

Original Research Article


A comparative evaluation of two different methods of insertion of i-gel airway in laparoscopic surgeries: a randomized prospective study

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Abstract

Background and Aim: With the advent of supraglottic airway devices, laryngeal mask airway (LMA) has become a standard alternative to endotracheal intubation in the airway management. i-gel with its unique features is slowly emerging as an effective airway device. Gum elastic bougie (GEB) guided insertion of i-gel facilitates better alignment of the drainage tube with the esophageal sphincter and hence could provide better protection of the airway during regurgitation. Our study aims to compare the efficacy of i-gel placement, when placed with or without the GEB in laparoscopic surgery.

Materials and methods: Eighty patients were randomly allocated to one of the two groups using coded envelopes as follows: Group-1 – (n=40) i-gel was inserted as per manufacturer's instructions and Group-2 - (n=40) i-gel was inserted using GEB guided technique. First attempt success rate, mean insertion time and mean seal pressure were compared between the groups.

Results: The first attempt success rate was significantly lower in Group 1(52.5%) as compared to Group 2(82.5%). The least time taken for insertion was for Group 1(10.58+/-2secs) and was statistically significant. The mean seal pressures were higher in Group 2 though not statistically significant.

Conclusion: i-gel is a cuffless supraglottic airway device having a reasonable overall success rate with faster insertion time. The insertion and seal pressures improve when guided by a bougie.

Key words

Supraglottic airway, anticipated difficult intubation, elective surgery, aspiration, protection of airway.

Introduction

Tracheal intubation and controlled ventilation is the gold standard for anesthetic management of patients undergoing laparoscopic surgery. With the advent of supraglottic airway devices, laryngeal mask airway (LMA) has become a standard alternative in the airway management [1, 2, 3].

A recent introduction in the disposable generation of supraglottic devices is the i-gel airway (Intersurgical Ltd., U.K.). The mask of the i-gel is designed anatomically to fit the perilaryngeal and hypopharyngeal structures [4, 5]. It also has features designed to separate the gastrointestinal and respiratory tracts. When correctly inserted and positioned, the device isolates the glottis from the upper esophagus thus protecting the lungs from possible aspiration making it useful in laparoscopic surgery [6, 7].

Gum elastic bougie (GEB) guided placement aligns the esophageal end of the tube to the upper esophageal sphincter, thus facilitating better placement [8]. So, we plan to conduct a randomized study to compare the efficacy of i-gel, when placed with or without the gum elastic bougie in laparoscopic surgeries.

Aim and objectives

To compare i-gel, when placed with or without GEB in patients undergoing laparoscopic surgery with respect to:

- Ease of insertion,
- Airway sealing pressure

Materials and methods

Eighty patients of either sex as per American Society of Anesthesiologists (ASA) physical status class I or II, between 16-70 years of age, scheduled to undergo laparoscopic surgery were included in the study.

Exclusion criteria

- Patients with known difficult airway
- Cervical spine disease
- BMI >35 kgm⁻²
- Mouth opening <2.5cm
- Patients at risk of aspiration – full stomach, hiatus hernia, gastroesophageal reflux disease
- History of upper gastro-intestinal surgery, bleeding or clotting abnormalities, esophageal trauma, esophageal varices or evidence of upper gastro-intestinal bleed.
- Pregnant patients

The patients were kept fasting for 6 hours prior to scheduled time of surgery. They were premedicated with tab. Alprazolam 0.25 mg and tab Ranitidine 150mg at bedtime and 2 hours preoperatively. After arrival in the operation theatre routine monitoring such as HR, NIBP (SBP, DBP), ECG, SpO₂, EtCO₂ and respiratory rate were performed.

Patients were then randomly allocated to one of the two groups using coded envelopes as follows: Group-1 – (n=40) i-gel was inserted as per manufacturer's instructions [4]

Group-2 - (n=40) i-gel was inserted using GEB guided technique

Induction of anesthesia was achieved with standardized general anesthetic technique comprising of inj. Glycopyrrolate 0.2 mg followed by inj. Fentanyl 2 mcg/kg, inj. Propofol 2 mgkg⁻¹ and inj. Vecuronium 0.1mgKg⁻¹ IV. Anesthesia was maintained with Isoflurane 0.75% in 66% N₂O in O₂. Patient's lungs were ventilated for 120 seconds via face mask using anesthesia breathing system. The appropriate size of i-gel was used as per weight criteria. In group 2, the airway was inserted using GEB technique. For GEB guided technique the i-gel was prepared preinduction, by passing a well lubricated 12 FG,

GEB (Portex tracheal tube introducer, Portex Ltd., UK) down the drain tube such that the curved end of the bougie protrudes from the proximal end of the drain tube and the straight end of the bougie protrudes approximately 30 cm from the distal end of the drain tube.

Under gentle laryngoscopic guidance, the distal portion of the GEB was placed 5-10 cm into the esophagus while the assistant held the airway device at the proximal portion of the GEB. After removing the laryngoscope, the airway device was guided over the GEB using digital manipulation till it was placed into the hypopharynx. At this stage GEB was removed while retaining the airway in position. After insertion, the airway device was connected to the anesthesia breathing system. Positive pressure ventilation was commenced. Correct placement of the device was confirmed by; manual ventilation and auscultation of breath sounds, ability to ventilate the patient without substantial leak at an airway pressure at ≤ 20 cms water and square wave capnography.

The following data was collected:

Ease of insertion

The time interval between picking up the i-gel and obtaining an effective airway as documented

by appearance of first square wave capnogram was recorded as the insertion time.

A maximum of three insertion attempts was allowed before the placement of the device was considered a failure. In the event of complete or partial airway obstruction or a significant leak the airway device was removed and reinsertion attempted. In case of failure alternative airway device was used to secure the airway.

Oropharyngeal seal pressure

Oropharyngeal seal pressure was determined by switching off the ventilator at a fixed gas flow of 3 litres min^{-1} and recording the airway pressure (maximum allowed 40 cm of water) at which equilibrium was reached.

Results

The sample size was calculated to be 40 in each group with an error of 0.05 and power of 80%, considering at least 20% difference in the oropharyngeal leak pressure relative to the expected mean between the devices [9]. All data were statistically analyzed using SPSS software version 22. Demographic data that was comparable in both the groups was as per **Table – 1**. Though the insertion was faster in Group 1; the overall success rate, first attempt success rate and the mean seal pressure was better in Group 2 (**Table – 2**).

Table - 1: Shows the demographic data that was comparable in both the groups ($p < 0.05$).

| Demographic data | Group 1 | Group 2 | P-value |
|-------------------------|-------------------|-------------------|---------|
| Age(years) | 44.75 \pm 13.45 | 41.50 \pm 11.69 | 0.252 |
| Sex(M:F) | 7:33 | 8:32 | 0.891 |
| BMI(kg/m ²) | 22.99 \pm 3.70 | 23.23 \pm 3.48 | 0.763 |
| ASA Grade(I:II) | 39:1 | 37:3 | 0.305 |

Discussion

The success rate of group 1 was 85% and group 2 was 92.5% with first attempt success rate being higher for Group 2 as compared to Group 1. There was more number of failures in group 1 as compared to group 2. Our results are in accordance with Wharton et al. and Gatward, et al. who reported a first attempt success rate of

82.5% and 86% respectively [10, 11]. Contrast to Gosalia, et al. who found a higher success rate with i-gel and bougie guided i-gel (96% vs.100%). The time and attempt to place the device was nearly equal in both the groups [8]. In our study the poor success rate was due to failed pharyngeal placement in 6 patients of Group 1

and due to leak at <20 cms H₂O in 3 patients in Group 2.

The mean insertion time was 10.58±2.0 secs for Group 1 with maximum of 16 secs and minimum

of 8 secs. For Group 2 it was 16.86±6.16 secs with maximum of 38 secs and minimum of 9 secs. The least time taken for insertion was for Group 1 and was statistically significant (p value=0.000).

Table - 2: Shows that though the insertion was faster in Group 1; the overall success rate, first attempt success rate and the mean seal pressure was better in Group 2.

| Observations | Group 1 | Group 2 | P-value |
|------------------------------|------------|------------|---------|
| Overall success Rate | 85% | 92.5% | - |
| First attempt success rate | 52.5% | 82.5% | 0.02 |
| Failed insertion | 15% | 7.5% | - |
| Mean insertion time(secs) | 10.58±2.0 | 16.86±6.16 | 0.00 |
| Mean seal pressure(mm of Hg) | 30.13±6.32 | 30.75±6.15 | 0.133 |

Gosalia, et al. studied i-gel in 50 adult patients with and without bougie and described the insertion time taken for the placement of the device as recorded in seconds from the entry of the distal tip of the device between the incisors to the first recording of the capnographic curve was comparable (13.2±2.6 vs. 13.0 ±2.8 secs) [8]. In contrast we observed faster insertion time without bougie guided placement and there is a statistically significant difference in the insertion time (10.58±2.04 vs.16.86±6.16). We recorded the time interval between picking up the i-gel and obtaining an effective airway which was judged by; manual ventilation and auscultation of breath sounds, ability to ventilate the patient without substantial leak at an airway pressure at ≤20cms water and square wave capnography. The observed difference could be explained by different method of recording the insertion time.

Our results showed that the mean seal pressure in Group 1 is 30.13± 6.32 mm of Hg and in Group 2 was 30.75 ± 6.15 mm of Hg. The seal pressures were comparable between both groups (p value = 0.661). The mean seal pressure after 15 mins in Group 1 was 31.82±6.47 and in Group 2 was 32.43±5.67. There has been an increase in seal pressure in both the groups after 15 mins. Our results are in accordance with Singh et al. who recorded a higher sealing pressure with Proseal LMA (29.6 cm H₂O) than with i-gel (25.27 cm H₂O) (p < 0.05), but the airway sealing pressure

of i-gel was very well within the normal limit to prevent aspiration [12]. Richez, et al. inserted i-gel in 71 women undergoing gynaecological surgery and recorded a mean seal pressure of 30 ± 7 cmH₂O (similar to ours), and average peak pressure of 11 ±3 cmH₂O [13].

Conclusion

i-gel is a cuffless supraglottic airway device having reasonable overall success rate with faster insertion time. The insertion success improves when guided by bougie. Gum elastic bougie guides the cuff towards the upper oesophageal sphincter and reduces the chances of impaction of cuff at the back of the mouth and prevents its fold over on itself thus providing a better placement of the device and therefore probably leading to a better seal pressure. Oropharyngeal pathology can be identified as a laryngoscope is used in GEB guided technique and the time-consuming tests for malposition are not required as malposition is rare with this technique.

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