ProSeal laryngeal mask airway[™] insertion in the prone position: Optimal utilization of operation theatre personnel and time?

Bimla Sharma, Jayashree Sood, Raminder Sehgal, Chand Sahai, Anjali Gera

Department of Anaesthesiology, Pain and Perioperative Medicine, Sir Ganga Ram Hospital, New Delhi, India

Abstract

Background: Positioning an anesthetized patient prone is challenging with regard to manpower requirement, time to surgical readiness and airway management. The ProSeal laryngeal mask airwayTM (PLMA) is emerging as a suitable alternative, both as a primary and a rescue airway device to the tracheal tube (TT) for patients undergoing surgery in the prone position.

Materials and Methods: In this prospective randomized study, 70 patients scheduled to undergo pilonidal sinus excision in prone position were allocated to two groups of 35 patients each, depending on the position of the patient at induction and device placement: Group S (device placed while supine) and Group P (device placed while prone). We compared the manpower requirement, time to surgical readiness, efficacy and safety of the PLMA for airway management in the two groups.

Results: The number of personnel [5 (4-6) vs. 3 (3-3); P < 0.001] required for positioning the patient and surgical readiness time (22.1 ± 3 vs. 5.9 ± 0.9 min; P < 0.001) was higher in group S. There was no difference between the two groups with regard to efficacy and safety of the PLMA. Incidence of blood on the PLMA cuff and sore throat was comparable in the two groups (P = 1.000).

Conclusion: We conclude that induction and placing the PLMA in the prone position by experienced users require fewer personnel and reduces surgical readiness time.

Key words: Equipment, ProSeal laryngeal mask airway, technique, prone position

Introduction

Procedures done in the prone position are of concern to the anesthesiologist with respect to management of respiratory, cardiovascular, nervous and musculoskeletal systems.^[1] The conventional approach to airway management in these patients is to intubate the trachea with a non-kinkable tracheal tube in the supine position and turn the patient prone while assuring unhindered ventilation. However,

Address for correspondence: Dr. Bimla Sharma, Department of Anaesthesiology, Pain and Perioperative Medicine, Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi - 110 060, India. E-mail: bimsharma@rediffmail.com

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placing the patient prone requires adequate manpower and additional time, which delays time to surgical readiness. The inadvertent loss of airway in this position may be lifethreatening regardless of the airway device used, including the tracheal tube (TT).^[2-4] Potential problems with the airway device may vary from obstruction to displacement and even accidental extubation. There are several reports supporting the use of supraglottic airway devices (SAD), especially, the classic laryngeal mask airway (cLMA) and its variants in the prone position.^[4-8] The ProSeal laryngeal mask airway (PLMA), a 2nd generation SAD has more evidence for clinical efficacy and safety than its counterparts because it provides higher oropharyngeal seal pressure (OSP) and better protection against aspiration.^[9-11] In this prospective study, we hypothesized that allowing the patient to position himself / herself comfortably prone followed by induction and device placement will require less manpower and reduce time to surgical readiness as compared to anesthetizing in the supine position and then turning patient prone.

Materials and Methods

After obtaining approval from the hospital ethics committee and written informed consent from the patients, seventy adult patients with American Society of Anesthesiologists (ASA) physical status I-II, scheduled to undergo pilonidal sinus excision in the prone position were enrolled for the study. Exclusion criteria included limited mouth opening (interincisor gap <50 mm), Mallampati class ≥ 3 , oropharyngeal pathology, body mass index ≥ 26 kg/m², pulmonary disease, and patients at risk of aspiration. The patients were randomly allocated by computer generated numbers, kept in opaque sealed envelopes [Figure 1] to one of two groups of 35 patients each, depending on the position of the patient at induction: Group S (device placed while supine) and Group P (device placed while prone). All PLMA insertions were performed by the primary investigator with more than 10 years experience in the use of the PLMA.

After venous access in the operation theater (OT), the patients were premedicated with intravenous ranitidine 50 mg, metoclopramide 10 mg, glycopyrrolate 0.2 mg, and midazolam 1 mg. Patients in group S were positioned supine on a trolley with head on a firm ring, 7 cm high. Patients in group P were asked to lie comfortably prone on gel based chest and pelvic supports on the operating table with head and neck rotated to the left side. The transport trolley was positioned alongside the operating table at a slightly lower level so that the patient could be rapidly turned supine should the airway management fail. Standard monitoring including pulse oximetry, electrocardiograph, non-invasive blood pressure and capnography was applied. The anesthesiologist stood at the head end of the OT table. Anesthetic technique was standardized for all patients. After preoxygenation for 3 minutes, anesthesia was induced with fentanyl citrate 1.5 mcg/kg, and propofol 2 mg/kg. After loss of eyelash reflex, the patients were ventilated via a face mask. When required, additional boluses of propofol were given till jaw relaxation. Appropriately sized PLMA as per manufacturer's instruction was selected and inserted using the digital technique by the standard midline approach in group S after ascertaining no response to jaw thrust.^[12] The correct placement of the device was confirmed by bilateral auscultation of chest and placement of the gastric tube through the drain tube. The placement of the gastric tube was confirmed by gastric aspiration and or epigastric auscultation. The device was secured and maintained in position by a cotton tape and or an adhesive tape. The patients were positioned prone ensuring a relatively free abdomen with chest and pelvic supports. The anesthesiologist protected the airway device while supporting the head, one to two persons rolled the patient, and another one to two persons received the patient prone. Additional personnel were requisitioned for tall and heavy patients if required. In group P, the PLMA was inserted with the head in the midline (head lifted by the assistant) or lateral position. The insertion technique varied with the number of attempts in both the groups. The first attempt was the standard digital technique, using the index finger. In the second attempt, the gastric tube was advanced through the drain tube 8-10 cm, beyond the distal tip of the PLMA, guiding the tip of the cuff into the oesophagus followed by digital insertion of the mask.^[13,14] A maximum of two attempts were allowed, failing which the patient was intubated with a tracheal tube.

An initial dose of 0.08 mg/kg of vecuronium bromide was administered for muscle paralysis after PLMA placement.



Figure 1: CONSORT 2012 flow diagram

Anesthesia was maintained with sevoflurane and 50% oxygen in nitrous oxide supplemented by intermittent blouses of vecuronium and fentanyl. Mechanical ventilation was initiated with FiO₂ 0.3, V_T- 8 ml/kg, I/E ratio of 1:2 and respiratory rate of 12 per minute. The FiO₂ and respiratory rate were adjusted to maintain $\text{SpO}_2 > 95$ % and EtCO₂ between 36 to 44 mmHg. Optimal oxygenation was defined as ${\rm SpO}_{_2}$ >95 %, suboptimal as ${\rm SpO}_{_2}$ between 90 to 95 % and failed as $SpO_2 < 90$ %. Ventilation was considered optimal if the EtCO₂ was <45 mmHg, suboptimal if EtCO₂ exceeded 46 mmHg and failed if $EtCO_2$ was >55 mmHg. Intravenous infusion of diclofenac sodium 75 mg was given 30 minutes before the end of procedure. After completion of the procedure, the patient was turned supine on the trolley. The neuromuscular blockade was reversed and the PLMA was removed with the patient fully awake. Postoperative pain was managed with boluses of fentanyl and NSAIDs.

The PLMA insertion was graded as easy, when it was successful at first attempt without any additional maneuvers (head hyperextension, mask rotation, finger manipulation or table tilt of 15° on the side the head was turned). It was graded as difficult, if more than one attempt or additional manoeuvres were required. A failed attempt was defined as removal of the device from the mouth. The number of insertion attempts was recorded. The insertion time defined as the time interval between holding the PLMA to confirmation of correct placement by bilateral air entry on chest auscultation was noted. Efficacy of the device was judged by correct placement, OSP, ventilation and oxygenation.

The time to surgical readiness was defined as the time from induction of anesthesia till the patient was finally positioned and handed over to the surgeon. The number of people required to position the patient during the surgery were recorded in both groups.

The following intraoperative complications were documented: failed use, displacement of device, airway obstruction, tongue, lip or dental trauma and blood detected on the PLMA cuff on its removal. Duration of surgery was also recorded.

In the post-anesthesia care unit, the patients were monitored for heart rate, arterial pressure, SpO_2 , and respiratory rate. Patients were asked about sore throat in the post-anesthesia care unit and 24 hours later. All data were collected by an anesthesiologist not participating in the study.

Statistical analysis

The primary variable was the manpower requirement for positioning the patients. Based on a pilot study of 30 patients (15 patients in each groups), it was seen that number of persons (Mean \pm SD) required in group S was 4 ± 2 while in group P, it was 3 ± 0 . We calculated that a sample size of 32 patients per group would be required to detect a significant difference between the two groups using alpha set at 0.05 and beta at 0.2. However, we included 35 patients per group in anticipation of possible dropouts. The secondary outcomes were: time to surgical readiness, ease of PLMA insertion, efficacy and safety of the device and complications such as blood on mask and sore throat. The data were analyzed using SPSS (version 17, Chicago, IL, USA). Results are expressed as mean \pm SD, median (min-max) or number and percentages. Comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Chi-square test or Fisher's exact test as appropriate. Nonnominal distributed continuous variables were compared using Wilcoxon Rank Sum test. A P-value > 0.05 was considered statistically significant.

Results

All patients completed the prospective study. There were no differences between the groups with regard to age, gender, weight, height and BMI [Table 1]. The ASA physical status, Mallampati class and duration of surgery were also comparable in both groups.

The intra and postoperative details are shown in [Table 2]. The different sizes of PLMA used were also comparable in the two groups. The overall insertion success rate for the PLMA was 100% in both the groups, at first attempt in 31 (88.57%) patients in group P and 32 (91.42%) patients in group S. In two patients with short necks in group P, the PLMA was placed at first attempt with the head lifted in the midline position by the assistant. No patient required rotation back into the supine position for airway management.

Table 1: Patient characteristics and duration of surgery				
	Group S (n = 35)	Group P (n = 35)	<i>P</i> -value	
Age (yr)	24.69 ± 6.02	27.34 ± 8.53	0.137	
Sex Male/Female (n)	28/7	30/5	0.526	
Weight (kg)	73.26 ± 13.51	73.69 ± 11.53	0.887	
Height (cm)	169.70 ± 9.81	170.50 ± 7.89	0.706	
Body mass index (kg/m ²)	25.14 ± 4.62	25.36 ± 3.78	0.827	
ASA grade I/II (n)	33/2	34/1	1.000	
Mallampati grade 1/2 (n)	11/24	12/23	1.000	
Duration of surgery (min)	45(30-60)	50(40-60)	0.579	

Group P = Prone at device placement, Group S = Supine at device placement. Data are number (n), mean \pm standard deviation and median (inter-quartile range). 'P < 0.5 is considered significant

gement data	nt data	Table 2: Airway manageme
Group S Group P P-valu (n=35) (n=35)	Group S (n=35)	
4/18/13 2/23/10 0.434	4/18/13	PLMA size 3/4/5
31/4 32/3 0.602	31/4	PLMA attempts 1/2
12 (10-12) 12 (12-12) 0.065	12 (10-12)	PLMA insertion time (sec)/ attempt
ficult 31/4 32/3 1.000	31/4	PLMA insertion Easy/ Difficult
ıre 38.17±3.19 37.97±2.57 0.744	38.17±3.19	Oropharyngeal seal pressure (cm H ₂ O)
H ₂ O) 14.11±3.42 15.11±3.70 0.244	14.11 ± 3.42	Peak Airway Pressure (cm H_2O)
5 (4-6) 3 (3-3) *<0.00	5 (4-6)	Personnel required for positioning (n)
nin) 22.1±3 5.9±0.9 *<0.00	22.1 ± 3	Surgical readiness time (min)
35/0/0 35/0/0 —	35/0/0	Oxygenation-Optimal/ Suboptimal/failed
35/0/0 35/0/0 —	35/0/0	Ventilation-Optimal/ Suboptimal/Failed
1 1 1.000	1	Blood on mask
0 1 1.000	0	Sore throat
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	14.11±3.42 5 (4-6) 22.1±3 35/0/0 35/0/0 1 0	(cm H ₂ O) Peak Airway Pressure (cm H ₂ O) Personnel required for positioning (n) Surgical readiness time (min) Oxygenation-Optimal/ Suboptimal/failed Ventilation-Optimal/ Suboptimal/Failed Blood on mask Sore throat

Group P = Prone at device placement, Group S = Supine at device placement, PLMA insertion easy: Successful at first attempt, difficult: If more than one attempt required or need for additional maneuvers, Data are number (n), mean \pm standard deviation and median (inter-quartile range), *P < 0.5 is considered significant

Insertion time and ease of insertion were similar in the two groups [Table 2]. The peak airway pressures were also comparable in the two groups. The manpower requirements for positioning [6 \pm 0.6 vs. 3; P < 0.001] and surgical readiness time [22.1 \pm 3 vs. 5.9 \pm 0.9 min; P < 0.001], were considerably reduced in group P.

Ventilation and oxygenation were comparable in the two groups. There was no incidence of desaturation or airway obstruction in any patient during the induction or the maintenance phase of anesthesia. Blood was visible on the cuff of the PLMA at removal in one patient of group P. One case of sore throat was also reported in group P.

Discussion

In this prospective study, the PLMA proved to be a safe and efficacious device in patients undergoing surgery in the prone position. More personnel were required in group S to position the patient than in group P. The induction, PLMA placement and subsequent maintenance of anesthesia were comparable in the two groups. Surgical readiness time was reduced in group P. Hemodynamic stability was maintained in both groups.

Operations performed in the prone position require significant OT time and necessitate additional manpower for proper positioning of the patient. Induction and device placement in the prone position avoids the displacement of OT personnel from other tasks as significantly less number of people is required in shifting the patient. The surgical readiness time was also achieved faster in group P than in group S (P < 20.001).

Recently, the wider use and acceptance of SADs in non conventional scenarios have influenced the choice of airway management.^[9,15] According to the Fourth National Audit Project of the Royal College of Anesthetists, the primary airway management device for general anesthesia was a SAD in 56.2% patients as compared to the TT (38.4%) and face mask (5.3%).^[16] Use of the LMA family has been reported in adult as well as pediatric patients, both as a primary and a secondary rescue airway device in the prone position.^[6,7,4,2,3] One case report describes the use of the i-gel in prone position.^[17]

The airway may be more easily managed and better protected from regurgitation in the prone position.^[5] Following induction in the prone position, the jaw and tongue fall anteriorly, creating more oropharyngeal space and thereby facilitating mask ventilation and insertion of the PLMA.^[18] We found no difference in the ease of insertion between the two groups which is in agreement with previous studies.^[19,20]

The PLMA and LMA Supreme have been designed for positive pressure ventilation. There are several reports of its use for surgery in prone position because of its non-kinkable airway tube and decreased pharyngolaryngeal morbidity.^[2,16,17] Both have been used successfully as primary airway device in prone patients.^[19-24] In a study comparing LMA Supreme with the PLMA in patients anesthetized in prone position, both the devices were found to be efficient.^[23] However, the PLMA required fewer manipulations and achieved a higher OSP. A manikin study has compared the ease and time of insertion and the number of attempts of insertion of LMA Supreme and Soft Seal in different positions.^[25] The results of LMA Supreme in prone position are comparable to our study. In our study, the OSP was comparable in the two groups and was similar to that reported in the supine position in earlier studies.^[26,27]

Perioperatively, the prone position may be associated with many physiological changes and complications. Splinting of the abdomen in the prone position is associated with a reduction of pulmonary compliance that can affect oxygenation and ventilation. This can continue in spite of proper positioning. Self positioning of the patient under the anesthesiologist's guidance prevents chest and abdomen compression and position related injuries to the peripheral nerves. There was no incidence of failed or suboptimal ventilation or oxygenation in any patient. Prone position is associated with risk of increased intragastric pressure during controlled ventilation. We inserted a gastric tube to empty the gastric contents in all the study cases. The gastric tube also served other important functions. Firstly, it aided insertion of the airway device for the second attempt as it improved the success rate as well as decreased the insertion time. Secondly, when left *in situ* it functioned as a guide to reinsertion in case of accidental displacement of the mask, as the device can be easily railroaded back in position in such an eventuality.^[28]

The PLMA also has a role as a rescue device in the event of accidental extubation during procedures performed in the prone position.^[29] Reintubation with a TT in such a scenario requires urgent supine position as both laryngoscopy and intubation are difficult while prone. Although there are more reports of 1st generation LMA use in these cases, the PLMA being superior to the LMA should be a better choice.

Intraoperatively, there was no case of airway obstruction or device displacement in the two groups. Postoperative morbidity, such as blood on the mask or sore throat, was also within the previously reported range.^[22]

We undertook several safety measures as patients with difficult airway and those belonging to ASA physical status III and IV and at risk of aspiration were excluded from the study. All patients were preoxygenated to prevent desaturation during the process of placement of the device. Moreover, muscle relaxants were administrated only after insertion and confirmation of correct placement of the device to avoid loss of airway control. Placement of a transport trolley alongside the operating table ensured that the patient could be rapidly turned supine should the airway management fail [Figure 2]. The device was properly secured with a cotton tape and or adhesive tape and the gastric tube was left in situ to help reinsertion of device in case of its displacement. The FiO₂ and respiratory rate were adjusted to maintain SpO₂ >95% and EtCO₂ between 36 and 44 mm Hg. Targets for perioperative monitoring of oxygenation and ventilation were also defined. Also, all PLMA insertions were done by an experienced anesthesiologist well versed with the use of the device.

This study has some limitations. An independent observer recorded most of the studied variables but the study was blinded only for postoperative complications. Our patients underwent pilonidal sinus excision surgery of about 2-hour duration, with a relatively free access to the airway. The success rate of insertion achieved in our study may not be the same in the hands of an inexperienced user.



Figure 2: ProSeal LMA insertion in Prone Position, (a) Self positioned patient in prone position. A trolley can be seen along side the OT table, (b) Preoxygenation in the prone position with the anesthesiologist standing at head end and showing the PLMA with the gastric tube coming out of the drain tube, (c) Digital insertion of PLMA, (d) Secured PLMA with gastric tube *in situ* and a cuff pressure monitor

We conclude that PLMA is suitable for airway management in the prone position by experienced anesthesiologists as it permits better utilization of OT time and personnel. These advantages need to be confirmed in larger studies. There is a need to explore its use as the primary airway device for patients with any potential risk of difficult ventilation in the prone position. Insertion of PLMA in prone position in patients with easy airway undergoing elective surgical procedures should be encouraged to gain proficiency, thereby, reducing the potential for adverse patient outcomes.

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