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Transjugular intrahepatic portosystemic shunt (TIPS) placement: A comparison of outcomes between patients with hepatic hydrothorax and patients with refractory ascites

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Transjugular intrahepatic portosystemic shunt (TIPS);
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Abstract
Purpose: To compare the outcomes in patients who had transjugular intrahepatic portosystemic shunts (TIPS) placed for hepatic hydrothorax with those who had it placed for refractory ascites.
Materials and methods: One hundred and forty-seven patients who underwent TIPS placement for refractory fluid accumulation were included. There were 97 men and 50 women with a mean age of 56.1 ± 9.7 (SD) years (range: 25—81 years). Of those, 32 patients (32/147; 21.8%) had refractory hepatic hydrothorax and 115 (115/147; 78.2%) had refractory ascites. Electronic medical records were reviewed for all patients to determine demographic, procedural related, and outcomes data. Both traditional analysis and a propensity score matching analysis were performed, to account for differences in baseline laboratory values, etiology of cirrhosis, age, and average number of paracenteses/thoracenteses per week. Survival analysis was also performed to compare post-TIPS survival by indication.
Results: Differences in response rates, in terms of fluid accumulation reductions, at 1, 3, and 6 months were not significant ($P = 0.19$, $P = 0.33$, and $P = 0.28$, respectively). A successful propensity score matching was made between 24 hepatic hydrothorax and 46 ascites patients. After propensity score matching the response rates at 1, 3, and 6 months remained non-significant ($P = 0.3$, $P = 0.71$, and $P = 0.78$ respectively). No differences in mean overall survival were found between hepatic hydrothorax patients (672 days) and ascites patients (1224 days) ($P = 0.15$).

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Conclusion: The clinically relevant outcomes of improvement in fluid accumulation and overall survival do not appear to be significantly different in patients who have TIPS placed for refractory hepatic hydrothorax or and those who have TIPS placed for ascites.

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Transjugular intrahepatic portosystemic shunts (TIPS) is now primarily used to treat patients with refractory ascites [1]. This trend is likely to continue as recent reports have suggested there might be a survival benefit for patients treated with TIPS by comparison with those treated with serial large volume paracentesis [2,3]. While numerous publications exist on the effects and benefits of TIPS placement for ascites a relatively few exist on the treatment of hepatic hydrothorax (HHT), which is a related disease.

HHT is seen in 5—12% of patients with cirrhosis [4—6]. Although the exact mechanism of HHT has not been fully elucidated, the most common theory is that abdominal ascites passes through the diaphragm by way of small fenestrations, aided by negative intrathoracic pressure [7,8]. Initial management for HHT is similar to that of ascites and includes maximal salt restriction and maximal tolerable diuretic use. However, up to 25% of HHT patients will become refractory to treatment, greater than the approximately 10% of ascites patients who become refractory [9,10]. Pleurodesis and pleurovenous shunts are possible surgical treatments, however, they have been associated with rapid fluid reaccumulation and a considerable complication profile [11,12]. The risk of bleeding and pneumothorax has led some to recommend against thoracentesis as a regular long-term treatment in patients with pre-renal azotemia [13]. Furthermore, repeated need for thoracentesis has been shown to reduce the quality of life for patients [13]. TIPS, has therefore become the mainstay of treatment for refractory HHT.

While the American Association for the Study of Liver Disease (AASLD) has recognized refractory HHT as an indication for TIPS, relatively little data has been published on this issue comparatively [14—22]. A recent meta-analysis, which excluded case reports, found only 198 patients published in the literature [23]. Furthermore, the data often encompasses experiences with TIPS using both covered and uncovered stents, of questionable modern utility given the clear benefit covered stents provide on patency rates [24—26]. Therefore, in clinical practice it is common for clinicians to apply data from patients with refractory ascites treated with TIPS to HHT patients. Considering that patients are less tolerant to fluid in the pleural space than in the relatively larger anatomical space of the abdomen, the question of whether improvement following TIPS placement for HHT would be seen less frequently is raised.

The purpose of this retrospective study was to compare the outcomes in patients who had TIPS placed for hepatic hydrothorax with those who had it placed for refractory ascites.

Materials and methods

Patients

Institutional Review Board approval was obtained for this study. All patients who underwent TIPS placement between January 1st, 2006 and December 31, 2016 at a single academic center were retrospectively included. During that time 251 patients underwent TIPS placement, of which 32 were excluded (27 because they were lost to follow up and 5 because they had bare metal stents placed).

A total of 147 patients who underwent TIPS placement for refractory fluid accumulation were included. There were 97 men and 50 women with a mean age of 56.1 ± 9.7 (SD) years (range: 25—81 years). Of those, 32 patients (32/147; 21.8%) had refractory HHT and 115 (115/147; 78.2%) had refractory ascites.

Procede details

TIPS placement was completed utilizing a previously published technique [24—29]. In brief, access was gained to the hepatic veins by way of a right internal jugular vein puncture. A limited venogram was performed to confirm hepatic venous anatomy. A CO_2 portogram was then performed. A Rosch-Uchida® TIPS set (Cook medical) was then utilized to gain access to the portal vein. The length of stent was then measured utilizing a marking catheter, after which a Viatorr® (WL Gore) was placed. Post-placement dilatation was made to 8 or 10 mm, depending on operator preference. Post-placement pressure measurements were then obtained.

Data collection

The electronic medical record was reviewed for each patient to determine their demographic data, etiology of cirrhosis, reason for TIPS placement, pertinent pre-TIPS laboratory data, as well as volume and frequency of thoracentesis and/or paracentesis. The volume of paracentesis/thoracentesis prior to TIPS was calculated by adding up the total volume removed for each patient in the 4 week period prior to TIPS and dividing it by 4 (weeks). The total number of paracentesis/thoracentesis procedures was also collected within the 4 week period prior to the TIPS. The pertinent procedural factors were also recorded including volume of ascites and/or pleural fluid removed at the time of TIPS, TIPS stent size, post-placement stent dilatation size, and post-procedural portosystemic gradient

Table 1 Clinical and laboratory data before transjugular intrahepatic postosystemic shunt placement.

Variable	Hepatic hydrothorax	Ascites	*P*-value
Age (years)	54.3 ± 11.3 [25–70]	56.7 ± 9.3 [32–81]	0.27
Sex			0.99
Male	21 (65.6%)	76 (66.1%)	
Female	11 (34.4%)	39 (33.9%)	
Cause of cirrhosis			0.28
Alcohol	10 (31.3%)	55 (47.8%)	
Hepatitis C	5 (15.6%)	14 (12.2%)	
Alcohol and Hepatitis C	6 (18.8%)	9 (7.8%)	
NASH	4 (12.5%)	21 (18.3%)	
Other	7 (21.8%)	16 (13.9%)	
Creatinine, (mg/dL)	1.05 ± 0.6 [0.5–3.57]	1.14 ± 0.44 [0.32–3.05]	0.47
Total bilirubin, (mg/dL)	2.01 ± 1.22 [0.3–5.5]	1.7 ± 1.23 [0.1–6.6]	0.20
INR	1.63 ± 0.4 [1.08–2.84]	1.4 ± 0.25 [0.98–2.41]	0.003
Sodium, (mg/dL)	133.5 ± 7.9 [119–160]	134.1 ± 6.1 [113–144]	0.71
Albumin, (g/dL)	2.64 ± 0.6 [1.5–3.9]	2.86 ± 0.46 [1.3–4.1]	0.06
MELD score prior to TIPS	15.2 ± 4.4 [8–31]	13.5 ± 3.4 [7–23]	0.04
Child-Pugh Score prior to TIPS	9.4 ± 1.2 [7–12]	8.8 ± 1 [7–12]	0.008
Volume of fluid removed/week prior to TIPS, (mL)	2443 ± 1475 [1200–7000)	6784 ± 2806 [1500–14,500)	<0.0001
Volume of fluid removed at time of TIPS, (mL)	3142 ± 2927 [300–13,300]	5380 ± 3060 [800–15,000]	0.007
Number of thoracenteses/paracenteses per week prior to TIPS	1.31 ± 0.58 [0.5–2]	1.06 ± 0.55 [0.25–3]	0.06

Qualitative variables are expressed as mean ± standard deviation. Numbers in brackets are ranges. Categorical variables are expressed as raw numbers. Numbers in parentheses are percentages. Creatinine: creatinine serum level; INR: international normalized ratio; MELD: model for end-stage liver disease; TIPS: transjugular intrahepatic portosystemic shunt.

measurements. Patient outcomes were also evaluated including complications, survival, and response. Treatment response was graded at three time points. At one, three, and six months patients were delegated into three categories: no improvement (less than 50% reduction in number of paracenteses/thoracenteses per week), partial improvement (at least 50% reduction in number of paracenteses/thoracenteses needed per week), and complete improvement (no further paracenteses/thoracentesis needed), consistent with previously published criteria [30].

Statistical analysis

Descriptive statistics were reported as proportion, percentage or mean ± standard deviation (SD), as appropriate. Differences between HHT patients and ascites patients were searched for using Student *t* test for continuous variables or Fisher's exact test for categorical variables. Propensity score matched control was generated using greedy-matching algorithm at 2:1 ratio based on subject's age, MELD score, cause of cirrhosis, and average number of thoracentesis or paracentesis. Outcomes were compared between HHT and propensity score matched controls. A *P*-value $\leq$ 0.05 was considered as indicating statistical significance. All analyses were performed using the SAS system (v. 9.4; SAS Institute).

Results

The demographic and pre-TIPS data comparison between the HHT and ascites cohorts is reported in Table 1. Patients in the HHT cohort had significantly higher mean international normalized ratios (INR) (1.63 HHT vs. 1.40 ascites; $P = 0.003$), model for end-stage liver disease (MELD) score (15.2 HHT vs. 13.5 ascites; $P = 0.04$), and Child-Pugh scores (9.4 HHT vs. 8.8 ascites; $P = 0.008$). The ascites patients had a higher average volume of fluid removed per week (2443 mL HHT vs. 6784 mL ascites; $P < 0.0001$) prior to TIPS and more volume removed at the time of TIPS (3142 mL HHT vs. 5380 mL ascites; $P = 0.007$). However, no differences in fluid removal procedures (thoracentesis or paracentesis) per week were found between HHT patients (1.31/week) and ascites patients (1.06/week) ($P = 0.06$).

Pertinent procedural factors are presented in Table 2. All patients had an expanded polytetrafluoroethylene (ePTFE) covered Viatorr® stent placed for TIPS. The most common size placed for each cohort was 10 mm (26/32 [96.3%] HHT vs. 98/115 [91.6%] ascites; $P = 0.75$). The stents were most commonly dilated to 10 mm in HHT patients (14/26, 53.9%) and 8 mm in ascites patients (59/96, 61.5%), but the difference was not significant ($P = 0.47$).

The data for complete, partial, and non-responders to TIPS for the HHT and ascites cohort are reported in Table 3. While the HHT group demonstrated less complete (6/31 [19.4%] HHT vs. 35/103 [34%] ascites) and partial responses

Table 2 Procedural data of transjugular intrahepatic postosystemic shunt placement.

Variable	Hepatic hydrothorax	Ascites	*P*-value
Pre-procedural PSG, (mmHg)	18.2 ± 5.9 [12—37]	17.2 ± 5.7 [10—35]	0.59
Post-procedural PSG, (mmHg)	6.5 ± 3.1 [1—13]	7.5 ± 2.8 [0—14]	0.11
Diameter of TIPS, (mm)			0.75
7	0 (0%)	1 (0.9%)	
8	1 (3.7%)	8 (7.5%)	
10	26 (96.3%)	98 (91.6%)	
Post-TIPS dilatation, (mm)			0.47
6	0 (0%)	1 (1%)	
7	0 (0%)	1 (1%)	
8	12 (46.2%)	59 (61.5%)	
9	0 (0%)	2 (2.1%)	
10	14 (53.8%)	33 (34.4%)	

Qualitative variables are expressed as mean ± standard deviation. Numbers in brackets are ranges. Categorical variables are expressed as raw numbers. Numbers in parentheses are percentages. TIPS: transjugular intrahepatic portosystemic shunt; PSG: portosystemic gradient.

Table 3 Outcomes data after transjugular intrahepatic portosystemic shunt placement.

	Hepatic hydrothorax cohort (%)	Ascites cohort (%)	*P*-value
Ascites/pleural fluid at 1 month			0.33
Completely resolved	6/31 (19.4%)	35/103 (34%)	
Partially resolved	11/31 (35.5%)	30/103 (29.1%)	
No response	14/31 (45.1%)	38/103 (36.9%)	
Ascites/pleural fluid at 3 months			0.19
Completely resolved	11/27 (40.8%)	58/98 (59.2%)	
Partially resolved	7/27 (25.9%)	20/98 (20.4%)	
No response	9/27 (33.3%)	20/98 (20.4%)	
Ascites/pleural fluid at 6 months			0.28
Completely resolved	14/28 (50%)	59/98 (59.8%)	
Partially resolved	4/28 (14.3%)	19/98 (19.6%)	
No response	10/28 (35.7%)	20/98 (20.6%)	
Propensity score matching analyses			*P*-value
Ascites/pleural fluid at 1 month			0.71
Completely resolved	4/24 (16.7%)	10/40 (25%)	
Partially resolved	9/24 (37.5%)	12/40 (30%)	
No response	11/24 (45.8%)	18/40 (45%)	
Ascites/pleural fluid at 3 months			0.37
Completely resolved	8/23 (34.8%)	19/38 (50%)	
Partially resolved	6/23 (26.1%)	10/38 (26.3%)	
No response	9/23 (39.1%)	9/38 (23.7%)	
Ascites/pleural fluid at 6 months			0.78
Completely resolved	10/22 (45.4%)	22/40 (55%)	
Partially resolved	4/22 (18.2%)	7/40 (17.5%)	
No response	8/22 (36.4%)	11/40 (27.5%)	

(11/31 [35.5%] HHT vs. 30/103 [29.1%] ascites) with a corresponding higher number of non-responders (14/31 [45.1%] HHT vs. 38/103 [36.9%] ascites) at one month, this was not significant ($P = 0.33$). A similar pattern was seen at 3 months with the HHT patients showing a complete, partial, and no response distribution of 11/27 (40.8%), 7/27 (25.9%), 9/27 (33.3%) respectively. This showed fewer responses than the ascites cohort which demonstrated complete, partial and no response distribution of 58/98 (59.2%), 20/98 (20.4%), and 20/98 (20.4%) respectively, but this was significant ($P = 0.19$). At 6 months the number of non-responders was larger in the HHT cohort (10/28, 35.7%) as compared to the ascites cohort (20/97, 20.6%), but this was not significant ($P = 0.28$).

A successful propensity score match was made for 24 HHT patients to 46 ascites patients. When the propensity

score matching (PSM) was applied the outcomes became even more equivalent between the two groups (Table 3). In the PSM, at one month the HHT patients had 4/24 (16.7%), 9/24 (37.5%), 11/24 (45.8%) of complete, partial and no response respectively. This was as compared to the ascites patients who demonstrated 10/40 (25%), 12/40 (30%), 18/40 (45%) of complete, partial, and no response respectively ($P = 0.71$). Similar results were seen at 3 months with HHT patients showing 8/23 (34.8%) complete response as compared to ascites patients who showed 19/38 (50%) complete response ($P = 0.37$). Finally, at 6 months, there were 8/22 (36.4%) non-responders in HHT patients and 11/40 (27.5%) non-responders in ascites patients ($P = 0.78$).

The average follow up time was not different between HHT patients (924.9 days) and ascites patients (900 days) ($P = 0.45$). During the follow up period 44 ascites and 21 HHT patients died. The overall survival of the two groups was not significantly different with a mean overall survival of 672 days in HHT patients and 1224 days in ascites patients ($P = 0.15$). Seven of 115 ascites patients (6%) died within the first 90 days and 1 (1%) died in the first 30 days. Conversely, 4/32 (12.5%) HHT patients died in the first 90 days and 1 (3%) died in the first 30 days. Neither the 30 or 90 day mortality rates were different ($P = 0.25$ and $P = 0.38$, respectively). No differences in the incidence of hepatic encephalopathy were found between patients with HHT (10/32; 31.3%) and those with ascites (37/114; 32.5%) ($P = 0.99$). All HE events were grade 1 or 2 and ultimately controlled by medications.

Discussion

HHT is a relatively rare complication of cirrhosis and while refractory HHT is recognized as an indication for TIPS, relatively little data has been published on the subject. This data is further flawed in that it commonly reports experiences with bare metal stents, of questionable modern utility given the clear superiority of ePTFE covered stents in terms of patency. Therefore, clinicians frequently quote data relating to TIPS placed for ascites to refractory HHT patients. Given the smaller anatomic space of the pleural cavity it is unclear whether outcomes are equivalent for these two cohorts of patients, which to the authors' knowledge had not previously been studied. However, this study found no significant difference in HTT and ascites patients in terms of resolution of fluid accumulation or overall survival.

The HHT cohort had significantly higher baseline INR, MELD, and Child-Pugh scores as compared to the ascites cohort. There has been some suggestion that HHT is associated with deteriorating clinical status and quality of life [13,15], however, the reasons for these differences are not explained by this study. They may represent a sampling error given the relatively large number of patients in the ascites cohort as compared to the HHT cohort. These baseline differences are a part of the reason a PSM analyses was felt to be needed. The study, also demonstrated that ascites patients had a larger amount of fluid removed on an average week prior to TIPS and at the day of TIPS placement. Given the larger size of the abdominal cavity, as compared to the pleural space, this was an expected finding. Also, unsurprising was the trend toward a larger number of procedures performed for fluid removal in HHT patients (1.31/week HHT vs. 1.06/week ascites, $P = 0.06$). The relative inability of patients to tolerate fluid buildup in the pleural space before becoming symptomatic in part drove the authors to evaluate this subject.

This study demonstrates an overall improvement (complete and partial responders) in fluid accumulation in 54.9%, 66.7%, and 64.3% of HHT patients at 1, 3, and 6 months, consistent with other published data, which have demonstrated improvement rates between 58% and 79% [14—22]. Given that overall improvement can be challenging to define at times, we used previously published and stringent guidelines for complete, partial, or no improvement at three time points [30]. While the analysis showed more complete and partial responses in the ascites cohort at 1,3, and 6 months, the two groups did not differ significantly ($P = 0.33$ at 1 month, $P = 0.19$ at 3 months, and $P = 0.28$ at 6 months). Due to the baseline differences in pertinent predictors of TIPS success, such as MELD score, it was felt a PSM was needed. After PSM the outcomes between the two groups became more equivalent.

The overall survival was not different between HHT and ascites patients. However, the survival of ascites patients was nearly twice that of HHT patients. This seems to be consistent with previous authors findings that HHT is associated with deteriorating clinical status [13]. The mean overall survival of 672 days in HHT patients compares favorably to the survival reported by Dhanasekaran et al. of 517 days in there review of 73 patients treated with TIPS for HHT [15]. This improved survival may be explained by several factors. First, the average MELD score was lower in this cohort (15.2) than there's (18.5). Secondly, Dhanasekaran et al. cohort consisted primarily of patients who had uncovered stents placed for their TIPS (54/73), uncovered stents are known to have worse patency rates, which theoretically may negatively affect survival, however this has not been clearly demonstrated in the literature [15,24—26]. The 30 and 90 day mortality of 3% and 12.5% seen in this cohort was also lower than the 45 day mortality of 17.7% seen in a recent meta-analysis [23], which too may be explained by baseline characteristics.

This study has a number of limitations. First, its retrospective design which is compounded by the fact that not all data points were available for each patient. Second, the number of HHT patients, while comprising one of the largest cohorts reported to date, is still relatively small. Lastly, the single center location means that the findings here may not be applicable to all centers. However, despite these limitations this is the first paper, to the authors' knowledge, to compare the outcomes in HHT and ascites patients.

In conclusion the clinically relevant outcomes of improvement in fluid accumulation and overall survival do not appear to be significantly different in patients who have TIPS placed for refractory HHT or ascites, suggesting that TIPS in an effective treatment for HHT.

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Disclosure of interest

The authors declare that they have no competing interest.

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