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Does a supreme laryngeal mask airway (SLMA) selected on the basis of a patient's weight provide an optimal fit in Indian population?

Abstract

Background: The Supreme laryngeal mask (SLMA), is a second generation Laryngeal mask airway (LMA) introduced in 2007. Designed in the West on Caucasian population, most studies have been conducted on the same population. There is no study to evaluate the fit of a SLMA chosen on the weight based criteria in Indian population.

Aim: The aim or objective of the study was to identify whether SLMA selected on the basis of weight criteria provides an appropriate fit in Indian population?

Keywords: SLMA, fit, optimal, Indian

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Introduction

The Supreme laryngeal mask (SLMA), a second generation Laryngeal mask Airway(LMA) is a single use, latex free device with an anatomical curve. It has a gastric drain tube allowing access to gastric contents and a cuff which provides 2 seals, one at the oropharynx and the other at the upper end of the oesophagus, separating the respiratory from the digestive tract. Correct placement produces a leak-free seal against the glottis with the tip at the upper oesophageal sphincter. Available in sizes 1 to 5, SLMA size selection is based on the actual body weight of a patient (size 3, 30-50 kg, size 4, 50-70kg, size5, 70-100kg). Maximum recommended cuff volumes are 20ml/30ml/45ml respectively and the cuff pressures should be ≤60 cm H_2O. The average Indian weighs 55Kg, and most females would require a size 3 SLMA and males, a size 4. To select a SLMA for a patient, the same weight based criteria is used, however stature, facial features, airway anatomy, average weight and height differ in Indian population in comparison with the West. The LMA was designed in the West on Caucasian population with most studies on the same population.

Methods

After Institutional Review Board approval and registering with the Clinic Trials Registry- India(CTRI/2015/08/006133), ASA I and II adult patients undergoing general anesthesia with a SLMA were enrolled in the study during a 4 month period, from July to October 2014. Surgeries such as; implant placement for radiotherapy, breast surgeries, bone and soft tissue surgery, penectomy, TURBT, orchidectomy were included. A well informed written consent was obtained preoperatively. Children below 18 years of age and patients undergoing emergency procedures were excluded. Anesthesia was induced with propofol, fentanyl and a muscle relaxant, and maintained with isoflurane, nitrous oxide and oxygen, with positive pressure ventilation in a circle system. The SLMA size was chosen based on actual weight of patient. Information including patient's age, sex, weight in kilograms, retrognathia if present , mouth opening in centimetres, Mallampatti classification, jaw slide, whether difficult airway anticipated, size selected, ease of placement, insertion attempts and whether inserted partially inflated or fully deflated, was collected. The operating theatre, anesthetist's opinion on the SLMA, whether it is acceptable or not for perioperative use but it needs to reposition or changed to a different device and manipulations required intra-operatively were noted. Position of the SLMA bite block was noted. The 'Bubble test' performed. The discrepancy between the set and expired tidal volume, capnograph pattern (square wave, obstructed pattern or none) and peak airway pressures were documented. A well lubricated 14 Fr gastric tube was passed through the drain tube and gastric contents aspirated to confirm correct placement. The fit of the SLMA was considered optimal if; the fixation tab was 1.5-2.5 cm from upper lip, the bite was between the teeth, no audible or measurable leak of tidal ventilation, the gastric tube inserted easily through the drain tube and a square wave pattern of the CO_2 waveform obtained with peak pressures within the normal limit. If any of the above mentioned criteria were absent but tidal ventilation was acceptable, the SLMA fit was considered acceptable. The fit was considered poor if any of the above mentioned criteria were not met along with an audible and measurable leak of tidal ventilation. A failed insertion was defined as a failed passage, a persistent air leak, malposition or ineffective ventilation.

The OLP or seal pressure was obtained by closing the expiratory valve of the circle system with a fixed gas flow of 3 L/min and noting the airway pressure at which gas leak occurred. The volume of air required to inflate the cuff was documented. The SLMA was fully deflated or partially inflated, and the dorsal surface lubricated with water soluble lubricant before insertion. High intra cuff pressures are known to reduce pharyngeal mucosal perfusion, cause nerve compression and neuropraxia, with postoperative pharyngolaryngeal complications such as sore throat, dysphasia, dysphonia and nerve injury. Sore throat is defined as, "the constant pain or discomfort in the throat independent of swallowing". Dysphagia is "difficulty or pain caused by swallowing." Intra cuff pressures were recorded using a handheld manometer. The presence of blood on the device at removal, postoperative sore throat and dysphagia were documented. Sample size was based on the duration of study i.e., a period of 4 months and rest of the parameters as described above were evaluated based on cases with successful insertion. Data was analyzed using SPSS 18. Demographic data are represented as mean ±SD or Median (IQR) where appropriate. Categorical data were analyzed using Chi Square test; $p<0.05$ was considered statistically significant.

Results

Two hundred and eighteen patients were enrolled in the study conducted from July to October 2014 (Figure1). Of these, 186(85.4%) were female and 32(14.6%) were male. Fifty-seven had intracavitary implant placement, 115 underwent breast surgeries, 31 transurethral bladder. In twenty four (11%) the SLMA required repositioning at induction and 5(2.2%) required repositioning intraoperatively. In the 20 patients where SLMA insertion failed, 2 were managed with an LMA classic, 9 changed to ETT, 4 managed on bag and mask ventilation, and in 5 patients a different sized SLMA was inserted. The SLMA was successfully inserted in 198(90.8%) patients (Figure 2). In 172(86.9%) patients, the SLMA was inserted successfully at first attempt. The success rate increased to 98.5% at second attempt and 100% at third attempt (Figure 3).

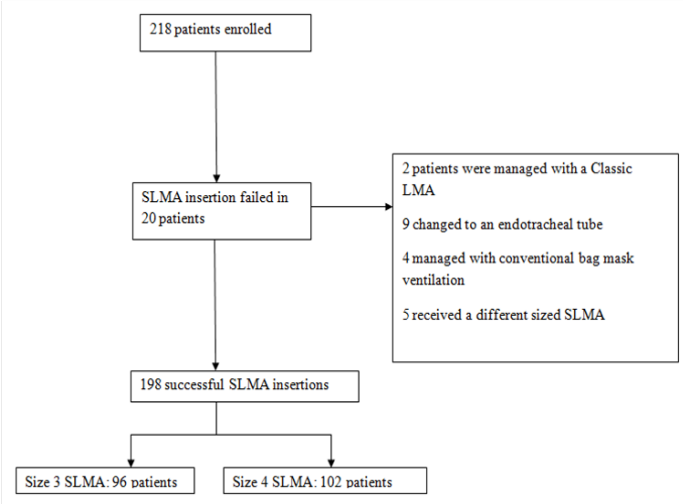

Figure 1 Flow of patients enrolled in the study.

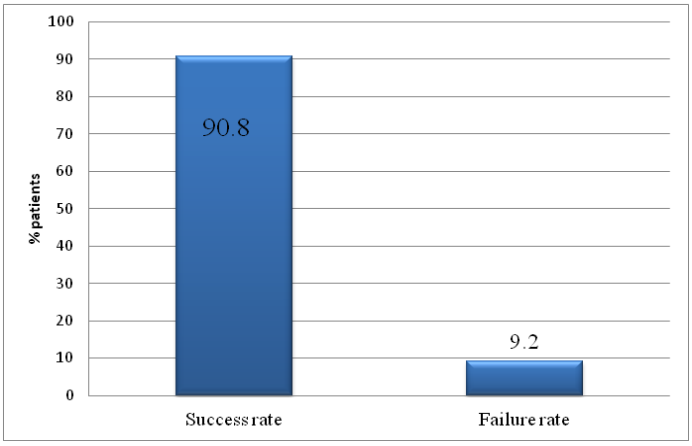

Figure 2 Success rate at insertion (n=218).

Of the 198 successful SLMA insertions, in 96 patients a size 3 SLMA was used. Among these, 88 patients were in the 30-50 kg range while 8 weighed more than 50 kg. Of the 102 patients who had a size 4 SLMA placed, 86 were in 50-70 kg range while 16 were in the 70-100 kg range as shown in Table 1. As per the criteria used for deciding the placement or fit, only 76(38.4%) SLMAs were found to be optimally placed, in 107(54%) the fit was acceptable while in 15 cases (7.5%) it was poor. However, the OT anesthetists found the SLMA fit and ventilation to be adequate in 196(98.9%) patients. A nasogastric tube could easily pass through the drain tube in 94.9 % of the 198 cases. In those with a suboptimal fit (n=107), the gastric tube could be easily passed in 92.5%. Even with a poor fit, the gastric tube could be passed easily in 13 of the 15 cases. This indicates a proper positioning of the SLMA at the upper end of the oesophagus despite the fit appearing suboptimal as per the criteria. In 10(5.1%) patients the gastric tube could not be passed which indicates less than ideal positioning at the upper end of the oesophagus and the larynx with risk of aspiration of gastric contents negating the benefits of using a SLMA.

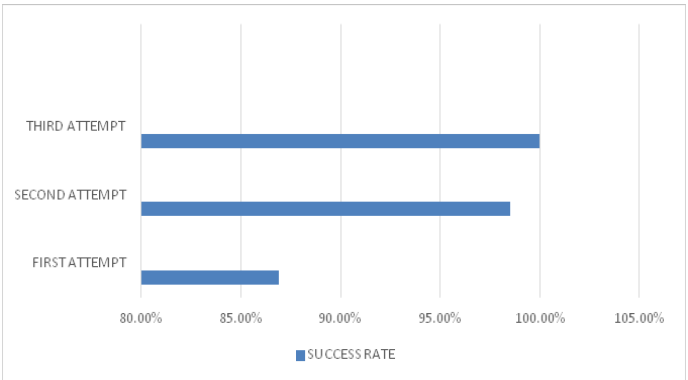

Figure 3 Attempts and success at placement of the SLMA (n= 198).

Table 1 Patient weight and SLMA sizes selected

Weight range	Size 3	Size 4
30-50 Kg	88	0
50-70 Kg	8	86
70-100Kg	0	16
Total	96	102

A positive 'bubble test' was found in 35(17.7%) cases. In thirty of these, the fit was either optimal or acceptable. The fixation tab was positioned between1.5-2.5cm from the upper lip, in 97(49%) cases. The Capnograph was found to be obstructed in 9 cases (4.5%). However, the SLMA fit was poor only in 2 of these cases while in 7 the fit was acceptable. In the 107cases where the fit was acceptable, the bubble test was positive and capnograph showed an obstructed pattern in 7(6.5%) cases. The mean and median cuff pressures, seal pressures and peak airway pressures are as shown in Table 2. The median cuff pressure was found to be 52cm H_2O (Range: 14-120cm H_2O). This shows that the cuff pressure was significantly higher than the recommended.

Table 2 Cuff, Seal & airway pressures

	Cuff pressure cm H_2O	Seal pressure cm H_2O	Peak pressure cm H_2O
Mean	57.8	26.9	16
Median	52	28	15
Range	14–120	12-60	9–34

The maximum volume of air recommended for cuff inflation in a size 3 SLMA is 20 ml and 30 ml for size 4 SLMA. The volume of air used for cuff inflation ranged from 15-30 ml for a size 3 SLMA and 20-30 ml for a size 4 SLMA. The volume of air used for cuff inflation and its relation with intracuff pressures is as shown in Table 3. A weak

linear correlation was found between increasing cuff pressure and seal pressure, with a correlation coefficient of 0.277. Twenty one (10.6%) SLMA's had blood on them at removal suggesting trauma at insertion. The incidence of sore throat was 9.1% (n=18), while 2.5% (n=5) complained of dysphagia in the postoperative period. The incidence of postoperative complications in those with cuff pressure ≤60cm H_2O was 2.5% which increased to 5.1% (p value 0.035) in those with cuff pressure >60cm H_2O. No complications were found when the cuff pressures were less than 40cm H_2O (Figure 4).

Table 3 Volume of air injected and cuff pressures

Size of SLMA	Volume of air(ml)	Cuff pressure <60 cm H_2O	Cuff pressure >60 cm H_2O
3	15	1 (1)	0 (0)
3	20	56(56)	19 (19)
3	25	9 (9)	4 (4)
3	30	4 (4)	7 (7)
4	20	4 (3.6)	2 (1.8)
4	25	2 (1.8)	1 (0.9)
4	30	44 (40)	46 (41.8)
4	35	3 (2.7)	6 (5.5)
4	40	1 (0.9)	1 (0.9)

*Data represented as n (%)

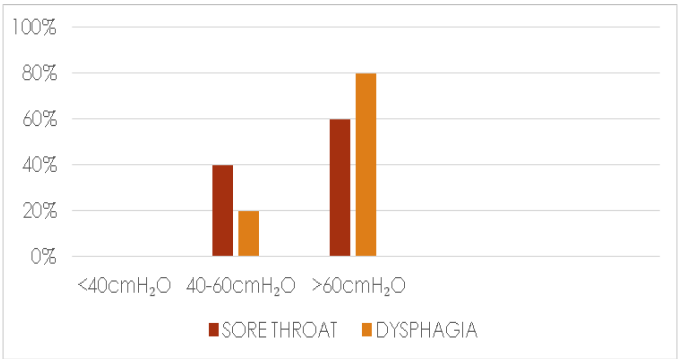

Figure 4 Cuff pressures and postoperative complications.

In 179 cases (90.4%) SLMA was inserted fully deflated and in 19 cases (96%) it was partially inflated at insertion. The incidence of trauma was 21.1% (4 cases) when the device was inserted with the cuff partially inflated and 9.5% (17 cases) when inserted in a fully deflated condition. However the difference was not statistically significant (p=0.120). A difficult airway though anticipated in 5(2.5%) patients, SLMA insertion was successful in all of them and none required repositioning. SLMA placement was found to be difficult in 23(10.6%) of the total study population, i.e. 218 patients.

Discussion

In this prospective study in 218 patients, we found that the SLMA chosen as per the weight based criteria provided an optimal fit in only 38.4% patients. It was successfully placed at first attempt in 86.9% patients. Several other studies[1–3] have documented first attempt success rates of 95-98%. In the present study, we had a lower overall success rate of 90.8% and a first attempt success rate of 86.9%. We attribute this to the differences in the genetic makeup and differences in stature, weight, built, and facial features between Asian and Caucasian population. Y-M Hur et al.[4] found that genetic factors contribute to the differences in variability of height, weight, and BMI between Caucasians and East Asians. Jack Wang et al.[5] found Caucasians to be significantly taller, heavier, than Asians. The lower success rate could also be attributed to the fact that the SLMA's were inserted not only by experienced anesthetists but also by trainees. Optimal placement was observed in 38.4% patients in our population, however, the fit of the SLMA was found to be acceptable in 54% and poor in 7.5% patients.

Despite a low incidence of optimally placed SLMA's, a square capnograph trace was present in 95.5% cases and the gastric tube could be passed successfully in 94.9%.This indicates that despite the fit at the oral cavity being suboptimal in most patients, the placement at the laryngeal and cricopharyngeal inlet was relatively acceptable. The gastric tube could not be passed in 5.1% cases unlike in other studies[3,6] where it could be passed easily at first attempt in all patients. The "bubble test" was positive in 17.7% cases in our study which indicates incomplete separation of the airway & the gastrointestinal tract. Thus the second seal was not obtained and the risk of aspiration of gastric contents did exist. The fixation tab was correctly positioned i.e., 1.5-2.5cm from the upper lip in only 49% of cases. Despite the above disparity in the fit, the OT anesthetist perceived the ventilation to be adequate and continued with the existing supraglottic device in 86.7% cases. This suggests that anesthetists appear reluctant to change to an alternate LMA or airway device if the ventilation is perceived to be adequate despite the apparent suboptimal fit. The other reason could be the added cost to the patient per LMA.

In our study, though the median volume of air used for cuff inflation was 20 ml for size 3 SLMA and 30 ml for size 4, the volume ranged from 15-30 ml for size 3 and 20-30 ml for size 4 which is much higher than that recommended. This could possibly be explained by the fact that in 24 patients, a one size smaller SLMA was used. In 16 patients who weighed >70 Kg a size 4 SLMA was used instead of the recommended size 5 which is not easily available. The cuff was therefore probably overinflated with the aim of minimizing a leak.

In 81(40.9%) patients, the intracuff pressures were way above the recommended (≤60 cm H_2O). The incidence of pharyngolaryngeal complications was significantly higher at 5.1% when the intracuff pressure was >60 cm H_2O as opposed to 2.5% when the cuff pressure was ≤60 cm H_2O. Other studies[7,8] have documented a similar result with intracuff pressures >60 cm H_2O. In our study, the mean seal pressure was 26.9 cm H_2O and the median seal pressure was 28 cmH_2O which is similar to other studies.[8] A 100% success rate, was obtained when the SLMA was inserted with the cuff partially inflated and 93.3% when inserted fully deflated. This result was similar to that obtained by Matta et al.[9] but Brimacombe, in his study,[10] found that insertion with the cuff fully deflated resulted in fewer failures. Our study had a few limitations, it was an observational, non randomized study, the SLMA was inserted by experienced anesthetists as well as trainees, this may account for a lower first attempt SLMA insertion success rate as compared to previous studies. Also, for the group, 70-100 Kg size 4 was put due to unavailability of size 5, this might have contributed to some erroneous result.

The selection of an appropriate SLMA size is determined by the manufacturer's recommendation based on weight criteria. Other techniques such as that used for selecting a Guedel's oral airway[11] have been suggested. Recent studies[12] also indicate that, the ideal

body weight is probably a better criterion for size selection as opposed to actual body weight. This technique could possibly help in selecting an SLMA which will provide an optimal fit or placement in our patient population. Our study also proves a valid point that alternative methods would probably help provide a better fit in our patients.

Conclusion

An optimal fit of the SLMA was possible in less than 1/3rd patients in our population. However, placement at laryngeal and cricopharyngeal inlet appeared to be correct in almost all patients .We attribute this suboptimal fit at the lip and teeth to the difference in the facial features and built of Indians in comparison to the Western population.[13,14]

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Conflicts of interest

Author declares that there is no conflicts of interest.

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