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Original Research Article

A Comparative Study of LMA Supreme with I-Gel in Spontaneously Breathing Anaesthetised Adult Patients Undergoing Elective Short Surgical Procedures

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Abstract:

Background: In this study, we wanted to evaluate the performance of two supraglottic airway devices i-gel and LMA supreme in spontaneously breathing patients undergoing elective short surgical procedures under general anaesthesia.

Methods: This was a hospital based randomized prospective study conducted among 60 patients who underwent short surgical procedures under general anaesthesia, belonging to ASA class I and II in Chigateri General Hospital, Women and Children Hospital and Bapuji Hospital, attached to J.J.M Medical College, Davangere from December 2012 to July 2014, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Results: The first-time insertion rate was similar in both the groups (30 with LMA supreme compared to 29 with i-gel LMA). The insertion of i-gel was easy in 16 patients and moderately difficult in 14 patients. The insertion of LMA supreme was easy in 24 patients, moderately difficult in 5 patients and difficult in 1 patient. There were no significant haemodynamic changes between i-gel and LMA supreme with respect to heart rate, blood pressure and arterial saturation (SpO2). Complications were not significantly different between the two groups.

Conclusion: We conclude that both devices are suitable for routine use during maintenance of anaesthesia in spontaneously breathing patients under general anaesthesia with normal airways. Both LMA supreme and i-gel appear to be effective in establishing a clinically patent airway and have high success rates of insertion, without haemodynamic changes and low morbidity. LMA supreme was slightly easier to insert than the i-gel. Supraglottic devices which can avert the complications of endotracheal intubation are feasible emerging alternative options.

Keywords: Laryngeal Mask Airway, LMA Supreme, I-gel, Supraglottic Airway Devices.

Introduction

The major responsibility of the anaesthesiologist is to secure airway and provide adequate ventilation to patients subjected to general anaesthesia. The most vital element in providing respiration is maintenance of patent airway. The tracheal intubation is the gold standard method for maintaining a patent airway during general anaesthesia. Maintaining a patent airway is essential for adequate oxygenation and ventilation and failure to do so even for a brief period of time can be life threatening. Inability to maintain airway explains more than 30 % of deaths in anaesthesia.[1] Laryngoscopy and endotracheal intubation produce reflex sympatho-adrenal stimulation and are associated with raised levels of plasma catecholamines, hypertension and tachycardia.[2] Airway devices available can be classified as intraglottic and extraglottic airway devices, which are employed to protect the airway both in elective as well as emergency situations.[3]The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Dr. Archie Brain, a British anaesthesiologist, for the first time introduced the laryngeal mask airway designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation. The insertion is simple and atraumatic. Careful observations and clinical experience have led to several refinements of Brain's original prototype leading to development of newer supraglottic airway devices with better features for airway maintenance.[4] i-gel is a new, supraglottic airway device, for use during anaesthesia, with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. The i-gel has several other useful design features including a gastric channel which allows early recognition of regurgitation of gastric contents and passage of a drainage tube.[5] The LMA supreme is a new supraglottic airway device, made up of medical grade PVC and is latex-free. It has an anatomically shaped airway tube into which a separate drain tube has been incorporated and a modified inflatable cuff, designed to offer higher airway seal pressures around the laryngeal opening. This also incorporates an integral bite block and a tab for adhesive tape fixation of the device. The firm, elliptical and anatomically shaped airway tube facilitates easy insertion, without placing fingers in the patient's mouth or requiring an introducer tool for insertion, includes patented fins designed to prevent occlusion of the airway by the epiglottis.[6]

Aims and Objectives

To study and compare two supraglottic airway devices - i-gel and LMA supreme, in anaesthetised adult patients with spontaneous ventilation, with respect to

Ease of insertion

Number of insertion attempts

Haemodynamic changes like heart rate, blood pressure and oxygen saturation (SpO_2)

Incidence of Adverse Effects Like: Regurgitation / aspiration, Tongue or lip trauma, post-operative sore throat, dysphagia or hoarseness, Blood on device, Laryngospasm.

Methods

This was a hospital based randomized prospective study conducted among 60 patients who are undergoing elective short surgical procedures under general anaesthesia belonging to ASA class I and II at Chigateri General Hospital, Women and Children Hospital and Bapuji Hospital attached to J.J.M Medical College, Davanagere from December 2012 to July

2014 after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

The study population which fulfilled the inclusion and exclusion criterion was randomly divided into two groups with 30 patients in each group using sealed envelopes containing the name of the group and the patient was asked to pick up the envelope.

Inclusion Criteria

Patients aged between 18 - 60 years

American Society of Anaesthesiologists (ASA) grade I-II

Mallampati (MP) grade 1 and 2

Body Mass Index (BMI) between 20 - 25 kg/m^2

Scheduled for elective surgeries

Exclusion Criteria

Age < 18 years and > 60 years

ASA III and IV

MP 3 and 4

Patients having any abnormality of the neck, anticipated difficult airway

Mouth opening ≤ 2 cm

Upper respiratory tract infections

History of obstructive sleep apnoea

Obese patients with BMI > 25 kg/m^2

Patients with increased risk of aspiration

Duration of surgery > 1hour

Study Group I had i-gel LMA inserted (n = 30)

Study Group S had supreme LMA inserted (n = 30). Result values were recorded using a preset proforma.

Study Procedure

Pre-anaesthetic evaluation was done on the evening before surgery. Pre-anaesthetic examination was conducted assessing.

General condition of the patient

Airway assessment by Mallampati grading

Nutritional status and body weight of the patient

A detailed examination of the cardiovascular system

A detailed examination of the respiratory system

The following investigations were done in all patients:

Haemoglobin estimation

Urine examination for albumin, sugar and microscopy

Blood sugar

Blood urea and serum creatinine

Standard 12-lead electrocardiogram

All patients included in the study were pre-medicated with tablet diazepam 10 mg and tablet ranitidine 150 mg orally at bedtime, on previous night. They were kept nil orally from 10 pm onwards on the previous night. On arrival of the patient in the operating room, a 20-gauge intravenous cannula was inserted, and an infusion of dextrose normal saline was started. The patient's head was placed on a soft pillow of 10 cms before induction of anaesthesia with the neck flexed and head extended. The patient was connected to multiparameter which records heart rate, non-invasive measurements of systolic blood pressure, diastolic blood pressure, mean arterial pressure and continuous ECG monitoring and oxygen saturation. The baseline systolic, diastolic and mean arterial blood pressure, saturation and heart rate were recorded. Patients were pre-medicated with Inj. Metoclopramide 10 mg. I.V., Inj. Glycopyrrolate 0.2 mg, Inj. Pentazocine 0.5mg/kg and Inj. Midazolam 0.05 mg/kg I.V. Preoxygenation with 100 % oxygen given for 3 mins. Anaesthesia was induced with Inj. propofol 2 mg/kg I.V. with Inj. lignocaine 2 % I.V. given prior to prevent pain on injection with propofol. Induction of anaesthesia was confirmed by

loss of verbal communication with the patient and loss of eyelash reflex. If coughing, gagging, or body movement occurred during insertion, a further dose of propofol 0.5 mg/kg will be given to achieve an adequate depth of anaesthesia. Once an adequate depth of anaesthesia was achieved, the allotted device was inserted according to the manufacturer's instructions. The patient's head was placed in sniffing the morning air position. The standard pre-tests for both the devices were performed. The airway devices were coated with a water-soluble lubricant and inserted with the patient's head in the standard intubating position. Group I had i-gel inserted, size was chosen by anaesthetist based on patient's body weight and manufacturer's recommendation, size 3 for patients weighing between 30 - 50 kgs, size 4 for patients between 50 - 90 kgs. For Group S patients, LMA supreme size 3 for 30 to 50 kgs patients, size 4 for 50 to 70 kgs patients and size 5 for 70 to 90 kgs patients was used as per manufacturer's recommendation. The standard technique of insertion was followed. The device was connected to breathing circuit and patient ventilated manually. Once in place, the cuff of LMA supreme was inflated with the specified amount of air according to the size as recommended to create an effective seal. The LMA was taped to the upper lip in the usual manner. After securing the device in place, anaesthesia was maintained with 30 % O_2 + 70 % N_2O + intermittent Inj. propofol. IPPV was done till spontaneous ventilation was regained. Adequacy of ventilation was assessed by observing chest expansion and auscultation of breath sounds.

The following parameters were assessed

Number of attempts required to insert each device. It was graded as 1 attempt, 2 attempts, 3 attempts or abandoned.

Ease of insertion described according to subjectiveness of single user as easy, moderately difficult, difficult or impossible.

Hemodynamic parameters [Heart rate, Blood pressure, Oxygen saturation (SpO_2)] basal, after insertion of device, at 5 mins, 15 mins, 30 mins and after removal of device.

Intra and post-operative complications with each device assessed such as, regurgitation/aspiration, tongue/lip injury, blood on device, sore throat, hoarseness, dysphagia and laryngospasm.

At the end of procedure, when the patient was fully awake and adequate airway reflexes attained, the devices were removed after deflating the cuff. Data obtained was coded and entered into a Microsoft excel spreadsheet. The categorical data was expressed in terms of rates, ratios and percentage and continuous data expressed in terms of mean +/- standard deviation. Student's unpaired t test was used to compare quantitative variables in both groups and change in pressure compared with student's paired t test for each group independently. The categorical data was compared with Chi square test. The probability value (p value) less than or equal to 0.05 was considered to be statistically significant.

Statistical Methods

Data was entered in MS Excel and analysed using Statistical Package for Social Sciences

(SPSS) software. Results were presented as tables.

Results

Table 1: Duration of Surgery

Duration	**Group I**		**Group S**	
	Mean	**SD**	**Mean**	**SD**
	21.5	7.1	20.5	6.7
t value	0.56			
P value	0.28, NS			
ASA GRADING				
ASA	Group I		Group S	
	No.	%	No.	%
1	21	70.0	26	86.7
2	9	30.0	4	13.3
Total	30	100	30	100
$X^2 = 2.46$ P = 0.12, NS				
MALLAMPATI (MP) SCORE				
MP	Group I		Group S	
	No.	%	No.	%
1	22	73.3	20	66.7
2	8	26.7	10	33.3
Total	30	100	30	100
$X^2 = 0.32$, P = 0.57, NS				
NUMBER OF ATTEMPTS				
No. of attempts	Group I		Group S	
	No.	%	No.	%
1	29	96.7	30	100.0
2	1	3.3	0	0
3	0	0	0	0
A	0	0	0	0
Total	30	100.0	30	100.0
$X^2 = 1.02$, P = 0.31, NS				
EASE OF INSERTION (E/M/D/I)				
Ease of Insertion	Group I		Group S	
	No.	%	No.	%
E	16	53.3	24	80.0
M	14	46.7	5	16.7
D	0	0.0	1	3.3
I	0	0.0	0	0.0
Total	30	100.0	30	100.0
$X^2 = 6.83$, P = 0.03, S			P < 0. 05, S	

In group I, the mean duration of surgery was 21.5 ± 7.1 minutes and in group S it was 20.5 ± 6.7 minutes which was statistically not significant (p = 0.28).

In ASA grading, it is seen that statistically there is no significant difference in both the groups. In the Mallampati score, it is seen that statistically there is no significant difference in the Mallampati score in both the groups. In number of attempts, it is seen that 29 of 30 (96.7 %) insertions in Group I were in the first attempt and only 1 patient required 2nd attempt. All insertions 30 (100 %) in the Group S were in first attempt. There was no significant difference between both the groups. The insertion of i-gel in Group I patients was easy in 16 patients and moderately difficult in 14

patients. The insertion of LMA supreme in Group S patients was easy in 24 patients, moderately difficult in 5 patients and difficult in 1 patient. The ease of insertion was statistically significant between the two groups. (p = 0.03). The LMA supreme was rated easier to insert than the i-gel.

Table 2: Heart Rate Comparison

HR	Group I		Group S		Mean Diff	t Value	P Value
	Mean	SD	Mean	SD			
Basal	80.3	12.9	85.3	13.1	4.9	1.47	0.15, ns
AI	96.2	12.9	98.0	11.8	1.9	0.59	0.56, ns
5'	88.6	11.7	89.2	11.6	0.5	0.18	0.16, ns
15'	82.0	8.1	85.1	11.5	3.1	1.22	0.23, ns
End	94.2	11.6	98.0	10.4	3.8	1.35	0.18, ns
Unpaired t test P > 0.05, Not Sig. (NS)							
Systolic Blood Pressure Comparison							
SBP	Group I		Group S		Mean Diff	t Value	P Value
	Mean	SD	Mean	SD			
Basal	115.0	10.6	117.3	8.5	-2.23	-0.90	0.37, NS
AI	129.0	10.8	133.1	8.4	-4.10	-1.64	0.11, NS
5'	117.9	11.6	114.5	8.9	3.37	1.27	0.21, NS
15'	119.6	9.2	115.8	7.7	5.87	1.73	0.43, N S
End	125.1	11.2	119.6	10.8	5.50	1.93	0.06, NS
Unpaired T Test, P > 0.05, Not Sig. (NS)							
Diastolic Blood Pressure Comparison							
DBP	Group I		Group S		Mean Diff	t Value	P Value
	Mean	SD	Mean	SD			
Basal	75.6	12.2	75.1	8.2	0.47	0.17	0.86, ns
AI	75.5	11.5	76.8	11.2	1.27	0.44	0.66, ns
5'	74.1	10.3	74.5	6.3	-0.40	-0.18	0.85, ns
15'	72.2	10.7	75.2	7.5	-3.00	-1.26	0.21, ns
End	80.4	16.6	75.1	8.1	5.30	1.57	0.12, ns
Unpaired t test P > 0.05, Not sig.(NS)							

The basal heart rate was comparable in both the groups. Statistical evaluation between the groups showed no significant difference in HR changes between Group I and Group S after insertion, at 5 min, 15 min and after removal of devices.

Statistical evaluation between the groups showed no significant difference in SBP changes between Group I and Group S after insertion, at 5 min, 15 min and after removal of devices.

Statistical evaluation between the groups showed no significant difference in DBP changes between Group I and Group S after insertion, at 5 min, 15 min and after removal of devices.

Table 3: Mean Arterial Pressure Comparison

MAP	Group I		Group S		Mean Diff	t Value	P value
	Mean	SD	Mean	SD			
Basal	93.9	11.4	91.8	9.8	2.10	0.77	0.447
AI	94.2	10.9	95.8	9.7	-6.93	0.60	0.53
5'	89.2	9.7	89.7	8.0	-0.50	-0.22	0.828

15'	87.1	8.7	88.2	9.9	-1.07	-0.45	0.658
End	91.2	9.3	89.80	9.6	9.20	0.81	0.72
Unpaired t test* P < 0.05, S P > 0.05, Not sig. (NS)							
SpO_2 Comparison							
SPO_2	Group p I				Group S		
	Mean		SD		Mean		SD
Basal	99.4		0.7		99.7		0.5
AI	99.1		1.1		99.2		0.8
5'	98.8		0.8		99.4		0.5
15'	99.0		0.8		99.2		0.6
End	98.9		0.5		99.1		0.6
Unpaired t test* P < 0.05, S P > 0.05, Not sig. (NS)							
Complications							
Complications	Group I				Group S		
	No.		%		No.		%
Blood on device	2		6.7		2		6.7
Laryngospasm	1		3.3		2		6.7
Sore throat	3		10.0		4		13.3
Tongue / Lip injury	3		10.0		1		3.3
None	21		70.0		21		70.0
Total	30		100.0		30		100.0

Statistical evaluation between the groups showed no significant difference in MAP changes between Group I and Group S after insertion, at 5 min, 15 min and after removal of devices. The mean SpO_2 was comparable in both the groups. Statistical evaluation between the groups showed no significant difference in SpO2 changes between Group I and Group S after insertion, at 5 min, 15 min and after removal of devices. Blood on device was noted in 2 patients in both the groups. Laryngospasm was seen in 1 patient in Group I and in 2 patients in Group S. 3 Patients in Group I developed sore throat and 4 patients in Group S developed sore throat. Tongue/Lip injury was noted in 3 patients in Group I and in 1 patient in Group S. None of the patients developed hoarseness or dysphagia, regurgitation/aspiration. Complications were comparable in both the groups and were not statistically significant.

Discussion

Dr. Brain's classic-LMA (C-LMA) was introduced into clinical practice in 1988 and has an enormous body of evidence to support the use both in terms of efficacy and safety. There are over 2500 papers and some 270 million uses. The literature describes only one death directly attributable to the device, although this is certainly an underestimate. Before the C-LMA, airway management options consisted of face mask or tracheal intubation. 20 years on the CLMA and still the dominant choice of airway for anaesthesia in UK being used in an estimated 50 % of cases.[7] In the past 25 years with the development of various supraglottic devices, the armamentarium for airway management has increased. The best evidence requires a randomized controlled trial comparing new devices, properly powered to detect clinically relevant differences in clinically important outcomes. The present prospective randomized study was undertaken to compare two supraglottic airway devices i-gel and LMA supreme in patients

undergoing short surgical procedures under general anaesthesia with spontaneous ventilation with respect to the number of attempts for insertion, ease of insertion, hemodynamic changes and complications. The study population consisted of 60 patients belonging to ASA I and II divided randomly into two groups using simple closed envelope method with 30 patients in each group

Group I – 30 patients in whom I gel was used

Group S – 30 patients in whom LMA supreme was used

Demographic Criteria

Both the groups were comparable and there was no statistically significant difference with regards to mean age, weight, sex, duration of surgery, MP grading, size of the device selected.

Number of Attempts

In this study, insertion of i-gel was successful in 96.7 % of patients in first attempt and 3.3 % in second attempt as compared to 100 % with supreme LMA in first attempt. Very similar results were found in studies conducted by E.F.F Chew et al. [8] Fernandez et al. [9] Suman et al.[10]W.H.L Teoh[11] et al. So both i-gel, SLMA could be inserted easily in the 1st attempt.

Ease of Insertion

One of the primary objectives was to compare the ease of insertion between the 2 devices. The grading of insertion was done similar to the study conducted by Dr. Ruchi Gupta et al. [12] where ease of insertion was described according to the subjectiveness of the single user as easy, moderately difficult, difficult or impossible.

In our study in group I, insertion was easy in 16 (53.3 %) of patient, moderately difficult in 14 (46.7 %) and difficult in none of the patients. In group S, insertion of LMA was easy in 24 (80 %) of patients, moderately difficult in 5 (16.7 %) and difficult in 1 (3.3 %) patients.

There was statistically significant difference between the two groups with respect to ease of insertion, the insertion of SLMA was found comparatively easier and required less skill as compared to i-gel.

This was comparable to a study done by E F F Chew et al. in which insertion of SLMA was also easier compared to i-gel. (97.8 % in SLMA v/s 93.3 % in i-gel).

Haemodynamic Changes

During insertion of the supraglottic airway device, the pressor response (i.e., increase in HR & BP), may be induced by passage of the device through the oral and pharyngeal spaces, pressure produced in the larynx and pharynx by the inflated cuff.[13] During removal of the device, the hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of cuff.

The following hemodynamic parameters were recorded in all patients.

Heart rate (HR) in bpm

Systolic blood pressure (SBP) mm Hg

Diastolic blood pressure (DBP) mm Hg

Saturation SpO2

The above haemodynamic parameters were monitored in the following time interval – basal after insertion, 5 min, 15 min and 30 min after removal of device.

In our study, there was no statistically significant difference between i-gel and SLMA with regard to HR, SBP, DBP and SpO2. This is comparable to the study done by W. H. L. Teoh2010 et al. [11] who in their studies found no significant differences between i-gel and SLMA with regard to hemodynamic changes.

There was a rise in HR SBP, and DBP after insertion of the device in both the groups which were comparable and could be due to the pressor response generated but they were not significant statistically.

Complications

The inflatable supra glottic airway devices, during insertion, the deflated leading edge of mask can catch the epiglottis edge and cause it to down fold or impede proper placement beneath the tongue and can cause pharyngeal injury. They can also cause tissue distortion, venous compression and nerve injury. Also, deeper posterior of LMA in pharynx is responsible for more number of complication such as sore throat.[12]

In our study, sore throat was present in 3 (10 %) patients in Group I and in 4 patients (13.3 %) in Group S which was not statistically significant .1 patients with i-gel had laryngospasm whereas 2 of the patients with SLMA developed laryngospasm.

The incidence of tongue/lip injury was 3 (10 %) in i-gel group and 1 (3.3 %) in SLMA group and blood on the device was seen in 2 patients (6.7 %) in both groups. None of the patients developed hoarseness or dysphagia, regurgitation/aspiration.

In a study done by E F F Chew et al.[8] laryngospasm was seen in 2 patients with SLMA and none in i-gel group. Sore throat was seen in 2 patients in i-gel group and in 4 patients in SLMA group. Mucosal injury was seen in 4 patients in i-gel group and 3 in SLMA group. In a study done by Suman Chattopadhyay et al.[10] blood on device was seen in 3 patients with igel and 4 patients in SLMA group. Lip trauma was seen in 3 patients in i-gel group and in 2 patients in SLMA group. Post-operative sore throat was seen in 3 patients in i-gel group and in 4 patients in SLMA group.

Our results were similar to the above studies. Incidence of complications was similar and minimal in both the groups.

Conclusion

We conclude that both devices are suitable for routine use during maintenance of anaesthesia in spontaneously breathing patients under general anaesthesia with normal airways. Both LMA supreme and i-gel appear to be effective in establishing a clinically patent airway and have high success rates of insertion, without haemodynamic changes and low morbidity. LMA supreme was slightly easier to insert than the i-gel. Supraglottic devices which can avert the complications of endotracheal intubation are feasible emerging alternative options.

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