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Original Research Article

Comparative study of Igel with proseal LMA for ease of insertion and effect on hemodynamics in pediatric patients

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ABSTRACT

Background: Supraglottic airway devices offer several advantages over endotracheal tube with regards to ease of insertion, hemodynamic stability, decreased airway morbidity, reduced requirement of drugs and smoother emergence from anesthesia. Objective was to compare two supraglottic airway devices, Igel and proseal LMA, with respect to ease of insertion, number of insertion attempts, time taken for placement of device and hemodynamic changes.
Methods: This prospective, randomized observational study was conducted in a tertiary care hospital in India after obtaining approval from the ethical committee of the institute. Sample size consisted of 80 patients who were randomized into two groups with each group having 40 patients.
Results: In our study it was found that Igel was easier to insert in 95% of the patients as compared to proseal laryngeal mask airway, whose insertion was found easy in 77.5% of the patients. There was higher success rate in first attempt insertion for Igel as compared to proseal laryngeal mask airway. 95% of the patients had successful device insertion in single attempt in group Igel and 77.5% of the patients had successful device insertion in single attempt in proseal laryngeal mask airway group. Time taken to insert Igel was significantly less (15.2 seconds) as compared to proseal laryngeal mask airway (26.1 seconds).
Conclusions: The ease of insertion of Igel is better as compared to insertion of proseal laryngeal mask airway. The success rate in first attempt insertion for Igel is higher as compared to proseal laryngeal mask airway. Time taken to insert Igel was significantly less as compared to proseal laryngeal mask airway. However, there was no difference in hemodynamic parameters and oxygen saturation between the two groups.

Keywords: Igel, Laryngeal mask airway, Proseal, Supraglottic devices, Ventilation

INTRODUCTION

Airway management is one of the most important skills in the field of anaesthesiology. The anaesthesiologist must ensure a patent airway and adequate ventilation. Endotracheal intubation is being considered as the gold standard technique till date. However, it has certain disadvantages like exaggerated hemodynamic response, airway morbidity, dental trauma, barotraumas, coughing and bucking usually during emergence from anesthesia, etc.[1] Furthermore, in pediatric patients, due to anatomical reasons (large omega shaped epiglottis, higher and more anterior situation of glottis) and physiological reasons (reduced functional residual capacity (FRC) and higher oxygen requirement) intubation may be difficult and chances of hypoxia increase.[2]

The laryngeal mask airway (LMA) is a supraglottic airway device (SAD) designed to maintain a patent

airway, which sits outside and creates a seal around the larynx. It is relatively non-invasive as compared to endotracheal intubation and in scenarios where endotracheal intubation is not mandatory, laryngeal mask airway has emerged as a formidable choice over endotracheal intubation.[3] Pediatric patients have specific characteristics that are quite different from those of adults, and their intubation therefore has a number of unique features.[4] This age group is likely to be associated with higher rate of complications of laryngoscopy and intubation, because of this, supraglottic airway devices (SADs) have been increasingly used in recent years in children.[5]

Supraglottic devices offer several advantages over endotracheal tube with regards to ease of insertion, hemodynamic stability, favourable respiratory mechanics, decreased airway morbidity, reduced requirement of drugs and smoother emergence from anaesthesia. Insertion of supraglottic airway device causes less laryngeal trauma and less sympathetic stimulation than endotracheal tube (ETT).[6,7] In cases of anticipated difficult airway management, supraglottic airway devices are increasingly preferred due to their efficacy and safety.[8] They can be used safely and effectively for both spontaneous as well as controlled ventilation in pediatric patients. Commonly used supraglottic airway devices today are second generation ones, which are provided with gastric channel for passing oro-gastric tube through it in the stomach.[9] While proseal laryngeal mask airway has a pneumatic cuff to be filled with air to provide proper oropharyngeal seal, Igel has temperature sensitive self-inflating non pneumatic membranous cuff. It has a buccal cavity stabilizer and integral bite block which helps in alignment of the device with oropharyngeal curvature of the patient and prevent malrotation. There is a channel for gastric suction placement and an epiglottic rest with a protective ridge which prevents down folding of the epiglottis during insertion.[10] It was designed to create a non-inflatable, anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures while avoiding compression trauma. The shape, softness and contour accurately mirror the perilaryngeal anatomy to create the perfect fit, so that compression, displacement and trauma are significantly reduced and has cheaper manufacturing costs due to simplicity of design.[11]

The various advantages of supraglottic airway devices are less stimulation of sympathetic nervous system leading to lower hemodynamic instability, the patient even in light plane of anaesthesia better tolerates it, ease of insertion and smooth recovery, avoidance of laryngoscopy and muscle relaxant, they do not displace bacterial colony from oral or nasal to lower respiratory tract, in situation like cannot ventilate cannot intubate it is used as a life saving device in securing the airway, less injury to airway compared to endotracheal tube and recovery and emergence time is less.[12] But it has certain disadvantages like, it does not provide protection against aspiration so contraindicated in full stomach patients, not useful in patients with glottic and supraglottic obstruction, or pathology, it is not a definite airway, patient with poor lung compliance cannot be recommended as it needs high inflation pressure, difficult to insert in patients with less mouth opening and in patients with oral and cervical pathology like large goitre, tumor.[13,14]

Supraglottic airway devices can cause complications like gastric content aspiration, gastric distension, complete or partial airway obstruction, traumatic injuries to the tongue, soft palate, uvula, tonsils, epiglottis and pharyngeal mucosa, dislodgement occurs accidentally when not in proper position, cuff is overinflated or inappropriate size is used, damage to laryngeal mask airway(LMA), failure to inflate or deflate can occur, bronchospasm, dysphagia and nerve injury may occur during laryngeal mask airway (LMA) use.[15,16]

Aims and objectives

The aim of this study was to compare two supra glottic airway devices, Igel and proseal LMA, with respect to ease of insertion, number of insertion attempts, time taken for placement of device and hemodynamic changes during use of supraglottic airway device.

METHODS

This prospective, randomized observational study entitled was conducted in the department of anaesthesiology and critical care, Sher-i-Kashmir Institute of Medical Sciences, Srinagar, from December 2019 to June 2021, after obtaining approval from the ethical committee of the institute. Sample size consisted of 80 patients who were randomized into two groups with each group having 40 patients, group P (proseal) and group I (Igel).

Inclusion criteria

For selection of patients the inclusion criteria were children between age group 2 to 8 years of either sex, American Society of Anaesthesiologists (ASA) class I/II and elective surgical procedures of duration not more than 2 hours with no need for endotracheal intubation.

Exclusion criteria

Patients with anticipated difficult airway (mouth opening of <2 finger, mallampati class 4, limited neck extension, history of previous difficult intubation), restricted mouth opening, cervical spine disease, patients with upper respiratory tract infections, patients at the risk of gastroesophageal regurgitation (e.g. hiatus hernia, full stomach etc.), patients with airway related conditions such as trismus, trauma or mass and patients undergoing any oral or nasal surgeries, were excluded from the study.

After preoxygenating the child with 100% oxygen for 3 minutes, intravenous induction with propofol (2 mg/kg

body weight) and fentanyl (2 µg/kg) was done. Following induction, mask ventilation was performed until conditions suitable for device insertion (lack of response to jaw thrust, loss of eyelash reflex etc.) were obtained. Size of the device was selected according to the body weight of the patient. For Igel, size 2 was used for the children weighing 10 to 25 kg and size 2.5 in those weighing 25 to 35 kg. For proseal laryngeal mask airway (PLMA) we used size 2 for children between 10 to 20 kg weight and size 2.5 for those between 20 to 30 kg weight. The cuff was then inflated according to the size of the proseal LMA (PLMA) i.e.; 10 ml of air for size 2 and 14 ml of air for size 2.5.

Before inserting the device, we noted baseline hemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation.

At the time of insertion of device, ease of insertion, total number of attempts made to insert the device and the total time taken for successful placement of the device were recorded.

The ease of insertion was categorized as either easy (E) or difficult (D). Supraglottic airway device insertion was considered easy if no manipulation was required and if there was a need to manipulate the airway, device insertion was considered to be difficult.

The total number of attempts made for insertion of supraglottic airway device were noted. The total time taken for insertion of supraglottic airway device was measured with the help of a stop watch. Time was measured in seconds.

After the insertion of supraglottic airway device, changes in hemodynamic parameters (heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure) and oxygen saturation from baseline were recorded.

Before and after removal of the device, changes in hemodynamic parameters (heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure) and oxygen saturation was also noted. The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA).

Continuous variables were expressed as Mean±SD and categorical variables were summarized as frequencies and percentages. Graphically the data was presented by bar and pie diagrams. Student's independent t-test or Mann Whitney U-test, whichever feasible, was employed for comparing continuous variables. Chi-square test or Fisher's exact test, whichever appropriate, was applied for comparing categorical variables. A p value of less than 0.05 was considered statistically significant. All p values were two tailed.

RESULTS

This study was conducted to evaluate the two supraglottic airway devices, proseal laryngeal mask airway (PLMA) and Igel regarding ease of insertion, number of attempts of insertion, total time taken for insertion of the device, hemodynamic changes and effect on oxygen saturation at different time intervals, in 80 patients of ASA grade I/II, of either sex, aged 2 to 8 years going for elective short surgical procedures with spontaneous ventilation.

Our study showed that the mean age of patients in two groups was comparable. Mean age in group Igel was 4.1 years and in group proseal was 4.9 years. The difference was statistically insignificant (p value >0.05).

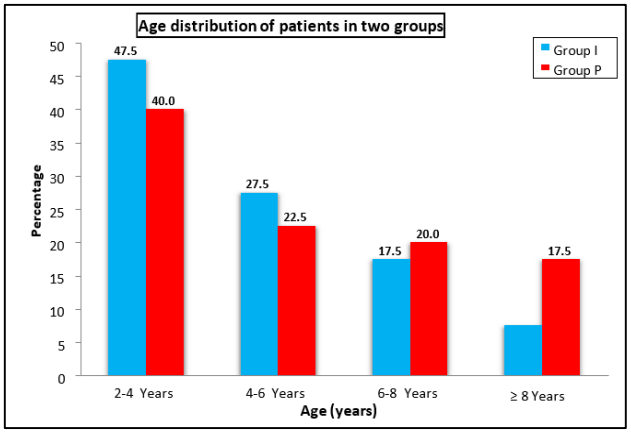

Figure 1: Bar graph depicting mean age (in years) of the patients in group I and group P.

The mean age (in years) of patients in group I was 4.1 years and in group p was 4.9 years. The groups were comparable in mean age and the difference was statistically insignificant (p value 0.142) (Figure 1).

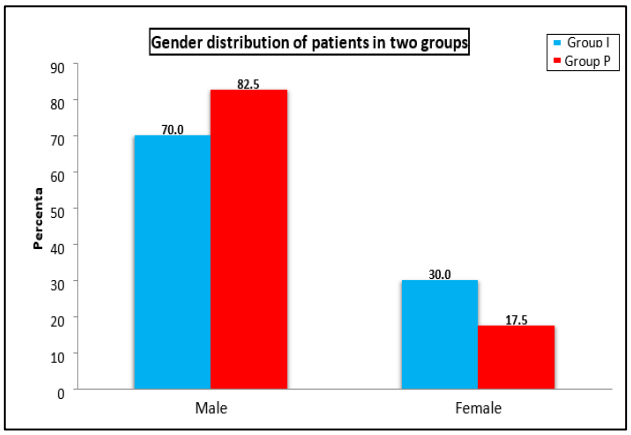

Figure 2: Bar graph depicting the gender distribution of patients in group I and group P.

In group I, 70% of the patients were male and 30% of the patients were female. In group P, 82.5% of the patients

were male and 17.5% of the patients were female (Figure 2).

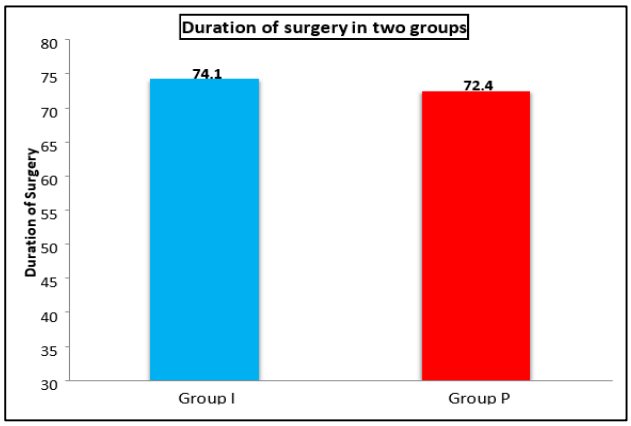

Figure 3: Bar graph depicting the comparison based on duration of surgery (in minutes) in two groups.

Figure 3 shows the comparison based on duration of surgery (minutes) in two groups. The mean duration of surgery in group I was 74.1 minutes and in group P was 72.4 minutes. The difference was statistically insignificant.

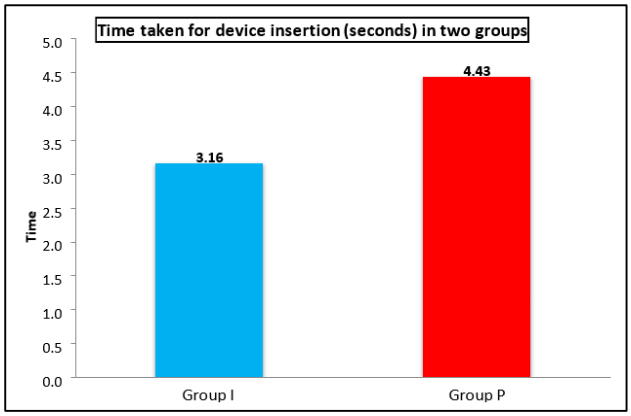

Figure 4: Bar graph depicting the mean supraglottic airway device insertion time in group I and group P.

Figure 4 shows that mean supraglottic airway device insertion time (seconds) in group I was 15.2 seconds and in group P was 26.1 seconds. The difference between the two groups regarding mean insertion time of supraglottic airway device was statistically significant.

Figure 5 shows that in 95% of the cases in group I the supraglottic airway device was inserted in single attempt and in group P, in 77.5% of the cases the supraglottic airway device was inserted in single attempt. The difference between the two groups regarding average number of attempts required for supraglottic airway device insertion was statistically significant.

Figure 6 shows that in 95% of cases in group I, supraglottic airway device was inserted easily and in 77.5 % of cases in group P the device was inserted easily. The difference between the two groups regarding ease of insertion of the device was statistically significant ($p<0.05$).

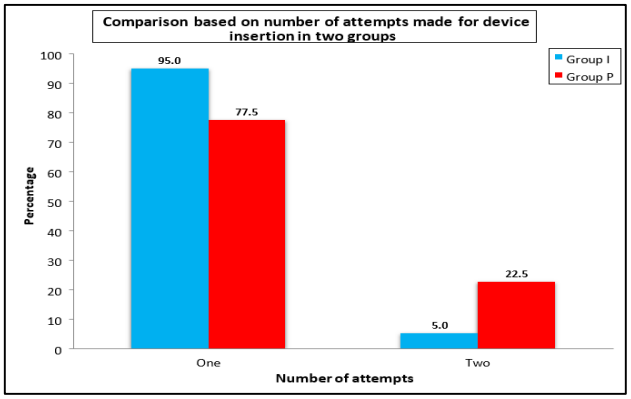

Figure 5: Bar graph depicting the average number of attempts required to insert the supraglottic airway device in two groups.

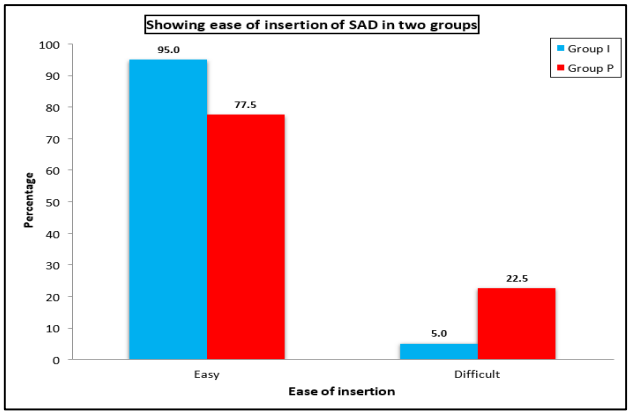

Figure 6: Bar graph depicting mean difference between the ease of insertion of supraglottic airway devices in two groups.

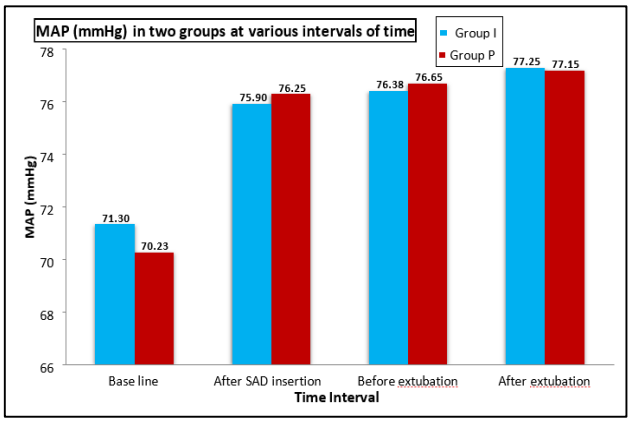

Figure 7: Bar graph depicting comparison of mean arterial pressure (mmHg) in two groups at baseline, after device insertion, before and after device removal.

Figure 7 shows the comparison of mean arterial pressure (mmHg) in two groups at baseline, after device insertion, before and after device removal. The mean arterial pressure was 71.30 mmHg, 75.90 mmHg, 76.38 mmHg and 77.25 mmHg at various time intervals for group Igel. For group proseal mean arterial pressure was 70.23 mmHg, 76.25 mmHg, 76.65 mmHg and 77.15 mmHg at different time intervals.

DISCUSSION

This study was conducted to evaluate the two supraglottic airway devices, proseal laryngeal mask airway (PLMA) and Igel regarding ease of insertion, number of attempts of insertion, total time taken for insertion of the device, hemodynamic changes and effect on oxygen saturation at different time intervals, in 80 patients of ASA grade I/II, of either sex, aged 2 to 8 years going for elective short surgical procedures with spontaneous ventilation.

Our study showed that the mean age of patients in two groups was comparable. Mean age in group Igel was 4.1 years and in group proseal was 4.9 years. The difference was statistically insignificant (p value >0.05). The gender distribution, height (cm) and weight (kg) of the patients in both the groups were comparable and were statistically insignificant (p value >0.05).

The hemodynamic parameters and effect on oxygen saturation at different time intervals were also comparable and statistically insignificant (p value >0.05).

In this study we found that both proseal laryngeal mask airway (PLMA) and Igel were successfully inserted in all the patients and there was no case of failed insertion in any of the two groups. The ease of insertion of Igel was found to be better than proseal laryngeal mask airway. In group Igel 38 patients (95%) had easy insertion of the device and in 2 patients (5%) insertion of the device was difficult. The group proseal showed 31 patients (77.5%) had easy insertion and 9 patients (22.5%) had difficulty in insertion of the device. This was statistically significant. P value was <0.05.

The results from our study were similar to those obtained in the study conducted by Chauhan et al titled "Comparison of clinical performance of the Igel with LMA proseal", who found that Igel was easier to insert with a better anatomic fit.[10]

In our study we also compared the total duration of supraglottic airway device insertion and it was found that the total time taken to insert Igel was less as compared to proseal laryngeal mask airway. Igel had a mean duration of 15.2 seconds and proseal laryngeal mask airway had a mean duration of 26.1 seconds. P value was <0.001 which was statistically significant.

Our study regarding total time taken to insert the device correlates with the study conducted by Pratibha et al.[17]

In our study we also compared the total number of attempts that were made to insert Igel and proseal laryngeal mask airway and it was found that 38 patients (95%) had successful supraglottic airway device insertion in a single attempt and 2 patients (5%) had success in second attempt in group Igel. In group proseal, however, 31 patients (77.5%) had a successful device insertion in a single attempt and 9 patients (22.5%) had success in second attempt. This difference was statistically significant. P value was <0.05.

Similar results were also found in the study conducted by Jadhav et al titled "comparison of two supraglottic airway devices in short surgical procedures", who found that the success rate of first attempt insertion was more with group Igel.[18] It was found that the first attempt success rate was higher with Igel as compared to proseal laryngeal mask airway.

Therefore, in our study, Igel was found to be better than proseal laryngeal mask airway regarding ease of insertion, total number of attempts and its placement is also rapid. This may be attributed to the fact that Igel is made up of a thermoplastic elastomer with a soft durometer which has a gel like feel. This material makes the device easy to introduce. Secondly it has a buccal cavity stabilizer and integral bite block which helps in alignment of the device with oropharyngeal curvature of the patient and prevents malrotation. It also has a temperature sensitive self-inflating non-pneumatic membranous cuff, that accurately mirror the peri-laryngeal anatomy to create a perfect fit hence less chances of displacement.

Supraglottic airway devices can cause complications like gastric content aspiration, gastric distension, complete or partial airway obstruction, traumatic injuries to the tongue, soft palate, uvula, tonsils, epiglottis and pharyngeal mucosa, dislodgement occurs accidentally when not in proper position, cuff is overinflated or inappropriate size is used, damage to laryngeal mask airway (LMA), failure to inflate or deflate can occur, bronchospasm, dysphagia and nerve injury may occur during laryngeal mask airway (LMA) use.

Our study has few limitations that need discussion. We excluded children with difficult airway. Therefore, the results of this study cannot be concluded for patients with difficult airway. Also because of the small sample size, our study offers almost no conclusive evidence of the safety of the device, which requires data from a considerably larger cohort in a routine practice.

CONCLUSION

On the basis of our study it can be concluded that the ease of insertion of Igel is better as compared to insertion of proseal laryngeal mask airway. The success rate in first attempt insertion for Igel is higher as compared to proseal laryngeal mask airway. Time taken to insert Igel is

significantly less as compared to proseal laryngeal mask airway. However, there is no difference in hemodynamic parameters and oxygen saturation between the two groups.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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