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Original Research Article

A comparative study of supraglottic airway devices Baska mask and ProSeal-laryngeal mask airway in short gynaecological procedures

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ABSTRACT

Background: Baska Mask® (BM) a newer Supraglottic Airway Device (SAD) considered to cause low incidence of Postoperative Pharyngolaryngeal Complications (POPC). This study was designed to assess efficacy, safety and early and late POPC between BM and commonly use ProSeal LMA (PMLA).
Methods: Patients between 18 to 60 years of age undergoing elective short gynecological procedures were randomized into two groups, to receive ventilation with either BM (group 1, n=50) or an PMLA (group 2, n=50).
Results: There was no significant difference in the ease of insertion for both the devices ($p<0.24$). There was no significant difference in the number of attempts for both the devices ($p<0.69$). When compared to PLMA, the time (in seconds) required for insertion of BM was significantly less in duration (20.9 vs. 16) ($p<0.0001$). Between the two groups significant hemodynamic changes noticed after removal of SGA. The blood staining of device was similar in both groups. Failure to place device, postoperative complication like laryngospasm and bronchospasm did not occur in both BM and PLMA groups.
Conclusions: In conclusion, findings of this study support that BM takes significantly shorter placement time and provides a better seal as compared to PLMA but without any reduction in laryngopharyngeal complications.

Keywords: Airway, Baska mask, Pharyngolaryngeal complications, ProSeal laryngeal mask airway

INTRODUCTION

As anesthesiologists, the prime responsibility is to secure airway. Endotracheal Tube (ETT) is the proven standard-of-care for airway management in adults undergoing General Anaesthesia (GA). However, Supraglottic Airway Devices (SAD) may offer distinct advantages over the ETT in terms of increased speed and reliability of placement, maintaining hemodynamic stability during induction and emergence, better oxygenation during emergence and increased patient satisfaction by decreasing the incidence of Postoperative Sore Throat (POST) and voice alteration.[1,2]

The Baska Mask® (BM) is the latest addition to an array of SAD in clinical use. It has many of the features of other SAD.[3,4] These include the cuff of the BM is not an inflatable balloon but a membrane which inflates on every breath during Intermittent Positive Pressure Ventilation (IPPV), which is moulded to take up the shape of the supraglottic airway to achieve a superior seal when opposed to the larynx, potentially reducing the risk of oropharyngeal tissue and/or nerve damage induced by cuff over inflation, a known complication with other SAD.[4,5] In BM, the cuff differs from other 'non-inflatable' cuffs in that; it is continuous with the central channel of the device. An increase in IPPV pressure, the cuff itself is 'inflated' and increases the oropharyngeal

seal. With existing extra glottic airway devices, an increase in IPPV merely increases the leak. The BM with its cuff less membranous bowl, would withstand higher inflation pressures, have a faster placement time, and have no problem with diffusion of nitrous oxide despite longer duration of use that would lead to less postoperative laryngopharyngeal morbidity as compared to commonly used SAD PLMA.

There is a paucity of studies comparing PLMA with BM as a ventilatory device. Thus, this study was designed to assess oropharyngeal leak pressure following insertion and compare early and late postoperative complications.

METHODS

After Approval from the Institutional Ethics Committee, written informed consent was obtained from the patients. A total of 100 patients between 18 to 60 years age operated in July 2016 - March 2017, undergoing non-urgent elective short gynecological surgeries like dilatation and curettage, hysteroscopy, and sterilization were enrolled for this prospective, randomized study. Patients with any neck pathology, increased risk of gastric aspiration and morbid obesity (BMI >40) were excluded from the study. Patients with history of severe cardio-respiratory, renal and respiratory disorders were also excluded from the study.

According to a computer-generated randomization chart, the patients were assigned to one of the two treatment groups. Patients in group BM inserted appropriate size BM and in group PLMA, ProSeal LMA inserted. Patient were kept nil per orally 08 hours prior to the procedure, as per the standard fasting protocol. In the morning of surgery, these patients were premedicated with Inj. Glycopyrrolate 0.2 mg IV and Inj. Midazolam 1mg IV before shifting them to the operation theatre. A standard anaesthesia sequence was followed. Anaesthesia was induced in the supine position with the patient's head in the neutral position, resting on a pillow about 8 cm in height. GA was induced with titrated dose of propofol 1.5-2 mg/kg after premedication with fentanyl 2 µg/kg. Intra operative monitoring including Heart Rate (HR), Electrocardiogram (ECG), Pulse Oximetry (SpO_2), Blood Pressure (BP) and End Tidal Capnometry ($EtCO_2$) were established and baseline readings were recorded. The plane of anaesthesia was deepened by Sevoflurane (2-3%) to facilitate placement of SGA. The patient was either left breathing spontaneously or assisted if required to maintain an end- tidal CO_2 ($EtCO_2$) of 32 + 2 mm Hg. GA was maintained with O_2, N_2O and sevoflurane.

All SGAs size selected based on manufacturer's recommendation. The patient was either left breathing spontaneously or assisted if required. Adequacy of ventilation was defined as maintenance of SpO_2 >95%, EtCO2 < 50 mmHg and tidal volumes >6 ml/kg. The SGA was removed when protective reflexes returned to normal. Insertion time was calculated time between picking up the mask and successful placement. The success of insertion was assessed by the number of insertion attempts (was counted as an attempt when the SGA was taken in and out of the mouth) and maximum three attempts were allowed for particular SGA. Oropharyngeal leak pressure was determined immediately following mask insertion and at 15 min of surgery by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and noting the airway pressure (max allowed was 40 cm H_2O) at which equilibrium will be reached. Complications following extubation like coughing, bleeding from oral cavity or trachea, trauma to lips/ tongue/ teeth, nausea and vomiting, sore throat, dysphagia and dysphonia were noted.

The data was tabulated in Microsoft Excel data sheet; SPSS software (version 21.0; SPSS Inc, Chicago, IL) was used for the analysis. The independent t test was used to compare the patient demographic profile. All the data obtained from the observations was compiled and subjected to relevant tests like t test, Pearson Chi-Square as required for statistical analysis, p value <0.05 was considered significant.

RESULTS

Ease of SGA insertion was studied in 100 patients from July 2016 to Mar 2017. Out of a total of 885 patients listed for surgery during the study period, 727 patients did not meet inclusion criteria and 58 patients were not included due to refusal or unavailability of investigator. Both Baska mass (group BM) and ProSeal LMA (group PLMA) group had 50 patients each. No patient had history of difficult intubation. Patients in BM group were significantly younger as compared to PLMA group ($p<0.01$) (Table 1). Both the groups were comparable with respect to weight, ASA grade and the duration of ventilation (Table 1). The hemodynamics (HR, SBP, and DBP) was found to be significantly less in group PMLA after 5 min of removal of SGA (Table 2).

Table 1: Demographic profile and clinical characteristics of patients in both the group.

Parameter		Group BM	Group PMLA	p value
Age in years		30.9±6.46	34.1±6.7	0.01
Weight (kg)		64.2±6.9	61.2±8.3	0.05
Duration of ventilation		29.6±4.5	28.4±4.2	0.15
ASA status	I	48	42	0.56
	II	2	8	

#all values expressed as Mean±SD or as expressed otherwise, BM- Baska mask, PLMA-Proseallaryngeal mask airway.

Table 2: Systemic hemodynamic parameters at different time interval (values expressed as Mean±SD or number) during observation period in two groups.

Value		T1	T2	T3	T4	T5	T6	T7
HR	Group BM	75.4±5.8	76.5±5.5	76.8±5.6	77.3±5.8	78±5.2	78.5±5	79.6±4.9
	Group PMLA	76.3±8.4	78.2±8.9	79.7±9.1	80.5±9.7	80.8±9.5	82.2±8	82.3±8
p value		0.56	0.26	0.05	0.05	0.09	0.009	0.04
SBP	Group BM	121.3±7	121.9±17.4	123.6±10.5	120.2±12.2	120.4±11.1	123.5±11.3	127.2±10.3
	Group PMLA	121.4±9.1	122.9±9.4	120.4±13.2	118.2±12.9	121.3±11.4	122.1±11.7	123.2±11.8
p value		0.97	0.70	0.18	0.41	0.67	0.55	0.07
DBP	Group BM	73.1±4.4	73.7±5.9	73.4±6	72.2±7	72.7±6.3	73.6±7.3	76.3±6.6
	Group PMLA	72.3±3.7	72.5±5.9	72.8±7.7	71.1±7.6	71.8±6.4	72.1±5.8	73.1±6.5
p value		0.29	0.33	0.66	0.44	0.48	0.25	0.01
$EtCO_2$ mmHG	Group BM	31.9±2.1	32.4±1.5	32.4±1.7	32.3±1.6	38.6±42.5	32.3±1.6	32.6±1.8
	Group PMLA	31.6±1.4	32.1±2.2	32.4±2	32.3±2	32.4±1.5	32.2±1.6	32.6±1.5
p value		0.39	0.43	0.95	0.95	0.30	0.71	0.86

#T1- Baseline (Pre induction),T2- 1 min after successful insertion of SGA,T3- 5 min after successful insertion of SGA, T4-15 min after successful insertion of SGA,T5-25 min after successful insertion of SGA, T6 - 1 min after removal of SGA ,T7-5 min after removal of SGA , HR-Heart rate, SBP-Systolic Blood Pressure, DBP- Disystolic blood pressure, SGA- Supraglottic airway

Table 3: Various observation data (data are expressed in number and percentage).

Parameter		Group BM	Group PLMA	p-value
Ease of insertion (%)	No	45(90)	41(82)	p<0.24 Pearson chi-square-1.329[a] Df-1
	Yes	5(10)	9(18)	
Number of attempt (%)	1	47(94)	46(92)	p<0.69 Pearson chi-square-1.329[a] Df-1
	2	3(6)	4(8)	
Time taken to insertion of device (sec)		16±2.6	20.9±4	0.0001
Oropharyngeal leak pressure (cmH20)		31.2±4.8	25.8±3.3	0.0001
Cough incidence (%)	N	45(90)	41(82)	0.24
	Y	5(10)	9(18)	
Sore throat (%)	N	45(90)	43(86)	0.53
	Y	5(10)	7(14)	
Nausea and vomiting (%)	N	47(94)	46(93)	0.69
	Y	3(6)	4(7)	
Bleeding from oral cavity	N	47(94)	45(90)	0.46
	Y	3(6)	5(10)	
Dysphonia (%)	N	45(90)	45(90)	
	Y	5(100	5(10)	
Dysphagia (%)	N	45(90)	43(86)	0.53
	Y	5(100	7(14)	
Trauma to lips /tongue /teeth (%)	N	47(94)	46(93)	0.69
	Y	3(6)	4(7)	

#all values expressed as Mean±SD or as expressed otherwise

There was no significant difference in the ease of insertion for both the devices (Table 3). There was no significant difference in the number of attempts for both the devices. When compared to ProSeal LMA, the time required for insertion of Baska Mask was significantly less in duration (p<0.0001). Oropharyngeal pressure is found less in PLMA group (p<0.0001). When compared to Baska Mask, the blood staining of device was similar in ProSeal LMA. Traumatic injury to the airway was similar in both the groups. In postoperative adverse events, there was no significant difference in both the groups. Failure to place device, postoperative complication like laryngospasm and bronchospasm did not occur in both groups.

DISCUSSION

This study compared two commonly used SADs and showed the superiority of BM over ProSeal device. Few studies have compared the two devices and have given

similar results in various surgical settings.[6] There are various studies comparing the advantages of the newer generation of SGA devices with older ones. It that the ease of insertion, in group of BM was easy for 90% of cases which is identical to that observed by Sharifa Ali Sabeeh Al-Rawahi et al.[7] Author noted that the number of attempts needed to place the device correctly were similar in both of the groups as observed by Sharifa Ali Sabeeh Al-Rawahi et al.[7] The mean insertion time was significantly shorter in the BM group as compared to the PLMA group by a mean of 4.92 sec which is identical to that observed by Van Zundert and was noted Gatt and to that observed by Sharifa Ali Sabeeh Al-Rawahi et al.[7,8] The study conducted by Sharifa Ali Sabeeh Al-Rawahi et al, shows mean insertion time 16.43±4.54 and 21.45±6.13 for BM and PLMA respectively ($p<0.001$). This may be attributed to two factors. First, any difficulty in negotiation of the oropharyngeal curve could be easily overcome by pulling the tab of the BM which increases its distal curvature. Second, being devoid of an inflatable cuff, time to inflate the cuff and volume adjustment as required in ProSeal LMA, is not needed. Therefore, in view of duration attempts the BM was better than ProSeal LMA.

Both PLMA and BM are essentially dual channel subpharyngeal airway devices with the provision for separation of airway from gastric tract. It has been observed in earlier studies that airway seal is improved by 50% while using PLMA.[9] This is attributed to a second posterior cuff fitted to improve the seal. Although BM is devoid of an inflatable cuff, it was noted that the sealing pressure was significantly higher with BM as compared to PLMA. The mean sealing pressure in the group of BM was 31.2 with the standard deviation of 4.8 and in the group of PLMA, it was 25.8 with the standard deviation of 3.3 ($p<0.0001$). The study conducted by Sharifa Ali Sabeeh Al-Rawahi et al, shows mean sealing pressure was significantly higher in the BM group ($p<0.013$). The seal pressure ranged from 15-40 cm H2O and 14-32 cm H2O in the BM and PLMA group respectively. The BM sealing pressure recorded in this study is in agreement to that noted by Alexiev V et al, and van Zundert T et al.[8,10]

Author observed hemodynamic changes during insertion, intraoperative period and after removal in both the groups. The difference in terms of HR, SBP, saturation, $EtCO_2$ is not significant intraoperative period. This is in accordance with the study done by Sharifa Ali Sabeeh Al-Rawahi et al.

Association of BM and PLMA with complication following surgery was done using Pearson Chi-Square test and there are no significant differences in the mean of above mentioned laryngopharyngeal complications like coughing, sore throat, nausea or vomiting, bleeding from oral cavity, dysphagia, dysphonia, trauma to lips/ tongue/ teeth. Other complications like bronchospasm and laryngospasm did not occur in both the groups. Sharifa Ali Sabeeh Al-Rawahi et al, in their study also did not observe any significance. Their finding demonstrates that there is no relationship between cuff pressure and laryngopharyngeal complaints.[7] This has also been observed by Figueredo E et al.[11]

CONCLUSION

In conclusion, findings of this study support that BM takes significantly shorter placement time and provides a better seal as compared to ProSeal LMA but without any reduction in laryngopharyngeal complications.

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