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Supraglottic Airway Devices I-Gel And ILMA (Intubating Laryngeal Mask Airway) for Ease of Insertion and as Conduit for Blind Endotracheal Intubation: A Prospective Comparative Study

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Abstract

Introduction: Supraglottic airway devices are helpful in patients with difficult airways and in emergency situations and in cardiopulmonary resuscitations [1]. Some supraglottic airway devices are used for blind or fibreoptic bronchoscopy {FOB} guided intubation in the airway management . They can be efficiently used as rescue airway devices in patients with difficult airway and their use has increased in anaesthesia practice and emergency medical services [2]. *Aim:* This study is done to evaluate the efficacy of supraglottic airway devices I-GEL and ILMA as emergency ventilatory devices by comparing ease of insertion and as conduits for blind endotracheal intubation which can be used in difficult intubating conditions. *Methods:* 60 patients posted for surgical procedures under general anaesthesia. Patients fulfilling inclusion criteria were included in the study and were enrolled and analysed.Patients induced with appropriate Induction gents and Non depolarizing muscle relaxants and ventilated for 3 min prior to SAD insertion and again ventilated for one minute prior to blind ETT intubation. *Group A:* ILMA (30) inserted after 3 min ventilation followed by blind ETTintubation. *Group B:* I GEL (30) inserted after 3 min ventilation followed by blind ETTintubatio. Variables such as ease of insertion, number of attempts and duration of insertion of SADS, number of attempts and duration of blind ETT insertion and postoperative sorethroat, dysphagia etc were compared. The collected data were statistically analysed and tabulated. *Results:* The statistical analysis tools used in this study for the comparison of demographic variables, ease of insertion, number of attempts and duration of insertion of SAD, number of attempts and duration for ETT insertion ,failure and postoperative sorethroat and dysphagia were chi square test and fishers exact test. The p value derived for ease of insertion , number of attempts, and duration of insertion of SGADS I-GEL and ILMA were $p < 0.001$ favouring I- GEL. Likewise the p value derived for number of attempts and duration for ETT insertion through I-GEL and ILMA were $p< 0.0001$ favouring ILMA . The p value derived for incidence of postoperative sore throat and dysphagia was $p<0.0125$, favouring I-GEL. It was concluded that from above results that I-GEL is a better device for emergency rescue ventilation because of its ease of insertion and lesser incidence of postoperative sore throat and dysphagia as compared to ILMA whereas ILMA is a better device for blind endotracheal intubation compared to I-GEL. *Conclusion:* It can be safely concluded that I-GEL is easier to insert and a better airway device for emergency rescue ventilation compared to ILMA and ILMA is a better conduit for blind endotracheal intubation than I-GEL.

Keywords: I-GEL; ILMA; Endotracheal Intubation.

Introduction

Supraglottic airway devices are helpful in patients with difficult airways and in emergency situations and in cardiopulmonary resuscitations [1]. Some supraglottic airway devices are used for blind or fibreoptic bronchoscopy {FOB} guided intubation in the airway management. They can be efficiently used as rescue airway devices in patients with difficult airway and their use has increased in anaesthesia practice and emergency medical services [29].

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Aim of the Study

To compare supraglottic airway devices , I-GEL and INTUBATING LMA { ILMA } for ease of insertion and as a conduit for blind endotracheal intubation.

Objectives of the Study

1. To study the effectiveness of Supraglottic airway devices I-GEL And ILMA {Intubating Laryngeal Mask Airway} in emergency airway management 9].
2. To evaluate the feasibility for blind endotracheal intubation using I-GEL and ILMA {Intubating Laryngeal Mask Airway} as conduits in difficult intubation conditions.

Materials and Methodology

Type of Study: A prospective, Comparative study

Place of Study: Government Kilpauk Medical College and Hospital

Sample Size: The formula for calculating sample size is given as

N = {Z1alpha/2 .sigma/E } 2 , Where N = sample size Sigma = population standard deviation

E = margin of error

Z = the value for the given confidence interval

Confidence level is estimated at 95% Standard deviation 3.79:Z value of 1.96.

Margin of error is estimated at ±1. Power of study 80 percent.The sample size calculated was 56. To comp-ensate for dropouts 60 adult patients satisfying the inclusion criteria was enrolled in the study.

Inclusion Criteria

1. Adult patients undergoing elective surgery requiring general anaesthesia.
2. ASA physical status 1 – 2
3. Patients with age >18 years and <60 years
4. Patients with height:150-180cm
5. Patients who have given valid informed consent
6. Patients with MPC I & II

Exclusion Criteria

1. Patients not satisfying inclusion criteria.
2. Patients requiring techniques such as rapid sequence induction.
3. Patients with oral pathology with distorted anatomy.
4. Patients with Trismus/TMJ pathology/ MPC III & IV
5. Pregnant, Gastroesophageal reflux disease & hiatus hernia patients
6. Patients who are unconscious or severely ill.
7. Morbidly obese patients.
8. Patients with neck swelling/thyroid.
9. Patients with post burns contracture neck

Methodology

This Study was conducted on 60 patients undergoing elective surgery under general anaesthesia, after getting approval from Institutional ethics committee. Written informed consent was obtained from all patients. After premedication with Ranitidine 50 mg and Metoclopramide 10 mg intravenously

30 minutes before induction, patient was shifted to the operation theatre. In the operation theatre, after establishing an intravenous route,Ringer lactate solution was started. Standard monitors were connected eg. NIBP, ECG , ETCO2 , SPO2 . All patients received intravenous Glycopyrrolate 0.2mg, Fentany 2microgram/kg and Midazolam 0.03mg/kg, 10 minutes before induction of anaesthesia. All the patients was preoxygenated with 100% oxygen for 3 minutes. Induction was done with appropriate inducing agents and Musle relaxation was facilitated with appropriate Nondepolarising Muscle relaxants and mask ventilation was continued for 3 minutes with mixture of Oxygen, and Nitrous oxide. Depending on body weight the following sizes of the SADs (I- GEL/ILMA) and endotracheal tube (ETT) were chosen with little change in manufacturer's recommendations. Size of SAD Patients bodyweight in kilograms ETT Internal diameter size

I-GEL

Size 3 {three } 30-50 kg7.0mm

Size 4 {four } 50-90kg 7.5mm

ILMA

Size 3 {three} 30-50kg 7.0mm

Size 4{four} 50-70kg 7.5mm

Size 5 {five} >70kg 7.5mm

Conventional PVC (Polyvinylchloride) endotracheal tube (Portex) is used for blind endotracheal intubation. Both SADs and ETT are lubricated with 2% Lignocaine jelly prior to use. The I-gel supraglottic airway device was inserted in extended neck position {classical method }, while the ILMA was inserted in neutral neck position. Duration of successful SAD insertion is defined as the time elapsed from the insertion of SAD between the dental arches until the confirmation of successful ventilation determined by chest wall movement, auscultation of breath sounds, capnography and absence of oropharyngeal leak with peak airway pressure of > 20 cm of H_2O [1]. The time will be measured with the help of a stopwatch. The number of attempts required for SAD insertion were recorded. A failed attempt is defined as removal of the device from the mouth before it is reinserted .If the device is not successfully inserted in third attempt this is recorded as failure of SAD insertion.

Following this, blind tracheal intubation is to be attempted through SAD. Duration of successful blind tracheal intubation through SAD is defined as the time elapsed from passing the ETT through SAD until the confirmation of successful ventilation, which is determined by chest rise, auscultation of breath sounds and capnography. In I-GEL group, SAD was removed using one size smaller tracheal tube. {In case of I-GEL since it is not provided with the stabilizer rod } In ILMA group ETT was removed using the stabilizer rod provided along with the ILMA set .When resistance is felt during ETT Insertion in I-GEL group following manuevers can be used

1. ETT was rotated 90 degree counterclockwise and then inserted
2. Cricoid pressure26

IN ILMA group ETT , was inserted with

1. Reverse orientation,
2. Inserted with conventional technique and then rotated through 180 degree once it crosses the proximal opening in LMA 1.

In both the study groups, maximum three attempts at device insertion and maximum three attempts at tracheal intubation were allowed. If tracheal intubation through the device is unsuccessful, it was performed by direct laryngoscopy or the procedure was completed with the SAD in place depending on the implications and need of the surgical procedure

Parameters Analysed

Ease of Insertion Based on Subjective Score

Easy	-	score 1
Satisfactory	-	score 2
Diifficult	-	score 3

Number of Attempts for Sad Insertion and Blind Tracheal Intubation

Maximum of three attempts each for SAD insertion and ETT insertion were done. More than three attempts taken, was considered failure.

Duration for Insertion of Sad and Blind Tracheal Intubation

Calculated from the time duration that elapsed from passage of SAD through the dental arches and ETT through the SAD to the confirmation of successful ventilation confirmed clinically and by Endtidal carbondioxide concentration monitoring.

The Presence Or Absence of Postoperative Dysphagia, Sorethroat Hoarseness of Voice etc. Was enquired at the end of the procedure. All patients were observed in the recovery room for half an hour postoperatively and shifted to postoperative ward for further care. All recorded data were collected and statistical analysis were done.

Observation and Results – Statistical Analysis

This prospective non randomized, double arm, single blinded, Comparative study was done to evaluate the efficacy of supraglottic airway devices I-GEL and ILMA as emergency ventilatory devices and their ability as conduit for blind intubation [10].

Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using SPSS version 16 and Microsoft Excel 2007 [10].

Majority of the ILMA group patients belonged to 21-30 years age class interval (n=13, 43.33%) with a mean age of 30.50 years. In the I-GEL group patients, majority belonged to 21-30 years class interval (n=13, 43.33%) with a mean age of 30.60 years. The

association between the intervention groups and age distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test. Majority of the ILMA group patients belonged to female gender (n=19, 63.33%). In the I-GEL group patients, majority too belonged to female gender (n=18, 60.00%). The association between the intervention groups and gender status is considered to be not statistically significant since p > 0.05 as per chi squared test. Majority of the I-LMA group patients belonged to ASA 1(n=25, 83.33%). In the i-Gel group patients, majority too belonged to ASA 1 (n=22, 73.33%). The association between the intervention groups and ASA status is considered to be not statistically significant since p> 0.05 as per chi square test.

Majority of the ILMA group patients belonged to 51-60 kgs weight class interval (n=17, 56.67%) with a mean weight of 57.10 kgs. In the I-GEL group patients, majority belonged to 51-60 kgs weight class interval (n=14, 46.67%) with a mean weight of 54.13 kgs. The association between the intervention groups and weight distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test. Majority of the ILMA group patients belonged to 151-160 cms height class interval (n=22, 73.33%) with a mean height of 156.73 cms. In the I-GEL group patients, majority belonged to 151-160 cms height class interval (n=21,70.00%) with a mean height of 156.73 cms. The association between the intervention groups and height distribution is considered to be not statistically significant since p> 0.05 as per unpaired t test.

Majority of the ILMA group patients had ease of insertion score 2 (n=16, 53.33%). In the i-Gel group patients, majority had ease of insertion score1 (n=21, 70.00%). The decreased incidence of ease of insertion score 1 (easy) in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of <0.0001 as per fishers exact test.

Majority of the ILMA group patients had 2 attempts for SAD insertion (n=17, 56.67%). In the I-GEL group patients, majority had 1 attempts for SAD insertion (n=19, 63.33%). The increased number of attempts for SAD insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of <0.0001 as per Fishers exact test.

Majority of the ILMA group patients had 11-15 secs as duration for SGAD insertion (n=15, 50.00%) with a mean of 14.90 secs . In the I-GEL group patients, majority had 6-10 secs as duration for SGAD insertion (n=19, 63.33%) with a mean of 6.70 secs. The increased mean duration for SGAD insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of <0.0001 as per unpaired t test.

Majority of the ILMA group patients had 1 attempt for ETT insertion (n=22, 73.33%). In the I-GEL group patients, majority had 2 attempts for ETT insertion (n=18, 60.00%). The decreased number of attempts for ETT insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of <0.0001 as per fishers exact test.

Fig. 1: I-GEL

Fig. 2: Various sizes of IGEL

I-gel size	Patient Size	Patient weight guidance (kg)
1	Neonate	2-5
1.5	Infant	5-12
2	Small paediatric	10.25
2.5	Large paediatric	25-35
3	Small adult	30-60
4	Medium adult	50-90
5	Large Adult+	90+

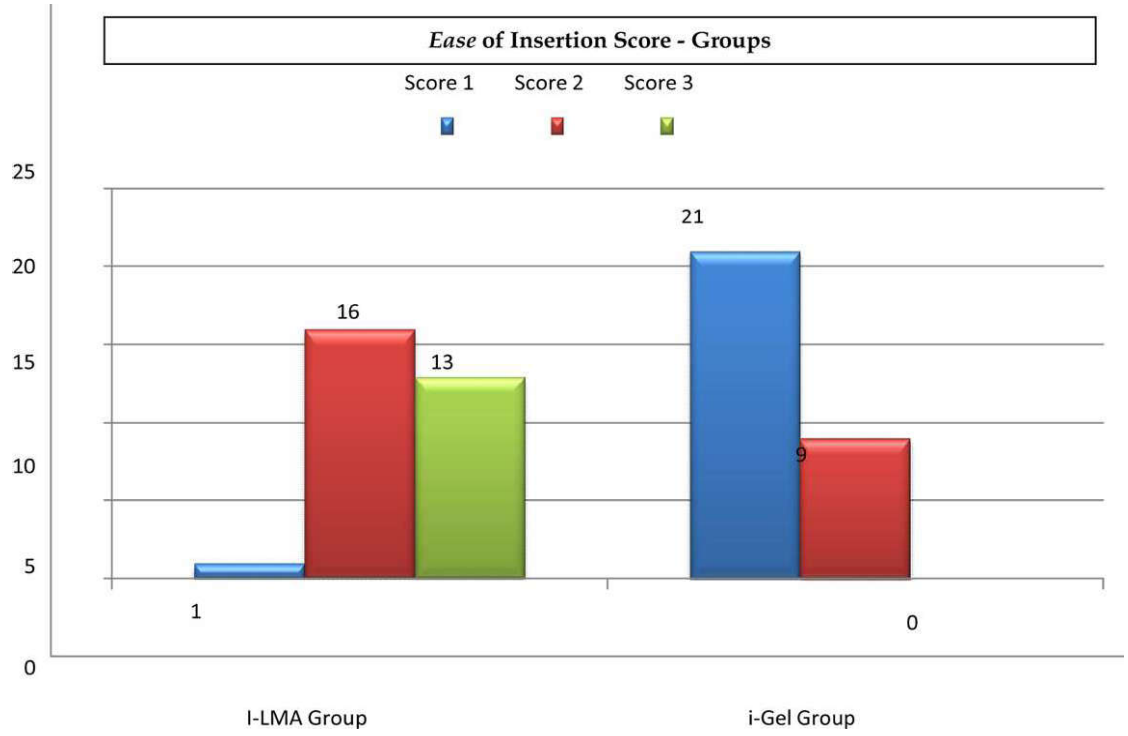

Fig. 3: Ease of insertion score

Table 1:

	ILMA Group	I-GEL Group	P value
Age Distribution	30.50±9.92	30.60±8.59	0.9669
Weight Distribution	57.10±6.54	54.13±7.41	0.1055
ASA I	25	22	0.3472
ASA II	5	8	
MALE	11	12	0.7906
FEMALE	19	18	
Height Distribution	156.73±4.79	156.77±5.29	0.9797

Table 2:

Ease of Insertion Score - Groups	ILMA Group	%	I-GEL Group	%
Score 1	1	3.33	21	70.00
Score 2	16	53.33	9	30.00
Score 3	13	43.33	0	0.00
Total	30	100	30	100
P value Fishers Exact Test	<0.0001			

Table 3:

Number of Attempts for SAD Insertion - Groups	ILMA Group	%	I-GEL Group	%
One Attempt	1	3.33	19	63.33
Two Attempts	17	56.67	11	36.67
Three Attempts	9	30.00	0	0.00
> Three Attempts	3	10.00	0	0.00
Total	30	100	30	100
P value Fishers Exact Test			<0.0001	

Table 4:

Duration for SAD Insertion - Groups	ILMA Group	%	I-GEL Group	%
≤ 5 secs	0	0.00	11	36.67
6-10 secs	4	13.33	19	63.33
11-15 secs	15	50.00	0	0.00
16-20 secs	8	26.67	0	0.00
> 20 secs	3	10.00	0	0.00
Total	30	100	30	100

Table 5:

Duration for ETT Insertion - Groups	ILMA Group	%	I-GEL Group	%
No Attempt	3	10.00	0	0.00
≤ 5 sec	10	33.33	0	0.00
6-10 sec	15	50.00	1	3.33
11-15 sec	2	6.67	16	53.33
16-20 sec	0	0.00	10	33.33
> 20 sec	0	0.00	3	10.00
Total	30	100	30	100

Table 6:

	ILMA Group	I-GEL Group
Duration for ETT Insertion - Groups for SAD Insertion Mean	14.90±4.52	6.70±2.17
Duration for ETT Insertion	5.90±3.08	12.90±5.10
P value Unpaired t Test	<0.0001	

Table 7:

Number of Attempts for ETT Insertion - Groups	ILMA Group	%	I-GEL Group	%
No Attempt	3	10.00	0	0.00
One Attempt	22	73.33	1	3.33
Two Attempts	5	16.67	18	60.00
Three Attempts	0	0.00	8	26.67
> Three Attempts	0	0.00	3	10.00
Total	30	100	30	100
P value Fishers Exact Test			<0.0001	

Table8:

Failure of SAD Insertion (more than 3 attempts)	ILMA Group	%	I-GEL Group	%
Yes	3±	10.00	0	0.00
No	27	90.00	30	100.00
Total	30	100	30	100
P value Fishers Exact Test			0.1186	

Table 9:

Failure of Blind Endotracheal Intubation	ILMA Group	%	I-GEL Group	%
Yes	0	0.00	3	10.00
No	30	100.00	27	90.00
Total	30	100	30	100
P value Fishers Exact Test			0.1186	

Table 10:

Postoperative Dysphagia/Sore Throat	ILMA Group	%	I-GEL Group	%
Yes	14	46.67	5	16.67
No	16	53.33	25	83.33
Total	30	100	30	100
P value Fishers Exact Test			0.0125	

Majority of the ILMA group patients had 6-10 secs as duration for ETT insertion (n=15, 50.00%) with a mean of 5.90 secs. In the I-GEL group patients, majority had 11-15 secs as duration for ETT insertion (n=16, 53.33%) with a mean of 12.90 secs. The decreased mean duration for ETT insertion in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of <0.0001 as per unpaired t test.

Majority of the ILMA group patients belonged to failure of SAD less than three attempts status (n=27, 90.00%). In the I-GEL group patients, majority too belonged to failure of SAD less than three attempts status (n=30, 100.00%). The association between the intervention groups and Failure of SAD Insertion (more than 3 attempts) status is considered to be not statistically significant since p >0.05 as per chi squared test.

Majority of the ILMA group patients belonged to no failure of blind endotracheal intubation status (n=30, 100.00%). In the I-GEL group patients, majority too belonged to no failure of blind endotracheal intubation status (n=27,90.00%). The association between the intervention groups and no failure of blind endotracheal intubation status is considered to be not statistically significant since p > 0.05 as Fishers exact test.

Majority of the ILMA group patients had no postoperative dysphagia/sore throat (n=16, 53.33%). In the I-GEL group patients, majority had no postoperative dysphagia/sore throat (n=25, 83.33%). The increased incidence of postoperative dysphagia/sore throat in ILMA group compared to the I-GEL group is considered to be statistically significant with a p value of 0.0125 as per Fishers exact test.

Discussion

Expertise in Airway management is a critical skill in the safe administration of anaesthesia6 . For managing a difficult airway some of the pre requisites are

1. Proper airway assessment
2. Meticulous selection of proper patient and proper preoperative optimization
3. Selection of well trained and experienced personnel in airway management
4. Equipments and devices for safe airway management .

The major factor in anaesthesia related morbidity is related to difficult mask ventilation and difficult intubation. Difficult tracheal intubation { successful intubation requiring more than 3 attempts or taking longer than 10 min } occurs in one to four percent of the population [6] .

Over the past few years there have been much focus on devices to decrease the problem of difficult airway and ventilation . The utmost problem is inability to oxygenate, ventilate or the combination of these factors . Over the past two decades there have been a search for equipment and devices for attenuating the problem of difficult oxygenation and ventilation [6]. Supraglottic airway devices are one such innovation discovered and are helpful in difficult airways and in emergency life threatening situations. The use of supraglottic airway devices as a means of rescue in patients who are difficult to intubate or ventilate has increased in the field of anaesthesiology and emergency medicine.

These devices require

1. Less technical skills
2. Associated with less increase in intracranial pressure /intraocular pressure /intragastric pressur
3. Has good device tolerance

Many studies were done to evaluate the efficacy of supraglottic airway devices as emergency rescue airway devices and also as conduit for blind or fibreoptic guided endotracheal intubation.The present study was done to compare the supraglottic airway devices I- GEL and ILMA for ease of insertion to assess their ability to function as emergency rescue airway devices and also as a conduit devices for tracheal intubation in difficult intubation condition.

Demographic Data

The demographic variables were similar in both groups and there were no statistically significant changes {p> 0.05 }.

Other Datas

Supraglottic Airway Device {Sad} Ease of Insertion and Number of Attempts

In the study conducted by Bhandari et al and Halwagi et al they demonstrated 100 percent success rate for both I-GEL and ILMA insertion, either in first or second attempt. With first attempt of SAD insertion, the successful ventilation rate was 95% In I-GEL group and in ILMA group it was 90%. It was 100% in both the groups in the second attempt8 In this study, 70% of patients {21 patients } in I-GEL group got a score of 1 compared to 3.33% {1 patient} in ILMA group. 9 patients {30%} in I-GEL group got a score of 2 while 21 patients {53.3%} in ILMA group got the same score . score of 3 was given to 13 patients {43.3%} in ILMA Group while in I-GEL group no patients found to be difficult. Regarding the number of attempts in ILMA group only one patient {3.33% }was able insert in one attempt as compared to 19 patients {63.33% } in I-GEL group. 17 patients {56.67% } in ILMA group and 11 patients {36.67% } in I-GEL group were inserted in the second attempt . 9 patients {30 % } in ILMA group needed third attempt where as I-GEL group dint needed the third attempt . 3 patients {10 % } in ILMA group needed more than three attempts. From these recordings and analysis it can be concluded that I-GEL was a better device for emergency rescue ventilation device when compared to ILMA since the data analysed using Fischers exact test and the p value derived was significant < 0.0001, in both criterias ie, ease of insertion and number of attempts [8].

Duration of Insertion of Supraglottic Airway Device

In the study conducted by Bhandari et al they concluded that the time for successful ventilation with I-GEL was 20.92 seconds and 31.75 seconds in ILMA group {p < 0.001 }. In my study only 4 patients 13. 33% needed less than 10 seconds for insertion while all other patients needed more than 10 seconds. In I-GEL group all patients {100%} were inserted in less than 10 seconds. Thus it can be concluded from the above data and analysis I GEL was the better device for emergency rescue ventilation since the p value derived using unpaired t test was significant p < 0.0001 .

Blind Endotracheal Intubation

In the study conducted by Bhandari et al, first attempt success rate for blind tracheal intubation was comparable in both the groups and overall success rate in second attempt was higher in i-gel group as compared to ILMA group, unlike the results of Halwagi et al (2012) and Sastre et al (2012) who noticed higher success rate of blind tracheal intubation with ILMA. Bhandari et al observed that time for successful intubation through I-GEL was 20.41 seconds and 30 .68 seconds in ILMA group .

In our study 22 patients were intubated using ILMA in first attempt compared to only one patient in I-GEL. 5 patients in ILMA group needed second attempt and 18 patients in I-GEL group needed the same. 8 patients in I- GEL group needed third attempt but that was not the case in ILMA group. 3 patients in ILMA group were not attempted intubation since the insertion of SAD took more than three attempts in these patients. In I-GEL group intubation failed in three patients. The p value derived using fishers exact test was significant < 0.0001.

Also regarding the duration for intubation, 28 patients in ILMA group were intubated in less than 10 seconds only 2 patients needed more than 10 seconds. In I-GEL group only 4 patients were intubated in less than 10 seconds were as 23 patients needed more than 10 seconds. In 3 patients in I- GEL group intubation attempt failed. Thus it can be concluded that blind intubation using ILMA was better than I-GEL since the p value derived was also significant <0.0001 using unpaired t test .

Failure of Sad Insertion {More Than 3 Attempts}

In the study by Bhandari et al, they demonstrated 100% success rate both for I-GEL and ILMA and there were no failures in each group. In my study regarding SAD insertion only 3 patients in ILMA group needed more than 3 attempts and they were not attempted insertion and was considered as failure . In I-GEL group all 30 patients were inserted , either in the first or second attempt and thus no failures were recorded . Since the majority in each group had successful SAD insertion, it can be concluded that the association between the intervention groups and Failure of SAD Insertion (more than 3 attempts) status is considered to be not statistically significant since p >0.05 as per chi squared test.

Failure of Blind Endotracheal Tube Intubation

In the study by Bhandari et al and Halwagi et al both demonstrated a 100% success rate for blind

endotracheal intubation in either groups ie I-GEL and ILMA. This was done either in the first or second attempt using cricoid pressure in case of I-GEL and reverse orientation of the tube in case of ILMA. In our study majority of the patients in either group I-GEL and ILMA were intubated except in case if I-GEL group where there was 3 failures, because these patients needed more than three attempts and also duration went past 20 seconds. Since majority of the patients in both I-GEL and ILMA group were blindly intubated using SAD, it can be concluded that the association between the intervention groups and failure of blind endotracheal intubation status is considered to be not statistically significant since $p > 0.05$ as per fishers exact test.

Postoperative Sore Throat , Dysphagia , Hoarseness

In the study by Bhandari et al there were no incidence of sore throat or dysphagia in either groups [1]. in study conducted by Keijer et al incidence of sore throat was more in ILMA group. Sameer etal concluded that ILMA group had more incidence of dysphonia. In our study 14 patients in ILMA group complained of sore throat, dysphagia etc whereas only 5 patients in I-GEL group complained so and the p value derived was significant $p< 0.0125$. By conventional criteria the association between the intervention groups and postoperative dysphagia/ sore throat status is considered to be statistically significant since $p < 0.05$using Fishers exact test and it can be concluded ILMA has more chances of postoperative sorethroat and dysphagia.

Conclusion

It can be safely concluded from above study results that I-GEL is a better emergency ventilatory device comparable to the study by Kleine- Brueggeney et al and ILMA as better conduit for blind endotracheal intubation comparable to the study by Halwagi et al and Sastre etal but unlike Bhandari et al.

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