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### Title

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### Permalink

<https://escholarship.org/uc/item/5sg5k0w4>

### Journal

Clinical and translational gastroenterology, 12(5)

### ISSN

2155-384X

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### Publication Date

2021-05-01

### DOI

10.14309/ctg.0000000000000355

Peer reviewed

# Accuracy and Safety of 1,055 Transjugular Liver Biopsies in Postliver Transplant Patients

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**INTRODUCTION:** The purpose of this study was to investigate the rates of complications and diagnostic yield of transjugular liver biopsy (TJLB) in deceased donor liver transplant (DDLT) recipients.

**METHODS:** From January 2009 to December 2019, 1,055 TJLBs were performed in 603 adult DDLT recipients with a mean age of 54 ( $\pm 12$  years). Data were retrospectively reviewed to determine the diagnostic efficacy and incidence of major and minor complications in the 3-day and 1-month period after TJLB. In addition, data were stratified according to platelet count and international normalized ratio to determine the safety of TJLB in patients with varying degrees of coagulopathy.

**RESULTS:** TJLB yielded diagnostic rate of 98.1% (1,035/1,055), with an overall complication rate of 8.3% (88/1,055). Major complications accounted for 0.85% (9/1,055), and minor complications occurred in 7.48% (79/1,055). When patients were stratified by platelet count (0–50, 51–100, 101–200, 201–300, and  $>300 \times 10^3$  platelets/ $\mu\text{L}$ ), no significant difference was noted in complication rates (9.5%, 8.6%, 7.6%, 8.5%, and 10.7%, respectively). When grouped by international normalized ratio (0–1, 1.1–2.0, 2.1–3.0, and  $>3.0$ ), there was no statistical difference in complication rates (8.3%, 8.5%, 7.7%, and 0%, respectively).

**DISCUSSION:** TJLB is a safe, adequate, and effective method to investigate hepatic disorders in DDLT recipients with severe coagulopathy.

*Clinical and Translational Gastroenterology* 2021;12:e00355. <https://doi.org/10.14309/ctg.0000000000000355>

## INTRODUCTION

Tissue sampling of the liver allograft after liver transplantation (LT) often is required to evaluate graft dysfunction and guide management. Histopathologic examination of liver tissue can help assess for rejection, recurrent disease, steatosis, vascular compromise, or ischemia-reperfusion injury and can inform immunosuppression medication dosing and other therapeutic interventions (1). Tissue for histopathology can be obtained through a percutaneous transabdominal or transjugular route. The bleeding risk associated with the percutaneous transabdominal approach often precludes this method of biopsy in deceased donor liver transplant (DDLT) patients. Transjugular liver biopsy (TJLB), thus, presents a safe alternative with reported success rates reaching 87%–98% (2–7).

First developed in 1964 as an alternative to percutaneous liver biopsy, TJLB is now considered the standard of care for hepatic tissue sampling (1). It can be performed safely even in high-risk

patients such as those with ascites, coagulopathy, or cirrhosis (1–3,5,7–9). The intravascular route of TJLB greatly reduces the rate of hemorrhage (10,11). If bleeding does occur, it is more likely to cause intravascular rather than intracapsular or extracapsular hemorrhage, which presents significantly less risk to the patient's hemodynamic status (8,9). The reduced risk of hemodynamic compromise also makes TJLB the preferred method for obtaining tissue in patients whose clinical status is tenuous (2,3). Despite the clinical benefit of TJLB, major complications such as hemorrhage and even death have been reported (2,4,6,11).

The objective of this study was to determine the diagnostic yield and overall complication rates of TJLB in post-DDLT patients. We also performed subgroup analyses of complications based on coagulation status as determined by pre-procedure international normalized ratio (INR) and platelet counts.

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**Received November 10, 2020; accepted April 5, 2021; published online May 21, 2021**

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## MATERIALS AND METHODS

### Patient selection and demographic information

This retrospective study was approved by the Institutional Review Board (IRB#10-000469). Data were collected from 2 academic hospitals associated with a nationally accredited liver transplant program. Electronic access to medical records for 603 adult patients was obtained, and demographic, medical, laboratory, and procedural information on a total of 1,055 transjugular liver biopsies performed in DDLT recipients between January 2009 and December 2019 were collected. All biopsies were performed with a 19-gauge TJLB kit (Argon Medical, Athens, TX, or Cook Medical, Bloomington, IN).

### Laboratory assessment

We obtained preprocedure values for INR, prothrombin time, activated partial thromboplastin time, platelet counts, total serum bilirubin, and serum creatinine levels. The INR subgroups were INR of 0–1, 1.1–2.0, 2.1–3.0, and 3.1 or higher. Patients were also divided by platelet count into 5 groups: 0–50, 51–100, 101–200, 201–300, and  $300 \times 10^3$  platelets/ $\mu\text{L}$  (plt/ $\mu\text{L}$ ) or higher. Fibrinogen levels are not routinely measured at our institution and were not included in the analysis. Technical success and complication rates were measured and analyzed separately for each subgroup.

### Diagnostic yield

Pathology reports were accessed and analyzed to determine the technical success and diagnostic yield of each procedure. A biopsy was deemed successful based on the ability to obtain a histopathologic diagnosis from the sample obtained. Independent analysis of the tissue samples was performed by multiple board-certified liver specialist pathologists at our institution. Core samples containing at least 11 central portal triads were considered to be successful biopsies.

### Complications

Complications were evaluated and categorized by timeframe and severity. Complications were grouped as occurring within the first 3 days or between days 4–30 post-TJLB and graded as major or minor based on the Society of Interventional Radiology guidelines (12). Major complications required major therapy, escalation of care, or prolonged hospitalization or resulted in permanent adverse sequelae or death. Major complications included intraperitoneal bleeding, cardiac arrhythmia, hepatic artery thrombosis, and inadvertent biopsy of an adjacent organ. Minor complications required minimal therapy without overnight hospitalization or lasting sequelae and included fever, abdominal pain, and hypotension.

### Statistical analysis

Continuous variables were reported as means  $\pm$  SD, whereas categorical data were expressed as numbers and percentages. The Student *t* test was used to compare continuous variables, and the Pearson  $\chi^2$  test or Fisher exact test was used to compare categorical variables between the 2 groups. *P* values  $<0.05$  were considered statistically significant. All statistical analyses were performed using SPSS software version 22.0 (SPSS, Chicago, IL).

## RESULTS

### Patient demographics

A total of 1,055 biopsies were performed in 603 adult patients who had previously undergone LT, with a mean age of 53.5 ( $\pm 12.0$ , range 18–87) years (Table 1). The primary indication for biopsy was to rule out rejection in 87.6%. Primary liver diagnoses before LT included hepatitis C infection ( $n = 301$ ), alcoholic liver disease ( $n = 128$ ), nonalcoholic steatohepatitis ( $n = 56$ ), cryptogenic cirrhosis ( $n = 42$ ), hepatitis B infection ( $n = 37$ ), primary sclerosing cholangitis ( $n = 33$ ), autoimmune hepatitis ( $n = 26$ ), fulminant hepatic failure ( $n = 25$ ), and primary biliary cirrhosis ( $n = 19$ ). Other diagnoses included Wilson disease, total parenteral nutrition–induced liver injury, abetalipoproteinemia, amyloidosis, Alagille syndrome, Budd-Chiari disease, and  $\alpha$ -1 antitrypsin disease.

### Laboratory assessment

Preprocedure laboratory values of all patients are displayed in Table 1. Notable mean laboratory values included platelet count  $144.1 (\pm 78) \times 10^3$  plt/ $\mu\text{L}$ , INR 1.27 ( $\pm 0.3$ ), total serum bilirubin 4.9 ( $\pm 6.9$ ) mg/dL, and serum creatinine 1.48 ( $\pm 1.2$ ) mg/dL.

### Diagnostic and technical outcomes

An average of 3.53 ( $\pm 0.85$ , range 3–6) scores with an average of 15.89 ( $\pm 4.34$ , range 8–30) complete portal tract were obtained. The diagnostic success rate (defined as diagnosis of liver disorder) of TJLB was 98.1% (1,035/1,055). The common diagnoses were recurrent hepatitis (33.0%), rejection (28.7%), no rejection (10.3%), ischemia/ischemic cholangiopathy (7.6%), immune-mediated liver injury (5.2%), cholestasis (5.2%), and others (8.1%) including biliary obstruction, cytomegalovirus hepatitis, drug-induced liver injury, steatosis, cholangitis, nodular regenerative hyperplasia, and recurrent primary sclerosing cholangitis and post-transplant lymphoproliferative disease. The technical success rate (defined as obtaining a core tissue sample) was 100% (1,055/1,055). In 95.2% (1,004/1,055) of the procedures, ultrasound-guided access of the right internal jugular vein was used. The hepatic venous access was obtained through the right hepatic vein in 94.0% (992) and through the middle hepatic vein in 6.0% (63) of cases. In 58.6% (618/1,055) of the biopsy was with hemodynamic evaluation including systemic, free hepatic, and wedge hepatic pressure measurements.

### Complications

The overall complication rate for LT patients undergoing TJLB was 8.3% (88/1,055) (Table 2). Most complications occurred within 3 days postprocedure (93%, 82/88), whereas the minority occurred between days 4 and 30 (7%, 6/88). Of 88 overall complications, 86 complications (86/991, 8.7%) occurred in inpatient biopsies, which was not statistically significant compared with those in outpatient biopsies (2/64, 3.1%,  $P = 0.1169$ ). Of the 1,055 biopsies, 618 TJLBs were performed with pressure measurements, and it was associated with 48 complications (7.8%), which was not statistically significant compared with 40 complications from TJLB without pressure measurement (9.1%,  $P = 0.3854$ ).

Major complications occurred in 0.85% (9/1,055) patients and included intraperitoneal bleeding requiring an additional embolization procedure, intraabdominal infection, inadvertent renal biopsy, hepatic artery thrombosis requiring a 6-month anticoagulation, a retained guidewire with an additional procedure to attempt to remove the wire without success, and massive hemorrhage from the jugular access site requiring intensive care unit

**Table 1. Patient characteristics**

		Overall
No. of biopsies		1,055
Inpatient vs outpatient		991 (93.9%):64 (6.1%)
Age		53.5 ± 12.0 (range 18–87)
Sex		M 360:F 243
International normalized ratio		1.27 ± 0.3
Prothrombin time		12.9 ± 5.9
Activated partial thromboplastin time		31.9 ± 10.4
Platelet count (plt/ $\mu$ L)		144.1 ± 78.7
Total bilirubin (mg/dL)		4.9 ± 6.9
Serum Cr		1.48 ± 1.20
Model for end-stage liver disease		14.1 ± 8.7
		N
Primary liver diagnosis before liver transplant	Hepatitis C	301
	Alcoholic liver disease	128
	Nonalcoholic steatohepatitis	56
	Cryptogenic cirrhosis	42
	Hepatitis B	37
	Primary sclerosing cholangitis	33
	Autoimmune hepatitis	26
	Fulminant hepatic failure	25
	Primary biliary cirrhosis	19

transfer and multiple transfusion. No TJLB-related death was noted. Minor complications occurred in 7.5% (79/1,055) patients, with the most common being abdominal pain ( $n = 44$ ); other minor complications included fever, minor bleeding such as neck oozing or hematoma, and hypotension. Of the complications that occurred within the first 3 days, major complications accounted for 0.66% (7/1,055) and minor for 7.1% (75/1,055). Of the complications that occurred between days 4 and 30, major complications accounted for 0.19% (2/1,055) and minor for 0.38% (4/1,055).

Bleeding complications occurred in 11 patients, corresponding to an overall bleeding rate of 1.0% (11/1,055). Four patients had intraabdominal bleeding, a major complication, whereas the remaining 7 patients had neck site bleeding (4) and hematemesis/melena (3), which were minor complications.

#### Complications in coagulopathic patients

**Low platelet count.** The summary of complications in patients with low platelet count is demonstrated in Table 3. LT recipients had a complication rate of 9.47% (9/95) for platelet counts from 0 to  $50 \times 10^3$  plt/ $\mu$ L within the first 3 days postprocedure; 8.21%

(22/268) patients with platelets between 51 and  $100 \times 10^3$  plt/ $\mu$ L had complications within the first 3 days, and 0.37% (1/268) had a complication between days 4 and 30. Patients with a platelet count of  $101\text{--}200 \times 10^3$  plt/ $\mu$ L had a complication rate of 6.75% (31/459) on days 1–3 and 0.87% (4/459) on days 4–30. All

**Table 3. Complications in patients with low platelet counts**

Complication rate by platelet count				
	Complication rate at 3 d		Complication rate at 1 mo	
Platelet count 0–50	9/95	9.47%	0/95	0.00%
Platelet count 51–100	22/268	8.21%	1/268	0.37%
Platelet count 101–200	31/459	6.75%	4/459	0.87%
Platelet count 201–300	15/177	8.47%	0/177	0.00%
Platelet count 300+	5/56	8.93%	1/56	1.78%
	$P > 0.05$		$P > 0.05$	
Complication rate by low platelet count and blood product transfusion				
Total = 363	Transfused (n = 51)		Not transfused (n = 312)	
Platelet count 51–100	3/33	9.10%	6/62	9.68%
	$P = 0.925$			
Platelet count 101–200	2/18	11.11%	21/250	8.40%
	$P = 0.693$			

**Table 2. Overall complications**

Overall complication rate	88/1,055 (8.3%)	
	3 d	30 d
Major complications	7/1,055 (0.66%)	2/1,055 (0.19%)
Minor complications	75/1,055 (7.10%)	4/1,055 (0.38%)

complications for patients with platelet counts of  $201\text{--}300 \times 10^3$   $\text{plt}/\mu\text{L}$  occurred within the first 3 days, at a rate of 8.47% (15/177). Patients with platelet counts of  $301 \times 10^3$   $\text{plt}/\mu\text{L}$  and above experienced complications at a rate of 8.93% (5/56) on days 1–3 and 1.78% (1/56) on days 4–30. These complication rates were not statistically different among the groups (all  $P > 0.05$ ).

A subset of patients with a platelet count of  $100 \times 10^3$   $\text{plt}/\mu\text{L}$  or less received blood products (an average of 1.13 units of platelet given to 51 patients) on the day before, day of, or day after the procedure at a rate of 14.0% (51/363) when deemed clinically necessary by the treatment team. The complication rate for the patients with platelet counts of  $0\text{--}50 \times 10^3$   $\text{plt}/\mu\text{L}$  with transfusion was 9.10% (3/33, 2 patients with neck site oozing and one patient with abdominal pain). In comparison, the complication rate among patients who did not receive periprocedural blood products was 9.68% (6/62). This was not statistically significantly different ( $P = 0.925$ ). For patients with platelet counts of  $51\text{--}100 \times 10^3$   $\text{plt}/\mu\text{L}$ , the complication rate was 11.1% (2/18, 1 patient with neck site oozing and 1 patient with melena) in patients with transfusion, compared with a rate of 8.4% (21/250) among patients who did not receive periprocedural blood products. These values were not significantly different from one another ( $P = 0.693$ ).

**Elevated INR.** The summary of complications in patients with elevated INR is demonstrated in Table 4. Those with an INR of 0–1 had a complication rate of 7.83% (18/230) within the first 3 days and 0.43% (1/230) after the first 3 days. For INR of 1.1–2, 7.80% (60/769) of patients experienced complications on days 1–3 and 0.65% (5/769) on days 4–30. Patients with an INR of 2.1–3.0 had a complication rate of 7.69% (4/52), all within the first 3 days. There were 4 patients in the study with an INR of 3.1 or higher but no one in this group experienced any complication.

Patients with an INR greater than 1.5 ( $n = 210$ ), 25.2% (53/210) received periprocedural blood products, averaging 0.35 units of FFP ( $n = 42$ ), 0.15 units of cryoprecipitate ( $n = 21$ ), and 0.24 units of platelets ( $n = 28$ ) per subject. The complication rate for the patients with transfusion was 9.43% (5/53). In comparison, the complication rate among patients without transfusion was

8.92% (14/157). This was not statistically significantly different ( $P = 0.911$ ).

#### Complications related to anticoagulant therapy

Practice guidelines at our institution dictate that anticoagulant therapy be held before TJLB procedure. Outpatients in the cohort were instructed, and inpatients were asked to stop their anticoagulation therapy according to the applicable manufacturer guidelines. Patients ( $n = 42$ ) with cardiovascular disease, such as those with recent coronary artery stents or left ventricular assist devices placement, were exceptions to this general rule. Overall, these patients on anticoagulant therapy did not have a significantly different rate of complication (3/42) compared with the remaining study cohort ( $P = 0.782$ ).

#### DISCUSSION

LT recipients often require histopathologic tissue analysis during the diagnosis and treatment of their disease. TJLB can be used safely and effectively even in critically ill and LT patients. For these patients, percutaneous biopsy may present an unacceptable risk, and TJLB is a viable and safe alternative. Overall complication rates as high as 20% have been reported with percutaneous liver biopsies (2–4,10,13). However, TJLB provides a means of maximizing the rate of technical success, whereas minimizing the risk of major complications such as intraperitoneal bleeding or death. TJLB can be indicated for a number of reasons, including severe coagulopathy, high-volume ascites, abdominal obesity, postliver transplant evaluation, or fulminant hepatic failure (2,7,10).

The purpose of our 11-year retrospective study was to determine the safety profile of TJLB in DDLT recipients with critical clinical comorbidities/conditions. This study, which is the largest of its kind to date, to our knowledge, provides a detailed description of the complications associated with TJLB and the timing of complications, which have not previously been reported in the literature. Overall, we found an overall complication rate of 8.3%. This rate is higher than the rates reported in the current literature, which range from 0 to 2.8% (0% in 124 TJLBs (14), 0% in 43 TJLBs (15), 0.5% in 183 TJLBs (16), 1.8% in 111 TJLBs (17), and 2.8% in 138 TJLBs (18)). However, many of these previous studies have reported only the major complications or did not classify their complications into major or minor complications. Our study used a broader definition of both major and minor complications. For example, our study defined a minor complication as any type of reported neck or abdominal pain with or without medication use, whereas other studies only included those patients with neck or abdominal pain requiring medication. In addition, our study investigated the highest number of patient cohorts than other studies, which may demonstrate true complication rate in these post-LT patients.

One of the major complications of TJLB is intraperitoneal hemorrhage after liver capsule perforation during tissue sampling. In our study, 4 patients (0.38%) experienced nonfatal intraperitoneal hemorrhage. Additional major complications found in our study included peritonitis and retained guidewire in 1 patient each. The overall major complication rate in our analysis was 0.85%, which is comparable with the previously reported complication rates of 0%–2.8% (14–18).

Complication rates of the post-LT patients with coagulopathy at the time of TJLB were also investigated as a distinct subgroup. This has not yet been reported in the literature, and it has a

**Table 4. Complications in patients with high international normalized ratio (INR)**

Complication rate by INR				
	Complication rate at 3 d		Complication rate at 1 mo	
INR 0–1	18/230	7.83%	1/230	0.43%
INR 1.1–2.0	60/769	7.80%	5/769	0.65%
INR 2.1–3.0	4/52	7.69%	0/52	0.00%
INR 3.0	0/4	0.00%	0/4	0.00%
	$P > 0.05$		$P > 0.05$	
Complication rate by high INR and blood product transfusion				
Total = 210	Transfused (n = 53)		Not transfused (n = 157)	
INR > 1.5	5/53	9.43%	14/157	8.92%
	$P = 0.911$			



significant impact on our daily practice of treating LT recipients. In our study, patients were stratified by both platelet count and INR. An additional analysis was performed on patients who received periprocedural blood products (within 1 day of the procedure). When taken as a whole, these subgroup analyses, which account for different platelet counts and INRs and for periprocedural blood product administration, demonstrate that none of these measures significantly impacts the complication rate of TJLB. Specifically, the administration of periprocedural blood products (fresh frozen plasma, platelets, or cryoprecipitate) had no statistically significant impact on the rates of complication. This is an important finding because the current clinical guidelines may suggest use of transfusion in these patients who may not require any transfusion.

The low complication rates among the patients in our study provide evidence of the safety of TJLB, even in those patients with extremely high or low platelet counts or those with supra-therapeutic INRs. Although low platelet counts are the primary concern when considering a patient's suitability for TJLB, we found that those with the highest platelet counts actually had the highest complication rate. However, this difference was not statistically significant. In addition, among those patients with supra-therapeutic INR, those with INRs greater than 2.0 did not have a higher complication rate compared with those with INR of 0–1.0 and 1.1–2.0. In a subgroup analysis, LT-patients with anticoagulant therapies did not have higher complication rates of TJLB than the rest of the cohort. These findings strongly suggested that TJLB is extremely safe in liver transplant recipients who often have coagulopathy due to underlying liver disease, post-LT condition, or use of anticoagulant during post-LT recovery.

The overall bleeding-related complication rate in our study was 1.0%, including both major (intra-abdominal hemorrhage) and minor bleeding complications (neck oozing and hematemesis). The rate of bleeding-related complications did not increase significantly among coagulopathic patients. As such, TJLB has a low-enough bleeding risk that it is acceptable for patients with severe coagulopathy in LT patients.

This retrospective study relied solely on electronic medical records. Therefore, there is the expected risk of misclassification bias during data collection. However, this risk was somewhat reduced because of homogeneity of the data collection process owing to the primary use of 2 reviewers. The study was also performed on data gathered based on the practice of a single faculty group. As such, clinical practice was uniform in the study population. For example, certain laboratory values, including fibrinogen levels, thromboelastography, and rotational thromboelastometry, were not routinely measured preprocedurally. These values, which are reliable markers of bleeding risk, are not available for most of the study population, and consideration should be given to gathering this information in the future. In addition, given the low event rate of bleeding-related complications among the patient population, the overall risk of bleeding complications associated with the TJLB procedure may be falsely decreased. A larger cohort should be studied to further explore this possibility. Moreover, because these patients often underwent surgical interventions or other procedures soon after their TJLB, it is impossible to attribute some complications to a specific procedure or determine whether it was sequelae of active disease. Future directions may include stratifying the patient population by severity of care. In this study, no distinction was

made between patients being cared for in an intensive care unit vs regular ward, which could have a significant bearing on the impact of potential complications and the recording of said complications.

In conclusion, TJLB can be safely performed in a wide range of LT recipients with excellent results. This includes patients with extremely low platelet counts and a wide range of INR values. For TJLB, success rates are high, overall complication rates are low, and the risk of major complication is extremely favorable, making this an ideal diagnostic study for LT recipients with even the most critically ill conditions.

#### CONFLICTS OF INTEREST

**Guarantor of the article:** Edward Wolfgang Lee, MD, PhD, FSIR.

**Specific author contributions:** M.J.S., S.S., P.D., E.W.L., D.F., and R.W.B.: conception and design of study. M.J.S., P.D., S.S., and E.W.L.: collecting and interpreting data. M.J.S., S.S., J.P.M., F.K., and E.W.L.: drafting the manuscript. M.J.S., S.S., J.D., P.D., J.P.M., F.K., V.A., S.A.P., D.F., R.W.B., and E.W.L.: critical revision and editing, and final approval of the accepted article.

**Financial support:** None to report.

**Potential competing interests:** None to report.

## Study Highlights

#### WHAT IS KNOWN

- ✓ Tissue sampling of the liver allograft after liver transplantation (LT) is essential.
- ✓ Both percutaneous and transjugular/transcatheter biopsy methods are available.
- ✓ Transjugular/transcatheter method may be safer in patients with post-LT coagulopathy.
- ✓ Biopsy in patients on anticoagulation therapy may not be safe.

#### WHAT IS NEW HERE

- ✓ Transjugular/transcatheter liver biopsy can be safely performed in a wide range of LT recipients with excellent results.
- ✓ Transjugular/transcatheter liver biopsy in patients with extremely low platelet counts and a wide range of international normalized ratio values can be safely performed.
- ✓ Transjugular/transcatheter liver biopsy can be safely performed in patients on anticoagulation therapy.

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