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Donor Characteristics of Pancreas Transplantation in Australia and New Zealand: A Cohort Study 1984-2014

Xi (Alex) Peng, PhD,[1] Patrick J. Kelly, PhD,[1] William R. Mulley, PhD,[3,4] Henry Pleass, PhD,[2] Helen Pilmore, PhD,[5,6] and Angela C. Webster, PhD[1,2]

Background. The aim of this study was to audit the characteristics of pancreas donors over time in Australia and New Zealand. Pancreas transplantation was introduced in Australian and New Zealand in 1984. **Methods.** We analyzed data from the Australia and New Zealand Islet and Pancreas Transplant Registry, 1984 to 2014. We investigated the variation of donor characteristics of sex, age, body mass index, smoking status, blood group, multiple organ donation, cytomegalovirus status, terminal creatinine, hypertension, and cause of death for pancreas transplantation over time. We used χ^2 test (Fisher test when necessary) or analysis of variance to test difference for categorical or continuous characteristics, respectively. **Results.** There were 628 pancreas donors from 1984 to 2014. Donor body mass index (from 21.9 to 24.0, $P < 0.001$) and age (from 23.9 to 28.5, $P = 0.02$) have both increased while terminal creatinine has decreased (86.3 to 73.3, $P = 0.01$) from 1995 to 2014. In the meantime, the proportions of donors with hypertension (from 19% to 1%, $P < 0.001$) and who were smokers (from 54% to 15%, $P < 0.001$) have decreased. Profile of cause of donor death has also changed over time ($P = 0.06$) with increase in cerebral hypoxia/ischemia (from 3% to 17%) and reductions in intracranial hemorrhage (27% to 13%). **Conclusions.** Many donor characteristics have changed over time. The most significant changes appear to reflect changes in the general population, rather than changes in donor selection.

(*Transplantation Direct* 2016;2: e99; doi: 10.1097/TXD.0000000000000610. Published online 11 August 2016.)

BACKGROUND

Pancreas transplantation for type I diabetes mellitus promises improved glycemic control and offers insulin independence and has been associated with improvements in diabetic retinopathy, neuropathy, and vasculopathy.[1] Globally, pancreas transplantation is almost always undertaken in association with kidney transplantation in patients with type 1 diabetes mellitus with end stage kidney disease. The first pancreas transplantation was performed in 1966 at the University of Minnesota.[2] In Australia, the first case of simultaneous pancreas and kidney transplantation for patients with type 1 diabetes mellitus was carried out in 1984, whereas the first simultaneous pancreas and kidney transplant in New Zealand took place in 1998.[3]

Suitable selection of donors is the key to the success of pancreas transplantation.[4] Several studies have investigated the association between donor characteristics and graft outcomes, for example, older age is known to be a risk factor for graft failure in pancreas and kidney transplants.[5] Australia and New Zealand and international guidelines for donor selection have been revised over time, aiming to maximize the donor pool while at the same time optimizing graft and patient survivals. In 2003, the USA Organ Procurement Transplantation Network set a donor age upper limit of 50 years. In 2005, Organ Procurement Transplantation Network further decided that donors older than 50 years and/or with a body mass index (BMI) of more than 30 could be allocated for pancreas islet transplantation.[6] A shortage of donors and

Received 7 March 2016. Revision requested 8 June 2016.

Accepted 11 June 2016.

[1] *Sydney School of Public Health, University of Sydney, Sydney, NSW, Australia.*

[2] *Centre for Transplant and Renal Research, Westmead Hospital, Westmead, NSW, Australia.*

[3] *Department of Nephrology, Monash Medical Centre, Clayton, Victoria, Australia.*

[4] *Centre for Inflammatory Diseases, Department of Medicine, Monash University, Clayton, Victoria, Australia.*

[5] *Department of Renal Medicine, Auckland City Hospital, Grafton, Auckland, New Zealand.*

[6] *Department of Medicine, Auckland University, Grafton, Auckland, New Zealand.*

The authors declare no funding or conflicts of interest.

X.P., P.K., and A.W. participated in research design. A.P., P.K., W.M., H.Pl., H.Pi., and A.W. participated in the writing of the article. A.P., P.K., W.M., H.Pl., H.Pi., and A.W. participated in the performance of the research. X.P., P.K., and A.W. contributed new reagents or analytic tools. X.P., P.K., and A.W. participated in data analysis.

Correspondence: Angela C Webster, 304a Edward Ford Building A27, Sydney School of Public Health, University of Sydney, Sydney, NSW 2006, Australia. (angela.webster@sydney.edu.au).

ISSN: 2373-8731

DOI: 10.1097/TXD.0000000000000610

increased waiting list numbers and waiting times have led to endeavours to increase donation through acceptance of extended criteria donors including donation after circulatory death.[3,7] Donor characteristics may also be changing over time due to changes of characteristics in the general population, but evidence from prior study is sparse.

The aim of this study was to audit and describe the characteristics of all pancreas donors in Australia and New Zealand and to examine how these donors have changed over 31 years, from the first transplant in 1984 to the end of 2014.

MATERIALS AND METHODS

We used data from the Australian and New Zealand Islet and Pancreas Transplant Registry (ANZIPTR). This registry records all pancreas transplants from both countries since the inception of pancreas transplantation.

We performed a retrospective cohort study of all donors that resulted in a solid organ pancreas transplant (simultaneous, pancreas after kidney, or pancreas alone) in Australia and New Zealand from 1984 to 2014. Donors of islet cells were not included. Donor characteristics we examined included sex, age, BMI, smoking status, blood group, kidney organ donation, hypertension, cytomegalovirus (CMV) status, terminal creatinine and cause of death, and any change of these characteristics over time. Cause of death was classified as cerebral hypoxia, cerebral infarct, intracranial hemorrhage, traumatic brain injury, non-neurological, and other neurological condition based on Australia and New Zealand Organ Donation Registry standard classification.[8] Adult BMI was classified as underweight (<18.5 kg/m^2), normal range (18.5 < 25.0 kg/m^2), overweight (25.0 < 30.0 kg/m^2), and obese (≥30.0 kg/m^2). Child and adolescent (2 to 18 years) BMI was classified into the same categories using age-specific thresholds.[9]

Categorical and continuous characteristics were summarized as proportion or mean with standard deviation, respectively, overall and by year. Years were grouped from 1984 to 1994 into a single category and then every 5 years there after (1995-1999, 2000-2004, 2005-2009, 2010-2014). Ages were grouped to 4-25, 26-35, 36-45, and 46-55 years. Pearson χ^2 test (or Fisher exact test if required) or analysis of variance was used to test differences across year groups, *P* less than 0.05 was considered statistically significant. Statistical analysis was conducted using SAS 9.3. Some donor characteristics were not investigated if the associated missing values accounted for more than 20% of the total sample. Where data was not collected routinely at the inception of ANZIPTR, but added at later dates, we could not expect data to be missing at random. For this reason, we opted not to impute data, but have identified where data is most missing.

RESULTS

In total, there were 628 solid organ pancreas transplants reported from 1984 to 2014, with 582 transplants performed

TABLE 1.

Pancreas transplant donor characteristics, 1984-2014

Donor characteristic, N+	Overall, N (%)	1984-1994, N (%)	1995-1999, N (%)	2000-2004, N (%)	2005-2009, N (%)	2010-2014, N (%)	*P*
Male (N = 517)	309 (60)	[a]	43 (64)	93 (66)	92 (57)	81 (55)	0.19
Age[b] (N = 571), y	27.5 (10.0)	26.8 (11.1)	23.9 (9.6)	27.7 (10.2)	28.1 (10.2)	28.5 (9.1)	0.02
BMI[b] (N = 479), kg/m^2	24.0 (4.4)	[a]	21.9 (6.5)	24.4 (4.5)	24.4 (3.5)	24.0 (3.4)	<0.001
Hypertension (N = 602)	28 (5)	9 (16)	13 (19)	3 (2)	2 (1)	1 (1)	<0.001
Smoking history (N = 487)							<0.001
Current/former	151 (31)	[a]	30 (54)	66 (50)	34 (22)	21 (15)	
Never	336 (69)	[a]	26 (46)	66 (50)	122 (78)	122 (85)	
Blood group (N = 426)							0.94
O	198 (46)	[a]	[a]	48 (46)	82 (50)	68 (44)	
A	172 (41)	[a]	[a]	44 (42)	64 (38)	64 (41)	
B	40 (9)	[a]	[a]	10 (9)	15 (9)	15 (10)	
AB	16 (4)	[a]	[a]	3 (3)	5 (3)	8 (5)	
Organs donated (N = 603)							<0.001
Pancreas only	32 (6)	0 (0)	0 (0)	3 (2)	19 (11)	10 (7)	
Kidney	567 (94)	60 (100)	66 (99)	138 (97)	157 (88)	146 (94)	<0.001
CMV status (N = 423)							0.56
Ig G negative	133 (31)	[a]	[a]	39 (33)	53 (33)	41 (28)	
Ig G positive	290 (69)	[a]	[a]	78 (67)	107 (67)	105 (72)	
Terminal creatinine[b] (N = 493), μmol/L	78.6 (46.2)	[a]	86.3 (34.8)	82.6 (73.1)	76.6 (31.1)	73.3 (25.9)	0.17
Cause of death (N = 506)							0.06
Cerebral hypoxia/ischemia	55 (11)	[a]	2 (3)	15 (10)	14 (9)	24 (17)	
Cerebral infarct	17 (3)	[a]	2 (3)	4 (3)	6 (4)	5 (4)	
Intracranial hemorrhage	85 (17)	[a]	18 (27)	28 (20)	20 (12)	19 (13)	
Traumatic brain injury	328 (65)	[a]	41 (61)	91 (65)	112 (71)	84 (60)	
Non-neurological	13 (3)	[a]	3 (5)	1 (1)	3 (2)	6 (4)	
Other neurological	8 (1)	[a]	1 (1)	1 (1)	3 (2)	3 (2)	

+ N can be different for different characteristics due to the variation of number of missing values.

[a] Results are not reported due to more than 20% missing values of total population for that period time.

[b] Mean (standard deviation) is calculated for numeric variables.

in Australia and 46 in New Zealand. Pancreas transplantation became more frequent over time. There were 71, 79, 142, 178, 158 pancreas transplants in period of 1984 to 1994, 1995 to 1999, 2000 to 2004, 2005 to 2009, 2010 to 2014, respectively.

Overall data quality was fair. Donor sex, age, and type of transplant had less than 10% missing values. Some donor data started routine collection after the registry was started. This has lead, over time, to some differential absence of data for earlier years, compared with later years for the newer data point. Donor terminal creatinine, blood group, CMV status, BMI, and smoking history had between 10% and 19% missing values, with most missing values occurring in the earlier years. However, because of the evolution of data collection within the ANZIPTR, some donor characteristics were not collected routinely until later years. Thus, when looking overall, these data had more than 20% of values missing, and so were not included in the data characterization. Examples of these data were donor drug and alcohol consumption, terminal urea, serum glucose, amylase, and lipase at the time of procurement.

Table 1 and Figure 1 present the summary statistics and distribution for all donor characteristics examined. Although not statistically significant, male donors predominated but the proportion of male donors slightly decreased from 64% in 1995 to 1999 to 55% in 2010 to 2014 ($P = 0.19$). Donor age also increased over time from 26.8 to 28.5 years ($P < 0.02$), with a decrease in the 4 to 25 years age group (from 57% to 40%; see Figure 1A) and increases in both the 26 to 35 years (from 18% to 33%) and 36 to 45 years age groups (from 15% to 24%). However, the proportion of donors who were 46 to 55 years decreased slightly over time from 10% to 3%. Average donor BMI increased from 21.9 kg/m^2 in 1995 to 1999 to 24.0 kg/m^2 in 2010 to 2014 ($P < 0.001$) which was mainly due to the increase of those overweight from 30% in 1995 to 1999 to 36% in 2010 to 2014 (Figure 1B). Donor terminal creatinine decreased from 86.3 μmol/L 1995 to 1999 to 76.3 μmol/L in 2010 to 2014 ($P = 0.17$).

The proportion of donors with hypertension decreased significantly over time from 16% to 1% ($P < 0.001$). The proportion of donors with a cigarette smoking history decreased over time from 54% to 15% from 1995 to 1999 to 2010 to 2014 ($P < 0.001$). There was no variation for the proportions of donors previously infected with CMV infection ($P = 0.56$) across the period. Blood group distribution frequency did not change over time ($P = 0.94$).

Pattern of cause of donor death changed over time from 1995 to 1999 to 2010 to 2014 ($P = 0.06$, Table 2), with an increase in cerebral hypoxia/ischaemic (from 3% to 17%) and a reduction in intracranial hemorrhage (from 27% to 13%). However, traumatic brain injury remained the most common cause of death (60%-71% of deaths). Almost all donors donated after brain death, but there were 4 donors who donated after circulatory death (DCD) (1 case in 2007, 1 case in 2012 and 2 cases in 2014).

DISCUSSION

We have described changes in pancreas donor characteristics over time in Australia and New Zealand since inception. Donors have become older and fatter, but less likely to be hypertensive or to have smoked. Donor cause of death has also changed.

We were unable to look in detail at some donor characteristics, such as drug and alcohol consumption, terminal urea, serum glucose, amylase and lipase at the time of procurement, as these data were not routinely collected in the early years of pancreas transplantation by ANZIPTR. Thus, these missing data prohibited what would have been interesting analyses. Given our study was about donor epidemiology, and not donor selection or recipient outcomes; we did not investigate any donor risk scores such as preprocurement pancreas allocation suitability score (P-PASS) or pancreas donor risk index (PDRI). Although calculation and use of donor risk scores might be inherently appealing, their usefulness in pancreas transplantation is questionable.[10] P-PASS correlates poorly with outcomes, and PDRI is of limited use. Other work suggests surgeons do not find P-PASS particularly helpful in their decision to accept organs.[11]

According to the guidelines from the Transplantation Society of Australia and New Zealand, donor age from 3 to 45 years is recommended.[12] Pancreas transplantation in Australian and New Zealand is slowly growing, but is largely capped to prevent donor kidneys exiting the kidney donor pool, as those waiting for a kidney alone have much longer

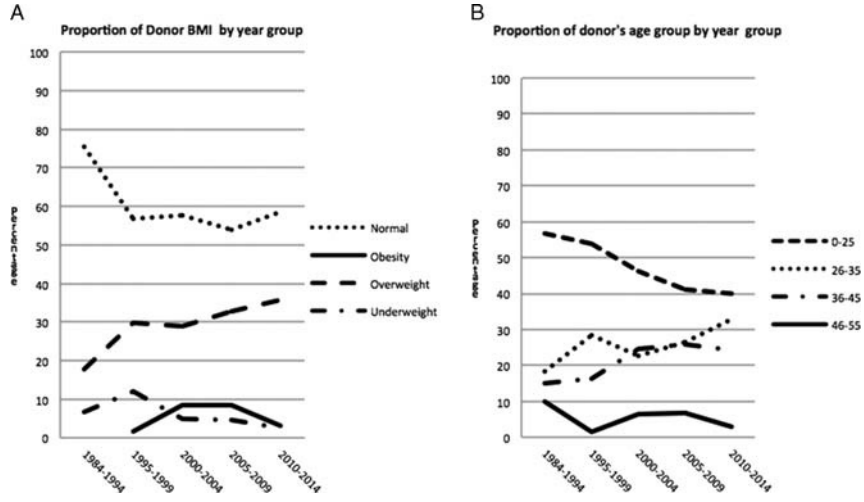

FIGURE 1. Distribution of donor characteristics over time.

TABLE 2.

Distribution of donor cause of death by age group

Cause of Death	4-25, N (%)	26-35, N (%)	36-45, N (%)	46-55, N (%)	Total, N (%)
Cerebral hypoxia/ischemia	27 (10)	16 (11)	12 (10)	1 (6)	56 (10)
Cerebral infarct	4 (1)	7 (5)	5 (4)	1 (6)	17 (3)
Intracranial hemorrhage	30 (11)	29 (20)	39 (31)	7 (43)	105 (19)
Non-neurological condition	11 (4)	3 (2)	1 (1)	0 (0)	15 (3)
Other neurological condition	7 (3)	2 (1)	0 (0)	0 (0)	9 (2)
Traumatic brain injury	194 (71)	87 (60)	67 (54)	7 (43)	355 (64)
Total	273 (49)	144 (26)	124 (22)	16 (3)	557 (100)

$P < 0.001$.

wait times. Extended criteria donors are not used in the pancreas transplant program. There were a small percentage of donors (5%) who were older than 45 years, but this proportion had not increased, presumably because of adherence to these national guidelines. The proportion of older donors was similar to those in the United States.[13] Several studies reported that older donors (older than 45 years) were associated with increased perioperative complications and significantly poorer long-term graft survival and function, but this finding is not universal.[4,14–16] Pediatric donors were found to have the same or better outcomes compared with adult donors despite an assumed lesser islet cell mass and greater surgical technical difficulties.[17,18]

Our results showed that donor BMI has increased over time. The most likely explanation for this is a reflection of the increase in BMI in the general population.[13,19] The proportion of overweight or obese adults in the general population has increased in recent decades; from 57% in 1995 to 61% in 2007 to 2008 and 63% in 2011 to 2012. However, only 5% of Australasian pancreas donors were obese compared with 11% of pancreas donors in the United States.[20] Donor BMI is a known risk factor affecting pancreas graft utilization and survival outcome,[21] although it is thought to have less impact on graft survival than donor age.[22] The reasons for the observed poorer outcomes from obese donors are not precisely known. Fat necrosis and infection in poorly preserved peripancreatic fat or higher rates of subclinical diabetes in obese donors are possible contributing factors.[23] The decision to retrieve donor organs after donation referral is made by a multidisciplinary team in Australia and New Zealand, so the influence of surgical expertise on donor retrieval is unlikely to be a factor in the changing epidemiology of donors over time. There is also regular turnover of organ retrieval team members as part of training, ensuring relative stability of expertise on teams through time. The discard rate of any organs in Australia and New Zealand is very low to negligible. In Australia in the 2 years 2013 to 2014, there was 1 pancreas donor abandoned during retrieval, and 0 pancreata discarded after retrieval.

The proportion of hypertensive donors has decreased over time which could be due to the declining prevalence of untreated hypertension in the general population and also because it is unlikely that clinicians would recommend a hypertensive patient as a donor. Since 1980, the prevalence of hypertension has decreased markedly for both males and females in Australia: the proportions of men aged 25 to 34 years and 35 to 44 years with high blood pressure have more than halved from 28.5% to 12.1% and 40.2% to 17.7%, respectively, from 1980 to 2011-2012 and have decreased for women with the same age groups from 18.4% to 12.2 and 44.0% to 22.1% during the same period.[24] Hypertensive donors are considered to be expanded criteria donors (ECD) for kidney transplantation. However, transplantation of expanded criteria kidneys yields a substantial survival advantage over maintenance on dialysis.[25] The transplantation of ECD kidneys has increased steadily over the past decade.[26] The relationship between pancreas transplant survival and donor hypertension has not been thoroughly explored as yet.

Nonsmoking status is not a criterion for pancreas procurement in Australia and New Zealand. However, prevalence of cigarette smoking has decreased dramatically in Australia and New Zealand, and is mirrored in pancreas donor profiles. Smoking rates fell from 22.4% in 2001 to 2002 to 16.3% in 2011 to 2012 in the general population.[19] Candidates may not be considered for donation in some centers in the United States unless they have been tobacco free for at least 8 weeks before donation.[27]

Approximately two thirds of donors showed serological evidence of CMV exposure in our study. Again, this appears to reflect the prevalence of exposure in the general population.[28,29]

Donor terminal creatinine levels have decreased over time in our cohort. Whether kidneys from high terminal creatinine donors are "marginal" and eligible for transplantation or should be discarded is still controversial. Elevated serum creatinine may reflect acute kidney injury which may be largely reversible, and not chronic kidney disease. Previous studies investigating donors with higher terminal creatinine are contradictory. One study reported similar 5-year graft survival rates for recipients of donors with higher and lower terminal creatinine,[30] whereas another study reported statistically significant decrease in graft survival for aged donors (≥55 years) with lower serum creatinine (<80 mL/min).[31]

Cause of death has also changed over time. This might be due to the association between the cause of death and age ($P < 0.001$; see Table 2). Cerebrovascular or nontraumatic causes of donor brain death are associated with a high risk of technical failure. Pancreas transplants from DCD are still rare. There has been a reluctance to use organs from hemodynamically unstable donors or DCD.[32] However, more recently, pancreas transplants procured from DCD donors have reported comparable outcomes to those procured after brain death.[33] The proportion of DCD in the United States has increased steadily in recent years accounting for over

4% of pancreas donations in 2010.[34] In our cohort, there were only 4 DCD retrievals, although 2 in 2014 support an expectation that the number of DCDs will increase over time.

In conclusion, donor characteristics have changed over time, mostly reflecting changes in the general population. We expect cause of death may change over time as DCDs become more accepted. Further work will examine whether the donor characteristics of our cohort are associated with graft or patient survival.

ACKNOWLEDGMENT

The authors thank all staff at the ANZIPTR registry and at contributing units for the data in ANZIPTR that we analysed (anziptr.org)

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