THE SAHLGRENSKA ACADEMY

ULTRAFRED – Ultrasound Facilitated Removal of Intercostal Drain

Degree Project in Medicine

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Abstract

Background

While clinicians agree that ultrasound has proven as accurate or better than chest x-rays in diagnosing pneumothorax and hemothorax, the utilization of ultrasound as an adjunct to clinical findings in the decision algorithm for intercostal drain removal in posttraumatic injuries has not been thoroughly researched.

Methods

Patients undergoing treatment by drainage for traumatic chest injuries received two surgeon-operated ultrasound examinations in addition to standard care; one chest x-ray (CXR) before drain removal and one after. All decisions regarding patient treatment were based on based on clinical findings and CXR results. Ultrasound results were compared to the results of the CXRs, to establish if safe removal of drainage could be determined through ultrasound instead of CXR.

Results

Attempts were made to calculate Kappa Agreement, to test significance with Fisher's Exact test and McNemar's test as well as post hoc Power. For the examinations before drain removal specificity was found to be 100 %, sensitivity 0 %, negative predictive value (NPV) 75% and positive predictive value (PPV) 0 %. For the total amount of examinations specificity was 92.9 %, sensitivity 0%, NPV 86.7 % and PPV 0 % (p=1.00, post hoc power 8.3%). Kappa agreement was - 0.091 (p = 0.696). When clinical relevance was incorporated specificity reached 93.8 %, sensitivity 0 %, NPV 100 % and PPV 0 %.

Conclusion

Ultrasound results does not differ from the results of CXR (p = 1.000), but with a post hoc power of 8.3 %, this statement lacks statistical basis. So far, ultrasound seems promising as an adjunct to clinical findings however, low numbers of included patients considerably prevented the statistical analyses desired for proper conclusions to be drawn. Further research is required to correctly assess the exchangeability between CXR and ultrasound in the evaluation for intercostal drain removal.

Background

In the field of trauma surgery, traumatic pneumothorax and hemothorax is common. Pneumothorax prevalence varies between 9 to 20.6 % of traumatic chest injuries (1-5), hemothorax prevalence varying between 2.9 to 34.5 % (1, 2, 6). In Sweden approximately 1000 patients each year are admitted to hospital with traumatic pneumothorax, 150 in the county Västra Götaland, alone. For hemothorax, the number of admissions are around 700 patients per year in Sweden and 100 in Västra Götaland (7).

Golden standard for diagnosing traumatic pneumothorax and hemothorax is well established as a chest computer tomography (CT) (5, 8-20). However, for monitoring the course of treatment most hospitals use chest x-rays (CXR) (10, 17, 21-23) as composite golden standard since CXR is more accessible (24) and the quantity of ionizing radiation the patient is exposed to is much lower than when using CT scans (24, 25). The utilization of CXR leads to missed pneumothoraces that would have presented on CT (5), so called occult pneumothoraces (3). Over the recent decades several studies have been published investigating ultrasound, which from a radiation- and accessibility point-of-view is an even more favorable option for diagnosing pneumothorax and hemothorax. Nowadays, clinicians agree that ultrasound has similar or superior specificity and sensitivity to CXR in diagnosing pneumothorax (9-13, 15, 18, 19, 24, 26-31), as well as pleural effusion (13, 31-35). Numerous case reports and letters have been published, urging clinicians to use ultrasound instead of CXR (36, 37).

One of the major factors to its appeal is the simplicity of the procedure and therefore quick learning curve (5, 17, 19, 26, 30, 38-40). Multiple studies have produced highly accurate results for ultrasound examinations performed by surgeons or emergency physicians with little to no knowledge of ultrasound prior to the study start. The study protocols dictate

operators to complete an ultrasound course and obtain a certificate in the use of clinical ultrasound before being able to enroll patients in the study (5, 10, 17, 19, 27, 30, 38, 39).

Ultrasound technique

Where to place the ultrasound probe to accurately visualize the presence of a pneumothorax depends on the position in which the patient is seated and the size of the pneumothorax (41). Older studies advocate that free air most often collects anteromedially (42-46) and when the distribution of free air in the thorax is visualized through CT after traumatic injuries, three areas of the anterior chest wall stand out as potential examination points (41). A study examining which probe location on the anterior chest wall was best for finding clinically relevant pneumothorax showed that the fourth intercostal space examined in the midclavicular line displays high accuracy for finding clinically relevant pneumothorax in the supine patient (10). Nonetheless, exact intercostal space cannot always be determined, causing difficulties for operators to follow such exact directives.

Free pleural effusion collects at the basal, dorsal part of the lung, usually in the costophrenic sinuses, when the patient is positioned in a supine position (34, 35).
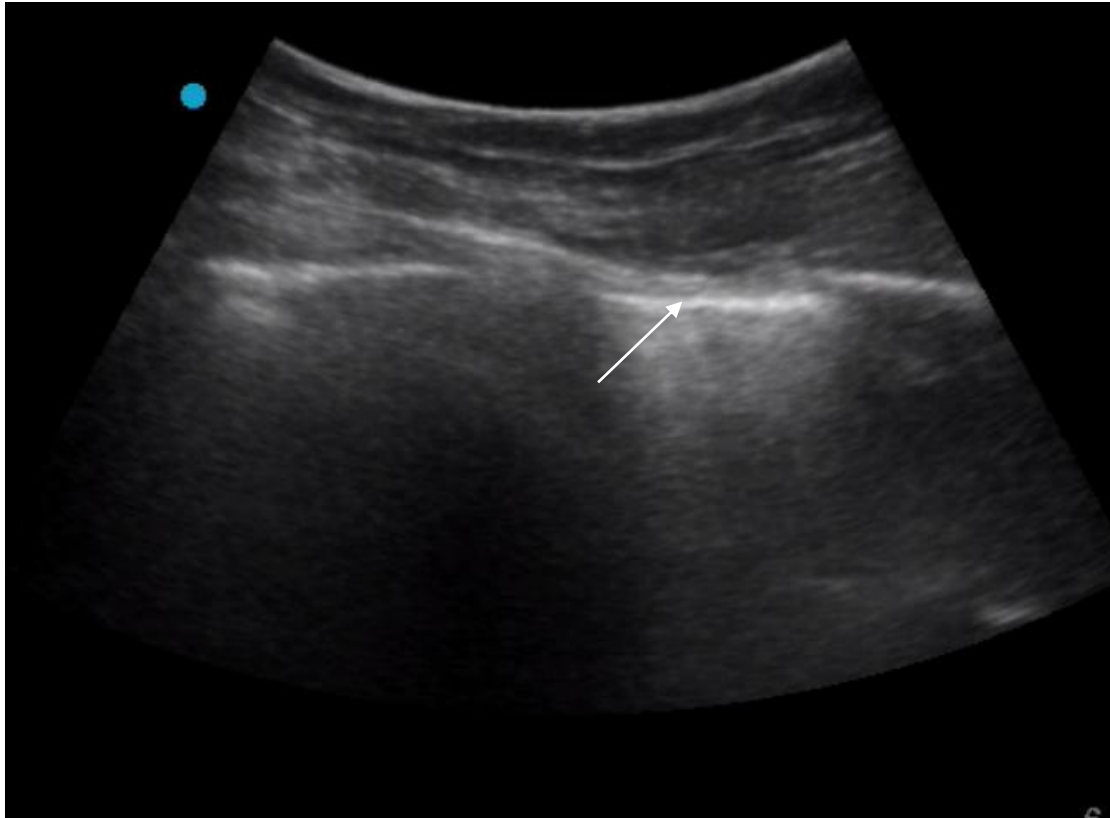
Image 1
Ultrasound image viewed in the midclavicular line parallel to the sternum around intercostal space 3-4. Arrow pointing at pleural line, where the lung sliding sign and lung pulse sign can be seen

Patients examined for pneumothorax are placed in a supine position, with slightly elevated head end. Different signs or artifacts are associated with either pneumothorax or pleural effusion. When ruling out pneumothorax the recommended signs are lung sliding, B-lines and lung pulse (31), the most described sign being lung sliding (12). Lung sliding is seen when the visceral and parietal pleura slides along each other at in- or expiration. If this sign is seen at the pleural line (*Image 1*) it rules out pneumothorax in this area. If it is not seen, the visceral and parietal pleura are disconnected indicating that pneumothorax is present in this area. The loss of lung sliding sign is due to the free air collected in the intrapleural space separating the two layers from each other.

Image 2 B-lines
Ultrasound image viewed in the
midclavicular line parallel to the
sternum around intercostal space 3-4.
Arrow marking one of the B-lines in this
picture.

B-lines, or comet tail artifacts, is another sign of use when looking for pneumothorax (13, 31,

47-49). This sign indicates full lung expansion. The ultrasound image displays white

reverberations, like sunrays, from the outer ribcage reaching in to the lung (*Image 2*). If this

sign is present, pneumothorax can be ruled out in that area. Even if highly accurate, this sign

is not as accurate as lung sliding (9).

The third sign indicating full lung expansion is "lung pulse". The ultrasound image displays a pulsation of the pleural line synchronized with the cardiac rhythm. Lung pulse originates from the physical cardiac activity causing vibrations that transmits through the lung, generating a pulsation of the pleural line (*Image 1*). If this sign is seen, pneumothorax can be ruled out in this area (13, 14, 31, 49). All three of these signs can be used to establish the presence of pneumothorax or not (31, 47), however they cannot from one probe location accurately assess the size of the pneumothorax (19, 50).
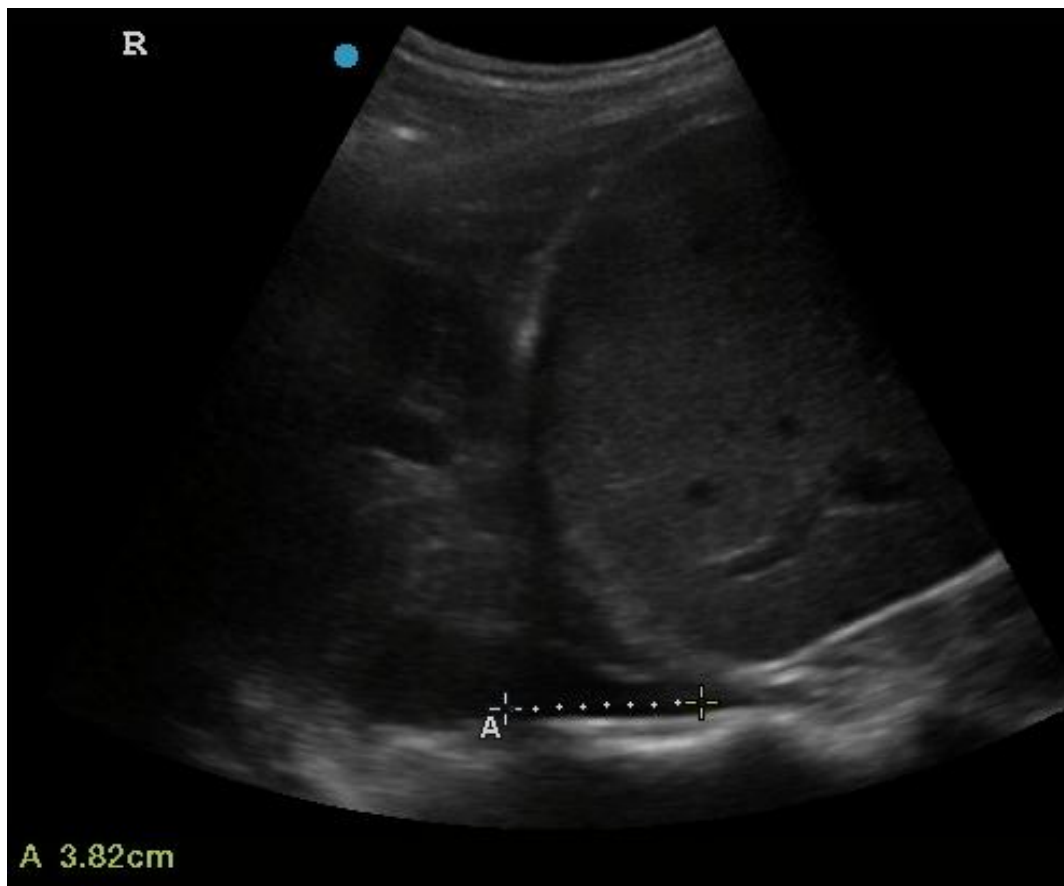
Image 3
Ultrasound image from midaxillary view visualizing the diaphragm.
Thoracic Spine Sign and the measurement for estimation of pleural effusion

Pleural effusion is visualized and the amount of fluid estimated through the thoracic spine sign (51-53). The patient is examined in a supine position, approximately 45 degrees elevated at head end with the transducer placed in the midaxillary line picturing the diaphragm. In the

absence of pleural effusion, the vertebrae column cannot be visualized above the diaphragm since the air filling the lungs disrupts the ultrasound waves. However, if pleural effusion is present the fluid enhances the ultrasound waves which subsequently reach the vertebrae column, producing an image of the vertebrae column as far cranially as the fluid occupies the intrapleural space. The length of the vertebrae column visible above the diaphragm is measured in millimeters and multiplied by twenty to estimate the amount of pleural fluid in milliliters in the intrapleural space (52) (*Image 3*).

Intercostal drain and ultrasound

Patients diagnosed with traumatic pneumothorax are either treated conservatively with active monitoring or with intercostal drainage attached to a water sealed chamber, with or without suction. Drain output in terms of air leakage and fluid quantity is monitored. When drainage of either air or fluid no longer is present, the patient is considered for intercostal drain removal. Combined with clinical findings an adjunct examination is performed, most commonly a CXR, to rule out residual pneumothorax or pleural effusion. Ultrasound has similar or superior accuracy than that of chest x-ray in diagnosing pneumothorax (9-13, 15, 18, 19, 24, 26-31), as well as pleural effusion (13, 31-35), but the use of ultrasound for assessing the treatment by intercostal drain is still under debate. Publications are proposing that extended duration of intercostal drain treatment causes pleural adhesions (21), subcutaneous emphysema interferes with results (8, 10, 24, 26) and lung contusion affects ability to find pneumothorax (10) producing false results for ultrasound. The research concerning the use of ultrasound as an adjunct to clinical findings for determining course of treatment after traumatic chest injuries has only just started and studies published so far has shown promising results (10, 17, 22). To our knowledge, there has only been one study

examining ultrasound as the primary tool when assessing for intercostal drain removal (10).

This study aims to increase the amount of evidence in this field of research.

Overall aims

The primary aim of this study is to assess whether clinician operated bedside ultrasound safely can replace CXR as an adjunct to clinical findings in the decision algorithm for intercostal drain removal after traumatic chest injuries.

Secondly, to establish specificity, sensitivity, negative predictive value and positive predictive value of ultrasound examinations compared to composite golden standard CXR. More specifically for the presence of pneumothorax, clinically relevant pneumothorax and pleural effusion.

Specific Aims

To assess whether this study design is feasible for examining the overall aims mentioned above.

Ethics

Ethical considerations according to the WMA Declaration of Helsinki and the Universal Declaration of Human Rights were discussed and an application for ethical approval was submitted. Patients received written and oral information and were required to sign an informed consent before entering the study. All participation was voluntary and patients could exit the study at any time without stating a reason. Ultrasound has no documented long-term side effects and ultrasound results did not alter the treatment of the patient. Ethical approval was granted on February 7th, 2018 by the Regional Ethics Committee of Gothenburg. Dnr: 027-18.

Method

This blinded, prospective observational study was conducted at the department of Trauma Surgery, Sahlgrenska University Hospital.

All patients of age 18 or older admitted to the trauma unit at the Sahlgrenska University Hospital with traumatic pneumo- and / or hemothorax receiving treatment with intercostal drain between 12th of February 2018 and 13th of April 2018 were eligible to enter the study. Participants were informed verbally, and written information was distributed when signing the informed consent.

Ultrasounds were performed by surgeons who had completed an ultrasound training course (eFAST). The surgeons also had to perform at least 30 thoracic ultrasounds of which at least five had to be positive for either pneumothorax or pleural effusion before receiving their certification. Only after certification were surgeons allowed to enroll patients in the study.

All patients received standard care, which includes a CXR to help determine when to end the chest tube treatment, and a CXR after the chest tube has been removed to rule out residual pneumothorax or pleural effusion. Decisions concerning patient care were based on clinical findings combined with CXR results. In addition to the CXR all patients were examined with ultrasound in conjunction with the CXRs. The surgeon performing the ultrasound was not the treating physician and therefore blinded to the CXR results. Meanwhile, the treating physician was in his/her turn blinded to the ultrasound findings. An external radiologist with no knowledge about the study at all interpreted the CXRs. The results from the ultrasound were noted in the case report form and images were saved for documentation.

Examinations were performed bedside with the patient in supine position with approximately 20 degrees inclination at the head end. The ultrasound machine used was the Secma Sonosite Edge (Askim, Sweden). In this study, the C60 5-2 MHz curved array transducer was primarily used at both ultrasound probe locations. In cases where a clear view was not obtained, the HFL38 13-6 MHz linear array transducer was used as an alternative. To evaluate pneumothorax, the probe was placed parallel to the sternum in the midclavicular line at the vertically highest point on the chest wall. Both hemithoraces were examined and documented separately. Ultrasound images were analyzed for lung sliding sign, B-lines and lung pulse. Images presenting with one of the three signs present, indicative of full lung expansion, ruled out pneumothorax. The sign utilized for validation was noted in the database.

Secondly the probe was placed in the midaxillary line at the diaphragm to assess the presence of pleural effusion through visualization of the thoracic spine sign. The quantity of pleural fluid in milliliters was estimated through measuring the vertebrae column visible above the diaphragm and multiplying the distance in millimeters by factor twenty. Both the presence of thoracic spine sign and the estimation of pleural fluid was noted in the ultrasound case report form.

CXRs were performed in best possible position, most desirably in erect position with an anterior-posterior and sagittal view. If this was not tolerated by the patient, best view possible was accepted and noted in the case report form.

Statistical Methods

Data collection and statistical analyses were made using IBM SPSS version 25.0, (SPSS Inc; Chicago, Illinois).

Data collection

In database 1, data regarding presence of pneumothorax and pleural effusion was noted for the two examination tools, each hemithorax presented as separate cases. Examination results before and after drain removal was noted in separate columns. CXR results regarding pneumothorax had an additional column stating clinical relevance of a contingent pneumothorax. Since pneumothorax examined by ultrasound in one probe location cannot accurately determine size, no judgement of clinical relevance could be extracted from the images and was therefore not accounted for in the database. CXR view, clinical findings, drain duration and other information from the case report form including drainage output, mechanism of injury and initially sustained injuries were also noted in database 1. Patient characteristics, such as age, mechanism of injury, gender, other injuries sustained in the trauma etc, were collected from medical records and noted directly in database 1.

A separate database, database 2, was created to enable an overall comparison of all paired examinations to test statistical method. In this database each hemithorax was documented as separate cases; left and right. Since patients received two paired examinations, each two cases (left and right) were also separated into two cases, one being the pair of examinations before and one being the pair after the drain removal. This resulted in four paired examinations for each enrolled patient. This was done solely to see over all agreement between CXR and ultrasound. Results regarding pneumothorax, pleural effusion and the clinical relevance of the possible pneumothoraces found with CXR were documented. No further information was recorded in this database, since database 1 contained all the detailed information for sub analyses and descriptive statistics.

Analyses

Frequency tables and intervals were created to extract information about the patient sample. Using CXRs as golden standard specificity, sensitivity, negative predictive value and positive predictive value for the ultrasound examinations before drain removal on the affected hemithorax as well as the total amount of examinations were calculated, separating the results for pneumothorax and hemothorax.

A Kappa agreement test, establishing in what degree two examination tools with categorical variables agree, was performed to examine concordance between the two modalities on database 1 as well as database 2. Level of significance was set at $p < 0.05$. Fischer's exact test, a significance test appropriate for small sample sizes and categorical outcomes, and McNemar's test, testing if the mismatches in results between the modalities were statistically significant, were both performed to test level of significance of the difference in results between the two modalities. Since the examination tools had similar expected outcome, p-values were expected to be high. Due to this, calculations of observed power were performed post hoc to establish the power of the study to find a difference if there was any.

Results

During this period, six patients were eligible for the study. Of these six, two did not sign an informed consent and was therefore not included in the study. The four patients remaining all completed the study protocol. Because of this, none of the statistical analyses below are of statistical significance or could not be performed on the data obtained. The analyses were performed solely for educational purposes and practice for the completed study.

The dressing covering the exit site of the intercostal drain prevented operators from obtaining clear ultrasound images of the costophrenic sinuses and data could not be collected. Due to this are the statistics below solely based on the results for pneumothorax.

Study population

Of the four patients two were male and two were female. Age varied between 40 and 93. Three patients' injuries were caused by blunt trauma and one patient's injuries were caused by penetrating trauma. All injuries treated with intercostal drain were located on the right side of the thorax, no patient sustained injuries that required treatment on the left side of the thorax.

Descriptive statistics

Average drain duration was calculated to 3 days, ranging from 2 – 4. Three patients had bedside, supine CXR examinations before and after drain removal, only one could comply to an erect CXR view.

Time between paired examinations was calculated for examinations before and after removal. For the examinations before drain removal time between examinations ranged from 0.33 to 29.5 hours, after drain removal the time between examinations ranged from 1 to 22 hours. For the paired examinations with 22 hours discrepancy a mismatch between results was recorded. However, the other two mismatches in results had 2 and 12.67 hours between examinations.

Statistical analyses

A comparison between ultrasound and CXR results before drain removal is the most relevant statistical analysis for the overall aim chosen to investigate. Unfortunately, the low number of included patients prevented a successful procedure of such statistical calculations. Hence, only four outcomes were calculated for the four paired examinations before drain removal. Specificity reached 100 %, sensitivity was 0 %, negative and positive predictive value was 75 % and 0 % respectively. No other attempted calculations could be performed since ultrasound results were constant (all negative for pneumothorax), or the sample size was too small.

The rest of the statistical analyses were performed on the total amount (both before and after drain removal and separating left from right side) of paired examinations, increasing the number of cases by multiples of four, in this case generating 16 paired examinations.

TABLE 1. Crosstabulation demonstrating the results of ultrasound compared to the composite golden standard CXR for the presence of pneumothorax.

TABLE 1.

			CXR results Pneumothorax		
			No	Yes	Total
Ultrasound results Pneumothorax	No	*n*	13	2	15
		NPV	*86.7 %*	13.3 %	100.0 %
		Specificity	**92.9 %**	100.0 %	93.8 %
	Yes	*n*	1	0	1
		PPV	100.0 %	*0.0 %*	100.0 %
		Sensitivity	7.1 %	**0.0 %**	6.3 %
Total		*n*	14	2	16

92.9 % (bold), sensitivity of 0 % (bold), NPV - Negative predictive value of 86.7 % (bold, italics) and PPV - Positive predictive value of 0 % (bold, italics).

In 13 of 16 cases ultrasound and CXR results were identical. In two cases was CXR positive for pneumothorax when ultrasound was negative and in one case was ultrasound positive for pneumothorax when CXR was negative. This generated a specificity, probability of correctly discarding pneumothorax, of 92.9 %, a sensitivity, probability to correctly confirming pneumothorax, of 0 %, a negative predictive value, probability of absent pneumothorax if ultrasound is negative, of 86.7 % and a positive predictive value, probability of existing pneumothorax if ultrasound is positive, of 0 %. All results are in relation to the CXR results.

TABLE 2. Crosstabulation demonstrating the results of ultrasound compared to the composite golden standard CXR for the presence of clinically relevant pneumothorax.

TABLE 2			Clinically relevant CXR results		Total
			Pneumothorax		
			No	Yes	
Ultrasound results Pneumothorax	No	*n*	15	0	15
		NPV	***100.0 %***	0.0 %	100.0 %
		Specificity	**93.8 %**	0.0 %	93.8 %
	Yes	*n*	1	0	1
		PPV	100.0 %	***0.0 %***	100.0 %
		Sensitivity	6.3 %	**0.0 %**	6.3 %
Total		Count	*n*	0	16

Specificity 93.8 % (bold), sensitivity of 0 % (bold), NPV - Negative predictive value 100 % (bold, italics) and PPV - Positive predictive value 0 % (bold, italics).

In 15 of 16 cases ultrasound and CXR results are identical. In one case was ultrasound positive for pneumothorax when CXR was negative. This generated a specificity, probability to correctly discard pneumothorax, of 93.8 %, a sensitivity, probability to correctly confirm pneumothorax, of 0 %, negative predictive value, probability of absent pneumothorax if

ultrasound is negative, of 100 % and a positive predictive value, probability of existing

pneumothorax if ultrasound is positive, of 0 %. All results are in relation to the CXR results.

Kappa agreement was calculated to -0.091 with an approximate significance of 0.696 for the

results evaluating the presence of pneumothorax. No calculations could be performed on the

results incorporating clinical relevance due to CXR results being constant.

Fisher's exact test for the comparison between total amount of examinations only regarding

the presence of pneumothorax was calculated to a 2-tailed $p = 1.000$ and for the presence of

clinically relevant pneumothoraces corresponding number could not be calculated because

CXR results were all negative for clinically relevant pneumothorax and therefore considered a

constant. The same problem occurred for McNemar's test when calculating significance in

differences on the material comparing ultrasound to clinically relevant CXR results, hence no

p-value could be established. When performing McNemar's test on the results between

ultrasound and the presence of pneumothorax in CXR results, a 2-sided p-value of 1.000 was

found.

Observed power for the total amount of examinations was calculated to 8.3% comparing the

results for the presence of pneumothorax between the two modalities, and 15.5% when

comparing the presence of clinically relevant pneumothorax.

Discussion

Due to a low number of included patients, the statistical analyses requested for answering the overall aim chosen for this study were unsuccessful. The statistical methods were tested on the total amount of examinations solely to examine the feasibility of the current study protocol for the extension of this degree project. This, however, does not alter the fact that the results are inconclusive. The following discussion is disregarding the statistical significance of the results in the study and was conducted for educational purposes.

The results of this study suggest that ultrasound is highly accurate in ruling out the presence of pneumothorax. It is however very poor in finding existing pneumothorax. If the ultrasound does not display pneumothorax, the result can be trusted. If it is positive for pneumothorax, the result cannot be trusted.

For the patient undergoing treatment it is of importance whether the detected pneumothorax is clinically relevant. When the results of the ultrasound (without clinical relevance incorporated) are compared to the clinically relevant pneumothoraces found with CXR on the total amount of examinations ultrasound is highly accurate in ruling out pneumothorax. The level of accuracy found in this degree project is in line with previous studies comparing ultrasound to CXR for the detection of pneumothorax after drainage (22), as well as detection before drainage (10) where negative predictive value varied between 92 and 100% compared to CXR.

Fisher's exact test and McNemar's test both produced p-values indicating no statistically significant difference between the results of ultrasound and CXR for the presence of pneumothorax. No p-value could be calculated when incorporating clinical relevance. This, in theory, discards the null hypothesis assuming ultrasound had lowered accuracy than CXR.

However, the power to find a difference if there was one between the two examination tools was too low in this material. Hence, it cannot be stated that ultrasound is as good as CXR at this stage in the study.

The Kappa agreement was in this test close to zero, indicating poor agreement, worse than coincidence. Additionally, the calculated Kappa was not significant. However, when exclusively looking at percentage of identical results between CXR and ultrasound, 81 % of examinations regarding the presence of pneumothorax were identical, and 94 % when incorporating clinical relevance. The poor agreement and low significance were probably due to the limited number of positive results for pneumothorax. Increased numbers of included patients and positive outcomes are required to accurately calculate Kappa agreement, why continued studies are necessary to gain truthful results.

There is a possibility the low rate of positive results for pneumothorax continues throughout the examined patients are close to finished with their treatment, and the initial pneumothorax is not predicted to persist. This could present as an issue in the final statistical analyses since no tool can be assessed when only showing negative outcomes. If no positive outcomes are recorded, the study protocol might need alteration to properly answer the overall aims of this study.

Drain duration as a confounding factor has been debated. In the study by Dente et al pleural adhesions due to the intercostal drain was thought to be the reason for false positive results with ultrasound, kept in mind that ultrasound was only compared to CXR and not CT (39). Kwan et al. did not find lowered accuracy depending on increased drain duration in the thorax, rather the opposite (10) and a comparison by Saucier et al. between ultrasound and

CXR showed 100% concordance in detection of pneumothorax after removed intercostal drain following thoracic surgery, a procedure that would contribute to the formation of adhesions more than the chest tube insertion alone (23). In our material drain duration in the thorax does not seem to affect the outcome of the ultrasound results compared to CXR results. However, no statistical analysis was performed since the low number of patients disabled the calculations. Additional research is required to confirm or deny a connection between drain duration and lowered accuracy for ultrasound. In the extension of this study a sub analysis regarding the subject will be performed.

The surgeon including patients in this study made several observations that could potentially affect the results. Firstly, the dressing covering the exit site of the intercostal drain interfered with the ultrasound through obstructing clear images and therefore could no data be collected regarding pleural effusion of the side affected by drainage. This problem will likely continue to interfere with ultrasound results since the intercostal drain requires a dressing covering the exit site. This raises the question – is it important to evaluate pleural effusion before deciding to remove the intercostal drain? If yes, another ultrasound sign looking at pleural effusion from another direction, or another adjunct tool for pleural effusion estimation must be utilized. For this, drainage output could prove an important instrument. In the extension of this study, sub-analyses regarding drainage output compared to CXR findings will be performed.

Secondly, the clientele sustaining injuries requiring intercostal drainage seems to differ from general population. Especially the patients with penetrating injuries represented a group of people not too keen on being studied or recorded by an ultrasound machine, a problem contributing to the low number of included patients. Patients with penetrating wounds seems more likely to decline study involvement compared to patients with blunt trauma, also causing

a bias selection of patients included, something to be aware of when implicating the results on general population.

Thirdly, when patients suffer from multiple rib fractures in- and exhaling causes pain. Patients respond to this by decreasing the tidal volume to refrain from moving the injured ribs. The small volumes of air inhaled decreases the movement of the visceral pleura along the parietal pleura, making the lung sliding sign difficult to visualize and interpret. Operators need to be aware this to perform correct examinations and interpretations. If the patient is unable to produce large enough volumes of air for lung sliding to be seen, operators must be certain B-lines and lung pulse are absent before stating a positive result for pneumothorax in the ultrasound form.

There is a possibility that the surgeon performing the ultrasounds were anticipating a negative result since the treatment was expected to be completed and therefore no pneumothorax was supposed to remain. However, since the study is blinded and the surgeon performing the ultrasound was unaware of the results of the CXR as well as the patient's course of treatment, the room for bias of the estimator has been minimized. Additionally, since we included the unaffected sides in the overall comparison between ultrasound and CXR the surgeon was obviously not blinded to the absence of an intercostal drain on that side.

Tube size in this study was 28 - 36 Fr, differing from Galbois et al who used a small catheter (17) to drain traumatic chest injuries. A larger tube would theoretically cause a larger surgical trauma than a small catheter, possibly creating more adhesions that could interfere with results, as mentioned by Dente et al (21). In this small material it is impossible to say if this interfered with the results. In the extension of this study, if results are different from those

produced by other with similar study designs, this could prove to be an explanation. Kwan et al, the only study with comparable study design, does not state tube size (10).

Possible implications

If, in the extension of this study, ultrasound continues to show high accuracy for pneumothorax evaluations compared to CXR, there is support for conducting a randomized trial where patients receive either ultrasound or CXR as evaluation tool before drain removal. With this study design is it possible to calculate specificity, sensitivity, NPV and PPV for both tools and therefore state accuracy of ultrasound independent of CXR results.

A study performed by Johnson et al on a pediatric population, willing to reducing the quantity of ionizing radiation, discussed if the CXR after drain removal was necessary at all with results showing that in only 9 cases of 160 did the course of treatment alter due to the CXR results (54). Sepehripour et al suggested the use of CXRs as follow up after drain removal in patients post cardiothoracic surgery only if it was clinically indicted (55). If physicians used ultrasound instead, a radiation free, easy and accurate tool, the exposure to radiation would be non-existent without sacrificing the examination of the patient.

Potential benefits from replacing CXR with ultrasound as an adjunct to clinical findings for removing intercostal drain are less radiation, quicker examination (8, 13, 17, 23, 32, 39) and more cost-effective care of patients. Since ultrasound is a one-time investment and CXR costs per time used and the overall resources required for one CXR (transport to radiology, interpretation of CXR frames by radiologist) are greater than for one ultrasound (surgeon and ultrasound machine already at ward). Adding the fact that the course of treatment requires at least two CXRs or ultrasounds the resources and time saved are of a substantial amount.

In this degree project ultrasound was recorded positive in one patient when CXR was negative for clinically relevant pneumothorax. The mismatch in results between paired examinations occurred after the drain had been removed and would not have resulted in drain reinsertion if the decision had been based upon the ultrasound. However, it could have led to an added CXR to establish clinical relevance. This borders to some concerns of replacing CXR with ultrasound. Since the ultrasound is proven a more accurate tool for the diagnosis of pneumothorax (9-13, 15, 18, 24, 26-29), it might contribute to overtreatment. Ultrasound's inability to establish clinical relevance of possible pneumothoraces also contributes to this risk. Currently quite a large percentage of pneumothoraces displayed by CT are occult on CXR (3, 5). The use of ultrasound could potentially contribute to unnecessarily prolonged drain duration since occult pneumothoraces are less likely to need drainage (3, 20). For the patient, the prolonged drain duration extends the risk of complications such as infections, and postpones hospital discharge. It is therefore vital with continuous research for more accurate results, but also to establish a safe decision algorithm where the risk for overtreatment is minimized.

Other published conditions potentially creating false positive results for ultrasound are bullous emphysema and injuries sustained in the trauma such as lung contusion or subcutaneous emphysema (26, 39), subcutaneous emphysema being the most emphasized. However, Blaivas et al. state that experienced operators should be able to separate the signs for pneumothorax from subcutaneous emphysema (18). Some studies also mention that subcutaneous emphysema interferes with CXR results (10, 14). In this study, only one patient had subcutaneous emphysema and both examinations before and after had identical results. Since patients with traumatic chest injuries go through a CT scan upon arrival at the hospital,

bullous emphysema would have been caught early and taken into consideration ahead of ultrasound examinations.

False negative results with ultrasound compared to CT are represented by pneumothoraces that are either more apical or basal, significantly smaller and less frequently need treatment by drainage (3, 20, 26). These described pneumothoraces were to the same extent or more often missed by CXR when comparing to CT scans (15, 56). Due to this, one can assume false negative results are already accounted for in the standard care of today.

Limitations

This study comes with several limitations. Most obviously, the low number of patients enrolled in the study limits our possibilities of producing significant results. With only four patients completing the study, the most relevant statistical analyses were impossible to calculate. Even for the calculations based on the total number of paired examinations conclusions cannot be drawn at this early stage. The enrollment continues in the extent of this study, and further analyses will be made in the future.

All patients were admitted to one unit, making this a monocenter study. It is unsure whether the results presented in this study apply to other centers worldwide. However, the preliminary results produced by this limited number of patients are in line of those published by others. It seems therefore that results are comparable regardless of geographic locations or hospital routines.

Another issue regarding generalization is that solely one operator had completed the certification when this degree project was published, and was therefore the only one including and examining patients. Since ultrasound is operator dependent (8, 14, 24) the results of ultrasound examinations in this study cannot be assumed to apply for all surgeons.

The time between paired examinations was not standardized which resulted in a time span between some of the paired examinations that exceeded reasonable limits. At this stage it cannot be determined if prolonged times affected the outcome because the small sample size does not enable sub-analyses. Increased amount of time between paired examinations is hazardous, since the paired examinations in this study may not measure the same status of the patient. If, in the continuation, a cut-off time between examinations is suggested, analyses can be made using only the examinations with time differences below said cut-off. This issue will be addressed in the extension of this study.

As mentioned before, the dressing surrounding the exit site of the intercostal drain prevented operators from obtaining a clear view of the costophrenic sinuses with ultrasound. Due to this the collection of data and calculation of statistics regarding pleural effusion were not possible. The aim of investigating ultrasound as examination tool for pleural effusion before drain removal was not reachable.

Future improvement

A sample size estimation was performed (57) based on the numbers produced at this early stage for the continuation of the study. It established that 33 paired examinations are required to measure a difference between the two tools with a power of 80% and significance level of 0.05. Calculations were based on the presence of a pneumothorax on the drain affected side before drain removal, not regarding clinical relevance. However, with only 4 paired examinations, one positive outcome alters the numbers significantly. It is unlikely the difference between the tools will remain this large (ultrasound had 0 % positive outcomes, CXR had 25 % positive outcomes) and a margin of safety is desirable.

Conclusions

The study protocol seems feasible for the evaluation of pneumothorax, and the statistical methods are usable if positive outcomes from ultrasound and CXR are recorded in the continuation. The study protocol is, however, not feasible for the evaluation of pleural effusion, another ultrasound method or evaluation tool is for this required.

Regarding the overall aims, ultrasound results are not significantly different from CXR results in this degree project. However, with a post hoc power of merely 8.3 %, this statement lacks statistical relevance. So far, no conclusions can be drawn from this study whether ultrasound can replace CXR in every day standard care as an adjunct to clinical finings in the decision algorithm for intercostal drain removal due to unsuccessful statistical analyses, mostly caused by a limited number of included patients. It is difficult to say how these results could affect patient care at this stage in the study, even though the potential benefits are substantial if CXR proves safe to replace with ultrasound. Continued inclusion, with lessons learned from this pilot degree project, can hopefully answer this question in the future.

Populärvetenskaplig sammanfattning

Varje år drabbas cirka 150 personer i Västra Götaland av våld mot bröstkorgen. Detta kan resultera i lungkollaps, vilket innebär att luft hamnar mellan lungan och bröstkorgsväggen i lungsäcken, eller att blod ansamlas i lungsäcken. Man behandlar dessa skador med ett dränage som läggs in i lungsäcken och suger ut luft eller blod som normalt sett inte ska vara där. När man ska avsluta dränbehandlingen gör man en hjärtlungröntgen för att se att vätskan och luften i lungsäcken är borta innan man drar ut dränaget, samt en hjärtlungröntgen efter man har tagit ut dränaget för att se att luft och vätska inte har återsamlats i lungsäcken. I vår studie har vi undersökt om ultraljud istället kan användas som verktyg för att bestämma om det finns luft eller vätska i lungsäcken både före och efter att man har dragit ut dränaget. Alla patienter fick skriva på ett samtycke till studien och genomgick sedan två ultraljud och två hjärtlungröntgen, före och efter vi hade avlägsnat dränaget.

De initiala resultaten av studien visar att ultraljud kan utesluta närvaro av luft i 93 % av fallen. I de fall ultraljud indikerar att det inte finns luft i lungsäcken, stämmer detta till 87% överens med hjärtlungröntgen som är det vedertagna diagnosinstrumentet. Däremot kunde inte ultraljud hitta luft i lungsäcken vid två tillfällen när hjärtlungröntgen indikerade en luftansamling. Det visade sig dock att dessa ansamlingar av luft var för små för att spela roll för patientens behandling. Så med andra ord missade ultraljud endast en liten mängd luft som inte var betydande för patienten. Vid ett tillfälle såg ultraljudet en ansamling av luft som inte hittades av hjärtlungröntgen, vilket skulle kunna resultera i att patienten får ha sitt dränage längre tid än nödvändigt.

När man kontrollerade ifall resultaten var tillräckligt underbyggda statistiskt, visade det sig att inga av resultaten hade tillräckligt med underlag för att kunna dra några slutsatser ifrån på grund av för få patienter i vårt material.

På grund av dränagets bandagering kunde vi inte få något resultat för ultraljud som undersökte närvaro av blod i lungsäcken. Detta kunde därför inte analyseras statistiskt.

Det man kan säga i nuläget är att det verkar som att ultraljud kan användas istället för hjärtlungröntgen, vilket i så fall skulle spara patienten onödig strålning, samt göra att sjukvården sparar tid och resurser, men att hittills kan vi inte bevisa något. Därför fortsätter vi att inkludera patienter till vår studie och hoppas kunna redovisa säkrare resultat i framtiden.

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