ORIGINAL ARTICLE

Comparison of Insertion Characteristics of Prewarmed I-gel and I-gel at Room Temperature in Adult Patients Undergoing Elective Surgeries- A Randomized Control Trial

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Abstract

Background: I-gel is usually inserted at room temperature, but in certain studies it was found that I-gel may mould to the laryngeal structures faster if pre-warmed. The present study was conducted to investigate this hypothesis by comparing the airway sealing pressure and leak volume amount between prewarmed I-gel devices and those kept at room temperature in paralysed adult patients on Volume Controlled Ventilation mode of ventilator posted for elective surgeries. **Material and Methods:** 70 patients were randomly allocated into 2 groups using computer generated randomisation. In Group C, airway was secured with I-gel at room temperature. In Group W, patients airway was secured with I-gel which was prewarmed at 42^0celcius. **Results:**The mean insertion time of prewarmed I-gel was 11.94 ±1.59 seconds whereas that of I-gel at room temperature was 14.20 ±1.80 seconds which was stastitically significant. Mean leak volume after one minute and 30 minute of insertion in W group was lesser than C group and the difference was statistically significant (p=0.048).**Conclusion:** Prewarmed I-gel does not provide a higher sealing pressure or better insertion success rate even in the presence of muscle relaxants. However prewarmed I-gel had smaller insertion time and leak volume than control group.

Key Words: Laryngeal Mask Airway, Supraglotic Airway Devices

Introduction

Supraglottic airway devices (SAD) have been described as missing link between face mask and ETT.[1] The advantages of SAD include avoidance of laryngoscopy, less invasive, better tolerance by the patients, increased ease of insertion, improved haemodynamic stability during emergence, less sore throat, hands free airway and easier placement even by inexperienced personnel.[2]

I gel is made of Styrene Ethylene Butadiene Styrene (SEBS) and is anatomically preformed to mirror the peri-laryngeal structures and hypopharyngeal structures without the use of an inflatable cuff. This supraglottic airway without a cuff has potential advantages including easier insertion and use, minimal risk of tissue compression and stability after insertion. The I-gel is designed as a

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single patient use, disposable device.[3]

The insertion of I-gel has also been found to be significantly easier and faster compared with other SADs.[4] Thehaemodynamic response to insertion of I-gel was significantly less than that for endotracheal intubation and is a reflection of an increase in sympathoadrenal activity due to oropharyngeal and laryngotracheal stimulation which is less with I-gel insertion.[5,6]

It is designed to render an anatomical impression over the inlet of larynx and works in conformity with the patients anatomy thereby significantly decreasing displacement and compression trauma. This facilitates the quick, simple, and safe insertion of I-gel in resuscitation and anaesthesia.[7] Comparing I-gel to conventional SADs, a greater airway sealing pressure has already been demonstrated.[8]

I-gel is usually inserted at room temperature, but in certain studies, it was found that I-gel may mould to the laryngeal structures faster if pre-warmed. The present study was conducted to investigate this hypothesis by comparing the airway sealing pressure and leak volume amount between I- gel prewarmed to 42º celsius and those kept at room temperature in adult patients posted for elective surgeries.

Material and Methods

The present prospective randomized comparative study was conducted in the Department of Anaesthesiology and Intensive Care, Government Medical College, Jammu in the year 2020-21. After attaining approval of the Ethical committee of the institute (IEC number IEC/GMC/2021/723 dated 28-12-2021),the present study included 70 patients of either gender, ranging from 18-70 years, belonging to ASA 1 and 2, scheduled for elective surgery under general anaesthesia.

Exclusion criteria included patients with cervical spine pathology, allergic to any drug used in the study, history of hiatus hernia, gastroesophageal reflux, Patients with BMI > 30 and patients with known or predicted difficult airway.

Preanaesthetic check-up was done one day prior to the surgery and informed written consent was taken from each patient enrolled in the study.. Patients were randomly allocated into 2 groups using computer generated randomisation. Using G power software, it was estimated that the least number of patients required in each group with 80% power and 5% significance is 34. Hence 35 patients were included in each group to include the dropouts.. In Group C, the airway was secured with I-gel at room temperature. In Group W, patients airway was secured with I-gel which was prewarmed at 42º celsius.

The patient was prepared by overnight fasting and was premedicated with tablet alprazolam 0.25 mg and tablet pantoprazole 40 mg orally the night before surgery. On the morning of surgery, patients was given injection diclofenac 75 mg intravenous in 100 ml of normal saline 30 minutes before surgery. All baseline parameters were recorded. Patient was given injection tramadol 1mg/kg intravenous and was preoxygenated with 100% oxygen for 3 minutes. Anaesthesia was induced with injection propofol 2-2.5 mg/kg intravenous till loss of verbal contact with the patient. Neuromuscular blockade was achieved with injection succinylcholine 1.5 mg/kg. Patient was ventilated manually with 100% oxygen after which the I-gel of appropriate size was inserted. In group W, I-gel was prewarmed to 42º C in a water bath attached with a thermometer (FEDUS professional digital thermometer) before insertion. In group C, I-gel was stored at room temperature (approximately 23^{0}celcius).Using the classical recommended technique, appropriate sized I-gel preloaded with a gastric tube was inserted.

After placement, the device was connected to the anaesthesia machine and correct placement of the device was judged by auscultation, adequate chest expansion on manual ventilation, square wave capnography and end tidal CO_2 between 35-45 mmHg. Anaesthesia was maintained with 33% O_2, 66% N_2O and 0.5-1% isoflurane (to achieve MAC 1).Relaxation was maintained with loading dose of atracurium 0.5mg/kg followed by maintenance dose of atracurium 0.1 mg/kgi/v. Ondansetron 0.1 mg/kg i/v was administered towards the end of the procedure. At the end of procedure, neuromuscular blockade was antagonized by injection neostigmine 50 mcg/kg and glycopyrrolate 10 mcg/kg.

Insertion time of I-gel was defined as the time in seconds when the device crosses the incisors to the attachment of the breathing system to the SAD and delivery of the first tidal volume. Once sufficient ventilation was confirmed after Igel insertion,patient's head was placed in a neutral position,theexpiratory valve was closed, fresh gas flow was adjusted to 3 litres per minute, and ventilatory pressure was monitored to determine the airway sealing pressure. The pressure at which the manometer's needle connected to the anaesthesia circuit reaches equilibrium with an audible air

leak from the oropharynx up to a maximum pressure of 40 cm H2O is known as the oral laryngopharyngeal sealing pressure (OLP). The leak volume was calculated as inspiratory volume minus expiratory volume.

The present study was conducted to compare the insertion characteristics of the prewarmed I-gel and I-gel at room temperature.Primary outcomes included insertion attempts and time and ventilatory responses like leak volume and oropharyngeal leak pressures.Secondary outcomes included intraoperative and postoperative complications.

The data thus collected was analyzed. Appropriate statistical tests were applied. The expression for continuous variables was mean ± SD. Percentages and frequencies were used to summarise categorical values. Bar and line diagrams were used to visually represent the data. Student's independent t-test or Mann Whitney U-test, whichever feasible, was used for comparing continuous variables. For comparing categorical variables, the chi-square test or Fisher's exact test was used, depending on which was more appropriate. It was deemed statistically significant when $P < 0.05$.

Results

There was no statistically significant difference with respect to age, sex, weight, height and BMI distribution between the two groups.

Table 1. Comparison of Baseline Parameters Between two Groups

			Mean	Std. Deviation	Minimum	Maximum
Mean Age	Control	35	41.7143	10.69241	25	62
	Warm	35	45.0571	14.32592	18	68
Mean Weight	Control	35	60.6857	6.22505	50	74
	Warm	35	59.8571	5.94159	52	74
Mean Height	Control	35	157.2286	4.97692	148	168
	Warm	35	147.1714	7.42605	136	159
BMI	Control	35	24.4696	1.06151	22.83	26.22
	Warm	35	27.5873	0.77982	26.48	29.27

Table 2 demonstrates the number of insertion attempts and insertion time in two groups. The difference of first successful insertion rate was not significant statistically. The mean insertion time of prewarmed I-gel was 11.94 ±1.59 seconds whereas that of I-gel at room temperature was 14.20 ±1.80 seconds. The difference of insertion time of I-gel in two groups was significant statistically (p=0.0001).

In group C, the mean leak volume after 1 min and 30 minutes of I gel insertion was 35.6 ± 6.84 mL and 29.29 ± 7.19 mL respectively. In group W, the mean leak volume after 1 min and 30 minutes of I-gel insertion was 28.03 ± 4.23 mL and 22.69 ± 4.15 mL respectively. The leak volume decreased with time in both the groups. However, mean leak volume after 1 minute and 30 minute of insertion in W group was lesser than C group i.e. leak volume decreased as it expands on prewarming and makes a good seal in the airway and the difference was statistically significant (p=0.048). In both the groups, the mean OLP increases with time. However the OLP was not significantly increased on prewarming the I-gel. (Table 3)

Table 2. Comparison of Insertion Attempts and Insertion time in Seconds

Insertion Attempt	Control		Warm		
	No.	%age	No.	%age	
1	32	91.42857	34	97.14285714	
2	3	8.571429	1	2.857142857	
Insertion Time	Control (35)		Warm (35)		P-value
Mean	14.20		11.94		P < 0.0001
Standard Deviation	1.09		1.03		

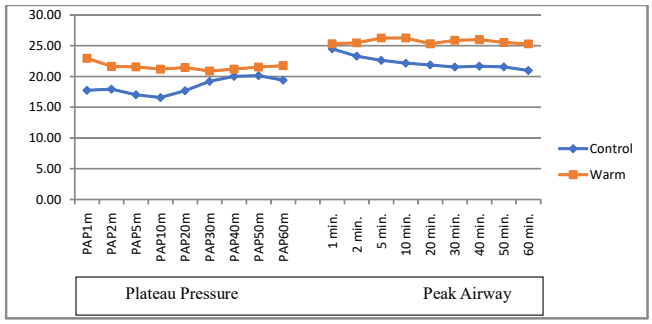

Figure 1: Plateau and Peak Airway Pressure Post Insertion of I gel in 2 Groups

None of the patients in two groups had any intraoperative complications like laryngospasm, bronchospasm, hypoxia or regurgitation. 2 patients (5.7%) in group C and 1 patient (2.8%) in group W had blood stain after removal of I-gel.2 patients (5.7%) had complaint of sore throat in group C and none patients in group W had any postoperative complications of sore throat, dysphagia, dysphonia or hoarseness.

Discussion

I-gel cuff is usually inserted at room temperature, but in certain studies it was found that it may mould to the laryngeal structures faster if pre-warmed. The present study was conducted to investigate this hypothesis by comparing the airway sealing pressure and leak volume amount between I- gel prewarmed to 42° celcius and

Table 3 Comparison of Leak Volume and Orolaryngopharyngeal Pressures in Two Groups

	Control		Warm		
Minutes	After 5 min. of insertion	After 30 min. of insertion	After 5 min. of insertion	After 30 min. of insertion	P Value
Leak Volume					
No.	35	35	35	35	0.048776
Mean	35.6	29.2857	28.0286	22.6857	
Std. Deviation	6.83503	7.18893	4.28737	4.14992	
Minimum	25	20	20	15	
Maximum	50	40	35	34	
OLP					
No.	35	35	35	35	0.927852
Mean	25.8857	29.6286	25.5143	28.4286	
Std. Deviation	1.9062	2.59055	1.63368	2.0042	
Minimum	22	26	24	26	
Maximum	30	34	29	32	

those kept at room temperature in adult patients undergoing elective surgeries.

In our study, we found that in both the groups, I-gel was successfully inserted in all patients and there was no case of failed insertion in any of the two groups. The difference in the ease of insertion of I-gel was statistically not significant. The results from our study were similar to those obtained in the study conducted by Nishiyama *et al.,* Komasawa *et al* and Reddy *et al* who also found that prewarming of I-gel to 42º celsius did not increase the success rate of insertion in anesthetized, non- paralyzed patients.[9,10,11]

In our study, the mean insertion time of I-gelwas 14.20 ±1.80 seconds in the group C whereas 11.94 ±1.59 seconds in the group W. The difference in insertion time in two groups was significant statistically (p= 0.0001). The results from our study were similar to those obtained in the study conducted by Nishiyama *et al* and Wang *et al*.[9,12]

The orolaryngopharyngeal sealing pressure (OLP) measures how effectively a SAD seals over the larynx. High OLP are important as they indicate efficiency of device in terms of airway protection, feasibility of positive pressure ventilation and likelihood of successful LMA placement. It is regarded as the most important marker of the safety of such devices.I-gel has already demonstrated a higher airway-sealing pressure when compared to traditional SADs.[8] We found that the mean sealing pressure increased with time in our study. Even though the mean sealing pressure in Group C was consistently higher than Group W, this difference was not statistically or clinically significant.(p= 0.927). The results of our study were similar to those obtained by the study conducted by Reddy *et al* who also considered the effect of prewarming on the sealing pressure over time and found no significance statistically in the two groups.[11]

Zheng *et al* observed that increased sealing pressure suggests that the i-gel cuff fits the pharyngeal structure better and can reduce the chance of pulmonary aspiration and regurgitation and protect the airway more effectively.(13) OLP was not significantly increased on prewarming the I-gel. The improvement in the sealing pressure over time 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 and not due to softening of I-gel at body temperature, studied by Dingley *et al* which contradict our study.[14] Martin *et al* also observed in his study that better sealing following insertion is due to temperature-dependent volume expansion and weight increase.[15]

Leak volume was decreased with time in both the groups. The cuff of I-gel was found to fit to laryngeal structure faster when prewarmed to body temperature than kept at room temperature and thus leak volume was smaller in W group than C group. This difference was statistically significant (p= 0.048). The results of our study were similar to those obtained by the study conducted by Nishiyama *et al* and Komasawa *et al* who found that leak volume tended to be smaller in the warm group as

compared to the cold group.[9,10]

Conclusion

From our study, we can conclude that prewarmed I-gel does not provide a higher sealing pressure or better insertion success rate even in the presence of muscle relaxants. However prewarmed I-gel had smaller insertion time and leak volume than control group.

Limitations

Our study has few limitations. There was no blinding in the data collection which is possible source of bias. Oropharyngeal leak pressure, which is one of the most important outcome, can vary according to the method of measurement (eg. Audible leak vs manometric stability).The study involved patients with normal airway under the effect of muscle relaxants and whether the same outcome can be extrapolated to patients with difficult airway or spontaneously breathing patients is subject to performance of similar large scale study.

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