

Paediatric Emergency Front of the Neck Access: Assessing a New Learning Approach on an infant-sized rabbit model

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Abstract

Background: Cannot-intubate cannot-ventilate situations in healthy children are uncommon but often associated with poor outcome. Several airway management algorithms suggest emergency tracheal access. Little agreement exists on how to perform emergency front of the neck access (eFONA) in children <8 years. We studied the learning curves of clinicians performing simulated paediatric eFONA.

Methods: After watching an instructional video 50 physicians, from 5 medical specialties, performed 10 emergency tracheotomies on rabbit cadavers. We analysed their learning curves relative to performance time and concurring injuries.

Results: With an overall success rate of 94%, performance time decreased from 107 sec (SD 45) to 55 sec (SD 17) over 10 attempts. The learning curve was steep between the first and the fourth attempt with an 11% decrease in performance time (95% CI: 9-13%, $p < 0.001$) per attempt and then flattened to a 4% (95% CI: 3-5%, $p < 0.001$) decrease per attempt between the fourth and the tenth attempt. Age, years of clinical experience and sex showed a significant effect on the learning curve, whereas medical specialty and adult eFONA experience did not. The 58% (95% CI: 44-72%) probability for severe injury during the first attempt decreased to 14% (95% CI: 8-20%) as of the second attempt. Males were more likely to cause minor injuries than females ($p < 0.001$).

Conclusions: Irrespective of medical specialty paediatric clinicians acquired the eFONA technique within 4 attempts and were on average able to establish an airway in < 1 minute when performing emergency tracheotomy on a paediatric airway simulator.

Background

Cannot-intubate cannot-ventilate situations in healthy children are uncommon but often associated with poor outcome.^{1, 2} Unlike adults, healthy children frequently experience functional airway obstruction.³ Unrecognized functional airway obstructions are one of the leading causes of perioperative respiratory adverse events in healthy children.⁴ Clinical assessment, anticipatory planning and the use of algorithms help lessen the likelihood of untoward outcomes of cannot-intubate cannot-ventilate scenarios.⁵ In children, the onset of oxygen desaturation following apnoea occurs much sooner than in adults. Rapid desaturation in children following apnoea is a pathophysiological consequence resulting from higher oxygen consumption, reduced functional residual capacity and a higher closing capacity compared to adults.^{6, 7} The common final pathway of many paediatric difficult airway algorithms leads to obtaining emergency tracheal access.^{5, 6, 8-10} In children < 8 years, the literature offers equivocal guidance on how to train for and perform emergency front of the neck access (eFONA) as a life-saving measure.^{5, 11, 12} The need to obtain eFONA in an infant or small child is one of the most terrifying situations a clinician can experience. Unfortunately, these situations are linked to poor survival^{13, 14} and are undermined by the fact that eFONA bears considerable risk for complications.¹⁵ The Association of Paediatric Anaesthetists of Great Britain and Ireland's "Cannot-Intubate Cannot-Ventilate Guidelines" for children aged 1–8 years recommends percutaneous cricothyroidotomy when a trained surgeon is not available.¹² However, no consensus exists regarding the preferred transtracheal route.¹² In needle-based cricothyroidotomy the ease with which a child's supple airway can be compressed may lead to posterior wall puncture and other procedural complications.¹⁶ Metterlein et al. analysed a needle-based cricothyroidotomy on a paediatric scale animal model. Despite a purported 100% success rate, 20% of the attempts showed fractures of the laryngeal cartilage and 13% of the attempts caused posterior tracheal wall injury.¹⁷ This stands in contrast to the 36% success rate reported in adult emergencies.¹³

Furthermore, in infants the dimensions of the cricothyroid membrane are too small to pass a tracheal tube between the cricoid and the thyroid cartilage. The risk of damaging the laryngeal cartilage discourages surgical cricothyroidotomy in < 5 year-olds,¹⁸ rendering surgical tracheotomy as a viable alternative. In a study performing modified surgical tracheotomy on euthanized piglets, 8 of 10 insertions proved successful.¹⁹ However, little evidence about concurring injuries and no evidence regarding improvement and learning was provided. Data from actual paediatric emergencies are lacking. Practicing on adult mannequins reduces cricothyroidotomy times and improves success rates by the fifth attempt.²⁰ Participants performing percutaneous needle-puncture cricothyroidotomy on skin-covered pig larynxes showed flattening of the learning curve after the fourth attempt.²¹

Currently there is no clear guidance relative to which technique (needle vs. surgical) to use and how to practice for it.²² The aim of this study was to investigate the ramifications of participants learning emergency tracheotomy on a realistic infant-sized animal-cadaver training model. We investigated how participants acquire a particular kind of eFONA procedure while monitoring learning curves and concurring injuries.

Materials and Methods

Following approval by the Ethics Committee Bern (Req-2018-00067) and ClinicalTrial.gov registration (NCT03576352), 50 consenting physicians (10 paediatric intensivists, 10 paediatric emergency physicians, 10 paediatric surgeons, 10 paediatric anaesthesiologists and 10 emergency response physicians) without previous paediatric tracheotomy experience were included in this study.

After watching an instructional video, participants performed 10 consecutive emergency tracheotomies. The simulated paediatric airway, was the cranial portion of a rabbit cadaver ("Zika-

Zimmermann" rabbit, aged 84-87 days, live weight 2.8-3.2 kg) with a shaven neck. The refrigerator-cooled cadavers were exposed to room temperature for 2 hours before emergency tracheotomy. For each attempt, a fresh cadaver was prepared and professionally disposed of after the procedure. An instructional video narrated the 4 steps of the adapted emergency tracheotomy in German¹⁹, as outlined in Figure 1. The video was two minutes and thirty seconds in length. No additional explanations were provided. Participants were permitted to watch the video as often as desired. Participants were encouraged to:

- perform emergency tracheotomies in < 60 seconds
- incise < 3 cartilaginous tracheal rings
- make a skin incision of ≤ 5 cm and to avoid injuring neighbouring structures.

Before watching the video and following the completion of 10 emergency tracheotomies, participants rated how competent they felt performing this type of eFONA (visual analogue scale 0 to 10).

Prior to emergency tracheotomy, the cadavers were strapped to a wooden block in the supine position. Study participants were requested to perform 10 consecutive emergency tracheotomies without causing unnecessary harm. A member of the study team recorded performance time with a stopwatch. Performance time was defined as the time from touching the skin until ventilation of the trachea was confirmed by lung expansion. After each attempt, incurred injuries were examined, verbalized and recorded by a member of the study team. Injuries were classified as minor (harm to trachea during skin incision, or incision of 3 or 4 tracheal cartilaginous rings), or severe (injury that could compromise eFONA-success or larynx or trachea functionality). All attempts were video recorded. Injuries, performance time, number of traumatized cartilaginous rings, length of skin incision and position of the tube were documented separately on the case report form, ensuring redundancy of data collection.

Success was defined as correct insertion of a tracheal tube (Sheridan uncuffed TM, ID 3.0, Teleflex Medical, Co Westmeath, Ireland) with concurrent lung inflation.

Primary outcome was performance time of emergency tracheotomy representing the time from skin palpation until ventilation was confirmed by visualizing lung expansion.

Secondary outcomes were injuries to cricoid, thyroid and trachea as well as failures which were defined as paratracheal tube placement and any other condition rendering lung ventilation impossible .

To validate the rabbit airway as a simulated infant trachea, magnetic resonance imaging of 10 randomly selected rabbit cadavers was performed measuring the antero-posterior diameter at the cricoid level and between 4th/5th cervical vertebra. These 10 rabbits contributed to the pool of cadavers used to perform emergency tracheotomy.

Statistical Analyses

All analyses were done in Stata (StataCorp LLC, College station, Texas, USA) or R.²³ Baseline characteristics are presented as mean with standard deviation (SD) or median with quartiles and as absolute and relative frequencies for continuous and categorical variables, respectively. The performance time of emergency tracheotomy was modelled on the log-scale to improve normality and homoscedasticity of the residuals (as checked by quantile-quantile and residuals vs fitted plots) and to restrict performance time to positive values. This implicitly assumes that explanatory variables have additive effects on log-time and multiplicative effects on time. We used linear mixed effects models with a random intercept for the participants to take correlation between measurements of the same participant into account. Models were fitted using restricted maximum likelihood. Results are presented as geometric mean ratios with 95% confidence intervals (CI) based on Satterthwaite's approximation for the degrees of freedom. The attempt was included as a covariate assuming a linear or piecewise linear effect (via linear splines) on log time. We fitted models with up to five knots that were equally spaced or placed according to the raw data. We compared the models (refitted by maximum likelihood) using likelihood ratio tests and the Akaike and Bayesian information criteria (AIC and BIC, appendix Table 6). The best model used a single

knot at the fourth attempt and was used to predict performance time with 95% CI and prediction interval.

The probabilities of no injury, mild injury, severe injury and failure were modelled using multinomial logistic regression with cluster-robust standard errors ²⁴. Results are presented as relative risk ratio vs. no injury with 95% CI based on a normal approximation. We assumed linear or piecewise linear effects of the attempt on the relative risks based on linear splines. Models with up to five knots were fitted and compared using likelihood ratio tests, AIC and BIC (possible appendix Table 7). The best model used a single knot at the second attempt and was used to predict the probability of no injury, minor injury, a severe injury or failure with 95% CIs.

The effects of sex, age, medical specialty, tracheotomy experience, current hierarchical function and years of clinical experience were analysed by adding the covariate and its interaction with attempt to the model. The interaction reflects the influence of the covariate on the learning curve. A p-value for interaction was derived from a likelihood ratio test of the model with and without the interaction. For linear spline models, the interaction with each spline term was analysed using Wald tests.

The study was explorative, and we did not control for the overall type I error rate. Results need to be interpreted accordingly. The 50 physicians represented a convenience sample, which was in proportion to the number of physicians employed by Bern Children's Hospital. We cannot comment on the rate of type II errors, as no formal power calculation was performed.

Results

Study participants' characteristics are presented in Table 1. The mean anterior-posterior diameter at level of the cricoid in the rabbits measured by magnetic resonance imaging was 6.8 mm (SD 0.7) and 4.7 mm (SD 0.9) at the C4/C5 level.

Performance time was reduced from 107 sec (SD 45) to 55 sec (SD 17) from the 1st to the 10th emergency tracheotomy attempt (Figure 2a). Performance time was modelled with a single knot at attempt four (Figure 2b, appendix Table 2a), i.e. assuming two different effects for attempts one through four (phase I) and attempts four through ten (phase II). Improvement was more pronounced during phase I resulting in an 11% (95% CI: 9 - 13%, $p < 0.001$) decrease in time for each attempt compared to a 4% (95% CI: 3 - 5%, $p < 0.001$) decrease in phase II (Figure 2b, appendix Table 2a). Improvement was significantly lower in phase II (by a factor of 1.08, 95% CI: 1.05 - 1.12, $p < 0.001$).

There was no evidence suggesting that participants' medical specialty, previous clinical or simulator-based adult tracheotomy experience or hierarchical function affected the learning curve. Age and years of clinical experience as well as sex showed a significant effect on the learning curve (Figure 3). The learning curve was dependent on age during phase II: With every decade, the improvement in performance time per emergency tracheotomy attempt decreased by 2% (95% CI: 1 - 4%, $p = 0.008$) (possible appendix Table 3). Men performed their first emergency tracheotomy 24 sec faster than women (95% CI: 7.0 - 41, $p=0.006$). However, when examining all 10 emergency tracheotomies, women improved significantly faster than men during phase I and their learning curve was 7% (95% CI: 1 - 12%, $p = 0.015$) steeper per attempt (possible appendix Table 4). As of attempt four (phase 2), no difference was found between sexes (Figure 3b). Clinical experience did not influence the learning curve in phase I ($p = 0.79$). However, more experience did lead to a flatter learning curve in phase II with each decade of clinical experience reducing the improvement in performance time by 2% per attempt (95% CI: 0 - 4%, $p=0.025$) (Figure 3c, appendix Table 5).

Among the 500 emergency tracheotomies we identified 76 (15%) minor injuries, 82 severe injuries (16%) and 28 (6%) failures. Minor injuries and failures remained stable throughout all attempts, whereas severe injuries decreased (Figure 4a). We modelled injuries and failures using linear splines with a single knot at attempt two (Figure 4b). The probability for severe injury decreased

from 58% (95% CI: 44 - 72%) after the first attempt to 14% (95% CI: 8 - 20%) in the second attempt (Figure 4), whereas minor injuries (16 vs 11%) and failures (4 vs 5%) remained stable throughout all attempts. Following the second attempt only very minor changes were observed, resulting in the following probabilities at the end of the learning curve: 64% (95% CI: 55-73%) no injury, 20% (95% CI: 13-27%) minor injury, 10% (95% CI: 5-15%) severe injury and 7% (95% CI: 3 -11%) failures (Figure 4b, appendix Table 2b).

We did not find any evidence that age, sex, preceding clinical or simulator-based adult tracheotomy experience, medical specialty, years of clinical experience or current hierarchical function influenced the learning curve relative to injury rates. However, males were more likely to cause minor injuries than females ($p<0.001$). Men had an increased relative risk for minor injury (vs. no injury 2.8, 95% CI: 1.5-5.3, $p=0.001$) and failures (3.0, 95% CI 1.1-8.0, $p=0.033$) (Figure 5).

Discussion

Reduction of emergency tracheotomies performance time to an average of less than 60 seconds accompanied by a 94% success rate are the key findings of this trial investigating how physicians acquired a potentially lifesaving skill on a rabbit-cadaver serving as an infant airway-simulator after watching an instructional video. Despite a high success rate, injuries and paratracheal tube placement remained common.

The need to obtain eFONA in an infant or small child is one of the most terrifying situations a clinician can experience. Realistic assessments, anticipatory planning, use of algorithms and other difficult airway aids help lessen the likelihood of untoward outcomes of cannot-intubate cannot-ventilate situation.⁵ Nonetheless, clinicians tasked with paediatric airway management, should possess the necessary expertise and training to salvage a cannot-intubate cannot-ventilate situation. The placement of a trans-tracheal cannula in a paediatric cannot-intubate

cannot-ventilate situation is questionable^{19, 25, 26} due to high failure and complication rates, leaving surgical tracheotomy as a viable alternative.

In the absence of studies investigating emergency tracheotomy skill acquisition, we sought to study the learning curve of this technique following repeated attempts. Ethical considerations preclude practicing this procedure on humans or human cadavers.

Acquiring a skill set such as eFONA by way of video instructions permits standardized performance analyses. The emergency tracheotomy technique reported in this study yielded a high success rate with averaged performance times of less than 60 seconds within 10 attempts.

Advanced statistical modelling revealed a clear inflection point in the learning curve after the 4th attempt (Figure 2b). This is in line with previously described eFONA learning curves on manikins²⁰ and animal cadavers.²¹ The steeper, first part of the learning curve (phase I) could be interpreted as the learning portion of the procedure whilst acquiring the skill demonstrated in the video. The second, flatter portion (phase II) seems to represent skill perfection during which hand-eye coordination is refined. Interestingly, the learning curve did not hinge on the physicians' specialty (Figure 3d) or previous eFONA-experience. This suggests that clinicians should not rely on medical background and or surgical (operative) expertise as these did not represent predictors of success. Age, years of clinical experience and sex did however influence the learning curve. Advanced age and increasing clinical experience predicted flattening of the learning curve in phase II (Figure 3a, c). This is in line with reports describing that the capacity for implicit (sequential) learning decreases beyond the age of 45.²⁷ Although females showed better overall performance with procedural learning tasks, their rate of learning was equivalent to males.²⁸ Our results are in concert with these findings (Figure 3b). Further similarities to our study results are suggested by the fact that women were shown to have longer reaction or performance times related to problem solving strategies. However, women perform more accurately at the expense of longer reaction times. This reflects a decreased risk for inflicting injury and failure among women²⁹ and could indicate that women paid more attention to accuracy rather than to velocity,

especially during their first attempt in phase I. With increasing routine, their confidence increased allowing them to catch up to men over the remaining attempts during phase I (Figure 3b). The dimensions of rabbit tracheas measured by magnetic resonance imaging correspond with the values described for children between 0 and 2 years of age,³⁰ making the rabbit an acceptable compromise for navigating ethical concerns and the demand for realistic simulators.^{31, 32} Despite anatomical similarities in dimensions, proportions and tissue texture, the challenges posed to the participants in this study were eased by the fact that the emergency tracheotomy was performed on a cadaver which lessened both physiological, especially bleeding, and psychological (failing vital signs, stressful work environment) confounders, both of which would have aggravated emergency tracheotomy in a living child. Another limitation of the study was its explorative character and the absence of a formal power calculation.

The significance of this study is the large cohort of a variety of specialists who achieved the set goal of performing emergency tracheotomy in less than one minute with a success rate of 94%. Despite a peak in complications during the first attempt and subsequent drop following the first attempt, a sizeable and steady injury rate prevailed throughout the remaining attempts (Figure 4). This is noteworthy, as participants appeared to swiftly reduce their complication rate (severe injuries and failures) after a relatively limited amount of training.

Although noticeable, the 17% complication rate at attempt 10 reported in this study is still lower than the complication rates reported for other paediatric eFONA techniques, including the catheter over needle technique (33%),¹⁷ the wire-guided technique (69%),²⁶ the cannula technique (36%),^{25, 33} the scalpel technique (38%)^{25, 26} and much lower than the 40% complication rate described in the literature.³⁴ Practicing 10 repetitive emergency tracheotomies may have boosted the competitive spirit among participants, resulting in a potentially greater number of injuries. This may have allowed the performance focus to shift from fast and injury free to just fast.

This study does not intend to encourage the practice of emergency tracheotomies in the clinical setting. The results of this study show how clinicians with limited but focused training were able

to master a potentially lifesaving technique with both high success rates and desirable performance times which were superior to those of other eFONA-techniques. This fact provokes the thought whether emergency tracheotomy trained clinicians tasked with paediatric airway management might benefit from having an emergency tracheotomy -set readily available in their difficult airway cart.

Conclusion

This study introduces a successful training modality simulating the challenges posed by an infant airway in a cannot-intubate cannot-ventilate situation. Irrespective of medical specialty clinicians acquired the eFONA technique within 4 attempts and were able to establish an airway in < 1 minute when performing emergency tracheotomy on an infant-sized rabbit model. Steady skill improvement was observed yielding a 94% success rate. Injury rates and learning curve were not influenced by the providers' experience and medical specialty. Video-instruction followed by practice enables swift skill acquisition of this advanced invasive technique.

296 **Authors' contributions**

297 Study design, conduct, analysis, and manuscript preparation: T.R., F.U.

298 Patient recruitment, conduct of the study: T.R., J.L.

299 Study design, conduct, and finalizing the manuscript: R.G., L.T., J.L.

300 Statistical analysis: L.B.

301

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306

307 **Declaration of interest**

308 None declared.

309

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Figures and Tables

Figure 1: The 4 steps of the adapted emergency tracheotomy.

Step 1: Orientation by palpating the rabbit's trachea and larynx, vertical midline skin incision (#10 curved scalpel blade)

Step 2: Strap muscle separation (scalpel and two Backhaus clamps), exposure of the trachea and the cricoid cartilage; anterior luxation of trachea with 3rd clamp.

Step 3: Vertical tracheal puncture (tip of scissors) between cricoid cartilage and 1st tracheal ring and incision of first two tracheal rings.

Step 4: Insertion of a tracheal tube into the trachea followed by lung inflation

Figure 2: Emergency tracheotomy learning curve.

a) Boxplots of the raw data with boxes drawn from the lower to the upper quartile, whiskers extend to the most extreme data point that is no more than 1.5 times the interquartile range of the box. All points outside this range are depicted as circles.

b) Predicted emergency tracheotomy performance time for each attempt with 95% confidence and prediction interval assuming two separate effects for attempts 1-4 (phase I) and 4-10 (phase II). Raw data depicted as circles.

Figure 3: Influence of a) age, b) sex c) years of clinical experience and d) medical specialty on the learning curve. Predictions for emergency tracheotomy performance time (seconds) for each attempt at specified values of the covariate assuming separate effects for attempts 1-4 (phase I) and 4-10 (phase II). a) Age (p for interaction = 0.003), b) sex (p for interaction = 0.02) and c) years of clinical experience (p for interaction = 0.037) showed a significant overall effect on the learning curve, whereas d) participant's medical specialty (p for interaction = 0.18) did not.

Figure 4: **a)** Number of participants at each attempt causing minor or severe injuries or failing to correctly place the tracheal tube. **b)** Predicted probability of no injury, minor injury, severe injury and failure with 95% confidence intervals assuming two separate effects for attempts 1-2 and 2-10.

Figure 5: Influence of sex on injury probability. Predicted probability of no injury, minor injury, severe injury and failure with 95% confidence intervals for men and women assuming two separate effects for attempts 1-2 and 2-10.

Table 1: Participant characteristics

Figures and Tables

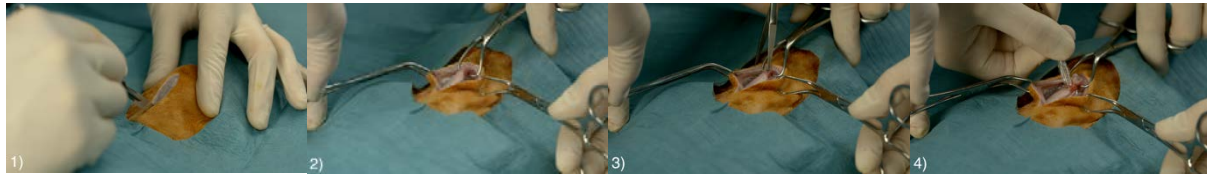


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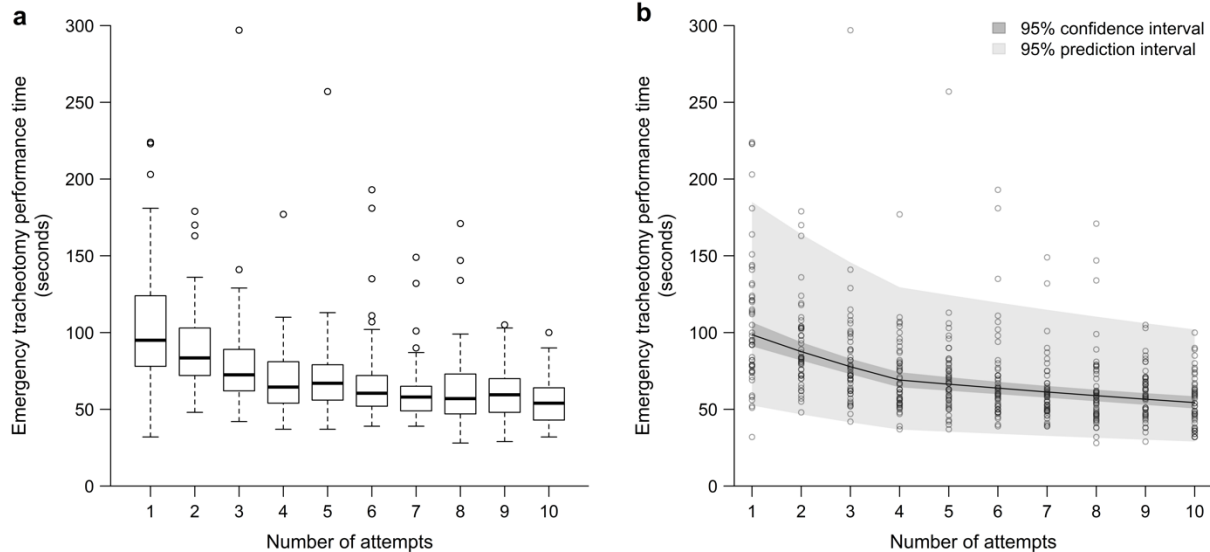
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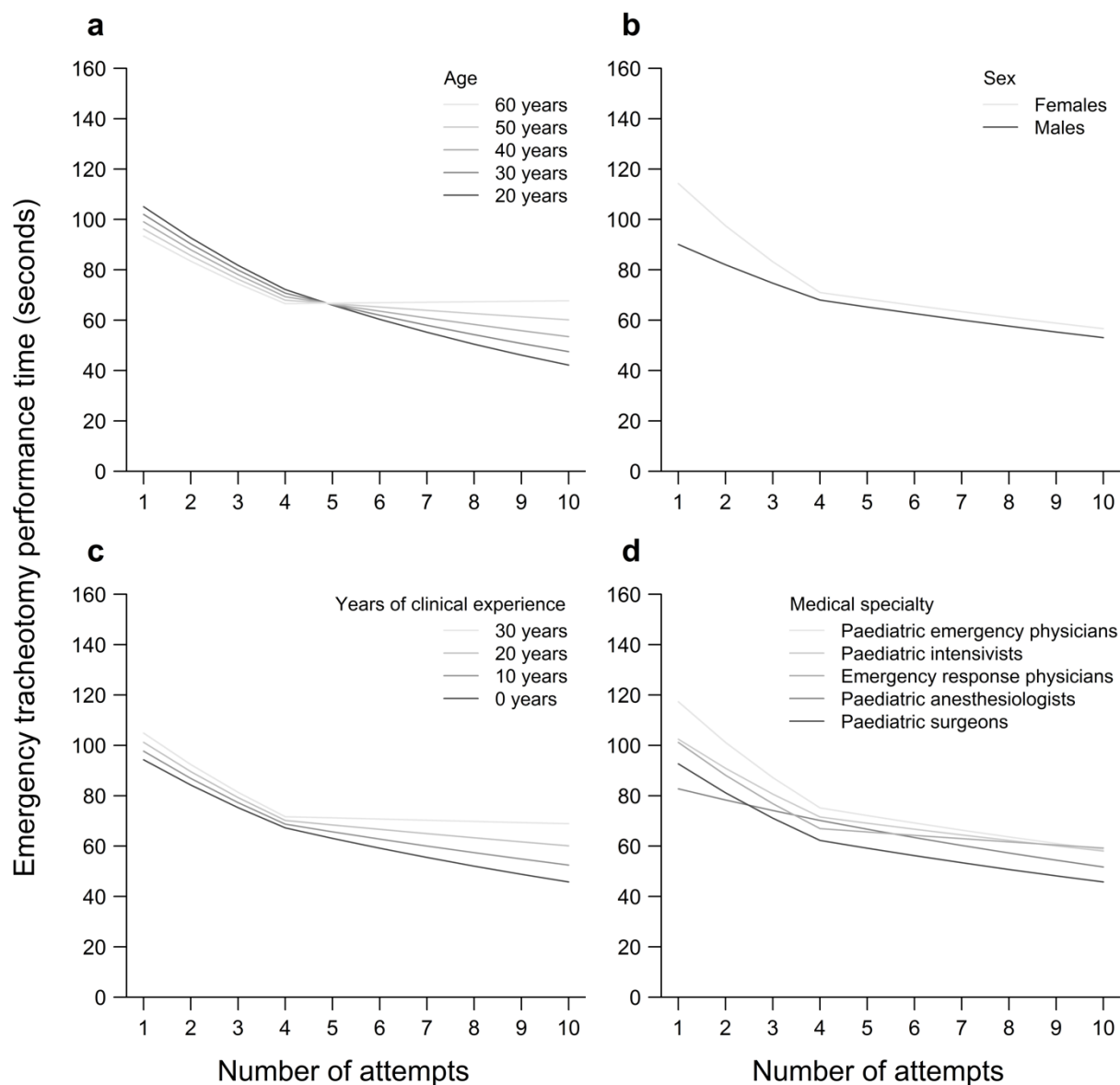
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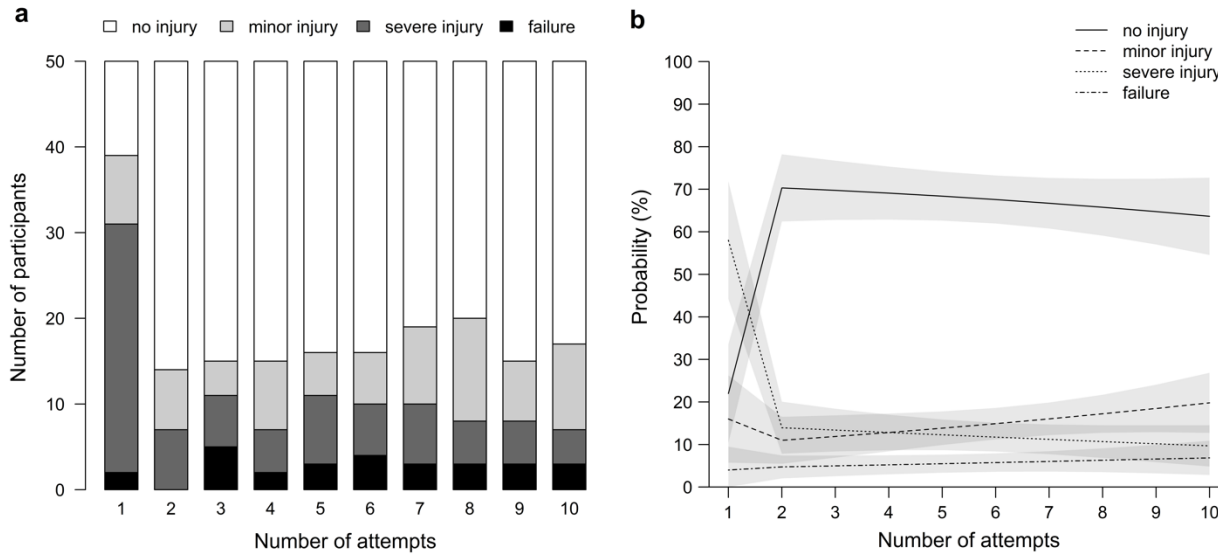
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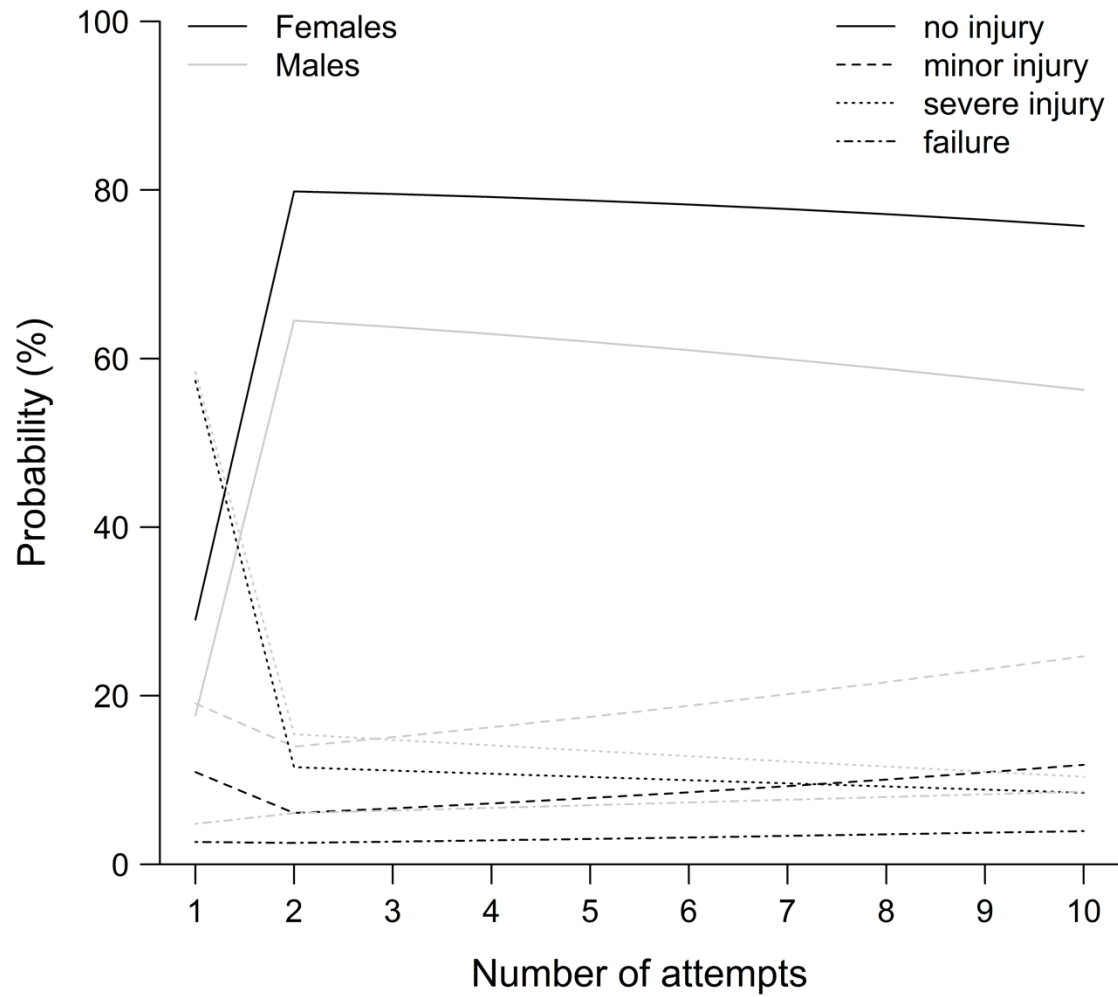
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Figure 4: **a)** Number of participants at each attempt causing minor or serve injuries or failing to correctly place the tracheal tube. **b)** Predicted probability of no injury, minor injury, severe injury and failure with 95% confidence intervals assuming two separate effects for attempts 1-2 and 2-10.



463 Figure 5: Influence of sex on injury probability. Predicted probability of no injury, minor injury, severe
 464 injury and failure with 95% confidence intervals for men and women assuming two separate effects for
 465 attempts 1-2 and 2-10.



468 Table 1: Participant characteristics

469

Age (years)	42 (7.4)
Sex	
Female	19 (38%)
Male	31 (62%)
Years of clinical experience (years)	13 (7.2)
Hierarchical function	
Fellows	10 (20%)
Attendings	34 (68%)
Chiefs/Heads of Department	6 (12%)
Previous clinical tracheotomy experience in adults	12 (24%)
Previous simulator-based tracheotomy experience	29 (58%)
Pre-training VAS self-confidence to perform paediatric emergency tracheotomy	0.6 [0.0, 2.3]
Post-training VAS self-confidence to perform paediatric emergency tracheotomy	7.7 [2.5, 10]

Results presented as n (%), mean (SD) or median [lower quartile, upper quartile]; participants estimated their average rating pre-/ post emergency tracheotomy training on a visual analogue scale (VAS) 0-10

470 **Electronic Appendix**

471 We are including the following tables on the journal's web site:

472 Table 2 (coefficients from the main models)

473 Table 3 (the effect of age on attempt)

474 Table 4 (the effect of sex on performance time)

475 Table 5 (the effect of experience on performance time)

476 Table 6 (model selection for performance time)

477 Table 7 (model selection for injuries)