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COMPARATIVE EVALUATION OF LARYNGEAL MASK AIRWAY SUPREMETM AND I-GELTM FOR PERI AND POST OPERATIVE COMPLICATIONS

Anaesthesiology

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ABSTRACT

Objectives- this was a comparative evaluation of Laryngeal mask airway supremetm and I-Geltm for peri and post operative complications.

Study Design— this was a Hospital based, randomized, single blind Interventional study conducted in the department of Anaesthesiology, SMS Medical college & attached group of hospitals, Jaipur,.Sample size was calculated to be 45 in each group(Laryngeal mask airway supremetm S group and I-Geltm I group) at alpha error 0.05 & power 80% to verify the expected difference of 1.5(±2.5)sec. (as per seed article) in mean insertion time among I GELTM group and LMA SupremeTM group.

Result and discussion: In our study we found that Airway trauma was observed only in one patient in group I and in two patients in group S. The difference was statistically not significant (p=1.000). The perioperative complication which included Coughing, broncho & laryngospasm, hypoxia, regurgitation/aspiration were noted. Coughing & bronchospasm was noted in one patient in group S. The difference was statistically not significant (p=1.000). The post-operative complication (24 hr post surgery) which included blood staining/hoarseness of voice/sore throat/difficulty in swallowing/vomiting were noted. Sore throat was noted in one patient in the group I & 3 in group S. Blood staining of the device in one patient in the group I & 2 in group S. The difference was statistically not significant (p=1.000).

Conclusion: This study demonstrates that new Supraglottic airway devices I-GelTM and LMA SupremeTM were better alternative to endotracheal tube in patients undergoing elective surgeries under general anesthesia. But peri and post operative complications were more in Laryngeal mask airway supremetm group than I-Geltm group .Further multicentre mega trials were indicated to assess safety and performance compared to other supraglottic airway devices.

KEYWORDS

Introduction

The major responsibility of the anaesthesiologist is to provide adequate ventilation to the patient because airway related problems are still the most common cause of anaesthesia related morbidity and mortality[1]. Supraglottic devices are useful advent in the airway management, filling a niche between the facemask and tracheal tube in terms of both the anatomical position and the degree of invasiveness[9]. The Laryngeal Mask Supreme™ is a newly developed single-use supraglottic airway device with its esophageal drainage tube to suction gastric content4,5. The I-GEL™ is a novel single-use, latex free extraglottic airway device that differs from the LMAS as it does not have an inflatable cuff. The rim of the mask is designed to conform to the anatomical shape of the larynx. This enables the device to provide an airtight seal without the cuff mechanism. The tube consists of two channels, where it is possible to intubate the trachea through the breathing tube and to insert a gastric tube through the drain tube 2.

Present study has been planned as prospective randomized clinical study comparing both LMA SupremeTM and I-GelTM in elective surgeries under general anesthesia in terms of peri and post operative complications

MATERIAL AND METHODS

STUDY LOCATION:

The study was conducted in the department of Anaesthesiology, SMS Medical college & attached group of hospitals, Jaipur.

STUDY DESIGN:

Hospital based, randomized, single blind Interventional study

STUDY PERIOD:

After approval from research review board to till the desired sample size complete.

SAMPLE SIZE :

Sample size was calculated to be 45 in each group at alpha error 0.05 & power 80% to verify the expected difference of 1.5(±2.5)sec. (as per seed article) in mean insertion time among I GELTM group and LMA SupremeTM group.

STUDY GROUPS:

Patients were divided in 2 groups of 45 each on basis of airway device to be used:

Group I I- GelTM group (N=45)

Group S LMA SupremeTM (N=45)

Eligibility criteria:

Inclusion Criteria:

- Those undergoing elective surgery (upto 3 hr) under general anesthesia like abdominal surgeries, peripheral surgeries involving upper limb.
- Those of ASA 1 and II.
- MPG1 and MPG II.
- Those between ages 18 to 60 yrs.
- Those with no history of post operative nausea and vomiting during any previous surgery under general anesthesia.
- Those without any dental abnormalities.

Exclusion Criteria:

- Those not giving consent.
- Those with high risk of aspiration (gastro esophageal disease, morbid obesity, hiatus hernia, pregnancy).
- Those with Body Mass Index (BMI) greater than 35 kg/m2.
- Those having Mouth opening less than 2.5 cm.
- Those with history of Oral, Faciomaxillary and Ophthalmic surgeries.
- Those having artificial dentures.

Methodology –

This study included 90 Patients (age 18-60 years) who underwent elective surgery under general anaesthsia. The Patients were divided into 2 groups of 45 each (group I & group S) on the basis of inclusion and exclusion criteria. A form was completed for each subjects.Data of peri and post operative complications compared, correlated andstatistically analyzed.Salient features of this study were: - mean age of patients in Group I and Group S were 31.09±10.39 and 35±11.01 years respectively. **68.89% patients in group I & 68.89% patients** in group S were female. Mean weight being 64.02±13.91 kg in group I and 64.22 ±14.99 kg in Group S. mean height being 163.02 ± 8.61cm in group I and 163 ± 8.08 cm in Group S.mean BMI being 23.80± 2.96 kg/m2 in group I and 23.83±3.45 kg/m2 in Group S.

Observations

Table-1 DISTRIBUTION ACCORDING TO AIRWAY TRAUMA

Tongue, lip, dental trauma	Group I		Group S		P value
	Frequency	%	Frequency	%	
NO	44	97.78%	43	95.56%	1.000 (NS)
YES	1	2.22%	2	4.44%	
TOTAL	45	100%	45	100%	

Table -2 DISTRIBUTION ACCORDING TO PERIOPERATIVE COMPLICATION

PERIOPERATIVE complication	Group I		Group S		P value
	Frequency	%	Frequency	%	
Coughing	0	0%	1	2.22%	1.000 (NS
Bronchospasm/laryngospasm	0	0%	1	2.22%	
Hypoxia SpO2<90%	0	0%	0	0%	
Regurgitation & Aspiration	0	0%	0	0%	

Table -3 DISTRIBUTION ACCORDING TO POSTOPERATIVE COMPLICATION

Post operative complication	Group I		Group S		P value
	Frequency	%	Frequency	%	
Blood staining of device	1	2.22%	2	4.44%	1.000 (NS
Sore Throat	1	2.22%	3	6.67%	
Hoarseness of voice	0	0%	0	0%	
Difficulty in swallowing	0	0%	0	0%	
Vomiting	0	0%	0	0%	

Discussion –

In our study we found that- Air way trauma distribution in the two groups was comparable. Airway trauma was observed only in one patient in group I and in two patients in group S. The difference was statistically not significant (p=1.000). Compared with the other studies - Gupta Vikas et al. (2015)10 reported that airway trauma observed in 3.33% cases in I gel and 6.67% in SLMA group.

Perioperative complication distribution in the two groups was comparable. The perioperative complication which included Coughing, broncho & laryngospasm, hypoxia, regurgitation /aspiration were noted. Coughing & bron chospasm was noted in one patient in group S. The difference was statistically not significant (p=1.000).Raquazzi R et al. (2012)7 reported that broncho/ laryngeospasm was observed in 2% cases in I gel & 3% cases in LMA supreme group.

The post-operative complication (24 hr post surgery) which included blood staining/hoarseness of voice/sore throat/difficulty in swallowing/vomiting were noted. Sore throat was noted in one patient in the group I & 3 in group S. Blood staining of the device in one patient in the group I & 2 in group S. The difference was statistically not significant (p=1.000). Post-anaesthesia airway morbidity has gained widespread attention, especially in a health environment where cost containment is essential and patient satisfaction is of high priority. Gupta Vikas et al. (2015)10 reported that sore throat observed in 3.33% cases in I gel and 6.67% in SLMA group. Ashish Kannaujia et al. (2009)6studied I-GelTM reported a very low incidence of airway morbidity. Four percent patients in their study complained of sore throat in the postoperative period which subsided within 24 hrs. None of the patient complained of dysphonia or dysphagia .

CONCLUSION-

This study demonstrates that new Supraglottic airway devices I-GelTM and LMA SupremeTM were better alternative to endotracheal tube in patients undergoing elective surgeries under general anesthesia. But peri and post operative complications were more in Laryngeal mask airway supremetm group than I-Geltm group .Further multicentre mega trials were indicated to assess safety and performance compared to other supraglottic airway devices.

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