Article published online: 2024-05-18

Outcome of Transjugular Intrahepatic Portosystemic Shunt in Patients with Cirrhosis and Refractory Hepatic Hydrothorax: A Systematic Review and Meta-analysis

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Indian J Radiol Imaging

Abstract

Background Around 5% of patients with cirrhosis of the liver develop hepatic hydrothorax (HH). For patients with refractory HH (RHH), transjugular intrahepatic portosystemic shunt (TIPS) has been investigated in small studies. Hence, the present meta-analysis aimed to summarize the current data on the outcome of TIPS in patients with RHH.

Methods From inception through June 2023, MEDLINE, Embase, and Scopus were searched for studies analyzing the outcome of TIPS in RHH. Clinical response, adverse events (AEs), mortality, and shunt dysfunction were the primary outcomes assessed. The event rates with their 95% confidence interval were calculated using a random-effects model.

Results A total of 12 studies ($n = 466$) were included in the final analysis. The pooled complete and partial response rates were 47.2% (35.8–58.5%) and 25.5% (16.7–34.3%), respectively. The pooled incidences of serious AEs and post-TIPS liver failure after TIPS in RHH were 5.6% (2.1–9.0%) and 7.6% (3.1–12.1%), respectively. The pooled incidences of overall hepatic encephalopathy (HE) and severe HE nonresponsive to standard treatment after TIPS in RHH were 33.2% (20.0–46.4%) and 3.6% (0.4–6.8%), respectively. The pooled 1-month and 1-year mortality rates were 14.0% (8.3–19.6%) and 42.0% (33.5–50.4%), respectively. The pooled incidence of shunt dysfunction after TIPS in RHH was 24.2% (16.3–32.2%).

Conclusion RHH has a modest response to TIPS in patients with cirrhosis, with only half having a complete response. Further studies are required to ascertain whether early TIPS can improve the outcome of patients with cirrhosis and HH.

Keywords
- portal hypertension
- cirrhosis
- pleural effusion
- hepatic hydrothorax
- transjugular intrahepatic portosystemic shunt

DOI https://doi.org/10.1055/s-0044-1786828.
ISSN 0971-3026.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

Introduction

Hepatic hydrothorax (HH) is defined as a large transudative pleural effusion in a patient with liver cirrhosis and portal hypertension in whom a primary cardiopulmonary, renal, or malignant process has been ruled out. A diagnostic thoracocentesis often confirms the diagnosis and excludes other causes.[1,2] Unlike ascites, HH is relatively uncommon and occurs in only 5% to 10% of patients with liver cirrhosis.[3–5] The exact pathophysiology of HH is not completely understood; however, leakage of peritoneal fluid into the pleural space through the tiny diaphragmatic pores is considered the most widely accepted mechanism. In addition, a negative pleural pressure also contributes to the one-way flow of fluid from the peritoneal to the pleural space.[6–8] HH usually occurs on the right side (85%). HH is often associated with ascites, and isolated HH is noted only in up to 20% of patients.[3,9]

The mainstay of treatment includes diuretic therapy, salt and fluid restriction, and management of the underlying liver disease. Despite the optimization of medical therapy, some patients with HH require repeated therapeutic thoracocentesis.[1,2] When therapeutic thoracocentesis is required more than once every 2 to 3 weeks, even after maximal optimization of diuretic therapy and dietary salt restriction, it is called refractory HH (RHH). RHH is associated with poor prognosis and necessitates early liver transplantation.[1,2,10]

As a therapeutic option, thoracocentesis is a simple procedure; however, repeated need for it has been shown to reduce the quality of life. Pleurodesis and indwelling pleural catheter placement are other available alternatives in patients with RHH; however, they have been associated with procedure-related morbidities.[1] The transjugular intrahepatic portosystemic shunt (TIPS) procedure is a minimally invasive procedure used to decompress the portal pressure by creating an artificial shunt between the portal and hepatic veins.[11] However, unlike refractory ascites, data on TIPS in RHH are limited. The current meta-analysis aims to evaluate the outcomes of TIPS in patients with RHH.

Methods

The current meta-analysis was conducted as per the updated Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[12]

Database Search

All relevant studies were searched from 2000 to October 31, 2023, in MEDLINE, Embase, and Scopus using the following keywords: (Cirrhosis OR End stage liver disease) AND (Hydrothorax OR Effusion) AND (TIPS OR Transjugular intrahepatic portosystemic stent shunt). The title and abstract of the retrieved studies were screened by two independent reviewers, who then assessed the full texts for eligibility prior to inclusion. Additionally, the bibliographies of the included studies were screened for relevant studies. A third reviewer resolved any disagreement.

Study Inclusion

Both prospective and retrospective studies fulfilling the following criteria were included in the present systematic review and meta-analysis: (1) *study population*: patients with cirrhosis and RHH; (2) *intervention*: TIPS placement; (3) *outcomes*: efficacy and safety of TIPS in RHH. Editorials, correspondences, case reports, case series (<10 patients), conference abstracts, and review articles were excluded. Studies with insufficient or irrelevant clinical data were also excluded.

Data Extraction and Quality Assessment

Two reviewers independently extracted the data, while a third reviewer arbitrated any conflicts. Each study's title, first author, year of publication, country, number of patients, age and sex distribution, indication for TIPS, outcome metrics, and follow-up time were all listed on the form. Using a modified Newcastle–Ottawa scale for cohort studies,[13] two independent reviewers evaluated the quality of the included studies. In the event of a disagreement, a third reviewer was contacted.

Outcomes Assessed

The primary outcomes of the study were response to TIPS, procedure-related adverse events (AEs), post-TIPS hepatic encephalopathy (HE), TIPS dysfunction, and mortality. The response was again recorded as complete or partial as per the individual studies' definitions. Periprocedural AEs were graded as per the standard guidelines.[14] Stent dysfunction was defined as complete occlusion or significant reduction in the lumen of the shunt or a significant change in the velocity on Doppler or recurrence of initial symptoms.

Data Analysis

Using a random-effects inverse-variance model, the pooled proportions were calculated. I^2 and the p-value for heterogeneity were used to evaluate the studies' degree of heterogeneity. I^2 values of 25%, 50%, and 75% were regarded as the cutoffs for low, moderate, and considerable heterogeneity, respectively.[15] A p-value of less than 0.10 was considered statistically significant. To assess publication bias, funnel plots were visually inspected. Egger's test was used for the assessment of the small-study effect. The sensitivity analysis was performed utilizing a leave-one-out meta-analysis, where one study is removed at each analysis, to analyze each research's impact on the overall effect-size estimate and find influential studies. STATA software (version 17, StataCorp., College Station, TX) was used for statistical analysis.

Result

Baseline Characteristics of the Studies and Quality Assessment

Overall, 925 records were identified, of which 12 studies were included in the final analysis (►**Fig. 1**). ►**Table 1** and ►**Table 2** show the baseline characteristics and outcomes of the individual studies included in the present meta-analysis. All the studies were retrospective in nature, with

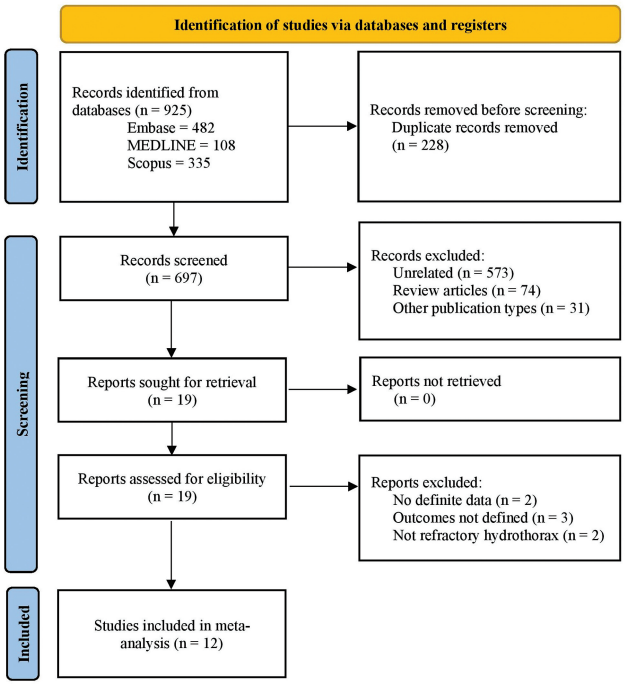

Fig. 1 PRISMA flowchart for study selection and inclusion process.

the majority being from the United States.[16–22] The sample size of the studies varied from 12 to 132, with mean age varying from 45.2 to 63 years. The proportion of male patients ranged from 33.3% to 65.6%. Six studies used uncovered stents,[16–18,22–24] three used covered stents,[21,25,26] one used both stents,[19] and the conference abstracts did not mention the type of stent used.[20,27] The definition of outcomes used in various studies is summarized in ►**Supplementary Table S1** (available in the online version only). ►**Supplementary Table S2** (available in the online version only) shows the quality analysis for the included studies. Nine studies were of medium quality,[16–19,22–24,26,27] and three were of low quality.[20,21,25]

Clinical Response

All 12 studies ($n = 466$) reported on the complete clinical response, while 11 studies ($n = 334$) reported on the partial and no response of TIPS in patients with cirrhosis and RHH. The pooled complete and partial response rates were 47.2% (95% confidence interval [CI]: 35.8–58.5; $I^2 = 84.2\%$) and 25.5% (95% CI: 16.7–34.3; $I^2 = 74.6\%$), respectively (►**Fig. 2A, B**). The pooled rate of no response with TIPS in refractory RHH was 23.3% (95% CI: 18.5–28.1; $I^2 = 10.3\%$) (►**Fig. 2C**).

On subgroup analysis of studies reporting 1-month outcome, the pooled complete response, partial response, and no response rates were 47.5% (95% CI: 37.0–58.0; $I^2 = 44.0\%$), 23.3% (95% CI: 14.1–24.3; $I^2 = 48.3\%$), and 22.2% (95% CI: 14.6–29.8; $I^2 = 27.7\%$), respectively.

Adverse Events

The incidence of serious AEs after TIPS in RHH was reported in 6 studies with 164 patients. The pooled incidence of serious AEs after TIPS in RHH was 5.6% (95% CI: 2.1–9.0;

Table 1 Baseline characteristics of the studies included in the meta-analysis

Author, year	Country	Study design	Study period	*N*	Age, y	Male	Child–Pugh status	Type of stent
Gordon 1997[16]	US	Retrospective	1992–1995	24	Mean: 58.2	14 (58.3%)	A0/B5/C19	Uncovered
Jeffries 1998[17]	US	Retrospective	1993–1997	12	Mean: 54.5 (41–72)	4 (33.3%)	A1/B5/C6	Uncovered
Siegerstetter 2001[23]	Germany	Retrospective	1994–1995	40	Median: 54 (31–70)	21 (52.5%)	A0/B24/C16	Uncovered
Spencer 2002[18]	US	Retrospective	1995–2000	21	Mean: 56 (37–74)	12 (57.1%)	A0/B7/C14	Uncovered
Wilputte 2007[24]	Belgium	Retrospective	1992–2001	28	Mean: 53.6 (38–77)	15 (53.6%)	A0/B12/C16	Uncovered
Dhanasekaran 2010[19]	US	Retrospective	1992–2008	73	Mean: 55.6	40 (54.8%)	–	Mixed
Mitchell 2011[20]	US	Retrospective	2008–2010	21	61.7 ± 8.2	–	9.0 ± 1.5	–
Campos 2016[25]	Portugal	Retrospective	2000–2014	19	63 ± 9	11 (57.9%)	A2/B8/C9	Covered
Young 2016[21]	US	Retrospective	2006–2016	32	54.3 ± 11.3	21 (65.6%)	9.4 ± 1.2	Covered
Jindal 2019[26]	India	Retrospective	2010–2017	51	45.2 + 7.9	–	10.6 + 1.7	Covered
German 2019[27]	US	Retrospective	2010–2015	132	Median: 58	76 (50%)	–	–
Harimoto 2020[22]	Japan	Retrospective	2003–2016	20	61.1 ± 10.8	13 (65%)	A0/B9/C11	Uncovered

Table 2 Outcome of individual studies included in the meta-analysis

Author, year	*N*	Complete response	Partial response	Serious adverse events	Hepatic encephalopathy	1-mo mortality	1-y mortality	Shunt dysfunction
Gordon 1997[16]	24	14	5	1	9	5	6	3
Jeffries 1998[17]	12	5	2	2	4	3	7	4
Siegerstetter 2001[23]	40	28	5	1	–	5	17	16
Spencer 2002[18]	21	12	2	3	9	6	12	4
Wilputte 2007[24]	28	16	3	2	–	4	17	6
Dhanasekaran 2010[19]	73	43	15	–	11	14	38	18
Mitchell 2011[20]	21	4	11	–	–	–	–	–
Campos 2016[25]	19	6	5	–	12	4	6	1
Young 2016[21]	32	11	7	–	10	1	4	–
Jindal 2019[26]	51	10	25	4	8	9	20	–
German 2019[27]	132	83	–	–	–	16	51	–
Harimoto 2020[22]	20	8	10	–	2	0	6	7

$I^2 = 0.0\%$). A total of 8 studies with 236 patients reported the incidence of liver failure after TIPS. The pooled incidence of post-TIPS liver failure in patients with RHH was 7.6% (95% CI: 3.1–12.1; $I^2 = 37.2\%$).

Overall, eight studies ($n = 235$) and seven studies ($n = 191$) reported on the incidence of HE and severe HE, respectively, after TIPS in patients with RHH. The pooled incidence of HE after TIPS in RHH was 33.2% (95% CI: 20.0–46.4; $I^2 = 82.6\%$).

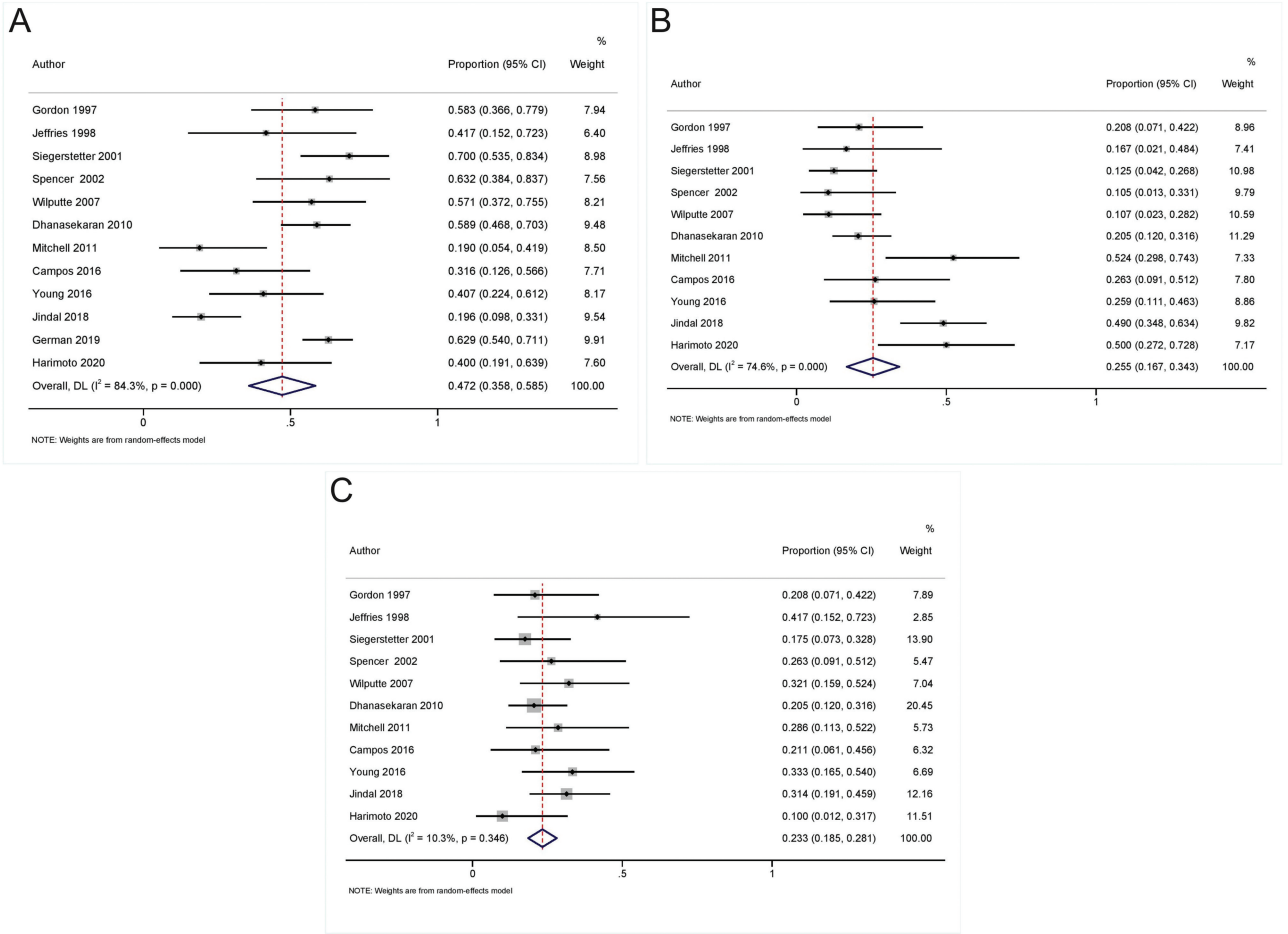

Fig. 2 Forest plot showing the pooled (**A**) complete response rate, (**B**) partial response rate, and (**C**) nonresponse rate with transjugular intrahepatic portosystemic shunt in patients with cirrhosis and refractory hydrothorax.

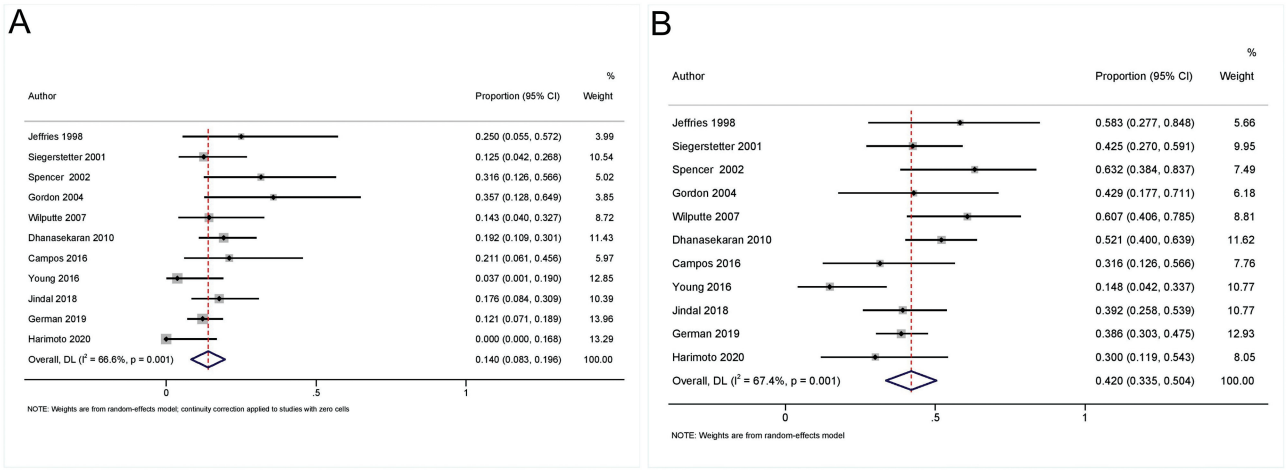

Fig. 3 Forest plot showing the pooled (**A**) 1-month mortality rate and (**B**) 1-year mortality rate with transjugular intrahepatic portosystemic shunt in patients with cirrhosis and refractory hydrothorax.

The pooled incidence of severe HE, nonresponsive to standard HE treatment, was 3.6% (95% CI: 0.4–6.8; $I^2 = 16.3\%$).

Mortality

A total of 11 studies ($n = 435$) reported on the 1-month and 1-year mortality after TIPS in patients with cirrhosis and RHH. The pooled rate of 1-month mortality was 14.0% (95% CI: 8.3–19.6; $I^2 = 66.6\%$) (►**Fig. 3A**), while the pooled rate of 1-year mortality was 42.0% (95% CI: 33.5–50.4; $I^2 = 67.4\%$) (►**Fig. 3B**).

Shunt Dysfunction

Overall, eight studies ($n = 221$) reported the incidence of shunt dysfunction on follow-up of patients with cirrhosis and RHH undergoing TIPS. The pooled incidence of shunt dysfunction after TIPS in RHH was 24.2% (95% CI: 16.3–32.2; $I^2 = 47.3\%$).

Publication Bias and Sensitivity Analysis

Visual inspection of the funnel plot (►**Supplementary Fig. S1** [available in the online version only]) showed evidence of publication bias for the outcomes of partial response and 1-month mortality. There was evidence of a small-study effect on Egger's test for the outcome of 1-month mortality (►**Supplementary Table S3** [available in the online version only]). There were no significant changes in the pooled event rate of various outcomes on leave-one-out analysis.

Discussion

Liver transplantation is the definitive therapy for HH. However, it is possible only for a limited number of patients. TIPS is a viable option for these patients, if not as a bridge therapy, then at least as a palliative treatment.[1,2] The current meta-analysis shows that approximately three-fourths (73%) of the patients with RHH respond to TIPS with an acceptable complication rate. Without liver transplantation, 1-year mortality rate approaches nearly 40% even after TIPS in these patients.

The pooled complete and partial response rate for RHH following TIPS was found to be approximately 47.2% and 25.5%, respectively, i.e., nearly half of the patients with RHH respond completely to TIPS and nearly one-fourth of the patients respond partially to TIPS. However, there was substantial heterogeneity in the current study, which could be due to the fact that all the available studies are retrospective and uncontrolled, with included patient profiles varying among the studies regarding baseline liver disease and other associated risk factors. Siegerstetter et al reported that older patients (>60 years) had significantly shorter relapse-free survival than younger patients (odds ratio: 3.3; 95% CI: 1.3–8.1, $p < 0.01$).[23] Nonresponse indicates advanced disease, and in the study by Spencer et al, nonresponders had multisystem organ failure, and all but one died within 30 days.[18] Thus, the predictors of RHH response to TIPS are multifactorial, and further larger studies are required to analyze these factors.

The major complication rate after TIPS ranges from 3% to 5%.[14,28] The current meta-analysis revealed a pooled incidence of serious AEs in the higher range (5.6%), including a higher incidence of post-TIPS liver failure (7.6%). Given that RHH is associated with advanced liver disease, the increased number of patients with low baseline liver function may account for the higher incidence of post-TIPS AEs. Another major outcome of this meta-analysis includes the incidence of post-TIPS HE, an important predictor of post-TIPS mortality. The pooled incidence rate of HE was 33.2%. Nevertheless, most episodes of HE responded to medical therapy except for 3.6% of cases. This rate falls within the HE rates observed with TIPS for established indications.[14,29] The heterogeneity in the incidence of post-TIPS HE between various studies highlights the fact that its diagnosis is subjective.

The pooled 1-month and 1-year mortality rates in the present analysis were 14.0% and 42.0%, respectively. This suggests that nearly half of the patients receiving TIPS for RHH succumb to death after a year of TIPS without liver transplantation. The substantial heterogeneity in survival in the present meta-analysis could be due to differences in the

baseline liver function and other comorbid conditions that vary among different studies. Dhanasekaran et al reported that baseline creatinine was a significant predictor of 30-day mortality on multivariate analysis (hazard ratio: 3.42; 95% CI: 1.2–9.9; $p = 0.024$).[19] Additionally, variation in TIPS timing among the different studies could significantly influence post-TIPS survival.

Outcomes after TIPS rely on patient selection. Young et al compared the outcomes of TIPS between patients with RHH and with refractory ascites and found that survival of the patients with RHH (672 days) was nearly half of that of patients with refractory ascites (1,224 days), although the difference was not statistically significant. This difference in survival was possibly due to overall poorer baseline liver function in the RHH group than in the refractory ascites group.[21] Furthermore, another larger series by Gou et al showed no difference in post-TIPS survival between patients with HH and refractory ascites. In addition, the 1-year mortality in patients with HH receiving TIPS was 12%, significantly lower than that of our meta-analysis because TIPS was performed early before the patients had developed RHH.[30] Few previous studies have also shown that patients with HH under 60 years with good liver function respond well to TIPS and have a high survival rate.[23,24,31] Therefore, TIPS should be considered early in patients with HH to have a survival advantage. However, the optimal timing for TIPS is largely unknown, necessitating further, large multicentric prospective studies.

Our analysis showed a pooled stent dysfunction rate of 24.2%. The usage of bare stents in TIPS creation has shown a higher rate of TIPS dysfunction, and 6 of the 10 studies using bare stents may be an important factor for the higher rate of shunt dysfunction. A paradigm shift has occurred in TIPS creation from bare stent to e-polytetrafluoroethylene (e-PTEE) covered stent to improve the stent patency rate. In a subgroup analysis, Dhanasekaran et al examined patients with and without covered stents and discovered no statistically significant difference in survival despite the fact that patients with covered stents had higher patency rates.[19] Thus, further studies with covered stents are required to estimate the actual rate of stent dysfunction.

Despite the encouraging outcomes, these results should be interpreted cautiously as the meta-analysis has several limitations. First, all the studies are retrospective, increasing the risk of selection bias. Second, complete and partial response definitions vary between studies, contributing to heterogeneity. Unlike that of refractory ascites, a randomized controlled trial evaluating the role of TIPS in HH is lacking. RHH is relatively uncommon. A step-up approach is often preferred in its management. These factors make conducting a randomized controlled trial on RHH unfeasible.

To conclude, RHH has a modest response to TIPS, with three-fourths of patients responding to TIPS, and only half of the patients having a complete response. Around 5% to 10% of cases of patients with RHH undergoing TIPS develop serious AEs and post-TIPS liver failure. While one-third of the patients develop HE after TIPS, less than 5% of the cases develop severe HE, nonresponsive to standard treatment. Despite the modest response rate, survival after TIPS in RHH remains poor, with one-seventh of the patients having mortality within a week and around two-fifths having mortality within a year. Due to limited data, further studies with covered stents are required to analyze whether early TIPS can improve the outcome of patients with cirrhosis and HH, before progressing to RHH.

Conflict of Interest

None declared.

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