

# Comparative evaluation of Intubating Laryngeal Mask Airway (ILMA), I-gel and Ambu AuraGain for blind tracheal intubation in adults

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## Abstract

**Background and Aims:** The supraglottic airway devices (SADs) that allow direct (without an intermediary device like Aintree or airway exchange catheters) tracheal intubation can be invaluable for field use in conditions ideally managed by intubation. Whilst fiberoptic-guided intubation is the method of choice, if these 'direct-intubation' SADs could provide high success rates for blind tracheal intubation, their scope of use can increase tremendously. Our study assesses intubating laryngeal mask airway (ILMA), i-gel and Ambu AuraGain for blind tracheal intubation in adults.

**Material and Methods:** Ninety adults undergoing elective surgery were randomized into three equal groups. After induction of anesthesia, the group-specific SAD was inserted and on achieving adequate ventilation, blind tracheal intubation was attempted over two attempts. Success rates and time of achieving adequate device placement and tracheal intubation through these were evaluated. Data were analyzed using SPSS version 17.0 and  $P < 0.05$  was considered statistically significant.

**Results:** All three devices could achieve adequate ventilation within two allowed attempts. Successful tracheal intubation rates were significantly better with ILMA than i-gel on first attempt (87% vs. 27%,  $P < 0.001$ ) and after second attempt that was supplemented with optimization maneuvers (100% vs. 40%,  $P < 0.001$ ). No patient could be intubated through Ambu AuraGain within two attempts. Time taken for successful tracheal intubation did not differ significantly ( $P = 0.205$ ) with ILMA or i-gel.

**Conclusion:** Out of ILMA, I-gel and Ambu AuraGain, ILMA is the best device for blind tracheal intubation in adults with normal airways.

**Keywords:** Airway control, endotracheal intubation, laryngeal mask airway, resuscitation

## Introduction

The supraglottic airway devices (SADs) are used not only in difficult airways, emergency life-threatening situations and in out-of-hospital cardiopulmonary arrest (OHCA) conditions, they are also being used as definitive airway device during elective surgeries.<sup>[1,2]</sup>

In trauma victims with injury in and around the airway, burns patient with smoke inhalation injury, life-threatening emergencies in pregnant and pediatric patients, endotracheal intubation is the routine standard of care. However, when there is unavailability of expertise or equipment for direct laryngoscopy or distortion of airway, the SADs can serve

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as a bridge to tide over this critical period. Subsequently endotracheal intubation can be carried out at a more appropriate location. While most SADs facilitate intubation by providing an unobstructed passage from mouth to the glottic opening, only a few allow passage of an endotracheal tube (ETT) without an intermediary device. The intubating laryngeal mask airway (ILMA), i-gel and Ambu AuraGain are among such devices.<sup>[3-6]</sup>

Intubation through any SAD is ideally recommended under fiberscope guidance. However, at centers that do not have fiberscope in the emergency department, blind intubation may be attempted through these 'direct intubation' SADs (that do not require intermediary devices like Aintree or airway exchange catheters). Thus we conducted this study to evaluate three SADs as conduits for blind intubation: the ILMA, a first generation SAD with a known high success rates for blind intubation and two 'direct-intubation' second generation devices having drain tubes, i-gel and Ambu AuraGain, believing that any SAD (first and second generation) that allows highest success rates for blind intubation should be considered as the device of choice to tide over airway crisis situations (in field or within hospital).

## Material and Methods

After Institutional review board approval and ethical clearance (F. No/11/IEC/MAMC/2015/317) this prospective, randomized study was conducted on patients undergoing surgery under general anesthesia in a public tertiary care hospital. The CTRI registration number is CTRI/2017/10/010240. Written informed consent was taken from all the patients.

The inclusion criteria for the study were patients of age group of 18-65 yrs of either sex, ASA grade 1, 2, 3, Mallampati class 1-2, thyromental distance of more than 6 cm, inter-incisor gap of more than 3 cm, range of neck movement  $>90^\circ$  and BMI less than 30 kg/m<sup>2</sup>. Patients with known airway abnormalities, increased risk of aspiration and pregnant patients were excluded from the study.

The patients were randomly allocated to three groups by computer-generated random numbers, depending upon the supraglottic airway device used: Group IL (n = 30) where ILMA was used, Group IG (n = 30): where i-Gel was used and Group AG (n = 30) where Ambu-AuraGain was used for blind endotracheal intubation [Figure 1- CONSORT diagram].

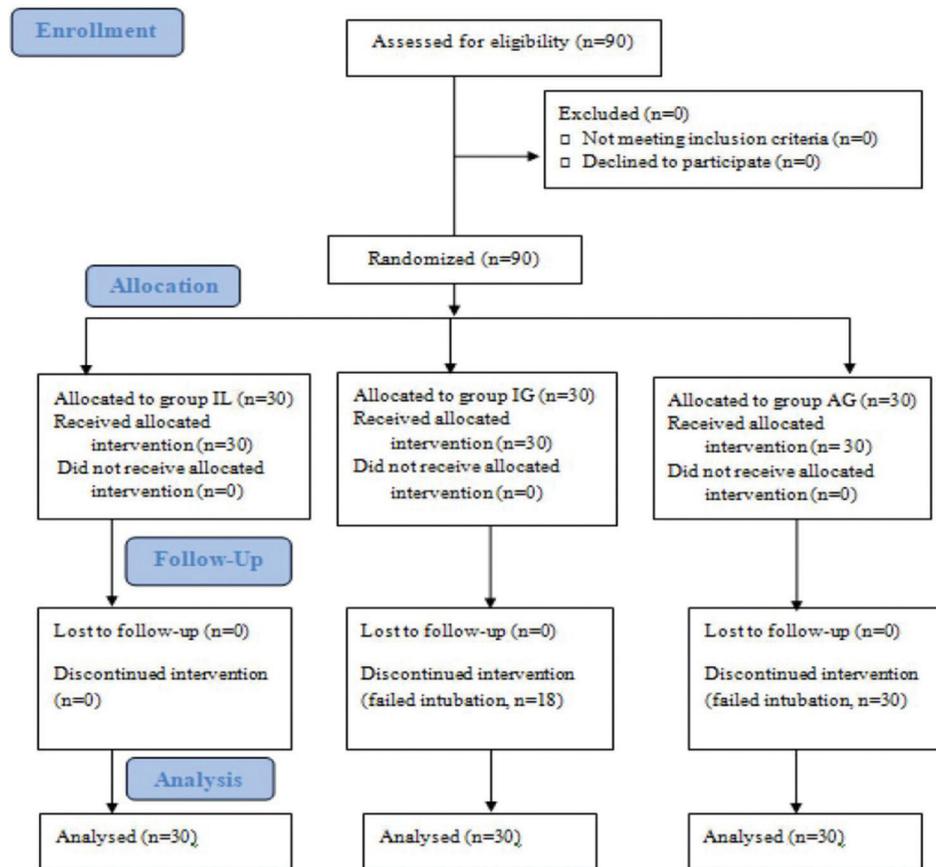
A detailed pre-anesthetic check-up (PAC) was conducted and investigations were done as per the age, surgical condition and associated disease of patients. Those anesthesiologists who had performed at least five blind tracheal intubations in

manikins with each of the three supraglottic airway devices and at least five blind tracheal intubations in patients through various SADs were allowed to participate in the study.

The patients were hooked to standard monitoring of SpO<sub>2</sub>, noninvasive blood pressure (NIBP) and electrocardiogram (ECG) and pre-oxygenated for three minutes of tidal volume breathing with 100% O<sub>2</sub>. At this time E<sub>TCO2</sub> monitoring was also started. Intravenous fentanyl (2 µg/kg) was given. General anesthesia was induced with IV propofol (2 mg/kg), and muscle relaxation was achieved with IV vecuronium (0.1 mg/kg). Patients' lungs were ventilated with 50-50% of oxygen-nitrous oxide and 1% isoflurane. The allotted supraglottic airway device (SAD) was inserted after three minutes of giving muscle relaxants. Size three was chosen for all female and size four for all male patients as the first choice. Standard pre-use checks were performed on all three devices and the devices were inserted after recommended lubrication with patient in sniffing position.

Ease of SAD insertion was graded on a subjective score of 1 to 3: 1- Easy, 2- Satisfactory and 3- Difficult. The time for successful SAD insertion, measured with the help of a stopwatch, was taken as the time elapsed from the insertion of SAD between the dental arches until the confirmation of successful ventilation by chest wall movement, auscultation of breath sounds and square wave capnography. If successful ventilation was not established, standardized maneuvers were used ((i) Up-down adjustment; (ii) 6 cm pull out followed by re-insertion; (iii) Same as (ii) along with jaw thrust). An attempt was defined as either successful device placement or removal of the device from the mouth before reinsertion. The number of maneuvers and attempts required for SAD insertion were recorded. If the device could not be successfully inserted in the second attempt as well, this was recorded as failure of SAD insertion and the case was dropped from the study. It was subsequently managed by alternative technique deemed necessary.

Following this, blind tracheal intubation was attempted through SAD using an ILMA-ETT (endotracheal tube) (#6.5 for female and #7 for male patients). When beginning the process of intubation through the ILMA, Chandy-1 maneuver (holding the ILMA by its handle and making slight side-to-side and up-down adjustment to achieve the best ventilating position) was performed in every case where ILMA was the SAD used. If no resistance was felt during insertion of ETT it was advanced beyond the SAD and its cuff was inflated with required amount of air. Successful placement of the ETT was confirmed by visible chest rise, 5-point auscultation of breath sounds and capnography. Time taken of successful blind tracheal intubation through SAD was defined as the time elapsed from introduction of the ETT into the SAD until the



**Figure 1:** CONSORT flow diagram

confirmation of successful ventilation as described above. Once the position of ETT was confirmed, the SAD was removed using the ILMA stabilizing rod in all the groups.

In case resistance was felt during ETT insertion, standardized maneuvers were tried in all three groups ((i) ETT rotation through 180° and (ii) Jaw thrust). In addition, the first maneuver that was attempted with ILMA was Chandy 2 maneuver for intubation (lifting the ILMA with its handle, perpendicular to the ILMA handle) before attempting the other two maneuvers. Maneuvers used were recorded. A failed attempt was defined as entry of ETT in the esophagus. For second attempt, the same maneuvers were used in the same order. In all the study groups, a maximum of two attempts at tracheal intubation were allowed. If tracheal intubation through the device was unsuccessful in two attempts, the case was managed by alternative technique deemed necessary.

In addition, any lip trauma, dental injury and blood mixed secretions over SAD and ETT at the time of its removal were observed. In all the groups, intra- and post-operative analgesia was standardized; i.e., IV fentanyl 2 µg/kg just before induction and then 0.5 µg/kg every hour, plus diclofenac 1.5 mg/kg in the first bottle of IV fluid and then IM 1.5 mg/kg

every 8 hours for the first 24 hours. In postoperative period, at 2 hours and 24 hours, an investigator who was blinded to the study, asked the patients about throat pain, dysphonia, dysphagia and for any change in voice (hoarseness). Throat pain (at rest) was graded on a score of 0 to 3; 0- no pain, 1- mild pain/discomfort only; 2-moderate pain and 3- severe pain. Dysphonia, dysphagia and hoarseness were graded as absent or present.

Statistical analysis: The success rate of first attempt blind tracheal intubation was 40% in i-gel group (Sastre JA *et al.* 2012)<sup>[6]</sup> as compared to 74% in the ILMA (Kapoor S *et al.*, 2014).<sup>[7]</sup> As no study with these three devices has been done before assuming the above as reference values, the minimum required sample size at 5% level of significance and 80% power was obtained as 30 patients in each group. The quantitative variables in all three groups were expressed as mean ± sd and compared using ANOVA and unpaired *t*-test. The qualitative variables were expressed as frequencies/percentages and compared using Chi-square test. A value of  $P < 0.05$  was considered statistically significant. Statistical Package for Social sciences (SPSS) version 17.0 was used for statistical analysis.

## Results

A total of 90 patients divided into three equal groups of thirty each were analyzed. There was no significant difference in the baseline patient characteristics in the three groups [Table 1]. Adequate ventilation was achieved with the first attempt in 80% cases of ILMA and Ambu AuraGain insertion and 67% of i-gel insertion and in all patients after the second attempt in all the three groups [Table 2]. The number of patients who did not require any maneuver during SAD insertion was significantly more with Ambu AuraGain than the other two SADs but the difference between ILMA and i-gel was not significant [Table 2]. Time for successful ventilation

was significantly more with ILMA than with the other two SADs [Table 2].

Blind tracheal intubation was successful on the first attempt in 87% cases (26 patients) through ILMA and in 27% cases (eight patients) through IG ( $p < 0.001$ ). After the second attempt the success rate improved to 100% with ILMA and to 40% (12 patients) through i-gel ( $p < 0.001$ ). No patient could be intubated blindly through Ambu AuraGain in both attempts [Table 3]. During ETT insertion through ILMA 77% cases (23 patients) did not require any maneuver for successful blind intubation. With i-gel six (20%) patients needed one of the two designated maneuvers and another six (20%)

**Table 1: Baseline patient demographics**

VARIABLES	ILMA (IL)	I-gel (IG)	Ambu Aura-Gain (AG)	P
Sex (Male/Female)	16/14	13/17	11/19	0.425
Age (mean±SD)	35.30±7.33	36.17±10.2	35.13±10.1	0.899
Weight (mean±SD)	59.97±7.61	58.67±10.5	59.00±8.83	0.847
Height (mean±SD) (mtrs)	1.55±0.04	1.53±0.05	1.55±0.05	0.227
BMI (mean±SD)	24.73±3.43	24.73±3.4	24.51±2.99	0.957
Mouth opening	4.96±0.33	4.85±0.47	4.95±0.36	0.487
Thyromental distance	7.84±0.52	7.81±0.51	7.84±0.5	0.969
Modified Mallampati Class (1/2)	7/23	10/20	7/23	0.6

**Table 2: Device insertion characteristics of the three SADs**

	ILMA (IL)	I-gel (IG)	Ambu Aura-gain (AG)	P
Ease of SAD insertion (easy/satisfactory/difficult)	21/7/2	16/6/8	20/5/5	0.323
1 <sup>st</sup> attempt success rate, n (%)	24 (80%)	20 (67%)	24 (80%)	0.382
Overall success rate, n (%)	30 (100%)	30 (100%)	30 (100%)	
Insertion time (seconds)	43.23±16.47 <sup>ab</sup>	28.73±17.91 <sup>b</sup>	25.07±11.61 <sup>ac</sup>	<sup>a</sup> $P < 0.001$ ; <sup>b</sup> $P = 0.002$ ; <sup>c</sup> $P = 0.352$
Maneuvers used for SAD placement n (%)				
No manoeuvres	8 <sup>df</sup> (27)	4 <sup>ef</sup> (13)	15 <sup>de</sup> (50)	<sup>d</sup> $P = 0.032$ ; <sup>e</sup> $P = 0.001$ ; <sup>f</sup> $P = 0.098$
Up down adjustment	7 (23)	8 (27)	7 (23)	
6 cm pull out f/b reinsertion	5 (17)	1 (3)	1 (3)	
6 cm pull out f/b reinsertion + jaw thrust	4 (13)	1 (3)	0 (0)	
Up down + 6 cm pull out f/b reinsertion	3 (10)	10 (3)	3 (10)	
All three manoeuvres	3 (10)	6 (20)	4 (13)	

**Table 3: ETT insertion through the three SADs**

	ILMA (IL)	I-gel (IG)	Ambu Aura-gain (AG)	P
No. Of attempts of ETT insertion (1/2)	26/4	8/22	0/30	<0.001
1 <sup>st</sup> attempt success rate, n (%)	26 (87%)	8 (27%)	0%	<0.001
Overall success rate, n (%)	30 (100%)	12 (40%)	0%	<0.001
Time taken for successful placement (seconds)	53.2±25.01	41±33.86	-	0.205
Maneuvers used for ETT placement n (%)				
No maneuver	23 (77)*	0	0	
Chandy maneuver (only for ILMA)	3 (10)*	NA	NA	
ETT rotation through 180° & Chandy maneuver	3 (10)*	NA	NA	
Jaw thrust & Chandy maneuver	1 (3)*	NA	NA	
ETT rotation through 180°	NA	5 (17)*	0 (0)	
Jaw thrust	NA	1 (3)*	0 (0)	
ETT rotation through 180° & Jaw thrust	NA	24 (80) <sup>†</sup>	30 (100) <sup>‡</sup>	

NA=not applicable; \*All were successful; †Six were successful; ‡None were successful

**Table 4: Post operative complications**

	ILMA (IL)	I-Gel (IG)	Ambu Aura-gain (AG)	P
DYSPHONIA (yes/no)				
At 2 h	5/25	5/25	1/29	0.191
At 24 h	0/30	0/30	0/30	
DYSPHAGIA (yes/no)				
At 2 h	3/27	5/25	3/27	0.661
At 24 h	1/29	1/29	1/29	0.364
HOARSENESS (yes/no)				
At 2 h	3/27	5/25	4/26	0.749
At 24 h	0/30	0/30	0/30	0.364
THROAT PAIN (No pain/Mild/Moderate/Severe)				
At 2 h	13/16/1/0	18/12/0/0	13/16/1/0	0.581
At 24 h	24/6/0/0	24/6/0/0	24/6/0/0	0.787

needed both the maneuvers for successful intubation. Intubation could not be achieved in the remaining eighteen (60%) even after employing both the maneuvers and exhausting both the attempts. No patient could be successfully intubated through Ambu AuraGain even after using all the maneuvers and both the attempts [Table 3]. The time to achieve successful intubation through both the SADs (ILMA and i-gel) was not significantly different [Table 3]. There was no significant difference in the postoperative complications in the three groups [Table 4].

## Discussion

Supraglottic devices (SADs) are important part of difficult airway algorithms and resuscitation protocols.<sup>[2,8-10]</sup> Although ventilation through them achieves the primary goal of securing the airway in unconscious or anesthetized patients, it still may not be enough in certain situations where endotracheal intubation is the necessity. Endotracheal intubation is possible through almost all SADs, either with the help of intermediaries (airway exchange catheter, Aintree catheter or bougie; e.g., LMA classic, LMA-ProSeal etc., or directly (e.g., ILMA, i-gel, Ambu AuraGain, intubating laryngeal tube suction (ILTS), Air-Q etc.).<sup>[11]</sup> We chose ILMA, i-gel and Ambu AuraGain for our study as these are commonly available and used SADs and tracheal intubation is possible through these without help of any intermediaries.

Our study shows that ILMA, i-gel and Ambu AuraGain are equally easy to use and are 100% successful as ventilatory devices within two attempts. With the help of maneuvers: up down adjustment, 6 cm pull out followed by reinsertion and jaw thrust these devices can be readily inserted. However, Ambu AuraGain could be placed successfully without any maneuver significantly more often than other two devices ( $p < 0.001$ ). This may be due to Ambu AuraGain being nonmetallic and thus more malleable than the ILMA, having a tip that is thinner and thus more streamlined than i-gel, less stiff

than both i-gel and ILMA and having a curvature that is somewhere in-between the relatively straighter i-gel and the more acutely bent ILMA.

Fiberscope guided intubation is the ideal method where ETT can be guided into the trachea under fiberoptic vision through the SAD. However, intubation using a fiberscope may not always be possible, more so in developing countries where there is lack of equipment and dearth of trained personnel to perform this procedure. So, in the above scenario blind tracheal intubation through the supraglottic device remains the only practical choice.

We allowed ourselves only two attempts for intubation as we feel that multiple attempts and maneuvers can cause airway trauma and edema that can potentially jeopardize even ventilation with SADs. The idea to use the ILMA-ETT also stemmed from the same thought process. It may be prudent to continue with successfully placed SAD (even first generation like ILMA) for ventilation rather than risking desaturation by jumping into the Vortex of difficult airway.<sup>[8]</sup>

First attempt success rate of blind tracheal intubation was significantly more through ILMA than via i-gel. A few cases required Chandy maneuver alone or with ETT rotation through 180° or with jaw thrust maneuvers to successfully insert endotracheal tube. By the end of second attempt all patients could be successfully intubated through ILMA. For i-gel and Ambu AuraGain maneuvers were required in all cases either because resistance was encountered at some or other point while inserting ETT or because the first attempt was unsuccessful. Twelve patients could be successfully intubated through i-gel by using one or more of these maneuvers but no patient could be successfully intubated through Ambu AuraGain even after two attempts. Similar results were seen in studies by Kapoor *et al.*, Halwagi *et al.* and Sastre *et al.* where they compared blind

tracheal intubation through ILMA vs i-gel.<sup>[6,7,12]</sup> But study by Bhandari *et al.*<sup>[13]</sup> and Choudhary *et al.* found i-gel to be a better SAD suited for blind intubation as compared to ILMA.<sup>[13,14]</sup>

We speculate that the different shape of airway tube in each device may cause this [Figure 2]. The curved shape of ILMA stem directs the tube anteriorly, while the relatively straight shape of i-gel stem has a tendency to direct the tube posteriorly, thus increasing the risk of esophageal intubation or snaring the arytenoids. Ambu AuraGain is relatively less straight than i-gel and less curved than ILMA which again directs the ETT posteriorly. The 100% success rate of blind tracheal intubation through ILMA could be attributed to the fine up-down adjustments of the device which was done to achieve best ventilation position at the time of ETT insertion (Chandy 1) that probably enabled optimal alignment of laryngeal aperture and bowl of the ILMA. And the further manipulation during intubation (Chandy 2) where the handle is used to lift the ILMA away from posterior pharyngeal wall, brings its bowl right next to the laryngeal inlet. The deeper placement of distal airway tube opening in Ambu AuraGain increases the distance traveled by the soft ETT to reach laryngeal inlet thereby making it even worse for blind intubation.

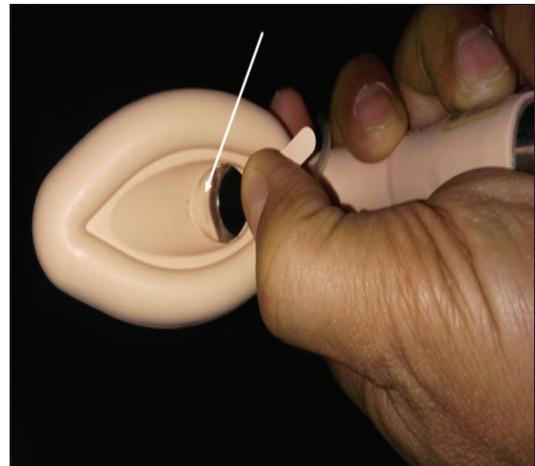
The presence of V-shaped ramp in the floor of the mask aperture of ILMA also directs the ETT towards the glottis as it emerges from the ILMA [Figure 3]. The epiglottic elevating bar [Figure 4] itself prevents the epiglottis from coming in the way of the ETT by lifting the epiglottis away from the path of ETT. Even after use of Chandy 2 maneuver, if any hindrance was encountered in passing the ETT smoothly addition of ETT rotation or jaw thrust was successful in avoiding the obstruction. Hence it is suggested to use the Chandy maneuvers as default maneuvers whenever ILMA is inserted to improve the first attempt success rate.

Because of the difference in the design and notably the absence of handle which helps in stabilization and gentle manipulation of the ILMA, none of the above could be extrapolated to the other two SADs which resulted in high failure rates of i-gel and zero success through Ambu AuraGain. Although both ILMA and Ambu AuraGain have almost similar anatomical curve, the deep-seated opening of airway tube in Ambu AuraGain probably further reduces its efficacy as a conduit for blind intubation.

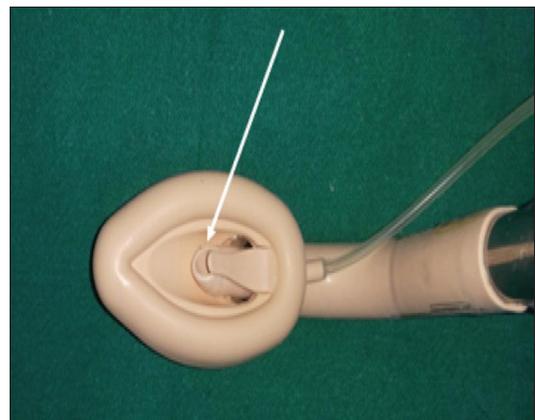
We also observed that rotating the ETT through 180° increased the likelihood of tracheal intubation in i-gel. Rotation could prevent the impingement of the tip of tracheal tube on the arytenoid cartilage during insertion as also suggested by Halwagi *et al.*<sup>[12]</sup> But similar maneuvers could not lead to any success in intubation with Ambu



**Figure 2:** Different directions of the ILMA ETT after coming out from the three SADs



**Figure 3:** V-shaped ramp at the floor of mask aperture of ILMA seen after lifting the epiglottic elevating bar



**Figure 4:** ILMA ETT coming out from the ILMA after lifting the epiglottic elevating bar

AuraGain suggesting that the ending of airway channel deep in the bowl of the cuff, directed the ETT posteriorly beyond the boundaries of laryngeal inlet, causing esophageal intubation.

In our study, the time taken for ILMA insertion ( $43.23 \pm 16.47$  seconds) is significantly more than that of i-gel and Ambu AuraGain ( $P < 0.001$ ). The more rigid body of the ILMA makes introduction through teeth difficult. The use of Chandy 1 maneuver also takes time to achieve optimal ventilation. However, the difference is clinically insignificant and is more than compensated if it is being used to facilitate blind intubation.

One can question our choice of ILMA as one of the SADs when 2<sup>nd</sup> generation SADs inherently provide a channel for gastric drainage and have been shown to have better performance than first generation SADs in terms of better oropharyngeal leak pressures (OLP).<sup>[15]</sup> We chose ILMA because, although it is a first generation SAD but it has the best success rates for blind intubation and any SAD chosen to tide over an airway crisis situation that is best dealt with by early intubation must perform as well or better than ILMA. Moreover, there is lack of robust clinical evidence favouring 2<sup>nd</sup> generation SADs as far as the risk of aspiration is concerned.<sup>[16-19]</sup> And our study clearly shows that for such situations, ILMA should be the device of choice in centers that do not have easy accessibility to fiberoptic.

Our study has certain limitations. It was carried out in patients with normal airways and the most successful device that we used (ILMA) is still available only in sizes 3/4/5 that are suitable mostly for adult population.

## Conclusion

Although ILMA, i-gel and Ambu AuraGain are equally effective ventilation devices, ILMA is the best device for blind tracheal intubation in adults with normal airways and promises nearly 100% first attempt success if optimization manoeuvres are used in the first attempt itself. Both i-gel and Ambu AuraGain do not appear to be suited for such eventuality.

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## Conflicts of interest

There are no conflicts of interest.

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