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COMPARISON OF EASE OF INSERTION OF CLASSIC-LMA VS I-GEL SUPRAGLOTTIC AIRWAY DEVICE IN SHORT GYNECOLOGICAL SURGERY - A RANDOMIZED INTERVENTIONAL STUDY.

Anaesthesiology

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ABSTRACT

Introduction: Airway management is one of the most important skill in the field of Anaesthesiology, and inability to secure the airway can lead to catastrophic outcome. Supraglottic airways devices can be used in surgery which are done under general anaesthesia in order to avoid the complications related to laryngoscopy. This Study was aimed to record the functional c between Classic-LMA and I-gel in anaesthetized spontaneously breathing adult patients posted for minor day care gynaecological surgeries. **Material and Methods:** Patients undergoing short surgical procedures were randomly assigned to I-gel or classic LMA. Anesthesia was induced and the supraglottic airway device was inserted. The functional difference between Classic–LMA and I–gel was observed in terms of ease of insertion, airway leak pressure, hemodynamic stability and complications (if any). **Results:** The first-time insertion rate was more with I-gel as compared to Classic-LMA. The mean duration of insertion of device was significantly shorter and the mean airway leak pressure was more with I-gel as compared to Classic-LMA. **Conclusions:** Both devices were easy to insert and insertion of I-gel was more rapid. The I-gel provides a better airway sealing pressure as compared to Classic-LMA, so I-gel is better when used for IPPV.

KEYWORDS

Diastolic Blood Pressure, Heart Rate, I-gel, Ease of Insertion, Laryngeal Mask Airway Classic, Systolic Blood Pressure, Airway sealing pressure.

INTRODUCTION

Before 1990, only the face mask and the Endotracheal tube were the available airway devices. Since then several supraglottic airway devices have been developed, of which the laryngeal mask airway (LMA) is the most popular one.[1] The LMA fills a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. Laryngoscopy stimulate the sympathetic nervous system resulting in raised heart rate, increased blood pressure, dysrhythmias and increased intra cranial tension. Supraglottic airways device can be used in surgery which are done under general anaesthesia in order to avoid these complications.

The Classic-LMA is a supraglottic airway device with an inflatable cuff which produces a low-pressure seal around the laryngeal inlet and helps in ventilation.

I-gel, relatively new supraglottic airway device which has an anatomically designed, non-inflatable mask, which is soft, gel like and transparent, made of a thermoplastic elastomer which adapts to the airway upon insertion. The device has a buccal cavity stabilizer, thereby reducing the risk of malposition. The buccal cavity stabilizer also houses the airway tubing and a separate gastric channel. The device has an integral bite block. The device also has an epiglottic blocker which prevents down folding of the epiglottis and obstruction of the distal airway opening.[2]

The claimed potential advantages of I-gel include ease of insertion and use with minimal tissue compression and congestion, fewer airway complications and more stability following insertion.[5,6]

Many studies have been done to compare I-gel with Proseal LMA. But not many studies have been done to compare the clinical uses of the two supraglottic airway devices namely I-gel and Classic-LMA. Hence, this study was undertaken.

AIM:

The Study was aimed to record the functional difference between Classic-LMA and I-gel in anaesthetized spontaneously breathing adult patients posted for minor day care gynaecological surgeries under general anaesthesia in terms of the Ease of insertion of the device (number of attempts and duration of insertion), hemodynamic changes, Airway leak pressure, Incidence of gastric insufflations and postoperative device related complications (if any).

METHODOLOGY

After taking due permission from institutional ethics committee, the present randomized study was conducted in total 72 Patients (ASA Grade I & II) with age between 18 and 60 years & BMI of 20 to 25 kg/m^2 posted for minor day care gynaecological surgeries under general anaesthesia. The Eligible cases were randomly allocated into two study groups (36 patients in each group).

- **Group A (Classic-LMA):** Patient's airway was secured with Classic-LMA.
- **Group B (I-gel):** Patient's airway was secured with I-gel in this group.

Patients with anticipated difficult airway, H/o Gastro Esophageal Reflux disease(GERD) and patients who require more than 3 attempts for I-gel or Classic-LMA insertion by a single anaesthesiologist were excluded from study.

Pre-anaesthetic evaluation was done on the evening before surgery. All patient were premedicated with, Inj Ranitidine 50mg iv, Inj metoclopramide 10mg iv, Inj Glycopyrrolate 0.2mg iv 30mins prior to surgery. The patients were pre-medicated with inj midazolam 2mg iv, inj Fentanyl 1mcg/Kg iv. Pre induction baseline Heart Rate (HR), Blood Pressure (BP) and oxygen saturation (SpO_2) were recorded.

Anaesthesia was induced with Inj propofol 2mg/kg iv & confirmed by loss of verbal communication and loss of eye-lash reflex. Size of Classic-LMA [size-3 (30-50 kg), size-4 (50-70 kg), size-5 (70-100 kg)] and I- gel [size-3 (small adult- 30-60 kg), size-4 (medium adult- 50-90 kg), and size-5 (large adult- 90+ kg)] was selected according to the weight of the patient. Placement of airway was confirmed by presence of good bilateral symmetrical chest movements, square wave form on capnograph, normal end tidal CO_2 and stable SpO_2 (more than 95%). The cuff pressure was measured, with the help of Portex Cuff Pressure monitor and ensured to be 60 cm of H_2O. Immediately after insertion patient was ventilated with IPPV until resuming spontaneous breathing. Then patient was allowed to breathe spontaneously till the end of surgery. Anaesthesia was maintained by using 66% N_2O, 33% O_2 with 1-2% sevoflurane and without any neuromuscular blocking agent.

At the end of the surgery nitrous oxide and Sevoflurane were discontinued and only O_2 was given until smooth recovery of consciousness. The device was removed after resuming consciousness

and when patients started responding to oral commands. The oral cavity was examined for any injuries like lip, dental, tongue injuries and also device was inspected for blood staining which indicated pharyngo-laryngeal injury. 18-24 hours after surgery patient was interviewed for any post-operative morbidity like irritation in throat, difficulty in swallowing and any change in voice.

In case of failure to insert the LMA properly as judged by an audible leak or inability to achieve adequate chest expansion, the device was removed and reinserted. Maximum three attempts were allowed and if effective ventilation could not be achieved endotracheal intubation was done and, proposed surgical procedure was carried out. That case was excluded from the study.

Ease of insertion in terms of time taken for insertion of the device and number of attempts was noted. Time taken for insertion was from grasping of the device to observing a square wave capnograph trace on monitor. (the insertion time). Airway leak pressure was measured by closing the adjustable pressure limiting valve (APL) of the circle system at fixed gas flow of 3 lit/ min and pressure at which audible leak was heard, taken as the leak pressure. Gastric insufflation was determined by epigastric auscultation with the help of stethoscope, during inspiration. Hemodynamic parameters (Heart rate and Blood Pressure) were measured at baseline, just after insertion and at 1 & 5 minute of insertion of the device.

STATISTICALANALYSIS:

Statistical analysis was performed with the SPSS, version 21 for Windows statistical software package (SPSS inc., Chicago, IL, USA). The Categorical data was presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data was presented as mean and standard deviation and were compared by students t-test. Probability was considered to be significant if less than 0.05.

RESULTS

A total of 72 patients, no patients were excluded based on exclusion criteria.

Table-1: Demographic profile:

	Group-A	Group-B	p-value
Mean age in years	28.08	27.78	0.776 (NS)
Mean BMI	22.34	22.58	0.389 (NS)
ASA grade I & II	36/0	36/0	-

Both the groups were comparable and there was no statistically significant difference regarding age, weight, body mass index of patients in two groups. There were no episodes of desaturation (SpO_2 <95%) with both the groups during insertion, maintenance and removal of the airway device. There was no statistically significant difference in SpO_2between both the groups.

Table-2: Comparison of ease of insertion in both the groups

	Group-A	Group-B	p-value
Number of attempts (I/II)	33/3	34/2	1.00 (NS)
Mean Time taken for insertion of device (seconds)	24.78	21.42	0.0003 (S)
Mean Airway leak pressure (cm of H_2O)	20.17	24.14	<0.001 (S)
Gastric insufflation(cases)	9	6	0.562 (NS)

Out of total number of 72 patients, the insertion was achieved in first attempt in 67 patients and second attempt was required only in 5 patients out of which 3 were for classic- LMA and 2 were for I-gel. The number of attempts required for insertion were also comparable and the difference was not significant statistically. (p=1.00)

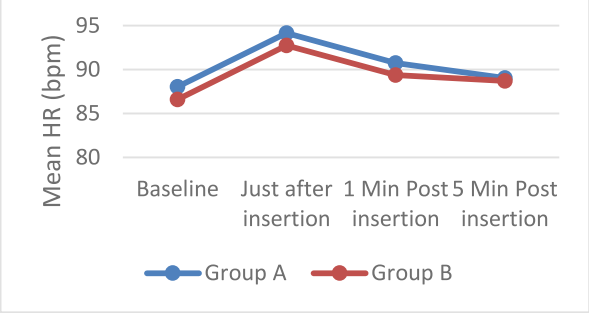
The mean time required for insertion of I-gel was less than classic LMA. Difference was statistically significant(table-2).

The mean airway leak pressure with I-gel is more than Classic-LMA. Difference was highly significant statistically(table-2).

Gastric insufflation was seen in 15 cases, out of which 9 were for Classic-LMA and 6 were for I-gel. Difference was not statistically significant.

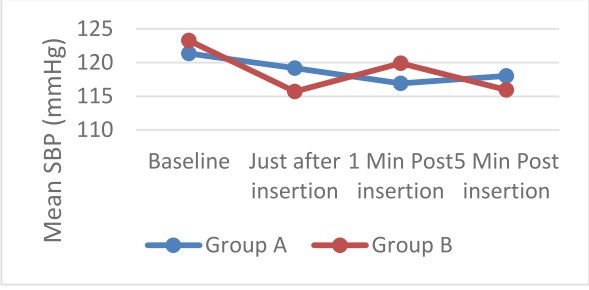
Table-3: Hemodynamic comparison in both the groups

	Group-A	Group-B	p-value
Mean Heart Rate (base line)	88.06	86.61	0.632 (NS)
Mean Heart Rate (just after insertion)	94.17	92.75	0.666 (NS)
Mean Heart Rate (1 min post insertion)	90.75	89.39	0.653 (NS)
Mean Heart Rate (5 min post insertion)	89.06	88.72	0.918 (NS)
Mean Systolic BP (base line)	121.36	123.28	0.372 (NS)
Mean Systolic BP (just after insertion)	119.19	115.72	0.247 (NS)
Mean Systolic BP (1 min post insertion)	116.92	119.92	0.222 (NS)
Mean Systolic BP (5 min post insertion)	118.03	115.94	0.399 (NS)
Mean Diastolic BP (base line)	78.03	79.42	0.458 (NS)
Mean Diastolic BP (just after insertion)	75.47	75.33	0.950 (NS)
Mean Diastolic BP (1 min post insertion)	73.78	76.19	0.263 (NS)
Mean Diastolic BP (5 min post insertion)	74.61	74.83	0.918 (NS)



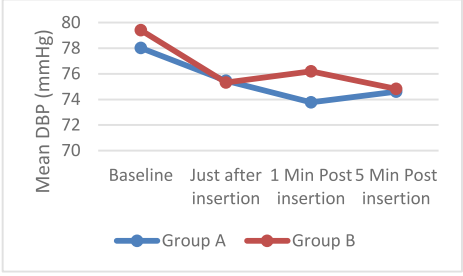
Graph 1: Mean Heart rate comparision in both the groups

Comparison of pre insertion, 1 Minute post insertion, and 5 Minute post insertion heart rate in group-A and group-B cases did not show any statistically significant difference(Table-3).



Graph 2: Mean systolic blood pressure comparision in both the groups

Comparison of pre insertion, 1 Minute post insertion, and 5 Minute post insertion systolic blood pressure in group A and group B cases did not show any statistically significant difference (Table-3).



Graph 3: Mean diastolic blood pressure comparison in both the groups

Comparison of pre insertion, 1 Minute post insertion, 5 Minute post insertion Diastolic blood pressure in classic LMA and I-gel cases did not show any statistically significant difference (Table-3).

Table-4: Complications

	Group-A	Group-B	p-value
Lip, Dental & Tongue injuries (cases)	5	2	0.426 (NS)
Blood staining on device(cases)	5	5	0.733 (NS)
Post Removal Cough (cases)	2	0	0.473 (NS)
Post-operative dysphagia(cases)	0	1	1.00 (NS)
Post-operative Nausea Vomiting(cases)	1	1	0.473 (NS)
Post-operative throat irritation & changes in voice	0	0	-

Thirteen cases had complications in group A, 9 cases had complications in group B. 7 cases had lip injury, 2 cases had post removal cough, 2 cases had nausea and vomiting, 1 case had dysphagia. 10 cases had blood stain on airway device. Out of the 7 cases of lip injury 5 cases were from group A and 2 cases were from group B. Out of 2 cases with post removal cough all were from group A. 1 case with post op nausea and vomiting was from each group. Out of 10 cases of blood staining on airway 5 were from group A, while 5 were from group B. None of the cases had laryngospasm, pulmonary edema during intra operative or post-operative period. In terms of development of either intra-operative or post-operative complications, the difference between the two groups was not found to be statistically significant (Table-4).

DISCUSSION

The aim of the study was to compare the Ease of Insertion of airway device between Classic-LMA and I-gel in anaesthetized spontaneously breathing adult patients posted for minor day care gynaecological surgeries under general anaesthesia.

The study involved 72 patients of ASA I & II physical status. They were randomized in to 2 groups: Group – A (Classic-LMA) and Group – B (I–gel) and following parameters were analysed.

- Number of attempts for insertion of device.
- Duration of insertion of device (in seconds).
- Airway leak pressure (in cm of H_2O).
- Hemodynamic parameters.
- Gastric insufflation.
- Airway injuries.
- Complications.

Both the groups were comparable and there was no statistically significant difference regarding age, weight, body mass index of patients in two groups.

In this study, insertion of group B airway device (I-gel) was successful in first time insertion in 94.44% cases as Compared to 91.66% first time insertion with Classic-LMA. Airway manipulation like jaw thrust was required during second attempt of insertion in 5.55% of patient of I-gel insertion and 8.33% patients with Classic-LMA insertions. The difference between two groups was not statistically significant. Very similar results were found in studies conducted by Helmy AM et al.[16] Uppal V et al.[11] Franksen H.[13] Amini S .[14] Siddiqui AS .[17] Priyamvada gupta et al.[18] and A. Rajendran et al.[20] In all these studies there was no statistically significant difference between two groups regarding number of attempts for insertion of device. In Janakiram et al.[28] study, the success rate with first time I-gel insertion was only 54%, and with c-LMA of 86% which was statistically highly significant. This is because the author has used large size I-gel in 14 patients due to presence of audible leak and hence required second attempt. However, in our study we did not have such problem and comparable between both the devices. In N. Prateebha et al.,[19] 2016, I-gel inserted successfully in first attempt in 100% of cases as compared to c-LMA in 84% of cases, which was statistically significant. (p-value-0.003). The 100% success rate in insertion of I-gel in this study can be attributed to the prior training received by the final year postgraduate students under the supervision of anaesthesia consultants in handling the I-gel.

The time for insertion of device was considered according to the study conducted by Helmy AM et al.[16] from picking up the device to confirmation of effective ventilation by bilateral chest movement, square wave pattern capnography on moniter, normal range end tidal CO_2 and stable arterial SpO_2 (>95%). In our study, the time for insertion of I-gel (21.42 seconds) was shorter as compared to Classic-LMA (24.78 seconds) which was highly significant statistically (p=0.0003). The I-gel Supraglottic airway device is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to Classic-LMA which has a cuff to be inflated after its insertion. Similar to our results, Helmy AM et al.[16] Uppal V et al.[11] Priyamvada gupta et al.[18] N. Prateebha et al.[19] A. Rajendran et al.[20] also had significant difference in the insertion times. In study done by Franksen H et al.[13] Amini S et al.[14] Ali A et al.[15], though the mean time for I-gel insertion was clinically shorter as compared to Classic-LMA, it was not statistically significant.

Airway leak pressure detection was performed in a similar manner done by Uppal V et al.[11] in their study. The difference in the oropharyngeal sealing pressure between group A and group B were statistically significant in our study (p<0.001) similar to the previous studies of Janakiram .[28] Franksen H .[13] Amini S .[14] Helmy AM .[16] Priyamvada gupta et al.[18] A. Rajendran et al.[20] indicating I-gel can be preferred over Classic-LMA for IPPV. Airway leak pressure of I-gel in our study was comparable with Uppal V et al.[11] Helmy AM et al.[16] and A. Rajendran et al.[20] studies and of Classic-LMA with Amini S et al.[14] Priyamvada gupta et al.[18] A. Rajendran et al.[20] study.

While inserting and removing the airway device, the hemodynamic changes are produced because of mechanical contact between device and oropharyngeal structures, pressure over the larynx and pharynx produced by inflated cuff and dome of airway device .[12] In our study, there was no important difference between two groups regarding all hemodynamic parameters. The results of our study were similar to the studies done by Helmy AM et al.[16], Franksen H et al.[13] A. Rajendran et al.[20]

Jindal P et al.[12] in their study observed that I-gel produced less haemodynamic changes compared to other Supraglottic airway devices. Since I-gel can change its shape according to temperature, at normal body temperature it correctly fits into perilaryngeal structures and does not produce much pressure over anatomical structures, hence produces less hemodynamic changes when compared to Classic-LMA which because of an inflatable cuff can produce more haemodynamic changes.

In our study there were no episodes of desaturation (SpO_2 <95%) with both the groups during insertion, maintenance and removal of the airway device. There was no significant difference in SpO_2 between both the groups.

The inflatable Supraglottic airway devices during insertion, the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue and can cause pharyngeal injury. Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury.[7]

In our study, at the end of procedure, the patients were inspected for any trauma to oral cavity, which is similar to study done by Siddiqui AS et al.[17] Lip injury was noted in 5 patients in group A out of 36 and in 2 patients out of 36 in group B. However, the incidence was not statistically significant. Similar results have been observed in studies done by Helmy AM et al.[16] and A. Rajendran et al.[20]

In our study in five patients from each group, after removal supraglotic device was found blood stained, which was statistically not significant in the study conducted by Siddiqui AS et al.,[17] blood on device was noted in 18% cases of LMA group while none in the I-gel group which was statistically significant. The authors attributed the cause might be due to the pressure produced by inflatable cuff, resulting in trauma to adjoining structures.

The patients were interviewed for any postoperative complications like Post-operative Dysphagia, Nausea, Vomiting, Post-operative throat irritation, changes in voice after 18-24 hours.

Cough, on removal of airway, was seen in two patients of Classic-LMA group, while none fron I-gel group. This suggests that cuff of Classic-LMA causes edema resulting in post extubation cough. I-Gel which is

an un-cuffed perilaryngeal sealer produces less trauma thereby causing no cough.

Only one patients in group B had developed dysphagia post operatively compared to none in group-A. Our results were consistent with the studies done by Siddiqui AS et al.[17] and A. Rajendran et al.[20] where the difference between two groups regarding postoperative morbidity was not statistically important.

In our study one patient from each group developed post-operative nausea vomiting. Our result are similar to the study done by Helmy AM et al.[16] Franksen H et al.[13] A. Rajendran et al.[20] where the difference between two groups regarding postoperative morbidity was not statistically important.

In our study no patient developed post-operative throat irritation and changes in voice from both the groups. Keijzer C et al.[31] in their study compared the post operative throat and neck complications between LMA and I-gel. They found there were more incidence of throat irritation and pain during swallowing at first hour, first day, and second day in the group A as compared with the group B. And also more incidence of neck pain noted in Classic-LMA group. Since there is no cuff in I–gel, it causes less number of postoperative throat and neck pain.

CONCLUSION

It is concluded that both Classic-LMA and I-gel can be used safely and effectively during general anaesthesia with spontaneous breathing in selected patients. Both Classic-LMA and I-gel did not cause any significant alterations in the hemodynamic status of patients. Both the devices were easy to insert. But insertion of I-gel was more rapid as time taken for insertion of airway was much lesser than insertion of Classic-LMA. Leak pressure was significantly higher with I-gel than with Classic-LMA so I-gel can be used for IPPV as well. I-gel can be used for CPR by an unskilled worker, as it is easy and quick to insert.

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