

Who Pays for Biliary Complications Following Liver Transplant? A Business Case for Quality Improvement

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We use biliary complication following liver transplantation to quantify the financial implications of surgical complications and make a case for surgical improvement initiatives as a sound financial investment. We reviewed the medical and financial records of all liver transplant patients at the UMHS between July 1, 2002 and June 30, 2005 (N = 256). The association of donor, transplant, recipient and financial data points was assessed using both univariable (Student's *t*-test, a chi-square and logistic regression) and multivariable (logistic regression) methods. UMHS made a profit of \$6822 ± 39 087 on patients without a biliary complication while taking a loss of \$5742 ± 58 242 on patients with a biliary complication (p = 0.04). Reimbursement by the payer was \$55 362 higher in patients with a biliary complication compared to patients without a biliary complication (p = 0.001). Using multivariable logistic regression analysis, the two independent risk factors for a negative margin included private insurance (compared to public) (OR 1.88, CI 1.10–3.24, p = 0.022) and biliary leak (OR = 2.09, CI 1.06–4.13, p = 0.034). These findings underscore the important impact of surgical complications on transplant finances. Medical centers have a financial interest in transplant surgical quality improvement, but payers have the most to gain with improved surgical outcomes.

Key words: Biliary complication, liver transplant, quality improvement, surgical complications, transplant finances

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Recently, we proposed an infrastructure for transplant surgical quality improvement (1). Unfortunately, any comprehensive quality improvement initiatives, such as the American College of Surgeons—National Surgical Quality Improvement Program (NSQIP), will be expensive. A structured quality improvement initiative might require highly trained nurses and a sophisticated data auditing and collection infrastructure. In order to initiate a transplant surgical quality improvement effort, a viable business model for quality improvement must be established. A national transplant surgical quality improvement program requires a significant investment from providers and payers, but it remains unclear which party has the largest financial stake in quality improvement.

Undoubtedly, there will be resistance from the transplant community to augment the reporting of the clinical transplant data. Transplant centers and medical centers already bear the costs of significant mandatory clinical reporting. Per the Department of Health and Human Services, the data submitted to the Organ Procurement Transplant Network (OPTN) by the Organ Procurement Organizations (OPO) and transplant medical centers is considered mandatory under 121.11(b)(2) of the 'OPTN final rule'. Though this reporting is burdensome and expensive, the transplant community and our patients have greatly benefited from the analysis of this data by United Network for Organ Sharing (UNOS) and the Scientific Registry for Transplant Recipients (SRTR) and the subsequent policy and practice changes. Medical centers also bear the burden of massive amounts of data reporting (much of it regarding 'quality measures') required by JCAHO (Joint Commission on Accreditation of Hospital Organizations) and CMS (Center for Medicare Services). Any initiative increasing the amount of reporting and need for additional transplant center infrastructure would be particularly burdensome to smaller transplant centers.

Within our focus on transplant surgical quality improvement, we view the opportunity to collect more data on surgical complications as an investment. Obviously surgical complications have a deleterious effect on patient outcomes, but they also are expensive. With this paper, we attempt to calculate the expense of a common post-transplant surgical complication, biliary leak and stricture. We attempt to quantify which parties have the largest financial stake in this complication. With this data, we make a case for surgical improvement initiatives as a sound

Table 1: Background characteristics of the groups of liver transplant recipients with and without a biliary complication

	No biliary complication (N = 170)	Biliary complication (N = 86)	p-value
Recipient age (years)	40.0 ± 21.4	47.3 ± 14.1	0.006
Recipient sex (male)	98 (57.6%)	55 (64.0%)	NS
MELD (Lab)	22.4 ± 5.7	23.3 ± 6.6	NS
Donor age	30.2 ± 18.3	39.6 ± 17.1	0.0003
Donor sex (male)	79 (46.4%)	43 (50.0%)	NS
HTK preserve ¹	103 (60.6%)	38 (44.2%)	NS
Total ischemia (h)	9.3 ± 2.4	9.3 ± 2.4	NS
Graft loss ²	26 (15.3%)	11 (12.8%)	NS
DCD donor	8 (4.7%)	4 (4.6%)	NS

DCD donor is a donor following cardiac death.

¹HTK: histidine-tryptophan-ketoglutarate solution (compared to University of Wisconsin solution).

² Defined as retransplantation or death.

financial investment, which results from improved surgical quality.

Methods

Clinical data

Following Institutional Review Board approval, the electronic records for all adult and pediatric (age ≤ 18 years) recipients of deceased donor liver transplants (including split liver transplants and livers donated following cardiac death) performed between July 1, 2002 and June 30, 2005 at the University of Michigan Health System (UMHS) were retrospectively evaluated. Data regarding donor, transplant and recipient characteristics as well as graft and patient outcomes were obtained from both a prospectively collected database and review of the electronic medical record.

Definition of biliary complication

For the purposes of this study, biliary complications were defined as detection of a leak or stricture in the intrahepatic or extrahepatic biliary tree on cholangiogram. Analysis was limited to biliary complications diagnosed within the first 6 months following transplant.

Financial data

We obtained inpatient and outpatient financial data on physician procedural fees (surgeon, gastroenterologist, interventional radiologist and nephrologists), facility fees and reimbursements on each patient from the internal cost-accounting database at the University of Michigan. We collected financial data from the day of transplant (including the transplant operation) to 6 months post-transplant. We only account for costs of care within our health system and organ acquisition costs and reimbursements were subtracted out of each patient's financial record and thus eliminated from the analysis. The TSI system (Transitions Systems, Inc., Shoreview, MN) was used to identify total hospital costs (direct and indirect) and reimbursements. Reimbursements to the medical center were calculated based on a modeled revenue for reimbursements (constantly updated average for a payer based on hospital charges). The TSI system tracks the use of all resources and assigns estimates of cost based on direct acquisition costs for supplies and time-and-motion studies for labor costs. This method of activity-based cost accounting is widely believed to be the most accurate method of estimating the true economic cost of an episode of care (2). Hospital margins were calculated by the formula: (hospital reimbursements – hospital total costs).

Statistical analysis

The association of donor, transplant, recipient and financial data points was assessed using an unpaired Student's *t*-test for continuous variables and a chi-square analysis for categorical variables. We used a univariable logistic

regression analysis to look for risk factors for a negative margin for the hospital. We define negative margin as a profit <\$0 for the first 6 months of care following the liver transplant operation. We then evaluated independent risk factors for a negative margin by a multivariable logistic regression using covariates in the model if they were statistically significant at the *p* < 0.10 level on univariable analysis. All statistical analyses were performed using Statview (version 5.0.1) (Abacus Concepts, Inc., Berkeley, CA).

Results

The baseline characteristics of the study population (256 consecutive deceased donor pediatric (N = 49) and adult (N = 207) liver transplants done between July 2002 and June 2005) are detailed in Table 1. We note that the patients with biliary complications were significantly older and received a liver from a significantly older donor. As expected, biliary complications were associated with more days in the hospital the first 6 months following the transplant, more readmissions and more clinic visits (Table 2). The biliary reconstructions were completed via a duct-to-duct anastomosis (N = 226, 90.2%) or by a biliary enteric anastomosis (N = 25, 9.8%). Cholangiogram was completed in 48% of all patients: either a percutaneous transhepatic cholangiogram (PTC tube), an endoscopic retrograde cholangiogram (ERCP) or a Turcotte tube (internal-external tube that enters the cystic duct stump with one end traversing the biliary anastomosis and the other to external bag drainage). Patients with a Turcotte tube (N = 42) had a routine cholangiogram completed on postoperative day 7 or earlier if appropriate. The day of the routine Turcotte tube injection, only 10 patients had a clinical indication for a cholangiogram (clinical suspicion of a biliary complication) and all 10 of these patients received either an ERCP or a PTC tube following the Turcotte tube injection. Conversely, 10 of the remaining 32 patients who had a Turcotte tube cholangiogram had an ERCP or PTC tube for what may have been a clinically insignificant abnormal finding (very small leak possibly around the tube or a size discrepancy between the donor and recipient ducts). Since it is not possible to clearly determine which of these 10 patients had a biliary duct lesion that required intervention, they were considered to have had a biliary complication. An ERCP

Table 2: Inpatient and outpatient characteristics of liver transplant recipients with and without a biliary complication

	Biliary complication	No biliary complication	Difference	p value
Length of stay (days) after transplant	15.8 ± 18.0	12.6 ± 13.0	3.2	0.10
Hospital days first 6 months	46.7 ± 44.0	25.1 ± 25.8	21.6	0.0001
Readmissions	2.0 ± 1.9	1.0 ± 1.2	1	0.0001
Clinic visits first 6 months	20.4 ± 9.8	17.5 ± 9.5	2.9	0.03

LOS: length of stay.

Table 3: Differences in physician procedural fees between liver transplant recipients with and without a biliary complication

	Biliary complication	No biliary complication	Difference	p-value
Transplant surgery	\$22 614 ± 6257	\$22 342 ± 4825	\$272	0.7
Gastroenterology	\$4066 ± 4181	\$153 ± 724	\$3913	0.0001
Interventional radiology	\$1872 ± 3292	\$72 ± 394	\$1800	0.0001
Nephrology	\$1996 ± 5036	\$364 ± 1536	\$1632	0.0001

Table 4: Summary of the financial implications of a biliary complication in liver transplant recipients for the hospital, physicians and insurer

	No biliary complication		Biliary complication	
	Pediatric (N = 42)	Adult (N = 117)	Pediatric (N = 7)	Adult (N = 74)
Hospital costs	\$130 375 ± 71 166	\$154 255 ± 104 179	219 836 ± 58 564	\$209 143 ± 185 212
Hospital reimbursement	\$135 985 ± 66 004	\$163 528 ± 102 169	\$201 061 ± 53 113	\$199 636 ± 157 834
Hospital profit	\$5609 ± 29 198	\$9272 ± 40 883	(\$18 775 ± 35 311)	(\$8491 ± 53 014)
Physicians fees	\$22 724 ± 4319	\$23 322 ± 5418	\$29 802 ± 8139	\$31 500 ± 9390
Physician fee reimbursement	\$8323 ± 2343	\$12 345 ± 3185	\$12 476 ± 3267	\$15 143 ± 4873
Total insurer reimbursement	\$144 308 ± 68 347	\$175 873 ± 105 354	\$213 537 ± 56 380	\$214 779 ± 162 707

was done in 45 patients, a PTC tube was done in 59 patients, and 20 patients had both and ERCP and a PTC tube. The complication rate was 33.8 in patients with a duct-to-duct biliary reconstruction and 33.0% in the patients with a biliary enteric reconstruction. Patients with a roux were associated with a significantly lower total costs (\$137 651 ± 67 707 vs. \$178 101 ± 143 094, $p = 0.05$) and lower reimbursement (\$140 293 ± 72 894 vs. \$180 713 ± 129 610, $p = 0.04$). The hospital margins were similar between the two groups.

The professional fees (procedural related only) are largely unchanged for the transplant surgeon whether or not the patient has a biliary complication, reflecting the fact that only two patients were reoperated upon for management of their complication. As expected, the gastroenterology and interventional radiology services bill a significant amount on patients with biliary complications (Table 3). In addition, nephrologists' fees are significantly higher in patients with biliary complications.

The summary financial data for the groups with and without biliary complications are shown in Table 4. It is notable that our medical center made a profit of \$6822 ± 39 087 on patients without a biliary complication while taking a loss of \$5742 ± 58 242 on patients with a biliary complication, a financial difference of over \$12 000 per patient. Remarkably, reimbursement by the payer to the physicians and medical center was \$55 362 higher in patients with a biliary complication.

Though limited by the small number of biliary complications among pediatric recipients ($N = 7$), we compared financial data between pediatric and adult recipients (Table 5). Pediatric biliary complications (compared to adult) were associated with more admissions in the first 6 months ($4.6 ± 2.8$ vs. $2.8 ± 1.7$, $p = 0.019$). Children without a biliary complication ($\$130 375 ± 71 166$) had lower costs than adults without a biliary complication ($\$154 255 ± 104 579$; $p = 0.107$), adults with a biliary complication ($\$209 143 ± 185 212$; $p = 0.009$) and children with a biliary complication ($\$219 836 ± 58 564$; $p = 0.003$). The mean reimbursements for adults and children with biliary complications was similar (difference \$1425). A biliary complication in a child is associated with a \$24 384 profit loss for the medical center and \$69 229 in additional payments by the insurer. Eight of the pediatric (and none of the adult) have split grafts and there were two biliary complications. These transplants and complications were not noted to be significantly more expensive in our small series (data not shown).

Based on this data we analyzed multiple donor and recipient characteristics by univariable logistic regression to determine risk factors for a medical center negative margin following liver transplant (Table 6). We classified our biliary complications into any biliary complication and also into biliary stricture (intrahepatic or extrahepatic) and biliary leak. Of note, biliary leak, dialysis and total inpatient days in the first 6 months following transplant were the only clinical variables that predicted a negative margin.

Table 5: Summary of the financial implications (pediatric and adult) of a biliary complication in liver transplant recipients for the hospital, physicians and insurer

	Biliary complication	No biliary complication	Difference	p-value
Hospital costs	\$214 968 ± 178 192	\$149 897 ± 99 159	\$65 071	0.0002
Hospital reimbursement	\$208 307 ± 158 925	\$156 719 ± 95 254	\$51 588	0.0014
Hospital profit	\$5742 ± 58 242	\$6822 ± 39 087	\$12 564	0.04
Physicians fees	\$31 161 ± 9270	\$23 395 ± 6009	\$7766	0.0001
Physician fee reimbursement	\$15 144 ± 4505	\$11 370 ± 2920	\$3775	0.0001
Total insurer reimbursement	\$223 451 ± 163 430	\$168 089 ± 98174	\$55 362	0.001

Table 6: Univariable analysis of risk factors for a liver transplant course that results in a negative hospital margin

Risk factor	p value	Coefficient	95% CI
Biliary leak	0.028	2.167	1.087–4.319
Dialysis	0.050	1.930	1.000–3.751
Private insurance*	0.019	1.900	1.111–3.247
Inpatient days first 6 months	0.002	1.015	1.006–1.024
Hospital charges	<0.001	1.001	1.000–1.001
Any biliary complication	0.059	1.660	0.981–2.815
Recipient sex (female)	0.152	1.471	0.867–2.500
Biliary stricture	0.623	1.160	0.642–2.097
MELD	0.242	1.026	0.983–1.070
LOS after transplant	0.289	1.010	0.992–1.028
Donor age	0.543	1.005	0.990–1.020
Total ischemia	0.322	1.001	0.999–1.003
Recipient age	0.559	0.996	0.983–1.009
Donor creatinine	0.463	0.892	0.656–1.211

MELD: Model of Endstage Liver Disease; LOS after transplant, length of stay after liver transplantation.

*Compared to public insurance.

Based on this univariable analysis, we created a multivariable model to determine independent risk factors for a negative margin liver transplant course. The two independent risk factors for a negative margin included private insurance (compared to public) (OR 1.88, CI 1.10–3.24, $p = 0.022$) and biliary leak (OR = 2.09, CI 1.06–4.13, $p = 0.034$).

We then compared biliary leak to biliary stricture, eliminating patients who had both a leak and a stricture (N = 22). We noted that biliary leaks presented earlier than strictures, were associated with significantly more inpatient days in the first 6 months (31.1 ± 23.2 vs. 53.9 ± 22.0 , $p = 0.016$), total costs ($\$178\,234 \pm 123\,324$ vs. $\$261\,970 \pm 194\,548$, $p = 0.029$) and insurer reimbursement ($\$210\,236 \pm 145\,657$ vs. $\$280\,819 \pm 260\,345$, $p = 0.04$) compared to biliary stricture. Biliary leak was associated with a lower hospital margin, but the difference was not statistically significant ($\$3435 \pm 25\,213$ vs. $\$11\,961 \pm 56\,235$, $p = 0.23$).

Discussion

In order to build a business case for transplant surgical quality improvement, it is important to assign costs to poor quality. We take biliary complication following liver transplantation as an example of poor surgical quality to build a financial argument for quality improvement. With this arti-

cle, we have established that biliary complications are expensive for the medical center, but even more expensive for the payer. Specifically, a biliary complication costs the UMHS \$12 000 in margin per case and payers reimburse UMHS an additional \$55 000 per case. The implications for physician fees are less impressive. We also note that biliary leaks are significantly more expensive than biliary strictures. In addition, we note that biliary leak is the only independent clinical risk factor for a negative medical center margin. These findings underscore the important impact of surgical complications on medical center finances. While all parties (patient, physician, payer and medical center) have an interest in quality improvement, based on our data, it seems clear the medical centers and payers have a shared financial interest in transplant surgical quality improvement, with payers holding the largest financial stake.

Medical center administrators and insurance carriers are aware of the high cost of surgical complications. In one study, median hospital costs were lowest for patients without complications (\$4487) compared with those with minor (\$14 094) and major complications (\$28 356) ($p < 0.001$) (3). In the VA system, reductions in postsurgical pneumonias alone (exclusive of other complications) have resulted in annual savings of \$9.3 million (4,5). With the introduction of the model of endstage liver disease (MELD) era, liver transplant patients are becoming more complex and likely complications will become more common and expensive (6–8).

Our analysis is admittedly limited in scope. First, we fail to quantify opportunity costs for the medical center, which generally runs at capacity. For example, having a liver transplant patient with a biliary complication in a bed prevents another, potentially 'profitable' patient from occupying that bed. Thus, the actual loss from biliary complications may be higher for the medical center. Second, we focus on the financial implications to the payer, the medical center and the providers, but not on the costs to the patient or society. Certainly a complicated post liver transplant course will deleteriously affect patient productively. Third, our cost data is based on the UMHS cost accounting methodology, and accounting assumptions are inherently imperfect and will have significant impact on data and associated conclusions. In addition, the financial implications of complications likely vary widely between centers making direct comparisons to another center difficult. For example, it is

likely unique for our center to have a much higher risk for a negative margin with private payers compared to public payers. Finally, we are unable to disclose the specific financial agreements between UMHS and individual private payers, per agreement between the authors and the UMHS finance department.

There is no clear data indicating that quality improvement initiatives such as the NSQIP, the Leapfrog Group or other initiatives improve care (9–11). Considering this, the second step to building a business case for transplant surgical improvement is demonstrating that quality improvement works. Presumably, a focused effort on surgical quality improvement developed by transplant physicians (and not payers or government agencies) will reduce complications, though this claim is supported only by observational data (4,12–14). It is possible that improvements in surgical quality are related to secular trends rather than a specific influence of quality improvement initiatives. Our group would suggest study of this challenge to quality improvement initiatives, in addition to study of our transplant quality improvement program, to determine the most effective approaches to quality improvement.

A prospective, standardized infrastructure of data collection and risk-adjusted analysis from multiple transplant centers should allow much greater understanding of best clinical practices, and would foster a quality improvement action plan to reduce biliary complications. For example, if a center is a statistical outlier for low rates of biliary complications, not only could the preoperative, donor, intraoperative and postoperative data be queried, but also this center could report their specific methods of transplant biliary reconstruction. Such an approach would likely have significant financial implications to medical centers and payers. To extrapolate our findings to the national data, assuming a biliary complication rate of 15% among the deceased donor liver transplant patients done in the United States during fiscal year 2004–2005 (N = 6082) (15–17), insurance carriers reimbursed medical centers an additional \$50 million and medical centers lost \$11 million in profits directly related to biliary complications. Even a modest improvement in the rate of biliary complications would have significant economic impact. Based on similar observations, our group has attracted the attention of a large private payer in our state to fund a 'pay for participation' surgical quality improvement initiative, which they presumably see as a sound financial investment (Michigan Surgical Quality Cooperative) (10). In addition, a national transplant quality improvement program would allow focus on much more than biliary complications, offering ample promise for transplant centers, medical centers, payers and most importantly, for patients.

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