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*RAPID COMMUNICATION*

# Safety evaluation of donors for living-donor liver transplantation in Chinese mainland: A single-center report

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## Abstract

**AIM:** To discuss the safety of donors during living donor liver transplantation (LDLT) and the authors' experience with 50 cases.

**METHODS:** Between January 1995 and March 2006, 50 patients with end-stage liver disease received LDLT in our department. Donors (at the age of 27-58 years) were healthy and antibody (ABO)-compatible. The protocol of evaluation and selection of donors, choice of surgical methods and strategy applied in the safety evaluation of donors were analyzed.

**RESULTS:** A total of 115 candidate donors were evaluated for LDLT at our center. Of these, 50 underwent successful hepatectomy for living donation. The elimination rate for donors was 43.5%. Positive hepatitis serology and ABO incompatibility were the main factors for excluding candidates. All donors recovered uneventfully. The follow-up time ranged from 3 to 135 mo. The incidence of major and minor medical complications was 12.0% and 28.0%, respectively.

**CONCLUSION:** LDLT provides an excellent approach to the problem of donor shortage in China. With a thorough and complete preoperative workup and meticulous intra- and postoperative management, LDLT can be performed with minimal donor morbidity.



**Key words:** Liver transplantation; Living donor; Safety; Evaluation

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## INTRODUCTION

Global shortage of cadaveric organs has been a serious obstacle to the development of liver transplantation (LTX), limiting the application of this life-saving therapy[1]. Living-donor liver transplantation (LDLT), as an innovative surgical technique to expand the available donor pool, has become popular in recent years. It was initially performed in Sao Paulo, Brazil, in 1988[2]. The recipients, from a Brazilian case series, died of medical complications shortly after the procedure. This was soon followed by a report from Strong *et al*[3] in Australia and Broelsch *et al*[4] in USA in 1989. Subsequently, the procedure was developed both in Asia and USA. In early 1990s, almost all the recipients were children. Removal of a partial left liver lobe for donation is a more conservative surgical procedure and has been shown to have a low risk for morbidity and mortality. With the experience in pediatric cases and cadaveric split-liver transplantation, LDLT has finally been extended to adult patients using mainly right lobe grafts. The first right hepatic lobe LDLT was reported in 1994[5], which has led to a dramatic increase in adult-to-adult right hepatic lobe LDLT.

Despite the advantages of LDLT, the procedure has received criticism for the risk it imposes on healthy persons who will undergo a major operation without any potential health benefit. There have been several cases reported about donor death and significant donor morbidity (as high as 67%)[6-8]. It is clear that the risk of living liver donation is not negligible. The dictum "primum non nocere" (first do no harm) for the donor should remain the central factor for the whole process of LDLT[9].

In response to the shortage of cadaveric organs and a continually growing waiting list, the first case of LDLT in Chinese mainland was initiated at our center in 1995. The recipient, a man with primary liver cancer, received the left liver graft from his wife. Since then LDLT activity in Chinese mainland has been increasing rapidly. Accordingly, there is a greater concern for the safety of donors. However, no systemic reports on the safety of living liver donors are available in China. This study was to analyze the data of donors for LDLT in our center to illuminate the factors affecting the safety of donors.

## MATERIALS AND METHODS

From January 1995 to March 2006, 50 patients including 14 adults (aged 18 years or older) underwent LDLT at the First Affiliated Hospital of Nanjing Medical University. The age of donors ranged from 27 to 58 (mean 36.4 ± 12.3) years. Forty-nine donors fulfilled relationship within the third degree of consanguinity with recipients and 1 donor was a volunteer having good relationship with the recipient. Characteristics of donors are listed in Table 1.

**Table 1 Evaluated donor demographics ($n$ = 115)**

| Evaluated donors | Evaluated and accepted donors | | Evaluated and rejected donors |
|---|---|---|---|
| Age (yr, range, mean ± SD) | 27-58 (36.4 ± 12.3) | | 31-55 (37.4 ± 10.6) |
| Weight (kg, mean ± SD) | 53.7 ± 12.9 | | 64.4 ± 14.3 |
| Sex | M | 13 | 23 |
| | F | 37 | 42 |
| Relationship to recipient | Mother | 33 | 16 |
| | Father | 12 | 28 |
| | Wife | 2 | 9 |
| | Husband | 0 | 3 |
| | Uncle | 1 | 5 |
| | Sister/brother | 1 | 4 |
| | Volunteer | 1 | 0 |

**Table 2 Current donor evaluation protocol at the First Affiliated Hospital of Nanjing Medical University**

| | |
|---|---|
| Basic requirements | 20–60 yr<br>Relationship: relatives or unrelated volunteers<br>Blood type: identical or compatible |
| Step Ⅰ | Clinical evaluation: initial informed consent, history and physical examination<br>Laboratory: blood group, liver and renal function<br>Serology: HBsAg, HBsAb, HBcAb, anti-HCV, anti-HIV |
| Step Ⅱ | Clinical examination: psychological evaluation<br>Laboratory: hematology, coagulation profile, blood sugar, electrolytes, HLA typing, cross-matching, alpha-1-antitrypsin, ferritin, tumor markers (AFP, CEA,CA199, CA50), arterial blood gas,urine and stool analysis, pregnancy test (female)<br>Serology: HBV DNA, RPR, antibody for CMV, EBV, HSV, varicella and rubella viruses<br>Imaging study: Chest radiograph, abdominal ultrasound, ECG |
| Step Ⅲ | Imaging study: CT angiography and volumetry, MR cholangiography |

### *Evaluation and selection of donors*

The criteria for donor selection among different centers, and a thorough evaluation process consisting of three to six stages in most centers are described elsewhere[10,11]. The donor evaluation protocol was designed for testing proceeded from simple and noninvasive to more complex and invasive, assuming continued donor willingness and lack of contraindications to donation. Testing assured the donor safety and then evaluated the quality of graft. The minimal age for consideration was 20 and the upper age limit 60. The donor-recipient pair must be blood group identical or compatible. The donor evaluation protocol followed at our center is outlined in Table 2.

When a potential recipient came to our center, he and his family members were informed of the need for an early liver transplantation and provided with information, upon their request, regarding living donor transplantation without specific reference to those who might be an appropriate candidate for liver donation. If the family members agreed to receive LDLT, the risks and benefits of the procedure would be explained in general. Initial counseling focused on the evaluation protocol, with emphasis on invasive testing, surgical procedure, and all possible risks of the donor hepatectomy. The donor should make the decision voluntarily, without any coercion. To reduce the pressure on potential donors, informed consent was obtained in the absence of other family members. The donor was given the opportunity to withdraw at any time, with the assurance that an excuse would be provided by the transplant team.

Only after informed consent was made, could the evaluation of donors for medical or surgical suitability be commenced. Acute or chronic medical illness was excluded by a detailed history and physical examination, and all donors were screened by laboratory tests including complete blood cell count, liver and renal biochemistry values, and viral serologic studies. Positivity of hepatitis B surface antigen, human immunodeficiency virus antibody, or hepatitis C virus antibody constituted an outright ineligibility of the potential donor. Donors with diabetes mellitus or hypertension under regular control were not rejected. The psychologic status of the potential donor was assessed by a clinical psychologist. High-resolution abdominal ultrasonography (US) was performed to evaluate the quality of liver parenchyma, exclude the presence of tumors, and confirm the patency of blood vessels. Chest radiography and electrocardiography were performed to exclude cardiopulmonary disease. Computed tomography (CT), CT volumetry, multiple detector three-dimensional CT angiography, and three-dimensional magnetic resonance (MR) cholangiography were performed to assess liver volume and identify unsuspected intra-abdominal pathology and anomalous vasculature incompatible with donation. Liver biopsy was not routinely performed in our center. If there was radiographic evidence of fatty infiltration or parenchymal liver disease, even with normal liver function, echo-guided liver biopsy of the segments to be donated was performed. If a questionable result arose from the standard protocol, more testing may have been indicated.

After completion of each step, the donors' statuses were reevaluated and a decision of whether to proceed was made by the transplant team. The Ethics Committee of the First Affiliated Hospital of Nanjing Medical University approved the surgical procedures.

Donor evaluation continued in the operating room with intraoperative cholangiography and ultrasonography. These studies were used for planning operative strategy and excluding the presence of prohibitive anatomical variations not detected by the preoperative work-up.

### *Surgical procedures for donors*

The donors were prepared on the operating table with care to avoid sores at the pressure points. The abdomen was entered through a bilateral subcostal incision with a

**Table 3 Exclusion criteria for 65 potential donors**

| Step | Exclusion | *n* |
|---|---|---|
| Ⅰ | Clinical evaluation | 4 |
| | Blood type | 27 |
| | Diabetes | 1 |
| | Hepatitis B (core Ab +) | 17 |
| | Hepatitis C | 2 |
| | Autoimmune hepatitis | 1 |
| Ⅱ | Psychological evaluation | 1 |
| | Cardiac evaluation | 2 |
| Ⅲ | CT or MRI findings | 1 |
| | CT volumetry (steatosis-GRBW) | 3 |
| Ⅳ | Second consent | 6 |

GRBW: graft recipient body weight.

vertical midline extension. Harvesting of the left lobe of liver from a living donor was performed as previously described[12,13]. The left hepatic artery was dissected, exposing the left portal vein lying posteriorly. After complete left portal vein dissection, the bile duct or ducts were sharply transected at the edge of the graft. Finally, parenchymal dissection was performed using an ultrasonic dissector along the line marked on the liver surface according to intraoperative ultrasonogram, and all tubular structures were ligated or sutured.

For right lobectomy, the surgical technique has been described in detail elsewhere. After mobilization of the right lobe, the hilar plate was lowered and the right bile duct or ducts were divided sharply. All portal vein branches to the caudate process were divided and ligated. The right lobe of liver was then rotated toward the left side for division of right triangular ligament and tiny venous branches between the anterior surface of the inferior vena cava and posterior surface of paracaval portion of the caudate lobe. The right hepatic vein and the right inferior hepatic vein larger than 5 mm were preserved for reimplantation. Transection was done with both electrocautery and an ultrasonic dissector. The stumps of the right hepatic artery, right portal vein, and hepatic veins were closed with continuous nonabsorbable surgical sutures.

The grafts were harvested without blood vessel clamping or graft manipulation in order to optimize their viability. Intraoperative ultrasonography was performed to identify the presence of a large inferior hepatic vein (accessory left or right hepatic vein) and to study the junction of the middle hepatic vein with the inferior vena cava. After cholecystectomy, operative cholangiography via cystic duct cannulation was performed to study the bile duct anatomy. In all cases, the graft was immediately transferred to the back-table for flushing of the hepatic artery and portal vein with preservation fluid at 4℃ and prepared for implantation.

### *Postoperative management*

The donors were cared for in the intensive care unit with attention to adequate tissue oxygenation and perfusion. Antimicrobial medications were prescribed to prevent infection. Parenteral nutrition consisting of a mixture of branched-chain amino acid-enriched solution, dextrose, and medium- and long-chain triglycerides was administered in all donors immediately after the hepatectomy to stimulate liver regeneration. Oral nutrition was encouraged once bowel activity returned. Chest physiotherapy and incentive spirometry were routinely given. Early ambulation was advocated. Daily laboratory monitoring continued until liver function normalized and hemoglobin and electrolytes were stable.

### *Follow-up*

Outcomes related to complications and ongoing symptoms were defined as medical outcomes. A major medical complication was defined as a medical problem requiring surgical or procedural repair, hospitalization, or intravenous therapy. A minor medical complication was defined as a medical problem either resolved spontaneously or requiring oral medical therapy.

A specific research assistant was in charge of the whole follow-up. The methods were taken including record table, telephone follow-up and return visit.

### *Statistical analysis*

Data are expressed as mean ± SD. Statistical analysis was completed by using SPSS 10.0 (SPSS Inc, Chicago, IL).

## RESULTS

A total of 115 candidate donors were evaluated for LDLT at our center. Of these, 50 underwent successful hepatectomy for living donation. A total of 65 potential donors (56.5%) were excluded at different points of the work-up. Positive hepatitis serology and ABO incompatibility were the main contraindications to donation. After the first step, volunteers withdrew from donation due to effects from family, relatives and society, with society being the main reason for exclusion. Reasons for exclusion of potential donors are listed Table 3.

Donor livers were resected from segments Ⅱ, Ⅲ, and Ⅳ (including the middle hepatic veins) in 36 cases, segments Ⅱ, Ⅲ, and part of Ⅳ (not including the middle hepatic veins) in 4 cases, segments Ⅴ, Ⅵ, Ⅶ, and Ⅷ (not including the middle hepatic veins) in 9 cases and segments Ⅴ, Ⅵ, Ⅶ, and Ⅷ (including the middle hepatic veins) in 1 case. The mean measured graft volume was 246 ± 57 g in pediatric recipients and 736 ± 189 g in adult recipients. The average graft/recipient weight ratio (GRWR) was (1.21 ± 0.43)%. Two child patients, who received small-graft with a GRWR less than 0.8%, recovered without any serious complications.

The mean duration of the operation from skin incision to closure was 7.6 ± 1.2 h and the mean blood loss was 450 ± 130 mL. The mean stay of donors in the intensive care unit (ICU) was 1.2 ± 0.4 d and the mean hospital stay was 9.3 ± 1.8 d. In the immediate postoperative period, all donors exhibited a significant transient elevation of liver enzymes and hyperbilirubinemia on postoperative day. Normalization of serum transaminases and total bilirubin was accomplished by postoperative d 5 to 7. In contrast, prothrombin time exhibited a mild postoperative elevation that declined to normal level within 3 d. During follow-up, CT showed that the remaining liver in the right-lobe

**Table 4 Donor medical outcomes**

| Donor medical outcomes | *n* (%) |
|---|---|
| Survival | 50/50 (100) |
| Complications | |
| Major | 6/50 (12.0) |
| Biliary leak | 2 |
| Pneumonia | 2 |
| Initial stage of liver dysfunction | 1 |
| Pleural effusions | 1 |
| Minor | 14/50 (28.0) |
| Delay in return to normal bowel function | 5 |
| Pain | 3 |
| Sore throat | 2 |
| Foot paresthesias | 2 |
| Persistent short-term memory loss | 1 |
| Chronic fatigue | 1 |
| Ongoing symptoms | |
| Yes | 28 (56.0) |
| No | 22 (44.0) |
| Abdominal discomfort | 15 |
| Scar numbness | 6 |
| Loss of appetite, nausea | 3 |
| Poor appetite | 3 |
| Diarrhea | 2 |
| Weakness | 1 |
| Nausea | 1 |
| Difficulty sleeping | 1 |
| Sought other physician assistance | |
| Yes | 12 (42.9) |
| No | 16 (51.1) |

Major and minor complications are defined in Methods. Under ongoing symptoms, the number of symptoms reported is greater than 28.

donors grew as large as (or larger than) the original one after 10 to 14 mo, whereas the recovery time of the left-lobe donors was 6 to 11 mo. Maximum liver growth occurred within the first month after donation, followed by a gradual increase during the first postoperative year.

The follow-up time ranged from 3 to 135 mo. Follow-up was not lost for any one. Up to March 2006, the first living donor in Chinese mainland, who donated her left liver graft to her husband, was followed up over 11 years. She was in good health and returned to work. The mean recovery time of 41 donors who were followed up for more than 6 mo, was 6.0 ± 1.5 mo, the mean time to return to work was 8.0 ± 1.0 mo, and 35 of them returned to normal work even earlier.

No reoperation was performed and no death occurred in this series. Six of the 50 (12.0%) patients had major complications. One donor suffered from symptoms at the initial stage of liver dysfunction, which disappeared after conservative management. Two donors had biliary leakage requiring percutaneous drainage and antibiotic treatment. One donor required chest tube placement because of right pleural effusions. Two donors had pneumonia, requiring antibiotics intravenously. Fourteen of the 50 (28.0%) patients had minor complications related to the operation and were managed conservatively. Complications included delayed bowel function, pain, sore throat, foot paresthesias, persistent short-term memory loss and chronic fatigue. Symptoms occurred at the time of survey in 28 patients (56.0%). These symptoms led 12 patients to seek medical intervention and resolved after treatment. Medical outcomes are listed in Table 4.

## DISCUSSION

The development of LDLT in China experiences three stages: pediatric living donor liver transplantation (PLDLT), adult-to-adult living donor liver transplantation (ALDLT), emergency or high-urgency living donor liver transplantation (ELDLT). To ensure the safety of donors, we identified three basic principles for the selection of donors: independent decision on donation, no contraindication for donation, and avoidance of coercion in the process of donation. These principles were strictly fulfilled with no exceptions.

The evaluation process may involve invasive liver biopsy, angiography, and endoscopic retrograde cholangiopancreatography, *etc*. With advances in radiologic evaluation of the liver, donors can be safely evaluated and liver resection approaches can be planned with new imaging techniques. In our series, CT volumetry, multiple detector, three-dimensional CT angiography, and three-dimensional magnetic resonance (MR) cholangiography were employed to provide an accurate picture of liver vascular anatomy and liver volume measurement for surgery.

Kubota *et al*[14] showed that individuals with normal liver function could tolerate resection of up to 60% of nontumorous liver. The present data, albeit limited, indicate that residual liver volume, accounting for 27% of the total volume, is the lowest limit for supporting survival, provided that the liver itself is not fatty. To allow a safety margin, the residual liver volume, accounting for 30% of the total volume, is probably the lowest limit. Accordingly, CT volumetry should be routinely performed because the volume of the resected graft could be quite variable.

Liver biopsy is not performed only upon indication. If there is radiographic evidence of fatty infiltration or parenchymal liver disease, even with normal liver function, echo-guided liver biopsy from the segments to be donated is performed. The amount of steatosis is a matter of concern because fatty liver is probably more vulnerable to injury during ischemia-reperfusion. Liver grafts with a mild degree of fatty change can be used for liver transplantation without adverse effects. However, liver grafts with a moderate or severe degree of fatty change lead to primary graft dysfunction in recipients[15]. Therefore, it is wise to limit the macroscopic fat content to less than 10% and even lower when the planned resection volume exceeds 60%.

Our lower and upper age limits were set at 20 and 60 years, respectively. The minimal age of 20 years mainly concerns the issue of informed consent. There are some issues on which the upper age limit should be set. It was reported that liver transplantation with grafts from donors older than 65 years can achieve good results[16]. To lower the risk of donors and recipients, we set the upper age limit at 60 years.

Parents are the majority of donors for pediatric patients, but the parents of adult recipients are frequently not candidates for donation due to their advancing age or underlying disease. The "one-child" policy in China

limits the availability of siblings as donors. Consequently, genetically unrelated donors may be necessary alternatives to conventional living donation for adults. However, any commercially available human organs must be extremely forbidden. In our series, one man with severe liver failure due to hepatitis B and cirrhosis needed timely liver transplantation. Since his wife and relatives were excluded because of medical or psychological reasons, he finally received the right liver graft from his friend.

In our study, positive hepatitis B serology was the main reason for exclusion besides ABO incompatibility. Positive hepatitis B serology occurred in 26.2% of potential donors. Because of the high prevalence of hepatitis B virus infection in China, whether donors with positive hepatitis B core antibody should be ruled out is still controversial.

Four anatomic grafts have been described for LDLT[17], including the entire right liver lobe (Couinaud segments Ⅴ-Ⅷ), the entire left liver lobe (Couinaud segments Ⅱ-Ⅳ), the left lateral segment (Couinaud segments Ⅱ-Ⅲ), and the extended right liver (Couinaud segments Ⅳ-Ⅷ). The type of graft selection depends mostly on the size disparity between the donor and recipient. In general, the left lobe comprising segments Ⅱ-Ⅳ (including or not including the middle hepatic veins) is used for pediatric recipients and segments Ⅴ-Ⅶ (including or not including the middle hepatic veins) for adult recipients.

Whether graft resection for LDLT includes the middle hepatic vein is an important issue. Maema *et al*[18] have reported their experience in living donor left lobectomy with (extended left lobe) or without (standard left lobe) resection of the middle hepatic vein. They believe that venous outflow is essential to both function and regeneration[18]. Inadequate outflow results in decreased segmental portal flow and poor segmental regeneration. Even when no grafts are grossly congested, regeneration is clearly impaired in grafts but not in the middle hepatic vein, suggesting that the right lobes should be used.

Sufficient medical data indicate that segments Ⅱ-Ⅲ and part of segment Ⅳ (not including the middle hepatic veins) can be removed and would not compromise the donor's metabolic potential. In the series, LDLT was performed in 4 cases with removal of segments Ⅱ-Ⅲ and part of segment Ⅳ (not including the middle hepatic veins). Although the graft volume met the metabolic demand of the recipient, graft congestion due to poor venous outflow delayed recovery of the recipient postoperatively. As experience and confidence grow, extended left lobectomy (segments Ⅱ-Ⅳ, including the middle hepatic veins) is wildly applied in LDLT in our center. LDLT was performed in 36 cases and extended left lobectomy in 2 cases whose GRWR was 0.97% and 1.06%, respectively. Both donors and recipients recovered uneventfully and were in good health. We concluded by reconstructing middle hepatic vein tributaries or other accessory venous tributaries, graft congestion, apt to thrombosis and graft dystrophia or primary dysfunction due to poor venous outflow can be solved properly.

To overcome the barrier of graft size matching for adult recipients, right lobectomy was performed for ALDLT in our study. This method was initially described by Habib and Tanaka[19], who attempted to harvest a left lobe for LDLT when anatomic considerations favored a right-lobe hepatectomy. We consider that for right lobe grafts, inclusion or exclusion of the middle hepatic vein depends mostly on the size disparity between the donor and recipient, as well as the adequacy of graft volume, remnant liver volume, and configuration of the hepatic venous anatomy. If the size of the donor and recipient is similar, right lobectomy (Couinaud segments Ⅴ-Ⅷ, not including the middle hepatic veins) is preferred to ALDLT in our center. To avoid graft congestion, the right inferior hepatic vein larger than 5 mm can be reconstructed to secure adequate drainage.

If the size disparity between the donor and recipient is conspicuous (the size of the recipient was much bigger than that of the donor), extended right lobectomy (Couinaud segments Ⅳ-Ⅷ, including the middle hepatic veins) can be employed to obtain an adequate graft volume. Utilization of extended right lobe liver grafts (the middle hepatic veins) in ALDLT was introduced by the University of Hong Kong Medical Center in 1996[20]. We first performed extended right lobe-LDLT in 2005. About 60% of the donor liver volume was resected for donation. The donor suffered from symptoms at the initial stage of liver dysfunction, which disappeared after conservative treatment. We consider that it is necessary to leave the donor with a residual liver volume, accounting for at least 30% of the total liver volume, and to use grafts containing minimal fatty to secure the safety of donors.

To ensure that the remnant liver regenerates quickly after operation, intraoperative trauma to the remnant liver must be minimal. Thus, we exercised the liver carefully and intermittently rotated the right lobe during mobilization, exerted no Pringle maneuver during liver transection, reconstructed the falciform ligament to prevent left lobe rotation into the right subphrenic cavity, and initiated postoperative parenteral nutrition support to stimulate liver regeneration[21]. Methylene blue was injected into the common bile duct via the cystic duct cannula to detect bile leakage from the right hepatic duct stump and transection surface.

In conclusion, LDLT can achieve acceptable survival and solve the issue of donor availability. We believe that with a thorough and complete preoperative workup and meticulous intraoperative and postoperative management, LDLT can be performed.

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