

**NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE**

PANCREAS ADVISORY GROUP

ISLET TRANSPLANT ACTIVITY AND OUTCOME
SUMMARY

INTRODUCTION

- 1 Islet transplant data has been collected by NHSBT since the introduction of four transplant and follow-up forms in July 2010. Data were collected retrospectively for all transplants since 1 April 2008 to ensure a complete data set since the commissioning of islet transplantation in the UK.

DATA

- 2 Islet transplant activity and end of year transplant list for the last three financial years were analysed. Data on 160 (101 routine and 59 priority) islet transplants performed in the UK where the routine transplant was performed between 1 April 2010 and 31 March 2016 were analysed from the UKTR. Outcome data are reported for all routine transplants.

RESULTS

- 3 In 2016/17 there were 34 islet transplants performed, three more than 2015/16. In 2016/17 there was one simultaneous islet kidney transplant performed at Manchester. The number of patients on the islet transplant list at 31 March 2017 was 21, 16 routine and 5 priority, compared with 28 in 2015/16.
- 4 Kaplan-Meier estimated one year graft survival for routine only grafts is 78%, 95% CI (63 – 88) and for routine grafts followed by a priority graft is 96%, 95% CI (87 - 99). There were statistically significant differences between the two groups $p < 0.004$.
- 5 The median annual rate of severe hypoglycaemic events fell from 7.5 events (IQR 0-34.5) at time of transplant, to none at one, two and three years post-transplant. 65 (78%) patients experienced no severe hypoglycaemic events in the first year post transplant.
- 6 Median HbA1c fell from 64 mmol/mol (IQR 56-75) at time of transplant, to 51 mmol/mol (IQR 42-59) at one year and 54 (IQR 47-62) three years post-transplant was. Reduction in HbA1c was reported for 71 (87%) patients at one year post transplant.
- 7 The median insulin dose fell from 0.51 units/kg (IQR 0.35-0.61) at time of transplant to 0.25units/kg at one year and 0.27 at three years post-transplant. Reduction in insulin dose for the whole time period was reported for 39 patients.

SUMMARY

- 8 In 2016/17 the number of islet transplants had increased from 2015/16 whilst the number on the waiting list at the end of the financial year had decreased. Graft function, reduction in rate of severe hypoglycaemic events, reduction in HbA1c and reduction in insulin dose at one-year, two years and three years post routine transplant have been reported.

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INTRODUCTION

- 9 Islet transplant data has been collected by NHSBT since the introduction of four transplant and follow-up forms in July 2010. Data were collected retrospectively for all transplants since 1 April 2008 to ensure a complete data set since the commissioning of islet transplantation in the UK.
- 10 The recent increase in transplant activity and the continued efforts to improve form return rates have contributed to a small, but emerging national islet transplant registry. This paper provides basic summaries of outcomes.

DATA

- 11 Data on islet transplant activity and end of year transplant list between 1 April 2014 and 31 March 2017 from the UK Transplant Registry (UKTR) were analysed.
- 12 Data on 160 (101 routine and 59 priority) islet transplants performed in the UK where the routine transplant was performed between 1 April 2010 and 31 March 2016 were analysed from the UKTR. Outcome data are reported for all routine transplants. Where outcome data are unavailable from UKTR, data collected by the UKITC clinical research forms have been considered. This data has been provided by the Newcastle research group who collate and maintain the research data base.
- 13 All islet transplant outcome data reported are specific to the routine transplant.
- 14 The four key measures of islet transplant outcome are:
- i. Graft function
 - ii. Reduction in HbA1c (mmol/mol)
 - iii. Reduction in annual rate of severe hypoglycaemic events
 - iv. Reduction in insulin dose

All outcomes are reported at one-year, two-years and three-years post routine transplant.

RESULTS

- 15 **Table 1** shows the number of islet transplants performed by each centre in the UK for the last three financial years between 1 April 2014 and 31 March 2017 by transplant type. **Table 2** shows the number of patients on the islet transplant list at 31 March 2015, 31 March 2016 and 31 March 2017 by islet status.
- 16 A Kaplan-Meier survival plot showing one year graft survival by type of graft is presented in **Figure 1**. Estimated one year graft survival for routine only grafts

is 78%, 95% CI (63 – 88) and for routine grafts followed by a priority graft is 96%, 95% CI (87 - 99). There were statistically significant differences between the two groups $p < 0.004$.

- 17 **Figure 2** shows a Kaplan-Meier survival plot of five year graft survival by type of graft. Estimated five year graft survival for routine only grafts is 42%, 95% CI (24 - 58) and for routine grafts followed by a priority graft is 68%, 95% CI (45 - 83). There were statistically significant differences between the two groups $p = 0.0001$.
- 18 The median rate of severe hypoglycaemic events is presented in **Figure 3**. The median annual rate fell from 7.5 events (IQ range: 0 to 34.5) at time of transplant, to none at one, two and three years post-transplant. At one year post transplant data were available in 83 cases and 52 patients (63%) had a reduced number of events at one year post transplant.
- 19 Sixty five patients, 78%, experienced no severe hypoglycaemic events during the first year following their routine transplant, whilst 18 (22%) patients experienced between 1 and 9 events.
- 20 Median HbA1c is reported in **Figure 4**. Overall median HbA1c fell from 64 mmol/mol (IQ range: 56 to 75) at time of transplant, to 51 mmol/mol (IQ range: 42 to 59) at one year post-transplant. The median HbA1c at three years post-transplant was 54 (IQ range: 47 to 62). Data were available to calculate the reduction in HbA1c in 85 cases at one year post transplant and in 71 patients (87%) a reduction in HbA1c was reported.
- 21 Fifteen patients, 15%, had HbA1c less than 53 mmol/mol at time of transplant and 47 patients, 55%, had HbA1c less than 53 mmol/mol at one-year post transplant. Of the 45 patients with HbA1c recorded at three years post-transplant, 20 (44%) had an HbA1c less than 53 mmol/mol.
- 22 **Figure 5** shows the median insulin dose at transplant and 3 months, 6 months, one year, two and three years post-transplant. The median insulin dose fell from 0.51 units/kg (IQ range: 0.35 to 0.61) at time of transplant to 0.27 units/kg (IQ range: 0.15 to 0.39) at 3 months post-transplant. This reduction in dose was fluctuated at one year, two years and three years post-transplant (0.25 units/kg, 0.29 units/kg and 0.27 units/kg respectively). Reduction in insulin dose for the whole time period was reported for 39 patients.

SUMMARY

- 23 In 2016/17 the number of islet transplants had increased from 2015/16 and the number on the waiting list at the end of the financial year had decreased. Graft function, reduction in rate of severe hypoglycaemic events, reduction in HbA1c and reduction in insulin dose at one-year, two years and three years post routine transplant have been reported.

Table 1 UK islet transplant activity between 1 April 2014 and 31 March 2017, by transplant type and financial year

Transplant Centre	2014 - 2015							2015 - 2016							2016 - 2017						
							Total							Total							Total
	ITA	IAK	IAP	IAPK	SIK	N	%	ITA	IAK	IAP	IAPK	SIK	N	%	ITA	IAK	IAP	IAPK	SIK	N	%
Bristol	1	0	0	0	0	1	4	1	0	0	0	0	1	3	1	0	0	0	0	1	3
Edinburgh	6 ¹	0	0	1	0	7	30	18 ³	1 ¹	0	0	0	19	61	16 ²	1	0	0	0	17	50
King's	0	0	0	0	0	0	0	1	0	0	0	0	1	3	3	0	0	0	0	3	9
Manchester	1	0	0	1	0	2	9	0	0	0	1	0	1	3	2	0	0	0	1 ¹	3	9
Newcastle	2 ¹	2	0	0	0	4	17	7	0	0	0	0	7	23	3	0	0	0	0	3	9
Oxford	5	0	0	0	0	5	22	2	0	0	0	0	2	6	7 ¹	0	0	0	0	7	21
Royal Free	4 ¹	0	0	0	0	4	17	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	19	2	0	2	0	23	100	29	1	0	1	0	31	100	32	1	0	0	1	34	100

ITA = Islet transplant alone IAK = Islet after kidney IAP = Islet after pancreas IAPK = Islet after simultaneous kidney/pancreas SIK = Simultaneous kidney/islet

¹ Includes 1 DCD transplant

² Includes 2 DCD transplants

³ Includes 5 DCD transplants

Table 2 UK islet transplant list, 31 March 2015 to 31 March 2017, by islet status and financial year

Transplant Centre	31 March 2015				31 March 2016				31 March 2017			
			Total	%			Total	%			Total	%
	Routine	Priority	N		Routine	Priority	N		Routine	Priority	N	
Bristol	4	0	4	11	2	1	3	11	0	0	0	0
Edinburgh	15	3	18	50	91	2	11	39	8 ¹	0	8	38
King's	1	0	1	3	2	0	2	7	0	0	0	0
Manchester	2	1	3	8	1	1	2	7	2	1	3	14
Newcastle	4	2	6	17	1	4	5	18	2	1	3	14
Oxford	4	0	4	11	5	0	5	18	4	3	7	33
Royal Free	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	30	6	36	100	20	8	28	100	16	5	21	100

¹ Includes 1 SIK recipient

Figure 1 One-year graft survival following routine islet transplantation performed in the UK between 1 April 2010 and 31 March 2016

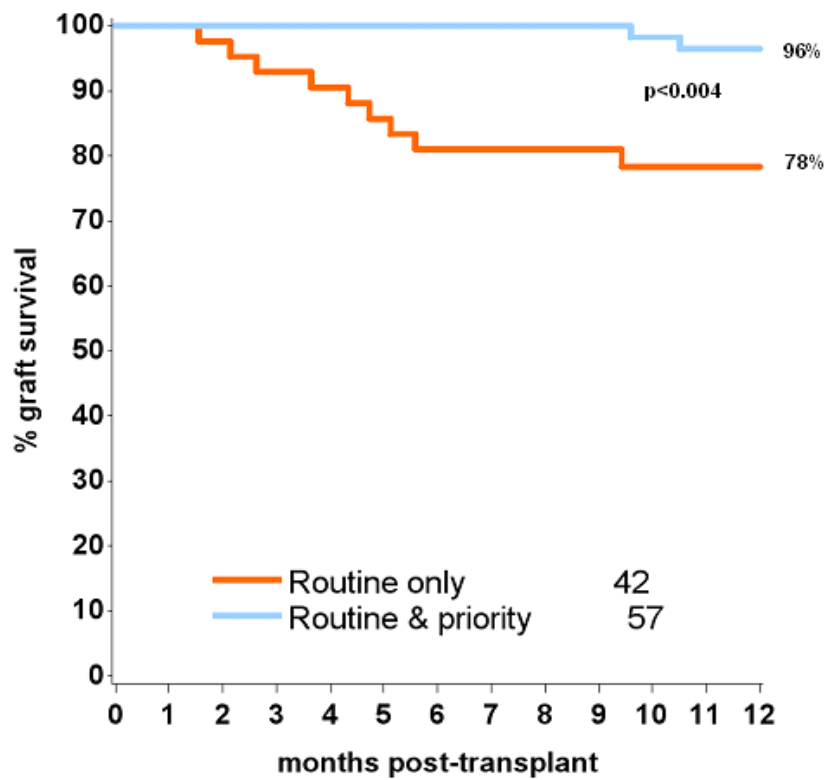


Figure 2 Five-year graft survival following routine islet transplantation performed in the UK between 1 April 2010 and 31 March 2016

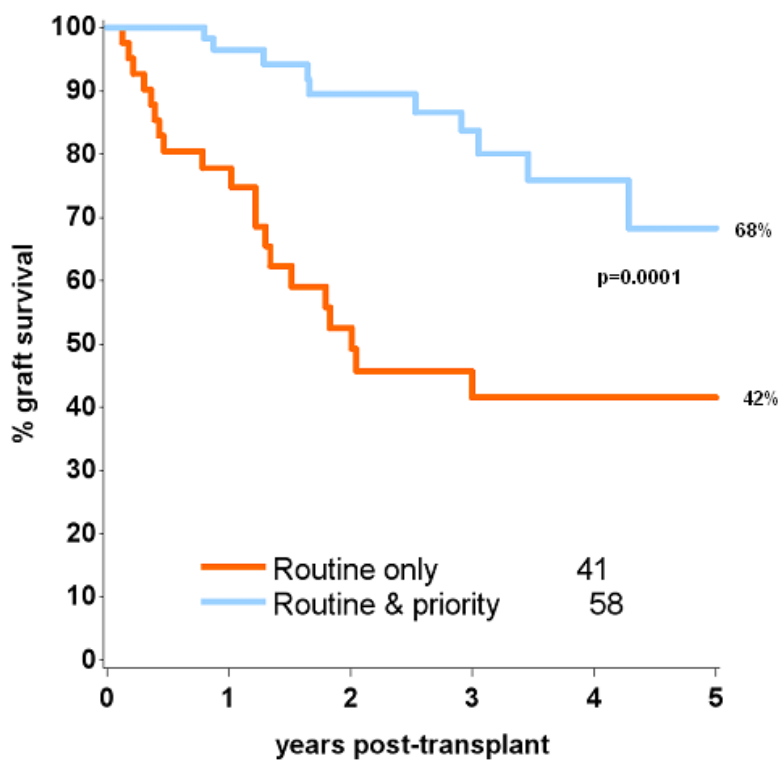


Figure 3 Reduction in severe hypoglycaemic events three years post-transplant, 1 April 2010 – 31 March 2016

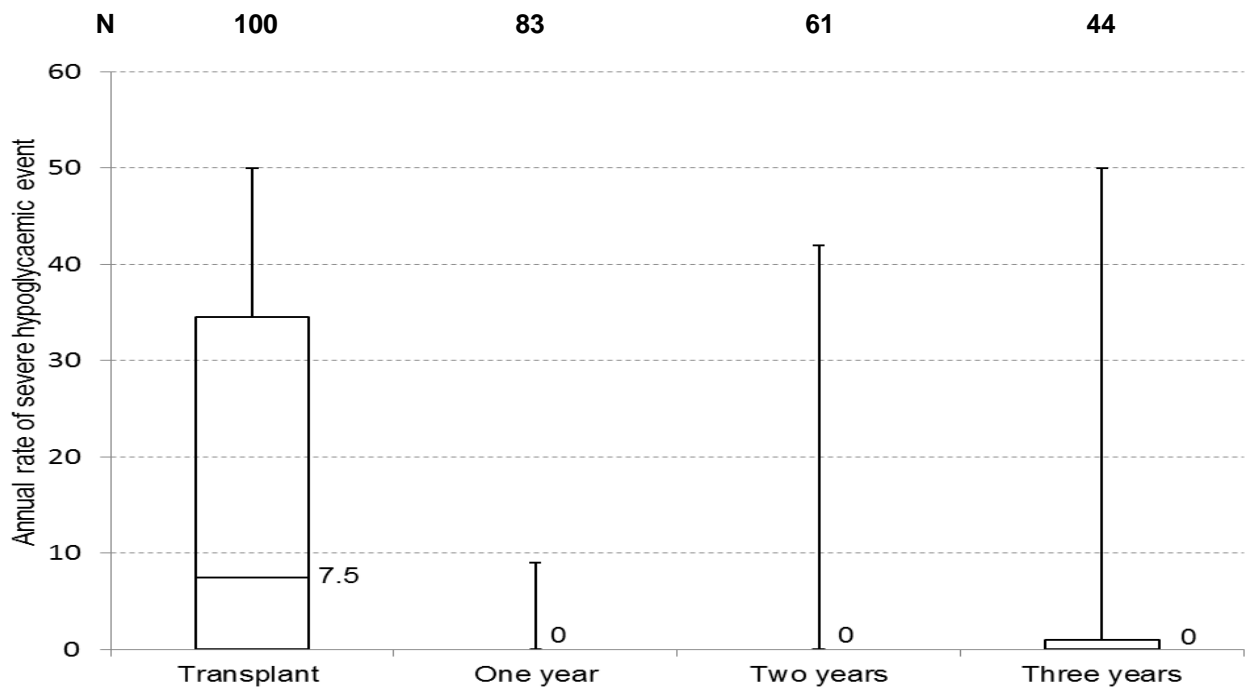


Figure 4 Reduction in HbA1C three years post-transplant, 1 April 2010 – 31 March 2016

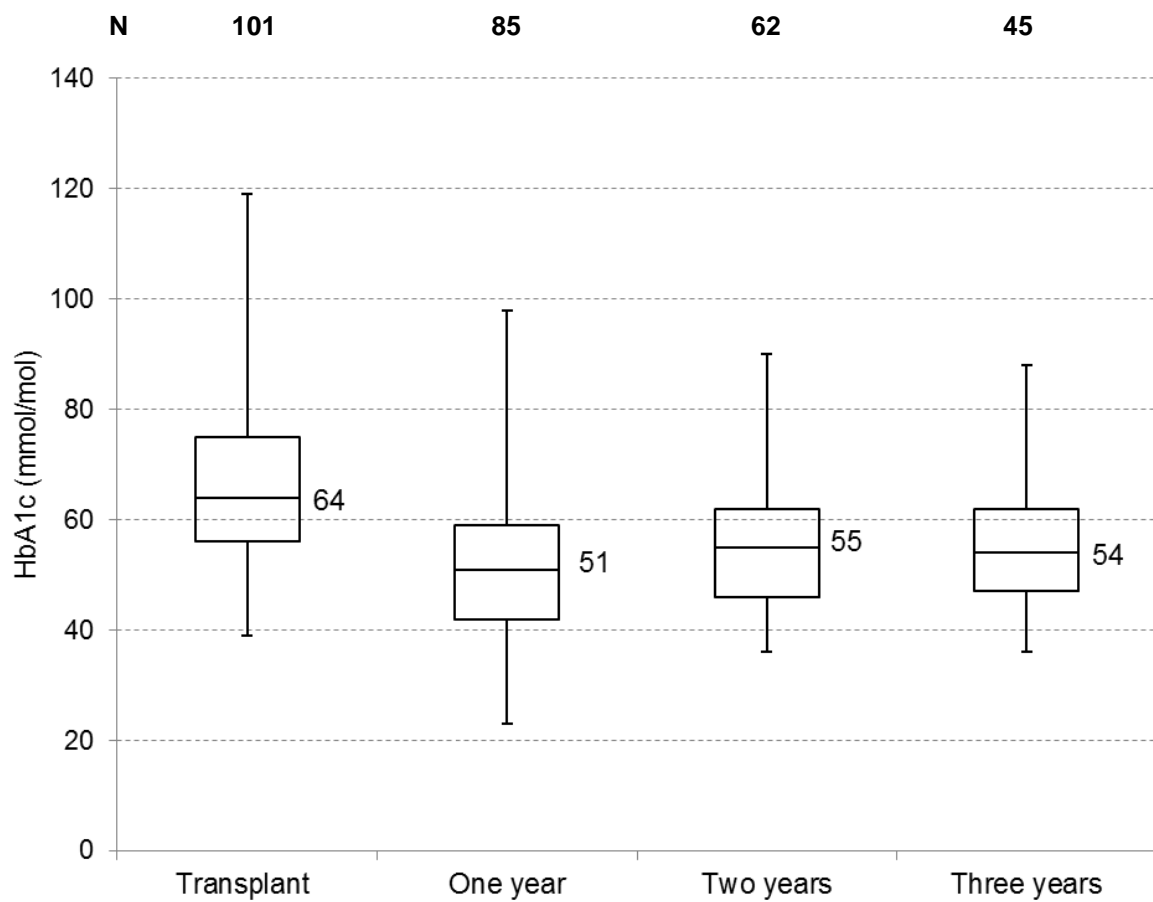


Figure 5 Insulin dose three-years post-transplant,
1 April 2010 – 31 March 2016

