Living Donor Liver Transplant is a Transparent Activity in India

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Living donor liver transplant (LDLT) has progressed rapidly in India with at least two major centers performing over 200 transplants annually. There have been concerns regarding donor safety as donor deaths have been reported worldwide. In India, there is a possible underreporting of donor complications and mortality leading to the allegation that LDLT is a clandestine activity.

Deceased donor liver transplantation activity may be less transparent as there are no national guidelines for retrieval and allocation of organs. LDLT is for a named person and as the activity can only be conducted in major hospitals with involvement of over 100 medical personnel in each operation, it cannot be a clandestine operation. Government regulations require licensing of hospitals following inspection by senior doctors and reporting of transplant activity periodically.

About 2500 living donor liver transplants have been conducted in India and there have been 7 donor deaths reported in India. Rather than not being transparent, donor morbidity and mortality has received excessive media attention.

Most liver transplant activity in India is well organized with clearance from hepatologists and anesthetists. Unrelated donation needs to be cleared from a State appointed Authorization Committee. Foreigners cannot be transplanted without State clearance and approval of the concerned embassy. The donor risk is discussed and the success of the recipient operation is also explained to all patients.

The ever-increasing popularity of the operation in spite of the high cost and the requirement for donation from a family member suggests that many patients are living healthy life after transplantation. Overall LDLT is a transparent activity in India. (J CLIN EXP HEPATOL 2013;3:61–65)

Living donor liver transplantation all over the world has been mired in an ethical debate relating to whether donor surgery is safe or not.¹ Many physicians believe that it is not and therefore those of us who do LDLT are thought to be nontransparent. In this article, right lobe liver transplant² will first be discussed, then how it is done in India and thereafter questions relating to transparency will be addressed and the reader will be left to decide whether it is a transparent activity or not.

RIGHT LOBE LIVING DONOR LIVER TRANSPLANTATION

In 1998, when the first living related liver transplantation was done at the Apollo Indraprastha Hospitals in Delhi,³ it was a landmark event for the country. It changed the par-

adigm for treatment of patients with end-stage liver disease. Theoretically every patient could now have a liver transplant operation and not die while on the waiting list.

However, in right lobe liver transplantation, donor hepatectomy is a major operation for the donor and unfortunately donor deaths have occurred. This aspect of right lobe transplantation has received widespread publicity and has also given the impression that there is underreporting of this unfortunate event. Apart from this, right lobe liver transplantation is a hugely successful operation⁴ and many hospitals and doctors are under pressure to start this procedure.

ISSUES RELATING TO TRANSPARENCY IN LIVING DONOR LIVER TRANSPLANT (LDLT)

Many physicians, particularly those who are not directly involved in the care of patients with liver failure, believe that living donor liver transplant is not a transparent activity in India. When they talk about transparency, they are mainly concerned with the issue of donor morbidity and mortality.

On the other hand, deceased donor liver transplantation (DDLT) activity in the country is perhaps more prone to being nontransparent with concerns about equitable distribution, appropriate use of a scarce resource and criteria

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Abbreviations: LDLT: living donor liver transplant; HOTA: Human Organ Transplant Act; DDLT: deceased donor liver transplantation

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for sharing organs between private and public hospitals.⁵ Further, there is as yet no national or even a regional common waiting list. Some organs are wasted, as they are not exported outside the state of donation when there is no suitable recipient within the State. As it may hurt cadaveric donation, in general only the positive side of cadaveric transplantation is highlighted and discussed.

As right lobe liver transplantation involves huge amounts of money, is done mainly in private hospitals⁶ and many of the patients are from abroad,⁷ there is a great scope for illegal activity. In general, the scandals that involve transplant activity are organ trafficking, poor results, donor morbidity and poor postoperative care of donors. However LDLT has benefitted a huge number of patients and by and large remained “clean” by strict adherence to the Human Organ Transplant Act (HOTA).⁸

In liver transplantation, there is an additional issue of indicated transplant.⁹ In kidney transplant the need for transplant becomes very clear once the patient goes on regular dialysis. In liver transplant if it is done too early one runs the risk of patient mortality and if one delays it too much, then the success of the operation is jeopardized. The MELD scoring system, which is mainly applicable to cadaveric transplantation, is used in the developed world to guide when the transplant should be done. With the MELD scoring system, a cadaveric liver goes to the patient who is most likely to die without a transplant at that time. In LDLT, this model does not apply as one would want to do the operation at the time when the patient is relatively stable and therefore can undergo this major operation successfully.¹⁰ There is a possibility then that the transplant may be done early after scaring the patient that he will die quickly.

LIVING DONOR LIVER TRANSPLANT PROCESS IN INDIA

Setup

However in reality, LDLT can only be carried out in a multi-specialty hospital, which is always in the media glare. A typical liver transplantation operation will involve over 100 personnel. After the patient approaches a liver transplant surgeon, usually on his or her own initiative, as even now there is no systematic referral for transplant in our country, they decide whether they want to proceed with the transplant. They are told about costs and the need for a family member to donate part of their liver. If they want to still go ahead, the donor work up is conducted and the case presented to the Authorization Committee.

Authorization Committee

All private hospitals now have a 10–12 member hospital based committee in case of donation from a near relative. When the donation is from an extended family member,

the State based Authorization Committee decides. Following clearance from the Authorization Committee, in many centers in India, the case will be presented in a multidisciplinary Board meeting before taking up the patient for transplant. In case of near relative, the process is pretty straightforward. When it comes to extended family members as donors, the case has to be presented to the State Authorization Committee, which conducts an interview of the donor and the recipient and looks at the financial status of the pair and only if and when they are convinced is permission granted. In case the donor and recipients have separate states of domicile, then a NOC (no objection certificate) has to be obtained prior to transplant from their State of domicile.

MONITORING OF TRANSPLANT ACTIVITY

The Health Ministry has to be informed about the number of cases done every month. Liver transplant cannot be conducted without inspection and permission by the government. This license has to be renewed every few years. Four doctors, usually from major government hospitals in the country, do this inspection for renewal of the license. Thus a system is in place to ensure a transparent LDLT.

However there are still areas where there may be a lack of transparency. These areas will be highlighted and then the readers can decide whether transparency is possible in such areas.

UNRELATED DONATION

Do unrelated donors get transplanted? Yes.¹¹ However most of these transplants are from extended family members. For example, the law makes it difficult for anyone from the “in laws” side to donate. There is a provision in the law that emotionally related donors can donate. Thus, if a brother in law wants to donate, transplant clinicians encourage it. The case goes to the Authorization Committee and they decide on the donation. The only way an irregularity can happen is if the integrity of the entire committee is compromised.

MEDICAL TOURISM

There is a huge amount of medical tourism involved in LDLT. The Law states that the certificate from the Embassy is essential to allow transplant from these individuals.¹² All transplants in foreigners therefore have to be cleared by the Consulate. Further, in normal circumstances, the Law does not allow donation by an Indian donor if the recipient is a foreigner.

EARLY OR UNINDICATED TRANSPLANT

Often there is an allegation that transplants may be conducted in patients who would not be transplanted in the

developed world. In most of the developed world transplants are done from cadaveric donation. Therefore there is a tendency to restrict donation to individuals who the society thinks are responsible members of the society and also to recipients in whom the best long-term results are possible. Two examples where changes from established practice has now become acceptable are quoted.

At Apollo Indraprastha Hospitals, much before the article appeared in NEJM,¹³ patients with alcoholic steatohepatitis whose family were very keen that they should have a transplant, underwent transplantation of course, during the counseling sessions, it was made clear to them that there was a risk of recidivism. On most occasions the answer of the family was that they would sort it out once the transplant was successful. A similar contentious issue has been transplants for HCC. Some centers will transplant patients with HCC, no matter what the size and what the number of nodules, as long as there is no extrahepatic disease or portal vein invasion. This does not mean that there is a lack of transparency as it is well recognized that even in these situations a 50% 5-year survival is possible.¹⁴ In many cases, patients, who spend upward of Rs. 20 lacs and get a donation from a family member, have already done their research. To say that they can be persuaded into a transplant is to doubt their intelligence.

DONOR RISK IS UNDERPLAYED

Yes, this could be true but it does not mean that there is no transparency. Some of the big centers have now had experience of hundreds of transplants and almost all donors have recovered completely. There is enough literature about unexplained deaths after any procedure. Deaths have been reported after laparoscopic cholecystectomy, liposuction and hernia surgery. However the argument has been that in these procedures the patient is relieved of his suffering. What about pregnancy? Last month, there was a report that the use of condoms has prevented 95,000 pregnancy related deaths.¹⁵ Perhaps LDLT should be thought of as similar to pregnancy. Both give life. That a family may not be aware of the possibility of donor death is not true. Most of patients come to a transplant surgeon after surfing on the Internet.¹⁶

THE SUCCESS OF RECIPIENT OPERATION IS OVERSTATED

It may be so but only the foolhardy surgeon in the private sector will not counsel the patient for the eventuality of recipient death postoperatively. Everyone of those who specialize in Hepatology in India will candidly admit that the biggest advance in our country has been the availability of a successful liver transplant program.

REPORTING IN A SCIENTIFIC FORUM

What about reporting results in a scientific forum?¹⁷ There is a little bit of surgical 'egoism' in these presentations. However it must be borne in mind that this has been an eternal problem. The 2-week result of the transplant operations it is nearly 100%. At 1 month, it is 95% and at 3 months it 90% and at 1 year it 85%. There are many factors, which go into the success of the operation including patient selection and his or her condition prior to the operation. Is it right to deny an operation to someone who has only 70% chance of success? If we were to include high-risk patients in one's series, then off course the results would be skewed.

ABSENCE OF AUDIT IN INDIA

In most liver centers when patients die after acute or chronic liver failure, not an eyebrow is raised. However should a patient die after a transplant operation, it is big news and everyone in the hospital from the sweeper to the Director is aware of this unfortunate event. Shouldn't the nonsurgical deaths be subjected to scrutiny as well? In reality there are no benchmarks for medical treatment in India. Even in the West, the benchmarks are mainly for surgical procedures. In liver transplantation, a survival of over 80% is very good considering that in the absence of transplant the outcome is certain death, albeit in a few months time.

IS THE ISSUE OF TRANSPARENCY A COVER FOR NOT DOING LIVING DONOR LIVER TRANSPLANT (LDLT)?

There is a great pressure in the private sector to establish a liver transplant program. Equally so, there is a pressure in the government sector.⁶ An easy defense is that the procedure is associated with poor results and tremendous donor morbidity and mortality. In a series from Asan Medical Centre, Seoul, Korea, the results of one thousand consecutive LDLTS showed no donor deaths. In the author's own series of over 800 transplants, there was one donor death at 6 weeks from subarachnoid hemorrhage in a female donor who had previously received treatment for intra-abdominal malignancy. This fact was conveniently hidden by the donor. The steps of this operation have now been nicely worked out and provided one is willing to spend 12 continuous hours on one operation, the results are nearly always positive.

IS IT TRUE THAT THE RESULTS OF LIVING DONOR LIVER TRANSPLANT (LDLT) ARE INFERIOR TO DECEASED DONOR LIVER TRANSPLANTATION (DDLT)?

Many series have now shown that the results of LDLT may actually be better.¹⁸ That this operation has changed the

life of many Indians is obvious from the fact that in 2005, the author's group conducted less than 25 operations. In 2012, in the last 6 months, it has conducted over 150 operations. The popularity of this operation would not have been there had this been associated with poor results.

ARE ALL SEEMINGLY ALTRUISTIC DONATIONS ACTUALLY SO?

Altruism in donation is very difficult to assess.¹⁹ Most donors gain something from donation, be it emotional or financial gain or the pleasure of fulfilling one's duty. The motivation for donation from a parent to a child is in a different category as compared to a donation from a brother. The law looks at all donations from near relatives as being similar. In one instance, a brother donated on the condition that the property dispute between them would be resolved. Situations such as these never come to the knowledge of the treating Unit and certainly never to the Authorization Committee who only have one meeting with the donor and recipient. This situation is akin to commercialization. However no system can prevent this kind of lack of transparency.

IF KIDNEY TRANSPLANT IS ASSOCIATED WITH SCAMS, WHY SHOULD LIVER BE AN EXCEPTION?

The kind of scams that have plagued kidney transplant all over the world have so far not been reported in LDLT in India.²⁰ LDLT surgeons have to spend hours in the OT and subsequently 2 intense postoperative weeks to aid in patient recovery. Any illegal activity results in stress that harms patient recovery. There is another difference as compared to kidney transplant. As a nephrologist looks after most patients with chronic renal failure, the surgeon sometimes gets to know the patient and the donor very late. It is quite a common practice for a nephrologist to surgically create an AV fistula for dialysis, the follow up is again with the nephrologist but when it comes to illegal activity it is only the surgeon who is responsible. Therefore to equate the two transplants with the same criticism would be inappropriate.

COOPERATION BETWEEN CENTERS

Some of the leading surgeons have not reported their experience when they have helped other centers in the country to establish their programs. No one can dispute that this is not a healthy practice. However should the outcome there be reported by the established center as part of its result, when it is well known that the postoperative care of the donor and recipient cannot be ensured by the group which helped at the time of operation? The author strongly

thinks that the onus of transparency lies with the center that sought the help rather than those who provided the help.

NATIONAL REGISTRY

A registry is essential but who will check the accuracy of what is put in the registry? Should there not be a registry for patients with chronic liver disease? Liver transplant activity is well recorded in all hospitals involved in the procedure and the Health Ministry has the data of donors and recipients. As liver transplant is such a successful operation, a registry should be created to record details of all patients of cirrhosis. This will help in decreasing the death from cirrhosis, as most of adult causes of cirrhosis are preventable.

Let the knowledgeable reader decide whether LDLT is a transparent activity in India based on what has been written.

CONFLICTS OF INTEREST

The author has none to declare.

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