

Study Protocol

Comparison of I-gel and Laryngeal Mask Airway Proseal for Clinical Performance in Short Surgical Procedures under General Anaesthesia: A Study Protocol

ABSTRACT

BACKGROUND: Maintenance of proper airway is one of the most critical duties of anaesthetist during surgical and operative procedures. Face mask and endotracheal tube are traditionally used for airway delivery and maintenance. Supraglottic airway devices(SAD) became a normal fixture in managing airway. I-gel is novel supraglottic device, which is thermoelastic, single use, disposable material. This study aims to compare the two Supraglottic Airway Devices I-gel & Laryngeal Mask Airway Proseal in clinical performance in short surgical procedures under general anaesthesia.

METHODOLOGY: This Prospective observational comparative study will be conducted at Dept. of Anesthesia, AVBRH, Wardha. 60 patients will be enrolled and randomized in two groups. In Group I, I-gel will be used whereas in Group P, Proseal LMA will be used for spontaneous ventilation during short General anaesthesia procedures. Data will be compiled and statistical analysis will be done by using appropriate statistical tests.

EXPECTED RESULTS: I-gel can be expected superior in terms of attempts and duration needed for insertion, hemodynamic stability and post-operative complications, compared to Proseal LMA.

CONCLUSION: I-gel proves to be superior compared to PLMA with reference to insertion ease and other operational issues.

KEY WORDS : Anaesthesia, Proseal LMA, I-gel, Insertion, Fiberoptic view, Airway, Ventilation.

INTRODUCTION

An anaesthetist's primary duty is to provide a patient with the necessary ventilation. The airway is a critical element in providing functional respiration. The face mask and endotracheal tube (ETT) are two methods of traditional airway delivery and maintenance that have been developed.[1] Supraglottic airway devices(SAD) became a normal fixture in managing airway. They will be mounted outside the trachea and provide anaesthetist free hand to achieve a gas tight airway.[2]

Laryngeal Mask Airway (LMA) classic, was introduced in 1989, is the first popular supraglottic device. It was mentioned by Archie Brain 1st[2]. Later, many new devices integrated in to the family of LMA to fulfil the requirements.

In clinical practice, Archie Brain introduced the LMA proseal (PLMA) in 2000 with its latest enhanced function that is cuff which is redesigned to strengthen the seal around the glottis and also has a tube drain to serve as a channel bypass if there is some regurgitation of contents of stomach, seal of PLMA being more efficient than that of the LMA classic [3,4]. The tube placed for drain prevents insufflations of gastric contents & with the aid of bougie [5-6], Ryle's tube can be easily inserted & it also helps in easy positioning of mask.[2][7]

For controlled & spontaneous ventilation, LMA's may also be used. Different forms of LMA are not only used in anesthesia used in other clinical situations, such as cardiopulmonary resuscitation (CPR) [6-10], pre-hospital emergency use and complicated airway control[11,12], In spite of all this, LMA is contraindicated in conditions such as high airway resistance, poor pulmonary compliance[13], and in conditions having more risk of regurgitation, pregnant women with a gestation period longer than 14 weeks, morbidly obese patients, hiatus hernia, any factors associated with delayed gastric emptying.

By supplying airtight sealing for the efficient transport of inhalational anaesthetic agents at the level of bronchioles and alveoli, airway management by LMA will be carried out [1]. Typically there will be loss of muscle tone of the upper airway while patients are in the state of anesthesia, as a consequence tongue and epiglottis will be dropping back against posterior wall of pharynx, there by obstructing the air flow in and out, resulting in breathing obstruction. In addition to the anesthetic agents, the central nervous system and respiratory center there are depressed by completely removing the respiratory drive of the patient. LMA prevents those issues associated with upper airway obstruction by bypassing the tongue and preserving the patency of the airway. Airway patency and protection can be retained with the inflated LMA cuff, which also comes from a low pressure seal over the opening of the glottis. There are different methods of implementing LMA proseal-introducer technique, wireless technique, Bougie or fiberoptic guided technique.

I-gel is novel supraglottic device. Dr. Mohammad Aslam Nasir developed this device in January 2007[1-2]. Indeed, it is an anatomical unit. It has a soft, non-inflatable cuff that fits by mirroring the peri-laryngeal frame work [2,14,15]. Each receives a suitable impression, thus holding up the seal by enveloping the inlet of larynx. For patients who breathe spontaneously and even for those who are on intermittent positive pressure ventilation, the seal produced will be enough (IPPV). It is possible to autoclave the LMA.

In order to remove the possible risk of rotation after insertion, it is anatomically wide & concave and thus reduces the risk of mal-positioning. The tip will be positioned in the opening of the upper oesophagus when this system is correctly inserted, thereby providing the esophagus & stomach with a gastric channel. This then facilitates suction, allows the nasogastric tube to move through and can also facilitate venting. With good positioning in the anatomical position and the least risk of laryngo-pharyngeal trauma, ventilation will be extremely successful. I-gel is thermo-elastic material, single-use & disposable.

RATIONALE:

Supraglottic airway devices (SAD) had now became a standard object in management of airway, filling a niche b/w facemask & endotracheal tube (ETT). It acts a good alternative to bagmask ventilation there by freeing the hands of anaesthetist and with also benefit of less gastric

distension .They also avoid the complications of endotracheal tube intubation with early recovery and ambulation of patient. We are doing this study to know the Ease of insertion (insertion attempts & duration of attempt) b/w the I-gel and laryngeal mask airway proseal, so they can be utilized more often in short surgical procedures.

AIM:

To compare the two Supraglottic Airway Devices I-gel & Laryngeal Mask Airway Proseal in clinical performance in short surgical procedures under general anaesthesia.

OBJECTIVES :

PRIMARY OBJECTIVE:

- Comparison of Ease of insertion i.e. attempts of insertion and duration of attempt.

SECONDARY OBJECTIVE:

- To compare Fiberoptic view of glottis opening.
- To compare hemodynamic changes during

- Insertion
- Intraoperative period
- Removal of Device

- To compare incidence of complications like, trauma to the lip-tongue-oral mucosa, bronchospasm , laryngospasm
blood staining of device, sore throat.

METHODS

STUDY DESIGN: Prospective observational randomized comparative study.

STUDY PERIOD : two years

SETTING: This study will be carried out following the approval of the Jawaharlal Nehru Medical College (JNMC) Acharya Vinoba Bhave Rural Hospital (AVBRH) Ethics and Screening Committee, Datta Meghe Institute of Medical Sciences (DMIMS), Sawangi (Meghe), Wardha. All patients undergoing elective surgery prior to the operation will be given written and informed consent.

PARTICIPANTS:

a) INCLUSION CRITERIA:

- 20-60yrs aged patients.
- Both males and females included.
- ASA class I & II.
- Patients registered for surgical procedures of short duration under general anaesthesia.

b) EXCLUSION CRITERIA:

- ASA class III & above patients.
- Any contraindications for general anaesthesia.
- Morbid obesity BMI>30.
- Patients posted for head and neck surgery.

- Patients with increased risk of pulmonary aspiration, Gastro esophageal reflex disease, completely edentulous patients, difficult airway.
- Uncooperative patients and patients not willing to participate.

c) MATERIALS REQUIRED:

- Proceal laryngeal mask airway 3 & 4.
- I-GEL airway 3 & 4.
- Drugs- Glycopyrrolate, midazolam, fentanyl/Butrum, Propofol, Isoflurane/Sevoflurane, Ondansetron.

STUDY SIZE: Calculation of sample size was performed using openepi.com . Assumption of Mean duration for insertion in seconds 21.98 (+ or -) keeping power at 80% & alpha error at 0.05, sample of thirty patients will be needed to detect minimum difference of 20 percent in the Mean duration of insertion b/w 2 groups. We will allocate sixty patients in 2 groups with thirty each to compensate for possible dropouts. The patients will be randomly given allocation into 2 groups based on a computer-generated number table.

METHODOLOGY: Sixty patients will be randomly selected for various short surgical procedures such as Dilatation & Curettage, hysterectomy, Fibroadenoma excision; After consent form is signed, randomization will be done into 2 groups depending on the device used:

group - I : I - gel (n-30)
group - P : PLMA (n-30)

All patient's will be kept NBM for 6 hrs before taking for surgery. In the operation theatre, multi-parameter monitors will be attached to the patient and parameters like pulse rate, Ecg, non invasive blood pressure, Spo₂, and Etco₂ will be considered and noted. For fluid management and infusion's one peripheral IV line (intravenous line) will be secured in upper arm/ forearm. They will be given premedication, injection glycopyrrolate 0.2 milligrams, injection .midazolam 1milligram, injection. Butorphanol 1milligram and baseline vital parameters will be noted. Patient will be given preoxygenation with hundred percent O₂ for three minutes, then patient will be given induction with injection. Propofol 2.5 milligram/kilogram body weight and the depth of anaesthesia will be intensified with sevoflurane 2 percent in O₂ and by using bagmask ventilation. Patient's will be given a Sniffing position before inserting the device .

If necessary an ancillary dose of Propofol will be given to get the needed anaesthesia depth of before insertion of device. Loss of eye lash reflex & Complete jaw relaxation will confirm adequate depth.

Once required anaesthesia depth is achieved, insertion of selected device will be done by an qualified anaesthetist.

In Group I and Group P, respectively, sufficient sizes of previously lubricated (water-based jelly) I-Gel and laryngeal mask airway proceal will be inserted. Maximum attempts will be limited to two, and if not the patient will be treated in the with a suitable sized endotracheal tube. Patient will be maintained with O₂, N₂O, & Sevoflurane.

Square wave capnography, SPO₂ greater than 95 percent, bilateral chest rise and breath sounds auscultation in front of the patient's neck will confirm proper placement of the inserted

device.[16]. An insufficient chest rise, an irregular capnogram, a decrease in SpO₂ of <95% would indicate an inappropriate positioning of the device.

Anesthetics will be tapered off at the end of the surgical procedure. When spontaneous eye openings are observed, the device will be removed. It will note the presence of visible blood stains above the device. Complications will be reported and handled accordingly, if any.

DATA MEASUREMENT:

1. INSERTION CONDITIONS

ease of insertion	- easy - difficult -impossible
number of attempts	- < 2 attempts
Time taken for insertion (time from device pick-up to breathing system attachment)	- (time from device pick-up to breathing system attachment) - i-gel (30 seconds) - PLMA(35-40seconds)
Jaw relaxation (three point scale) – gross/moderate/slight.	

2.FIBEROPTIC VISUALIZATION

After securing the airway, bronchoscope will be passed through airway tube of the device and laryngeal inlet will be viewed and graded accordingly:[10]

RADE	
	only VC visible
	C + post. epiglottis
	C + ant. epiglottis
	V/C invisible

#VC = vocal cords

3.HEMODYNAMIC PARAMETERS:

Heart rate , systolic & diastolic BP,MAP will be regularly assessed and recorded as follows:

- Baseline, pre-insertion, 1min, 5min & at time of device removal.

4.COMPLICATIONS:

Trauma to lip/tongue/oral mucosa	resent/ Absent
Sore throat	resent/ Absent
Blood staining of device	resent/ Absent
Laryngospasm & bronchospasm	resent/ Absent
Sore throat	resent/ Absent

STATISTICAL METHODS:

Statistical analysis will be done by using descriptive statistics i.e. Mean, Standard deviation, Standard error of mean and by using inferential statistics chi-square test , student's unpaired t test. All the results will be tested at 5% level of significance.

EXPECTED OUTCOME/RESULTS:

Expecting that compared to LMA proseal , I-gel can be secured in lesser number of attempts and lesser duration of insertion and i-gel is hemodynamically more stable with minimal or no post-operative complications.

DISCUSSION:

PLMA is a relatively modern SAD with a cuff that inflates and enhances the seal and have a tube drain for gastric aspiration prevention and insertion of gastric tubes.

I-gel a newly designed supraglottic airway single-use device with a cuff that does not inflate , devoid of inflatable cuff complications. Its construction is intended to mirror peri laryngeal anatomy that offers a glottis fit. In our study two groups will be demographically (age, gender ,BMI) similar and compared.

Singh I. et. al. noted clinical success of I-gel with LMA proseal in patients undergoing elective surgical procedures in sixty class I & II ASA patients. Sixty people were administered into two classes . I-gel class I - (n=30) and PLMA class P (n=30). They observed that compared to the LMA proseal class , the favourable outcome of 1st insertion attempt and ease of Ryle's tube placement are more with the I-gel class . Compared to I-gel, Tongue-lip-dental trauma, blood staining of devices was more in LMA proseal . With either devices they found no grounds for laryngospasm bronchospasm, aspiration risk , hoarseness of voice. [17]

A study by Kannaujia A. et. al. on I-GEL in fifty patients of ASA class I & II to know the insertion time, oropharyngeal pressure, airway stability. They found that at 1st attempt, insertion rate was ninety percent and 2nd was 100 percent . 11 seconds was the median insertion time at first attempt. In fifty percent cases gastric tube placement was done.100% was the achievement rate for gastric tube insertion. oropharyngeal airway seal pressure was twenty centimetre water. They had no significant adverse event in perioperative period. From there study they concluded that I-gel was better than LMA because I-gel is trouble free to insert, not needed any manipulations, better maintenance of airway in a short time.[18]

SHIN WJ et. al. did the comparative study between LMA proseal, I-gel & LMA-classic to assess insertion success rate, hemodynamic changes, seal pressure and post-operative complications. They found that insertion rate was similar in this groups. There was no significant hemodynamic changes occurred in these groups during placement of device . The pressure leak noted to be excessive in both I-gel & LMA proseal relative to LMA-classic.The post-op complications - sore throat was higher in LMA-classic than other 2 devices.[19]

J.J GATWARD, et. al. conducted study among 100 patient's who were registered for surgeries. I-gel was device of choice. In 86 cases 1st was attempt successful, eleven cases at second attempt was done. Three cases had been inserted at 3rd attempt. Fifteen seconds was the median insertion time. There was single episode of regurgitation. They concluded that in ninety percent cases I-gel was easier to insert and also provides an effective airway management.[20]

Keijzer C. et. al. compared standard laryngeal airway mask and I-gel in two hundred eight patients. One hundred three patients had La Premiere supraglottic device & one hundred nine

patients had I-gel inserted. They gave a conclusion that compared to La Premiere laryngeal mask airway, I-gel resulted in decreased frequency of post-op complaints, dysphagia[21]. Similar study was reported by Samruddha R [21-32].

CONCLUSION:

I-GEL & PLMA are being studied to know which is better and efficient with regards to ease of insertion evidenced by number of attempts required and duration for every attempt, fiberoptic view of the glottic opening, hemodynamic parameters and incidence of complications like blood staining of device, sore throat, bronchospasm and laryngospasm.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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UNDER PEER REVIEW