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Improving Pleural Procedures: Training, Image Analysis and Pleural Manometry

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Abstract

Background Adverse events related to thoracentesis and chest tube insertion are common. International guidelines recommend improved procedural training and mandatory use of ultrasound (US). A particular problem can arise when managing a malignant pleural effusion. If lung entrapment is present, this changes the optimal treatment strategy.

Aims To increase the safety and therapeutic efficacy of pleural procedures, by improving training and extending the utility of US and pleural manometry to guide these procedures.

Methods The aims will be achieved through three study arms.

1. Assessment tools: Objective tools to assess the competency of physician-performed chest tube insertion (the Chest Tube Insertion Competency Test: TUBE-iCOMPT) and thoracic US (the Ultrasound-Guided Skills and Tasks Assessment Test: UG-STAT) were written in line with international evidence-based guidelines. The reliability and accuracy of the tools was demonstrated by applying them to assess a cohort of doctors performing thoracic US and chest tube insertion.

2. US of the intercostal artery (ICA): A method to visualise the ICA with US was initially developed on a cohort of patients undergoing routine thoracic ultrasound prior to thoracentesis. The sensitivity and specificity of US to screen for a vulnerable intercostal artery was then assessed in a second study, by comparing the position of the ICA found by US with that on computed tomography (CT) chest examination.

3i. Pleural manometry: A new method for continuous pleural manometry during thoracentesis (compared with the traditional intermittent method) was developed. By transducing pleural pressures from an epidural catheter sitting within the pleural effusion, pressure measurements can be made without halting the flow of fluid through the drainage catheter. On a cohort of patients undergoing thoracentesis, pleural manometry was performed simultaneously using the traditional and the new method. Differences in opening pressure and pleural elastance derived from each technique were compared, before demonstrating the feasibility of fully automated pleural manometry allowed by the new technique, by connecting the system to a urodynamics machine.

3ii. US and entrapped lung: A method to identify malignant entrapped lung with US prior to pleural effusion drainage was developed and assessed. Thoracic US with an echocardiogram machine was performed on a cohort of patients prior to thoracentesis. The displacement (mm) and deformation (%) of the atelectatic lower lobe due to the transmitted cardiac impulse, was measured using motion mode (M Mode) and speckle-tracking imaging (STI) respectively. The gold standard diagnosis of lower lobe entrapment was made according to post-drainage radiology. Data was randomly divided into a development and validation set. Data from the development set was used to construct receiver-operating curves (ROC), which described the ability of US to identify lung entrapment. Optimal diagnostic cut-offs selected from the ROC curves were then applied to the validation set, and diagnostic indices calculated.

Results

1. Both the TUBE-iCOMPT and UG-STAT showed a high degree of test-retest and inter-tester reliability, and were able to appropriately separate participants into beginner, intermediate and advanced groups.

2. Ultrasound was able to identify a vulnerable intercostal artery with a sensitivity of 86% and specificity of 30%. The performance of a high-end machine was not significantly better than a mobile machine, and an appropriately trained respiratory physician was as good as an experienced radiographer.

3i. There was no statistical difference in opening pressures (p=0.49) or pleural elastance (p>0.10) derived from each technique. The new technique allowed for fully automated real-time display of pleural pressures, drainage volumes and pleural elastance.

3ii. Motion analysis with US showed good diagnostic power to identify malignant entrapped lung prior to pleural effusion drainage, with an area under the ROC of 0.79 for M Mode and 0.86 for STI. The sensitivity and specificity were 50% and 85% for M Mode and 71% and 85% for STI respectively.

Conclusions

This PhD thesis has produced studies that will have a real impact on clinical practice. It has developed objective assessment tools with initial pilot studies demonstrating their validity. They could now provide the impetus for further studies to develop and refine such

methods for procedural competency assessment. While these studies are underway individual hospitals could use the tools to track an individual's progress through training and use these assessments as feedback opportunities. It has also produced novel extensions to the current use of ultrasound by the pulmonologist, documenting for the first time the possible use of US to identify a vulnerable ICA prior to chest drainage procedures and prospectively identify malignant lung entrapment. It has refined the current technique of pleural manometry, simplifying the practice for clinicians and allowing for fully automated recording and calculation of relevant parameters. These novel tools now provide the stimulus to further clinical study as outlined above. In time it is hoped these tools may improve outcomes and reduce adverse events suffered by our patients.

Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

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Dr Matthew Salamonsen

Publications during candidature

Peer Reviewed Papers

- Thoracic ultrasound demonstrates variable location of the intercostal artery
  Salamonsen M, Ellis S, Paul E, Steinke K, Fielding D
  Respiration 2012;83:323-329

- Physician-performed ultrasound can accurately screen for vulnerable intercostal arteries prior to chest drainage procedures
  Salamonsen M, Dobeli K, McGrath D, Readdy C, Ware R, Steinke K, Fielding D
  Respirology 2013;18:942–947

- A new instrument to assess physician skill at thoracic ultrasound including pleural effusion mark-up:
  Salamonsen M, McGrath D, Steiler G, Ware R, Colt H, Fielding D
  Chest 2013; 144(3):930–934

- A new instrument to assess physician skill at chest tube insertion – the TUBE-iCOMPT
  Salamonsen M, Bashirzadeh F, Ward H, Fielding D
  Thorax Online First, published on March 26, 2014 as 10.1136/thoraxjnl-2013-204914

- A new method for performing continuous manometry during pleural effusion drainage
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- Novel use of pleural ultrasound techniques can identify entrapped lung prior to effusion drainage
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Conference Abstracts

- Novel use of pleural ultrasound techniques can identify entrapped lung prior to effusion drainage
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  Primary author: M. Salamonsen
  Secondary authors: A. Lo, A. Ng, F. Bashirzadeh, W. Wang, D.I.K Fielding

- A new instrument to assess physician skill at thoracic ultrasound including pleural effusion mark-up: the UG-STAT
  Congress of The American Thoracic Society 2013
  Primary author: M.Salamonsen
  Secondary authors: R. Ware, H.G. Colt' D.I.K. Fielding

- Validation Of A Method For Continuous Pleural Manometry
  European Congress on Bronchology and Interventional Pulmonology 2013
  Primary author: M. Salamonsen
  Secondary authors: R. Ware, D.I.K. Fielding

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  Thoracic Society of Australia and New Zealand Annual Scientific Meeting 2013
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- Validation of a new instrument to assess physician skill at chest tube insertion: the TUBE-iCOMPT
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- Physician-performed ultrasound can reliably screen for a vulnerable intercostal artery prior to chest drainage procedures
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Publications included in this thesis

Chapter 2

A new instrument to assess physician skill at chest tube insertion: the TUBE-iCOMPT

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Contributor	Statement of contribution
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Chapter 3

A new instrument to assess physician skill at thoracic ultrasound including pleural effusion mark-up: The UG-STAT

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Chapter 4

Thoracic ultrasound demonstrates variable location of the intercostal artery

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Physician-performed ultrasound can accurately screen for a vulnerable intercostal artery prior to chest drainage procedures

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Chapter 6

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Chapter 7

Novel use of pleural ultrasound techniques can identify entrapped lung prior to effusion drainage

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Contributions by others to the thesis

The principal supervisor, Dr David Fielding was involved in the conceptualization and planning of all studies, and edited all write-ups.

The staff in The Department of Thoracic Medicine at The Royal Brisbane and Women's Hospital, assisted in recruitment of patients and the performance of procedures, which formed part of the studies.

Staff in the Department Medical Imaging at The Royal Brisbane and Women's Hospital, including David McGrath, Craig Readdy, Karin Dobeli and Karin Steinke assisted with ultrasound and CT scans, and facilitated my involvement in their department.

Dr Robert Ware assisted with the study design and statistical analysis in most studies.

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Keywords

pleural effusion, ultrasound, thoracentesis, intercostal catheter, procedural training, pleural malignancy, pleural manometry, lung entrapment, trapped lung

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Abbreviations

US	Ultrasound
ICA	Intercostal artery
RPO	Re-expansion pulmonary oedema
EBUS	Endobronchial Ultrasound
BSTAT	Bronchoscopy skills and tasks assessment test
BSET	Bronchoscopy step-by-step evaluation tool
EBUS-STAT	Endobronchial ultrasound skills and tasks assessment test
ICS	Intercostal space
IPC	Indwelling pleural catheter
CT	Computed tomography
PEL	Pleural elastance
STI	Speckle tracking imaging
SR	Strain rate
TDI	Tissue Doppler imaging
ROI	Region of interest
TUBE-iCOMPT	Chest tube insertion competency test
ICC	Intraclass correlation coefficient
ICC (Chapter 4 only)	Intercostal catheter
ANCOVA	Analysis of covariance
CI	Confidence interval
UGSTAT	Ultrasound-guided skills and tasks assessment test
M Mode	Motion mode
ROC	Receiver operating curve
EBUS	Endobronchial ultrasound
TSANZ	Thoracic Society of Australia and New Zealand

Chapter 1

Introduction, Literature Review and Study Design

Literature Review

Introduction

Pleural effusions are a common medical problem with an annual incidence of approximately 1.5 million in the United States alone[1]. Investigation and treatment usually require some sort of drainage procedure, most commonly thoracentesis or chest tube insertion[2]. Although the use of ultrasound (US) to guide such procedures reduces adverse events and has become the medical standard, there is still an alarming rate of morbidity and mortality associated with these procedures[3]. Factors consistently associated with these complication include lack of doctor procedural training and supervision, the inability of routine pleural US to identify the intercostal artery (ICA) and poor clinical decision making leading to an excessive number of unnecessary procedures[4].

Training

Traditional medical training

Traditional training in Medicine has followed the apprenticeship model typified by the phrase 'see one, do one, teach one'. Trainees imitate the actions of skilled mentors and are subjectively assessed by their supervisors[5]. One of the problems with this traditional apprenticeship paradigm, is that the amount of training required by any individual to gain a particular level of expertise varies[6-8]. Also centres do not have standardised procedural training programs and so trainees get variable experience depending on where their training occurs[9,10]. Thus not all trainees reach the expected level of procedural competence by the end of their training[10-12].

Procedural Adverse events

Safety of medical and surgical procedures, including thoracentesis and chest tube insertion, has traditionally been directly ascribed to the technical abilities of the operator[13]. Re-evaluation of this assumption was forced following the publication of two landmark reports, which highlighted the number of adverse events occurring in hospitals as a consequence of procedural errors. In the USA it was estimated that as many as 98,000 people die in any given year from medical errors[14], while in the UK, an audit over a four year period (2005 to 2008) revealed 12 deaths and 15 cases of serious harm due to erroneous insertion of chest tubes[4,15]. The latter report identified a number of modifiable factors that lead to adverse events. These included: lack of physician training and supervision, inadequate imaging and knowledge of published insertion guidelines, as well as inappropriate choice of insertion sites. These finding have been replicated in large reviews[16]. In parallel with this, there has been a growing understanding of the importance of a local system that incorporates quality improvement initiative, universal protocols and effective communication[17,18].

Adverse events related to thoracentesis and chest tube insertion

Complications associated with thoracentesis and chest tube insertion have been summarised by Wrightson and include: accidental chest tube removal or blockage (average 4–14%), chest tube malpositioning (1–7%), haemothorax (1–6%), iatrogenic pleural infection (2–3%), significant pain (6–12%), pneumothorax (3–9%), and re-expansion pulmonary oedema (RPO; 0–1%)[19]. The incidence of more serious adverse events such as visceral injury and even death, are harder to quantify. To improve the safety of these procedures requires process change, reinforced by intensive training and a change in the medical culture[20]. Appropriate training allows operators to recognise and modify a range of factors that lead to adverse events [3].

Probably the most important patient-related factor is to only perform the diagnostic or therapeutic procedure in those who are likely to benefit - Primum non nocere (first, do no harm)[21]. Another key to reducing adverse events is to prevent unnecessary procedures. Effusions of a known cause, should not undergo repeated thoracentesis unless there is a therapeutic benefit to the patient. For example, bilateral effusions in a patient with clinically-overt heart failure, do not need to be tapped before a trial of diuresis[22]. The appropriate first step in investigating a pleural effusion is usually a diagnostic tap, not insertion of a chest tube[2].

The major procedural-related factor associated with adverse events is the absence of US guidance[23,24]. Use of US to guide the ideal site for thoracentesis or chest tube insertion, reduces the incidence of unsuccessful (dry) taps, inadvertent organ injury, and pneumothorax[25,26]. Non-emergent procedures should be performed in hours in a dedicated procedure room. System and institutional policy-related factors, are also critical and include: providing effective training programs, developing and implementing institutional procedural guidelines, performing non-emergent procedures in office hours in a procedure room, having adequate supervision and staff support, using standardised and familiar equipment, ensuring effective communication between team members and the use of pre-procedural checklists[27-29].

The effectiveness of introducing such measures into clinical practice, and the consequent reduction in adverse events is exemplified by a landmark study performed at the Mayo Clinic in 2009[30]. By restricting physicians performing thoracentesis to only those who had completed a structured training program and proved procedural competence, and making bedside US-guidance mandatory for all thoracenteses, the rate of post-procedure pneumothorax was reduced from 8.6% to 1.1%. More recently, a larger study has shown that similar low complication rates can be achieved across a large tertiary hospital, regardless of whether pulmonologists or non-pulmonologist performed the procedure, when a program of standardised training, mandatory US guidance and a pre-procedure pleural checklist were instituted[31].

Evolution of medical training

Consequent to acknowledgement of the inadequacy of traditional teaching methods, there has been a switch from a structure and process-based system (which defines the training experience by a specified exposure eg the requirement to perform 100 bronchoscopies during respiratory medicine training) to a competency-based system, where the educational process is defined and driven by the desired outcome (e.g., competence to perform a bronchoscopy unsupervised)[32-34]. This change has been cemented by 21st century societal views, where accountability to the public for the competence of practicing physicians, has become a driving force behind educational guidelines[35].

Acknowledgement of this procedure-related morbidity and mortality and the need for a change in approach to procedural training prompted the establishment of The Australian Commission on Safety and Quality in Health Care[36]. This is an independent authority which monitors medical procedural practice and adverse events in Australia, and coordinates improvements in safety and quality in health care. As part of this, they have developed an online training module for chest drain insertion available free to all doctors, nurses and allied health practitioners[37].

Training in the 21st Century

Recent international guidelines state that procedural training should involve a combination of didactic learning, simulation training and supervised practice until the candidate is competent[27,38,39]. There are now internet-based resources for procedural skills, including thoracentesis and the insertion of chest tube[40,41]. These are free of charge and accessible to anyone with an internet connection, and provide the theoretical knowledge previously only available through textbooks or lectures.

Initial hands-on training should commence with simulation rather than live patients, as this provides a risk free environment for the acquisition of basic skills[38,42]. In support of this, there has been a plethora of publications in the last five years describing outcome-based training programs utilising simulated scenarios, with improved trainee competence, satisfaction and patient outcomes[6,11,30,32,43-48]. Performance on simulators has been found to reliably reflect performance on patients and expected proceduralist competence based on clinical experience[8]. With the development of virtual reality simulators, the realism and availability of these systems to trainees promise to continue to improve[49-52].

Assessment tools

If competence is to become the new metric by which to assess adequacy of training, then objective assessment tools to assess this competence must be developed[5]. There are various types of assessment, such as multiple-choice questionnaires, directly observed procedures with checklist assessment points or more subjective global rating scales[53-57]. Checklists can often miss 'intangibles' in performance i.e. how all the steps are put together, and may disadvantage experts who tend to take short cuts in appropriate contexts. Global rating scales while capturing these intangible markers of performance, are subjective and can lack reliability, due to lack of specific criteria against which assessment is made[58,59]. Thus the most practically useful assessment tools use a combination of several different methodologies, which can partially compensate for flaws in any one method[60-63]. Once an assessment tool is created, it needs to demonstrate reliability (the degree to which the measurement is accurate and reproducible) and validity (whether the assessment measures what it claims to measure), before clinical application[64].

Three studies highlight all the above issues, in the development of tools to assess competency at performing diagnostic bronchoscopy and endobronchial ultrasound (EBUS): the Bronchoscopy skills and task assessment tool (BSTAT) and Bronchoscopy step-by-step evaluation tool (BSET)[65], and the Endobronchial Ultrasound Skills and Tasks Assessment Tool (EBUS-STAT)[66]. They measure the skill of a bronchoscopist performing a diagnostic bronchoscopy or EBUS procedure, and each makes use of the different assessment methods detailed above. Objective checklist-style marking points cover all the individual elements and nuances that make up a safe and effective procedure while confirming the proceduralist can identify and enter all the individual bronchial segments (BSTAT and BSET) or locate all the lymph node stations and correctly perform transbronchial needle aspiration (EBUS-STAT). Visual quizzes test participant recognition of anatomy and the normal or pathological appearances of bronchoscopic or EBUS images. The BSET involves a series of graded training manoeuvres that direct the learner through the incrementally difficult moves of bronchoscopy while the examiner subjectively scores the performance of each manoeuvre according to a global rating scale, focusing on four different aspects of procedural skill: scope manipulation, body posture and hand positions, identification of anatomy and the ability to perform specific exercises. Studies validating these assessment tools involved two examiners concurrently scoring 22 participants (ranging in level from novice to expert) on two separate occasions. Reliability of the assessment tools was demonstrated by strong test-retest and inter-tester score agreement, while validity was supported by the assessment instruments' ability to discriminate between novice, intermediate and expert bronchoscopist.

Prior to this thesis, no tools existed to assess proceduralist competence at thoracic US or chest tube insertion.

Current Use of Thoracic US

US is a rapidly becoming an invaluable clinical tool across a range of medical disciplines, largely owing to its ease of use, lack of radiation and portability. When used to guide thoracentesis or chest tube insertion, it reduces adverse events and increases success[67]. Despite this, it's potential benefit to the practice of respiratory physicians is underestimated[68] and a large recent audit in the United Kingdom showed US was utilised in only 69% of thoracentesis or chest tube insertion procedures[69]. There are 2 different techniques whereby US can be used to guide thoracentesis or chest tube insertion: 'X marks the spot' or real-time guidance[70]. The 'X marks the spot' technique is the most easily learnt and consequently most widely practiced[28]. Thoracic ultrasound is used to image the effusion and anatomical structures such as the diaphragm as well as identify areas where the lung is in close proximity to the chest wall and thus at risk of needle puncture. Once the optimal site for puncture is located, an ‘X’ is marked on the skin before the US probe is put down and the needle introduced in the traditional manner[27]. It is important that the US is performed immediately prior to needle insertion, as remote ‘X marks the spot’ with subsequent thoracentesis at a later time is associated with the same rate of adverse events as a blind procedure [24]. For real-time guidance, US is initially used in the same way to locate the ideal site for needle insertion. However the needle is then inserted obliquely beneath the US probe, such that the needle can be directly visualised traversing the chest wall and passing into the pleural effusion[71]. Although not required for drainage of larger non-septated effusions, real-time US guidance is safer for drainage of small effusions, may allow safe pleural drainage in the presence of coagulation disorders and is often necessary to access loculated or organised effusions[27,28,70,72-74].

Importance of the Intercostal artery

Traditionally, the intercostal neurovascular bundle has been thought to run in the sub-costal groove behind the inferior border of each rib[75], and thus be protected from injury during procedures through the inter-costal space (ICS). This is not always the case however, as evidenced in a number of studies. As a trend, the neurovascular bundle is located lower in the ICS in positions closer to the spine, and steadily migrates behind the overlying rib as one moves more laterally[46]. Despite this reliable trend, significant variation between individuals has been observed. Wraight et al documented the position of the neurovascular bundle, relative to the superior rib, within intercostal spaces 4 to 6 in the mid-axillary line of 38 cadavers. The location of the ICA relative to the ribs within the ICS was highly variable, ranging from 50% of the ICS above to 43% of the ICS below the inferior border of the superior rib[76]. Another factor influencing the location of the ICA at any specific point is the tortuosity of its course. Tortuosity of the artery has been shown to increase with age, most markedly so above the age of 60, where its course can be almost sinusoidal[77]. Finally, an additional vessel located in the inferior region of the ICS, the collateral artery, has been reported in cadaveric dissection studies[76,78]. In all cases, a collateral artery arose from the ICA between the corresponding vertebra and angle of the rib, and could be as large as the ICA.

Visualisation of the ICA with Doppler US has been well described, especially in studies of chest wall tumours, and has a characteristic spectral pattern on pulse wave Doppler[79-83]. In these studies, the US probe is orientated transversely, along the ICS, such that the ICA is imaged in the longitudinal plane. The ICA has a typical monophasic high impedance flow signal on spectral Doppler analysis, which allows its differentiation from bronchial and pulmonary blood vessels[83]. However, acknowledgement of the ability of US to visualise the ICA has not been widespread in the international community, as evidenced by its absence from a number of recent reviews[3,84,85]. Indeed, some international pleural procedure guidelines have published statements refuting the ability of thoracic US to image the intercostal vessels at all[27].

To reduce inadvertent injury to the ICA during thoracentesis or chest tube insertion, it is recommended to insert the needle just above the superior margin of the underlying rib[19,27]. However, bleeding from a lacerated ICA continues to be a rare but serious complication of these procedures[16,26,86].

Management of malignant pleural effusion

The presence of malignant cells in the pleural space indicates disseminated cancer and confers a worsened prognosis[87], with a median survival of four months[88]. Cancers that most commonly involve the pleura are lung (in men) and breast (in women)[89]. The bulk of the remainder are due to lymphomas, cancer of the gastrointestinal or genitourinary tracts, cancer of unknown primary and malignant mesothelioma[90]. Due to past crocodolite mining, Australia has the one of the highest rates of mesothelioma in the world[91].

Treatment of pleural malignancy does not prolong survival, so management is directed towards palliation[92]. Options include observation, repeated thoracentesis, chemical pleurodesis (via chest tube or thoracoscopy) or insertion of an indwelling pleural catheter

(IPC)[93]. Factors affecting which option is appropriate include predicted survival time, symptom, underlying cancer type and responsiveness to systemic therapy, the ability of the lung to fully expand following drainage of the effusion, and patient preference[92,94,95].

As all interventions are palliative, if the diagnosis is known and a patient does not have symptoms attributable to the pleural effusion, or has symptoms that don't improve following drainage of the pleural effusion, observation alone is recommended[95]. Thoracentesis can provide effective symptomatic benefit, but is associated with a high (98-100%) rate of recurrence[96] and is therefore only recommended in patients whose life expectancy is short (1-3 months) or who have very slowly re-accumulating pleural fluid[92]. For patients with a longer life expectancy and who gain symptomatic benefit from effusion drainage, the options for management are pleurodesis or insertion of an indwelling pleural catheter[97].

Chemical pleurodesis is a procedure that obliterates the pleural space and prevents re-accumulation of pleural fluid, by inducing adhesion between the visceral and parietal pleura[98]. Instillation of a sclerosant such as talc as a slurry through an intercostal catheter, or insufflation at thoracoscopy, incites an inflammatory reaction, activation of the coagulation system and deposition of fibrin[99,100]. In a large meta-analysis of more than 1000 patients undergoing chemical pleurodesis, successful pleurodesis (defined as the non-reaccumulation of pleural fluid) was 64%[101]. Although not all reports are consistent and there is a lack of large prospective randomised trials, for most patients there is probably little difference in the success rates between introduction of sclerosant via chest tube or thoracoscopy, although the latter may be superior in people with loculated pleural collections[102-104]. Predicting who will have a successful pleurodesis is difficult[105]. Earlier studies found a pH <7.2 was useful however a more recent systematic review refutes this[106]. Karnofsky performance status < 70 and a massive pleural effusion on CXR have also been associated with poor pleurodesis outcomes[89]. Good apposition between the visceral and parietal pleura is required for pleurodesis. In accordance with this, the main factor leading to unsuccessful pleurodesis, is failure of the lung to fully expand following pleural fluid drainage, the so called 'trapped lung'[98,107-111], which may occur in up to 30% of people with malignant pleural effusion[103]. Documentation of full lung expansion with imaging, following complete drainage of the effusion, is recommended prior to pleurodesis[107] although some guidelines, based on expert opinion, still recommend pleurodesis if more than half the lung is not trapped[95]. Thus pleurodesis is an appropriate management option for patients whose symptoms are relieved by drainage of the pleural effusion, have a life expectancy greater than 1-3 months, and whose lung fully re-expands following pleural fluid drainage[88].

Insertion of an IPC is an alternative first line treatment and the appropriate choice for patients with lung entrapment or who have had a failed pleurodesis [95,107,112-114]. An IPC is a fine bore chest tube, that is tunnelled under the skin before exiting, reducing catheter-associated infection allowing for longer-term use in the outpatient setting[115]. Relief of dsypnoea is achieved in more than 90% of patients[116]. In a randomised study, survival was unchanged when compared with chemical pleurodesis, and around 40% underwent spontaneous pleurodesis during the course of the trial[117]. More recent studies have replicated these results, demonstrating comparable symptom relief[118]. IPCs have the added benefit that they can be inserted as an outpatient procedure and are associated with fewer inpatient days for the life of the patient[119]. A study specifically examining the efficacy of IPC for patients with trapped lung, showed 10 of 11 patients to have symptomatic improvement[120]. The major complications associated with IPCs are catheter dislodgement, the development of loculations and infection[121].

Identification of entrapped lung and pleural manometry

Definition of entrapped lung

Failure of the lung to fully re-expand following drainage of a pleural effusion has been described since the early 20th century[122-124] and termed trapped lung. Trapped lung is the mechanical complication of a restrictive visceral pleura, increased elastic recoil of the lung or endobronchial obstruction[125]. The naming of this clinical entity can cause confusion, as it implies a single aetiology, whereas in reality trapped lung can be due to various pathologies, and so a more precise system of classification has been proposed[126]. Lung entrapment is the term given to restriction of lung expansion due to an active pleural process or active inflammation. Common causes include malignancy, haemothorax, empyema/complicated parapneumonic effusion, uraemia with pleural effusion, radiation therapy, rheumatoid pleurisy or post coronary artery graft bypass surgery[125]. Trapped lung on the other hand, is a more benign condition that occurs as the consequence of remote pleural inflammation. Resolution of the inflammatory response results in the formation of a fibrous pleural peel, which restricts lung expansion after pleural fluid is drained[111]. Finally, pleural malignancy does not clearly fall into the category of trapped or entrapped, and the term non-expandable lung is often used.

Current methods to identify unexpandable lung

Trapped and entrapped lung have characteristic profiles on pleural fluid analysis, thoracoscopic appearance, pleural biopsy, imaging and pleural[111,125,127-130]. An effusion in trapped lung develops due to an excessively negative intrapleural pressure, which draws fluid from the blood according to Starling's law[131]. The pleural effusion is typically pauci-cellular with a mononuclear predominance and is a transudate (low protein and LDH), while thoracoscopy reveals a thin pleura that restricts lung expansion and on histology shows mature fibrosis[127]. Imaging may show ipsilateral mediastinal shift and a mildly thickened visceral pleura (normally only visible on air-contrast computed tomography (CT)[130]. In the case of entrapped lung however, pleural fluid accumulates due to elevated capillary permeability which accompanies active pleural inflammation. The fluid is exudative with an elevated white cell count (lymphocyte or neutrophil predominance depending on the underlying aetiology)[125]. Imaging usually reveals contralateral mediastinal shift, more marked pleural thickening and evidence of accompanying pathology[125].

In a study by Light et al[128] observing pleural pressure changes during thoracentesis, it was proposed that a negative opening pleural pressure and an elevated pleural elastance (PEL) (change in pleural pressure divided by the volume of pleural fluid removed) of >25cmH2O/L occurred in patients with trapped lung. They also posited that the opening pressure and PEL may give clues to the aetiology of the effusion (malignancy vs infection). It has now been established that the PEL, calculated during thoracentesis, differentiates between those with normal, entrapped and trapped lungs (Figure 1)[126,132]. In the presence of normal underlying lung, opening pressure is positive and removal of pleural fluid results in very little pressure change. In the case of trapped lung, opening pressure is negative (usually <-5cmH2O) and PEL is elevated (typically >19-25cmH2O/L)[109,127,133], with a steep PEL curve reflecting a dramatic change in pleural pressure as effusion is removed. Entrapped lung is characterised by a positive opening pressure and a bimodal PEL curve. Initially there is little change in pleural pressure as pleural fluid is removed. Once a critical point is reached however, such that the restriction of the underlying lung is unmasked, pleural pressure drops rapidly, and the slope of the PEL curve resembles that of trapped lung[125].

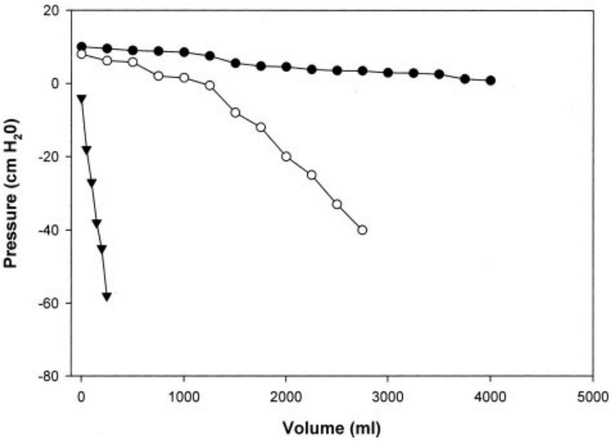

Figure 1 Pleural elastance curves for normal (black dots), entrapped (circles) and trapped (black triangles) lung. (Reproduced with permission from Doelken et al. Pleural manometry: technique and clinical implications. Chest 2004)

Although pleural manometry can predict lung entrapment with some success, this technique has not gained wide acceptance, and entrapped lung is normally only diagnosed on imaging following complete evacuation of the effusion or failure of pleurodesis[95]. Better predictors for the presence of lung entrapment are desperately needed[134].

Pleural manometry to guide thoracentesis

Although the ability of pleural manometry to provide information on the physiology of the pleural space and allow identification of trapped or entrapped lung during pleural effusion drainage is widely acknowledged, its role in routine clinical practice to guide thoracentesis is less clear[135,136]. This is because there is inconsistent and sometimes conflicting evidence on the benefits of pleural manometry during thoracentesis, it requires equipment that is not readily available to most pulmonologists and needs additional training[135]. Some argue that pleural manometry can shed light on the cause of pneumothorax following thoracentesis[137], guide safe large volume thoracentesis[133,138] and predict those who will benefit from a successful pleurodesis[109]. A study of 185 patients undergoing thoracentesis, showed that large volumes of pleural fluid (up to 6.5l) can be safely drained if pleural manometry is performed and drainage ceased if pleural pressure falls below -20cmH20[138]. Critics of the technique point out that the evidence for avoidance of re-expansion pulmonary oedema by terminating fluid drainage once pleural pressure drops to a critical value, is only founded on early animal studies, the results of which have been extrapolated to clinical practice in humans[139,140]. However, due to the high mortality associated with re-expansion pulmonary oedema (up to 20%)[141], and the fact that pleural manometry is not performed in most centres around the world, current guidelines err on the side of caution and suggest that no more than 1.5L of fluid is removed at any one time[27,107].

Pleural Manometry – Technique

Pleural pressure can be measured during thoracentesis by use of a water manometer[128], an overdamped water manometer (by means of 2 lengths of IV tubing connected via a 22g needle inserted into an ejection port)[126] or an electronic transducer connected to a standard ICU or anaesthetic monitor[132] (Figure 2). At times of recording intrapleural pressure, flow through the system is stopped (with a three-way stopcock or similar) so that the pressure measured in the tubing on the outside of the chest, is equal to the intra-pleural pressure. Following recording of the pressure, drainage is recommenced. This process is iterated however many times the pressure needs to be recorded, but typically every 250ml up till the drainage of 1L of pleural fluid, and then after drainage of each 100mls thereafter[126,128]. A recent study described a method of recording pleural manometry with an electric transducer connected to a standard laptop computer, by means of an analogue-to-digital converter, such that data could easily be analysed with computer software in real time[142]. With all current methods, flow through the system has to be stopped during pressure recording to avoid artefactual measurements.

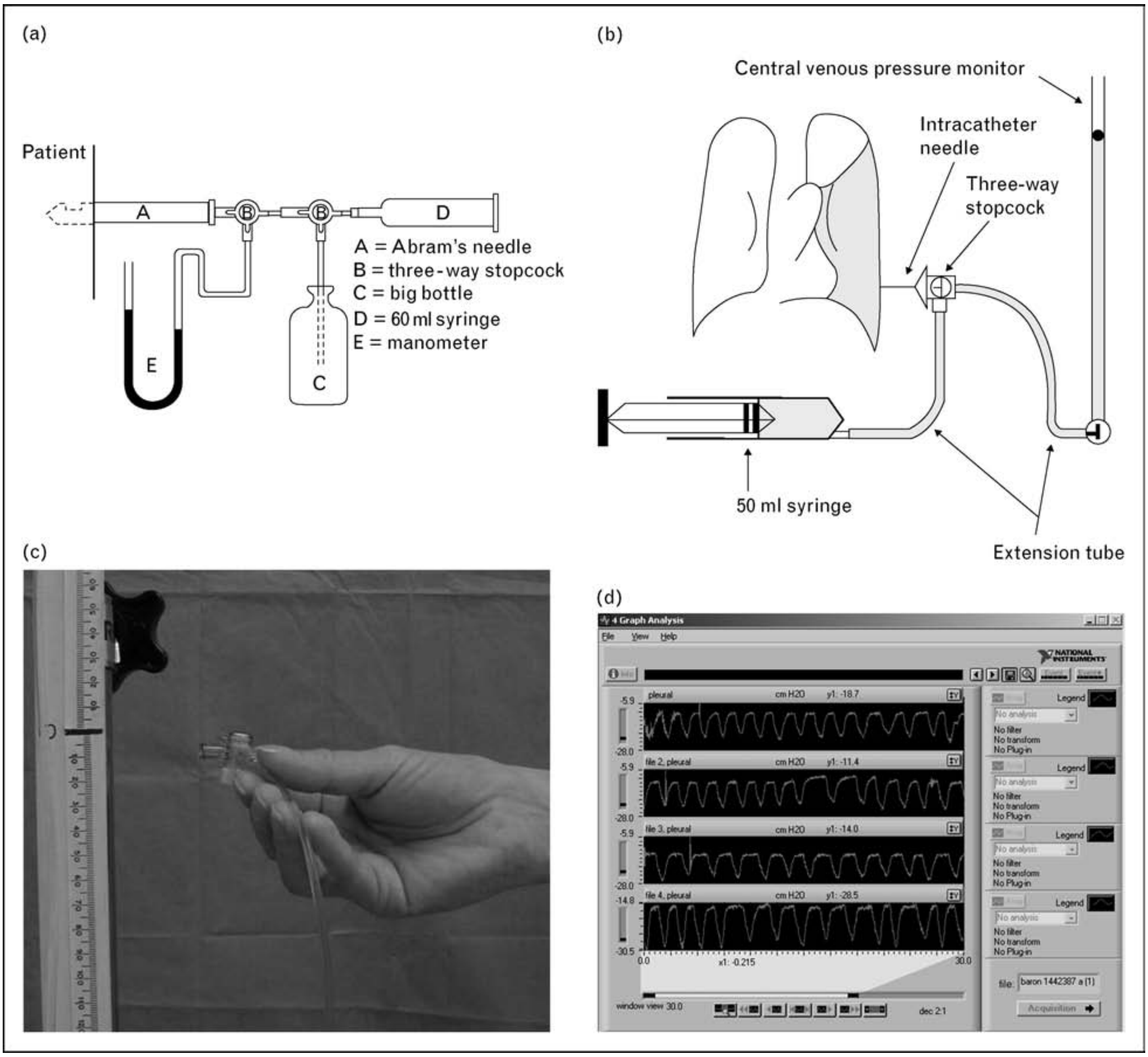

Figure 2 Methods for performing pleural manometry. (a) U-shaped manometer used by Light et al[128] (b) Manometer used by Lan et al[109] (c) Bedside manometry, courtesy of Peter Doelken MD. (d) Screenshot of pleural manometry using BioBench software (National Instruments, Austin, Texas, USA). (Reproduced with permission from Feller-Kopman. Therapeutic thoracentesis: the role of ultrasound and pleural manometry. Curr Opin Pul Med 2007)

Measurement of tissue deformation by US: Elastography and Speckle-Tracking Imaging

Recent progress in US technology has led to the development of elastography, which quantifies tissue elasticity or it's deformation due to some applied force. This deformation is described by tissue strain (ε), which is mathematically defined as the change in length of a region, divided by its original length $\varepsilon = (l-l_0)/l_0$ [143].

Malignant tissue tends to be stiffer than non-malignant tissue[144] and elastography now has an established role for identification of malignancy in the assessment of breast masses, prostate disease and lymph nodes accessible by endoscopy or bronchoscopy[145-148]. In these situations strain associated with random movement due to surrounding vascular pulsations is measured. As the magnitude of strain will vary according to the force of these random vascular pulsations [149], the ratio of the strain in the diseased tissue to that in non-diseased adjacent tissue is calculated, as a way of normalising measurements in different locations and at different times[150].

Echocardiographic strain imaging is used in cardiology to analyse the contractility of the myocardium throughout the cardiac cycle, using either tissue Doppler analysis or Speckle-Tracking Imaging (STI)[151,152]. By convention, negative strain indicates fibre shortening or myocardial thinning, whereas a positive value describes lengthening or thickening, relative to a designated point of reference. Change in strain per unit time is termed the strain rate (SR). As SR (1/s) is the spatial derivative of tissue velocity (mm/s), and strain (%) is the temporal integral of SR, all of these three parameters are mathematically linked to each other[153] (Figure 3). Strain gives information on the magnitude of tissue deformation, while SR describes the timing of that deformation[154].

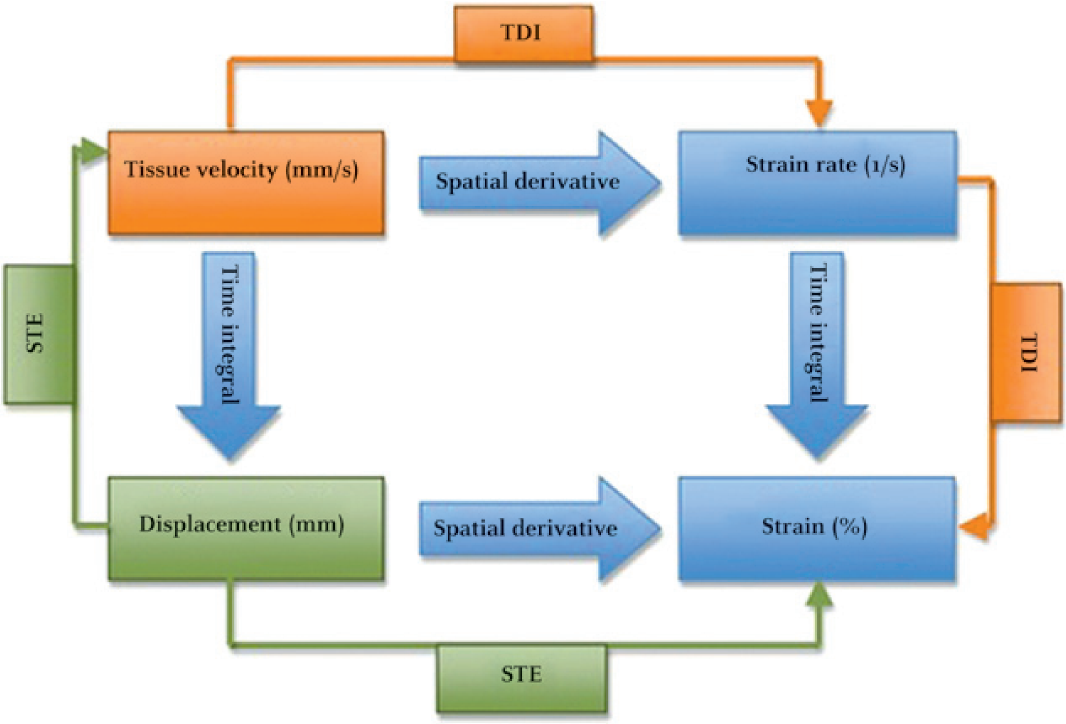

Figure 3 Mathematical relationship between different deformation parameters and mode of calculation for speckle tracking echocardiography (STE) and tissue Doppler imaging (TDI). STE primarily assesses

myocardial displacement, whereas TDI primarily assesses tissue velocity. (Reproduced with permission from Blessberger et al. Non-invasive imaging: Two-dimensional speckle tracking echocardiography. Basic principles. Heart 2010)

Speckle Tracking Imaging

STI is performed as an offline analysis of the ultrasound cine loops, which are linked with an ECG recording such that analysis can be gated to the cardiac cycle. Some 'speckles' within the ultrasound image, that are generated randomly due to reflection, refraction and scattering of the echo beams, are stable across time. These speckles can be tracked throughout the cardiac cycle and act as natural acoustic markers of myocardial motion (Figure 4). The software selects and tracks clusters of speckles (termed kernels) within a manually outlined region-of-interest (ROI), and can then directly calculate the strain occurring within this region[152,155,156].

To perform analysis accurately, ultrasound cine loops must be captured with a frame rate as high as possible, ideally greater than 50Hz[156]. From a practical point of view, this does constrain the dimensions of the image recorded (as returning echoes must be collected before new ones are emitted from the ultrasonic probe), and so there is a play-off between depth of field and sector width when acquiring suitable images[155].

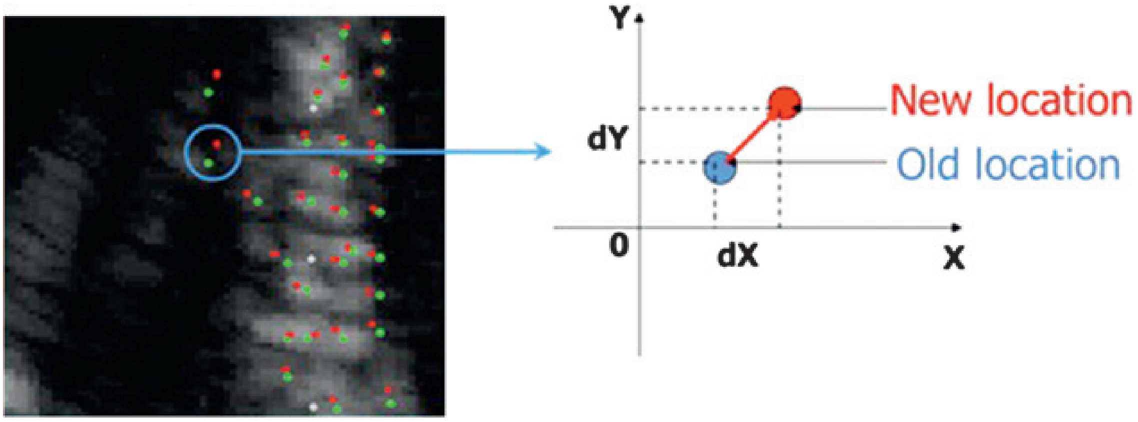

Figure 4 Displacement of acoustic markers from frame to frame. Green dots represent the initial position and red the final position of the speckles. (Reproduced with permission from Blessberger et al. Non-invasive imaging: Two-dimensional speckle tracking echocardiography. Basic principles. Heart 2010)

For offline analysis, the operator needs to manually outline a region of interest (ROI), which the software then automatically divides into six equal sections. Following filtering of the raw data, the software calculates strain versus time plots for each section[156]. Results have been shown to be highly robust and reproducible, with negligible inter-observer variability between skilled echocardiographic examiners[157].

Current speckle tracking analysis algorithms are able to calculate three directions of strain, which characterise the contraction of the heart: Radial strain measures movement relative to the long axis of the heart and thus reflects myocardial thickening and thinning; longitudinal strain assesses movement from base to apex; and circumferential strain is calculated as the change in length perpendicular to the radial and long axes (Figure 5)[155].

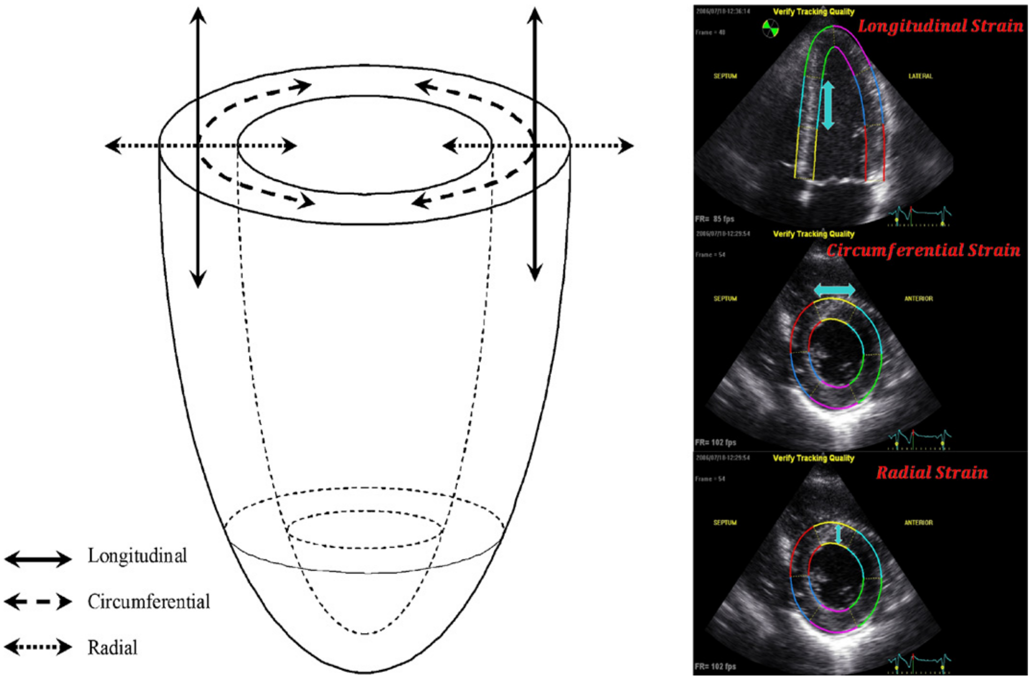

Figure 5 Local heart coordinate system illustrating the 3 orthogonal axes: circumferential, radial and longitudinal. Colour-coded regions-of-interest are manually entered during offline analysis. (Reproduced with permission from Leung et al. Emerging Clinical Role of Strain Imaging in Echocardiography. Heart Lung Circul 2010)

Limitations of STI

As mentioned above, image quality needs to be high with an adequate frame rate[153,158,159]. Because the analysis is performed on 2D images, out-of-plane movement within the ROI will confound results[160,161]. STI works by tracking clusters of pixels within the image. If the structure being analysed moves out-of-plane through the US image, it is incorrectly analysed by the software as tissue deformation. This shortcoming will be overcome by the introduction of 3D STI [162]. Finally, when manually selecting the ROI, the operator needs to be careful to only select the target tissue, to avoid introducing erroneous results[156].

Hypothesis and rationale

The underlying hypothesis for this PhD thesis is that the safety and efficacy of pleural procedures can be increased, by improving physician procedural training and extending the utility of US and pleural manometry to guide these procedures.

Thesis Design

Three project arms will be completed to support this hypothesis. The aims of and rationale for these three arms are:

1. **To develop and validate objective tools to assess the competency of physician-performed thoracic US and chest tube insertion.**

In the era of competency-based assessment of procedural skills, validated assessment tools are required. Currently there exists no instruments to assess performance of physician-performed thoracic US or chest tube insertion.

2. **To demonstrate a method to visualise the intercostal artery (ICA) at standard thoracic US, and evaluate its clinical utility.**

If US can be used to screen for a vulnerable ICA prior to thoracentesis or chest tube insertion, then the incidence of laceration of the ICA could be reduced.

3. **Identification of entrapped lung**

3i) To improve and simplify the current method of pleural manometry by developing a technique for continuous pressure recording during thoracentesis.

Although pleural manometry during thoracentesis has some utility to identify unexpandable lung and guide safe large-volume drainage, it is not performed widely around the world. Development of a simplified technique that allows continuous drainage and automated measurements may increase increase its use.

3ii) To investigate the ability of motion and strain analysis with ultrasound to prospectively identify trapped lung prior to thoracentesis.

Prospectively identifying trapped lung prior to thoracentesis, would allow the correct intervention to manage a malignant pleural effusion (pleurodesis or insertion of an IPC) in any given individual to be planned in advance, such that only one definitive procedure is required.

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Chapter 2 (paper)

A new instrument to assess physician skill at chest tube insertion: The TUBE-iCOMPT

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AUDIT, RESEARCH AND GUIDELINE UPDATE

A new instrument to assess physician skill at chest tube insertion: the TUBE-iCOMPT

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ABSTRACT

Currently no tool exists to assess proceduralist skill at chest tube insertion. As inadequate doctor procedural competence has repeatedly been associated with adverse events, there is a need for a tool to assess procedural competence. This study aims to develop and examine the validity of a tool to assess competency at insertion of a chest tube, using either the Seldinger technique or blunt dissection.

A 5-domain 100-point assessment tool was developed inline with British Thoracic Society guidelines and international consensus—the Chest Tube Insertion Competency Test (TUBE-iCOMPT). The instrument was used to assess chest tube insertion in mannequins and live patients. 29 participants (9 novices, 14 intermediate and 6 advanced) were tested by 2 blinded expert examiners on 2 occasions. The tool's validity was examined by demonstrating: (1) stratification of participants according to expected level of expertise (analysis of variance), and (2) test-retest and intertester reliability (intraclass correlation coefficient). The intraclass correlation coefficient of repeated scores for the Seldinger technique and blunt dissection, were 0.92 and 0.91, respectively, for test-retest results, and 0.98 and 0.95, respectively, for intertester results. Clear stratification of scores according to participant experience was seen ($p<0.0001$). There was no significant difference between scores obtained using mannequins or live patients. This study has validated the TUBE-iCOMPT, which could now be incorporated into chest tube insertion training programmes, providing a way to document acquisition of skill, guide individualised teaching, and assist with the assessment of the adequacy of clinician training.

INTRODUCTION

No tool currently exists to assess proceduralist skill at chest tube insertion. This is despite the fact that adverse events related to thoracentesis and chest tube insertion are common, and that inadequate doctor training has been identified as a key contributory factor.[1] As trainees acquire skills at different rates, tools to assess when an individual is competent to perform a procedure are required.[2]

There are two different techniques used for insertion of a chest drain: Seldinger and blunt dissection. Although the practice of the Seldinger technique is increasing, it is not necessarily a safer or more efficacious method and both techniques are still used around the world.[3] This study aims to develop and examine the validity of a tool to assess physician skill at insertion of a chest tube, using either the Seldinger or blunt dissection method.

METHODS

Tool development

We developed an assessment tool that allows evaluation of chest tube insertion using either the Seldinger or blunt dissection technique—the Chest Tube Insertion Competency Test (TUBE-iCOMPT) (see online supplements). The test consists of five assessment domains: Domain 1, Preprocedural checks; Domain 2, Patient positioning and local anaesthetic; Domain 3, Blunt dissection skills; Domain 4, Seldinger skills; Domain 5, Suturing, drain connection and dressing. Scoring for each domain consists of a panel of objective check-box-style points and a more subjective global rating scale. To assess the Seldinger technique, Domains 1, 2, 4 and 5 are scored, while blunt dissection requires Domains 1, 2, 3 and 5. Testing of either technique gives a final score out of 100.

Testing protocol

The study was approved by the institutional ethics committee. Consenting participants were recruited from a tertiary teaching hospital in Brisbane between October 2011 and October 2013. Participants were classified according to previous experience as novice (no chest tube insertions), intermediate (attendance at a chest tube insertion workshop, but nil tube insertions in live patients), or advanced (more than 30 chest tube insertions in live patients).

Initially, the TUBE-iCOMPT was used to assess each subject inserting a chest tube in a mannequin (Super Annie http://www.simcentral.com.au), using blunt dissection (28Fr Argyle Trocar Catheter, Covidien, Mansfield, USA) and the Seldinger technique (16Fr Thal Quick Chest Tube, Cook Medical, Bloomington, USA), on two occasions 1–4 weeks apart. Two blinded expert examiners (interventional pulmonologists) and a senior respiratory trainee scored each performance either in real time or at a later date from a video recording.

Following data collection using mannequins, the TUBE-iCOMPT was applied to assess a group of intermediate and advanced subjects inserting a chest tube into live patients. Intermediates were closely supervised. If they required prompting or correction of technique, they were scored zero for the corresponding point on the TUBE-iCOMPT.

Statistical analysis

Data within groups was examined for normality and found to be well approximated by a normal distribution. To examine test validity, the reproducibility of scores and the instrument's ability to discriminate between subjects of varying experience were assessed. The reproducibility of test-retest scores (occasion 1 vs occasion 2) and inter-tester scores (pulmonologist 1 vs pulmonologist 2 vs advanced trainee) were gauged on results derived from mannequin testing by calculating the intraclass correlation coefficient (ICC). The tool's ability to discriminate between subjects of varying experience was assessed by comparing groups with analysis of variance (ANOVA). As an indication of the correlation between results from live patient and mannequin testing, scores corresponding to each group were plotted against one another, and significant differences between the two assessed with Student t test. Statistical analysis was performed with STATA software V.12 (StataCorp, College Station, Texas, USA).

RESULTS

Consenting participants numbering 29 were recruited for mannequin testing of the Seldinger and blunt dissection techniques (9 novices, 14 intermediates and 6 advanced) and 12 different participants for live patient testing (4 advanced Seldinger technique, 6 intermediate Seldinger technique, 1 advanced blunt dissection, 2 intermediate blunt dissection).

As can be seen in figure 1, the tool accurately stratified participants according to experience with non-overlapping 95% CIs, when used to assess the Seldinger technique and blunt dissection. The mean scores (95% CI) derived from mannequin testing for novices, intermediates and advanced were 42.2 (39.5 to 45.0), 71.3 (69.4 to 73.1) and 87.6 (86.5 to 88.7), respectively, for the Seldinger technique, and 48.6 (45.7 to 51.5), 74.3 (72.6 to 75.9) and 87.0 (85.7 to 88.4), respectively, for blunt dissection. Groups were all significantly different at the $p<0.0001$ level (ANOVA). These groups remained distinct when testing was performed using live patients, and the results were not significantly different to those obtained from mannequin testing (intermediates $p=0.56$, advanced $p=0.10$).

Differences between groups of varying experience remained highly significant even when each test domain was examined in isolation ($p<0.005$) except for domain 1 where there was no significant difference between adjacent groups (ie novice vs intermediate, intermediate vs advanced) ($p=0.07–0.5$).

Results from mannequin testing showed robust reproducibility. For intertester data, the ICC between the expert examiners was 0.98/0.95 (Seldinger/blunt dissection), while that between the expert examiners and the advanced trainee was 0.96/0.95 (Seldinger/blunt dissection technique). For test-retest data, the ICC was 0.92/0.91 (Seldinger/blunt dissection).

DISCUSSION

This study has validated a new instrument to assess skill at insertion of a chest tube, using either blunt dissection or the Seldinger method. The test accurately stratifies participants according to skill level and is reliable, giving highly reproducible results on repeat testing, when marked by examiners of differing experience or when the procedure is performed on live patients or mannequins. The instrument could now be incorporated into chest tube insertion training programmes, providing a way to document the acquisition of skill, guide individualised teaching and assist in the assessment of the adequacy of clinician training.

Although there are numerous facets to what constitutes the validity of a new test, there is general consensus that for a new evaluative tool to be clinically valid, it must be reproducible and measure what it purports to measure, in this case, procedural competence.[2] Although it is the repetitive practice of a technique that leads to competence, the number of procedures performed is not in itself a reliable indicator of competence. For this reason, a number of different aspects of validity were addressed in the design of the TUBE-iCOMPT. The assessment points in the instrument were constructed from international consensus of over 100 health professionals, including pulmonologists, intensive care specialists and cardiothoracic surgeons, on the essential steps of correct chest tube insertion.[4] Weighting for the individual assessment points was assigned in line with British Thoracic Society Guidelines.[5] A global rating scale was included to address the intangible components of procedural competence gained with time. Finally, there was a large separation between groups of varying experience (novice, intermediate, advanced), to maximise the (imperfect) delineation between levels of expected competence.

A major strength of the TUBE-iCOMPT is its flexibility. The five scoring domains, each comprised of a combination of check-list-style marking points and a global rating scale, allow the instrument to assess the generic skills required for the safe insertion of any needle or tube into the pleural space, while remaining flexible enough to assess either blunt dissection or the Seldinger method. It should be noted however, that procedural competence does not necessarily equate to overall clinical competence, which also requires other skills, such as clinical judgement, as to when and what pleural procedure should be performed.

This study has not attempted to answer the question of what score is required to indicate a particular level of competence,

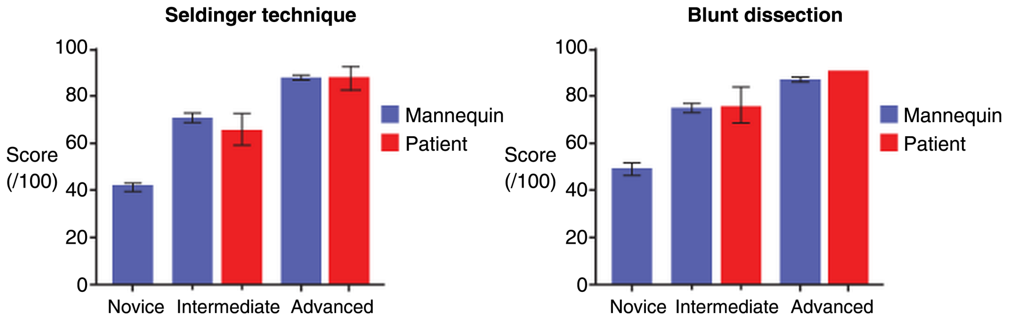

Figure 1 Test scores by group for Seldinger technique and blunt dissection. The columns represent mean scores and error bars 95% CI.

such as when a trainee is ready to perform unsupervised procedures on a patient. To define this relationship, further study is required. However, the score obtained with the assessment tool should not be seen as an end unto itself, but rather as a useful addition to a comprehensive teaching programme, which helps the trainee recognise specific deficiencies in their technique while allowing the trainer to follow the student's acquisition of skills and appropriately tailor further instruction.[2]

One possible limitation to this study is that a large amount of the data was derived from applying the TUBE-iCOMPT to assess procedures performed on a mannequin. We believe this was justified to establish the reproducibility of the instrument, as repeated testing needed to be made during a procedure with standardised complexity (which is not the case with live patient procedures). Following establishment of the test's reproducibility using mannequins, the performance of the tool when used with live patients was assessed. Further, we feel that it is important the TUBE-iCOMPT can discriminate between operators of different skill level and identify specific deficiencies in technique, regardless of whether the procedure is performed with mannequins or live patients, as initial training in simulated clinical environments is rapidly becoming the standard for procedural training.

In conclusion, this TUBE-iCOMPT constitutes a useful contribution to the growing number of instruments available to assess the procedural skill of pulmonologists. This study has validated the TUBE-iCOMPT, which could now be incorporated into chest tube insertion training programmes, providing a way to document the acquisition of skill, guide individualised teaching and assist in the assessment of the adequacy of clinician training.

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Contributors MRS 60%: Wrote the assessment instrument, designed the study, recruited and (Guarantor) tested the participants, analysed the data and wrote the manuscript. FB 10%: Expert assessment of participants. AJR 5%: Advanced registrar assessment of participants. HEW 5%: Assisted in writing of the assessment instrument and manuscript. DIKF 20%: Assisted in writing of the assessment instrument and study formulation, expert assessment of participants, assisted with the manuscript preparation.

Competing interests None.

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TUBE-iCOMPT

Name... Date .... Examiner...

Position.............................. Experience: Instructional course ☒ Yes ☒ No

Chest tubes inserted:
- Seldinger ......
- Blunt dissection ......

Ensure all equipment is available on bed, including a range of suture types/sizes.

Please **read instructions** in **red** below**. Do NOT** give any **extra prompting** or **ask additional questions,** unless the required equipment is not available.
Place a tick in square brackets beside each assessment point for each correct answer/action.
If participant requires prompting, score zero for that point. No partial marks given.

1. Pre-procedural checks - to be performed as a quiz

Total /16

2. Patient Positioning and Local Anaesthetic

"Describe how you prepare the area to start the procedure" "What position would you put the patient in?"
"What location would you ideally insert a chest tube and how would you locate this point?"

"Now please put in the L.A. Talk through what you are doing." When candidate starts injecting L.A., ask "what volume would you give."

- Positions patient appropriately (1 point) [ ]
- Determines insertion site
  - mentions use of ultrasound. May have mentioned in pre-procedural checks (4 points) [ ]
  - identifies triangle of safety using anatomical landmarks (2 points) [ ]
- Uses strict aseptic technique (2 points) [ ]
- Uses adequate volume of LA - 3 mg/kg (1 point) (lignocaine 1% - 20 ml / 70 kg) [ ]
- Inserts needle over superior border of rib (2 points) [ ]
- Aspirates pleural space to confirm correct location and diagnosis (4 points) [ ]
- Infiltrates all layers esp skin, pleura ± periosteum (3 points) [ ]

Overall performance:

Unsatisfactory		**Below Average**		**Satisfactory**			**Above Average**	**Excellent**	
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**

Total /28

3. Blunt dissection skills

"Now could you please insert a chest tube for a haemothorax using blunt dissection, connect it to the drain and secure to the skin. Talk through what you are doing"
As inserts chest tube ask "How far would you insert the chest tube?"
Once chest tube is inserted, ask "How would you confirm the tube is in the pleural space?"

- Removes trocar (4 points) [ ]
- Makes skin incision along and parallel to the superior margin of the rib (2 points) [ ]
- Blunt dissects with artery forceps (or similar), to spread subcutaneous fat and muscles (4 points) [ ]
- Punctures parietal pleura with tip of forceps (2 points) [ ]
- Ensures dissected track adequate width for tube (1 point) [ ]
- Inserts wound closure suture mid-wound (1 point) [ ]
- Inserts chest tube with forceps (2 points) [ ]
- Does not use excessive force (4 points) [ ]
- Ensures all side holes of tube in pleural cavity (2 points) [ ]
- Attaches tube to drain or clamps while suturing (2 points) [ ]
- Confirms pleural placement (swing, fluid drainage) (2 points) [ ]

Overall performance:

Unsatisfactory		**Below Average**		**Satisfactory**			**Above Average**	**Excellent**	
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**

Total /35

Name...................................

4. Seldinger skills

"Now could you please insert a chest tube for a parapneumonic effusion using the Seldinger technique. Talk through what you are doing. "
While candidate is inserting wire, ask "What would you do if resistance is felt on passing the guide wire?"
As inserts chest tube ask "How far would you insert the chest tube?"
Once chest tube is inserted, ask "How would you confirm the tube is in the pleural space"

- Introducer needle passed over top margin of rib (3 points) [ ]
- Aspirates pleural space to confirm intra-pleural placement of the introducer needle (4 points) [ ]
- Notes depth of chest wall with introducer needle (2 points) [ ]
- Confirms guide wire moves freely on insertion (1 point) [ ]
- Explains what to do if resistance is felt on passing the guide wire (1 point) [ ]
- Skin incision with scalpel to allow dilators to be passed (1 point) [ ]
- Dilators not passed >1cm past pleura (4 points) [ ]
- Guide wire not kinked or contaminated 2 points) [ ]
- Equipment all inserted in the same plane (2 points) [ ]
- Chest tube inserted without excessive force (1 point) [ ]
- Ensures all side holes of tube are in the pleural space (1 point) [ ]
- Attaches tube to drain, clamps or turns off 3-way tap while suturing and dressing (2 points) [ ]
- Confirms pleural placement (Swing, air leak, fluid drainage) (2 points) [ ]

Overall performance:

Unsatisfactory		Below Average		Satisfactory		Above Average		Excellent	
0	1	2	3	4	5	6	7	8	9

Total /35

5. Suturing, drain connection and dressing

"Now could you connect the chest tube to the drain, secure to the skin and dress"
(or describe how you would if drain/dressings not available)
If doesn't volunteer information, ask "Where would you apply tape?"
When finished ask "Is there anything else you would like to do?"

- Uses stout, non-absorbable suture material (eg Mersilene 0 or silk 0/1) (2 points) [ ]
- Secures chest tube with stay or anchoring suture without compressing tube (3 points) [ ]
- Connects drain/removes chest tube clamps (2 points) [ ]
- Uses appropriate dressing (1 point) [ ]
- Secures tubing to skin e.g. mesenteric tape tag (1 point) [ ]
- Tapes junction of chest tube and drainage tube (1 point) [ ]
- Orders CXR to confirm chest tube placement (2 points) [ ]

Overall performance:

Unsatisfactory		Below Average		Satisfactory		Above Average		Excellent	
0	1	2	3	4	5	6	7	8	9

Total /21

Total

Blunt dissection technique

1. Pre-procedural checks /16

2. Patient Positioning and Local Anaesthetic /28

3. Blunt dissection skills /35

5. Suturing, drain connection and dressing /21

/100

Seldinger technique

1. Pre-procedural checks /16

2. Patient Positioning and Local Anaesthetic /28

4. Seldinger skills /35

5. Suturing, drain connection and dressing /21

/100

TUBE-iCOMPT Quiz

Name .... **Date ....**

1. List what you would do and check before inserting a chest tube. Where would you perform the procedure?

TUBE-iCOMPT Quiz Answers

1. ***List what you would do and check before inserting a chest tube, and where would you perform the procedure?***

- Performs risk assessment (2 points)
- ’Time out' (checks):

  - consent (2 points)

  - patient ID (1 point)

  - x-ray (1 point)

  - side/site for chest tube (2 points)
- Checks clinical signs (1 point)
- Considers premedication (1 point)
- Obtains reliable venous access (1 point)
- Ensures continuous oximetry (1 point)
- Uses an assistant (1 point)
- Checks equipment is available and on hand (1 points)
- Performs procedure in procedure room or clean area (1 point)
- Checks blood coagulation studies (1 point)

Total /16

Chapter 3 (paper)

A new instrument to assess physician skill at thoracic ultrasound including pleural effusion mark-up: The UG-STAT

CHEST

Original Research

PULMONARY PROCEDURES

A New Instrument to Assess Physician Skill at Thoracic Ultrasound, Including Pleural Effusion Markup

Matthew Salamonsen, MBBS; David McGrath, MScApp; Geoff Steiler, MBBS; Robert Ware, PhD; Henri Colt, MD, FCCP; and David Fielding, MBBS

Background: **To reduce complications and increase success, thoracic ultrasound is recommended to guide all chest drainage procedures. Despite this, no tools currently exist to assess proceduralist training or competence. This study aims to validate an instrument to assess physician skill at performing thoracic ultrasound, including effusion markup, and examine its validity.**

Methods: **We developed an 11-domain, 100-point assessment sheet in line with British Thoracic Society guidelines: the Ultrasound-Guided Thoracentesis Skills and Tasks Assessment Test (UGSTAT). The test was used to assess 22 participants (eight novices, seven intermediates, seven advanced) on two occasions while performing thoracic ultrasound on a pleural effusion phantom. Each test was scored by two blinded expert examiners. Validity was examined by assessing the ability of the test to stratify participants according to expected skill level (analysis of variance) and demonstrating test-retest and intertester reproducibility by comparison of repeated scores (mean difference [95% CI] and paired *t* test) and the intraclass correlation coefficient.**

Results: **Mean scores for the novice, intermediate, and advanced groups were 49.3, 73.0, and 91.5 respectively, which were all significantly different ($P < .0001$). There were no significant differences between repeated scores.**

Conclusions: **Procedural training on mannequins prior to unsupervised performance on patients is rapidly becoming the standard in medical education. This study has validated the UGSTAT, which can now be used to determine the adequacy of thoracic ultrasound training prior to clinical practice. It is likely that its role could be extended to live patients, providing a way to document ongoing procedural competence.** ***CHEST 2013; 144(3):930–934***

Abbreviations: ICC = intraclass correlation coefficient; UGSTAT = Ultrasound-Guided Thoracentesis Skills and Tasks Assessment Test

Thoracic ultrasound is an indispensable tool to assist in the diagnosis and treatment of pleural effusions. When used to guide needle insertion, it increases the success and safety of thoracentesis and chest tube insertion,[1,2] and international guidelines now recommend its mandatory use to guide all pleural drainage procedures.[3]

The paradigm shift in medical procedural training from experiential (where the training experience is defined by the number of procedures performed) to competency-based[4] learning warrants the development of instruments specifically designed to assess procedural skill. Furthermore, individuals acquire skills at different rates and so require differing durations of procedural training to become competent.[5] Assessment instruments provide a snapshot of an individual's place on the learning curve, potentially indicating

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areas where remedial or additional training is needed, and with consideration of changing 21st century societal views of physician practice, they provide objective evidence of acquired procedural skills to assure accountability to the general public.[6]

The aim of this study was to develop a tool to assess physician skill at thoracic ultrasound, including pleural effusion markup, and to examine its validity. The Ultrasound-Guided Thoracentesis Skills and Tasks Assessment Test (UGSTAT) was modeled on similar tests to assess bronchoscopy[7,8] and was designed to measure the incremental skill level obtained as an individual progresses from novice to intermediate to advanced thoracic sonographer.

Materials and Methods

Test Development

The UGSTAT tests skill level up to the point of skin markup at the best site for pleural needle insertion but does not include real-time imaging, such as is used for small, complex effusions. It consists of 11 assessment domains that cover knowledge of ultrasound knobology, recognition of ultrasound images that illustrate common pleural effusion appearances, the ability to perform a thoracic ultrasound and mark an appropriate site for drainage of a pleural effusion, and a global rating scale for the assessor to assign a mark according to his or her overall impression of the subject's ability (e-Appendix 1). Because ultrasound is a heavily operator-dependant skill,[9,10] specific assessment of manual dexterity is included. The theoretical content of the assessment points is based on guidelines for training in pleural ultrasound published by the British Thoracic Society.[3] To standardize administration of the test, assessors only read out the questions and instructions written in red on the report form for each task.

Participant Selection and Testing Protocol

The study was approved by the institutional ethics committee (The Prince Charles Hospital Human Research Ethics Committee, approval number HREC/11/QPCH/86). Consenting participants were recruited from three large tertiary teaching hospitals and divided into three groups: novice, intermediate, and advanced. The novice group comprised medical students, hospital medical officers, and junior respiratory medicine trainees with no prior ultrasound experience. Novices were given a 10-min introduction to thoracic ultrasound in the week prior to testing. The intermediate group comprised respiratory medicine physicians or trainees who attended an instructional thoracic ultrasound course but had not completed the required five thoracic ultrasound studies on real patients. The advanced group completed an instructional course and > 20 thoracic ultrasound studies on real patients and comprised pulmonologists, sonographers, and radiologists. These criteria were chosen to define advanced skills because it is the minimal requirement for accreditation in physician-performed thoracic ultrasound by the Australasian Society for Ultrasound in Medicine,[11] with these guidelines being based on the British Thoracic Society guidelines. No participants had contributed to the writing of the assessment tool.

Each participant was recorded on video while performing thoracic ultrasound on a pleural effusion phantom (Thoracentesis Phantom; Blue Phantom) (Fig 1) on two occasions 2 to 4 weeks apart. They were asked questions and directed to perform the tasks from the UGSTAT. Two independent expert assessors scored the performances at a later date with the UGSTAT; each assessor was blinded to the other's markings and the skill level of participants. In cases where an assessor was unsure of what to score, a mark of zero was recorded for that assessment point. One assessor was the senior sonographer in our tertiary referral institution, and the other was a dually trained sonographer-radiology fellow.

Statistical Analysis

Sample size calculations were based on our primary aim to distinguish skill levels among the three groups. Assuming an intraclass correlation coefficient (ICC) of 0.9 and two repeated measures per participant, we calculated that we would need to test 22 individuals in order for the lower bound of the 95% CI of our estimate to be at least 0.8.[12]

Data within groups were examined for normality and found to be well approximated by a normal distribution. We used a repeated-measures analysis of variance model to assess the ability of the test to distinguish among the three groups of participants. As an indicator of measurement error, the agreement between test-retest scores (ie, results from an individual on repeat testing) and intertester scores (ie, results for an individual participant from the two assessors) were assessed by calculating the mean difference between scores with 95% CIs and comparing test scores with the paired t test. The reliability of the test, that is, how well repeated test scores correlated in the population studied, was measured with the ICC. Statistical analysis was performed with Stata 12 (StataCorp LP) software.

Results

Twenty-two participants were tested, including eight in the novice group, seven in the intermediate group, and seven in the advanced group. In the advanced group, the median number of ultrasound cases on real patients prior to assessment was 200 (range, 30-200). For the intermediate group, the median time from having the instructional course to first assessment was 3 weeks (range, 2-26 weeks). The time taken to administer the test was between 6 and 14 min. Preliminary testing demonstrated good agreement between UGSTAT scores of participants assessed with a pleural effusion phantom vs a real patient.[13]

Performances of the three groups (novice, intermediate, advanced) are shown in Figure 2, which demonstrates the ability of the test to accurately stratify participants according to experience level. The mean scores for the novice, intermediate, and advanced groups were 49.3 (95% CI, 43.4-55.2), 73.0 (95% CI, 68.1-77.9), and 91.5 (95% CI, 88.8-94.3), respectively. All the groups were significantly different from one another at the $P < .0001$ level.

Test-retest and intertester scores are shown in Table 1 and displayed graphically in Figure 3A and 3B. Repeat testing was performed at a median of 3 weeks (range, 1-6 weeks) after the first test. Overall, there was a high level of reliability, with an ICC for test-retest and intertester scores of 0.85 and 0.94, respectively. There was a small learning effect seen in the test-retest data (ie, improvement in score between

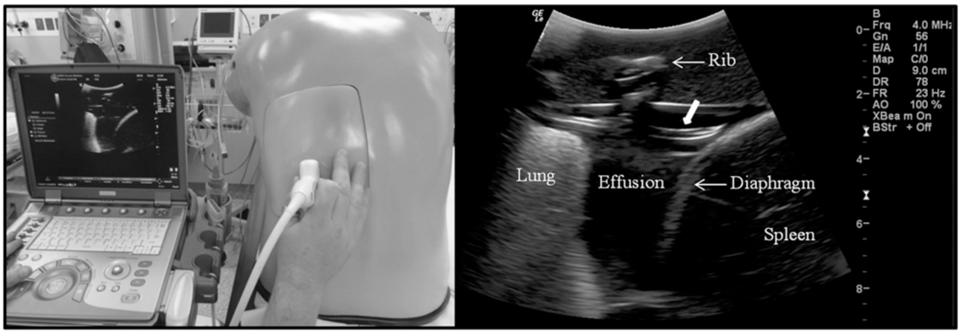

FIGURE 1. Ultrasound pleural effusion phantom and portable ultrasound machine used for testing and optimized ultrasound image of the phantom. Bold arrow indicates an ultrasound artifact characteristic of this phantom.

test 1 and test 2), which was only significant when the results of all groups were combined. This is visible in Figure 3A and is reflected in the slightly lower ICC for test-retest than for intertester data.

DISCUSSION

This study has introduced and validated a new tool for the assessment of physician-performed thoracic ultrasound, including markup for pleural effusions. The test gives results that are reliable and accurately reflect the skill level of those being assessed. In a time when ultrasound is becoming integral to the practice of the pulmonologist, this tool could be used to determine the adequacy of physician thoracic ultrasound training prior to clinical practice or to provide a way to document ongoing procedural competence.

For a test to be valid, it must fulfill two requirements: (1) test what it purposes to test and (2) give results that are reproducible (ie, give the same results on repeated applications).[14] With respect to the former criterion, the knowledge and manual skills tested by the UGSTAT are based on current international guidelines,[3] and as shown by the analysis of variance, it is able to accurately stratify subjects according to their expected level of skill. Reproducibility is a little more complicated because it is an umbrella term that covers both the agreement between scores on repeated measures and the reliability of the test. These are similar, but subtly different parameters.[15] Agreement relates to the measurement error and indicates how similar scores from repeated measures are. Reliability indicates how well subjects can be distinguished, despite this measurement error, within any given population. Therefore, a test may have a high level of reliability, despite significant differences in repeated test scores, if there is sufficient variability among subjects in the population. A high level of agreement is required for evaluative tests, whereas good reliability is needed for discriminative tests.[16] In the present study, we analyzed both parameters, assessing agreement by calculating the mean difference in repeated test scores with 95% CIs while gauging the reliability of the test by deriving the ICC. Overall, the results compare well with evaluations of other instruments.[7,8,17-19]

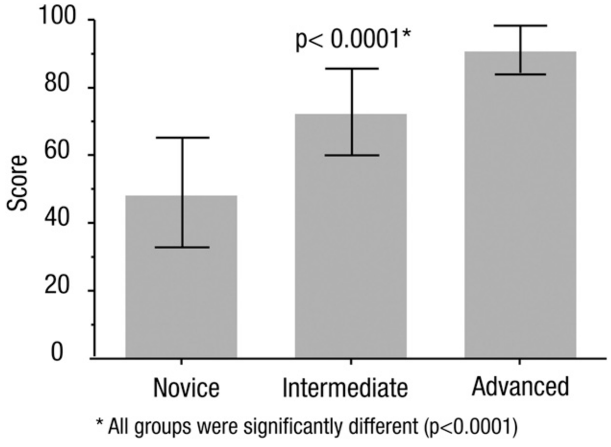

FIGURE 2. Mean test scores according to group. Error bars represent 95% CIs.

Some relatively inexperienced participants had a clear natural affinity for procedural tasks compared with others and far more rapidly developed the manual dexterity required for competent scanning. This finding is reflected in the greater spread of test scores for the novices compared with intermediate or advanced participants (Fig 2). The variability in the rate of acquisition of new skills among individuals has been well documented[5] and, indeed, is one of the main reasons for the change from experiential to competency-based medical teaching. The acquisition of new skill is apparent in the learning effect seen between test 1 and test 2 in the present study. Although this learning effect was only statistically significant when the combined data were analyzed, one would intuitively expect it to be most obvious in the novice group, and this group showed the strongest trend to improvement between the two tests. Another factor that likely contributed

Table 1—*Comparison of Test-Retest and Intertester Scores for Groups of Varying Experience*

Repeated Measure	Test 1	Test 2	Mean Difference (95% CI)	*P* Value[a]
Test-retest				
All	68.1	72.4	4.3 (0.8 to 7.8)	.02
Novice	46.2	52.4	6.2 (−0.7 to 13.1)	.07
Intermediate	71.1	74.9	3.8 (−4.4 to 12.0)	.34
Advanced	90.2	92.9	2.7 (−0.4 to 5.7)	.08
Intertester				
All	69.9	70.7	0.8 (−1.6 to 3.2)	.48
Novice	49.1	49.5	0.4 (−3.1 to 4.0)	.79
Intermediate	73.1	73.0	−0.1 (−5.8 to 5.7)	.98
Advanced	90.4	92.6	2.2 (−2.0 to 6.4)	.27

Data are presented as mean scores unless otherwise indicated.
[a] Significant difference between repeated measures.

to the significant learning between test 1 and test 2 is that performance of thoracic ultrasound to mark up for thoracentesis is not as technically complex as other procedures, such as bronchoscopy. To further compound this, testing was performed on a pleural effusion phantom, which had an effusion with fixed characteristics such that participants had a slight advantage on the second round of testing because of retained knowledge of the position and character of the pleural effusion from the previous assessment.

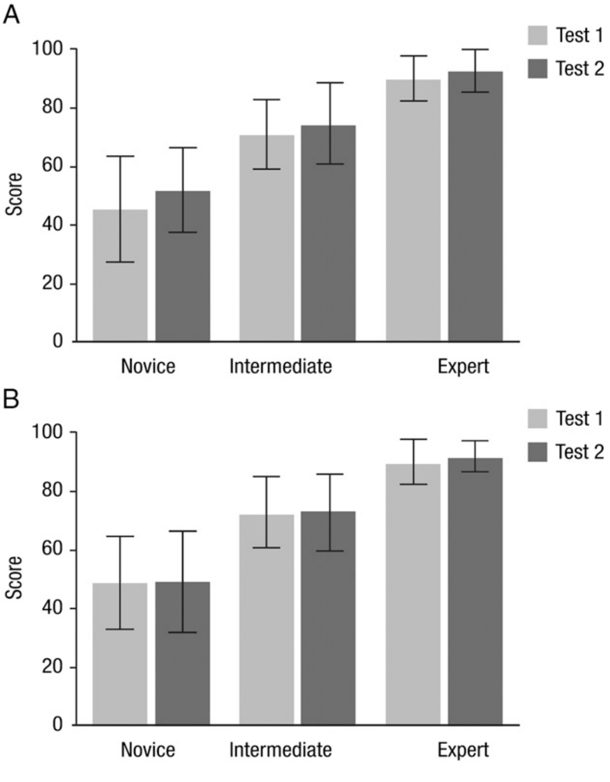

Figure 3. A, Mean test-retest scores by group. B, Mean intertester scores by group. Error bars represent the 95% CIs.

This study has several limitations. Testing was recorded on video, which the assessors scored at a later date. Some of the subjective "feel" of a subject's skill is probably not as easily detected when watching a video as when the procedure is observed directly. Furthermore, when scoring from video, assessors are unable to clarify with the subject any assessment point where they are unsure of what to score. We chose to score performances from video because to recruit the required number of study participants, testing had to be performed in a variety of locations and at different times, which meant that the assessors could not always be present to mark the procedures at the time of testing. Scoring performances recorded on video was the best way to standardize the testing and marking environment. Another factor that was mentioned previously is that ultrasound was performed on a pleural effusion phantom, which is probably less technically demanding than scanning a real patient. Part of an expert's skill becomes apparent when he or she is able to adapt to variations such as body habitus and to tailor scanning to individual patients. However, in the same way that we believe that physicians should not be learning to perform procedures on patients, we believe that assessments can be designed, developed, and tested in models before they are applied to the clinical setting in real patients. Despite the combined effect of all these factors, which would have increased the variability between test scores and reduced the distinction among groups (novice, intermediate, advanced), statistical measures of agreement and validity remained significant.

CONCLUSIONS

Procedural training on mannequins prior to unsupervised performance on patients is rapidly becoming the standard in medical education. This study validates the UGSTAT, which can now be used to determine the adequacy of thoracic ultrasound training prior to clinical practice. It is likely that its role could be extended to live patients, providing a way to document ongoing procedural competence.

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Author contributions: Dr Salamonsen had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Dr Salamonsen: contributed to the study formulation, data collection, and writing of the manuscript.
Mr McGrath: contributed to the scoring of ultrasound performances with the UGSTAT and review of the manuscript.
Dr Steiler: contributed to the scoring of ultrasound performances with the UGSTAT and review of the manuscript.
Dr Ware: contributed to the statistical analyses and review of the manuscript.

Dr Colt: contributed to the writing of the UGSTAT, formulation of the study, and writing of the manuscript.
Dr Fielding: contributed to the writing of the UGSTAT, formulation of the study, interpretation of results, and writing of the manuscript.

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Role of sponsor: The sponsors had no role in the design of the study, the collection and analysis of the data, or in the preparation of the manuscript.

Additional information: The e-Appendix can be found in the "Supplemental Materials" area of the online article.

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CHEST Online Supplement

A New Instrument to Assess Physician Skill at Thoracic Ultrasound, Including Pleural Effusion Markup

Matthew Salamonsen, MBBS; David McGrath, MScApp; Geoff Steiler, MBBS;
Robert Ware, PhD; Henri Colt, MD, FCCP; and David Fielding, MBBS

e-Appendix 1. Ultrasound-Guided Thoracentesis Skills and Tasks Assessment Test (UGSTAT). Reprinted with permission from Brochoscopy International.

DOI: 10.1378/chest.12-2728

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Ultrasound-Guided Thoracentesis Skills and Tasks Assessment Test (UGSTAT)

Name: ______________________________ Position ____________

Assessor Name: ________________________ Date _____________

Prior thoracic US experience: Educational Course ☐ Yes ☐ No # US performed to date: ___

Instructions

Ensure all equipment is available including US machine, probes and US gel.

Please **read instructions in red** below. **You may repeat instructions and assist with location of the US controls when asked, but Do NOT** give any **extra prompting** or **ask additional questions.** If a participant **requires prompting**, **score zero** for that assessment point.

Educational Item	Score
1. "Please tell me what the following controls on the US machine do: - name each control (1 point each, target 10 points) ☐ On/Off ☐ Depth ☐ Focus ☐ Time-gain-Compensation (TGC) ☐ Freeze ☐ Overall gain ☐ Harmonics ☐ Dynamic range ☐ Frequency control ☐ Image capture	Score ____/10
2. "Tell me the name of each of these probes" point to linear and convex probe. (3 points each, target 6 points) ☐ Linear ☐ Curved	Score ____/6
3. "What would you do to prepare the US machine for the exam? What probe would you use? How would you position the patient?" (3 points each, target 12 points) ☐ Patient data ☐☐ Presettings ☐ Probe ☐ Patient position	Score ____/12
4. "Now start the US exam. You may ask for the location of specific US controls. Describe what you are doing." **Uses correct probe grip, orientation and handling.** (3 points each, target 6 points) ☐ Grip ☐☐ Orientation and handling	Score ____/6
5. Able to optimize sonographic image. You can assist if required but score zero if assistance is given. (3 points each, target 9 points) ☐ Depth ☐ Focus ☐ Time-Gain-Compensation	Score ____/9
6. "Please show me the liver/spleen (dependent on side), lung, and superior margin of rib" (4 points each, target 12 points). ☐☐ Liver or Spleen inferior to effusion ☐☐ Lung superior to effusion ☐☐ Rib margin	Score ____/12
7. "Show me the area on the chest wall corresponding to the maximal depth of effusion" (target 4 points) ☐ Identifies site on chest wall corresponding to maximal depth of effusion	Score ____/4
8. "Now measure the distance from skin to effusion and skin to a suitable needle depth" (target 3 points) ☐ Accurately measures distance to effusion and suitable needle depth	Score ____/3
9. "Would you describe loculations as absent, minor or extensive? Please place your finger on the skin where you would mark to insert the needle" Check the mark to confirm it is at superior border of rib. (4/3/3 points each, target 10 points) ☐ Correctly indicates absent loculations ☐ ID correct site on skin for needle insertion ☐ Site is at top of rib	Score ____/10
10. Ask candidate to complete Sonographic Imaging Descriptions quiz (1 point each, target 10 points) ☐ Image 1 ☐ Image 2 ☐ Image 3 ☐ Image 4 ☐ Image 5 ☐ Image 6 ☐ Image 7 ☐ Image 8 ☐ Image 9 ☐ Image 10	Score ____/10
11. Overall performance/fluidity of movement (Score 0 for unsatisfactory, 9 for satisfactory, 18 for excellent - target 18 points) ☐ Unsatisfactory ☐ Satisfactory ☐ Excellent	Score ____/18

FINAL GRADE PASS NEEDS IMPROVEMENT **SCORE** ________/100

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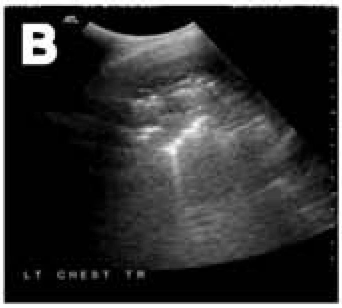

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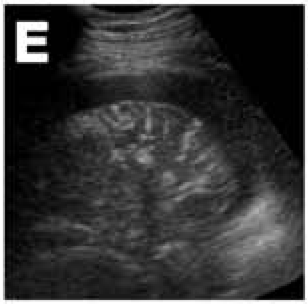
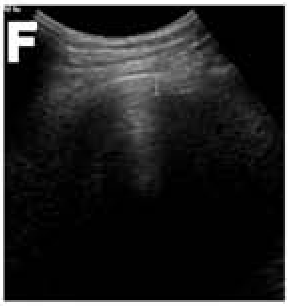
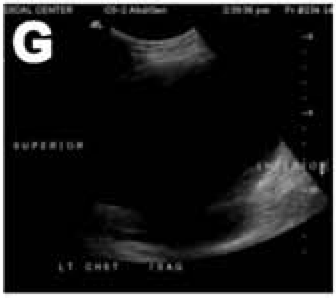
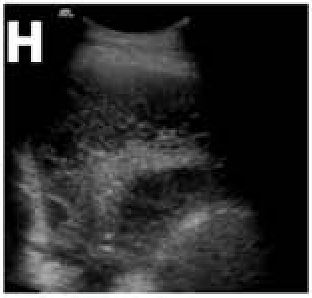




USGT-STAT Question 10: Match the sonographic photo (A-F) to the corresponding 5 descriptions (Only one response per description)

____ No Response	____ 1. Complex effusion with hyperechogenic shadows	____ 2. Multiloculated (complex septated) effusion
____ 3. Ribs with posterior acoustic shadowing	____ 4. Anechoic left-sided effusion	____ 5. Lung consolidation (hepatization)





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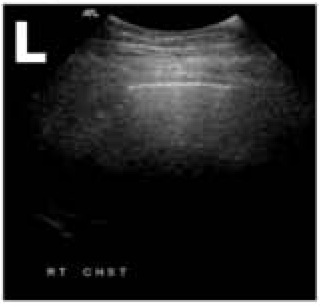

USGT-STAT Question 10: Match the sonographic photo (G-L) to the corresponding 5 descriptions (Only one response per description)

____ No Response	____ 6. Floating lung sign	____ 7. Complex non septated effusion
____ 8. Diaphragmatic nodules	____ 9. Effusion in severely obese person	____ 10. Large anechoic effusion

Chapter 4 (paper)

Thoracic ultrasound demonstrates variable location of the intercostal artery

Interventional Pulmonology

Respiration

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Thoracic Ultrasound Demonstrates Variable Location of the Intercostal Artery

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Key Words
Doppler ultrasonography · Intercostal artery · Intercostal catheter · Pleural effusion · Thoracocentesis

Abstract
Background: Ultrasound (US) guidance is advocated to reduce complications from thoracocentesis or intercostal catheter (ICC) insertion. Although imaging of the intercostal artery (ICA) with Doppler US has been reported, current thoracic guidelines do not advocate this, and bleeding from a lacerated ICA continues to be a rare but serious complication of thoracocentesis or ICC insertion. ***Objectives:*** It was the aim of this study to describe a method to visualise the ICA at routine US-guided thoracocentesis and map its course across the posterior chest wall. ***Method:*** The ICA was imaged in 22 patients undergoing US-guided thoracocentesis, at 4 positions across the back to the axilla. Its location, relative to the overlying rib, was calculated as the fraction of the intercostal space (ICS) below the inferior border of that rib. ***Results:*** An ICA was identified in 74 of 88 positions examined. The ICA migrated from a central 'vulnerable' location within the ICS near the spine (0.28, range 0.21–0.38; $p < 0.001$) towards the overlying rib (0.08, range 0.05–0.11; $p < 0.001$) in the axilla. ***Conclusions:*** The ICA can be visualised with US and is more exposed centrally within the ICS in more posterior positions; however, there is a marked variation between individuals, such that the ICA may lie exposed in the ICS even as far lateral as the axilla. Future studies need to identify which patients are at risk for a 'low-lying' ICA to further define the role of US imaging of the ICA during thoracocentesis or ICC insertion.

Introduction

Thoracocentesis or intercostal catheter (ICC) insertion are frequently performed as an initial diagnostic and/or therapeutic procedure for patients with pleural effusion [1, 2]. Potential complications include pneumothorax, damage to the viscera, skin or pleural space infection or bleeding due to laceration of the intercostal artery (ICA) [3]. The optimal site for thoracocentesis is within the 'triangle of safety' [4th to 6th intercostal space (ICS) mid-axillary line] as this minimises the inadvertent injury of anatomical structures [4]. However, in clinical practice, loculations, body habitus and other factors frequently mandate thoracocentesis through the posterior chest wall [4], which increases the risk of ICA laceration [5]. Use of ultrasound (US) to guide pleural procedures is associated with a reduced rate of adverse events [6], and its routine use has recently been advocated for all thoracenteses and ICC insertions [4]. Doppler US has been

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extensively used to examine the vascular supply of pulmonary and chest wall tumours [7–9], and its ability to specifically image the ICA has been established [10, 11]. However, acknowledgement of this has not been widespread in the international community, as evidenced by its absence in a number of recent reviews [12–14]. Indeed, some international guidelines have published statements refuting the ability of thoracic US to image the intercostal vessels [4]. As such, bleeding from a lacerated ICA or ICA pseudoaneurysm continues to be a rare but serious complication [15–18].

This study aims to describe a method to identify the ICA while performing routine US-guided thoracocentesis and to document the variation in position of the ICA, relative to the ICS, across the posterior chest wall to the mid-axillary line. We hypothesise that there will be considerable variation in the location of the ICA between individuals. It may be that in a subset of individuals, with increased bleeding risk due to an underlying coagulopathy or a posteriorly placed effusion, screening for a low-lying ICA should be performed with US prior to thoracocentesis.

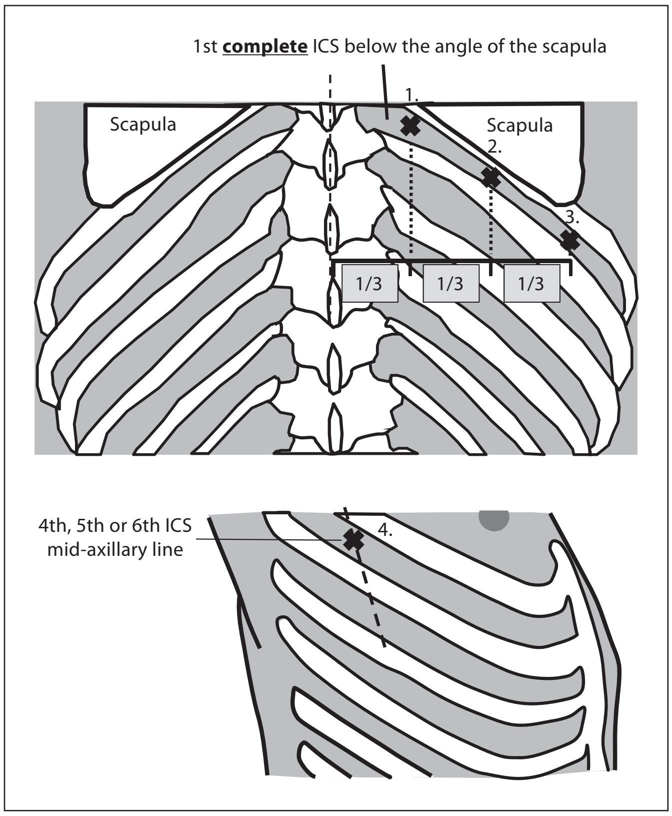

Fig. 1. Diagram of 4 positions examined for a right-sided examination.

Materials and Methods

Study Design

The primary aim of this study was to prove the feasibility of visualising the ICA at routine US-guided thoracocentesis. Twenty-two consecutive patients undergoing US-guided thoracocentesis between November 2010 and January 2011, for any medical reason, were recruited. The study was approved by the institution ethics committee, and written informed consent was obtained from all participants.

Methods

Thoracic US was performed using a standard commercially available machine (Zonare z.one ultra or Philips ATL HDI 5000) with a linear probe (4–7, 5–10 or 7–12 MHz) held flat to the skin and perpendicular to the line of the ribs. The investigators performing the US examination were a radiologist and a respiratory physician, neither with specialist thoracic ultrasonographer-level experience. An ICA was defined as a pulsatile tubular structure within the ICS on colour flow Doppler imaging, in accordance with the vascular access algorithm described by Kumar and Chuan [19]. The ICA was identified within the first complete ICS inferior to the angle of the scapula, at 3 positions across one side of the back and in the 4th, 5th or 6th ICS in the mid-axillary line on the ipsilateral side (fig. 1). These positions were chosen as they represented common sites used for thoracocentesis and were easily identifiable during thoracic US, assuring standardisation of the positions examined across the study population. They did not necessarily correlate with the actual site used for thoracocentesis in each subject. Initially, a 7- to 12-MHz linear probe was used; however, in some patients with a large amount of subcutaneous tissue, a lower frequency probe (5–10 or even 4–7 MHz) gave better views of the ICS. Care was taken to keep the probe flat to the skin and perpendicular to the line of the ribs. In the majority of cases, the ICA was identifiable with colour Doppler imaging as a round, pulsatile structure within the ICS inferior to the overlying rib. Where it was not clearly visible, a number of sequential steps were taken: (1) adjust the pulse repetition frequency of the US beam; (2) subtle side-to-side and heel-toe movements of the probe to adjust the direction of the US signal; (3) ask the patient to hold breath; (4) analyse the signal with power Doppler [20], and (5) try a different frequency probe. If a structure resembling the ICA was seen, but was not clearly pulsatile, spectral Doppler analysis was used to confirm arterial flow [21].

Measurement of the distance between the inferior border of the overlying rib and the inferior border of the ICA on colour Doppler imaging as well as the width of the ICS was made as shown in figure 2. These points were chosen as the intervening distance represents the minimum clearance below the superior rib required to guarantee that no damage is done to the ICA when performing thoracocentesis.

Analysis

Statistical analysis was performed with SAS software version 9.2 (SAS Institute, Cary, N.C., USA). Data were examined for normality and found to be well approximated by a normal distribu-

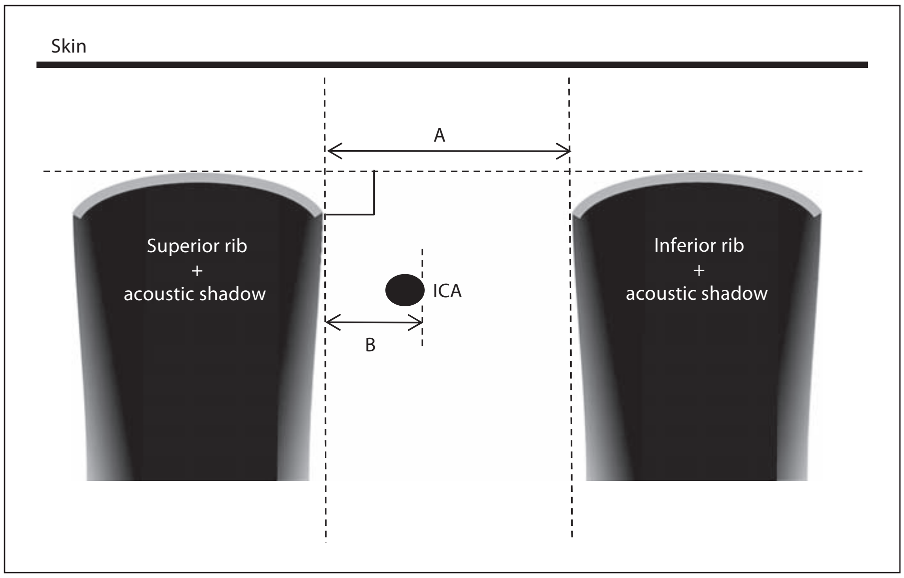

Fig. 2. Diagram showing the method used to measure ICA location within the ICS. The location is expressed as B/A, or the ratio of the distance of the ICA below the superior rib (B) to the width of the ICS (A).

tion after log transformation. Repeated measures analysis of variance (ANOVA) was used to assess the statistical significance of variation in the ICA position, relative to the ICS, in different locations across the chest wall. The effects of age were assessed by including this as a covariate in the model. Results from the repeated measures ANOVA model were presented as geometric means with 95% confidence intervals. Statistical significance was set at a two-sided p value of 0.05.

Results

Characteristics of the study population are shown in table 1. Age ranged from 16 to 92 years, and 11 of 22 subjects were females. Five subjects had suspected or proven malignant effusions, of which none had pleural or chest wall malignant disease at the site of US examination of the ICA.

Out of the 88 positions examined, an ICA was visualised in 74 positions with colour Doppler. No additional vessels were found with the use of power Doppler. A typical colour Doppler appearance of the ICA is shown in figure 3 and a spectral Doppler trace confirming arterial blood flow in figure 4. The ICA could not be visualised on 14 occasions (1 at position 2, 5 at position 3, and 8 at position 4), and this did not correlate significantly with age or body mass index. The location of the ICA, at each position across the back, is expressed as the ratio of the distance of the ICA below the superior rib to the width of the ICS (fig. 2) and is displayed graphically in figure 5. As can be clearly seen, there is a steady migration of the ICA superiorly towards the overlying rib at positions progressively lateral. This was significant at the $p < 0.001$ level, confirming that this migration is a reliable finding. However, the range in position of the ICA at any given point, between any 2 subjects, is quite large, as documented by the 95% confidence intervals. This did not correlate with age. Even as far lateral as the mid-axillary line, the ICA was up to 0.2 of the ICS below the superior rib.

Discussion

This is the first description, to our knowledge, of a method to visualise the ICA during routine US-guided thoracocentesis. Similar to previous studies, the report confirms the general trend of the ICA to migrate towards the overlying rib in more lateral positions. However, it also highlights that there is considerable variation in this trend between individuals, such that in a small percentage of people, the ICA remains exposed in the ICS and vulnerable to injury, even as far lateral as the axilla.

Traditionally, the intercostal neurovascular bundle has been thought to run in the sub-costal groove behind the inferior border of each rib [22]. Thus, ‘safe’ insertion of a needle through the ICS by passing just above the superior border of the inferior rib has been recommended [4, 23]. However, the relationship between ICA and sub-costal groove is probably less reliable than previously thought. Wraight et al. [24] documented the position of the neurovascular bundle, relative to the supe-

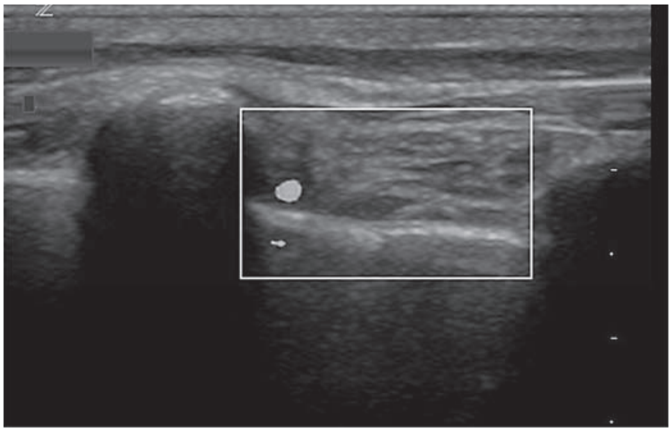

Fig. 3. Colour flow Doppler image of an ICA inferior to a rib shadow.

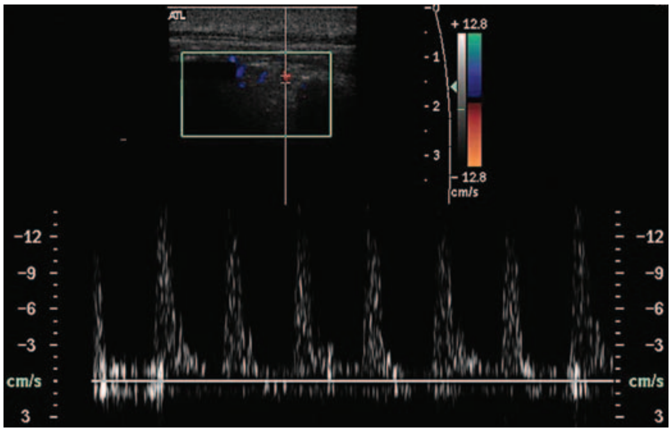

Fig. 4. Spectral Doppler trace of an ICA demonstrating arterial flow.

Color version available online

Table 1. Patient characteristics

Sex	Age, years	BMI	Primary diagnosis	Reason for tap
M	46	30.5	hepatohydrothorax	therapeutic
M	77	21.0	NSCLC	diagnostic
M	82	30.7	post-CABGS	diagnostic/therapeutic
M	56	38.9	metastatic melanoma	therapeutic
M	67	20.6	NSCLC	diagnostic
F	79	24.2	NSCLC	diagnostic
M	84	25.2	post-CABGS	diagnostic/therapeutic
F	50	17.9	CLD/hepatohydrothorax	therapeutic
F	92	16.4	breast cancer	diagnostic
F	46	23.3	pneumonia	diagnostic/therapeutic
F	74	21.9	pneumonia	diagnostic
M	53	14.7	pneumonia	diagnostic
F	59	30.3	sub-phrenic collection	diagnostic
F	26	15.1	after lung transplant	diagnostic/therapeutic
F	16	35.9	pneumonia	diagnostic/therapeutic
F	62	25.6	heart failure	diagnostic
M	83	25.2	pneumonia	diagnostic
F	43	18.7	ILD/heart failure	diagnostic
M	73	28.1	NSCLC	diagnostic
F	45	22.5	CLD/hepatohydrothorax	therapeutic
M	44	33.4	pneumonia	diagnostic/therapeutic
M	66	23.3	ESRF	therapeutic

BMI = Body mass index; NSCLC = non-small cell lung cancer; CABGS = coronary artery bypass graft surgery; CLD = chronic liver disease; ILD = interstitial lung disease; ESRF = end-stage renal failure.

rior rib, within ICS 4–6 in the mid-axillary line of 38 cadavers. The position of the ICA was highly variable, ranging from 50% of the ICS above to 43% of the ICS below the inferior border of the superior rib. A recently published study of CT angiograms showed a steady migration of the ICA towards the overlying rib in locations progressively lateral [5]. This meant that the ICA was effectively ‘protected’ by the superior rib in locations >6–8 cm from the costovertebral junction. However, it is of note that only the mean results of ICA locations for the

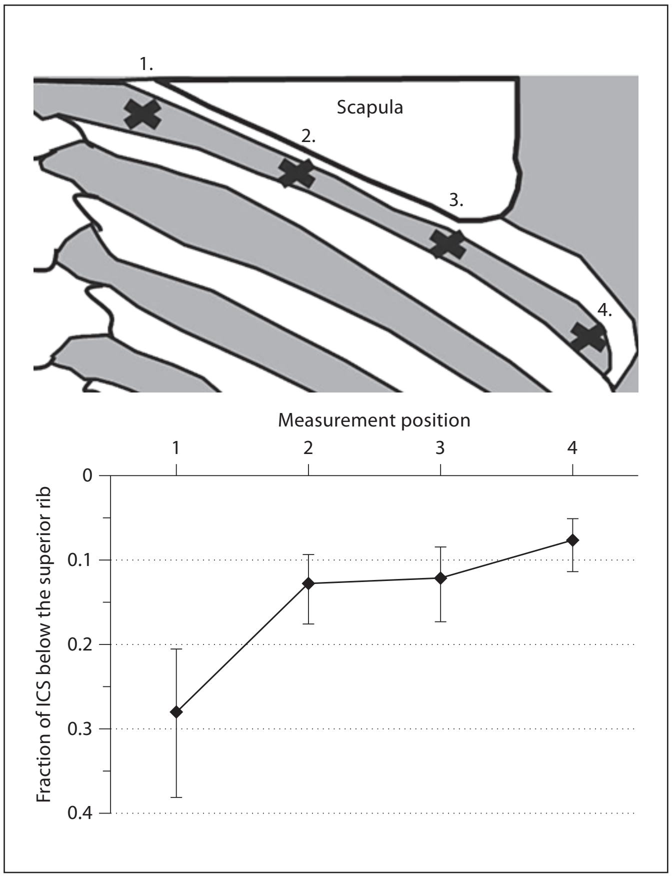

Fig. 5. Graph shows ICA location at the 4 positions measured, as illustrated in the picture above. Data points represent geometric means, and error bars show 95% confidence intervals.

study population were presented. No information on the variance within the population was reported. Thus, the position of the ICA at any given location, for any given individual, may not have been as predictable as it is for the population at large. Another factor impacting on the location of the ICA within the ICS is the tortuosity of its course. A study of thoracic aortograms [25] showed that the degree of tortuosity of the ICA increased with age, especially in those >60 years old where its appearance could be almost sinusoidal. Finally, an additional vessel located in the inferior region of the ICS, the collateral artery, has been reported in cadaveric dissection studies [24, 26]. In all cases, a collateral artery arose from the ICA between the corresponding vertebra and angle of the rib, and could be as large as the ICA. These findings have led some authors to suggest that the 'safe zone' for thoracocentesis should be located 50–70% down into an ICS, rather than immediately superior to the lower rib as traditionally taught [24]. However, in our experience, due to body habitus, poor co-operation or medical instability, it is often not possible to be this accurate with needle placement.

In our study, there is a predictable migration of the ICA upwards towards the overlying rib as one moves progressively lateral across the back. That is, the ICA is more exposed in the centre of the interspace in positions more posterior. This is consistent with recently published findings [5]. However, our data have also shown that the actual position of the ICA within the ICS (whether protected by the rib above or exposed) at any given position, in any given individual, is variable. Even as far lateral as the mid-axillary line, the ICA may lie 20% of the way down into the ICS. This has been shown in previous dissection studies [24] and has serious implications for safety when performing procedures through the ICS.

The technique adopted in this study used standard US equipment routinely employed to guide thoracocentesis and ICC insertion. In the cases where no ICA could be seen, there are two possible explanations. Either the ICA was 'hiding' behind the rib at the position inspected or the ICA was within the ICS, but for a variety of possible reasons, we were just unable to see it. There are a number of factors which may have made imaging of the ICA more difficult in this study. The US probe was held perpendicular to the line of the ribs (and thus the overall line of the ICA), with the ICA viewed in cross-section. This is not the optimum to detect flow with Doppler US and probably reduced the sensitivity of US to identify the ICA. In a previous description of Doppler US imaging of the ICA [11], the probe was held more transversely, in the line of the ribs, such that the ICA was visualised along its course. This allowed accurate beam steering in the direction of blood flow, and thus, maximised the chances of visualising the ICA. This was important in this previous study as Doppler US was used quantitatively to calculate flow velocity and impedance indices within the ICA. However, the primary aim in our study was to document the position of the ICA relative to the overlying rib using Doppler US in a qualitative manner only. This could not be done accurately without viewing the entire ICS in cross-section, and so, we feel our method is valid for this more limited objective. Another factor influencing successful imaging of the ICA in our study was the body habitus of the subjects. In obese patients, an increased thickness of the chest wall degraded signal quality making the ICA harder to visualise. Use of a lower frequency probe with better penetration was useful in these cases. Positions closer to the spine were easier, possibly because the ICA tends to lie lower in the ICS, and thus, there is less chance of the superior rib impairing views. Patient clinical state, including their ability to maintain posture, and an increased respiratory rate which enhances movement artefact, also had a marked influence. A number of manoeuvres and use of US imaging techniques as outlined in Materials and Methods proved useful in some difficult cases. As mentioned, colour Doppler will not detect flow if the angle of movement is perpendicular to the line of the US beam. Small side-side movements of the probe may optimise the angle of incidence between US beam and blood flow, improving the Doppler image. It is also possible that in some cases, an absence of tortuosity meant the course of the ICA reliably followed the line of the rib and was thus invisible to a Doppler beam directed perpendicularly down from the skin. According to previous studies, this should be more common in younger patients [5, 25], which was not found in our study, possibly due to a small sample size. The use of power Doppler analysis, which is not angle dependent [20], should theoretically overcome this problem.

There were a number of limitations to this study. Low subject number potentially reduces the applicability of our results to the population at large. However, the high statistical significance, despite these low numbers, suggests results are robust. Due to the distance between the US probe on the skin where images were acquired, and the ICS where distances were calculated, it is possible that parallax errors were generated in measurements. However, we feel these are unlikely to be significant, as ensuring that the US probe remained perpendicular to the skin and line of the ribs proved relatively simple, and the geometry employed for measurements (fig. 2) was not complicated. Not all images of the ICA were confirmed to have arterial flow with spectral Doppler analysis. Even though images not analysed with spectral Doppler had clearly pulsatile signals consistent with arterial flow [19], it is possible that some of the recorded images were of venous rather than arterial structures. When imaged in cross-section, US is also unable to map the tortuosity of vessels. It may be that inter-subject variability in the location of the ICA is due to capturing the ICA at differing points of its tortuous course, rather than a shift in position of the entire artery. Although consistent with previous studies [5], the apparent ‘lower-lying’ location of the ICA closer to the spine may possibly reflect greater tortuosity of the ICA as one moves progressively posteriorly. As mentioned earlier in the discussion, the presence of a collateral artery which typically runs in the lower part of the ICS has been reported. This vessel was not specifically looked for in this study, and it is possible that some of the images of a ‘low-lying’ ICA actually represented a collateral artery. Finally, procedure time was not recorded in this study. The feasibility of incorporating screening for the ICA with US before thoracocentesis or ICC insertion into clinical practice depends largely on the extra time this would add to the procedure. We anticipate vascular imaging would only be necessary in a subset of patients, for example those with small posteriorly placed effusions or patients with coagulopathy.

Despite its deficiencies, this study has demonstrated the feasibility of visualising the ICA at standard US-guided thoracocentesis. It has defined a number of relevant questions to be addressed in future studies and has implications for thoracocentesis and ICC insertion. Although the trend for the ICA to migrate under the superior rib as one moves laterally is reliable, the actual position of the ICA in any individual at any given position across the back is highly variable and may be well down into the middle of the ICS. This is particularly true in older patients and closer to the spine. Screening for an artery within the ICS, utilising thoracic US, may reduce the incidence of its inadvertent laceration during thoracocentesis or ICC placement. Future studies need to define populations ‘at risk’ for having a vulnerable ‘low-lying’ intercostal or collateral artery within the ICS, and the additional screening time for such an artery with US would add to the procedure. They also need to clarify the sensitivity of thoracic US for identifying the position of the ICA relative to the overlying rib. If no ICA is seen on US, is it because the artery is behind a rib (and thus protected from injury during thoracocentesis) or simply that US was unable to visualise it on that occasion, due to factors related to the patient, imaging technique or operator experience. This question could be resolved by correlating US findings with an alternative imaging modality such as CT angiography.

Financial Disclosure and Conflicts of Interest

The authors declare that there are no conflicts of interest.

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Chapter 5 (paper)

Physician-performed ultrasound can accurately screen for a vulnerable intercostal artery prior to chest drainage procedures

Official Journal of the Asian Pacific Society of Respirology
Respirology

ORIGINAL ARTICLE

Physician-performed ultrasound can accurately screen for a vulnerable intercostal artery prior to chest drainage procedures

MATTHEW SALAMONSEN,[1] KAREN DOBELI,[2] DAVID MCGRATH,[2] CRAIG READDY,[2] ROBERT WARE,[3] KARIN STEINKE[2] AND DAVID FIELDING[1]

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ABSTRACT

Background and objective: **Laceration of the intercostal artery during pleural procedures is a rare but serious complication. This study evaluates the utility of thoracic ultrasound (US) to screen for a vulnerable vessel compared with the gold standard computed tomography (CT).**
Methods: **Before undergoing contrast-enhanced CT chest, thoracic US was performed on 50 patients with a high-end and portable machine, and an attempt made to visualize the vessel at three positions across the back to the axilla. These positions were labelled with radio-opaque fiducial markers. On both US and CT images, the location of the vessel at each position, relative to the overlying rib, was calculated and compared.**
Results: **The vessel was unshielded by a rib according to CT in 114 of the 133 positions. The sensitivity, specificity and negative predictive value of portable US to image the vessel, when it was within the intercostal space on CT, was 0.86, 0.30 and 0.27 respectively. The performance of a high-end machine was not significantly different. The median time required for a pulmonologist to locate the vessel was 42 s and 18 s for the portable and high-end US respectively.**
Conclusions: **US can be used to screen for a vulnerable vessel prior to pleural procedures, in a time amenable to use in clinical practice. Further, it is achievable by a pulmonologist using a portable US machine. If thoracentesis or chest tube insertion is being performed on a patient at increased risk of bleeding, screening for a vulnerable vessel with US prior to beginning the procedure is recommended.**

Key words: Doppler ultrasonography, intercostal artery, intercostal catheter, pleural effusion, thoracentesis.

Abbreviations: CT, computed tomography; US, ultrasound.

SUMMARY AT A GLANCE

This paper examines the ability of US to image the intercostal artery, using CT angiography as a gold standard comparator, and demonstrates that a physician can reliably identify a vulnerable intercostal artery using thoracic US, prior to chest drainage procedures.

INTRODUCTION

Thoracic ultrasound (US) is recommended to guide thoracentesis and chest tube insertion[1] to reduce adverse events and increase efficacy.[2,3] Despite the use of US however, laceration of the intercostal artery (hereafter called the vessel) continues to be a rare but serious complication of thoracentesis or chest tube insertion.[4] This is because thoracic US in its currently practiced form by the pulmonologist does not image the vessel[1] and so does not identify a vulnerable vessel within the intercostal space (hereafter called the space) prior to the procedure. In a small feasibility study, we showed that the vessel could be readily visualized at routine thoracic US.[5] However, there was no gold standard control in the study, so in cases where no artery was seen it was unclear if this was because the vessel was behind, and thus 'protected' by, the overlying rib (a true negative), or that the artery was 'vulnerable' within the space but that US was unable to image it (a false negative).

This study further explores the sensitivity, specificity and negative predictive value of the test—does non-visualization of the vessel by US truly indicate the vessel is safely behind a rib? We compared thoracic US with a gold standard measure, computed tomography (CT) chest with enhanced imaging of intercostal vessels.

METHODS

Study design

We conducted a prospective diagnostic study at a tertiary referral hospital in Brisbane, Australia, between

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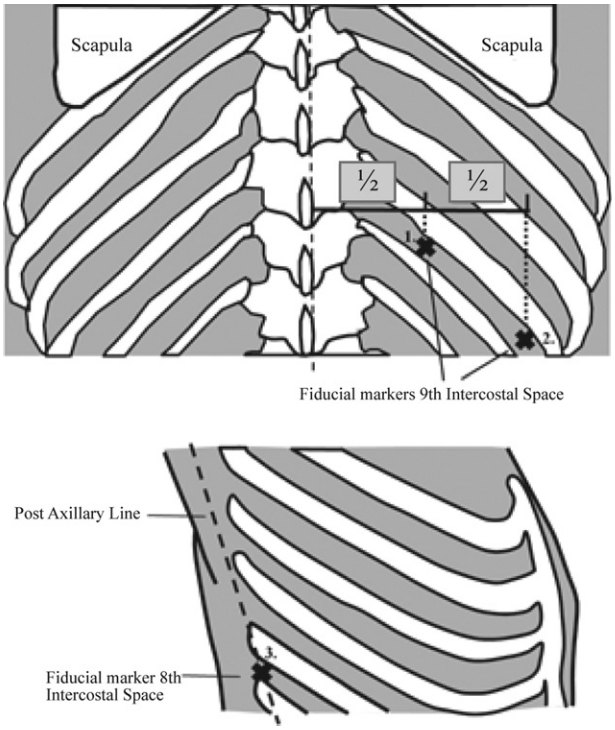

Figure 1 The three positions used for examination of the vessel: Position 1; 9th space roughly halfway between the spinous process and angle of scapula. Position 2; 9th space roughly inferior to the angle of the scapula. Position 3; 8th space in the posterior axillary line.

July 2011 and February 2012. Consecutive consenting medical patients who were undergoing routine CT chest were recruited. All patients received both US and CT. Age, height, weight, medical history and body mass index were recorded for each participant. The study was approved by the Institutional Ethics Committee.

The primary study outcome was the sensitivity, specificity and negative predictive value of US to image the vessel within the space, using CT angiography as the gold standard. Secondary study outcomes were times taken to image the vessel (sonographer and pulmonologist), the difference in performance between a portable and a high-end US machine and identification of patient factors which impact upon the ability of US to visualize the vessel.

US image acquisition and analysis

Prior to CT scanning, participants underwent US examination with a portable machine (e Logiq 500, GE Medical System, Milwaukee, WI, USA) and a high-end machine (iU22, Philips Medical Systems, Bothell, WA, USA). The US exams were performed by a pulmonologist and position 2 was additionally examined by a senior sonographer, alternating between portable and high-end machine for each participant. A linear probe (8 or 9 MHz) was used to inspect the intercostal space in three locations across the chest wall (Fig. 1). For the first 17 participants, only positions 1 and 2 were examined, as it was only after this that the method for tracking the vessel on CT scans was refined sufficiently to allow localization of the vessel around to the axilla. The correct space was found by counting up spaces from the most inferior rib. Patients were positioned prone with arms crossed above their heads, similar to the posture for CT scanning. The probe was orientated longitudinally and perpendicular to the skin, such that the position of the vessel within the space could be evaluated with respect to the superior and inferior rib. The pulse-repetition-frequency was set to optimize Doppler evaluation of low flow (8 to 14 cm/s) and the colour gain increased until just before colour artefact began appearing in the image. The vessel was defined as a pulsatile structure within the space. If a structure resembling the vessel was seen but was not clearly pulsatile, then pulse wave Doppler was used to confirm a characteristic arterial spectral waveform.[6] If a vessel could not be located, initially power Doppler and then a convex probe (4 MHz) was tried, up to a maximum examination time of 2 min. Time taken to identify the vessel following optimization of the B-mode image at position 2 was recorded for each operator, who was blinded to the other's examination. At each location, the thickness of the chest wall, the width of the space and the distance between the middle of the vessel and the lower border of the superior rib was measured. Finally, radiological fiducial markers (IZI Medical Products Corp, Baltimore, MD, USA) were placed on the patient's skin at all three positions, allowing these sites to be identified on the subsequent CT images.

CT image acquisition and analysis

An arterial phase contrast-enhanced CT examination of the chest was performed on a 256-slice scanner (Brilliance iCT, Philips Medical Systems, Cleveland, OH, USA), with subjects lying supine. Using vessel extraction software (Advanced Vessel Analysis, Philips Medical Systems), the course of the vessel was tracked and marked posteriorly in the 9th space and across the axilla in the 8th space (Fig. 2). The fiducial markers applied during ultrasonography confirmed that the correct vessel had been identified. As mentioned previously, for the first 17 patients, the vessel was tracked only as far lateral as position 2.

The width of the space and the distance between the vessel and the lower border of the superior rib were measured at the location perpendicular to skin at each fiducial marker. Measurements were made by a senior CT radiographer, blinded to the US results. The tortuosity of the vessel at positions 1–3 was graded visually from zero to three, according to the method described by Carney and Ravin.[7]

Statistical analysis

The sensitivity, specificity and negative predictive value of each US machine to visualize the vessel, using CT angiography as the gold standard, were calculated with 95% confidence intervals. A positive CT result indicates the vessel is located within the space

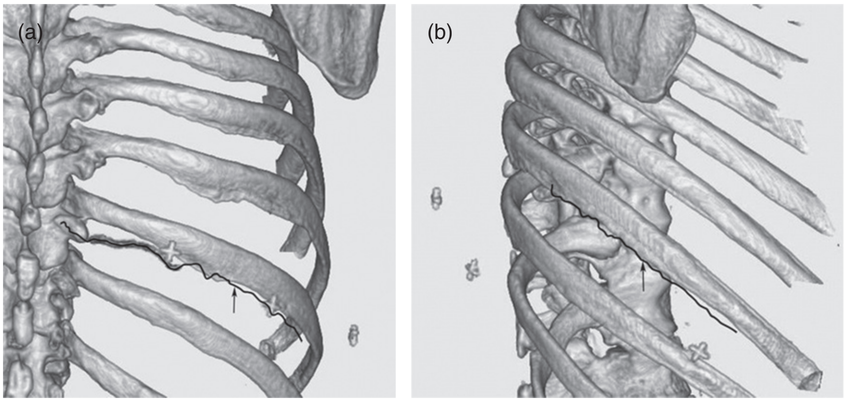

Figure 2 (a) Posterior volume-rendered computed tomography (CT) image showing fiducial markers (white crosses) and tracked vessel (arrow) in the 9th space. A medial section of the vessel has been manually coloured to demonstrate how the tracked line accurately follows the vessel's course. (b) Lateral volume-rendered CT image showing fiducial markers (white crosses) and tracked vessel (arrow) in the 8th space.

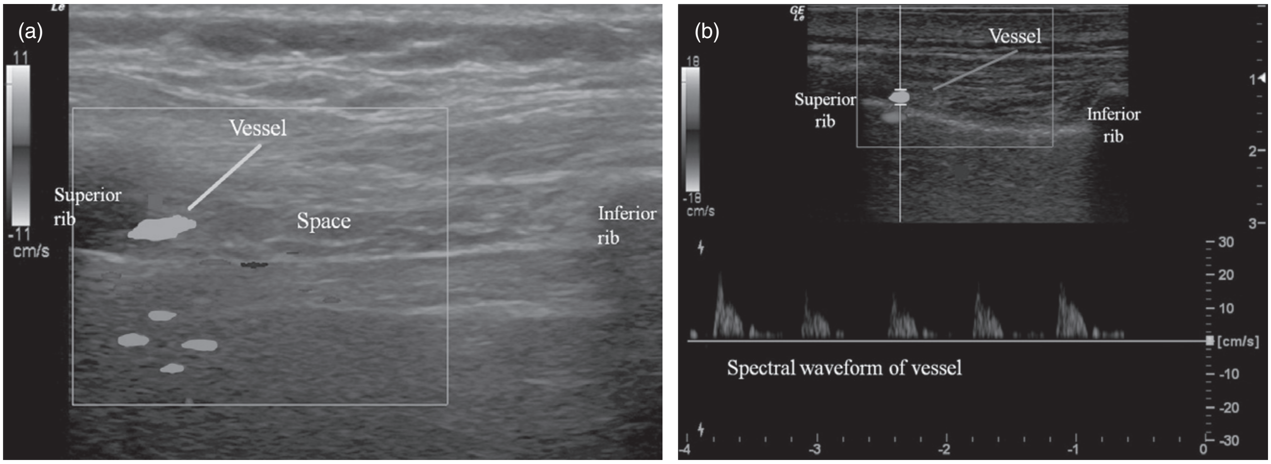

Figure 3 (a) Doppler image of the vessel using the 8 MHz linear ultrasound probe. (b)-Pulse wave Doppler image of the vessel. Note: there is a mirror image of the vessel deep to the pleural line.

and a negative result indicates that the vessel is behind the overlying rib. The sensitivity is the probability that US can 'see' a vessel located in the space on CT, and the specificity is the probability that US is unable to 'see' a vessel within the space when it is located behind the rib on CT. The negative predictive value is thus the probability that the vessel is protected behind the rib when US is unable to see it. Negative likelihood ratios were additionally calculated for each US machine, to give an indication of the negative predictive value if the effect of the prevalence of the artery lying within the space was removed (i.e. the performance of each US machine if it was used to scan a different region of the chest where the prevalence of an artery within the space was different).

The time taken to identify the vessel by a pulmonologist and senior sonographer at position 2, on both a high-end and portable US machine, were expressed as median (interquartile range) and compared using the Mann–Whitney test. The association between patient characteristics and the ability of US to image the vessel when it is located within the space on CT were assessed using multiple logistic regression models. Main effects included in the multivariable model were age, body mass index, chest wall thickness and vessel tortuosity.

RESULTS

Fifty consecutive patients were recruited for the study. Twenty eight (56%) were males, median age was 65 years (range 23–83) and median body mass index was 28 kg/m^2 (range 16–57). CT scans had been ordered for investigation of known or suspected lung cancer (29 patients), parenchymal lung disease (18 patients) or mediastinal adenopathy (3 patients). None had pleural or chest wall disease. From a possible 133 positions (only positions 1 and 2 were examined in the first 17 patients), the intercostal artery could be identified at 128 on CT images.

In 114 of the 133 positions examined, a pulsatile vessel was located with US (Fig. 3a) and pulse wave Doppler showed a waveform characteristic of an intercostal artery[6] (Fig. 3b). If identification of the vessel within the space is taken as positive, and localization of the vessel behind the rib (or non-visualization by US) is negative, then 2 × 2 contingency tables for US compared with CT can be created (Fig. 4). Diagnostic indices relating to the ability of US to visualize a vessel, using CT as the gold standard are shown in Table 1. For the five data points that the vessel was not visible on CT (all position 3), the vessel was designated as within the space.

(a)

	CT positive	CT negative	
US positive	97	14	111
US negative	16	6	22
	113	20	133

(b)

	CT positive	CT negative	
US positive	99	15	114
US negative	14	5	19
	113	20	133

Figure 4 Two-by-two contingency tables summarizing visualization of the vessel within the space by portable ultrasound (US) (a) and high-end US (b), compared with computed tomography.

Table 1 Diagnostic indices for the portable and high-end US machines

	Portable US	High-end US
Sensitivity[†]	0.86 (0.78–0.91)	0.88 (0.80–0.91)
Specificity[‡]	0.30 (0.13–0.54)	0.25 (0.10–0.49)
Negative predictive value[§]	0.27 (0.12–0.50)	0.26 (0.10–0.51)
Negative likelihood ratio[¶]	0.47 (0.24–0.93)	0.49 (0.23–1.10)

[†] Sensitivity (95%CI)—probability that US 'sees' a vessel classified as positive on CT.

[‡] Specificity (95%CI)—probability a vessel is not 'seen' in the space with US, when it is negative on CT.

[§] Negative predictive value—probability that the vessel is behind the rib on CT when it is not 'seen' with US.

[¶] Negative likelihood ratio—the likelihood that a vessel protected on CT is not 'seen' by US.

CT, computed tomography; US, ultrasound.

Table 2 lists the times taken to identify the vessel according to whether a portable or high-end machine is used and whether a sonographer or pulmonologist performs the scan. Identification of the vessel takes less time when a high-end machine is used compared with a portable one, but there is no significant difference in times taken between a sonographer and a pulmonologist.

Multivariate analysis revealed no significant effect of patient variables (age, skin thickness, body mass index, vessel tortuosity) on the ability of US to image the vessel. A convex probe allowed visualization of the vessel in eight cases where it was not seen with the linear probe. Five of these patients were obese with a chest wall thickness ≥ 40 mm. The use of power Doppler did not afford any benefit over colour Doppler.

Modified data

During the study, we noted that US could sometimes 'see' a vessel when it was behind the rib on CT (i.e. a false positive). This was probably due to small geometric differences between the US and CT examinations, which led to an over-calling of positive results with US. The position for evaluation of the vessel was taken as perpendicular to the surface of the skin at the fiducial markers. Despite careful attention, the actual angle between skin and probe could not be confirmed as exactly 90°. For analysis of CT images however, computer software allowed precise measurement of angles (Fig. 5a). Further, small 'heel-toe' angulations of the US probe, which are a fundamental part of standard scanning technique, led to an 'up' angle of the US field allowing resolution of images a short distance behind each rib (Fig. 5b).

As the vessel lies close to the bottom edge of the superior rib for most of its course (Fig. 2), these small discrepancies between US and CT could have led to US 'overcalling' vessels as being within the space. The inadvertent small upward angle of the US probe could have given an extra few millimetres to the intercostal space which were 'virtual' compared with the true perpendicular width measured on the CT image. The mean diameter of the posterior intercostal artery is 3 mm,[8] which equated to 15% of the mean intercostal space width in this study (20.4 mm). This top 15% of the space by US could either include vessels truly in the space or those in a virtual extra width due to the up angle of the probe. (Fig. 5b). To account for this possibility, we calculated modified diagnostic indices where a negative is defined as the vessel being non-visualized or present in the superior 15% of the space and a positive as the vessel residing in the lower 85% of the space (Fig. 6). If this modified criteria is used to define a positive or negative result, then the sensitivity, specificity and negative predictive values are 0.95, 0.97 and 0.96 respectively for the portable US and 0.97, 0.90 and 0.97 respectively for the high-end US. Results of the multivariate analysis are also affected, and an association between increasing chest wall thickness and failure to see a vulnerable vessel with the portable machine (odds ratio 2.7 (1.2–6.1) for each 10 mm increase in thickness) is revealed.

DISCUSSION

This study has confirmed the feasibility of visualizing the intercostal artery at routine thoracic US as part of clinical practice. If an intercostal artery (ICA) is lying within the intercostal space, the sensitivity of US to image it approaches 90%. Further, one does not need to be a highly trained sonographer nor use a high-end US machine to succeed. A respiratory physician who routinely practises US can identify the ICA using a portable US machine in a time amenable to use in clinical practice. In patients at increased risk of bleeding from a lacerated vessel during thoracentesis or chest tube insertion, such as when a posterior approach is mandated (e.g. to drain a posteriorly loculated effusion) or a bleeding diathesis exists, we would advocate the use of US to screen for an exposed 'vulnerable' vessel at the proposed site for needle insertion, prior to beginning the procedure.

Current guidelines recommend that thoracentesis or chest tube insertion be performed over the superior border of the inferior rib, within the triangle of

Table 2 Times taken to locate the vessel at position 2

	Portable US	High-end US	Significance
Sonographer time (s)	37 (28.5–70)	10 (4.5–36.25)	$P = 0.01$
Pulmonologist time (s)	42 (29.5–100)	18 (10.25–36)	$P = 0.002$
Significance*	$P = 0.10$	$P = 0.44$	

* Significance of difference in times between pulmonologist and sonographer.
US, ultrasound.

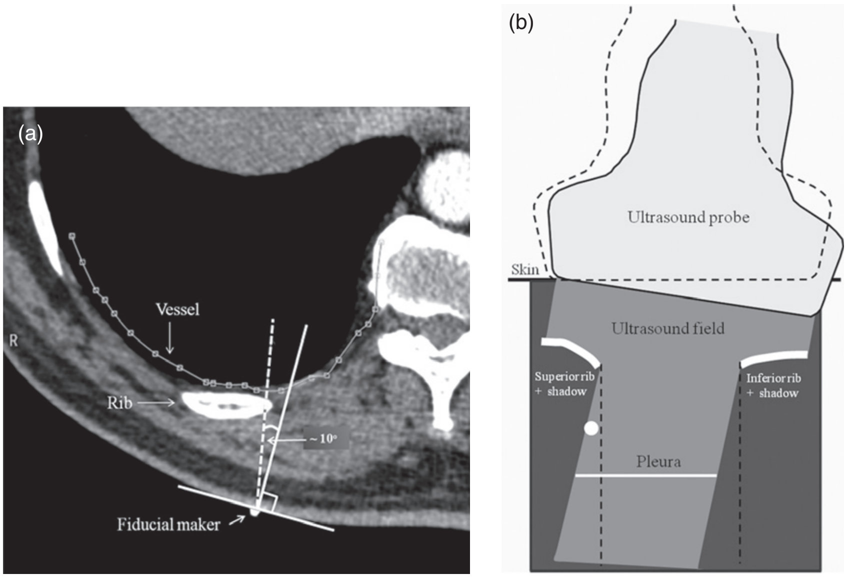

Figure 5 (a) Proposed explanation for why the ultrasound (US) could have imaged a slightly different part of the vessel to computed tomography (CT). If the US probe was not held precisely perpendicular to the skin (thus creating a small deviation in angle from the intended path of the US beam), this could alter the section of vessel analysed and thus whether it was behind the rib or in the space. Solid white line: perpendicular to fiducial marker. Dotted white line illustrates 10° off centre. Grey line: vessel. (Note an axial CT is of course not in the normal downward plane of the rib.) (b) Proposed explanation for how US could have imaged the vessel when it was located behind the overlying rib. A slight 'heel-toe' angulation of the probe could result in an 'upward' direction of the US field, allowing visualization of the vessel (white circle) behind the superior rib. If the probe is held completely flat to the skin (dotted outline), then the rib shadow (vertical dashes) would hide the vessel.

safety, to minimize risk to the vessel.[1] The vessel begins its course exposed posteriorly, within the middle of the space, and progressively moves towards the 'safety' of the overlying rib as it travels laterally. Although this is a reliable trend,[9] there are individual outliers within any given population of patients, where the vessel may still be exposed within the space as far lateral as the axilla.[5,10] Further, in clinical practice, we are not always able to accurately insert the needle over the superior border of the inferior rib, due to patient habitus or posture. For these reasons, even when the vessel is lying relatively protected by the overlying rib, erroneous insertion of the needle into the superior part of the space could result in vessel laceration.

A major limitation of this study was the potential for discrepancy in the precise position the vessel was analysed at CT and US, and the ability of US to resolve images of the vessel lying behind the overlying rib, due to an 'up-angle' of the US field created by probe manipulation. This might have been compounded

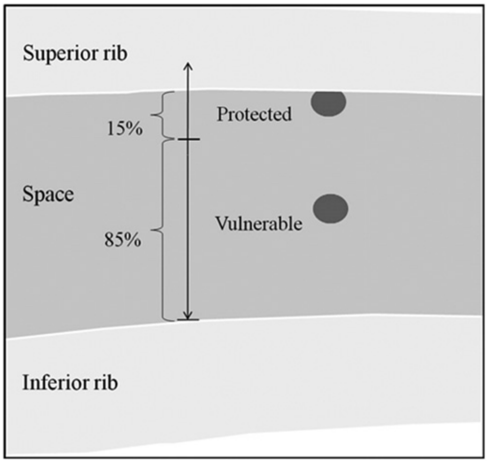

Figure 6 Diagram for modified data, showing the classification of a vessel (dark grey circles) as protected or vulnerable.

further by slight changes in the width of the space when patients turned from prone (used for US examination) to supine (used for CT scanning). Finally, in five patients, the vessel could not be identified at position 3 on CT. To make results as 'honest' as possible, the worst case scenario was assumed where the vessel lay vulnerable within the space in these patients. These factors probably resulted in significant disagreement between the two imaging modalities' classification of the vessel as within the space or behind the rib. We speculate that this could account for the low specificity (i.e. vessel interpreted as vulnerable on US when it was protected on CT) seen in this study. The modified data however remove the possible impact of US seemingly visualizing a vessel within the space when it was not, and we believe that diagnostic indices calculated from this modified data more accurately represent the true clinical utility of US to screen for a vulnerable vessel. In practice, the lower part of the intercostal space is the most important to interrogate, as this is where a needle will be passed, and data relating to the lower 85% of the space still have practical value.

It could be speculated that the vascular structure imaged with US in our study was not always the intercostal artery. However we believe accurate identification of the vessel was confirmed by the high-impedance monophasic spectral waveform recorded with pulse wave Doppler from the arterial structure imaged with US. This is consistent with descriptions of the intercostal artery in studies examining the vascular supply of chest wall tumours.[6]

Our impression during scanning was that increasing body mass index and chest wall thickness made imaging of the vessel with US more difficult and extended examination time, especially with the portable US machine. This is supported by the results of multivariate analysis on the modified data, which show a negative impact of increasing chest wall thickness on the ability of the portable US machine to visualize a vulnerable vessel.

In summary, we have shown that the intercostal artery can be imaged at standard thoracic US, and not only can this be achieved in a time amenable to use in clinical practice, but it does not require a highly trained sonographer nor a high-end US machine. If the clinician is not able to visualize the vessel with US, he or she can be confident that it does not lie vulnerable in the middle or lower region of the space.

Acknowledgements

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Chapter 6 (Paper)

A new method for performing continuous manometry during pleural effusion drainage

Interventional Pulmonology

Respiration

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A New Method for Performing Continuous Manometry during Pleural Effusion Drainage

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Key Words

Pleural pressure · Manometry · Pleural effusion management

Abstract

Background: Pleural manometry can predict the presence of trapped lung and guide large-volume thoracentesis. The current technique for pleural manometry transduces pressure from the needle or intercostal catheter, necessitating intermittent cessation of fluid drainage at the time of pressure recordings. ***Objectives:*** To develop and validate a technique for performing continuous pleural manometry, where pressure is transduced from an epidural catheter that is passed through the drainage tube to sit within the pleural space. ***Methods:*** Pleural manometry was performed on 10 patients undergoing thoracentesis of at least 500 ml, using the traditional intermittent and new continuous technique simultaneously, and pleural pressures were recorded after each drainage of 100 ml. The pleural elastance (PEL) curves and their 95% confidence intervals (CIs), derived using measurements from each technique, were compared using the analysis of covariance and Student's paired t test, respectively. ***Results:*** There was no significant difference in PEL calculated using each method ($p > 0.1$); however, there was a trend towards the CI for the PEL derived from the continuous method being narrower ($p = 0.08$). Fully automated measurement of drainage volume and pleural pressure, with real-time calculation and display of PEL, was achieved by connecting the system to a urodynamics machine. ***Conclusions:*** Pleural manometry can be transduced from an epidural catheter passed through the drainage tube into the pleural space, which gives continuous recording of the pleural pressure throughout the procedure. This allows for automated calculation and display of the pleural pressure and PEL in real time, if the system is connected to a computer with appropriate software.

Introduction

Pleural manometry during drainage of a pleural effusion can predict the presence of unexpandable lung [1–3] and guide safe large-volume thoracentesis [4]. However, most pulmonologists are not familiar with the technique for pleural manometry and so it is not commonly performed [5, 6].

The traditional method for measuring pleural pressure during thoracentesis is by connection of a manometer to the thoracentesis needle or intercostal catheter [7, 8]. With this method, drainage must be temporarily ceased at the time of pressure recordings because any flow of fluid past the pressure manometer will invalidate the measurements. We have found this intermittent technique (i.e. the intermittent method) to be somewhat cum-

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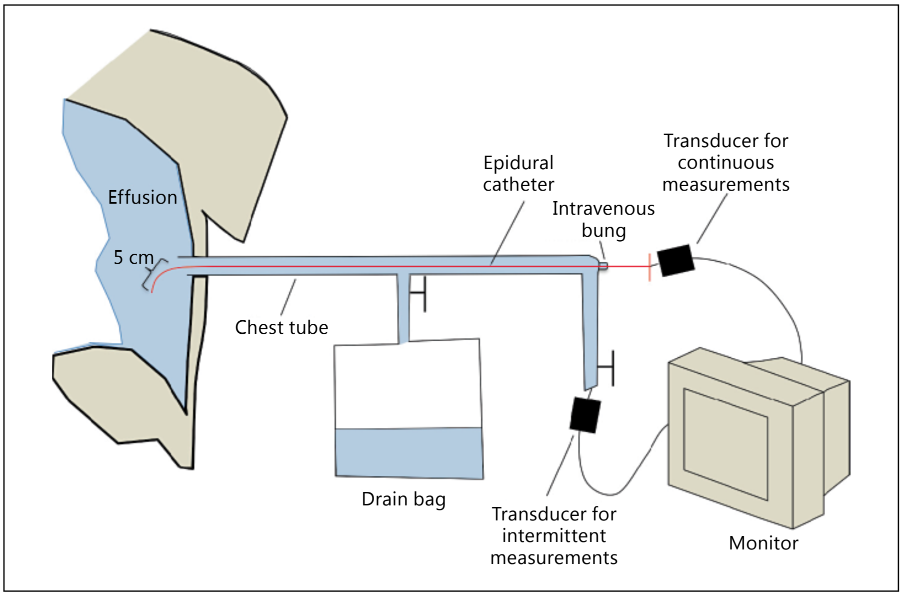

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Fig. 1. Procedure setup for pleural manometry using the intermittent and continuous methods simultaneously.

bersome and increase the complexity of the procedure. We have developed a simplified method for pleural manometry that allows for continuous recording (i.e. the continuous method) by transducing the pleural pressure via a sterile epidural catheter that is passed through the drainage tube to sit within the pleural effusion during drainage. This setup is analogous to that used for urodynamics, which has been well documented [3]. This study aims to validate this new continuous method for pleural manometry by demonstrating that the pleural elastance (PEL) measurements calculated using each technique for any given patient are equivalent.

Materials and Methods

Study Design

This was a prospective cohort study conducted at a tertiary referral hospital between May 2012 and May 2013. The study was approved by the institutional ethics committee. Consenting patients undergoing pleural drainage of at least 500 ml were recruited.

Methods

During effusion drainage, pleural manometry was performed simultaneously with both the traditional intermittent method and the new continuous technique (fig. 1). The epidural catheter was passed through a self-sealing intravenous bung (Icon Medical, Auburn, N.S.W., Australia) at the site of entry into the chest tube, ensuring that the drainage system remained watertight. Both transducers were zeroed at the height of catheter entry through the skin. Following zeroing, the system was opened to allow the opening pleural pressure obtained from each technique to be recorded. Then, after drainage of each 100 ml while there was still flow through the chest tube, the pressure was recorded using the continuous method. Immediately following each such recording, the flow through the tube was halted by way of a 3-way tap, while the pressure transduced using the intermittent method was noted. The system was then opened to allow a further 100 ml drainage, and so on, until the end of the procedure. The people recording the pressures for each method were blinded to the results of the other method. Pressure-volume relationships derived from the data were inspected visually for linearity. There were no cases of a bimodal pressure-volume relationship [1] and so the PEL, which equals the change in pressure per unit volume, was calculated using linear regression of all the data points from each patient.

Following acquisition of data using the two methods simultaneously, the feasibility of a fully automated system made possible by the new continuous recording method was demonstrated in a single patient by connecting the system to a standard urodynamics machine (Neomedix System Aquidata, Belrose, N.S.W., Australia). The epidural catheter, which was inserted through the chest tube such that its tip was within the pleural space, was connected to the machine's pressure transducer and the drainage bag was attached to a weighted cell, which transduces a change in weight (a surrogate measure of drain volume). Following zeroing of the machine, the chest tube was opened allowing free flow of pleural fluid into the drainage bag, while the changing pleural pressure was monitored via the epidural line. The setup for this procedure is shown in figure 2.

Analysis

PEL lines were calculated for each technique using standard linear regression models. These were then compared between techniques using analysis of covariance. The technique (intermittent/continuous) and the volume were entered as main effects, as well as the technique-by-volume interaction. Opening pressures and confidence intervals (CIs) for the PEL, derived with each tech-

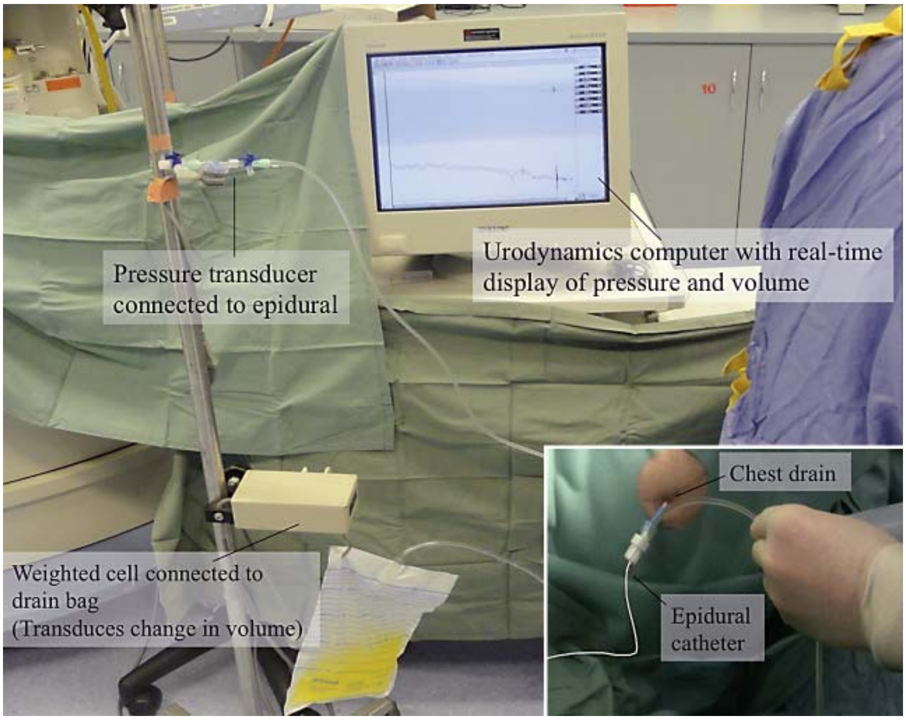

Fig. 2. Setup for chest drainage with pleural manometry using an automated urodynamics machine. In the insert, the epidural catheter is seen deployed inside the chest drain into the pleural space.

nique, were compared using Student's paired t test. Statistical analysis was performed with GraphPad Prism software version 6 (GraphPad Prism La Jolla, Calif., USA) and STATA software version 12 (StataCorp, College Station, Tex., USA).

To calculate the power of rejecting the null hypothesis that the PEL values differ between techniques for each individual, we assumed there would be 11 observations on each individual measured from a volume of 0–1 liters in increments of 0.1 liters. Furthermore, it was clinically important that the standard deviation of the regression errors would be 1 and that there would be a difference in PEL values of >4. A value of 4 was chosen, as this would be the difference in PEL required to alter its classification from a normal to a trapped physiology [2, 9]. If we sampled 10 individuals, with α = 0.05, we would have 79% power to detect at least one significant difference in PEL values between techniques.

Results

Eleven patients were recruited to the study. The median age was 70 years (range 55–73) and the median volume drained was 1,050 ml (range 500–1,500). Seven patients had a diagnosis of pleural malignancy, 1 had pleural infection, 2 had heart failure and 1 had chronic nonspecific pleuritis. No patients had trapped lung, defined as complete separation of the visceral from the parietal pleura on postdrainage imaging.

Table 1. Drainage parameters and comparison of PEL values derived for each patient using each technique

Patient No.	Tube size, FR	Volume, l	PEL (±95% CI)		p value
			intermittent	continuous	
1	8	1.0	–17.6 (4.0)	–16.9 (4.5)	0.59
2	8	1.5	–1.8 (0.6)	–2.3 (0.8)	0.30
3	8	1.4	–8.3 (1.5)	–6.8 (3.4)	0.41
4	8	1.5	–15.5 (9.1)	–15.0 (8.6)	0.93
5	8	0.9	–11.1 (2.9)	–8.9 (2.1)	0.10
6	8	0.9	–9.9 (4.0)	–6.8 (2.2)	0.12
7	8	1.1	–9.5 (5.4)	–7.5 (3.3)	0.47
8	8	1.1	–10.4 (5.5)	–11.3 (4.4)	0.76
9	16	0.9	–7.5 (11.7)	–9.9 (7.6)	0.65
10	10	0.5	–12.1 (8.0)	–8.6 (4.7)	0.42

Clinical characteristics for each patient, including PEL values for each technique, are shown in table 1. Both PEL values and opening pressure were well approximated by a normal distribution. The PEL values were not significantly different between techniques for any patient, with a smallest p value of 0.10. This is reflected in the high concordance between PEL obtained from each technique, with a mean difference (95% CI) of 0.98 cm H_2O/l (–0.35 to 2.31). An example of this is displayed in figure 3a,

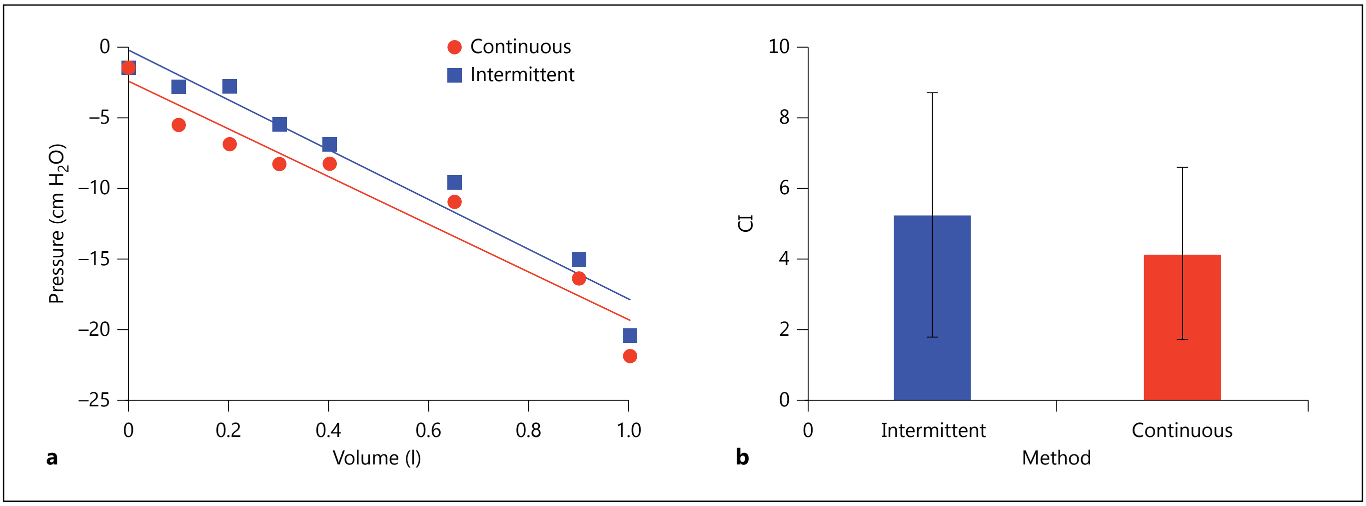

Fig. 3. a Example of pressure recordings obtained from simultaneous measurements using the two techniques with linear regression lines. **b** Mean CIs for the continuous compared with the intermittent technique (error bars represent standard deviation).

Color version available online

Table 2. Comparison of opening pressures derived from each method for each patient

Patient No.	Opening pressure, cm H_2O		Difference, cm H_2O
	intermittent[a]	continuous[b]	
1	–1.4	–1.4	0.0
2	0.0	0.0	0.0
3	1.4	1.4	0.0
4	0.0	2.7	–2.7
5	–1.4	4.1	–5.5
6	0.0	–1.4	1.4
7	–1.4	–4.1	2.7
8	5.4	0.0	5.4
9	0.0	0.0	0.0
10	1.4	–4.1	5.5

[a] Pressure derived using the intermittent technique.
[b] Pressure derived using the continuous technique.

where data for patient No. 4 are displayed (p value for difference in slopes = 0.93). There was a trend for PEL values derived with the continuous method to have a smaller 95% CI (p = 0.08; fig. 3b), i.e. the PEL values obtained with the continuous method were more tightly grouped around the PEL line. There was no significant difference in opening pressures (p = 0.49; table 2).

The automated real-time pressure, volume and PEL plots obtained when the system was connected to an urodynamics machine are shown in figure 4.

Discussion

This study has documented a new method for performing pleural manometry, which allows for the continuous measurement of pleural pressure during pleural effusion drainage. The technique is simple to perform and it may make pleural manometry more accessible to the pulmonologist, increasing its use around the world.

Currently, most pulmonologists do not perform pleural manometry during pleural effusion drainage, despite its potential utility to guide safe large-volume thoracentesis and aid in the diagnosis of trapped lung. There is no commercially available equipment designed specifically for the procedure [5], and we found the traditional intermittent method of pleural manometry to be cumbersome when we were first learning the technique. Because pressure is transduced from the drainage device on the outside of the chest, flow must be halted temporarily at the time of pressure recordings. Typically, this is done every 250 ml up to 1 liter, and then every 100 ml thereafter [8]. Furthermore, pressures and volumes must be manually recorded and the PEL calculated at a later time. When using this traditional intermittent method, we also experienced difficulties due to air bubbles that rose from the drainage bag or underwater seal. If these migrate to sit within the drainage catheter between the point of pressure transduction and the pleural cavity, they would invalidate the pressure measurements. With the new refined method for continuous pleural manometry, because the pressure is transduced from an epidural catheter

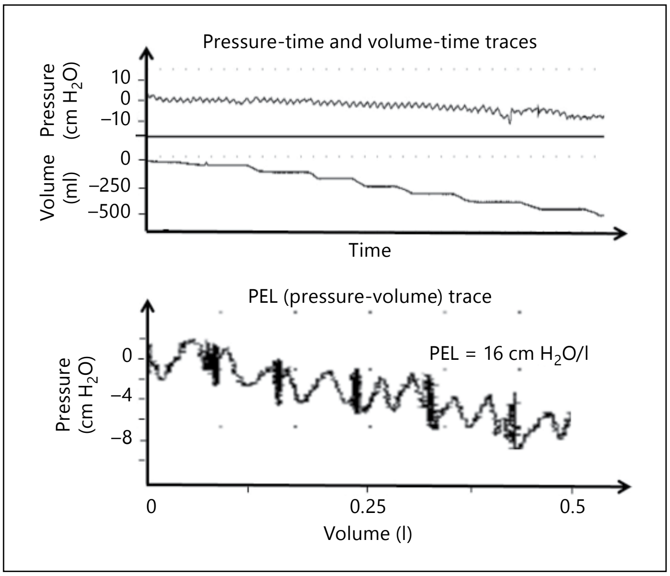

Fig. 4. Real-time pressure, volume and PEL plots obtained with a urodynamics machine.

which sits within the thoracic cavity away from pleural fluid flow, it can be recorded continuously throughout drainage and any air bubbles within the drainage device do not affect the measurements.

There was no statistically significant difference between the opening pressures measured by each technique, although this could differ by a small amount for each individual patient. This would reflect the small difference in relative height between the drainage catheter and the end of the epidural cannula, which protruded 5 cm beyond the end of the chest tube within the pleural space. The important point is that a small change in opening pressure would not affect the calculated PEL, as the PEL only reflects the change in pleural pressure per unit volume of fluid removed from the chest. There was also a trend towards narrower CIs for the PEL derived with the continuous technique, which probably reflects a reduction in noise that could be introduced during the repetitive opening and closing of drainage with the intermittent technique. In this study, we showed that, using the new continuous method, pleural manometry can be fully automated. This is quite simple and can be achieved by connecting the pressure transducer and drainage-volume transducer (in this case, from a weighted cell which transduces the change in weight of the drainage bag) to a computerized system that can plot pressure-volume values in real time and calculate the PEL. We used a urodynamics machine for this because it was easily available in our center, but it would not be hard to simply use a laptop computer with the appropriate software installed [10]. A further simplification could be achieved if double lumen chest tubes and thoracentesis kits were commercially available. The pressure transducer could be connected directly to the second lumen, obviating the need to insert an epidural catheter into the pleural space. At this time, however, we are only aware of a 24-Fr double lumen chest tube (Thal-Quick Double Lumen Chest Tube, Cook Medical, Bloomington, Ind., USA), which is much larger than what is required for most cases of effusion drainage.

One of the other benefits of pleural manometry is that it leads to a better understanding of the pathophysiology of pleural effusions [11] and may provide additional information on the mechanism of pneumothorax generation during effusion drainage in the presence of trapped lung. Towards the terminal part of thoracentesis in the presence of trapped lung, once the pleural pressure drops to a particular excessively negative value, the pressure is seen to partially normalize and continues to do so during further drainage, such that there is no further reduction in pleural pressure [12]. This has been hypothesized to be due to transient pressure-dependent parenchymal-pleural fistulae, but the exact mechanism could not be further investigated due to the intermittent nature of pressure recording [12] so the behavior of the pleural pressure during times of active fluid drainage could not be seen. The new method of continuous manometry overcomes this problem and may allow the pathophysiology of pneumothorax generation during effusion drainage in the presence of trapped lung to be better characterized.

There were two possible limitations to this study. Firstly, in order for a reliable pressure to be transduced from the epidural catheter, there must be no significant flow of fluid past the tip of the catheter within the pleural cavity. The catheters in this study were of a small bore, but if a larger bore was used (e.g. 16–20 Fr) and flow rates were higher, one could argue that measurements might be less reliable. However, in 1 patient in our study, a 16-Fr tube was used, and there was no significant difference between the pressure values obtained with the intermittent or the continuous method. Furthermore, in cases where a smaller caliber tube was used, a standard aspirating syringe was used to facilitate fluid drainage, which temporarily increased the negative pressure applied to the drainage catheters. Despite this, in no cases was there a significant difference between the intermittent and continuous methods. The second limitation of the study is that there were no cases of a bimodal PEL, such as can occur in the presence of trapped lung [2]. It is important to bear this limitation in mind, but we do not believe it would affect the performance of the continuous technique. A bimodal PEL, while usually associated with a greater pressure drop, would not be associated with an increased flow rate of fluid from the chest, which, for the reasons described above, would be needed to affect the pressure measurements. The aim of this study was not to assess the utility of the continuous method to identify the pathology associated with an abnormal or bimodal PEL, such as trapped lung, but rather to show that it gives the same results as the traditional intermittent method.

In conclusion, we have developed a new method for performing pleural manometry, which allows for the continuous measurement of pleural pressure during effusion drainage. The technique offers a simplification on the current method, and would also allow a more complete investigation of the pathophysiology of pneumothorax generation following thoracentesis in the presence of trapped lung. The technique allows for the automated recording of pleural pressures and calculation of the PEL, and would become even more straightforward if a larger range of double lumen chest tubes and thoracentesis kits became commercially available.

Acknowledgements

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Chapter 6
Supplement

Pleural manometry performed during thoracentesis can provide two useful types of information. Firstly, using a maximally negative pleural pressure of -20cmH_2O to limit thoracentesis can allow safe removal of larger volumes of fluid compared with the limit of 1.5L as recommended by most guidelines[1,2]. Secondly, the shape and slope of the pleural elastance (PEL) curve provides information on the pathophysiology of the pleural space and allows differentiation between normal, entrapped and trapped lung[3].

Although the preceding publication in Chapter 6 on a new method for performing continuous pleural manometry demonstrated a high level of agreement between the traditional intermittent and new continuous method for calculation of PEL, apart from a short analysis on opening pressures, it did not present data or analysis on the absolute pleural pressures obtained during the study. This supplement examines the agreement between absolute pressure changes derived from the intermittent and continuous methods.

Opening pressures

As stated in the preceding chapter, although there was no statistically significant difference between the opening pressures derived from each technique, there were small differences in individual patients (see Table 2 Chapter 6). These pressures can be seen in Figure 1 displayed as a Bland Altman plot. The small differences in opening pressure occurred because the tip of the epidural catheter within the pleural space (where continuous pressures were recorded from) was up to 5cm above or below the thoracentesis catheter (from where the intermittent pressure measurements were recorded).

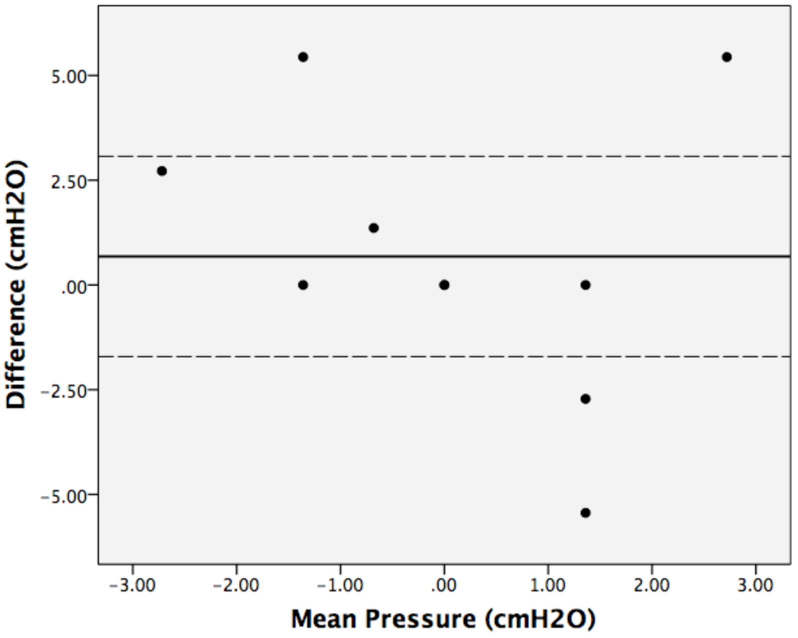

Figure 1 Bland Altman Plot showing agreement between opening pressures obtained from the intermittent versus continuous techniques

Comparison of all pressure recordings

The values for continuous pressure recordings were corrected according to the difference in opening pressure between the two techniques for each subject, to account for the difference in pressure transduction height due to the variable position of the tip of the epidural catheter within the pleural space (Figure 1, Chapter 6).

Figure 2 shows the agreement between matched individual pressure recordings obtained from the intermittent versus continuous techniques for each subject on a Bland Altman Plot. The intraclass correlation coefficient (ICC) was 0.99 and the mean difference in scores (95%CI) was -0.83cmH_2O (-6.07 - 4.41), revealing a very high level of agreement between the two techniques.

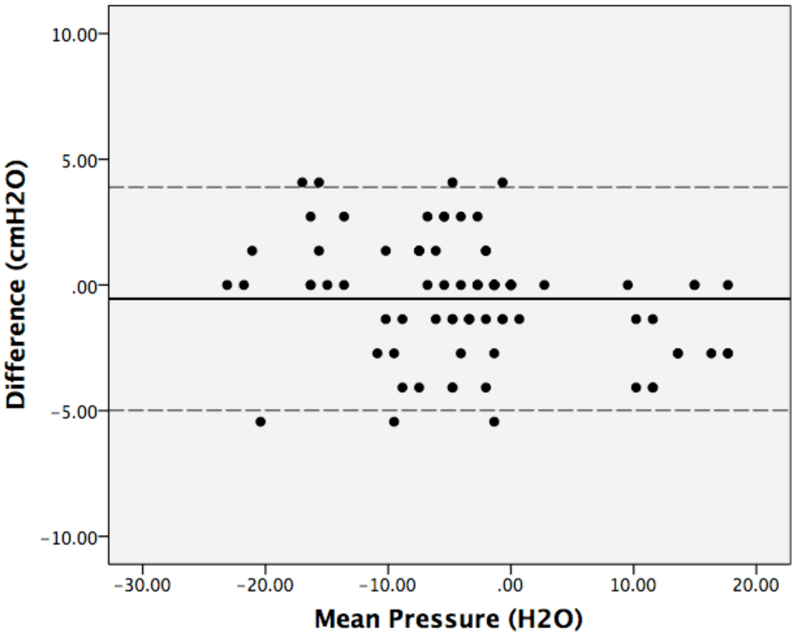

Figure 2 Bland Altman Plot showing agreement between pressures obtained from the intermittent versus continuous techniques

Linear regression of the pressure differences displayed in the Bland Altman plot (Figure 2) revealed a small but significant proportional bias with a correlation coefficient of -0.29 (P = 0.009). To say this in a more intuitively understandable way, as the mean pleural pressure became progressively more negative during thoracentesis, the pressure difference between the 2 techniques (Intermittent-continuous) became greater.

Discussion and conclusions

The strength of agreement between measurements taken by the intermittent and continuous techniques, as assessed by the ICC and mean difference in scores was very high. The greatest difference between matched pressure recordings in the entire data set was <10cmH2O. This is less than the possible variation due to the arbitrary height at which the thoracentesis needle is inserted through the chest wall[4]. Along with the high level of agreement in PEL (documented in Chapter 6), this confirms that the new continuous method for performing pleural manometry could legitimately be used in a clinical setting to obtain accurate pressure measurements.

The small but significant proportional bias found on linear regression is counter-intuitive and we can only speculate as to the cause for this. The pressure difference was calculated as the intermittently recorded pressure – continuously recorded pressure. Bernoulli's principle states that for an increase in the speed of a fluid past a pressure transducer, there is a simultaneous decrease pressure[5]. Therefore, from a basic theoretical perspective, a greater flow of fluid past the end of the epidural catheter, from where the continuous pressure measurements were transduced, would result in a reduction of the continuously measured pressure. In our procedures, as the pleural effusion was drained and the intra-pleural pressure became progressively more negative, this would reduce the flow of fluid through the drainage tube (and past the tip of the epidural catheter) and therefore result in a relatively smaller difference between intermittently and continuously recorded pressures, which is the opposite to what the linear regression analysis suggests. Consistence with this theoretical evidence against the hypothesis that flow past the epidural catheter affects continuous pressure measurements, is that in the case where a 16Fr intercostal catheter was used (the largest bore drainage tube in the series and thus the case with the highest flow rate), the difference in pressure recordings was only -1.36-4.10cmH_2O, well within the confidence limits for data in this series.

Another possibility is that the proportional bias was a chance finding. There were only 10 instances where the difference in pressure recordings was above 5cmH2O, and as can be visually seen in the Bland Altman plot in Figure 2, it is these relatively few recordings that would have had the strongest influence on the negative correlation coefficient. Finally, it could be due to noise in the measurements. As can be seen in Figure 3b in Chapter 6, there was a greater amount of noise in the intermittent compared with continuous measurements. When ceasing flow for intermittent measurements, the pressure displayed by the electronic transducer takes some time to become stable. Ideally we should have waited till pressure measurements over at least 4 consecutive respiratory cycles were stable[6], however this was not done. It is possible that at higher intrapleural pressures the time taken for the intermittent transducer reading to stabalise was prolonged and thus the pressure recorded was erroneous. We acknowledge this as a possible limitation in the design of the study.

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Chapter 7 (paper)

Novel use of pleural ultrasound techniques can identify entrapped lung prior to effusion drainage

CHEST™

Novel Use of Pleural Ultrasound Can Identify Malignant Entrapped Lung Prior to Effusion Drainage

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BACKGROUND: The presence of entrapped lung changes the appropriate management of malignant pleural effusion from pleurodesis to insertion of an indwelling pleural catheter. No methods currently exist to identify entrapped lung prior to effusion drainage. Our objectives were to develop a method to identify entrapped lung using tissue movement and deformation (strain) analysis with ultrasonography and compare it to the existing technique of pleural elastance (PEL).

METHODS: Prior to drainage, 81 patients with suspected malignant pleural effusion underwent thoracic ultrasound using an echocardiogram machine. Images of the atelectatic lower lobe were acquired during breath hold, allowing motion and strain related to the cardiac impulse to be analyzed using motion mode (M mode) and speckle-tracking imaging, respectively. PEL was measured during effusion drainage. The gold-standard diagnosis of entrapped lung was the consensus opinion of two interventional pulmonologists according to postdrainage imaging. Participants were randomly divided into development and validation sets.

RESULTS: Both total movement and strain were significantly reduced in entrapped lung. Using data from the development set, the area under the receiver-operating curves for the diagnosis of entrapped lung was 0.86 (speckle tracking), 0.79 (M mode), and 0.69 (PEL). Using respective cutoffs of 6%, 1 mm, and 19 cm H_2O on the validation set, the sensitivity/specificity was 71%/85% (speckle tracking), 50%/85% (M mode), and 40%/100% (PEL).

CONCLUSIONS: This novel ultrasound technique can identify entrapped lung prior to effusion drainage, which could allow appropriate choice of definitive management (pleurodesis vs indwelling catheter), reducing the number of interventions required to treat malignant pleural effusion.

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ABBREVIATIONS: IPC = indwelling pleural catheter; M mode = motion mode; PEL = pleural elastance; ROI = region of interest; STI = speckle tracking imaging

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Traditionally, the primary treatment of patients with a malignant pleural effusion is pleurodesis.[1,2] The most common cause for pleurodesis failure is the presence of lung entrapment by tumor, which restricts expansion of the lung and prevents apposition of the visceral and parietal pleura.[3,4] In the presence of entrapped lung, an indwelling pleural catheter (IPC) should be inserted. Currently, there are no methods to identify entrapped lung prior to drainage of a malignant pleural effusion[5] and so many patients require more than one procedure for definitive management.

A number of ways exist to analyze the motion of tissue using ultrasonography, which could be used to identify a lung with restricted movement. Motion mode (M mode) quantifies tissue displacement and is widely available on current ultrasound machines.[6] A more sophisticated technique, called elastography, quantifies tissue deformation, and expresses it as strain, which is a dimensionless measure of the change in length of a tissue with time.[7-9]

We hypothesized that an entrapped lung would less readily transmit the cardiac impulse, resulting in less motion and strain (deformation) as compared with a nonentrapped lung and, furthermore, that this would be identifiable with ultrasonography. This study aims to develop, and examine the diagnostic accuracy of, a method to diagnose entrapped lung using M mode and speckle tracking imaging (STI) strain analysis with pleural ultrasound, prior to pleural effusion drainage.

Materials and Methods

Study Design

This was a prospective multicenter cohort study, conducted between March 2012 and October 2013. The study was approved by the Human Research Ethics Committee at Royal Brisbane and Women's Hospital (Queensland, Australia) (approval number: HREC/11/QRBW/452).

Consenting patients undergoing drainage of at least 500 mL for suspected malignant pleural effusion were recruited. The primary outcome was the ability of predrainage M mode and STI to identify entrapped lung as defined by postdrainage radiology and to compare this with pleural manometry.[10] Secondary outcomes were the utility of these modalities to predict pleurodesis failure (defined as reaccumulation of the pleural effusion on chest radiograph during the study period) and the identification of factors that increase the chance of false-positive and false-negative results.

Methods

Prior to undergoing effusion drainage, a targeted pleural ultrasound of the ipsilateral lower lobe was performed using an echocardiogram machine (Vivid E9; GE Healthcare), by either a senior echocardiographer or a pulmonologist trained in the use of the cardiac equipment. Following identification of the diaphragm through the posterior chest wall, the probe was moved progressively superior until the first imaging of atelectatic lung was achieved. Cine loops were then acquired during breath hold at functional residual capacity for three or more cardiac cycles.

M Mode and Strain Analysis

M mode and strain analysis were performed offline (EchoPAC version 108.1.5; GE Vingmed, General Electric Co) by an experienced cardiologist, blinded to the clinical and radiologic details of each patient. Strain was measured with STI, a technique developed for assessing myocardial contractility[11] (Fig 1). The software calculates the strain in a direction radially outward from the center of a manually inserted region of interest (ROI). To provide data for reliability testing, 20 ultrasound scans were also analyzed by two other doctors (one cardiologist and one pulmonologist) and for a second time by the primary cardiologist (2 months after the initial analysis), providing intertester and test-retest data, respectively.

Pleural Manometry

During drainage of the pleural effusion, manometry was performed. Pleural elastance (PEL) was calculated, according to the well-established technique summarized by Feller-Kopman.[10]

Gold-Standard Scoring of Lung Entrapment on Postdrainage Radiology

The gold standard for the diagnosis of entrapped lung was the consensus opinion of two interventional pulmonologists, using postdrainage radiology and any available clinical details. Patients were allocated to one of five categories: 0, definitely free; 1, probably free; 2, definitely entrapped; 3, probably entrapped; and 4, unable to score (Fig 2).

Statistical Analysis

Statistical analysis was performed using the computer package SPSS (IBM). All measurements (M mode, STI, PEL) were well approximated by a normal distribution. The probably and definitely categories of the gold-standard diagnosis were grouped so that all patients were classified as entrapped, free, or unable to score. Patients designated as unable to score were excluded from the analysis. The dataset was then randomly divided into a development and validation set by the statistical software. Data from the development set were used to construct receiver-operating curves describing the diagnostic accuracy of M mode, STI, and PEL to identify entrapped lung, and cutoffs were chosen to maximize sensitivity and specificity.[12] For PEL, a cutoff of 19 cm H_2O was selected, as this is the value most commonly used in the literature.[13] Applying these cutoffs to the validation set, the sensitivity, specificity, positive predictive value, and negative predictive value of each method to identify entrapped lung and failed pleurodesis were calculated.

To identify factors associated with false positives (entrapped lung on ultrasound but free lung on postdrainage imaging) and false negatives (free lung on ultrasound but entrapped lung on postdrainage imaging), a multivariate logistic regression model was constructed and applied to the entire dataset. Variables entered were diagnosis, effusion size and side, drainage volume, full or partial atelectasis of the lower lobe, septations visible at ultrasound, left ventricular function, endobronchial obstruction or consolidation of the lower lobe on CT images, and the presence of through-plane motion on the ultrasound cine loops.[14] To assess reliability between repeated analyses, mean differences and the intraclass correlation of test-retest and intertester results were calculated.

Results

Eighty-three consecutive patients were recruited for the study; two were excluded as they were designated as not scorable on postdrainage radiology (Fig 2). Fifty-one were men, and the mean age was 66 years (62-70 years) (95% CI). The final diagnosis was pleural malignancy (59%), parapneumonic (8%), heart failure (4%), and other (29%). Mean pleural drainage volume was 1,351 mL (1,194-1,509 mL) (95% CI).

There were 34 patients in the development set and 47 in the validation set. The number of patients in each of the gold-standard diagnostic groups is shown in Table 1.

The surrounding effusion provided a clear sonographic window to image the atelectatic lower lobe with ultrasonography. Typical M mode and STI appearances of entrapped and free lung are shown in Figure 3.

Receiver-operating curves derived from the development set, demonstrating the diagnostic abilities of STI, M mode, and PEL to identify entrapped lung, are shown in Figure 4. The area under the curve was 0.86, 0.79, and 0.69 for STI, M mode, and PEL, respectively. Results were similar if only the definitely free and definitely entrapped categories of the gold standard were used (STI, 0.88; M mode, 0.76; and PEL, 0.70).

Table 2 shows the sensitivity, specificity, positive predictive values, and negative predictive values calculated from the validation set. Cutoffs used to delineate positive from negative results were 6% for STI, 1 mm for M mode, and 19 cm H_2O for PEL.

Twenty-nine patients underwent pleurodesis following complete effusion drainage. The decision of whether to undergo pleurodesis was made by the treating clinician according to clinical information available at the time. Of those who underwent pleurodesis, there was reaccumulation of the pleural fluid in 12. The sensitivity and specificity (using the previous diagnostic cutoffs) to predict pleurodesis failure were 60% and 93% for STI, 60% and 93% for M mode, and 25% and 100% for PEL.

Details of significant variables identified in the multiple regression analysis, which are associated with false-negative (ie, free lung on ultrasound but entrapped lung on postdrainage imaging) or false-positive (ie, entrapped lung on ultrasound but free lung on postdrainage imaging) classifications, are shown in Tables 3 and 4. Reliability was high, with small differences in repeated results and a high intraclass correlation coefficient (Table 5).

Discussion

This study documents a novel approach to the identification of malignant entrapped lung, using preprocedure ultrasonography. M mode and STI strain analysis of the atelectatic lung gave very favorable results for diagnostic parameters, and measurements demonstrated a high level of reliability. Although some features can suggest

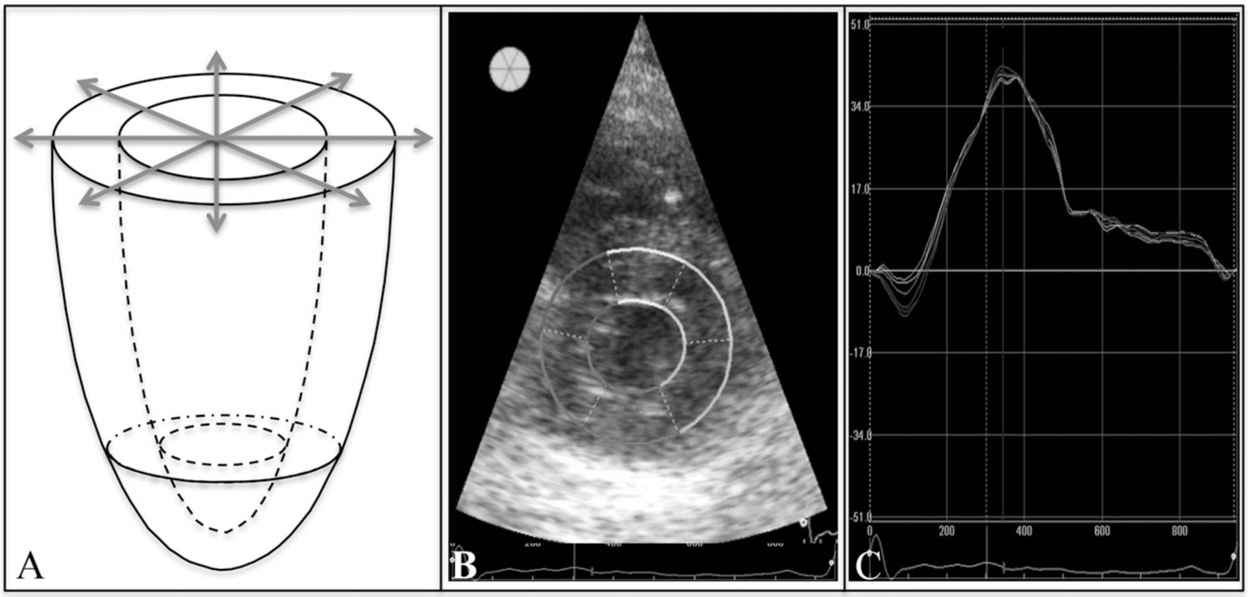

Figure 1 – *Calculation of myocardial radial strain with speckle tracking imaging (STI). A, Diagram detailing the cross-section of the heart, showing the direction of radial strain measurements (arrows). B, A region of interest (ROI), corresponding to the cross-section of the heart, is placed on the gray-scale ultrasound image. C, The software calculates strain in a radial direction and produces six-color traces, corresponding to the six-color-coded areas in the ROI. Strain is expressed as a percentage.*

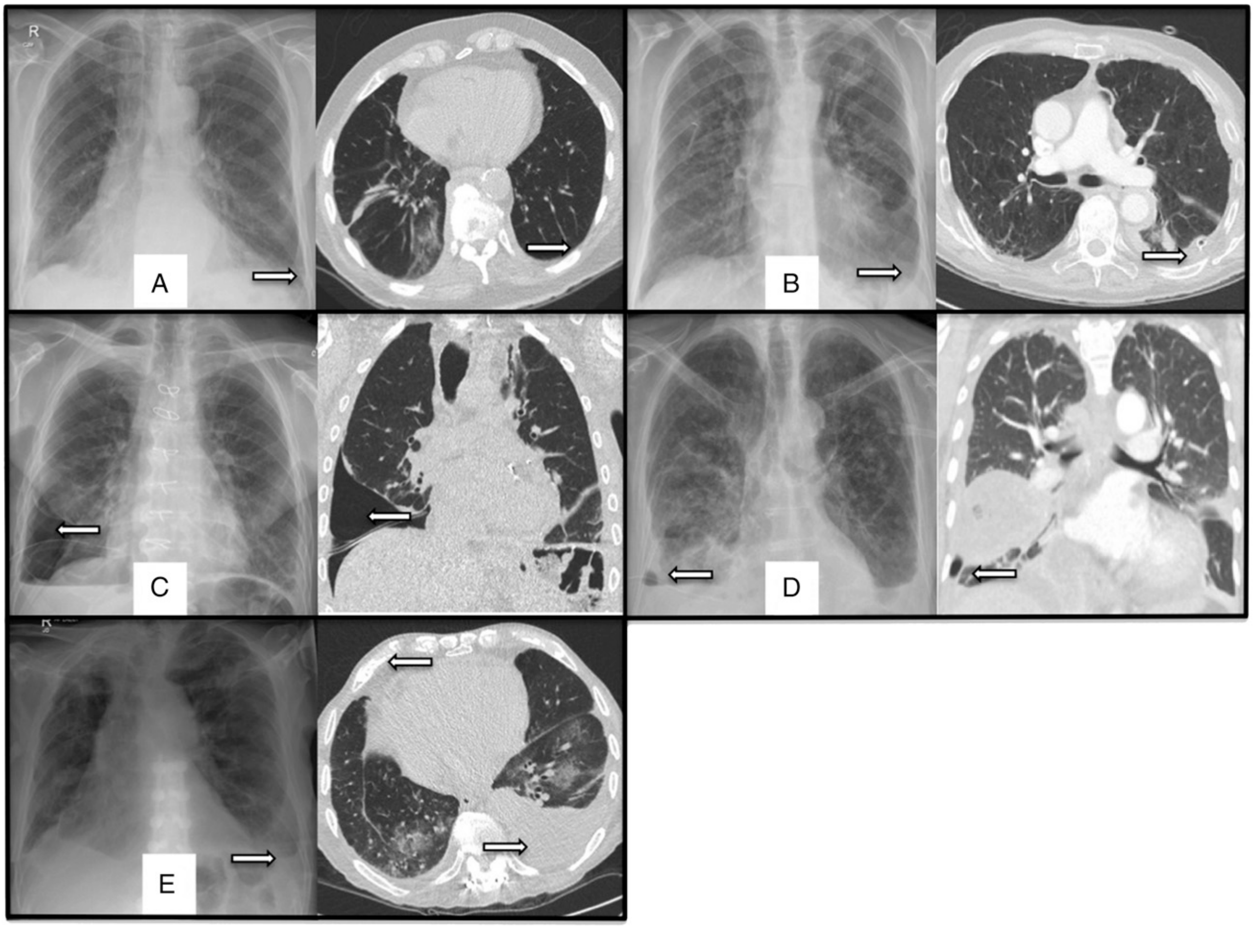

Figure 2 – *Entrapped lung scoring by radiograph (left images in each panel) and CT scan (right images in each panel). A, Definitely free. Complete apposition of parietal and visceral pleura (arrows). B, Probably free. Apposition of parietal and visceral pleura in most places but some residual pleural fluid (arrows). C, Definitely entrapped. Air separating the visceral and parietal pleura around the lower lobe (arrows) (a chest tube is also seen within the pleural space). D, Probably entrapped. Some air between visceral and parietal pleura in places around the lower lobe but residual pleural fluid obscuring some areas (arrows). E, Unable to score. Insufficient drainage of pleural fluid to allow designation in one of the prior categories (arrows).*

the presence of entrapped lung (thickening of the visceral pleura at ultrasound, elevated PEL, or basilar pneumothorax on postdrainage imaging), it is often very difficult to detect this important clinical phenomenon prior to effusion drainage. Pleural fluid frequently obscures the visceral pleura, chest radiograph can be inadequate to show isolated entrapment of the lower lobe, and the chronicity of the effusion may not be clear. This new method offers a noninvasive way to reliably identify lung entrapment before any drainage procedure is performed.

TABLE 1] Patient Numbers in Gold-Standard Diagnostic Categories

Set	Definitely Free	Probably Free	Definitely Entrapped	Probably Entrapped	Total
Development	11	9	12	2	34
Validation	18	13	14	2	47

The identification of entrapped lung early in the management of malignant pleural effusion could allow for streamlining of patient care directly to insertion of an IPC. In our experience, the appreciation of lung entrapment often does not occur until following the discharge of a patient postpleurodesis, when the effusion and symptoms return. Not only does this delay the appropriate insertion of an IPC, but it also results in an additional procedure. Furthermore, if the patient does not live locally, the opportunity to definitively manage his or her problem may be lost. In line with this, IPCs are becoming more widely used as an upfront treatment option for malignant pleural effusion, however, there are resource issues with IPCs, particularly with follow-up, in those who live remotely and in patients with a life expectancy > 6 weeks.[15,16] Better case selection for IPC insertion, confined more to those just with entrapped lung, may lead to improved patient care and resource utilization.

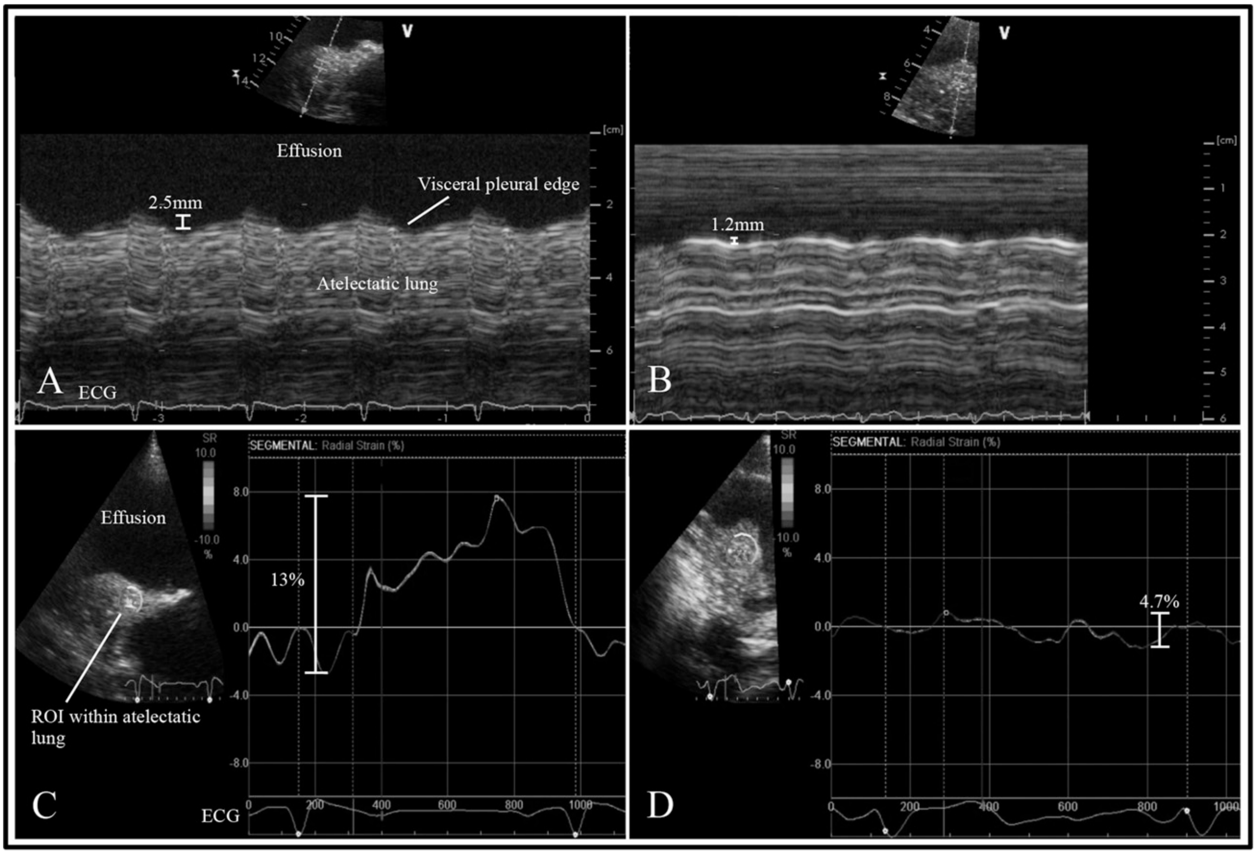

Figure 3 – *A-B, Motion-mode (M-mode) analysis of free lung (A) showed greater cardiac-associated motion than entrapped lung (B). C-D, Strain measured with STI was greater for free lung (C) than entrapped lung (D). Note the relationship of movement and strain to the cardiac cycle (ECG). See Figure 1 legend for expansion of other abbreviations.*

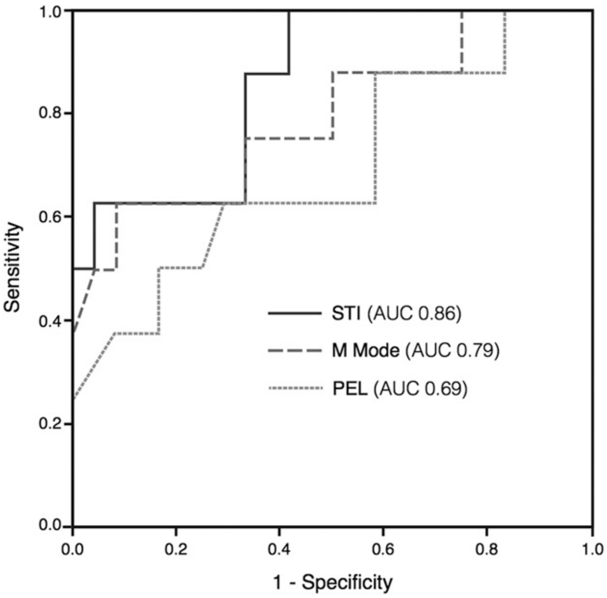

Figure 4 – *Receiver-operating curves derived from the development set for STI (solid line), M mode (dashed line), and PEL (dotted line). AUCs for each methodology are shown. AUC = area under the curve; PEL = pleural elastance. See Figure 1 and 3 legends for expansion of other abbreviations.*

Although this article only addressed the use of these new ultrasound techniques to guide management of malignant pleural effusion, it is possible that with further study, they could be applied to assist in other areas of pleural effusion management, such as thoracentesis (eg, to limit drainage volume in the setting of entrapped lung, preventing symptom development, or a postdrainage pneumothorax ex vacuo) or to indicate when surgery is required in the management of pleural infection.

It is of note that pleural manometry performed less well in this study than elsewhere published as a method to diagnose entrapped lung.[17] This highlights one of the key differences between pleural manometry and this new ultrasound technique. PEL reflects the changing pressure within the entire hemithorax, whereas ultrasound analysis is specific to the segment of lung analyzed. In this study, entrapped lung was defined as entrapment of the lower lobe only. In the cases where the other lobes were not entrapped and expanded normally, the impact on PEL would be less marked. We believe this is why pleural manometry, in this study,

TABLE 2] Diagnostic Indexes to Diagnose Entrapped Lung

Modality	% (95% CI)			
	Sensitivity	Specificity	PPV	NPV
STI strain	71 (42-91)	85 (62-97)	77 (46-95)	85 (58-94)
M mode	50 (23-77)	85 (62-97)	70 (35-93)	71 (49-87)
PEL	40 (12-74)	100 (77-100)	100 (40-100)	70 (46-88)

M mode = motion mode; NPV = negative predictive value; PEL = pleural elastance; PPV = positive predictive value; STI = speckle tracking imaging.

had a lower sensitivity than in previous publications where lung entrapment was defined as separation of the parietal and visceral pleura throughout the whole hemithorax.[17]

The amount of displacement and strain of any given piece of lung depends on the magnitude of the force applied to it (in this case from the transmitted cardiac impulse).[9] Therefore, the distance of the imaged lung segment from the heart and also how well the lung transmits the impulse could affect strain. Results from the multivariate analysis were consistent with this. The magnitude of displacement and strain was reduced for the right lower lobe compared with the left lower lobe (as the left lower lobe rests closer to the heart) and also if the lung was only partially atelectatic (as aerated lung acts as a capacitor, absorbing some of the kinetic energy from the transmitted cardiac impulse). Both these factors were associated with false-positive results (ie, misclassification of free lung as entrapped). In other areas of the body, this problem is overcome by taking the ratio of the strain in the diseased tissue to that in nondiseased adjacent tissue.[18] This has the effect of standardizing the force applied in any given region of the body. This is not possible in the case of atelectatic lung, as there is no adjacent "normal" tissue that is equally distant from the heart (aerated lung cannot be imaged with ultrasound). Another limitation particular to STI is that out-of-plane motion of the atelectatic lung through the two-dimensional ultrasound image affects the measurements.[14,19] STI works by tracking clusters of pixels within the image. If the atelectatic lung swings out of plane through the ultrasound image, it is incorrectly analyzed by the software as tissue deformation. This is reflected in its association with false negatives seen on the multivariate analysis (all four patients with entrapped lung and out-of-plane motion on ultrasound were incorrectly classified as free). Three-dimensional STI would overcome this problem.[20]

TABLE 3] Patient Numbers for Variables Associated With False-Negative or False-Positive Diagnoses

OOPM	Effusion Side	Degree of Atelectasis
Yes 9	Right 49	Complete 57
No 72	Left 32	Partial 24

OOPM = out-of-plane motion of the imaged atelectatic lung through the ultrasound image.

Our results could suggest an approach whereby if the ultrasound strongly suggests entrapped lung (strain < 5% [STI] or displacement < 0.8 mm [M mode]), an IPC should be inserted. If the lung is clearly free (strain > 7% [STI] or displacement > 1.2 mm [M mode]), then a pleurodesis is appropriate. However, if the ultrasound analysis is close to the cutoff between free and trapped lung (strain 5% to 7% [STI] or displacement 0.8-1.2 mm), then a chest tube should be inserted and the decision of whether to pleurodese or insert an IPC should be made once postdrainage radiology confirms the presence or absence of entrapped lung. It may be that applying catheter suction is appropriate in these cases.

There are a number of limitations to the design of this study. The identification of isolated lower lobe entrapment can be difficult and some patients may have been misclassified. For a diagnosis of entrapped lung to be made, there had to be air between the visceral and parietal pleura around the lower lobe, in the absence of an air leak through the chest catheter. However, following

TABLE 4] Variables Associated With False-Negative or False-Positive Diagnoses

Method	Variable	OR	Significance, *P* Value
False negative			
STI	OOPM	10.8	.001
False positive			
STI	Right side	5.33	.021
M mode	Right side	3.97	.048
M mode	Incomp Atel	6.07	.014

Incomp Atel = incomplete atelectasis of the imaged lower lobe; Right side = right-sided pleural effusion. See Table 2 and 3 legends for expansion of other abbreviations.

TABLE 5] Test-Retest and Intertester Reliability of Ultrasound Measures

	Test-Retest		Intertester	
Method	Mean Difference (95% CI)	ICC	Mean Difference (95% CI)	ICC
STI, %	0.50 (−0.20-1.20)	0.98	0.0 (−1.04-0.04)	0.90
M mode, mm	0.09 (−0.07-0.25)	0.95	0.0 (−0.13-0.13)	0.91

ICC = intraclass correlation coefficient. See Table 2 legend for expansion of other abbreviations.

effusion drainage, sometimes there is initial separation of the visceral and parietal pleura that resolves in time and represents lung that is slow to reexpand but is not entrapped. Furthermore, in some cases, there was incomplete drainage of fluid from the pleural space such that it was not clear if the lung would fully reexpand had the fluid been completely drained. To address this uncertainty, probably entrapped and probably free categories for postdrainage assessment were created. When scoring patients to these categories, the judgers were able to gather other clues to support or reject the presence of entrapped lung, such as thickening of the visceral pleura, volume loss in or mediastinal shift toward the ipsilateral hemithorax, persistence in the shape of the visceral pleural silhouette on chest radiograph predrainage and postdrainage, or the appearance of the lung at pleuroscopy when these images were available. They were also allowed to use any follow-up radiology available at the time of scoring, which in some cases was more than a year following the procedure. Another point of note is that strain analysis, such as that found in many respiratory departments, is not currently available on most portable ultrasound machines. It is, however, quickly finding its place in clinical management and will probably be available as a standard feature on most machines soon.[8,9]

In summary, this study offers a significant contribution to the assessment of malignant entrapped lung, a clinical entity traditionally difficult to identify prior to pleural effusion drainage. This noninvasive technique may be able to guide decision-making about the timing of pleural interventions and prompt the early insertion of an IPC in cases of malignant entrapped lung. Although there are limitations to this technique that require further investigation to fully elucidate, this study serves as an introduction and “proof of concept.” It could lead to a reduction in the number of procedures required to treat malignant pleural effusion.

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Chapter 7
Supplement

Chapter 7 described the diagnostic performance of 2 novel pleural ultrasound-based methods to identify entrapped lung and compared it to the established method based on PEL. However, it did not analyse the possible additional benefit of combining these diagnostic methods, which would allow the clinician to decide which method or combination of methods is best to use in any given clinical situation. Its section regarding the prediction of successful pleurodesis was also brief.

This chapter supplement addresses these deficiencies.

Combining diagnostic methods to identify entrapped lung

To assess the effect of combining different diagnostic methods, the diagnostic odds ratio (dOR), a global measure of test accuracy[1], was calculated for each component method and the various possible combinations. These results are shown in Table 1, along with the corresponding sensitivity and specificity.

STI alone or in combination with M Mode (both tests positive) gave the best diagnostic accuracy, as measured by the dOR. The addition of M Mode to STI improved specificity but reduced sensitivity. Although the addition of PEL to STI improved specificity further, it reduced dOR and markedly reduced sensitivity.

Modality	**Diagnostic Odds Ratio** (95% CI)	**Sensitivity %** (95% CI)	**Specificity %** (95% CI)
STI	21 (6-72)	71 (42-91)	85 (62-97)
M Mode	9 (3-27)	50 (23-77)	85 (62-97)
PEL	7 (2-34)	40 (12-74)	100 (77-100)
All modalities positive			
STI + M Mode	21 (5-82)	56 (39-73)	94 (84-98)
STI + PEL	19 (2-170)	33 (16-56)	97 (87-99.5)
M Mode + PEL	-- ---- [1]	28 (13-51)	100 (91-100)
STI + M Mode + PEL	-- ---- [1]	28 (13-51)	100 (91-100)
Any modality positive			
STI or M Mode	13 (4-38)	73 (55-86)	82 (70-90)
STI or PEL	17 (4-69)	72 (49-88)	87 (73-94)
M Mode or PEL	14 (4-54)	72 (49-88)	84 (70-93)
STI or M Mode or PEL	14 (4-54)	72 (49-88)	84 (70-93)

Table 1 Diagnostic indices derived from combinations of diagnostic modalities.

[1] Unable to calculate (as the diagnostic odds ratio requires the calculation of x/(1-Specificity) which in this case is x/0).

Prediction of pleurodesis failure

Although the prediction of entrapped lung is useful, the prediction of pleurodesis failure is arguably more important clinically, as it directs the appropriate management of malignant pleural effusion to insertion of an indwelling pleural catheter[2]. Until the development of these new ultrasonic methods described in the previous chapter, there have been no reliable predictors of pleurodesis outcome[3] and the presence of underlying lung entrapment has been identified with post-drainage radiology. Thus the power of these new ultrasonic methods to predict pleurodesis failure should be made with respect to the post-drainage radiological assessment of lung entrapment.

Of the 81 patients in the study, 29 underwent a pleurodesis procedure. Of these 29, 9 had evidence on post-drainage radiology of lung entrapment and 12 failed pleurodesis, as defined by re-accumulation of pleural fluid on follow-up imaging. 7 of 12 failed pleurodeses had lung entrapment radiologically. The decision of whether or not to attempt pleurodesis did not follow a consistent management algorithm, but was made by the treating doctor at the time, and so varied depending on clinician experience and knowledge in this area.

Table 2 shows the diagnostic indices for the three methods (STI, M Mode and PEL) to predict pleurodesis failure, in comparison to the presence of lung entrapment on post-drainage imaging.

Modality	**Sensitivity %(95%CI)**	**Specificity %(95%CI)**
Radiology[11]	42 (15-72)	86 (57-98)
STI	60 (21-79)	93 (77-97)
MM	60 (23-77)	93 (62-96)
PEL	25 (4-80)	100 (71-100)

Table 2 Diagnostic indices of different modalities to predict pleurodesis failure

[1] Entrapment of lower lobe on post drainage CXR and/or CT

Discussion and conclusions

This chapter supplement has extended the analysis performed in the preceding chapter, to investigate if varying combinations of the diagnostic methods improves accuracy over the techniques when used in isolation, and has also presented the pleurodesis data in reference to the presence of lung entrapment on post-drainage radiology.

As shown in table 1, combining the varying methods to predict lung entrapment does not improve overall diagnostic accuracy when compared with the component methods used individually. STI alone or in combination with M Mode remains the most powerful predictor. This is probably due to the fact that all the methodologies are examining the same thing, albeit with a different technique. They are assessing the mechanical restriction of the lung as it moves and expands with evacuation of pleural fluid. Thus the difference in individual sensitivity and specificity of the varying techniques reflects the technical ability of each technique to identify this, and so it follows that combining them would not afford an increase in diagnostic power. As discussed in the previous chapter, the relatively low sensitivity of PEL is probably because lung entrapment in this study was defined as entrapment of the lower lobe only, where as PEL reflects pressure changes in the entire hemithorax.

Successful pleurodesis requires 2 conditions to be met. Firstly, there must be full re-expansion of the underlying lung following effusion drainage, to allow apposition of the parietal and visceral pleura[4]. Secondly, functional mesothelial cells must be present, to activate the inflammatory cascade that leads to fibrosis and obliteration of the pleural space[5]. Thus while lung entrapment prevents pleurodesis, its absence is not sufficient in itself to assure pleurodesis success.

There are a number of strong limitations to the pleurodesis data and analyisis presented in this chapter, which probably prevent legitimate interpretations being reached. There was no consistent algorithm used by clinicians to guide decision on if and when to attempt pleurodesis, but rather the decision was made according to each clinician’s individual experience and knowledge. Further, as lung entrapment in this study was defined as only lower lobe entrapment, it was not unreasonable to attempt pleurodesis despite the presence of lower lobe entrapment, if it was felt the patient might still benefit from pleurodesis of the remaining parts of the lung. Thus, almost one third of the patients undergoing pleurodesis (9 of 29) had lung entrapment on post-drainage radiology.

If one bears these limitations in mind when looking at the data presented in table 2, although it appears that STI and M Mode perform well in comparison to radiology for predicting pleurodesis failure, these numbers may well be misleading and are probably confounded by the inclusion of patients with lung entrapment in the cohort undergoing pleurodesis. Given that all the techniques (including post-drainage radiology) only assess lung re-expansion and not the presence or absence of functional mesothelial cells (the other factor required for successful pleurodesis), a priori one would not expect the ultrasound-based techniques to perform better than post-drainage imaging.

In summary a number of conclusions can be made from this chapter supplement. Although the ultrasound-based methods described in this thesis have good power to identify lung entrapment, their combination with or without PEL does not improve results. This is probably because all methods are measuring the same thing in a slightly different way. The inclusion of a substantial number of patients with lung entrapment in the pleurodesis cohort, prevents the comparison of these new methods with traditional post-drainage radiology to predict pleurodesis failure.

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Chapter 8

Discussion, Conclusions and Future Research

Introduction

The practice of thoracentesis and chest tube insertion varies widely, and there is a high rate of procedure-related morbidity and mortality[1]. In multiple international reviews of procedure-related adverse events, the absence of US to guide intervention and inadequate doctor training, have repeatedly been identified as factors strongly associated with these adverse events[2,3]. A particular problem may arise in the case of malignant pleural effusion, when the presence of lung entrapment which necessitates a different treatment path, initially goes unnoticed leading to an unnecessary increase in the number of pleural interventions required to treat the condition[4]. This thesis aimed to directly address these factors through three different but complimentary lines of investigation. Firstly, assessment tools for pleural US and chest tube insertion were developed and validated which will contribute to improved doctor procedural training. Secondly, the utility of US to identify a vulnerable ICA prior to needle or tube insertion into the pleural space was examined and the operator technique described. Thirdly, to improve identification of malignant entrapped lung 2 different techniques were developed: 1. A simplified method allowing for continuous pleural manometry during effusion drainage and 2. Novel application of ultrasound motion analysis to prospectively identify entrapped lung prior to effusion drainage. All the studies in this thesis are preliminary and larger studies will be needed across broad patient populations to hopefully take these findings into mainstream clinical practice. Nonetheless by having procedural training and procedural safety as the theme, these studies have addressed important issues for clinicians involved in pleural disease today.

Development of assessment tools: the USGT-STAT and TUBE-iCOMPT

Despite the change to competency-based training and assessment, no tools currently exist to evaluate the performance of pleural US and chest tube insertion by respiratory physicians. The USGT-STAT and TUBE-iCOMPT fill this void. This thesis has investigated the performance of these assessment tools when procedures are performed on both mannequins and live patients. This is important as procedural training is increasingly being conducted in simulated environments prior to practice on live patients.

Reliability analysis showed both tests to have a high level of test-retest and inter-tester agreement while also being able to clearly differentiate doctors according to skill level. This is probably due to structure of the marking sheets. The detailed checklist-style marking points and clear, easy to follow examiner instructions are essential to maintain objectivity and consistency of scoring by differing examiners and at different times, while the subjective global rating scales included in each tool are important to capture the more intangible components of competence gained by experts over time.

One of the major difficulties when designing these assessment tools and studies, was to prove that the tools' assessment of procedural skill was valid. Ideally there would be a gold standard by which to judge this, but currently no such gold standards exist. This problem confronted researchers designing similar tools for bronchoscopy[5]. In both studies, one criterion to address the instruments validity was to show they could discriminate between proceduralists with different prior experience (novice, intermediate, advanced). Clearly if this had been the only measure of validity for the assessment tools, then they would be no more useful than simply asking a subject how many procedures they had previously performed. However, the validity of the assessment tools was also supported by a number of other factors. The assessment points in both instruments were constructed from international guidelines (UGSTAT) or the consensus of over 100 international health professionals (including pulmonologists, intensive care specialists and cardiothoracic surgeons), on the essential steps of correct chest tube insertion (TUBE-iCOMPT). Weighting for the individual assessment points was assigned in line with British Thoracic Society Guidelines. A global-rating-scale was included in each tool to address the intangible components of procedural competence gained with time. Finally, there was a large separation between groups of varying experience (novice, intermediate, advanced), to maximise the (imperfect) delineation between levels of expected competence. Nonetheless the true validity of the instruments ability to measure competence is sub-optimal but at this stage there is no gold standard. We have to start somewhere and these studies have paved the way to further future research in this area. For example as has been done in bronchoscopy[6], chest tube insertion competency could be assessed at check points in a cohort of new trainees as they progressed through insertion of 10 to 20 to 40 tubes.

Assessment tools can be used to assist procedural training in 2 ways[7]. Firstly the checklist marking points act as a gold standard, covering all the individual elements and nuances required for an optimal procedure. If they are incorporated into training programs, they help standardise and optimise training across different centres. Secondly they provide a way to accredit a proceduralist's competence, which will be critical in this age of doctor accountability. At this stage (in Australia) we need to address the former first – standardising and improving training. The accrediting body in Australia, the Thoracic Society of Australia and New Zealand (TSANZ), have published guidelines for bronchoscopy and interventional pulmonology training[8]. In parallel with this, assessment tools with appropriate checklists have been developed for flexible bronchoscopy, EBUS, thoracic US and chest tube insertion (all available for free download at www.bronchoscopy.org)[5,7,9,10]. There needs to be a specified person in each training centre who takes responsibility for the procedural instruction of trainees and applies the various assessment tools to standardise and optimise training. Although it has been shown that purely numbers of procedures alone do not correlate with competence, the papers also show that if teaching is done according to a gold-standard, then all trainees do become competent after a set number of procedures, eg 100[6]. It is the rate of skill acquisition that separates individuals. Thus if training is optimised and standardise across centres, accreditation becomes a lot more simple, and would most likely involve a 'pass' score on an assessment tool combined with a logbook documenting a minimum number of procedures.

In relation to the actual clinical impact of the various scoring systems in thoracic procedures, this has been examined in a study on bronchoscopy training[6]. A regime consisting of simulated training with regular application of an appropriate checklist style assessment tool, improved the rate of skill acquisition by trainees. The assessment instrument provides a way to complete the hands on training and often provides a means of feedback even at that pre clinical stage. It also indirectly drives the content of the hands on training in that the full range of procedural points need to be covered. Our pleural procedure studies in this thesis cannot lead to a recommendation of their use at this time, but with further validation studies as outlined below, the instruments could gain some validity in this direction.

To make the assessment tools easily accessible for use in pulmonology training programmes around the world, they have been made available for download at www.broncoscopy.org. This website is a free online resource, affiliated with The World

Association of Bronchology and Interventional Pulmonology, which provides expert teaching and training content for interventional pulmonary physicians and trainees.

A number of limitations exist to this section of the thesis. The studies are preliminary but serve as a starting point for further future development. The assessment tools in this study were only applied to a limited number of trainees in a limited number of geographical locations.within one major Australian city. The training experience varies markedly in different centres[11] and so the tools need to be applied to larger populations of trainees, covering more diverse training locations and environments, along with the individual nuances in teaching and technique that accompany these places. The tools must remain robust when applied in these varying settings. The fundamental problem of lack of a gold standard by which to compare the test makes validation difficult. The validity of the tools could be further assessed with longitudinal studies, that document the ability of these assessment instruments to track the acquisition of skills as a trainee progresses from novice to intermediate to expert proceduralist. Finally, none of the studies in this thesis have defined which scores should indicate a particular level of competence, such as when a trainee is ready to perform supervised procedures on patients or when a doctor is considered ‘expert’ enough for unsupervised practice. Longitudinal studies would assist with this, as mentioned above. At this stage, centres wanting to use these tools could possibly set their own thresholds for demarcating specific levels of competence. More important would be regular testing for example after each 5 or 10 tube insertions by new trainees to assess progress and allow directed feedback. They may also wish to allocate certain items (eg checking for the presence of a patient coagulopathy or removing the catheter trocar before insertion of a chest tube) as automatic fails if they are missed.

With respect to defining cut-off scores to delineate levels of procedural skill, there are a number of ways this could be accomplished. The contrasting-group method[12] defines the scores to delineate novice from intermediate from advanced as the score indicated by the intersection of the population curves for each category. A problem with this is that the criteria we used to define groups of varying skill were imperfect (eg novices 0 procedures, intermediates <5 procedures, experts > 20 procedures). We know that simply the number of procedures performed is an imprecise way of identifying skill level (indeed this is the very reason for the change to competency-based teaching and assessment), and in our studies we acknowledge this limitation. Maybe a better option would be to address this problem in a different way. Medical procedures are suited to 'Mastery learning and assessment', as each trainee should ideally become competent in all the individual elements required for a safe and effective procedure[7]. Thus the score to indicate when a doctor is competent to perform a procedure unsupervised on a patient should be virtually 100%. Applications of the test earlier in the training period serve only to enhance learning, by documenting each student's individual progress and identifying specific areas that require further attention.

Future possible studies to further develop and validate the UGSTAT and TUBE-iCOMPT could include:

1. Longitudinal studies with regular assessment of individual trainees as they progress from novice to expert. The assessment tool scores need to track this learning curve and when applied at varying stages of instruction, be able to provide a 'snapshot' which documents each trainee's position on this learning curve.

2. Following longitudinal validation as in point 1, studies that demonstrate enhanced training and more rapid acquisition of procedural skills, when these assessment tools are applied regularly throughout the training period. This could also include data from trainees, showing enhancement of the learning experience from their perspective.

3. Studies to define which cut-off scores delineate novice from intermediate from expert. These cut-offs could then be used for accreditation purposes by institutions, documenting when a clinician is competent to perform procedures unsupervised on patients.

4. Studies demonstrating improved clinical outcomes, such as less procedure-related adverse events, when the use of these assessment tools (to guide learning and document competence) are incorporated into institutional policies and guidelines. This would be similar to what has been done with reduced post-thoracentesis pneumothorax when ultrasound-guidance is mandatory[13].

Visualisation of the ICA at thoracic ultrasound

Despite the introduction of US to guide thoracentesis or chest tube insertion, laceration of the ICA continues to be a rare but potentially serious complication[14]. This is probably because routine US to guide such interventions does not include identification of the ICA. We showed in 2 studies that not only can US readily visualise the ICA, but that it can be achieved in a relatively short time (<1 minute), regardless of whether a high-end or portable US is used or whether a senior sonographer or pulmonologist performs the scan.

Another factor that became apparent during the 2 studies, was the high variability in the position of the ICA within an individual patient. The ICA is exposed within the space in posteromedial locations of the chest wall. Further, the course of the ICA can be highly tortuous, almost sinusoidal in those over 60 years of age[15]. Thus if a vulnerable ICA is identified prior to insertion of the needle through the intercostal space, a small change in the location for needle insertion (eg 1 cm medial or lateral) could mean the ICA is protected by the overlying rib, and this could be confirmed with US prior to starting the procedure.

A number of limitations need to be acknowledged with respect to these studies. They are preliminary investigations and serve only as a ‘proof of concept’. The patients enrolled did not have pleural pathology, which could potentially impact on the visibility of the ICA. Also, given the low incidence of clinically apparent ICA laceration following thoracentesis, much larger studies would need to be performed to show an actual reduction in the rate of ICA laceration if US is used to screen for a vulnerable artery prior to needle puncture. A further limitation to these studies was that they did not examine the utility of US to visualise the ICA during real-time guidance of the needle for thoracentesis or chest tube insertion. Rather US was used to identify and mark the ideal location, prior to needle insertion, and the procedure was then performed blindly. We designed the studies thus as this ‘X marks the spot’ technique is by far the most commonly employed around the world. Lastly, it needs to be shown that US can track the path of the ICA rather than just locating it in a single position, such that the relationship of needle to artery can be tracked in real-time through different tissue planes.

Future directions for research will need to address this limitation and describe the utility of visualising the ICA during real-time US-guided thoracentesis or chest tube insertion. Real-time US guidance is the logical next step in the evolution of pleural procedures. This is discussed further in the section on probe development below.

Identification of malignant entrapped lung: US motion analysis and pleural manometry

The presence of entrapped lung within a malignant effusion directs appropriate management from pleurodesis to insertion of an indwelling catheter[4]. Pleural manometry during pleural effusion drainage has some utility to identify lung entrapment, but the current technique is cumbersome and so pleural manometry is performed in few centres around the world[16]. It needs to be acknowledged that it is not only the presence of lung entrapment that directs treatment. This is also influenced by the degree of lung entrapment (eg lower lobe only vs entire lung) and symptom relief following thoracentesis.

A new method for performing continuous manometry during pleural effusion drainage

This study documented a refinement to the current intermittent technique for performing pleural manometry, by demonstrating that reliable measurements could be made continuously if the pleural pressure is transduced via an epidural catheter passed through the chest tube to sit within the pleural space. This has the advantage that the system can be 'set-up and left', rather than the traditional intermittent technique where the operator must repeatedly halt the drainage of fluid and manually record pressures throughout the procedure. This simplification may result in the increased performance of pleural manometry along with its benefits around the world.

The main limitation to this study was the absence of subjects with entrapped lung. However, the only differentiating feature of such patients, is the slope of the pleural elastance curve, and our study included subjects with a wide range in pleural elastance (-1.8 cmH_2O to -17.6cmH_2O). There are no known specific factors associated with trapped lung which might interfere with or alter the process of pressure transduction, using either the traditional intermittent or new continuous technique. Thus we feel the new technique could be successfully applied to patients with entrapped lung.

Although there has recently been released a small disposable pleural manometry manometry device (Mirador Biomedical, Seattle WA), previously the uptake of this procedure has been hindered by the lack of commercially available equipment. Future research needs to occur in partnership with industry, such that equipment for performing pleural manometry, utilising the new continuous methodology developed as part of this thesis, is developed and made commercially available. If double lumen chest tubes and thoracentesis kits were available, similar to the Thai Quick 24Fr Double Lumen Chest Tube (Cook Medical, Bloomington, U.S.A.) but in smaller sizes such as required for the majority of pleural drainage procedures, then the manometer could be connected directly to the second lumen, obviating the need for an epidural catheter to transduce pressure from within the pleural space. If the system was then connected to a computer with appropriate software installed, pleural pressures, drainage volume and pleural elastance could all be displayed automatically in real-time. This would dramatically simplify the procedure, provide useful results in real-time and likely increase the performance of pleural manometry worldwide.

A possible future study would be to apply this continuous pleural manometry to aid understanding the pathophysiology of pneumothorax generation following thoracentesis in the presence of underlying trapped lung. This has been the topic of a previous publication, but the intermittent nature of traditional pleural manometry in this study, prevented accurate tracking of pleural pressure changes in between times of pressure transduction[17].

Identification of malignant entrapped lung with US

This study described for the first time a method to identify entrapped lung prior to drainage of a malignant pleural effusion. The restricted movement and deformation of the atelectatic lower lobe within the effusion can be identified by M Mode and Speckle-Tracking strain analysis, with an area under the ROC curve of 0.79 and 0.86 respectively. This technique could be applied to identify entrapped lung in the presence of a malignant pleural effusion prior to any drainage procedure, allowing streamlining of management directly to insertion of an indwelling pleural catheter.

An assessment of combining both ultrasound-based and pleural-manometry based techniques for identifying entrapped lung revealed no additional benefit and STI remained the most accurate method. This is because all methods (STI, M Mode and PEL) essentially measure the same thing (movement and expansion of the lung). Differences in the sensitivity and specificity between the modalities reflects limitations inherent to each technique, rather than a fundamental difference in what each technique is measuring.

The major limitation of the study was that the gold standard diagnosis of lung entrapment, by post-drainage radiological appearance, was imperfect. Following effusion drainage, sometimes there is initial separation of the visceral and parietal pleura that resolves in time and represents lung that is slow to re-expand but is not trapped. In some cases there was incomplete drainage of fluid from the pleural space such that it was not clear if the lung would fully re-expand had the fluid been completely drained. The effect of this imperfection in the gold standard would have reduced the apparent ability of US to correctly identify entrapped lung in our study.

A reasonable question would be why we chose to examine strain in the atelectatic lung using STI with an echocardiogram machine, when elastography (which also measures strain) is available on smaller ultrasound machines more likely to be available to pulmonologists around the world. There are 2 reasons for this. Firstly, we wanted to analyse deformation of the atelectatic lung in relation to the transmitted cardiac impulse and therefore the strain-time curves generated by the software needed to be linked with the cardiac cycle. Secondly, non-cardiac US machines measure strain due to random vascular pulsations throughout the body. In order to normalise results despite the regional variations in the magnitude of the vascular pulsations, current machines calculate a ratio of the strain in the diseased tissue with adjacent ‘normal’ tissue. This is not possible in the case of atelectatic lung however, as the only ‘normal’ adjacent tissue is aerated lung, which cannot be imaged with US. Although the use of an echocardiogram machine in this study limits the immediate translation of results into clinical practice, it is important to note that ultrasound technology is rapidly evolving with elastography becoming more widely available on smaller machines. The method by which the machine calculates strain depends only on the software installed, and so it would not be hard to adapt current machines to perform the analysis used in our study. This has been a proof of concept study, and the results need to be replicated using the portable US machines typically used in respiratory medicine departments, once this modality of motion analysis becomes available on such machines.

The study introduces a completely new way of investigating pleural disease. Analysis of the lung with US is limited as US cannot penetrate aerated lung. However when the lung is atelectatic, such as occurs within a pleural effusion, it contains no air and is thus amenable to US analysis. The stage is set for future studies to apply the US motion analysis techniques developed in this study, to other non-malignant pleural conditions. Of particular interest would be to study whether strain and M Mode analysis can predict when surgery is required to manage pleural space infection. Current guidelines suggest initial drainage of the pleural space with tube thoracotomy and referral for surgery if there is incomplete fluid drainage and ongoing sepsis. There is no way to predict if a septated pleural collection will drain without surgery, and it may be that application of techniques developed in this study, can provide this answer.

Future studies to take this work further could be:

1. Replication of results using a mobile ultrasound machine such as is used routinely by pulmonologists to guide thoracentesis or chest tube insertion. This would extend the applicability of results beyond the need to use an echocardiography machine, which is difficult in a clinical setting.

2. Studies of cases where lung entrapment resolves (ie serial measurements), such as can occur in pleural infection. It may be that this quick and simple-to-perform US analysis could inform clinicians when medical treatment of pleural infection is likely to fail and guide earlier, appropriate surgical referral.

3. Studies to examine the reproducibility of the technique by different operators at different times ie. inter and intra-observer variability.

Time for an US probe tailored to the requirements of the pulmonologist?

Currently, probes used for thoracic US examination are 'borrowed' from ones designed for use on other body parts eg abdomen, thyroid[18]. No US equipment exists which is tailored specifically for the requirements of respiratory physicians. High frequency linear probes are used to image the chest wall, while lower frequency convex or sector probes are typically employed to visualise an effusion[19]. Thus the operator needs to change probes when examining differing depths of the thorax. The technique for real-time needle guidance is awkward and requires the probe to be held with one hand while the needle is inserted at an oblique angle beneath the probe with the other hand (Figure 1). A big advance would be the availability of a probe specifically designed to guide thoracentesis or chest tube insertion in real-time.

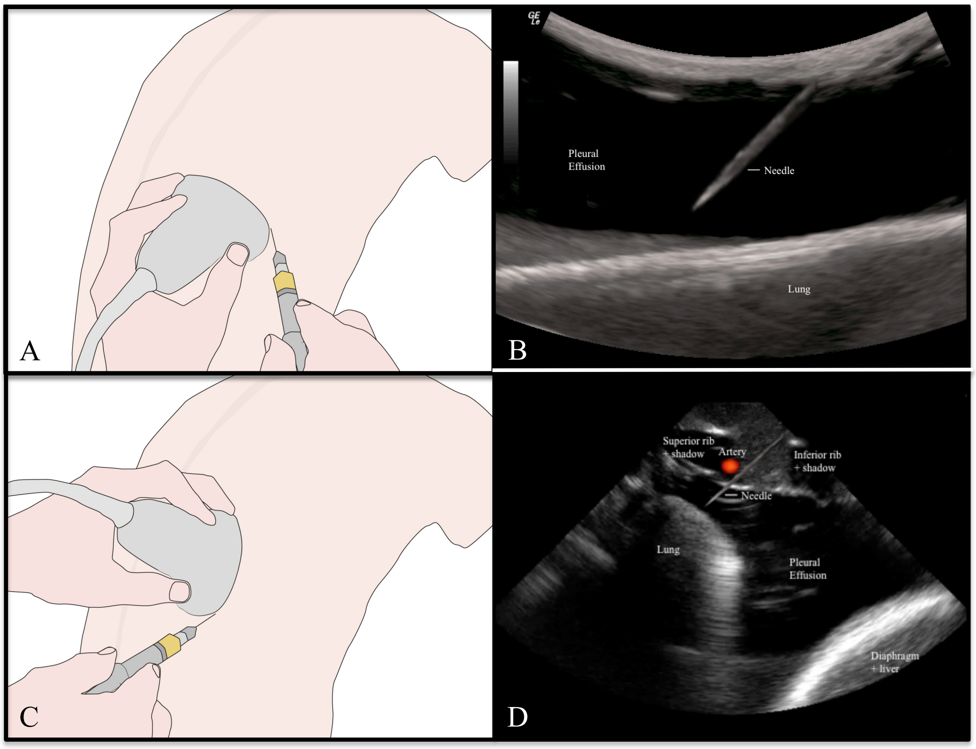

Figure 1 Current techniques for real-time US-guided thoracentesis. A,B: Probe is held transversely and needle inserted obliquely beneath it with other hand. Note inability to image superior-lying potentially ‘at risk’ lung and ICA. C,D: Probe is held longitudinally and needle inserted obliquely beneath it with other hand. Note needle path risks laceration to the ICA or lung.

Proposed Probe Design

- Ultrasound probe suited for longitudinal orientation on the chest, such that the image captures both the superior and inferior rib.
- Wideband US array (eg frequency 5-10MHz) which would allow high-resolution imaging of both deep structures (10-15cm), such as atelectatic lung and the heart within a large pleural effusion, and near structures (1-3cm) such as a potentially vulnerable ICA.
- US array is a phased array, which diverges outwards from probe such that a needle inserted immediately below the probe in the long axis of the US field, can be imaged in real-time.
- A needle guide incorporated into the end of the probe allows the operator to insert the needle perpendicular to the skin in a manner familiar to that already taught and practiced.

- Location of the needle guide at the inferior end of the probe allows insertion of the needle in the lower portion of the intercostal space, such that there is no risk of laceration to the ICA.
- Electromagnetic tracking of the needle could be included to improve identification of the needle tip as it is inserted into the chest.
- As the needle is inserted under real-time guidance, small effusions may be safely drained without risk of needle puncture to the lung or diaphragm. Procedures could also be performed safely in patients at increased risk of bleeding (eg liver cirrhosis, treatment with an anti-coagulant), because the ICA could be positively identified and avoided during needle puncture.

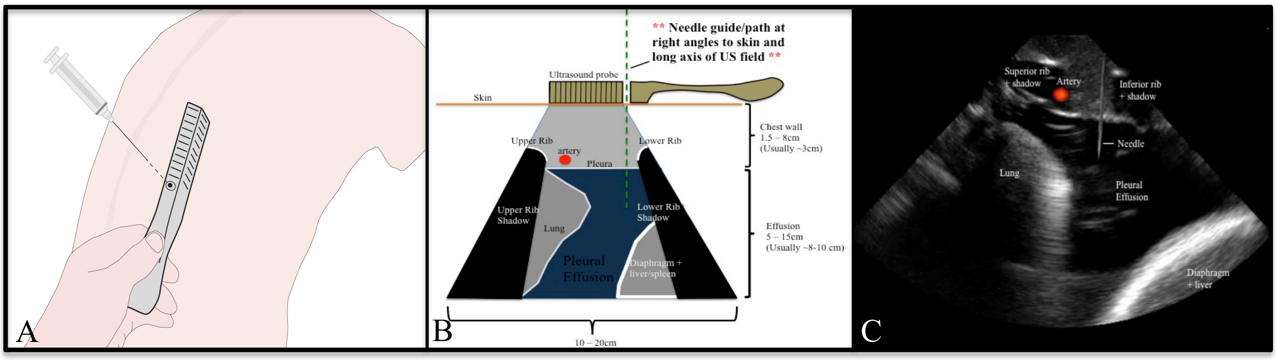

Figure 2 Proposed new US probe design. A: The probe is designed to be held with one hand, orientated in the longitudinal plane on the back, while the needle is inserted with the other hand, at right angles to the skin and through a specifically designed needle guide in the probe at the lower end of the US array B: Schematic diagram showing relative positions of anatomical structures and needle path C: US image showing entry of needle above lower, rib away from the ICA or 'at-risk' superior-lying lung

Conclusions

This PhD has produced studies that will impact directly on the clinical management of pleural effusions. It has developed objective assessment tools with initial pilot studies demonstrating their validity. They could now provide the impetus for further studies to develop and refine such methods for procedural competency assessment. While these studies are underway individual hospitals could use the tools to track an individual's progress through training and use these assessments as feedback opportunities. It has also produced novel extensions to the current use of ultrasound by the pulmonologist, documenting for the first time the possible use of US to identify a vulnerable ICA prior to chest drainage procedures and prospectively identify malignant lung entrapment prior to effusion drainage. It has refined the current technique of pleural manometry, simplifying the practice for clinicians and allowing for fully automated recording and calculation of relevant parameters. These novel tools now provide the stimulus to further clinical study as outlined above. In time it is hoped these tools may improve outcomes and reduce adverse events suffered by our patients.

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