

Direct versus video laryngoscopy with standard blades for neonatal and infant tracheal intubation with supplemental oxygen: a multicentre, non-inferiority, randomised controlled trial



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Summary

Background Tracheal intubation in neonates and infants is a potentially life-saving procedure. Video laryngoscopy has been found to improve first-attempt tracheal intubation success and reduce complications compared with direct laryngoscopy in children younger than 12 months. Supplemental peri-procedural oxygen might increase the likelihood of successful first-attempt intubation because of an increase in safe apnoea time. We tested the hypothesis that direct laryngoscopy is not inferior to video laryngoscopy when using standard blades and supplemental oxygen is provided.

Methods We did a non-inferiority, international, multicentre, single-blinded, randomised controlled trial, in which we randomly assigned neonates and infants aged up to 52 weeks postmenstrual age scheduled for elective tracheal intubation to either direct laryngoscopy or video laryngoscopy (1:1 ratio, randomly assigned using a secure online service) at seven tertiary paediatric hospitals across Australia, Canada, Italy, Switzerland, and the USA. An expected difficult intubation was the main exclusion criteria. Parents and patients were masked to the assigned group of treatment. All infants received supplemental oxygen (1 L/Kg per min) during laryngoscopy until the correct tracheal tube position was confirmed. The primary outcome was the proportion of first-attempt tracheal intubation success, defined as appearance of end-tidal CO₂ curve at the anaesthesia monitor, between the two groups in the modified intention-to-treat analysis. A 10% non-inferiority margin between direct laryngoscopy or video laryngoscopy was applied. The trial is registered with ClinicalTrials.gov (NCT04295902) and is now concluded.

Findings Of 599 patients assessed, 250 patients were included between Oct 26, 2020, and March 11, 2022. 244 patients were included in the final modified intention-to-treat analysis. The median postmenstrual age on the day of intubation was 44.0 weeks (IQR 41.0–48.0) in the direct laryngoscopy group and 46.0 weeks (42.0–49.0) in the video laryngoscopy group, 34 (28%) were female in the direct laryngoscopy group and 38 (31%) were female in the video laryngoscopy group. First-attempt tracheal intubation success rate with no desaturation was higher with video laryngoscopy (89.3% [95% CI 83.7 to 94.8]; n=108/121) compared with direct laryngoscopy (78.9% [71.6 to 86.1]; n=97/123), with an adjusted absolute risk difference of 9.5% (0.8 to 18.1; p=0.033). The incidence of adverse events between the two groups was similar (−2.5% [95% CI −9.6 to 4.6]; p=0.490). Post-anaesthesia complications occurred seven times in six patients with no difference between the groups.

Interpretation Video laryngoscopy with standard blades in combination with supplemental oxygen in neonates and infants might increase the success rate of first-attempt tracheal intubation, when compared with direct laryngoscopy with supplemental oxygen. The incidence of hypoxaemia increased with the number of attempts, but was similar between video laryngoscopy and direct laryngoscopy. Video laryngoscopy with oxygen should be considered as the technique of choice when neonates and infants are intubated.

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Introduction

Tracheal intubation in neonates and infants can be technically challenging even for experienced medical professionals and can require multiple attempts. However, multiple attempts are associated with a higher

incidence of life-threatening complications.^{1,2} Although experience is associated with a high success rate of tracheal intubation at the first attempt and a lower rate of respiratory adverse events,^{3,4} a difficult tracheal intubation in neonates and young infants results in an increased

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Research in context

Evidence before this study

Neonates and infants represent a vulnerable population and the procedure of tracheal intubation, even in elective conditions, can be challenging. Direct laryngoscopy has been the technique of choice for many decades. The use of video laryngoscopy with a standard Miller or Macintosh blade has showed increased success rates of first attempt tracheal intubation and reduced the incidence of complications, if compared with standard direct laryngoscopy. The success of a first attempt at tracheal intubation is crucial because the rate of complications increases with more intubation attempts. However, such success can be affected by several anatomical factors, in addition to the stability of physiology during the intubation manoeuvres. A subanalysis of the Nectarine study showed that more than 50% of the reported difficult intubations had a Cormack-Lehane score of 1–2 (which indicates a full or partial visualisation of the glottis, or arytenoids visualisation, indicating that tracheal intubation should be easy). Even if most of the attempts in the study were done using direct laryngoscopy, it is unlikely that an already good view is improved by the use of video laryngoscopy. One of the reasons for unsuccessful intubation is the rapid oxygen desaturation when the laryngoscopy manoeuvre is being performed in a patient who is apnoeic. Apnoeic oxygenation has been shown to increase the likelihood of a successful first-attempt tracheal intubation because it prolongs the safe apnoea time. For this study, we searched PubMed and the Cochrane library in English between Jan 1, 1990, and May 1, 2021, using various combinations of search terms (“high-flow oxygen”, “low flow oxygen”, “neonatal and infant tracheal intubation”, “direct laryngoscopy”, and “video laryngoscopy”). We found 33 articles, and nine were clinical trials. Three articles reported an increased first-attempt intubation rate with video laryngoscopy, whereas four articles showed a reduced incidence of desaturation when supplemental oxygen was applied to increase the safe apnoea

time. None of the available trials compared the successful intubation rate with different intubation devices under oxygen supplementation. The evidence supports the use of video laryngoscopy to increase the success of first attempt at intubation, but none of the current literature reported the success rate with the application of oxygen during the apnoea time, especially when the traditional direct laryngoscopy is used. Because of the heterogeneity of techniques applied and different flow rates of oxygen administered, the previous findings cannot be generalised.

Added value of this study

This international trial found that the success rate of the first attempt of tracheal intubation in anaesthetised neonates and young infants is significantly higher with video laryngoscopy than with direct laryngoscopy. The hypothesis that direct laryngoscopy is non-inferior to video laryngoscopy was not met, because the margin of a 10% difference between the two techniques was exceeded. Consequently, the results from this study support the use of video laryngoscopy for routine tracheal intubation in neonates and infants undergoing general anaesthesia. Moreover, the low incidence of complications such as hypoxia, severe bradycardia, and oesophageal intubation in both groups might be related to the use of continuous supplemental oxygen and the expertise of staff at the tertiary level paediatric hospitals involved.

Implications of all the available evidence

The current trial adds new evidence on airway management in neonates and small infants. The use of video laryngoscopy should be preferred in routine clinical practice. However, adding oxygen during laryngoscopy, either direct or video laryngoscopy, might be considered a new standard of care when neonates and infants need to be intubated because it reduces the rate of adverse events. The exact amount of supplemental oxygen to be delivered still needs to be established.

incidence of cardio-respiratory instability.^{2,5–8} Neonates and young infants have high oxygen consumption, low functional residual capacity, a small closing capacity, and an increased risk for airway collapse.⁹ These issues are exacerbated under general anaesthesia and muscle relaxation,^{10,11} and can lead to life-threatening oxygen desaturation.¹² The younger the child, the shorter the apnoea tolerance.¹³

Supplemental, periprocedural, high-flow nasal oxygen increases the likelihood of successful tracheal intubation on the first attempt using direct laryngoscopy in neonates by nearly 18%¹⁴ and increases the safe apnoea time by more than 80 s in neonates and infants,¹⁵ confirmed by other studies.¹⁶ Furthermore, video laryngoscopy using a standard blade (Miller and Macintosh) improved the success rate of first attempts at tracheal intubation and reduced complications compared with standard direct laryngoscopy, particularly in young children, infants, and neonates.¹⁷ Video laryngoscopy might increase the success

of intubation at the first attempt but does not decrease the time to intubation or the number of attempts for intubation.¹⁸ Identifying a technique that can improve the success of first-attempt tracheal intubation while improving apnoea tolerance in young infants and neonates is highly desirable and will improve patient safety.

In addition, video laryngoscopy might not always be immediately available in every setting. The administration of supplemental oxygen during tracheal intubation in small infants might result in longer apnoea tolerance, mitigating any clinically relevant time differences between direct laryngoscopy or video laryngoscopy. Oxygen might allow more time to safely intubate a neonate even with a direct laryngoscope, which might be of relevance in settings with low resources. In addition, a preliminary pilot study on 20 patients showed that, with supplemental oxygen, direct laryngoscopy had a similar first-attempt success rate to video laryngoscopy

(Riva T, unpublished). Therefore, based on the current literature and the pilot data, we hypothesised that direct laryngoscopy is not inferior to video laryngoscopy when using standard blades and supplemental oxygen is provided in anaesthetised neonates and infants requiring elective tracheal intubation.

Methods

Study design

After obtaining ethics committee approval for each participating site and registration, this non-inferiority, international, multicentre, single-blinded, randomised controlled trial compared tracheal intubation using either direct laryngoscopy or video laryngoscopy, both with periprocedural supplemental oxygen (F_iO₂ 1.0). Seven paediatric tertiary hospitals across Australia (n=1), Canada (n=1), Italy (n=1), Switzerland (n=3), and the USA (n=1) participated.

Participants

Included participants were neonates and infants aged up to 52 weeks postmenstrual age requiring tracheal intubation for non-emergency surgical and non-surgical procedures, either in the paediatric operating room or the paediatric or neonatal intensive care unit. There was no lower age or weight limit for study participation. Exclusion criteria were an expected difficult intubation, the use of an alternative airway management strategy, such as flexible bronchoscope-assisted intubation through a supraglottic airway, congenital heart disease mandating a FiO₂ of less than 1.0, cardiopulmonary collapse requiring advanced life support, and emergency surgery. During the pre-anaesthesia visit, the parents of eligible patients were approached for their child's study participation and written informed consent was signed.

Randomisation and masking

Patients were randomly assigned 1:1 to either direct laryngoscopy with Miller blades (Optima CLX, Armstrong Medical, Colerain, Ireland), or C-MAC video laryngoscopy with Miller blades (Karl Storz, Tuttlingen, Germany). The randomisation list was generated using a secure online service by an independent member of the research team of the Department of Anesthesiology and Pain Therapy of the Bern University Hospital and stratified for the study sites. Before the induction of anaesthesia, the sealed opaque envelopes with the allocated treatment were opened by the research team member and the randomised study intervention was assigned. Parents and patients were masked to the assigned group of treatment.

Procedures

Participants were prepared according to the local standard operating procedures for paediatric anaesthesia in each centre. Before the induction of anaesthesia, vital signs (pulse oximetry, electrocardiogram, non-invasive blood pressure, and end-tidal CO₂) were monitored. Participants

were pre-oxygenated before the induction of anaesthesia for 1 min via a facemask with FiO₂ of 1.0 and flow rates of 6 L per min. Anaesthesia was induced with: (1) intravenous induction with either thiopentone (4–7 mg/kg), ketamine (0.5–2.0 mg/kg), propofol (1–4 mg/kg), or midazolam (0.5–1.0 mg/kg), or inhalational induction with incremental volatile agents with or without nitrous oxide; (2) opioids at the discretion of the anaesthesiologist in charge; and (3) a non-depolarising muscle relaxant (rocuronium 0.5–1.0 mg/kg, cis-atracurium 0.2–0.5 mg/kg, or vecuronium 0.1 mg/kg).

After the induction of anaesthesia, bag-mask ventilation with 100% oxygen was initiated and neuromuscular blockade was assessed by train-of-four monitoring using a train-of-four watch (Organon, Dublin, Ireland) to achieve a train-of-four stimulation of 0 at the ulnar nerve or the posterior tibial nerve. After bag-mask ventilation was discontinued, supplemental oxygen was provided for every study participant, and applied as follows: first, oral intubation, 1 L/kg per min via neonatal nasal cannula (O₂-Star curved nasal cannula, Dräger, Germany); and second, nasal intubation, 1 L/kg per min via nasal cannula (Vygon, Ecouen, France) or via the anaesthesia circuit through the tracheal tube placed in the nose.

The route of intubation was left to the anaesthesiologist in charge of the patient and in line with institutional routine practice. The following tracheal tubes were chosen according to bodyweight: for less than 1 kg, an uncuffed tube with an internal diameter of 2.5 mm (Sheridan tracheal tube, Teleflex, Morrisville, NC, USA, or Vygon tracheal tube, Vygon, Ecouen, France) was used; for 1–3 kg, an uncuffed tube with an internal diameter of 3.0 mm was used; and for more than 3 kg, a cuffed tube with an internal diameter of 3.0 (Microcuff tracheal tube, Avanos Medical devices, Alpharetta, Georgia, USA) or uncuffed tube with an internal diameter of 3.5 mm were used. A Miller blade size of 0 was used for children weighing less than 1 kg and size 1 for children weighing more than 1 kg.

After the first unsuccessful intubation attempt with the randomly assigned method, the protocol permitted additional attempts with the same device, but not to exceed four intubation attempts. After the first attempt, a switch to a different method was allowed. Additional devices, such as rigid stylets or gum elastic boogies, could be used at any stage.

Study termination criteria were a successful intubation, the occurrence of a cannot intubate, cannot oxygenate emergency, unsuccessful intubation requiring a supraglottic device, or malfunction of equipment. In cases of unexpected difficult intubation or unsuccessful intubation, a local difficult airway algorithm was followed.¹⁹

Outcomes

The primary outcome was the proportion of first-attempt tracheal intubation success in children

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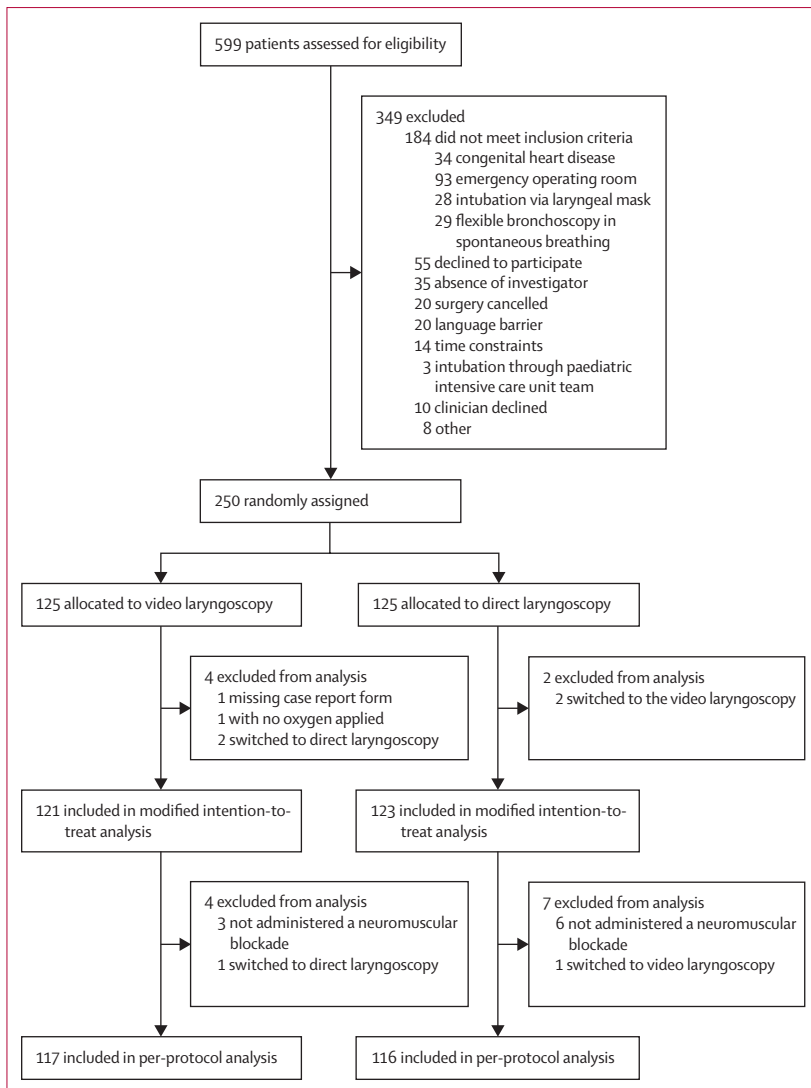


Figure 1: Trial profile for the primary outcome population

receiving supplemental oxygen in each group; successful intubation was defined by the appearance of an end-tidal CO₂ curve on the anaesthesia monitor. Secondary outcomes were the occurrence of moderate (SpO₂ <90%) and severe (SpO₂ <80%) desaturation, with or without bradycardia, during intubation; overall number of attempts; intubation time (from the first introduction of laryngoscope between the lips until positive capnography reading); the first end-tidal CO₂ after successful intubation; percentage of glottic opening (POGO) from 0% to 100%;^{20,21} need for additional devices at any step of intubation; Cormack-Lehane score; and the need to switch from one technique to another. Complications during and after airway management, such as oral or airway injury with bleeding, emesis, pulmonary aspiration of gastric contents, hypotension requiring treatment, hypoxia

causing bradycardia requiring chest compressions, pneumothorax, and the administration of resuscitation drugs, as well as post-extubation stridor, were recorded. Furthermore, any additional respiratory complications occurring within the first 24 h were recorded.

Outcomes were recorded by a member of the research team, independent of the staff caring for the patient, who was unmasked to treatment allocation. Data were transferred to a secure, web-based data integration platform (REDCap, REDCap Software, Vanderbilt University, Nashville, TN, USA) hosted at Bern University Hospital.

Statistical analysis

Based on previous data,¹⁷ a non-inferiority trial was designed. The null hypothesis stated that the difference in the first-attempt success rate with video laryngoscopy versus direct laryngoscopy would be larger than 10% (non-inferiority margin; one-sided hypothesis). The alternative hypothesis stated that the difference in the first-attempt success rate would be smaller than or equal to 10% between the two groups. To establish the sample size, we assumed a first-attempt success rate of 95% for both groups. That required 100 patients per group for a power of 90% and a significance level of 0.025. Accounting for a 20% dropout rate and inter-centre variability in success rates, we aimed to enrol a total of 250 patients. Initially, 200 patients were planned to be enrolled, to aim for a power of 80% and a significance level of 0.025. Over the course of the study, there were unforeseen uncertainties regarding the participation of some centres, because some centres could not continue with clinical research and other centres continued to recruit patients. Enrolment was initially equally distributed among participating centres (40 patients from each centre, but only ten from Aarau, Switzerland), but then redistributed for logistic reasons. We planned only ten patients in Aarau, Switzerland, because of the small size of the centre. Considering the initial aim of having approximately 40 children per centre to maintain homogeneity, we ended up with 250 patients enrolled with all participating centres actively recruiting. Subsequently, the power of the study was enhanced to 90%. This increase in the sample size was announced to the leading ethics committee at Bern University Hospital and the analysis plan was updated accordingly. The interpretation of non-inferiority results follow the extension of the CONSORT 2010 Statement.²²

The primary results are based on a modified intention-to-treat (mITT) analysis and a per-protocol sensitivity analysis. The mITT analysis included all patients undergoing either direct laryngoscopy or video laryngoscopy with standard blades, whereas the per-protocol analysis excluded patients who received a different intubation method than allocated, and patients who did not receive the required neuromuscular blocking agents. For the

primary outcome, a crude and adjusted two-sided ($100 \times [1 - 2\alpha]\%$) CI (with α indicating the error) and mean estimate of the difference in the first-attempt success rate between the two treatment groups was computed and compared with the non-inferiority region. The crude estimates were based on a generalised linear mixed-effect logistic regression model with a random offset for each institution. The adjusted estimates were based on a multivariable logistic regression model with the covariate's treatment group, American Society of Anesthesiology physical status, weight on day of intubation, degree of medical professional's experience (measured by the number of years since board certification, <5 years vs ≥ 5 years), and the associated estimated marginal means of the multivariable logistic regression. A generalised linear mixed-effect logistic regression model was numerically non-feasible for the adjusted estimates since some institutions only had medical professionals with the same level of experience (appendix p 2).

In terms of secondary outcomes and adverse events, adjusted risk differences similar to the primary outcome were shown in the case of a binary outcome. For multinomial secondary outcomes (eg, number of attempts until successful intubation, Cormack-Lehane score, and POGO score), a Fisher's exact test was used. A Mann-Whitney test was used for group comparisons of continuous variables (time to achieve successful intubation and end-tidal CO_2 after successful intubation).

As post-hoc exploratory analyses, the adjusted risk differences among techniques of choice, experience of the medical professional, postmenstrual age, and weight at birth were assessed by including the corresponding interaction of the factor with the treatment group in the multivariable logistic regression model. The statistical significance of the interaction was examined with a likelihood ratio test. Owing to the exploratory nature of the post-hoc analyses, no p-value adjustment for multiple comparisons was performed. The linearity between the incidence of adverse events as a function of the number of attempts was examined with a Mantel-Haenszel χ^2 test.

Data were summarised with counts and percentages in the case of categorical variables. Numerical variables were summarised with mean and SD when normally distributed and with median and IQR otherwise. All analysis were performed with R (version 4.02). The statistical analysis plan is available in the appendix (pp 7–9). This study is registered with ClinicalTrials.gov (NCT04295902).

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Oct 26, 2020, and March 11, 2022, 599 patients were assessed for eligibility, of whom 250 were randomly

	Direct laryngoscopy (n=123)	Video laryngoscopy (n=121)
Institution		
Aarau, Switzerland*	5 (4%)	5 (4%)
Bern, Switzerland	31 (25%)	29 (24%)
Geneva, Switzerland	10 (8%)	10 (8%)
Genoa, Italy	19 (15%)	21 (17%)
Montreal, Canada	20 (16%)	20 (17%)
Perth, Australia	20 (16%)	18 (15%)
Philadelphia, USA	18 (15%)	18 (15%)
Gestational age at birth, weeks	38.0 (35.0–39.0)	38.0 (36.0–39.0)
Sex		
Male	89 (72%)	83 (69%)
Female	34 (28%)	38 (31%)
History of previous difficult intubation	0	2 (2%)
Known congenital abnormality		
Known or suspected myopathy	0	0
Congenital heart disease	7 (6%)	4 (3%)
Chromosomopathy	3 (2%)	2 (2%)
Other congenital malformations	32 (26%)	31 (26%)
Craniofacial abnormality		
Limited mouth opening	0	0
Macroglossia	2 (2%)	3 (2%)
Micrognathia	2 (2%)	1 (1%)
Limited neck movement	1 (1%)	1 (1%)
Obstructing airway	1 (1%)	0
Dysmorphism	1 (1%)	4 (3%)
Facial asymmetry	1 (1%)	0
Cleft lip or palate	0	1 (1%)
Neck mass	0	1 (1%)
Other craniofacial abnormality	4 (3%)	4 (3%)
Intubation and anaesthesia		
Postmenstrual age at intubation, † weeks	44.0 (41.0–48.0)	46.0 (42.0–49.0)
Weight on day of anaesthesia, grams	4178 (1044)	4386 (1124)
Procedure done in operating room or diagnostic suite	123 (100%)	121 (100%)
Reason for intubation		
Surgery	120 (98%)	118 (98%)
Diagnostic procedure	3 (2%)	3 (2%)
Degree of planning		
Elective or semi-elective intubation	118 (96%)	119 (98%)
Urgent intubation	5 (4%)	2 (2%)

(Table 1 continues on next page)

assigned (n=125 to video laryngoscopy; n=125 to direct laryngoscopy). Six patients were excluded from the mITT analysis: four because of a switch to the alternate group of the trial decided by the attending anaesthesiologist, one because of a missing case report form, and one because of protocol deviation, which was a failure to use oxygen during laryngoscopy. Finally, 244 patients were included in the mITT analysis (n=121 in the video laryngoscopy group; n=123 in the direct laryngoscopy group; figure 1), and 233 for the per-protocol sensitivity analysis (n=117 in the video laryngoscopy group; n=116 in the direct laryngoscopy group).

See Online for appendix

	Direct laryngoscopy (n=123)	Video laryngoscopy (n=121)
(Continued from previous page)		
American Society of Anesthesiology physical status		
I (healthy patient)	40/123 (33%)	37/120 (31%)
II (mild systemic disease)	40/123 (33%)	50/120 (42%)
III (severe systemic disease)	37/123 (30%)	33/120 (28%)
IV (life threatening condition)	6/123 (5%)	0/120
SpO ₂ ‡	99.0 (98.0-100.0)	99.0 (97.0-100.0)
Induction		
Inhalational	58/123 (47%)	61/121 (50%)
Intravenous	65/123 (53%)	60/121 (50%)
Neuromuscular blocking agent		
	117 (95%)	118 (98%)
Anaesthesia drugs for intubation		
Sevoflurane	78 (63%)	69 (57%)
Halothane	0	1 (1%)
Isoflurane	0	1 (1%)
Midazolam	6 (5%)	7 (6%)
Propofol	27 (22%)	35 (29%)
Thiopentone	30 (24%)	24 (20%)
Ketamine	1 (1%)	1 (1%)
Atropine	4 (3%)	2 (2%)
Sufentanil	0	0
Fentanyl	69 (56%)	80 (66%)
Alfentanil	1 (1%)	1 (1%)
Remifentanyl	5 (4%)	5 (4%)
Opioids		
Morphine	2 (2%)	2 (2%)
Data shown as n (%), n/N (%), mean (range), or mean (SD). *Enrolment was initially equally distributed among participating centres (40 patients from each centre, ten from Aarau, Switzerland), but then redistributed for logistic reasons. †Data missing from one institution (n=208). ‡Data available for n=111 patients in both treatment groups (data were missing for 14 patients in each group).		

Table 1: Patients' characteristics

Baseline patients' characteristics are summarised in table 1. The median age of the included patients was 44.0 (IQR 41.0–48.0) postmenstrual weeks in the direct laryngoscopy group and 46.0 (42.0–49.0) postmenstrual weeks in the video laryngoscopy group at intubation. Oral intubation was chosen 193 times (79%) and nasal intubation 51 times (21%). Supplemental oxygen was delivered 204 (84%) times via nasal cannula, and 40 (16%) times via the anaesthesia circuit, with a median flow of 4.0 L/min (IQR 3.3–5.0; table 2).

The mITT analysis showed that the use of video laryngoscopy is associated with a significantly higher first-pass success rate (108 [89.3%; 95% CI 83.7–94.8] of 121 patients), when compared with direct laryngoscopy (97 [78.9%; 71.6–86.1] of 123 patients), with an adjusted absolute risk difference of 9.5% (0.8–18.1; p=0.033; figure 2). Therefore, the non-inferiority margin was not reached. Similarly, the per-protocol analysis showed a successful first attempt in 105 (89.7% [84.2–95.2]) of 117 patients in the video laryngoscopy group versus 92 (79.3% [71.9–86.7])

	Direct laryngoscopy (n=123)	Video laryngoscopy (n=121)
Specialty of the medical professional, anaesthesia	123 (100%)	121 (100%)
Technique of choice		
Oral intubation	95 (77%)	98 (81%)
Nasal intubation	28 (23%)	23 (19%)
Type of tracheal tube		
Cuffed	51 (41%)	47 (39%)
Uncuffed	31 (25%)	37 (31%)
Microcuffed	41 (33%)	37 (31%)
Pre-oxygenation applied with oxygen 100% for at least 1 min		
	122 (99%)	120 (99%)
Oxygen administered during intubation		
Route of oxygen administration		
Nasal cannula	102 (83%)	102 (84%)
Tracheal tube	21 (17%)	19 (16%)
Flow of oxygen given, L/min	4.00 (3.0-5.0)	4.50 (3.5-5.0)
Size of blade used, international standard		
0	39 (32%)	46/119 (39%)
1	84 (68%)	73/119 (61%)
Degree of the medical professionals' experience		
Trainee or registrar		
<5 years' experience	24 (20%)	23 (19%)
≥5 years' experience	64 (52%)	64 (53%)
Experience with neonatal intubations		
0-10 neonatal intubations		
	30 (24%)	25 (21%)
11-50 neonatal intubations		
	34 (28%)	39 (32%)
>50 neonatal intubations		
	59 (48%)	57 (47%)
Data shown as n (%) or median (IQR).		

Table 2: First attempt characteristics

of 116 patients in the direct laryngoscopy group (absolute risk difference 9.9% [0.8–19.0]; p=0.033; table 3).

The post-hoc subgroup analysis showed no statistically significant interactions between the treatment group and technique of choice, medical professionals' experience, birthweight, or age at birth, suggesting no influence of these factors on the difference in the first-attempt success rate between direct laryngoscopy and video laryngoscopy (figure 2). Non-inferiority was not shown in all subgroups (figure 2). Time to achieve successful intubation was 36.5 s (IQR 23.0–54.8) in the video laryngoscopy group and 32.0 s (IQR 21.0–50.0) in the direct laryngoscopy group (unadjusted comparison; p=0.122; table 3). All patients were intubated in both groups within four attempts; when adjusted for American Society of Anesthesiology physical status, patient weight, and the medical professionals' experience, the number of attempts did not differ between the two groups (p=0.28).

The rate of complications was not different between the two groups (video laryngoscopy, five patients [4%] of

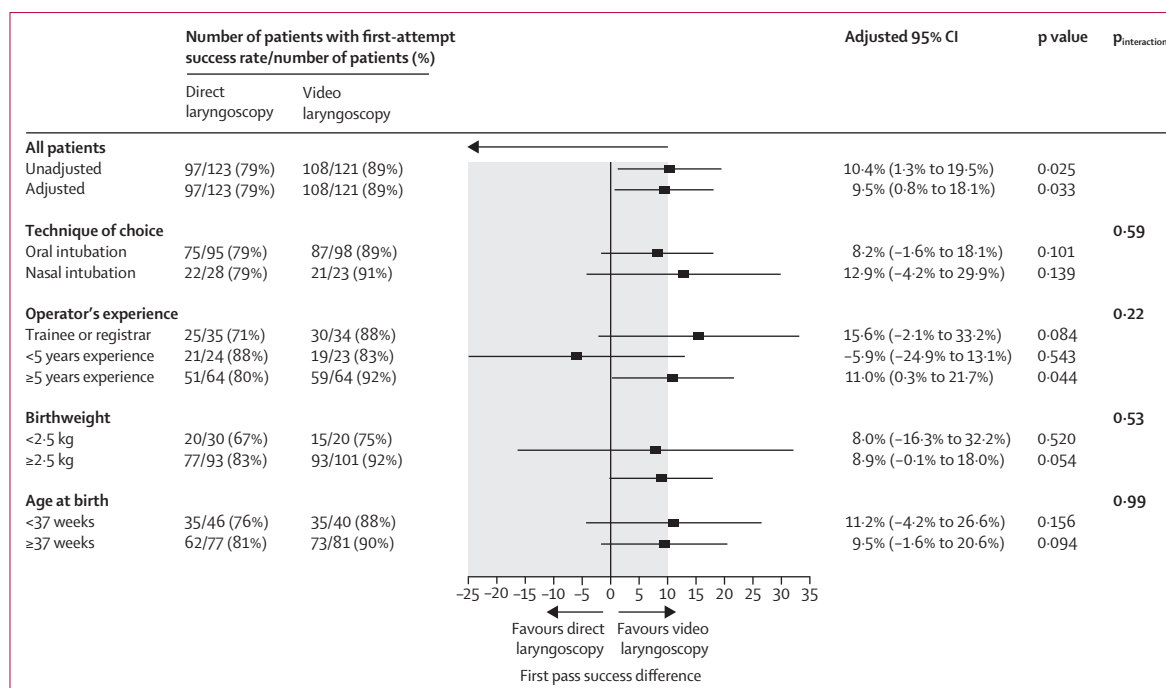


Figure 2: Difference in first-attempt success rate for direct laryngoscopy and video laryngoscopy

The risk differences for all patients and individual subgroup post-hoc analyses, adjusted for American Society of Anesthesiology physical status, degree of operators' experience (number of years since board certification, <5 years vs ≥5 years), and the weight of the patient on the day of anaesthesia using a multivariable logistic regression model. The non-inferiority margin of 10% is indicated as the shaded grey area and left pointing arrow.

121 had adverse events; direct laryngoscopy, eight patients [7%] of 123 had adverse events; adjusted risk difference -2.5% [95% CI -9.6 to 4.6%]; $p=0.49$; table 3). The complication rate increased with the number of attempts (13 [5%] of 244 patients on the first attempt, five [13%] of 40 on the second attempt, and one [17%] of six on the third attempt; $p=0.0499$). Oesophageal intubation, clinically relevant bradycardia, and cardiac arrest did not occur in any patient of either group (table 3).

The video laryngoscopy group had significantly better Cormack-Lehane score and POGO score when compared with direct laryngoscopy (table 3). External laryngeal manipulation to improve the glottic view was required less often in the video laryngoscopy group than in the direct laryngoscopy group (table 3).

Neither the rate of extubation immediately after the procedure nor the rate of immediate respiratory complications post-extubation differed significantly between the two techniques (table 3). One case (1%) of a serious adverse event unrelated to tracheal intubation in the direct laryngoscopy group was reported to the central ethics committee (massive intraoperative haemorrhage; table 3). One child (1%) in the direct laryngoscopy group had post-extubation stridor resulting in reintubation. The post-extubation need for supplemental oxygen did not differ significantly between the two groups ($p=0.99$). Post-anaesthesia complications occurred seven times in six patients with no difference between the groups.

Discussion

This international, multicentre, randomised controlled trial confirmed that the first-attempt success rate for elective tracheal intubation in anaesthetised neonates and young infants younger than 52 weeks postmenstrual age when using continuous supplemental oxygen was significantly higher with standard blade video laryngoscopy than with direct laryngoscopy. The non-inferiority margin of 10% for direct laryngoscopy was not reached, indicating that direct laryngoscopy cannot be considered equally effective to video laryngoscopy when used for tracheal intubation in young patients. Both groups had a low incidence of complications, such as hypoxia, severe bradycardia, and oesophageal intubation, which might have been because of the use of continuous supplemental oxygen in both groups and the technical expertise of staff at the tertiary level paediatric hospitals involved.

The VISI study, a multicentre, randomised controlled trial, reported that the first-attempt tracheal intubation success rate using standard blade video laryngoscopy was significantly higher compared with the use of standard blade direct laryngoscopy for infants up to 6.5 kg.¹⁷ Our results show that video laryngoscopy with standard blades is beneficial in terms of a higher success rate than direct laryngoscopy compared with recent published data,¹⁴ with a better view of the glottis, and intubation attempts never exceeding four.

This trial confirmed a higher rate of first-attempt success when video laryngoscopy with a standard blade is used,

	Direct laryngoscopy (n=123)	Video laryngoscopy (n=121)	Adjusted risk difference (95% CI)*	p value
Primary endpoint (intubation at first attempt)				
Modified intention-to-treat-analysis	97 (79%)	108 (89%)	9.5% (0.8 to 18.1)	0.033
Per-protocol analysis	92/116 (79%)	105/117 (90%)	9.9% (0.8 to 19.0)	0.033
Secondary endpoints (modified intention-to-treat-analysis)				
Number of attempts until successful intubation	0.11†
1	97 (79%)	108 (89%)
2	22 (18%)	11 (9%)
3	3 (2%)	2 (1%)
4	1 (1%)	0
Time of the successful intubation attempt, ‡ s (median [IQR])	32.0 (21.0–50.0)	36.5 (23.0–54.8)	..	0.122
End-tidal CO ₂ after successful intubation, § mmHg (median [IQR])	39.0 (31.8–45.0)	41.0 (34.0–46.0)	..	0.32
Cormack-Lehane score	0.0091†
1 (full view of the glottis)	66 (54%)	86/120 (72%)
2a (partial view of glottis)	37 (30%)	26/120 (22%)
2b (only arytenoid cartilages visualised)	7 (6%)	6/120 (5%)
3 (only epiglottis visualised, none of the glottis seen)	10 (8%)	2/120 (2%)
4 (neither glottis or epiglottis seen)	3 (2%)	0/120
POGO score	0.0003†
76–100 (full view of the glottis)	69 (56%)	93/120 (78%)
51–75 (partial view of glottis)	31 (25%)	23/120 (19%)
26–50 (only half of vocal cord and arytenoid visible)	8 (7%)	3/120 (3%)
1–25 (only lower fourth of vocal cord and arytenoid visible)	7 (6%)	1/120 (1%)
0 (no glottic structure visible)	8 (7%)	0/120
Need for additional help	50 (41%)	51 (42%)	1.6% (–10.6 to 13.7)	0.80
Stylet	29 (24%)	43 (36%)	10.3% (–0.5 to 21.1)	0.06
Bougie	2 (2%)	0	–1.9% (–5.1 to 1.2)	0.23
Cricoid external laryngeal manipulation	14 (11%)	3 (2%)	–6.4% (–11.0 to –1.8)	0.0071
McGill nipper	12 (10%)	9 (7%)	–2.1% (–9.5 to 5.4)	0.59
C-MAC with Miller blade	0	1 (1%)	0.6% (NA)	>0.99
Video laryngoscope or direct laryngoscope Macintosh blade	0	1 (1%)	0.1% (NA)	>0.99
Adverse events and difficult airway				
Adverse events during intubation	8 (7%)	5 (4%)	–2.5% (–9.6 to 4.6)	0.49
Oxygen desaturation <90%	1 (1%)	2 (2%)	0.6% (–1.6 to 2.8)	0.62
Oxygen desaturation <85%	2 (2%)	1 (1%)	0.4% (–13.0 to 13.8)	0.96
Oxygen desaturation <80%	4 (3%)	2 (2%)	–1.1% (–3.6 to 1.3)	0.37
Bradycardia <100 beats per min	1 (1%)	0	–1.0% (–3.0 to 1.0)	0.31
Bradycardia <80 beats per min	0	0
Bradycardia <60 beats per min	0	0
Cardiac arrest (need for chest compression)	0	0
Other¶	2 (2%)	0	–6.4% (–12.3 to –0.6)	0.030
Difficult airway	3 (2%)	1/120 (1%)	–1.6% (–4.6 to 1.5)	0.31
Reason for failed or abandoned intubation attempt				
Insufficient view	13 (11%)	3 (2%)	–6.1% (–10.8 to –1.4)	0.011
Oxygen desaturation or adverse event, or both	2 (2%)	1 (1%)	–0.6% (–2.6 to 1.4)	0.56
Need for extra device or help, or change of technique	11 (9%)	7 (6%)	–3.0% (–10.5 to 4.5)	0.44
Hand change	1 (1%)	0	–0.3% (–1.8 to 1.1)	0.65
Other	3 (2%)	2 (2%)	–0.8% (–3.1 to 1.5)	0.50

(Table 3 continues on next page)

	Direct laryngoscopy (n=123)	Video laryngoscopy (n=121)	Adjusted risk difference (95% CI)*	p value
(Continued from previous page)				
Follow-up				
Extubation immediately after the procedure	102/118 (86%)	107/117 (91%)	-2.2% (-11.8 to 7.3)	0.65
If not immediately, extubation within the first 24 h after the procedure	9/16 (56%)	4/10 (40%)	2.4% (-25.5 to 30.4)	0.86
The reason if not within the first 24 h	>0.99†
Information not available	4/7 (57%)	5/6 (83%)
Serious adverse event (not related to intubation)	1/7 (14%)	0/6
Other	2/7 (29%)	1/6 (17%)
If extubated (immediately or within the first 24 h), any respiratory complication occurred	4/112 (4%)	2/113 (2%)	0.6% (-1.0 to 2.3)	0.45
Type of complication (multiple per patient possible)				
Stridor	1 (1%)	0	-0.1% (-0.6 to 0.4)	0.75
Laryngospasm	0	0
Bronchospasm	0	0
Need for reintubation	1 (1%)	0
Need for high-flow nasal oxygen	1 (1%)	1 (1%)	0.0% (-1.1 to 1.1)	0.99
Need for low-flow nasal oxygen	2 (2%)	1 (1%)	0.4% (-5.4 to 6.2)	0.90
Pneumothorax	0	0
Data are n (%) or n/N (%), unless otherwise specified. POGO=percentage of Glottic opening. *Adjusted for medical professionals' experience, American Society of Anesthesiology physical status, and bodyweight on day of anaesthesia using a multivariable logistic regression model. Because of the almost complete separation in the medical professionals' experience across the participating institutions (appendix p2), a statistical approach using a generalised linear mixed effect model with a random offset for each institution was not possible. †Fisher's exact test. ‡Time of the successful intubation attempt was measured in 99 patients in the direct laryngoscopy group and 108 patients in the video laryngoscopy group. §End-tidal CO ₂ after successful intubation was measured in 96 patients in the direct laryngoscopy group and 108 patients in the video laryngoscopy group. ¶Probably tracheal stenosis from the glottic plane, because baseline desaturation was only 87% (congenital cardiac malformation). No glottic structure visible because of blood, required more muscle relaxant, first tube too tight, endotracheal tube removed when stylet removed, or no suction set up or copious secretions.				
Table 3: Outcomes and adverse events				

but there was no difference in the number of attempts or in the time to achieve successful intubation between direct laryngoscopy or video laryngoscopy. These results suggest that the use of video laryngoscopy with standard blades improved the glottic view, which is reflected by a better glottic opening (POGO) and Cormack-Lehane scores and reduced external laryngeal manipulation of the glottis. However, although the glottic view is an important factor, the skillset and experience of the medical professional probably contribute to successful intubation. We performed this trial in dedicated paediatric centres and found a lower proportion of difficult intubation (2%) compared with that found in another large European audit (5.8%), which also incorporated non-specialised centres and where supplemental oxygen was not standard.² Additionally, the shared view during video laryngoscopy enables a team approach to tracheal intubation and improves support from other health-care personnel during laryngoscopy and tracheal intubation. The entire team might be guided by the same visual aid during airway management. Furthermore, video laryngoscopy with standard blades allows a dual approach to tracheal intubation: indirectly through the screen, and by direct visualisation of the glottis. This benefit might be appreciated when teaching neonatal tracheal intubation, since the instructor can guide the trainee with greater ease through the shared airway

view. Improved first-attempt success has been reported by residents coached by supervisors watching the video laryngoscope screen compared with traditional coaching without video laryngoscopy.²³ Video laryngoscopy assists verbal feedback to trainees, resulting in higher first-pass tracheal intubation success compared with direct laryngoscopy, and reducing the rate of adverse events, such as oesophageal intubations and peripheral oxygen desaturation.²⁴

None of the participating patients required more than four intubation attempts. This finding is likely because of the inclusion of only children with normal airways as well as the expertise available in these dedicated paediatric centres, and emphasises the importance of specialist expertise. American Society of Anesthesiologists Guidelines for the management of paediatric difficult airways highlight the importance of skillsets of attending physicians, the need to develop an action plan, including limiting the number of airway management attempts, and optimisation of oxygenation administration throughout airway manoeuvres.²⁵

Both high-flow and low-flow oxygen have been shown to increase the safe apnoea time during airway instrumentation.^{15,16} Some studies have shown the effectiveness of apnoeic oxygenation during tracheal intubation by improving first-attempt tracheal intubation

success rate.^{14,26} Although the current study was not aimed at investigating the beneficial effect of oxygen supplementation on the occurrence of complications, the lower rate of complications compared with previous studies^{2,7,27} might be attributed to the supplemental peri-procedural oxygen. The intubation techniques did not seem to affect the rates of extubation immediately after the procedure and the respiratory complications in post-anaesthesia care unit.

There are some limitations to our study. Because of the obvious difference between the C-MAC video laryngoscope and the direct laryngoscope, both the clinical investigators and the study team in charge of data acquisition were not masked. All patients received supplemental oxygen, thus we do not know the effect of the first-attempt tracheal intubation success rate of each device without oxygen. Furthermore, it is not known what the optimal interface (eg, nasal cannula or nasopharyngeal airway) and flow of oxygen for supplementation are. Considering the ethical implications of doing a randomised trial with no supplemental oxygen, the next step would be to identify the optimal flow of supplemental oxygen to administer. The patients in this study underwent general anaesthesia requiring tracheal intubation, with anaesthetists accustomed to performing tracheal intubation. Our results might differ in settings outside of the operating room with clinicians who have less experience with tracheal intubation or under emergent conditions, for example in situations where blood or secretions might affect the video laryngoscopic view. All our patients had normal airways, and therefore our findings cannot be directly extrapolated to children with difficult airways or to those intubated in the delivery room or intensive care unit. Finally, our study setting involved tertiary paediatric centres and should be interpreted with caution when findings are translated into non-specialised, mixed practice hospital settings. However, it should be noted that previous studies have shown that first-pass success rates are improved compared with direct laryngoscopy in less experienced providers using video-assisted laryngoscopy for infants.²⁴

In conclusion, the evidence is inconclusive that direct laryngoscopy with oxygen is non-inferior to video laryngoscopy with oxygen. Video laryngoscopy with standard blades in combination with continuous supplemental oxygen in neonates and infants might increase the success rate of first-attempt tracheal intubation compared with direct laryngoscopy (ie, even though the results are significantly different between the groups, it did not meet the threshold for non-inferiority). Regardless of the technique used for tracheal intubation, the incidence of hypoxaemia and other adverse events was low in both groups, which might in part be attributable to the administration of supplemental oxygen and the level of experience of the staff involved.

Collaborators

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Contributors

TR, EC, RBa, AGG-M, M-AP, BSvU-S, DS, RG, WH, LT, AF, TE, and ND wrote the protocol and manuscript. MH was the study statistician. TR, EC, RBo, RG, WH, LT, BSvU-S, and DS obtained the funding. TR, ND, and WH directly accessed and verified the data. All authors were involved in the data analysis and interpretation and read and approved the final manuscript.

Declaration of interests

RG is the treasurer of the European Airway Management Society. All other authors declare no competing interests.

Data sharing

Research data and other material (eg, study protocol and statistical analysis plan) will be made available to the scientific community upon request immediately after publication, with as few restrictions as possible. All requests should be submitted to the corresponding author who will review with the other investigators for consideration, in line with the ethics regulations of the trial sites. Ethics approval is needed.

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