



Liver Donation

This letter has been written to provide individuals considering liver donation (LD) with information about the rationale for living donation, the assessment process; the operation; post-operative care; and the alternatives, benefits, and the risks of this surgery.

Abbreviations

Deceased donor	DD
Living Donor	LD

Reasons to Consider Liver Donation

The option of living liver donation reduces the risk of health deterioration and death for patients who need a liver transplant. In Toronto, at any point in time, there are usually about 250 people waiting for liver transplantation. The waiting time for deceased donor (cadaveric) liver transplantation in blood group O patients listed in our program is about 4+ years. It is increasingly rare for a blood group O recipient to be transplanted while he/she is still well enough to wait at home. The current waiting time for blood group A recipients is about 2 years. The waiting time for a blood group B recipient is about 3 years. The waiting time for blood groups AB recipients averages six to twelve months. In 2004, more than 70 people died during their work-up for liver transplantation or while waiting for a donor organ.

Benefits and Risks for the Transplant Recipient

Benefits. Living donation offers several advantages in comparison to waiting for an organ from a deceased donor. First, it provides a unique opportunity to restore good health to a close friend or family member. Second, it provides the recipient with a high quality organ. Third, the transplant can be performed at an optimal time, before the recipient's health deteriorates unduly.

Risks. The one-year survival rates of liver transplantation using a living donor graft or a deceased donor are approximately 80-90%. Although graft function is usually excellent after living liver donation, there is a slightly increased risk of surgical complications associated with the anastomoses (joins) of the bile duct (about a 10-25% rate of leaks and strictures (narrowing) with LD versus 5-10% with DD) and hepatic artery thrombosis (a clotting rate of about 2% with LD versus 1% with DD). These complications can usually be managed without the need for further surgery and without affecting long term graft function. Physicians and surgeons in the Toronto Liver Transplant Programs believe that the slightly increased risk of technical complications associated with living donation are outweighed by the benefit of being transplanted at time when it is most beneficial.

Principles Guiding the Assessment Process for Live Liver Donation

- Recipients of living donor grafts must satisfy the criteria for deceased donor liver transplants or meet expanded criteria for transplantation that are within predefined protocols that have been approved by team members.
- The intended recipient must consent (agree) to living donation.
- Most potential recipients for living donation remain on the deceased donor waiting list while the living donor work-up is in progress. The opportunity for living donation does not affect the status of the recipient on the deceased donor list. Deceased donor organs are offered according to the standard allocation algorithm, irrespective of whether or not the recipient has a potential living donor.
- Living donation must be voluntary and altruistic.
- Donors must be between 18 and 60 years of age.
- Donor safety is the priority during the assessment. The duration of work up is determined by availability of healthcare resources, the donor's schedule, and the complexity of the donor's health issues. It may take days, weeks, or sometimes months to complete all of the necessary tests, and to confirm to the satisfaction of all health care professionals on our team that living liver donation is an appropriate and safe option.
- If the screening questionnaire reveals major health issues, we may ask the donor to provide a letter of support from his/her attending doctor before starting the work-up. This opinion would be considered carefully by the transplant team but the preliminary recommendation on suitability would not be binding.
- OHIP pays for the direct costs of liver donation. However, neither OHIP nor the hospital will compensate donors for time lost from work, travel expenses, outpatient medication costs, etc. If a donor travels from another country to donate; only assessment tests, physician, and hospital costs are covered by the recipient's OHIP. Travel costs are not covered, nor are the costs of any investigations or follow-up done in their country of origin.
- In some circumstances, living liver donation is not possible or appropriate. For living organ donation to proceed, there must be agreement between the donor, recipient, and the medical team. Unusual ethical issues may be taken to the Transplant Ethics Committee for review and advice. Since the physicians and members of the transplant team also act as moral agents, the final decision to perform the living donor transplant rests with the transplant doctors. There is no obligation for the transplant team to perform a live donor liver transplant if the medical and surgical team believes that the potential for harm outweighs the benefits. If we decide that live donation is inappropriate we will offer referrals to other programs for second opinions.

- Recipients of living donor grafts must agree to let us provide donors with information about the cause of the recipient's liver disease, the anticipated rate of success with living donor liver transplantation; and the potential for disease recurrence.
- It is the donors responsibility to communicate to the team if there are any concerns, or issues that need to be addressed regarding the assessment.
- By policy, living donation is not performed as an emergency procedure at our center. We believe that it is important to have a well rested, experienced team for this surgery to be performed as safely as possible.
- If more than one potential donor volunteers, the donors are investigated in order according to the date we receive the health questionnaire and blood type confirmation (unless the intended recipient and donors meet and collectively instruct us otherwise).

Living Donor Assessment.

Candidates for liver donation must be in excellent physical and emotional health. A history of cancer and/or an active infection are contraindications to organ donation. The donor must have normal or near normal liver function. The liver must have a pattern of blood supply and a distribution of bile ducts that are suitable for transplantation. Donors should have family or friends that can provide support before, during and after the surgery.

Upon request, potential donors will be provided with an information package on liver donation. *It is the donor's responsibility to let us know if they are interested in proceeding.* If a potential liver donor does not contact us within 4 weeks of sending the donor information package, we will assume that they are not interested in pursuing this option at this point in time.

Before starting a work-up, we ask potential donors to confirm that they will be available to undergo the donor surgery within the next 2 weeks to 3 months provided 1) no contraindications are found and 2) they still want to proceed after learning more about the procedure. If a potential donor prefers to wait longer than 3 months, we will delay starting the work-up until the 2-3 month time frame applies.

Smoking and the birth control pill are avoidable risk factors for blood clots after surgery. Therefore, we strongly advise donors to stop smoking for at least one month prior to donation. We also ask woman taking the birth control pill to stop this medication and use two alternative forms of contraception for 4-6 weeks before donation.

If a contraindication is found, the donor is notified and the work-up is stopped. The results of the health tests performed during the work-up are sent to the family doctor with a request that he/she follows up these tests. If a reversible contraindication is corrected (a fatty liver for example) the work-up can be restarted once we are notified by the treating doctor that the problem has been corrected.

The work-up is outlined below. If the donor prefers another order for these investigations, they should let the donor office know about their preferences.

The team assessing the donor is specifically focused on protecting the donor's interest's and well being. The screening tests are organized by the Donor Office. Blood samples are obtained to confirm blood group compatibility and normal organ function. An electrocardiogram and a chest x-ray are obtained to confirm normal heart and lung function. If these studies are normal, then a CT (computerized tomography), ultrasound, and MRI (magnetic resonance imaging) scans are arranged at the Toronto General Hospital. The surgeons then review these tests to ensure that the liver is healthy and the anatomy is suitable for transplant surgery. In some cases further studies such as a liver biopsy, an x-ray of the bile ducts (ERCP) or an angiogram of the blood vessels supplying the liver are required at this stage.

If the screening blood work and scans are satisfactory, the potential donor is informed of the target surgery date. The donor then undergoes a number of consultations with health care specialists. The potential donor is seen by a social worker, psychiatrist, an independent medical doctor who does not work directly with the transplant team, and one or more of the transplant surgeons. An independent medical assessment is obtained to determine the medical risks associated with liver donation for each individual. Sometimes this doctor will suggest that additional testing be done. The transplant team is informed whether liver donation is possible or inappropriate. These consultations provide potential donors with an opportunity to confidentially opt-out or decline liver donation for medical, social, or personal reasons without having to provide an explanation to the intended recipient or to the transplant team.

Donors usually meet with two different surgeons during the assessment period to discuss the surgery in detail. The first appointment takes place early in the process; the second one occurs when the work up has been completed. During the first meeting with a surgeon, the donor is asked to sign an informed consent form after reviewing the surgery, benefits, risks, and alternatives. The surgeon who obtains this consent may not be the one who performs the operation. Post-operative care may be provided by a different surgeon than the one performed the operation. Patients will be reviewed by a transplant surgeon at least once after surgery in the out patient clinic, but care at subsequent out-patient visits may be provided by a nurse practitioner and/or by a family doctor who works with the liver transplant team.

The team may decide it is not possible for a donor to proceed for a variety of reasons which would be discussed with the donor in detail. Currently, only about 20% of those who indicate an interest in liver donation actually undergo this surgery. The reasons for not proceeding to surgery include unsuitable blood vessel structure, abnormal blood tests, and medical problems not previously identified such as diabetes. Some potential donors may decide that proceeding with living donation is not appropriate for them after starting their assessment. Donors are supported in whichever decision they make.

If a potential donor does not attend a required test, the test will be re-booked and the donor informed by telephone. This may be done twice. If the donor fails to come for the same test three times a letter will be sent requesting that the donor call the nurse to rebook. If we do not hear from the donor within two weeks of sending this letter, the transplant centre will assume that the donor does not wish to proceed with the workup. The recipient will then be informed that the donor is not suitable at this time and that a work-up on an alternate donor may commence.

Potential donors must directly communicate with us regarding the booking of tests; we will not book tests that are requested by third parties (family members, friends, recipients, etc).

The assessment for liver donation is a dynamic process. At any stage, the potential donor or the health care team may decide that it is not suitable to proceed with liver donation. Unless specifically requested, recipients are not given information on the reason why a donor is unsuitable, to protect the confidentiality of the donor.

There is a risk of transmitting infections via organ donation. Potential donors should immediately report any fever, flu-like illness, or neurological symptoms. If a donor has active infection, they should not donate part of their liver because they could transmit this illness to the recipient. To minimize the risk of disease transmission, we obtain blood tests to check for infections at the start of the donor assessment, and again a few days before the surgery date. Donors should also 1) take steps to avoid disease transmission through sexual contact; and 2) avoid being bitten by mosquitoes, which could transmit the West Nile virus infection, by wearing long sleeve shirts and long pants, and using mosquito repellent.

Recreational drugs, including alcohol, should be avoided completely before surgery and for at least two months after the surgery.

Live Donor Surgery

The planned surgery date is changed in more than 50% of cases due to 1) cancellations caused by other transplants of a critical nature; 2) resource limitations (availability of hospital beds and nurses primarily); or "bumping" when we adjust the surgery list to give priority to the sickest recipients. When a donor surgery is cancelled, we try to re-schedule the surgery as soon as possible.

If a donor needs to travel by airplane to have the surgery, we ask that they complete their air travel at least two days before the surgery. Sitting in an airplane for a prolonged time increases the risk of blood clots during and after the surgery.

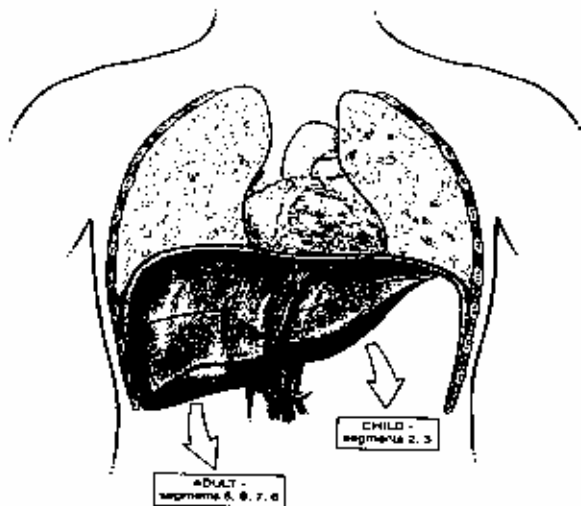
Donors are admitted to hospital at 6:00 AM on the morning of surgery. No food or fluids are allowed after midnight the night before your surgery. After arriving, you will change into a hospital gown and an intravenous will be inserted into your arm. Your blood pressure and temperature will be checked. You then go to the "holding" area outside the operating room and then to the operating room. You will receive antibiotics and a blood thinner to prevent blood

clots. After you are asleep (anaesthetized), various tubes will be inserted to drain the contents of your stomach and bladder, to provide intravenous fluids, and to monitor your blood pressure.

Surgery begins with a careful examination of the internal structures, including an intra-operative ultrasound and an x-ray of the bile duct. Then, the surgeons expose the blood supply and bile ducts to the part of the liver that is going to be removed (see diagram below).

Sometimes at this point, despite satisfactory preoperative tests, we find a pattern of blood vessels or bile ducts that would make the transplant unusually risky for the donor or the recipient. In this situation, we do not proceed with the donor surgery. The gallbladder is removed and the incision is closed. This happens in about 5% of donor surgeries.

In the more usual circumstances, after completing the initial assessment, the liver tissue is divided as described below. The operation lasts 6-8 hours. Following this, the donor goes to the recovery room for 2-3 hours and then returns to the step down unit of the ward to which they reported in the morning.



Right lobe donation involves removing segments 5,6,7, and 8. Left lateral segment donation involves removing segments 2 and 3. Left lobe donation involves removing segments 2,3, and 4. The liver grows back to its normal size in about 6 weeks.

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Post-operative Care

Liver donors are cared for by a transplant team that includes surgeons, hepatologists (liver specialists), nurses, pain specialists, a generalist doctor, and trainees.

Initially, post-operative pain is managed by either a patient controlled analgesia pump or an epidural catheter. After 2-4 days oral pain relievers such as Tylenol #3 are prescribed. The pros and cons of the different methods of pain control will be reviewed by the anesthetist at the time of the pre-admission visit.

Most donors are discharged from hospital about one week after the operation. Drainage tubes inserted during the surgery (nasogastric tube, intravenous, bladder catheter, incision drainage tube) are gradually removed over the first few days. Most patients are able to start eating and drinking about the 3rd to 5th postoperative day. Liver function blood tests are monitored during your hospital stay and after leaving hospital. An ultrasound is also usually done either before discharge or in the first few weeks after discharge.

Most patients develop mild jaundice after the donor surgery. The jaundice usually resolves without any treatment but if it persists or becomes more severe, patients may require an ultrasound study or special x-rays of the bile ducts (ERCP) to rule out complications.

Donors are placed on a blood thinner after surgery, which requires a daily injection during your hospital stay and for 6 weeks after discharge from hospital. It is important to be physically active after surgery in order to reduce the risk of forming blood clots. Therefore, we ask donors to 1) avoid air travel or prolonged car trips for 4 weeks postoperatively; and 2) to get out of the car every hour and walk for approximately fifteen minutes to promote blood flow in your legs if they are traveling for more than one hour during the first three months after surgery,

Most complications are apparent soon after surgery, but some complications can develop following discharge from hospital. Patients must contact the Donor Office immediately if they develop new abdominal pain, redness or swelling around their incision, yellow skin, a fever, cough or shortness of breath; or if the donor office is close, go immediately to the Toronto General Hospital or local Emergency Department. .

A follow-up clinic visit is arranged 2-4 weeks after discharge. At this visit you will have an ultrasound and blood work done, and you will see one of the transplant surgeons. After leaving hospital, patients are asked to walk or exercise each day to gradually build up their stamina. Many patients have a slight leakage from the sites where the drains were inserted for several weeks after surgery. It is common to experience a "letdown" or mild depression while recovering from this surgery. This usually resolves quickly but support is available if this occurs. We will continue to follow you closely.

Although it is usually possible to return to work after 6 weeks, it usually takes three to four months before patients are able to return to all of their normal activities at their usual stamina level.

Benefits, Surgical Risks and Potential Complications

There are two potential health benefits for donors: 1) previously unidentified health issues maybe detected during the donor work-up and 2) many people who donate part of their liver are proud and satisfied (justifiably!) with their decision to help and report an improved sense of self-esteem.

Liver donation is associated with significant risks. No matter how carefully the donor surgery is performed, there is the potential for complications that could result in permanent disability or death. Thus, it is vital that persons considering donation have a good understanding of the nature of this surgery, the benefits, and the risks, and the alternatives. Some of the risks of this procedure are outlined below. Feel free to ask for additional information.

- More than 2000 living liver donor procedures (right and left lobe grafts) have been performed throughout the world. In North America and elsewhere, there have been a number of deaths after liver donation. **The risk of death is estimated to be 0.2-0.5% with left lobe donation and 0.3-1% with right lobe donation.** The risk of death is higher after live donation than the risk after common surgical procedures on the heart (bypass surgery, for example).
- The surgery is performed through a large upper abdominal incision that results in mild, permanent weakness in the abdominal wall and a small patch of numbness beneath the incision, just above the umbilicus (navel).
- The remaining liver segment grows and resumes normal function after donation. Based on the experience with liver resections performed for tumors, provided there is no inadvertent injury to the remaining liver segment at the time of the operation, we do not anticipate any long-term ill effects.
- Some, but not all, of the risks of this surgery include; an adverse reaction to anesthesia, stroke, heart attack, blood clots in the legs or lung, fluid around the lung (pleural effusion), fluid retention (edema), mild or severe infections, bleeding requiring transfusions which can rarely cause infections, re-operation, bile leakage, injury to adjacent organs such as the spleen, stomach, or intestine, an injury to the remaining liver segment's blood vessels or bile ducts resulting in liver failure, and persistent incisional pain. Several donors in the United States have required liver transplantation for treatment of liver failure after donating part of their liver.
- If complications occur, they could impair the donor's ability to obtain health or life insurance, as well as affecting the donor's lifestyle and/or ability to maintain or obtain employment. Potential donors should consider consulting an insurance agent and/or speaking to their employer about the surgery itself, which even without complications, might impact on their insurability or job security. Staff from the transplant program would be pleased to provide any information that is required.
- No matter how carefully the transplant is performed, there is the potential that your intended liver recipient might die after the transplant surgery. If this happens, donors will know that they have done everything possible to help a loved one. Nonetheless, potential donors should consider carefully how you might respond to the stress of dealing with the recipient's death.

- In the highly unlikely event that your liver segment had been removed and the intended recipient had developed a complication that made transplantation impossible (a so-called "orphan" graft), we will assume that we have your permission to place your liver segment into another recipient. Worldwide, this problem has only happened a few times; it has never happened in Toronto so far.
- Because liver donation is a new procedure, unforeseen problems may be identified as we gain further experience with this operation.

Results of Liver Donation at the UHN

Outcomes of Liver Donor Operation. Over 150 donor liver procedures have been performed at the UHN from June 1996 to September 30, 2005 with no deaths and no long term complications. Median operative time was 390 minutes, estimated blood loss was 800cc and there were no intra-operative complications. As expected with major surgery, many donors experienced complications. Three patients had unsuitable anatomy and the plan to remove the liver segment was abandoned. The frequency of early post-operative donor complications was 16%. Early post-operative bleeding requiring re-operation occurred in 4 pts (4%); these were among the only patients who required blood transfusions from someone else. Other morbidities include 3 pts. (3%) with bile leaks that required endoscopic treatment, 3 abscesses requiring insertion of a drainage tube in the radiology department (3%), 2 pts. with blood clots to the lung (pulmonary emboli - 2%), and 5 patients with wound incision hernias (5%) that required repair.

Outcomes of recipient operation (live donor liver transplantation). Patients receiving liver donor liver transplants have done well. Survival after live donor liver transplantation has been similar to survival after deceased donor liver transplantation (~85% at one year). There has been a higher rate of bile duct complications in live donor recipients compared with deceased donor recipients (~20% versus ~5%) but most of these complications have resolved with non-surgical management.

Decision to Be Assessed for Living Donation – The Next steps

Individuals who want to be assessed for living liver donation should read and sign the attached pages.

Coordination of Liver Donation

The Living Liver Donor Office (416) 340-4800 Ext. 6581 will coordinate your assessment. Please let us know if you have any questions. We will forward copies of all test results done during your assessment to your family doctor at the end of your assessment. If you wish to speak with someone who has undergone the liver donor surgery, please let the office know, and we will arrange an opportunity to speak with one of the past donors.

DOCUMENTATION OF THE DECISION TO BE ASSESSED FOR LIVER DONATION

SUMMARY

I understand that liver donation surgery entails significant risks and offers no direct medical benefit to the donor. I understand that I may obtain more information about living liver donor transplants from the Multi-Organ Transplant Program Website located on the UHN website www.uhn.ca or by talking with one of the physicians, or surgeons. If I undergo the donor surgery, I understand that I will require careful follow-up and that the Toronto General Hospital Transplant program will contact me from time to time after this surgery to inquire about my health, insurance, employment and overall well being.

CONFIDENTIALITY

Hospital personnel who are involved in the course of my care may review my medical record. They are required to maintain confidentiality as per law and the policy of UHN. I understand that if I do become a donor, data about my case, which may include my identity, may be sent to other places involved in the transplant process as permitted by law.

SIGNATURES

I have read this document and I understand the risk, benefits and alternatives to living liver donation. I wish to proceed with the evaluation to find out if I can be a donor.

Printed Name of Potential Donor

Signature

Date

Printed Name of Witness

Signature

Date