An Evaluation of a Novel Medical Device Versus Standard Interventions in the Treatment of Tension Pneumothorax in a Swine Model (*Sus scrofa*)

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ABSTRACT

Introduction

Tension pneumothorax is a common cause of preventable death in trauma. Needle decompression is the traditional first-line intervention but has high failure rates. We sought to evaluate the effectiveness and expedience of needle thoracostomy, surgical tube thoracostomy, and Reactor™ thoracostomy – a novel spring-loaded trocar insertion device.

Materials and Methods

Yorkshire swine underwent controlled thoracic insufflation to create tension pneumothorax physiology for device comparison. Additional experiments were performed by increasing insufflation pressures to achieve pulseless electrical activity. Intervention was randomized to needle thoracostomy (14 gauge), tube thoracostomy (32Fr), or Reactor™ thoracostomy (36Fr). Air leak was simulated throughout intervention with 40–80 mL/kg/min insufflation. Intrathoracic pressure monitoring and hemodynamic parameters were obtained at 1 and 5 minutes.

Results

Tension physiology and tension-induced pulseless electrical activity were created in all iterations. Needle thoracostomy ($n = 28$) was faster at 7.04 ± 3.04 seconds than both Reactor thoracostomy ($n = 32$), 11.63 ± 5.30 ($p < 0.05$) and tube thoracostomy ($n = 32$), 27.06 ± 10.73 ($p < 0.01$); however, Reactor™ thoracostomy was faster than tube thoracostomy ($p < 0.001$). Physiological decompression was achieved in all patients treated with Reactor™ and tube thoracostomy, but only 14% of needle thoracostomy. Cardiac recovery to complete physiologic baseline occurred in only 21% (6/28) of those treated with needle thoracostomy whereas Reactor™ or tube thoracostomy demonstrated 88% (28/32) and 94% (30/32) response rates. When combined, needle thoracostomy successfully treated tension pneumothorax in only 4% (1/28) of subjects as compared to 88% (28/32) with Reactor™ thoracostomy and 94% (30/32) with tube thoracostomy ($p < 0.01$).

Conclusions

Needle thoracostomy provides a rapid intervention for tension pneumothorax, but is associated with unacceptably high failure rates. Reactor™ thoracostomy was effective, expedient, and may provide a useful and technically simpler first-line treatment for tension pneumothorax or tension-induced pulseless electrical activity.

INTRODUCTION

Despite the constant evolution of treatments and technology in trauma care, the profile of preventable causes of death in both civilian and military populations remains largely unchanged.[1,2] Hemorrhage control measures targeting compressible and non-compressible sources of bleeding have garnered much of the recent focus in trauma research and led to the development of improved devices and intervention. In contrast, the second most common cause of preventable death, tension pneumothorax (tPTX), has seen comparatively little research or advancement. Current Tactical Combat Casualty Care (TCCC) guidelines continue to recommend insertion of a 14Ga 3.25" angiocatheter in the 2nd or 3rd intercostal space in the midclavicular line as first-line treatment. Remarkably, this treatment is the same that was initially described in the first TCCC manual printed in 1996[3] despite mounting evidence suggesting that needle decompression (ND) is both unreliable and ineffective.[4] Pre-hospital personnel routinely cite concerns of catheter kinking and obstruction, and historical data demonstrates failure of decompression in up to 60% of treated patients.[5] In 2018, the TCCC committee added verbiage allowing medics to utilize larger bore angiocatheters (10 g) and ND placement into the anterior axillary line at the 4-6th intercostal space.[6] While these greater allowances provided a small incremental improvement, they fail to address the other noteworthy drawbacks of current treatment methodologies.

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Care beyond the initial treatment of tension can require repeated evacuation of air from the chest as the accumulation of intrathoracic air may lead to additional episodes of tension physiology. In-hospital treatment of tPTX typically includes conversion of the needle decompression to the placement of a chest tube or pigtail catheter. Importantly, this provides not only initial decompression but also serves to keep the chest decompressed and may even represent definitive management for patients with this pathology. Placement of a chest tube, however, requires a set of instruments and a level of procedural competence that makes its generalizability to deployed medics problematic and potentially dangerous.[7–9] Unskilled providers could cause additional injury to the lung, heart, or mediastinal structures thereby further complicating an already injured patient's prognosis. In this setting, when a soldier suffers a tPTX on the battlefield, we are left with a noticeable gap in care between the initial decompression and placement of a chest tube, creating the conditions for inadequate care and potential for increased mortality during transit. To fill this need, we sought out a field-expedient way to provide definitive management of tension pneumothorax and tested it against both standard field treatment (14 g angiocatheter) and gold-standard surgical tube thoracostomy (32fr chest tube).

A novel, FDA-approved device for chest tube insertion, the Reactor™ (Sharp Medical Products; Geneva, IL), has previously demonstrated reproducible placement of a trocar through which up to a 36Fr chest tube may be inserted. As the possible solution to the treatment gap, we hypothesized that this simplified spring-loaded device (Fig. 1) would provide superior initial and sustained tPTX decompression versus the standard needle thoracostomy in a live swine model (*Sus scrofa*).

MATERIALS AND METHODS

Experimental Oversight

Experiments were performed with strict adherence to the guidelines on the use of laboratory animals from the National Institute of Health. Our Institutional Animal Care and Use Committee (IACUC) was consulted and gave approval prior to any procedures.

Experimental Procedure

All procedures were performed on 35–45 kg *Sus scrofa* after obtaining general endotracheal anesthesia via inhalational anesthetic. After placement of a carotid arterial monitor and Swan Ganz catheter, a validated method of tPTX was utilized to reproducibly create tension physiology.[10] A laparotomy was performed through which bilateral transdiaphragmatic 10 mm balloon-tipped laparoscopic trocars were placed (Fig. 2). After obtaining baseline hemodynamic measurements, each hemithorax was sequentially insufflated with CO_2 insufflation while continuously monitoring intrathoracic pressure, cardiac output, and cardiac index. When cardiac output reached half of its baseline value, the subject was intervened upon utilizing one of three randomized interventions: needle decompression (ND) with 3.25" 14Ga angiocatheter in the 2nd or 3rd intercostal space at the midclavicular line, surgical tube thoracostomy (TT) with placement of a 32fr chest tube, or the Reactor™ device (RT) 36fr trocar. During ND, the needle was removed and the catheter left in place during the intervention interval. TT was performed through a 3 cm skin incision overlying the 4th or 5th intercostal space along the anterior axillary line. Blunt dissection was then utilized to enter the pleural cavity followed by a 32fr chest tube directed superiorly within the chest. RT was performed through a 2.5 cm skin incision overlying the 4th or 5th intercostal space along the anterior axillary line. Sequential firings of the spring-loaded blade allowed dissection of the intercostal muscles and mild forward pressure allowed entry into the pleural cavity. After entering the chest, the device was removed and the pre-loaded 36fr trocar left in place.

Chest insufflation was maintained at a rate of 40–80 mL/kg/min to simulate a moderate to severe continuous air leak. Continuous intrathoracic pressure was recorded and cardiac index measured at 1 and 5 minutes. As previously

FIGURE 1. Reactor thoracostomy device – a novel FDA-approved spring-loaded bladed trocar insertion device.

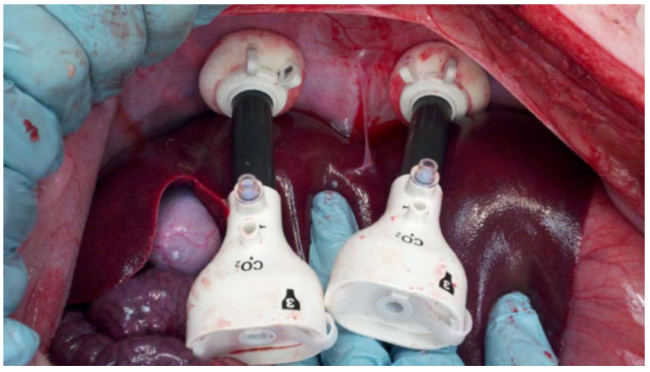

FIGURE 2. Experimental design as developed by Hatch et al. – bilateral transdiaphragmatic 10 mm balloon-tipped laparoscopic trocars placed through a midline laparotomy.

described for this model, tension physiology was defined as a greater than 50% decrease in cardiac output with the immediate pre-insufflation measure used as the baseline.[4,10] Thoracoscopic video via the diaphragmatic port was recorded to assess for iatrogenic lung or cardiac injury. After 5-minute values were obtained, the chest was completely decompressed via the laparoscopic trocars, airtight closure of the chest wall intervention sites was confirmed, and the subject was given sufficient time to return to physiological baseline.

After physiological recovery, a second iteration was performed on the same hemithorax. Insufflation was increased until PEA arrest was achieved as noted by loss of palpable common iliac pulse. Subjects were again intervened upon using the same procedure used during the first iteration (i.e., ND, TT, or RT) and hemodynamic parameters were similarly measured. Sequential iterations were then repeated on the contralateral hemithorax in all surviving subjects.

Subject Randomization

A total of 24 subjects underwent randomization. Randomization was performed utilizing excel number generation and proportional assignment such that 8 swine were assigned to each experimental procedure. Four iterations were performed on each subject for an intended total of 32 iterations per procedure. Two subjects in the ND arm died prior to completion of all intended procedures. In total, 32 iterations were performed with both RT and TT and 28 with ND.

Outcomes

The primary outcomes tested during this experiment were the time until intervention completion, achievement of physiological decompression, and cardiac recovery.

Timing of intervention duration was started when the operating practitioner first touched a surgical tool or instrument. All necessary equipment was laid out on a surgical stand prior to iteration initiation but no site marking or landmark identification was preplanned. To decrease the risk of sharp-related injuries, no assistance was provided during any of the procedures and all scalpels and needles were capped prior to procedure initiation. Timing was completed when the practitioner placed his/her last tool back onto the surgical stand.

Physiological decompression was defined as intrathoracic pressure reaching or dropping below 3 mmHg during the monitored 5-minute postintervention period. This pressure was chosen after analysis of average baseline central venous pressure (CVP) in the 8 model development subjects. With an average CVP of 3.2 mmHg, intrathoracic pressures less than or equal to 3 mmHg would be less likely to cause significant hemodynamic derangement.

Cardiac recovery was defined as cardiac index reaching or exceeding 100% of its baseline value. Cardiogenic shock is defined in humans as a cardiac index falling below 1.8 L/min/m^2.[11] With a generally accepted lower limit of normal average baseline cardiac index of 2.4 L/min/m^2[12], it is understood that there is a range of diminished cardiac index that would not classify as shock. We intended cardiac recovery, however, to capture the subjects in whom the intervention completely relieved the hemodynamic alterations caused by thoracic insufflation. Without a concomitant injury, we should expect subjects to be able to reach or exceed baseline values. Therefore, cardiac recovery was defined as a cardiac index returning to or exceeding baseline values within the 5-minute monitored period.

The secondary outcome tested during this procedure was the number of intrathoracic injuries due to procedure performance. Transdiaphragmatic laparoscopic trocars allowed for continuous monitoring throughout the tested interval.

Data Analysis

Data analysis was performed using SPSS 22 Software (IBM; Armonk, NY). Results were analyzed using comparative and descriptive statistical analysis. Nominal values were compared utilizing one-way ANOVA. Ordinal data were compared using Chi-Square and Fischer's exact testing where appropriate. Results were deemed statistically significant at a P value threshold of < 0.05.

RESULTS

Ninety-two interventions were completed on 24 Yorkshire Swine by four surgeons. With respect to procedural performance times, ND (7.04 s $\pm$ 3.04) was significantly faster than both RT (11.63 s $\pm$ 5.30) or TT (27.06 s $\pm$ 10.73) ($p < 0.001$), but RT was significantly faster to complete and achieve relief of tension physiology than traditional TT ($p < 0.001$).

Physiological decompression was defined as intrathoracic pressure reaching 3 mmHg or less during the 5-minute post-intervention period (Table I). Both RT (32/32) and TT (32/32) achieved this in 100% of iterations. Needle Decompression, however, only reached this threshold in 4 of 28 iterations

TABLE I. Group Descriptive and Comparative Statistics. *P*-values are from Chi-square and Fisher's Exact testing against RT

Variable	Group	*N*	# Successful (%)	*P* Value
Physiological Decompression [IP $\leq$ 3 mmHg]	ND	28	4 (14.2)	<0.001
	RT	32	32 (100.0)	
	TT	32	32 (100.0)	1.000
Cardiac Recovery [CI $\geq$ Baseline]	ND	28	6 (21.4)	<0.001
	RT	32	28 (87.5)	
	TT	32	30 (93.8)	0.391
Comined Success [IP $\leq$ 3 mmHg AND CI $\geq$ Baseline]	ND	28	1 (3.6)	<0.001
	RT	32	28 (87.5)	
	TT	32	30 (93.8)	0.391

ND – needle decompression; RT – reactor thoracostomy; TT – tube thoracostomy;
N – Number, IP – Intrathoracic Pressure, CI - Cardiac Index.

(14.2%, $p < 0.001$). Post-intervention intrathoracic pressure averages at 1 and 5 minutes further demonstrate this difference. Needle decompression resulted in average pressures of 8.43 ± 3.29 mmHg and 7.15 ± 3.29 mmHg at 1 and 5 minutes, respectively, whereas RT achieved 0.25 ± 0.76 mmHg and 0.26 ± 0.68 mmHg and TT achieved 0 ± 0 mmHg at both measured time points (ND vs. RT, $p < 0.001$; RT vs. TT, $p = 0.68$). Furthermore, when measuring only those iterations which achieved physiological decompression, RT met this threshold at an average of 13.8 s $\pm$ 6.8 as opposed to 16.5 s $\pm$ 7.7 with TT ($p = 0.149$) and 73.7 s $\pm$ 62.2 with ND ($p < 0.001$).

Cardiac recovery was defined as a subject's cardiac index returning to or exceeding their baseline value within the 5-minute post-procedure window. There was no significant difference in baseline cardiac index for all three interventions (Table II). To allow for small variances in starting value, 1 and 5-minute cardiac indices were calculated into percentages of the baseline value. Values greater than or equal to 100% therefore, signified a successful physiologic recovery. RT reached successful recovery in 87.5% (28/32) patients as compared to 93.8% (30/32) following TT ($p = 0.391$). ND only resulted in a cardiac recovery in 21.4% (6/28) within the post-procedure window ($p < 0.001$).

When defining the successful treatment of tPTX as a combination of physiological decompression and cardiac recovery it was found that 87.5% (28/32) of those intervened upon with RT met these criteria. This was compared with only 3.6% (1/28) of subjects intervened upon with ND ($p < 0.001$) and 93.8% (30/32) of those intervened upon with TT ($p = 0.391$).

Only one unintentional intrathoracic injury resulted from the interventions performed in this study. During an iteration of ND, the needle was seen to puncture the pericardium. Despite this, there was no apparent injury to the underlying myocardium on postmortem examination. All other device placements - including 27 ND, 32 TT, and 32 RT - achieved the desired intrathoracic position without aberrant placement in the subcutaneous tissue or identified intrathoracic injury. Due to this low incidence of iatrogenic injury, no statistical comparisons were made amongst the groups.

DISCUSSION

Despite the evolution of trauma care, tPTX remains a common preventable cause of death in both the civilian and military settings. Our results add to the growing body of literature demonstrating that not only does ND fail to decompress the

TABLE II. Group Descriptive and Comparative Statistics. *P* -values are from one-way ANOVA testing

Variable	Group	*N*	Mean	SD	*P*-Value
Operating time (*s*)	ND	28	7.0	3	<0.001
	RT	32	11.6	5.3	
	TT	32	27.1	10.7	<0.001
Baseline IP (mmHg)	ND	28	2.1	1.8	0.505
	RT	32	1.5	1.4	
	TT	32	1.3	1.2	
Intervention pressure (mmHg)	ND	28	13.8	4.4	0.199
	RT	32	13.6	3.6	
	TT	32	14.3	4.4	
IP 1 min post intervention (mmHg)	ND	28	8.4	3.3	<0.001
	RT	32	0.3	0.8	
	TT	32	0.0	0.0	
IP 5 min post intervention (mmHg)	ND	28	7.2	3.3	<0.001
	RT	32	0.1	0.6	
	TT	32	0.0	0.0	
Lowest IP achieved (mmHg)	ND	28	6.5	3.3	<0.001
	RT	32	0.1	0.6	
	TT	32	0.0	0.0	
Time to physiologic decompression (s)	ND	28	73.7	62.2	<0.001
	RT	32	13.8	6.8	
	TT	32	16.5	7.7	
CI at baseline (L/min/m^2)	ND	28	5.4	2.0	0.53
	RT	32	4.5	0.9	
	TT	32	4.7	1.0	
CI at 1 min (% baseline)	ND	28	60.9%	30%	<0.001
	RT	32	111.8%	31%	
	TT	32	124.0%	41%	
CI at 5 min (% baseline)	ND	28	72.5%	34%	<0.001
	RT	32	109.0%	29%	
	TT	32	116.6%	25%	

ND – needle decompression, RT – reactor thoracostomy, TT – tube thoracostomy,
N – number, IP – intrathoracic pressure, CI – cardiac index.

chest to physiologic pressure levels, but it also fails to allow for complete cardiovascular recovery[13–15]. The combined failure rate of 96.2% with ND underscores the fact that an updated treatment methodology is sorely needed for rapid, effective treatment of tPTX.

Prior studies have attempted to find alternate ways of decompressing the chest. In 2013, Lubin et al. developed a modified Veress needle (mVN) technique that was significantly better than ND at chest decompression (100% v 21%, $p < 0.001$). The small caliber of the device, however, demonstrated continued physiologic insult well beyond the time of intervention and return of cardiac output to 80% of its baseline took, on average, 70 seconds (SD 86).[16] The importance of the caliber of the intervention was further elucidated by Leatherman et al. in 2017. Using a model that was modified to include a persistent air leak and pleural blood, these investigators created PEA arrest and intervened with 14 G ND, mVN, 10 G ND, and 3 mm laparoscopic trocar. As predicted, the 10 G ND and 3 mm laparoscopic trocars demonstrated far superior rates of successful return of spontaneous circulation (100% and 100%) when compared to those exhibited by 14 G ND and mVN (50% and 57%).[13]

Work at our institution with the RT device began in 2017. At this time, cadaveric studies were performed to evaluate the efficacy of the large-bore (36Fr) trocar as compared to 14 G ND. Our initial findings suggested that, similar to prior experiments with larger caliber devices, RT was better able to successfully decompress the chest (88% v 48%, $p < 0.001$) and, furthermore, that it did so in a significantly shorter time (82 s v 26 s, $p < 0.001$).[4]

In the present study, we found similar efficacy of RT and TT suggesting that a rapid and complete decompression of the chest is not only possible but reproducible for providers who may lack surgical tube thoracostomy skills. This issue becomes more important when we discuss this injury pattern in the context of severe multi-system trauma, where tPTX does not arise in isolation but is one of many potentially life-threatening injuries. Thus, efforts to minimize the total physiologic insult secondary to tPTX may be even more important.

The novel RT device demonstrated significant improvement in expediency over traditional TT. As we expand medical/surgical capabilities at the point of injury and throughout the pre-hospital phase of care, we must consider the fact that devices and procedures will invariably be entrusted into lesser skilled providers' hands. Therefore, simple, reliable and safe methods to treat tPTX are imperative. While our study suggests that the Reactor device was both intuitive and simple to use and the four providers became facile within minutes of first being introduced, further studies would be necessary to prove that this ease-of-use extends to providers of differing skill levels.

An additional notable benefit of the Reactor device is the ability to obviate the need for multiple surgical instruments for chest tube placement. In the hospital setting, limiting the number of required items improves the provider's ability to perform life-saving treatments rapidly and without additional preparatory steps. In a field scenario, this limited packing list improves portability, maneuverability, and overall utility. One of the limitations of the device, however, is that it remains too large to expect front-line medic providers to carry sufficient devices for all contingencies. The advantage of a 14Ga angiocatheter is that its compact size allows each soldier to carry his/her own device in the individual first aid kit (IFAK). We believe that further modifications are required before the Reactor™ device can gain this level of ubiquity.

These results represent an exciting possible progression in the treatment of tPTX. As the military medical community embraces the seeming inevitability of prolonged field care, innovation that allows for both acute and subacute treatment of injuries related to trauma will gain greater importance. The Reactor device represents an acute intervention that allows for easy transition to prolonged treatment. It is this type of innovation that will stop the gaps in care from becoming dangerous chasms.

LIMITATIONS

There are several limitations to consider in the interpretation of study results. First, all procedures were performed by general surgery residents and staff surgeons. Thus, the efficiency and successful performance of all three procedures may not translate to non-surgical providers. One particular aspect of this limitation is our inability to comment on misplacement of the Reactor device. In our study, continuous laparoscopic monitoring demonstrated that all interventions appropriately entered the chest cavity. Although it is important to note that no providers were allowed to watch the monitor as the intervention occurred, it is likely that the experience of the providers had an effect on this outcome. As such, we were unable to evaluate if and/or how the Reactor device may encounter similar issues.

Second, the currently available sizing of the Reactor device limited direct comparisons of intervention size. In its current form, the Reactor device deploys a 36Fr sheath. This large size is meant to easily allow pass-through transition to a smaller chest tube for more secure transportation of an injured patient. Its large size, however, made direct comparisons difficult given readily available chest tube sizing. As such, we chose the largest readily available tube (32Fr) as our comparison in order to model gold-standard tube thoracostomy in the most favorable light possible. Regardless of our upsizing, this lack of a direct comparison limits the generalizability of our findings and recommendations have been made to create smaller iterations of the Reactor™ device to limit tissue damage and improve portability.

Additionally, our study cannot comment upon the ability of any of these interventions to prevent reaccumulation of tPTX after the limited five-minute period of study. Tension pneumothorax is associated with an ongoing air leak that

necessitates prolonged treatment and frequent reevaluation. While our five-minute postintervention period can give a window into the likely long-term efficacy of these devices, we cannot draw any conclusions without additional studies that incorporate follow-up at least as long as the average time of transport to definitive care.

Lastly, our model tested all three devices under pure PTX conditions without any component of hemothorax or hemopneumothorax that would likely be encountered in severe chest trauma. It is possible that outcomes would differ in a model of tension physiology related to hemopneumothorax.

Despite these limitations, the results suggest equivalent efficacy of the RT with traditional TT in the treatment of tPTX and offer further evidence of the ineffectiveness of traditional needle decompression.

CONCLUSIONS

Tension pneumothorax is a common cause of trauma-related morbidity or death that is readily treatable given appropriate early recognition and timely intervention. Standard first-line treatment with ND has been consistently demonstrated to be associated with unacceptably high rates of initial failure or short-lived efficacy. Traditional TT is effective but may not be able to be performed without the appropriate surgical skillset and in the out of hospital environment in both civilian and military settings. The Reactor device can be rapidly utilized to treat tPTX with efficacy similar to TT. The Reactor represents a novel spring-loaded trocar device that shows promise as a one-step acute treatment capable of transitioning to definitive care of tPTX. Further studies are required to investigate whether the device's ease-of-use translates to less experienced providers, and to definitively demonstrate the safety and efficacy of this device in a variety of settings.

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PRESENTATION

The results of this study were delivered as an oral presentation at the 5th annual meeting of the SAGES Society of Military Surgeons, April 11, 2018 in Seattle, WA, the 10th annual Military Health System Research Symposium, August 20, 2018 in Kissimmee, FL, the 104th annual American College of Surgeons Clinical Congress, October 21, 2018 in Boston, MA, and the 42nd annual meeting of the ACS Committee on Trauma, March 21, 2019 in Chicago, IL.

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