

Innovative Technique for Percutaneous Catheter Guided Drainage of Symptomatic Pleural Effusion in Obese Patients with Uncorrectable Coagulopathy: Safety and Feasibility

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ABSTRACT

Background: Current data regarding high risk catheter thoracocentesis is limited with this background, the aim of present study was to evaluate safety and feasibility of Innovative technique for percutaneous catheter thoracocentesis in obese patients with uncorrectable coagulopathy. **Methods:** During the study period from January 2019 to October 2020, 20 patients, of which 14 (70%) men and 6 (30%) women ranging from 45 to 70 years (mean 53.4 ± 10.6 years) were subjected to this new technique of pleural catheter insertion. **Results:** The majority of cases had chronic liver disease associated pleural effusion, followed by end stage kidney disease. Mean BMI of 28 kg/m^2 was observed. Mean skin and subcutaneous thickness was $4.5 \pm 0.5 \text{ cm}$. Technical success was 100% and clinical success was 95%. 10% developed pneumothorax. The catheter was dislodged in one case that required catheter reinsertion. The mean duration of drainage ~ 5.8 days. 20% patient experienced mild chest pain after the insertion of the catheter. One patient had blockage of catheter and two had infection. 10% developed pneumothorax after insertion of catheter. **Conclusions:** This Innovative technique for percutaneous catheter guided drainage of symptomatic pleural effusion in bedridden patients with uncorrectable coagulopathy provides safe, reliable and effective drainage of echo free effusion.

Key words

Percutaneous Catheter Guided Drainage, Pleural Effusion, Small Bore Catheter, USG-Ultrasonography

Introduction

Pleural effusion is an abnormal accumulation of fluid in the pleural cavity. Presence of pleural effusion suggests underlying disease which may be the disease of the pleural membranes itself or disease of thoracic or abdominal organs. Percutaneous pleural drainage is the third most frequently performed procedure in the intensive care unit. Still tube thoracostomy remains the standard procedure for pleural effusions drainage in most centres (Munnell, 1997). Although thoracocentesis is generally considered safe, placement of a large-bore (French) chest tube is an invasive procedure with potential morbidity and complications (Roberts et al., 1998). Drainage tube insertion is associated with few dreaded complications particularly in immobile bedridden patients with uncorrectable coagulopathy, one such complication being haemothorax or hematoma formation which can further worsen the prognosis of the patient. Complication rates of tube thoracostomy are higher in bedridden critically ill patients (Remérand et al., 2007).

According to society of intervention radiology (SIR) guidelines, Laboratory Thresholds for Performance of a percutaneous drainage should be $\text{INR} < 2$ and Platelet $> 50,000$ and is a low risk procedure for bleeding related procedure

if laboratory parameters are within the threshold values (Tripodi et al., 2017),(Patel et al., 2019),(Havelock et al., 2010)

For high risk patients, where percutaneous intervention/drainage is contraindicated due to deranged laboratory parameters, we developed an innovative technique for placement of small bore pigtail catheter for drainage of pleural effusion. Current data regarding high risk catheter thoracocentesis is inconclusive particularly in obese patients with uncorrectable coagulopathy and innovative technique we used is not described in literature. With this background, the aim of present study was to evaluate safety and feasibility of Innovative technique for percutaneous catheter thoracocentesis in obese patients with uncorrectable coagulopathy.

Materials and Methods

The current work is a pilot study of pigtail catheter insertion in pleural cavity in-patient using a new innovative technique performed at a tertiary care hospital. This prospective non randomized observational single-institution study was approved by the institutional review board.

All adult patients with symptomatic pleural effusions who were planned to have chest tube insertion were included. We included obese patients with sub cutaneous plane thickness >5cm, BMI>28 with deranged coagulation profile. Informed signed consent was obtained from eligible patients. The diagnosis of pleural effusion was based on clinical and imaging evaluations (chest radiography /CT scan thorax/USG thorax)

Detailed history taking and complete medical examination were done on all patients. Coagulation profile was evaluated in all patients. Pre and post procedural USG/chest radiographs were done to determine the efficacy of drainage. All procedures were done at the bedside under local anaesthesia (2% lidocaine) and with ultrasonography (USG) guidance. The site of catheter insertion was determined as per USG findings. All procedures were performed according to standard hospital protocols. We screened patients for occurrence hemothorax by assessing for a decrease in hemoglobin greater than 2g/dl or evidence of increase output/ reaccumulation of pleural fluid. Hemothorax in present the study was defined as a pleural fluid hematocrit $\geq$ 50% of the blood.

The therapy was considered successful if the opacity cleared on chest radiograph/CT chest and confirmed on ultrasonography of the chest and also if there was no need for a second intervention (repeat catheter placement, tube thoracostomy, or operation) within 72 hours after removal of the catheter.

The end point of the study was either the resolution of the effusion or symptoms or a decision to remove the catheter or the need for another intervention.

Intervention and technique

Percutaneous catheter placement is a sterile procedure; consequently, we use to wear sterile gloves and use sterile drapes, sterilised materials on a sterilised puncture site and follow the universal infection prevention and control guidelines. Hardware for percutaneous pigtail drainage insertion is summarized in **table 1** and **figure 1**.

Table 1: General equipment required for Percutaneous pigtail drainage insertion

For the Operating	Over the Procedure tray	For the Patient
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person		
• Headcover	• Sterile drapes	• Sterilization of puncture site
• Surgical mask	• Sterile cut sheet	• Sterile drapes
• Hand disinfectant	• Luer lock Syringes (10 mL)	• Informed consent (whenever possible)
• Sterile gown	• Local anaesthetics(2% lignocaine)	
• Surgical- gloves	• Sterile Normal saline	
	• USG-probe	
	• Sterile Probe cover	
	• Puncture needle(18G)	
	• Stiff Guidewire	
	• Scalpel and dilator(6F (French)& 8F	
	• Pigtail Catheters (8F)	
	• Suture and medical dressing	
	• Connector and water seal bag	



Figure 1. Basic hardware required are catheter directed pleural effusion drainage are (a) Connector(b) Syringe with xylocaine (c) Drainage Catheter (d) Fascial dilator (e) Puncture needle (f) Guidewire (g) Suture (h) Pigtail catheter (i) Curvilinear probe (j) Linear probe with sterile cover

Our technique was combined modified tandem needle technique and modified Seldinger technique, following are the steps:

1. **Identification of puncture site:** USG curvilinear (low frequency probe) probe was used for quantification of effusion and linear (high frequency probe) probe along with doppler was used for identifying appropriate site marking of needle placement in the thorax in midaxillary line or posterior axillary line and identification of upper and lower rib in intercostal space. Marking of the skin using needle cap or marker is done directly perpendicular with upper margin of the lower rib.
2. **Placing guiding needle:** 2% Xylocaine(~10-15ml) was infiltrated over the skin and directly over the periosteum of the underlying rib. Leave the 25G needle over the rib which will act as the landmark or guiding needle for further steps.
3. **Placing tandem needle:** Give a small (3-5mm) incision above the 25G needle and using 18G puncture needle (Chiba) through the incision so that it hits the upper margin of the rib over which local anaesthesia (LA) was

given, using the 25G needle as marker or guiding needle. Slightly withdraw the Chiba needle after hitting the rib and direct cranially to puncture the parietal pleural and feel for give away as needle enters the pleural space. Aspiration of fluid with a syringe confirms correct needle tip position. Double check the tip of the needle in the pleural effusion/cavity to confirm the position of the needle using a curvilinear probe(as low frequency probe have better axial resolution).

4. **Insertion of Guidewire:** Remove the 25G needle and the stylet of the Chiba needle following which 0.035inch stiff guide wire was passed into pleural effusion/cavity. Confirm the position of the guidewire in the pleural effusion by USG curvilinear probe and remove the puncture needle over the wire without disturbing the position of the wire.
5. **Insertion of catheter:** Over the wire (OTW) sequential track dilatation was done with 6F and 8F fascial dilator. Check that the guidewire was moving freely in and out of the dilator throughout this process to avoid kinking the guidewire. The dilator should not be introduced more than 1 cm beyond the depth from skin to parietal pleura; aggressive dilator insertion increases the risk of visceral injury. Over the wire (OTW) the pigtail catheter (8F) is passed, making sure that the last side hole was within the pleural space. Remove the guidewire, leaving the pigtail catheter in place. Confirm the position of the pigtail catheter in the pleural effusion/cavity using USG curvilinear probe.
6. **Fixing the catheter:** Secure the drainage catheter with nonabsorbable suture and dressing after giving 5min firm compression and connected to the drainage system. Rescan the patient for any internal echoes and look for the change in the colour of the drain output
7. The catheter was attached to a standard water seal bag/thoracic drainage system. The catheter can be removed as soon as the drainage was less than 100 mL per day for 3 consecutive days
8. Train /teach the technical/nursing staff for catheter care and drainage monitoring.

The above steps are diagrammatically represented in **figure 2 and figure 2a** with US images shown in **figure 3**.

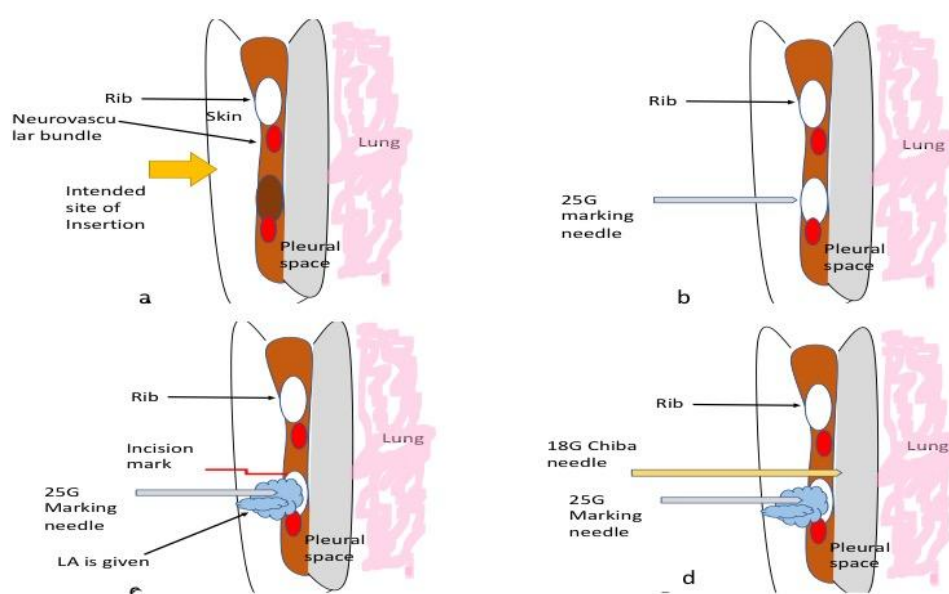


Figure 2.(a).USG screening is done to mark the intended site using both linear and curvilinear probe(b).25G needle is

used for LA(local anesthesia) infiltration and act as tandem needle(c).Local anesthesia is given and incision is given above the needle (d).18G needle is inserted into the pleural space using 25G needle as guide just above the upper margin of rib

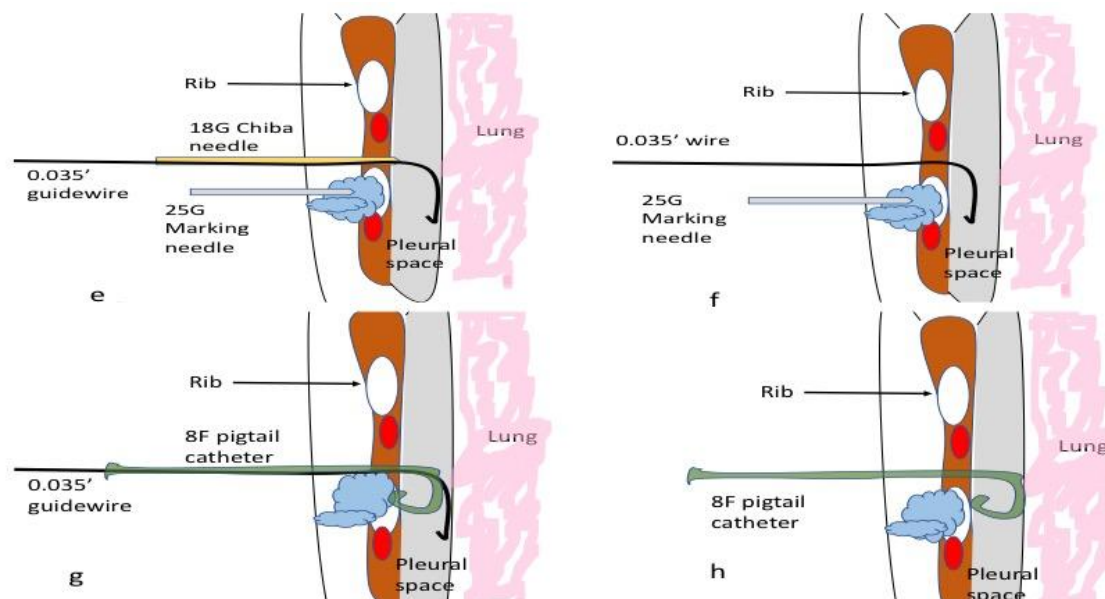


Figure 2a. (e).0.035" stiff guide wire is passed through the Chiba needle and position is confirmed by USG (f).Chiba needle is withdrawn and also the 25G needle (g).After blunt dilatation of track by fascial dilators, 8F pigtail is inserted into the pleural space over the wire (h). Guidewire is withdrawn and position of the pigtail is confirmed by USG and fixed by external sutures and dressing

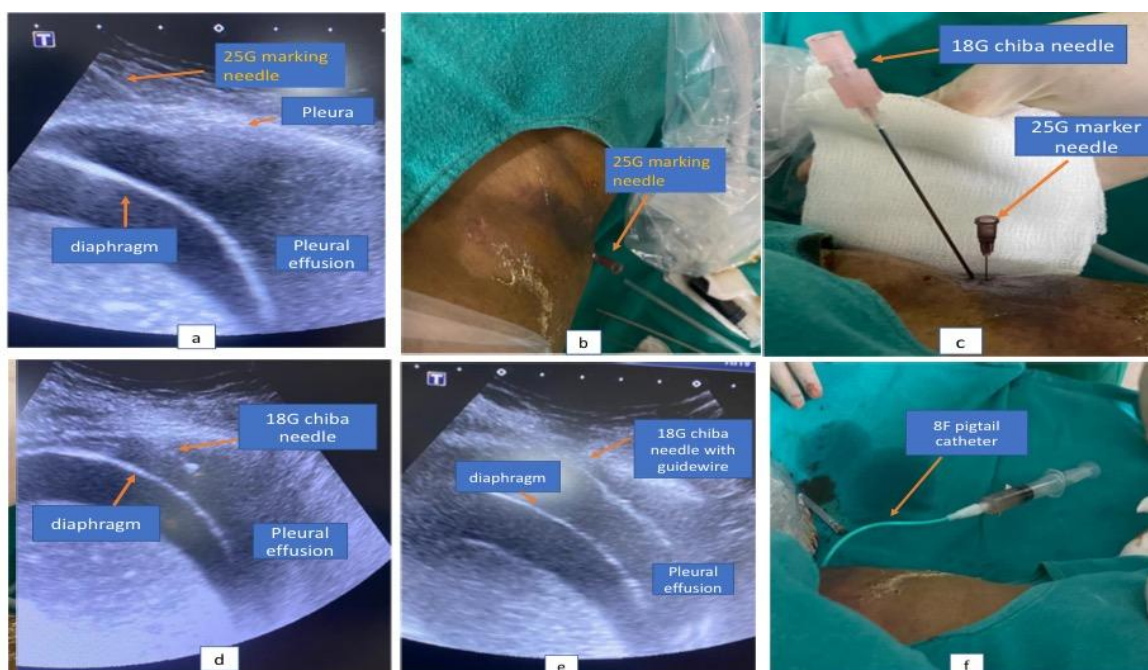


Figure 3. (a).US image showing placement of 25G (gauge) marker needle placement with LA(local anaesthesia) injection (b).25G marker needle left in situ which will guide or marker in insertion of 18G Chiba needle in further steps(c).18G Chiba needle inserted cranial to and along trajectory of 25G marker needle (d,e).US image showing placement of 18G Chiba needle into pleural cavity(position of the needle is confirmed by curvilinear probe) followed by guidewire placement and serial dilatation (f).Final positioning of 8F pigtail catheter into pleural cavity following

pigtail is secured by sutures and dressing was done.

Statistical analysis

Statistical presentation and analysis was conducted using arithmetic mean, percentage and standard deviation.

Results

During the study period from January 2019 to October 2020, 20 patients, of which 14 (70%) men and 6 (30%) women ranging from 45 to 70 years (mean 53.4 ± 10.6 years) were subjected to this new technique of pleural catheter insertion. Nine cases underwent two procedures for bilateral pleural effusion. Duration of drainage was about 5.8 ± 2.4 days and amount drained was 2395 ± 470 ml. Mean INR was 2.6 and mean platelet count was 45,250/ μ l. Basic clinical character is summarized in **table 2**.

Table 2: Demography, clinical data, and complications of patients having catheter insertion for pleural effusion using innovative technique.

Variables	Values
Total number of patients	20
Age (in years) (mean $\pm$ SD)	53 ± 10.6
Gender	
Male	14
Female	6
Mean skin and subcutaneous thickness (mean $\pm$ SD)	4.5 ± 0.5 cm
INR (mean)	2.6
Platelet count (mean)	45,250 per microliter
BMI (mean)	28 kg/m^2
Duration of drainage (mean $\pm$ SD)	5.8 ± 2.4 days
Amount of drained fluid	2395 ± 470 mL
Complications	Number of patients (percentage)

• Pain at insertion site	4 (20%)
• Pneumothorax	2(10%)
• Blockage of the catheter	1(5%)
• Infection	2(10%)

The majority of cases (86%) had chronic liver disease associated pleural effusion, followed by end stage kidney disease (14%). Associated obesity with mean BMI of 28 kg/m² was observed. Mean skin and subcutaneous thickness was 4.5±0.5cm. Procedures were performed successfully without any significant complications in all patients. Pleural fluid was transudative in all patients without any echoes/debris on USG screening.

The drainage was successful in all cases. Two cases (10%) developed pneumothorax. In all of them the pneumothorax was clinically insignificant and resolved without any further interventions. The catheter was dislodged in one (5%) case that required catheter reinsertion.

Four cases (20%) experienced mild chest pain after the insertion of the catheter. In all of them, the pain was relieved with paracetamol intravenous infusion without the need for any narcotics. One patient had blockage of catheter and two had infection, one each of cellulitis and pleuritis (on fluid analysis). No patient developed empyema after catheter insertion.

Discussion

In present study we used the ‘Combined modified tandem needle technique and modified Seldinger technique’ which prevents haemorrhagic complications at multiple steps. Firstly, at entry site by choosing the site of insertion at the upper border of lower rib of a particular intercostal space as neurovascular bundle lies in the groove at lower border of rib. Ribs and intercostal space otherwise cannot be felt by palpation method or by USG in some of these patients since they are obese, with diffuse subcutaneous oedema and are also bedridden (making the positioning of patient and probe difficult). We use USG guidance site marking technique as direct real time needle guidance was technically challenging in these obese patients with subcutaneous oedema and needle manipulation can add to the chances of haemorrhagic complications (Wrightson et al., 2010). In literature it was reported that USG leads to an improvement in the diagnosis and allows the detection of the best puncture site and the fluid quantification (Balik et al., 2006), (Diacon et al., 2003).

Secondly, by constant monitoring the position of the guidewire which can cause trauma to the opposite side pleura or lung can lead to haemorrhage. Thirdly, using small bore catheter reduces the chances of haemorrhage (as depicted in **figure 4**). Fourthly, by preventing the excess length insertion of guidewire and dilators into the pleural space, as it was done under direct real time USG guidance. It was noted that positioning of percutaneous pleural drainage with USG guidance increases the procedure success rate and safety (Liang et al., 2009). International guidelines recommend USG guidance for pleural drainage procedures (Havelock et al., 2010). Fifthly, rescanning the content of the pleural effusion and surrounding soft tissue for any local hematoma/haemorrhage. Sixthly, modified Seldinger technique is more of a blunt dissection compare to as in trocar technique in which there are more chances of sharp trauma to the subcutaneous and vascular tissue. It was noted that blunt dissection technique is a lower risk of complications and tube malposition (Kesieme et al., 2012), (Baldt et al., 1995). In terms of complications particularly haemorrhage/haemothorax

and pneumothorax, as per BTS guidelines (Havelock et al., 2010) was lower in the present study, this may be related to the technique and use of ultrasonography. Similar trends are noted in previous studies, which attributed to the use of the Seldinger technique and small-bore catheter (Luketich et al., 1998), (Morrison et al., 1992), (Walsh et al., 1989), (Seaton et al., 1995).

In the current study, the procedure clinical success rate was 95% with 100% technical success. We had not seen any bleeding related complication in present study however previous literature have reported variable procedure success rates from 72.9% to 93.7% (Saffran et al., 2000), (Musani et al., 2004), (Lin et al., 2011). Previous studies reported hemorrhagic complications related to thoracentesis were much higher in groups with deranged coagulation profile (Hibbert et al., 2013), (Mahmood et al., 2013). In a meta-analysis, bleeding complication rate of 1.0% (Wilcox et al., 2014). However, Ault et al. (Ault et al., 2015) found no association between deranged coagulation profile with the incidence of bleeding complications. Small-bore catheter directed pleural drainage is less invasive and thus better tolerated by patients compared to chest tubes, with no compromise in efficacy. Pain caused by chest drain insertion is less on using small bore pigtail catheters as they do not impinge on the neurovascular bundle (as illustrated in the graphical representation in **figure 4**) (Luketich et al., 1998). Saffran et al. (Saffran et al., 2000) and Musani et al. (Musani et al., 2004) suggests that small-bore catheters are less invasive and have better patient tolerability and compliance. Small bore catheter also prevents sudden large volume thoracentesis and thus prevents the hemodynamic circulatory failure.

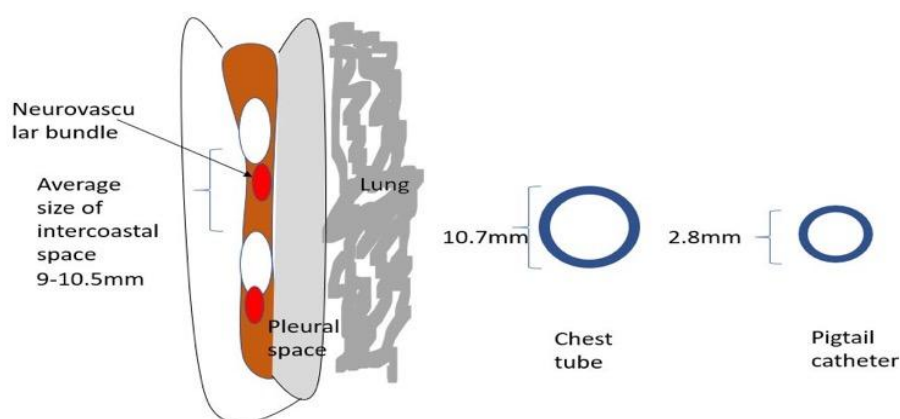


Figure 4. Graphical representation of relative sizes of the average intercostal distance in the adult (mid-axillary line), two commonly used chest tube sizes (24 F or 32 F), and the 8 F pigtail catheter. 3F(French)=1mm. Small bore pigtail are less likely to impinge the neurovascular bundle, therefore more likely reduce the pain and chances of hemorrhage.

In previous studies, mean small bore catheter dwell time varied between 3 to 7.5 days which is comparable with present study (Saffran et al., 2000), (Musani et al., 2004), (Lin et al., 2011). Catheter dislodgment was noted in 0.5% cases, which was lower than the incidence described in previous studies (Liu et al., 2003), (Iepsen & Ringbæk, 2013). This may be attributed to catheter care we explained to the staff in the end of the procedure.

Infection rate in present study was 10% (one each of cellulitis and pleuritis) comparable with previous studies in which infection rate with small bore catheter was 9.5% (Iepsen & Ringbæk, 2013). The incidence of iatrogenic pneumothorax in present study was 10%, slightly higher than reported in previous study in patients who underwent USG guided thoracentesis and lower than reported in tube thoracostomy (Grogan et al., 1990). In previous study it was found that lower BMI, thicker skin fold, more needle passage and less operator experience result in more likelihood of pneumothorax (Ault et al., 2015). In none of the case of iatrogenic pneumothorax required active intervention in present study.

Limitations

The current study concentrated on the innovative technique only, a comparative study between traditional approach and this technique could have yielded better conclusion. Also limited etiologies of pleural effusion were included, which may lead to selection bias and have affected the success rates. We also acknowledge that very small sample size was studied which is not justified to advocate a firm conclusion; however, it can help in adding knowledge to the limited literature.

Future studies are warranted to compare simple pigtail catheter placement technique and this modified technique with patient stratification based on indication and with a standardized protocol to help reduce confounding factors.

Conclusion

This Innovative technique in high risk percutaneous catheter directed thoracentesis in bedridden patients with uncorrectable coagulopathy provides safe, reliable, and effective drainage of echo free effusion. There is minimal chance of hemorrhagic complications for catheter thoracentesis in patients with deranged coagulation profile, attributed to safe technique and small-bore catheter which help in maintaining the anatomical integrity of the intercostal space. Adoption of this technique enables intervention radiologist/clinician/surgeon to minimize the procedure related complication and provide a valuable addition to his/her armamentarium that allows effective pleural drainage, particularly in high risk cases.

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