

BMJ Open Efficacy of various types of laryngoscope (direct, Pentax Airway Scope and GlideScope) for endotracheal intubation in various cervical immobilisation scenarios: a randomised cross-over 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 immobilisation scenarios: manual in-line stabilisation (MILS), Philadelphia neck collar (PNC) (moderate limit of mouth opening) and Stifneck collar (SNC) (severe limit of mouth opening).

Design: Randomised cross-over simulation study.

Setting and Participants: 35 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 differences 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 with 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 MILS. DL is not suitable in both neck collar scenarios. PAWS showed faster intubations in MILS, but was not suitable in the SNC scenario. GVL is most suitable in all cervical immobilisation 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 immobilisation 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 immobilisation should be established in these patients to avoid any devastating neurological outcome until any possibility of cervical spine injury is completely excluded.² However, there are obstacles to successful ETI in patients with cervical immobilisation. Immobilisation 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 immobilisation with a conventional laryngoscope is considered difficult.^{5–6}

Various airway management techniques to overcome the difficult ETI conditions in patients with cervical immobilisation 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, British Columbia, Canada), have been studied to determine the easiest ETI to use in patients with cervical immobilisation.^{8 9}

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

METHODS

This was a simulation study with a prospective randomised cross-over design. Our study protocol was reviewed by our Institutional Review Board (KUHO05126). 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 immobilised 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 (DL) with a Macintosh laryngoscope, PAWS and GVL. An expert demonstrated intubation with each device. Participants were allowed to practise intubation on a SimMan (Laerdal, Stavanger, Norway) and RespiTrainer Advance with ETVIEW (IngMar Medical, Pittsburgh, Pennsylvania, 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 1-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 immobilisation 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 immobilisation 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, New Jersey, USA). The participants then performed intubation of the cervically immobilised manikins with each DL, PAWS and GVL laryngoscope. A cuffed 7.5 mm diameter endotracheal tube (Mallinckrodt Medical, Athlone, Ireland) was used. To minimise any learning effect, laryngoscopes and immobilisation 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 immobilisation 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, the degree of laryngeal visualisation was recorded according to a modified Cormack-Lehane (CL) classification. We included cases in which the 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 a neck collar scenario, we predicted the mean value of DL and SD (measured mean time 30, 40 and 50, and SD was 20 s). For an α error of 5% and a power of 80% in the comparative study incorporating three equal-sized groups, we estimated that the minimal sample size of each group was 32 cases. Data for overall intubation success, pressure to teeth, number of attempts for successful ETI and the grades of glottic visualisation were analysed using a χ^2 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

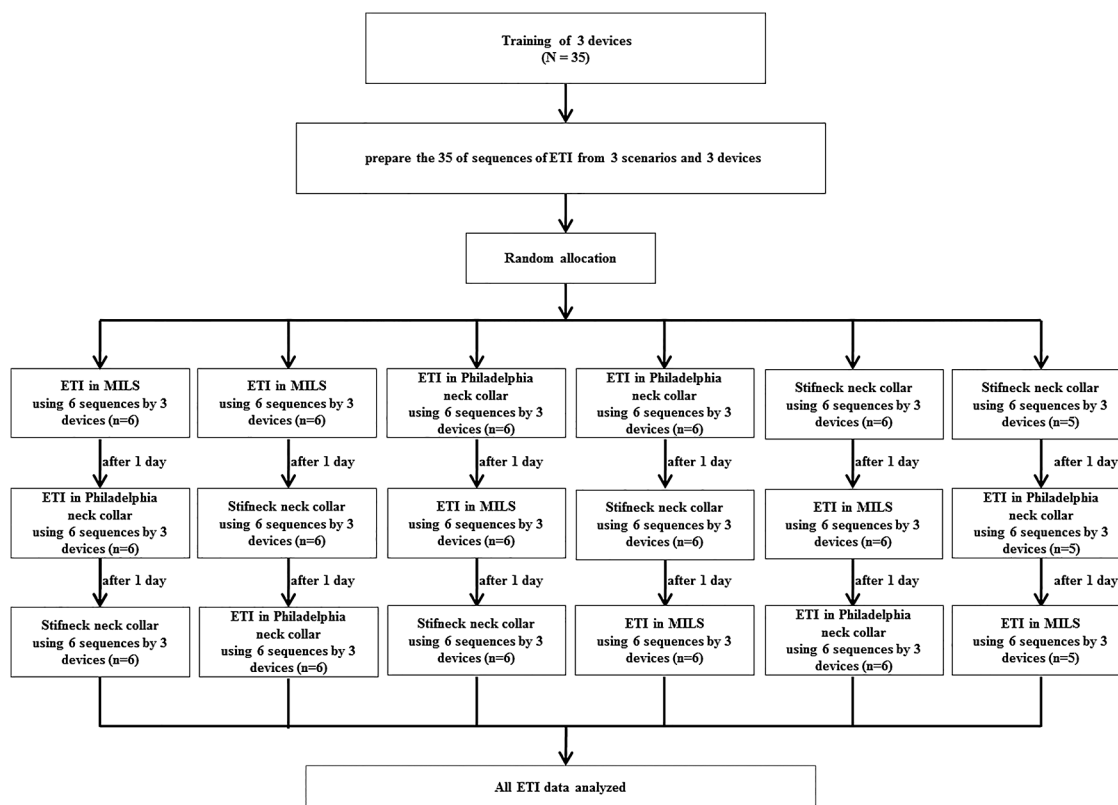


Figure 1 Flow diagram of the study.

of the vocal cords or failed intubation). Data were analysed using IBM SPSS Statistics for Windows software (V.21.0; IBM, Seoul, Korea).

RESULTS

Thirty-five physicians participated in the study. Their mean (SD) age was 31.1 (2.7) years, and 22 (62.8%) were men. Of the 35 physicians, 14 were emergency physicians, 8 worked in intensive care and 13 worked in general ward rooms. Twenty-four had experienced 30–40 successful ETIs, eight had experienced 40–50 successful ETIs and three 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 GVL (table 1). First-attempt success rate of ETI by 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 with 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. Owing to 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 stabilisation	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)	–
Neck immobilisation with a Philadelphia neck collar	Pressure to teeth, n (%)	12 (34.3)	22 (62.9)	6 (17.1)	<0.001
	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
Neck immobilisation with a Stifneck collar	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
	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

ETI, endotracheal intubation; PAWS, Pentax Airway Scope.

Table 2 Number of attempts of intubation trial for successful endotracheal intubation in three scenarios

Devices	Number of successful ETIs	Number of attempts for success			p Value
		1 (%)	2 (%)	3 (%)	
Manual in-line stabilisation					
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 immobilisation 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 immobilisation 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)	

ETI, endotracheal intubation; PAWS, Pentax Airway Scope.

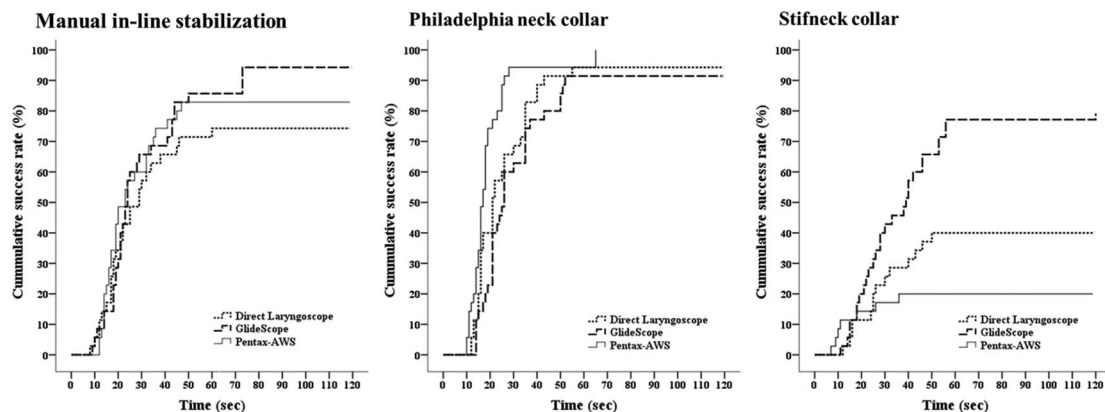


Figure 2 Kaplan-Meier analysis of cumulative endotracheal intubation success rate using direct laryngoscopy, GlideScope and Pentax AWS in various cervical immobilisation scenarios: manual in-line cervical stabilisation, Philadelphia neck collar and Stifneck collar. ETI, endotracheal intubation; MILS,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

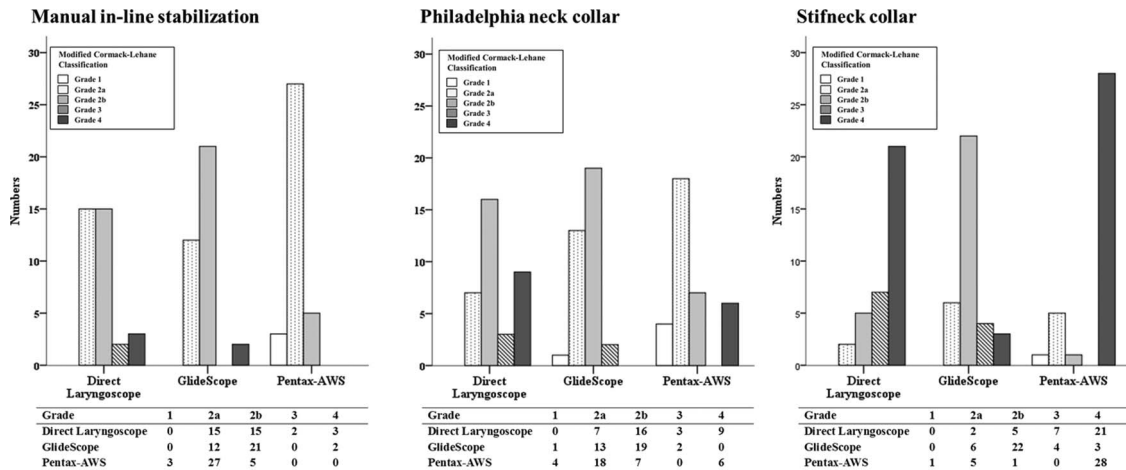


Figure 3 Graphs of Modified Cormack-Lehane classifications of endotracheal intubation using direct laryngoscopy, GlideScope and Pentax AWS in various cervical immobilisation scenarios: manual in-line cervical stabilisation, Philadelphia neck collar and Stifneck collar. Pentax AWS, Pentax Airway Scope.

DISCUSSION

Neck immobilisation is an inevitable obstacle to the success of ETI in patients with trauma.^{3 4} Establishing optimal methods or devices for successful ETI is a key requirement in the airway management of patients with trauma 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 randomised cross-over study to compare the success of ETI in patients with cervical stabilisation and related data from physicians performing DL, GVL and PAWS in various simulated neck immobilisation 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 immobilisation scenario (moderate limit of mouth opening), GVL showed the highest ETI success rate (94.3%), followed by PAWS (82.9%). Under the Stifneck collar cervical immobilisation 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 immobilisation while intubating patients with trauma with suspected cervical spine injury.² However, its safety and effectiveness in MILS during intubation has been questioned by various studies.¹¹ Some data suggest that MILS may not properly support full immobilisation 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 visualisation by preventing head extension and neck flexion, and this may adversely affect the patient outcome by delayed or failed intubations.^{14 15} A too rigid position in MILS especially increases 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 similarly showed a 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 in 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. In 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*,⁸ 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). A clinical study by Malik *et al*⁶ reported a 100% success rate for DL in MILS with an indefinite time permitted for ETI. 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. Another study has shown higher success rates of ETI in the simulation setting.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 shortening the time to intubation.¹⁷

A neck collar is commonly used to immobilise the cervical spine with the aim of avoiding any secondary injury to the spine in traumatised patients. The collar interrupts the view of the glottis, as well as 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 ETI with MILS after removal of the collar's anterior part might be a better option to the patients with neck collar immobilisation.

However, considering some practical limitations of MILS, the immediate intubation without neck collar removal is not easily abandoned in patients wearing neck collars. 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 either not available on site or is not able to administer a 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 immobilise 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 supraglottic 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 contravene ethical guidelines. In 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 a low ETI success rate and delay in time to complete ETI by DL in scenarios where a cervical collar was used for immobilisation compared with stabilisation with MILS. In this 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 shown that cervical collars significantly reduce the 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 maximised where a Philadelphia cervical collar is used for immobilisation. 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 interincisor 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 immobilisation technique. Participants who were unfamiliar with 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 was proper laryngoscope to use for ETI among the various devices in various cervical immobilisation scenarios. Airway device selection might primarily depend on individual skill levels and preference, as well as on the institutional availability of equipment. However, not all patients with trauma needing emergency airway management can be managed in the same way. In prehospital or hospital settings, various neck immobilisation scenarios may exist during ETI in

patients with trauma 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 patients with trauma with cervical injury. The strategy should not be tailored solely to the physician's abilities, but also to the neck immobilisation 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 neurological compromise. When patients require emergency ETI under cervical collar immobilisation, DL may 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 a 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 immobilisation 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 GVL and PAWS, these novel devices were less familiar to the participants who were more experienced with DL. Our participants were familiar with DL than novel video laryngoscope. It may affect a relatively higher positive outcome such as success in ETI and lower incidence of 'pressure to teeth'. Third, this study was conducted with a simulation design using a manikin. A simulation study cannot realise the anatomical variance of humans and the possible conditions for patients with trauma 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 particular, PAWS may be more vulnerable to blocking of the camera lens than 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 GVL.

Contributors SOP conceived and designed the study. SOP, DYH and KRL took part in procedure of simulation trials. JWK and SOP participated in writing and correcting the manuscript. All authors participated in analysis and interpretation of data. All authors read and approved the manuscript. SOP takes responsibility for the paper as a whole.

Competing interests None declared.

Ethics approval Konkuk university hospital Institutional Review Board .

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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