A COMPARISON OF THREE SUPRAGLOTTIC AIRWAY DEVICES: THE LMA CLASSIC, THE AMBU AURA40 LARYNGEAL MASK AND THE i-gel IN SPONTANEOUSLY BREATHING ANAESTHETISED PATIENTS

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ABSTRACT

BACKGROUND

To test and compare LMA Classic, Ambu Aura40 and i-gel in terms of ease of insertion, efficacy and complications.

MATERIALS AND METHODS

90 patients between 18-70 years of age of ASA I and II scheduled for short surgical procedures were enrolled into the study. They were randomly divided into 3 groups of 30 each. Ease of insertion was assessed by number of attempts for correct positioning of the device. Efficacy was assessed using fibre optic bronchoscope to visualise glottis through the supraglottic device. Oropharyngeal leak pressure was studied using an analogue manometer (Medisys) connected to the expiratory limb of the breathing circuit to measure the airway pressure.

RESULTS

The LMA Classic, Ambu Aura40 laryngeal mask and the I-gel are effective ways of securing the airway in patients undergoing elective short surgical procedures. LMA Classic required more attempts overall to secure the airway compared to the other two devices in this study. Glottic view scores were intermediate to the other two devices. It had the least Oropharyngeal Leak Pressure (OPLP) compared to the other devices. The Ambu Aura40 laryngeal mask required the least number of attempts to secure the airway among the devices studied. Therefore, in a 'Cannot Ventilate, Cannot Intubate' situation, this might be the better device compared to the other two devices in this study. The Glottic view as obtained with a fiberoptic bronchoscope was the best with the Ambu Aura40 laryngeal mask among the devices studied. This might be useful in guiding an airway exchange catheter into the trachea and using it as an intubation aid. The Oropharyngeal Leak Pressures (OPLP) was intermediate to the other two devices. The I-gel had the highest Oropharyngeal Leak Pressure (OPLP) among the devices studied. Therefore, this device would be preferable in situations requiring positive pressure ventilation. I-gel had the most sub-optimal positioning as determined by fiberoptic bronchoscopic positioning. Due to the buccal stabilizer of the I-gel, it is the most stable of the devices studied and therefore would be most suitable for surgeries in positions other than supine. The I-gel has an inbuilt bite guard which provides an additional measure of safety during emergence. The gastric channel also allows quick access to gastric contents when required. The incidence of complications was nil with the I-gel in this study.

CONCLUSION

Ambu Aura40 is the superior device in comparison to the other devices. The I-gel is useful in situations requiring positive pressure ventilation and added stability. LMA Classic was not as effective as the other two in securing an airway and was associated with minimal incidence of complication.

KEYWORDS

LMA Classic, Ambu Aura40, I-gel, comparison.

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BACKGROUND

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™ (LMA North America Inc., California, USA) 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.[1] 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.

Since the introduction of the LMA Classic, several laryngeal masks have been introduced which differ in shape, stiffness, cuff properties and constituent material.[2] The Ambu Aura40™ (Ambu A/S, Copenhagen, Denmark) laryngeal mask and the I-gel™ (Intersurgical Ltd,

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Wokingham, U.K.) are two such devices. Apart from being used to maintain the 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 cardio-pulmonary resuscitation.[1] Although several studies have been conducted to compare the Ambu AuraOnce laryngeal mask (single use device) with the LMA Classic[3,4,5,6,7] and the I-gel airway (single use device) with the LMA Classic;[8,9] we found that there were no studies comparing the LMA Classic, Ambu Aura40 (multiple use devices) and the I-gel, which are devices used extensively and regularly in our institution.

Hence an attempt was made to compare the above devices in terms of their 1) Ease of insertion as defined by the number of attempts required to secure an airway 2) Positioning as revealed by fiberoptic bronchoscopic assessment of the glottic view 3) Oropharyngeal leak pressure 4) Intra-operative and post-operative complications.

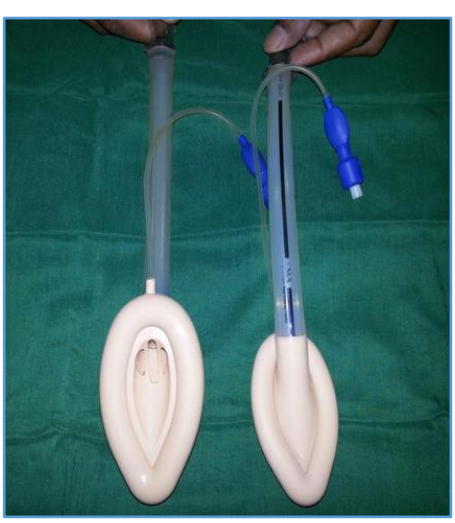
Aims and Objectives

This study aims to test and compare the LMA Classic, Ambu Aura40 and the I-gel in terms of their:

- Ease of insertion (Number of attempts required for optimal positioning).
- Efficacy (Fiberoptic Positioning & Oropharyngeal Leak Pressure).
- Incidence of intra-operative and post-operative complication.

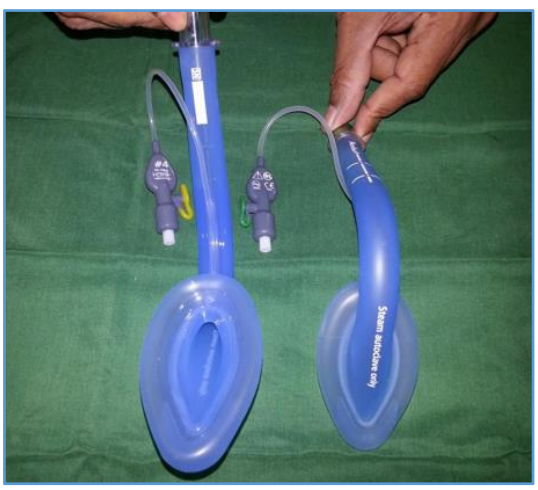
MATERIALS AND METHODS

Approvals of the institutional scientific and ethics committees were obtained prior to the commencement of the study. The study was carried out entirely by the primary investigator to avoid operator bias.



Description of Materials Used LMA Classic

The LMA Classic™ (LMA North America Inc., California, USA) was designed to secure the airway by establishing an end to end circumferential seal around the laryngeal inlet with an inflatable cuff.[10] It consists of a curved tube (shaft) connected to an elliptical spoon shaped mask (cup) at a 30-degree angle. There are two flexible vertical bars at the entry of the tube into the mask to prevent obstruction of the tube by the epiglottis. The mask is surrounded by an inflatable cuff. An inflation tube and self-sealing pilot balloon are attached to the proximal wider end of the mask. At the machine end of the tube is a standard 15 mm connector. The LMA is made from medical grade silicone.[11] Markings denote the size of the device and a black line runs along the length of the shaft to allow its proper orientation. The device is designed for reuse after sterilization up to 40 times.



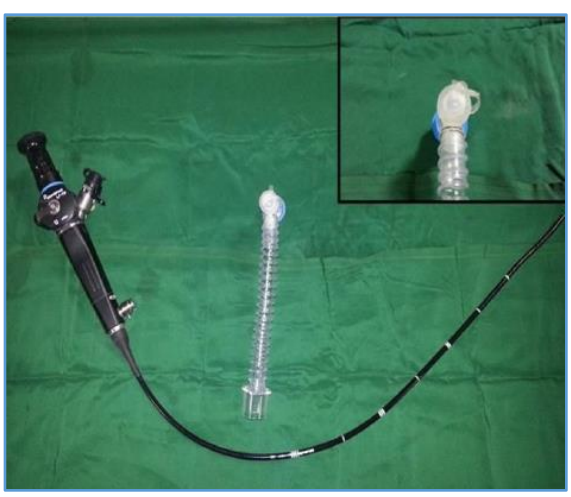
Ambu Aura40 Laryngeal Mask

The Ambu Aura40™ (Ambu A/S, Copenhagen, Denmark) laryngeal mask consists of an oval inflatable cuff at the patient end which is moulded to the shaft to form a single unit for providing extra safety. The shaft has a built-in anatomically correct curve for easy insertion. The tip of the cuff is reinforced to resist folding over during insertion and plugs the upper oesophageal sphincter. It has a color-coded pilot balloon which identifies mask size and provides precise tactile indication of the degree of inflation. The device is ergonomically shaped for firm grip during insertion and has convenient depth marks to confirm position after insertion. Markings on the pilot balloon denote the appropriate size of the device for patient weight along with the volume of air required to inflate the cuff. It is made of silicone.[12] The device is designed for reuse after sterilization up to 40 times.

I-gel

I-gel™ (Intersurgical Ltd, Wokingham, U.K.) is a 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 called Styrene Ethylene Butadiene Styrene (SEBS)[13] which adapts to the airway upon insertion.[14] The device has a buccal cavity stabilizer which has a propensity to adapt its shape to the oropharyngeal curvature of the patient. It is anatomically widened and concave to eliminate the potential for rotation, thereby reducing the risk of malposition. This buccal cavity stabilizer also houses the airway tubing and a separate gastric channel. The tube section is firmer than the soft bowl of the gastric channel. The device has an integral bite block which is marked with a horizontal black line, which acts as a guide to depth of insertion. The gastric channel runs through the device from its proximal opening at the side of the flat connector wing to the distal tip of the non-inflatable mask. The gastric channel allows suction, detection of leak and passage of a gastric tube. The device also has an epiglottic blocker which prevents down folding of the epiglottis and obstruction of the distal airway opening.[15] Markings on the device denote appropriate size of the device for patient weight. The I-gel is a single use device.

Airway Manometer (Medisys)



Fiberoptic Bronchoscope (Olympus) with Catheter Mount

Inset shows the port on the catheter mount through which the fiberoptic bronchoscope is passed allowing for visualisation of the glottis without interfering with patient ventilation.

Study Protocol

Inclusion Criteria

1. Patients between 18 and 70 years of age.
2. ASA status of either I or II
3. BMI below 40 kg/m^2
4. Scheduled for short surgical procedures in either supine or lithotomy positions.

Exclusion Criteria

1. Patients with a known or predicted difficult airway.
2. Patients at increased risk for aspiration.
3. Patients with active respiratory tract infections or a reactive airway.
4. Patients with any pathology of the neck or cervical spine.
5. Edentulous patients.

90 patients satisfying the above criteria were enrolled into the study. They were randomized into three groups using the chit-in-a-box method for the use of one of three device: LMA Classic, Ambu laryngeal mask or I-gel for the maintenance of airway during the anaesthetic. All patients were pre-medicated with oral Ranitidine 150 mg, Metoclopramide 10 mg and Alprazolam 0.5 mg one hour prior to the induction of anaesthesia.

Anaesthesia was induced using Fentanyl 2 µg/Kg and Propofol 2 mg/Kg. After achieving adequate anaesthetic depth, the randomly chosen, appropriately sized airway device was inserted according to manufacturer recommendations for the Ambu laryngeal mask[16] and the I-gel.[14] The LMA Classic was inserted without intra-oral digital manipulation since this is the technique followed in our institution. Studies have shown that the LMA Classic can be inserted successfully without the need to insert the index finger into the patient's mouth.[9] The cuffs of the LMA Classic[17] and the Ambu laryngeal mask[12] were inflated with a sufficient amount of air for each device and within a maximum intra-cuff pressure of 60 cms H2 0 as recommended by the manufacturer. A successful insertion of the device was defined as per the parameters described below. After insertion, the device was connected to the breathing circuit and anaesthesia maintained by the use of inhalational agents, nitrous oxide and oxygen. Analgesia was supplemented as per the anaesthetist's discretion. The following parameters were then studied.

Ease of Insertion

Number of Attempts

The number of attempts for the correct positioning of the device was counted. Correct positioning was determined by the appearance of at least 6 square traces on the capnograph and the ability to deliver at least 4 ml/Kg tidal volume. The insertion was termed as a failure if the number of attempts exceeded 3 and recorded as such. Every time

the device was taken out of the patient's mouth, it would be counted as 1 attempt.

Efficacy

Fiberoptic View

The fiberoptic view of the glottis was determined using a fiberoptic bronchoscope passed into the supraglottic device via a catheter mount so that ventilation of the patient was not interfered with. The bronchoscope was introduced until the junction of the shaft and the cuff of all three devices to ensure comparability of glottic views. The following scoring system[18] was then used for evaluating the glottic view-

1 = Vocal Cords entirely visible.
2 = Vocal Cords or Arytenoids Cartilages partially visible.
3 = Epiglottis only visible.
4 = No laryngeal structures visible.

Oropharyngeal Leak Pressure

For all studies, to eliminate the possibility of instrument bias and to ensure comparability of readings, an analogue manometer (Medisys) was connected to the expiratory limb of the breathing circuit (circle system) to measure the airway pressure. Once the patient was breathing spontaneously, the adjustable pressure limiting (APL) valve was closed completely. The fresh gas flow was then fixed at 3 L/min. The trachea was then auscultated while monitoring pressure readings on the manometer. The lowest airway pressure at which leak occurred as evidenced by the sound of air leaking around the supraglottic device was noted as the oropharyngeal leak pressure.

Complications

Intraoperative complications: The occurrence of the following intra-operative complications were looked for and recorded.

- Airway Loss – Inability to maintain the airway further with the device in use.
- Laryngospasm
- Coughing

Postoperative Complications

The occurrence of the following post-operative complications was looked for and recorded by observation and by interviewing the patient in the post anaesthesia care unit (PACU) after 60 minutes.

1. Blood on the device
2. Laryngospasm
3. Coughing
4. Sore Throat
5. Hoarseness of Voice

Data was analysed using Statistical Package for the Social Sciences (SPSS) software for Windows. The ANOVA, Pearson's chi-Square and Bonferroni tests were used for statistical analysis of recorded data.

RESULTS

90 patients undergoing short surgical procedures were randomly assigned to be ventilated using one of the three supraglottic airway devices following induction of anaesthesia. The results obtained from the 90 subjects were tabulated and analysed using standard statistical principles and techniques. The results are summarized as follows-

Age	36.23 ± 10.98	39.10 ± 10.79	39.20 ± 12.92	0.534
Height (cms)	164.23 ± 6.70	161.57 ± 7.16	163.76 ± 6.76	0.282
Weight (Kg)	67.56 ± 15.27	61.84 ± 13.64	64.11 ± 13.49	0.294
BMI	24.81 ± 4.29	23.63 ± 3.89	23.72 ± 3.75	0.447

Table 1. Age, Height, Weight and BMI were Comparable in all Groups

Patient Group	Sex		ASA	
	Male	Female	Class I	Class II
LMA Classic	46.7%	53.3%	70.0%	30.0%
Ambu Aura40	30.0%	70.0%	80.0%	20.0%
I-gel	40.0%	60.0%	63.3%	36.7%

Table 2. Sex Distribution (P = 0.411) and ASA Status (P = 0.358) were also Comparable in all the Groups

The number of patients in each group who underwent surgeries in the supine and lithotomy positions were calculated. This was found to be statistically significant. But this data does not have any clinical significance as the observations were carried out with the patient in the supine position in all cases.

Airway Characteristics

Patient Group	Mouth Opening	
	5 cm	>5 cm
LMA Classic	3.3%	96.7%
Ambu Aura40	0%	100%
I-gel	0%	100%

Table 3. The Airway Characteristics of the Patients Studied I.E. Mouth Opening

Patient Group	Thyromental Distance	
	6 cm	>6 cm
LMA Classic	16.7%	83.3%
Ambu Aura40	6.7%	93.3%
I-gel	13.3%	86.7%

Table 4. Thyromental Distance

Patient Group	MALLAMPATI SCORE		
	I	II	III
LMA Classic	56.70%	43.30%	0%
Ambu Laryngeal Mask	30.0%	66.70%	3.3%
I-gel	43.30%	56.7%	0%

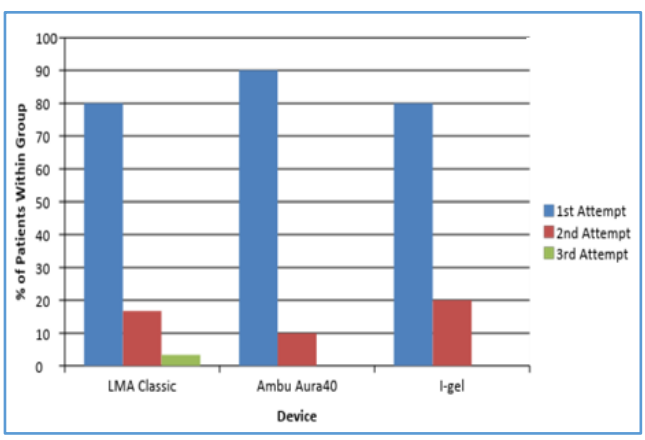
Table 5. The Mallampati Score were also Noted and Statistically Analysed

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

Table 6. The Results were not Statistically Significant as given in the Table below

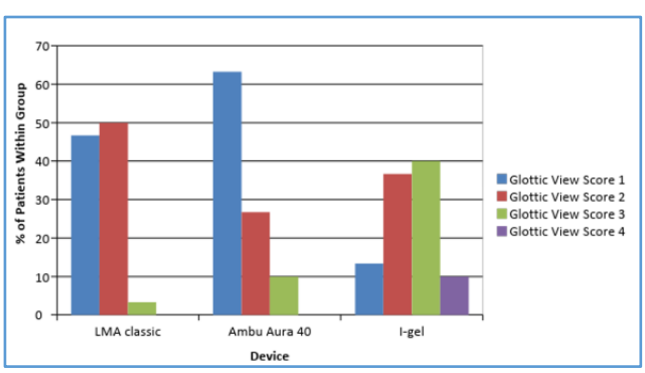
Device Parameters

The number of attempts at insertion needed to get a proper positioning of each device was noted and analysed (Graph 1). The Ambu Aura40 could be positioned successfully with a single attempt in 90% of the patients in whom the device was used (27 out of the 30 patients studied), whereas successful placement at first attempt could be achieved only in 80% of the subjects in both the LMA Classic and the I-gel groups. Successful positioning during the next or second attempt was more with I-gel compared to LMA classic (20.0% and 16.7% respectively). However, this result does not show a statistical significance (P = 0.518). 1 patient in the LMA Classic group (3.3%) needed 3 attempts for successful positioning. There were no instances of failure to secure an airway with the chosen device.



Graph 1. Ease of Insertion

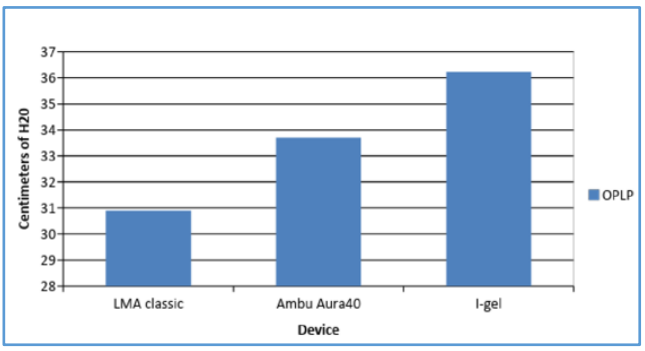
The glottic view observed via fibreoptic bronchoscope was recorded in all patients (Graph 2). 63.3% of patients in whom Ambu Aura40 laryngeal mask was used had a glottic view grade of 1 while only 46.7% and 13.3% of patients in the LMA classic group and the I-gel group had a similar glottic view respectively. This was statistically significant (P = 0.000).



Graph 2. Glottic view Score

Patient Group	Predominant Glottic view	Percentage (within group)
LMA Classic	2	50%
Ambu Aura40	1	63.3%
I-gel	3	40%

Table 7. The Predominant Glottic View Obtained with Each Device is as Follows



Graph 3. The Oropharyngeal Leak Pressure (OPLP)

The oropharyngeal leak pressure (OPLP) measured while using each device was measured and the average was calculated. It is as follows (Graph 3)

DISCUSSION

Laryngeal masks have played an important role in airway management since the introduction of the LMA Classic in 1988. Since then, several laryngeal masks varying in their shape, stiffness, cuff properties and clinical applications have come into existence. In addition to their use during routine anaesthetics, they have also been recommended for use in difficult airway scenarios[19,20] and in cardio-pulmonary resuscitation.[1] Therefore it is imperative that we be familiar with each device and its attendant advantages and disadvantages. In our institution we use the LMA Classic, Ambu Aura40 laryngeal mask and the I-gel extensively. To the best of our knowledge no literature exists that compare these devices.

We analysed 90 patients scheduled to undergo short surgical procedures using a laryngeal mask for maintaining the airway intra-operatively. The patients were then randomized to the use of one of the three laryngeal masks during the anaesthetic.

All three 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. Some of the surgeries involved patients being in the lithotomy position but in all cases the observations were done with the patient in the supine position.

Ease of Insertion

After induction of anaesthesia, the randomly chosen device of appropriate size was inserted and the number of attempts needed for proper positioning of the device was noted. In our study, the Ambu laryngeal mask could be positioned

successfully within a single attempt in 90% of the patients in whom the device was used whereas successful placement in the first attempt could be achieved only in 80% of the subjects in both the LMA classic and I-gel groups. This result was not significant statistically. However, we feel that this has considerable clinical relevance because the number of attempts taken reflects the amount of time taken to secure an airway. Instances of successful positioning in the second attempt were more with the I-gel compared to the LMA Classic. There were no instances of failure to secure the airway with any of the three devices within three attempts.

We feel that the Ambu Aura40 laryngeal mask may have been easier to position due to its pre-formed curvature which conforms to the anatomical curvature of the airway. In contrast, the I-gel was significantly harder to insert. This may be due inappropriate device size recommendations by the manufacturer.[21] However, once inserted the I-gel was extremely stable due to its built in buccal stabilizer.

Efficacy- Glottic View

The fiberoptic bronchoscope is a clinically proven tool to determine optimal positioning of laryngeal masks.[22] Therefore fiberoptic bronchoscopic view was recorded in all cases after securing a satisfactory airway. An ideal glottic view of grade 1 was noted in 63.3% of the patients in whom the Ambu Aura40 laryngeal mask was used whereas only 46.7% of patients in the LMA Classic group and 13.3% in the I-gel group had a similar glottic view. This is statistically significant.

Taking the above results into consideration, it may be concluded that the Ambu laryngeal mask requires the least number of attempts for optimal positioning. It is also worth mentioning that a poor glottic view need not necessarily imply a compromised airway.[23,24]

Oropharyngeal Leak Pressure (OPLP)

The oropharyngeal leak pressure is the airway pressure at which gases begins to leak around the cuff of the laryngeal mask airway device. A higher oropharyngeal leak pressure is a marker of efficacy and safety when using laryngeal mask airway devices.[25] Oropharyngeal leak pressure was measured using an analogue manometer connected to the expiratory limb of the breathing circuit to measure the airway pressure while auscultating over the trachea for gas leak around the device. We found that the oropharyngeal leak pressure was the highest with the I-gel (Mean OPLP 36.23 ± 3.00). In comparison with the other two devices, this difference is statistically significant. Therefore, we can conclude that the I-gel offers a better seal than the other two devices in the study.

We attribute this to the shape, softness and contour of the non-inflatable cuff which closely reflects perilaryngeal anatomy thereby providing a snug fit between the device and the airway.

Complications

LMA Classic

There were 2 incidents of intraoperative airway loss, due to cuff leak while using the LMA Classic. In one case, the device was removed and replaced with another device and in another case, repeated inflations of the cuff were enough as the surgery had almost concluded. One patient had traumatic airway insertion as evidenced by blood on the device. Three patients complained of sore throat in the post-operative period. Both these complications were noted in those patients in whom multiple attempts were required to secure the airway. This was statistically significant.

Ambu Aura40 Laryngeal Mask

In one instance blood was found at the time of removal of the device. No other intra-operative or post-operative complications were noted.

I-gel

No intra-operative or post-operative complications were noted with this device. This is probably due to the soft, gel like nature of the I-gel cuff due to which compression and displacement trauma are significantly reduced or eliminated.[14]

CONCLUSIONS

In our study we compared three laryngeal mask airway devices: LMA Classic, Ambu Aura40 and the I-gel. Taking into consideration the parameters evaluated in our study, i.e. ease of insertion, fibreoptic bronchoscopic view, oropharyngeal leak pressure and the incidence of intra-operative and post-operative complications, we feel that overall the Ambu Aura40 is the superior device in comparison to the other devices. The I-gel is especially useful in situations requiring positive pressure ventilation and added stability. The I-gel also allows for access to the alimentary tract via its gastric channel. The LMA Classic was not as effective as the other devices in securing an airway and was associated with a minimal incidence of complications in our study.

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