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A Comparative Assessment of Ease of Insertion, Oropharyngeal Leak Pressures and Hemodynamic Responses Following Placement of Baska Mask Versus I-Gel

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Abstract:-

- ***Background:***

New supraglottic devices are being introduced into the market with various claims regarding their safety and efficacy.

- ***Objectives:***

To compare number of attempts at insertion, oropharyngeal leak pressure, associated trauma, fiberoptic assessment of proper placement and the hemodynamic changes with use of Baska mask and I Gel.

- ***Material and methods:***

The present study was a prospective, randomized, study. Sixty patients undergoing surgeries under general anesthesia were included. Patients were divided into two equal groups and received anesthesia following a standardized protocol. In Group B patients Baska mask was used whereas I-Gel was used in Group I to provide anesthesia. Statistical analysis was done using Chi-square test and Independent sample t-test as applicable.

- ***Results:***

Time taken for securing airway and number of attempts taken were significantly higher in Group B. Incidence of trauma was comparable. Oropharyngeal leak pressure (OLP) was significantly higher in Group B (36.33±5.68 vs 25±5.79), percentage of patients with Grade I-III score on fiberoptic assessment was also significantly higher in Group B. Both groups had comparable heart rate (HR) and mean arterial pressure (MAP) before induction, after induction and at 10 min after securing airway. At 1, 3 and 5 minutes after securing airway Group B had significantly higher HR and MAP.

- ***Conclusion:***

I Gel insertion was quicker, less traumatic, required fewer attempts and was associated with blunted hemodynamic responses. But OLP was significantly higher with better fiberoptic assessment score of proper placement with use of Baska mask.

Keywords:- *Oropharyngeal, Pressure, Mask, Hemodynamic, Anesthesia.*

I. INTRODUCTION

New supraglottic devices (SGD) are being introduced into the market with various claims regarding their safety and efficacy. Supraglottic devices are increasingly replacing the requirement of endotracheal intubation for general anesthesia. In this study we were trying to compare the ease and adequacy of insertion of two supraglottic airway devices (SGD) namely Baska mask, a recently introduced SGD and I-Gel to know whether which device was superior in terms of the study questions.

Primary objective of the present study was to compare the number of attempts taken at insertion of the supraglottic device between Baska mask and I-Gel in surgical patients under general anesthesia with controlled ventilation. Secondary objectives were comparison of oropharyngeal leak pressure, any associated trauma while inserting the SGD, fiberoptic view score of the respective devices to assess proper placement and the hemodynamic changes with use of both the devices.

II. MATERIAL AND METHODS

It was a prospective, randomized study. The study subjects and outcome assessor were blinded. After obtaining Institutional Ethical Committee clearance (IEC/AIIMS/PAT/184.B/2017 dated 07.07.2017) and informed consent from all the patients prior to the procedure the study was conducted. Study was conducted in sixty surgical patients with thirty in each group. Patients undergoing elective surgery requiring general anesthesia, belonging to American Society of Anesthesiologists physical status (ASA PS) I and II, aged between 20 and 40 years were recruited into the study. Patients with significant respiratory disease, recent history of upper respiratory tract infection, and those at risk of regurgitation and aspiration like full stomach, pregnancy, obese patients with body mass index >30 kg/m^2, symptomatic hiatus hernia or severe gastroesophageal reflux disease were excluded from the study.

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Sample size was calculated based on a pilot study with 20 patients in which Baska mask was used in ten patients and I-Gel was used in the other group of ten patients. More than two attempts at securing airway was found to be 10% in I-Gel group as compared to 55% in Baska mask group. Based on this result with 99% power and 20% error, the sample size was calculated as 26 per group to obtain statistically significant results. We recruited sixty patients into the present study with thirty in each group.

Patients in both groups were kept fasting for solid food as per our institutional protocol, for a minimum of 6 hours. Clear fluid was allowed to all patients till 2 hours before surgery. Intravenous fluids were started based on the 4:2:1 rule in all patients.

All the patients who were recruited into the study were randomly divided into 2 groups, B and I, based on computer generated sequence of numbers. Allocation concealment was done using sequentially numbered opaque sealed envelopes.

After shifting patient to the operating room, routine preinduction monitors like pulse-oximeter, noninvasive blood pressure and electrocardiogram, were attached in the preoperative room. General anesthesia was induced in all patients using fentanyl 2 mcg/ kg and propofol 1.5-2 mg/kg intravenously till there was loss or response to verbal commands. Vecuronium 0.1 mg/kg was then given to all patients and the patients were mask ventilated with isoflurane 1% in oxygen for 3 minutes. In Group B patients Baska mask was used whereas I-Gel was used in Group I to secure the airway. All devices were placed by anesthesiologists with experience of more than five years.

Number of attempts taken to secure airway with the SGD specific to the study group was noted. An additional attempt was defined when the device was removed from the oral cavity fully to be reinserted again. No more than three attempts were permitted for each device. Maneuvering during placement did not constitute an attempt. Maneuvering such as jaw thrust and external laryngeal manipulations were permitted to aid proper placement of SGD and to ensure adequate patient ventilation. Failure to secure airway even after three attempts warranted endotracheal intubation and those patients were excluded from the study. After satisfactory placement of supraglottic device number of attempts at insertion was noted. A square wave form on capnography and satisfactory ventilation were considered for adequate supraglottic device placement.

Airway sealing pressure or oropharyngeal leak pressure (OLP) was assessed using aneroid manometer dial. With the patient's head placed in the neutral position, the OLPs were determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min. The OLP was deemed to be the pressure in the circuit when an audible noise was heard over the mouth or a palpable leak was felt over the neck whichever came earlier. At this time there was equilibrium of airway pressure in the breathing circuit. For safety concerns, the maximal allowable OLP was 40 cm water. Fiberoptic evaluation of the anatomical position of the Baska Mask® airway was noted against the glottic opening using the Brimacombe scale and was scored[1]as described in Table 1.

The hemodynamic parameters like heart rate and mean arterial pressure were documented before induction (baseline), after induction, then 1,3,5 and 10 minutes after securing the airway. Trauma while inserting the device was noted in both groups as evidenced by presence of blood on the supraglottic device while removing at the end of surgery.

Chi-square test was used to compare the categorical variables in Group B and I. Independent sample t-test was used to compare the continuous variable in both the groups. Statistical analyses were conducted using SPSS Version 20.0 for Windows (IBM Corporation ARMONK, NY,USA).

III. RESULTS

The distribution of demographic parameters and ASA physical status were comparable in both groups (Table 2). Time taken for securing airway and the number of attempts taken were significantly more in Group B as compared to Group I ($p<0.05$). But incidence of trauma did not show any statistically significant difference. Oropharyngeal leak pressure was significantly higher in Group B (36.33±5.68 vs 25±5.79, $p <0.001$). The percentage of patients who had Grade I-III score on fiberoptic assessment was also significantly higher in Group B (46.7vs10%, Table 3). Both groups had comparable heart rate (HR) and mean arterial pressure (MAP) before induction, after induction and at 10 min after securing airway. At 1, 3 and 5 minutes after securing airway Group B had significantly higher HR and MAP ($p<0.05$, Table 4). No patient in either group required endotracheal intubation.

IV. DISCUSSION

In the present study it was observed that I-Gel insertion compared to Baska mask was significantly quicker, less traumatic and required fewer attempts. But the oropharyngeal leak pressure as well as percentage of patients with better score on fiberoptic assessment indicating proper SGD placement was significantly higher with Baska mask. However, I-Gel insertion was associated with attenuated heart rate and mean arterial pressure responses.

Supraglottic devices are devices that keep the upper airway patent for unobstructed ventilation mostly under anesthesia. They are also called as extraglottic or periglottic airway devices. The first-generation SGDs have replaced endotracheal intubation and general anaesthesia with face masks in >40% of general anesthetics. Second-generation SADs have allowed more reliable positive-pressure ventilation, have integrated bite blocks, and act as better conduits for tracheal tube placement. They have reduced the risk of pulmonary aspiration of gastric contents.[2]

First generation supraglottic devices develop air leak during positive pressure ventilation when peak pressures exceed 16-20 cm H_2O. This disadvantage was overcome in second-generation devices which usually maintain seal pressure at 25-28 cm H_2O. It has been shown that with the use of third generation supraglottic device like Baska mask the mean airway seal pressures varied between 33 ± 7 cm H_2O to 35.7± 13.3 cm H_2O.[3,4]The increase in seal pressure in turn reflects the efficiency of the device for use under controlled ventilation especially during laparoscopic surgeries where higher mean airway pressures are common.

I-Gel is a second generation supraglottic airway device made from medical grade thermoplastic elastomer which is now being widely used in anesthesia and resuscitation. It is designed to form a non-inflatable, anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures without compression trauma. The shape, softness and contours of I-Gel help the SGD to conform to the perilaryngeal anatomy in a better way. It has a drain tube placed laterally to the airway tube which allows the insertion of a gastric tube. Non-inflatable cuff, integrated bite block, reduced incidence of trauma while insertion, option for gastric access and superior seal pressure are some of the advantages I Gel has over the first generation SGDs.

Failed insertion of I Gel was found to occur only in <5% patients and it was shown to provide high airway leak pressures. Males, impaired mandibular subluxation, poor dentition, and older age were few of the factors which were associated with failure in proper placement of I-Gel. Serious adverse events were found to be rare with I-Gel insertion.[5,6]The 93% first-attempt success and 96% overall success rate are similar to other second-generation supraglottic airway devices like the LMA ProSeal.[7]The I-Gel provided leak pressures in the upper range of comparable supraglottic airway devices, but not as high as the ProSeal Laryngeal Mask.[8]

In a meta-analysis of randomized controlled trials,[9]it was found that LMA-Supreme and I-Gel were equally successful and rapid in insertion. But, the LMA-Supreme was shown to be easier for gastric tube insertion and was associated with higher incidence of postoperative sore throat compared with the I-Gel.

With the introduction of new third-generation supraglottic airway device like Baska mask, it is generally believed that the airway will be better secured than with the older generation supraglottic airway devices.[10,11]Baska mask incorporates an airway tube with a tab to help negotiate the palato-pharyngeal curve. It has two large tubes entering the sump area for high suction clearance of the sump and a large sump reservoir to collect any fluid entering the pharynx. The bite block runs over the full length of the airway tube.[12] It is a self-sealing membrane cuff extraglottic airway device in which cuff' seal is provided by a thin, pliable, conformable diaphragm which virtually adheres, at each breath, to the laryngeal introitus. As the air during positive pressure ventilation inflates the cuff and seals the airway, it results in improvement in the seal reducing leak and hence ventilation becomes more efficient.[13] It can be inserted blindly and is associated with a reduced risk of aspiration.

OLP is used to quantify the efficacy of the supraglottic device in sealing the airway. It in turn indicates airway protection, proper placement of the device and efficacy of positive pressure ventilation. The functional analysis of I Gel with Baska mask during laparascopic surgeries with controlled ventilation was done by Ramaiah R et al[14] and Chaudhary.[15] It was found that both airways devices were suitable for laparascopic surgeries, but I-gel was quicker and easier to insert, while Baska mask gave good oropharyngeal airway seal. Similar observations were made in our study as well. More patients in the Baska mask group in our study had Grade I-III score on fiberoptic assessment which indicates a more favorable placement of the SGD. This also could have contributed to the higher OLP seen in that group other than the structural advantages the Baska mask have over I-Gel.

The accelerated hemodynamic responses observed in Group B in our study could be because in that group securing airway took more time and attempts. However, the incidence of traumatic insertions did not show any significant difference between groups. The higher OPL pressures observed with use of Baska mask in our study clearly supports the superiority of it during controlled ventilation.

The drawbacks of our study were that only the patient and outcome assessor were blinded and all the airway device placements were not performed by a single anesthetist. Though the procedures were performed by anesthetists with minimum five years of experience, errors due to varying levels of individual skill could not be totally eliminated.

V. CONCLUSION

I Gel insertion was found to be quicker, less traumatic and required fewer attempts as compared to Baska mask insertion. Though I-Gel insertion was associated with blunted hemodynamic responses, the oropharyngeal leak pressure was significantly higher with Baska mask in patients under general anaesthesia with controlled ventilation.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest. There is no source(s) of support in the form of grants, equipments or drugs.

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Anterior-posterior rima glottidis (APrima) distance	
Grade I	75-100%
Grade II	50-75%
Grade III	25-50%
Grade IV	0-25%
Grade V	No vocal cords, only epiglottis visible
Grade VI	No epiglottis or epiglottis visible

Table 1:- Fiberoptic assessment of anatomical position of the Baska Mask airway against the glottic opening

Variable		Group B		Group I		P value
		Mean	SD	Mean	SD	
Age in years		43.7	13.4	47.9	13.5	0.258
Weight in kg		63.5	13.2	66.3	10.8	0.379
		n	%	n	%	
Gender	Male	20	66.7	20	66.7	1.000
	Female	10	33.3	10	33.3	
ASA PS 1		13	43.3	16	53.3	0.438
ASA PS 2		17	56.7	14	46.7	

Table 2:- Comparison of demographics and ASA physical status. Abbr: SD; standard deviation, n; number of patients, ASA PS; American Society of Anesthesiologists physical status

Variable		Group B		Group I		P value
		no	%	no	%	
Attempt 1		21	70	29	96.7	0.012*
Attempts 2 or more		9	30	1	3.3	
Trauma	Yes	2	6.7	0	0	0.492
	No	28	93.3	30	100	
FOB assessment	Grade I-III	14	46.7	3	10	0.003*
	Grade IV-VI	16	53.3	27	90	
		Mean	SD	Mean	SD	
Oropharyngeal leak pressure in cm H_2O		36.33	5.68	25	5.79	<0.001*
Time taken to secure airway in sec		63.42	8.7	24.8	2.3	<0.001*

Table 3:- Comparison of attempts at securing airway, time taken and sealing pressures. Abbr: SD; standard deviation, n; number of patients, FOB; Fiberoptic bronchoscopy, * statistically significant

Time	Group B		Group I		P value
	Mean	SD	Mean	SD	
Baseline HR	97.95	11.16	97.55	5.48	0.839
HR after induction	92.9	10.46	94.58	6.5	0.607
HR 1 min after intubation	112	6.99	101.15	6.62	<0.001*
HR 3 min after intubation	108.85	8.84	95.4	5.95	<0.001*
HR 5 min after intubation	99.45	6.29	93	5.66	0.001*
HR 10 min after intubation	93.38	7.64	90.48	7.36	0.093
Baseline MAP	86.72	12.903	85. 92	13.485	0.710
MAP after induction	82.65	15.641	84.78	13.426	0.370
MAP 1 min after intubation	94.98	5.4	88.88	8.47	0.003*
MAP 3 minafter intubation	93.25	4.68	87.93	7.51	0.005*
MAP 5 minafter intubation	93.38	3.28	87.85	5.7	<0.001*
MAP 10 minafter intubation	91.50	18.401	89.03	17.578	0.387

Table 4:- Comparison of heart rate and mean arterial pressures. Abbr: HR; heart rate, MAP; mean arterial pressure, SD; standard deviation, * statistically significant