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Original Research Article

Comparison of Air-Q ILA and I-gel supragottic airway device for airway management during general anaesthesia- A randomized controlled trial

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Abstract

Introduction: Air-Q ILA and i-gel are frequently used as a primary airway and also as a conduit for subsequent tracheal intubation. Intubation through these Supraglottic airway devices (SAD) has garnered a special enthusiasm since they are privileged with a lesser cost, shorter learning curve and provision for ventilating the patient in between failed attempts of intubation. Since previous studies have not compared the tracheal intubation success rate with these two supraglottic airway devices (SAD), we performed a prospective randomized controlled trial to compare the success rate of endotracheal intubation through air-Q ILA and i-gel.

Materials and Methods: After obtaining approval from the institutional research and ethics committee, seventy patients with ASA physical status I and II aged between 18 to 60 years, with normal airways (MP Grade I and II), scheduled for elective surgery were included in the study They were randomized into two study groups (air-Q group or i-gel group). After the insertion of SAD, fiberoptic bronchoscope was passed through it to assess the Brimacombe score. Intubation was attempted through the SAD by blind technique using conventional polyvinyl chloride (PVC) endotracheal tube of appropriate size after removing the fibreoptic bronchoscope. First attempt tracheal intubation success rate, overall tracheal intubation success rate and intubation times were evaluated between the two groups

Results: Insertion of SD and subsequent ventilation was successful in all 70 patients in both groups. First-attempt blind intubation success rate through air-Q was significantly higher than i-gel (air-Q- 25, I-gel-14)

Conclusion: Success rate of blind intubation was higher in air-Q when compared to I-gel, albeit the good fibreoptic view of glottis provided by both the devices. We suggest that both devices can be used for blind intubation in the first attempt. If this first attempt fails, it is prudent to use fibreoptic bronchoscope for subsequent attempts of intubation through these SADs.

Introduction

Earlier, the difficult airway management was focused primarily on tracheal intubation, and this concept was revolutionized by the introduction of supraglottic airway devices (SAD), which changed this primary concept of endotracheal intubation to oxygenation and ventilation. Intubation through SADs has garnered a special enthusiasm since they are privileged with a lesser cost, shorter learning curve and provision for ventilating the patient in between failed attempts of intubation.

Although successful intubation is reported with various SADs, ILMA is considered as an ideal conduit for endotracheal intubation.[1-4] The factors such as higher cost, non-availability of paediatric sizes, need for specialized endotracheal tubes, reports of adverse events like oesophageal perforation and the hindrance to fibreoptic bronchoscope guided intubation by the epiglottis-bar makes it difficult for routine airway management. There has been a constant evolution in the designs of the intubating SADs with varying degrees of success to overcome the above said disadvantages.

One such advancement is Air-Q (Cookgas, St. Louis, MO, USA), which is a newly introduced SAD used as a conduit for intubation.[5-7] The salient features of this SAD are the presence of wider and pre-curved airway tube and a detachable airway connector to facilitate passage of standard sized endotracheal tubes. The absence of epiglottis-bar and feasibility of using conventional PVC tubes are the added advantages of this SAD.

I-gel (Intersurgical Ltd., Berkshire, UK), a supraglottic airway device with a non-inflatable cuff made of thermoelastic polymer was accurately shaped to mirror the perilaryngeal anatomy.[8] The availability of relatively wider airway diameter, lesser incidence of epiglottic downfolding and better fibreoptic visualization of glottis facilitates its use

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as a conduit for tracheal intubation.[9–11] There are no trials comparing the success rate of intubation between these two SADs. Hence, we performed a prospective randomized controlled trial to compare intubation success rate through air-Q and I-gel using conventional PVC endotracheal tube (ETT) in patients with the normal airway. The primary objective was to compare the first attempt intubation success rate and overall intubation success rate between the two groups. The secondary objective was to compare the success rate of SAD insertion, ease of SAD insertion, SAD insertion time, Brimacombe score, ET intubation time and device removal time between two groups.

Materials and Methods

This single blinded Randomized controlled trial was conducted between (January 2013 to December 2014), after obtaining approval from institutional research and ethics committee (Committee approval No.IEC/SC/2012/4/88). This trial was registered under Clinical Trials Registry-India (CTRI/2015/06/005905) A total of seventy patients with ASA physical status I and II aged between 18 to 60 years, with normal airways (MP Grade I and II), scheduled for elective surgery were enrolled in the study after obtaining written informed consent from patients. Patients with head and neck pathology, mouth opening <2.5cms, BMI >35 kg/m^2 and patients at risk of aspiration were excluded. The patients enrolled in the study were randomized into one of the two groups (air-Q group or i-gel) by sealed envelope technique by the study investigator.

In the operating room, standard monitors like pulse oximetry, NIBP, ECG & capnography were applied. Anaesthesia was induced with Inj. fentanyl 2mcg/kg, propofol 2mg/kg and vecuronium 0.1mg/kg after preoxygenation. Mask ventilation with sevoflurane (3%) and 6 litres of 100% oxygen was carried out until adequate neruromuscular blockade. After ensuring adequate neuromuscular blockade (loss of twitch response), appropriate sized SAD was inserted by the anaesthesiologist with patient head in extension. The size of the SADs (air-Q/ I-gel) and endotracheal tubes (ETT) were chosen based upon the weight of the patient as per manufacturer's recommendations.

The number of attempts taken by the anaesthesiologists to successfully insert the device was recorded. The successful placement of SAD and the adequacy of ventilation were determined by chest wall excursion, auscultation of breath sounds and appearance of square-wave capnograph trace. A maximum of 3 attempts were allowed. In patients where the seal was inadequate with resultant ineffective ventilation or those that required more than 3 attempts were considered as failure and excluded from the study. The time taken for SAD insertion was measured from the time SAD was passed in between the incisors until the appearance of capnograph trace on the monitor. The ease of SAD insertion was graded subjectively as follows:1-easy, 2-difficult.

In addition, fibreoptic bronchoscope (FOB) was passed through the SAD to assess the Brimacombe score as follows:

4. Only vocal cords visible
3. Vocal cords plus posterior epiglottis visible
2. Vocal cords plus anterior epiglottis visible
1. Vocal cords not seen

If the Brimacombe score was <4, then manoeuvres such as external laryngeal pressure or jaw thrust with a up-down movement of SAD followed by external laryngeal pressure were performed with the bronchoscope in situ to assess the improvement in glottic view. Then bronchoscope was removed after the assessment of glottis

Intubation was attempted through the SAD by blind technique using conventional PVC endotracheal tube of appropriate size employing those manoeuvres which optimised the laryngeal view. To improve the success rate of intubation, the ETT was rotated 90 degrees anticlockwise before insertion.[12] The correct placement of tracheal tube was confirmed by auscultation and appearance of square-wave capnograph trace. In the absence of capnograph waveform, the tracheal tube was removed and further attempts were made until the trachea is intubated. In both the groups, a maximum of three attempts of intubation were allowed with 2 blind attempts and 1 fibreoptic guided attempt in patients with Brimacombe score 3 or 4 and one blind attempt and 2 fibreoptic guided attempt in patients with Brimacombe score 1 or 2. In the event of failed intubation even with three attempts, either the airway was secured using convetional laryngoscopy or anaesthesia continued with aid of SAD at anaesthesiologist's discretion. (Fig. 1). In each attempt, the intubation time was recorded from the moment of insertion of the tracheal tube /bronchoscope until the appearance of the capnograph waveform. The overall intubation time was the sum of all attempts excluding the gap in between the attempts. The patient was ventilated with isoflurane and oxygen mixture in between the attempts.

SAD removal was facilitated with the air-Q stylet in both the groups after successful intubation of the trachea. After the removal of SAD, correct placement of tracheal tube was confirmed by auscultation and appearance of square-wave capnograph trace. SAD removal time was measured from the disconnection of breathing circuit from the SAD until the reappearance of capnograph waveform on the monitor. Then, the anaesthesia was maintained as per the attending anaesthesiologist's discretion. The presence of adverse events such as accidental extubation during SAD removal, oesophageal intubation, desaturation, bronchospasm and blood/bile staining of SAD after its removal were recorded. These patients were followed up in the postoperative period for 48 hours to obtain information about adverse effects like sore throat, hoarseness of voice and dysphagia.

Sample size calculation and Statistical Analysis

The sample size was calculated using the software, PS Power and Sample Size Calculations, version 3.0.43. The

calculated sample size was 32 patients per group using the following values: α = 0.05, power = 0.80, P0 = 0.70 and P1 = 0.325. This was based on the mean success rate of blind intubation on the first attempt with the air-Q and i-gel reported in the previous trials.[13–15]A sample size of 35 patients per group was chosen in this trial to allow for the potential drop-outs of patients.

Data were analysed using IBM SPSS. Continuous data were expressed as mean and standard deviation (SD) and categorical data were expressed in number (%). Continuous data were analyzed using Student t-test (2-tailed, unpaired), and categorical data were analyzed using Fisher exact test. Mann-Whitney U test was used for analysing non-parametric variables between the groups and Wilcoxon Signed Rank test for within the group.

Results

Patient Characteristics

Seventy patients (35 in each group) participated in this study. No participants were excluded from statistical analysis. Patient characteristics were comparable in both the groups (Table 1).

SAD Insertion

Insertion of SAD and subsequent ventilation was successful in all 70 patients. 31 (88.6%) of the 35 air-Q were inserted on the first attempt and 4(11.4%) were inserted on the second attempt. 34(97.1%) of the 35 I-gel were inserted on the first attempt and 1(2.9%) was inserted on the second attempt.

First attempt SAD insertion time was lower in the I-gel group when compared to air-Q group (I-gel 17.53±4.03 sec vs. air-Q - 21.37±2.43 sec. p<0.001). The overall SAD insertion time was also lower in the I-gel group compared to air-Q group (I-gel - 18.31±6.11sec vs. air-Q - 23.23±6.42 sec, p=0.002). Ease of SAD insertion was comparable in both the groups (Table 2).

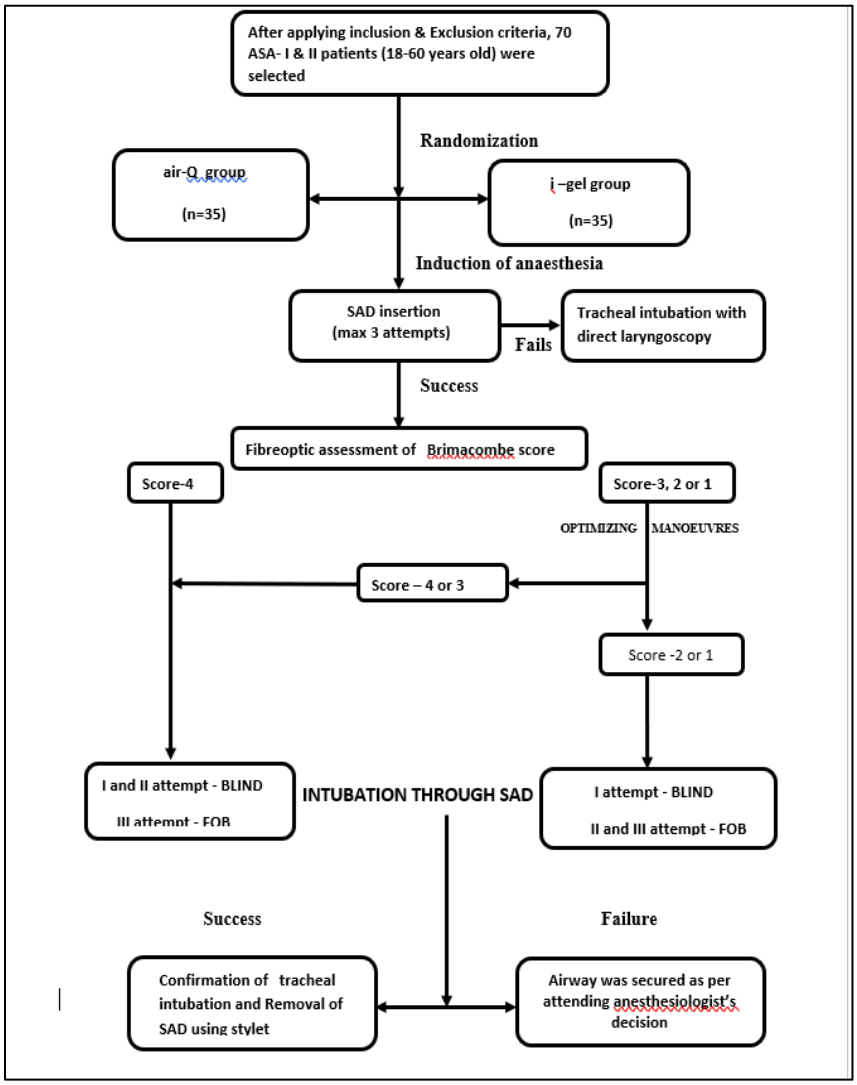

Fig. 1: Study methodology

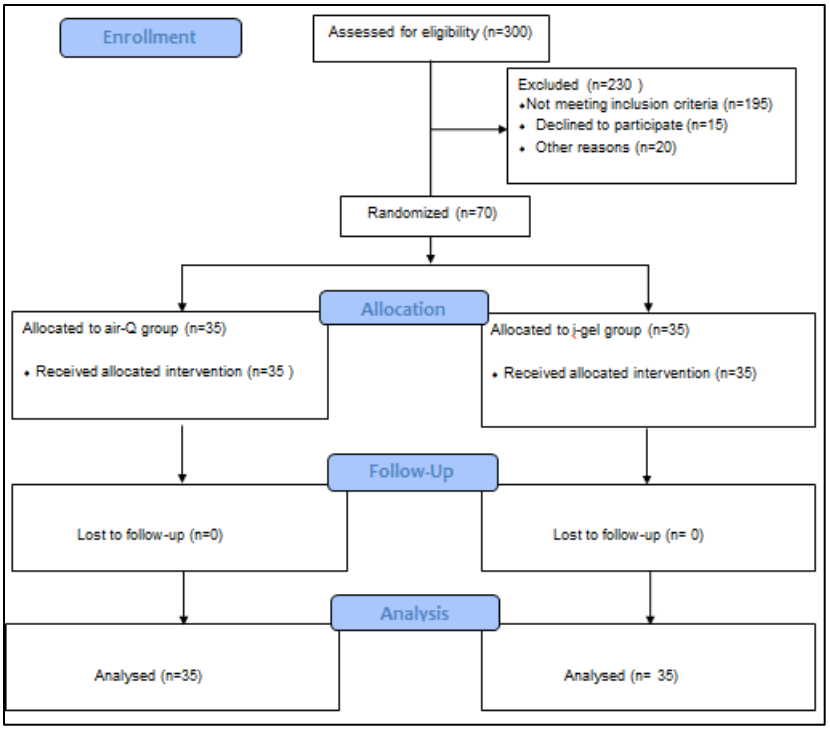

Fig. 2: Consort flow diagram

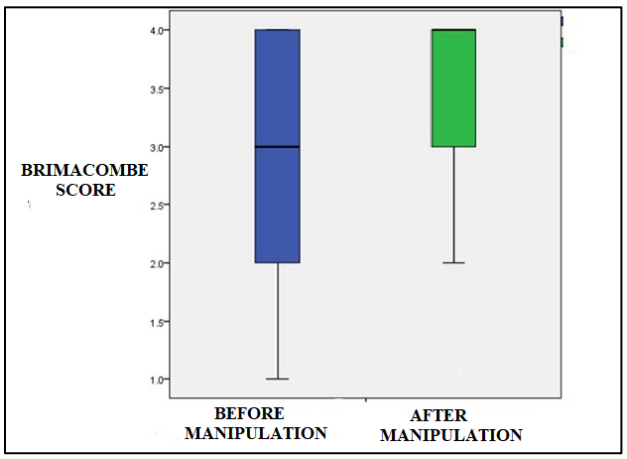

Fig. 3: Brimacombe score in air-Q group

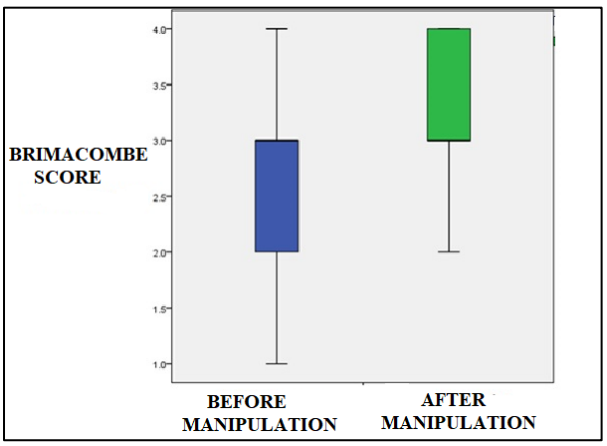

Fig. 4: Brimacombe score in I-gel group

Table 1: Patient characteristics

	Air-Q group (n=35)	i-gel group (n=35)	P - value
Age (years)	42.86 ± 11.97	41.49 ± 11.05	0.620
Sex(male/female)	15/20	16/19	1.00
Weight(kg)	60 ± 6	59 ± 6.0	0.642
Height (m)	1.9 ± 0.1	2 ± 0.0	0.321
BMI ($kg/m^{2)}$	23.0 ± 3.8	22.8 ± 3.4	0.782
Mouth opening(cm)	3.9 ± 0.4	3.9 ± 0.4	0.976
MMP (1/2/3)	12/17/6	11/20/4	0.709

Data were expressed as mean ± SD or number.
MMP – Modified Mallampatti class.

Table 2: SAD insertion characteristics in both the groups

	Air-Q group (n=35)	i-gel group (n=35)	P - value
First attempt success rate	31(88.6%)	34(97.1%)	0.356
First attempt insertion time (s)	21.37 ± 2.43	17.53 ± 4.03	<0.001
Overall insertion time (s)	23.23 ± 6.42	18.31 ± 6.11	0.002
Ease of insertion 1 easy 2 difficult	 30(85.7%) 5(14.3%)	 34(97.1%) 1(2.9%)	 0.198
No of attempts of SAD insertion 1 2	 32(91.2%) 3(8.5)	 34(97.1%) 1(2.8)	 0.356

Data were expressed as mean ± SD or number (%).

Table 3: Fibreoptic view of glottis in both the groups.

	Air-Q group (n=35)	i-gel group (n=35)	P value
Before manipulation Median (IQR)	 3 (2-4)	 3 (2-3)	 0.001
After manipulation Median (IQR)	 4 (3-4)	 3 (3-4)	 0.000
Before manipulation 4 3 2 1	 12(34.3%) 13(37.1%) 8(22.9%) 2(5.7%)	 5(14.3%) 19(54.3%) 10(28.6%) 1(2.9%)	
After manipulation 4 3 2 1	 19(54.3%) 10(28.6%) 5(14.3%) 1(2.9%)	 13(37.1%) 15(42.9%) 7(20%) 0	

IQR- interquartile range

Table 4: Intubation success rate between two groups

	air-Q group (n=35)	i-gel group (n=35)	P value
First attempt success rate	25(71.4%)	14(40.0%)	0.008
Second attempt success rate			
1. Blind attempt	2(5.7%)	2(5.7%)	1.000
2. Fibreoptic guided attempt	3(8.6%)	7(20.0%)	0.172
3. overall Second attempt success rate	5(14.3%)	9(25.7%)	0.232
Overall success rate after two attempts	30(85.7%)	23(65.7%)	0.050
Success rate after three attempts	33(94.3%)	31(88.6%)	0.393

Table 5: Time for tracheal intubation and SAD removal in both the groups

	air-Q group	i-gel group	P value
First attempt (Seconds)	16.96 ± 1.71 (n=25)	17.71 ± 1.94 (n=14)	0.218
After second attempt (Seconds)	43.40 ± 3.85 (n=5)	48.11 ± 12.38 (n=9)	0.430
After third attempt (Seconds)	55.00 ± 5.00 (n=3)	55.13 ± 4.91 (n=8)	0.971
Overall intubation time (Seconds)	36.18 ± 37.15 (n=33)	56.87 ± 42.17 (n=31)	0.039
SAD removal time (Seconds)	28.18 ± 2.30	45.58 ± 5.34	0.001

Data were expressed as mean ± S

Table 6: Adverse events in both the groups

Adverse events	air-Q group (n=35)	i-gel group (n=35)	P value
Oesophageal intubation	4(11.4%)	13(37.1%)	0.012
Blood staining on device removal	1(2.9%)	2(5.7%)	1.000
Bronchospasm	1(2.9%)	0	1.000
Desaturation	1(2.9%)	0	1.000
Post-operative throat pain	2(5.7%)	2(5.7%)	1.000
Hoarseness of voice	1(2.9%)	0	1.000
Bile staining on device removal	0	0	-

Data were expressed as number (%)

Fibreoptic view of Glottis

Brimacombe score was comparable and significant improvement in glottic view was achieved after the manipulations in both the groups. Before manipulations, Brimacombe score of either 3 or 4 was observed in 71.4%(25) patients in air-Q group and 68.6%(24) patients in I-gel group. After manipulations, 83%(29) patients in air-Q group and 80%(28) patients in the I-gel group had the score of either 4 or 3 (Table 3, Fig. 3&4)

Tracheal Intubation

The first attempt intubation success rate was significantly higher in air-Q group 71.4%(25) compared to I-gel group 40%(14), (P=0.008). After two attempts, the success rate of intubation improved to 85.7%(30) in air-Q group and 65.7%(23) in I-gel group,(P=0.05). Of the 5 patients who were intubated in the second attempt in the air-Q group, blind intubation was performed in 2 patients and fibrescope guided intubation in 3 patients. Of the 9 patients who were intubated in the second attempt in the I-gel group, blind intubation was performed in 2 patients while fibrescope guided intubation in 7 patients. (Table 4)

The intubation success rate after three attempts was also higher in air-Q group compared to I-gel {94.3%(33) vs. 88.6%(31), P=0.393}. But this difference was not statistically significant.

Tracheal Intubation Time

There was no difference in the first attempt intubation time between the SADs (16.96±1.71s for air-Q and 17.71±1.94s for I-gel, p= 0.218). However there was a statistically significant difference in overall intubation time between the two groups. (36.18±37.15s for air-Q and 56.87±42.17 s for I-gel, P=0.039) (Table 5).

The SAD removal time varied significantly between two groups (28.18±2.30 s for air-Q and 45.58 ±5.34 s for I-gel, p< 0.001). There was no incidence of accidental extubation during device removal.

Adverse Events

The incidence of oesophageal intubation was more in I-gel 37.1%(13) than air-Q 11.4%(4); (p=0.012). The incidence of other adverse events was shown in (Table 6).

Discussion

SADs are recommended not only as rescue device for ventilation in cannot ventilate and cannot intubate (CVCI) situations but also as airway conduit to facilitate intubation of the trachea in the management of difficult airway.[16] This signifies SADs role in the management of difficult airway and in the prevention of airway-related complications which are major causes of morbidity and mortality in anaesthesia practice. Hitherto, intubation of the trachea is conventionally being done using direct laryngoscopy which is not always possible in the presence of difficult airway where use of intubating SADs has simplified intubation of the trachea with minimal airway risk. In this study, we compared the success rate of blind intubation through air- Q with that of I-gel, which are considered as an alternative to ILMA Fastrach for tracheal intubation.

We demonstrated successful SAD insertion in all the patients in both the groups. However, we found significant shorter insertion time in I-gel group when compared to air-Q

group. This could be attributed to the presence of pre-shaped longitudinal curvature and rigid structure of I-gel

The fibreoptic view of glottis evaluated using Brimacombe score was comparable in both the groups. The presence of larger airway outlet and proper fit of these SADs in the perilaryngeal space provided a good view of the glottis in most of the patients. In fewer patients with poor glottic view (Brimacombe score 1 or 2), we noted a significant improvement in glottic view with the application of manoeuvres such as external laryngeal pressure and jaw thrust with the up-down movement of SADs in both the groups. In particular, these manoeuvers improved the Brimacombe score by 1 in 34.3% of patients in air Q group and 37.1% of patients in I-gel group. Similarly, Khan et al have also reported improvement in POGO score and success rate of blind intubation through air-Q with the application of external laryngeal pressure.[17]

This study demonstrated the successful tracheal intubation in the first attempt in 14 patients (40%) in the I-gel group. However, the success rate improved to 88.6% with fibreoptic guidance. This finding is corroborating with other study results where a success rate of 40% to 69% with blind intubation and 93% with fibreoptic guided intubation were found in patients with normal airways[12,18-20] In patients with difficult airways, the reported success rate was only 15% for blind intubation and 96% for fibreoptic guided intubation through i-gel.[13,21] Despite the presence of good glottic view in 80% cases, we demonstrated successful blind intubation in only 40% cases. This is due to hinging of the tracheal tube on arytenoid cartilage/posterior laryngeal structures or entering into the esophagus with blind intubation.[13] This can be attributed to the relatively straight shape of the airway tube and the unfavourable angle of emergence of the tracheal tube from the I-gel.[14] This also explains the increased incidence of esophageal intubation with I-gel (Fig. 5). The application of external laryngeal pressure lowers down the glottic inlet so that ETT enters the trachea instead of oesophagus. Halwagi AE et al found that 90 degrees counter clockwise rotation of ETT before insertion improved the success rate by 50% by preventing the impingement of tip of the bevel on right arytenoids cartilage.[12] Hence we have included these manoeuvres as an integral part of our study protocol. In spite of these manoeuvres, success rate for blind intubation was lower for I-gel.

In the air Q group, successful blind intubation in the first attempt was noted in 71.4%(25) patients, and the intubation success rate improved to 94.3%(33) patients with fibreoptic guided technique. However, earlier studies showed lower success rate with air Q (58%). This finding was initially attributed to its poor structural design, the lack of a specialized endotracheal tube and lack of adequate experience with its use.[22] But the subsequent trials have reported higher success rate (70% for the first blind attempt and 95% for fiberoptic bronchoscope-guided attempt).[15] This might be attributed to longer learning curve with blind intubation. Thus, success rates obtained for both first attempt and the overall intubation using the air-Q in our study were similar to the recent trials.[15,17] In addition, our study showed a higher success rate of blind intubation in air-Q group (71.4%) when compared to that of I-gel group (40%). This finding could be attributed to the presence of unique design of the air-Q device such as pre-curved airway tube, proper fitting of rigid PVC cuff in the hypopharynx and the presence of an elevation ramp in the airway opening. This feature obviates the need for the use of fibreoptic bronchoscope and facilitates tracheal intubation with ease.

Despite the above-said differences in the blind intubation success rate between the groups, we found the overall success rate of intubation to be comparable between the groups. This improvement in the success rate of intubation after the final attempt in both the groups could be attributed to the ability to negotiate trajectory misalignments between the tracheal tube from SAD and the glottic opening by the continuous visualisation of the airway with fibreoptic bronchoscope. Intubation failure was observed in two patients in the air-Q group and four patients in i-gel group even with the fibreoptic guidance. This was due to the failure to visualise glottis due to airway trauma and bleeding.

Another observation made was the presence of a statistically significant difference in the overall intubation time between the SADs (36.18±37.15s for air Q and 56.87±42.17 s for I-gel, P value-0.039). This difference in intubation time was skewed by the fact that more patients were intubated using fibreoptic bronchoscope in the I-gel group, thus prolonging the intubation time in that group.

Air-Q removal stylet was used for SAD removal in both the groups. The diameter of air-Q removal stylet is smaller than that of the ILMA stabilizing rod which facilitated easy removal of the SADs. The removal time was found to be high in the I-gel group when compared to air Q group. This could be due to the increased friction noted between the stylet and pilot balloon within the narrow lumen of I-gel despite adequate lubrication of the pilot balloon. In addition, the wider diameter of air-Q facilitated the rapid removal of the device by reducing the friction between the stylet and pilot balloon.

Except for the increased incidence of esophageal intubation in I-gel group (37.1%), the other adverse events were rare in both groups. Neoh EU et al. has reported a higher incidence of sore throat and blood staining of air-Q after its removal.[15] The lesser incidence of these events in our study was because of the adequate lubrication of the SAD & ETT and early use of fibreoptic bronchoscope in case of poor view of glottis which prevented traumatisation of airway.

This study was conducted in patient group with normal airways. Hence, this result cannot be extrapolated to patients with abnormal or difficult airway where the use of such intubating SADs have a mighty role. The oropharyngeal leak pressures with SAD and hemodynamic response to tracheal intubation are not evaluated in this study.

Conclusion

Success rate of blind intubation was higher in air-Q when compared to I-gel, albeit the good fibreoptic view of glottis provided by both the devices. Success rates of fibreoptic guided intubation through both the devices were comparable. We suggest that both devices can be used for blind intubation in first attempt. If this first attempt fails, it is prudent to use fibreoptic bronchoscope for subsequent attempts of intubation through these SADs.

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Conflict of Interest: None.

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