INTRODUCTION

The Emergency Cricothyroidotomy (EC) constitutes the final step in difficult airway algorithms and secures a patent airway via a front-of-neck access. Among the various available EC techniques, the main distinction is whether the procedure is surgical and scalpel-based EC or percutaneous and needle-based EC.

The EC is a seldom, but crucial, event. The procedure normally follows other conventional airway manoeuvres. When the EC procedure is called up on, the patient may have a rapidly deteriorating oxygenation, and the EC is often associated with a critical clinical situation.

Background: Airway management is a paramount clinical skill for the anaesthesiologist. The Emergency Cricothyroidotomy (EC) constitutes the final step in difficult airway algorithms securing a patent airway via a front-of-neck access. The main distinction among available techniques is whether the procedure is surgical and scalpel-based or percutaneous and needle-based.

Methods: In an experimental randomized crossover trial, using an animal larynx model, we compared two EC techniques; the Rapid Four Step Technique and the Melker Emergency Cricothyrotomy Kit®. We assessed time expenditure and success rates among 20 anaesthesiologists and related this to previous training, seniority and clinical experience with EC.

Results: All participants achieved successful airway access with both methods. Average time to successful airway access for scalpel-based EC was 54 (±31) seconds and for percutaneous EC 89 (±38) seconds, with 35 (95% CI: 14–57) seconds time difference, \( P = .003 \). Doctors with recent (<12 months) EC training performed better compared to the non-training group (37 vs 61 seconds, \( P = .03 \) for scalpel-based EC, and 65 vs 99 seconds, \( P = .02 \) for percutaneous EC). We found no differences according to clinical seniority or previous real-life EC experience.

Conclusions: Our study demonstrated that anaesthesiologists achieved successful airway access on an animal experimental model with both EC methods within a reasonable time frame, but the scalpel-based EC is performed more promptly. Recent EC training affected the time expenditure positively, while seniority and clinical EC experience did not. EC procedures should be regularly trained for.
Experimental studies have shown opposing findings regarding success rate and time expenditure for the different techniques. New knowledge can be determining for future quality standards, and further studies are recommended.6-11

The 2015 recommendations by The UK Difficult Airway Society advocate a surgical approach in the “cannot intubate, cannot oxygenate”(CICO)-situation.2 This followed the 2011 National Audit by the Royal College of Anaesthetists (NAP4), where a high failure rate is found in anaesthesiologist-performed percutaneous EC compared to the predominantly surgeon-performed scalpel-based EC.12

In Norway, characterized by numerous smaller hospitals, anaesthesiologists are expected to resolve all aspects of a CICO-situation, and percutaneous EC with The Melker Emergency Cricothyroidotomy Kit is still in use.

The aim of this study was to compare anaesthesiologists' success rate and time expenditure of scalpel-based EC with the Rapid Four-Step Technique and percutaneous EC with The Melker Emergency Cricothyrotomy Set on an experimental animal model. We also assessed the impact of previous training, previous clinical experience with EC, and seniority.

2 | METHODS

2.1 | Ethics

Oslo University Hospital Data Protection Official approved the study, Ref. no. 2014/15394. All participants signed an informed consent form. Live animals were not used, and the study was exempted from formal ethical approval by the Regional Ethics Committee.

2.2 | Study design and participants

The study was an experimental randomized crossover trial using an animal larynx model to compare two EC techniques. The scalpel-based Rapid Four Step-Technique and The Melker Emergency Cricothyrotomy Kit® by Cook Medical, USA, which is a Seldinger-based percutaneous procedure,13,14

It is stated that the ovine larynx is similar to human airways and can be a realistic experimental model, closely approximating an adult human larynx with similar insertion- and penetration forces during cricothyroid cannulation.15-17 The ovine larynx has been widely used in experimental settings.15,18,19

In this study-model the airway consisted of airway structures from sheep, extending from base of tongue to the level of the distal trachea, with overlying skin and subcutaneous tissue from chicken. The study model was placed on an examination table. The participants could stand on either side of the model, and they were able to stabilize it with a “laryngeal handshake”.20 The experimental model is shown in Figure 1.

Both procedures were performed in randomized order determined by drawing a card from an envelope to nullify a learning effect. The procedures were undergone theoretically by the principal investigators, and the participants had the possibility to familiarize themselves with the equipment set-up. In the Rapid Four Step-technique we used a Scalpel No. 10 (Swann-Morton®, England), a tracheal hook (18 cm retractor with blunt prong, Heljestrand®, Sweden), a cuffed 6.0 mm Endotracheal tube cut at 20 cm (Mallinckrodt®, Ireland), a 10 cc syringe (Terumo®, Belgium) and a self-inflatable bag (Ambu® Resuscitator). The set-up is shown in Figure 2.

A Ovine larynx build up with subcutaneous fat and overlying skin from chicken.

B Experimental model stabilised by “laryngeal handshake”.

C “Laryngeal handshake” and scalpel incision.

FIGURE 1 Experimental model. A, Ovine larynx build up with subcutaneous fat and overlying skin from chicken. B, Experimental model stabilized by “laryngeal handshake”. C, “Laryngeal handshake” and scalpel incision.
In the percutaneous technique we used The Melker Kit® containing a mini scalpel No. 15, a 18 G cannula introducer needle (7 cm), a 6 cc syringe, a guide wire and a 5.0 mm tracheostomy tube mounted on a curved introducer and a self-inflatable bag (Ambu® Resuscitator). In addition we used a 10 cc syringe (Terumo®, Belgium) to inflate the cuff. The set-up is shown in Figure 3.

The focus was on the technical skill performance of the procedure, and no external stressors were introduced. After conduction of the procedure, the principal investigators inspected the specimen. Correct placement and eventual tracheal damages was noted. The participants conducted the first and second procedure consecutively. All participants performed both procedures.

2.3 | Outcome measures

The primary outcome measure was duration of the procedure until successful airway access for the two EC techniques.

We measured the time interval from the first skin incision to the first successful inflation with a self-inflatable bag (Ambu® Resuscitator) on the tube successfully placed in the trachea on the airway model.

As the EC procedure is the last step in securing a patent airway in an emergency situation, there was no cut-off time defining failure to perform the procedure. We had pre-defined failure as the participant not being able to access the trachea and/or not achieving successful airway access.

Secondary outcome measures were the impact of seniority, previous EC training and clinical experience with EC situations, on the duration of the procedures, and on the overall success of the procedure. We defined previous EC-training as organized animal-, manikin- or cadaver-training within 12 months prior to the study. Our test model was not introduced to the participants prior to the day of the experiment.

2.4 | Statistical analysis

The results are stated in seconds with standard deviation (SD). We used paired samples T test to assess the time difference for the primary outcome measure. Independent samples T test was used to compare the performance of the different subgroups. Two-tailed test was used and significance assumed for \( P < .05 \). The time difference between the procedures in the dataset was tested for normality, and found to be normally distributed. We used SPSS-software (Statistical Package for the Social Sciences, IBM, version 24) for statistical analysis of study results, and sample size was estimated with Statulator Sample Size Calculator (Statulator.com).

Based on previous studies, we assumed mean time to successful ventilation to be 60 and 80 seconds for scalpel-based EC and percutaneous EC, respectively.\(^9\) With an expected 20 seconds difference for the two groups and a SD of 20 seconds, we would need 14 pairs to determine with 90% power a two-sided \( P < .05 \).

3 | RESULTS

Twenty anaesthesiologists participated in the experiment. All participants achieved successful airway access with both scalpel-based EC and percutaneous EC. The mean time to successful airway access was 54 (±31) seconds for scalpel-based EC and 89 (±38) seconds for percutaneous EC. Thus, the scalpel-based EC was significantly faster than percutaneous EC with a time difference of 35 (95% CI: 14-57) seconds, \( P = .003 \) (Table 1).

One incision penetrated the dorsal trachea during a scalpel-based EC procedure and the tube was initially erroneously placed in the mediastinum. This was acknowledged when attempting to ventilate with the self-inflatable bag (Ambu® Resuscitator), and the procedure was continued until successful placement was achieved. The longest time to achieve successful airway access was 152 and 174 seconds for scalpel-based EC and percutaneous EC, respectively.
Six doctors (30%) had participated in EC training within 12 months prior to the study. This group was significantly faster than the no-training group to perform both scalpel-based EC and percutaneous EC (Table 1).

Having performed EC in a real life situation (n = 5), or being a consultant (n = 7) vs resident anaesthesiologist, did not significantly affect the time spent to successfully perform the procedures.

Doctors performing scalpel-based EC first (n = 10) used in mean 60 and 47 seconds for the percutaneous EC and the scalpel-based EC procedure, respectively. Doctors performing percutaneous EC first used in mean 93 and 85 seconds for the percutaneous EC and the scalpel-based EC procedure, respectively (Table 2).

The participants were asked to grade three statements regarding the two procedures and the expected usefulness of the experiment in future clinical situations on a Likert-scale (1 = disagree completely, 7 = agree completely) (Table 3).

### DISCUSSION

Our study shows that on an experimental animal model, anaesthesiologists at a mid-sized Norwegian hospital performed a scalpel-based EC-procedure more promptly than the percutaneous procedure. Still, all participants achieved successful airway access with either EC procedure within a reasonable time frame. Previous EC training affected the results positively, while seniority and clinical experience with the EC procedure did not.

Randomized studies comparing needle- with scalpel-based EC techniques are necessarily experimental, and various models

### TABLE 1

Overall results (in s) regarding scalpel-based emergency cricothyroidotomy and percutaneous cricothyroidotomy with mean time to successful airway access, standard deviation (SD) and P-value for comparison (two-sided, paired, t test)

|                      | Scalpel-based EC | Percutaneous EC |
|----------------------|------------------|-----------------|
| **Overall results**  |                  |                 |
| Time (s) SD P-value  | 54 31 .003       | 89 38 .003      |
| **Subgroups**        |                  |                 |
| Consultant+          | 65 44 .36        | 100 31 .31      |
| Consultant−          | 48 22            | 83 41           |
| EC training last 12-mo + | 37 10 .03   | 65 17 .02      |
| EC training last 12-mo− | 61 35       | 99 40           |
| CICO clinical experience+ | 60 29 .59 | 75 20 .21      |
| CICO clinical experience− | 51 33       | 94 41           |

**Note:** Subgroup results (in s) with mean time to successful airway access, SD and P-values for comparison (two-sided, unpaired, t test)

### TABLE 2

Characteristics and time to successful airway access according to group randomization

|                      | Scalpel-based | Percutaneous | Consultant | EC training last 12 mo | EC clinical experience |
|----------------------|---------------|--------------|------------|------------------------|------------------------|
| **Scalpel-based**    |               |              |            |                        |                        |
| Procedure first      | 47 3          | 60           | 3          | 2                      | 2                      |
| (n = 10)             |               |              |            |                        |                        |
| **Percutaneous**     |               |              |            |                        |                        |
| Procedure first      | 85            | 93           | 4          | 4                      | 2                      |
| (n = 10)             |               |              |            |                        |                        |

### TABLE 3

Participants’ evaluation of the experiment after conduction, graded on a Likert-scale. (1 = disagree completely, 7 = agree completely)

|                                    | Mean value | Standard deviation | 95% confidence interval |
|------------------------------------|------------|--------------------|-------------------------|
| The conduction of the scalpel based-technique taught me something useful for my clinical practice | 6.3        | 0.9                | (5.6-6.8)               |
| The conduction of the Seldinger-procedure taught me something useful for my clinical practice | 6.2        | 1.0                | (5.7-6.7)               |
| Do you feel more confident to resolve a “Cannot intubate, cannot oxygenate”-situation after participating in this experiment? | 6.1        | 1.0                | (5.6-6.7)               |
are used, eg artificial airways/manikin models, animal models and human cadavers. Results have been inconsistent, favouring both EC techniques.

Some studies have been inconclusive regarding time expenditure for the different procedures,\(^5,21\) while others have found the scalpel-based EC being the more rapid procedure.\(^7,22\) To our knowledge, no experimental studies have reported the Melker Kit to be faster than a scalpel-based EC, however Schaumann and colleagues found that percutaneous EC with the Arndt Emergency Cricothyroidotomy Catheter Set (Cook Critical Care, Bloomington, IN) was significantly faster than the scalpel-based EC.\(^27\)

Regarding success rate, some experimental studies have reported scalpel-based EC to be the procedure of choice.\(^22,24\) Mariappa and colleagues, however, found 100% success-rates for the Melker Kit, vs 55% success for a surgical procedure.\(^6\) One study found very high complication-rate for the Melker Kit, 64%.\(^28\) This is in contrast with our study, where we found no complications with the Melker Kit and a 5% complication rate with scalpel-based EC.

Experimental EC studies are criticized for being underpowered and too heterogeneous.\(^5,10,29\) Definition of start- and end-points for time measurements and the simulated clinical scenarios vary. This implies that it is hard to make comparisons between the results. EC studies use different approaches, different kind of models, and there are also major differences in the participants background. This makes overall interpretation difficult. Using results from previous studies, adjusting for the different definitions used, there is sufficient data available to do meaningful assessment of required sample size.\(^5,15,22\) Defining time expenditure from first skin incision/puncture to successful ventilation attempt with a self-inflatable bag on the endotracheal tube correctly placed in the trachea is in line with previous studies, excludes factors such as availability of equipment, and can be translated to a clinical setting.\(^15,30\) Using cut-off times to define failure is arguably not translatable to a clinical CICO-situation where the EC procedure is a last resort.

Animal models represent a limitation, as it is at best a moderately realistic proxy for the CICO-situation. The anatomical factors associated with a difficult airway, the bleeding from perfused tissue, and the psychological stress associated with a CICO-event in a clinical setting, is not reproducible in an experimental model. Still, several authors have advocated the importance of both the training and the technical assessment that simulation and experimental study designs allow for.\(^31\) Our model is in accordance with previous research, and the results from the questionnaire after the procedure (Table 3) indicate that the participants experienced the model as relevant to their clinical work.

We measured the time spent for the actual performance of the procedure, and any differences between the two procedures regarding preparation of the two different methods are not included. We find it reasonable that any difference in preparation-time goes in favour of a scalpel-based approach, and thus in the direction of our principal finding.

The group randomized to do the scalpel-based technique first, performed both procedures faster than the opposite group. In a crossover design, there is always a possibility for bias because of a learning-effect. In this experiment the two groups were adequately randomized, and the apparent advantage to start with the scalpel-based technique remains unexplained.

An additional limitation is the unavoidable open design where both clinicians and assessors are aware of which EC method is tested. The number of participants recruited was scaled according to the sample size estimates to assess the primary outcome. The numbers in each subgroup are therefore small, hence the results from the subgroup analyses should be interpreted with caution.

The debate whether to discontinue needle-based percutaneous EC techniques continues.\(^37\) Observational data have been strongly in favour of surgical techniques. However, there are important system-specific aspects to consider. The NAP4 results were based on findings in a health care system where surgeons are readily available to perform scalpel-based EC.\(^12\) Other observations are based on pre-hospital data with EC performed by both anaesthesiologists and emergency physicians.\(^38\) For settings where anaesthesiologists are the only available resource to resolve all aspects of airway management, it is the preference and the performance of the anaesthesiologist, which should guide the future direction. Anaesthesiologists may prefer needle-based techniques due to familiarity with Seldinger-based vascular access procedures.\(^21,41,42\) To date, experimental studies have not shown superiority in the anaesthesiologists’ performance of any EC technique to the extent where one can discard the rest.\(^5,10\) The option to choose either a surgical or a percutaneous EC procedure therefore remains in several difficult airway guidelines.\(^1,4,43\) The extremely high failure rate of percutaneous EC in the NAP4 certainly calls for validation of the results as well as further analysis of contributing factors. Several system and technical factors are suggested in the report, but the need for anaesthesiologists to keep their EC skills updated, irrespective of the EC method of choice, is a key recommendation.

5 | CONCLUSION

The study shows that there are benefits in terms of time expenditure for choosing a scalpel-based EC in the time critical CICO-situation. However, the attempted percutaneous EC all resulted in successful ventilation on the animal larynx model. The 35-second time difference should be taken into consideration when choosing preferred EC technique, both at an individual practitioner and at a system-level. Regardless of the chosen strategy, the EC procedure should be regularly trained for.

CONFLICT OF INTERESTS

None declared.

ORCID

Åke Erling L. Andresen  https://orcid.org/0000-0002-5445-0096
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