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A COMPARATIVE STUDY OF BUSKA MASK VERSES PROSEAL LARYNGEAL MASK FOR GENERAL ANAESTHESIA IN ELECTIVE SURGICAL PATIENTS.

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ABSTRACT **BACKGROUND:** The baska mask brings together features of LMAProseal, LMA supreme, I-gel, SLIPA. Baska mask also features a number of unique improvements. Proseal LMA which is considered to be gold standard 2nd generation supraglottic airway device for surgical procedures. We hypothesized that with its cuff less membranous bowl; the baska mask would withstand higher inflation pressure, have a faster placement time and have no problem with diffusion of nitrous oxide despite longer duration of use that would lead to less post operative laryngopharyngeal morbidity as compared to PLM in patients undergoing surgical procedures

MATERIAL AND METHOD: This study is aimed to compare Baska mask with Proseal laryngeal mask for general anaesthesia in elective surgical patients into two groups BM 65 patients and group PLM 65 patients. This study is a Prospective randomized comparative study. The study is scheduled to be completed in a period of 18 months, including 6 months for analysis of data and thesis writing. Elective surgical patients of age 20-40 years of either sex who will give voluntary consent and ready to participate in the study.

Sample Size: Using (Sharifa Ali Sabeeh Al-Rawahi et al.2013)[1], the calculated median at 5% level of significance and 78% power under two sided test criteria is 27.5. Based on said median, the calculated sample size is 130 at 5% level of significance with 78% power under same test situation.

RESULTS: It was observed in this study that it took a mean of 18.5 sec to place the BM and 21.11 sec to place PLM, which is identical to that observed by van Zundert and Gatt.[7] Our finding suggests that BM placement time was significantly shorter as compared to PLM..Although BM is devoid of an inflatable cuff, we noted that the sealing pressure was significantly higher with BM as compared to PLM..

CONCLUSION: In conclusion, findings of this study support our hypothesis that BM takes significantly shorter placement time and provides a better seal as compared to PLM but without any reduction in laryngo-pharyngeal morbidity. This study re-enforces earlier studies that Baska® Mask is a welcome addition to the list of SGDs.

KEYWORDS : Buska mask, proseal laryngeal mask, deep breathing exercises, incentive spiromerty.

INTRODUCTION

It has been nearly 25 years since Dr. Archie Brain in UK introduced the 1st supraglottic airway device- the laryngeal mask airway. The baska mask is the latest addition to an array of supraglottic devices in clinical cases. It is available in four sizes [1,2]

a. #3 : 30-50kg
b. #4 : 50-70kg
c. # 5: 70-100kg
d.#6 :> 100kg

The Baska Mask Brings Together Features Of:

1. LMAProseal i.e. high seal pressure, gastric access port and bite block, which facilitates ventilation, provide airway protection and minimizes airway obstruction respectively.
2. LMA supreme i.e. oval shaped, anatomicallycurved airway tube which incorporates a gastric drain tube.
3. I-gel i.e. a gel like cuff instead of inflatable balloon.
4. SLIPA i.e. a cuffless, anatomically pre-shaped sealer with a sump reservoir.

Baska Mask Also Features A Number Of Unique Improvements:

1. A self sealing membranous, variable pressure, non-inflatable, recoiling cuff made of medical grade silicone.
2. A gastric reflux high flow suction clearance system.
3. An inbuilt "tab" to increase its angulation.
4. A 90 degree suction elbow.

Proseal LMA [3] which is considered to be gold standard 2nd generation supraglottic airway device for surgical procedures. We hypothesized that with its cuffless membranous bowl; the baska mask would withstand higher inflation pressure, have a faster placement time and have no problem with diffusion of nitrous oxide despite longer duration of use that would lead to less post operative laryngopharyngeal morbidity as compared to PLM in patients undergoing surgical procedures.

MATERIALAND METHOD

This study is aimed to compare Baska mask with Proseal laryngeal mask for general anaesthesia in elective surgical patients.

Study Design:
Prospective randomized comparative study.

Research Setting:
The study will be conducted among general elective surgical patients.

Duration Of Study:
The study is scheduled to be completed in a period of 18 months, including 6 months for analysis of data and thesis writing.

Study Population:
Elective surgical patients of age 20-40 years of either sex who will give voluntary consent and ready to participate in the study.

Sample Size:
Using (Sharifa Ali Sabeeh Al-Rawahi et al.2013)[1], the calculated median at 5% level of significance and 78% power under two sided test criteria is 27.5. Based on said median, the calculated sample size is 130 at 5% level of significance with 78% power under same test situation.

Group BM: Baska mask (65 patients)
Group PLM: Proseal laryngeal mask (65 patients)

Sampling Technique: The sealed envelope technique.

Inclusion Criteria:
1) Patients between age group of 20 – 40yrs.
2) ASA grade 1 & 2.
3) Posted for elective surgery requiring general anaesthesia in supine position.
4) Informed written consent. 4
5) Solid food was not allowed for 6 hours preoperatively and clear liquids were permitted up to 4hrs prior to induction of anaesthesia.

Exclusion Criteria:

1) Who are at increased risk of aspiration of gastric content.
2) Patients with BMI>30, having known tendency to nausea/vomiting or pharyngeal pathology.
3) If mouth opening was less than 2.5 cm.
4) Undergoing head and neck surgeries or any surgeries in non-supine position.
5) With h/o cardiovascular diseases, metabolic and central nervous system diseases.

METHODOLOGY:

The proposed study will be carried out in S N Medical College, Agra. Permission will be sought from the head of the department for accomplishing the research work. Subjects baseline hemodynamic data will be recorded after placement of routine monitors when subject will arrive in operating room.

Plan Of Anaesthesia:

All patients will uniformly premedicate with IV midazolam 1gm, IV glycopyrrolate 0.2 mg and IV fentanyl 1.0-1.5 microgm/kg prior to induction of anaesthesia.

Anaesthesia will be induced in supine position with patients head in neutral position with IV propofol 2-2.5 mg/kg and IV vecuronium 0.1 mg/kg. Anaesthesia will be maintained with inhalational isoflurane, oxygen and nitrous oxide. Device placement will be judged by capnographic curve and tidal volume delivery.

If device placement was considered inadequate, as judged by poor capnographic curve and/or delivery of inadequate tidal volume (fractional loss of >20% of set tidal volume), jaw thurst will be performed and device moved up and down. In case of PLM cuff volume was also re-adjusted. Continuous ineffectiveness was treated as failure and patients airway managed by endotracheal intubation.

At the conclusion of surgery, residual neuromuscular paralysis will be revised using a mixture of neostigmine and glycopyrrolate. PLM/BM was removed after establishing adequate respiration and patients eye opening response on verbal commands.

The Following Parameters Included Under The Study Are:

1) Airway sealing pressure in cm of H2O at 5 minutes post placement. The airway sealing pressure was the pressure at which leak starts. This leak pressure was calculated as the plateau airway pressure reached with fresh gas flow 6l/min, and pressure adjustment valve set at 70 cmH_2O.
2) Insertion time needed for placement of device was defined as time in seconds from device touching the teeth to first recorded rectangular capnograph curve.
3) Number of attempts to correctly place the device.
4) Duration for which device remains in oropharynx.
5) Haemodynamic variables including systolic bp, diastolic bp, heart rate.
6) Laryngopharyngeal morbidity score: sum of sore throat, dysphagia and hoarseness.

Laryngopharyngeal morbidity parameter with scores[1]

Scores	0	1	2	3
Sore throat	None	minimal	Moderate	Severe, never an SAD again
Dysphagia	None	minimal	Moderate	Severe, cannot eat
Hoarseness	None	minimal	Moderate	Severe, cannot speak

Statistical Analysis

The calculated median at 5% level of significance and 78% power under two sided test criteria is 27.5. Based on said median, the calculated sample size is 130 at 5% level of significance with 78% power under same test situation. For analysis of continuous variable independent sample't' test were applied and for categorical variables chi-square test was used. Value of 'p' <0.05 was considered significant in this study.

RESULTS

Table-1: Distribution Of Cases According To Age

Age (years)	BM		PLM	
	NO.	%	NO.	%
20-25	28	43	35	54
25-30	19	29	17	26
30-35	12	18	8	12
35-40	6	9	5	8
	65	100	65	100
Mean±SD	27.19±4.95		26.19±4.75	
p value	0.24			

Both the group were comparable with respect to age distribution. Both the group BM and PLM were almost of same age group and there was no significant difference.

Table-2: Distribution Of Cases According To Sex

Sex	BM		PLM	
	NO.	%	NO.	%
Male	34	56.66	26	43.33
Female	45	64.28	25	35.71
Mean±SD	39.5±0.88		25.5±0.09	
p value	0.0001			

Both the group were compared with respect to sex distribution.

Table-3: Distribution Of Cases According To SGD Size

SGD Size	BM		PLM	
	NO.	%	NO.	%
3	37	57	17	26
4	19	29	21	32
5	9	14	27	42
Mean±SD	21.67±1.57		21.67±0.66	
p value	1			

Table-4: Distribution Of Cases According To Duration Of Anesthesia

Time (min)	BM		PLM	
	NO.	%	NO.	%
30-50	35	54	37	57
50-70	18	28	16	25
70-90	12	18	12	18
Mean±SD	52.92±15.46		52.31±15.57	
p value	0.82			

Both the group were compared with respect to duration of anaesthesia in minutes. As shown in above table, duration was almost equal in both the groups.

Table-5: Distribution Of Cases According To Number Of Attempts

No. Of Attempts	BM		PLM	
	NO.	%	NO.	%
1	58	89	52	80
2	6	9	9	14
3	1	2	4	6
Mean±SD	21.67±2.56		21.67±2.19	
p value	1			

There was no significant difference in mean number of attempts required for SGD placement in either group.

Table-6: Distribution Of Cases According To Insertion Time

Time (sec.)	BM		PLM	
	NO.	%	NO.	%
15-20	52	80	24	36.92
20-25	13	20	35	54
25-30	0	0	6	9
Mean±SD	18.5±2		21.11±3.10	
p value	0.0001			

Both the groups were compared with respect to insertion time. The mean insertion time was significantly shorter in BM group as compared to PLM group by a mean of 2.61 seconds as shown in above table.

Table-7: Distribution Of Cases According To Sealing Pressure

Sealing pressure (cm H_2O)	BM		PLM	
	NO.	%	NO.	%
25-30	8	12	23	35
30-35	21	32	36	55
35-40	36	55	6	9
Mean±SD	34.65±3.50		31.19±3.07	
p value	0.0001			

Both the group were compared with respect to sealing pressure in BM

and PLM. Mean sealing pressure was significantly higher in BM group (p = 0.0001) as compared to PLM group. The sealing pressure ranges from 30-40 mm H_2O and 26-35 cm H_2O in the BM and PLM group respectively.

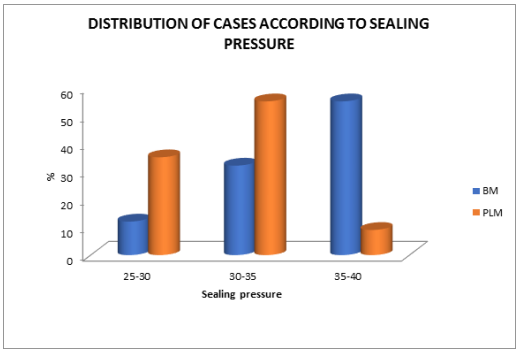


Table-8: Parameters At 1 Hour

		BM		PLM		P VALUE
		NO.	%	NO.	%	
LPMScore	0	56	86	51	78	0.74
	1	4	6	8	12	
	2	3	5	4	6	
	3	2	3	2	3	
Mean±SD		16.25±5.70		16.25±5.01		
Sore Throat		9	14	14	22	0.92
Dysphagia		5	8	6	9	0.85
Hoarseness		2	3	2	3	0.103

There was no significant difference in mean LPM at 1 hour as well in individual score. We noted higher incidence of sore throat as compared to dysphagia and hoarseness in both the group at 1 hour.

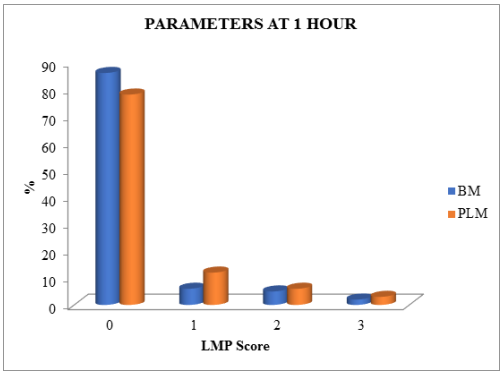
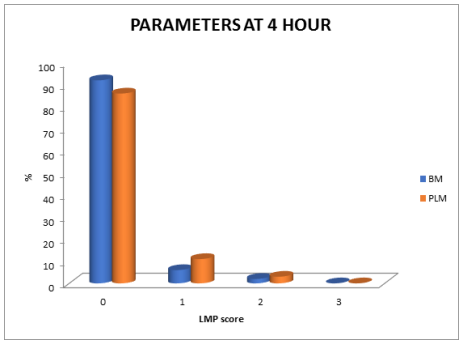


Table-9: Parameters At 4 Hour

		BM		PLM		P Value
		NO.	%	NO.	%	
LPMScore	0	60	92	56	86	0.14
	1	4	6	7	11	
	2	1	2	2	3	
	3	0	0	0	0	
Mean±SD		16.25±6.28		16.25±5.73		
Sore Throat		5	8	9	14	0.26
Dysphagia		1	2	2	3	0.17



There was no significant difference in mean LPM score at 4 hours as well in individual component score. However, we noted higher incidence of sore throat as compared to dysphagia in both group at 4 hours. Hoarseness of voice had completely disappeared by 4thhour in either group.

Table-10:Haemodynamic Parameters

	Pre induction		1 minute		5 minutes		p value
	Mean	SD	Mean	SD	Mean	SD	Mean
Pulse (per min.)	91.38	16.85	92.16	20.23	92.81	18.01	0.65
SBP (mmHg)	125.14	18.899	124.56	24.58	127.11	23.37	0.54
DBP (mmHg)	77.82	12.27	79.21	16.35	82.01	16.45	0.053
MBP (mmHg)	91.7	14.65	91.99	20.77	95.76	18.92	0.06

There is no significant haemodynamic changes at 1 and 5 min. after insertion of device ($p < 0.05$ was taken as significant) as shown in above table. Mean heart rate changed.

from 91.38 of pre-induction to 92-16 at 1 min with 92.18 at 5 min after insertion. The mean arterial pressure changed from 91.7 of pre-induction to 91.99 at 1 min. and 95.76 at 5 min after insertion.

DISCUSSION

The study was conducted to evaluate the two airway devices ProsealLMA [6] and Buska mask in the view of ease of insertion, number of attempts, airway sealing pressure, haemodynamic changes and post-operative laryngopharyngeal morbidity. The study was conducted to 130 patients of both sexes aged 20-40 years going for elective surgical procedure with positive pressure ventilation. All patients were divided into two groups of 65 patients each.

We noted that the number of attempts needed to place the device correctly, were similar in both of the groups. This demonstrates that the short learning curve of 10 BM placements is sufficient for its correct placement. In addition, it was observed in this study that it took a mean of 18.5 sec to place the BM and 21.11 sec to place PLM, which is identical to that observed by van Zundert and Gatt.[31] Our finding suggests that BM placement time was significantly shorter as compared to PLM. 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 PLM, is not needed. However, it may be argued that a short placement time of the BM by 3 sec as compared to PLM may not be of much clinical significance.

Both PLM and BM are essentially dual channel supralaryngeal airway devices with the provision for separation of airway from gastric tract. It has been observed in earlier studies that the airway seal is improved by 50% while using PLM[32]. This is attributed to a 13 second posterior cuff fitted to improve the seal.[33] Although BM is devoid of an inflatable cuff, we noted that the sealing pressure was significantly higher with BM as compared to PLM. This mean difference of 3.46 cmH_2O seal pressure between the two devices may be of clinical importance in patients with decreased thoracic compliance. The BM sealing pressure recorded in this study is in agreement to that noted by other workers.[7] We concur with Laffey *et al* that there is a gradual improvement in BM seal against the glottis over first 2-3 minutes. This may be due to thermolability of the membranous mask which makes it more adaptable to the shape of laryngeal outlet over time and hence a better seal.

An inflatable cuff in SGDs has often been held responsible for LPM.[4,5] However, in this study, we did not observe any significant difference in the mean LPM score at 1 and 4 hours as well in individual component scores between the two devices. Our finding demonstrates that there is no relationship between cuff pressure and laryngo-pharyngeal complaints. This has also been observed by others.[5]

We also studied haemodynamic changes namely pulse rate, systolic blood pressure, diastolic blood pressure and mean blood pressure at pre-induction, 1 minute and 5 minute after placement of device. Haemodynamic response in both group have no statistically significant changes.

This study was handicapped by not including patients younger than 20 years or obese patients, due to non-availability of suitable sized BM. We have had BM of #3, 4 or 5. We had 13 patients who were overweight (BMI< 30) but none were obese.

CONCLUSION

In conclusion, findings of this study support our hypothesis that BM takes significantly shorter placement time and provides a better seal as compared to PLM but without any reduction in laryngo-pharyngeal morbidity.

Baska mask also contains integrated bite block preventing airway occlusion.

Our data showed that both the devices are safe airway devices in patients undergoing elective surgery as judged by stable haemodynamics, good oxygenation and adequate ventilation. We consider that residual gastric fluid should be removed by gastric aspiration.

This study re-enforces earlier studies that Baska® Mask is a welcome addition to the list of SGDs.

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