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The Difficulty Improving Type 1 Diabetes Outcomes at a Population Level

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Abstract

Aims

The goal of this research was to first audit the clinical data of adult patients with type 1 diabetes mellitus (T1DM) managed by the Endocrinology department at an Irish Hospital. This data was then compared with a similar study carried out 6 years previously. This would then help determine if, owing to improvements in technology, education or guidelines, overall patient outcomes have improved.

Methods

A retrospective cross-sectional analysis of patients' clinical data was performed, determining the mean values and proportion of patients meeting recommended goals. Independent T-tests were used to compare these mean values to those of the previous audit.

Results

The total number of adult patients managed at the centre increased from 797 in 2013 to 1501 in 2019. The mean age was similar, 42.9 ± 14.9 in 2019 compared to 40.3 ± 14.8 in 2013. There was slight improvement in the mean HbA1c from 69.4 to 68mmol/mol with a p-value <.05. There was no notable change in lipid profile values and mean blood pressure readings saw a slight increase. The results were also consistent with an audit carried out in all T1DM patients in Scotland in 2017.

Conclusion

Despite continuing research and innovation, it can be difficult to improve clinical outcomes in T1DM at a population level.

Introduction

Type 1 Diabetes(T1D) is an autoimmune disorder associated with many complications, that can lead to a lower quality of life as well as early mortality. Complications are divided into short term, such as diabetic ketoacidosis and hypoglycaemia, and long-term. Long term complications are often defined as either microvascular or macrovascular. Microvascular complications include diabetic nephropathy, retinopathy and neuropathy while macrovascular complications include strokes and cardiovascular disease (CVD) [1]. However, with intensive management, these complications can be prevented, thereby improving long term outcomes and reducing mortality [2, 3].

In order to provide a standard for treatment goals, the American Diabetes Association (ADA) has released recommendations for clinical values relating to diabetes [4], which can be seen in table 1. These factors, if improved, reduce the risk of certain complications. The factors primarily relating to macrovascular complications are lipid profile values, blood pressure and body mass index (BMI). The target used for glycaemic control is glycated Haemoglobin (HbA1c), which directly correlates with microvascular complications.

With the incidence of T1D increasing throughout Europe each year [5], there is a need to regularly audit patient populations. The ADA guidelines provide a standard to compare to, quantifying the average standard of care for patients. Previously, in 2013, an audit was done on patients with T1D, who attended the Centre for Diabetes, Endocrinology and Metabolism (CDEM) at Galway University Hospital (GUH) between June 2011 and June 2013. The clinical values (HbA1c, blood pressure & lipid profile values) of the patients were retrospectively analysed and then compared to the ADA guidelines. The primary finding at the time was that glycaemic targets were achieved by a far smaller proportion of patients than with blood pressure and lipid values [6].

The aim of this research was to conduct a similar audit of a more recent patient population and compare the results to those of 2013. It could then be determined whether there has been statistically significant improvement in the relevant clinical values. However as the audit was of the entire pool of patients, which has increased since 2013, the two cohorts are not directly linked. The goal was not to assess for improvements in the patients audited in 2013, but instead to compare the overall status of the entire population of patients attending GUH at two different points in time. With the development of new technologies, patient education systems and guidelines in the treatment of Diabetes, the hope would be for outcomes to improve [7, 8]. The results may also be contrasted with similar studies performed in other parts the world. Should outcomes be found to be better in other jurisdictions, future management could be improved by incorporating techniques used there.

Methods

This was a retrospective cross-sectional analysis of clinical data of patients with T1D, managed at CDEM, Galway University Hospital. This centre is a consultant-led tertiary referral clinic that provides diabetes care for patients in the west of Ireland. The cohort was comprised of all those with T1D who attended the centre between June 2013 and June 2019.

The laboratory data recorded for each patient was serum Hba1c(mmol/mol), triglycerides, total cholesterol, LDL-cholesterol, HDL-cholesterol, albumin-creatinine ratio (ACR) and the glomerular filtration rate. Other clinical information recorded included gender, age, insulin regime information, weight (kg), BMI, insulin type and regime, as well as systolic and diastolic blood pressure. All the aforementioned physical measurements were performed by a licenced clinician or nurse. The most recent value recorded for each patient was used and this data was then used to find the proportion & percentage of values within ADA recommended ranges. The mean and standard deviation was also found for continuous variables. Only values taken between June 2013 and June 2019 were included in the statistical analysis.

The ADA clinical recommendations for 2014 can be seen in table 1 [4]. These are updated annually, however the 2014 guidelines were used in the previous audit and, to aid statistical comparison, were also selected for this manuscript. Microalbuminuria was defined as an ACR between 2.5mg/mmol and 30 mg/mmol for men and between 3.5mg/mmol and 30mg/mmol for women. Macroalbuminuria was considered an ACR of 30mg/mmol or higher in either sex [9]. A decreased GFR was defined as <60 ml/min/1.73m^2. The statistical significance of comparing the means of the two audits was assessed with independent T-tests. Results were considered statistically significant if resulting p-value was <.05

As the data was collected as part of a clinical audit, no ethical approval was needed. All patient data was anonymised and stored on site at GUH.

Results

Clinical profile

There were 1501 patients with diabetes T1D managed at the diabetes centre between the dates of June 2013 and June 2019. The mean age of the cohort was 42.9. The group was 49.2% male and 50.8% female.

The full clinical profile can be seen in table 2. HbA1c had the lowest prevalence of control amongst patients at 15.4% with a mean of 68 ± 17.2. The next lowest was body mass index with 40.2% of patients. Overall, the majority of patients with recorded values met the recommended lipid profile values, 61.9%, 75.1%, 88% & 81.4% for LDL, total cholesterol, HDL and triglycerides respectively. 223 out of 1204 (18.5%) patients had microalbuminuria while a further 87 (7.2%) had macroalbuminuria.

Table 1: ADA recommendations 2014	
Value	Advised range
Hba1c	<53mmol/mol
sBP	<140mmHg
dBP	<90mmHg
BMI	<=25kg/m^2
Total cholesterol	<5.2mmol/L
LDL-cholesterol	<2.6mmol/L
HDL-cholesterol	>1mmol/L for men >1.3mmol/L for women
Triglycerides	<1.7mmol/L

Table 2: Clinical values relevant to treatment of diabetes			
Variable	Mean (SD)	Patients at goal (%)	N (% of cohort)
HbA1c(mmol/mol)	68.0(17.2)	197(15.4%)	1283(85.5%)
HbA1c (%)	8.4(2.12)	^^^	^^^
sBP(mmHg)	128.3(15.1)	963(78.7%)	1224(81.6%)
dBP(mmHg)	74.6(10.1)	860(70.4%)	1222(81.4%)
Total cholesterol(mmol/L)	4.6(1.0)	921(75.1%)	1226(81.7%)
LDL cholesterol(mmol/L)	2.4(.9)	755(61.9%)	1220(81.3%)
HDL cholesterol(mmol/L)	1.6(.5)	1029(88.0%)	1169(77.9%)
Triglycerides(mmol/L)	1.2(.8)	999(81.4%)	1227(81.8%)
Body Mass Index(kg/m^2)	26.6(4.8)	584(41.6%)	1195(79.6%)
Goals defined in table 1.			

Comparison to previous profile

Comparing the means of the two audits, there was a slight but statistically significant improvement in HbA1c, improving from 69.6mmol/mol to 68mmol/mol. Independent T tests returned a p value .04. The prevalence of well-controlled levels showed similar mild improvement with 15.4% in 2019 compared to 14.8% in 2013. Both systolic & diastolic blood pressure results showed a deterioration in mean between the two. BMI & all lipid profile values bar HDL demonstrated no statistically significant change between the two audits.

Table 3: Results of 2013 profile compared to 2019					
	2013 profile		2019 profile		p-value
Variable	Mean (SD)	Patients at goal (%)	Mean (SD)	Patients at goal (%)	
HbA1c(mmol/mol)	69.6(17.8)	14.8%	68.0(17.2)	15.4%	.044
sBP(mmHg)	125.1(15.8)	84.3%	128.3(15.1)	78.7%	<.001
dBP(mmHg)	73(9)	75.1%	74.6(10.1)	70.4%	<.001
Total cholesterol(mmol/L)	4.6(1.1)	69%	4.6(1.0)	75.1%	-
LDL cholesterol(mmol/L)	2.4(.8)	61.7%	2.4(.9)	61.9%	-
HDL	1.7(.5)	84.8%	1.6(.5)	88%	<.001
cholesterol(mmol/L)	1.2(1.2)	81.7%	1.2(.8)	81.4%	-
Triglycerides(mmol/L)	26.4(4.8)	46%	26.6(4.8)	41.6%	.34
Body Mass Index(kg/m^2)					

Comparison with other studies

A survey was carried out in Scotland in 2019, allowing a comprehensive review on diabetes care for the entire population of the country. This was a cohort of significant size and included HbA1c records for 30,263 adult Type 1 patients. As a nearby nation with similar levels of diabetes, the survey provides a good baseline to compare the results of this study with. It reported that 25.8% of type 1s had a HbA1c less than 58mmol/mol [10]. The cohort of the study carried out at GUH had a similar frequency with 26.6% below 58mmol/mol.

Discussion

The results of the 2019 audit demonstrated, much like its 2013 counterpart, that glycaemic targets are more difficult to achieve than cardiovascular and lipid targets. There has been incremental improvement in mean HbA1c values overall, possibly owing to increases in patient education programs and the use of newer technologies. The dose adjusted for normal eating (DAFNE) educational program is used locally and is associated with improvements in HbA1c [11]. Though statistically measurable, the improvement is not large enough to likely result in a notable change in the incidence of complications for the population at large.

This study is limited by looking only at the population of patients in one region. It cannot be determined whether these results are indicative of all patients with type 1 diabetes in Ireland or whether there are significant differences between the different networks of the Health Service Executive.

In order, to assess the entire population of T1DM patients, a national database would need to be established that collates all clinical data from across the various networks. The previously cited Scottish Diabetes Survey is annually published report using a system such as this, that has aided in the comparison of care across regions and the modest improvement of outcomes across 10 years.

Glycaemic control remains the most important aspect of type 1 management, as it is significantly correlated with both microvascular and macrovascular complications. But this research supports, that current methods of diabetes management may have reached a point where significant improvement at a population level are untenable. Despite increased educational efforts, the majority patients are still unable to reach HbA1c targets and will inevitably face complications in the long term. This idea is supported internationally by the annual Scottish surveys which initially showed improvement in the number of patients reaching HbA1c targets from 2010 to 2016 but has since plateaued, even showing a slight reduction between 2018 and 2019 [10]. It is possible that some proposed treatment methodologies will solve this issue in the future, namely dual hormone pump devices and stem cell B-cell transplantation. However, these are still at an early stage of development with uncertain viability [8, 12].

Declaration of Conflicts of Interest:
The authors have no conflicts of interest to declare.

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