Comparative Evaluation of Supraglottic Devices i-gel and Fastrach LMA as Conduit for Blind Endotracheal Intubation

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ABSTRACT

Introduction: Recent supraglottic airway device (SAD) has been claimed to be efficient for airway management and can also be used as a conduit for endotracheal intubation. However intubating LMA is specifically used for this purpose. In the present randomized controlled study, success rate and ease of blind endotracheal intubation through two different SAD's "iGel" and LMA Fastrach was evaluated and their complication if any were also studied.

Material and Methods: The present study was being conducted in the department of anesthesia, M.L.B. Medical college, Jhansi, after approval from Hospital Ethical committee. The subject of study comprises of patients belonging to ASA I and II, Presenting for surgery under general anesthesia. After obtaining written and informed consent and a thorough evaluation patients are randomly divided in 2 groups, i.e. group A(i-gel) and group B(Fastrach), where igel and Fastrach LMA were used for Blind endotracheal intubation respectively. Following induction of anesthesia SAD was inserted and on achieving adequate ventilation, endotracheal intubation was attempted. Success at first attempt and overall success rates were noted as also the intubation time. Data were analysed using IBM SPSS Statistics 20.0 software (Statistical Package for Social Sciences by International Business Machines Corporation). $P < 0.05$ wasconsidered as statistically significant.

Results: Ventilation with either of the SAD was found to be adequate and no difference was found. The rate of success tracheal intubation in first attempt was 65% in Group A and 71.67% in Group B, while overall success rate of tracheal intubation was 88.33% in Group A when compared to 91.67% in Group B. Time taken for successful tracheal intubation through LMA Fastrach was lesser (21.50 sec) when compared to i-gel (26.90 sec). Complication rates were comparable in both the groups.

Conclusion: LMA Fastrach is a better device for blind intubation but as far as rescue ventilation is concern i-gel is better due to its easy and quick insertion.

Key words: i-gel, Blind Intubation, Laryngeal Mask Airway, LMA Fastrach.

INTRODUCTION

Endotracheal intubation is a definitive method of securing the airway and is routinely done by direct laryngoscopy and visualization of vocal cords. Inspite of this involves distortion of upper airway to bring larynx into the line of sight[1] and sometimes tracheal intubation fails in situations such as high larynx, facial trauma, etc. But disadvantages of tracheal intubation, which involves rigid laryngoscopy and associated concomitant hemodynamic responses and damage to the oropharyngeal structures at insertion, are the big concerns which questions its popularity.[2] Although these responses may be of short duration and of little consequence in healthy individuals, serious complications may occur in patients with underlying coronary artery disease, reactive airways, or intracranial neuropathology.[4]

Laryngeal mask airway (LMA) is a new concept and boon in airway management developed by British Anesthesiologist Dr. Archie Brain in 1983.[1] It is a highly satisfactory device in securing an airway[5], it's drawback with positive pressure ventilation (PPV), especially in obese patient and patient with decreased pulmonary compliance prompted him further to find a better airway device.

A number of supraglottic airway devices (SADs) are designed for use as a conduit to facilitate endo-tracheal intubation and use by primary responders at cardiac arrest or other emergencies outside the hospital. Supraglottic airway devices are intrinsically more invasive than use of a facemask for anaesthesia, but less invasive than tracheal intubation.

Major difference between standard c-LMA and LMA Fastrach lies in the makeup and function of the shaft which is rigid in LMA Fastrach as compared to soft silicone shaft of c-LMA which is helpful in doing adjusting maneuvers to align the mask's opening with that of glottis.

The i-gel is a new single-use SAD. It does not have an inflatable cuff, made from a soft, gel-like and transparent thermoplastic elastomer (styrene ethylene butadiene styrene). It creates a non-inflatable seal which is a mirror impression of the supraglottic anatomy. It has specific design features such as an epiglottic ridge, a gastric channel and a ridged flattened stem to aid insertion and reduce the risk of rotation. I-gel has also been used as a conduit for tracheal intubation and in rescue airway management.

The aim of this study was to compare the success rate of blind tracheal intubation through the i-gel versus the LMA Fastrach during general anesthesia in supine position in term of, ease of insertion, insertion attempts, insertion time and postoperative complications.

MATERIAL AND METHODS

The present study was conducted in the department of anesthesia, M.L.B. Medical college, Jhansi, following approval of Hospital Ethical committee. The subject of study comprised of patients belonging to ASA I and II, Presenting for surgery under general anesthesia. After obtaining written and informed

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consent and a thorough evaluation patients between 20 –65 yrs of age and weighing 35–70 kg were randomly allocated to 2 groups, i.e. group A and group B, where igel and Fastrach LMA were used for Blind endotracheal intubation respectively. ASA Grade III and IV, Anticipated difficult airway, Pregnant women, Patients with risk of hiatus hernia, Oro-pharyngeal pathology, Lung diseases associated with low compliance/high airway resistance, Cardiovascular disorders and Patients with anticipated full stomach were excluded.

Patients under study were divided into two groups as follows:-

Group-A Patients whose airway was managed with i-Gel.

Group-B Patients whose airway was managed with Fastrach LMA.

All patients were instructed to remain fasting for 8 hours prior to surgery and medicated night before surgery with Tab. Alprazolam 0.25mg and Tab. Ranitidine 150mg.

Intravenous fluid (ringer lactate /normal saline) was started. A multichannel monitor showing pulse rate, Electrocardiography, Oxygen saturation, Non-invasive blood pressure and End-tidal carbon dioxide ($EtCO_2$) was connected and base line reading was recorded. All patients of Group A and Group B were premedicated with Glycopyrrolate 0.2 mg, Midazolam 0.02 mg/kg and Fentanyl 2 µg/kg IV. Preoxygenation was done for 5 min and induced with Injection propofol 2 mg/kg IV in slow incremental dose till the loss of verbal command and ease of mask ventilation was noted. After confirming adequate mask ventilation, Vecuronium 0.1 mg/kg I/V was administered to facilitate intubation. Once the jaw relaxation was achieved, Supraglottic device was inserted. The investigator had experience of blind intubation with LMA Fastrach and i-gel each before the study on patients which were not included in this study.

According to body weight of the patient i.e No-3 SAD for 35-50 Kgs and No-4 SAD 50-70 Kgs selection of size of the LMA Fastrach and the i-gel was done.

For the lubrication of the SADs, water based lubricating jelly was applied on the dorsal surface of the device. Both SADs were introduced as per user guide provided by manufacturer. The i-gel was inserted in "sniffing morning air position" with flexion at neck and extension at atlanto-occipital joint, while the LMA Fastrach was inserted in neutral position. Adequate ventilation was confirmed by auscultation, chest movements and $EtCO_2$ waveforms. When there was an audible leak and ventilation was not adequate, while ventilating with an inspiratory pressure of 20 cm H_2O, different maneuver causing change in depth of insertion was performed. Use of different size of SAD was attempted if required.

The cuff was then inflated with upto 20 ml of air for size 3 and 30 ml of air for size 4 Fastrach LMA. After connecting to the Bain circuit, lungs were manually ventilated to check for an effective airway. Correct placement of SAD was confirmed by bilateral air entry and capnography

Time required for insertion of device was taken from removal of the facemask to the time where adequate ventilation was established through SAD with auscultatory and capnographic confirmation.

Silicon reinforced endotracheal tubes (ETT) were used for blind tracheal intubation in both the groups. Endotracheal Tube was lubricated with lubricating jelly(water-based) and checked for passage through device prior to insertion. Size 7.0/7.5 mm internal diameter (ID) ETT will be used in patients weighing > 50 kg and 6.0 mm ID ETT for patients < 50 kg.

In group A, ETT was rotated 90° counter-clockwise during insertion which was used earlier by Halwagi et al[6] and found increase in success rate, so it was used in our study. If the resistance was felt during insertion of ETT, device was readjusted and stabilized at the point of maximum ventilation and chest expansion, and an assistant was asked to perform external laryngeal manipulation by applying backward pressure on thyroid cartilage had increased success rate of intubation and decrease the chances of impingement of bevel of ETT on glottic structures.

In group B, If resistance was encounter during insertion of tracheal tube, a standardised maneuver and algorithm was applied on the basis of the distance at which the resistance was felt, as recommended by manufacturer. Chandy's Maneuver increase rate of ET tube insertion. If no resistance was felt during insertion of tracheal tube, it was advanced fully into the ILMA. Intubation was consider successful, if adequate ventilation produced a chest rise and a capnographic waveform. Time required for blind endotracheal intubation was defined from disconnection of the breathing circuit from SAD to auscultatory and capnographic confirmation of the tracheal intubation and SAD was then removed.

In both groups, three attempts at device insertion and intubation were allowed with proper preoxygenation before each attempt. Attempt of Intubation was only be allowed if appropriate ventilation was obtained through SAD. If blind tracheal intubation through the SAD was not successful, it was performed by direct laryngoscopy and it was considered as a failure and duly recorded.

Anaesthesia was maintained with nitrous oxide and oxygen (66:33), isoflurane and incremental doses of vecuronium using O_2 and N_2O in ratio of 1:2 and Isoflurane. After completion of surgery, the residual neuromuscular blockade reversal was achieved with neostigmine (50 microgram/kg) and glycopyrrolate (10 microgram/kg).

During postoperative period and upto 24 h patients were evaluated for any adverse event or postoperative complaints such as sore throat, pain on swallowing and hoarseness and treated accordingly if required.

To evaluate a 10% difference in first attempt success rate in ETT insertion between devices with a type-1 error of 0.05 and a power of 90%, sample size was estimated and 60 patients in each group were included to allow for potential drop outs.

STATISTICAL ANALYSIS

We analysed distributed data by using *t*-test, and categorical data by Chi-square test. Continuous data were recorded as mean and standard deviation, whereas categorical data were recorded as number of patients and percentage which was analysed using IBM SPSS statistics 20.0 software. $P < 0.05$ was considered statistically significant.

RESULTS

Out of 174 patients, 45 were excluded and 9 didn't give informed consent, remaining 120 were randomly divided into two group of 60 each. Demographic data are similar and comparable in

Variables	Group A	Group B	P Value
Sex (M/F)	24/37	27/33	0.712
Age (years) Mean± S.D	31.917±10.247 yrs	30.867±8.460 yrs	0.542
Weight (Kg) Mean± S.D	51.717±6.618	50.633±6.987	0.384

Table-1: Demographic characteristics

SAD detail	Group A		Group B		
	No. of Patient	%	No. of Patient	%	
SAD Insertion					
First attempt	50	83.3%	39	65%	
Second attempt	7	11.7%	16	26.7%	
Third attempt	3	5%	5	8.3%	
Failed	0	0%	0	0%	
Total	**60**	**100%**	**60**	**100%**	
Time of insertion	**Mean**	**S.D**	**Mean**	**S.D**	**P value**
First attempt	18.500	± 1.212	29.641	± 1.063	<0.0001
Second attempt	27.857	±2.478	41.125	±1.586	<0.0001
Third attempt	42.333	±2.517	50.6	±1.516	0.0010
Over all	20.850	±5.965	34.45	±7.141	<0.0001

Table-2: Details of Airway device insertion

ETT detail	Group A		Group B		
	No. of Pt	%	No. of Pt	%	
ETT Insertion					
First attempt	39	65.00%	43	71.67%	
Second attempt	8	13.33%	8	13.33%	
Third attempt	6	10.00%	4	6.67%	
Failed	7	11.67%	5	8.33%	
Total	**60**	**100%**	**60**	**100%**	
Time for insertion	**Mean**	**S.D**	**Mean**	**S.D**	**P value**
First attempt	23.000	±1.433	18.953	±0.925	<0.0001
Second attempt	32.375	±2.446	27.750	±1.389	0.0004
Third attempt	45.000	±2.000	36.500	±2.517	0.0003
Over all	26.906	±7.517	21.509	±5.374	<0.0001

Table-3: Details of ETT Insertsion

S. No	Morbidity	Group A		Group B	
1.	Laryngospasm	0	0%	0	0%
2.	Sore throat	11	18.33%	14	23.33%
3.	Hoarsness of voice	8	13.33%	10	16.67%
4.	Trauma to airway	2	3.33%	3	5%
5.	Nausea and Vomiting	15	25%	19	31.67%

Table-4: Comparision of postoperative Morbidity

both groups in term of sex, age and weight [Table 1].

There was no difference found in insertion of SAD and ventilation through SADs between the two groups, that is, i-gel and ILMA. With the first attempt of SAD insertion, the successful ventilation rate was 83.3% in A group and 65% in B group with a time of insertion in first attempt was 18.5±1.212 for group A and 29.641±1.063 for group B respectively. With the second and third attempts of SAD insertion, the successful ventilation rate was 100% in both the groups. Total time to achieve successful ventilation with SAD was shorter in group A [Table 2]. With the first attempt, blind tracheal intubation was successful in 65% cases (39patients) of A group and in 71.67% cases (43 patients) of group B. With the second attempt, blind tracheal intubation was successful in 78.33% cases (47 patients) of group A and 85% cases (51 patients) of group B. Time to achieve successful intubation through the SADs was 23.00±1.433 s in the group A when compared to 18.953±0.925 s in group B (P <0.0001) in first attempt while it was 26.906±7.517 s for group A and 21.509± 5.374s for group B respectively [Table 3]. In regards to postoperative morbidities both groups were comparable [Table 4].

Demographic data were similar and comparable in both groups in term of sex, age and weight [Table 1]. In group A, insertion success rate was 83.3% for 1st attempt, 11.7% for 2nd attempt and 5% for 3rd attempt. In group B, insertion success rate was 65% for 1st attempt, 26.7% for 2nd attempt and 83% for 3rd attempt. Overall success rate was 100% in each group. There were no failed insertion of SAD were found in either group.

There was significant difference in time taken for insertion of SAD, more time required in group B in comparison to group A (p ≤.0001) in respect to number of attempts and overall time.

In group A, success rate of Endotracheal intubation through SAD was 65% in 1st attempt, 13.33% in 2nd attempt and 10% in 3rd attempt with 11.67% Failed intubation.

In group B, success rate of Endotracheal intubation through SAD was 71.67% in 1st attempt, 13.33% in 2nd attempt and 6.67% in 3rd attempt, with 8.33% of failed intubation.

Number of successful ET tube insertion on 1st, 2nd and 3rd attempts in both the groups were similar and comparable.

There was significant difference in time taken for endotracheal

intubation through SAD, more time required in group A in comparison to group B ($p \leq 0.0004$) for 1st, 2nd and 3rd attempt. The number of failed intubation through SAD in each group i.e 5 (8.33%) in group B and 7 (11.67%) in group A were excluded for further studies and comparison (table-3).

Inference

Incidence of laryngospasm was 0% in both groups. Incidence of sore throat was more in group B i.e 23.33% (14/60) compared to 18.33% (11/60) in group A. Hoarseness of voice was more in group B i.e 16.67% (10/60) compared to 13.33% (8/60) in group A. Trauma to airway was more in group B i.e 5% (5/60) compared to 3.33% (2/60) in group A. Nausea and Vomiting was more in group B i.e 31.67% (19/60) compared to 25% (15/60) in group A. Overall post-operative morbidities were found to be comparable and insignificant.

DISCUSSION

In present study insertion success rate in group A was 83.3% for the 1st attempt while in Group B, it was 65% for the 1st attempt. There was no failed insertion in either group. Overall success rate of insertion of supraglottic devices and adequate ventilation in both the groups was 100% which was similar to various previously conducted studies.[3,6,7,9] The difference in results of present study to that was conducted by Halgawi A,et al[6] 2012, Kapoor S et al[3] 2014 and G. Bhandari et al 2013[7] which was might be due to anatomical variation of airway to the size of SAD in this region and less familiarity with LMA Fastrach than i-gel during the present study. And was found to similar to that conducted by Sastre et al (2012)[9] Time taken in one, two, three attempts and overall time both groups shows significant statistical difference which coincides to the result of Sastre et al (2012)[9], Halgawi A,et al[6] 2012, Kapoor S et al[3] 2014 and G. Bhandari et al 2013.[7] This difference of time is probably due to i-gel structure, which has non-inflatable seal that is a mirror impression of the supra-glottic anatomy.

As far as intubation through SADs is concerned, Fastrach provided better intubating conditions with a high 1st attempt success rate (71.67%) as compared to that of i-gel(65%). The overall success rate was also higher with group B (91.6%) than group A (88.33%) which coincides with the results of Kapoor S et al[3] 2014, Halwagi et al. (2012)[6] and Sastre et al. (2012)[9] noticed higher success rate of blind tracheal intubation with ILMA. This could be due to design of fastrach which is especially mend for endotracheal intubation than igel which is a supraglottic device, can be used as a conduit for intubation and a "V" shaped tracheal tube guiding ramp in LMA Fastrach that centralizes the ET Tube towards the glottic aperture as the ET Tube emerges from the metal shaft and guides it anteriorly to reduce the risk of arytenoids trauma and oesophageal placement[13] and the presence of the handle in LMA Fastrach which resulted in stabilization and manipulations which could not be done in i-gel. So in group A, external manipulation of the larynx needed to be done. Therefore when first attempt of blind intubation was unsuccessful in group A, stabilization of i-gel at the point of maximum chest expansion by readjustment was done and took the help of an assistant to apply external laryngeal pressure. This resulted in better overall success rate of ET tube insertion through i-gel (88.67%) as compared to studies by Halwagi et.al[6] (73%), Kapoor S et al[3] (82%), Bhandari et al 2013[7] (77.5%) and Sastre et.al[9] (40%). In group B, ET tube was inserted with reverse orientation[10-12] as this method resulted in higher success rate in various studies.[10-12] It optimizes the ET tube with the angle of trachea resulting in better first-attempt success rate of ET tube insertion.

Time taken for Endotracheal intubation by Fastrach LMA was 18.953±0.925 seconds (mean±SD) for one attempt with overall mean of 21.509±5.374 seconds (mean±SD) while that of igel was 23.00±1.433 seconds (mean±SD) for one attempt with overall mean of 26.906±7.517 seconds (mean±SD). Showing that intubation through Fastrach LMA took lesser time than i-gel, which is found to be statistically highly significant($p<0.0001$) and are in agreement to Kapoor S et al[3] 2014, Halwagi et al. (2012)[6] and Sastre et al. (2012)[9] less time taken in intubation through fastrach. On the contrary Bhandari et al 2013[7] showed lesser time with i-gel as compare to fastrach LMA group, which they attribute to use of i-gel regularly.

However, 8.33% patients in group B and 11.33% in group A failed to be intubated during the study, requiing laryngoscopic intubation, and was thus excluded from further study and comparison. This failure was found more during initial stage might be due to less familiarity to SADs as conduit for endotracheal intubation.

In present study hemodynamic changes were comparable as is showed by insignificant statistical difference during induction, SAD insertion, intubation and throughout the surgery.

Incidence of nausea and vomiting was high in both groups as compare to other morbidity, but was comparable and found to be insignificant. This high incidence of nausea was due to anesthetic drugs, inhalational agents, long duration of surgery. Incidence of post-operative morbidities are comparable and in agreement with Keijzer et al[8] (2009), Sastre et al (2012)[9], Halgawi A, et al[6] 2012, Kapoor S et al[3] 2014 and G. Bhandari et al 2013.[7]

The use of wire reinforced tubes would have resulted in better success rate as used in present study, but conventional PVC tubes are readily available and cheaper. However, in LMA Fastrach, there was no difference in successful blind tracheal intubation with conventional tracheal tube and silicon wire reinforced tracheal tube in studies conducted by Lu et al.[11] and Kundra et al.[14] but in case of i-gel further studies are required.

It can therefore be inferred that both Fastrach LMA and i-gel are suitable devices to be used as conduit to endotracheal intubation particularly in susceptible patients where hemodynamic disturbances during intubation are not required. I-gel seems to have an edge over fastrach due to its ease of insertion, intubation and cost effectiveness.

CONCLUSION

It can therefore be concluded that both Fastrach LMA and i-gel are suitable devices to be used for ventilation and also as conduit to endotracheal intubation particularly in susceptible patients where hemodynamic disturbances during intubation are not required. I-gel seems to have an edge over fastrach due to its ease of insertion, intubation and cost effectiveness.

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