Comparison of effectiveness of intubation by way of ‘‘Gum Elastic Bougie’’ and ‘‘Intubating Laryngeal Mask Airway’’ in endotracheal intubation of patients with simulated cervical trauma

Esra Yildiz Sut, Solmaz Gunal, Mehmet Akif Yazar*, Beyazit Dikmen

Department of Anesthesiology, Ankara Training and Research Hospital, Ankara, Turkey

Received 12 January 2016; accepted 29 March 2016
Available online 30 May 2016

KEYWORDS
Difficult airway;
Cervical trauma

Abstract
Purpose: In this study, we evaluated the effectiveness of intubations by way of '‘Gum Elastic Bougie'’ and '‘Intubating Laryngeal Mask Airway’’ in endotracheal intubation of patients with simulated cervical trauma.
Method: 134 patients were included in the study. All patients were placed cervical collar for a simulated cervical trauma. Patients were allocated randomly into three groups: Group NI (n = 45) intubation with Macintosh laryngoscopy, Group GEB (n = 45) intubation with Gum Elastic Bougie, and Group ILMA (n = 44) intubation with Intubating Laryngeal Mask Airway. The number of intubation attempts, success of intubation, duration of complete visualization of the larynx, duration of intubation, user’s performance score, hemodynamic changes and the observed complications were recorded.
Results: Success of intubation in the first attempt was highest in Group GEB while it was lowest in Group ILMA. Regarding the intubation success, rates of successful intubation were 95.6%, 84.4% and 65.9% in Groups GEB, NI, and ILMA, respectively. Durations of visualization of larynx and intubation were shorter in Groups NI and GEB than in Group ILMA. This difference was statistically significant (p < 0.05) while there was no significant difference between Groups NI and GEB. The number of patients with ‘‘good’’ intubation performance was significantly higher in Group GEB while the number of patients with ‘‘poor’’ intubation performance was significantly higher in Group ILMA (p < 0.05).

* Corresponding author.
E-mail: makifyazar@hotmail.com (M.A. Yazar).

http://dx.doi.org/10.1016/j.bjane.2016.03.001
0104-0014/© 2016 Sociedade Brasileira de Anestesiologia. Published by Elsevier Editora Ltda. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
Introduction

Endotracheal intubation is the first and the most important invitation to ensure the airway safety in patient undergoing general anesthesia. Endotracheal intubating in difficult airway conditions is more important for patient's airway safety. Some of the difficult airway conditions are the limitation of cervical spine movement and the cases must be kept limited neck movement. Neck movements must be particularly limited in neck trauma patients. It is extremely important to quickly and uncomplicated intubate this patient for their vital functions. So various methods have been suggested to intubate this patient. In these studies, we aimed to compare the effectiveness of Fastrach-LMA (Intubating Laryngeal Mask Airway – ILMA) has been developed for blind intubation in difficult airway conditions and Gum Elastic Bougie (GEB).

Method

After local ethics committee approval (the registration protocol number 3449), this study was performed prospectively at the Ankara Training and Research Hospital between March and June 2011. 135 patients scheduled for elective surgery, between 18 and 65, ASA criteria I–II, were included in the study. Procedures were explained in detail to all patients. Patients who had history of difficult intubation, cervical postural disorders, undergoing cervical surgery, body mass index over 30 kg m⁻², mallampati score III–IV, thyromental distance less than 6 cm, risk of gastric aspiration and pregnant was excluded form study.

The mouth opening, thyromental distances, and Mallampati scores were recorded in the preoperative assessment performed one day before the surgery. The cases were taken to the operating room without any premedication and were monitored with regard to Electrocardiogram (ECG), non-invasive blood pressure, pulse oximeter, and EtCO₂. The patients were split into three groups and cervical collar (Stiffneck Original Collar, Laerdal Medical Corporation, USA) was employed to establish simulated difficult intubation. After the removal of the collar, mouth opening was measured. All the cases inhaled 100% O₂ for 3 min (6 L min⁻¹), induction was established using 1 mcg kg⁻¹ fentanyl citrate and 4–7 mg kg⁻¹ thiopental. Muscle relaxation was achieved via

Conclusions: We conclude that GEB, which is cheap and easily accessible, should be an advantageous choice in cervical trauma patients for both the easeness of intubation and patient morbidity and mortality. © 2016 Sociedade Brasileira de Anestesiologia. Published by Elsevier Editora Ltda. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
were unsuccessful LMA categorized more intubation Cormack-Lehane male groups external sevoflurane.

The "operator performance assessment" of the anesthesiologist performing the intubation was categorized as "good", "moderate", and "poor". The complications arising during intubation (mucosal damage, dental trauma, lip injury, torn cuff, hypoxia (SpO2 < 95%), and esophageal intubation) were recorded. Subsequent to intubation, presence of blood on the Endotracheal Tube (ETT) cuff or any sign of sore throat expressed by the patient after recovery were noted, as well. Hemodynamic parameters were monitored throughout the entire operation and recorded before induction, right after induction, and at every 5 min for 15 min.

**Statistical analysis**

"SPSS for Windows 16.0.1" package program was used for the statistical analysis. The study data were expressed as mean, standard deviation, percentage, and numeric values. The intergroup comparisons of the measured data were performed by the Mann–Whitney U test and the intragroup comparisons were carried out by the Wilcoxon test. The comparisons of the countable data were performed by the Chi-square test; p < 0.05 was recognized as statistically significant.

**Results**

One patient from the ILMA group was excluded from the statistical analysis since he could not be intubated; the patient was awakened to plan fiberoptic intubation. A total of 134 patients, 82 female and 52 male, were included in the study. The mean age was 46.7 years and the average BMI was 26.9 kg. The values acquired in the preintuba- tion examination of the groups are shown in Table 1: ASA and Cormack–Lehane classification, as well as sternomen- tal, thyromental and mouth opening were included. There was no statistically significant difference between these data. Success at first intubation attempt was highest in the GEB group and lowest in the ILMA group. The difference between the groups in this regard was statistically significant (p < 0.05). The distributions of number of attempts at intubation are shown in Table 2. Although suc- cessful intubation was achieved in the first 2 attempts, the

*Figure 1* Gum elastic bougie.

*Figure 2* Intubating Laryngeal Mask Airway.

<table>
<thead>
<tr>
<th>Table 1: Demographic data on the groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>NI (n = 45)</td>
</tr>
<tr>
<td>Sex (F/M)</td>
</tr>
<tr>
<td>Age (mean±SD)</td>
</tr>
<tr>
<td>BMI</td>
</tr>
<tr>
<td>ASA I/II</td>
</tr>
<tr>
<td>SMD (cm)</td>
</tr>
<tr>
<td>TMD (cm)</td>
</tr>
<tr>
<td>MO (cm)</td>
</tr>
<tr>
<td>Cormack- Lehane Classification</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

BMI, body mass index; SMD, sternomen- tal distance; TMD, tiro- mental distance; MO, mouth opening (while inserted colar); SD, standard deviation.
Moreover, comparison to the difference deemed the procedure. The "good" performance rate was significantly higher in the GEB group ($p < 0.05$).

"Poor" performance rate was 29% ($n = 13$) in the ILMA group which was significantly higher than those in the NI and GEB groups ($p < 0.05$). The operator performance rates relative to groups are shown in Table 5. There was no statistically significant difference between the three groups with regard to SBP, DBP, HR, SpO2 and EtCO2 values before intubation, right after intubation, and at 5, 10, and 15 min after intubation. The data involving these hemodynamic parameters are shown in Table 6. In terms of intubation complications such as hypoxia, laryngospasm, or lip injury, one patient in each of ILMA and NI groups developed hypoxia, one patient in the NI group developed lip injury, while another exhibited laryngospasm. It was necessary to remove the cervical collar in 2 patients in each of NI and GEB groups, and in 8 patients in the ILMA group.

The total number of complications in the ILMA group was 15 (34%), while it was 3 (6%) and 6 (13%) in the GEB and NI groups, respectively. The difference between the groups was statistically significant ($p < 0.05$). There was no significant difference between the groups relative to frequency of sore throat. The intraoperative complication and postoperative sore throat values relative to the groups are shown in Table 7.

**Discussion**

In this study, we compared the success rates of intubation with GEB and ILMA in patients difficult to intubate due to cervical limitation. GEB was observed to be more advantageous with regard to ease of intubation, as well as in patient morbidity and mortality. Patients with a cervical trauma are regarded as difficult intubation cases. There are ongoing studies for determining the best intubation method in patients suspected of having cervical trauma. Moreover, various methods are being investigated such as awake blind nasal, oral, or fiberoptic intubation; direct laryngoscopy with head and neck stabilization; cricothyrotomy, indirect laryngoscopy with Bullard laryngoscope, and blind oral intubation with Augustine guide and Combitube.

There are two major risks involving the intubation of patients with cervical spine injuries. First risk is prolonged intubation along with the risk of vomiting and aspiration, generally occurring in non-fasted patients. Second most common risk is cervical spine excision, particularly within the functional unit of the occiput-C3, or defensive cervical spine movements leading to additional cervical spine and neurological damage in sedated patients.
Table 6 The hemodynamic parameters of groups.

<table>
<thead>
<tr>
<th></th>
<th>NI (mmHg)</th>
<th>GEB (mmHg)</th>
<th>ILMA (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>113.9 ± 17.4</td>
<td>117.2 ± 16.5</td>
<td>109.4 ± 18.7</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DBP</td>
<td>72.0 ± 9.9</td>
<td>73.6 ± 11.8</td>
<td>70.1 ± 11.9</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR</td>
<td>69.4 ± 10.8</td>
<td>72.0 ± 13.8</td>
<td>69.3 ± 8.8</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SpO₂%</td>
<td>98.5 ± 0.9</td>
<td>98.8 ± 1.0</td>
<td>99.1 ± 0.9</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtCO₂</td>
<td>28.8 ± 1.5</td>
<td>28.2 ± 1.7</td>
<td>28.0 ± 1.5</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; SpO₂, oxygen saturation; EtCO₂, end-tidal carbon dioxide; BI, before intubation.

Table 7 The intraoperative complication and postoperative sore throat values relative to the groups.

<table>
<thead>
<tr>
<th></th>
<th>NI (n = 45)</th>
<th>GEB (n = 45)</th>
<th>ILMA (n = 44)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative complications (+/−) (n,%):</td>
<td>6 (13)/39 (86)</td>
<td>3 (6)/42 (93)</td>
<td>15 (34)/29 (65)</td>
<td>0.02*</td>
</tr>
<tr>
<td>Postoperative sore throat (+/−) (n,%):</td>
<td>29 (64)/16 (35)</td>
<td>33 (73)/12 (26)</td>
<td>22 (50)/22 (50)</td>
<td>0.07</td>
</tr>
</tbody>
</table>

(+/−), complication present/complication absent.

* ILMA group vs. GEB and NI group: p < 0.05.

The protection of the cervical spine following trauma is an essential part of patient management. Advanced trauma life support requires the continuous cervical immobilization of patients by a semi-rigid cervical collar. The collar should not be removed until ruling out significant neck trauma. In such patients requiring intubation, fiberoptic intubation is the best choice. However, intubation is often an emergency procedure that is carried out under stressful conditions far from ideal. It is difficult to apply direct laryngoscopy in patients with cervical collar, and generally it cannot be performed. The use of semi-rigid collars increases the Cormack–Lehane grade 3 and 4 laryngoscopic view during direct laryngoscopy, while reducing the mouth opening. To ensure optimal view in direct laryngoscopy, manual in-line stabilization is an alternative technique. In such cases, the collar should be removed with minimal cervical movement by an experienced trauma team and the neck of the patient should be kept in in-line position on a firm ground. After the intubation, the collar should be placed again.

Avidan et al. compared the success rates of ventilation and intubation using direct laryngoscopy and the ILMA applied on manikin and patients by inexperienced healthcare workers who received a basic training before the intubation. The success rate of ILMA insertion was 100%, while the success rate of intubation using direct laryngoscopy was 84%, and the success rate of intubation using ILMA was 98% in manikins. On the other hand, the success rates of ILMA insertion, intubation using direct laryngoscopy, and intubation using ILMA were 100%, 35%, and 43% in patients, respectively. Adequate ventilation was achieved in 78% of patients in whom a face mask was used and in 98% of patients in whom ILMA was used. Thus, they concluded that ILMA could be useful in emergency oxygenation and ventilation, while also adding that their results were not supporting the use of ILMA by inexperienced personnel in advanced airway management. Wattl et al. evaluated the impact of direct laryngoscopy and ILMA on cervical spine mobility and the intubation status. Insertion of ILMA was
successful at first attempt in 100%, intubation with ILMA was successful in 92.5%, intubation time with ILMA at first attempt was 39 s (31–57), and intubation time with laryngoscopy was 21 s (16–34). ILMA was found to cause less extension during intubation as compared to direct laryngoscopy and direct laryngoscopy was observed to provide rapid intubation in the absence of difficult intubation conditions, however, ILMA was providing faster and safer intubation in difficult intubation cases.

Nileshwar et al. evaluated the efficacy of Bullard laryngoscopy vs. ILMA in patients with simulated cervical immobilization and ILMA was observed to provide intubation faster than the BL. The intubation success rate was 90% in the BL group and 74% in the ILMA group; however, the difference was not statistically significant. Nakazawa et al. tested blind intubation with ILMA in patients who underwent cervical spine surgery. ILMA was successfully inserted in 100%, patients with a Halo bandage required a second attempt, success rate at first attempt was 60% in intubation with ILMA, and the procedure failed in 10% of the patients. They reported that achievement of ILMA insertion and intubation with ILMA did not cause head and neck movements, and they associated failure of blind intubation with using improper mask sizes. Komatsu et al. evaluated intubation with ILMA in patients of cervical spine surgery with a rigid collar and in normal surgery patients with no collar. Collar use was observed to narrow the mouth opening, while increasing the Mallampati score. Overall intubation success rate was 96% in patients with collar and 18% of the patients required more than 2 attempts. Intubation time was 60 s in patients with collar and 50 s in patients with no collar. They reported that in cases using immobilized rigid collar, particularly in those where fiberoptic approach is impossible, intubation with ILMA might be a safe option for the airway management.

In the study of Bilgin et al., total intubation success rate was 87%, the success rate at first intubation attempt was 47% and the success rate at second intubation attempt was 77% in the ILMA group. The ILMA insertion time was 26.8 s and the total intubation time with ILMA was 70 s. They reported ILMA as a useful device in the management of difficult airways. Bein et al. conducted a study on patients anticipated to show difficult airway management. In the ILMA group, successful intubation rate at first and second attempts were 70% and 90%, respectively. Intubation could not be achieved in 5% of the patients, while the ILMA insertion time was 28 s and the ILMA intubation time was 70 s. They noted ILMA as an advantageous device in the management of difficult airways, as well. In another study, the median blind intubation time with ILMA was 87 s, total success rate was 94%, while the rates of success at first and second attempts were 67% and 86%, respectively.

In the present study, the results concerning the total success rates for ILMA insertion, success rates relative to number of attempts, ILMA insertion time, and intubation time with ILMA were comparable to the values reported in the literature. The differences may be associated with the study design, definition of success, and determination of the times. The significantly “poor” operator performance in ILMA patients is believed to be arising from the inadequacy of ILMA in cases with cervical mobility limitation. In this study, success at first and second intubation attempts were 95.6% and 97.7%, while the success rate was 99.5% in the GEB group. Laryngeal visualization time was 12.6 s and the intubation time was 36.0 s. Regarding the operator performance, GEB application was good in 86% and poor in 4%.

Gum Elastic Bougie (GEB) is commonly used in practice in the UK. The application of GEB in difficult oral intubation has been increasing over the past years. While it was used in 45% of difficult intubation cases in 1984, it was determined to be the first choice in 100% of such cases in 1996; Cardiff describes GEB as the method of choice in cases of difficult intubation. When the visualization of the glottis is not good during laryngoscopy, GEB is recommended. In cases of unanticipated difficult intubation, use of GEB is claimed to accelerate the intubation process. Various studies have noted the efficacy of GEB in the management of cases presenting with difficult intubation. Patients of Cormack–Lehane grade 3 have been reported to have a GEB success rate of 94–100%, 17,18,19

Noguchi et al. compared the use of GEB and stylet in patients receiving cricoid pressure. They used the modified laryngeal classification of Cook. The endotracheal GEB insertion time in patients anticipated to present easy intubation was 12 s and the intubation time was 31 s. In patients anticipated to present a difficult intubation, endotracheal GEB insertion time was 15 s and the intubation time was 33 s. They noted that cricoid pressure would complicate the tracheal intubation, while adding that GEB use was an easy method to increase the success rate of tracheal intubation. In the study of Komatsu et al. endotracheal GEB insertion time of GEB was 21 s and the intubation time was 49 s. Endotracheal GEB insertion was successful at first and second attempts in 73% and 89.6%, respectively. Intubation was successful at first and second attempts in 83.3% and 95.8% of the patients, respectively. Overall success rate of GEB was 89.6%. Messa et al. investigated the simplicity and success of intubation with GEB in the management of difficult airway. The success rate of intubation with GEB was 94% and the intubation time was 20.4 s. They reported a high success rate for GEB use in the management of difficult airways. In the present study, our results concerning GEB use were comparable to the ones reported in the literature.

Repeated attempts at intubation, aiming to maintain the airway safety may lead to higher complication rates including hypoxia, pulmonary aspiration, and hemodynamic side effects. Repeated intubation attempts, particularly in patients with difficult airway, may also result in laryngeal perforation or pharyngeal stricture. Therefore, intubating the patient with less manipulation and in shorter time should reduce the complication rates to minimal levels.

Prolonged laryngoscopy and intubation may cause many complications such as hypoxia and increased secretion. Particularly in the presence of indications complicating the intubation procedure, each anesthesiologist should be aware of the fact that risk of prolonged or failed intubation is high.

In this study, ILMA group exhibited significantly prolonged times for laryngoscope insertion, larynx visualization, and total intubation. We associated these prolonged times with the 3 stage intubation procedure of the ILMA. Intubation with ILMA is expected to take more time since it is consisted of three stages: insertion of the ILMA, insertion
of the endotracheal tube, and removal of the ILMA. GEB requires shorter times because GEB manipulation is simpler than ILMA and ML, leading to easier laryngeal visualization and endotracheal intubation. In the present study, although we found shorter intubation times in the GEB group than in the NI group, the difference was not statistically significant. Patients with a cervical collar require more manipulation during the insertion of ILMA which has a negative effect on the time and success of the intubation process. Owing to its special design, GEB requires less manipulation.

Laryngoscopy and endotracheal intubation trigger sympathetic response by the mechanical stimulation of the larynx and trachea, leading to increases in the plasma catecholamine levels which may in turn cause tachycardia, hypertension, arrhythmia, or myocardial ischemia. Factors such as age, weight, and body mass index are known to influence the success of and hemodynamic responses to the intubation process.

The ILMA may exert a pressure over the oropharyngeal structures and cervical spine, leading to back slides in the cervical vertebrae resulting in increased hemodynamic response due to raised levels of stimulation. Moreover, the epiglottic elevator of the ILMA may stimulate periepiglottic structures and arouse a strong hemodynamic response by affecting the supralaryngeal region known to be rich of nociceptor receptors. In addition, while removing the ILMA after intubation, the back and forth movement of the intubation tube may create a strong friction, leading to increased hemodynamic response, as well.

Kihara et al. categorized 75 normotensive and 75 hypertensive patients into 3 groups consisted of 25 patients in a randomized fashion; performed intubation using direct laryngoscopy, “lightwand”, and ILMA; and recorded the hemodynamic data before and after intubation, as well as before and after intubation. Although there was no difference between the groups in normotensive patients, hypertensive patients demonstrated a reduced hemodynamic response in the ILMA group. HR was observed to increase after the intubation as compared to baseline value in all groups, however, there was no significant difference between the groups. The authors associated the reduced hemodynamic response with lower degree of receptor stimulation in that region. In the study of Baskett et al. conducted on 500 patients, hemodynamic data were recorded after induction during ILMA insertion, intubation, and ILMA removal. Mean HR and BP increased following the insertion of the ILMA, and demonstrated a significant increase after the intubation, however, no significant change was observed during the removal.

In the present study, hemodynamic parameters showed an increase at 0 min as compared to preintubation values, while no difference was determined between the groups. The intragroup increases were not statistically significant; therefore, these raised values were thought to be normal responses to intubation. Albeit not statistical; SBP, DBP, and HR were clinically lower at 0 min in the ILMA group, which was associated with the presence of less stimulation in that region, since it is known that an advantage of intubation with ILMA is that it does not stimulate the base of tongue, epiglottis, and pharyngeal receptors. Therefore, cardiovascular response to endotracheal intubation with ILMA is expected to be low.

In this study, no significant difference was observed between the groups with regard to preintubation and postintubation levels of SpO2 vs. EtCO2. Only one patient in each of ILMA and NI groups developed hypoxia. Although intubation times were significantly longer in the ILMA group as compared to NI and GEB groups, the unchanged SpO2 vs. EtCO2 values were explained with the absence of a significantly prolonged intubation time. The reason is the entire FRC (approximately 2300 mL) comprises O2 in patients receiving 100% oxygen for 2 min as a standard procedure for preoxygenation which delays hypoxia following apnea 4–5 min. Both the changes in the hemodynamic parameters and our results concerning the SpO2 vs. EtCO2 levels were consistent with those reported in the literature.

Many complications may arise during intubation such as trauma to the lip, dental and mucosal injuries, and desaturation. Also, pharyngeal structures may be damaged in blind intubation with ILMA. In the literature, there are studies reporting development of edema in the epiglottis following blind intubation. Moreover, there is a study reporting the death of a patient due to esopharyngeal perforation because of blind intubation. It is not easy to evaluate postoperative sore throat incidence of ILMA, however, some studies recognize that this incidence is up to 67%. However, some studies have found no significant difference between ILMA and direct laryngoscopy with regard to postoperative sore throat.

Bilgin et al. observed higher rates of postoperative sore throat in the ILMA group and explained this with the necessity to apply more manipulation. In their study, Nileseshwar et al. compared ILMA and BL, and found no significant difference between the two groups in terms of sore throat. Moreover, there was no significant intergroup difference with regard to intubation-related trauma. They found blood on the ETT in 2 of 3 cases which required a third intubation attempt in the BL group, while there was blood on the ETT in all the patients that required a third intubation attempt in the ILMA group. They associated this finding with higher incidence of soft tissue trauma in patients needing a third intubation attempt.

In the present study, 2 patients in each of NI and GEB groups, and 8 patients in the ILMA group could be intubated after the removal of the cervical collar; one patient in each of ILMA and NI groups developed hypoxia, while in the NI group, 1 patient had lip injury and one patient exhibited laryngospasm. The complications in the ILMA group showed significant differences as compared to the NI and GEB groups, which was a finding consistent with the studies of Baskett et al. and Choyce et al. Postoperative sore throat is often associated with the number of manipulations. In the present study, there was no significant difference with regard to postoperative sore throat.

Conclusion

We believe that GEB should be preferred in patients with a cervical trauma, since it is a cost-effective and widely available adjunct providing ease of intubation, while showing lower mortality and morbidity rates.
Conflicts of interest

The authors declare no conflicts of interest.

References