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Post-paracentesis Ascitic Fluid Leak in Patients with Cirrhosis of Liver and its Management: A Prospective Study

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Background: **Ascites is the most common complication of decompensated cirrhosis of liver requiring paracentesis for diagnostic and therapeutic purposes. The ascitic fluid leak can develop after paracentesis in patients with cirrhosis leading to significant morbidity if persistent. We aimed to study the incidence and predictors of post-paracentesis leak in patients with ascites.** ***Methods:*** **In this prospective study, patients with cirrhosis undergoing therapeutic paracentesis were followed up, and those patients who developed persistent leak were included as cases. Controls were randomly selected in a 2:1 ratio from the group of patients who did not develop leak. Clinical and laboratory parameters were compared between the two groups.** ***Results:*** **A total of 256 patients underwent 1126 sessions of therapeutic abdominal paracentesis over a period of 14 months. Post-paracentesis leak was seen in 55 (4.8%) patients while only 20 (1.7%) patients had persistent leak. The management of leak was in a stepwise manner initially with tincture benzoin with tight dressing followed by topical cyanoacrylate adhesive and followed by autologous blood patch in those not responding. The persistent leak group had higher proportion of patients with parietal edema, higher PT-INR and Child-Pugh score, lower mid-upper arm circumference, short physical performance battery score, and handgrip strength. On multivariate analysis, only the presence of parietal edema was an independent predictor of post-paracentesis persistent leak (odds ratio 10.35, 95% confidence interval 1.61–66.54, $P = 0.014$).** ***Conclusion:*** **Persistent leak after paracentesis develops in a minority of patients with cirrhosis. The presence of parietal edema is a risk factor for persistent leak. The majority of these patients can be managed in a stepwise approach. (J Clin Exp Hepatol xxxx;xxx:xxx)**

Ascites is the commonest decompensation event in the natural history of cirrhosis of liver.[1,2] Paracentesis is both a diagnostic as well as a therapeutic modality for patients with ascites. Patients with gross ascites require large-volume paracentesis (LVP) while those with end-stage liver disease (ESLD) require frequent therapeutic paracenteses.[3] One of the complications of this simple bedside procedure is ascitic fluid leak. Post-paracentesis ascitic fluid leak occurs in around 5% of patients undergoing paracentesis.[4] Leaks can occur if a Z-tract has not been properly performed during the procedure, or if a large-bore needle is used.[5] Although the majority of the leaks can be managed medically, persistent significant drainage from non-closing paracentesis tracts may develop in patients with ESLD. Significant morbidity is associated with protracted leaks, including a high risk of infection[6] and discomfort for the patient from frequent soiling of clothes. Current management of ascitic fluid leak includes the medical optimization of ascites with diuretic therapy, repeat therapeutic paracentesis with proper technique, or placing an ostomy bag over the site until drainage ceases. The British guidelines for the management of ascites suggest patient to lie on the opposite side for 2 h if there is leakage of any remaining ascitic fluid after the paracentesis and/or a suture (ideally purse-string) inserted around the site of drainage.[2] Various other methods have been tried, including topical application of tincture benzoin, fibrin glue injection,[7] cyanoacrylate glue injection,[6] autologous blood patch[5], and layered surgical closure of abdominal wall.[7] Till now, there has been no study to study the incidence and predictors of ascitic fluid leak in patients of cirrhosis undergoing paracentesis. We also hypothesized that patients with sarcopenia have reduced muscle mass which may be associated with thinning of anterior abdominal wall muscles leading to the higher incidence of post-paracentesis leak. Hence, this study was aimed at studying the incidence of post-paracentesis leak in patients of cirrhosis of liver undergoing

Keywords: ascites, paracentesis, post-paracentesis leak, cirrhosis, complication

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Abbreviations: BMI: Body mass index; ESLD: End-stage liver disease; GS: Gait speed; HS: Handgrip strength; INR: International normalized ratio; LVP: Large-volume paracentesis; MUAC: Mid-upper arm circumference; SPPB: Short physical performance battery; US: Ultrasound

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therapeutic paracentesis and to analyze the predictors of post-paracentesis leak including sarcopenia.

METHODS

This is a single-center observational prospective unmatched case control study that was conducted in the Department of Gastroenterology of a tertiary care center from February 2020 to April 2021. The study was approved by the institutional ethical committee (EC/OA-39/2020).

Patient Selection

All patients of cirrhosis of liver who had ascites diagnosed on physical exam or radiographic imaging and were undergoing therapeutic paracentesis in the department of Gastroenterology of a tertiary center were assessed for the development of leak. Transient leaks may develop after paracentesis which stops spontaneously by lying down on opposite side or with pressure. Patients who continued to have leak even after 6 h of procedure were considered as persistent leak. Among those patients who do not develop post-paracentesis leak, controls were randomly selected from this group in a 2:1 ratio.

All patients underwent routine investigations, such as complete blood count, renal and liver function test, prothrombin time, ascitic fluid and urine examination, upper gastrointestinal endoscopy, and ultrasonography of abdomen. The diagnosis of cirrhosis of liver as the cause of ascites was made based on the radiological evidence of shrunken liver, dilated portal vein with periportal or other collaterals, endoscopic evidence of portal hypertension in the form of presence of varices and/or portal hypertensive gastropathy, and presence of high serum ascites albumin gradient.[8] Patients were treated as per standard treatment guidelines and treating physician's discretion.[3]

Contraindications of paracentesis included uncooperative patient, overlying skin infection, severe coagulopathy (accelerated fibrinolysis or disseminated intravascular coagulation) or severe thrombocytopenia (platelets <20,000/ml), and severe bowel distension.[3] Exclusion criteria included the following: (i) patients undergoing diagnostic paracentesis, (ii) ascites due to etiology other than cirrhosis of liver, (iii) ascitic leak secondary to other etiologies, such as umbilical hernia rupture, leaking trocar sites, or abdominal surgical site, and (iv) all contraindications for paracentesis as above.

Technique

Patients underwent paracentesis at the bedside under sterile technique with sterile gloves, masks, and antiseptic solution, as described by Thomsen *et al.* regarding the performance of paracentesis.[9] Therapeutic paracentesis was performed using 18-gauge needle (length = 38 mm)/18-G lumbar puncture needle (if no fluid drained with standard needle) in the left or right lower quadrant of abdomen using Z-technique. Patients were given 100 ml of 20% intravenous albumin following the procedure and were observed for the development of any leak. Initial management of leak involved repeat therapeutic paracentesis at a different site (if completely not drained), optimization of diuretics, and local application of tincture benzoin with tight dressing for 24 h. Cases that improved were considered as minor leaks and those who did not improve were considered as major leaks. Patients who had persistent leak were managed by topical cyanoacrylate application followed by high-flow air delivered through nasal cannula to dry the glue.[10] Autologous blood patch was applied to patients who continued to have leak, despite above methods. Application of autologous blood patch was done as described by Khan *et al.* which involves four-quadrant injection of 20 ml blood adjacent to the leaking paracentesis tract in the subcutaneous tissue and deeper into the peri-leak tissue.[5] Injection was continued while withdrawing the needle from the tissue to create an iatrogenic hematoma to obliterate the tract.

Assessment of nutrition was done by calculating the body mass index (BMI) corrected for ascites and pedal edema, mid-upper arm circumference (MUAC), and short physical performance battery (SPPB), which includes three simple bedside tests: balance test, gait speed (GS) test while walking 4 m, and chair stand test. SPPB has been validated for assessment of sarcopenia and prediction of mortality in patients with cirrhosis of liver.[11]

Data Analysis

Continuous variables were presented as median and range while categorical variables were expressed as frequencies and percentages. The comparison of continuous variables between the case and control groups was performed using Mann–Whitney U test. Categorical data between the groups were compared using the chi-square test or Fischer's exact test as appropriate. The propensity score was used for matching cases and controls. Multivariate analysis using Cox regression model was used to identify independent risk factors for the prediction of post-paracentesis leak in both unmatched and matched cohorts. A *P*-value of <0.05 was considered statistically significant. All statistical analysis will be done using SPSS software version 20.0.

RESULTS

A total of 1126 abdominal paracentesis was performed in 256 patients over a period of 14 months. The baseline characteristics of the study population are described in Table 1. The number of procedure-related adverse events developing in patients undergoing paracentesis is enumerated in

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Table 1 Baseline Characteristics of Patients Included in the Study.

	N = 256
Mean age ±SD, in years	49.08 ± 10.91
Male sex, n (%)	210 (82.03%)
Etiology of chronic liver disease	
Alcohol	112 (43.7%)
NASH	32 (12.5%)
Hepatitis B	21 (8.2%)
Hepatitis C	16 (6.2%)
Budd-Chiari syndrome	35 (13.7%)
Others	40 (15.6%)
Child-Pugh score	
Score B	167 (65.23%)
Score C	89 (34.76%)

Note: NASH: Non-alcoholic steatohepatitis.

Figure 1. The ascitic fluid leak developed in 45 patients after 55 (4.8%) sessions of paracentesis. Transient/self-limited leak was seen in 35 patients while 20 patients developed persistent leak. Major bleeding requiring intervention developed in two patients in the form of hemoperitoneum. Both patients underwent conventional angiography showing an aneurysm of inferior epigastric artery and were managed successfully with coil embolization.

Figure 2 shows the management of persistent leak developing after therapeutic paracentesis. All 20 patients were initially managed with local application of tincture benzoin with tight dressing. Half of the patients had control of leak while 10 patients continued to have leak. These 10 patients were managed with topical cyanoacrylate adhesive application with the application of high-flow air to dry the glue. Seven patients responded to local adhesive application, and the remaining three patients with persistent leak were managed with autologous blood patch around the site of leak.

Comparison of Parameters Among Patients Who Developed Persistent Post-paracentesis Leak and Controls

Table 2 compares the clinical and laboratory parameters between the patients who developed persistent leak after paracentesis and controls. There was no difference between the two groups with respect to the age, sex, presence of umbilical hernia or hydrothorax, site and volume of paracentesis, and liver and renal function parameters. Patients who developed persistent leak had a higher proportion of patients with parietal edema (P = 0.000). The median PT-INR and Child-Pugh score were significantly higher in the patients with persistent leak, while MUAC, SPPB score, and handgrip strength were significantly lower in the patients with persistent leak. A 1:1 propensity score matching (matched for the presence of parietal edema, serum albumin, PT-INR, MUAC, SPPB score, and handgrip strength) identified 16 cases and 16 controls without any significant difference between the two groups.

Predictors of Persistent Leak After Paracentesis

A multivariable model was generated to analyze both unadjusted and adjusted odds ratio for factors associated with the primary outcome of persistent leak. The model included the presence of parietal edema, PT-INR, serum albumin, MUAC, SPPB score, and handgrip strength (Table 3). Among these parameters, only the presence of parietal edema was found to be an independent predictor of persistent leak after paracentesis in both unmatched and matched analysis.

DISCUSSION

The present study demonstrates that a small fraction of cirrhotic patients develop complications after paracentesis with persistent leak developing in 1.7% of the patients and major leak in 0.8%. The presence of parietal edema was an independent predictor of persistent leak after paracentesis. The cause of increased incidence of leak in patients with

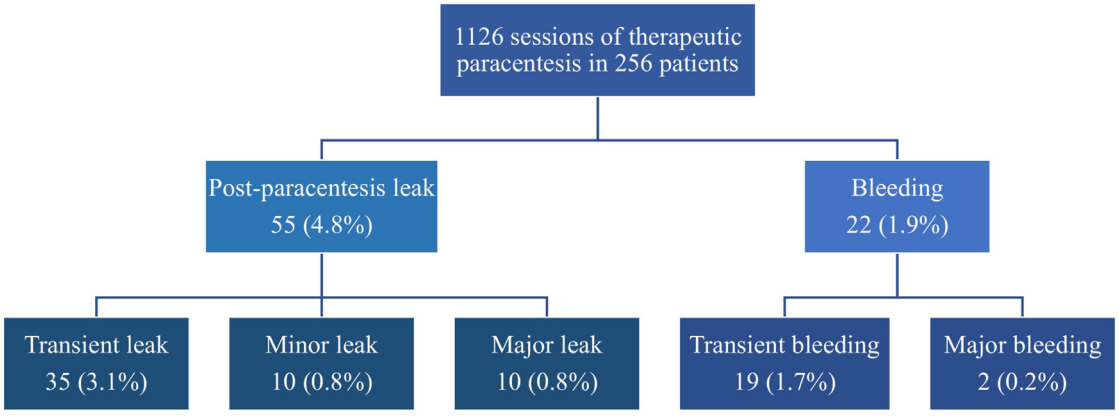

Figure 1 Procedure-related adverse events developing after paracentesis.

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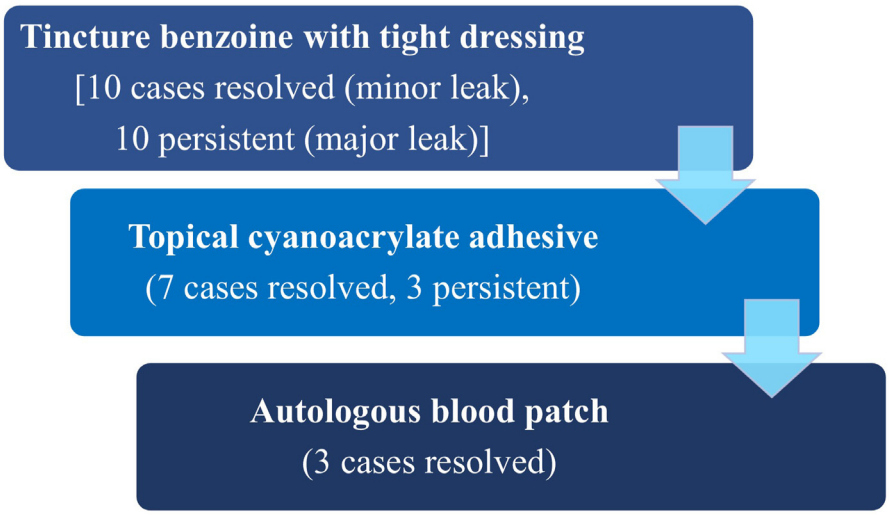

Figure 2 Sequence of management of persistent leak in the study.

Table 2 Comparison of Parameter between Patients with Persistent Leak and those with No Leak.

Parameters	Persistent leak (n = 20)	No leak/controls (n = 40)	*P*-value
Age, in years	50 (28–76)	50 (30–67)	0.796
Male sex, n (%)	15 (75%)	37 (92.5%)	0.103
Umbilical hernia, n (%)	4 (20%)	5 (12.5%)	0.464
Parietal edema, n (%)	12 (60%)	4 (10%)	**0.000**
Hydrothorax, n (%)	4 (20%)	3 (7.5%)	0.208
Previous history of post-paracentesis leak, n (%)	7 (35%)	5 (12.5%)	0.083
Paracentesis in right iliac fossa, n (%)	5 (25%)	20 (50%)	0.096
Volume of paracentesis	6.0 (3.5–8.0)	5.4 (4.0–9.0)	0.712
Sr. bilirubin, in mg/dL	3.2 (0.9–26.3)	2.3 (0.8–17.2)	0.384
Sr. alanine transaminase, in IU/L	33 (7–84)	41 (11–117)	0.401
Sr. albumin, in mg/dL	2.6 (1.6–3.6)	2.7 (1.9–3.6)	0753
PT-INR	1.40 (0.85–2.40)	1.1 (0.76–1.60)	**0.000**
Sr. creatinine, in mg/dL	1.20 (0.60–5.30)	1.35 (0.70–4.40)	0.455
Child-Pugh score	10 (8–13)	9 (7–13)	**0.004**
Child-Pugh class C, n (%)	10 (50%)	10 (25%)	0.081
MELD score	20 (8–28)	15 (6–30)	0.075
Body mass index, in kg/m^2	20.5 (16.2–29.7)	21.6 (15.6–28.1)	0.343
MUAC, in cm	22.5 (16.2–28.5)	24.4 (17.5–36)	**0.036**
SPPB score	7 (4–10)	9 (5–11)	**0.031**
Handgrip strength, in kg	32.9 (18.2–50.2)	42.3 (22.4–68.2)	**0.016**

Note: MELD: Model for end-stage liver disease, MUAC: Mid-upper arm circumference; SPPB: Short physical performance battery. Bold indicate significant difference.

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Table 3 Multivariable analysis of factors associated with the development of persistent Leak.

Parameters	Odds ratio (unmatched cohort) (95% CI)	*P*-value	Odds ratio (matched cohort) (95% CI)	*P*-value
Presence of parietal edema	**10.50 (1.65–66.87)**	**0.013**	**8.18 (1.02–65.54)**	**0.048**
PT-INR	19.14 (0.86–424.08)	0.062	3.46 (0.88–136.59)	0.508
Serum albumin	1.06 (0.22–5.03)	0.941	0.57 (0.09–3.73)	0.561
MUAC	0.84 (0.63–1.13)	0.250	0.91 (0.64–1.30)	0.615
Handgrip strength	1.03 (0.90–1.17)	0.696	1.06 (0.89–1.26)	0.50
SPPB	0.67 (0.36–1.23)	0.194	0.62 (0.26–1.48)	0.282

Bold indicate significant difference
MUAC, Mid-upper arm circumference; SPPB, Short physical performance battery

parietal edema may be due to the failure of insertion of needle in proper Z-tract leading to a straight tract.

All the paracentesis procedures performed in our study were done by traditional blind technique. The British guideline recommends ultrasound (US)-guided LVP to reduce the risk of adverse events and increase the success of the procedure.[2] In a randomized study, paracentesis was successful in 95% of the patients in the US-guided group compared to 61% in the traditional technique group.[12] Patel *et al.* reported a lower incidence of adverse events with US-guided procedures (1.4% vs. 4.7% with blind paracentesis, $P = 0.01$).[13] However, in another study to assess the safety of LVP performed without US-guidance based on the clinical experience of the operator, no major procedure-related complications were observed.[14] Despite this difference in outcomes, the fact that two patients developed hemoperitoneum due to inferior epigastric artery aneurysm suggests that where US is available, LVP should always be performed under USG guidance to prevent complications and unnecessary hospitalization.

In a previous study on the risk of post-paracentesis complications in patients with cirrhosis,[4] the incidence of minor and major complications after paracentesis was 8.9% and 1.6%, respectively. Around 5% of the procedures were associated with ascitic fluid leak, among which 2.9% were self-limited and 2.1% were persistent leaks requiring a stoma pouch. On multivariate analysis, therapeutic paracentesis and Child-Pugh class C status were associated with an increased risk of complications. The incidence of post-paracentesis leak was similar in our study (4.8%) with 1.7% of the procedures being associated with a persistent leak. However, given the fact that the previous study considered both diagnostic and therapeutic paracentesis and we included only patients undergoing therapeutic paracentesis, the overall incidence of leak appears to be lower with LVP in our study.

The use of fibrin glue was initially described for ruptured umbilical hernia in a patient with ESLD[13] and subsequently Sadik *et al.*[7] used this technique for the management of ascitic leak in 14 patients with ESLD. Immediate resolution of leak was seen after injection of 3–5 ml of fibrin glue in all cases. Five patients had a recurrence of leak within 24 h of first injection but none of the patients with post-paracentesis leak had recurrence. The use of N-butyl cyanoacrylate glue has been described in two case reports for the management of ascitic fluid leak developing after paracentesis.[6,10] In one patient, 1-ml glue was injected into the needle track of the procedure[4], while in the other patient, cyanoacrylate was applied at the puncture site, followed by high-flow oxygen per nasal cannula for drying.[10] In both the cases, the resolution of leak was seen without any recurrence. In our study also, none of the patients had a recurrence of leak after resolution with cyanoacrylate.

Autologous blood patches have been utilized for the management of persistent cerebrospinal fluid leak following lumbar puncture as well as post-amniocentesis amniorrhea.[15] In a pilot study by Khan *et al.*,[5] six cirrhotic patients with ascitic fluid leak received blood patch with the amount of blood varying from 17 to 30 ml. All the patients achieved the resolution of the leak within 24 h, without any recurrence within 30 days, and no adverse effects were reported. Similar to the previous study, we observed a complete resolution of leak in patients who had persistent leak even after tight dressing and topical therapy. Hence, an autologous blood patch can be an excellent therapeutic approach for the control of persistent ascitic fluid leak non-responsive to standard therapy.

As per the Asian Working Group for Sarcopenia, patients at risk of sarcopenia should be screened with handgrip strength (HGS) and GS, as well as muscle mass measurement in those having low HGS or low GS.[16] The assessment of sarcopenia in our study was done by the means of handgrip strength and SPPB. Although patients who developed leak had significantly lower MUAC, SPPB score, and handgrip strength, none of these were independent predictors of leak.

To the best of our knowledge, this is the first study to elaborate the predictors of ascitic fluid leak developing after paracentesis and its stepwise management. The prospective nature of the study and comparison with controls adds to the strength of the study. In the absence of guidelines for management of post-paracentesis ascitic fluid leak, here,

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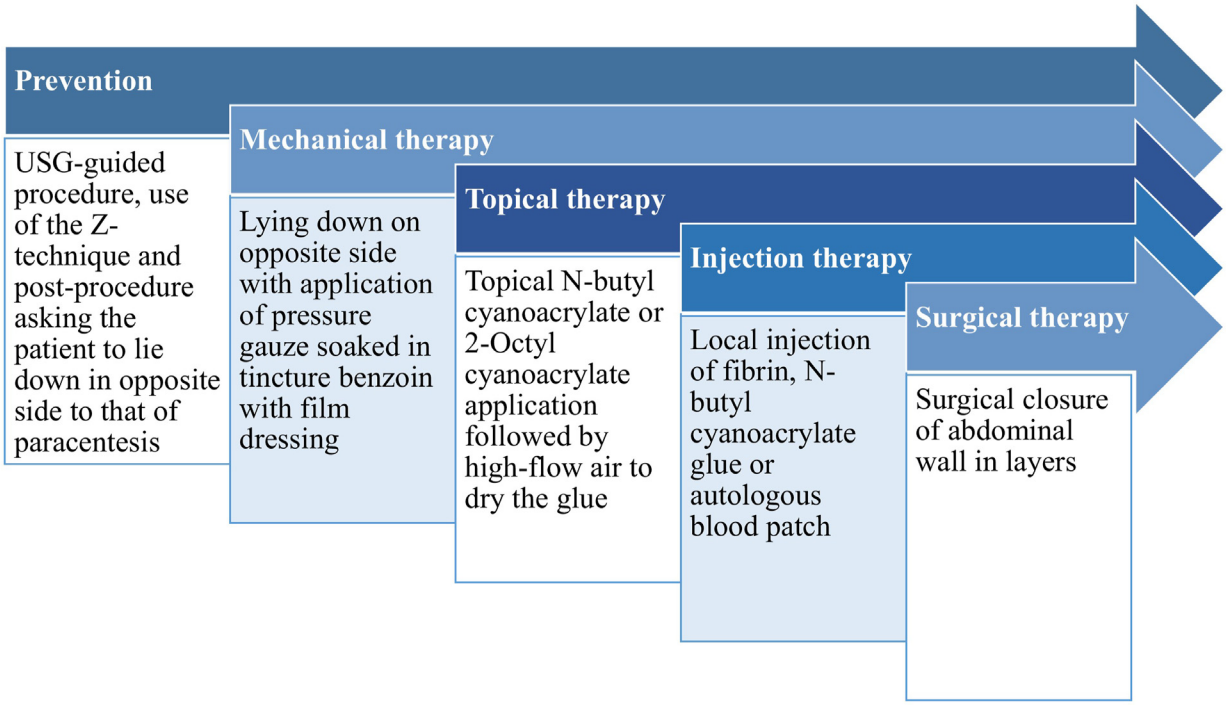

Figure 3 Proposed algorithm for prevention and management of post-paracentesis leak.

we propose a stepwise approach to the management of post-paracentesis leak developing in patients with cirrhosis (Figure 3).

There are few limitations of the present study, the first limitation being small sample size. A larger sample size would have helped better estimate the incidence of post-paracentesis leak and analyze the predictors. Secondly, we could not assess whether US-guided paracentesis would have reduced the incidence of complications, such as leak and bleeding. Lastly, although PT-INR was found to be a significant predictor of leak on univariate analysis, the role of viscoelastic tests could not be analyzed.

To conclude, although the traditional blind technique can be safely used for therapeutic paracentesis in most patients with cirrhosis, it can be associated with life-threatening adverse events, such as hemoperitoneum. US guidance should be considered when available during LVP to reduce the risk of adverse events. The presence of parietal edema puts the patient at risk for the development of an ascitic fluid leak. Hence, the mobilization of the edema by manual pressure before needle insertion by Z-technique can help reduce the leak incidence. Patients developing ascitic fluid leak can be managed by a stepwise approach involving topical and injection therapy.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

All the authors (SG, SH, NP, AK, and APS) contributed equally to study conception and design, data collection, analysis and interpretation of results, and drafting the manuscript preparation. All authors reviewed the results and approved the final version of the manuscript.

CONFLICTS OF INTEREST

The authors have none to declare.

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