DOI: 10.48165/ijabms.2022.243811

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original article

COMPARISON OF TWO SECOND GENERATION SUPRAGLOTTIC AIRWAY DEVICES I-GEL VERSUS LMA PROSEAL IN PATIENTS UNDERGOING ELECTIVE SURGERIES.

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ABSTRACT:

INTRODUCTION:

Management of airway is one of the primary responsibilities of anesthesiologist[1].

Supraglottic airway devices have become a standard fixture in airway management, filling a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. They have separate gastric channel to reduce regurgitation & pulmonary aspiration[2].

Proseal LMA has unique double cuff arrangement, main cuff is inflated to seal the laryngeal opening and additional pharyngeal cuff helps to improve the airway seal which make the PLMA ideal for positive pressure ventilation. 'I-gel' is a non-inflatable supraglottic airway device designed to avoid compression trauma.

Objectives of the study were Quality of insertion, Complications during insertion, Quality of airway sealing, Analysis of hemodynamic parameters, Post-operative complications.

METHODS: Total 60 patients were divided in 2 groups: A & B. Airway secured with I-gel & PLMA respectively.

Ease of insertion of devices, airway sealing quality score, ease & number of attempts of gastric tube insertion were noted.

RESULTS: I-gel is better than PLMA in term of faster & easy insertion requiring less manipulation with low incidence of complications during insertion, less hemodynamic stress response and lower postoperative complications.

CONCLUSION: Among the second generation supraglottic airway device I-gel is a better & safe alternative to PLMA during elective surgeries.

KEYWORDS: I-gel, Proseal LMA, supraglottic airway device

INTRODUCTION:

Supraglottic airway devices have become a standard fixture in airway management, filling a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. These devices sit outside the trachea and provide a hands-free means of achieving a gas tight airway. The Proseal laryngeal mask airway (PLMA) was introduced by Archie Brain in clinical practice in 20003. It has unique double cuff arrangement in which main cuff seals the laryngeal opening when inflated, and an additional pharyngeal cuff helps to improve the airway seal. These features make the PLMA ideal for application of positive pressure ventilation. second tube was placed lateral to the airway channel to facilitate passage of nasogastric tube, to separate respiratory and esophageal pathways and permit escape of gastric content to reduce risk of gastric insufflations, regurgitation and pulmonary aspiration4.Further they have reinforced airway tube to prevent kinking and a built in bite block to reduces the possibility of airway obstruction. To overcome the limitation of PLMA (high cost, demand for careful handling to prevent cuff damage and relative difficulty of insertion) a new and cheaper supraglottic airway device "I-gel" has been developed by Dr. Mohammad Aslam Nasir in January 2007. I-gel is a single use noninflatable supraglottic airway device. It is designed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and peri-laryngeal structures to avoid the compression trauma that can occur with inflatable supraglottic airway devices. The tip of the distal non-inflatable cuff lies in the proximal opening of the esophagus, isolating the esophageal opening from laryngeal inlet. The seal created is sufficient for both spontaneously breathing patients and for positive pressure ventilation4. The present study was designed to compare two second generation supraglottic airway devices (I-gel versus LMA Proseal) in patients undergoing elective surgeries.

OBJECTIVES:

The objectives were:

1) Quality of insertion: (a) Ease of insertion

(b) Number of attempts

2) Complications during insertion.

3) Quality of airway sealing

4) Analysis of hemodynamic parameters.

5) Post-operative complications.

METHODS: After approval from the institutional review board (IRB), comparative observational study was conducted in total 60 adult patients of ASA grade I & II, aged between 18-60 years of either sex scheduled for elective surgical procedures under general anesthesia. Patients with known difficult airway, Cervical spine disease, Mouth opening <2.5 cm, Full stomach, Hiatus hernia or Gastro-oesophageal reflux disease were excluded from the study.

The thorough preoperative check-up and examination was done and all routine investigations were with in normal limits. Patients kept nil orally for at least 6 hours pre- operatively. Informed and written consent was taken.

In operating room, all standard monitors including electrocardiograph, NIBP, pulse -oximeter and ETCO2 were applied and baseline reading noted. Intravenous line secured with IV cannula (18 G) and IV fluid started.

The size of the device used was decided by patient's body weight and manufacture's recommendation.

Patient was divided into two Groups A and B. Device was selected by odd & even method. In odd no. I-gel (Group A) and in even no. PLMA (Group B) selected. Selected device was lubricated with hydrating jelly before insertion.

All patients were premedicated with following drugs Inj.Glycopyrrolate 0.004 mg/kg IV, Inj. Ondansetron 4mg IV, Inj. Fentanyl 2µg /kg IV.

Preoxygenation with 100% oxygen for 3 min, Induction was done by Inj. Propofol 2.5mg/kg IV. Adequate depth of anesthesia was considered by loss of eye lash reflex and relaxation of jaw. If adequate depth is not achieved than additional dose of inj. Propofol 0.5 mg/kg IV given. Once an adequate depth of anesthesia was achieved, patient's airway was secured by selected device. In Group A I-gel, While in Group B LMA Proseal was inserted.

In Group B after insertion, cuff was inflated with air (as per size of PLMA) till the absence of audible leak. An effective airway and proper placement of the device was judged by a square wave capnograph trace, bilateral symmetrical chest expansion, and no audible leak. Both the devices were fixed by taping the tube over the chin. The device was connected to a Bain's circuit and anesthesia was maintained using 50% oxygen, 50% nitrous oxide, Sevoflurane 2-3% & IV inj.atracurium 25mg & repeated 5 mg as per requirement. Patients ventilated with intermittent positive pressure ventilation.

The quality of insertion of device was recorded. It includes ease of insertion and number of insertion attempts of device. Ease was defined as no resistance to insertion in the pharynx in a single maneuver. Difficult insertion was considered if resistance to insertion or one or more maneuver like gentle pushing and pulling of the device, chin lift, jaw thrust, head extension and neck flexion required to insert airway. The number of insertion attempts was also recorded. If an effective airway could not be achieved, the device was removed and second attempt was done. A maximum of three attempts were tried for adequate placement, after which insertion was recorded as a failure, and airway was secured with an appropriate- sized ETT and was excluded from the study. Complications during insertion like coughing, gagging, laryngospasm, bronchospasm and regurgitation/aspiration were noted.

Airway sealing quality was recorded by ASQS as determined by percentage loss of delivered tidal volume (inspiratory (set) – expiratory (outcome) volume on ventilator display screen).

Airway sealing quality score

1	No leak detected
2	Minor leak of tidal volume (Vt loss <20%)
3	Moderate leak of tidal volume (Vt loss 20% - 40%)
4	Insufficient seal (Vt loss >40%)

Patients' vitals were measured preoperatively, before induction, immediately after insertion, 1, 3, 5, 10, and 15 min after insertion of device. After completion of surgery, anesthetic agents were discontinued, and patient reversed with inj. Neostigmine 2.5mg and inj

Glycopyrrolate 0.04mg IV. After proper suctioning of oral cavity, after deflating the cuff of PLMA (directly for I-gel) device was removed. Duration of surgery was noted.
Postoperative complications like sore throat, hoarseness of voice, bronchospasm/laryngospasm, injury of the lips, teeth or the tongue and device was inspected for any blood stain were noted. Statistical analysis was done by unpaired t Test. All the continuous variables were recorded as mean ± SD. Chi square test was used for association between two attributes like ease of insertion of device, airway sealing quality score. Data's were analyzed using 'GraphPad' software. 'p' value of <0.05 was considered as statistically significant, whereas 'p' value of <0.001 was taken as highly significant.

RESULTS:
There was no significant difference between the two groups with respect to demographic details and ASA grading as shown in table 1.

TABLE 1: DEMOGRAPHIC DATA
The ease of insertion was more with I-gel 27 (90.0%) than PLMA 20 (66.6%) which was statistically significant ($p<0.05$). In both the groups in all the patients, device was inserted successfully within two attempts. The I-gel & PLMA was inserted in the first attempt in 28(93.3%) & 22(73.3%) patients respectively, which was statistically significant ($p<0.05$) as shown in figure 1.

FIGURE 1: QUALITY OF INSERTION

Fewer complications were noted during insertion of device. In Group A, only 1 (3.33%) patient had coughing/gagging while in Group B, 5 (16.66%) patients had coughing during insertion of device. No patients had laryngospasm, bronchospasm and regurgitation/aspiration in any group as shown in table 2.

Patient data	Group A	Group B
Number of patients	30	30
Age (years)	32.06±12.83	28.3±9.43
Gender male/female	11/19	8/22
Weight (kg)	57.6±6.16	54.6±4.28
ASA grade(I/II)	22/8	23/7

TABLE 2 – COMPLICATION DURING INSERTION

Complications	Group A	Group B
Coughing / Gagging	1 (3.33%)	5 (16.66%)
Bronchospasm	0	0
Laryngospasm	0	0
Regurgitation/ aspiration	0	0

Adequate ventilation was achieved in both the groups. ASQS as determined by percentage loss of delivered tidal volume were comparable between two groups. Score 1/ 2 was noted in 24(80.0%)/ 6(20%) and 25(83.33%)/ 5(16.66%) in Group A & B patients respectively (p=0.738), which was statistically not significant (p>0.05) as shown in table 3.

TABLE 3 – AIRWAY SEALING QUALITY SCORE

Score	Group A	Group B	P value
1	24 (80%)	25 (83.33%)	0.738
2	6 (20%)	5 (16.66%)	
3	0	0	
4	0	0	

In both the groups, pre-op (121.7±9.30/124.8±8.71), (80.7±6.55/80.9±5.52) and before induction (125.2±9.39/126.0±8.44), (81.0±6.37/80.2±5.17) MAP was comparable. Immediately after insertion (127.4±9.36/133.4±8.21), (83.2±6.56/89.0±4.81) & 1 min after insertion (129.2±9.65/134.3±8.12), (82.2±5.93/89.2±4.96), MAP was increased in both the groups but was higher in Group B than Group A and was statistically significant (p<0.05) as shown in table 4.

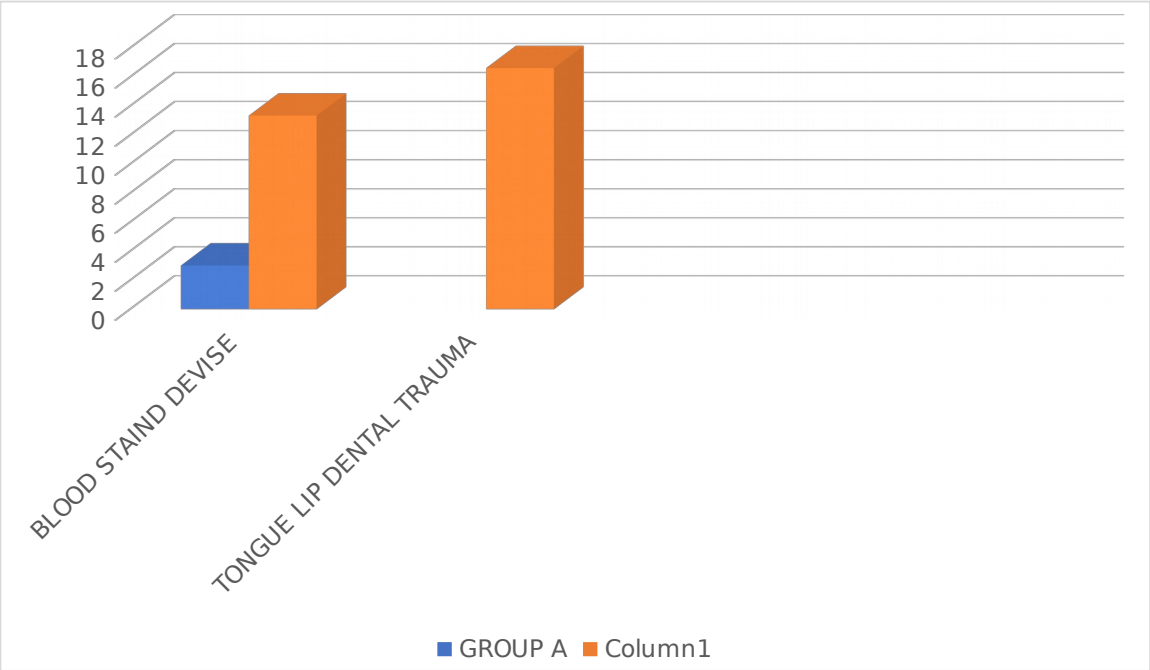
TABLE 4 -ANALYSIS OF MEAN ARTERIAL PRESSURE

	Group A (n=30)	Group B (n=30)	P value
Pre-op	94.5±6.74	95.3±5.49	0.616
Before induction	95.8±6.78	95.2±5.33	0.704
Immediately after insertion	97.8±6.69	103.5±5.11	0.0005

1 min after insertion	97.9±6.60	103.9±5.08	0.0002
3 min	97.4±6.04	101.3±5.23	0.0097
5 min	96.7±5.80	99.9±5.21	0.0284
10 min	95.8±5.85	98.4±5.22	0.0745
15 min	95.6±5.71	96.4±5.20	0.5727

The number of post-operative complications occurring in Group B was greater than in Group A. Blood-stained device was noted in 1 (3.33%) patient in Group A against 4 (13.33%) in Group B. Tongue-lip-dental trauma was noted in 5 (16.6%) in Group B where none in Group A. There was no incidence of sore throat, hoarseness of voice and bronchospasm / laryngospasm in any group as shown in figure 2.

FIGURE 2- Post-operative complications:



DISCUSSION:

Endotracheal intubation has long been considered to be gold standard for patients requiring general anesthesia. The development of supraglottic airway device –LMA can be considered as a mile stone in anesthesiology and became indispensable part of airway management. Various types of supraglottic devices are widely used for securing and maintaining airway and are alternative to tracheal intubation5.

The Proseal laryngeal mask airway (PLMA) came into existence in 2000. It has modified double cuff to improve seal around the glottis and a drain tube to provide a channel for aspirating gastric contents4, 6-8. But it too had few disadvantages like demand for careful handling to prevent cuff damage, difficulty in insertion and high cost.

I-gel is an innovative supraglottic airway device with non-inflatable cuff which has potential advantages including easier insertion and use, minimal risk of tissue compression, stability after insertion (no position change with cuff inflation) and manufacturing advantages in terms of simplicity and decreased cost. It is designed to anatomically fit the peri-laryngeal structures and a channel for gastric suction catheter placement5. Further, it has been designed to achieve a mirror impression of the pharyngeal and laryngeal structures and to provide a peri-laryngeal seal without cuff inflation17.

This study was designed to compare second generation supraglottic airway devices (I-gel versus LMA Proseal) during elective surgeries for quality of insertion, complication during insertion, quality of airway sealing, hemodynamic stability, SpO2, ETCO2 changes and postoperative complications.
In 2009 Ishwar Singh et al compared clinical performance of I-gel with proseal LMA in elective surgeries. They concluded that I-gel - a new supraglottic device, is easier to insert, requires less attempts of insertion, less traumatic and has easier gastric tube placement9.
complications were comparable. They concluded I-gel is an effective and safe alternative supraglottic airway device10.

In 2015 Preeti Agarwal, Deepak Kumar et al compared clinical performance and hemodynamic changes of I-gel with LMA Proseal. The ease of insertion was more with group I (I-gel) (29/30) than with group II (PLMA) (23/30) ($p<0.05$). Blood staining of device, tongue and lip was more with group II ($p>0.05$). Changes in MAP was significant higher in group II than Group I ($p<0.05$). It was concluded that I-gel airway is better alternative, user friendly device than PLMA in patients with high risk and having predicting difficult airway because of ease of insertion and maintenance of hemodynamic stability11.

In 2016 Renu Bala, Susheela T, Sanjay J et al compared hemodynamic changes associated with insertion of three different supraglottic airway devices (Classic LMA vs PLMA vs I-gel). They concluded all three supraglottic airway devices cause similar hemodynamic changes but I-gel has higher success rate, take less time for insertion, associated with less perioperative complications and lead to comparatively less pressor response12.
In 2017 SG Curpod et al compared the clinical performance of I-gel and PLMA in adult patients. Mean insertion time for I-gel was significantly lower than PLMA ($p< 0.001$), I-gel was easier to insert ($p < 0.762$). ASQS as determined by percentage loss of delivered tidal volume were comparable between two groups. I-gel provided a better fibreoptic view of glottis than PLMA. Gastric tube placement, hemodynamic parameters and complications were comparable. They concluded I-gel is an effective and safe alternative supraglottic airway device10.
Easy insertion and a smaller number of attempts influence the feasibility of supraglottic airway devices.
The ease of insertion was more with I-gel than PLMA 20 which was statistically significant. Device was inserted successfully within two attempts. The I-gel & PLMA was inserted in the

first attempt in 28(93.3%) & 22(73.3%) patients respectively, which was statistically significant ($p<0.05$). This was comparable to previous study done by Ishwar singh et al in 2009.

Both the devices were tolerated well and clear airway was maintained throughout anesthesia.
In Group A, only one patient had coughing/gagging while in Group B, five patients had coughing during insertion of device. No patients had laryngospasm, bronchospasm and regurgitation/aspiration in any group.

Airway sealing quality score was comparable in both the groups which was statistically not significant ($p>0.05$). This was comparable to previous study done by SG Curpod.
In both the groups, pre-op and before induction MAP was comparable. Immediately after insertion & 1 min after insertion, MAP was increased in both the groups but was higher in Group B than Group A and was statistically significant ($p<0.05$).
These results were comparable with previous study done by Preeti Agarwal, Deepak kumar et al in 2015, Renu Bala, Susheela T, Sanjay J et al In 2016.
The mean duration of surgery (32.0±5.19/31.5±4.58) was comparable in both the groups.
The number of post-operative complications occurring in Group B was greater than in Group A. Blood stained device was noted in 1 patients in Group A against 4 in Group B. Tongue-lip-dental trauma was noted in 5 in Group B where none in Group A. There was no incidence of sore throat, hoarseness of voice and bronchospasm / laryngospasm in any group. These results were comparable with previous study done by In 2015 Preeti Agarwal, Deepak kumar et al.

CONCLUSION:

Both second generation SADs, PLMA and I-gel were tolerated well and comparable in securing a patent airway and quality of airway sealing in patients undergoing elective surgeries. I-gel is better than PLMA in terms of faster and easy insertion requiring less manipulation with a low incidence of complications during insertion, less hemodynamic stress response and lower incidence of postoperative complications. To conclude with, Among Second generation supraglottic airway device (I gel versus PLMA) I-gel is a better and safe alternative to PLMA during elective surgeries.

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CONFLICT OF INTEREST: Nil

FUNDING: Nil

ACKNOWLEDGEMENT: Nil