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Classic Laryngeal Mask Airway Versus I -Gel in Terms of Ease of Insertion in Short Surgical Procedures- a Randomized Control Trial

Kachhara AG[1]* and Sadawarte PS[2]

[1]Senior Resident, Apollo, Hospital, Bengaluru, Karnataka, India

[2]Associate Professor, Department of Anaesthesiology, NKP Salve Institute of Medical Sciences and Research Centre (NKPSIMS), India

***Corresponding author:** Apeksha G Kachhara, Senior Resident, Apollo, Hospital G-43, Zonasha Elegance, Dine anjaneya swamy temple road, Harlur, Bengaluru, Karnataka, India, Tel: +91-9967410262; Email: apek_kachhara@yahoo.co.in

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Abstract

Background: I-gel is an innovative supraglottic airway device designed to create non-inflatable anatomical seal, at the same time avoiding compression trauma likely with inflatable supraglottic airway devices. With the present study, I-gel was assessed for superiority in terms of ease of insertion against the classic laryngeal mask airway in anesthetized spontaneously breathing patients during short elective surgical procedures.

Methods: This single blind randomized controlled trial was conducted over two years at a tertiary care teaching hospital on 60 anesthetized spontaneously ventilated patients undergoing elective surgical procedures. Two groups were formed and compared on the basis of airway device used: Group I (cLMA group, 30 participants), Group II (I-gel group, participants). Number of attempts, insertion time and seal pressure were recorded for each procedure in both the groups. Parameters like Spo2, Etco2 were monitored during the surgical procedure. Selected potential immediate and delayed postoperative complications were also duly noted and compared.

Results: Mean insertion time of I-gel group was observed to be lesser (17.59 secs) than that of cLMA group (29.57 secs), while mean seal pressure of I gel (25.38 cm of H2O) was more than that of cLMA (22.33 cm of H2O) and the differences were statistically significant ($p<0.001$).

Conclusion: Insertion of I-gel is more rapid and with a better seal pressure than achieved with usage of cLMA.

Keywords: Laryngeal mask airway; I- gel; Insertion time; Ease of insertion

Abbreviations: IEC: Institutional Ethics Committee; LMA: laryngeal mask airway; SGADs: Several supraglottic airway devices.

Introduction

Proper airway management during surgery is of paramount importance from an anaesthesiologist's perspective. Airway management has come a long way from the development of endotracheal intubation by Macewen (1880) and use of facemask with either an oral or a pharyngeal airway to the present day usage of sophisticated devices. Laryngoscopy and intubation have the inherent risk of variable hemodynamic responses like increase in the level of plasma catecholamine,

hypertension, tachycardia, arrhythmia, myocardial ischemia along with increase in intracranial and intraocular pressures [1-3]. Supraglottic airway devices avoid hemodynamic responses associated with endotracheal intubation and are hence being preferred lately. The laryngeal mask airway (LMA) has been well established for airway management in both anaesthesia and resuscitation, albeit with the use of inflatable cuff leading to risk of tissue distortion by edema, venous compression and congestion and nerve injury, along with potential risk of aspiration due to lack of airway protection from gastric contents.

Further factors limiting its usage are more than one attempt for device insertion and air leakage especially during positive pressure ventilation. The mentioned limitations prompted scientists to invent new devices for airway management. Several supraglottic airway devices (SGADs) are specifically designed to reduce the risk of aspiration. A supraglottic airway without an inflatable cuff (like I-gel) has several other potential advantages; including easier insertion, minimal risk of tissue compression and stability after insertion [4-6]. But the results have been documented to be inconsistent and need further substantiation. With the above research gap in mind, the present study was undertaken with the objective of comparison of classic laryngeal mask airway and I- gel in terms of ease of insertion in anesthetized spontaneously breathing patients during short elective surgical procedures.

Materials and Methods

The study was initiated after obtaining necessary clearance from the Institutional Ethics Committee (IEC). This was a single blind randomized controlled trial conducted over two years (December 2015 to November 2017) in a tertiary care teaching institute from central India. The estimated sample size was 24 in each group (calculated on the basis of previous similar study by previous study by Helmy AM, et al) [7]. Considering the failure rate, sample size of 30 patients was finalized in each group (total 60). The patients were randomly divided into two groups and the randomization was done by using the software randomizer analyzer. Allocation concealment was achieved using opaque envelopes with serial numbers. Only the patients were blinded to the type of device used (intervention).

- Group I (cLMA group): (n=30)
- Group II (I-gel group) : (n=30)

Following selection criteria were adopted for participant enrolment:

Inclusion Criteria

- Patients of age group 18 to 60 years
- ASA physical status I, II with Mallampati classification- I,II [8,9]
- Elective surgery under general anaesthesia with spontaneous ventilation (duration < 1 hour)
- Supine position with neutral position of neck during surgery

Exclusion Criteria

- Patients with anticipated difficult face mask ventilation, laryngoscopy and intubation
- Recent history of upper respiratory tract infection
- Upper gastro-intestinal surgery
- BMI > 25 Kg/m^2
- History of obstructive sleep apnoea or GERD
- Patients with condition which may increase the risk of a full stomach e.g. hiatus hernia, sepsis, pregnancy etc.
- Refusal to give consent

Procedural Details

After written informed consent, careful pre anaesthetic check-up was carried out in all the patients across groups with detailed clinical history, thorough clinical examination-both general and systemic with vital parameters. A Multichannel monitor was attached and standard anaesthesia was induced with inj. Propofol. Appropriate sized device using body weight as the guide was selected. Once optimum depth of anaesthesia was achieved, allotted device was lubricated and inserted with patient in 'sniffing the morning air' position. Each device was inserted by the same anaesthesiologist. If there was resistance during insertion of either device then airway manoeuvres like chin lift, jaw thrust, head extension or flexion of neck were allowed. 'Insertion with deep rotation' was used for I-gel and up and down movement was used for cLMA. The device was secured in place by taping it down from maxilla-to-maxilla and was connected to closed circuit. In both groups, successful airway insertion was ensured before proceeding further.

Various preoperative, intraoperative and postoperative variables were evaluated. 'Number of attempts' to establish adequate ventilation was noted. Failed attempts were defined as removal of device from mouth. If insertion was failed, insertion was re-tried after 1 minute of positive pressure ventilation with face mask with 100% O_2 and after giving titrated dose of Inj. Propofol. Airway was maintained using endotracheal tube in case of failure and the case was excluded from the study. 'Insertion time' was noted in seconds by an independent observer. If more than one attempt was required, then addition of insertion time in each attempt was considered as insertion time. 'Seal pressure' was measured by closing the expiratory valve of the circle system at a fixed low gas flow (3L/min), observing the air-way pressure at which equilibrium would reach. At this point, gas leakage was heard at the mouth, at the epigastrium (epigastric auscultation) or coming out of the drainage tube (I-gel group). Heart rate, systolic and diastolic Blood pressure were noted at baseline, after induction, at insertion

and then every minute till five minutes after insertion of the device. SpO_2 and ET-CO_2 were monitored before induction and continuously throughout the surgery. Incidences of post-operative airway complications were thoroughly assessed. On removal of device, blood on device (indicating trauma to the pharyngo-laryngeal framework), lip or dental injury, post-extubation cough and laryngospasm were noted. After regaining full consciousness, the patient was asked about sore throat (constant pain independent of swallowing), dysphagia (difficulty or pain with swallowing), dysphonia (difficulty or pain while speaking), and tongue numbness; immediately, post operatively and after 24 hours. Comparison of mean scores between the two groups was calculated by student-t test and proportion of qualitative variables between two groups by chi-square test. P value < 0.05 was considered as statistically significant. SPSS version 20.0 was used for data entry and analysis.

Results

In all, a total of 60 participants (30 inn each group) were recruited and data analysed. The mean age of the participants was 34±14 years with 69% participants being females. The mean BMI was 19.28 kg/m^2. Ten percent patients belonged to ASA physical status II. The differences between two groups were not significant for above variables. When the number of attempts was analysed amongst participants, 90% had "successful first attempt insertion" in I gel group, while the figure stood at 96.7% in the cLMA group, the difference being statistically insignificant. (p value- 0.611) (Table 1).

Number of Attempts I-gel		Group		Total
		LMA		
1	No.	27	29	56
	%	90.0%	96.7%	93.3%
2,3	No.	2	1	3
	%	6.7%	3.3%	5.0%
>3	No.	1	0	1
	%	3.3%	0.0%	1.7%
Total	No.	30	30	60
	%	100.0%	100.0%	100.0%

Table 1: Comparison of the two groups for number of attempts for insertion (P value = 0.611).

Mean insertion time of cLMA group was 29.36 + 5.74 seconds, while it was 15.41 + 4.8 seconds for the I-gel group. The difference in insertion time was statistically highly significant (p < 0.001). Mean seal pressure was 22.33 + 1.72 cm of H_2O in cLMA group and 25.38 + 3.70 cm of H_2O in the I-gel group, the difference again being highly significant. (p < 0.001) (Table 2).

Groups		N	Mean	Std. Deviation
Insertion time (in seconds)	LMA	30	29.36	5.739
	I-Gel	29	15.41	4.848
Seal pressure (in cm of H_2O)	LMA	30	22.33	1.729
	I-Gel	29	25.38	3.698

Table 2: Comparison of mean insertion time and seal pressure.

Comparison of postoperative airway complications between the two groups revealed them to be present in 10.3% in I-gel group and 3.3%in cLMA group. The difference between the two was not statistically significant. In actual; in cLMA group one patient had blood on device, while in I-gel group one patient each had blood on device, laryngospasm and sore throat respectively (Table 3).

Vital parameters were assessed at baseline, after induction, at insertion and then every minute till five minutes after insertion of the device. There was no significant difference in heart rate and systolic blood pressure between both the groups at any point in time during study. But difference between the groups in diastolic blood pressure 5 minutes after insertion of device was statistically significant (p-0.013).

Complication I-gel		Group		Total
		LMA		
Present	No.	3	1	4
	%	10.3%	3.3%	6.8%
Absent	No.	26	29	55
	%	89.7%	96.7%	93.2%
Total	No.	29	30	59
	%	100.0%	100.0%	100.0%

Table 3: Comparison of postoperative airway complications.

Discussion

Supraglottic airway devices have brought in significant improvement in the way airways are being managed during elective anaesthesia. cLMA has been in vogue for routine airway management for elective surgery and during cardiopulmonary resuscitation, but with certain limitations. I-gel airway is an innovative supraglottic airway management device, made of a medical grade thermoplastic elastomer, which is soft, gel-like and transparent. Certain purported advantages of I-gel over cLMA are superior seal pressure, reduced trauma, gastric access and integral bite block. With the present study, we aimed to substantiate the superiority in our set-up by comparing the two supraglottic devices cLMA classic and I-gel in relation to ease of insertion, seal pressure, post-operative airway complications and hemodynamic responses. Sixty participants fulfilling the mentioned selection criteria were studied. Surgery duration of <1 hour was included, as prolonged surgery may increase the cuff pressure in cLMA and increase the chances of post-operative airway complications as also in patients with recent upper respiratory tract infection. Surgery in supine position with neutral position of neck were selected to reduce device movement.

ASA physical status I, II were selected to avoid haemodynamic variations. Patients with full stomach, GERD were excluded to avoid chances of aspiration. No statistically significant difference was observed between mean ages of the groups (I gel group- 32.30±12.50 years, cLMA group- 34.77±12.65 years, p- 0.949). Similar study conducted by Helmy AM et al observed the mean age of patients in I-gel group to be 38.29±12.4 years and in cLMA group to be 41.62±13.4 years, the difference being statistically insignificant.[7] The distribution is also in line with the findings of studies conducted by Durrani HD et al, Ari ED et al and Chauhan, et al [10-12]. There was no significant difference between the two groups with respect to gender distribution. Mean BMI in group cLMA was 19.06 ± 3.18 kg/m^2, while it was 19.51±3.17 kg/m^2 in I-gel group. This difference was not statistically significant (p-0.585). This is in agreement with the findings of previous similar studies. There was no significant difference in ASA grade of patients between the groups, also in line with observations of similar studies and furthering the comparability of two study groups [7,12,13]. In the study, 90% of the cases in I-gel group had "successful first attempt insertion" as compared to 96.7% in cLMA group. Better ease of insertion in cLMA can be attributed to our training and routine usage of cLMA. But, the difference was still not statistically significant (P=0.611).

Study conducted by Durrani HD et al observed no difference for "successful first attempt insertion" in both cLMA and I-gel groups. Prateebha N et al in their study observed that the success rate in the first attempt was 100% with I-gel group as compared to 84% in cLMA group (p value = 0.003), which is in contradiction to observations of present study . The 100% success rate in insertion of I- gel in the Prateebha N et al study may be attributed to prior training under the supervision of anaesthesia consultants [10,14]. The mean insertion time in cLMA group was 29.36 seconds, while it was significantly lower in I-gel group (15.41 seconds). As no cuff inflation is required in the I-gel insertion and the device can simply be pushed into place, lesser time was required to achieve an effective airway. Similar findings were observed by Helmy AM et al, with the mean duration of insertion attempts observed to be 15.62±4.9 seconds in I-gel group and 26.2± 17.7 seconds in cLMA group, with the difference being statistically significant (P=0.0023) [7]. The comparatively lower insertion time in I-gel group has also been documented by Ari Ed, et al. Hashemian SM, et al and Prateebha, et al in previous similar studies. However, Pournajafian A et al and Durani HD et al could not establish statistically significance, probably due to lesser power of studies [11-14,10,15]. Mean seal pressure was 22.33 + 1.72 cm of H_2O in cLMA group and 25.38 + 3.70 cm of H_2O in the I-gel group, the difference again being highly significant. The efficacy of seal depends on the fit between oval-shaped groove that surrounds the glottis and also the oval shaped cuff of laryngeal mask airway device. I-gel is designed in such a way that it will anatomically fit to the perilaryngeal and hypolaryngeal structures without the use of inflatable cuff.

The results with respect to seal pressure are corroborative of the observations of majority of available evidence [7,13-17].

The overall incidence of post-operative airway complications, for reasons unknown, was insignificantly higher in I-gel group, similar to findings of studies conducted by Pournajafian A, et al and Das B, et al [15,16]. No significant difference was observed between the two groups with respect to heart rate and systolic blood pressure levels at the studied intervals. There was no statistically significant difference in diastolic BP before insertion, at induction, after insertion, at 1 minute, at 2 minutes, at 3 minutes and at 4 minutes ($p>0.05$), but diastolic blood pressure was more in cLMA group than I-gel group at 5 minutes after insertion ($p =0.013$). The difference was clinically insignificant though. Study by Helmy AM et al had observed no significant difference in diastolic BP between cLMA and I gel groups, while Prateebha, et al. observed significant difference ($p =0.0001$) in diastolic BP during insertion and at 1, 3, 5, 10, 15, 20, 25 min post-insertion and during removal between cLMA and I-gel groups, though no significant difference was observed at baseline.[7, 14]

In conclusion, it can be said that both cLMA and I-gel are suitable for spontaneous ventilation in anaesthetized patients for short surgical procedures and I-gel may be considered preferentially over cLMA for faster insertion and better seal pressure.

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