Original Article

Comparison of actual and ideal body weight for selection of appropriate size of ProSeal™ laryngeal mask airway in overweight and obese patients: A prospective, randomised study

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ABSTRACT

Background and Aims: The ProSeal™ laryngeal mask airway (PLMA) has advantages of providing better cuff seal and the presence of a gastric drain tube. The manufacturer recommends actual body weight (ABW) for size selection. Pharyngeal area reduces with increase in body mass index (BMI); hence, in overweight patients, PLMA selected on ABW may not fit well. We hypothesised that the ideal body weight (IBW) would be more appropriate in size selection of PLMA. **Methods:** This randomised, single-blind study included 124 patients of 20–60 years and American Society of Anesthesiologists Class I–II, with BMI >25. Patients were randomly divided into two groups. In Group ABW, PLMA was selected based on ABW (62 patients) and in Group IBW, PLMA was selected based on IBW (62 patients). The primary outcome was the first-attempt insertion success rate. Oropharyngeal air leaks, gastric air leaks, drain tube air leaks, insertion difficulty scores and postoperative complications were assessed. Fibre-optic view (Grade I–IV) was assessed for proper placement by a blinded assessor. Statistical analyses were performed using Chi-square test or Fisher's exact test. **Results:** First-attempt insertion success rate and overall insertion success rates were similar in both the groups. Group IBW patients had significantly less resistance during insertion, lower peak airway pressures, successful nasogastric tube insertions, better fibre-optic views and less post-operative complications. Oropharyngeal leak pressure and instrumentation used for insertion were comparable. **Conclusion:** IBW is preferable for the size selection of the PLMA in overweight and obese patients compared to the ABW.

Key words: Airway, ideal body weight, laryngeal masks, obesity, overweight, ProSeal

INTRODUCTION

The ProSeal™ laryngeal mask airway (PLMA), a second-generation laryngeal mask airway (LMA), has several advantages over classic LMA including higher seal pressure and the presence of a gastric drain tube. It achieves a reliable airway with a low incidence of displacement and avoids pharyngolaryngeal morbidity. The manufacturers of PLMA recommend size selection by actual body weight (ABW). In adult patients, a size 3 PLMA is recommended for 30–50 kg, a size 4 for 50–70 kg, a size 5 for 70–100 kg and a size 6 for >100 kg.[1,2] Obesity increases the fat tissue around upper airway and decreases the pharyngeal cross-sectional area. Furthermore, it is reported that pharyngeal area reduces with increase in body mass index (BMI).[3] As a result, in overweight and obese patients, PLMA selected on ABW may not fit well in a narrower upper airway because of fat deposition. In overweight and obese patients, several drugs are given according to ideal body

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weight (IBW) to prevent overdosing of drugs given on the basis of ABW. Kim *et al*.,[3] in a study using the LMA Classic™ in overweight patients, suggested that size selection of the LMA Classic™ when done according to IBW allows an easier and more rapid insertion with fewer complications than selection based on ABW. Similarly, we hypothesised that the IBW would be more appropriate in size selection of PLMA in overweight and obese patients. Therefore, this study was planned to determine whether ABW or IBW is appropriate for the size selection of PLMA in overweight and obese patients with BMI more than 25 kg/m^2.

METHODS

After Institutional Ethics Committee approval, 124 patients between the age of 20–60 years belonging to American Society of Anesthesiologists (ASA) Physical Status I–II, with BMI more than 25 kg/m^2, undergoing surgery under general anaesthesia and requiring PLMA, were included in this randomised, single-blind study. BMI was classified[4] as overweight: 25–29.9 kg/m^2; obesity, Class I: 30–34.9 kg/m^2; serious obesity, Class II: 35–39.9 kg/m^2 and extreme obesity, Class III: equal to or more than 40 kg/m^2.

This study was registered in the Clinical Trial Registry-India (CTRI/2015/02/005541). In all patients, the airway was assessed by Mallampati airway class, mouth opening and range of neck movements. Written and informed consent was obtained from all the patients a day before the surgical procedure. Patients with Mallampati airway Class III or IV, oral, head and neck surgery, history of gastro-oesophageal reflux disease, patients posted for emergency surgery and ASA Physical status III and above were excluded from the study. Patients were randomly divided into two groups by computer-generated random numbers by the Institutional Clinical Research Secretariat. Allocation concealments were performed by opaque sealed envelope by one coinvestigator not involved in the insertion of PLMA and subsequent collection of patient's data related to PLMA insertion. In Group ABW (62 patients), the size of PLMA was selected based on ABW, whereas in Group IBW (62 patients), the size of PLMA was selected based on IBW. IBW was calculated using J. D. Robinson Formula (1983) for males, IBW = (52 kg + 1.9 kg per inch over 5 feet) and for females, IBW = (49 kg + 1.7 kg per inch over 5 feet).

In both the groups, recommended sizes according to body weight (actual or ideal) were size 3 for 30–50 kg, size 4 for 50–70 kg, size 5 for 70–100 kg and size 6 for >100 kg.

In the operating room, monitoring was established with electrocardiogram; non-invasive blood pressure and pulse oximetry and baseline parameters were noted. After pre-oxygenation with 100% oxygen for 3 min, anaesthesia was induced with fentanyl 2–3 μg/kg and propofol 2.5–3.0 mg/kg given over 30 s All the patients were in supine position with the head placed on a head ring, and the anaesthesiologist was allowed to give sniffing position for PLMA insertion. Once the jaw was relaxed, PLMA was inserted by an anaesthesiologist well trained in PLMA insertion (more than 2 years of anaesthesia training and >100 LMA insertions). Neuromuscular blocking agent, if required, was administered after PLMA placement and checking for proper placement.

The primary outcome was the first attempt insertion success rate. Insertion of the PLMA was called successful if there was slight outwards movement of PLMA with air inflation, cuff was not visible in oral cavity, observation of lung inflation and chest expansion on manual ventilation and a normal exhaled carbon dioxide trace on the capnograph.

Once the PLMA was inserted, the cuff was inflated with air using the maximum recommended inflation volume. Placement of PLMA was confirmed by manual ventilation and IPPV using capnography. Mechanical ventilation was started with a tidal volume of 8 ml/kg, a respiratory rate of 12/min and an inspiratory: expiratory ratio of 1:2. After three failed attempts for insertion of PLMA, insertion was considered as failure and alternative technique of airway management was used as per discretion of the attending consultant anaesthesiologist. When insertion was successful, intra-cuff pressure was set at 60 cm H_2O using cuff pressure monitor and PLMA was fixed.

The presence/absence of oropharyngeal air leaks, gastric air leaks (detected by listening with a stethoscope over the epigastrium) and drain tube air leaks (detected by placing lubricant over the proximal end of the drain tube) was noted. Oropharyngeal leak pressure was checked by connecting the PLMA to the anaesthesia circuit and keeping the fresh gas flow at 3 L/min with the adjustable pressure limit valve closed till 30 cm H_2O. The pressure at which the auscultatory leak started was noted from the

anaesthesia workstation. If there was no leakage until 30 cm H_2O, the oropharyngeal leak pressure was recorded as 30 cm H_2O. A well-lubricated 60 cm long, 12-Fr gastric tube was inserted through the drain if there was no air leak through the drain tube. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy. After the placement of PLMA, anaesthesiologist who inserted PLMA was asked to rate the insertion difficulty score from 1 to 4 (1 = no resistance, 2 = mild resistance, 3 = moderate-to-severe resistance and 4 = failed to insert). Once PLMA placement was successful as judged by clinical parameters, a fibrescope was quickly inserted through the through the ventilating tube of the PLMA by a blinded consultant anaesthesiologist, and the placement of the PLMA was graded (in <30 s) as per Brimacombe and Berry classification[5,6] (Grade 4 = only vocal cords visible; Grade 3 = vocal cords plus posterior epiglottis visible; Grade 2 = vocal cords plus anterior epiglottis visible; Grade 1 = vocal cords not fibreoptically visible; and Grade 0 = failure to insert or to function).

Cardiorespiratory data were collected as baseline, every minute for 5 min before the PLMA insertion, every minute after 5 min of PLMA insertion and thereafter every 5 min for 30 min after PLMA insertion. Any episodes of bradycardia (heart rate <40/min), tachycardia >100/min or systolic hypotension (systolic blood pressure [SBP] <80 mmHg) and systolic hypertension (SBP >160 mm Hg) were documented. Any episodes of hypoxia (SpO_2 <90%) or other adverse events were noted. Any visible trauma during insertion was noted. Duration of surgery was recorded. Post-operative complications such as sore throat, throat pain, blood on PLMA and airway oedema were also noted in all the patients.

Basis for sample size was based on prior clinical experience (audit of the past 6-month data) indicating the first-attempt success rate amongst PLMA insertion on ABW basis as 0.7 (70%). Assuming the true first-attempt success rate for PLMA on IBW basis as 0.9 (90%), we needed 62 patients in each group to reject the null hypothesis with probability (power) of 0.8. The type I error probability associated with this test of this null hypothesis was 0.05.

Data for statistical analysis are presented as mean ± standard deviation or frequencies (percentage) as appropriate. Normality was assessed by Kolmogorov–Smirnov test. Normally distributed data were analysed using independent *t*-test. Non-normal data were assessed by Mann–Whitney U-test. Categorical variables were analysed using Chi-square test or Fisher's exact test as appropriate. $P < 0.05$ was considered as statistically significant.

RESULTS

One hundred and twenty-four patients were randomised into either Group ABW or Group IBW [Figure 1]. The baseline characteristics including age, sex ratio, ASA grade, Mallampati scoring and duration for surgery were comparable between the two groups. Actual and Ideal body weights, heights and BMI of all the patients are shown in Table 1. BMI of patients was 25–29.9 kg/m^2 in 66.9%, 30–34.9 kg/m^2 in 27.4%, 35–39.9 kg/m^2 in 4.8% and equal to or more than 40 kg/m^2 in 0.8% of patients and both the groups were statistically comparable in terms of BMI distribution.

Size and characteristics of PLMA inserted are shown in Table 2. The PLMA was inserted successfully

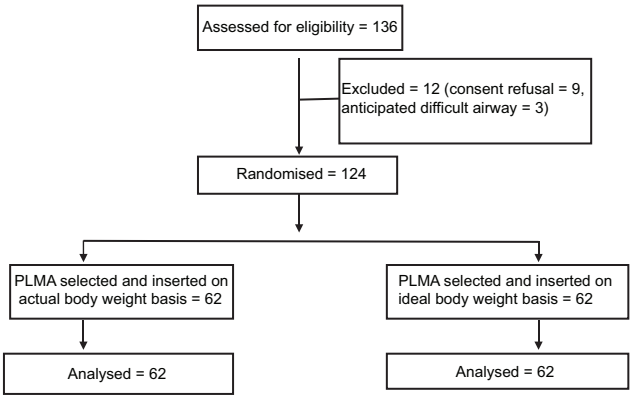

Figure 1: Consort flow diagram of the randomisation and treatment allocation

Table 1: Actual and ideal body weight, height and body mass index in both groups

Parameters	ABW group (*n*=62), *n* (%)	IBW group (*n*=62), *n* (%)	*P*
ABW (kg), mean±SD	69:97±9.20	69.45±9.90	0.869
IBW (kg), mean±SD	51.52±3.64	51.92±4.69	0.948
Height (cm), mean±SD	153.48±5.84	153.68±6.72	0.877
BMI (kg/m^2)			
Overweight (25-29.9)	40 (64.5)	43 (69.4)	0.664
Obesity, Class I (30-34.9)	19 (30.6)	15 (24.2)	
Serious obesity, Class II (35-39.9)	3 (4.8)	3 (4.8)	
Extreme obesity, Class III (≥40)	0	1 (1.6)	

BMI – Body mass index; SD – Standard deviation; IBW – Ideal body weight; ABW – Actual body weight

Table 2: Insertion characteristics and fibre-optic views of patients in actual and ideal body weight groups

Parameters	ABW group (*n*=62), *n* (%)	IBW group (*n*=62), *n* (%)	*P*
Successful insertion at the first attempt	46 (74.2)	54 (87.1)	0.069
Overall final successful PLMA placement	58 (93.4)	61 (98.3)	0.365
PLMA size used			
3	0	31 (50)	<0.001
4	38 (61.3)	31 (50)	
5	24 (38.7)	0	
Insertion difficulty score			
1 (no resistance)	42 (67.7)	53 (86.9)	0.027
2 (mild resistance)	10 (16.1)	7 (11.5)	
3 (moderate resistance)	9 (14.5)	1 (1.6)	
4 (inability to insert)	1 (1.6)	0	
Oropharyngeal audible leak at			
<30 cm H_2O	7 (11.3)	8 (12.9)	1.000
At 30 cm H_2O	55 (88.7)	54 (87.1)	
Peak airway pressure (cm of H_2O)	21.19	17.58	0.002
Gastric air leak present	14 (22.6)	5 (8.1)	0.044
Nasogastric tube insertion success	47 (75.8)	57 (91.9)	0.015
PLMA changed intraoperatively to another PLMA or endotracheal tube	7 (11.3)	1 (1.6)	0.049
Fibreoptic views (Brimacomb and Berry grade)			
0	5 (8.1)	1 (1.6)	<0.001
1	6 (9.7)	5 (8.1)	
2	25 (40.3)	8 (12.9)	
3	10 (16.1)	29 (46.8)	
4	16 (25.8)	19 (30.6)	
Post-operative complications (sore throat, throat pain, blood on PLMA and tongue congestion)	23 (37.1)	1 (1.6)	<0.001

PLMA – ProSeal laryngeal mask airway; IBW – Ideal body weight; ABW – Actual body weight

in the first attempt in 74.2% in ABW group and 87.1% patients in IBW group. This difference was statistically insignificant ($P = 0.069$). Overall PLMA insertion success rate was also comparable in two groups (93.4% in the ABW group and 98.3% in the IBW group).

There was no resistance to insertion of the PLMA in 67.74% of patients in the ABW group compared to 86.9% of patients in the IBW group ($P = 0.027$).

PLMA sizes used in two groups were also significantly different; patients in IBW group required smaller sizes as compared to patients in ABW group. No patient required size 5 in IBW group and no one required size 3 in ABW group. Oropharyngeal leak pressures were comparable in both the groups. The gastric air leak was significantly higher in ABW as compared to IBW (22.6% in ABW vs. 8.1% in IBW, $P = 0.044$).

The average peak airway pressures were significantly lower in IBW group as compared to ABW group (17.58 cm of H_2O vs. 21.19 cm of H_2O, $P = 0.002$). Nasogastric tube insertion without PLMA manipulation was significantly more successful in IBW group as compared to ABW group (91.93% *vs*. 75.80%, $P = 0.015$).

Significantly better fibre-optic views (Brimacombe and Berry grading 3 or 4) were observed in IBW group as compared to ABW group (77% *vs*. 41%, $P = 0.000$). PLMA was needed to be changed intraoperatively in one patient (replaced with larger size) in IBW group as compared to seven patients (all seven patients needed smaller airway) in ABW group ($P = 0.049$), which is statistically significant.

The incidence of post-operative complications (sore throat, throat pain, blood on PLMA and airway oedema) was 37% (23 patients) in ABW group; one patient complained of sore throat in the IBW group ($P < 0.001$). Analysis of different BMI in respective groups is shown in Table 3.

DISCUSSION

In our study, we found that the insertion success rate at the first attempt was lower in the ABW group (74.2%) than in the IBW group (87.1%), but this is not statistically significant ($P = 0.069$). However the

Table 3: The first-attempt success rate and overall success rate in different body mass index subgroups

BMI (kg/m²)	First attempt success rate		*P*	Overall success rate	
	ABW group, *n* (%)	IBW group, *n* (%)		ABW group, *n* (%)	IBW group, *n* (%)
Overweight (25-29.9)	31 (81.6)	39 (90.7)	0.200	35 (94.6)	40 (97.6)
Obese, Class I (30-34.9)	10 (52.6)	14 (93.3)	0.010	17 (89.5)	15 (100)
Serious obesity, Class II (35-39.9)	3 (100)	1 (33.3)	0.223	3 (100)	3 (100)
Extreme obesity, Class III (≥40)	0	0	-	0	1 (100)

BMI – Body mass index; IBW – Ideal body weight; ABW – Actual body weight

ideal weight group had significantly easier placement with lower peak pressures and higher success with nasogastric tube insertion. Fibre-optic views (Brimacombe and Berry grade) were significantly better in the ideal weight group. Furthermore, the incidence of post-operative complications in 24 h was significantly lower in the IBW group than in the ABW group.

LMA is designed to be placed in the hypopharynx with the cuff positioned caudal to the level of rami of jaw and tonsils. Use of larger size masks increased the risk of the cuff being located in the oral cavity, which could lead to a sore throat or nerve damage. For this reason, it is recommended to replace the larger mask with a mask one size smaller if the cuff of the larger mask is visible through the mouth.[7] They also commented that the use of a smaller mask could increase the incidence of air leak.

Obese patients are more inclined to have the smaller upper airways,[8,9] and it is more likely that a smaller mask will have a better sealing function due to the more adequate placement of its cuff. As a decreased upper airway size could be expected in our enrolled patients who were also overweight or obese, a smaller device might be placed more comfortably in these patients. Our study is in agreement with a previous study,[3] in terms of first-attempt success rate, ease of placement, size of LMA used, Brimacombe and Berry fibre-optic scores and also post-operative complications. They also reported a higher incidence of sore throat and dysphonia in ABW group compared to the selection based on the IBW.

Post-operative pharyngolaryngeal morbidities are considered a major problem when using supraglottic airway devices.[10,11] The inadequate or faulty positioning of the cuff after insertion of the bigger size mask could be a cause of post-operative complications including sore throat.[7] The use of larger masks in obese patients with a smaller upper airway may inflict injury on the soft tissue of the upper airway during device insertion, reflecting the more difficult insertion seen in the ABW group. In our study, no patient required size 5 PLMA in IBW group and hence, despite the comparable duration of surgery in both the groups, there were significantly less post-operative complications in IBW as compared to ABW group.

When IBW and ABW groups were compared in subgroup analysis of different BMI, the first attempt success rate and overall success rate were similar in overweight (BMI 25–29.9 kg/m²) and serious obese, Class II (BMI 35–39.9 kg/m²) subgroups. Although there is significantly higher first-attempt success rate (93.3%) in obese, Class I (BMI 30–34.9 kg/m²) patients in IBW as compared to 52.6% in ABW, $P = 0.010$, total number of patients in this subgroup was only 27.4%. No definitive conclusion can be drawn from this subgroup analysis, and this can only be hypothesis generating.

In a previous study, size of the LMA Supreme™ was determined by body weight and thyromental distance for proper placement in terms of efficacy of controlled ventilation, ease of placement and pharyngeal sealing. The authors included patients with BMI up to 30 kg/m² and showed that in overweight patients (BMI >23 kg/m²), LMA supreme use, selected on the basis of ABW was less efficient in terms of guaranteeing better positive-pressure ventilation, facilitating device placement and reliable pharyngeal sealing, as compared to LMA Supreme selected on the basis of thyromental distance.[12]

In a study[13] involving overweight and underweight children, ABW and IBW were considered in both the groups; the authors concluded that with PLMA selected on ABW basis, oropharyngeal leak pressure was significantly higher in overweight patients as compared to PLMA selected on IBW basis, and in underweight children, PLMA selected on IBW was significantly better in terms of higher oropharyngeal leak pressures. In their study, sizes of PLMA, ease of insertion, peak airway pressures and fibre-optic grading were comparable in both the groups.

Apart from the body weight, there are several other factors that can be of interest for size selection of LMA.[1,2,14,15] A previous study on LMA selection,

involved 300 adult patients,[16] with 144 patients being selected based on patient's gender (size 5 for males and size 4 for females) and another 156 patients selected based on the ABW (recommended by manufacturers). They found that gender-related selection provided better ventilating conditions than actual weight-based selection. Height was also considered in selecting proper size of an LMA.[17]

Our study has few limitations. First, majority of our patients were females (88.7%), so we are not sure if these data can be generalised for male patients also. Second, we did not measure intra-cuff pressure intraoperatively after the initial measurement, which may have affected post-operative complications. Third, we have not assessed the time taken for PLMA insertion in both groups. Finally, first-attempt success rate in our study was statistically insignificant. This may be because, while our sample size was calculated assuming 70% success rate in ABW and estimated success rate at 90% in IBW group, the actual outcomes in our study showed a success rate of 74.2% in ABW group and 87.1% (less than our assumption) in IBW group; thus, our study is slightly underpowered to detect a significant difference and a larger study may find a statistically significant difference.

CONCLUSION

IBW can be a better parameter for the size selection of the PLMA in overweight and obese patients. In this study, selection of the size of PLMA based on IBW and ABW resulted in similar first-attempt success rates and overall success rates, but the choice based on IBW lead to greater ease of insertion, better ventilating conditions and better sealing.

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Conflicts of interest

There are no conflicts of interest.

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