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Unrelated renal transplantation: an ethical enigma

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Abstract

End-stage renal disease (ESRD) is a condition better discussed than suffered. People suffering from ESRD are at a disadvantage not only financially, but also emotionally and in terms of the quality of their lives.

The majority of their productive time is spent in hospital, on dialysis machines, or in the search for a suitable kidney donor, so that they may be able to improve upon the quality of their remaining lifespan. Only a "lucky few" are able to find a suitable matching donor, be it living (related) or a cadaver, whilst the others are left to fend for themselves.

As the supply fails to cope with the demand, people go to the extent of exploring the pool of "unrelated donors". Though not legalised yet, this is one domain yet to be explored in its entirety, both on humanitarian as well as ethical grounds.

Our current work hopes to highlight this scenario and also provides a few options that may well become "ethically acceptable" in the not-so-far future.

Introduction

*"Kidneys are special, in their own way...
So special are they, that, they have their own day...
From removal of wastes.... to helping our health gain.....
Be it morning or evening.... sunshine or rain."*

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The above stanza typically exemplifies the work put in by our kidneys non-stop to keep us healthy. Like any tireless machine, they are continuously at work to ensure that no "toxicity" ever sets in. What would happen if this God-given gift developed fatigue and closed shop?

A hypothetical scenario

Consider a hypothetical scenario:

Pooja, an 18-year-old girl, is her parents' only child. Theirs is a nuclear family, belonging to the upper socioeconomic strata. What is wrong with this, one would ask. Well, Pooja has been surviving on alternate-day haemodialysis since the past five years because she suffers from end-stage renal disease (ESRD). She spends more than 60% of her time shuttling between home and hospital, her parents in tow, utilising the remainder of her time on her studies and recreation. Where did she go wrong? Did she not take good care of her kidneys?

Why can she not go in for a renal transplant and replace her machinery? She can, but she needs a donor. Her parents, though more than willing, have been ruled out on account of ABO incompatibility. She was enrolled in the cadaveric transplant wait list five years ago. Over this period, she has moved up from a dismal wait list number of 275 to a probable 120. It is safe to say that she will figure on the operation theatre list only after another 3–4 years.

What is Pooja's fault here? Born and brought up in a nuclear, modern family, there are hardly any other relatives, willing to donate their kidneys, simply out of "love and affection" for her, as acceptable under the norms of the Transplantation of Human Organs Act (THO Act) (1).

The Transplantation of Human Organs Act and pitfalls

The THO Act (1) was passed in 1994, to regulate the removal, storage and transplantation of human organs for therapeutic

purposes, and for the prevention of commercial dealings in human organs. It defines all possible organ donors, as well as the role of various regulatory bodies. However, it also goes on to state that in the absence of a first-degree relative (mother, father, son, daughter, brother, sister, spouse and pending amendment, grandparents), special permission may be obtained from a government-appointed authorisation committee to prove that the motive of donation is "purely altruism and affection" for the recipient (1). It is this very loophole of "love and affection" that has been repeatedly used, or rather misused, to legalise unrelated renal transplants (1, 2).

In view of the ever expanding pool of ESRD patients, the rift between the demand and supply of "kidneys" has only widened, resulting in the widespread use of the misnomer of "love and affection" (1,2). In addition, this provision has led to a tremendous increase in "transplant tourism" from those countries with strict law enforcement agencies to countries such as India and China, where law enforcement is somewhat lax. As a result, such countries have been nicknamed "warehouses for kidneys" and for India the specific term is "The Great Indian Kidney Bazaar" (2,3,4).

Its ramifications have led to a "wedding among unequals", viz an organ-wedding between wealthy, but desperate people, dependent on dialysis machines, with those economically impoverished destitute, who are more than willing to part with one of their kidneys, for short-term monetary gains to pay off their debts, without having any understanding of the physical and psychological implications (4,5). Strangely, surveys carried out by various non-governmental organisations (NGOs) found that even five years after such commercial donation, more than 84% of such donors were still drowning in various debts (despite receiving the promised sum of money) (6).

The problem

So, where does the crux of the problem lie? Have such nefarious activities become widely accepted because of the improper enforcement of the THO Act or is it a societal issue? The dictum "When you can buy one, why donate?" (5, 6) still holds very much true. What we need to explore is whether in today's self-centred, self-proclaimed "modern" society, in which there is scant bonding between relations, there is any scope of expanding the law so as to legalise unrelated transplants.

In India, despite the THO Act (1), neither has organ commerce stopped, nor has the number of deceased donors increased to take care of the organ shortage. India currently has a deceased donation rate of 0.05–0.08/million population (7), which is way below the requirement.

This entire social scenario has led to a boom in unrelated transplantation, mostly under the cloak of a legal authority from an authorisation committee that takes advantage of the loopholes in the interpretation of the THOA Act. Evidence of this lies in the various kidney racket scams over the years, eg the Gurgaon kidney scam (2008) and the Lucknow scam (2011) (8). *Prima facie* evidence even suggested the involvement of a senior police officer and a "quack" (8).

These are just a few instances that have come forth into the public domain and these may be just the tip of the iceberg. Hence, the need to get to the root of the problem, so as to be able to "nip the evil in the bud", in an ethically acceptable manner.

So, should Pooja and her economically sound parents pursue this very course? Transplant ethicists would say an overwhelming, "No"; but non-purists would say, "Why not, if they can afford to?"

Let us look at both aspects.

Legalisation of unrelated transplants: the good, the bad or ugly?

Unrelated organ transplantation has been legalised in countries such as Iran and Singapore, where the basis of legalisation is that most "lawsuits" are filed post-transplantation only if the capital gain promised to the donor has not been paid as committed by the recipient. Hence, an authority that can regulate this *give and take* would not only reduce black marketing and the role of middlemen, but would also ensure that the donor receives adequate compensation in a timely and legal manner (9). Needless to say, this would also help to shorten the long deceased donor transplant waiting lists (7,9).

What, however, is an "adequate" compensation? As per an American study, a kidney donation subjects the individual to a loss of around 4.5 years of livelihood, which in monetary terms, can be equated to around USD \$98,000 (10). Needless to say, everyone cannot afford such a colossal sum of money and only a privileged few would benefit (9). Additionally, what would be "adequate" would also vary from country to country. Though the importance of a kidney is the same, be it in a developed or a developing nation, the compensation would never be the same, unless regulated by an appellate authority worldwide.

Taking this a step further, some people have even advocated a legalised "organ auction" to ensure that the donor is adequately compensated by the highest bidder, or synchronously, by the recipient and a government authority specifically set up for this purpose. In today's society, in which "health insurance" is sacrosanct, altruists have advocated such insurance for these "unrelated donors" so that they are protected, medically and in the long term, against any loss of "productive life-years" due to organ donation, at any later stage and age of life.

Ethicists and disciplinarians would, however, beg to differ. They would say that a kidney is not a "commodity" to be bought and sold. They would argue that the procedure of organ donation has short- and long-term effects on the donor as well as his/her family, and this needs thorough understanding and awareness. Organ donors need to be followed up not only in the pre-donation work-up, but also with annual health check-ups throughout their life to pre-emptively detect and treat any possible disease or infirmity.

Most unrelated "altruistic" donors and their "unwillingly willing" families are not even aware of the possible aftermath

of the procedure or its long-term effects. The only stimulus for donation remains “monetary”, the aim being to overcome immediate socioeconomic difficulties, and as such, these donors may be inadequately worked up for donation so as to fast-track the entire process.

Though the legalisation of unrelated donation may help overcome the acute shortage of organs, it should not be without its own “disclaimer”.

The Indian scene and state of mind

Currently, there are over 120 transplant centres in India, performing around 3000–4000 kidney transplants annually. According to rough estimates, around 15% are unrelated transplants, for which the kidney was donated out of “love and affection” (11). Since the legal appellate authority has no knowledge of such unrelated transplants, it is impossible to judge their exact number both in India and elsewhere, and these figures could just represent what can be extrapolated from the microscopic to the gross level. This, however, does not take away from the overall issue; instead, it makes it all the more important to deal with.

The economic disparity between the donors and recipients makes it very difficult to believe how the downtrodden donors could suddenly develop such affection towards the economically sound recipients. It is evident that despite the fact that the THO Act was passed more than 20 years ago, it has neither curbed commerce, nor helped in the promotion of deceased donation to bridge the rift.

If organised properly and in a timely manner, deceased organ donation, commonly known as “cadaveric transplant”, has the potential to take care of the greater part of the demand for renal transplantation in a particular state. These transplants, though technically more demanding and requiring a higher level of organisational skill, have gained acceptance in the culture of only very few states in India. These are Kerala, Gujarat, Tamil Nadu, Andhra Pradesh and Maharashtra. Probably it is the people in these states who are truly following the norm of “charity begins at home” simply by donating the organs of their deceased near and dear ones.

The organisation of such cadaveric transplantation has also been left to certain NGOs, with little or no cooperation from government agencies. Not only does this put increased pressure on the already overloaded “living donation programme”, but it also leads to a manifold wastage of life-saving organs from potential brain-dead donors or those who have succumbed to road traffic accidents. A very high level of motivation and compassion is mandatory to orchestrate a deceased donor transplant programme across all states in the country, as well as worldwide.

Cultural and religious beliefs form another roadblock to this programme. In countries such as India, religious beliefs generally discourage organ harvesting from cadavers, thus making it hard to convince relatives to donate the organs of their loved ones whilst the heart is still beating. A brain-dead patient, kept “alive” via a life support system, looks completely

normal and thus, most relatives find it impossible to accept that the person is in a vegetative state and will certainly never allow the removal of organs from the patient. Therefore, to ensure that this huge organ pool does not go to waste, there is a need to bring about a sea change in the sociocultural beliefs of people (11).

On the other hand, what is the harm in letting people with ESRD / chronic kidney disease / renal failure remain on dialysis until they find a cadaveric donor, or until any first-degree relative willingly donates his or her kidney? There is absolutely no harm, but, as per recent Indian data, one must consider how long the 650 government-authorised dialysis units available would be able to sustain the burden of the approximately 80,000 new patients annually diagnosed with ESRD (12,13).

Renal transplantation generally offers a longer lifespan and better quality of life than long-term dialysis. However, nearly every country is facing an acute shortage of kidneys for transplantation. In the USA, 50,000 individuals are waiting for kidney transplantation, yet only 15,000 kidneys are transplanted annually (5). The shortage is even more severe in developing countries. Even though India has four times the population of the USA, Indian physicians transplant fewer than 4000 kidneys annually, and a number of the organs are received by non-Indian transplant tourists (12,13,14).

Another facet of the entire picture is that patients of ESRD have a very poor quality of life and mostly suffer from social neglect due to their substantial “in dialysis” time.

A fervent plea made by a group of 90 Indian patients awaiting renal transplant via the unrelated donor programme against the ban aptly summarised the situation. They stated: “True, hard destiny forces people to sell their kidneys, but by this act, they bless ill-fated people like us with a new lease of life. This country has the unique distinction of giving rebirth to ESRD patients.” (15). However, they also clarified that they are not opposed to the bill, but urged the government to allow the unrelated donor programme to continue till such time as all hospitals switch over totally to the cadaveric programme.

Introspection

The main reason for the increasing number of patients on the renal transplant waiting lists is the steady growth of a patient population that needs renal replacement therapy worldwide. At the end of 2001, as per WHO estimates, approximately 1,479,000 people were alive in the world just because they had access to dialysis and renal transplant facilities. This number increased to 1,783,000 by the end of 2004 and exponentially thereafter (14,15). The major factors that contribute to the continuous growth in the number of patients with ESRD are universal aging of populations, higher life expectancy of treated patients with ESRD, and the increasing access of a generally younger patient population from developing countries to dialysis and renal transplantation facilities. Effective strategies to prevent the increase in the number of patients with ESRD or new treatment modalities that are either superior to

or an alternative to dialysis and renal transplantation are not expected to be available at least in the coming decade. Herein lies the need to find alternative feasible solutions.

According to a recent report (15), in a case similar to that of Pooja's, a transplant team at Mumbai has successfully carried out a transplant from mother to son, despite ABO incompatibility. The only glitch, so to say, is that the patient needed plasma exchange and induction via Rituximab, and was admitted almost 15 days prior to the actual transplant, which exponentially increased the costs to nearly 7 times the normal. How many people can afford this in an impoverished and developing country, or even in a developed country, is a matter of debate. Also, the long-term follow-up results are not yet available, so it cannot be safely extended to become a standard of care.

Role of marginal donors:

"Marginal donors" or "expanded criteria donors" are a pool of the population that needs immediate attention so as to reduce the dearth of organs. This involves using suboptimal cadaveric renal allografts, non-heart-beating donors or living donors with acceptable medical risks (16). This expanded pool would include elderly living donors (with an age-corrected glomerular filtration rate), living hypertensive, diabetic or proteinuric donors, living dyslipidaemic donors, living donors with a history of malignancy, as well as donors with a history of nephrolithiasis (16).

"Expanded criteria donors", a category coded in 2002, are defined as kidney donors over the age of 60 years without any co-morbidity or donors over the age of 50 years with any two co-morbidities out of hypertension, death from a cerebrovascular accident or serum creatinine levels of above 1.5 mg/dl (17). The upper age limit for such donation has still not been defined (17).

A shortcoming could be the overall graft survival from such donors, which has been reported to be overall inferior to graft survival in recipients of kidneys from donors who meet the standard criteria and are medically fit (18,19).

Despite the pitfalls of "marginal donation", it would probably still lead to an increase in the legally and socially acceptable related organ transplantation rate. Moreover, such donation has been found to be more cost-effective for patients than is leading a life that is dialysis-dependent in the long term (20).

As is rightly said, "Every single drop accumulates to form an ocean." So, too, every single acceptable kidney would help to improve the lives of the ocean of people with renal failure, struggling to find a medically, ethically and legally acceptable donor.

Future scope

Another immediate strategy that can be utilised to prevent organ exhaustion is "swap or pair transplants". This involves an exchange of kidneys between two pairs of people (two couples) based on their ABO compatibility, to benefit each

other's recipient. This would probably be the most ethical mode of unrelated transplantation.

New cost-efficient therapies are the need of the hour to salvage the situation for patients with renal failure. Man, by nature, is a thinking animal and medical science is evolving by leaps and bounds. The role of tissue engineering, stem cells or "in-vitro kidneys" in providing alternative organ resources needs to be explored in the near future.

One such step in this direction has been taken by researchers in the USA, where a prototype of a surgically implantable, artificial kidney has been developed. Human trials of these "wear-on" kidneys are awaited before they can be accepted into the field of "renal transplantation". Till such time, it would probably be safe to say that unrelated renal transplantation forms the "ledge of a precipice".

Perhaps the following paragraph gives an apt insight into the mindset of an ESRD patient and his family:

*Donate to a stranger.....Keep another family whole....
While filling your heart and inspiring your soul.....
Who knows, when you give a part of yourself.....
You'll end up more fulfilled and complete, much much
more, than before....*

Thus, it would be safe to say that though transplant recipients may obtain a "net gain" and the impoverished kidney donors may incur a "net loss" in the long term, there are no trials or studies to prove the same, and how the right balance – legally, socially as well as ethically – can be obtained remains to be debated so that there is a "win-win" situation for all.

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COMMENTARY

Trade in kidneys is ethically intolerable

DOMINIQUE E MARTIN

Abstract

In India, as in most countries where trade in human organs is legally prohibited, policies governing transplantation from living donors are designed to identify and exclude prospective donors who have a commercial interest in donation. The effective implementation of such policies requires resources, training and motivation on the part of health professionals responsible for organ procurement and transplantation. If professionals are unconvinced by or unfamiliar with the ethical justification of the relevant laws and policies, they may fail to perform a robust evaluation of prospective donors and transplant candidates, and to act on suspicions or evidence of illicit activities. I comment here on a paper by Aggarwal and Adhikary (2016), in which the authors imply that tolerance of illicit commercialism in living kidney donation programmes is not unreasonable, given the insufficiency of kidneys available for transplantation. I argue that such tolerance is unethical not only because of the harmful consequences of kidney trafficking, but because professional tolerance of commercialism undermines public trust in organ procurement programmes and impairs the development of sustainable donation and transplant systems.

Introduction

The use of financial incentives to increase living kidney “donation” has been the subject of debate among ethicists

and transplant professionals since the 1980s. The persisting problem of insufficient supply of human kidneys for transplantation in many countries is repeatedly cited as a rationale for the introduction of legal markets in kidneys (1). Illicit trade in kidneys also remains a widespread problem, and some commentators have argued that the introduction of regulated markets – sometimes described as “incentive programmes” – would reduce such trafficking and prevent the harms associated with the black market (eg. 2). Aggarwal and Adhikary draw attention to this complex issue in the context of India, presenting an ambivalent position on the incentive debate (3). In this commentary, I clarify some of the points they raise and contend that a permissive approach to kidney trafficking is ethically unjustifiable. Specifically, I argue that Aggarwal and Adhikary underestimate the negative impact of kidney trafficking on organ sellers, transplant recipients, and the broader organ donation and transplantation system. I further argue that regulated incentive programmes are likely to replicate many harms associated with illicit kidney markets and suggest that a more robust approach to the prevention of kidney trafficking, together with greater investment in efforts to reduce the burden of end-stage renal disease (ESRD) and to facilitate and encourage living and deceased donation, will ultimately improve equitable access to transplantation in India.

The law governing transplantation in India

Aggarwal and Adhikary refer to the Transplantation of Human Organs Act (THOA), 1994, which was enacted in 1995 (4). It specifically prohibited payment for organs, and required review by an authorisation committee of all prospective living donors who are unrelated to the intended recipient, defined as all those not spouses, children, parents or siblings, but who wish to donate “by reason of affection or attachment towards the recipient or for any other special reasons”(4).¹

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