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Living-Donor Liver Transplantation in the United States: Identifying Donors at Risk for Perioperative Complications

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Donor safety has been scrutinized by both the medical community and the media. Variability exists in reported donor complications and associated risk factors are ill defined. Use of administrative data can overcome the bias of single-center studies and explore variables associated with untoward events. A retrospective cohort study identifying living liver donors in two large healthcare registries yielded 433 right and left lobe donors from 13 centers between 2001 and 2005. Perioperative complications were identified using International Classification of Diseases, 9th Revision (ICD-9) coding data and classified according to the Clavien system. Logistic regression models identified factors associated with complications. There was one perioperative death (0.23%). The overall complication rate was 29.1% and major complication rate defined by a Clavien grade $\geq$3 was 3.5%. Center living-donor volume (OR = 0.97, 95% CI = 0.95–0.99) and the ratio of living-donors to all donors (living and deceased) (OR = 0.94, 95% CI = 0.92–0.96) were associated with a lower risk of all complications. Donor age $>$50 years (OR = 4.25, 95% CI = 1.22–14.87) was associated with a higher risk of major complications. Living liver donation is currently performed with a low risk of major morbidity. Use of administrative data represents an important tool to facilitate a better understanding of donor risk factors.

Key words: Living-donor liver transplantation, outcomes, surgical complications

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Introduction

Living-donor liver transplantation (LDLT), since its inception in 1989 for use in pediatric recipients (1), and subsequent transition to the adult recipient population has become a viable option and an important source of hepatic grafts. In the United States, LDLT experienced a rapid growth that peaked in 2001, but since then has seen a decrease in the number of donor hepatectomies performed each year, currently accounting for only 5% of liver transplants (2).

A possible reason for the decrease is the highly publicized death of a donor in early 2002 in New York (3). This event has led to subsequent scrutiny from both the medical and lay communities resulting in increased hesitancy from both donors and centers. This scrutiny has invited a renewed focus on the issue of donor safety.

There are numerous single-center studies that have reported their complications and quantified the risk imposed on the donor (4–16). However, due to the lack of a standardized classification system, and the biases inherent to single-center studies, the reported rates of morbidity have been variable. A strong bias exists against reporting complications as exemplified in a recent study from Massachusetts General Hospital. Approximately, one of two deaths and three of four complications were not reported in the morbidity and mortality conference when compared to data collected using the American College of Surgeons—National Surgical Quality Improvement Program (17).

Administrative data may abrogate some of these limitations and at the same time offer an efficient mechanism for examining large number of patients, thereby providing significant statistical power. Most states maintain discharge data that is readily accessible in the public domain (18); many of these feed into a larger, national aggregate of data (19). The goal of the study was to evaluate living liver donor complications utilizing an alternate data format which potentially could address the limitations of statistical power and bias found in previous studies.

Methods

Data source/study population

This is a retrospective cohort study that identified living liver donors by utilizing discharge-coding data from two healthcare registries. New York State (NYS) maintains statewide, patient-level discharge data from all nonfederal health care institutions through the NYS department of health. This unit, known as the Statewide Planning and Research Cooperative System (SPARCS), is legislatively mandated to collect discharge data, which

includes patient and center characteristics, diagnoses and therapies, which are coded using International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes, services, and charges, with mechanisms in place to allow for data review and correction of errors (20). This database has previously been utilized to provide important information on outcomes of surgical procedures such as open versus endovascular abdominal aortic aneurysm repair, carotid endarterectomy and in assessing trauma management (21–23). A second database, the University Healthsystem Consortium (UHC)(24) which represents large academic medical centers throughout the United States, was also queried.

For this study, discharge data from 2001 through 2005 for adult patients (age $\geq$ 18) admitted with a primary diagnosis of liver donor (ICD-9-CM code V59.6) were extracted from the SPARCS database. This code does not distinguish between the types of lobes donated. Of these, only the subset of patients with a primary procedure diagnosis of hepatic lobectomy (ICD-9-CM code 50.3) or partial hepatectomy (ICD-9-CM code 50.22) were included. This eliminated discharge data for preoperative workup admissions and the admissions during which no procedure was performed; this yielded 379 donors from five centers. A similar query with the UHC clinical database for the years 2004 and 2005 added another 126 donors from 11 centers. We excluded 72 donors from this subset representing donors from three centers, which were already captured with the SPARCS database, for a total 433 liver donors from 13 centers.

Three different mechanisms were used to further validate the data beyond the internal review process used by each database system. The discharge data was compared to Organ Procurement and Transplantation Network (OPTN) (2) data with respect to number of cases per year for each center; 11 of the 13 centers were within $\pm$2 cases for each year of data; one center was within $\pm$4 cases for 1 year and within $\pm$1 case for the remaining years; one center was within $\pm$17 cases for 1 year and within $\pm$5 cases for the remaining years. These differences likely lie in the mechanism of capturing patients. In the SPARCS database, as with all databases of discharge data, a patient is assigned to a given year based on the date of discharge, not date of procedure. As such, those patients donating at the end of the year but being discharged at the beginning of the next can expect to cause deviation from OPTN numbers, especially at higher volume centers. Prior to combining the data from the two datasets, the three common institutions to both datasets were compared with respect to number of discharges per year, patient demographics (age, race, gender), ICD-9-CM diagnosis and procedure codes, and length of stay (LOS); there was 100% congruence between datasets. Similarly, the discharges captured from our institution were compared with our own internal database, and again reflected 100% congruence with respect to demographics and ICD-9-CM codes.

In both databases, comorbidities and complications were identified using ICD-9-CM coding data. Complications were stratified using a modified Clavien system (Table 1) (25,26). The specific codes (single or in combination) for identified complications are as follows: Atelectasis (518.0 + 997.3), ileus (560.1 + 997.4), fever (78.06), pleural effusion (511.9 + 997.3), hematemesis (578.0 + 997.4), intestinal obstruction (560.9 + 997.4), need for blood transfusion (285.1 + 997.4), pneumonia (486 + 997.3), UTI (599.0 + 997.5), cellulitis (682.2, 682.3), bacteremia (790.7), C. diff colitis (008.45 + 997.4), wound infection (998.5 + 86.04), pnuemothorax (512.1), intraoperative vessel injury (998.2 + 39.32/39.59), brachial plexus injury (953.4), acute respiratory failure (518.81) and cardiac arrest (427.5 + 997.1).

The SPARCS database, unlike UHC, provides surgeon identifiers. This data was used to calculate surgeon experience, which was defined as time from medical school graduation. This was felt to be a better measure for surgeon experience than age, as some surgeons may have chosen to attend medical school at an older age. Medical school graduation dates were obtained from the New York State Education Department, Office of the Professions website (27).

Table 1: Modified Clavien classification of postoperative complications (25,26)

Grade	Definition
1	Requiring no pharmacologic treatment, or only antiemetic, antipyretic, analgesic, diuretic agent
2	Requiring pharmacologic treatment with agent other than those allowed for in grade 1 Requiring blood transfusion[1]
3	Requiring surgical, endoscopic or interventional radiologic procedure
4	Life-threatening complication
5	Death

[1]Nonautologous, nonintraoperative.

Statistical analysis

Chi-square analysis was used to test bivariate relationships between donor/center risk factors and perioperative complications and to determine subsequent entry into multivariate logistic regression models, the requirement for which was a p-value < 0.10. Adjusted odds ratios were calculated using multiple logistic regression; separate models were formulated for all complications and major complications. Means were compared using analysis of variance (ANOVA); a Bonferroni correction was applied to multiple comparisons. Means are reported with $\pm$SD. Results for the chi-square test and ANOVA are reported using p-values, and odds ratios are reported with 95% confidence intervals (95% CI). All data management and statistical analysis was performed using SPSS version 14 (SPSS Inc., Chicago, IL). This study was approved by the Institutional Review Board (IRB) of the University of Rochester.

Results

Donor demographic data are shown in Table 2; mean age was 36 $\pm$ 10 (SD), and ranged from 18 to 59. Mean annual center volume was 23 $\pm$ 15: 8 $\pm$ 6 and 25 $\pm$ 15 for the UHC and SPARCS subsets, respectively, reflecting several large volume centers located in NYS. As expected, the donor population, irrespective of age, was generally healthy. Table 2 also provides information on the prevalence of identified comorbidities; 20% of donors had a single comorbidity and 2% had two or three comorbidities.

The perioperative mortality rate was 0.23% (1/433). The one death occurred on postoperative day 3 in a 57-year-old male whose donation was complicated by respiratory failure and sepsis. The overall complication rate was 29.1% and major complication rate, defined by a Clavien grade 3 or higher, was 3.5%. Grades 1 and 2 complications versus grade 3 and higher complications were chosen to differentiate major versus minor as it was felt that need for an invasive intervention should classify a complication as being major due to the additional risk introduced by the intervention. Major and minor complications, with associated rates of occurrence, are listed in Table 3. Therapeutic

Table 2: Donor and center characteristics

Characteristic	N[1]	Percent[2]
Age		
18–30	140	32.33
31–40	146	33.72
41–50	109	25.17
>50	38	8.78
Gender		
M	209	48.27
F	224	51.73
Race		
White	318	73.44
African American	17	3.93
Asian	8	1.85
Other	52	12.01
Unknown	38	8.78
Comorbidity[1]		
Smoker	39	9.01
Hypertension	20	4.62
Asthma	19	4.39
Obesity	5	1.15
Sleep apnea	3	0.69

[1]A patient can have multiple comorbidities.
[2]Percent of total, N = 433.

Table 3: Postoperative complications during admission by Clavien grade (25,26)

Grade	Complication	N[1]	Rate[2] (%)
1	Atelectasis	16	3.70
	Ileus	15	3.46
	Fever	14	3.23
	Pleural effusion	11	2.54
	Hematemesis	1	0.23
	Intestinal obstruction	1	0.23
2	Need for blood transfusion[3]	14	3.23
	Pneumonia	7	1.62
	UTI	6	1.39
	Cellulitis	4	0.92
	Bacteremia	2	0.46
	C. difficile colitis	1	0.23
	Wound infection	1	0.23
3	Pneumothorax	2	0.46
	Intraoperative vessel injury	2	0.46
	Brachial plexus injury	1	0.23
4	Acute respiratory failure	3	0.69
	Cardiac arrest	2	0.46
5	Death	1	0.23

[1]Patients can have multiple complications.
[2]Percent of total, N = 433.
[3]Nonautologous, nonintraoperative.
UTI = urinary tract infection.

procedures performed post liver donation are listed in Table 4; one donor returned to the operating room for bleeding on postoperative day 2, and three donors had biliary stents placed endoscopically.

In a multivariate analysis, several covariates were tested for an association with peri-operative complications. Two models each were created for any complication and major complication. The first model for both included only donor characteristics, which included age, gender, race, tobacco use, hypertension, obesity and respiratory disease. The second model added in center characteristics, which were annual center volume and ratio of living donors to all donors (living and deceased), and, in a subset analysis using the SPARCS database, surgeon experience. Center annual living-donor volume (OR = 0.97, 95% CI = 0.95–0.99) and the ratio of living donors to all donors (OR = 0.94, 95% CI = 0.92–0.96) were associated with a lower risk of any complication. For major complications, in the donor characteristics-only model, donor age >50 (OR = 4.25, 95% CI = 1.22–14.87) and African American race (OR = 5.40, 95% CI = 1.04–28.09) were associated with major complications; only donor age >50 remained significant in the subsequent model including center characteristics. In the subset analysis, surgeon experience was not a significant predictor of any or major complication.

Additionally, median LOS was 7 days, with a mean of 7 ± 1.8 days, ranging from 3 to 14 days. Not surprisingly, donors with any complication (mean LOS = 7.66 vs. 6.73, p-value < 0.001), or major complication (mean LOS = 8.07 vs. 6.96, p-value < 0.05), had a higher mean LOS. The UHC subset tracks readmissions to the original hospital. There were 11 (8.7%) readmissions out of 126 donors. The various indications for readmission are provided in Table 5.

Discussion

Choosing to donate a portion of one's liver is a heroic, and potentially life-changing event. The responsibility, however, falls on the medical community to ensure that the donor

Table 4: Postoperative therapeutic procedures

Procedure	N[1]	Percent[2]
Respiratory		
Continuous ventilation < 96 h	3	0.69
Reinsertion of endotracheal tube	3	0.69
Insertion of chest tube	1	0.23
GI		
Endoscopic insertion of biliary stent	3	0.69
Percutaneous abdominal drainage	1	0.23
Insertion of nasogastric tube	1	0.23
Other		
Return to OR—bleeding	1	0.23
Return to OR—unknown	1	0.23

[1]Each patient can have multiple procedures. The three patients who were reintubated also were kept on mechanical ventilation for up to 96 h.
[2]Percent of total, N = 433.
GI = gastrointestinal; OR = operating room.

Table 5: Indications for readmission and time from discharge

Indication	N	Percent[1]	Time from discharge[2]
Incisional hernia	3	2.38	419
Pleural effusion	3	2.38	17.6
Wound infection	2	1.59	18
Empyema	1	0.79	7
DVT	1	0.79	28
Ileus	1	0.79	2

[1]Percent of total, N = 126 (UHC dataset).
[2]Number of days from initial discharge, value is mean if N > 1.
DVT = deep venous thrombosis.

is informed of the risks of the procedure and the potential short and long-term complications. The current state of knowledge regarding donor complications is challenged by study design, with most data derived from single centers with short-term follow-up. It is this lack of clarity that has led to recent calls by the lay and medical communities for greater outcomes information and oversight among living organ donors (28,29). The ongoing Adult to Adult Living Donor Liver Transplantation cohort (A2ALL) study sponsored by the NIH will go far to address many of these issues (30). Concern regarding donor outcomes is in congruence with the growing interest in patient safety as emphasized by the Institute of Medicine (31).

The A2ALL study group recently presented an overall complication rate of 38% among donors using a similar classification system for postoperative morbidity, and most of the complications were of low severity (32). These findings are similar to the ones reported in this study, but other reports of postoperative complications have been quite variable, ranging from 0% to 67% (4–6,11). Most of the variability is due to the lack of a standardized system for classifying complications, which is further confounded by a bias against reporting complications. Several of these studies, however, have reported declining rates of complications over time, perhaps accounting for some of the variability.

It is clear that partial liver donation can be performed safely with a relatively low risk of major perioperative morbidity, as confirmed by this study. This study adds to our current understanding of perioperative complications by defining for the first time variables which may predict an untoward event at the time of donation. As might be expected, based on studies of nondonor complications, increased age is associated with complications (33). Older donors should be considered for LDLT, but with caution. Unique to LDLT and hepatic resection is the concept of liver regeneration. In a review, Olthoff summarized data from both animal and human studies that have shown a decreased, and delayed, capacity for regeneration in older donors (34). This diminished capacity has also been shown in the recipient population with respect to early graft regeneration from older donors and graft survival (35,36). Remnant liver regeneration may be associated with donor outcomes, although a clear link between the two has not yet been established. Donors of African American race, in this study, were more likely to have major complications when examining only donor characteristics. However, due to their relatively small number in this study (17/433), caution should be used when interpreting these results.

Annual center volume was also found to be associated with postoperative outcomes, which too has previously been reported in nondonor studies (37). In addition, the percentage of liver transplants from living donors' relative to deceased donors was also associated with donor perioperative morbidity, even when controlling for hospital volume. From a systems-based practice perspective, perhaps a center that is more focused on LDLT, and subsequently the living donor, will have better outcomes.

One limitation of this study is the inability to discriminate between left and right lobe donation. There is a potential difference in morbidity, mortality, extent of operation and subsequent recovery that exists between the different types of resections (right lobectomy, left lobectomy and left lateral segmentectomy). Some differences with respect to rates and severity of postoperative morbidity have previously been reported in single-center experiences (6,38,39). However, an examination of OPTN data for the centers and time frame of this study indicates that a majority of LDLT were adult recipients (individuals > 18 years of age); as a median percent, adults made up 96% of the recipients of a LDLT (2). Therefore, the variance introduced by pediatric recipients is likely minimal, given that the vast majority of adult recipients are receiving right lobes.

Another limitation of this study is that the use of administrative data for detecting complications that occur beyond the perioperative period is problematic and not easily addressed. Statewide administrative databases may be able to detect readmissions, however not all donors live near the donor hospital and may seek healthcare at other institutions or in other regions of the country. The UHC database is able to identify those donors who were readmitted to the original donor hospital, but not those admitted to other hospitals. Though it is intuitive that the donors may seek further medical care from the same institution, especially large university-based hospitals, this may not necessarily be true. Thus, those who can be identified may only represent a small fraction of readmissions. Complications managed on an outpatient basis are not captured here, as this data is derived from inpatient admissions. This likely represents an underestimation of the complications managed in the outpatient setting.

Despite the limitations, administrative data are an efficient means of examining large number of patients. This type of data lend themselves to the analysis of donor and center risk factors for particular outcomes such as morbidity and mortality, which may be difficult to address in smaller single-center studies. They have previously been utilized

to help identify risk factors for poor outcomes in various settings (33,37,40–42). Administrative data may help to overcome potential biases of single-center studies, as the personnel trained to abstract codes from charts are independent of patient care, physicians and studies utilizing the data. The addition of a validated and standardized tool to assess surgical complications facilitates such an analysis. Although some have urged caution with the use of this type of data (43), several studies have validated its accuracy when compared to chart reviews (44,45).

In the context of organ donation, use of administrative data along with a standardized tool to measure complications represents an important methodology to facilitate a better understanding of donor risk factors. The issue of donor safety will continually need to be revisited to maintain an accurate, real-time assessment of the practice of living liver donation, especially so that the potential donor is able to make the most informed decision possible.

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