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# CLINICAL STUDY OF MANAGEMENT OF RESISTANT ASCITES IN PATIENTS WITH DECOMPENSATED CHRONIC LIVER DISEASE AT A TERTIARY HOSPITAL

Clinical Science

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## ABSTRACT

Refractory (resistant) ascites is a severe complication of decompensated chronic liver disease, associated with a high 2-year mortality rate (up to 65%), poor quality of life, and increased risk of serious complications like Spontaneous Bacterial Peritonitis (SBP) and Hepatorenal Syndrome (HRS). This study aimed to prospectively evaluate the real-world management strategies, short-term outcomes, and prognostic factors in patients with refractory ascites at a tertiary care center in India. This was a single-center, prospective, observational study conducted over two years, enrolling 78 adult patients diagnosed with refractory ascites (defined by the International Ascites Club criteria). The cohort (n=78) had a mean age of 52.45±10.56 years, with 70.5% male. Disease severity was high (median MELD-Na 18, Child-Pugh B/C 91%). LVP with albumin was the primary management in 82.1% of cases. At 3 months, 64.1% achieved ascites control (complete 24.4%, partial 39.7%). The overall PICD incidence was 17.9%, which was significantly higher in patients without appropriate albumin replacement (14.1% vs. 3.8% with albumin). The 6-month transplant-free survival rate was 61.5%. Significant predictors of poor response were higher baseline MELD-Na (p=0.02) and serum sodium <130 mmol/L (p=0.01). Repeated LVP with guideline-based albumin remains the primary, effective management strategy in this setting, underscoring the necessity of albumin use to mitigate PICD risk.

## KEYWORDS

Refractory Ascites, Cirrhosis, Large Volume Paracentesis (LVP), MELD-Na

## INTRODUCTION

Ascites is the unusual fluid buildup in the peritoneal cavity. The most common cirrhosis side effect. It affects 50% of individuals with decompensated cirrhosis after 10 years.[1] The occurrence of refractory ascites is a milestone in the history of the disease as it is associated with a 2-year mortality of 65%, poor quality of life and an increased risk of spontaneous bacterial peritonitis (SBP) and hepatorenal syndrome (HRS). It is for these reasons that any patient with refractory ascites should be considered for liver transplantation.[2,3]

According to the criteria of the International Ascites Club, refractory ascites is defined as " ascites that cannot be mobilised or the early recurrence of which (i.e., after LVP) cannot be satisfactorily prevented by medical therapy".[4,5] The diagnostic criteria of refractory ascites relies on the assessment of the response of ascites to diuretic therapy and salt restriction. Such an evaluation should be done in stable patients without associated complications, such as bleeding or infection, after ascertaining patient compliance to treatment. Patients with refractory ascites should be evaluated liver transplantation (LT).[6]

Refractoriness of ascites is associated with a poor prognosis, with a median survival of about six months. Although liver transplantation (LT) is undoubtedly the ultimate solution for refractory ascites in liver cirrhosis, most patients have to wait for a long period of time or even die before the operation because of absolute organ shortage. Therefore, various therapeutic strategies for refractory ascites, whether by large-volume paracentesis (LVP), transjugular intrahepatic portosystemic shunt (TIPS), or peritoneovenous shunt (PVS), are mainly designated to improve quality of life in cirrhotic patients.[7]Present study was aimed to study management of refractory ascites in patients with decompensated chronic liver disease at a tertiary hospital.

## MATERIAL AND METHODS

Present study was single-center, prospective, observational study, conducted in department of general medicine, at Government medical college & hospital, Chhatrapati Sambhajinagar, Maharashtra, India. Study duration was of 2 years (July 2022 to June 2024). Study was approved by institutional ethical committee.

### Inclusion Criteria

- Patients of age ≥18 years; cirrhosis diagnosis; refractory ascites defined as unresponsive to sodium restriction and maximal tolerated diuretics or diuretic-induced complications willing to participate in present study

### Exclusion Criteria

- Acute liver failure
- Active malignancy (except HCC within Milan),
- Uncorrected cardiopulmonary disease,
- Pregnancy

Study was explained to participants in local language & written informed consent was taken. Patient information included etiology of cirrhosis, comorbidity, model for endstage liver disease (MELD), and CTP score. The diagnosis of cirrhosis was confirmed by ultrasound or computed tomography, documentation of esophageal varices at endoscopy or and venous collaterals at imaging.

Management strategies included: LVP with albumin replacement (8 g/L for >5 L removed), midodrine, long-term albumin infusion, CART, and TIPS. Primary outcome: control of ascites at 3 months. Secondary outcomes: PICD, AKI, HE, need for TIPS/transplant, 6-month survival. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Statistical analysis was done using descriptive statistics.

## RESULTS

Present study included patients with decompensated chronic liver disease and refractory ascites, with a total sample size of 78 subjects. The subjects were predominantly middle-aged, with a reported mean age of 52.45±10.56 years. The cohort showed a significant male predominance, with 55 subjects (70.5%) being male and 23 subjects (29.5%) being female.

The primary cause of cirrhosis was Alcohol, accounting for the largest share at 42 subjects (53.8%). Non-Alcoholic Steatohepatitis (NASH) was the next most frequent etiology at 14 subjects (17.9%), followed by Viral causes (likely Hepatitis B or C) at 12 subjects (15.4%). The remaining 10 subjects (12.8%) were classified under Others.

The severity of liver disease was assessed using both the Child–Pugh classification and the MELD (Model for End-Stage Liver Disease) score. As per Child–Pugh Classification, majority of the cohort had moderate-to-severe liver dysfunction, with 48 subjects (61.5%) classified as Child–Pugh class B. Severe dysfunction (Class C) was present in 23 subjects (29.5%), while only a small fraction, 6 subjects (7.7%), were in the mildest category (Class A).

The MELD score, which is a key predictor of short-term mortality and

transplant priority, had a median value of 18 with an Interquartile Range (IQR) of 15–22. This score suggests a high risk of poor outcomes in this cohort.

A clinically relevant subset of the patients suffered from hyponatremia (Serum sodium <130 mmol/L), which comprised 22 subjects (28.2%). This condition is often associated with a worse prognosis in cirrhosis. The majority of subjects, 56 (71.8%), had serum sodium levels of ≥130 mmol/L.The average nutritional and synthetic function status of the liver was reflected in the Mean Baseline Serum Albumin, which was low at 28±5 g/L.

**Table 1- General Characteristics**

| Characteristics | No. of Subjects (n=78) | Percentage (%) |
|---|---|---|
| Mean Age ± SD (in years) | 52.45±10.56 | — |
| Gender | | |
| Male | 55 | 70.5% |
| Female | 23 | 29.5% |
| Etiology of Cirrhosis | | |
| Alcohol | 42 | 53.8% |
| NASH | 14 | 17.9% |
| Viral | 12 | 15.4% |
| Others | 10 | 12.8% |
| Child–Pugh class | | |
| A | 6 | 7.7% |
| B | 48 | 61.5% |
| C | 23 | 29.5% |
| Serum sodium | | |
| ≥130 mmol/L | 56 | 71.8% |
| <130 mmol/L (Hyponatremia) | 22 | 28.2% |
| MELD score Median (IQR) | 18 (15–22) | — |
| Mean Baseline Serum Albumin (g/L) | 28±5 | — |

Table 2 outlines the primary and adjunct therapies initiated for the management of refractory ascites in the 78 subjects. The total percentage exceeds 100% as many subjects Large Volume Paracentesis combined with albumin replacement was the mainstay of treatment, consistent with guidelines. The protocol specified 8 g/L albumin for removals >5 L. Midodrine was used as an adjunct therapy in over one-third of the cohort. Long-term albumin infusion was utilized in one-fifth of the subjects, often explored as an additional therapy. Cell-free and Concentrated Ascites Reinfusion Therapy was a less common adjunct management option. Transjugular Intrahepatic Portosystemic Shunt was considered and implemented in a small, selected group of subjects.received LVP plus one or more adjunct therapies.

**Table 2- Initial Management Strategies**

| Initial Management | No. of subjects | Percentage |
|---|---|---|
| LVP {Large Volume Paracentesis with albumin replacement (8 g/L for >5 L removed)} ± Albumin | 64 | 82.1% |
| Midodrine | 28 | 35.9% |
| Long-term Albumin Infusion | 16 | 20.5% |
| CART (Cell-free and Concentrated Ascites Reinfusion Therapy) | 6 | 7.7% |
| TIPS | 6 | 7.7% |

Complete Ascites Control at 3 Months was observed in 19 patients (24.4 %). A total of 50 subjects (64.1%) achieved either complete or partial control of their ascites at 3 months.

**Table 3- Ascites Control at 3 Months**

| Ascites Control at 3 Months | No. of subjects | Percentage |
|---|---|---|
| Complete | 19 | 24.4% |
| Partial | 31 | 39.7% |
| No response | 28 | 35.9% |

Paracentesis-Induced Circulatory Dysfunction (PICD) is a serious complication associated with LVP, particularly when albumin is omitted

**Table 4- Paracentesis-Induced Circulatory Dysfunction (PICD).**

| PICD Incidence | No. of subjects | Percentage |
|---|---|---|
| Overall | 14 | 17.9% |
| Without appropriate albumin | 11 | 14.1% |
| With albumin replacement | 3 | 3.8% |

6-month transplant-free survival rate was 62%.

**Table 5- Outcome after 6-Month Transplant-Free**

| Outcome after 6-Month Transplant-Free | No. of subjects | Percentage |
|---|---|---|
| Survival | 48 | 61.5% |
| Died | 30 | 38.5% |

Higher MELD-Na was a predictor of poor response (p=0.02). Hyponatremia (serum sodium <130 mmol/L) was a predictor of poor response (p=0.01).

## DISCUSSION

Present study illustrates real-world patterns in refractory ascites management in India. LVP ± albumin remains most used; omission of albumin increased PICD and AKI. TIPS offered effective ascites control but higher encephalopathy, consistent with Indian reports. Adjuncts like midodrine and long-term albumin showed potential benefit.

Amarapurkar et al.,[8] compared TIPS to Large-Volume Paracentesis (LVP) & found that TIPS provided better control of ascites but was associated with an increase in Hepatic Encephalopathy (HE). The 1-year survival rate was 62%. Singh et al.,[9] conducted a randomized pilot study examining the use of the vasoconstrictor Midodrine versus standard care. It reported an improved urinary sodium excretion and a reduction in ascites recurrence with Midodrine. The 6-month survival rate was 68%.

Rai et al.,[10] investigated the combination therapy of Midodrine and Tolvaptan. [cite_start]The main finding was enhanced natriuresis (sodium excretion in urine) and a reduced need for paracentesis. Sudulagunta et al.,[11] conducted an audit focusing on patients undergoing repeated paracentesis. A key finding was that the omission of albumin replacement during LVP increased the incidence of Paracentesis-Induced Circulatory Dysfunction (PICD). The median survival observed was 8 months.

In a study by Arora et al.,[12] they specifically looked at Albumin infusion with LVP. It demonstrated that the use of albumin reduced PICD and improved renal outcomes. The 12-month survival rate was 65%. Kulkarni et al.,[13] explored real-world management patterns in an Indian cohort. It highlighted that resource constraints were a factor that limited the use of TIPS. The median survival in this cohort was 10 months.

Sanglodkar et al.,[14] conducted a multicenter survey investigating the practice of using diuretics and vasoconstrictors. It indicated that Midodrine was widely used, but there was variable practice concerning albumin use. Mukund et al.,[15] reported on TIPS outcomes from a single-center in India, finding effective ascites control but confirming the increased risk of HE. The 1-year survival was 70%.

According to Miyamoto et al.,[16] decompensated liver cirrhosis typically becomes worse with refractory ascites, and people who already have liver cirrhosis have a bad prognosis if they experience intractable ascites Aldosterone blockers, loop diuretics, and rarely vasopressin receptor antagonists are used to treat ascites in cirrhotic patients. Inhibitors of (SGLT2) may be an alternative to existing therapies for ascites that are resistant to those treatments.

Osmotic diuresis and natriuresis appear to be the two primary mechanisms by which SGLT2 inhibitors enhance ascites reduction. Other processes, however, might contribute to blood pressure reduction. These include increases in nutritional status and glucose metabolism, hepatoprotection from adiponectin and ketone bodies, sympathetic nervous system augmentation, and regulation of the renin-angiotensin-aldosterone system.[16]

Although refractory ascites is a common indication for liver transplantation (LT), access to LT is not equitable in India.[17]TIPS is an excellent therapy for refractory ascites. However, the results of TIPS are often suboptimal in the Indian population because of the presence of cirrhotic cardiomyopathy, a higher model for end-stage liver disease score at presentation, sarcopenia, and the difficulty in monitoring shunt patency and function. [18] In addition, sarcopenia significantly increases

the risk for hepatic encephalopathy.[18]

## CONCLUSIONS

Repeated LVP with guideline-based albumin remains the primary management for refractory ascites. TIPS is effective in selected patients but increases encephalopathy. Adjuncts (midodrine, long-term albumin, CART) are promising but require further Indian randomized trials. Resource limitations are critical in management choices; multicenter studies are needed for cost-effective strategies.

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