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RESEARCH ARTICLE

COMPARISON OF I-GEL AND LMA-PROSEAL IN ADULT PATIENTS UNDERGOING DAY CARE PROCEDURES

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ABSTRACT

Background and objective: Supraglottic device holds the most important part of an anaesthetic gadget. Supraglottic airway device is a life saver for both the patient and the anaesthesiologists alike when there a failed intubation such as a CVCI situation. LMA Proseal and I-Gel are popular among the many supraglottic devices that are available now as it has a gastric drainage port. This study was to compare the efficacy of both the devices.

Observation and results: After ethical committee clearance and approval, 60 adults of both sexes under ASA I and II category to undergo general anesthesia for day care surgery were randomly allotted into two groups I & L, I being I-Gel and L being Proseal LMA. Demographic variables in both the groups showed no significant differences. I-Gel had a higher mean insertion time than that of Proseal LMA with a P value of <0.05 and also the ease and success of insertion in the first attempt was greater in Proseal LMA than in I-Gel with the P value of <0.05. The airway leak pressure was similar without any statistical difference. The hemodynamic changes were similar in both the groups without any statistical variations. Adverse events were noted such as blood stain on the device with I-Gel and sore throat in both with a slight increase in pLMA.

Conclusion: Proseal LMA has a better profile in terms of its lower insertion time and also has a higher first attempt success when compared to I-Gel.

INTRODUCTION

Airway catastrophes are known to occur frequently and the mortality and the morbidity associated with any CVCI situation is a well-documented problem all over the world. Airway safety and skills required in intubation, its complications and the resulting adverse events are common[1,2]. The most secure airway is accomplished by an endotracheal intubation which requires skill and practice and it carries its risk of sympathetic response and can also incite a life threatening laryngospasm and bronchospasm in hyper reactive airway[3,4].

These complications of intubation have initiated the research towards alternative ways of securing airway. Airway management was revolutionized towards the end of last century by the invention of the supraglottic device by Dr AIJ Brain which was named as the Laryngeal Mask Airway (LMA) [5, 6, 7].

Though invented as an alternative to endotracheal intubation and as a rescue device in difficult intubation and ventilation scenario it failed to provide fool proof protection against aspiration especially in patients with a full or partial stomach contents. So many models and modifications towards a safer design were made and the most useful made it beyond the clinical trial into practice. Arguably the design Proseal LMA became popular as it separates respiratory tract and oesophageal gastric tract with a drainage tube and an additional dorsal cuff[8,9,10].

Similarly other supraglottic designs also made it past the clinical trial, one such device is I-Gel which is an uncuffed perilaryngeal airway with a gastric channel and it reduces the trauma of the inflatable supraglottic devices because of its integrated gel design[11, 12].

Aim

To compare the efficacy of I-Gel and Proseal LMA for ease, time and attempts of insertion and also the airway leak pressure and the complication associated with the supraglottic device.

I Gel

I-Gel is a soft, transparent, non-inflatable supraglottic device which is made up of thermoplastic elastomer that can achieve a good perilaryngeal anatomical seal avoiding compression trauma. I-Gel has no latex and also exerts a minimal tissue compression than a conventional LMA. It also has a gastric

channel (separate from the airway) which can act as a vent for stomach contentents[11, 12, 13].

LMA Proseal

The limitation of the first models of Laryngeal Mask Airway lead to further experiments and modifications that made way for many more innovative models. Though many designs originated and ideas conceived the most practically useful LMAs made itself into the clinical trial and later into practice. Proseal LMA was introduced as Laryngeal mask airway incorporating drainage tube (LMADT) which clearly demarcates trachea and oesophagus ultimately avoiding aspiration and aids gastric drainage [14, 15, 16]

MATERIALS AND METHODS

After procurement of the institutional ethical committee approval 40 adult patients of both the sexes categorized under American Society of Anaesthesiologists (ASA) grade I and II undergoing general anaesthesia for an elective day care procedure were signed up for this study which was conducted between April 2013 and August 2013. The airway device insertion was done by the first author and the data entry was made by the second author.

Selection criteria included American society of Anaesthesiologists category I and II, Age 20 to 50 years, Weight 40 to 65 Kgs, Day care procedures and Mallampatti Class I and II.

Patients falling in ASA category III or more, Mallampatti class III or more, patients with a history of difficult airway or airway disease, cardiopulmonary disease, known patients of GERD, hiatus hernia, cervical musculoskeletal anomalies, patients with Obstructive Sleep Apnea were excluded from the study and so was unwilling patients.

Randomization of the patients into two groups I and L was done with a closed envelope predetermined number and single blinded. All patients were pre evaluated completely as per institutional guidelines. All patients were advised overnight fasting along with anti-aspiration prophylaxis with 10 mg of metoclopramide and 150 mg of ranitidine tablets the night before procedure.

Intra venous access with 18 G IV cannula was obtained in the patient holding area and multiparametric monitoring was done in the operating theater viz. Electrocardiography, pluseoxymetry and non-invasive blood pressure. The patients were pre-medicated with Inj Glycopyrrolate 0.2 mg IV, inj. Ranitidine 50 mg IV and inj. Metoclopramide 10 mg IV about 10 minutes before induction.

Pre induction baseline vitals were recorded and intravenous injections midazolam 0.02mg/Kg and 2 micrograms/Kg fentanyl was given in the OR followed by pre-oxygenation with 100% oxygen for three minutes. Induction was done with Propofol 2mg/Kg IV. Jaw thrusting was used to assess the depth of anaesthesia for the supraglottic device insertion[17]. After the standard positioning the supraglottic device was inserted as per the recommended technique and in case of pLMA cuff inflated to an intracuff pressure of 45mmHg. Proper insertion and placement was assessed by the adequacy of chest expansion, end tidal CO_2, absent gastric insufflation, absence of an audible leak and also by auscultation. Standard maneuvers such as chin lift, jaw thrust, head movements such as flexion or extension for both the devices. Gentle maneuvering of the device is also done and with ventilation adequacy reassessment.

Insertion grades were assessed as 1 as Easy and 2 as Difficult in case of inadequate chest expansion, absence of required end tidal CO2 and the presence of an audible leak. In such difficulty device was reinserted or another size was chosen and not more than a couple of attempts permitted and successive failure or failed insertion was graded as 3 and supraglottic device insertion abandoned for muscle relaxant assisted endotracheal intubation. The number of attempts required in getting adequate and effective ventilation is also noted.

Time taken for insertion – time taken from picking up the device until achievement of effective ventilation.

Maintenance of anaesthesia was done with a ratio of oxygen, nitrous oxide (1:3) and sevoflurane 1-2 %.

Gastric drain tube insertion was graded as easy if passed in a single attempt, difficult if it requires a second attempt and graded as failure if not successful after the second attempt.

Oropharyngeal leak pressure noted in the pressure gauge at the point of hearing the audible noise just lateral to the thyroid cartilage Vital parameters were noted at insertion and also at 1,3 and 5 minutes after insertion.

Complications were also recorded that included blood staining, sore throat, bronchospasm, laryngospasm, desaturation, gastric distension etc.

After the surgery inhalational anaesthetic cut off and the device was removed when patient becomes conscious and obeys commands. Patient was then shifted to recovery and later reviewed.

OBSERVATION AND RESULTS

This study was conducted between April 2013 and August 2013. Sixty patients fitting in American Society of Anaesthesiologists grade I and II of either sex were randomised into two groups I and L scheduled for day care procedure.

The gender distribution was comparable without any statistical difference in both the groups, with 16 men and 14 women in I group and 15 of each sex in L group.

Age distribution was also similar in both the groups mean age of 36.17 ± 8.14 in I group and 36.23±7.11 in L group and there was no statistical significance between the groups.

The mean weight recorded was 61.74 ±6.482 Kgs in I group and in L group it was 62.10±6.354 Kgs without any statistical significance.

The mean Body Mass Index was 24.080±2.0816 in I group and 23.826±2.0231 in L group and the groups were comparable and were not statistically significant

Mallampatti grading of one was present in 24 patients (80%) in each of the groups and the rest (4%) was graded as mallampatti two and were statistically equal.

Ease of insertion

Supraglottic device was inserted in all the patients without any failures, in I group it was easy in 17 patients and difficult in 13 patients (manipulations and reinsertion required) compared to L group where the grade of insertion was easy in 27 patients

and difficult in 3 patients (manipulations required) and the P value (<0.05) calculated was statistically significant. Table 1.

Table1 Ease of insertion

Group	I	II	P Value
I-Gel	17	13	<0.05
Proseal LMA	27	3	

Attempts taken for device insertion

First attempt was successful in 29 patients of L group and 22 of I group. One patient in L group and 8 in I required a reinsertion of the device and the P value (0.026) calculated was significant.

Table 2 Number of Attempts

Group	I	II	Pvalue
I-Gel	22	8	<0.05
Proseal LMA	29	1	

Time taken for insertion

The maximum time required to insert I-Gel was approximately 26 seconds against Proseal LMA which was 19 seconds. The earliest recorded time of insertion was 23 seconds for I-Gel and 17 seconds for pLMA and the mean time for I-Gel insertion was 26.30 ± 2.90 seconds against pLMA-where the time was 19.27 ± 2.02 seconds which was significant (P Value <0.05).

Table 3 Time for insertion

Group	Mean	SD	P value
I Gel	26.30	2.90	<0.05
Proseal LMA	19.27	2.02	

Ease of insertion of gastric tube

In the majority of patients the gastric tube was inserted in the first attempt among which the larger success was with L group (29/30) than the I group (17/30). Only two patients of L group required a second attempt compared to 13 patients P value was significant. We experienced no failures to insert the gastric tube.

Table 4 Ease of insertion of Gastric Tube

Group	1	2	P value
I-Gel	17	13	<0.05
Proseal LMA	29	1	

Oropharyngeal seal pressure

The maximum oropharyngeal seal pressure in both the groups was 32 cm H2O. The minimum oropharyngeal pressure was 19 cm H2O in both the groups. The mean OSP was 24.20 ± 3.225 Cm H_20 in I-Gel and 25.04 ± 3.322 Cm H_20 in LMA-S and the P value calculated at 0.398 which was insignificant.

Table 5 Oropharyngeal seal pressure

Group	Mean OSPCm H_2O	Std Deviation	P value
I Gel	24.20	3.225	0.398
Proseal LMA	25.04	3.322	

Complications

Though there were no major adverse events such as laryngospasm, desaturation etc. noted in our study, 3 patients in I group had blood staining on the device and one patient had post-operative sore throat. In the L group postoperative sore throat was found in 3 patients and one patient had hiccups

Mean heart rate were comparable but did not show any significant difference statistically. Similarly there was no difference statistically between both the groups in terms of systolic and diastolic pressures of pre induction, during and also at first, third and fifth minute. The mean arterial pressure also showed no significant statistical difference between the groups before, during and after induction

Microsoft office Excel 2010 was used for entering data and the subsequent analysis was done with statistical software IBM SPSS 15 version. The analysis was considered significant if P value was less than 0.05. Student's t test was used to calculate demographics, time for device placement, variables of hemodynamics and oropharyngeal leak pressure and Chi-square test to analyze attempts of insertion.

DISCUSSION

Supraglottic airway has undoubtedly revolutionized airway management, used on millions of patients worldwide since its introduction two and half decades ago. Limitations of primitive models lead to improvisation of the device by the inventor Dr. AIJ Brain. Other supraglottic devices also made it beyond clinical trials into practice one, of which is I-Gel. We chose to compare the efficiency of I-Gel with that of Proseal-LMA.

Review Of Literature

Ishwar Singh *et al*[18] compared I-Gel and LMA-Proseal in terms of airway sealing pressure, ease of insertion and that of gastric tube placement. The trauma inflicted to the airway by I-Gel and LMA-Proseal was assessed. They concluded that I-Gel had a better ease of insertion and gastric tube placement and Proseal had a superior airway sealing pressure though both had a seal pressure that can prevent aspiration. Proseal also had higher incidence of blood staining and lip injury. Their final conclusion was that I-Gel can be inserted easily than Proseal and had lower attempts on insertion and was also less trauma inducing to the airway.

WJ Shin *et al*[19] in their study compared three devices, I-Gel, Proseal LMA and classic LMA in patients undergoing orthopedic procedures and they assessed hemodynamic stability, airway leak pressure, volume of leak and also the success rate and complications. Though it was observed a similar success rate and stable hemodynamics in all the three, leak pressure was higher in both I-Gel and Proseal. Sore throat following device insertion was higher in classic LMA and they concluded that I-Gel can be an alternative device.

Lee AK*et al*[20] did a comparison between the analogous devices LMA Proseal and Supreme. They studied the ease of insertion and postoperative complications in both and made a conclusion that there were no differences between them.

Hosten T *et al*[21] did a similar study comparing LMA-Supreme and LMA-Proseal for lap cholecystectomy observed that the success rate and oropharyngeal seal pressure was almost identical, however the mean airway insertion time was less with LMA-Supreme.

Sharma B *et al*[22] valued the respiratory mechanics in I-Gel and Proseal LMA in laparoscopic cholecystectomy. They studied the oropharyngeal seal pressure, dynamic compliance and fiber optic view. The fiberoptic view was comparable between the

two but the oropharyngeal seal pressure was higher in PLMA and dynamic compliance was significant in I-Gel group.

Lopez A M *et al*[23] with LMA-Supreme and Proseal LMA insertion in prone position studied 120 patients. The devices were inserted by experienced anaesthesiologists. The insertion time and the first attempt success rate had no differences except a few manipulations that were required in Proseal LMA. The mean OLP in Proseal group was 31 and 27 cm H_2O in Supreme LMA group. The complications like postoperative sore throat and blood staining were similar.

Verghese C *et al*[24] compared LMA-Supreme and Proseal LMA in female patients who had elective lower abdominal surgeries under PPV. The first attempt success rate, insertion time, oropharyngeal seal pressure and gastric tube placement were comparable. The volume of air required to achieve optimum cuff pressure (60 cm H_2O) was 22.4 ml in LMA-Proseal and 21.9 ml in LMA-Supreme.

Zehra Ipek Arslam *et al* [38] in spontaneously breathing children undergoing lower abdominal elective surgeries compared size 2 LMA-Proseal with size 2 LMA-Supreme. Thedemographic variable, ease of insertion and ventilation, number of attempts taken for insertion, ease of gastric tube placement, hemodynamic changes on insertion, postoperative were quite similar. The only significant difference found was the oropharyngeal seal pressure that was 21.3±4.2 Cm H_2O for LMA-Supreme and 24.6±5.5 Cm H_2O for Proseal LMA.

Both the devices in our study were mostly similar except for the fact that one of the devices had an inbuilt cuff made of thermoplastic elastomer which has its own drawbacks. In all the patients the supraglottic device insertions were successful and among those most were effective in the first attempt at 73.3% with PLMA being most successful among the two at 90% and I-Gel at 56.6%. This was contrasting to the studies done by Ishwar Singh *et al* but consistent with WJ Shin *et al*. In one of the patients the appropriate size of I-Gel specified could not be negotiated as he had a small mouth and a larger tongue. In one patient a smaller sized I-Gel had to be reinserted as the appropriate size for the weight could not be negotiated. This could be because of the guidelines for choice of sizes 3 and 4 in I-Get that were overlying.

The first attempt success rate with both the devices together was at 85% with pLMA being most successful first attempt at 96.66% and I-Gel at 73.33%. Second attempt success rate was 26.67 in I-Gel and 3.44% in pLMA. The overall success rate was 100% and there were no failure of insertion. While most of the studies showed no failures of insertion the first attempt success rates do vary between studies. Ishwar singh[18] concluded that I-Gel was easier to insert than pLMA. Comparing the devices the first attempt success rate in our study was more with pLMA than with I-Gel with a statistical significance. This is similar to the studies elsewhere Shin WJ *et al*, verghese *et al*.

Mean time taken for insertion with I-Gel was 26.30 seconds and the same was better in pLMA at 19.27 seconds, the earliest was 17 seconds for pLMA and it stood at 23 seconds for I-Gel. This was significant because the ease as well as the attempts show that insertion was much more effective in pLMA that is well supported by shin WJ *et al*, verghese *et al*, lee AK *et al*. studies have reported similar or even lower time taken with pLMA insertion in prone position Lopez AM *et al*. This could relatively describe the better ease of insertion in case of pLMA where the presence of deflatable cuff will make a difference.

Oropharyngeal seal pressure was quite alike in both the groups at 24.20±3.92 in I-Gel group and 25.04±3.32 in pLMA group. It could be because of the non-inflatable cuff which is made of a thermoplastic elastomer that molds in the body temperature to fit in to yield a good perilaryngeal seal. On the other hand Proseal has an additional posterior cuff that helps in the stability of the device by fitting in anatomically well and also in demarcating respiratory and GI tract. Most of the studies confirm this similarity in the OSP between both Levitan *et al*, Shin WJ *et al*.

In the majority of patients the gastric tube was inserted in the first attempt among which the larger success was with L group (29/30) than the I group (17/30). Only one patient in L group required a second attempt compared to 13 patients P value was significant. We experienced no failures to insert the gastric tube.

Though we did not encounter a failure in the insertion of the gastric tube in both the groups there was a bit of difficulty in the I-Gel group as it required a second attempt (43.33%) to attain 100% success, but Proseal group required just one second attempt and the rest were all done in a single attempt (96.66%) the results corresponds to the studies done previously.

Hemodynamic changes were remarkably similar in both the groups without any statistical significance during insertion, a minute after and also at 3 minutes and 5 minutes. Both the devices exerted indistinguishable hemodynamic responses when observed.

As with any devices, supraglottic airways are also known to cause certain common complications like desaturation, sore throat postoperatively, blood staining of the device, dental trauma, bronco-laryngeal spasm etc. and also some unusual complications like, nerve damage, tongue cyanosis, dysarthria, dysphonia etc. as an isolated incidence.

Blood staining was seen in 3 of the I-Gel patients and among those one had a sorethroat, compared to a similar incidence of sore throat in 3 patients, but staining was not seen in pLMA group. The incidence of sore throat in LMAs was hypothesized to be because of the inflatable cuff. Another possible explanation could be because of increase in cuff pressure with the use of nitrous oxide. One patient in the pLMA group had hiccups and spontaneously resolved on deepening of inhalational agent.

CONCLUSION

Both the devices are safe, secure and an effective supraglottic airway in both spontaneous and controlled ventilation and are comparable in efficacy with an effective gastric drainage. LMA Proseal is better than I-Gel in terms of lesser insertion time, ease of insertion and the success in attempts.

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