Evaluation of a novel thoracic entry device versus needle decompression in a tension pneumothorax swine model

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ABSTRACT

Introduction: Tension pneumothorax (tPTX) remains a major cause of preventable death in trauma. Needle decompression (ND) has up to a 60% failure rate.

Methods: Post-mortem swine used. Interventions were randomized to 14G-needle decompression (ND, n = 25), bladed trocar with 36Fr cannula (BTW, n = 16), bladed trocar alone (BTWO, n = 16) and surgical thoracostomy (ST = 11). Simulated tPTX was created to a pressure (p) of 20 mmHg.

Results: Success (p < 5 mmHg by 120 s) was seen in 41 of 68 (60%) interventions. BTW and BTWO were consistently more successful than ND with success rates of 88% versus 48% in ND (p < .001). In successful deployments, ND was slower to reach p < 5 mmHg, average of 82 s versus 26 s and 28 s for BTW and BTWO respectively (p < .001). Time to implement procedure was faster for ND with an average of 3.6 s versus 16.9 s and 15.3 s in the BTW and BTWO (p < .001). Final pressure was significantly less in BTW and BTWO at 1.7 mmHg versus 7 mmHg in ND animals (p < .001).

Conclusion: Bladed trocars can safely and effectively tPTX with a significantly higher success rates than needle decompression.

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1. Introduction

Tension pneumothorax (tPTX) and ultimately pulseless electric activity (PEA) cardiac arrest is a major cause of in mortality in trauma population in both inpatient and prehospital settings. It has been identified as one of the leading causes of preventable death in the military on the battlefield second only to non-compressible hemorrhage. Current Tactical Combat Casualty Care (T-CCC) guidelines as well as civilian trauma centers recommend needle decompression (ND) as first-line therapy for decompression of tPTX in the field.1 This is despite consistent evidence that ND has been shown to be unreliable and ineffective in decompressing a tPTX.2–4 Swine models have similarly shown failure rates up to 58% with needle decompression.5 Furthermore, conventional chest tube insertion, although more reliable clinically, is currently discouraged for field or en-route care due to technical skill needed and size of wound created.1

A novel, FDA approved device for chest tube insertion named the Reactor™ (Sharp Medical Products, Geneva, IL) has been shown to effectively create a thoracostomy for chest tube insertion using a blunt bladed trocar (Fig. 1). This system comes equipped with a trocar and cannula for thoracostomy creation and conduit for chest tube insertion (Fig. 1). No published studies have evaluated a blunt bladed trocar system similar to this novel device for the creation of a thoracostomy for rapid relief from tPTX. We hypothesize that tPTX can be relieved more rapidly and reliably using this novel device than ND in a validated porcine tPTX model.6 Primary outcome was overall success rates with secondary observations being made for operating time, time to decompression and post deployment safety (see Figs. 2 and 3).

2. Methods

All experiments were performed in adherence to the guidelines on the use of laboratory animals of the National Institute of Health. Approval for animal research was obtained from the Institutional Animal Care and Use Committee (IACUC) and the federal

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A validated method of reliably obtaining tPTX physiology has been previously developed in our lab and was utilized in this study. Briefly, elevated intrathoracic pressures is via carbon dioxide insufflation through celiotomy and diaphragmatic placement of laparoscopic balloon-tipped trocars. Each hemithorax was insufflated to 20 mmHg after which the chest wall received one of three interventions depending on randomization: needle thoracostomy, surgical chest tube placement, or bladed-trocar thoracostomy with Reactor™ device (Sharps Medical, Geneva, IL). Insufflation was maintained at a rate of 40–80 ml/kg/min to simulate moderate to severe continuous air leak. Mechanical volume control ventilated maintenance at a rate of 40 breaths/min with 100% oxygen. The pleural cavity was entered using downward directed incision made sharply in the 4th to 6th intercostal space in the anterior axillary line followed by blunt dissection. Entrance into the pleural cavity. All instruments were removed from the wound and on release of air was met and decompression was observed.

Fig. 1. A) Bladed trocar device being inserted in 4th intercostal space. B) Snap shot of blade at end of trocar as it rotates out during deployment in an intra thoracic picture. The blade retracts immediately after release of the trigger to be protected by the blunted tip.

Bladed trocar thoracostomy was performed with accompanied sleeve and without (BTW and BTWO) after 1-cm skin incision was made sharply in the 4th to 6th intercostal space in the anterior axillary line followed by blunt dissection, entrance into the pleural cavity. All instruments were removed from the wound and once release of air was met and decompression was observed.

Fig. 2. Comparison of intervention groups for time needed for intrathoracic decompression after creation of tPTX. Brackets show p values of post hoc analysis.

68 interventions were completed on 16 Yorkshire swine by four certified ATLS course instructors. The average weight was 41.3 kg and mean time of operative intervention was 10.7 s. The average total time from beginning of intervention to an intrathoracic pressure below 5 mmHg was 38.6 s. It took 7.8 s on average to reach an intra-thoracic below 10 mmHg and mean time for pressures reaching below 5 mmHg was an additional 21.3 s. The overall mean lowest pressure at the conclusion of the experiment was 3.8 mmHg.

Only 3 failures were seen where pressures did not decrease to below 10 mmHg and all three were in the ND group. An additional 13 interventions were unable to reach a pressure of less than 5 mmHg, 9 in the ND group (48%) and 2 in the BTW as well as the BTWO groups (12.5%). No failures were seen in the ST group (Chi-Square 13.9, p = .003).

Table 1 shows all values for the different groups as well as one-way ANOVA p values for significance. Mean values for operating time, pressure <90 mmHg, pressure <5 mmHg, time and lowest final pressure were found to be statistically significant between and within groups (p < .0001). Bonferroni post hoc analysis revealed that ND on average was completed quicker when compared to the other three groups with an operating time of 3.6 s compared to BTW (16.9 s, p < .0001), BTWO (15.4 s, p < .0001) and ST (10.94, p = .002). There was not a significant difference between either the BTW or BTWO groups when compared to ST (p = .11, p = .50 respectively). All thoracostomy groups were superior to ND
in time to reach pressure <10 mmHg and <5 mmHg with all post hoc comparison p values < 0.0001 (mean values seen in Table 1). BTW and BTWO were not significantly slower than ST for pressure <10 mmHg with p = 1.00 for both. This was also true for true pressure <5 mmHg with p = 1.00 for BTW and p = .50 for BTWO. No differences were seen for BTW when compared to BTWO (p = 1.00 for 10 mmHg and p = .32 for <5 mmHg).

Total experiment time was longer on post hoc analysis in the ND group (82s) when compared to all three thoracostomy groups for 10 mmHg and pressure <5 mmHg (p<0.0001 for all). These outcomes were validated by comparison to ATLS instructors to account for potential technique variability and no significant differences were found.

4. Discussion

Even in the face of significant morbidity and mortality tPTX remains a rapidly treatable cause of death in both blunt and penetrating trauma. Pitfalls and inadequacies of needle decompression is not a new issue facing trauma providers.5,7 Even in the face of well-established hazards of ND, they remain the first line treatment in both military and civilian centers. Needle thoracostomy is simple to perform, affords quick deployment with theoretically low morbidity—if not considering the risk of failure. Furthermore, in the prehospital setting ND is easy to tote and includes all necessary equipment in one unit. For these reasons, ND has been hard to replace as the preferred initial treatment of tPTX. Our results reiterate the speed at which a ND can be performed at the same time highlighting an impressive lack of efficacy at 48% failure rate.

Failure to adequately release tPTX has been due to dislodge-ment, lack of catheter constitution, and issues with catheter length including occlusion or inability to penetrate the pleura.2,7–9 Alternatives to needle decompression have been studied in both swine and human models with results showing superiority to needle thoracostomy using existing surgical equipment, which include Veress needles and laparoscopic 5 mm trocars. These devices were superior both in timeliness of releasing tPTX and overall success rates.10,11 Authors have also tried to mitigate high failure rates with ND by attempting to identify adequate ND catheter lengths.12 Issues have also been identified with where on the chest wall ND is performed. It is well known in military populations, where men with large muscular builds often make successful ND in the mid-clavicular line more difficult and more susceptible to failure due to the pectoralis muscles. To this end, studies have shown

**Table 1**

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<th>Variable (s)</th>
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<th>N</th>
<th>Failure # (%)</th>
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ND-Needle Decompression, BTW-Bladed trocar with cannula, BTWO-Bladed trocar without cannula, ST-surgical thoracostomy, N-number, SD-standard deviation, CI-Confidence interval, s-seconds, kg-kilograms.

that changing the recommended location may result in higher success rates for ND.\textsuperscript{2,4}

The novel blunt bladed trocar system introduced for rapid thoracostomy in this study presents a device that may be at least comparable to ND in terms of simplicity in deployment and ease of transport. It also is an ‘all-in-one’ system that has been shown to swiftly and consistently create a highly effective and reproducible thoracostomy for tPTX decompression. Further, the ability of the bladed trocar to appear to be equally effective with and without associated sleeve cannula with an acceptable safety profile. We believe that the skills needed are not significantly greater than those typically learned by military and civilian medics making this device a feasible alternative to needle decompression. Furthermore, it has no expiration date and is durable for single use in austere and pre-hospital settings.

Perhaps most exciting as these results were also no different to results seen with a standard surgical thoracostomy. Surgical thoracostomy has been limited in adoption in the pre-clinical setting due to the typical need for >3 instruments and surgical skill. The bladed trocar system may obviate these barriers and provide a new feasible alternative to ND with the benefits of ST.

A potential limitation is in reference to cost. One device is approximately ten times more expensive than the standard needle decompression kit. However, two main counterpoints should be considered. First, the cost of the device may be at least partially offset as often it requires two or more needle decompression kits to be used before any benefit is seen. Further, it can be argued that having a device that is reliable in the treatment of a life-threatening issue is invaluable and should be of paramount concern.

Evidence provided by this study for bladed trocars should be used with caution as it is a cadaveric model in a swine thorax and is thus not immediately applicable to the clinical setting. However, given these initial findings we are currently testing a live animal model where PEA arrest is induced and the efficacy of the device will be tested in an in vivo experiment which will hopefully lead to the pursuance of larger, clinical trials. Finally, the safety of the device will need to be further vetted in trauma scenarios where tPTX is not the clear diagnosis. These types of scenarios will also be tested in our live animal model. We found a very low incidence of injury to intrathoracic tissues despite blind placement. The somewhat obvious caveat here is that these tissues where inherently pushed away from our entrance site.

5. Conclusions

Tension PTX is the second most common cause of preventable death from trauma. The standard first line care of ND is inadequate with unacceptably high failure rates. Standard surgical thoracostomy is not feasible in the pre-hospital setting. A blunt bladed trocar system for rapid decompression of tPTX is simple, safe and reliably effective and should be considered as an alternative to ND in suspected tPTX.

Disclosures and conflicts of interest

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amjsurg.2017.12.014.

References
