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Original Research Article

Comparison of Efficacy between Baska Mask and I-GEL (Supraglottic Airway Devices) in Patients Undergoing Elective Surgery

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Abstract

Background: Two fresh varieties of second-generation supraglottic airway devices are the Baska mask and i-gel. The purpose of this study was to examine the insertion, ventilation, and post-insertion problems of these two devices.

Methods: Eighty adult patients scheduled for elective surgery under general anaesthesia were divided into two groups at random: Group IG: i-gel (n = 40) and Group BM: Baska mask (n = 40). Oropharyngeal leak pressure, tidal volume, peak airway pressure (PAP), post-insertion problems, ease of insertion, number of attempts, insertion time, number of corrective manoeuvres, and ease of insertion were all evaluated.

Results: In comparison to Group BM, Group IG demonstrated significantly shorter median insertion times (13.3 [interquartile range, IQR 7.8] vs. 17.0 [IQR 9.6] s; a higher percentage in the "very easy" ease of insertion category (62.5% vs. 10.0%; P <0.001; a higher percentage in the no corrective manoeuvre category (92.5% vs. 72.5%; P = 0.003); and a higher When compared to Group IG, Group BM generated PAP that was considerably greater (12.7 [1.8] and 11.5 [2.2] cm H_2O, respectively; P = 0.010). Other parameters showed no appreciable variations.

Conclusions: The i-gel performed faster, easier, required fewer correction manoeuvres, and caused less throat pain after surgery than the Baska mask. However, a higher produced PAP indicated that the Baska mask had a superior cuff seal.

Keywords: tidal volume, anaesthesia, elective surgery, post-operative nausea and vomiting, oropharynx, pain.

Introduction

The development of supraglottic airway devices (SGADs) heralded a new era in airway management and is regarded as a significant step in enhancing anaesthesia patient safety. In 1983, Archie Brain launched the LMA-Classic, a first-generation SGAD, into clinical use at TRAvent Medical in Maidenhead, United Kingdom [1].

The original purpose of first-generation SGADs was to secure the airway instead of using an endotracheal tube in

emergency situations. They were just simple airway tubes. It then demonstrated advantages for people having general anaesthesia [2]. The development of improved second-generation SGADs over the years has been a result of several improvements, with the goal of allowing a higher positive airway pressure while lowering the danger of pulmonary aspiration by including a gastric access port for evacuation of the stomach contents [3].

The second generation of SGADs has evolved, and one example of this is the i-gel (Intersurgical Ltd, Wokingham, UK). It gets its name from the soft, gel-like substance that goes into making it. Without the use of an inflated cuff, its shape, softness, and curves precisely mimic the perilaryngeal anatomy to achieve the ideal fit and a dependable perilaryngeal seal. This essential component indicates that the i-gel injection is intended to be simple, quick, and consistently reliable. Other unique elements of the i-gel, such as the gastric channel, integral bite block, buccal cavity stabiliser, and epiglottic rest, may offer further advantages.

The buccal cavity stabiliser aids in insertion and eliminates the potential for rotation; the gastric channel has proximal and distal ends that can provide an early warning of regurgitation and allow for the passage of a nasogastric tube to empty the contents of the stomach and facilitate venting [4,5]. The integral bite block reduces the possibility of airway channel occlusion.

Material and Methods

In this single-blinded, randomised controlled experiment, patients undergoing elective surgery at the ESIC MCH in Bihta, Patna, from September 2021 to August 2022 were compared to the Baska mask and the i-gel. Patients between the ages of 18 and 60 who were in American Society of Anesthesiologists (ASA) classes I and II and had a body mass index (BMI) of less than 35 kg m-2 met the inclusion criteria. Patients who were pregnant, undergoing laparoscopic or head and neck surgery, had a prior history of challenging intubation, or were at risk of aspiration were not allowed to participate in the trial. Patients who needed an unexpected tracheal intubation, muscle paralysis, or unanticipated hospitalisation to an intensive care unit after surgery were excluded from this study.

At least one day before to surgery, patient eligibility screening was done as part of pre-operative evaluation. Using computer-generated randomization software, a total of 80 adult patients who were scheduled for elective surgery were divided into two groups: Group BM: Baska mask (n = 40) and Group IG: i-gel (n = 40). Then, a sealed envelope was used to disguise the randomization allocations.

Each selected patient received a Tab. Anxit 0.5 mg premedication the night before surgery. When the patient arrived to the OT reception area, the anaesthetic nurse looked through the envelope containing the randomization allocation to determine the type of SGAD that will be used for that specific patient.

The operator was not made aware of the chosen SGAD until immediately prior to the implantation.

All patients were subjected to normal anaesthetic monitoring upon entry into the OT, including non-invasive blood pressure monitoring, an electrocardiogram, capnography, and pulse oximetry.

The anaesthetic nurse was in charge of setting up the SGAD. According to the suggestions made by the manufacturers of each device, the size of the Baska mask and the i-gel were selected based on the patients' desired body weight. The Baska mask was recommended in sizes 3 for patients under 50 kg, 4 for patients between 50 and 70 kg, and 5 for patients over 70 kg, whereas the i-gel was recommended in sizes 3 for patients between 30 kg and 60 kg (small adult), 4

for patients between 50 kg and 90 kg (medium adult), and 5 for patients over 90 kg (large adult). As instructed by the manufacturers, the Baska mask and the i-gel were prepared with the proper lubrication using lignocaine gel. Each device was inserted using a manner that followed the manufacturer's instructions.

The insertion was performed with the patient's head in the neutral position.

Both a sufficient end-tidal carbon dioxide waveform and significant bilateral chest expansion were indicators of successful implantation. The anaesthesia nurse used a digital timer to record the insertion time, which was defined as the amount of time from the moment the device was provided to the operator until acceptable ventilation was obtained. After successful insertion, a 4-point verbal rating scale was used to assess how easy the insertion was (VRS; Table 1). Each patient was given a maximum of three tries, and each new effort was regarded as a reinsertion of the device.

Table 1: Ease of insertion scale for SGAD insertion

Scale	Difficulty	Denomination
0	Very easy	Assistant help not required, No tactile resistance encountered
1	Easy	Jaw thrust by assistant or tactile resistant encountered
2	Difficult	When jaw thrust and deep rotation are required, or second attempt was required for successful device insertion
3	Fail	Insertion not possible despite manoeuvres, resulting in intubation after 3 unsuccessful attempts

If the SGAD was ineffective, modifications might be carried out by either extending the depth of insertion, rotating the SGAD, or slightly withholding it. Each adjustment was noted as a manoeuvre attempt, and the device was taken out if the manoeuvres failed to achieve effective ventilation. A device that was one size larger was inserted if a major leak was the primary cause of the issue. A smaller device was implanted if the original size was deemed to be excessively large.

The term "insertion attempt" refers to a change in device size. After three attempts, tracheal intubation was done if the SGAD insertion failed.

A failed insertion was defined as having three unsuccessful tries or taking longer than 120 seconds to complete. This included the time when the airway device was taken out of the mouth and ventilation with a bag-mask was required in between insertion attempts. Breathing was assisted in patients who experienced brief post-induction apnoea until adequate spontaneous ventilation resumed. Sevoflurane was used throughout the procedure to maintain anaesthesia without the aid of any muscle relaxants.

At baseline, before induction, and at 1 min, 3 min, 5 min, 10 min, and 20 min after SGAD insertion, heart rate, systolic blood pressure (mm Hg), diastolic blood pressure (mm Hg), mean arterial pressure (mm Hg), and oxygen saturation were measured.

After successful insertion and adequate ventilation with the closed-circuit mechanical ventilator in the operating room, the oropharyngeal leak pressure (OLP) was measured. By maintaining a flow rate of 4 L min-1 and a maximum pressure limit of 40 cm H2O, the airway pressure was steadily increased. The OLP was defined as the pressure at which a stethoscope picked up audible sounds just lateral to the thyroid cartilage. Five minutes after a successful SGAD insertion, the peak airway pressure (PAP) in cm H2O was recorded. Five minutes after successful insertion, the amount of tidal volume (VT) that was expired and inspired was also recorded.

Sevoflurane inhalation was terminated following surgery, and the patient was then ready for extubation. When the patient was awake and met all requirements for anaesthetic recovery, the airway device was removed. After the SGAD was removed, complications like damage to the teeth, gums, or tongue were evaluated. It was proven that the SGAD had blood stains on it.

The patient was then observed in the post-operative recovery area while being questioned to determine whether complications such as soreness or pain in the throat, nausea, or vomiting had occurred. Anti-emetics were given if a patient suffered post-operative nausea or vomiting (PONV). Before being let out of the OT recovery bay, a 4-point VRS was used to gauge the severity of throat soreness. No pain was given a value of 0, mild pain a rating of 1, moderate pain a rating 2, and severe pain a rating 3.

Version 24.0 of SPSS was used for the statistical analysis (IBM Corp., USA). The Chi-square or Fisher's exact test was used to analyse categorical data. The Mann-Whitney test or independent t-test were both used for the study of the numerical data. Statistical significance was determined by a P-value of.05. The power of the study was 0.8.

Results

In total, 80 patients were enrolled in the trial, and according to their SGAD type, they were split into two groups with 40 patients each.

Between Group BM and Group IG, there were no appreciable variations in terms of age, gender, weight, height, BMI, Mallampati score, thyromental distance, mouth opening measurement, or length of operation (Table 2).

There was a substantial difference between the two groups in terms of ease of insertion (P <0.001).

Table 2: Demographic profile

Variable	Group BM (n=40)	Group IG (n=40)	p-value
Age (years), Mean±SD	33.8±11.6	30.2±11.1	0.166
Body mass (kg), Mean±SD	66.3±8.3	66.6±9.9	0.893
Height (cm), Mean±SD	168.5±6.5	168.7±7.7	0.925
BMI (m kg^{-2}), Mean±SD	22.7±2.7	23.3±2.6	0.387
Thyro-mental distance (cm), Mean±SD	4.8±0.6	49±0.6	0.511
Mouth opening (cm), Mean±SD	3.9±0.6	4.0±0.6	0.378
Duration of anaesthesia (Min), Mean±SD	102.1±42.5	104.1±41.0	0.833
Mallampati, m(%)			>0.95
1	32.0(50.8)	31.0(49.2)	
2	8.0(50.0)	8.0(50.0)	
3	0.0(0.0)	1.0(100.0)	
Gender, n(%)			0.651
Female	16.0(47.1)	18.0(52.9)	
Male	24.0(52.2)	22.0(47.8)	

In comparison to Group BM, Group IG demonstrated a greater percentage of'very easy' insertions (62.5% vs. 10.0%). Comparing Group IG to Group BM (0.0% and 5.0%, respectively), there was also no failure of insertion. However, the majority of Group BM (77.5%) remained in the category of "easy" insertion, which was still viewed as a positive result (Table 2). Additionally, the median insertion time for the Group IG was considerably lower than that for the Group BM (13.3 s [interquartile range, IQR 7.8] and 17.0 s [IQR 9.6], respectively; P <0.001; Table

2). There were no discernible variations between the groups in terms of the quantity of insertion attempts (P = 0.055).

However, when comparing Group IG and Group BM, Group IG demonstrated a marginally greater percentage of successful single attempts (92.5% vs. 77.5%; Table 2). There was a significant difference between the two groups in the number of corrective manoeuvres performed following insertion (P = 0.003), with Group IG displaying a larger percentage in the "no manoeuvre at all" category than Group BM (92.5% vs. 72.5%; Table 2).

Group IG demonstrated substantially inferior ventilation quality than Group BM in terms of produced PAP (11.5 cm H2O [2.2] and 12.7 [1.8] cm H_2O, respectively; P = 0.010; Table 3). The mean PAP for Group BM was still thought to be in a good range, though. Other ventilation parameters, including inspired and expired VT or OLP, showed no obvious variations (Table 3).

There was a significant difference in throat pain between the two groups in terms of complications (P = 0.042). In comparison to Group BM, Group IG had a higher number of participants reporting no throat pain (67.5% vs. 42.5%). Other problems, like blood stains on the device, PONV, and airway trauma, showed no appreciable differences.

Table 3: Quality of supraglottic airway device insertion

Parameter	Group BM (n=40)	Group IG (n=40)	p-value
Ease of insertion scale, n(%)			<0.001
Very easy	4.0(10.0)	25.0(62.5)	
Easy	31.0(77.5)	14.0(35.0)	
Difficult	3.0(7.5)	1.0(2.5)	
Fail	2.0(5.0)	0.0(0.0)	
Insertion time (S), median (IQR)	17.0(IQR9.6)	13.3(IQR7.8)	<0.001
Number of insertion attempts, n(%)			0.055
1	31.0(77.5)	37.0(92.5)	
2	7.0(17.5)	1.0(2.5)	
3	1.0(2.5)	2.0(5.0)	
>3	1.0(2.5)	0.0(0.0)	
Number of corrective menoeuvres after insertion, n(%)			0.003
0	29.0(72.5)	37.0(92.5)	
1	11.0(27.5)	1.0(2.5)	
2	0.0(0.0)	1.0(2.5)	
≥3	0.0(0.0)	1.0(2.5)	

Table 4: Ventilation parameters and oropharyngeal leak pressure

Variable	Group BM (n=40)	Group IG (n=40)	p-value
Inspired tidal volume (VT) (mL), Mean±SD	436±43.2	441.1±47.7	0.673
Expired VT (mL), Mean±SD	420.4±41.9	424.9±47.6	0.663
Peak airway pressure (cm, H_2O), Mean±SD	12.7±1.8	11.5±2.2	0.010
Oropharyngeal leak pressure (cm, H_2O), Mean±SD	23.7±3.4	24.5±2.5	0.242

Table 5: Complications of supraglottic airway device insertion

Variable	Group BM (n=40)	Group IG (n=40)	p-value
Blood stained, n(%)			>0.95
No	39.0(97.5)	39.0(97.5)	
Yes	1.0(2.5)	1.0(2.5)	
Post-operative nausea or vomiting, n(%)			>0.95
No	38.0(95.0)	37.0(92.5)	
Yes	2.0(5.0)	3.0(7.5)	
Airway injury, n(%)			No applicable
No	40.0(100.0)	40.0(100.0)	
Yes	0.0(0.0)	0.0(0.0)	
Throat pain score, n(%)			0.042
No pain	17.0(42.5)	27.0(67.5)	
Mild pain	22.0(55.0)	13.0(32.5)	
Moderate pain	1.0(2.5)	0.0(0.0)	

Discussion

The Baska mask and i-gel were the two most recent varieties of second-generation SGADs that were the subject of our study. Our findings demonstrated that compared to the Baska mask, the i-gel resulted in a significantly shorter median insertion time, a higher percentage of patients rating the process as "very easy," a higher percentage of patients reporting no need for corrective manoeuvres, and a higher percentage of patients reporting no postoperative throat pain. A better cuff seal may be shown by the Baska mask's superiority in the category of higher produced PAP. The number of attempts, inspired or expired VT, OLP, and consequences such blood stains on the device, PONV, and airway damage, on the other hand, did not differ significantly from one another.

Studies comparing the Baska mask with i-gel have recently been conducted, with conflicting results. Our investigation confirms that the parameters of the i-gel are superior to those of the Baska mask in a few experiments. In 150 patients receiving outpatient urologic treatments, Bindal *et al*. conducted a comparison research of three types of SGADs: the Baska mask, i-gel, and LMA Classic. Only insertion and breathing timings were significantly different between the three groups among the few factors evaluated.

In comparison to the other groups, the Baska mask had the longest insertion and ventilation periods, measuring 12.04 s ±6.25 s and 21.26 s ±8.53 s, respectively. The LMA-Classic group demonstrated the quickest times, 5.78 s ±1.72 s for insertion and 11.72 s ±4.72 s for ventilation. The LMA-Classic also had the best first-attempt success rates (98%), followed by the i-gel (92%), and the Baska mask (88%). Additionally, compared to the other groups, 20% of the Baska mask group required additional manoeuvres. This study found that the LMA-Classic and igel performed better than the Baska mask in terms of insertion and ventilation times, first-attempt success rates, and the need for additional manoeuvres [6-10].

In 200 patients undergoing urologic surgery, Kara *et al*. conducted a comparison study between the Baska mask and i-gel. Compared to the Baska mask, the median insertion time for the i-gel was much shorter (7 s [5–12] and 14 s [6–25], respectively). The remaining characteristics (number of attempts to install the device, sealed pressure, and number of post-operative problems) [11] did not show any appreciable variations.

A few research have emphasised the Baska mask's advantages over the i-gel in terms of specific criteria. In 100 female patients having quick, elective gynaecological operations, Garg *et al*. compared these two SGADs. The Baska mask provided a greater airway seal pressure and easier insertion than the i-gel, according to the study's findings. When compared to the i-gel, the Baska mask achieved a much greater airway seal pressure (35.8 cm H2O ±10.3 cm H2O and 26.9 cm H2O ±7.5 cm H2O, respectively).

Similarities existed between other factors and problems [12]. The sealing pressure of the Baska mask was significantly higher than that of the i-gel in another study by Sachidananda et al. in 50 patients having minor surgical operations (28.9 cm H2O ±3.5 cm H2O and 25.9 cm H2O± 2.5 cm H2O, respectively).

The groups' differences in other factors, such as the first-time insertion success rate, insertion time, and problems, were not significant [13]. The Baska Mask revealed considerably higher OLP than the i-gel than 97 patients undergoing elective laparoscopic cholecystectomies (29.6 cm H2O ±6.8 cm H2O and 26.7 cm H2O ±4.5 cm H2O, respectively).

The usage of airway manipulation, insertion time, fiber-optic views of the glottis, heart rate, me\an arterial pressure, PAP, lung compliance, and perioperative problems, on the other hand, were comparable parameters [14]. According to a study by Kara et al. and validated by our research, the Baska mask offered a PAP that was significantly greater than that of the i-gel(15.8 cm H2O ±0.9 cm H2O and 14.9 cm H2O± 1.7 cm H2O, respectively) [11].

The i-gel was superior in several of the metrics, according to our results, but the margin of difference was actually quite little. The simplicity of insertion might be enhanced with further instruction in the proper technique and early application of the Baska mask's special insertion tab.

The smoothness of the insertion will be improved by familiarity with specific gadgets. The majority of the operators in our study were unfamiliar with the i-gel and Baska mask since they had only recently been launched and made accessible in our centre, even if they had prior experience inserting other kinds of first- or second-generation SGADs. One of the shortcomings of our study was also the inter-observer variability. The Baska mask shown advantage in OLP in some of the studies, as previously mentioned. Although the OLP in our sample was comparable, a higher produced PAP indicates a solid cuff seal. Our study evaluated additional ventilation quality measures, including the value of the expired and inspired VT, in comparison to other recent studies comparing these two SGADs. These characteristics were similar for both SGADs, which suggested that the non-inflatable cuff SGADs may provide enough VT during ventilation.

Conclusion

The i-gel was superior to the Baska mask in terms of simplicity, speed, lack of need for corrective manoeuvres, and reduction of post-operative throat pain. Due to a greater produced PAP, the Baska mask had a better cuff seal.

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