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CASE REPORT

Comparison of the Levitan FPS Scope™ and the single-use bougie for simulated difficult intubation in anaesthetised patients

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Summary

A randomised cross-over study was performed in 34 patients with no evidence of airway difficulties, following induction of general anaesthesia, to compare the efficacy of the Levitan FPS scope™ (LFPS) and the single-use bougie for tracheal intubation during simulated grade IIIa laryngoscopy. Success rates for intratracheal placement of the device, and the time required for insertion and tracheal intubation were recorded. Both devices were equally successful (31/34 for the LFPS vs 29/34 for the bougie) for insertion into the glottis. The mean insertion time for the LFPS was statistically longer than that for the bougie (4.4–12.5 s) but this difference was not clinically relevant. Intubation times were similar between the two devices. Major problems hindering successful intubation using the LFPS were the presence of a narrow epiglottic-pharyngeal wall space and copious secretions. An inability to maintain the desired shape was the principal cause of failure with the bougie.

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There is, at present, a lack of large comparative studies comparing the use of malleable fibreoptic scopes in the management of the difficult airway. Optical scopes such as the Bonfils Retromolar Intubation Fibreoscope (Karl Storz Endoscopy, Tuttlingen, Germany) and the Shikani Optical Stylet (Clarus Medical, Minneapolis, MN) have been commercially available since 1983 and 1996, respectively [1]; however, there is still limited evidence of their clinical efficacy in the literature [2]. Another optical scope is the Levitan FPS (First Pass Success) scope (Clarus Medical) (Fig. 1).

The Levitan FPS (LFPS), which is a shorter streamlined version of the Shikani Optical Stylet [3], was first described in 2005 [4]. Shortening the overall length allows greater ergonomic handling of the scope during intubation and the device 'is intended for use in every laryngoscopy, replacing a standard stylet for shaping and handling of the tracheal tube' [4].

The scope is approximately 30 cm long and consists of a malleable steel sleeve containing optical and light-carrying fibreoptic fibres that transmit an image to the eyepiece. There are two options for a light source, either a standard fibreoptic laryngoscope handle or a specially designed light-emitting diode. The scope tip should be recessed approximately 1 cm proximal to the end of the tracheal tube lying alongside the Murphy eye of most tracheal tubes (Fig. 2). To achieve the correct positioning of the scope inside the tracheal tube, most tubes will need to be cut to 28 cm at their proximal end. It can be inserted into a tracheal tube of 6 mm internal diameter (ID) or greater.

The designer [4] has recommended that the scope should be kept straight along the length of the tracheal tube with a 35° bend at the proximal tube cuff (Fig. 1). For difficult intubations, the tip is positioned 'under direct vision until it is close to, but below and away from, the tip of the epiglottis' [4]. Once positioned, the

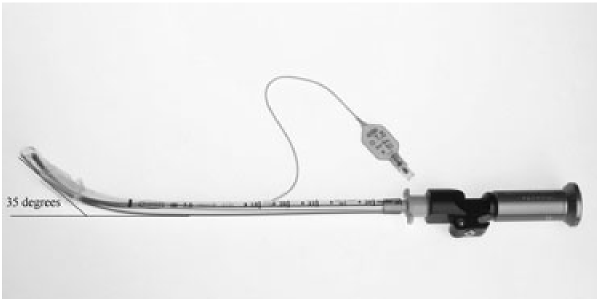

Figure 1 Levitan FPS scope enclosed by a size 7.5 mm ID tracheal tube (trimmed at 28 cm).

Figure 2 Tip of Levitan FPS scope just inside the bevel of the tracheal tube.

operator then uses the eyepiece to locate the glottic opening and pass the distal end of the tracheal tube-scope into the subglottic area. The tracheal tube is then railroaded into the trachea and the scope removed.

This study assesses the Levitan FPS scope in difficult airway management by comparing its performance with the Portex single-use bougie (Portex Tracheal Tube Introducer, 15Ch, Coude tip, 600 mm length, 40° angle 25 mm from tip; Smiths Medical International Ltd. Hythe, Kent, UK) in anaesthetised patients.

Methods

Following local institutional ethics committee approval, informed consent was obtained from 34 adult patients (American Society of Anesthesiologists grade 1–3) presenting for elective surgery requiring tracheal intubation. Patients with a past history of difficult tracheal intubation, or with clinical signs of potential difficulty with tracheal intubation (i.e. a modified Mallampati score of 3 or 4, limited mouth opening, thyromental distance < 4 cm, limited neck movement or upper airway disease) were not included. Patients' age, weight, height, ASA rating, and airway assessment (Mallampati grade, thyromental distance, mouth opening) were recorded. One investigator (KG) performed all of the intubations to eliminate interobserver variability. In accordance with previous published recommendations for other malleable fibreoptic scopes such as the Bonfils Retromolar Intubation Fibrescope [5, 6], this study was conducted when KG had performed 30 tracheal intubations using the LFPS with both the Macintosh blade and manual chin-lift [4, 5, 7].

Routine non-invasive monitoring was established and the patient was placed in the classic 'sniffing position', which the operator felt was optimal for intubation. Following 3 min pre-oxygenation, patients were anaesthetised using a titrated dose of propofol and 1.5 $\mu g.kg^{-1}$ fentanyl. Neuromuscular blockade was established using 0.1 $mg.kg^{-1}$ vecuronium and monitored using a peripheral nerve stimulator with train-of-four stimulation of the ulnar nerve at the wrist. The patients' lungs were ventilated by bag and facemask with 2–3% sevoflurane in 100% oxygen for 3 min. Using a size 3 Macintosh laryngoscope blade, the laryngoscopic view was graded according to Cormack and Lehane [8]; patients assessed to be grade III or greater were not included in the study. Simulation of a grade IIIa view [9] was then achieved by lowering the laryngoscope blade such that the epiglottis was allowed to just obscure the view of the arytenoid cartilages. This method is an accepted technique for difficult airway simulation [10, 11]. An operator held the laryngoscope in position to maintain the simulated grade IIIa view while the investigator confirmed the simulated view and proceeded with intubation.

Similar to other studies [7], we have previously found that the presence of airway secretions can be a significant problem hindering successful intubation with the LFPS. Therefore the airways of all patients were suctioned prior to the insertion of each device. Assessment of the LFPS and the Portex single-use bougie was performed in each patient. The order in which these were placed was determined following randomisation (according to a closed envelope selection process); however, only the second device was used to railroad the tracheal tube into the trachea. Group allocation occurred following initial airway assessment, consent and recruitment, but prior to induction of anaesthesia. The LFPS was preloaded with a tracheal tube whether it was allocated as the first or second device. The investigator could only shape the bougie or the LFPS before its use. The operator holding the laryngoscope looked away to remain blinded to the performance of the investigator so that no adjustment of the laryngoscope could be made to aid or hinder the investigator. Neither the operator nor the investigator was blinded to the study device. Correct intratracheal placement of the bougie was indicated by feeling clicks as the bougie slid over the tracheal rings and resistance of the bougie as it reached the small bronchi [12, 13]. When the first device was deemed to have passed the glottis (confirmed by elevating the epiglottis as required), it was removed. Bag-mask ventilation with 2–3% sevoflurane in 100% oxygen was resumed for 3 min. The second device was then assessed after having been preloaded with a standard cuffed tracheal tube; 8 mm ID for males and 7 mm ID for females (Portex Ltd, Hythe, Kent, UK).

Times were recorded from the moment the investigator picked up the suction device to the moment when the study device was thought to have entered the trachea ('insertion time'); and to the moment carbon dioxide appeared on the capnograph trace following intubation ('total time'). The difference between the total time and insertion time was the 'intubation time'. Insertion times were recorded for both the first and second devices, but intubation time was recorded only for the second device.

If the investigator failed to intubate the patient's trachea within 60 s or the $S_{p}O_{2}$ was reduced to < 93%, bag-mask ventilation was re-instituted and the other device was used to intubate the patient's trachea. Only one continuous attempt at insertion and intubation was allowed. Movement of the laryngoscope, the patient's head or external laryngeal manipulation was not allowed, and any complications or difficulties were recorded.

This was a 2 × 2 cross-over trial (AB/BA cross-over design – 2 treatments, 2 periods). Demographic data and airway assessments were analysed using an independent *t*-test, Chi-squared test and Mann–Whitney *U*-test. Insertion time was analysed using two-way cross-over analysis of variance (ANOVA) [14]. The success rate of the two devices was analysed using Prescott's test.

The statistical software used was the SAS System for Windows Release 9.13 (SAS Institute Inc., Cary, NC). For the sample size calculation [15], we planned to detect the within-patient mean difference of insertion times between the two devices of not < 10 s with a standard deviation of 15. Therefore, the required sample size with 90% power was 26 at the two-sided 5% level of significance. When considering a 20% failure rate, the total number of needed patients was calculated to be not > 33. We therefore recruited 17 patients for the LB treatment sequence and 17 patients for the BL treatment sequence.

Results

Patient characteristics and pre-operative assessments are shown in Table 1. Body weights were significantly different between the two groups (p = 0.04) and there was no difference in airway assessments.

Table 1 Patients' characteristics and airway assessments. Values are mean (SD [range]) or median (interquartile range) [range] or number of observations.

	Group 1 (*n* = 17)	Group 2 (*n* = 17)	p
Age (years)	56.3 (17.5 [30–84])	52.1 (14.7 [19–79])	0.55
Sex, M : F	7 : 10	6 : 11	0.72
Weight; kg	70.9 (15.3 [48–103])	81.7 (14.7 [62–106])	0.04
Height (cm)	169.3 (9.9 [155–190])	169.4 (7.5 [155–183])	0.98
ASA, 1 : 2	9 : 8	6 : 11	0.30
Thyromental distance; cm	5 (4–5) [4–5]	5 (4–5) [4–5]	0.49
Mouth opening; cm	4 (4–5) [4–5]	4 (4–4) [3–5]	0.24
Modified Mallampati Score, 1 : 2	10 : 7	8 : 9	0.49
Initial Laryngoscopy Grade, 1 : 2	13 : 4	14 : 3	1.00

Group 1 = treatment order LB (first device = LFPS, second device = single-use bougie).
Group 2 = treatment order BL (first device = single-use bougie, second device = LFPS).

Prescott's test showed no significant difference in the rate of successful insertion between the LFPS (successful in 31 out of 34) and the bougie (29 out of 34) (p = 0.71) (Tables 2 and 3). In those patients who had both devices inserted successfully (*n* = 26), the mean (SD) insertion time for the LFPS was 13.3 (3.2) s if used as the first device and 21.1 (16.0) s if used as the second device. The longer mean insertion time for the LFPS, when used as the second device, was due to prolonged insertions (50–52 s) in three patients. All three insertions were delayed due to copious secretions between the posterior wall of the epiglottis and the glottic opening. These

Table 2 Status of successful insertion. Values in number.

	Period 1 (1st trial)	Period 2 (2nd trial)	Both trials completed
Group 1 – LB sequence (*n* = 17)	16	12	11
Group 2 – BL sequence (*n* = 17)	17	15	15

Table 3 Contingency table for Prescott's test.

Group	(0,1)	(0,0) and (1,1)	(1,0)	Total
1 (LB)	1	11	5	17
2 (BL)	0	15	2	17
Total	1	26	7	34

0 = failure, 1 = success.

Table 4 Insertion times (completed patients only, $n = 26$). Values in mean (SD).

	Period 1 (1st trial)	Period 2 (2nd trial)	p
Group 1 – LB sequence ($n = 11$)			Seq: 00.2213 Pat(Seq): 0.0937 Period: 0.1593 Treatment: < 0.0001
Insertion time	13.3 (3.2)	8.9 (2.1)	
Within-patient treatment difference (L–B)	4.4 (2.9)		
Group 2 – BL sequence ($n = 15$)			
Insertion time	8.6 (2.0)	21.1 (16.0)	
Within patient treatment difference (L–B)	12.5 (15.4)		

Table 5 Intubation time (values in mean (SD [range])).

	Group 1 (LB)	Group 2 (BL)	p
Device used to intubate	Single-use Bougie	Levitan FPS	–
No. of patients	12	15	–
Intubation time; s	20.1 (6.6 [7–28])	19.9 (6.2 [9–35])	0.93

secretions remained despite pharyngeal suctioning prior to scope insertion.

The mean insertion time for the bougie was 8.6 (2.0) s if used as the first device and 8.9 (2.1) s if used as the second. All cases of failure with the bougie occurred due to a lack of memory in the device and its failure to maintain the 40° angle at the tip.

The results of the insertion times showed that there was no obvious difference in the two sequence groups (p = 0.09) (Table 4), which indicates that there was no carry-over effect in the trial and that the washout period was long enough to reset to baseline. No adverse effects were documented using either device. The intubation times were not statistically significantly different between the two devices (p = 0.93) (Table 5).

Discussion

We found in this study that the Levitan FPS scope and the single-use bougie were equally successful for insertion of a tracheal tube into the glottis during simulated grade IIIa laryngoscopies (31/34 and 29/34, respectively). In the patients who had the devices successfully inserted, the mean insertion times for the bougie (8.6–8.9 s) were significantly and consistently shorter than with the LFPS (13.3–21.1 s). This reflects the greater technical expertise required when using the LFPS compared to the bougie, which is a very simple device that can be rapidly deployed. However, the difference in these times was so short that it would probably not be clinically relevant. Once the device was in the glottis, the intubation times were similar for both devices.

Simulation of grade III laryngoscopy is a method commonly used to evaluate the utility of airway devices in the difficult airway situation. Otherwise it would be very difficult to recruit large numbers of patients as this is an uncommon condition. However, to what extent this model reflects an actual grade III laryngoscopy in clinical practice remains debatable [11, 16]. We have chosen a simulation model as it is the next logical step from manikin studies to research into actual difficult intubations. Specifically, only grade IIIa laryngoscopy was performed due to the poor performance of the single-use bougie and to a lesser extent the fibrescope in grade IIIb laryngoscopy (when the epiglottis touches the posterior pharyngeal wall) [10]. The use of a Macintosh laryngoscope is consistent with clinical practice as both the bougie and the LFPS are commonly used in conjunction with direct laryngoscopy, although the latter can be used alone using jaw and tongue lift and a more extreme bend angle on the scope (70°). The presence of a separate blinded operator performing direct laryngoscopy differs from clinical practice in which a single operator performs both the direct laryngoscopy and insertion of the bougie or the LFPS. This ensures that grade IIIa laryngoscopy was maintained throughout intubation to minimise bias.

The LFPS is one of several optical scopes designed to combine the advantages of fibreoptic guidance with the semirigidity, simplicity, and familiarity of a standard stylet [4, 17]. In contrast to the bougie and the flexible fibrescope, the LFPS is inserted preloaded with the tracheal tube and the whole unit must first be navigated past the posterior edge of the epiglottis to allow intubation. In our study, there were two main determinants of successful insertion of the scope into the subglottic space. Firstly, the gap between the epiglottis and posterior pharyngeal wall and, secondly, the size of the space between the posterior surface of the epiglottis and the glottic opening. The gap between the epiglottis and the posterior wall of the pharynx created problems when the outside diameter of the tracheal tube exceeded this space. When this occurred, the epiglottis was down-folded by the insertion of the tracheal tube-scope unit. The tip of the tracheal tube must be used to lift the epiglottis to allow the scope to visualise the glottis. After the epiglottis was lifted, the gap that was produced between the posterior surface of the epiglottis and the glottic opening was then critical. If this gap was too small, it was not possible to focus the LFPS due to crowding of glottic and supraglottic structures on the scope. The limited view produced by having the scope inside the tracheal tube also made finding the glottic opening difficult when there was a narrow space in the supraglottic region. The importance of this hypopharyngeal space in relation to the size of the tracheal tube is highlighted by the fact that all cases of failure were due to either one or both of these spaces being too narrow.

The fixed curvature and bulk of the tracheal tube-scope unit means that it may be difficult to advance the unit towards the glottis even if a relatively clear view of the laryngeal inlet is obtained. In one study using the Shikani Optical stylet, 10% of intubations required reshaping of the scope curvature to achieve successful intubation [3]. The recommendation of a 35° bend angle for the LFPS is based on a previous study which assessed the optimal scope bend angle that allowed tip visualisation and manoeuvrability without compromising the ability for tracheal tube passage due to impaction on the anterior tracheal rings by the scope tip [18].

In common with other devices using fibreoptic technology, airway secretions can significantly hinder successful passage of the optical scope into the glottis [3, 7]; as we have found in our study, there were three instances in which insertion of the LFPS required 50 s or longer due to presence of copious secretions in the airway despite prior suctioning. A removable oxygen connector at the proximal end of the scope allows oxygen to be insufflated at 5–10 $l.min^{-1}$ from the distal end of the tracheal tube and this may help to keep secretions away from the tip of the scope, prevent fogging of the lens, and thus improve visualisation. Another observation is that once the LFPS is loaded onto the tracheal tube, the tip of the tube frequently presents as a crescent, obscuring the visual field of the scope. A 90° clockwise rotation of the tracheal tube on the scope will eliminate this quite effectively. In fact, with this rotation, the bevel of the tube is pointing upwards, which allows the tip of the tracheal tube to be placed under the epiglottis more effectively.

The learning curve for many optical scopes is approximately 20–25 uses [6, 19] and this is consistent with our own personal experience. Even though we decided to have only one investigator (KG) who had over 30 intubation experiences with the LFPS performing all intubations in this study, there may still be a bias against the LFPS due to the vastly greater experience the investigator had in using a simple bougie. The fact that our study is based on the performance of an experienced operator means that our results cannot be extrapolated to practitioners without adequate training in the use of this device.

It has been documented that the single-use bougie is associated with reduced efficacy [20, 21] and greater potential for tissue trauma compared with the multi-use bougie [22]; however, we chose to study the single-use bougie due to concerns over the potential for microbial [23] and prion [24] contamination of such equipment and the fact that many hospitals have now replaced the multi-use with single-use bougies. All cases of failed bougie insertion in our study were due to the inability to maintain the bend with the device; this is consistent with previous work [21].

The cross-over design of this study may potentially introduce bias. There were three cases of prolonged insertion (50–52 s) with the LFPS due to copious secretions. These occurred when the LFPS was used as the second device. Conceivably, prolonged bag-mask ventilation and repeat laryngoscopy may stimulate increased secretions in the airway which may not be adequately removed by suctioning under direct vision, thus producing bias against the LFPS as secretions should have minimal effect on the performance of the bougie. All instances of failed bougie insertion also occurred when this was used as the second device; however, all were due to failure of the bougie to retain the desired shape, and the sequence in which it was used is likely to have had minimal impact on this technical aspect. The impairment of visualisation with an LFPS in the presence of secretions could, however, be considered a disadvantage of the device.

In unexpected grade III laryngoscopy, the most frequently employed device to facilitate intubation is the bougie due to its ready availability, simplicity, and familiarity. However, the use of a bougie is essentially blind and may increase the risk of tissue trauma and unrecognised oesophageal intubation. Optical scopes which permit visualisation of the glottis during intubation are an attractive alternative. Devices such as the Bonfils intubation fibrescope and the Shikani Optical stylet have been available for clinical use for a number of years. Although there are case reports and case series documenting efficacy of these devices in management of both routine and difficult airways [3, 5, 17, 25–29], large comparative studies assessing their efficacy compared with alternative airway devices are lacking. Two studies [30, 31] have compared the optical scopes (LFPS and the

Shikani optical stylet) with the bougie. These studies were performed with simulated grade III laryngoscopy in manikins with operators having minimal prior experiences with the devices. Both studies reported impressive success rates with the optical scopes compared with the bougie, even in simulated grade IIIb laryngoscopy. The reason for the difference in the results between our study and these may be the presence of a larger space in the supraglottic space of manikins than patients.

Conceivably, by allowing visual confirmation of intratracheal placement, the LFPS has a major advantage over the bougie insertion, in that the bougie is essentially blind and relies on such clinical signs as hold-up and clicks, which are not 100% reliable [12, 32, 33]. This confirmation by the LFPS should avoid inadvertent oesophageal intubation. It can also avoid trauma associated with repeated attempts at blind bougie insertions. Compared with the flexible fibrescope, it is relatively inexpensive, more robust, portable, requires shorter preparation time and, with its rigidity, allows ease of handling comparable to a standard bronchoscope. The major limitations are the requirement for previous experience with its use before proficiency is gained, problems with blood or secretions in the airway, limiting the view, difficulty obtaining a clear laryngeal view when there is insufficient space in the periglottic area, reduced manoeuvrability compared with the bougie or fibrescope due to its bulk when preloaded with tracheal tube, and the ever-present concern over infection risk associated with multiple-use devices. Even though we did not study grade IIIb laryngoscopy, its utility in this setting is likely to be limited given our observations that a narrow epiglottic-pharyngeal wall space significantly impedes successful insertion even in a simulated grade IIIa laryngoscopy.

The current role of the LFPS in clinical practice remains uncertain. Results from our study suggest equivalent efficacy compared with the single-use bougie with the theoretical advantage of avoiding inadvertent oesophageal intubation by allowing continuous visual monitoring of the hypopharynx and the glottis. There are, however, several limitations to its use. It is likely that this device would have limited use in grade IIIb or IV laryngoscopy, and therefore offers no real advantage over the cheap, disposable and familiar bougie.

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