RESEARCH
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EVALUATION OF AIRWAY ISOLATION WITH TWO CUFFLESS SUPRAGLOTTIC AIRWAY DEVICES: RANDOMIZED CLINICAL STUDY.

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Abstract
Minor gynaecological surgical procedures under general anaesthesia require a patent airway. Supraglottic airway devices have been widely used for airway management. A study was undertaken to compare sealing pressure of two cuffless supraglottic airway After approval from the institutional ethical committee, a randomised single-blinded study was conducted on 60 American Society of Anesthesiologists' physical status I and II female patients aged 18–45 years who underwent minor surgical procedures under general anaesthesia. Patients were randomly categorized into two groups of 25 each; group Baska® mask and group I-gel, sealing pressure, brimacombe grading noted. The results were analysed using unpaired t-test, Mann-Whitney U test, Chi-square test and ANOVA. A p value <0.05 was considered to be statistically significant. Out of 50 patient's airways for 25 were secured with I gel and for 25 were secured with baska based on sealing pressure at leak is visualized by fibreoptic broncoscope in both group for BASKA (mean=31.5), I GEL (mean=28.3). The Baska mask® with its unique morphological design and air shaft withstand high sealing pressure than i gel. The sealing pressures of the Baska mask® are superior to those of the I-gel and it is a better alternative airway device for short surgical procedures with minimum complications.

Keywords: Supraglottic airway device, baska, I-gel,brimacombe

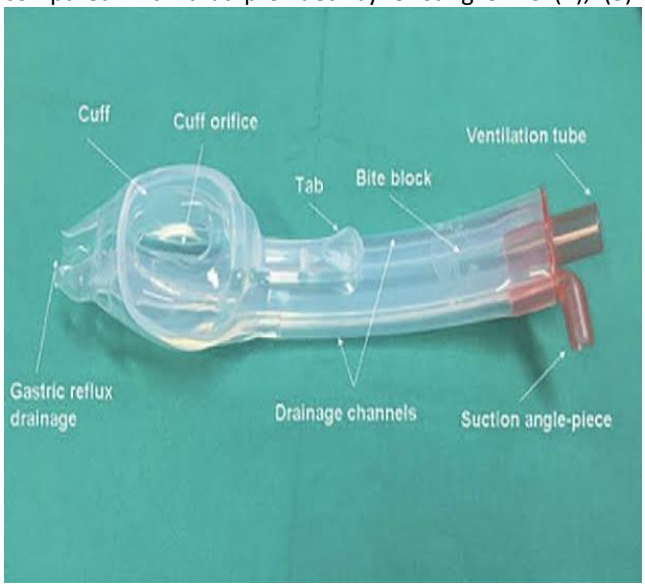
INTRODUCTION

Supraglottic airway devices (SGA) are commonly used in modern anaesthesia practice and have been widely used as an alternative to tracheal intubation during general anesthesia (1). In anesthesia supraglottic airway devices are used during spontaneous or intermittent positive pressure ventilation. In emergency situations they are a valuable emergency tool for airway management. Several studies have also demonstrated their safe use during short laparoscopic procedures. The newer cuffless supraglottic devices have also been found to have a low incidence of aspiration. A limited number of studies exist that have compared the use of different types of SAD in short gynecological procedures.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 laparoscopic procedures. This study was conducted to quantify the airwayseal provided by two cuffless supraglottic airway devices, the I - gel, and the baska, and to determine which device provides better isolation at higher airway pressures.

Igel- (Intersurgical Ltd,workingham,Berkshire,U.K),is a supraglottic airway device anatomically designed non inflatable mask that fits onto perilaryngeal framework,it has buccal cavity stabilizer with airway channel and gastric tube insertion port

Baska - (Proact medical Ltd,French forest NSW,Australia) is a new supraglottic non inflatable airway device that has a self-sealing membranous cuff that inflates during inspiration and deflates during expiration.it also has oesophageal drainage inlet and side channel to facilitate aspiration of gastric content and integrated bite block. Baska was first introduced in 2012, it provides more efficient ventilation by automatically inflating the cuff during positive pressure ventilation. The cuff differs from other non-inflatable cuffs in that it is continuous with the central channel of the device. As the pressure increases with positive pressure ventilation, the cuff automatically inflates and provides better oropharyngeal leak pressure (OLP)

compared with that provided by existing SADs (2), (3).



METHODS:

This study was conducted in saveetha medical college after approval from the institutional ethical committee (CTRI/ 2022/12/047944) and written informed consent was obtained from all patients.It is a prospective randomized control study including 25 patients

A total of 60 patients were randomly allocated into three groups of 25 patients each.

1. Group I – I-GEL (n = 25)
2. Group B – BASKA (n = 25)

INCLUSION CRITERIA

Patient aged between 18-45 years, patients undergoing elective short gynecological procedures lasting for less than 60 minutes procedures and ASA PS grade 1 & 2

EXCLUSION CRITERIA

we excluded patient with Anticipated difficult airway, Patients having neck pathology, Pregnant women, ASA PS grade 3 and above, any patient with Abdominal / airway / respiratory pathologies which may denote a higher risk for aspiration, Incorrect placement of the airway device as evidenced by the fibreoptic view and Patient refusal.

Routine pre-anaesthetic evaluation, including blood tests, were performed for all patients. The night before the surgery and the morning of the surgery, all patients were premedicated with oral pantaprazole 40 mg and alprazolam 0.5 mg. As per ASA guidelines, fasting protocol was followed. On shifting the patient to the operation theatre, intravenous access was checked and started on intravenous fluids. Basic monitors like ECG, NIBP, SpO2 and capnography were connected and monitored.before inducing anesthesia,subjects were randomly assigned to either IGEL group or BASKA group. subject randomization was done using computer generated random numbers, which were held in a series of sealed envelopes until the subject arrived in the operating room. Induction of anaesthesia was performed with adequate preoxygenation with 100% oxygen followed by Inj.Fentanyl 2mcg/Kg and Inj.Propofol 2mg/Kg intravenously. After confirming adequate mask ventilation, the patient was paralyzed with Inj.Atracurium 0.5 mg/Kg. The appropriate airway device was inserted after 3 minutes by an experienced anaesthesiologist with a minimum of 3 years' experience. The appropriate size of the device was selected based on subject bodyweight, height and manufacturer guidelines. For I-gel, size 3 was used when patients weight was less than 50 kg, size 4 was used when weight was between 50 kg and 70 kg. For Baska, size 3 was used for subject weight between 30 kg and 50 kg, size 4 used when weight between 50kg and 70 kg. The anaesthesia circuit was connected, and the patient's ventilation was assessed with both auscultation and capnography to ensure there were no obvious leaks. Mechanical ventilation was maintained with oxygen and nitrous oxide with an FiO2 of 50% along with 2% sevoflurane. All patients underwent intermittent positive pressure ventilation with a tidal volume of 7ml/kg and respiratory rate of 12 -14 breaths per minute. The baseline peak airway pressures were noted. A fibreoptic bronchoscope was used to confirm the correct placement of supraglottic airway device. With the use of a catheter mount, the fiberoptic bronchoscope was passed through the ventilation channel of the device without interfering with the ventilation and to make sure there was no leak. The accurate seating of the airway device was confirmed by the ability to see the complete glottis cupped by the cuff of the device.The fibreoptic scope was then passed into the patients nostril along the lateral border of the airway device till the contact area between the outer border of the cuff and the pharyngeal wall were visualized. The patient's peak airway pressures were gradually raised by changing to manual ventilation and closing the APL valve. The peak airway pressure at which a leak was visualized as evidenced by the appearance of air bubbles between the cuff and the pharyngeal wall was noted to be the airway pressure till which airway isolation was provided by the device.After the end of the surgical procedure and following adequate spontaneous efforts by the patient, neuromuscular blockade was reversed with Inj.Neostigmine 2.5 mg and Inj.Glycopyrolate 0.5 mg. Patient was then extubated after becoming awake and responsive.

The collected data were analysed and to describe the data descriptive statistics frequency analysis,percentage analysis were used for categorical variables and the mean and S.D were used for continuous variables. To find the significant difference between the bivariate samples in independent groups the independent sample t test was used. To find the significance in qualitative categorical data chi square test was used.In all above statistical tools the probability value 0.05 is considered significant level.

RESULTS: Out of 50 patients airway for 25 were secured with I gel and for 25 were secured with baska based on sealing pressure at leak is visualized in both groups for BASKA (mean=31.5), I GEL (mean=28.3).

BRIMACOBE SCORE IN FOB VIEW:

Score	View
4	Only cords seen
3	Cords plus posterior epiglottis seen
2	Cords plus anterior epiglottis seen
1	Cords not seen, but function adequate
0	Cords not seen, failure to function

The mean sealing pressure of the Baska® mask was significantly higher when compared with the I-gel

Two Means - Hypothesis testing for two means (equal variances)

Standard deviation in group I = 3.11

Standard deviation in group II = 3.65

Mean difference = 2.86

Effect size = 0.846153846153846

Alpha Error (%) = 5

Power(%)=80

T-Test

Group Statistics

Groups		N	Mean	SD
Age	BASKA	25	31.5	8.7
	I GEL	25	31.2	8.1

p - value	** Highly Statistical Significant at p < 0.01
p - value	* Statistical Significant at 0.01 ≤ p ≤ 0.050
p - value	# No Statistical Significant at p > 0.050

Independent Samples Test

		Levene's Test for Equality of		t-test for Equality of Means						
									95% Confidence Interval of the	
		F	Sig.	t	df	p-value	Mean Difference	Std. Error Difference	Lower	Upper
Age	Equal variances assumed	.841	.364	.152	48	.880	.3600	2.3754	-4.4161	5.1361

T-Test

Group Statistics

Groups		N	Mean	SD
HR 0min	BASKA	25	77.8	4.7
	I GEL	25	77.1	4.9
HR 5min	BASKA	25	79.0	5.2
	I GEL	25	74.9	4.1
HR 10 min	BASKA	25	77.8	5.5
	I GEL	25	75.6	6.6
HR 15 min	BASKA	25	81.0	7.0
	I GEL	25	77.8	8.0
HR 20 min	BASKA	25	76.4	7.7
	I GEL	25	78.6	7.5
HR end of the procedure	BASKA	25	79.5	9.2
	I GEL	25	78.4	8.6

sided = 2Required sample size per group = 22

Independent Samples Test

		Levene's Test for Equality of		t-test for Equality of Means						
		F	Sig.	t	df	p-value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Lower	Upper
HR 0min	Equal variances assumed	.034	.854	.503	48	.617	.6800	1.3519	-2.0383	3.3983
HR 5min	Equal variances assumed	2.437	.125	3.145	48	.003	4.1600	1.3226	1.5007	6.8193
HR 10 min	Equal variances assumed	.199	.657	1.258	48	.214	2.1600	1.7169	-1.2920	5.6120
HR 15 min	Equal variances assumed	.022	.883	1.482	48	.145	3.1600	2.1328	-1.1283	7.4483
HR 20 min	Equal variances assumed	.059	.809	-1.006	48	.320	-2.1600	2.1479	-6.4787	2.1587
HR end of the procedure	Equal variances assumed	.146	.704	.429	48	.670	1.0800	2.5187	-3.9842	6.1442

Group Statistics

Groups		N	Mean	SD
Sealing pressure at equilibrim	BASKA	25	15.20	1.5
	I GEL	25	15.12	1.6
Sealing pressure at leak is visualized	BASKA	25	31.6	3.9
	I GEL	25	28.2	3.9

Independent Samples Test

		Levene's Test for Equality of		t-test for Equality of Means						
		F	Sig.	t	df	p-value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Lower	Upper
Sealing pressure at equilibrim	Equal variances assumed	.696	.408	.181	48	.857	.0800	.4409	-.8065	.9665
Sealing pressure at leak is visualized	Equal variances assumed	.404	.528	3.150	48	.003	3.4400	1.0919	1.2446	5.6354

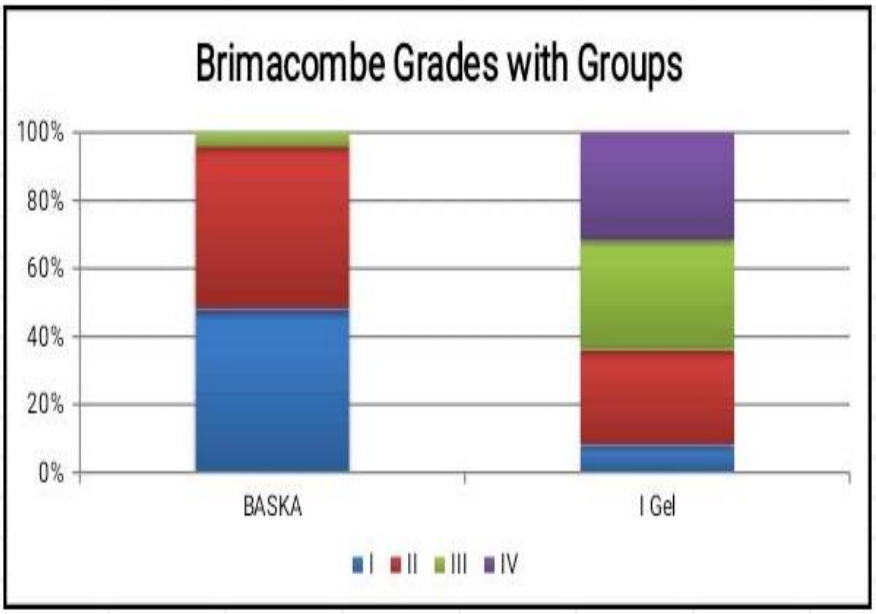
Brimacombe Grades * Groups

Crosstabulation

			Groups		
			BASKA	I GEL	Total
Brimacombe Grades	I	Count	12	2	14
		%	48.0%	8.0%	28.0%
	II	Count	12	7	19
		%	48.0%	28.0%	38.0%
	III	Count	1	8	9
		%	4.0%	32.0%	18.0%
	IV	Count	0	8	8
		%	0.0%	32.0%	16.0%
Total		Count	25	25	50
		%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	p-value
Pearson Chi-Square	21.903[a]	3	.0001



Based on sealing pressure between two groups, Baska =25, Igel=25, mean of sealing pressure at equilibrium for BASKA is 15.20, S.D 1.5, for IGEL mean 15.12, S.D 1.6
Sealing pressure at leak visualized is for BASKA mean 31.6, S.D 3.9 For I GEL mean 28.2, S.D 3.9
P value at equilibrium =0.857, at visualized leak=0.003

T-Test

Group Statistics

Groups		N	Mean	SD
Sealing pressure at equilibrim	BASKA	25	15.20	1.5
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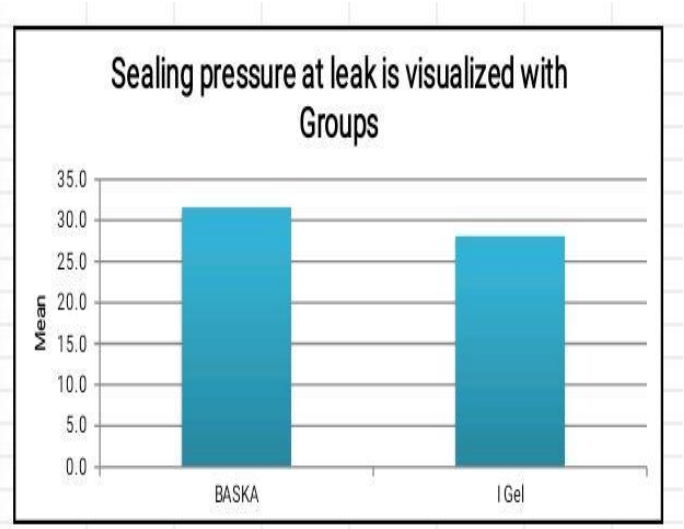
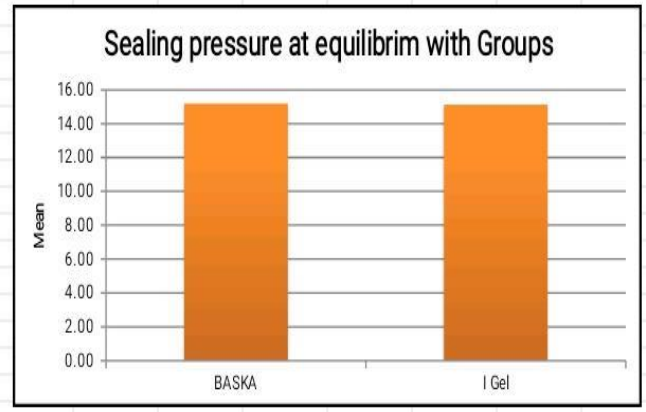
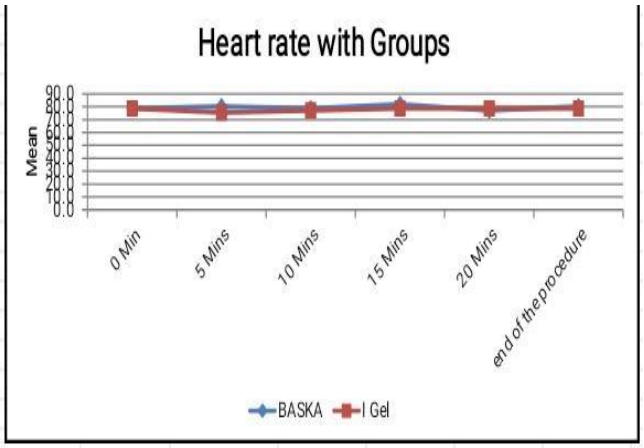




In relation to heart rate there is no significant differance between two groups



DISCUSSION:

Supraglottic airway devices (SADs) are used to keep the upper airway open to provide unobstructed ventilation. Early (first-generation) SADs rapidly replaced endotracheal intubation and face masks in > 40% of general anesthesia cases due to their versatility and ease of use. Second-generation devices have further improved efficacy and utility by incorporating design changes. Individual second-generation SADs have allowed more dependable positive-pressure ventilation, are made of disposable materials, have integrated bite blocks, are better able to act as conduits for tracheal tube placement, and have reduced risk of pulmonary aspiration of gastric contents. SADs now provide successful rescue ventilation in > 90% of patients in whom mask ventilation or tracheal intubation is found to be impossible. However, some concerns with these devices remain, including failing to adequately ventilate, causing airway damage, and increasing the likelihood of pulmonary aspiration of gastric contents. Careful patient selection and excellent technical skills are necessary for (4) Supraglottic airway management devices comprise a family of medical devices that facilitate oxygenation and ventilation without endotracheal intubation. Cuffless SGAs including Baska and igel are compared in this study. They provide better airway sealing characteristics than classic LMA, have an additional drainage tube for stomach decompression to reduce the risk of pulmonary aspiration, and are designed for use with spontaneous or positive pressure ventilation (PPV). Baska mask is a newer third generation supraglottic airway device according to new Miller's classification of SAD in 2014[19], with additional safety features, requiring comparative studies with the existing second-generation devices to evaluate its safety and efficacy. There is a gradual improvement in the Baska mask seal against the glottis over the first 2-3 minutes, which might be due to the thermolability of the membranous mask, making it more adaptable to the shape of the laryngeal outlet over time (4), (5)

This study was conducted to compare the airway sealing pressure of the BASKA mask and Igel LMA and sealing pressure at equilibrium, and leak was visualized,using fibreoptic bronchoscopy BRIMACOMBE SCORING done and grading assessed.

There were no complications while inserting the SAD in both the groups. In our study there were no intraoperative complications in both the groups and no untoward hemodynamic changes occurred in either of the groups.

The primary outcome of mean airway sealing pressure was significantly higher with a p-value < 0.05 in BASKA group compared with igel group

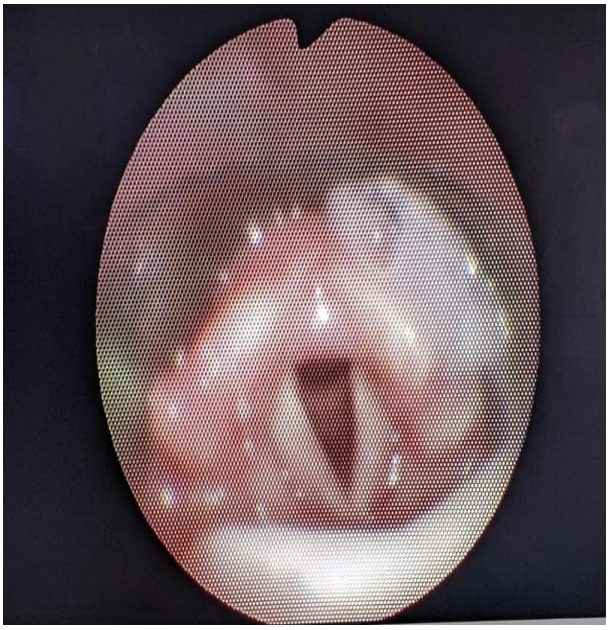
Based on brimacombe score better grading is visualized by FOB in BASKA group than I GEL group

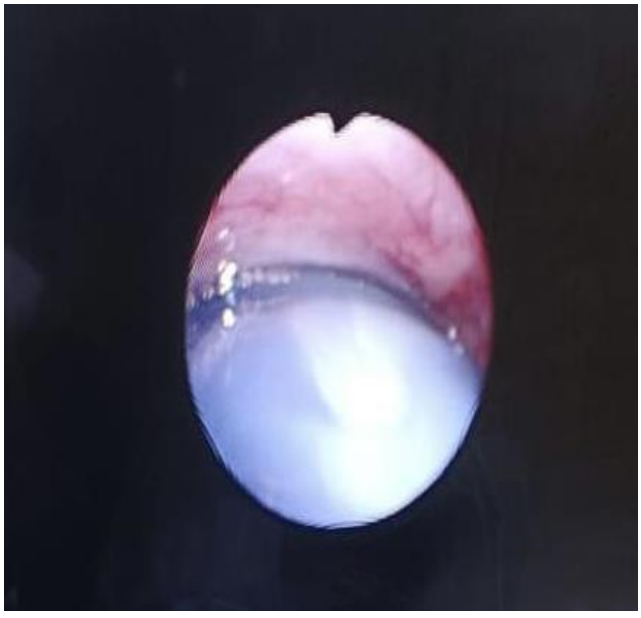
There is no much statistical significance in view of patient heart rate and age group in relation to brimacombe grading and sealing pressure

No adverse events were recorded during intraoperative and postoperative periods. After device removal, there was no patient with visible trauma to oral tissues and no blood staining of SGD. This could be attributed to gentle insertion of SGD with adequate muscle relaxation without using any undue force. Brimacombe et al. (7), who compared the face mask and LMA, reported that the incidence of complications, such as sore throat, increased as the LMA cuff volume increased, with statistically significantly higher number of complications occurring with the use of larger

cuff volumes. Hence, complications such as sore throat are thought to be caused by the volume of air inflated into the cuff rather than the size of the cuff.

Cuff of Baska mask is soft, self- sealing, pliable membranous structure not requiring inflation to provide adequate seal with glottis. It inflates and deflates during inspiration and expiration respectively exerting intermittent pressure on tracheal mucosa. This is an advantage over most other inflatable cuffed SGDs whose continuously over-inflated cuffs can exert excess pressure and injure surrounding tissue or cause nerve damage causing dysphonia. I-gel has a non-inflatable cuff made of soft gel like thermoplastic elastomer that reduces perilaryngeal tissuetrauma.





LIMITATION:

We include patient aged between 18 and 45 years of age,patient undergoing short gynaecological procedures,ASA 1 and 2.

CONCLUSION:

The Baska mask® with its unique morphological design and air shaft withstand high sealing pressure than i gel. The sealing pressures of the Baska mask® are superior to those of the I-gel and it is a better alternative airway device for short surgical procedures with minimum complications.

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