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A Randomised Controlled Trial Comparing I-Gel Supraglotic Airway and the Classic Laryngeal Mask Airway

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Abstract

Background: Difficult airway has always been a matter of concern for yesterdays and even todays anesthesiologist. In order to counter such difficult airways, many supraglottic airway devices have been invented. The i-gel without an inflatable cuff is one such airway device having several potential advantages. *Objective:* We compared I-gel with LMA-classic with respect to ease of insertion and post-operative complications namely cough, hoarseness of voice and blood traces over the surface of the device. *Methodology:* 100 anesthetized patients, breathing spontaneously, ASA I–II, undergoing minor surgical procedures (duration < 60 minutes) were randomly allocated to have an i-gel (n = 50) or LMA-classic (n = 50) inserted. Patients were interviewed for cough, hoarseness of voice and blood traces over the surface of the device at 2 hr post-operatively. *Results:* Ease of insertion was significantly higher ($p < 0.013$) in the i-gel group (86%) compared with the LMA-classic Group (60%). The incidence of cough was significantly lower with the i-gel than with LMA-classic at 2 hours (3 Vs 10). Similar results were seen for hoarseness of voice (2 Vs 7). The incidence of blood traces over the surface of the device was also lower for I-gel than LMA-classic (1 Vs 6). *Conclusion:* In this randomized study, the I-gel was found to have significant high success rate for insertion at first attempt compared to LMA-classic. The incidence of post-operative complications was significantly less. Also, i-gel has an advantage over LMA-classic in that it has an integral tube through which stomach contents can be aspirated and also prevent excessive inadvertent ventilation of the stomach.

Keywords: I-gel; LMA-classic; Ease of insertion; Post-operative complications.

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Introduction

Supraglottic airway devices are routinely used during anesthesia for spontaneously breathing patients. Difficult airway has always been matter of concern for yesterdays and even todays anesthesiologist.[1] In order to counter such difficult airways, many supraglottic airway devices have been recently introduced. The i-gel airway (Intersurgical Ltd, Wokingham, Berkshire, UK), latex free is a novel supraglottic airway device without an inflatable cuff designed to fit the peri-laryngeal and hypopharyngeal structures. It is made up of a gel-like material filled with medical grade thermoplastic elastomer gel (styrene ethylene butadene styrene).[5] It also has a port for gastric tube placement. The claimed potential advantages include easier insertion and use with minimal tissue compression and stability following insertion.[2,3]

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In this randomized controlled study, we compared i-gel with LMA-classic with respect to ease of insertion and post-operative complications namely cough, hoarseness of voice and blood traces over the surface of the airway device.

Material and Methods

The present study, was conducted in the Department of Anesthesiology, Basaveshwara Medical college Hospital and Research Centre, Chitradurga after obtaining institutional ethics committee approval and written informed consent. 100 patients belonging to ASA I–II, between *18–60 years* of age of either sex undergoing minor elective surgeries lasting < *60 minutes* were enrolled into the study. Patients with significant acute or chronic lung disease, at risk of regurgitation or pulmonary aspiration (hiatus hernia, gastro-oesophageal reflux, full stomach), anticipated difficult airway, ASA III and IV, Mallampati grading III/IV (morbid obesity, pharyngeal masses) were excluded from the study. Also, if the device was not successfully inserted in the second attempt patients was excluded from the study. Patients were allocated randomly according to computer generated randomisation sheet into two groups: i-gel group, group I (n = 50) and LMA-classic group, group L (n = 50).

All patients underwent pre-operative fasting according to hospital guidelines. A thorough pre-anesthetic evaluation was carried out. The size of device was decided by the anesthesiologist based on the patient's body weight and the manufacturer's recommendation. The standard pre-use tests for both devices were performed. Both devices were lubricated using 2% lignocaine gel on the tip and posterior surface of the devices. LMA-classic was fully deflated prior to insertion.

No pre-medication was administered in the pre-anesthetic room. Once the patient was in the anesthetic room standard monitors (pulse oximeter, ECG, NIBP, $etCO_2$) were attached. Patient was pre-oxygenated with 100% O_2 for *3 minutes*. Pre-medication was done with intravenous glycopyrrolate *0.005 mg/kg*, midazolam *0.05 mg/kg*, fentanyl *2 micro g/kg*. Anesthesia was induced using intravenous propofol *1.5–2 mg/kg*. Anesthesia was considered adequate for insertion when the patient was unresponsive, had lost the eyelash reflex and until jaw relaxation of the patient was achieved. i-gel and LMA-classic was introduced in all patients by experienced anesthesiologist. No airway manipulation like jaw thrust, chin lift was done for i-gel.

Once an adequate depth of anesthesia was achieved the device was introduced in all patients by experienced anesthesiologist. Effective airway was confirmed by chest auscultation, square wave on capnograph trace and normal SpO_2 > 95%. Maintainance was done with 1.0–2.0% isoflurane, 50:50 O_2/N_2O gas mixture. Two insertion attempts were allowed for each device. If the insertion failed after two attempts, the insertion was considered as a failure. If two attempts were unsuccessful either an alternative device was inserted or the trachea was intubated. The ease of insertion was graded as 0 = easy, 1= moderate or 2 = difficult. Easy insertion being defined as, in which there was no resistance to insertion in the pharynx in a single manoeuver. Moderate insertion was defined as the one in which little resistance was felt while passing the device. A difficult insertion was defined in which resistance was felt with airway manipulation while passing the device.The device was removed after ascertaining that the patient was able to open his or her mouth to command. 100% oxygen was administered for *3 minutes* before shifting to post-anesthesia care unit. In post-anesthesia care unit oxygen *4 litre/minute* administered by simple face mask. During emergence and removal, the presence or absence of blood traces over the device were recorded. Patients were interviewed before leaving the recovery area to elicit the presence of cough and hoarseness of voice at *2 hours*.

Inter group differences were evaluated using the unpaired t-test. Chi-square test was done to check any correlation between age, sex, ease of insertion and the complications noted. A p-value of < 0.05 was considered significant.

Results

100 patients were recruited into the study. All patients enrolled in the study were included in the analysis. There was no difference between the two groups with respect to demographic and surgical performance, shows in Table 1. The mean age and weight in i-gel group were *36.6 ± 12.56 years* (range *18–60 years*) and *60.3 ± 6.55 kg* (*50–90 kg*) respectively. The ease of insertion was scored as easy in 43 cases (86%) with i-gel compared to 30 cases (60%) with LMA-classic which was statistically significant (p < 0.05), shows in Table 2. Three patients (6%) coughed in Group I compared to 10 patients (20%) in Group L and 2 patients (4%) complained of hoarseness in Group I as with 7 patients (14%) in Group L. Upon removal of the device, blood traces was seen in one patient (2%) in Group I compared to 6 patients (12%) in Group L, shows in Table 3.

Table 1: Demographic Data (Age, Weight, Sex Distribution)

	Age	Weight	Male	Female
I-gel	36.6 ± 12.56	60.3 ± 6.55	21 (42%)	29 (58%)
LMA-classic	36.9 ± 12.66	60.8 ± 6.31	16 (32%)	34 (68%)

Table 2: Comparison of Ease of Insertion

	Easy	Moderate	Difficult
I-gel	43 (86%)	5 (10%)	2 (4%)
LMA-classic	30 (60%)	13 (26%)	7 (14%)

Table 3: Distribution of Post-operative Complications

	Cough	Hoarseness of voice	Blood traces
I-gel	3 (6%)	2 (4%)	1 (2%)
LMA-classic	10 (20%)	7 (14%)	6 (12%)

Discussion

Insertion of the i-gel airway was easy in the vast majority of cases. The ease of insertion was more with i-gel (43/50) than with LMA-classic (30/50). The i-gel, once lubricated, is often inserted with remarkably little friction between it and the tissues. J J Gatward *et al.* says, the fact that there is no cuff to inflate also speeds insertion.[6] In a recent clinical study, i-gel had a firsttime success rate of 90%. Five patients (10%) needed second attempt, while none needed third attempt.

Its relative ease of insertion and design features that aim to reduce the risk of aspiration have already led to suggestion that the i-gel may have a role in airway management during cardiopulmonary resuscitation.[2,3] Anatomical positioning of the i-gel appears to compare well with other supraglottic airway devices. The buccal cavity stabilizer has a widened, elliptical, symmetrical and laterally flattened cross sectional shape, providing good vertical stability upon insertion which is an advantage over LMA-classic with inflatable cuffs where mechanical inflation can cause movement of the device because the distal wedge shape of the mask is forced out of the upper oesophagus.[1]

This study demonstrated that the use of LMA-classic was associated with a higher incidence of cough (20% Vs 6%) and a higher incidence of hoarseness (14% Vs 4%) in patients at 2 hr post-operatively. Trauma to the soft tissues during LMA-classic insertion may account for the higher incidence of post-operative hoarseness in the immediate post-operative period.[4] Incidence of blood staining of the device was more with LMA-classic (6/50) than with i-gel (1/50). Levitan and Kinkle presumed that inflatable masks have the potential to cause tissue distortion, venous compression and nerve injury.[7]

Conclusion

The i-gel is a cheap and effective device which is easier to insert (statistically significant as compared to LMA-classic). It has other potential advantages like less blood staining of the device and less tongue, lip and dental trauma. Also, i-gel has an advantage over LMA-classic in that it has an integral tube through which stomach contents can be aspirated and also prevent excessive in-advertent ventilation of the stomach.

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