Comparison of the Dart Target™ and Traditional Landmark Method for the Placement of Chest Decompression Needles in the Treatment of Tension Pneumothorax

MAJ USA (Ret) Michael Morrison, DSc, MPAS, PA-C
MAJ John Knight, MD
MAJ USA (Ret) Paul Allen DSc, MPAS, PA-C, FAAPA

Disclaimer

San Antonio Military Medical Center (SAMMC)
Institutional Review Board approved.

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

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This study did not involve the use of medications requiring FDA approval.

Introduction

Tension pneumothorax is a potentially life threatening condition, fatal if not treated appropriately.

Causes of preventable death on the battlefield
- Hemorrhage
- Tension pneumothorax
- Airway compromise
- Hypothermia
Study Purpose

- Compare placement, penetration, time and complications of the Dart Target™ to Traditional Landmark Method (TLM) on a cadaver specimen

Relevance

- Harcke et al. (Winter 2013) Feedback to the field (FB2F) Needle Thoracentesis Decompression: Observation From Postmortem Computed Tomography and Autopsy
  - 16 Cases 23 attempts
  - 6 attempts still under investigation
  - 17 attempts
    - 13 anterior approach – 6 successful
    - 4 lateral approach at anterior axillar line – all 4 successful

TLM Devices

- Catheter/Needle
- Case
- Catheter/Needle
- Cover
MCDS™

- Mojo Dart needle (14-gauge, 3.25" needle/catheter unit)
- Dart Target™

Dart Target™ Placement

Dart Target™ Placement
Dart Target™

Significance
- Alternative to traditional landmark method
- Mitigate combat stress during this critical life saving skill
- Limited clinical data available for the Dart Target™

Hypothesis
- Research Hypothesis: The Dart Target™ will increase first time successful placement, penetration, take less time, and reduce potential complications in the treatment of a tension pneumothorax
Methods

- This was a mixed methods study
- Prospective randomized crossover quasi-experimental design comparing the Dart Target™ and TLM.
- Qualitative survey of study participants
- Since cadavers were used, there were minimal medical risks to participants entered into this study; informed consent was waived

**INCLUSION CRITERIA:**
- Volunteers
- Previously trained in needle decompression
- Medical providers at Brooke Army Medical Center, U.S. Army Medical and Dental Department Center (AMEDD C&S) and School, and Centre of Emergency Health Science (CEHS) Bulverde TX.
- Level of experience ranged from combat medic to emergency medicine physician.

**EXCLUSION CRITERIA:** Personnel not trained in needle decompression
Methods

- Outcome measures
  - Primary – Proper placement – 2nd ICS/MCL
  - Secondary – Penetration, Time, Neurovascular Bundle, placement in unsafe area (medial placement over anatomical structures)
  - Survey data concerning preference

- Randomization
  - Rand random number generator by Alejandro Vargas 2.2.2, May 01, 2013
  - Cadaver, Side, and Method

- Setting:
  - Facility support: The (CEHS) in Bulverde, TX and (AMEDD C&S)
  - Six sessions were conducted
  - Six non-embalmed, non-frozen cadavers were used

Methods

- Placement: 2nd ICS/MCL equal or less than 15mm from designated point
- Time: procedure completed in less than 30 seconds from determination of tension physiology
- Penetration: Through the chest wall into the pleural space
- Neurovascular complications: Needle catheter unit penetration through the artery/vein/nerve running under the rib
- Placement in unsafe area (medial placement over anatomical structures)

Methods

- Cadaver Preparation
  - Second intercostal space mid-clavicular line identified/marked by expert
  - Chest – athletic tape between clavicles and nipples
  - Axilla – incision placed to provide window for verification
Methods

- Performance
  - Training conducted prior on both methods with practice period
  - Randomized Cadaver
  - Needle Decompression Landmark Method
  - Dart Target ™ Decompression Method
  - Distance from correct point, Penetration, Time, Neurovascular and medial placement were recorded

Methods

- Qualitative Survey
  - Five questions
  - Likert Scale
  - Ease of use and preference explored

Statistical Analysis

- SPSS Sample Power, Version 2.0 was used to estimate required sample size needed for a power of 0.8, with an alpha of 0.05
- We assumed 100% success for placement, less than 30 seconds for time, adequate chest cavity penetration, and needle catheter avoidance of neurovascular bundle and medial placement for potential complications
- To detect a difference of 10% in any of these parameters, a sample size of 100 subjects per method acting as their own controls was determined.
Statistical Analysis

- Independent sample t-test for precision/placement
- 2X2 contingency test for time, penetration and complication

Results

- One hundred and six volunteer medical providers performed two procedures on each cadaver
- Statistically significant and a potentially clinically significant difference between the Dart Target™ group 1% and TLM group 10.5% (p = 0.019) for needle placement in the Medial/Medial Superior danger area
- No statistically significant difference in correct placement in the Dart Target™ group 19.8% when compared to the TLM 45.3%

- Statistically significant difference in time to placement in < 30 seconds, Dart Target™ 2.8% compared to TLM 79.2% (p < 0.001)
- No statistically significant difference in:
  - Penetration (p > 0.611)
  - Neurovascular complication (p > 0.460)
Results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Dart</th>
<th>TLM</th>
<th>Dart</th>
<th>TLM</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (&lt;30 seconds)</td>
<td>2</td>
<td>37</td>
<td>84</td>
<td>87</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Correct placement rate</td>
<td>21</td>
<td>48</td>
<td>86</td>
<td>88</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Adequate penetration rate</td>
<td>99</td>
<td>97</td>
<td>93.45</td>
<td>92.50</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>NV bundle compromise rate</td>
<td>15</td>
<td>11</td>
<td>16%</td>
<td>10.4%</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Great than 15mm Medially</td>
<td>1</td>
<td>21</td>
<td>1%</td>
<td>10.5%</td>
<td>&lt;0.019</td>
</tr>
</tbody>
</table>

Figure 1: Time to completion in seconds by method

Figure 4: Greater than 15 millimeters from point (Medial Danger Area)
A12  Better, but you are mixing yes/no 30 seconds rates with mean time; pick one. I put a sort of sample table in the results section of the manuscript

Author, 11/2/2014
Results

Figure 4. Greater than 15 millimeters from point (Medial Danger Area)

Figure 3. Distribution of distance from the neurovascular bundle by technique. In the box plots, the median is the dark line within the box. The box represents the interquartile range (IQR) with the 25th and 75th percentiles, the whiskers represent the 10th and 90th percentiles, and the error flags represent the largest and smallest observed values that are not outliers. Outliers (o) are values more than 1.5 box-lengths from the quartile. Extremes (*) are values more than 3 box-lengths from the quartiles.

Penetration

Figure 6. Penetrations by Method
Landmark Method Preferred

Discussion

- Increased penetration rate 92-94%
- Advanced training level - 56% had performed the TLM clinically
- Dart Target™ designed for younger fit military model for 2nd ICS/MCL
- Medial Danger Area
- Potential for untrained provider use to be safe and effective

Limitations

- Most cadavers were emaciated
- During two data collection days, only one cadaver was available
- No female cadaver specimens
- Inexperience with new product
- Combat stressors not simulated
Conclusion

- No statistically significant difference in placement, penetration or neurovascular complications
- Statistically significant difference in time favoring the TLM over the Dart Target™
- Statistically significant difference in potentially dangerous placement rates favoring the Dart Target™ over the TLM

Future Studies
  - Include female
  - Younger cadavers/more types
  - Stressors