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A study to compare the occurrence of immediate post-operative airway complications and morbidityamong the three devices: Baska mask, I-Gel supraglottic airway device and LMA-Proseal

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Abstract
The novel features of the Baska mask are its integrated bite-block, which prevents airway block due to patients biting the device and an extended hand-tab attached to the cuff which helps the operator to manipulate its degree of flexion while inserting the device. Last but not the least, the device can be inserted in neutral head position. The Baska mask is available in four sizes, paediatric and adult, in single use and reusable types. Pre-anaesthetic evaluation of all patients were done on the previous day of surgery by an anaesthesiologist. All patients under the above-said inclusion criteria, were randomly allocated into following groups after taking informed, written and valid consent from their parents/guardian:Group B(n=30): patients receiving Baska mask Group I (n=30): patients receiving I-Gel,Group P (n=30): patients receiving LMA-ProSeal.Post-operative blood-staining of device on removal was seen in only one patient (3.3%) in group P and cough in one patient in group B (3.3%) which were insignificant with a p value of 0.36. Other complications (desaturation, laryngospasm, aspiration, mucosal/lip trauma, dysphagia, hoarseness) were not observed in any patient.
Keywords: Post-operative airway complications, Baska mask, I-Gel supraglottic airway device

Introduction
The newest addition to the family of supraglottic airway devices, the Baska mask (Logikal Health Products PTY Ltd., Morisset, NSW, Australia), has many innovative features in addition to those common with other supraglottic airways. It has a non-inflatable cuff continuous with the central channel of the device so that it gets self-inflated with positive pressure ventilation, thus making ventilation more efficient by improving the seal and minimising leak[1].The dorsal surface of the cuff is designed so as to clear away oropharyngeal secretions or contents to its side channels from where they can be suctioned out. These features provide additional protection to the airway and bring down the risk of pulmonary aspiration of supraglottic contents. The Baska mask also has an inlet sealing onto the upper oesophagus[2].The peculiar design of the cuff moulded to fit to the supraglottic airway safeguards the oropharyngeal tissues and nerves from potential damage due to over-inflation, observed with other supraglottic airways. The other novel features of the Baska mask are its integrated bite-block, which prevents airway block due to patients biting the

device and an extended hand-tab attached to the cuff which helps the operator to manipulate its degree of flexion while inserting the device. Last but not the least, the device can be inserted in neutral head position. The Baska mask is available in four sizes, paediatric and adult, in single use and reusable types[3].

I-Gel is a disposable latex-free novel supraglottic airway device (Intersurgical Ltd., Wokingham, UK) made of thermoplastic elastomer (Styrene Ethylene Butadiene Styrene) which makes it transparent with soft, gel like consistency. Adult sizes were introduced in 2007, and by 2010 paediatric sized I-Gel came into use. It also has a non-inflatable cuff which eases insertion and provides greater stability after insertion with minimal tissue injury. In addition, by virtue of its thermo adaptability, I-Gel can improve its seal over peri-laryngeal structures as time progresses. As per Miller's classification, it comes under uncuffed peri-laryngeal sealers[4, 5].

Although LMA Classic introduced by Archie Brain was a revolutionary step in airway management, the founder continued to construct and experiment various prototypes between 1981-86 incorporating features like improved seal and drainage tube to divert away gastric contents. Ultimately, a batch of ProSeal LMAs, designed to provide better airway seal, safely separate the respiratory and gastrointestinal tracts and allow better ventilation, were released in 2000. The ProSeal is a latex-free reusable LMA made of medical-grade silicone[6].

Methodology

A prospective randomised single blinded comparative study was planned, with the randomisation sequence being computer-generated.

Pre-anaesthetic evaluation of all patients were done on the previous day of surgery by an anaesthesiologist. All patients under the above-said inclusion criteria, were randomly allocated into following groups after taking informed, written and valid consent from their parents/guardian:

Group B(n=30): Patients receiving Baska mask Group I (n=30): patients receiving I-Gel.

Group P(n=30): Patients receiving LMA-ProSeal.

All patients in each group were maintained on nil per oral as per standard guidelines prior to surgery and pre-medicated with Tab. Ranitidine 1.5mg/kg the night before surgery.

Half an hour before surgery, patients were premedicated with midazolam atomised intranasal spray 0.2 mg/kg. After shifting the patients into the Operation theatre, an intravenous line was secured using a 22/24-gauge IV cannula on the non-dominant hand and an appropriate intravenous fluid was connected to the same. Intravenous fluid was given according to the deficit, maintenance and intraoperative loss requirement calculated per kg body weight.Patients were also connected to a multiparameter monitor and baseline pulse oximetry (SpO_2), non-invasive blood pressure (NIBP), pulse rate and electrocardiography (ECG) were noted.

Patients were pre-medicated with Inj. Glycopyrrolate 0.004 mg/kg and Inj. Fentanyl 2 mcg/kg intravenously followed by preoxygenation with 100% Oxygen for 3 minutes, and then induced with Inj. Propofol 2 mg/kg intravenously. This was followed by facemask ventilation with 100% oxygen until optimal conditions for supraglottic device insertion were attained, i.e., eyelash and airway reflexes disappear.

Airway was then secured by an experienced anaesthesiologist with an appropriately sized supraglottic device as per manufacturer's recommendation of weight-based estimate and clinical judgement while the investigator recorded the duration and ease of insertion, post-insertion airway seal pressure, ease of insertion of gastric tube, hemodynamic parameters and post-operative laryngopharyngeal morbidity.

For insertion, the supraglottic device was lubricated with lignocaine-gel and inserted bypushing past the front teeth towards the hard palate, avoiding the tongue and then slid downwards and backwards until a definitive resistance isencountered. Before insertion,cuff of LMA-ProSeal was fully deflated. While inserting Baska mask, the tab of the mask was used

to help negotiate the palato-pharyngeal curve when it was fully within the mouth.

An effective airway was confirmed by bilateral symmetrical chest movement on manual ventilation, square wave capnography, absence of audible leak of gas and lack of gastric insufflations. In case of failure of insertion of device or ventilation through it, two more attempts of insertion were allowed. If placement failed even after third attempt, the airway was to be secured through another suitable airway device and the case excluded from our study.

After securing the device in place, an appropriately sized well lubricated gastric tube was introduced into the stomach through the gastric drainage port. Anaesthesia was maintained using 66% nitrous oxide and 33% oxygen with 1.5-2% sevoflurane and patients were allowedto breathe spontaneously through a Jackson-Rees circuit.

At the end of operation, anaesthetic agents were discontinued and patients were ventilated with 100% Oxygen. At a lighter plane, when patient started responding to pain stimuli, the supraglottic airway device was removed and inspected for any bloodstaining.

Patients were reviewed in the post anaesthetic care unit before sending to postoperative ward for monitoring of vitals. They were also assessed for post-operative complications for 24 hours.

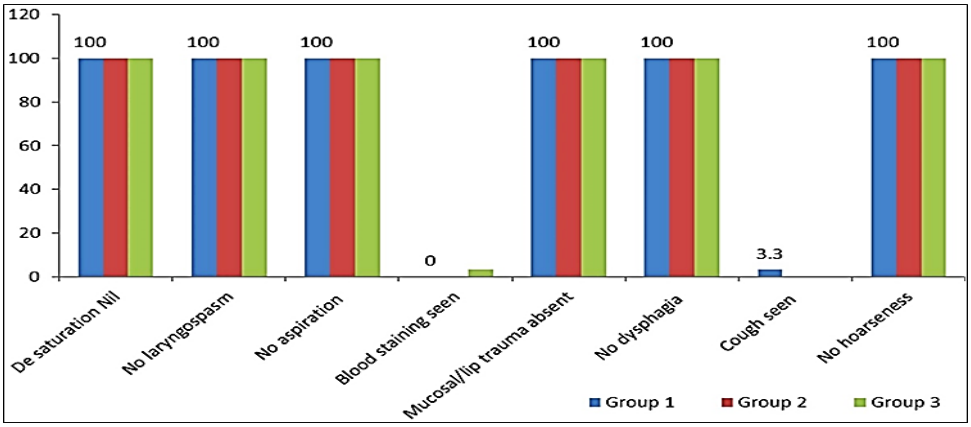
Complications during insertion, maintenance and removal of device, including desaturation (less than 95%), laryngospasm, aspiration of gastric contents, blood staining of the device, mucosal/lip trauma and postoperative airway complicationslike, cough, dysphagia and hoarseness were noted for each child.

Results

Table 1: Post-operative complications among study participants (Group B: Baska mask, Group I: I Gel and Group P: LMA ProSeal)

Sl.No.	Features	Group B (N=30)		GroupI (N=30)		Group P (N=30)		p value#
		n	%	n	%	n	%	
1.	DesaturationNil	30	100	30	100	30	100	NA
2.	Nolaryngospasm	30	100	30	100	30	100	NA
3.	No aspiration	30	100	30	100	30	100	NA
4.	Blood stainingseen	0	0	0	0	1	3.3	0.36
5.	Mucosal/liptrauma absent	30	100	30	100	30	100	NA
6.	No dysphagia	30	100	30	100	30	100	NA
7.	Cough seen	1	3.3	0	0	0	0	0.36
8.	No hoarseness	30	100	30	100	30	100	NA

Note: # p value based on Chi-square test, NA-Not Applicable



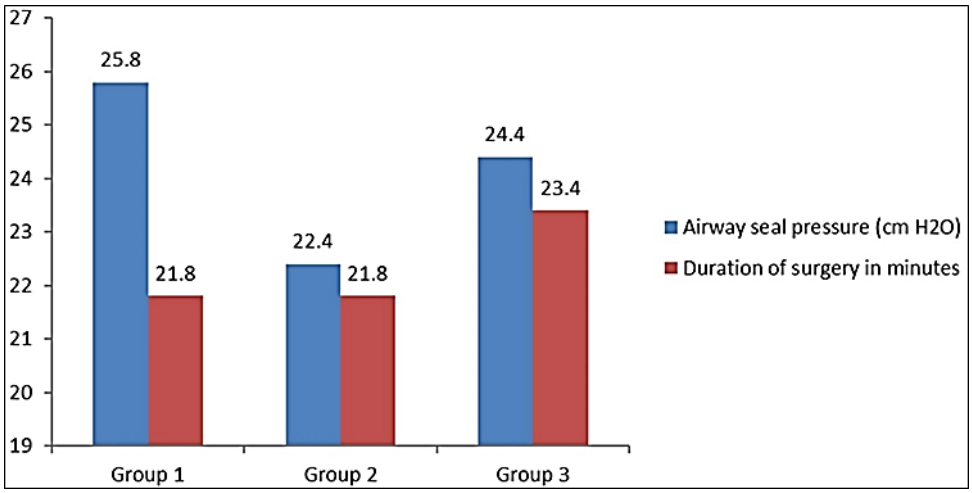
Graph 1: Post-operative complications among study participants (Group-1: Baska mask, Group-2: I Gel and Group-3: LMA ProSeal)

Comparison of occurrence of post-operative complications were done by Chi-square test,which gave insignificant results. Post-operative blood-staining of device on removal was seenin only one patient (3.3%) in group P and cough in one patient in group B (3.3%) which were insignificant with a p value of 0.36. Other complications (desaturation, laryngospasm, aspiration, mucosal/lip trauma, dysphagia, hoarseness) were not observed in any patient.

Table 2: Comparison of airway seal pressure and duration of surgery of study participants (Group B: Baska mask, Group I: I Gel and Group P: LMA Proseal)

Features	Group B (N=30)		Group I (N=30)		Group P (N=30)		p value#
	Mean	SD	Mean	SD	Mean	SD	
Airwayseal pressure (cm H_2O)	25.8	1.6	22.4	1.1	24.4	1.1	0.001*
Duration of surgeryin minutes	21.8	3.1	21.8	3.9	23.4	3.1	0.13

Note: #p value based on ANOVA test, SD-Standard deviation.



Graph 2: Comparison of airway seal pressure and duration of surgery of study participants (Group-1: Baska mask, Group-2: I Gel and Group-3: LMA Proseal)

Comparison of airway seal pressure among the three study groups by ANOVA test gave significant results with a p value of 0.001. Mean airway seal pressure in group B was 25.8 cm H_2O with a standard deviation of 1.6, 22.4 cm H_2O with a standard deviation of 1.1 for groupI and 24.4 cm H_2O with a standard deviation of 1.1 for group P. Results imply that group Bhad significantly higher airway seal pressure than groups P and I. Duration of surgery were comparable in all three groups with a p value of 0.13, which is insignificant.

Discussion

Occurrence of post-operative complications was insignificant in all three study groups. Post-operative blood-staining of device on removal was seen in only one patient (3.3%) in group P and cough in one patient in group B (3.3%) which were insignificant with a p value of 0.36. Other complications (desaturation, laryngospasm, aspiration, mucosal/lip trauma, dysphagia, hoarseness) were not observed in any patient. Mitra S *et al.* [7], ShanmugaveluG *et al.*[8],Garg A*et al.*[9]and Aziz RA *et al.*[10]recorded insignificant incidence of postoperative complications. Mitra S *et al*. had reported bloodstaining of device with PLMA in 4 out of 30 children studied and 1 out of 30 children with igel. Shanmugavelu G *et al*. reported bloodstaining on removal in3 out of 30 subjects in igel group against 2 out of 30 in Baska group and sore throat in 4 patients at 2 hours and 1 patient at 24 hours postoperatively in igel

group compared to one case in Baska group.Garg A *et al*. recorded bloodstaining in 5 cases of Baska group and 4 of igel group outof 50 cases in each and no other complications. Aziz RA *et al*. reported bloodstaining on removal in 5 of igel and 3 of Baska group, sore throat in 3 and hoarseness in 1 patient each in igel group, while sore throat and hoarseness were observed in only one patient each in Baska group.

None of the patients in our study required securement of alternative airway device due to failure of insertion of SAD or abandonment of procedure. One of the main limitations of our studywas that only ASA 1-2 (low risk) patients with apparently normal airways were studied.

Conclusion

Baska mask takes longer time for insertion than LMA ProSeal and igel but maintains superior airway seal pressures than LMA ProSeal and igel and hence can be used as a safe alternative.

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