A COMPARISON OF CLINICAL PERFORMANCE OF I-GEL WITH PROSEAL LMA IN PATIENTS UNDERGOING MASTECTOMY

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ABSTRACT

AIM

To assess the ease of insertion of I-gel and ProSeal LMA and incidence of post op complications. Study design-A prospective randomised controlled trial comparing the clinical performance of I-gel and ProSeal LMA.

METHODS

After induction and good muscle relaxation LMA/I-gel was introduced as per randomised computer allocation. After insertion, nasogastric tube was inserted through the gastric channel. Parameters monitored were heart rate, nubp, SpO2, ETCO2 at 1, 5 minutes after insertion of the device and thereafter every 5 minutes till the end of surgery. In case of failure, airway was secured with an endotracheal tube. Ease of gastric tube insertion was noted at the end of surgery; postop complications were noted. Blood staining of the device, injury to the lips, teeth, and tongue were noted. Incidence of sore throat 24 hrs. after surgery was also noted. Statistical analysis was done with SPSS software.

RESULTS

Age, height, weight and BMI were comparable in both groups. The airway characteristics was also comparable in both the groups. Ease of introduction was also the same for both the groups, but the time taken was much lesser for I-gel group. The ease of insertion of gastric tube was much easier for the I-gel group. Blood staining of the device was more with the ProSeal LMA group. There was no injury to any of the structures mentioned above. Postop sore throat was more in the ProSeal LMA group.

CONCLUSION

From our study, we conclude that the airway can be secured much faster with I-gel than ProSeal LMA. Postop sore throat was much less for I-gel than ProSeal LMA. Both were comparable in number of attempts of insertion, gastric tube introduction. Trauma to the airway structures was also minimum with both I-gel and ProSeal LMA.

KEYWORDS

I-gel, ProSeal LMA, Nasogastric Tube.

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INTRODUCTION: Safe and effective airway management is the foundation of quality anaesthetic practice. Supraglottic airway devices have revolutionised airway management since the invention of the LMA Classic by Dr. Archie Brain in 1988. They fill a niche between the face mask and the endotracheal tube in terms of both anatomical position and degree of invasiveness. The ease of insertion, safety and the global increase in the number of day care surgeries have led to their increased use in routine anaesthetic practice.[1,2]

Since the introduction of the LMA Classic, several laryngeal masks have been introduced which differ in shape, stiffness, cuff properties and constituent materials. Apart from being used to maintain airway routinely during an anaesthetic, laryngeal masks have now come to play an important role in the management of difficult airways and in emergent situations such as cardiopulmonary resuscitation.[3,4,5,6,7,8]

To overcome limitations of available supraglottic airway devices (relative difficulty of insertion, demand for careful handling to prevent cuff damage, tissue compression) new device I-gel was developed.

I-gel airway is a novel supraglottic airway device which has non inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures. It avoids compression trauma that occur with inflatable supraglottic airway devices like ProSeal LMA. A supraglottic airway LMA, nasogastric tube without inflatable cuff has several advantages including easier insertion and minimal risk of tissue compression.[9]

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Only minimal number of studies had been conducted between I-gel and ProSeal LMA. We compared I-gel and ProSeal LMA for their ease of insertion and incidence of post-operative complications.

AIMS AND OBJECTIVES: This study aims to test and compare the I-gel and ProSeal LMA in terms of their

- Number of attempts of insertion of device.
- Time of insertion of device.
- Number of attempts of gastric tube insertion through the device.
- Post-operative blood stain on device, trauma to tongue, lip and tooth.
- Incidence of post-operative sore throat.

MATERIALS AND METHODS: Approvals of the Institutional Scientific and Ethics Committees were obtained prior to commencement of the study.

Study Design: Prospective randomised trial comparing clinical performance of I-gel with ProSeal LMA.

Sample Size:

I-gel	30
ProSeal LMA	30

Inclusion Criteria:

1. Patients with ASA physical status class 1 (a normal healthy patient).
2. ASA physical status class 2 (with mild systemic disease that results no functional limitation).
3. Age 35 to 60 years.
4. Female patients undergoing mastectomy.

Exclusion Criteria:

- Patients with known difficult airway.
- Patients with cervical spine disease.
- Patients who is morbidly obese.
- Patients with hiatus hernia, gastro-oesophageal reflux disease.
- Patients not willing to take part in study.

Duration of Study: Study period was from January 2013 to December 2013.

Methods: All the patients received injection midazolam 1 mg, glycopyrrolate 0.2 mg, ranitidine 50 mg and ondansetron 4 mg intravenously 45 minutes before surgery. Anaesthesia was induced with propofol 2-2.5 $mg.kg^{-1}$ and fentanyl 1 to 1.5 $\mu g.kg^{-1}$. Neuromuscular blockade was achieved with vecuronium 0.1 $mg.kg^{-1}$. Both I-gel and LMA–ProSeal were lubricated with water soluble jelly. Once adequate depth is achieved either of two devices selected by randomised computer table was inserted. Both devices were fixed by taping the tube over the maxilla and lubricated gastric tube was placed into the stomach through the gastric channel.

Maintenance was achieved by oxygen, nitrous oxide, isoflurane and intermittent doses of intravenous vecuronium. Intraoperative heart rate, noninvasive blood pressure, oxygen saturation and end tidal carbon dioxide were recorded before induction and at 1 and 5 minutes after insertion of device and then at every 5 minutes interval till the end of surgery. An effective airway was judged by a square wave capnograph trace, normal thoraco-abdominal movement and absence of leak. If an effective airway could not be achieved, the device was removed and three attempts were permitted before failure of insertion was recorded. If three attempts were unsuccessful either an alternative device is inserted or the trachea was intubated by direct laryngoscopy.

Ease of Insertion: The number of attempts for the correct positioning of the device was noted. Correct positioning was determined by the appearance of at least 6 square traces on the capnograph and ability to deliver tidal volume of at least 4 mL/kg. The insertion was termed as a failure if the number of attempts exceeded 3 and was recorded as such. Every time the device was taken out of the patient's mouth, it would be counted as 1 attempt.

Time of insertion was recorded by independent observer and defined as time interval between picking up the device and securing effective airway.

Gastric Tube Insertion: The ease of placement of gastric tube was also recorded and its correct placement is confirmed by injection of air and epigastric auscultation or aspiration of gastric contents. Failure of gastric tube placement was also recorded and it was defined as failure if we are unable to advance the gastric tube into the stomach within three attempts.

At the end of surgical procedure, anaesthesia was discontinued, patient was reversed with standard dose of neostigmine and glycopyrrolate and the device was removed.

Postoperative Complications: Blood staining of the device and tongue, lip and dental trauma were recorded. Incidence of sore throat was also recorded 24 hours after surgery.

Data was analysed using statistical Package for Social Sciences (SPSS) software for Windows. Independent t test, Pearson's chi-square tests were used for statistical analysis of recorded data.

Results and Observations: Sixty female patients undergoing elective modified radical mastectomy were randomly assigned to be ventilated using one of the two supraglottic devices (I-gel or ProSeal LMA). The results obtained from 60 subjects were tabulated and analysed using standard statistical principles and techniques.

Parameter	I-gel group (Mean±SD)	ProSeal LMA group (Mean±SD)	P value
Age	54.20±2.64	53.77±2.04	0.481
Height (cm)	155.50±2.57	154.60±2.20	0.151
Weight (kg)	51.47±5.39	50.73±3.93	0.550
BMI	21.27±2.04	21.21±1.40	0.911

Table 1: Age, Height, Weight and BMI were Comparable in both Groups

Patient group	ASA	
	Class I	Class II
I–gel	43.3%	56.7%
ProSeal LMA	36.6%	63.4%

Table 2: Comparison of ASA Physical Status between both Groups

P value 0.792.

The airway characteristics of the patients studied i.e. mouth opening (Table 3), thyromental distance (Table 4), and the Mallampati score (Table 5) were also noted and statistically analysed.

Patient group	Mouth opening	
	5 cm	>5 cm
I–gel	0%	100%
ProSeal LMA	3.3%	96.7%

Table 3

Patient group	Thyromental distance	
	6 cm	>6 cm
I–gel	13.3%	86.7%
ProSeal LMA	16.7%	83.3%

Table 4

Patient group	Mallampati score		
	I	II	III
I-gel	30%	70%	0%
ProSeal LMA	46.6%	53.4%	0%

Table 5

The airway characteristics of both I–gel and ProSeal LMA groups were comparable.

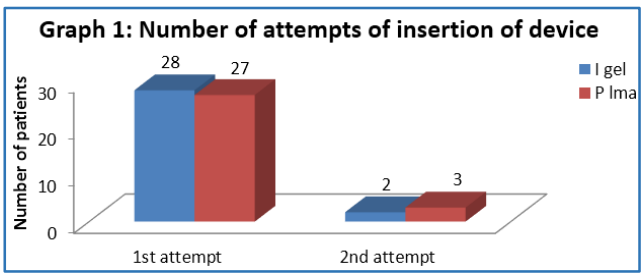
Parameters studied	P value
Mouth opening	0.364
Thyromental distance	0.484
Mallampati class	0.695

Table 6

Device Parameters: The number of attempts at insertion needed to get proper positioning of each device was noted and analysed (Table 7, Graph 1). The I-gel could be positioned successfully with a single attempt in 93.4% of the patients in whom the device was used (28 out of 30 patients studied). The ProSeal LMA was positioned in single attempt in 90% of patients in whom device was used (27 out of 30 patients used). Remaining patients in both groups were successfully placed with I-gel or ProSeal LMA in second attempt. None of the both devices needed third attempt for positioning.

Patient group	Number of attempts		
	1	2	3
I-gel	93.4%	6.6%	0%
ProSeal LMA	90%	10%	0%

Table 7



The results do not show any statistical significance (P value 0.64) between both groups.

Insertion time for I-gel and ProSeal LMA were noted in all the patients and statistically analysed (Table 8).

Patient group	Insertion time (Mean±SD)
I-gel	11.73 ± 1.06 seconds
ProSeal LMA	14.52 ± 1.06 seconds

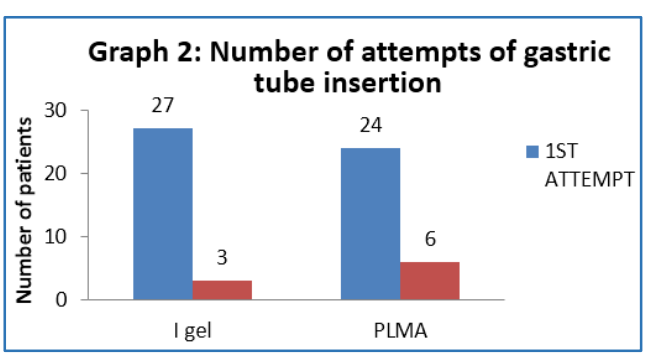
Table 8

Insertion time difference is statistically significant. (p value=0.00).

The number of attempts of gastric tube insertion between I-gel and ProSeal LMA groups were studied (Table 9, graph 2).

Patient group	Number of attempts of gastric tube insertion		
	1	2	3
I-gel	90%	10%	0%
ProSeal LMA	80%	20%	0%

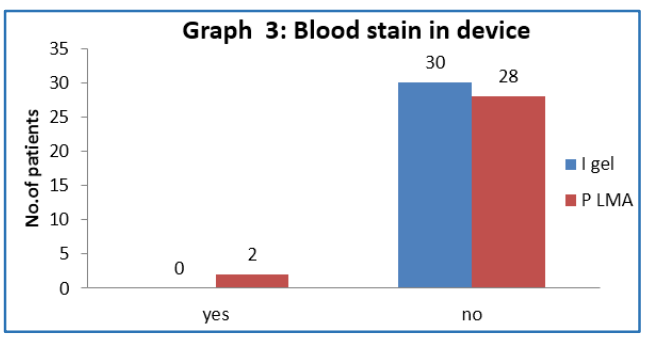
Table 9



There was no difference in number of attempts of insertion of gastric tube between two groups. P value 0.286. Trauma during insertion was studied through blood stain in device and injury to tongue, lip and tooth (Table 10, 11) (Graph 3, 4).

Patient group	Blood stain in device	
	Yes	No
I-gel	0%	100%
ProSeal LMA	6.7%	93.3%

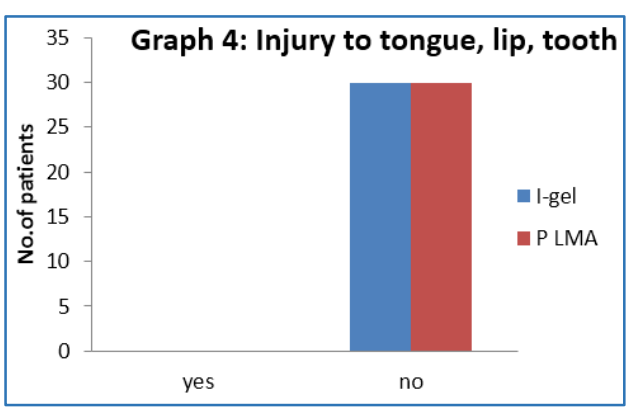
Table 10



There was no blood stain of device in all 30 patients inserted with I-gel. 2 out of 30 patients in ProSeal LMA group had blood stain on device. Difference was statistically insignificant. (P value 0.492).

Patient group	Trauma to lip, tongue, tooth	
	Yes	No
I-gel	0%	100%
ProSeal LMA	0%	100%

Table 11

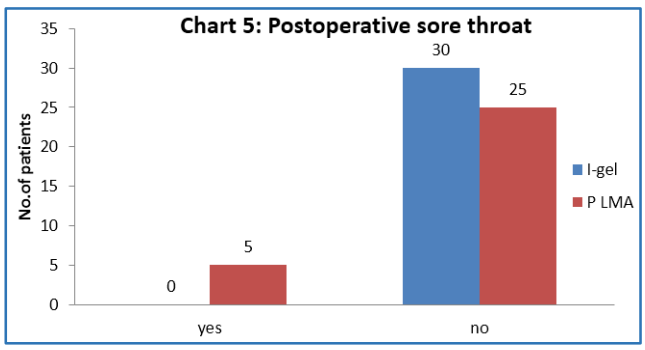


There were no injury to tongue, lip and tooth in both groups.

Post-operative sore throat was recorded in both groups and statistically analysed (Table 12, graph 5).

Patient group	Sore throat	
	Yes	No
I-gel	0%	100%
ProSeal LMA	16.6%	83.4%

Table 12



There was statistically significant difference between both groups. (p value 0.02).

DISCUSSION: The ASA algorithm for difficult airways was published in 1993 and stressed early attempt at insertion of the LMA if face mask ventilation was not adequate. The laryngeal mask revolutionised anaesthetic practice and by 1995 had been used in excess of 100 million patients and was available in more than 80 countries throughout the world. The LMA had now been widely accepted as a form of airway management. Since the introduction of LMA Classic in 1988, several laryngeal masks varying in shape, stiffness, cuff properties. Therefore, it is imperative that we be familiar with each device and its added advantages and disadvantages. We compared I-gel with ProSeal LMA.

We analysed 60 patients scheduled to undergo modified radical mastectomy using a laryngeal mask for maintaining the airway intraoperatively. The patients were then randomised to use one of the two laryngeal masks during anaesthetic.

Two groups were comparable in terms of age, sex and ASA status. Height, Weight and BMI were also statistically comparable. The airway characteristics of all patients studied in terms of mouth opening, thyromental distance and the Mallampati scores were also comparable.

Ease of Insertion: After induction of anaesthesia, the randomly chosen device of appropriate size was inserted, number of attempts of insertion and time of insertion of device is noted. In our study, I-gel could be positioned successfully within single attempt in 93.4% (28/30) of the patients and in ProSeal LMA successful placement in first attempt was achieved in 90% (27/30) of the patients. This result was not statistically significant. In all remaining patients, I-gel and ProSeal LMA was successfully positioned in second attempt. There were no instances of failure to secure airway with any of the two devices within three attempts.

Time of insertion was recorded by independent observer and defined as time interval between picking up the device and securing effective airway. In our study, mean insertion time for I-gel group was 11.73±1.06 seconds and for ProSeal LMA it was 14.52±1.06 seconds.

In study conducted by Gaurav Chauhan et al[10] comparing I-gel and ProSeal LMA in 80 patients, the median insertion time with I-gel was 11.82±1.81 seconds and for ProSeal LMA was 15.13±2.91 seconds.

Our results are in close approximation to this study. Since no cuff inflation is needed in I-gel, insertion time is shorter compared to ProSeal LMA.

Singh et al[9] compared I-gel and ProSeal LMA for number of attempts of insertion. First attempt insertion was successful in 100% patients with I-gel and 93.3% patients with ProSeal LMA which was statistically insignificant.

Gastric Tube Insertion: The ease of placement of gastric tube was more with I-gel 90% (27/30) in first attempt than ProSeal LMA 80% (24/30), though the difference was not statistically significant.

Post-Operative Complications: We studied the incidence of blood stain on device, trauma to tongue, lip, tooth and sore throat. With ProSeal LMA blood stain in device was seen in 6.7% patients (2/30), but in I-gel group there was no blood stain on device. This was statistically insignificant.

There was no trauma to tongue, lip or tooth in both groups. Sore throat was assessed by hoarseness of voice 24 hours after surgery. In I-gel group none of the patients had sore throat but in ProSeal LMA 16.6% (5/30) patients had sore throat which was statistically significant.

Devices with inflatable mask have the potential to cause tissue distortion, venous compression and nerve injury which increase postoperative sore throat.[11,12,13,14] In our study, there was no sore throat incidence in I-gel group patients, this is probably due to soft, gel like nature of I-gel cuff due to which compression and displacement trauma are significantly reduced.

SUMMARY AND CONCLUSIONS: In our study, we compared I-gel and ProSeal LMA for number of attempts for insertion of device, time of insertion of device, number of attempts for gastric tube insertion through device, post-operative blood stain on device, trauma to lip, tooth, tongue and incidence of post-operative sore throat.

From our study, we conclude that the effective airway can be secured faster with I-gel compared to ProSeal LMA, and the incidence of sore throat is less with I-gel. This may be because of soft and non-inflatable cuff in I-gel. I-gel and ProSeal LMA are comparable in terms of number of attempts of insertion of device, gastric tube insertion through device. Trauma during insertion is minimal in both I-gel and ProSeal LMA.

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