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ORIGINAL RESEARCH

Evaluation of the Efficacy of I-gel Supraglottic Airway Device in Relation to Ease of Insertion, Time Taken to Establish Effective Ventilation and Gastric Insufflation

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ABSTRACT

Introduction: I-gel is a novel supraglottic airway device with anatomically designed, non-inflatable mask, which is soft gel like and transparent made of medical grade thermoplastic elastomer called styrene ethylene butadiene styrene.The present study is carried out to evaluate the efficacy of I-gel with regard to easiness of insertion of I-gel, number of insertion attempts, time taken and maneuvers required; time taken to establish effective ventilation and gastric insufflation.

Material and Methods: A prospective randomized controlled study was conducted on 40 patients scheduled for elective surgical procedures and requiring controlled ventilation. Patients were induced with thiopentone 4-6 mg/kg. Size 3 I-gel was used in patients weighing 30-60 kg and size 4 I-gel was used in patients weighing 60-90 kg. Correct I-gel insertion was assessed clinically by subjective assessment of appropriate length of airway tube outside the mouth, gastric insufflation and adequacy of manual ventilation which was assessed by proper chest expansion and presence of CO_2 waveform.

Results: The study included the patients with MMP classI/II and ASA grade I/II. The mean time taken for insertion was 14.75±1.48 seconds and 95% patients required single attempt for successful device insertion and 5% patients required second attempt for successful device insertion. In two patients head tilt and chin lift maneuver was used for the correct placement of the device.In 38(95%) patients the insertion of the I-gel was scores very easy(grade1) and in 2(5%) patients it was scored easy(grade 2).

Conclusion: I-gel is an effective supraglottic airway device which can be rapidly inserted. It provides a leak free glottis seal during positive pressure ventilation. The nasogastric tube can be easily placed.

Keywords: Anaesthesia; I-gel; supraglottic airway device.

INTRODUCTION

Supraglottic airway devices (SADs) are devices that keep the upper airway clear for unobstructed ventilation. SADs have also been called supraglottic airways and extraglottic or periglottic airway devices. [1] The presently available supraglottic airway devices like LMA-ProSeal have limitations of high cost, demand for careful handling to prevent cuff damage

and relative difficulty of insertion and in order to overcome these limitations a new and cheaper supraglottic airway device I-gel has been developed.[2]

I-gel is a novel supraglottic airway device with anatomically designed, non-inflatable mask, which is soft gel like and transparent made of medical grade thermoplastic elastomer called styrene ethylene butadiene styrene.[3]The soft, non inflatable cuff fits snugly onto the perilaryngeal framework and its tip lies in the proximal opening of the oesophagus, isolating the oropharyngeal opening from the laryngeal inlet. The outer cuff shape ensures that the blood flow to the laryngeal and perilaryngeal framework is maintained and helps the possibility to reduce neurovascular compression trauma to the nerves.[4]The present study is carried out to evaluate the efficacy of I-gel with regard to easiness of insertion of I-gel, number of insertion attempts, time taken and maneuvers required; time taken to establish effective ventilation and gastric insufflation.

MATERIAL AND METHODS

A prospective randomized controlled study was conducted on 40 patients admitted at Heritage Institute of Medical Sciences (HIMS), Bhadwar, Varanasi, Uttar Pradesh (India) scheduled for elective surgical procedures and requiring controlled ventilation. Patient inclusion criteria consisted of age 18-60 years, ASA physical status I-II, patient undergoing elective surgical procedures requiring endotracheal intubation for providing anaesthesia and patient with normal airway. Exclusion criteria waspredicted difficult airway, oesophageal reflux disease,BMI >30, history of adverse reaction, surgery more than 4 hours and patient refusal.

A thorough pre-anaesthetic evaluation was done for all patients.Routine haematological, biochemical & radiological investigations appropriate for surgical procedures was done.

Detailed airway assessment was done for all patients using Lemon method.All patients were given diazepam 10mg and ranitidine 150mg orally the night before surgery and at 6a.m with sips of water. After selection and pre-anaesthetic evaluation patients were shifted to operation theatre where in I/V line was set up. All base line parameters were recorded. All necessary monitors were set up for recording SPO_2, Capnography(CO_2), NIBP,HR.Patients received glycopyrrolate (0.01mg/kg), ondansetron 4mg & pentazocine(0.5mg/kg) before induction.

Patients were induced with thiopentone 4-6 mg/kg. Loss of eyelash reflex was accepted as an end point of induction of anaesthesia using thiopentone. After loss of consciousness succinylcholine 1.5mg/kg I/V was given.Size 3 I-gel was used in patients weighing 30-60 kg and size 4 I-gel was used in patients weighing 60-90 kg. The I-gel was held like a pen guided into the pharynx with index finger of the operator at the head of the patient and I-gel operator facing caudally, with head extended and neck flexed. Under direct vision the I-gel was grasped along the integral bite block and was introduced continuously into the mouth towards the hard palate until resistance was felt. Adequate placement of I-gel was assessed by gently squeezing the reservoir bag and observing the end-tidal CO_2 waveform and movement of the chest wall. Gastric tube was inserted through gastric drain outlet.

Correct I-gel insertion was assessed clinically by subjective assessment of appropriate length of airway tube outside the mouth, gastric insufflation and adequacy of manual ventilation which was assessed by proper chest expansion and presence of CO_2 waveform. The presence of gastric insufflation was determined by the epigastric auscultation. Confirmation of the correct placement of the gastric catheter was confirmed by detecting the injected air by auscultation of the epigastrium and aspiration of the gastric contents.

After introducing I-gel, anaesthesia was maintained with 67%N_20, 33%O_2, halothane, intravenous analgesic & muscle relaxant. Monitoring of HR, SBP, DBP, MAP, SPO_2, $ETCO_2$ was done before drug administration, immediately after induction, 1min, 3min, 5min, 10min, 15min, 20min, 25min, 30min then after every five minutes till the end of surgery.At the end

of surgery neostigmine 0.05mg/kg I/V + glycopyrrolate 0.02mg/kg was administered for reversal of residual muscle relaxation and I-gel was taken out.HR, SBP, DBP, MAP,SPO_2 was recorded prior to induction/baseline, immediately after induction, I-gel insertion, at 1min, 3min, 5min, 10min, 15min ,20min, 25min and 30min of surgery. End tidal CO_2 monitoring was done.

RESULTS

The patients included were in the age range of 18-54 years. 16(40%) patients were in the age group of 18-30 years, 12(30%) patients were in the age group of 31-40 years, 11(27.50%) patients in the age group of 41-50 years and 1(2.50%) patient was in the age group of above 50 years. The mean age of the patients was 34.55±9.70.

The study included both male and female patients where 70% (28) were female and 30%(12) were male.The weight of the patients included in this study was 51.28±5.42. The BMI of the patients included in this study were 22.21±0.77

The study included patients with MMP class I/II. 75% (30) patients belonged to MMPC I and 25% (10) patients belonged to MMPC II (table 3).

31(77.50 %) patients were ASA grade 1 and 9(22.50%) patients were ASA grade II (table 4).

The mean (SD) time of insertion (from picking up the I-gel to the connection of the circuit) as noted was 14.75±1.48 (table 5).

38(95%) patients required single attempt for successful device insertion and 2(5%) patients required second attempt for successful device insertion (table 6).

In two patients in this group the placement was not correct as judge by the clinical criteria so the head tilt and chin lift maneuver was done and the device was correctly placed. The p value was 0.00 (p value <0.05) which is statistically significant (table 7).

Ease of I-gel insertion was graded subjectively on a scale from 1 to 4(1=very easy, 2= easy, 3= difficult, 4=very difficult). Insertion was scored very easy in 38(95%) cases and easy in 2(5%) cases (table 8).

The correct placement of the device was clinically judged by the following parameters (table 9)**:**

1) Subjective assessment of appropriate length of airway tube outside the mouth
2) Adequacy of manual ventilation was assessed by following:

a) Chest expansion
b) Presence of CO_2 waveform

3) Gastric insufflations

Appropriate length of the airway tube was outside the mouth in 100% patients. Adequacy of manual ventilation was assessed by proper chest expansion which was 100% in all patients and presence of CO2 waveform which was seen in all 40(100%) patients. No gastric insufflation was seen in any patient with I-gel.

Nasogastric tube placement was graded from 1 to 4 (1=very easy, 2=easy, 3=difficult, 4=very difficult). Insertion of gastric tube was possible in every case and was very easy in 37(92.5%) patients and easy in 3(7.5%) patients (table 10).

Table 1: Age distribution

Age Groups	Group(I-gel)	Mean + SD
18-30	16 (40.00%)	34.55+9.70
31-40	12 (30.00%)	
41-50	11 (27.50%)	
Above 50 years	1 (2.50%)	
Total	40	

Table 2: Sex distribution

Variables		Results
Gender	**Female**	28 (70.0%)
	Male	12 (30.0%)
Weight (Kg)		51.28±5.42
BMI (Kg/m2)		22.21±0.77

Table 3: Modified Mallampatti (MMP) Classification

MMPC	Group (I-gel)
	MPS
MMPC 1	30 (75.0%)
MMPC II	10 (25.0%)
Total	40 (100.0%)

Table 4: ASA Grading

	Group (I-gel)
Grade 1	31 (77.50%)
Grade II	9 (22.50%
Total	40 (100.0%)

Table 5: Time Of Insertion

	Mean	**SD**
TIME TAKEN	14.75	1.48

Table 6: No. Of Attempts

	Group(I-gel)
	NOA
1st attempt	38
	95.0%
2nd attempt	2
	5.0%
Total	40
	100.0%

Table 7: Maneuvers used

	Group (I-gel)	p-value
None	38	0.00
	95%	
Head tilt, chin lift	2	
	5%	
Total	40	
	100.0%	

Table 8: Ease of insertion of I-gel

Grade	Number of patients
1(very easy)	38(95%)
2(easy)	2(5%)

3(difficult)	0(0%)
4(very difficult)	0(0%)

Table 9: Assessment of correct placement of the device

Assessment of correct placement of the device		I-gel
Appropriate length of the airway tube outside the mouth	**Yes**	40(100%)
	No	0(0%)
Chest expansion (Adequacy of manual ventilation)	**Adequate**	40(100%)
	Inadequate	0(0%)
Presence of CO2 waveform	**Present**	40(100%)
	Absent	0(0%)
Gastric insufflations	**Yes**	0(0%)
	No	40(100%)

Table10: Nasogastric tube placement

Grade	Number of patients
1(very easy)	37(92.5%)
2(easy)	3(7.5%)
3(difficult)	0(0%)
4(very difficult)	0(0%)

DISCUSSION

The I-gel is a recently introduced SGAD with incorporated drain tube. The I-gel is a non-inflatable device which is made of a thermoplastic elastomer and designed to create an anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures.[5]Prospective observational study was done in paralysed anaesthetized patients. After the induction of anaesthesia, device insertion was carried out by the technique as recommended by the manufacturers in the instruction manual. The size of the device was selected according to the weight of the patient as recommended by the manufacturers. The insertion characteristics was assessed, both subjectively (operator's subjectiveness) as well as objectively (time taken for insertion, number of attempts at insertion and maneuvers).

The time taken for insertion was calculated from the time of picking up the device to connection of the breathing circuit after device insertion and appearance of capnograph wave form. The time of insertion of the I-gel was 14.75sec in the present study.Teoh et al[6] reported comparable times for the first capnograph trace for the I-gel (15.4 ± 8.2 sec).Helmy A et al[7] reported the mean duration of insertion attempts for the I-gel to be(15.6±4.9 sec). Christiaan Keijzer et al[8] reported the mean insertion time of the I-gel to be (8.5±6.3 sec). Uppal V et al[9] reported the median insertion time for the I-gel to be 12.2sec.Gatward JJ et al[10] reported the median time for insertion of the I-gel to be15 sec.

Chauhan G et al[11] reported the mean insertion time for the I-gel(11.12±1.814 sec).Our results are comparable with the study done by Teoh et al,[6] Amr M. Helmy et al[7] and Gatward JJ et al[10] and Chauhan G et al[11] in respect to time of insertion of I-gel. However, in the other studies time taken for insertion was less as compared to our study.

In our study the I-gel could be successfully placed in 38(95%) cases in first attempt. Only in 2(5%) cases I-gel could be inserted in second attempt. A study conducted by Richez et al[12] to evaluate I-gel found that the overall insertion success rate was 97% irrespective of the anaesthesiologist's previous experience with the I-gel. Chew et al[13] in his study found the first attempt and overall success rate of the I-gel to be 93.3 and 100%.Gatward JJ et al[10] in his study found that the first insertion attempt was successful in 86 patients, second attempt in 11

patients, and third attempt in three patients.Teoh WHL et al[14] in his study found that the I-gels were successfully inserted on the first attempt in 94% patients.Jindal P et al[15] in his study found that in 96% patients I-gel was successfully inserted on first attempt and 4% in second attempt.Helmy AM et al[7]found that the I-gel is easily and rapidly inserted in over 90% of the cases in first attempt, 7.2% in second and 2.5% in third attempt.Gasteiger L et al[16] in their study found that the first attempt and overall insertion success were 97% and 100% respectively.

In the present study the first attempt and overall insertion success rate of the I-gel was 95% which is comparable to other studies.[12-15] Some audible leak during ventilation was noticed in two patients following I-gel insertion. The leak was corrected by the head tilt, chin lift maneuver. The leak disappeared and adequate manual ventilation was achieved.

Jindal P et al[15] in their study mentioned that insertion of the I-gel does not require any maneuver. However, in our study only two patients required head tilt chin lift maneuver after which leak disappeared and adequate ventilation was achieved.

Ease of insertion of the I-gel which was graded from 1 to 4(1= very easy, 2= easy,3= difficult, 4= very difficult). In 38(95%) patients the insertion of the I-gel was scored very easy(grade 1) and in 2(5%) patients it was scored easy(grade 2). Richez B et al[12] in their study found the insertion success rate was 97% and in 93% cases it was scored very easy and easy in 7% cases.

Helmy et al[7] in their study mentioned that insertion success rate was 100% and it was scored very easy in 90% cases, easy in 7.5% cases and difficult in 2.5% cases. Teoh WHL et al[14] in their study found that in 96% cases I-gel were successfully inserted on the first attempt with much ease.Pretson R[17] in his study found that I-gel was easy to insert and insertion success rate was 97% cases.Chauhan G et al[11] in their study found insertion success rate was 96% and it was scored very easy in 95% cases and in 5% cases it was scored easy.

The correct placement of the device was scored by a number of clinical criteria i.e appropriate length of airway tube outside the mouth, adequacy of manual ventilation which was assessed by adequate chest expansion and presence of CO_2 waveform and gastric insufflation.Appropriate length of the airway tube outside the mouth was found in all 40(100%) patients. Adequate manual ventilation was achieved for all the patients i.e 100% with adequate chest expansion and presence of CO_2 waveform. Gastric insufflation was not observed in any of the patients.

Smooth passage of nasogastric tube was graded with respect to the ease of insertion from 1 to 4(1= very easy, 2= easy, 3= difficult, 4= very difficult)]. The insertion of nasogastric tube was possible through I-gel in all the cases. The insertion success rate was higher with I-gel. In 37(92.5%) cases it was scored very easy(grade 1) while in 3(7.5%) cases it was scored easy(grade 2) . Size 12 French was used with I-gel as recommended by manufacturers because I-gel has a narrow drain tube opening. There was no episode of desaturation (SPO_2< 99%) in any patient at any time during the course of the study.Helmy et al[7] also found the success rate of gastric tube insertion with the I-gel to be 95%. B. Richez et al[12] in their study found that the gastric tube was inserted in 100% of the cases through the I-gel.Teoh WHL et al[14] in their study found that the gastric tube insertion was easier and achieved more quickly with I-gel than LMA Supreme.Uppal V et al[18]also found the success rate of gastric tube insertion with the I-gel to be 97%.The present study is comparable to the study done by Helmy et al,[7] B. Richez et al,[12] W. H. L. Teoh et al[14] and Uppal V et al[18] where also there was a high success rate of the gastric tube placement.

CONCLUSION

I-gel is an effective supraglottic airway device which can be rapidly inserted. It provides a leak free glottis seal during positive pressure ventilation.The nasogastric tube can be easily

placed.Hence, we conclude that I-gel can be safely and effectively used for airway management during positive pressure ventilation.

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