A RANDOMIZED TRIAL COMPARING TWO CUFFED EMERGENCY CRICOThYTOMY DEVICES USING A WIRE-GUIDED AND A CATHETER-OVER-NEEDLE TECHNIQUE

Thomas Metterlein, MD,* Matthias Frommer, MD,* Christian Ginzkey, MD,† Jan Becher, MD,‡ Frank Schuster, MD,* Norbert Roewer, MD,* and Peter Kranke, MD*

*Department of Anesthesiology, †Ear, Nose, and Throat Department, and ‡Department of Internal Medicine, University of Würzburg, Würzburg, Germany

Reprint Address: Thomas Metterlein, MD, Department of Anesthesiology, University of Würzburg, Oberdänrbacher Str. 6, Würzburg 97080, Germany

Abstract—Background: According to different algorithms of airway management, emergency cricothyrotomy is the final step in managing the otherwise inaccessible airway. As an alternative to an open surgical procedure, minimally invasive approaches exist. Various sets for different methods are commercially available. QuickTrach™ (VBM Medizintechnik GmbH, Sulz am Neckar, Germany) contains a plastic cannula over a metal needle for direct placement in the trachea, whereas a guide-wire is used for the actual placement of the cannula in the Melker Set™ (Cook Group Incorporated, Bloomington, IN). Objective: We hypothesize that the direct puncture involving less discrete steps is faster to perform. However, it will lead to more complications due to the higher force needed to place the relatively thick needle. Method: After approval of the local ethics committee, the study was performed on cadavers of 16 adult sheep. A wire-guided cricothyrotomy was compared with a catheter-over-needle technique. Successful placement and performance time were compared. Complication rate and maximal achieved airway pressure were evaluated. Data is given as mean and interquartile range, and Mann-Whitney U-test (p < 0.05) for significant differences. Results: With the wire-guided technique, successful placement was possible in all attempts. The catheter-over-needle method was successful in 63% and had a higher complication rate (75% vs. 13%). The cannula-over-needle method allowed a faster cricothyrotomy (32 [2–34] vs. 53 [52–56] s). Both methods allowed the delivery of similar maximal airway pressures (50 [44–51] vs. 48 [43–53] mbar). Conclusion: The wire-guided method proved to be the more reliable technique, leading to fewer complications. However, the direct puncture was faster to perform. Placed accurately, both devices allowed sufficient ventilation. © 2010 Elsevier Inc.

Keywords—cricothyrotomy; tracheotomy; emergency airway management; QuickTrach™; Melker Set™

INTRODUCTION

The difficult airway algorithm of the American Society of Anesthesiologists recommends the approach of a surgical airway as a final step (1). Cricothyrotomy is a surgical procedure intended to gain control of an otherwise not manageable airway (2,3). It is an easy, quick, and potentially life-saving intervention. If performed correctly, the complication rate should be very low because the technique per se is straightforward and is known from other fields of medical management (e.g., inserting central venous catheters). However, most physicians, even those regularly involved in airway management, have limited experience with this technique. Due to its emergency character, it is rarely used and always takes place in a crisis situation.

This trial was supported by departmental funding.

Received: 23 April 2009; Final submission received: 15 November 2009; Accepted: 4 April 2010
Compared to an open surgical procedure, two less invasive techniques have been introduced as alternatives to a conventional open surgical procedure. One approach makes use of the Seldinger method using a guide-wire to insert the cannula. Studies have not yet demonstrated significant differences for procedure time and complication rate between the open surgical and the wire-guided technique (4,5). Another approach uses a catheter-over-needle technique for direct puncture to secure the airway. This method also is fast and easy to perform (6,7). Previous investigations compared the wire-guided technique with the cannula-over-needle method and demonstrated a significant difference in procedure time, easiness, and complication rate, favoring the direct puncture method (8). However, a response to this study indicated a potential limitation due to the setup using prepared porcine larynges that were stapled on wooden boards. A higher potential for traumatic complications using the cannula-over-needle technique in a more real-life situation was suggested (9).

This study again compared two non-surgical cricothyrotomy techniques: the wire-guided (Melker Set™; Cook Group Incorporated, Bloomington, IN) and the cannula-over-needle (QuickTrach™; VBM Medizintechnik GmbH, Sulz am Neckar, Germany) approach with respect to insertion time, success rate, complications, and functional quality of the established airway. However, in contrast to previous investigations, a model with cadavers of full-grown sheep was chosen. Recently developed cannulas with inflatable cuffs also allowed the comparison of maximal achieved airway pressure and pressure of the inflated cuff.

METHODS

With approval of the local ethics committee, two anesthesiologists (a third-year resident and a senior anesthesiologist) performed this randomized trial in a standard operation theatre. The two participants were familiar with both sets and had the chance to practice each insertion technique for 1 h on manikins a month before the investigation. For the study, cadavers of 16 female 9-month-old sheep were used. We compared a wire-guided cricothyrotomy set with a catheter-over-needle set. Both devices have an inflatable cuff and are commercially available (Figures 1, 2).

The sheep were fully heparinized and euthanized with T61 (Intervet, Wiesbaden, Germany) while under deep anesthesia. After their deaths, the whole anterior neck region was shaved and the animals were placed in a supine position. The weight of the sheep was documented. For each of the participants, the sheep were randomly allocated to the performed technique.

The guide-wire group used the Melker Set™ (Cook Medical Inc., Bloomington, IN) consisting of a needle, a syringe, a guide wire, a scalpel, a dilatator, a 5-mm (inner diameter) cannula with an inflatable cuff, and a syringe for blocking the cuff. The catheter-over-needle group used the QuickTrach II™ (VBM Medizintechnik GmbH, Sulz am Neckar, Germany), consisting of a syringe, a conical-shaped needle, a plastic 4-mm (inner diameter) cannula with an inflatable cuff, and a stopper. The stopper is intended to prevent the needle from being inserted too deeply. The risk of a posterior wall perforation is supposed to be reduced with this device. In the second group, a separate number 11 stab scalpel (Feather Safety Razor Co., Osaka, Japan) was used for a 3-mm stab incision before puncture with the catheter-over-needle because this is not included within the set.

For both approaches, two time intervals were defined. The first time interval was started with the “decision” to gain a surgical airway up to the actual start of the
cricothyrotomy. While the participant examined the anatomical structures and identified the puncture site, a second person opened and prepared the set. The second time interval started with the puncture (wire-guided) or stab incision with the scalpel (cannula-over-needle) and ended with the first successful ventilation or when the time limit of 180 s was reached. This time limit was chosen because 3 min are considered the maximum accepted time to achieve a surgical airway in case of a total airway obstruction (4,10). Exceeding this time limit was considered as failure. In both approaches, the needle was advanced in a 45° angle to the prelaryngeal skin in caudal direction. Intratracheal position of the needle was confirmed by aspiration of air. After placement of the cannula, the cuff was inflated with the recommended volume and the cannula was connected to an anesthesia circuit. Successful manual ventilation was confirmed clinically by inspection and auscultation. Afterwards, airway pressure was increased until an air leak occurred. Then the pressure of the cuff was measured.

Finally, an otorhinolaryngologist who was not present during the procedure and blinded to the used technique opened the larynx and the trachea, allowing complete inspection of the involved structures. The correct position of the cannula was confirmed and possible damage was evaluated. Complications, including fracture of cricoid, thyroid, or tracheal cartilage, injury of the posterior tracheal wall pre-, para-, post-tracheal localization of the cannula, and guide-wire kinking, were registered on a standard form. After the study, both participants were asked to indicate their preferred method before revealing the complication or failure rate with each device.

Due to the low number of animals, data were supposed to be non-parametrically distributed and are shown as median with interquartile range (i.e., 25% and 75% quartile). Mann-Whitney U-test was used to test for differences between guide-wire and cannula-over-needle technique; $p < 0.05$ was considered to be significant.

RESULTS

Using the guide-wire technique, a correct intratracheal placement of the cannula was achieved in all eight attempts (100%) (95% confidence interval [CI] 63–100%) (Figure 3). Using the catheter-over-needle method, the success rate was five of eight attempts (63%) (95% CI 30–86%). In the second group, one paratracheal placement was observed (Figure 4). In two other cases, the cannula perforated the posterior tracheal wall, resulting in connective tissue emphysema (Figure 5). In two further cases, damage to the mucosa of the posterior wall occurred without perforation of the trachea. Therefore, the latter were counted as successful attempts. In the guide-wire group, only one case of a small lesion in the
The course of the procedure, as well as peak airway pressure and cuff pressure, are listed in Table 1. A significant difference in the procedure time could be seen (p < 0.05). No significant differences exist for weight, preparation time, maximal airway pressure, and cuff pressure.

As asked for their preferred method in a real emergency situation, both participants favored the guide-wire technique.

DISCUSSION

This study compared success rate, time for the procedure, complication rate, achieved maximal airway pressure, peak airway pressure, and cuff pressure of two different cricothyrotomy techniques: the wire-guided (Melker Set™) and the catheter-over-needle (QuickTrach™) method. The main findings are that the wire-guided technique had a 100% success rate, whereas the cannula-over-needle method allowed successful ventilation in only 63% of the investigated cases. The catheter-over-needle technique can be performed more quickly (32 s vs. 53 s). However, the wire-guided technique leads to fewer complications (13% vs. 63%). With both methods, reasonable maximal airway pressures (50 mm Hg [QuickTrach™] vs. 48 mm Hg [Melker Set™]) could be delivered before an air-leak occurred. Inflating the cuff with the recommended volume led to similar cuff pressures (70 mm Hg [QuickTrach™] vs. 65 mm Hg [Melker Set™]).

Several studies have already been published on the wire-guided technique (4,5,7,10,11). Eisenburger et al. compared the wire-guided technique with a standard surgical technique in human cadavers (4). The performance time was 100 s and 102 s, respectively. No difference in complication (10% vs. 15%) could be found (4). A similar study was published by Chan et al., again finding no differences in cricothyrotomy time and complication rate (5). One of the first studies investigating the catheter-over-needle technique showed a shorter performance time, especially when a stab incision was made before puncture (83 s [without incision] vs. 35 s [with incision]). However, there was a relatively high complication rate, with 4% serious ones (i.e., para-tracheal placement) and 27% minor problems (i.e., injury to the surrounding soft tissue and cartilage) (6). Due to these results, a stab incision was made in this study, in contrast to the recommendations of the manufacturer. The reason for the company’s advice is mainly the lower incidence of bleeding after a blunt dilatation of the artificial airway (12). Sheepskin is very similar but not identical to human skin. With the stab incision, a possible confounder was thought to be eliminated. The stab scalpel had a blade length of 5 mm. Due to the depth of the pre-tracheal tissue and the diameter of the trachea, a posterior wall injury due to the stab incision was considered very unlikely.

In a more recent study, Vadodaria et al. compared four different cricothyrotomy kits in human manikins (8). A 100% success rate was found, with both techniques within acceptable time limits of 51 s (catheter-over-needle) and 38 s (wire-guided). Rather surprising, because the wire-guided technique involves more steps than the direct puncture with the catheter-over-needle method. The observed complication rate was identical, with two cases of damage to the posterior wall in each group of 10 attempts (8). Fikkers et al. found different results comparing the two methods on prepared pig larynxes (13). The catheter-over-needle technique was faster (48 s vs. 150 s) and had a lower complication rate (1 vs. 5; out of 20 attempts) (13). For the anesthesiology and ear, nose, and throat residents who performed the cricothyrotomies, the catheter-over-needle technique was subjectively easier to perform and would therefore be the preferred method in a real emergency situation. However, a response to the publication indicated a potential limitation of the trial due to the setup using prepared porcine larynges that were stapled on wooden boards.
The reply suggested different results in a more real-life setting (9).

This study tried to achieve such a goal and led to accordant results. The complication rate of the catheter-over-needle technique was relatively high in this trial. In 37%, no successful ventilation was possible due to an incorrect placement. The explanation for this might be the force that was needed to place the cannula. Even after the stab incision of the skin, subcutaneous fat, connective tissue, and the cricothyroid membrane have to be dilated bluntly. The needed force led to a compression of the trachea due to the compliant anterior wall. The risk of damage to the posterior wall increases with the decreased anterior-posterior diameter of the trachea. The sudden “giving way” of the membrane at the moment of maximal applied force increases the risk of posterior wall damage. This could be shown fiberoptically with a similar device in an in vivo study with human bodies (14).

Due to the lateral mobility, it was rather difficult to stabilize the larynx with one hand performing the puncture with the other. This lateral mobility led to one placement slightly lateral to the trachea. Due to the force needed to insert the cannula-over-needle, it is harder to remain at the exact intended position.

For accurate placement of the guide-wire, no excessive force is needed due to the small and sharp needle. Once the wire is placed, a reliable tract for the subsequent more-or-less forceful passage of the dilator and the cannula exists (15). The separation of the two steps “puncture and dilatation” allow more accuracy in the first step and helpful guidance for the second. The risk for potential trauma to surrounding structures is therefore minimized and the success rate increased. A kinking of the wire as one possible complication due to the blunt dilatation, but was not observed.

The fact that two steps rather than one step have to be performed leads to a significant difference between the procedure times of both methods. The guide-wire technique involves more discrete steps and therefore takes longer. Time-consuming problems described in prior studies, such as forgetting to remove the needle before feeding the dilator onto the wire or removing the wire too early, were not seen (13). This might be due to the fact that the procedures were performed by two anesthesiologists who generally are very familiar with the wire-guided technique and due to prior training with both kits. The used guide-wire has one more flexible and one stiffer end. Perforations of the posterior wall due to incorrect introduction of the guide-wire, as seen in other trials, did not occur (13).

In prior publications, 3 min was considered as maximal acceptable time for establishment of a surgical airway in case of a total obstruction of the upper airway (4,10). Even the longest attempt using the wire-guided method took only 68 s and is therefore well within tolerable limits.

The preparation time again was very similar for both methods. Both sets only have to be opened and the included syringes filled with water.

Both participants have never performed the procedure on a patient before and were therefore not prejudiced and motivated to find out the optimum technique. The time it took to establish the emergency airway was not different between the two physicians, despite different levels of training. Previous knowledge and training might not have an extensive influence on the performance. There was also not a substantial discrepancy in performance time between the first and the following attempts for both sets, indicating that the plateau of the learning curve was already reached after just one practice session. In prior studies with other sets, such a plateau was reached only after at least five attempts (16). Again, a possible indication for the practicability of both investigated sets. However, it still is reasonable that more and intensified training would improve the results. For such an infrequently performed and complicated procedure, loss of skill will undoubtedly take place over time.

Compared to other emergency-airway devices, both investigated sets have an inflatable cuff to allow better ventilation. The concern that the blunt preparation through skin, soft tissue, and cricothyroid membrane might harm the cuff was not seen in any of the used sets. The cuff remained undamaged and could be inflated with the recommended volume of air, resulting in rather high cuff pressure for both sets (65 mm Hg [Melker Set™] vs. 70 mm Hg [QuickTrach™]). Cuff pressures higher than the tracheal capillary pressure (20–30 mm Hg) in function of time lead to tracheal ischemia with subsequent complications (17). In an emergency situation, this late complication is, of course, not a major concern.

Due to the inflatable cuff, both devices permit the delivery of high airway pressures before an air leak occurs (50 mbar [Melker Set™] vs. 48 mbar [QuickTrach™]). This allows the use of positive end-expiratory pressure and the recruitment of atelectatic lung areas; obese or bronchopulmonarily compromised patients benefit thereof. Using an anesthesia circuit, expiratory volume and end-expiratory PCO₂ can be measured and ventilation adjusted.

The tight seal of the inflatable cuff also prevents a possible pulmonary aspiration. Emergency patients are rarely fasting. The failed attempt of a mask ventilation or a possible esophageal intubation lead to a distension of the stomach, with an increased risk of regurgitation.

**Limitations**

The produced setting using an animal cadaver reflects the real-life situation only to a certain degree. It does not completely replicate the emergent airway conditions in humans. The stress of a real emergency and other dis-
tracting factors like obvious trauma, restlessness of the patient, or agitated personnel were not generated. Other interesting complications like infection or tracheal stenosis could not be examined (18).

Certain animals can be used as a realistic model for airway studies. Prior trials found no significant differences in insertion and penetration force between human cadavers and various animal models (15). The sheep skin resembles human skin better than the skin of many other animals. Patients with tumors of the head and neck region often have altered skin conditions due to radioand chemotherapy. The anatomical structures of the neck region of sheep and humans are very similar but of course not identical. However, the real-life scenario of a “cannot intubate, cannot ventilate” situation mainly occurs in patients with unfavorable anatomy. Therefore, the heterogeneity of a sheep neck is probably more practical than the uniform design of a human simulator.

Whether involvement of other personnel who practice the wire-guided technique less frequently, such as paramedics, would lead to different results, has to be investigated in further trials.

CONCLUSION

The wire-guided technique proved to be a reliable method for an emergency cricothyrotomy. Within a reasonable time, decent ventilation was achieved. The cannula-over-needle method proved to be faster but not as reliable. Ventilation with this approach was possible in only 63%.

REFERENCES

ARTICLE SUMMARY

1. Why is the topic important?
   To establish a surgical airway is the final step in a “cannot intubate, cannot ventilate” situation. Such a life-threatening emergency situation is rare but still occurs in various situations.

2. What does this study attempt to show?
   This study compares two different minimally invasive approaches of an emergency cricothyrotomy (direct puncture vs. wire-guided technique). Aim was to find the most suitable method.

3. What are the key findings?
   The wire-guided technique proved to be more reliable and had fewer complications; direct puncture, however, was faster to perform.

4. How is the patient care impacted?
   The wire-guided technique as the more reliable method should be favored over direct puncture in an emergency situation.