Next steps

M. Kinoshita^{1,2}, A. Doolan^{1,2}

- 1. Coombe Women and Infants University Hospital, Cork Street, Dublin.
- 2. Royal College of Surgeons Ireland, St Stephen's Green, Dublin.

Irish breastfeeding rates have slowly improved over the last fifteen years, ¹ but remain among the lowest in Europe and worldwide. ^{2,3} Nationally, 60% of mothers have initiated breastfeeding by the time they leave the maternity hospital. ⁴ Only 15% of babies are given breastmilk at six-months of age⁵ despite this being the recommended duration of exclusive breastfeeding. The Royal College of Physicians of Ireland (RCPI) has published a position paper, endorsed by the Faculty of Paediatrics, Institute of Obstetricians and Gynaecologists and Faculty of Public Health Medicine, with commitment to supporting breastfeeding through medical education and within its own membership. ⁶

The HSE's Five Year Breastfeeding Action Plan (2016-2021) recognizes the positive impact of breastfeeding on both child and population health.⁵ While breastfed infants have a lower risk of sudden infant death syndrome, allergy and acute infections, in later life they have improved cognitive performance and lower risk of obesity and type 2 diabetes.³ Mothers who have breastfed have reduced risks of breast cancer, ovarian cancer and type 2 diabetes.³ Recent data identified additional long-term benefits associated with breastfeeding even including a reduction in COVID-19.⁷

Despite robust empirical evidence about the benefits of breastfeeding, additional supports are required within hospitals and the community to enable women to reach their breastfeeding goals. The National Infant Feeding Policy provides guidance on antenatal discussion about breastfeeding, skin to skin contact following delivery and avoidance of giving breastfed infants formula unless medically indicated. Unfortunately, to date the implementation of this and other national breastfeeding guidelines has been limited. The National Maternity Experience Survey 2020 identified areas for improvement based on feedback from mothers. Within hospitals this includes revising the Baby Friendly Hospital Initiative in Ireland and improving access to training for healthcare professionals. While these recommendations are not new, they are now aligned with the self-reported interests of mothers.

During the current pandemic essential services for infants and their families have been curtailed. Public health nurses, normally in a unique position to identify breastfeeding difficulties, have had to decrease their face-to-face contact with new mothers and infants. Specialists such as lactation consultants have largely moved remotely. Community and familial supports have been lost with restricted personal contacts and cancellation of breastfeeding groups.

Even with these challenges, recent decisions made around breastfeeding in Ireland are encouraging. Irish maternity hospitals were early adopters of guidance from the World Health Organization against the separation of mother and baby in the case of maternal Sars CoV-2 infection as benefits of breastfeeding outweigh concerns. The decision from the National Immunisation Advisory Committee to offer breastfeeding mothers vaccination according to their risk group is welcome especially as this differed from the approach initially taken in the UK. This stance had implications for front line healthcare professionals who would otherwise have been ineligible for vaccination. Breastfeeding women have traditionally been excluded from treatment groups but this should not be the default approach without biologically plausible concern. Since November 2020, the HSE's Breastfeeding Policy for Employees has allowed breastfeeding breaks for up to two years post partum. This significant extension beyond the six-month period currently in Irish legislation demonstrates how breastfeeding can be valued and facilitated in the workplace.

One of the biggest challenges that persists is the clear socioeconomic divide in breastfeeding statistics. Mothers in lower socioeconomic groups, with less formal education and who are younger are less likely to breastfeed. As well as normalising breastfeeding through primary and secondary school education, it is essential that breastfeeding information and timely support be provided within the public healthcare system. It can be difficult to access public lactation support as there are a limited number of International Board Certified Lactation Consultants (IBCLCs) with variable distribution within the HSE. While breastfeeding is natural, it can be challenging particularly in the early days and weeks. It is essential to set realistic expectations for parents especially as there is frequently a lack of familial experience with breastfeeding. This should be coupled with basic information about normal infant feeding behaviour and provision of specialist help if needed.

Breastfeeding, like many physiological functions, sometimes requires specialist support but should be considered within the remit of healthcare professionals, including physicians, to provide initial evaluation, advice and onward referral when necessary. Doctors are expected to advise and prescribe for breastfeeding mothers based on best available evidence, however there is limited research and few approved resources to guide decision-making. Breastfeeding can usually safely continue with considered medication prescription. Evidence-based resources, such as Wendy Jones' breastfeeding-and-medication.co.uk, can provide clarity for healthcare professionals. Without this, convention is often to avoid treatment, delay treatment or stop breastfeeding around medical events and procedures. A recent article by Colleran et al. demonstrated that 70% of professionals recommended against breastfeeding following CT or MRI with contrast media when evidence suggests that no disruption in breastfeeding is required.⁸

Breastfeeding should also be enabled and promoted within healthcare settings. Women who are breastfeeding and require admission to hospital should have access to expressing facilities or access to their babies for direct feeding.

Ireland has a complicated relationship with the industry of breastmilk substitutes. Ireland exported just under €1.3 billion of formula in 2017⁹ which represents a significant share of the global market. Formula companies continue to advertise to parents and medical professionals via specialised formulas in conflict with the WHO Code of Marketing of Breastmilk Substitutes. It has also been suggested that formula companies targeted parents via social media and used uncertainty around COVID-19 to promote formula.¹⁰ The marketing tactics used are selective, poorly regulated and, unfortunately, ubiquitous.

There is a positive trend in breastfeeding rates nationally, but progress is slow. RCPI has made recommendations to address some of the current barriers to breastfeeding. Breastfeeding should be recognised for its health benefits at a population level and its relevance to doctors in a range of specialties. Implementing current policies, addressing inequalities in access to breastfeeding support and providing education for healthcare professionals are fundamental steps that will enable more women to breastfeed in Ireland.

Corresponding Author:

Meredith Kinoshita
Paediatric Specialist Registrar
Coombe Women and Infants University Hospital,
Cork Street,
Dublin 8.

E-Mail: meredithkinoshita@rcsi.ie

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The Development of a National Paediatric Psycho-Oncology Service

C. Besani^{1,2,3}, A. Dunne^{1,2,3}, S. D'Arcy-Bewick², C. Owens¹, J. Pears¹, A. O'Marcaigh¹, A. Malone¹, G. Fortune², M. Capra¹, O. P. Smith^{1,3}

- 1. National Children's Cancer Service, Children's Health Ireland at Crumlin.
- 2. Paediatric Psychology Department, Children's Health Ireland at Crumlin.
- 3. National Children's Research Centre.

Abstract

Aims

To investigate the psychological care provided to children and young adolescents with cancer and their families within the National Children's Cancer Service (NCCS), Ireland, in respect of the national and international standards of care.

Methods

A retrospective audit of 316 referrals made over 32 months by the NCCS to the psychology service in malignant haematology and oncology was performed.

Results

The audit revealed that out of 316 patients, a yearly average of 189 (50%) of urgently referred patients received psychological support within the NCCS between January 2013 and August 2016. Furthermore only 20 (22%) undergoing haematopoietic stem cell transplantation (HSCT), 14 (22%) referred to the paediatric palliative care team, and 84 (62%) of teenage patients received psychological input during this timeframe.

Conclusion

The audit revealed that the current psychology service provision is failing to meet the international standards of care. Due to the data provided by this audit, in conjunction with a clinical risk assessment of the service, funds for the post of principal psychologist have been secured. Further psychology posts (HSCT, late-effects and neuropsychology), and development of the psychoncology model of care are required to ensure equality of access and evidence-based psychological care for all children with cancer.

Introduction

Approximately 200 children/young adolescents (0-16 years) are diagnosed with cancer annually in Ireland. The role of the National Children's Cancer Service (NCCS) is to diagnose, plan treatment and follow-up care for all children/young adolescents diagnosed with cancer in Ireland¹. In addition to newly diagnosed patients, the service sees an average of 700 patients annually on an outpatient basis. Furthermore, the NCCS also acts as an advisory and response service for 16 shared care centres throughout Ireland. The National Cancer Strategy 2017-2026^{1,2} recognises that current services are under pressure and patient numbers will continue to increase. The National Cancer Control Program (NCCP)¹ identifies the provision of safe, high quality and patient-centred care as the primary aim of all cancer services. This involves care that is evidence-based, timely, efficient, effective and equitable. To achieve this model of care, the Strategy identified the need of establishing multi-disciplinary psycho-oncology teams in each of the eight designated adult cancer centres and the NCCS. Despite an increase in child/young adolescent cancer diagnoses, the psychology personnel provision for the NCCS has been one full-time senior clinical psychologist since 2003.

Psycho-oncology, a relatively new sub-speciality, has facilitated the integration of the psychological domain into the disease-specific speciality of oncology/haemato-oncology³. Psycho-oncology is a sub-speciality within oncology/haemato-oncology that focuses on the: (1) psychological responses of patients, families, and caregivers, to the diagnosis of cancer; and (2) the behavioural, social, medical and psychological factors that may affect the disease process⁴, and impact on compliance and response to treatment. The psychological issues connected to childhood cancer have been well documented, with receipt of a potentially life-threatening paediatric cancer diagnosis having been found to be universally distressing and potentially traumatising for both children and their families⁵⁻⁶. Paediatric psychology has a unique role within the multidisciplinary team⁶ (Table 1).

Table 1. Key roles of paediatric psychologists working within malignant haematology and oncology settings.

Key Roles

Assessing vulnerabilities and promoting resilience, coping and adjustment to cancer and throughout different parts of treatment from diagnoses, treatment, end of treatment and/or relapse.

Supporting the medical team in managing nausea, procedural pain, procedural distress and other side-effects of treatment.

Assessing and increasing adherence to treatment.

Assessing, monitoring, and when possible, reducing and/or rehabilitating neuropsychological effects.

Facilitating transition to palliative care and preparation for end of life.

Empirical evidence suggests that cancer patients who have their psychological needs met during treatment have a greater quality of life (QOL) and better health outcomes⁷. Despite a wealth of research documenting the psychological risks for children and their families faced with a paediatric cancer diagnosis, significant differences have been found in the standard of psychological care offered to patients across services⁸. An international group of professionals worked to develop evidence-based standards for psychosocial care in paediatric oncology, conducting in-depth systematic reviews of the available research evidence: The 15 Standards for the Psychosocial Care of Children with Cancer and Their Families⁸ (Table 2).

Table 2. Standards for the Psychosocial Care of Children with Cancer and Their Families.

Standards

- 1. Youth with cancer and their family members should routinely receive systematic assessments of their psychosocial health care needs.
- 2. Patients with brain tumours and others at high risk for neuropsychological deficits as a result of cancer treatment should be monitored for neuropsychological deficits during and after treatment.
- 3. Long-term survivors of child and adolescent cancers should receive yearly psychosocial screening for:
 a) adverse educational and/or vocational progress, social and relationship difficulties; b) distress, anxiety, and depression and c) risky health behaviours. Adolescent and young adult survivors and their parents should receive anticipatory guidance on the need for life-long follow-up care by the time treatment ends and repeated at each follow-up visit.
- 4. Youth with cancer and their family members should have access to psychosocial support and interventions throughout the cancer trajectory and access to psychiatry as needed.
- 5. Paediatric oncology families are at high risk for financial burden during cancer treatment with associated negative implications for quality of life and parental emotional health. Assessment of risk for financial hardship should be incorporated at time of diagnosis for all paediatric oncology families. Domains of assessment should include risk factors for financial hardship during therapy including preexisting low-income or financial hardship, single parent status, distance from treating centre, anticipated long/intense treatment protocol, and parental employment status. Targeted referral for financial counselling and supportive resources (including both governmental and charitable supports) should be offered based on results of family assessment. Longitudinal reassessment and intervention should occur throughout the cancer treatment trajectory and into survivorship or bereavement.
- 6. Parents and caregivers of children with cancer should have early and ongoing assessment of their mental health needs. Access to appropriate interventions for parents and caregivers should be facilitated to optimise parent, child and family well-being.
- 7. Youth with cancer and their family members should be provided with psychoeducation, information, and anticipatory guidance related to disease, treatment, acute and long-term effects, hospitalisation, procedures, and psychosocial adaption. Guidance should be tailored to the specific needs and preferences of individual patients and families and be provided throughout the trajectory of cancer care.
- 8. Youth with cancer should receive developmentally appropriate preparatory information about invasive medical procedures. All youth should receive psychological intervention for invasive medical procedures.

- 9. Children and adolescents with cancer should be provided opportunities for social interaction during cancer therapy and into survivorship following careful consideration of the patients' unique characteristics, including developmental level, preferences for social interaction, and health status. The patient, parent(s) and a psychosocial team member (e.g., designee from child life, psychology, social work, or nursing) should participate in this evaluation at time of diagnosis, throughout treatment and when the patient enters survivorship; it may be helpful to include school personnel or additional providers.
- 10. Siblings of children with cancer are a psychosocially at-risk group and should be provided with appropriate support services. Parents and professionals should be advised about ways to anticipate and meet siblings' needs, especially when siblings are unable to visit the hospital regularly.
- 11. In collaboration with parents, school-age youth diagnosed with cancer should receive school re-entry support that focuses on providing information to school personnel about the patient's diagnosis, treatment, and implications for the school environment and provides recommendations to support the child's school experience. Paediatric oncology programs should identify a team member with the requisite knowledge and skills who will coordinate communication between the patient/family, school, and the health care team.
- 12. Adherence should be assessed routinely and monitored throughout treatment.
- 13. Youth with cancer and their families should be introduced to palliative care concepts to reduce suffering throughout the disease process regardless of disease status. When necessary youth and families should receive developmentally appropriate end of life care [which includes bereavement care after the child's death]. This includes psychological preparation for end of life.
- 14. A member of the health care team should contact the family after a child's death to assess family needs, to identify those for negative psychosocial sequelae, to continue care, and to provide resources for bereavement support.
- 15. Open, respectful communication and collaboration among medical and psychosocial providers, patients and families is essential to effective patient- and family- centred care. Psychosocial professionals should be integrated into paediatric oncology care settings as integral team members and be participants in patient care rounds/meetings. Paediatric psychosocial providers should have access to medical records and relevant reports should be shared among care team professionals, with psychological report interpretation provided by psychosocial providers to staff and patients/families for patient care planning. Psychosocial providers should follow documentation policies of the health system where they practice in accordance with ethical requirements of their profession and state/federal laws. Paediatric psychosocial providers must have specialized training and education and be credentialed in their discipline to provide developmentally appropriate assessment and treatment for children with cancer and their families. Experience working with children with serious, chronic illness is crucial as well as ongoing relevant supervision/peer support.

Within this context, there was a need to conduct a clinical audit of the dedicated psychology provision in the NCCS, to facilitate continuous service development and quality improvement⁹, and to explore whether the current provision was meeting the international standards of care (standards 1,4,7,8,12,13)⁸.

Methods

A retrospective, cross-sectional review of referrals made by the NCCS to the psychology service from January 2013 to August 2016 was performed in September 2016. The data collected was classified into total number of newly diagnosed patients, number of patients undergoing haematopoietic stem cell transplantation (HSCT), referred to palliative care, referred to psychology, seen by psychology and not seen by psychology. The chair of the hospital's research ethics committee was contacted prior to the conduct of this audit, to discuss ethical considerations (to include anonymisation of data), its development and publication.

Results

The total number of patients diagnosed within the NCCS per year, the total number referred for psychological support, the total number who were subsequently seen, and the total number who were not seen are summarised in Figure 1. This data is presented yearly from 2013 to 2016. These statistics exclude active, ongoing, and relapsed cases.

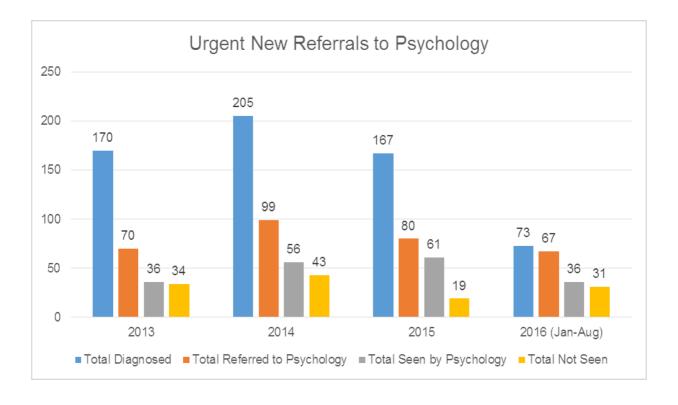


Figure 1. Urgent New Referrals to Psychology.

In 2013, 36 (51%) of urgent, newly referred patients had access to psychological support within that year. In 2013, the NCCS had access to one full-time senior clinical psychologist for oncology and haemato-oncology.

In 2014, there were 205 patients diagnosed with cancer, the highest number recorded in a single year to date and not surprisingly, the psychology service received the highest number of new, urgent referrals for psychological support (99). The total number of patients who accessed psychological support improved slightly upon the preceding year, with 56 (57%) seen by a psychologist in 2014: 43 (43%) of patients were not seen. In 2014, the NCCS had access to two part-time (0.5) senior clinical psychologists, one for oncology and one for haemato-oncology, and both anecdotally reported dedicating more than 0.5 to each speciality to try to fill the gaps of the service.

In 2015, the highest percentage of urgently referred patients were seen by a clinical psychologist due to an increase in psychology service provision; 61 (76%) seen: 19 (24%) not seen. For 6 months of that year, the NCCS had access to three part-time (0.5) senior clinical psychologists, two for oncology and one for haemato-oncology.

From January to August 2016, the psychologist saw 36 (54%) of urgent, new referrals, while 31 (46%) remained not seen.

A more detailed analysis of the data was conducted to explore specific areas of clinical need highlighted by the literature⁸: HSCT, palliative care and young adolescents.

The psychological support received by patients undergoing HSCT between January 2013 and August 2016, patients in palliative care between 2014 and 2015, and young adolescent patients between January 2013 and August 2016 (Figure 2).

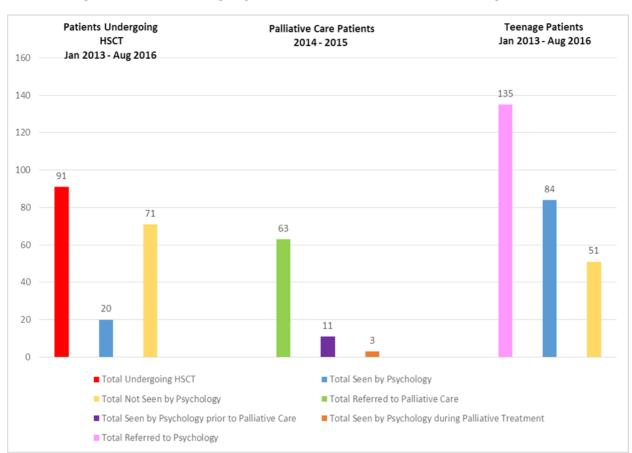


Figure 2. Patients Undergoing HSCT, Palliative Care Patients and Teenage Patients.

Of the 91 patients undergoing HSCT, approximately 20 (22%) received psychological input. Children, young adolescents and their families received support from other members of the psychosocial multidisciplinary team, including a complimentary therapist, play specialists, and social workers.

Of the 63 patients from the NCCS who were referred to the palliative care team between 2014 and 2015, 15 (24%) were offered psychological input during their cancer treatment. 14 (22%) availed of the psychological support offered; 11 (17%) before they became palliative, and 3 (3%) after they were referred to the palliative care medical consultant.

Of the 135 teenage patients who were referred for psychological support between January 2013 and August 2016, approximately 84 (62%) received psychological input from a psychologist.

Discussion

This audit demonstrates that the current psychology provision within the NCCS is failing to meet international standards of care. This provision creates inequalities in patient care and does not currently facilitate every child/young adolescent diagnosed with cancer to have access to psychological support throughout their cancer journey. The data revealed approximately 189 (50%) of urgent, newly referred patients received psychological support within the NCCS between 2013 and 2016. The only exception was in 2015, where 61 (76%) of urgent, new referrals had access to psychological care. Notably, dedicated psychology provision was increased that year due to additional personnel support within the psychology service, bringing the dedicated provision to 1.5 (WTE) for six months of 2015.

The audit also revealed a significant difference between 2013 and 2016 in the number of patients referred to the psychology service and the number of patients seen. These findings should be interpreted within the limitations of this study, highlighted below. However, the authors feel a possible interpretation of the increase in number of referrals and number of patients seen may be found in the specific psycho-oncology training of the new psychologist, and psycho-educational programme that was introduced in 2016. This result is supported by the National Cancer Strategy 2017-2026¹ and empirical literature, which indicate the need for staff working in this area to have specific training and supervision within the sub-speciality. This is essential to provide staff with the knowledge and skills required to provide safe, high quality and patient-centred psycho-oncological care. The need for more psychological care was already indicated in the National Clinical Programme for Paediatrics and Neonatology¹¹0. Furthermore, the NCCP and the current Cancer Strategy¹ recognise the need to employ multi-disciplinary psycho-oncology teams, including psychologists, who have an appropriate level of seniority and expertise in psycho-oncology to guarantee this appropriate provision of care.

For this reason, there is a need to employ a principal psychologist with expertise in paediatric psycho-oncology¹; a role that is already present in four of the eight designated adult cancer centres in Ireland. This person would deliver specialised interventions for families experiencing the highest level of psychological distress and would offer training and supervision to other psychologists and healthcare staff working within the NCCS, in the 16 shared-care hospital centres, and in mental health community services.

The literature suggests high levels of staff burnout in the field of child/young adolescent oncology/haemato-oncology, and psychological support and supervision for staff may be instrumental in facilitating staff retention within the NCCS¹¹⁻¹⁶. Due to the work of the NCCS in conjunction with the hospital management team, data from this audit, and a clinical risk assessment conducted recently by the psychology department and NCCS, funds for this post have now been secured.

To meet the international standards of psychosocial care⁸, which are more specific to psychology (1, 2, 3, 4, 7, 8, 9, 10, 11, 12, 13, 15) it is proposed that three additional psychology posts are also required: one full time senior psychology post in HSCT, one for the late effects clinic (survivorship programme), and one senior neuropsychologist. This increased provision will facilitate the psychooncology service in assessing and providing psychological intervention to every child/young adolescent with cancer receiving active and maintenance treatment in the National Children Cancer Service, at appropriate time for screening and for treatment if/when needed. The medical/nursing team will be asked to automatically refer every child/young adolescent diagnosed with cancer to the Psycho-Oncology Service, using a new referral form that has been piloted in the service, this would provide information to screen with priority the most urgent cases, but every family will receive a formal screening and when needed intervention. In collaboration with Professor Anne Kazak, The Children's Hospital of Philadelphia, the service is ready to pilot an Irish version of the screening tool recommended by the standards of care (Psychosocial Assessment Tool, Standard 1)⁸.

This proposal of three additional posts is based on the current number of newly diagnosed patients entering the service each year for children age 0-16. Together with the NCCP, the NCCS is working to increase the age of treatment and include young adults in the service, creating a Children and Adolescent Service with Cancer (0-23). If this is successful, in the future, the most updated research evidence-based data and service user's involvement, will be used to design appropriate service for this cohort of patients.

The NCCS have identified HSCT as an area of particularly high priority need for increased psychological services. Currently, approximately 20 (22%) of children/young adolescents undergoing HSCT receive psychological input. Although the HSCT programme at the NCCS has previously been accredited by the Joint Accreditation Committee for the International Society of Cellular Therapy (JACIE) and the European Society for Blood and Marrow Transplantation (EBMT), the failings of the NCCS to provide appropriate access to a psychologist before, during and after transplantation¹⁷, specifically due to a lack of psychologists, has been identified. The psychological needs of children, young adolescents and their families are higher during and following transplantation due to the medical complexity of this treatment and the psychological challenges of isolation.

The results of this audit should be interpreted in respect of its limitations. Due to limited psychology resources, a dedicated database for psycho-oncology referrals was not in operation from 2013-2016. Exact data pertaining to the number of newly referred cases who were not seen by a psychologist, who subsequently moved to adult or community-based waiting lists, were re-referred, or who may have died without being seen, is unknown.

A research innovation grant received in 2018 has provided the service with a functional database, facilitating the collection of more precise data in the future and a prospective database has been active since the employment of the Principal Psychologist in January 2020 and in this information is now recorded.

In conclusion, the strong partnership between psychology, and child/young adolescent haemato-oncology/oncology has facilitated, albeit slowly, the genesis of paediatric psycho-oncology. However, the psycho-oncology service will continue to fail to meet the international standards of psychosocial care without additional personnel. With the correct staffing, paediatric psycho-oncology services in Ireland will be able to support children, young adolescents and families, and develop, through clinical research, developmentally targeted clinical knowledge, to inform and integrate within the medical care of children and young adolescents with cancer. This is essential, as evidence suggests that cancer patients who have their psychological needs met during treatment have a greater QOL and better health outcomes⁷. As clinicians looking after children/young adolescents with cancer and their families, we must keep striving to meet this goal.

Declaration of Conflicts of Interest:

The authors have no conflicts of interest to disclose.

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Corresponding Author:

Dr Chiara Besani,
Principal Clinical Psychologist and Principal Investigator,
Oncology and Haematology Specialities,
Children's Health Ireland (CHI), Crumlin,
Dublin 12.

E-Mail: besanic@tcd.ie

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Characteristics of Centenarians in the Irish Hip Fracture Database

P.C.P. Hogan¹, H. Ferris², L. Brent³, P. McElwaine⁴, T. Coughlan⁴

- 1. Department Age-Related Healthcare, Tallaght University Hospital.
- 2. National Quality Improvement Team, Health Service Executive Ireland.
- 3. National Office of Clinical Audit.
- 4. Department Medical Gerontology, Trinity College Dublin.

Abstract

Aim

Hip fractures are common amongst older people and result in significant morbidity and mortality. The Irish Hip Fracture Database (IHFD) collects data, from the 16 trauma orthopaedic units in Ireland, on patients aged 60 years and older who sustain hip fractures. This study aims to describe the characteristics of those patients aged 100 years and older in this database.

Methods

A retrospective analysis of the IHFD from 2012 to 2017. Characteristics of those patients aged 100 years and over were collected and analysed.

Results

57 patients were identified for inclusion, 52 (91%) of which were women. Mean age was 101, while mean length of stay was 22.6 days. 51 (89%) fractures were due to low velocity trauma, consistent with likely high rates of osteoporosis in this group. The great majority underwent operative intervention. 50 (88%) were discharged alive. Fracture type varied widely. Only 24 (42%) patients were documented to have been seen by a geriatrician during admission. There were low reported rates of co-morbid medical conditions, likely due to lack of recorded data, rather than true low rates of co-morbidities in this group.

Discussion

This study provides insight into this distinct group of people, with important implications for future healthcare planning and budgeting.

Introduction

Hip fractures are devastating injuries which result in excess mortality and disability ^{1,2}. The Irish Hip Fracture Database (IHFD) is a clinically-led, web-based national clinical audit and was established to record the case-mix, care standards and outcomes of patients over the age of 60 who present to 16 trauma centres in Ireland. By providing continuous feedback to the hospitals, the audit encourages improvements in compliance with care standards. The IHFD was established by joint collaboration between the Irish Institute of Trauma and Orthopaedic Surgery (IITOS) and the Irish Gerontological Society (IGS) and in 2013 the National Office of Clinical Audit (NOCA) took over operational governance of the audit³. The term centenarian refers to those people aged 100 years and over. The Central Statistics Office (CSO) of Ireland recorded 456 centenarians in Ireland in the most recent census in 2016⁴. The proportion of older individuals is projected to increase in coming years. The aim of this study was to quantify patients aged 100 years and older in the IHFD and to describe the characteristics of this cohort.

Methods

Data collection for the IHFD is conducted locally at each site by an audit coordinator. The cases are entered retrospectively from patient records into the IHFD portal on the Hospital In-Patient Enquiry (HIPE) system, which is managed by the Healthcare Pricing Office (HPO). This data is then merged with a hospital admission episode and the data gets validated by NOCA⁵.

A retrospective analysis was conducted of 15,603 data entries in the IHFD from 2012 to 2017. Data on patients aged 100 years and older was extracted and baseline characteristics recorded which included age, sex, and co-morbidities where documented. Comorbid conditions are recorded in the IHFD as that extrapolated from HIPE. We also assessed in-patient mortality, length of stay, trauma and injury types, surgery performed, peri-operative assessment by medical and physical therapy staff and discharge destination. Data is also presented on patients aged 99 years and younger for comparison.

Statistical analysis was performed using R version 4.0.3. Descriptive statistics were used to analyse the characteristics of centenarians. This group was compared to patients aged 99 years and younger. Deviation from the mean for gender and length of stay/ITU days was analysed using the Mann-Whitney U test. Categorical data was compared using Fisher's exact test.

In order to comply with the General Data Protection Regulation (GDPR), it was necessary to group some results together (any result where fewer than 5 patients are reported). Statistical analysis was done prior to this grouping of data.

Results

57 patients aged 100 years and over were identified in the IHFD between the years 2012 to 2017 (range 100-105). The characteristics of these patients can be seen in table 1. Note when reviewing table 1, that results which were grouped for GDPR compliance are indicated in parenthesis under the heading "Other". Co-morbid conditions experienced by fewer than 5 patients were omitted from table 2. Those listed in table 2 therefore represent the most commonly reported conditions.

52 (91%) centenarians were women, while 5(9%) were men – a significantly higher proportion than the younger patients. There were relatively similar numbers of fractures each year, with a peak of 14 fractures in 2015 and a low of 9 fractures in 2012. The average length of stay of centenarians was slightly longer than younger patients at 22.6 days, but this was not significant. In total centenarians occupied 1,287 days, 13 of which were intensive care unit days. In-hospital mortality amongst this cohort was 12% (n=7), which is significantly higher than the average across the database (n=681, 4%).

The majority of traumas were low velocity (n=51/89%). Most of the fracture types were either displaced intracapsular (n=17/29%) or intertrochanteric (n=26/42%) – the other fracture types are listed in table 1. The great majority of patients proceeded to surgery, the details of which can also be found in table 1.

With regard to peri-operative care, 24(42%) of the patients were seen by a geriatrician during their admission, 11(19%) of these were seen pre-operatively. 5(9%) patients had an abbreviated mental test (AMT) score recorded. 19(33%) patients were mobilised on the day of, or day after surgery. This is significantly less than the proportion of younger patients mobilised. 15(26%) were assessed by physiotherapy on the day of or day after surgery.

There was a significant difference in discharge destination between centenarians and younger patients. However, when comparing new nursing home admissions to all other discharge destinations, the proportion is relatively similar (9% of centenarians compared to 6% of younger patients) and the difference is not statistically significant.

Table 1: Clinical data (Results which were grouped for GDPR compliance are indicated in

parenthesis under the heading "Other")

<u>'</u>	I	Ta		D 1 (0.05)
		Centenarians	Non-centenarians	P-value (<0.05)
		(n=57)	(n=15546)	
Gender	Men	5 (9%)	4788 (31%)	0.006
	Women	52 (91%)	10758 (69%)	
Age	Mean	101	78	NA
	Range	100-105	1-99	
Mortality	Survived to discharge	50 (88%)	14865 (96%)	0.012
_	Death	7 (12%)	681 (4%)	
Length of stay	Mean	22.6	19.6	0.972
	Total	1287	304070	
Intensive care days	Total	13	4116	0.388
Trauma type	Low velocity	51 (89%)	14020 (90%)	0.203
	Other (incl. high velocity, unknown, not			
	documented and no data)	7 (11%)	1526 (10%)	
Fracture type	Intracapsular	20 (35%)	7013 (45%)	0.449
	Intertrochanteric	26 (46%)	5485 (35%)	
	Other (incl. not documented)	11 (19%)	2855 (19%)	
	No data	0 (0%)	193 (1%)	
Pathological fractures	Malignant	0 (0%)	290 (2%)	0.916
	Non-pathological	51 (89%)	13084 (84%)	
	Other (incl. atypical, other and no data)			
		6 (11%)	2172 (14%)	
AMT performed	Yes	5 (9%)	1316 (8%)	0.853
	No	38 (67%)	10606 (68%)	
	Patient refused	0 (0%)	51 (<1%)	
	Not documented or no data	14 (24%)	3573 (23%)	
Pre-operative medical	Geriatrician	11 (19%)	1865 (12%)	0.069 (assessment
assessment	Medical physician	11 (19%)	2356 (15%)	vs no assessment)
	Other (incl. not seen, not documented			
	or no data)	36 (62%)	11325 (73%)	
Assessment by	Yes	24 (42%)	5691 (36%)	0.201
geriatrician during	No	15 (26%)	5521 (36%)	
admission	Not documented or no data	18 (32%)	4334 (28%)	
Grade of geriatrician	Consultant	21	4749 (30%)	0.427
performing assessment	Other	12	2325 (15%)	
	Not documented or no data	23	8472 (55%)	
Operation	Internal fixation: dynamic hip screw	20 (35%)	3745 (24%)	0.866
	Internal fixation: IM nail	13 (23%)	3165 (20%)	
	Hemi-arthroplasty	19 (33%)	6623 (43%)	
	Total hip replacement	0 (0%)	550 (4%)	
	Other (incl. no operation, other, not			
	documented, no data)	5 (9%)	1463 (9%)	
Mobilised day of or day	Yes	19 (33%)	8151 (53%)	0.004
after surgery	No	16 (28%)	2396 (15%)	
	Not documented or no data	22 (39%)	4999 (32%)	
Physiotherapy	Yes	15 (26%)	5445 (35%)	0.761
assessment day of or day	Other (incl. no, not documented or no	42 (74%)	10101 (65%)	
after surgery	data			
Discharge destination	New admission to nursing home	5 (9%)	934 (6%)	0.001
	Return to nursing home	10 (17%)	408 (3%)	
				(0.393 for new
	Other (incl. rehabilitation, convalescent	5 (9%)	4868 (31%)	admission to
	care or home to private residence)			nursing home vs
				any other
	Other (incl. other and no data)	37 (65%)	9336 (60%)	destination)

Table 2: Co-morbid medical conditions.

Condition	No of	% of
	patients	patients
Cardiovascular		
Hypertension	10	18%
Hypotension	7	12%
Congestive heart failure	6	11%
Respiratory		
Lower respiratory infection	11	19%
Genitourinary		
Urinary tract infection	8	14%
Acute kidney failure	6	11%
Chronic kidney disease	6	11%
Neurological		
Dementia	17	30%
Delirium	5	9%
Haematological		
Anaemia	5	9%

Discussion

This study sheds light on the characteristics of a group of patients aged 100 years and older who have sustained a hip fracture. The data are notable for the high rate of mortality in this group, as evidenced by the 3-fold higher death rate. This has implications for future healthcare planning and budgeting as the number of patients aged 100 years and older increases.

Importantly, the data indicates that with the exception of mortality, outcomes among centenarians are relatively similar to younger patients. In addition, the majority of centenarians survived to discharge and did not have a significantly longer length of stay, validating active management in this cohort.

Centenarians who were women were more likely to have a hip fracture compared to men than younger women. This may be related to the fact that women are more likely to reach the age of 100 in Ireland than men⁴. In addition, women lose bone density at a faster rate than men, which may also contribute to this discrepancy⁶.

With regard to perioperative care, just under half of centenarians had a documented assessment by a geriatrician in the peri-operative period. Best practice guidance would suggest that all frail, older patients should have comprehensive geriatric assessment performed during admission to improve outcomes, reduce delays to surgery, minimise delirium, promote early mobilisation and reduce subsequent falls⁷. There was a low rate of delirium screening based on the number of recorded AMT scores. It should be further noted that the AMT is not a good screening test for delirium and has been replaced by the 4AT in more recent iterations of the IHFD. Additionally, a significantly smaller proportion of centenarians were mobilised on the day of or day after surgery. It is not entirely clear why this is, though it may reflect the frailty status of these patients. Extrapolating from the data on place of residence, more centenarians were care home residents pre-admission, which would suggest a higher level of frailty in this group. Nevertheless, further work should try to identify the reasons why these patients are not mobilised early and, if possible, to improve practice around early mobilisation. The data provides evidence that ongoing work is required to ensure that all frail, older adults presenting with hip fractures may benefit from structured orthogeriatric care. It is noteworthy that during the study period, many of the trauma centres in Ireland did not have dedicated orthogeriatric services. Since 2018 however, there has been development of many services throughout the country. Future studies may focus on the differences this has made to the care of patients with hip fractures.

Most traumas were low velocity, which suggests a high rate of osteoporosis and other diseases of bone predisposing to fractures in this cohort. Osteoporosis is a condition commonly known to be associated with ageing, with 29% of male centenarians and 56% of female centenarians suffering from this condition⁸. A high number of patients in this cohort also resided in nursing homes. It has been shown that rates of osteoporosis in female nursing home residents over the age of 85 may be in excess of 85%. It is therefore important to screen and commence appropriate treatment for patients at risk to prevent serious injury.

The patients in this cohort had low rates of co-morbid medical conditions, based on data obtained from HIPE records. 17 of 57 patients had a diagnosis of dementia recorded, which is low for a group of centenarians¹⁰. 5 had reported delirium, which is low even for a cohort of hospitalised patients with hip fractures¹¹. Less than 5 patients had osteoporosis listed as a co-morbidity, which reflects the generally poor documentation, recognition and treatment of this condition even after a major fracture such as hip fracture.

The findings of this study are broadly in line with a number of other European studies looking at hip fractures in centenarians. Hip fractures in centenarians are associated with excess mortality compared to hip fractures in younger patients^{12,13,14}. An Italian study also indicated higher mortality compared to centenarians admitted for other reasons¹⁵. The proportion of patients with hip fractures who were aged 100 and over was also similar to that in a Danish study using a similar national database¹³.

This study has a number of limitations. Firstly, despite the large number of patients in the database, the sample size of centenarians is small, meaning that there may be differences between centenarians and younger patients which are not detected in this study. The small sample size has also limited our ability to report full results, due to the requirement to comply with GDPR. In addition, mortality data is reported as an absolute number rather than being linked to specific cases. It has therefore not been possible to perform multivariate or regression analyses on the data. There is also no data available for the period following discharge, which means it has only been possible to report in-hospital mortality. With regard to reporting of co-morbid medical conditions, it is likely that the low rates of co-morbid medical conditions and conditions associated with ageing is due to failure to document diagnoses to the HIPE database, rather than this cohort truly having low rates of these conditions, representing a further limitation. Despite these limitations, the study has several strengths. This was a nationwide, population-based cohort. Data collection was comprehensive, and quantity of missing data was broadly similar between centenarians and younger patients, making inferences more reliable. The study provides evidence that centenarians with hip fractures in Ireland receive good care but provides insight into areas which can be improved – for example, early mobilisation and structured orthogeriatric assessment, which may help to reduce in-hospital mortality.

It is hoped that this data will add to the growing body of data on older adults with traumatic injury and will assist with future planning of services that cater to the needs of the oldest old to improve outcomes for this particularly vulnerable group.

Declaration of Conflicts of Interest:

Nothing to declare.

Corresponding Author:

Patrick CP Hogan
Tallaght University Hospital.
E-Mail: hoganpc@tcd.ie

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Cutaneous Melanoma and Sentinel Lymph Node Biopsy; An Epidemiology Study of Population Level Data

L. Scanlon^{1,2}, A.J.P. Clover²

- 1. School of Medicine, University College Cork, Cork City, Ireland.
- 2. Department of Plastic Surgery, Cork University Hospital, Wilton, Cork.

Abstract

Aims

Cutaneous melanoma accounts for 90% of all melanoma cases diagnosed. In addition, the incidence of cutaneous melanoma is increasing by approximately 3-7% yearly, and it is the most rapidly increasing cancer diagnosed in white populations worldwide.

The aim of this study is to assess the survival benefit of Sentinel Lymph Node Biopsy (SLNB) in cutaneous melanoma in an Irish population.

Methods

Population based data was obtained from the National Cancer Registry of Ireland (NCRI) on all patients with a cutaneous melanoma diagnosed over a 20-year period 1994-2014 and predictors of Overall Survival (OS) were assessed.

Results

13302 patients were identified with a melanoma diagnosis between 1994-2014. OS varied with gender, age, smoking and marital status, anatomical location and TMN stage. 2196 (17%) patients underwent SLNB, which included 710 patients in the stage 1 melanoma category (<11% of this group).

Undergoing a SLNB was not an independent predictor of improved OS (p=0.440). However, a positive SLNB result was an independent predictor of OS (0.001).

Conclusion

This Irish population-based data re-affirms demographic indicators of poorer survival. A positive SLNB result indicates poorer survival; however, the precedent itself is not a predictor of OS.

Introduction

Skin cancer, particularly melanoma, is a significant problem in Irish Society and worldwide and overall incidence is rising in Ireland and worldwide at an alarming rate^{1,2}. The National Cancer Registry of Ireland (NCRI) identifies, analyses and reports on the incidence and prevalence of all cancers diagnosed in Ireland. It is a national centralised database with staff based in hospitals throughout Ireland.

The NCRI predicts that the number of new skin cancers diagnosed each year in Ireland will double by 2040¹.

Cutaneous melanoma accounts for 90% of all melanoma cases diagnosed and is the most rapidly increasing cancer diagnosed in white populations worldwide^{3,4}. It is particularly prevalent in Ireland compared to other European countries due to a combination of genetic predisposition to the phenotypic pale skin, light eye colour and high skin sensitivity to the sun and pulsed ultraviolet light^{5,6,7}.

The role of SLNB in the treatment of melanoma has been widely debated but remains a useful prognostic tool and is widely used as part of the staging process in patients diagnosed with intermediate thickness melanomas^{8,9}.

A positive result will often infer which patients require lymph node dissection and further treatment¹⁰.

A number of studies have assessed the benefit of undergoing a SLNB in cutaneous melanoma patients; demonstrating a survival benefit in intermediate thickness melanoma patients who undergo SLNB, versus patient who undergo observation alone^{10,11}. In addition, a number of studies have reported varying levels of survival benefit in patients who had negative SLNB results versus positive SLNB results^{12,13,14,15,16}.

To our knowledge, this is the first Irish population-based study, assessing the role of SLNB in melanoma.

Methods

Data was obtained from the National Cancer Registry of Ireland (NCRI) relating to all patients with cutaneous melanoma diagnosis over a 20-year period January 1994 to December 2014.

A descriptive analysis of patient demographics was undertaken, and univariate analysis was carried out using Kaplan Meier Estimate.

Analysis was carried out to assess whether age, sex, smoking status, marital status, anatomical location of the melanoma, melanoma stage, SLNB conducted and SLNB result were predictors of survival.

Pairwise comparisons were carried out for variables that consisted of more than two groups and a Bonferroni correction was applied to the univariate analyses, as necessary, to adjust the p-values and control for type 1 error that can arise as a result of making multiple comparisons.

Multivariate analysis was carried out using Cox regression analysis. Two models were undertaken using regression analysis to assess: if undergoing a SLNB predicts survival and if SLNB results predict survival after controlling for age group, gender, smoking status, marital status, cancer stage, anatomical location, and HSE region of residence.

All statistical analysis was carried out using SPSS software version 24.

A p value of <0.05 was considered to indicate a significant difference.

Results

13302 patients were diagnosed with cutaneous melanoma between 1994 and 2014.

OS reduced with increasing age between all age groups (all p<0.001) with the exception of the survival difference between <24 and 25-49 (p=0.899) (Table 1). Males had shorter OS compared to females (OS 65.4% M; 75.1% F) (Figure 1). and this was statistically significant (p<0.001).

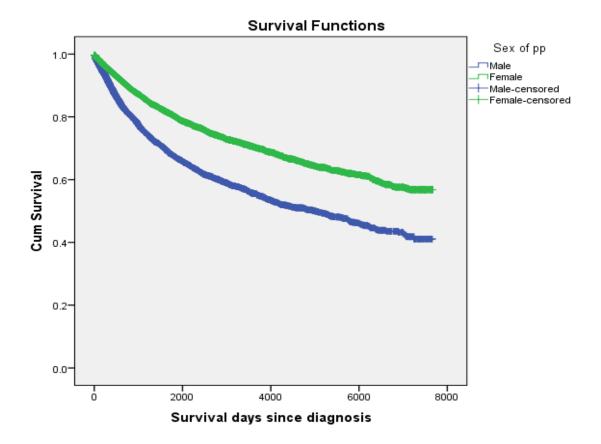


Figure 1: Overall Survival by Gender.

OS varied inversely with TMN stage; stage 4 had statistically shorter OS compared to all the other groups (p<0.001 for all comparisons), stage 3 had shorter OS compared to stage 1 and 2 (p<0.001 for both) and stage 2 had a statistically significant shorter survival time than stage 1 (p<0.001). While OS was higher for stage 0 or In-situ melanoma compared to stage 1, and stage 2, this was not statistically significant (p=0.805, p=0.180 respectively); however, when compared to stage 3, there was a statistically significant difference (p=0.023) (Table 1).

	Overall Survival	
Gender		
Males	65.4%	
Female	75.1%	
Age (groups)		
<24	86.6%	
25-49	87.7%	
50-69	77.3%	
70+	48.8%	
Smoking Status		
Never	62.9%	
Ex-smoker	55.8%	
Current Smoker	58.7%	
Marital Status		
Single	69.4%	
Married	73%	
Widowed	46.6%	
Separated/Divorced	75.6%	
HSE Region		
DNML	72.2%	
DNNE	71.5%	
South	71.5%	
West	68.2%	
Anatomical Location		
Head/Neck	62.3%	
Trunk	77.7%	
Upper Limb	77.5%	
Lower Limb	75.2%	
Overlapping/Unspecified	40.3%	
Stage		
Stage 0	93.8%	
Stage 1	86.4%	
Stage 2	62.9%	
Stage 3	49%	
Stage 4	21.2%	
SLNB Conducted		
Yes	72.9%	
No	70.6%	
SLNB Result		
Positive	59.2%	
Negative	86.1%	
Nodal Metastasis		
Yes	48.4%	
No	77.2%	

Table 1: Overall Survival and Patient Demographics and Clinical Characteristics.

In total, a relatively small number of patients 2196 (17%), underwent SLNB and this included 710 patients in the stage 1 melanoma group (<11% of this group).

There was a small variation in OS in patients who underwent SLNB compared to those who did not; 72.9% versus 70.6% and this was statistically significant for all stages with the exception of stage 1; stage 1 88.7% versus 86.1% (p=0.73), stage 2 76.7% versus 59.2% (p=0.001), stage 3 63.2% versus 42.4% (p<0.001), stage 4 29.6% versus 18.1% (p=0.002) (Figure 2). However, after controlling for marital status, age group, gender, smoking status, cancer stage, anatomical location, and HSE region, undergoing a SLNB was not a statistically significant independent predictor of OS (Hazard Ratio=1.052, 95% Confidence Interval 0.924-1.198, P=0.440).

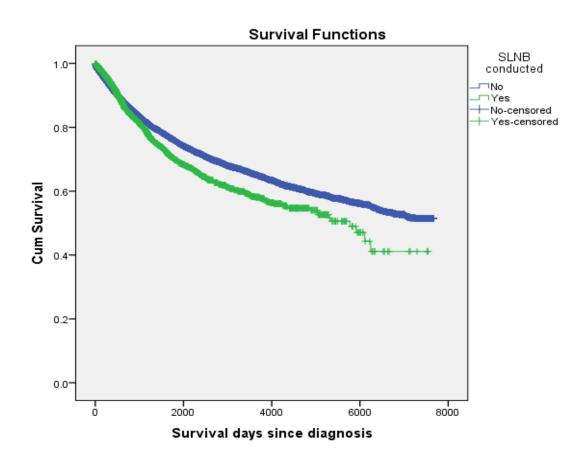


Figure 2: Overall Survival and SLNB conducted.

Patients with a positive SLNB had significantly shorter OS than those with negative SLNB results (p<0.001) (Figure 3) and this was an independent predictor of survival (Hazard Ratio 2.243, 95% Confidence Ratio 1.413-3.562, p=0.001).

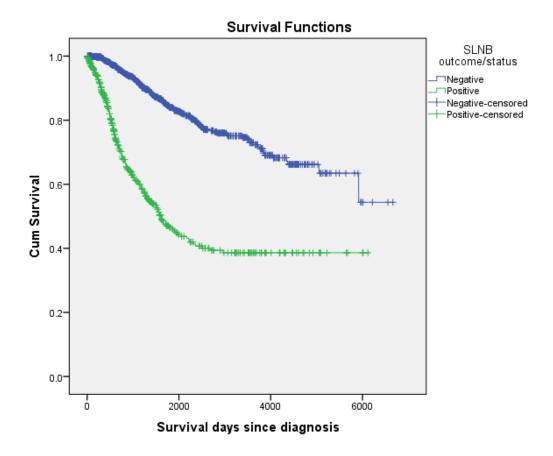


Figure 3: Overall Survival and SLNB result.

OS varied with anatomical location of the melanoma; patients in the overlapping/unspecified group had a statistically significant shorter OS compared to all other groups (p<0.001 for all comparisons) (Table 1). In addition, patients in the head/neck group had statistically shorter OS compared to the trunk (p<0.001), upper limb (p<0.001) and lower limb (p<0.001) (Table 1).

OS varied with smoking status; patients who had never smoked had longer OS compared to the other groups (never smoker versus current smoker p=0.002, never smoker versus ex-smokers p<0.001) (Table 1). Surprisingly, those who were current smokers had statically significant longer OS when compared to ex-smokers (p=0.004) (Table 1).

Married patients had statically significant longer survival than those who were single (p=0.001). Those who were widowed had a significantly shorter survival time compared to all other groups (p<0.001) while there was no significant difference between those who were separated/divorced and those who were married or single (p=0.977 and p=0.189 respectively) (Table 1).

Discussion

This is the first population level data specifically assessing OS in melanoma patients in the Irish population; it confirms and supports previously acknowledged independent predictors of OS.

This study found a number of patient demographics impacted on OS of cutaneous melanoma patients. Older age, male sex, positive smoking status and being widowed or single all predicted poorer OS. In addition, anatomical location, TNM stage and SLNB result all affected OS. Consistent with the published literature, OS varied inversely with age^{10,13,17}. Recent studies have assessed the survival benefit of undertaking a SLNB in cutaneous melanoma and the survival benefit of positive versus negative SLNB results with a large variation in the survival benefit reported.

Our study found that male patients had shorter OS compared to their female counter parts; consistent with other large studies which have reported a similar, if less marked difference in prognosis based on patient gender^{10,13,17,18}. Male patients generally tend to be more reluctant to engage in health screening which may account for this variation. High profile campaigns such as "Movember" and "Mens Health Week" have specifically targeted men in order to break down barriers and improve men's participation in health screening.

In our study, non-smokers had longer OS compared to current and ex-smokers (62.9% versus 58.7% and 55.8% respectively). Surprisingly, current smokers had longer OS compared to ex-smokers. This is consistent with Warren et al who found an increased Disease Specific Mortality (DSM) when comparing smokers to ex-smokers or non-smokers for all cancers¹⁹. OS is reduced in all smokers due to the numerous negative health effects of smoking, in addition, the poor wound healing associated with smoking could be particularly relevant in cutaneous melanoma patients with large surgical wounds, contributing to poorer OS in smokers. Smoking status is self-reported in the NCRI database which may limit the validity of this result.

Marital status has been widely reported as a prognostic indicator of survival and the reasons for this remain somewhat unclear^{18,20}. We surmise that the social support involved in the detection and treatment of melanoma may contribute to the improved OS rates in patients who are/were married.

OS varied greatly based on anatomical location of the melanoma with overlapping/unspecified having by far the worst OS (40.3%). Head and neck melanomas were also associated with worse OS when compared to the trunk, upper limb and lower limb. Studies have reported that anatomic tumour location was a significant prognostic factor in melanoma, Tejera-Vaquerizo et al reported that melanoma of the head and neck was independently associated with lower melanoma specific survival (MSS)^{18,21}.

Not surprisingly, OS was inversely related to cancer stage, Cheng et al reported very similar figures to our study for stage 1-3, reporting 5 year MSS; stage 1 89%, Stage 2 61%, stage 3 40.6%, however Cheng et al reported much worse stage 4 survival of 8.2% compared to our study¹⁰.

Cancer stage is inherently linked to prognosis and survival and, as expected, higher stage was associated with lower OS for all stages.

We noted a small but significant increase in OS in patients who underwent a SLNB compared to those who did not, 72.9% versus 70.6%; this concurs with other large population level studies^{10,11}.

OS in patients who underwent SLNB were also assessed for each cancer stage and the difference in OS was statistically significant for all stages with the exception of stage 1.

However, on further analysis after controlling for marital status, age group, gender, smoking status, cancer stage, anatomical location, and HSE region, the difference in OS in patients who underwent SLNB compared to those who did not, was not statistically significant. SLNB is recommended for patients with intermediate thickness melanomas and is often also undertaken in patients with a high suspicion of lymphatic spread clinically²². As such, it is not surprising that undertaking a SLNB does not predict improved OS.

Numerous studies have assessed the survival benefit of SLNB negative versus positive results in varying manners and with varying results, however, all agree that a negative SLNB result incurs a significant survival benefit compared to a positive SLNB result^{12,13,14,15,16}. Our results concur with the literature; patients who had a positive SLNB result had a much lower OS compared to those with a negative SLNB result (59.2% versus 86.1% respectively). After controlling for patient demographics, SLNB result was a significant independent predictor of OS. Patients who had a positive SLNB result were 2.243 times more likely to die than those with a negative SLNB result.

As with cancer stage, a positive SLNB is inherently linked to poorer OS, defining it as a more advanced, aggressive disease stage and resulting in poorer OS.

The role of SLNB is changing; initially used as a diagnostic tool to indicate whether patients should proceed to completion lymph node dissection, large trials have failed to show a significant improvement in survival as a result of undergoing SLNB and increasingly the value of completion sentinel lymph node dissection is being questioned^{23,24}. The treatment of melanoma has been undergoing a paradigm shift with the successful treatment of metastatic disease using immunotherapy. Large trials of neoadjuvant treatment are now reporting a survival advantage of neoadjuvant immunotherapy as opposed to observation^{8,24}. As such the role of SLNB is becoming increasingly important as a gateway to neoadjuvant treatment.

This is a retrospective study from a pre-formed database and was limited to the information that had been collected by the NCRI.

In conclusion, cutaneous melanoma is a growing problem in Irish society. A number of factors predict OS of cutaneous melanoma patients. Older age, male sex, positive smoking status and being widowed or single all predict poorer OS. In addition, melanomas of the head and neck or overlapping/unspecified region, melanoma of a higher TNM stage and positive SLNB results all predicted lower OS rates.

Despite recent research to the contrary, undergoing a SLNB was not indicative of higher OS once other variables were controlled for.

Declaration of Conflicts of Interest:

The authors declare that there is no conflict of interest.

Corresponding Author:

Lorraine Scanlon,
School of Medicine,
University College Cork,
Cork City,
Ireland and Department of Plastic Surgery,
Cork University Hospital,
Wilton,
Cork.

E-Mail: LorraineScanlon@rcsi.ie

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Guidelines for the use of the Attend Anywhere Platform for Telecommunications within the Pain Service

J.R. Skelly, T. O'Connor

Dept. of Anaesthesia, Intensive Care and Pain Medicine, Sligo University Hospital, Ireland.

Abstract

Introduction

Remote consultation is of growing in importance and gaining popularity in both primary and secondary healthcare settings. Reduced necessity for a physical presence of the patient within the healthcare setting is of particular benefit in the current COVID-19 era. It is also of benefit to a diverse group of patients, for example: those who are geographically distant from the base hospital, those suffering from mobility issues or chronic illness, those who require chaperoning as well as those with limited access to transport. We have developed guidelines for the use of the medical telecommunications platform, Attend Anywhere, which has been utilised across the English and Scottish National Health Services, as well as with the Australian Health service, and is now available in Health Service Executive (HSE) settings.

Herein we describe and recommend a process that we have found helpful, and we propose guidelines on how a Health Care Worker (HCW) might consider approaching a virtual consultation when initiating and safely executing a patient encounter on Attend Anywhere, in a secure and efficient manner. The guidelines were created following review of the literature on previous experience by others with this software, as well as recent guidance published by the Irish Medical Council. A proportion of this guidance is transferable to other platforms.

Methods

We also undertook a short survey of our patients and physicians in Sligo University Hospital, who used Attend Anywhere over a six-week period to gauge their satisfaction levels with the experience., We estimated distance that our patients would have travelled for their appointment had the traditional face-to-face consultation been carried out. We noted whether we considered the medium appropriate for the patient consultations.

Results

53 patients took part and satisfaction was rated from satisfied to very satisfied on a 3-point scale for all stakeholders. In addition, we found that remote consultation, when compared to face-to-face consultation, alleviated an average of 144km of unnecessary travel *per appointment*. Remote consultation was deemed appropriate in all cases and no rescheduled face-to-face appointments were required due to failure of the consultation due to difficulties encountered.

Conclusion

The authors recommend the implementation of the described guidance, with suggested Checklist, Information leaflet and Consent form, as a means of ensuring the confidentiality of the consultation and to ensure that processes are adhered to that optimise protection for both the patient and the clinician, while reducing the burden of attendance to the healthcare location.

Introduction

The use of digital platforms for remote consultations is becoming increasing common among primary and secondary care globally, including Ireland, where there is increasing prevalence of virtual clinics among secondary care services especially in this COVID-19 era¹. It is therefore important that the safe access to, and application of, an accredited platform that is available to all HSE staff is paramount.

In the setting of a remote consultation there are some important responsibilities for the healthcare professional to consider;

Firstly, to ensure that the use of telecommunications is secure and confidential, in particular, that HSE guidance for General Data Protection Regulation (GDPR) is adhered to.

Secondly, to ensure that all clinicians carrying out remote consultations are aware of their personal responsibilities *in providing a confidential consultation service* and are supported by information governance training, as well as on going auditing processes.

This document is based on relevant standards provided by the Irish Medical Council, The Medical Protection Society as well as those produced in the UK by the NHS and the Royal College of General Practitioners ²⁻⁷ to ensure the use of telecommunication software for remote consultation adheres to best practice, protecting both patients and clinicians from security risks.

Several studies have shown the benefit of implementation of telecommunication services in chronic conditions - including decreased emergency department (ED) attendances⁸, improved medication adherence, biomarkers and decreased financial burden on patient⁹⁻¹¹. Particularly of relevance in the current era is the reduced patient footfall within the primary and secondary care setting.

A systematic review of mobile technologies for health interventions in chronic conditions found that the potential of the tools is high. In 50 studies, 56% of patients exhibited improved regimen adherence, and 40% showed a significant clinical outcome¹².

This guideline suggests a process that might be followed in setting up and carrying out a telecommunications consultation. Specifically, we outline the use of a successfully piloted platform newly available to the HSE called Attend Anywhere.

In particular, we describe an information leaflet as well as a checklist that we have found useful to ensure that privacy of setting, personnel present and informed consent has been documented prior to remote consultation. We also include a sample Consent Form that can be signed after patient has received, read and understood the Information Leaflet.

Prior to Consultation

Patient selection should be carried out to identify the cohort for which this method of consultation would be beneficial.

Patient related aspects include:

- Amenability of the patient's condition (e.g., requirements for: examination, testing, imaging or blood work, intervention).
- Requirement of the patient to undergo intervention
- Ease of access to the hospital including: location, access to transport, mobility, health issues which may exacerbated by the journey (e.g. chronic pain).

Technical aspects include:

- Personal comfort with the technology,
- Access to the hardware and secure internet connection, access to a suitable area for privacy.

Preparation should be considered prior to the initial consultation. We suggest a checklist for undertaking a remote consultation and within this, the responsibilities of both the clinician and the patient (Table 1).

Table 1: Roles and Responsibilities.

Role	Responsibilities/Key Tasks
IT Support team	Technical set up of Attend Anywhere account and secure password
Clinician	Explanation of an Attend Anywhere remote consultation to the
	patient and gaining patient consent.

It is the clinician's responsibility to liaise with the HSE-endorsed IT Department to arrange for telecommunications software to be loaded onto a HSE-issued device including desktop personal computers/laptops/iPads and mobile phones. Attend Anywhere is a secure and internationally utilised platform ¹³ which has recently become endorsed by the HSE for use in patient consultations.

A secure password should be set up to access the software.

Prior to the consultation (Table 2).:

- Informed consent:
 - The patient should be provided with adequate information about the process of remote telecommunications in order to give informed consent to the process. (See example patient information leaflet (Fig. 1)(view)).
- In keeping with guidance from the Irish Medical Council, the same principles in gaining valid informed consent apply in telemedicine as do in face-to-face consultations, and healthcare professionals should make sure that patients have given their consent to conduct the consultation through telemedicine and consent to any treatment provided ². This consent can be gained in person or verbally over the telephone, in preparation for the consultation.
- Verbal consent from the patient, or their legal representative, should be gained prior to initiation of the remote consultations (Fig.2) This can be gained through explanation and provision of relevant information (Fig.3). If a patient is deemed to lack capacity for a decision at a given time, despite efforts to assist them in understanding the nature of the decision that is to be made, a personal representative who legal authority for their health and welfare can do this on their behalf.
- All questions regarding the proposed remote consultation should be answered.

Table 2: Documentation required prior to the Consultation.

Form / Template	Purpose			
Patient Information	To be provided to, and read by, the patient prior to gaining			
leaflets	consent. (Fig.1)			
Patient Consent Form	To be explained to and signed by the patient prior to the			
	Telecommunications consultation if possible. (Fig.2)			
If not possible, verbal consent can be confirmed and documented as such.				

Figure 2: Attend Anywhere Consultation Consent Form.

Patient Consent to the Use of Attend Anywhere for remote consultation

Affix Label Here

- I have read and understand the information provided in the preceding page regarding Attend Anywhere consultations. I have had the opportunity to discuss this information and all my questions have been answered to my satisfaction.
- I hereby give my explicit consent for the use of Attend Anywhere in my medical care and authorize the Clinician (doctor and/or nurse) to use Attend Anywhere to undertake remote consultations.

•					
Patient Name:	Date of Birth://				
Address:					
	Patient Signature:				
Verbal Consent attained via	telephone Attend Anywhere 🗆				
•	ot being able to give consent, the patients' representative name and				
address should be complete	ed along with signature				
Patient Representative					
Name:					
Signature:					
Power of Attorney					
NOK					
Verbal Consent attained via telephone/ Attend Anywhere®					

Figure 3: Remote Consultation (Attend Anywhere) Checklist. (For the clinician (doctor or nurse)).

Ren	note Consultation (Attend Anywhere) Checklist	Person Responsible
1	The patient has received an explanation of the use of Attend Anywhere for a remote consultation with the Clinic Staff	Clinician
2	A copy of the remote consultation patient information leaflet has been given and explained to the patient.	Clinician
3	Any concerns about remote consultation have been addressed	Clinician
4	Verbal Consent has been gained from the patient, or their representative	Clinician
5	The clinician has prepared his/her office to maximise privacy as per of the Standing Operating Procedure (SOP)	Clinician
6	The patient is undertaking the consultation from their home	Clinician and Patient
8	On answering the Attend Anywhere call, the Clinic Staff member should ask whether or not the patient feels it is appropriate to undertake the consultation and clarify that the patient's confidentiality can be confirmed.	Clinician
9	The clinician will introduce themselves to the patient and confirm that the patient is happy to take part in the remote consultation.	Clinician
10	The patients identify should be checked by asking them to confirm their name, address and date of birth.	Clinician
11	The clinician should explain that if a physical examination is required, the clinician will invite the patient to come to the practice.	Clinician
12	Prior to concluding the consultation, the clinician and patient should agree that the patient understands the outcome of the discussion and have no further questions.	Clinician and Patient
13	The clinician will record the observations and outcome of the consultation in the same way as a face to face consultation is recorded in the patient's record and ensure any agreed actions are carried out.	Clinician

During the consultation

Privacy

Patient:

The immediate area where the patient will be located during the remote consultation should be carefully considered to maximise privacy, to ensure that confidentiality will be maintained. Usually, the most suitable area for the consultation is in the patient's own home. If required and agreed by the patient, family members can also be present. Local access to participating medical sites may also be available in certain locations and as such access should be arranged if deemed necessary.

Clinician:

The immediate area where the clinician will conduct the remote consultation should be carefully considered to maximise privacy, to ensure that confidentiality will be maintained. Ideally the consultation should be held from a private room with the door and windows closed. This should emulate the environment used for face-to-face consultations, without the provision of a physical examination area. The Clinician should ensure that there is no personal confidential data on view that can be observed by the patient. Telephones in the immediate vicinity should be put on silent. It is recommended that a door sign is used to identify that the room should not be entered during the consultation.

Timing

Telecommunication consultations should be carried out by the clinician during a defined Telecommunication Clinic or as part of a conventional clinic. Patients should have agreed to a specific time at which the consultation is to be carried out and, as stated above, all patients should have given verbal consent to partake in the consultation *prior to contact being made* via the online service.

Process of conducting the consultation

Once the clinician is confident that their environment is appropriate, the Attend Anywhere online waiting room should be attended by the clinician at a time which has been agreed with the patient.

On entering the remote consultation, the patient should be requested to acknowledge whether or not it is appropriate to undertake the consultation and should state that they are willing to proceed.

- The clinician should state that the patient's confidentiality can be confirmed within the clinicians setting.
- The clinician should introduce themselves to the patient and verbally verify the patient's consent to take part in the remote consultation.
- The patients' identity should be checked by asking them to confirm their name, address and date of birth.

The consultation should proceed, and the clinician should be mindful that the patient is following and understanding what he/she is being asked and what is being discussed.

Should a prescription or intervention be required as a result of the remote consultation, the clinician should satisfy themselves that an adequate assessment of the patient's needs have been made and consider:

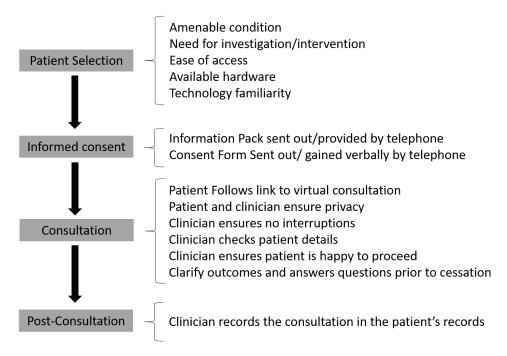
- The limitations of the medium through which they are communicating with the patient.
- The need for physical examination or other assessments e.g. investigations MRI, Blood test.
- Access to the patient's medical record.
- How necessary information and advice to the patient will be provided.

Concluding the consultation

Prior to concluding the consultation, the Clinician should clarify that the patient understands the outcome of the discussion and that all questions have been answered.

The clinician will document the observations and outcome of the consultation in the same way as a face-to-face consultation is recorded in the patient's records and any agreed actions that have been carried out. Telecommunication consultations should not be recorded by either party except where formal consent has been gained to do so. A summary of the consultation will be recorded by the clinician in the patient's record in keeping with current practice. A flow diagram outlining the process is shown in Figure 4.

Figure 4. Process of undertaking a Telecommunications Consultation.



Technical Aspects

While WebRTC video call media traffic is protected with AES 256-bit encryption between web browsers, the expectation that this is an adequate protection in the patient healthcare setting would be naïve. For example, call encryption does not prevent hacking if someone is able to highjack the signalling and listen in on the call.

As the volume of video consultations grow, there is a heightened public awareness around privacy and security, and the measures taken to protect against: Someone impersonating a clinician. Example: Gaining access to the video room; Unauthorised observation of a consultation. Example: Gaining unauthorised access ('hacking') the video call signalling; Third parties accessing the history of a consultation. Example: Observing the call logs on the patient device).

Unlike provider-centric meetings, video chat, or conferencing-based architectures (which are inherently less private and secure), Attend Anywhere has a three-tier privacy and security model that involves: Ensuring access is via a single point on the service provider website; Creating private video rooms for each consultation; Ensuring that the media signalling cannot be hacked in order to impersonate a clinician, or observe a consult. (Not simply protecting the call content.); Ensuring only authorised service providers from the clinic can join patients' rooms; Ensuring the media content is secure.

The Management Console is compliant with government privacy policies in Australia and the UK¹⁴.

The Management Console is implemented and run according to a System Security Policy approved by NHS National Services Scotland. This incorporates GDPR- and UK Data Protection Act 2018-compliant controls and policies¹⁴.

Patients enter online Waiting Areas via a trusted service provider website and wait in their own private video room. It does not matter if a Clinician is running overtime with another patient, as there is no chance of people running into each other. The room is deleted after the consultation.

Patients can be seen by any Clinician authorised to access the Waiting Area. Authorisation is accessed by a unique login and assigned roles in the platform. Organisation Administrators are responsible for assigning this access to their staff.

The Management Console does not retain patient identifiable information which means patients using the Attend Anywhere service leave no digital footprint.

The Attend Anywhere Management Console hosting and web application has multiple layers of protection from web attacks and exploits which include:

Web Application Firewall (WAF) with comprehensive Open Web Application Security Project (OWASP) Top 10 coverage, Distributed Denial-of-Service (DDoS) protection, Application server systems protection covering: Malware and virus protection, Automated system vulnerability assessment, on host intrusion protection and detection system, Virtual patching providing automatic update of protection modules for newly discovered vulnerabilities even before operating system or vendor patches are available.

We developed a suggested Information Leaflet (Fig. 1); a suggested consent form (Fig 2) and a suggested checklist for clinician prior to commencing a remote consultation (Fig 3).

<u>Survey</u>

Methods

We carried out a survey of all patient, as well as clinician, satisfaction over a 3 month period. Data recorded included:

- Number of consultations,
- Indications for clinic referral,
- Distance from the hospital,
- Number of consultations deemed inadequate and subsequent face-to-face alternative arranged,
- Patient satisfaction and clinician satisfaction were recorded: score range: 1-3 (1= not satisfied; 2=satisfied; 3=very satisfied)

Results

53 patients were surveyed. All were referred to the service due to chronic pain issues. All 53 patients underwent remote telecommunications consultation during the 3 month period. 100% of patients reported a satisfaction score of 2-3 and were keen to continue in the process.

Patients lived between 4-104km from the hospital with a median distance of 72km.

No consultations were deemed inadequate due to the medium and there were no additional face-to-face appointments required.

A similar result was obtained for the clinical staff who all reported a satisfaction score of 2 - 3 in their experience of using Attend Anywhere.

All patients have agreed to, and have had, subsequent remote consultations booked for on-going follow up.

Discussion

We have described a suggested guidance to implement a secure and validated telecommunications software and in doing so to reduce the requirement for patient face-to-face attendance in the healthcare premises. Given the current pressure to reduce patient footfall and shift to virtual clinics, the recent availability of this software has come at a most opportune moment for the HSE.

The HSE has made available information related to the use of the Attend Anywhere platform ¹⁵, while these had not yet been developed at the time of initiation of our service, it has informed and consolidated our guidelines.

The IMC have also recently published guidance related to the running of a telecommunications clinic ^{2,7} which has also informed our guidelines.

In addition, and with the expansion of remote consultations in the light of the COVID-19 pandemic, the Medical Protection Society has produced guidance for the provision of telecommunications consultation³ which informed our guidelines.

We suggest that these guidelines (Checklist, Information leaflet, Consent form) will serve as a basis for clinicians to gain confidence in this new medium and adopt their practices to include them, for the benefit of both clinician and patient.

Our survey has shown that patient and clinician satisfaction is very high and both groups wish continuation of our remote consultation service. We have demonstrated that this process can be an extremely effective form of consultation.

The majority of chronic pain patients attending our clinic for face-to-face consultation travel to the hospital by car and require an accompanying person, requiring often that a relative or friend be free to spend a significant part of the day of consultation in the hospital and driving, missing work for an often costly consultation.

Our survey showed that a potential 106 individual contacts with the hospital were avoided, 53 inperson consultations were avoided with a median round trip distance of 144km of traveling being avoided, amounting to a possible 7,632km of avoided unnecessary travel for chronic pain sufferers. It is noteworthy that this travel distance avoidance is the impact of 3 months remote consultations in one clinic. It could be considered that if this was applied to similar patient cohorts across multiple outpatient services, the distance travelled by a large number of patients in a geographical catchment area such as ours, which includes: Sligo; Leitrim; Donegal South & West Cavan as well as North & East Mayo, would be dramatically decreased. The not inconsiderate reduced time saved for the accompanying person, the travel costs incurred and the reduction in avoidable road use is likely to be significantly beneficial to the patient cohort.

In addition, using emissions data obtained from Sustainable Energy Authority of Ireland ¹⁶, the reduction in carbon emissions related to just our featured cohort would amass to 855kg over this short period (112g CO2/km) these numbers are also probably a gross underestimation as they are based on new cars sold in 2017. In addition, the most recent available data regarding the cost per kilometre of running an average car in Ireland, taking all running costs into consideration, indicates an average cost of 23.8 cent/km ¹⁷. On reflection of this numbers again its obvious that in this cohort alone there was an approximate saving of circa €1,800 (or €34 per person per hospital attendance). These figures are related to averages and are estimated values, which may very well underestimate the true figure, however it's easy to imagine the vast impact a nationwide implementation of this practice could have and the impact it could make on an environmental level as well as for the personal finances of certain patients traveling long distance several times a year for multiple appointments.

Based on patient and clinician feedback we recommend the implementation of the described guidance and checklist as an *AIDE MEMOIRE*, ensuring the confidentiality of the consultation so that both the patient and the clinician are protected, while reducing the burden of attendance to the healthcare location.

Declaration of Conflicts of Interest:

The authors have no conflicts of interest to declare.

Corresponding Author:

Dr. Richard Skelly Sligo University Hospital, The Mall, Rathquarter, Co. Sligo.

E-Mail: jamesrichardskelly

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A Study of GP Workload and Satisfaction

R. Say¹, J. Collins², K. Holmes², J. Lucey³, S. Murphy³, S. Buckley³, T.I. Curran¹

- 1. Ross Medical Practice, Killarney Primary Care Centre, Killarney, Co Kerry.
- 2. Brandon Medical Centre, Hoffmans Terrace, Basin Road, Tralee, Co. Kerry.
- 3. Dromcollogher Medical Centre, Newcastle West Road, Dromcollogher, Co. Limerick.

Abstract

Aims

In this novel study in the Irish setting, we quantified the number items managed per General Practitioner (GP) consult, how each item is managed, and impact on a GP's job satisfaction.

Methods

Participating GPs at two surgeries completed a questionnaire - integrated into the practice management software - after each consultation that satisfied the inclusion criteria during a four-week period.

Results

Due to feasibility constraints, 500 of 857 (58.3%) completed questionnaires were randomly selected for our sample. GPs manage an average of 1.76 items per consultation. Older patients presented with more items. Greater number of presenting items led to less being managed on the day 71% (n=5) for 5 items vs. 95.2% (n= 246) for 1 item, longer consultation duration (mean = 14.63 minutes (4-45) and decreased GP satisfaction, mean 8/10 (2-10).

Conclusion

Increasing the number of items in a GP consultation has a statistically significant effect on duration of consultation, how each item is managed, and even GP satisfaction.

Introduction

General practice consultations are becoming longer and more complex, reflecting the changing demography, epidemiology, and health-related behaviour and expectations of our patient populations. Pressures within the healthcare system also lead to increased workload for general practitioners (GPs)¹. These increased pressures coincide with a manpower crisis in general practice as a result of an increase in emigration among newly trained GPs, an increase in part time work by numerous existing GPs, and many GPs retiring. In the absence of significantly improved recruitment and retention of doctors in the field, these trends will place increasing time pressure on those who remain to deliver an ever more complicated and administratively demanding service 2. With these factors in mind, the primary concern remains the standard of care delivered to our patients. Many patients attend with multiple health-related problems and these can be difficult to manage within a time-limited appointment³. International research suggests that, given appropriate opportunity, patients with multiple issues will raise an average of 1-3 concerns per consultation ⁴. In the UK, the average number of issues presented by patients was 2.5 per consultation ⁵. However, when physicians solicit for problems at the start of the consultation this typically elicits a single concern ⁶. From both a patient's and a clinician's point of view, time is regarded as crucial resource. GPs often experience time pressures, particularly in keeping to schedule. Conversely, patients feel that they want more time, or that the doctor did not have enough time to listen to them 7. Research on consultation durations in Ireland shows that the average duration of a consultation was 14.1 min for the 9 years spanning 2010 to 2018 and patients had an average time between consultations of 99 days ². This is longer than the 5–11.7 min reported in the UK, and shows an increase over the period. It is purported that each additional presenting complaint can add 2 minutes to the consultation 8. This research is the first to document the number of items that patients present with in Irish general practice and the resultant effects on consultation duration and GP satisfaction. The authors hope that this study will highlight the pressures and resource requirements of this vital area of healthcare.

Methods

This research aims to assess the number of items managed by a GP in the course of a routine patient encounter, how time is managed, and whether this impacts upon a general practitioner's job satisfaction. Analyses were performed to: quantify the number of items that patients present with in a routine GP consultation, ascertain how the GP manages each item, investigate any correlations that may exist between patient demographics and the number of items that they present with, and attempt to discern consultation-factors that impact a GP's satisfaction with the consultation (indicated by a Likert scale within the questionnaire). The research also recorded demographic qualities of every patient, consultation duration and the satisfaction of the GP after every consultation.

A literature review was carrying out via PubMed; we found that no research of this type has previously been undertaken in Ireland. This multi-site, cross-sectional study employed a non-validated questionnaire, because a validated questionnaire relevant to our study did not exist.

The questionnaire was integrated into practice management software at two sites: one singlehanded practice and one multi-doctor practice consisting of three full time GPs. Participating doctors were invited to complete a questionnaire after each consultation that satisfied the inclusion criteria during a four-week period. This questionnaire was saved into the patients' chart, but no identifiers were saved, and the data was input into the study spreadsheet anonymously. Because a questionnaire was completed following every consultation, some patients had multiple questionnaires completed if they attended multiple times during the study period. A "presenting item" or "item" was defined as an issue requiring doctor action in the form of a decision, diagnosis, treatment or monitoring. Ethical approval and a consent declaration to proceed without explicit consent were granted by the Clinical Research Ethics Committee of the Cork Teaching Hospitals, University College Cork, Ireland in October 2018. The study population consisted of all encounters involving patients who attended a doctor in each practice during the specified fourweek period. This provided a cross-section of all age ranges, genders and a mixture of public and private patients. All encounters with patients who were seen by a doctor in Brandon and Dromcollogher Medical Centres during a four-week period in November 2018 were included. Patients excluded were those seen as a home visit or a nursing home visit, via phone consultations or those who were not seen by a doctor i.e. seen by the nurse or secretary. The minimum number of completed questionnaires required to power the study (with outcome measures being number of items and GP satisfaction) was calculated as being 30. 500 of 857 (58.3%) completed questionnaires were included as a random sample for data analysis. This substantial sample size was included to increase the sensitivity and power of the study, while respecting the feasibility constraints of the researchers. A pilot study was carried out for one week prior to commencement to test the questionnaire and data collection process; survey modifications were made from paper to an online format as a result. There were twelve questions in total, involving multiple choice, yes/no and Likert scale type questions. Questionnaires that were incomplete (missing one or more data points) were discarded prior to random sample selection.

Data from the completed questionnaires were coded and entered into Microsoft Excel 365 and then transferred to SPSS software for analysis with the assistance of a statistician. Several analytical functions were performed on the data to determine power, statistical significance, rejection of null hypothesis (that there is no correlation between patient demographics and number of presenting items or GP satisfaction) and correlation. Statistical significance was said to be achieved if the p value \leq 0.05. Charts and tables were constructed from these analyses for visual interpretation.

Results

Demographics

The sample of 500 patient encounters displayed a predominance of female patients (57% female (n=285) to 43% male (n=215). The mean patient age was 50.72 years with a wide age-range (1 to 95 years). The patient encounters involved mostly public patients; 76% (n=380) public patients compared to 24% (n=120) private.

Number of Presenting Items

The majority (51.8%, n=258) of the 500 consultations analysed involved only one presenting item, with more presenting items being less common. With an average of 1.76 items per consultation, GPs managed 76% more issues than their daily patient list would suggest (table 1).

Number of Presenting Items	Frequency (=n)	Percentage
1	258	51.8%
2	143	28.5%
3	67	13.3%
4	25	5.0%
≥5	7	1.4%
Total	500	100%

Table 1. Number of presenting items.

Management of Presenting Items

As the number of items increased, the GP was more likely to defer management to a follow-up consultation. Figure 1 shows that for all patient encounters involving two items the second item was deferred in 3.70% (n=5) of cases, whereas for all patient encounters involving five or more items the last item was deferred in 28.60% (n=2) of cases.

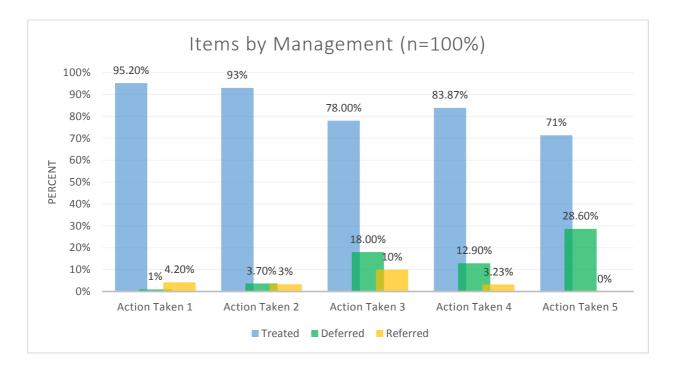


Figure 1. Presenting items by management plan displayed as percentage of each presenting item.

Correlation between Patient Demographics and Number of Presenting Items

A statistically significant association between patient age and the number of presenting items was found in two age groups (table 2). The red boxes demonstrate the cells that are most responsible for the rejection of the null hypothesis (that there is no correlation between patient demographics and number of presenting items or GP satisfaction). As expected, the number of presenting items increases with increasing age.

Age		Number of Items				
		1	2	3	4	5
34 and Under	Count	95	25	7	1	1
	Expected Count	66.8	36.7	17.2	6.4	1.8
35 to 55	Count	68	34	14	4	1
	Expected Count	62.7	34.5	16.1	6.0	1.7
56 to 70	Count	54	38	21	10	0
	Expected Count	63.7	35.0	16.4	6.1	1.7
71 and Older	Count	43	46	25	10	5
	Expected Count	66.8	36.7	17.2	6.4	1.8

Table 2. Association between age and number of presenting items.

Statistically Significant Correlations Between Age, Duration of Consultation, GP satisfaction and Number of Items

			Age	Duration	Satisfaction	Items
Spearman's rho	Age	Correlation	1.000	.122**	043	.317**
		Coefficient				
		Sig. (2-tailed)		.006	.333	.000
		N	500	500	500	500
	Duration	Correlation	.122**	1.000	378**	.400**
		Coefficient				
		Sig. (2-tailed)	.006		.000	.000
		N	500	500	500	500
	Satisfaction	Correlation	043	378**	1.000	287**
		Coefficient				
		Sig. (2-tailed)	.333	.000		.000
		N	500	500	500	500
	Items	Correlation	.317**	.400**	287**	1.000
		Coefficient				
		Sig. (2-tailed)	.000	.000	.000	
		N	500	500	500	500

^{**.} Correlation is significant at the 0.01 level (2-tailed).

Table 3. Correlations between age, duration of consultation, GP satisfaction, and presenting items.

Age and duration showed a weak, though statistically significant, positive correlation demonstrating more time was spent with older patients. A positive correlation was also seen between age and number of items.

A statistically significant moderate negative correlation was found between duration and GP satisfaction and between GP satisfaction and number of presenting items. These findings show that GPs reported greater satisfaction with fewer items and shorter consultations.

Duration and number of items showed a moderate statistically significant positive correlation i.e., more presenting items resulted in longer consultations.

Discussion

This study led to several interesting findings. Demographic data, per consultation, revealed a female predominance, with a mean age of 50.72 years and largely public GMS status. Patient age correlated with duration and number of presenting items which suggests elderly patients tended to present with more items, and their consultations were longer. Almost half (48.2%, n=241) of consultations involved more than one presenting item, the average being 1.76 items per consultation; this means that GPs manage 76% more items than their daily consultation list suggests. As the number of items per consultation increases, more items are deferred for later management. GPs must work within the bounds of time, thus an increasing number of issues correlated with increased consultation time and decreased GP satisfaction, both to statistically significant degrees. This study reveals the clear impact of GP workload on satisfaction, setting it within the observed trend in increasing workload and burnout amongst GPs ⁹. This is the first study of its kind the in the Irish setting and it aligns with established findings in the international literature which demonstrates that GPs regularly managed more than one item per consultation but is lower than the average figure for presenting complaints in the UK ^{4,5}.

The strengths of the study included the considerable sample size; even after reducing the sample size for feasibility purposes, the statistical power of this study is formidable. Because of the large sample size, many of the study correlations were statistically significant. This was a mixed urban and rural study and demographic data was varied in relation to age, gender and GMS status, which allowed for a diverse study population and is representative of the nature of everyday General Practice. The short, easily employed questionnaire used here makes this study readily reproducible.

The study's major limitation is the dependence on doctor self-reporting. The doctors were aware of the study hypothesis and this, together with the Hawthorne effect, could have led to inaccurate data being recorded. Attempts were made to counter this by facilitating immediate completion of the questionnaire following the consultation. The questionnaire was designed to be quick and easy to complete and, following the pilot study, it was incorporated into the GP software to further streamline the data collection process.

Direct observation by researchers or via video recordings would be superior but less feasible ¹⁰. Previous studies employing such methods have found a common limitation to be the subjectivity of the analysis of the data ^{11, 12}. Even direct observation is limited by the difficulty in describing issues considered by a GP in making decisions, but not necessarily acted upon, for example, the patient's co-morbidities and social background. Hence, the study may underestimate the complexity of consultations from the GP's perspective. There was also a limitation in using a non-validated questionnaire but on review of the dataset gathered it is apparent that the instrument used was fit for purpose. This study was carried out in two practice settings which limits extrapolation to the wider Irish population. Replicating the study in other rural and urban settings may reveal interesting results. Because our focus was on quantity of items per GP consultation (not necessarily unique patient encounters), we did not correlate the impact of how items were managed on GP satisfaction, nor did we remove repeat presentations within the data collection period from our sample. Doctor factors such as personal differences with the patient are difficult to control for, introduce unavoidable inter-rater reliability issues, and represent an additional limitation of the study.

In conclusion, this study notes that consultations in general practice are multifaceted encounters, with multiple complaints managed by a GP within a single consultation. This study demonstrates that increasing the number of items has a statistically significant effect on duration of consultation, how each item is managed, and even GP satisfaction. There are wider implications in terms of GP contract negotiations, resource planning, and guideline implementation. These factors should be taken into account by both the medical profession and policy makers in future.

Declaration of Conflicts of Interest:

The authors declare no conflict of interest.

Corresponding Author:

Ryan Say Ross Medical Practice, Killarney Primary Care Centre, Killarney, Co. Kerry

E-Mail: ryan.patrick.say@gmail.com

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Assessment of Layperson Knowledge of AED use in Sports Clubs

P. Ryan¹, G. Twomey², É. Falvey³

- 1. Department of Anaesthesia and Intensive Care, Cork University Hospital, Ireland.
- 2. National Ambulance Service Ireland.
- 3. Dept of Sports and Exercise Medicine, University College Cork, Ireland.

Abstract

Aims

To investigate knowledge and attitudes among sports club members toward AEDs, and to examine the potential benefits of an educational programme as an intervention for increasing awareness and willingness to use an AED.

Methods

A number of selected sports clubs were visited, and participants aged ≥16 were asked to complete a questionnaire relating to current awareness and attitudes toward AEDs, and their willingness to use the device. Each participant then attended a 2-hour small-group teaching session where they were educated on the role and use of an AED, with opportunity to practice AED use in a controlled environment. After receiving teaching, each individual again completed the questionnaire.

Results

142 people participated in the study. Before teaching, the average level of knowledge regarding AED use was relatively low. The most common reason identified for unwillingness to operate an AED was lack of knowledge on how to correctly use the device. Paired data analysis showed that attendance at a 2-hour educational programme led to a significant improvement in layperson awareness and understanding of AED use. After teaching, 77.5%(n=110) of participants reported that they would definitely be willing to use an AED, compared with 20.4%(n=30) before teaching.

Conclusion

A structured educational programme can increase layperson awareness, confidence and willingness to operate an AED.

Introduction

Sudden cardiac arrest (SCA) is a condition in which the heart suddenly and unexpectedly stops beating, and usually causes death if not treated within minutes¹. In Ireland, SCA causes up to 5000 deaths each year, 70% occurring outside of the hospital setting^{2, 3}. Global incidence of out-of-hospital SCA ranges from 20-140/100000 people, and national survival rates range from 2%-11%³. The current out-of-hospital cardiac arrest survival rate in Ireland stands at 6.4%⁴.

AEDs have become increasingly available in sports and leisure clubs, allowing members to defibrillate with minimal delay if necessary. Early defibrillation for SCA improves the chances of successful resuscitation and survival⁵⁻⁸. Chance of survival from an out-of-hospital cardiac arrest falls by 7%–10% per minute that passes without intervention⁹. It is unclear whether members of the public are sufficiently prepared or willing to use an AED.

Prior to commencement of the study, a systematic review of existing international literature relating to this topic was undertaken¹⁰. It was found that there is a paucity of literature relating to layperson understanding of AED function and use¹⁰. A study of distribution of AEDs in amateur sports clubs in Cork encouragingly found that of the 218 amateur sports clubs randomly surveyed in Cork, 81.3%(n=126) owned an AED¹¹. However, no data currently exists relating to layperson knowledge and attitudes toward AEDs in Ireland.

The primary objectives of the study were to investigate existing knowledge and attitudes among sports club members toward AEDs, and to examine the potential benefits of an educational programme as an intervention for increasing awareness and willingness to use an AED.

Methods

The study population was members of Cork GAA clubs aged 16 years and over. A standardized email was sent to the secretary of every GAA club registered in the East Cork and Cork City divisions. In total 49 clubs were emailed, of which 9 responded. Each club who expressed interest in taking part were included in the study. A total of 12 teaching sessions were delivered over a 2-month period in 9 different locations.

Participants aged ≥16 years were asked to complete a paper questionnaire relating to their current awareness of the existence, purpose and practical use of the AED within the club. The questionnaire also examined their attitudes toward AEDs, and their willingness to use the device. As no standardised, validated survey exists in relation to public knowledge and attitudes toward AEDs, we formulated a 25-part questionnaire using physician expertise, designed to target the key elements relevant to AED understanding and awareness. A pilot test of the questionnaire was conducted prior to use.

Each participant then attended a standardized 2-hour small-group teaching session at their club, delivered by the same qualified instructor, outlining the chain of response to a SCA as described by the AHA guidelines¹². The learning outcomes for the course were recognising a cardiac arrest, efficiently alerting emergency services, performing hands-only CPR and understanding the role of an AED. Each participant was given the opportunity to perform CPR and practice AED-use on mannequins in a controlled environment. After receiving teaching, each individual again completed an identical questionnaire.

We compared individual questionnaire responses before and after attendance at the training course. The collected data was normally distributed, so a series of 'paired t-tests' were performed to investigate the effect of the intervention on participants' responses and to test the null hypothesis that training has no impact on participant knowledge.

Results

In total, 142 people took part in the study. Males accounted for 67.6%(n=96) of the subject-group. Age distribution of participants showed 11.3%(n=16) aged 16-18, 2.8%(n=4) aged 19-21, 3.5%(n=5) aged 22-30, 19%(n=27) aged 31-40 and 63.4%(n=90) aged>40 years. Participants' roles in their sports club were varied: Coach 39.5%(n=56), Player 19.7%(n=28), Parent/Supporter 19%(n=27), Committee-Member 18.3%(n=26), Other 3.5%(n=5).

Twelve participants (8.5%) reported past experience of working in a healthcare capacity. Twenty participants (14.1%) had received some form of prior teaching in relation to AEDs. Twenty-four of those surveyed (16.9%) reported that they knew of somebody who had required use of an AED.

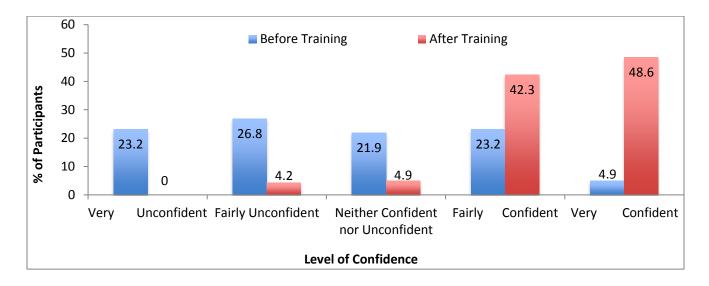
Regarding baseline awareness of AEDs, 98.6%(n=140) had heard of the term defibrillator while 64.1%(n=91) had heard of the term AED. 69 participants (48.6%) identified AED as meaning Automated External Defibrillator. 96 participants (67.6%) correctly identified the international AED symbol from a series of images.

Regarding access to their club's AED, 88.7%(n=126) of participants were aware if their club owned an AED, 62%(n=88) knew the exact location, and 20.4%(n=29) reported having the means to access/open their AED. 107 participants (75.4%) identified cardiac arrest as the most appropriate situation for AED-use from 5 optional scenarios. 30 participants (21.1%) identified the correct sequence of response to a SCA.

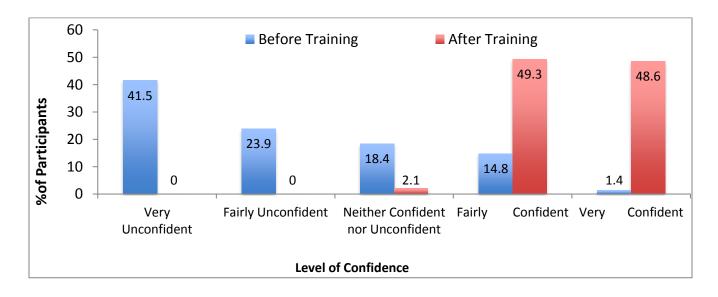
Regarding the function of the AED, 90.8%(n=129) selected that the AED starts the heart; 9.2%(n=13) selected that it stops the heart. After attendance at the 2-hour teaching session, 94.4%(n=134) correctly identified that the AED acts by stopping the abnormal electrical activity of the heart when it delivers a shock.

Participants were presented with a diagram of the chest and asked to select the two areas for pad placement. Before the teaching session, 10.6%(n=15) were able to correctly identify the appropriate positions for pad placement, compared with 93%(n=132) after teaching.

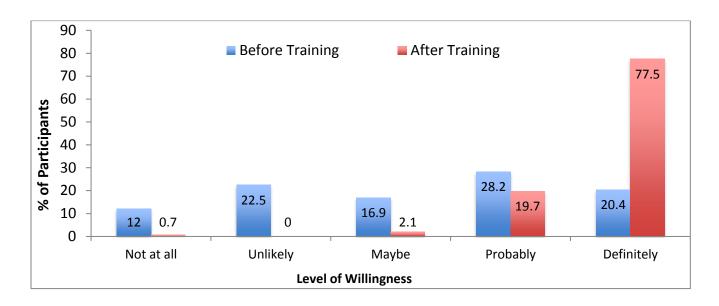
Participants were asked to evaluate their own confidence in their ability to access their club's AED in the event of a SCA. Participants were then asked to rate their confidence in their ability to correctly use the AED in the event of a SCA. Finally, we asked participants to evaluate how willing they would be to obtain and use an AED if a player required defibrillation during a match that they were attending. Participants' responses from before and after teaching are represented in Graph 1, Graph 2 and Graph 3.



Graph 1: Confidence to Access AED.

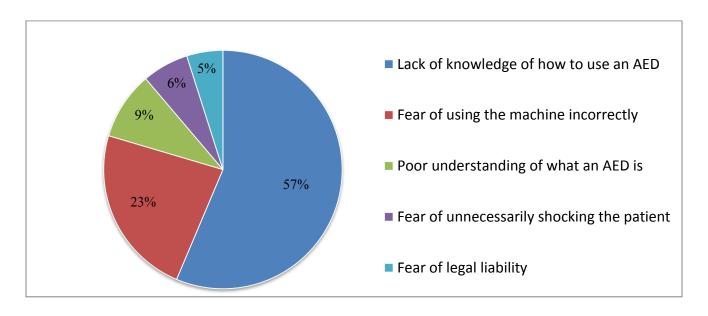


Graph 2: Confidence to Correctly Use AED.



Graph 3: Willingness to Use AED.

Prior to training, each study participant was asked to identify the main reason that they might be hesitant or unwilling to use an AED in the event of a SCA, and the results are displayed in Graph 4.



Graph 4: Reason for Unwillingness to Use AED.

All participants stated that they felt more people in the club should be educated on the purpose and function of the club defibrillator. As an additional aspect to the study, trained personnel inspected each AED, pads and storage-unit. It was found that 2 of the AEDs were out of battery, and 2 had pads that were out of date.

Discussion

Team coaches were the best-represented group at the teaching sessions. Only 2.8%(n=4) of participants were aged 19-21. Regarding death during sporting activities, it is this age group who are particularly at risk of SCA due to HOCM, which has an estimated prevalence of 1 in 500¹³. Further efforts are needed to target and inform this cohort of the role of the AED. These individuals are likely to be potential bystanders if a teammate collapses during training or a match.

Only 20.4%(n=29) of those studied reported that they had the means to open or access the AED, whether by key or using a PIN-code. Most AEDs are stored in locked cabinets for anti-theft and anti-vandalism reasons. However, the fact that only 1 in 5(n=29) reported being able to access the device if required was concerning. AEDs need to be clearly visible and stored in an easily accessible location.

More than 75%(n=107) of participants were able to correctly identify the recommended order of response to a SCA after teaching, compared with 21.1% (n=30) before teaching. This is a very encouraging outcome of the teaching programme. We also found a significant increase (>80%, n=117) in the number of participants who could correctly identify the correct positions for placement of AED pads on the chest. Pad-placement is an important aspect of efficient defibrillation and it was observed that only 10.6%(n-15) of participants could identify the correct positions on the chest. After teaching, 93%(n=132) of participants identified the correct pad positions. If larger numbers of the lay-population are more informed on performing good CPR and using an AED correctly as part of the chain of survival, it is hoped this will lead to improved outcomes from out-of hospital SCA¹⁴.

Prior to training there was a large variation in participants' confidence to access an AED, with only 4.9% reporting that they were 'very confident'. The 'after-training' responses indicate a large increase in participants' confidence, with just under half reporting that they would be 'very confident' that they could access an AED if required to do so.

Before training, a large proportion of the studied population were not confident in their ability to use an AED, with 41.5%(n=59) reporting that they would be 'very unconfident'. After training, there was a significant increase in participants' confidence to correctly operate the device. Almost all (97.9%, n=139) reported that they would be either 'fairly confident' or 'very confident' to use an AED. Attendance at the 2-hour session led to a substantial increase in participants' confidence to both access and use an AED.

The key finding of this study relates to the willingness to use an AED. In order to improve the national out-of-hospital cardiac arrest survival rate of 6.4%, we need laypersons to be willing to attempt to use an AED to save the life of an individual who suffers a SCA⁴. In Ireland, AEDs have become increasingly available in public places and there has also been considerable investment in developing the National Ambulance Service to allow an appropriate emergency response, which continues right through to advanced in-hospital care.

However, these important measures are less effective unless they are incorporated into a structured chain of response where laypersons have adequate knowledge to use the AED effectively while awaiting medical support. The emergency services' ability to intervene is dependent upon and interconnected with the role of the layperson. Bystander CPR and early use of an AED are critical links in the chain, and it is imperative that the importance of the layperson in performing these roles is recognised, and that appropriate resources are directed toward public education.

Before training, we found considerable variation in participants' willingness to use an AED. A large proportion of the studied participants were unsure if they would try to use an AED. After teaching, 77.5%(n=110) of participants said that they would 'definitely' use an AED. This highlights that a structured educational programme can significantly increase layperson willingness to use an AED. Young adults were found to be very responsive to teaching; all participants (n=20) in the 16-21 age-category reported that they were both 'very confident' and 'definitely willing' to use an AED after training.

The primary reason for unwillingness to use an AED was 'lack of knowledge of how to use an AED.' Fear also played a role in some participants' unwillingness to use an AED: fear of using the machine incorrectly, fear of unnecessarily shocking the patient and fear of legal liability. Having identified why people are unwilling to use an AED, we can address these gaps in understanding and knowledge. We can allay their fears and concerns through targeted teaching, in order to further increase layperson willingness to use this important device.

Our study is limited by small sample size and sampling bias. Those who chose to participate in the study were likely to be more motivated or interested in AEDs than those who chose not to participate. Consequently data may overestimate the awareness of AEDs and the likelihood of use. Furthermore our survey could only measure what people said they would do, not what they would actually do.

Our results show that average levels of awareness and understanding of the role and use of an AED in the sporting setting are relatively poor. Previous research has indicated that extensive public education is needed before AEDs can be expected to maximize their public health influence¹⁵⁻¹⁸. AEDs must not only be placed in strategic locations such as sports clubs, but must be then complemented with practical training methods in order to realise their full benefit.

This study shows that a structured educational intervention leads to significantly improved knowledge of AED use, as well as increased confidence and willingness to use the device. If an educational course of this nature is implemented effectively on a broader scale through a strategic campaign then it is hoped that this will translate to the prevention of death in tragic circumstances, and long-term improvement in the out-of-hospital cardiac arrest survival rate. Attendance at a 2-hour educational programme led to a significant increase in layperson awareness and understanding of the role and purpose of an AED.

Further initiatives should include a broader range of sports-clubs and should be made accessible to laypeople in the community. Referees and players should be targeted as important subgroups to receive training. This programme could be considered as a module for second-level students. The establishment of nationwide AED registries would be beneficial for structuring and arranging the provision of an appropriate educational campaign like this.

Finally, the fact that 2 of the 9 sites surveyed had AEDs which were out of battery emphasises the need for regular maintenance and servicing of AEDs.

Ethical Approval:

Ethical approval for this study was requested and granted by the Clinical Research Ethics Committee of the Cork Teaching Hospitals, prior to commencement of data collection.

Declaration Conflicts of Interest:

There were no conflicts of interest to declare. There was no support from any organisation for the submitted work and no other relationships or activities that could appear to have influenced the submitted work.

Research Reporting Checklist:

The methods for the interventional component of this study were designed using the TIDieR (Template for Intervention Description and Replication) Research Checklist obtained from the EQUATOR network.

Corresponding Author:

P. Ryan

Dept. of Anaesthesia and Intensive Care, Cork University Hospital,

Ireland.

E-Mail: pauljeromeryano30@gmail.com

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A Survey of Latent Tuberculosis Screening and Treatment Practices in a Tertiary Centre

J. O'Connell¹, E. de Barra^{1,2}, C. McNally^{1,2}, S. McConkey^{1,2}

- Department of International Health and Tropical Medicine, Royal College of Surgeons in Ireland, Dublin 2
- 2. Beaumont Hospital, Royal College of Surgeons in Ireland Hospital Group, Health Service Executive

Abstract

Aim

Knowledge of latent tuberculosis infection (LTBI) screening and treatment practices are lacking in Ireland, where LTBI is not programmatically surveyed or managed. The aim of this research was to describe current clinical practice when screening and treating patients for LTBI in a tertiary referral centre in Ireland.

Methods

A 17-question survey relating to LTBI screening and management practices with both open-ended questions and close ended multiple-choice questions was created using SurveyMonkey. The survey target sample was healthcare workers in the tertiary centre who direct LTBI screening and treatment for patients at risk of TB disease in their respective departments.

Results

The response rate to the survey was 45% (21/47). Seventy-one percent (15/21) of those surveyed responded to the question "What barriers exist to screening patients for latent TB in your clinical practice?". Fifty-three percent (8/15) said that they found it difficult to access LTBI testing and 27% (4/15) cited accessing the interferon-gamma release assay (IGRA) result as a barrier. Forty-three percent (9/21) responded that there was not a clear referral pathway for patients that they would like specialist input on when diagnosing and managing patients with LTBI.

Conclusion

Access to LTBI testing, LTBI test results, TB specialist services and the use of rifamycin-based regimens should be improved in this tertiary centre. Consideration should be given to developing a national LTBI education programme for healthcare professionals and updating national LTBI treatment guidelines.

Introduction

Latent tuberculosis infection (LTBI) is a state of persistent immune response to stimulation by Mycobacterium tuberculosis (Mtb) antigens with no evidence of clinically manifest active disease.¹ It is estimated that 23% of the world's population has LTBI.² In the World Health Organisation (WHO) European Region, the estimated prevalence of LTBI is 13.7% (95% confidence interval (CI) 9.8-19.8). TB reactivation is most likely to occur within two years of infection and in Europe an estimated 0.2% to 0.3% of those with LTBI are recently acquired infections (within two years).² Of those with recent LTBI in the WHO European Region, 29.5% are infected with isoniazid resistant Mtb, the highest such proportion among any WHO region.² Assuming 0.15% of those latently infected develop TB disease, then the disease incidence among this population alone is estimated to be 16.5 cases per 100,000 population per year by 2035.2 In countries with a low incidence of TB and established systems for contact tracing, like Ireland (incidence of 5.6 cases per 100,000 of population³), most TB disease is due to TB reactivation.^{2,4} The WHO Framework Towards Tuberculosis Elimination in Low Incidence Countries highlights the importance of systematic screening for LTBI in at-risk groups to achieve TB elimination (less than 1 case per million of population).5 People living with HIV, contacts of pulmonary TB cases, patients initiating anti-tumour necrosis α treatment, dialysis patients, patients preparing for organ transplantation and patients with silicosis should undergo systematic screening for and treatment of LTBI according to the WHO.5 Systematic screening and treatment of LTBI may also be considered for prisoners, health workers, migrants from countries with a high burden of TB, homeless people and people who use illicit drugs. 5 However, the risk benefit of LTBI treatment will vary depending on the patient's risk of TB reactivation and risk of treatment-related adverse events. Knowing what current clinical practices are when screening and managing LTBI is important to understand how effectively LTBI care is being provided and how it could be improved. However, knowledge of LTBI screening and treatment practices is lacking in Ireland, where LTBI is not programmatically surveyed or managed. The aim of this research was to describe current practices when screening and treating patients for LTBI in a tertiary referral centre in Ireland.

Methods

A 17-question survey with both open-ended questions and close ended multiple-choice questions was created using SurveyMonkey (SurveyMonkey Inc., www.surveymonkey.com). The survey target sample was healthcare workers in the tertiary centre who direct LTBI screening and treatment in their respective departments for patients who, according to national guidelines, should be screened for LTBI.⁵ A list of hospital specialists, clinical nurse specialists and advanced nurse practitioners was drafted from the hospital internal directory and recorded in Microsoft Excel (Microsoft Corporation, 2018). The total number of entries in this excel spreadsheet defined the denominator of the survey response rate. The survey was disseminated via internal hospital email. The survey was sent a total of three times to all those on the list at two-weekly intervals. Responses were analysed using Microsoft Excel. Qualitative data were analysed and coded by author 1 according to the themes expressed in the responses. Ethical approval from the Royal College of Surgeons in Ireland Research Ethics Committee was received to perform this survey.

Results

The response rate to the survey was 45% (21/47) and included hospital specialists, clinical nurse specialists, advanced nurse practitioners and occupational health specialists. Figure 1 demonstrates that among the 20 respondents able to offer a response regarding patients on immunosuppressive treatment, 75% (15/20) said they frequently offered this cohort LTBI screening. Among the 15 respondents able to offer a response regarding recent TB case contacts, 73% (11/15) said they frequently offered this cohort LTBI screening. Regarding patients with silicosis, people living with HIV, people who are homeless and people in prisons, 62% (13/21), 48% (10/21), 43% (9/21) and 43% (9/21) of respondents, respectively, reported that they did not encounter this cohort often enough to answer. With regard to people from high TB incidence countries, only 50% (8/16) of respondents reported offering this cohort LTBI screening frequently.

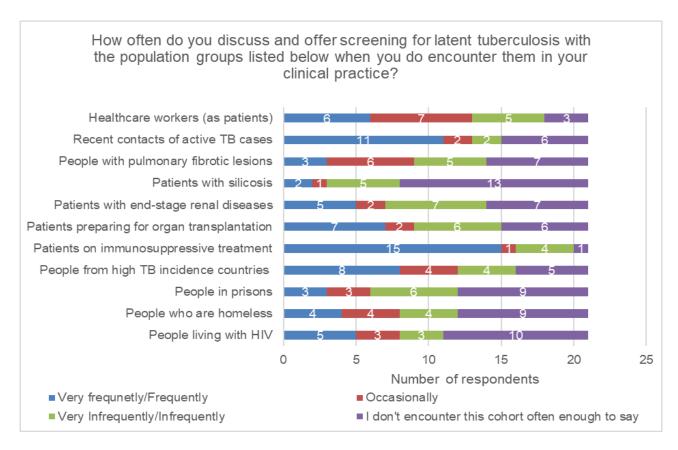


Figure 1: How often do you discuss and offer screening for latent tuberculosis with the population groups listed below when you do encounter them in your clinical practice?

Seventy-one percent (15/21) of those surveyed responded to the question "What barriers exist to screening patients for latent TB in your clinical practice?". Fifty-three percent (8/15) said that they found it difficult to access LTBI testing. Respondents cited problems such as a lack of 2TU tuberculin skin tests (TST), lack of clinic space to read TSTs and for testing with interferon-gamma release assays (IGRA), barriers were sourcing and filling out order request forms, accessing phlebotomy to draw the sample, the frequency and location of sample processing and the time taken to request the test.

Difficulty accessing the IGRA test result was reported as a barrier by 27% (4/15) of respondents. A perception among healthcare workers of the risk of TB in at-risk cohorts being low was cited as a barrier by 20% (3/15). A lack of systems to identify all the target cohort for screening, a failure of patients to attend for screening when invited, and healthcare workers not knowing who to screen were each cited by 7% (1/15) of respondents as barriers to screening for LTBI.

Forty-five percent (9/20) of respondents said they did not have a guideline or protocol they followed when screening or managing LTBI. Among the 55% (11/20) that reported having a guideline or protocol, multiple were followed (American Thoracic Society/Infectious Diseases Society of America (2 respondents), Health Protection Surveillance Centre Guidelines on the Prevention and Control of Tuberculosis 2010 (1), Centre for Disease Control and Prevention (1), British Transplant Society (1), European Crohn's and Colitis Organisation (2), British Thoracic Society (1), departmental protocol (3)). Risk factor assessment for TB, an assessment for active TB and an assessment for LTBI treatment contra-indications were performed frequently by most respondents (Figure 2). Pre-test counselling, however, was performed frequently by only 48% (10/21).

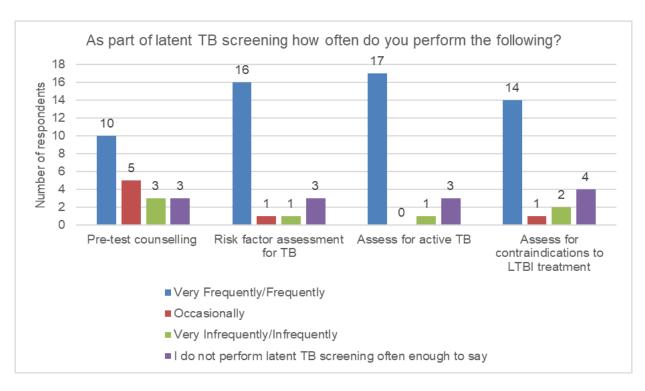


Figure 2: As part of latent TB screening how often do you perform the following?

Across all risk groups, IGRA was the screening test most frequently reported as being used by respondents (n=21) (Figure 3). Among healthcare workers, people with pulmonary fibrotic lesions, patients with silicosis, patients with end-stage renal diseases, patients preparing for organ transplantation, patients on immunosuppressive treatment, people in prisons and people who are homeless, IGRA was reported as being used with or without TST by all respondents. While IGRA remained the most frequently reported test used to screen people living with HIV, people from high TB incidence countries and recent case contacts for LTBI, in each of these cohorts, one respondent reported using TST alone.

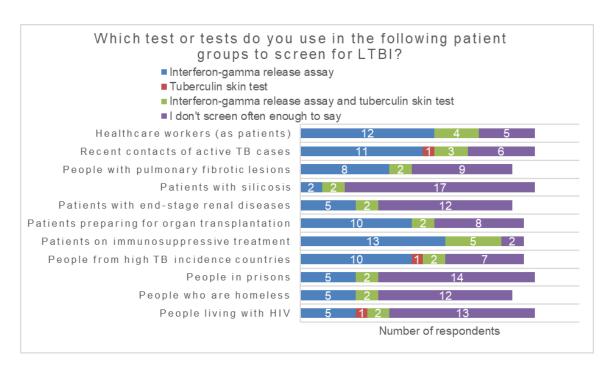


Figure 3: Which test or tests do you use in the following patient groups to screen for latent TB?

Most respondents (57% (12/21)) reported that they have treated patients for LTBI without referring to a TB specialist and 43% (9/21) reported that there was not a clear referral pathway for patients that they would like specialist input on when diagnosing and managing LTBI. If referring a patient for specialist TB review, 38% (8/21) of healthcare professionals surveyed would refer patients to the infectious diseases department and 33% (7/21) would refer patients to the respiratory medicine department.

Respondents strongly agreed or agreed that they were confident in their ability to perform LTBI screening (90% (19/21)), initiate LTBI treatment (50% (10/20%)), monitor LTBI treatment (48% (10/21)) and manage complications of LTBI treatment (43% (9/21)) (Figure 4).

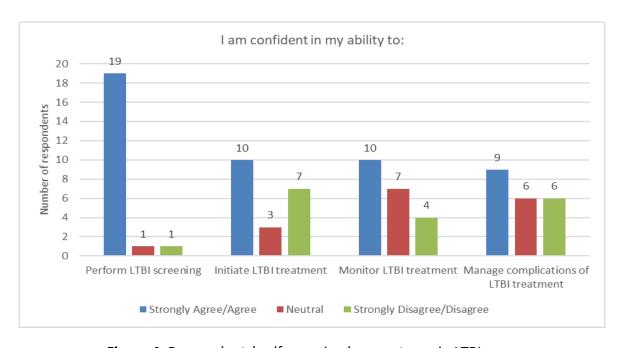


Figure 4: Respondents' self-perceived competency in LTBI care.

There were 13 respondents to the question of what LTBI regime they usually prescribe when they do treat LBTI, 62% (8/13) prescribed Isoniazid for either six or nine months, 23% (3/13) prescribed rifampicin and isoniazid for three months and 15% (2/13) prescribed rifampicin monotherapy for four months.

Discussion

This research describes LTBI screening and treatment practices among healthcare professionals who direct such care for patients at risk of TB disease. The main findings were that patients on immunosuppressive treatment and TB case contacts were those most often reported as being offered LTBI screening frequently, but only 50% of those surveyed reported offering people from countries with a high incidence of TB screening frequently. Barriers to LTBI screening identified were primarily logistical (difficulties accessing testing and retrieving results), but also a lack of knowledge because at-risk patients were reportedly perceived by healthcare professionals to be low risk for TB disease. This research has identified areas where clinical practice could be improved, namely the performance of pre-test counselling when screening for LTBI, monitoring patients on LTBI treatment, managing the complications of LTBI treatment and reducing the use of isoniazid monotherapy as the first-choice treatment regimen. Deficits in the processes of LTBI care were the reported lack of a clear referral pathway, and the large proportion of respondents (45%) who reported that there was no guideline or protocol which they followed when screening for LTBI.

Based on the identified barriers, areas for clinical practice improvement, and deficits in care processes, recommendations for quality improvement can be made. The process of quality improvement may be pursued in isolation at a local level, but this may be challenging for healthcare providers if multiple simultaneous quality improvement initiatives are pursued, dividing their time and efforts. Many deficits in quality in TB care are a result of system-wide problems that may be better solved at a system level rather than a local level. Therefore, recommendations arising from this research may have both local and national relevance.

The logistical barriers to LTBI screening identified should be resolved at a local level within the hospital. Removing such barriers identified will be important to scale up effective LTBI screening. However, because these barriers are multifactorial, they will require engagement with multiple stakeholders, such as phlebotomists, laboratory personnel, information-technology technicians, and hospital managers at a local level.

The reported low perception of the risk of TB disease, low performance of pre-test counselling, and low confidence in performing aspects of LTBI treatment should be addressed. This could be done through a programme of LTBI education for healthcare professionals. This is recommended by the European Centre for Disease Prevention and Control and is a feature of other effective TB programmes such as that of the Netherlands.^{8,9} An LTBI education programme would be best established nationally rather than locally to maximise benefit from the resources expended in its development.

The referral pathway for accessing TB services locally should be improved. Although most respondents (57%) said they treated LTBI without referring to a TB specialist, only a minority agreed they were confident in monitoring treatment or managing complications. This suggests the need for a referral pathway is primarily for treatment rather than diagnostic purposes. When initiating treatment, a high proportion of respondents (62%) reported using isoniazid monotherapy. The use of newer rifamycin-based regimens should be encouraged where possible given the potential for isoniazid resistant LTBI and it is known they cost less, require fewer appointments, and have superior treatment adherence and completion rates. ^{10,11,12} This could be done through the development and promotion of updated national guidance on LTBI treatment given the reported multiplicity of guidelines in use and, for many, the absence of a reference guideline or protocol.

A limitation of this study was the small sample size and low response rate, meaning response bias cannot be excluded. Although this survey targeted healthcare professionals who direct LTBI care among at-risk patients in their respective departments, practices among other healthcare professionals within their departments, such as trainees or general nursing staff, may differ. The single centre nature of this survey limits the generalisability of some of the findings. Primary care physicians, who are important in any population-based effort for systematic disease prevention and control, were not surveyed. Future research evaluating LTBI care practices in primary care will be important if a programmatic approach to LTBI is to be taken in Ireland.

In summary, effectively screening for and treating LTBI is key for countries with a low incidence of TB to achieve elimination by reducing the incidence of TB reactivation and secondary disease transmission. This research has identified opportunities and made recommendations to improve local and national LTBI screening and treatment.

Declaration of Conflicts of Interest:

The authors declare they have no conflicts of interest to declare.

Corresponding Author:

James O'Connell,
Department of International Health and Tropical Medicine,
Royal College of Surgeons in Ireland,
Dublin 2.

E-Mail: jamesoconnell@rcsi.com

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A Comparison of Community-Acquired and Hospital-Acquired Hypernatraemia in Patients who are Acutely Admitted to Hospital

M. Brennan¹, L. Mulkerrin¹, D. Wall², P.M. O' Shea^{3, 4}, E.C. Mulkerrin^{1, 4}

- 1. Department of Geriatric Medicine, Saolta University Health Care Group (SUHCG), University Hospital Galway, Co. Galway.
- 2. School of Mathematics, Statistics and Applied Mathematics, National University of Ireland Galway.
- 3. Department of Clinical Biochemistry, Saolta University Health Care Group (SUHCG), Galway University Hospitals, Galway, Ireland.
- 4. School of Medicine, National University of Ireland Galway, Galway, Ireland.

Abstract

Background

Hypernatraemia is associated with a short-term mortality of 20-60%. Age-related physiological changes predispose patients to hypernatraemia. This study reviewed acutely admitted patients comparing those with community-acquired (CAH) and hospital-acquired hypernatraemia (HAH).

Methods

A retrospective study of 102 consecutive acute medical in-patients with serum [Na]>145 mmol/L was conducted. Baseline characteristics, clinical presentation, laboratory values, monitoring, management and outcomes were compared between CAH and HAH groups.

Results

Patients were exclusively older (>69 years). Forty patients (39.2%) had CAH and sixty-two (61.8%) had HAH. Those with CAH were more likely to be NH residents, have dementia and reduced mobility. Most HAH patients had mild hypernatraemia initially (75.8%, n=47), and higher rates of acute kidney injury (27% (n=11) vs 8% (n=3)/p=0.02) were observed. Monitoring was inadequate and no patient had a free water deficit documented. Medication review and intravenous fluid prescribing was similar between groups. The median length of stay of discharged HAH patients was longer (22.5 vs 8 days/p=0.005). Mortality rates were similar (47% (n=29) vs 37% (n=15)/p=0.416). Time from admission to death was higher in HAH patients (16 vs 8 days/p=0.008).

Conclusions

Both CAH and HAH present similarly, however, older patients with cognitive/physical impairments are at an increased risk. Early identification of high-risk patients and adherence to best practice guidelines is required.

Introduction

Hypernatraemia is associated with significant morbidity and a short-term mortality between 20-60%¹⁻³. Hospitalised patients may present with or acquire hypernatraemia during their admission. Age-related decline in organ function, appetite, illness and disability, and increased fluid requirements predispose older adults to dehydration and hypertonicity⁴⁻⁶. Thirst is the main line of defence against hypernatraemia. Patients with an intact thirst mechanism can sense a rise in serum osmolality and rectify this by sourcing and consuming water⁷. Impaired thirst occurs with normal ageing⁸. Additionally, cognitive and physical disabilities act as barriers to this process, predisposing to dehydration⁹.

Community-acquired hypernatraemia (CAH) is present in 1-2% of Emergency Department admissions and has been less well studied than hospital-acquired hypernatraemia (HAH) ¹⁰. CAH is usually hypovolaemic, and associated with a lower mortality compared with HAH^{11,12}. One study on CAH found the presence of Alzheimer's disease, impaired oral intake and concomitant treatment with Renin Angiotensin-System (RAS) blockers were positively associated with the development of hypernatraemia¹³.

Hypernatraemia may be acquired during hospitalisation, especially in severely unwell patients due to the combination of being unable to drink sufficient water; poor urine concentrating ability due to renal failure; osmotic diuresis from high serum urea concentrations, and water losses through large urine or gastrointestinal outputs^{14,15}. HAH is an independent mortality risk factor both in critical care and non-critical care environments¹⁶⁻¹⁸. It has a worse prognosis than CAH and patients tend to do worse than those with other electrolyte abnormalities such as hyponatraemia¹⁹ The relative contribution that hypernatraemia adds to the poor prognosis in critically unwell patients is unclear. One study found hypernatraemia directly contributed to mortality in 16% of cases¹.

Hypernatraemia requires preventative measures and active management on the part of the treating physician. Every patient should undergo a thorough evaluation of underlying causes, calculation of free-water deficit, replacement via oral/intravenous routes. Serum sodium levels should be monitored to ensure the rate of correction is appropriate. The risks of over-correction appear to be negligible however, and it is now recognised that under-correction poses the greater risk as longer duration of hypernatraemia is associated with poorer outcomes than the absolute sodium levels reached²⁰. Frequent monitoring should be performed as per best practice guidelines²¹⁻²³. The authors have recently submitted a description of suboptimal management and monitoring of this patient population²⁴.

The authors hypothesized that patients with hypernatraemia on presentation and those that acquire it may differ in key patient characteristics, time course of their illness and approach to their management. The aim of this study was to perform a descriptive review and compare community-acquired and hospital-acquired hypernatraemia in terms of patient demographics, clinical presentation, co-morbidities, changes in sodium and renal function, management, and patient outcomes.

Methods

Ethical Approval was granted from the Research Ethics Committee of National University of Ireland, Galway. A retrospective cross-sectional study was conducted. The study population was defined as general medical in-patients with serum sodium concentrations >145 mmol/L using the Galway University Hospital Laboratory Information System (GUH-LIS). A sample of 145 patients was chosen using anonymised medical record numbers. Inclusion criteria were age >18 years, medical admission for >24 hours and availability of electronic or paper-based medical notes. Exclusion criteria were direct ICU admissions, admissions under oncology/haematology/surgical specialities, death/discharge <24 hours of admission and duplicate samples.

The following data was collected retrospectively: age, sex, clinical presentation, co-morbidities, and medications. The GUH-LIS was interrogated to obtain serum biochemistry parameters performed using Roche Diagnostics Cobas® 8000 chemistry analyser.

Evaluation of the management was based on calculated free water deficit, frequency of biochemical monitoring, medication review and intravenous fluid prescriptions. Primary diagnosis and patient outcomes were retrieved from electronic discharge summaries. All collated data was recorded in Microsoft Excel® 2016 and statistical analysis performed using Minitab® 2018. Parametric data were represented as mean (standard deviation) and compared using student's independent t-test. Non-Gaussian data was represented as median (interquartile range) and compared using Kruskal-Wallis test. Comparison of proportions was performed using the chisquared test. A p-value <0.05 was deemed statistically significant.

Results

Baseline Characteristics

There were 102 patients included, 63% were male. The baseline characteristics are detailed in Table 1 below. Forty patients had CAH and sixty-two had HAH. More HAH patients were admitted from home (68% vs 30%/p=<0.001) and CAH patients included more NH residents (55% vs 32%/p=0.026). A small number of CAH group were admitted from other care pathways. The median age of both groups was similar (81(73.8-87.3) vs 80(69.3-87.8) years/p=0.5). The clinical presentation of admitted patients were categorised as presenting with features of hypovolaemia, reduced level of consciousness (LOC) or infection. Patients could be assigned to more than one category, if applicable. There was no difference in frequency of these presentations, however, more CAH patients presented with all three features (35% vs 15%, p=0.027). CAH patients had higher frequency of dementia (75% vs 44%/p=0.004) and reduced mobility (70% vs 48%/p=0.05). The frequency of diabetes, CKD and cardiovascular disease was similar. Those prescribed regular diuretics (44% vs 28%, p=0.154) and RAS blockers (27% vs 10%, p=0.061) were similar.

Laboratory Results

The mean Sodium concentration ([Na]) on admission was higher in CAH patients (153.6 (+/-6.14) vs 138.7 (+/-4.6)/p<0.001). In HAH patients, 79% (n= 49) had normal [Na], and 21% (n=13) low [Na] on presentation. More HAH patients had mild hypernatraemia (75.8% vs 35%/p<0.001) on the first hypernatraemic sample. More CAH patients had moderate (5% vs 16.1%/p=0.034) and severe (27.5% vs 8,1%/p=0.012) hypernatraemia on initial sampling. The median time from admission to HAH was 4 (2-10.25) days. CAH patients had a higher maximum recorded Sodium ([Na]) recorded, 156(153-160.75) vs 153(151-157), p=0.002. The proportion of patients with a [Na]>160 mmol/L was also higher in CAH group, 28% vs 8%, p=0.008.

The median [Urea] on admission was higher in CAH group, 15.3(8.8-22.3) vs 8.95(6.3-12.9), p=0.002. There was no difference in the median [Creatinine] on admission, 106.5(70.5-197.8) vs 100.5(77.5-138.3), p=0.437.

There was no difference between median [Urea] or [Creatinine] on admission in CAH group compared to the renal profiles of the HAH group at the time of developing hypernatraemia. More HAH patients had an acute kidney injury (AKI) during their admission (27% vs 8%/p=0.02). There was no difference in frequency of AKI on presentation (29% vs 45%/p=0.137).

Table 1: Baseline characteristics of study population.

Study Characteristic	HAH% (n=62)	CAH % (n=40)	P value	
Males	63% (39)	63% (25)	1.000	
Age^	81 (73.8-87.3)	80 (69.3-87.8)	0.537	
Source of Patient				
Nursing Home	32.3% (20)	55% (22)	0.026	
Home	67.7% (42)	30% (12)	<0.001	
Other Hospital	0	75% (3)	0.058	
Psychiatric Hospital	0	5% (2)	0.151	
Other residential facility	0	2.5% (1)	0.392	
Clinical Presentation				
Hypovolaemia	74% (46)	83% (7)	0.461	
Reduced LOC	55% (34)	68% (27)	0.286	
Infection	63% (39)	75% (30)	0.290	
All three	15% (9)	35% (14)	0.027	
Co-morbidities				
Dementia	44% (27)	75% (30)	0.004	
Reduced Mobility	50% (30)	70% (28)	0.052	
Diabetes Mellitus	11% (7)	20% (8)	0.354	
CKD	18% (11)	178% (7)	1.000	
Cardiovascular Disease	82% (51)	70% (28)	0.229	

Regular Medications					
Diuretics	44% (27)	28% (11) 0.154			
RAS Blockers	27% (17)	10% (4)	0.061		
Admission Laboratory Value	Admission Laboratory Values: Sodium/[Na] mmol/L,[Urea] mmol/L, [Creatinine] umol/L % (n)				
Serum sodium/[Na]*	138.7 ((± 4.6)	153.6 ((± 6.14)	<0.001		
Serum sodium/[Na]^	139 (135.75-142)	153 (149-157.5)	<0.001		
Serum Urea^	8.95 (6.27-12.90	15.3 (8.83-22.27)	0.002		
Serum Creatinine^	100.5 (77.5-138.3)	106.5 (70.5-197.8)	0.437		
Severity of hypernatraemia	on first sample: [Na] mm	ol/L: % (n)			
Mild 146-150	75.8% (47)	35% (14)	<0.001		
Moderate 151-155	16.1% (10)	35% (14)	0.034		
Severe > 156	8.1% (5)	27.5% (11)	0.012		
Renal Profile on initial hype	rnatraemic sample: % (n)				
Serum Urea^	12.65 (8.43-17.85)	15.3 (8.83-22.27)	0.165		
Serum Creatinine^	97 (69.5-165.5)	106.5 (70.5-197.8)	0.399		
Highest Sodium Recorded: 9	% (n)				
Highest recorded*	154 ((±3.6)	157.9 ((± 6.9)	0.002		
Highest recorded^	153 (151-157)	156 (153-160.75)	0.002		
Mild (145-149 mmol/L)	5% (3)	0	0.278		
Moderate (150-154	53% (33)	35% (14)	0.103		
mmol/L)					
Severe (155-159 mmol/L)	34% (21)	38% (15)	0.832		
Very Severe >160	8% (5)	28% (11)	0.008		
mmol/L)					
Acute Kidney Infection (AKI): % (n)					
On admission	29% (18)	45% (18)	0.137		
During hospitalisation	27% (17)	8% (3)	0.020		
No AKI	44% (27)	48% (19)	0.839		

CAH: community acquired hypernatraemia. CKD: Chronic Kidney Disease HAH: hospital acquired hypernatraemia LOC: level of consciousness, RAS: renin angiotensin system, *: data stated as mean ± standard deviation, ^: data stated as median (Interquartile range)

Management of Hypernatraemia

Monitoring of hypernatraemic patients was suboptimal. More HAH patients did not have a [Na] measured at 12 hours (90% vs 70%/p=0.015). There was no difference between monitoring at 24-hours, (19% vs 35%/p=0.103) or 48-hours (13% vs 5%/p=0.308). More CAH patients had q-12 hourly [Na] measurements over the initial 48 hours period of hypernatraemia (15% vs 3%/p=0.054). No evidence of a calculated free water deficit was found for any patient.

In HAH patients, of those prescribed diuretics, 55% (n=15) had no change, 30% (n=8) were stopped/held and 15% (n=4) had a dose reduction. In the CAH group, 55% (n=6) had no change and 45% (n=5) were stopped/held. For those prescribed RAS blockers, 76% (n=13) of HAH group and 75% (n=3) of CAH group continued these medications.

Hypotonic fluids (5% Dextrose or 0.45% NACL) were prescribed in 32% (n=20) of HAH and 42.5% (n=17) of CAH group. Volume resuscitation with 0.9% NACL followed by hypotonic fluids was prescribed in 4.8% (n=3) of HAH and 10% (n=4) of CAH group. Isotonic fluids (0.9% NACL or Hartman's solution) were prescribed in 50% (n=31) of HAH and 40% (n=16) of CAH group. No fluids were prescribed in 4.8% (n=3) of HAH and 5% (n=2) of CAH group, see *Table 2* below.

Table 2: Management of hypernatraemia: monitoring, medication review and intravenous fluid regime.

Management	HAH (n=62)	CAH (n=40)	P value		
Monitoring of Serum [Na]					
No monitoring at 12 hours	90% (56)	70% (28)	0.015		
No monitoring at 24 hours	19% (12)	35% (14)	0.103		
No monitoring at 48 hours	13% (8)	5% (2)	0.308		
Q12 hour monitoring for 48 hours	3% (2)	15% (6)	0.054		
Medications: % (n)					
Diuretics	HAH (n=27)	CAH (n=11)			
Stopped/Held	30% (8)	45% (5)	0.457		
No change	55% (15)	55% (6)	1.000		
Reduced	15% (4)	0	0.303		
ARB/ACEi	HAH (N=17)	CAH (N=4)			
Stopped/Held	24% (4)	25% (1)	1.000		
No change	76% (13)	75% (3)	1.000		
Calculation of Free Water Deficit: (า)				
Documented Calculation of Free	0% (0)	0% (0)	1.000		
Water Deficit					
Intravenous Fluid Regimes: (n)	Intravenous Fluid Regimes: (n)				
Hypotonic Fluids	32% (20)	42.5% (17)	0.302		
Volume resuscitation followed by	4.8% (3)	10% (4)	0.426		
hypotonic fluids					
Isotonic/Hypertonic Fluids	50% (31)	40% (16)	0.416		
No fluids/Dialysis	4.8% (3)	5% (2)	1.000		
Missing Data	8% (5)	2.5% (1)	0.399		

CAH: Community-acquired Hypernatraemia. HAH: Hospital acquired Hypernatraemia, ^: data stated as median (Interquartile range), LOC: level of consciousness, ARB: Angiotensin Receptor Blocker, ACEi: Angiotensin Converting Enzyme inhibitor; 0.9% NaCl: Normal Saline, P-value ≤0.05 deemed statistically significant.

Outcomes

Hypernatraemia resolved in 45% (n=28) HAH and 35% (n=14) CAH patients, p=0.410. The median duration was similar between groups (5 (2-8.5) vs 4 (2.75-8)/p=0.906). There was no difference in ICU admissions, 13% (n=8) vs 2.5% (n=1), p=0.085.

The most common primary diagnosis was LRTI in both groups 56% (n=35) in HAH and 63% (n=25) in CAH. Infection from other sources, most commonly urinary, was the next most common diagnosis 23% (n=14) and 20% (n=5) respectively, Acute neurological events, including stroke, traumatic brain injury and seizures accounted for 20% (n=14) of HAH and 7.5% (n=3) of CAH group. Decompensated heart failure accounted for 11% (n=7) of HAH and 2.5% (n=1) CAH group.

There was no significant difference in the discharge rate or destination between groups. The discharge rate of HAH patients was 53% (n=33) and 63% (n=25) in CAH patients. In HAH group, 33% (n=11) were discharged home, 39% (n=13) to previous NH, 12% (n=4) were new NH discharges. Other discharge destinations included hospice, 6% (n=2) and rehabilitation, 9% (n=3). In CAH group, 64% (n=16) were discharged to previous NH, 20% (n=5) to home, and 16% (n=4) to hospice care. The median length of stay (LOS) for HAH group was significantly longer than for CAH, 22.5 (9-48.75) vs 8 (5-17) days, p=0.005.

The mean sodium on discharge was similar, $142.1.8 \pm 5.7$ vs 144.5 ± 6.7 mmol/L, p=0.144. Hypernatraemia was persistent on day of discharge in 30% (n=10) of HAH and 36% (n=9) CAH group. More CAH patients had hypernatraemia documented on discharge correspondence, 18% (n=6) vs 52% (n=13), p=0.011.

The mortality rate was similar between groups, 47% (n=29) vs 37% (n=15), p=0.416. The median time from admission to death was longer in the HAH group, 16 (10.25-22.50) vs 8 (2-14) days, p=0.008. See *Table 3* below

Table 3: Outcomes of CAH and HAH patients.

Study Cohort	HAH (n=62)	CAH (n=40)	P Value		
Resolution: % (n)					
Full Resolution	45% (28)	35% (14)	0.410		
Duration of Hypernatraemia: Se	erum [Na]>145mm	ol/L			
Duration/days*	6.4 (± 5.3)	6 (±5.0)	0.800		
Duration/days^	5 (2-8.5)	4 (2.75-8)	0.906		
Diagnosis	Diagnosis				
LRTI	56% (35)	63% (25)	0.681		
Other infection	23% (14)	20% (5)	0.298		
Stroke/TBI	15% (11)	5% (2)	0.073		
Seizures	5% (3)	2.5% (1)	1.000		
ADHF	11% (7)	2.5% (1)	0.144		
Other	11% (7)	18% (7)	9.392		

Critical Care					
ICU Admission	13% (8)	2.5% (1)	0.085		
Discharges					
Patients Discharged	53% (33)	63% (25)	0.416		
Discharge Destination					
Home	33% (11)	20% (5)	0.375		
Previous NH	39% (13)	64%(16)	0.111		
New NH	12% (4)	0% (0)	0.126		
Hospice	6% (2)	16% (4)	0.387		
Rehab/Convalescence	9% (3)	0% (0)	0.251		
Serum sodium concentration at	Discharge (DC)				
Sodium* (mmol/L)	142.1.8 (± 5.7)	144.5 (±6.7)	0.144		
Hypernatraemia on DC	30% (10)	36% (9)	0.779		
Hypernatraemia on DC letter	18% (6)	53% (13)	0.011		
Length of Stay (LOS)					
Number of days^	22.5 (9-48.75)	8 (5-17)	0.005		
Mortality: % (n)					
Number of Deaths	47% (29)	37% (15)	0.416		
Median no. of days to death	16 (10.25-22.50)	8 (2-14)	0.008		

NH: Nursing Home, *: data stated as mean \pm standard deviation, ^: data stated as median (Interquartile range), ICU: Intensive Care Unit. NH: Nursing Home, LRTI: Lower respiratory tract infection, TBI: Traumatic brain injury, DC: Discharge ADHF: Acute decompensated heart failure, P-value \leq 0.05 deemed statistically significant.

Discussion

This retrospective review of revealed key differences between hospital-acquired and community-acquired hypernatraemia. Although clinical presentations and primary diagnoses, were similar, they differed in their illness trajectory.

Those with CAH were more likely to be NH residents with dementia and reduced mobility. Previous studies reported 10-fold higher prevalence and 2-fold risk of in-hospital mortality in NH residents²⁵. Hypernatraemia in CAH was more severe and reached higher maximum values, and thus a much larger free water deficit. This possibly reflects multi-morbidity and reduced access to laboratory testing in some community settings.

HAH developed within days of hospitalisation and progressed in hospital to a greater extent than CAH. This may represent either a failure to recognise or treat hypernatraemia appropriately in the early stages, or the development of hypernatraemia in the setting of progressive severe illness.

Overall monitoring of hypernatraemia in the entire population was suboptimal as highlighted in a previous article²⁵. Here, the CAH patients had earlier and more frequent monitoring, potentially due to the severity of their hypernatraemia at diagnosis. Many patients continued to be prescribed potentially inappropriate medications.

Less than one-third of HAH patients and less than half of CAH patients received hypotonic fluids, the preferred choice for correction in the absence of haemodynamic compromise. Undercorrection was universal, and no patient was over-corrected.

The most common diagnosis was LRTI, a similar finding to other published studies¹⁹, while other infections and acute neurological events accounted for most other diagnoses in keeping with the admitting presentations. LOS of those discharged was longer in those with HAH, possibly reflecting hypernatraemia occurring in tandem with an evolving prolonged and severe illness and hence a longer hospital stay¹. Although mortality rates were similar, time from admission to death was longer in the HAH group, likely reflecting a higher proportion of independently living adults with a higher functional baseline. Conversely the higher number of NH residents with cognitive and physical impairment along with more severe hypernatraemia, reflected severe frailty in the CAH group which is associated with earlier recognition of irreversible pathology and decisions regarding ceilings of care¹⁰.

Strengths of this study include a representative real-world study sample and thorough data collection using multiple sources. Limitations include retrospective design, single-centre study and a relatively small sample size. Hypernatraemia should be considered as a marker of quality of care. Earlier identification (especially in HAH) and addressing provision of adequate fluid intake early in their course could result in quicker resolution of hypernatraemia which is associated with better outcomes. A quality improvement initiative aimed at adherence to best practice guidelines for management of both CAH and HAH is planned for our hospital on the basis of these findings.

Ethical approval:

Ethical approval was granted from the Research Ethical Committee of National University of Ireland, Galway.

Declaration of Conflicts of Interest:

The authors declared no potential conflict of interest that could be perceived as prejudicing the impartiality of the research, authorship, and/or publication of this article. The authors received no financial support for the research, authorship and/or publication of this article.

Corresponding Author:

Dr Michelle Brennan

Geriatric Specialist Registrar MB BCh BAO MRCPI MSc Clinical Research
Department of Geriatric Medicine, Saolta University Health Care Group (SUHCG), University
Hospital Galway, Newcastle Road, Galway H91 YR71, Ireland.

E-Mail: michellem.brennan@hse.ie

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A 10-Year Audit of Penile Prosthesis Insertion

A.T. Looney, B.E. Seery, L.C. Yap, P. Mohan Beaumont Hospital, Dublin, Ireland.

Abstract

Introduction

Penile prosthesis (PP) insertion is the gold standard surgical treatment option for men with refractory Erectile Dysfunction (ED). PP insertion is considered effective but has a well-documented array of complications. Our aim was to assess outcomes following single-surgeon insertion of PP for ED within an Irish cohort.

Methods

Following review of the Hospital In-Patient Enquiry (HIPE) system, a retrospective chart review of all patients who underwent PP insertion over a 10-year period from 2008-2017 inclusive was performed, and an electronic database was analysed for results.

Results

One-hundred-and-eleven PPs were inserted in 96 patients. The most common aetiology for ED in our cohort was post-prostatectomy, affecting 25 (26%) patients. The most frequently implanted device was a 3-piece inflatable PP (3p-IPP) (AMS 700[™]; American Medical Systems Inc., Minnesota, USA) and the peno-scrotal approach was utilised in the majority of patients (86, 77.5%). No intraoperative complications were recorded. Twelve (12.5%) patients developed peri-operative complications. Thirteen (13.5%) patients required device revision, the majority for device failure. Of the 71 patient satisfaction responses, 61 (85.9%) patients were satisfied with their PP.

Conclusions

This single-surgeon retrospective audit of PP surgery demonstrates complication rates in-line with internationally published data. Patients should be adequately counselled regarding possible complications, including device failure and erosion. PP insertion should be considered for suitable patients with refractory ED.

Keywords: Penile prosthesis, erectile dysfunction, penis surgery.

Introduction

The community prevalence of ED in the general male population is estimated to be in the region of 40% for those aged 40, and 70% for those aged 70¹. Despite the availability of medical therapies, including oral phosphodiesterase type 5 inhibitors and intraurethral, topical or intracavernosal alprostadil, implanted penile prostheses (PP) remain a very relevant treatment option, as many men become refractory to medical therapy or seek a more effective and permanent therapy.

PPs are also a useful treatment adjunct in men who have significant penile curvature or fibrosis, men with priapism who have not responded to initial therapies, along with those who have phalloplasties and in some renal transplant patients^{2,3}.

Since their initial appearance in 1970, significant progress has been made in improving the reliability and quality of devices, and in making them more user-friendly. This, coupled with greater surgical experience and techniques to reduce infection rates and operative time, means improved patient outcomes^{4,5}. There is international evidence demonstrating that PPs are efficacious, safe and result in good patient satisfaction levels⁶⁻⁸, although little has been published within an Irish population. The European Association of Urology Guidelines apply a strong rating for its recommendation of offering PP (if other treatments fail or based upon patient preference)⁹. The current American Urological Association guidelines also advise strongly that men with ED should be informed of the option of PP implantation¹⁰.

Patient selection is a key component to successful outcomes; the patient must be well-motivated, with reasonable manual dexterity (especially for an inflatable device) and must be made aware of the potential complications and limitations of surgery¹¹.

A range of PPs are available on the international market, but there are no head-to-head studies that demonstrate superiority of one implant over another¹². The three-piece inflatable penile prosthesis (3p-IPP) is considered the gold standard by many urologists and has the highest patient satisfaction rating^{2,13} – this consists of an abdominal reservoir, a scrotal pump and dual cylinders placed in the corpus cavernosa. Semi-rigid, or malleable prostheses are also useful in more complex patient cohorts¹³. The main producers of inflatable protheses at present are Boston Scientific, who in 2015 acquired American Medical Systems (AMS) [AMS Inc, Minnesota, USA]. They produce a two-piece inflatable device (AMS AmbicorTM) and a number of three-piece inflatable devices (e.g. AMS 700 CX TM; AMS 700 LGX TM; AMS 700 CXR TM). Coloplast (Humlebæk, Denmark) also produce three-piece inflatable devices (Titan TM; Titan OTR NB TM; Titan Zero Degree TM), as do Zephyr (Zephyr Surgical Implants, Switzerland) who produce the ZSI 475 TM. Semi-rigid devices frequently used include AMS SpectraTM, AMS TactraTM, Coloplast GenesisTM, and the Zephyr ZSI 100TM.

In this study, we report a single-surgeon, single-centre 10-year experience of PP insertion.

Methods

A retrospective chart review of all patients who underwent PP insertion in a single tertiary-referral public teaching hospital was performed over the 10-year period from 2008-2017 inclusive. The Hospital In-Patient Enquiry (HIPE) system was utilized to obtain a register of patients who underwent PP surgery. In addition, theatre lists for the 10-year period were obtained, retrospectively reviewed and cross referenced to HIPE data. An electronic database was then analyzed for results. Of note, the principal surgeon in this study also performs this procedure in 2 additional private institutions, but the study was performed solely in this single public institution.

Each procedure was carried out in a similar manner. With insertion of 3p-IPP, the most frequently used device in our cohort, the following surgical steps were followed.

Pre-operatively, the patient has skin swabs and urine analyzed to out rule significant contamination or infection. They have a full medical work-up to ensure they are infection free systemically, paying particular heed to their cutaneous and urinary systems. The morning of their procedure, patients have a full body wash on the ward with Chlorhexidine Gluconate 4% weight/volume (w/v) cutaneous solution. They receive Gentamicin and Vancomycin (as per local microbiology protocol) intravenously on induction of anesthesia, and PP cases are performed as the first operation of the day. Lower abdominal and pubic hair is shaved, and patients undergo a further 10-minute preoperative scrub with Chlorhexidine Gluconate 4% w/v cutaneous solution. Theatre traffic is minimized. When possible, a representative from the medical device company attends the procedure to aid with the device preparation. Surgeons use double-gloving and a non-touch technique. A catheter is inserted to allow urethral identification and to decompress the bladder. A penoscrotal (or infrapubic) approach is taken and operative time is minimized where possible. Meticulous hemostasis is ensured to reduce the risk of hematoma and infection, and therefore, no blind dissection is performed. The corpus spongiosum is laterally retracted and dissection through Dartos/Buck's fascia is performed to identify the tunica albuginea. The corpus cavernosa are incised and dilated bilaterally - proximally towards the crus and distally towards the glans. A Furlow is used to measure each corpus.

The cylinder size is then selected and components (reservoir, pump and cylinders) prepared. An antimicrobial coating is used if the patient is deemed higher risk for infection (e.g. revision procedure, immunosuppressed patient). The cylinders are inserted via each corporotomy and the reservoir is implanted by creating a defect in the transversalis fascia to the pre-vesical space. The pump is implanted in the most dependent part of the scrotum. An inflate/deflate test is then carried out, tubing connected, and a final inflate/deflate test performed. If required, the reservoir volume is adjusted at this point.

Each layer is closed, and a supportive dressing is applied with the device partially inflated. The penis is affixed to the abdominal wall overnight and the catheter is removed the following day. Patients are given verbal and written post-operative instructions, including advice to pull down on the pump in the scrotum numerous times per day, and to begin cycling the device four weeks post-operatively. Intercourse is advised from six weeks post-operatively.

The patient is seen back at the outpatient clinic for a post-operative review at 3 weeks, 6 weeks (for device activation), 3 months, 6 months and 12 months – and further reviews occur if required or on request. All patients are issued with a device identification card which they are advised to carry on their person.

Results

Over the study period, 111 PPs were inserted in 96 patients. The median patient age at time of PP insertion was 60.0 years [range: 33.4-80.2 years]. The peno-scrotal approach was used most frequently (86, 77.5%). The median length of stay for patients was 2.6 days [range: 2-5 days]. The catheter was usually removed on the first post-operative day, but patients were not discharged until they were voiding with confidence, had their pain well-controlled and were freely mobilizing.

The most frequently encountered reason for our cohort's ED was radical prostatectomy (N = 25, 26%), cardiovascular disease (N = 17, 17.7%) and diabetes mellitus (N = 15, 15.6%) [Table 1]. Ninety-six 3p-IPPs (75 AMS 700^{TM} devices and 21 Coloplast TitanTM devices) and 15 semirigid prostheses (11 AMS SpectraTM and 4 Coloplast GenesisTM) were inserted.

No intraoperative complications were recorded. Twelve (12.5%) patients developed post-operative complications including hematoma and infection [Table 2]. Four patients developed mild transient haematuria that was presumed to be due to urethral contusion – these patients were managed by extending their catheterization period, but no further perioperative issues arose in this cohort. Thirteen (13.5%) patients required at least 1 revision procedure – 11 patients required one revision for device failure (8) or erosion/infection (3), and 2 patients required a re-revision procedure. Of these 2 patients, one developed infection of both of his first two devices and the second patient was dissatisfied with his erectile function following insertion of his malleable prosthesis but then suffered device failure of his 3p-IPP. Of note, 8 of the 13 patients (61.5%) who required a revision procedure had been fitted with the AMS 700TM prosthesis, which has since been recalled due to complications resulting in device failure.

Of the 8 patients with device failure, 2 of these were felt to be due to kinking of the tubing, 1 was due to tubing becoming disconnected from the reservoir, and 1 was due to migration of the reservoir. The other 4 patients did not have the failed device component definitively recorded in their medical records.

Regarding patient follow-up, the median follow-up was 14 months. Overall patient satisfaction was reviewed in the outpatient clinic at the 6-month post-operative review. Patients were asked "How would you rate your overall satisfaction with the PP on a scale from 1 to 5 (with 1 being very dissatisfied, 2 being dissatisfied, 3 being neither satisfied nor dissatisfied, 4 being satisfied and 5 being very satisfied)?"

There were 71 recorded responses from the 96 patients in the study [Figure i]. Sixty-one (85.9%) patients were either satisfied or very satisfied overall. Three (4.2%) patients were very dissatisfied or dissatisfied with their outcome. Two of these patients had experienced device failure and the third had developed Floppy Glans Syndrome.

Table (1) Chief Aetiology of Erectile Dysfunction.

Chief Aetiology of ED	Patient Numbers N=96
Prostatectomy	25 (26.0%)
Cardiovascular disease	17 (17.7%)
Diabetes Mellitus	15 (15.6%)
Other pelvic surgery / radiation	8 (8.3%)
Neurological disease	8 (8.3%)
Priapism	5 (5.2%)
Trauma	5 (5.2%)
Other	13 (13.5%)

Table (2) Peri-operative complications by Clavien-Dindo¹⁴ classification.

Peri-operative	Clavien Dindo Classification	Patient Numbers
complications		
Hematoma	IIIB	4
	(Complication requiring surgical intervention	
	under general anaesthesia)	
Hematuria	I	4
	(Complication deviating from normal post-	
	operative course, not requiring	
	pharmacological treatment)	
Infection (superficial)	II	3
	(Complication requiring pharmacological	
	treatment)	
Pulmonary Embolism	IVa	1
	(Life threatening complication with single	
	organ dysfunction)	

Survery Respondants N = 71 40 37 35 **NUMBER OF PATIENTS** 30 25 25 20 15 10 5 1 0 1 Very dissatisfied 2 Dissatisfied 3 Neither Satisfied 4 Satisfied 5 Very Satisfied nor Dissatisfied

Figure (3) Overall Satisfaction with Penile Prosthesis.

Discussion

The PP is a useful tool in the urologist's armamentarium when dealing with the patient with refractory ED. Intensive pre-operative and post-operative counselling is recommended, as realistic expectations need to be set, and a well-motivated patient is crucial in the rehabilitation phase post-operatively. Meticulous attention should be paid to the peri-operative period - including patient preparation, intraoperative factors and post-operative recovery in order to minimize complications.

To the author's knowledge, there have been no published series to date regarding the Irish experience at PP insertion. Challenges that our team encountered in running a PP service include difficulties in ring-fencing inpatient beds for what is considered benign, elective and expensive surgery, and difficulties in obtaining funding to acquire a psychologist and/or nurse specialist, which would greatly add to the patients' experiences and outcomes.

Our results, however, demonstrate that overall, patients are satisfied with their PP and our outcomes are in-keeping with international published literature⁶⁻⁸. In previous literature assessing Irish patient cohorts, it is clear that sexual dysfunction, particularly post cancer-surgery, poses a significant challenge for some men¹⁵, and definitive treatments are a welcome adjunct in their treatment algorithm.

Regarding the limitations of this paper, its retrospective nature and relatively small patient numbers may have affected the accuracy of our outcomes. Ideally, we would have had a formal questionnaire that examined different domains of sexuality, such as the quality of life and sexuality with penile prosthesis (QoLSPP)¹⁶ for each patient and their partners, and a longer median follow-up would have been preferable in order to identify late failure of devices. Also, patient cross-over from the public hospital that the procedures were performed into other institutions means that some data may not have been captured adequately.

Corresponding Author:

Aisling T. Looney

ORCID: 0000-0003-1323-9136

c/o Dept of Urology,

Beaumont Hospital,

Beaumont,

Dublin 9.

E-Mail: aisling.looney@gmail.com

Declaration of Conflicts of Interest:

The authors have no conflicts of interest to declare.

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Placental Swab in Supporting Diagnosis of Vertical Transmission in SARS-CoV-2 Positive Mothers

I. Sweeney¹, N. Al Assaf², R. Khan²

- 1. School of Medicine, University of Limerick, Limerick, Ireland.
- 2. Department of Neonatology, University Maternity Hospital Limerick, Limerick, Ireland.

Abstract

Aims

To review the evidence regarding the possibility of fetal vertical transmission in COVID-19 positive pregnant mothers by diagnosing through placental swabs.

Methods

The search terms 'pregnant COVID-19 positive mothers', 'fetal vertical transmission' and 'placental swabs' were used. 20 papers were selected.

Results

183 COVID-19 positive pregnant women were identified whose 184 placentas and 185 neonates were also analysed by RT-PCR or immunohistochemistry and/or in situ hybridization for the presence of SARS-CoV-2 (one case of monochorionic diamniotic twins and one case of dichorionic diamniotic twins). 183 liveborn neonates were successfully delivered primarily via caesarean section (99%). 2 mothers did not deliver liveborn infants due to severe preeclampsia resulting in a termination of pregnancy and a miscarriage, both occurring in the second trimester. 9 neonates tested positive for SARS-CoV-2 (5%). We report no neonatal mortality after live birth and no maternal mortality. 17 placentas tested positive for SARS-CoV-2 out of a total of 184 tested (9%). Of these 17, 7 cases of SARS-CoV-2 were identified in the maternal, neonatal and placental tissue.

Conclusion

There is no concrete evidence of vertical transmission occurring between mother and infant. We propose further research investigating the effects of COVID-19 on pregnant women by using RT-PCR to test the mother, placenta, vaginal fluid, breast milk and infant for SARS-CoV-2 at various stages of transmission.

Introduction

On March 11 2020, the World Health Organisation declared that the pneumonia outbreak of coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a pandemic.¹ Due to its highly transmissible nature, as of May 13 2021, there was a total of 159,949,065 confirmed cases of COVID-19, including 3,322,439 deaths across the five continents.² With COVID-19's sustained spread across the globe, pregnant women are unfortunately not indiscriminate from contracting the virus. This may be attributed to the changes to the cardiorespiratory and immune system during pregnancy thereby increasing a woman's susceptibility to severe infection and hypoxic compromise.³

Lopes de Sousa et al published a systematic review in June 2020 and concluded that there is no concrete evidence for vertical transmission of COVID-19 but acknowledged that significant knowledge gaps exist and they cannot rule out this possibility.⁴ The presence of COVID-19 has been assessed in neonates born to COVID-19 positive mothers by examining the placenta⁵, and carrying out nucleic acid testing on breast milk⁶ and vaginal mucus.⁷

Two epidemics in the past two decades, namely severe acute respiratory syndrome (SARS-CoV) in 2002 and Middle East respiratory syndrome coronavirus (MERS-CoV) in 2014 promote more serious complications than COVID-19 during pregnancy with approximately one third of infected pregnant women dying from the illness.³ However, similarly to COVID-19, there have been no documented cases of vertical transmission seen in SARS or MERS to date.⁸

Today, the effects of COVID-19 on pregnancy and neonatal outcome are being studied in real-time by researchers across the globe. This paper aims to review the current literature regarding the possibility of fetal vertical transmission in COVID-19 positive pregnant mothers by diagnosing through placental swabs.

Methods

Articles were searched using the following databases: Pubmed, ScienceDirect, Medline, Embase, Web of Science.

All studies in the review were selected using these databases, none were hand selected. Studies relating to pregnant COVID-19 positive mothers and fetal vertical transmission and placental swabs were selected.

We followed the guidelines according to PRISMA, MOOSE, Cochrane Handbook of Systematic Reviews of Interventions.

Search terms used were: Pregnant COVID-19 positive mothers + fetal vertical transmission + placental swabs.

Inclusion criteria: Studies performed on above terminologies along with overlapping of terminologies from September 2019 to 13 May 2021 were included and studies performed outside of this timeframe were excluded.

Results

A review of studies focusing on pregnant COVID-19 positive mothers and placental swabs in the context of fetal vertical transmission has been performed. The 20 studies we reviewed are summarised in Table 1 [view].

Maternal Outcome

This literature review comprises 183 COVID-19 positive pregnant women whose 184 placentas and 185 neonates were also analysed for the presence of SARS-CoV-2. We report no maternal mortality. A large number of women were asymptomatic although various mothers suffered from common COVID-19 symptoms such as myalgia, cough, sore throat, fever and fatigue. Comorbidities included obesity, hypertension, diabetes, preeclampsia, hypothyroidism and asthma. ⁹⁻²⁸ One woman opted for termination of pregnancy due to symptomatic SARS-CoV-2 complicated by severe preeclampsia in the second trimester. ²⁰ Another woman with symptomatic SARS-CoV-2 presented in the second trimester with a miscarriage. ¹⁴

Neonatal Outcome

183 liveborn neonates were successfully delivered primarily via caesarean section including one case of monochorionic diamniotic twins and one case of dichorionic diamniotic twins (99%). 9 neonates tested positive for SARS-CoV-2 (5%). We report no neonatal mortality after live birth.

Yu et al reported one positive neonate who had mild shortness of breath and x-ray findings of mild pulmonary infection. ¹³ Kirtsman et al described one positive neonate who had neutropenia, mild hypothermia, feeding difficulties and intermittent hypoglycaemic episodes. ¹⁸ Sisman et al reported one positive neonate who developed fever, respiratory distress and hypoxia. ²¹ Vivanti et al described a case of a positive neonate with neurological manifestations including poor feeding, axial hypertonia and ophistotonos. ²² Five positive neonates remained asymptomatic. ¹⁶, ²³, ²⁴, ²⁸

Laboratory Investigations

RT-PCR or immunohistochemistry and/or in situ hybridization identified SARS-CoV-2 in 17 placentas out of a total of 184 tested (9%). Of these 17, 7 cases of SARS-CoV-2 were identified in the maternal, neonatal and placental tissue. These 7 mothers all displayed signs and symptoms of SARS-CoV-2 with 5 of the neonates delivered by caesarean section. ^{16, 18, 21-24} Interestingly, SARS-CoV-2 was also identified in the placentas of both mothers who did not deliver their neonate due to severe preeclampsia²⁰ and a miscarriage though both neonates tested negative. ¹⁴

Discussion

Baud et al and Hosier et al's studies describe two women suffering an adverse outcome during their pregnancy, notably miscarriage¹⁴ and severe preeclampsia respectively.²⁰ The miscarriage occurred in a symptomatic 28 year old woman at 19 weeks gestation. Baud et al concluded that the miscarriage appeared to be related to placental infection with SARS-CoV-2 which demonstrated mixed inflammatory infiltrates composed of neutrophils and monocytes on histological examination. Contamination during delivery was deemed unlikely given that all swabs from the foetus including the axillae, meconium, mouth and fetal blood were negative.¹⁴

Wong et al reported a 57% miscarriage rate in a study of 12 pregnant women conducted during the 2002 SARS epidemic. They attributed this to acute or chronic placental insufficiency caused by severe maternal respiratory failure and hypoxemia thereby reducing uterine placental flow.²⁹

Hosier et al's study showed a 35 year old COVID-19 positive woman who presented at 22 weeks gestation with severe preeclampsia. This patient chose to terminate her pregnancy due to her heightened risk of maternal morbidity and mortality. High levels of SARS-CoV-2 were identified in the placenta and the invasion of intervillous macrophages was also seen on histology. Hosier et al concluded that COVID-19 may have contributed to placental inflammation resulting in early-onset preeclampsia and worsening maternal disease. It is important to note, however, that this patient was previously diagnosed with gestational hypertension which is a risk factor for her later developing preeclampsia in this pregnancy. No definitive evidence for fetal infection was described.²⁰

Shanes et al examined 16 placentas in COVID-19 positive women. The-placentas showed features of maternal vascular malperfusion, most prominently decidual arteriopathy and increased incidence of chorangiosis. Although, placental swabs were not performed which makes it unclear whether it was a local phenomenon or a systemic phenomenon.⁵ Similarly, Hosier et al showed similar risk factors for maternal vascular malperfusion, i.e. gestational hypertension and preeclampsia.²⁰ This may tentatively imply a link between COVID-19 and severe preeclampsia.

Mulvey et al analysed five COVID-19 positive mothers' placentas and concluded a thrombotic fetal vascular malformation phenomenon along with probable placental thrombosis lead to placental insufficiency. All five newborns were successfully delivered which may be attributed to the mothers developing COVID-19 closer to full term. They hypothesize that infection earlier in the gestational course may have more serious consequences such as placental insufficiency with associated miscarriages or low birth weight infants.³⁰ This may be why the two adverse outcomes in our study described by Hosier et al and Baud et al occurred during the second trimester.

Linehan et al in Cork, Ireland described a case of third trimester maternal COVID-19 infection with demonstrable SARS-CoV-2 placentitis. They concluded that SARS-CoV-2 placentitis is an uncommon but noteworthy complication of maternal COVID-19 infection which can lead to placental damage, potentially resulting in fetal compromise. This may be due to placental pathologies such as fetal vascular malperfusion and maternal vascular malperfusion.³¹

Of the 20 studies we analysed for our literature review, 6 studies confirmed a high possibility of vertical transmission in utero. Notably, these 6 studies were the same ones which identified 7 cases of SARS-CoV-2 in the maternal, neonatal and placental tissue. 16, 18, 21-24 Vivanti et al reported a case of proven congenitally transmitted infection on the basis of confirmed SARS-CoV-2 virus in the amniotic fluid prior to the rupture of membranes. 22

Dong et al showed elevated IgM antibody levels 2 hours after birth in a neonate born to a mother with COVID-19 suggesting that vertical transmission is possible, even if it is uncommon. This neonate also had elevated cytokines and a leucocytosis. IgM antibodies do not cross the placenta and normally appear 3 to 7 days after infection suggesting the infection occurred in utero. Confusingly, this infant repeatedly tested negative for SARS-CoV-2 on the nasopharyngeal swabs.³² It is important to consider the accuracy of nasopharyngeal and oral swab RT-PCR assays for SARS-CoV-2 which is deemed to have a sensitivity of between 56% and 83%.³³

The major limitation of our study is the small sample size of only 183 COVID-19 positive pregnant women and thus we cannot conclusively rule out the possibility of vertical transmission, though we deem it unlikely. However, we can consider that COVID-19 may affect the placental tissue due to the detection of the virus in certain cases.

After reviewing multiple studies and investigating the nature of placental physiology in SARS-CoV-2 positive mothers we conclude that there is no concrete evidence of vertical transmission occurring between mother and infant.

However, due to the novelty of the pandemic this small number of studies represent low levels of evidence due to the inconsistencies across the different studies reported. As the cases continue to rise worldwide, we expect the evidence to become more concrete on this topic with the development of more robust case control studies and long-term follow-up with the mothers and children.

Our literature review highlights the urgent need for a large scale study to be designed investigating the effects of COVID-19 on pregnant women by using RT-PCR to test the mother, placenta, vaginal fluid, breast milk and infant for SARS-CoV-2 at various stages of transmission.

Declaration of Conflicts of Interest:

There are no conflicts of interest to declare.

Corresponding Author:

Isabelle Sweeney School of Medicine, University of Limerick

E-Mail: sweeneyi@tcd.ie

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Perspectives of Interstitial Lung Disease Patients and Carers During COVID-19

N. Cassidy¹, D. Sheahan², L. Fox^{1,3}, L. Brown^{1,4}, L. Galvin¹, E. Cassidy¹, M. Sheridan¹, G. O'Dowd¹ K.M.A. O'Reilly^{1,3}

- 1. The Irish Lung Fibrosis Association, Dublin, Ireland.
- 2. Invisio Ltd., Blessington, Co. Wicklow, Ireland.
- 3. Mater Misericordiae University Hospital, Dublin, Ireland.
- 4. St. Vincent's University Hospital, Dublin, Ireland.

Abstract

Aim

To gain an understanding of the impact of COVID-19 on the daily life, healthcare needs, mental wellbeing and outlook of patients with Interstitial Lung Disease (ILD) and their caregivers.

Methods

ILD patients and caregivers were invited to participate in a quantitative survey. Respondents could self-select to then participate in in-depth structured telephone interviews. Survey data was compared to Department of Health COVID-19 public opinion tracker findings for the comparable time period.

Results

There were 170 survey respones (111 patients and 59 caregivers) and 14 in-depth interview participants. 32% (n=36) of patients and 42% (n=25) of caregivers expressed extreme worry regarding COVID-19 on a 1-10 scale. 83% (n=92) of patients expressed concern about safe hospital access, 33% (n=37) had received a telephone consultation with their clinician, 43% (n=48) reported test delays, 47% (n=52) were exercising less, 23% (n=26) reported worse sleep and 15% (n=17) reported being financially worse off. Carers reported that sleep was worse for 58% (n=34), 42% (n=25) reported being worse off financially, and 40% (n=24) reported a worse diet. Worry (66%, n=39), stress (51%, n=30), anxiety (49%, n=29) were commonly reported by carers.

Discussion

ILD patients and caregivers reported higher levels of worry regarding COVID-19 compared to the general public. Alternative pathways for quality ILD patient care and interventions to reduce the burden of care on ILD caregivers are required.

Introduction

Interstitial lung disease (ILD) is an umbrella term for a number of disorders associated with lung fibrosis. ILDs are characterised by increasingly disabling breathlessness, cough and fatigue with progressive impacts on patients' activities of daily living and quality of life (QoL). Idiopathic pulmonary fibrosis (IPF), the most prevalent ILD, is estimated to affect around 1,000 patients in Ireland, with median survival from diagnosis of 4.5 years.^{1,2}

ILD patients are highly medically vulnerable to coronavirus (COVID-19).³ Overall mortality in ILD patients hospitalised with COVID-19 in an international multi-centre study was 49%, significantly higher than matched controls (HR 1.6, p<0.003).⁴ In April 2020 Irish authorities issued advice that ILD patients should "cocoon", i.e. stay at home and avoid physical contact with others.⁵

The Irish Lung Fibrosis Association (ILFA), a patient organisation founded to support patients and families affected by ILD, conceived and supported this research in order to gain a deeper understanding of the impact of the COVID-19 pandemic on ILD patients, their caregivers and healthcare professionals working in this field. Here we focus on the results from ILD patients and caregivers, data from healthcare professionals has been previously reported in this journal.⁶ Our findings have implications not just for our own organisation, but also for clinicians working in this field.

Methods

We conducted quantitative and qualitative research, in the form of survey questionnaires and indepth structured telephone interviews, with ILD patients and informal caregivers and/or family members of ILD patients. The aim was to gain greater understanding of the impact of the COVID-19 pandemic on daily life, healthcare needs, mental wellbeing and future outlook of ILD patients and caregivers.

ILD patients and caregivers were invited to participate in a survey via an email/letter from ILFA to its stakeholders and postings on ILFA's social media. The surveys (online or via telephone if required) were designed to collect information on respondents' demographics, worry in relation to COVID-19, impact on daily living and access to healthcare, emotional well-being, level of support, use of technology, future implications and ILFA's advocacy priorities. Those who had completed the survey could self-select to participate in a telephone interview. Interviews were conducted by independent research professionals and were structured to address cocooning, basic daily needs, healthcare needs, communication, effect on mental wellbeing, supports from HSE and other organisations, long term implications and any other concerns. Interviews were recorded and transcribed for thematic analysis.

We compared findings from our research to data from the Department of Heath COVID-19 Public Opinion Tracking Research, which measured worry in relation to COVID-19 in 1,500 adults at a comparable time point (20th April 2020).⁷

Results

The survey research was conducted from April 16th to May 5th, 2020. Survey responses were gathered from 111 ILD patients and 59 informal caregivers. Seven ILD patients and seven caregivers participated in structured in-depth telephone interviews, conducted from April 28th to May 20th, 2020.

Demographics

Table 1: Patient and Caregiver Demographics.

	All Patients (n=111)		Caregivers (ı	า=59)
	N	%	N	%
Male	63	57	8	14
Age Category:				
18-60 years	26	23	44	75
61-70 years	42	38	11	19
71+ years	43	39	4	7
Receiving supplemental oxygen	37	33		
IPF Diagnosis	89	80		

Reported Worry about COVID-19

On a scale of 1 (not at all worried) to 10 (extremely worried), 32% (n=20) of patients and 42% (n=25) of caregivers were extremely worried about COVID-19. The average worry rating was 7.4 and 8.1 in patients and caregivers, respectively. The most common worry for patients was contracting COVID-19 (74%, n=47), for caregivers it was the health of family and friends (90%, n=53). When asked to indicate their level of concern regarding particular topics (figure 1), 83% (n=52) of patients were concerned about their ability to safely access hospital care if needed, with 88% (n=52) of caregivers sharing this concern for the patient they cared for.

Three quarters of patients were reassured by the Government's response to COVID-19, and although 74% (n=47) were confident of the ability of the health service to meet society's needs during the outbreak only 62% (n=39) were confident in its abilities to meet their own healthcare needs.

Potential medical supply issues
Implications of the restrictions on my mental health
My/My patient's ability to access GP services
Implications of restriction on my health
Length of restrictions
My/My patient's ability to safely access hospital care

Caregivers Patients

0 20 40 60 80 100

Figure 1: Sources of Reported Concern for Patients and Caregivers*.

Impact on Daily Living

Almost half (47%, n=30) of patients were exercising less since the COVID-19 measures began, this increased to 65% (n=41) for those living in Dublin, but 14% (n=9) were exercising more. Almost one quarter (23%, n=14) reported worse sleep and 15% (n=9) were financially worse off. For carers, sleep patterns were worse for 58% (n=34), 42% (n=25) were worse off financially, and 41% (n=24) reported eating a worse diet. Telephone interviews found that carers were either cocooning themselves or were limiting themselves to essential excursions.

Impact on Access to Healthcare

Since the COVID-19 restrictions began, 33% (n=21) and 43% (n=27) of patients had received a telephone consultation with their hospital respiratory team and GP, respectively. Only 11% (n=7) of patients had tests carried out as planned, 40% (n=25) of those had experienced delays in obtaining results, and 43% (27) had tests delayed. Two thirds were happy with their direct medical care, with the remainder indicating they needed additional support around individual patient specific issues (6%, n=4), oxygen concerns (6%, n=4), updates on tests and progression of condition (5%, n=3), or more GP communication or support (5%, n=3), amongst other issues.

^{*}Percentage of patients and caregivers a little or very concerned about each issue

Interviews revealed that cancellations or delays with medical appointments were a source of anxiety for patients. Patients who had received telephone consultations were generally happy with this service, although there were concerns regarding access to lung function tests and the subtle differences of face to face versus telephone communication.

All patients interviewed were reluctant to attend hospital if they needed to, or had already had a situation where they avoided the hospital: "If I was told during a consultation (with GP) that I had to go to the hospital, I would go but I would be very apprehensive about going to the hospital. I'd take any move possible, rather than actually go into a hospital as of now."

Support

Forty-four per cent of patients (n=28) indicated no additional supports were required from ILFA, compared to 33% (n=19) of caregivers. The most commonly identified area for additional ILFA support among patients was to continue to advocate for patients and raise awareness of ILDs (13%, n=8), whereas for caregivers this was to keep in touch (17%, n=10). In interviews patients were largely happy with supports available from either the HSE or other organisations, but two caregivers identified a need for counselling services: "A counselling service that understand what you're going through" and "I think where a lot of services fall down they don't have counsellors. They just need someone to talk to that understands and not a family member because they can't really say what they think and feel."

Use of Technology

Whilst smart phone ownership amongst patients was high (80%, n=50), this dropped to 64% (n=40) in the over 70s cohort and 5% (n=3) of all patients did not have access to either a smartphone, tablet or a laptop. Almost two-thirds (63%, n=40) of patients used phone-based apps to help them in their daily life.

Emotional Wellbeing

Almost half (46%, n=29) of patients reported feeling happiness in the day preceding the survey, but multiple negative emotions were also reported, including anxiety (33%, n=21), sadness (23%, n=15) and loneliness (11%, n=7). Few carers reported feeling positive emotions, with worry (66%, n=39), stress (51%, n=30), anxiety (49%, n=29), frustration (44%, n=25), sadness (41%, 24) and boredom (37%, n=22) being more commonly reported than either enjoyment (36%, n=21) or happiness (29%, n=17).

None of those Intolerance Anger Physical pain Lonliness Fear Happiness Enjoyment Boredom Sadness Frustration Anxiety Stress Worry Patient 10 20 30 40 50 60 70 Caregiver

Figure 2: Patient and Caregiver Emotions^.

^Percentage of Patients and Caregivers who reported experiencing each feelings "a lot" on the preceding day of the survey

Long Term Implications and Future Care Planning

Over half of patients surveyed (56%, n=35) had not discussed treatments that they would not like to receive in the event of them becoming seriously unwell, with 32% (n=20) having such discussions with close family and 11% (n=7) with healthcare professionals. Most (65%, n=41) were not aware of the Irish Hospice Foundation's Think Ahead document on end of life planning, and only 3% (n=2) had completed it. Several patients interviewed expressed grave concerns about the long term impact of COVID-19 on their future: "Truthfully, I'm only praying to God that I live through it" and "If we don't start doing transplants in the next 12 months... the window for me... that's not a good situation. It's a tragic situation."

Advocating for Change

When asked to prioritise areas of ILFA's advocacy work, patients and caregivers ranked advocating for a clinical care pathway for lung fibrosis as the most important (figure 3). This was consistent across all patient demographics.

Figure 3: Prioritisation of Areas for Patient Advocacy Ranked by Patients and Caregivers[†].

Area of Advocacy	Patients	Caregivers
That lung fibrosis has its own clinical care pathway like cancer	1.8	2.3
Promoting more awareness of the condition among GPs	3.0	3.2
More access to pulmonary rehab	3.2	3.4
Promoting more awareness of the condition among hospital staff	3.9	3.9
Promoting more awareness of the condition among the wider public	4.1	4.5
Improving access to oxygen supplies	4.7	3.7

 $[\]dagger$ Average importance ranking where 1 = most important, 5 = least important.

Discussion

This research was conducted during severe national COVID-19 restrictions in Ireland. Reported worry regarding COVID-19 among ILD patients and caregivers was higher than that of general public during the comparable period (average rating of 7.4 and 8.1 versus 6.6, respectively).⁷ The ability of the ILD patients to safely access hospital services was a key concern. Less than two-thirds of ILD patients were confident in the health service's abilities to meet their healthcare needs, and all patients interviewed were reluctant to attend hospital. This has serious ramifications for both scheduled and emergency ILD patient care, including the management of acute exacerbations or other potential outcomes arising from ILD patients' significant co-morbidities.⁸ A 45% reduction in emergency department (ED) presentations during COVID-19 restrictions was observed in Ireland, comparable to that reported in the US.^{9,10} Research from one US centre indicated that patient reluctance to attend the ED was due in part to lack of awareness of the hospital's risk mitigation strategies, and a need for clinician reassurance regarding when to attend.¹¹ ILD patient education materials detailing hospitals' procedures for COVID-19 risk mitigation, the importance of attending acute services if required, along with advice on when to attend hospital, may help to address such concerns and reduce the downstream repercussions of hospital avoidance.

There were unmet needs in the continuity of care for ILD patients at this time, with one third indicating they needed additional support and only 33% (n=21) having had a telephone consultation with their hospital respiratory team. Delays in consultations, assessments, or receiving test results were a source of concern, and alternative pathways for quality ILD patient care are required. Although telephone consultations were not considered optimal for ease of communication, or where assessments were required, telemedicine was generally well accepted by patients. Given the reluctance of patients to access hospital services, ILD healthcare professionals should consider optimisation of telemedicine during the pandemic. Concerns have previously been raised regarding the use of telephone communication with geographically isolated ILD patients, due to the exclusion of carers and the lack of visual clues potentially adversely affecting recognition of anxiety, depression or appreciation of patients' understanding. Such geographical isolation is analogous to the COVID-19 situation and multi-disciplinary ILD team video consultations have been proposed as a superior approach to remote care.¹²

In terms of remote assessments; use of digital platforms to record home spirometry in IPF patients has been shown to be feasible, and can provide a reliable estimate of lung function once attention is given to technique.¹³ Whilst usage of smartphones was high among patients, it did decline in those over 70, and some may need assistance with technology.

Markers of emotional distress and negative impacts on daily life were more common among caregivers than patients. Previous research has shown that caregiving for ILD patients significantly impairs health related QoL, particularly emotional health.¹⁴ Novel interventions are required to reduce the burden of care and improve the QoL of ILD caregivers during the pandemic, with implications for both patient organisations and the multidisciplinary ILD team. Caregivers identified that counselling services would be helpful, and professional psychological supports for those with ILDs could potentially be extended to include caregivers. Further studies are required to assess the relative effectiveness of strategies to support caregivers.

It was evident that patients are aware of the implications of the pandemic on their futures. Despite this, few patients had discussed their preferences around care should they become seriously ill. Research has shown that there are multiple inadequacies in palliative care of patients with ILDs, with deficiencies in advice or education on how to approach future care and end of life planning being just one aspect of this.¹⁵

Whilst many of the findings of this research relate to new issues brought about by COVID-19, some themes, including the burden of caregiving and inadequacies in palliative care, have previously been identified. Patients and caregivers agreed that campaigning for a clinical care pathway for ILD was the most important area of ILFA's advocacy work. In line with this mandate, ILFA will continue to advocate for change in this area for the benefit of ILD patients, carers and healthcare professionals - to meet both pre-existing challenges and new issues arising from the COVID-19 pandemic.

Declaration of Conflicts of Interest:

The authors have no conflicts of interest to declare.

Corresponding Author:

Nicola Cassidy, Irish Lung Fibrosis Association, PO Box 10456, Blackrock, Co. Dublin, Ireland.

E-Mail: info@ilfa.ie

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COVID-19 Pandemic and Maternal Perspectives

N.B. Janjua¹, A.F. Mohamed², S.A. Birmani², O. Donnelly³, A.H. Syed³, M. Essajee³

- 1. Department Obstetrics and Gynecology, University Hospital Waterford, Co. Waterford, Ireland.
- 2. Department of Obstetrics and Gynecology, Wexford General Hospital, Co. Wexford, Ireland.
- 3. Department of Obstetrics and Gynecology, Cavan General Hospital, Co. Cavan. Ireland.

Abstract

Aim

Coronavirus (COVID-19) pandemic has affected perinatal women worldwide. Our study aimed to describe the opinions of perinatal women about COVID-19 related knowledge, attitude, and practices.

Methods

Pregnant and Postnatal women (n=223) were included and those who did not consent, and less than 16 weeks' gestation, were excluded. SPSS version 26 was used for descriptive statistics.

Results

Most of the women had good knowledge about COVID 19 regarding its nature, transmission, & symptoms. Their information sources were news (139/206=67.5%) and the internet (85/206=41%). Women understood the uncertainty around its effect on pregnancy; as it is a novel infection. A substantial number of women were concerned (130/206=63%), upset by social isolation (86/206=42%), negatively impacted by the visitor restrictions in hospital (154/206=75%), and faced COVID-19 related reduced household finances (97/206=47%). Most of them used hand washing (201/206=98%) & social distancing (191/206=93%) as preventive measures. They reported compromised contact with General Physician (GP) service as compared to the hospital service (85/206=41% Vs 31/206=15% respectively) during the pandemic.

Conclusions

The main challenges of the COVID-19 pandemic for perinatal women are the jeopardized GP & hospital services & psychological distress. It is imperative to incorporate telemedicine & virtual visits to tackle the burden of the COVID-19 pandemic. Perinatal women, are particularly vulnerable to the psychological impacts of the COVID-19 pandemic & societal lockdown, thus necessitating holistic interventions.

Keywords: Maternal, COVID-19 pandemic, Psychological impact, GP service, Hospital service.

Introduction

International researchers have been updating us about different aspects of COVID-19 in pregnancy e.g. foeto-maternal transmission of COVID-19¹ and an increased risk of premature birth in infected pregnant women.² The pandemic has put an unprecedented burden on maternity and labour wards. The healthcare system has a constant threat of collapse in case of an outbreak.³ Moreover, it also affects the mental health of healthcare workers.⁴

The COVID-19 pandemic has potentially deleterious effects on healthy pregnant women, both directly and indirectly by targeting their physical, social, and psychological well-being. Fear of the unknown, COVID-19 induced social isolation and, financial constraints are the prominent challenges for the obstetric population during this pandemic.

Our study aimed to hear the voices of pregnant and postnatal women as consumers of the health care services during the COVID-19 pandemic. Its objective was to survey the maternal knowledge, attitudes, practices, and concerns regarding the COVID-19 pandemic.

Methods

This study was a cross-sectional knowledge, attitudes, practices, (KAP) survey study over two months, conducted in the Department of Obstetrics and Gynaecology of a General Hospital of Ireland between 15th May 2020 to 15th July 2020. All of the study participants gave written consent after we explained the objectives of the survey and reassured them about the anonymity of data.

The study participants included antenatal and postnatal women, presenting to the antenatal outpatient department, day-care assessment unit, emergency department, or admitted in the maternity ward. The sampling method was convenience sampling. Women who did not consent or complete their questionaries and those with a gestation of less than 16 weeks were excluded.

The study tool was a hard copy questionnaire, designed after discussing it with a team of obstetricians, patients, and midwives. It aimed to yield representative data variables. "Survey Monkey" tool⁵ was used to make the questionnaire. Data outcome variables included questions regarding the demographic characteristics of the women, their views on how Coronavirus was transmitted, common symptoms, effects of COVID -19 on the pregnancy, and what preventive measures, they were practicing. It also explored their views on their experience/contact with their GP and Hospital services during the COVID -19 pandemic, and the effects of the pandemic on their psychological well-being and financial constraints they suffered due to the pandemic. The questionnaire tool was revised after a pilot of 20. The hard copy questionnaires were completed by the study participants and we aimed to cover 10% of the target population.

Data was recorded on IBM SPSS Statistics version 26 as variables reflecting study protocol. Basic numerical tests were used for descriptive analysis to generate results.

Mean ± SD was calculated for the quantitative data e.g. gestation (weeks). Frequency and percentages were calculated for nominal as well as qualitative variables using IBM SPSS Statistics version 26.

Results

Among the women who were offered to participate, eleven did not consent to be included in the study, giving a sample size of 223 in a General hospital in Ireland with 1300 births yearly (17% of the target population). The incomplete questionnaires (n=17) were excluded from the study for further analysis (88% response rate).

Most (192) of the study participants were antenatal (93%) with a small number (n=14) of postnatal women (7%) and none of them had COVID-19 infection.

Table 1 [view] shows the different demographic characteristics and basic information of the study population. Among the study population, 153/206 (74.3%) of the women were currently employed. The gestational age ranged from 16 to 42 weeks with a mean of 30.54±6.93 weeks.

The women's responses to the questions related to various aspects of the Coronavirus, its effects on pregnancy, and their attitudes, are enlisted in Table 1. Most of the women (172/206=83.5%) stated that it was a viral infection transmitted by the respiratory secretions of the infected person, and touching objects of the infected person (118/206=57.3%). News (139/206=67.5%) was the most frequent source of information followed by the Internet (85/206=41.2%). Verbal communication and internet searches were used by 89/206 (43.2%) of women. Cough, fever, and shortness of breath were reported as the commonest COVID-19 symptoms by the study population. There was uncertainty among most women about the effects of COVID-19 on pregnant women e.g. susceptibility, proneness for serious complications, and recovery. The same is also true regarding its effects on the foetus such as miscarriage, impaired development, prematurity, and transmission.

A substantial number of women (130/206=63%) showed a concern for themselves, their baby, or their family and reduced household finances related to COVID-19 infection (97/206=47%). Most of the women (185/206=90%) did not feel anxious when attended by health care professionals wearing personal protection. Regarding their practices, women used hand washing and social distancing as preventive measures (201/206=98% & 191/206=93% respectively) (Table 1). More women reported that their contact with their GP service was compromised as compared to hospital services (85/206=41% Vs 31/206=15%) (Table 1), with few of them using masks (79/206=38%). The majority of the women (186/206=90%) responded that they should contact their GP via telephone to take advice if they suspected a COVID-19 infection.

Discussion

The COVID-19 pandemic has impacted health care services. Many studies have focused on various aspects of COVID-19 in pregnancy among infected women^{6,7} all over the world. Our study reflects and adds to the existing data, by surveying the perspectives of healthy pregnant and postnatal women regarding COVID-19 and health services.

Most of the women in our study were multiparous, Irish, and employed, and 5.8% (12/206) of women were from Black, Asian, and Minority Ethnic (BAME) backgrounds. Most of the study participants were antenatal (192/206, 93%); firstly, as a result of convenience sampling and secondly, because the number of antenatal women attending the clinic was more than that of the postnatal patients. Most of them were of the age group 20-34 years and in the second trimester of pregnancy. Women's knowledge regarding its cause and mode of spread was good. This study emphasized the importance of news and internet as sources of information over GPs & midwives (67.5% & 41.2% Vs 29.6% & 31.5%). Interestingly, patients reported that the source of information to be obstetric doctors in only 32/206=15.5% of cases. This could be explained by time constraints, increased workload on doctors due to peer COVID-19 infection, focussed attention on obstetric complications of pregnancy and given that most women were antenatal; they might have been in contact with their GP more often than obstetric doctors. Among study participants, 29.6% and 31.5% sourced information from GP and midwife respectively – while still very low, at least 30% approximately, sourced information from a healthcare professional. These findings express the constraints imposed by COVID-19 on our healthcare system as well as uncertainty around novel COVID-19 infection.

The importance of verbal communication and internet resources as a type of communication can't be overemphasized. These results advocate for the use of free telephone helplines for antenatal and postnatal ladies and providing evidence-based information available online.

The women in our study group correctly identified cough, and fever as the commonest symptoms among the pregnant population which is also supported by the PregCov-19 review. Due to rapidly evolving evidence, the uncertainties expressed by women regarding COVID-19 susceptibility, developing serious complications, effects on the foetus are understandable. Previously it was thought that COVID-19 was not transmissible to foetuses and pregnant women were at high risk of infection. The Interest is a suggested but uncommon transmission and good recovery in most pregnant women. Moreover, COVID-19 is associated with preterm delivery.

Perinatal women make a vulnerable group for the psychological impacts of COVID-19 and societal lockdown. Many women (130/206=63.1%) in our study showed concern for themselves, baby, or their families about COVID-19 infection. Among the women who expressed being affected by the visitor restriction hospital policy (154/206=75%), 52% (80/206) reported being anxious. Moreover, 42% (86/206) of women were upset by COVID-19 induced social isolation, and 47 % (97/206) faced reduced household finances related to COVID-19 infection.

Few studies have reported that the COVID-19 pandemic is related to a lack of support from a partner during labour and family and friends after delivery¹⁵ and an increase in the prevalence of perinatal anxiety and depression. Matthew Pierce, et al, found that being young, a woman, and living with children, especially preschool-age children, were associated with mental distress under pandemic conditions. They also stated that mental health deterioration is associated with pre-existing health inequalities, such as gender, age, and low income. Moreover, a study by Ryo Kato and Mtohiro Okada¹⁹ explains that financial support reduces suicidal rates. Hence, COVID-19 induced social isolation, jeopardized health services and financial deprivation are potential compounding factors for perinatal mental health issues, and this should be addressed systematically with comprehensive efforts.

Findings from the women's responses in the survey related to Maternal psychological distress, compounding factors, their potential sequelae, and the suggestions by the authors to address these issues are illustrated in Figure 1. Because of temporal changes in mental health status, we emphasize the importance of performing mental health checks more frequently, including at OPD & hospital visits, and based on preliminary triage, referral and pathway of care need to be devised and implemented for high-risk women.

The best prevention to protect patients and careers is social distancing ¹⁰ and maintaining basic personal hygiene. ²⁰ The majority of our study participants used hand washing and social distancing to prevent COVID-19 infection and only 38% (79/206) of women used masks; these statistics are likely to be different now as it is recommended to wear a face mask in all health care settings. More women reported that their contact with their GP service was compromised as compared to hospital services (41.3% Vs 15%). This explains the increased deterioration of GP services compared to hospital services during the pandemic. Few recent studies have also shown a sizeable decrease in antenatal and postnatal appointments, changes in screening methods for pregnancies with diabetes and growth restriction^{21,22} and refused/delayed perinatal mental health services. ²³ The effects of these unintended changes in healthcare pathways are not clear yet and need further research. At this point, the importance of telemedicine and virtual visits in selective cases can't be overemphasized to combat strains on healthcare systems in a smart way. On the other hand, the majority of the women in our study showed dependence on their GP for expert advice (90%), thus reinforcing the consumer preference and importance of the GP system in our healthcare system.

Albeit our study did not focus specifically on pregnant health care workers, they face unique stresses during this pandemic, namely increased workload, COVID-19 hospital breakouts, cross-infection risk, inability for cocooning and need to look after infected sick patients, thus posing mental distress. The current recommendation of the Royal College of Obstetricians and Gynaecologists is that women less than 28 weeks can look after infected patients if they use personal protection measures and are more than 28 weeks pregnant. Thus, the decision for healthcare pregnant women to continue work in these hostile conditions needs to be individualized and there is a need for further research in this particular area.

Regarding the limitations of our study, it was a single centred study with a small sample size and the sampling method was convenience, thus sampling bias can't be out ruled. In this quantitative survey study, all the questions were closed-ended, thus there could be a small possibility of response bias. The anonymization of data and making survey questions simpler, neutral, and easier helped us to eliminate it. The study could have added important information if women were asked about the impact of the COVID-19 on domestic abuse. Although we had a considerable representation (5.8%) of women of BAME background, we were unable to highlight the views and concerns of perinatal women with language barriers in this study; this leaves the necessity for studying addressing the views, concerns, and needs related to the COVID-19 pandemic of this subgroup of perinatal women in the future.

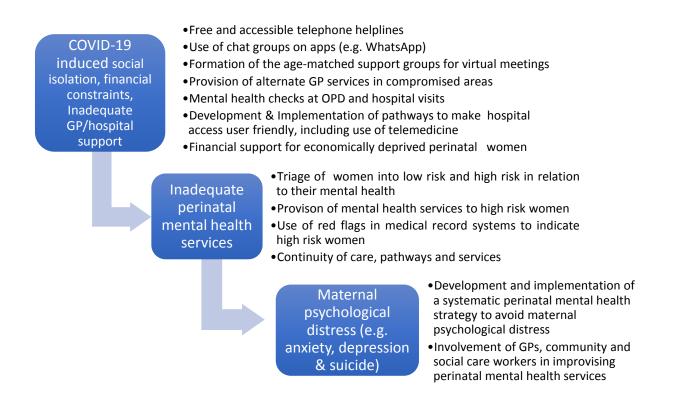


Figure 1: Findings from the women's responses in the survey; Maternal psychological distress, compounding factors and their potential sequelae, and the suggestions by the authors to address these issues during the COVID-19 pandemic.

The direct and indirect implications of the COVID-19 pandemic on perinatal women, healthcare staff, and services could continue to unfold over the coming decades. The main challenges of the COVID-19 pandemic for perinatal women are the jeopardized GP and hospital services and psychological distress. It is imperative to incorporate telemedicine and virtual visits to tackle the burden of the COVID-19 pandemic and maintain the safety of perinatal women and health care staff.

We suggest the development of free telephone helplines, and chat groups for perinatal women and providing evidence-based web pages and platforms for them to search. Perinatal women are particularly vulnerable to the psychological impacts of the COVID-19 pandemic and societal lockdown, thus it's important to streamline perinatal mental health services to cater to the needs of women at risk of psychological sequelae with holistic interventions. Mental health impacts and financial constraints are intertwined; thus, we advocate financial support for financially deprived, at-risk women. Pregnant health care staff and women of BAME background also face unique challenges, with increased mental distress, necessitating future research in this area.

Declaration of Conflicts of Interest:

We did not seek financial help at any time at any stage of this study. The authors declare that there is no conflict of interest.

Corresponding Author:

Nusrat Batool Janjua
Department of Obstetrics and Gynecology,
University Hospital Waterford,
Co. Waterford.
Ireland.

E-Mail: nusrat janjua@hotmail.com

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- 1. Margaret Flynn. Senior Midwife. Department of Obstetrics and Gynecology, Cavan General Hospital, Cavan.
- 2. Professor Dr. Naveed Kausar Janjua, Chemistry Department, Quaid-i-Azam University, Islamabad, Pakistan.

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Impact of a National Lockdown on Cycling Injuries

J. Foley, M. Robinson, J. Ryan, J. Cronin

Department of Emergency Medicine, St. Vincent's University Hospital, Dublin 4.

Abstract

Introduction

The Sars-CoV-2 pandemic led to a national lockdown in Ireland from March 12th to June 7th, 2020. The present study aimed to assess the change in the pattern of cycling attendances to an Irish ED during a pandemic.

Methods

This is a retrospective before-and-after study carried out at a university hospital ED. We compared cycling attendances during Lockdown (LD) (13th March-7th June 2020) with Pre-Lockdown (PLD) (January 1st-March 12th, 2020). Furthermore, we also compared lockdown to an historical control period during the equivalent dates in 2019 (i.e. March 13th-June 7th, 2019)

Results

There were 151 cycling attendances during LD, 122 in PLD and 164 during the control period. The number of cyclists presenting during "rush hour traffic" in the LD period was 30 (19.9%) versus 42 (34.4%) during PLD (p<0.05) and 51 (31.1%) during the control period (p<0.05). During LD, 8 (5.3%) collisions involved a motor vehicle compared to 26 (21.3%) in PLD (p<0.05) and 43 (26.2%) during the control period (p<0.05).

Conclusion

Lockdown did not result in increased cycling attendances to this ED. The patients who did sustain a cycling-related injury during lockdown were less likely to have collided with a motor vehicle compared to the control period. The reduction in motor vehicle collisions could be attributed to less traffic congestion and highlights the potential benefits of road-user segregation.

Keywords: Cycling trauma, COVD-19, injury, bicycle, road traffic collisions, road-user segregation, lockdown.

Introduction

A global pandemic was declared on the 11th of March 2020 with countries around the world implementing a variety of physical distancing interventions to prevent community transmission of Sars-CoV-2 ^{1, 2}. These measures included school and workplace closures, community contact tracing, social distancing and case isolation in order to flatten the curve of the pandemic and reduce the duration of the outbreak ^{3, 4}.

The COVID-19 pandemic reached Ireland on February 29th and within three weeks, cases had been identified in every county. On March 12th, the government implemented physical distancing interventions resulting in closure of schools, colleges, childcare facilities, cultural institutions, and the cancellation of large gatherings. On March 27th, further lockdown measures were introduced including a ban on all non-essential travel and contact with people outside of the home. These measures were kept in place until June 7th.

The lockdown presented significant alterations to daily life in Ireland among which, was a reduction in the number of people commuting to work with the Central Statistics Office (CSO) reporting that there were 70% less cars on the road for the lockdown period when compared with the same period for the previous year ⁵. This period of lockdown also resulted in more people exercising in Ireland, with Sport Ireland reporting an additional 500,000 walkers, 450,000 runners and 220,000 cyclists when compared to 2019, with an overall decrease in inactivity of 8% in adults ⁶. It would seem plausible therefore, that an increase in cyclists and a decrease in motor vehicles sharing the road could potentially lead to less collisions and result in a morbidity and mortality reduction.

The aim of this study was to examine the impact of a lockdown because of a global pandemic on cycling-related attendances to an Emergency Department (ED) and to report any differences in mechanism of injury, injury severity and mortality.

Methods

This is a retrospective before-and-after study carried out at an urban university hospital ED with an annual census of almost 60,000 attendances in 2019. We compared cycling-related attendances during Lockdown (LD) (13th March-7th June 2020) with Pre-Lockdown (PLD) (January 1st-March 12th, 2020). Furthermore, we also compared LD to an historical control period without physical distancing during the equivalent dates to LD in 2019 (i.e. March 13th-June 7th, 2019). The LD period was longer than PLD (87 days versus 70), so per-day figures are reported where appropriate. Maxims®, the ED information system, was interrogated for triage records with the keywords "bike", "cycling", "cycle", "cyclist", "biking", "bicycle" and derivates thereof, including potential misspellings. Medical records were analysed for data including demographics, mechanism of injury, mode of attendance, disposition, injuries sustained and mortality. The most severely injured body region was determined by the practitioner's documentation in the notes, and the final diagnosis attributed to each patient. Time of attendance was split into three distinct time periods: 0800-1559, 1600-2359 and 0000-0759. Rush-hour traffic was defined as the hours between 0700-0900 and 1600-1900 from Monday to Friday.

Means with standard deviations are reported for continuous variables with a normal distribution and compared using students t-test. Chi-square tests were used to determine associations between categorical variables and age group or outcome with a continuity correction being applied for 2×2 tables. For data analysis, we used Statistical Package for Social Sciences (SPSS version 26, IBM, USA). A p-value less than 0.05 was considered statistically significant.

Results

Demographics

There were 151 cycling-related presentations during LD (1.7 per day), 122 in PLD (1.7 per day) and 164 during the control period (1.9 per day). The baseline patient characteristics are displayed in Table 1. There was no difference in the mode of attendance for the study periods, with 34% of cyclists attending via ambulance in LD (n=51) and PLD (n=41) and 35% via ambulance in the control period (n=57). The number of cyclists presenting during "rush hour traffic" in the LD period was 30 (19.9%) versus 42 (34.4%) during PLD (p<0.05) and 51 (31.1%) during the control period (p<0.05).

Table 1. Patient Characteristics (LD, PLD and Control).

	LD (n=151)	PLD (n=122)	Control (n=164)	P Value
Gender (% Male)	68.9	68.0	73.8	p=0.87
Age (years)	41.2 (SD 15.7)	38.2 (SD 13.1)	37.1 (SD 14.5)	p=0.09
	Range 14-76	Range 16-76	Range 14-77	
Time of Arrival (%)	1600-2359	0800-1559	1600-2359	p<0.05
	(50.3%, n=76)	(51.6%, n=63)	(43.3%, n=71)	

Mechanism of Injury

During LD, 138/151 (91.4%) collisions were isolated cyclist collisions compared to 94/122 (77.0%) during PLD (p<0.05) and 118/164 (71.9%) during the control period (p<0.05). During LD, 8 (5.3%) collisions involved a motor vehicle compared to 26 (21.3%) in PLD (p<0.05) and 43 (26.2%) during the control period (p<0.05).

The mechanisms of injury for each study period are displayed in Figure 1 (Next Page).

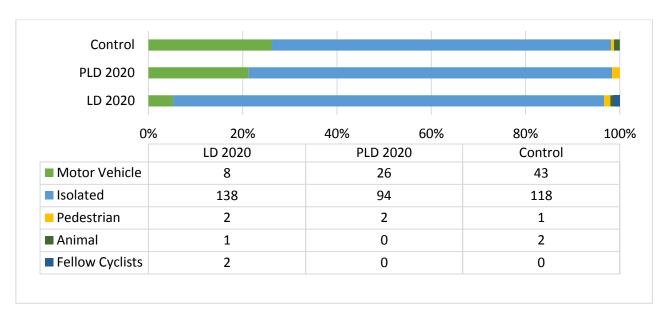


Figure 1. Mechanism of injury for the study periods.

Injury

The most severely injured body regions for each period are displayed in Figure 2. The upper limb was most commonly injured for all time periods, but more cyclists sustained upper limb injuries in LD (n=83) than in PLD (n=52) (p<0.05) and the control period (n=63) (p<0.05).

Head injury was identified at triage as the main body part injured in LD (n=30, 19.9%) which was lower than PLD (n=38, 31.1%) (p<0.05) and the control period in 2019 (n=50, 30.5%) (p<0.05). A CT scan of the head was performed for 17.2% of patients (n=26) during LD versus 13.9% of patients (n=17) during PLD and 16.5% of patients (n=27) during the control period (p=0.45). There were 2 patients who had head injuries with abbreviated injury scale (AIS) scores above 3 during LD versus 8 patients in the control period (p=0.06) versus zero patients during PLD (p=0.2).

There were no significant differences noted between the proportion of injuries to any of the other body regions.

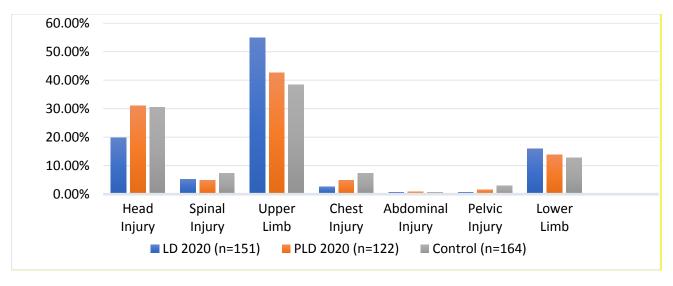


Figure 2. Most severely injured body region (%) for LD, PLD and Control.

Disposition

The admission rate for LD was 16.6% (n=25) versus 8.7% (n=13) during PLD (p=0.05). An operative procedure was performed on 18.5% (n=28) of cyclists in LD versus 10.6% (n=13) in PLD (p=0.06) and 6.7% (n=11) in the control period (p<0.05). The sites of surgery are shown in Table 2. No patients were admitted to ICU during PLD or LD while 1 patient was admitted during the control period. There were no mortalities during PLD or LD and there was 1 mortality in the control period.

LD 2020 (n=28)	PLD 2020 (n=13)	Control (n=11)
Wrist (n=14)	Wrist (n=4)	Tibial plateau (n=3)
Femur (n=3)	Neck of femur (n=2)	Wrist (=2)
Ankle (n=2)	Olecranon (n=2)	Olecranon (n=2)
Metacarpal/phalanx (n=2)	Ankle (n=2)	Elbow dislocation (n=1)
Olecranon (n=2)	Humerus (n=1)	Thoracotomy for chest injuries (n=1)
Clavicle (n=1)	Facial wounds (n=1)	Ankle (n=1)
Paravertebral block for chest injury (n=1)	Acromion (n=1)	
Tibial plateau ORIF (n=1)		
AC dislocation (n=1)		
Neck of femur (n=1)		

Table 2. Operative Procedure Sites (LD, PLD and Control)*.

Discussion

This is the first study to examine the effect of a global pandemic on ED presentations of cycling related injuries. While it was reported nationally that the numbers of cyclists increased during the COVID-19 lockdown, the numbers of cycling-related presentations to this hospital was not significantly higher or lower than PLD or the control period.

Given the closure of sports clubs, gyms and outdoor playing facilities, the increase in numbers cycling could be attributed to people seeking alternative means of exercise. Cycling shops in Ireland widely reported that sales increased substantially during the initial stages of the lockdown period ⁷. The increase in the number of cyclists may also be attributed to people avoiding public transport due to the various government guidelines restricting the number of people using public transport and people minimising their risk of infection ⁸.

Most attendances during LD were outside of normal working hours, which could be explained by people cycling after their working day for recreational purposes. This could also explain why LD had significantly less attendances during the rush-hour period than PLD or the control. However, it may be the case that there were cyclists on the roads during the rush-hour period in LD, but the reduction in traffic on roads resulted in a safer environment for cyclists, and subsequently less collisions and less ED attendances.

^{*}injuries are fractures unless otherwise specified

This study found that there were fewer collisions with a motor vehicle and proportionately more isolated cyclist collisions in LD than PLD and the control period. It has been established previously that one in four cycling presentations that present to hospital occur as a result of motor vehicle collisions and one in five of these collisions happen during rush hour traffic ⁹. International literature has shown that dedicated bicycle lanes, separation of road users and enhanced cycling infrastructure result in less collisions, less hospital attendances and less mortalities from cycling injuries ¹⁰⁻¹². There was a significant reduction in motor vehicles on roads in Dublin during lockdown. This may have contributed to the decrease in the number of cyclists presenting to ED because of a collision with a motor vehicle.

Single (or isolated) cyclist collisions have been shown to be an under-studied cause of cycling injuries and mechanisms including potholes, "loss of control events" and technical issues can be contributory towards collisions ^{9, 13}. These cyclists may sustain severe injuries also, and while less motor vehicle collisions will likely result in less severe injuries, an isolated fall from a bike can result in significant injuries requiring imaging, surgery or potentially ICU admission. However, when a cyclist has a collision with a motor vehicle, the injuries tend to be more significant and have a higher morbidity and mortality ^{14, 15}. Our findings would support the suggestion that segregation of road users and improved cycling infrastructure could potentially result in a morbidity and mortality reduction.

There were significantly less head injuries and significantly more upper limb injuries sustained during LD. Previous studies have shown that cyclists who collide with motor vehicles are more likely to sustain more significant injuries, including head injuries ^{14, 15}. It could therefore be hypothesised that due to the lower incidence of motor vehicle collisions in this study during LD, that less patients sustained significant head injuries as a result. However, there was no difference regarding the frequency of CT scans of the head or incidence of AIS3 head injuries between the different time periods. The higher numbers of upper limb injuries during LD may be explained by the increased number of isolated cyclist collisions, with the injured party using their upper limb to protect themselves when they fall. These injuries can be severe and, in this study, accounted for 71.4% of the operative procedures performed during LD. There were significantly more procedures performed during LD than PLD or the control period, and this was likely as a direct result of the increased number of upper limb injuries in the LD period. The numbers of mortalities and ICU admissions were very low in this single-centre study and showed no difference to the control periods. It is possible that a larger multicentre study over a longer period would show a difference in these outcomes.

Lockdown secondary to the COVID-19 global pandemic did not result in increased numbers of patients presenting to hospital with cycling-related injuries in our institution. The patients who did sustain a cycling-related injury during lockdown were less likely to have collided with a motor vehicle and were less likely to have sustained a head injury compared to the control period. The reduction in motor vehicle collisions may be attributed to less traffic congestion and highlights the potential benefit of segregating road users when implementing safety strategies for cycling.

Declaration of Conflicts of Interest:

The authors declare no conflicts of interest.

Corresponding Author:

Dr. James Foley,
Department of Emergency Medicine,
St. Vincent's University Hospital,
Elm Park,
Dublin 4.

E-Mail: jamesfoley@rcsi.ie

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Impact of COVID-19 Lockdown Restrictions: Ambient NO₂ and Asthma Hospital Admissions

K.I. Quintyne^{1,2}, C. Kelly¹, A. Sheridan¹, P. Kenny³, M. O'Dwyer³

- 1. Department of Public Health, Health Service Executive (HSE) North-East, Navan, Co. Meath.
- 2. School of Public Health, University College Cork, College Road, Co. Cork.
- 3. National Ambient Air Quality Unit (NAAQU), Environmental Protection Agency (EPA), Clonskeagh Road, Co. Dublin.

Abstract

Aim

The World Health Organization (WHO) declared the COVID-19 pandemic a global health emergency. Many countries of the world, including Ireland, closed their borders and imposed nationwide lockdown. During this period, all major anthropogenic transport activities, which contribute to atmospheric pollution, were restricted. The current study examines the impact of the transport restrictions on ambient nitrogen dioxide (NO₂) concentrations and hospital admissions for asthma across Ireland.

Methods

This is a retrospective population-based cohort study. National ambient air quality monitoring network data were analysed to investigation variations in NO₂ concentrations. Asthma hospital admissions data were collected from the HSE Hospital In-patient Enquiry (HIPE) for Cork, Dublin, and Meath.

Results

During the period of transport restrictions, there were reductions in the annual mean NO₂ for Cork, Dublin and Meath (i.e. $12\mu g/m^3$ to $11\mu g/m^3$ (p = 1); $25\mu g/m^3$ to $17\mu g/m^3$ (p < 0.001); and $23\mu g/m^3$ to $21\mu g/m^3$ (p = 1)). Reductions in asthma hospital admissions were also observed. Among the 8,471 patient episodes included in this study, the mean [SD] age at admission was 47.2[22.9] years; 61% were female (n=5,134); mean [SD] length of stay was 4.9[10.9] days.

Conclusion

The findings of this study provide an opportunity to explore the impact of NO₂ emissions for Cork, Dublin and Meath on asthma hospital admissions, in order to improve air quality modelling and policy development of management of asthma.

Keywords: COVID-19; Air pollution; Ambient NO₂; Transport restrictions; Hospital morbidity.

Introduction

Coronavirus disease 2019 (COVID-19) is a declared pandemic of the 21st century.¹² It was initially identified in Wuhan, China in December 2019 as a pneumonia of unknown origin. The peculiarity of COVID-19 is that it is spread through droplets, and has spread rapidly globally.² The outbreak of COVID-19 has led many countries to shut their borders and impose nationwide lockdown. In Ireland, the COVID-19 transport restrictions were introduced from March 2020 to mitigate for contagion within the community.

Due to the COVID-19 lockdown, anthropogenic vehicular energy-consuming activities were restricted. These transport restrictions recommended that residents in Ireland reduce transport through closure of non-essential services; encouragement of where possible for employees to work remotely; and only allow individuals to movements within limited distance of their places of residence (initially two kilometres then five kilometres). ³ As the pandemic progressed and levels of COVID-19 in the community reduced, these travel restrictions were relaxed in May 2020, with the proviso that all non-essential travel was kept to a minimum to reduce congregation and propagation of infection.³ In September 2020, Dublin saw the return of travel restrictions, which limited residents in Dublin from leaving the county. This was followed in October 2020 with reintroduction of full lockdown for Ireland due to rise in COVID-19 cases.³ Gradual relaxation of travel restrictions started in early December 2020, but due to rapid rise in cases was short-lived and resulted in full travel restrictions returning in December 2020.³ Reports on compliance with the government advice and guidelines COVID-19 varied from 60% to 80% from April to November 2020.4 Recent studies using ground-based monitoring data have reported significant changes in ambient air pollutants during lockdowns.⁵⁻¹⁰ The concentrations of ambient nitrogen dioxide (NO₂) declined significantly internationally, but varied geographically based on local confounding factors.

There are increasing reports in the literature about the impact of NO_2 on the natural history of persons with asthma (i.e. aggravating or triggering exacerbations). Additionally, research has noted that short-term exposure (i.e. less than 24 hours) even for annual mean NO_2 values of less than $50\mu g/m^3$, have been associated with increased hospital admissions. There is growing evidence to suggest that long-term exposure to NO_2 levels below the World Health Organization (WHO) recommended air quality annual mean guideline of $40\mu g/m^3$ can be associated with less favourable health outcomes (i.e. hospital admissions, and mortality). 15-17

Traffic is the major cause of air pollution, and a major source of outdoor NO₂ in Ireland.¹⁸ There has been increasing attention of ambient air pollution from anthropogenic vehicular sources; a shift has occurred for tackling impact on human health and adherence to international commitment to air quality directives.

In this study, ambient NO₂ levels obtained from national ambient air quality network monitoring system were used to understand the impact of COVID-19 lockdown restrictions on the NO₂ concentrations in across Ireland. It will also explore the relationship between NO₂ and acute asthma hospital admissions for residents in Cork, Dublin, and Meath between 2018 and 2021.

This would allow the authors to add to the national and international bodies of evidence about the effect of ambient NO₂ on human health in Ireland and could validate scientific interpretation and support air pollution management, including inputs for air quality modelling.

Methods

This study used routinely gathered hospitalisation data collected from the Health Service Executive (HSE) Hospital In-Patient Enquiry (HIPE) system.¹⁹ This repository is a well established, quality assured, national hospital care information system that uses ICD10-AM/ACHI/ACS coding to capture demographic, clinical and care data at discharge on all episodes of emergency and elective care across publicly funded hospitals in Ireland. Daily counts of hospital admissions were obtained for residents (all ages) with an address in Cork, Dublin, and Meath admitted on same day. These admissions were individuals with primary diagnoses of asthma (ICD 10AM codes J45, J46) for January 2018 to February 2021.

The NO₂ data collected from the national ambient air quality monitoring network in Cork, Dublin, and Meath were obtained from the Environmental Protection agency (EPA). The daily average results from each station were provided, and these were all combined to an overall daily average for Cork, Dublin, and Meath was generated. A further strategy was used: this involved employing equal cut-off points (i.e. quartiles) by ordering the distribution to review the impact of high versus low levels of NO₂.

In order to identify the impact on the acute hospital services, the following variables were examined: number of admissions; average age on admission (years); average length of stay (days); and gender. To take account for potential differences in age-profile of cases, data for asthmarelated admissions were stratified according to the following age groups: 0 - 17 years; 18 - 64 years; and 65 +years.

Raw and calculated data was collated and entered into Excel (Microsoft 2016) and exported into IBM SPSS Statistics for Windows, Version 26.0 (Armonk, NY). We analysed the data by applying descriptive statistics. All results were considered significant at p < 0.05 (two-tailed). For correlation of metric variables, Spearman rank order (rho), and for correlations of nominal variables, the χ 2-test, and for small sample sizes, the Fisher's Exact test was used. All results of various statistical tests are of an explorative nature.

Finally, as this research uses routinely collected data the population level rather than the individual level, it conforms to the Helsinki Declaration, and does not require approval from an ethics committee.

Results

The daily hospital admission data in Cork are shown in Figure 1, and revealed overall decreasing numbers of admissions for the three-year period (p < 0.001), that corresponded to a decrease in annual mean NO_2 levels (p < 0.001).

The daily hospital admission data in Dublin are displayed in Figure 2, and has shown overall reducing numbers of admissions for the three-year period (p < 0.001), which corresponded to a decrease in annual mean NO_2 levels (p < 0.001).

The daily hospital admission data in Meath are displayed in Figure 3, and highlighted overall decreasing numbers of admissions for the three-year period (p = 0.005), that corresponded to a decrease in annual NO_2 levels (p = 0.003).

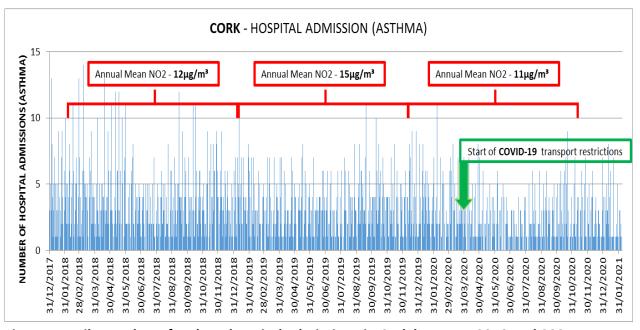


Figure 1: Daily number of asthma hospital admissions in Cork between 2018 and 2021.

Data provided from HIPE from 2020 to present is provisional, and subject to final validation.

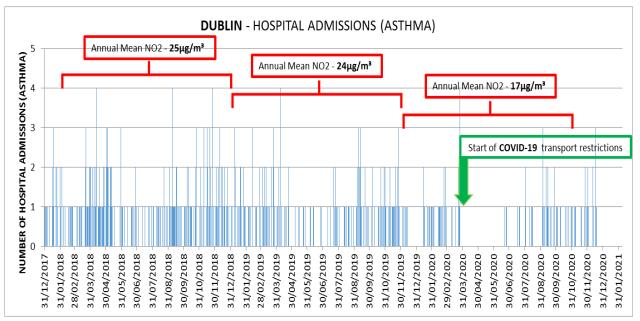


Figure 2: Daily number of asthma hospital admissions in Dublin between 2018 and 2021.

Data provided from HIPE from 2020 to present is provisional, and subject to final validation.

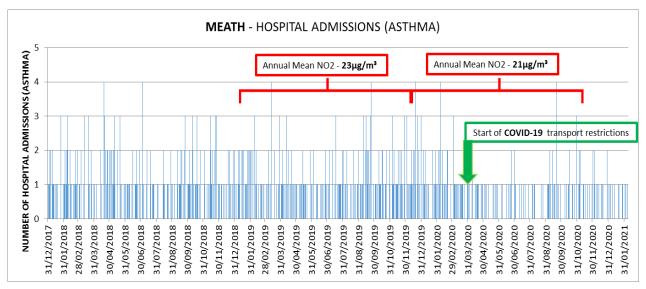


Figure 3: Daily number of asthma hospital admissions in Meath between 2018 and 2021.

Data provided from HIPE from 2020 to present is provisional, and subject to final validation. Among the 8,471 patient episodes included in this study, the mean [SD] age at admission was 47.2[22.9] years; 61% were female (n=5,134); mean [SD] length of stay was 4.9[10.9] days. The impacts of stratified levels of ambient mean NO_2 levels on hospital by county are described in **Table** 1. It highlighted statistically significant increases in number of asthma admissions in Cork and Meath with increasing levels of NO_2 . It additionally revealed that the ambient levels of NO_2 in Meath did not exceed $31\mu g/m^3$.

Table 1: Distribution of asthma hospital admissions for residents of Cork, Dublin, and Meath stratified by level of NO₂ from 2018 and 2021.

CHARACTERISTICS	MEAN NUMBER OF DAILY HOSPITAL ADMISSIONS					
CHARACTERISTICS	≤ 15µg/m³	$16 - 30 \mu g/m^3$	31 - 45μg/m³	≥ 46µg/m³	χ² TEST	
ASTHMA - CORK						
All ages	3.15	3.70	3.87	3.60	0.004	
0 – 17 years	1.21	1.23	1.14	1.00	0.848	
18 – 64 years	2.29	2.65	2.53	2.75	0.050	
65 + years	1.56	1.69	1.68	1.67	0.438	
ASTHMA - DUBLIN						
All ages	1.24	1.31	1.43	1.44	0.140	
0 – 17 years	2.63	2.75	2.75	3.28	0.072	
18 – 64 years	1.66	1.69	1.68	1.87	0.338	
65 + years	3.56	3.68	3.67	4.48	0.046	
ASTHMA - MEATH						
All ages	1.21	1.55	No data	No data	0.005	
0 – 17 years	1.08	1.00	No data	No data	0.526	
18 – 64 years	1.13	1.21	No data	No data	0.450	
65 + years	1.06	1.33	No data	No data	0.109	

Data provided from HIPE from 2020 to present is provisional, and subject to final validation.

 X^2 testing for Cork and Dublin compared $\leq 15 \mu g/m^3$ and $\geq 46 \mu g/m^3$ results

 X^2 testing for Meath compared $\leq 15\mu g/m^3$ and $16 - 30\mu g/m^3$ results.

Discussion

The main finding of this study using routinely gathered information was that there were reductions in levels of ambient NO₂ across Ireland from 2018 to 2020 were statistically associated with decreases in asthma hospital admissions. The reduction in this transport-related air pollutant (i.e. NO₂) was in large part due to the introduction of COVID-19 lockdown restrictions, which discouraged movement beyond distance from home and in turn reduced vehicular emissions. These findings are consistent with recently published reports.^{5-7 9 10 17 20} There was some variation in the levels of ambient NO₂ noted in the areas selected for review, and the degree in reductions noted over the investigation period was not consistent. Additionally, it should be noted that Cork did not experience as high levels of ambient NO₂ as Dublin and Meath. These findings are probably related to heterogeneous combinations of population density, level of vehicular use, level of available mass transit infrastructure, and distribution of ambient air quality monitoring stations. Similiar factors have also be noted in literature. ^{8 16}

This study provides evidence of an association between population exposure to ambient air pollution (i.e. NO₂) and aggravation or exacerbation of asthma episodes that warrant acute hospital admissions. The decreases in ambient NO₂ and asthma hospital admissions following the introduction of COVID-19 lockdown restrictions coincided with overall reduction in acute hospital admissions due to pressure on healthcare system from COVID-19. This is not controlled for in this review, as it would require differential calculations on all diseases and requirements for acute and emergency hospital admissions. To support the results obtained, it was noted that there was a statistically significant correlation and impact from changes in NO₂ levels and asthma hospital admissions (i.e. showing that increases in daily ambient NO₂ and high overall ambient levels of NO₂ above the WHO threshold are associated with increases in hospital admissions in all areas). Furthermore, each area under review coincidentally did not have any major air pollution episodes (i.e. single limited event or ongoing events) reported to the HSE and EPA to support other factors influencing these findings. It should however be noted that this study cannot comment on whether NO₂ is the causal agent or rather serving as a marker of transport-related air pollution mixture for these findings.

Based on the results, it is reasonable to infer that the ambient NO₂ levels have short-term impact on asthma hospital admissions in Cork, Dublin and Meath. It has varying degrees of impact in the areas under review with different age groups being predominantly affected. The latter findings might be related to the socio-demographic factors in each area. Similar findings have been documented in the literature.²⁰ These findings may also be in addition to the implementation of the clinical asthma programme and further rollout of the asthma chronic disease management programme by General Practitioners (GPs); and the co-benefit outcome of COVID-19 restrictions, whereby circulation of respiratory pathogens that might trigger infective exacerbations of asthma were not allowed to propagate. These have also been reported in recent reports.^{9 10 17}

It was also noted that the number of episodes of ambient NO_2 levels exceeding the WHO annual mean guideline of $40\mu g/m^3$ have reduced with the introduction of COVID-19 lockdown restrictions. Given that vehicular transport is the major source of ambient NO_2 in Ireland, it is reasonable to assume that there is no other explanation for the change in this ambient air pollution.

A previously acknowledged caveat is that the ambient air quality monitoring network in Ireland may not have historically been sufficient to accurately characterise the spatial patterns for ambient NO₂ across Ireland. This can potentially lead to under-estimates in this daily ambient air pollutant. These may occur because the ambient air quality network has a limited number of stations, some of which might be more sued during transport restrictions. A number of statistical approaches have been employed to reduce this occurrence, including modelling and development of forecasting frameworks. However, these strategies are not a substitute for improved data collection, and the EPA is currently and continually enhancing and expanding the ambient air quality network.

There are a series of limitations linked to this study. The first limitation is that there is not homogenous distribution of ambient air quality monitoring units in all areas under investigation. The placement of units is based on predetermined criteria that conform to the European Environmental Agency (EEA) guidelines, and it would not be advisable to place these monitoring units in areas that are not compliant, as it will be challenging to validate the results obtained. The second limitations is related to the lack individual level information on medical co-morbidities and smoking status. This might have to further quantify the level of impact on persons at high-risk for impact of high levels of NO2. Access to this level of information would be useful and relevant, but would require ethical approval, which was not necessary to undertake this current piece of work. In addition, the third limitation is that some of the individuals with asthma included might have impact from poor air quality episodes, which do not result in hospital admissions. Ambulatory care in general practice, outpatient settings, emergency room visits that do not conclude in hospital admission, and pharmacy attendances are not traditionally captured by the HIPE system. Given that there is no consistent and equitable way to gather any of the aforementioned healthcare interactions, the hospital admissions is the best surrogate for capturing morbidity related to poor ambient NO₂ levels for this piece of work.

Among residents in Cork, Dublin and Meath, decreases in ambient NO2, between 2018 and 2020, were significantly associated with lower asthma hospital admissions, following the introduction of COVID-19 lockdown restrictions. It also revealed that the ambient NO_2 levels were predominantly compliant with WHO annual mean guideline of $40\mu g/m^3$. The findings of this work should serve as an impetus for development of air quality policy in Ireland to sustain lower levels of ambient NO_2 .

Acknowledgements:

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Ethical Approval:

This research uses routinely collected data the population level rather than the individual level; it conforms to the Helsinki Declaration, and does not require approval from an ethics committee.

Declaration of Conflicts of Interest:

The authors declare no conflict of interest.

Corresponding Author:

Dr Keith Ian Quintyne Department of Public Health Railway Street Navan Co. Meath

E-Mail: keithi.quintyne@hse.ie

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A Comparison of the Performance of SARS-CoV-2 Antibody Assays in Healthcare Workers with COVID-19

C. Kerr ¹′², J. Dunne ³, G. Hughes ¹′², F. Cox ³, M. Healy ⁴, P. Holmes ⁴, F. O'Rourke ⁵, C. O'Brien ³, D. Coyne ⁶, V. Crowley ⁴, B. Crowley ⁵, N. Conlon ³, C. Bergin ¹′²

- 1 Genitourinary Medicine and Infectious Diseases Department (GUIDe), St. James's Hospital, Dublin.
- 2 Department of Medicine, School of Medicine, Trinity College Dublin, Dublin.
- 3 Department of Immunology, St. James's Hospital, Dublin.
- 4 Department of Biochemistry, St. James's Hospital, Dublin.
- 5 Department of Microbiology, St. James's Hospital, Dublin.
- 6 Department of Virology, National Blood Centre, St James's Hospital, Dublin.

Abstract

Aims

Since its emergence, significant interest surrounds the use of SARS-CoV-2 serological tests as an alternative or as an adjunct to molecular testing. However, given the speed of this pandemic, paralleled with the pressure to develop and provide serological tests in an expediated manner, not every assay has undergone the rigorous evaluation that is usually associated with medical diagnostic assays. We aimed to examine the performance of several commercially available SARS-CoV-2 IgG antibody assays among participants with confirmed COVID-19 disease and negative controls.

Methods

Serum taken between day 17 and day 40 post onset of symptoms from 41 healthcare workers with RT-PCR confirmed COVID-19 disease, and pre-pandemic serum from 20 negative controls, were tested for the presence of SARS-CoV-2 IgG using 7 different assays including point-of-care (POC) and laboratory-based assays.

Results

Assay performance varied. The lab-based Abbott diagnostics SARS-CoV-2 IgG assay proved to be the assay with the best positive and negative predictive value, and overall accuracy. The POC Nal von Minden GmbH and Biozek assays also performed well.

Conclusion

Our research demonstrates the variations in performance of several commercially available SARS-CoV-2 antibody assays. These findings identify the limitations of some serological tests for SARS-CoV-2. This information will help inform test selection and may have particular relevance to providers operating beyond accredited laboratories.

Introduction

SARS-CoV-2 is the novel coronavirus which causes COVID-19 disease. As of early May 2021, over 150 million SARS-CoV-2 infections have been recorded globally, resulting in over 3 million deaths ¹. Since its emergence, significant interest surrounds the use of SARS-CoV-2 serological tests as an alternative or an adjunct to molecular testing. The major advantage of serological tests over their molecular counterparts is their assumed ability to identify individuals who have previously been infected. This information can enable better understanding of COVID-19 epidemiology. It may also have the potential to inform individual risk of future disease, though this depends on further research in the area of post-infection immunity ².

The arrival of COVID-19 has brought with it the development of several novel laboratory-based and point-of-care (POC) serological tests that target different antigens of the SARS-CoV-2 virus. ELISA (enzyme linked immunosorbent assays), CLIA (Chemiluminescent immunoassay), CMIA (Chemiluminescent microparticle immunoassay - a subtype of CLIA) (electrochemiluminescence immunoassay) are laboratory-based tests that test serum or plasma samples for the presence of antibodies and can give results in hours. They detect antibodies to viral antigens by measuring the intensity of a colour or signal change upon the addition of an enzyme substrate. These are high-throughput tests and can give both quantitative and qualitative results. LFA (lateral flow assays) meanwhile can be carried out at the point-of-care (POC) using serum, plasma, whole blood or finger prick samples. These tests work by detecting antibodies via a colour change in the test strip. LFA are small, rapid tests that are used outside the laboratory and give results within minutes. However, they are low throughput tests and give a qualitative result only. Such tests were the subject of commercial promotion during the early days of the pandemic with some companies advertising their tests for sale to businesses and employers among others 3, though health agencies and regulatory authorities expressed caution over their use and interpretation outside of national testing strategies ^{4, 5}.

The aim of our study was to examine the performance of several commercially available SARS-CoV-2 antibody assays.

Methods

Ethical approval for this study was granted by the St. James's Hospital and Tallaght University Hospital research ethics committee in April 2020 (reference 2020-04 List 15) with prior existing ethical approval in place to analyse pre-pandemic reference samples for assay quality and development purposes (reference 2016-09 (CA)2).

Symptomatic healthcare workers with COVID-19 disease confirmed by RT-PCR were randomly selected from an existing hospital database of COVID-19 positive patients and invited to participate in the study. Informed consent was obtained, and serum samples were collected from participants during April 2020. Stored serum samples predating the pandemic were included for analysis as negative controls. These samples were taken from outpatients in non-infectious/inflammatory states.

Serum samples were processed and tested for the presence of SARS-CoV-2 IgG antibodies using the assays described in Table 1. The Abbott assay results were interpreted using the manufacturers recommended signal/cut off (S/CO) ratio at the time of 1.4. Samples at or above this S/CO were determined to be positive. Samples below the S/CO were determined to be negative. Results from the 2 other laboratory assays (DIA.PRO Diagnostic Bioprobes Srl and EUROIMMUN AG) were calculated according to their manufacturers specifications and reported as negative, borderline or positive. For the purposes of analysis, borderline results were interpreted as being positive. The lateral flow assay results were assessed and recorded by the authors as per their manufacturers' instructions. Only the IgG results from the lateral flow assays were included in this research.

Sensitivity and specificity were calculated for each assay. The positive and negative predictive values of each assay were calculated using a disease prevalence of 3.1%. This figure was the estimated SARS-CoV-2 seroprevalence in a Dublin population according to a national study carried out in July 2020 (Study to Investigate COVID-19 Infection in People Living in Ireland (SCOPI)) ⁶.

Table 1. List of assays tested, including the manufacturer, type of assay and platform involved. CMIA = Chemiluminescence microparticle immunoassay, ELISA = Enzyme-linked immunosorbent assay, LFIA = Lateral flow immunoassay.

Manufacturer	Name of Test	Format	Target	Platform
Abbott Diagnostics	SARS-CoV-2 IgG assay	CMIA	Nucleocapsid protein	Abbott Architect i4000sr
DIA.PRO Diagnostic Bioprobes Srl	COVID-19 IgG Enzyme Immunoassay	ELISA	Nucleocapsid and spike proteins 1 & 2	Dynex DS2 Automated ELISA system
EUROIMMUN AG	Anti-SARS-CoV-2 ELISA (IgG) assay	ELISA	S1 spike protein	Dynex DS2 Automated ELISA system
Biozek	COVID-19 IgG/IgM Rapid Test Cassette	LFIA	SARS-CoV-2 antigen- coated particles	Rapid Test Cassette
Hangzhou Testsea Biotechnology	SARS-CoV-2 IgG/IgM Test Cassette	LFIA	SARS-CoV-2 antigen- coated particles	Rapid Test Cassette
Nal von Minden GmbH	COVID-19 IgG/IgM Test	LFIA	SARS-CoV-2 antigen- coated particles	Rapid Test Cassette
Wuhan UNscience Biotechnology	COVID-19 IgG/IgM Rapid Test Kit	LFIA	SARS-CoV-2 antigen- coated particles	Rapid Test Cassette

Results

Forty one healthcare workers with COVID-19 disease confirmed by RT-PCR (13 male and 28 female) were recruited to this study. The median age of these participants was 42 years (IQR 34-50 years). All participants experienced symptomatic COVID-19 disease prior to serum sample collection. 4 participants (3 female and 1 male) were hospitalised during the course of their illness, though none were admitted to ICU. All participants were between 17 and 40 days post the onset of their symptoms at the time of sample collection (median 30 days, IQR 23-34 days). Stored prepandemic serum samples from 20 participants, 5 male and 15 female, were used as negative controls. The median age of these participants was 40 years (IQR 35-52 years).

Results from control participants are shown in Table 2. Several false positive results can be seen throughout the samples. This data suggests that false positive detections are not sample specific. Table 3 highlights the results of different assays tested on participants with confirmed COVID-19. As can be seen from this table, seropositivity does not always correlate with disease severity, as not all participants who were hospitalised due to COVID-19 disease had detectable antibodies across all assays, in contrast to several of the non-hospitalised participants.

Table 4 demonstrates the variability of sensitivity results across different platforms and manufacturers. There was significant variation in test sensitivity between assays; sensitivity ranged from 61% - 98%. The three lowest performing assays in terms of sensitivity were from the LFA group. These were the assays from Biozek (80%), Nal von Minden GmbH (76%) and Hangzhou Testsea Biotechnology (61%). The assays with the highest sensitivities were the lab-based DIA.PRO Diagnostic Bioprobes Srl (98%) and Euroimmun AG (93%) assays, followed by the point-of-care LFA from Wuhan UNscience Biotechnology (90%).

Specificity also varied, though not as widely as sensitivity, across all the assays tested, ranging between 90% - 100%. The assay with the lowest specificity was the lab based DIA.PRO Diagnostic Bioprobes Srl, which had a specificity of 90%, followed by the lab based Euroimmun AG and LFA Wuhan UNscience Biotechnology, both at 95%. The three other point-of-care LFAs (Biozek, Nal von Minden GmbH and Hangzhou Testsea Biotechnology) had the highest specificities at 100%, along with the lab-based assays from Abbott.

Negative predictive values (calculated using a disease prevalence of 3.1% (6)) were consistently high (with the lowest calculated negative predictive value being 99% (shared by the three LFAs from Biozek, Nal von Minden GmbH and Hangzhou Testsea Biotechnology). However, significant differences were noted between the positive predictive values of the assays, with results ranging from 24% - 100%. Given the low estimated disease prevalence, any false positive results among control samples led to a drastic reduction in the positive predictive value of the assay. False positive results in the control group resulted in 3 assays performing poorly in this category (DIA.PRO Diagnostic Bioprobes Srl at 24 %, and Euroimmun and Wuhan UNscience Biotechnology assays at 37%. The lab-based Abbott assays, as well as the point-of-care LFAs from Nal von Minden GmbH, Biozek and Hangzhou Testsea Biotechnology, performed best with positive predictive values of 100%.

Table 2. Overview of basic participant demographics and results from assays tested on "prepandemic" negative control samples. "Positive" results are highlighted in red font and "negative" results in black font. "Borderline" results are highlighted in blue font and were considered "positive" in terms of analysis.

Sample number	Gender	Age	Abbott Diagnostics	DIA.PRO Diagnostic Bioprobes Srl	EUROIMMUN AG	Nal von Minden GmbH (IgG only)	Wuhan UNscience Biotechnology (IgG only)	Biozek (IgG only)	Hangzhou Testsea Biotechnology (IgG only)
1	F	38	Neg	Borderline	Neg	Neg	Neg	Neg	Neg
2	F	33	Neg	Neg	Neg	Neg	Neg	Neg	Neg
3	F	51	Neg	Neg	Neg	Neg	Neg	Neg	Neg
4	М	17	Neg	Neg	Neg	Neg	Neg	Neg	Neg
5	М	71	Neg	Neg	Neg	Neg	Neg	Neg	Neg
6	F	35	Neg	Neg	Neg	Neg	Neg	Neg	Neg
7	М	39	Neg	Neg	Neg	Neg	Neg	Neg	Neg
8	F	36	Neg	Neg	Neg	Neg	Neg	Neg	Neg
9	М	49	Neg	Neg	Neg	Neg	Neg	Neg	Neg
10	F	44	Neg	Neg	Neg	Neg	Neg	Neg	Neg
11	F	40	Neg	Neg	Neg	Neg	Neg	Neg	Neg
12	F	21	Neg	Neg	Neg	Neg	Neg	Neg	Neg
13	М	41	Neg	Neg	Neg	Neg	Neg	Neg	Neg
14	F	56	Neg	Neg	Neg	Neg	Neg	Neg	Neg
15	F	62	Neg	Pos	Neg	Neg	Neg	Neg	Neg
16	F	39	Neg	Neg	Neg	Neg	Neg	Neg	Neg
17	F	55	Neg	Neg	Neg	Neg	Pos	Neg	Neg
18	F	30	Neg	Neg	Pos	Neg	Neg	Neg	Neg
19	F	71	Neg	Neg	Neg	Neg	Neg	Neg	Neg
20	F	30	Neg	Neg	Neg	Neg	Neg	Neg	Neg

Table 3. Overview of basic participant demographics and results from the various assays tested on symptomatic participants with proven COVID-19. "Positive" results are highlighted in red font and "negative" results are highlighted in black font. "Borderline" results are highlighted in blue font ("borderline" results were considered "positive" in terms of analysis).

Participant number	Admitted to Hospital?	Gender	Age	Days Post symptom onset	Abbott Diagnostics	DIA.PRO Diagnostic Bioprobes Srl	EUROIMMUN AG	Nal von Minden GmbH (IgG only)	Wuhan UNscience Biotechnology	Biozek (IgG only)	Hangzhou Testsea Biotechnology (IgG only)
1	Yes	F	59	18	Pos	Pos	Pos	Pos	Pos	Pos	Pos
2	No	М	28	23	Pos	Pos	Pos	Pos	Pos	Pos	Pos
3	No	F	27	21	Pos	Pos	Pos	Pos	Pos	Pos	Pos
4	No	F	35	34	Pos	Pos	Pos	Neg	Pos	Neg	Neg
5	No	F	50	21	Pos	Pos	Pos	Pos	Pos	Pos	Pos
6	No	F	41	35	Pos	Pos	Pos	Pos	Pos	Pos	Pos
7	No	F	43	23	Neg	Pos	Borderline	Pos	Neg	Pos	Pos
8	No	М	35	32	Pos	Pos	Pos	Pos	Pos	Neg	Neg
9	No	F	64	29	Pos	Pos	Pos	Pos	Pos	Pos	Pos
10	No	М	49	26	Pos	Pos	Neg	Neg	Pos	Pos	Neg
11	Yes	F	26	26	Neg	Neg	Neg	Neg	Neg	Neg	Pos
12	Yes	F	31	21	Pos	Pos	Pos	Pos	Pos	Pos	Neg
13	No	М	35	30	Pos	Pos	Pos	Neg	Pos	Pos	Neg
14	No	F	40	30	Pos	Pos	Pos	Pos	Pos	Neg	Pos
15	No	М	50	23	Pos	Pos	Pos	Pos	Pos	Pos	Pos
16	Yes	М	48	25	Neg	Pos	Pos	Neg	Neg	Neg	Neg
17	No	F	27	27	Pos	Pos	Pos	Pos	Pos	Pos	Pos
18	No	F	59	31	Pos	Pos	Pos	Pos	Pos	Pos	Pos
19	No	F	29	31	Pos	Pos	Pos	Pos	Pos	Pos	Pos
20	No	F	28	39	Pos	Pos	Pos	Pos	Pos	Pos	Pos
21	No	F	62	34	Pos	Pos	Pos	Pos	Pos	Pos	Neg
22	No	F	42	28	Pos	Pos	Pos	Pos	Pos	Pos	Pos
23	No	F	37	35	Pos	Pos	Pos	Neg	Pos	Pos	Neg
24	No	F	24	32	Pos	Pos	Pos	Pos	Pos	Pos	Pos
25	No	F	46	30	Pos	Pos	Pos	Pos	Pos	Pos	Neg
26	No	М	43	17	Neg	Pos	Borderline	Neg	Neg	Neg	Neg
27	No	F	57	32	Pos	Pos	Pos	Pos	Pos	Pos	Pos
28	No	F	48	23	Pos	Pos	Pos	Pos	Pos	Pos	Pos
29	No	F	40	34	Pos	Pos	Pos	Neg	Pos	Pos	Neg
30	No	М	24	40	Pos	Pos	Pos	Neg	Pos	Pos	Neg
31	No	F	45	34	Pos	Pos	Pos	Pos	Pos	Pos	Pos
32	No	F	43	33	Pos	Pos	Pos	Pos	Pos	Pos	Pos
33	No	М	53	36	Pos	Pos	Pos	Pos	Pos	Pos	Pos
34	No	М	40	40	Pos	Pos	Pos	Pos	Pos	Pos	Pos
35	No	F	27	31	Pos	Pos	Pos	Pos	Pos	Pos	Neg
36	No	F	51	35	Neg	Pos	Pos	Pos	Pos	Neg	Pos
37	No	М	52	21	Pos	Pos	Pos	Pos	Pos	Pos	Neg
38	No	F	34	25	Neg	Borderline	Neg	Pos	Pos	Pos	Neg
39	No	F	59	27	Pos	Pos	Borderline	Neg	Pos	Neg	Neg
40	No	М	38	27	Pos	Pos	Pos	Pos	Pos	Pos	Pos
41	No	М	54	21	Pos	Pos	Pos	Pos	Pos	Pos	Pos

Table 4. Assay results for pre-pandemic (negative control) and COVID-19 positive participant samples are shown here, as well as calculations for assay sensitivity, specificity, positive & negative predictive value and accuracy. * = includes one result reported as "borderline". ** = includes three results reported as "borderline".

Manufacturer	Name of Test	Total no. of COVID-19 samples	True Positive	False Negative	Total no. of Controls	True Negative	False Positive	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value(95% CI)	Negative Predictive Value (95% CI)	Accuracy (95% CI)
Abbott Diagnostics	SARS-CoV-2 IgG assay	41	35	6	20	20	0	85% (71% - 94%)	100% (83%- 100%)	100%	100% (99%- 100%)	100% (93%- 100%)
DIA.PRO Diagnostic Bioprobes Srl	COVID-19 IgG Enzyme Immunoassay	41	40*	1	20	18	2	98% (87%- 100%)	90% (68%-99%)	24% (8%- 54%)	100% (99%- 100%)	90% (80%- 96%)
EUROIMMUN AG	Anti-SARS- CoV-2 ELISA (IgG) assay	41	38**	3	20	19	1	93% (80%- 98%)	95% (75%-99%)	37% (8%- 80%)	100% (99%- 100%)	95% (86%- 99%)
Nal von Minden GmbH	IgG only	41	31	10	20	20	0	76% (60%- 88%)	100% (83%- 100%)	100%	99% (99%- 100%)	99% (93%- 100%)
Wuhan UNscience Biotechnology	IgG only	41	37	4	20	19	1	90% (77%- 97%)	95% (75%- 100%)	37% (8%- 80%)	100% (99%- 100%)	95% (86%- 99%)
Biozek	IgG only	41	33	8	20	20	0	80% (65%- 91%)	100% (83%- 100%)	100%	99% (99%- 100%)	99% (93%- 100%)
Hangzhou Testsea Biotechnology	IgG only	41	25	16	20	20	0	61% (45%- 76%)	100% (83%- 100%)	100%	99% (98%-99%)	99% (92%- 100%)

Discussion

Our research demonstrates the variations in the performance of several commercially available SARS-CoV-2 antibody assays, which has implications for assay selection and interpretation in clinical practice.

Accuracy describes the overall probability that a sample result is correctly classified and considers the specificity and sensitivity of an assay in light of an overall disease prevalence. The assay in our study which demonstrated the highest accuracy was the Abbott assay at 100%, followed by the assays from Nal von Minden GmbH, Biozek and Hangzhou Testsea Biotechnology. However, the small samples size of our study and this must be borne in mind when interpreting accuracy, which favours specificity in regard to disease prevalence.

Serological assays are being investigated to explore their utility in complementing RT-PCR tests in the confirmation of COVID-19 disease. These assays potentially have a very important role to play in our response to the COVID-19 pandemic, enabling us to gain a better understanding of disease epidemiology by allowing us to gather data on disease spread through national epidemiological studies. At the time of writing, four SARS-CoV-2 vaccines have been licensed by the EMA and several more are in phase 3 clinical trials with dozens in earlier stages of development. Serological assays will be integral to assessing host vaccine response among vaccine recipients. They can possibly help in informing individual risk of future disease, though this latter point depends on further research in the area of post-infection immunity ². Caution is however advised with regards to the use of antibody tests outside of national testing strategies ⁵, in particular the inappropriate unsupervised use of point-of-care LFAs.

Knowledge of future disease risk could be of importance in informing future workforce planning, especially in the healthcare sector. Healthcare workers (HCWs) are particularly at risk of contracting COVID-19 in the course of their duties ⁷ and through social risks and, as such, may be considered a vulnerable group in the context of the global COVID-19 pandemic. ⁸ HCWs may contract COVID-19 through symptomatic ⁹ or asymptomatic ^{10, 11} transmission and may in turn be asymptomatic carriers of the virus. Though molecular testing via oro- and nasopharyngeal swabs is the recommended diagnostic and surveillance method to detect current COVID-19 infection in symptomatic individuals, serological testing may be a sensitive method to detect the presence of prior exposure to COVID-19, especially in the asymptomatic or mildly symptomatic population. ¹². SARS-CoV-2 antibody testing studies conducted in individual healthcare centres in the UK ¹³ and Europe ¹⁴ have revealed significant seropositivity in asymptomatic staff as well as interesting findings related to seroconversion rates among different staff sectors. Public Health England (PHE) have implemented a country wide programme of community based HCW COVID-19 antibody testing in order to better understand the trend of infection within the HCW population ¹⁵.

The rapid spread of the pandemic fostered pressure to develop and roll out new serological tests in an expedited manner, and thus certain assays may not have undergone the same regulatory scrutiny that is usually associated with medical diagnostic approval. As a result, uncertainty exists around the accuracy of some serological tests that have become available since the advent of the pandemic ¹⁶. The pace of serological diagnostic development in the face of pressing demand has also meant that some tests may not have undergone extensive validation, which is required to put their clinical relevance in context before they are made commercially available. At the time of the commencement of this research (April 2020), 91 different manufacturers had notified the Food and Drug Administration (FDA) of their intention to offer internally validated tests for commercial use ¹⁷. At that time, the FDA indicated that the laboratories should, after notifying the FDA, validate their assays as appropriate and include a report commenting on the limitation of their tests ^{17, 18}. Such an absence of oversight raises concerns about the performance of some of the commercially available assays.

Further concerns exist around the performance of unvalidated POC tests which are used outside of regulated environments such as accredited laboratories. The relative inferiority of lateral flow assays in this regard means their use should be met with caution, and perhaps even discouraged unless accompanied by expert oversight.

Our research analysed four such POC tests (the four lateral flow assays). The three poorest performing assays in terms of sensitivity in this small study were from the POC group.

Caution should be advised in the interpretation of COVID-19 serology results. Accurate serological interpretation requires robust assay validation as well as an understanding of immunobiology and knowledge of the relevant clinical details. The clinical scenario pertaining to the person undergoing testing, and details on symptomatology, play an extremely important role in the accurate interpretation of serological results. A study published in Clinical Medicine ¹⁹ showed that serological result interpretation for SARS-CoV-2 can vary significantly, even among clinicians. This highlights the need for expert guidance in the interpretation of results, especially in the context of a novel disease and new assays. Input from expert clinical and laboratory scientists should be sought if doubt exists around assay result interpretation. This point should be borne in mind when choosing a serological assay to test patients for SARS-CoV-2 seropositivity, teamed with knowledge of different assay performances and optimal testing timeframes.

Studies continue to emerge showing the potential for false positive and false negative antibody results. One case report showed how cross reactivity and a false positive result occurred in a case of granulomatosis with polyangiitis ²⁰. Incidences of false positive results have been seen in patients suffering from acute infectious conditions, especially infection with Epstein-Barr virus and hepatitis B virus ²¹. Other causes of false positive results include rheumatoid factor, human antianimal antibodies (produced through animal contact, vaccination, blood transfusion, use of drugs of animal origin etc.), and cross reactions between coronaviruses in the same subgenus or different subgenuses (though this is thought to be relatively rare in clinical practice) ²². False negative results have been attributed to issues around assay formats, the selection of viral antigens and antibody types, diagnostic testing windows, antibody level fluctuation and individual variance ²³.

There are limitations to this study. Firstly, this is a small study. Any false positive or false negative results in a small sample among a population with a low disease prevalence can lead to wide ranging results in terms of sensitivity and specificity. Details of the presence of pre-existing infectious or inflammatory conditions in the control group were not recorded. However, the control samples were taken from patients in non-infectious/inflammatory states.

Despite the limitations, our research found that the lab-based Abbott diagnostics SARS-CoV-2 IgG assay proved to be the assay with the best positive and negative predictive value, and overall accuracy, when tested among participants with confirmed COVID-19 disease and negative controls. The point-of-care Nal von Minden GmbH IgG and Biozek assays also performed well. Serological assays for SARS-CoV-2 have multiple potential roles to play in the response to the COVID-19 pandemic, including complementing RT-PCR testing, assessing previous exposure, augmenting epidemiological COVID-19 research, evaluating vaccine efficacy or informing future workforce planning and individual risk of future disease. However, the rapidly evolving nature of the pandemic has expedited the introduction of many diagnostic assays for SARS-CoV-2 antibodies, some of which may not have undergone rigorous validation. Assay result interpretation requires a knowledge of the type of assay employed, the environment in which it is used, its accuracy and an understanding of its limitations.

Declaration of Conflicts of Interest:

None of the authors have any conflicts of interest to declare.

Ethics Approval:

Full ethical approval for this study was granted by the St. James's Hospital and Tallaght University Hospital research ethics committee in April 2020 (reference 2020-04 List 15) with prior existing ethical approval to analyse pre-pandemic reference samples for assay quality and development purposes (reference 2016-09 (CA)2).

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Corresponding Author:

Colm Kerr

Genitourinary Medicine and Infectious Diseases Department (GUIDe), St. James's Hospital, Dublin/Department of Medicine, School of Medicine, Trinity College Dublin, Dublin.

E-Mail: colmkerr@gmail.com

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Period of Purple Crying Program for the Prevention of Abusive Head Trauma/Shaken Baby Syndrome

E. Power, 1,2 F. Sharif, 3,4,5

- 1. University Hospital Limerick, Limerick.
- 2. School of Medicine, University College Dublin.
- 3. Department of Paediatrics, Mullingar Regional Hospital, Westmeath.
- 4. Department of Paediatrics, Royal College of Surgeons in Ireland (RCSI), Dublin.
- 5. Department of Paediatrics, University College Dublin, Dublin.

Abstract

The *Period of PURPLE Crying* Program is an educational program delivered to parents of newborn children that aims to reduce the incidence of abusive head trauma/shaken baby syndrome¹. The program was developed by a research-based, non-profit organisation and has already been implemented in many countries around the world. It educates parents on what to expect during the first few months of their newborn infant's life, allowing parents to become more informed and better prepared to care for their child. The recent surge in the number of cases of abusive head trauma in children during the COVID-19 pandemic has highlighted the need for greater resources being made available to parents. The *Period of PURPLE Crying* Program is one such resource that could be implemented in Ireland.

Introduction

Primary care providers in Paediatrics are in a unique position to educate parents and carers of newborn babies in order to ensure the best start to life in a safe and nurturing environment. One of the most distressing situations in Paediatrics is child abuse, the worst form of it being abusive head trauma (AHT) in children, also known as shaken baby syndrome (SBS). This problem has come to the fore in recent months with the news that there has been a marked increase in the incidence of AHT in infants during the COVID-19 pandemic.² It is widely agreed that one of the main precipitants of AHT is frequent and consistent periods of crying by the infant, leading to feelings of frustration, anger and hopelessness in the parent, resulting in AHT.³ The primary course of action for AHT in children is preventative through the use of parental education resources, such as that of the *Period of PURPLE Crying* program.

Why is abusive head trauma so concerning?

Brain and head injuries are the most common cause of death from trauma in children less than 2 years of age, with somewhere between 14 and 40 cases of AHT per 100,000 children occurring each year.⁴ Fifteen percent to twenty-three percent (15-23%) of children with AHT die within hours or days, while approximately one-third of survivors become severely disabled, one-third become moderately disabled and one-third have no or mild symptoms.⁵ Although the incidence is relatively small, the magnitude of the consequences is significant. While there is insufficient data on the exact numbers of AHT in children in Ireland, one Irish study has shown that the awareness of AHT remains low, with 50% of parents of newborns claiming that they had no prior knowledge of AHT or SBS.⁶ Recent research reporting that there was a 1493% increase in cases of AHT during the first month of the COVID-19 lockdown in the United Kingdom has also underpinned the need for increased parental awareness with regard to preventing AHT.² Thus, education is needed to ensure that parents are aware of what to expect from newborns, particularly in relation to the normal physiology of infant crying in the first few months of life and how to cope with such, so that there is increased awareness and decreased incidence of AHT.

What type of education is recommended?

The *Period of PURPLE Crying* program is a research-based non-profit charity educational program for parents, that was developed jointly by Dr Ronald G. Barr, a developmental paediatrician, and the National Center on Shaken Baby Syndrome in the USA. The program is already implemented in various countries around the world. The program has two aims; the first is to support caregivers in their understanding of early increased infant crying and the second is to reduce the incidence of AHT.¹ Healthcare professionals register for the hour-long course, which is composed of a number of videos, a booklet and implementation training. They are then equipped with the knowledge, tools and resources necessary to educate parents. This information is then delivered to parents, who receive their own set of program materials, consisting of a 10-page booklet along with a DVD or mobile application containing the 10-minute *Period of PURPLE Crying* video and a 17-minute *Crying, Soothing and Coping* video. This use of a take-home video and booklet allows parents access to the information whenever they may need it and they can also share the knowledge with anyone caring for their baby.

What does Period of PURPLE Crying mean?

The "Period of PURPLE Crying" is the period in the first few months of an infant's life whereby the infant excessively cries. It is often described as "infantile colic" and accounts for 10-20% of paediatrician visits for infants aged from 2 weeks to 3 months⁷. This colic is described as crying that lasts longer than 3 hours per day, 3 days per week for 3 weeks.⁸ This diagnosis is of no benefit to parents as there is little to offer in terms of treatment, leaving parents feeling under-supported and overwhelmed. The term "Period of PURPLE Crying" has been used as a replacement for the outdated "colic" as it encompasses the key aspects of what parents can expect from their infant with regards to crying.

The word "PURPLE" is an acronym for:

Peak of crying: your baby may cry more each week, the most in month 2, then less in months 3-5

Unexpected: crying can come and go and you don't know why

Resists soothing: your baby may not stop crying no matter what you try

Pain-like face: a crying baby may look like they are in pain, even when they are not

Long lasting: crying can last as much as 5 hours a day, or more

Evening: your baby may cry more in the late afternoon and evening

The word *Period* means that the crying has a beginning and an end.⁹

Such a simple message allows parents to understand that what their child is experiencing is not abnormal and that they are doing nothing wrong.

What studies have been carried out to test for the effectiveness of this program?

A study consisting of 20 hospitals in the New York State Hudson Valley region found that prior to implementation of an educational program for parents, there were 2.8 injuries associated with AHT per year. Following initiation of the program, this figure fell to 0.7 injuries per year, a reduction of 75%. Similar studies have also found reductions following implementation of parent education programs. In addition to the reduction in AHT, other benefits included an increased awareness among parents of what to do when a baby is crying, with 93% of parents in one study rating the program as useful to them. 12

Is the program cost-effective?

Apart from the benefits of child safety, for a program to be successfully implemented it must also be cost-effective to society. A 2019 study in British Columbia, Canada, completed an incidence-based cost-of-illness analysis of data collected over a 12 year period and found that an investment of just \$5 (€4.24) per newborn through the *Period of PURPLE Crying* program resulted in a \$273.52 (€231.87) per child cost avoidance by society and a \$14.49 (€12.28) per child cost avoidance by the healthcare system.¹³

Is the program acceptable to parents and medical personnel?

Simonnet et al found that parents regarded the intervention as acceptable and useful, while healthcare professionals such as paediatricians and nurses found that they could easily provide a short talk to parents during the newborn examination.¹⁴ It is evident then that the program is beneficial and acceptable to all of the stakeholders involved.

What is the next step?

Contact has already been made with the National Center on Shaken Baby Syndrome in Utah, USA about the possibility of implementing the *Period of PURPLE Crying* program in Ireland. This would first involve a pilot study being completed at Mullingar Regional Hospital comprising of nurses, midwives and doctors. The aim of the pilot study would include a review of the fit and feasibility of implementing the program in universal child health services in Ireland. The universal National Healthy Childhood Programme includes child health screening, developmental surveillance and immunisations. This universal service provides for parent contacts with a healthcare professional at least 25 times from pregnancy through to the child's third birthday.¹⁵ This programme already provides information and education on issues including child safety, breastfeeding, infant mental health, nutrition and so represents a logical platform through which to implement the Period of *PURPLE* Crying Program.

Conclusion/Recommendation

While it is evident that more research is needed in Ireland regarding exact figures of AHT, the effectiveness of the program in educating parents about infant crying and coping methods to deal with it cannot be ignored. With the incidence of AHT increasing in recent months, research-based educational programs such as *Period of PURPLE Crying* are needed to ensure that the most vulnerable members of society are adequately cared for. We, as clinicians, owe it to all the babies who suffered this horrific type of child abuse and to those who are at risk of suffering from it.

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Declaration of Conflicts of Interest:

The authors have no conflicts of interest to declare.

Corresponding Author:

Dr Edmond Power,
University Hospital Limerick,
Dooradoyle,
Co. Limerick,
Ireland.

E-Mail: edmond.power@ucdconnect.ie

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Identification and Management of Children and Adolescents with Obesity Referred to a General Paediatric Outpatient Department

J. McGirr¹, G. O'Malley^{2,3}, Ó. Walsh^{1,4}

- 1. Department of General Paediatrics & Adolescent Medicine, Children's Health Ireland at Temple Street, Dublin, Ireland.
- 2. W82GO Child and Adolescent Weight Management Service, Children's Health Ireland at Temple Street, Dublin, Ireland.
- 3. School of Physiotherapy, Division of Population Health Sciences, Royal College of Surgeons in Ireland, Dublin, Ireland.
- 4. Department of General Paediatrics, Children's Health Ireland at Connolly, Dublin, Ireland.

Abstract

Aims

To identify all children and adolescents with overweight or obesity attending the outpatient department and audit our processes in their identification and management against NICE standards.

Methods

A retrospective chart review was performed. BMI charts were used to identify children and adolescents with overweight/obesity. The patient journey was audited to ascertain if overweight/obesity was identified by the clinician, whether this was communicated to the child or adolescent/their carer and whether intervention was offered.

Results

There were 669 scheduled appointments and 27.3%(n=127) of children ≥2 years and adolescents were identified with overweight/obesity. Children and adolescents referred for reasons not primarily related to obesity management were identified (90.6% (n=115)) and this group was analysed. Height and weight and/or BMI were communicated in 13.9% (n=16) of referral letters. A record of discussing growth was observed in 15.7% (n=18) of cases. Growth measurements were included in the post-clinic correspondence to the primary care physician in 56.8% (n=63) of letters.

Discussion

Further research is required to ascertain what barriers exist to the discussion of growth. Additional education of healthcare providers is necessary to develop standardised procedures around processes related to child and adolescent growth.

Introduction

In Ireland, 19% of primary school children and 26% of adolescents have either overweight or obesity ^{1,2}. Current guidelines recommend that growth measurement be standard practice with each professional paediatric contact and that children and adolescents be offered tailored clinical intervention^{3,4}. This study aimed to identify all children and adolescents with overweight (BMI≥91st centile) or obesity (BMI≥98th centile) attending the outpatient department and to audit our processes in their identification and management against NICE Guideline CG189 and Quality Standard QS127^{5,6}. Our ultimate aim was to facilitate earlier detection and opportunities for early intervention, including collaboration with primary care services. With the introduction of electronic records providing automated generation of BMI centile charts, we are presented with a valuable new resource in the outpatient department to assist us in achieving this aim.

Methods

A retrospective electronic chart review was performed following institutional approval. BMI growth charts (UK BMI 2-20 years), generated for every patient ≥2 years on arrival at clinic, were used to identify children and adolescents (2-18 years) with overweight/obesity attending the department for any reason in January and February 2020. Those referred primarily for assessment and management of obesity were excluded from further analysis. The patient journey from referral to post-clinic correspondence was audited using a standardised data form and NICE QS127 to ascertain if overweight/obesity was identified by the clinician, whether this was communicated to the child/their carer and whether intervention was offered for this important medical condition. Overweight, obesity, severe obesity and morbid obesity were defined as per UK BMI chart cut-offs.

Results

There were 669 scheduled appointments in the General Paediatric Outpatient Department during the study period, 87.7%(n=587) of which were attended. The large majority (98% (n=466)) of the 475 children and adolescents who attended the department had a recorded height and weight. Their BMI growth charts were reviewed and 27.3%(n=127) were identified with overweight or obesity. Children and adolescents referred for reasons not primarily related to the assessment and management of obesity were identified (90.6% (n=115)) and this group was further analysed.

Demographic profile

The sex distribution was 41.7%(n=48) female and 58.3%(n=67) male. Their average age was 8.8 years (SD=4.18 years). Twenty-five percent (n=29) of children and adolescents were from socioeconomic areas described as disadvantaged/very disadvantaged while 20%(n=23) were from affluent/very affluent areas⁷.

Referral letter

Three quarters (75.7%(n=87)) of children and adolescents were referred by their GP and 10.4%(n=12) were referred from the Emergency Department. Height and weight and/or BMI were communicated in only 13.9%(n=16) of referral letters.

Growth measurement

UK BMI charts identified 47%(n=54) of children and adolescents with overweight, 40%(n=46) with obesity, 11.3%(n=13) with severe obesity and 1.7%(n=2) with morbid obesity⁸.

Clinical encounter

A record of discussing growth with patients/their carers was observed for 15.7%(n=18). This discussion was initiated with 1.9%(n=1/54) of children and adolescents identified with overweight, 23.9%(n=11/46) with obesity and 46.2%(n=6/13) with severe obesity. Permission to discuss growth was not documented in any cases.

Outcome of growth-related discussion (n=18)

One third (33.3%(n=6)) were provided with general lifestyle advice only. Four (22.2%) children/adolescents were referred to the national Tier 3 hospital-based weight management service, while a further 11.1%(n=2) were already attending/waiting to be seen. One adolescent (5.6%) >16 years did not meet referral criteria- they were provided with lifestyle advice and their GP was asked to refer to local services. The following additional referrals were made; 11.1%(n=2) referred to psychology, 5.6%(n=1) referred to hospital dietician, 5.6%(n=1) referred for Prader-Willi testing. One growth related discussion (5.6%) was in the context of medication with weight-gain as a side-effect and a decision was made to continue with it.

Post-clinic correspondence

In the post-clinic correspondence to the primary care physician (n=111), height and weight and/or BMI were communicated in 56.8% (n=63) of letters.

Discussion

The percentage of children attending our department with overweight/obesity is higher than those seen in the general populational (overweight 47% vs. 19%; obesity 40% vs 9% and severe obesity 11.3% vs. 1.8%)⁹. Whilst growth measurement occurred systematically and BMI centile charts were generated electronically, the findings were rarely shared with children and adolescents/their carer and only included in the post-clinic letter to the General Practitioner in approximately half of the cases. Further research is required to ascertain whether barriers exist to the discussion of growth with presenting families, how the decision to include or omit a growth discussion is documented and how communication with primary care might be enhanced.

Additional education of healthcare providers is necessary to develop standardised procedures around the processes for referral, clinical encounter and post-clinic actions related to child growth. With overweight/obesity affecting one fifth of primary school children and one quarter of adolescents in Ireland, it is essential that we initiate and document growth related discussions and that our assessment and management of these children and adolescents is aligned with best practice. This will help us meet the significant health needs of this vulnerable population.

Declaration of Conflicts of Interest:

The authors declare that there is no conflict of interest.

Corresponding Author:

Jessica McGirr
Department of General Paediatrics,
Children's Health Ireland at Temple Street,
Dublin 1, Ireland.

E-Mail: jessicamcgirr6@gmail.com

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Crisis Presentations of Children and Adolescents with Neurodevelopmental Disorders

C.S Orji¹, L. Sharkey²

- 1. Mental Health Intellectual Disability Team Linn Dara CAMHS services.
- 2. HSE Community Healthcare East Mental Health services.

Abstract

Aim

To inform the development of a care pathway for children and adolescents with neurodevelopmental disorders presenting to Children's Health Ireland (CHI) at Tallaght Emergency Department.

Methods

A retrospective study of cases with a neurodevelopmental disorder diagnosis (Autism Spectrum Disorder and/or Mild to Profound Intellectual Disability) presenting to the hospital Child Psychiatry services over a six-year period (Jan 2014 – December 2019).

Results

72 patients identified, Autism Spectrum Disorder diagnosis most common (N=67, 93%). Nearly half of cases presenting with risk concerns (N= 35, 49%), same day hospital discharge (N = 53, 74%) and inpatient admission (N=19, 29%).

Discussion

Access to relevant community disability supports is significantly limited in Ireland with a resultant increase in carer stress and crisis presentations to the emergency department for psychosocial and disability related reasons.

Introduction

The limited availability of disability specific supports in the community for children and adolescents with neurodevelopmental disorders and their families remains a maintaining factor to behaviours that challenge, carer stress and crisis presentations to emergency services. Children with neurodevelopmental disorders may struggle even further in an emergency department setting as there are often potential sensory distress triggers in an acute clinical environment. Hospital admission can be challenging given the finite environmental supports available for these children and adolescents in such inpatient settings.

Methods

Cases with an Autism spectrum disorder and/or Mild – Profound Intellectual disability (ID) diagnosis presenting to the hospital Child Psychiatry services over a six-year period (Jan 2014 – December 2019) were examined.

Results

Seventy - two (72) cases were identified and analysed.

Age	Range 6 - 16 years					
	Mean 14 years					
Gender	Males 47 (65%)					
	Females 25 (35%)					
Diagnosis	Autism (with or without ID) 67 (93%).					
	Mild ID 4 (31%)					
	Moderate ID 8 (62%)					
	Severe ID 1 (7%)					
Presenting concern	Self-harm/self- injurious behaviours 35 (49%)					
	Aggression 17 (24%)					
Follow up	Generic CAMHS 53(74%)					
	Mental Health ID service 10 (14%)					
	Residential care 2(3%)					
	Psychiatric Inpatient Unit 1 (1%)					
	GP 6 (8%)					
Length of Hospital stay	Same day discharge 53 (74%)					
	Inpatient admission 19 (26%)					
Repeat Presentation	7 (8%)					

An average of two to three day hospital admission. Majority of patients were admitted out of hours to facilitate next day assessment by child psychiatry services. One case presented to the emergency department nine times between July 2018 – March 2019 for carer stress and burn out.

Discussion

A systematic literature review was undertaken to ascertain the prevalence of self-harm and suicidal behaviour in children and young people under 18 years old with a diagnosis of autism spectrum disorder (ASD) with or without an intellectual disability. There was variation in the reported prevalence rates, but results suggested that rates of both self-harm and suicidal behaviour may be elevated in ASD compared to the general population.¹

Challenging risk behaviours among children and adolescents with Autism spectrum disorder may stem from diverse risk factors including environmental problems, comorbid acute psychiatric conditions or somatic illness such as epilepsy or acute pain². A paediatric medical assessment to confirm or exclude an organic cause should be completed as indicated. Children with neurodevelopmental disorders are at an increased risk of developing mental illness and a comprehensive psychiatric assessment and management of identified mental health disorders will improve overall functioning and quality of life. Risk behaviours in this population may be triggered or maintained by environmental, social and sensory factors particularly in those children and adolescents functioning in the moderate to profound degree. In a study of seven risk factors associated with self - injurious behaviours in children and adolescents with autism spectrum disorder, abnormal sensory processing was the strongest single predictor of self-injury followed by sameness, impaired cognitive ability and social functioning³. Social skills deficits associated with an Autism spectrum disorder diagnosis may contribute to challenging behaviours particularly in adolescence. Parents of children with intellectual disability, especially where there is a diagnosis of comorbid autism spectrum disorder and challenging behaviour experience increased psychological distress and lower quality of life⁴.

Because children with neurodevelopmental disorders have complex needs, a holistic approach to diagnosis and intervention is highly warranted including in the assessment and treatment of behavioural and emotional disorders⁵. The management of behavioural challenges in this population requires unified multidisciplinary input involving relevant paediatric medical, child psychiatry and community disability services.

There were a number of repeat presentations to the emergency department for disability related reasons as children and adolescents remain on waitlists for intervention over several years. There were nine social admissions to the CHI at Tallaght paediatric inpatient unit in 2019 and some families refused hospital discharge until residential care, respite care or home support was provided. Access to disability supports is limited in Ireland with a consequent increase in carer stress and crisis presentation to the emergency services for respite and care supports. Hospital services commit to organising interagency meetings with disability service management and social work services to advocate for families and to enable hospital discharge.

A working group set-up in Children's Health Ireland at Tallaght is organising a care pathway for children and adolescents with neurodevelopmental disorders presenting to the emergency department. This pathway is informed by best practise guidelines and will seek collaboration from community disability services in management planning particularly for those children and their families presenting for psychosocial and disability related reasons.

Declaration of Conflicts of Interest:

I declare there are no conflicts of interests with this publication.

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Paediatric Emergency Department Children's Health Ireland at Tallaght.

Corresponding Author:

Chizoba Susana Orji
Community Mental Health Intellectual Disability services - Buttercup suite
Linn Dara Outpatient Building
Cherryorchard Campus
Ballyfermot Dublin 10
E-Mail: Susana.orji@hse.ie

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Whispering Tuberculosis

D. ALNafisee, A. Farrell, C. O'Donnell, H. McLoughlin

Portiuncula University Hospital, Ballinasloe.

Abstract

Presentation

We describe a case of reactivation of latent pulmonary tuberculosis (TB) invading the larynx and causing dysphonia.

Diagnosis

A previously healthy 30-year old woman was found to have bilateral pulmonary TB 5-months after being thoroughly investigated for hoarseness. Initial chest x-ray (CXR) and CT-neck were normal. Vocal cord biopsies were negative for granulomata.

Treatment

The patient was commenced on standard four drug Anti-TB treatment (ATT) and completed a one-year course. Unfortunately, the development of a laryngeal web caused persistent dysphonia.

Discussion

Patients with laryngeal TB are more likely to present to ENT surgeons, because of the initial symptom of hoarseness. Multiple tests must be completed before out-ruling TB. HRCT or sputum culture is recommended, as TB may not be evident on initial CXR. A collaborative approach between Respiratory and ENT teams is required. Prompt diagnosis is essential. Speech therapy input will be important in our patient's recovery.

Introduction

Laryngeal tuberculosis (LTB) is a rare and highly infectious disease¹. LTB can develop by direct spread of bacilli in bronchial secretions or haematogenous spread from a distant primary focus ¹. We describe a case of LTB that was labelled as idiopathic laryngitis, leading to a delayed diagnosis of TB.

Case Report

A 30-year old Asian woman presented with a 3-week history of a dry cough, low-grade fever and shortness of breath on exertion, on a background of only 5-month history of hoarseness.

She had been investigated by an ENT surgeon regarding this hoarseness that later progressed to dysphonia. At the time of ENT review, CXR and CT-neck revealed no abnormalities. Routine bloods and an autoimmune screen including-ANA, ANCA, anti-ENA, C3/C4, were normal. Nasopharyngolaryngoscopy (NPL) exams, showed congestion and later large amounts of tenacious material clinging to the vocal cords. Two vocal cord biopsies were undertaken showing non-specific inflammation. No granulomas were identified. Sputum was not sent for TB culture. She was initially treated for suspected laryngopharyngeal reflux and then Co-Amoxiclav (625mg TDS X 7/7) and Prednisolone (5mg OD x 5/7) were prescribed for Bacterial laryngitis.

The patient was a non-smoker with no significant past medical history. Bilateral wheeze and reduced air entry were noted on auscultation. Second CXR 4-months later, revealed hyperinflation and extensive bilateral pulmonary nodular densities most prominent in the left peri-hilar region. Admission bloods showed — white blood cell count of 8 with low lymphocyte count of 0.8 and CRP of 32.6. Renal and liver function tests were normal. She denied night sweats or weight loss despite having low BMI 18. There was no recent travel history. BCG scar was present. TB screening, for work purposes, two years earlier had been negative (CXR). HIV and Hepatitis screening was negative. High resolution computed tomography (HRCT) of the thorax demonstrated alveolar infiltrates suggestive of pulmonary TB.

Prior to starting ATT, bronchoscopy revealed white plaques on the larynx and the right main bronchus. Bronchoalveolar lavage (BAL) was positive for Acid-fast Bacilli. A fully sensitive Mycobacterium tuberculosis was isolated. The public health team was informed. She continued to be followed-up in the Respiratory and ENT clinics, as she had by then developed an anterior glottic web (AGW) that led to aphonia. The patient has completed a one-year course of ATT, two months of ethambutol and pyrazinamide and 12 months of rifampicin and isoniazid. She has had slow recovery of her voice after one year of anti TB treatment.



Figure 1: HRCT Thorax 5-months after initial presentation of hoarseness-Multiple nodules predominantly in the subpleural mid zones, mediastinal lymph nodes, several of the nodules had adjacent tree-in-bud type opacification.



Figure 2: Anterior glottic web and right vocal cord TB deposit.

Discussion

Laryngeal TB is the most common granulomatous disease of the larynx and represents less than 2% of extra-pulmonary TB cases¹. Among the risk factors identified are smoking, immunosuppression, immigration from high-risk areas and multi-drug resistant organisms^{2,3}. The pattern of presentation has changed in recent years. Previously patients described odynophagia, weight loss and night sweats, but the most common complaint more recently is hoarseness. The nonspecific nature of presenting complaints and low incidence of LTB may lead to delayed diagnosis.⁵

Management involves ATT from 6-months to 1 year, longer in duration compared with pulmonary TB ¹. On average it takes 18-weeks for the larynx to return to its normal appearance ⁴. Voice outcomes improve after ATT, but in a minority of patients vocal cord immobility is a permanent complication secondary to fibrosis and adhesions⁴. Two months after initiating ATT, the patient reported no improvement in aphonia. NPL exam showed an AGW, more common in patients with delayed treatment. Surgical intervention is not recommended until a patient completes 12 months treatment. She has minimal voice recovery 10-months post ATT and attends Speech and language therapy.

Patients with laryngeal TB are more likely to present to ENT surgeons because of the initial symptom of hoarseness, therefore multiple TB tests should be completed before diagnosing Idiopathic laryngitis. HRCT Thorax and sputum culture is recommended as part of the ENT workup. Multi-disciplinary management between ENT surgeons, respiratory physicians and speech and language therapists is essential once a diagnosis has been made to ensure the best outcome for the patient.

Declaration of Conflicts of Interest:

The authors have no conflict of interests to declare.

Corresponding Author:

Dr Hilary McLoughlin Respiratory Department, Portiuncula University Hospital, Ballinasloe,

Co. Galway.

E-Mail: Hilary.McLoughlin@hse.ie

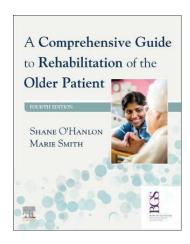
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Book Review by O. Hannigan

A Comprehensive Guide to Rehabilitation of the Older Patient, Fourth Edition By Shane O'Hanlon and Marie Smith

Rehabilitation is one of the foundational cornerstones of medicine for the older person, and it is a complex process requiring input from multiple healthcare professionals with expertise in various disciplines. The fourth edition of a what was previously a textbook largely dedicated to physical therapy has undergone an overhaul itself under the stewardship of Dr Shane O'Hanlon, a consultant Geriatrician in St. Vincent's and St. Columcille's Hospital, and Marie Smith, a Nursing Quality Manager from the Royal College of Surgeons in Ireland. A hugely collaborative approach was taken to all aspects of this book.



The chapter titles were crowd sourced through the British Geriatrics Society website, and chapter authors represent a huge cross spectrum of medical specialities, with a significant international presence, with Ireland very well represented. Medicine, nursing, physiotherapy, occupational therapy, speech and language therapy and social work are all represented, aligning with the core principles of the multi-disciplinary approach to rehabilitation espoused in the book. The end result is a fantastic, modern, truly comprehensive guide to an area which even since the last edition of this book in 2014 has changed and advanced significantly.

The book is structured in such a way as to allow it to be easily read from start to finish, or to read singular chapters without having to reference heavily from what comes before and after. The book is divided into six distinct units, with thematically linked chapters. The first unit covers the basics of rehabilitation in the elderly, and the core concepts underpinning it, such as frailty and the comprehensive geriatric assessment. The units then mirror the patients journey through the rehabilitation process. The next two units introduces the multidisciplinary team and their role in the rehabilitation process, with each chapter written by a relevant expert from each speciality.

The fourth unit progresses onto specific issues encountered during the rehab process and their relevant treatments. Common issues such as falls, pain and cognition are covered, but also covered are less often considered but still extremely important topics such as sexuality, oral health and sleep and fatigue.

The fifth unit covers specialty and organ specific rehab processes, like stroke and cardiac rehab, whiles the final unit covers the discharge process. Each individual chapter then has a uniform structure; they begin with a case study, then talk through the individual theme of the chapter in a progressive manner, with intermittent references to the case study, and finish with a summary of the key findings, often with a resolution of the case from the beginning, and some mcqs related to the chapter content. This structure allows chapters to be skimmed as needed, or else studied more closely as is needed. Each chapter references up to date material, so all of the chapters provide best practice evidence-based medicine, but in language that is easily understood and accessible.

To give an example of the type of content covered in the book in the chapter dedicated to trauma in the older person, we are given an example of an 83 year old woman who has fallen down 10 flights of stairs and has suffered many major traumatic injuries including but not limited to rib fractures, a pneumothorax, a liver laceration and a subdural haematoma . We are then brought back to the basic principles of trauma in the older person, the idea of the Injury Severity Score (ISS) and its use in quantifying injuries and their outcomes. Management of trauma is then covered, with multiple easy to follow diagrams and illustrations providing context and statistics. In this chapter rib fractures, pneumothorax and pulmonary contusions are covered, and how we rehabilitate the patient from these. We then revert back to our case, where we find our patient has needed a huge amount of input from multiple services, including a chest drain in the emergency department, an epidural from anaesthetics, and non-surgical management of her fractures, but careful multi-disciplinary input, allowing her to progress from transferring to a chair on her second day on the ward leads to her being discharged ten days after admission with supportive therapy from a community based physiotherapist.

The book is an extremely modern and up to the minute take on the rehabilitation process, with each chapter written by an expert from across the medical spectrum. The collaborative nature of the book allows all facets of rehabilitation, from the basics like setting treatment goals to extremely detailed and illness specific treatment. This book is as at home on the shelf of a physiotherapist as it is a geriatrician. Aside from the people providing rehab, this book is also extremely relevant and recommended reading for the most important people, the patients themselves. This book is a must have for anyone working with older persons, and even for those engaging in rehab themselves.

Corresponding Author:

Dr Oisín Hannigan
Specialist Registrar in Medicine for the Elderly and Stroke Medicine,
St. Vincent's University Hospital.
E-Mail: hannigao@tcd.ie



Heart Rate Variability-Guided Exercise During Chemotherapy in Triathlete with Stage 1 BRCA1-Mutated Breast Cancer

A. Talbot¹, M. McCabe², B. Daly², D. Gallagher^{3,4}

- 1. Royal College of Surgeons in Ireland, Dublin.
- 2. Sports Med Ireland, 32 Kildare St, Dublin.
- 3. Mater Private Hospital, Eccles Street, Dublin.
- 4. St. James' Hospital, James' Street, Dublin.

Dear Editor,

Heart rate variability (HRV) is a measurement of the difference in the time interval between each heartbeat. HRV during chemotherapy has been used to help to provide individualised exercise guidance for patients. There are no current guidelines for exercise during chemotherapy for cancer patients in Ireland.

A forty-four-year-old nulliparous female triathlete with a sixteen-pack year history of smoking presented to her GP with night sweats and a right breast lump. Wide local excision (WLE) revealed a grade 3 13.5mm triple negative invasive BRCA1 mutated ductal carcinoma. Sentinel lymph node biopsy confirmed pT1cN0M0 disease. As a competitive triathlete the patient's cardiopulmonary fitness was optimal at baseline involving between one- and four-hours aerobic or strength training per day with one day rest per week. Prior to her diagnosis, HRV measurements were used to optimise training. Throughout treatment, training regimes were altered based on HRV to allow continued training without excessive cardiovascular strain. Exercise during treatment involved between thirty minutes to two hours of physical activity per day. HRV was monitored using a HR monitoring device connected to a smart phone application.² Each morning, baseline HR and HRV were recorded over one minute. The root mean square of successive differences (RMSSD) between each heartbeat was used to measure HRV. Reduction in HRV below one standard deviation from baseline HRV of the previous two days was used as an indicator of reduced capacity for intense exercise.² The lowest daily HRV recorded was 63.5ms on cycle two day nine of AC chemotherapy. HRV ranged from 63.5ms to 101.8ms during chemotherapy. A meaningful reduction in HRV occurred during both AC and Taxol chemotherapy as compared with daily average HRV at baseline and one year after chemotherapy.

Knowledge of these alterations allowed for adaptation of exercise regimes to avoid excessive cardiopulmonary strain. One year later following completion of chemotherapy with minimal side effects the patient qualified for an international triathlon consisting of a 3.86km swim, 180.25km cycle and 42.2 km run.

Adjuvant chemotherapy involved four cycles of AC (doxorubicin, cyclophosphamide) and ten cycles of paclitaxel chemotherapy. The first cycle of paclitaxel was omitted due to neutropenia (absolute neutrophil count 0.7 x10⁹/L). Four AC cycles and nine cycles of paclitaxel were subsequently well tolerated. Side effects experienced by the patient included 4lb weight loss, alopecia and fatigue. Fatigue improved with light aerobic exercise. Six weeks following completion of chemotherapy the patient underwent a bilateral mastectomy and bilateral oophorectomy due to familial risk of recurrence. Transabdominal oophorectomy was avoided due to risk of damage to abdominal musculature and impact to future training.

Exercise is an underutilised method of maintaining physical strength and alleviating fatigue during and after cancer treatment. There is often a negligible difference in expectation for physical exercise between all patients undergoing chemotherapy. Despite being an international triathlete, this patient was given the same exercise recommendations as patient with cancer. A study completed by Irish oncology nurses identified the main barrier to exercise as lack of specific guidelines.³ The Clinical Oncology Society of Australia (COSA) and American Cancer Society recommend 150 minutes of aerobic exercise per week with two resistance sessions incorporated.⁴ Tailored exercise regimens based on HRV and baseline fitness should be considered with a view to ultimately formulating evidence-based exercise guidelines for patients in Ireland.

Corresponding Author:

Alice Talbot Royal College of Surgeons in Ireland, Dublin.

E-Mail: alicetalbot@rcsi.ie

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Knowledge of Safe Opiate Storage and Disposal in Urology Patients

C. J. O'Connor¹, N. Murray¹, H. Richards², D.B. Hennessey¹

- 1. Department of Urology, Mercy University Hospital, Cork.
- 2. Department of Clinical Psychology, Mercy University Hospital, Cork.

To the editor,

Worldwide, there is increasing rates of opiate misuse, morbidity, and mortality reported. This increase is due in part to the over-prescription of opiate medication for post-operative pain, which is related to a pain management style, that aims to manage pain pre-emptively and maximise patient satisfaction. ^{1,2} The overconsumption and abuse of opiate medication poses notable public health and socioeconomic burdens. In our hospital we recently performed a study to examine post-operative opiate use, storage and disposal in patients who underwent urological surgery. Primary outcomes were the completion of opiate prescriptions and continued opiate use. Secondary outcomes were the safe storage and disposal of unused opiate medication.

All patients > 18 years age and who were scheduled for major or intermediate urology surgery were included in the study. Patients less than 18 years of age, patients with psychiatric conditions or chronic pain were excluded from the study. No inducements to participate were offered. Post discharge, patients were contacted by telephone and were asked if they had completed their opiate prescription, if they were still taking opiates. If they had unused opiates, was their opiate mediation at home and if so, how was it stored (locked or unlocked); and finally did the patient have knowledge of safe opiate disposal. Opiate keeping was defined as having opiate medications at home for six weeks or more. Safe disposal of opiate medications was defined as bringing the medication back to a pharmacy or flushing of the medication down a toilet.

The mean age of participants was 58 years. The majority of procedures, (80.5%) were endoscopic, open surgery (18.6%) and laparoscopy (0.9%). 39 (34.5%) patients were discharged on a five-day course of opiate medication. Six (15.3%) of patients discharged on opiate medication had sought another opiate prescription. Four patients identified pain-specific reasons relating to surgery, and 2 identified pre-existing medical conditions for seeking another prescription. Twenty-two patients (56.4%) did not finish their five-day course of opiates.

Seventeen (77%) of these patients reported that their unused opiate medication was at home, and of these, almost three quarters kept the medication in an unlocked location. Knowledge about safe drug disposal was available for all participants. Only 24 individuals (21.2%) indicated they knew how to dispose of their unused medication safely. There was no association between drug disposal knowledge and gender, type of surgery or being discharged on opiates. There were no differences between those who did and did not have accurate drug disposal knowledge and age.

This study, we believe, is the first of its kind in an Irish setting which examines both opiate use and safe disposal of opioid medication post urological surgery. Only a small number of patients in this study were still taking opiate medication six weeks post-operatively. However, many patients kept their opiate medication at home, unlocked, and knowledge of safe disposal practices was poor. Future efforts should be aimed at informing patients around safe disposal practices, limiting the amount of opiate medication prescribed, monitoring opiate prescribing, and using alternative pain regimens post-operatively.

Corresponding Author:

Dr Charles O'Connor
Department of Urology,
Mercy University Hospital,
Cork,
Ireland.

E-Mail: mrcharlesoconnor@gmail.com

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The Impact of Climate Change on Healthcare

N. Hussaini^{1,4}, L. Coughlan^{1,4}, D. Flynn^{2,4}, P. Miller^{2,4}, T.K. Daly^{3,4}, B. Crowley^{3,4}, A. Hussaini^{5,6}

- 1. School of Medicine, Trinity College Dublin, Dublin, Ireland.
- 2. School of Medicine, National University of Ireland, Galway, Galway, Ireland.
- 3. School of Medicine, University College Cork, Cork, Ireland.
- 4. Association of Medical Students, Ireland.
- 5. Lifeline Cardiology Clinic, Limerick, Ireland.
- 6. Mater Private Hospital, Cork, Ireland.

Dear Editor,

Climate change penetrates all levels of society. Recently, the dialogue of climate change has been growing in presence and shifting in ideas. In this letter we analyse the thoughts of medical students on climate change.

Climate change is no longer a hypothetical, distant or credibly deniable threat. The WHO estimates climate change will cause approximately two hundred and fifty thousand additional deaths per year between 2030 and 2050. Of these, thirty-eight thousand will be due to heat exposure in elderly people, forty-eight thousand due to diarrhoea, sixty thousand due to malaria, and ninety-five thousand due to childhood undernutrition ¹.

Anxiety is a growing complication of climate change. It has permeated all facets of society and will necessitate essential action for its dissolution. As future health care professionals we have a clear obligation to recognise this anxiety and to advocate on behalf of those most at risk. In particular, this abstract will focus on two key areas: the anxiety amongst those with potential environmental impacting illnesses, and the anxiety amongst those from less than favourable geography. Island and costal nations are some of those most at risk from this climate trajectory ². Unfortunately, we may be left with the destruction of homes, communities, and countries, and we will be catalyst for our eviction.

Healthcare waste management is an established challenge for many hospitals and healthcare systems. An increasing global reliance on single use plastics and equipment has produced many new issues in regard to the sustainability and environmental impact of the waste products disposal methods. On average, high-income countries generate up to 0.5 kg of hazardous waste per hospital bed per day ³. This perpetuates not only a moral obligation to reduce the waste produced but also a financial incentive.

The catastrophic effects of migration are evident worldwide. Adverse weather events have forced humans to migration, with number of people seeking asylum expected to increase by twenty-eight percent on the turn of the century ⁴. As we live through a time of viruses, famine and food shortages how can we most effectively protect those whose livelihoods are most subject to the mercy of the weather? With this increased number of refugees and migrants, employment, food supply, transport, medicine and energy supply as we know it must evolve to provide for these people

It is evident that measures must be taken to educate and support doctors in tackling this crisis and thus improving patient care. Doctors must take a leadership role in educating themselves and the general population on these issues as well as advocating for legislation and government support.

Corresponding Author:

Naayema Hussaini, School of Medicine, Trinity College Dublin, 152-160 Pearse Street, Dublin 2.

E-Mail: nahussai@tcd.ie

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Identifying Factors that Influence Patient's Trust in General Practitioners

F. Borhan¹, Z. Borhan², F. Borhan², N. Borhan³

- 1. Irish College of General Practitioners.
- 2. International School of Capital Medical University.
- 3. Royal College of Surgeons in Ireland.

Trust is fundamental for a positive patient-GP relationship. This prospective exploratory study aims to identify factors that influence patient's trust in General Practitioners (GPs). Empirical studies have determined that patient's trust in physician is associated with timely diagnosis¹, continuity of care, reduced referral rates, and patient's self-reported ability to manage their chronic disease.

A 6-month survey was conducted in an Irish urban practice, Scanlon Medical Centre, Tullamore, between February to July 2020, after permission from the GP Principal. The authors devised a paper questionnaire asking patients to score their trust in GPs based on 10 factors. Patients scored their trust using a 5-point Likert scale (1=No trust, 2=Slightly trust, 3=Neutral, 4=Mostly trust, 5=Completely trust).

Factors were chosen on the knowledge of the authors that were felt to influence trust. The 10 factors were, 1. (Behaviour) GP's behaviour towards the patient during consultation (being empathic, respectful, and attentive), 2. (Knowledge) GP's thorough knowledge of the patient's medical problems and provision of successful treatment, 3. (Communication) GP's communication about medical problems and treatment in a manner that the patient understands, 4. (Honesty) GP's honesty about the patient's medical condition or when an error may have occurred in relation to care, 5. (Staff) Good care provided by other staff in the GP's Practice (Nurses & Receptionists), 6. (Social) GP's good reputation portrayed by social circle of family and friends, 7. (Media) GP's good reputation portrayed by the media, 8. (Involvement) GP's involvement of the patient in decisions about care and treatment options, 9. (Accessibility) GP's accessibility (how easily and early a GP can be contacted), 10. (Video) Having a Video consultation with a GP (using Internet or mobile medical applications to connect with a GP). Patients routinely attending the practice voluntarily participated in the survey. Participants included registered patients of the practice who consented to the study and aged ≥ 18 years. Participant responses were collated using Microsoft Excel.

Our study included N=235 participants, 70 males and 165 females. Most participants aged under 65 years (65%, n=153/235). The mean duration of GP continuity of care in participants was 20 ± 10 years. As score 5 represents complete trust, for each factor we analysed the total number of participants who answered score '5=Completely trust'.

Of the 10 factors, 'communication' had the greatest number of participants who answered score '5=Completely trust' (85%, n=200/235). Thereafter, knowledge (79%, n=186/235), behaviour (74%, n=175/235), honesty (74%, n=175/235), staff (74%, n=175/235), involvement (73%, n=172/235), accessibility (68%, n=161/235), social (57%, n=133/235), media (48%, n=112/235), and video (30%, n=70/235).

Our study concludes that 'communication' had the greatest number of respondents for score '5=Completely trust'. This may suggest that the communication of the GP can lead to trust more readily than any of the factors in the questionnaire. A trusting doctor-patient relationship is facilitated by improved communication². An effective, empathic physician-patient communication leads to improved patient compliance, better clinical outcomes, and reduction in "doctor-shopping" and malpractice litigations³. The COVID-19 pandemic challenged Irish General Practice during the study period. In such times trust between patient-GP is even more crucial. Patient's trust in GPs is high⁴.

Ethical Approval:

This study was granted full Ethical approval by the Ethics Committee of the Irish College of General Practitioners.

Corresponding Author:

Dr. Fareeda Borhan, General Practitioner Irish College of General Practitioners.

E-Mail: fareedaborhan@rcsi.ie

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A Stroke Survivor on Writing in Lockdown

M. Quinn

Irish National Audit of Stroke Governance Committee.

Dear Sirs,

As we tentatively take our first steps out of lockdown it is appropriate to consider how we best used the great amount of free time that the pandemic and subsequent restrictions allowed for. In my case I took up something that I had always enjoyed doing, and that was writing. I suppose you could say that writing was in my DNA and whether it was taking minutes, compiling various types of reports or writing citations or indeed newspaper notes, it was something that I generally enjoyed and was considered to be good at. There are however many turns and twists along the road of life and often we have no control over where life will take us.

In 2013, I suffered a stroke which had a profound impact on my speech and my cognitive function. I can clearly recall the absolute terror of that moment, of trying to speak while doing an interview on local radio, and of no words coming out of my mouth. It is something that I am reminded of every time I do a radio interview. Apart from my speech my cognitive function was badly affected and considering my background in writing I found this to be extremely challenging. In the months and years after the stroke I challenged myself time and time again to regain my ability to write with the same fluency as I had before. The pandemic gave me a unique opportunity to work on my writing and I did this in writing some articles for my local newspaper before coming up with the idea of writing a book. I knew that this would involve a lot of research and would challenge me greatly in relation to my cognitive ability, but it was something that I felt that was within my grasp and would be a great achievement.

Being a lover of local history, I came to the idea of recognising Tipperary people from history who were noteworthy for various different reasons. I found that the more I looked the more I discovered, and I eventually stopped at 86. The research and compilation on each person was quite a challenge and there were days when I would start my writing and would have to discontinue as my brain would shut down or I would experience 'brain fog' or I would be completely fatigued. Anyone that has suffered a stroke will know exactly what I mean by this and will know how challenging it is for stroke survivors. It was important for me not to over task the brain and to allow time for rest and recuperation after long periods of research.

Suffering a stroke changed my life completely and presented me with many challenges to overcome but the challenge of writing and having a book published was nevertheless something that I relished undertaking.

Most people will not recognise or understand the level of the challenge of cognitive impairment because it is not something visual to people but dealing with impaired cognitive function following a stroke is tremendously difficult. Many people have used lockdown to do very different things. In my case it was to compile a book titled 'Tipperary People of Great Note', and to have it published by Orpen Press, but it was also to keep my brain active and in doing so to stay mentally well. Your brain is similar to a muscle, you need to use it, or you lose it so it was crucially important for me to keep my brain in shape.

I hope that all stroke survivors will take confidence from my achievement and will know that there is still so much that can be accomplished in life after stroke.

Corresponding Author:

Martin Quinn

Member of the Irish National Audit of Stroke Governance Committee/ Author of the book 'Tipperary People of Great Note'.

E-Mail: martinquinns@eircom.net



Lessons Learned from COVID-19: Intern Peer Teaching During a Pandemic

L.F. Kiely^{1,4}, M.J. Hannon^{3,4}, I. O'Sullivan^{2,5}

- 1. Department of Dermatology, South Infirmary Victoria University Hospital, Ireland.
- 2. Department of Emergency Medicine, Cork University Hospital, Ireland.
- 3. Department of Endocrinology, Bantry General Hospital, Bantry, Co. Cork, Ireland.
- 4. University College Cork, Cork, Ireland.
- 5. Postgraduate Medical Education Service, Cork University Hospital, Ireland.

Dear Editor,

The potential for the COVID-19 pandemic to overwhelm the Irish healthcare system necessitated an increase in the number of frontline healthcare workers. This included the early recruitment of over 1000 interns six weeks in advance of their predicted start date. This 2-tier intern system created a unique opportunity for established interns to pass on wisdom to their novice counterparts.

Peer-teaching fosters an approachable environment and benefits tutors by consolidating knowledge and provides valuable teaching skills.^{2,3}

We sought to establish intern peer-led teaching as a means to educate and alleviate the anxiety of new doctors beginning their career amidst a global pandemic.

Newly recruited interns were invited to complete anonymised surveys regarding their confidence and level of preparedness relating to on-call duties, and their perceived areas of strengths and weaknesses. Nine 15-minute intern peer-led tutorials were organised focusing on common IOC duties including management of chest pain, fever, falls, electrolyte abnormalities and delirium. Confidence levels were reassessed subsequent to the tutorials with follow-up questionnaires. Peer-tutors were surveyed on whether the experience increased their knowledge of the subject matter.

Of the 60 interns invited to attend the tutorials, 39 completed the survey (65% response rate). Twenty-nine (74.4%) felt 'somewhat confident' beginning IOC duties, ten (25.6%) were 'not confident' with no students (0%) 'very confident'. The duties interns felt least prepared for were pharmacology (71.8%; 28/39), medical emergencies (66.7% 26/39), ECG interpretation 64.1% (25/39) and triaging multiple calls (51.3%; 20/39).

Thirty-two (82.1%) felt most prepared for procedures (venesection, cannulation, catheterisation), with fifteen (38.5%) comfortable with patient review. Overall, thirty-nine (100%) respondents found peer-led teaching beneficial.

A follow-up survey was performed with twenty-five respondents (42% response rate). Twenty-five (100%) believed the talks increased their confidence for IOC shifts. Twenty-four (96%) felt confident they would be able to call for help. Twenty-five (100%) respondents would recommend similar sessions in the future.

Five (55.6%) peer tutors had no prior teaching experience; six (66.6%) felt the tutorial improved their own knowledge of the topic. Nine (100%) said they would do it again.

Due to the unprecedented COVID-19 pandemic, medical students were recruited six weeks earlier than their counterparts in years gone by. IOC duties are daunting for any newly qualified doctor but much more so amidst a global healthcare crisis. Ten (25.6%) students were 'not confident' with no students (0%) claiming to be very confident.

Thirty-two (82%) of our interns felt most prepared for procedural skills which we speculate is as a result of starting their post earlier and with increased peer supervision.

Peer and near-peer teaching have been shown to be an effective pedagogical method as students find the information more relevant² in addition to creating a more approachable environment.

Peer teachers gain the opportunity to increase personal knowledge and acquire teaching experience.⁴ Six (66.6%) tutors felt the process improved their knowledge of the topic and 100% would opt to get involved again.

We believe this can set a precedent and improve the educational experience of new doctors by providing them with pertinent information prior to starting 'on-call' duties.

Corresponding Author:

Lisa F. Kiely
Department of Dermatology,
South Infirmary Victoria University Hospital,
Ireland.

E-Mail: lkiely@gmail.com

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Increased number of medical interns to be recruited earlier to support effort against COVID-19

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Knowledge is Power – Surveying Patients' Understanding During HSE IT Shutdown

E. Pender, B. Coffey, K.M. Idris, J. Hynes, M.E. Laing

Department of Dermatology, Galway University Hospitals.

Dear Editor,

The shutdown of HSE IT systems in response to a ransomware attack brought our dependence on the electronic health record and online resources into sharp focus.

When faced with outpatient department (OPD) cancellations, our department contacted patients scheduled for review where a contact number could be obtained, to ascertain whether patients scheduled for OPD needed urgent review (before IT services could be expected to be restored).

Our hospital uses a "paper-light" system, in which most patients have had their paper records digitised and stored on an Electronic Health Record accessible throughout the hospital. As such, we did not have access to historic notes, correspondence, referral letters or investigations. We relied on patients to inform us of their reason for attending the dermatology OPD (in a tertiary referral centre), their diagnosis and current treatment. We took the opportunity to survey our patients' understanding of their reason for attending OPD and their subsequent diagnosis and treatment.

Research has demonstrated that healthcare professionals' understanding of their patients' health beliefs differs from the patients' actual beliefs¹. Nineteen patients across two scheduled OPDs were contacted by phone in a two-day period. Patients were consented to take part in a survey regarding understanding of their condition. Sixteen patients (84%) were aware of reason for referral to OPD. With regards their subsequent diagnosis, four patients (21%) were awaiting results of investigations before a diagnosis was confirmed. Of the remaining patients, nine (60%) were unaware of their diagnosis. Regarding treatment, five (26%) of the patients were not currently being treated. Nine (64%) were aware of their treatment – medication name and frequency, though not always aware of doses. Five (36%) were unable to name the treatment prescribed for them.

Communication between healthcare professionals and patients is complex. A healthcare professional may leave an encounter with the impression that a diagnosis and treatment plan have been clearly explained. However, studies have revealed that patients often do not agree, and may not understand the plan going forward. This in turn affects outcomes, including adherence to treatment, recovery and future relationships with healthcare providers².

Patient-held health records have been extensively studied but are not commonly employed in the Irish system – one notable exception being antenatal joint-care. Studies have shown that patient-held records can be of practical and psychological benefit to patients – giving patients an accessible record and empowering them to participate in discussions and decisions³. Patient-held records (used in conjunction with the current system of hospital-held records) would not only prove useful during an IT shutdown, but in situations where records created elsewhere are not accessible, by acting a point of reference for coordination of patient care - particularly given the fact that patients with complex health issues may be cared for in multiple hospitals, which in Ireland do not share a single electronic record.

This ransomware attack has highlighted wider issues in our healthcare system. Lessons need to be learned and acted upon going forward, notably the importance of effective communication, and of patient centred care.

Corresponding Author:

E. Pender
Department of Dermatology
Galway University Hospitals
Newcastle Rd.
Galway.

E-Mail: emily.pender@ucdconnect.ie

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Anxiety and Depression Scores Amongst NCHDs During the SARS-CoV-2 Pandemic

E. Brennan, S. O'Meara, B. Hayes

Occupational Health Department, Beaumont University Hospital.

Dear Sir,

I was one of many healthcare staff across Ireland reallocated to a different role during the first wave of the Covid-19 pandemic in 2020. For 3 months of my medical internship year, I worked within the Occupational Health Department and through this witnessed the enormous psychological impact the pandemic placed on healthcare staff. Pre-existing stressors within our health system were exacerbated such as understaffing due to sick leave and increasing numbers of critically unwell patients with the addition of new workplace stressors including feelings of inadequacy performing new tasks or new roles, lack of adequate breaks from personal protective equipment (PPE) and a fear of infecting loved ones.¹

Through an anonymous online survey distributed to Non Consultant Hospital doctors (NCHDS) within an Irish tertiary centre, we aimed to assess the prevalence of anxiety and depression during the first wave of the covid-19 pandemic amongst NCHDs and therefore highlight a need for further action and psychological support for NCHDS post-pandemic. The survey was a 20-item questionnaire which included the Hospital anxiety and depression (HADS) score, A self-reported health question and the work-ability index score. Sociodemographic data was also collected including gender, level of training and marital status.

A total of 82 NCHDS responded to the survey with interns making up the majority of the respondents at 72% and also included 5% SHOs and 22% registrars making up the total. The median HADS score was 12.5 (range 4-27) with the highest level being in registrars at 15.5. The median anxiety score for the whole group was 8, which is determined to be mild anxiety. The overall median depression score was 5 which does not meet the criteria for depression. The majority of those surveyed described their general health as very good (n=33%,40%). Only one NCHD (1.2%) described their general health as poor and only 4 (4.9%) as fair. Overall, the median workability score was 6 (range 3-10) with the lowest scores being seen in females with a median of 6 compared to 7 in males.

This small study highlights the psychological impact of the pandemic on NCHDs during the first wave of Covid-19 in early 2020 and similar results have been reflected worldwide in various studies amongst doctors ³. It has been recognized that global pandemics such as SARS-COV2 can have long lasting psychological impacts. In a study of long-term psychological side effects from Canadian frontline staff who worked during the 2003 SARS Pandemic, Data showed that 29-35% of these hospital workers experienced a high degree of post event stress and trauma.³

As we progress through the vaccine roll out and as inpatient case numbers fluctuate, it is essential to avoid burnout and low morale amongst medical staff ⁴. Many of the current stressors within the system will only be exacerbated as we struggle to catch up with long waiting lists and delayed investigations thus it is essential that institutions put in place tangible measures to support workers psychological wellbeing during these extraordinary times.

Corresponding Author:

Dr Elysha Brennan
Occupational Health Department,
Beaumont University Hospital.
E-Mail: Elyshabrennan@rcsi.ie

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