ORIGINAL RESEARCH

I-gel supraglottic airway use is efficient and safe during minimal flow anesthesia with volume controlled ventilation - a randomized controlled trial

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ABSTRACT

Background: A fear of potential gas leak limits the wide spread use of minimal flow anesthesia with supraglottic airway devices. Second generation supraglottic airway devices have been claimed to be come with good airway seal. I-gel is one of these and it has been extensively evaluated for spontaneous as well as assisted ventilation. We conducted this study to evaluate its use with low flow anesthesia and volume controlled ventilation.

Methodology: In a prospective randomized controlled trial, 50 patients undergoing laparoscopic surgeries for less than 2 h duration were administered general anesthesia, with controlled ventilation, using either endotracheal tube or an I-gel for airway control. The total fresh gas flow was gradually reduced until it was 400 mL/min. Patients were monitored for evidence of loss of respiratory gas volume in the breathing circuit and other parameters for ventilation failure.

Results: Ventilation could be maintained at a fresh gas flow of 400 mL/min, without clinical or volumetric evidence of gas leak in all patients in the two groups. Two patients in the I-gel group had intraoperative gas leak leading to ventilator failure alarm but the same was corrected by repositioning of the head. The vital signs, peak airway pressure, end-tidal carbon dioxide, set tidal volume and expired tidal volumes were statistically similar in the two groups.

Conclusion: I-gel supraglottic airway can be safely and efficiently used for laparoscopic surgery using minimal flow anesthesia and volume controlled ventilation.

Key words: Supraglottic airway device; I-gel; Minimal flow anesthesia.

Abbreviations: Supraglottic airway device – SAD; Volume controlled ventilation – VCV; Pressure controlled ventilation – PCV; Endotracheal tube – ETT; Laryngeal Mask Airway - LMA

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INTRODUCTION

Airway management has become less invasive with the introduction of supraglottic airway devices (SAD). A survey on usage of SADs in 11,910 patients demonstrated their safety and efficacy for gynecologic laparoscopy, gynecologic laparotomy and other procedures of > 2 h duration, during spontaneous

as well as controlled ventilation.[1] Specialized second generation SADs, such as Proseal and I-gel, have become popular for laparoscopic surgeries as good airway seal can be achieved with them.[2,3] However, SAD are less commonly used for low flow anesthesia as poor glottic fit and leak can compromise gas exchange. The use of SAD to deliver low flow and minimal flow anesthesia has been restricted to anesthesiologists experienced with their use and with the use of minimal flow anesthesia.[4] This study was formulated to show the safety and efficacy of I-gel (Intersurgical Ltd, Berkshire, UK) use during minimal flow anesthesia with volume controlled ventilation (VCV) for laparoscopic surgery of < 2 h duration.

METHODOLOGY

After approval from institutional ethics committee, a prospective, interventional, blinded, randomized controlled trial was conducted on 50 American Society of Anesthesiologists grade 1-3 patients, undergoing laparoscopic surgeries (Table 1) lasting < 2 h. The trial was registered with Controlled Trial Registry India with ID CTRI/2015/06/009163.

Patients undergoing concomitant procedures; with pulmonary disease; hypersensitivity to one or more medications; previous thoracic surgery; increased risk of aspiration; morbid obesity; and anticipated difficult airway were excluded. On enrolment, written informed consent was obtained from all participants.

The sample size was estimated considering a mean difference of 0.25 between the two groups as clinically significant, based on the study by Uppal et al. comparing I-gel with endotracheal tube (ETT) using pressure controlled ventilation (PCV).[2] For a standard deviation value of 0.05, using a power of 80% and significance value of 0.05 for a two-sample t-test comparing two groups, a total of 25 patients per group were needed. Patients were allocated into two groups, I-gel group and ETT group, by computer-generated randomization. All patients were subjected to routine preoperative assessment and fasting protocol. A standardized general anesthesia induction protocol was followed, comprising of fentanyl 1-2 mcg/kg intravenous (IV) and propofol 1.5-2 mg/kg IV. The airway was secured by an appropriate size ETT or I-gel after administration of atracurium. I-gel size was selected in accordance with manufacturer's guidelines (<50 kg: I-gel size 3; 50–70 kg: size 4; and >70 kg: size 5). All airway interventions were performed by a single user, who had experience of over 500 I-gel insertions. Appropriate placement of I-gel was confirmed by observing an end-tidal CO_2 ($EtCO_2$) waveform and movements of the chest wall. Orogastric tube was passed through the gastric tube channel in all cases in the I-gel group. The head end of the patient was then covered by a sheet for the purpose of blinding of the next anesthetist who was the designated observer of ventilator parameters.

Anesthesia was maintained with desflurane in oxygen and nitrous oxide titrated to maintain FiO2 of 0.5 (based on inspired oxygen monitoring at the patient end). A Drager Fabius Plus anesthesia delivery system (Dräger Medizintechnik GmbH, Lübeck, Germany) was used in all cases. Intraoperative monitoring consisted of heart rate, electrocardiography, pulse oximetry, $EtCO_2$, temperature and non-invasive blood pressure. VCV, using a semi-closed circle breathing system, was delivered to all patients with the tidal volume set as 6-8 mL/kg; respiratory rate to maintain $EtCO_2$ between 30-40 mmHg; inspiratory-expiratory ratio of 1:2; no peak end-expiratory pressure; and a pressure limit of 30 cmH2O.

A total fresh gas flow (FGF) of 6 L/min was used until the target expired desflurane concentration (MAC 0.8) was achieved. In both groups, FGF was then reduced to 1 L/min. FGF was thereafter reduced by 100 mL/min till the total FGF was limited to 400 mL/min or till there was no ventilation failure alarm or desaturation. The FGF was not reduced, under any circumstance, to less than 400 mL/min for safety reasons. The primary objective was to establish minimum adequate FGF in the breathing circuit with no failure to adequately ventilate the lungs. To determine the primary outcome, the set tidal volume, expired tidal volume, airway pressure and total FGF delivered, apart from the routine parameters, were recorded every minute till reduction of FGF to 400 mL/min. Thereafter all parameters were recorded every 15 min. The operating surgeon was asked to visually check for gastric distention during surgery.

At the end of the procedure, neuromuscular blockade was reversed and the airway device was removed. Patients were followed up for 24 h after surgery for secondary outcomes related to the use of the device i.e. complaints of sore throat, dysphagia, sore jaw, dysphonia, numbness of tongue or oropharynx, blocked or painful ears, reduced hearing or neck pain.

Statistical analysis: Statistical analysis was done with MedCalc (version 16.1; www.medcalc.org). Data were reported as mean ± SD. Analysis of data between the groups was done by Student's t-test for independent samples. For categorical values, Chi-square test was applied. A p value of less than 0.05 was considered statistically significant.

RESULTS

All 50 enrolled patients completed the study. Both groups were comparable in terms of age, height, weight, and demographics (Table 2). Patients were positioned the two groups as per requirements of the

Table I: Comparative surgical procedures in the groups

Surgery	ET Group n=25	I-gel Group n=25
Laparoscopic cholecystectomy	14	14
Laparoscopic hernioplasty	4	6
Laparoscopic appendectomy	1	-
Laparoscopic hiatus hernia repair	1	-
Laparoscopic ovarian surgery	1	1
Diagnostic laparoscopy & hysteroscopy	-	2
Total laparoscopic hysterectomy	-	2
Laparoscopic myomectomy	4	-

Table 2: Demographic data

Parameters	ET Group n=25	I-gel group n=25	p-value
Age (y)	48.80 ± 13.64	49.08 ±14.96	0.95
Weight (Kg)	67.252 ± 14.40	68.50 ± 13.93	0.82
Height (cm)	160.48 ± 7.06	161.58 ± 8.55	0.62
Gender Male/Female	8/17	7/18	0.76
Duration of surgery (min)	77.5 ± 43.79	59.09 ± 34.07	0.089
Trendelenburg Position (n)	10	11	
Reverse Trendelenburg Position (n)	15	14	

Table 3: Study data

Parameters	ET Group n=25	I-gel group n=25	p-value
Heart rate (bpm)	76.09 ± 2.20	70.34 ± 6.15	0.001
Systolic blood pressure (mmHg)	125.59 ± 11.34	115.04 ± 11.47	0.0122
Diastolic blood pressure (mmHg)	75.17 ± 6.09	73.52 ±10.05	0.5699
Peak airway pressure (cmH_2O)	24.84 ± 5.02	22.00 ± 3.86	0.0837
End-tidal carbon dioxide (mmHg)	32.03± 0.299	32.52 ± 1.80	0.2909
Set tidal volume (mL)	480 ± 28.87	493.2 ± 22.12	0.0758
Expired tidal volume (mL)	505.73 ± 28.16	496.50 ± 25.29	0.2509

surgery. 10 patients in ETT group and 11 patients in the I-gel group were placed in Trendelenburg position during surgery, while the remaining patients were placed in reverse Trendelenburg position for surgery (Table 2). The systolic/diastolic blood pressure, peak airway pressures and $EtCO_2$ were statistically comparable in the two groups. There was a statistically significant difference in the mean heart rates in the two groups but as the study objectives were unrelated to hemodynamics and the difference was not clinically significant, the two groups were considered similar. Set and expired tidal volume in the two groups were statistically similar (Table 3). The duration of surgery was longer in the ETT group than in the I-gel group (77.5 ± 43.79 min vs 59.09 ± 34.07 min) but the difference did not approach statistical significance (p = 0.089). Ventilation could be maintained at an FGF of 400 mL/min, without clinical or volumetric evidence of a gas leak, in all patients. Two patients in the I-gel group had intraoperative gas leak leading to ventilator failure alarm. However, repositioning of the head corrected the leak. Gastric distention was not reported in any patient by the operating surgeons. There were no cases of regurgitation or gastric aspiration during the intraoperative period. During the postoperative period, two patients from ETT group complained of sore throat and one patient in the I-gel group complained of difficulty in swallowing. No other complication was noted in either group.

DISCUSSION

High FGF techniques have been the mainstay of anesthesia practice for several years. In 1952, Foldes described the use of 1 L/min FGF in closed breathing systems.[5] In 1974, Virtue validated his findings and used an even lower FGF of 500 mL/min.[6] The advent of better anesthesia delivery technology has permitted delivery of low and minimal FGF, with a good margin of safety, as breathing systems are leak free. Traditionally ETTs have been used for low and minimal flow anesthesia, however, SADs provide as efficient a gas-seal as ETTs and can thus be used in operating rooms without causing pollution.[7] Since, halogenated inhalational anesthetic agents can catalyze the breakdown of ozone, use of low flow anesthesia and avoiding high FGF can protect the ecology by emitting smaller amounts of ozone-depleting and heat-trapping greenhouse gases.[8,9]

Rebreathing of gases in closed breathing systems prevents loss of heat, drying of mucous membrane, lower rate of airway inflammation/infection and

reduces inhalational anesthetic agent consumption by more than 75%.[10,11] After the saturation point is met, uptake of anesthetic from alveoli is reduced and the agent in the excess gases is vented out.[12] Minimal flow anesthesia helps reduce wastage by limited addition of respiratory and anesthetic gases into the circuit, thus balancing uptake. Although SADs do not provide watertight seal, Laryngeal Mask Airway (LMA) has been shown to provide as efficient a seal as ETT with reduced loss of anesthetic gas from the closed circuit.[13,14] Honemann et al (2013) found that LMA and ETT could be used at FGF of 0.5 L/min in 84.7% and 98.3% of cases respectively. However, in their study, airway leaks did not permit any reduction in FGF in three patients with LMA (3.3%).[15] LMA has been compared with cuffed ETT in children during PC ventilation and found to be efficient even at an FGF of 0.2 L/min.[16] Airway sealing pressures with I-gel have been reported to vary between 25 cm H2O and 30 cm H2O.[17,18] Although the safety of I-gel during gynecological laparoscopic surgeries has been demonstrated, the leak was reported to be greater in the Trendelenburg position.[19] Use of SAD during low and minimal flow anesthesia with controlled ventilation has been shown by others to be safe in Trendelenburg position.[1,4,20] The airway seal of I-gel has been found to be adequate with chest compressions during cardiopulmonary resuscitation and as a result, an I-gel resuscitation pack has been introduced.[21,22] We did not find any clinical or volumetric evidence of a leak in surgeries done in Trendelenburg position. I-gel is reported to be as efficient and safe as an ETT during PCV, which is more efficient and safer than VCV with an SAD.[2,23] I-gel has also been used successfully with VCV and for mechanical ventilation lasting for 48 h with PCV.[24,25]

We used VCV and found its use safe with I-gel, with no evidence of leak in the breathing system. A very small loss of tidal volume was seen in the I-gel group in our study which was statistically insignificant.

The incidence of clinically detectable gastric insufflations and regurgitation with use of SAD, in general, is 0–0.3% and 0.07%, respectively. The incidence of aspiration with LMAs in fasted patients is 0.012%.[26] Three cases of regurgitation, including one confirmed gastric aspiration, have been reported with use of I-gel in a study of 280 patients.[27] A meta-analysis of 547 studies on LMAs has however shown that the incidence of pulmonary aspiration with LMA use is uncommon and not higher than that associated with the use of face mask and ETT for day care surgery.[28] There was no laparoscopic evidence of gastric insufflation, regurgitation, or gastric aspiration in the I-gel group in our study. LMA use has been reported to be associated with lower incidence of complications such as sore throat, cough and difficulty in swallowing as compared to ETT, during low flow VCV.[29] In our study, we noted complaints of sore throat in two patients in ET group while one patient from I-gel group complained of difficulty in swallowing.

Patients in both groups remained hemodynamically stable throughout the procedure. Changes in peak airway pressures noted during the study were comparable in both groups. Loss of tidal volume was noted in the I-gel group but was statistically insignificant on analysis. Our study had a limitation that both the devices were inserted by a single experienced user and the results may not be replicated by inexperienced users. Further larger studies need to be conducted on I-gel and other second-generation SAD to establish their efficiency during minimal flow anesthesia.

CONCLUSION

Based on the results of our study, we conclude that I-gel can be safely and efficiently used during minimal flow anesthesia, with a total FGF of 400 mL/min, with volume controlled ventilation for laparoscopic surgery of less than two hours duration.

Conflict of interest: None declared by the authors.

Authors' contribution: All authors took part in the conduct of the study, data collection and manuscript preparation.

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