Original Research Article

A prospective randomized study comparing the efficacy of the LMA Classic[TM], the AMBU Aura40 Laryngeal Mask[TM] and the I-Gel[TM] using fiberoptic bronchoscope in spontaneously breathing anesthetized patients

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Abstract

Background: Supraglottic airway devices (SAD's) have revolutionized airway management both inside and outside the operating room ever since the invention of the LMA Classic.

Objectives: Objective of this study was to compare efficacy of LMA classic, Ambu Aura laryngeal mask and I-gel in terms of ease of insertion, fiberoptic bronchoscopic assessment of the glottic view, oropharyngeal leak pressure, intra and post-operative complications.

Material and methods: Ninety patients of ASA Grade 1 or 2, aged 18–70 years, scheduled for elective short surgical procedures requiring general anesthesia were randomly divided in to three groups as LMA Classic, Ambu Aura40 laryngeal mask and I-gel group whose airway were secured with these devices. Anesthetic technique was standardized and maintained on spontaneous breathing. The number of attempts for the correct positioning (at least 6 square Etco2 traces on the capnograph and 4 ml/kg tidal volume) of the device were counted. Glottic view was noted by fiberoptic bronchoscope passed into the supraglottic device and graded as 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 (OPLP) was measured. Intra and post-operative complications were looked for and recorded.

Results: Ambu Aura40 could be positioned successfully in a single attempt in 90% of the patients (27 out of the 30), whereas it's only 80% in both the LMA Classic and the I-gel groups without a statistical significance (P = 0.518). Successful positioning during the next or second attempt was more with I-gel compared to LMA classic (20.0% and 16.7% respectively). 63.3% of Ambu laryngeal mask group had a glottic view grade of 1 while only 46.7% and 13.3% of patients in the LMA classic and the I-gel group had a similar glottic view respectively which was statistically significant (P = 0.000). Significantly higher mean OPLP with I-gel 36.23 ± 3.00 and least with LMA classic 30.90 ± 2.15 (p=0.000). 3 patients (10%) in the LMA Classic group complained of sore throat in the post-operative period which was statistically significant (P = 0.045).

Conclusion: Over all Ambu Aura40 laryngeal mask airway device is superior in comparison to the other devices with respect to parameters studied. I-gel due to high oropharyngeal pressure leak could be useful in positive pressure ventilation. The LMA Classic is associated with a minimal incidence of sore throat in our study.

Key words

Ease of insertion, Glottic view, I-gel, Ambu Aura40.

Introduction

Safe and effective airway management is the foundation of quality anaesthetic practice. Securing and maintaining the airway is top priority of every anesthesiologist. Endotracheal intubation remains gold standard for this purpose, which requires special training and skills like mask holding, oxygenation, laryngoscopy etc. Intubation process is not without airway complication [1, 2]. Misplaced tracheal tubes in difficult circumstances outside operating room may cause brain damage or death of patient. Katz, et al. reported that up to 25% of endotracheal tubes inserted by paramedics in emergency were found to be improperly placed [3].

Supraglottic airway devices (SAD's) have revolutionized 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 [4]. These devices are used as an excellent alternative to mask ventilation and tracheal intubation where they serve as primary airway devices. 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. They can also be used as secondary airway device outside operating room as in emergency difficult airway management [5] in cannot ventilate and cannot intubate situation as a rescue device and in cardio-pulmonary resuscitation [4].

In comparison to endotracheal intubation, usage of SAD's doesn't require special skills and training. Paramedics can use these airway devices in emergency situation. European guidelines for resuscitation accepted the relatively safe and easy use of supraglottic airway devices (SAD's) by operators with limited airway management experience. To decrease the "hands-off" time, emphasis on tracheal intubation was reduced in favor of supraglottic devices [6].

Since the introduction of the LMA Classic, several laryngeal masks have been introduced which differ in shape, stiffness, cuff properties and constituent material [7]. The Ambu

Aura40™ (Ambu A/S, Copenhagen, Denmark) laryngeal mask and the I-gel™ (Intersurgical Ltd, Wokingham, U.K.) are two such devices.

The LMA Classic™ which is reusable, is made from medical grade silicone, 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.

The Ambu Aura40™ laryngeal mask which is made of silicone [8] 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 esophageal sphincter. The device is ergonomically shaped for firm grip during insertion and has convenient depth marks to confirm position after insertion. It can be used up to 40 times I-gel™ which meant for single use 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 [9]. The device has a buccal cavity stabilizer which has a propensity to adapt its shape to the oropharyngeal curvature of the patient. This buccal cavity stabilizer also houses the airway tubing and a separate 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 allows suction, detection of leak and passage of a gastric tube. The device also has an epiglottic blocker which prevents obstruction of the distal airway opening.

Hence an attempt was made to compare the above devices in terms of their ease of insertion as defined by the number of attempts required to secure an airway, positioning as revealed by fiberoptic bronchoscopic assessment of the glottic view, oropharyngeal leak pressure, intra-operative and post-operative complications.

Material and methods

Ninety patients (both male and female) of American Society of Anesthesiologists grades 1 or 2, aged 18–70 years, BMI below 40 kg/m^2 scheduled for short surgical procedures in either supine or lithotomy positions requiring general anesthesia with supraglottic airway devices were enrolled for the study. Written informed consent was taken from patients. Data was collected over a period of 12 months (Nov 2012–Nov 2013) at a corporate tertiary care center with postgraduate training facility. The study was approved by the institutional review board (Hospital Ethics Committee for Human Research), which supervised the data collection and safety issues.

Exclusion criteria were patients with cardio-respiratory comorbities who require endotracheal intubation (ASA-3 and above). Patients with a known or predicted difficult airway, increased risk for aspiration (morbid obesity, hiatal hernia), active respiratory tract infections or a reactive airway. Patients who were edentulous, any pathology of the oral cavity, neck or cervical spine etc.

Sample size estimation

In our study, we have calculated sample size with a significance level of p<0.05 corresponding to confidence level of 95 %(α-error 1.96) and power of 90% to detect a difference of 15% between groups. The minimum number calculated was 29. However to compensate loss of data in some patients, we have taken total of 90 subjects, with 30 in each group.

Randomization

Based on a computer generated random number table using Microsoft Excel (created using Microsoft Excel 2003 software, Redmond, WA), all the patients were randomized into 3 groups, with 30 patients in each group. These three groups whose airway was secured with LMA

Classic, Ambu Aura40 laryngeal mask and I-gel during surgeries.

Patients were assessed and evaluated as per the routine preoperative protocol. All the patients were kept nil by mouth 6 hours before the surgery. All patients were pre-medicated with oral Ranitidine 150 mg, domeperidone 10 mg and Alprazolam 0.5 mg in the night.

Intra-operative period

Standard monitors like Electrocardiography, non-invasive blood pressure, pulse oximetry and capnogram were used during the intraoperative period. Baseline vitals noted. After pre-oxygenation for 3 minutes, all the patients were induced with intravenous propofol 2 mg/kg, fentanyl 2 µg/kg and lignocaine 1.5 mg/kg. After achieving adequate anaesthetic depth, as per random table number appropriately sized airway device was inserted according to manufacturer recommendations for the Ambu laryngeal mask [8] and the I-gel [9].

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 [10]. The cuffs of the LMA Classic [11] 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 cm H_2O 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 with isoflurane (0.8-1.5%) in oxygen and air (50:50). Analgesia was supplemented with intravenous paracetamol 1 gm. The following parameters were then studied.

A) 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.

B) Efficacy

1. 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 [13] 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

2. 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.

C) Complications

- Intra-operative complications like airway loss (Inability to maintain the airway further with the device in use), laryngospasm, coughing etc. were looked for and recorded.

- Postoperative Complications like blood on the device, laryngospasm, coughing, sore throat, hoarseness of voice etc. were looked for and recorded by observation and by interviewing the patient in the post anaesthesia care unit (PACU) after 60 minutes.

Statistical Analysis: Data was analyzed 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

We recruited total 90 patients, randomly divided into 3 groups of 30 each, whose airway was secured using one of the three supraglottic airway devices following induction of anaesthesia. The results obtained from the 90 subjects were tabulated and analyzed using standard statistical principles and techniques. The three groups were demographically well matched and no statistical significance with respect to age, sex, weight, height, BMI and ASA grade as per **Table - 1** (p>0.05).

Table - 1: Demographics.

Parameter		Group L (LMA Classic) (n =30)	Group A (Ambu Aura40) (n =30)	Group I (I-gel) (n =30)	P value
Age (year)		36.23 ± 10.98	39.10 ± 10.79	39.20 ± 12.92	0.534
Sex	Male: Female (%)	46.7:53.3	30.0:70.0	40.0:60.0	0.411
Height (cm)		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
ASA Grade	1:2(%)	70.0:30.0	80.0:20.0	63.3:36.7	0.358

Airway characteristics

The airway characteristics of the patients studied i.e. mouth opening, thyromental distance and the Mallampati (**Table - 2**) score were also noted and statistically analyzed. There was no statistically significant changes in these parameters in all the 3 study groups (p>0.05).

Table - 2: Airway characteristics.

Patient Group	Mouth opening		Thyromental Distance		Mallampati Score		
	5 cm	>5 cm	6 cm	>6 cm	I	II	III
LMA Classic	3.3%	96.7%	16.7%	83.3%	56.70%	43.30%	0%
Ambu Aura40	0%	100%	6.7%	93.3%	30.0%	66.70%	3.3%
I-gel	0%	100%	13.3%	86.7%	43.30%	56.7%	0%
p-value	0.364		0.484		0.695		

Ease of insertion

The number of attempts at insertion needed to get a proper positioning of each device was noted and analyzed (**Table – 3, 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.

Table - 3: Showing ease of insertion.

Patient Group	Attempts		
	1	2	3
LMA Classic	80.0%	16.7%	3.3%
AMBU Laryngeal Mask	90%	10%	0%
I-gel	80%	20%	0%

Glottic View

The glottic view observed via fibreoptic bronchoscope was recorded in all patients (**Table – 4, 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). Predominant glottic view obtained in classic LMA, Ambu Aura40 and in I-gel was 2 (50%), 1 (63%) and 3(40%) respectively.

Table - 4: Glottic view seen through fibreoptic bronchoscope.

Patient Group	Glottic View			
	1	2	3	4
LMA Classic	46.7%	50.0%	3.3%	0%
Ambu Aura40	63.3%	26.7%	10.0%	0%
I-gel	13.3%	36.7%	40%	10%

Oropharyngeal leak pressure

Oropharyngeal leak pressures are commonly performed with the LMA to indicate the degree of airway protection, the feasibility for positive pressure ventilation and the likelihood for successful supraglottic airway placement [14]. We found a higher mean OPLP with I-gel 36.23 ± 3.00 and least with LMA classic 30.90 ± 2.15 which was of statistical significance p=0.000 (**Table – 5, Graph - 3**).

Table - 5: Oropharyngeal leak pressure (OPLP) measured.

Patient Group	Mean Oropharyngeal Leak Pressure (cm H_2O)
LMA classic	30.90 ± 2.15
Ambu Aura40	33.77 ± 4.5
I-gel	36.23 ± 3.00

Complications

There were 2 incidents of intra-operative 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. No other intra-operative complications such as laryngospasm or

coughing were noted. Traumatic device insertion as evidenced by blood on the device was noted in 1 patient each in the LMA Classic and Ambu Aura40 group but this was not found to be statistically significant. 3 patients in the LMA Classic group complained of sore throat in the post-operative period. This is statistically significant (P = 0.045). There were no other post-operative complications (laryngospasm, hoarseness or cough). There were no incidences of intra-operative or post-operative complications in the I-gel group.

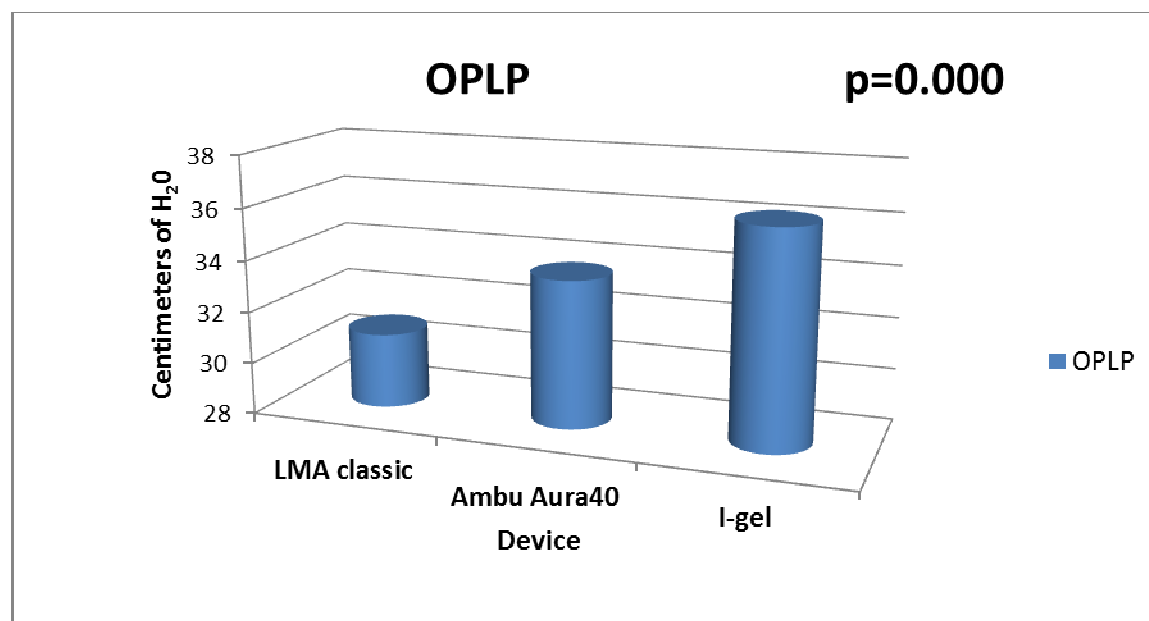**Graph - 1:** Showing ease of insertion of airway devices in 3 study groups.
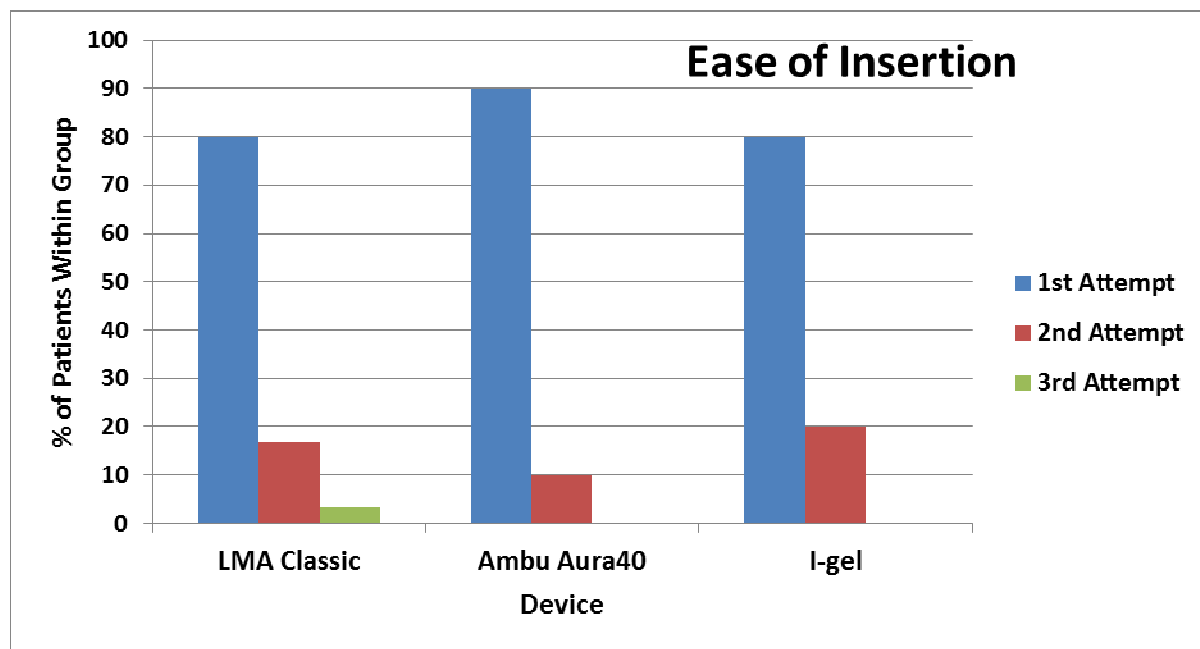
Graph - 2: Showing glottic view seen through fibreoptic bronchoscope.
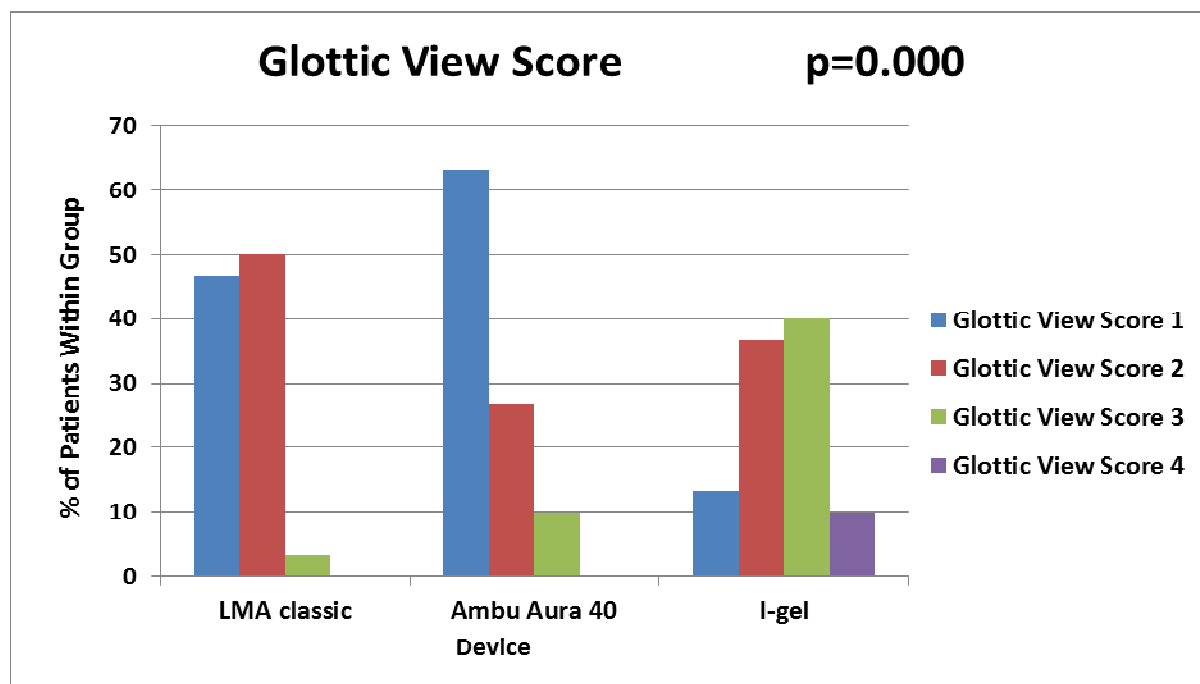
Graph - 3: Showing oropharyngeal leak pressure (OPLP) in study groups.

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 anesthetics, they have also been recommended for use in difficult airway scenarios [5, 15] and in cardio-pulmonary resuscitation [4]. 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 or very few literature exists that compare these devices.

We analyzed 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. Study done by Janakirman, et al. [16] had first attempt success rate significantly higher in LMA group 86% than in i-gel group (54%). 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 and attendant risks. 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 [9]. However, once inserted the I-gel was extremely stable due to its built in buccal stabilizer. On contrary, study conducted by Jeeven singh and co-workers [17] found more ease of insertion with i-gel 22/24 than that with cLMA group 19/24; p = 0.023 which is of statistical significance. Ambu Aura 40 laryngeal mask was not included in their study.

Efficacy
Glottic View: The fiberoptic bronchoscope is a clinically proven tool to determine optimal positioning of laryngeal masks [18]. 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 [19, 20].

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 [21]. Study done by Helmy AM, et al. [22] showed that Leak pressure was significantly higher with I-gel than LMA (25.6 ± 4.9 vs. 21.2 ± 7.7 cm H_2O) with p value 0.016 and thus incidence of gastric insufflation was significantly lower with I-gel. 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. 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: Contrary to the findings of study done by Amr. H. Helmy [22] where they compared i-gel with LMA in 80 patients and found blood on device in 5% cases of i-gel and 10% cases of LMA, we did not encounter any intra-operative or post-operative complications with this device similar to study conducted by Donaldson W and co-workers [23], 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 [9]. These three devices were well tolerated throughout the anesthesia and emergence.

To summarize LMA Classic requires more attempts overall to secure the airway, glottic view scores were intermediate, had least Oropharyngeal Leak Pressure (OPLP), and incidences of complications namely intra-operative airway loss, traumatic insertion and post-operative sore throat were slightly higher in comparison to the other devices. The Ambu Aura40 laryngeal mask required the least number of attempts to secure the airway, this may be useful in a 'Cannot Ventilate, Cannot Intubate' situation, and glottic view as obtained with a fiberoptic bronchoscope was the best. This might be useful in guiding an airway exchange catheter into the trachea and using it as an intubation aid. Further studies are required to validate this point. 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. It is the most stable of the devices studied and therefore would be most suitable for surgeries in positions other than supine it has bite guard and gastric channel as added advantage. The incidence of complications were nil with the I-gel in this study.

Limitations of this study: It was a single center study. We studied only low risk patients (ASA 1 and 2) having normal airways (Malampatti I and II). Many more clinical trials with large sample size are required for further evaluation in this regard.

Conclusion

Over all Ambu Aura40 laryngeal mask airway device is superior in comparison to the other devices with respect to ease of insertion, fibreoptic bronchoscopic view, oropharyngeal leak pressure and least incidence of intra and post-operative complications. I-gel due to its added stability could be useful in situations requiring positive pressure ventilation, which also allows for access to the alimentary tract via its gastric channel. The LMA Classic was not as effective as the other devices and was associated

with a minimal incidence of complications in our study.

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