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RESEARCH REPORT

Emergency front-of-neck access in infants: A pragmatic crossover randomized control trial comparing two approaches on a simulated rabbit model

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Abstract

Background: Rapid-sequence tracheotomy and scalpel-bougie tracheotomy are two published approaches for establishing emergency front-of-neck access in infants. It is unknown whether there is a difference in performance times and success rates between the two approaches.

Aims: The aim of this cross-over randomized control trial study was to investigate whether the two approaches were equivalent for establishing tracheal access in rabbit cadavers. The underlying hypothesis was that the time to achieve the tracheal access is the same with both techniques.

Methods: Between May and September 2022, thirty physicians (pediatric anesthesiologists and intensivists) were randomized to perform front-of-neck access using one and then the other technique: rapid-sequence tracheotomy and scalpel-bougie tracheotomy. After watching training videos, each technique was practiced four times followed by a final tracheotomy during which study measurements were obtained. Based on existing data, an equivalence margin was set at $\Delta = \pm 10$ s for the duration of the procedure. The primary outcome was defined as the duration until tracheal tube placement was achieved successfully. Secondary outcomes included success rate, structural injuries, and subjective participant self-evaluation.

Results: The median duration of the scalpel-bougie tracheotomy was 48 s (95% CI: 37–57), while the duration of the rapid-sequence tracheotomy was 59 s (95% CI: 49–66, $p = .07$). The difference in the median duration between the two approaches was 11 s (95% CI: −4.9 to 29). The overall success rate was 93.3% (95% CI: 83.8%–98.2%). The scalpel-bougie tracheotomy resulted in significantly fewer damaged tracheal rings and was preferred among participants.

Conclusions: The scalpel-bougie tracheotomy was slightly faster than the rapid-sequence tracheotomy and favored by participants, with fewer tracheal injuries. Therefore,

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we propose the scalpel-bougie tracheostomy as a rescue approach favoring the similarity to the adult approach for small children. The use of a comparable equipment kit for both children and adults facilitates standardization, performance, and logistics.

Trial Registration: ClinicalTrials.gov identifier: NCT05499273.

KEYWORDS

airway management, children—emergency front of neck access—cannot intubate, cannot ventilate, simulated difficult airway, surgical approaches

1 | BACKGROUND

A "cannot intubate, cannot oxygenate" (CICO) situation during airway management is rare but associated with adverse outcome.[1,2] A UK database of airway management reported a CICO incidence of 0.24% in adults describing one case in 225 patients with difficult airway management, and an even lower incidence in children.[3,4] A recent prehospital emergency front-of-neck access (eFONA) systematic review reported only five studies with 29 children and a pooled success rate of 74% with a variety of techniques.[5] There is a lack of knowledge regarding epidemiology and how to perform eFONA in children younger than 8 years of age. When a CICO situation occurs, the subsequent onset is hypoxemia and ensuing bradycardia demand time-sensitive decisive action.[6] Untreated hypoxemia leads to cardiac arrest, brain injury, and, ultimately, death within minutes.[6,7] Rapid surgical tracheal access is the final common step in pediatric difficult airway algorithms for re-establishing oxygenation.[1,2,6]

Pediatric airway practitioners should be prepared to promptly perform eFONA. Training should reflect the challenges posed by a pediatric CICO situation realistically. Two recent studies have explored eFONA approaches using predefined tracheotomy kits on a rabbit cadaver.[8,9] The rapid sequence tracheotomy (RST) approach is remarkable for the anterior luxation of the trachea, which consists of encircling the trachea with a Backhaus clamp and pulling it anteriorly, facilitating the vertical puncture of the tracheal cartilage with the tip of a scissors before inserting the tracheal tube.[8] The scalpel-bougie-tracheotomy (SBT) approach does not require anterior luxation of the trachea but calls for a vertical incision of the trachea with the tip of a scalpel, followed by the insertion of a bougie over which the tracheal tube is introduced into the trachea.[9] In both studies, participating airway practitioners successfully established eFONA in less than 1 min while demonstrating a measurable learning curve within a few attempts.

Both studies lacked the elements of situational mental stress posed by an eFONA procedure performed on a child suffering a real-life CICO situation, including concurring hemorrhage and the acoustics of crashing vital signs. The objective of this pragmatic, randomized controlled cross-over equivalence study was to compare the performance times of the two above-mentioned approaches in a simulated environment with enhanced realism. The underlying hypothesis was that emergency front-of-neck access can be achieved with both techniques in equal time. Pediatric airway practitioners were confronted with a realistic eFONA-training model that encompassed anatomical, psychological, and clinical challenges.

2 | MATERIALS AND METHODS

The Cantonal Ethics Committee Bern determined that this study did not require approval based on Swiss human research laws (Req-2022-00174). Following ClinicalTrials.gov registration (NCT05499273), and after signing informed consent, 30 physicians (15 pediatric intensivists and 15 pediatric anesthesiologists) were randomized to two groups. The randomization was generated by an independent research team member using a secure online service (www.sealedenvelope.com) and kept in sealed opaque envelopes until the first training session. Study participants were randomized in blocks of 10.

Study participants in Group 1, first watched the RST training video[10] and then practiced the RST approach on four rabbit cadavers. Following these four practice sessions, participants performed the study assessment for RST, which was video recorded. Subsequently Group 1 participants watched the SBT training video,[9] practiced the SBT approach on four rabbit cadavers and then performed the study assessment of SBT which was also video recorded.

The RST-eFONA technique consists of the following steps[8]:

1. Tracheal location and palpation, vertical midline skin incision followed by strap muscle separation.
2. Exposure of the trachea and cricoid followed by anterior luxation of the trachea with a Backhaus towel clamp.
3. Vertical puncture with a tip scissors between the cricoid and the 1st tracheal ring followed by a vertical incision of no more than two rings.
4. Insertion of an age adapted endotracheal tube into the trachea followed by lung ventilation.

The SBT eFONA technique consists of the following steps[9]:

1. Tracheal palpation and vertical midline skin incision of 2–3 cm from the cricoid in a caudal direction followed by a layer-by-layer incision down to the external surface of the trachea.
2. Longitudinal tracheal incision of two/three rings.
3. Insertion of an 8 Fr Frova intubation catheter through the incision into the distal trachea.

4. Insertion of a tracheal tube (inner diameter 3.0 mm, cuffed) over the Frova catheter securing the airway permanently.

Figure 1 reports the steps of both techniques, and a video can be downloaded from supplemental material (Video S1).

Group 2 participants followed the same practice sessions and assessment tracheotomies as Group 1 for both approaches but in reverse sequence, first the SBT, followed by the RST (Figure 1).

Throughout the trial, participants could rewatch either instructional video as often as desired. Participants were advised to execute tracheotomies in less than 1 min, keep the skin incision to an achievable minimum, spare the first tracheal ring, sever no more than two tracheal rings, and minimize collateral damage to neighboring structures and organs.

The simulated pediatric airway provided for this study was the cranial portion (from the diaphragm on up) of rabbit cadavers (Zika-Zimmermann rabbits, aged 81–89 days, weighing 2.7–3.3 kg) with the neck portion shaved in a standardized rectangular shape from the mandible to the clavicle, as described earlier.[8,9,11–13] Rabbit cadavers were acquired commercially, after having been slaughtered exclusively for food production purposes unrelated to this study. This was done under the supervision of a veterinarian, and in accordance with Swiss law. Prior to tracheotomy, the torso of the rabbit was strapped in a supine position with the head inside a baby mannequin's head, and a shoulder roll placed behind the rabbit's neck to induce hyperextension, simulating the anatomical conditions of a newborn (Figure 1). Participants were given a fresh rabbit cadaver at each eFONA training and assessment attempt. Psychological

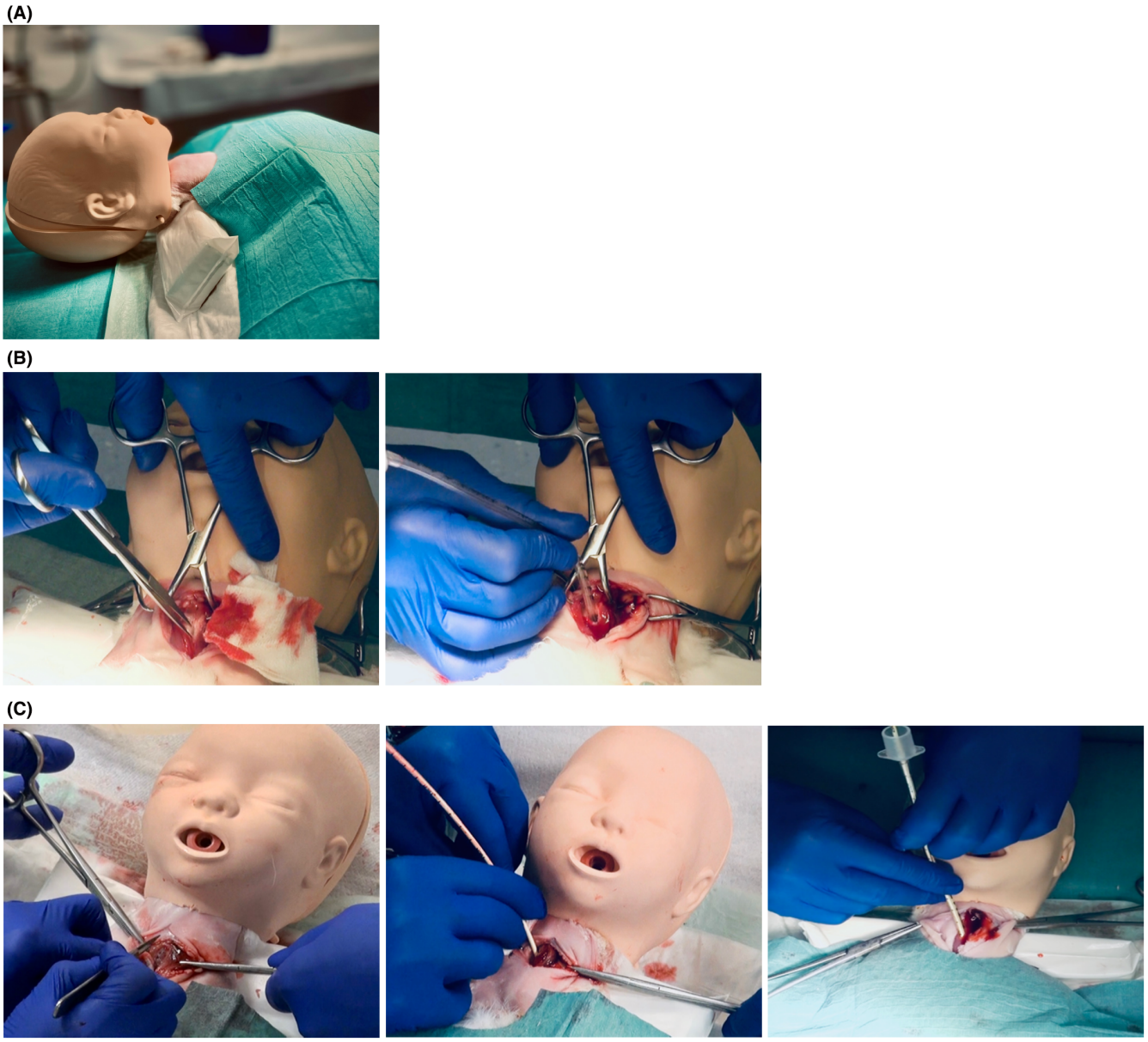

FIGURE 1 (A) Rabbit cadaver position; (B) rapid-sequence-tracheotomy approach, with the tracheal luxation and tube insertion; (C) scalpel-bougie-tracheotomy approach, with tracheal incision, bougie insertion, followed by tube insertion.

stressors were induced by an audible computer-generated oxygen saturation monitor and concurring tone, indicating continuous desaturation and ensuing bradycardia (Laerdal Debrief Viewer). During the eFONA attempts, artificial blood (SAFEX-Universal-Effektblut C, Günther-Schaidt Safex-Chemie GmbH, Tangstedt, Germany) with a continuous infusion rate of 200 mL/h through a subcutaneously placed 16 Gauge peripheral infusion catheter was used to enhance clinical realism.

The primary outcome was the performance times of the tracheotomy approaches measured from the time the skin was touched until the ventilation bag was connected. Procedure times of more than 2 min were rated as unsuccessful.

Secondary outcomes were success rate, injuries to the cricoid, the thyroid, number of damaged tracheal rings, perforation of the posterior tracheal wall, paratracheal tube placement, length of skin incision, and subjective participant self-evaluation of performance

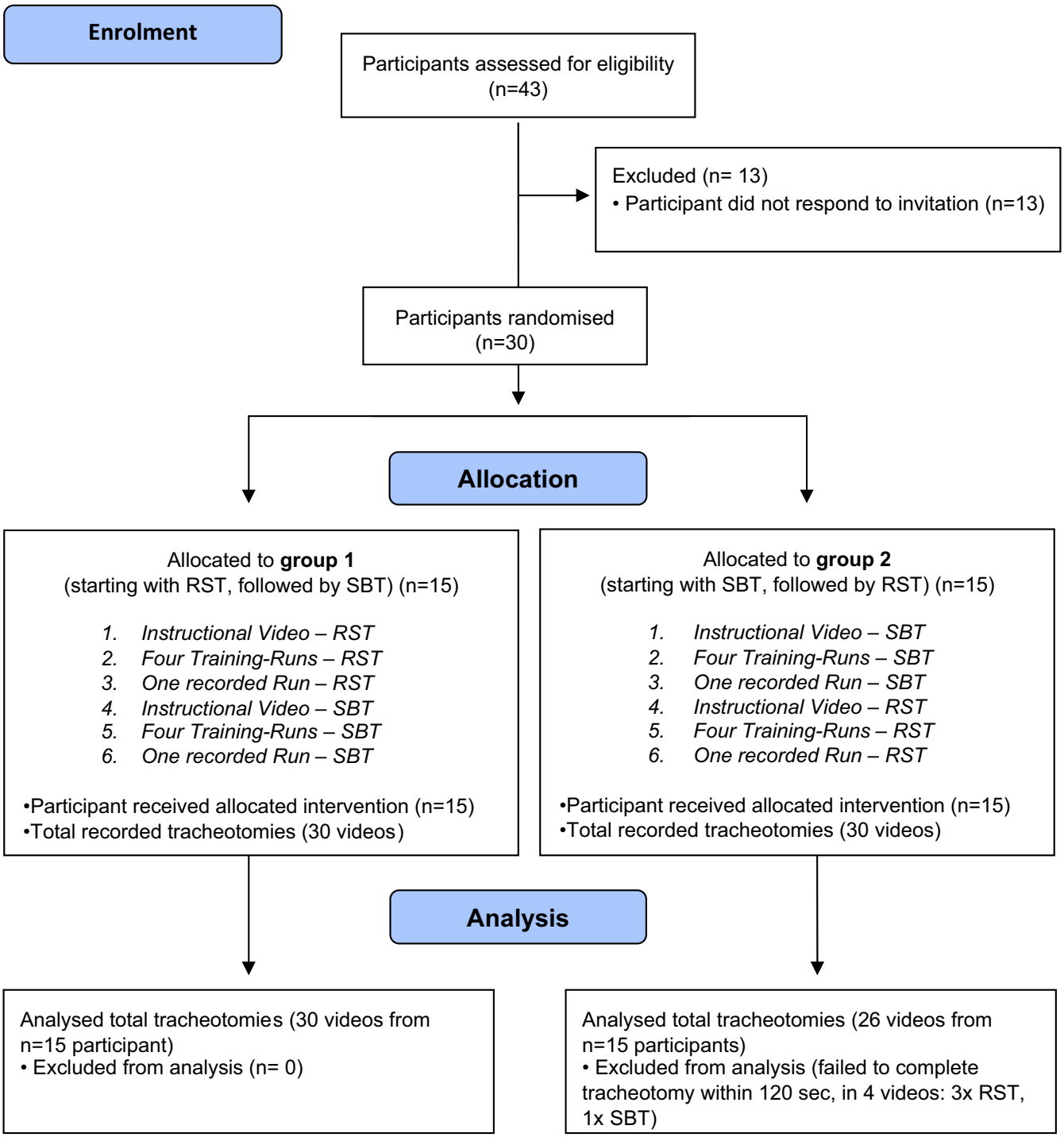

FIGURE 2 CONSORT flow diagram. Thirty participants were invited to participate (enrolment). They performed one technique and then the other in accordance with group allocation. A total of 56 videos were analyzed.

after the participants had completed both tracheotomy assessments. Participant characteristics, including age, sex, experience, specialty, and grade of medical staff were recorded. The self-assessment questionnaire (integer scale 0 no agreement to 10 best agreement) queried their eFONA competence, confidence, and comparative and subjective preference of the two approaches.

3 | STATISTICS

Due to the logistical constraints of the study a predefined, a priori sample size of 30 participants was set. Based on previous data,[8,9] we chose an equivalence design and we estimated an equivalence margin of $\Delta = \pm 10$ s for the procedure duration. The null hypothesis of the study was that the performance time of the two emergency front-of-the-neck access approaches is not equivalent. After 11 participants had completed the study, an exploratory data analysis was performed with no impact on the predefined sample size. However, we adjusted the significance level of the final analysis accordingly ($\alpha = .0492$ according to an O'Brien-Fleming approach).

Categorical variables were summarized with counts and percentages. Numerical quantities were summarized with mean and standard deviation for normally distributed variables (determined using a Shapiro-Wilks test) and with median and interquartile range otherwise. Differences in participant characteristics between the two sequences were assessed using standardized mean differences.

For the analysis of outcomes, only successful attempts were considered when analyzing the primary, secondary, and exploratory outcomes. For the primary outcome, a linear mixed effect model with a random offset for each participant to account for the repeated measure design of this study assessed the carry-over effect concerning the treatment sequence. Because the primary outcome was skewed, an Ordered Quantile transformation was applied. The statistical significance of carry-over of the sequence of the treatment groups (i.e., RST first, then SBT vs. SBT first, then RST) was examined using a likelihood-ratio test. Since the sequence was not statistically significant for the primary outcome, the difference in duration between RST and SBT was computed using quantile regression and the associated estimated marginal means.

Equivalence was determined based on the inspection of the lower and upper boundaries of the 95.1% confidence interval of the mean difference in median duration times. Equivalence was declared when the lower and upper boundaries were within the predefined margin of $\Delta = \pm 10$ s. The duration of each individual method was shown with the median and bootstrapped 95.1% confidence intervals for the median.

The secondary outcomes were analyzed in a similar manner. Depending on the distribution of the outcome, a generalized linear mixed model (GLMM) was calculated, and the statistical significance of the order of the treatment groups was examined using a likelihood-ratio test. Outcomes with percentages were analyzed with a GLMM using a binomial distribution. Outcomes with bounded values (i.e., the questionnaire) employed a GLMM with a beta distribution and transformed values in the (0,1) interval to properly account for the bounded value range of the answers to the questionnaire.

No *p*-value adjustments for multiple comparisons were performed for exploratory outcomes. Missing data are reported in the tables and no imputation was performed. All analyses were performed using R version 4.0.2.

4 | RESULTS

A total of 60 evaluated emergency tracheotomies were performed by 30 study participants (Consort Diagram and participant characteristics are shown in Figure 2 and Table 1). The median performance time was as follows: 48.0 s (95% CI: 37.0–57.0) with SBT versus 59.0 s

TABLE 1 Baseline participants' characteristics. Data presented as *n* (%), mean (SMD).

	Group 1	Group 2	
	N = 15	*N* = 15	SMD
Age (y)	42.5 (7.0)	41.7 (7.6)	0.11
Sex, female	5 (33.3%)	8 (53.3%)	0.40
Have you ever performed an emergency tracheotomy on a human being?	6 (40.0%)	5 (33.3%)	0.14
Have you ever performed a tracheotomy on a rabbit cadaver?	7 (46.7%)	4 (26.7%)	0.42
Have you ever performed a tracheotomy in a simulation?	12 (80.0%)	8 (53.3%)	0.59
Speciality			
Pediatric anesthesia	6 (40.0%)	9 (60.0%)	0.41
Pediatric critical care	9 (60.0%)	6 (40.0%)	
Grade of medical staff			
Registrar	2 (13.3%)	2 (13.3%)	1.15
Consultant	8 (53.3%)	12 (80.0%)	
Head of department	5 (33.3%)	1 (6.7%)	

TABLE 2 Primary and secondary outcomes for all attempts and stratified by rapid-sequence-tracheotomy (RST) and scalpel-bougie-tracheotomy (SBT) approach.

	All attempts	Rapid-sequence tracheotomy	Scalpel-bougie tracheotomy	*p*
Primary outcome[a] (duration; RST vs. SBT)				
Median duration, sec	57.0 (54.5–65.5) [*N* = 56/60]	59.0 (49.0–66.0) [*N* = 27/30]	48.0 (37.0–57.0) [*N* = 29/30]	.07
Group 1	49.5 (44.0–53.5) [*N* = 30/30]	52.0 (42.0–59.0) [*N* = 15/15]	47.0 (38.0–55.4) [*N* = 15/15]	.14[c]
Group 2	60.5 (46.5–62.5) [*N* = 26/30]	66.0 (43.5–73.0) [*N* = 12/15]	58.5 (46.0–79.0) [*N* = 14/15]	
Median difference in duration, sec	–	11.0 (−4.9–26.9) [*N* = 56/60]		–
Secondary outcome (success rate; RST vs. SBT)				
Success rate[b]	56/60 93.3% (83.8% – 98.2%)	27/30 (90.0%) 90.0% (73.4–97.9%)	29/30 96.7% (82.7% – 99.9%)	.30
Group 1	30/30 100% (88.4% – 100%)	15/15 100% (78.1% – 100%)	15/15 100% (78.1% – 100%)	.58[c]
Group 2	26/30 86.7% (69.2% – 96.3%)	12/15 80.0% (51.8% – 95.7%)	14/15 93.3% (68.0% – 99.8%)	
Difference in success rate	-	−6.7% (−19.2% – 5.9%)		
Secondary outcome (complications; RST vs. SBT)				
Paratracheal tube placement	4/60 (6.7%)	3/30 (10.0%)	1/30 (3.3%)	.32
Group 1	0/30 0% (95%-CI 0% - 11.6%)	0/15 0% (0% - 21.9%)	0/15 0% (0%–21.9%)	.05[c]
Group 2	4/30 13.3% (3.7% - 30.8%)	3/15 (20.0%) 20.0% (4.3% - 48.2%)	1/15 6.7% (0.2% - 32.0%)	
Length of skin incision[b], cm	3.9 (1.0) [*N* = 56/60]	4.1 (1.0) [*N* = 27/30]	3.7 (1.0) [*N* = 29/30]	.10
Group 1	4.0 (1.0) [*N* = 30/30]	3.9 (1.1) [*N* = 15/15]	4.1 (1.0) [*N* = 15/15]	.022[c]
Group 2	3.7 (1.0) [*N* = 26/30]	4.2 (1.0) [*N* = 12/15]	3.3 (0.8) [*N* = 14/15]	
Tracheal damage incurred during skin incision[b]	10/56 17.9% (8.9% - 30.4%)	5/27 18.5% (6.3%–38.1%)	5/29 (17.2%) 17.2% (5.8%–35.8%)	.90 (.41[c])
Injury to thyroid[b]?	4/56 7.1% (2.0%–17.3%)	2/27 7.4% (0.9%–24.3%)	2/29 6.9% (0.8%–22.8%)	.94 (.99[c])
Injury to cricoid[b]?	24/56 42.9% (29.7%–56.8%)	15/27 55.6% (35.3%–74.5%)	9/29 31.0% (15.3%–50.8%)	.06 (.024[c])
Group 1	18/30 60.0% (40.6%–77.3%))	11/15 73.3% (44.9%–92.2%)	7/15 46.7% (21.3%–73.4%)	.024[c]
Group 2	6/26 23.1% (9.0%–43.6%)	4/12 33.3% (9.9%–65.1%)	2/14 14.3% (1.8%–42.8%)	
Injury to posterior tracheal wall[b]?	0/56 0% (0%–6.4%)	0/27 0% (0%–12.8%)	0/29 0% (0%–11.9%)	–
Median number of damaged tracheal rings	2.0 [1.0–3.0] [*N* = 56/50]	2.00 [1.0–2.0] [*N* = 27/30]	2.0 [2.0;3.0] [*N* = 29/39]	.018
Group 1	2.0 [1.0–2.0] [*N* = 30/30]	2.00 [1.0–2.5] [*N* = 15/15]	2.0 [1.0–2.50] [*N* = 15/15]	.008[c]
Group 2	2.0 [2.0–3.0] [*N* = 26/30]	2.00 [1.0–2.0] [*N* = 12/15]	3.0 [2.0–4.0] [*N* = 14/15]	

Abbreviations: RST, rapid-sequence tracheotomy (RST), scalpel-bougie-tracheotomy (SBT).

[a]Medians and interquartile ranges (Q1–Q3) are shown.

[b]Count and percentages are shown.

[c]Likelihood ratio test (LRT) regarding the statistical significance of the order of the training, that is, RST then SBT versus SBT then RST.

(95% CI: 49.0–66.0) with the RST, without statistical difference (Table 2 and Figure 3). However, the difference in the median duration exceeded the predefined equivalence margin of Δ = ±10 s (11 s; 95% CI: −4.9 to 29.0), and the two approaches cannot be considered equivalent (Figure 3B). The primary outcome was not influenced by the order in which the tracheotomies were performed, that is, the allocation sequence (Group 1 vs. Group 2, $p = .14$).

The overall success rate was 93.3% (95% CI: 83.8%–98.2%), with four participants failing to complete the tracheotomy within 120 s. The success rate of SBT was 96.7% (95% CI: 82.7%–99.9%), while the success rate of the RST was 90.0% (95% CI: 73.4%–97.9%). The order of allocation of the procedure sequence did not influence the success rate. Significantly fewer damaged tracheal rings were observed using the SBT approach (Table 2).

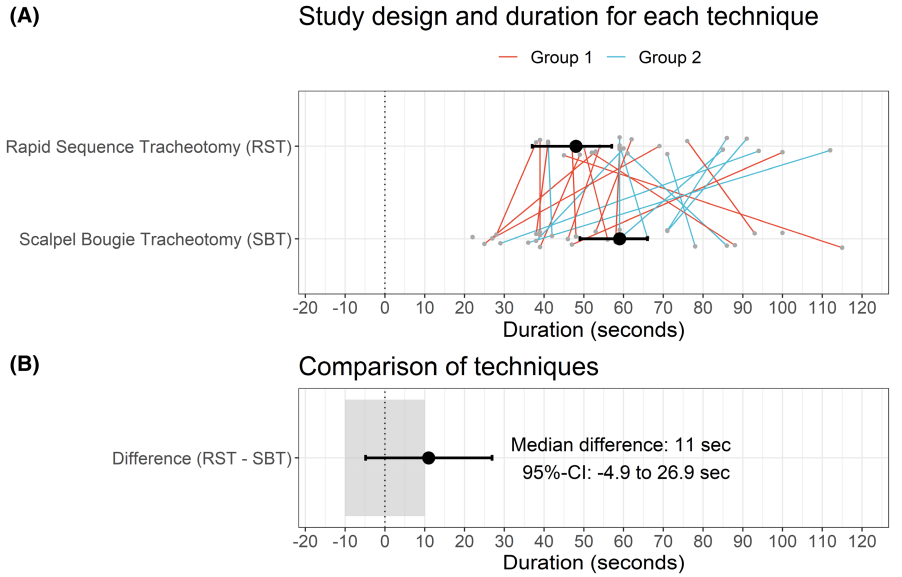

FIGURE 3 Performance time to successful ventilation (primary outcome) stratified according to applied approach and analyses of the equivalence of the duration. (A) Duration of individual participants are shown with colored dots (red: Group 1, blue: Group 2) and the median and associated 95%-confidence interval is shown in black. Only successful attempts are shown (N=56/60); points without a colored line attached to them represent participants who demonstrated a successful attempt with only one of the approaches. (B) Equivalence analyses of the performance time.

The results of the questionnaire are presented in Table 3. Participants expressed a significant preference for the SBT approach over the RST approach.

5 | DISCUSSION

The most relevant finding of this prospective crossover educational study was that the median performance time difference was 11.0 (−4.9–29.0) s (Figure 3), confirming that the two approaches were not equivalent. Our survey documented a highly significant participant preference for the SBT approach ($n=24/29$) over the RST approach ($n=5/29$). The similarity between the SBT as a rescue approach in small children and the eFONA approach practiced in adults might explain why the scalpel-bougie approach was rated as more familiar by the study participants.

The training and assessment used in this study was derived from previous animal cadaver simulation studies.[8,9,14] The decision to have four training sessions with each eFONA approach before taking the study measurement was based on the fact that the learning curve flattened out after four attempts as shown in earlier studies.[8] We included new features such as auditory and patient monitor visual prompts and hemorrhage following skin incision. This was done with the intention of creating a more realistic setting including crashing vital signs and visibility impairing persistent hemorrhage during the procedure. Despite concurring physiological and psychological stressors, study participants acquired the skills of both approaches within four attempts and performed the emergency procedure in less than 60 s. Several participants cited difficulty identifying anatomical structures as the ongoing hemorrhage impeded their ability to perform the tracheotomies.

Although the success rate between the two approaches were not significantly different, some findings did favor the SBT approach. Significantly fewer tracheal ring and cricoid injuries occurred during SBT tracheotomies. Tracheal and laryngeal injuries have an enormous and lasting impact on small children if they are lucky enough to survive such a life-threatening intervention. An observed disadvantage of the RST approach was that the infant's head served as an obstacle for the clinician's ability to perform the vertical tracheal puncture with the tip of the scissors as this puncture needs to be performed in a cranial caudal direction. Since the previous RST study did not include a mannequin head,[8] it is conceivable that this potential challenge may not have been identified in the initial study.

This study demonstrates that previously inexperienced clinicians can acquire the skill set required to perform eFONA in small children in about a minute, by watching training videos with little preceding haptic experience.[8,9,14] Preparing airway practitioners for eFONA in neonates and small infants is feasible, as it enables clinicians to practice and perform an invasive and potentially life-saving intervention within a clinically acceptable period, irrespective of the approach used. Data from the NECTARINE observational study, showed that neonates and small infants have a difficult airway rate of up to 5.8%, which is much higher than that among older children and adults[15] The risk of encountering difficult airways in the general pediatric population is quoted to be 0.28%.[16] Among children with anticipated and unanticipated difficult airways, the PeDi-Registry showed an eFONA rate of 2%[17] with an additional 3% of severe complications, including cardiac arrest and death. Some of these patients may have benefitted from eFONA.[18] The Association of Paediatric Anaesthetists Great Britain & Ireland recommends a percutaneous needle cricothyroidotomy[19] for CICO situations, and Prunty et al showed that percutaneous cricothyroidotomy might represent the best recommendation for managing such a scenario.[20] However he alleged success rate of 100% for the percutaneous cricothyroidotomy stands in contrast to the 43% success rate reported in real CICO-situations in adults[21] including two pediatric case reports which described the need to rescue the airways with a surgical access after an unsuccessful percutaneous cricothyroidotomy.[22,23] Furthermore, the complication rates of the wire-guided technique

TABLE 3 Results of the questionnaire exploring participants' self-reported competencies to perform an emergency tracheotomy and preferences between the rapid-sequence-tracheotomy (RST) and scalpel-bougie-tracheotomy (SBT) approach on an integer scale (0 no agreement to 10 best agreement). Data are given in medians and interquartile ranges [Q1;Q3] or *n* (%).

	All participants	Group 1	Group 2	*p*
1. How competent do you consider yourself performing an emergency tracheotomy on a child? (0–10 scale)	1.50 [1.00;3.75] (*N* = 30/30)	3.00 [1.00;5.50] (*N* = 15/15)	1.00 [0.50;3.00] (*N* = 15/15)	.21
2. Would you consider performing an emergency tracheotomy on a child, if the need would arise? (0–10 scale)	8.00 [3.00;10.0] (*N* = 30/30)	9.00 [5.50;10.0] (*N* = 15/15)	6.00 [2.00;10.0] (*N* = 15/15)	.26
3. How similar would you deem a rabbit's larynx compared to a child's larynx? (0–10 scale)	8.00 [6.75;8.00] (*N* = 24/30)	8.00 [6.50;8.00] (*N* = 11/15)	8.00 [7.00;8.00] (*N* = 13/15)	.63
4. How competent do you feel to perform an emergency tracheotomy on a child following this training? (0–10 scale)	7.00 [6.00;8.00] (*N* = 30/30)	8.00 [6.50;8.00] (*N* = 15/15)	7.00 [5.50;8.00] (*N* = 15/15)	.36
5. Which approach do you prefer?				>.99
RST approach	5/29 (17.2%, 95% CI: 5.8%–35.8%)	4/14 (28.6%)	1/15 (6.67%)	<.001[a]
SBT approach	24/29 (82.8%, 95% CI: 64.2%–94.2%)	10/14 (71.4%)	14/15 (93.3%)	<.001[a]

Abbreviations: RST, rapid-sequence tracheotomy; SBT, scalpel-bougie tracheotomy.

[a]Posthoc binomial test if the percentages of the preferred methods differ (H0: pRST = pSBT = 0.5, H1: pRST≠0.5, pSBT≠0.5) because the order of the method does not have a significant impact on the preference ($p > .99$). The mean estimate and 95% confidence intervals were as follows: RST preferred (17.2%, 95% CI: 5.8%–35.8%), SBT preferred (82.8%, 95% CI: 64.2%–94.2%).

(69% of complications) were higher compared to the scalpel technique (38%).[20] With proper training the complication rate remained below 10% in the current study.

The 2022 American Society of Anesthesiologists practice guidelines for the management of the difficult airway[2] emphasize the importance of advanced preparation, including the use of checklists,[24] limiting the number of intubation attempts, using advanced intubation techniques, and optimizing the administration of oxygen during intubation attempts.[25] All these factors play a central role in preventing CICO situations. Implementation of these guidelines should be complemented by efforts to continuously refine and maintain the skills of airway practitioners tasked with pediatric airway management. Targeted tracheotomy skills training and simulations, in particular, should also be practiced to enhance clinical readiness. This, in conjunction with meticulous preparation and anticipation[26] could help reduce decision-making time and improve outcomes.

Although both approaches were performed in less than 1 min with a success rate of >90%, the numerically shorter performance time, lower number of tracheal injuries and participants' indicated preferences may all favor the SBT approach. This is a variation of the approach recommended for adults.[27,28] These instruments are familiar to and used by many airway practitioners. Pediatric eFONA standardization would simplify algorithms, streamline training, and facilitate the preparation of emergency kits. The main difference with adults would be that for children under the age of 8 years, access to the airway would be through the trachea and not through the cricothyroid membrane because its size does not allow a tracheal tube to pass through in young children.[29]

The major limitation of this study is that despite anatomical, physiological, and psychological similarities, comparative tracheotomies were performed on an animal cadaver, bearing considerable differences compared to a living child. This, and the single-center study design raises the question of how realistic this simulation really is and how our results might be generalized to the performance of eFONA in living patients.

Based on the available data, this study was designed to power the investigation of equivalency between the two techniques. Owing to logistical reasons and limited resources (animal cadaver availability and number of pediatric specialists), we were unable to power this study to demonstrate the superiority of RST or SBT.

6 | CONCLUSION

This study compared the rapid-sequence tracheotomy to the scalpel-bougie tracheotomy in a simulated animal model for small children in a CICO situation using enhanced simulation features (crashing vital signs and artificial hemorrhage). The outlined training model was feasible and achieved a > 90% success rate in less than 60 s within four training sessions for either teaching approach. The rapid-sequence tracheotomy and the scalpel-bougie tracheotomy were not found to be equivalent. Although the two approaches did not show significant differences in performance

time, the scalpel-bougie tracheotomy was slightly faster than the rapid-sequence tracheotomy, was favored by participants, and had fewer tracheal injuries. Therefore, the scalpel-bougie tracheostomy should be chosen by practitioners as rescue approach for small children. The use of a comparable equipment kit for both children and adults facilitates standardization, performance, and logistics.

AUTHOR CONTRIBUTIONS

TRiv, TRie, FU, AF, and RG were involved in study design, conduct, analysis, and manuscript preparation. SG, TRiv, and AF were involved in patient recruitment and conduct of the study. TRiv, TRie, FU, ND, AF, RG, and ACL were involved in study design, conduct, and finalizing the manuscript. MH was involved in statistical analysis. All authors read and approved the final manuscript.

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PRIOR PRESENTATIONS

Preliminar results were presented at the ESPA 2022 in Lisbon, Portugal, by Simon Goerge, September 30, 2022, the Swissanaesthesia 2022 in Interlaken, Switzerland, and the Euroanaesthesia 2023 in Glasgow, UK by Thomas Riva.

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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