

Short- and Long-Term Outcomes of Every Graft Recovered During a Multi-Organ Procurement Procedure Including the Intestine

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ABSTRACT

Background. The development of intestinal transplant (Tx) programs introduces thymoglobulin donor treatment as well as an almost complete warm dissection of the abdominal organs to allocate them to different recipients. Our aim is to assess the reproducibility and feasibility of the surgical technique of multi-organ procurement with the use of thymoglobulin donor pre-treatment and report the short- and long-term outcomes of every graft harvested as part of multi-organ procurement (MTOp), including the intestine.

Methods. Data were collected of all organs harvested from MTOp, including the intestines allocated to our center from March 2006 to July 2011. Data from 92 recipients and 116 organs procured from 29 MTOp were analyzed. Twelve hearts, 2 lungs, and 1 cardio-pulmonary block were transplanted; primary graft dysfunction developed in 4 of the 12 hearts and in the cardio-pulmonary block.

Results. The survival rate was 75% and 100% for hearts and lungs, respectively. Nineteen livers, 9 kidney-pancreas, 19 kidneys, and 29 intestines were transplanted. Delayed graft function (DGF) of the pancreas developed in 3 of 9 kidney-pancreas, and the other 3 exhibited DGF of the kidney; 4 of 19 Tx kidneys had DGF. The survival was 84%, 78%, 95%, and 65.5% for livers, kidney-pancreas, kidneys, and intestines, respectively.

Conclusions. Organs procured during MTOp including the intestine can be safely used, increasing organ availability and transplant applicability without compromising allocation, quality, and long-term results of the non-intestinal-procured organs.

To improve organ use in different recipients from a single donor, intestine transplant programs have encouraged the use of an almost complete warm dissection during the procurement of the abdominal organs, as proposed by Abu-Elmagd [1]. Some centers, including our own, have proposed the use of anti-thymocyte donor treatment before intestine procurement to minimize the risk of graft-versus-host disease (GVHD) based on the hypothesis that thymoglobulin might reduce donor-to-recipient lymphocyte trafficking after reperfusion of the intestinal graft.

Some recent reports on basic research describe other potential benefits of the use of anti-thymocyte donor treatment before harvesting, reducing the degree/incidence of post-transplant renal dysfunction in rodents; however, this effect has not been shown in humans yet [2].

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With the development of the intestine transplant program at our institution in 2006, the need to use thymoglobulin as part of the procurement was submitted before and approved by the Scientific Committee of the INCUCAI (*Instituto Nacional Central Unico Coordinador de Ablación e Implante*, National Procurement and Transplant Institute). The potential impact of the well-known pulmonary side effect caused by cytokine release syndrome as well as the effect on the other organs procured aroused some concerns.

To assess the reproducibility and feasibility of the surgical technique of multi-organ procurement, with the use of thymoglobulin donor pre-treatment, we evaluate the outcomes of each individual organ procured as part of the multi-organ procurement (MTOp), including the intestines. We performed a multicenter study, collecting data from 29 transplant programs nationwide. All of them received the organs procured from intestine donors allocated to our center between March 2006 and July 2011.

MATERIALS AND METHODS

We conducted a retrospective, multicenter study including all the centers involved in the engraftment of organs procured from MTOp, including the intestines, allocated to our center. Both donor and transplant center data were provided by the INCUCAI. A survey was sent to all the participating programs to collect follow-up data of the recipients, including graft survival, patient survival, delayed graft function (DGF), primary graft dysfunction (PGD), organ-specific laboratory tests, survival, and mean follow-up time.

To unify the criteria, for hearts, PGD was defined as severe dysfunction of the cardiac allograft featuring hypotension, low cardiac output, and high filling pressures in the absence of secondary causes of graft failure such as hyperacute rejection, refractory pulmonary hypertension, or technical surgical problems [3]. For lungs, PGD was defined as a PaO₂/FiO₂ coefficient below 200 mm Hg during the first 72 hours or assisted mechanical ventilation for more than 5 days for primary lung dysfunction [4]. For livers, PGD was defined as non-life-sustaining function of the liver requiring retransplantation or leading to death within 7 days after orthotopic liver transplant, and DGF was defined as the presence of a serum ALT >2000 IU/L and prothrombin time values of at least 16 seconds (<40% activity) between day 2 and day 7 after liver transplantation [5]. For pancreas, DGF was defined as the need for scheduled exogenous insulin on discharge after a technically successful transplant. PGD was defined as the inability to reach insulin independence at any time after transplant [6]. For kidneys, DGF was defined as a form of acute renal failure resulting in posttransplantation oliguria and requiring at least one dialysis session within the first 7 days after transplantation [7]; for intestines, PGD was considered when graft loss occurred within the first 2 weeks after transplantation for neither technical nor immunologic reasons [8], and DGF was defined as the impossibility to achieve full enteral nutrition by 2 to 6 weeks after transplant [9].

In intra-thoracic transplants, the cardio-pulmonary block implanted was analyzed independently from the hearts and lungs.

The mean follow-up time for heart recipients was 43 \pm 18 months; for lung recipients, 39 \pm 0 months; for liver recipients, 33 \pm 21 months; for kidney-pancreas (KP) recipients, 32 \pm 20 months; for kidney recipients, 36 \pm 22 months; and for intestine recipients, 30 \pm 21 months.

Follow-up laboratory testing and frequency as required by the survey were, for liver recipients, serum bilirubin and transaminase levels (24 hours, 1 week and 1 month after transplant) and prothrombin time (day 2, day 4, and day 7 after transplant); for kidney-pancreas recipients, serum lipase, amylase (24 hours and 1 month after transplantation), and creatinine levels (48 hours, 1 week and 1 month after transplant); and for kidney recipients, creatinine levels (48 hours, 1 week and 1 month after transplant). All the organs were transplanted to ABO-compatible recipients. Retrospective cross-match and human leukocyte antigen (HLA) matching with the recipients were used for heart, pancreas, and kidney transplants. HLA matching with the recipients was prospectively performed for all the intestines and pancreases implanted at our institution.

The demographics, cause of death, time on mechanical ventilation, and last laboratory values of the donors are summarized in Table 1. All the donors were pre-treated with methyl-prednisolone (adults: 1 g/kg; children: 20 mg/kg) and 1.5 mg/kg of thymoglobulin starting 30 minutes before going into the operating room, given for a 2- to 3-hour period before cross-clamping. Every team involved in these procedures was informed of and agreed on the need for thymoglobulin administration at the time of organ allocation.

Table 1. Donors Demographics, Characteristics, Cause of Death, Mechanical Respiratory Assistance Time, and Actual Terminal Laboratory Values

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Sex	
Male	14
Female	15
Age (y)	11.9 (0.11–39.5)
Location	
Local	11
Regional	2
National	16
Cause of death	
ACV hemorrhagic	7
Meningitis	4
TEC transit accident	7
TEC gunfire	6
TEC domestic accident	2
Cardiac arrest	1
CO intoxication	1
Airway obstruction	1
MRA time (days)	4.47 (0.95-23)
Weight (kg)	36.71 (5-80)
Length (cm)	125.62 (62-175)
Blood type and Rh	
O+	22
A+	7
Laboratory values	
Ph	7.42 ± 0.10
PO ₂ (mm Hg)	240.30 ± 128.06
Na (mEq/L)	147 ± 12
K (mEg/L)	4.05 ± 0.84
Urea (mg/dL)	33 ± 17
Creatinine (mg/dL)	0.75 ± 0.54
Glucose (mg/dL)	134 \pm 41
Amylase (UI/L)	110 \pm 122
Bilirubin (mg/dL)	0.65 ± 0.46
AST (UI/L)	52 ± 48
ALT (UI/L)	38 ± 26

All the donors were given a selective digestive decontamination solution together with an antibiotic preparation (amphotericin B/mycostatin, tobramycin/gentamicin, and polymyxin E), which was administered through a nasogastric tube without lavage at the time of donor surgery. University of Wisconsin solution was used for both in situ flushing and cold storage.

Organs were allocated according to the guidelines drafted by the INCUCAI.

Statistical analysis was performed with the use of SPSS software (SPSS Inc, Chicago, Ill). Continuous variables are reported as a mean \pm standard deviation. Graft survival curves were generated by means of Kaplan-Meier (KM) methods [10].

RESULTS

Twenty-nine transplant programs, based in 18 hospitals nationwide, participated in the survey. From 29 MTOp (10 adult donors and 19 children), 127 of 129 organs procured were implanted in 101 recipients. Five intra-thoracic and 19 abdominal transplantation programs from Argentina accepted organs harvested according to the previously depicted principles of multiple organ procurement [1,11–13] and thymoglobulin donor pre-treatment. Twenty-four of 29 programs (83%) answered the survey, reporting data from 92 recipients of 116 organs, including those in our final

cohort used for analysis (Fig 2). From these 92 recipients, 50 were female (54.3%) and 42 were male (45.7%); the mean age was 25.1 years (0.1–67).

Intra-Thoracic Transplants

Twelve hearts, 2 lungs, and 1 cardio-pulmonary block were implanted in 5 programs. Cold ischemia time was 206 ± 51 minutes for hearts, 314 ± 15 minutes for lungs, and 256 minutes for the cardio-pulmonary block. PGD developed in 4 of 12 hearts and in the cardio-pulmonary block; 1 of these 4 hearts was recovered. Seventy-five percent of the hearts and 100% of the lung transplant recipients were alive at the end of the study (Table 2). The KM survival curve for the heart programs shows a 75% survival rate at 5 years (Fig 1). The mean follow-up time for heart recipients was 43 ± 18 months and for lung recipients was 39 ± 0 months.

Abdominal Transplants

Seventy-six transplants were performed including liver, kidney-pancreas, kidney, and intestine. None was rejected for anatomical reasons.

Liver Grafts. Nineteen liver allografts (15 whole livers and 4 splits) were implanted. Cold ischemia time was 441 \pm

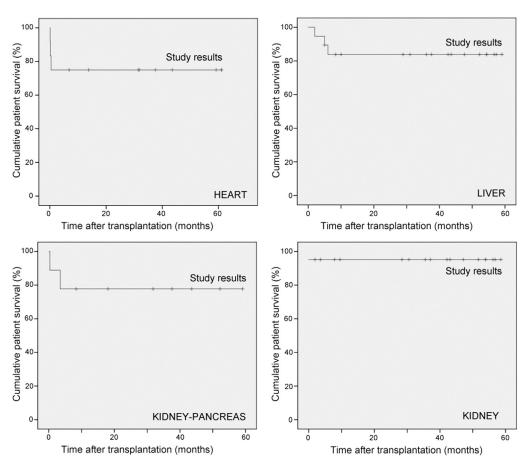


Fig 1. Kaplan-Meier survival curve of grafts within the first 5 years after transplantation for study results.

Intra-Thoracic Transplantation Programs							
Organ	Patients	PGD	Recovered	Organ Survival	Patient Survival		
Heart	12	4/12 (33.3%)	1/4 (25%)	9/12 (75.0%)	9/12 (75.0%)		
Lung	2	0 (0%)	0 (0%)	2/2 (100.0%)	2/2 (100.0%)		
CP Block	1	1 (100%) [†]	0 (0%)	0/1 (0.0%)	0/1 (0.0%)		

Table 2. Intra-Thoracic and Abdominal Transplantation Programs

Abdominal Transplantation Programs							
Organ	Tx	PGD	DGF	Organ Survival	Patient Survival		
Liver	19						
Splits	4	0 (0.0%)	0 (0.0%)	4/4 (100.0%)	4/4 (100.0%)		
Whole	15	0 (0.0%)	0 (0.0%)	12/15 (80.0%)	12/15 (80.0%)		
Kidney-Pancreas	9						
Kidney	9	0 (0.0%)	3/9 (33.3%)*	7/9 (78.0%)	7/9 (78.0%)		
Pancreas	9	3/9 (33.3%)*	0 (0.0%)	6/9 (66.7%)	7/9 (78.0%)		
Kidney	19	1/19 (5.26%)	4/19 (21.1%)	17/19 (89.5%)	18/19 (94.7%)		
Intestine	29						
Isolated	22	0 (0.0%)	0 (0.0%)	17/22 (77.3%)	18/22 (81.8%)		
+ Liver	2	0 (0.0%)	0 (0.0%)	1/2 (50.0%)	1/2 (50.0%)		
Multivisceral	5	2 [£] /5 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		

Abbreviations: CP block, cardio-pulmonary block; PGD, primary graft dysfunction; DGF, delayed graft function. *On different recipients.

92 minutes. No PGD or DGF was reported. The mean serum bilirubin and transaminase peak levels within the first 48 hours after surgery were, total bilirubin = 8.20 ± 5.12 mg/dL, ALT = 2378 ± 2975 IU/L, AST = 1250 ± 1207 IU/L, which then fell rapidly to total bilirubin = 6.54 ± 7.19 mg/dL, ALT = 69.78 ± 61.09 IU/L, and AST = 150.6 ± 263.6 IU/L on the 7th day after transplant. The normal values at the end of the first month were total bilirubin = 1.48 ± 0.7 mg/dL, ALT = 30 ± 13.19 IU/L, and AST = 38.94 ± 24.62 IU/L. The prothrombin time was $79 \pm 13.83\%$ on day 2, $82 \pm 12.84\%$ on day 4, and $84 \pm 14.96\%$ on day 7. Three of the liver recipients (15.8%) died within the first year because of infectious diseases (intraabdominal abscess and peritonitis), although their grafts were still functional. The rest of the recipients (84.2%)

were alive at the end of the study (Table 2). KM survival rate for the 19 liver recipients was 84% at 60 months (Fig 1). The mean follow-up time for liver recipients was 33 ± 21 months.

KP Grafts. Nine KP transplants were performed, 1 in a pediatric patient with en bloc kidney + pancreas. Cold ischemia time was 561 ± 185 minutes. Serum lipase and amylase levels peaked within 48 hours after transplantation (amylase = 252 ± 134 IU/L; lipase = 253 ± 199 IU/L) and fell to normal levels by the end of the first postoperative month (amylase = 100 ± 52 IU/L; lipase = 88 ± 59 IU/L) in all the recipients. Creatinine levels peaked within 48 hours after transplant (5.89 ± 3.83 mg/dL), fell after 1 week (2.01 ± 2.75 mg/dL), were back to normal levels after 1 month (1.20 ± 0.45 mg/dL), and remained normal after 1

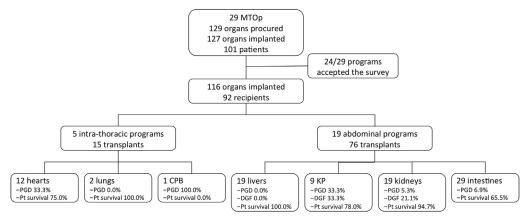


Fig 2. Flow diagram shows distribution of organs accepted and implanted. MTOp, multi-organ procurements; PGD, primary graft dysfunction; Pt, patients; DGF, delayed graft function; KP, kidney-pancreas.

[†]1 = PGD; 1 = sepsis/liver failure.

year (1.10 \pm 0.14 mg/dL). Three of the KP recipients required insulin for an average of 5 days (DGF, 33.3%); the other 3 presented DGF of the kidney (33.3%) and required hemodialysis. One of the DGF patients had to undergo removal of the pancreas graft because of a duodenal fistula and sepsis and died 1 week after transplant. One KP recipient had to undergo removal of the pancreas graft because of venous thrombosis but survived, another patient died of sepsis within the first year after transplant, and a total of 7 patients are alive (78.0%) (Table 2). KM survival rate for the 9 KP recipients was 78% at 60 months (Fig 1). The mean follow-up time for KP recipients was 32 \pm 20 months.

Kidney Grafts. Nineteen kidneys were implanted. Cold ischemia time was 885 ± 395 minutes. The 19 kidney recipients had a creatinine peak 48 hours after transplant $(6.79 \pm 2.60 \text{ mg/dL})$, which fell after 1 week $(4.19 \pm 2.74 \text{ mg/dL})$, came back to normal levels after 1 month $(1.25 \pm 0.59 \text{ mg/dL})$, and remained within the normal range at the end of the first year $(1.04 \pm 0.30 \text{ mg/dL})$. One kidney recipient had vein thrombosis and graft loss (PGD, 5.26%). Among the others, 4 of 19 had DGF (21.1%) and needed hemodialysis, and all but one (89.5%) had functional grafts at the end of the study (Table 2). KM survival rate for the 19 kidney recipients was 95% at 60 months (Fig 1). The mean follow-up time for kidney recipients was $36 \pm 22 \text{ months}$.

Intestine Grafts. All of the 29 retrieved intestine grafts were implanted in 28 patients (14 adults and 14 children) (22 isolated intestines, 2 combined liver-intestine, and 5 multivisceral, from which 1 was a multivisceral retransplantation en bloc with kidneys). Cold ischemia time was 478 ± 131 minutes. Nine of the 28 (32.1%) intestine recipients died (two of them were multivisceral recipients); 1 because of PGD of the liver and the other one because of sepsis leading to both liver and multiorgan failure. The other 7 died because of either GVHD (n = 1) or infectious diseases (n = 6).

Total parenteral nutrition was discontinued in all the survivors, and full enteric nutritional autonomy was achieved after 30 ± 14 days (Table 2). KM survival rate for the 29 intestine recipients was 65.5% at 60 months (Fig 1). The mean follow-up time for intestine recipients was 30 ± 21 months.

DISCUSSION

This study was conducted 5 years after initiating our intestine transplant program to assess the impact of the new procedure requiring a different donor approach and organ allocation system, aiming to answer some concerns from the Argentinean transplant community related to the use of preharvesting thymoglobulin donor treatment, mainly associated with the reported cytokine release syndrome and the potential side effects on the lung as target organ, and some technical aspects related to optimizing both organ and vessel allocation and sharing mainly between pancreas and intestine. Although some of these concerns were clarified by Abu Elmagd et al when they described the technical details

of the multi-organ procurement including the intestine, they did not report either the short- or long-term results of the other organs procured with the intestine.

Therefore, we proposed answers to these questions to ensure that the technique can be safely reproduced in our country to make the best use of a scarce resource and reach optimal organ procurement and long-term results within the international transplantation standards. To the best of our knowledge, this is the first report about the short- and long-term results of all organs harvested during an intestine procurement procedure.

Regarding the intra-thoracic organs procured from our series of donors, 25% of the transplanted hearts had PGD; however, 1 of 4 was able to recover and therefore the long-term survival rate was 75%. These results were comparable to the incidence of PGD and survival reported by Taylor et al, accounting for 40% of the mortality within the first 30 days after heart transplant and 18% of the mortality from the second month to the end of the first year [14] and comparable to the ISHLT guidelines reporting an incidence of PGD from 1.4% to 30.7% [15]. In the case of lungs, the incidence of PGD in recent studies has ranged from 11% to 57% [16,17], whereas in our case series it was 0%. The experience was not optimal in the reported case of a heart-lung transplantation due to the poor health status of the recipient.

None of the livers procured with the intestine, including the split grafts, had development of PGD, which is a lower rate as compared with international reports. The long-term survival for the livers (84%) did not differ from the results reported by the SRTR (81%) [18].

In terms of kidney transplant, it is important to highlight that allocation after procurement in Argentina differs from that in other countries. Therefore, regardless of the city where the procurement takes place, kidneys are shipped to Buenos Aires and then allocated. As a result, cold ischemia time is longer, with a reported incidence of DGF of 64.2% [19]. It is also important to underline that although all the intestines were procured from ideal donors, the same allocation system was used; for this reason, the mean ischemia time for isolated kidney transplants was 885 ± 395 minutes, which does not differ from the kidneys procured from donors in whom the intestine was not procured. However, the incidence of DGF was only 21.1%. This result is remarkably lower when it is compared with national DGF average kidney transplants in our country. On the basis of these results, we could hypothesize that the reduced incidence of DGF might be the result of a beneficial effect of thymoglobulin as pre-procurement donor treatment, as recently reported by Cicora et al [13] in a rat model and considered a clinical proof of principle. However, specific research and prospective studies should be conducted to validate this hypothesis.

Even for the intestines, PGD decreased from the previously reported 10% [20] to 0% in isolated or liver-combined transplants and to 6% in multivisceral transplants in this series.

Together with the introduction of this technique, we created a serum bank, and all intestine and pancreas

recipients in our institution were able to undergo prospective cross-match tests. Such a bank may be created in most regions of our country to optimize cold ischemia time, adding an extra benefit to the approach proposed for multiorgan procurement.

Only one intestine transplant recipient died of GVHD; the recipient had the risk factors for development of the disease. The patient was a boy who had undergone multivisceral re-transplant with splenectomy and had also received a kidney as part of the graft. Wu et al [21], from the University of Miami, reported that all patients with the characteristics described in our recipient had the highest risk for development of GVHD with a significantly lower long-term survival, 10% versus 50% at 50 months.

In summary, the current results prove that multivisceral procurement according to the protocol described is safe for all organs. The incidence of PGD or DGF did not differ from single-organ procurements. Furthermore, for some organs, such as livers or kidneys, results are better than those observed with a comparable donor in which the intestine was not used. Thymoglobulin could be safely used during multi-organ donor procurement, without compromising other organs.

When comparing KM long-term survival curves from our programs with results reported by UNOS, we found out that the survival rate at 5 years was higher for our liver and kidney programs—84% versus 65% and 95% versus 71%, respectively,—with comparable results for heart and KP programs (75% versus 70% and 78% versus 76%, respectively).

To conclude, organs procured during MTOp, including the intestine, may be safely used. Although longer organization time and team efforts are needed, both short- and long-term graft and patient survival rates are better than those obtained in regular procurement procedures without the intestines, as reported by national and international series. Further studies are essential to show whether PGD, DGF, and graft survival might be improved by the use of thymoglobulin in donors before procurement.

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