

Evaluation of Flexible Tip Bougie in simulated difficult intubation: a randomized cross-over manikin study

Tong Yin **Kuan**¹, Abdul Hadi **Mohamed**²

¹Department of Anaesthesiology and Intensive Care, Hospital Teluk Intan, Teluk Intan, Perak, Malaysia; ²Department of Anaesthesiology and Intensive Care, Kulliyah of Medicine, International Islamic University Malaysia, Kuantan, Pahang, Malaysia

Abstract

Introduction: Both video laryngoscopes and bougies play major role in difficult airway management. Even when a video laryngoscope is available to improve intubation view, there are instances when the vocal cords are visible, but intubation cannot be achieved. In these cases, bougies have a role in assisting intubation. This study aimed to compare the efficacy of the Flexible Tip Bougie with others in simulated difficult intubation.

Methods: This study was designed as a randomized, cross-over, simulation manikin study. It involved 42 medical officers from the Department of Anaesthesiology. In the study, participants performed intubation under simulated difficult airway conditions. Three types of bougie were used by each participant in random order: (1) Flexible Tip Bougie, (2) Portex Single-Use Introducer, and (3) Frova Intubating Introducer.

Results: The intubation success rate was 100% for the Flexible Tip Bougie, 78.6% for the Frova Intubating Introducer, and only 50% for the Portex Single-Use Introducer ($p < 0.001$). The median intubation time was shortest with the Flexible Tip Bougie,

Correspondence: Dr. Kuan Tong Yin, MD, Master of Medicine (Anaesthesiology), Department of Anaesthesiology and Intensive Care, Hospital Teluk Intan, Jalan Changkat Jong, 36000 Teluk Intan, Perak, Malaysia.
E-mail: tykuan88@gmail.com

at 16.08 s (interquartile range [IQR]: 6.13); 18.25 s (IQR: 18.07) with Frova, and 19.39 s (IQR: 37.60) with Portex ($p = 0.449$). The ease of use was lowest with Portex (69.64, standard deviation [SD]: 32.45), average with Frova (50.59, SD: 29.98), and highest with Flexible Tip (16.67, SD: 21.86; [$p < 0.001$]).

Conclusion: In this manikin study, the Flexible Tip Bougie was more efficient in achieving successful intubation and easier to use than the Portex and Frova introducers in a difficult intubation scenario.

Keywords: airway management, intubation, laryngoscope, manikin

Introduction

Endotracheal intubation is a very important skill in anaesthetic practice. The incidence of difficult intubation is approximately 5% in the general population that undergoes anaesthesia.¹ For failed intubation, the incidence is 1 in 2000 among elective patients, 1 in 300 among the obstetric population, and 1 in 50 to 100 in the intensive care unit (ICU) or emergency department.² Furthermore, swift endotracheal intubation is required in difficult circumstances, especially during the COVID-19 pandemic, to minimize the risk of infection to medical personnel and for patient safety.

According to the Difficult Airway Society (DAS) Guidelines published in 2015, both video laryngoscopes and bougies play a major role in difficult airway management.³ Video laryngoscope is the preferred choice (44%) followed by bougie (24.8%) in the event of difficult intubation based on the Malaysia National Audit on Anaesthetic Airway Management of 2015.⁴ Despite video laryngoscopes being now available to improve intubation view, this does not guarantee a successful intubation.⁵ Situations arise where the vocal cords are visible, but intubation cannot be achieved. This is because the video laryngoscope camera is located at the tip of the blade, so the distance to the vocal cords is shorter with wider viewing angle (50°–60°).⁶ However, the significant curves of the airway and laryngoscope blade need to be overcome in order to ensure successful placement of the endotracheal tube (ETT).⁷ This is where bougies have a role in assisting endotracheal intubation.

The bougie is an airway adjunct that is widely used during difficult intubation around the world. However, there is no consensus on the gold-standard bougie due to discrepancy of findings based on previous studies. Most bougies are straight with an angled tip and can be bent only to certain extent, but the curvature cannot be amended during the intubation process.⁷ The Flexible Tip Bougie (Construct

Medical, Hawthorn, Australia) was first launched in 2017. Its unique feature is that the tip can be flexed anteriorly or posteriorly by using a slider.⁸ Therefore, it offers an extra advantage during intubation attempts. A few recent studies that evaluated the efficacy of the Flexible Tip Bougie among medical personnel showed positive results.^{7,9-11}

This study aimed to compare the efficacy of Flexible Tip Bougie with the Portex Single-Use Introducer (Smiths Medical, Minneapolis, MN, USA) and the Frova Intubating Introducer (Cook Medical, Bloomington, IN, USA) in simulated difficult intubation in terms of successful rate of intubation, intubation time, and ease of use in order to explore a better bougie.

Methods

This study was designed as a randomized, cross-over, and experimental manikin study and conducted in the Department of Anaesthesiology and Intensive Care, Hospital Tengku Ampuan Afzan (HTAA), Kuantan and Sultan Ahmad Shah Medical Centre International Islamic University Malaysia (SASMEC @IIUM). This study was registered with the National Medical Research Registry (NMRR) - NMRR-18-3577-45184. Ethical approval was obtained from Medical Research and Ethics Committee (Ethics approval number: KKM/NIHSEC/P19-382(12)) and IIUM Research Ethics Committee (Ethics approval number: IIUM/504/14/11/2/IREC2019-160). Forty-two medical officers (MOs) were recruited, of which 15 MOs were from HTAA and 27 MOs were from SASMEC @IIUM. Voluntary written informed consent was obtained from each participant.

A Laerdal Airway Management Trainer (Laerdal Medical, Stavanger, Norway) was used to simulate a Cormack Lehane grade 3A laryngeal view so that only the tip of the epiglottis could be seen (percentage of glottic opening = 0). It was achieved by applying a Laerdal Stifneck Select Extrication Collar (Laerdal Medical, Stavanger, Norway) to the neck (Fig. 1). Participants were not allowed to remove the cervical collar, alter the head position, or apply external laryngeal pressure during intubation attempts. Three types of bougies were tested in this study: the Flexible Tip Bougie (Fig. 2), the Portex Single-Use Introducer (Fig. 3), and the Frova Intubating Introducer (Fig. 4).

Before starting the study, participants were given sufficient time to practise intubation with all bougies on unmodified airway. During data collection, participants were instructed to perform a single intubation attempt on simulated difficult airway manikin with each type of bougie by using GlideScope with GVL 4 blade



Fig. 1. Manikin model of difficult intubation with Glide Scope.

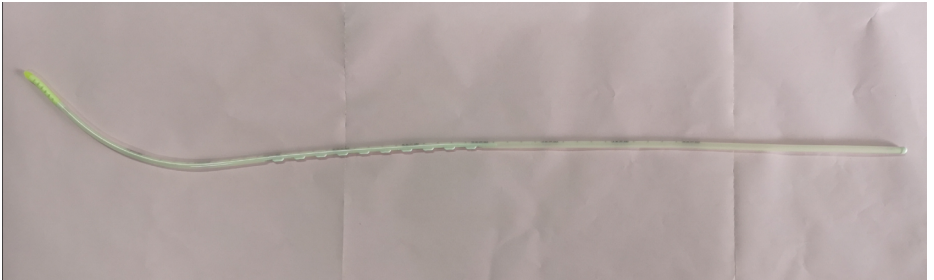


Fig. 2. Flexible Tip Bougie.



Fig. 3. Portex Single-Use Introducer.

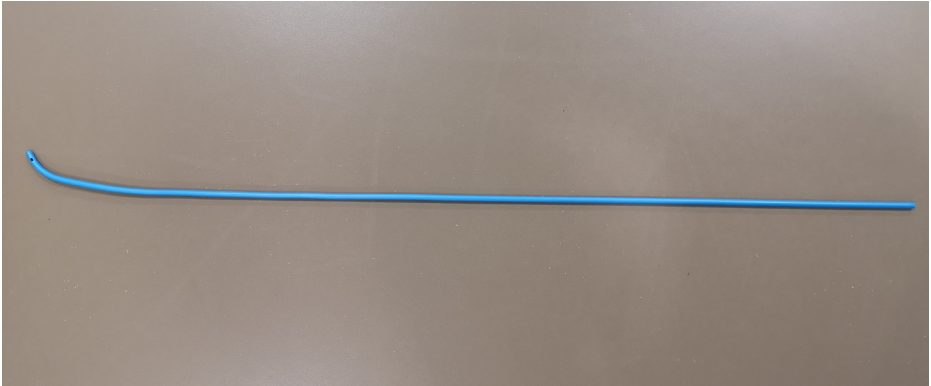


Fig. 4. Frova Intubating Introducer.

(Verathon Medical, Burnaby, Canada). The order of bougies was randomized by using the closed envelope technique with 6 possible orders of arrangement (Fig. 5). The percentage of glottic opening upon video laryngoscopy obtained by each participant was recorded, where full vocal cord visualisation was documented as 100%. A cuffed ETT with internal diameter of 7.0 mm (Ideal Healthcare, Sungai Petani, Malaysia) was used in this study.

The site of ETT placement was confirmed by investigator. Intubation success rate was the primary outcome in this study. A successful intubation was defined as tracheal placement of the ETT when it was possible to ventilate the lungs of the manikin with a self-inflating bag connected to the ETT. A failed intubation was declared for oesophageal placement of ETT, abandoned attempt of intubation, or intubation time exceeding 8 minutes, which is the safe apnoea time of a healthy pre-oxygenated patient. The secondary outcome was intubation time, defined as the time from when the participant took the bougie until the bougie was totally removed from the ETT after completion of intubation. After the intubation attempts, participants were required to provide subjective opinions about ease-of-use of each bougie used via a 5-point Likert scale with its associated visual aids, in which:

- 1: very easy
- 2: easy
- 3: ok
- 4: fiddly
- 5: very difficult.

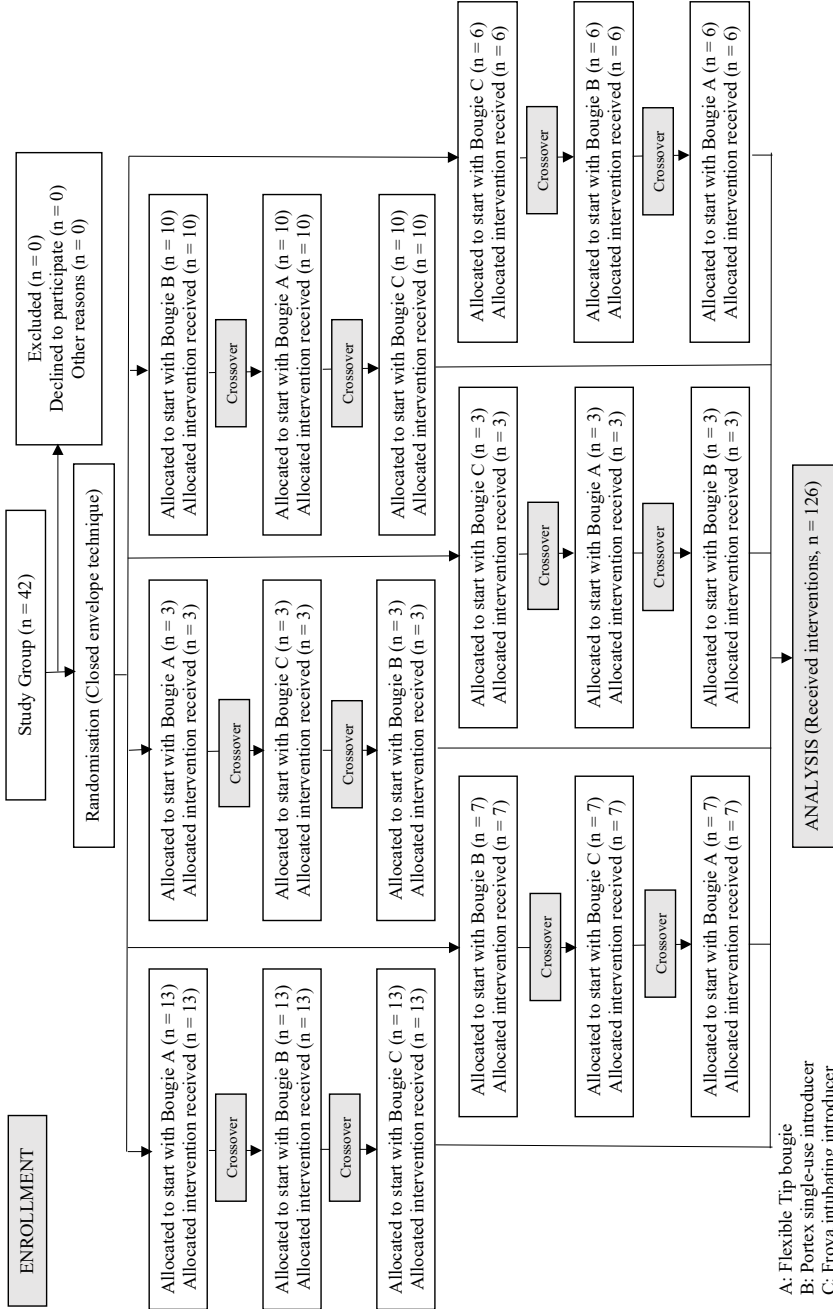


Fig. 5. Randomization flow chart.

Data processing and statistics

Sample size calculation was performed based on primary outcome by using the population proportion formula.¹² A minimum of 25 subjects were required in this study. However, 42 participants were successfully recruited. Statistical analyses were performed using statistical program R (version 3.6.1).¹³ A p value < 0.05 was considered as statistically significant.

Cochran's Q test was applied to assess differences in the intubation success rate among all bougies. Then, post-hoc analysis was performed with pairwise McNemar test to identify the pairs which were significantly different. Friedman test was employed to compare the intubation times for successful intubations and to determine the statistical difference for each group. In addition to that, ease-of-use score obtained from the 5-point Likert scale was rescaled to a comparable mean score of 100. Then, the differences among all bougies were evaluated using repeated measures analysis of variance (ANOVA) and followed by pairwise comparisons via multiple paired t -tests to identify the pairs which were significantly different in term of ease-of-use score. All results are shown as median and interquartile range (IQR), mean and standard deviation (SD), or counts and percentages (%).

Results

A total of 42 MOs in the Department of Anaesthesiology and Intensive Care were recruited. The background characteristics of participants are depicted in Table 1. There were 19 male and 23 female participants. Median age was 31 years old. Mean percentage of glottic opening obtained by participants using GlideScope was 50.95% (SD: 18.59).

Table 1. Background characteristics of participants and descriptive statistics on glottic views

Variable	<i>n</i>	%
Male	19	45.0
Female	23	55.0
Age (years)	42	31 (4) ^a
Work experience (months)	42	36 (51.75) ^a
Percentage of glottic opening score	42	50.95 (18.59) ^b

Values are number, median (interquartile range), or mean (standard deviation).

^aMedian (interquartile range); ^bmean (standard deviation)

The intubation success rate was highest with the Flexible Tip Bougie (100%), followed by the Frova Intubating Introducer (78.6%). The Portex Single-Use Introducer had the lowest success rate (50%) among all 3 bougies. The differences were statistically significant for all comparisons (p value < 0.001; Table 2).

Table 2. Intubation success rate

	Flexible Tip Bougie (A)	Portex Single-Use Introducer (B)	Frova Intubating Introducer (C)	p value	Adjusted p values for between-device differences
Intubation success rate	42/42 (100%)	21/42 (50%)	33/42 (78.6%)	< 0.001 ^a	A vs. B < 0.001 ^b A vs. C = 0.003 ^b B vs. C = 0.002 ^b

Values are proportional (%).

^aCochran's Q test; ^bpairwise McNemar test (post-hoc analysis)

The median intubation time was shortest with the Flexible Tip Bougie, at 16.08 s (IQR: 6.13) followed by the Frova Intubating Introducer at 18.25 s (IQR: 18.07), and the Portex Single-Use Introducer at 19.39 s (IQR: 37.60). The median intubation time did not differ significantly among these bougies (p = 0.449; Table 3).

Table 3. Intubation time

Variable	Flexible Tip Bougie	Portex Single-Use Introducer	Frova Intubating Introducer	p value
Intubation time, s (IQR)	16.08 (6.13)	19.39 (37.60)	18.25 (18.07)	0.449*

s: seconds; IQR: interquartile range

Values are median (interquartile range). Time is reported only for successful intubation.

*Friedman test

Ease-of-use score obtained from the 5-point Likert scale was rescaled to a comparable mean score of 100 to facilitate comparison between the 3 bougies, with higher scores standing for greater difficulty of use. The Flexible Tip Bougie was perceived as the easiest to use with the lowest mean ease-of-use score of 16.67 (SD: 21.86). The ease-of-use was average for the Frova Intubating Introducer (50.59, SD: 29.98). The Portex Single-Use Introducer was considered the most difficult to use with the highest score (69.64, SD: 32.45). All these differences were statistically significant (p value < 0.001; Table 4).

Table 4. Ease-of-use score

Variable	Flexible Tip Bougie (A)	Portex Single-Use Introducer (B)	Frova Intubating Introducer (C)	p value	p values for pairwise comparisons*
Ease-of-use score (SD)	16.67 (21.86)	69.64 (32.45)	50.59 (29.98)	< 0.001 ^a	A vs. B < 0.001 ^b A vs. C < 0.001 ^b B vs. C = 0.008 ^b

SD: standard deviation; Ease-of-use score (after rescaling) with 0 being “very easy” to 100 being “very difficult”.

Values are mean (standard deviation).

*Adjustment for multiple comparisons: Bonferroni; ^arepeated measures analysis of variance (ANOVA) with sphericity assumed; ^b paired t-test (post-hoc analysis)

Discussion

This is the first study in Malaysia evaluating multiple bougies at one time, comparing the Flexible Tip Bougie and the commonly available Portex Single-Use Introducer and Frova Intubating Introducer.

This study showed that the intubation success rate was highest with Flexible Tip Bougie (100%), followed by Frova Intubating Introducer (78.6%) and Portex Single-Use Introducer (50%), indicating that the Flexible Tip Bougie is more efficient. Our results are in line with those obtained by Mahli *et al.*, which indicated that the Flexible Tip Bougie (98.4%) had significantly higher success rate than the Portex Single-Use Introducer (85.5%).¹⁰ Another study by Evrin *et al.* concluded that the success rate of the Flexible Tip Bougie group (91.3%) was higher than for a standard bougie (SUMI, Sulejowek, Poland; 73.9%).¹⁴ Research carried out by Frass *et al.* also showed the Flexible Tip Bougie (51.4%) to be superior than a standard bougie stylet (ONTEX, Chennai, India; 37.8%) in term of intubation success rate.⁹ Brunckhorst *et al.* demonstrated that the Flexible Tip Bougie had a better success rate than the Frova Intubating Introducer (100% vs. 80%, respectively).⁸

There are 2 major distinctive characteristics of Flexible Tip Bougie that very likely contribute to its high intubation success rate. Firstly, it has a pre-curved anterior body of approximately 45° that allows the tip to reach the vocal cords easily when used together with the GlideScope, which has a blade angulation of approximately 60°. Both the Portex Single-Use Introducer and the Frova Intubating Introducer

have a straight body with limited tip bend (40° and 65°, respectively), which makes it more difficult to reach the vocal cords despite a clear view. Secondly, the Flexible Tip Bougie has a controllable tip that can be flexed anteriorly to reach the vocal cords to facilitate intubation and flexed posteriorly once passing through the vocal cords to avoid impingement on the anterior tracheal rings as well as to prevent tracheal injury.

The median intubation time was shortest with Flexible Tip Bougie (16.08 s), followed by the Frova Intubating Introducer (18.25 s) and the Portex Single-Use Introducer (19.39 s). However, there was no significant difference among 3 devices. The results are on a par with a study by Vowles *et al.* that showed similar intubation times with the Flexible Tip Bougie (34.9 s) and the Frova Intubating Introducer (33.2 s).⁷ However, our results differ from a few previous studies that showed the Flexible Tip Bougie to be more efficient in terms of intubation time. Mahli *et al.* demonstrated that the intubation time was significantly faster with the Flexible Tip Bougie (32.0 s) than the Portex Single-Use Introducer (41.5 s).¹⁰ Another study conducted by Cormack *et al.* obtained results indicating that total intubation time was significantly shorter with the Flexible Tip Bougie (37.5 s) compared to the Frova Intubating Introducer (63.0 s).¹¹ Additionally, the results from Evrin *et al.* also showed that intubation time was significantly faster with the Flexible Tip Bougie (29.0 s) than a standard bougie (38.0 s).¹⁴ Again, the intubation time with the Flexible Tip Bougie (37.0 s) was significantly shorter than with a standard bougie (55.0 s) in a study by Frass *et al.*⁹ Brunckhorst *et al.* also concluded that the intubation time was significantly faster with the Flexible Tip Bougie (77.2 s) as compared to the Frova Intubating Introducer (142.2 s).⁸ The difference in our results could be due to the fact that our sample size calculation was performed based on the primary outcome, and the current sample may not be large enough to power the study in order to detect a statistically significant difference in intubation time. Therefore, it warrants future research with larger sample size to detect a difference.

Among the studied bougies, the Flexible Tip Bougie was rated as the easiest to use by participants. The Portex Single-Use Introducer was considered the most difficult to use. The differences were statistically significant for all comparisons. The preference towards the Flexible Tip Bougie was not affected by the order of attempts, as the order was randomized using the closed envelope technique to minimize order effect. The results remain in line with several previous studies which were in favour of the Flexible Tip Bougie compared to others in term of ease of use.^{7-11,14} According to feedback from the participants, the Flexible Tip Bougie is easier to use because of its anterior curve of body and the flexible tip that can be directed both anteriorly and posteriorly. In the scenario of difficult airway, it is important to select the easiest to use and most familiar bougie to facilitate successful intubation.

The mean percentage of glottic opening obtained by participants using GlideScope was 50.95%. It improved from 0% (Cormack Lehane grade 3A), indicating that video laryngoscopes greatly improve laryngeal view for difficult airways. This result is consistent with those observed in studies by Brunckhorst *et al.* and Batuwitage *et al.*, which demonstrated percentages of glottic opening of at least 40% and 50%, respectively, with the C-MAC D-blade video laryngoscope (Karl Storz Endoscopy, Tuttlingen, Germany).^{8,15}

This study has several limitations. First, the difficult airway was simulated in a manikin, which does not present the same scenario as real patients. Participants may approach the simulator differently than they do actual patients. However, this decision was deliberate and dictated by the fact that recruiting real patients for this study could threaten the patients' lives. Another limitation is pertaining manikin use in this study. Manikins may mimic many but not all difficult airways. Human airways are complex and diverse. Therefore, results from manikin studies may not accurately translate to real subjects. With manikins, airway trauma associated with bougies cannot be assessed. However, this warrants future research regarding airway trauma since there were favourable results towards the Flexible Tip Bougie in this study. Lastly, only MOs were included, which limits the generalizability of results towards specialists and paramedics.

Conclusion

In this simulation manikin study, the Flexible Tip Bougie used in conjunction with GlideScope proved more efficient in achieving successful intubation and was easier to use than the Portex Single-Use Introducer and the Frova Intubating Introducer in a difficult intubation scenario.

Declarations

Ethics approval and consent to participate

This study obtained ethics approval from the Medical Research & Ethics Committee (MREC) [Ref. No.: KKM/NIHSEC/P19-382(12)] and IIUM Research Ethics Committee (IREC) [Ref. No.: IIUM/504/14/11/2/IREC 2019-10] prior to initiating the study. Informed consent from the participants in this study had been obtained and well-kept with no reuse or reproduction of information.

Competing interests

None to declare.

Funding

None to declare.

Acknowledgements

Special thanks and acknowledgements to the staff in the Department of Anaesthesiology and Intensive Care of Sultan Ahmad Shah Medical Centre @IIUM (SASMEC @IIUM) and Hospital Tengku Ampuan Afzan (HTAA) for their continuous support in this study.

References

1. Heinrich S, Birkholz T, Irouschek A, Ackermann A, Schmidt J. Incidences and predictors of difficult laryngoscopy in adult patients undergoing general anesthesia. *J Anesth.* 2013;27(6):815–21. <https://doi.org/10.1007/s00540-013-1650-4>
2. Cook TM, MacDougall-Davis SR. Complications and failure of airway management. *Br J Anaesth.* 2012 Dec;109(1 Suppl):I68–85. <https://doi.org/10.1093/bja/aes393>
3. Frerk C, Mitchell VS, McNarry AF, et al. Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. *Br J Anaesth.* 2015;115(6):827–48. <https://doi.org/10.1093/bja/aev371>
4. Ministry of Health Malaysia [Internet]. National Audit on Anaesthetic Airway Management; [cited 2022 Dec 22]. Available from: <http://www.moh.gov.my/index.php/pages/view/1131>
5. Lascarrou JB, Boisrame-Helms J, Bailly A, et al. Video laryngoscopy vs direct laryngoscopy on successful first-pass orotracheal intubation among ICU patients: a randomized clinical trial. *JAMA.* 2017;317(5):483–93. <https://doi.org/10.1001/jama.2016.20603>
6. Angadi SP, Frerk C. Videolaryngoscopy and Cormack and Lehane grading. *Anaesth.* 2011;66(7):628–9. <https://doi.org/10.1111/j.1365-2044.2011.06777.x>
7. Vowles BJ, Rodda B, Ringrose D. Evaluation of intubating adjuncts to videolaryngoscopy in a simulated difficult airway: a manikin cross-over study. *Anaesth Intensive Care.* 2021;49(4):327–9. <https://doi.org/10.1177/0310057X211012275>
8. Brunckhorst TL, Grimmett W, Mun-San Kwan MM. Evaluation of a new bougie design for the difficult airway: a manikin crossover trial. *Anaesth Intensive Care.* 2018 Sep;46(5):544–5. Cited in: PubMed; PMID 30189828.
9. Frass M, Smereka J, Ruetzler K, Szarpak L, Robak O. New Flexible Tip Bougie catheter for difficult airway intubation: a randomized, crossover pilot study. *Disaster Emerg Med J.* 2019;4(2):50–4. <https://doi.org/10.5603/DEMJ.2019.0010>

10. Mahli N, Md Zain J, Mohamad Mahdi SN, et al. The performance of Flexible Tip Bougie™ in intubating simulated difficult airway model. *Front Med.* 2021 May 7;8:[6 p.]. <https://doi.org/10.3389/fmed.2021.677626>
11. Cormack J, Langley B, Bhanabhai LR, Kluger R. A randomised crossover comparison of two endotracheal tube introducers: the FROVA and the Flexible Tip Bougie for GlideScope intubation of a difficult airway manikin by infrequent intubators. *Int J Emerg Med.* 2020 Jul 17;13(1):[7 p.]. <https://doi.org/10.1186/s12245-020-00298-6>
12. Machin D, Campbell M, Fayers PM, Pinol A. Sample size tables for clinical studies [Internet]. 2nd ed. New Jersey: Wiley-Blackwell; 1997 Jan [cited 2019 Apr 10]. Available from: <https://books.google.com.my/books?id=zPQhQ8d-4JwC>
13. The R Project for Statistical Computing [Internet]. Austria: R Core Team; [cited 2019 Nov 1]. Available from: <https://www.r-project.org/>
14. Evrin T, Smereka J, Gorczyca D, et al. Comparison of different intubation methods in difficult airways during simulated cardiopulmonary resuscitation with continuous chest compression: a randomized cross-over manikin trial. *Emerg Med Int.* 2019:[7 p.]. <https://doi.org/10.1155/2019/7306204>
15. Batuwitage B, McDonald A, Nishikawa K, Lythgoe D, Mercer S, Charters P. Comparison between bougies and stylets for simulated tracheal intubation with the C-MAC D-blade videolaryngoscope. *Eur J Anaesthesiol.* 2015;32(6):400–5. <https://doi.org/10.1097/EJA.000000000000070>



Experience True HD in Video Laryngoscopy

Solely distributed by:



KARL STORZ SE & CO. KG, Dr.-Karl-Storz-Straße 34, 70532 Tuttlingen/Germany, www.karlstorz.com



The New C-MAC® FIVE S

For the most stringent demands – the premium class for single use

- Exceptional rigidity with very good guidance properties
- Good gliding properties, particularly when removing the Endotracheal Tube (ETT)
- Successful addition to the C-MAC® system



KARL STORZ SE & CO. KG, Dr.-Karl-Storz-Straße 34, 70532 Tuttlingen/Germany, www.karlstorz.com