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A randomized cross-over study comparing surgical cricothyrotomy techniques by combat medics using a synthetic cadaver model

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ABSTRACT

Objective: Cricothyrotomy is a complex procedure with a high rate of complications including failure to cannulate and injury to adjacent anatomy. The Control-Cric™ System and QuickTrach II™ represent two novel devices designed to optimize success and minimize complications with this procedure. This study compares these two devices against a standard open surgical technique.
Methods: We conducted a randomized crossover study of United States Army combat medics using a synthetic cadaver model. Participants performed a surgical cricothyrotomy using the standard open surgical technique, Control-Cric™ System, and QuickTrach II™ device in a random order. The primary outcome was time to successful cannulation. The secondary outcome was first-attempt success. We also surveyed participants after performing the procedures as to their preferences.
Results: Of 70 enrolled subjects, 65 completed all study procedures. Of those that successfully cannulated, the mean times to cannulation were comparable for all three methods: standard 51.0 s (95% CI 45.2–56.8), QuickTrach II™ 39.8 s (95% CI 31.4–48.2) and the Cric-Control™ 53.6 (95% CI 45.7–61.4). Cannulation failure rates were not significantly different: standard 6.2%, QuickTrach II™ 13.9%, Cric-Control™ 18.5% ($p = 0.106$). First pass success rates were also similar (93.4%, 91.1%, 88.7%, respectively, $p = 0.670$). Of respondents completing the post-study survey, a majority (52.3%) preferred the QuickTrach II™ device.
Conclusions: We identified no significant differences between the three cricothyrotomy techniques with regards to time to successful cannulation or first-pass success.

1. Introduction

1.1. Background

Airway management is a critical component of the resuscitation of critically ill and injured patients. In the civilian setting, surgical cricothyrotomy is a measure of last resort in patients in whom all other airway management efforts fail. This procedure entails placing an endotracheal tube through an incision in the cricothyroid membrane to establish a definitive airway for the purposes of oxygenation and ventilation [1,2]. This procedure is relatively uncommon, historically accounting for approximately 1.1% of emergency department (ED) airways [3] with more contemporary data placing this number as low as 0.1% [4]. Higher proportion of airways managed in the prehospital setting require cricothyrotomy, ranging up to 14.9% in trauma cohorts [5]. However, Tactical Combat Casualty Care guidelines (02 Jun 2014 edition) recommends the use of the surgical cricothyrotomy as the intervention of choice when a definitive airway is necessary during the early phases of care.

Several surgical assist devices have been marketed to help optimize success with this rarely performed and potentially life-saving procedure [6,7]. These devices were invented to simplify and expedite the cricothyrotomy procedure. In so doing, these devices seek to maximize success while minimizing time to completion, particularly among novice healthcare providers. Limited data suggests these devices may facilitate faster endotracheal airway insertion compared to standard open surgical technique [6].

1.2. Importance

Cricothyrotomy is a particularly important skill for military combat medics as airway compromise is the second leading cause of preventable death on the battlefield [8-11]. This reality has prompted a series

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of investigations into adjunctive devices to optimize airway management on the battlefield [12-14]. The cricothyrotomy procedure remains the sole definitive airway technique taught to medics as paralysis is unnecessary and there are fewer equipment needs than for oral endotracheal intubation [15]. Unfortunately, data from combat operations in Iraq and Afghanistan indicate that the proportion of cricothyrotomy procedures performed by combat medics resulting in successful cannulation may be as low as 67% [16]. Also, civilian data report high rates of complications associated with this procedure when performed in the prehospital setting [17].

Surgical airway assist devices could be particularly useful for combat medics given their limited prior airway experience. Moreover, the chaotic nature of airway management in the combat environment highlights the need for adjuncts to simplify otherwise complicated procedures such as cricothyrotomy. Data on the use of these devices in the combat setting are limited to only 4 cases (3 of which resulted in successful endotracheal intubation) [7]. Further investigation is necessary to optimize success with this challenging procedure.

1.3. Goal of this investigation

We compared outcomes among United States (US) Army combat medics (68W) using three techniques performing surgical cricothyrotomies in a synthetic cadaver model: [1] standard open technique, [2] the Control-Cric™ System, and [3] the QuickTrach II ™ device. Our primary outcome was time to successful cannulation.

2. Methods

2.1. Study design and setting

We conducted a prospective, randomized, crossover trial comparing three separate surgical cricothyrotomy techniques among US Army combat medics in a synthetic cadaver model (SynAtomy Adult Airway Trainer, Syndaver Labs, Tampa, FL). The study took place at the Army Medical Department Center and School (AMEDDCS) at Joint Base San Antonio, Texas. The Regional Health Command – Central Institutional Review Board reviewed and approved the study (protocol C.2016.088e). We reported our results in accordance with the Consolidated Standard of Reporting Trials (CONSORT) Statement [18].

2.2. Selection of participants

All US Army combat medics beginning training as part of the Critical Care Flight Paramedic (CCFP) program based out of Fort Sam Houston, TX were eligible for study participation. There were no study exclusion criteria. All medics had prior training as part of the US Army's advanced individual training (AIT) for combat medics. This comprised general medical skills to the emergency medical technician-basic level with an additional 7 h of cricothyrotomy instruction. This additional airway training includes at least 12 insertions on a training manikin (Simulaids Critical Airway Management Trainer Model 68454, Saugerties, NY). To graduate from previous combat medic training, all medics had successfully performed a cricothyrotomy on this manikin using a standard open surgical technique in 60 s or less.

We approached all combat medics during initial in-processing into the CCFP program and provided each medic an informational sheet describing the study. During the study period, we approached 3 classes each sized at 35 medics over the course of 4 months. Medics amenable to participation provided consent prior to study start.

2.3. Interventions

Participants were sequentially randomized to perform three separate techniques: [1] surgical cricothyrotomy by standard open surgical technique (Fig. 1), [2] Control-Cric™ System comprising the Cric-Key™ and Cric-Knife™ (Pulmodyne, Indianapolis, IN, Fig. 2), and [3] QuickTrach II™ device (VBM, Medizintechnik GmbH®, Sulz am Neckar, Germany, Fig. 3). Prior to study start, participants received 15 min of instruction regarding 2 of the techniques, Control-Cric™ and the QuickTrach II™.

The instruction for the standard open technique had been provided during prior training [6]. In brief, investigators reviewed the equipment (Fig. 1) and procedures for this technique. Medics were able to perform the cricothyrotomy in whatever fashion they preferred even if that differed from the method taught during AIT.

The instruction for the Control-Cric™ System (Fig. 2) comprised a video available online (https://www.youtube.com/watch?v=CE36DGbcdf0). This technique again entails identification of the cricothyroid membrane and manually securing the trachea. The operator makes a horizontal incision at the level of cricothyroid membrane with the Cric-Knife™ and advances the integrated sliding tracheal hook to secure the tracheal opening. Next, the operator inserts the Cric-Key™ introducer to guide insertion of a 5.0 cuffed Melker cricothyrotomy airway cannula (Cook Critical Care, Bloomington, IN). The operator confirms placement by feeling for tracheal rings and then removes the Cric-Key™, leaving the airway in place. Finally, the operator inflates the cuff with 10 cm^3 of air [6,19].

The instruction for the QuickTrach II ™ device (Fig. 3) similarly utilized an online video (https://www.youtube.com/watch?v=ANjpujmYfU0). The device insertion entails identification of the cricothyroid membrane, manually securing the trachea, and insertion of the device in a posteroinferior direction at the level of the membrane while aspirating using a 10 cm^3 syringe filled with normal saline. Upon seeing return of bubbles into the syringe, the operator then retracts the device's proximal green stopper. The operator then removes the distal red stopper (whose function is to ensure the needle does not puncture the posterior tracheal wall) and advances the device into the trachea while continuing to aspirate. Once the device phalanges are flush against the skin, the operator removes the needle entirely from the device and inflates the device cuff using a 10 cm^3 syringe [20].

We permitted participants time to ask questions. We then unpackaged and pre-assembled all equipment for the 3 devices. We allowed participants approximately 10 min each to handle the equipment for the 3 techniques. We did not permit any practice attempts. The participants then performed the 3 techniques on the synthetic cadavers.

We utilized a randomization sequence in permuted blocks of 6 to equally distribute participants across each of the 6 possible sequences of techniques (Fig. 4). Participants performed all procedures on 3 synthetic cadavers. We replaced the synthetic tissue through which the participants cut after each procedure. After completing each technique, we enforced a 20 minute wash-out period before starting the next study technique.

2.4. Measurements

All participants completed a pre-study survey soliciting their demographics, sex, and time since graduating AIT. We also gathered data on the total number of prior cricothyrotomies performed in living patients and in simulation or laboratory settings. Finally, the pre-study survey queried whether the participant had any prior experience with surgical airway assist devices.

During the study period, investigators measured the time required to achieve successful airway cannulation for each of the 3 devices. They initiated time measurement once the participant touched the synthetic cadaver. They stopped time measurement at the moment the participant inflated the cuff of the airway device or they verbally indicated they were done with the procedure. Investigators also recorded the number of attempts at airway cannulation. If the participants completely withdrew the cannula from the airway during an attempt such that it no longer had any physical contact with the synthetic cadaver, we