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ORIGINAL ARTICLE

A randomized controlled comparison of the Bonfils fiberscope and the GlideScope Cobalt AVL video laryngoscope for visualization of the larynx and intubation of the trachea in infants and small children with normal airways

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Summary

Background: The Bonfils fiberscope (BF) used without the assistance of a laryngoscope failed to improve the view of direct laryngoscopy in children with normal airways. We hypothesized that if BF is supported by a laryngoscope—as recommended by its inventor—it can provide comparably good visualization of the glottis as the GlideScope® Cobalt AVL video laryngoscope (GS).

Methods: We included 100 children with normal airways in a randomized controlled trial. The study consisted of assessing the airway by direct laryngoscopy (DL), followed by intubation using either the BF or the GlideScope. Main outcome measures were the quality of visualization of the larynx by the percentage of glottis opening seen (POGO) and the time needed for intubation of the trachea.

Results: Visualization of the larynx (POGO) using the BF was significantly better than with DL ($P = 0.016$) or with GS ($P = 0.001$). The DL provided an allover better visualization than GS, although this difference was not significant and solely attributable to children weighing <15 kg. Intubation was successful in all cases with both devices. The time needed for intubation was shorter using the BF (36 ± 8 s) than with the GlideScope (49 ± 12 s, $P < 0.001$).

Conclusion: The Bonfils fiberscope significantly improved the view on the larynx compared with direct laryngoscopy and the GlideScope and enables shorter intubation time than with the GlideScope.

Background

The Bonfils fiberscope (BF) and the GlideScope Cobalt AVL video laryngoscope (GS) both proved to be useful in adults. Two prospective studies comparing BF and DL in children with normal airways found the BF difficult to use with a high failure rate (1,2). However, in both the investigations, no laryngoscope was used supporting the BF as recommended by the developer (3).

The GS has been shown to be very useful in pediatric practice (4), but despite good visualization of the larynx, navigating the tube into the trachea can be difficult. According to our personal clinical experience, these difficulties depend on the patient's age. The smaller the patients are, the worse intubation conditions can be.

Therefore, we hypothesized that with the recommended technique, intubation with BF provides a comparably good visualization of the larynx as with the GS

but has advantages during the positioning of an endotracheal tube.

Materials and methods

Study population

The study population consisted of pediatric patients <7 years of age who required general anesthesia with endotracheal intubation for elective surgery at the Children's Hospital, Cologne. Exclusion criteria were patients with a history or occurrence of difficult mask ventilation or difficult intubation or a Cormack and Lehane grade >2 during DL or higher-risk classifications than ASA II.

Study design

This study was a single-center, randomized controlled trial. Just two investigators conducted the trial, who were both consultant pediatric anesthesiologists. Participating infants and children were randomly assigned to either BF or GS as the method for intubation. Randomization was stratified by investigator, restricted by permuting blocks of varying length, and implemented by means of sequentially numbered, opaque, sealed envelopes. The random allocation sequence and the envelopes were generated in advance by the participating statistician.

Patients were premedicated with oral Midazolam, and an intravenous catheter was placed at a skin site previously anesthetized with EMLA® cream. Intravenous induction was performed with Sufentanil and either Propofol or Thiopental. In cases where intravenous access was difficult, an inhalational induction with Sevoflurane was performed and anesthesia completed intravenously thereafter. Patients' lungs were mask-ventilated with 100% oxygen. Every patient received a neuromuscular blocking agent, either mivacurium or rocuronium, depending on the duration of the procedures. Three minutes thereafter, DL was performed and judged by the investigator not assigned by randomization while placing the tip of the laryngoscope into the vallecula. The patients' lungs were then mask-ventilated with 100% oxygen again. Then, a second visualization with either BF or GS and subsequent endotracheal intubation were performed by the assigned investigator. Because the DL was previously performed by the other investigator, the second visualization was not influenced by already knowing the child's specific anatomy. Intubation attempts were interrupted if the oxygen saturation dropped below 90%.

Materials

Direct laryngoscopy (DL) was performed with Macintosh curved blades.

The BF is a semirigid optical stylet with a 40° distal curved tip onto which the endotracheal tube is loaded. It is available in two pediatric sizes (Table S1) as described elsewhere (5).

The GlideScope® (GS) Cobalt AVL (Verathon Inc., Bothell, WA, USA) is a recently introduced modification of the GlideScope video laryngoscope with 60° angled pediatric blades (Table S2). It consists of a digital color monitor and a reusable video baton with a digital camera at its tip onto which the appropriately sized single-use blade is attached. The GS enables automatic white balancing, exposure, and focusing and contains an antifog feature.

Intubation technique

The device assigned by randomization was always prepared for use before the patient-centered care was started. The BF was attached to a video camera, and an antifog solution was applied to the lens. An appropriately sized endotracheal tube was then loaded onto the BF, so that the tip of it overlapped the tip of the scope slightly. The investigator then placed a laryngoscope into the vallecula with his left hand and introduced the BF with his right hand. After visualization of the larynx, the armed BF was passed through the vocal cords and into the trachea. While the tube was held in its position by the assisting anesthesia nurse, the BF was carefully removed followed by the laryngoscope. The correct endotracheal tube position was confirmed by auscultation of bilateral lung fields and capnography.

The GS was prepared by placing the video baton into an appropriate blade following the recommendation of the manufacturer at least 2 min before use, to allow the video baton to prewarm, thus activating the antifog feature of the device. An appropriately sized endotracheal tube was prepared by placing a stylet into it and then bending the tube to approximate the curve of the GS blade. The GS was placed into the mouth in the midline position and advanced into the vallecula. The tube was introduced parallel to the GS blade and advanced until entering the view field. Subsequently, it was carefully placed between the vocal cords and advanced into the trachea while the stylet was held in position by the assisting nurse. Finally, the stylet was retracted from the tube, the GS was carefully removed, and the correct endotracheal tube position was confirmed as described with BF.

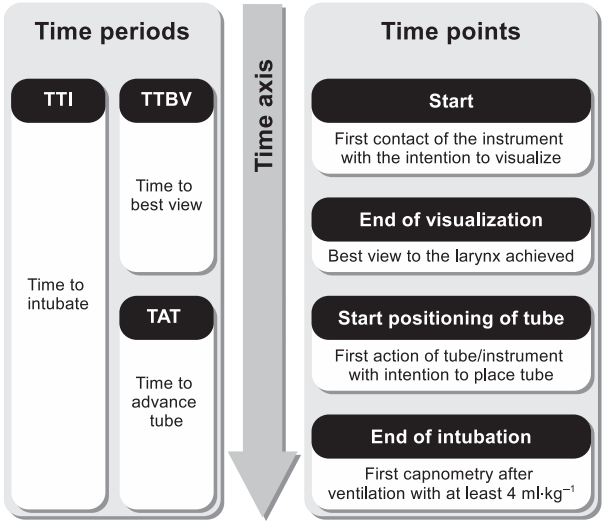

Figure 1 Time definitions.

Outcome measures

The main outcome measure was the quality of visualization. The time needed to intubate was obtained as the second outcome measure (as defined in Figure 1). Visualization was graded using the Cormack and Lehane grading system and the percentage of glottis opening seen (POGO) (6). Additional measurements were the image quality and the ease of intubation. We also recorded the dosage of administered drugs, lowest oxygen saturation value, and first endtidal carbon dioxide value measured after intubation. Any postoperative side effects such as throat pain, stridor, and hoarseness were also noted.

Sample size

A previous study by Vlatten *et al.* (7) compared DL with the use of a Storz video laryngoscope and found that the time to intubation (TTI) averaged 28% longer when using the video laryngoscope. Another study by the same authors measured the TTI with DL compared with the use of the BF and found no significant differences (8). Therefore, for power calculation, we assumed a similar difference in TTI between GS and BF. The *t*-test indicated that our study would need approximately 45 patients per group to detect a standardized effect 0.59 = 6/10.1 (delta/sigma, (7)), with 80% power at two-sided alpha 5%. In Vlatten's study comparing DL with a video laryngoscope (7), the median POGO score was 97.5 for DL and 100 for the video laryngoscope. Assuming a POGO of <100% in 50% of patients using DL and in only 1% of patients using GS, the corrected chi-squared test would require 15 patients per group (alpha 5%, power 80%). To demonstrate noninferiority of GS vs BF regarding visualization quality would require group sizes of 54 patients per group to exclude a difference of more than 10% points in imperfect POGO (<100%) with 80% power (9). Thus, we planned to include 50 patients per group.

Statistical evaluation

Observed data distributions were summarized by count (percentage) (qualitative data) or mean (SD) and median (minimum to maximum) (quantitative variables). Differences between groups were evaluated by the *t*-test (time measurements) or the Wilcoxon's rank-sum test (quality judgments) stratified by investigator (ANOVA with type II SS without interaction, van Elteren test). *P*-values lower than 0.05 were deemed statistically significant. Analyses were performed using SPSS 20 (IBM Corp., Armonk, NY, USA) and STATA SE 12 (StataCorp LP, College Station, TX, USA).

Results

A total of 100 patients as planned were included and randomized, of whom 91 patients were finally evaluable (Figure 2). Demographic data (Table 1) or induction of anesthesia (Table S3) showed no significant differences between the BF and the GS groups.

Table 1 Demographic data and descriptive observances

	GS (*n* = 47)	BF (*n* = 44)
Investigator A (*n*/%)	23/49%	22/50%
Investigator B (*n*/%)	24/51%	22/50%
Male (*n*/%)	30/64%	26/59%
Female (*n*/%)	17/36%	18/41%
Age (years, median (min/max))	2.0 (0/7)	1.1 (0/7)
Age < 1 year (*n*/%)	15/32%	22/50%
Weight (kg, mean (min/max))	11.2 (2.0/27.0)	11.1 (1.6/27.0)
Weight < 15 kg (*n*/%)	36/77%	34/77%
Success at first attempt (*n*/%)	44/94%	42/95%
Success at second attempt (*n*/%)	3/6%	2/5%
Lowest oxygen saturation		
(%, mean ± SD)	98.6 ± 5.9	99.6 ± 1.6
(%, min/max)	60/100	90/100
(*n* < 90%)	1	0
First endtidal CO_2 after Intubation		
(mmHg, mean ± SD)	37.3 ± 7.7	36.2 ± 6.9
(mmHg, min/max)	14/60	20/62

GS, GlideScope; BF, Bonfils; SD, standard deviation.

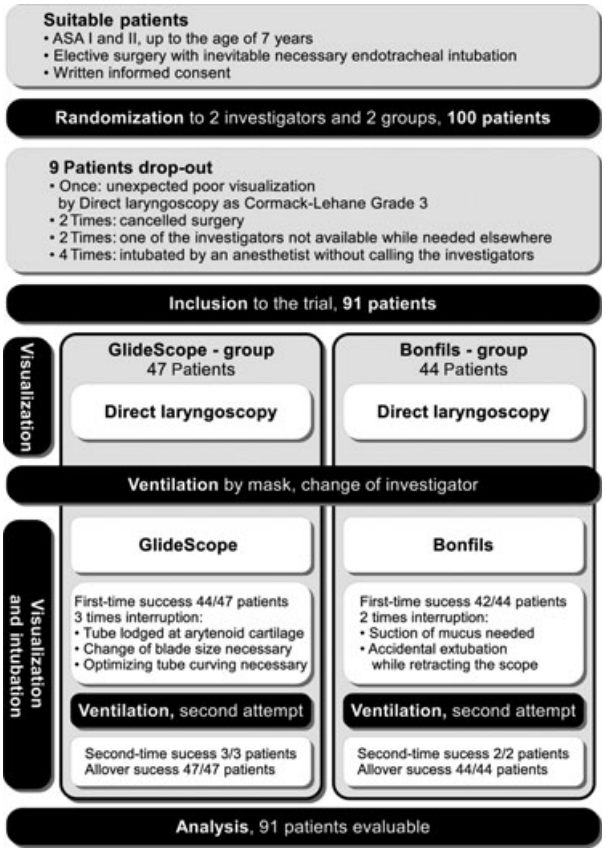

Figure 2 Study flowchart.

Visualization with DL was similar in both groups (Table 2). The second visualization by BF was significantly better than with DL and significantly better than with the GS. In contrast to this, the second visualization using the GS provided in average worse results than with DL, whereas this did not show significance and was solely attributable to children weighing <15 kg (Figure S1).

Both groups were similar according to the time required to obtain the best view of the larynx (TTBV) with DL, BF, or GS (Table 3). The time to intubate (TTI) was significantly longer in the GS group because it took longer to introduce the endotracheal tube into the trachea (TAT) using the GS compared with the BF (Figure 3) with neither significant nor relevant differences between the two investigators. We observed a weight-related tendency toward shorter TTI (Figure S2).

The image quality and the easiness of intubation were rated higher with the BF than with the GS (Table 2). There were no differences in the lowest oxygen saturation reading during the intubation or first endtidal carbon dioxide values measured immediately after the first sufficient ventilation (Table 1). The oxygen saturation

Table 2 Visualization observances by direct laryngoscopy (DL) and study groups (GlideScope = GS or Bonfils = BF)

	GS (*n = 47*)	BF (*n = 44*)
First visualization by DL		
Cormack–Lehane (Grade I, *n*/%)	41/87%	37/84%
Cormack–Lehane (Grade II, *n*/%)	6/13%	7/16%
P (van Elteren test) for difference between devices: 0.678		
POGO (< 100%, *n*/%)	6/13%	7/16%
Absolute difference of proportions (95% CI): 4 (−11 to 18)%		
P (van Elteren test) for difference between devices: 0.747		
Second visualization by GS or BF		
Cormack–Lehane (Grade I, *n*/%)	38/81%	44/100%
Cormack–Lehane (Grade II, *n*/%)	10/21%	0/0%
P (van Elteren test) for difference between devices: 0.003		
POGO (< 100%, *n*/%)	10/21%	0/0%
Absolute difference of proportions (95% CI): −21 (−32 to −9)%		
P (van Elteren test) for difference between devices: 0.001		
Comparison of POGO values by 2nd/1st visualization		
2nd visualization worse than 1st	9	0
2nd visualization better than 1st	5	7
P (exact binominal test)	*0.424*	*0.016*
Image quality (*n*, %)		
1 = excellent	27/58%	39/89%
2 = not perfect	17/36%	5/11%
3 = difficult to use for this issue	3/6.4%	0
P (van Elteren test) for difference between devices: <0.001		
Ease of Intubation (*n*, %)		
1 = excellent	8/17%	36/82%
2 = easy to perform	21/45%	7/16%
3 = feasible with some effort	18/38%	1/2%
P (van Elteren test) for difference between devices: <0.001		

POGO, percentage of glottis opening seen; CI, confidence interval.

Table 3 Time periods (in seconds) by study groups

	GS (*n = 47*)	BF (*n = 44*)	*P* (ANOVA)
TTBV with DL (s, mean ± SD)	7.4 ± 3.3	7.2 ± 2.2	0.671
TTBV with DL (s, min/max)	3.5/23.6	3.8/11.7	
TTBV (s, mean ± SD)	11.8 ± 6.9	13.5 ± 5.8	0.225
TTBV (s, min/max)	4.8/35.7	4.9/32.5	
TAT (s, mean/SD)	36.9 ± 11.3	23.0 ± 6.3	<0.001
TAT (s, min/max)	13.5/64.2	13.2/43.4	
TTI (s, mean/SD)	48.7 ± 12.5	36.5 ± 7.5	<0.001
TTI (s, min/max)	27.8/79.4	26.0/58.9	
TTI differentiated by investigators 1 and 2			
(1) TTI (s, mean ± SD)	50.5 ± 13.2	38.2 ± 7.8	0.115
(2) TTI (s, mean ± SD)	47.1 ± 11.2	34.8 ± 6.6	

TTBV, time to best view; TAT, time to advance tube; TTI, time to intubate; SD, standard deviation (definitions see Figure 1).

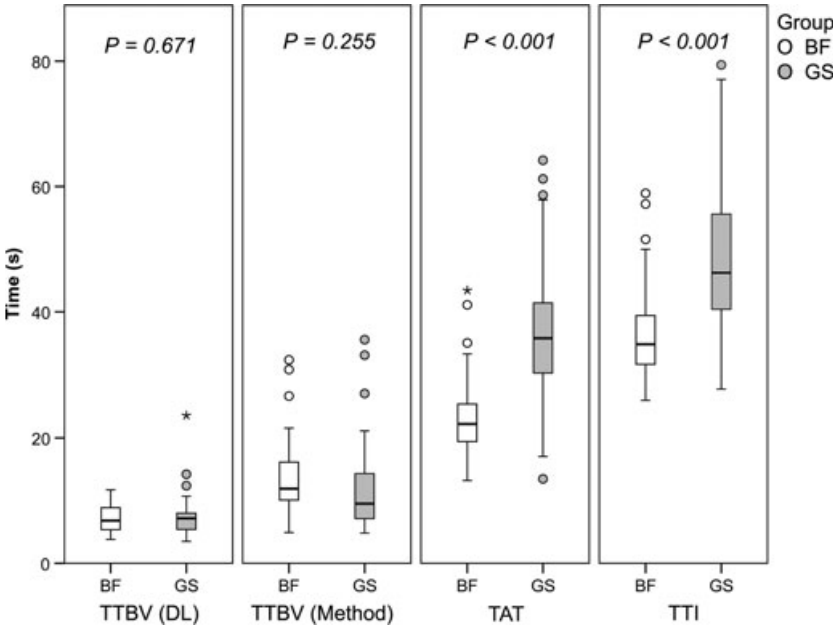

Figure 3 Time period during direct laryngoscopy and with the randomized method (BF or GS). GS = GlideScope®, BF = Bonfils fiberscope, DL = direct laryngoscopy, TTBV = time to best view; TAT = time to advance tube; TTI = time to intubate. The median is identified by a line inside the box, and the length of the box is in the interquartile range (IQR). Values more than three IQRs from the end of the box are labeled as extreme, denoted with an asterisk (*). Values more than 1.5 IQRs but <3 IQRs from the end of the box are labeled as outliers (o). *P*-values in van Elteren test.

dropped below 90% for several seconds in just one patient of the GS group when the endotracheal tube was accidentally lodged in the arytenoid cartilage and had to be repositioned. No further harm to the child occurred.

Side effects

None of the patients had any postoperative side effects except for one patient in the GS group who noted a sore throat in the recovery room that resolved spontaneously after 1 h.

Discussion

In this study, it could be demonstrated that the BF and the GS are both suitable devices for the intubation of infants and small children with normal airways. However, using the BF, a better visualization of the larynx was achieved and less time for endotracheal intubation was needed than with the GS.

Standard endotracheal intubation requires aligning the oral and tracheal axes by proper head positioning (10) and anteriorly shifting of the tongue by a laryngoscope, allowing a straight view of the larynx. The strongly angled blade of the GS and the video camera near to its tip enable a good laryngeal visualization 'around the corner'. However, due to its curving and width, the space which the tube has to pass through is curved and narrow. Additionally, the main part of the passage through this cannot be seen before entering the view field of the GS. Both facts make navigation of the tube more challenging than during DL. A study in adults affirmed the inability to intubate 2% of all patients despite a full view of the vocal cords (11). Undoubtedly, the time required for the intubation process is an even more distinctive criterion to differentiate difficulties in the navigation of the tube. The majority of studies comparing video laryngoscopy or GS with DL have shown longer TTI in adults (12) as well as in children (4,7,13).

A recent trial by Fiadjoe *et al.* (14) observed comparable intubation times with GS and DL in 60 infants despite significant longer time for the tube passage. They postulated that the main reason for their short intubation times was the high amount of clinical experience with the GS. Both investigators of our current trial are experienced consultant pediatric anesthetists and have frequently been using the GS and the BF since it became available. In our opinion, experience cannot reduce a systematic difference attributed to the more demanding performance using the GS compared with DL, especially if both methods are conducted with the same routine. Another difference to our trial was the stronger angulation of the preformed tube while using the GS, which was described as hockey-stick bend at the tip. Although it is generally recommended that the curve of the tube matches the curve of the blade, stronger angulation of the tube might produce quicker intubation times, as suggested by others (15,16).

However, the Fiadjoe *et al.*'s definition of the time to intubate did not include the time to remove the stylet

and to establish mechanical ventilation. Studies using a comparable time definition provide TTI measurements that are equivalent to our trial (4,12,16).

Fiadjoe *et al*. (14) even found better laryngeal views with GS than with DL in infants. In contrast to their trial, we compared both the methods on the same patients and were able to exclude a possible incomparability of the treatment groups. We encountered difficulties especially with the size 1 blade, which has a very short distance between the camera lens and its tip. Hence, the camera lens was sometimes obstructed by the epiglottis. Fiadjoe's investigators were allowed, 'if the view was partly obstructed by the epiglottis', to place the tip of the laryngoscope underneath without reporting how often this was carried out. Although it is a widely performed practice to lift the epiglottis directly, we feel safer avoiding it whenever possible, thus minimizing the risk of injury.

Our study is the first to indicate better visualization with the DL compared with GS. During several trials in adults, comparisons showed better visualization with GS, with only few exceptional cases (17,18).

However, our result was only attributable to the patients weighing <15 kg (Figure S1). This impression is backed by the observances of a weight-related tendency to shorter TTI (Figure S2).

The major advantage of the BF in comparison with other video-supported devices is the position of the optical system inside the endotracheal tube. This enables a continuously visible passageway of the tube, where obstacles can be seen and circumnavigated easily. The effectiveness of the BF in our study is in contrast to the results of two other authors, who found the use of the BF in children difficult with a high failure rate and an increased intubation time (1,2). These authors did not use a laryngoscope with the device, although the inventor of the BF, P. Bonfils, recommended doing so. Thereby, contact of the scope with the mucosa followed by contamination of the lens was almost inevitable.

Limitations of this study

Although we planned the comparison of the visualization by BF or GS as an investigation for noninferiority, we demonstrated the superiority of BF. This unexpected finding is in accordance with current regulatory guidance (19) and, strictly speaking, not a limitation of our findings but an enhancement. Planning this trial, we underestimated the BF and overestimated GS, which is attributable to the available literature.

While this study was randomized, it was not blinded. The conductor cannot be blinded to the method he is using. Although blinding of additional assessors regarding judgment of visualization would have been possible, for example using video recording, this, in our opinion, would not have been beneficial. Whereas the generation of the laryngeal view is affected by the conductor, the judgment of the established picture follows objective criteria.

This study was conducted in healthy children, and results may not be applicable to those with difficult airways. As there are very few pediatric patients with difficult airways, evaluation of such devices in normal children is a legitimate first step to judge their performance. In case of the BF, this became particularly necessary due to the contrary results with normal children in previous studies (1,2). Encouraged by our good results with the BF in normal children, we are currently conducting a study of children with difficult airways.

Conclusions

Our study demonstrated that both the BF and the GS are useful devices for visualization of the larynx and tracheal intubation in infants and small children with normal airways. Interestingly, we observed poorer visualization scores with GS than with DL. We attributed this to increased technical difficulties of visualizing the larynx and endotracheal placement of the tube in small patients. Supporting this impression, poorer visualization scores with the GS than with DL occurred solely in patients <15 kg of body weight.

There was a significantly shorter TTI and better visualization with the BF than with the GS. This was attributable to a more challenging performance required in positioning the tube into the trachea while using the GS due to its strong-angled blade and the width of its tip.

As long as the BF can be used in combination with displacement of the tongue using a laryngoscope, it provides a better visualization in patients <15 kg and offers a faster intubation procedure. Thus, it is tempting to speculate that BF might also be useful for endotracheal intubation of small patients with difficult airways. Other devices must be used for patients with an extremely restricted mouth-opening or those who require a nasally placed endotracheal tube. Future studies are necessary to compare both the BF and the GS in infants and small children with difficult airways.

Acknowledgments

The manufacturer of the GlideScope® video laryngoscope (Verathon Medical Deutschland GmbH, of Rennerod, Germany) supported this trial by loaning a GlideScope and its accessories for the study period.

Ethical approval

This study was approved by the Ethics Committee of the University of Witten/Herdecke, Germany (contact information: Ethics Committee of the University of Witten/Herdecke, Alfred-Herrhausen-Str. 50, Germany—58448 Witten, http://www.ethik-kommission-uwh.de/Kontakt/kontakt.html), and registered at the German Clinical Trials Register (DRKS00000715) on February 2, 2011. This study was conducted from March 2011 to August 2011 in accordance with the Helsinki Declaration. Written informed consent was obtained from the parents or legal guardians in every case prior to the enrollment. This research was carried out without funding.

Conflict of interest

No conflicts of interest declared.

Supporting information

Additional Supporting Information may be found in the online version of this article:

Figure S1 Difference of percentage of glottis opening seen (POGO) with Bonfils fiberscope (BF) or GlideScope® (GS) minus POGO by direct laryngoscopy (DL), set in relation to patient's weight.

Figure S2 Time to intubation by groups (BF or GS), set in relation to patient's weight.

Table S1 Available sizes for the Bonfils fiberscope and appropriate tube sizes.

Table S2 Available blade sizes for the GlideScope® Cobalt AVL.

Table S3 Induction of anesthesia; et% = endtidal anesthetic gas concentration, i.v. = intravenous, SD = standard deviation.

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