

A Study to Compare Efficacy of Cuffed Oropharyngeal Airway with Laryngeal Mask Airway in Patients Undergoing Elective Short Surgical Procedures Under General Anaesthesia with Spontaneous Ventilation

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Abstract

Background: In this study, we wanted to evaluate the efficacy of cuffed oropharyngeal airway (COPA) when compared to laryngeal mask airway (LMA) in patients aged 18 to 60 years undergoing elective short surgical procedures under general anaesthesia with spontaneous ventilation.

Materials and Methods: This was a hospital based randomized prospective study conducted among 100 patients who underwent elective short surgical procedures of duration < 45 mins 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: Insertion of COPA was very easy in 46 patients and moderately difficult in 2 patients. Insertion of LMA was easy in 41 patients, moderately difficult in 6 patients, difficult in 2 patients and impossible in 1 patient. The first-time insertion rate was more with COPA when compared with LMA. Airway manipulation like jaw thrust was required more with COPA than with LMA. The mean duration of insertion was significantly lower with COPA than with LMA. There were no significant haemodynamic changes between COPA and LMA with respect to heart rate, blood pressure and arterial saturation (SpO₂). LMA had slightly more incidence of post-operative sore throat, cough and laryngospasm compared to COPA.

Conclusion: With respect to physiologic alterations using the devices and overall clinical problems, the COPA and LMA are equivalent. The LMA is associated with a better airway quality and fewer manipulations during use but a higher incidence of complications. The COPA offers advantage in terms of cost, rapid insertion in unskilled hands and low complication rate but the major drawback being frequent airway manipulations and a poor hands-free anaesthesia.

Keywords: Laryngeal Mask Airway, Cuffed Oropharyngeal Airway, Efficacy of Insertion, Airway Manipulation.

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Introduction

Airway is the passage through which the air/gas passes during respiration. Artificial devices which have a lumen serve as a conduit for passage of air or gases. 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. Respiratory events are the most common anaesthetic related injuries following dental damage. The 3 main causes for respiratory injuries are inadequate ventilation, oesophageal intubation and difficult tracheal intubation. Inability to maintain airway explains more than 30 % of deaths in anaesthesia.[1] Before 1990, only the face mask and the endotracheal tube (ETT) were the available airway devices. Since then, several supraglottic airway devices have been developed, like laryngeal mask airway and cuffed oropharyngeal airway.[2] With a face mask, one or more of the anaesthesia provider's hands are in continuous use, and higher fresh gas flows are often needed. When compared with patients who are managed on supraglottic airway device, patients managed on face mask have more episodes of oxygen desaturation, require more intra-operative airway manipulations and present more difficulties in maintaining an airway. In spontaneously breathing patients, the work of breathing is higher with a face mask than with a supraglottic airway device. Using an airway and/or continuous positive pressure will reduce the work of breathing.[2] Supraglottic airway devices have become a standard fixture in airway management, filling a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. These devices sit outside the trachea but provide hands free means of achieving a gas-tight airway.[2] The LMA was conceived and designed by Dr. Archie Brain in U.K. in 1981.[3] Following prolonged research, it was released in 1988. At an early stage in

its development, the inventor realized its potential in the management of the difficult airway. Today, it has a clearly established role as an airway device in the elective setting where neither the procedure nor the patient requires tracheal intubation. It has now become an established part of routine airway management and has proved extremely useful in managing the difficult airway. The LMA fills a niche between the face mask (FM) and tracheal tube (TT) in terms of both anatomical position and degree of invasiveness. Since the introduction of LMA in 1981, it has gained widespread popularity for airway management. This device which is intermediate in design between a face mask and a tracheal tube, is inserted blindly into the pharynx where it forms a low pressure seal around the laryngeal inlet.[3] Despite its various advantages, in addition to being expensive, there are certain disadvantages also like aspiration of gastric contents, aerophagia, uvular bruising, laryngospasm etc.[3] In order to find an alternative, in 1992 Greenberg and Toung introduced COPA, a disposable piece of equipment, which is cheaper but has a use similar to LMA.3 The cuffed oropharyngeal airway (COPA; Mallinckrodt Medical, Athlone, Ireland) is a new supraglottic airway device that has been available in the United States since mid-1997. The device is a modified Guedel airway with an inflatable distal cuff and a proximal connector for attachment to the anaesthesia breathing system.[4] The COPA was designed to displace the tongue, elevate the epiglottis, and form an airtight seal in the proximal laryngopharynx. The study was conducted in order to evaluate the efficacy of the COPA compared to LMA in our set of patients, with regards to number of attempts at insertion, insertion time, ease of insertion, airway manipulations, haemodynamic variables and complications.

Aims and Objectives

To evaluate the efficacy of COPA compared to LMA in patients aged 15 to 60 years undergoing elective short surgical procedures under general anaesthesia with spontaneous ventilation with regard to the number of attempts at insertion, insertion time, ease of insertion, airway manipulations, haemodynamic variables and complications.

Materials and Methods

This was a hospital based randomized prospective study conducted among 100 patients who underwent elective short surgical procedures of duration < 45 mins. 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.

Inclusion Criteria

ASA grade I and II
Age 18 to 60 years
Short surgical procedures (< 45 min duration)

Exclusion Criteria

Patient refusal
ASA grade III and IV
MP III and IV
Emergency surgeries
Patients at risk for pulmonary aspiration - GERD, Achalasia cardia, morbid obesity, delayed gastric emptying.
Reactive airway- Bronchial asthma, COPD, active smokers
Cleft lip and cleft palate
Abnormalities of the oral cavity
Patients not NPO
Pregnancy

Study Procedure

Pre-anaesthetic evaluation was done on the evening before surgery. 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 patients was asked to pick up the envelope.

All patients included in the study were pre-medicated with tablet diazepam 10 mg and tablet ranitidine 150 mg orally at bedtime the previous night before surgery. They were kept nil orally for solids 10 pm onwards on the previous night and for clear fluids up to 2 hours before induction.

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 cm 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 SBP, DBP, MAP, and continuous electrocardiogram (ECG) monitoring and oxygen saturation. The baseline systolic, diastolic blood pressure, saturation and heart rate were recorded. Patients were pre-medicated with Inj. Pentozocine 0.5 mg/kg, Inj. Glycopyrrolate 0.2 mg and Inj. Midazolam 0.05 mg/kg. After pre-oxygenation with 100 % oxygen for 3 mins via a face mask with bain's circuit, anaesthesia was induced with Inj Propofol 2 mg/kg i.v wit 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. 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 C had COPA inserted, size was chosen by placing the distal top of the

device at the angle of the jaw of the supine patient with the tooth guard 1 cm beyond the lips, COPA being perpendicular to the ground. Guedel or reverse guedel insertion technique was followed.

Group L had LMA inserted, the size 3 classic-LMA for patients weighing 30 - 50 kgs., size 4 for 50 - 70 kgs. and size 5 for patients of > 70 kgs. The standard technique of insertion was followed.

Once inserted, the cuff was inflated with sufficient air to create an effective seal. The COPA was secured using the enclosed elastic fixation strap and the LMA was taped to the upper lip in the usual manner.

After securing the device in place, anaesthesia was maintained with 33 % O₂ + 66 % N₂O + intermittent Inj. Propofol using Bain circuit. 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.

Insertion time noted as the time of removal of face mask to confirmation of breath sounds with device in place.

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.

Hands free anaesthesia assessed according to manipulations of airway required if required or not.

Haemodynamic parameters (NIBP, pulse, saturation) basal, after insertion of device, 5 mins., 10 mins., 15 mins., 30 mins.

Intra and post-operative complications with each device assessed such as sore throat, coughing, lip/dental injury, blood on device, laryngospasm.

At the end of procedure, when the patient was fully awake and adequate airway reflexes attained, the devices were removed without deflating the cuff to remove the secretions along.

Statistical Methods

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. 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.

Results

The ASA, MP and device size distribution among the 2 groups all of which were statistically not significant.

In 46 (92 %) out of 50 patients, COPA was inserted in 1st attempt and in 4 (8 %) patients, it was inserted in 2nd attempt when compared to LMA in which only in 37 (74 %) patients it could be inserted in 1st attempt, in 10 (20 %) patients, it could be inserted in 2nd attempt and 2 patients (4 %) required 3rd attempt and it was abandoned in one patient. This was statistically not significant but compared to LMA, COPA has more first attempt insertion.

Table 1

Variables		COPA	LMA	Statistical Analysis
ASA	I	42	42	Not significant
	II	8	8	
MP	I	17	24	Not significant
	II	29	18	
	III	4	8	
Size		30 (8)	25 (3)	Not significant
		20 (9)	25 (4)	
Variables		COPA	LMA	Statistical Analysis
Number of attempts	First attempt	46	37	Not significant
	Second attempt	4	10	
	Third attempt	0	2	
	Abandoned	0	1	
Time in sec (mean & SD)		14.5 2.77	26.28 4.59	T = 15.49, P < 0.000(S)
EASE of Insertion	Easy	46	41	Not significant
	Moderately difficult	2	6	
	Difficult	2	2	
	Impossible	0	1	
Airway manipulation	Single manipulation	24	12	$\chi^2 = 5.91, P < 0.01(S)$
	No manipulation	26	37	

The main time taken for insertion of COPA (14.5 ± 2.77 sec) was significantly less when compared to LMA (26.28 ± 4.59 sec) ($p < 0.000$ - highly significant). Our results indicate that COPA insertion required less time as compared to LMA.

Easy insertion was possible in 46 (92 %) of patients, moderately difficult in 2 (4 %) and difficult in 2 (4 %) requiring jaw thrust and other airway manipulate in group C whereas with LMA easy insertion was possible in only 41 (82 %), moderately

difficult in 6 (12 %), difficult in 2 (4 %) and impossible in 1 patient which was statistically not significant.

Once device was in place, more number of airway manipulations were required to maintain an unobstructed airway in Group C (24 patients 48 %) whereas only 12 patients (24 %) required manipulation with LMA which was highly significant statistically ($p < 0.01$). Thus, LMA provided better hand free anaesthesia compared to COPA.

Table 2

Heart Rate					
Measures	COPA		LMA		Statistical Analysis Unpaired t Test
	Mean	Std. Deviation	Mean	Std. Deviation	
Basal	87.88	12.79	89.55	11.44	0.68, NS
AI	94.08	13.33	98.98	13.38	1.82, NS
After 5 min	93.60	12.99	97.02	11.63	1.38, NS
After 10 min	90.12	12.87	93.22	10.06	1.33, NS
15 min	89.4	13.4	93.5	17.4	1.32, NS
30 mins	84.8	12.4	88.4	9.43	1.63, NS
Inter Group Comparison of SBP					
	COPA		LMA		

	Mean	Std Deviation	Mean	Std Deviation	Statistical Analysis Unpaired t Test
Basal	122.36	13.35	121.43	9.45	0.97, NS
AI	129.76	13.63	128.43	10.04	0.79, NS
After 5 min.	129.36	13.83	128.33	9.34	0.68, NS
After 10 min.	123.80	11.84	122.98	8.40	0.59, NS
After 15 mins.	123	16.3	119	8.84	1.52, NS
After 30 mins.	120	6.63	122	9.43	1.22, NS
DBP (mm/Hg)					
Measure	COPA Group		LMA Group		Statistical Analysis Unpaired t Test
	Mean	Std. Deviation	Mean	Std. Deviation	
Baseline	75.5	11	74.2	8.58	0.83
After induction	81.8	10.8	83.8	8.28	0.79
After 5 min	81.4	11.1	80.9	8.9	0.44
After 10 min	78	10	79	8.9	0.29, NS
15 min	75	8.5	78	9.9	1.62, NS
30 min	76	4.9	78	8.8	1.40, NS

The basal HR was comparable in both the groups. Statistically, evaluation between the groups showed no significant changes in HR between Group C and L after insertion and at 5, 10, 15, 30 min after insertion. Though there was an increase on HR following insertion of both the devices, it was comparable among the 2 groups and was statistically not significant.

The basal, after insertion 5, 10, 15 and 30 min SBP was comparable among the 2 groups and was not statistically significant.

Though there was a slight rise in SBP following insertion of both the devices, it was comparable and statistically not significant.

The basal, after insertion 5, 10, 15, 30 min DBP were comparable in both groups and was not statistically significant. Though there was a slight rise in DBP following insertion of both devices, it was statistically not significant.

Table 3

SpO₂				
Measure	COPA Group		LMA Group	
	Mean	Std. Deviation	Mean	Std. Deviation
Baseline	98	0.7	98	0.6
After induction	98.9	0.52	98.7	0.47
After 5 min	98.9	0.49	98.7	0.48
After 10 min	99	0.38	98.8	0.44
15 min	99.3	0.46	99	0
30 min	99.3	0.46	99	0
Complications				
Parameters	COPA Group		LMA Group	
	Frequency	Percentage	Frequency	Percentage

Cough	Present	4	8	8	16
	Absent	46	92	42	84
Lip / Dental injury	Present	2	4	2	4
	Absent	48	96	48	96
Blood on device	Present	4	8	4	8
	Absent	46	92	46	92
Sore throat	Present	4	8	8	16
	Absent	46	92	42	84
Laryngospasm	Present	0	0	2	4
	Absent	50	100	48	96
Aspiration	Present	0	0	0	0
	Absent	50	100	50	100

The mean SpO₂ was comparable in both the groups and the statistical evaluation showed no significant difference in SpO₂ between Group C and L after insertion and at 5, 10, 15 min intervals after insertion.

Lip / Dental injury was present in 2 (%) in both Group C and Group L which was not statistically significant. Blood on removal of device was present in 4 (8%) in both group C and L which was not statistically significant. Sore throat was present in 4 (8%) in group C and 8 patients (16%) in group L which was not statistically significant but comparatively more in LMA Group. The sore throat was mild requiring no treatment. Cough was present in 4 (8%) of patients in Group C and 8 (16%) of patients in Group L which was not statistically significant but compared to COPA group, LMA group had more incidence of post op cough. 2 patients (4%) had laryngospasm on insertion of LMA and no such episodes in Group C.

Discussion

In this study, insertion of COPA was successful in 92% of patients in first attempt when compared to 74% with LMA in first attempt. Airway manipulations like head tilt, jaw thrust was required in 4 patients with COPA whereas with 12 patients with LMA to insert the device. In 1 patient, LMA could not be inserted despite airway manipulation and was abandoned. This was not statistically significant.

Very similar results were found in studies conducted by Ruchi Gupta et al. [3] Indula Panchal [5] et al. Janet M Van Vlymen[6] et al., Voyagis et al.[7].

So compared to LMA, COPA could be inserted more easily in the 1st attempt.

Time of insertion

The time of insertion was considered according to the study conducted by Dr. Ruchi Gupta et al. [3] as the time of removal of face mask to confirmation of breath sounds with device in place. In our study, the time of insertion of COPA (14.5 Sec) was shorter compared to LMA (26.28 SEC) which was highly significant statistically.

Consistent with our results, Ruchi Gupta et al. [3] Janet M Van Vlymen et al. [6] Nakata Y et al.[8]also had significant differences in insertion times. So, COPA had a shorter insertion time compared to LMA.

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., where case of insertion was described according to the subjectiveness of the single user as easy moderately difficult, difficult or impossible.

In our study, case of insertion of COPA was easy in 46 (92%) of patient, moderately difficult in 2 (4%) and difficult in 2 (4%) of

patients. In group L, insertion of LMA was easy in 41 (82%) of patients, moderately difficult in 6 (12%) and difficult in 2 (4%) patients and was impossible in one patient. There was no statistically significant difference between the 2 groups with respect to ease of insertion, but the insertion of COPA was found comparatively easier and required less skill as compared to LMA.

Our study compared the ease of insertion of devices with the study conducted by Ruchi Gupta et al. where easy insertion was possible in 92% cases of group C v/s 80% in group L which were comparable but no failed insertion in any of the patients was observed.

So, COPA was easier to insert in unskilled hands when compared to LMA.

Airway manipulation

One of the primary objectives was to compare the airway manipulation between the 2 devices. This was assessed as per a similar study conducted by Ruchi Gupta et al. [3] and Janet M Van Vlymen et al. [6] in which inadequate ventilation was corrected by manipulating the patient's airway in chin lift, jaw thrust or repositioning the airway.

In our study, airway manipulations were required for 24 patients (48%) in Group C as compared to 12 patients (24%) in group 2 which was statistically significant ($P < 0.01$). This was compared with studies done by Ruchi Gupta et al., Janet M Van Vlymen et al. [6] Voyagis et al.[7], Yavascaoglu B et al.,[9] Ezri et al.[10] JR Brimacombe et al.[11] Indula D Panchal et al.[5] in which airway manipulations were more with COPA as compared with LMA.

Hence, LMA provided a better 'hands free' anaesthesia when compared to COPA. This could be because of basic difference in airway design. The cuff of LMA occupies the wider proximal end of hypopharynx. The need for airway manipulations with COPA is probably related to that variable gap between the distal end of the devices

and laryngeal inlets. A large inter-lumen gap can become obstructed by base of tongue due to action of gravity [12] combined with reduced bone in anaesthetized pharyngeal muscles.

Simple adjustments in head and necks position probably improve airway by stretching the anterior part of neck and pharyngeal structures thus compensating for reduced tone. These manoeuvres also elevate the epiglottis.[13] The inter-lumen gap with LMA is negligible as long as the epiglottis is not down folded or entrapped. Hence airway supportive measures are not required.

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.[14] During removal of the device, the haemodynamic 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 hemodynamic parameters were monitored in the following time interval – basal, after insertion after 5 min, 10 min, 15 min and at 30 min.

In our study, there was no statistically significant difference between COPA and LMA with regard to HR, SBP, DBP and SpO₂. This is comparable to the study done by Ruchi Gupta et al., Yavascaoglu B et al. who in their studies found no significant differences between COPA and LMA with regard to haemodynamic 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.

Conclusion

We conclude that with respect to physiologic alterations using the devices and overall clinical problem, both the COPA and LMA are equivalent. The LMA is associated with a better airway quality and fewer manipulations during use but a higher incidence of complications. The COPA offers advantage in terms of cost, rapid insertion in unskilled hands and low complication rate but the major drawback being frequent airway manipulations and a poor 'hands free anaesthesia'. Ultimately, both devices were similar in establishing a safe and effective airway for spontaneously breathing anaesthetised adults.

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