International Journal of Research in Medical Sciences
Barman RK et al. Int J Res Med Sci. 2021 Apr;9(4):1076-1081
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20211354

Original Research Article

Efficacy of two-person technique for I-gel insertion: a prospective observational study

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Received: 16 February 2021
Revised: 14 March 2021
Accepted: 15 March 2021

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ABSTRACT

Background: Recently anesthesiologists favoring I-gel over ET in securing airway during general anaesthesia because of better haemodynamic response and post-operative complications. In this study, we have assessed the efficacy of two -person technique for insertion of I- gel in paralysed patients.
Methods: I- gel is insertion was done in 40 patients undergoing general anaesthesia. Insertion time, number of attempts, air leaks, Tidal volume (TV) and expired tidal volume (ETV), emergence from anaesthesia, post-operative complications were assessed.
Results: Mean insertion time was 14.02±1.99 seconds. Insertion was successful in 37 patients (92.5%) in first attempt. 3 (7.5%) patients needed second attempts. Emergence from anaesthesia was satisfactory in all cases (100%).3 patients (7.5%) had mild cough and there were blood stained in the device in 2 cases (5%).
6 patients (15%) had mild, 5 patients (12.5%) had moderate sore throat in first 24 hours. 4 patients (10%) had mild pain during swallowing.
Conclusions: Two- person technique for insertion of I-gel is easier and lower insertion time with fewer complications.

Keywords: I-gel, Supraglottic airway, Two-person technique

INTRODUCTION

Majority of upper abdominal surgeries are performed under general anaesthesia or sometimes patients may need to be converted into general anaesthesia from regional anaesthesia. Securing airway is of utmost importance for anaesthesiologist in performing general anaesthesia. Over the years endotracheal intubation played a vital role for mechanical ventilation during general anaesthesia. Now a day's supraglottic airway devices (SAD) such as laryngeal mask airway (LMA), I-gel serves as one of most important technique for securing airway for mechanical ventilation, also as a mode of securing airway in ASA difficult airway algorithm. Supraglottic airway device (SAD) provides less hemodynamic changes, less respiratory complications and morbidity.[1,2] I-gel is one of the supraglottic airway devices used in the era of modern anaesthesia. I-gel is a supraglottic airway device with an anatomically designed nonflatable, soft, gel like and transparent mask made up of thermoplastic elastomer (Intersurgical Ltd., Workingham, England).[3] I-gel has been used in awake patient and under light sedation. Traditionally I-gel insertion is performed by a single operator where he opens the mouth with one hand while inserting with the other hand. There are other techniques of insertion also. In one technique, I-gel was inserted with its concavity facing the hard palate and once it

reaches the oropharynx it was rotated 180 degree to attain its final position.[4] Whereas in it can also be inserted by jaw thrust technique.[5] Our study is to assess the efficacy of two person technique for I-gel insertion where one operator opens the mouth with both hand while the other operator will insert.

METHODS

The study was conducted on 40 patients in surgery OT of Tezpur Medical College and Hospital from 11th September -2019 to 10th September -2020 after receiving approval from institutional and ethical committee

It was a prospective observational study. Quantitative variables were described as mean±SD; qualitative variables were described as number (percentage). For parametric data analysis, a paired sample t-test was used. For nonparametric data analysis, Chi-squared test was used for analysis. A p value <0.05 was considered to be statistically significant. Statistical analysis were done by using Statistical Package of Social Sciences (SPSS) version 24.

Study population

American Society of Anaesthesiologists (ASA) I and II physical status patients posted for various elective abdominal and surface surgeries.

Inclusion crtiteria

ASA I and II patients, abdominal surgeries, surface surgeries, adequate mouth opening i.e. >3 fingers width, surgeries less than 3 hours durations and having age18-65 years were included in the study.

Exclusion criteria

Intraoral mass, inadequate mouth opening i.e; <3 fingers with, laparoscopic surgeries, ENT surgeries were excluded from the study.

All patients were visited in the night before surgery and explained about the anaesthetic plan and the outcomes. Written and informed consent was taken. All patients were received oral alprazolam 0.5 mg and injection pantoprazole 40 mg in the night before surgery and in the morning on the day of surgery. In the operation room an intravenous line was secured and monitors were applied which included NIBP, ECG, pulse oximetry and capnography. Patients were premedicated with injection glycopyrolate 4 microgram /kg, fentanyl 1 microgram/kg and midazolam 0.02 mg/kg of body weight. After preoxygenation with 100% oxygen for 3 mins, induction was done with 2-2.5 mg/kg propofol with the targeted end point of induction being the loss of eyelash reflex. Relaxation was achieved with bolus injection of atracurium 0.5mg/kg and mask ventilated for 3 mins with 40% O2 and 60% N_2O. Airway was secured with I-gel and insertion was done according to our study design where I-gel was inserted by two operators contrary to the traditional technique. Size of the I-gel was chosen according the body weight as per manufacturer's instruction.[3] Back and sides of the cuff were lubricated with lignocaine jelly. In this study the patient's head was placed in morning sniffing position and mouth was opened by jaw thrust maneuver using two hands of one operator. The lubricated device was grasped along the integral bite block by another operator who was not involved in the study and was introduced into the mouth in the direction towards the hard palate and was glided downwards and backwards along the hard palate until definite resistance was felt. The device was connected to the breathing system. Breathing system used during the study was MINDRAY A5 workstation. Fresh gas airflow is adjusted to 4L/min. An effective airway was confirmed by bilateral symmetrical chest movement, square waveform on capnograph, minimal or no oral leak of gases and normal SpO_2 (>95%). Insertion time was recorded as time from insertion of I-gel into the mouth to appearance of the first capnographic square waveform. The device was secured with adhesive tape. If the airway was not effective, manipulations were done in the form of increasing the depth of insertion, giving jaw thrust or chin lift or changing to a larger size of the device. Even after manipulation for the second time if there was no square wave capnograph, the device was removed from the mouth and reinserted. Each 'attempt' was defined as re-insertion of the I-gel into the mouth and the respective numbers was counted and recorded. The ease of insertion of the airway device was subjectively assessed on a 5-point scale (1=easy, 2=not so easy, 3=difficult, 4=very difficult, 5=impossible).If it was not possible to maintain an effective airway even after 3 insertion attempts; the device was taken as failure and alternative technique endotarcheal intubation was used.[6]

Anaesthesia was maintained with 33% oxygen, 67% N_2O and 0.6% isoflurane in volume control ventilation (VCV) mode with tidal volume of 8ml/kg of body weight at the rate of 12/min with I:E ratio 1:2 to maintain normocapnia. Relaxation is maintained with incremental dose of atracurium during the anaesthetic period.

Heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2) and end tidal carbon dioxide (EtCO2) were recorded before induction (baseline), before device insertion (T0), every minute for the first 5 min after insertion of the airway device and henceforth, every 5 min for the entire duration of the surgery.

Airway leaks were then performed during the period by hearing the leak sound and by placing Auscultation by pacing a stethoscope just lateral to thyroid cartilage and assessed as minimal, moderate and no leak. Oral capnograph was placed inside the mouth and values were recorded.

Inspired tidal volumes (TV) and expired TV (ETV) were recorded and compared.

At the end of surgery during the emergence from anaesthesia, post-operative complications blood stained, desaturation, laryngospam/brochospasm, cough and regurgitation was noted and documented. Satisfactory emergence from anaesthesia was achieved or not was also documented.

During the recovery period, postoperative questionnaires were asked in the recovery room about sore throat, pain during swallowing and marked as mild, moderate and severe. Pain the jaw, pain in mouth, pain in speaking, tongue swelling and incidence of vomiting were assessed and recorded.

RESULTS

Data, presented as mean±standard deviation or numbers of patients (%) were tabulated and analyzed in Microsoft excel 7. We studied 40 patients, of which 21 female patients (52.5%) and 19 male patients (47.5%) with a mean age of 39.1±11.194 years (range 18-65 years), mean weight of 60.05±7.97 kg and a mean height of 164.07±7.07 cms. The ASA physical status grading was Grade I (n=31), Grade II (n=9). The modified Mallampati classification was class 1 (n=27), class 2 (n=10), class 3 (n=3). The mean duration of procedures was 45.975±22.663 mins (range 11 -120) mins (Table 1). Insertion of I-gel was easy (100%) in all the cases. The mean time for insertion was found to be 14.025±1.99 seconds. I-gel insertion were successfully placed in 37patients (92.5%) in first attempt. 3 patients (7.5%) need second attempts. Third attempt and device failure was not noticed during our study (Table 2).

Table 1: Demographic variance.

Variable	Mean±(SD)
Age (years)	39.1±11.194
Sex	
Female	21 (52.5%)
Male	19 (19.5%)
Height (cm)	164.078±7.076
Weight (kg)	60.05±7.9773
ASA status	I -31 (77.5%) II-9 (22.5%)
Modified Mallampati score	I-27 (67.5%) II-10 (25%) III-3 (7.5%)
Duration of surgeries	45.975±22.663 mins

Table 2: Frequency of manipulation and no of attempts of I-gel insertion.

Size (3/4)	25/15
Manipulation frequency(0/1/2)	34/1/2
No of attempts	
First attempt	37 (92.5%)
Second attempt	3 (7.5%)
Third attempt or device failure	0
Time taken for insertion	14.025±1.99

There was a slight decrease in heart rate and NIBP (SBP, DBP and MAP) at T0; otherwise there was no difference in variation of heart rate and NIBP. (Table 3 and Table 4).

Table 3: Heart rate response.

	Baseline	TO	1 min	2 min	3 min	4 min	5 min	10 min	15 min	30 min	During extubation
HR±SD	83.75 ±8.24	78.6± 6.78	86.55± 11.58	86.82 ±8.06	86.2± 5.56	85.47± 6.57	85.22 ±6.09	83.75 ±7.15	83.35± 8.02	86.12± 7.70	92.45±6.03

Table 4: Blood pressure response.

	Baseline	T0	1 min	2min	3 min	4 min	5 min	10 min	15 min	30 min	During extubation
SBP±SD	126.6 ±7.658	106.5 ±5.42	123.17 ±7.31	121.87 ±7.25	121.45 ±7.84	120.12 ±6.21	118.75 ±6.686	121.07 ±6.244	121.1 ±6.753	123.38 ±10.183	132.675 ±7.028
DBP±SD	81.15 ±5.97	63.54 ±6.345	78.975 ±6.21	77.525 ±7.38	76.075 ±7.39	74.625 ±6.84	73.625 ±6.68	74.65 ±5.04	74.94 ±6.102	76.411 ±7.80	86.225 ±5.53
MAP±SD	96.02 ±6.17	85.345 ±6.123	93.45 ±6.29	92.05 ±7.016	90.8 ±7.140	89.55 ±6.5239	88.675 ±6.590	89.7 ±5.5985	90.21 ±5.648	92.05 ±8.101	101.025 ±7.241

Table 5: Emergence from anaesthesia.

Regurgitation	Emergence from anaesthesia				Blood stained
	Satisfactory	Desaturation	Cough	Laryngospasm/ Bronchospasm	
0	100%	0	3	0	2

SPO_2 during the period was in the range of 98-100% in all cases (Figure 1). Airway leaks were detectable in 6 cases in initial 2 mins and thereafter no leaks were noticed. In oral capnograph there was visible capnogram during initial 2 mins and thereafter no such capnograph noticed. A square wave capnogram was seen in all patients, and arterial oxygen saturation was stable in all patients (100%). End tidal expired volume at baseline, T0, 1 min, 2 mins, 3 mins, 4 mins, 5 mins, 10 mins, 15 mins, 30 mins and during extubation were 7.175±0.71, 7.12±0.56, 7.175±0.67, 7.25±0.58, 7.175±0.67, 7.2±0.68, 7.25±0.74, 7.2±0.68, 7.225±0.69, 7.3±0.68, 7.225±0.69 ml/kg respectively (Figure 2).

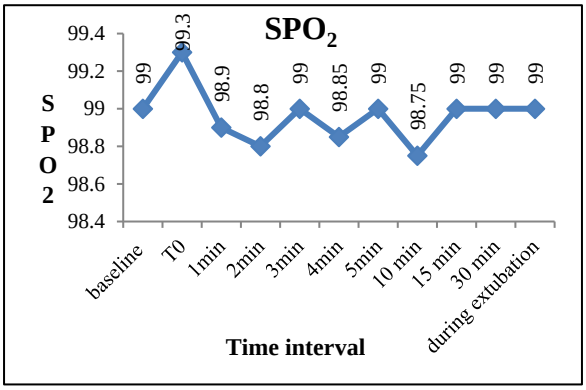

Figure 1: Oxygen saturation representation.

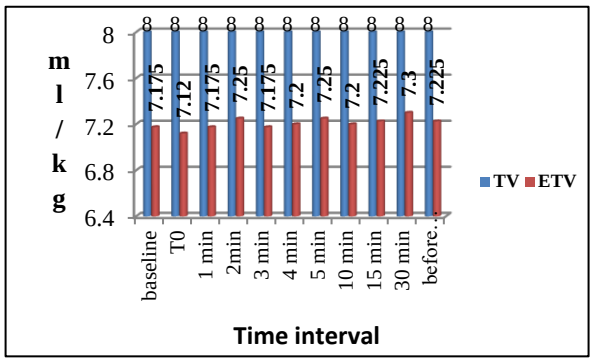

Figure 2: Comparison of TV and ETV.

There were no complications of pharyngolaryngeal or anaesthetic morbidity as defined during insertion, maintenance and removal of the device. There were no incidences of brochospasm/laryngospam, desaturation and regurgitation in any of the cases during emergence from anaesthesia. Emergence from anaesthesia was satisfactory in all cases (100%). 3 patients (7.5%) had mild cough and there were blood stained in the device in 2 cases (5%) (Table 5). During the postoperative period 6 patients (15%) had mild, 5 patients (12.5%) had moderate sore throat in first 24 hours. 4 patients (10%) had mild pain during swallowing. There were no incidences of pain in mouth, pain in jaw, pain in speaking, tongue swelling and vomiting (Table 6).

Table 6: Postoperative questionnaires.

	Sore throat	Pain during swallowing	Pain in jaw	Pain in mouth	Tongue swelling	Vomiting
Mild	6	4				
Moderate	5	0	0	0	0	0
Severe	0	0				

DISCUSSION

Supraglottic airway devices (SAD) such as classic laryngeal mask airway (cLMA), proseal LMA (pLMA), Supreme LMA (sLMA), Laryngeal tube suction II (LTS-II), Streamlined liner of the pharynx airway and I-gel have been established in clinical anaesthesia and have been shown to be safe and efficient.[7] Recently I-gel has gained popularity amongst anaesthesiologists over these SADs in clinical anaesthesia as it is easy to use, cost effective and sometimes reusable.

Familiarity of a newer airway device is of importance, because especially in difficult airway situations such as the 'can't ventilate, can't intubate' scenario, an easy-to-use supraglottic airway device may help to improve the patient's outcome considerably.[8] The main findings of our prospective, observational study are as follows: insertion success, time required for adequate ventilation and subjective rating of the handling of the I-Gel by a different technique of insertion using two persons for insertion.

The results of our small study are very encouraging and satisfactory. I-gel was successfully inserted in all patients 100% with ease and allowed effective controlled ventilation in all cases. I- gel was successfully inserted in first attempt in 37 cases while 3 patients needs second attempt. In a study conducted by Richez et al found insertion success rate was 97%.[9] There were no third attempt and device failure in our study. The mean time for insertion is lower and percentage of single attempts of insertion is much higher (92.5%) as compared to study conducted by Gatwart et al.[10] In their study they have conducted in nonparalysed patients whereas our study was conducted in paralysed patients. In a study conducted by Meghasharda et al, mean time for insertion of I-gel by reverse insertion technique was found to be 17.5±6.5 seconds whereas in conventional technique it is around 20.8±5.9.[4] In our study it was 14.025±1.993 seconds. Thus mean time for insertion of I-gel was found to be less with our technique of insertion. Airway manipulation was needed in only 3 patients for achieving effective airway and ventilation. Manipulations are mainly increasing the depth of the insertion. Changing of the device was not

recorded in our study. Kannaujia et al also found similar results with a similar study.[11]

In our study all patients were ventilated with I-gel and there were satisfactory end tidal expiratory volume (ETV) and end tidal CO_2 ($ETCO_2$) and it was found to provide adequate ventilations without any adverse events .In a study conducted by Goyal et al, where 119 patients between the age of 6 months to 18 years were ventilated with I-gel and it was found to provide adequate ventilation without any adverse effects though the insertion technique was classic one.[12]

Regarding the haemodynamic parameters, no statistically significant variation in the heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were recorded during the intraoperative period except just before insertion of I-gel. It was probably due to sedative and hypotensive effects of propofol. Seyed et al and Jindal et al also did similar studies and reported acceptable haemodynamic parameters which are in accordance with our study.[13,14]

Airway leak and oral capnograph showed minimal leak during initial 2 minutes which subsides thereafter is comparable with study conducted by Soi et al. They studied in laparoscopic Cholecystectomy whereas our study was on open and surface surgeries.[15] There was no evidence of regurgitation and aspiration in any of the cases. In our study, we included only elective patients who were adequately fasting preoperatively which are in accordance with study conducted by Jadhav et al.[16] There were mild cough in 3 patients (7.5%) during extubation which subsides within minutes and there were no desaturation either. Coughing was noted in 6% of the patients in a study conducted by Siddique et al.[17] There was no evidence of pain in jaw, pain in mouth, tongue swelling, vomiting, injury to lip, teeth or tongue. There were bloods on the device after removal in 2 patients (5%). In a study conducted by Atef et al found similar results having blood on the device 2 patients (5%).[18] However, Acott et al did not find blood in any of the cases.[19]

15% patients have mild sore throat while 12.5 % patients have moderate sore throat in the first 24 hour post operative periods which were in consistent with the results found by Richez et al.[9] I-gel therefore appears to be a suitable device for anaesthesia using controlled ventilation in our study. Our study can only examine efficacy and other determinants which are required to determine safety, but we encountered no major complications.

Limitation

Our study has few limitations. It was an observational study and sample size was smaller. It did not have any control group. Therefore, it cannot be established that our technique is better or suitable than the conventional technique for insertion of I gel in clinical anaesthesia. Furthermore, larger studies including randomized control trials are needed to accurately establish our technique in clinical practice. However, it will open a new window for further more research work on newer technique of supraglottic airway device insertion.

CONCLUSION

We evaluated the two person technique for placement of I-gel (Supraglottic airway device) and found that it was associated with easier insertion and lower placement time. The placement of the device was appropriate and it was not associated with any complications. Further larger studies and randomized control trial are required for have more statistical significance.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Barman RK, Hazarika P, Hazarika A. Efficacy of two-person technique for I-gel insertion: a prospective observational study. Int J Res Med Sci 2021;9:1076-81.