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The multi-organ procurement: Training and the utility of organs in a public sector hospital in Gujarat

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Abstract

Background: Deceased donor organ transplantation is an established method of transplantation in Europe and North America. In India, the deceased donation is rising despite socioeconomic and healthcare differences from the western world. There is a need to evaluate the utility of organs procured by public sector hospital and training of such procedures.

Method: It is a retrospective study of the procurement procedures done by the team from January 2015 to March 2020. The data is retrieved from records regarding age, sex, cause of brain death, biochemical, haematological, serological, radiological, histopathological parameters like a biopsy, location of the donor organs, organ procurement team and how the procurement was carried out, injuries occurred while procurement and utility of organs with or without usual or unusual repair or reconstructions. If organs were not procured or discarded then reasons for doing so is recorded.

Result: 316 donations have taken place. Out of those donations, out of 632 kidneys recovered, 568 kidney transplants were done, 312 livers were recovered out of them, 272 liver transplants were done, and 8 pancreases

have been harvested. 30 hearts and 4 lungs were also recovered and used by other centres. Head trauma was the cause of brainstem death 174 cases (55%) followed by CV stroke in 116 cases(36.7%) and anoxia in 25 cases(7%). The mean age of the donor is 50 years and 183 (69%) donors were male and 82 (31%) were females.

The procurement team was headed by consultant in 240 (75%) occasions, transplant fellow in 76(24.1%) occasions. The procurement was done by a consultant in 200(63.3%) occasions, by fellow under the supervision of consultant in 40 (12.6%) cases and independently by transplant fellow in 76(24.1%) occasions.

Out of all kidneys recovered on 217, 32 and 11 occasions, kidneys were used separately, dual transplant and single kidney only used respectively. On 31 occasions kidneys were discarded and on 24 occasions, kidneys were used by other centres.

Out of 312 livers recovered in procurement, 266 were used in the usual manner, 39 were not used because of unusable quality, 3 livers were split and used and 4 livers were not used due to injury.

Conclusion: Deceased donor transplant is increasingly done in India. Organ utility is optimum at the centre under study. Training fellowship offers adequate and good quality training for multiorgan procurements. Similar programs should be started for education and capacity building in this field.

Keywords: Multiorgan procurement, transplant training, cold ischemia time, liver transplant, kidney transplant, cadaver organ donation, deceased donors

Introduction

The need and utility of kidney and liver transplant are proven worldwide for end organ failure. [1] [2] [3] [4,5] [6].

Activity related to transplants from brainstem death donors in India stemmed from the enactment of Transplantation of Human Organs Act in 1994. This act defined brain stem death, its declaration and had provisions for transplant from organs recovered from such donor. It was amended in 2003, 2011 and 2014 to now existent Transplantation of Human Organs and Tissues Rules. Accordingly, national, regional and state regulatory bodies were formed and are called NOTTO(National Organ and tissue transplant organization)[7], ROTTO(Regional organ and tissue transplant organization), and SOTTO (State organ and tissue transplant organization) respectively. The SOTTO was set up in 2015 in the state of Gujarat and became functional in January 2019.[8]

Liver transplant is established now as a standard treatment of decompensated cirrhosis. Living donor liver transplant is a major type of liver transplant done in India [9]. According to the global observatory for donation and transplant(GODT) [10] living donor transplantation is a major form of transplant in India however the donation after brain death is in increasing trend in India, the year-wise donations after brain death in India in 2013, 2014, 2015, 2016, 2017, 2018 were 340, 408, 666, 930, 773, 875. There is an increase in donation after brainstem death donations to 257%. So, there is a need to increase the number of trained specialists and infrastructural development at tertiary centres in India, more so in government settings.

The training for deceased donor multi-organ procurement is in the form of fellowship after general surgery residency in the USA and European countries. The deceased donor transplants predominate in the USA and Europe. So the exposure for training in such procedures is excellent in such programs. Although the

number of deceased donations increased, there was no structured program to train surgeons in the field of deceased organ donation and transplantation. Moreover, most of the living donor transplants, which predominate in India occur in private sector hospitals where teaching is not necessarily a norm.

The centre of the study is a tertiary care public sector hospital in Gujarat. It is one of the leading centres in the country in deceased donor kidney and liver transplantation. The intercity multi-organ sharing was started in 2008 in Gujarat. A state university named the Gujarat University of Transplant Sciences[11] has been set for the development of transplant science in state and country. As team gained wider experience over 7 years, the abdominal organ transplantation fellowship program was started in April 2015 at this hospital under the aegis of Gujarat University of transplantation sciences which included training of general surgeons in multi-organ procurement and abdominal organ transplantation. The eligibility criteria for the fellowship were a postgraduate degree in general surgery and a one-year experience post-degree. Candidates were selected based on an interview which tested knowledge and aptitude. Now 4 years have been completed since the start of such training programs. The study was aims to estimate the quality and safety of multi-organ procurement in such a program.

It aims to study the demography of deceased donors, variables of donation, biochemical parameters of the donor, data on personnel involved in procurement and utility of organs recovered. The discard of organs and its causal association to donor demographics and donor biochemical parameters need to be evaluated. If any injury related to the procurement procedure has occurred then the fate of such organ is studied.

Since demographic and socioeconomic peculiarities command the priorities of law makers, the education for transplant sciences is sporadic and need is manifold. The institute of study is one of few public sector run hospitals which have status of state university hospital and potential of expanded services and education in transplant sciences. This fellowship is a sterling example of such effort.

Materials and methods

It is a retrospective study of the procurement procedures done by the team from a public sector hospital in the state of Gujarat from January 2015 to March 2020. The data are retrieved from hospital records regarding demographic data of donor like age, sex, height, weight, BMI, cause of brain death, the circumstance of brain death, mechanism of injury, ICU stay, history of diabetes, hypertension, malignancy, alcoholism were obtained. Haematological, Biochemical and serological parameters at the time of donation including haemoglobin, total leucocyte count, platelet count, international normalized ratio(INR), creatinine, urea, SGPT, SGOT, ALP, HIV- Elisa, Hbs Ag, anti HCV antibody, C-reactive protein, triglycerides, total cholesterol, kidney biopsy and liver biopsy was recorded from available records. Procurement logistic data like location of the donor organs, organ procurement team and how the procurement as carried out, injuries occurred while procurement and utility of organs with or without usual or unusual repair or reconstructions was recorded. If organs were not procured, or not used after procurement then the reason for same are studied. An analysis is obtained regarding the biochemical parameters and demography of the organs which were not found suitable for transplants. Number of biopsies

The study was done following the Helsinki declaration. Ethical committee clearance was taken to obtain data from hospital records.

Major cities in the state of Gujarat are approximately 250-300 kilometres away from the centre which is situated in Ahmedabad. The referring physician under whose care the deceased donor is admitted is in constant touch with the transplant team and treatment of the deceased donor is guided. The team includes a senior surgeon, transplant fellows, urology residents, two anesthesiologist residents along with 2 staff nurses and operating room assistants. The whole team is experienced in the matter of evaluation of the donor, legal and ethical aspects of organ donation and logistics involved in carrying out surgical procedures in unfamiliar operating rooms and varying degrees of stability of the donor. The surgical instruments and disposables are carried along with the team to remain independent and not be a burden on any donor hospital.

The procurement is done by the method described by Starzl T et al [12] with modification in terms of limited dissection of porta and HTK was used for cold perfusate. Trainee transplant fellows are given stepwise to perform under supervision after he has assisted 10 cases. They perform steps namely exposure (thoracoabdominal), infrarenal control, supra celiac control, aortic cannulation and perfusion, hilar dissection(warm phase), kidney recovery, liver recovery, pancreas recovery in a sequential manner, promoting to next step as once they are confident and comfortable with previous steps. They are allowed to perform independently after 5 cases of performance under supervision.

The fellowship program is for 3 years, during which the fellow is rotated among liver transplant, kidney transplant, pancreas transplant, immunology and research. The fellow gets clinical exposure in preoperative evaluation and post-operative care of transplant recipients and donors. The primary responsibility of treating liver failure cases that are suffering from sequale of cirrhosis and evaluated for transplants is borne by fellows. The post-transplant cases with rejection, infection, renal failure, vascular, biliary or other complications are treated by fellows under guidance of consultant who allows fellow to treat independently according to the performance. The fellow is responsible for preoperative evaluation of living donors for kidney and liver transplants. The fellow assists in follow-up care of transplant recipients and donors. They are responsible for performing procedures like oesophagogastroduodenoscopy, liver biopsy, percutaneous procedures like percutaneous drain placement and percutaneous transhepatic biliary drainage tube placement. Apart from multiorgan procurement, they assist and operate sequentially in procedures like donor right and left hepatectomy, recipient hepatectomy, kidney transplant recipient surgery (open, laparoscopic and robotic), pancreas transplants, donor nephrectomy, bench prepharations and other corrective surgeries for complications of transplants. In recipient surgery steps of hepatectomy are allowed in following sequence: left lobe mobilization, portal dissection, right lobe mobilization, inferior vena cava dissection. As far as graft implantation is concerned, biliary anastamosis is allowed to fellows followed by vena caval anastamosis and portal anastamosis. The hepatic artery anastamosis is allowed last. For kidney transplant bed prepharation is allowed first followed by venous reconstruction, arterial reconstruction and ureteric implantation. The

fellow is assisted by consultant and performance is evaluated. If fellow is found comfortable, he is allotted next step. Trainee does independent procedure steps once they have performed under supervision for atleast 10 cases.

Results and Discussion

In the last 5 years (2015-2020) 316 donations have taken place. The number of donations occurred year wise from 2013 to 2020 were 40,64,69,60, 62, 16. Out of those donations, out of 632 kidneys recovered, 568 kidney transplants were done,312 livers were recovered out of them, 272 liver transplants were done, and 8 pancreases have been harvested. 30 hearts and 4 lungs were also recovered and used by other centres.

The cause of brain stem death, the circumstance of death and mechanism of injury are shown in table 1. Donor demography and blood reports are shown in table 2. The utility and discard of kidneys and livers is summarized in table 3,4 and 5. Injury to liver while procurement are summarized in table 6.

On one occasion kidney was discarded due to vascular injury. On five occasion's kidney required unusual vascular or ureteric reconstructions in form of uretero-ureteric anastomosis for short ureter or the double ureter, double or triple pantaloons for cut short arterial branches.

In India, transplants were started and flourished predominantly in private or corporate hospitals of large cities. Most of the transplants done in India are from living donors. Transplant activity is a resource-intensive activity so a lag is seen in public sector hospitals for the development of such a facility. At the same time need of the organs for the cure of end-stage disease is increasing and their roles have been clearer and firmly established. Affordable transplant in a public sector hospital is a viable option and need of the hour.

The training for performing such procedures was obtained by initial Indian transplant surgeons from western countries. There are more than 50 fellowship programs in the USA owing to clinical exposure generated by robust organ sharing system governed by UNOS. The average number of organ donations occurring in the USA are 7000-9000 per year [13]. Clinical fellows form the main workforce in that system.

The dedicated training in abdominal organ transplant surgery is lacking in India. The subject of transplant surgery is not considered independent surgical subspeciality but a part of other subspecialties like urology, surgical gastroenterology, or hepatobiliary surgery.

The state of Gujarat has accepted THOA in 1994 and was granted the status of SOTTO in 2018. The deceased donor transplant activity was controlled by public sector hospital given lack of proper organ distribution system. Patient-centric system of organ distribution akin to UNOS is developed in 2019 for the state of Gujarat. The numbers of organ donations have progressively increased over the last 5 years in the state of Gujarat and India. Considering substantial clinical exposure, abdominal organ transplant surgery fellowship was started at a public sector hospital in Ahmedabad city in the state of Gujarat.

The median distance of procurement hospital was 203 km and it is covered by road. Approximate time for travel is 4.5-6 hours for most of the centres. This leads to a minimum cold ischemia time of 6-9 hours. The outcomes of organs post-transplant are best with low cold ischemia time(less than 6-12 hours)[14 15]. The most

common cause of death is a traumatic head injury in 55% of cases. This, maybe in a part, is due to high rate of motor vehicle accidents(1290 accidents/day, 405 deaths/day) [16] taking place in India and overall young and mobile population. The most common age group is 50-64 years comprising of 99 donors (31%) while 59 (19%) were above 65% so in all more than 50% donors were more than 50 years old. CV stroke is the cause of death in 36.7% similar to 40 % in SRTR dataset of 2018.[13] Commonest circumstance of death is motor vehicle accident in 45.8% cases while in UNOS database of all donation is the natural cause (43%) [17]. Commonest mechanism of death was blunt injury (54.4%) while in UNOS database it is intracranial haemorrhage in (36.5%)[17].

Donors with HIV positive serology are not considered for the donation given the risk of transmission of infection. We have used 2 donors with hepatitis B virus positivity. They had 3 log HBV DNA copies and 6 log DNA copies. One liver was used and all kidneys were used in HBV positive patients. 310 (98.2%) donors had CMV IG G positivity asserting ubiquitous nature of the virus.

Multiple factors were taken into consideration while using kidneys in patients. The donor characteristics that define an expanded criteria donor (ECD) kidney include age > or = 60 years, or age 50-59 years plus two of the following: cerebrovascular accident as the cause of death, preexisting hypertension, or terminal serum creatinine greater than 1.5 mg/dl.[18]

Out of 127 ECD kidney donations 71(55.9%) were transplanted normally, 25(19%) times dual transplant was done 26(20%) times both kidneys were discarded and 5(3%) times, one kidney was used and one was discarded. As compared to the trend in the US [19], the utility of ECD donors is high where kidneys from only 18% of ECD donors were used. The utility of ECD kidneys in the US is affected by disincentives associated with poorer outcomes.[19]. Biopsies of donor's kidneys were done when doubt existed regarding the use of kidneys as single or dual transplants. Injuries to kidneys occurred on 6 occasions and consisted of vascular injury in 4 occasions and ureteric injury in 2 occasions. On one occasion the only kidney was not usable. The rest of the times they were used by unusual vascular and ureteric reconstructions. The centre has experience of more than 6000 kidney transplants to have the ability to utilize such kidneys.

Out of 43 discarded livers, half were deemed prohibitively fatty on visual impression, consistency, ultrasound. Biopsy could be taken only in 5 occasions out of which 3 times liver was not used after confirmation of fatty liver. Biopsy could not be taken in all suspected livers as the expertise and availability of reading frozen biopsy t remote centres is not always available. On 7 occasions liver was not used in views of no available recipient and median donor age is 3 years, which means there were unused pediatric donor livers. This is because few pediatric recipients in the waitlist could survive until a transplant is available. Such patients need expert pediatric hepatology care which is not commonly available. Livers were discarded due to vascular injury on 4 occasions, consultants and trainee surgeons were operating surgeons in 2 cases each. So there is no difference in discard rates due to injury based on operating surgeons. On 5 occasions livers were not used as the donors suffered hemodynamic compromise or cardiac arrest before the procurement could start. Such livers suffered unknown periods of ischemia before retrieval. The hepatic enzymes trends

of discarded livers suggest that these were more injured organs as compared to all livers. According to UNOS annual report for the year 2018, out of 10721 donors, 7763 (72.4%) of livers were utilized. In our series out of 316 donors, 273 (86.4%) livers were utilized which is comparable.

This study has many limitations. It is done retrospectively, so systematic data collection could not be achieved. The anthropometric data of donors could not be collected as these were not available in accurate form. The use of KDPI or KDRI scores was not available in documents so analysis of such scores is not possible. The decision to use livers based on biopsy is not possible regularly. There is no completely functional systematic data collection system in India although the NOTTO is established and is functional in principles. Due to the lack of uniform policy across the country, some organs went unused for the want of recipients.

Cause of brain stem death	Number (%)
Anoxia	25(7%)
CV stroke	116(36.7%)
Head trauma	174(55%)
Tumor	1(0.3%)
The circumstance of brain stem death	Number (%)
Homicide	2(0.6%)
Suicide	2(0.6%)
Motor vehicle accident	145(45.8%)
non-motor vehicle accident	29(9.1%)
Natural	138(43.6%)
Mechanism of injury	Number (%)
Asphyxia	4(1.2%)
Blunt injury	172(54.4%)
Cardiovascular	46(14.5%)
Drug intoxication	1(0.3%)
Intracranial haemorrhage	86(27.2%)
Natural cause	5(1.5%)
Seizure	1(0.3%)

Table 1: Cause, mechanism and circumstance of brainstem death

Age (years)	Number (%)	Donor malignancy	Number (%)
<1	0(0)	Yes	3(1)
1 to 5	6(1.9)	No	313(99)
6 to 10	2(0.6)	Donor diabetes	
11 to 17	11(3.4)	Yes	66
18 to 34	62(19.6)	No	250
35 to 49	75(23.8)	Donor hypertension	
50 to 64	99(31.4)	Yes	101
65+	59(18.7)	No	215
Unknown	1(0.3)		
		Team head	Number (%)
The median distance of procurement	203 km	Consultant	240(75.9)
		Transplant fellow	76(24.1)
Sex (males/females)	Number (%)		
Male	222(70.2)	Performed by	Number (%)
Female	94(29.8)	Consultant	200(63.3)
		Transplant fellow	116(36.7)
Blood group	Number (%)		
A negative	3(0.94)	Laboratory	Mean ±SD
B negative	8(2.53)		
O negative	2(0.6)	Hb(grams/dl)	10.9±2.13
AB negative	1(0.3)	Total leucocyte count (/cu mm)	14047 ±5509
A positive	63(19.9)	Platelet count (/cu mm)	153946 ± 74497
B positive	104(32.9)	INR	1.27± 0.39
O positive	115(36.3)	SGPT(IU/L)	113±135, median =32
AB positive	20(6.3)	SGOT(IU/L)	195±229, median=59
		ALP(IU/L)	83±29.7
Hepatitis B positive	Number (%)	Creatinine(mg/dl)	1.66±0.84
Yes	2(0.6)	Urea(mg/dl)	52±21
No	314(99.4)	Bilirubin(mg/dl)	0.84±0.45
		Direct bilirubin(mg/dl)	0.31±0.22

Hepatitis C positive	Number (%)	Indirect bilirubin(mg/dl)	0.53±0.3
Yes	0(0)	HSCRP(mg/dl)	146±69
No	316(100)	Triglyceride(mg/dl)	144±69.6
		Cholesterol(mg/dl)	126 ±36
		Sodium(meq / l)	149 ± 9.8

Table 2: donor and procurement variables; SGPT: Serum Glutamic Pyruvic Transaminase, SGOT: Serum Glutamic Oxaloacetate Transaminase, ALP: Alkaline Phosphatase, HSCRP: Highly selective C - reactive protein

Kidney utility	Number of donors	mean creatinine	median age
Single used	11	1.67	50
Planned discard	31	1.56	70
Both separately	217	2.5	45
Dual	32	1.47	59.5
Other centres	24		

Table 3: Utility of kidneys

Cause of kidney discard	number of donors	Kidneys discarded	median age	mean creatinine
Overall	316		50	1.6
Overall discard	37	68	58	2.3
CKD	20	40	70	2.9
Diseased	7	10	50	1.7
Discard after biopsy	6	12	70	2.6
Vascular injury	1	1		
Misplaced	1	1		
Poorly perfused	1	2		
Renal stone disease	1	2		

Table 4: Causes of kidney discard

Causes of liver discard	Number	median age(yr)	mean SGPT(IU)	mean SGOT(IU)
Overall donors	316	50	113	195
All cause	43	47	300	578
Fatty liver	21	54	559	1148
No recipient	7	3	117	198
Prolong ischemia or donor cardiac arrest	5	39	217	103

Vascular injury	4	35	27	47
Cirrhotic liver	3	49	52	129
Donor consent not available	1	43	26	47
Time constrain	1	40		
Infection	1	24	198	162

Table 5: Causes of liver discard

Injury to liver	Number	not used	Procurement surgeon			
			consultant		Fellow	
			Discarded	Used	discarded	Used
Vascular injury	8	4	2	4	2	0
Capsular tear	1	0	0	1	0	0
Laceration	3	0	0	2	0	1

Table 6: procurement injury to the liver

Conclusion

The deceased donor abdominal organ transplants are increasingly gaining importance because of the availability of organs and rising demand. Manpower training is necessary. The abdominal organ transplants can be done in public sector hospitals also if the administrative will and dedicated team are available. The organ utility is at par to global standards. Better data collection and assimilation will help understand and plan to correct any caveat remaining in the transplant field in India.

Abbreviations

NOTTO- National Organ and tissue transplant organization, ROTTO- Regional organ and tissue transplant organization, SOTTO- State organ and tissue transplant organization, SGPT- Serum Glutamic Pyruvic Transaminase, SGOT- Serum Glutamic Oxaloacetate Transaminase, ALP- Alkaline Phosphatase, HIV- human Immunodeficiency Virus, HbsAg- Hepatitis B surface Antigen, HCV- Hepatitis C virus, HTK – Histidine Tryptophan Ketoglutarate, UNOS- United Network For Organ Sharing, THOA- Transplant of Human Organ Act, CMV- Cytomegalovirus, SRTR- Scientific Registry of Transplant Recipients, KDPI- Kidney Donor Profile Index, KDRI- Kidney Donor Risk **Index, HBV- Hepatitis B virus, ECD- Expanded Criteria Donor**

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