

SPECIAL ARTICLE

A Survey of Liver Transplantation from Living Adult Donors in the United States

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ABSTRACT

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BACKGROUND

The transplantation of the right lobe of a liver from a living adult donor into an adult recipient has been performed increasingly frequently in the United States. Although the use of grafts from living donors is standard practice in transplantation in children, their use in adults remains controversial.

METHODS

To study the use of liver transplantation from a living donor, we sent a 24-item questionnaire to all liver-transplantation programs in the United States. Data on indications, evaluation, and outcomes were analyzed with the use of univariate and multivariate methods. Data on recent transplantations were gathered from the Scientific Registry of Transplant Recipients and directly from the transplantation programs.

RESULTS

Questionnaires were returned by 84 of the 122 programs (69 percent) describing the results of 449 adult-to-adult transplantations of partial livers from living donors that were performed in 42 centers. Fourteen centers had performed more than 10 such transplantations each and together accounted for 80 percent of such transplantations. Centers that performed such transplantations also performed more transplantations of livers from cadaveric donors and more transplantations from living donors in children than centers that did not perform the adult-to-adult procedure ($P=0.002$ and $P=0.001$, respectively). A total of 45 percent of potential donors who were evaluated eventually donated a lobe of their liver; 99 percent of these donors were genetically or emotionally related to the recipient. Complications in the donor were more frequent in the centers performing the fewest transplantations from living donors in adults and included biliary complications requiring intervention (in 6.0 percent), reoperation (in 4.5 percent), and death (in one donor [0.2 percent]). Among the recipients, 1.6 percent did not meet criteria for receipt of a cadaveric transplant; cancer, retransplantation, and acute liver failure were uncommon indications for transplantation from a living donor. Biliary complications occurred in 22.0 percent of recipients, and vascular complications occurred in 9.8 percent.

CONCLUSIONS

Adult-to-adult liver transplantation from a living donor is increasingly performed in the United States but is concentrated in a few large-volume centers. Mortality among donors is low, but complications in the donor are relatively common.

THE USE OF LIVING DONORS FOR LIVER transplantation was initiated more than a decade ago for infants, children, and small adults, among whom mortality was escalating at that time because of the lack of cadaveric donors of appropriate size.^{1,2} Initially, the procedure involved the removal of the left lateral segment of the liver (approximately 20 percent of the hepatic mass) from an adult donor and its transplantation into a child or small adult. In a prospective trial, the procedure was shown to be associated with rates of survival of both the graft and the recipient that were similar to those found with the transplantation of cadaveric livers.³ More important, morbidity and mortality among donors were low.²⁻⁵ Liver transplantation from living donors in children is now common practice at numerous transplantation centers worldwide, accounting for approximately 30 percent of liver transplantations performed in children.

During the past decade, a critical shortage of cadaveric organs for adults in need of liver transplants has developed. During this time, the waiting period for liver transplantation and the rate of death among patients on waiting lists have increased by a factor of more than 10.^{6,7} Despite the use of cadaveric donors who are older, are hemodynamically unstable, or have antibodies to hepatitis B or C, the donor pool has expanded only marginally.⁸⁻¹¹ The use of living donors for adult recipients was therefore initiated.¹²⁻¹⁴ In most cases, this procedure requires that the larger right lobe (accounting for approximately 55 to 60 percent of the hepatic mass) be removed from the donor. The medical, surgical, ethical, and financial aspects of adult-to-adult liver transplantation from living donors were recently summarized at a workshop sponsored by the National Institutes of Health (NIH).¹⁵

The lack of comprehensive data and of a centralized registry to collect data on morbidity and mortality among donors and recipients has led some experts to call for limitations on which centers can perform the procedure or for regulation by government agencies.^{16,17} We conducted a nationwide survey of adult-to-adult liver transplantation from living donors in an attempt to define the current practice with regard to this procedure, including its frequency, the indications for its use, and the rate of complications associated with it. To the best of our knowledge, these are the most comprehensive data available on adult-to-adult liver transplantation from living donors in the United States, although smaller surveys have been conducted in other countries.^{18,19}

METHODS

We conducted a survey by questionnaire to determine patterns of practice and outcomes in transplantation centers in the United States with regard to adult-to-adult liver transplantation from living donors. Our aim was to assess the number of programs performing or planning to perform such transplantations, these programs' volumes of transplantation procedures involving both cadaveric livers and lobes from living donors in both adults and children, the methods of evaluating potential donors and outcomes in the donors, the indications for transplantation and the outcomes in the recipients, as well as the degree of institutional support. A 24-item survey was tested at three sites (New York Presbyterian Hospital, Virginia Commonwealth University, and the University of North Carolina), revised, and then mailed to all 122 liver-transplantation programs registered with the United Network for Organ Sharing (UNOS). The medical and surgical director of each program received a copy. Programs that did not respond were contacted up to three times by e-mail and telephone. Data were collected on transplantations performed by the end of October 2000 in order to ensure homogeneity between those collected before and after the NIH meeting.

Data were analyzed with the use of Stata software (version 6.0, Stata) and with t-tests, z-tests, and chi-square tests, as appropriate, for univariate analyses. Logistic and linear regression were used to analyze predictors of donation, complications, and length of stay. An alpha level of 0.05 was considered to indicate statistical significance. Subsequently, an audit was performed at eight centers to verify the reported volumes of transplantations as well as the rates of major complications. Updated volumes of transplantations for 2001 were obtained from the Scientific Registry for Transplant Recipients, which had ascertained all deaths with the Death Master File of the Social Security Administration. Deaths, transplantations, and volumes of transplantations up to September 2002 were verified with the individual transplantation centers.

RESULTS

TRANSPLANTATIONS PERFORMED

Eighty-four of the 122 programs registered with UNOS (69 percent) responded to the survey. These 84 centers performed more than 90 percent of all transplantations of cadaveric livers in the United

States in 1999 and 2000. Forty-two programs reported performing at least 1 adult-to-adult liver transplantation from a living donor (range, 1 to 71 transplantations; median, 5) between 1997 and 2000, providing data on a total of 449 such transplantations. These transplantations accounted for virtually all of the liver transplantations from living donors performed in adults during this period, according to data from UNOS.²⁰

Table 1 shows the numbers of centers and the numbers of liver transplantations performed in adults and children by the survey participants between 1997 and 2000. The numbers of adult-to-adult liver transplantations from living donors increased from only 1 in 1997 to 266 in 2000. During the same period, the number of liver transplanta-

tions from living donors in children increased slightly (from 85 to 102) at the 84 centers; by 1999, such pediatric transplantations were outnumbered by the operations in adults. Thus, the total number of liver transplantations from living donors increased markedly, whereas the numbers of transplantations of cadaveric livers performed at the same centers varied little (Fig. 1).

PROGRAMS PERFORMING TRANSPLANTATIONS

The number of programs performing liver transplantations from living donors in adults increased from 1 program in 1997 to 38 in 2000; 42 different programs performed at least one such transplantation each during the study period. Of the 42 programs responding to the survey that had not performed such a transplantation, 32 (76 percent) planned to start doing so within the next 12 months. Programs already performing adult-to-adult liver transplantations from living donors had a higher mean volume of transplantations of cadaveric livers into adults than did those that had not performed adult-to-adult transplantations from living donors (mean, 202 vs. 107 over the study period; $P=0.002$) and were more likely to perform transplantations from living donors in children (67 percent vs. 31 percent, $P=0.001$). The number of programs performing such transplantations in children doubled during this period, whereas the numbers of programs performing transplantations of cadaveric livers in adults and children did not change substantially. The number of liver transplantations from living donors in adults performed by a given program varied widely, ranging from 1 to 47 in 2000. Fourteen centers had performed more than 10 liver transplantations from living donors over the study period; these centers accounted for 362 of all such transplantations (80.6 percent). Thirty programs (79 percent) performed fewer than 10 such transplantations each in 2000.

INDICATIONS FOR TRANSPLANTATION FROM A LIVING DONOR

Indications for liver transplantation from a living donor included hepatocellular carcinoma in 35 recipients (7.8 percent), retransplantation in 11 recipients (2.4 percent), and acute liver failure in 10 recipients (2.2 percent). Data on other, more conventional indications were not collected. Seven recipients (1.6 percent) did not meet the criteria for receipt of a cadaveric transplant. In comparison, cancer, retransplantation, and acute liver failure

Table 1. Numbers and Types of Liver Transplantation Performed in Adults and Children, According to Year.

Variable	1997	1998	1999	2000
Adults				
Cadaveric livers				
No. of centers	62	70	73	75
No. of transplantations/center				
Mean \pm SD	48 \pm 39	47 \pm 39	48 \pm 36	43 \pm 36
Range	4–180	6–200	1–180	1–180
Total no. of transplantations	2976	3290	3504	3225
Livers from living donors				
No. of centers	1	7	27	38
No. of transplantations/center				
Mean \pm SD	1	3 \pm 4	6 \pm 6	7 \pm 9
Range	—	1–12	1–27	1–47
Total no. of transplantations	1	21	161	266
Children				
Cadaveric livers				
No. of centers	39	49	45	48
No. of transplantations/center				
Mean \pm SD	11 \pm 9	10 \pm 10	9 \pm 7	8 \pm 7
Range	1–31	1–50	1–33	1–29
Total no. of transplantations	429	490	405	384
Livers from living donors				
No. of centers	17	20	28	34
No. of transplantations/center				
Mean \pm SD	5 \pm 4	4 \pm 3	4 \pm 3	3 \pm 3
Range	1–14	1–12	1–12	1–15
Total no. of transplantations	85	80	112	102

were the indications for transplantation in 2.7 percent, 9.6 percent, and 8.2 percent, respectively, of recipients of cadaveric liver transplants nationally in 1999, according to UNOS.²⁰

EVALUATION OF POTENTIAL DONORS

In almost all programs, potential donors were evaluated before surgery by a hepatologist (90 percent), social worker (95 percent), and psychiatrist or psychologist (86 percent). However, in only 50 percent of the programs did the potential donor see a physician who was not part of the transplantation team, and the potential donor was evaluated by an ethicist in only a few programs (17 percent). An average of 45 percent of potential donors who were evaluated were eventually accepted and underwent the operation for donation.

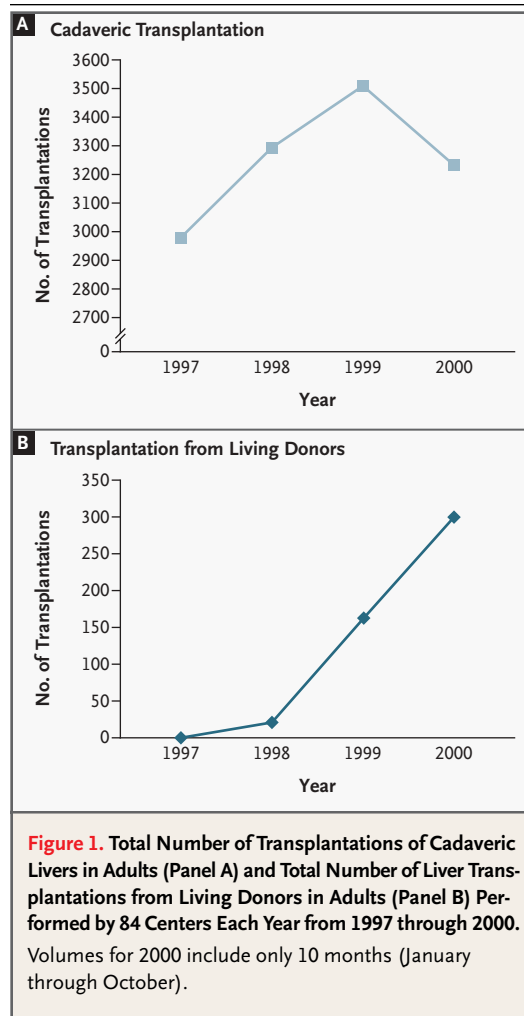
The types and frequencies of invasive diagnostic procedures that donors routinely underwent during evaluation are shown in Table 2. Most programs either did not require or were selective in performing liver biopsy and arteriography in potential donors. A quarter of the programs did not perform liver biopsies in prospective donors. In about half of the programs, endoscopic retrograde cholangiopancreatography (ERCP) was performed to evaluate the donor's bile-duct anatomy, and about a third of the programs used magnetic resonance cholangiopancreatography.

A total of 334 living donors (74.4 percent) were genetically related to the recipient, 60 (13.4 percent) were friends, and 49 (10.9 percent) were spouses. There were three "good samaritans" who donated.

COMPLICATIONS

Overall, 65 of the 449 donors (14.5 percent) had one or more complications of partial-liver donation (Table 3). At the time of our survey, only one death of a donor had been reported (death rate, 0.2 percent). Thirty-eight donors (8.5 percent) had to be rehospitalized for complications related to the procedure, with the most common complication reported being bile leak, which occurred in 27 donors (6.0 percent). Other complications were the need for blood transfusion and the need for reoperation. In the programs in the highest quartile for the rate of complications in donors, more than one third of donors had complications; these centers performed fewer liver transplantations from living donors (mean, 4) than the remaining programs did (mean, 14; $P=0.004$).

In counseling potential donors, personnel at the



transplantation centers quoted mortality figures that varied from less than 1 in 1000 to more than 1 in 100 (Fig. 2). Most programs cited a risk of death between 0.1 percent and 1 percent. However, 5 percent of programs stated that the risk of death was greater than 1 percent, and the same percentage of programs quoted a risk that was lower than 0.1 percent. There was no correlation between the quoted level of risk and the proportion of potential donors who ultimately underwent the operation for donation (data not shown).

The rates of complications were also reported for the recipients of liver transplants from living donors: biliary complications occurred in 99 recipients (22.0 percent), and vascular complications occurred in 44 recipients (9.8 percent). Data on mortality among recipients were not collected in this survey.

Table 2. Number of Transplantation Centers Reporting the Use of Liver Biopsy, Arteriography, and Endoscopic Retrograde or Magnetic Resonance Cholangiopancreatography as Part of the Evaluation of Potential Living Donors.

Procedure	All Donors	Selected Donors	No Donors
Liver biopsy	6 (14)	25 (60)	11 (26)
Arteriography	6 (14)	11 (26)	25 (60)
Cholangiopancreatography*			
Endoscopic retrograde	20 (50)	4 (10)	2 (5)
Magnetic resonance	14 (35)	—	—

* Data were missing for two transplantation centers.

Table 3. Complications of Partial-Liver Donation in 449 Live Donors.*

Type of Complication	No. of Donors (%)
Death	1 (0.2)
Need for rehospitalization	38 (8.5)
Bile stricture or leak	27 (6.0)
Nonautologous blood transfusion	22 (4.9)
Need for reoperation	20 (4.5)
Major postoperative infection	5 (1.1)
Other	10 (2.2)
Total	65 (14.5)

* Some donors had more than one complication.

LENGTH OF STAY

The median lengths of stay for donors in the intensive care unit and in the hospital were 0.25 and 6 days, respectively. There was no association between the length of stay and the numbers of liver transplantations from living or cadaveric donors performed at each center.

AUDIT

An audit of eight transplantation programs was performed to assess the rates of major complications (biliary complications, need for nonautologous blood transfusion, need for reoperation, and death). These programs performed 147 transplantations (range, 1 to 49 per program) during the study period. No discrepancies were found in volumes or in

the rates of major complications (need for reoperation, biliary complications, need for nonautologous blood transfusion, or death) in the donors in these programs. Additional comparisons were made with data from the Scientific Registry for Transplant Recipients and from the recent audits of programs conducted by the New York Consortium for Liver Transplantation. Complication rates reported in the survey exceeded those in both these other reports for all types of major complications in donors, except that there was a higher rate of blood transfusion according to the Scientific Registry (18.2 percent, vs. 4.9 percent in our survey), although the Scientific Registry did not differentiate between autologous and nonautologous transfusion. The rates reported in the Scientific Registry and by the New York Consortium for biliary complications (4 percent and 3 percent, respectively), reoperation (3 percent and 1 percent, respectively), and rehospitalization (13 percent and not reported, respectively) were similar to or lower than those reported in our survey (Table 3).

VOLUMES AND OUTCOMES IN 2001

According to the Scientific Registry, 394 liver transplantations from living donors were performed in adults in 50 centers in 2001. Twelve programs performed more than 10 such transplantations each; four of these programs had performed fewer than 10 such transplantations the previous year. Only one program that had performed more than 10 such transplantations in 2000 (11 performed fewer than 10 in 2001 (8). Thirteen programs performed only one such transplantation each. The mean and median number of transplantations performed by a given program were 7 and 4, respectively (range, 1 to 53).

DEATHS AND SERIOUS ADVERSE EVENTS IN DONORS

Since the time of the survey, there have been two additional deaths reported in donors. One death occurred in January 2002, three days after the operation for donation. An additional death of a donor by suicide two years after donation was deemed by the transplantation center, which had discussed the matter with the transplant recipient, to be unrelated to donation, although the details were not known. Three donors have been put on waiting lists for transplantation of a cadaveric liver. One of these donors was put on a waiting list five days after donation and received a cadaveric transplant three days later because of a diagnosis of the Budd–Chiari syn-

drome. Another of the three donors died without having received a transplant and was included in the survey data as the only death reported. The third donor was put on a waiting list for transplantation seven days after donation because of a diagnosis of subfulminant liver failure; this donor has subsequently been removed from the waiting list because of improvement in liver function.

DISCUSSION

The results of our national survey show a marked increase in the number of liver transplantations from living donors performed in adults between 1997 and 2000, at a time when the numbers of liver transplantations from living donors in children and of transplantations of cadaveric livers in adults and children remained constant or decreased. Half the programs surveyed had performed at least one liver transplantation from a living donor in an adult, and 75 percent of the remaining programs planned to start performing such transplantations in 2001. According to data from UNOS, however, the number of centers performing liver transplantations from living donors in adults increased from 27 in 1999 to 50 in 2001, but only 3 centers in addition to those reported here have performed more than 10 such transplantations. In this survey, 14 centers accounted for more than 80 percent of the transplantations from living donors performed in adults. The centers that performed such transplantations were more likely to be larger-volume centers and to have previously performed liver transplantations from living donors in children.

Guidelines for evaluation of potential living liver donors are not standardized. In this survey, most centers reported that potential donors were assessed by a hepatologist, a social worker, and a psychologist or psychiatrist. However, only half the centers used a physician who was not associated with the transplantation team or an independent ethicist to evaluate the potential donor, an approach that was used and recommended in pediatric liver transplantation from living donors.^{1,21} In addition, this survey indicated that invasive procedures such as liver biopsy, arteriography, and ERCP were performed inconsistently with various programs performing these procedures in none, some, or all potential donors. The indications for these procedures and their effect on outcomes were not assessed in this study. Since such invasive procedures are a source of complications in potential donors, some of whom will

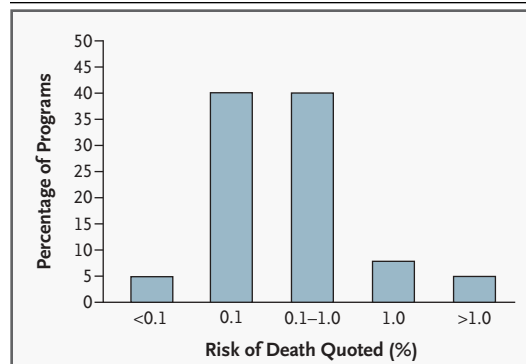


Figure 2. Risk of Death Associated with the Operation for Liver Donation as Quoted to Potential Living Donors by Liver-Transplantation Centers Performing Liver Transplantations from Living Donors in Adults.

not ultimately donate, the role of these procedures needs to be better defined. In this study, the nature of the evaluation and tests performed did not affect the proportion of patients who eventually donated and did not correlate with the occurrence or non-occurrence of postoperative complications or the length of the hospital stay after donation.

The risk of death quoted by the transplantation team to potential donors varied by more than a factor of 10, from less than 0.1 percent to more than 1 percent, reflecting uncertainty about the magnitude of the actual risk. The reported mortality rate among donors in our survey was 1 in 449 (0.2 percent). The rate in Europe is 1 in 123 (0.8 percent),¹⁸ and the rate in Japan is 0 in 215 (0 percent)¹⁹; all of these rates are lower than the rate of 1 percent or greater estimated recently.¹⁶ Since this survey was conducted, two more donors have died in the United States, and at least one of these deaths was clearly related to donation.¹⁷ On the basis of the 394 liver transplantations from living donors reported to UNOS in 2001²⁰ and a similar or higher number for 2002, an additional death might have been expected, given an overall mortality of 0.2 percent associated with the operation for donation. In total, there have been four catastrophic outcomes (three deaths and one transplantation), for a rate of approximately 0.4 percent.

Although the mortality rate among living liver donors was less than 1 percent, complications were not uncommon, with biliary complications occurring in 6.0 percent of donors and rehospitalization required in 8.5 percent. The occasional deaths and

the high rate of complications after liver donation have led to recommendations for federal regulations or restrictions on transplantation programs that can perform this operation.^{17,21} There are established criteria for participation in UNOS, which is required for receipt of cadaveric organs. Furthermore, federal regulations set requirements for liver-transplantation programs funded by the Centers for Medicare and Medicaid Services.

Most innovative surgical procedures, however, are introduced and adopted without restrictions or oversight above and beyond the granting of credentials and the setting of requirements by local hospitals. For example, living donors were initially used for kidney transplantation, despite the limited success of immunosuppressive regimens and the potential (still not clearly defined) for hyperfiltration injury due to having a single kidney. Despite this possible complication, the procedure has proved to be safe, and although renal failure has developed in some donors, its frequency appears to be very low. Several series have, however, documented mild increases in proteinuria and hypertension.²²⁻²⁵ Although no evidence of renal dysfunction was described in these studies, the long-term risk to donors is not precisely defined. Scrutiny has often been less intense for other innovative types of surgery, including both relatively safe operations (e.g., laparoscopic cholecystectomy and radial keratotomy) and more radical operations (e.g., lung-reduction surgery for emphysema and lung transplantation from a living donor).

Methods for the donation of portions of livers by living persons for transplantation in children were developed in the United States at the University of Chicago according to a protocol approved by the institutional review board and with the use of a rigorous process for obtaining informed consent for the first 20 donations.²⁶ This prospective approach offered a unique example of self-regulation and ethical analysis by a program; it was not followed in other centers as the use of the procedure proliferated. Early during the development of methods for adult-to-adult liver transplantation from living donors, several transplantation programs (such as that at Virginia Commonwealth University) had protocols and consent forms that were approved by their hospital-based institutional review boards when they began performing liver transplantation from living donors in adults. This approach has not subsequently been widely used.

The major strengths of our study are that it was broad-based and collected data on a wide range of methods of donor evaluation and outcomes. The 84 centers that responded to the survey performed over 90 percent of the transplantations of cadaveric livers reported to UNOS in 1999 and 2000. The findings are limited, however, by the potential for selection bias: centers that had poor outcomes may have been less likely to report their data. However, given the small volumes of transplantations performed by these centers, the effect of such a bias would be limited. Second, the outcomes reported were not independently verified in the majority of cases. Underreporting may have occurred, particularly with regard to complications. However, an audit of several large programs confirmed the data for major complications, and the data showed higher rates of complications than those reported to UNOS. Given the intense news-media attention to deaths of donors, it is unlikely that there were additional deaths not accounted for in this report. Finally, we did not collect long-term data on either donors or recipients or on aborted donation procedures.

In summary, adult-to-adult liver transplantation from living donors, which was first performed in the United States in 1997, has become an increasingly common approach to liver transplantation and currently accounts for approximately 5 percent of liver transplantations performed in adults. Our data show wide variation in the numbers of transplantations performed at individual centers and variations in the procedures used for the evaluation of potential donors, the follow-up procedures used, and the complications associated with liver donation. Overall mortality among donors is approximately 0.2 percent, but the rate of complications in donors is substantial, with serious complications occurring in 14 percent of donors. There is a critical need for further information and prospective collection of data on adult-to-adult liver transplantation from living donors. Furthermore, we need prospective clinical research studies aimed at determining the optimal process for evaluation, the necessary components of informed consent, the relation of characteristics of the donor and the recipient to outcome, and the potential long-term adverse effects of partial-liver donation.

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