

The Impact of the New State Body for Transplantation on Lung Transplantation Waiting List Mortality

A. Daly, S. Cremen, D.G. Healy

Department of Cardiothoracic Surgery, Mater Misericordiae University Hospital, Eccles St, Dublin 7, Ireland

Abstract

Introduction

Organ Donation Transplant Ireland (ODTI) was established in 2014 to provide leadership and governance of the transplant programme in Ireland. We aim to establish if the implementation of ODTI translates into a decrease in waiting list mortality.

Methods

A retrospective analysis of all patients listed for lung transplantation on the Irish Heart and Lung Transplant Programme, between January 2011 and December 2016, was performed. We compared mortality on the waiting list before and after the establishment of ODTI.

Results

During the study period, a total of 259 patients were on the lung transplant list. Sixty percent of patients underwent lung transplantation. Following establishment of ODTI, there was a statistically significant reduction of waiting list mortality from 46% in the era prior to ODTI to 33% after ODTI formation ($p=0.02$).

Conclusion

This study demonstrates the establishment of the governing body ODTI reduced mortality on the lung transplant waiting list.

Introduction

The lung transplantation programme began in 2005 in Ireland. Starting with low volume activity and gradually building on experience, Bartosik *et al* demonstrated that the initial experience of lung transplantation demonstrated favourable outcomes with a one year survival rate of 94.1%.¹

Once a high quality programme was established, a focus on volume while maintaining that quality evolved. While our post lung transplant survival remains excellent, we aim to establish if this increased transplant activity results in a decrease in waiting list mortality after the establishment of Organ Donation Transplant Ireland (ODTI). ODTI is governed by the Health Service Executive and the National Organ Donation and Transplant Advisory group. ODTI, in conjunction with the Health Product Regulatory authority developed the "Framework for Quality and Safety of Human Organs intended for Transplantation" to outline the governance of organ donation². The framework established operational procedures for the organ donation process, from organ procurement to implantation. Additionally, a reporting system was implemented for mandatory reporting of serious adverse events to facilitate quality assurance.

With additional resources and increased experience, our centre has been enabled to expand the transplant programme to include extended donor-criteria and subsequently increase the number of transplantations performed. We aim to establish if the increase in activity corresponds to a decrease in waiting list mortality or simply an increase in patients who are listed.

Methods

This is a retrospective, single-centre, cohort study including all patients who were on the active lung transplant list over a five year period from January 2011 until December 2016. We compared patients listed for lung transplantation 3 years before and 3 years after the establishment of ODTI. The study is reported in accordance with STROBE guidelines.

The setting is a single-centre, the National Centre for Cardiothoracic Surgery, with a general cardiothoracic caseload of approximately 800 cases per annum. Nine consultant cardiothoracic surgeons work at the unit, six of whom perform lung transplantation. Weekly multidisciplinary team meetings are held with transplant physicians, psychiatrists with an interest in transplant assessment, social workers and other allied health professionals. To date, the unit has an experience of more than 200 lung transplantations.

All patients who were on the active lung transplant waiting list in the Republic of Ireland during the study period were included. All patients had end-stage lung disease and were at least 18 years old.

Exposure was considered being listed on the active-lung transplant list. Outcomes included; death awaiting transplant or transplantation. The outcomes were measured until the end point of the trial.

The chi-squared test was used to assess the relationship between mortality on the waiting list before and after the establishment of ODTI. A p value of 0.05 was considered statistically significant.

Results

Patient population

From January 2011 until December 2016, there were a total of 259 patients on the active lung transplant, in the Republic of Ireland, 227(88%) of whom were newly listed during the study period.

In the study cohort, 163 (65%) were male. Mean age was 50 years (range 18 years – 74 years). Aetiology of lung disease included; interstitial lung disease (ILD) (45%, n=115), cystic fibrosis (CF) (29%, n=74) chronic obstructive airway disease (12%, n=30). Other diagnoses included; alpha-1 antitrypsin deficiency (3%), bronchiolitis obliterans (2%), bronchiectasis (2%), LAM (1%), pulmonary hypertension (3%), sarcoid (2%), polymyositis (<1%).

Survival Data

One-hundred and fifty-six (60%) of patients underwent lung transplantation, 73 (46%) of whom received a double lung transplant. Mean time from listing to transplantation was 319 days (range 0-2058 days). One-hundred and three (66%) patients underwent transplantation within 12 months of being listed for lung transplant. One-year survival post transplant was 98% (n=153 of 156). The mortality rate on the waiting list was 31% (n=79 of 259). Mean time to death was 389 days (range 7-2428 days). At the end of the study period 24 (9%) remained on the active transplant list.

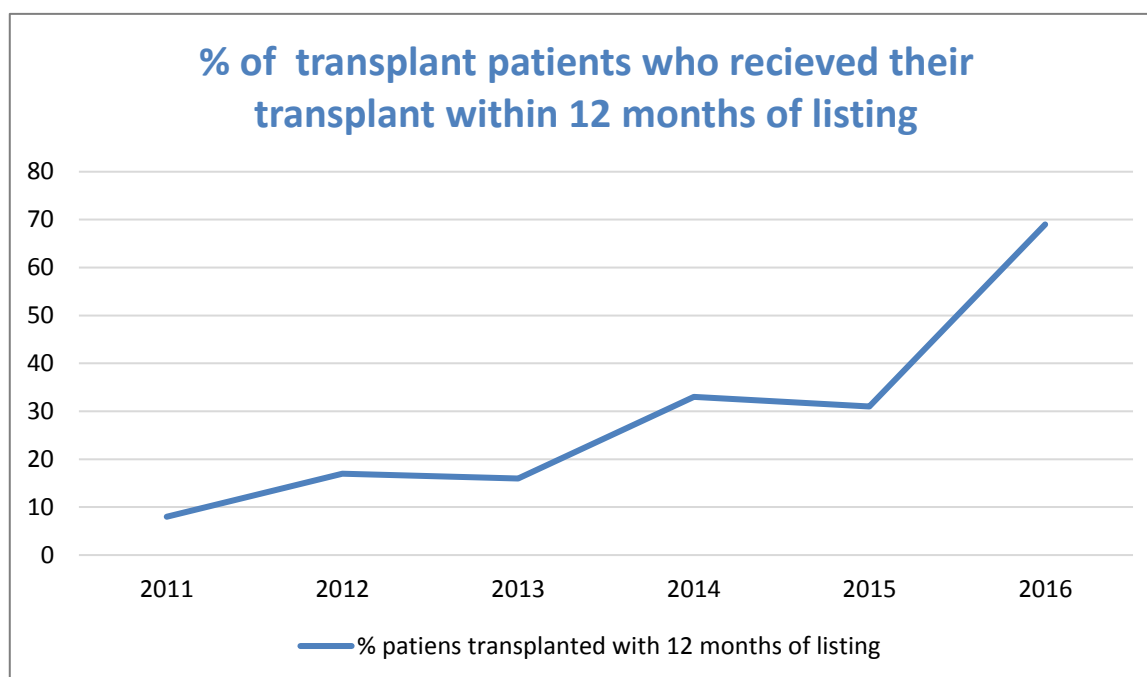
From 2011 to 2016 an absolute four-fold increase in transplant activity is noted. The relative transplant rate increased from 15.6% of patients on the list in 2011 to 36% of patients on the list in 2016. The establishment of ODTI related to a statistically significant reduction in waiting list mortality from 46% before ODTI establishment to 33% after ODTI formation (p=0.02). (Table 1). The rate of transplantation within 12 months of listing has steadily improved from 8% in 2011 to 69% in 2016 (Figure 1).

Table 1. Outcomes on lung transplant waiting list over time.

Year	Number on list*	Transplanted	Death on list
2011	51	8	10 (20%)
2012	70	14	20 (29%)
2013	77	32	9 (12%)
2014	84	31	20 (24%)
2015	76	36	9 (12%)
2016	96	35	11 (11%)

**including existing patients who remained on the active transplant list from preceding years, who had not received a transplant or died*

Figure 1. Transplantation rate within 12 months of initial listing over time.



Sub population analysis

We compared to two largest cohorts of patient's listed for lung transplant; patients diagnosed with CF and patients diagnosed with ILD. Mean waiting time to transplant for patients with CF was 307 days, whereas for patients with ILD it was 224 days.

Discussion

In total, two-hundred and fifty-nine patients were on the active lung transplant list during the study period, 60% received a transplant, 31% died on the waiting list and 9% remained on the waiting list. There is an inverse association between transplantation and mortality on the waiting list (i.e. as the rate of transplantation increases, the mortality rate on the waiting list decreases). With increased transplant activity over time, the rate of transplantation within twelve months of listing has improved nearly eight-fold, from 8% to 69%.

The rate of mortality on the lung transplant waiting has steadily declined over time from 20% in 2011 to 11% in 2016. When analysing the impact of the ODTI we found that the establishment of ODTI coincides with a statistically significant reduction in waiting list mortality ($p=0.02$). We propose that the decrease in waiting list mortality is related to the establishment of ODTI and accompanying increased government funding, resulting in; the establishment of

regional donor co-ordinators in hospitals, increased staff training and consequently improved transplantation awareness and improved donor optimisation at donor sites. Furthermore, the use of extended donor criteria has also improved donor utilisation and transplantation rates.

This study is limited by its retrospective nature. Furthermore, while a decreased waiting list mortality was demonstrated with increased transplantation activity, long-term survival post transplantation was not an outcome measure in this study and therefore this study cannot comment on directly if increasing transplantation activity improves survival of patients listed, although one year survival remains superb at 98%. This may be important as while increasing transplant activity is multifactorial, using extended-donor criteria is one variable which may increase transplantation numbers but may offer suboptimal survival outcomes compared to adhering rigidly to donor criteria. This requires further evaluation.

Suitable donor organs is the rate limiting factor in all transplant surgery. Since the beginning of the lung transplant programme in 2005, the health service has made considerable progress in developing the service. Organ Donation and Transplant Ireland (ODTI) was established in 2014 to provide a strategic framework for organ transplantation in Ireland and for the delivery of the National Procurement Service in order to maximise transplant activity. The use of extended-donor criteria, lobar transplantation, donor-cardiac-dead donors and Ex-Vivo Lung Perfusion have also contributed to increased lung transplantation. Using these strategies, a decrease in mortality on the waiting list is noted from 46% before establishment of ODTI to 33% after the establishment of ODTI. Corresponding trends are evident during fluctuating periods of transplantation, for example, in 2014 a decrease in transplant activity was mirrored by an increase in waiting list mortality. Furthermore, there has been a steady improvement in the rate of transplantation within twelve months since the establishment of ODTI.

In conclusion, formal establishment of the governing body ODTI has resulted in maximising donor opportunities, increased lung transplantation, increased transplantation within 12 months of listing and decrease in mortality on the lung transplant waiting list.

Acknowledgements:

We would like to acknowledge all the efforts of the transplant professionals in Ireland for their continued dedication, in particular the lung transplant group; D Eaton, JJ Egan, H Javadpour, J Klienerova, JF McCarthy, L Nolke, O O'Connell, KC Redmond.

Declaration of Conflicts of Interest:

The authors declare no conflict of interest.

Corresponding Author:

Professor David Healy,
Department of Cardiothoracic Surgery,
Mater Misericordiae University Hospital,
Eccles St,
Dublin 7,
Ireland
Email: dhealy@svhg.ie

References:

1. Bartosik W, Egan JJ, Soo A, Remund KF, Nölke L, McCarthy JF, Wood AEI. A review of the lung transplantation programme in Ireland 2005-2007. *Eur J Cardiothorac Surg* [Internet]. 2009 May [cited 2014 Jun 27];35(5):807–11; discussion 811. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19346136>
2. Quality and Safety Framework, Organ Donation and Transplant Ireland, Health Service Executive HPR. A Framework for Quality and Safety of Human Organs Intended for Transplantation [Internet]. 2014 [cited 2019 Nov 29]. Available from: <https://www.hse.ie/eng/about/who/acute-hospitals-division/organ-donation-transplant-ireland/publications/odti-quality-and-safety-framework-for-human-organs-intended-for-transplantation.pdf>