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A Comparative Study of Airway Management and Hemodynamic Response During Insertion of I-Gel Airway, Laryngeal Mask Airway, Cuffed Endo-Tracheal Tube

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ABSTRACT

Background: Securing a safe airway is essential for oxygenation and ventilation in management of critical patients in all specialities and during conduction of anaesthesia. Endotracheal tubes has been the mainstay for airway control. Hence need for various devices to secure airway was realized, leading to development of many supraglottic devices. **Methods:** This prospective, randomized study was conducted in a tertiary care teaching hospital. It included 90 American Society of Anesthesiologists (ASA) grade I-II patients, randomly allocated into 3 groups, undergoing elective surgical procedures under general anaesthesia. It was designed to compare cETT, cLMA and i-gel LMA. Primary outcome measure was number of insertion attempts. We also compared ease of insertion, insertion time, haemodynamic changes and incidences of airway trauma and complications. For statistical comparison pearson's chi-square test for nominal data, ANOVA test for comparison between multiple variables within the study and control groups and unpaired t-test to compare numerical variables were used. **Results:** The First attempt insertion success and ease of insertion for the three devices were comparable, with i-gel scoring the highest among all. Mean time of insertion was lowest for i-gel (16.83s±3.49s) followed by cLMA (25.23±5.46s) and cuffed ETT (27.6±4.3s), which was statistically significant. The basal vitals with respect to heart rate, systolic, diastolic and mean blood pressure were comparable in all the three groups. **Conclusion:** It may be concluded that use of i-gel airway offers more favourable hemodynamic stability as compared to endotracheal tube and cLMA and is associated with less postoperative complication.

Keywords: Airway management; i-gel; Intubation, Intratracheal; Laryngeal Masks; Respiration, Artificial.

INTRODUCTION

Securing a safe airway is essential for oxygenation and ventilation in conduction of anaesthesia and management of critical patients. Use of face mask and the endotracheal intubation was the mainstay in the management of airway till 1990. In-spite of this, difficulties were encountered in many cases for mask ventilation and endotracheal intubation. Hence need for other devices to secure airway was realized and then many supraglottic devices were developed of which the laryngeal mask airway (LMA) and i-gel airway are the most popular one.[1,2]

Many studies have been done to compare i-gel with Proseal-LMA. But not many studies have been done to compare the clinical uses of the two supra glottic airway devices namely I-gel and classic-LMA (cLMA) in comparison to the most widely used cuffed endotracheal tube (cETT). In this study, we compared i-gel LMA, cLMA and cETT under general anaesthesia for elective surgeries. Primary outcome measure was number of insertion attempts. We also compared ease of insertion, insertion time, haemodynamic changes and incidences of airway trauma and complications.

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MATERIALS AND METHODS

After approval from the Institutional Ethical Committee, ninety patients were studied in a randomized prospective study, designed to compare cETT, cLMA and i-gel LMA. This study was conducted according to Good Clinical Practice standards and the Helsinki Declaration. Our study followed the CONSORT recommendation. (Fig 1) The period of the study was from June 2015 to June 2016.

American Society of Anesthesiologists (ASA) class I & II patients, between the age of 20-50 years of either sex, with MPS I and II undergoing elective surgical procedure of duration 1-1½ hour were

selected for the study. The exclusion criteria included patients having ASA grade III and above, patients with recognised or threatened risk of gastro oesophageal reflux, obese patients with BMI > 30, pregnant women, laparoscopic procedures, coexisting cardiac diseases and/or patients on anti-hypertensive medication or any medication that effect the cardio-vascular system.

Following detailed pre-anaesthetic check-up, informed written consent was obtained from patient fulfilling the required criteria. Ninety patients were equally randomized to three groups namely Group A (i-gel, n=30), Group B (cLMA, n=30) and Group C (cETT, n=30). Randomization was done by an anaesthetist who was not involved in the operating room procedure through a computer-generated randomization programme. Participants were assigned to specific groups by the operating room nurse in-charge.

After attaching the standard monitors (ASA Recommended) patients were premedicated with injection Midazolam 0.05mg/kg, Glycopyrrolate 0.2mg, Ranitidine 50mg, Ondansetron 4mg and Fentanyl 2mcg/kg intravenously. All patients were pre-oxygenated for 3 minutes and anaesthesia was induced with injection Propofol 2mg/kg body weight. Relaxation was initiated with inj succinycholine (1.5mg/kg). Once adequate depth was achieved (i.e. absence of eyelash reflex, easy up and down movement of lower jaw, no reaction to pressure applied to both angles of mandibles) cETT or cLMA or i-gel appropriate for weight of patient was selected and lubricated with water soluble jelly and inserted as per the manufacturers guidelines.

An effective airway was confirmed by bilateral symmetrical chest expansion on manual ventilation, Auscultation of breath sounds, square waveform on capnography, stable oxygen saturation, no audible leak of the gases and lack of gastric insufflations. After successful insertion, the cuff of the ETT and cLMA were inflated with air. Air insufflation was done according to size and type of device. The device was fixed from maxilla to maxilla.

Anaesthesia was maintained with Oxygen, Nitrous oxide and Sevoflurane with intermittent doses of Vecuronium as muscle relaxant in closed circuit with a circle absorber and ventilated with intermittent positive pressure ventilation. At the end of surgical procedure anaesthesia was discontinued and patient reversed with standard dose of Neostigmine and Glycopyrrolate and device removed. Complication if any, were noted.

Patients were continuously monitored in the intra-operative period and various predefined parameters were noted. Insertion attempts were recorded as number of attempts required for the insertion of each device was noted. The ease of insertion was graded subjectively on a scale from 1 to 3 as very easy, easy and difficult respectively. Insertion of device was recorded as; very easy (when assistant help was not required), easy (when jaw thrust was needed by assistant) and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion).[3] Insertion time was defined as time required from picking up the device, to the time of confirmation of effective ventilation by bilateral symmetrical chest movement, square waveform on capnograph, normal range end tidal CO2 and stable SpO2 (>95%).[2,4-7] Cardiovascular and Haemodynamic changes which included pulse rate, non-invasive blood pressure (NIBP) - systolic and diastolic, mean arterial pressure (MAP). The haemodynamic parameters were measured before induction (BL), just after insertion of device (A0), 1 minute, 3 minutes and 5 minutes post insertion of devices (A1, A3, A5).

The patient was inspected for any injury of the lips, teeth or tongue and the device was inspected for blood stain after its removal at the end of the surgery.[3] Patient was interviewed for any post-operative complications 18-24 hours after surgery like sore throat, dysphagia and hoarseness. Post-operative sore throat was graded as nil, mild, moderate and severe.[6,8]

Statistical analysis

The data was documented in Microsoft excel sheets and analysed using SPSS statistics software version 24 (IBM SPSS Inc., Chicago, IL, USA). Pearson's chi-square (with continuity correction where applicable) test for nominal data. One-way analysis of variance (ANOVA) test for comparison between multiple variables within the study and control groups. Unpaired t-test to compare numerical variables.

Values were reported as the mean ± SD; statistical significance was attributed to two-tailed $P<0.05$.

RESULTS

The overall demographic profile of the patients was comparable among the all the three groups. [Table 1]

First attempt insertion success was 97% with i-gel, 90% with cLMA and 83% with cETT. Though the success rate was more with i-gel and cLMA in comparison to cuffed ETT intubation, it had no statistical significant. [Table 2].

The ease of insertion of devices was noted to be very easy in 97% of patients of i-gel group, where difficulty in placement was noted in only 1 patient. For cETT and cLMA the insertion was deemed very easy in 80% and 87% respectively. In cETT group 17% cases required assistance and were therefore considered easy. On the contrary with cLMA, only one patient required assistance. Among all the three groups no statistical significance was noted. [Table 2]

Mean time of insertion was lowest for i-gel, i.e. 16.83s±3.49s followed by 25.23±5.46s for cLMA

and 27.6±4.3s for cuffed ETT which was statistically significant. [Table 2]

The basal vitals with respect to heart rate, systolic, diastolic and mean blood pressure were comparable in all the three groups. [Table 3] Statistical evaluation showed no significant difference in change in HR between groups i-gel and cLMA before, during and after insertion. In cETT group pulse rate increased immediately after laryngoscopy and intubation as compared to baseline and it decreased after 1 min but the value was more than baseline even after 5 min. The pulse in ETT group was also statistically higher after insertion and even after 1, 3 and 5 min. ($p<0.01$). Similarly, results were comparable between i-gel and cLMA group for systolic, diastolic and mean blood pressures. While with ETT, blood pressure parameters rose significantly after insertion. Statistically comparing the three groups there is significant difference between them. ($p<0.01$)

Higher incidence of lip injury was noted in cLMA group. The incidence of sore throat and dysphagia in cETT group was as high as 12 and 4 patients respectively as compared with the i-gel and cLMA groups. 6 patients in cLMA group experienced dysphagia as compared to 4 in i-gel and 2 in cETT group.

Table 1: Comparison of Demographic data.

Parameters	Group-A (i-gel, n=30)	Group-B (cLMA, n=30)	Group-C (cETT, n=30)
Mean Age (Years)	37.37±10.6	34.2±10.6	34.63±7.41
Gender (F/M)	26/04	24/06	25/05
Mean Weight (Kgs)	55.5±13.52	55.5±13.53	55.5±13.54

Data are presented as number of patients and mean ± SD.

Table 2: Comparison of Device parameters

Parameter	Group-A (i-gel, n=30)	Group-B (cLMA, n=30)	Group-C (cETT, n=30)	p Value
Insertion Attempts (1st/2nd/3rd)	29/01/00	27/03/00	25/04/01	0.5
Ease of insertion (Very easy/Easy/Difficult)	29/00/01	25/02/03	24/05/01	0.1
Insertion Time (Sec)	16.83±3.49	25.23±5.46	27.6±4.3	<0.001*

Data are presented as number of patients and Mean ± SD. There is statistically significant difference between groups (*).Group-A: i-gel, Group-B: cLMA, Group-C: cETT

Table 3: Comparison of Haemodynamic variables between the three group.

Parameter	Measurement at	Group-A (i-gel, n=30)	Group-B (cLMA, n=30)	Group-C (cETT, n=30)	p-Value
Heart Rate (HR)	Basal (BL)	82.77±14.93	85.07±15.28	86.77±7.60	0.497
	Insertion (A0)	96.57±17.03	92.8±12.28	120.87±8.64	p<0.01*
	1 min(A1)	88.83±15.04	89.033±12.38	125.77±21.02	
	3 min(A2)	84.87±12.03	88±13.29	134.67±8.17	
	5 min(A5)	80.43±12.24	86.9±12.87	111.33±8.095	
Systolic BP (SBP)	Basal (BL)	120.167±10.62	117.53±10.53	121.933±4.60	0.171
	Insertion (A0)	133.2±16.17	129.97±9.47	144.33±8.40	P<0.01*
	1 min(A1)	122.87±9.96	120.433±13.25	155.8±7.15	
	3 min(A2)	117.7±9.39	114.7±10.18	161.86±6.58	
	5 min(A5)	116.33±7.68	111.033±9.45	136.733±7.80	
Diastolic BP (DBP)	Basal (BL)	74.5±9.89	75.9±10.30	82.67±4.01	0.70
	Insertion (A0)	79.4±10.28	87.56±13.09	98.13±5.55	P<0.01*
	1 min(A1)	78.133±10.25	81.83±10.44	100.67±5.47	
	3 min(A2)	74.4±8.04	76.3±8.7	103.2±5.21	
	5 min(A5)	74.4±9.85	74.43±9.30	92.33±3.40	
Mean BP (MAP)	Basal (BL)	89.72±9.11	89.78±8.66	95.76±3.97	0.32
	Insertion (A0)	97.33±10.48	101.7±10.36	113.53±5.13	P<0.01*
	1 min(A1)	93.04±8.53	94.70±10.04	119.04±4.85	
	3 min(A2)	88.83±6.98	89.10±8.16	122.76±4.66	
	5 min(A5)	88.38±8.00	86.63±8.07	107.13±3.85	

DISCUSSION

Laryngoscopy and tracheal intubation, to achieve airway control in anaesthesia practice; have been consistently bothering anaesthesiologist with regards to regular occurrence of the pressure responses associated with it. It has adverse effects on cardiovascular system. The present study was designed to assess the suitability of i-gel and cLMA as a substitute to conventional laryngoscopy and intubation.

In the present study, 90 cases were selected and randomly assigned to demographically three identical groups of 30 each and responses to airway management and hemodynamic response during insertion of i-gel airway, laryngeal mask airway, cuffed endotracheal tube were compared.

The first attempt insertion success was highest with i-gel similar to studies in the past.[9-13] In study by Janakiram et al,[14] the success rate with first time i-gel insertion was only 54% and with LMA it was

86% which was statistically highly significant. The result was attributed to use of larger sized i-gel in 14 patients which led to presence of audible leak and hence required 2nd attempt. However, in our study we did not have such problem and hence the success rate of first time insertion was comparable between both the devices.

In study of Pennanth JH et al,[15] ninety-four percent of the students successfully ventilated the lungs on their first attempt with the LMA, whereas only 69% intubated the trachea on their first attempt with the ETT ($P < 0.01$). This corroborates to our study. Though the values in our study comparing the three was not statistically significant, these results reiterate that LMA requires less attempt than ET Tube.

One of the objective was to compare the ease of insertion between the devices. In our study, the insertion of i-gel was found comparatively easier and required less skill as compared to cLMA and ETT. Similar results were found in studies done in past.[16,17,12,14] As also reported by Pennanth JH et al.[15] cLMA was easier to insert than ETT, though no statistical significance was observed.

The time for insertion of i-gel (16.8s) was shorter compared to LMA (25.2s). The i-gel having a non-inflatable cuff and firm in consistency is much easier for insertion as compared to LMA. The i-gel is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to c-LMA which has a cuff to be inflated after its insertion. Consistent with our results, is the study result of Franksen H et al,[10] Amini S et al,[11] Ali A et al.[17] The mean insertion time of cETT was 27.7s which was more than the other two devices, which was similar to study of Watcha MF et al,[18] who found that the insertion time of the LMA required significantly less time as compared to ET Tube.

During the insertion of LMA and i-gel, pressor response (i.e. increase in heart rate and arterial pressure), may be induced by the passage of device through the oral and pharyngeal spaces, pressure produced in the larynx and the pharynx by the inflated cuff and the dome of the LMA. But in ET Tube both laryngoscopy and intubation too induce pressor response. In our study, there was no statistically significant difference between i-gel and LMA with regard to change in heart rate, systolic, diastolic and mean blood pressure. The results of our study were similar to the studies done by Helmy AM et al.[13] Franksen H et al.[10] who in their studies found no significant difference between i-gel and cLMA with regard to haemodynamic.

Jindal P et al.,[19] in their study observed that i-gel produced less haemodynamic changes compared to other SADs. The authors concluded that i-gel effectively conforms to the peri-laryngeal anatomy despite the lack of an inflatable cuff, it consistently achieves proper positioning for supraglottic ventilation and causes less hemodynamic changes as compared to other supraglottic airway devices like LMA which because of an inflatable cuff can produce more haemodynamic changes. The baseline pulse rate, SBP, DBP, MAP increased significantly after insertion of i-gel and LMA but started decreasing in 1 min and came to baseline in 3 minutes and by 5 minutes to preoperative value. Whereas in ETT group, baseline pulse rose significantly immediately after laryngoscopy and intubation it decreased after 1 min but was much more than baseline even after 5 min and did not reach the baseline. The pulse in ETT group was also statistically higher after insertion and even after 1, 3 and 5 min ($p<0.01$). Shetty AN et al,[20] conducted a study and found that LMA is a good alternative to endotracheal intubation with minimum hemodynamic response and side-effects. Many studies from the past also have had similar conclusions.[21-23]

During insertion of the inflatable supra glottis airway devices, the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue and can cause pharyngeal injury. Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury.

The patients in our study were inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery, however no significant injuries were noted.

Postoperatively, i.e. 18-24 hours after surgery, patients were interviewed for any complications like sore throat, dysphagia and hoarseness. Only 1 patient in i-gel group had developed sore throat post operatively compared to 1 patients in LMA group and 12 pts in ETT group. The incidence was not statistically different when compared between the groups. The sore throat in all the cases were mild requiring no treatment.

Our results were consistent with the studies done by Siddiqui AS et al.[12] In publications by Franksen H et al.[10] Helmy AM et al.,[13] the difference between LMA and i-gel regarding post-operative complications was not statistically significant except nausea and vomiting which was significantly higher in LMA due to high incidence of gastric insufflation. In study by Keijzer C et al,[24] there was a higher incidence of sore throat and dysphagia at 1, 24, and 48 hours in the LMA group compared with the i-gel group. Because of the absence of an inflatable cuff, the authors hypothesized that use of the i-gel produced fewer postoperative throat and neck complaints compared with a standard LMA.

CONCLUSION

It may be concluded that use of i-gel airway offers more favourable hemodynamic stability as compared to endotracheal tube and cLMA and is associated with less postoperative complication as it is

minimally invasive to the airway and it may be consider as an important adjunct in minimizing the pressure responses to laryngoscopy and intubation. The most commonly used device ET Tube produces the maximum pressor response.

REFERENCES

1. Brimacombe J, Berry A, Brain AIJ. The laryngeal mask airway: In: Sandier AN, Doyle DJ, eds. The difficult. airway: I. Philadelphia : WB Saunders, 1995: 411-37.
2. Rasanan J. The Laryngeal mask airway. First class on Difficult Airway. Finnanest 200:33(3);302-05.
3. Davies PRF, Tighe SO, Greenslade GL, Evans GH. Laryngeal mask airway and tracheal tube insertion by unskilled personnel. Lancet 1990; 336: 977-9.
4. Aro L, Takki S, Aromaa. Technique for difficult intubation. Br. J. Anaesth 1971; 43: 1081.
5. Kannaujia A, Srivastava U, Saraswat N, Mishra A, Kumar A, Saxena S. A Preliminary Study of i-gel:A New Supraglottic Airway. Indian Journal of Anaesthesia 2009;53(1):52-6.
6. Keller C, Brimacombe J, Bittersohl J, Lirk P, Goedecke A. Aspiration and the laryngeal mask airway: three cases and a review of the literature, British Journal of Anaesthesia 2004;93(4):579-82.
7. Killian G: Ueber directe Bronchoskope. Munch Med wochenschr 45:844-847;1898.
8. Teoh WHL, Lee KM, Suhitharan T, Yahaya Z, Teo MM, Sia ATH.Comparison of the LMA Supreme vs the i-gel in paralysed patients undergoing gynaecological laparoscopic surgery with controlled ventilation, Anaesthesia 2010;65:1173-9
9. Uppal V, Gangaiah S, Fletcher G, Kingsella J. Randomized crossover comparison between the i-gel and the LMA-Unique in anaesthetized, paralysed adults. Br J Anaesth 2009;103(6):882-5.
10. Franksen H, Renner J, Hanss R, Scholz J, Doerges V, Bein B. A comparison of the i-gel™ with the LMA-Unique in non-paralysed anaesthetised adult patients. Anaesthesia 2009;64:1118-24.
11. Amini S, Khoshfetrat M. Comparison of the Intersurgical Solus laryngeal mask airway and the i-gel supralaryngeal device. Anaesthesia 2010;65(8):805-9.
12. Siddiqui AS, Raees US,Siddiqui SZ, Haider S, Raza SA. Comparison of performance and safety of i-gel with laryngeal mask airway (classic) for general anaesthesia with controlled ventilation. Anaesth, Pain and Intensive Care 2010;14(1):17-20.
13. Helmy AM, Atef HM, El-Taher EM, Henidak AM. Comparative study between i-gel, a new supraglottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients, Saudi J Anaesth2010;4(3):131-6)
14. Janakiraman C, Chethan DB, Wilkes AR, Stacey MR, Goodwin N. A randomised crossover trial comparing the i-gel supraglottic airway and classic laryngeal mask airway. Anaesthesia 2009;64:674-8.
15. John H. Pennant et al (1993): comparison of endotracheal tube and LMA in airway management by paramedical personnel: Anaesthesia analgesia, 1992: 74 ; 531-534 Crawford D.C. et al : Br. J. Anaesthe.:1987; 39;707.
16. Richez B, Saltelf L, Banchereaur, Torrielli, Cros AM. A New Single UseSupraglottic Airway Device with a Noninflatable Cuff and an EsophagealVent:An Observational Study of the i-gel. Anesth Analg 2008;106(4):1137-9.
17. Ali A, Ali L, Sheikh NA, Siddique SA. Airway device: comparison of i-gel supraglottic with laryngeal mask airway. Professional Med J 2010 Dec;17(4):643-7.
18. Watcha MF, White PF, Tychsen L, Stevens JL.Comparative effects of laryngeal mask airway and endotracheal tube insertion on intraocular pressure in children. Anesth Analg. 1992 Sep;75(3):355-60.
19. Jindal P, Rizvi A, Sharma JP. Is i-gel a new revolution among supraglottic airway devices? A comparative evaluation. MEJ Anesth 2009;20(1):53-8.
20. Shetty AN, Shinde VS, Chaudhari LS. A comparative study of various airway devices as regards ease of insertion and haemodynamic responses. Indian J Anaesth 2004 ; 48(2) : 134 -137.
21. Braude N, Clements EAF, Hodges UM, Andrews BP. The pressor response and laryngeal mask insertion – A comparison with tracheal intubation Anaesthesia 1989;44;551-54.
22. I.G. Wilson, D. Fell, S.L. Robinson and G. Smith : "Cardiovascular responses to insertion of the laryngeal mask". Anaesthesia 1992 ; volume 47, page 300-02.
23. Alexander CA, Leach AB. Incidence of sore throat with the laryngeal mask. Anesthesia 1989; 44: 791.
24. Keijzer C, Buitelaar DR, Efthymiou KM, Sramek M, Cate J, Ronday M, et al.A Comparison of postoperative throat and neck complaints after the use of the i-gel and the La Premiere disposable laryngeal mask: A double blinded, randomized, controlled trial. Anaesthesia and Analgesia 2009;109(4):1092-5.

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