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Original Research Article

Comparison of Functional Efficacy of LMA Protector versus Baska Mask in Non-Paralysed Patients Undergoing Elective Laproscopic Surgeries – A Prospective Randomised Study

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Conflict of interest: Nil

Abstract

Background: Laparoscopic surgeries are being used more commonly than ever before for a wide variety of procedures because of the advantages they offer over conventional open surgeries. Similarly, supraglottic airway devices (SADs) provide several benefits over endotracheal intubation, including ease of insertion, reduced hemodynamic changes, and less airway manipulation, making them an attractive alternative in appropriate laparoscopic procedures.

Methods: A prospective study which includes 60 ASA 1 & 2 patients belonging to 18-65 years of age groups. They were randomly allocated into 2 groups. Group LMA P; where LMA protractor was used in anesthetised and non-paralysed patients. Group BM; where buska mask was used in anesthetised and non-paralysed patients. The primary objectives of the study was ease of insertion of SAD (number of attempts), Oropharyngeal leak pressure (in cms of H_2O), secondary objectives-Time taken for insertion, Volume of air to achieve the intracuff pressure of 60cms of water (in ml in protector), Vocal cord visibility under fiberoptic scope, Successful gastric tube insertion, adverse effects like blood stained on airway device sore throat and dysphagia.

Results: the mean duration of LMA insertion in Group LMA P (12.93 + 3.26, P>0.05), in Group BM (13.00 + 4.46, P>0.05). The mean OLP in group LMA P was 32.83+ 3.29, whereas mean OLP of group BM was 31.70+3.96(P> 0.05).

Conclusion: We have concluded that both SADs have similar functional efficacy, in laparoscopic surgeries.

Keywords: Buska mask, LMA protractor, functional analysis, Laparoscopic cholecystectomy.

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Introduction

Laparoscopic surgeries are being used more commonly for variety of surgeries than ever before, due to the advantages it offers over conventional method of open surgeries. General anaesthesia with endotracheal intubation is a gold standard technique for laparoscopic surgeries [1]. Airway management during laparoscopic surgeries is complicated by intraperitoneal insufflation of carbon dioxide and changes in patient's position, resulting in increased airway pressure secondary to increased intra-abdominal pressure, increased risk of pulmonary aspiration of gastric contents and necessitates having leak proof airway. Supraglottic airway devices have shown to be an alternative, suitable substitute for endotracheal intubation, because of less airway manipulation and steady haemodynamic status. The way the SAD suits the architecture of the airway, the seal they produce, and their functional efficacy vary from one to other. SADs provides an alternative airway rescue without muscle relaxants or laryngoscopy, causing less hemodynamic disturbances and agitation. Advantages of SADs over endotracheal tubes are that they are less invasive, avoidance of laryngoscopy induced stress response, ease of insertion, improved hemodynamic stability, smoother awakening and fewer airway related complications. Nowadays more than 40% of general anaesthesia is successfully managed with supraglottic airway devices. SADs vary in their airway architecture, sealing site, breathing performance, seal pressure, safety and better tolerance by patients [2,3,4,5,6,7,8]. Buska mask is a third generation self-sealing supraglottic airway device that combines (contains) the features of second generation SADs. Non inflatable cuff improves the sealing pressure, offering effective ventilation and reduce the complications like pulmonary aspiration. Self-recoiling cuff of Buska mask maintains a semi dilated seal during resting conditions. Wide distal aperture offers an inbuilt sump chamber to the exit of upper oesophagus, which acts as a gastric reflux drainage system. [2] Buska mask has high seal pressure, gastric access port and bite block which facilitates the ventilation smoothly, provides airway protection and minimize airway obstruction [9]. Buska mask significantly reduces the requirement of anaesthetic drugs, post-operative pharyngo-laryngeal complications like sore throat, hoarseness of voice, dysphonia and post-operative nausea and vomiting.

LMA protector is a third generation SAD, first used in 2015, and is made up of medical grade silicon with two large volume gastric drainage channels which emerge proximally as separate ports and enter a chamber behind the cuffed bowl. This chamber narrows distally into the orifice located at the end of cuff to communicate distally with upper oesophageal sphincter. A suction tube may be attached to the male drainage port around the laryngeal region or a well lubricated gastric tube may be passed through the female drainage port to the stomach. The airway tube and cuff are 100% silicon phthalate free, designed to confirm airway anatomy. Silicon cuffs have been shown to reduce the risk of sore throat and achieve higher seal pressure compared to PVC cuff. A bite block and fixation system which prevents proximal displacement during its use ensures that distal end seals around the upper oesophageal sphincter. It has an integrated cuff pressure indicator, the cuff pilot, providing easier adjustment and monitoring of cuff pressure [10,11,12,13,14,15,16,17,18].

The aim of present study is to compare the functional analysis and ease of insertion of Buska mask vs LMA protector in elective laparoscopic surgeries, in non-paralysed patients under general anaesthesia.

Materials and Methodology

The study was conducted in 60 patients of age group between 18-65, of ASA I and II who were posted for elective laparoscopic surgeries under general anaesthesia. Patients were randomly allocated into two groups by using closed opaque envelope technique, patients were divided into two groups (n=30 each)

1. Group LMA-P -LMA Protector was inserted in patients after induction before paralysis (non-paralysed)
2. Group BM –Buska mask was inserted in patients after induction before paralysis (non-paralysed)

After obtaining institutional ethical committee clearance, patients who are undergoing elective laparoscopic surgeries were evaluated thoroughly on previous day. After preanesthetic checkup, patients were advised to take Tab Ranitidine 150 mg and Tab Alprazolam 0.5 mg, on previous night of surgery. All patients were advised to be nil orally for solid food for 6 hours. On the day of surgery, in the OR multiparameter monitors were connected to the patient.

After securing IV line, patients were premedicated with Inj. Midazolam 1mg + Inj Fentanyl 2mcg/kg + Inj Dexamethasone 8mg + Inj Ondansetron 4mg. Patients were induced with Inj Xylocard 1.5mg/kg+ Inj Propofol 2mg/kg. Patients were ventilated for 30 seconds and either of two SADs were inserted. For LMA Protector, cuff was inflated using cuff pressure manometer, which showed 60cmH_2O.

Bilateral air entry confirmed. SAD placement confirmed by fiberoptic bronchoscope by visualizing vocal cords. Anaesthesia was maintained by using Inj. Vecuronium 0.1mg/kg, by IPPV with O_2+N_2O+ISOFLURANE 0.5-1% .Oropharyngeal leak pressure was checked. A well lubricated 16G GASTRIC TUBE was tried to pass through female port into the gastric access channel.

The primary objectives of the study are:

1. Ease of insertion of SAD (number of attempts)
2. Oropharyngeal leak pressure (in cms of H_2O)

The secondary objectives of the study are:

1. Time taken to insert SAD
2. Volume of air needed to achieve the intracuff pressure of 60cms of H_2O (in ml in protector)
3. Vocal cord visibility under fiberoptic scope(% of visibility of vocal cords- grade I/grade II/ grade III)
4. Successful gastric tube insertion, n (%)-1st attempt, 2nd attempt and Not possible
5. Adverse effects like:
   - Blood stains on airway device (%)
   - Sorethroat after one day of surgery (%)
   - Dysphagia or hoarseness of voice (%)

Inclusion Criteria

- All patients of ASA I and II,
- Belonging to age group of 18-65 years of either sex,
- All modified mallampatti grade 1 and 2

Exclusion Criteria

- All patients of ASA III and IV
- Mouth opening <2cm
- Upper airway pathology

- Patient refusal
- Pregnant patient
- Patients with comorbid conditions associated with cardiovascular, renal, respiratory and CNS pathology.
- Coagulation abnormalities.
- BMI>35kg/m^2

Definitions

Ease of LMA insertion: Subjective scale I to IV

I- No resistance

II- Mild resistance

III- Moderate resistance

IV- Inability to place the device

1. Successful placement: Ability to achieve tidal volume of at least 7ml /kg with normal $EtCO_2$ waves.

2. Duration of obtaining successful airway in seconds: From the time of end of mask ventilation after induction to successful insertion of SAD, confirmation through capnography wave forms.

3. Failure of insertion: 3 unsuccessful attempts of device insertion, after mask ventilation by expert, in insertion of SAD.

4. Intra cuff pressure: The device is inserted with zero cuff pressure, after insertion the volume of air used to bring the cuff pressure to 60 cm H_2O.

5. Vocal cord visibility: By fibreoptic assessment. After insertion of the device and inflation of the cuff, the anatomical airway position of the device was assessed by fibreoptic airway assessment via airway channel. The view score as follows:

- Grade I: clear view of the vocal cords and epiglottis.
- Grade II: View of posterior commissure and epiglottis only.
- Grade III: view of epiglottis only
- Grade IV: no laryngeal structures visible

6. OLP: Oropharyngeal leak pressure test measured by closing the expiratory valve of anaesthetic circle system at fixed gas flow rate (4L) and noting the equilibrium airway pressure. It is used to quantify the efficacy of airway sealing in supraglottic airway devices, by detecting audible noise over trachea by keeping stethoscope over the trachea.

7. Adverse effects: Sore throat assessed by 4 points scale

1. No complaints of sore throat at 12hrs and 24hrs postoperatively
2. Mild sore throat (on enquiry)
3. Moderate sore throat (complaints without enquiry)
4. Severe sore throat (associated with soreness and throat pain).

8. Successful gastric tube insertion: 1st attempt, 2nd attempt, not possible.

Statistical Methods: Sample size is calculated with alpha =5% and admissible error = 10%. Numerical variables were presented as a mean and standard deviation or median, whereas categorical data were presented using frequency and percentage. The following tests were applied according to the type of variables. Chi -square test for categorical variables. L test for independent variables. In case of non-normality of scales alternative non parametric test will be engaged. Therefore, reached the sample size of minimum of 30 each group.

Sample size for one mean, normal distribution:

$n= (Z\alpha + Z\beta)\ 2^{*}\sigma^2$

- The size of effect that is clinically worthwhile to detect(d)=10.5
- The probability of falsely rejecting a true null hypothesis=(a)=0.05,Za=1.96
- The probability of failing to reject a false null hypothesis-(B) =0.08,Zß=0.84
- The standard deviation of the population being studied(SD or ©)=20.0

$N= (1.96 + 0.84)\ 2*(20)2/(10.5)^2$

N=30 per group

Sampling: purposive sampling.

Type of study: comparative.

Descriptive: mean, standard deviation frequency and percent.

Inferential statistics: Non parametric Chi-square test.

Parametric: t test-independent and paired samples, ANOVA- repeated measures.

Results

The study conducted in 60 patients of ASA 1 and 2, belonging to the age group of 18 to 65 of either sex were randomly allocated into 2 groups [n = 30]

1. Group LMA-P -LMA protector was inserted in patients after the induction before paralysis (non-paralysed)
2. Group BM – Buska mask was inserted in patients after the induction before paralysis (non- paralysed)

The demographic data of the study like age, sex, weight, height, BMI, indication for surgery and Mallampatti grading were not statistically significant.

Table 1: Data of age among groups

			Groups		Total
			Group LMA P	Group BM	
ages	<30	Count	5	1	6
		% within groups	16.70%	3.30%	10.00%
	31-40	Count	9	10	19
		% within groups	30.00%	33.30%	31.70%
	41-50	Count	2	9	11
		% within groups	6.70%	30.00%	18.30%
	51-60	Count	9	5	14
		% within groups	30.00%	16.70%	23.30%
	60+	Count	5	5	10
		% within groups	16.70%	16.70%	16.70%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	8.317	4	0.081

	N	Mean	Std. Deviation	Minimum	Maximum
Group LMA P	30	46.3333	14.96279	18	78
Group BM	30	46.9333	13.0488	26	72
Total	60	46.6333	13.92226	18	78

Table 2: Data showing BMI among groups

	Groups	N	Mean	Std. Deviation	Std. Error Mean
BMI	Group LMA P	30	25.8653	3.91463	0.71471
	Group BM	30	27.4	3.62396	0.66164

		t-test for Equality of Means			
		t	Df	Sig. (2-tailed)	Mean Difference
BMI		-1.576	58	0.121	-1.53467

Table 3: Showing Data of MP class among groups

			Groups		Total
			Group LMA P	Group BM	
MP_class	I	Count	4	3	7
		% within groups	13.30%	10.00%	11.70%
	II	Count	23	25	48
		% within groups	76.70%	83.30%	80.00%
	III	Count	3	2	5
		% within groups	10.00%	6.70%	8.30%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	0.426	2	0.808

Table 4: Showing data of ASA grade among groups

			Groups		Total
			Group LMA P	Group BM	
ASA_grade	I	Count	13	19	32
		% within groups	43.30%	63.30%	53.30%
	II	Count	17	11	28
		% within groups	56.70%	36.70%	46.70%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	2.411	1	0.121	
Fisher's Exact Test				0.195

Table 5: Showing Data of time taken for insertion of SADs and ETCO2 after insertion of SADs

	Groups	N	Mean	Std. Deviation	Std. Error Mean
TIME taken for-LMA	Group LMA P	30	12.9333	3.2688	0.5968
Insertion in seconds	Group BM	30	13	4.46442	0.81509
ETCO2 after -LMA insertion	Group LMA P	30	36.7	3.42556	0.62542
	Group BM	30	34.7	5.73044	1.04623

	t-test for Equality of Means			
	T	df	Sig. (2-tailed)	Mean Difference
Time taken for-LMA insertion	-0.066	58	0.948	-0.06667
ETCO2 after-LMA insertion	1.641	58	0.106	2

Table 6: Showing number of attempts for insertion of SADs among groups

			Groups		Total
			Group LMA P	Group BM	
Successful insertion attempts	1	Count	27	24	51
		% within groups	90.00%	80.00%	85.00%
	2	Count	3	6	9
		% within groups	10.00%	20.00%	15.00%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	1.176	1	0.278	
Fisher's Exact Test				0.472

Table 7: Showing Ease of insertion of SADs

			Groups		Total
			Group LMA P	Group BM	
Ease of insertion of SADs	Minimal	Count	17	17	34
		% within groups	56.70%	56.70%	56.70%
	Moderate	Count	13	13	26
		% within groups	43.30%	43.30%	43.30%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	0	1	1	
Fisher's Exact Test				1

Table 8: Showing vocal cord visibility under fibreoptic inspection

			Groups		Total
			Group LMA P	Group BM	
Vocal cord visibility grading	1	Count	18	18	36
		% within groups	60.00%	60.00%	60.00%
	2	Count	8	11	19
		% within groups	26.70%	36.70%	31.70%
	3	Count	4	1	5
		% within groups	13.30%	3.30%	8.30%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.274	2	0.321

Table 9: Showing gastric tube insertion attempts among groups

			Groups		Total
			Group LMA P	Group BM	
Gastric tube insertion attempts	Not possible	Count	5	5	10
		% within groups	16.70%	16.70%	16.70%
	1	Count	21	22	43
		% within groups	70.00%	73.30%	71.70%
	2	Count	4	3	7
		% within groups	13.30%	10.00%	11.70%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	0.166	2	0.92

Table 10: Showing oropharyngeal leak pressure test among the groups after insertion of SADs

	groups	N	Mean	Std. Deviation	Std. Error Mean
OLP	Group LMA P	30	32.8333	3.2914	0.60093
	Group BM	30	31.7	3.96667	0.72421

	groups	N	Mean	Std. Deviation	Std. Error Mean
OLP	Group LMA P	30	32.8333	3.2914	0.60093
	Group BM	30	31.7	3.96667	0.72421

Table 11: Showing mean heart rate at various intervals among groups

	groups	N	Mean	Std. Deviation	Std. Error Mean
BASAL_HEART_RATE	Group LMA P	30	88.5667	13.9869	2.55365
	Group BM	30	91.8333	12.70374	2.31938
HR_AFTER_INDUCTION	Group LMA P	30	92.1667	12.18276	2.22426
	Group BM	30	95.4667	14.33042	2.61636
HR_AFTER_INSERTION_OF_LMA	Group LMA P	30	96.1333	11.06948	2.021
	Group BM	30	95.5333	14.55248	2.65691
HR_AT_2nd_MINUTE	Group LMA P	30	94.6667	12.8421	2.34464
	Group BM	30	92.7	13.46554	2.45846
HR_AT_6th_MINUTE	Group LMA P	30	86.9667	20.67062	3.77392
	Group BM	30	90.2667	13.68597	2.4987
HR_AT_10th_MINUTE	Group LMA P	30	91.4	13.16893	2.40431
	Group BM	30	92.2667	13.3802	2.44288
HR_AT_15th_MINUTE	Group LMA P	30	90.3667	10.79107	1.97017
	Group BM	30	87.3333	12.40504	2.26484

Independent Samples Test				
	t-test for Equality of Means			
	t	**Df**	**Sig. (2-tailed)**	**Mean Difference**
BASAL_HEART_RATE	-0.947	58	0.348	-3.26667
HR_AFTER_INDUCTION	-0.961	58	0.341	-3.3
HR_AFTER_INSERTION_OF_LMA	0.18	58	0.858	0.6
HR_AT_2nd_MINUTE	0.579	58	0.565	1.96667
HR_AT_6th_MINUTE	-0.729	58	0.469	-3.3
HR_AT_10th_MINUTE	-0.253	58	0.801	-0.86667
HR_AT_15th_MINUTE	1.01	58	0.316	3.03333

General Linear Model

Descriptive Statistics				
	groups	Mean	Std. Deviation	N
BASAL_HEART_RATE	Group LMA P	88.5667	13.9869	30
	Group BM	91.8333	12.70374	30
	Total	90.2	13.34903	60

HR_AFTER_INDUCTION	Group LMA P	92.1667	12.18276	30
	Group BM	95.4667	14.33042	30
	Total	93.8167	13.29138	60
HR_AFTER_INSERTION_OF_LMA	Group LMA P	96.1333	11.06948	30
	Group BM	95.5333	14.55248	30
	Total	95.8333	12.82234	60
HR_AT_2nd_MINUTE	Group LMA P	94.6667	12.8421	30
	Group BM	92.7	13.46554	30
	Total	93.6833	13.08317	60
HR_AT_6th_MINUTE	Group LMA P	86.9667	20.67062	30
	Group BM	90.2667	13.68597	30
	Total	88.6167	17.45997	60
HR_AT_10th_MINUTE	Group LMA P	91.4	13.16893	30
	Group BM	92.2667	13.3802	30
	Total	91.8333	13.16926	60
HR_AT_15th_MINUTE	Group LMA P	90.3667	10.79107	30
	Group BM	87.3333	12.40504	30
	Total	88.85	11.62817	60

Tests of Within-Subjects Effects					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	2716.267	6	452.711	6.327	0
change * groups	643	6	107.167	1.498	0.178
Error(change)	24899.02	348	71.549		

Profile Plots

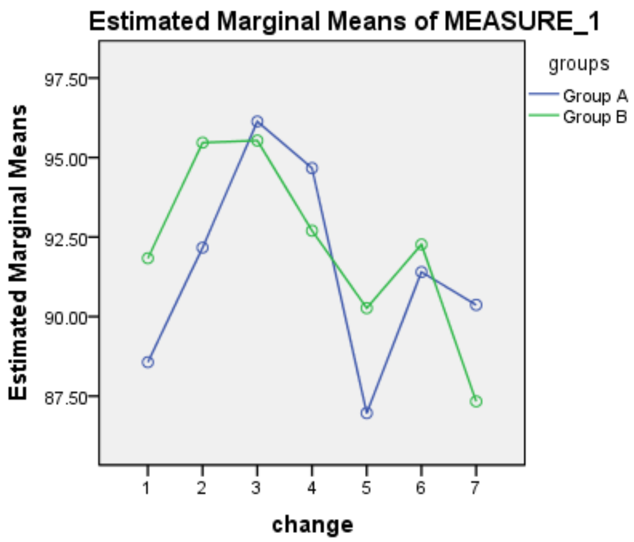

Figure 1:

Table 12: Showing systolic blood pressure at various interval of time among groups

Group Statistics					
	groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
BASAL_SYSTOLIC_BLOOD_PRESSURE	Group LMA P	30	133.7	14.50363	2.64799
	Group BM	30	134.1667	11.75932	2.14695
SBP_AFTER_INDUCTION	Group LMA P	30	124	17.83062	3.25541
	Group BM	30	121.3333	14.60593	2.66667
SBP_AFTER_INSERTION_OF_LMA	Group LMA P	30	133.5	20.52207	3.7468
	Group BM	30	124.1	19.2378	3.51233
SBP_AT_2nd_MINUTE	Group LMA P	30	124.7	17.45368	3.18659

	Group BM	30	118.6667	18.21014	3.3247
SBP_AT_6th_MINUTE	Group LMA P	30	123.0333	14.23808	2.59951
	Group BM	30	117.7667	14.50014	2.64735
SBP_AT_10th_MINUTE	Group LMA P	30	125.2	18.35737	3.35158
	Group BM	30	120.5667	19.17736	3.50129
SBP_AT_15th_MINUTE	Group LMA P	30	125.4	18.78848	3.43029
	Group BM	30	120.5667	14.79675	2.7015

Independent Samples Test				
	t-test for Equality of Means			
	t	**df**	**Sig. (2-tailed)**	**Mean Difference**
BASAL_SYSTOLIC_BLOOD_PRESSURE	-0.137	58	0.892	-0.46667
SBP_AFTER_INDUCTION	0.634	58	0.529	2.66667
SBP_AFTER_INSERTION_OF_LMA	1.83	58	0.072	9.4
SBP_AT_2nd_MINUTE	1.31	58	0.195	6.03333
SBP_AT_6th_MINUTE	1.419	58	0.161	5.26667
SBP_AT_10th_MINUTE	0.956	58	0.343	4.63333
SBP_AT_15th_MINUTE	1.107	58	0.273	4.83333

General Linear Model

Descriptive Statistics				
	groups	**Mean**	**Std. Deviation**	**N**
BASAL_SYSTOLIC_BLOOD_PRESSURE	Group LMA P	133.7	14.50363	30
	Group BM	134.1667	11.75932	30
	Total	133.9333	13.09272	60
SBP_AFTER_INDUCTION	Group LMA P	124	17.83062	30
	Group BM	121.3333	14.60593	30
	Total	122.6667	16.21536	60
SBP_AFTER_INSERTION_OF_LMA	Group LMA P	133.5	20.52207	30
	Group BM	124.1	19.2378	30
	Total	128.8	20.28258	60
SBP_AT_2nd_MINUTE	Group LMA P	124.7	17.45368	30
	Group BM	118.6667	18.21014	30
	Total	121.6833	17.94388	60
SBP_AT_6th_MINUTE	Group LMA P	123.0333	14.23808	30
	Group BM	117.7667	14.50014	30
	Total	120.4	14.49278	60
SBP_AT_10th_MINUTE	Group LMA P	125.2	18.35737	30
	Group BM	120.5667	19.17736	30
	Total	122.8833	18.75813	60
SBP_AT_15th_MINUTE	Group LMA P	125.4	18.78848	30
	Group BM	120.5667	14.79675	30
	Total	122.9833	16.94307	60

Tests of Within-Subjects Effects						
Source		**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change		8400.448	6	1400.075	7.319	0
change * groups		824.99	6	137.498	0.719	0.635
Error(change)		66568.85	348	191.29		

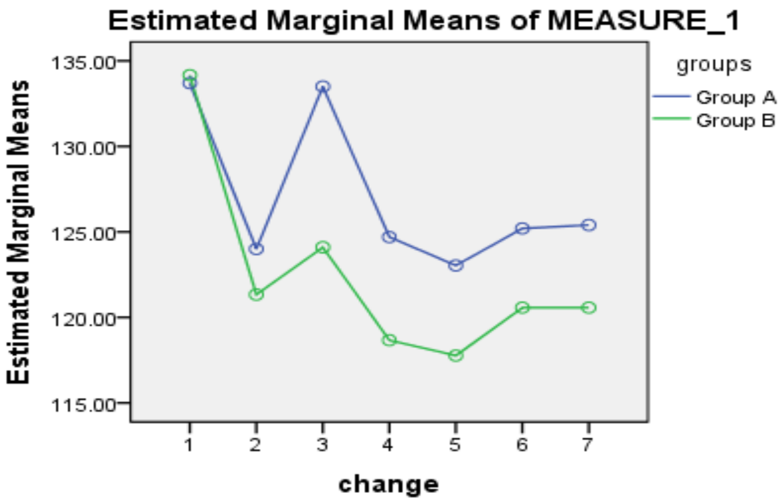

Figure 2:

Table 13: Showing diastolic blood pressure at various interval among groups

Group Statistics					
	Groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
BASAL_DIASTOLIC_BLOOD_PRESSURE	Group LMA P	30	84.6	7.56398	1.38099
	Group BM	30	85.4667	10.80145	1.97207
DBP_AFTER_INDUCTION	Group LMA P	30	79.7333	12.13696	2.2159
	Group BM	30	78.2	13.87978	2.53409
DBP_AFTER_INSERTION_OF_LMA	Group LMA P	30	85.2	14.61553	2.66842
	Group BM	30	78.9	16.08887	2.93741
DBP_AT_2nd_MINUTE	Group LMA P	30	81.7667	12.65097	2.30974
	Group BM	30	75.2	14.03542	2.56251
DBP_AT_6th_MINUTE	Group LMA P	30	79.5333	10.36484	1.89235
	Group BM	30	75.5333	13.37196	2.44137
DBP_AT_10th_MINUTE	Group LMA P	30	80.4667	12.13355	2.21527
	Group BM	30	77.1	13.17351	2.40514
DBP_AT_15th_MINUTE	Group LMA P	30	81.6	12.09902	2.20897
	Group BM	30	77.5667	11.55701	2.11001

Independent Samples Test				
	t-test for Equality of Means			
	t	**Df**	**Sig. (2-tailed)**	**Mean Difference**
BASAL_DIASTOLIC_BLOOD_PRESSURE	-0.36	58	0.72	-0.86667
DBP_AFTER_INDUCTION	0.455	58	0.65	1.53333
DBP_AFTER_INSERTION_OF_LMA	1.588	58	0.118	6.3
DBP_AT_2nd_MINUTE	1.903	58	0.062	6.56667
DBP_AT_6th_MINUTE	1.295	58	0.2	4
DBP_AT_10th_MINUTE	1.03	58	0.307	3.36667
DBP_AT_15th_MINUTE	1.32	58	0.192	4.03333

Descriptive data				
	groups	**Mean**	**Std. Deviation**	**N**
BASAL_DIASTOLIC_BLOOD_PRESSURE	Group LMA P	84.6	7.56398	30
	Group BM	85.4667	10.80145	30
	Total	85.0333	9.25526	60
DBP_AFTER_INDUCTION	Group LMA P	79.7333	12.13696	30
	Group BM	78.2	13.87978	30
	Total	78.9667	12.94966	60
DBP_AFTER_INSERTION_OF_LMA	Group LMA P	85.2	14.61553	30
	Group BM	78.9	16.08887	30

	Total	82.05	15.56661	60
DBP_AT_2nd_MINUTE	Group LMA P	81.7667	12.65097	30
	Group BM	75.2	14.03542	30
	Total	78.4833	13.65494	60
DBP_AT_6th_MINUTE	Group LMA P	79.5333	10.36484	30
	Group BM	75.5333	13.37196	30
	Total	77.5333	12.03169	60
DBP_AT_10th_MINUTE	Group LMA P	80.4667	12.13355	30
	Group BM	77.1	13.17351	30
	Total	78.7833	12.67065	60
DBP_AT_15th_MINUTE	Group LMA P	81.6	12.09902	30
	Group BM	77.5667	11.55701	30
	Total	79.5833	11.90541	60

Tests of Within-Subjects Effects					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	2436.99	6	406.165	4.125	0.001
change * groups	610.581	6	101.763	1.034	0.403
Error(change)	34263.57	348	98.459		

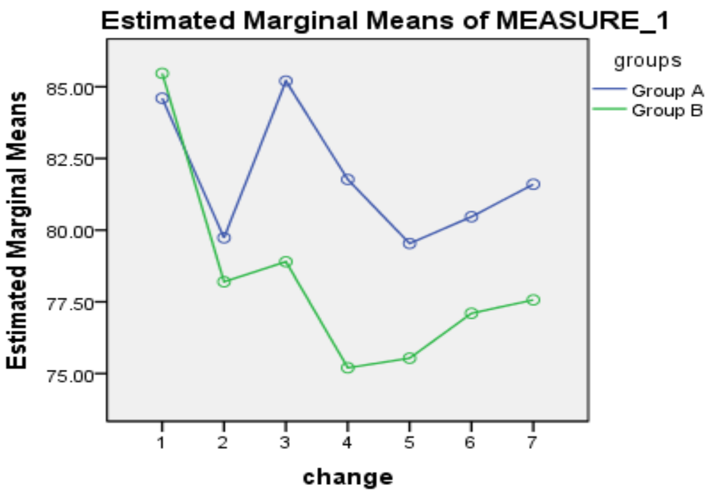

Figure 3:

Table 14: Showing MAP at various interval of time among groups

Group Statistics					
	groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
BASAL_MEAN_ARTERIAL_BLOOD_PRESSURE	Group LMA P	30	100.2	8.03613	1.46719
	Group BM	30	98.9	9.91464	1.81016
MAP_AFTER_INDUCTION	Group LMA P	30	94.0667	12.76021	2.32969
	Group BM	30	90.5	13.00597	2.37455
MAP_AFTER_INSERTION_OF_LMA	Group LMA P	30	100.5667	14.74773	2.69255
	Group BM	30	93.4333	16.36372	2.98759
MAP_AT_2nd_MINUTE	Group LMA P	30	96.3667	12.66677	2.31263
	Group BM	30	89.5333	13.87812	2.53379

MAP_AT_6th_MINUTE	Group LMA P	30	93.5	10.31487	1.88323
	Group BM	30	89.3333	12.80715	2.33825
MAP_AT_10th_MINUTE	Group LMA P	30	95.6667	12.97035	2.36805
	Group BM	30	91.6667	15.11869	2.76028
MAP_AT_15th_MINUTE	Group LMA P	30	96.5333	13.24499	2.41819
	Group BM	30	92.0667	12.27257	2.24066

Independent Samples Test					
		t-test for Equality of Means			
		t	df	Sig. (2-tailed)	Mean Difference
BASAL_MEAN_ARTERIAL_BLOOD_PRESSURE		0.558	58	0.579	1.3
MAP_AFTER_INDUCTION		1.072	58	0.288	3.56667
MAP_AFTER_INSERTION_OF_LMA		1.774	58	0.081	7.13333
MAP_AT_2nd_MINUTE		1.992	58	0.051	6.83333
MAP_AT_6th_MINUTE		1.388	58	0.171	4.16667
MAP_AT_10th_MINUTE		1.1	58	0.276	4
MAP_AT_15th_MINUTE		1.355	58	0.181	4.46667

Descriptive Statistics				
	groups	Mean	Std. Deviation	N
BASAL_MEAN_ARTERIAL_BLOOD_PRESSURE	Group LMA P	100.2	8.03613	30
	Group BM	98.9	9.91464	30
	Total	99.55	8.97157	60
MAP_AFTER_INDUCTION	Group LMA P	94.0667	12.76021	30
	Group BM	90.5	13.00597	30
	Total	92.2833	12.9	60
MAP_AFTER_INSERTION_OF_LMA	Group LMA P	100.5667	14.74773	30
	Group BM	93.4333	16.36372	30
	Total	97	15.85742	60
MAP_AT_2nd_MINUTE	Group LMA P	96.3667	12.66677	30
	Group BM	89.5333	13.87812	30
	Total	92.95	13.61632	60
MAP_AT_6th_MINUTE	Group LMA P	93.5	10.31487	30
	Group BM	89.3333	12.80715	30
	Total	91.4167	11.71887	60
MAP_AT_10th_MINUTE	Group LMA P	95.6667	12.97035	30
	Group BM	91.6667	15.11869	30
	Total	93.6667	14.11054	60
MAP_AT_15th_MINUTE	Group LMA P	96.5333	13.24499	30
	Group BM	92.0667	12.27257	30
	Total	94.3	12.85816	60

Tests of Within-Subjects Effects						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Change		2957.648	6	492.941	4.867	0
change * groups		357.781	6	59.63	0.589	0.739
Error(change)		35247.14	348	101.285		

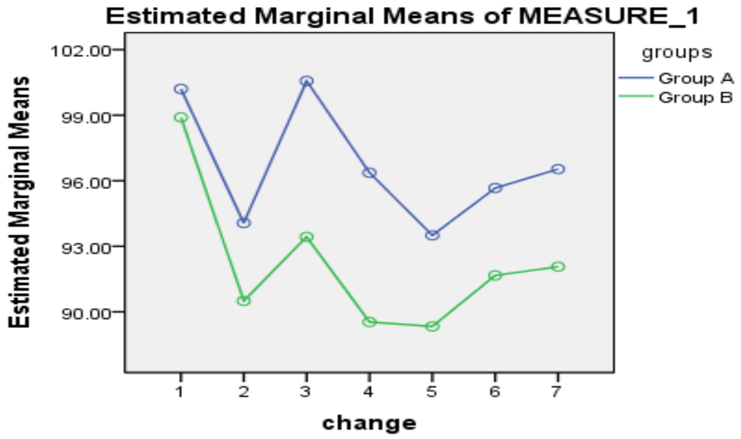

Figure 4:

Table 15: Showing SPO2 at various interval of time among groups after SAD insertion

Group Statistics					
	groups	N	Mean	Std. Deviation	Std. Error Mean
BASAL-SPO2	Group LMA P	30	98.7667	0.89763	0.16388
	Group BM	30	98.8333	0.87428	0.15962
SPO2-AFTER_INDUCTION	Group LMA P	30	99.5667	0.56832	0.10376
	Group BM	30	99.5333	0.50742	0.09264
SPO2-AFTER INSERTION OF LMA	Group LMA P	30	99.7667	0.43018	0.07854
	Group BM	30	99.6333	0.49013	0.08949
SPO2 AT 2nd MINUTE	Group LMA P	30	99.9	0.30513	0.05571
	Group BM	30	99.7667	0.43018	0.07854
SPO2_AT_6th_MINUTE	Group LMA P	30	99.9333	0.25371	0.04632
	Group BM	30	99.9333	0.25371	0.04632
SPO2_AT_10th_MINUTE	Group LMA P	30	99.9667	0.18257	0.03333
	Group BM	30	99.9	0.30513	0.05571
SPO2_AT_15th_MINUTE	Group LMA P	30	99.9667	0.18257	0.03333
	Group BM	30	99.9	0.30513	0.05571

Independent Samples Test					
		t-test for Equality of Means			
		t	df	Sig. (2-tailed)	Mean Difference
BASAL_SPO2		-0.291	58	0.772	-0.06667
SPO2_AFTER_INDUCTION		0.24	58	0.811	0.03333
SPO2_AFTER_INSERTION_OF_LMA		1.12	58	0.267	0.13333
SPO2_AT_2nd_MINUTE		1.385	58	0.171	0.13333
SPO2_AT_6th_MINUTE		0	58	1	0
SPO2_AT_10th_MINUTE		1.027	58	0.309	0.06667
SPO2_AT_15th_MINUTE		1.027	58	0.309	0.06667

Descriptive Statistics				
	groups	Mean	Std. Deviation	N
BASAL_SPO2	Group LMA P	98.7667	0.89763	30
	Group BM	98.8333	0.87428	30
	Total	98.8	0.87914	60
SPO2_AFTER_INDUCTION	Group LMA P	99.5667	0.56832	30
	Group BM	99.5333	0.50742	30
	Total	99.55	0.53441	60
SPO2_AFTER_INSERTION_OF_LMA	Group LMA P	99.7667	0.43018	30
	Group BM	99.6333	0.49013	30
	Total	99.7	0.46212	60
SPO2_AT_2nd_MINUTE	Group LMA P	99.9	0.30513	30
	Group BM	99.7667	0.43018	30

	Total	99.8333	0.37582	60
SPO2_AT_6th_MINUTE	Group LMA P	99.9333	0.25371	30
	Group BM	99.9333	0.25371	30
	Total	99.9333	0.25155	60
SPO2_AT_10th_MINUTE	Group LMA P	99.9667	0.18257	30
	Group BM	99.9	0.30513	30
	Total	99.9333	0.25155	60
SPO2_AT_15th_MINUTE	Group LMA P	99.9667	0.18257	30
	Group BM	99.9	0.30513	30
	Total	99.9333	0.25155	60

Tests of Within-Subjects Effects						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Change		60.414	6	10.069	56.018	0
change * groups		0.462	6	0.077	0.428	0.86
Error(change)		62.552	348	0.18		

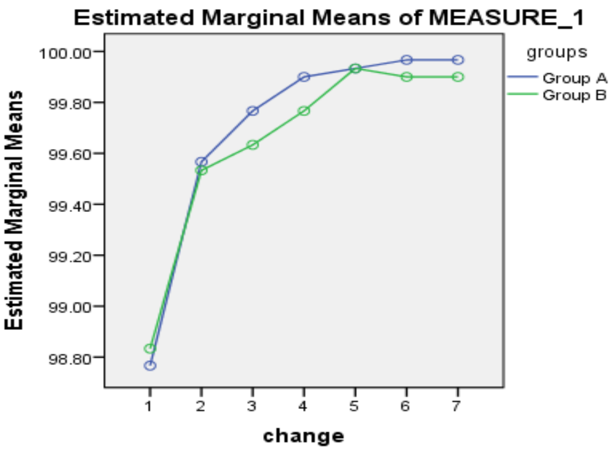

Figure 5:

Table 16: Showing adverse effects among groups after removal of SADs

Adverse Effects			**Groups**		**Total**
			Group LMA P	**Group BM**	
Blood Stained On Device After Removal	No	Count	26	25	51
		% within groups	86.70%	83.30%	85.00%
	Yes	Count	4	5	9
		% within groups	13.30%	16.70%	15.00%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	0.131	1	0.718	
Fisher's Exact Test				1

Table 17: Showing adverse effect of sore throat among groups

Adverse Effects			**Groups**		**Total**
			Group LMA P	**Group BM**	
Sore Throat	No	Count	26	20	46
		% within groups	86.70%	66.70%	76.70%
	Yes	Count	4	10	14
		% within groups	13.30%	33.30%	23.30%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	3.354	1	0.067	
Fisher's Exact Test				0.125

Table 18: Showing adverse effect of dysphagia among groups

			groups		Total
			Group LMA P	Group BM	
Adverse Effect Dysphagia	No	Count	28	27	55
		% within groups	93.30%	90.00%	91.70%
	Yes	Count	2	3	5
		% within groups	6.70%	10.00%	8.30%
Total		Count	30	30	60
		% within groups	100.00%	100.00%	100.00%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	0.218	1	0.64	
Fisher's Exact Test				1

Discussion

The study was conducted in 60 ASA 1 and 2 patients, belonging to the age group of 18-65 years, who were electively posted for Laparoscopic Cholecystectomy. Laparoscopic Cholecystectomy is a very commonly surgical procedure for Cholelithiasis. General anaesthesia with endotracheal tube is a gold standard anaesthesia procedure. In recent trends, for Laparoscopic procedures, the Supraglottic airway devices have shown to be suitable substitute for endotracheal intubation, because of the benefits it offers including less airway manipulation and stable hemodynamic (Noor Sultana). The second generation supraglottic airway devices like Buska mask and LMA Protector offers higher oropharyngeal leak pressure, which provides better seal against the glottis, which is crucial for positive pressure ventilation (Zehra Ipek Arslan).

The demographic data like Age, Sex, BMI, Mallampati class, ASA grading, diagnosis, and duration of surgery were comparable among the groups, which was not statistically significant (P>0.05). In present study the mean duration of LMA insertion in Group LMA P (12.93 + 3.26, P>0.05), in Group BM (13.00 + 4.46, P>0.05). In both the groups SADs inserted by Second year postgraduates who had an experience of minimum 20 LMA insertion. The duration of insertion was calculated from the time of holding the SAD (30 seconds after induction with Propofol without muscle relaxant) to complete insertion of SAD. After insertion the circuit was connected and bilateral air entry was confirmed and ETCO2 was recorded (36.70 + 3.42, 34.70 + 5.73). Though the time taken for insertion of LMA Protector was less than Buska mask, which was statistically not significant (P>0.05). Number of attempts to insert LMA P 90.0% achieved in first attempt whereas in Buska mask 80.0% was successful in first attempt, which was not statistically significant (P>0.05). In our study, ease of insertion in both the groups, insertion with the minimal resistance (56.7%), moderate resistance (43.3%), the overall insertion was easy with LMA protractor, though it was not statistically significant (P>0.05). Vocal cord visibility after the insertion of SAD through fibreoptic scope, grade 1 visibility in both the groups was 60%, grade 2 visibility in group LMA P was 26.7% whereas group BM was 36.7%, grade 3 visibility in LMA P was 13.3% whereas in group BM 3.3%, statistically which was not significant. Successful Gastric tube insertion in first attempt 70% was successful in LMA P group, whereas 73.3% was successful in buska mask, in second attempt 13.3% was successful in group LMA P, whereas 10.0% was successful in buska mask, 16.7% in either group not able to pass the gastric tube. The overall result was not statistically significant. Oropharyngeal leak pressure (OLP)(oropharyngeal leak pressure test measured by closing the expiratory wall of circle system at fixed gas flow rate(4L), noting the equilibrium airway pressure, which is used to quantify the efficacy of airway sealing by detecting the audible notice by stethoscope over the trachea).The mean OLP in group LMA P was 32.83+ 3.29, whereas mean OLP of group BM was 31.70+3.96 (P> 0.05), which was not statistically significant. The hemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure at various interval of time in both the groups statistically not significant (P>0.05). Adverse effects like blood stain on SADs (13.3% seen in group LMA P, 33.3% in group BM), which was not statistically significant. The other adverse effects like sore throat (13.3% seen in group LMA P, 33.3% in group BM), which was not statistically significant). Dysphagia within 24 hours after removal of SADs was noticed 6.7% in group LMA P, 10.0% in group BM, which was statistically not significant. Our study can be comparable with Zehra Ipek ARSLAN et all, though their study was similar to ours but their parameters are different, the ease of insertion of LMA P was easy when compared to buska mask.

We have also noticed the time taken for insertion was less in LMA P when compared to BM though it was not statistically significant. Our study can also be compared with Rajesh raman et all, they have also noticed similar results among buska mask and LMA protractor groups. OLP was better in buska mask when compared to LMA which was also noticed in Zehra Ipek Et all, Rajesh raman Et all, Noor sulthana study.

Conclusion:

To conclude both LMA protractor and buska mask, have almost similar in their functional analysis, though there are slight differences in ease of insertion (better in LMA P) and OLP (better in BM) both can be safely used in laparoscopic cholecystectomy surgeries.

The time taken for insertion of LMA Protector was less than Buska mask, which was statistically not significant (P>0.05). The mean OLP in group LMA P was 32.83+ 3.29, whereas mean OLP of group BM was 31.70+3.96(P> 0.05),

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