Section: Anaesthesiology

Original Research Article

A COMPARATIVE STUDY BETWEEN INTUBATING LARYNGEAL TUBE SINGLE- DISPOSABLE (ILTS –D) AND AIR-Q FOR THEIR INTUBATING CHARACTERISTICS IN ADULT PATIENTS OF NORTH INDIA – A PROSPECTIVE RANDOMIZED STUDY.

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Abstract

Background: Airway management is the essence of anesthesiology. Constant efforts have been made in the field of airway management which has led to the development of novel and better devices. The actual motive remains to successfully safeguard the airway. Laryngeal Mask Airway was developed between 1981-1988 by Archie Brain when he encountered difficult airway and the need for a missing component for airway management was felt. iLTS–D has been recently introduced in the family of 3rd generation SAD. The objective of this study was to compare this novel device with Air – Q in terms of intubation characteristics. **Materials and Methods:** Elective endotracheal intubation was performed by using iLTS –D and Air –Q on 60 patients randomly divided into two groups of 30 each: Group AQ (Air-Q) and Group iLTS – D with similar mode of premedication. Primary objective was to note intubation time with both the devices and secondary objective were success of intubation, haemodynamic changes and complications. **Result:** Time taken to intubate in Group iLTS-D was 87.19 ± 3.43 sec and in Group AQ was 86.82 ± 3.87 sec. (p=0.73). Success of intubation was 63.33% in Group iLTS-D and 86.67% in Group AQ. Air-Q and iLTS-D took comparable time to intubate the trachea. **Conclusion:** Air- Q was found to be better than iLTS –D in terms of success of intubation.

INTRODUCTION

Airway management is the cornerstone of anesthesia. Securing the patient's airway is prime responsibility of the anesthesiologist to ensure patient's safety. Tracheal intubation with direct laryngoscopy remains the gold standard method of securing the patient's airway since time immemorial. It provides the most reliable means of ventilation and oxygenation and protection against regurgitation and pulmonary aspiration. However, it requires a great deal of clinical expertise to master and failing in case of which may lead to failed intubation and catastrophic consequences. One can't deny the fact that anesthesiologist can encounter difficult airway scenarios that can be anticipated by array of bedside clinical tests but the variability in predicting the difficult airway is large. These patients are not necessarily impossible intubations rather unexpected difficult intubations. A difficult airway strikes like a bolt from the blue and the most challenging and dreaded situation for the anesthesiologist. This started the quest for the missing component which would bridge the niche between the face mask and endotracheal tube.[1] Laryngeal mask airway was conceived, designed and developed between 1981-1988 by Archie Brain when he encountered difficult airway.[2] Prioritization of patient's ventilation is mandatory and supraglottic airway devices requires a special mention in such scenarios.[3] They can be placed both rapidly and easily and with minimal training. Its domain is not limited to operation theaters as a ventilation device for short surgical procedures but has spread to emergency department and out of hospital settings.[4] A success rate for placement of supraglottic airway device reaches 100% in operation theatre.[5] Since the development of laryngeal mask airway an array of supraglottic airway devices have been designed and some of these devices have been modified to be used for gastric drainage and conduits for endotracheal intubation. Intubating Laryngeal Tube Single- Disposable (iLTS-D) has been recently introduced in the family of supraglottic airway devices. This novel device offers an added advantage of insertion of endotracheal tube through them.[6]

There had been no studies comparing iLTS-D with any other supraglottic airway device. This compelled us to compare this novel device with Air-Q as both the devices have intubating channel that serve as conduit for endotracheal tube. We hypothesized that iLTS-D will perform similar to Air-Q in securing of airway.

MATERIALS AND METHODS

Following Institutional Review Board and Ethical Committee approval and approval from clinical trial registry of India, sixty patients undergoing elective surgery under general anesthesia of ASA grade 1and 2, Mallampati grade 1-3, age 20-50 years, either sex, weight 40 to 70 kg, height >125 cm were included in the study. Written informed consent was taken from the patients. Patients with anticipated difficult intubation, upper airway tumors or foreign bodies, history of spine instability, scheduled for major cardio-vascular and thoracic surgery, with coagulation disorders, undergoing emergency procedures were excluded from the study. All patients were subjected to a thorough pre-anesthetic checkup in the Pre-anesthetic checkup clinic as per the protocol followed in our hospital. Patients were randomly selected through computer generated random number table.

Patients in group iLTS-D (n = 30) were intubated by Intubating Laryngeal Tube Single- Disposable and in group Air-Q (n = 30) were intubated by Air-Q. Before using the devices, the anesthesiologists practiced 10 intubations with each device,5 on mannequin and 5 on live patients till they became well-versed with the use of both the devices. All intubations were performed by a single anesthesiologist.

Standard ASA monitors were attached in the operating room. This included electrocardiograph (ECG), pulse oximetry (SpO_2), capnography ($EtCO_2$), non-invasive blood pressure (NIBP).[7]

All patients were pre-medicated 15 minutes prior to induction of anesthesia with Inj. Midazolam 0.04 mg/kg, Inj. Dexamethasone 0.1 mg/kg and Inj. Fentanyl 2.0 mcg/kg.

After 5 minutes of pre-oxygenation with 100% oxygen(O_2), patients were induced with Inj. Propofol 2-3 mg/kg till the loss of the eyelash reflex. Muscle Relaxation was achieved by Inj. Rocuronium 0.6 mg/kg. Following adequate paralysis, the corresponding airway device was inserted and intubation done through the device as per the protocol. Intubation was confirmed by capnographic tracing. Anesthesia was maintained by oxygen, nitrous oxide (40:60), inhalational isoflurane and Inj Rocuronium. Ventilation was controlled throughout the surgery. At the end of surgery residual muscle paralysis was reversed with injection neostigmine and injection glycopyrrolate. Time taken was measured from placing the device into oral cavity, with subsequent passage of tube and appearance of capnographic tracing indicating successful intubation. Pulse rate (PR) and mean arterial pressure (MAP) changes from pre-induction to post-intubation values at 0, 3 and 5 min were recorded. Complications such as blood on ETT, sore throat and hoarseness of voice were noted.

Primary objective of the study was to record the time taken for intubation through the two devices measured as the time (sec) taken between placing the device into oral cavity and placement of endotracheal tube through it. Secondary objectives were to note the success of intubation through the two devices, haemodynamic changes and complications if any. A maximum of three attempts were allowed. A failed attempt was defined as removal of the device from the mouth before re-insertion. In between two consecutive attempts patient was ventilated by face mask. After failure of maximum three attempts intubation was performed using alternative intubation technique and the case was recorded as failed. The ease of insertion of devices was graded as easy (grade 1) and difficult (grade 2). Similarly, the grade of ease of insertion of tracheal tube was noted as easy (grade 1) and difficult (grade 2). The hemodynamic responses such as heart rate, mean arterial blood pressure and oxygen saturation after placement of device and intubation, complications like trauma to lips, tongue or pharynx, post-extubation staining of the tube with blood and post-operative sore throat were noted.

Sample size was calculated as thirty in each group. The α level was set at 0.05, power of study was 80% ($\beta = 1–0.8$) and ($d = \mu 1 - \mu 2 = 1.2$), $Z\alpha/2$ is dependent to level of significance which for 5% this is 1.96, $Z\beta$: is dependent on power and for 80% this is 0.84.

$$n = \frac{(Z_{(1-\alpha/2)} + Z_{(1-\beta)})^2 (sd_1^2 + sd_2^2)}{d^2}$$

$P < 0.05$ was considered statistically significant.

Non parametric data like gender was analyzed using Fisher´s exact test, Mallampati grades were analyzed using the Chi-square multiple contingency table. Parametric data like age, weight were analyzed using the Unpaired t-test. Data for time taken for intubation was analyzed using Unpaired t-test. Data for number of attempts was analyzed using t-test. Ease of intubation were analyzed using Chi square test. Data for hemodynamic changes were analyzed using Unpaired t test between the two groups. Data for post-operative complications like blood on endotracheal tube, sore throat postoperatively were analyzed using Fisher's exact test.

RESULTS

Eighty-two patients were recruited between November 2016 and November 2018 but ultimately 60 patients were found eligible for the study. Patient characteristics and the airway parameters were comparable in the two groups (Table 1). Average time to intubate in cases of iLTS-D group was 87.19 s and in Air-Q group was 86.82 s which was comparable (P = 0.7). Eighteen patients were intubated successfully in first attempt in (iLTS-D) group compared to twenty-six in Air-Q group; however, the difference was not statistically significant (P = 0.6). Nine cases were reported to be failed in iLTS-D group compared to two in Air-Q group (P = 0.04). [Table 2]. Jaw thrust was used with both the devices. The PR and MAP were higher immediately after intubation in both groups, but the differences were comparable. [Figure 2].

There were two cases of blood on ETT, three cases of sore throat and no case of hoarseness of voice 24 h postoperatively in (iLTS-D) group, whereas in Air-Q group, one cases of blood on ETT, four cases of sore throat and no cases of hoarseness of voice 24 h postoperatively.

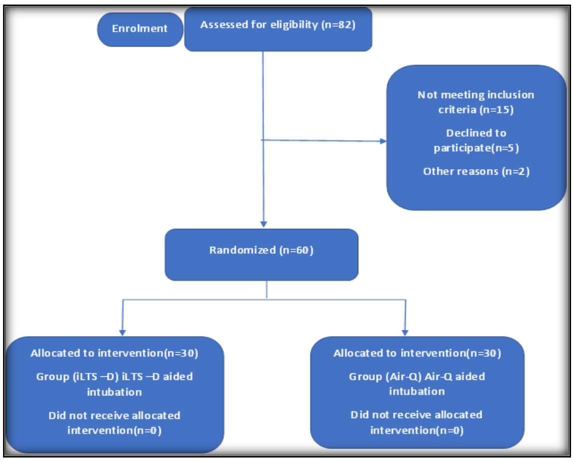

Figure1: Consort diagram

Table 1: Demographic Characteristics in intubating Laryngeal Tube Single-Disposable (iLTS –D) and Air-Q (Air-Q) groups. Continuous data are expressed as mean ± S.

	GROUP iLTS-D	GROUP Air-Q	P value
Age (years)	35.8±13.95	37.83±11.78	0.55
Sex (M/F)	5/25	4/26	1.00
Weight (kg)	55.73±7.329	57.83±8.06	0.29
Mallampati grades 1/2/3	8/15/7	6/16/8	0.65

Table 2: Intubation Characteristics in intubating Laryngeal Tube Single-Disposable (iLTS –D) and Air-Q (Air-Q) groups. Continuous data are expressed as mean ± S.

	GROUP iLTS-D	GROUP Air-Q	P value
TIME TO INTUBATE (sec)	87.19 ± 3.43	86.82 ± 3.87	0.73
EASE OF INSERTION (1/2)	30/0	30/0	1.00
EASE OF INTUBATION (1/2)	19/11	26/4	0.74
SUCCESS OF INTUBATION	21/9	28/2	0.04

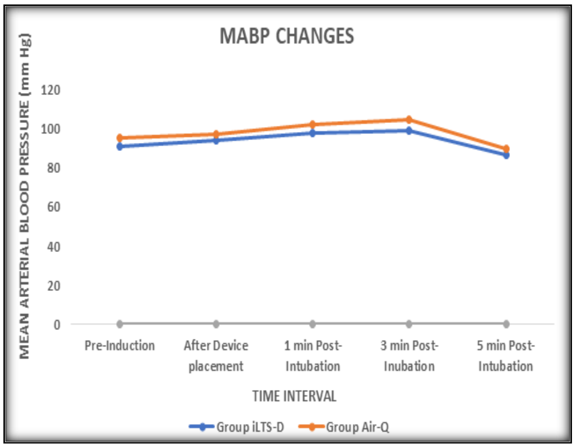

Figure 2: Distribution of Mean Arterial Blood Pressure changes at various intervals in both the groups.

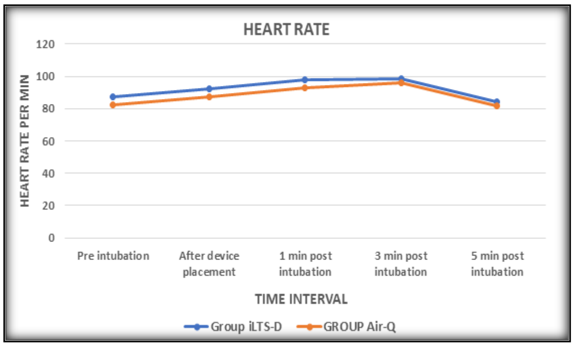

Figure 3: Distribution of Heart rate changes at various intervals in both the groups.

Figure 4: intubating Laryngeal Tube Single- Disposable (iLTS –D)

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Figure 5: Air-Q

DISCUSSION

Time taken to intubate with iLTS-D was more than Air-Q but the difference was comparable between both groups (P >0.05), the reason may be that once there is proper alignment of laryngeal inlet and ventilation ports of the two devices, the tube could easily pass through it. It took more time to intubate through iLTS-D as difficulty was encountered in passing the tube through the airway canal and ventilation ports to enter the trachea. This may be explained by the narrower airway canal of iLTS-D and the length of the canal is also more as compared to Air-Q.

Incidence of successful intubation in first attempt in cases of iLTS-D and Air-Q were 56.67% and 86.67% respectively whereas incidence of success of intubation within 3 attempts was 70% in iLTS-D and 93.33% in Air-Q. The reason for higher success rate with Air-Q was probably because it provided better intubating conditions owing to its special inbuilt features. [8] The airway lumen of Air-Q is wider and shorter. There is liberal space for the endotracheal tube to pass through Air- Q for an easy and smooth intubation. The airway tube is more hyper-curved which makes its passage through oropharyngeal axis easy owing to its shape. Elevation ramp is present for facilitation of intubation. Another reason could be the exclusion of patients with anticipated difficult airway and failed intubations. Joffee et al found 92% success rate of intubation through Air-Q very similar to our study.[9]

Ease of insertion of device was 100% with both the devices. It can be placed both easily and rapidly. Little expertise is required to learn its use.[10] The mask cuff seals effectively the laryngeal inlet to aid patient's ventilation. Better mask heel serves the purpose of improved seal. The inferior surface has horizontal ridges for the appropriate airway alignment. So, it proved to be an appropriate device for maintaining airway in elective cases and an alternative for combating emergency situations by effectively ventilating the patient.[11] The devices could prove to be a savior in un-anticipated difficult airway, emergency department, ventilation in short procedures or in MRI or CT suites.

The laryngeal inlet and the ventilation ports also fail to fall in line making the intubation process burdensome. This mandated the change in head position and change in the position of device. Similar findings were reported by Manpreet et al that the 'head extension' maneuver ('Mandheeral 1') and 'up-to-one-inch-out' withdrawal maneuver ('Mandheeral 2') are beneficial for successful ventilation through the iLTS-D and blind endotracheal intubation through the device. The maneuvers help the most in improving the intubating conditions. Adequate ventilation, Oropharyngeal leak pressure (OLP) and successful intubation through the device was achieved using these two maneuvers.[12]

The devices were inserted using two handed jaw thrust maneuver by an assistant for the smooth insertion into the mouth. This maneuver helped to lift the tongue and epiglottis off the pharyngeal wall to make a clear path for the devices iLTS-D and Air-Q. Ganzouri et al and Khan et al used jaw thrust for the insertion of Air-Q.[13,14]

There was significant rise at 1min post intubation due to mechanical stretching of laryngeal structures during intubation and also application of jaw thrust maneuver used to aid insertion of device. Subsequent heart rate at 3 min and 5 min were comparable in both the Groups.

Supraglottic airway devices are associated with better haemodynamic profile than laryngoscopy as they do not stimulate the laryngeal structures.[15] The airway can be secured with LMA without significant pressor response and should be considered when anaesthetizing patients with coronary artery disease.[16] Supraglottic airway devices can prove to be good alternative to laryngoscopy and intubation considering the prevention of pressor responses during airway management.[17]

The incidence of post-operative blood staining on airway devices was found to be comparable. The occurrence of blood stained ETT in both the Groups may be attributed to minor trauma due to blind manipulation of device position for the passage of endotracheal tube. The incidence of post-operative sore throat was also comparable

However, our study suffered limitation that the sample size was small, so the results of this study could not be applied to general population. The study was undertaken on elective cases, so it could not reflect the device performance in difficult airway scenarios. Blinding of the anaesthesiologist was not possible, hence this study has potential of bias. Further comparative studies with larger sample size is needed to evaluate the competence of iLTS-D as a device for intubation with greater emphasis on patients with difficult airways, previously failed intubation and in emergency scenarios.

CONCLUSION

The iLTS-D device has proved to be comparable to Air-Q in terms of time taken for intubation but has lower success rate for endotracheal intubation.

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