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Abstract	Tension pneumothorax is a life-threatening condition that can develop when either the visceral pleura is disrupted, or with injury to the tracheobronchial tree. Rapid, accurate diagnosis and appropriate management are required to prevent significant atelectasis, hypoxia, circulatory arrest, and ultimate patient demise. Needle decompression is the current standard of care for the management of tension pneumothorax. Healthcare providers struggle to assess the success of decompression due to a lack of any immediate objective feedback. The gaseous composition of tension pneumothorax is similar to that of end respiratory gas. Including an increased partial pressure of carbon dioxide in comparison to atmospheric air, which makes colorimetric capnography an ideal confirmatory test. The colorimetric capnography device may help the healthcare providers to make an objective and accurate assessment of the success of the needle decompression, in particular in prehospital environments.
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Keywords (separated by '-')	Tension pneumothorax - Thoracostomy - Capnography - Decompression
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Footnote Information	
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Tension pneumothorax decompression with colorimetric capnography: pilot case series

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Abstract

Tension pneumothorax is a life-threatening condition that can develop when either the visceral pleura is disrupted, or with injury to the tracheobronchial tree. Rapid, accurate diagnosis and appropriate management are required to prevent significant atelectasis, hypoxia, circulatory arrest, and ultimate patient demise. Needle decompression is the current standard of care for the management of tension pneumothorax. Healthcare providers struggle to assess the success of decompression due to a lack of any immediate objective feedback. The gaseous composition of tension pneumothorax is similar to that of end respiratory gas. Including an increased partial pressure of carbon dioxide in comparison to atmospheric air, which makes colorimetric capnography an ideal confirmatory test. The colorimetric capnography device may help the healthcare providers to make an objective and accurate assessment of the success of the needle decompression, in particular in prehospital environments.

Keywords Tension pneumothorax · Thoracostomy · Capnography · Decompression

Introduction

Tension pneumothorax is a life-threatening condition that can be fatal without proper diagnosis and immediate intervention [1, 2]. Emergency medical providers are taught to perform needle decompression (ND) to treat patients with suspected tension pneumothorax [3]. In an analysis of post-mortem combat casualties that underwent ND, the authors demonstrated that 54% of attempts at the 2nd intercostal space in the midclavicular line (MCL) never penetrated the

pleural space [1, 4]. Several other studies reported an ND failure rate of 29–36% in patients with suspected tension pneumothorax in the same anatomic location [1, 4, 5]. The major cause of these decompression failures was the lack of immediate feedback other than a “gush of air.” In noisy pre-hospital (e.g., Emergency vehicle sirens, battlefields, etc.) and in-hospital (trauma bay) environments, this subjective assessment can be fraught with failure. A more ideal method for objective feedback would rely on visual change. This may provide a more pronounced, expeditious, and objective

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cue, potentially saving lives, in particular in prehospital environments.

Visual recognition of the respired gas during decompression could be a simple technique for confirming the successful placement of ND. The gaseous composition of tension pneumothorax is similar to that of end respiratory gas with an increased partial pressure of carbon dioxide compared to the normal atmosphere, which makes colorimetric capnography an ideal confirmatory test [6]. We have developed a new device based on colorimetric capnography to help providers rapidly and accurately objectively confirm needle thoracotomy placement. Therefore, this device carries the potential to decrease the mortality rate among patients with tension pneumothorax [6–8].

This pilot study had two aims: (1) to refine the device prototype and train prehospital personnel and (2) to perform human testing to evaluate the feasibility of using the NTCO2 adjunct in the pre-hospital setting.

We suggest that incorporating colorimetric capnography into needle decompression would lead to earlier and more accurate detection of the success of the decompression compared to the current standard of care.

Methods

We performed a single-center, observational, Phase 0 trial of the safety of using the NTCO2 for emergent pre-hospital placement as an adjunct to the standard of care therapy (needle decompression). Inclusion criteria were adult patients who were injured traumatically (blunt or penetrating), with suspected tension pneumothorax. The diagnosis of suspected tension pneumothorax was based on clinical symptoms/signs such as hypotension, absence of breath sounds on affected hemithorax, deviation of the trachea towards the unaffected side, left /right sided or bilateral chest pain, and hypoxia or radiograph depending on clinical scenario.

Exclusion criteria were history or diagnosis of mental illness, patient less than 18 years, prisoners, and patients with a suspected BMI ≥ 30 kg/m² (i.e., about 80 kg for 1.60 m). Given the emergency nature of this study, subjects are unable to provide consent and the device only analyzed waste gases, the IRB approved a waiver of consent. Eligible patients received NTCO2 + standard of care placement.

The primary endpoint of this study was be the detection of CO2 after needle decompression by clinical providers. The presence or absence of a color change was recorded by these providers and later compared against clinical findings of successful decompression or findings on autopsy if patient died from co-morbid injuries. The secondary endpoint of this study is to determine the feasibility of using the NTCO2 adjunct in the field.

Study device

We used a custom-designed device. Prototypes were manufactured by Midwest Interventional (Systems Fridley, MN) under appropriate manufacturing conditions. Briefly, the device has a colorimetric capnography indicator to be exposed to escaping gas contained within a chamber with a one-way valve. The capnography indication paper was placed in this chamber, distal to a one-way valve that prevents air ingress during decompression but allows free gas egress from the needle. This colorimetric capnography paper is blue/purple in ambient air (0.04% CO2 by volume), but when exposed to expired air (5% CO2 by volume), it changes to bright yellow in < 10 s. The ND was placed by medical personnel after appropriate education about the device functionality. The patients were positioned appropriately according to the clinician's judgment. In awake and cooperative patients, a semi-decubitus position, while on the bed (angled at 45°) with the arm behind the head and exposing the axillary area is common practice. However, in the setting of a pre-hospital environment, this is often not be feasible, and various other positions may be employed. The second intercostal space is identified at the midclavicular line, consistent with the standard of care. The standard needle thoracostomy, with the NTCO2 adjunct attached, is then placed through this anatomic location into the thoracic cavity. Vital signs are monitored, typical routine ATLS care is provided and transportation of the patient occurs. The following data was captured prospectively: underlying diagnosis requiring NT, method of insertion (NTCO2 + standard of care, the standard of care), number and location of NT insertion sites if initial decompression fails, opinion on ease of use, and ability to position NT in desired location and orientation, any difficulties encountered with NT insertion, and adverse events.

Results

Five patients presented with suspected tension pneumothorax, all blunt mechanism following motor vehicle crash. The mean age was 43.1 ± 14.5 years (range 24–58 years); all patients were male.

Of the five patients, two underwent bilateral needle decompression resulting in the deployment of seven devices total.

In two patients, device CO2 sensing colorimetric capnography changed colors after needle insertion, and the patients showed clinical improvement after emergent decompression indicating a successful decompression.

Needle decompression was performed in patients in the pre-hospital setting, whereas one patient underwent

needle decompression in the emergency department once he arrived at the hospital. For two of the patients, needle decompression was performed immediately at the scene of the accident after the tension pneumothorax was suspected.

Three patients died, and in one of them, the needle decompression resulted successfully, and symptoms improved after the ND and the colorimetric indicator paper changed color. However, these patients suffered multiple other injuries and ultimately expired. These patients were in extremis without pulse in the field (Fig. 1).

Case 1

32-year-old male. The patient sustained multiple traumas including multiple rib fractures, fracture of the right clavicle, cervical hematoma and pneumothorax. After needle decompression was performed, there was a large rush of air and the patient's condition improved. The device was not affixed until after decompression. *The color did not change (Outcome—Alive).*

Case 2

24-year-old male. The patient presented with multiple gunshot wounds, pneumothorax, hemorrhagic shock and traumatic brain injury. Bilateral needle decompression was performed, with a rush of air present in the left side and improvement of the vital signs. *The device was affixed properly and the color changed shortly after decompression (Outcome—Alive).*

Case 3

58-year-old male. The patient sustained multiple blunt force injuries after motor vehicle accident. The patient was hypotensive with decreased breath sounds unilaterally. Needle decompression was performed with *improvement of the vital signs, no auditory “gush of air” and a positive color change.* The patient underwent operative exploration but died secondary to hemorrhagic arrest. Autopsy found bilateral hemothorax (50 mL on the right, 1000 mL on the left), multiple rib fractures, complete transection of the descending

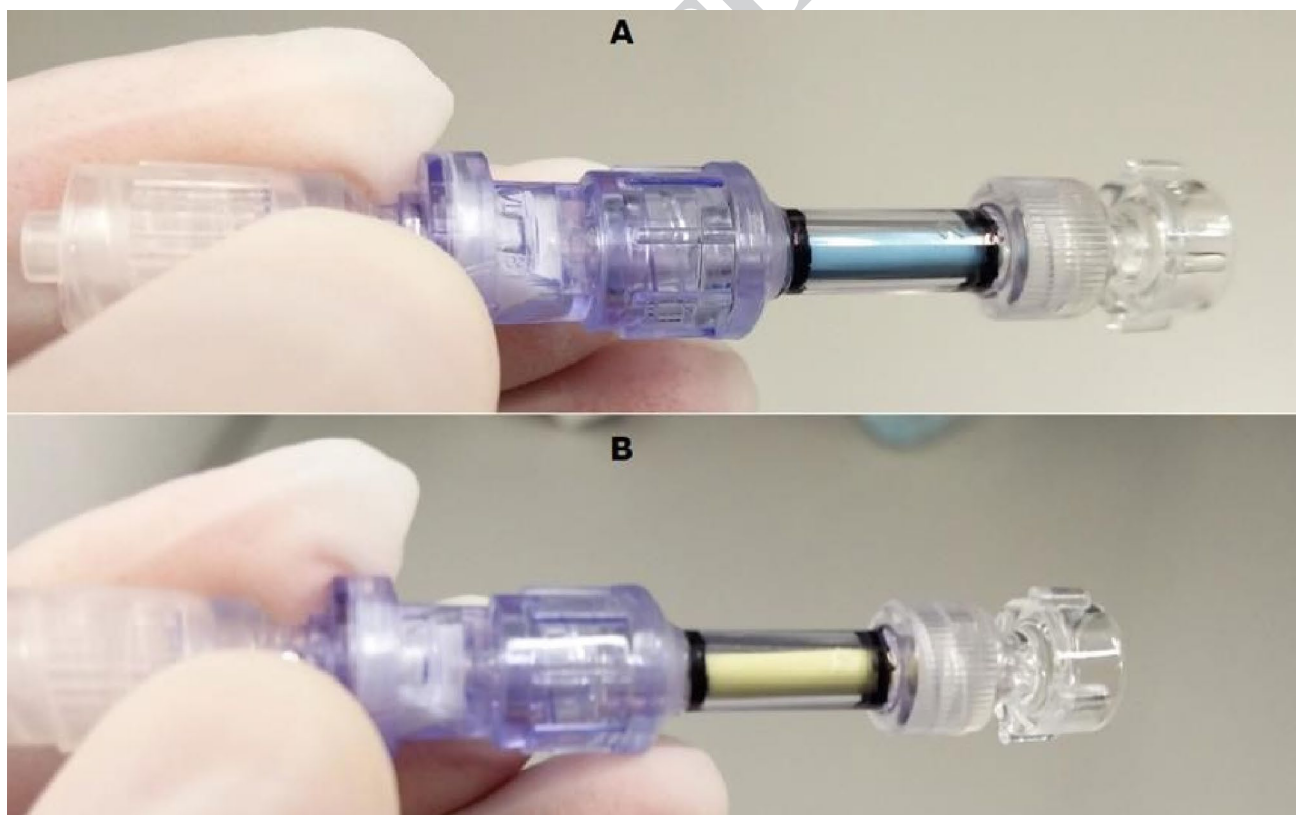


Fig. 1 The device has a chamber for a colorimetric capnography indicator exposed to escaping gas and a one-way valve. The capnography indication paper was placed in this chamber, distal to one-way valve that prevents air ingress during decompression but allows free gas

egress from the needle. This colorimetric capnography paper is blue/purple (a) in ambient air (0.04% CO₂ by volume), but when exposed to expired air (5% CO₂ by volume), it changes to bright yellow (b) within 3–5 s

proximal aorta and pneumothorax. (*Outcome—Deceased in the OR*).

Case 4

56-year-old male. The patient sustained multiple blunt force injuries after motor vehicle accident. The patient was in circulatory arrest. Needle decompression performed per asystolic traumatic protocol. No change in the patient's status was observed *or color change* after decompression. (*Outcome—pronounced deceased on the scene and not transported on the hospital*). Autopsy found hemothorax with laceration of the azygos vein, contusion of the right lung lower lobe, multiple rib fractures and abrasion on the right anterior chest.

Case 5

54-year-old male. The patient was involved in a motor vehicle accident. Auto intrusion > 12" inches into the compartment. The patient was in circulatory arrest. Needle decompression performed per asystolic traumatic protocol. The device was placed due to decreased breath sounds bilaterally. No change in the patient's status was observed. *No color change* (*Outcome—pronounced deceased on the scene and not transported to the hospital*). The autopsy demonstrated multiple blunt force injuries.

Discussion

Tension pneumothorax is a life-threatening condition that can be fatal without diagnosis and immediate intervention. Tension pneumothorax occurs in 3–5% of major trauma patients managed in the pre-hospital environment [7, 8]. Needle decompression is the standard of care for patients with tension pneumothorax and is considered a life-saving procedure. The ATLS guidelines recommend attempts be made to diagnose this condition during the initial assessment in the field [3]. Pre-hospital providers and physicians rely on the classic clinical findings to diagnose tension pneumothorax which our study replicates [1]. Current guidelines recommend that an auditory “gush of air” be a marker of successful decompression [3]. The settings in which ND is performed are loud, noisy, stressful, and chaotic, which makes the audible gush of air highly subjective and hard to detect [6]. Therefore, a visual device to eliminate the operator's subjectivity may be more useful and accurate. In our study one of the patients who had a positive color change with the device did not have an auditory cue for decompression. This suggests utility.

In a previous study using an animal model, needle capnography decompressions showed a 100% success rate in

comparison to 60% in the standard of care needle decompression [6]. In our study we elected to provide descriptive information only given the limited environment, small number of patients, and not being able to truly differentiate tension pneumothorax from hemothorax given similar clinical presentation in the field.

This device requires further clinical assessment but results of this trial are promising. Effective color change corresponding to clinical improvement after decompression. Was demonstrated. This may have efficacy for field confirmation in both civilian and military settings if commercial opportunities for manufacturing develop and regulatory scrutiny are met. Improving care for those who are injured with tension pneumothorax is critical.

After decompression and color change of the device in those with pneumothorax, vital signs improved with the exception of those who were suffering circulatory arrest. Our blunt trauma management algorithm for those patients recommends immediate bilateral decompression to rule out tension as the cause of the circulatory arrest, which in this study was two of the patients. In patients with hemothorax or other pathology for the circulatory arrest such as hemorrhage having the device not turn color is favorable for management. This suggests that needle decompression performed when tension physiology is not the cause does not lead to false positives. This allows medical personnel to move on to other management of the injured.

This method of capnography is not quantitative it provides valuable information for providers in the field. Although the device offers information by way of a chemical reaction, it does not constitute a purely qualitative test, since the color changes based on the concentrations of the CO₂ in the expired air (EtCO₂ < 0.5%—purple/blue, EtCO₂ 0.5–2%—tan, EtCO₂ > 2%—yellow). Considering both its qualitative and semi-quantitative attributes, we believe colorimetric capnography to be an appropriate denomination. As visual confirmation results in more objective and efficient ND, this device could potentially reduce the failure rate of decompression, provide appropriate field diagnostics and eliminate tension pneumothorax as a cause of circulatory arrest and enable providers to focus on other potential causes.

This device may allow providers of different levels of education and knowledge to perform needle decompression in an objective manner that they can easily and efficiently assess for the success of decompression.

Conclusion

This human study confirmed that the colorimetric capnography device is applicable to the prehospital care of patients and with requiring minimal training, the color change was

visibly and rapidly apparent and has potential clinical utility. Using our methodology, needle decompression with colorimetric capnography can eliminate bias, and produce more predictable decompression results. This device and method may replace the current standard of care and help prehospital trauma providers to do their job in an efficient and objective manner.

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Declarations

Conflict of Interest Mayo Foundation has a financial interest in technologies developed by some authors. Dr. Aho reports patent disclosures for multiple technologies which he does not receive royalty.

Ethics approval This study was approved by the Mayo Clinic Institutional Review Board and all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national standards and consistent with the 1964 Helsinki declaration and its later amendments.

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