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# Outcomes in Cirrhotic Patients Receiving Transjugular Intrahepatic Portosystemic Shunt (TIPS) Versus Repeat Paracentesis for Recurrent Ascites

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## Abstract

**Purpose:** Many cirrhotic patients who cannot undergo liver transplantation are symptomatically treated for recurrent ascites with paracenteses and/or transjugular intrahepatic portosystemic shunts (TIPS). This study aimed to determine if there were reduced time between paracenteses, reduced hospital admissions from bacterial peritonitis, variceal bleeds, and hepatic encephalopathy for cirrhotic patients who did receive TIPS compared to those who did not receive TIPS.

**Materials and Methods:** A retrospective analysis was performed on cirrhotic patients with refractory ascites between January 1, 2008 and December 31, 2016 at a single institution. Demographics, history, labs, paracenteses, TIPS, and hospitalization information were documented. Shared frailty and chi-square tests were used to determine time between paracenteses and hospitalization rates after the placement of TIPS.

**Results:** 344 patients with refractory ascites were included. Median age 57 years, male (62%) and white (85%). Cirrhotic etiology included alcohol (45%) and hepatitis C (37%). Ninety-two (27%) received TIPS. Patients averaged 26.2 days between paracentesis pre-TIPS and 51.5 days post-TIPS. The data suggest an association between TIPS and the risk of paracentesis for ascites (Chi-sqr=80.1 $p<0.01$). A sixty percent reduction in the risk of a paracentesis post-TIPS was observed in our particular sample (estimated Hazard Ratio=0.40 estimated 95% CI (0.33, 0.49)). Rates of hospitalizations for adverse events were not different between patients with and without TIPS: bacterial peritonitis ($p=0.13$ $X^2=2.25$ $df=1$), variceal bleeding ($p=0.23$ $X^2=1.46$ $df=1$), or hepatic encephalopathy ($p=0.46$ $X^2=0.53$ $df=1$).

**Conclusion:** TIPS placement increased the time between paracentesis without increasing hospital admission rates for bacterial peritonitis, variceal bleeding, or hepatic encephalopathy. This suggests that TIPS placement should be considered earlier in the cirrhotic disease process to improve symptomatic control which decreases the need for frequent paracentesis. Secondarily, associated hospital costs and risks of frequent paracenteses could be reduced.

**Keywords:** Cirrhotic; Transjugular Intrahepatic Portosystemic Shunt (TIPS); Paracentesis

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## Introduction

### Background

According to the 2017 Centers for Disease Control (CDC) national vital statistics, cirrhosis is the 10th leading cause of death in the United States with greater than 40,000 deaths per year [1]. Mortality due to chronic liver disease continues to be on the rise, especially in those patients with alcoholic cirrhosis [2,3]. In the United States, there was a 65% increase in cirrhosis deaths from 1999 to 2016 from approximately 20,000 to 34,000 [3]. Approximately. 3% (.27) of the population are affected by cirrhosis, with a greater incidence in non-Hispanic African Americans, Mexican Americans, and Native Americans seeing the highest rates [3,4]. Many patients may remain undiagnosed meaning the prevalence may be even higher in certain populations and communities [4,5,6].

Cirrhosis places a serious economic burden on patients [7,8]. The main financial burden of cirrhosis specifically was $7.37 billion based off the National Inpatient Sample (NIS) database [9]. Major etiologies include hepatitis B and C infections, alcohol abuse, and nonalcoholic steatohepatitis (NASH) [8]. The presence of cirrhosis and its comorbidities has further driven the increase in financial hardships [10]. Because of advances in pharmacotherapy and surgical intervention, the cost continues to rise [8]. The main drivers for increased cost are due to three procedural complications: mechanical ventilation, non-red blood cell transfusions, and hemodialysis [9]. Other complications associated with cirrhosis include acute kidney injury (AKI), infection, non-pulmonary hypertension, gastrointestinal (GI) bleed, ascites, hepatorenal syndrome, variceal bleeding, hepatocellular carcinoma, hepatic encephalopathy, hyponatremia, malnutrition, and spontaneous bacterial peritonitis [9]. Complications frequently include portal hypertension, which in turn may result in ascites, varices, and hepatic hydrothorax [9,11,12,13]. As longevity is increased with improving therapy, unfortunately so does the economic and financial burden [9,14].

Ascites associated with cirrhosis is the abnormal accumulation of transudative fluid in the peritoneal cavity due to portal hypertension. It is one of the main complications of cirrhosis which causes increased portal hypertension resulting in decreased hepatic perfusion [11,13]. Ascites is a poor prognostic indicator with a 15% mortality rate 1-year after first presentation and 44% mortality rate at 5-years after first presentation [15]. Ascites is considered refractory upon recurrence after paracentesis or when no longer tolerant or responsive to sodium restriction or diuretic therapy [11,16]. Treatment usually consists of routine paracentesis, pharmacotherapy, diet modulations, or TIPS [13,16].

TIPS is an image-guided endovascular procedure which bypasses blood flow from the portal venous system to the hepatic venous system, thus creating a new passage for venous blood flow. This interventional therapy is used to decrease portal venous and mesenteric venous pressure. These increased pressures may consequentially lead to bleeding varices, ascites, and other gastroenterological complications [17]. TIPS is used for control of ascites symptoms and has been shown to resolve ascites in 60-70% of patients, effectively reducing the need for serial paracentesis [11,17,18,19]. TIPS offers superior control compared to large volume paracentesis (LVP) in the management of refractory ascites and may also improve survival [20,21,22]. Mean hospital stays were also decreased in those with TIPS with an average of 17 days compared to those with LVP at 35 days [21].

The purpose of our study was to investigate whether TIPS placement reduced the time between paracenteses, reduced the number of hospitalizations due to hepatic encephalopathy (HE), spontaneous bacterial peritonitis, and gastroesophageal variceal bleeding in patients with refractory ascites due to end-stage liver disease.

## Materials and Methods

Institutional review board approval was obtained, and patient medical records were reviewed in compliance with Health Care Portability and Accountability Act guidelines. Patients were included in this single institution study if they met the following inclusion criteria: were 18 years of age or older; had an image-based diagnosis of cirrhosis; were diagnosed with refractory ascites from May 2008 through December 2016. For the purpose of our study, refractory ascites was defined as having three therapeutic paracenteses within 365 days and/or received a TIPS. Patients were excluded from the study if they met any of the following criteria: were under 18 years of age; had a Model for End-Stage Liver Disease (MELD) score > 18 prior to TIPS placement; had a TIPS placed for reason other than refractory ascites; or received a liver transplant. In total, 344 patients were included in the study with 92 (26.8%) of them receiving a TIPS.

Relevant demographic, clinical (cirrhosis etiology and admission diagnoses when hospitalized), laboratory, procedural, and follow-up information (complications, including post-procedural encephalopathy, spontaneous bacterial peritonitis (SBP), and hemorrhage) were obtained from patient medical records and imaging exams. All data were stored in REDCap data capture tools [23].

A gap time analysis was utilized to determine if there was a difference in mean days between paracenteses in those patients who did not receive TIPS versus those receiving TIPS. The shared frailty model of time (days) between paracenteses contains a dichotomous covariate for MELD (<18, >=18), TIPS placement as a time-varying covariate, an interaction term between TIPS and dichotomous MELD and a random effect for each subject that controls for the correlation

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among a subject's repeated measures. A significance level of 0.05 was used throughout the analysis of the primary aim. The analysis was completed with PROC PHREG in SAS software 9.4. Subjects were observed until transplant, death, or lost to follow-up. For most subjects, follow-up did not end with a paracentesis thus they were censored at the end. The null hypothesis was specified as H0: The risk of having a paracentesis is the same pre- and post-TIPS. Chi-squared tests were used to examine the association between TIPS and hospitalizations for hepatic encephalopathy, gastroesophageal variceal bleeding, spontaneous bacterial peritonitis.

## Results

In total, 344 patients with refractory ascites were included. Median age at time of refractory ascites was 57 years and most patients were male (62%) and white (85%) (Table 1). The main etiologies of cirrhosis were alcohol induced (45%) and hepatitis C-induced (37%) (Table 2). Of these 344 patients that were included in the study, 92 (26.8%) received TIPS procedure. Median time of follow up after ascites became refractory was 466 days for patients who received a TIPS and 140 days for those not receiving a TIPS (Table 3).

The interaction of TIPS and dichotomous MELD (<=18, >18) does not have a statistically significant effect in the frailty model (Chi-square=1.39, p-value=0.24). In other words, the interaction term does not have a statistically significant association with time between paracenteses and therefore can be removed from the model.

After excluding the interaction term but keeping a random effect for each subject and dichotomous MELD (<=18, >18) as a covariate, the data demonstrate TIPS and the time between paracenteses are associated (Chi-sqr=77.9 p<0.01). A 59% reduction in the risk of a paracentesis post-TIPS was observed in our sample (estimated Hazard Ratio=0.41 estimated 95% CI (0.33, 0.50). The covariate, dichotomous MELD, is not statistically significantly associated with the time between paracenteses (Chi-sqr=0.23, p=0.63). Typically, MELD would be removed from the model and a simplified model would be constructed. However, given the role of MELD scores in deciding whether to place TIPS, we felt it was important to account for MELD in the analysis.

A third model of time between paracentesis was constructed that stratified by MELD and included TIPS placement as a time-varying covariate and a random effect for each subject. The observed data demonstrates TIPS and the time between paracenteses are associated (Chi-sqr=80.1 p<0.01). A 60% reduction in the risk of a paracentesis post-TIPS was observed in our sample (estimated Hazard Ratio=0.40 estimated 95% CI (0.33, 0.49).

**Table 1:** Demographic Characteristics

| Table 1 | All | | No TIPS | | TIPS | |
|---|---|---|---|---|---|---|
| | N | Column % | N | Column % | N | Column % |
| N | 344 | 100 | 252 | 73.2 | 92 | 26.8 |
| **Gender** | | | | | | |
| Female | 130 | 37.8 | 89 | 35.3 | 41 | 44.6 |
| Male | 214 | 62.2 | 163 | 64.7 | 51 | 55.4 |
| **Ethnicity** | | | | | | |
| Non-Hispanic/Latino | 322 | 93.6 | 236 | 93.7 | 86 | 93.5 |
| Hispanic/Latino | 22 | 6.4 | 16 | 6.3 | 6 | 6.5 |
| **Race** | | | | | | |
| White | 293 | 85.2 | 212 | 84.1 | 81 | 88 |
| Black, Afr American | 19 | 5.5 | 15 | 6 | 4 | 4.3 |
| Other | 3 | 0.9 | 3 | 1.2 | 0 | 0 |
| Unknown | 29 | 8.4 | 22 | 8.7 | 7 | 7.6 |
| **Age at Refractory (3 paras < 365 or TIPS)** | | | | | | |
| N | 344 | | 252 | | 92 | |
| Minimum | 22 | | 23 | | 22 | |
| 25th %-tile | 50 | | 50 | | 50 | |
| Median | 57 | | 57 | | 58 | |
| Mean | 55.4 | | 55.5 | | 55.2 | |
| Std Dev | 10.7 | | 10.3 | | 11.8 | |
| 75th %-tile | 62 | | 62 | | 62 | |
| Maximum | 81 | | 81 | | 78 | |

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**Table 2:** Cirrhosis etiology

| Cirrhosis causes | All | | No TIPS | | TIPS | |
|---|---|---|---|---|---|---|
| | N | % of Sample | N | Col % | N | Col % |
| N | 344 | 100 | 252 | 73.2 | 92 | 26.8 |
| Alcohol Induced | 154 | 44.8 | 115 | 45.6 | 39 | 41.1 |
| Alpha1 Antitrypsin Deficiency | 6 | 1.7 | 5 | 2 | 1 | 1.1 |
| Autoimmune Hepatitis | 12 | 3.5 | 8 | 3.2 | 4 | 4.2 |
| Cirrhosis, No Mention of Alcohol | 2 | 0.6 | 2 | 0.8 | 0 | 0 |
| HCC | 13 | 3.8 | 9 | 3.6 | 4 | 4.2 |
| Hemochromatosis | 3 | 0.9 | 3 | 1.2 | 0 | 0 |
| Hepatitis B | 3 | 0.9 | 3 | 1.2 | 0 | 0 |
| Hepatitis C | 126 | 36.6 | 96 | 38.1 | 30 | 31.6 |
| NAFLD or NASH | 61 | 17.7 | 39 | 15.5 | 22 | 23.2 |
| Primary Biliary Cirrhosis | 7 | 2 | 6 | 2.4 | 1 | 1.1 |
| Primary Sclerosing Cholangitis | 8 | 2.3 | 6 | 2.4 | 2 | 2.1 |
| Wilson's Disease | 0 | 0 | 0 | 0 | 0 | 0 |
| Other Cause | 1* | 0.3 | 1 | 0.4 | 0 | 0 |
| Unknown | 22 | 6.4 | 13 | 5.2 | 9 | 9.5 |

**Table 3:** Follow-Up Time (days)

| Follow-Up Time (days) | All | No TIPS | TIPS |
|---|---|---|---|
| All (N) | 344 | 252 | 92 |
| Minimum | 1 | 1 | 30 |
| Median | 193 | 140 | 466 |
| Mean | 413.6 | 319.1 | 672.4 |
| Std Dev | 535.7 | 445.7 | 664.5 |
| Maximum | 3,248 | 2,639 | 3,248 |

**Table 4:** Time Between Paracenteses

| Time between paracentesis | Pre-TIPS | | All Pre-TIPS | Post-TIPS |
|---|---|---|---|---|
| | N=263 | | N=263 | |
| | Never have TIPS | Eventually have TIPS | | TIPS |
| | n=186 | N=77 | | N=66 |
| People with post-refractory paracentesis (N) | 186 | 77 | 263 | 66 |
| Paracenteses (N) | 1,180 | 266 | 1,446 | 222 |
| **Days between paracentesis** | | | | |
| Median (IQR) | 9 (7,20) | 10 (7,15) | 9 (7,19) | 16 (7,41) |
| Mean (sd) | 27.4 (74.4) | 20.9 (48.2) | 26.2 (70.3) | 51.5 (119.4) |

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**Table 5:** Hospitalization Information

| Outcomes | | No TIPS | TIPS | All | P-value*, test statistic |
|---|---|---|---|---|---|
| Hospitalized for bacterial peritonitis | N (%) | 57 (22.6%) | 14 (15.2%) | 72 (20.6%) | 0.13 $X^2$=2.25 |
| Hospitalized for Variceal Bleeding | N | 48 (19%) | 23 (25%) | 71 (20.6%) | 0.23 |
| | Column % | 19 | 25 | 20.6 | $X^2$=1.46 |
| Hospitalized for encephalopathy, PSE | N | 123 (48.8%) | 49 (53.3%) | 172 (50%) | 0.46 $X^2$=0.53 |

*Chi-squared test, df=1

The gap analysis showed patients averaged 26.2 days between paracentesis before TIPS. Those who went on to have TIPS averaged 51.5 days between paracentesis post-TIPS (Table 4). There was no difference in hospitalizations relating to bacterial peritonitis (p=0.13 X2=2.25 df=1), variceal bleeding (p=0.23 X2=1.46 df=1), and hepatic encephalopathy (p=0.46 X2=0.53 df=1) between patients who received a TIPS and those who did not (See Table 5).

## Discussion

This study found a 60% reduction in the risk of a paracentesis after patients received TIPS and is consistent with other findings in the literature. There was no statistically significant difference between TIPS and non-TIPS patients regarding hospital admissions from hepatic encephalopathy, variceal bleeding, and spontaneous bacterial peritonitis (See Table 5). This suggests that TIPS placement should be considered earlier in the cirrhosis disease process to improve symptomatic control and decrease the need and associated costs of frequent paracenteses.

Further studies should focus on deciphering whether there is a correlation between earlier TIPS intervention in refractory ascites, hepatic encephalopathy, variceal bleeding, and spontaneous bacterial peritonitis. Some physicians are weary of TIPS intervention due to a suspected increase in hepatic encephalopathy from unfiltered portal venous blood containing impurities and unprocessed metabolites and toxins such as ammonia, although risk is difficult to stratify amongst patients [24]. The question needing to be answered is whether this potential risk is outweighed by the other systemic benefits of TIPS while end-stage liver failure patients await transplantation.

Limitations to this study were due to variation in follow up times between those patients receiving TIPS and those who did not. Mean follow up time for those receiving TIPS was 466 days and 140 days for those not receiving TIPS. Longer follow up time for non-TIPS patients would provide more accurate comparison of outcomes and complications. An increase in follow-up or more symmetrical timing could lead to a more accurate representation and comparison of outcomes.

## Conclusion

In conclusion, our study found that TIPS placement was associated with an increase in mean time between paracenteses. There was no statistically significant reduction in bacterial peritonitis, variceal bleeding, or hepatic encephalopathy. These findings suggest that TIPS placement should be considered earlier on in cirrhotic disease to improve symptomatic control of portal hypertension. In result, this would decrease the need for frequent paracentesis. Associated benefits including but not limited to hospital fees and risks of frequent paracenteses can also be reduced.

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## Declaration of interest

Contributing authors have no conflicts of interests to declare.

## Author Contributions

1. Guarantor of integrity of the entire study: Alli, Lemons
2. Study concepts and design: Lemons, Fearn, Alli, Hill
3. Data collection: Everett, Everett, Davis
4. Literature research: Fearn, Lemons
5. Statistical analysis: Wang, Hunt, He
6. Manuscript preparation: Mayr
7. Manuscript editing: Walter, Mayr, Rohr, Fearn, Wang, Hunt, He

## Ethical Standards

1. This study was funded by CTSA Award # UL1TR002366 for the data analysis and interpretation of data.
2. The authors declare that they have no conflict of interest.
3. For this type of study formal consent is not required. This article does not contain any studies with animals performed by any of the authors. IRB approval was obtained internally through the University of Kansas Medical Center's IRB.

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4. For this type of study informed consent is not required.
5. For this type of study consent for publication is not required.

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