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Evaluating the Use of the Universal Stylet Bougie (USB) on Intubation time among Patients with simulated Cervical Spine Immobilization by Using a Rigid Collar

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KEYWORDS

USB, cervical spine, Immobilizatio , rigid collar.

Abstract:

Background: Airway management in patients with cervical spine injuries who require cervical stabilization represents a challenge to anesthesiologists. Several devices and intubating techniques have been investigated to reach the best practice for these patients. Awake fiberoptic intubation represents the most secure method for endotracheal intubation in these patients however, its lack of constant availability remains its major constraint. The video laryngoscope is the second most-used device in patients with cervical spine injuries. Together with the help of the aiding devices for endotracheal intubation, the video laryngoscope had increased success rates in difficult airway situations.The USB device represents an advancement in airway management as it has a unique design that enables it to be used as a stylet or bougie. In this study, we aimed to investigate the use of the USB device in shortening the intubation time in a simulated difficult airway scenario by limiting neck extension using a rigid neck collar.

Methodology:45 ASA I and II patients undergoing elective surgery under general anesthesia and requiring endotracheal intubation were enrolled in the study. A rigid cervical collar was applied to all patients after anesthetic induction to simulate a difficult airway condition. They were assigned to 3 groups. In group A, ETI was done using the USB as a bougie. In group B, ETI was done using the USB as a stylet. In group C, ETI was done by the video laryngoscope alone.

Results: the use of the USB as a bougie was superior in reducing the intubation time significantly (45.7 seconds) more than using it as a stylet (83.1 seconds). It also achieved a 100 % incidence of successful endotracheal intubations as a bougie versus 86.67 % as a stylet. Moreover, the incidence of the successful first attempt was 93.33 % in using the USB as a bougie while using it as a stylet had 66.67% of the successful first attempt of tracheal intubations.

Conclusion: The USB device had a more effective role as a bougie than as a stylet in shortening the intubation time and achieving higher intubation success rates in patients with simulated difficult airway conditions using rigid neck collars.

INTRODUCTION:

Airway management in patients with cervical spine injury who require adequate immobilization of the unstable cervical spine to avoid serious neurological damage represents a very challenging situation for the anesthesiologist. (1) Several methods have been used to stabilize the spine, however, the most effective and advisable by advanced trauma life support (ATLS) is the application of a neck collar. Although the application of a cervical collar is favorable, it increases the difficulty of endotracheal intubation with a standard Mackintosh laryngoscope as it limits the mouth opening, prevents neck extension, and subsequently impairs glottic visualization.(2)

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Various intubating techniques and devices have been investigated in patients with cervical spine injury among which, thefiberoptic and video-assisted laryngoscopies. Awake fiberoptic intubation is considered by far the most reliable method in cervical spine trauma patients however, lack of availability and experience of use remain its main constraints.(3)

The second most used device in patients with unstable cervical spine who require cervical immobilization is video assisted laryngoscope.The video laryngoscope allows for glottic visualization with minimal neck movement compared with the conventional Mackintosh laryngoscopy. (4)

Other aiding devices used in endotracheal intubation are stylet or a tracheal tube introducer ("bougie"). A stylet is a malleable metal rod placed inside the endotracheal tube to facilitate its passage into the trachea. A bougie is a thin plastic rod passed into the trachea, over which the endotracheal tube is inserted.(5)

The Universal Stylet Bougie, or USB™, represents an advancement in the design and development of tracheal introducers (bougies) and stylets. The traditional design of the stylet and bougie has been considered incompatible. The stylet requires certain rigidity to allow different angulations of the tracheal tube. However, the bougie needs to be malleable enough to allow positive alignment with the trachea and hence correct placement of the tracheal tube. (6)

The unique design of the USB™ means that the device can be used as a stylet or as a bougie. It consists of two metals inserted on both sides and a flexible middle section. The USB can easily be manipulated to a variety of angles when used as a stylet. Also, it has the flexibility required to be used as a bougie. In addition, the hexagonal shape provides less contact with the inner surface of the tracheal tube, providing particularly easy insertion and removal. (6)

In this study, we are simulating a difficult intubating condition by limiting the cervical neck extension by applying a rigid neck collar.Subsequently, we will assess whether using the USB device could improve the successful rate of intubation in these patients.

Aim of the study:

Our study aims to evaluate and compare the use of Universal Stylet Bougie (USB) when it is used as a bougie versus when it's used as a stylet, on the intubation time using video laryngoscope in patients with cervical spine immobilization using a rigid neck collar.

Sample size calculation:

The sample size calculation was done by G*Power 3.1.9.2 (Universitat Kiel, Germany). According to a previous study (7), the mean ± SD of intubation time (the primary outcome) was 26.83 ± 8.61 min with Stylet Group and 47.18 ± 16.46 min with Bougie Group. The sample size was based on the following considerations: 1.54 effect size, 95% confidence limit, 95% power of the study, group ratio 1:1, and three cases were added to each group to overcome dropout. Therefore, we will recruit 15 patients in each group.

Methodology:

This is a prospective, randomized single-blinded controlled study that was conducted in theDepartment of Anesthesia and Surgical Intensive Care Unit at Theodor Bilharz Research Institute after approval by the research ethics committee and patient informed consent. The trial was registered at ClinicalTrials.gov.ID: NCT06521749.

45 Patients were enrolled in the study and randomized using computer-generated random numbers then divided into three groups. Because of difficulties with blinding an intubation device, experienced anesthesiologistsand research assistants were not blinded to the study group, only the patients were blinded.

Patients were allocated, according to the study group into:

- **Bougie Group: (Group A):**Endotracheal intubation was attempted using the video laryngoscope and the USB device was used as a bougie. (Figure 1)

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- **Stylet Group: (Group B):**Endotracheal intubation was attempted using the video laryngoscope and the USB device was used as a stylet. (Figure 2)
- **Control Group: (Group C):**Intubation of the trachea with an endotracheal tube was attempted by using only the video laryngoscopy.

Figure 1: USB as a bougie. (6)

Figure 2: USB as a stylet. (6)

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45 ASA I and II, aged 18- 60 years old undergoing elective surgery under general anesthesia and requiring tracheal intubation were included in the study. Patients with any of the following were excluded from the study: Age < 18 years and ≥ 60 years, Pregnancy, BMI >35 kg/m^2, Emergency surgery or full stomach, Patients with suspected difficult airway; e.g., high neck circumference, airway masses, mouth scars, neck scars, or history of snoring, patients with cervical spine pathology and patients with any cardiac disease.

Anesthesia Technique:

A preoperative assessment, including a history, physical examination, laboratory data review, and ASA classification assignment, was performed on all patients before the procedure. Anesthesia and procedural consent will be obtained.

Upon arrival to the operating room, basic monitoring including Electrocardiography (ECG), Non-invasive Blood Pressure (NIBP) monitor and pulse oximetry were attached, nerve stimulator was to ensure adequate muscle relaxation. Baseline readings including blood oxygen saturation (Spo2), heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were recorded.

All patients were pre-oxygenated with four to five breaths of 100% oxygen and Intravenous induction of anesthesia using propofol (2 mg/Kg), fentanyl (1.5 µg/Kg) and atracurium (0.5 mg/Kg). After 3 minutes of mask ventilation with 1 MAC (minimum alveolar concentration) of sevoflurane, the neck was immobilized with a rigid cervical collaradjusted to the correct size and applied according to the manufacturer's instructions. Endotracheal intubation was performed by an experienced anesthesiologist using the video laryngoscope (BESDATA ® BD-DF Reusable video laryngoscopy).

Patients were randomly assigned into either**:**

A) Bougie Group :

The USB was used as a bougie. After the video laryngoscope was inserted into the mouth and adequate glottic visualization was achieved, the anesthesiologist attempted to pass the bougie into the trachea. If successful, an assistant loaded the endotracheal tube over the bougie and the anesthesiologist guided the tube through the vocal cords and into the trachea to the desired depth while keeping the laryngoscope in the mouth.

B) Stylet Group :

The USB was used as a stylet. After the video laryngoscope was inserted into the mouth and adequate glottic visualization was achieved, the anesthesiologist attempted to intubate the trachea with an endotracheal tube + stylet with a bend angle of 25 degrees – 35 degrees. If difficulty in the passage was encountered, the anesthesiologist withdrew, rotated, or reshaped the tube and stylet it as needed.

C) Control Group :

After the video laryngoscope was inserted into] the mouth and adequate glottic visualization was achieved, the anesthesiologist attempted to intubate the trachea with an endotracheal tube using video Laryngoscopy only.

Tracheal intubation was considered a failure if it was not accomplished within three attempts, or in the event of desaturation (SPO2< 90%). Generally, face mask ventilation was carried between attempts, to maintain oxygenation.

If attempting endotracheal intubation failed, the rigid collar was removed, facemask ventilation was resumed and the trachea was intubated with the video laryngoscope according to the decision of the anesthesiologist in charge.

Primary outcome:

The time required for intubation was the time measured afterthe application of the video-laryngoscope inside the mouth and glottic visualization till the inflation of the endotracheal tube cuff.

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Secondary outcome:

1- The number of attempts

2- Intubation success rate.

3- Lip or dental injuries were assessed after the procedure.

4- Incidence of oesophageal intubation.

Statistical Analysis

Statistical analysis was done by SPSS v27 (IBM©, Chicago, IL, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean and standard deviation (SD) and were analyzed by ANOVA (F) test with post hoc test (Tukey). Qualitative variables were presented as frequency and percentage (%) and were analyzed utilizing the Chi-square test. A two-tailed P value < 0.05 was considered statistically significant.

Results:

In this study, 60 patients were assessed for eligibility, 9 patients did not meet the criteria and 6 patients refused to participate in the study. The remaining 45 patients were randomly allocated into three equal groups (15 patients in each). All allocated patients were followed up and analyzed statistically. (Figure 3)

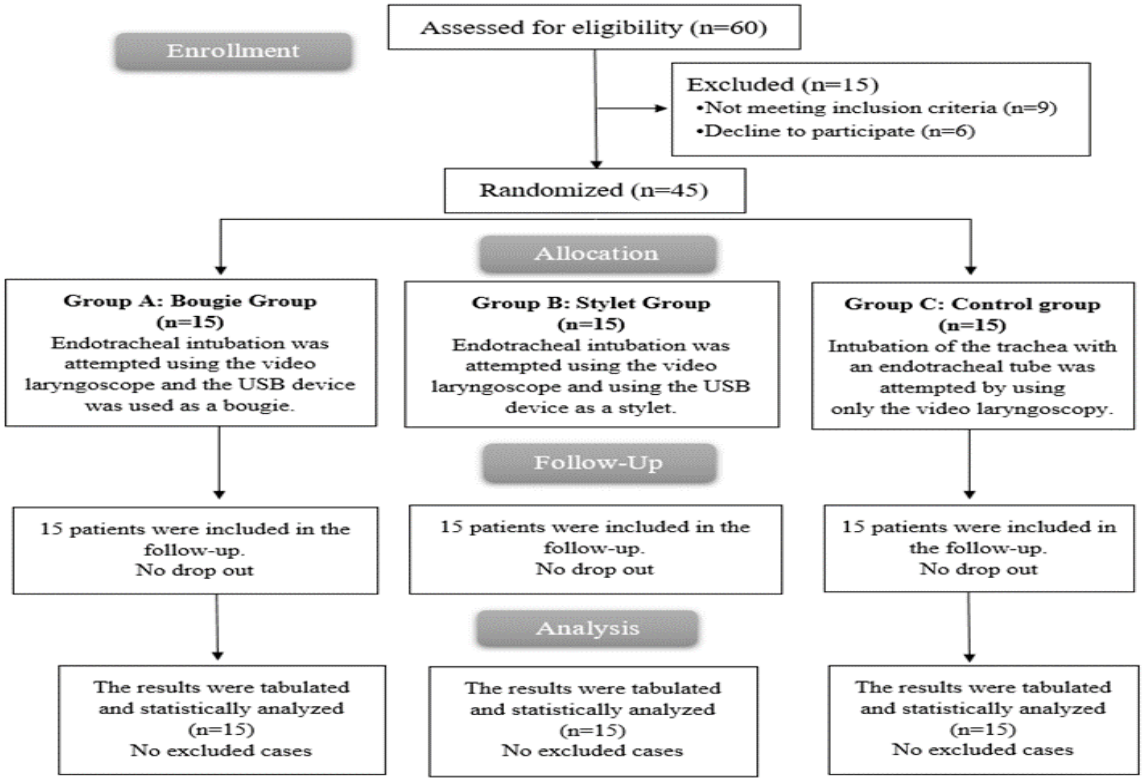

Figure 3: Flow chart.

The demographic data including age, sex, ASA, and BMI of the studied groups showed no significant difference between them. Table 1

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Table 1: Demographic data and BMI of studied groups:

			Group A (N=15)	Group B (N=15)	Group C (N=15)	P-value
Age (Years)	:	mean ± SD	44.9 ± 8.94	45.3 ± 10.27	43.8 ± 10.69	P:0.99
Sex	:	Male	6 (40%)	8 (53.33%)	6 (40%)	0.698
		Female	9 (60 %)	7 (46.67%)	9 (60%)	
ASA	:	I	7 (46.67%)	8 (53.33 %)	12 (80%)	0.126
		II	6 (40%)	7 (46.67%)	3 (20%)	
		III	2 (13.33%)	0 (0%)	0 (0%)	
BMI (Kg/m^2)	:	mean± SD	26.1± 2.49	25.7 ± 2.18	26.1± 2.08	0.863

ASA: American Society of Anaesthesiologists, BMI: Body mass index. Data presented as mean± SD or Number (%) as appropriate.*Significant as P value ≤0.05.

The Mallampati classification of the studied groups did not show any significant difference between them. Table 2.

Table 2: Mallampati classification of the studied groups:

			Group A (N=15)	Group B (N=15)	Group C (N=15)	P-value
Mallampati classification	:	I	4 (26.67 %)	3 (20%)	5 (33.33%)	0.281
	:	II	7 (46.67 %)	8 (53.33%)	10 (66.67%)	
		III	4 (26.67%)	4 (26.67 %)	0 (0%)	

Data presented as Number &%.

Analysis of the intubation criteria showed the following: Intubation time was lower in the A group (45.7 ± 12.74) than in the B group (83.1 ± 23.09) with a highly significant P1-value (< 0.001). It was also lower in Group A (45.7 ± 12.74) than in GroupC (94.1± 9.47) with a highly significant P2-value (< 0.001).The intubation time was also lower in group B (83.1 ± 23.09) in comparison with group C (94.1± 9.47) with no significant difference between them. (P3-value = 0.162). Table 3

The incidence of a successful 1st attempt was higher in the A group (93.33%) than in group B (66.67%) with no significant difference between them. Also, the incidence of a successful 1st attempt was significantly higher in group A (93.33%) than in group C (40%) with a P-value (P=0.003). In addition, itwas higher in Group B (66.67%) than in Group C (40%) there was no statistical difference between them. Table 3

The number of attempts of tracheal intubation showed the following: group A had the least number of attempts compared to groups B and C. Although, the number of attempts was lower in Group A than in Group B, there was no significant difference between them. Also, the number of attempts was significantly lower in Group A and Group B than in Group C with a P-value (< 0.001). Table 3

The rate of successful tracheal intubation was significantly higher in group A (100%) and group B

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(86.76%) than in group C (40%) with a P-value (<0.001). Table 3

Table 3: Analysis of the intubation criteria showed the following:

			Group A (N=15)	Group B (N=15)	Group C (N=15)	P-value
Intubation time	:	Mean ± SD	45.7 ± 12.74	83.1 ± 23.09	94.1± 9.47	P1< 0.001*
						P2<0.001*
						P3=0.162
Incidence of successful 1st attempt	:	N (%)	14 (93.33%)	10 (66.67%)	6 (40%)	P1=0.068
						P2=0.003*
						P3=0.198
N. of attempts	:	One	14 (93.33%)	9 (60%)	1 (6.67%)	< 0.001*
		Two	1 (6.67%)	3 (20%)	5 (33.33%)	
		Three	0 (0 %)	2 (13.33%)	8 (53.33%)	
Intubation success rate	:	N (%)	15 (100 %)	13 (86.67%)	6 (40%)	< 0.001*

Data presented as mean± SD or Number (%) as appropriate.*Significant as P value ≤0.05,P1: P value between Group A and Group B, P2: P value between Group A and Group C, P3: P value between Group B and Group C.

Analysis of the adverse events that occurred during tracheal intubation showed the following: accidental Oesphgeal intubation did not occur in any of the patients of group A. However, it had a higher significant incidence in group C (33.33%) than in group B (13.33%) with a P-value (0.04). Incidence of lip or dental injury was significantly higher in group C (33.33%) than in group B (13.33%) versus none of the patients of group A with a P-value (0.040).The incidence of hypoxia was significantly higher in group C (33.33%) versus 0(0%) in groups A and B with a P-value (0.004). Postoperative sore throat was significantly higher in C group 3 (20%) versus 0 (0%) in both groups A and B with a P-value (0.040).

Table 4: Adverse events during tracheal intubation:

			Group A (N=15)	Group B (N=15)	Group C (N=15)	P-value
Incidence of Oesphgeal intubation	:	N &%	0 (0%)	2 (13.33%)	5 (33.33%)	0.040*
Incidence of injury	:	N &%	0 (0%)	2 (13.33%)	5 (33.33%)	0.040*
Incidence of hypoxia	:	N &%	0 (0%)	0 (0%)	5 (33.33%)	0.004*
Incidence of sore throat	:	N &%	0 (0%)	0 (0%)	3 (20%)	0.040*

Data presented as Number &%.

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Hemodynamic measurements of the studied groups showed the following: heart rate (Figure 4) and MAP (Figure 5) measurements at different time points were comparable between the 3 groups. Also, there was no statistically significant difference between the HR measured after 1 minute of intubation between the studied groups.(Figure 4).

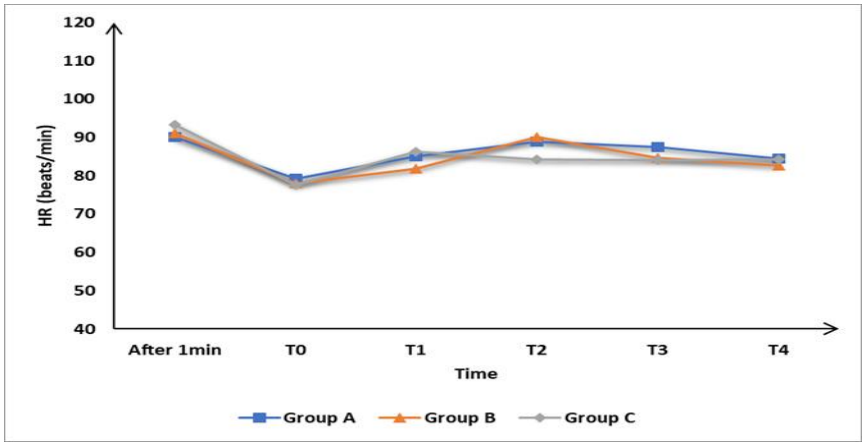

Figure 4: HR measurements of the studied groups.

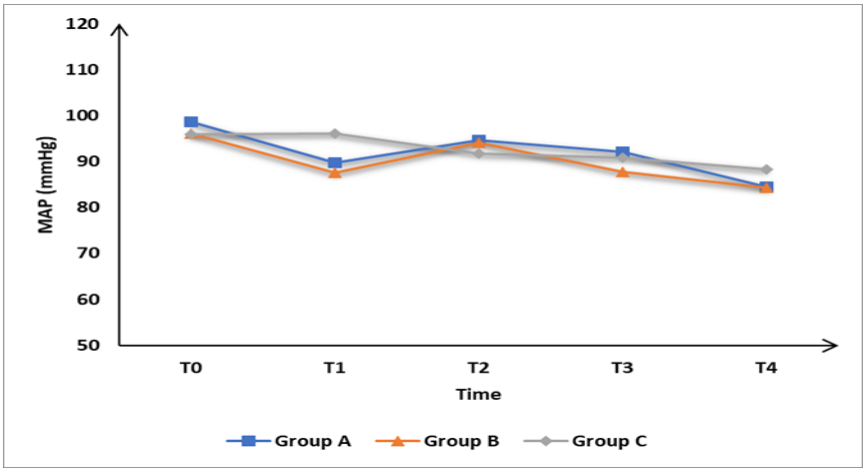

Figure 5: MAP measurements of the studied groups.

Spo2 measurements at different time points were in the clinically accepted ranges in the 3 groups, yet it showed the following: there was no statistically significant difference between Spo2 measured at T0, T3, and T4 between the studied groups. However, Spo2 measured at T1 was significantly higher in groups A and B than in group C with a P-value of (0.002 and 0.009) respectively. Also, there was a significant difference between spo2 measured at T2 as it was significantly higher in groups A and B than in group C with P-values (0.015 and 0.025) respectively. There was no statistically significant difference between Spo2 measured at T1 and T2 between groups A and B (Table 5)

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Table 5: Spo2 measurements of the studied groups:

			Group A (N=15)	Group B (N=15)	Group C (N=15)	P-value
T0	:	Mean ± SD	98.73 ± 0.59	98.6 ±0.83	98.6 ±0.63	0.831
T1	:	Mean ± SD	99.8 ± 0.41	99.13± 0.64	95.13 ± 6.02	P1=0.86 P2= 0.002* P3=0.009*
T2	:	Mean ± SD	100 ± 0	99 ± 0.26	99 ± 1.6	P1=0.979 P2=0.015* P3=0.025*
T3	:	Mean ± SD	100 ± 0	100 ± 0	99.93 ±0.26	0.376
T4	:	Mean ± SD	100 ± 0	100 ± 0	99.93 ±0.26	0.376

Data were presented as mean ± SD.*Significant as P value ≤0.05, P1: P value between Group A and Group B, P2: P value between Group A and Group C, P3: P value between Group B and Group C.

Discussion:

The current study evaluated the USB device with its unique design which enables it to be used as a bougie or as a stylet in a simulated difficult airway scenario using a rigid cervical neck collar and a video-assisted laryngoscope.Its use as a bougie was superior inreducing the intubation time (45.7 seconds) more than using it as a stylet(83.1 seconds). It also achieved a 100 % incidence of successful endotracheal intubations as a bougie versus 86.67 % as a stylet.Moreover, the incidence of the successful first attempt was 93.33 % in using the USB as a bougie while using it as a stylet had 66.67% of the successful first attempt of tracheal intubations.The number of attempts to achieve successful tracheal intubation was lowest with the USB as a bougie than with using it as a stylet.

Despite that, the video laryngoscope hasrecently proven as an effective device in glottic visualization. Yet, its sole usage did not achieve a high success rate in the current study. The simultaneous use of the USB device and the video laryngoscope decreased the incidence of oesphgeal intubations from 33.3% in the video laryngoscope group to 13.3% in the stylet group and 0 % in the bougie group. Regarding the local airway complications associated with endotracheal intubation;lip injury, dental injury, and postoperative sore throat showed higher incidence in the control group compared to both bougie and stylet groups, this might be due to multiple trials of endotracheal intubations performed in patients of thecontrol group.

Cervical spine immobilization by hard neck collars or manual inline stabilization has been known as the best practice methodto prevent secondary brain damage and fatal neurological consequences by eliminating 50% of abnormal and excessive movements of unstable cervical vertebrae. Restricting the motion of the cervical spine prevents the direct alignment of the oropharyngeal structures required by the standard Mackintosh laryngoscope to achieve successful tracheal intubation. (8) Recently many alternative intubating devices have been developedthatdon’t need alignment of the laryngeal, pharyngeal, and oral axes to achieve successful tracheal intubation.Therefore they might be of superior benefit over the standard laryngoscopy in certain situations. (9)

According to Barry N. Singleton, et al 2021meta-analysis, they evaluated a variety of 26 devices excluding the flexible fiberscope in adult patients with cervical spine immobilization.The main finding of this study was that most of the used devices

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e.g.: McGrath™, C-MAC™ D Blade significantly improved first-pass success of endotracheal tube (10) and provided higher Cormack - Lehane grade I of tracheal inlet viewin these patients. (11)Although these devices reduced the local airway complications, none of them significantly decreased intubation times compared to the Macintosh, which had an average intubation time of 36.7 seconds (range: 11.0 - 73.2 seconds).(12) In the current study, the used technique for endotracheal intubation managed to reduce the intubating time (45.7 ± 12.74 seconds) in the bougie group and (83.1 ± 23.09 seconds) in the stylet group.

In 2024, Debas Y. Melesse,et al conducted another systematic review and meta-analysis involving 73 studies. These studies involved a variety of intubating devices and different intubating techniques used in patients with cervical spine injuries. (13)They reported that Awake fiberoptic intubation is an excellent option for cooperative patients with elective and semi-urgent cervical spine injuries. Its main advantage is that it enables monitoring of neurologic statusbefore and after endotracheal intubation.However, the lack of constant availability remains its main drawback besides the longer intubation time than theMacintosh laryngoscope reference device. (14)

Video laryngoscope with its variable versions has recently gained popularity in difficult airway management scenarios. (15)Meta-analyses of RCTs comparing video-assisted laryngoscopy with direct laryngoscopy in patients with predicted or simulated difficult airways reported improved laryngeal views, a higher frequency of successful intubations, and a higher frequency of first-attempt intubations with video-assisted laryngoscopy. However, there were no differences in the intubation time or local airway complications. (16)These data suggested that for patients with cervical spine immobilization, a video laryngoscope should be the preferred method of intubation in the emergency department. (17)

Bougie is one of the adjuvant devices thatease endotracheal intubation in patients with difficult airway and it was rated according to the Malaysia National Audit on Anesthetic Airway Management (2015) as the 2nd most preferred device (24.8%) after the video Laryngoscope (44.6 %). (18).It was also previously reported that itincreases thefirst-attemptsuccess rate of endotracheal intubation. (19)

Up to the knowledge of the authors, the USB device has not been investigated as an aiding device in endotracheal intubation of simulated difficult airway scenarios. Different types of bougies and stylets have been investigated in elective, emergency, simulated difficult scenarios, and manikins designed for special airway management cases.

Brian E. Driver, et al 2018comparedthe standard bougie with an endotracheal tubeequipped with a styletin the emergency room setting and found, that using a bougieresulted in a higher first-attempt intubation success rate (96 %) versus (87 %) for the endotracheal tube equipped with a stylet. However, the intubation time was insignificant between the bougie group (36 seconds) and the stylet group (38 seconds). (20) These results align with our results regarding the higher success rate of 1st attempt in the bougie group 93.33% versus 66.67% in the stylet group. However, in our study, we found that the bougie group had the shortest intubation time compared to the stylet and the control groups. The main difference between the current study and Brian E. Driver, et al is that the chosen criteria of airway difficulty were based on a subjective assessment of the patient by the anesthesiologist in charge before and during intubation which made the interpretations very variable. However, in the current study, we applied rigid cervical collars to all patients which unify the difficulty factor in all patients.

George Kovacs, et al (2007) designed a comparative manikin study to evaluatethe standard bougie and a fiberoptic stylet in a difficult airways scenario and reported a comparable mean time tosuccessful intubation of 31 seconds in fiberoptic stylet versus 45 seconds in the bougie group. (21) Unlike our results which showed that using the USB device as a bougie achieved the shortest intubation time (45.7 seconds) compared to (83.1 seconds) for the stylet group

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and (94.1 seconds) for the control group. The difference between our results and the previously mentioned study might be becausethe manikin model didn't reflect the actual degree of difficulty present in patients with cervical spine injuries. This might have causedthe fiberoptic stylet to be significantly more effective than the bougiein facilitating tracheal intubation.

MuhammetKorkusuz, et al 2023 investigated the use of a videolaryngoscopeand a stylet to assess the intubation time in obese patients.The intubation times of obese patients were shorter with direct laryngoscopy, with orwithout a stylet when compared to those with the videolaryngoscope, with or without a stylet.Also, the use of stylet did not shorten the intubation time. (22)These results come along with our results regarding, the intubation time which was comparable between in stylet group and the control group. However, the main limitation of MuhammetKorkusuz, et al study is the selection of obese patients which represents a different aspect of airway difficulty.

According to Jaden Tollman, et al meta-analysis done in 2022 investigating tracheal tube introducers' use in the pre-hospital settings. They stated that the bougie had a higher significance over the stylet when combined with the video laryngoscope. Also, they suggested that stylets offer speed of endotracheal tube insertion while bougies provide ease of use. Both of the aiding devices had similar rates of complications. They concluded that in the absence of a video laryngoscope, endotracheal intubation should be carried out according to the experience of the health practitioner and the personal preference of the device used. (23)

Limitation: The main limitation of this study, is that the blinding of the intubating device is not possible. This might lead to the potential bias of the performer and the assessor. The other limitation is that the USB device was not investigated with the reference device of endotracheal intubation which is the Mackintosh laryngoscope so further studies are required to compare its effectiveness with the standard Mackintosh laryngoscope.

Conclusion: The use of the USB device as a bougie was superior to its usage as a stylet in shortening the intubation time and achieving higher success rates of 1st intubation attempt in patients with cervical spine immobilization by a rigid neck collar.

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