

Research Article

A proposed novel ultrasound-guided percutaneous dilatational tracheostomy technique - the in-plane wire-in-needle approach: study design and rationale for multicenter randomized controlled clinical trial

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ABSTRACT

Background: The current evidence regarding the applications of Ultra Sound (US) in Percutaneous Dilatational Tracheostomy (PDT) is encouraging. US guided PDT (US-PDT) has recently been recommended in difficult cases and is given a preference compared to bronchoscope guided PDT. The question on the difference in safety and efficacy of the different approaches in US-PDT (with or without the use of any technique to improve needle visualization) during US-PDT and whether it is likely to make a difference needs to be answered.

Methods: Literatures examining the different US-PDT approaches as well as whether any technique to improving needle visualization that has been used during US-PDT in MEDLINE, PubMed, EMBAS E, and the Cochrane Central Register of Controlled Trials were searched for in an attempt to answer the two questions raised. No study has yet compared the in plane to the out of plane approach for US-PDT nor looked at improving needle visualization during US-PDT. This raised the need for a clinical trial looking at the difference between the different US-PDT approaches with or without ways to improve needle visualization during US-PDT.

Results: Utilizing the best available evidence in US guided procedures in the Intensive Care Units (ICU), we proposed a study design that we think is likely to make a difference in US-PDT practice. The study is designed to assess the safety and efficacy of US guided PDT using the in-plane (I.P.) approach enhanced with the use of Wire-in-needle approach (W.I.N.A) and rocking motion of the transducer compared to the traditional out-of-plane approach without W.I.N.A.

Conclusions: The proposed (In-plane Wire-In-needle approach = I.P.W.I.N.A) as a potential to be a standard of care in US-PDT has its own limitations. Its safety, efficacy and feasibility in Randomized Controlled Clinical Trials research settings needs to be tested and verified.

Keywords: Ultrasound guidance, Percutaneous dilatational tracheostomy, Out-of-plane approach, In-plane approach, Needle visibility, Safety, Efficacy

INTRODUCTION

As Ultra Sound (US) technology continues to progress, its scope becomes only limited by the operator expertise, not the bedside US unit. With the increasing availability of bedside ultrasonography in the intensive care setting,

real-time ultrasound guidance have been advocated as potential tools to further improve the safety and efficacy of the US-PDT procedure.^{1,2} Two-dimensional (2D) ultrasound imaging is the most commonly used guidance for needle placement during US-PDT due to its real-time nature and low cost. Needle visualization is important for

safe and successful US-PDT. However, artifacts like reverberation and comet tail, always distort the image. Even when the needle is well aligned with the ultrasound image, it is not easy to see the needle, especially for an inexperienced practitioner.

There are two methods of orienting the needle relative to the US beam in US-guided procedures: the in plane and out of plane approaches.^{3,4} In the in plane needle approach, the needle is inserted in the same plane as the US beam. In this plane, needle-beam alignment is critical to visualize the shaft of the needle (seen as a bright hyperechoic straight line). However, this straight line is also a result of artifacts that does not reflect the true dimensions of the needle.⁵

Moreover, this technique requires manual coordination whilst looking at the 2-dimensional image on the US screen. In the presence of very narrow width of the US beam, this makes aligning the needle within the US beam, as it is advanced, difficult to maintain.⁶ In the out of plane needle approach, the longitudinal axis of the needle is inserted in a plane perpendicular to that of the US beam.⁴ Visualizing the needle tip in this approach can be difficult, as only a cross-sectional area of the needle is imaged (seen as a hyper echoic dot). To make it more difficult, the needle shaft may be mistaken for the tip as both have a similar appearance in cross-section.

The use of real-time sonographic imaging with visualization of the needle path is routinely used for other bedside procedures, such as the insertion of central venous catheters.^{7,8} In general, although various techniques to improve needle visibility have been suggested, most have their own limitations. In US-PDT, the importance of real-time assessment of needle position cannot be overstated.⁹

Without accurate identification of the position of the needle it is possible that damage to collateral structures may occur, even if the tracheal rings have been correctly visualized using ultrasound before starting with a correct position of the needle.

Having said the above, we felt that evidence on US-PDT and its best practice regarding safety and efficacy of different US-PDT approaches using the in-plane compared to the traditional out-of-plane approach as well as various techniques to improve needle visualization needs to be evaluated in order to make best use of it during US-PDT.

METHODS

Rationale

Real-time US guidance makes it possible to follow the needle path during tracheal puncture and to determine the final position of the tracheostomy tube.¹⁰ However, intraluminal air prevents the visualisation of structures

such as the posterior pharynx and the posterior wall of the trachea with US; therefore, injury to the posterior wall of the trachea cannot be completely avoided.¹¹ Knowledge and correct placement of the needle is important for safe practice and is paramount to success of US-PDT. Precise needle manipulation is also mandatory. With the use of real-time ultrasonography and actual visualization of the needle path up to the tracheal lumen, it is expected that injury to surrounding structures in general and to the posterior tracheal wall in particular, is decreased.¹²

In the out of plane approach and compared to the in plane needle approach, it is more difficult to identify the needle tip. Needle tip in this approach is often guided indirectly by an anechoic acoustic shadow seen immediately below it. Moreover and since the image obtained could be at any level along the needle shaft, a cross sectional view of it could be mistaken for the needle tip leading to more risk of posterior wall injury and /or tracheal tube malposition than in the in plane approach.^{13,14} Tracheal tube malposition may result in the tube lying at an angle to the tracheal axis and abutting the lateral or posterior tracheal wall which can cause partial tube lumen obstruction, which has been implicated in failure to wean from ventilation and otherwise unexplained episodes of desaturation.^{15,16}

Improving needle visibility is thus likely to minimize posterior tracheal wall injury as well as the chance of positioning of the tracheostomy either too distally or too laterally with its risks of complications.^{17,18}

We therefore performed a literature review to examine the efficacy and safety of US-PDT in MEDLINE, PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials looking for trials reporting on:

1. Safety and efficacy of US-PDT using the in-plane compared to the traditional out-of-plane approach
2. Possible technique that could improve real-time sonographic guidance of the needle path during PDT.

The terms used were 'safety efficacy', 'ultrasound', 'tracheostomy', and 'needle visualization'. Prospective trials that reported procedural safety or efficacy data for both the intervention group and a control group of US-PDT were included. Case reports, review articles, letters to the editor, and surveys were excluded.

Despite an increasing number of publications in the recent literature describing favorable results and advocating the use of US-PDT, there is a paucity of high-quality evidence.^{19,20} No literature existed to answer any of the two questions we made. Likewise, a recent systematic review failed to identify such a trial.²¹ This raised the need to design a randomized controlled clinical trial looking at possible role of the different US-PDT approaches with and without a technique to improve

needle visualization to improve the safety and efficacy of US-PDT.

On the other hand and recently, a novel ultrasound-guided vascular access technique has been described, involving the use of a needle preloaded with the guide wire without the use of a syringe (Wire-in-needle (WIN)).^{22,23} The transducer is positioned in a long axis over the selected vein. The needle is placed at the center of the transducer in-line with the ultrasound beam and the trajectory of the vessel with the bevel up. After the tip of the needle is seen entering the vessel, the wire is subsequently advanced into the vessel. Several advantages to this technique include eliminating the risk of dislodging the needle tip when the syringe is removed from the needle as in the classic Seldinger technique, as well as increased echogenicity of the needle containing the wire on ultrasound imaging. Moreover, the visualization of the entire needle and vessel concurrently, minimize chance of puncture of the posterior wall, in addition to facilitating proper line placement.

Since no other technique has been reported, the use of novel techniques in US during PDT that is known improve needle visualization could play a role in achieving the goals in US-PDT. We think that utilizing the WIN approach could help improving correct puncture site in the midline or between 11 and 1 o'clock position (less than 30° deviation from midline on right or left side).

DISCUSSION

To answer the question whether using the in-plane approach in guiding the needle puncture in the midline over the trachea, compared to the out-of-plane approach can improve the US guided PDT safety and efficacy, we think a prospective randomized controlled clinical trial comparing these two approaches in adult intensive care patients requiring PDT should be conducted. We also hypothesize that the addition of a WIN to the in-plane approach, along with rocking motion of the transducer into the path of the needle (if it has deflected out of the image plane) will improve needle visualization during US-guided PDT and shorten the procedure time. In addition, we also think that this technique will help appropriately position tracheal puncture in the midline or between 11 and 1 o'clock position. Less than 30° deviation from midline on right or left side thus preventing tracheal tube malposition.

Inclusion criteria

Should include eligible adult intensive care patients defined as being older than 18 years of age at the time of enrolment and requiring a percutaneous dilatational tracheostomy for clinical reasons.

Exclusion criteria

Patient under 18 years with either of coagulation disorders (platelet count of below 80,000 mm⁻³ and an international normalized ratio of more than 1.5), infection at the puncture site, emergency tracheostomy or pregnancy should be excluded.

Sample size

Lacking published data on US guided PDT, we estimated that a sample size of 50 would be required to detect a statistically significant difference with a 0.05 confidence interval and statistical power over 80%.

Details of US-PDT and the study groups

US-PDT will be performed after deep sedation and muscle relaxation. Patients will be ventilated under volume-targeted mechanical ventilation with a 100% fraction of inspired oxygen (FiO₂). Continuous hemodynamic monitoring (five-lead electrocardiogram, blood pressure, heart rate, and pulse oxygen saturation) will be performed. Endotracheal tube (ETT) will then be withdrawn under direct laryngoscopic guidance until the tube's balloon lies just below the vocal cords. The same US machine, probe (10 to 5 MHz linear array probe) as well as the same tracheostomy kit will be used in each study group and all centers. The protocol will require 3 operators: one manages the airway while the other two perform the US-guided PDT (an assistant and an operator).

Prior to PDT, an US examination of the neck region with transversal sections to identify arteries, veins, thyroid, trachea, and endotracheal tube and measure the thickness of the skin to the anterior tracheal wall will be performed to exclude a need for open tracheostomy. The patient will then be randomized for inclusion in the study.

In both the group, position of guide wire entry on bronchoscopic view will be determined after proper alignment of the scope. A picture will be printed for all cases. Images will be reviewed by an independent member to evaluate the guide wire position to determine the angle of deviation from midline (at a later stage). For the study purpose, if the operator is happy about the guide wire position procedure will be completed as usual. An obviously displaced guide wire beyond 30° from midline will have to be replaced. Only the first placed guide wire will be included in the analysis. An US image of the longitudinal view showing the guide wire will also be printed for latter evaluation by an independent radiologist to determine the level of puncture (target between the first and second or second and third tracheal rings). Bronchoscopy will also be performed at the completion of the procedure (i.e. after placement of the tracheostomy tube) to roll out:

1. Posterior tracheal wall injury

2. Tracheal tube malposition (tube lying at an angle to the tracheal axis and abutting the lateral or posterior tracheal wall).

Study groups

In-plane Wire-In-needle approach “I.P.W.I.N.A” group

A longitudinal view will be obtained to locate the cricoids cartilage, the tracheal and rings and then determine the level of puncture site (between the first and second or second and third tracheal rings). The transducer is then held stationary with the non-dominant hand while advancing a needle preloaded with guide wire using the dominant hand. The guide wire will then be visualized as a hyper echoic signal within the lumen of the trachea. If not and while inserting the guide wire, a rocking motion of the transducer will be utilized (as a techniques to improve echogenicity of needle). An US image of this view as well as bronchoscope view of the guide wire entry point will then be obtained. PDT will then proceed as usual.

Control groups

Out-of plane group

A longitudinal view will first be obtained to locate the cricoids cartilage, the tracheal and rings and then determine the level of puncture site (between the first and second or second and third tracheal rings). At the puncture site, the transducer will be rotated to the transverse view of the neck. A puncture needle with a saline filled syringe is introduced perpendicularly to the skin and advanced until the needle is seen to pass the anterior trachea wall during an aspiration of air. Then the needle is angled caudally to prevent retrograde passage of the guide wire. The syringe is then removed from the needle, guide wire introduced and needle is removed. During the procedure, needle will be visualized in an ‘out-of plane’ mode (that is, the needle path will be determined by the presence of a distinct acoustic shadow ahead of the needle). The guide wire will then be visualized as a hyper echoic signal within the lumen of the trachea on longitudinal sections. An US image of this view as well as bronchoscope view of the guide wire entry point will then be obtained. PDT will then proceed as usual as in the study group.

Advantages

Blinding

Patients will be randomized in a 1:1 ratio to the study groups using permuted blocks of four and six, and allocation concealment will be maintained by using sequentially numbered, opaque, sealed envelopes created according to published recommendations.

An independent member of the research team who is not directly involved with the study in any other capacity will create the randomization sequence using a computer algorithm. The patients will be enrolled by selecting the top most sequentially numbered envelope, which contained the study group allocation. The independent member will also review images to evaluate the guide wire position to determine the angle of deviation from Medline (at a later stage).

Ethical issues

Only patients requiring a percutaneous dilatational tracheostomy for clinical reasons should be included for which consent will be taken as a routine. No other interventions (other than US (free of risk) will be added in the study group to the routinely performed US-PDT. Study consent could therefore be waived.

Limitations

I.P.W.I.N.A has its own limitations. Its safety, efficacy and feasibility in Randomized Controlled Clinical Trials research settings needs to be tested before making it a standard if care.

CONCLUSION

Studies comparing the use of in plane and out of plane approach for US-PDT as well as techniques to improve needle visualization during US-PDT are yet to be born. Based on the best available evidence in the use of US guided procedure in the ICU, we think the proposed I.P.W.I.N.A has a great potential to be more safe and efficacious than any other currently practiced US-PDT procedure. However, the suggested I.P.W.I.N.A approach for the US-PDT has its own limitations. It needs to be tested and verified before making it a standard of care.

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