

Comparison of Gum Elastic Bougie and Macintosh Laryngoscope in Pre-hospital Pediatric Airway Management; A Randomized, Prospective Study

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Abstract

Objective: Endotracheal intubation (ETI) in children requires good techniques and experience. Gum elastic bougie (GEB) is a practical, inexpensive, easy-to-use airway method in the adult airway. Through GEB, ETI is a method that can be learned after a short training. We evaluated the effectiveness of this method, which has not yet been validated in pediatric patients in prehospital pediatric airway applications.

Materials and Methods: This study was designed as a study simulating the prehospital period with a mannikin. Practitioners were asked to perform intubation by conventional intubation or GEB.

Results: This study was conducted with 48 emergency medical technicians and paramedics. Four (8.3%) of the practitioners had experience using GEB. In terms of first-pass success, no difference was found between ETI via GEB and Macintosh blade conventional ETI [91.7% (44/48), 93.8% (45/48), respectively, $p=1.000$]. Use of GEB increased ETI time [28.6 ± 6.0 sec vs. 17.1 ± 4.0 sec, mean df: 11.3 sec (95% CI: 9.7-12.8), $p<0.001$]. While 87.6% of the practitioners evaluated the use of GEB as very easy and easy, 83.3% of the practitioners evaluated the traditional method as very easy and easy ($p=0.914$).

Conclusion: GEB does not make any difference in pediatric airway management in terms of first-pass success. However, the use of GEB in terms of ETI durations increases the duration of ETI. Besides, the use of GEB is seen as a method that can be applied more efficiently, even in inexperienced groups.

Keywords: Airway control, gum elastic bougie, pediatric, pre-hospital

Introduction

Endotracheal intubation (ETI) in children requires good techniques and experience. Since the pediatric airway is more sensitive to trauma, repetitive intubation attempts should be avoided [1]. The correct selection of the tube size, the laryngoscope's blade, and the pediatric airway anatomy knowledge are essential. Gum elastic bougie (GEB) is a practical,

inexpensive, and easy-to-use airway method in the adult airway [2,3]. ETI through GEB is a method that can be learned after a short training [4]. The use of this method in pediatric patients has not yet been confirmed.

Pediatric and adult airways have distinct anatomical differences (prominent occiput, large tongue, etc.). These differences should be known in airway management.



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The American Society of Anesthesiologists defined a difficult airway as the inability to insert the endotracheal tube in three or more attempts with direct laryngoscopy or more than 10 minutes [5]. Tests and evaluation methods used for difficult intubations are generally not appropriate or practical for children [6]. The difficult airway is defined as the clinician’s difficulty during ventilation, laryngoscopy, and intubation [7]. The difficult airway is a significant cause of brain damage, cardiac arrest, and death in pediatric patients [8]. However, studies have which the success rate at the first attempt in difficult intubation with direct laryngoscopy in pediatric patients is 3% [9].

It would be appropriate to use a high first entry success method, rapid application, easy to learn, and inexpensive method in ensuring airway safety of pre-hospital pediatric patients.

This study compares the first entry success and intubation times of Macintosh laryngoscope and GEB applications on a pediatric airway model after pre-hospital healthcare workers’ pediatric airway training. It is predicted that GEB will increase the chances of success.

Materials and Methods

This study was designed as a randomized, prospective crossover ambulance simulation study using mockups. Kocaeli University Non-Interventional Clinical Research Ethics Committee approval was obtained for our study (2018/202).

Emergency medical technicians (EMT) and paramedics working in emergency health services were included in this study. The study was conducted in a training hall environment with 48 participants during the 10th and 11th months of 2018. EMT and paramedics, who will perform the ETI intervention, were given general information about the study, but they were blinded to its specific purpose. Before the study, the participants were given theoretical training on the ETI procedure and GEB by an emergency medicine specialist. Later, the participants were allowed to practice on the mannequin with both the Macintosh blade and the GEB when they felt sufficient (approximately 30 min each), and practical training was given (Figure 1). Written consent was obtained from those who wanted to participate in the study. In the study, “Advanced Child Airway Management Trainer with Stand LF03762U life/form the USA” a model of an 8-year-old child that allows ventilation with BVM suitable for human anatomy was used. PlusMed brand number 2 Macintosh blade, 12 Fr, 65 cm long VBM Medizintechnik brand GEB, Beybi brand 5.5 mm ETT, BVM, lubricant were used.

Participants were randomized after obtaining written consent. For both groups, an equal number of cards were created for each group with 1 or 2 on the same scale. The cards were folded in half, and each card was placed in a dark envelope. Envelopes were mixed in a bowl and participants were asked

to select an envelope. Participants who chose one were asked to do ETI with a Macintosh blade first and then via GEB, and those who chose two were asked to do ETI via GEB first and then with a Macintosh blade.

A camera was placed in the study room to see the stretcher and participant. Throughout the study, the participants were informed that the video would be recorded. The data related to the video were transferred to pre-prepared data entry forms. Since the participants made their attempts in the ambulance in a sitting position, they were allowed to attempt the same position as the ambulance stretcher and the same height as the ambulance practitioner seats in a sitting position. The lubricant was applied to the endotracheal tube before ETI. Holding the laryngoscope by the practitioner was considered the start time of the intervention. The end time was determined when intubation on the model was observationally successful (ventilation of the lungs with BVM after ETI). Each participant was given 2 min for each method. Regardless of which method the participants started randomly, they were asked to try the same method again in case of unsuccessful attempts. Participants’ first login success, ETI durations, a number of attempts, ETI experiences were recorded. After all, attempts were completed, the participants were asked to evaluate the difficulty levels of the intervention methods according to the Likert scale as 1- very easy, 2- easy, 3- neutral, 4- difficult, and 5- very difficult. The responsible researchers regularly checked the data collection and recording processes.

The primary outcome variable of the study was defined as initial success. Secondary outcome variables; ETI time, the number of trials for ETI, and difficulty rating according to the Likert scale.

Statistical Analysis

The study’s data were analyzed using the “SPSS for Windows, Version 20.0” package program. The study’s data were presented

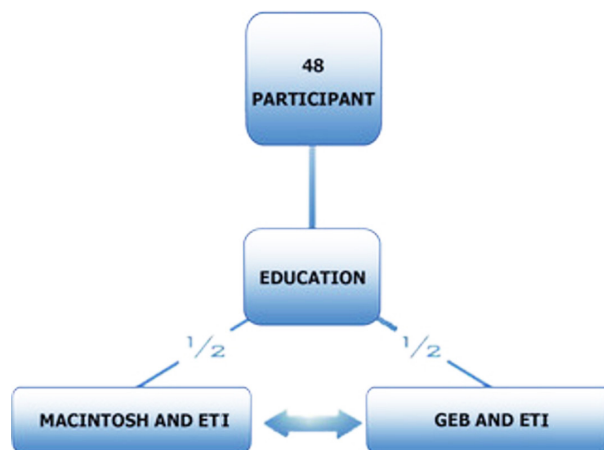


Figure 1. Study shema
 GEB: Gum elastic bougie, ETI: Endotracheal intubation

with the mean value 0.005 standard deviation (\pm SD), number, and percentage values. A 5 second difference in 20 seconds ETI time was considered significant. When alpha error probability was accepted as 0.05 and beta error probability as 0.2, the number of samples required for each group was calculated as 23. The Kaplan-Meier test was used to evaluate the average ETI times between the Macintosh and GEB groups. The McNemar test was used to compare ETI success rates between the GEB and Macintosh groups. Qualitative data were evaluated with a mean \pm SD and percentile values. Statistical significance was taken as $p \leq 0.05$.

Results

The average age of the practitioners participating in the study was 24, and 26 (54.2%) of the 48 practitioners were women. Four (8.3%) of the practitioners had previous experience of using GEB. Practitioners' experience in the pediatric age group was limited. While 38 of 48 practitioners stated that they had never intubated pediatric patients before, all participants stated that they performed pediatric airway intubation on a manikin at least once. All participants had completed the pediatric advanced life support training program, which is available in service training programs.

No statistically significant difference was found between ETI via Macintosh blade and ETI via GEB in first-pass success. ETI success was 91.7% (44/48) via GEB, and 93.8% (45/48) with a macintosh blade, $p=1.000$ (Table 1). While 75% (3/4) of the

participants using GEB were successful in the second attempt, 100% (3/3) were successful in the second attempt when using the Macintosh.

However, the average successful ETI time was longer in ETI via GEB than using only macintosh blades. The average successful ETI time via GEB was found to be 28.6 ± 6.0 sec, the average successful ETI time with the Macintosh blade was 17.1 ± 4.0 sec, mean df: 11.3 sec (95% CI: 9.7-12.8), $p < 0.001$ (Figure 2).

Practitioners reported no implementation difficulties between using GEB and using macintosh blades. 43.8% (21/48) of the participants evaluated the use of GEB as very easy, 43.8% (21/48) as easy, 10.4% (5/48) moderately difficult and 2.1% difficult (1/48). While 39.6% (19/48) of the participants evaluated the Macintosh usage as very easy, 43.8% (21/48) as easy, 12.5% (6/48) moderately difficult, and 4.2% (2/48) difficult ($p=0.914$) (Figure 3). This difference was not statistically significant.

Discussion

One of the essential duties of the first and emergency personnel is to ensure airline safety. Although some different methods and tools have emerged with developing technology to ensure airway safety, traditional ETI with direct laryngoscopes, especially before the hospital, is frequently applied. Conventional ETI can be quite challenging when the degree of laryngoscopic view is suboptimal [10]. Pediatric airway management is as challenging and essential as it is in adult patients. There are fewer studies on pediatric airway

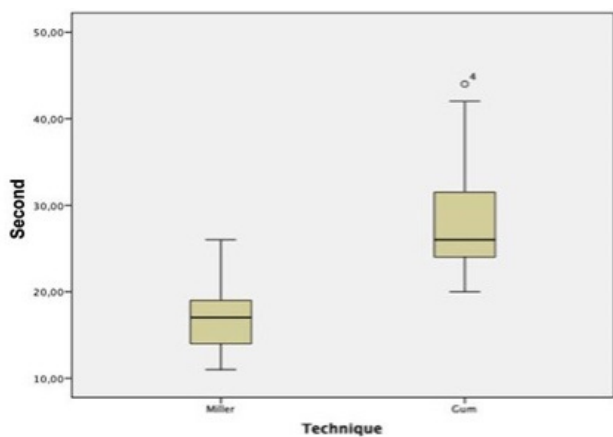


Figure 2. Success ETI time
ETI: Endotracheal intubation

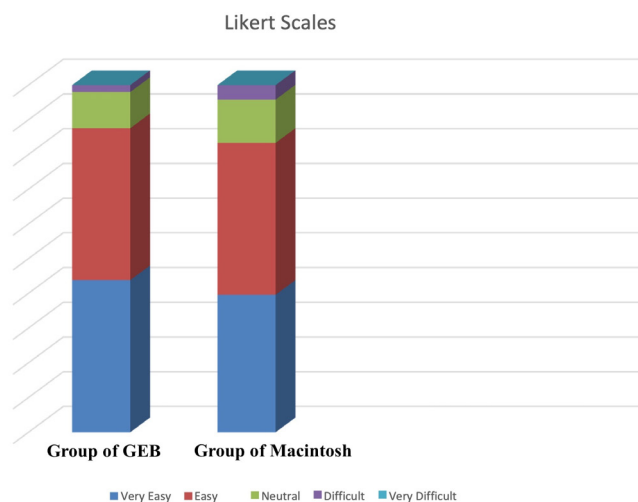


Figure 3. Distribution of groups according to Likert scales

Table 1. Successful ETI rates and average ETI times			
	GEB (n=48)	Machintosh (n=48)	p value
First success rate (m, %)	44 (91.7)	45 (93.8)	1.000
Mean ETI time (s, m)	28.6 (6.0)	17.1 (4.0)	<0.001

ETI: Endotracheal intubation, GEB: Gum elastic bougie

management than are adult airway management. Therefore, studies on pediatric airway management are needed. GEB is recommended in various guidelines in the first steps of difficult airway management [11,12]. Due to the unique difficulties of pre-hospital airway management (lack of staff experience, not always optimal environment provided, equipment limitation, etc.), various delays can be experienced, especially in the pediatric age group, and quite fatal results are observed. Therefore, GEB, one of the recommended equipment for difficult airway management, especially in the pre-hospital and pediatric age groups, may help manage airway management. We carried out this study to hypothesize that GEB can be beneficial in terms of the first entry success in ETI in pre-hospital ambulance simulation, pediatric airway model.

The practitioners recruited to our study have advanced airway intervention licenses. ETI's decision and implementation of are decided by EMTs and paramedics outside the hospital, who constitute the first step of the emergency health services. For this reason, we included EMTs and paramedics as practitioners in this study, which we designed as an ambulance simulation. However, especially in some countries, ETI can only be performed by a physician or under a physician's supervision. In a field study by Jabre et al. [4] in France, GEB was used by physicians in difficult intubation, and it was shown to be beneficial.

In our study, there was no statistically significant difference between the two groups in terms of first pass success.

We obtained overlaps with some of the previous studies that were frequently conducted on adult patients or models. In our study, the average successful ETI time was longer in ETI than using only macintosh blades via GEB. The average successful ETI time was 28.6 ± 6.0 sec via GEB and 17.1 ± 4.0 sec with the macintosh blade. In a model study by Ohchi et al. [13] no difference was found between ETI groups in intubation with a Macintosh blade with and without using GEB in terms of ETI success. However, in the same study, the presence of stomach contents in the airway was simulated. ETI via GEB was found to be statistically more successful in the presence of stomach content. In terms of time, in the usual scenario, GEB extended the ETI time. However, when the presence of stomach contents in the airline was simulated, ETI via GEB shortened the successful intervention time compared with ETI with only Macintosh.

In a model study by Komasaawa et al. [14] no difference was found between ETI groups in intubation with a Macintosh blade with and without using GEB in terms of ETI success. However, ETI via GEB was statistically more successful when chest compression was applied to both groups' models. No

significant difference was found in either scenario in terms of duration.

An infant model was used in another model study by Komasaawa et al. [15]. In this study, no difference was found between ETI groups in normal (Cormack Lehane 1-2) and cervical stabilization (Cormack Lehane 3), using a Macintosh blade, with and without GEB. When the model was in anteflexion (Cormack Lehane 4), ETI was found to be more successful through GEB. No difference was found in terms of duration in the normal state terms of duration, but GEB shortened the duration of successful ETI in cervical stabilization and anteflexion.

In the model study by Maruyama et al. [16] successful ETI time via GEB significantly prolonged the time in all different scenarios (average, chest compression, cervical stabilization) compared to intervention with only Macintosh, and this situation is consistent with other studies in the literature [17-19]. However, using a single model in our study may make it difficult to compare it with other studies on this subject.

In our study, we used the Likert scale to evaluate the application status of the use of GEB and the practitioners' traditional methods of intubation subjectively. We asked all participants to perform this scale, regardless of whether they performed both applications successfully or unsuccessfully. According to the Likert scale, the use of GEB may cause problems for the participants both in terms of intubation experience and difficulty of use. However, 16.7% of the practitioners stated that the method was moderately difficult or difficult according to the Likert scale in ETI made using only the Macintosh blade. Even if there is no statistically significant difference between the two groups, these results can be interpreted differently, considering that 87.5% of the participants had intubation experience with the Macintosh blade. However, only 8.3% of the participants have experience with GEB. Although using GEB is an easy-to-learn method, this difference in experience may have affected the results. In some previous studies, it has been reported that the use of GEB has shown limited success in increasing the success of ETI in emergency physicians who have not applied the method before [20,21]. In contrast, in the study conducted by Driver et al. [17] physicians preferred to use GEB in 435 (80%) of 543 ETI interventions performed in an emergency room where the use of GEB is common, and they achieved first-pass success in 95% of these cases [16]. ETI may be possible via the GEB application to provide a more successful airline management in case of improvements in user experience.

Although GEB is a recommended method in adults with difficult airway conditions, information about its use in the pediatric age group is limited. Difficult intubation is relatively rare (3%), and it should be kept in mind that the procedure may be difficult due to anatomical differences in the pediatric age group [4].

Study Limitations

Our study has several limitations. These include the fact that the study is a manikin study and the absence of chest compression, cervical collar, airway secretion, blood, and stomach content, which may be present in real patients, complicating the ETI procedure. In cases where these factors were present, GEB could be more beneficial in terms of both the duration and the first pass's success [22,23]. Besides, most of the study practitioners were inexperienced with GEB. As stated in the study's methodology, although the training was given before the study, the practitioners may have felt inadequate about the experience. Another limitation is the absence of an ambulance simulation to better simulate the ambulance environment.

Conclusion

Our study found that the success of ETI through GEB, which has strong recommendations for its use in difficult airway management in the literature, was not different from the success of traditional Macintosh blade-mediated intubation in standard pediatric airway management. However, in terms of ETI durations, the duration was found to be statistically longer in the GEB group. We believe that if manipulations make airway management difficult, GEB can shorten the ETI time and increase the first entry's success. In our study, most of the practitioners' application of GEB was considered an easier method, although there was no statistically significant difference. Additionally, using a single model in our study may be a limitation that affects our results. We believe that if pre-hospital practitioners gain similar application experience in using GEB, more successful results in airway management can be achieved.

Ethics

Ethics Committee Approval: Kocaeli University Non-Interventional Clinical Research Ethics Committee approval was obtained for our study (2018/202).

Informed Consent: Written consent was obtained.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Y.B., H.Ö., E.Ç., H.C.H., Concept: Y.B., A.E.Ö., S.K., H.C.H., Design: Y.S.D., Data Collection or Processing: Y.B., H.C.H., Analysis or Interpretation: A.E.Ö., S.K., Literature Search: Y.B., H.Ö., Y.S.D., H.C.H., Writing: Y.B., A.E.Ö., H.C.H.

Conflict of Interest: No conflict of interest was declared by the authors.

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