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Effect of a pleural checklist on patient safety in the ultrasound era

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ABSTRACT

Background and objective: **Bedside ultrasound allows direct visualization of pleural collections for thoracentesis and tube thoracostomy. However, there is little information on patient safety improvement methods with this approach. The effect of a checklist on patient safety for bedside ultrasound-guided pleural procedures was evaluated.**
Methods: **A prospective study of ultrasound-guided pleural procedures from September 2007 to June 2010 was performed. Ultrasound guidance was routine practice for all patients under the institution's care and the freehand method was used. All operators took a half-day training session on basic thoracic ultrasound and were supervised by more experienced operators. A 14-item checklist was introduced in June 2009. It included systematic thoracic scanning and a safety audit. Clinical and safety data are described before (Phase I) and after (Phase II) the introduction of the checklist.**
Results: **There were 121 patients in Phase I (58.7 ± 18.9 years) and 134 patients in Phase II (60.2 ± 19.6 years). Complications occurred for 10 patients (8.3%) in Phase I (six dry taps, three pneumothoraces, one haemothorax) and for 2 patients (1.5%) in Phase II (one significant bleed, one malposition of chest tube) ($P = 0.015$). There were no procedure-related deaths. The use of the checklist alone was associated with fewer procedure-related complications. This was independent of thoracostomy rate, pleural effusion size and pleural fluid ultrasound appearance.**
Conclusions: **A pleural checklist with systematic scanning and close supervision may further enhance safety of ultrasound-guided procedures. This may also help promote safety while trainees are learning to perform these procedures.**

Key words: checklist, patient safety, pleura, thoracostomy, ultrasonography.

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SUMMARY AT A GLANCE

Little information exists on patient safety improvement methods in the era of thoracic ultrasonography. We evaluated the effect of a checklist in a before-and-after study of 255 patients. Complications decreased from 8.3% to 1.5%, suggesting that a pleural checklist may further enhance safety of ultrasound-guided procedures.

INTRODUCTION

Pleural procedures cause significant morbidity and mortality,[1] and pleural ultrasound is recommended to enhance procedural safety, for instance, to reduce the risk of iatrogenic pneumothorax.[2,3] Bedside thoracic ultrasound allows direct, point-of-care visualization of pleural collections for thoracentesis and tube thoracostomy.[4] It also permits precise measurement of chest wall thickness and selection of an appropriate aspiration needle length.

Using checklists is another method for patient safety improvement. It has been shown to improve patient survival by decreasing central line-related bloodstream infections and inpatient surgical complications.[5] Checklists have also helped to improve team communication, to mitigate critical information degradation through consecutive handovers in the intensive care unit and to avoid cognitive errors in diagnosis.[6–8] Even with high baseline standards of care, checklists can be valuable. For example, a comprehensive surgical safety checklist was associated with reduction of surgical complications and mortality in several Dutch hospitals.[9]

Thoracic ultrasonography was used to guide our pleural procedures as a service standard since 2007. We postulated that a checklist could enhance patient safety on top of thoracic ultrasound utilization. We thus aimed to investigate the effect on patient safety of a pleural procedure checklist that contained items that encouraged systematic checking of procedural indications, adequate patient preparation and monitoring, and clinical audit for complications.

METHODS

Thoracic ultrasound method

We performed a prospective safety audit of ultrasound-guided pleural procedures (thoracentesis, tube thoracostomy, Abrams needle closed pleural biopsy, medical thoracoscopy) from September 2007 to June 2010. Ultrasound-guided pleural procedures were routine practice for all patients under our care and the freehand method was used. All operators were familiar with pleural procedures done conventionally without ultrasonography and took a half-day practical session on basic thoracic ultrasound using plastic simulators. All bedside procedures were done or supervised by one of four senior fellows, including three of the authors (S.K.C., J.K., C.A.P). While informed consent was obtained for all pleural procedures, our Ethics Review Board waived the need for additional consent for research (DSRB B/2012/00586).

Pleural procedures were done either in the wards (for thoracentesis, tube thoracostomy or Abrams needle closed pleural biopsy) or in the endoscopy suite (for medical thoracoscopy). Ultrasound equipments were from Sonosite Inc, Bothell, WA, USA: P17 5-1 MHz transducer or C60e 5-2 MHz transducer attached to the MicroMaxx machine, or C15 4-2 MHz transducer attached to the 180PLUS machine.

Patients initially lay in the semi-recumbent position. Scanning of the chest from caudal to cephalad was done along the following lines: mid-axillary line from the kidney to the axilla and mid-clavicular line from the liver/spleen to the clavicle. If possible, the patient then sat upright, facing away from the operator. Scanning of the patient's back from caudal to cephalad was done along the following lines: posterior axillary line from the kidney to the axilla and mid-scapular line from the kidney to the scapula. The operator located the largest and most accessible pocket of fluid (or air for pneumothoraces) for thoracentesis and marked the location on the chest wall. Immediately after that and under aseptic conditions, the same operator then applied local analgesia and performed the pleural puncture at the marked site. We used a freehand method and not a real-time technique as we felt that the former was more practically manageable and less cumbersome.

Pleural safety checklist

We designed a sequential 14-item checklist and introduced it on 16 June 2009. It included systematic thoracic scanning and a safety audit. The same four senior fellows supervised all procedures. The checklist comprised the points that we felt were clinically important (Table 1). Points 1 to 10 would prompt the operator to carefully prepare for the procedure and to double-check on the pleural collection characteristics before actual puncture. In particular, Point 3 reinforced the need for systematic scanning, which was part of our protocol for all ultrasound-guided pleural procedures. Points 11–14 did not help prevent complications but served to quickly detect problems so that appropriate rescue steps could be taken early.

Table 1 Pleural safety checklist

1	Check completeness of equipment
2	Check for a clear indication
3	Locate a specific area for the pleural procedure
4	Check pre-procedural thoracic imaging
5	Check coagulopathy and other risks
6	Verify patient consent
7	Provide reasons for procedure done after office hours
8	Name the attending physician
9	Use bedside ultrasound
10	Document ultrasound appearance of fluid: Anechoic, or complex nonseptated, or complex septated
11	Measure pulse oximetry and heart rate continuously during the procedure
12	Obtain a post-procedural chest X-ray
13	Monitor parameters (including pulse oximetry) hourly for at least 4 h after the procedure
14	Document any complications (inclusive of dry taps, any amount of bleeding, haemodynamic compromise, respiratory compromise, pneumothorax)

Apart from operator self-reporting of complications, post-procedural chest radiographs (or occasionally computed tomography scans) were checked for pneumothoraces. We also checked the case records of the patients identified via the pleural checklists for additional complications to avoid underreporting. Complications related to pleural procedures were determined *a priori* to include the following: pneumothorax, subcutaneous emphysema, haemothorax, failed procedures due to dry taps, significant bleeding and any cardiorespiratory compromise. Dry taps were considered important complications as the inability to aspirate fluid might mean that visceral organs such as liver or spleen were instead punctured. Persisting with chest tube placement after a dry tap can also lead to disaster if the tube were inserted into visceral organs, diaphragm or lung parenchyma. Notably, visceral injury is considered the most important complication of pleural aspiration by the British Thoracic Society.[2]

We sought to improve the use of the checklist by designing it in consultation with the physician staff, then promoting it at our weekly departmental meetings and through email broadcasts. When cases of non-adherence were detected, reminders were sent to the physicians involved. We further enlisted help from the ward nurses, who would prompt doctors to complete the checklist before each pleural procedure.

Statistical analysis

Clinical and safety data are described before (Phase I) and after (Phase II) the introduction of the checklist. Univariate comparisons of proportions, means and medians were done using Fisher's exact test, Student's *t*-test and Wilcoxon rank-sum test respectively. Multivariable analysis of factors that might influence the complication rate was done using logistic regression controlling for checklist use, performance of tube thoracostomy, effusion size $\geq$ 50% of the hemithorax and presence of a complex nonseptated ultrasound pattern (as this pattern could resemble that of visceral organs). For multivariate analysis, four cases of tube thoracostomy for pneumothorax were excluded because effusion size and ultrasound pattern would not apply. Statistical analyses were performed using Stata 11 (StataCorp LP, College Station, TX, USA) and PASW 18 (SPSS Inc., Chicago, IL, USA), and level of significance was set at a two-tailed P-value < 0.05. We previously reported our results in abstract form at the European Respiratory Society 2010 conference.

RESULTS

From September 2007 to June 2010, 255 patients were studied, with 121 patients in Phase I and 134 patients in Phase II. Baseline characteristics before and after checklist introduction were comparable (Table 2), except that after checklist introduction, more thoracenteses and fewer tube thoracostomies were done, and there were fewer patients with complex nonseptated pleural effusions. There were only three patients (all in Phase I) who were undergoing mechanical ventilation during the pleural procedures, and they suffered no complications. Comorbidities such as congestive heart failure, chronic obstructive pulmonary disease, liver cirrhosis, diabetes mellitus, chronic renal disease and cancer were well matched (P-values all >0.3). In-hospital mortality was similar in both study phases and deaths were due to underlying disease conditions rather than iatrogenic complications.

After introduction of the checklist, the proportion of complications decreased from 8.3% to 1.5% ($P = 0.015$) (Table 3). Only the use of the checklist was associated with fewer procedure-related complications on both univariate and multivariate analyses (adjusted odds ratio 0.171, 95% confidence interval: 0.035–0.835, $P = 0.029$) (Table 4).

In order to answer the question of whether increasing experience could lessen the complication rate, data from the pre-checklist introduction phase (Phase I) were studied. The complication rates between the first 61 cases and the later 60 cases in Phase I were virtually identical (five complications in each group, $P = 1.000$). Similar analysis of the post-checklist phase was not done as the complication rate was too low for any meaningful result.

DISCUSSION

Our study showed that the use of a pleural checklist enhanced patient safety by reducing the procedural complication rate from 8.3% to 1.5%. This beneficial effect was independent of thoracostomy rate, pleural effusion size and pleural fluid ultrasound appearance. The results included a variety of procedural complications inclusive of iatrogenic pneumothorax and are applicable to a broad range of pleural procedures (thoracentesis, tube thoracostomy, Abrams needle closed pleural biopsy and medical thoracoscopy).

Several methods have been used to lessen the morbidity and mortality associated with pleural procedures. In some cases, only a few experienced operators were given the privilege to perform these procedures.[10] This would directly improve safety but may impair the learning experience of fresh trainees and may inadvertently lead to an erosion of expertise in later generations of pulmonologists. Furthermore, such a restrictive model is not applicable in teaching institutions responsible for the spread of procedural skills. In other instances, new technologies such as ultrasonography were employed. The premise is that

Table 2 Patient characteristics

	Phase I (before checklist) $n = 121$	Phase II (after checklist) $n = 134$	P-value
Age in years ± SD	58.7 ± 18.9	60.2 ± 19.6	0.528
Males (%)	87 (71.9)	101 (75.4)	0.570
Aetiology (%)			
Parapneumonic/empyema	46 (38.0)	42 (31.4)	0.292
Tuberculous	17 (14.0)	30 (22.4)	0.106
Malignant	30 (24.8)	34 (25.3)	1.000
Fluid overload	19 (15.7)	10 (7.5)	0.048*
Uraemic pleuritis	0 (0.0)	1 (0.7)	1.000
Pulmonary embolism	2 (1.7)	0 (0.0)	0.224
Haemothorax	1 (0.8)	2 (1.5)	1.000
Asbestosis	2 (1.7)	2 (1.5)	1.000
Pneumothorax	0 (0.0)	4 (3.0)	0.124
Yellow nail syndrome	0 (0.0)	3 (2.2)	0.249
Uncertain	4 (3.3)	6 (4.5)	0.752
Hospital LOS in median days, 5th–95th percentiles	9, 2–48	10, 2–34	0.546
In-hospital mortality (%)	14 (11.6)	14 (10.7)	0.844

* Statistically significant.
LOS, length of stay; SD, standard deviation.

Table 3 Procedure details and procedure-related complications

	Phase I (before checklist) $n = 121$	Phase II (after checklist) $n = 134$	*P*-value
Procedure type (%)			
Thoracentesis	19 (15.7)	40 (29.9)	0.008*
Thoracostomy	93 (76.9)	77 (57.5)	0.001*
Pleural biopsy	7 (5.8)	13 (9.7)	0.351
Thoracoscopy	2 (1.7)	4 (3.0)	0.686
Effusion size ≥ 50% of hemithorax (%)	69 (57.0)	61 (46.9)†	0.130
Side of puncture (right/left)	61/60	79/55	0.208
Puncture position: posterior/lateral	27/94	45/89	0.052
Ultrasound pattern (%)			
Anechoic	31 (25.6)	39 (29.1)	0.576
Complex nonseptated	60 (49.6)	49 (36.6)	0.043*
Complex septated	30 (24.8)	42 (31.3)	0.267
Pneumothorax	0 (0.0)	4 (3.0)	0.124
Size of chest tube: small/large‡	87/11 ($n = 98$)	74/12 ($n = 86$)	0.657
Proportion of complications (%)	10 (8.3)	2 (1.5)	0.015*
Types of complications	6 dry taps 3 pneumothoraces 1 haemothorax	1 significant bleeding stopping the procedure 1 chest wall malposition of tube thoracostomy	NA

* Statistically significant.
† Excludes four cases of pneumothorax.
‡ Small—size 7–12; large—size 20–28.
NA, not applicable.

Table 4 Analysis of factors that may determine procedure-related complications

	Complications present ($n = 12$)	Complications absent ($n = 239$)	Univariate *P*-value	Logistic regression analysis† OR	95% CI	*P*-value
Use of checklist (%)	2 (16.7)	128 (53.6)	0.016*	0.171	(0.035, 0.835)	0.029*
Use of thoracostomy (%)	9 (75.0)	157 (65.7)	0.756	0.889	(0.209, 3.784)	0.873
Effusion size ≥ 50% of hemithorax (%)	8 (66.7)	122 (51.0)	0.380	1.735	(0.473, 6.364)	0.406
Complex nonseptated U/S pattern (%)	5 (41.7)	104 (43.5)	1.000	0.756	(0.227, 2.522)	0.650

* Statistically significant.
† $n = 251$. Analysis excludes four cases of tube thoracostomy for pneumothorax because factors like thoracentesis, effusion size and ultrasound pattern would not apply. Nonetheless, no complications were noted for these four excluded cases.
CI, confidence interval; OR, odds ratio; U/S, ultrasound.

ultrasound allows visualization of pleural collections, improving success rates of pleural aspirations and pleural access.[11–13] Nonetheless, uncontrolled use of technology alone may not lead to patient safety improvement[14] and may conversely encourage operator overconfidence. As an illustration, the reported pneumothorax rate for ultrasound-guided thoracentesis could be up to 4.9%,[15] and the risk in mechanically ventilated patients appeared not to be improved by ultrasound use alone in a recent meta-analysis.[16]

To our knowledge, there has been little prior evaluation of a pleural safety checklist. Such a checklist is also not promulgated in current pleural safety guidelines.[2] Before the introduction of our pleural checklist, our complication rates were comparable with published results. We had a 2.5% pneumothorax rate, which falls within reported pneumothorax rates of 1.1–4.9% using ultrasound-guided thoracentesis.[10,15,17,18] We nonetheless sought further improvement as complications existed despite direct on-site supervision by experienced operators. We have found that usage of our 14-point pleural checklist, on top of thoracic ultrasonography, added a layer of safety to our practice. Quantitatively, the total rate of complications dropped from 8.3% to 1.5%. Qualitatively, potentially life-threatening complications such as visceral organ punctures (suggested by dry taps) and visceral pleural punctures (leading to pneumothoraces) have been eliminated. Nonetheless, some complications remained despite adherence to the checklist, proving that pleural procedures—as with all medical procedures—can never be completely risk free. After checklist introduction, we still had one case of significant thoracentesis site bleeding (likely from inadvertent puncture of an underlying vessel not visualized on ultrasound), which fortunately did not require any escalation of care or blood transfusion. We had another instance of chest tube misplacement within the chest wall of an obese patient, likely due to faulty insertion technique by a less experienced operator.

Several reasons may explain why implementation of our 14-point checklist led to improved complication rates. The use of a checklist served as a memory aid and controlled pause for operators to systematically perform crucial preparatory steps such as confirming the indication, verifying pre-procedural coagulation test results and requesting for post-procedural close monitoring. For example, the senior operator might deem pleural drainage to be unnecessary in cases of transudative effusions associated with heart failure. Alternatively, the senior operator on review of a plain radiograph might request for a computed tomography thorax to delineate complicated pleural anatomy before attempting any pleural procedure. This might improve the proper selection of the needle entry site and explain why there was a marked decrease in dry taps between Phases I and II. Furthermore, the pleural procedure might be delayed until coagulopathy was corrected, thus avoiding excessive bleeding. There may additionally be a selection bias for 'safer' cases after introduction of the checklist. While we did not manage to collect data on pleural procedures that were planned but which were eventually abandoned because of the checklist, more stringent selection of cases is a desired outcome. Importantly, this did not come at the expense of service capability because we rarely had to seek help from interventional radiology or cardiothoracic surgery for pleural procedures. The checklist might also have helped boost the overall safety climate among our team members, leading to better teamwork and communication.[19–23]

Our pulmonology unit decided to permit less experienced operators, under close and direct supervision, to perform the ultrasonography and the pleural procedures. We resolved not to restrict these procedures to a small group of senior personnel[10] and preferred to employ a continuous audit and quality improvement strategy to reduce complications. The pleural checklist was introduced as part of this process and to facilitate hands-on learning in a safe and controlled environment. This practice model is pragmatic, good for staff morale and allows less experienced operators to learn new skills from more experienced fellows, eventually generating more of the latter.

Our study has several limitations. Firstly, the before-and-after study design can bias the result whereby the experience and hence complication rates of the operators may improve with time. Similarly, our study design did not allow us to eliminate regression to the mean and any Hawthorne effects. However, thoracic ultrasonography was already used as a service standard for more than 6 months before our audit was conducted and secondary analysis of the pre-checklist phase data did not reveal any difference in complication rates between the earlier 61 compared with the later 60 cases. Secondly, we are unable to determine which components of the checklist were the key factors that lead to improved safety. It is likely that the mechanisms driving the beneficial effect of our pleural checklist were multifactorial.[5] Thirdly, some complications attributable to the pleural procedures could be missed or disregarded, although unlikely because we have actively included complications that have not been defined *a priori*, for example, chest tube misplacement within the chest wall. Fourthly, our results may only apply to patients who are not mechanically ventilated, although mechanical ventilation need not necessarily mean more complications.[24,25] Fifthly, there were more tube thoracostomy insertions in Phase I than in Phase II, but this difference did not affect the complication rates in subsequent univariate or multivariate analyses. Finally, cases of non-adherence may be missed when no pleural checklist is filled, although we have tried our best to minimize these with constant reminders at our weekly unit meetings and via email broadcasts.

We hope our study can generate interest in conducting further research to advance pleural procedural safety. A randomized controlled trial using a pleural safety checklist is needed to confirm the results of our before-and-after study, although we believe that the results would be concordant, as in the case of surgical safety checklists.[5,9] Further study could also be directed at the effects of using a pleural checklist on training safety and on more effective methods to improve checklist adherence, for example the Barrier Identification and Mitigation tool.[26] While our checklist is fairly short and simple to use, some clinicians would still find checklist use cumbersome. Despite this, the majority would probably agree that patient safety is paramount and would subscribe to using the checklist.[19] Based on the results of our quality improvement audit, our institution has implemented this checklist as a hospital-wide requirement since July 2011.

In conclusion, a pleural checklist with systematic scanning and close supervision may further enhance safety of ultrasound-guided procedures. The decrease in complications was independent of thoracostomy rate, pleural effusion size and pleural fluid ultrasound appearance. Using a pleural checklist may also facilitate safe ultrasound training.

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