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Real-world effectiveness and safety of handheld ultrasound in pleural procedures

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Abstract

The use of ultrasound for pleural procedures is associated with a decreased risk of complications. Handheld ultrasounds allow for easier evaluation of the pleural space. Limited data exists for the use of such devices for pleural procedures. The primary objective of our study was to assess the effectiveness and safety of handheld ultrasound for pleural procedures. We performed a prospective observational study, including all consecutive patients who underwent pleural procedures using the handheld ultrasound between September 2021 and November 2023. A total of 332 pleural procedures were attempted with handheld ultrasound, of which 329 pleural procedures (99.1%) were successfully performed. The median volume of fluid drained was 500 (interquartile range: 300-800). Thoracentesis was performed in 127 patients (38.5%), tube thoracostomy in 179 patients (54.4%), and medical thoracoscopy in 23 patients (7.0%). Exudative pleural effusions were found in 264 patients (80.0%), of which 152 (46.2%) were determined to be due to infectious etiologies. A total of 4 (1.2%) patients had a complication due to the procedure. 2 patients (0.6%) had a pneumothorax, while 2 patients (0.6%) developed a hemothorax. A total of 101 patients had either low platelets ($<50\times10^9$/L) or use of anti-platelet or anti-coagulant drugs. 128 patients (38.8%) were on positive pressure support during the pleural procedure. Our study shows that handheld ultrasounds are effective and safe for pleural procedures, including cases with septated pleural effusions and patients on anti-platelet or anti-coagulant drugs.

Key words: bleeding, complications, handheld ultrasound, pleural effusion, positive pressure ventilation.

Introduction

Pleural effusion is a common and challenging clinical problem with an estimated incidence of 1.5 million new pleural effusions annually in the United States [1,2]. The management of these effusions may entail the performance of various pleural procedures including diagnostic thoracentesis, therapeutic thoracentesis, tube thoracostomy and medical thoracoscopy. Depending on the institution and expertise, these interventions may be done by a pulmonologist, interventional radiologist, or thoracic surgeon. Prior to the era of ultrasound, these procedures were performed based on anatomic landmarks and clinical examination. The use of ultrasound has been associated with a significant decrease in risk of complications when compared with non-image guided drainage [3-5].

In addition, ultrasonography provides real time assessment of pleural effusion in terms of its size, shape, movement of the diaphragm and the presence or absence of pleural thickening or nodularity [6,7]. Portable ultrasound machines have allowed for evaluating patients at the bedside without the need to transport the patient to a dedicated room. However, these machines are costly, bulky and storing them may be cumbersome. These factors may prohibit physicians from transporting the machine to evaluate the pleural space unless there are pre-established plans to perform a procedure. Handheld ultrasound machines have been developed to try to overcome this barrier, allowing for easier and quicker evaluation of the pleural space. As these are smaller machines, they typically come with a smaller screen size which may hypothetically limit its use when a pleural procedure is deemed necessary. To this date, no study has evaluated the use of such devices in the management of pleural effusions and use for pleural procedures in clinical practice.

Materials and Methods

Study setting and subjects

This was a prospective observational study performed at a single academic tertiary care hospital in Karachi, Pakistan. Our hospital has Joint Commission International Accreditation and is the major referral center of the country with a bed capacity of 500 patients. This study was performed between the period of September 2021 and November 2023. All consecutive patients seen by the inpatient or outpatient pulmonary service with a suspected pleural effusion based on chest radiography or computed tomography were evaluated by the handheld ultrasound. The patient was included in the study if an effusion was confirmed with the handheld ultrasound and drainage of the fluid was indicated. Patients were excluded if no fluid was found or if the procedure was not deemed necessary. All procedures were done under the guidance of the handheld ultrasound. Once the effusion was identified, the entry site was marked for the point of entry and then the pleural procedure was performed as per standard. Procedures were not done under real-time ultrasound guidance. In select patients, the proceduralist performed color doppler with the same handheld probe to assess for vessels in the intercostal space.

Pleural procedures included diagnostic and therapeutic thoracentesis, tube thoracostomy and medical thoracoscopy. Two experienced attending physicians with formal ultrasound training performed or directly supervised pulmonary fellows performing the ultrasound guided pleural procedures. Under the discretion of the of the attending physician, some pleural interventions were performed in patients with relative contraindications (on positive pressure ventilation, on antiplatelets or anticoagulation, and patients with platelets $<50 \times 10^9$/L). Patients who had platelet count $<20 \times 10^9$/L were transfused prior to the procedure.

Exudate effusions were diagnosed based on Light's criteria (pleural fluid protein > 0.5 of serum protein, pleural fluid LDH > 0.6 of serum LDH, or pleural fluid LDH > $2/3^{rd}$ of serum LDH upper limit of normal). Empyema was diagnosed based on the presence of frank pus or microbiological growth in the pleural fluid culture. Parapneumonic effusion was diagnosed if there was a neutrophilic exudative pleural fluid analysis in the absence of frank pus or microbiological growth. Tube thoracostomy was performed in a parapneumonic effusion if it was found to be a complicated parapneumonic effusion (glucose < 40 mg/dL, LDH > 1000 IU/L, pH < 7.20) or if the parapneumonic effusion size was found to be greater than 500 ml on chest ultrasound findings. Pleural tuberculosis was diagnosed if there was a lymphocytic exudative effusion, with a high adenosine deaminase level or a pleural biopsy with Mycobacterium Tuberculosis PCR positivity. Informed consent was waived for this study. The study protocol and informed consent waiver was approved by the Institutional Review Board of the university (2023-8600-24701).

We used a handheld ultrasound device (C4PL, Sonostar, Guangzhou, China) for all the pulmonary procedures and chest ultrasounds (Figure 1). This device projects the ultrasound images wirelessly to any smartphone or tablet. The device itself is the size of an average smartphone, measuring 160 x 65 mm, with a curvilinear and linear probe with doppler. The handheld ultrasound findings were written in the medical record; however, the images were not saved into the medical record. The primary objective of our study was to assess the effectiveness and safety of using a handheld ultrasound for pleural procedures. Our secondary objectives were to evaluate the safety of performing pleural procedures using the handheld ultrasound in patients with a potentially higher risk of complications, such as patients on positive pressure ventilation or anti-platelet agents.

Statistical analysis

Data were collected on Microsoft Excel (Microsoft Office 16). IBM SPSS version 26.0 (IBM Corp.) was used for statistical analysis. Chi-squared test was used to analyze the difference in complication rates in patients who were on anti-coagulants or positive pressure ventilation in comparison to those who were not.

Results

Over the span of 2 years, we performed a total of 549 chest ultrasounds for evaluation of pleural effusion. A total of 217 patients did not undergo a pleural procedure. Of them, 204 patients had either no effusion or had a minimal effusion that was not amenable to an intervention, and 13 patients had a highly loculated effusion on ultrasound evaluation, warranting management via video-assisted thoracoscopic surgery (VATS). A total of 332 pleural procedures were attempted, of which 329 procedures had successful aspiration of pleural fluid, while 3 patients had an unsuccessful drainage. Of the 3 patients, 2 patients had large bore chest tubes placed for empyema without any drainage, and 1 patient had a dry tap performed. The remainder 329 patients underwent successful pleural procedures using the handheld ultrasound guidance, and no patient required the subsequent use of a conventional ultrasound machine during the procedure or subsequently after the procedure. All thoracentesis and tube thoracostomies were performed at the patients' bedside. No indwelling pleural catheters were placed in this study. VATS was performed in 22 (6.7%) patients after the initial pleural procedure. When using the finder needle, successful aspiration of pleural fluid on the first attempt was achieved in 299 patients (90.6%). The median volume of fluid drained was 500 ml (IQR 300-800). Further details are listed in Table 1.

Procedure and pleural fluid characteristics

Thoracentesis was performed in 127 patients (38.5%), while a tube thoracostomy was done in 179 patients (54.4%). A 12-french small-bore chest tube was the most frequently placed tube, in 95 patients (53.0% of all tubes). Medical thoracoscopy was performed in 23 patients (7.0%).

Of the 329 pleural effusions, 264 (80.0%) of them were found to be exudative pleural effusions. Further details are listed in Table 2.

Safety and complications

A total of 4 (1.2%) patients had a complication after their procedure. Two patients (0.6%) developed a pneumothorax, while two patients (0.6%) developed a hemothorax. There was no mortality due to the complications. None of these patients developed worsening respiratory failure and they did not require escalation of care. Of the 2 pneumothorax patients, 1 was observed without intervention, and the other patient received a needle aspiration only. Neither patient required a chest tube for the pneumothorax. Both hemothoraces were due to venous bleeds as they accumulated within 24-48 hours after the primary pleural procedure. They were diagnosed with chest x-ray imaging and a pleural fluid: serum hematocrit ratio > 50%. Both hemothorax patients received a chest-tube post procedure and did not require further intervention. Both patients who had a hemothorax were on anti-platelet drugs and on positive pressure ventilation. Hemothorax was more likely in patients who were on anti-platelet drugs (4.0% vs 0%), compared to those who were not ($\chi^2 = 11.2$, $p=0.02$).

Out of the 329 pleural procedures, a total of 101 patients had a relative contraindication due to a bleeding risk. Of these, 50 patients (15.2%) were on anti-platelet agents, 37 (11.2%) were on anticoagulants, and the platelet count was less than 50×10^9/L in 14 patients (4.3%).

127 patients (38.6%) were on positive pressure support during the pleural procedure. Out of those, 101 (30.7%) were on non-invasive ventilation and 26 (7.9%) were on mechanical ventilation. Both pneumothorax complications occurred in patients receiving non-invasive ventilation ($\chi^2 = 3.2$, $p=0.15$). Further details are listed in Table 2.

Parapneumonic effusions and empyema

A total of 264 patients (80.0%) were diagnosed with exudative pleural effusions. Out of those, 152 (46.2%) were determined to be due to infectious etiologies. Microbiological cultures yielded growth in 39 cases (11.8%). There were a total of 53 (16.1%) empyemas of which 48 (90.5%) received chest tubes. One of them had VATS performed after the thoracentesis. Four of the remaining empyemas were small collections, managed with therapeutic thoracentesis and antibiotics alone. Parapneumonic effusion was diagnosed in 70 patients (21.3%) of which 49 (70.0%) received chest tubes. Tuberculous pleural effusion was found in 29 (8.8%) of which 8 (33.3%) received chest tubes. VATS was performed in 12 out of 53 (22.6%) empyema patients, and in 3 patients with parapneumonic effusion (4.3%). Further details of etiologies of pleural effusions are shown in Figure 2.

Discussion

Our study is the largest cohort to date of patients undergoing pleural procedures with handheld ultrasound guidance. Handheld ultrasound machines may have the potential advantage of being easier to move around, with a simpler user interface, and may be less intimidating to patients when compared to conventional portable ultrasound machines. These devices require a smaller capital investment. Most of our patients had exudative effusions, along with many patients being on anti-platelets, anti-coagulants or on positive pressure ventilation. Therefore, our real-world study suggests that pleural procedures can be performed safely and effectively using a handheld ultrasound device.

Prior studies report a complication rate of approximately 0.01 - 6.0% for pneumothorax using conventional ultrasound machines [3-5,8,9]. Our rates for complications are on the lower spectrum when compared to prior studies, with a pneumothorax rate of 0.6%. Our hemothorax risk was 0.6%, and prior studies report a similar bleeding risk of 0.1 - 1% [9,10]. It should be noted that our cohort included patients at a relatively higher risk of bleeding complications including patients with platelet count <50k, as well as patients on antiplatelets and anticoagulants. Despite this, the overall bleeding rate was low at 0.6%. Dangers et al found that the bleeding complication rate for patients on anti-platelet drugs was 3.2% [11]. The incidence of bleeding complications in patients on anti-platelet drugs in our study was 4.0%. Dammert et al reported no bleeding complications on patients who underwent small-bore chest tubes in patients on clopidogrel [12]. We recommend that every patient should be individually assessed for the urgency of needing a pleural procedure. If a patient has significant respiratory compromise needing drainage or needs a timely diagnosis, then pleural procedures should not be delayed. Our study shows acceptable safety of handheld ultrasound for performing pleural procedures in patients with low platelets, or use of anti-platelet or anti-coagulant drugs.

We performed 128 (38.8%) of our pleural procedures in patients receiving positive pressure ventilation, with the majority being on non-invasive ventilation (102 patients). The overall pneumothorax rate was 0.6%. Both pneumothoraces occurred while the patients were on non-invasive mechanical ventilation. Therefore, the pneumothorax rate with pleural procedures on positive pressure ventilation was 1.6% in our study (P=0.15). Prior data shows that risk of

pneumothorax with thoracentesis may be increased when patients are on mechanical ventilation [8]. However, our findings suggest that the pneumothorax risk remains small and can be safely performed with appropriate risk-benefit evaluation for the patient. It is difficult to discern whether being on NIV was the sole reason for the development of pneumothorax in these cases. Another potential contributing factor may be the difficulty in positioning due to their respiratory status which may have made the procedure more challenging.
Our study used the Sonostar handheld ultrasound, and did not compare different handheld ultrasounds; therefore, we cannot generalize these findings to all handheld ultrasounds. However, in clinical practice we have used the Butterfly and Phillips Lumify handheld ultrasound. In our experience, most handheld ultrasounds would provide similar image quality and results should be replicable in a similar setting. Handheld ultrasound costs vary between $2500 – 8000 USD depending on the brand. Most portable ultrasounds range between $10,000 to 40,000 USD, therefore, are much more costly than handheld ultrasounds. Handheld ultrasounds can be used for diagnostic purposes, with studies showing appropriate views for pleural ultrasound [13,14]. Newhouse et al found that handheld ultrasounds provide marginally lower image quality compared to portable ultrasound, and a safe site was found in 96.3% of patients with the handheld ultrasound [15]. Compared to portable ultrasounds, handheld ultrasound are easier to transport especially in large hospitals to perform bedside procedures, and may provide similar efficacy and image quality at a significantly lower cost [16]. Figure 3 shows images obtained from the handheld ultrasound in various pleural pathologies. Our study has some limitations. Firstly, our study was a single center study, which reduces the generalizability of these findings to all users. Secondly, due to resource limitations, we could not have a comparison arm as we did not have consistent access to a standard portable ultrasound machine. However, use of the portable ultrasound machine was not part of our study. Thirdly, we performed all these procedures at bedside, which may differ from conventional practice of performing in a procedure suite.

Conclusions

Our study suggests that handheld ultrasounds can be effectively and safely used for pleural procedures, including those with septated pleural effusions, patients on positive pressure ventilation and patients with relative bleeding contraindications. Further studies are needed to compare handheld ultrasounds to portable ultrasounds, and to compare different handheld ultrasounds.

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Table 1. Baseline characteristics of the study population.

Patient characteristics	Number (%)
Age	58.4±17.1 years
Gender (male)	190 (57.6)
Comorbidities	
Hypertension	177 (53.8)
Diabetes	119 (36.2)
Cardiac Dysfunction	52 (15.8)
Malignancy	76 (23.1)
End-stage renal disease	35 (10.6)
Cirrhosis	21 (6.4)
Platelet count ranges (x 10^9/L)	
>150	282 (85.7)
100-149	16 (4.8)
50-99	17 (5.2)
20-49	6 (1.8)
<20	8 (2.4)
Use of anti-platelet agent	50 (15.2)
Aspirin	8 (2.4)
Clopidogrel	34 (10.3)
Aspirin and clopidogrel	8 (2.4)
Use of an anti-coagulant	37 (11.2)
Direct oral anti-coagulant	17 (5.1)
Unfractionated heparin or	18 (5.4)
therapeutic enoxaparin	2 (0.6)
Warfarin	

Table 2. Pleural interventions performed.

Procedural Data	**Number (%)**
Pleural procedures successfully performed	329/332 (99.1)
Complications Hemothorax Pneumothorax	4 (1.2) 2 (0.6) 2 (0.6)
Pleural procedure site - Right	196 (59.4)
Successful aspiration of fluid on 1st aspirate	299(90.6)
Fluid drained in initial aspirate (median)	500 mL (IQR 300 – 800)
Exudative pleural effusion	264 (80.0)
Pus on initial aspirate	41 (12.4)
Septated effusion on ultrasound	73 (22.1)
Thoracentesis	127 (38.5)
Medical thoracoscopy	23 (7.0)
Tube thoracostomy 8 French small-bore chest tube 10 French small-bore chest tube 12 French small-bore chest tube Large bore > 20 French chest tube	179 2 (1.1) 72 (40.2) 95 (53.0) 10 (5.6)
Procedures performed on platelets < 50 x 10^9/L Thoracentesis Small-bore chest tube	 6 (1.8) 8 (2.4)
Procedures performed on anti-platelet drugs Thoracentesis Small-bore chest tube	 29 (8.8) 21 (6.4)
Procedures performed on therapeutic anticoagulation Thoracentesis Small-bore chest tube	 25 (7.6) 12 (3.6)
Procedures performed on positive-pressure ventilation Thoracentesis Small-bore chest tube	 40 (12.2) 87 (26.4)

Figure 1. Image of the handheld Ultrasound that was used for the pleural procedures. It connects wirelessly to a smartphone or tablet.

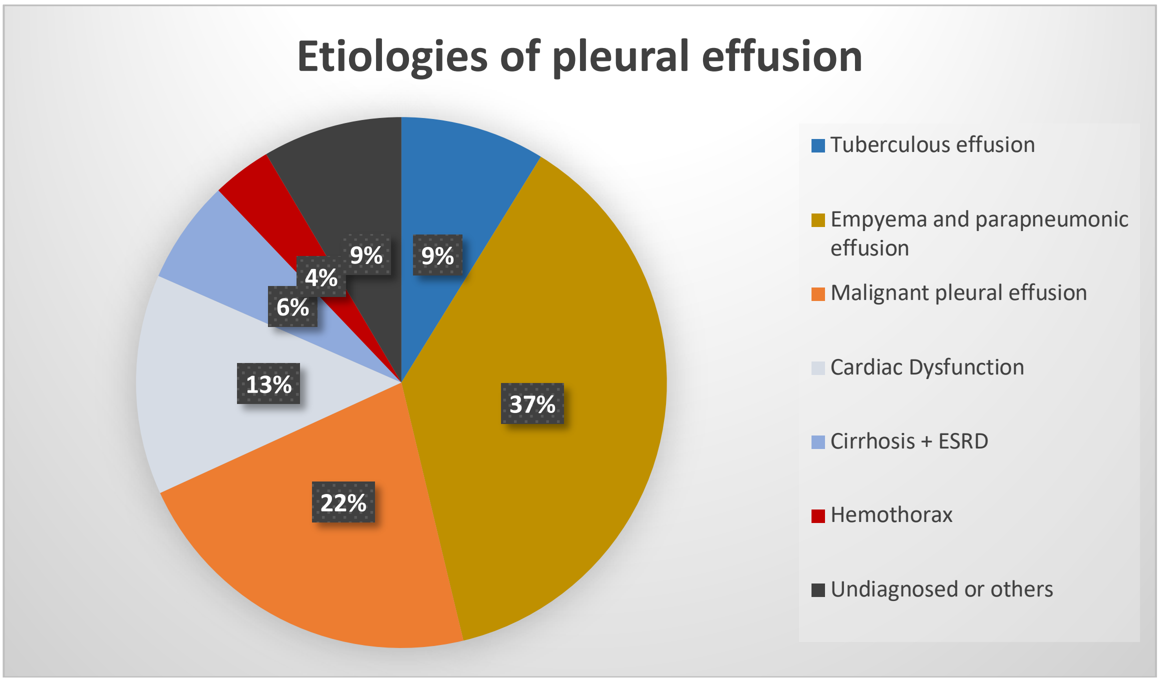

Figure 2. A pie chart depicting different etiologies of pleural effusions that were drained under handheld ultrasound guidance. *Of the 72 malignant pleural effusions, 12 were due to hematological malignancies and 60 were due to solid organ malignancies. **There were 12 tube thoracostomies done for hemothoraces, 5 were hemothoraces due to trauma, and 7 were spontaneous hemothoraces due to malignancy and/or anticoagulation. ***All patients with ESRD were on hemodialysis.

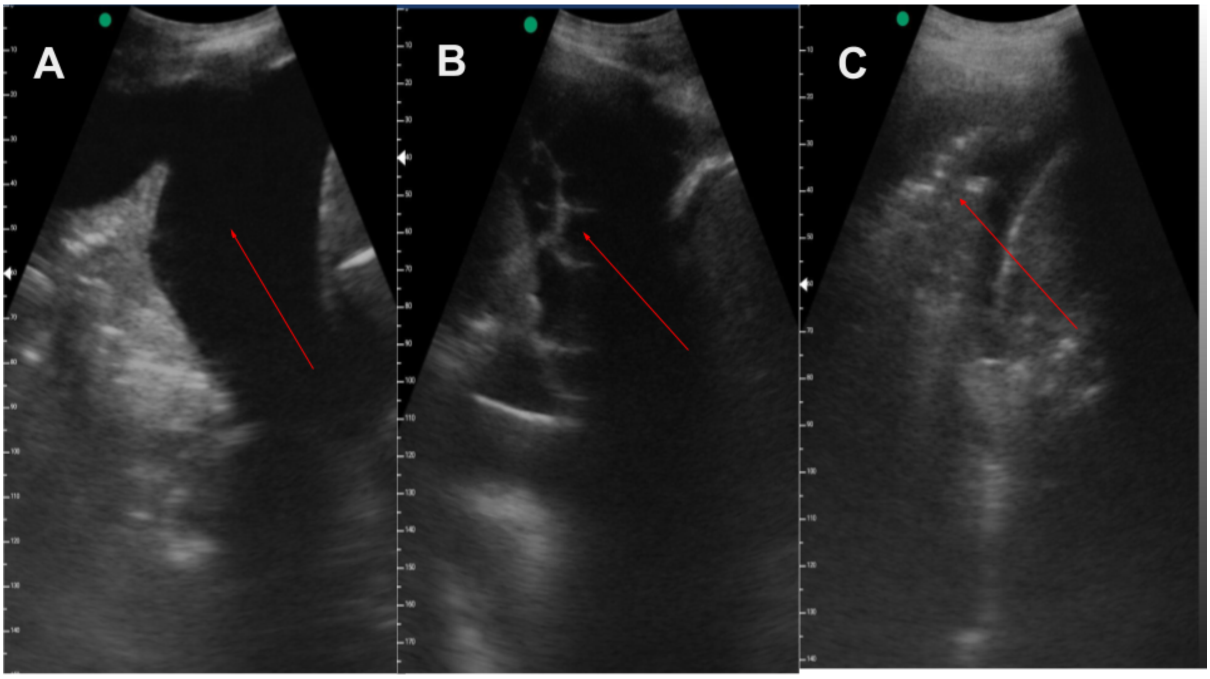

Figure 3. A) Image from the handheld ultrasound showing a simple moderate sized pleural effusion with underlying lung atelectasis. Thoracentesis was performed for this pleural effusion; B) image from the handheld ultrasound showing a complicated pleural effusion with multiple septations. A small-bore chest tube was placed for this effusion; C) image from the handheld ultrasound showing a small pleural effusion with predominantly consolidated lung. No pleural procedure was performed on this effusion.