**UNRELATED RENAL TRANSPLANTATION: AN ETHICAL ENIGMA**

**Running Title:** Unrelated Renal transplantation.

**Type of Article:** Discussion.

**Abstract:**

End Stage Renal Disease (ESRD) is a condition better discussed than suffered. People suffering from ESRD are shorthanded, not only financially, but also emotionally as well as in their quality of lives.

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 up with demands, 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 entirety, on both 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.

**Keywords:**

Cadaver donors; Ethical Enigma; Kidney ; Transplant tourism; Unrelated renal transplant;

**UNRELATED RENAL TRANSPLANTATION: AN ETHICAL ENIGMA**

*“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. “*

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 on the move, to ensure no *“toxicity”* ever sets in. But, what would happen if this God given gift developed fatigue and shut shop?

**A Hypothetical Scenario:**

Consider a hypothetical scenario-

Pooja, an 18 year old girl, is the only child of her parents. Theirs is a nuclear family, belonging to the upper socio-economic strata. What’s wrong with this, one would ask. Well, Pooja is surviving on alternate day haemodialysis, since the past 5 years, on account of End-stage renal disease. She spends more than 60% of her time shuttling between home and hospital, her parents in tow, with whatever remainder of her time left, utilized in study and recreation. What is her misendeavour? Has she not taken good care of her kidneys?

Why can’t she go in for a renal transplant and replace her machinery? She can, however she needs a donor. Her parents, though more than willing, have been ruled out on account of ABO incompatibility. She has been enrolled 5 years ago, on the cadaveric transplant wait list, where she has moved on, from a dismal wait list number of 275, to a probable 120, over this period. 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” [1].

**The Transplantation of Human Organs Act (THO) and Pitfalls:**

The Transplantation of Human Organs Act (THO) [1] was adjudicated way back 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 authorization 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 in order to legalise unrelated renal transplants[1,2].

In lieu of the ever expanding pool of End-stage renal disease (ESRD) patients, the rift between the demand and supply of “kidneys” has only widened, resulting in widespread use of this misnomer of “love and affection” of the THO act[1,2].

Additionally, it has led to a tremendous increase in “*Transplant Tourism*” from those countries having strict law-enforcement agencies, to countries such as India and China, where this is somewhat lax, leading to such countries being nick-named as “*Warehouses for Kidneys*” or specifically for us, “*The Great Indian Kidney Bazaar”* [2,3,4]*.*

It’s 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- government organisations (NGO’s) , even 5 years after such commercial donation, found more than 84% of such donors still remaining drowned in various debts (despite receiving the promised sum of money)[6].

**The Problem:**

So, where lies the crux of the problem? Is it in the proper enforcement of the THO law or is it a societal issue, that such nefarious activities have become widely accepted. The dictum *“when you can buy one, why donate”* [5,6] still holds very much true. In today’s self-centered, self-proclaimed “*modern”* society, where bonding between relations has become an abyss, is there any scope of expanding the law, so as to legalise unrelated transplants, is what needs to be explored.

In India, despite the THO act [1], neither has the organ commerce stopped, nor have the number of deceased donors increased, to take care of this 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 authorization committee, to take advantage of the loopholes of the interpretation of this act, as evident from the various kidney racket scams, over the years, viz. the Gurgaon kidney racket Scam(2008) and the Lucknow Scam(2011) [8]. Prima facie evidence even suggested the involvement of a senior police officer and a “quack” doctor [8].

These are just a few instances that have come forth into the public domain, and may even be just the tip of the iceburg, that is yet to be unravelled. Thus, the need to get to the root of this 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 other non-purists would opt for a “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 like Iran and Singapore, where the basis of legalising this, lies on the fact that most “law suits” occur, post transplantation only if the capital gain promised to the donor hasn’t been fulfilled 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 middle men, but would also ensure an adequate compensation reaching the donor in a timely and legalised manner [9]. Needless to say, this would also help to cut short the long deceased-donor transplant waiting lists [7,9].

What is however, 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, equates to around 98000 US dollars[10]. Needless to say that such an exorbitant sum of money can’t be afforded by everyone 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, needless to say, would never be the same, unless regulated by an appellate authority worldwide.

Taking this a step even further, some people have even advocated an *“Organ Auction”* in a legalised manner, 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, where “health insurance” is sacrosanct, altruists have advocated such insurance for these “unrelated donors”, so as to be take care-of, both medically as well in the long term, for 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, and 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. Not only in the pre-donation workup, but also later in life, with annual health check-ups, organ donors need to be followed up for their lifetime, to pre-emptively pick up and treat any possible disease or infirmity.

Most of the unrelated, “altruistic” donors and their “unwillingly-willing” families are not even aware of the possible aftermath of the procedure, as well as the long term effects, and the only stimulus for donation, remains “monetary”, so as to overcome immediate socio-economic difficulties, and as such, they may be inadequately *worked-up* for donation, so as to fastrack the entire process.

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

**The Indian Scene & State of Mind:**

Currently, there are over 120 transplant centres in India, performing around 3000-4000 kidney transplants annually, with rough estimates of around 15% as unrelated transplants, where donation was done out of “love and affection”[11]. Being done against the legal appellate authority’s knowledge, it is impossible to judge the exact numbers of such unrelated transplants being done both in India as well as elsewhere, and these figures could just be those that can be extrapolated from the microscopic to the gross level. This however, doesn’t dampen the overall issue, rather makes it all the more significant to be dealt with.

Nevertheless, the economic disparity between the donors and recipients however makes it a very hard pill to digest, as to how these downtrodden people suddenly developed such affection towards the economically sound recipient. Nevertheless, it is clearly evident that the THO act, despite having been passed more than 20 years ago, has neither curbed commerce, nor helped in promotion of deceased donation, to bridge the rift.

Deceased organ donation, commonly known as “cadaveric transplant” if organised properly and in a timely manner, has the potential to take care of the majority of the demands of renal transplantation of a particular state . These transplants, though more technically demanding and requiring a higher level of organisational skill, have become inculcated into the culture of only a very few states in India, viz. Kerala, Gujarat, Tamil Nadu, Andhra Pradesh and Maharashtra. Probably it is these states that are following the norm of *“charity begins at home”* to the core, by providing a new dawn in the lives of several patients, simply by donating the organs of their deceased near and dear ones.

The organisation of such cadaveric transplantation has also been left to certain NGO’s (Non Government organisations) with little or no co-operation 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 in order to orchestrate a deceased donor transplant programme across all states in our country, as well as worldwide.

Cultural and religious beliefs form another road block to this programme. In countries as India, religious beliefs generally discourage organ harvesting from cadavers, thus making it very 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 life-support system will look 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 their loved ones. Thus the need to bring about a sea change in the socio-cultural beliefs of peoplein order to ensure that this huge organ-pool doesn’t get wasted [11] .

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

Compared with long-term dialysis, renal transplantation generally offers a longer life span and a better quality of life. However, nearly every country is facing an acute shortage of kidneys for transplantation. In the United States, 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. Despite India having 4 times the population of the United States, 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 to this entire picture is that these patients of End-stage renal disease (ESRD) have a very poor quality of life and are almost social neglects, due to their substantial *“in dialysis”* time.

A prevent plea made by a group of 90 Indian patients awaiting renal transplant, via the unrelated donor programme against the ban, aptly summarises 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 re birth to ESRD patients”* [15]*.* However, they also clarified that they aren’t 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:**

To introspect, the main reason for this 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 further exponentially thereafter [,14, 15]. The major factors that contribute to this continuous growth in the number of patients with ESRD has been explained by universal aging of populations, higher life expectancy of treated patients with ESRD and increasing access to dialysis and renal transplantation facilities of a generally younger patient population from developing countries. The effective strategies to prevent increasing numbers of patients with ESRD or new treatment modalities to be either superior or as an alternative to dialysis and renal transplantation are not expected to be available at least in the upcoming decade. Herein lays the need to find alternative feasible solutions.

In a recent report [15], in a case similar to that of Pooja’s, a transplant team at Mumbai, has successfully carried out a transplant, despite ABO incompatibility , from mother to son. 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 could afford this, in an impoverished, developing and even a developed society, is a matter of debate. Also, the long term follow-up results are not yet available, to safely extend this as 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 this organ-dearth. They imply 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 [GFR]), living hypertensive, diabetic or proteinuric donors, living dyslipidemic donors, living donors with history of malignancy as well as donors with a history of nephrolithiasis[16].

As per the definition of “*Expanded Criteria Donors*”, coded in 2002, 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 > 1.5 mg/dl, would be acceptable [17]. What should be the upper limit of age for such donation, has still not been defined [17].

Another shortcoming could be the overall graft survival from such donors, which has been reported to be overall inferior when compared to reciepients of the standard criteria-medically fit, donor kidneys , [18, 19].

Despite all pitfalls of “Marginal donation”, they would in turn still probably lead to an increase in the legally and socially acceptable related organ transplantation rate.

Moreover, economically too, they have been found to be more cost-effective, when compared with long term dialysis-dependent life[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 thes ocean of people with renal failure, struggling to find a medically, ethically and legally acceptable donor.

**Future Scope:**

*“Swap or Pair transplants”* could also be an immediate strategy that can be utilised to prevent organ-exhaustion. Here, there is an exchange of kidneys between two pairs of people(two couples) based on their ABO compatibility, to benefit each other’s recipient. This probably would be the most ethical of unrelated transplantation.

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

One such step in this direction has been put forth by researchers in United States, where they have developed a prototype of a surgically implantable, artificial kidney. Human trials are the next in line for these “wear-on” kidneys to 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”.*

Maybe the following paragraph may give 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 have 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, is what remains to be debated, so as to obtain a “win-win” situation for all.

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