Emergency Cricothyrotomy Performed by Surgical Airway–naive Medical Personnel

A Randomized Crossover Study in Cadavers Comparing Three Commonly Used Techniques

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ABSTRACT

Background: When conventional approaches to obtain effective ventilation and return of effective spontaneous breathing fail, surgical airway is the last rescue option. Most physicians have a limited lifetime experience with cricothyrotomy, and it is unclear what method should be taught for this lifesaving procedure. The aim of this study is to compare the performance of medical personnel, naive to surgical airway techniques, in establishing an emergency surgical airway in cadavers using three commonly used cricothyrotomy techniques.

Methods: Twenty medical students, without previous knowledge of surgical airway techniques, were randomly selected from their class. After training, they performed cricothyrotomy by three techniques (surgical, Melker, and QuickTrach II) in a random order on 60 cadavers with comparable biometrics. The time to complete the procedure, rate of success, and number of complications were recorded. A success was defined as the correct placement of the cannula within the trachea in 3 min.

Results: The success rates were 95, 55, and 50% for surgical cricothyrotomy, QuickTrach, and Melker, respectively (P = 0.025). The majority of failures were due to cannula misplacement (15 of 20). In successful procedures, the mean procedure time was 94 ± 35 s in the surgical group, 77 ± 34 in the QuickTrach II group, and 149 ± 24 in the Melker group (P < 0.001). Few significant complications were found in successful procedures. No cadaver biometric parameters were correlated with success of the procedure.

Conclusion: Surgical airway–naive medical personnel establish emergency cricothyrotomy more efficiently and safely with the surgical procedure than with the other two commonly used techniques. **(Anesthesiology 2016; 125:295-303)**

ANY physician or healthcare worker may face an emergency situation where a patient's airway is impaired. While intubation is the standard airway management, it might rarely be impossible, leading to the nightmarish "cannot-intubate, cannot-ventilate" situation.[1–4] Despite numerous oral intubation devices developed within the last two decades, some patients will require an airway access through the anterior neck—the so-called surgical airway.

Tracheotomy involves an access to the tracheal airway below the cricoid cartilage and is considered as a longer, more invasive procedure, usually reserved for surgeons.[5] In truly emergent situations, airway access should be provided through the area within the least amount of tissue and vessels between the anterior neck skin and the airway. Anatomically, the most favorable area is the cricothyroid ligament,[6] and the procedure is called cricothyrotomy.

For obvious ethical and organizational reasons, there is no prospective study comparing emergency cricothyrotomy techniques on living patients, and it seems doubtful that such study will ever take place. A meta-analysis of prehospital airway access techniques in patients found published studies of low quality but concluded that the surgical cricothyrotomy was associated with success rates of 90%, while nonsurgical cricothyrotomy had lower success rates (65%).[7] The studies on cricothyrotomy using human cadavers are sparse,[8–13] used

What We Already Know about This Topic

- Emergency cricothyrotomy is recommended in many airway management guidelines when cannot-ventilate, cannot-intubate situation occurs
- Whether the cricothyrotomy should be performed either surgically or nonsurgically is a significant topic to be determined

What This Article Tells Us That Is New

- This prospective, randomized, crossover trial compared the success rate and complication of three different cricothyrotomy techniques performed by 20 surgical airway–naive medical personnel in 60 cadavers
- The success rates were 95, 55, and 50% for surgical cricothyrotomy, QuickTrach, and Melker, respectively. The majority of failures were due to cannula misplacement during nonsurgical cricothyrotomy

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different-size cannulas,[9,12] were performed by specific groups of physicians,[9,12,13] or were performed by experimented physicians.[10,13] Furthermore, most studies have not set an upper time limit to consider the procedure as successful.[14] Nevertheless, it appears that the techniques with the higher success rates are the surgical technique,[8] the Melker set,[9,10,12] and the QuickTrach set, which were chosen for this study.

A related aspect of emergency cricothyrotomy is that, contrary to the majority of surgical procedures, it cannot be taught in the real situation: most often medical students receive a theoretical teaching without any practice; the procedure is rarely taught on animals (although anatomical differences make such practice of limited usefulness[15]); and exceptionally programs provide single-cadaver training. It is unclear that any teaching program, medical school, paramedics, or army, provides repeated practice of the procedure on several cadavers.[16] For a procedure that is supposed to be lifesaving, this is close to an aberration.

The aim of this study is to assess the efficiency and safety of three commonly used techniques/sets for cricothyrotomy—the Melker set, the QuickTrach II set, and the surgical technique— when performed in cadavers by surgical airway–naive medical personnel.

Materials and Methods

To approximate current medical practice where cricothyrotomy is rarely performed, the subjects were medical students without any previous knowledge of surgical airways. Subjects performed the three techniques of cricothyrotomy in a randomized order, and therefore the study can be considered a randomized crossover trial. The Consolidated Standards of Reporting Trials flowchart (fig. 1) and checklist (appendix) were followed.

Subjects

In order to exclude subjective preferences associated with personal practice, as well as any previous experience with airways, we decided to enroll medical students with enough knowledge about anatomy but with no previous medical or surgical experience. Fourth-year (out of 6 yr) medical students from the University of Graz (Graz, Austria) were randomly selected among all students in the class. No previous information besides "an airway-related procedure experiment" was given. Some declined to participate, and some were unavailable on the day of the experiment (fig. 1). All were present on the day of the experiment, and there were no withdrawals.

Training

Subjects were first given an oral presentation with visual support, which lasted about 80 min. The presentation explained the purpose of the study, reviewed the relevant anatomy, and demonstrated each of the three techniques with schemas, drawings, and videos. Each cricothyrotomy technique was allowed approximately the same time in the presentation, about 20 min. After answering questions, one of the authors demonstrated the individual procedure sets in three smaller groups of subjects, and each subject was allowed to touch, experience, and ask questions on any aspects of the set and the procedure. The entire process lasted about 2 hr.

Surgical Techniques

The Melker set (Cook® Medical, USA), based on the popular Seldinger technique, involves the following: (1) an incision of the skin; (2) a needle puncture of the cricotracheal ligament; (3) localization of the airway by aspirating air bubbles in the fluid-filled syringe; (4) a guide wire placement through the needle into the trachea; (5) the removal of the syringe; (6) the dilation of the passage by a catheter placed over the guide wire; (7) the introduction of the ventilation cannula into the trachea. The conic end of the dilator is adapted to the hole of the cannula in order to facilitate the passage through tissues by making the leading edge rigid in addition to preventing injuries by blunting the relatively sharp edge of the cannula.

The QuickTrach device (VBM, Medizintechnik GmbH®, Germany) is made of a solid trocar-like insertion needle, on top of which is placed the ventilation cannula. The entire system is introduced together in a single move into the tracheal lumen, followed by the removal of the needle, leaving the cannula in its definitive place. The QuickTrach II is an evolution of the former model by including a cuffed cannula and a protection piece to prevent introducing the needle too deeply and injuring the posterior tracheal wall. The instructions manual of the QuickTrach II specifies that no skin incision is needed before introduction, because of the very sharp cutting end and tapered cone-shaped trocar.

The surgical technique consisted of a vertical skin and subcutaneous tissue incision. The cricothyroid ligament was then located with a finger within this wound, and a horizontal incision of the cricothyroid ligament was made. Whenever the cricothyroid ligament could easily be located through the intact skin, a single transfixing horizontal incision was also allowed. A fingertip was introduced into the tracheal lumen for dilation, passage size estimation, and to help the placement of a hook into the tracheal lumen. The hook was used to grab and pull on the cricoid cartilage anteriorly and inferiorly. A Shiley 4-LPC (Covidien, USA) cuffed cannula was then inserted into the tracheal lumen, followed by the removal of the hook. The surgical instruments available for the study were limited to a scalpel, a hook, and the cannula.

Palpation of critical landmarks such as the laryngeal superior prominence (Adam's apple), cricoid cartilage, and cricothyroid ligament was encouraged before beginning the procedure. For every technique, the subjects were taught to maintain the cadaver head in hyperextension with one hand, at least during the critical steps of the procedure.

Cannula

To avoid biases from previous studies,[9] cannulas of relatively similar sizes were employed: the outer diameter was

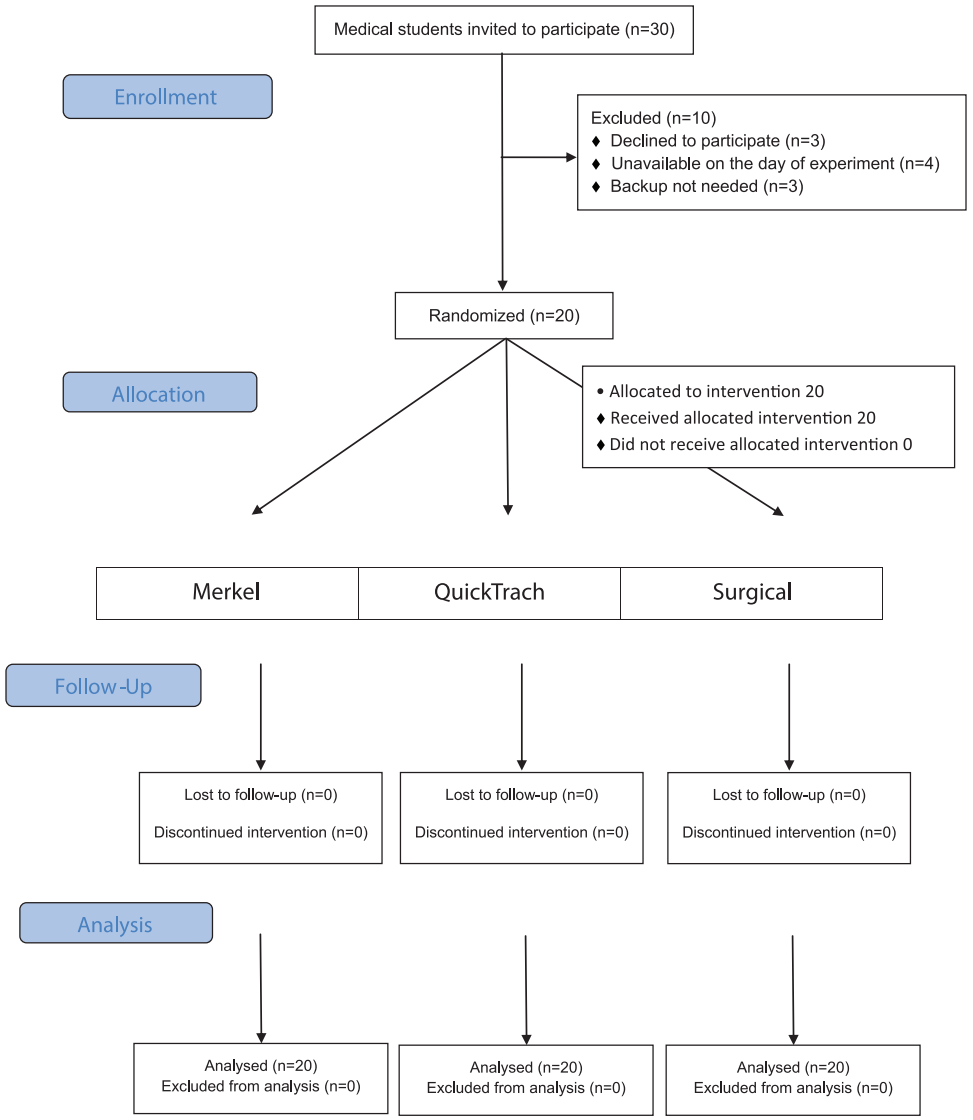

Fig. 1. The Consolidated Standards of Reporting Trials flowchart.

9.4 mm for the Shiley 4-LPC (surgical technique), 8.2 mm for the cannula provided with the Melker set, and 7.6 mm for the QuickTrach II cannula. Cuffed cannulas were chosen because the performance of uncuffed devices in airway obstruction has been found suboptimal.[17] A better matching of cannula sizes was not possible without modifying the existing device sets, thus raising other methodologic problems, such as matching of the needle, dilators, and trocar tips to the cannula.

Cadaver Preparation

Sixty adult human cadavers with an intact head, neck, and torso were randomly selected by one of the authors (Dr. Feigl). All cadavers were donated to the Institute of Anatomy of the Medical University Graz under its Anatomical Donation Program's approval and embalmed with Thiel's method.[18] This embalming method provides lifelike conditions and optimal preconditions for the investigative purpose of this study.[19,20]

For each cadaver, the following preoperative measures were collected: neck circumference at the level of the cricoid cartilage, the sternomental distance, the thyromental distance, as well as the possibility to palpate the cricothyroid ligament. Based on the neck circumference, cadavers were divided into two groups: big and thin. Each cadaver was used only once, so each procedure was performed on an intact neck. Each of the subjects had all three cadavers belonging to the same neck circumference group.

Randomization

The randomization proceeded separately in each cadaver group (30 cadavers divided into big and thin). The subjects were also randomly assigned to one of the cadaver groups. Then, each cadaver was randomly assigned to one procedure; finally, the

order of execution of the three different techniques per subject was also selected randomly. The randomization procedure was carried out by an online randomization algorithm (http://www.randomization.com) by one of the authors (Dr. Graber).

The randomization procedure was contained and resulted in 20 "identifiers" S1 to S10 (for small cadavers) and B1 to B10 (for big cadavers). These identifiers were written on paper cards, which were folded and placed in an opaque bucket. Before starting the experiment, each subject drew one card. For each identifier, the cadaver number and order were predetermined, and thus the procedure sequence. The cadaver identity for each of the three "sessions" was concealed until the beginning of the procedure, when each subject was directed to the attributed cadaver.

Outcome Variables

The success of the procedure was defined as the tip of the cannula placed within the tracheal lumen in 3 min. The time to perform the procedure was measured using a stop watch from the lifting of the coversheet placed over the head, neck, and torso to the completion of cannula insertion, according to the subject. The stop watch was started and stopped by the subject. The 3-min time limit was fixed because it is considered to be about the maximum duration before hypoxic lesions would occur, whenever no ventilation is performed, and because previous studies have found cricothyrotomy feasible in less time.[10] A stress factor was added by giving the subjects the time at every minute.[9] The subjects were allowed to continue the procedure up to 6 min, at which point they would be asked to stop for organizational purposes.

At the end of the procedure, the correct position of the cannula within the trachea was assessed by fiber-optic examination with a flexible endoscope inserted through the lumen of the cannula. In few doubtful cases, direct laryngoscopy with an intubation blade and concomitant endoscopic subglottic examination was used. In failures for both duration and misplacement, failure for misplacement was counted.

The cricothyrotomy cannula was then removed, and the wound, trachea, and larynx were further examined for possible lesions and false passage using rigid and flexible endoscopes. Finally, palpation of the larynx was used to evaluate for cartilage fractures that might have remained undetected. In doubtful cases, the neck incision was extended and the larynx was dissected.

The evaluation of complications was performed by two of the authors (Drs. Heymans and Dulguerov), without previous knowledge of the cricothyrotomy technique used, although differences in cannula aspects made for easy learning of the type of cricothyrotomy technique, and therefore no real blinding of the outcome evaluation can be claimed.

The entire experimental procedure of the three cricothyrotomy procedures and their evaluation lasted about 1 hr and was carried out at the dissection facilities of the Department of Anatomy, University of Graz. The outcomes were predefined and not modified during or after the experiment.

Preference Questionnaires

After the presentation of the surgical techniques and after the completion of the experiment, the subjects filled a questionnaire concerning their subjective preference for any of the technique and their confidence in performing the procedure in a real situation.

Statistical Analysis

We used success rates of cricothyrotomy to calculate sample size. Since no estimated rate of success for emergency cricothyrotomy by surgical airway–naive subjects is available, published difference in cricothyrotomy success rates of prehospital airway access techniques in patients[7] was used, with a conservative estimate of 20% difference. For an α error of 0.05 and 80% power, a sample size of 15 per group was calculated using G*Power (Heinrich-Heine-Universität Düsseldorf—http://www.gpower.hhu.de/)[21] for multigroup comparison of proportions using χ^2 statistics. The sample size was increased to 20 per group to allow for potential withdrawals and incompletion.

Characteristics of cadavers were compared using Student's *t* test for continuous variables and Pearson chi-square for categorical variables. Time of procedure between techniques was compared for significant differences with generalized estimating equations (GEE) with an identity link, an exchangeable correlation matrix, and a robust estimator to account for the fact that time of procedure may be skewed to the right. This model was used to account for nonindependence of the data due to the fact that each subject operated on three cadavers. Success proportions between techniques were also compared using generalized estimating equations but with a logit link. Since techniques and order of execution were randomized, all models included only techniques as predictor (no adjustment). *P* values for significant differences were set at 0.05 and bilateral tests used. The analysis was carried out with the IBM SPSS version 22 software package (International Business Machines Corporation, USA).

Results

The 20 subjects included in the study (10 men and 10 women) were between 22 and 28 yr old (mean age, 24.6 yr). They were recruited in December 2013, and there were no losses or exclusions after randomization; no follow-up problem were encountered since the experiment was carried out during a single day.

The cadavers' biometric data are detailed in table 1, and the differences between cricothyrotomy groups were not significant. Necks with a perimeter between 28 and 34.9 cm formed a first group of "thin neck," and the others, between 35 and 48 cm, formed the group of "big neck." The cricothyroid ligament was easily palpable in 51 cadavers, difficult to appreciate in 5, and not palpable in 4.

Ninety-five percent (19 of 20) of the surgical techniques were successful, compared to 55% (11 of 20) for the QuickTrach II and 50% (10 of 20) for the Melker groups

Table 1. Cadaver Characteristics (Mean ± SD) according to the Cricothyrotomy Techniques

Biometry	Surgical Technique (n = 20)	QuickTrach II (n = 20)	Melker (n = 20)	*P* Value
Age (yr)	78.2 ± 13.4	77.4 ± 13.8	75.1 ± 14.6	0.763
Men/women	12/8	11/9	13/7	0.846
Height (cm)	170.9 ± 8.0	169.1 ± 10.5	170.2 ± 8.7	0.814
Weight (kg)	73.9 ± 18.0	64.2 ± 11.6	69.8 ± 14.4	0.127
Cervical circumference (cm)	36.5 ± 4.5	35.3 ± 4.4	35.5 ± 3.4	0.619
Thyromental distance (cm)	8.7 ± 0.8	8.2 ± 1.1	8.4 ± 0.8	0.209
Sternomental distance (cm)	17.7 ± 1.5	17.3 ± 1.7	16.9 ± 1.4	0.260
Big/thin necks	10/10	10/10	10/10	1
Cricothyroid ligament palpable/difficult to palpate/not palpable	17/0/3	16/3/0	18/2/0	0.159

Table 2. Comparison of Efficacy and Safety Features of the Three Cricothyrotomy Techniques

	Surgical Technique (n = 20)	QuickTrach II (n = 20)	Melker (n = 20)	*P* Value
Success rate (%)	19 (95)	11 (55)	10 (50)	0.025
Failure due to time limitation (%)	0	1 (5)	4 (20)	0.203
Incorrect placement (%)	1 (5)	8 (40)	6 (30)	0.106
Cricothyrotomy time over 3 min	0	3	6	0.257
Time to complete the procedure—mean (s)	94 ± 35	77 ± 34	149 ± 24	< 0.001
Total complications in successful procedures	1	4	1	0.018
SPC: posterior tracheal wall lesion	1	3	1	
SPC: esophageal perforation		1		
Total complications in failed procedures	1	8	6	0.205
FPC: esophageal intubation	1	2	1	
FPC: pretracheal false passage		4	3	
FPC: cannula in pharynx		1	2	
FPC: broken device		1		

FPC = failed procedure complications; SPC = successful procedure complications.

(P = 0.025). The majority of failures were due to cannula misplacement, rather than time, except for the Melker set (table 2). In successful procedures, the mean procedure time was 94 ± 35 s in the surgical group, 77 ± 34 in the QuickTrach II group, and 149 ± 24 in the Melker group (fig. 2).

In successful procedures, only one complication occurred in both the surgical and Melker groups: a posterior tracheal wall superficial wound; in the QuickTrach II group, three superficial wounds of the posterior tracheal wall were present, while in one case, an esophageal perforation was found. Failures occurred because of cannulas placed outside of the trachea: one cannula in the surgical group was inserted into the esophagus; in the QuickTrach II group, four insertions were in the pretracheal soft tissues, two in the esophagus, and one through the larynx into the supraglottic larynx; in the Melker group, three cannulas were in the pretracheal soft tissues: one in the esophagus and two through the larynx into the supraglottic larynx.

Four cricothyroid ligaments were not palpable: three belonged to the surgical group and one to the QuickTrach II. Among the three belonging to the surgical group, all procedures were successful, whereas the one of the QuickTrach II group failed because of a false passage in the pretracheal tissue. There was no statistical difference in success rates between the "thin neck" and "big neck" groups according to the cricothyrotomy technique, and neither was any neck measurement correlated with cricothyrotomy success.

While the pretest preferences (table 3) seemed divided between the QuickTrach II and the surgical technique, the majority of the posttest preferences favored the surgical technique (P < 0.001).

Discussion

The "cannot-intubate, cannot-ventilate" situation seems to occur in 1 of 25,000 elective surgical procedures[2] and in 1 of 150 emergency field intubations.[4] Because of improvement of airway management algorithms, intubation devices, and neuromuscular blockade, the necessity of surgical airways has been declining,[22] raising questions for appropriate training, even for emergency department physicians.[23] A recent survey of graduating emergency department residents found that only 22% had performed cricothyrotomy on a patient.[24]

While the published success rates of highly trained personnel for cricothyrotomy remain high (above 90%),[25] the critical question is how and what to teach to the majority of

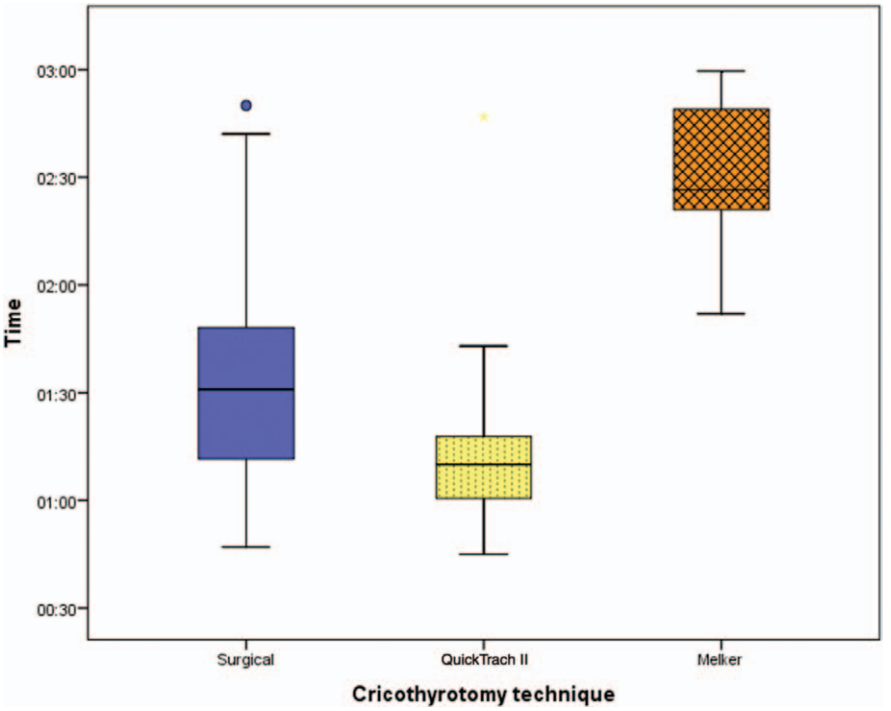

Fig. 2. Time to complete the procedure using the three cricothyrotomy techniques.

Table 3. Preferences of the Operators before (Pretest) and after (Posttest) the Cricothyrotomy Procedures

Preferences	Surgical Technique		QuickTrach II		Melker	
	Pretest	Posttest	Pretest	Posttest	Pretest	Posttest
The easiest	9	17	10	3	1	0
The fastest	7	17	13	3	0	0
The safest	12	20	2	0	6	0
The best	11	20	7	0	2	0

physicians. The only cadaver study with a design similar to ours, *i.e.*, with nonexperienced medical personnel as subjects, found similarly that surgical cricothyrotomy techniques performed better than the percutaneous ones.[8] Possibly, the surgical technique is more adaptable and forgiving since 70% of trained anesthesiologists have trouble localizing the exact site for percutaneous cricothyrotomy puncture.[26]

The reluctance to use a scalpel has to be transcended. Different cricothyrotomy sets were developed because some believe that the techniques are less invasive and more accessible to nonsurgeons. In untrained medical students, the performance with such sets was inferior to the surgical technique. Because of the infrequent performance of cricothyrotomy by the majority of physicians, we believe that our study closely resembles the knowledge and competence of the majority of the medical personnel. Therefore, we recommend that percutaneous cricothyrotomy sets be replaced in all "crash" carts by a scalpel or a set based on the surgical cricothyrotomy technique.

While the techniques used in commercial sets such as the Melker and QuickTrach appear standardized, there are variations in what is exactly the surgical technique.[27] After intact skin palpation of relevant structures (step 1), a vertical midline skin incision (step 2) is emphasized because it can be extended up or down if not correctly placed and because fewer vessels are located at the midline.[6] Although rarely emphasized, we recommend finger palpation through the subcutaneous tissue (step 3) and even in the trachea as a guide, as a dissector, and as a dilator; finger palpation is oblivious to bleeding and a better guide to the ligament, being the "surgeon's eye" during cricothyrotomy.[28] A horizontal incision of the lower aspect of the cricotracheal ligament[6] (step 4) allows for tension release and better opening. A hook permits to maintain the skin and the tracheal opening. Caudal traction (step 5) is recommended because the cricoid cartilage is more resistant and in order to prevent laryngeal injuries. We did not use a dilator, forceps, or a retractor during this experiment. Finally, a cuffed cannula is inserted (step 6). The different names used in the literature correspond often in lumping different steps together rather than actual variations, as in the "rapid four-step technique"[29] or the "three-step technique."[30] Possibly, a standardized approach and a wider hook might reduce the procedure time.[31]

Several shortcomings of this study can be foreseen. First, although the anatomy of human cadavers make the experiment realistic, it still does not correspond to the real situation, especially for bleeding and other stress factors. Cadavers do not bleed, and this could result in an overestimation of the surgical cricothyrotomy success in the current study. Lesser bleeding is seen as an advantage with the percutaneous techniques,[10] but bleeding could be minimized if the palpation technique is emphasized in surgical cricothyrotomy. Stress is certainly a major factor during cricothyrotomy in alive patients, but there is no clear reason why stress would favor one of the cricothyrotomy techniques in the current study. Since it is probably impossible to realize a prospective randomized study on cricothyrotomy, it is difficult to study these questions more realistically.

Second, the effect of training (learning curve) on the outcome has not been addressed in this study: if we have demonstrated that untrained medical personnel should be advised to use a surgical cricothyrotomy, it remains unclear whether with the repetition of the procedure the outcome might be different, *i.e.*, percutaneous techniques being as successful as or more successful than surgical cricothyrotomy. However, previous studies in emergency department physicians do not necessarily support that idea: in repeating cricothyrotomy seven times in human cadavers, no clear learning curve was observed.[12] A somewhat related question is what cricothyrotomy should trained medical personnel (surgeons, anesthetists, emergent department physicians, or paramedics) use. Previous cadaver studies found similar performance for surgical cricothyrotomy and the Melker set by intensive care[9] and emergency department[10,12] physicians, and therefore we tend to recommend surgical cricothyrotomy for all medical personnel. However, newer technologies such as ultrasound guidance of percutaneous systems might improve their success rate in the future.[32,33]

In conclusion, our results indicate that medical personnel naive to surgical airway techniques establish a surgical airway more efficiently using surgical cricothyroidotomy. Since the vast majority of clinicians perform emergency airway infrequently, our observation might apply to the majority of them. Whether surgical cricothyrotomy remains superior in advance-trained medical personnel requires further study.

Research Support

Cricothyrotomy sets were obtained at a discount price from manufacturers. Travel expenses were paid by departmental funds. Cadavers were provided by the Institute of Anatomy, Medical University of Graz, Graz, Austria.

Competing Interests

The authors declare no competing interests.

Reproducible Science

Full protocol available at: pavel.dulguerov@hcuge.ch. Raw data available at: pavel.dulguerov@hcuge.ch.

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Appendix

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	9
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	9
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
	11b	If relevant, description of the similarity of interventions	6-7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11
	13b	For each group, losses and exclusions after randomisation, together with reasons	11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14-5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-5
Other information			
Registration	23	Registration number and name of trial registry	NA
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.