BMJ Paediatrics Open

Video versus direct laryngoscopy to improve the success rate of nasotracheal intubations in the neonatal intensive care setting: a randomised controlled trial

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To cite: Tippmann S, Schäfer J, Winter J, *et al*. Video versus direct laryngoscopy to improve the success rate of nasotracheal intubations in the neonatal intensive care setting: a randomised controlled trial. *BMJ Paediatrics Open* 2023;**7**:e001958. doi:10.1136/bmjpo-2023-001958

Received 22 March 2023
Accepted 13 June 2023

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ABSTRACT

Objective To assess whether video laryngoscopy (VL) for tracheal intubation of neonates results in a higher first-attempt success rate and fewer adverse tracheal intubation-associated events (TIAEs) when compared with direct laryngoscopy (DL).

Design Single-centre, parallel group, randomised controlled trial.

Setting University Medical Centre Mainz, Germany.

Patients Neonates <44$^{0/7}$ weeks postmenstrual age in whom tracheal intubation was indicated either in the delivery room or in the neonatal intensive care unit.

Intervention Intubation encounters were randomly assigned to either VL or DL at first attempt.

Primary outcome First-attempt success rate during tracheal intubation.

Results Of 121 intubation encounters assessed for eligibility, 32 (26.4%) were either not randomised (acute emergencies (n=9), clinicians' preference for either VL (n=8) or DL (n=2)) or excluded from the analysis (declined parental consent (n=13)). Eighty-nine intubation encounters (41 in the VL and 48 in the DL group) in 63 patients were analysed. First-attempt success rate was 48.8% (20/41) in the VL group compared with 43.8% (21/48) in the DL group (OR 1.22, 95% CI 0.51 to 2.88). The frequency of adverse TIAEs was 43.9% (18/41) and 47.9% (23/48) in the VL and DL group, respectively (OR 0.85, 95% CI 0.37 to 1.97). Oesophageal intubation with concomitant desaturation never occurred in the VL group but in 18.8% (9/48) of intubation encounters in the DL group.

Conclusion This study provides effect sizes for first-attempt success rates and frequency of TIAEs with VL compared with DL in the neonatal emergency setting. This study was underpowered to detect small but clinically important differences between the two techniques. The results of this study may be useful in planning future trials.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Tracheal intubation in neonates is difficult to perform and frequently associated with adverse events.
⇒ Video laryngoscopy appears to improve first-pass success rates in training situations and may reduce the number of associated adverse events.

WHAT THIS STUDY ADDS

⇒ Video laryngoscopy is a feasible primary approach for nasotracheal intubation in the neonatal intensive care setting.
⇒ Clinical trials investigating video laryngoscopy are challenging. Future studies should consider selection of alternative endpoints and randomisation at group rather than individual level.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Clinicians may be more confident about the safe use of video laryngoscopy in the neonatal intensive care unit and the delivery room.
⇒ The results of this study may be helpful in planning larger efficacy studies.

INTRODUCTION

Video laryngoscopy (VL) is increasingly used in the neonatal intensive care setting and has the potential to facilitate training and education as well as the quality of the intubation process.[1] When compared with direct laryngoscopy (DL), VL offers potential advantages in terms of ease and efficacy. The improved view of anatomical structures seems to improve the first-pass success rate and the safety of the procedure, for example, by reducing adverse tracheal intubation-associated events (TIAEs).[2–6] Using VL appears prudent, since tracheal intubation is difficult to perform in neonates and is frequently associated with adverse TIAEs.[7] However, clinical trials of VL in the neonatal intensive care setting are rare. Available randomised controlled trials (RCTs) focus on the first-pass success rate as the primary outcome and the number of intubation attempts, the duration of the intubation procedures and occurrence of TIAEs as secondary outcomes.[2 3 7 8] Evidence for the benefits of VL

is basically limited to outcomes from training and educational settings, with only one randomised trial involving both, the delivery room (DR) and the neonatal intensive care unit (NICU).[2–5]

The aim of this study was to compare VL with DL in all tracheal intubation encounters in the neonatal intensive care setting. We hypothesised that VL would improve the first-pass success rate and reduce the frequency of adverse TIAEs.

METHODS

Study design and setting

The trial was performed between February 2020 and August 2021 in the DR and NICU at the University Medical Centre Mainz, Germany. This trial was a single-centre, parallel group, RCT. Intubation encounters were randomly assigned to either VL (intervention group) or DL (control group) at first attempt. Intubation encounters were allocated in a 1:1 ratio using a computer-generated allocation sequence with blocks of varying lengths and sequentially numbered opaque envelopes. Randomisation was stratified for the DR and the NICU. Given the nature of the intervention blinding of parents, medical staff and outcome assessors was not feasible.

Participants

Neonates $<44^{0/7}$ weeks postmenstrual age in whom tracheal intubation was indicated either in DR or in the NICU were eligible for inclusion in the study. Multiple births were allocated as individuals. Exclusion criteria were as follows: (1) parental decline of participation, (2) equipment failure, (3) intubation outside the DR or the NICU or (4) clinicians' preference for either of the two methods.

Primary and secondary outcome measures

The primary endpoint was the first-pass success rate, that is, the passage of the tracheal tube through the vocal cords during the first insertion of the laryngoscope, confirmed by three criteria: Auscultation, chest elevation and chest X-ray.

Secondary outcomes were as follows: (1) the frequency of adverse TIAEs. Adverse TIAEs comprised death, cardiopulmonary resuscitation, administration of adrenaline, airway injury/bleeding, chest wall rigidity, vomiting, oesophageal intubation with or without concomitant oxygen desaturation to less than 80%, treatment of arterial hypotension, treatment of pain or discomfort, intraventricular haemorrhage, pneumothorax, Intubation of a main bronchus, difficult bag mask ventilation, use of additional equipment required or change of classification from urgent to emergency intubation and (2) moderate bradycardias (heart rate less than 100/min) and moderate oxygen desaturations to less than 80%; (3) severe bradycardias (heart rate less than 60/min) and severe oxygen desaturations to less than 60%; (4) number of attempts until successful intubation; (5) tracheal tube malpositioning on the first X-ray following intubation; (6) optimal view of the larynx (Cormack-Lehane classification system grade 1)[9 10] and (7) frequency of cross-over from VL to DL and vice versa.

Informed consent

Parents were approached by members of the medical team. Study rationale and process were explained in an understandable manner. Followingly, parents received additional written information. Informed consent was given orally and written. Parents could decline participation or end trial participation prematurely without experiencing any disadvantages in clinical care. Different approaches of informed consent were possible: full prospective informed consent, either (1) antenatally, or (2) following admission to the NICU, or (3) using a deferred consent approach. The deferred consent approach was used since tracheal intubations can occur unexpectedly after birth. Neonates, requiring emergent (intubation required to secure airway immediately) or urgent intubation (intubation required to secure airway promptly) within the first 24 hours of life were randomised and allocated to DL or VL without prior parental consent. Parents were then approached within 24 hours following allocation to explain the nature of the trial, their infant's probable participation and were requested for retrospective consent. If the parents declined to participate in the study, the infant's data were not included in the analysis.

Trial procedures

Before the start of the study, all residents, fellows and neonatologists were trained in the use of VL and DL. VL was performed using Infantview laryngoscope (ACUTRONIC Medical Systems AG, Switzerland) with Miller blades sizes 0 or 1. DL was performed using Saling micro blade size 00, Miller blades sizes 00, 0 and 1 or Macintosh blades size 0 and 1 (Proact Metal Max+-Combi). When VL was used, it was standard practice, for both, the intubating person, and the supervisor, to view on the screen during intubation. All tracheal intubations were performed according to a local standard operating procedure. Except for emergency intubations, premedication was routinely administered in the form of analgesia (fentanyl 2 µg/kg) and sedation (midazolam 0.1 mg/kg) according to the local standard protocol. A muscle relaxant (vecuronium 0.1 mg/kg) was administered if intubation conditions were considered inadequate after analgesia and sedation. As is common in many German academic hospitals, most initial attempts were performed by paediatric residents. If the intubation was not successful at first attempt, crossover was allowed to VL or DL, respectively. Changing the intubating person was also allowed.

Data on infant and provider characteristics, as well as primary and secondary outcomes, were assessed immediately following the intubation encounter in writing using standardised forms that had been previously developed

and used.[7] After a double-checking, data were transferred to an electronic database.

Sample size estimation and statistical analysis

The sample size was calculated based on success rates previously reported in non-randomised trials.[11] To detect an increase in the first-attempt success rate (primary outcome) from 50% in the DL group (control) to 80% in the VL group (intervention) with 80% power and a significance level of 5%, 78 intubation encounters were required. Assuming non-compliance and an expected crossover rate of 5% in each group, the sample size was finally estimated at 90 intubation encounters.

Descriptive statistics were used to present baseline characteristics of infants and intubation encounters with nominal data provided as numbers and percentages and quantitative data as medians and iIQRs. We used intention-to-treat analysis for all endpoints. For binary endpoints, generalised linear mixed models with a fixed effect for study arm and a random effect for neonates were fitted using a logit link and binomial distribution. For count outcomes, we fitted mixed-effect negative binomial regression models with a fixed effect for study arm and a random effect for neonates. Results are provided as OR and rate ratios (RR) with associated 95% CIs, respectively. A two-sided $p<0.05$ was considered statistically significant. All analyses were performed using Stata V.15 (StataCorp).

Monitoring and regulatory issues

Reporting in this article is based on the CONSORT (Consolidated Standards of Reporting Trials) 2010 Statement for reporting parallel group randomised trials.[12]

Patient and public involvement

Patient or public representatives were not involved in the planning of this trial. Eligible parents were given detailed verbal and written information about the study.

RESULTS

Sample characteristics

Of 121 intubation encounters assessed for eligibility, 32 (26.4%) were either not randomised (emergencies (n=9), clinicians' preference for either VL (n=8) or DL (n=2)) or excluded from the analysis (declined consent (n=13)). Finally, 89 intubation encounters (41 in the VL and 48 in the DL group) in 63 patients were analysed. Figure 1 illustrates the flow diagram of patient inclusion

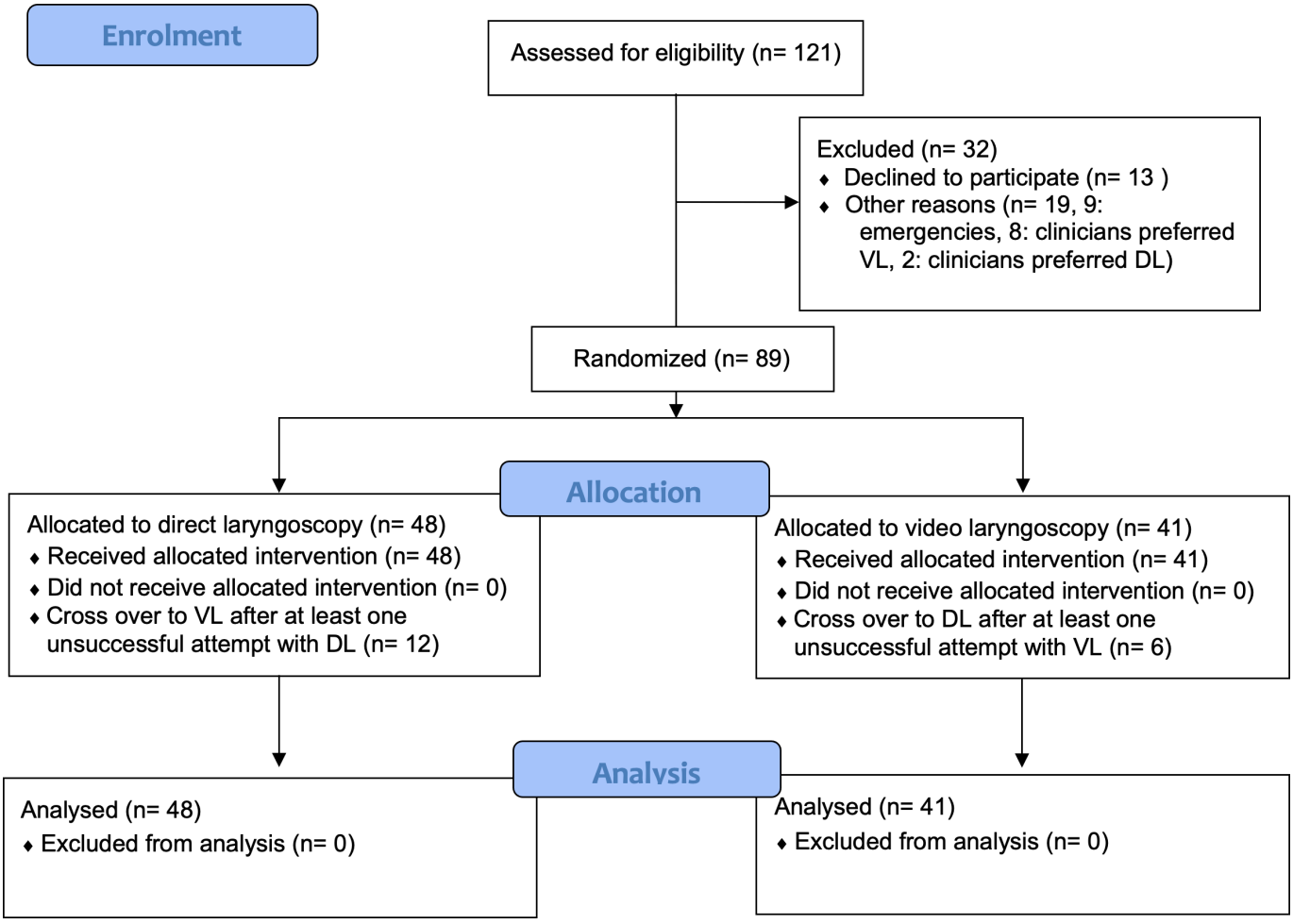

Figure 1 Flow diagram of patient enrolment, randomisation and analysis. DL, direct laryngoscopy; VL, video laryngoscopy.

Table 1 Characteristics of infants

No of infants (n)	63
Male sex, n (%)	38 (60.3)
Singleton, n (%)	48 (76.2)
GA at birth in weeks, median (IQR)	30 (26–34)
Birth weight in g, median (IQR)	1300 (850–2420)
Apgar score at 5 min, median (IQR)	8 (6–9)
Apgar score at 10 min, median (IQR)	8 (7–9)
Surfactant treatment, n (%)	36 (57.1)
Congenital anomalies, n (%)	2 (3.2)
Prenatal steroids, n (%)	47 (74.6)

GA, gestational age.

and randomisation. Primary outcome data were complete for all intubation encounters included in the study.

The characteristics of participating infants are shown in table 1. The main indication for intubation was respiratory failure associated with oxygenation difficulties or respiratory acidosis. Thirty-six intubation encounters occurred in the DR and 53 in the NICU. In this study, intubations were predominantly performed in critical clinical situations. In almost every 10th intubation encounter, the patient could not be adequately stabilised before intubation. The most frequent indication for intubation was oxygenation failure in both groups, followed by tachydyspnoea and surfactant administration which is in line with other studies. No intubations due to accidental extubations occurred. The use of premedication during intubation was similar in both groups, but many infants were intubated without receiving muscle relaxants. There were no technical limitations while using the laryngoscopy devices. The smallest infants weighed 415 g when intubated with VL and 490 g when intubated with DL. Detailed characteristics of intubation encounters are summarised in table 2.

Primary and secondary outcomes

First-attempt success rate was 48.8% (20/41) in the VL group compared with 43.8% (21/48) in the DL group (OR 1.22, 95% CI 0.51 to 2.88).

The frequency of any adverse TIAE was 43.9% (18/41) and 47.9% (23/48) in the VL and DL group, respectively (OR 0.85, 95% CI 0.37 to 1.97). Table 3 summarises the characteristics of adverse TIAEs by intervention arm. While the frequency of adverse TIAE was comparable between the study arms, oesophageal intubation with concomitant desaturation never occurred in VL group, but in 18.8% (9/48) of intubation encounters in the DL group.

Moderate bradycardias (heart rate <100/min) or oxygen desaturations to less than 80% occurred in 29.3% (12/41) and 43.9% (18/41) of intubation encounters in the VL group compared with 31.3% (15/48) and 45.8% (22/48) in der DL group (OR 0.79, 95% CI 0.25 to 2.46 and OR 0.89, 95% CI 0.35 to 2.28). Severe bradycardias (heart rate <60/min) or oxygen desaturations to less than 60% occurred in 9.8% (4/41) and 29.3% (12/41) of intubation encounters in the VL group compared with 8.3% (4/48) and 22.9% (11/48) in der DL group (OR 1.03, 95% CI 0.18 to 5.86 and OR 1.43, 95% CI 0.48 to 4.27).

There was no difference in the mean number of attempts until successful intubation (2.2 attempts in both groups, RR 1.01, 95% CI 0.73 to 1.39).

Laryngoscopic view was optimal in 62.5% (25/40) and 45.8% (22/48) of first intubation attempts in the VL and DL group, respectively (OR 1.97, 95% CI 0.84 to 4.63).

Tube insertion depth at first X-ray was correct in 85.4% (35/41) and 79.2% (38/48) in the VL and DL group, respectively (OR 1.54, 95% CI 0.51 to 4.66).

In the VL group, 14.6% (6/41) of intubations were ultimately performed with DL, while in the DL group, 25.0% (12/48) of intubations were ultimately performed with VL (OR 0.51, 95% CI 0.17 to 1.52).

DISCUSSION

We compared VL with DL for all intubation encounters in the neonatal intensive care setting. In this study, the primary outcome, the first-pass success rate, did not differ significantly between the two groups, yet there was a trend in favour of VL. This study was planned under the assumption that VL would have a significant impact on the rate of successful first attempts. Based on previous studies and own experience, an improvement of 30% was expected.[7 11] However, our results suggest that a potential positive effect of VL is significantly lower than what had been assumed. This study was not sufficiently powered to demonstrate that the observed trend in favour of VL was not random. A recent study investigating video versus DL for neonates and infants scheduled for elective surgery found a difference in first-pass success rates of approximately 10%.[13] To substantiate possible beneficial effects of VL, larger sample sizes will be required that enable the detection of smaller, yet clinically significant, beneficial effects of VL compared with DL with adequate power.

Our study nevertheless provides further evidence that VL is a feasible primary approach to tracheal intubation in critically ill term and preterm infants.[14] Intubation is a highly complex procedure. The success of intubation at first attempt does not only depend on the intubation method (choice of laryngoscope) but also on a variety of other factors. Huitink and Bouwman summarise the following complexity factors: human factors, experience, location, patient factors, equipment and time pressure.[15] This makes it difficult to plan and conduct studies in this area and to interpret and compare study results. Several studies showed that use of VL resulted in an improved first pass success rate when used in educational situations.[4 5 7] In our study, the first intubation attempts were mostly performed by residents.[6 16] However, not only junior physicians with little intubation experience, but

Table 2 Characteristics of intubation encounters by intervention arm

	DL	VL
N	48	41
PMA at intubation in weeks, median (IQR)	29.0 (26.0–33.5)	29.0 (27.0–33.0)
Weight at intubation in g, median (IQR)	1077.5 (755.5–1760.5)	1220.0 (815.0–1695.0)
Cardiorespiratory support prior to intubation*, n (%)		
FiO_2>0.21	44 (91.7)	38 (92.7)
CPAP	36 (75.0)	30 (73.2)
Bag-mask ventilation	26 (54.2)	23 (56.1)
Cardiac compressions	0 (0.0)	1 (2.4)
Prior intubations, n (%)	15 (31.3)	12 (29.3)
Stabilisation of patient before intubation†, n (%)	44 (91.7)	38 (92.7)
Indication for intubation*, n (%)		
Oxygenation failure	35 (72.9)	32 (78.1)
Respiratory acidosis	19 (39.6)	19 (46.3)
Apnoea	15 (31.3)	10 (24.4)
Chest compressions	0 (0.0)	2 (4.9)
Replacement of endotracheal tube	1 (2.1)	1 (2.44)
Surfactant administration	25 (52.1)	19 (46.3)
Tachydyspnoea	25 (52.1)	24 (58.5)
Upper airway obstruction	2 (4.2)	2 (4.9)
Elective (surgery, transport)	3 (6.3)	2 (4.9)
Unplanned extubation	0 (0.0)	0 (0.0)
Other‡	5 (10.4)	5 (12.2)
Nasotracheal intubation, n (%)	48 (100.0)	40 (97.6)
Intubation in delivery room, n (%)	19 (39.6)	17 (41.5)
Intubation in NICU, n (%)	29 (60.4)	24 (58.5)
Emergency intubation§, n (%)	0 (0.0)	4 (9.7)
Premedication, n (%)		
No premedication	4 (8.3)	2 (4.9)
Fentanyl only	2 (4.2)	1 (2.4)
Midazolam only	1 (2.1)	0 (0.0)
Fentanyl and midazolam	20 (41.7)	20 (48.8)
Fentanyl, midazolam and vecuronium	21 (43.8)	18 (43.9)
First attempt proceduralist, n (%)		
Paediatric resident	28 (58.3)	23 (56.1)
Neonatologist	10 (20.8)	11 (26.8)
Physician experience¶, n (%)		
<10 intubations	15 (31.9)	13 (31.7)
≥10 intubations	32 (68.1)	28 (68.3)
Neonatal nurse experience**, n (%)		
<10 intubations	10 (22.2)	7 (17.5)
≥10 intubations	35 (77.8)	33 (82.5)

*Multiple selections allowed.
†Stabilisation of an infant was defined as SaO_2>90% and HR>100/min.
‡Other indications included pneumothorax, abdominal distension, choanal atresia, endotracheal tube obstruction.
§Intubation required to immediately secure the airway.
¶Data available for 88 out of 89 intubation encounters.
**Data available for 85 out of 89 intubation encounters.
CPAP, continuous positive airway pressure; DL, direct laryngoscopy; FiO_2, fraction of inspired oxygen; HR, heart rate; NICU, neonatal intensive care unit; PMA, postmenstrual age; SaO_2, oxygen saturation; VL, video laryngoscopy.

Table 3 Adverse tracheal intubation associated events by intervention arm

Category*, n (%)	DL	VL
Any	23 (47.8)	18 (43.9)
Death	0 (0)	0 (0)
Chest compressions	1 (2.1)	0 (0)
Administration of epinephrine	1 (2.1)	1 (2.4)
Airway injury	1 (2.1)	0 (0)
Bleeding from the upper respiratory tract	5 (10.4)	3 (7.3)
Thoracic rigidity	2 (4.2)	0 (0)
Vomiting	1 (2.1)	0 (0)
Oesophageal intubation without concomitant desaturation	5 (10.4)	2 (4.9)
Oesophageal intubation with concomitant desaturation	9 (18.8)	0 (0)
Treatment of arterial hypotension	2 (4.2)	3 (7.3)
Treatment of pain or discomfort	9 (18.8)	10 (24.4)
Intraventricular haemorrhage	0 (0)	0 (0)
Pneumothorax	1 (2.1)	0 (0)
Intubation of a main bronchus	0 (0)	2 (4.9)
Difficult bag-mask ventilation	6 (12.5)	4 (9.8)
Use of additional equipment required	1 (2.1)	4 (9.8)
Change of urgency from 'urgent' to 'emergency'	2 (4.2)	2 (4.9)

*Intubation encounters could be associated with multiple adverse events.
DL, direct laryngoscopy; VL, video laryngoscopy.

also senior physicians already very experienced in DL had to be trained to perform VL in preparation of this study. This might contribute to the understanding of unexpected and differing study results. Ultimately, it is unclear how much training is required to be able to perform a neonatal intubation (with whatever technique) safely.[17] It appears to be critical to have to learn two techniques at the same time.[3 17 18] Finally, it remains unclear whether the technique of nasotracheal intubation as performed in this study when compared with orotracheal intubation would affect study outcomes.

The overall frequency of adverse TIAEs, and desaturations and bradycardias did not differ significantly between groups. It was noticeable, however, that oesophageal intubation with concomitant desaturation did never occur in the VL group. Various studies have reported that oesophageal intubation is the most common and severe adverse TIAE.[6 7 14 18] This raises the question which TIAEs are important and whether it is more important to prevent certain adverse TIAEs than others. Future studies should classify TIAEs according to their severity. For example, the NAESS (neonatal adverse event severity scale) score could be used as a point of reference.[19] Also, the safety of neonatal intubations is difficult to measure and is influenced by many other factors than the choice of laryngoscope, in particular team experience, airway stabilisation measures and premedication.[7 20]

The median number of intubation attempts and tube malpositioning did not differ between groups and were comparable to other studies.[2 16]

Though there seemed to be a trend in favour of VL, VL did not significantly improve laryngoscopic view. However, as has been observed in adult studies in anaesthesia, an improved view does not necessarily result in improved first-pass success rates.[9 10] The exact reasons for this are still not well understood.

After the first intubation attempt, the randomly allocated method of laryngoscopy was changed frequently in both directions, but ultimately a quarter of the intubation attempts started with DL were ultimately performed with VL. Hence, it appears challenging to randomise on the individual level and to study both techniques simultaneously. Randomisation at the individual level presupposes that both techniques must be trained, kept on hand and mastered ad hoc. The quality of intubations, as a result, may suffer. For future trials, it appears advisable to consider alternative study designs, like a stepped wedge cluster randomised design.

Limitations

The present study is limited in several ways. First, despite allocation concealment and no protocol deviations after allocation concealment, potentially meaningful imbalances in baseline variables cannot be excluded. Second, it is plausible that confounding variables were associated with the primary or secondary outcomes, thus potentially threatening unbiased effect estimation. Third, a larger sample size in a larger effectiveness trial would probably attenuate this limitation. Moreover, a stratified randomisation procedure or alternative trial designs could be used to improve baseline balance of important predictors of the endpoints such as gestational age, weight and prior difficult intubations.

CONCLUSION

This study provides effect sizes for first-attempt success rates and frequency of TIAEs with VL compared with DL in the neonatal emergency setting. This study was underpowered to detect small but clinically important differences between the two techniques. Non-randomisation, exclusion from analysis and treatment cross-over were frequent. The results of this study may be of help when planning subsequent trials.

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Acknowledgements The authors want to thank the entire team of the neonatal intensive care unit of the University Medical Centre Mainz for their support in conducting the study as well as the parents of the participating infants. Study results are part of the doctoral thesis of one coauthor (JS).

Contributors ST coordinated and supervised data collection, evaluated the analyses, and drafted the initial manuscript; JS participated in data collection,

carried out the statistical analyses, and critically reviewed the manuscript; JW evaluated the analyses, and critically reviewed the manuscript; A-KM participated in data collection, evaluated the analyses, and critically reviewed the manuscript; KS evaluated the analyses, and critically reviewed the manuscript; MS participated in data collection, and critically reviewed and revised the manuscript; ME supervised and performed the statistical analyses, and critically reviewed and revised the manuscript. EM supervised the study, and critically reviewed the manuscript; AK as the guarantor of the study conceived the idea, conceptualised, designed and supervised the study, and evaluated the analyses; All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Rhineland-Palatinate Medical Association, ID: 2019-14405. Participants gave informed consent before taking part in the study.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request.

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