

Observational Study

Deceased donor organ procurement injuries in the United States

Tim E Taber, Nikole A Neidlinger, Muhammad A Mujtaba, Elling E Eidbo, Roxane L Cauwels, Elizabeth M Hannan, Jennifer R Miller, Anil S Paramesh

Tim E Taber, Indiana Donor Network, Indianapolis, IN 46202, United States

Nikole A Neidlinger, Donor Network West, San Francisco, CA 94583, United States

Muhammad A Mujtaba, Department of Nephrology, University of Texas Medical Branch, Galveston, TX 77550, United States

Elling E Eidbo, Roxane L Cauwels, Elizabeth M Hannan, Jennifer R Miller, Association of Organ Procurement Organizations, Vienna, VA 22182, United States

Anil S Paramesh, Tulane Transplant Institute, New Orleans, LA 70112, United States

Anil S Paramesh, Louisiana Organ Procurement Association, New Orleans, LA 70002, United States

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Correspondence to: Anil S Paramesh, MD, FACS, Tulane Transplant Institute, 1415 Tulane Ave, HC-5, New Orleans, LA 70112, United States. anil.paramesh@hcahealthcare.com
Telephone: +1-504-9880783
Fax: +1-504-9887510

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Abstract

AIM: To determine the incidence of surgical injury during deceased donor organ procurements.

METHODS: Organ damage was classified into three tiers, from 1-3, with the latter rendering the organ non-transplantable. For 12 consecutive months starting in January of 2014, 36 of 58 organ procurement organization's (OPO)'s prospectively submitted quality data regarding organ damage (as reported by the transplanting surgeon and confirmed by the OPO medical director) seen on the procured organ.

RESULTS: These 36 OPOs recovered 5401 of the nation's 8504 deceased donors for calendar year 2014.

A total of 19043 organs procured were prospectively analyzed. Of this total, 59 organs sustained damage making them non-transplantable (0 intestines; 4 pancreata; 5 lungs; 6 livers; 43 kidneys). The class 3 damage was spread over 22 (of 36) reporting OPO's.

CONCLUSION: While damage to the procured organ is rare with organ loss being approximately 0.3% of procured organs, loss of potential transplantable organs does occur during procurement.

Key words: Organ procurement; Deceased donations; Organ procurement organization; Organ injury; Organ transplantation

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Core tip: This study represents a unique report looking into the incidence of surgical injuries during deceased donor organ procurement. There is no other large scale study reporting this. This represents a multi-organizational study, collecting data prospectively over a period of a year. This study will hopefully help define the problem and contribute to the development of basic standards that organ procurement organizations can follow across the country.

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INTRODUCTION

Organ transplantation remains one of the enduring miracles of modern medicine. The ability to replace a dysfunctional organ with a functional allograft that returns the recipient to health is truly an impressive feat. Human organ transplantation essentially started in 1954 with the first successful kidney transplant^[1]. Early transplant successes were limited by the lack of availability of adequate immunosuppression. With the advent of cyclosporine in 1983, the modern era of transplantation began^[2]. Organ transplantation, since that time, has been limited less by the ability to maintain viability of allografts post-transplant than by the supply of transplantable organs^[3]. As most organ transplants are deceased organs, the willingness of potential donor families to agree to organ donation has become paramount. Despite the altruism of these families, over time, there has developed a mismatch of supply and demand with the current waitlist (April 2016) of patients for a solid organ transplant exceeding 121000. Hence, there has been an imperative to ensure that any organ procured should be uninjured during the procedure in

order to maximize utilization. Little data exists in the literature regarding procurement injury. The aim of this study was to determine the incidence of procurement injury in the United States. Organ procurement organization (OPO) system and to further stratify the impact of these injuries by developing a graded scoring system directly linked to the extent of loss.

MATERIALS AND METHODS

There are currently 58 OPOs in this country performing organ procurement. The Association of OPOs (AOPO) serves to unify these individual OPO's and to assist in the sharing of knowledge of best practices in the many tasks performed by the OPOs. Within each OPO, organ procurement is overseen by a medical director to whom each is extended an offer for membership within the AOPO medical council. It is within this medical council that, in 2013, a discussion culminated in the desire to ensure that the "gift of life" of an organ donation should be protected. The medical directors agreed upon a national standard of measurement of organ damage. These levels of damage were agreed upon and range from a level of "0" (no damage); level "1" (minimal damage sustained upon procurement requiring no intervention); level "2" (damage sustained upon procurement requiring some surgical repair but not rendering the allograft non-transplantable); and finally level "3" (damage sustained upon procurement rendering the allograft non-transplantable). These levels of damage would be reported by the transplanting surgeon and reviewed and agreed upon by the medical director of the procuring OPO in consultation with the medical advisory board within that OPO (as deemed necessary by the individual medical director).

After the aforementioned preliminary agreement was reached, this study commenced and included all deceased donors from whom solid organs were procured for transplantation from January 1, 2014 through December 31, 2014. All 58 OPOs were encouraged to prospectively collect data during this period. Data was sent to the AOPO national office where it was transferred to a database and separated by month and OPO. Data was collected for transplantable solid organs: Heart, lung, liver, kidney, pancreas and intestine. Data was subsequently analyzed in an organ-specific fashion. Only data collected for the entire 12 mo of the study was included for evaluation. As noted above, levels of damage were defined as class 1, class 2 or class 3. For each level 3 injury, a written description of the injury was provided to AOPO.

All data for this analysis were collected prospectively in our OPO database. Continuous variables are presented as mean/median. Number and type of organ procured at each OPO and class of injury were reviewed. Class of injury was expressed as 1, 2 or 3 and reported as a frequency at each OPO. Chi square test was used for categorical variables. A two-tailed *P* value of < 0.05 was considered to be significant. The program - graph pad

Table 1 Participating organ procurement organizations

Arkansas Regional Organ Recovery Agency
Donor Network West
Life Sharing - A Donate Life Organization
Donor Alliance Inc.
Life Choice Donor Services
Washington Regional Transplant Community
Life Alliance Organ Recovery Agency
Life Quest Organ Recovery Services
LifeLink of Florida
Legacy of Life Hawaii
Indiana Donor Network
Louisiana Organ Procurement Agency
New England Organ Bank
The Living Legacy Foundation of Maryland
Gift of Life Michigan
Life Source
Mid-America Transplant Services
Mississippi Organ Recovery Agency
Midwest Transplant Network
Carolina Donor Services
Nebraska Organ Recovery System
New Jersey Organ and Tissue Sharing Network
Live-On-NY
Lifebanc
Life Connection of Ohio
Lifeline of Ohio
Life Center Organ Donor Network
Life Share Transplant Donor Services of Oklahoma
Pacific Northwest Transplant Bank
Center for Organ Recovery and Education
Tennessee Donor Services
Life Gift Organ Donation Center
Southwest Transplant Alliance
Life Center Northwest
Wisconsin Donor Network
UW Organ and Tissue Donation

Table 2 Recovery data with Injuries

Recovered intestine	128
Transplanted intestine	77
Type 1	2
Type 2	0
Type 3	0
Recovered pancreas	855
Transplanted pancreas	648
Type 1	7
Type 2	3
Type 3	4
Recovered heart	1726
Transplanted heart	1617
Type 1	6
Type 2	2
Type 3	1
Recovered lung	2437
Transplanted lung	2004
Type 1	16
Type 2	1
Type 3	5
Recovered liver	4396
Transplanted liver	3928
Type 1	58
Type 2	16
Type 3	6
Recovered kidney	9501
Transplanted kidney	7889
Type 1	156
Type 2	86
Type 3	43

Table 3 Number of type 3 injuries (one year) by organ procurement organization

OPOs with 1 injury	7
OPOs with 2 injuries	5
OPOs with 3 injuries	6
OPOs with 4 injuries	2
OPOs with 6 injuries	1
OPOs with 10 injuries	1

prism - was used to perform statistical evaluation.

The need for consent in the United States is regulated by local Institutional Review Boards. The consent for brain dead (BD) donors for research is not legally required when no additional tissue, *etc.*, is taken from the donor^[4]. For that reason this study was Institutional Review Board (IRB) exempt and IRB consent was not requested.

RESULTS

A total of 36 OPOs (out of a potential 58) participated in the prospective collection of data (Table 1). An additional 3 OPOs submitted data but were not included in the analysis as this data was not a complete years' collection. By excluding partial year's data, we aimed to minimize selection bias. OPO size (donors/year) varied from 43 to 305 donors/year (mean 147.5; median 141). These 36 OPOs recovered a total of 5401 of the nation's 8594 deceased donors in 2014. From these donors, 19043 procured organs' data was analyzed. Of the donors, 4347 were BD donors and 870 were donation after cardiac death (DCD) donors. Data was reported in terms of both recovered and transplanted organs. The

OPO: Organ procurement organization.

most frequent type of injury was class 1 (Table 2). Class 2 injuries were usually but not always intermediate in number between class 1 and class 3 injuries. In order of increasing incidence of injury, type 3 injuries were compared to recovered organs and occurred in the following frequencies: Intestine: 0/128 (0%); heart 1/1726 (0.05%); liver: 6/4396 (0.14%); lung: 5/2437 (0.21%); kidney: 43/9501 (0.42%); pancreas: 4/855 (0.47%). A total incidence then of class 3 injury in the 19043 organs procured was 0.3%. Among individual OPOs, there were a total of 22 OPOs that reported at least one type 3 injury (Table 3). The median number of class 3 injuries per OPO (in OPOs that had at least 1 injury) was 2.0 with a mean of 2.7 and a mode of 1. One OPO reported 10 class 3 injuries during the year of data collection, one OPO reported 6 and 2 OPOs reported 4 class 3 injuries. The remaining OPOs reporting class 3 injuries fell in the range of 1-3 injuries for the year (#18).

Table 4 Causes of class 3 injury

Organ	# injuries	Cause
Intestine	0	N/A
Pancreas	4	Vascular injury (2) Traction injury to organ (2)
Heart	1	Vascular injury (1)
Lung	5	Vascular injury (2) Inadequate trachea for anastomosis (1) Not specified (1)
Liver	6	Vascular injury (3) Capsular tear (2) Not specified (1)
Kidney	43	Vascular injury (27) Capsular tear (7) Ureteral transection (5) Not specified (3) Failure to flush artery adequately (1)

In looking at OPO size as being predictive of the number of class 3 injuries, 3 of 4 of the OPOs having at least 4 class 3 injuries were larger than the median OPO size in the total cohort (147.5 donors/OPO) but this did not reflect their frequency. The incidence of class 3 injury within this subset of OPO’s having at least 4 injuries ranged from 1.3% (of procured organs) to 4.4% with the highest incidence occurring in the OPO with 10 class 3 injuries. Further evaluation of this subgroup of 22 OPOs with class 3 injuries, 7 had only 1 and 5 only had 2. In the subgroup of OPOs with at least 3 class 3 injuries (#10), only 6 of the OPOs had an incidence of over 2.1%. In looking at the highest incidence of injury, 4 OPOs had an incidence of at least 3.9% (range 3.9%-4.7%). In contrast to that noted above in regards to total injuries and OPO size, 3 of these 4 OPOs were smaller OPOs as defined by annual donor numbers (< 147.5 donors/year). Finally, arbitrarily using a 2% injury rate irrespective of number of injuries, there were 7 OPOs that fell within this parameter. Of those OPOs, 5 were in the smaller OPO group (again - as defined as < 147.5 donors/year) and 2 were in the larger group. From a statistical analysis standpoint, using chi square testing, a higher incidence of class 3 injury was observed in the smaller OPOs (grouped together: < 147.5 donors/year) vs larger OPOs (> 147.5 donors/year) with a P value of 0.044.

As class 3 injuries rendered the allograft unable to be transplanted, a summary was received for each lost organ (Table 4). In all allografts (with the exception of pancreas that sustained a “traction” injury) vascular damage was the most common injury rendering the organ non-transplantable. The total BD vs DCD donors were noted but the only data regarding donor type supplied on failed organs was in the narrative. Of note, however, 2 of 6 livers felt to be non-transplantable were noted to be DCDs and 4 of the 43 kidneys. Unfortunately, this data was gleaned from the narrative and not specifically collected so a comparison of DCD vs BD donors reflecting the likelihood of class 3 injuries cannot be made.

DISCUSSION

There have been retrospective reviews regarding surgical damage during procurement but to our knowledge, this is the first prospective look at the surgical outcome of organs procured from deceased donors gathered at the United States OPO level^[5,6]. For that reason, an acceptable degree of surgical damage seen during procurement could not be known. The technique required in procuring organs for donation requires the skills of a vascular surgeon and the insights of a transplant surgeon. Surgical damage may be related to the procurement procedure itself or may be related to the cause of death of the donor (trauma). Damage rendering the organ non-transplantable may be related to parenchymal damage, injury to the vasculature or other parts of the organ (ureter, etc.). The surgeon is required to procure the organ without injury to any of these structures^[7]. In addition, they must obtain enough of the vasculature to allow for anastomosis into the recipient. This desire for adequate vessel length, though, must be balanced with the needs of the other procuring surgeons. Frequently vessel lengths are shared between donor surgeons and a degree of communication and cooperation is required and almost always achieved. Anomalous anatomy also may play a part in organ injury^[8]. This is especially true in the procurement of small organs (pancreas)^[9]. Finally, the insight of the transplanting surgeon should not be overlooked in the determination of transplantability of the organ. If a marginal organ is procured and found to have a significant injury that could potentially impact its function, the transplanting surgeon might be more disinclined to transplant this organ. This could especially be the case in the procurement of a marginal or DCD organ as has been seen previously in DCD kidneys^[10]. Unfortunately, this study was not designed to compare damage seen in BD vs DCD donors. In some cases this information was contained in the narrative describing the injury but as this was not consistent, that information is not reported here.

Despite all the enumerated pitfalls involved in organ procurement, the frequency of organ injury during procurement is rare. The motivation and the skill of the procuring and transplanting surgeon combine to make this outcome predictable. In looking for trends within class 3 injuries, the very scarcity of these injuries made such efforts difficult. What was seen, however, in the OPOs with the highest levels of class 3 injuries was that the injuries tended to cluster within months and then disappear in the months following. In reading the narrative associated with injuries, it was evident that procurement injuries resulted in feedback to the procuring surgeons. It was likely then that such feedback either improved the future focus of the procuring surgeon or resulted in a change or a call for mentorship (in at least one case) in the procuring team. This study would then support the importance of a collegial

discussion with the procurement team in the instance of organ injury.

In looking at class 3 injuries, as noted previously, 14 of the 36 participating OPOs had no such injuries while 3 of 4 of the highest raw number of injuries occurred in larger OPOs (> 147.5 donors/year). However in looking at the frequency of injury of > 2%, smaller OPOs made up the majority of this subset (see above). It does appear then that smaller OPOs by size tend to have a statistically significantly higher likelihood of having a greater frequency of class 3 injury - again arbitrarily defined as a frequency of > 2%. At least one of the reasons for this can be the smaller margin for error when fewer donors are procured. Other potential causes for this would be speculative without further data collection.

Certainly the vast majority of this discussion has been focused on class 3 injuries. The numbers of class 1 and 2 injuries certainly exceed class 3 but, as these do not result in a lost allograft, there is a lessened imperative to examine these events. However, it is likely that these events may be harbingers of class 3 injuries. As no narrative was provided for class 1 and class 2 injuries, it is unknown as to whether OPOs have these discussions after these events. By providing feedback to individual procuring surgeons not just in class 3 but also in the event of a class 1 or 2 injury, there would seem to be potential for improving an individual's procurement surgeon's skills and so avoid future type 3 injuries. These events therefore should continue to be reviewed on an individual OPO level.

Finally, the collection of this data provides OPOs a perspective on their effectiveness in organ procurement. Individual OPOs can, by continuing to follow their surgical injury rate, have an idea as to where their injury rate falls within the national benchmarks. While the goal for surgical damage continues to be the lack of damage, careful review of the frequency of different damage levels will give individual OPOs continuous feedback on at least one aspect of their quality.

The strengths of this study include the prospective data collection, the inclusion of 36 of 58 OPOs as well as the use of the entire 12 mo of data during the collection period. The inclusion and review of the narrative also gave insight into the individual OPOs efforts in enhancing quality. The weaknesses of this study include the lack of participating would have shown a higher level of surgical injury but that outcome again would not be a *fait accompli*. Additionally, expanding data collection to include determination of BD vs DCD donors, names of procurement teams and levels of experience of these teams would have been helpful in interpreting the data. Finally, as the degree of damage was first quantitated by the transplanting surgeon, there is a potential for under-reporting type 1 and 2 injuries if the procuring team were from the transplanting center. This degree of underreporting should not be seen, however with type 3 injuries as the loss of an organ would be evident to the on-site OPO coordinators. Taking all of these concerns

into account, the goal of this study was to establish a standard in the description of procurement surgical damage and a baseline of injury rate. Examined in this light, this study achieved its goals.

A 12 mo collection of surgical damage data from 36 of 58 OPOs in the United States was reviewed. In the entire group, surgical damage was a rare event with the loss of allograft seen in less than 0.5% of procured organs. The majority of the surgical damage seen was related to vascular injuries. Incidence of class 3 injury appears to be higher in OPOs with smaller donor volumes.

COMMENTS

Background

There is a paucity of information about organ injuries during deceased donor procurements. This has significant importance into the numbers of organs that are transplanted every year. This study set out to document and report, for the first time, the incidence and grades of surgical injury to organs during their procurement across the United States. This has the potential to set national standards for quality and offer future ideas for research.

Research frontiers

As the waiting list for organ transplants gets bigger, there has been recent impetus for research to look at more ways to obtain such organs. One such important way would be to identify the numbers of organs that are lost to injury during procurement.

Innovations and breakthroughs

There have been no previous large scale reports of this kind, hence the novelty of this study.

Applications

This study offers for the first time, a national perspective on procurement organ injuries. It helps define a national problem, which the authors know little about. This offers the potential to establish national standards for organ procurement organizations, training of transplant surgeons, and even insurance and regulatory purposes.

Terminology

OPO: Organ procurement organizations. These are independent organizations, contracted with the United Network of Organ Sharing in the United States. Their purpose is the responsibility of procurement and distribution of organs from deceased donors in their assigned geographic area; AOPO: Association of OPOs. A national organization representing all of the 58 OPOs across the United States.

Peer-review

This study is a large scale multi-organizational report looking into the incidence of surgical injuries during deceased donor organ procurement, collecting data prospectively over a period of a year. Organ damage was classified into three tiers, with the latter rendering the organ non-transplantable.

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