OROPHARYNGEAL LEAK PRESSURE COMPARISON AMONG NON-INFLATABLE CUFF DEVICES FOR ELECTIVE SURGERIES IN ADULT PATIENTS

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Abstract:

Background and aims: *Archie Brain in 1988 introduced LMA (Laryngeal mask airway). Since then, many Extraglottic Airway Devices (EADs) have been introduced with several modifications. The Baska mask is the latest EADwith non-inflatable cuff. In the limited studies that were conducted on Baska mask, showed lots of variation in oropharyngeal leak pressure (OLP) ranging from 26cmH_2O to 41.53cmH_2O hence, we studied OLP as our primary objective.*

Subjects and methods*: Following approval, 200 patients aged 18-60 years with American Society of Anaesthesiologist's Physical Status (ASA PS) I-II were randomized into two groups, Group B (Baska mask) or Group I (I-gel).Sample size calculated by Alternative hypothesis, alpha 0.05 and power 0.8 .SPSS version 24 used with Continuous data by independent t-test, Chi-square test for categorical data and Significance level p<0.05.OLP, insertion time, fibreoptic view, ease of insertion and removal, haemodynamic changes, post-operative complications were noted.*

Results: *Mean OLP was 37.34±2.38cmH_2O and 30.59±4.82cmH_2O for Group B and Group I respectively (p-value < 0.0001).Mean insertion time was 15.23±1.32 seconds for Group B and 11.19±1.70 seconds for Group I (p<0.0001). Fibre-optic view was better with Group B (p<0.0001) and had higher incidence of sore throat (p<0.0001). No statistical significant in number of attempts, ease of insertion, and haemodynamic changes seen.*

Conclusion: *The OLP for Baska mask is superior to that of I-Gel. Time for insertion was less in I-gel but a significantly better fibre-optic view was provided by Baska mask.Thus Baska mask showing a better clinical profile.*

Key words*: Oropharyngeal leak pressure, Baska mask, I-gel.*

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INTRODUCTION

Modifications to the original airway introduced by Dr. Brain in 1983 were made to prevent aspiration by introducing a separate port for gastric content aspiration.[1]I-gel is the second generation EAD which is single use, designed and developed by Mohammed Nasir.[2] The Baska mask which is the third generation EAD is introduced recently, designed and developed by KanagBaska. When compared to second generation EAD, Baska mask has several novel features.[3]Baska mask showed lots of variation in sealing

pressure ranging from 26cmH_2O[4] to 41.53 cmH_2O[5].Hence a prospective, single blinded, randomized controlled study was taken up to compare the routinely used I-GEL with a newly introduced BASKA MASK at Tertiary care hospital to assess safety and efficacy of both the devices.

MATERIAL AND METHODS

Following ethical committee approval (JSS/MC/PG/4623/2018-19), 200 patients posted for non-emergency surgical procedures under GA with BMI<30, belonging to ASA 1 and II were included. Randomization was done through sealed envelope technique. A thorough pre anaesthetic evaluation was conducted 24 hours prior to the procedure and informed written consent was obtained. Standard ASA NPO guidelines were advised to all the patients.

Pre-operative basal standard monitors including ECG, NIBP, and pulse oximetry was attached, and base line parameters noted. Patient was pre-oxygenated for 3 minutes with closed circuit. All patients were uniformly premedicated with intravenous midazolam (0.02mg/kg), Fentanyl (1mcg/kg). Induction of anaesthesia was done using Injection Propofol (2mg/kg), Injection Vecuronium (0.1 mg/kg) and ventilated with oxygen and Isoflurane. End tidal carbon dioxide levels were measured to confirm ventilation. After 5 minutes and following adequate relaxation of jaw, a well lubricated Baska mask sized 3 or 4 and I-GEL size 3 or 4 (according to the manufacturers' recommendations of weight based estimate plus clinical judgement) was placed and connected to Drager fabius plus work station.

I-Gel was well lubricated and introduced into the mouth with the cuff facing downwards and passed along the curvature of the hard palate until resistance was met. The Baska mask was held at the proximal end and was introduced into the mouth. When resistance was felt against hard palate, it indicated that the mask tip was at the upper part of the oesophagus. A clear airway was secured.

Manoeuvres were performed to ensure proper device placement. Despite all trouble-shooting efforts, if ventilation was inadequate, a definitive airway was secured by an endotracheal tube. Patient was maintained on mechanical ventilation with Isoflurane (0.8% to 1.5%), and a mixture of nitrous oxide (70%) and oxygen (30%).

Parameters such as pulse rate and non-invasive blood pressure were recorded before and after insertion. Time taken for insertion was measured and compared between the two devices and defined as time in seconds from when the device is at the upper incisor teeth to the first recorded ETCO2 waveform. Only the time recorded during successful insertion was counted. OLP was measured after 5 mins of insertion and defined as pressure at which there is audible leak. It was calculated by using the plateau pressure at which equilibrium was achieved, when FGF (fresh gas flow) was 6 Litre/min with APL valve set at 70 cm H_20, and also the Anaesthesiologist was auscultating for audible leak with the stethoscope over the neck.

Fibreoptic endoscopy grading was done, Fibreoptic laryngeal view was assessed using a Brimacombe grading scale which is as follows: 4 = only vocal cords visible; 3 = vocal cords along with posterior epiglottis visible; 2 = vocal cords along with anterior epiglottis visible; 1 = vocal cords not visible, but function; 0 = failure to function where vocal cords not visible.[6]

Intraoperative analgesia was additionally managed with infusion of Inj. Paracetamol 1000mg IV. At the conclusion of surgery, patient was reversed from neuromuscular blockade with Neostigmine and Glycopyrrolate. Post-operative pain was treated as per institutional protocol. Postoperative scoring of Laryngopharyngeal Morbidity (LPM) done as mild, moderate and severe.

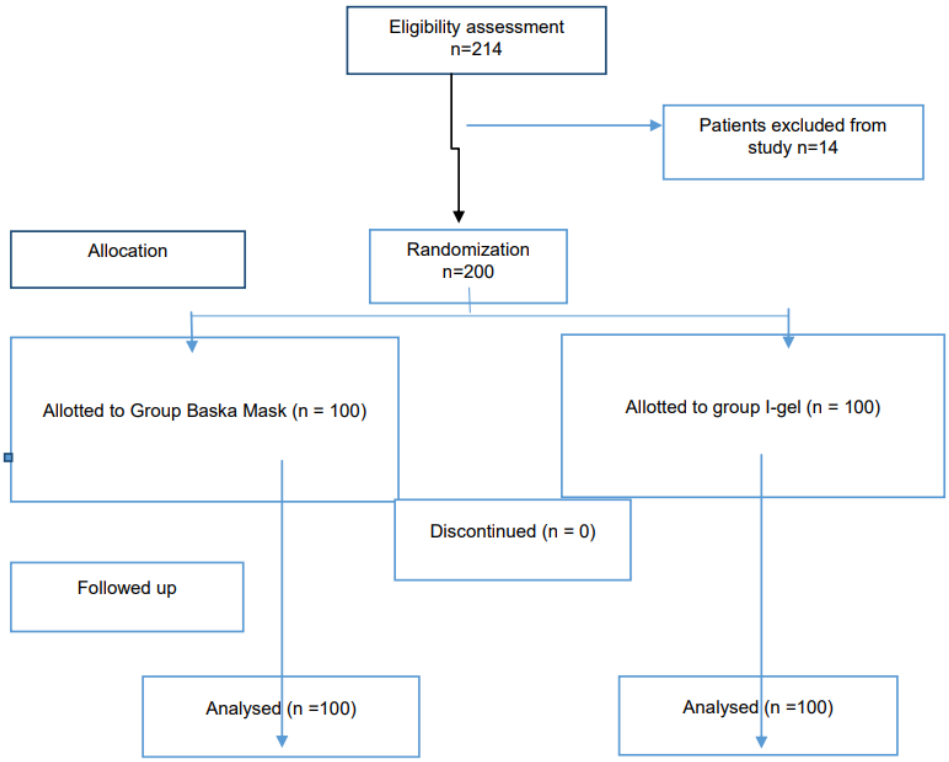
The sample size is calculated by using Alternative hypothesis where confidence interval of 95% (α) and power of 80% (β). Taking a difference of 10 cmH_2O, OLP between Baska mask and I Gel as significant based on our pilot studies and previous study[7], considering alpha and beta values, we got our sample size came as 63 in each group. We studied a total of 200 patients and divided into two groups of 100 each in order to increase the power of the study.

Statistical analysis was performed using SPSS version 24. Continuous data presented as mean±SD using the independent t-test, ordinal data as median compared using Mann-Whitney U test. Categorical data were compared using Chi-square test. Significance level for all analyses was p value <0.05

RESULTS

200 patients were recruited who met inclusion criteria out of 214.

Consort flow chart



None of the 200 selected patients were excluded in either of the study groups. Additionally, there was no significant difference with respect to age and gender.

Table 1: Demography and fibreoptic view

		Group				p
		Baska		I Gel		
		Number	%	Number	%	
Age category	<20	7	7.0%	7	7.0%	0.4
	21-30	29	29.0%	24	24.0%	
	31-40	33	33.0%	28	28.0%	
	41-50	26	26.0%	29	29.0%	
	>51	5	5.0%	12	12.0%	
	Total	100	100.0%	100	100.0%	
Gender	Female	53	53.0%	49	49.0%	0.6
	Male	47	47.0%	51	51.0%	
Anatomical position by Brimacombe grading	I	7	7.0%	6	6.0%	<0.0001*
	II	0	.0%	35	35.0%	
	III	17	17.0%	36	36.0%	
	IV	76	76.0%	23	23.0%	

OLP of Group B was 37.34cmH2O which provided better sealing pressure than Group I (30.59cmH20), with statistical significance (p value less than 0.0001). Brimacombe grade 4 was seen in 76% of patients in Group B compared to 23% in the Group I. Thus Baska mask provided with a better Laryngoscopic view fibre optically with statistical significance ($p < 0.001$).
Insertion time too showed a statistically significant difference of $p<0.0001$.Group Irequired a mean time of 11.19 seconds compared to 15.23 seconds for Group Baska. There was no statistically significant in ease of insertion($p=0.02$) and alsoHaemodynamic changes before and after insertion were not clinically significant($p>0.2$).

Table 2: Types of surgeries

		Group			
		Baska		I Gel	
		Count	%	Count	%
Surgery	Colostomy reversal	9	9.0%	6	6.0%
	Fibroadenoma excision	30	30.0%	25	25.0%
	Lap Appendicectomy	9	9.0%	11	11.0%
	Lap cholecystectomy	6	6.0%	10	10.0%
	TAH	10	10.0%	11	11.0%
	Tibia fracture	17	17.0%	9	9.0%
	PCNL Anterior approach	3	3.0%	10	10.0%
	Upper limb radius fracture	16	16.0%	18	18.0%

LPM assessment showed mild postoperative sore throat in 54% patients of Group Baska and 23% in Group I-Gel ($p<0.0001$). There was no post-operative dysphagia or dysphonia in both the groups.

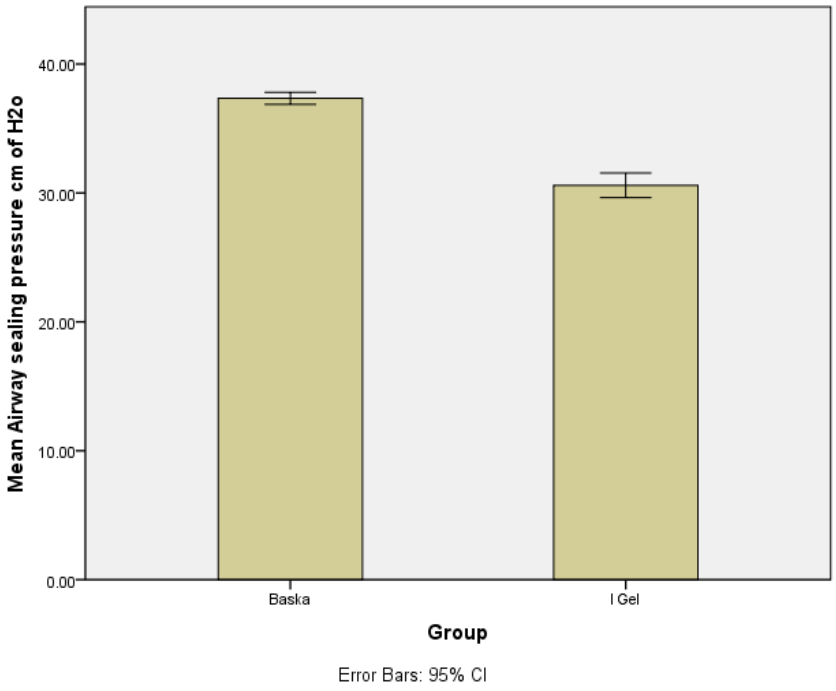
Table 3: Insertion time, OLP, Haemodynamic changes

	Group				p
	Baska		I Gel		
	Mean	SD	Mean	SD	
Insertion Time in seconds	15.23	1.32	11.19	1.70	<0.0001*
OLP cm of H2o	37.34	2.38	30.59	4.82	<0.0001*
PR/minute before insertion	77.80	9.83	76.37	8.84	0.3
PR/minute soon after insertion	85.73	8.31	82.09	8.71	0.003*
SBP mm of Hg before insertion	126.92	9.92	126.05	10.68	0.6
DBP mm of Hg before insertion	75.56	7.18	73.72	8.32	0.1
SBP mm of Hg soon after insertion	133.06	6.91	130.06	7.58	0.004*
DBP mm of Hg soon after insertion	82.10	5.19	79.48	7.52	0.005*
Change PR/min (A-B)	7.93	5.32	5.72	5.21	0.003*
Change SBP mm of Hg (A-B)	6.14	5.32	4.01	7.03	0.017*
Change DBP mm of Hg (A-B)	6.54	6.27	5.76	8.85	0.5

Table 4: Ease of insertion and removal, postoperative complications

		Group				P value
		Baska		I Gel		
		Number	%	Number	%	
Postop sore throat	Nil	44	44.0%	77	77.0%	<0.0001*
	Mild	54	54.0%	23	23.0%	

	Moderate	2	2.0%	0	.0%	
Postop dysphagia	Nil	100	100.0%	100	100.0%	-
Postop dysphonia	Nil	100	100.0%	100	100.0%	-
Intraop complications	None	100	100.0%	100	100.0%	-
Ease of insertion	Difficult	3	3.0%	0	.0%	0.02*
	Easy	86	86.0%	77	77.0%	
	Very Difficult	1	1.0%	0	.0%	
	Very Easy	10	10.0%	23	23.0%	
Ease of removal	Easy	96	96.0%	79	79.0%	<0.0001
	Very easy	4	4.0%	21	21.0%	



DISCUSSION

Keller C and his colleagues[8]have studied four different means of assessing the oropharyngeal leak pressure of LMA by:

1. Audible noise detection,
2. End tidal CO2 in oral cavity,
3. Observing the aneroid manometer dial,
4. Direct auscultation over the neck.

The authors concluded that all the four methods were equally good in clinical studies. But they opined that manometric stability test may be more appropriate than the others.

Aneroid manometer dial method was the most commonly used technique in majority of the studies.[4,7,9,10,11,12,13]

Combination of above two different methods would give a more accurate OLP. In the study conducted by Son Ron Choi and colleague's[9], the combination of two methods have been used for better accuracy.

Hence in our study, we have combined the manometer pressure method and direct auscultation over the neck method for calculating the OLP.

In our study, Group Baska had higher OLP than Group I-gel with statistical significance ($p<0.0001$). An OLP of 37.34 cmH_2O for Group Baska compared to 30.59 cmH_2O with I-gel was obtained. This is in concordance with several other studies.

Our study compares with the study conducted by R. Dhanasekaran et al[12] who compared Baska mask, I-Gel and Pro-seal LMA with OLP of 38.33±4.353 cmH2O for group Baska, 30.57±2.174 cmH2O for group I-Gel respectively. Refai N.A.R et al[10] conducted a study comparing both airways,Mean OLP was significantly higher in group Baska than group I-Gel (38.83±4.044 vs. 26.50±2.389 cmH_2O respectively). These results are also similar in our study.

Usha Kumari Chaudhary and colleague's compared both devices, they found the OLP was statistically significant with higher in group Baska than group I-Gel (29.54± 1.41cmH2O vs. 23.16 ± 3.07 cm H2O, P =0.02 respectively)[14]. OLP of both the devices was less when compared to our study, probably due to single method of measuring OLP and the time when OLP was measured, were not clearly defined.

SON RON CHOI and colleagues compared both the airways found that Baska mask had a better OLP than I-Gel which was statistically significant (29.6 ± 6.8 cmH2O and 26.7 ± 4.5 cmH2O, respectively; P = 0.014).[9] However the OLP was comparatively less than our study, probably due to the patients of higher BMI (upto 35kg/mts^2) selected. Additionally, to measure the OLP, they have adjusted the APL valve to 40 cmH2O, with FGF of 3 L/min, unlike our study.

Another study was conducted by Aziz et al,[15]in obese patients (BMI 25 to 40kg/mts^2) reported a statistically significantly higher sealing pressure with Baska Mask (28.6$\pm$2.9) than with I-gel (25.8$\pm$3.2) p= 0.0008. OLP for both the devices was less compared to our study, probably due to higher BMI upto 40kg/mts^2 in their study.

Shanmugavelu G et al, found OLP was significantly greater for Baska mask (26±5.8cmH2O) than I-Gel (22±4.1cmH2O) showing significant statistical difference (p-0.0008),[4]though theOLP measured in their study of both the devices was less compared to our study, probably due to use of single method and use of 5L/min of FGF (our study 6L/min) for measuring OLP.

By comparing all the above studies, cause for variations in OLP may be because of following reasons:

1. Method used for measuring OLP
2. APL valve pressure and fresh gas flow
3. BMI of the patients.

In our study we noted a mean time of insertion of 11.19 seconds for Group I-gel as compared with 15.23 seconds for Group Baska with high statistical significance ($P<0.0001$).

In studies comparing Baska mask and I-Gel, Aziz R.A.R et al[15],Shanmugavelu G et al[4], Chaudhary U.K et al[14]insertion time for I-Gel was less than Bask mask with statistical significance and it compares with our results.

The exact position of the cuff was confirmed fibre optically and scored. It is evident that a properly placed Baska mask provides positioning of the cuff against the glottis, as confirmed by fibreoptic view and thus helps to achieve good ventilation and also higher sealing pressures. Better the grading more is the sealing pressure.

Studies comparing this particular parameter are sparse and hence we took it up to add to the existing body of information about the SADs and their precise placements. We noted that Group Baska provided a grade four (optimal/best) anatomical positioning in 76/100 patients as compared to only 23/100 patients in Group I-gel ($p<0.0001$).

No adverse events occurred intra operatively in both groups. There was not much difference in LPM, except for mild postoperative sore throat after 2 hours which was seen in 54/100 patients in Group Baska compared to 23/100 in Group I-gel. Two patients in Group Baska had moderate sore throat.

CONCLUSION

The OLP for Baska mask is superior to that of I-Gel. I-gel required lesser time for insertion but a significantly better fibre-optic view was provided by Baska mask. The hemodynamic changes, laryngopharyngeal morbidity were not significant clinically. We conclude that both Baska and I-gel can be safely used in patients undergoing elective procedures. However, Baska mask may have clinical advantage by providing a favourable Fibre optic view, better OLP and hence an improved clinical profile.

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