RANDOMISED CONTROLLED STUDY COMPARING TWO SUPRAGLOTTIC AIRWAY DEVICES: THE I-GEL AND THE CONVENTIONAL LARYNGEAL MASK AIRWAY IN ANAESTHETIZED PATIENTS

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ABSTRACT

BACKGROUND

Supraglottic airway devices may be used in hospitals for low-risk patients undergoing elective surgery, in spontaneous or positive pressure ventilation, for more complex patients and operations, for difficult airway management, for airway rescue, out of hospital use by less experienced or novice users, and during cardiopulmonary resuscitation.

AIM OF STUDY

To evaluate and compare I-Gel with Laryngeal mask airway for haemodynamic responses, ease of insertion and post extubation complications in anaesthetised patients.

MATERIALS AND METHODS

The study design was randomized and controlled. The patients were divided into 2 groups of 25 each with the help of computer generated random allocation. All patients were of ASA I physical status. Patients in Group I were intubated with Classic LMA and Group II with I-Gel. Following successful placement-the pulse rate, systolic blood pressure, diastolic blood pressure, end tidal CO_2 and SpO_2 were noted at insertion, at 1 min, 3 min and 5 min after insertion. The ease of insertion, the number of attempts taken for successful insertion, the time taken for insertion and presence or absence of residual air leak were noted.

RESULTS

Patients who were intubated with LMA had statistically significant high PONV, otherwise both the devices are statistically similar in all other parameters monitored.

CONCLUSION

In conclusion, it can be said that the I-Gel is inserted rapidly, and has lesser incidence of nausea and vomiting than the LMA.

KEYWORDS

Supraglottic Airway Devices, Laryngeal Mask Airway, I-Gel, Complications.

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INTRODUCTION: Obstruction to airway was a poorly understood phenomenon prior to 1874. Opening the mouth with a wooden screw and drawing the tongue forward with a forceps or a steel-gloved finger was the height of airway management. Recognition that the base of the tongue falling against the posterior pharyngeal wall accounted for most airway obstruction did not occur until 1880. Though the tracheal intubation was first described[1] in 1788, Credit for the first use of supraglottic airway is given to Joseph Thomas Clover (1825-1882). Cuffed supraglottic airways were initially described in the early part of the 20th century. Three factors led to the development of these devices: the introduction of cyclopropane (which was explosive and required an airtight circuit for appropriate gas containment), the fact that blind and laryngoscopic-guided tracheal intubation remained a difficult task, and a recognized need for protection of lower airway from blood and surgical debris in the upper airway. The Primrose cuffed oropharyngeal tube, the Shipway airway (a Gudel oropharyngeal airway fitted with a cuff) and the Lessinger airway were predecessors of the modern supraglottic devices.

By 1981, two types of airway management prevailed: tracheal intubation or the anaesthesia face-mask/Guedel airway. Although both were time-tested, each had its failings (apart from airway failure in a small number of patients). Tracheal intubation was associated with both dental and soft tissue injury and cardiovascular stimulation,[2] and mask ventilation often required a hands-on-the-airway technique. These difficulties led to the reconsideration of supraglottic airways.

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The two supraglottic airway devices most commonly being used currently are:

1. The Laryngeal Mask Airway and
2. The I-Gel.

Therefore, we designed this prospective, randomized study to determine which device among the two, can be an efficacious one for airway management during routine practice in anaesthesia.

AIM OF STUDY: Various supraglottic devices such as the Laryngeal Mask Airway (LMA), the I-Gel and perilaryngeal airways have been introduced. The present study is undertaken to evaluate and compare I-Gel with LMA in terms of ease of insertion, time taken for insertion, number of attempts for successful insertion, air leak, end tidal carbon dioxide, oxygen saturation, haemodynamic responses such as change in heart rate, blood pressure and post-extubation complications such as airway injury and post-operative sore throat in anaesthetised patients.

MATERIALS AND METHODS: The present clinical study was conducted at Gandhi Hospital, Secunderabad. The study design was randomized and controlled.

Inclusion Criteria: The study was carried out in 50 patients of either gender, aged 20 to 40 years, belonging to ASA Grade I physical status, with adequate mouth opening measured by an inter-incisor gap of >4cm, who were scheduled for elective surgical procedures under general anaesthesia.

Exclusion Criteria: Patients with cardiovascular or respiratory disorders, diabetes, hypertension, of physical status ASA Grade II and above, obesity with BMI >25 kg/m^2, difficult airway with Mallampati grade II and above, cervical spine abnormalities, abnormal dentition, patients with upper respiratory tract infections, obstructive sleep apnoea syndrome, gastro-oesophageal reflux disease, non-fasting status and patients who needed emergency surgeries were not included in the study.

After having obtained an approval from the institutional committee, written and informed consent was taken from each patient. Pre anaesthetic evaluation was conducted a day before surgery to obtain a detailed history. A complete physical examination including a through airway assessment was done. Routine investigations like complete blood picture, blood grouping and typing, blood urea, serum creatinine were done.

On the day of surgery, the Boyle's anaesthesia machine was checked, appropriate sized LMA, I-Gel, lubricating gel i.e., 2% Lignocaine jelly, an empty 20cc syringe, endotracheal tubes including an undersized tube, two working laryngoscopes, emergency drugs like Dopamine, Adrenaline and Atropine, emergency instruments like the stylet, bougie, AMBU and a charged defibrillator were kept ready. A working suction apparatus was also kept ready.

After confirming the fasting status, the patient was shifted to the operating room and transferred onto the operating table. Intravenous access was secured with a large bore catheter and Lactated Ringer started. Standard monitors like ECG, pulse oximetry and non-invasive blood pressure were applied and basal readings recorded.

The anaesthesia technique was standardized for both groups. Patients were pre medicated with inj. Midazolam 1 mg IV, Inj. Ondansetron 4 mg IV, Inj. Glycopyrrolate 0.2 mg IV and Inj. Fentanyl 2 mcg/kg body weight, 3 min before induction. Preoxygenation with 100% oxygen was done for 3 minutes followed by induction with Inj. Propofol 2 mg/kg body weight.

Using computer generated random allocation, the patients were divided into two groups with 25 patients in each group, to have either the I-Gel or LMA inserted. Both the I-Gel and the LMA were lubricated with 2% Lignocaine jelly. After adequate depth of anaesthesia was achieved, patient was placed in the 'sniffing the morning air' position.

In Group I, the LMA Classic was inserted with a size 3 used for patients weighing 30 to 50 kg and a size 4 for 50 to 70 kg body weight. The LMA cuff was inflated with 20 ml and 30 ml of air for sizes 3 and 4 respectively as recommended by the manufacturer.

In Group II, the I-Gel was inserted, its size chosen according to the patient's body weight. A size 3 for patients weighing 30-50 kg and a size 4 for 51-90 kg was used.

In either Group, after the device was inserted, it was connected to the breathing circuit, end tidal CO_2 monitor was attached and the basal reading noted. Adequate ventilation was assessed by chest movement, auscultation, stable oxygenation not less than 95%, and a square wave capnogram. In both the groups, if it was not possible to ventilate the lungs, airway manoeuvres such as chin lift, jaw thrust, head extension, or flexion on the neck were allowed. In the case of I-Gel, the position was also allowed to be adjusted by gently pushing or pulling the device. After any manoeuvre, adequacy of ventilation was reassessed. A maximum of three attempts were allowed for insertion and the case excluded from the study in case of failure to insert in three attempts.

Following successful placement of the supra laryngeal device, the pulse rate, systolic blood pressure, diastolic blood pressure, end tidal CO_2 and SpO_2 were noted at insertion, at 1 min, 3 min and 5 min after insertion. The ease of insertion, the number of attempts taken for successful insertion and the time taken for insertion calculated from the time of picking up the device till establishment of adequate ventilation, and presence or absence of air leak were noted. Patients were maintained on 66% N_2O in Oxygen, with Halothane and assisted ventilation until spontaneous ventilation was established.

At the end of the operation, anaesthetic agents were discontinued, allowing smooth recovery of consciousness. The device was removed after the patient regained consciousness spontaneously and responded to verbal command to open the mouth.

Dysphagia, dysphonia, nausea, vomiting, and trauma of mouth, teeth or pharynx assessed by blood on the device post removal and sore throat were recorded and reassessed within 24 hours.

RESULTS: In the present study, the parameters were recorded and the data entered into Statistical Package for Social Services (SPSS 15.0). Statistical analysis was done using Paired-Samples T test. Probability values <0.05 were considered statistically significant.

The study was carried out in 50 patients aged between 20 and 40 years, of either sex, belonging to ASA physical status I, scheduled for elective surgical procedures. The patients were randomly divided into two groups, each group of 25 patients who either had the LMA or the I-Gel inserted.

	Group 1	Group 2
No. of Patients	25	25
Airway device inserted	LMA	I-Gel

Table 1: Division of patients into 2 groups

The groups were compared for physical characteristics (age, weight), ease of insertion, the time taken for insertion, the number of attempts required, presence or absence of airway leak, haemodynamic parameters (pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure), the SpO_2, $ETCO_2$ and post-operative complications (cough, airway trauma, sore throat, dysphonia, dysphagia, post-operative nausea and vomiting).

	Group I (LMA) (Mean±SD)	Group II (I-Gel) (Mean±SD)
Number of patients	25	25
Age	29.88±9.88	28.56±7.42
Weight	49.96±7.96	49.86±6.17
Male:Female	6M:19F	6M:19F

Table 2: Demographic profile of two groups

The patients in two groups were comparable for age, weight and sex ratio. The difference between the two groups was not statistically significant (p>0.001).

	Group I (LMA)	Group II (I-Gel)	P value
Ease of insertion	Difficulty 7: Easy 18 38.88% difficult	Difficulty 5: Easy 20 25% difficult	0.2978
Time taken	46.09±8.67	40.15±9.65	0.0266
No. of attempts	1.2±0.40	1.12±0.33	0.4507
Airway leak	Present 10: Absent 15 40% Present	Present5: Absent 20 20% Present	0.1294

Table 3: Ease of insertion, no. of attempts & airway leak variation

The p value for mean time of insertion was 0.02(<0.05) and hence statistically significant, indicating that the I-Gel was inserted much faster than the LMA. The other parameters compared above in both the groups were statistically insignificant.

	Group I (LMA) (Mean±SD)	Group II (I-Gel) (Mean±SD)	p value
Baseline	86.72±18.60	84.60±16.58	0.7018
At insertion	87.48±14.62	85.00±14.06	0.6001
At 1 min	86.92±10.61	87.60±13.19	0.8417
At 3 min	87.48±8.71	87.92±11.09	0.8767
At 5 min	89.68±9.80	87.48±10.48	0.4472

Table 4: Pulse rate variation

There was no statistically significant difference in pulse rate variation between the two groups before and after insertion.

	Group I (LMA) (Mean±SD)	Group II (I-Gel) (Mean±SD)	p value
Baseline	116.84±13.61	119.56±10.11	0.4266
At insertion	111.48±14.26	109.00±7.77	0.4492
At 1 min	104.80±16.06	105.68±8.43	0.8095
At 3 min	102.12±14.73	103.36±7.56	0.7098
At 5 min	104.16±12.84	102.24±8.13	0.5308

Table 5: Systolic blood pressure variation

There was no statistically significant difference in systolic blood pressure variation between the two groups before and after insertion.

	Group I (LMA) (Mean±SD)	Group II (I-Gel) (Mean±SD)	p value
Baseline	76.56±12.38	78.08±9.45	0.6279
At insertion	67.40±8.77	69.72±7.77	0.3273
At 1 min	62.80±12.60	66.32±8.69	0.2560
At 3 min	60.12±11.74	64.84±7.43	0.0960
At 5 min	61.48±7.19	64.52±6.92	0.1344

Table 6: Diastolic blood pressure variation

There was no statistically significant difference in diastolic blood pressure variation between the two groups before and after insertion.

	Group I (LMA) (Mean±SD)	Group II (I-Gel) (Mean±SD)	p value
Baseline	88.28±12.42	90.00±10.53	0.6000
At insertion	81.60±10.40	82.64±7.04	0.6807
At 1 min	76.36±13.30	79.12±8.54	0.3871
At 3 min	74.12±12.58	77.52±7.13	0.2457
At 5 min	75.40±8.31	76.76±7.92	0.5394

Table 7: Mean arterial pressure variation

There was no statistically significant difference in mean arterial pressure variation between the two groups before and after insertion.

	Group I (LMA) (Mean±SD)	Group II (I-Gel) (Mean±SD)	p value
Baseline	99.56±0.80	99.64±0.75	0.7187
At insertion	99.84±0.47	99.88±0.43	0.7575
At 1 min	100±0	100±0	Perfect data
At 3 min	100±0	100±0	Perfect data
At 5 min	99.96±0.19	100±0	0.3219

Table 8: SpO_2 variation

There was no statistically significant difference in SpO_2 variation between the two groups before and after insertion.

	Group I (LMA) (Mean±SD)	Group II (I-Gel) (Mean±SD)	p value
At 1 min	34.88±2.64	35.12±2.68	0.7514
At 3 min	34.56±2.03	34.32±2.34	0.7009
At 5 min	33.96±2.08	33.44±1.89	0.3601

Table 9: End tidal CO_2 variation

There was no statistically significant difference in end tidal CO_2 variation between at 1, 3 and 5 min after insertion.

	Cough	Airway trauma	Sore throat	Dysphonia	Dysphagia	PONV
Group I (LMA)	5/25 20%	5/25 20%	5/25 20%	0/25 0%	2/25 8%	10/25 40%
Group II (I-Gel)	2/25 8%	2/25 8%	3/25 12%	0/25 0%	1/25 4%	3/25 12%
p value	0.2274	0.2274	0.4442	N/A	0.5543	0.0286

Table 10: Post-operative complications incidence

There was higher incidence of PONV in LMA group than the I-Gel group, which showed a statistically significant p value of 0.02 ($p<0.5$). No statistically significant difference in other complications between the two groups.

DISCUSSION: Since tracheal intubation is associated with many disadvantages such as need for technical skill in laryngoscopy and intubation, the deleterious haemodynamic response to laryngoscopy and intubation,[2] accidental oesophageal or endobronchial intubation, a high incidence of airway trauma, post extubation complications such as sore throat, tracheal stenosis, etc., the supraglottic airway devices such as the LMA and the I-Gel were introduced which can avoid most of the above mentioned complications. The LMA proves a useful alternative to maintaining the airway which also requires lesser skill in insertion and obviates the need for laryngoscopy. The I-Gel is a new supraglottic device, introduced to provide a better anatomic fit with the supra laryngeal cartilage framework, owing to its gel like cuff which does not require any inflation after insertion and is also less prone to cause airway trauma.

In the present study, the LMA and I-Gel groups were identical with respect to physical characteristics. In the present study, the ease of insertion and ventilation, and the incidence of airway leak in both the groups were found to be similar with no statistical difference. This result is in accordance with the previous study done by Dr. Ansar Ali et al[3] who compared the LMA with the I-Gel and concluded that there is statistically no significant difference between I-Gel and LMA regarding ease of insertion. In another comparison between the LMA Unique and the I-Gel, V. Uppal et al[4] concluded that, both types of airways were inserted at the first attempt and the number of manipulations required after insertion to achieve a clear airway was the same in both the groups. They further stated that there was no significant difference between the airway leak pressures of the two devices. To further consolidate this finding, a study conducted by Theiler LG et al[5] showed that both the airway devices had similar insertion success and clinical performance. In the study conducted by Parul Jindal et al[6] they found no difference in number of intubation attempts in both the devices. A study conducted by Fernandez Diez A et al[7] proved that the seal pressure and compliance were similar in the two groups.

In the present study, the time taken for insertion was significantly lesser for the I-Gel than the LMA. This finding is consistent with the study done by Amr M. Helmy et al,[8] who concluded that the I-Gel was significantly more rapidly inserted than the LMA. Cattano D et al,[9] also found in their study that the I-Gel had a faster insertion time than the LMA. V. Uppal et al,[4] stated that the mean insertion time for I-Gel was significantly less than that for LMA. Stroumpouis K et al,[10] J. R. Lee et al,[11] and J. J. Gatward et al,[12] in their respective studies, also found a similar conclusion that the I-Gel is inserted much rapidly than the LMA.

There was no significant difference found in the haemodynamic parameters such as the pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure, from the baseline up to the time of insertion, at 1 minute after insertion, at 3 minute after insertion or at 5 minute after insertion of the device in either of the groups in the presently conducted study. This result is consistent with the previous study conducted by Amr M. Helmy et al,[8] who concluded in their study that both LMA Classic and I-Gel do not cause any significant alteration in the haemodynamic status of the patients. The study done by Cattano D et al,[9] who compared the standard vital signs between the two devices also found no significant difference in the haemodynamic parameters. Subhro Mitra et al,[13] also found no differences in the demographic and haemodynamic data in the two groups.

In the present study there was no significant difference found between the two devices regarding the variation in SpO_2 from the baseline, to the time of insertion, at 1 minute, at 3 minute or at 5 minute after insertion. The end tidal CO_2 measured at 1 minute, at 3 minute or at 5 minute also showed no significant difference in variation. These results are in agreement with the previous studies conducted by

Amr M Helmy et al,[8] who concluded that both the devices do not cause any significant alteration in the SpO_2 or end tidal CO_2 values. Bimla Sharma et al,[14] in their study concluded that both devices provided optimal ventilation and oxygenation.

In the present study, the occurrence of post-operative complications such as post removal cough, airway trauma, sore throat, dysphagia was higher in the LMA group than the I-Gel group but there was no statistically significant difference seen. This finding is in accordance with the studies of Cattano D et al,[9] who concluded that the two devices were similar in post-operative sore throat, hoarseness, and dysphagia incidence, Subhro Mishra et al,[13] who stated that post-operative complications were comparable between the I-Gel and LMA ProSeal. In contrast the study conducted by Ishwar Singh et al[15] concluded that the I-Gel caused lesser airway trauma than the LMA.

In the present study the occurrence of post-operative nausea and vomiting was significantly higher in the LMA group than the I-Gel group. This result is in accordance with the previous study result of Amr M. Helmy et al[8] who found that the postoperative complications were not significantly different except nausea and vomiting, which was statistically significantly higher in LMA group, among both LMA and I-Gel patients.

CONCLUSION: In the present study, the comparative evaluation of the two supraglottic airway devices, the I-Gel and the LMA in anaesthetized patients, the following conclusions can be made from the present study.

- Both the I-Gel and the LMA have similar ease of insertion. The number of attempts required, for insertion are similar. The incidence of airway leak after insertion is similar in both the devices.
- The I-Gel is inserted more rapidly than the LMA.
- Both I-Gel and LMA do not cause any significant haemodynamic response after insertion and are efficient devices in maintainance of ventilation.
- The post-operative complications are similar with both devices, except for PONV which is significantly higher in LMA.

In conclusion, it can be said that the I-Gel is inserted rapidly, and has lesser incidence of nausea and vomiting than the LMA, and the two devices are similar in efficiency in all other aspects.

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