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Personal Viewpoint

# Reducing Pediatric Liver Transplant Complications: A Potential Roadmap for Transplant Quality Improvement Initiatives Within North America

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**Though robust clinical data are available within transplantation, these data are not used for broad-based, multicentered quality improvement initiates. This article describes a targeted quality improvement initiative within the Studies of Pediatric Liver Transplantation (SPLIT) Registry. Using standard statistical techniques and clinical expertise to adjust for data and statistical reliability, we identified the pediatric liver transplant centers in North America with the lowest hepatic artery thrombosis rate and biliary complication rates. A survey was completed to establish current practices within the entire SPLIT group. Surgeons from the highest performing centers presented a detailed, technically oriented overview of their current practices. The presentations and discussion that followed were recorded and form the basis of the best practices described herein. We frame this work as a unique six-step approach roadmap that may serve as an efficient and cost effective model for novel broad-based quality improvement initiatives within transplantation.**

**Key words: Best practices, biliary complications, hepatic artery thrombosis, pediatric liver transplantation, quality collaboration, quality improvement**

**Abbreviations: HTK, histidine-tryptophan-ketoglutarate; MSQC, Michigan Surgical Quality Collaborative; OPTN, Organ Procurement and Transplantation Network; QI, quality improvement; SPLIT, Studies of Pediatric Liver Transplantation.**

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## Introduction

Few areas of medicine have more robust clinical outcomes data than transplantation. Transplant centers are required to report large amounts of data regarding transplant candidates, recipients and donors. These data are currently used to inform policy and assure quality and have led to an explosion of health services research in the field of clinical transplantation. Undoubtedly, this research has improved the management and care of transplant patients.

Despite the mass of data available, clinical transplant registries have not been leveraged for broad-based quality improvement programs. Certainly, these data are used by regulators and payers to measure performance, but that is quality assurance and not quality improvement. As has been described before, quality improvement takes much more than just high quality data; it requires clinical expertise, a collegial and noncompetitive atmosphere, and a comprehensive quality improvement plan (1,2). Clinician-driven collaboratives such as the Michigan Surgical Quality Collaborative (MSQC) the and the New England Cardiovascular Disease Study Group have demonstrated significant success with improving outcomes and accelerate improvements in practice (2–8). For example, the MSQC (a collaborative of 52 Michigan hospitals) has resulted in a 15% reduction in length of stay, 18% reduction in surgical site infections and a 2.6% reduction in surgical complications resulting in an $85 million in Statewide savings (3,9,10). Considering the robust available data, narrow case-mix, and small clinician community, transplantation is well suited to use these validated QI methods (1). A potential template for such efforts involves our recent work within the Studies for Pediatric Liver Transplantation (SPLIT) group.

SPLIT was established in 1995, and to date has a detailed database of over 4000 pediatric liver transplant recipients in the United States and Canada. This group has a track record of contributing important research and policy

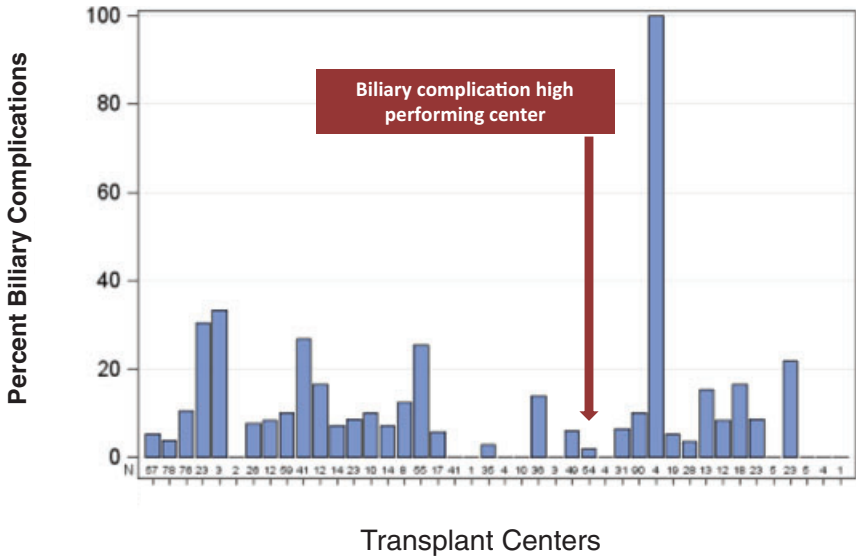


**Figure 1: Biliary complication rates across North American pediatric liver transplant centers.**

initiatives in pediatric liver transplantation (11–19). Recently, our group began to focus on the variation in outcomes across transplant centers within the collaborative. Using data from the SPLIT and Organ Procurement and Transplantation Network (OPTN) databases, we observed a 1-year survival that ranged from less than 50% to 100%. Even when we considered the unreliability of measuring performance at low-volume pediatric transplant centers, there remained a 20% differential in 1-year survival among transplant centers in North America. Appreciating the important limitations of analyses like these, observations such as this one and others motivated our group to establish a Clinical Care and Quality Improvement Committee within SPLIT.

With this manuscript, we will describe one arm of our QI efforts within SPLIT relating to technical aspects of the transplant operation. In this regard, our first two targets for quality improvement were the incidence of hepatic artery thrombosis and biliary complications. As with mortality data, we noted a broad variation in rates of these morbid complications following pediatric liver transplantation. With help from the highest performing transplant centers; we have developed best practices and a comprehensive quality improvement plan. A key component of the plan is to discuss the importance of this work as well as to disseminate best practice guidelines, which in part is the motivation for this manuscript. Finally, we will highlight future quality improvement plans within this collaborative, focusing on our goal to improve the care of children with end-stage liver disease.

More broadly, this approach to QI is adapted from successful work with clinician led QI collaboratives within Michigan and New England (3,5–8). Motivated by these successes, the transplant community should consider this work as a roadmap for much needed, physician driven QI efforts within transplantation.

## Step 1: Identification of the Highest Performing Centers

Though all efforts were made to follow rigorous methods, selection of high-performing centers involved more than just statistical analysis. We choose hepatic artery thrombosis and biliary complications because they are common, clinically relevant, have significant variation between centers and are reliably reported within the SPLIT database. Though specific definitions for these complications do exist, members of the committee discussed extensively the reliability of the data reporting. Data reporting fields that could be verified (such as transplant volume) were cross-reference with OPTN data in an effort to assure that only centers with a good track record of data reporting were considered for these efforts. We chose a relatively recent observation period (2005–2009). Members of the SPLIT QI committee identified the highest performing centers, considering hospital rankings, data reliability and potential confounding clinical variables. Broad variations in outcomes were noted (Figures 1 and 3). We first ranked transplant centers based on their unadjusted hepatic artery thrombosis and biliary complication rates (center-specific adjusted outcomes were not feasible due to small sample size). In a further effort to optimize the reliability of these data, low-volume transplant centers (< 10 transplants) were eliminated from consideration (20). Potential confounding variables such as rates of living donor, age of recipients, split transplants were taken into account. However, the high-performing centers also had high rates of living and split transplants, even though both of these variables are well known as risk factors for hepatic artery thrombosis and biliary complications (21–24).

Careful consideration was taken in the process of reviewing center-specific outcomes. First, QI committee members were blinded to the center identification. Second,

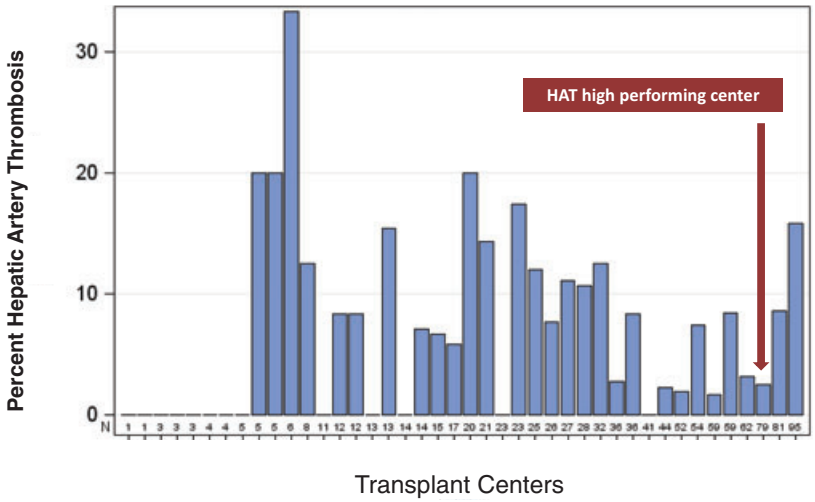


**Figure 2: Hepatic artery thrombosis rates across North American pediatric liver transplant centers.**

the entire focus of the committee effort was on high-performing centers, thereby negating concerns of public ridicule and competitive advantage among members of low-performing centers. It is important to note that focusing on low performance is not a productive QI approach, as has clearly been established with previous work (2). Once the de-identified highest performing centers were chosen, a member of the data coordinating center (not a clinician) discussed with the high-performing center whether they would be willing to participate in these efforts and thereby have their outcomes data identified to members of SPLIT. Both of the high-performing centers were happy to participate, share their expertise and have their exceptional outcomes exemplified and celebrated.

## Step 2: Survey of Best Practices

Since hepatic artery thrombosis and biliary complications are primarily surgical issues, we surveyed surgeons within SPLIT regarding their own practices. The hepatic artery thrombosis survey (10 questions) involved questions of use of anticoagulants, thoughts on specific technical considerations that minimize hepatic artery thrombosis, questions regarding donor selection and questions regarding the surgical team. The biliary complications survey (8 questions) involve questions regarding use of duct to duct anastomoses, use of biliary stents, selection of suture type and technique, and management of biliary complications. The purpose of the survey was not to establish best practices, but was to establish current practices and lead discussion at the QI session at the annual SPLIT meeting. It was clear after 90 min of discussion that there was broad variation in current practices. Specific best practices will be highlighted in the following sections. The specifics of the responses to the questions are not detailed herein because of the remarkable variation in responses, making interpretation difficult. Moreover, it was clear that the complexity of the technical approaches was best suited to discussion and not a survey of practices.

## Step 3a: Best Practice Report: Hepatic Artery Thrombosis

Using the survey as a framework, we then asked a surgeon from the highest performing center (lowest hepatic artery thrombosis rate) to give a talk on best practices, specifically focusing on the surgical technique. The program presented the following as key components of their best practices:

1. High-volume pediatric and adult liver transplant program with high-volume surgeons and a high-volume living donor liver transplant program.
2. No intraoperative anticoagulation.
3. No touch technique and avoid traction injury to the artery.
4. Hand-held Doppler verification of flow in both postanastomotic and intrahepatic locations.
5. Split transplants:
   a. Child gets the entire artery.
   b. Usually anastomosed to a branch patch of the recipient hepatic artery and gastroduodenal artery.
   c. Leave the artery just the right length or very long.
   d. 7–0 Prolene sutures with parachuting the back wall and interrupting the front wall.

e. Infrarenal conduit (10% of cases) if concerns about size or inflow.

6. Living donor transplant:
   a. Careful preoperative planning with ultrasound and CT scans.
   b. Management of the graft outflow is critical. Use the ostia of the left and middle hepatic veins and open diagonally onto the inferior vena cava.
   c. Use microsurgical techniques for the arterial anastomosis. This center collaborates with pediatric plastic surgeons for the arterial anastomoses.

   d. Dissect the artery as far back as possible and help the micro-surgeon set up the anastomosis.
   e. One or two arteries with end-to-end anastomoses using 8–0 interrupted nylon sutures.
   f. Assure that there is no kink in the artery when the retractor is released.
7. Liberally leave the abdomen open whenever concerns that the fascial closure is too tight.
8. IV dipyridamole 30 mg and heparin 500 U in 50 mL D5 (<20 kg @ 5 mL/h, >20 kg @ 10 mL/h) with transition to aspirin when patient taking full PO diet with 1 day of overlap of these therapies.
9. While in the intensive care unit keep the central venous pressure around 10 and keep the patient normotensive.
10. Careful consideration regarding over transfusion—no transfusions are given without specific permission of the attending surgeon.
11. Ultrasound with Doppler assessment of the arterial flow is completed on postoperative day 1 and thereafter if the liver function tests rise.

## Step 3b: Best Practice Report: Biliary Complications

Using the survey as a framework, we then asked a surgeon from the highest performing center (lowest biliary complication rate) to give a talk on best practices, specifically focusing on the surgical technique. The program presented the following as key components of their best practices:

1. Many biliary complications began at the donor operation: the senior attending surgeon does the donor operation when splitting of the liver is planned.
2. A segment II/III graft (deceased donor) gets the entire celiac trunk, the main and left portal vein and the left bile duct.
3. Liver flush with histidine-tryptophan-ketoglutarate (HTK) solution.
4. All efforts are made to minimize both cold and warm ischemia times.
5. Interrupted suture technique on the arterial anastomosis—many biliary complications start with inadequate arterial reconstruction.
6. Completion of the biliary-enteric anastomosis with interrupted absorbable suture and over a stent.
7. No utilization of T-tubes.
8. Duct to duct biliary anastomosis using interrupted prolene sutures with the knots tied on the outside.

## Step 4: Plan to Disseminate Best Practices

A critical component of broad-based QI efforts involves dissemination of best practices. Clearly as clinician considered changes to their practice, it is critical that the purported "best practices" come from a credible source. Fortunately, SPLIT had established itself as such, with a track record of efforts that have improved the care of pediatric liver transplant patients. Based on the feedback from our SPLIT annual meeting, attendees thought the SPLIT QI symposium was valuable. Additional efforts will be needed to disseminate these best practices. Our plan involves the following:

1. Submission of the proceedings of the SPLIT QI symposium to the American Transplant Congress for presentation.
2. Publication of the proceedings of the SPLIT QI symposium in a journal widely read by clinicians specializing in transplantation.
3. Dissemination of the proceedings and best practices to all active members of SPLIT.
4. Specifically requesting that nonsurgeon clinicians share these proceedings with their surgical colleagues.

## Step 5: Assessing the Effectiveness of the QI Program

Data collection within SPLIT continues. We plan to continue to follow rates of hepatic artery thrombosis and biliary complications within the collaborative group. We hope to note a decrease in complication rates over the next several years. We will continue to reinforce these best practices at meetings and conference calls. We plan a repeat survey of current practices in approximately 1 year to assess potential changes in practice.

## Step 6: Future Targets for QI by SPLIT

Our group selected hepatic artery thrombosis and biliary complications as our first targets for quality improvement for several critical reasons. First of all, these are essentially surgical complications and as a result identification of cause-effect relationships is somewhat clearer. Second, these practices seemed like good potential targets for enacting change. Thirdly, we noted broad variation in both practices and outcomes, suggesting significant opportunities for improvement. Finally, there was a clear appreciation for the significant morbidity and potential mortality related to both hepatic artery thrombosis and biliary complications.

As we move forward, our next QI targets will likely fulfill similar characteristics. Current considerations include duration of intubation following liver transplantation, length of stay following transplantation in the hospital and in the intensive care unit, incidence of severe postoperative surgical infections and incidence of late biliary complications. Thereafter, we plan to target more complex outcome such as nutrition status both pre-and posttransplant, rejection and immunosuppression management, long-term

incidence of opportunistic infections, as well as functional measures such as quality of life, frailty, functional status and school performance.

Importantly, maintaining a robust database and program like SPLIT has been a struggle, initially extramurally funded but now funded by participating institutions. Pediatric liver transplant programs clearly appreciate the utility of participation, but new approaches to fund such efforts are needed to assure that high quality and clinically relevant data are available to drive future important QI efforts. In addition, more efforts to leverage existing data within transplantation are needed.

## Using this Work as a Roadmap Forward within Transplantation

Using the approach discussed herein, a broad based, multiinstitutional national quality improvement program within transplantation seems attractive within the United States or Canada. Certainly there are opportunities for improvement, considering the broad variation in outcomes across transplant centers within North America (1,25). The next step is to focus on a high volume procedure (i.e. adult liver transplantation) and a low volume procedure (i.e. multivisceral abdominal transplantation). Current data exists on center-specific outcomes. Though the data are imperfect and fails to fully appreciate capture case complexity, clinical experts can use it to identify high-performing centers. These centers can present their processes (both medical and surgical); experts can complete site visits to high-performing centers. The focus on celebrating high-performing centers and not using these data for center-specific or regional centers is absolutely critical. Moreover, collegiality must be maintained for a successful QI collaborative. This may sound naive within the competitive nature of transplantation, but transplantation is no more competitive the surgical marketplace in regions and States, where effective physician driven QI collaboratives have improved care of patients (3,5,7,8,26,27). National societies such as the American Society of Transplantation and the American Society of Transplant Surgeons are well suited to lead these QI efforts, providing infrastructure, expertise and most importantly mechanisms for dissemination of results. Clear best practices and improvement goals must be established, and outcomes must be measured to determine success or failure of best practice initiatives. If initial efforts are efficacious, the next step is expansion and partnership with payers. The previous work has clearly identified a valid financial case for effective quality improvement (7,28–30).

## Conclusion

SPLIT continues to provide a springboard for enhanced quality initiatives for pediatric liver transplantation. While data-driven observational quality improvement initiatives can never replace the scientific rigor of the randomized controlled trial, they offer a practice-based, real-world demonstration of how data can be leveraged to enhance care and disseminate best practices. Similar approaches, leveraging expertise across North American and using currently available data (such as OPTN data) offer significant promise to improve care, in both low volume (multivisceral transplantation) and high volume (deceased donor adult liver transplantation), highly complex fields. Driven by clinician experts, analysis of the best practices within the best-performing centers has the potential to not only improve but also accelerate how quality improvement initiatives can benefit transplant patients on a broad scale.

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## Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

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