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A COMPARISON BETWEEN THE IGEL AND THE BASKA MASK IN SPONTANEOUSLY VENTILATING ANAESTHETISED PATIENTS

Anesthesiology

Shivani Fotedar

ABSTRACT

Supraglottic airway devices (SAD) are now widely used for surgeries requiring general anesthesia. They also have a role in airway management for resuscitation as first responder devices, rescue devices or for their use during patient extraction.The study aims to compare the BASKA mask and the Igel over varied parameters and establish, the superior supraglottic airway device, amongst the two.This was a prospective, randomized study conducted on 80 patients divided in 2 groups viz. I- gel and BASKA. Patients were induced and I- gel or BASKA was inserted without any muscle relaxation. Time to insert, no. of attempts taken, heamodynamics and post operative complications were recorded.

KEYWORDS

LMA, Igel, BASKA, Anaesthesia, Spontaneous ventilation

INTRODUCTION

Securing airway during administration of Anaesthesia is of vital importance and significant urgency wherein lapses can lead to catastrophic outcomes. Traditionally, this has been accomplished by either bag and mask ventilation or through placement of endotracheal tube (ETT) followed by ventilation. In extreme emergencies and unskilled hands, mouth to mouth respiration during resuscitation has also been recommended. Each of these methods has its own difficulties, hazards and at times, unacceptable outcomes.1,2 Supraglottic airway devices (SAD) are now widely used for surgeries requiring general anesthesia. They also have a role in airway management for resuscitation as first responder devices, rescue devices or for their use during patient extraction. The Difficult airway society and the ILCOR have also included the SADs in their algorithm 6,7. In order to understand them the SADs can be classified in two broad ways; either on the basis of presence or absence of an inflatable cuff or as first generation and second generation SADs. [3]

Though different SADs have been mutually compared on various parameters, comparison between the BASKA and the I-gel in terms of their performance and better suitability amongst spontaneously breathing adult patients has not been investigated enough. Besides there are hardly any studies on Indian subjects and in Indian settings considering the different racial and anthropometric attributes of ethnic Indian population. Thus there is ample reason to undertake another study, comparing the clinical performance and ease of insertion of the devices.[8,9]

This study intends to compare the two devices.

Aim

- To compare the BASKA and the Igel over varied parameters, and establish, the superior supraglottic airway device, amongst the two.2,5,7

Objectives

To compare the function of the I-gel and BASKA under the following headings :

- Ease of insertion of the device (Assessed by the duration taken to insert the device).
- Number of attempts taken to insert the device
- Hemodynamic changes on inserting and after inserting the device
- Postoperative complications (procedure related complications) if any to be recorded 2,5,7

METHODS

After obtaining ethical committee approval a sample size of 80 patients was decided to conduct the study. The randomisation was done on a computer generated lottery method.

Inclusion criteria :

Patients belonging to age groups between 20 - 60 years, ASA grade 1 or 2, MP grade 1 or 2 with surgeries not lasting for more than an hour were selected for the study.

Exclusion criteria :

Full stomach patients, caesarean sections, emergent surgeries, a BMI of less than 20 or more 28 or patients unwilling to enroll for the study.

Prior to the day of surgery, the patients were visited as per the pre anaesthetic check protocol.

A fully informed consent was taken. Pre medication with Tab Diazepam 5mg was given and patients were advised to stay nil per oral till the morning of surgery.On arrival in the operation theatre, the patient was made to lie supine. Multiparameter monitors were attached, and all the baseline parameters (NIBP, SpO2, ECG, EtCO2 and Heart Rate) were recorded.

Patients were preoxygenated for 3 minutes, with 100% oxygen followed by Inj. midazolam 2 mg iv, Inj. Glycopyrrolate 0.01 mg / kg iv, Inj. Ondansetron 0.1mg / kg iv and Inj. Fentanyl 2 mcg /kg iv were also given. Induction was carried out using Injection Propofol 2 mg/kg IV. The patient was kept on spontaneous ventilation and maintained on Halothane, Oxygen and Nitrous Oxide in titrated MACs. After achieving an adequate depth of anaesthesia, the Supraglottic Airway Device (Igel or BASKA) whichever was chosen, was inserted. Time taken for the insertion was recorded. For both the devices, the size of the device was decided by the patient's body weight and the manufacturer's recommendation, for that particular body weight. The standard pre use test for both the devices was performed,

which included inflation and checking of the cuff along with it's structural integrity and colour. For the them being a reusable device, there were no pre use tests which were required to be carried out. Both the devices were lubricated on the posterior surface and the tip, using a water based gel (KY jelly), prior to the insertion of the device.1,15 . The Bains circuit was attached to the devices connector end. The patient was kept on spontaneous ventilation and adequate concentrations of MAC of Halothane and Nitrous oxide were delivered by the machine. In both the groups, if it were impossible to insert the Supraglottic Airway Device, after consecutive attempts, the following maneuvers were done. A Chin lift, in order to open the airway, along with a Jaw thrust and a Head extension, or Flexion of the neck was done.

(Chandy Varghese maneuver) In case of the BASKA, the position was adjusted, by pushing or pulling the device through the tab provided on the dorsal surface . After any maneuver, adequacy of ventilation was assessed, by auscultating the chest, and making sure that there is equal air entry bilaterally. If the insertion of the device failed in a single attempt, then two more attempts were allowed. The procedure was abandoned, after failure of the third attempt and the patient was intubated or awakened. This case was henceforth, not included in the study group. The heart rate, blood pressure, etCO2 and SpO2 were recorded at the time of insertion and every minute for the first 5 minutes and then, every 5mins till the time the procedure endedOxygen and Nitrous oxide were given for maintenance of anesthesia, in a 50 : 50 ratio along with halothane. No muscle relaxant was used. At the completion of the surgery, the Igel or the BASKA was removed after the patient gained consciousness which was observed by resumption of the reflexes of the cornea and eyelash. After the patient's gag reflex resumed the device was removed. 5 minutes, of dedicated postoperative oxygenation, was done before shifting the patient to the recovery. Each patient, was questioned immediately after removal of the device to determine whether the following complications have

occurred or not for the first 24 hrs postoperatively. The complications likely to occur and be noted were sore throat, constant throat pain independent of swallowing action, dysphagia, dysphonia, sore jaw, numbness of tongue or oropharynx, blocked or painful ears, reduced hearing or neck pain. Also, post extubation cough, breath holding or laryngospasm were also taken into consideration.1,4,10,11

STATISTICAL TOOLS EMPLOYED :

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean±SD.

RESULTS AND DISCUSSION

Table 1: Demographics

		Igel	BASKA	p – value
Age		38.64	36.85	0.528
BMI	24.78	25.11		0.675
Sex	Male	22	17	0.263
	Female	18	23	

Table no. 2 : Types of Surgery

Type of surgery	I-gel	BASKA	p – value
Minor eye procedures	2	3	0.822
Hernioplasties	13	15	
ORIF	15	10	
Incision and drainage	4	7	
Fibroadenoma excision	4	5	
Burr hole for SAH and drainage	2	0	

Table 3 : MP grading

MPgrade	I-gel	BASKA	P-value
1	34(85.0)	29(72.5)	0.531
2	6(15.0)	11(27.5)	

Table 4 : Duration of Insertion

Duration of insertion	I-gel	BASKA	P-value
(seconds)	Median	Median	0.001
	5.0 (5.0 to 6.0)	23.0(10.5-26.5)	

Table 5 : Number of attempts taken to insert device

Attempts	I-gel	BASKA	p-value
1	37 (92.5)	32(80)	0.027
2	3(7.5)	7(17.5)	
3	0	1(2.5)	

Table 6: Post operative complications

Complications	I-gel (n=40)	BASKA(n=40)	P-value*
Sore throat	0 (0.0%)	2(5%)	0.026
Dysphagia	0 (0.0%)	0(0.0%)	0.00
Dysphonia	0 (0.0%)	1(2.5%)	0.211
Earache	0 (0.0%)	0(0.0%)	0.00
Nausea	0 (0.0%)	0(0.0%)	0.00
Vomiting	0 (0.0%)	0(0.0%)	0.00

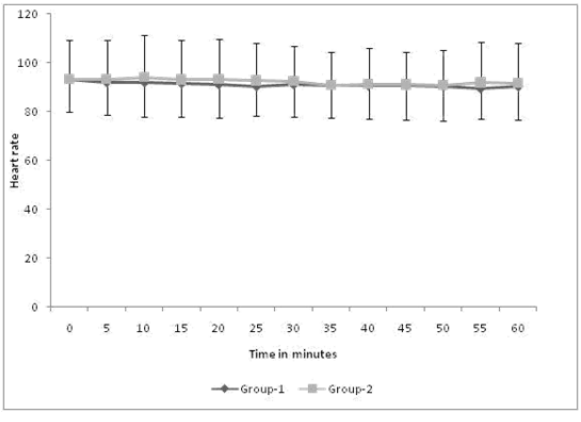

Figure 1 : Changes in Heart Rate

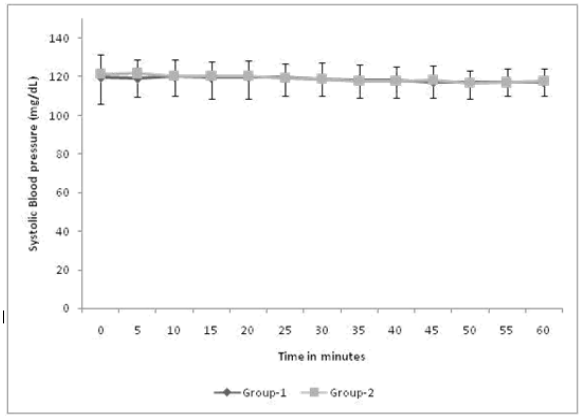

Figure 2 : Changes in systolic blood pressure

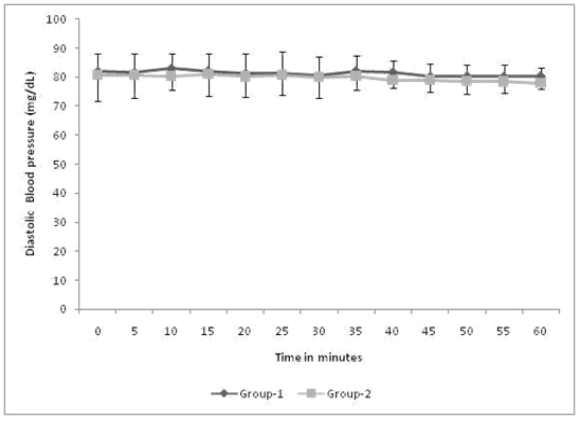

Figure 3 ; Changes in Diastolic blood pressure

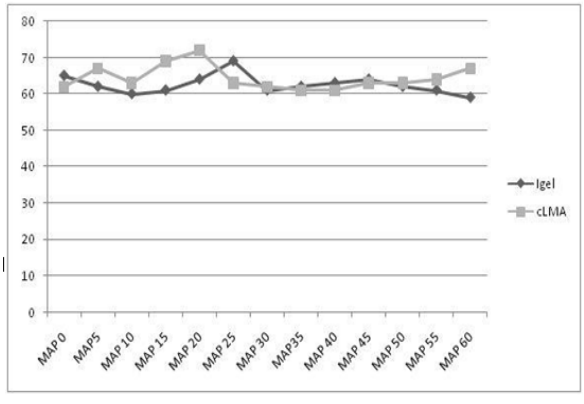

Figure 4 : Changes in mean blood pressure

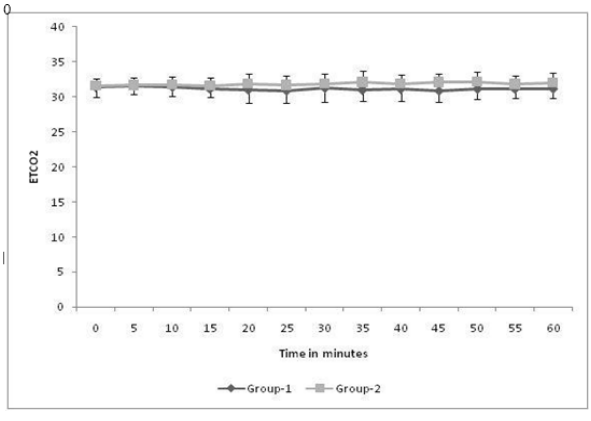

Figure 5 : Changes in etCO2

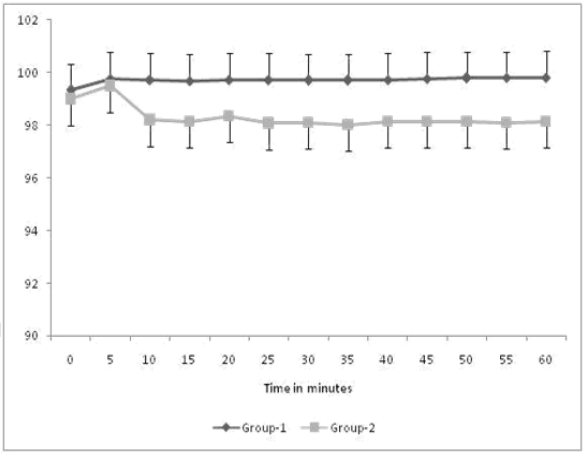

Figure 6 : Changes in spO2

Of the total of 80 cases, 40 were studied for BASKA and 40 for the I-gel over a period of one and a half years. In the BASKA group 23 were females and 17 were males. In the I-gel group, 18 were females and 22 were males. The age spectrum in both the BASKA group and the I-gel group was from 20 yrs to 60 yrs. The modal value for the I-gel was to 38 yrs and for -BASKA was 27 yrs. This was found to be of no statistical significance with 'p values' of 0.528 and 0.263 respectively for age and gender variation. Hence the patient groups receiving I-gel and BASKA respectively were comparable across all age groups and did not have any sampling bias in this study with respect to age and gender. (Table 1) Patients were also assessed on the basis of their BMI for both the groups. In the BASKA group the BMI varied from 21 Kg/M2 to 35 Kg/M2(mean 23) and in the I-gel group from 17 Kg/M2 to 30 Kg/M2(mean 29). The modal value for the BMI in the I-gel group was 18 Kg/M2 and for the BASKA was 22 Kg/M2 and was of no statistical significance.

The list of surgeries that were undertaken for the study was also stratified between the two groups. The BASKA was used in 3 minor eye procedures, 13 hernioplasties, 15 Open Reduction and Internal Fixation (ORIF) with tension band wiring, 7 incision and drainages and 5 excisions of fibro adenoma of the breast. (Table 2) On the contrary, the I-gel was used in 3 minor eye procedures, 15 hernioplasties, 10 ORIF with Tension band wiring, 7 incision and drainages and 5 fibro adenoma excisions. I-gel was also used once in a patient with Sub-Dural hematoma requiring drainage.

All the surgeries lasted for less than two hours. There were no intra operative surgical complications and anesthesia was administered as planned for the study groups. On applying the statistical tests for the type of surgeries the p – value was found to be insignificant(0.822).

The American society of Anesthesiologists has devised a grading system to assess the severity of illness, of the patients being undertaken for surgery. The ASA physical status classification system has six well defined classes. Out of these, as previously discussed under materials and methods, patients belonging to only ASA class 1 and 2 were considered for the study. For the BASKA group, 29 belonged to ASA grade 1 and 11 belonged to ASA grade 2. For the I-gel group, 34 belonged to ASA 1 and 6 belonged to ASA 2. It was found that the difference in the frequency of different ASA grades between the BASKA and I-gel group had no statistical significance as the p value was 0.172.

As a part of the airway assessment tools, The Mallampati scores of all the patients were recorded. According to the design of the study, only MP grade 1 and 2 were included in the study. In the BASKA group 29 patients had MP grade 1 and 11 patients had MP grade 2. In the I-gel group 34 patients had MP grade 1 and 6 patients had MP grade 2. The difference in the MP grades between both the groups was found to be statistically insignificant with a p value of 0.531 (Table 3) The SADs which have been included in this study are devices which require a skilled operator to place them into the patient's oropharynx. The ease with which one is able to insert the device and place it at the intended location in a correct manner requires minimal skill. Besides after routine use even an unskilled practitioner is expected to use it comfortably with minimal failures and untoward effects.

The I-gel and BASKA being uncuffed devices, do not require inflation. The ease by which a skilled person is able to insert an SAD is judged by the time taken for inserting the device and the number of attempts needed to achieve the patent airway. In the patients having undergone insertion of the BASKA the median duration of insertion was 23 seconds. For the patients belonging to the I-gel group the median duration was much lesser, it being 5 seconds. The median range of time taken by the BASKA group was 10.5 – 26.5 seconds, whereas the median range of time taken by the I-gel group was 5 -6 seconds. On applying the required statistical tests, the p value was found to be of significance, it being 0.001. (Table 4) While comparing two SADs the attempts taken to insert a given SAD in a patient are also a tool for assessing the ease of insertion of that device and it contributes to the judgment regarding the better device.

In the BASKA group out of the 40 patients there were 32 in whom the device was successfully inserted and rightly placed in the first attempt. A second attempt at insertion was required in 7 patients in whom the correct placement could not be achieved during the first attempt which was assessed by the absence of an adequate chest lift on ventilation using the bag after the insertion, five point auscultation of the chest for breath sounds, and monitoring of the EtCO2 and the SpO2. There was only one patient where a third attempt was made for insertion and placement after two failed attempts at it.(Table 5) . In the I-gel group out of the total of 40 patients the device was successfully inserted and appropriately placed in 37 patients in the first attempt where as 3 patients required reinsertion of the device despite attempting various listed maneuvers (Chandy) for ensuring correct placements. In these three patients the I-gel was not properly placed and had to be repositioned after complete removal. Third attempt was not required in any of the patients.

The total number of attempts for ensuring safe and patent airway in 40 patients in case of BASKA group was (32*1 + 7*2 + 1*3) 49 whereas the same in case of 40 patients in the I-gel group were (37*1 + 3*2) 43. The difference in the two values is statistically significant and the p value was calculated using the required statistical tests and it was found to be 2.7% (p=0.027)

In both the study groups (c-LMA & I-gel) the recordings were made for base line heart rate, systolic blood pressure, diastolic blood pressure and the mean arterial pressure for all the patients.

The heart rate was measured using the ECG recording of the R-R intervals shown in the multi parameter monitor attached to the patient. Though continuous monitoring was done for the study purposes the heart rates at time intervals of 5 minutes were recorded and immediately following the insertion and placement of the device. The mean heart rate in the BASKA group was 93.1 per minute where as in the I-gel group it was 93.25 per minute. The difference in the values was found to be statistically insignificant with a 'p value' of 0.705. Hence, there was no significant difference, in the changes in the heart rate brought about by insertion, of the I- gel or the c-LMA. (Line diag. 1)

The systolic blood pressure was measured by attaching a cuff in the right upper arm of every patient. The cuff covered 40% of the arm surface area and underwent timed inflations to give 5 minute systolic and diastolic blood pressure recordings.

The mean systolic pressure (SBP) in the BASKA group was found to be 121.6 mm of Hg where as it was 119.65 mm of Hg in the I-gel group. The difference between the two values was found to be statistically insignificant with a 'p value' of 0.769. (Line diag. 2)

The mean diastolic blood pressure (DBP) for the BASKA group was 80.8 mm of Hg and the same for the I-gel group was 82.15 mm of Hg. The difference between the values of the mean diastolic pressure in both the groups was again found to be of no statistical significance with a 'p value' of 0.229. (Line diag. 3)

The mean arterial pressure (MAP) was also calculated using the standard formulae for all the patients in both the groups. Mean of the MAP for all the patients in the BASKA group was 60.25 mm of Hg and the same for the I-gel group was 62.65 mm of Hg. The difference between these two values was again found to be of no statistical significance and the 'p value' for MAP was 0.749.(Line diag. 4)

The end tidal carbon dioxide measurement is considered as a gold

standard test, for confirming tracheal intubation rather than esophageal and also about the circulatory status of the patient. If a patient is in shock, the End tidal carbon dioxide (EtCO2) would rise. Moreover, it is used as a tool in cardiopulmonary resuscitation to assess return of spontaneous circulation. In our study, as the patient was on spontaneous ventilation under anesthesia, the EtCO2 values would help in identifying if there was any ventilatory fatigue during the surgery. It was measured using a mainstream capnometer and a reading was obtained every five minutes till the time the SAD was removed and a mean value of all the readings for each patient and the mean of all the readings of all the patients in both the groups respectively was obtained.

In the BASKA group the mean EtCO2 was 31.55 mm of Hg whereas in the I-gel group the mean EtCO2 was 31.38 mm of Hg. The difference between the values from the two groups was found to be statistically insignificant with a 'p value' of 0.532.(Line diag. 5)

The spO2 is a measure of saturation of the hemoglobin with oxygen and works on the principle of absorption spectrophotometery. This is also used as a means for assessing adequacy of ventilation.The mean spO2 for the BASKA group was 99% and the same for the I-gel group was 99.3%. The difference in the mean values from both the groups was found to be of no statistical significance and the 'p value for the same was calculated to be 0.843.(Line diag. 6)

There are certain set of complications which may occur at the time of insertion of the devices. As discussed previously, the larynx and the parynx are richly supplied by a plexus of nerves which originate from the vagus and the glossopharengeal nerve. The blood supply is derived from the superior and inferior thyroid arteries. The larynx is formed by, a mucosa covered cartilaginous framework which can get easily injured if the proper technique for device insertion is not applied. Such injuries can also occur incidentally also. They get identified postoperatively after cessation of anaesthesia. The patients may complain of sore throat associated with post device removal cough, dysphagia which would mean pain during swallowing, dysphonia meaning difficulty in vocalizing which could be due to injury to the superior, inferior or recurrent laryngeal nerve. Associated cyanosis or numbness of the tongue with ear ache due to blockade of the Eustachian tube can also occur. Injury to the laryngo pharynx if not managed on time can also lead to life threatening infections. Nausea and vomiting may be reported as despite the patient being on spontaneous ventilation there could be a certain amount of gastric insufflations which would lead to distention and hence, nausea followed by vomiting postoperatively. In the current study, the following post operative complications were accounted for, in both the groups. (Table 6)

In the Igel group none of the patients reported any complications. In the BASKA group 5 % patients reported of sore throat and cough post extubation which resolved within 6 hours of post surgery recovery period. On applying the statistical tests, the p value was found to be significant (0.026). Dysphonia was reported in 2.5 % patients with a P – value of 0.211 which was insignificant .None of the patients, in both the Igel and BASKA groups reported of any dysphagia which would be characterized by difficulty in ingestion of food or swallowing, ear ache, nausea or vomiting.

T.M.Cook, C. Green et al (2010) studied 8 different types of supraglottic airway devices which included the Igel and it was concluded that insertion of the Igel is the easiest.[12]

S. Ramesh, R Jayanthi(2011) conducted a study on supraglottic airway devices in children and concluded that the supraglottic airways devices are a better option since there are a number of problems associated with the face mask or the endotracheal tube. The LMA classic and the LMA Proseal having been proven of their efficacy were replaced by an adequately sized Igel.[13]

Chew EE et al (2010) compared the LMA supreme and the Igel in spontaneously breathing ventilating patients. The comparisons were drawn over the success rate, ease of insertion and the incidence of intra and post op complications. Leak pressures were also compared the same same being higher for the LMA supreme than the Igel (25.6 cm of H2O v/s 20.7 cm of H2O) and a P value of 0.0001. The ease of insertion and the attempt rate were similar for both the groups. In addition, the fiberoptic view was better for the Igel group.[14]

C.D.T. James wrote a historical note on Sir William Macewen and anaesthesia and brought to light Sir Macewen's work on the consequences of tracheal intubation leading to glottis edema. It was useful work as the various drawbacks of tracheal intubation were brought to light.[15]

Rebecca Preston (2011) reviewed the role of the Igel in resuscitation. In 2009 it was included in the resuscitation guidelines by various groups including The European Resussscitation Guidelines and The Difficult Airway Society (DAS) extubation guidelines. The review examined the published evidence of Igel focusing on the data which is relevant for it's use[16]

CONCLUSION

The following sets of conclusions are drawn here :

The I gel takes a lesser amount of time for insertion as compared to the BASKA.

The calculated mean for the Igel being 5s as compared to 23s for the BASKA.

On applying the relevant statistical tests, a P-value of 0.001 was obtained, it being highly significant.

The Igel is easier to insert as compared to the BASKA. Most of the Igels were successfully inserted in the first attempt. 7 cLMAs and 2 Igels required a second attempt and 1 cLMA required a third attempt for insertion. A P-value of 0.027 was obtained which was statistically significant.

The Heart rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial blood pressure, Oxygen saturation and the End tidal Carbon dioxide were comparable between both the groups and there was no statistical significance of the same.

Incidence of sore throat as a post operative complication is found to be higher in the BASKA group as compared to the Igel group. A P-value of 0.026 was obtained which was found to be significant.

Overall, the Igel appears to be a better supraglottic airway device as compared to the BASKA.

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