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REPORTS OF ORIGINAL INVESTIGATIONS

Applied forces with direct *versus* indirect laryngoscopy in neonatal intubation: a randomized crossover mannequin study

Forces appliquées lors de laryngoscopie directe ou indirecte pour l'intubation néonatale : une étude randomisée croisée sur mannequin

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Abstract

Purpose *In adult mannequins, videolaryngoscopy improves glottic visualization with lower force applied to upper airway tissues and reduced task workload compared with direct laryngoscopy. This trial compared oropharyngeal applied forces and subjective workload during direct vs indirect (video) laryngoscopy in a neonatal mannequin.*

Methods *We conducted a randomized crossover trial of intubation with direct laryngoscopy, straight blade videolaryngoscopy, and hyperangulated videolaryngoscopy in a neonatal mannequin. Thirty neonatal/pediatric/anesthesiology consultants and residents participated. The primary outcome measure was the maximum peak force applied during intubation. Secondary outcome measures included the average peak force applied during intubation, time needed to intubate, and subjective workload.*

Results *Direct laryngoscopy median forces on the epiglottis were 8.2 N maximum peak and 6.8 N average peak. Straight blade videolaryngoscopy median forces were 4.7 N maximum peak and 3.6 N average peak. Hyperangulated videolaryngoscopy median forces were 2.8 N maximum peak and 2.1 N average peak. The differences were significant between direct laryngoscopy and straight blade videolaryngoscopy, and between direct laryngoscopy and hyperangulated videolaryngoscopy. Significant differences were also found in the top 10th percentile forces on the epiglottis and palate, but not in the median forces on the palate. Time to intubation and subjective workload were comparable with videolaryngoscopy vs direct laryngoscopy.*

Conclusions *The lower force applied during videolaryngoscopy in a neonatal mannequin model suggests a possible benefit in reducing potential patient harm during intubation, but the clinical implications require assessment in future studies.*

Registration *ClinicalTrials.gov (NCT05197868); registered 20 January 2022.*

Résumé

Objectif *Sur les mannequins adultes, la vidéolaryngoscopie améliore la visualisation glottique avec une force plus faible appliquée aux tissus des voies aériennes supérieures et une charge de travail réduite par*

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rapport à la laryngoscopie directe. Cette étude a comparé les forces appliquées sur la zone oropharyngée et la charge de travail subjective au cours d'une laryngoscopie directe vs indirecte (vidéolaryngoscopie) sur un mannequin néonatal.

Méthode *Nous avons réalisé une étude randomisée croisée d'intubation par laryngoscopie directe, vidéolaryngoscopie à lame droite et vidéolaryngoscopie avec lame hyperangulée sur un mannequin néonatal. Trente spécialistes diplômés et résidents en néonatologie, en pédiatrie et en anesthésiologie y ont participé. Le critère d'évaluation principal était le pic de force maximal obtenu pendant l'intubation. Les critères d'évaluation secondaires comprenaient la force maximale moyenne appliquée pendant l'intubation, le temps nécessaire pour intuber et la charge de travail subjective.*

Résultats *Les forces médianes appliquées sur l'épiglotte lors de la laryngoscopie directe étaient de 8,2 N pour le pic maximum et de 6,8 N pour le pic moyen. Les forces médianes appliquées lors de la vidéolaryngoscopie à lame droite étaient de 4,7 N pour le pic maximum et de 3,6 N pour le pic moyen. Les forces médianes appliquées lors de la vidéolaryngoscopie avec lame hyperangulée étaient de 2,8 N pour le pic maximum et de 2,1 N pour le pic moyen. Les différences étaient significatives entre la laryngoscopie directe et la vidéolaryngoscopie à lame droite, et entre la laryngoscopie directe et la vidéolaryngoscopie avec lame hyperangulée. Des différences significatives ont également été observées dans le 10^{e} percentile supérieur des forces sur l'épiglotte et le palais, mais pas dans les forces médianes sur le palais. Le délai d'intubation et la charge de travail subjective étaient comparables entre la vidéolaryngoscopie et la laryngoscopie directe.*

Conclusion *La force plus faible appliquée lors de la vidéolaryngoscopie dans un modèle de mannequin néonatal suggère un avantage possible de réduction des lésions potentielles pour le patient pendant l'intubation, mais les implications cliniques doivent être évaluées dans des études futures.*

Enregistrement de l'étude *ClinicalTrials.gov (NCT05197868); enregistré le 20 janvier 2022.*

Keywords infant newborn · intubation · laryngoscopy · mannequin · videolaryngoscopy

Approximately 1% of neonates require intubation at birth.[1] The implementation of a less invasive approach has significantly reduced the exposure of health care providers to neonatal intubation.[2] Previous studies have reported a wide range of success rates (20–70%) for pediatric residents and neonatology fellows.[3]

During direct laryngoscopy, the traditional laryngoscope is introduced into the mouth and lifted to enable the visualization of vocal cords, applying a force to the base of the tongue. This maneuver may cause direct trauma to the tissues and precipitate adverse reactions.[4] In neonates, intubation has a high rate of adverse events such as esophageal intubation, airway trauma, significant bradycardia, and severe intraventricular hemorrhage.[5–7]

Recent studies showed that videolaryngoscopy may decrease the occurrence of adverse events during neonatal intubation and improve the success of intubation in less experienced medical staff.[8, 9] Videolaryngoscopy provides an indirect view of the larynx using a video camera.[10] Videolaryngoscopy may use blades similar to the traditional curved (Macintosh) and straight (Miller) blades or modified blades. Of note, a hyperangulated blade provides a 60–90-degree view of laryngeal structures compared with the 15–30-degree view provided by the Macintosh or Miller blade,[11] allowing visualization of the glottis without aligning the oral cavity, pharynx, and larynx. The vocal cords cannot be directly visualized with this videolaryngoscope, so the endotracheal tube (ETT) should be introduced using a preangled stylet that matches the blade curvature.

According to an adult mannequin study, videolaryngoscopy may improve glottic visualization, with lower forces applied to upper airway tissues,[12] and reduce task workload compared with direct laryngoscopy.[13] We hypothesized that such an approach may provide similar benefits during neonatal intubation. To investigate this, we compared oropharyngeal applied forces and perceived workload during direct laryngoscopy, straight blade videolaryngoscopy, and hyperangulated videolaryngoscopy in a neonatatal mannequin.

Methods

Study design

This was a randomized, controlled, crossover trial of intubation with three laryngoscopes in a neonatal mannequin model. The trial implemented a six-sequence, three-period, three-treatment scheme (ABC/BCA/CAB/ACB/BAC/CBA), which is uniform within sequences and periods and balanced with respect to first-order carryover effects.[14] The simulation was performed at the University of Padua (Padua, Italy) between 20 and 26 January 2022. The Ethics Committee of the University of Padua deemed that formal ethical approval was not required since this was a simulation study on a mannequin (protocol No. 0002658). Written informed consent was obtained from participants.

Participants

Level III neonatal intensive care unit (NICU) and pediatric intensive care unit (PICU) consultants, pediatric residents, anesthesiology consultants, and anesthesiology residents participated in the study. The exclusion criterion was refusal to participate.

Randomization

All participants were randomly assigned to one of the six sequences in a 1:1:1:1:1:1 ratio. Randomization was performed using a computer-generated random assignment list. Arm assignments were placed in sequentially numbered, sealed, opaque envelopes.

Procedures

Participants in the ABC arm were assigned to perform the intubation with a direct laryngoscope (A), followed by intubation with a straight blade videolaryngoscope (B), and intubation with a hyperangulated videolaryngoscope (C). Participants in different arms were assigned to perform the intubations in different sequences (BCA/CAB/ACB/BAC/CBA). A washout period of four hours was included.

Before the simulation, an expert on videolaryngoscopy intubation showed each participant the videolaryngoscopy intubation technique with a Miller blade and a hyperangulated blade on a neonatal mannequin. The same approach was used to show each participant the direct laryngoscopy intubation technique with a Miller blade. Each participant was asked to practice with all devices on the mannequin before their recorded laryngoscopy attempts.

In the simulation, participants were asked to intubate a full-term neonatal mannequin (Laerdal NewBorn Anne; Laerdal, Stavanger, Norway) using three different laryngoscopes: a standard direct laryngoscope with Miller blade size 1, a videolaryngoscope with Miller blade (GlideScope® Spectrum™ S1; Verathon Inc., Bothell, WA, USA), and a videolaryngoscope with hyperangulated blade (GlideScope® Spectrum™ LoPro S1; Verathon Inc.). A 3-mm ETT was used for each intubation. A stylet was inserted in the ETT. During intubation with the hyperangulated blade videolaryngoscope, we used a preformed stylet (GlideRite® stylet size small; Verathon Inc.).

During each intubation attempt, a researcher noted the time to intubation and number of intubation attempts. An intubation attempt was considered as failed if the ETT was not positioned in the trachea or if the attempt lasted more than 60 sec.[13] We chose this interval to take into account the heterogeneous intubation experience of our participants.

During each procedure, force measurements were acquired using three force sensors (FlexiForce A301; Tekscan, Inc., Norwood, MA, USA) fixed through a double-sided tape at three different sites of each blade. One sensor (epiglottic sensor) was placed on the distal surface of the blade in correspondence to the area in contact with the epiglottis during intubation and two sensors (palatal sensors) on the proximal surface of the blade at the area in touch with the upper gum and hard palate (Figure). The whole blade surface was then covered with heat-sink tubes to hide the sensor from the study participants and to protect the sensors during the procedure. Each force sensor had a sensing area of 9.53-mm diameter, 0.203-mm thickness, $<$ 5-µsec response time, $\pm$ 3% linearity error, and 0–111-N force range, suitable for the described application.[15] The output signal from the sensors was conditioned and amplified with the electronic components suggested in the sensor's data sheet and acquired by means of an Arduino Uno board (Arduino, Turin, Italy). Using LabVIEW software (National Instruments, Austin, TX, USA), data from each sensor were individually filtered with a floating mean filter with ten samples to remove part of the noise, and saved in a text file. Sensor calibration curves were extrapolated from bench tests, and integrated in the LabVIEW scripts, one for each laryngoscope. A graphic user interface for debugging and visualizing the collected data in real time was implemented as shown in Electronic Supplementary Material (ESM) eFig. 1. Data saving started when the laryngoscope was introduced into the mouth and ended when the laryngoscope was pulled out of the mouth. The selected Arduino board and its interface with LabVIEW software guaranteed an adequate sensor signal sampling.

Outcome measures

The primary outcome measures was the maximum peak force (maximum force recorded, expressed as Newton [N]) during intubation. Output data were analyzed with Matlab software (MathWorks, Natick, MA, USA). Data not concerning the intubation phase (the recordings before the insertion and after the removal of the laryngoscope from the mouth) were discarded and the primary outcome measures were derived by analyzing the relative maximums of the cleaned data. A relative maximum was identified as the value in which a variation of the derivative sign occurred and was organized in a vector. Then, the maximum and mean of the vector were calculated to obtain the maximum and average peak force, respectively.

The secondary outcome measures included the average peak force (average of all peak forces) recorded during

Figure Position of epiglottic sensors in direct laryngoscope (i), straight blade videolaryngoscope (ii), and hyperangulated blade videolaryngoscope (iii); position of palatal sensors in direct laryngoscope (iv), straight blade videolaryngoscope (v) and hyperangulated blade videolaryngoscope (vi).

intubation, the time needed to intubate, and the subjective workload. The time needed to intubate was calculated as the time elapsed from the introduction of the laryngoscope into the mouth to the time the ETT passed through the vocal cords, after stylet removal. The subjective workload relative to each laryngoscope was assessed using the National Aeronautics and Space Administration Task Load Index (NASA TLX; NASA Ames Research Center, Mountain View, CA, USA) protocol, which is a multidimensional subjective workload rating procedure based on a weighted average of ratings of six factors (mental demand, physical demand, temporal demand, performance, effort, and frustration level).[16] The NASA TLX was calculated as follows: 1) before the simulation, the participant assigned a weight to the six factors; 2) at the end of each intubation, the participant rated the six factors on a visual rating scale; and 3) at the end of the simulation, the weighted sum of the factors was calculated and the NASA TLX obtained. For each participant, the same set of weights was used to rate the laryngoscopes as described in the NASA TLX manual[16] when the contribution of the six factors to their workload was assumed to be similar.

Data collection

All data were collected by an observer who was not involved in the simulation. Data were recorded on a data sheet designed for the study and stored in a password-protected computer.

Blinding

The characteristics of the interventions did not allow blinding of participants and outcome assessors. The statistician who analyzed the data was blinded to treatment allocation.

Statistical analysis

As we were unable to predict the magnitude of the difference in forces applied with the devices, a formal sample size calculation could not be performed during study planning and a convenience sample size of 30 participants was chosen for the trial.

In the analysis of forces, the 50th percentile (median) and top 10th percentile were calculated as relevant indicators of both maximum and average peak force, while median and top 10th percentile of the paired differences between two devices were used for comparisons. The top 10th percentile difference in forces was chosen to assess the maximum difference in applied forces.[12] Bootstrap confidence intervals (CI) were calculated for percentiles and differences, and any CI for the difference not including zero suggested a statistically significant difference.

Because of coverage error of bootstrap CIs for percentiles in small-sized samples, empirical bootstrap 99% CIs were calculated using resampling with replacement to create 1,000 samples of the same size as the original.[12]

The time to intubate and NASA TLX score were analyzed in a similar manner: medians (with empirical bootstrap 99% CIs) were calculated as relevant indicators and medians of the paired differences between two devices were used for comparisons.

Statistical analysis was performed using R 4.1 (R Foundation for Statistical Computing, Vienna, Austria).[17]

Results

The trial included seven level III NICU and PICU consultants, 15 pediatric residents, seven anesthesiology consultants, and one anesthesiology resident. Experience with direct laryngoscopy was limited (< 10 intubations) in 17 participants, moderate (10–50 intubations) in five participants, and high (> 50 intubations) in eight participants. Experience with videolaryngoscopy was limited (< 10 intubations) in 23 participants, moderate (10–50 intubations) in two participants, and high (> 50 intubations) in five participants.

Complete data were obtained for all participants using direct laryngoscopy (A), straight blade videolaryngoscopy (B), and hyperangulated videolaryngoscopy (C). All participants performed the allocated procedure and there was no loss to follow-up (ESM eFig. 2).

Table 1 displays median and top 10th percentile for maximum peak force and average peak force recorded by the epiglottic sensor. When comparing direct laryngoscopy *vs* straight blade videolaryngoscopy, median differences were greater than zero (maximum peak, 3.2 N; 99% CI, 1.2 to 6.1; average peak, 3.1 N; 99% CI, 0.9 to 5.9), as well as top 10th percentile differences (maximum peak, 8.2 N; 99% CI, 6.4 to 11.7; average peak, 6.7 N; 99% CI, 5.5 to 8.4).

When comparing direct laryngoscopy *vs* hyperangulated videolaryngoscopy, median differences were greater than zero (maximum peak, 5.3 N; 99% CI, 3.9 to 7.2; average peak, 4.9 N; 99% CI, 3.7 to 7.0), as well as top 10th percentile differences (maximum peak, 8.7 N; 99% CI, 5.6 to 11.1; average peak, 7.3 N; 99% CI, 4.1 to 8.8).

Table 2 displays medians and top 10th percentiles for maximum peak force and average peak force recorded by the palatal sensor. When comparing direct laryngoscopy *vs* straight blade videolaryngoscopy, there was no detectable median difference (maximum peak, -0.1 N; 99% CI, -4.4 to 1.9; average peak, 0.0 N; 99% CI, -4.4 to 2.4), while top 10th percentile differences were greater than zero (maximum peak, 7.6 N; 99% CI, 5.1 to 13.1; average peak, 6.9 N; 99% CI, 5.4 to 10.9).

When comparing direct laryngoscopy *vs* hyperangulated videolaryngoscopy, the median difference was greater than zero for maximum peak force (3.0 N; 99% CI, 0.1 to 5.5) but not for average peak force (1.9 N; 99% CI, -1.1 to 3.8), while top 10th percentile differences were greater than zero (maximum peak, 8.9 N; 99% CI, 7.1 to 12.6; average peak, 7.7 N; 99% CI, 6.9 to 10.8).

More than one attempt was required by two participants with direct laryngoscopy, by two participants with straight blade videolaryngoscopy, and by three participants with hyperangulated videolaryngoscopy. There was no detectable median difference in time to intubate and NASA-TLX score with B or C compared with A (Table 3).

Table 1 Median and top 10th percentile (with bootstrap 99% confidence interval) for maximum and average peak force recorded by the epiglottic sensor

Measure	Percentile	Reference: direct laryngoscopy (A)	Experiment 1: straight blade videolaryngoscopy (B)	Experiment 2: hyperangulated videolaryngoscopy (C)	Paired difference (A-B)	Paired difference (A-C)
Maximum peak force (N)	Median (bootstrap 99% CI)	8.2 (6.9 to 10.0)	4.7 (3.5 to 5.9)	2.8 (1.8 to 3.3)	3.2 (1.2 to 6.1)	5.3 (3.9 to 7.4)
	Top 10th percentile (bootstrap 99% CI)	11.3 (8.9 to 13.3)	7.3 (3.7 to 8.9)	4.6 (4.1 to 5.9)	8.2 (6.4 to 11.7)	8.7 (5.6 to 11.1)
Average peak force (N)	Median (bootstrap 99% CI)	6.8 (5.1 to 8.5)	3.6 (2.5 to 4.7)	2.1 (1.5 to 1.6)	3.1 (0.9 to 5.9)	4.9 (3.7 to 7.0)
	Top 10th percentile (bootstrap 99% CI)	9.7 (8.5 to 10.9)	5.4 (1.1 to 6.1)	3.3 (2.2 to 4.0)	6.7 (5.5 to 8.4)	7.3 (4.1 to 8.8)

Any CI for the difference between forces not including zero indicated a statistically significant difference

CI = confidence interval

Table 2 Median and top 10th percentile (with bootstrap 99% confidence interval) for maximum and average peak force recorded by the palatal sensor

Measure	Percentile	Reference: direct laryngoscopy (A)	Experiment 1: straight blade videolaryngoscopy (B)	Experiment 2: hyperangulated videolaryngoscopy (C)	Paired difference (A-B)	Paired difference (A-C)
Maximum peak force (N)	Median (bootstrap 99% CI)	4.2 (0.5 to 7.2)	3.2 (1.3 to 5.5)	1.0 (0.9 to 1.4)	-0.1 (-4.4 to 1.9)	3.0 (0.1 to 5.5)
	Top 10th percentile (bootstrap 99% CI)	9.6 (7.4 to 12.3)	8.6 (1.0 to 12.6)	1.7 (0.4 to 2.3)	7.6 (5.1 to 13.1)	8.9 (7.1 to 12.6)
Average peak force (N)	Median (bootstrap 99% CI)	2.4 (0.0 to 4.1)	1.5 (0.0 to 2.6)	0.4 (0.1 to 0.6)	0.0 (-4.4 to 2.4)	1.9 (-1.1 to 3.8)
	Top 10th percentile (bootstrap 99% CI)	7.9 (6.9 to 10.4)	6.8 (0.1 to 10.4)	1.0 (0.0 to 1.4)	6.9 (5.4 to 10.9)	7.7 (6.9 to 10.8)

Any CI for the difference between forces not including zero indicated a statistically significant difference

CI = confidence interval

Table 3 Time to intubate and NASA-TLX score

Measure	Percentile	Reference: direct laryngoscopy (A)	Experimental 1: straight blade videolaryngoscopy (B)	Experimental 2: hyperangulated videolaryngoscopy (C)	Paired difference (A-B)	Paired difference (A-C)
Time to intubate (s)	Median (bootstrap 99% CI)	16 (10 to 19)	17 (15 to 18)	24 (19 to 33)	1 (-2 to 6)	-2 (-5 to 9)
NASA TLX	Median (bootstrap 99% CI)	31 (20 to 42)	32 (23 to 44)	27 (14 to 37)	1 (-5 to 10)	1 (-5 to 6)

Any CI for the difference not including zero indicated a statistically significant difference

CI = confidence interval; NASA TLX = National Aeronautics and Space Administration Task Load Index

Discussion

Our findings show that less force was required during intubation with videolaryngoscopy compared with direct laryngoscopy in a neonatal mannequin. Moreover, no detectable difference was found in terms of success, time to intubation, and perceived workload.

The strengths of the study include the crossover design, an objective and reliable force measurement thanks to precise and solid technological solutions, and the participation of medical staff with heterogeneous experience with the laryngoscopes. Nonetheless, the reader should be aware of the limitations of this study. First, the mannequin removes the anatomical variability among patients. Second, the magnitude of the recorded forces may be biased by the low-stress environment of the simulation, although literature suggests that the forces used in an adult mannequin are very close to those applied to humans.[12, 18] Third, the findings should only be generalized to medical staff with similar experience.

Evidence suggests some advantages of videolaryngoscopy in terms of improved laryngeal view, reduced intubation trauma, and higher chance of success at first-attempt intubation in neonates, children, and adults.[8, 9, 19–24] In addition, less force seems to be required during indirect laryngoscopy compared with direct laryngoscopy in adult mannequins and patients.[12, 24–26] Our findings extend this advantage to a neonatal simulation setting. We hypothesized that, *in vivo*, less applied force is likely to reduce local trauma and adverse clinical reactions.[4, 8] On the other hand, we acknowledge that the magnitude of a harmful applied force during intubation is currently unknown. Of note, the magnitude of the applied force was lower in a neonatal mannequin (our data) than in an adult mannequin.[12] As a comparison, the reader should be aware that the classic Sellick manouevre exerts around 30–40 N.[27]

A previous study in adult mannequins reported full success of intubation attempts, all of which were performed in clinically acceptable time (< 95 sec).[12] In our neonatal

mannequin study, most participants performed the procedure in one attempt within 30 sec, with no detectable differences in success and time to intubation between indirect and direct laryngoscopy. While another study in adult mannequins suggested that videolaryngoscopy may reduce task workload compared with direct laryngoscopy,[13] we found no detectable difference in perceived workload during simulation with a neonatal mannequin. We speculate that such differences may be attributed to the mannequin characteristics (neonatal *vs* adult) and the low experience with videolaryngoscopy among our participants.

Our findings extend previous data from adult mannequins to neonatal mannequins and provide useful information about applied force during neonatal intubation. Such simulation results should be confirmed in clinical settings to assess the magnitude of the applied force and their consequences in neonatal patients. Further studies may also compare videolaryngoscopy with straight blade *vs* hyperangulated blade, as the latter may reduce the need for anterior force applied to the tissues. Moreover, further research may investigate the learning curve for hyperangulated videolaryngoscopy in the neonatal setting since this is a completely different technique to Miller/Macintosh laryngoscopy.

Conclusions

In a neonatal mannequin model, less force was required during intubation with videolaryngoscopy than during intubation with direct laryngoscopy. No detectable differences were found in success, time to intubation, and perceived workload. The decrease in applied force may be a desirable benefit of videolaryngoscopy (i.e., possibly reduced patient harm), but the clinical implications require assessment in future studies.

Author contributions *Francesco Cavallin* was responsible for the statistical design and analysis, and contributed to study protocol, data interpretation, and writing of the manuscript. *Chiara Sala* contributed to study protocol, data collection, data interpretation, and writing of the manuscript. *Sabina Maglio* and *Selene Tognarelli* contributed to study protocol, prototypes realization and calibration, data collection, data interpretation, and critical review of the manuscript. *Benedetta Bua* and *Paolo Ernesto Villani* contributed to study design, data collection, data interpretation, and critical review of the manuscript. *Arianna Menciassi* contributed to study design, data interpretation, and critical review of the manuscript. *Daniele Trevisanuto* conceived the study and contributed to study design, data interpretation, and writing of the manuscript. All authors agree to be accountable for all aspects of the work.

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