

Intubation without use of stylet for McGrath videolaryngoscopy in patients with expected normal airway

A randomized noninferiority trial

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Abstract

Background: During McGrath videolaryngoscope (VL) intubation, a stylet endotracheal tube maintaining an upward distal tip angle is recommended by some manufacturers. However, a stylet endotracheal tube can elicit rare but potentially serious complications. The purpose of this study was to demonstrate that a nonstylet tube with exaggerated curvature would be noninferior to a stylet tube for orotracheal intubation using McGrath VL in patients with expected normal airway, by comparing the time to intubation and ease of intubation.

Methods: One hundred forty patients, ages 19 to 70 years (American Society of Anesthesiologists physical status I–II), undergoing tracheal intubation for elective surgery were randomly allocated to the nonstylet group (n=70) or the stylet group (n=70). Anesthesia induction consisted of propofol, remifentanyl, and rocuronium. The primary outcome was time to intubation assessed by a blind observer. Cormack and Lehane glottic grade, ease of intubation, and intubation difficulty score (IDS) were also assessed.

Results: Median time to intubation [interquartile range] was not different between the nonstylet group and the stylet group (26 [24–32.5] s vs 27 [25–31] s, $P=0.937$). There was no significant in median IDS between the nonstylet group and the stylet group ($P=0.695$).

Conclusion: This study shows that a nonstylet endotracheal tube with exaggerated curvature has a similar performance to a stylet tube with a hockey-stick curvature during intubation using McGrath VL regarding time taken to successful intubation and easiness of intubation.

Abbreviations: BIS = bispectral index, IDS = intubation difficulty score, VL = videolaryngoscope.

Keywords: anesthetic technique, laryngoscopy, McGrath videolaryngoscope, stylet

1. Introduction

The videolaryngoscope (VL) has an established role in endotracheal intubation over direct laryngoscopy, as it provides better laryngeal view and higher success rate in difficult airway patients, and as an educational tool.^[1–3] Among various VLs, the McGrath VL (Aircraft Medical, Edinburgh, Scotland) has a high-resolution liquid crystal display monitor mounted on the top of

the handle and an angulated single-use blade of adjustable length. The McGrath VL offers excellent laryngoscopic views in patients with normal airway and an increased success rate in patients with simulated difficult airway.^[4,5]

During McGrath VL intubation, a direct line of oral, laryngeal, and pharyngeal axis is not created. So, a stylet endotracheal tube maintaining an upward distal tip angle of 60° is recommended by some manufacturers, as with other VLs.^[4,6,7] However, a stylet endotracheal tube can elicit rare but potentially serious complications, such as palatal perforation and pulmonary migration of a plastic coating fragment.^[8–11] Thus, a simple and effective technique without a stylet during orotracheal intubation may be desirable in patients using McGrath VL.

In this study, a modified curved endotracheal tube was used instead of a stylet endotracheal tube. The endotracheal tube was bent to exaggerate the already present Magill curve by connecting both ends of the endotracheal tube, letting it pass anteriorly into the larynx.^[12] The hypothesis of this study was that a nonstylet endotracheal tube with exaggerated curvature might be as effective as a stylet endotracheal tube for endotracheal intubation using McGrath VL. To test the hypothesis, we performed a randomized, noninferiority clinical study.

The purpose of this study was to demonstrate that a nonstylet tube with exaggerated curvature would be noninferior (similar) to a stylet tube for orotracheal intubation

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using McGrath VL in patients with expected normal airway, by comparing the time to intubation and ease of intubation.

2. Methods

After the approval of the institutional review board (Ajou University Hospital, Suwon, Korea), and registration in ClinicalTrials.gov (NCT02642367), we obtained written informed consent for the study from all patients. We enrolled 140 patients 19 to 65 years of age who were undergoing general anesthesia for ENT surgery and who had American Society of Anesthesiologists physical status I or II. Exclusion criteria included cervical spine injury, rapid sequence induction, body mass index $>35 \text{ kg/m}^2$, and airway pathology. Preoperative airway examination was assessed, including Mallampati score, thyromental distance, mouth opening, neck mobility, and status of dentition.

Patients received no premedication prior to surgery. In the operating room, standard monitoring was applied, including pulse oximeter, electrocardiogram, noninvasive blood pressure, and bispectral index (BIS) using a BIS Quattro sensor (Covidien LLC, Mansfield, MA). Patients were randomly allocated to the nonstylet group ($n=70$) or the stylet group ($n=70$) using a computer-generated randomization table. After the administration of oxygen for 3 min, anesthesia induction was conducted with propofol effect-site concentration of $4.0 \mu\text{g/mL}$ and remifentanyl effect-site concentration of 4.0 ng/mL using an Orchestra 2-channel target-controlled infusion pump (Fresenius Vial, Brezins, France). At loss of spontaneous respiration, bag mask ventilation with 100% oxygen was applied. Rocuronium 0.6 mg/kg was administered to achieve neuromuscular blockade. Tracheal intubation was performed 2 min after rocuronium injection, confirming disappearance of train of 4 responses. Intubation was performed by 1 of 2 anesthesiologists with more than 10 years of clinical experience and who had each performed at least 20 successful intubations with the McGrath VL (SYL and JYK). In the nonstylet group, the endotracheal tube (Portex Ltd, Hythe, Kent, UK) was bent to exaggerate its curvature by joining the distal tip of the tube for 3 min prior to endotracheal intubation (Fig. 1). In the stylet group, a malleable intubating stylet (Covidien, Ireland) with a hockey-stick curvature was inserted in the endotracheal tube, after which the distal tip of tube was bent just above the cuff to a 60° angle. The size of the endotracheal tube for male and female patients was 7.5 and 7.0 mm, respectively.

The primary outcome measure was time to intubation, defined as the time from the insertion of the laryngoscope blade into the oral cavity to the detection of end-tidal CO_2 trace. A blind observer who was unaware of the patient group and intubation procedure continuously watched a monitor positioned behind each patient and measured the time to intubation. If the intubation time exceeded more than 60 s or SpO_2 became $<95\%$, mask ventilation was applied before second attempt. The anesthesiologists performing the intubation accessed laryngoscopic views according to the Cormack and Lehane grade. Easy of intubation was subjectively measured as intubation difficulty score (IDS) (0=easy intubation; 1–5=slight difficulty; >5 major difficulty).^[13] Mean arterial pressure, heart rate, SpO_2 , and BIS were recorded at baseline, 1 min after anesthetic infusion, and before and 1 min after intubation.

3. Statistical analysis

Sample size was calculated based on a previous study,^[14] in which the mean and standard deviations of the time to intubation

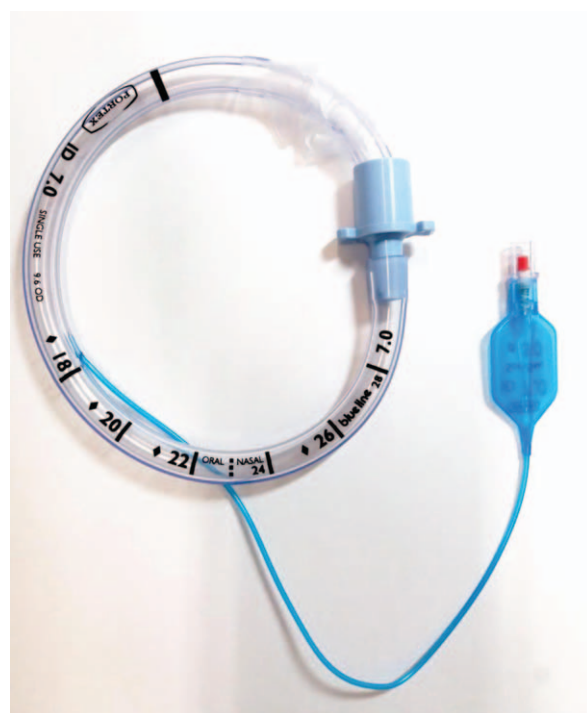


Figure 1. Endotracheal tube with exaggerated curvature.

were estimated at 40 s and 19 s. For noninferiority of the stylet group versus the nonstylet group, a maximum difference of 8 (the noninferiority limit, Δ) in the time to intubation was assumed acceptable, 70 patients were required in each group with an α -error of 0.05 and a power of 0.8. The total sample size was 140 patients in the 2 groups. Statistical analyses were performed using IBM SPSS version 21.0 for Windows. Data are expressed as mean \pm standard deviation, median [interquartile range], or number of patients (%). Categorical data were analyzed using the chi-squared test, and continuous data between the groups were analyzed using an independent t test. A P value <0.05 was considered statistically significant.

4. Results

A total of 140 patients were allocated and completed the study (Fig. 2). There were no significant differences in patient characteristics and airway assessment findings between the groups (Table 1).

In the majority of patients (137 patients, 98%), endotracheal intubation was successful within 60 s on the first attempt (2/70 [2.8%] in the nonstylet group vs 1/70 [1.4%] in the stylet group, $P=1.00$). A Kaplan–Meier plot was illustrated to show the intubation success as a function of time (Fig. 3). Median time to intubation [interquartile range] was not different between the nonstylet group and the stylet group (26 [24–32.5] s vs 27 [25–31] s, $P=0.937$) (Table 2). Mean difference between the groups in time to intubation was -0.2 s (95% confidence interval -4.48 to 4.08) (Fig. 4). Regarding the degree of difficulty in intubation, there was no significant in median IDS between the nonstylet and stylet groups ($P=0.695$), and the proportion of patients with IDS=0 was not different between the nonstylet and stylet groups (83% vs 86%). Laryngoscopic glottis view grade was not different between the 2 groups. There were no significant

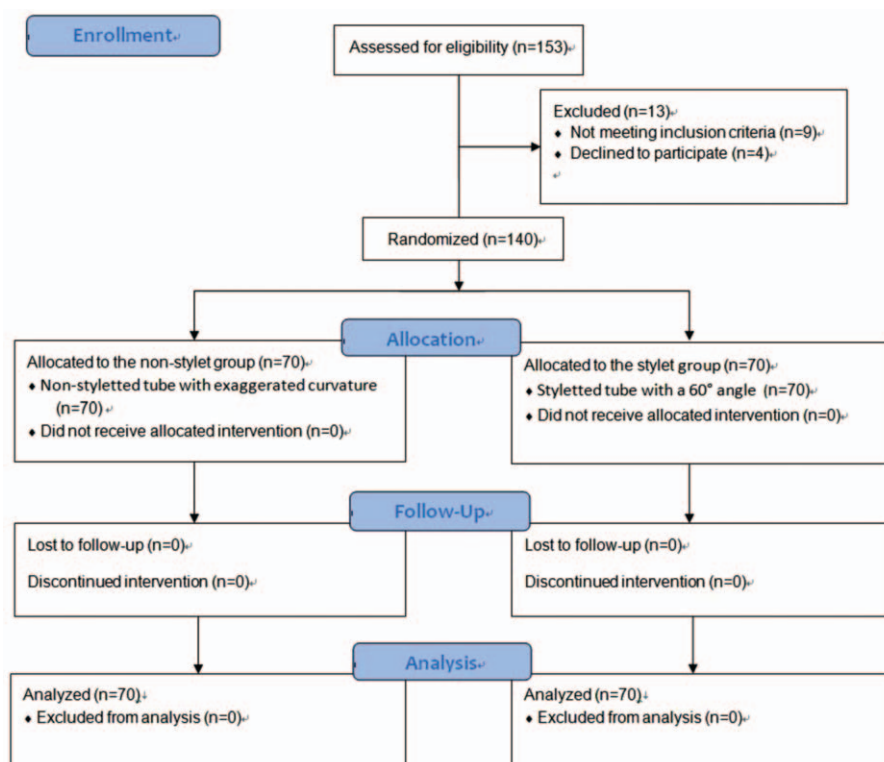


Figure 2. Patient allocation flow diagram.

differences in hemodynamic and BIS values between the groups over time. During endotracheal intubation, major complications including mucosal perforation and dental damage did not occur.

5. Discussion

This study shows that, in the terms of the time to intubation and difficulty of intubation using McGrath VL, a nonstyletted endotracheal tube with exaggerated curvature is not different compared with a styletted tube in patients with expected normal airway. There were no differences in success rate at first attempt between the groups and no traumatic injuries to the airway using a nonstyletted or styletted endotracheal tube.

Although indirect VLs may provide a better glottis view than direct laryngoscopy,^[1,2] a major concern of all indirect VLs is that the indirect glottis view complicates insertion of the endotracheal tube.^[4] This problem is likely because the indirect McGrath or

GlideScope VL is inserted in the midline and advanced over the tongue because of the lack of necessity for sweeping the tongue laterally, whereas direct classic laryngoscopy is usually inserted on the right side of the tongue, which is compressed and deflected laterally. Several techniques are suggested to improve the success rate during intubation using indirect VLs; these include withdrawal and reinserting the blade, external laryngeal pressure, and increased lifting force.^[15] A previous report studying indirect VLs suggested that among various improvement techniques, the use of stylet with a relatively pronounced curve at the distal end was the most helpful technique in facilitating orotracheal intubation using indirect VLs.^[16] Stylet use can essentially compensate for the geometrical weaknesses of indirect VL and may play an important role during intubation using McGrath VL.^[16] The authors reported that during intubation using McGrath or GlideScope VL, the use of stylet could improve the success rate of intubation at first attempt. In this study, the success rate at first attempt was 98.6% when using the McGrath VL with a styletted endotracheal tube by experienced laryngoscopists. This result is comparable to the previously reported success rate of 93%.^[5]

Because a styletted endotracheal tube may cause rare, but potentially serious, complications due to its rigidity,^[8-11] this study used a nonstyletted endotracheal tube with an exaggerated curvature and compared the results with a styletted endotracheal tube during intubation using McGrath VL. An exaggerated curvature is achieved by a simple maneuver of connecting both ends of the tube, which has been described to be useful in blind nasal intubation,^[12] and prevents the esophageal intubation as it tends to go upward. This may be most beneficial in what is called as the “anterior” airway, which the glottis is not fully visualized because of the curve and bulky tongue base. In this study, a

Table 1

Patients' characteristics.

	Nonstylet group (n = 70)	Stylet group (n = 70)
Sex, M/F	38/32	36/34
Age, y	38 ± 15	37 ± 13
Weight, kg	64 ± 11	65 ± 12
Height, cm	166 ± 8	167 ± 8
ASA physical status, I/II	59/11	55/15
Mallampati score, I/II/III	47/15/8	46/15/9
Thyromental distance, cm	9.5 ± 0.9	9.4 ± 1.2
Mouth opening, cm	4.6 ± 0.6	4.5 ± 0.6

Values represent mean ± standard deviation or number of patients. ASA = American Society of Anesthesiologists.

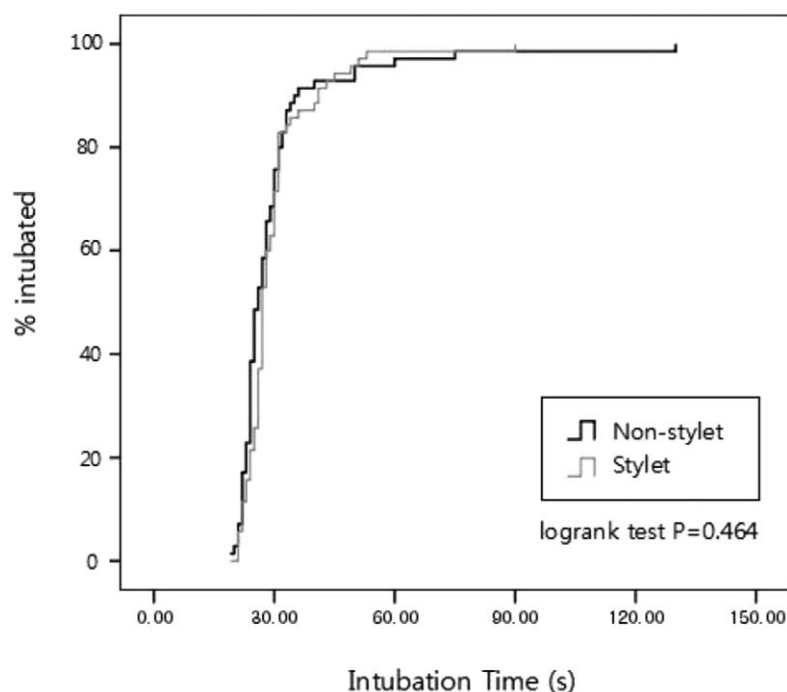


Figure 3. Kaplan–Meier plot demonstrating the success rate of intubation as time progressed.

nonstyletted tube with exaggerated curvature had similar efficacy for intubation using McGrath VL compared with a styletted endotracheal tube. There were no differences in time to intubation, IDS score, and success rate at first attempt between the styletted and nonstyletted groups in this study. Thus, we expect that this simple maneuver could be helpful for intubation using McGrath or other indirect VLs without the stylet use, even in the nonexpert.

Both groups had no major complication associated with intubation, such as mucosal perforation and dental damage. A previous study reported that the Endoflex tube, which has a flexible distal end to allow the distal curve to be adjusted, might be related to less laryngeal morbidity compared with a styletted endotracheal tube.^[17] In their study, the Endoflex tube did not reduce vocal fold injury or postoperative hoarseness, but produced lower shimmer values, which reflects edema of vocal folds, compared with a styletted tube.^[17] Further studies to evaluate the association between the stylet use and laryngeal morbidities could be useful.

This study has some limitations. Firstly, the experienced anesthesiologists were not blinded to the use or nonuse of stylets. Hawthorne effects might have affected the performance during intubation and the results.^[18] Secondly, because this study was performed by experienced anesthesiologists using the McGrath VL, our results might not completely extrapolate to the novice. Thirdly, since we used only the McGrath VL, other indirect VLs, which have different features associated with a blade, might have different results concerning stylet use. Further study might be needed to elucidate the effect of stylet use according to different VLs.

In conclusion, a nonstyletted endotracheal tube with exaggerated curvature has a similar performance to a styletted tube with a hockey-stick curvature during intubation using the McGrath VL device in regard to time taken to successful intubation and easiness of intubation. During intubation using the McGrath VL device, we recommend a nonstyletted tube with exaggerated curvature instead of the styletted tube in patients with normal airway.

Table 2

Intubation profiles.

	Nonstylet group (n = 70)	Stylet group (n = 70)	P
Time to intubation, s	26 (19–130 [24–32.5])	27 (21–90 [25–31])	0.937
Glottic grade (I/IIa/IIb/III), n (%)	63/7/0/0 (90/10/0/0)	62/8/0/0 (89/11/0/0)	0.785
Increased lifting force, n (%)	10 (14)	9 (13)	0.805
Optimal external laryngeal manipulation, n (%)	4 (6)	2 (3)	0.681
Intubation difficulty score	0 (0–5 [0–0])	0 (0–5 [0–0])	0.695
Ease of intubation, n (%)			0.642
Easy	58 (83)	60 (86)	
Slightly difficulty	12 (17)	10 (14)	
Major difficulty	0 (0)	0 (0)	

Values represent median (range [interquartile range]) or number of patients (%).

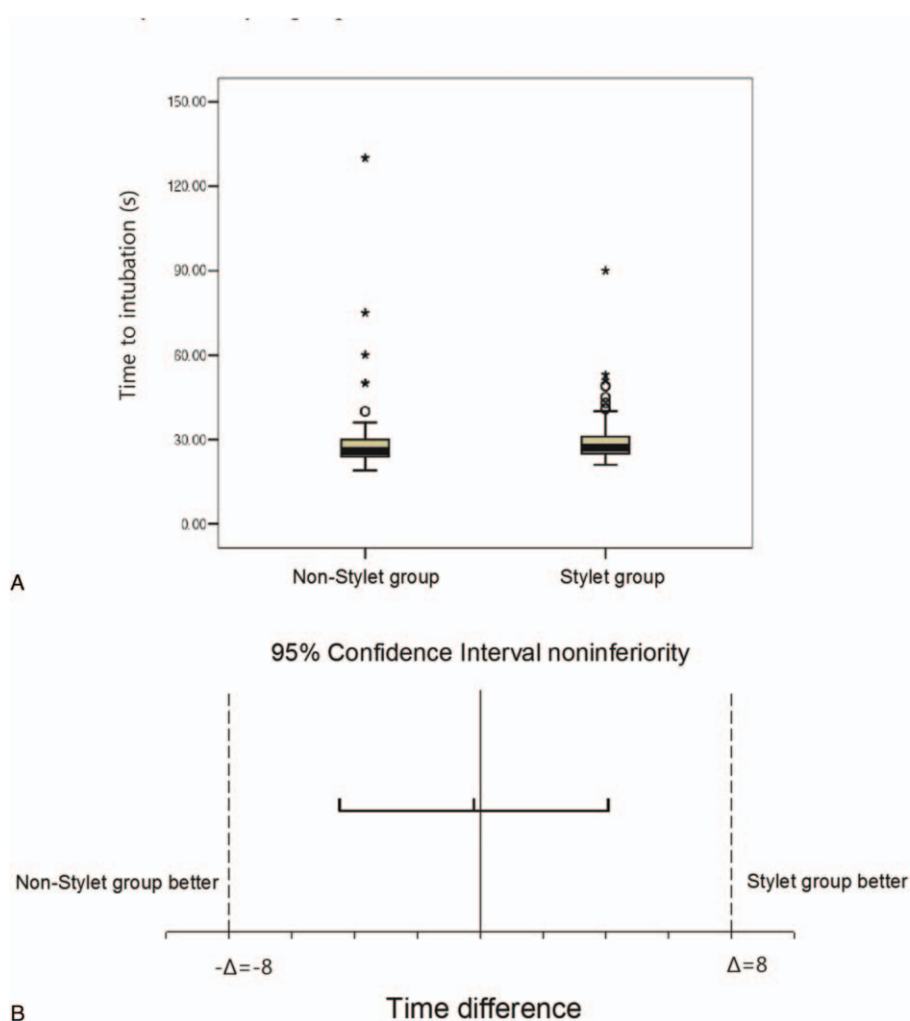


Figure 4. Box plots illustrating the time to intubation in the nonstylet and stylet groups (A) and mean time difference in the time to intubation (B). The horizontal line in the box, the outer horizontal lines of the box, and error bar indicate median, the 25th and 75th interquartiles, and 95% confidence interval (CI), respectively. As the 95% CI of time difference (-4.48 to 4.08 s) in this study is within the upper and lower limits of noninferiority (Δ), the result demonstrates the noninferiority (equivalence) between the nonstylet and stylet groups.

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