Safety and efficacy of insertion of supraglottic devices in anaesthetised patients by first-time users

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Keywords: first-time users; laryngeal mask airway; i-gel

Abstract

Background: Over the years, several supraglottic devices have been developed, but the most recent one is the i-gel®. It is a new device with some distinctive features that set it apart from many of its competitors. This study was designed to determine the safety and efficacy of placing different airway devices by first-time users.
Methods: Fifty volunteer doctors who are regularly involved in cardiopulmonary resuscitation and emergency medicine were divided into two groups on the basis of their experience and were timed to insert the two supraglottic devices, i-gel® and laryngeal mask airway (LMA), in ASA grade I, II and III anaesthetised patients under expert guidance. The haemodynamic parameters were recorded and the volunteers were asked to complete a questionnaire.
Results: In both the groups, i-gel® was inserted in less time than LMA. The time taken for insertion of i-gel® by both the groups was not significant. The success rate of inserting i-gel® by both groups was not significant ($p > 0.05$). Ninety-six percent of participants in both the groups found that i-gel® was easier to insert and required minimal adjustment.
Conclusion: Our results suggest that i-gel® is rapidly inserted by novices, and produces haemodynamic changes compared to those resulting from insertion of classic LMA. We suggest that the device is safe and can be used by first-time users and experts in cardiopulmonary resuscitation and in emergencies.

Introduction

The discovery of endotracheal intubation has not only made the administration and maintenance of anaesthesia easy, but has also helped in saving many lives. Placement of an endotracheal tube has been considered to be the gold standard in airway management, but recently concern has been raised that the risks of failed intubations, misplaced tubes and prolonged intubation times may outweigh the benefits.[1]

Supraglottic airway devices have been used as an alternative to the bag valve mask (BVM) or endotracheal tube in the resuscitation scenario. The use of the laryngeal mask airway (LMA™) has been well documented for this indication.[2,3]

The i-gel® is a new device that may prove to be a viable alternative to the LMA.

The i-gel® is a novel single-use, non-inflatable supraglottic airway for use in anaesthesia during spontaneous or intermittent positive pressure ventilation.[4]

This study was designed to compare the ease of insertion and efficacy of the LMA and the i-gel® by first-time users and to record their feedback, the haemodynamic parameters at the time of insertion, and any complications during and after the insertion.

Materials and methods

After obtaining approval from the institute's ethics committee and informed consent from the patients, this prospective study was carried out at the Himalayan Institute of Medical Sciences, Dehradun, India. Doctors/paramedical staff who could be potentially involved in airway management and cardiopulmonary resuscitation were invited to

participate. They were divided into two groups, each according to their experience. Group A comprised doctors who had performed > 30 insertions. Group B comprised resident doctors/paramedical staff who had no experience of inserting airway devices.

Each volunteer was asked to insert two devices: the classic LMA sizes (i.e. size 3 or size 4) and also the i-gel® sizes (i.e. size 3 or size 4). This made a total of two interventions per volunteer. Then, each group was further subdivided into two groups. In group A1, a participant inserted the i-gel® and in group A2, a participant introduced the LMA. In group B1, a participant inserted the i-gel® and, in group B2, a participant inserted the LMA.

Participants in group B were introduced to the device and given time to practise on a mannequin. The participants, under experienced guidance, performed insertion in ASA grade I–III patients, of either sex, in the age group 20–50 years, scheduled for elective surgery. Patients belonging to ASA grade IV, with blood pressure > 150/100 mm Hg, a history of sore throat within 10 days, patients with a full stomach, and patients scheduled for head and neck surgery were excluded from the study.

After obtaining a detailed history, and carrying out a physical examination and other necessary investigations, patients were kept fasting for 10 hours before surgery. All the patients were given diazepam tablet 10 mg at night and 5 mg at 6 am on the morning of surgery.

After confirming consent and fasting status the intravenous (IV) line was established with an 18 G cannula and Ringer's lactate was started. All the monitors were placed in position and baseline readings of heart rate; systolic, diastolic and mean arterial pressure; SpO_2, and an electrocardiograph (ECG) were noted. The patient was put in the supine position and the head placed on a pillow 7 cm in height. The patient was preoxygenated with 100% oxygen for three minutes. The patient was then slowly induced with injection fentanyl 2–5 μg/kg and injection propofol 1.5–2.5 mg/kg. Face mask ventilation was done with 66% nitrous oxide in oxygen with 1–2% sevoflurane until optimal conditions for device insertion were attained, i.e. jaw relaxation. For each insertion, both the airway devices were well lubricated according to the manufacturers' instructions. The volunteers were instructed to stand at the head of the patient. All the equipment was kept at the side of the head of the patient. The volunteer was given the count of three, at which point he/she was to pick up the device and attempt to introduce it using standard techniques. Each attempt was timed using a stopwatch. The end point of each insertion was taken when there was bilateral chest movement, a square wave on a capnograph and $SpO_2 > 95\%$. If these findings were not present, the participant was instructed to insert the device again. The attempt was considered a failure if it was not possible to maintain an effective airway after three attempts. Then the experienced senior anaesthetist introduced the device. The time taken for insertion, number of attempts and haemodynamic changes were observed and recorded.

The surgeon was requested not to clean, drape or position the patient until five minutes had elapsed after placement of the supraglottic device so as to avoid any stimuli likely to interfere with the findings. Serial heart rate, arterial pressure, SpO_2 and ECG recordings were noted at the time of insertion, and one, three and five minutes following insertion.

Anaesthesia was maintained on oxygen and nitrous oxide (66%) and sevoflurane (1–2%) and the patient was kept on spontaneous respiration, as no muscle relaxant was used.

At the end of the procedure, all the patients breathed 100% oxygen. When the patient was able to open the mouth on command, oral suctioning was done, the airway patency and respiratory depth were then confirmed, and subsequently the device was removed. Any buccal mucosal injury, lip and/or tooth injury or blood stain on the device were recorded. All the participants were then given a questionnaire to complete, questioning them about their experiences with each device. This questionnaire comprised the following questions:

1. Which device was easier to insert?
2. What problem/s did you encounter with the other device?
3. Which device required minimum deviation from the standard technique of insertion?
4. Which device took the shortest time to insert?
5. Which device would you prefer to use in routine practice?
6. Which device would you prefer to use in an emergency?
7. Assess the anxiety you experienced before or during insertion: a. worrying; b. slightly worrying; c. not worrying

Analysis of data
ANOVA with Scheffe's test made comparisons between the groups: $p < 0.05$ was considered statistically significant and $p > 0.05$ was considered non-significant.

Observations

There were no significant difference in patient characteristics among the four groups (Table I).

The success rate of inserting an i-gel® on the first attempt was 96% and 88% in groups A1 and B1, respectively. i-gel® was inserted in a second attempt by 8% and in a third attempt by 4% in group B1. There was one case of failed LMA insertion by group B. At the time of insertion, there was no fall in saturation, no dental or mucosal trauma and no ECG changes. The i-gel® was 67% faster to insert than the LMA by the inexperienced ($p < 0.05$). Time taken for insertion of i-gel® by both groups was non-significant ($p < 0.5$). (See Table II).

There was no significant difference ($p > 0.05$) in heart rate at any time among all the groups (Figure 1), but there was a significant difference ($p > 0.05$) in systolic, diastolic and mean arterial blood pressure from baseline until 5 minutes after insertion between group A1 and group A2. Similarly, in group B there was significant difference in the systolic, diastolic and mean arterial blood pressure when the inexperienced volunteer inserted i-gel® and LMA.

There was no significant difference in systolic, diastolic and mean arterial blood pressure after insertion of i-gel® by either the experts or the inexperienced, but we did observe a significant increase in systolic, diastolic and mean arterial blood pressure from the baseline when LMA was introduced by first-time users (Figure 2).

Figure 1: Comparison of heart rate at different time intervals (I-0: at the time of insertion, I-1: 1 minute after insertion,I-2: 2 minutes after insertion, and I-5: 5 minutes after insertion.

Figure 2: Comparison of systolic blood pressure at different time intervals (I-0: at the time of insertion, I-1: 1 minute after insertion, I-2: 2 minutes after insertion, and I-5: 5 minutes after insertion).
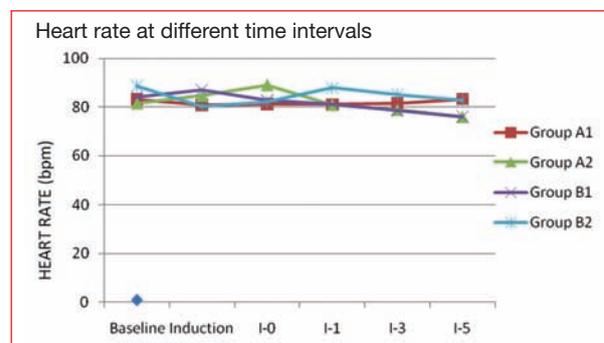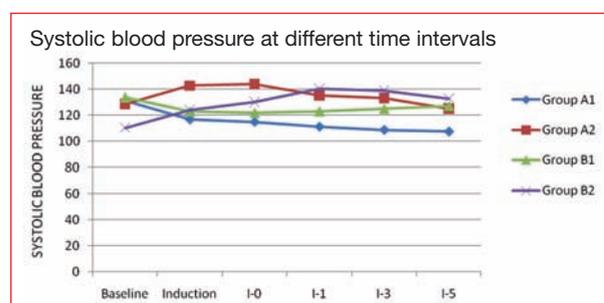

On comparing groups A1 and A2, there was a significant difference in the rate pressure product (RPP) seen at the time of insertion and then one minute after insertion. On comparing groups B1 and B2, there was a significant difference in the rate pressure product from insertion to five minutes after insertion. There was no significant difference between groups A1 and B1.

The results of the questionairre after evaluation have been summarised in Table III.

Discussion

The i-gel® airway uses an anatomically designed mask made of a gel-like thermoplastic elastomerstyrene-ethylene/butadiene-styrene.[5] The soft, non-inflatable cuff fits snugly onto the perilaryngeal framework and the tip of the i-gel® is located into the upper oesophageal opening, providing a conduit via the gastric channel to the oesophagus and stomach. This then allows for suctioning and passing of a nasogastric tube, and can facilitate venting. The i-gel® is designed to

Table I: Demographic data of the patients

	Group A1	Group A2	Group B1	Group B2
Age: Mean ± SD Range	38.52 ± 8.89 22–53	38.04 ± 8.71 26–57	38.24 ± 9.76 20–53	37.82 ± 8.17 24–55
Sex Male:Female	14:11	12:13	13:12	15:10
ASA Grade I:II	14:11	15:10	13:12	13:12
Mallampatti (MP) Grade I:II	13:12	14:11	13:12	15:10

Table II: Details of the airway management

	Group A1	Group A2	Group B1	Group B2
Insertion attempts 1/2/3/failed	24:1	23:2	22:2:1	21:2:1:1
Size 3:Size 4	11:14	13:12	12:13	10:15
Time for insertion Mean ± SD	4.68 ± 1.07	7.68 ± 0.69	5.24 ± 0.92	15.84 ± 3.6

Table III: Responses of the 50 volunteers (given in percentage)

Question	Group A	Group B
Easier to insert	96 i-gel®	96 i-gel®
Minimal alteration	96 i-gel®	88 i-gel®
Least time to insert	100 i-gel®	92 i-gel®
Routine use	80 either, 16 i-gel®, 4 LMA	96 i-gel®
Emergency use	92 i-gel®	96 i-gel®
Anxiety	None	60% slight worry LMA

conform with the anatomy of the upper airway so that compression and displacement trauma are significantly reduced or eliminated. The seal created is sufficient for both spontaneously breathing patients and for IPPV (intermittent positive pressure ventilation). The i-gel® does not have aperture bars, like some other supraglottic devices, but it has a small ridge projecting from the proximal section of the bowl, which is designed to act as an epiglottic blocker. This helps to prevent the epiglottis from down-folding. In the very unlikely event that an epiglottis should still down-fold, the airway channel exits so deeply into the bowl of the cuff that there is no danger of the epiglottis being able to interfere with the fresh gas flow.[6–8]

During the insertion of the LMA, a pressor response (i.e. increase in heart rate and arterial pressure) may be induced by the passage of the LMA through the oral and pharyngeal spaces, and pressure may be produced in the larynx and the pharynx by the inflated cuff and the dome of the LMA. These pressure impulses are transmitted to the brain through the trigeminal, glossopharyngeal and the vagus nerves. These nerves carry the afferent impulses to the vasomotor centre, which in turn activates the sympathoadrenal system to release catecholamines, resulting in increased cardiac output, rather than increased systemic vascular resistance. The cardiovascular response is maximal during the stimulation of the epipharynx, whereas the response arising from the stimulation of tracheobronchial tree is least marked.[9] During removal of the LMA, the haemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of the cuff.[10]

There was no episode of gastric regurgitation in any patient. The seal pressure rendered by both devices was comparable.

Participants in both groups found the i-gel® easier to insert than the LMA, and it required minimal alteration to the standard technique. The problems that the novices faced with the LMA were the following:
• Cuff inflation takes time
• Found device more complicated to handle
• Tongue manipulation needed

• LMA appeared to be more difficult
• Felt more worried/anxious

The i-gel® has been used in anaesthesia during spontaneous or intermittent positive pressure ventilation.[11] The ease with which non-airway experts can be trained to insert the i-gel® makes this new device potentially very useful during resuscitation. Many institutes have considered keeping stock of the i-gel® on their resuscitation trolley and are training staff in its use during resuscitation courses.[12] However, to date, the i-gel® is currently not a part of the Immediate Life Support or Advanced Life Support courses, and does not appear in any advanced/difficult airway algorithms. The results of our study are encouraging, and with further confirmation from other studies, the i-gel® may soon be considered for incorporation into existing airway management algorithms.[13]

There are two limitations to our study: all the subjects had normal airways and were normotensive. Hence our results may not apply to patients with difficult airways and hypertensive patients.

Conclusion

i-gel® effectively conforms to the perilaryngeal anatomy, despite the lack of an inflatable cuff, and it consistently achieves proper positioning for supraglottic ventilation. Its use also results in less haemodynamic change compared to other supraglottic airway devices. Our results suggest that the i-gel® can be rapidly inserted in patients by novice users, and it compares favourably with other available supraglottic airways.

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