
**“COMPARISON OF EASE AND TIME TAKEN FOR
TRACHEAL INTUBATION THROUGH THE INTUBATING
LARYNGEAL MASK AIRWAY WITH THE AIR-Q IN
ADULTS. A ONE YEAR HOSPITAL BASED RANDOMIZED
CONTROL STUDY”**

By
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BELAGAVI, KARNATAKA-**

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Belagavi, Karnataka**

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Sir/Madam,

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LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists
BP	-	Blood Pressure
cm	-	Centimeter
CO ₂	-	Carbon dioxide
etCO ₂	-	End tidal carbon dioxide
ETT	-	Endotracheal tube
H ₂ O	-	Water
i-gel	-	Intersurgical
ILA	-	Intubating Laryngeal Airway
ILMA	-	Intubating Laryngeal Mask Airway
Inj.	-	Injection
IV	-	Intravenous
kg	-	Kilogram
LMA	-	Laryngeal mask airway
mg	-	Milligram
min	-	Minute
ml	-	Millilitre
PLMA	-	Proseal laryngeal mask airway
PR	-	Pulse rate
RR	-	Respiratory rate
SAD	-	Supraglottic airway device
Sec	-	Seconds
SPO ₂	-	Saturation percentage of oxygen

ABSTRACT

Introduction: Laryngeal mask airway (LMA) has been the cornerstone in the management of difficult airway . Though Intubating LMA (ILMA) as a conduit for tracheal intubation has been the standard device, identification of other alternate reliable devices would aid in choosing the ideal device for intubation. Hence, an attempt is being made to assess the performance of Air-Q compared to ILMA with regards to ease and time taken for intubation insertion through the LMAs , as well as the ease and duration of insertion of the airway devices.

Methodology: The present randomized clinical trial was conducted on 60 ASA I and II patients aged weighing 50 to 100 Kgs posted for elective surgeries under general anaesthesia in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. Patients were allocated into two equal groups, Group A- ILMA (n=30) and Group B - Air-Q (n=30). All the data collected were analysed. Comparisons between continuous variables of two groups were done by unpaired Student's t-test .Comparing categorical variables were done by chi-square -test. All p-values were considered significant when p-values less than 0.05.

Results: Insertion was easy for significantly more patients in Air-Q group (27/30,90%) compared to ILMA group (16/30, 53.3%) . With regards to intubation, our study proved intubation to be easy in little more than two third of ILMA group patients (22/30,73.33%). Moderate difficulty in insertion was seen only in 8 patients in ILMA group (26.67%). All 30 patients in group Air-Q (100%) showed moderate difficulty for intubation. This difference was found to be statistically significant. (**p<.0001**).

The mean duration of intubation was 37.13 ± 0.48 sec in ILMA group and higher (47.73 ± 4 sec) in Air Q group. This difference was found to be statistically significant ($p=0.0001$), while the mean duration of insertion of the device was significantly ($P<0.0001$) longer in ILMA group in our study, compared to Air-Q group (19.6 s vs 11.9 s). Visible blood on the device was noted in 6 patients in the ILMA group and 1 patient in Air-Q group which was statistically insignificant. No bronchospasm and laryngospasm were noted in patients of either group.

Conclusion: In our study, the Air-Q was easier to insert than the ILMA in anaesthetized paralysed adult patients, but it took a statistically significant longer time to intubate through the Air-Q when compared with the ILMA.

Keywords: Air-Q, Intubating Laryngeal Airway (ILA), Intubating Laryngeal Mask Airway(ILMA), Fastrach, Supraglottic airway device.

CONTENTS

SL. NO.	TOPIC	PAGE NO.
1.	INTRODUCTION	1-3
2.	AIMS AND OBJECTIVES	4
3.	REVIEW OF LITERATURE	5-11
4.	METHODOLOGY	12-17
5.	RESULTS	18-26
6.	DISCUSSION	27-30
7.	CONCLUSION & SUMMARY	31
10.	BIBLIOGRAPHY	32-33
11.	ANNEXURE I – CONSENT FORM	41-45
12.	ANNEXURE II – ETHICAL CLEARANCE	46
13.	ANNEXURE III – PROFORMA	47-51
14.	ANNEXURE III - PHOTOGRAPHS	52
15.	ANNEXURE IV – KEY TO MASTER CHART	53
16.	ANNEXURE V – MASTER CHART	54-55

LIST OF TABLES

TABLE NO.	DESCRIPTION	PAGE NO.
1	Sex Distribution	19
2	Mean age	19
3	Mean weight	20
4	ASA grade distribution	21
5	MPG grade distribution	21
6	Ease of insertion	22
7	Duration of insertion	23
8	Ease of intubation	24
9	Duration of intubation	25
10	Complications	26

LIST OF GRAPHS

TABLE NO.	DESCRIPTION	PAGE NO.
1	Mean weight	20
2	Ease of insertion	22
3	Duration of insertion	23
4	Ease of intubation	24
5	Duration of intubation	25

INTRODUCTION

The airway will always be a vital importance to an anesthesiologist. Securing and maintaining an airway which is patent for a smooth and successful surgical experience without adverse effects is the primary objective of an anesthesiologist.¹⁻³

Endotracheal Intubation by Direct laryngoscopy has been the gold standard method to obtain a secured airway to provide adequate oxygenation and ventilation. However in many occasions, there may be difficulty or failure to intubate by Direct laryngoscopy leading to significant airway related complications.¹⁻⁵

“Difficult tracheal intubation (defined as successful intubation requiring more than three attempts or taking longer than 10 minutes) occurs in 1.1% to 8.5% of patients. Failed tracheal intubation occurs at an incidence of 0.01% to 0.03%”.⁵

In the recent years, there has been significant advances in the practice of airway management. The advancement is well established by the introduction of newer modified airway devices, namely videolaryngoscopes ,Laryngeal Mask Airways (LMAs) fiberoptic bronchoscopes with few of them included in the Algorithm for Difficult Airway. Hence attention is being concentrated on these devices to obviate the most dreaded problem – ‘difficult tracheal intubation’.²⁻⁸

Among these devices , for the management of difficult airway the “Laryngeal mask airway” has been the cornerstone and has been a rescue airway device in anticipated or unanticipated difficult airways. It is recommended by many guidelines, viz the American Society of Anaesthesiologists.

The first supraglottic airway device to be discovered was LMA Classic by ARCHIE BRAIN in the year 1981.⁵ Since the time of its discovery modifications were made on Classic LMA for easier and effective usage.

These modifications lead to invention of newer supraglottic airways namely LMA SUPREME , PROSEAL , LMA FASTRACH, SLIPA, I-GEL. The latest being the 'AIR-Q', or 'the Intubating Laryngeal Airway' (ILA). Some of these LMA's namely, Intubating Laryngeal Mask Airway (ILMA), I-gel ,have been designed to be utilised as a conduit for tracheal intubation. This is particularly useful in unanticipated difficult airways especially in surgical patients mandating tracheal intubation.⁵⁻¹⁰

Intubations through these LMA's can be accomplished either by Fiberoptic (FO) guidance or directly by blind technique.¹¹⁻¹⁷

The Intubating LMA (ILMA) also known as LMA Fastrach has been designed to specifically aid in tracheal intubation. The ILMA overcomes the challenges encountered during passage of the tracheal tube (TT) as seen with classic LMA and facilitates ease in respect to guiding of the TT towards the glottis.¹⁸⁻²⁷

However the ILMA has specific limitations. The breathing tube of the device is found to be rigid, making it inappropriate for prolonged use and can cause a pressure effect leading to damage to posterior pharyngeal wall. The ILMA also needs a specific silicone TT and is not designed for paediatric population.²⁸⁻³³

The Air-Q (a newer alternative device to ILMA) has some advantages over the ILMA. The conducting tube of the device is shorter, wider ,has a removable connector and hence a polyvinyl chloride endotracheal tube (ETT) can be effortlessly placed and

also the device can be easily removed with the tube in situ successfully. It can also be used in the pediatric population.³⁴⁻³⁸

The Intubating LMA (ILMA) Fastrach, has been the standard device for tracheal intubation. However, identification of other alternate reliable devices would aid in choosing the ideal device for intubation.

Hence an attempt is being made to assess the performance of Air-Q compared to ILMA with regards to ease and time taken for the endotracheal tube intubation in an adult population who are posted for surgeries under general anaesthesia.

AIMS &OBJECTIVES

AIM

To study the efficacy of Air-Q with ILMA in adult patients undergoing General Anesthesia.

OBJECTIVES

The objectives of this study were:-

Primary objective

To compare the ease and time to tracheal intubation (TTI) through ILMA and Air- Q.

Secondary objective

To compare the ease and success of placement of the supraglottic airway devices- ILMA and Air-Q.

REVIEW OF LITERATURE

“Airway management competence necessitates :-

- (1) Knowledge of the airway anatomy and its physiology ,
- (2) The ability to assess the patient’s airway for the anatomic features that correlate with difficult airway management,
- (3) Skill with the various devices for airway management,
- (4) Appropriate application of the American Society of Anesthesiologists (ASA) algorithm for difficult airway management.”⁵

The LMA, originally discovered by Archie Brain, has been described as the missing link between the facemask and the tracheal tube and it has gained widespread popularity. Previously many studies were conducted where intubation with supraglottic airway devices was compared with traditional direct laryngoscopy .

The advantages of the supraglottic airway devices include

- avoidance of laryngoscopy,
- less invasiveness of the respiratory tract
- better tolerance by the patients
- increased ease of placement
- improved hemodynamic stability
- less coughing, less sore throat
- hands-free airway
- easier placement by inexperienced personnel.³⁹⁻⁴⁷

The advancements in airway management, propagated to the development of many modifications in the LMA. Some of these newer LMA are being designed to aid in tracheal intubation– ILMA, I-gel, Air-Q.

The ILMA, is a modification of the LMA, in use from 1997 and was designed specifically to aid tracheal intubation by behaving as a conduit. It has a success rate for endotracheal intubation of approximately 93%.

A.I.J. BRAIN et al.¹⁸ in 1997, assessed “the efficacy of ILMA, as a ventilatory device and blind intubation guide.” In 99.3% patients tracheal intubation was found to be possible (149 of 150). In 50% of the patients tracheal intubation in the 1st attempt resistance was performed without encountering any resistance, one additional manoeuvre for proper alignment was required in 19% of the patients and 2-4 adjusting manoeuvres for successful intubation was required in 31%(46) of the patients. Potential problems in intubation were seen in 13 of the patients. In 10 of these 13 patients, successful first attempt intubation was possible without encountering any resistance ; 3 of 13 of the patients required one adjusting manoeuvre, which was significantly lower in patients with a difficult (predicted or known) airway (P <0.05). They concluded that, “the ILMA on initial assessment appeared to be an effective ventilatory device and intubation guide for routine and difficult airway patients who are not at risk of gastric aspiration.”

Hwan S. Joo et al.¹¹ in 1999 studied, “tracheal intubations using ILMA with fiberoptic guidance (ILMA-FOB) and ILMA inserted blindly without fiberoptic guidance (ILMA-Blind) were compared with the control group of direct laryngoscopy.” All three groups displayed the same success rates for tracheal intubation (97%). The ILMA-FOB group was observed to have a longer total intubation time of 77 s while

ILMA-Blind took 53.5s and 48.5 s for laryngoscopy. The mean arterial blood pressure had a larger increase during tracheal intubation in the laryngoscopy group. They concluded by stating : “ the ILMA can be used as a primary airway for oxygenation and ventilation. The ILMA inserted blindly and the ILMA with fiberoptic guidance in women with normal airways are suitable alternatives to laryngoscopy for tracheal intubation”.

“The Air-Q Intubating Laryngeal Airway” (ILA) is one of the latest supraglottic airway device having a less rigid ,shorter ,wider breathing tube . It allows for successful airway maintenance under general anaesthesia, aswell as tracheal intubation with a cuffed endotracheal tube (ETT) (up to 8.5 mm IDs) blindly or fibreoptic guided in adult as wellas pediatric patients.This has been made possible due to the presence of a removable connector.

Air-Q does not have an epiglottis elevating bar which has proved to be an important factor in the prevention of haemodynamic stress response caused by stimulation of the epiglottis and the peri-epiglotticstructures.This proved to be an advantage over the LMA Fastrach .When a failure to intubate scenario was encountered the Air Q can be used as a definitive airway. This too was said to be a major advantage over the LMA Fastrach. ⁴⁸

In the year 2011, Karim et al⁴⁹ studied two disposable devices namely, LMA Fastrach and the Air-Q in 154 healthy patients undergoing tracheal intubation for elective surgery.Blind intubation was successful after two attempts in 99% of LMA Fastrach group patients and 77% of the Air-Q group patients showed the same findings (p < 0.0001). Fibreoptic assistance was employed for intubation during the third attempt.100% success in intubation after 3 attempts was see in the LMA

Fastrachgroup while Air-Q group showed a success rate of 95%. As a conduit to facilitate blind tracheal intubation, LMA Fastrach appeared to be over-powering the Air-Q. However, regarding the number of insertion attempts no statistical significant difference was documented (a success rate of 88.57% for the Fastrack vs. a success rate of 82.86% for the Air-Q).

Another RCT in 2011 was conducted on 80 patients by Abdel Raouf El-Ganzouri et al¹⁴ to study Air-Q for the success rate of blind intubation success rate with fiberoptic laryngoscopy guided intubation ,and observed 70% success with blind intubation while in Fiberoptic intubation it was found to be statistically significant ($p < 0.05$) with 97.5% success. The total time to intubate was found to be longer in the Air-Q blind intubation group than in the group in which FO assisted intubation through Air-Q was performed,and a statistically significant difference was seen ($p < 0.05$). He, thus concluded – “Air Q as a safe supraglottic airway with a low potential for airway trauma under general anaesthesia and was said to be a useful alternative for handling difficult airways ,when backed up by the presence of a flexible fiberscope.”

Wolfgang Erlacher et al.⁵⁰ carried out a study in 2011, to compare CobraPLUS and Air-Q with Fastrach for blind tracheal intubation. According to the device used 180 adult patients were randomized into 3 groups with documented BMI, Mallampati score, Cormack–Lehane classification, interincisor gap and thyromental distance .The quality of ventilation was found to be excellent for all devices. A slight reposition was required in 3 patients in the CobraPLUS group aswell as 2 patients in the ILMA and the Air-Q groups needed. Blind intubation through the CPLA was successful in 47%, through the Air-Q in 57%, whereas the Fastrach group had a success rate of 95%. Except one patient,in all fiberoptic intubation was possible . Prediction of difficult

blind intubation could not be assessed with the registered scores and measures. They found that all devices appeared to be safe airways. The Fastrach ILMA proved to be a reliable facilitator for blind intubation. Fibrescopic intubation was found to be easy in CobraPLUS and Air-Q . With the parameters that were used, failed intubation could not be predicted.

Talaat M. Abdel-Halim and colleagues⁴⁸ in 2014 performed a study on 100 patients scheduled to undergo elective surgeries to “compare Air-Q and Intubating LMA when used as a conduit for endotracheal intubation.”The Air-Q took 13.300 ± 3.471 s to intubate the trachea, whilst the time taken for ILMA was 19.640 ± 4.737 s ($p < 0.001$).The Air-Qs peak airway pressure was found to be 26.400 ± 2.176 cm H₂O vs 25.260 ± 1.468 cmH₂O in ILMA ($p < 0.01$). Full view of vocal cords amounted to In 78% and 26% of Air-Q and ILMA patients, respectively the entire vocal cords could be visualised ($p < 0.001$). The time taken for endotracheal insertion in Air-Q was 33.5 ± 6.795 s vs, 39.5 ± 6.566 s ($p < 0.001$) in ILMA. Blood stain was found on supraglottic device In 46% and 22% of cases of Air-Q and ILMA groups respectively ,blood staining of the devices was documented ($p < 0.01$). They concluded , “Air-Q to be an excellent conduit for endotracheal intubation compared to the ILMA.”

In a study done by Moustafa Abo Shamaet al⁵¹ in the year 2015 , “comparison of the intubating laryngeal mask airway (ILMA) with the Air-Q for blind tracheal intubation during surgical procedures under general anaesthesia” was done. He concluded that incidence of hemodynamic changes was significantly higher in the Air-Q group than the fastrach group and the insertion time of the endotracheal tube as well as the percentage of ease of insertion in ILMA showed a statistically significantly higher value than Air-Q.

VirenBhaskarAttarde et al.³⁴ in 2016 , performed a study “ to assess the efficacy of the Air Q ILA regarding ease of insertion, adequacy of ventilation, rate of successful intubation, haemodynamic response and airway morbidity.”In first attempt 88.3% of patients the Air-Q ILA was successfully inserted and 11.7% patients in second attempt. 100% of patients were adequately ventilated. 76.7% of patients with Air Q ILA proved to be successfully intubated and 23.3% of patients using Air Q ILA were intubated by direct laryngoscopy after failure with two attempts. The heart rate changes post-intubation proved to be statistically significant ($P < 0.0001$).Sore throat and mild airway trauma were observed in 10% and 5% respectively.They concluded “Air-Q ILA to be a reliable device as a supraglottic airway ensuring adequate ventilation as well as a conduit for endotracheal intubation.It was found to benefit the patient by avoiding the stress of direct laryngoscopy and was also found to be a superior alternative device for use in a difficult airway.”

In another study by SK Malhotra et al²⁸in 2016, “assessed whether use of two different endotracheal tubes (ETTs) (standard polyvinyl chloride [PVC] and reinforced PVC) increases the success rate of blind intubation through Air - Qwhen compared with intubating laryngeal mask airwaykeeping ILMA as control”, and concluded that “the overall success rate after three attempts was more with Air - Q (96.6%) as compared with ILMA (91.6%) .But no significant difference was seen between the groups ($P = 0.43$).”

Siamdoust S.S. et tal⁵² in 2018 ,compared “the Success Rate of Intubation Between the LMA Fastrach and AirQ-ILA in patients undergoing elective surgery during general anaesthesia.” The intubation time in the AirQ-ILA group was found to be significantly longer ($P < 0.05$) when compared with the LMA fastrach group. No

significant difference with respect to device insertion and tube insertion attempts among the groups was observed ($P > 0.05$). Also, the device insertion and intubation success rate in either of the groups showed no statistically significant difference ($P > 0.05$).

METHODOLOGY

This study titled “**Comparison of ease and time taken for tracheal intubation through the Intubating Laryngeal Mask Airway with the Air-Q in adults. A One year Hospital based Randomised Control Study**” was conducted in the “Department of Anaesthesiology”, “KLES Dr. Prabhakar Kore Hospital” , Belgaum during the period of “January 2018 to December 2018”.

Study design : A one year randomized controlled trial.

Source of Data : Adult patients undergoing elective surgical procedures requiring general anaesthesia, at KLES Dr. Prabhakar Kore Hospital, Belgaum.

Randomisation: The patients were assigned to their groups ILMA or Air-Q group using a computer generated table.

Sampling procedure : Sample size was calculated taking the time for intubation as the criteria from the results of previous similar studies and substituting the values in below stated formula:

Sample size was calculated using the formula as below;

$$n = \frac{(Z_1 + Z_2)^2 (S_1^2 + S_2^2)}{(x_1 - x_2)^2}$$

where,

“Level of significance is 5% (=0.05)”

“Power of the test is 80% (=0.84)”

Hence

$$Z = 1.96$$

$$Z = 0.84$$

\bar{X}_1 is the mean of the Insertion time of the ETT in LMA Fastrach(47.58s)

\bar{X}_2 is the mean of the Insertion time of the ETT in Air-Q (38.86s).

s_1 is the standard deviation of the Insertion time of the ETT in LMA Fastrach (10.53s)

s_2 is the standard deviation of the Insertion time of the ETT in Air-Q (9.46s).

The sample size obtained using these values was 30 in each group. Hence a total of 60 patients were equally distributed into two groups namely,

Group A :- ILMA.

Group B :- Air Q.

Selection criteria

Inclusion

- ASA grade I and ASA grade II.
- Weight 50-100 kgs
- Non Cardiac /Non Neurological elective surgeries
- Written Informed consent

Exclusion

- Pathology of the neck or upper respiratory tract.
- Presence of any significant acute or chronic lung disease, heart disease or neurological diseases.
- Emergency surgery.
- Presence of a high risk of pulmonary aspiration.

After the study was approved by the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum, all the patients in adherence with the inclusion criteria were explained about the study being undertaken and a written informed consent was obtained before enrollment. After the enrollment, general physical examination and systemic examination was carried out and the data was recorded on a predesigned and pretested proforma.

Investigations

All the patients were investigated preoperatively for.

- Haemoglobin .
- Routine urine examination.
- Random blood sugar.
- Blood urea and serum creatinine.
- Chest X-ray.
- ECG

The findings of these investigations were recorded on the proforma which was previously designed according to the study.

Procedure: According to standard anaesthesia protocol routine monitoring devices such as electrocardiograph, non-invasive blood pressure monitoring , pulse oximetry (SPO₂) were attached in the operating room.

The airway device to be inserted was prepared for insertion with the cuff completely deflated , and its dorsal surface lubricated with a clear, water based gel.

The following sizes of ILMA and AirQ airway and TTs were used in the study based upon the weight of the patients:

- ILMA: Size 4 (50-70 kgs) and reinforced cuffed PVC ETT of maximum size 7.0 mm ID.
- ILMA: Size 5 (70-100 kgs) and reinforced cuffed PVC ETT of maximum size 8.0 mm ID.
- Air-Q: Size 3.5 (50-70 kgs) with cuffed ETT of maximum size 7.5mm ID.
- Air-Q: Size 4.5 (70-100 kgs) with cuffed ETT of maximum size 8.5 mm ID.

An I.V. access was established. All the patients were preoxygenated with 100% oxygen for three minutes and were premedicated with an anti-sialogogue Inj. Glycopyrrolate 0.005mg/kg (IV), a sedative Inj. Midazolam 0.05mg/kg (IV) and an analgesic Inj. Fentanyl 2µg/kg (IV).

Induction of anaesthesia was performed with Inj. Propofol 2mg/kg (IV). Neuromuscular blockade was achieved with Inj. Vecuronium 0.1mg/kg (IV) after confirming adequate mask ventilation. The patient was ventilated for four minutes with the help of a facemask and then the airway device was inserted as per the manufacturer's recommendations.

Successful placement of the device was assessed by adequate chest expansion, absence of audible leak and gastric insufflation (by epigastric auscultation) ,and square wave capnography.

After the placement of the Supraglottic Airway Device was confirmed , the appropriate size ETT was inserted and intubation was considered “successful” by auscultation for bilateral air entry ,monitoring end-tidal carbon-dioxide and SpO₂> 95% after removal of supraglottic airway device. All insertions (LMA and ETT) were performed by an experienced anaesthesiologist.

Definition of variables :

- Ease of insertion : subjective (easy, moderate [minimal resistance], difficult [significant resistance] or impossible)
- Ease of intubation : subjective (easy, moderate [minimal resistance], difficult [significant resistance] or impossible)
- The success of each intubation :was taken when there was bilateral chest movement, a square wave on a capnograph and SpO₂> 95% after removal of supraglottic airway device.

“Failed insertion included any of the following .

- Failed passage into the pharynx.
- Malposition of the device (air leaks).
- ‘Ineffective ventilation’ (maximum expired tidal volume <6 ml/kg or/and end tidal CO₂> 60 cm of H₂O).
- More than three attempts”

If the device could not achieve a satisfactory airway as defined above, the patient's trachea was intubated conventionally by direct laryngoscopy.

Anaesthesia was maintained with 50:50 oxygen-nitrous oxide mixture, isoflurane and inj. Vecuronium 0.025mg /kg(IV) boluses.

At the end of the procedure, adequate reversal of the neuromuscular blockade was achieved with . Glycopyrrolate 0.01mg/kg and Inj. Neostigmine 0.05mg/kg injected intravenously. After the return of protective airway reflexes, the ETT was removed.

The aetiology of failed insertion (if any) was documented. Any episodes of laryngospasm and bronchospasm were documented. The presence of visible blood was checked after the device was removed and findings were noted accordingly.

Statistical analysis

Data obtained was coded and entered into Microsoft excel spreadsheet. Statistical package SPSS 20 was used for analysis.

The categorical data was expressed in terms of rates, ratios and percentage and continuous data was expressed as mean \pm standard deviation (SD). Comparisons between continuous variables of two groups were done by unpaired Student's t-test. Comparing categorical variables were done by chi-square -test. All p-values were considered significant when p-values less than 0.05.

RESULTS

The study was conducted in “the Department of Anaesthesiology”, “KLES Dr. Prabhakar Kore Hospital”, Belgaum during the time period of “January 2018 to December 2018”.

A total of 60adult patients, undergoing elective surgeries under general anaesthesia were studied. Patients were randomly allocated by computer generated table into one of the two groups

- Group A: ILMA (n=30)
- Group B: Air-Q (n=30)

Data obtained was coded and entered into Microsoft excel spreadsheet. Statistical package SPSS 20 was used for analysis.

The data was analysed and results obtained were tabulated as below.

Table 1. Sex distribution

SEX	ILMA (n=30)		Air-Q (n=30)	
	Number	Percent	Number	Percent
Male	16	53.3	18	60.0
Female	14	46.7	12	40.0
Total	30	100%	30	100%

In our study, there were 16 males, 14 female patients in ILMA group and 18 males, 12 female patients Air-Q group, male to female ratio being 1.14:1 in ILMA group and 1.5:1 in Air-Q group. This was statistically insignificant.

Table 2 . Mean age

Groups	n	Mean(years)	SD	t-value	P-value
ILMA	30	42.9333	13.74	-0.49	0.625
Air-Q	30	49.9661	12.07		

The mean age was 42.9 years in group ILMA and in group Air-Q was 49.9 years.

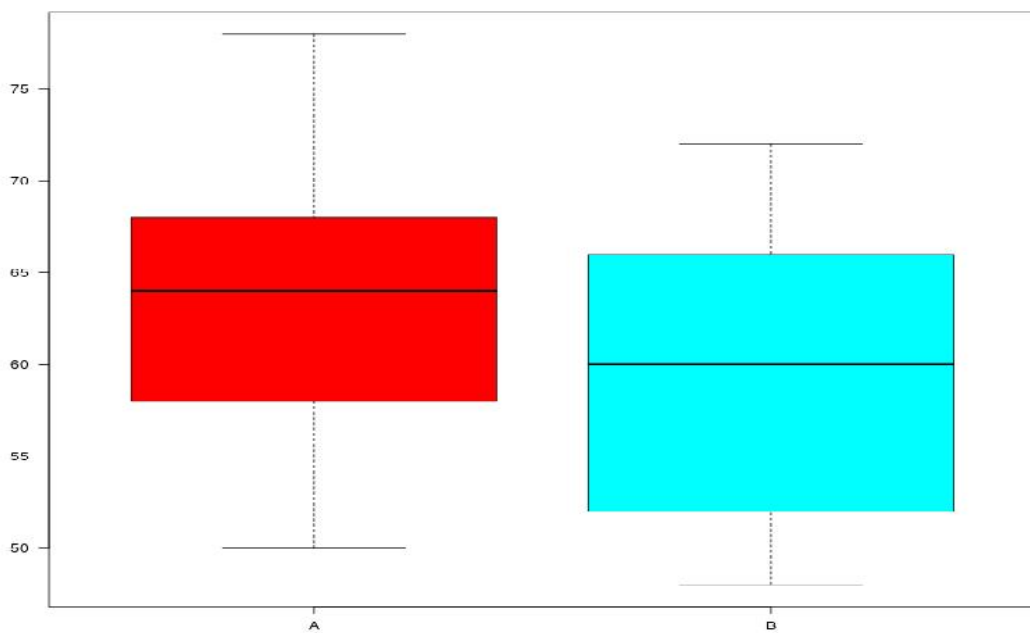
The age difference between the two groups was not statistically significant ($p = 0.625$)

Table 3. Mean weight

Groups	n	Mean(kg)	SD	t-value	p-value
ILMA	30	64.33	6.87	2.58	0.012
Air-Q	30	59.6	7.34		

The mean weight (kg) in Air Q was insignificantly lower than mean weight in group ILMA (62.6 vs 64.33) ,while the age difference between the two groups was not statistically significant with the mean age (years) in group ILMA being 42.9 and 49.9 years in group Air-Q (p = .012).

Graph 1. Mean weight



The graph above compares the mean weight and standard deviations of

A- ILMA group , B-Air-Q group.

Table 4. ASA grade

ASA grade	ILMA(n=30)	%	Air-Q (n=30)	%
Grade 1	20	66.7	22	73.3
Grade 2	10	33.3	8	26.7
Total	30	100.00	30	100.00

In this study, 22 patients of ASA grade 1 were in Air-Q as compared to 20 patients in ILMA (73.3% vs 66.7%). However the result was not significant ($p = .573$)

Table 5.MPG Grade

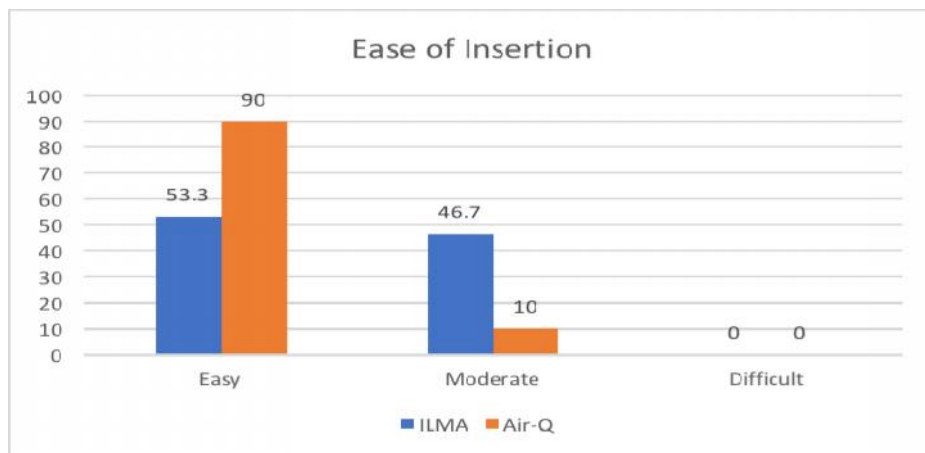
MPG grade	ILMA(n=30)	%	Air-Q (n=30)	%
Grade I	18	60	15	50.00
Grade II	12	40	15	50.00
Total	30	100.00	30	100.00

In the present study, 60% of patients in ILMA group had Mallampati grade I in comparison to 50% of patients in Air-Q group. The two groups did not show statistically significant difference ($p = .400$).

Table 6. Ease of insertion

Ease of insertion	ILMA(n=30)		Air-Q(n=30)	
	Number	%	Number	%
Easy	16	53.3	27	90.00
Moderate	14	46.7	3	10.0
Difficult	0	0	0	0
Total	30	100.00	30	100.00

Graph 2.-Ease of Insertion

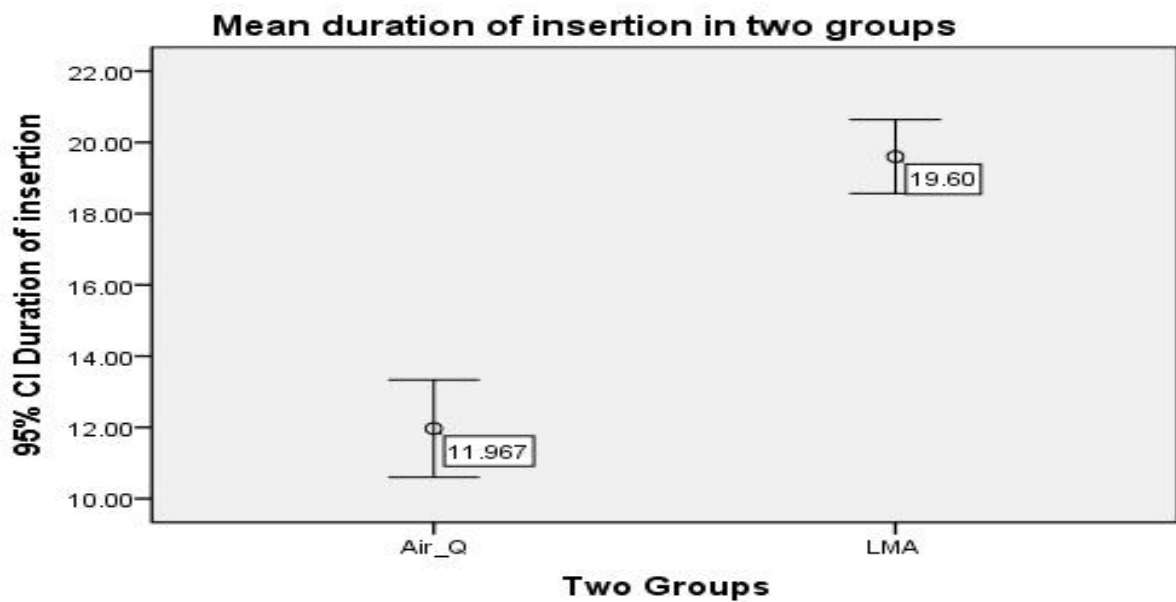


Our study showed insertion was easy for more number of patients, insertion was easy in 16 patients in ILMA group (53.3%) and 27 patients in Air-Q group (90%). Moderate insertion was seen in 14 patients in ILMA group(46.7%) and 3 patients in group Air-Q (10%). This difference was found to be statistically significant ($p=0.02$). Insertion was easy for significantly more patients in Air-Q group compared to LMA group. There were no failed insertion.

Table 7 .Duration of insertion

Group	n	Mean duration(seconds)	SD	Standard Error Mean	P-value
ILMA	30	19.6000	2.77427	.50651	.0001
Air-Q	30	11.9667	3.66233	.66865	

Graph 3.

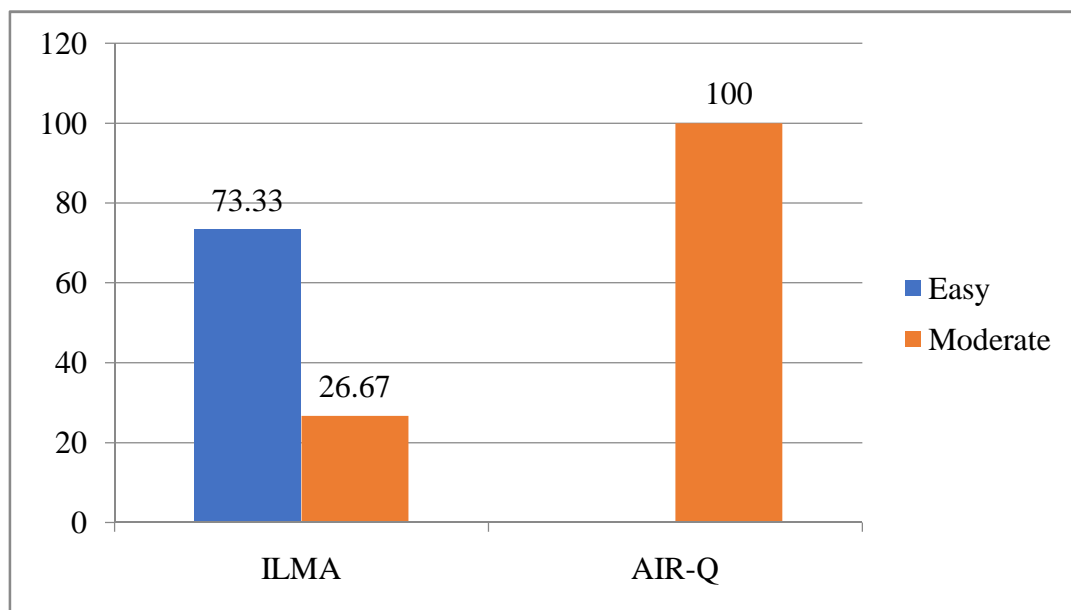


In our study, the mean duration of insertion was significantly longer in LMA group compared to Air-Q group. (19.6 vs 11.9) (**P<.0001**) as shown in the above graph.

Table 8. Ease of intubation

Ease of intubation	ILMA(n=30)		Air-Q(n=30)	
	Number	%	Number	%
Easy	22	73.33	0	0
Moderate	8	26.67	30	100.0
Difficult	0	0	0	0
Total	30	100.00	30	100.00

Graph 4.Ease of Intubation

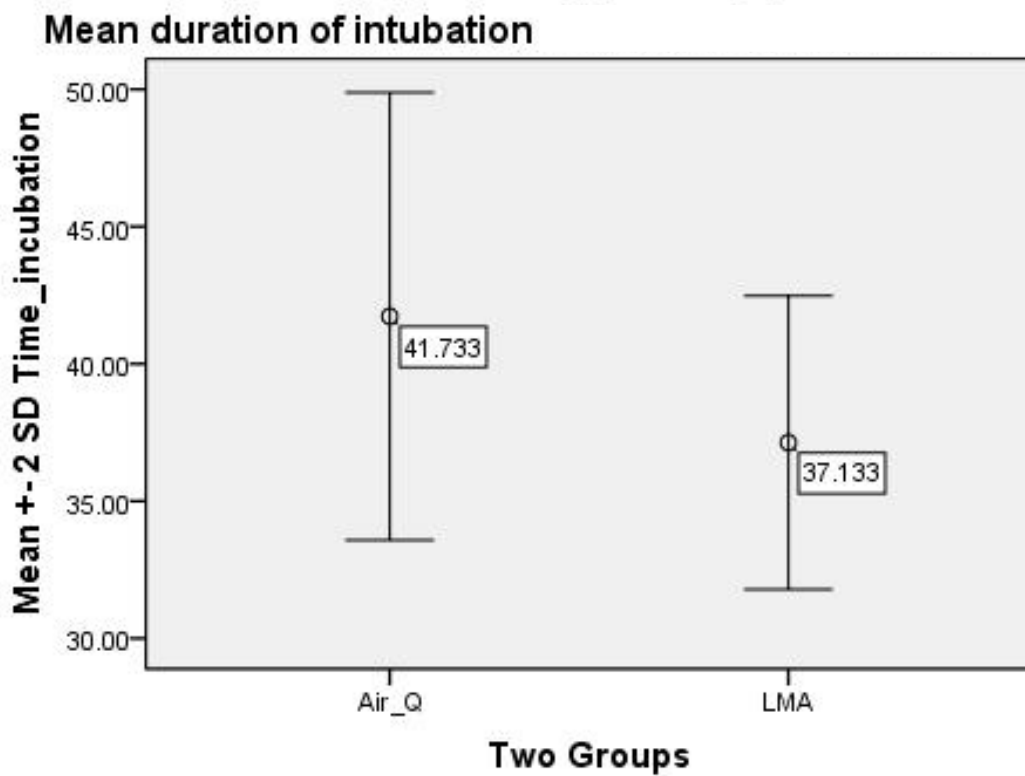


In our study, intubation was easy in two third of ILMA group patients (73.33%). Moderate difficulty in insertion was seen only in 8 patients in ILMA group (26.67%). All 30 patients in group Air-Q (100%) showed moderate difficulty. This difference was statistically significant. ($p<.0001$). There were no failed intubations.

Table 9. Duration of intubation

Group	n	Mean duration(seconds)	SD	Standard Error Mean	P-value
ILMA	30	37.1333	2.67470	.48833	.0001
Air-Q	30	41.7333	4.07628	.74422	

Graph 5.



In our study, the mean duration of intubation was 37.13 ±0.48 sec in ILMA group and higher (47.73±4 sec) in Air-Q group. This difference was statistically significant (p=0.0001).

Table 10. Complications

Complications	ILMA(n=30)		Air-Q(n=30)		p value
	Number	%	Number	%	
Laryngospasm	0	0	0	0	-
Bronchospasm	0	0	0	0	-
Visible blood on the device	6	3.33	1	20	p=0.1

In our study, visible blood on the device was noted in 6 patients in ILMA group (20%) and 1 patient in Air-Q group(3.3%). No bronchospasm and laryngospasm were noted in patients of either group. Since the numbers are very small, we did not look for statistical difference.

Summary of the results: Statistically significant difference were observed in ease of insertion, duration of insertion, ease of intubation, and duration of intubation between the two devices.

DISCUSSION

Supraglottic airway devices (SADs) are being widely accepted as a suitable alternative to tracheal intubation for the performance of general anesthesia. They can be easily inserted, well tolerated, cause fewer hemodynamic changes, have satisfying respiratory mechanics and fewer airway morbidity. The SADs are also been recommended in the current guidelines on cardiopulmonary resuscitation.

ILMA is one of the very first LMA's that were designed specifically for tracheal intubation and is also considered the standard LMA for tracheal intubation .It consists of a rigid breathing tube requiring a specific silicon endotracheal tube for intubation .

The "Air-Q" consists of a shorter, wider conducting tube, with a removable connector for easy insertion and removal of a standard endotracheal tube.

This study was undertaken to compare the ease and time to tracheal intubation through ILMA and Air- Q as the primary objective and to compare the ILMA and Air-Q for ease of insertion as the secondary objective.

A total of 60 ASA status I and ASA status II patients posted for elective surgery under general anaesthesia ,randomly divided into 2 groups of 30 each, were enrolled in our study.

In our study, there were 16 males, 14 female patients in ILMA group and 18 males, 12 female patients Air Q group, male to female ratio being 1.14:1 in ILMA group and 1.5:1 in Air-Q group. This was statistically insignificant.

The mean weight (kg) in Air Q was insignificantly lower than mean weight in group ILMA (62.6 vs 64.33), while the age difference between the two groups was also found not to be statistically significant with the mean age (years) in group ILMA being 42.9 and 49.9 years in group Air-Q ($p = 0.625$).

In the present study, 63.33% of patients in ILMA group had Mallampati grade I in comparison to 50% of patients in Air Q group.

In this study, 22 patients of ASA grade I were in Air Q as compared to 20 patients in ILMA (73.3% vs 66.7%). However the result was not significant ($p = 0.573$).

The supraglottic airway devices (SADs) have gained popularity due to the ease it provides for placement and, not to forget – ‘hands free maintenance’, along with a relatively secure airway. Insertion of SADs are less stimulating to sympathetic nervous system than laryngoscopy and tracheal intubation. It is also better tolerated at lighter levels of anaesthesia, potentially decreasing side effects and hospital stay.

In our study, ease of intubation proved to be easy in two third of ILMA group patients (73.33%). Moderate difficulty in intubation was seen only in 8 patients in ILMA group (26.67%). All 30 patients in group Air-Q (100%) showed moderate difficulty. This difference was statistically significant. ($p < .0001$).

In the present study, the mean duration of intubation was 37.13 ± 0.48 sec in ILMA group and higher (47.73 ± 4 sec) in Air Q group. This difference was statistically significant ($p = 0.0001$).

Neoh EU et al⁸, compared the ‘Air-Q’ and the ‘ILMA’ for the conduct of general anaesthesia. The ease of tracheal intubation using the ILMA was significantly

superior to using the Air-Q with 93.68% vs 75% of the patients showing easy intubations in ILMA and Air-Q respectively.

In a study done by Seydalireza Seyed Siamdoust et al⁵², it was found that in the Air-Q group, the intubation time (23.92±7.08 vs 17.93±4.4) was found to be showing a significantly longer time than the ILMA group ($P < 0.001$).

The rigid metal body equipped with the handle in the ILMA allowed better maneuvering at the laryngeal inlet during intubation while in the Air-Q, application of cricoid pressure being the only means of maneuvering, didn't prove to be as easy at times. Also the specific silicone ETT used in the ILMA was found to be more flexible during intubation when compared to the more rigid standard PVC ETT used during intubation in Air-Q.

Our study showed insertion of the LMAs was easy for more patients, insertion was easy in 16 patients in ILMA group (53.3%) and 27 patients in Air-Q group (90%). Moderate insertion was seen in 14 patients in ILMA group (46.7%) and 3 patients in group Air-Q (10%). This difference was statistically significant ($p=0.02$). Insertion was easy for significantly more patients in Air-Q group compared to ILMA group.

The mean duration of insertion of the devices in our study, was significantly longer in ILMA group, compared to Air-Q group (19.6 vs 11.9 s) ($P<.0001$). There were no failed insertions.

The cuff of the Air-Q being more rigid and the body being more flexible than that of the ILMA, could have led to its easier and earlier insertion.

In the study by SK Malhotra et al²⁸ time taken for insertion of Air-Q was 15 seconds compared to 30 seconds in ILMA group ,this difference was significant statistically (P = 0.00)..The ease of device placement was found to be easier with the Air-Q ,but was not statistically significant (P= 0.63).

In the study by Moustafa Abo Shamaa et al⁵¹,the difference observed in the mean insertion time of the devices was not statistically significant (P = 0.353). The insertion time of the device among the patients of Group I (ILMA) had a mean of 22.57 ± 6.67 s vs 23.91 ± 5.27 s among the patients of Group II (air-Q) .

SeydalirezaSeyedSiamdoust et al⁵² in their study found the device insertion time in Air-Q (21.92 ± 5.4 vs 17.92 ± 5.94) to be showing a significantly longer time than the ILMA group (P < 0.001).

Thus, the results of these various studies comparing the efficacy of the Air-Q with already established devices such as ILMA in adult patients are comparable.

LIMITATIONS

Patients having a normal airway anatomy were enrolled in the present study ; thus, no conclusions can be derived about patients with difficult airways.

Anesthesiologist was not blinded to the devices being used.

Investigators performing the test were well-experienced .Thus, finding might not be the same (successful) in the hands of the inexperienced.

Certain measurements used in this study like ease of insertions of the LMAs and ease of intubation through the devices, are subjective in nature.

SCOPE FOR FURTHER STUDIES

Further studies can be done to evaluate the ILMA and Air-Q in the difficult airway scenario.

They can also be studied in the ICU setting.

SUMMARY & CONCLUSION

Our present study titled **“Comparison of ease and time taken for tracheal intubation through the intubating laryngeal mask airway with the Air-Q in adults. A One year Hospital based Randomised Control Study ”** was aimed to study the efficacy of AIR-Q with ILMA in adult patients undergoing General Anesthesia.

The study was conducted in 60 ASA grade I and ASA grade II adult patients of both sexes, weighing between 50 and 100 kgs posted for elective surgeries under general anaesthesia in ‘KLES Dr. Prabhakar Kore Hospital and Medical Research Centre’, Belgaum during the period of January 2018 to December 2018. After obtaining the approval from the hospital ethical committee, the patients were randomly allocated to group A: ILMA (n=30) and group B: Air-Q (n=30). The demographic data were comparable in both groups.

Preoperative preparation and premedication were similar in both the groups. Patients were preoxygenated with 100% oxygen for 4 minutes and then, induced with propofol 2mg/kg(IV) and vecuronium 0.1mg/kg (IV). The airway device was inserted in strict accordance with the recommendations of the manufacturer.

The ease of insertion of the airway device and the endotracheal tube along with the time taken for insertion of the device as well as tube was recorded. Anaesthesia was maintained with isoflurane in 50:50 oxygen-nitrous oxide mixture and vecuronium.

The patient was given neuromuscular reversal and the airway device was removed after the end of the surgery and examined for the presence of visible blood. Laryngospasm and bronchospasm if occurred, were noted.

Our study showed insertion of the LMAs was easy for more patients, insertion was easy in 16 patients in ILMA group (53.3%) and 27 patients in Air-Q group (90%). Moderate insertion was seen in 14 patients in ILMA group (46.7%) and 3 patients in group Air-Q (10%). This difference was found to be statistically significant (**p=0.02**). Insertion was easy for significantly more patients in Air-Q group compared to ILMA group. There were no failed insertions.

With regards to intubation, our study proved intubation to be easy in little more than two third of ILMA group patients (22/30, 73.33%). Moderate difficulty in insertion was seen only in 8 patients in ILMA group (26.67%). All 30 patients in group Air-Q (100%) showed moderate difficulty. This difference was found to be statistically significant. (**p<.0001**).

In our study, the mean duration of intubation was 37.13 ±0.48 sec in ILMA group and higher (47.73±4 sec) in Air Q group. This difference was found to be statistically significant (**p=0.0001**). While, the mean duration of insertion of the device was significantly (**P<.0001**) longer in ILMA group in our study, compared to Air-Q group (19.6 vs 11.9 s).

To conclude, in our study, the Air-Q was easier to insert than the ILMA in anaesthetized paralysed adult patients, but it took a statistically significant longer time to intubate through the Air-Q when compared with the ILMA.

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ANNEXURE I : CONSENT FORM

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in “**Comparison of ease and time taken for tracheal intubation through the intubating laryngeal mask airway with the Air-Q in adults. A One year Hospital based Randomised Control Study**”. conducted by Dr. _____, Post Graduate in M.D. Anaesthesiology under the guidance of Dr _____, Professor, Department of Anaesthesiology, J.N. Medical College, Belagavi under KLE university, Belagavi.

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

The purpose of the research is to evaluate efficacy of two different supraglottic airway devices regarding airway sealing pressure, ease of their insertion, and post op hoarseness of voice.

Procedure Involved:

If you agree to enroll yourself in my study, you will be premedicated with Ondansetron 4mg, Ranitidine 50mg intravenously 15 min before surgery. Glycopyrrolate 0.005mg/kg, Midazolam 0.05mg/kg, Fentanyl 2mcg/kg are

administered intravenously. Following pre-oxygenation for 4minutes anaesthesia will be induced with Propofol 2 mg/kg titrated to loss of verbal contact with the patient, loss of eyelash reflex and relaxation of jaw. If coughing, gagging or body movement occurs during insertion of device, propofol 1mg/kg will be added to achieve an adequate level of anaesthesia. For the safety reason of patients before the insertion of any of the devices after loss of verbal contact, the anaesthetist will check that hand-ventilation with a face mask is possible. Once the patient becomes apnoeic and LMA insertion depth is achieved on the basis of clinical judgement, (i.e. jaw relaxation), the deflated LMA Fastrach or Air Q of appropriate size based on weight will be inserted. The patients will be assigned to their groups using envelope method, i.e. LMA Fastrach or Air Q group.

Benefits and Risks

These airway devices have become very popular because of their ability to maintain an airway without perturbing the trachea and can be used in patients without muscle relaxation who are only lightly anesthetized. There is incidence of postoperative sore throat and blood staining on the LMA Fastrach and Air Q.

Voluntary participation / Withdrawal

Taking part in the study is voluntary; you may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at Dr. Prabhakar Kore Hospital.

Alternatives

Even if you decline the participation in the study, you will get the routine line of management.

Confidentiality

All information collected about you during the course of the study will be kept confidential. The code numbers will identify you in this study records and the information from this study may be published but your identity will be confidential in any publication. The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

- In emergency to protect your rights and welfare.
- If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research.

Compensation

In the event of injury, related to the study, treatment will be made available at Dr. Prabhakar Kore Hospital and MRC, Belagavi. No reimbursement, compensation or free medical care will be given by law.

Queries/ Contact details

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. _____, Post Graduate student, Department of Anaesthesiology , JNM College, KLES Hospital and MRC, DeptDr. _____, Professor and HOD, Dept. Of Anaesthesiology, JNMC College, KLES Hospital and MRC, Belagavi,

If you have any queries about your right as a study subject, you may call Dr. RoopaBellad, Professor of Paediatrics as Chairman of J. N. Medical College Institutional Ethics Committee on Human Subjects Research at J. N. Medical College, Belagavi

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

I, _____ voluntarily agree to participate as a subject for the study. By signing this consent form I am not giving up any of my legal rights, I may withdraw myself from the study anytime. I am signing the consent form after having read or been read form in my own vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print : _____

Date: _____

Witness Name : _____

Signature: _____ Date:

Investigators Name: _____

Signature: _____

Date: _____

Place: _____

ANNEXURE II –ETHICAL CLEARANCE LETTER



K.J.SOMAIYA UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
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Ref: MDC/DOME/57

Date: 22/11/2017

To,

PG student in Anaesthesiology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **“COMPARISON OF EASE AND TIME TAKEN FOR TRACHEAL INTUBATION THROUGH THE INTUBATING LARYNGEAL MASK AIRWAY WITH AIR-Q IN ADULTS A ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY”**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE III - PROFORMA

“Comparison of ease and time taken for tracheal intubation through the intubating laryngeal mask airway with the Air-Q in adults. A One year Hospital based Randomised Control Study ”

Name & Address of the patient:

Age of the Patient: _____ IP. No. _____

Weight of Patient: _____ Sex. _____

Anaesthesiologist: _____ Surgeon: _____

PREANAESTHETIC EVALUATION:

Chief Complaints:

Past History:

- History of Diabetes Mellitus/Hypertension/Asthma/Tuberculosis
- Previous Anaesthetic procedure/Previous surgeries:
- History of renal disease, hepatic disease and neurological diseases.

Family History:

General Physical Examination:

Weight: Temperature: Pallor: Height

Cyanosis: Pedal Oedema: Clubbing:

Pulse : B.P: RR:

Airway Assessment:

Teeth: Jaw Movements: MP Grading:

SYSTEMIC EXAMINATION:

Cardiovascular System:

Respiratory System:

Per Abdomen:

Central Nervous system:

Spine assessment:

INVESTIGATIONS:

Hb%:

Platelet count:

Any Other:

ASA STATUS: Grade 1 / 2

Diagnosis:

Proposed Surgery:

Definition of variables :

- **Ease of insertion** : subjective (easy, moderate [minimal resistance], difficult [significant resistance] or impossible)
- **Ease of intubation** : subjective (easy, moderate [minimal resistance], difficult [significant resistance] or impossible)
- **The success of each intubation** : was taken when there was bilateral chest movement, a square wave on a capnograph and SpO₂ > 95% after removal of supraglottic airway device.

-

- **Failed insertion included any of the following .**
 - Failed passage into the pharynx.
 - Malposition of the device (air leaks).
 - ‘Ineffective ventilation’ (maximum expired tidal volume <6 ml/kg or/and end tidal CO₂> 60 cm of H₂O).
 - More than three attempt

STUDY ANALYSIS

“Comparison of ease and success of tracheal intubation through the intubating laryngeal mask airway with the Air-Q in adults . A One year Hospital based Randomised Control Study ”

Readings will be recorded in the following manner:

Group: _____.

Mallampati Grading	
Time taken to place the device (SGA)	
Ease of placement of Device (SGA)	
Time taken for intubation	
Ease of intubation	

Complications :-

Signature of Staff in charge :-

ANNEXURE IV – KEY TO MASTER CHART

PARAMETERS:-

ASA – American Society of Anaesthesiologists

cm - centimeter

F - female

kg - kilogram

M – male

INTUBATION DETAILS :-

SGA – Supraglottic Airway Device

Sec - second

ANNEXURE III - PHOTOGRAPHS



PHOTOGRAPH: AIR- Q (3.5/4.5)



PHOTOGRAPH: ILMA

S.no	I.P. No	Parameters						Intubation Details			
		Age (years)	Weight (kgs)	Height (cms)	Sex Male :Female	ASA STATUS	Mallampati grading	Time taken for insertion (secs)	Ease of placement of Device (SGA)	Time taken for intubation (secs)	Ease of intubation
1	821678	30	65	160	M	I	II	7	E	50	M
2	850689	27	50	158	F	I	I	13	E	40	M
3	850235	28	60	156	M	I	II	15	E	45	M
4	860599	54	65	160	F	II	II	12	E	40	M
5	854198	25	70	168	M	I	II	8	E	45	M
6	855789	30	52	155	F	I	I	4	E	48	M
7	853412	21	65	160	M	I	I	10	E	40	M
8	856115	30	66	158	F	I	II	6	E	35	M
9	875430	19	50	160	M	I	II	14	E	40	M
10	877802	42	60	156	F	I	I	20	M	35	M
11	875901	454	50	162	M	II	II	8	E	37	M
12	878285	30	60	154	F	I	I	10	E	42	M
13	879322	65	67	163	M	II	I	15	E	46	M
14	879300	60	55	145	F	II	I	13	E	44	M
15	879224	35	56	165	M	I	II	12	E	38	M
16	879526	30	48	152	M	I	I	12	E	42	M
17	882243	29	54	150	M	I	I	18	M	41	M
18	826781	48	68	158	F	I	I	10	E	38	M
19	886016	42	60	156	F	II	II	13	E	48	M
20	884428	29	48	154	M	I	I	12	E	44	M
21	885309	40	68	162	F	I	I	10	E	43	M
22	881738	41	68	165	M	II	II	12	E	46	M
23	881745	45	72	175	M	II	II	12	E	44	M
24	854399	25	52	145	M	I	II	11	E	48	M
25	886273	31	62	156	M	I	I	20	M	41	M
26	904192	32	56	157	F	I	II	10	E	40	M
27	902462	62	62	164	M	I	I	13	E	38	M
28	903740	25	52	148	F	I	II	13	E	38	M
29	902987	40	58	154	M	I	I	16	E	36	M
30	903751	30	69	175	M	II	II	10	E	40	M

Sno	I.P. No.	Parameters						AIRWAY FINDINGS		
		Age (years)	Weight (kgs)	Height (cms)	Sex Male -Female	ASA	Mallampati grading	Time taken to place the device (SGA) (secs)	Ease of placement of Device (SGA)	Time taken for intubation (secs)
1	850218	50	64	160	F	I	I	20	E	35
2	850519	46	58	158	M	I	I	18	M	34
3	868382	42	65	160	F	I	II	16	M	38
4	867107	38	58	158	F	I	I	21	M	33
5	868378	44	70	170	M	II	II	20	M	40
6	868400	27	50	156	M	I	II	16	E	38
7	868565	42	60	156	F	II	I	15	E	39
8	879224	30	56	164	F	I	I	18	E	34
9	869292	35	58	160	M	I	I	17	E	35
10	864208	54	56	156	M	I	I	20	M	38
11	864676	48	60	160	F	II	II	22	M	42
12	864808	27	68	157	F	I	I	18	E	36
13	819655	65	65	156	F	II	II	20	M	40
14	880690	70	75	170	M	II	I	22	M	38
15	880512	29	64	156	F	I	II	20	M	36
16	880747	36	70	170	M	I	I	18	E	37
17	880315	60	75	173	M	II	I	22	M	38
18	884287	30	64	165	M	I	I	18	E	36
19	889448	48	78	172	M	I	II	24	M	42
20	884432	19	65	168	M	I	II	22	E	40
21	839224	69	78	160	F	II	I	20	E	36
22	826372	40	70	170	M	II	II	28	M	42
23	886107	40	58	168	M	II	I	22	E	38
24	882167	42	65	179	M	I	I	20	E	32
25	891869	63	68	164	F	I	I	18	E	36
26	906350	49	56	156	F	II	I	16	E	36
27	906489	32	68	174	M	I	I	16	E	34
28	892075	55	64	158	F	I	II	19	E	34
29	905106	19	60	164	F	I	II	20	M	38
30	904952	39	64	158	M	I	II	22	M	39

Ease of intubation
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