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The efficacy of various types of laryngoscope (Direct, Pentax Airway Scope, and GlideScope) for the endotracheal intubation in various cervical immobilization scenarios: A randomized crossover simulation study

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Key Words: Direct laryngoscopy, video laryngoscopy, tracheal intubation, cervical collar stabilization

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ABSTRACT

Objective To compare the efficacy of direct laryngoscopy (DL), Pentax Airway Scope (PAWS), and GlideScope video-laryngoscope (GVL) systems for endotracheal intubation (ETI) in various cervical immobilization scenarios: manual in-line stabilization (MILS), Philadelphia neck collar (PNC) (moderate limit of mouth opening), and Stifneck collar (SNC) (severe limit of mouth opening).

Design Randomized crossover simulation study.

Setting and Participants Thirty-five experienced physicians who had > 30 successful ETI experiences at a tertiary hospital in Seoul, Korea

Primary and secondary outcome measures Participants performed ETI using PAWS, GVL, and DL randomly in simulated MILS, PNC, and SNC scenarios in our simulation centre. The end points were successful ETI and the time to complete ETI. In addition, modified Cormack–Lehane (CL) classification and dental injuries were recorded.

Results In MILS, there were no significant difference in the rate of success of ETI between the three devices 33/35(94.3%) for DL vs. 32/35(91.4%) for GVL vs. 35/35(100.0%) for PAWS; p=0.230). PAWS achieved successful ETI more quickly (19.8 s) than DL (29.6 s) and GVL (35.4 s). For the PNC scenario, a higher rate of successful ETI was achieved with GVL 33/35(94.3%) than PAWS 29/35(82.9%) or DL 25/35(71.4%) (p = 0.040). For the SNC scenario, a higher rate of successful ETI was achieved with GVL 28/35(80.0%) than DL 14/35(40.0%) and PAWS 7/35(20.0%) (p < 0.001). For the PNC and SNC scenarios, GVL provided a relatively good view of the glottis, but a higher incidence of dental injuries occurred.

Conclusions Three devices are suitable for ETI in the MILS. DL is not suitable in both neck collar scenarios. PAWS is the best device for MILS immobilization, and is suitable for PNC

immobilization, but is not suitable for SNC immobilization. GVL is the best device for PNS and SNC immobilization, but may cause dental injuries more frequently.

Strengths and limitations of this study

- This is the first study to report the diverse efficacy of the three typed laryngoscopy for intubation of various cervical spine immobilization scenarios
- A simulation design cannot precisely reproduce the real endotracheal intubation situation
- Our study does not measure the degree of neck movement, and thus it cannot evaluate whether the procedures are safe or not.

INTRODUCTION

Seriously injured patients often require emergency endotracheal intubation (ETI) to maintain an airway or supply sufficient oxygen to avoid airway obstruction and serious hypoxia. In victims of major trauma or patients with severe injury, accompanying cervical spine injuries should also be considered.[1] Therefore, ETI should only be applied with cervical immobilization in seriously injured patients to prevent additional devastating neurologic outcome until any possibility of cervical spine injury is completely excluded.[2] However, there are obstacles to successful ETI in patients with cervical immobilization. Immobilization of the cervical spine puts a limitation on head extension and neck flexion, and so optimal alignment of the three airway axes and exposure of the vocal cords cannot be established easily.[3,4] ETI of patients with cervical immobilization with a conventional laryngoscope is considered difficult.[5,6]

Various airway management techniques to overcome the difficult ETI conditions in patients with cervical immobilization have been examined, such as supraglottic airway management, intubation using a lighted stylet, and video-laryngoscopes.[7] Video-laryngoscopes, including the Pentax Airway Scope system (PAWS; Pentax Corporation, Tokyo, Japan), GlideScope video laryngoscope (GVL; Saturn Biomedical System, Burnaby, BC, Canada), have been studied to determine the easiest ETI to use in patients with cervical immobilization.[8,9]

Considering the various properties of these devices, each may have different effectiveness in diverse neck immobilization scenarios using methods including wearing various types of neck collars or manual in-line stabilization (MILS). However, there is limited data regarding the appropriate selection of laryngoscope devices for each cervical immobilization scenario.

The aim of this study was to compare various types of laryngoscopes to determine whether any particular device is better able to manage the airway in a model of intubation with cervical immobilization in a simulated setting.

METHODS

This was a simulation study with a prospective randomized crossover setting. Our study protocol was reviewed by our Institutional Review Board (KUH005126). After their approval of the research, we recruited participants from among the experienced physicians in our hospital. Only Physicians with experience of >30 successful ETIs in a clinical setting were enrolled.

After agreeing to participate in this study, all participants attended airway management and intubation training at the simulation centre of our institution before the trials. First, we gave verbal instruction for intubation using direct laryngoscopy with a Macintosh laryngoscope (DL), PAWS, and GVL. An expert demonstrated intubation with each device. Participants were allowed to practice intubation on a SimMan (Laerdal, Stavanger, Norway) and RespiTrainer Advance with ETView (IngMar Medical, Pittsburgh, PA, USA) patient simulator airway-trainer manikins until they were successful. Successful performance was defined as three consecutive successful intubations within 120 s for each device in both airway-trainer manikins.

After one week, participants were recalled to our simulation centre. We explained the objective of the study, and participants provided their informed written consent to participate. Cervical immobilization was achieved by applying MILS or either of the two different types of collars to an airway trainer manikin (Laerdal Airway Management Trainer; Laerdal). MILS was applied by an experienced emergency physician grasping both sides of the

manikin's head and neck, thus preventing movement of the head and neck. Cervical collar immobilization was achieved using either of two different semi-rigid cervical collars; the Stifneck Collar (Laerdal) and the Philadelphia neck collar (Philadelphia Cervical Collar Co., Thorofare, NJ, USA). The participants then performed intubation of the cervically immobilized manikins with each DL, PAWS, and GVL laryngoscope. A cuffed 7.5 mm diameter endotracheal tube (Mallinckrodt Medical, Athlone, Ireland) was used. To minimize any learning effect, laryngoscopes and immobilization techniques were used in random order using a sealed envelope selection method (Figure 1). After first contact with each device, all procedures ended when the participants declared the completion of intubation within the maximum 120 s time limit. Successful intubation was verified by visible chest rise of the manikin during bag-valve mask ventilation after intubation. Failed intubation was tracheal intubation that required more than 120 s or oesophageal intubation. After each intubation attempt, up to 10 min was allowed for operator rest and recovery.

The endpoints were successful ETI and the time to complete ETI defined as the time taken from touching each device to the participant declaring completed intubation after the endotracheal tube stylet had been removed. Degree of laryngeal visualization was recorded according to a modified Cormack–Lehane (CL) classification. We included cases in which operator could not view the oral cavity and glottis at all into grade 4. We also recorded dental injury ("yes" or "no") using an audible "ddal-kak" sound made when any device contacted an upper incisor with pressure. All procedures were recorded using a camcorder (Samsung, Seoul, Korea), and all the time variables were precisely analysed by reviewing the recorded data. Data for overall intubation success, presence of dental injury, and the grades of glottic visualization were analysed using a chi-square or Mann–Whitney rank-sum test. Values of $p < 0.05$ were considered significant. We used Kaplan–Meier analysis to compare the

intubation success time between the laryngoscopes to overcome censored attempts (failed viewing of the vocal cords or failed intubation). Data were analysed using IBM SPSS Statistics for Windows software (version 21.0; IBM, Seoul, Korea).

RESULTS

Thirty-five experienced physicians participated in the study. Their mean (standard deviation) age was 31.1 (2.7) years old, and 22 (62.8%) were men. Of the 35 physicians, 14 were emergency physicians, eight worked in the intensive care, and 13 worked in general ward rooms. Twenty-four participants had experienced 30–40 successful ETI, eight had experienced 40–50 successful ETI, and three physicians had experienced over 50 successful ETIs.

ETI performance on the manikin with simulated neck injury under the MILS scenario

There were no significant difference in the rate of successful ETI between the three devices in the MILS scenario [33 (94.3%) for DL vs. 32 (91.4%) for GVL vs. 35 (100.0%) for PAWS; p = 0.230] (Table 1). PAWS showed the fastest mean time to successful ETI (19.8 s), better view of the glottis, and lowest incidence of dental injury compared with either DL or GVL (Table 1 and Figures 2 and 3). Otherwise, the longest time needed to complete ETI and high incidence of dental injury was with the GVL (Table 1).

ETI performance on the manikin with simulated neck injury under the Philadelphia neck collar scenario

A higher rate of successful ETI was achieved with GVL 33 (94.3%) than PAWS 29 (82.9%) or DL 25 (71.4%) (p = 0.040). GVL showed the fastest mean time to successful ETI

compared with other devices. However, there was no significant difference between the three devices. In GVL, a better view of the glottis was reported (Figure 3), but more dental injuries were observed than with other devices (Table 1). Otherwise PAWS achieved a moderate rate of successful ETI, but a poor view of the glottis (6 of grade 4) with the lowest incidence of dental injury.

ETI performance on the manikin with simulated neck injury under the Stifneck collar scenario

Compared with GVL 28 (80.0%), DL 14 (40.0%) and PAWS 7 (20.0%) achieved significantly lower rates of successful ETI ($p < 0.001$). Mean time to successful ETI for DL and PAWS were longer than with GVL. Because of the tight neck collar, the view of the glottis was very poor in most cases of DL and PAWS (21 and 28 cases respectively). Otherwise GVL showed a relatively good view of the glottis (most cases were grade 2b), but a higher incidence of dental injuries occurred (Table 1).

Table 1 Data for endotracheal intubation and related complications in three scenarios

		Direct laryngoscope (n = 35)	GlideScope (n = 35)	PAWS (n = 35)	p- value
Manual in-line stabilization	Successful ETI, n (%)	33 (94.3)	32 (91.4)	35 (100.0%)	0.230
	Estimated time to successful ETI (s), mean (SD)	29.6 (4.1)	35.4 (4.7)	19.8 (2.1)	0.001
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Dental injury, n (%)	12 (34.3)	22 (62.9)	6 (17.1)	<0.001
Neck immobilization with a Philadelphia neck collar	Successful ETI, n (%)	25 (71.4)	33 (94.3)	29 (82.9)	0.040
	Estimated time to successful ETI (s), mean (SD)	50.7 (7.6)	34.6 (4.5)	40.0 (6.4)	0.309
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Dental injury, n (%)	9 (25.7)	18 (51.4)	6 (17.1)	0.006
Neck immobilization with a Stifneck collar	Successful ETI, n (%)	14 (40.0)	28 (80.0)	7 (20.0)	<0.001
	Estimated time to successful ETI (s), mean (SD)	99.3 (7.0)	51.8 (6.7)	83.5 (6.5)	<0.001
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Dental injury, n (%)	11 (31.4)	26 (74.3)	4 (11.4)	<0.001

DISCUSSION

Neck immobilization is an inevitable obstacle to the success of ETI in trauma patients.[3,4] Establishing optimal methods or devices for successful ETI is a key requirement in the airway management of trauma patients with neck injuries.[10] The most suitable airway management for each specific situation should be used; however, there are few data regarding this issue. We performed a randomized crossover study to compare the success of ETI in patients with cervical stabilization and related data from experienced physicians performing DL, GVL, and PAWS in various simulated neck immobilization settings. In the MILS scenario, experienced physicians showed a high rate of successful ETI with all laryngoscopes. PAWS had advantages over other laryngoscopes, including a better modified CL grade and faster time for ETI. In the Philadelphia neck collar immobilization scenario (moderate limit of mouth opening), the GVL showed the highest ETI success rate (94.3%), followed by PAWS (82.9%). Under the Stifneck collar cervical immobilization scenario (extreme limits of mouth opening), GVL achieved a higher ETI success rate (80.0%), but a higher incidence of dental injury was observed.

MILS is well known as a standard technique according to adult trauma life support guidelines for cervical immobilization while intubating trauma patients with suspected cervical spine injury.[2] MILS might impede glottic visualization by preventing head extension and neck flexion, which is necessary for optimal alignment of the three airway axes.[11,12] In this study, there was no difference in the ETI success rate between DL, GVL, and PAWS. However, less time was taken to achieve ETI with PAWS than with other laryngoscopes. PAWS has a display screen with a target symbol for accurate ETI location, and a side channel for guidance of the endotracheal tube. These guidance cues may contribute to shorten the time to intubation.[13]

A cervical neck collar is an essential device for immobilizing trauma patients with a cervical spine injury.[2] It maintains cervical immobilization to prevent any secondary injury to the cervix in these patients. The collar does not only interrupt the view of the glottis, but also makes it difficult to handle the airway device because of the reduced mouth opening. It may be more difficult to perform ETI in patients wearing a neck collar than is the case with MILS.[14] Our study demonstrated low ETI success rate and delay in time to complete ETI by DL in scenarios where a cervical collar was used for immobilization compared with stabilization with MILS. A previous study has showed that cervical collars significantly reduce mouth opening to varying degrees depending on the various types of neck collars.[15]

Our results are consistent with those of previous studies[16], and provide more detailed ETI performance data for the various devices. For the Philadelphia neck collar, which is semi-rigid and allows only a moderate limit of mouth opening, both types of video laryngoscopy have superiority over DL. The advantage of video laryngoscopy, which provides an indirect view of the glottic opening, is maximized where a Philadelphia cervical collar is used for immobilization. This suggests that video laryngoscopy is likely to be more suitable for ETI than DL when a Philadelphia cervical collar is used. There were varying results for the two video laryngoscopes using the Stifneck cervical collar: GVL has shown high success rates for ETI, but PAWS was not so successful. The major reason for this difference was that the inter-incisor distance is reduced more by a Stifneck collar than by a Philadelphia neck collar. The PAWS blade is too bulky to be inserted into the narrow opening of the mouth when using a Stifneck collar; however, the GVL blade has the advantage of being more slender.

Despite the high ETI success rate by GVL, intubation time was not shortened because of difficulties in handling the endotracheal tube. In addition, frequent dental injury was

reported in ETI by GVL regardless of the cervical immobilization technique. GVL consists of a blade with a lens and an external display monitor. While intubating patients with a GVL, clinicians seldom check the patient's oral cavity because they should watch the external display monitor to identify the glottic opening. Therefore, participants who were not skilled in GVL might have difficulty in handing the blade. A "ddal-kak" sound was regarded as dental injury in this study. The "ddal-kak" sound occurred even with minimal pressure on an upper incisor. The high sensitivity of the manikins used also contributed to the frequent incidence of dental injury.

It is never easy to balance safe cervical protection with effective ETI performance in patients with cervical injury under real-world conditions. The mainstay of our study is that there were diverse laryngoscopes that were the most suitable to use for ETI in each cervical immobilization scenario. Airway device selection might primarily depend on individual skill levels and preference, and the institutional availability of equipment. However, not all trauma patients needing emergency airway management can be managed in the same way. In pre-hospital or hospital settings, various neck immobilization scenarios may exist during ETI in trauma patients with serious neck injuries; some patients may wear one of the various types of neck collar or others may have no neck collar in situ. In addition, the number of rescuers, patient urgency level, and device availability may affect the ETI performance.

Our study demonstrated the strategy of advanced airway management in trauma patients with cervical injury. The strategy should not be tailored to physician abilities, but also to the neck immobilization status and the efficacy of each device. If a second rescuer is available, the operator can immediately intubate using the MILS technique in patients without a neck collar. ETI can also be conducted using the MILS technique after removal of the anterior portion of the neck collar in patients wearing a neck collar. Direct and video

laryngoscopies may be available when patients require ETI under MILS. In particular, PAWS is likely to be the better ETI option because of its faster time. If a second rescuer is not available, the operator should intubate with a neck collar in situ. In addition, the operator should perform the ETI without removing the neck collar when they feel removal may be harmful, even if another rescuer is available. Removing the neck collar may occasionally be time consuming, leading to hypoxia and secondary neurologic compromise. When patients require emergency ETI under cervical collar immobilization, DL may be not be the primary choice, but GVL or PAWS would be a good choice. However, there may be limited success with PAWS in some types of neck collar with seriously reduced mouth opening, such as the Stifneck collar. GVL seemed to be superior to other laryngoscopes when used with various types of neck collars; however, GVL could cause dental injuries because of the difficulty in handling the device within the reduced open mouth space and oral cavity.

Our study has several limitations. First, we could not fully blind the participants to the airway device or the immobilization technique being used. Second, study participants did not have equal experience of ETI between the three devices. Although we trained participants to achieve sufficient skills in both GVL and PAWS, these novel devices were less frequently used by the participants who were more experienced with a DL. Users with inherently more accumulated real-world experience of DL may relatively affect a more positive outcome than with novel video laryngoscopy. Third, this study was conducted with a simulation design using a manikin. A simulation study cannot realize the anatomical variance of humans and the possible conditions for trauma patients such as lens contamination by bleeding or secretions.

CONCLUSIONS

DL showed high success rate in the MILS scenario, but not in either of the neck collar scenarios. PAWS was the superior device in the MILS scenario and could be used in the Philadelphia neck collar immobilization scenario, but was not suitable in the Stifneck collar immobilization scenario. GVL is most suitable in both neck collar scenarios, but higher incidences of dental injuries were observed with GVL than with other devices.

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Competing interests

No author has any conflict of interest

Contributors

SOP established the main conception and designed this study. Each author took part in procedure of simulation trials (SOP, DYH, KRL), analysis and interpretation of data (SOP, JWK, KJB, YHL), and participated in writing and correcting the manuscript (JWK, SOP). All authors read and approved the manuscript. SOP takes responsibility for the paper as a whole.

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Not commissioned; externally peer reviewed

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Figure legends

Figure 1 Flow diagram of the study.

Figure 2 Kaplan–Meier analysis of cumulative endotracheal intubation success rate using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

Figure 3 Graphs of Modified Cormack–Lehane classifications of endotracheal intubation using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

Figure 1 Flow diagram of the study.

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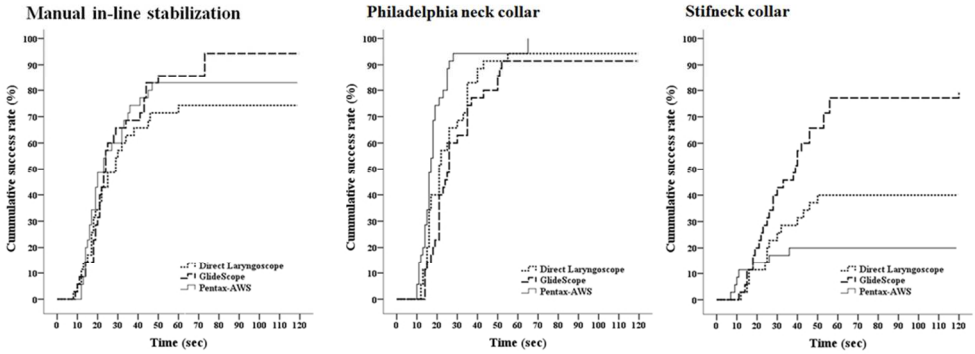

Figure 2 Kaplan–Meier analysis of cumulative endotracheal intubation success rate using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

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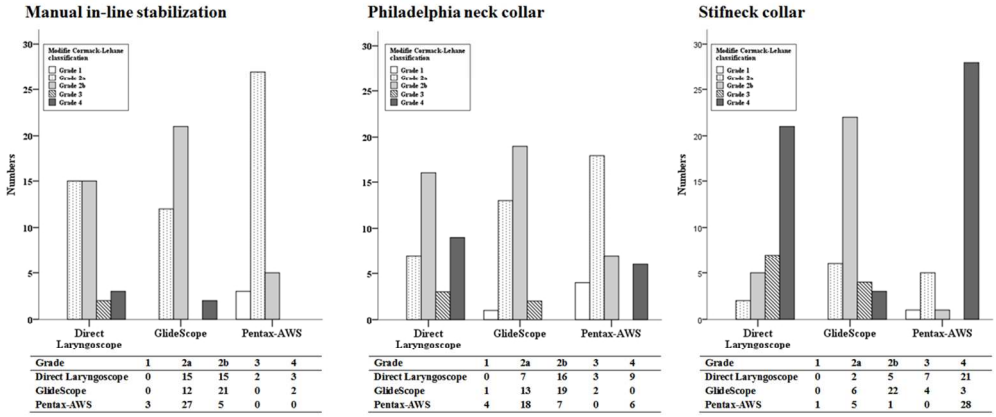


Figure 3 Graphs of Modified Cormack–Lehane classifications of endotracheal intubation using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

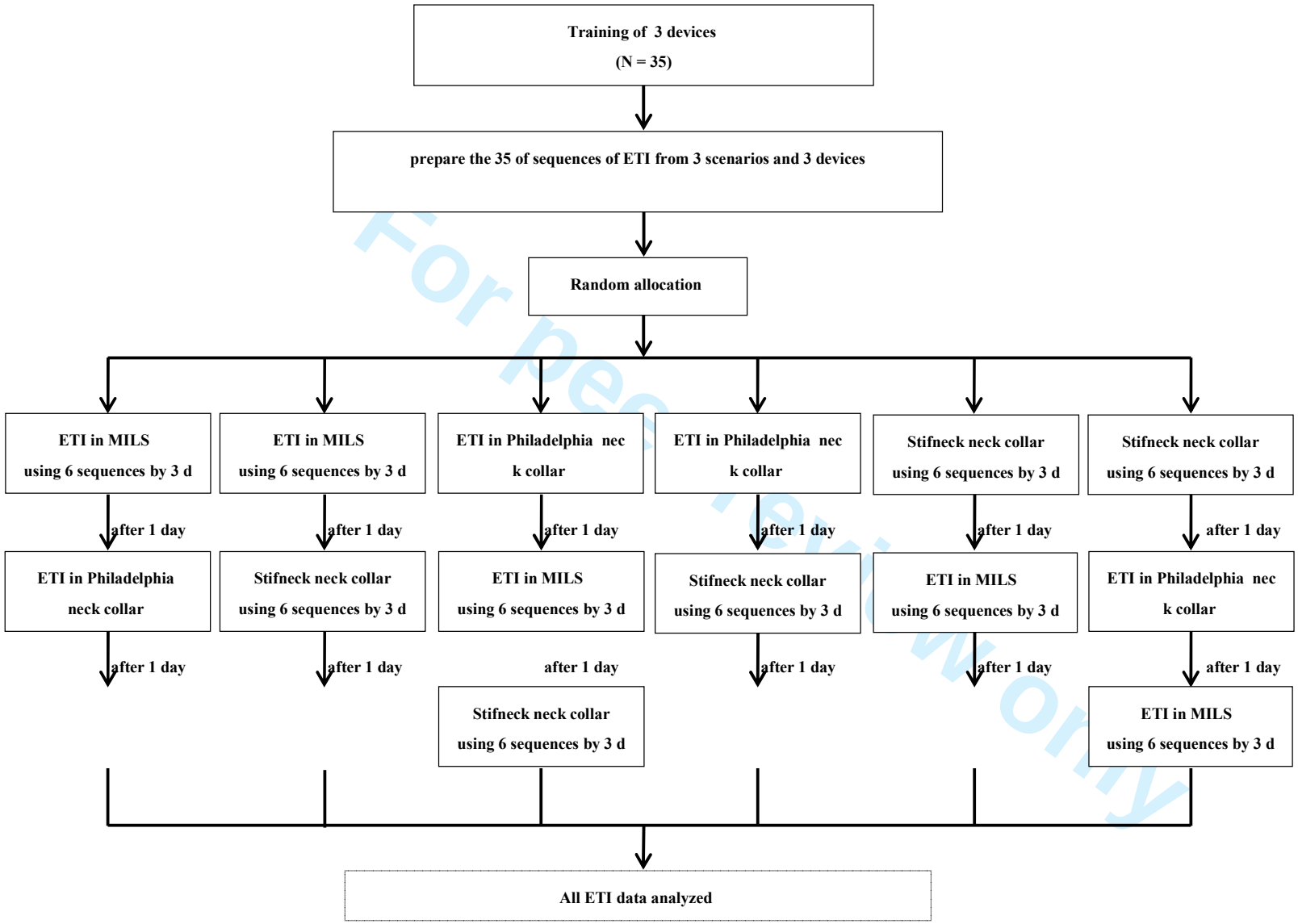
118x53mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7-8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8-9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-13
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.



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The efficacy of various types of laryngoscope (Direct, Pentax Airway Scope, and GlideScope) for the endotracheal intubation in various cervical immobilization scenarios: A randomized crossover simulation study

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ABSTRACT

Objective To compare the efficacy of direct laryngoscopy (DL), Pentax Airway Scope (PAWS), and GlideScope video-laryngoscope (GVL) systems for endotracheal intubation (ETI) in various cervical immobilization scenarios: manual in-line stabilization (MILS), Philadelphia neck collar (PNC) (moderate limit of mouth opening), and Stifneck collar (SNC) (severe limit of mouth opening).

Design Randomized crossover simulation study.

Setting and Participants Thirty-five physicians who had > 30 successful ETI experiences at a tertiary hospital in Seoul, Korea

Primary and secondary outcome measures Participants performed ETI using PAWS, GVL, and DL randomly in simulated MILS, PNC, and SNC scenarios in our simulation centre. The end points were successful ETI and the time to complete ETI. In addition, modified Cormack–Lehane (CL) classification and pressure to tooth were recorded.

Results In MILS, there were no significant difference in the rate of success of ETI between the three devices 33/35(94.3%) for DL vs. 32/35(91.4%) for GVL vs. 35/35(100.0%) for PAWS; p=0.230). PAWS achieved successful ETI more quickly (19.8 s) than DL (29.6 s) and GVL (35.4 s). For the PNC scenario, a higher rate of successful ETI was achieved with GVL 33/35(94.3%) than PAWS 29/35(82.9%) or DL 25/35(71.4%) (p = 0.040). For the SNC scenario, a higher rate of successful ETI was achieved with GVL 28/35(80.0%) than DL 14/35(40.0%) and PAWS 7/35(20.0%) (p < 0.001). For the PNC and SNC scenarios, GVL provided a relatively good view of the glottis, but a frequent pressure to tooth occurred.

Conclusions Three devices are suitable for ETI in the MILS. DL is not suitable in both neck collar scenarios. PAWS is the best device for MILS immobilization, and is suitable for PNC immobilization, but is not suitable for SNC immobilization. GVL is the best device for PNS

and SNC immobilization, but may cause pressure to tooth more frequently.

Strengths and limitations of this study

- This is the first study to report the diverse efficacy of the three typed laryngoscopy for intubation of various cervical spine immobilization scenarios
- A simulation design cannot precisely reproduce the real endotracheal intubation situation
- Our study does not measure the degree of neck movement, and thus it cannot evaluate whether the procedures are safe or not.

INTRODUCTION

Seriously injured patients often require emergency endotracheal intubation (ETI) to maintain an airway or supply sufficient oxygen to avoid airway obstruction and serious hypoxia. In victims of major trauma or patients with severe injury, accompanying cervical spine injuries should also be considered.[1] Therefore, cervical immobilization should be established in these patients to avoid any devastating neurologic outcome until any possibility of cervical spine injury is completely excluded.[2] However, there are obstacles to successful ETI in patients with cervical immobilization. Immobilization of the cervical spine puts a limitation on head extension and neck flexion, and so optimal alignment of the three airway axes and exposure of the vocal cords cannot be established easily.[3,4] ETI of patients with cervical immobilization with a conventional laryngoscope is considered difficult.[5,6]

Various airway management techniques to overcome the difficult ETI conditions in patients with cervical immobilization have been examined, such as supraglottic airway management, intubation using a lighted stylet, and video-laryngoscopes.[7] Video-laryngoscopes, including the Pentax Airway Scope system (PAWS; Pentax Corporation, Tokyo, Japan), **and** GlideScope video laryngoscope (GVL; Saturn Biomedical System, Burnaby, BC, Canada), have been studied to determine the easiest ETI to use in patients with cervical immobilization.[8,9]

Considering the various properties of these devices, each may have **differing** effectiveness in diverse cervical immobilization scenarios using methods including wearing various types of neck collars or manual in-line stabilization (MILS). However, there is limited data regarding the appropriate selection of laryngoscope devices for each cervical immobilization scenario.

The aim of this study was to compare various types of laryngoscopes to determine

whether any particular device is better able to manage the airway in a model of intubation with cervical immobilization in a simulated setting.

METHODS

This was a simulation study with a prospective randomized crossover design. Our study protocol was reviewed by our Institutional Review Board (KUH005126). After their approval of the research, we recruited participants from among the physicians in our hospital. Physicians with experience of >30 successful ETIs in a clinical setting were enrolled. Video laryngoscopes were introduced to the Korean physicians when we started the experiment, and previously they had no experience in their use. They also had no prior clinical experience of ETI in patients with an immobilized neck. To balance the skill levels for each of the airway devices, we held an airway training programme before the study.

After agreeing to participate in this study, all participants attended airway management and intubation training at the simulation centre of our institution before the trials. First, we gave verbal instruction for intubation using direct laryngoscopy with a Macintosh laryngoscope (DL), PAWS, and GVL. An expert demonstrated intubation with each device. Participants were allowed to practice intubation on a SimMan (Laerdal, Stavanger, Norway) and RespiTrainer Advance with ETView (IngMar Medical, Pittsburgh, PA, USA) patient simulator airway-trainer manikins until they were successful. Successful performance was defined as three consecutive successful intubations within 120 s for each device in both airway-trainer manikins.

After one week, participants were recalled to our simulation centre. We explained the objective of the study, and participants provided their informed written consent to participate. Cervical immobilization was achieved by applying MILS or either of the two different types

of collars to an airway trainer manikin (Laerdal Airway Management Trainer; Laerdal). MILS was applied by an experienced emergency physician grasping both sides of the manikin's head and neck, thus preventing movement of the head and neck. Cervical collar immobilization was achieved using either of two different semi-rigid cervical collars; the Stifneck Collar (Laerdal) and the Philadelphia neck collar (Philadelphia Cervical Collar Co., Thorofare, NJ, USA). The participants then performed intubation of the cervically immobilized manikins with each DL, PAWS, and GVL laryngoscope. A cuffed 7.5 mm diameter endotracheal tube (Mallinckrodt Medical, Athlone, Ireland) was used. To minimize any learning effect, laryngoscopes and immobilization techniques were used in random order using a sealed envelope selection method (Figure 1). After first contact with each device, all procedures ended when the participants declared the completion of intubation within the maximum 120 s time limit. During ETI, multiple attempts were allowed within time limits. Successful intubation was verified by visible chest rise of the manikin during bag-valve mask ventilation after intubation. Failed intubation was tracheal intubation that required more than 120 s or oesophageal intubation. After each intubation attempt, up to 10 min was allowed for operator rest and recovery.

Our primary outcome measure was successful ETI by various laryngoscopes in various cervical immobilization conditions. Our secondary outcome measure was the time taken to complete ETI. This was defined as the time taken between touching each device to the participant and completing intubation when the operator removed the stylet after tube placement in the trachea in the case of DL or GVL, or completing the tube placement in the trachea in the case of PAWS. The attempt numbers for successful ETI were measured. In addition, degree of laryngeal visualization was recorded according to a modified Cormack–Lehane (CL) classification. We included cases in which operator could not view the oral

cavity and glottis at all into grade 4. We also recorded "pressure to tooth" ("yes" or "no") indicating a risk of tooth injury using the audible clicking sound made when any device contacts an upper incisor.

All procedures were recorded using a camcorder (Samsung, Seoul, Korea), and all the time variables were precisely analysed by reviewing the recorded data. We calculated the minimal sample size of our simulation study based on the time of completing successful ETI. Referencing a pilot manikin study in neck collar scenario, we predicted the mean value of DL and standard deviation (SD) (measured mean were 30, 40 and 50, and standard deviation (SD) was 20 sec). For an alpha error of 5% and a power of 80% in the comparative study incorporating three equal-sized groups, we estimated that minimal sample size of each group was 32 cases. Data for overall intubation success, pressure to tooth, No. of attempts for successful ETI and the grades of glottic visualization were analysed using a chi-square or Mann–Whitney rank-sum test. Values of $p < 0.05$ were considered significant. We used Kaplan–Meier analysis to compare the intubation success time between the laryngoscopes to overcome censored attempts (failed viewing of the vocal cords or failed intubation). Data were analysed using IBM SPSS Statistics for Windows software (version 21.0; IBM, Seoul, Korea).

RESULTS

Thirty-five physicians participated in the study. Their mean (standard deviation) age was 31.1 (2.7) years old, and 22 (62.8%) were men. Of the 35 physicians, 14 were emergency physicians, eight worked in the intensive care, and 13 worked in general ward rooms. Twenty-four participants had experienced 30–40 successful ETI, eight had experienced 40–50 successful ETI, and three physicians had experienced over 50 successful ETIs.

ETI performance on the manikin with simulated neck injury under the MILS scenario

There were no significant **differences** in the rate of successful ETI between the three devices in the MILS scenario [33 (94.3%) for DL vs. 32 (91.4%) for GVL vs. 35 (100.0%) for PAWS; p = 0.230] (Table 1). In addition, there was no difference in the attempt numbers for successful ETI between the three devices (Table 2).

PAWS showed the fastest mean time to successful ETI (19.8 s), better view of the glottis, and lowest incidence of pressure to tooth compared with either DL or GVL (Table 1 and Figures 2 and 3). Otherwise, the longest time needed to complete ETI and high incidence of pressure to tooth was with the GVL (Table 1). First attempt success of GVL was lower than other devices (Table 2).

ETI performance on the manikin with simulated neck injury under the Philadelphia neck collar scenario

A higher rate of successful ETI was achieved with GVL 33 (94.3%) than PAWS 29 (82.9%) or DL 25 (71.4%) (p = 0.040), and more attempts for successful ETI were observed in the GVL users (Table 2). GVL showed the fastest mean time to successful ETI compared with other devices. However, there was no significant difference between the three devices. In GVL, a better view of the glottis was reported (Figure 3), but more pressure to tooth were observed than with other devices (Table 1). Otherwise PAWS achieved a moderate rate of successful ETI, but a poor view of the glottis (6 of grade 4) with the lowest incidence of pressure to tooth.

ETI performance on the manikin with simulated neck injury under the Stifneck collar scenario

Compared with GVL 28 (80.0%), DL 14 (40.0%) and PAWS 7 (20.0%) achieved significantly lower rates of successful ETI ($p < 0.001$). In addition, there was no difference in the attempt numbers for successful ETI between the three devices (Table 2). Mean time to successful ETI for DL and PAWS were longer than with GVL. Because of the tight neck collar, the view of the glottis was very poor in most cases of DL and PAWS (21 and 28 cases respectively). Otherwise GVL showed a relatively good view of the glottis (most cases were grade 2b), but a higher incidence of pressure to tooth occurred (Table 1).

Table 1 Data for endotracheal intubation and related complications in three scenarios

		Direct laryngoscope (n = 35)	GlideScope (n = 35)	PAWS (n = 35)	p- value
Manual in-line stabilization	Successful ETI, n (%)	33 (94.3)	32 (91.4)	35 (100.0%)	0.230
	Estimated time to successful ETI (s), mean (SD)	29.6 (4.1)	35.4 (4.7)	19.8 (2.1)	0.001
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Pressure to tooth, n (%)	12 (34.3)	22 (62.9)	6 (17.1)	<0.001
Neck immobilization with a Philadelphia neck collar	Successful ETI, n (%)	25 (71.4)	33 (94.3)	29 (82.9)	0.040
	Estimated time to successful ETI (s), mean (SD)	50.7 (7.6)	34.6 (4.5)	40.0 (6.4)	0.309
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Pressure to tooth, n (%)	9 (25.7)	18 (51.4)	6 (17.1)	0.006
Neck immobilization with a Stifneck collar	Successful ETI, n (%)	14 (40.0)	28 (80.0)	7 (20.0)	<0.001
	Estimated time to successful ETI (s), mean (SD)	99.3 (7.0)	51.8 (6.7)	83.5 (6.5)	<0.001
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Pressure to tooth, n (%)	11 (31.4)	26 (74.3)	4 (11.4)	<0.001

Table 2 No. of attempts of intubation trial for successful endotracheal intubation in three scenarios

			No. of attempts for success			
	Devices	No. of success	1 (%)	2 (%)	3 (%)	p-value
Manual in-line stabilization	Direct laryngoscope	33	30 (90.9)	2 (6.1)	1 (3.0)	0.795
	GlideScope	32	30 (93.8)	1 (3.1)	1 (3.1)	
	PAWS	35	34 (97.1)	1 (2.9)	0 (0.0)	
Neck immobilization with a Philadelphia neck collar	Direct laryngoscope	25	24 (96.0)	1 (4.0)	0 (0.0)	0.044
	GlideScope	33	28 (84.8)	5 (15.2)	0 (0.0)	
	PAWS	29	27 (93.1)	0 (0.0)	2 (6.9)	
Neck immobilization with a Stifneck collar	Direct laryngoscope	14	13 (92.9)	1 (7.1)	0 (0.0)	0.627
	GlideScope	24	24 (88.9)	3 (11.1)	0 (0.0)	
	PAWS	7	7 (100)	0 (0.0)	0 (0.0)	

DISCUSSION

Neck immobilization is an inevitable obstacle to the success of ETI in trauma patients.[3,4] Establishing optimal methods or devices for successful ETI is a key requirement in the airway management of trauma patients with neck injuries.[10] The most suitable airway management for each specific situation should be used; however, there are few data regarding this issue. We performed a randomized crossover study to compare the success of ETI in patients with cervical stabilization and related data from physicians performing DL, GVL, and PAWS in various simulated neck immobilization settings. In the MILS scenario, physicians showed a high rate of successful ETI with all laryngoscopes. PAWS had advantages over other laryngoscopes, including a better modified CL grade and faster time for ETI. In the Philadelphia neck collar immobilization scenario (moderate limit of mouth opening), the GVL showed the highest ETI success rate (94.3%), followed by PAWS (82.9%). Under the Stifneck collar cervical immobilization scenario (extreme limits of mouth opening), GVL achieved a higher ETI success rate (80.0%), but a higher incidence of pressure to tooth was observed.

DL with MILS is a standard technique according to adult trauma life support guidelines for cervical immobilization while intubating trauma patients with suspected cervical spine injury.[2] However, its safety and its effectiveness in MILS during intubation has been questioned by various studies.[11] Some data suggest that MILS may not properly support full immobilization because of increases in pressure transmitted to the cervical spine by the laryngoscope.[12] Increased subluxations were found with MILS in a clinical study.[13] MILS may often impede glottic visualization by preventing head extension and neck flexion, and this may adversely affect the patient outcome by delayed or failed intubations.[14,15] Especially, too rigid position in MILS increase the difficulty in intubation, and this may result in the high

failure rate of ETI. Thiboutot et al. reported around a 50% failure rate of ETI when experienced anaesthesiologists were asked to intubate using DL under rigidly applied MILS in their clinical trial.[5]

In our study, all devices showed a similar high success rate of ETI in a MILS scenario. In particular, the success rate of DL appeared to be greater than that in a clinical study by Thiboutot et al. This disparity of success rate between our study and the study by Thiboutot et al. may be explained by the different design used in the studies. In the study by Thiboutot et al., only 30 s was allowed for the operator to complete ETI successfully, and other applications during ETI were not allowed. By contrast, we allowed multiple attempts for ETI within a maximum 120 s in our study. A longer permitted time and an allowance for multiple attempts may have contributed to the relatively high success rate in our study. In a clinical study by Enomoto et al, researchers set a time limit of 120 s for ETI and allowed multiple attempts, and the success rate of DL for ETI in MILS was 89.4% (93/104).[8] A clinical study by Malik et al. reported a 100% success rate for DL in MILS with indefinite time permitted for ETI.[6] In addition, the simulation environment may be more favourable for high success in ETI than in actual clinical settings. The use of manikins may be a less threatening condition for operators because there is no fear of damage to the body in case of failure. Handling to achieve intubation may be more brutal, and this may lead to the relatively higher success rate. Moreover, manikins have no anatomical variance that can adversely affect the success of ETI. These factors may allow easier ETI in a simulation study than in an actual clinical situation. Other simulation study have also shown higher success rates than those obtained in clinical studies.[16]

With a view to shortening the time for successful ETI in a MILS scenario, it is important to note that less time was taken to achieve ETI with PAWS than with other

laryngoscopes. PAWS has a display screen with a target symbol for accurate ETI location, and a side channel for guidance of the endotracheal tube. These guidance cues may contribute to shorten the time to intubation.[17]

A neck collar is commonly used to immobilize the cervical spine with the aim of avoiding any secondary injury to the spine in traumatized patients. The collar does not only interrupt the view of the glottis, but also makes it difficult to handle the airway device because of the reduced mouth opening. It may be more difficult to perform ETI using the DL in patients wearing a neck collar than is the case with MILS. Intubation using DL in patients constrained by cervical collars may not be acceptable in clinical practice because it might lead to a higher rate of ETI failure.[18] It may be better option of patient wearing neck collar that ETI under MILS after removal of anterior part of cervical collar.

However, considering some practical limitations of MILS, the immediate intubation in patients wearing neck collars without removal of it is not easily abandoned. Intubation under MILS may be delayed in patients wearing a cervical collar because of the requirement for its careful removal. Additional cervical spine injuries may result during emergency removal of the collar also. In particular, we should consider the situation where a second rescuer is not available on site or a second rescuer is not able to administer safe MILS technique in an emergency. In some cases, the operator may have to postpone emergency ETI until an expert assistant for MILS is available on site. The most crucial benefit of a cervical collar is that it can immobilize the cervical spine more stably and consistently than MILS.

Many investigators have tried to demonstrate the feasibility of ETI while the patient is wearing a neck collar while using other airway devices, such as a supra-glottic airway device, optical stylet, or video laryngoscopy.[19-22] In the present study, we primarily tried to compare the efficacy of ETI between three types of devices in diverse scenarios. However, it is not

easy in a clinical setting to compare success, time to ETI, and complication rate between multiple devices because multiple trials on one patient may be dangerous and contravenes ethical guidelines. By contrast, a manikin easily allows repeated testing of ETI. In a simulated setting, although the direct application of results to actual clinical situations may be limited, the simulation may nevertheless provide data comparing the ability of operators to achieve ETI using various types of intubation devices in various scenarios.

Our study demonstrated low ETI success rate and delay in time to complete ETI by DL in scenarios where a cervical collar was used for immobilization compared with stabilization with MILS. In the present study, an important lesson was that operators who are novices in the use of video-assisted laryngoscopes performed better in the ETI for manikins wearing a cervical collar, and efficacy of ETI was variable between the various video laryngoscopes according to whether a cervical collar was present or not. A previous study has showed that cervical collars significantly reduce mouth opening to varying degrees depending on the various types of neck collars.[23] Our results are consistent with those of previous studies[24], and provide more detailed ETI performance data for the various devices. For the Philadelphia neck collar, which is semi-rigid and allows only a moderate limit of mouth opening, both types of video laryngoscopy have superiority over DL. The advantage of video laryngoscopy, which provides an indirect view of the glottic opening, is maximized where a Philadelphia cervical collar is used for immobilization. This suggests that video laryngoscopy is likely to be more suitable for ETI than DL when a Philadelphia cervical collar is used. There were varying results for the two video laryngoscopes using the Stifneck cervical collar: GVL has shown high success rates for ETI, but PAWS was not so successful. The major reason for this difference was that the inter-incisor distance is reduced more by a Stifneck collar than by a Philadelphia neck collar. The PAWS blade is too bulky to be

inserted into the narrow opening of the mouth when using a Stifneck collar; however, the GVL blade has the advantage of being more slender.

Despite the high ETI success rate by GVL, intubation time was not shortened because of difficulties in handling the endotracheal tube. In addition, frequent pressure to tooth was reported in ETI by GVL regardless of the cervical immobilization technique. GVL consists of a blade with a lens and an external display monitor. While intubating patients with a GVL, clinicians seldom check the patient's oral cavity because they should watch the external display monitor to identify the glottic opening. Then, this may easily cause the curved body of the blade to impinge on the upper teeth when the neck of the patient is immobilized. In the present study, the participants were unfamiliar with GVL and so might have had more difficulty in handling the blade than the DL. In addition, their bold manipulation of the device to achieve quickly successful ETI might also have contributed to increased pressures on the teeth. Otherwise, for DL and PAWS, many participants abandoned advancing the blade to the pharynx when the manikin was fitted with a cervical collar because the oral opening was too narrow, and then the possibility of pressure on the teeth was excluded. Ironically, these devices showed a lower incidence of pressure on the teeth during ETI than GVL, which was attempted frequently and succeeded despite the higher failure rate of repeated attempts.

It is never easy to balance safe cervical protection with effective ETI performance in patients with cervical injury under real-world conditions. The mainstay of our study is that there were diverse laryngoscopes that were the most suitable to use for ETI in each cervical immobilization scenario. Airway device selection might primarily depend on individual skill levels and preference, and the institutional availability of equipment. However, not all trauma patients needing emergency airway management can be managed in the same way. In pre-hospital or hospital settings, various neck immobilization scenarios may exist during ETI in

trauma patients with serious neck injuries; some patients may wear one of the various types of neck collar or others may have no neck collar in situ. In addition, the number of rescuers, patient urgency level, and device availability may affect the ETI performance.

Our study demonstrated the strategy of advanced airway management in trauma patients with cervical injury. The strategy should not be tailored to physician abilities, but also to the neck immobilization status and the efficacy of each device. If a second rescuer is available, the operator can immediately intubate using the MILS technique in patients without a neck collar. ETI can also be conducted using the MILS technique after removal of the anterior portion of the neck collar in patients wearing a neck collar. Direct and video laryngoscopies may be suitable when patients require ETI under MILS. In particular, PAWS is likely to be the better ETI option because of its faster time. If a second rescuer is not available, the operator might have to intubate with a neck collar in situ. In addition, the operator should perform the ETI without removing the neck collar when they feel removal may be harmful, even if another rescuer is available. Removing the neck collar may occasionally be time consuming, leading to hypoxia and secondary neurologic compromise. When patients require emergency ETI under cervical collar immobilization, DL may be not be the primary choice, but GVL or PAWS would be a good choice. However, there may be limited success with PAWS in some types of neck collar with seriously reduced mouth opening, such as the Stifneck collar. GVL seemed to be superior to other laryngoscopes when used with various types of neck collars; however, GVL could cause pressure to tooth frequently because of the difficulty in handling the device within the reduced open mouth space and oral cavity.

Our study has several limitations. First, we could not fully blind the participants to the airway device or the immobilization technique being used. Second, study participants did not

have equal experience of ETI between the three devices. Although we trained participants to achieve sufficient skills in both GVL and PAWS, these novel devices were less familiar to the participants who were more experienced with DL. Users with inherently more accumulated real-world experience of DL may affect a relatively higher positive outcome such as success in ETI and lower incidence of "pressure to tooth" than they do with novel video laryngoscopy. Third, this study was conducted with a simulation design using a manikin. A simulation study cannot realize the anatomical variance of humans and the possible conditions for trauma patients such as lens contamination by bleeding or secretions. If the patient's oral cavity is disordered, the direct view of an operator using DL may be better than the view from the screen of a video laryngoscope stuck in the oral cavity, because the video camera in a disordered cavity may be easily contaminated by blood or secretions. In this situation, DL may be more convenient than video laryngoscopy. Therefore, further consideration is required in clinical application.

CONCLUSIONS

DL showed high success rate in the MILS scenario, but not in either of the neck collar scenarios. PAWS was the superior device in the MILS scenario and could be used in the Philadelphia neck collar immobilization scenario, but was not suitable in the Stifneck collar immobilization scenario. GVL is most suitable in both neck collar scenarios, but higher incidences of pressure to tooth were observed with GVL than with other devices.

Competing interests

No author has any conflict of interest

Contributors

SOP established the main conception and designed this study. Each author took part in procedure of simulation trials (SOP, DYH, KRL), analysis and interpretation of data (all authors), and participated in writing and correcting the manuscript (JWK, SOP). All authors read and approved the manuscript. SOP takes responsibility for the paper as a whole.

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Figure legends

Figure 1 Flow diagram of the study.

Figure 2 Kaplan–Meier analysis of cumulative endotracheal intubation success rate using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

Figure 3 Graphs of Modified Cormack–Lehane classifications of endotracheal intubation using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

Figure 1 Flow diagram of the study.

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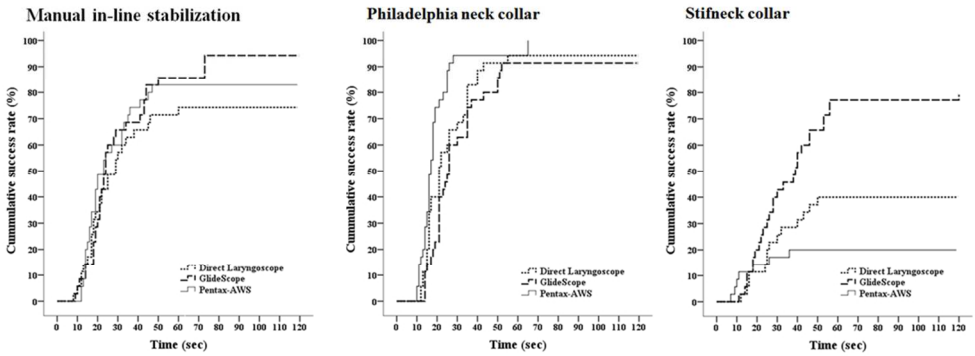

Figure 2 Kaplan–Meier analysis of cumulative endotracheal intubation success rate using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

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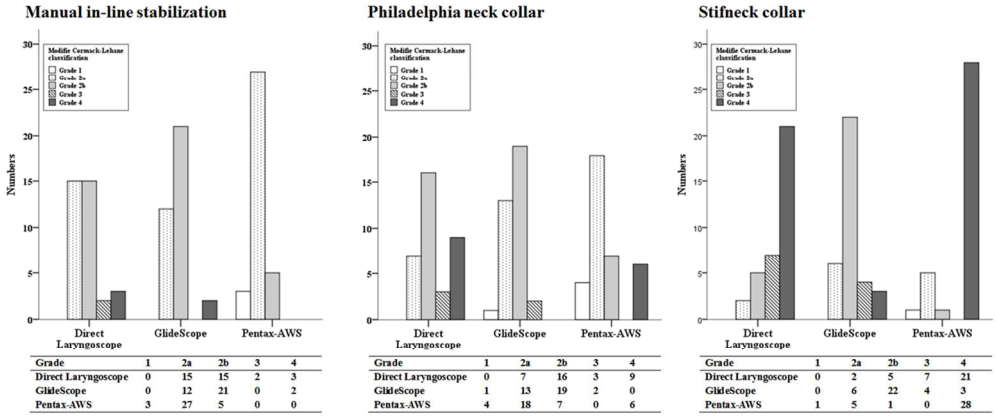

Figure 3 Graphs of Modified Cormack–Lehane classifications of endotracheal intubation using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

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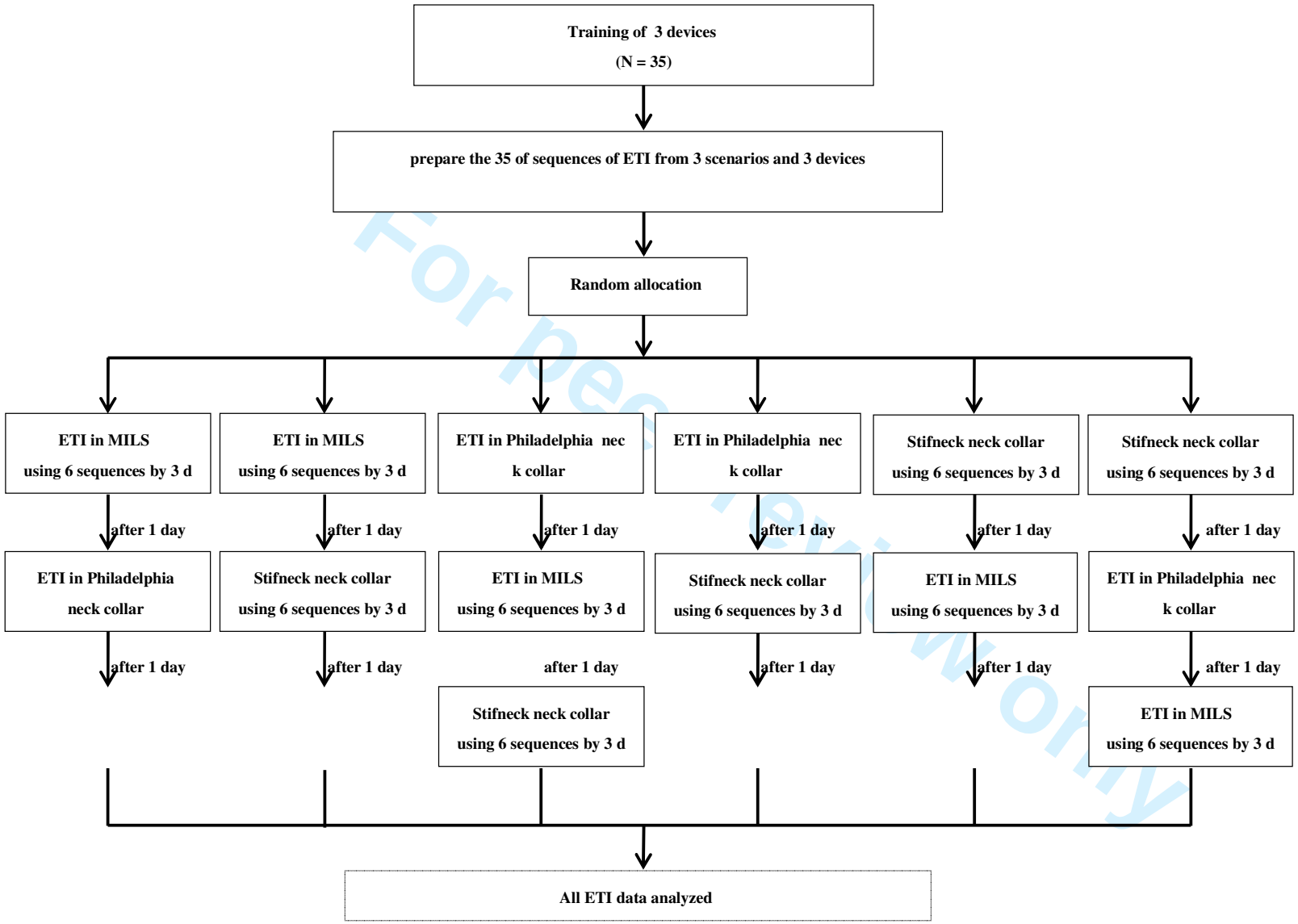
CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	8
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7-8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8-9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-13
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.



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The efficacy of various types of laryngoscope (Direct, Pentax Airway Scope, and GlideScope) for endotracheal intubation in various cervical immobilization scenarios: A randomized crossover simulation study

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The efficacy of various types of laryngoscope (Direct, Pentax Airway Scope, and GlideScope) for the endotracheal intubation in various cervical immobilization scenarios: A randomized crossover simulation study

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ABSTRACT

Objective To compare the efficacy of direct laryngoscopy (DL), Pentax Airway Scope (PAWS), and GlideScope video-laryngoscope (GVL) systems for endotracheal intubation (ETI) in various cervical immobilization scenarios: manual in-line stabilization (MILS), Philadelphia neck collar (PNC) (moderate limit of mouth opening), and Stifneck collar (SNC) (severe limit of mouth opening).

Design Randomized crossover simulation study.

Setting and Participants Thirty-five physicians who had > 30 successful ETI experiences at a tertiary hospital in Seoul, Korea

Primary and secondary outcome measures Participants performed ETI using PAWS, GVL, and DL randomly in simulated MILS, PNC, and SNC scenarios in our simulation centre. The end points were successful ETI and the time to complete ETI. In addition, modified Cormack–Lehane (CL) classification and pressure to teeth were recorded.

Results In MILS, there were no significant difference in the rate of success of ETI between the three devices 33/35(94.3%) for DL vs. 32/35(91.4%) for GVL vs. 35/35(100.0%) for PAWS; p=0.230). PAWS achieved successful ETI more quickly (19.8 s) than DL (29.6 s) and GVL (35.4 s). For the PNC scenario, a higher rate of successful ETI was achieved with GVL 33/35(94.3%) than PAWS 29/35(82.9%) or DL 25/35(71.4%) (p = 0.040). For the SNC scenario, a higher rate of successful ETI was achieved with GVL 28/35(80.0%) than DL 14/35(40.0%) and PAWS 7/35(20.0%) (p < 0.001). For the PNC and SNC scenarios, GVL provided a relatively good view of the glottis, but a frequent pressure to teeth occurred.

Conclusions All three devices are suitable for ETI in the MILS. DL is not suitable in both neck collar scenarios. PAWS showed faster intubations in the MILS, but was not suitable in the SNC scenario. GVL is most suitable in all cervical immobilization scenarios, but may

cause pressure to teeth more frequently.

Strengths and limitations of this study

- This is the first study to report the diverse efficacy of the three typed laryngoscopy for intubation of various cervical spine immobilization scenarios
- A simulation design cannot precisely reproduce the real endotracheal intubation situation
- Our study does not measure the degree of neck movement, and thus it cannot evaluate whether the procedures are safe or not.

INTRODUCTION

Seriously injured patients often require emergency endotracheal intubation (ETI) to maintain an airway or supply sufficient oxygen to avoid airway obstruction and serious hypoxia. In victims of major trauma or patients with severe injury, accompanying cervical spine injuries should also be considered.[1] Therefore, cervical immobilization should be established in these patients to avoid any devastating neurologic outcome until any possibility of cervical spine injury is completely excluded.[2] However, there are obstacles to successful ETI in patients with cervical immobilization. Immobilization of the cervical spine puts a limitation on head extension and neck flexion, and so optimal alignment of the three airway axes and exposure of the vocal cords cannot be established easily.[3,4] ETI of patients with cervical immobilization with a conventional laryngoscope is considered difficult.[5,6]

Various airway management techniques to overcome the difficult ETI conditions in patients with cervical immobilization have been examined, such as supraglottic airway management, intubation using a lighted stylet, and video-laryngoscopes.[7] Video-laryngoscopes, including the Pentax Airway Scope system (PAWS; Pentax Corporation, Tokyo, Japan), **and** GlideScope video laryngoscope (GVL; Saturn Biomedical System, Burnaby, BC, Canada), have been studied to determine the easiest ETI to use in patients with cervical immobilization.[8,9]

Considering the various properties of these devices, each may have differing effectiveness in diverse cervical immobilization scenarios using methods including wearing various types of neck collars or manual in-line stabilization (MILS). However, there is limited data regarding the appropriate selection of laryngoscope devices for each cervical immobilization scenario.

The aim of this study was to compare various types of laryngoscopes to determine

whether any particular device is better able to manage the airway in a model of intubation with cervical immobilization in a simulated setting.

METHODS

This was a simulation study with a prospective randomized crossover design. Our study protocol was reviewed by our Institutional Review Board (KUH005126). After their approval of the research, we recruited participants from among the physicians in our hospital. Physicians with experience of >30 successful ETIs in a clinical setting were enrolled. Video laryngoscopes were introduced to the Korean physicians when we started the experiment, and previously they had no experience in their use. They also had no prior clinical experience of ETI in patients with an immobilized neck. To balance the skill levels for each of the airway devices, we held an airway training programme before the study.

After agreeing to participate in this study, all participants attended airway management and intubation training at the simulation centre of our institution before the trials. First, we gave verbal instruction for intubation using direct laryngoscopy with a Macintosh laryngoscope (DL), PAWS, and GVL. An expert demonstrated intubation with each device. Participants were allowed to practice intubation on a SimMan (Laerdal, Stavanger, Norway) and RespiTrainer Advance with ETView (IngMar Medical, Pittsburgh, PA, USA) patient simulator airway-trainer manikins until they were successful. Successful performance was defined as three consecutive successful intubations within 120 s for each device in both airway-trainer manikins.

After one week, participants were recalled to our simulation centre. We explained the objective of the study, and participants provided their informed written consent to participate. Cervical immobilization was achieved by applying MILS or either of the two different types

of collars to an airway trainer manikin (Laerdal Airway Management Trainer; Laerdal). MILS was applied by an experienced emergency physician grasping both sides of the manikin's head and neck, thus preventing movement of the head and neck. Cervical collar immobilization was achieved using either of two different semi-rigid cervical collars; the Stifneck Collar (Laerdal) and the Philadelphia neck collar (Philadelphia Cervical Collar Co., Thorofare, NJ, USA). The participants then performed intubation of the cervically immobilized manikins with each DL, PAWS, and GVL laryngoscope. A cuffed 7.5 mm diameter endotracheal tube (Mallinckrodt Medical, Athlone, Ireland) was used. To minimize any learning effect, laryngoscopes and immobilization techniques were used in random order using a sealed envelope selection method (Figure 1). After first contact with each device, all procedures ended when the participants declared the completion of intubation within the maximum 120 s time limit. During ETI, multiple attempts were allowed within time limits. Successful intubation was verified by visible chest rise of the manikin during bag-valve mask ventilation after intubation. Failed intubation was tracheal intubation that required more than 120 s or oesophageal intubation. After each intubation attempt, up to 10 min was allowed for operator rest and recovery.

Our primary outcome measure was successful ETI by various laryngoscopes in various cervical immobilization conditions. Our secondary outcome measure was the time taken to complete ETI. This was defined as the time taken between touching each device to the participant and completing intubation when the operator removed the stylet after tube placement in the trachea in the case of DL or GVL, or completing the tube placement in the trachea in the case of PAWS. The attempt numbers for successful ETI were measured. In addition, degree of laryngeal visualization was recorded according to a modified Cormack–Lehane (CL) classification. We included cases in which operator could not view the oral

cavity and glottis at all into grade 4. We also recorded "pressure to teeth" ("yes" or "no") indicating a risk of teeth injury using the audible clicking sound made when any device contacts an upper incisor.

All procedures were recorded using a camcorder (Samsung, Seoul, Korea), and all the time variables were precisely analysed by reviewing the recorded data. We calculated the minimal sample size of our simulation study based on the time of completing successful ETI. Referencing a pilot manikin study in neck collar scenario, we predicted the mean value of DL and standard deviation (SD) (measured mean were 30, 40 and 50, and standard deviation (SD) was 20 sec). For an alpha error of 5% and a power of 80% in the comparative study incorporating three equal-sized groups, we estimated that minimal sample size of each group was 32 cases. Data for overall intubation success, pressure to teeth, No. of attempts for successful ETI and the grades of glottic visualization were analysed using a chi-square or Mann–Whitney rank-sum test. Values of $p < 0.05$ were considered significant. We used Kaplan–Meier analysis to compare the intubation success time between the laryngoscopes to overcome censored attempts (failed viewing of the vocal cords or failed intubation). Data were analysed using IBM SPSS Statistics for Windows software (version 21.0; IBM, Seoul, Korea).

RESULTS

Thirty-five physicians participated in the study. Their mean (standard deviation) age was 31.1 (2.7) years old, and 22 (62.8%) were men. Of the 35 physicians, 14 were emergency physicians, eight worked in the intensive care, and 13 worked in general ward rooms. Twenty-four participants had experienced 30–40 successful ETI, eight had experienced 40–50 successful ETI, and three physicians had experienced over 50 successful ETIs.

ETI performance on the manikin with simulated neck injury under the MILS scenario

There were no significant **differences** in the rate of successful ETI between the three devices in the MILS scenario [33 (94.3%) for DL vs. 32 (91.4%) for GVL vs. 35 (100.0%) for PAWS; p = 0.230] (Table 1). In addition, there was no difference in the attempt numbers for successful ETI between the three devices (Table 2).

PAWS showed the fastest mean time to successful ETI (19.8 s), better view of the glottis, and lowest incidence of pressure to teeth compared with either DL or GVL (Table 1 and Figures 2 and 3). Otherwise, the longest time needed to complete ETI and high incidence of pressure to teeth was with the GVL (Table 1). First attempt success of GVL was lower than other devices (Table 2).

ETI performance on the manikin with simulated neck injury under the Philadelphia neck collar scenario

A higher rate of successful ETI was achieved with GVL 33 (94.3%) than PAWS 29 (82.9%) or DL 25 (71.4%) (p = 0.040), and more attempts for successful ETI were observed in the GVL users (Table 2). GVL showed the fastest mean time to successful ETI compared with other devices. However, there was no significant difference between the three devices. In GVL, a better view of the glottis was reported (Figure 3), but more pressure to teeth were observed than with other devices (Table 1). Otherwise PAWS achieved a moderate rate of successful ETI, but a poor view of the glottis (6 of grade 4) with the lowest incidence of pressure to teeth.

ETI performance on the manikin with simulated neck injury under the Stifneck collar scenario

Compared with GVL 28 (80.0%), DL 14 (40.0%) and PAWS 7 (20.0%) achieved significantly lower rates of successful ETI ($p < 0.001$). In addition, there was no difference in the attempt numbers for successful ETI between the three devices (Table 2). Mean time to successful ETI for DL and PAWS were longer than with GVL. Because of the tight neck collar, the view of the glottis was very poor in most cases of DL and PAWS (21 and 28 cases respectively). Otherwise GVL showed a relatively good view of the glottis (most cases were grade 2b), but a higher incidence of pressure to teeth occurred (Table 1).

Table 1 Data for endotracheal intubation and related complications in three scenarios

		Direct laryngoscope (n = 35)	GlideScope (n = 35)	PAWS (n = 35)	p- value
Manual in-line stabilization	Successful ETI, n (%)	33 (94.3)	32 (91.4)	35 (100.0%)	0.230
	Estimated time to successful ETI (s), mean (SD)	29.6 (4.1)	35.4 (4.7)	19.8 (2.1)	0.001
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Pressure to teeth, n (%)	12 (34.3)	22 (62.9)	6 (17.1)	<0.001
Neck immobilization with a Philadelphia neck collar	Successful ETI, n (%)	25 (71.4)	33 (94.3)	29 (82.9)	0.040
	Estimated time to successful ETI (s), mean (SD)	50.7 (7.6)	34.6 (4.5)	40.0 (6.4)	0.309
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Pressure to teeth, n (%)	9 (25.7)	18 (51.4)	6 (17.1)	0.006
Neck immobilization with a Stifneck collar	Successful ETI, n (%)	14 (40.0)	28 (80.0)	7 (20.0)	<0.001
	Estimated time to successful ETI (s), mean (SD)	99.3 (7.0)	51.8 (6.7)	83.5 (6.5)	<0.001
	Oesophageal intubation, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
	Pressure to teeth, n (%)	11 (31.4)	26 (74.3)	4 (11.4)	<0.001

Table 2 No. of attempts of intubation trial for successful endotracheal intubation in three scenarios

	Devices	No. of success	No. of attempts for success			
			1 (%)	2 (%)	3 (%)	p-value
Manual in-line stabilization	Direct laryngoscope	33	30 (90.9)	2 (6.1)	1 (3.0)	0.795
	GlideScope	32	30 (93.8)	1 (3.1)	1 (3.1)	
	PAWS	35	34 (97.1)	1 (2.9)	0 (0.0)	
Neck immobilization with a Philadelphia neck collar	Direct laryngoscope	25	24 (96.0)	1 (4.0)	0 (0.0)	0.044
	GlideScope	33	28 (84.8)	5 (15.2)	0 (0.0)	
	PAWS	29	27 (93.1)	0 (0.0)	2 (6.9)	
Neck immobilization with a Stifneck collar	Direct laryngoscope	14	13 (92.9)	1 (7.1)	0 (0.0)	0.627
	GlideScope	24	24 (88.9)	3 (11.1)	0 (0.0)	
	PAWS	7	7 (100)	0 (0.0)	0 (0.0)	

DISCUSSION

Neck immobilization is an inevitable obstacle to the success of ETI in trauma patients.[3,4] Establishing optimal methods or devices for successful ETI is a key requirement in the airway management of trauma patients with neck injuries.[10] The most suitable airway management for each specific situation should be used; however, there are few data regarding this issue. We performed a randomized crossover study to compare the success of ETI in patients with cervical stabilization and related data from physicians performing DL, GVL, and PAWS in various simulated neck immobilization settings. In the MILS scenario, physicians showed a high rate of successful ETI with all laryngoscopes. PAWS had advantages over other laryngoscopes, including a better modified CL grade and faster time for ETI. In the Philadelphia neck collar immobilization scenario (moderate limit of mouth opening), the GVL showed the highest ETI success rate (94.3%), followed by PAWS (82.9%). Under the Stifneck collar cervical immobilization scenario (extreme limits of mouth opening), GVL achieved a higher ETI success rate (80.0%), but a higher incidence of pressure to teeth was observed.

DL with MILS is a standard technique according to adult trauma life support guidelines for cervical immobilization while intubating trauma patients with suspected cervical spine injury.[2] However, its safety and its effectiveness in MILS during intubation has been questioned by various studies.[11] Some data suggest that MILS may not properly support full immobilization because of increases in pressure transmitted to the cervical spine by the laryngoscope.[12] Increased subluxations were found with MILS in a clinical study.[13] MILS may often impede glottic visualization by preventing head extension and neck flexion, and this may adversely affect the patient outcome by delayed or failed intubations.[14,15] Especially, too rigid position in MILS increase the difficulty in intubation, and this may result in the high

failure rate of ETI. Thiboutot et al. reported around a 50% failure rate of ETI when experienced anaesthesiologists were asked to intubate using DL under rigidly applied MILS in their clinical trial.[5]

In our study, all devices showed a similar high success rate of ETI in a MILS scenario. In particular, the success rate of DL appeared to be greater than that in a clinical study by Thiboutot et al. This disparity of success rate between our study and the study by Thiboutot et al. may be explained by the different design used in the studies. In the study by Thiboutot et al., only 30 s was allowed for the operator to complete ETI successfully, and other applications during ETI were not allowed. By contrast, we allowed multiple attempts for ETI within a maximum 120 s in our study. A longer permitted time and an allowance for multiple attempts may have contributed to the relatively high success rate in our study. In a clinical study by Enomoto et al, researchers set a time limit of 120 s for ETI and allowed multiple attempts, and the success rate of DL for ETI in MILS was 89.4% (93/104).[8] A clinical study by Malik et al. reported a 100% success rate for DL in MILS with indefinite time permitted for ETI.[6] In addition, the simulation environment may be more favourable for high success in ETI than in actual clinical settings. The use of manikins may be a less threatening condition for operators because there is no fear of damage to the body in case of failure. Handling to achieve intubation may be more brutal, and this may lead to the relatively higher success rate. Moreover, manikins have no anatomical variance that can adversely affect the success of ETI. These factors may allow easier ETI in a simulation study than in an actual clinical situation. Other simulation study have also shown higher success rates than those obtained in clinical studies.[16]

With a view to shortening the time for successful ETI in a MILS scenario, it is important to note that less time was taken to achieve ETI with PAWS than with other

laryngoscopes. PAWS has a display screen with a target symbol for accurate ETI location, and a side channel for guidance of the endotracheal tube. These guidance cues may contribute to shorten the time to intubation.[17]

A neck collar is commonly used to immobilize the cervical spine with the aim of avoiding any secondary injury to the spine in traumatized patients. The collar does not only interrupt the view of the glottis, but also makes it difficult to handle the airway device because of the reduced mouth opening. It may be more difficult to perform ETI using the DL in patients wearing a neck collar than is the case with MILS. Intubation using DL in patients constrained by cervical collars may not be acceptable in clinical practice because it might lead to a higher rate of ETI failure.[18] It may be better option of patient wearing neck collar that ETI under MILS after removal of anterior part of cervical collar.

However, considering some practical limitations of MILS, the immediate intubation in patients wearing neck collars without removal of it is not easily abandoned. Intubation under MILS may be delayed in patients wearing a cervical collar because of the requirement for its careful removal. Additional cervical spine injuries may result during emergency removal of the collar also. In particular, we should consider the situation where a second rescuer is not available on site or a second rescuer is not able to administer safe MILS technique in an emergency. In some cases, the operator may have to postpone emergency ETI until an expert assistant for MILS is available on site. The most crucial benefit of a cervical collar is that it can immobilize the cervical spine more stably and consistently than MILS.

Many investigators have tried to demonstrate the feasibility of ETI while the patient is wearing a neck collar while using other airway devices, such as a supra-glottic airway device, optical stylet, or video laryngoscopy.[19-22] In the present study, we primarily tried to compare the efficacy of ETI between three types of devices in diverse scenarios. However, it is not

easy in a clinical setting to compare success, time to ETI, and complication rate between multiple devices because multiple trials on one patient may be dangerous and contravenes ethical guidelines. By contrast, a manikin easily allows repeated testing of ETI. In a simulated setting, although the direct application of results to actual clinical situations may be limited, the simulation may nevertheless provide data comparing the ability of operators to achieve ETI using various types of intubation devices in various scenarios.

Our study demonstrated low ETI success rate and delay in time to complete ETI by DL in scenarios where a cervical collar was used for immobilization compared with stabilization with MILS. In the present study, an important lesson was that operators who are novices in the use of video-assisted laryngoscopes performed better in the ETI for manikins wearing a cervical collar, and efficacy of ETI was variable between the various video laryngoscopes according to whether a cervical collar was present or not. A previous study has showed that cervical collars significantly reduce mouth opening to varying degrees depending on the various types of neck collars.[23] Our results are consistent with those of previous studies[24], and provide more detailed ETI performance data for the various devices. For the Philadelphia neck collar, which is semi-rigid and allows only a moderate limit of mouth opening, both types of video laryngoscopy have superiority over DL. The advantage of video laryngoscopy, which provides an indirect view of the glottic opening, is maximized where a Philadelphia cervical collar is used for immobilization. This suggests that video laryngoscopy is likely to be more suitable for ETI than DL when a Philadelphia cervical collar is used. There were varying results for the two video laryngoscopes using the Stifneck cervical collar: GVL has shown high success rates for ETI, but PAWS was not so successful. The major reason for this difference was that the inter-incisor distance is reduced more by a Stifneck collar than by a Philadelphia neck collar. The PAWS blade is too bulky to be

inserted into the narrow opening of the mouth when using a Stifneck collar; however, the GVL blade has the advantage of being more slender.

Despite the high ETI success rate by GVL, intubation time was not shortened because of difficulties in handling the endotracheal tube. In addition, frequent pressure to teeth was reported in ETI by GVL regardless of the cervical immobilization technique. The participants who were unfamiliar with the GVL had difficulty in handling the blade. Frequent pressure on the teeth seemed to result from a mistake by novice GVL users, in which they tend to use the blade as a direct laryngoscope and tilt it incorrectly. In addition, their assertive manipulation of the device to achieve successful ETI quickly might also have contributed to frequent pressure on the teeth in a simulated setting.

Otherwise, for DL and PAWS, many participants abandoned advancing the blade to the pharynx when the manikin was fitted with a cervical collar because the oral opening was too narrow, and then the possibility of pressure on the teeth was excluded. Ironically, these devices showed a lower incidence of pressure on the teeth during ETI than GVL, which was attempted frequently and succeeded despite the higher failure rate of repeated attempts.

It is never easy to balance safe cervical protection with effective ETI performance in patients with cervical injury under real-world conditions. The mainstay of our study is that there were diverse laryngoscopes that were the most suitable to use for ETI in each cervical immobilization scenario. Airway device selection might primarily depend on individual skill levels and preference, and the institutional availability of equipment. However, not all trauma patients needing emergency airway management can be managed in the same way. In pre-hospital or hospital settings, various neck immobilization scenarios may exist during ETI in trauma patients with serious neck injuries; some patients may wear one of the various types

of neck collar or others may have no neck collar in situ. In addition, the number of rescuers, patient urgency level, and device availability may affect the ETI performance.

Our study demonstrated the strategy of advanced airway management in trauma patients with cervical injury. The strategy should not be tailored to physician abilities, but also to the neck immobilization status and the efficacy of each device. If a second rescuer is available, the operator can immediately intubate using the MILS technique in patients without a neck collar. ETI can also be conducted using the MILS technique after removal of the anterior portion of the neck collar in patients wearing a neck collar. Direct and video laryngoscopies may be suitable when patients require ETI under MILS. In particular, PAWS is likely to be the better ETI option because of its faster time. If a second rescuer is not available, the operator might have to intubate with a neck collar in situ. In addition, the operator should perform the ETI without removing the neck collar when they feel removal may be harmful, even if another rescuer is available. Removing the neck collar may occasionally be time consuming, leading to hypoxia and secondary neurologic compromise. When patients require emergency ETI under cervical collar immobilization, DL may be not be the primary choice, but GVL or PAWS would be a good choice. However, there may be limited success with PAWS in some types of neck collar with seriously reduced mouth opening, such as the Stifneck collar. GVL seemed to be superior to other laryngoscopes when used with various types of neck collars; however, GVL could cause pressure to teeth frequently because of the difficulty in handling the device within the reduced open mouth space and oral cavity.

Our study has several limitations. First, we could not fully blind the participants to the airway device or the immobilization technique being used. Second, study participants did not have equal experience of ETI between the three devices. Although we trained participants to

achieve sufficient skills in both GVL and PAWS, these novel devices were less familiar to the participants who were more experienced with DL. Users with inherently more accumulated real-world experience of DL may affect a relatively higher positive outcome such as success in ETI and lower incidence of "pressure to teeth" than they do with novel video laryngoscopy. Third, this study was conducted with a simulation design using a manikin. A simulation study cannot realize the anatomical variance of humans and the possible conditions for trauma patients such as lens contamination by bleeding or secretions. If the patient's oral cavity is disordered, the direct view of an operator using DL may be better than the view from the screen of a video laryngoscope stuck in the oral cavity, because the video camera in a disordered cavity may be easily contaminated by blood or secretions. Especially, the PAWS may be more vulnerable to blocking of the camera lens than the GVL, because the camera lens of the Pentax device is located deeper and lower in the oral cavity area during intubation, compared with the higher and shallower position of the camera lens of the GVL.

CONCLUSIONS

DL showed high success rate in the MILS scenario, but not in either of the neck collar scenarios. PAWS showed faster intubations in the MILS, but was not suitable in the Stifneck collar immobilization scenario. GVL is most suitable in all cervical immobilization scenarios, but higher incidences of pressure to teeth were observed with GVL than with other devices.

Competing interests

No author has any conflict of interest

Contributors

SOP established the main conception and designed this study. Each author took part in procedure of simulation trials (SOP, DYH, KRL), analysis and interpretation of data (all authors), and participated in writing and correcting the manuscript (JWK, SOP). All authors read and approved the manuscript. SOP takes responsibility for the paper as a whole.

Provenance and peer review

Not commissioned; externally peer reviewed

Data sharing statement

No additional data are available.

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Figure legends

Figure 1 Flow diagram of the study.

Figure 2 Kaplan–Meier analysis of cumulative endotracheal intubation success rate using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

Figure 3 Graphs of Modified Cormack–Lehane classifications of endotracheal intubation using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

Figure 1 Flow diagram of the study.

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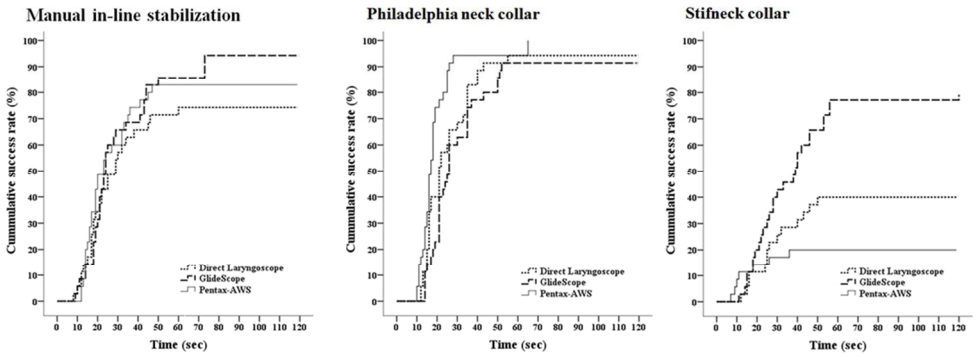

Figure 2 Kaplan–Meier analysis of cumulative endotracheal intubation success rate using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

97x36mm (300 x 300 DPI)

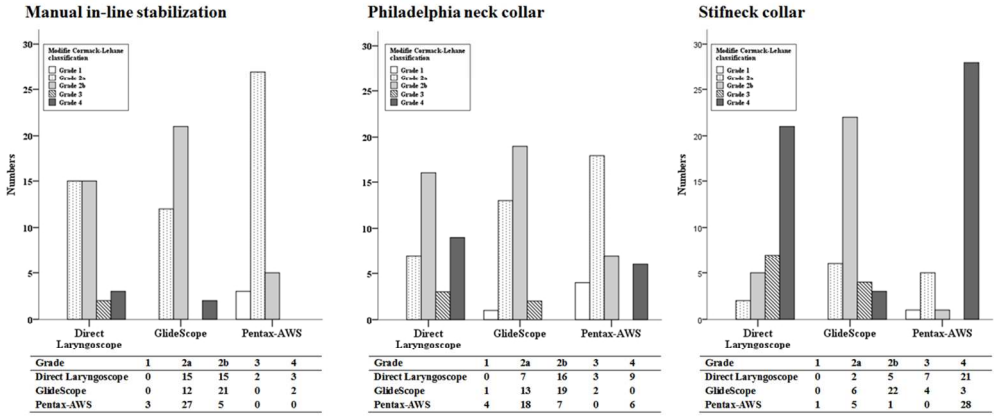

Figure 3 Graphs of Modified Cormack–Lehane classifications of endotracheal intubation using direct laryngoscopy, GlideScope, and Pentax AWS in various cervical immobilization scenarios: manual in-line cervical stabilization, Philadelphia neck collar, and Stifneck collar.

118x53mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	8
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7-8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8-9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-13
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.