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A COMPARATIVE STUDY OF BASKA MASK WITH AMBU AURAGAIN IN ADULT PATIENTS UNDERGOING SURGERY UNDER GENERAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

Introduction- Supraglottic airway devices (SGAD) provide a viable alternative to endotracheal intubation for airway management. Our study aimed to compare the clinical performance of Baska mask (B), a novel SGAD and Ambu Auragain (A), an anatomically curved second generation SGAD in patients undergoing general anaesthesia (GA). **Objectives-** To compare oropharyngeal leak pressure (OLP), time for insertion, number of attempts, ease of insertion, bronchoscopic view of glottis (Brimacombe score) & complications between the two devices. **Material and Methods-** Total of 60 patients of age ranges between 18 and 60 years of either sex, ASA Grade 1 and 2, receiving general anaesthesia were randomly allocated to either group A (n=30) group B (n=30). Following induction of anaesthesia, respective SGAD was inserted and oropharyngeal leak pressure (OLP), time for insertion, number of attempts, ease of insertion, bronchoscopic view of glottis (Brimacombe score) & complications were noted. Data collected was tabulated and analysed using appropriate statistical tests. **Results-** The demographic parameters in the two groups were comparable. OLP was significantly higher in group B(25.67±2.23 cm of H2O) as compared to group A(20.03±1.92 cm of H2O) with P<0.001.Time for insertion (15.90±4.24 seconds versus 22.40±5.91 seconds) was significantly lower for group B. Baska mask had significantly better ease of insertion than Auragain, (p=0.046). With higher Brimacombe score (3.57±0.5 versus 3.13±0.87, p=0.03), group B provided a better fibreoptic view of the glottis. No patients in either group required a second insertion attempt or faced device failure. Rate of complications was comparable between the two devices. **Conclusion-** With higher OLP, better fibreoptic glottic view, less time of insertion and better ease of insertion, Baska mask is a better alternative to Ambu auragain in patients undergoing general anaesthesia.

KEYWORDS

OLP, SGAD, Baska mask, Auragain, Brimacombe score

INTRODUCTION

Traditionally, endotracheal intubation has been used in conjunction with general anaesthesia to secure the airway. Laryngoscopy and intubation has a steep learning curve and may be associated with significant haemodynamic variation, trauma and associated postoperative sore throat[1]. SGADs (supraglottic airway device) are being increasingly used as alternative to endotracheal intubation due to above mentioned reasons.

First generation SGAD had lower OLP (oropharyngeal leak pressure) and no mechanism for gastric de-sufflation making patient vulnerable to aspiration of gastric content[2,3]. Ambu Auragain introduced in 2014, is an anatomically curved, cuffed second generation SGAD with wide airway airway channel and low friction ventral surface which allows easier insertion while Baska Mask being third generation SGAD, has advanced, non-inflatable, self sealing, variable pressure cuff and two channels for better gastric reflux drainage[4-8].

The present study was undertaken to compare the performance of these two devices in patients undergoing general anaesthesia.

MATERIALS AND METHODS

After approval of the institutional ethics committee, applying the inclusion & exclusion criteria and obtaining informed written consent, a total of 60 patients were included in this study.

Using a computer generated randomization chart, the patients were randomly allocated into Group A (Ambu Auragain group) and Group B (Baska Mask group) and the numbers were then kept in opaque sealed envelopes, to be opened in the operating room. A thorough pre anaesthetic evaluation with detailed medical and personal history following complete physical examination including airway assessment was done. Any relevant findings were duly noted. All selected patients were advised overnight fasting. In the preoperative holding area, a wide bore intravenous access was secured. Anaesthetic techniques were standardized for all patients. Inside the operation theatre, standard non–invasive monitors were attached and baseline readings were recorded following which sealed envelope was opened and randomly allocated supraglottic device was prepared for insertion. The correct size SGAD was selected using manufacturer's recommendation. The cuff integrity was checked by inflating it and checking for any leaks followed by deflating it and lubricating posterior surface of Ambu Auragain whereas both the surfaces of Baska Mask was lubricated using water based jelly.

Preoxygenation with 100% oxygen was done for three minutes. Premedication with Injection Midazolam 0.04mg/kg body weight and Injection fentanyl 2mcg/kg body weight IV was done followed by induction with 2.5mg/kg propofol IV and muscle relaxation was achieved using injection vecuronium 0.1mg/kg IV. Intermittent bag and mask ventilation was done for next three minutes. For both devices, with patient's head in neural position, a deflated, prelubricated appropriate size device was inserted for Ambu Auragain, cuff was inflated with air as per manufacturer's recommendation (cuff pressure <60mm of H20). In case of difficulty in insertion, concomitant jaw thrust or slight neck extension was tried to ease the passage of device and for Baska Mask, in case of difficulty in insertion, the tab was pulled to align the curvature of device to palatopharyngeal axis.

Time for insertion was calculated as time elapsed in seconds from the time that the anaesthesiologist picked up the SGAD to the time that the correct placement was confirmed by appearance of first trace of square wave capnograph and in case of multiple attempts, the time of insertion was taken as sum of time of individual attempts, number of attempts were calculated for each patient and an attempt at insertion was deemed to have failed if it does not succeed in 60 seconds or there is no square wave capnograph trace after insertion, the patient was preoxygenated with 100% oxygen for 1 minute before the next attempt and in case of failure of three attempts at insertion, the patient was intubated with appropriate size endotracheal tube and was excluded from final study. The ease of insertion was graded on a scale from 1-4 (1- very easy, 2-easy, 3- difficult, 4-fail) with permissible manoeuvres

mentioned above.

1	VERY EASY	Able to pass in one attempt, no extra manoeuvres required
2	EASY	Able to pass in one attempt with extra manoeuvres
3	DIFFICULT	Requires more than one attempt
4	FAIL	Failure to insert with 3 attempts

Once the airway device was in place, it was fixed by taping over the patient's cheek. Ananesthesia was maintained for all patient's using a mixture of O2 and N2O (50:50) with isoflurane at 1 MAC followed by ventilation on volume control mode with tidal volume 6-8ml/kg. The respiratory rate was adjusted to keep end tidal CO2 between 30-35 mmHg.

Bronchoscopic view of glottis was assessed after 2 minutes of successful insertion of device by passing a flexible fiberoptic bronchoscope (Pentax™, EB1970k) through the ventilatory channel and view of glottis was assessed using brimacombe score where (4-Only vocal cords are seen, 3-Vocal cords plus a part of posterior epiglottis seen, 2-Vocal cords plus anterior epiglottis seen, 1-Vocal cords not seen but ventilation possible, 0-Vocal cords not seen and ventilation not possible).

OLP was measured 5 minutes after successful insertion of device. With patient connected to circle system at spontaneous breathing mode, with fresh gas flow at 4 litres/minute and the adjustable pressure limiting valve (APL) closed. The OLP was taken as airway pressure at which equilibrium was reached. The maximum permissible airway pressure was limited to 40 cm of H20 to avoid barotrauma. All anaesthetic gases were stopped at the end of surgery and patients were ventilated with 100% oxygen. On appearance of first spontaneous breathing effort, neuromuscular blockage was reversed with neostigmine (0.05mg/kg) and glycopyrrolate (0.01mg/kg). Any complication occurring during insertion, intra operatively and while removing the device were noted.

Statistical Analysis

Sample size was calculated on the basis of variation in oropharyngeal leak pressure in Ambu Auragain and Baska Mask groups using the formula,

$$n = \frac{k(Z\alpha + Z\beta)2(\sigma 1 2 \sigma 2 2)}{d^2}$$

Where :

.$\sigma_1 = 3.00$, The SD of oropharyngeal leak pressure in Ambu Auragain group[9]

$\sigma_2 = 3.34$, The SD of oropharyngeal leak pressure in Baska Mask group[10]

- $d = \min(\sigma_1, \sigma_2)$, the minimum difference considered to be clinically significant
- $k = 1.0$ the design effect
- type I error $\alpha = 5\%$ corresponding to 95% confidence level , $Z_\alpha = 1.96$
- type II error $\beta = 10\%$ for detecting results with 90% power of study , $Z_\beta = 1.64$

The minimum sample is calculated to be n = 30 subjects in each group

OBSERVATION AND RESULTS

Table 1:

	GROUP A		GROUP B		SIGNIFICANCE
AGE (years)	**MEAN**	**SD**	**MEAN**	**SD**	P = 0.222
	35.83	14.70	31.33	13.47	
GENDER	**MALE**	**FEMALE**	**MALE**	**FEMALE**	P = 0.519
	7	23	5	25	
HEIGHT (cm)	**MEAN**	**SD**	**MEAN**	**SD**	P = 0.882
	151.57	3.95	151.73	4.65	
WEIGHT (kg)	53.60	9.44	52	9.05	P = 0.505
BMI (kg/m^2)	23.50	3.95	22.97	3.77	P = 0.602
MPG	I	11	I	8	P = 0.874
	II	19	II	22	
ASA	ASA-I 29	96.7%	27	90.0%	P = 0.301
	ASA-II 1	3.3%	3	10%	

There was no statistically significant difference between Group A and Group B with regards to mean age, gender distribution, mean height, mean weight, mean BMI, Mallampatti Grades (MPG) and ASA grades

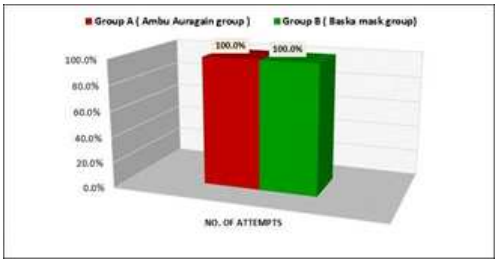

Fig. 1: Intergroup comparison of number of attempts

Analysis of data showed that all participants in both groups underwent successful insertion of respective devices in a single attempt. As there was no variability in the data, statistical test for significance were not applied.

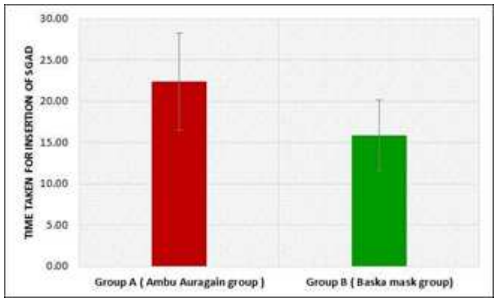

Fig. 2: Intergroup comparison of time taken for insertion of SGAD

In group A the mean time for SGAD insertion was 22.40 ± 5.91 seconds while in group B the taken for insertion was 15.90 ± 4.24 seconds. unpaired T test showed a significant difference between the two groups with p<0.001

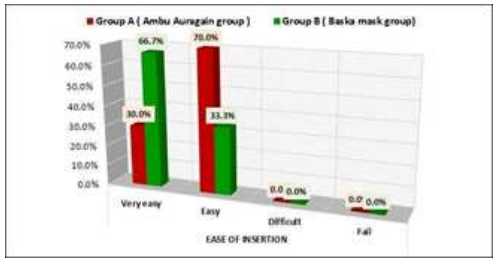

Fig 3: Intergroup comparison of ease of insertion of insertion

In group B, 66.6% of insertions were graded as very easy as compared to only 30% in group A, the percentage of easy insertions was 70% as compared to 33.3% in group B, none of the insertions were difficult or failed in either group. Chi square test showed a significantly higher ease of insertion with Baska Mask (p=0.004).

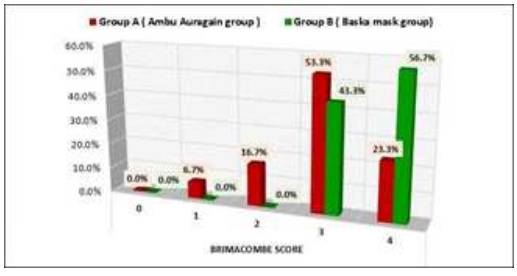

Fig 4: Intergroup comparison of Brimacombe score

56.7%(17/30) patients in Baska Mask group and 23.3%(7/30) patients in Ambu Auragain group had Brimacombe score of 4. A score of 3 was seen in 43.3%(13/30) patients in Baska Mask and 53.3%(16/30) patients in Ambu Auragain group. No patient had a brimacombe score of 0. The difference in Brimacombe score was statistically significant with p=0.009.

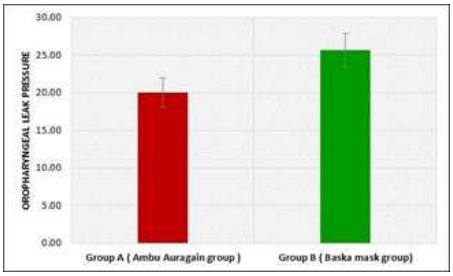

Fig 5: Intergroup comparison of oropharyngeal leak pressure

Statistical analysis shows mean OLP for group A to be 20.03±1.92 cm of H_2O while the same for Group B is 25.67±2.23 cm of H_2O. there is a statistically significant difference between the two groups($p<0.001$), suggesting that Baska Mask provides a better oropharyngeal seal.

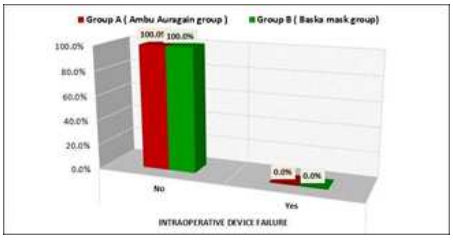

Fig 6: Intergroup comparison of intraoperative device failure

There were no intraoperative device failures across the two groups showing high reliability and functionality of both devices. As there was no variation in the data, no test of significance was applicable.

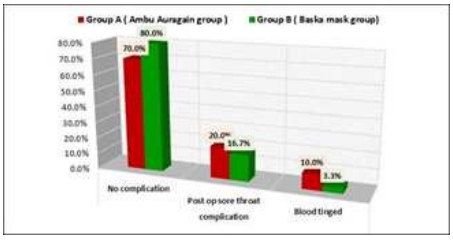

Fig 7: Intergroup comparison of complication

70% patients in Group A and 80% patients in group B suffered no complications due to SGAD. 1(3.3%) patient in Baska Mask group showed a blood tinged device on removal. 3(10%) patients in Group A suffered similar complications. 6(20%) complained of post operative sore throat compared to 5(16.7%) patients in group B who had similar complaint. Even though the incidence of complications is higher in group A, the difference is statistically insignificant($p=0.524$).

Table 2:

		GROUP A	GROUP B	SIGNIFICANCE
NO. OF ATTEMPTS		30 (100%)	30 (100%)	
TIME TAKEN FOR INTUBATION (seconds)		24.40±5.91	15.90±4.24	<0.001
EASE OF INSERTION	VERY EASY	9(30%)	20(66.7%)	P = 0.004
	EASY	21(70%)	10(33.3%)	
	DIFFICULT	0	0	
BRIMACOMBE SCORE	0	0%	0%	P = 0.009
	1	2(6.7%)	0%	
	2	5(16.7%)	0%	
	3	16(53.3%)	13(43.3%)	
	4	7(23.3%)	17(56.7%)	
OLP (cm H_2O)		20.03±1.92	25.67±2.23	P<0.001
INTRA OP DEVICE FAILURE	NO	30(100%)	30(100%)	
	YES	0	0	
COMPLICATION	NO COMPLICATION	21(70%)	24(84%)	P = 0.524
	POST OP SORE THROAT	6(20%)	5(16.71%)	
	BLOOD TINGED	3(10%)	1(3.31%)	

DISCUSSION

Evolutionary classification of SGADs divides these devices on the basis of their sealing mechanism into three generations with presence of inflatable seal, wedge seal and self-sealing mechanism in first, second and third generation respectively[11]. In addition, second and third generation SGADs have additional safety features like gastric suction ports and bite blocks etc

Ambu Auragain is a second generation, anatomically curved SGAD with an inflatable cuff and an inbuild gastric port, It has been studied extensively as an airway management device. Baska mask is novel, 3rd generation SGAD with a non-inflatable, self-energizing cuff with a large sump cavity and two drainage tubes.

The primary objective of this study was to determine which of the two SGADs had higher OLP when used for airway management in patients undergoing elective surgical procedures. The other objectives of the study included first attempt insertion rate, comparing insertion time, number of attempts, ease of insertion, fibreoptic view of glottic structures and complications between the two groups.

A total of 60 patients undergoing surgery under general anaesthesia were allocated into one of the two groups: in Group A(n=30):the airway was managed with Ambu Auragain and Group B(n=30): the airway was managed with Baska Mask

In present study statistically no significant difference between Group A and Group B with regards to mean age i.e 35.83±14.76 and 31.33±13.47, p value= 0.222, gender distribution, p value= 0.519, mean height 151.57±3.95 and 151.73±4.65, p value= 0.882, mean weight 53.60±9.44 and 52±9.05, p value=0.505, mean BMI 23.50±3.95 and 22.97±3.77, p value=0.602, mallampatti Grades (MPG), p value=0.270, ASA grades, p value=0.301, Type of surgery, p value=0.217, respectively.

The primary objective of this study was to compare the oropharyngeal leak pressures of Baska Mask and Ambu Auragain, the mean oropharyngeal leak pressure for group B was 25.67±2.23cm H_2O while the same for Ambu Auragain was 20.03±1.92cm H_2O. With a $p<0.001$ this result was statistically highly significant. Our findings are similar to study done by Raman et al[12] who compared Baska Mask and Ambu Auragain in 74 patients and found higher OLP for Baska Mask(31.32 ±2.59 cm H_2O) than Ambu Auragain (27.54 ± 1.32 cm H_2O). According to study done by Sachidananda et al[13] comparing Baska Mask to I-gel, the former showed significantly higher OLP(28.9 ±3.5 cm H_2O) than Igel (25.9 ± 2.5cm H_2O). A similar study by Singh et al[12] comparing Baska Mask in LMA Pro seal in 60 patients again confirmed the superiority of the pharyngeal seal of Baska Mask with OLP of (30.25 ± 3.34cm H_2O) compared to (23.50 ±4.05 cm H_2O) for LMA Pro seal (p value <0.001)

Unique features present in cuff of Baska Mask contribute to its high OLP. The membranous cuff of Baska Mask adapts to patient's laryngopharynx providing a good seal. The intra cuff pressures increases with increasing airway pressures during each breath further improving airway seal and OLP.

Studies by Wong et al[14] and Lopez et al[15] showed higher OLP of Ambu Auragain (26.4±2.8 and 34±5 cm H_2O respectively) as compared to LMA supreme which is another anatomically curved SGAD with inflatable cuff having values(21.6±3.4 and 29±5 cm H_2O respectively). However, Sabuncu et al[16] in their study comparing Ambu Auragain to Igel found no significant difference in OLP between the groups. Inflation of the cuff in Ambu Auragain might cause slight change in the cuff position resulting in reduction in OLP.

The two groups were compared on the basis of number of attempts required for successful insertion it was found that all patients in both groups had a successful insertion of respective device in first attempt.

Our findings are consistent with Sinasamy et al[17] who showed that overall insertion rate were comparable between Baska Mask and I-gel (p=0.055). However, Baska Mask (31/40, 77.5%) had slightly lesser first attempt success rate than I-gel (37/40, 92.5%). Similar results were also obtained by Singh et al[10] who found that over all number of attempts was comparable between Baska Mask (1.40±0.31) and LMA Pro seal (1.51±0.25). Sabuncu et al[16] in their study found 100% first attempt successful insertion rate in both I-gel and Ambu Auragain groups. Shariffuddin et al[18] found comaparable first attempt success between Ambu Auragain (86%) and LMA supreme (78%). Raman et al[12]reported 100% overall successful insertion rate between Baska Mask and Ambu Auragain. The first attempt successful insertion rates were also comparable between the two groups. The results of all these studies are similar to present study.

The high first attempt as well as over all successful insertion rate with both devices show their high dependency and safety. Both devices have unique features which markedly increased chances of successful insertion. Baska Mask has a soft membranous cuff which is lubricated on both dorsal and ventral surfaces and can be compressed to maneuver in the oral cavity. Slight curvature of the device along with the insertion tab which can be pulled to alter and align device curvature to the patient's oropharyngeal axis makes insertion easier. Ambu Auragain on the other hand is anatomically curved with a cuff which has a broad and smooth ventral surface allowing for easier insertion.

Time taken for insertion of Baska Mask and Ambu Auragain was compared in this study and showed significantly lesser time for Baska Mask (15.90±4.24 seconds) than Ambu Auragain (22.40±5.91 seconds) p value being <0.001. These results are consistent with the result obtained by Singh et al[10] who found significant low time to insert Baska Mask (14.25±3.82seconds) as compared to Pro seal LMA (22.01±2.64 seconds). Garg et al[19] also found significantly lower time to insertion with Baska Mask (7.3±2.7 seconds) as opposed to I-gel (12.4±4.5 seconds). Study comparing Baska Mask with Ambu Auragain by Raman et al[10] showed no significant difference in time for insertion. This deviation from our result could be due to difference in experience of the researcher in using these SGADs, especially Baska Mask which is relatively newer device.

Compressible membranous cuff and concomitant use of insertion tab to align device accordingly to the anatomical oropharyngeal curvature of the individual patient contribute to the faster insertion of Baska Mask. The additional time required to inflate the cuff in Ambu Auragain contributes to higher insertion time of the device.

This study also compared the ease of insertion of the two devices on a 4 point scale having 1=very easy, 2= easy, 3= difficult, 4= failure to insert the device. 66.6% (20/30) of insertions were recorded as very easy in Baska Mask group as compared to 30% (9/30) in Ambu Auragain group. This difference was statistically significant with Baska Mask providing a subjectively easier insertion. No insertion failures were noted in either groups. Raman et al[12] studied the ease of insertion in Baska Mask and Ambu Auragain group on a 3 point scale (1-3) and found no significant difference between the two. Study by Shariffuddin et al[18] compared ease of insertion of Ambu Auragain to LMA supreme on a 5 point scale with 74% insertions in LMA supreme group recorded as easy as compared to 48% in Ambu Auragain group. This difference in results from our study could be due to different definitions used for grading of difficultly in the studies. Ng et al[20] in their study compared ease of insertion of Baska Mask to endotracheal tube. Their study showed slightly better ease of insertion for Baska Mask than endotracheal tube. However, this difference was not significant and can be attributed to obviously higher level of skills required for endotracheal intubation.

The presence of insertion tab is a unique feature of Baska Mask. This tab can be pulled during insertion of the device to align it's curvature to the patient's oropharynx, thus making insertion easier. Intra group analysis of Baska Mask group that 40% (12/30) patients required the use of this tab for successful insertion

In this study we graded the fibreoptic bronchoscope view of glottic structures using the five point (0-4) Brimacombe score. Intergroup analysis showed Baska Mask having a significantly higher number of grade 4 views than Ambu Auragain group (56.7% vs 23.3% respectively). No patients in Baska Mask group had scores of 0, 1 or 2. Our results are similar to study done by Ng et al[20] who reported a brimacombe score of 4 in 58.6% (17/29) patients with Baska Mask. Another study by Raman et al[12] graded the fibreoptic view on a 4 point (1-4) scale and compared the same between Baska Mask and Ambu Auragain group. They obtained a full view of glottis in 33 out of 37 patients in Baska Mask and 28 out of 37 patients in Ambu Aurgain group. The result was therefore comparable between two groups.

Significantly higher number of grade 4 views with Baska Mask show a higher incidence of correct positioning and alignment with larynx with this group

Intraoperative device failure was defined as failure to achieve 80% of the set tidal volume at any point during the surgery, necessitating endotracheal intubation. No patient's in either group faced intraoperative device failure.

Review of literature failed to find any study with a similarly defined parameter.

Incidence of complications related device insertion were compared between the two groups. 10% (3/30) patients in Ambu Auragain group and 3.3% (1/30) patient in Baska Mask group showed blood tinged device on removal. These results are consistent with those of Sachinanada et al[13] and Garg et al[19]. who showed comparable incidence of blood tinged device between Baska Mask and I-gel, study by Wong et al[14] showed no statistically significant difference in incidence of blood tinged device between Ambu Auragain and LMA supreme. Post operative sore throat was seen in 16.7% patients in Baska Mask group and 20% patients in Ambu Auragain group with the difference being statistically insignificant. These results are similar to those obtained by Singh et al[10] who showed comparable incidence of sore throat between Baska Mask and LMA Pro seal.

Complications with the newer SGADs are rare but may include trauma while inserting, trauma to the peri laryngeal mucosa due to pressure from the cuff, nerve injury, post operative sore throat (POST) and aspiration of gastric content. Baska Mask cuff inflates only during inspiration and the cuff pressure never exceeds the peak inspiratory pressure thus reducing injury to peri laryngeal tissue. Absence of inflatable cuff also prevents diffusion of nitrous oxide and excess pressure of surrounding tissue.

The strength of present study is the comparative design and tertiary care hospital setting which included patients from a wide variety of demographic background and a variety of surgical procedures. Extensive literature search revealed a very limited pre-existing research on this topic with only one study by Rajesh Raman et al, (2023) comparing these devices in the Indian population. There were a few limitations to the present study, the sample size even though statistically adequate, was still small. In addition due to obvious differences between the two SGADs double blinding was not possible. The study did not include pregnant patients, obese patients, patients with comorbidities and individuals undergoing laparoscopic surgeries. We therefore recommend that further studies be carried out to assess the performance of Baska Mask and Ambu Auragain in the above subset of patients.

CONCLUSION

With higher OLP, better Bronchoscopic view of glottis, less time of insertion and better ease of insertion, Baska Mask was concluded to be better alternative to Ambu Auragain in patients undergoing general anaesthesia.

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