FIBEROPTIC CONFIRMATION OF PLACEMENT OF LMA PROSEAL & I-GEL IN ELECTIVE SURGERIES IN ADULTS.

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ABSTRACT INTRODUCTION

is one of the main roles carried out by the anaesthetist. The gold standard of securing and maintaining of the airway throughout a surgery is endotracheal intubation. Sore throat and stress response are some of the side effects of endotracheal intubation. Supraglottic airway devices (SGA) are useful in securing the airway and also keep the patency of the airway intact. The insertion of such devices also helps us in avoiding the side effects associated with endotracheal intubation. It is critical to figure out the best way to insert these devices and to confirm the proper placement of these devices as a prolonged time of insertion and unsuccessful placement can be disastrous. Fiber-optic bronchoscopy maybe used to assess the insertion of these devices and thus decrease complications.

AIM OF THE STUDY

Comparing the position of Proseal LMA and I-Gel with relation to glottic inlet using a fiberoptic bronchoscope. **PRIMARY OBJECTIVE**

Assessing the positionin relation to glottic inlet of Pro-SEAL LMA and I-GEL using a fiberoptic bronchoscope.

- SECONDARY OBJECTIVES
- Duration of LMA insertion
 Attempts taken for LMA insertion
- Attempts taken for LMA insertion
- Hemodynamic parameters
- > To assess adverse effects during LMA insertion, during the surgery and postoperativeperiod-
- o Cough
- Laryngeal spasm
- Blood stainin the LMA
- \circ Sore throat

METHODS

50 Patients were grouped into two groups - Group-P & Group-I. Pre-anaesthetic check-up and a thorough general examination was conducted for all the patients participating in the study. Written and informed consent was taken. The patients were premedicated and induction was done with Inj. Propofol and Inj. Succinylcholine. After adequate relaxation of the jaw was achieved, LMA was inserted. Vitals were taken down post LMA insertion and Fiber-optic grading was done. Post-procedure, the LMA was removed and the following outcome measures were noted down - 1) Duration taken for insertion of LMA. 2) Attempts taken for LMA insertion 3) Hemodynamic profile 4) Anticipated adverse effects.

CONCLUSION

We would like to conclude that I-Gel is a safe and a much reliable substitute to endotracheal intubation and also to Proseal LMA for keeping the airway patent during daycare procedures. It has the advantages of a good placement with relation to the inlet of the glottis and also provides adequate ventilation, lesser number of complications and a good hemodynamic profile throughout the procedure.

Keywords : LMA, SGA, Supra glottic airways device, Fiberoptic Bronchoscope, Glottic inlet, I-Gel, Proseal LMA.

INTRODUCTION

Securing and maintaining of the airway throughout a surgery is one of the main roles carried out by the anaesthetist. The gold standard for this purpose is the endotracheal intubation. Sore throat and stress response are some of the side effects of endotracheal intubation. On the other hand, face mask is sometimes used for procedures of short duration. Supraglottic airway devices (SGA) are useful in this regard that they are help us in securing the airway and also keep the patency of the airway intact. The insertion of such devices also helps us in avoiding the side effects associated with endotracheal intubation. It is critical to figure out the best way to insert these devices and to confirm the proper placement of these devices as a prolonged time of insertion and unsuccessful placement can be disastrous. Fiber-optic bronchoscopy maybe used to assess the insertion of these devices and thus decrease complications.

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MATERIALS AND METHODS

- **STUDY PERIOD:** 6 months.
- **STUDY AREA:** Department of Anaesthesiology, JNMC & AVBRH, Wardha.
- **RESEARCH DESIGN:** Randomized Comparative Study.
- STUDY POPULATION: Two groups with 25 patients each -
- Group P Proseal LMA.
- Group I I-Gel.

The project was proposed before the Ethics Committee of JNMC, DMIMSU & AVBRH Sawangi and was conducted after their approval. All patients were briefed regarding the study and written consent obtained before the commence of the study.

CRITERIAS FOR INCLUSION:

- -Patients between the ages of 18 60 years.
- -Patients belonging to grade I/II of ASA.
- -Elective short procedures.
- -Patients giving informed written consent.
- CRITERIAS FOR EXCLUSION:

-Patients with an ASA grade of III/IV.

- -Patients with full stomach.
- -Patients with gross anatomical airway variations.

-Patients with anticipated difficulty for maintaining a patent airway.

-Patients with URTI, H/o asthma, full stomach.1

-Patients posted for emergency surgeries.

-Pregnant patients.

SAMPLE SIZE

Sample Size For Comparing Two Means

	Input Data		
Confidence Interval (2-sid Power	led)	95% 80%	
Ratio of sample size (Gro	up 2/Group 1)	1	
	Group 1	Group 2	Difference
Mean	11.2	15.13	-3.93
Standard deviation	1.814	2.91	
Variance	3.2906	8.4681	
Sample size of Group 1		6	
Sample size of Group 2		6	
Total sample size		12	

*Difference between the means

Results from OpenEpi, Version 3, open source calculator--SSMean Print from the browser with ctrl-P or select text to copy and paste to other programs.

Variables	Group I ($n = 40$)	Group P ($n = 40$)	P value
Insertion time	11.2 ± 1.814	15.13 ± 2.91	0.001+(S)
Ease of insertion			
3	32 (80%)	25 (62.5%)	0.0004*(S
2	8 (20%)	15 (37.5%)	
1	0	0	
0	0	0	
Manipulations			
Yes	3 (7.5%)	17 (42.5%)	0.0001*(S
No	37 (92.5%)	23 (57.5%)	
Maneuvers			
No	37 (92.5%)	27 (67.5%)	0.0001=(S
1	3 (7.5%)	8 (20%)	
2 or more	0	9 (22.5%)	
Anatomic fit			
1	39 (97.5%)	30 (75%)	0.001*(S)
2	1 (2.5%)	7 (17.5%)	
3	0	2 (5%)	
4	0	1 (2.5%)	

*Chauhan, et al.: Chauhan G, Nayar P, Seth A, Gupta K, Panwar M, Agrawal N. Comparison of clinical performance of the I-gel with LMA proseal. J Anaesthesiol Clin Pharmacol 2013;29:56-60.

The total sample size required being 12, the study was conducted on a total sample size of 50 for reliable results.Patients were grouped into two groups as follows:

- P Group-Patients with Proseal as their airway device. 0
- I Group Patients with I-Gel as their airway device. 0

MATERIALS:

- Pro-SEALLMA and LMA I-Gel sizes III & IV, \geq
- \geq Fiberoptic bronchoscope,
- \triangleright Non- invasive multipara Monitor.
- \geq 18 Gauge Intravenous cannula,
- \geq Drugs - Glycopyrrolate, Fentanyl, Midazolam, Propofol,

Sevoflurane, Succinylcholine, Vecuronium.

Reversal agent –Neostigmine.

METHODOLOGY:

Patient satisfying inclusion criteria were added to the study. Informed consent was obtained after briefing the patient and the relatives. Patients were grouped into two groups - Group-P & Group-I. Pre-anaesthetic check-up and a thorough general examination was conducted for all the patients participating in the study. All the participants were kept NPO for a period of 6 hours prior to the designated time of operation. Vital parameters of the patients were noted in pre-operative room. After briefing of the study methods again, the induction of anesthesia was commenced. Baseline vital parameters were noted down after the patient was connected to non-invasive multipara monitors.

The patients were premedicated with Inj. Glycopyrrolate 0.2mg iv- and Inj. Fentanyl 100µg iv and pre-oxygenation done.Induction was done with Inj. Propofol 2mg/kg, Inj. Succinylcholine 2mg/kg. After adequate relaxation of the jaw was achieved, LMA was inserted. Maintenance was done using a mixture of oxygen, nitrous oxide and 2% Sevoflurane maintaining a FiO2 of 50%. Inj. Vecuronium was used for muscle relaxation. The patency of the airway and positioning of the LMA was checked by 5-point auscultation and auscultation over the neck.Vitals were taken down post LMA insertion and Fiber-optic grading was done.

Grade I : Larynx was seen.

Grade II : Larynx and the posterior surface of the epiglottis were seen.

Grade III: Larynx, tip/anterior surface of the epiglottis were seen.

Grade IV: Down folding of the epiglottis and the anterior surface of the epiglottis were seen.

Grade V: Down folding of theepiglottis and larynx were not seen.

Post-procedure, the LMA was removed and the following outcome measures were noted down - 1) Duration taken for insertion of LMA. 2) Attempts taken for LMA insertion 3) Hemodynamic profile 4) Anticipated adverse effects.

OBSERVATION AND RESULTS STATISTICAL ANALYSIS:

All the data that were collected during the study were expressed as mean value and as percentages. Appropriate statistical tests were carried out. Continuous variables were examined using the ANOVA single factor test & unpaired t-test.Categorical variables were examined using the Fischer Exact Test & the Chi-Square Test. A P value of 0.05 or less implied that the data was of significance statistically.

LMA	PATIENTS	PERCENTAGE
LMA Pro-SEAL	25	50%
I -GEL	25	50%

DISTRIBUTION OF PATIENTS ACCORDING TO AGE

YEARS - AGE	PRO-SEAL LMA	%	I-GEL	%
<20	0	0%	3	12%
21-30	16	64%	6	24%
31-40	8	32%	13	52%
>40	1	4%	3	12%
TOTAL	25	100%	25	100%

	AC	ΈE
LMA TYPE	MEAN	SD
PLMA	30.2	4.5
I-GEL	31.7	7.9
	P VALUE - 0.53	
	SIGNIFICANCE - NO	
	UNPAIRED T TEST	

	LMA	TYPE
ASA - PS	PLMA	I-GEL
ONE	22	22
TWO	3	3
	P VALUE - 0.64	
	NON-SIGNIFICANT	
	ODDS RATIO - 1.57	
	CHI SQUARE TEST	

HEIGHT IN CM	
MEAN	SD
161	2.6
158	2.2
P VALUE - 0.15	
UNPAIRED T TEST	
NON-SIGNIFICANT	
	HEIGHT MEAN 161 158 P VALUE - 0.15 UNPAIRED T TEST NON-SIGNIFICANT

		WEIGHT IN KG
	MEAN	SD
PLMA	62	5.8
I-GEL	59.6	6.51
	P VALUE - 0.19	
	UNPAIRED T TEST	
	NON-SIGNIFICANT	

	LMA	TYPE
LMA SIZE	PLMA	I-GEL
THREE	23	22
FOUR	2	3
	P VALUE - 0.644	
	NON-SIGNIFICANT	
	ODDS RATIO - 1.56	
	CHI SQUARE TEST	

	LMA	TYPE
NO OF ATTEMPTS	PLMA	I-GEL
ONE	23	23
TWO	2	2
	P VALUE - 0.639	
	NON-SIGNIFICANT	
	ODDS RATIO - 0.639	
	CHI SQUARE TEST	

	INSERTIC	ON TIME(IN SEC)
LMA TYPE	MEAN	SD
PLMA	17.35	4.4
I-GEL	14.87	3.89
-1	P VALUE - 0.038	
	SIGNIFICANT	

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		WEIGHT IN KG
	MEAN	SD
PLMA	62	5.8
I-GEL	59.6	6.51
	P VALUE - 0.19	
	UNPAIRED T TEST	
	NON-SIGNIFICANT	

	LMA	TYPE
LMA SIZE	PLMA	I-GEL
THREE	23	22
FOUR	2	3
	P VALUE - 0.644	
	NON-SIGNIFICANT	
	ODDS RATIO - 1.56	
	CHI SQUARE TEST	

	LMA TYPE	
NO OF ATTEMPTS	PLMA	I-GEL
ONE	23	23
TWO	2	2
	P VALUE - 0.639	
	NON-SIGNIFICANT	
	ODDS RATIO - 0.639	
	CHI SQUARE TEST	

	INSERTIC	ON TIME(IN SEC)
LMA TYPE	MEAN	SD
PLMA	17.35	4.4
I-GEL	14.87	3.89
	P VALUE - 0.038	
	SIGNIFICANT	
	UNPAIRED T TEST	

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	LMA TYPE	
FOB GRADING	PLMA	I-GEL
ONE	21	20
TWO	4	5
	P VALUE - 0.714	
	NON-SIGNIFICANT	
	ODDS RATIO - 0.761	
	CHI SQUARE TEST	

	LMA	TYPE
COMPLICATION	PLMA	I-GEL
PRESENT	6	4
ABSENT	19	21
ō	P VALUE - 0.481	
	NON-SIGNIFICANT	
	ODDS RATIO - 0.485	
	CHI SQUARE TEST	

	HEART RATE		P VALUE
TIMELINE	PLMA	I-GEL	
BASELINE	79.13 ± 5.20	80.15 ± 5.96	0.039
POST LMA 1 MIN	79.94 ± 5.86	81.96 ± 5.89	0.257
POST LMA 5 MIN	80.5±5.27	80.86±5.3	0.859
POST LMA 10 MIN	81.65±5.22	82.7±5.19	0.039
AFTER REMOVAL	80.1±5.1	82.2±4.74	0.002
P VALUE	0.117	0.462	
	NON-SIGNIFICANT	NON-SIGNIFICANT	

	SYSTOLIC BLOOD PRESSURE		P VALUE
TIMELINE	PLMA	I-GEL	
BASELINE	128.51±7.5	126.86 ±6.65	0.43
POST LMA 1 MIN	129.69 ±8.38	129.1 ±5.98	0.787
POST LMA 5 MIN	129 ±8.75	129.42 ±8.74	0.78
POST LMA 10 MIN	129.52 ±8.28	129.3 ±7.37	0.915
AFTER REMOVAL	131.48 ±7.3	129.29 ±7.3	0.314
P VALUE	0.74	0.65	
	NON-SIGNIFICANT	NON-SIGNIFICANT	

	DIASTOLIC BLOOD PRESSURE		P VALUE
TIMELINE	PLMA	I-GEL	
BASELINE	76.1±8.36	75.85±6.72	0.912
POST LMA 1 MIN	77.82±6.32	77.37±5.83	0.317
POST LMA 5 MIN	78.08±5.01	77.53±6.84	0.744
POST LMA 10 MIN	78.93±6.64	77.62±6.63	0.312
AFTER REMOVAL	78.98±5.59	77.76±6.99	0.244
P VALUE	0.49	0.91	
	NON-SIGNIFICANT	NON-SIGNIFICANT	

TIMELINE	SPO2		
	PLMA	I-GEL	P- VALUE
BASELINE	100	100	0
POST LMA 1 MIN	100	99.85±0.45	0.179
POST LMA 5 MIN	100	100	0.333
POST LMA 10 MIN	100	100	0.333
AFTER REMOVAL	100	100	0.333
P VALUE	1	0.705	
	NON-SIGNIFICANT	NON-SIGNIFICANT	

RESULTS

1. After the first attempt insertion was successful in 92% of cases with PLMA and 92% with I-gel, which is not statistically significant.

2. The average insertion time of PLMA is about 17.35 seconds, and that of i-gel is 14.87 seconds, which has statistical significance. Thus, this indicates that the insertion time of I-gel is relatively short.

3. Fiberoptic bronchoscope grade I was seen in 84% cases of PLMA and 80% of I-gel. This is statistically not significant.

4. Complications associated with PLMA insertion was 24%, while that of I-gel was 16%, which was not statistically significant.

5. In this study various parameters likeage, height, weight, pulse rate, oxygen saturation, systolic and diastolic blood pressure were compared between the two groups. The p values were all greater than 0.05 which holds no statistical significance.

Since there is no inflatable cuff, the duration of I-gel insertion and securing the airway is much shorter than the time required for PLMA. The ease with which insertion was done, the total number of attempts taken for LMA placement, the Fiberoptic bronchoscope grading of the view of the glottis, the hemodynamic response during insertion, and complications are similar in both devices.

DISCUSSION

Endotracheal intubation is the most secure way of maintaining airway control during general anesthesia. Stress response is seen during laryngoscopy and tracheal intubation as a result of the surge in sympatho-adrenal activity. Hence there is an increase in heart rate and blood pressure. During short surgical procedures, when TIVA is used and for volatile induction anesthesiologists use the face mask for induction and also for maintenance.

The great success rate associated with classic LMA has made it an important airway device for emergency airway maintenance and in general anesthesia. Since its invention the LMA has undergone multiple modifications thereby making it much more useful in difficult airway situations. Thus, there are multiple SADs in clinical practice nowadays.

With respect to the endotracheal tube, these devices provide much easier and quicker placement, a better hemodynamic stability especially during the time of induction of anesthesia and emergence from anesthesia, decreased incidence of complications, and low anesthesia requirements for the tolerance of the airway device. Hence, they are being used increasingly in daycare surgical procedures.

Classic LMA is the most often utilized Supraglottic airway device from the 1st generation of LMAs. Proseal LMA, I-Gel, and other devices in the latest generation of LMAS have special features that improve safety and effectiveness. The current research compares the placement of the devices in the glottic inlet by the use of a fiberoptic bronchoscope, ease of insertion, hemodynamic parameters and complications between two second-generation LMA's - PLMA and I-gel.

This prospective randomized comparative trial included 50 adult patients who were scheduled to have an elective brief surgical procedure and with an ASA grade of I or II. The patients were randomly grouped into two groups consisting of 25 participants each, and PLMA was provided to one group and I-gel to the other.

The demographic characteristics in our study were determined to be evenly distributed among the two groups based on statistical analysis, thus we moved on to comparing additional variables.

In the study, the LMA insertion following the first attempt was 92% for PLMA and 92% for I-gel. LMA insertion following the second attempt was 8% vs. 8%. The p-value was 0.639 which rendered these data statistically not significant. These are in accordance with the findings of Shimbori et al, Goldman et al, and Singh et al.

The absence of a cuff accounted for the shorter time of insertion for I-gel (14.87s) against that of Pro-seal LMA (17.35s). The p value was 0.038 thereby making this statistically significant. Helmy et al, Goel et al, and Jeon et al have all made comparable observations.

Fiberoptic bronchoscope was used to visualize the glottic inlet and the grading was I in 84% and II in 16% of the cases in the Proseal LMA group. The grading was I in 80% and II in 20% of the cases in the I-Gel group. The p value was 0.714 which is statistically non-significant. This is in accordance with Gasteiger, Brimacombe et al. findings.

Complications including laryngospasm, blood on the LMA, trauma to the airway and sore- throat were investigated. With a p-value of 0.481, which was statistically not significant, complications were determined to be 24 percent in the Proseal LMA group and 16 percent in I-gel group, suggesting that complications were not substantially higher in any of the groups. This is in line with Rukshanaa Najeebe et al.'s research.

Analysis of hemodynamic measures such as pulse rate, blood pressure, andoxygen saturation had a p value greater than 0.05. Thus making these statistically insignificant. This is consistent with the findings of Anjandas et.al.

SUMMARY

Classic LMA, first came into use in 1988, is an effective supraglottic airway device for keeping the airway patent in day care surgical procedures. PLMA and I-gel are two newer generation LMAs that have the added benefit of drainage tubes to evacuate the stomach contents and thus reducing the chances of aspiration.

The study was aimed to give a comparison between two LMAs of the new generation – Proseal LMA to I-gel with respect to adequacy of placement in the glottis, insertion ease and time, incidence of complications & hemodynamic response to insertion.

CONCLUSION

We would like to conclude that I-Gel is a safe and a much reliable substitute to endotracheal intubation and also to Proseal LMA for keeping the airway patent during daycare procedures. It has the advantages of a good placement with relation to the inlet of the glottis and also provides adequate ventilation, lesser number of complications and a good hemodynamic profile throughout the procedure. The ease associated with the insertion and the minimal time required for insertion make it a better choice for day care procedures.

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