

Clinical Performance of i-gel® and BlockBuster™ Laryngeal Mask Airway in Adult Patients during General Anesthesia: A Randomized Comparison

Abstract

Background: Supraglottic devices have revolutionized the current practice of airway management. We compared the clinical performance of a recently introduced BlockBuster™ Laryngeal mask airway with i-gel® in adult patients under general anesthesia. **Methods:** Following Institutional ethical clearance, the present study was conducted on 62 patients belonging to American Society of Anesthesiologists physical status 1 and 2 of either sex in the age group of 20–60 years under general anesthesia. Patients were randomly assigned to i-gel® (I) and BlockBuster™ (B) groups (31 per group). Time for successful insertion, insertion success rate, ease of insertion, oropharyngeal leak pressures (OLPs), and complications were assessed. **Results:** Mean insertion time of device was less in Group I (13.52 ± 2.58 s) than that of Group B (14.10 ± 2.04 s), which was neither clinically nor statistically significant ($P = 0.330$). OLP in Group B (24.52 ± 2.77 cm of H₂O) was found to be significantly higher compared to Group I (20.81 ± 2.56 cm of H₂O) with $P < 0.001$. Overall insertion and first attempt success was similar (i-gel® 31/31 [100%] and 29/31 [93.5%] and BlockBuster™ 31/31 [100%] and 29/31 [93.5%], respectively). Ease of insertion ($P = 0.684$) and complications ($P = 0.782$) of both the devices were comparable. **Conclusions:** Both the devices are useful and effective for airway management in adult under general anesthesia. Having a high OLP and comparable insertion time, risk of aspiration may be further reduced with the use of BlockBuster™ in comparison to i-gel®.

Keywords: Airway management, elective surgical procedure, general anesthesia, laryngeal masks, pressure, ventilation

Introduction

Adequate airway management is extremely important for general anesthesia, allowing ventilation and oxygenation as well as mode for anesthetic gas delivery. Maintaining the airway patency with minimal complications is utmost priority of the anesthesiologist. Supraglottic airway devices (SADs) introduced in clinical practice since early 80s have dramatically changed the current scenario of airway management. SADs with better seal and gastric access (added safety feature) are now being routinely used both in hospital and out of hospital for better patient management.

The i-gel® (Intersurgical Ltd., Berkshire, UK) a noninflatable, single use novel SAD [Figure 1] with a gastric drain port has an anatomically designed mask made from medical grade thermoplastic elastomer to adapt to the surrounding structures to provide a better seal, thus allowing higher

seal pressure during positive pressure ventilation.^[1]

The presence of an integrated bite block with a wide cylindrical airway channel that may be used as conduit for intubation through the device enhance the clinical features of the i-gel® and reduces the chances of device malposition and axial rotation.^[2]

A comparatively newer SAD called BlockBuster™ Laryngeal Mask Airway (Tuoren, Henan, China) invented by professor Ming Tian in 2012 is a second generation SAD which is increasingly gaining popularity [Figure 2]. Few studies have recently highlighted the utility of BlockBuster™ in providing adequate ventilation with gastric access and as a conduit for blind endotracheal intubation.^[3,4]

There is a lacuna of randomized study comparing the above-mentioned SAD; therefore; we planned this study to compare

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Figure 1: i-gel supraglottic device

the clinical performance and complications of i-gel® and BlockBuster™ Laryngeal mask airway in adult patients undergoing general anesthesia. The primary objective of our study was the time for successful insertion, ease and required attempts of insertion, oropharyngeal leak pressure (OLP), quality of ventilation, and complications were also assessed.

Methods

The study was approved from the institutional ethical committee (Ref. code: 102nd ECM II B-Thesis/P20) and registered under clinical trial registry of India (registration no. CTRI/2021/01/030332). All the principles of the Helsinki declaration were followed during the study course. Adult patients (aged 20–60 years) of American Society of Anesthesiologists (ASA) physical status 1 and 2 with body mass index (BMI) in range of 18–35 kg/m² scheduled for elective surgery (laparoscopic/open, upper/lower, and gastrointestinal procedures) requiring general anesthesia were eligible for inclusion in our study. Pregnant patients, patients with an interincisor distance of <3 cm, or patients with planned surgery in prone position and with any intraoral pathology were not part of the study. All study participants gave written, informed consent. A detailed preoperative assessment and airway examination was performed by one of the investigators and documented on the study proforma for each participant at least 2 days before surgery. The study was conducted in the operating rooms of our hospital for a period of 6 months starting from January 2021.

Patients were randomly allocated with the help of computer-generated random number table to either an i-gel® (Group I) or BlockBuster™ (Group B). All patients were fasted for at least 8 h before the surgery and were premedicated with oral alprazolam 0.25 mg and ranitidine 150 mg on the night before surgery.

Randomization sequences were kept in opaque, sealed envelopes, which were opened just before the arrival of the



Figure 2: LMA BlockBuster supraglottic device

patient to the operating room. Availability of the required SAD was ensured before the arrival of the patients to the operating rooms.

On the day of surgery, intravenous (IV) access was established and standard monitoring such as noninvasive blood pressures, pulse oximetry, electrocardiogram, and end-tidal carbon dioxide monitoring was initiated as per the institutional protocol. All patients were given IV ondansetron 0.1 mg/kg and IV midazolam 0.01 mg/kg and preoxygenated with 100% oxygen at 8 lpm of fresh gas flow (FGF) for 3 min. Anesthesia was then induced with IV fentanyl 2 µg/kg and propofol 2 mg/kg in slow incremental dose. With loss of eyelash reflex and confirming adequate bag mask, ventilation patients were paralyzed with the loading dose of IV vecuronium 0.1 mg/kg. Mask ventilation with oxygen was continued with FGF of 6 lpm for 3 min. As per the manufacturer's instructions and patients weight, appropriate device was lubricated using water soluble gel and inserted in accordance with manufacturer's recommendations. The device was inserted by the study investigators (who had minimum experience of 50 prior insertion of each device) in our study. In the BlockBuster™ group, the cuff was inflated with intracuff pressure standardized to 60 cm H₂O. A bilateral visible chest-rise with an end-tidal carbon dioxide waveform with gentle squeezing of the bag confirmed the appropriate placement of the SAD.

After confirming the adequate placement of the device, mechanical ventilation was initiated using volume-control mode with tidal volume set at 8 ml/kg and respiratory rate set at 12–16 breaths/min. FGF mixture at 3 lpm of (2 l oxygen + 1 l air) with 1.5%–2% sevoflurane and IV vecuronium 0.01 mg/kg was given to maintain end tidal carbon dioxide between 35 and 40 mmHg. Once the SAD was successfully placed, adequately sized Ryle's tube was inserted through the gastric tube port of the SAD.

The time of device insertion (calculated from the time of picking the device till the appearance of first

capnography trace) and other parameters such as ease of insertion (1 = easy insertion; 2 = moderate resistance; 3 = severe resistance, and 4 = unable to insert the device).

OLP which signifies airway sealing was determined just before the initiation of the surgical procedure, by assessing an audible leak over the patient's mouth upon closing the expiratory valve at 30 cmH₂O with a gas flow of 3 L/min. If there was no audible leak, a stethoscope was placed over the trachea to listen for the leak.

Requirement of airway maneuvers (neck extension/flexion, chin lift, and or slight modification of insertion depth of devices) for successful ventilation, first attempt success rate, number of attempts (maximum of two attempts were allowed, if in first attempt adequate ventilation was not achieved even with airway maneuvers then the device was removed followed by bag mask ventilation for 1 min before a second insertion attempt was made), and any associated complications were studied during the study. Inadequate oxygenation/ventilation scenario (inability to generate 6 ml/kg tidal volume during positive pressure ventilation, peripheral oxygen saturation <90%, and end-tidal carbon dioxide >50 mmHg despite device adjustment) was considered a device failure and endotracheal intubation was performed.

At the end of surgical procedure, sevoflurane was discontinued and IV neostigmine 50 ug/kg and glycopyrrolate 10 ug/kg was administered to antagonize the residual neuromuscular blockade. The supraglottic device was removed and examined for any traces of blood once the patient was awake and following commands. Any visible injury on the lips, teeth and tongue along with any episode of bronchospasm, desaturation, nausea, pharyngolaryngeal

pain, and coughing were also observed in the postoperative surgical unit.

The primary objective of our study was the time of successful insertion of the device, while the secondary objective included number of attempts, OLPs, ease of insertion, and associated complications if any. The sample size of 28 patients in each group was calculated based on variation in time of successful insertion based on a previous study with a type-1 error of 0.05 and a power of 90% to detect a 10% difference.^[5] We recruited 31 patients in each group to accommodate dropouts. Interpretation and analysis of obtained results was carried out using software Microsoft office Excel 2010 and analyzed using SPSS (IBM, SPSS Inc., USA) version 21.0 statistical analysis software. Student's *t*-test was used to analyze the parametric data, whereas the Mann-Whitney *U* test was applied to nonparametric data and Fisher's test to the categorical data. The probability values *P* = 0.05 or less were considered statistically significant.

Results

Seventy-five patients were assessed for eligibility, 13 of which were excluded (not meeting inclusion criteria). Thus, 62 patients were randomly allocated into Groups I and L [Figure 3].

The demographic features such as age, sex, body weight, height, BMI, airway parameters (Mallampati score, inter-incisor distance, and thyromental distance), ASA physical status, mean surgical duration, and the surgical procedures executed were comparable among the groups, with no statistically significant difference (*P* > 0.05), as mentioned in Table 1.

Table 1: Demographic variables and preoperative assessment parameters of the study groups

	Group I (n=31)	Group B (n=31)	<i>P</i>
Age (years)	36.10±13.13	39.16±12.17	0.344
Gender			
Male	14	17	0.446
Female	17	14	
Weight (kg)	60.16±8.86	61.07±8.24	0.610
Height (cm)	160.68±7.25	161.61±7.14	0.679
BMI (kg/m ²)	23.20±2.24	23.31±2.14	0.847
Mallampati score			
1/2/3/4	13/18/0/0	16/15/0/0	0.445
Inter-incisor distance (cm)	5.09±0.20	5.03±0.20	0.213
Thyromental distance (cm)	6.55±0.16	6.54±0.12	0.861
ASA PS			
1/2	23/8	21/10	0.576
Mean surgical duration (min)	100.74±38.89	88.45±29.35	0.165
Surgical procedures			
Laparoscopic surgical procedures (cholecystectomy, hernioplasty, appendectomy)	27	30	0.146
Open surgical procedures (appendectomy, cholecystectomy)	4	1	

Values are expressed as the mean±SD or number. Group I: i-gel® and Group M: BlockBuster™. BMI: Body mass index; ASA PS: American Society of Anesthesiologists physical status classification; SD: Standard deviation

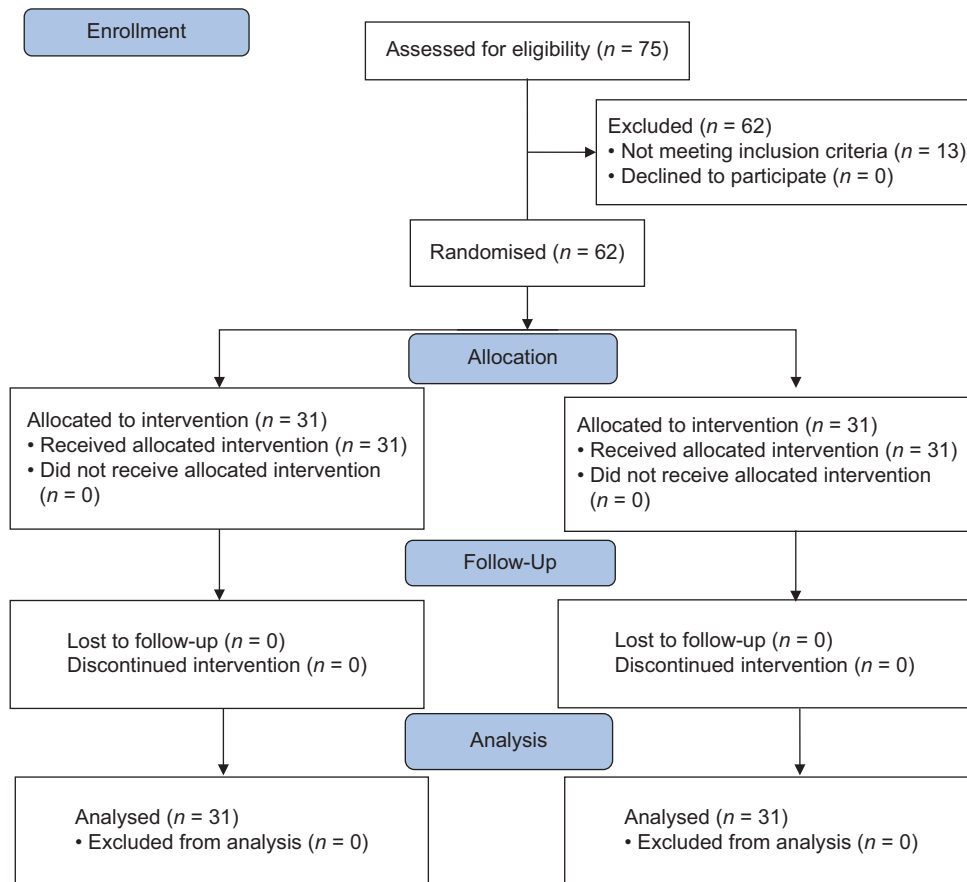


Figure 3: CONSORT flow diagram. Sixty-two patients were randomly allocated to two groups

The characteristics related to device insertions such as the insertion time, number of attempts, OLP, ease of insertion, airway maneuver requirements, adequate oxygenation/ventilation, device failure, and overall complications are shown in Table 2. The insertion time of device was less in Group I (13.52 ± 2.58 s) than that of Group M (14.10 ± 2.04 s), but the difference was not statistically significant ($P = 0.330$). The OLP in Group M (24.52 ± 2.77 cm of H₂O) was found to be significantly higher as compared to Group I (20.81 ± 2.56 cm of H₂O) with $P < 0.001$.

Discussion

Our study compared the clinical performance of two SADs in adult patients under general anesthesia. The mean time of insertion being our primary objective was found to be less with i-gel[®] in comparison to BlockBuster, but the difference was neither statistically significant nor clinically relevant. A recent study on pediatric patients mentions time of insertion for i-gel[®] and BlockBuster[™] < 20 s which is similar to the results of our study.^[6] Previous studies have highlighted the shorter insertion times with i-gel[®] owing to the absence of inflatable cuff and recommended its use for airway management during emergency and cardiopulmonary resuscitation.^[2,7] A mean time of device insertion of 12.2 s was described

in a previous study assessing the use of BlockBuster[™] as a conduit for blind endotracheal intubation which further validates the short insertion time observed with BlockBuster[™] in our study.^[4]

Insertion time is an important consideration while using SADs, especially during emergency and resuscitation where shorter duration of device insertion reduces the apneic duration and resultant hypoxic injury to vital structures of the human body. Interruptions in chest compressions for establishing an airway are one of the identified causes of reduced quality of cardiopulmonary resuscitation and are associated with decreased survival in humans.^[8]

In this study, the first attempt success rate and overall success rate were comparable between the i-gel[®] and the BlockBuster[™]. Similar to the results of our study, most previous studies on i-gel have shown first attempt success and overall insertion rates close to 90%–100%.^[5,6,9] Previous study on BlockBuster[™] has also claimed 96% first attempt success rates which is similar to our result.^[6,10] Easier insertion and high first pass success can be possibly explained by the structural analysis of BlockBuster[™], which has an inflatable cuff and an angulated (95°) airway tube which matches oropharyngeal curve and provides easy insertion without even using finger to guide the device into the mouth of the patient.^[11]

Table 2: Comparison of various parameters during insertion and overall complications between groups

	Group I (n=31)	Group B (n=31)	P
Insertion time (s)	13.52±2.58	14.10±2.04	0.330
OLP (cm H ₂ O)	20.81±2.56	24.52±2.77	<0.001
Insertion success, n (%)			
First attempt	29 (93.5)	29 (93.5)	1.000
Second attempt	2 (6.5)	2 (6.5)	
Overall	31 (100)	31 (100)	
Ease of insertion, n (%)			
1	15 (48.3)	18 (58.0)	0.684
2	14 (45.1)	12 (38.7)	
3	2 (6.4)	1 (3.2)	
4	0	0	
Airway maneuver requirement, n (%)			
Yes	9 (29.0)	6 (19.3)	0.374
No	22 (70.9)	25 (80.6)	
Inadequate oxygenation/ventilation scenario or any episode of failed insertion			
Yes	0	0	1.000
No	31	31	
Gastric tube successful insertion, n (%)			
Yes	31	31	1.000
No	0	0	
Overall complications, n (%)			
Sore throat	10 (32.2)	9 (29.0)	0.782
Blood staining	0	0	
Any other (injury to teeth/lips/tongue, pain)	0	0	

Values are mentioned as mean±SD, number of patients/proportion. Group I: i-gel®, Group M: BlockBuster™. SD: Standard deviation; OLPL: Oropharyngeal leak pressure

OLP is used to quantify the effectiveness of the SGDs in providing adequate airway sealing and protection from risk of aspiration.^[12] To ensure adequate ventilation, an ideal SADs should have an OLP > 20 cmH₂O.^[13] Mean OLP in our study was found to be approximately 4 cmH₂O higher for the BlockBuster™ than the i-gel® (both devices having mean OLP values higher than 20 cmH₂O) and this difference was statistically significant. A previous study using a cadaver aspiration model reported that the lack of an inflatable cuff may reduce the airway sealing ability of i-gel®.^[1] Cuffed SADs is able to conform to the variable pharyngeal anatomy than an un-inflatable cuffed device. Higher OLP observed with BlockBuster™ in a previous study as compared to our study could be possibly explained by the use of fiber-optic assistance to position the device in that study.^[4]

In our study, there was no incidence of failed insertion related to any of the SADs, with ease of insertion and airway maneuvering for insertion for both devices comparable with no statistical difference. The findings correlate with existing previous studies and could be explained by the fact that device insertion was attempted after induction of general anesthesia with neuromuscular blocking agents.^[4,6,10]

During the perioperative period, gastric tube placement was successful in both the groups with no reported incidence

of inadequate oxygenation/ventilation was there in our study, which clearly indicates the effectiveness of both the supraglottic devices to provide adequate ventilation with added safety of the second-generation SADs.

In terms of complication, the incidence of sore throat (self-limiting and no treatment was needed) was comparable between two groups with no statistical difference. No episode of blood staining or injury to perioral structures was noted in our study which could be explained by the expertise of the investigators performing device insertion.

Conclusions

We conclude that both the i-gel® and the BlockBuster™ having a unique preformed structural design are useful and effective for airway management in adult under general anesthesia. Having a high OLPs and comparable insertion time, risk of aspiration may be further reduced with the use of BlockBuster™ in comparison to i-gel® under general anesthesia.

Limitations

Our study does have some limitations which need to be mentioned like no measurement of hemodynamic variables during insertion and the perioperative period, the device insertion by investigators with adequate experience, and patients with normal physical status and airway parameters.

Ethical clearance

The study was approved by the Institutional Ethical Committee of King George's Medical University, U.P with Ref code: 102nd ECM II B-Thesis/P20 dated 03/09/2020.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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