

# Living Donor Liver Transplant is not a Transparent Activity in India

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**Living donor liver transplant has gained rapid popularity in India as a life saving procedure for end stage liver disease. The undoubted benefit for the recipient is clouded by a few unfavorable outcomes in donors which have led to allegations of lack of transparency. These factors are easily remediable with an attitude of self audit and self disclosure by transplant centers, enabling a truly informed consenting procedure. (J CLIN EXP HEPATOL 2013;3:66–69)**

Living donor liver transplant (LDLT)—the term itself implies a perfectly normal healthy human being undertaking an act of supreme sacrifice, mostly with gratifying results but with a risk of major morbidity or even death. Inherent to the definition are factors like lack of compulsion, no incentive other than altruistic or emotional and a fatalistic acceptance of the outcome. On the face of it, there seems to be little reason to question the ethics behind donating organs for loved ones. LDLT in comparison to deceased donor liver transplantation (DDLT) has always been a hotly debated issue, sometimes being projected as a savior and sometimes vilified as a modern evil created by the hand of surgeons.<sup>1</sup>

## LIVING DONOR LIVER TRANSPLANT—A BOON FOR DYING PATIENTS?

There is no denying that the LDLT as a procedure has opened new avenues to save patients dying on waiting lists. This is even more apparent in countries like India where deceased donors are far and few, and LDLT in the hands of competent surgeons has proven to be the panacea. The remarkable success and innovations have firmly placed India as a much sought after center for LDLT and thousands of people are given a renewed life through the noble altruism of others.<sup>2</sup> Even before the DDLT programme

could get going LDLT has been touted as the answer to organ shortage.

Emboldened by the good results surgeons have extended the boundaries of resection and indications for transplantation are being stretched. LDLT was first successfully introduced to the world as an adult-to-child procedure with a good safety margin for the donor. As the initial problems were overcome, the scope of the harvested organ has steadily increased so much so that a right lobe donation with the right and middle hepatic vein is advocated as the ideal adult-to-adult graft.<sup>3</sup> All these are at the cost of only one individual—the living donor and looming in the background is the specter of unethical practice, be it the informed consent, the verification of results and outcomes and the morbidity statistics.

## INFORMED CONSENT IN LIVING ORGAN DONORS

It is the right of every patient undergoing a major surgery to have a written informed consent. The process varies from country to country and is necessarily based on guidelines by the appropriate authority. The World Health Organization (WHO) has stated clearly in its Revised Guiding Principles<sup>4</sup> that “donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.” Even to date there are no national guidelines in India, countless committees notwithstanding. The Transplantation of Human Organs Act (THOA) Act 1994<sup>5</sup> does lay down stringent criteria for recognition of transplant centers but without a nodal database or registry there is no transparency on survival figures or outcomes. The THOA Act (Chapter IV, Section 13) mentions in the Appropriate Authority’s powers in para V ‘to inspect hospitals periodically for examination of the quality of transplantation...’. Although they inspect a center when it applies for renewal of registration, these results are not made public.

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*Abbreviations:* LDLT: living donor liver transplant; DDLT: deceased donor liver transplantation; WHO: World Health Organization; ALF: acute liver failure; THOA: Transplantation of Human Organs Act; UIDAI: Universal Identification Authority of India.

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A new center starting LDLT will go through a learning curve and will be loath to divulge the real statistics. LDLT should be considered unethical when performed at any center with suboptimal facilities or expertise. Large volume centers suffer from pooling of cases with advanced disease and are pressurized to do transplants in patients beyond criteria. In the USA an informed consent process with a standard patient information booklet is mandatory. In India each center has its own version and some none at all. With the added disadvantage of an emotional and largely low educated patient population the consenting process can often be sketchy. Literature supports this assumption even in western countries where it has been concluded that informed consent is a myth as most donors make instantaneous decisions without weighing the risks.<sup>6</sup> In this light it is even more important to convey the risk/benefit ratio clearly and lucidly. It does not matter whether the potential donor is a near relative or unrelated: the consenting process has to be the same, transparent and informed with true data and statistics.<sup>7</sup> An aggressive, detailed consenting procedure will also drive away potential donors and be counterproductive and hence most transplant units take the middle path.

## VOLUNTEERS OR COERCION

Freedom from coercion remains a fundamental right of the donor. The Random House Dictionary aptly describes coercion as “dominating or controlling (an individual) especially by exploiting fear, anxiety, etc;”.

An LDLT is a test of the emotional bond between donor and recipient. No other surgical procedure devised has the potential to harm than LDLT with no discernible health benefit to the donor. Without a complete transparent consenting procedure the role of emotional coercion cannot ever be put on the back burner as a non-issue. The sick recipient is usually announced as in dire need of a transplant and as the family desperately seeks a match from within, donation by one of its members is deemed justifiable since the family has accepted the risk/benefit ratio. However, this argument cannot be sustained in an unrelated donation where supposedly an emotional bond or sheer altruism is the driving force. The operation is always planned around the recipients need and not the donor’s mental acceptance and personal commitments. A suboptimal timing of surgery for both parties is also detrimental to results.

Donors in India are under intense pressure by the family and counseling of the donor privately is a rarity. No system exists to offer the potential donor a choice to “opt-out”, thereby negating pressure from the family. Largely done in private hospitals, LDLT will not be commercially viable if this option is exhibited to wavering donors. Nearly all centers make do with the transplant coordinator surrogating as a social worker as the whole concept of patient support from the social milieu is alien in India.

## ACUTE LIVER FAILURE

ALF is a medical emergency which carries a high mortality without intervention, namely a liver transplant. DDLT would be the ideal solution as LDLT requires an emergency, harrowing work up with no regards for the donor’s state of mind or acceptance of the risks involved.<sup>8</sup> ALF has a dramatic presentation and the element of anxiety driven coercion is at its peak. Though LDLT reduces the waiting time, its use in ALF is with a very narrow risk/benefit ratio and even large volume centers will agree that the results are inferior in comparison to chronic liver disease.

## AUTHORIZATION FOR DONATION

Unrelated donors have a more stringent scrutiny from an external authorization committee which severely stresses the individual. The most altruistic of donors is viewed with utmost suspicion and an undesirable end result often vitiates the atmosphere between the donor and recipient families.

The composition of the authorization committees is so heterogeneous that compromising the integrity of the whole committee is difficult. The lacuna lies in the documentation that is provided to establish a bond between the donor and recipient. The documentation required by the authorization committee includes police verifications, Panchayat certificates, proof of residence, etc. The failure of the Universal Identification Authority of India (UIDAI) Aadhar card implementation<sup>9</sup> and the endless fake PAN card scams<sup>10</sup> are an ample demonstration of the ease with which fake identities are built up and the deep subversion of the process. Identities and relationships can be bought and as the kidney racket of Gurgaon laid open,<sup>11</sup> touts are available for this special purpose.

The “Red Market”—Scott Carney’s<sup>12</sup> dramatic real life experience refers to the various medical activities through which the human body can generate a profit: surrogate motherhood, organ transplantation, drug testing, baby selling and blood farming. Middlemen take large profits and encourage the trade by assuring buyers that the transaction is conducted ethically. The relief at finding a suitable donor disguises what would otherwise be seen as exploitation. “The crimes are covered up,” Mr. Carney writes, “in a veil of altruistic ideals.” In a work of investigative journalism, he visits a tsunami refugee camp in Tamil Nadu whose inhabitants are so desperate (and the organ brokers so callous) that it is known as “Kidneyville.” The trade persists, according to Mr. Carney, as a result of a major flaw in the transplant system; while the law prohibits the buying and selling of organs, it does not prohibit anyone from billing for the services involved in transplanting organs. This provides doctors and hospitals with a financial incentive to perform transplants, while the costs of the organ procured are absorbed into the billing and easily hidden from view. You can buy an organ without knowing where it came

from, and it thus becomes mere tissue rather than part of a human being. Anonymity does not merely dehumanize donors, however; it also endangers them by making it easier for buyers and brokers to escape accountability for deaths and injuries. “Transparency,” Mr. Carney notes, “is capitalism’s most basic safety feature.”

The authorization committees have to face another devious problem. All states have not ratified the THOA and there is no uniformity of forms and affidavits from different states. In the case of foreigners a simple letter from the consulate is deemed enough and this is considered as clearance for a foreign national to undergo transplant in India without the normal stringent documentation required. This has spawned medical tourism which is often managed by non-medical personnel as a purely commercial venture and has popularized India as an LDLT center.

### IS THE PHYSICIAN TO BLAME?

It is held that malpractice in LDLTs is rare because unlike kidney transplantation the complexity of the procedure and higher risk to the liver donor serves as a caution for surgical teams that would indulge in an unethical liver transplantation especially because there is so much publicity attached to each operation. A few donor deaths have been recorded in India and the press has given wide publicity to these unfortunate events.<sup>13</sup> However, donor deaths have occurred in nearly all countries where LDLT is practiced including Europe, the USA, Turkey and Korea.<sup>14</sup> The ethical justification for the procedure and the ‘acceptable’ risk to the donor have also been widely debated. Interestingly, whereas transplant surgeons have placed the acceptable level of risk of donor mortality at less than 1%, a survey of the American public revealed an acceptance of mortality at 20%!<sup>15</sup>

Even DDLT in India not a stranger to controversy and lack of transparency. The recent death of a prominent politician who was flown Interstate to acquire an organ is still fresh in the public mind.<sup>16</sup> International standards set forth by the World Health Organization say that “the allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, and not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.” The WHO has also suggested that there may be ministerial and public oversight of updated comprehensive reports regarding the system of organ allocation in order to verify equitability and transparency.

### OUR RULES BEGET ORGAN TRADE

The Times of India on 4th September 2012 has reported a proposal by the Ministry of Health to amend rules in the organ transplant act to include ‘not so near’ relatives. Suggested modalities to establish the relationship with

the living donor have included a few bizarre suggestions like old photographs of donor and recipient staying together and sharing the same kitchen for more than 10 years. A hasty rebuttal was offered the next day by one of the committee members.

Until deceased donor organs are available to meet the need, living donation will be the need of the hour. Rather than make it difficult to donate by tightening rules and norms, what should be insisted on is greater transparency, dissipation of information, detailed counseling, donor advocacy and avoidance of coercion or inducement in any form. The increasing use of LDLT should not deter the medical community from researching ways to obviate the need of transplantation. In India, LDLT has deterred the expansion of DDLT.

### WHO DO THE LIVING DONATE FOR?

The high incidence of LDLT given to those with alcoholic cirrhosis has led to a recurring controversy regarding the eligibility of such patients for liver transplant.<sup>17</sup> The controversy stems from the view of alcoholism as a self-inflicted disease and the perception that those with alcohol-induced damage are depriving other patients who could be considered. This point has significance in the DDLT scenario with many takers for one organ, but this really is more appearance than fact, because right under the surface lurks a morass of ethical dilemmas and controversies which have threatened to undermine the entire practice of transplanting organs. These problems have only grown in scope as new medical advances have been made in recent years, with little prospect of an easy resolution any time soon.

Even the idea that organ transplants represent a great achievement in medicine is somewhat faulty. As Ronald Munson explains in this book “Raising the Dead,”<sup>18</sup> real medical miracles involve causing a person’s illness to disappear—the example of antibiotics is the clearest and most common. He mentions that organ transplants do not do this however: because a recipient has to take anti-rejection drugs for the rest of their lives, always fearing an infection which will get past their now-suppressed immune system, transplants simply trade one acute illness for another chronic condition.

Transplants aren’t a miracle, but they do work—ideally, they are a stopgap measure until something more permanent and effective can be developed. Fortunately, such a possibility does exist on the horizon, but it causes even more controversy than anything discussed so far. Eventually, people may be able to simply have replacement organs grown from their own DNA, eliminating matters of procurement, distribution, and even organ rejection. But this will apparently require the use of embryonic stem cells developed with cloning technology, opening up a host of different ethical debates.

## IS THE MEDICAL COMMUNITY AT FAULT?

LDLT is the brainchild of the medical community. Donor mortality is an accepted part of the risk involved and is palpably more than in a kidney transplant. Excluding coercion and the fact that the donor understands the risk—What is the mortality rate acceptable? Who decides this risk? Even if an emotionally charged willing donor accepts a death rate of 10%, should the medical community proceed with LDLT?

With the present level of data, records and transparency the fundamental problem lies in the fact that donor morbidity and mortality cannot be defined and quantified due to the variables involved. At the same time uncertainty on these cannot be taken as a roadblock to the consenting process.

If a patient is harmed after a procedure, than the doctor who performs it is also morally a partner in the implication. The difference being that the doctor after convincing the donor for a justifiable procedure, should also convince himself whether he is helping the donor achieve a morally justifiable act.

## CONFLICTS OF INTEREST

The author has none to declare.

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