

Supraglottic airway devices in short gynecological procedures: A randomized, clinical study comparing the Baska[®] mask and I-Gel[®] device

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ABSTRACT

Background: Supraglottic airway devices are used for anesthesia in elective surgical procedures circumventing the need for intubation. We investigated the efficacy and safety of Baska[®] mask in comparison to an I-Gel[®] device. **Methods:** In this cross-sectional, observational study, we randomized 100 female patients (age 18–45 years, American Society of Anaesthesiologists grade I or II) undergoing elective short gynecological procedures into two groups, to receive ventilation with either Baska mask[®] (group 1, $n = 50$) or an I-Gel[®] device (group 2, $n = 50$). We excluded patients with obesity, short neck, and known systemic and upper airway disorders. The primary outcome was the oropharyngeal airway seal pressure, and the secondary outcomes were the ease of insertion and the complication rate. The results were analyzed using Mann–Whitney U -test and Fisher's exact test, and correlation analysis was done by Spearman's correlation test. **Results:** A total of 56 patients underwent dilatation and curettage, whereas the remaining had hysteroscopy in the study. The airway seal pressure achieved was higher with Baska[®] mask than I-Gel[®] device (35.8 ± 10.3 and 26.9 ± 7.5 of cm H₂O, respectively; $P < 0.0001$). The ease of insertion ($P < 0.0001$) was better in group 1 and the complication rates were similar in both the groups ($P > 0.05$). **Conclusion:** Baska[®] mask offers a superior airway seal pressure with minimum complications in comparison to an I-Gel[®] device. Further studies with a large number of patients in different surgical settings are required to confirm our findings.

Keywords: Anesthesia, Baska mask[®], I-Gel device, supraglottic airway devices

Introduction

Supraglottic airway devices (SADs) are used for airway management in patients undergoing various surgical procedures under anesthesia.^[1] They offer an excellent noninvasive option for ventilation instead of the endotracheal tube (ET) and the face mask. The use of SADs has been increasing in the past decade for the ease of insertion and insignificant complications. SADs are mostly useful in emergency and critical situations, providing a rapid access to the airway. They also help in providing a rescue

access in patients with difficult intubation. Primary care physicians and family medicine practitioners may use these devices for the ease of insertion, even with limited training in emergency situations. The advantages of the SAD over ET include the ease of insertion, rapidity, low postoperative complications, and reduced autonomic imbalance during insertion.^[2] The SADs are positioned outside the larynx making them easy for use in certain clinical situations. The sealing site of the SAD varies from the base of the tongue and perilaryngeal sites. The advanced models of the SAD improve the efficacy of the ventilation and also a patient's safety. The models of SAD differ in the sealing mechanisms and aspiration protection designs.

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Access this article online

Quick Response Code:



Website:
www.jfmpc.com

DOI:
10.4103/jfmpc.jfmpc_359_18

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How to cite this article: Garg A, Lamba NS, Chandra NS, Singhal RK, Chaudhary V. Supraglottic airway devices in short gynecological procedures: A randomized, clinical study comparing the Baska[®] mask and I-Gel[®] device. *J Family Med Prim Care* 2019;8:1134-7.

The SAD are broadly divided into the first-generation devices (only breathing lumen) and second-generation devices (additional lumen for aspiration of the gastric contents).^[3] The complications with the first-generation devices include the increased risk of aspiration and poor ventilation. Baska[®] mask and I-Gel[®] device are the two commonly used second-generation SAD in anesthetic practice.^[4] Short gynecological procedures such as dilatation and curettage (D and C), hysteroscopy, and tubal ligation are usually done using short-term intravenous anesthesia. These procedures require monitored anesthesia care and are usually done using propofol.^[5] The use of SAD in such settings is beneficial and helps in the process of early recovery from the effects of surgery. A limited number of studies exist that have compared the use of different types of SAD in short gynecological procedures.^[6] Extensive literature search did not reveal any such study from our country. Hence, we conducted this study to compare the two SADs in anesthetic management of gynecological procedures.

Methods

We conducted this randomized, cross-sectional, observational study at a tertiary level armed forces referral hospital in India. All patients [age 18–45 years, nonobese, American Society of Anaesthesiology (ASA) grade I or II] undergoing an elective short gynecological procedure were included in the study. We included gynecological procedures that were expected to last only for less than 60 min in the study. The procedures include D and C, hysteroscopy, and tubectomy. We excluded patients with significant cardiac, renal, hepatic, and respiratory dysfunction, anticipated difficult airway, neck pathology, pregnant or nursing women, and ASA III or above. We also excluded patients having upper airway or gastrointestinal problems who are at a higher risk of aspiration. The patients were randomized using a computer-generated random table into two groups for ventilation: group 1 (Baska[®] mask) and group 2 (I-Gel[®] device). The allocation concealment was done using unique codes for the group by one investigator (VC), who was not aware of the final allotted group of the patient. The primary outcome was the median airway seal pressure achieved, and the secondary outcomes were the ease of insertion, time taken for insertion, and rate of postoperative complications. All patients received a preoperative counseling on the nature of the study and the procedure involved, and an informed consent was obtained. The study was approved by the institutional ethics committee of the Command Hospital, Chandimandir, in October 2014 as a postgraduate thesis project.

All the patients were assessed for measures of intubation (airway, mouth opening assessed by Mallampatti classification, dentures, neck circumference, cervical spine deformities, short neck, etc.) during the standard preanesthetic assessment. The patients were subjected to hematological and biochemical investigations to screen for systemic disorders. The demographic data (age, body weight, body mass index, ASA status) were

recorded in a predefined pro forma. All the patients were premeditated with oral ranitidine 150 mg and alprazolam 0.25 mg at 22:00 h in the night before the surgery and at 05:00 h on the day of surgery. A standard fasting protocol was used for all the procedures, and the patients were kept nil orally for 8 h prior to the surgery. The patients were premedicated with intravenous glycopyrrolate 0.2 mg and ondasetron 4 mg, 30 min before shifting them to the operation theater (OT).

A venous access was secured with 18G cannula, and intravenous infusion of Ringer's lactate solution was started on arrival into the OT. Anesthesia was induced in the supine position with the patient's head in the neutral position. The general anesthesia was induced using fentanyl and propofol in doses of 1 µg/kg and 2 mg/kg, respectively. The depth of anesthesia was increased by adjusting the sevoflurane vaporizer setting between 2% and 4.5% and also with additional increments of propofol, prior to the placement of SAD. The SAD masks were checked for any leaks after removing the factory seal. The device placement was done by only two investigators (AG and NSL) in the study. The entire body of the mask was lubricated with lignocaine jelly just prior to the insertion. The SAD was inserted as per standard recommendations issued by the manufacturer. The size of the mask was selected using clinical judgment and the manufacturer's recommendation. The patency of the airway was ascertained after the insertion of the SAD, and the same was connected to the breathing circuit. The patency was assessed with the presence of bilaterally symmetrical chest expansion, end tidal carbon dioxide (ETCO₂), pressure tracing with plateau, and leak fraction of below 25% of the tidal volume. Intermittent intravenous fentanyl doses were given for the maintenance of analgesia. Intraoperative monitoring includes electrocardiogram, oxygenation by pulse oximetry, blood pressure, ETCO₂, and body temperature. Anesthesia was maintained with sevoflurane in 66% nitrous oxide and 33% oxygen mixture targeting a minimum alveolar concentration value of 0.8%–1.2%. After the surgery, 100% oxygen was given through the mask to aid in the recovery. The SAD was removed after the return of consciousness and protective reflexes.

The success of insertion was defined as the number of attempts taken to insert the SAD appropriately. The ease of insertion and removal was defined on a 5-point scale with 0 being very easy and 5 being very difficult. The insertion time has been counted between the picking up of the mask and placement of the mask successfully. Oropharyngeal airway leak pressure was assessed immediately after the insertion of the tube and after 15 min of surgery. The airway seal pressure was assessed using manometric stability technique after closing the expiratory valve and noting the airway pressure at which the equilibrium is reached.^[7,8] The relevant postoperative complications observed after extubation include cough, local trauma, dysphonia, dysphagia, postoperative nausea and vomiting (PONV), and presence of gastric fluid in the oral cavity. The postoperative complications were assessed by two anesthesiologists (RKS and NSA), who were blinded to the type of the SAD used.

Data are presented as mean \pm standard deviation, and a comparison between the groups was done using nonparametric (Mann–Whitney *U*-test) and Fisher's exact tests. The sample size and power of the study analysis were performed to estimate the total number of patients required to be included in the study. It was estimated that a minimum of 45 patients would be required to ensure with a 95% confidence level and a confidence interval of 4, to diagnose the differences between the two SADs based on previous studies.^[9] Hence, we included 50 patients in each group giving 90% power to our study. Spearman's correlation test was used for correlation between numerical variables, and a *P* value of less than 0.05 was considered significant. Statistical analysis was done using the GraphPad Prism Software, version 6 (GraphPad Software, San Deigo, CA, USA).

Results

The study participants (100 females) had a mean age of 34.3 ± 2.3 years, body weight 53.2 ± 11 kg, and body mass index of 21.7 ± 4.6 kg/m². A total of 56 patients underwent D and C, whereas the remaining had hysteroscopy. The details and comparison about the demographic parameters are given in Table 1. The patients in group 2 were older than the patients in group 1 ($P < 0.0001$). The patients in group 1 using Baska[®] mask had a short insertion time and better airway seal pressure as shown in Table 2. The airway seal pressure achieved was higher with Baska[®] mask than I-Gel[®] device (35.8 ± 10.3 and 26.9 ± 7.5 of cm H₂O, respectively; $P \leq 0.0001$). The ease of insertion was lower in group 1 ($P < 0.0001$) and the complication rates were similar between both the groups as shown in Table 3 ($P > 0.05$). The first time success rate for insertion of Baska[®] mask was higher than that seen with I-Gel[®] (94% vs 70%), respectively ($P = 0.0033$). The failure of insertion was seen in five patients with I-Gel[®], whereas none of the patients using Baska[®] mask had a failure ($P = 0.0563$). When compared with I-Gel[®], the complication rates were similar to the use of

Baska[®] mask. The incidence of PONV was less with Baska[®] mask when compared with I-Gel[®] (2% vs 10%). None of the study participants had any complications with either of the SADs at the time of discharge.

Discussion

Our study compared two commonly used SADs and showed the superiority of Baska[®] mask over I-Gel[®] device. Few studies have compared the two devices and have given similar results in various surgical settings.^[10,11] Alexiev *et al.* have shown that Baska[®] mask was superior in comparison to classic laryngeal mask airway in a sample size of 150 patients.^[10] Another major advantage observed in our study is the 100% success rate of the insertion. We did not require using another SAD or ET for providing anesthesia in any patient of group 1 using Baska[®] mask. The overall success rate of 100% is a major reassuring fact, with the use of Baska[®] mask when compared with I-Gel[®] device. This helps in case selection and also expands the indication of Baska[®] mask in other laparoscopic procedures.^[12]

The first attempt device insertion success rate observed in our study (75%) was similar to that described by Alexiev *et al.* (73%) in gynecological procedures.^[10] The unique advantages of Baska[®] mask include the noninflatable cuff which leads to a good airway seal, integrated bite block, and also a conduit to aspirate the pharyngeal contents to minimize the risk of aspiration. Baska[®] mask is easier to insert due to its flexible head, and the overall success rate was 100% with minimal complication rate. The observed device leak pressure in group 1 using Baska[®] mask was higher than reported with I-gel[®] device suggesting a superior airway seal. The observed leak fractions and intraoperative EtCO₂ values were reassuring with the use of Baska[®] mask.

The precise positioning of Baska[®] mask is essential against the larynx as the cuff opening is smaller for the mask for ventilation.^[13] The leak pressure of about 45 cm H₂O suggests the presence of a good airway seal using Baska[®] mask. The patient comfort indices were reassuring with the use of Baska[®] mask and the same have been described in earlier studies.^[6,11] Our study confirms that the use of SAD is a potential alternative to ET in patients undergoing short gynecological procedures. Baska[®] mask has shown to be associated with fewer complications than I-Gel[®] device in safety analysis.^[14] The strength of our study includes randomized design in a sizeable number of patients with documented follow-up in a tertiary level care center. Extensive literature search did not reveal similar studies from our country.

Table 1: Demographic parameters between the two groups

Parameter	Group 1 (Baska [®]), n=50	Group 2, (I-Gel [®]), n=50
Age (years)	33.5 (6.2)*	39.9 (7.3)
Body weight (kg)	57.2 (13.1)	56.5 (12.5)
Airway assessment (MPCC)	1.1 (0.9)	1.2 (0.8)
ASA score (grade)	1.2 (0.7)	1.3 (0.6)
Duration of procedure (min)	35.2 (12.2)	38.4 (11.3)

*Mean (SD). MPCC: Mallampati Clinical Classification; ASA: American Society of Anaesthesiologists; SD: Standard deviation

Table 2: Comparison between device insertion-related parameters

Parameter	Units	Group 1 (Baska [®]), n=50	Group 2 (I-Gel [®]), n=50	<i>P</i>
Insertion in first attempt	n (%)	47 (94)	35 (70)	0.0033
Insertion in second attempt	n (%)	3 (6)	10 (20)	0.5221
Failed insertion	n (%)	0	5 (10)	0.0563
Insertion time	s	7.3 (2.7)*	12.4 (4.5)	<0.0001
Airway seal pressure	cm H ₂ O	35.8 (10.3)	26.9 (7.5)	<0.0001

*Mean (SD). SD: Standard deviation

Table 3: Complication rate between the two groups

Parameter	Units	Group 1 (Baska®), n=50	Group 2 (I-Gel®), n=50	P
Intraoperative desaturation	n (%)	0	0	1.0000
Laryngospasm	n (%)	0	0	1.0000
Lip damage	n (%)	0	0	1.0000
Blood staining on removal	n (%)	5 (10)	4 (8)	1.0000
PONV	n (%)	1 (2)	5 (10)	0.2044
Throat discomfort	n (%)	0	2 (4)	0.4949
Dysphagia/dysphonia	n (%)	0	0	1.0000

PONV: Postoperative nausea and vomiting

The limitations of our study include small sample size and lack of evaluation in patients with nongynecological surgeries. Our data being derived from a single center may have a referral bias and may not be applicable to other centers in India.

Conclusion

In conclusion, Baska® mask is a useful SAD for short gynecological procedures, in comparison to an I-Gel® device. Further randomized studies involving a large number of patients in different surgical settings are required to confirm the findings observed in our study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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