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

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. 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. 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. 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). 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 CO2
(EtCO2) 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, EtCO2, 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
EtCO2 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
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 EtCO2 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

**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. In 1974, Virtue validated his findings and used an even lower FGF of 500 mL/min. 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. 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. Rebreathing of gases in closed breathing systems prevents loss of heat, drying of mucous membrane, lower rate of airway inflammation/infection and

### Table 1: Comparative surgical procedures in the groups

<table>
<thead>
<tr>
<th>Surgery</th>
<th>ET Group n=25</th>
<th>I-gel Group n=25</th>
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<tbody>
<tr>
<td>Laparoscopic cholecystectomy</td>
<td>14</td>
<td>14</td>
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<tr>
<td>Laparoscopic hernioplasty</td>
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<td>6</td>
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<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Laparoscopic ovarian surgery</td>
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<td>1</td>
</tr>
<tr>
<td>Diagnostic laparoscopy &amp; hysteroscopy</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Total laparoscopic hysterectomy</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Laparoscopic myomectomy</td>
<td>4</td>
<td>-</td>
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</table>

### Table 2: Demographic data

<table>
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<tr>
<th>Parameters</th>
<th>ET Group n=25</th>
<th>I-gel group n=25</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>48.80 ± 13.64</td>
<td>49.08 ± 14.96</td>
<td>0.95</td>
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<tr>
<td>Weight (Kg)</td>
<td>67.252 ± 14.40</td>
<td>68.50 ± 13.93</td>
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<tr>
<td>Height (cm)</td>
<td>160.48 ± 7.06</td>
<td>161.58 ± 8.55</td>
<td>0.62</td>
</tr>
<tr>
<td>Gender Male/Female</td>
<td>8/17</td>
<td>7/18</td>
<td>0.76</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>77.5 ± 43.79</td>
<td>59.09 ± 34.07</td>
<td>0.089</td>
</tr>
<tr>
<td>Trendelenburg Position (n)</td>
<td>10</td>
<td>11</td>
<td></td>
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<tr>
<td>Reverse Trendelenburg Position (n)</td>
<td>15</td>
<td>14</td>
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### Table 3: Study data

<table>
<thead>
<tr>
<th>Parameters</th>
<th>ET Group n=25</th>
<th>I-gel group n=25</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate (bpm)</td>
<td>76.09 ± 2.20</td>
<td>70.34 ± 6.15</td>
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<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>125.59 ± 11.34</td>
<td>115.04 ± 11.47</td>
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<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>75.17 ± 6.09</td>
<td>73.52 ± 10.05</td>
<td>0.5699</td>
</tr>
<tr>
<td>Peak airway pressure (cmH2O)</td>
<td>24.84 ± 5.02</td>
<td>22.00 ± 3.86</td>
<td>0.0837</td>
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<td>End-tidal carbon dioxide (mmHg)</td>
<td>32.03 ± 0.299</td>
<td>32.52 ± 1.80</td>
<td>0.2909</td>
</tr>
<tr>
<td>Set tidal volume (mL)</td>
<td>480 ± 28.87</td>
<td>493.2 ± 22.12</td>
<td>0.0758</td>
</tr>
<tr>
<td>Expired tidal volume (mL)</td>
<td>505.73 ± 28.16</td>
<td>496.50 ± 25.29</td>
<td>0.2509</td>
</tr>
</tbody>
</table>
reduces inhalational anesthetic agent consumption by more than 75%. After the saturation point is met, uptake of anesthetic from alveoli is reduced and the agent in the excess gases is vented out. 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. 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%). 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. Airway sealing pressures with I-gel have been reported to vary between 25 cm H2O and 30 cm H2O. Although the safety of I-gel during gynecological laparoscopic surgeries has been demonstrated, the leak was reported to be greater in the Trendelenburg position. Use of SAD during low and minimal flow anesthesia with controlled ventilation has been shown by others to be safe in Trendelenburg position. 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. 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. I-gel has also been used successfully with VCV and for mechanical ventilation lasting for 48 h with PCV.

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%. Three cases of regurgitation, including one confirmed gastric aspiration, have been reported with use of I-gel in a study of 280 patients. 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. 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. 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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