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REPORTS OF ORIGINAL INVESTIGATIONS

Channelled *versus* nonchannelled Macintosh videolaryngoscope blades in patients with a cervical collar: a randomized controlled noninferiority trial

Lames de vidéolaryngoscopes Macintosh avec ou sans canal chez les patient·es muni·es d'un collier cervical : une étude randomisée contrôlée de non-infériorité

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Abstract

Purpose *Channelled blades have the advantage of avoiding stylet use and potential airway injury during videolaryngoscopic intubation. Nevertheless, the effectiveness of channelled Macintosh-type blades has not yet been fully established. We sought to assess the utility of channelled Macintosh-type blades for videolaryngoscopic intubation under cervical spine immobilization.*

Methods *We conducted a randomized controlled noninferiority trial in neurosurgical patients with a difficult airway simulated by a cervical collar. Videolaryngoscopic intubation with a reinforced tracheal tube was performed using a channelled Macintosh-type blade without a stylet (channelled group, n = 130) or a nonchannelled Macintosh-type blade with a stylet (nonchannelled group, n = 131). The primary outcome was intubation success rate. Secondary outcomes included time to intubation and incidence or severity of intubation-related complications (subglottic, lingual, and dental injuries; bleeding; sore throat; and hoarseness).*

Results *The initial intubation success rate was 98% and 99% in the channelled and nonchannelled groups, respectively, showing the noninferiority of the channelled group (difference in proportions −0.8%; 95% confidence interval [CI], −4.8% to 2.9%; predefined noninferiority margin, −5%; P = 0.62). Fewer participants in the channelled group had subglottic injuries than in the nonchannelled group (32% [32/100] vs 57% [54/95]; difference in proportions, −25%; 95% CI, −39% to −11%; P < 0.001). There were no significant differences between the two groups in the overall intubation success rate, time to intubation, and incidence or severity of other intubation-related complications.*

Conclusions *For videolaryngoscopic intubation in patients with a cervical collar, channelled Macintosh-type blades are an alternative to nonchannelled Macintosh-type blades, with a noninferior initial intubation success rate and a lower incidence of subglottic injury.*

Study registration *CRIS.nih.go.kr (KCT0005186); first submitted 29 June 2020.*

Résumé

Objectif *Les lames avec canal ont l'avantage de ne pas nécessiter l'utilisation d'un stylet et d'ainsi éviter les lésions potentielles des voies aériennes lors de l'intubation*

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vidéolaryngoscopique. Néanmoins, l'efficacité des lames avec canal de type Macintosh n'a pas encore été pleinement établie. Nous avons cherché à évaluer l'utilité des lames avec canal de type Macintosh pour l'intubation vidéolaryngoscopique lorsque le rachis cervical était immobilisé.

Méthode *Nous avons mené une étude randomisée contrôlée de non-infériorité chez des patient·es de neurochirurgie présentant des voies aériennes difficiles simulées par le port d'un collier cervical. L'intubation vidéolaryngoscopique avec une sonde trachéale renforcée a été réalisée à l'aide d'une lame Macintosh avec canal sans stylet (groupe avec canal, n = 130) ou d'une lame Macintosh sans canal avec stylet (groupe sans canal, n = 131). Le critère d'évaluation principal était le taux de réussite de l'intubation. Les critères d'évaluation secondaires comprenaient le temps d'intubation et l'incidence ou la gravité des complications liées à l'intubation (lésions sous-glottiques, linguales et dentaires, saignements, maux de gorge et enrouement).*

Résultats *Le taux de réussite initial de l'intubation était de 98 % et 99 % dans les groupes avec et sans canal, respectivement, montrant la non-infériorité du groupe lame avec canal (différence de proportions −0,8 %; intervalle de confiance [IC] à 95 %, −4,8 % à 2,9 %; marge de non-infériorité prédéfinie, −5 %; P = 0,62). Les lésions sous-glottiques ont été moins nombreuses dans le groupe avec canal que dans le groupe sans canal (32 % [32/100] vs 57 % [54/95]; différence de proportions, −25 %; IC 95 %, −39 % à −11 %; P < 0,001). Il n'y avait pas de différences significatives entre les deux groupes en matière de taux global de réussite de l'intubation, de temps d'intubation et d'incidence ou de gravité des autres complications liées à l'intubation.*

Conclusion *Pour l'intubation vidéolaryngoscopique des patient·es portant un collier cervical, les lames avec canal de type Macintosh constituent une alternative aux lames sans canal de type Macintosh, avec un taux de réussite d'intubation initial non inférieur et une incidence plus faible de lésions sous-glottiques.*

Enregistrement de l'étude *CRIS.nih.go.kr (KCT0005186); première soumission le 29 juin 2020.*

Keywords channelled blade · cervical collar · laryngoscope · Macintosh blade · nonchannelled blade · videolarnygoscope

Videolaryngoscopes are widely used as the preferred tool for difficult airway management.[1] Various types of videolaryngoscopes have been marketed with regard to the shape of the blade, the location of the camera and screen, and the presence of a guiding channel for the tracheal tube in the blade.[2] Among these properties, the guiding channel is designed to minimize manipulation of the tracheal tube in the upper airway without the need for a stylet, thereby avoiding stylet-related airway complications such as sore throat, subglottic injury, and tracheal and palatal perforations.[3–7]

In numerous studies comparing channelled and nonchannelled blades under various circumstances, the pure effect of guiding channels on videolaryngoscopic intubation is difficult to assess because other videolaryngoscopic properties, including blade shape, were diverse.[2,8–15] Although some studies have compared videolaryngoscopic blades of the same shape except for the guiding channel to exclude bias from other videolaryngoscopic properties, these studies only considered hyperangulated blades and showed inconsistent results.[8,10,11,13–15] In addition, compared with hyperangulated blades, Macintosh-type blades are known to have comparable intubation performance, with the advantage of shorter time to successful videolaryngoscopic intubation.[16] Therefore, a comparative study was warranted to evaluate the usefulness of guiding channels in Macintosh-type blades for videolaryngoscopic intubation, especially in patients with a difficult airway.

We hypothesized that the use of a channelled Macintosh-type blade without a stylet would be noninferior to the use of a nonchannelled Macintosh-type blade with a stylet in terms of the initial intubation success rate for videolaryngoscopic intubation in patients with a difficult airway simulated by a cervical collar. The overall aim of the present study was to compare intubation performance including initial intubation success rate (primary outcome measure) and intubation-related airway complications such as subglottic injury between channelled and nonchannelled Macintosh-type blades for videolaryngoscopic intubation in such patients.

Methods

Ethics

The Institutional Review Board of Seoul National University Hospital approved this single-centre, parallel-armed, randomized, and controlled noninferiority trial (number, 2005-188-1127; date of approval, 29 June 2020; chairperson, Ock Joo Kim; address, Seoul, Republic of Korea). The present study was registered prior to patient enrolment at the Clinical Research Information Service (KCT0005186; principal investigator, Hyongmin Oh; date of registration, 1 July 2020). On the day before surgery,

all participants provided written informed consent prior to enrolment. This study was conducted in accordance with Good Clinical Practice guidelines and the rules in the Declaration of Helsinki. The paper was written in compliance with the applicable Consolidated Standards of Reporting Trials guidelines.[17]

Participants

This study included patients aged 20–79 yr scheduled for elective neurosurgery under general anesthesia at Seoul National University Hospital. We excluded patients with a high risk of aspiration (gastroesophageal reflux disease and improper fasting duration), congenital or acquired lesions (tumour, polyp, trauma, abscess, inflammation, and foreign body) in the upper airway, history of surgery or intervention in the upper airway, coagulation disorders, and American Society of Anesthesiologists (ASA) Physical Status $\geq$ IV.

Randomization and blinding

An anesthesiologist who was not involved in this study generated a random allocation sequence. Using randomization software (Random Allocation Software version 1.0.0, Isfahan University of Medical Sciences, Isfahan, Iran), the anesthesiologist performed block randomization with a block size of 4. The anesthesiologist kept the random allocation sequence in an opaque envelope and released it before anesthetic induction. Based on this random allocation sequence, the anesthesiologist randomly assigned the enrolled patients to the channelled (use of a channelled Macintosh-type blade without a stylet) or nonchannelled (use of a nonchannelled Macintosh-type blade with a stylet) group in a 1:1 ratio. Patients and investigators who assessed intubation-related airway complications were blinded to the group assignment.

Protocol

Except for the intubation technique and devices, all anesthetic procedures were performed identically using a single protocol for both groups. Patients entered the operating room without premedication and were monitored using noninvasive blood pressure measurement, pulse oximetry, 3-lead electrocardiography, Bispectral Index™ (BIS™; Covidien/Medtronic; Dublin, Ireland) monitoring, and peripheral nerve stimulation. In the sitting position, modified Mallampati class; retrognathia; and interincisal, sternomental, and thyromental distances were measured. After changing to the supine position, the patient's head was placed on cotton towels with a total height of approximately 4 cm, and thyromental height was measured. Before preoxygenation, a semirigid cervical collar (Philadelphia® Tracheotomy Collar, Össur, Reykjavik, Iceland) was used to simulate a difficult airway. After confirming that the fraction of expired oxygen was $>$ 85% during preoxygenation, total intravenous anesthesia was induced using target-controlled infusion of propofol and remifentanil (effect site concentration, 4 $\mu g \cdot mL^{-1}$ for propofol and 4 $ng \cdot mL^{-1}$ for remifentanil). When loss of consciousness was confirmed, 0.6–0.8 $mg \cdot kg^{-1}$ rocuronium was administered to facilitate tracheal intubation. During bag-mask ventilation, the degree of its difficulty and use of oropharyngeal airways were noted.

For tracheal intubation, a videolaryngoscope (AceScope™, Ace Medical, Seoul, Republic of Korea) and a curved reinforced tracheal tube (Covidien™ Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced Murphy Eye, Medtronic, Dublin, Ireland; internal diameter, 7.0 mm for females and 7.5 mm for males), which was selected to avoid kinking of tracheal tube in the nonneutral head position during neurosurgery, were used. In the channelled and nonchannelled groups, channelled and nonchannelled Macintosh-type blades (AceBlade™, Ace Medical, Seoul, Republic of Korea; size MAC3 for females and MAC4 for males) were used, respectively (Fig. 1). Before intubation attempts, the tracheal tube was loaded into the guiding channel and mounted on a malleable aluminum stylet coated with polyvinyl chloride in the channelled and nonchannelled groups, respectively. The stylet was inserted into the tracheal tube so that its tip did not protrude beyond the tip of the tracheal tube and was angulated approximately 60° at the proximal margin of the endotracheal cuff.

After confirming that the train-of-four count was 0, one of the five attending anesthesiologists who had performed more than 100 successful videolaryngoscopic intubations performed orotracheal intubation. Mean arterial pressure, heart rate, peripheral oxygen saturation, and BIS were recorded immediately before intubation attempts. Tracheal intubation was initially attempted without assistance from other devices or maneuvers. Intubation-related time intervals began to be measured when inserting a videolaryngoscopic blade into the mouth. The tip of the videolaryngoscopic blade was placed on the vallecula to expose the glottis. If necessary, external laryngeal manipulation and direct epiglottis elevation with the tip of the videolaryngoscopic blade were applied sequentially, and the frequency of these additional maneuvers was noted. When obtaining the optimal glottic view, time to glottis visualization was recorded, and the degree of laryngeal visualization was evaluated by the percentage of glottic opening score and videolaryngoscopic Cormack–Lehane

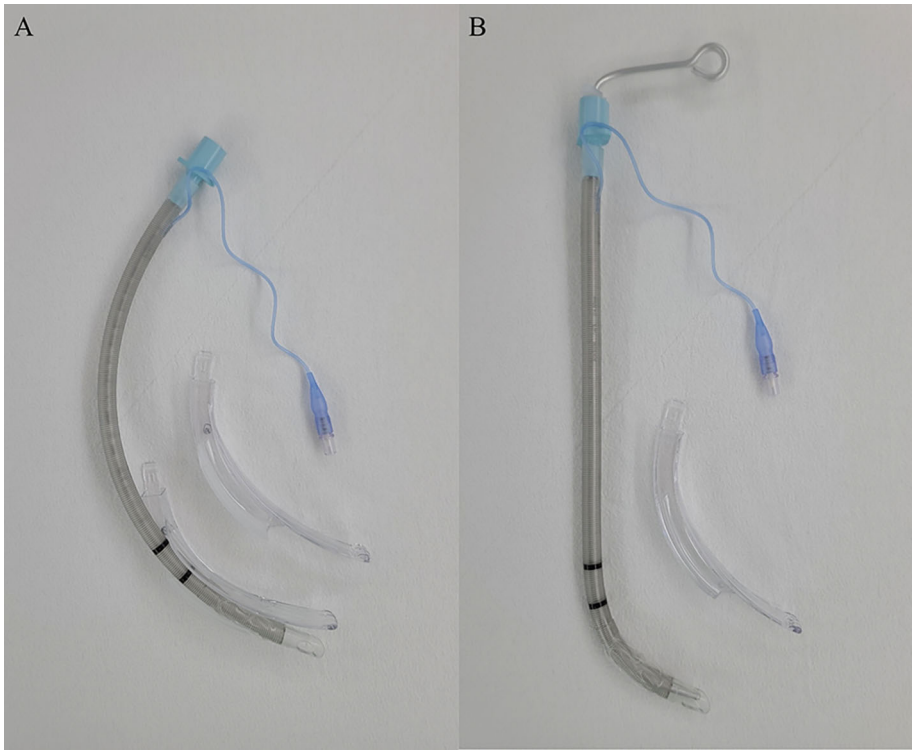

Fig. 1 Intubation devices used for videolaryngoscopic intubation. A channelled Macintosh-type blade with a preloaded tracheal tube was used in the channelled group (A), whereas a nonchannelled Macintosh-type blade with a styletted tracheal tube was used in the nonchannelled group (B).

grade. The tracheal tube was inserted into the trachea through the guiding channel in the channelled group and was advanced into the trachea after meticulously removing the stylet when the tip of the tracheal tube was placed on the glottis in the nonchannelled group. When the tracheal tube was placed at the optimal depth, time to tube placement was recorded. Intubation success was confirmed by waveform capnography, and time to capnogram detection was recorded at that time. Each intubation attempt was considered failed if tracheal intubation was not successful within two minutes or if the peripheral oxygen saturation (SpO_2) fell below 90%. Before the subsequent attempt, bag-mask ventilation was performed for one minute to maintain the SpO_2 at 100%. This study permitted a maximum of three consecutive attempts before recording an overall intubation failure. Mean arterial pressure, heart rate, SpO_2, and BIS were recorded once more after one minute after intubation success.

At the end of surgery, another attending anesthesiologist who was blinded to the group assignment assessed subglottic injury using a flexible fibrescope during tracheal extubation. To avoid patient reaction to airway stimulation, fibrescopic examination for subglottic injury was performed with sufficiently high effect site concentration of propofol and remifentanil and without reversal of neuromuscular blockade. After completing fibrescopic examination, mask-bag ventilation was conducted until spontaneous respiration was restored. Lingual and dental injuries and blood in the oral cavity and tracheal tube were also assessed. Hoarseness and sore throat were evaluated one hour and 24 hr after surgery. The severity of sore throat was rated using a numeric rating scale (0 for no pain and 10 for worst imaginable pain).

Demographic (sex, age, and body mass index), anesthetic (ASA Physical Status and duration), and surgical (site) variables were collected from electronic medical records.

Outcomes

The primary outcome measure was the initial intubation success rate (intubation success within two minutes without $SpO_2 < 90\%$ on the first attempt). Secondary outcome measures included other intubation performance (overall intubation success rate, intubation-related time intervals [time to glottis visualization, tube placement, and capnogram detection], degree of laryngeal visualization [percentage of glottic opening score and videolaryngoscopic Cormack–Lehane grade], frequency of additional maneuvers [external laryngeal manipulation and direct epiglottis elevation]) and intubation-related

airway complications (incidence and severity of subglottic injury and sore throat and incidence of lingual and dental injuries, bleeding [blood in the oral cavity and tracheal tube], and hoarseness). Blood pressure, heart rate, SpO_2, and BIS after intubation were also investigated.

Time to glottis visualization, tube placement, and capnogram detection were defined as time interval from inserting a videolaryngoscopic blade into the mouth to obtaining the optimal glottis view, placing tracheal tube at the optimal depth, and confirming intubation success by waveform capnography, respectively. The severity of subglottic injury was classified into three grades (grade 1 for mucosal hyperaemia with edema or slight submucosal hematoma, grade 2 for moderate submucosal hematoma, and grade 3 for mucosal laceration or bleeding).[5]

Sample size calculation

Since the initial intubation success rate using a videolaryngoscope with a nonchannelled Macintosh-type blade and stylet was 98% (117/120) in a previous study conducted in patients with a difficult airway simulated by a cervical collar, this study assumed that the initial intubation success rate using a videolaryngoscope with a channelled Macintosh-type bade and no stylet would be similar.[2] Also, as the initial intubation success rate using three widely used videolaryngoscopes with a nonchannelled blade and stylet was 95% (114/120), 85% (102/120), and 98% (117/120), respectively, in the same study, this study considered their average of 93% (333/360) clinically acceptable.[2] The minimum number of patients required was calculated to be 124 per group with a noninferiority margin of −5% (93%–98%), a one-sided α of 0.025, and a β of 0.2. Considering a dropout rate of 6%, this study required 264 patients.

Statistical analysis

All statistical analyses were performed primarily with the intention-to-treat method and secondarily with the per-protocol method using statistical software (IBM SPSS Statistics for Windows version 26, IBM Corp., Armonk, NY, USA). The normality of continuous variables was determined using the Shapiro–Wilk test. Categorical variables are presented as number (proportion), and continuous variables with normal and skewed distributions are presented as mean (standard deviation) and median [interquartile range (IQR)], respectively. Categorical variables were compared using the Chi square test and Fisher's exact test when $< 20\%$ and $\geq 20\%$ of cells,

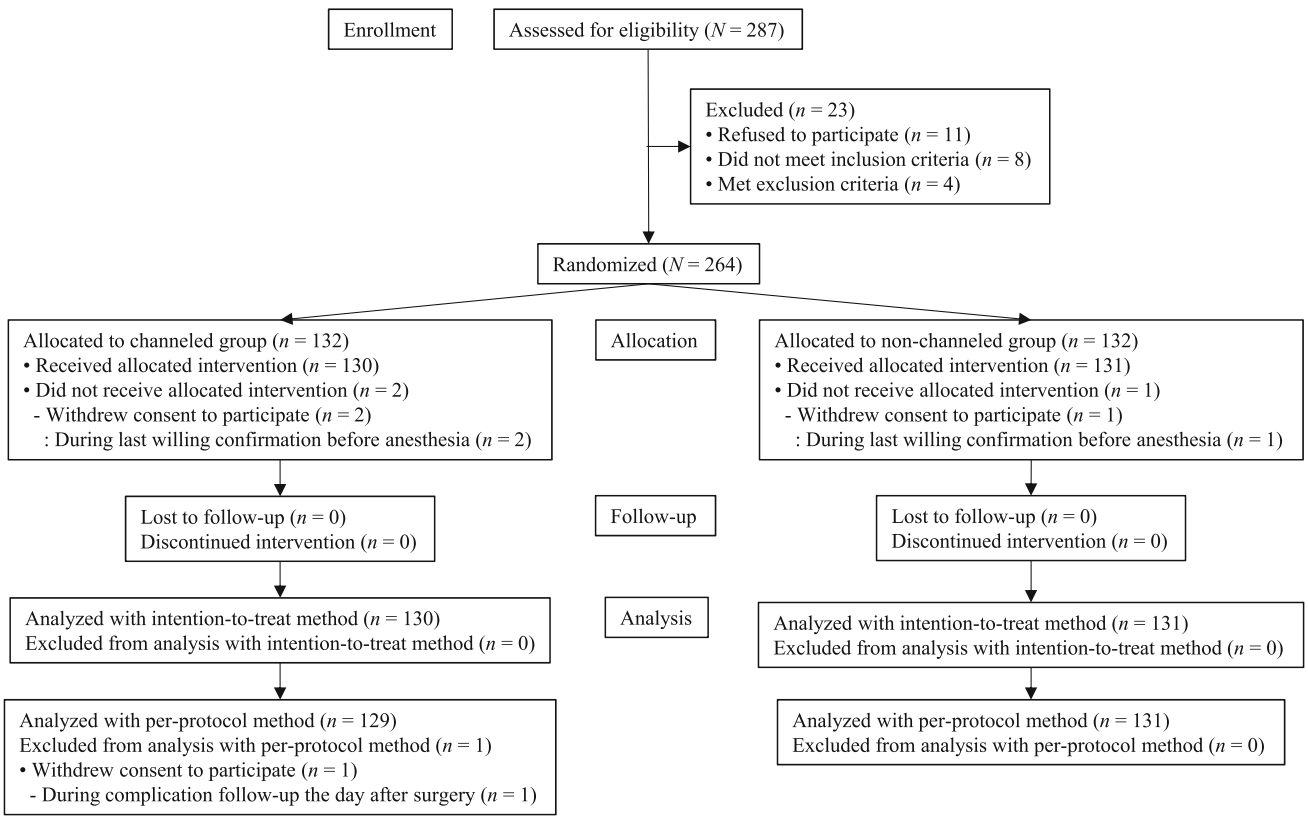

Fig. 2 Consolidated Standards of Reporting Trials flow diagram

Table 1 Comparisons of demographic, anesthetic, surgical, airway-related, and ventilation-related variables between the channelled and nonchannelled groups with the intention-to-treat method

	Channelled group $N = 130$	Nonchannelled group $N = 131$	Standardized difference
Demographics			
Age (yr)	63 [53–69]	62 [48–71]	0.03
Sex; male	40/130 (31%)	58/131 (44%)	−0.27
BMI ($kg \cdot m^{-2}$)	24.5 [21.8–26.8]	24.9 [23.1–27.5]	−0.22
Anesthesia			
ASA Physical Status, *n*/total *N* (%)			0.14
I	47/130 (36%)	44/131 (34%)	
II	71/130 (55%)	67/131 (51%)	
III	12/130 (9%)	20/131 (15%)	
Duration (min)	220 [170–282]	205 [150–265]	0.20
Surgery			
Site, *n*/total *N* (%)			0.09
Brain	34/130 (26%)	29/131 (22%)	
Spine	96/130 (74%)	102/131 (78%)	
Airway			
Modified Mallampati class, *n*/total *N* (%)			0.08
1	56/130 (43%)	48/131 (37%)	
2	48/130 (37%)	56/131 (43%)	
3	23/130 (18%)	25/131 (19%)	
4	3/130 (2%)	2/131 (2%)	
Retrognathia	4/130 (3%)	5/131 (4%)	−0.06
Interincisal distance (cm)	4.3 [4.0–5.0]	4.5 [4.0–5.0]	−0.09
Sternomental distance (cm)	16.0 [14.0–17.5]	16.0 [15.0–17.0]	−0.05
Thyromental distance (cm)	8.0 [7.5–9.0]	8.0 [7.5–9.0]	−0.14
Thyromental height (cm)	5.0 [4.5–6.0]	5.0 [4.5–6.0]	0.05
Bag-mask ventilation, *n*/total *N* (%)			
Difficulty			0.03
Easy	119/130 (92%)	118/131 (90%)	
Moderate	9/130 (7%)	12/131 (9%)	
Difficult	2/130 (2%)	1/131 (1%)	
Use of oropharyngeal airway	3/130 (2%)	0/131 (0%)	0.19

Values are presented as *n*/total *N* (%) or median [interquartile range]

ASA = American Society of Anesthesiologists; BMI = body mass index

respectively, had expected counts of < 5. Continuous variables with normal and skewed distributions were compared using Student's *t* test and the Mann–Whitney *U* test, respectively. For demographic, anesthetic, surgical, airway-related, and ventilation-related variables, we calculated standardized differences to show how unbalanced variables were between the channelled and nonchannelled groups and its absolute value of > 0.1 indicated imbalance. Statistical significance was set at a *P* value of < 0.05. We conducted a noninferiority analysis to determine whether the channelled group was noninferior to the nonchannelled group in terms of the initial intubation success rate. For this, we calculated a two-sided 95% confidence interval (CI) for the difference in the initial intubation success rate between the two groups (channelled group minus nonchannelled group) based on the used test. The noninferiority of the channelled group to the nonchannelled group was accepted when the lower margin of the two-sided 95% CI, equivalent to that of the one-sided 97.5% CI, was above the predefined noninferiority margin of −5.0%.

Table 2 Comparisons of intubation performance between the channelled and nonchannelled groups with the intention-to-treat method

	Channelled group $N = 130$	Nonchannelled group $N = 131$	Absolute effect size[a] (95% CI)	Odds ratio (95% CI)	P value
Intubation success rate					
Initial	128/130 (98%)	130/131 (99%)	−0.8% (−4.8 to 2.9)	0.49 (0.04 to 5.5)	0.62[b]
Second-attempt	2/130 (2%)	1/131 (1%)	0.8% (−2.9 to 4.8)	2.03 (0.18 to 22.7)	0.62[b]
Overall	130/130 (100%)	131/131 (100%)	NA	NA	NA
Intubation-related time intervals					
Time to glottis visualization (sec)	18 [13–28]	14 [10–22]	4 (1 to 6)	NA	0.003[c]
Time to tube placement (sec)	29 [22–44]	29 [20–38]	2 (−1 to 5)	NA	0.25[c]
Time to capnogram detection (sec)	53 [44–70]	52 [40–62]	3 (−1 to 7)	NA	0.13[c]
Laryngeal visualization					
Percentage of glottic opening score	60% [20–90]	50% [20–90]	0% (0 to 10)	NA	0.36[c]
Videolaryngoscopic Cormack–Lehane grade					0.64[d]
1	44/130 (34%)	40/131 (31%)	3% (−8 to 15)	1.16 (0.69 to 1.96)	0.57[d]
2	68/130 (52%)	76/131 (58%)	−6% (−18 to 6)	0.79 (0.49 to 1.29)	0.35[d]
3	18/130 (14%)	15/131 (12%)	2% (−6 to 11)	1.24 (0.60 to 2.59)	0.56[d]
Additional maneuver					
External laryngeal manipulation	10/130 (8%)	5/131 (4%)	4% (−2 to 10)	2.10 (0.70 to 6.3)	0.18[d]
Direct epiglottis elevation	18/130 (14%)	10/131 (8%)	6% (−1 to 14)	1.95 (0.86 to 4.39)	0.11[d]

Values are presented as number (proportion) or median [interquartile range]

[a]Difference in proportions or medians

[b]Fisher's exact test

[c]Mann–Whitney U test

[d]Pearson's Chi square test

CI = confidence interval; NA = not applicable

Results

Between July 2020 and May 2022, this study randomized 264 patients (Fig. 2). Of these, three patients dropped out just after randomization as they withdrew consent to participate, and 130 and 131 patients of the channelled and nonchannelled groups, respectively, were included in the intention-to-treat analysis. Fibrescopic examination for subglottic injury was performed in 100 and 95 patients of the channelled and nonchannelled groups, respectively, because of the availability of flexible fibrescopes. Some of demographic, anesthetic, airway-related, and ventilation-related variables showed imbalance between the channelled and nonchannelled groups (Table 1).

The initial intubation success rates were 98% and 99% in the channelled and nonchannelled groups, respectively, showing the noninferiority of the channelled group (difference in proportions, −0.8%; 95% CI, −4.8 to 2.9; predefined noninferiority margin, −5%; $P = 0.62$; Table 2). The overall intubation success rate was 100% in both groups. Intubation-related time intervals, degree of laryngeal visualization, and frequency of additional maneuvers were not significantly different between the two groups, except for the longer median [IQR] time to glottis visualization in the channelled group (18 [13–28] sec *vs* 14 [10–22] sec, difference in medians, 4 sec; 95% CI, 1 to 6; $P = 0.003$).

Participants in the channelled group had fewer subglottic injuries (32 [32%] *vs* 54 [57%]; difference in proportions, −25%; 95% CI, −39 to −11; $P < 0.001$), especially grade 1 (31 [31%] *vs* 46 [48%]; difference in proportions, −17%; 95% CI, −31 to −4; $P = 0.01$) and grade 2 (1 [1%] *vs* 7 [7%]; difference in proportions, −6%; 95% CI, −14 to 0; $P = 0.03$; Table 3). The incidence or severity of dental injury, bleeding, hoarseness, and sore throat was not significantly different between the two groups. There were no significant differences between the two groups in blood pressure, heart rate, SpO_2, or BIS values before and after intubation (Table 4).

As one patient in the channelled group dropped out after intervention as the patient withdrew consent to participate, the per-protocol analysis include 129 and 131 patients of

Table 3 Comparisons of intubation-related airway complications in the channelled and nonchannelled groups with the intention-to-treat method

	Channelled group $N = 130$	Nonchannelled group $N = 131$	Absolute effect size[a] (95% CI)	Odds ratio (95% CI)	P value
Injury					
Subglottic[b]	32/130 (32%)	54/131 (57%)	−25% (−39 to −11)	0.36 (0.20 to 0.64)	< 0.001[c]
Grade					0.002[c]
1	31/130 (31%)	46/131 (48%)	−17% (−31 to −4)	0.48 (0.27 to 0.86)	0.01[c]
2	1/130 (1%)	7/131 (7%)	−6% (−14 to 0)	0.13 (0.02 to 1.05)	0.03[d]
3	0/130 (0%)	1/131 (1%)	−1% (−6 to 3)	NA	0.49[d]
Lingual	4/130 (3%)	5/131 (4%)	−0.7% (−6.1 to 4.5)	0.80 (0.21 to 3.05)	1.00[d]
Dental	0/130 (0%)	0/131 (0%)	NA	NA	NA
Bleeding					
Blood in oral cavity	28/130 (22%)	27/131 (21%)	1% (−9 to 11)	1.06 (0.58 to 1.92)	0.85[c]
Blood in tracheal tube	13/130 (10%)	14/131 (11%)	−1% (−8 to 7)	0.93 (0.42 to 2.06)	0.86[c]
Hoarseness					
1 hour after surgery	36/130 (28%)	31/131 (24%)	4% (−7 to 15)	1.24 (0.71 to 2.16)	0.46[c]
24 hr after surgery[e]	25/130 (19%)	24/131 (18%)	1% (−9 to 11)	1.07 (0.58 to 2.00)	0.83[c]
Sore throat					
1 hour after surgery	56/130 (43%)	43/131 (33%)	10% (−2 to 22)	1.55 (0.94 to 2.56)	0.09[c]
Severity[f]	0 [0–3]	0 [0–3]	0 (0 to 0)	NA	0.11[f]
24 hr after surgery[e]	43/130 (33%)	49/131 (30%)	4% (−8 to 15)	1.18 (0.70 to 1.99)	0.54[c]
Severity[e,f]	0 [0–2]	0 [0–2]	0 (0 to 0)	NA	0.64[f]

Values are presented as *n*/total *N* (%) or median [interquartile range]

[a]Difference in proportions or medians.

[b]100 patients in the channelled group and 95 patients in the nonchannelled group due to the availability of flexible fibrescopes

[c]Pearson's Chi square test

[d]Fisher's exact test

[e]129 patients in the channelled group because of missing data

[f]Numerical rating scale (0 for no pain and 10 for worst imaginable pain)

[g]Mann–Whitney *U* test

CI = confidence interval; NA = not applicable

the channelled and nonchannelled groups, respectively. There was no difference in statistical significance between the intention-to-treat and per-protocol analyses (Electronic Supplementary Material [ESM] eTables 1–4).

Discussion

This randomized controlled noninferiority trial compared the efficacy and safety of videolaryngoscopic intubation between channelled and nonchannelled Macintosh-type blades in patients with a difficult airway simulated by a cervical collar. In the present study, the channelled blade was noninferior to the nonchannelled blade in terms of the initial intubation success rate and showed fewer subglottic injuries. Other intubation performances and intubation-related airway complications were comparable between the two blades.

The initial intubation success rate is critical in clinical practice because initial intubation failure is associated with more complications, including oxygen desaturation, aspiration, and airway injury.[18] The present study provides new knowledge on the initial intubation success rate for videolaryngoscopic intubation using a channelled Macintosh-type blade, which was found to be 98% in patients with a cervical collar. In previous studies, the initial intubation success rate for videolaryngoscopic intubation using a channelled hyperangulated blade was reported to be 37–87% and 80–100% in patients with and without a cervical collar, respectively.[2,8,11–13,19,20] The relative low initial intubation success rates of Airtraq™ (Mercury Medical®, Clearwater, FL, USA; 85%) and King Vision® (Ambu Inc., Copenhagen, Denmark; 87%) in patients with a cervical collar may be a result of their blades having a more acute angle and shorter length distal to their curvature.[2,13] The shapes of their blades might

Table 4 Comparisons of blood pressure, heart rate, oxygen saturation, and Bispectral Index™ values between the channelled and nonchannelled groups with the intention-to-treat method

	Channelled group $N = 130$	Nonchannelled group $N = 131$	Median difference (95% CI)	*P* value
MAP (mm Hg)				
Before intubation	74 [67–82]	75 [67–86]	−2 (−5 to 2)	0.30[a]
After intubation	86 [73–98]	86 [76–99]	−2 (−7 to 2)	0.37[a]
Heart rate (min^{-1})				
Before intubation	61 [53–71]	62 [56–71]	−2 (−4 to 2)	0.33[a]
After intubation	72 [63–84]	75 [65–86]	−2 (−6 to 2)	0.38[a]
SpO_2 (%)				
Before intubation	100 [100–100]	100 [100–100]	0 (0 to 0)	0.57[a]
After intubation	100 [100–100]	100 [100–100]	0 (0 to 0)	1.00[a]
BIS™				
Before intubation	50 [41–60]	51 [42–60]	−1 (−4 to 2)	0.63[a]
After intubation	49 [40–60]	48 [39–59]	1 (−2 to 4)	0.49[a]

Values are presented as median [interquartile range]

[a]Mann–Whitney *U* test

BIS™ = Bispectral Index™ (Covidien/Medtronic; Dublin, Ireland); CI = confidence interval; MAP = mean arterial pressure; SpO_2 = peripheral oxygen saturation

require manipulation to advance the two videolaryngoscopes into the pharynx while laying them; however, such manipulation would be difficult because a cervical collar hinders mouth opening and cervical spine motion.[21,22] The much lower initial intubation success rate of A.P. Advance™ (Venner Medical, Singapore; 37%) in patients with a cervical collar was speculated to be due to its large screen, which was not relevant to airway anatomy in the corresponding study.[2,13] Nevertheless, similar to this study, the initial intubation success rate was not significantly different between channelled and nonchannelled hyperangulated blades of the same shape in all studies investigating videolaryngoscopic intubation in patients with or without a cervical collar.[8,11,13]

Successful videolaryngoscopic intubation frequently requires a stylet because videolaryngoscopic blades usually have a relatively acute angle compared with a Macintosh blade, and the three airway axes are often difficult to align in patients requiring videolaryngoscopic intubation. Nevertheless, the use of stylets has been shown to increase the incidence of subglottic injury after videolaryngoscopic intubation in patients with a modified Mallampati class ≥ 3 in a previous study (65% *vs* 42%), similar to this study (57% *vs* 32%).[7] Since stylets were removed before the tracheal tubes were advanced into the trachea in both studies, it is believed that the stylet itself did not cause the increased incidence of subglottic injury when using a stylet. Instead, this is assumed to be because the tracheal tube, which was preshaped to be angulated anteriorly, curved anteriorly, and hit the anterior tracheal wall during stylet removal.[5,23,24]

In the present study, compared with the nonchannelled blade, the channelled blade had a significantly longer time to glottis visualization, but comparable time to capnogram detection. In a previous study investigating videolaryngoscopic intubation in patients with a cervical collar, Airtraq showed similar results for intubation-related time intervals between its channelled and nonchannelled blades, and the channelled blade of KingVision had a comparable time to glottis visualization and significantly shorter time to capnogram detection compared with its nonchannelled blade.[13] These findings suggest that the channelled blade might facilitate insertion of the tracheal tube after obtaining the glottic view, although it might have a disadvantage in inserting the blade into the mouth because of its relatively bulky size and hindered mouth opening by a cervical collar.

The incidence of subglottic injury was significantly different between the channelled and nonchannelled blades, but the incidence or severity of clinical manifestations including bleeding, hoarseness, and sore throat was not. This discrepancy has also been observed in a previous study and can be explained in two ways.[7] First, severe (grade 3) and moderate (grade 2) subglottic injuries were present in only 0.4–1.9% and 3.1–8.7% of patients, respectively, in both studies. Therefore, the majority of subglottic injuries may have not been severe enough to induce noticeable clinical manifestations. Second, not only

subglottic injury but also glottic or supraglottic injury cause clinical manifestations.[25] Nevertheless, unfortunately, this study did not investigate other laryngeal injuries. Additional studies are needed to elucidate the association between subglottic injury and clinical outcomes and clarify its clinical significance.

This study has several limitations. First, because we did not blind the anesthesiologists who performed tracheal intubation to the group assignment, we cannot rule out the possibility of performance bias. Second, it may be difficult to apply the results of this study to different intubation circumstances (intubation by inexperienced anesthesiologists or nonanesthesiologists, intubation in patients without a cervical collar, and intubation under cervical spine immobilization with manual in-line stabilization). In particular, the results of this study may not be reproducible when using a different tracheal tube, videolaryngoscope, and blade than the one used in this study, especially a hyperangulated blade, which is commonly used for videolaryngoscopic intubation in patients with a difficult airway. In addition, since this study simulated a difficult airway applying a cervical collar, the results may not be generalized to patients with other type of difficult airways, such as airway deformity due to trauma, disease, and treatment and cervical spine instability, which were not present in the enrolled patients. Third, although no patients in this study had multiple intubation attempts or a Cormack–Lehane grade of > 2 in their previous anesthetic records, it would have been better to pre-emptively exclude patients with a previously documented difficult airway from this study for ethical and technical reasons. Finally, there were some missing cases in evaluating subglottic injury due to the availability of flexible fibrescopes. Therefore, caution is needed when interpreting the results for subglottic injury.

In conclusion, this study found that the channelled Macintosh-type blade had a noninferior initial intubation success rate and a lower incidence of subglottic injury compared with the nonchannelled Macintosh-type blade for videolaryngoscopic intubation in patients with a difficult airway simulated by a cervical collar. These findings suggest that the channelled Macintosh-type blade is an alternative to the nonchannelled Macintosh-type blade for videolaryngoscopic intubation in patients with a cervical collar and potentially in patients with a difficult airway such as restricted mouth opening and limited cervical spine motion.

Author contributions *Kyung Won Shin* conducted the study, acquired, analyzed, and interpreted data, and drafted the manuscript. *Sang Phil Lee* designed the study and drafted the manuscript. *Taeyup Kim* acquired data and drafted the manuscript. *Seungeun Choi* conducted the study and revised the manuscript. *Yoon Jung Kim* designed and conducted the study and revised the manuscript. *Hee-Pyoung Park* designed and conducted the study, interpreted data, and revised the manuscript. *Hyongmin Oh* designed and conducted the study, acquired, analyzed, and interpreted data, and revised the manuscript.

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