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VALIDATION OF UNASSISTED, GUM ELASTIC BOUGIE GUIDED INSERTION OF PROSEAL LMA IN ANAESTHETISED PATIENTS (A STUDY OF 100 CASES)

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ABSTRACT

Maintenance of a patent airway remains as one of the important duties of an anesthesiologist. The inability to secure an airway with an endotracheal tube, in some cases, coupled with other disadvantages like exaggerated pressor responses and trauma to the oral structures and vocal cords had raised many questions till introduction of Laryngeal mask airway (LMA). Though, it was shown to have some distinct advantages, like no trauma to vocal cords, avoidance of laryngoscopy and minimal pressure responses, it clearly offered no protection against regurgitation of gastric contents into respiratory tract. Also, its unpopularity for effective positive pressure ventilation saw it being a second choice to the endotracheal tube. With the role of the Proseal-Laryngeal mask airway, this double lumen, double cuff LMA has some clear advantages over its predecessor. The double tube design separated the respiratory and alimentary tracts, providing a safe escape channel for the regurgitated fluids. The double cuff of the P-LMA gave a better seal around the glottis, hence establishing its superiority in IPPV. These properties increase the suitability of P-LMA in a group of patients who are more prone for aspiration. Also its simple insertion technique the need for this study is quite evident. We did our study with aims to calculate the success rate of insertion of Proseal-LMA with a bougie, ease of insertion and to see for certain complications with regards to Associated intraoperative or immediate postoperative complications namely, cough, sore throat, laryngospasm, bile stain over the tip of PLMA and tracheal aspiration.100 patients between age group of 18-80 years ASA grade I and II, posted for elective minor surgeries as well as emergency surgeries with modified Mallampati Score I/II II were to undergo bougie guided proseal LMA insertion. Intervention was nonassisted, GEB-guided insertion of proseal LMA in anesthetized patients. Ease of insertion was recorded. Intraoperative and postoperative hemodynamics were noted and complications namely cough, laryngospasm and tracheal aspiration were noted. Proseal LMA provides ease of insertion in 97% patients with preservation of haemodynemic stability. Complications such as coughing, gag reflex and sore throat occurs in less than 5% patients. GEB-guided placement of the PLMA without an aid of an assistant can be accomplished quickly and successfully without impacting the expected clinical performance of the device. Good haemodynamic stability can be achieved throughout the procedure with the use of a PLMA. Very few postoperative complications such as coughing, sore throat and dysponea are found with the use of EB-guided PLMA insertion technique.

Key words: Proseal LMA, airway, Gum elastic bougie.

INTRODUCTION

Maintenance of a patent airway remains as one of the important duties of an anaesthesiologist. However, despite his skills and experience it is not always an easy job for him in his day to day practice. There are moments, when the nature in its own way seriously patients with difficult airways. These situations are often encountered in real practice when an anaesthesiologist has a task of giving general anaesthesia [1, 2].

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Even though the time tested and an excellent airway securing device, viz the endotracheal tube is available to us at all times, but it too has its own demerits. Morbidities like presser responses, trauma to vocal cords and structures of oral cavity (during laryngoscopy), sore throat etc, are also a subject of botheration to the anaesthesiologist. Failure to intubate can cause mortality and account for 30% of overall anaesthetic brain damage and death in general surgical population [3].

This inability to secure an airway with an endotracheal tube, in some of such cases, coupled with other disadvantages like exaggerated pressor responses and trauma to the oral structures and vocal cords, had raised many questions over our overdependence on this device until Dr. Archie Brain in the year 1983 described a new device called the Laryngeal mask airway (LMA). Though, it was shown to have some distinct advantages, like no trauma to vocal cords, avoidance of laryngoscopy and minimal pressure responses, it clearly offered no protection against regurgitation of gastric contents into respiratory tract [4]. Also, its unpopularity for effective positive pressure ventilation saw it being a second choice to the endotracheal tube [5]. With the role of an LMA, being restricted to the difficult airway algorithms and a few other selective cases, Dr. Archie Brain came up with a new invention, or rather a modification of the Laryngeal Mask Airway (LMA) in year 2001[6]. This device was called the Proseal-Laryngeal mask airway. This double lumen, double cuff LMA has some clear advantages over its predecessor. The double tube design separated the respiratory and alimentary tracts, providing a safe escape channel for the regurgitated fluids. The double cuff of the P-LMA gave a better seal around the glottis [6, 7]. Hence establishing its superiority in IPPV. These properties increase the suitability of P-LMA in a group of patients who are more prone for aspiration. Also its simple insertion technique the need for this study is quite evident.

MATERIALS AND METHODS

This study was designed to calculate the success rate of bougie guided Proseal laryngeal mask airway insertion with regards to the ease of insertion and the associated complications viz cough, laryngospasm and tracheal aspiration in patients undergoing elective as well as emergency surgeries.

A sample of 100 patients was obtained. Each of them was to undergo bougie guided proseal LMA insertion.

After obtaining institutional ethics committee approval, this study was carried out on patients at civil hospital Ahmedabad. The patients posted for elective or emergency surgery, graded as ASA grade I or grade II were included in the study.

The selection chriteria were

- age group of 18-80 years
- ASA grade I and II
- posted for elective minor surgeries as well as emergency surgeries
- Modified Mallampati Score I/II

The exclusion criterion were

- Known difficult airway (MP-III or MP-IV)
- Mouth opening < 2.5 cms.
- Restricted neck extention, eg. Postburns neck contracture.
- Cervical spine disease.
- Body mass index > 35 kg/m^2.
- Hiatus hernia.
- Gastro oesophageal reflux disease (GORD).
- Prior oesophagectomy.
- Known oropharyngeal pathology which makes proper PLMA fit unlikely.

An informed written consent was obtained and as soon as the patient arrived in the operation theatre complex a quick pre- anaesthetic evaluation was done for emergency cases, and this was followed by intravenous administration of inj. Glycopyrrolate 0.004 mg/kg, inj. Emset 0.1mg/kg and ing. Fentanyl 2mic/kg in both elective as well as emergency cases.

Once the patient was shifted to the operation table, monitors (pulse oximeter, ECG, blood pressure cuff) were attached. Anesthesia was Induced in all the patients using propofol 2mg/kg and was maintained with sevoflurane 2-3% in 50% oxygen. Neuromuscular blocking drugs were not used as a part of induction. All PLMAs were placed using unassisted, gum elastic bougie guided technique. The cuff of each PLMA was first fully deflated and flattened. A well lubricated 15F, 60cm GEB was placed with straight end first into the proximal end of the vent port until approximately 20 cm extended past the distal end of the device (figure 18). Under laryngoscopic guidance, distal portion of GEB was placed 5 to 10 cm into the oesophagus. The laryngoscope was removed and PLMA was railroaded over the bougie until a firm stop was noted. The bougie was removed while PLMA was held in position [7-10]. The cuff was then inflated to achieve an appropriate seal. All insertions were performed in sniffing position with cuff fully deflated and using midline approach.

Insertion success was defined as device placement with observation of adequate ventilation within three attempts. An insertion attempt was marked if the device has to be removed from patient's mouth and reinserted. Insertion time was measured from investigator began to insert the laryngoscope blade in mouth to confirmation of ventilation by end tidal carbon dioxide tracing on the monitor. Before insersion the device was lubricated with water soluble surgical gel. Use of viscous lidocaine and

other topical anesthetics were not allowed. Three attempts were allowed before placement was considered a failure. Criteria for failed insertion include:

- Oropharyngeal impaction, ie. Failed passage into pharynx.
- Glottis impaction, ie. Airway obstruction by malposition as detected by air leak over oropharynx (listening over mouth)/stomach (auscultation over epigastrium)/drain tube (placing lubricant over proximal drain tube) and negative suprasternal notch tap test.
- Ineffective ventilation (exhaled tidal volume TVe<8 ml/Kg and ET CO_2>45 mm Hg.

INSERTION

Ease of insertion was recorded; easy insertion being defined as the one, in which there was no resistance to insertion in the pharynx in a single manoeuver. A difficult insertion was defined as the one in which resistance was felt while passing the P-LMA or if more than one attempt was required to place the P-LMA. If more than three attempts were required, patient would be excluded from the study.

After inserting the airway device, breath sounds were confirmed on auscultation and Ryles tube with adequate lubrication was introduced immediately after placement of P-LMA, through its drain tube. Vecuronium 0.08-0.12mg/kg or atracurium 0.5mg/kg was used for the maintenance of muscle relaxation. Cardiorespiratory data were collected every 5 min for first 20 min and then every 10 min till the completion of the procedure. Any episode of hypoxia (Sp O2 < 90%), bradycardia (<40/min), tachycardia (100/min) or systolic hypotention (SBP< 80 mm Hg) were recorded.

After reversing the muscle relaxation, extubation or P-LMA removal was carried out only once the patient was reversed and was awake and followed verbal commands. Upon removal, the presence of visible blood or bile was recorded. Patients were asked about the oropharyngeal complaints before discharge from recovery room and 24 hr postoperatively. Postoperative complications were looked for and recorded if any.

Statistical analysis was done, with unpaired students test being used to compare demographic data. Chi-square test was done to check any correlation between age and the complications noted. To find out whether differences found between two groups with regards to complications and ease of insertion, were statistically significant or not, test of proportion was done. A p-value of less than 0.05 was considered significant.

RESULTS

This study was carried out in 100 ASA grade I and II patients undergoing elective as well as emergency surgeries under general anaesthesia. Hundred PLMAs were placed in sixty two males and thirty eight females of ASA grade I and II patients. Mean (SD) age, height, weight, body mass index, were 39 (14) years, 175 (10) cm, 78 (23) kg and 25.4 (6) kg/m^2 respectively. Ninety seven PLMAs were successfully placed on first attempt. Two PLMAs required three attempts for successful placement. One PLMA could not be placed successfully. The mean insertion time (SD) was 28 (10) seconds and the mean (SD) duration of use was 52 (30) min.

Out of the complications which we studied, cough was the commonest complication observed. 5 out of 100 patients had cough. Two of them had postoperative sore throat. Three patients had gag after PLMA removal, one of them had regurgitation and one had bile stain over the tip of PLMA. There was no laryngospasm, bronchospasm and tracheal aspiration in any patient. No dysphonia was found in any patient.

In the P-LMA group, only 2 out of 50 patients had cough. Out of those 2 patients, 1 patient each belonged to the 15-25 years and 26-35 years age group. Whereas in the ETT group 6 patients falling in the age groups of 15-25 yrs had cough, whereas only 2 patients fell in 25-35 yrs age group. A statistical analysis was done to see any correlation between these complications and the age. A chi- square value of 0.030 and a P valve of 0.8630 was obtained and analysis showed no significance. Hence there was no correlation between age and the complication that occurred.

In 97 out of 100 patients P-LMA insertion was found to be easy, whereas P-LMA placement was recorded as difficult in only 2 cases and failed in 1 case.

Table 1. Demographic data, given as mean (SD)

age		39 (14) years
height		175 (10) cm
weight		78 (23) kg
BMI	25.4 (6) kg/m^2	

Table 2. Insertion data

Effective airway time	28 (10) sec
Attempts (1/2/3)	97/0/2

Table 3. Haemodynamic variables in form of mean (SD)

MAP pre –insertion (mm Hg)	68 (7)
MAP post-insertion (mm Hg)	65 (7)
HR per-insertion (beats/min)	104 (17)
HR post-insertion (beats/min)	103 (17)
MAP before removal	70 (10)
MAP after removal	60 (10)
HR before removal (beats/min)	110 (20)
HR after removal (beats/min)	104 (20)

Table 4. Analysis of incidence of intraoperative and immediate postoperative complications

Laryngospasm	0
Bronchospasm	0
Aspiration	0
Regurgitation	1
Gag reflex	3
Coughing	5
Sore throat	2
Dysphonia	0
Bile stain over the tip of PLMA	1

Table 5. Analysis of ease of insertion

PLMA insertion	Easy	Difficult	Failure
Percentage	97%	2%	1%

Fig 1. Number of patients in different age groups

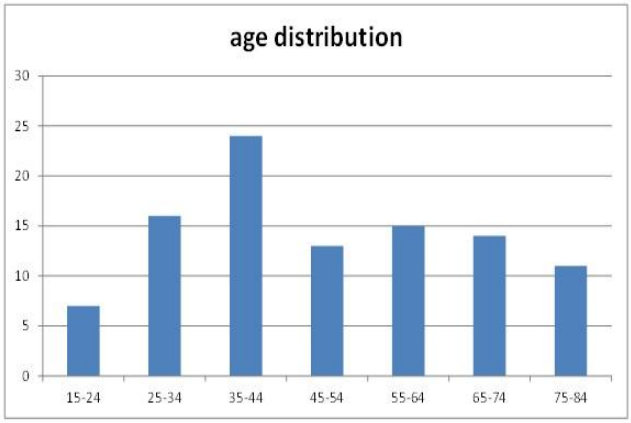


Fig 1. Number of males and females

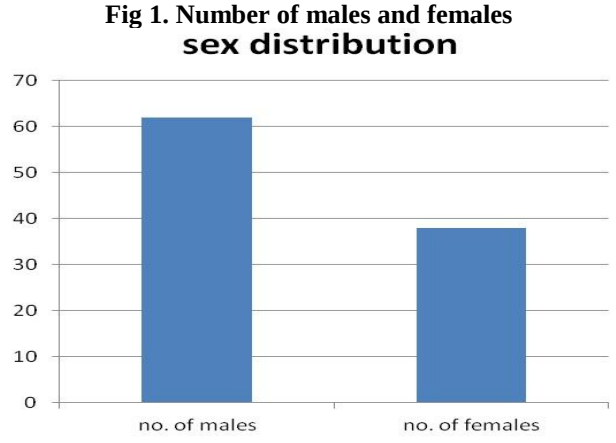


Fig 3.

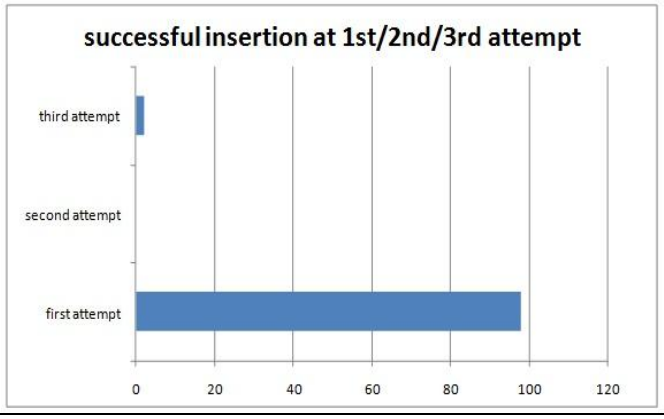


Fig 4.

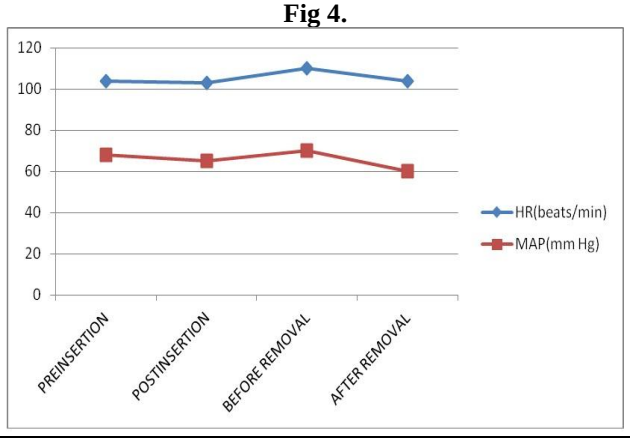
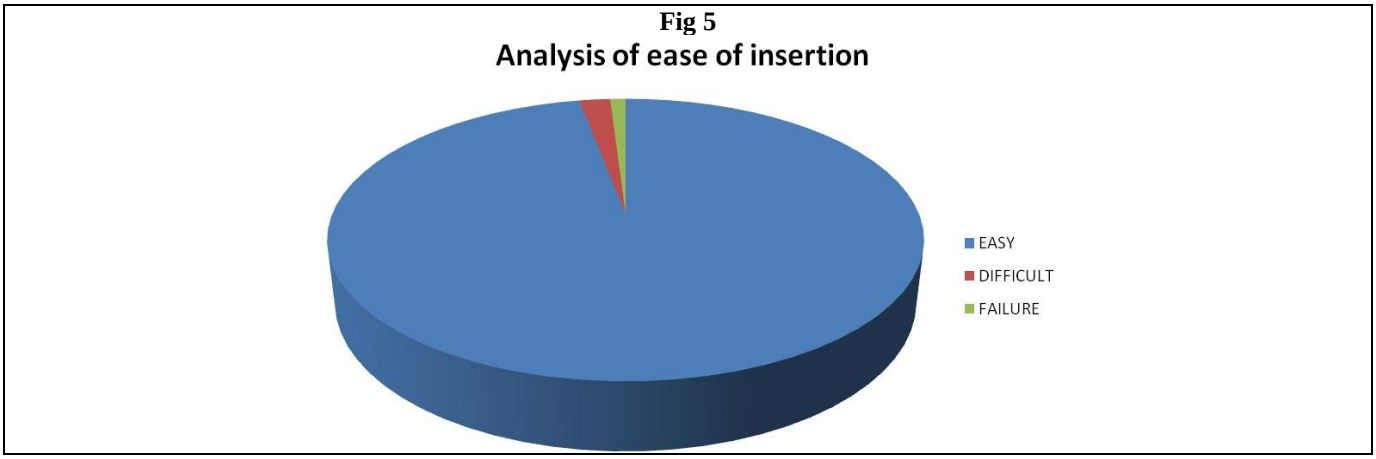


Fig 5



DISCUSSION

In order to counter difficult airways, many airway devices have been invented, but have always found their place in either plan B or plan C of difficult airway algorithms, whereas plan A has always been reserved for the endotracheal tube. This simply means that none of the other airway devices have been used as a primary airway in patients undergoing general anesthesia. This is probably related to the safety of these airway devices not being proved beyond doubt, in high risk patients. Over and above, the bougie guided technique has led to ease of insertion and successful insertion in more and more number of patients with difficult airway.

Proseal–laryngeal mask airway is one of such airway devices, which acquires a good seal in the suproaglottic region 6, 7 (more effective than C-LMA) and permits the gastric drainage, hence separating the respiratory from the gastrointestinal tract. This property makes it a useful device in patients with full stomach. Also, its simple insertion technique in a patient group, where chances of encountering a difficult airway is always a possibility, made us to conduct this study, where we have looked for the success rate of bougie guided insertion and also for the complications.

We have studied 100 ASA grade I and II pregnant patients, who were given a standardized anaesthesia. After giving intravenous premedication, monitors were connected and patients were induced with propofol 2mg/kg and P-LMA insertion was provided by the bougie guided technique.

Our results demonstrate that the unassisted, gum elastic bougie guided technique is highly successful on the first attempt. Our first attempt success rate and over all insertion success rate compare favourably with rates from several prior studies comparing assisted (two operator), GEB guided PLMA placement with digital and tool insertion or digital alone (98% vs. 97-100% and 100% vs. 100% respectively). Thus it is reassuring to know that GEB-guided PLMA placement, which has previously been reported to be nearly universally successful on initial attempt with two operators, does not need to be discarded from the airway manager's armamentarium in the absence of assistance.

In the case, where the P-LMA insertion was recorded as difficult, no ventilation could be achieved after insertion of the P-LMA. An attempt to insert the Ryles tube via the drain tube also failed. After confirming absence of breath sounds on auscultation, the P-LMA was immediately removed and then reinserted, the Ryles tube successfully introduced and the breath sounds confirmed on auscultation. An exact reason for the inability to achieve ventilation in the first time could not be found, but we feel that it could be due to impaction in hypopharynx because of improper placement of the bougie which was due to resistance to advancement of bougie by hypophryngeal tissue. This is one of the misplacements that could rarely occur with the LMA- Proseal. The mask was certainly not deep enough that it could have entered the glottis and obstructed the airway.

The second time, when P-LMA insertion was recorded as difficult, we inserted a size 4 P-LMA. In spite of a considerable effort, we could not insert a size 4 P-LMA and secure the airway. Following this a size 3 PLMA was used, with which we could secure the patients airway. Probably, on error of judgment in the size selection of the device was responsible for the insertion being recorded as difficult.

In a study conducted by Bimla Sharma, Abhijit Bhattacharya, V.P. Kumar, Chand Sahai and Jaya shree Sood5, use of Proseal Laryngeal mask airway was studied in 100 consecutive cases of laproscopic surgery. Amongst the various parameters, P-LMA placement was also studied, Insertion success rate was 80% for the first attempt, 14% for the second and in six patients, P-LMA was placed in third attempt. Their definition of ease of insertion was identical to that of ours. Out of 100 cases in 74 patients P-LMA placement was recorded as easy, whereas in 16 patients insertion of P-LMA was difficult. There were 3 failed insertions. Intubation LMA (I-LMA)

was placed in 1 and endotracheal intubation was performed in 2 patients.

In another study by N.R. Evans et al. a descriptive trial was carried out in 300 ASA grade I-III adult patients29. The ease of insertion was recorded in this study. In their study three insertion attempts were allowed before a failure of insertion was recorded before the case would be excluded from the study. In their study, P-LMA placement was successful after a single attempt in 243 out of 300 patients (81%), whereas 2 attempts were required in 45 patients and 3 attempts required in 6. There were six patients, in which failed P-LMA insertion was recorded. In our study P-LMA insertion was inserted in the first attempt in 97% of the cases, whereas difficulty was observed only in 3% of the cases. In one of the cases failed insertion was recorded.

The study conducted by Roger Maltby, Michael T., Neil C. Watson, David Leipert, Gordon H, compared the LMA- Proseal with the tracheal tube in 109 ASA grade I-III patients undergoing Laparoscopic cholecystectomy17. Amongst the various parameters studied, two of them were cough and laryngospasm or laryngeal stridor. 4 out of 109 patients were crossed over to ETT group and excluded from the study. 2 out of 50 patients in LMA- Proseal group had cough as compared to 48 out of 55 patients in the ETT group. Also laryngeal stridor or spasm was found in 2 out of 50 patients in the LMA-Proseal group whereas 5 out of 55 patients in ETT group had laryngeal stridor or laryngospasm, out of which 1 patient required brief manual ventilation. Statistically significant differences in this study were related to smoother emergence from anaesthesia in the LMA- Proseal group.

In our study, we found cough in 5 out of 100 patients. Just like in the study mentioned above, even in our study cough was found only at the time of emergence.

In another study conducted by Piper SN *et al.* endotracheal intubation has been compared with Proseal-laryngeal mask airway insertion in patients undergoing gynaecologic laparoscopy. Amongst the various parameters studied were mean arterial pressure, heart rate, coughing, sore throat, ease of insertion of airway device and ease of placing the gastric tube in both the groups. At the end of anesthesia 25 patients of ET tube group coughed as compared to none in the Proseal- LMA group. Also, the insertion of P-LMA was easier as compared to the ET tube. These are the differences which we observed in our study as well, and hence is in agreement with our study.

Apart from cough, two other complications which we looked for were laryngospasm and tracheal/pulmonary aspiration. A study conducted by Han TH, Brimacombe, Lee EJ, Yang HS, involved the use of a laryngeal mask airway in 1067 parturients8, who were to undergo elective cesarean section. Patients were fasted for six hours and given ranitidine/ sodium citrate. LMA was inserted by experienced users. Post delivery vecuronium and fentanyl were administered. An effective airway was obtained in 1060 patients (99%), with 1051 (98%) in the first attempt. There were not episodes of hypoxia (SpO2 <90%), laryngospasm and aspiration.

Unlike this study which was carried out in only elective LSCS cases, our study included all types of elective as well as emergency cases. In fact only 19 out of 100 were elective cases in our study, rest all being emergency. Though elective cases in our study were fasted overnight but emergency cases who have not been fasting were also accepted in our study. On arrival of our patients, emeset was given intravenously. Proseal laryngeal mask airway was used only by experienced P-LMA users, and ryles tube was secured in all 50 cases undergoing P-LMA insertion via the drain tube. In 1 out of 100 cases in the P-LMA regurgitation of semisolid and liquid gastric contents was observed. However, no aspiration or laryngospasm was noted in any of the 100 cases studied by us.

A major advantage of bougie guided technique is that it prevents the cuff folding over, which is the most dangerous of all LMA malpositions, because it is compatible with a clear airway and a good seal but the drain tube is occluded, which puts the patient at a higher risk of aspiration. Another advantage is that the OGT insertion rarely fails as the DT and the oesophagus are in alignment. In our study the most common cause of failure of OGT insertion was inadequate lubrication.there is a very high coefficient of friction between silicon (drain tube) and plastic (gastric tube). Yet another advantage is that diagniosing the aetiology of subsequent ventilator failure is easier as malposition of distal cuff can be eliminated from the list of possible causes.

The disadvantage of bougie guided technique is the potential for stimulation and trauma. However, there were no episodes of airway protective reflexes activation, and no any stressful haemodynamic responses, blood staining or postoperative airway morbidity. This is because only slight force is needed to view the hypopharynx as compared to the larynx. Avoiding the force during insertion of the laryngoscope and passage of bougie should reduce the risk of trauma. In our study, there was no any evidence of blood stain over the bowl of PLMA after its removal. In addition to less trauma, this could be due to lack of oropharyngeal impaction and fewer insertion attempts required.a bougie will soon be available which has an atraumatic distal portion to further reduce the risk.

No study involving the use of Proseal – LMA in pregnant patients has yet been reported9. However, there are some case reports, where P-LMA has been used in pregnant patients [10, 11]. No incidence of aspiration or laryngospasm was found in either of these cases reported. Incidence of aspiration in obstetric anaesthesia, using the endotracheal tube ranges from 1/10,000 to 15/10,000 and it seems to be significantly higher in cesarean deliveries than with other obstetric procedures47.No case of definite aspiration has been reported in pregnant patients with P-LMA use but an overall incidence of aspiration with P-

LMA in all patients undergoing various surgeries is available. In an estimated 100,0000 uses of the P- LMA (data on file LMA company) there are three cases of confirmed, and two of possible pulmonary aspiration (incidence: I in 200,000-300,000)17,36,37,38. In one of cases mentioned above, pulmonary aspiration occurred secondary to the unidentified fold over malposition.

We feel, we experienced an hypopharyngeal impaction and malposition in one of the cases in our study, where P-LMA insertion was recorded as difficult. However, we were quick to identify it by absence of breath sounds on auscultation and inability to pass the Ryles tube. In the case report mentioned above, fold over mal position remained unidentified as ryles tube was not inserted till mid of the surgery. We feel, Ryles tube insertion immediately following P-LMA insertion and confirmation of breath sounds on auscultation could help detect any mal position and hence minimizes the chances of aspiration.

Unfortunately, due to emergency nature of these surgeries, we could not record the weight of most of our cases. However most of our cases were mild to moderately built patients. This is evidenced by the fact that size 4 P-LMA was used in only 5 out of 50 cases involving P-LMA insertion, whereas size 3 P-LMA was used in rest of the 45 cases. Hence, the application of this study in a different population group (e.g. belonging to western countries) where patients are much larger and heavier than those in our part of the country, could have different results or consequences.

There are a few limitations in our study. Firstly, because this is a newer technique, a learning curve may exist, which is not reflected in our results and the success rate we report may be higher than what others initially recognize. Particularly, it is possible that the novice operator may be deceived by advancement of the distal mask tip over the bougie when the bougie is impacted in the hypopharynx and has not entered into the oesophagus second, we have conducted this study in elective as well as emergency cases. Hence, there was no uniform fasting period observed. Therefore the patients who gave a history of diet intake immediately before the surgery were more prone to regurgitation and aspiration than the ones who had fasted overnight. Third limitation was that we have included patients with all types of surgeries in which the patient was coming under ASA grade I and II. This includes cases with HTN also, which pose a more difficult analysis of haemodynamics throughout the procedure.

We thus confirm, that in a detailed study of 100 patients, bougie guided proseal laryngeal mask airway insertion was found to be much simpler and easier. Cough was the only significant complication observed. None of the patients experienced laryngospasm or tracheal aspiration.

CONCLUSION

From our study, we conclude that

1. GEB-guided placement of the PLMA without an aid of an assistant can be accomplished quickly and successfully without impacting the expected clinical performance of the device.
2. Good haemodynamic stability can be achieved throughout the procedure with the use of a PLMA.
3. Very few postoperative complications such as coughing, sore throat and dysponea are found with the use of EB-guided PLMA insertion technique

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CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest.

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