

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research article
ISSN 2394-3211
EJPMR

A PROSPECTIVE, RANDOMISED COMPARISON OF BASKA MASK, AMBU AURAGAIN AND LMA SUPREME IN SURGICAL PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

Dr. Garima Dabas¹* and Dr. Sahil Gupta²

¹Senior Resident, Department of Anaesthesia and Critical Care, Pt. JLNGMC, Chamba. ²Senior Resident, Department of General Medicine, Pt. JLNGMC, Chamba.

*Corresponding Author: Dr. Garima Dabas

Senior Resident, Department of Anaesthesia and Critical Care, Pt. JLNGMC, Chamba.

Article Received on 01/12/2022

Article Revised on 21/12/2022

Article Accepted on 11/01/2023

ABSTRACT

The most important concern for an anaesthesiologist in laparoscopic surgery is to secure and manage the airway complications due to pneumoperitoneum. The advantages of LMAs over Endotracheal Tube include improved hemodynamic stability at induction and during emergence and most commonly used SADs are second generation devices due to presence of nasogastric tubes, inbuilt bite blocks and having seal pressure of 25-28 cm H₂O. Because of the very similar design of Ambu AuraGain and LMA Supreme and self sealing, membranous, non-inflatable cuff of the Baska mask, this research paper compares the efficacy and safety of Baska mask, LMA Supreme and AAG.

KEYWORDS: LMA, AAG, Baska mask, LMA Supreme, ETT, OLP.

INTRODUCTION

Laparoscopic cholecystectomy is the gold standard for gall stone surgery and general anaesthesia is considered as gold standard but it causes increased catecholamine release, hypertension, tachycardia, myocardial myocardial contractility, ischaemia, depressed ventricular arrhythmias and intracranial hypertension. [1] The advantages of LMAs over Endotracheal Tube (ETT) include ease of insertion, avoidance of neuromuscular blocking agents, hence facilitating spontaneous breathing and avoiding translaryngeal placement with its attendant cardiovascular impact and intimate vocal cord contact. [2] LMAs are also associated with improved hemodynamic stability at induction and during emergence of anaesthesia. The most common SADs used in laparoscopic cholecystectomies are second generation LMAs.

In late 2007, Dr. Archie Brain invented a new second generation SAD i.e. LMA Supreme, that is made up of medical grade polyvinyl chloride (PVC) and latex free. The firm, elliptical and anatomically shaped double airway tube with an inbuilt bite block helps in easy insertion and protect the tube from the bite of patients. ^[3] The double cuff of the LMA Supreme provides a higher seal pressures of 37 cm H₂O and the cuff forms two seals i.e. oropharyngeal and upper esophageal seal. ^[4,5] It is available from size 1 to 5. Another second generation airway device was designed by Kanag and Meena Baska in 2012. Baska mask is made up of medically graded silicone and incorporates a non inflatable, self sealing,

membranous, variable pressure cuff which produces an oropharyngeal seal that increases proportionately with increasing airway pressure. Baska mask incorporates an integrated bite block, gastric reflux drainage system and indicator tab to facilitate insertion. It is available in 4 sizes, ranging from pediatric to adult. Ambu Aura Gain, a newer second generation SAD was further introduced in June 2014. It is a single use, cuffed SAD made up of PVC. It contains a preformed, anatomically curved shaft and a double lumen that ensures its rapid placement. It provides higher sealing pressures i.e. upto 40 cm H₂O and an inbuilt gastric port. Its airway tube is broader and can accommodate a bigger size of ETT, hence it can work as a conduit for intubation. [6,7]

Though, there were many studies that compared the clinical performance of LMA Proseal with these 3 SADs separately, but, there are not many studies in the literature which compare the clinical performance of Baska mask, Ambu Aura Gain and LMA Supreme. Because of the very similar design of Ambu AuraGain and LMA Supreme, we hypothesised that Baska mask would have higher sealing pressures than LMA Supreme and Ambu AuraGain. Hence, we compared these three SADs in terms of oropharyngeal leak pressure, ease of insertion, difference in the time taken to insert these devices and incidence of postoperative morbidities in 150 patients undergoing Laparoscopic Cholecystectomy in IGMC, Shimla.

AIM AND OBECTIVES

 ΔIM

Comparison of the efficacy and safety of Baska mask, Ambu AuraGain and LMA Supreme.

PRIMARY OBJECTIVE

Comparison of the oropharyngeal leak pressure, ease and accuracy of insertion and difference in time taken for the insertion.

SECONDARY OBJECTIVE

Ease and size of gastric tube insertion, difference in the incidence of postoperative complications and laryngopharyngeal morbidity.

MATERIAL AND METHODS

A randomized controlled, open label study had been done in 150 patients of either sex undergoing elective laparoscopic cholecystectomy after approval of Institutional Ethics Committee in IGMC Shimla with CTRI number CTRI/2021/07/034811. Patients were randomly allocated to one of the following three groups consisting of 50 patients each, i.e. Group I of Baska mask, Group II of Ambu AuraGain and Group III of LMA Supreme. The confidence level was taken as 95% with 5% significance level and the sample size was calculated with the help of G-power software.

Duration of Study

One year

Inclusion criteria

- 1. Patients giving consent.
- 2. ASA I and II.
- 3. Patients of either sex between 20-70 years.

Exclusion criteria

- 1. Difficult airway.
- 2. Mouth opening <2.5 cms.
- 3. ASA III and IV.
- 4. Any pathology of neck or upper respiratory tract.
- 5. BMI $> 30 \text{ kg/m}^2$
- 6. Surgery >2 hours.
- 7. Increased risk of aspiration

Preoperative visit

After performing the preanaesthetic checkup one day before surgery, premedication was given in the form of tablet alprazolam 0.5 mg and tablet ranitidine 150 mg at bed time and also at 6 a.m. in the morning prior to surgery. Patient was kept fasting overnight.

Anaesthetic technique

Preoxygenation with 100% oxygen for 3 minutes was done. The patients were then induced with intravenous injection fentanyl 2 μg/kg and propofol 1.5-2 mg/kg and atracurium 0.5 mg/kg. The Baska mask, Ambu AuraGain and LMA Supreme were thoroughly checked for their function and integrity. During the insertion of device, manipulations like adjusting insertion depth, jaw thrust,

head flexion or extension beyond sniffing position was done. Three attempts were allowed. When the insertion failed even after three attempts, then tracheal intubation was performed using a direct laryngoscope and it was recorded as failure. The correct insertion of the device was assessed by adequate bilateral chest rise and B/L equal air entry. A lubricated gastric tube of appropriate size was inserted through gastric channel and it was confirmed. OLP and the leak fraction were also noted. If leak was >8%, then the LMA was removed and the patient was intubated. Anaesthesia was maintained with isoflurane 1%-2.5% in 35% oxygen in nitrous oxide. At the end of surgery, the residual neuromuscular blockade was reversed by intravenous injection of neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. The Baska mask, Ambu AuraGain and LMA Supreme were removed and checked for any blood or bile stains.

Data Collection

- a. The insertion time was noted and defined as time in seconds from device touching the teeth to the first recorded bilateral equal air entry.
- b. Ease of insertion was also be noted and evaluated i.e. easy for no manipulation, fair for one manipulation, difficult for more than one type of manipulation.
- c. Number of attempts were also noted.
- d. The ease of placement and size of gastric tube was noted.
- e. OLP test was done with the adjustment valve set at 70 cm of H2O and oxygen flow at 6 litres/min after loss of spontaneous respiration.
- f. Device stability and function was assessed by calculating the leak fraction which was defined as tidal volume inspires-tidal volume expired/tidal volume inspired*100.
- g. Ease of removal of device was also noted and device was thoroughly checked.
- h. The postoperative morbidity was evaluated in the form of any trauma to lips, teeth, tongue, any coughing, ease to put gastric tube, any blood stain on the device and adequate clearance of the sump.
- Laryngopharyngeal morbidity(LPM) in the form of sore throat, dysphagia, dysphonia(hoarseness) was evaluated at extubation and 2 hours after the extubation and LPM score was given as follows: 0no morbidity is present, 1- minimal, 2- moderate, 3severe.

OBSERVATIONS AND RESULTS

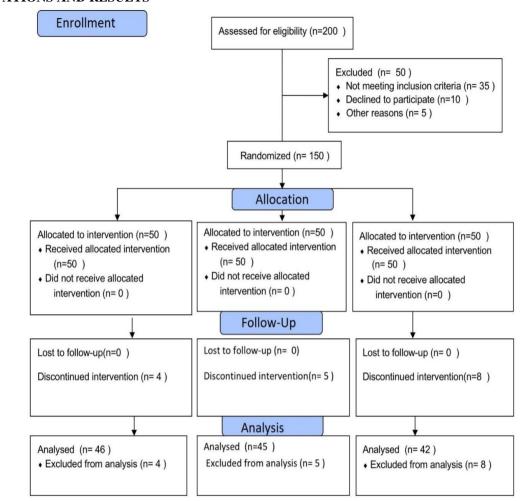


Figure 1: Flow Chart of patients in three groups.

We analyzed the data from 150 patients over one year and all the groups were homogenous for age distribution while there was significant difference for gender distribution i.e. females > males [p=0.001] and ASA physical status between the groups [ASA II > ASA I](p=0.006) (table 1).

Table No.1: Demographic profile of the patients.

b.i. Demographic p	BASKA	AAG	LMA SUPREME	1	
	N=50 (33.3%)	N=50(33.3%)	N=50(33.3%)	p value	
Female	32(64)	49(98)	39 (78)	0.001*	
Male	18 (36)	01(02)	11(22)		
Age (in yrs) (Mean±SD)	46.74±13.70	40.78±14.64	42.28±13.66	0.090	
Weight(in kg) (Mean±SD)	55.36±3.96	55.28±4.36	55.46±3.84	0.976	
Height (in cms) (Mean±SD)	159.58±3.88	158.22±4.17	158.56±4.01	0.216	
BMI (kg/m ²⁾ (Mean±SD)	21.75±1.48	22.07±1.44	22.07±1.56	0.449	
ASA I/II	12(24)/38(76)	24(48)/26(52)	27(54)/23(46)	0.006*	
MPS I/II/III	08(16)/ 30 (60)/ 12(24)	11(22)/ 28(56)/ 11(22)	11(22)/ 29(58)/ 10(20)	0.932	
Mouth Opening>3 cms	50 (100)	50 (100)	50 (100)	0.99	

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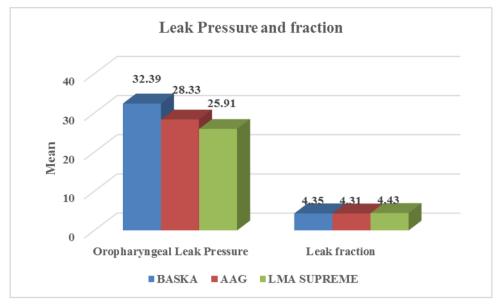
Table No.2: Size of SAD.

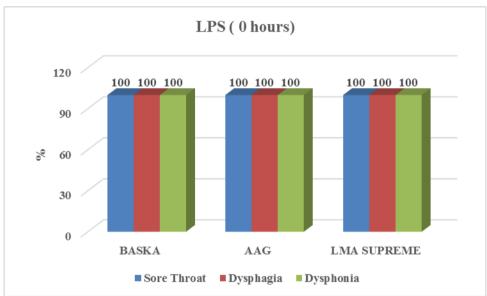
Size of SAD	BASKA N=50(33.3%)	AAG N=50(33.3%)	LMA SUPREME N=50(33.3%)	p value	
3	31 (62)	50 (100)	0(0.0)	0.0015	
4	19(38)	0	50(100)	0.001*	
No. Of Attempts	` ′		` /		
1	44 (88)	45(90)	36(72)	0.098	
2	02(04)	0	04(08)		
3	0	0	02(04)		
>3	04(08)	05(10)	08(16)		
Time Required(in minutes)		·	·		
Time from start to insertion of SAD	8.15±2.78	7.80±2.02	9.45±3.52	0.019*	
Time to adequate chest rise	8.93±2.82	8.68±2.03	10.35±3.44	0.014*	
Difference	0.78±0.46	0.88±0.32	0.90±0.57	0.400	
Time to B/L equal air entry	9.47±3.08	9.17±2.11	11.23±3.64	0.003*	
Ease of Insertion					
Easy	44(95.6)	45(100)	36(85.8)	0.028*	
Slightly difficult	02(4.4)	0	4(9.5)		
Difficult	0	0	2(4.7)		
Oropharyngeal Leak Pressure(cm H2O)	32.39±1.65	28.33±1.17	25.91±1.44	0.001*	
Leak fraction(%)	4.35±0.55	4.31±0.55	4.43±0.54	0.569	
Size of Gastric tube(in French)					
10	04(8.7)	3(6.7)	40(95.2)		
12	22(47.8)	16(35.6)	2(4.8)	0.001*	
14	20(43.5)	26(57.8)	0]	
Ease of Gastric tube Insertion					
Easy	46(100)	44(97.8)	40(95.2)		
Difficult	0(0.0)	1(2.2)	0(0.0)	0.064	
Could not pass	0(0.0)	0(0.0)	2(4.8)		
LPM Score at 0 hrs					
Sore Throat (No)	46(100)	45(100)	42(100)		
Dysphagia (No)	46(100)	45(100)	42(100)		
Dysphonia (No)	46(100)	45(100)	42(100)		
LPM Score at 2 hrs					
Sore Throat					
No	46(100)	45(100)	41(97.6)		
Yes	0	0	1(02.4)		
Dysphagia (No)	46(100)	45(100)	42(100)		
Dysphonia (No)	46(100)	45(100)	42(100)		

There was statistically significant difference observed for size of SAD between the groups as size 3 was used in 31/50 patients of Baska mask group, 50/50 patients in AAG group and 0/50 patients in LMA supreme group [62% vs 100% vs 0%]. Size 4 was used in 19/50 patients of Baska mask group, 0/50 patients of AAG group and 50/50 patients of LMA Supreme group [38% vs 0% vs 100%]. Successful placement of Baska mask in 44/50 patients (88%) in first attempt was comparable to AAG in 45/50 patients(90%) and LMA Supreme in 36/50 patients (72%). Overall success rate of all the three groups was comparable. The time required for successful insertion was least for AAG with median 7.8 sec followed by Baska mask (8.15sec - median) and LMA Supreme (9.45 sec). But the time required from the successful insertion to the adequate ventilation was least for Baska mask followed by AAG and LMA Supreme (p=0.003). Based on subjective judgement, AAG (100%) was rated as "easy" to insert as compared to Baska mask

(95.6%) and LMA Supreme (85.8%) {p= 0.02}. The oropharyngeal leak pressure is significantly higher in Baska mask group (32.39 \pm 1.65) than AAG group (28.33 \pm 1.17) and LMA Supreme (25.91 \pm 1.44) {p=0.001}. There was no significant difference in the leak fraction between the three groups (p=0.569). No statistically significant difference was observed between the groups for ease of insertion of gastric tube{p=0.06} but was observed for size of insertion (p=0.001) of gastric tubes. There was no statistically significant difference observed between the three groups in the incidence of postoperative complications.

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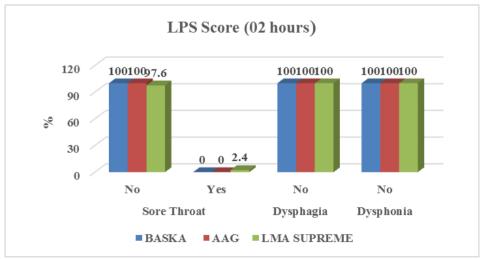
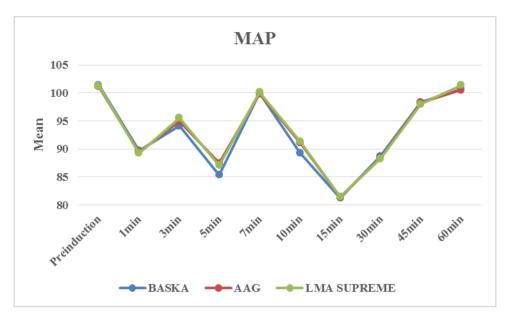
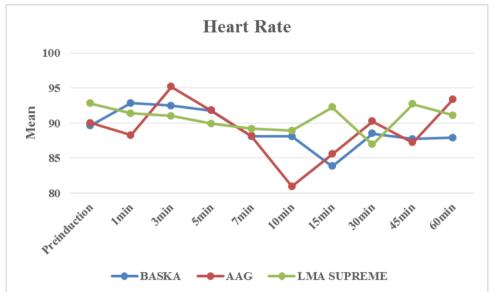
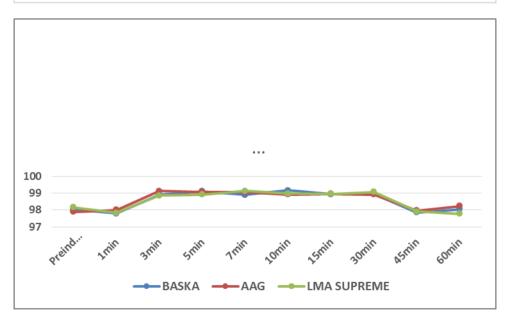


Figure 3: Intra-operative measurement of hemodynamics of patients in three groups.

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DISCUSSION

Our study compared the efficacy and safety of Baska Mask, AAG and LMA Supreme. All the three groups had significant difference for gender distribution i.e. females > males [p=0.001] and for ASA II > ASA I (p=0.006). This difference was observed due to higher prevalence of cholelithiasis in females and many patients were having Diabetes systemic Mellitus, hypertension, hypothyroidism, chronic smoker or drinker. The results of our study are in accordance with the previous studies. [8,12,13] SAD of size 3 was used in 62% patients in Baska mask group, 100% patients in AAG group and not used in LMA Supreme group (p=0.001). Whereas size 4 was used in 38% patients of Baska mask group, not used in AAG group and 100% patients of LMA Supreme group. This difference was observed due to the patients' characteristics especially gender as in our study. In other studies, Size 4 of LMA Supreme was inserted in maximum patients which was similar to our study. [9,16] Baska mask and AAG had higher success rates of insertion in first attempt than LMA Supreme(88% vs 90% vs 72%). These findings are concurrent with the similar study, in which Ambu AuraGain was inserted in 100% patients in first attempt. [10] The best first attempt insertion rate in AAG was due to its compact size, deflated cuff and preformed shape. Baska mask was also inserted successfully due to its cuffless, membranous flap seal that increases with IPPV and decreases with expiration. Whereas in LMA Supreme, the insertion was difficult due to its bulkier size. The time required for successful insertion was least for AAG with median 7.8 sec followed by Baska mask (8.15sec) and LMA Supreme (9.45 sec) (p=0.019). It was because the airway tube of AAG was preformed according to the oropharyngeal curve and Baska mask and LMA Supreme required further manipulations like chin lift or jaw thrust to insert. In our study, Baska mask provides a significantly higher OLP as compared to AAG and LMA Supreme, hence it results in greater airway protection during laparoscopic cholecystectomy. The OLP was higher in Baska mask group (32.39±1.65 cm H₂O) as compared to AAG group and LMA Supreme group (28.33 ± 1.17) cm H_2O and $25.91 \pm$ 1.44 H_2O){p=0.001}. There was no significant difference in the leak fraction between the three groups (p=0.569). Hence, all the three SADs are efficient in maintaining adequate ventilation during laparoscopic cholecystectomy and there was no need for the conversion into ETT intubation for ventilation. The higher OLP of Baska mask is attributed to the fact that it has self recoiling, membranous, non inflatable cuff which provides variable pressure ventilation. This is in accordance with the previous studies. [11,12,14,15] In our study, gastric tube was easily inserted in all the groups. But there was a significant difference in the size of gastric tube which was passed through these three devices (p=0.001). It is because Baska mask has a wider sump cavity and bigger fish mouthed gastric opening which allows gastric tube of bigger size to pass easily. Even the AAG has a bigger gastric drainage channel than

LMA Supreme. The findings are in accordance with previous studies which showed better gastric clearance in Baska mask and AAG. [8,12] The postoperative morbidity was comparable in all the three groups. These findings were in accordance with the previous studies. [9,10,12,13,14,15] The lower incidence of postoperative complications after removal of all the three SADs suggest that these SADs can be used effectively in the airway management of patients undergoing laparoscopic cholecystectomy. MAP, HR and SpO₂ were maintained throughout the surgery. Hence, all the three SADs are comparable and efficient in maintaining the hemodynamic stability throughout the laparoscopic surgery. These findings are in accordance with our study. [11,13,14]

LIMITATIONS

Our study had some limitations. It was a single centre study, and maximum patients had normal airway, insertion by expert anaesthesiologists and the inclusion of cost effectiveness of these SADs.

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