Evaluation of Head and Neck Position on Oropharyngeal Leak Pressure with Baska Mask and Streamlined Liner of Pharyngeal Airway (SLIPA™): A Randomized Clinical Trial

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Abstract: The primary objective was to compare oropharyngeal leak pressures of streamlined liner of pharyngeal airway (SLIPA™) and Baska mask at different head and neck positions. Assessing the fiberoptic view of glottis and ventilation score of both devices in different positions were the secondary objectives. Sixty patients ASA I-II, 18-60 years of either sex scheduled for short ambulatory surgery were included. Patients were randomly assigned in a 1:1 ratio to either the SLIPA™ or the Baska mask group. The effect of various head and neck positions was evaluated. Neutral position was maintained first then the patient was repositioned in the following positions: maximal extension, maximal flexion, and maximal rotation to the left. In each position, peak airway pressure and oropharyngeal leak pressure were noted. The ventilation score was assessed and fiberoptic views were noted. In both groups, oropharyngeal leak pressures and peak airway pressure were significantly higher with flexion. The fiberoptic score frequently decreased in flexion but with no effect on the ventilation. In comparison between the two devices, there was no significant change in the fiberoptic view of the glottis at different neck positions. So we concluded that, effective ventilation is possible with both Baska mask and SLIPA™ with the head in neutral, flexion, extension, and lateral rotation positions. But care should be taken with extreme flexion and the airway pressures need to be monitored. Baska mask has a better margin of safety than SLIPA™ due to better airway sealing pressures.

Keywords: Head and Neck Position, Oro-Pharyngeal Leak Pressure, Airway Devices

1. Introduction

Supraglottic airway devices (SGA) are used extensively during general anesthesia instead of tracheal intubation because of its less invasive nature [1]. The streamlined liner of the pharynx airway (SLIPA™) and the Baska mask are two of the latest addition to the Supraglottic airway devices.

The streamlined liner of the pharynx airway (SLIPA™) is a non-cuffed single-use SGA, its shape is designed to stick to the pharynx and palate [2, 3]. The shape of SLIPA™ has a hollow body which allows it to fit in the patient’s pharynx, sealing it without the use of an inflatable cuff. Its unique shape allows it to maintain a secure airway during positive pressure ventilation without the need to use any kind of fixation straps. Also it has a 50-ml empty internal space which allows the removal of pharyngeal secretions, thus reducing the risk of pulmonary aspiration [2, 4]. The Baska mask is a new single use SGA which is designed by Australian anesthetists Kanag and Meena Baska [5, 6]. The Baska mask has no orogastric tube but instead of it a sump and two drains are present [7]. Also its whole length of the airway tube is fortified with a bite block and is oval in shape. That unique oval shape fits the shape of the mouth and reduces rotation within the pharynx. Head and neck movement can lead to changes in the shape of the pharynx. This shape changes can alter the forces transmitted along the airway device during ventilation which may lead to displacement of the SGA and increasing the airway leak [8].
The primary objective of this study is to determine the effect of different head and neck positions namely, neutral, flexion, extension, and left rotation on the oropharyngeal leak pressures when SLIPA™ and the Baska mask are used. The secondary objectives are to assess and compare the fiberoptic view of the glottis, ventilation score, of both devices in different head and neck positions.

2. Methods

2.1. Patients and Study Design

After approval from the Institutional Ethics Committee of the Alexandria Main University Hospitals, this study was conducted on sixty patients of either sex with ASA physical status I-II. Their age ranged between 18-60 years and scheduled for short duration (<3 hr) ambulatory surgery. A written consent was obtained from all of the patients participating in the study after explaining the procedure of the study in details. The study was registered at the Pan African Clinical Trials Registry under the number PACTR201701001985265.

Patients with body mass index ≥25 kg/m² or have history of obstructive sleep apnea, or history of gastro-esophageal reflux were excluded from the study. Also patients with high risk of aspiration, anticipated difficult airway, any pathology of the neck, upper respiratory tract infection or potentially have full stomach were excluded. Patients were randomly divided into two equal groups either the SLIPA™ or the Baska mask group (30 patients in each group). Randomization was done using the computer and the result was held in sealed envelopes until the time of the operation. Preoperative examination of the maximum neck extension, flexion, and rotation were performed to all patients.

2.2. Surgical Procedure and Clinical Observations

On arrival to the operating room, standard monitoring (pulse oximetry, non-invasive blood pressure recording, electrocardiography, and capnography) was connected to the patient. An Intravenous line was inserted. Then a base line reading of blood pressure (BP), heart rate (HR), and respiratory rate were adjusted to keep the end-tidal carbon dioxide (EtCO₂) of 35 and 40 mm Hg.

The ventilation score was calculated based on three criteria: the presence or absence of a leakage with an airway pressure of 15cmH₂O, bilateral chest excursion with a peak inspiratory pressure of 20cm H₂O and a square wave capnogram, each item was given 0 if its item is absent or 1 point if it is present. Thus, the ventilation score equals 3 if all three criteria exist which is the maximum score [9, 10]. To evaluate the effect of changing the position of the head and neck on the SGA the patient’s head was put first in the neutral position in which a line joining the superior orbital margin and the external ear canal with the top of the shoulder is vertical. After that the patient’s head was rotated to its maximum to the left then maximally extended and maximally flexed. Peak airway sealing pressure and oropharyngeal leak pressure were measured in each position at fixed tidal volume of 10 mL/kg using a volume-controlled ventilator. All the data were collected three minutes after each position adjustment.

Oropharyngeal leak pressure was measured by putting the patient on a bag or manual mode with a closed adjustable pressure limiting (APL) valve and a fixed gas flow of 3L/min [11, 12] Airway pressure was allowed to increase (but not to exceed 40 cm H₂O) until a leakage sound is heard through a stethoscope placed over the patient’s mouth. If no sound was heard until 40 cm H₂O then the OLP was recorded as >40 cm H₂O [12].

An independent anesthetist with no knowledge of the study and is highly experienced in using the fiberoptic views using Brimacombe score. After passing a fiberoptic scope through the tube the tip of the fiberoptic was position 1cm proximal to the oropharynx. Then the Brimacombe score was noted (1 if the vocal cords not seen, 2 if the vocal cords plus anterior epiglottis seen, 3 if the vocal cords plus posterior epiglottis
seen, and 4 if only vocal cords visible) [13, 14]. At the end of surgery, neuromuscular blockade was antagonized with 0.05 mg/kg neostigmine and atropine 1mg. The SAD was routinely removed after the subject had regained consciousness and adequately responded to verbal command.

2.3. Statistical Analysis

Sample size was calculated, with a confidence interval of 95% and a power of 90%, based upon previous studies [10, 15]. The maximum sample size was 30 in each group for flexion with a difference between means of 4 cm of H2O for oro-pharyngeal leak pressures. SPSS Version 20 was used for statistical analysis. Statistical analysis was done with the paired t -test and unpaired t -test. Brimacombe scores and ventilation scores were compared using the Mann-Whitney test between groups and Wilcoxon test within the groups. P < 0.05 was considered significant.

3. Results

Descriptive details of patients are shown in (Table 1), as 60 patients were included (27 men and 33 women); age and BMI were 19–59 years, and 19–30 kg.m2, respectively. Both groups were comparable as regard to demographic characteristics.

| Parameter          | SLIPA™ group | BM group | Pvalue1 | Pvalue2 |
|--------------------|--------------|----------|---------|---------|
| Neutral            | 23±3.7       | 27.3±3.7 |         | <0.001* |
| Flexion            | 24.8±4.12    | 30±4.2   | 0.028345* | <0.001* |
| Extension          | 19.5±3       | 22.46±4.2| 0.000496* | 0.003*  |
| Lateral rotation   | 23.46±3.4    | 28.56±4.88| 0.293433 | 0.014*  |

Pvalue1 is the P value of different positions in comparison with neutral position in the same group. Pvalue2 is the P value of different positions in comparison to the other group. P <0.05 is considered significant.

In SLIPA™ group, peak airway pressures were significantly higher with flexion and lower with extension but with no statistical significance, but with rotation of head and neck peak airway pressure significantly slightly increase in comparison with neutral position. (Table 3). In Baska group, peak airway pressures were significantly higher with flexion with statistical difference but it did not change significantly with extension or with rotation of head and neck. There were statically difference between SLEPA™ group and Baska group as regard peak airway pressure in neutral and flexion positions and with lateral rotation of the head, but without any significant difference during extension position (Table 3).

| Parameter          | SLIPA™ group | BASKA    | Pvalue1 | Pvalue2 |
|--------------------|--------------|----------|---------|---------|
| Neutral            | 14.2±2.83    | 16.7±3.8 | 0.001*  | 0.004*  |
| Flexion            | 16.73±3.22   | 19.33±4.9| 0.014*  | 0.019*  |
| Extension          | 14.76±2.68   | 15.3±3.39| 0.060   | 0.501   |
| Lateral rotation   | 15.6±3.02    | 17.46±3.9| 0.034*  | 0.045*  |

Pvalue1 is the P value of different positions in comparison with neutral position in the same group. Pvalue2 is the P value of different positions in comparison to the other group. P <0.05 is considered significant.

The fiberoptic score frequently decreased in flexion (Tables 5, 6, and 7) but with no effect on the ventilation as shown in (Table 4). In comparison between the two devices, there was no significant change in the fibroptic view of the glottis at different neck positions.
The main objective of this study was to compare oropharyngeal leak pressures of SLIPA™ and Baska mask at different head and neck positions to find out which device is more suitable to be used when it is anticipated that the head position will not be in the neutral position during the surgery.

The pressure at which oropharyngeal leak happens when using positive pressure ventilation correlates to the degree of airway protection provided by the supra-glottic airway device used. This study demonstrated that the oro-pharyngeal leak pressures of the PLMA were lowest in the extension (18.5 vs 25.8±5.2 cm H₂O) and upper with extension (23.9 and 26.8 cm H₂O) when we compared the ventilation difficulty in ventilation with I-gel. Compared with the neutral position the head and neck when using the Cobra-PLA or LTS as indicated in Table 2.

We showed that effective ventilation can be obtained with the head and neck extended, rotated or flexed using either Baska mask or SLIPA™ when we compared the ventilation score in those positions. These findings have significant implications for surgeries that require various head and neck positions.

Previous studies were done to assess the influence of head and neck position on ventilation with first and second generations of supraglottic airway devices such as I-gel, laryngeal tube suction (LTS), ProSeal laryngeal mask airway (PLMA) and Cobra perilaryngeal airway (CobraPLA). One of the earlier studies was done by Xue and Mao et al. [16] in which they found difficult in the ventilation in seven patients on oropharyngeal leak pressure and ventilation scores during intubation. They concluded that the PLMA showed significantly lower oropharyngeal leak pressures than did the LTS or CobraPLA in the neck extension and rotation positions and should take care when changing the position of the head and neck when using the Cobra-PLA or LTS as ventilatory difficulty may occur. In contrast using the Baska mask or the SLIPA™ did not show any significant ventilation impairment in any head position.

Sanuki et al. [10] started the evaluation of effectiveness of head and neck positions on ventilation on I-gel airway devices, as they investigated the effect of different positions on oropharyngeal leak pressure and ventilation scores during ventilation with I-gel. Compared with the neutral position (25.8±5.2 cm H₂O), oropharyngeal leak pressure was significantly higher with flexion (28.5±3.4 cm H₂O, P=0.015) and lower with extension (23.9±4.2 cm H₂O, P=0.015), but similar with rotation (26.7±5.1 cm H₂O, P=0.667). Flexion of

| Brimacombe score | Neutral | Flexion | Extension | Lateral rotation |
|------------------|---------|---------|-----------|------------------|
| 4                | 12      | 9       | 13        | 9                |
| 3                | 16      | 10      | 13        | 15               |
| 2                | 1       | 7       | 3         | 5                |
| 1                | 1       | 4       | 1         | 1                |
| P value          | 0.361   | 0.072   | 0.240     |                  |

Data are in actual numbers. P <0.05 is considered significant.

| Brimacombe score | Neutral | Flexion | Extension | Lateral rotation |
|------------------|---------|---------|-----------|------------------|
| 4                | 14      | 13      | 14        | 11               |
| 3                | 12      | 11      | 11        | 13               |
| 2                | 2       | 2       | 3         | 5                |
| 1                | 2       | 4       | 2         | 1                |
| P value          | 0.062   | 0.091   | 0.141     |                  |

P value is the P value of different positions in comparison with neutral position in the same group.

Table 7. Comparison between two groups regarding fiberoptic view of glottis (4/3/2/1).

| Parameter         | SLIPA | BASKA | P value 1 | P value 2 |
|-------------------|-------|-------|-----------|-----------|
| Neutral           | 12,16,1,1 | 14,12,2,2 | 0.811     |
| Flexion           | 9,10,7,4 | 0.360 | 13,11,2,4 | 0.540     |
| Extension         | 13,13,3,1 | 0.072 | 14,11,3,2 | 0.483     |
| Lateral rotation  | 9,15,5,1 | 0.240 | 11,13,5,1 | 0.790     |

P value 1 is the P value of different positions in comparison to the other group.
P value 2 is the P value of different positions in comparison with neutral position in the same group.
P <0.05 is considered significant.

4. Discussion

The main objective of this study was to compare oropharyngeal leak pressures of SLIPA™ and Baska mask at different head and neck positions to find out which device is more suitable to be used when it is anticipated that the head position will not be in the neutral position during the surgery. When compared to the neutral head position, the head flexed significantly improved the airway seal pressure and the quality of ventilation of the ProSeal LMA (p < 0.05) and they concluded that head flexion improved airway seal and ventilation quality of the ProSeal LMA. A similar conclusion was demonstrated in this study showing the same effect of head flexion on ventilation and airway sealing when using Baska mask or SLIPA™.

Park and Han et al. [15] compared the oropharyngeal leak pressure in four head and neck positions: neutral, 45° of flexion, 45° of extension, and 45° of right rotation and also difficulty in ventilation was assessed in their work, in which one-hundred-thirty-nine patients (aged 18–70 yr) scheduled for minor surgical procedures were randomly used one of three supraglottic airway devices;the laryngeal tube suction (LTS), ProSeal laryngeal mask airway (PLMA) and Cobra perilaryngeal airway (CobraPLA). They found that, the leak pressures of the PLMA were lowest in the extension (18.5 vs 23.9 and 26.8 cm H₂O of LTS and CobraPLA, respectively; P ≤ 0.001) and in the rotation position (25.0 vs 29.4 and 28.5 cm H₂O of LTS and CobraPLA, respectively; P ≤ 0.005).

Also they found difficult in the ventilation in seven patients with LTS after neck flexion, which required tracheal intubation. They concluded that the PLMA showed significantly lower oropharyngeal leak pressures than did the LTS or CobraPLA in the neck extension and rotation positions and should take care when changing the position of the head and neck when using the Cobra-PLA or LTS as ventilatory difficulty may occur. In contrast using the Baska mask or the SLIPA™ did not show any significant ventilation impairment in any head position.

Sanuki et al. [10] started the evaluation of effectiveness of head and neck positions on ventilation on I-gel airway devices, as they investigated the effect of different positions on oropharyngeal leak pressure and ventilation scores during ventilation with I-gel. Compared with the neutral position (25.8±5.2 cm H₂O), oropharyngeal leak pressure was significantly higher with flexion (28.5±3.4 cm H₂O, P=0.015) and lower with extension (23.9±4.2 cm H₂O, P=0.015), but similar with rotation (26.7±5.1 cm H₂O, P=0.667). Flexion of
the head and neck adversely affected the ventilation score compared with the neutral position P=0.004. So they concluded that effective ventilation with I-gel can be performed in patients in whom the head and neck is extended or rotated, whereas flexion of the head and neck adversely affects ventilation. Clinically, flexion of the head and neck should be avoided during ventilation with I-gel.

Mishra and Nawaz et al. [8] in their study compared the effect of head and neck position on the oropharyngeal leak pressures and fibroptic view of the glottis and ventilation scores between ProSeal LMA and the I-gel. Compared with neutral position, oropharyngeal leak pressures were significantly higher with flexion and lower with extension but similar with rotation of head and neck. But the oropharyngeal leak pressure was significantly higher for ProSeal LMA compared with the I-gel in all positions. Peak airway pressures were significantly higher with flexion in both groups (however this did not affect ventilation), lower with extension in ProSeal group and comparable in I-gel group but did not change significantly with rotation of head and neck in both groups. They concluded that effective ventilation can be done with both ProSeal LMA and I-gel with head in all the above positions. ProSeal LMA has a better margin of safety than I-gel due to better sealing pressures except in flexion where the increase in airway pressure is more with the former. Extreme precaution should be taken in flexion position in ProSeal LMA.

In contrast to what Sanuki and Mishra concluded in their studies that I gel was not very efficient when used in the flexion position of the head, we demonstrated that using the Baska mask and the SLIPA™ when the head is flexed was effective.

Isserles and Rozenberg. [17] Suggested in their study, that neck flexion removes the longitudinal tension in the anterior pharyngeal muscles, allowing them to settle down onto the mask to form a better seal. Neck flexion causes a reduction in the anteroposterior diameter of the pharynx [18] This may explain the cause of a higher pressure seal in almost all the studies including our study when the head is flexed. The high sealing pressure and good ventilation score in different head position that the Baska mask has in comparison to other positions. As regard the air way sealing pressure, Baska mask pressures need to be monitored carefully. Also we concluded that during fibreoptic evaluation of glottis, a lower score was obtained with flexion in both devices, but there was no affection on the ventilation, which was evident from adequate delivered tidal volumes and comparable levels of end-tidal CO₂ between the neutral and flexion positions.

5. Conclusions

Based on the results of this study, effective ventilation is possible with both Baska mask and SLIPA™ in all head positions. As regard the air way sealing pressure, Baska mask has a better air way sealing pressure than SLIPA™; however, care should be taken with extreme flexion and the airway pressures need to be monitored carefully. Also we concluded that during fibreoptic evaluation of glottis, a lower score was obtained with flexion in both devices, but there was no affection on the ventilation, which was evident from adequate delivered tidal volumes and comparable levels of end-tidal CO₂ between the neutral and flexion positions.

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