

ORIGINAL ARTICLE

Potential of organ donation from deceased donors: study from a public sector hospital in India

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Introduction

India is the seventh largest country in the world, occupies 2.4% of land area but supports approximately one-sixth of world population (1.2 billion) [1]. The global prevalence of chronic kidney disease (CKD) is estimated to be 8–16% [2], and the disease burden is expected to grow. The risk is more in disadvantaged populations in poor developing countries who are already underprivileged with poor access to scarce healthcare resources [2].

The incidence of end-stage renal disease (ESRD) in India has been reported to be around 150 patients per million population per year [3,4]. Despite the availability of all renal replacement therapy (RRT) options, majority do not

Summary

Deceased donor organ programme is still in infancy in India. Assessing deceased donation potential and identifying barriers to its utilization are required to meet needs of patients with organ failure. Over a 6-month period, we identified and followed all presumed brainstem dead patients secondary to brain damage. All patients requiring mechanical ventilation with no signs of respiratory activity and dilated, fixed and nonreacting pupils were presumed to be brainstem dead. All events from suspicion of brainstem death (BSD) to declaration of BSD, approach for organ donation, recovery and transplants were recorded. Subjects were classified as possible, potential and effective donors, and barriers to donation were identified at each step. We identified 80 presumed brainstem dead patients over the study period. The mean age of this population was 35.9 years, and 67.5% were males. When formally asked for consent for organ donation ($n = 49$), 41 patients' relatives refused. The conversion rate was only 8.2%. The number of possible, potential and effective donors per million population per year were 127, 115.7 and 9.5, respectively. The poor conversion rate of 8.2% suggests a huge potential for improvement. Family refusal in majority of cases reflects poor knowledge and thus warrants interventions at community level.

receive any RRT, largely due to economic reasons. Only 2% of those who initiate haemodialysis (HD) remain on HD at 6 months after initiation [5,6]. Majority of HD units are in private sector, expensive and restricted to urban centres. Peritoneal dialysis (PD) has poor penetration due to physician bias and fear of infectious complications [5].

Kidney transplantation is available in major cities across India but relies heavily on living donors from near relatives and is grossly insufficient to meet the demand. Moreover, living donors are unable to help patients in need of other organ transplants. Deceased organ donation programme is still in its infancy, largely restricted to big institutions and hampered by the lack of a national policy for organ recovery or allocation. In addition, there are no facilities to take

care of potential deceased organ donors in the hospitals, and public awareness regarding deceased donation is poor. The majority of deceased donors are patients with primary central nervous system disorders like stroke or head trauma due to road traffic accidents [7–10]. According to Government of India estimates, there were 125 660 road traffic accident-related fatalities in India in 2009 [11]. It is estimated that 60–70% of patients dying due to road traffic accidents have head injuries and can become potential organ donors [12,13].

Organ transplantation in India is governed by The Transplantation of Human Organs Act (THOA) 1994, which has laid down legal and administrative framework to prevent organ trafficking and exploitation. Deceased organ donation is based on an opt-in policy whereby either the desire of the patient (if known) or willingness of next of kin to donate organs reigns supreme [14]. Till recently, it was not mandatory on part of physicians to seek deceased organ donation from brainstem dead patients. The recent amendment to THOA makes seeking deceased organ donation from brainstem dead patients mandatory on part of treating team and plans to provide a structured framework for organ recovery and allocation [14]. However, the THOA amendment rules have just been notified in March 2014 and are yet to be put into practice [15].

As increasing deceased organ donation rate is need of the hour, a careful and objective assessment of its actual potential and practical barriers are required so that a proper future framework can be formulated. In this regard, a critical pathway for deceased donation has been proposed [16]. Therefore, we prospectively studied and now report on the deceased organ donation potential at our tertiary care referral centre.

Methods

This study was carried out at the Postgraduate Institute of Medical Education and Research (PGIMER), one of the largest tertiary care referral and teaching hospitals in India with over 1800 beds and the only one serving the transplant needs of the union territory of Chandigarh. It has one of the oldest renal transplant programmes in the country with 180–200 kidney transplants annually, >90% of which are from living donors.

The study was a prospective assessment of all the intensive care units (ICU) or high-dependency units in the hospital, where patients who could become potential deceased organ donors were likely to be admitted. It was conducted in six such units (main ICU, respiratory ICU, neurological ICU, surgical ICU, surgical high-dependency unit and emergency services) over a 6-month period. All the events from suspicion of brainstem death (BSD), documentation and certification of BSD, counselling for organ donation,

willingness for organ donation and finally, organ retrieval and transplantation were prospectively recorded during this period. Patients with age ≤ 65 years who could become heart-beating donors were included for the purpose of this study. The study was approved by Institute Ethics Committee.

All patients requiring mechanical ventilation with no signs of respiratory activity and dilated, fixed and nonreacting pupils were presumed to be brainstem dead. BSD was defined and certified according to legal and administrative rules as defined in The THOA 1994 and The Transplantation of Human Organs Rules 1995, Government of India. Briefly, BSD was defined as the stage at which all functions of the brainstem had permanently and irreversibly ceased. Every patient was examined twice at least 6 h apart by a panel of four experts before BSD was certified. This panel consisted of treating doctor, neurosurgeon/neurologist, independent specialist doctor and a doctor from hospital administration services. This certification required filling Form 8 of The Transplantation of Human Organs Rules 1995, Government of India.

In this study, donors were defined as 'presumed brainstem dead' when BSD was diagnosed clinically. Possible deceased organ donors were defined as presumed brainstem dead patients in whom there were no medical contraindications for organ donation. Potential deceased organ donors were defined as those who had no medical contraindications for organ donation and in whom the process of BSD certification was completed. Consented deceased organ donors were defined as those in whom no medical contraindications for organ donation existed, BSD was certified, and the next of kin were willing for organ donation. Effective deceased organ donors were defined as those from whom at least one organ was recovered for transplantation. At each stage, the reasons for loss as an effective donor were recorded. The counselling team included a trained transplant coordinator. Conversion rate was defined as the percentage of potential deceased organ donors who actually became effective deceased organ donors. As our centre is the only organ transplantation centre within the administrative boundaries of union territorial region of Chandigarh, possible, potential and effective deceased organ donors per million population per year were calculated by dividing the number of donors in each category by the recent population figure (2001–2011 census, started in 2008, reported in 2011) and extrapolating the results to 1 year duration.

Data were analysed using Statistical Package for the Social Sciences (SPSS) software for Windows, version 20.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics was used to report the frequency of various outcomes at every stage. Independent-sample *t*-test and Fisher's exact test were used to test the association of becoming an effective

donor with age and sex, respectively. All *P*-values were two-tailed and considered to be significant at <0.05.

Results

The total number of patients who were admitted in the high-dependency unit, ICUs and emergency services area

of our hospital were 8871 during the 6-month study period. There were a total of 738 deaths of which 80 were presumed to be brainstem dead during their course in the hospital. Head injury secondary to trauma, cerebrovascular accident or stroke, presumed intracranial benign neoplasm or space occupying lesions, infections leading to sepsis and extra-cranial malignancy were responsible

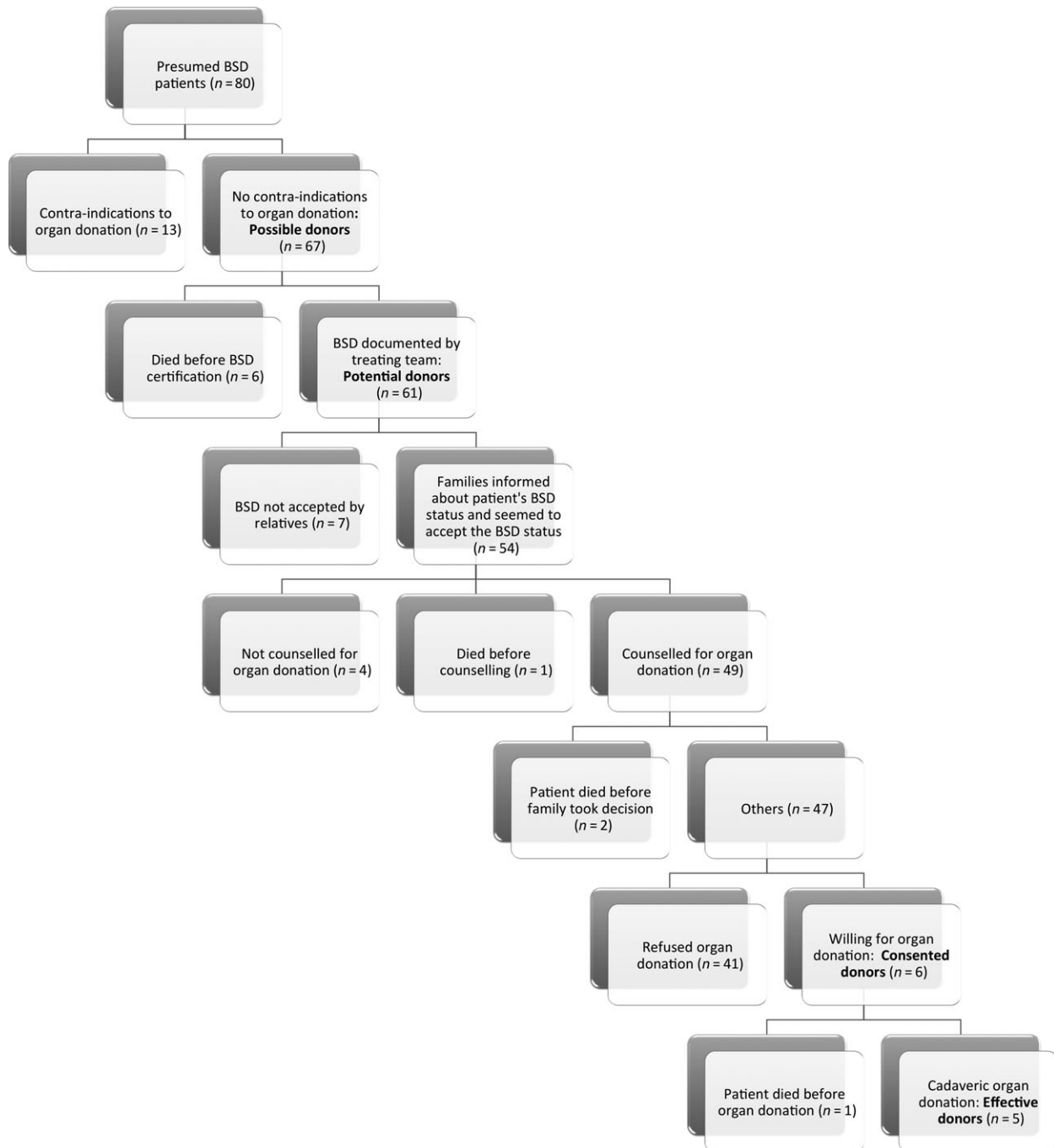


Figure 1 Observed course of 80 patients with presumed brainstem death (BSD) in emergency and intensive care units.

for BSD in 43, 18, 10, 6 and 1 of presumed brainstem dead patients. The cause could not be ascertained in two patients. The mean age was 36.1 (range 2–65) years, and 67.5% ($n = 54$) were males. Amongst the presumed brainstem dead patients, 13 had medical contraindications for organ donation and were not considered further for BSD certification and assessment for organ donation (Fig. 1). These medical contraindications included presumed or proven gram-negative septicaemia (either primary infectious disease or developed during hospital course), disseminated fungal infections and disseminated malignancy in 10, 2 and 1 patients, respectively. The remaining 67 patients were identified as possible deceased organ donors. Six possible deceased organ donors died before the formal declaration and certification of BSD. All were head injury patients who suddenly developed cardiac arrest. The remaining 61 patients, in whom BSD was documented and certified, were referred to as potential deceased organ donors. In seven of these, BSD status of the patient was not accepted by the family members despite the treating team informing them about clinical status and BSD certification in medical records (Table 1). The remaining 54 potential organ donor families were informed about their patients' BSD status and seemed to understand the concept at that time. Based on their previous interaction with the patients' family members, the treating team did not feel it appropriate to counsel four patients' family members for deceased organ donation. One patient expired while the family members were being counselled. The family members of 49 patients with certified BSD status were counselled for organ donation to the satisfaction of counselling team. Before the family members could discuss and decide, two such patients expired. In the remaining 47 patients whose families were counselled, an overwhelming majority of 87% (41 families) refused deceased organ donation. Therefore, only six patients were finally considered as consented deceased organ donors. One such patient expired suddenly after cardiac arrest before organs could be recovered. Finally, organs were recovered from five BSD patients who constituted effective deceased organ donors. Both kidneys were recovered from all five effective deceased organ donors, whereas cornea was recovered from two patients. All the organs which were recovered were utilized and transplanted. Mean age of effective deceased organ donors was 23.8 (range 6–52) years, with three males and two females. A comparison between effective donors and all other presumed brainstem dead subjects who were enrolled for the purpose of this study revealed that effective donors were more likely to be young ($P = 0.048$). However, gender difference amongst them was not significant ($P = 0.712$).

The reasons for not allowing deceased organ donation from BSD relatives in families which were counselled for the same were fear of backlash from society or other family members (16 patients), incomplete understanding of the concept of BSD despite acceptance of BSD status and repeated attempts at counselling (13 patients), a state of profound grief and mental distress culminating in refusal (8 patients), an apprehension that such an act will be financially taxing for the family because of direct and indirect expenses involved in maintaining such patients (2 patients) and unknown (2 patients, refused without reason, Table 1). The conversion rate for deceased organ donation (effective deceased organ donors*100/potential deceased organ donors) was 8.2%.

The latest population figure for the union territorial region of Chandigarh based on population census 2001–2011 (actual census started in 2008, reported in 2011) was 1 054 686 inhabitants [17]. Accordingly, estimated number of possible, potential and effective deceased organ donors per million population per year was 127, 115.7 and 9.5, respectively (calculated as number of donors in respective categories*2 (extrapolation for 1 year)*1 000 000/population).

Discussion

Renal transplantation offers the best hope of survival for patients with ESRD. In India, it is almost synonymous with living donor transplantation as deceased donor transplants constitute <2% of total transplants in the country [9,12]. Deceased donor programme faces many barriers, such as lack of a clear national policy, poor awareness amongst healthcare givers and general population and overburdened or inadequate infrastructure. Living related and spousal donors have been the major source of organ [18]. There are a few reports of assessment of knowledge and attitude towards organ transplantation in healthcare givers and general population. A recent study in an urban population reported a largely favourable attitude towards self-organ donation and allowing deceased organ donation from brainstem dead relatives with 75.9% and 63.3% of respondents, respectively, replying affirmatively [19]. However, knowledge of the concept of BSD seemed to be poor with 56.1% of respondents having felt that life after BSD was possible [19]. In a study of patients presenting to outpatient clinics at three large tertiary care referral centres, 59.6% of the respondents were willing to donate organs upon death [20]. In another study which included doctors, patients and general public as respondents, 62%, 23% and 29%, respectively, were willing to donate organs of their relatives after BSD [21]. We assessed the attitude of healthcare givers towards organ transplantation at our institute and found that 55% were willing to become organ donors,

Table 1. Causes for loss of potential donors* (*n* = 61).

| S. No | Cause | No. of donors (% of potential donors) |
|-------|--|--|
| 1. | Related to understanding of brainstem death (BSD) | |
| a. | Refusal to accept concept of BSD | 7 (11.5) |
| b. | Incomplete understanding of BSD concept culminating in refusal | 13 (21.3) |
| 2. | Related to profound grief or mental distress | |
| a. | Not counselled by treating team | 4 (6.6) |
| b. | Counselled by treating team but refused | 8 (13.1) |
| 3. | Fear of societal or family members' backlash | 16 (26.2) |
| 4. | Died during the process at various stages | 4 (6.6) |
| 5. | Fear of incurring expenses for maintaining BSD patient | 2 (3.3) |
| 6. | Refusal without reason | 2 (3.3) |

*5 became effective donors, lost 56 potential donors.

but surprisingly, 27% were undecided [22]. Therefore, it seems that although attitude is largely favourable, more awareness is required.

India does not have an organized network for deceased donor organ recovery, allocation and transplantation. Organ transplantation is governed by THOA 1994 which has been recently amended to provide a structural framework for aforementioned goals [14]. The new rules have been notified in March 2014 and plan to make seeking organ donation compulsory on part of treating doctors, establish national or regional organ and tissue removal and storage networks and form registries for organ transplant recipients and donors [15]. At present, there is no registry, and most of the clinical data about organ transplants and their outcomes have come from large public sector research hospitals. Despite these shortcomings, professional societies, state governments (e.g. Tamil Nadu, Andhra Pradesh and Gujarat) and few nongovernmental organizations (e.g. MOHAN Foundation) have forged local networks to drive deceased donations [9,12,13,23]. These efforts have met with limited success. The state of Tamil Nadu has a deceased organ donation rate of 1.2 per million population per year which is almost ten times of the estimated national rate of 0.08 per million population per year [13,24]. In absolute terms, approximately seven deceased donors were being utilized every month in Tamil Nadu [24]. In Gujarat, older donors (age \geq 70 years) and donation after cardiac death donors have been utilized to expand the donor pool [25,26]. However, there have been no attempts to identify the potential donor pool which could define the size of the

opportunity and develop a matrix for evaluating the effect of efforts to improve by the use of an identified terminology. A critical pathway for deceased donation has been described by the World Health Organization (WHO) to achieve reportable uniformity [16]. This study is the first prospective study from India to report actual deceased organ donation potential. Our study was carried out before the approach and critical pathway for deceased donation were published. Table 2 lists the definitions used by us and their counterparts in the new proposed critical pathway for deceased donation. Although utilized donors were not defined in our study, all actual donors became utilized donors as all recovered organs were transplanted.

In our study, 10.8% of all patients dying in the ICUs during the study period were presumed brainstem dead. About 16% of these presumed brainstem dead had contra-indications to organ donation, primarily in the form of disseminated infections. Although bacterial sepsis was taken as an absolute contra-indication for deceased organ donation in our patients, solid organs have been successfully recovered from such patients, transplanted with due precautions and have shown good outcome [27–29]. Overall, we lost 14.9% of the possible donors as they expired after sudden cardiac arrest at various stages from official certification of BSD to final recovery of organs after consent. These deaths were within relatively short periods after identification of BSD and perhaps could not have been avoided. About 76.3% of all presumed brainstem dead patients (91% of possible donors) were potential donors. This figure is comparable to what has been reported before from the developed world. In a large study from Germany which had 2019 patients with primary or secondary brain damage in 137 ICUs over 4-year period from 2002 to 2005, 64% were potential donors [30]. A nationwide survey in the United Kingdom (UK) had shown that approximately 66% of patients in whom a diagnosis of BSD was considered were potential donors [31].

A total of 11.5% of potential donors were lost as the families could not understand the concept of BSD and did not

Table 2. Definitions used in this study and their counterparts in the proposed critical pathway for deceased donation.

| S. No. | Definition used in this study | Definition proposed in the critical pathway for deceased donation [16] |
|--------|-------------------------------|--|
| 1. | Presumed brainstem dead | Potential donation after brain death donor |
| 2. | Possible donor | Possible donation after brain death donor |
| 3. | Potential donor | Eligible donation after brain death donor |
| 4. | Effective donor | Actual donation after brain death donor, type B |

accept the brainstem dead state of their patient. Amongst those who seemed to have understood the concept of BSD and were counselled, about a quarter expressed doubts over BSD state when talks of organ donation began and therefore refused organ donation. Overall, 32.8% of all potential donors were lost because of refusal to accept BSD at various stages of organ donation. This shows that awareness about the concept of BSD was poor amongst relatives of our patients. Poor knowledge about the concept of BSD has been previously reported from a selected urban population in India [19]. In about one-fifth of potential donors, adverse circumstances of profound grief and sorrow in next of kin either prevented the treating team from seeking organ donation or culminated in refusal wherever sought.

In combination, the three groups formed over 50% of the potential donor pool. The reasons for this denial were not explored but could be related to unfamiliarity with the concept of BSD and mistrust of the healthcare system. This pool may be regarded as nonmodifiable with respect to organ donation as it is highly individual specific, difficult to predict and variable. Still, personal communication skills and ability to tactfully and sensibly tackle such situations on part of treating team are important aspects which can at times convince relatives to allow organ donation. Therefore, it is necessary that the patients' relatives are taken into full confidence from the beginning, and their queries are appropriately addressed. In fact, authors of the large multi-centre study from Germany had suggested that physician rapport with relatives might have been a factor in better consent rate in smaller hospitals as opposed to large university hospitals [30].

Another 26% of potential donors were lost as the family decision makers in such difficult circumstances feared a family or societal backlash if they took a decision to allow organ donation. This is related to the social structure in India where large number of family members and in some instances even influential individuals outside the family are consulted before any such decision can be made. When such consultations cannot be made or the family feels too overwhelmed to carry out, it is easier to refuse.

An individual's willingness or unwillingness for organ donation during life was never cited as a reason for final decision taken by the relatives. In contrast, 16% of refusals in the UK were attributed to patient's unwillingness for organ donation which indirectly indicates some debate in family at some time over this issue [31]. Thus, it again reflects poor awareness about BSD and related deceased organ donation in our society. Overall, about 80% of the potential donors were lost as the family members either could not understand BSD properly or refused organ donation for some reason. In the German study, the primary reason for failure of conversion from potential to effective donors was refusal by relatives in almost three-fourth of

cases who did not become effective donors [30]. About 41% of relatives refused organ donation when approached for the same in the UK [31]. Therefore, refusal by family members seems to be the final rate-limiting step in actual realization of deceased organ donation potential. The reasons for refusal by family members seem to be related to mistrust in the healthcare system, poor understanding of BSD and deceased organ donation, beliefs, roles of extended family members in decision making and finally their individual capacities to overcome grief and stress. The need to systematically assess these factors and initiate directed interventions has been highlighted [30]. The interventions would require increasing awareness at the community level, reinforcement by making it part of school and college curriculum and improvement of confidence in the healthcare system. In a study at a German university, 42% of medical students reported positive influence of a lecture on organ donation [32]. It is important to realize that awareness and knowledge issues amongst healthcare workers also need to be simultaneously addressed. In our study population, effective donors were more likely to be younger but without any preference for either gender. In the survey from UK, age and gender were not found to be predictors of refusal for organ donation, but ethnic minorities were more likely to refuse organ donation as compared to white population [31]. Whether this is related to one's beliefs or other socio-cultural factors or is just a reflection of poor awareness is difficult to infer and requires critical evaluation.

Although highly variable and subject to variable definitions, available potential donors in developed countries have been reported to range from 40 to 65.4 donors per million population per year [33]. In the German study, there were 19.7 effective donors per million population per year with conversion rate of 47.2% in 2002–2005. This figure is still low when compared to Spain and the United States which had 34.4 and 26.3 actual deceased donors per million population per year, respectively, in 1999–2009 [34]. Poor conversion rate of just 8.2% in our study highlights the dismal state of deceased organ donation in India. However, the higher number of potential donors (115.7 donors per million population per year) suggests immense scope for increasing effective donors. The actual potential is likely to be even more as our study did not include older prospective donors (>65 years) and excluded donation after cardiac death donors. Approximately, 59% of potential donors were lost due to factors which seemed to be potentially modifiable in present context. Even if we assume that we would be able to convert only 50% of this potentially modifiable pool of possible donors into effective donors, it would ultimately translate into a 43.6 effective deceased organ donors per million population per year.

As the demand for donor organs greatly outstrips supply, it has led to unethical transplant practices especially in

poverty struck developing countries where either people are ready to donate due to ignorance and economic compulsions or at times have been exploited [35]. It is not only the native population in these countries who have benefited from this immoral and illegal transplantation practice, but it has led to a thriving shady business of transplant tourism and organ trafficking whereby patients from affluent developed countries often seek transplants in these countries in lieu of money [35]. The concept of national self-sufficiency in organ donation has been emphasized by the Doha Declaration of the Declaration of Istanbul Custodian Group (DICG) [35]. Improving deceased organ donation will not only improve access to transplantation but indirectly discourage unethical transplants [13,23].

Large multicentric studies with uniform definitions would provide a more reasonable estimate of such donor potential statistics [30]. Extrapolation of data generated from a single hospital as in our case may be prone to errors, but it gives us a conservative estimate of deceased organ donation potential. Although data collection is more homogeneous at single centre, our figures are likely to be an underestimate as other regional tertiary care hospitals with emergency ICUs but without organ transplantation facilities can also be potential deceased donor sources. The definitions used by us correlate with those proposed in the critical pathway for deceased donation. Finally, we were able to use only the kidneys as the expertise for transplantation of other organs was not available in our hospital.

Our study shows that systematic application of the critical pathway for deceased donation is possible, and there is a huge potential to increase deceased organ donation and has provided an objective insight into areas which should be further targeted to achieve that all of which are critical to policy formation. Importantly, public health interventions at all levels of healthcare services contact with society are needed to increase awareness about deceased organ donation and achieve this untapped potential.

Authorship

VJ, MM, VS, AKG and RKS: designed study. RA and VK: performed study. RA: collected data. VK: analysed data. VK and VJ: wrote the paper. All authors reviewed and approved the final version.

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