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# Pancreas transplantation using compatible but non-identical ABO blood group donors

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**Running head: Non-identical ABO pancreas transplant**

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**ABSTRACT**

There are limited data on the outcomes of pancreas transplants using ABO non-identical but compatible (NIC) donors.

**Methods:** A review of all pancreas transplants from a single institution from 01/2003 to 07/2016 (n=606) revealed 41 recipients of a NIC donor pancreas which were matched for age, race, gender, year and type of transplant with 41 ABO identical cases. Groups were compared for allograft survival, incidence of acute cellular rejection (ACR), length of hospital stay, 3-month readmissions and transfusion requirements. Serum haptoglobin and Lactate dehydrogenase were used to identify hemolysis in patients requiring repeated transfusions without overt blood loss.

**Results:** The 1-year graft survival was 100% and 88% in the study and control groups. In the study group, 6/41(14%) developed hemolysis, all of which were ABO O into A. All responded to donor blood type specific transfusions. **Discussion:** There are limited data on outcomes of solid organ transplant using NIC donors with almost none specifically addressing pancreas transplantation. In this study, graft survival was similar but 14% developed hemolysis, which was transient and treated with transfusion of donor blood type specific blood. **Conclusion:** NIC pancreas transplants have similar graft survival compared to ABO identical. Hemolysis may occur so some caution is required.

**KEY WORDS**

Pancreas transplantation

ABO blood group

Non-identical blood group transplantation

**INTRODUCTION**

Pancreas transplantation is an established treatment option for patients with type 1 diabetes mellitus (T1D) as well as select patients with type 2 diabetes mellitus. In the United States, 1.25 million people have T1D including about 200,000 youth (< 20 years old) and over a million adults (> 20 years old) [1]. Despite the high prevalence of T1D and improving transplant outcomes, the number of pancreas transplants have declined over the last decade[2-4]. In the year 2016, only 1013 pancreas allografts were transplanted (798 simultaneous kidney and pancreas (SPK) and 215 isolated pancreas transplants), which is down from a peak of 1484 pancreas transplants in 2004. This represents a 32% decrease[5].

The ABO blood group is the most important of all the blood group systems. There are four different ABO blood groups (see Table1), determined by whether or not an individual's cells carry the A antigen, the B antigen, both A and B antigens (AB) or neither (O). Normal healthy individuals, from early in childhood, develop antibodies against A or B antigens that are not expressed on their own cells. Recipients may receive organs from donors with the same or compatible blood types, meaning to which they do not have preexisting antibodies. Additionally, there are also potentially compatible combinations that involve the donor blood type A2 and there are instances where incompatible transplants are acceptable, but this is beyond the scope of this report.

There are numerous studies describing utilization of ABO non-identical but compatible (NIC) donors for heart [6, 7] and lung transplantation[8,9]. Most of these studies have shown no statistically significant difference in long term graft survival

among identical and NIC transplants. There are emerging studies regarding

intestine transplantation that may suggest that NIC intestine/multi-visceral

transplants may have higher rates of rejection[10]. Kim et al reported comparable

outcomes for ABO NIC and identical liver transplants[11]. Numerous reports have been

published documenting hemolysis in NIC liver, kidney and intestine transplants[12-14].

However, there is no data on the outcomes of pancreas transplants using NIC

donors except for a single case report of passenger lymphocyte syndrome after SPK

transplantation[15]. Currently, the United Network for Organ Sharing (UNOS) / Organ

Procurement and Transplantation Network (OPTN) policy is to only allocate SPK

allografts according to certain compatible blood types (Table 2). Specifically, blood

type O donors are only shared with NIC donors in situations where the recipient is

highly sensitized (calculated panel reactive antibody (CPRA) ≥80%) and has a zero

antigen human leukocyte antigen (HLA) mismatch. Similarly, blood group B donor

organs are exclusively shared with ABO identical recipients. Note again that these

policies apply exclusively to SPK allocation, with broader sharing across all

compatible ABO groups for isolated pancreas transplants such as pancreas after

kidney (PAK) and pancreas transplant alone (PTA), but currently the vast majority of

pancreas transplants performed in the United States are SPKs. These combinations

were intended to mirror kidney allocation, where there is such a significant

discrepancy between number of candidates waiting and number of organs available

that certain blood types and demographics would be significantly disadvantaged if

these limits were not set. For pancreas transplantation, however, where the volumes

are small and decreasing, it is unfortunate when there are situations where a

pancreas allograft could be transplanted if a suitable recipient were identified but yet

the donor organ is wasted. In fact, OPTN policy 5.4.E "Allocation to Candidates Not

on the Match Run" specifically addresses allocating an organ to a recipient that is not on the match run (as would be the case for many NIC donors) in order to avoid wasting a donor organ (in this case the pancreas). Nonetheless, this is contrary to the existing SPK allocation policy, which would require modification. Broader use of blood group NIC pancreas allografts may encourage local use of SPK allografts, which is currently the single best opportunity to place a pancreas allograft, and may lead to greater utilization of this scarce and underutilized resource. The goal of this study was to retrospectively review a single center's experience with NIC donors specifically to ensure the safety of this approach as the community moves toward embracing broader allocation of pancreas allografts across compatible ABO blood types.

**Materials and methods**

A retrospective analysis of medical record data at a single institution from January 2003 to July 2016 revealed a total of 606 recipients of a SPK, PAK or PTA. Inclusion criteria for the study were all candidates aged more than 18 years old who received a pancreas transplant from a NIC ABO blood group donor. The analysis revealed 41 recipients of a NIC donor pancreas. They were matched for demographic variables such as age, race, gender, year of transplant and type of transplant with 41 ABO identical pancreas transplants.

A review of medical history revealed that 4 patients had hypothyroidism, 3 had rheumatoid arthritis and 2 were on anticoagulation for hyper-coagulable states in the study group. In the control group, 3 patients had hypothyroidism, 1 had Grave's

disease and 2 were on anticoagulation for hyper-coagulable state and atrial fibrillation. However, none had any past medical history of hemolytic diseases.

Donor organs were procured in a standard fashion as described previously[16]. The recipient operation was performed through a midline incision. The pancreas was routinely positioned with the tail toward the pelvis and the head and duodenum oriented superiorly in order to facilitate the enteric anastomosis. Systemic venous drainage was performed to the right common iliac vein or to the vena cava. Arterial perfusion of the allograft was routinely established from the right common iliac artery. All pancreas allografts were drained enterically using a stapled technique as described elsewhere[17]. For SPK, the pancreas and kidney were typically placed ipsilaterally on the right side as described elsewhere[18].

The immunosuppression protocol consisted of induction with rabbit anti-thymocyte globulin (rATG) (5 mg/kg total dose) along with a single dose of rituximab (150 mg/m$^2$) and maintenance with tacrolimus (target trough 6-8 ng/ml) and sirolimus (target trough 3-6 ng/ml) for SPK and PAK with addition of mycophenolate mofetil 500 mg bid for PTA. Steroids were exclusively used as a premedication for rATG and were discontinued following induction in all recipients. All recipients received routine perioperative antibiotics, prophylaxis against cytomegalovirus with oral valgancyclovir and prophylaxis against Pneumocystis jiroveci pneumonia with trimethoprim and sulfamethoxazole, unless contraindicated. Systemic anticoagulation was not routinely used unless the patient had a specific history of a coagulation disorder.

Demographic and immunologic data collected included age, race, gender, HLA mismatch, class I, class II panel reactive antibody levels and CPRA level. The primary outcome for the study was blood product requirement for both cases and controls within the first year of transplant. The two groups were compared for secondary outcomes such as incidence of acute cellular rejection (ACR); length of hospital stay after transplant; number of readmissions within 3 months of transplant and projected 5year graft survival by Kaplan Meier analysis. Acute cellular rejection was diagnosed based on clinical presentation of elevated serum lipase and treatment included steroid boluses +/- rATG. Serum haptoglobin level, lactate dehydrogenase (LDH) and direct Coomb's test were used to identify hemolysis in patients needing repeated transfusions without overt blood loss.

Retrospective analysis of data on transplant patients at our center was reviewed and approved by the institutional review board. Statistical testing was performed on statistical software for the social sciences (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

**RESULTS**

The data was available for all patients in the study and control groups. The minimum follow up was 6 months. There were 41 recipients of a NIC pancreas transplant. Of these, 13 received an SPK,14 PAK and 14 PTA.  These were matched for age, race, gender, year of transplant and type of transplant with 41 ABO identical pancreas transplants.

The median age of the recipient was 43 years in the study group and 46 years in the control group with 44% males and 56% females in both cohorts. 95% of patients in the control group and 98% in the study group were Caucasian. The two groups were comparable for years of diabetes prior to transplant (29 years in the study group and 31 years in the control group) and body mass index (24.9kg/m$^2$ in the study group and 24.8 kg/m$^2$ in the control group). Patients were comparable for immunologic matching with a median of 4HLA antigen mismatch in both groups and median CPRA of 76% in study versus 83% in control group (Table 3). Three out of the 41 in the study group had a zero antigen mismatch. Of the 3, only one had a CPRA >80%. One patient in the study group had a positive T-cell cross-match with no donor specific antibody on high definition assay whilst no one had a positive B-cell cross-match in either of the groups.

In the study group, 3 patients had heparin related bleeding in the early post-operative period. One patient had Parvo B19 virus associated anemia and another patient developed gastrointestinal bleeding on post-operative day 6. One patient in the control group had an acute gastrointestinal bleed several weeks prior to the transplant. There was no statistically significant difference in the pre-operative hemoglobin (Hb) between the study group (Median Hb 12.4g/dl, mean±SD 12.7±2.1 g/dl) and controls (Median Hb 12.2g/dl, mean±SD 12.3±21.6 g/dl) (p value=0.10).

The mean number of units of packed red blood cell (PRBC) transfusions in the first year of transplant in the study group was 5.8 units, compared to 4.5 units in the control group (p>0.05). Six of 41 patients (14%) in the study group had hemolysis as evidenced by elevated LDH, decreased haptoglobin level and a positive Coomb's

test. All of these were donor blood type O into recipient blood type A transplants. Within the study group the mean number of units of transfused PRBCs within the 1st year for those with evidence of hemolysis was 9.3 and for those without hemolysis was 4.9 units. (p value =0.7) The patients with hemolysis did require more PRBC transfusions; however the small sample size limits us from drawing any significant conclusions from the data. None of the patients in the control group had any evidence of hemolysis or a positive Coomb's test during the duration of the study.

The average length of hospital stay after transplant was 8 days in the study group and 6.5 days in the control group (p>0.05). The rate of re-admission to hospital within the first 3 months after transplant was 55% and 40% in study and control groups (p>0.05). There was 1 case of ACR in the control group while none were seen in the study group (Table 4). The median 1 year graft survival by Kaplan-Meier was 100% in the study group and 88% in the control group (p<0.05). (Fig 1)

**DISCUSSION**

There are variable data on outcomes for liver, kidney, heart, lung and intestine transplantation using NIC donors[6-14]. There is, however, no data regarding pancreas transplantation using NIC donors. Currently the UNOS pancreas transplant committee is investigating options to allow broader allocation of ABO NIC SPK transplantation. Currently, the allocation system allows for blood group O donor organs to be utilized for blood group A, B or AB recipients only if the recipient has a zero antigen HLA mismatch and a CPRA greater than or equal to 80 percent and sharing of blood group A (but not B) donors for AB recipients. Additionally, the UNOS

pancreas committee recently identified an error in allocation programming which has since been corrected that allowed sharing of blood group B donors with AB recipients. It was in discussing this issue, and specifically the pancreas allografts that were transplanted in this setting that otherwise would likely have been wasted, that the concept of eliminating all ABO barriers to pancreas transplantation was brought up. This limitation was, after all, not based on any medical or clinical concerns for recipient outcome. Our study had patients who were not zero antigen mismatches and/or CPRA >80%. The long-term outcomes were comparable between the control and the study groups. This study, however, is limited by the relatively small size of the patient population and by the study design of a single center retrospective study. Nonetheless, this may be considered as a proof of principle and an initial step in considering pancreas transplantation across blood types outside of the current OPTN guidelines. Utilization of O donors for A, B or AB recipients could theoretically put patients with blood type O listed for a kidney alone at a disadvantage by taking a kidney away from the donor pool. However, SPK recipients are legitimately kidney transplant candidates with identical listing criteria to those on the isolated kidney transplant waiting list. This is in contrast to other combinations of kidney transplant with extra-renal organs where these criteria do not need to be met. The waiting list mortality rate is highest for SPK candidates as compared to kidney alone listed patients for other indications[19]. Patients listed for SPK also have been shown to have higher life years from transplant (LYFT) than kidney recipients[20]. Thus, utilization of pancreas and kidney transplantation for this patient population can be considered as an optimal utilization of a limited resource.

Allo-immune mediated hemolysis (AIH) is a known phenomenon in NIC stem cell and solid organ transplantation and is caused by donor derived lymphocytes producing antibodies against recipient blood group antigens[21, 22]. The risk for developing hemolysis is greatest for the ABO group O into A combination[21]. Antibodies against minor blood group antigens like Rhesus and Lewis antigens can also cause hemolysis[23-25]. Clinically significant hemolysis requiring blood transfusions has been reported to occur in about 70%, 40% and 17% in ABO NCI heart-lung, liver and kidney transplants respectively[21, 23]. The hemolysis is usually transient, occurring within the first 3 months after transplant, and can be treated with monitoring and transfusion of donor blood type specific PRBCs. Rarely, additional immunosuppression like corticosteroids, rituximab, immunoglobulin (IVIG) or plasmapheresis may be required[14]. In some instances, severe hemolysis can cause disseminated intravascular coagulation leading to organ failure and mortality. In our series, 14% of pancreas transplants manifested signs of hemolysis. All of these recipients were of blood type A and received blood type O donor organs. The hemolysis rate was less in this series when compared to other solid organ transplant recipients. The induction protocol with rATG and rituximab may have played a role in the incidence of hemolysis in this series. rATG usage for induction immunosuppression has been reported to cause a myriad of reactions including cytokine release syndrome, neutropenia, thrombocytopenia, hemolytic anemia and serum sickness[26]. Anemia may occur through different mechanisms in this setting including hemolysis, bonemarrow suppression or immune dysregulation. None of the patients needed additional therapies other than PRBC transfusions and the transfusion requirements for the identical ABO and the NIC ABO groups were

comparable. This may suggest that transplant across blood types is likely safe outside of the current immunological guidelines for organ allocation.

**CONCLUSION:** ABO compatible and ABO identical pancreas transplants have similar outcomes even when organs are used without a zero antigen mismatch or a CPRA > 80%. AIH may occur after such transplants and is frequently self-limited and can be managed with donor type specific blood transfusion and monitoring.

## ACKNOWLEDGEMENTS

## DISCLOSURE

**ABBREVIATIONS**

ACR = acute cellular rejection

CPRA = calculated panel reactive antibody

HLA = human leukocyte antigen

LDH = lactate dehydrogenase

NIC = ABO non-identical but compatible

PAK = pancreas after kidney transplant

PRBC = packed red blood cells

PTA = pancreas transplant alone

rATG = rabbit anti-thymocyte globulin

SPK = simultaneous kidney and pancreas transplant

T1D = type 1 diabetes mellitus

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**Table 1. ABO blood group antigen and antibody distribution in blood**

| Blood Type | Antibodies in circulation | Compatible blood type |
|---|---|---|
| O | Anti-A, anti-B, anti AB | O |
| A | Anti-B | A, O |
| B | Anti-A | B, O |
| AB | None | AB, A, B, O |

**Table 2. Allocation of Kidney-pancreas by blood type**

| Donor blood type | Blood type of the eligible candidates |
|---|---|
| O | O or Blood type A, B or AB if the candidate has a zero antigen mismatch with the donor and a CPRA ≥80% |
| A | A or AB |
| B | B |
| AB | AB |

**Table 3. Comparison of demographics and immunologic data for matched ABO identical and ABO compatible pancreas transplant patients.**

| | ABO identical | ABO compatible, not ABO identical | p-value |
|---|---|---|---|
| **OVERALL (number)** | 41 | 41 | |
| | | | |
| **Recipient demographics** | | | |
| Years of diabetes (mean, median) | 31 | 29 | 0.22 |
| Gender: Male (percent) | 44% | 44% | 1.00 |
| Race: White (percent) | 95% | 98% | 1.00 |
| Age (years, median(range)) | 46 | 43 | 0.69 |
| Body mass index (median) | 24.8 | 24.9 | 0.86 |
| | | | |
| **Transplant type** | | | |
| Simultaneous pancreas and kidney | 32% | 32% | 1.00 |
| Pancreas after previous kidney | 34% | 34% | |
| Pancreas transplant alone | 34% | 34% | |
| | | | |
| **Immunologic matching** | | | |
| Class I panel reactive antibody: 0% | 88% | 78% | 0.15 |
| Class II panel reactive antibody: 0% | 88% | 93% | 0.25 |
| Calculated panel reactive antibody: percent 0% | 83% | 76% | 0.48 |
| T-cell crossmatch positive | 0% | 2% (1) | 1.00 |
| B-cell crossmatch positive | 0% | 0% | 1.00 |
| Human leucocyte antigen mismatch: median number (mean) | 4 (4.2) | 4 (3.9) | 0.40 |

**Table 4. Comparison of clinical outcome measures for matched ABO compatible and ABO identical pancreas transplant patients .**

| | ABO identical | ABO compatible, not ABO identical | p-value |
|---|---|---|---|
| | n=41 | n=41 | |
| **Clinical outcomes** | | | |
| Acute cellular rejection within first year | 1 (2.4%) | 0 (0%) | 1.00 |
| Length of hospital stay (days) | 6.5 | 8 | 0.69 |
| Any readmission within 3 months | 40% | 55% | 0.34 |
| Peak post-transplant amylase | 220 | 241 | 0.61 |
| Peak post-transplant lipase | 138 | 135 | 0.65 |
| **Transfusion requirement (mean, median)** | | | |
| Packed red cells intraoperative | 0.4, 0 | 0.5, 0 | 0.74 |
| Packed red cells (first year) | 4.5, 2 | 5.8, 4 | 0.54 |
| Fresh frozen plasma (first year) | 0.4, 0 | 1.3, 0 | 0.36 |
| Platelets (first year) | 0.2, 0 | 0, 0 | 0.10 |
| 1-year graft survival | 88% | 100% | 0.05 |
| Median survival by Kaplan-Meier (months) | 110 | 119 | 0.27 |

**Figure 1. 5 year survival for matched ABO compatible and identical donor pancreas transplant recipients.**



Kaplan-Meier pancreas graft survival by case-control matching