Original research paper

A prospective randomised comparative study for comparison of two insertion techniques of proseal laryngeal mask airway in patients posted for short gynaecological procedures

[1]Dr. P Kowsalya, [2]Dr. Kajal Dalal, [3]Dr. Pritee Bhirud

[1]Assistant Professor, Mamata Medical College, Khammam, Telangana, India
[2,3]Consultant, Department of Anaesthesia, B.A.R.C. Hospital, Mumbai, Maharashtra, India

Corresponding Author:
Dr. P Kowsalya

Abstract

Background: This study compared two insertion techniques of Proseal LMA.
Method: After institutional ethics committee approval and patients consent, 100 women aged 18-60 years of ASA 1 & 2 were included in the study. We have excluded patients with known or predicted difficult airway, recent sore throat, mouth opening less than 2.5cm and with risk of aspiration (nonfasted or gastroesophageal reflux). Patients were divided into 2 groups of 50 each.
In Group A-Digital Technique for PLMA Insertion & in Group B- Rotational Technique for PLMA Insertion was used. Using chi-square test and student t-test statistical results were obtained.
Results: The insertion success rate at the first attempt was higher for the rotational technique than the standard technique. Insertion technique made no difference in insertion time. Blood on PLMA after removal less in the rotation technique. Sore throat at 1 hr and 24 hrs post-surgery less in the in the rotation technique than the standard technique.
Conclusion: We conclude that insertion of the PLMA is more successful with the rotation technique in comparison with standard technique of insertion.

Keywords: Proseal laryngeal mask airway, insertion technique, short gynaecological procedures

Introduction
Background

The Proseal laryngeal mask airway (PLMA) is a relatively new laryngeal mask Device with an added dorsal cuff to improve seal, along with a drainage tube to prevent Aspiration and gastric insufflation. The PLMA is more difficult to insert at first attempt than the classic laryngeal mask airway, with success rates at first attempt varying between 82% and 100% [3]. The main cause of failed insertion is impaction at the back of the mouth. Several techniques have been described to improve the insertion success rate. The manufacturer recommends that the ProSeal LMA be inserted using either manipulation with the fingers or a curved metal introducer. Nonetheless, first attempt success rates of ProSeal LMA insertion range from 81% to 87%, which is lower than the Classic LMA [6]. Insertion of PLMA with 90-degree rotation

may reduce the contact surface with the pharyngeal wall and make it easy to advance over the smooth angle against the posterior pharyngeal wall.

C.R. SOH*, A.S.B. NG. *et al*., suggested that the reverse technique is an acceptable alternative to the standard technique for inserting the LMA in children & clinically, a true difference of 10% in success rates would be a useful but modest difference in success of insertion rates [5]. Hence, we compared the ease of insertion of PLMA with two different techniques, i.e., Digital & Rotational Technique for PLMA Insertion.

Aim

The present study was conducted with the primary aim of the success rate of insertion at first attempt by two insertion techniques of Proseal laryngeal mask airway. The secondary outcomes were measured were incidence of pharyngeal mucosal trauma, hemodynamic changes.

Methods

This prospective randomised controlled study was conducted in B.A.R.C. Hospital, from November 2014 to November 2016 after obtaining ethical committee permission and informed patient consent. Hundred adult female patients of American Society of Anaesthesiologists (ASA) physical status I & II between the age of 18-60 years undergoing elective short duration gynaecological surgeries under general anaesthesia were enrolled for the study. Patients with known or predicted difficult airway, recent sore throat, mouth opening less than 2.5cm, risk of aspiration (nonfasted or gastroesophageal reflux).

Patients were allocated to the two insertion techniques based on computer generated random numbers. The assignments were concealed in opaque sealed envelopes until immediately before induction. 100 Consecutive patients who fulfil the inclusion criteria were randomized using the sealed envelope technique based on computer generated random numbers into two groups.

Group A: Digital Technique for PLMA Insertion.

Group B: Rotational Technique for PLMA Insertion.

- Baseline monitoring included electrocardiogram (ECG), heart rate, non-invasive blood pressure, oxygen saturation, capnography ($Etco_2$). Patients were be administered intravenously midazolam 0.03mg/Kg, intravenous fentanyl 1mcg/kg 3-5min before induction. Anaesthesia was given with the patient in the supine position and both techniques were performed with head in sniffing position. Anaesthesia was induced with propofol 2-3mg/kg intravenously after adequate jaw relaxation, size 3 PLMA was inserted. Digital technique was used to insert the PLMA in Group A patients, whereas rotation technique was used in Group B patients. Heart rate and mean blood pressure were recorded at 1min before and 10 and 15 min after insertion. In Digital technique, Posterior aspect of the deflated mask was coated with a water-based lubricant. PLMA cuff was fully deflated and held like a pen and inserted while pressing along the palatopharyngeal curve using index finger. In Rotational technique, PLMA was lubricated on the posterior and lateral aspects with the same water-based lubricant as in digital technique, the PLMA was inserted until the entire cuff is inside the mouth. It was rotated counter clockwise 90 degrees and advanced until resistance of the hypopharynx was felt and then straightened out in the hypopharynx. For both techniques, once PLMA was inserted into the hypopharynx, cuff was inflated with air to achieve cuff pressure of 60cm H_2o. Volume of air required for cuff inflation was noted. An effective airway was judged by a square wave capnography trace and no audible leak with peak pressure of 20cm H_2o. During

manual ventilation, oropharyngeal leaks were detected by listening over the mouth.
▪ PLMA was repositioned if air leaks up the drainage tube or ventilation was ineffective. Drainage tube leaks was detected by placing lubricant over the proximal end of the drain tube. If lubricant moved with respiration, PLMA was reinserted. The number of insertion attempts were recorded. The final confirmation of PLMA position was checked with the help of a fiber optic bronchoscope.

Grading of Fiber optic bronchoscope was follows:
▪ **Grade I:** Full view of vocal cords.
▪ **Grade II:** View of vocal cords partially blocked by epiglottis.
▪ **Grade III:** Only arytenoids seen.
▪ **Grade IV:** No laryngeal structures visible.

If Placement fails after three attempts, insertion was considered as a failure. Insertion time was defined as the time from picking up the device to attaching it to the breathing system after inflation of cuff. The ease of insertion was assessed by success rate at the first attempt. At the end of surgery after return of protective airway reflexes the PLMA was removed and was checked for presence or absence of blood. At 1 hour and at 24 hours' post-surgery the patient was assessed for sore throat.

Statistics

The primary aim was to compare the success rates of first attempts of PLMA in both techniques. Secondary outcome measures included insertion time, number of airway manipulations, postoperative complications, Number of insertion attempts and pharyngeal mucosal trauma.
After data collection, data entry was done in Excel. Statistical analysis was done with the help of SPSS version 21. Data analysis was done with help of summary measures mean and standard deviation and useful graphs was used. Quantitative data was analysed with help of 't' test to find the significant difference between two groups and to find 'p' value. Qualitative data was be analysed with help of Chi square test to find the significant difference between two groups and to find 'p' value.
$p > 0.05$ was considered as statistically not significant.
$p < 0.05$ was considered as statistically significant.
$p < 0.01$ was considered as statistically highly significant

Results
1) Demographics

All the parameters mentioned below are in the form of mean+/- SD.

Table 1: Comparison of demographic data

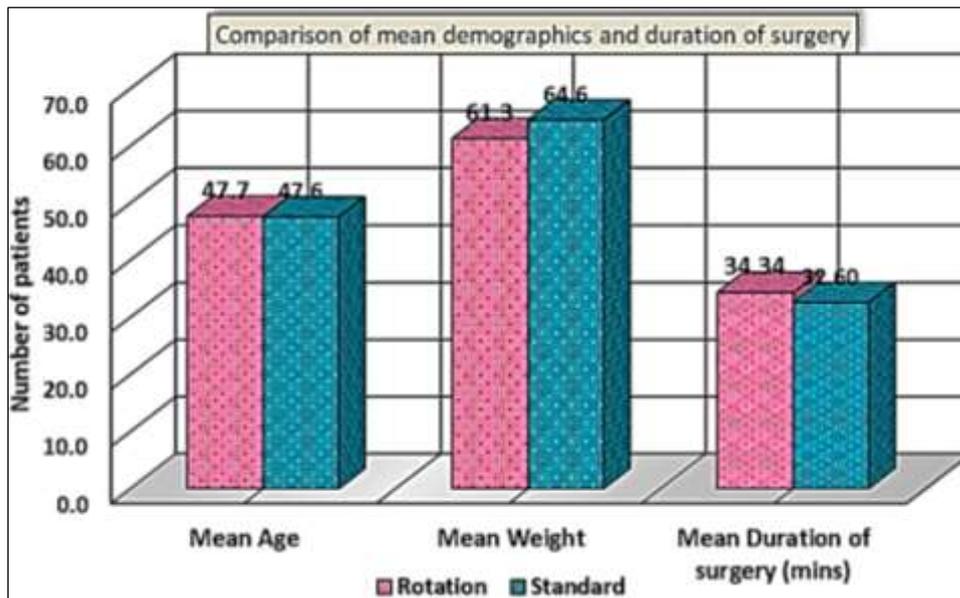| Variable		Rotation			Standard			t	df	p value
	N	Mean	Std. Deviation	Std. Error Mean	Mean	Std. Deviation	Std. Error Mean			
Age	50	47.70	8.615	1.218	47.56	7.877	1.114	.085	98	.933
Weight	50	61.30	7.075	1.001	64.56	9.183	1.299	-1.989	98	.050
Duration of surgery (mins)	50	34.34	8.918	1.261	32.60	7.440	1.052	1.059	98	.292

Fig 1: Comparison of demographic data

The age distribution of patients in the two groups was compared. The mean age in rotation group was 47.70+/-8.615 years and in standard group it was 47.56+/-7.877 years with a P value 0. 933 which is statistically not significant.

The mean weight in rotation group was 61.30+/-7.075, mean weight in standard group it was 64.56+/-9.183 with a P value 0.50 which is statistically not significant.

The mean duration of surgery in rotation group was 34.34+/-8.91mins, where as in standard group it was 32.60+/-7.44 mins with a p value 0.292 which is statistically not significant.

ASA Distribution

Table 2: ASA distribution

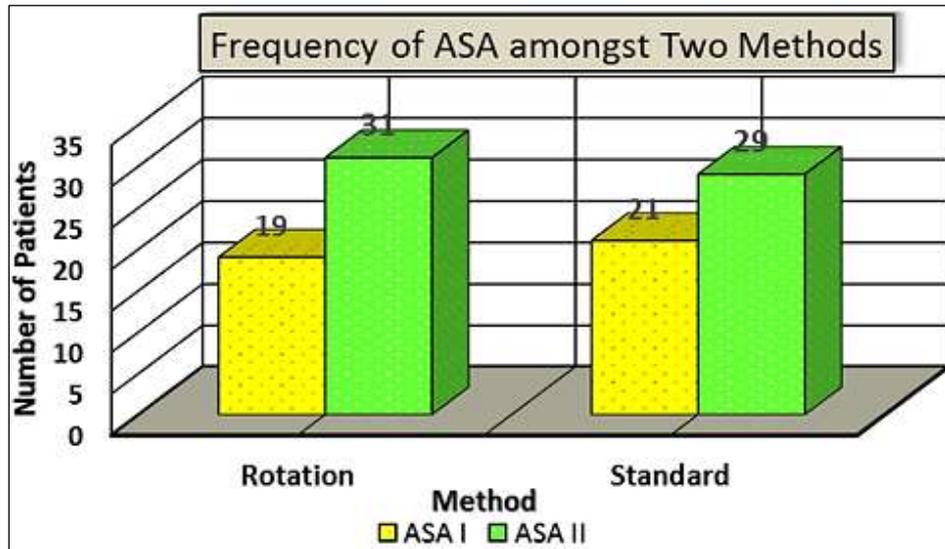|		ASA		Total
		I	**II**	
Rotation	n	19	31	49
	%	47.5%	51.7%	-50.0%
Standard	n	21	29	49
	%	52.5%	48.3%	-50.0%
Total	n	40	60	99
	%	100.0%	100.0%	0.0%
	Value	df	p value	Exact p value
Pearson Chi-Square	.167[a]	1	.683	.838
Fisher's Exact Test	.167	1	.683	.838

Fig 2: ASA distribution

Rotation group consisted of ASAI-19, and ASAII-31 patients, whereas in standard group consisted of ASAI -21 and ASAII-29 patients. Both groups were comparable with respect to ASA distribution with p-value 0.683. which is statistically not significant.

Comparison of number of attempts

Table 3: Comparison of number of attempts

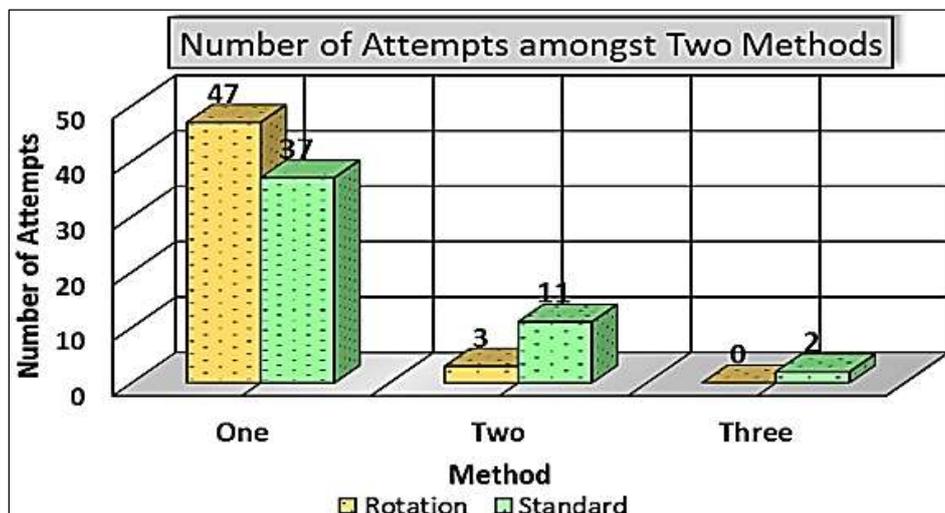|		Attempts			Total
		I	**II**	**III**	
Rotation	n	47	3	0	50
	%	94.0%	6.0%	0.0%	100.0%
Standard	n	37	11	2	50
	%	74.0%	22.0%	4.0%	100.0%
Total	n	84	14	2	100
	%	84.0%	14.0%	2.0%	100.0%
	Value	df	p value	Exact p value	
Pearson Chi-Square	7.762	2	.021	.014	
Fisher's Exact Test	7.331			.014	

Fig 3: Comparison of number of attempts

In rotation group, 47 patients had successful PLMA placement at first attempt and 3 patients had in the second attempt whereas in standard group 37 patients had successful placement in first attempt, 11 patients had in second attempt and 2 patients had in third attempt. The 'P' value was found to be 0.021.

Comparison of insertion time

Table 4: Comparison of insertion time

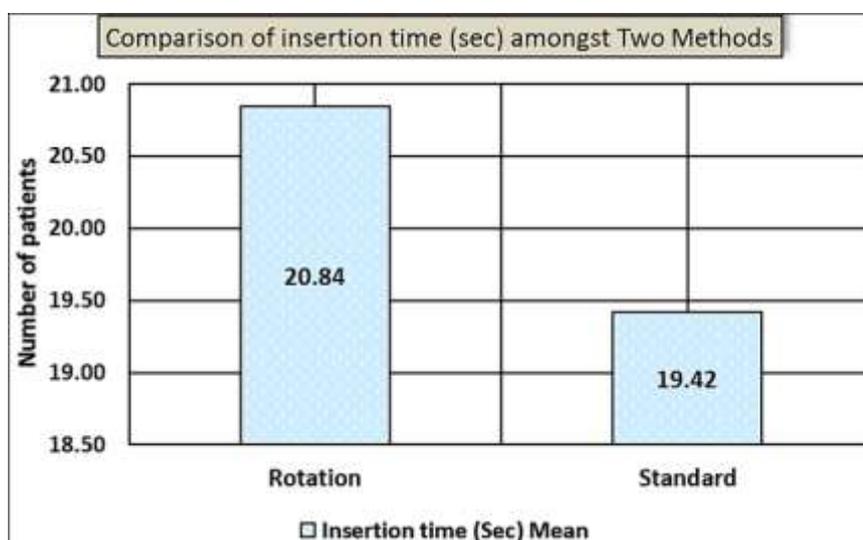|		Rotation			Standard			t	df	p value
	N	Mean	Std. Deviation	Std. Error Mean	Mean	Std. Deviation	Std. Error Mean			
Insertion time (Sec)	50	20.84	15.695	2.220	19.42	11.016	1.558	.524	98	.602

Fig 4: Comparison of insertion time

In rotation group, average insertion time was 20.84+/- 15.695 secs whereas in standard group it was 19.42+/- 11.016secs with 'P' value of 0.602 which is not significant.

Comparison of airway manipulations

Table 5: Comparison of airway manipulations

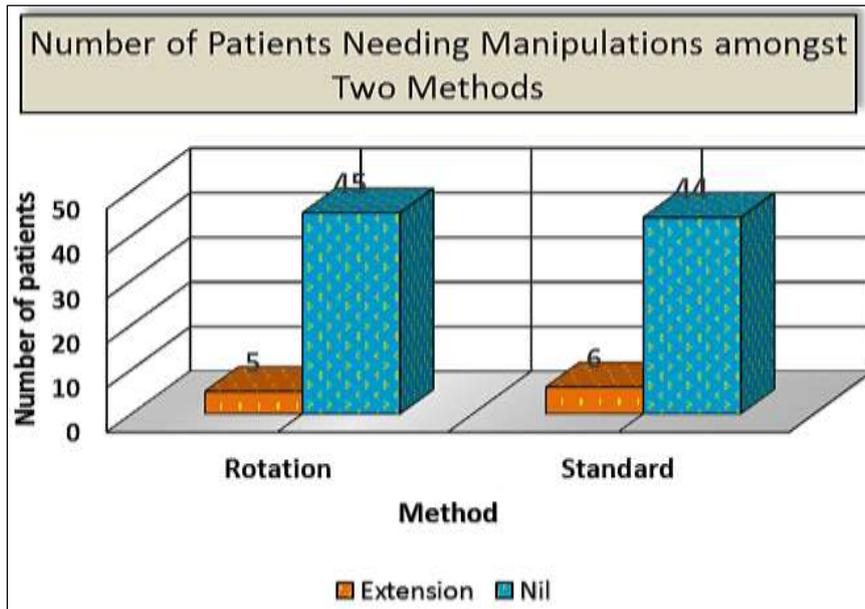|		Manipulations		Total
		Extension	Nil	
Rotation	n	5	45	50
	%	45.5%	50.6%	50.0%
Standard	n	6	44	50
	%	54.5%	49.4%	50.0%
Total	n	11	89	100
	%	100.0%	100.0%	100.0%
	Value	df	p value	
Pearson Chi-Square	.102	1	.749	
Fisher's Exact Test				

Fig 5: Comparison of airway manipulations

In rotation group, 5 patients required airway manipulations whereas in standard group 6 patients required airway manipulations. Both the groups comparable with a 'P' value of >0.05 which is statistically not significant.

Hemodynamic parameters
Comparision of heart rate (HR)

Table 6: Comparison of heart rate

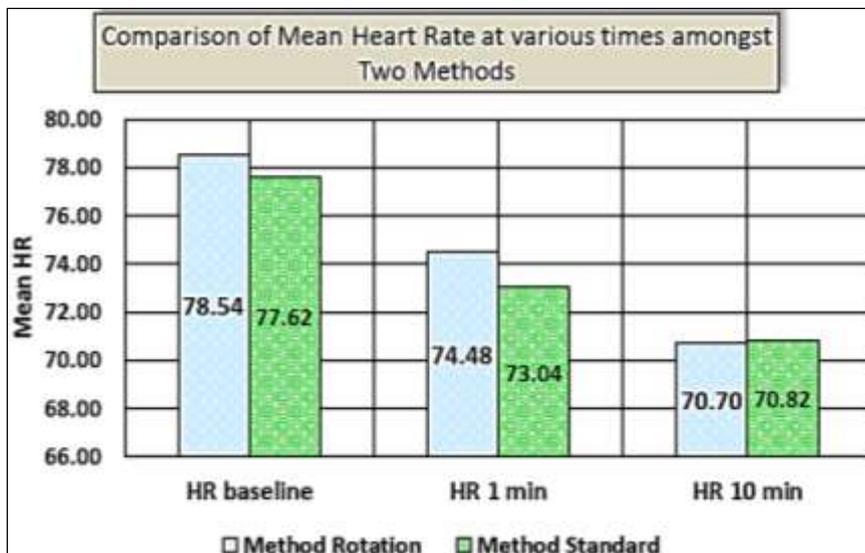|		Rotation			Standard			t	df	p value
	N	Mean	Std. Deviation	Std. Error Mean	Mean	Std. Deviation	Std. Error Mean			
HR baseline	50	78.54	9.040	1.278	77.62	8.114	1.147	.536	98	.593
HR 10 min	50	74.48	9.320	1.318	73.04	8.315	1.176	.815	98	.417
HR 15 min	50	70.70	10.132	1.433	70.82	10.445	1.477	.058	98	.954

Fig 6: Comparison of heart rate

Mean heart rate in both the groups were tabulated at various intervals of time, which was then analysed with the help of independent student 't' test. In rotation group, baseline mean heart rate was 78.54+/-9.040 and at 10 min was 74.48+/-9.32, at 15 min was 70.70+/-10.13. while in standard group, base line mean heart rate was 77.62+/-8.114 and at 10 min 73.04+/-8.31, at 15min 70.82+/-10.44 which was comparable with a P value 0. 593 which is statistically not significant.

Comparision of systolic blood pressure

Table 7: Comparison of systolic blood pressure

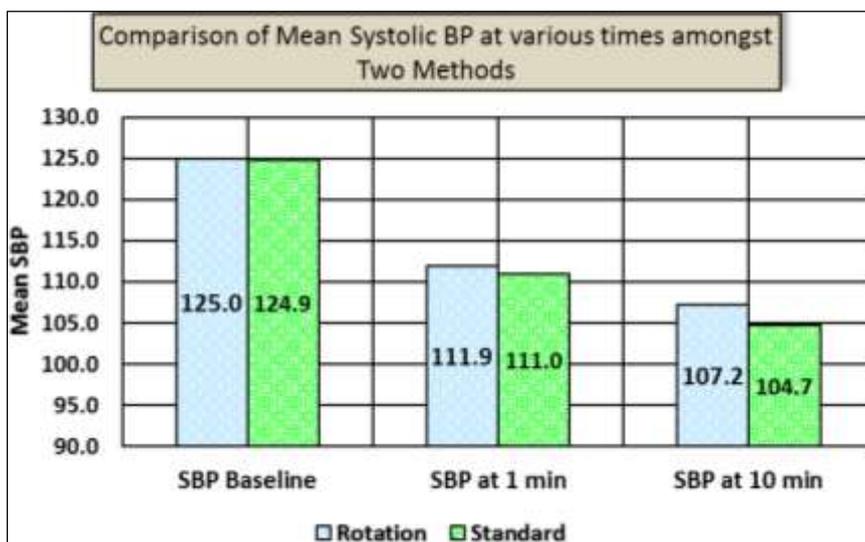| | N | Rotation | | | Standard | | | t | df | p value |
		Mean	Std. Deviation	Std. Error Mean	Mean	Std. Deviation	Std. Error Mean			
SBP Baseline	50	125.00	9.87	1.40	124.88	12.16	1.72	.054	98	.957
SBP at 10 min	50	111.94	11.37	1.61	111.04	11.28	1.60	.397	98	.692
SBP at 15 min	50	107.24	12.53	1.77	104.72	9.90	1.40	1.116	98	.267

Fig 7: Comparison of systolic blood pressure

Mean SBP (systolic blood pressure) in both the groups were tabulated at various intervals of time, which was also analysed with the help of independent student 't' test. 'P' value at all the time intervals comes to be >0.05 which is statistically not significant.

Comparision of mean diastolic blood pressure

Table 8: Comparison of diastolic blood pressure

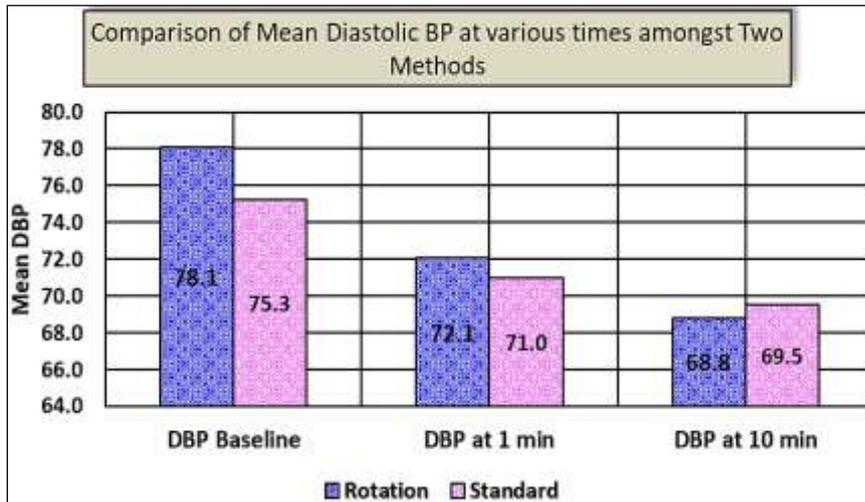| | N | Rotation | | | Standard | | | t | df | p value |
		Mean	Std. Deviation	Std. Error Mean	Mean	Std. Deviation	Std. Error Mean			
DBP Baseline	50	78.10	7.158	1.012	75.26	6.164	.872	2.126	98	.036
DBP at 10 min	50	72.060	8.0646	1.1405	70.980	5.4976	.7775	0.782	86.454	.436
DBP at 15 min	50	68.80	8.528	1.206	69.52	6.115	.865	-0.485	98	.629

Fig 8: Comparison of diastolic blood pressure

Mean DBP (diastolic blood pressure) in both the groups were tabulated at various intervals of time, which was also analysed with the help of independent student 't' test. 'P' value at all the time intervals comes to be >0.05 which is statistically not significant.

Comparision of fiberoptic grading

Table 9: Comparison of fiberoptic grade

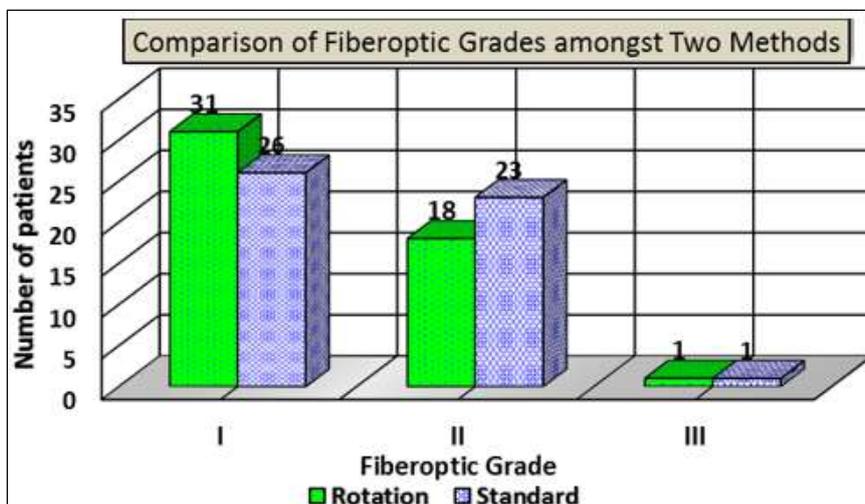|		Fiberoptic Grade			Total
		I	II	III	
Rotation	n	31	18	1	50
	%	54.4%	43.9%	50.0%	50.0%
Standard	n	26	23	1	50
	%	45.6%	56.1%	50.0%	50.0%
Total	n	57	41	2	100
	%	100.0%	100.0%	100.0%	100.0%
	Value	df	p value	Exact p value	
Pearson Chi-Square	1.048[a]	2	.592	.703	
Fisher's Exact Test	1.286			.703	

Fig 9: Comparison of fiberoptic grade

In rotation group, 28 patients had fiberoptic grade I, 8 patients had grade II whereas in standard group 26 patients had fiberoptic grade I, 23 patients had grade II,1 patient had grade III. The result gave a p value of 0.592 which is statistically not significant.

Comparision of blood on PLMA

Table 10: Comparison of blood on PLMA

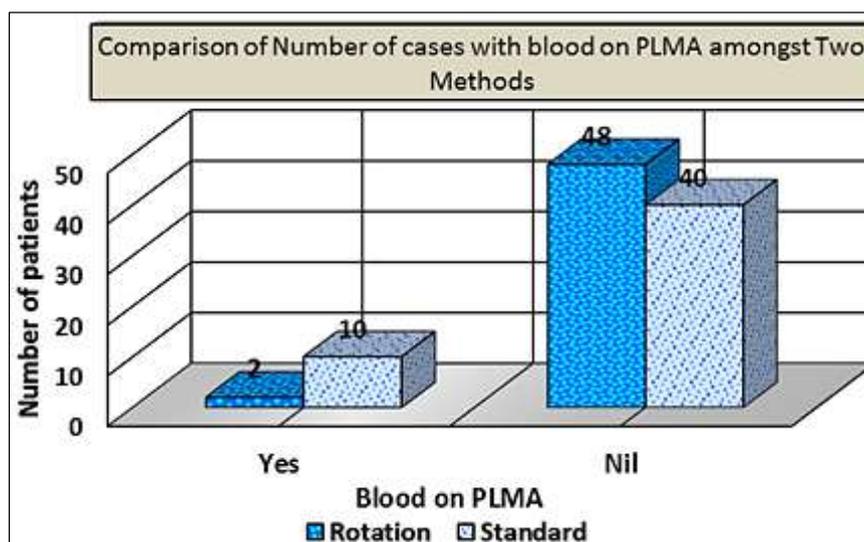|		Blood on PLMA		Total
		Yes	No	
Rotation	n	2	48	50
	%	16.7%	54.5%	50.0%
Standard	n	10	40	50
	%	83.3%	45.5%	50.0%
Total	n	12	88	100
	%	100.0%	100.0%	100.0%
	Value	df	p value	Exact p value
Pearson Chi-Square	6.061	1	.014	.028
Fisher's Exact Test				.028

Fig 10: Comparison of blood on PLMA

In rotation group, 2-patients had blood on PLMA, whereas in standard technique 10 -patients had blood on PLMA.
There was significant difference in both the groups with a p value of 0.028, Implying that the standard technique resulted in more patients having blood on PLMA at the time of removal.

Comparison of sore throat in recovery room

Table 11: Comparison of sore throat in recovery room

		Sore Throat Recovery		Total
		Yes	No	
Rotation	n	3	47	50
	%	16.7%	57.3%	50.0%
standard	n	15	35	50
	%	83.3%	42.7%	50.0%

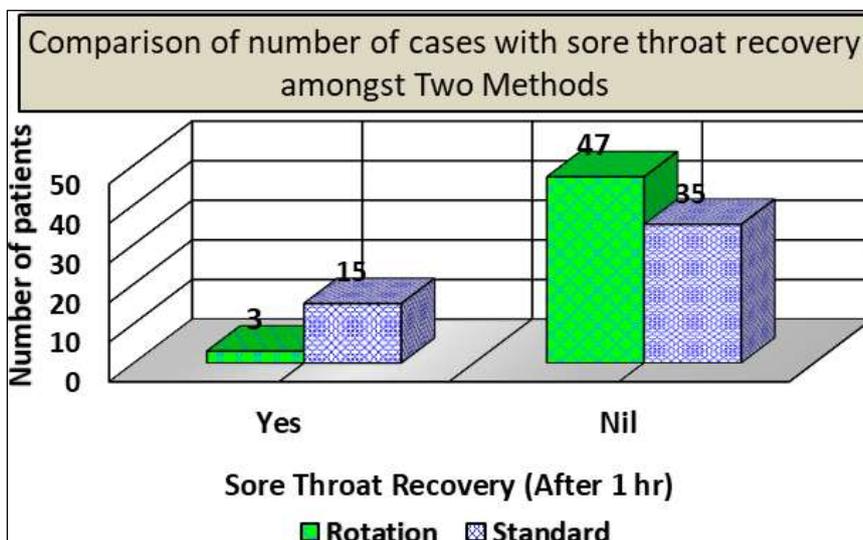| Total	n	18	82	100
	%	100.0%	100.0%	100.0%
	Value	df	p value	Exact p value
Pearson Chi-Square	9.756	1	.0002	.003
Fisher's Exact Test				.003

Fig 11: Comparison of sore throat

In rotation technique 3 patients developed sore throat, where as in standard technique 15 patients developed sore throat. There was significant difference in both the groups with p value of 0.002.

Hence the standard technique was associated with a significantly higher incidence of sore throat.

Comparison of sore throat after 24 hours

Table 12: Comparison of sore throat after 24 hrs

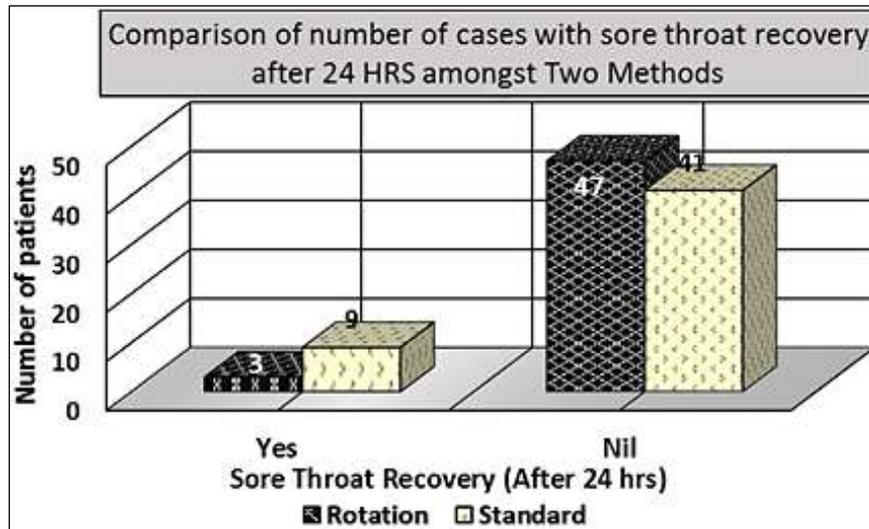|		Sore Throat Recovery (After 24 hrs)		Total
		No	Yes	
Rotation	n	47	3	50
	%	94.0%	6.0%	100.0%
Standard	n	41	9	50
	%	82.0%	18.0%	100.0%
Total	n	88	12	100
	%	88.0%	12.0%	100.0%
	Value	df	p value	
Pearson Chi-Square	3.409	1	.065	
Fisher's Exact Test	2.367	1	0.124	
Continuity Correction	3.549	1	0.060	

Fig 12: Comparison of sore throat after 24hrs

In rotation group 3 patients developed sore throat, where as in standard group 9 patients developed sore throat. There was no significant difference in the incidence of sore throat at 24hrs in both the groups (p= 0.065).

Discussion

The proseal laryngeal mask airway (PLMA) is a relatively new laryngeal mask device with an add dorsal cuff to improve seal, along with a drainage tube to prevent aspiration and gastric insufflation. The PLMA is more difficult to insert at first attempt than the classic laryngeal mask airway, with success rates at first attempt varying between 82% and 100% [1-4]. The main cause of failed insertion is impaction at the back of the mouth. Insertion of PLMA with 90 degree rotation may reduce the contact surface with pharyngeal wall and make it easy to advance over the smooth angle against the posterior pharyngeal wall.
We studied the success of insertion of Proseal LMA at first attempt, insertion time, hemodynamics, blood on PLMA and postoperative sore throat.

Demographic details: Both rotation and standard group were comparable with respect to age, weight, mallampati class, duration of surgery and ASA status.

Number of attempts

The success rate of insertion at first attempt in rotation group was 94% when compared to standard group which was 74% with significant 'p' value 0. 021. The overall success rate of insertion was found to be higher for rotation technique compared to standard technique. This is because the lateral edge reduces resistance between the PLMA and the posterior pharyngeal wall so it improves the ease of insertion. Another advantage of rotation technique is that there is no need to insert finger in to oropharynx for LMA insertion. The main cause of failed insertion with the standard technique is impaction at the back of mouth.
Y. Jeon *et al*. found that the success rate at first insertion was higher for the rotation group (100%) than for the standard group (83%), which is also similar to our observation [8].
J. Park *et al*. conducted a meta-analysis of the standard versus rotation technique for inserting supraglottic airway devices and found that the insertion success rate at the first attempt was significantly higher with the rotation technique than with the standard technique, which is comparable to our observation [9].

Systolic blood pressure and diastolic blood pressure

Systolic and Diastolic blood pressure in both the groups were comparable as p value was > 0.05 at all levels of observation. Thus, there was no significant difference in Systolic and Diastolic blood pressure at 1min,10min and 15min.

In our study insertion technique had no effect on blood pressure. We used intravenous fentanyl 1mcg/kg as premedication which could have its effects on haemodynamic response. larger size of PLMA can cause greater hemodynamic responses [7]. But we used size 3 PLMA for insertion in all patients irrespective of weight of the patient, which may have prevented increase in SBP and DBP.

Complications

Blood on PLMA: In rotation group, 16.7% patients had blood on PLMA, where as in standard group 83.3% patients had blood on PLMA with' p 'value 0. 014, which is statistically significant.

Postoperative pharyngolaryngeal morbidities are considered a major problem when using supraglottic airway devices. The incidence of blood staining was lower with the rotation technique due to reduced resistance between the lateral edge and the pharyngeal wall which causes less trauma and also due to lack of impaction at the back of the mouth causing lesser number of insertion attempts thereby leading to lesser pharyngeal trauma.

Comparison of sore throat at 1 hr post-surgery and 24 hr post-surgery

we observed that the incidence of sore throat at 1 hr post-surgery is statistically significant in rotation vs standard technique (16% vs 83%) with P=0.003.

We observed that the incidence of sore throat after 24hrs, was found to be similar in both the groups. (6% in rotation group vs 18%) with P=0.065.

In our study the Incidence of postoperative sore throat was lesser with rotation technique. This could be because in rotation technique the lateral edge reduces resistance between the PLMA and the posterior pharyngeal wall. Inserting the PLMA with its lumen rotated makes it easy to advance the PLMA over smooth angle against posterior pharyngeal wall. Additional factors such as intracuff pressure, use of lubrication and the operators skill are also associated with sore throat, which were standardised in our study.

Comparison of fibre optic grading: In rotation group 31 patients had fibre optic grade I, 18 patients had grade II, 1 patient had grade III, where as in standard group 26 patients had fibre optic grade I patients, 23 patients had grade II, 1 patient had grade III. Both groups were comparable with' P' value 0. 703. which is statistically not significant.

Placement of supraglottic airway into the correct position is important for several functions such as ensuring adequate ventilation, sealing and protecting the airway. The correct anatomic position was assessed by fibreoptic view.

Conclusion

We concluded that insertion of the PLMA is more successful with the rotation technique. Although both methods of insertion were satisfactory, the 90-degree rotation technique provided higher success rate at the first attempt and lower incidence of blood on the removed device and less incidence of postoperative sore throat, reflecting less mucosal trauma.

The rotational technique for insertion of PLMA may be considered favourably in comparison to the standard technique of insertion. Since the recovery profile of the patients in terms of

blood on the PLMA on removal and the incidence of sore throat is significantly less with the Rotational technique this method of insertion is recommended especially for day care surgeries.

References

1. Nichole Bosson. Laryngeal mask airway. West J Med [Internet], 2016. Available from: http://dx.doi.org/10.1016/B978-1-4377-2764-7.00022-1
2. Brimacombe J, Keller C. the proseal laryngeal mask airway. 2000;93(1):104-9.
3. Hwang J, Park H, Lim Y, Do S, Lee S, Jeon Y. Comparison of Two Insertion Techniques of ProSeal[TM] Laryngeal Mask Airway. Anesthesiology. 2009;110(4):905-7.
4. Cook TM. Laryngeal_mask_airway.
5. Soh CR, Ng AS. Laryngeal mask airway insertion in paediatric anaesthesia: Comparison between the reverse and standard techniques. Anaesth Intensive Care. 2001;29:515-9.
6. Chen MK, Hsu HT, Lu IC, Shih CK, Shen YC, Tseng KY, *et al*. Techniques for the insertion of the ProSeal laryngeal mask airway: comparison of the Foley airway stylet tool with the introducer tool in a prospective, randomized study. BMC Anesthesiol. 2014;14(1):105.
7. Evans NR, Gardner SV, James MFM, King JA, Roux P, Bennett P, *et al*. The ProSeal laryngeal mask: Results of a descriptive trial with experience of 300 cases. Br J Anaesth. 2002;88(4):534-9.
8. Jeon YT, Na HS, Park SH, Oh AY, Park HP, Yun MJ, *et al*. Insertion of the ProSeal??? laryngeal mask airway is more successful with the 90?? rotation technique. Can J Anesth. 2010;57(3):211-5.
9. Park JH, Lee JS, Nam SB, Ju JW, Kim M. Standard versus Rotation Technique for Insertion of Supraglottic Airway Devices: Systematic Review and Meta-Analysis. 2016;57(4):987-97.