Original Article

Does prewarming of i-gel improve insertion and ventilation in anaesthetised and paralysed patients? A prospective, randomised, control trial

ABSTRACT

Context: I-gel are supraglottic airway devices with non-inflatable gel-like cuff that is believed to mould to body temperature, to seal the airway. Hence a pre-warmed i-gel may seal faster, provide better ventilation and superior leak pressure.

Aims: To determine if pre-warming i-gel to 40°C improves insertion and efficacy of ventilation.

Methods and Materials: A prospective, randomised, controlled trial was done on 64 patients requiring anaesthesia with muscle relaxation for short duration. For those in group W, i-gel warmed to 40°C for 15 minutes before insertion was used, whereas for those in group C, i-gel kept at room temperature (approximately 23°C) was used. The airway sealing pressure over time, number of attempts and time taken for a successful insertion were noted.

Statistical Analysis: Mean sealing pressure between two groups was compared using independent sample *t*-test. Repeated Measures ANOVA was used to analyse mean sealing pressure at 0, 15 and 30 min. *P* value ≤ 0.05 was considered statistically significant.

Results: Sealing pressure improves over time in both the groups but the mean sealing pressure was higher in group C when compared to group W at all points of time, however this was clinically and statistically insignificant. Ease of insertion, time for successful insertion, insertion attempts, intra-operative manoeuvres were all comparable between the groups with no adverse effects.

Conclusions: Pre-warming of i-gel to 40°C does not improve the success rate of insertion or provide a higher sealing pressure in anaesthetised and paralysed patients when compared to i-gel at room temperature.

Key words: Airway management; anaesthesia; general; heating; paralysis; sealing pressure

Introduction

I-gel is a novel supraglottic airway device (SAD) that is designed to seal the airway without an inflatable cuff.[1] Since it is believed that i-gel cuff moulds to body temperature to fit the supraglottic region, a pre-warmed i-gel may seal faster, provide better ventilation and superior leak pressure.

There are very few randomized controlled trials done on pre-warming of i-gel and findings are inconsistent.[2,3] Thus we decided to investigate this hypothesis of cuff softening with temperature by measuring sealing pressure in i-gel devices warmed to 40°C and those placed at room temperature i.e., 23°C in anaesthetised and paralysed patients.

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Aamuktha Malyadha Reddy, Nita Varghese, Basavaraj Herekar, Udupi Kailashnath Shenoy

Department of Anaesthesiology, Kasturba Medical College, Manipal, Karnataka, India

Address for correspondence: Dr. Nita Varghese, Flat 305, Green View Apartments, Manipal - 576 104, Karnataka, India.
E-mail: nitavarghese@gmail.com

Subjects and Methods

We did a prospective, randomised, double-blinded, controlled trial on patients aged between 18-65 years of either gender belonging to ASA I or II, undergoing elective surgeries of short duration (<2 hours) requiring general anaesthesia in supine position or lithotomy position. Emergency surgeries and patients with a history of hiatus hernia, obstructive sleep apnoea, asthma, mental retardation, congenital heart disease, recent upper respiratory tract infection (<7 days) were excluded. Patients requiring rapid sequence induction, anticipated difficult airway or complete upper airway obstruction or suspected or known abnormalities of the airway were also excluded. Anaesthesiology postgraduate who was blinded to the group was observer one, he/she did the preoperative evaluation, ensured that the inclusion criteria were met, none of the exclusion criteria was present and obtained the written informed consent. Consultant anaesthesiologist in charge of the particular case was observer two and he/she managed the airway, introduced the i-gel as per randomisation and graded the fiberoptic view. Second consultant anaesthesiologist who was blinded to the group was observer three, assisted with recording the sealing pressure, number of insertion attempts and manoeuvers, time required for successful insertion, fibre optic view as noted by observer two and any postoperative complications.

After obtaining Institutional Ethics Committee approval (IEC) and Clinical Trials Registry of India (CTRI) registration (no REF/2018/03/018008), patients were selected based on inclusion and exclusion criteria and informed consent was obtained after explaining the study. Demographic data such as weight, height, body mass index (BMI) and gender were recorded.

The enrolled patients were allocated to one of the two groups based on a computer-generated randomisation table. Group W recieved i-gel warmed to 40°C for 15 minutes before insertion whereas Group C received i-gel kept at room temperature (approximately 23°C).

All patients were seen a day before surgery and informed consent was obtained from all. Nil per oral (NPO) duration and premedication was advised by the consultant anaesthesiologist in charge of the particular patient. On the day of surgery patient was identified, NPO was confirmed, and consent for anaesthesia and participation in the study was checked. Anaesthesia machine was checked and emergency drugs were loaded. The patient was shifted to operation theatre (OT), intravenous (IV) access was secured, standard monitoring including $EtCO_2$ was established and baseline vitals were noted. After pre-oxygenation with 100% oxygen for 3 minutes, IV Fentanyl (2 mcg/kg) and IV Propofol (2-3 mg/kg) were given in titrated doses. After checking for the ease of manual ventilation, the patient was paralysed with IV Atracurium (0.5 mg/kg), and anaesthesia was deepened with 2% isoflurane in 100% oxygen at 6 L/min. After 4 minutes of manual ventilation, i-gel of adequate size as per randomisation was placed with the patient's head in the neutral position. After successful insertion of i-gel, the patient was mechanically ventilated using PCV with isoflurane, oxygen and nitrous oxide/air.

A glove box adequate to fit an i-gel was selected for heating the i-gel [Figures 1-6]. A hole was made on the side of the box to place the hose of body warmer (Equator). The plastic sealing of the i-gel was removed on one side, and a skin temperature probe was attached to the stem of i-gel. The i-gel with the temperature probe was placed in the box, and then the hose was passed through the hole in the box. Pre-warming of the i-gel was done by raising the air temperature to 40°C in a heating cabinet using a forced hot air blower before introduction in the warm group. The i-gel was inserted once it was warmed to 40°C as displayed by the monitor. It was kept at room temperature (approximately 23°C) in the control group. A skin temperature probe was used to measure the i-gel temperature. A 3, 4 or 5 sized i-gel was used as per the manufacturer's guideline.

Determination of sealing pressure:[4] After insertion of i-gel, the patient was placed on manual mode, the fresh gas flow was adjusted and fixed to 3 L/min, the expiratory valve of the circle system was closed to 30 cm H_2O, and the sealing pressure was determined by the following methods.

Test 1 (Auscultation): The minimum airway pressure at which an audible gas leak happened was noted by placing a stethoscope over the neck lateral to the thyroid cartilage.

Test 2 (Manometer stability): The airway pressure at which the dial of the aneroid manometer [Figure 7] reaches equilibrium was noted as the pressure from the breathing

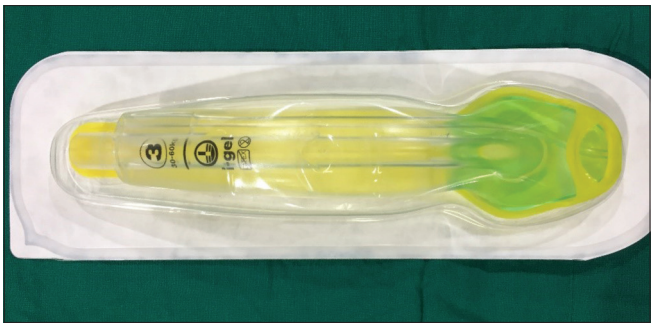

Figure 1: i-gel

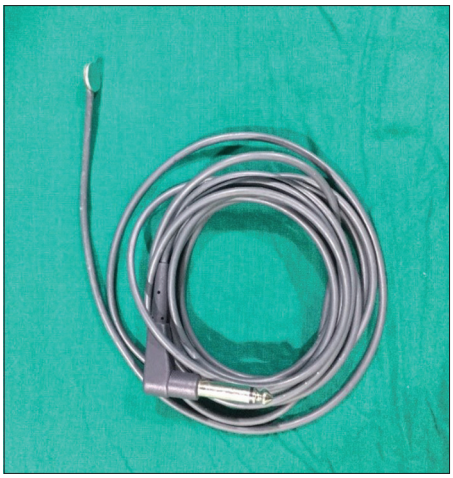

Figure 2: Skin temperature probe

Figure 4: Equator Body Warmer

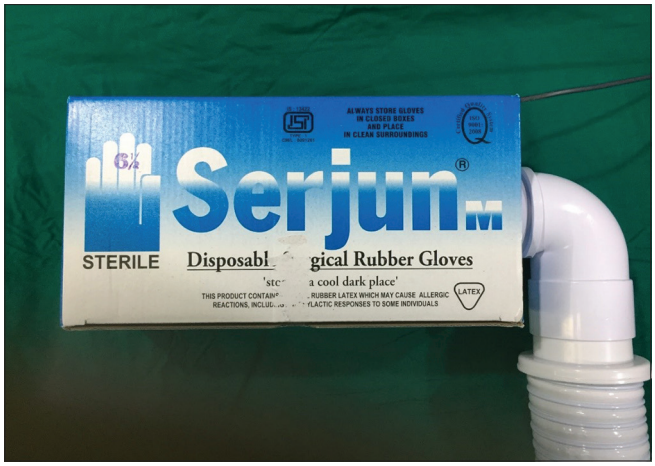

Figure 6: Method of heating

system raised (i.e., the airway pressure at which the fresh gas flow is in balance with the gas leak).

Airway pressures were not allowed to surpass 30 cm H_2O to avoid gastric insufflation. The anatomical position of the

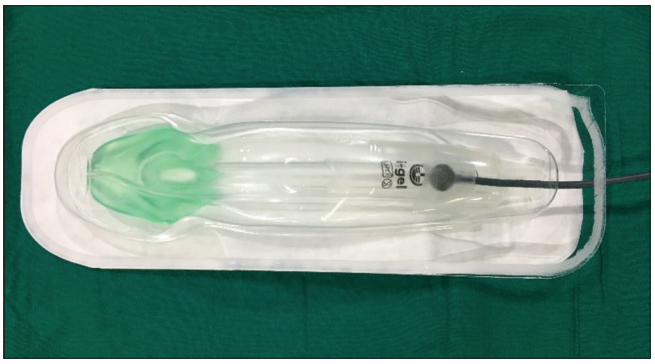

Figure 3: I-gel with skin temperature probe attached to stem

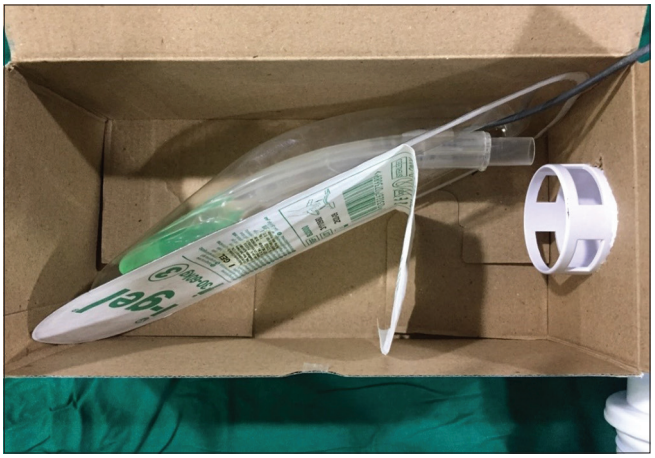

Figure 5: Method of heating

Figure 7: Aneroid manometer

i-gel was then determined by advancing a flexible fiberoptic bronchoscope into the i-gel to a point just proximal to its tip. The fiberoptic scope examination view was scored [Table 1].

Successful insertion was confirmed by free ingress and egress of gases and a normal capnograph curve. In case of failed ventilation (inability to get a capnography trace), second insertion attempt was done and the number of attempts of insertion (an attempt was considered every time the i-gel was taken out of the oral cavity and reintroduced) were

recorded. If manipulation was needed to obtain an effective airway, it was reported as either 'yes' or 'no' and manoeuvers necessary were noted. However, if the i-gel could not be placed in the third attempt, this was documented as a failure, and then airway was secured with either a proseal laryngeal mask airway (PLMA) or an endotracheal tube (ETT), and this participant was excluded from the study.

After the completion of surgery, all anaesthetics were discontinued and the patient woken up after reversal of neuromuscular blockade. The i-gel was taken out and sore throat, hoarseness of voice, throat pain and other postoperative complications if any were assessed after the patient was fully awake. The time for successful insertion was recorded from the introduction of i-gel to the sustained appearance of normal capnogram waveform. The number of insertion attempts were recorded in addition to the success rate of first insertion attempt. The attempt was reported as a failure if the i-gel could not be placed successfully in two attempts. Ease of insertion was graded [Table 2]. Sealing pressure was measured immediately, at 15 and 30 minutes after insertion. After confirming correct placement of i-gel, appropriate sized drain tube was placed through the gastric channel. Correct placement of gastric tube was confirmed by detection of injected air on epigastric auscultation or aspiration of gastric fluid. Airway manipulations (side to side rotation, gentle advancement, jaw thrust, withdrawal of device, neck extension) required to maintain airway patency were recorded. After the completion of surgery, i-gel was removed once the patient regained full consciousness. Presence of blood stain on i-gel, dental/tongue/lip trauma and hoarseness/stridor if any, was recorded after removal of the device. All patients were observed in the post anaesthesia care unit (PACU) ward by observer three immediately after shifting the patient to PACU to record postoperative complications such as sore throat, hoarseness of voice, difficulty in swallowing, cough or stridor if any.

Table 1: Fiberoptic scoring system score

1 Clear view of vocal cords
2 Only arytenoid cartilages visible
3 Only epiglottis visible
4 No laryngeal structures visible

Table 2: Ease of insertion

Grade	Attempts	Score
Easy	One attempt without manoeuvre	1
Moderately Easy	One attempt with manoeuvre/ Two attempts without manoeuvre	2
Difficult	Two attempts with manoeuvre/ Three attempts with or without manoeuvre	3

Sample size

Calculation of sample size was based on a comparison of mean sealing pressure at 15 minutes. From the pilot study, we observed a sealing pressure difference of 8.5 cm H_2O. Assuming a minimum difference of 6 cm H_2O in sealing pressure between two groups with a standard deviation of 8.5, the sample size needed in each group was 32 at 80% power with 5% type 1 error rate. Hence, a total of sixty-four patients were included in the study.

Statistical analysis

Standard statistical analysis was done using SPSS software. Mean ± standard deviation was used to summarise the demographic data such as age and BMI. Categorical variables like ASA, gender and insertion attempts, intraoperative manoeuvre were summarised by frequency and percentage. Mean sealing pressure between two groups was compared using an independent sample *t*-test. Repeated Measures ANOVA was used to analyse mean sealing pressure at 0, 15 and 30 min across the two arms. Chi-square test was used to compare gender and ASA distribution across groups. As data distribution was not symmetrical, comparison of time for successful insertion between two groups was done using Mann Whitney U test. Median was used to summarize time for successful insertion between two groups. A *P* value of less than 0.05 was considered statistically significant.

Results

All 64 patients completed the study, and no patient was lost for follow up. Demographic data with respect to age and BMI were comparable between the two groups, but height and weight showed statistically significant difference [Table 3]. ASA- PS and gender belonging to the two groups had no statistically significant difference [Table 4]. There was no statistically significant difference in the mean sealing pressure between the two groups [Table 5]. The changes in mean sealing pressure [Figure 8] tells us that sealing pressure improves over time in both the groups, but the mean sealing pressure was higher in group C when compared to group W at all points of time, but this was clinically and statistically insignificant. The number of insertion attempts and Intraoperative manoeuvres were compared [Table 6].

I-gel was inserted in a single attempt in all 32 patients in the warm group, but one patient out of thirty-two in control group required two attempts. Four patients in both groups required intraoperative manoeuvre after insertion of i-gel. Time for successful insertion and ease of insertion showed no statistically significant difference [Tables 7 and 8]. Otherwise gastric tube was placed successfully in all patients.

Table 3: Demographic data (age, weight, height, BMI)

	Group C ($n=32$)	Group W ($n=32$)	P^*
Age (years) Mean±SD	42.13±12.27	40.69±13.40	0.66
Weight (kg) Mean±SD	59.62±9.58	65.84±13.16	0.04
Height (cm) Mean±SD	157.41±9.24	165±8.55	0.001
BMI (kg/m^2) Mean±SD	23.63±2.78	23.98±3.13	0.67

*Independent *t*-test. Group W: The i-gel was warmed to 40°C for 15 minutes before insertion. Group C: The i-gel was kept at room temperature (~23°C)

Table 4: Demographic data (ASA-PS and Gender)

Categorical Variable	Group C ($n=32$)		Group W ($n=32$)	
	No. of patients	% of patients	No. of patients	% of patients
ASA				
1	24	75.0%	22	68.8%
2	8	25.0%	10	31.2%
Gender				
F	12	37.5%	8	25.0%
M	20	62.5%	24	75.0%

*Chi square test. Group W: The i-gel was warmed to 40°C for 15 min before insertion. Group C: The i-gel was kept at room temperature (~23°C)

Table 5: Sealing pressure in cm H_2O (mean±SD)

Time	Group C $n=32$	Group W $n=32$	P^*
0 min	24.66±4.78	22.81±5.94	0.79
15 min	25.66±4.36	23.69±5.89	
30 min	26.31±3.95	24.78±5.51	

*Repeated measures ANOVA. Group W: The i-gel was warmed to 40°C for 15 min before insertion. Group C: The i-gel was kept at room temperature (~23°C)

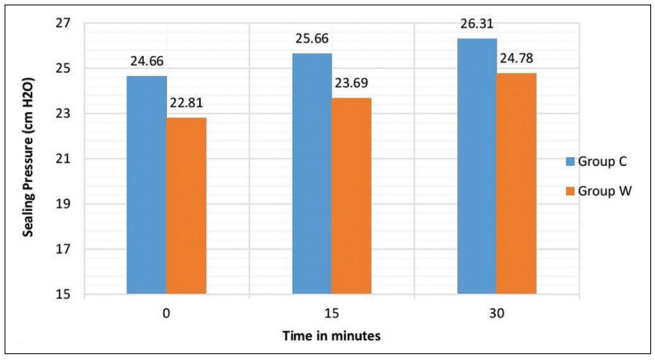

Figure 8: Mean sealing pressure

Fiberoptic scoring was one in all patients and there were no postoperative complications in both the groups.

Discussion

The i-gel is a novel SAD made up of styrene ethylene butadiene styrene (SEBS), a thermoplastic elastomer, which has a gel-like feel and soft durometer.[5] The mask of the i-gel is made to adapt to the hypopharyngeal and laryngeal framework with the use of a non-inflatable cuff which might soften at body temperature and increase the efficacy

Table 6: Insertions attempts and Intraoperative manoeuvre

Categorical Variable	Group C ($n=32$)		Group W ($n=32$)	
	No. of patients	% of patients	No. of patients	% of patients
Insertion attempts				
1	31	96.9%	32	100%
2	1	3.1%	0	0.0%
Intraoperative Manoeuvre				
Yes	4	12.5%	4	12.5%
No	28	87.5%	28	87.5%

Group W: The i-gel was warmed to 40°C for 15 minutes before insertion. Group C: The i-gel was kept at room temperature (~23°C)

Table 7: Time for successful insertion (sec)

Group	Percentiles			P^*
	25	50	75	
C	15.00	18.00	20.00	0.48
W	16.00	18.00	22.00	

*Mann Whitney U test. Group W: The i-gel was warmed to 40°C for 15 min before insertion. Group C: The i-gel was kept at room temperature (~23°C)

Table 8: Ease of insertion

Score	Group C $n=32$	Group W $n=32$	P^*
1	27	28	0.72
2	5	4	
3	0	0	

*Chi square test. Group W: The i-gel was warmed to 40°C for 15 min before insertion. Group C: The i-gel was kept at room temperature (~23°C)

of sealing after insertion. I-gel is designed to render an anatomical impression over the inlet of larynx and works in conformity with the patient's anatomy thereby significantly decreasing displacement and compression trauma. This makes i-gel insertion easy, fast and safe in anaesthesia and resuscitation. [6,7]

The leak pressure or pharyngeal sealing pressure measures how effectively a SAD seals over the larynx. A superior sealing pressure denotes the efficiency of a device during spontaneous or mechanical ventilation. The i-gel has already demonstrated a higher airway-sealing pressure when compared to traditional SADs.[8]

Studies prove that warming of the i-gel cuff to body temperature after insertion tends to provide a better sealing pressure which is attributed to its thermoplastic property. Against this background, Nishiyama *et al.* study on i-gel prewarmed to 37°C for 30 minutes in paralysed patients did not show any statistically significant difference in sealing pressure when compared to the i-gel at room temperature. However, they commented that the warm group had a propensity to have smaller insertion time, lesser number of attempts and a smaller leak volume. They believed that the

lack of a higher sealing pressure might be due to the cooling of i-gel during the insertion process.[2]

Komasawa *et al.* decided to test i-gel pre-warmed to a higher temperature of 42°C for 30 minutes in non-paralysed patients and found that pre-warming does not facilitate faster insertion or a better sealing pressure which they attributed to the lack of muscle relaxation.[8] Following this they thought that it may be worth investigating the effects of muscle relaxants on the insertion success rate and sealing pressure of i-gel as relaxants reduce the pharyngeal space and partially augment the fit of the i-gel. Hence, they replicated the previous study in paralysed patients and found that pre-warmed i-gel resulted in a higher success rate of insertion and provided better sealing pressures with smaller leak volumes at 30 seconds after mechanical ventilation which contradicted their previous finding.[3]

Since there were conflicting opinions regarding the benefit of warming the i-gel before insertion we decided to study whether i-gel pre-warmed to 40°C in anaesthetised and paralysed patients would allow the cuff to adapt to the perilaryngeal anatomy earlier than if it was at room temperature.

Although there are studies done on pre-warmed i-gel, all studies measured sealing pressure only immediately after insertion.[2,3,8] None of these studies considered the effect of pre-warming on the sealing pressure over time. Given this, we studied the effect of pre-warming on the sealing pressure of the i-gel not just immediately, but also at 15 and 30 minutes after insertion in both the groups. Mean sealing pressure was 24.66 cm H_2O in group C and 22.81 cm H_2O in group W at 0 minutes, it was 25.66 cm H_2O in group C and 23.69 cm H_2O in group W at 15 minutes, it was 26.31 cm H_2O in group C and 24.78 cm H_2O in group W at 30 minutes.

We observed that the mean sealing pressure increases over time within each group. Even though the mean sealing pressure was higher in the control group when compared to the warm group at all time points, this was neither statistically nor clinically significant.

The observations of the sealing pressure were similar to that reported by Nishiyama *et al.* where they also found that even though the warm group had a lower leak volume and higher leak pressure when compared to the control group it was not statistically significant. While komosava *et al.* reported a statistically significant higher sealing pressure and smaller leak volumes when i-gel was warmed to 42°C, they felt it was not clinically significant.

Dingley *et al.* evaluated the properties of i-gel cuff over clinical temperature ranges and found that there is a minimal decrease in hardness and resilience with warming. They observed that the thermoplastic elastomer of i-gel cuffs have a melting point above 200°C which is unlikely to be seen in clinical practice and hence the assumption that i-gel will soften as they warm up to the body temperature may be a myth. They also proposed that physical expansion of the cuff size with warming to body temperature is an unlikely mechanism by which the seal might improve over time. The improvement in the sealing pressure of the i-gel cuff over time as shown in many studies may be due to the redistribution of the interstitial fluid in the areas around the cuff or due to the interaction between saliva and the cuff material altering its property and allowing it to migrate to a position of better fit.[9,10]

This study done by Dingley *et al.* helped us to explain the finding in our study where the mean sealing pressure did not improve after warming when compared to the control group. Thus vouching for the hypothesis that cuff softening with temperature is unlikely to be the mechanism by which seal or fit of the i-gel improves with time after insertion.

Komosawa *et al.* found that the insertion success rate was significantly higher when i-gel was warmed to 42°C compared to the control group which they believed is a benefit of pre-warming the i-gel. However, our results showed that the number of attempts, insertion time, ease of placement of the i-gel were not different in the warm and control groups which correlates with the study done by Nishiyama *et al.* where i-gel pre-warmed was used with muscle relaxants as well as the study done by Komasawa *et al.* where pre-warmed i-gel was used without muscle relaxants. There were no postoperative complications in both the groups which is similar to the previous studies.[2,3]

Thus, we found that pre-warmed i-gel does not provide a higher sealing pressure or better insertion success rate even in the presence of muscle relaxants. Our study suggests that there is no benefit in warming the i-gel. Therefore, we can use the i-gel at room temperature for elective surgeries of short duration and emergency airway management.

Our study on pre-warming of i-gel has the following limitations:

- Even though BMI was comparable between the two groups, there was a significant difference in the weight and height of the patients between the two groups which might have affected the sealing pressure in the warm group

- We excluded morbidly obese patients in our study. Interpretation of efficacy of insertion in obese patients may further explain the role of muscle relaxants for i-gel insertion
- As all the patients in our study were confined to a single centre, a multicenter study or a meta-analysis would provide more details on the usage of pre-warming of the i-gel
- As the sample size of our study was relatively small with a preponderance of males, a larger sample size may be required to confirm our findings and understand the influence of various patient characteristics on the pre-warming of i-gel
- Unlike other studies where a heating cabinet with automatic temperature control was used to warm the i-gel, we used a handmade heating cabinet which may not have uniformly warmed the i-gel.

Finally, we conclude that pre-warming of i-gel to 40°C does not improve the success rate of insertion or provide a higher sealing pressure in anaesthetised and paralysed patients when compared to i-gel at room temperature.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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