The American Journal of Surgery xxx (2017) 1–4

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

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

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A R T I C L E I N F O

Article history:
Received 14 November 2017
Received in revised form
3 December 2017
Accepted 5 December 2017

Keywords:
Bladed trocar thoracostomy
Reactor
Needle decompression
Tension pneumothorax

A B S T R A C T

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 82s versus 26s and 28s for BTW and BTWO respectively (p < .001). Time to implement procedure was faster for ND with an average of 3.6s versus 16.9s and 15.3s 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.

Published by Elsevier Inc.

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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https://doi.org/10.1016/j.amjsurg.2017.12.014
0002-9610/Published by Elsevier Inc.

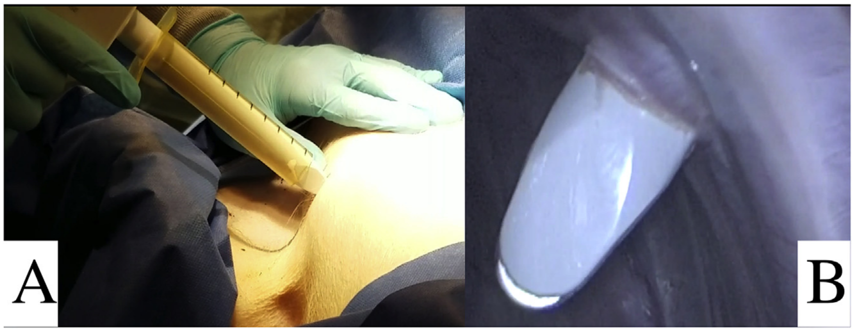

Fig. 1. A) Bladed trocar device being inserted in 4th intercostal space. B) Snap shot of blade at end of trocar as it rotates out during deployment in an intra thoracic picture. The blade retracts immediately after release of the trigger to be protected by the blunted tip.

authorities for animal research. All experiments were performed posthumously after euthanized of 30–40 kg *Sus scrofa* swine after use in separate IACUC approved experiments.

A validated method of reliably obtaining tPTX physiology has been previously developed in our lab and was utilized in this study.[6] Breifly, 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 was maintained at 10 ml/kg. Thoracoscopic video via the diaphragm ports was recorded to assess for iatrogenic lung injury. Overall success rates, procedure time, and time for decompression ($P < 5$ mmHg) and pressure at 2 min was recorded. Air tight closure of chest wall sites was confirmed and experiments repeated on the same hemithorax.

Animals were randomized to needle decompression (ND), surgical thoracostomy (ST), or blunt bladed trocar with or without 36Fr cannula (BTW or BTWO) ND was performed using a the standard 3¼-in, 14Ga catheter inserted into through the 2nd to 4th intercostal space, needle removed leaving the catheter in place and decompression was observed without subsequent intervention. Surgical thoracostomy was performed with a 2- to 3-cm skin 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 once release of air was met and decompression was observed.

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. The pleural cavity was entered using downward pressure and sequential firings of the rapidly deployed blade at the blunt tip of the device. Once in the pleural cavity the trocar was turned 180° and in BTW, the sleeve was inserted into the thoracostomy after which the device withdrawn and decompression observed.

Results were analyzed using descriptive and comparative statistics. Comparisons between nominal values were compared using mean values and, one-way ANOVA with post hoc Boniferroni correction. Ordinal data was analyzed using Chi-Square and Fischer's exact testing. All data analysis was completed using SPSS 22 Software (IBM, Armonk, NY).

3. Results

Sixty-eight interventions were completed on 16 Yorksire 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 <10 mmHg, pressure <5 mmHg, total 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 (16.9s, $p < .0001$), BTWO (15.4s, $p < .0001$) 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

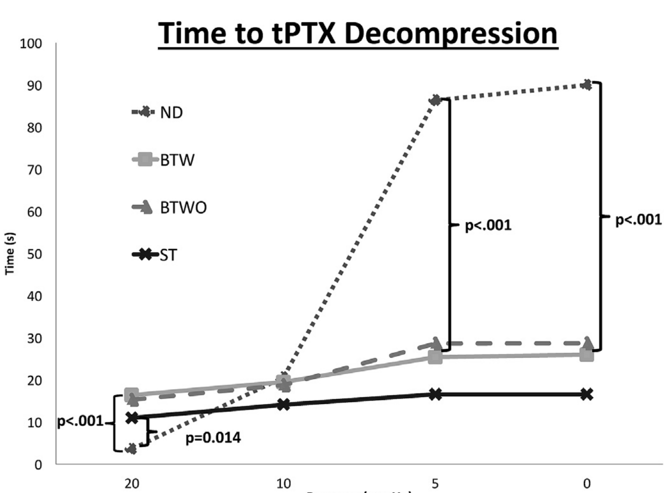

Fig. 2. Comparison of intervention groups for time needed for intrathoracic decompression after creation of tPTX. Brackets show p values of post hoc analysis.