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Second generation extraglottic airway devices (AMBU, Air-Q & I-LMA): a comparative study to assess the relative success rate in first attempt and safety for blind tracheal intubation

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ABSTRACT

Background and Aims: Since introduction of classic LMA by Archie Brain, the newer second generation extraglottic airway devices are easily available in the market; the current study was designed to assess and compare the relative success rate of blind endotracheal intubation in first attempt through LMA-Fastrach, Air-Q ILA, and Ambu Aura-i as a primary endpoint. **Methods:** One hundred and fifty patients aged between 18 and 60 years with ASA physical status I-II, MP Grade 1-II, undergoing elective surgery under general anaesthesia, were enrolled into this prospective, randomised, case–control study to compare the relative success rate of tracheal intubation through LMA- Fastrach™ (Group F=50 patients) Air-Q™ ILA (Group Q = 50 patients) and AMBU-Aura i (Group A=50 patients) in first attempt via standard PVC tube. **Results:** First attempt successful intubation through SAD was 92% in group F, 88% in group Q and 84% in Ambu aura i group but no significant difference was seen among the groups. However, tracheal intubation was performed successfully in shorter time with Air Q-ILA (34.91±11.61 sec) as compared to AMBU-Aura and ILMA (36.59±13.92 and 37.66±12.66 sec) which was statistically insignificant (p= 0.599). **Conclusion:** All the three second generation extraglottic airway devices are reliable and effective can be used as conduit for tracheal intubation safely without any major complication with high success rate.

Key words: Ambu® Aura-i™, blind endotracheal intubation, extraglottic airway devices, first attempt success rate, LMA- Fastrach™ Air-Q™ ILA

INTRODUCTION

In anaesthesia, inadequate airway management is associated with the risk of acute hypoxia which can rapidly lead to death or permanent neurological disability. Supraglottic/Extraglottic Airway Device (EAD) was introduced in 1983 by Dr. Archie Brain[1], which has become an established tool for anaesthesiologist involved in airway management and is recommended 5 times in difficult airway algorithm[2]. These effective gadgets have revolutionized the airway management, are used worldwide as a routine or rescue device by the healthcare providers and provide an effective method of securing an airway during anaesthesia or during an unexpected difficult airway situation.

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In the last 5 years, many different types of disposable SADs have gained widespread popularity. Varieties of supraglottic airway devices have been developed to facilitate the passage of tracheal tubes. Among the newer disposable SADs the AMBU LMA and Air-Q are now available easily in the market. The Intubating LMA (LMA- Fastrach) has also been used successfully in a high percentage of patients with a variety of difficult airway[3]. It was found to be particularly useful in patients with immobilized cervical spine. The superior characteristics of these devices for blind and fiber optically guided intubation are now acknowledged in clinical practice[4]. Recently, modified extra-glottic airway devices tailored to facilitate tracheal intubation in life threatening situations. They can be used to convert a "can't intubate, can't ventilate" critical situation into a" CAN intubate CAN oxygenate (CICO)" situation[5]. Therefore, in the present study we have taken AMBU LMA, Air-Q laryngeal airway and I-LMA for comparative evaluation. The current study is designed to assess the relative success rate of blind endotracheal intubation in first attempt through these devices as a primary endpoint. The Other parameters compared were time taken for device insertion, number of attempts required for the tracheal intubation through device, incidence of hypoxia, and mucosal injury during the procedure. Additional parameters compared between the groups were the pharyngolaryngeal morbidity as trauma to lip, tongue, and pharynx and incidence of postoperative sore throat.

MATERIAL AND METHODS

This prospective, randomized study was conducted following the approval of the Board of Studies, Department of Anaesthesiology and Ethical committee, J.N Medical College. All patients gave written informed consent. One hundred and fifty patients, aged between 18-80 years with ASA physical status I-II, were recruited for this study, and were divided randomly into three groups, determined by sealed envelopes.

Patients of group F [N=50] were intubated using ILMA (LM- Fastrach), patients of group Q [N=50] were intubated using AIR-Q ILA while patients of group A [N =50] were intubated using AMBU LMA. The LMA Fastrach has an established role for providing successful tracheal intubation therefore, assigned as the control group, while AMBU Aura-i and Air Q ILA group were assigned asthe experimental groups. Exclusion criteria includes patient with a history or signs of difficult airway management MP III- IV, inadequate cervical mobility, mouth opening < 2.5 cm, any oral cavity disease, cervical malformation, respiratory tract infections, patients at risk of regurgitation, lung disease and airway surgeries.

The present study was conducted with primary aim to assess the comparative success rate of blind tracheal intubation through the devices AMBU LMA and Air-Q in comparison to I-LMA. The other parameters compared were time taken for device insertion, number of attempts and laryngeal manipulation required for the tracheal intubation through devices. Additional parameters compared were the pharyngolaryngeal morbidity as trauma to lip, tongue, and pharynx, incidence of postoperative sore throat and hoarseness of voice.

Primary outcome was measured by determining the comparative success rate of the devices (AirQ and AMBU LMA) in comparison to LMA Fastrach. The Secondary outcome measured the ease of insertion of devices, insertion time of the devices, ease of insertion of tracheal tube and insertion time of tracheal intubation through the device. Finally the total time required for tracheal intubation (insertion time of device+insertion time of TT+ removal time of device). Number of attempts required for successful tracheal intubation through device, changes in SpO2 following device insertion and during placement of tracheal tube through the devices were also noted. Effective ventilation was judged by observation of chest wall movement, auscultation of bilateral breath sound and a square wave capnography trace. Additional Outcome measures were: Post extubation pharyngeal, laryngeal and esophageal (oropharyngolaryngeal) morbidity; which was assessed in terms of: Trauma to lip, tongue, and pharynx, blood staining on the device, hoarseness of voice throat pain and pain on swallowing.

Learning curve was achieved by doing 10 intubations using each of the devices on patients, prior to start of study. An an aesthesiologist, with at least 5-6 months of experience in airway management, assessed all patients before surgery and ensured that the inclusion criteria were met and none of the exclusion criteria were present. The age, weight, sex and height of patients were recorded. All patients were kept nil per oral for both solids and liquids for 6hrs before surgery. In the operation theatre, monitoring was established. This included an Electrocardiograph (ECG), pulse oximetry (SpO2), capnography (EtCO2) and non-invasive blood pressure (NIBP). Anaesthetic technique comprised of a uniform premedication with injection midazolam 0.04 mg/kg, ondansetron 0.15 mg/kg, and fentanyl 2.0 mcg/kg body weights intravenously.

The patients were pre-oxygenated for 3 minutes, or until

oxygen saturation (SpO2) reaches 100%. Anaesthesia was induced with, 2-3mg/kg of Inj. Propofol. Inj. Lidocaine 1.5mg/kg was given prior to induction of anaesthesia. Patients were relaxed with Inj. Succinylcholine 1.5mg/kg to facilitate device insertion and subsequent tracheal intubation and maintained with nitrous oxide and oxygen along with vecuronium bromide (0.08 mg/kg). Size of LMA was chosen according to weight of the patients. Lubrication of the front and back of the SAD and a jaw lift was carried out with head in neutral/extended position to facilitate its insertion. After insertion, the cuff was inflated, and its pressure adjusted to between 60-70 cm H2O. Proper placement was confirmed by effective ventilation was judged by, listening for signs of a leak, observation of chest wall movement, auscultation of bilateral breath sound and a square wave capnography trace. Adjustments were allowed to be made if ventilation was unsatisfactory.

Blind intubation through Air-Q was performed by advancing the tracheal tube slowly through ILA in a rotatory motion in the direction of the laryngeal inlet. When tube was advanced, finally the circuit was attached to the tracheal tube connector and capnography to confirm the successful tracheal placement. When successful intubation was achieved, endotracheal tube cuff was inflated and adequate ventilation was assessed and the device was removed after deflation of its cuff. Similarly blind intubation through AMBU Aura and LMA fastrach was done after ventilating the patient with the device, the circuit was disconnected and tracheal tube introduced with its curve facing towards the patient. It was gently advanced with twisting motion into the laryngeal inlet; cuff of the tube was inflated. The circuit was connected to tracheal tube connector and position of the tube and ventilation was confirmed by good chest rise, auscultation as well as with capnography, and study device was taken out after intubation. The SAD cross over was not permitted by ethical issue committee. The time elapsed between SAD insertion and insertion of tracheal tube through it, was noted with the help of stop watch, the recording of single or multiple events and the total running time including the time gaps in between event was noted. The following parameters recorded were

1. Insertion time of the study device was recorded from the moment the device enters the mouth until the appearance of proper capnograph waveform, the device was removed if no carbon dioxide is detected or the seal is inadequate and time of second attempt insertion was similarly recorded. If the device placement was considered inadequate, as judged by poor capnographic curve and/or delivery of inadequate tidal volumes (fractional loss of >20% of set tidal volume); jaw thrust was performed and the device moved up and down, and cuff volume was also re-adjusted. If the device failed to work effectively despite this maneuver, it was removed and re-inserted for a maximum of two attempts for correct placement. Finally the insertion time was taken as the sum of all attempts for proper insertion of the device.

2. Optimization manoeuvres required to perform tracheal intubation was assessed on a score of 0 to 2 as follows: 0 - No manoeuvres required; 1- External laryngeal pressure applied; 2-Use of cricoid manipulation along with external laryngeal pressure (appendix)

3. Insertion time of the tracheal tube**:** from the moment of insertion of the tracheal tube through the experimental device until the appearance of the capnograph waveform. If no carbon dioxide was detected, the tracheal tube was removed. The time of the second attempt was recorded in a similar fashion. The third attempt was not allowed for tracheal intubation through the device, however, fibreoptic grading of the laryngeal view was done in case of failure to intubate the trachea through the device at the end of second attempt. The insertion time was considered as the sum of all the attempts.

4. The total time: from the moment the SAD is placed until after it is removed with correct placement of the tracheal tube verified by capnography. The SAD is immediately removed after confirmation of successful intubation. The time needed to remove the SAD from the pharynx was also recorded (time from the initial disconnection of the tracheal tube from the breathing circuit until reconnection and verification of an expiratory carbon dioxide waveform).If required devices were withdrawn 5–8 cm with mandibular lift and inserted again, extension of head, cricoid pressure and changing size of SAD was done and was noted. If the SAD was not placed in two attempts, or oxygen saturation fell to 90%, direct laryngoscopy was utilized to secure the airway that case was considered as failure. Upon removal of the SAD, presence of any blood visible on the device was noted; indicative of trauma to the upper airway. The patients were questioned about the degree of sore throat and hoarseness before they left the recovery room and after 24 hr. These were assessed with a 0–3 scale: 0 = no complaint; 1 = mild complaint; 2 =moderate complaint; 3 = severe complaint. An adverse airway event was defined as: oxygen desaturation of 90% or less; significant airway trauma; or other major adverse events.

Fibreoptic laryngeal view grading was done according to Danha et al[6] when the tip of the fibrescope lies distally, at the mouth of the laryngeal mask and the tip of the fibrescope is not flexed, the Grade 1 – vocal cords seen in full; grade 2 – only part of the vocal cords seen; grade 3 – vocal cords not seen but at least one other glottic structure identifiable; e.g., any aspect of epiglottis, pyriform fossa or valecula grade 4 – vocal cords not seen and no identifiable glottic structure (appendix).

Recording of parameters was done as described above; each attempt at intubation was included in intubation time. The total time (T) taken was split into three parts namely: time taken to insert the SAD (T1), time taken to intubate through the SAD (T2) and time taken to remove the supraglottic device (T3), thus total time taken was noted in the proforma as T=T1+T2+T3. Ease of insertion of SAD was considered in 3 grades as- GRADE I: Insertion within pharynx without resistance in a single attempt GRADE II: Resistance to insertion or when >1 attempt or adjustment was required GRADE III: Failure to place the SAD Ease of insertion of tracheal tube was subjectively graded as Easy/Difficult. The initial Mallampati grading recorded during pre-anaesthetic assessment was correlated to the incidence of successful intubation and number of adjusting maneuvers was recorded (0, 1, ≥2). Trauma during insertion was assessed by presence or absence of blood on SAD after removal. Incidence of sore throat: Presence of an unpleasant sensation in the throat [which was not previously present] just prior to discharge from the Recovery Room [RR] and after 24 hr after surgery was recorded as evidence of sore throat.

Various supraglottic airway devices include AMBU LMA/ Ambu® AuraOnce™[7, 8], Air-Q® Intubating Laryngeal Airway[9–11], and I LMA / LMA Fastrach™[10,11]. The present study have chosen the I-LMA, AMBU-LMA and Air-Q among long list of other supraglottic airway devices for their well secured place in the field of difficult airway. These devices are dependable aid for tracheal intubation and ventilation.

Statistical analysis was done with the SPSS Version 17 for Windows (SPSS, Chicago, IL). Parametric data such as age, weight, time taken for intubation were analyzed using the ANOVA test. Non-parametric data such as sex, Mallampati grade, ease of intubation, number of attempts, number of adjusting maneuvers, post operative blood staining of ETT and sore throat were analyzed using Chi square test or Fisher's exact test whichever was applicable. The graphs were done using Microsoft Excel 2007. The numerical data were statistically presented in terms of mean and standard deviation. Categorical data were summarized as percentages. Sample size was derived by post- hoc method. For α=0.05, β=0.2 and power of study 80%, minimum sample size turned out to be 45. With our study groups of 50 patients each, 90% confidence level was achieved.

RESULTS

A total of 150 patients were enrolled in this study. All the three groups were comparable in term of demographic data (Table 1). The demographic data including male female ratio,mean age, mean weight and height and in relation to MP grading was comparable among groups (Table 1). The mean time taken to insert the supraglottic devices and time taken to intubate through SAD were comparable among the groups (p value >0.05)(Table 2). However, the time taken to take out devices were dissimilar statistically among the three groups (p <0.001). The shortest time taken to take out the device was found with Air-Q (Table2). Hence total time required for intubation through SAD was statistically significant among groups (p<0.01), the fastest with Air Q (96.4±14.16 sec) as compared to LMA fastrach (107.9±17.36 sec) and Ambu LMA (108.3±23.45 sec). First attempt intubation through SAD was successful in 92% (group F), 88% (group Q) and 84% (group Ambu aura i) (Table 2). Overall success rate of endotracheal intubation through these extraglottic devices was found

Table 1: Distribution of patients according to demographic data in the groups

Demographic Data	LMA-Fastrach™	air-Q™ ILA	Ambu LMA	P value
Gender(M:F)	26:24	20:30	20:30	0.38
Mean Age ± SD (Yrs)	34.66±13.57	37.02±13.68	35.39±13.89	0.68
Mean Weight± SD (kgs)	54.16±5.31	56.92±10.41	57.56±9.56	0.11
Mean Height (cms)	153.16±4.14	152.92±4.60	152.74±4.14	0.26
MP Grading 1 &II	24 & 26	29 & 21	24 & 26	0.5143

Table 2: Insertion of EAD (LMA-Fastrach™ air-Q™ ILA & Ambu Aura i),intubation through the device and post extubation outcome

Category	LMA-Fastrach™n=50	air-Q™ ILA n = 50	Ambu LMA n=50	P value
Intubation through Extraglottic Airway Device (EAD)				
Time for Intubation through EAD in 1st Attempt (Mean±SD seconds)				
Time to insert the device	29.29±10.30	28.17±10.96	32.17±14.20	0.25
Time to intubate	37.66±12.66	34.91±11.61	36.59±13.92	0.599
Time to take out SAD	41.86±9.37	35.14±7.67	41.68±8.86	0.0004
Total time for Intubation	107.9±17.36	96.4±14.16	108.3±23.45	0.004
Ease of passage SAD overall				
Grade 1	39	39	37	115/25
Grade 2	9	8	8	
Grade 3	2	3	5	
No. of attempts to insert SAD				
1st attempt	46	44	42	132
2nd attempt	2	3	3	8
Success/failure	48/2	47/3	45/5	140/10
Ease of passage of ETT through SAD				
Easy/ Difficult	36/8	35/8	32/9	103/25
No. of adjustment maneuvers requiredfor insertion of SAD				
0 (not required)	31 (62.0%)	34(68%)	30(60.0%)	P=0.89
1(one maneuver)	11(22.0%)	8 (16%)	10(20%)	
≥ 2 (>1 maneuvers)	08(16.0%)	8 (16%)	10(20%)	
IntubationSuccess(yes/ No)	44/4	43/4	41/4	P=0.89
Fiberoptic localization of laryngeal view, if failure	2(Grade3) 2 (Grade 4)	1(Grade 3) 3(Grade 4)	2(Grade 3) 2(Grade4)	
Post-extubation outcome				
Trauma to lips, mouth	Nil	Nil	1	1
Blood on SAD	3	3	5	0.67
Sore throat	11	12	10	0.89
Hoarseness	6			

to be 93.33%; however, the individual success rate was 96%,94% and 90% in group F, group Q and group A respectively (Table 2). The incidence of pharyngolaryngeal complications were found comparable among the groups (Table 2). Failure of intubation through these devices was followed by the Fiberoptic localization of laryngeal view by putting the fiberscope at the mouth of the EAD without flexing the fiberscope tip. All failure cases were found to be in the laryngeal view grade 3 or 4 (Table 2).

DISCUSSION

Failed or difficult tracheal intubation is infrequent but an important cause of mortality and morbidity. Adverse outcomes, that are associated with respiratory events, constituted the single largest class of injury in the American Society of Anaesthesiology Closed Claims Study[1]. Tracheal intubation is considered to be the "gold standard" for securing the airway[2] but it requires considerable training and practice. This is compounded by incidents of difficult airways that are not easily identified or predicted. According to PLAN B in new DAS guidelines (2015) for management of unanticipated difficult intubation second generation supraglottic devices are recommended after failed intubation via direct/video laryngoscopy[2]. Potential area needs update for management of unanticipated, unchallenged difficult airway are the exit strategy and role of extraglottic devices in these scenarios. Supraglottic/ extraglottic Airway Devices (SAD) have revolutionized the airway management in achieving the endotracheal intubation in first attempt, without any untoward consequences. he airway management through these devices does not require extensive training and skill, and failed endotracheal intubation is not a night mare now for an aesthesiologist. At the time of unanticipated difficult airway or CVCI situation, the allied healthcare providers

in suburban and rural areas with limited expertise can secure the definitive airway with these devices safely and successfully[2]. There have been speedy progress and improvement in the supraglottic airway design also. The new, improved extraglottic airway devices; apart from procuring the definitive airway, they have high success rate for tracheal intubation, to save the life of patients as well as health professionals.

This study was designed to assess the safety and relative success rate in first attempt for blind tracheal intubation, performed through the AMBU Aura-i and AIR-Q the Intubating Laryngeal Airway (ILA) The patients in the three groups were comparable with respect to age, sex, weight, height distribution and MP grade, there by the chances of biasing of results due to demographic profile of the patient were minimized.

The device was inserted in shortest time duration (28.2±10.96 seconds) with adequate ventilation with proper square wave pattern on capnographic curve in group Q as compared to group A which took bit longer mean time (32.2± 14.0 secs) for insertion of the SAD as compared to group F which has taken longest mean time (29.3± 10.3 secs) for insertion. But the differences among the three study groups regarding the insertion of device, for adequate ventilation, was found statistically comparable (P > 0.05). Different authors have defined the beginning and end-point of the insertion time differently. Thus, reported insertion times cannot always be compared. In term of insertion time, our results were comparable to the studies done by Hagberg et al[8], El-Ganzouri[12], Karim et al[13], Neoh et al[14], Suzzana et al[15], Badawi et al[16], and Yahaya et al[17]. Similar to other studies, the ease of insertion of the device was found to be comparable (P >0.05) among the three groups[12,13,15,16].

Though, the mean time to intubate through device was comparable among the groups (p>0.05) but the meantime to take out SAD from the mouth following tracheal intubation was significantly less in group Q (35sec.) as compared to ILMA group and group A (42 sec.) (p<0.001). Our observation was in full concurrence with those of numerous previous investigators[13,14,16,18,19]. However, for some unexplained reasons, our findings are in conflict with those of Joo et al[20].

The total mean time required to intubate through the device was found different among the three groups (P <0.001). In our study, the intubation time was significantly much less in group Q (96 seconds) (p<0.05) as compared to group F and group A (107 sec and 108 sec), although the later two were comparable statistically (p >0.05). The reason for this difference that the intubation time was similar but the removal time was more in Fastrach. This probably led to overall increase in intubation time. Similar results were obtained by Badawi et al[16]. However, our findings are not in agreement with the observations of Ganzouri et al[21] and Karim et al[13].

The success rate for blind tracheal intubation through SAD for LM- Fastrach was found comparable with intubation through Air-Q™ ILA, and Ambu Aura-i. Badawi et al (2014)[16] reported that the total success rate of blind intubation in 2 attempt for Air Q was 94.12% and for LMA Fastrach, was 96.47%, however, this difference was not statistically significant; hence our results were similar to those of Badawi et al[16].

In the present study, ILMA was found to have highest success rate as compared to AirQ AMBU Aura. Similar findings were reported by Neoh et al[14], Williams et al[22], Sudhir et al[23] and Ferson et al[24].

Difficulty faced to intubate blindly through the device was computed in term of manipulation required at laryngeal and cricoid region. It was found comparable among the three groups (p>0.05). The ease of intubation was found same among the three groups (p >0.05).

The pharyngolaryngeal morbidity compared, in term of trauma to lip, mouth, blood on SAD, and sore throat was found similar among the three groups (p>0.05). However, 6 patients with LMA-Fastrach™ complained of hoarseness, and this could be with the use of hard PVC tube instead of silicone-tipped ETT, which have impacted on the laryngeal structures as it exited through the supraglottic airway device in spite of prior lubrication. Therefore, extra force used to advance the PVC ETT and more manipulation could have caused more impact on the laryngeal structures leading to increased trauma and increased incidence of hoarseness[14]. Larger number of patients with air-Q™ ILA have complained about sore throat. It could be due to a bit harder and stiffer cuff of the device compared to the softer silicone cuff of the LMA-Fastrach™ which might have contributed additional trauma to the soft tissues in the pharynx.

CONCLUSION

This study showed that success rate of blind intubation through, ILMA, Air Q and AMBU Aura-i and ease of

intubation were comparable, when adjustment maneuvers were applied to aid intubation. In terms of total time taken for intubation with common PVC ETT; Air Q proves far better than other two SADs. These devices can be used safely and effectively even without achieving the proper learning curve. However, further comparative studies with larger sample size, in the clinical context, particularly in predicted difficult intubation scenarios and in patients with co existing morbidities, are necessary to further strengthen these findings.

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Appendix 1

The follwing scales were used for assessment

Extraglottic Airway Device (EAD) Insertion

Ease of insertion of EAD/SAD;

Grade I: Insertion within pharynx without resistance in a single attempt

Grade II: Resistance to insertion or when>1 attempt or adjustment was required

Grade III: Failure to place the SAD

Tracheal intubation

Optimization manoeuvres required to perform tracheal intubation as follows

0. No manoeuvres required

1. External Laryngeal pressure required (No cricoid manipulation)

2. Cricoid Manipulation also required

Ease of insertion of tracheal tube was subjectively graded

Easy/Difficult

Fibreoptic laryngeal grading in failure (Danha et al.) [14]:

Grade 1: Vocal cord seen in full;

Grade 2: Only part of the vocal cords seen;

Grade 3: Vocal cords not seen but atleast one other glottic structure identifiable; e.g. any aspect of epiglottis, valecula;

Grade 4: Vocal cords not seen and no identifiable glottic structure;

Post Operative pharyngolaryngeal morbidity

Trauma to lip, tongue or phaynx or blood staining of device, hoarseness of voice and pain on swalowing

Degree of sore throat before they left the recovery room,

0 = no complaint; 1 = mild complaint; 2 = moderate complaint; 3 = severe complaint.

Blood on device: 0 = absent, 1 = present