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A Prospective Randomized Study to Evaluate and Compare ILMA and Air-Q Intubating Laryngeal Airway

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ILMA ve Air-Q Laringeal Airway'i Değerlendiren ve Karşılaştıran Prospektif Randomize çalışma

ABSTRACT

Objective: *Our aim was to evaluate the Air-Q intubating laryngeal airway (ILA) as a primary airway device and conduit for tracheal intubation and to compare it with the intubating laryngeal mask airway (ILMA) which is currently the 'gold standard' supraglottic airway used as a conduit for tracheal intubation.*
Methods: *Eighty patients of either sex, aged 18-60 years scheduled for elective surgery were allocated into two groups. In Group I (n=40), the intubating laryngeal mask airway was used to secure the airway and in Group A (n=40), the Air-Q intubating laryngeal airway was used. Both devices were then compared and assessed as ventilation device and intubation conduit.*
Results: *ILMA had a higher first attempt intubation success rate (95%) as compared to ILA (72.5%) but both devices were comparable with respect to ease of placement and total time required for intubation.*
Conclusion: *Both ILMA and ILA were comparable as primary airway devices. The first attempt blind intubation success rate was significantly higher in Group I.*

Keywords: *Intubating laryngeal mask airway, endotracheal intubation, intubating laryngeal airway, conduit*

ÖZ

Amaç: *Amacımız; birincil hava yolu aracı ve trakeal entübasyon için konduit olarak Air-Q entübasyon laringeal airwayi (ILA) değerlendirmek ve şu anda 'altın standart' supraglottik hava yolu olarak kullanılan entübasyon laringeal maske airway (ILMA) ile karşılaştırmaktır.*
Yöntem: *Elektif cerrahi planlanan 18-60 yaşları arasındaki her iki cinsiyetten 80 hasta iki gruba ayrıldı. Grup I'de (n=40) hava yolu güvenliğini sağlamak için entübasyon laringeal maske airway ve Grup A'da (n=40) Air-Q entübasyon laryngeal airway kullanıldı. Daha sonra her iki araç karşılaştırıldı ve ventilasyon aracı ve entübasyon konduiti olarak değerlendirildi.*
Bulgular: *ILMA (%95), ILA'ya (%72.5) kıyasla daha yüksek ilk deneme entübasyon başarı oranına sahipti, ancak her iki araç da yerleştirme kolaylığı ve entübasyon için gereken toplam süre açısından benzerdi.*
Sonuç: *Hem ILMA hem de ILA, birincil hava yolu araçları olarak benzerdi. İlk denemede kör entübasyon başarı oranı Grup I'de anlamlı olarak daha yüksekti.*

Anahtar kelimeler: *Entübasyon laringeal maske airway, endotrakeal entübasyon, entübasyon laringeal airway, konduit*

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INTRODUCTION

Supraglottic devices (SGDs) have become the airway devices of choice for many surgical procedures, both for ventilation as well as for use as conduits for intubation. Dr. Archie Brain and Chandy Verghese introduced the intubating laryngeal mask airway (ILMA) [1] in 1997. This was used to facilitate blind rather than fiberoptic-assisted tracheal intubation. The ILMA consists of an anatomically curved, short rigid airway tube with an integral guiding handle and an epiglottic elevator bar and guiding ramp built into the floor of the mask aperture to facilitate intubation of the trachea (Figure 1). The ILMA does not carry diameter length limitations for tracheal tube as seen with standard laryngeal mask airway hence helps in guiding tracheal tube in to the glottis. Because of its anatomical curved shape, It does not require airway manipulation or insertion of the operator's fingers into the patient's mouth for successful placement. Since its introduction, it has been used for both blind and fiberscope-guided tracheal intubations in patients with difficult airways.

The intubating laryngeal airway (ILA) and its disposable version, the Air Q, is characterized by a preformed shape and a wide airway tube with a distally located large inflatable cuff designed to be put in the hypopharynx (Figure 2). The shape of the cuff tip has been designed to prevent the epiglottis from obstructing the lumen of the device and the absence of aperture bars allows easy passage of an endotracheal tube. The breathing tube of the ILA is shorter and wider and comes with a removable connector which makes the placement of a standard endotracheal tube easy [2]. The major advantage of the ILA is that conventional PVC endotracheal tube which is inexpensive and widely available is recommended to be used with it whereas silicone wire-reinforced ILMA specific and expensive endotracheal tubes are provided with ILMA. ILA devices are also available in pediatric sizes, small enough to allow their use in small children (< 30 kg). The ILA is specifically engineered for use both as a primary airway and as a rescue device to facilitate blind or fiberoptic guided intubation.

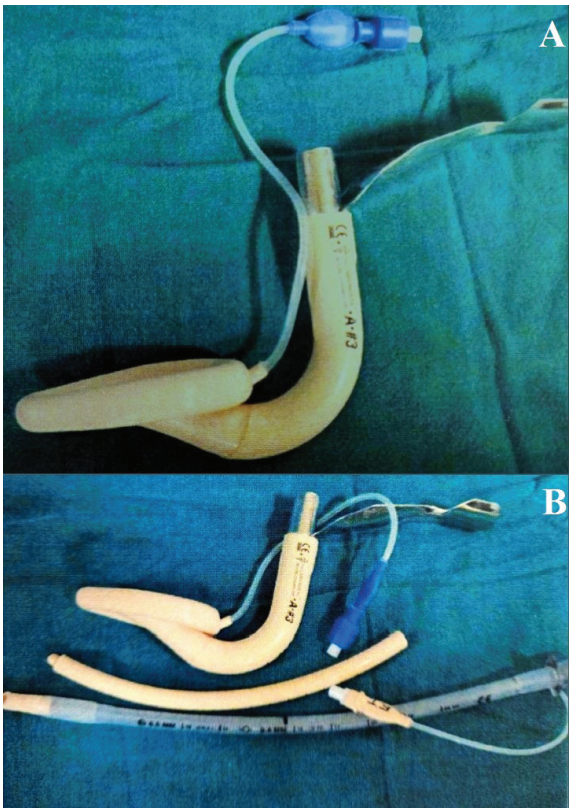

Figure 1. (A) Intubating Laryngeal Mask Airway (ILMA) (B) ILMA with dedicated endotracheal tube and stabilizing rod

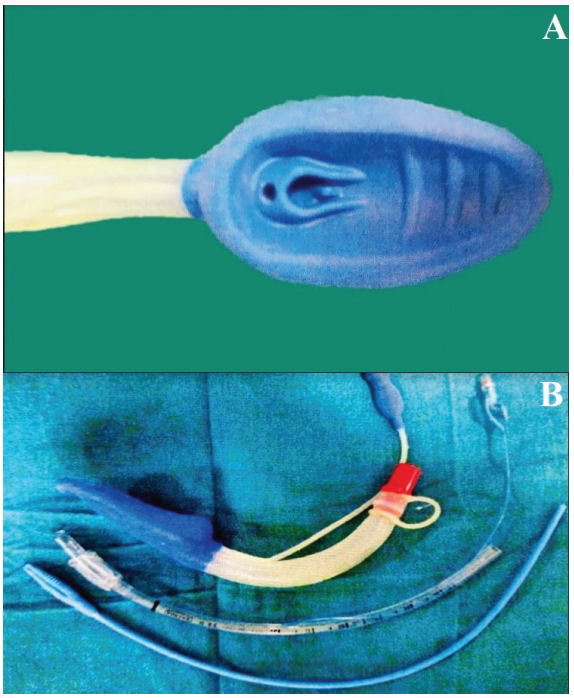

Figure 2. (A) Bowl of Air –Q with key hole shape aperture, accessory vent and mask ridges. (B) Air-Q with dedicated stylet and PVC endotracheal tube

In this study our aim was to evaluate the performance of the ILA as a primary airway device and conduit for blind tracheal intubation and to compare it with the ILMA, which is currently considered to be a 'gold standard' in supraglottic airways used as conduits for tracheal intubation.

MATERIAL and METHODS

A prospective, randomized study was conducted in a tertiary care hospital in New Delhi using two supraglottic devices, namely the Air-Q ILA and the ILMA airway. After Institutional ethical board approval (F.11/IEC/MAMC/10) along with informed consent, 80 patients of either sex of ages ranging between 18-60 years with American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective surgical procedures under general anaesthesia, requiring endotracheal intubation were included in the study. Patients with known/predicted difficult airway, increased risk of aspiration, obesity, pregnant patients and patients for head and neck surgery or procedures requiring other than supine position were excluded from the study.

Eighty patients of either sex were randomly allocated to one of the study groups using computer generated random number tables. Group allocations were sealed in opaque envelopes which were opened on the morning of surgery. In Group I, ILMA was inserted and in Group A, Air-Q ILA was used. Device insertion was carried out by an operator with an experience of at least one year in anesthesia and who had carried out a minimum of twenty successful insertions of both devices. Before induction of anesthesia, a flexible fiberoptic bronchoscope (OD 3.7 mm) was prepared and focused in both groups. The sizes of ILMA and Air-Q ILA size were chosen according to the patient's body weight, in accordance with the manufacturer's recommendations. The dedicated ILMA endotracheal tube (ETT) was used in Group I and a standard PVC cuffed ETT in Group A. Check tests of both airway devices were performed before use as recommended. For ILMA, size 3 with 7mm ETT was used in patients weighing 30-60 kg; size 4 with 7.5mm ETT in 50-90 kg and size 5 with 8mm ETT in patients weighing >90 kg. For Air-Q ILA, size 2.5 with 6.5 mm ETT was used in patients weighing 30-50 kg; size 3.5 with 7.5 mm 110 ETT in 50-70 kg and size 4.5 mm with 8.0 mm ETT in 70-100 kg.

After shifting the patients in to the operation theatre, intravenous (IV) access was secured and ASA standard monitor e.g Electrocardiogram, capnography ($ETCO_2$), pulse oximeter (SpO_2) and non-invasive blood pressure (NIBP) were attached. The patients were positioned supine with the pillow under the head and IV fentanyl 2 µg kg^{-1} was administered over 5 minutes before induction. After preoxygenation for 3 minutes, induction was done with IV propofol 1.5-2 mg kg^{-1} and muscle relaxation facilitated by IV rocuronium 0.6 mg kg^{-1}. Mask ventilation was continued with 1-1.5% isoflurane in oxygen and nitrous oxide (1:1) for 3 minutes. An independent anesthesiology colleague, with at least 3 years of experience then performed direct laryngoscopy with a Macintosh laryngoscope and graded the laryngeal view using Cormack and Lehane scale [3]. The grading was revealed only after completion of all airway procedures. The patient's lungs were again ventilated by facemask for a few breaths. The selected device of appropriate size was lubricated with a water based gel as recommended and inserted with the patient's head in neutral position. The ILMA was inserted by a one handed rotational movement in the sagittal plane as recommended. When we encountered difficulty in ventilation , we applied the "up-down maneuver" by withdrawing the ILMA by 6 cm and reinserting it, with the cuff inflated. If this also failed, we partially withdrew the ILMA, and if this also failed, we completely removed and reinserted the device. After proper positioning, the cuff was inflated with two thirds the maximum recommended volume of air. For inserting Air-Q, patient's mouth was opened and the front portion of the ILA mask was placed between the base of the tongue and the palate at a slight forward angle. It was then passed into position within the pharynx by gently applying inward and downward pressure. The device was advanced until a fixed resistance was felt. If there was resistance to advancement, mandibular lift was applied or a tongue blade was placed at the base of the tongue. If required, jaw lift and withdrawal of the ILA followed by reinsertion using Klein Maneuver was used to optimize positioning [4]. Once the device was inserted into the pharynx the cuff was inflated with 8-10 mL air. Effective ventilation

was defined as proper chest expansion, appearance of square wave on capnograph, absence of audible leak and lack of gastric insufflation. The ease of insertion was judged subjectively as smooth insertion, insertion with slight difficulty or moderate difficulty. Time to insertion was considered as the time from insertion of device into patient's oral cavity to the appearance of first square wave of capnograph. A failed attempt at insertion was defined as removal of the device from the mouth. A total of three attempts at insertion were allowed and the respective times were noted as T1, T2, and T3. Effective airway time was calculated by adding T1, T2 and T3. Between any two attempts, if the SpO_2 fell below 90%, the patient's lungs were to be ventilated with 100% oxygen till the SpO_2 above 95%. This time of ventilation was not counted as a part of the effective airway time. If placement failed after three attempts or 5 minutes, the insertion would have been recorded as failure of insertion and an alternate device inserted. After effective ventilation, cuff pressure was checked and adjusted to 60 cm H_2O and the leak pressure was checked by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min of oxygen and gradually increasing the peak pressure until a leak was audible as determined at the mouth or by auscultation over neck or to a maximum of 40 cm H_2O. Anatomical position of the device was assessed by passing the tip of a flexible fiberoptic bronchoscope (FOB) to the rim of the bowl of the supraglottic device and grading the view. This procedure was done using FOB through a swivel connector so as not to interrupt ventilation, by an independent observer and the grade was revealed later using Danha Grading as Grade 1-Vocal cords seen in full without any obstruction to the view, Grade 2-Only a part of the vocal cords seen, Grade 3-Vocal cords not seen but at least one other glottic structure is identifiable and Grade 4- Neither vocal cords nor any identifiable glottic structure is seen [5]. In both groups, after effective ventilation, blind tracheal intubation was attempted through the airway device. In Group I tracheal intubation was attempted through the ILMA using the dedicated ILMA ETT. If any resistance was felt, Chandy maneuver was applied (first manipulation) [6]. If endotracheal intubation was still not successful, appropriate management was undertaken based on the depth at which resistance was felt (second manipulation). In Group A, the connector was removed from the Air-Q ILA, and with the cuff fully deflated, a generously lubricated standard polyvinylchloride ETT was inserted through the Air-Q ILA to a depth of approximately 16-20 cm depending on Air-Q ILA size. The ETT was then gently advanced into the trachea. If any resistance was encountered, the following manipulations were attempted -ETT was withdrawn slightly, rotated and re-advanced, jaw thrust was applied or Klein maneuver was used. In both groups, correct tracheal intubation was confirmed by capnography. Intubation time was measured from time of placing the ETT in the device until its successful placement was confirmed. If blind intubation was unsuccessful, a single attempt was to be made to guide the ETT into the trachea through the SGD using a FOB. If this also failed, the device was to be removed and tracheal intubation was performed using a Macintosh laryngoscope. After successful tracheal intubation, the SGD was removed over the ETT with the aid of the stabilizer rod/stylet. The time taken for removal of the device was recorded from disconnection of circuit till complete removal of the device from the mouth. Anesthesia was maintained with isoflurane in oxygen and nitrous oxide (1:1) and intermittent boluses of rocuronium bromide. At the end of surgery, anesthesia was discontinued and the residual effect of muscle relaxant was reversed with IV neostigmine 60 μg kg^{-1} and glycopyrrolate 10 μg kg^{-1} and the trachea was extubated.

Any complications at insertion, intra-operatively and post-operatively were recorded. A total sample size of 80 patients was required to obtain significant differences between the two groups at 5% level of significance and power of study as 80% (with effect size 50%). All data were statistically analyzed using IBM Statistical Package for the Social Sciences (SPSS) statistical software, Version 22 (IBM corp. Released 2013. IBM SPSS Statistics for windows, Version 22.0.Armonk, NY: IBM corp). Qualitative data were analyzed using Chi-square test or Fisher Exact test. Quantitative data were analyzed using Student's t test for normally distributed data or Mann Whitney test for non-normal distribution. p value <0.05 was considered significant.

RESULTS

Demographic data and airway parameters were comparable in both groups (Table I). The two groups were also comparable with respect to the number of insertion attempts, ease of device insertion, fiberoptic view grading and removal time of airway device. Group I had a first attempt insertion success rate of 100% as compared to 92.5% in Group A (Table II). The success rate of intubation in the first attempt using ILMA was 100% as compared to 77.5% 195 using Air-Q ILA with a statistically significant intergroup difference (p=0.04). All 40 patients in Group I required the use of the Chandy Maneuver for successful intubation as compared to Group A where only 4 out of 40 patients required use of maneuvers. The insertion time of ETT and total time for successful intubation was comparable in both groups. In Group A, 5 out of 40 patients required the use FOB to aid the attempted blind intubation. On the other hand, FOB was not needed to guide endotracheal intubation in Group I for any patient (Table III). None of the patients required direct laryngoscopy and there was no incidence of desaturation in either group. Blood on the device was present in 3/40 patients in Group I and 6/40 patients in Group A (p=0.211). There was no incidence of displacement, leak or regurgitation after fixation of devices in either group.

Table I. Demographic data and airway parameters

Variables	Group I (n=40)	Group A (n=40)	p value
Age (years)	32.02±10.37	30.60±10.25	0.541
Sex			
Male	13 (32.5 %)	16 (40 %)	0.482
Female	27 (67.5 %)	24 (60 %)	
Weight (kg)	53.07±10.49	53.3±9.3	0.982
Height (cm)	152.9±5.9	154±4.5	0.100
MMP Score (I/II/III)	28/10/2	31/6/3	
TMD			
<6.5 cm	9	7	0.779
>6.5 cm	31	33	
CL Score 1/2/3	23/13/4	31/7/2	0.281

Data are expressed as mean±SD, number (n), and percentage (%), MMP-Modified mallampati score, TMD-Thyro-mental distance, CL Cormack Lehane score

Table II. Insertion characteristics

	Group I (n=40)	Group A (n=40)	p value
Number of attempts			0.241
One	40 (100%)	37 (92.5%)	
Two	0	3 (7.5%)	
Ease of insertion			1.000
Smooth	38 (95%)	37 (92.5%)	
Slight difficulty	1 (2.5%)	1 (2.5%)	
Moderate difficulty	1 (2.5%)	2 (5%)	
Insertion Time (sec)	19.2±7.8	21.42 ± 13	0.301
Fiberoptic laryngeal view (n,%)			0.444
I	27 (67.5%)	32 (80%)	
II	10 (25%)	6 (15%)	
III	3 (7.5%)	2 (5%)	

Data are expressed as mean±SD, number (n) and percentage (%)

Table III. Intubation characteristics

	Group I (n=40)	Group A (n=40)	P value
Number of attempts			
One	38 (95%)	31 (77.5%)	0.046
Two	2 (5%)	4 (10%)	
Three	0	5 (12.5%)	
Intubation time (sec)	18.7±6.7	21.0±13.8	0.322
Maneuvers required	40 (100%)	4 (10%)	<0.001
Total time for successful intubation (sec)	52.5±13.8	57.75±20.35	0.185

Data are expressed as mean±SD, number (n) and percentage (%).

DISCUSSION

Supraglottic devices are being increasingly used regularly in elective and emergency airway management. Over the past 30 years many variations and many supraglottic devices have come in to practice since invention of classic LMA. In this study we compared and evaluated the ILMA and Air-Q ILA as primary airway devices and intubation conduits and found that intubation success rate at first attempt was significantly higher in Group I but total time for intubation was comparable in both groups. All patients in Group I required use of maneuvers for facilitating intubation versus only 4 patients in Group A. The demographic data and airway characteristics were similar in both groups and both devices were comparable with respect to ease of placement, insertion time, sealing characteristics, alignment with the glottis opening, time and ease of tracheal intubation and device removal. In most of the cases insertion of both devices was easily performed as judged by the operator. Slight difficulty in insertion was seen during insertion of one ILMA and one Air-Q ILA insertion. Moderate difficulty was encountered with ILMA in one patient and in two patients in the Air-Q ILA group. Baskett et al [7] had also reported easy insertion of the ILMA in 88.8% of cases. Similarly, a study done by Neoh and Choy [8] showed no significant

statistical difference in the insertion of the Air-Q ILA and the ILMA. ILMA was successfully placed in all patients at first attempt in our study which was similar to the success rate reported by Joo and Rose [9]. We used mandibular lift to facilitate insertion of the Air-Q ILA at the outset and achieved a first attempt success rate of 92.5%. In our study no patient in either group required more than three attempts or more than 5 minutes to insert the supraglottic device. Time taken for insertion of ILMA was similar to ILA ie. 19.2±7.8 sec vs 21.42±13 sec, respectively which was similar to results of Karim and Swanson [10] who reported time of ILMA insertion to be about 30 sec as compared to 27 sec for ILA. In contrast, Malhotra et al [11] and Abdel-Halim et al [12] observed significantly shorter insertion time for Air-Q ILA as compared to ILMA which can be attributed to the use of tongue depressor for Air-Q ILA insertion, allowing adequate space available for easy insertion. As the device manufacturer states, the ILA is suitable for blind or fiberoscopic aided tracheal intubation so we decided to assess the relationship of the bowl of the mask to the laryngeal inlet. Prior to attempting blind intubation through the ILMA or ILA, the view of the laryngeal structures obtained through a fiberoptic bronchoscope placed through the device was noted by an independent observer and graded by Danha Grading [5]. Due to the presence of epiglottis elevating bar specialized maneuvers are required to facilitate passage of fiberscope through ILMA whereas no such maneuvers needed for ILA. Panjwani et al [13] suggested flexing the tip of the fibrescope fully just before it touch the epiglottic elevating bar to negotiate past the latter with little risk of damage to the tip of the fiberscope. But in our study we inserted ILMA tube to the epiglottic elevator bar, just enough to lift the bar and obtain a better view of the glottis and simultaneously prevent damage to the tip of the fiberscope. The vocal cords could be visualized i.e. a Danha 1/11 grade was observed through the ILMA in 92 .5% of the cases, whereas in the ILA group vocal cords were visible in 95% of the cases. This better view through the ILA as compared to the ILMA, though not statistically significant, may have contributed to this better placement of the device. The design of the ILA, with an area above the ventilating orifice for the epiglottis to rest on when properly positioned, may have contributed to this finding. In the Group I, blind intubation through the device was successful at first attempt in 38 out of 40 patients (95%) as compared to Group A, where the first attempt success rate was 31/40 (77.5%). Karim and Swanson [10] compared ILMA and ILA as conduits for blind tracheal intubation with similar results. In our study, FOB- assisted ETT placement was required in 5 patients in Group A and no patient in Group I required use of FOB for successful intubation. Ferson et al [6] had observed the rate of successful intubation after two blind attempts as 99% in Group I and 77% in Group A. In a study by Neoh and Choy [8] Air-Q had a success rate of 75% in three attempts whereas success rate was 97.4% when ILMA was used. In contrast, Malhotra et al [11] observed an overall better success rate for intubation with Air-Q ILA as compared to ILMA. In our study the insertion time of the ETT through both the ILMA and ILA was found to be almost similar in both groups. For all patients in Group I Chandy 1 and 2 maneuvers were used routinely to ease and hasten the intubation process. In 2 patients an additional up-down maneuver was applied when resistance was felt at 2-2.5 cm as a corrective measure to aid in the process of intubation. Abdel-Halim et al [12] had reported a longer time for intubation via ILMA as compared to Air-Q ILA which might be due to the fact that they used FOB for intubation in both groups and duration of insertion of ETT was calculated from the time the FOB entered the device until the anesthesia circuit was reconnected to the ETT. Pandit et al [14] were able to pass the tracheal tube within about 25 seconds compared with about 30 seconds reported by Karim and Swanson [10]. The total intubation time was also comparable in both groups i.e. 52.53±13.8 seconds in Group I vs. 57.75±20.35 sec in Group A . These total intubation times were much shorter than reported by Karim and Swanson [10] who studied the total time from the placement of the supraglottic airway until it was removed with correct placement of the tracheal tube verified by capnography without any time gaps and reported a total time of 185 sec in Group I and 219 sec in Group A. The success rate of blind intubation through ILMA has been shown to be dependent upon intubating technique, experience of the operator and the number of attempts allowed. We used Chandy maneuver in facilitating blind intubation via ILMA in Group I that might have contributed to higher intubation success rates. After successful endotracheal intubation through the device, removal of the device was easy in both groups without displacement of the tracheal

tube in any patient. Average time to the removal of the SGD was similar in both groups. The removable stylet of the ILA securely engages at the proximal end of the tracheal tube to allow easy passage of the pilot balloon, unlike the stabilizing rod of the ILMA. The incidence of contact with oral secretions /saliva and macroscopic blood visible on the device was similar in both groups during removal of the device following successful endotracheal intubation. No significant differences in incidence of sore throat and hoarseness were reported by Karim and Swanson [10] in both groups. Contrary to our findings Neoh and Choy [8] found that the presence of blood on the Air-Q ILA was significantly more than on the LMA Fastrach. Wong and Arora [15] recommended the use of the Air-Q ILA rather than the LMA Fast-track as a conduit for tracheal intubation, but this study had its own limitations of being done on mannequins rather than humans.

However our study had some limitations. We excluded patients with known / predicted difficult airways in whom both these devices may have a special utility. The ease of insertion was studied on a subjective scale. We studied the use of Air Q ILA only in adults and not in the pediatric age group. Also, we used a standard PVC ETT in the ILA group and the dedicated silicone tube in the ILMA group. The success rate of intubation through ILA may have been different if we had used the dedicated silicone ILMA tube in this group of patients. Furthermore this was not a double blind study as it was not possible for the investigators to be blinded to the study.

CONCLUSION

Both ILMA and ILA were comparable when used as a primary airway device. Both devices were comparable with respect to ease of placement, time for insertion, alignment with the glottis opening , time and ease of tracheal intubation and device removal. However ILMA had a higher rate of success in facilitating blind intubation than Air-Q ILA.

Ethics Committee Approval: Institutional Ethics committee MAMC approval was obtained. (F.11/IEC/MAMC/10- 02/09/2010)
Conflict of Interest: None
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Informed Consent: The patients' consent were obtained

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