Original Article

ISSN (0): 2456-7388; ISSN (P): 2617-5479

A Comparative Evaluation of Safety and Efficacy of Second and Third Generation Supraglottic Airways viz ProSeal-laryngeal Mask and the Baska Mask as Ventilatory Conduit for Airway Management

Sahu Krishn Kumar[1], Habib Syed Kamran[2], Bari Farhat[3], Haleem Shahla[4]

[1]MD Student, Department of Anaesthesiology & Critical Care, J.N. Medical College, AMU, Aligarh, India.

[2]MD, Assistant Professor, Department of Anaesthesiology & Critical Care, J.N. Medical College, AMU, Aligarh, India.

[3]MD Student, Department of Anaesthesiology & Critical Care, J.N. Medical College, AMU, Aligarh, India.

[4]MD, PhD, Professor, Department of Anaesthesiology& Critical Care, J.N. Medical College, AMU, Aligarh, India.

Abstract

Background: Supraglottic devices have revolutionized the airway management by providing the patent airway without endotracheal intubation. Proseal LMA has gastric drainage tube along with dorsal and ventral cuff. The Baska Mask® have membrane instead of cuff which inflates on every breath during Positive Pressure Ventilation (PPV). Aim: to compare BASKA mask and Proseal LMA in terms of safety and efficacy during positive pressure ventilation. **Subjects and Methods:** Settings and Design: Prospective, randomized, interventional study was conducted in 100 patients following approval by the Board of Studies and Ethical Committee. Patients were divided in two groups of 50 each. Written informed consent was taken before taking for surgery. Baska mask and Proseal LMA were compared as ventilatory conduit to compare the time to achieve effective ventilation, oropharyngeal leak pressure, fiberoptic laryngeal view scoring by POGO (Percentage of Glottic Opening) Scoring and pharyngolaryngeal morbidity. Statistical Analysis: done with the help of SPSS version 14 and p value less than 0.05 was taken significant **Results:** Total time required to achieving effective ventilation (seconds) was significantly less in BM group compared to group PLA (22.2 ± 6.91 sec vs 26.36 ± 8.66 sec, P < 0.001). Mean OLP was better in group BM (32.3.5 ± 3.01 cm H2O vs 31.06 ± 2.82 cm H2O). Anatomical alignment of SGD with glottis (POGO 100 %) was similar in both the groups, the group BM (43/50) and group PLA (41/50). Laryngopharyngeal morbidity was comparable between two groups. **Conclusion:** Our study support that the BASKA Mask is an effective conduit, provides better seal in significantly less time compared to ProSeal laryngeal mask and could be safely use for airway management in surgical patients.

Keywords: Second and third generation supraglottic Airways, Proseal laryngeal mask, Baska mask, ventilatory conduit

Corresponding Author: Dr. Shahla Haleem, Professor, Department of Anaesthesiology & Critical Care, J.N. Medical College, AMU, Aligarh, UP, India.
Email: shahlahaleem@yahoo.co.in
ORCID ID: 0009-0003-7015-3520

Received: 10 February **Revised: 15 March 2023** **Accepted: 30 March 2023** **Published: 11 April 2023**

Introduction

In 2000, Archie Brain devised gastric drainage tube to second generation ProSeal LMA to guards against pulmonary aspiration apart from the airway channel.[1-3] Baska Mask® (BM) a newer SAD, have non inflatable cuff, a membrane that inflates with each breath during intermittent positive pressure ventilation (IPPV).[4,5] It is moulded to take up the shape of SAD to achieve a superior seal, potentially lowering the risk of oropharyngeal tissue damage caused by cuff over inflation.[6,7] This study designed to compare the two devices belongs to second and third generation for their efficacy and utility as ventilatory conduit.

Subjects and Methods

Following approval by the Board of Studies, Department of Anaesthesiology, and Ethical Committee of this Institution, and written informed consent of the patient, the present study was conducted in J.N. Medical College Hospital AMU, Aligarh, on hundred patients undergoing elective surgery under general anaesthesia patients of either sex, between 18–60 years of age, weighing 40−70 kg, ASA physical status I -II and MP I, II and III Grades undergoing elective surgery under general anesthesia with controlled ventilation. Patient with mouth openings less than 3 cm or any pathology of oral cavity that may obstruct the insertion of device, expected duration of surgery longer than 3 hours, potentially full stomach, patients (morbid obesity, pregnancy, history of gastric regurgitation and heart burn, recent trauma and/or at risk of esophageal reflux as hiatus hernia), anticipated difficult airway and cervical spine

pathology were excluded from the study.

Sample Size Calculation: The sample size was calculated with respect to all the primary variables for a type I error of 0.05 and a test power of 95% and based on previous study. In an earlier study conducted by Kachakayala RK et al[8], the mean ± standard deviation OLP of the Baska Mask and Proseal LMA groups were (i.e. 31.2 ± 4.8 and 25.8 ± 3.3 respectively). To detect similar difference in means with 95% power, with the type 1 error of 0.05, sample size was found 50 in each group, was calculated with n Master software Version 2.0.

Randomization: All patients were randomly allocated using computer-generated tables, to allocate 100 patients into two equal groups. In Baska mask Group (BM) was used to provide controlled ventilation (n = 50) and in Group Proseal (P-LMA) was used as airway conduit (n = 50).

Anaesthetic Procedure: After preanesthetic check-up and clearance patients were made to fast overnight and received tablet alprazolam 0.25 mg, tablet ranitidine 150 mg, and tablet metoclopramide 10 mg orally night before surgery. In preoperative room peripheral intravenous (IV) access was secured with 20G/18G IV cannula. Patients were premedicated with Inj. Glycopyrrolate 0.2 mg IV, inj. midazolam 0.03 mg/kg, dexamethasone 0.1 mg/kg and fentanyl 1.5 mcg/kg of body weight. All these drugs were administered intravenously 15 min prior to transfer of the patient to the operation theatre.

In the operation room standard monitors included ECG, pulse oximetry, non-invasive blood pressure were connected and baseline values (values taken just before the start of the procedure) of HR, BP, SPO2 were recorded. After pre-oxygenation for 3 min, anaesthesia was induced with Inj. Propofol 2.0-3.0 mg/kg. After adequate muscle relaxation with Inj. Succinylcholine 1.5 mg/kg the appropriate-sized lubricated airway device, was chosen as per the weight of the patient. The supraglottic airway device was inserted as per the group allotment. The operator who has inserted the devices had achieved the learning curve after an experience of successful placement of each device in at least 20 patients before starting the study.

The airway was secured with the device depending on the group assigned to the patient. In group BM the Baska mask was hold by the stem and inserted towards the hard palate and advanced till some resistance is encountered. It should not be twisted or turn during insertion. The tab could be pulled if required to increase the curvature of the mask to get help in negotiating the palato-pharyngeal curve. The well lubricated gastric tube was inserted into the gastric channel port keeping the patient's head in sniffing position.

In PLMA group, the ProSeal LMA was inserted using the metal introducer in sniffing position. The patient's mouth was fully opened, well lubricated PLMA was inserted into the patient's mouth with help of introducer and was advanced into the pharynx till the resistance encountered. Now the introducer was removed, leaving the ProSeal in position. Cuff was inflated using cuff pressure gauge upto 60 cmH2O. The time when the device enters inside mouth till the appearance of the square wave pattern in capnographic waveform is the total time required to achieve effective ventilation (seconds). Thus it included time of insertion plus time to start the positive pressure ventilation. Time to achieve effective ventilation was noted by an independent assessor using a stopwatch.

The proper effective airway was said to ensured if there was bilateral chest expansion, square wave capnograph, lack of gastric insufflation, and no audible leak at peak airway pressure (PAP) of 20 cm of water during manual ventilation. Now, long acting muscle relaxant, vecuronium bromide 0.08 mgkg-1 was given intravenously to achieve neuromuscular blockade and anaesthesia was maintained with 60% N2O in Oxygen, along with vecuronium bromide and isoflurane.

Whatever airway manipulations required to achieve effective ventilation as jaw thrust, neck flexion or extension, chin lift, and/or reinsertion to change in the depth of device were also recorded. After securing the airway, the gastric catheter was passed into the stomach. The correct placement of the gastric tube was confirmed by auscultation over epigastric region while injecting air in gastric tube. The successful effective airway was considered following proper insertion of the device along with successful gastric tube insertion.

To assess the proper anatomical alignment of the SGD, and its grade, the POGO scoring was done through fibreoptic bronchoscope (FOB), fiberscope was passed into the airway tube of the supraglottic device, to keep its tip inside the distal end. The Fiber-optic view of the glottis/laryngeal grading by POGO score (percentage of glottic opening).[9]

Oropharyngeal leak pressure (OLP) was assessed by setting the APL valve of the circle system at 40 cm of water with fresh gas flow of 3 l/min. the OLP determined by observing the airway pressure at equilibrium until an audible noise is auscultated over the anterior neck and chest whilst observing the ventilator manometer during positive pressure ventilation this was noted as Oropharyngeal leak pressure, noted at 10 min of surgery at which equilibrium was reached. The max allowed airway pressure was taken 40 cm H2O.

Time of insertion of the device: from the moment the device enters the mouth until the appearance of the capnograph waveform. Time of second attempt similarly recorded and insertion time was taken as the sum of all attempts for proper insertion.

The grading of the laryngeal view was done by using the fiberscope, as percentage of glottic opening visualized (POGO Score).[10]

Grade I "full view of the glottis," (Full) – POGO 100%
Grade II "posterior commissure," (Partial) – POGO 50%
Grade III as "only arytenoids." – (None) --POGO 0%

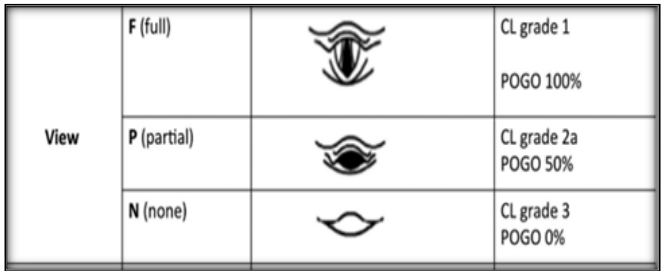

Figure 1: POGO score

Statistical Analysis

The following statistical tests were applied for the results. The comparison of the variables which were quantitative in

nature were analyzed using Independent t test. The comparison of the variables which were qualitative in nature were analyzed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0. For statistical significance, p value of less than 0.05 was considered statistically significant.

Results

A total of 100 study participants were included in the statistical analysis, All patients were randomly allocated (by using chit-in-box technique) for BASKA Mask and ProSeal LM (50 patients allocated in each group.) Analysing the demographic profile both the study groups were comparable with regard to age (years) (p value = 0.564), sex (p value 0.68), weight (kg)(p value=0.309), ASA grade (p value-0.766), No statistically significant differences were observed between the two groups with respect to demographic variables, MP and ASA grading.(Table-1)

The mean time required for insertion for ProSeal LMA was found to be higher with mean = 26.36 (S.D=8.66) against the BASKA Mask with mean = 22.2 (S.D=6.91). There was statistically significantly (p<0.005) difference between the two groups.

Table 1: Comparison of demographic data between two supraglottic devices

Parameters	BASKA Mask (n=50)	ProSeal Laryngeal Mask (n=50)	Total	P Value
Age(Yrs)mean± SD Median(25th-75th percentile)	38.48± 12.03 38(28-50)	34.84 ± 11.56 31(25.25-43.75)	36.66 ± 11.88 35(26-45.5)	0.564 0.126
Sex Male Female	20 (40%) 30 (60%)	18 (36%) 32 (64%)	38 (38%) 62 (62%)	0.68
Weight Mean ± SD Median(25th-75th percentile)	60.24 ± 6.43 59(55-65.75)	58.64 ± 5.21 58(54-63)	59.44 ± 5.87 58.5(54-65)	0.309 0.175
ASA Grade 1 II	44 (88%) 6 (12%)	43 (86%) 7 (14%)	87 (87%) 13 (13%)	0.766
MP Grade I Grade II Grade III Grade IV	26 (52%) 14 (28%) 7 (14%) 3 (6%)	28 (56%) 14 (28%) 4(8%) 4 (8%)	54 (54%) 28 (28%) 11 (11%) 7 (7%)	0.844

BM: Baska mask; PLMA: ProSeal laryngeal mask airway ; SD: standard deviation.

Table 2: Comparison of clinical Characteristics including device insertion attempts, insertion time, sealing pressure, ease of gastric tube insertion

Parameters	BASKA Mask(n=50)	ProSeal LMA(n=50)	Total	P value
Total time for achieving effective ventilation (secs)	22.2 ± 6.91	26.36 ± 8.66	24.28 ± 8.07	0.009
Ease of insertion of device (1/2/3) 1 2 3	42 (84%) 8 (16%) 0	40 (80%) 10(20%) 0	82 (82%) 18(18%) 0	0.603†
No. of Gastric tube insertion attempts 1 2	47 (94%) 3(6%)	46 (92%) 4(8%)	93 (93%) 7(7%)	1
POGO Score I II	43 (86%) 7 (14%)	41 (82%) 9 (18%)	84 (84%) 16 (16%)	0.585††

† Independent t test, †† = Chi square test

The laryngeal view grading was done as Percentage Of Glottic Opening visualized (POGO Score). The majority of the patients in both groups has shown POGO Score –I (84%). The BASKA Mask group had more number of POGO Score –I (n=43, 86%) compared to ProSeal LMA group (n=41, 84%) with a P value of 0.585 which was statistically not significant. (Table-2)

Table 3: Comparison of Oropharyngeal leak pressure (OLP) between two groups

Parameter	BASKA Mask(n=50)	ProSeal LMA(n=50)	Total	P value
Oropharyngeal leak pressure(cm of H_2O) Mean ± SD	33.5 ± 3.01	31.06 ± 2.82	32.28 ± 3.15	<.0001‡
Median(25th-75th percentile)	34(31.25-36)	30(29-33)	33(30-35)	

‡= Independent t test

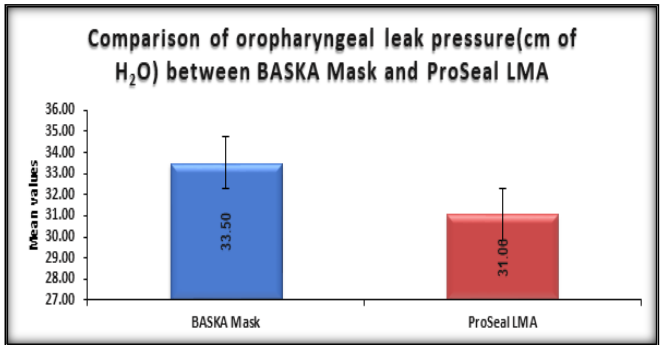

Figure 2: Oropharyngeal leak pressure (cm of H2O) trends between BASKA Mask and ProSeal LMA

The mean OLP between two groups was higher in BASKA Mask compared to ProSeal LMA (33.5 ± 3.01 vs 31.06 ± 2.82) with the P-value of <0.0001.(Table -3)

Table 4: Comparison of Laryngopharyngeal morbidity between two groups

Laryngopharyngeal morbidity	BASKA Mask(n=50)	ProSeal LMA(n=50)	Total	P value
Blood staining (No) Blood staining (yes)	43 (86%) 6 (12%)	43 (86%) 7 (14 %)	86 (86%) 13	1

			(16%)	
Laryngopharyngeal pain / Sore Throat	5 (10%)	7 (14%)	12 (12%)	0.538
Dysphagia (discomfort in swallowing)	1 (2%)	1 (2%)	2%	0.538
Hoarseness	4 (8%)	7 (14%)	11 (11%)	0.525

Discussion

The BM have "noninflatable" cuff, continuous with the main channel of the device. It provides an unique oropharyngeal self sealing, which proportionately increases with increasing airway pressure. During PPV, as pressure increases, the cuff inflates and mask distends increasing the pharyngeal seal and when pressure released, the mask deflates partially return to its initial state.[10,11]

The present comparative study demonstrated that the Baska mask in spite of cuffless device can withstand higher inflation pressures and provide better seal compared to proseal LMA. It can be placed in lesser time without problem of nitrous oxide diffusion even used for longer duration. It was found that there was less incidence of postoperative laryngopharyngeal morbidity compared to other commonly used supraglottic airway devices.

The mean time to achieve effective ventilation was significantly higher for ProSeal LMA group as compared with BASKA Mask group (26.36 ± 8.66 sec vs 22.2 ± 6.91 sec; P value 0.009), as additional time was required for removal of the introducer, cuff inflation and adjusting its pressure to 60 cm H2O with a hand-held manometer. In contrast, the Baska mask has a non-inflatable self-sealing membranous cuff. This is in accordance with the study conducted by Kachakayala RK et al[8] (2020), in their study the mean insertion time for BASKA mask was 16 ± 2.6 sec which was significantly shorter compared to Proseal LMA 20.9 ± 4 sec (P value- 0.0001). Similarly, Al-Rawahi SAS et al10 found that the mean insertion time in the Baska mask group was 16.43 ± 4.54 seconds while 21.45 ± 6.13 seconds in LMA-Proseal group which was statistically significantly(p value =0.001). They attributed faster insertion with Baska mask due to presence of a tab and a noninflatable cuff. Time required to inflate the cuff and cuff pressure adjustment to 60 cm of water with LMA-Proseal was not needed with Baska mask.

The mean OLP (cm H2O) after 5 minute of insertion of the SAD, observed (33.5 ± 3.01 vs. 31.06 ± 2.82; P < 0.0001) was significantly higher in group A (BASKA mask). This difference in mean OLP of 2.44 cm H2O can be of importance while ventilating patients with poor lung compliance or for surgeries requiring higher ventilation pressures. Jose et al.[11] compared Baska mask with LMA-Proseal in 52 adult paralysed patients undergoing general anaesthesia. Similar to our study they found that the OLP was higher with Baska mask (29.98± 8.15) as compared to that (24.50± 6.19) with LMA-ProSeal and the difference was statistically significant (p value =0.013). Similar to our study Agrawal et al.[12] compared Baska mask with PLMA in 80 patients undergoing general anaesthesia, observed the OLP was higher with Baska mask as compared to Proseal LMA. Thus, our study shows BASKA mask provides higher OLP as compared to ProSeal -LMA. The Baska Mask is a third generation supraglottic device has a self-sealing membranous, non-inflatable, recoiling cuff made of medical grade silicon.[13] It has a variable pressure cuff that inflates with each positive pressure inspiration and deflates during expiration. During intermittent positive pressure ventilation, as airway pressure increases, the membranous seal apposes to the glottis incrementally with time to increase oropharyngeal leak pressure. The higher oropharyngeal leak pressure means better seal of the device with glottis structures and implies that BASKA mask will be superior to ProSeal -LMA in especially patients who have high intrathoracic airway pressure due to pneumoperitoneum created for laparoscopic surgery or in patients with poor thoracic compliance and in those at risk of aspiration of secretions.

We assessed the anatomical alignment of the SAD by passing a fiberoptic bronchoscope through the airway tube of the device. The laryngeal view grading was done as Percentage of Glottic Opening visualized (POGO). POGO-100% was attained in 43 patients of BASKA mask group and in 7 patients. In the Group A, full view of the vocal cords (POGO-100%) was seen in 43 (86%) patients as compared to 41 (82%) patients in Group B. Partial view (POGO-50%) was observed in 7 (14%) patients in Group A and 9 (18%) patients in Group B. Furthermore none of the devices revealed thePOGO-0 %. There was no significant difference noted between both the SAD devices with respect to anatomical alignment (P- value=0.585).

The observations in the present study closely approximate the findings of Zundert TV et al.[14] who reported a near perfect view with Baska mask (50–100% of glottic aperture visible) in 72% of the patients while none of the patients showed an absent vocal cords/epiglottis view.

However, in-spite of above listed merits, the Baska mask is not as popular as compared to I-gel and other supraglottic device. The possible reason might be longer learning time may be required to achieve correct insertion of Baska mask. It is observed that if proper learning curve is not achieved in Baska Mask may either lead to difficulty in insertion or failure to insert the device which usually happens at the level of pharynx because of broader cuff size. However, in case of ProSeal LMA the learning curve is easy to achieve because the introducer used for its insertion compared to Baska mask.[15] Furthermore, if it is not properly seated, the tip rest into mid pharynx results in air leak through drainage tube during positive pressure ventilation, or it's tip can impacted and folded on epiglottis resulted in airway obstruction and air leak through the gastric channel tube.[16]

We found that Baska mask can secure the airway rapidly as compared to Proseal LMA with efficient sealing.

Conclusion

We concluded the properly placed BASKA Mask as a ventilatory conduit for Airway management is safe and effective supraglottic airway device takes significantly shorter time for insertion, provides higher oropharyngeal leak pressure thus better seal during controlled ventilation than second generation ProSeal LMA. Properly placed

Baska mask is superior to PLMA for achieving faster ventilation and especially safe in patients who require high intrathoracic airway pressure or have poor lung compliance.

References

1. Jannu A, Shekar A, Balakrishna R, Sudarshan H, Veena GC, Bhuvaneshwari S. Advantages, Disadvantages, Indications, Contraindications and Surgical Technique of Laryngeal Airway Mask. Arch Craniofacial Surg 2017; 18:223.
2. Sharma B, Sood J, Kumra VP. Uses of LMA in Present Day Anaesthesia. J Anesth Clin Pharmacol. 2007; 23:5–15.
3. Kanthed P, Sharma B, Sood J, Kumra VP. Comparison of LMA-ProSealTM with LMA ClassicTM in Anaesthetised Paralysed Children. Indian J Anaesth. 2008; 52:44–8.
4. Sachidananda R, Shaikh SI, Mitragotri MV, Joshi V, Ladhad DA, Mallappa M, et al. Comparison between the Baska Mask® and I-Gel for Minor Surgical Procedures Under General Anaesthesia. Turkish J Anesthesia Reanima. 2019 Jan 1;47(1).
5. Shanmugavelu G, Kanagarajan T. Comparing the functional analysis of I-gel with Baska mask in laparascopic surgeries: An observational study. Int J Res Med Sci. 2018; 6:1440-3.
6. Mahajan SR, Mahajan M, Chaudhary U, Kumar S. Evaluation of baska mask performance in laparoscopic cholecystectomy. IOSR J Dent Med Sci. 2018; 17:74-8.
7. Baska K, Baska M. Baska Mask. The new generation supraglottic airway with high volume suction clearance. Available on http://www.baskamask.com.au/main/page_about_the_mask.html [Accessed 30 December 2013].
8. Kachakayala RK et al. Int J Res Med Sci. 2020 Jan;8(1):285-289, DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20195924
9. O'Loughlin EJ, Swann AD, English JD, Ramadas R. Accuracy, intra- and inter-rater reliability of three scoring systems for the glottic view at videolaryngoscopy. Anaesthesia. 2017 Jul;72(7):835-839. doi: 10.1111/anae.13837. Epub 2017 Mar 24. PMID: 28337769.
10. Al-Rawahi SA, Aziz H, Malik AM, Khan RM. A comparative analysis of the Baska®Mask vs. Proseal®laryngeal mask for general anaesthesia with IPPV. Anaesth Pain Intensive Care. 2013;17(3):233–236.
11. Jose J, Kagalkar ND, Kattimani MM, Suntan A. Comparison of Baska Mask Versus Proseal Laryngeal Mask Airway in Elective Surgeries Under General Anaesthesia: A Randomized Clinical Trial. Cureus. 2023 Apr 10;15(4):e37366. doi: 10.7759/cureus.37366. PMID: 37182077; PMCID: PMC10170866.
12. Agrawal N, Singh A, Gupta A. Comparative study of Baska mask with proseal LMA in adult patients undergoing elective surgery under general anesthesia with controlled ventilation. J Anaesthesiol Clin Pharmacol. 2022 Apr-Jun;38(2):184-190. doi: 10.4103/joacp. PMID: 36171917; PMCID: PMC9511871.
13. Priya H, Sripriya R, Ravishankar M, Karthikeyan P, Charulatha R. Baska Mask is non-inferior to tracheal tube in preventing airway contamination during controlled ventilation in elective nasal surgeries: A randomised controlled trial. Indian J Anaesth. 2021;65(8):586-592. doi:10.4103/ija.IJA_237_21.PMID: 34584281; PMCID: PMC8445220.
14. Zundert Tv, Gatt S. The Baska Mask® -A new concept in Self-sealing membrane cuff extraglottic airway devices, using a sump and two gastric drains: A critical evaluation. J Obstet Anaesth Crit Care [serial online] 2012 [cited 2018 Oct 2]; 2: 23-30. Available from: http://www.joacc.com/text.asp?2012/2/1/23/99313.
15. Jayalekshmi S, Paul C, Thomas MK. Efficacy of Baska mask and Laryngeal mask airway supreme during positive pressure ventilation - A comparative study. J Anaesthesiol Clin Pharmacol. 2020 Jan-Mar;36(1):31-36. doi: 10.4103/joacp.JOACP_17_19. Epub 2020 Feb 18. PMID: 32174654; PMCID: PMC7047687.
16. Singh GK, Verma S, Ajit K, Monika S. Baska Mask Failure: Culprit Resides at the Posterior Commissure Archives of Anesthesiology and Critical Care 2021; 7(4): 303-304. Available online at http://aacc.tums.ac.ir.

How to cite this article: Kumar K S, Kamran S H, Farhat B, Shahla S H. A comparative evaluation of safety and efficacy of second and third generation supraglottic Airways viz ProSeal-laryngeal mask and the Baska mask as ventilatory conduit for Airway management. Anaesthesia. Acad. Anesthesiol. Int. 2023;8(1):5-9.

DOI: dx.doi.org/10.21276/aan.2023.8.1.2

Source of Support: Nil, **Conflict of Interest:** None declared.