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Respiration and the Airway

RESPIRATION AND THE AIRWAY

Randomized equivalence trial of the King Vision aBlade videolaryngoscope with the Miller direct laryngoscope for routine tracheal intubation in children <2 yr of age

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Abstract

Background. We conducted a randomized equivalence trial to compare direct laryngoscopy using a Miller blade (DL) with the King Vision videolaryngoscope (KVL) for routine tracheal intubation. We hypothesized that tracheal intubation times with DL would be equivalent to the KVL in children <2 yr of age.
Methods. Two hundred children were randomly assigned to tracheal intubation using DL or KVL. The primary outcome was the median difference in the total time for successful tracheal intubation. Secondary outcomes assessed were tracheal intubation attempts, time to best glottic view, time for tracheal tube entry, percentage of glottic opening score, airway manoeuvres needed, and complications.
Results. The median difference between the groups was 5.7 s, with an upper 95% confidence interval of 7.5 s, which was less than our defined equivalence time difference of 10 s. There were no differences in the number of tracheal intubation attempts and the time to best glottic view [DL median 5.3 (4.1–7.6) s *vs* KVL 5.0 (4.0–6.3) s; $P=0.19$]. The percentage of glottic opening score was better when using the KVL [median 100 (100–100) vs DL median 100 (90–100); $P<0.0001$]. Use of DL was associated with greater need for airway manoeuvres during tracheal intubation (33 *vs* 7%; $P<0.001$). Complications did not differ between devices.
Conclusions. In children <2 yr of age, the KVL was associated with equivalent times for routine tracheal intubation when compared with the Miller blade.
Clinical trial registration NCT02590237.

Key words: infant; laryngoscopes; paediatrics

Direct laryngoscopy is the most common technique performed in securing the paediatric airway. In small children, direct laryngoscopy may be more challenging because of anatomical factors, including a more cephalad larynx with a floppier epiglottis when compared with older children.[1 2] The Miller laryngoscope blade is largely regarded as the preferred blade to

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Editor's key points

- Videolaryngoscopes are useful in patients with difficult airways, but their roles in patients without predicted difficult intubation are not clear, particularly in small children.
- In children <2 yr of age, there were no significant differences between a Miller laryngoscope and a videolaryngoscope (the King Vision videolaryngoscope) in the ease of laryngoscopy and in time to intubate the trachea.
- In small children, the King Vision videolaryngoscope is as effective as the Miller laryngoscope in tracheal intubation.

expose the laryngeal inlet in infants and children during tracheal intubation.[3]

Videolaryngoscopy has been shown to be a useful tool in airway management, often improving laryngeal exposure in small children with difficult airways.[4–7] There has been a proliferation of videolaryngoscopes for paediatric use, and it has become an important adjunct in paediatric airway management. When used in children with normal airways, videolaryngoscopes have been shown to improve glottic views compared with direct laryngoscopy.[8 9] However, videolaryngoscopy prolongs the time for successful tracheal intubation because of a slower tracheal tube passage into the glottis when compared with direct laryngoscopy.[9] Nevertheless, videolaryngoscopes offer several advantages, including superior laryngeal views, while using less force during laryngoscopy, with the ability to teach and archive images of the glottis. For these reasons, experts have also advocated the use of videolaryngoscopes for routine airway management.[10]

The King Vision aBlade is a newly introduced videolaryngoscope for clinical use in children and has yet to be assessed in this patient population. The King Vision has a built-in video screen and is available in three paediatric sizes: 1, 2, and a two--channelled version (Fig. 1). Studies to date on the use of videolaryngoscopes in children have been performed on widely available established videolaryngoscopes that have separate external monitors (e.g. GlideScope, Storz, TruView, AirTraq) on the general paediatric population.[8 11–13] We therefore chose to compare the King Vision aBlade with direct laryngoscopy given its novelty as a newly released single-use, non-channelled, paediatric videolaryngoscope with a built-in monitor.

Given that the trachea in infants and small children may be more challenging to intubate, we chose to perform a randomized equivalence study to compare the King Vision 1 blade with the Miller 1 blade in children <2 yr of age. We hypothesized that the time for successful tracheal intubation with the King Vision would be equivalent to Miller blade direct laryngoscopy when used for routine tracheal intubation. Secondary outcomes included the number of tracheal intubation attempts, time to best glottic view, time for tracheal tube passage, laryngeal grades of view, airway manipulations required during tracheal intubation, and complications.

Methods

This study was approved by the Ann & Robert H. Lurie Children's Hospital's Institutional Review Board. Written informed consent was obtained from the parents of all patients. This trial has been registered (NCT02590237) at http://clinicaltrials.gov. Two hundred children ASA I–III who were ≤24 months in age and undergoing procedures where the trachea needed to be intubated were enrolled in this study. Children with a known history or suspicion of difficult airway or with congenital airway abnormalities were not enrolled in the study.

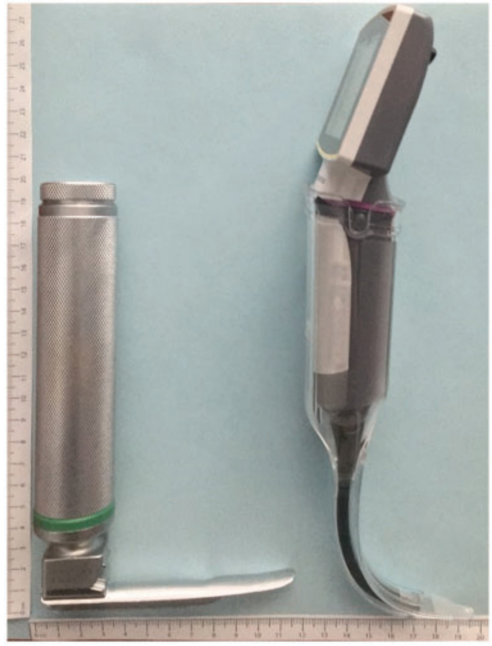

Fig 1 Miller blade (left) and King Vision aBlade size 1 (right). Note that the King Vision aBlade system has a built-in monitor with a single-use non-channelled blade.

The tracheas of children were intubated using either the Miller 1 direct laryngoscope or the King Vision videolaryngoscope based on a computer-generated randomized list. All tracheal intubations were performed by one of five expert study investigators who had each performed >1000 tracheal intubations with Miller blades in small children. Before this study, each study investigator had minimal experience (five or fewer uses) with the size 1 King Vision videolaryngoscope.

General anaesthesia was induced in all patients using nitrous oxide and oxygen with 8% sevoflurane. An i.v. line was then placed and rocuronium 0.6 mg kg^{-1} administered. Nitrous oxide was then discontinued and sevoflurane maintained with an end-tidal concentration of 3% and an end-tidal oxygen concentration >90% before all tracheal intubations.

Three separate times were then measured by an independent observer, as follows: (i) time to best glottic view, defined as entry of the laryngoscope blade past the lip and ending with the optimal view of the glottic opening; (ii) time for successful tracheal tube entry, defined as the length of time ending with removal of the device from the mouth; and (iii) time to successful tracheal intubation, defined as the length of time ending with observation of the first end-tidal capnogram after successful tracheal intubation. Both Cormack–Lehane grade of laryngeal views and Percentage of Glottic Opening (POGO) scores[14] were also assessed by the clinician intubating the trachea.

Each clinician was allowed a total of three attempts for successful tracheal intubation. The time was restarted in between each attempt. A failed attempt was defined as any evidence of oxygen desaturation (peripheral O_2 saturation $<$90%), any time the laryngoscope had to be withdrawn from the mouth, or if the tracheal tube could not be passed successfully into the trachea (e.g. oesophageal intubation). Outright failure was defined as the inability to intubate the trachea successfully within three attempts. If tracheal intubation was unsuccessful for any of the above reasons, the trachea would be intubated by direct laryngoscopy. Intraoperative complications, such as oxygen desaturation, laryngospasm, or bronchospasm, were also recorded.

Airway manoeuvres, such as anterior laryngeal pressure, neck extension/flexion, or both, were allowed to improve the laryngeal grade of view or passage of the tracheal tube during tracheal intubation. These manoeuvres were performed only when a suboptimal laryngeal view or resistance to tracheal tube passage was encountered; the total numbers and types of airway manoeuvres needed were recorded.

All tracheal tubes were removed after standard extubation criteria were met at the conclusion of the surgery. In the postanaesthesia care unit, every patient was assessed for hoarseness (hoarse cry), coughing, and stridor by a registered nurse.

The primary outcome measure of this study was the median difference in the total time to successful tracheal intubation.

An equivalence test of means using two one-sided tests on data from a parallel-group design with sample sizes of 98 in the direct laryngoscopy group and 98 in the King Vision videolaryngoscope group achieves 90% power at a 5% significance level. Based on a previous paediatric equivalence study comparing direct laryngoscopy with the GlideScope, we defined a tracheal intubation time difference of 10 s or less between the two devices as being clinically indifferent.[15] We assumed the expected difference in mean time to intubation between these two groups to be 6 s and the common SD for both groups to be 6 s. The equivalence boundary was then set at 10 s (i.e. equivalence would be declared if the upper 95% confidence interval was $<$10 s). Power analysis was performed using PASS version 12 (Kaysville, UT, USA). The Shapiro–Wilk and Anderson–Darling tests were used to test the assumption of normal distribution ($P>0.1$). Normally distributed data are presented as the mean (SD) and were analysed using an independent *t*-test for unequal variances. Non-normally distributed interval and ordinal data are reported as the median (interquartile range) and were compared among groups using the Wilcoxon–Mann–Whitney test. Categorical variables were presented as counts and evaluated using Fisher's exact test. Time to event data were compared between groups using the log rank test. A value of $P<0.05$ was used to reject the null hypothesis for the primary outcome, but a value of $P<0.01$ was used to avoid type I error in the analysis of subgroups. Intraoperative data were recorded using a standardized data collection sheet and entered in a database using Microsoft Excel 2010, then were evaluated using Stata 12 software (Stata Corporation 2011, Stata Statistical Software, Release 12; Stata Corp LP, College Station, TX, USA) for statistical analysis.

Results

All two hundred patients completed this study. Figure 2 represents the enrolment data for this study. Patient characteristic data are presented in Table 1. Primary outcome data are presented in Fig. 3. Comparative secondary outcome data regarding tracheal intubation are presented in Table 2. Comparative data regarding intra- and postoperative complications are presented in Table 3. There was one failure to intubate the trachea within three attempts with the King Vision videolaryngoscope because of failure to manoeuvre the tracheal tube into the trachea. This patient was successfully intubated using the Miller blade.

For the primary outcome, the median difference between the groups was 5.7 s, with an upper 95% confidence interval of 7.5 s, which was less than our defined equivalence time

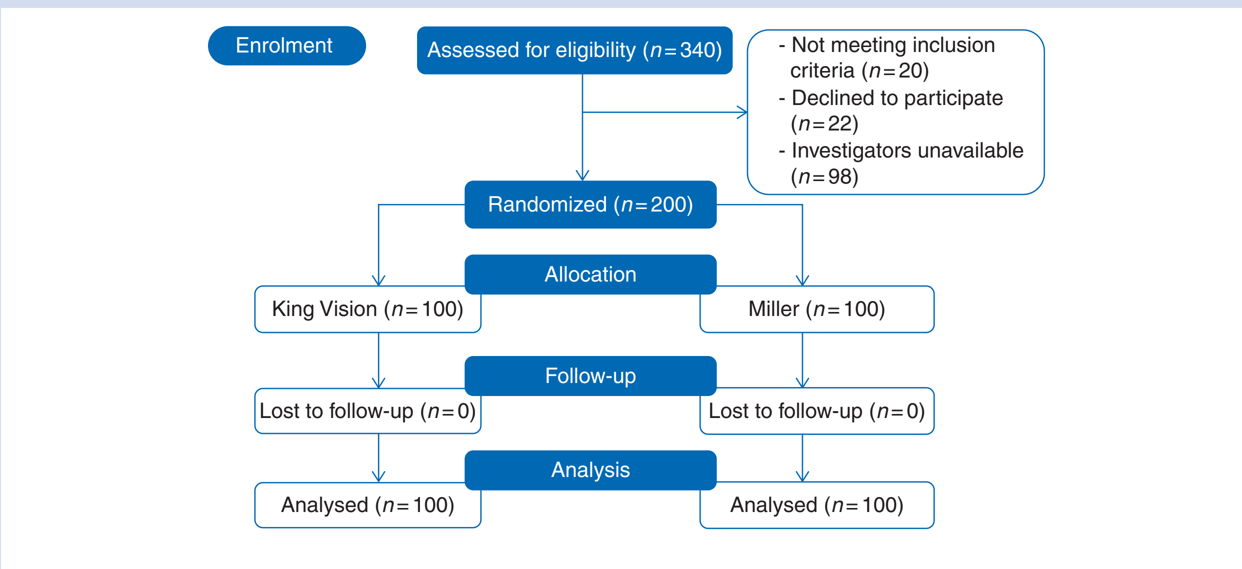

Fig 2 CONSORT diagram representing patient enrolment.

Table 1 Patient characteristics

	Miller (n=100)	King Vision (n=100)
Sex		
Female	16	16
Male	84	84
Age (months)	10.5 (6.5–15)	9 (6.5–15.5)
Height (cm)	73 (67.5–79)	73 (68–79)
Weight (kg)	9 (7.8–10.4)	9.2 (7.8–10.7)
ASA status		
I	49	59
II	48	35
III	3	6
Procedure duration (min)	97 (71–148)	103 (69–160)
Surgical procedure		
Urology	76	72
Ophthalmology	9	9
General Surgery	5	3
Orthopaedic	5	3
Otorhinolaryngology	2	5
Plastic surgery	0	4
Neurosurgery	2	3
Radiology	1	1

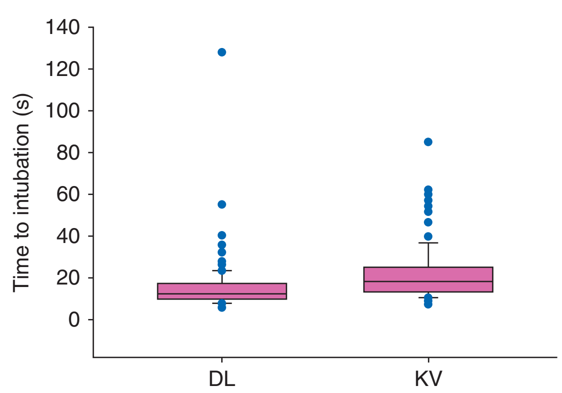

Fig 3 Box-and-whisker plots illustrating time to tracheal intubation (in seconds) with direct laryngoscopy with a Miller blade (DL) and King Vision videolaryngoscope (KV). The inner horizontal line within the box represents the median time for tracheal intubation, and the outer horizontal lines of the box represent the 25th and 75th quartiles. The horizontal lines of the whiskers represent the 95% confidence intervals.

difference of 10 s. The number of tracheal intubation attempts, Cormack–Lehane grade of laryngeal views, and the time to best glottic view did not differ significantly between the groups [Miller laryngoscope, median 5.3 (4.1–7.6) s *vs* the videolaryngoscope, 5.0 (4.0–6.3) s; P=0.19]. The percentage of glottic opening score was better for the videolaryngoscope [median 100 (100–100) vs DL median 100 (90–100); P<0.0001]. Use of a Miller laryngoscope was associated with greater need for airway manoeuvres during tracheal intubation (33 *vs* 7%; P<0.001), and the most common manoeuvre performed was anterior laryngeal pressure (27 *vs* 5%; P<0.001). The overall complications did not differ between devices (Table 3).

Table 2 Comparative data during tracheal intubation: secondary outcomes. The value n is also the percentage of patients. POGO, percentage of glottic opening

	Miller (n=100)	King Vision (n=100)	P-value
Intubation attempts (n)			
1	98	94	0.28
2	2	5	
3	0	0	
Failed	0	1	
Time to best glottic view (s)	5.3 (4.1–7.6)	5.0 (4.0–6.3)	0.19
Time for tracheal tube entry (from device in to device out; s)	12.3 (9.8–17.3)	18.2 (13.2–25.1)	<0.0001
Glottic view (n)			
Cormack–Lehane			
1	87	94	0.17
2	12	5	
3	1	1	
4	0	0	
POGO score (%)	100 (90–100)	100 (100–100)	<0.0001
Airway manipulations required (n)			
Yes	33	7	<0.001
No	67	93	
Anterior laryngeal pressure			
Yes	27	5	<0.001
No	73	95	
Neck extension			
Yes	3	0	0.24
No	97	100	
Anterior laryngeal pressure and neck extension			
Yes	3	1	0.62
No	97	99	

Discussion

The main finding in this study is that in children <2 yr of age, the King Vision videolaryngoscope accomplished equivalent times for successful tracheal intubation when compared with Miller blade laryngoscopy. Although the time to tracheal tube passage differed statistically between devices, the median difference between tracheal intubation times between devices is likely to be clinically insignificant. Use of the King Vision videolaryngoscope was also associated with better views of the larynx, with fewer airway manoeuvres needed during tracheal intubation.

Based on these results, the time to intubate the trachea with the King Vision videolaryngoscope is equivalent to that with a Miller laryngoscope in small children. It has been shown that in

Table 3 Complications and postoperative airway assessment. The value *n* is also the percentage of patients

	Miller (n=100)	King Vision (n=100)	*P*-value
Complications during Intubation (*n*)			0.62
Yes	3	1	
No	97	99	
Laryngospasm	1	0	
Bronchospasm	2	0	
Desaturation	0	1	
Postoperative airway assessment (*n*)			
Hoarseness			
Yes	14	21	0.26
No	86	79	
Coughing			
Yes	4	5	1.0
No	96	95	
Stridor			
Yes	1	1	1.0
No	99	99	

experienced hands, the GlideScope system was similar to a Miller laryngoscope with regard to the overall time to tracheal intubation in neonates and infants.[15] The similar times to tracheal intubation between the King Vision videolaryngoscope and direct laryngoscope in this study may be attributable to the use of an attached monitor *vs* an external videolaryngoscope monitor, allowing the clinician to see the laryngeal structures earlier during the blade insertion process while directly observing the patient, when compared with an external monitor where the kinaesthetic and hand eye skill needed may be more complex (i.e. observing patient, then the separate external screen, and then looking back at the patient). This was evidenced by no differences in the time to first glottic views with both laryngoscopes in this study. Additionally, there may also have been a transfer of videolaryngoscope skill onto the investigators from previous extensive experience with other videolaryngoscopes in small children. It is known that paediatric anaesthestists rapidly acquire the skill set to use videolaryngoscopes even with limited experience.[16]

Our findings regarding the ease of laryngoscopy and the ease of intubation using the videolaryngoscope are similar to previous reports in children with normal airways.[7 8 11–13 15] A recent meta-analysis comparing direct laryngoscopy with the Glidescope, Airtraq, TruView, Storz, and Bullard videolaryngoscopes also demonstrated an improvement in the view of the glottis when videolaryngoscopes are used at the expense of a prolonged time to intubation and increased failures,[9] primarily attributable to difficulty in manipulation and passage of the tracheal tube through the vocal cords. Despite better glottic views, videolaryngoscopes require additional hand–eye coordination for tube manipulation because the camera angle creates divergent anatomical and optical axes. This was evidenced by the one failure seen in our study with the King Vision videolaryngoscope despite an excellent view of the glottic opening.

Use of a videolaryngoscope for routine tracheal intubation in small children may have clinical implications, as follows: (i) a more cephalad and smaller larynx in this population can be seen better with fewer manoeuvres needed than with direct laryngoscopy, allowing for independent use of the device while maintaining similar tracheal intubation times and attempts as seen with direct laryngoscopy; (ii) archiving of images onto the anaesthesia record for subsequent anaesthetics;[10 17] and (iii) the possibility of real-time teaching of trainees because airway structures are seen simultaneously by both the trainee and the consultant.[17–19]

The results of our study should be interpreted in the context the following limitations. First, only small children with normal airways were enrolled, and these results cannot be extrapolated to children with abnormal airways. Future evaluations need to be done to investigate the performance of the King Vision videolaryngoscope in patients with difficult airways. Second, all tracheal intubations were performed by experienced laryngoscopists, and our results may not apply to less experienced clinicians (e.g. trainees). Studies on learning curves of videolaryngoscopy in comparison to direct laryngoscopy in trainees and in prehospital personnel are therefore warranted. Third, postoperative assessments in the postanaesthesia care unit were dependent on subjective assessment by the nurses. Fourth, we studied only the King Vision videolaryngoscope size 1 blade and the Miller 1 blade, and our results may not apply in older children when using different sizes of laryngoscopes. Lastly, although we demonstrated equivalence between the King Vision videolaryngoscope and Miller blade direct laryngoscope, our results may not apply to other videolaryngoscopes with similar morphology to the King Vision (e.g. Pentax AWS, McGrath). Future investigations comparing the King Vision videolaryngoscope with other more well-established paediatric videolaryngoscopes, such as the Glidescope, Storz, AirTraq, and Truview, are now needed.

In conclusion, the King Vision videolaryngoscope was associated with equivalent times for routine tracheal intubation when compared with Miller blade direct laryngoscopy in children <2 yr of age.

Authors' contributions

Conception and design of the study: N.J., J.H., L.S., A.H., G.S.D.O.
Data acquisition: N.J., J.H., L.S., A.H., A.S., B.A., S.B., G.S.D.O.
Data analysis: N.J., J.H., A.H., G.S.D.O.
Data interpretation: N.J., J.H., L.S., A.H., G.S.D.O.
Drafting the article: N.J., J.H., L.S., A.H., A.S., B.A., G.S.D.O.
Final approval of the version to be published: N.J., J.H., L.S., A.H., A.S., B.A., S.B., G.S.D.O.

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Declaration of interest

N.J. serves on the editorial boards of Pediatric Anesthesia, Journal of Anesthesia, and Journal of Clinical Anesthesia.
GSDO serves on the editorial board of Anesthesia & Analgesia and is the Editor in Chief of Journal of Clinical Anesthesia.

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Department of Pediatric Anesthesia at the Ann & Robert H. Lurie Children's Hospital.

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