Randomized comparative study between classic laryngeal mask airway and I gel Airway in obese patients having BMI 35-40 during elective non-abdominal surgery

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Abstract

Background: In this study, we compare between classic laryngeal mask airway versus I gel airway as a conduit for ventilation in obese patients having BMI 35 -40 during elective non-abdominal surgery. Methods: 50 Adult obesepatients having BMI 35-40 who are arranged for elective non-abdominal surgery under general anesthesia are randomly divided into 2 equal groups: 1-Group A(n = 25), in which classic laryngeal mask is used for ventilation. 2- GroupB (n = 25), in which I gel mask is used for ventilation. This study compared between cLMA and I gel regarding insertion success rate, the time of insertion, leaking pressure, assessment of position by fiber optic, hemodynamic, Spo2 for each device during insertion and maintenance of general anaesthesia and postoperative complications in obese patients. Results: The present study showed that the classic laryngeal mask airway and I gel mask airway are effective in ventilation in obese patients with shorter insertion time and higher leaking pressure in I gel mask than cLMA,these finding was statistically significant.there was hemodynamic stability and no episodes of hypoxia. There was statistical insignificance regarding all hemodynamic variables and oxygen saturation between both groups.There is no statistical significance difference two groups concerning position assessment by fiber optic,Regarding postoperative complicationsafter removal of the device, postoperative blood stain was found in 1 case in laryngeal mask and no cases for I gel, also 1 case of laryngospasm in laryngeal mask with no statistical significant differences between groups. Clinically no case of hoarseness of voice or sore throat in the study. Conclusion: Both supraglottic airway devices; the classic LMA and the I GEL mask are satisfactory devices providing high airway leaking pressures. Although both devices provide high airway leaking pressures, our study revealed that the I gel mask provides a better seal with the glottic aperture and shorter time of insertion than cLMA. Both devices showed also effective ventilation, more hemodynamic stability and no
episode of hypoxia with minimal post-operative complications. Trial registration: Clinical Trial registry on ClinicalTrials.gov, ID: NCT03843827

Background

There are a lot of supraglottic airway devices available which are used in general anesthesia to avoid hemodynamic changes during endotracheal intubation (1). and may be used in difficult airway (Obese patients) or may be a simple alternative to intubation in short term elective surgery in the supine position (2).

The introduction of LMA-Classic™ laryngeal mask airway (Classic™ LMA) by Dr. Archie Brain into clinical practice in 1988 brought about a revolution in anesthesia. (3). Many different variants of this device have been designed and marketed, trying to offer a simple and effective alternative to the endotracheal intubation. (4)

New generations come out with devices designed to increase safety and some have features which might reduce the risk of aspiration. (5,6)

I gel is a new type of laryngeal mask and doesn’t have an inflatable cuff. Because of its thermoplastic elastomeric structure, it exactly adapts to the supraglottic tissue by binding with body temperature, thus minimizing air leakage (7).

Methods:

This randomized controlled study was conducted in Kasr Al-Ainy Hospital, Faculty of medicine, Cairo University from September 2017 till March 2018, after approval of the Ethical committee and written patients consent. Study was registered in ClinicalTrials.gov (ID: NCT03843827)

There was a total number of 50 obese adult patients were included in this study. They were scheduled for elective non-abdominal surgery under general anesthesia. Those patients are allowed to fast for 6-8 h before surgery. They were randomly divided by
computer designed lists then concealed in closed envelopes into two equal groups: Fig 1

1- Group A (n = 25), in which LMA was used for ventilation.

2- Group B (n 25), in which I gel was used for ventilation.

Figure 1: Consort flow chart

Inclusion criteria: Adult healthy ASA II patients, both genders, BMI 35-40, aged 18 – 60 years, Mallampati grade I, II during elective non abdominal surgery ≤ 2 hour e.g. diagnostic arthroscopy, hysteroscopy and cataract.

2. Exclusion criteria: class III or IV, Age >60 years or <18 years, people with hypertension, diabetes, pregnancy, gastro oesophageal reflux disease, cardiovascular, renal disease, difficult mask ventilation, obstructive sleep apnea, any position rather than supine, any form of sore throat, patients allergic to any drugs used in the study and in PCV mode if measured tidal volume was lesser than 6 ml/kg it will be excluded.

Peri-operative Management:

Pre-operative assessment through:

After taking history, clinical examination, routine investigation and Mallampati airway assessment. An adequate intravenous line was inserted and secured then all patients received an intravenous anti-emetic, Ondansetron 4 mg and an antacid, Ranitidine 50 mg, 1 hour before the operation.

The patients are premeditated with intravenous atropine 0.01 mg/kg.

Intra-operative Management:

Basic monitoring was established; pulse oximeter, ECG, non-invasive blood pressure and co2 analyzer.
After preoxygenation using a facemask for 5 min, induction of anaesthesia is done with Fentanyl 2 ug/kg, Propofol 1.5-2.5 mg/kg and Atracurium 0.5mg/kg and Lidocaine 1 mg/kg before device insertion. The ventilatory strategy is pressure-controlled ventilation (PCV) to achieve tidal volume of 6-8 ml/kg and the peak inspiratory airway pressure is not more than 15 cmH2o. Maintenance of anaesthesia will be achieved by isoflurane and Atracurium. The randomly assigned supraglottic device for each group is inserted. Insertion time and trials of the study device are recorded for each device which started from removal of the ventilation mask until appearance of capnography waves. Proper positioning is confirmed by inspection of chest inflation bilaterally, auscultation of the chest bilaterally, absence of any leak sounds from the device, capnography readings of six successive waves and by fiber optic. The success rate is recorded. If placement is inadequate, manipulations are done in the following sequence, gentle pulling and pushing of the device, head flexion and extension, jaws thrust and chin lift. If after 3 attempts, the device is not properly inserted, endotracheal intubation is done, and those patients are excluded from the study. Hemodynamic data and episode of hypoxia are recorded just before device insertion, after device insertion, during removal, 1min after removal to monitor the occurrence of any hemodynamic changes due to device insertion. Leaking pressure will be performed as follows: set fresh gas flow at 3L/min, close the pressure limiting valve completely and then minimal airway pressure is measured at which an audible gas leak occurred using a stethoscope placed just lateral to the thyroid cartilage.(8)(9)(10) After recovery, patients will be asked about sore throat and hoarseness of voice in the form of yes or no.

Measurement tools

1- The ease of each device insertion and rate of success (three attempts at insertion were
allowed before the device was considered inappropriate, difficulty of insertion was graded as easy=1, moderate=2, difficult=3).

2-The time of each device insertion, (when the START from the removal of the face mask until appearance of first upstroke of capnography waves). 3-Assessment of position by fiber optic scoring system (61):

|   |                                  |
|---|----------------------------------|
| 1 | Clear view of vocal cords        |
| 2 | Only arytenoid cartilages visible |
| 3 | Only epiglottis visible          |
| 4 | No laryngeal structures visible  |

4- The oropharyngeal leak pressure.

5- Hemodynamic data (blood pressure and heart rate) are recorded just before device insertion, after device insertion, during removal and 1 min after removal.

6- The Presence of complications as laryngospasm, or post-operative blood stains, sore throat or hoarseness of voice is assessed after surgery.

Post-Operative Assessment:

At the end of surgery, the anesthetic gas was replaced with 100 % oxygen to facilitate patient recovery was assessed with the following removal criteria: return of consciousness, ability to protect the airway, Spontaneous breathing, regular respiratory rate and < 30 breaths/min, adequate tidal volume > 5 ml/Kg. Stable hemodynamic and metabolic status and adequate reversal of residual neuromuscular block by clinical tests.
The device was removed and checked for blood streaked mucous on it as a sign of airway trauma. After recovery and complete return of conscious level, Patients administered a simple questionnaire that assess the presence of sore throat and hoarseness postoperatively in the form of (Yes /No).

I. Sample size:

G-power software was used to calculate sample size. Sample size was calculated considering a power of 0.9 and a p-value of 0.05 to be statistically significant. The mean and standard deviation of the time to insertion was derived from a similar study (11) 18.3±6.5 in group (A), 24.4±7.7 in group (B) and was used to calculate sample size. The total calculated sample size was 50 patients (25in each group).

II. Statistical analysis

Data management and analysis are performed using Statistical Package for Social Sciences (SPSS) vs. 19. Numerical data were presented as means ± standard deviations (SD). Categorical data are presented as number and (percentages %).(12)

Comparisons between the two groups for normally distributed variables are done using the Student’s t-test; the Mann–Whitney test, a nonparametric test equivalent to the t-test, is used in ordinal and not normally distributed variables. The chi-square test or the Fisher’s exact test for small sample size is used to compare between the groups with respect to categorical data. P-values < 0.05 are considered significant. (13)

Results

This study was conducted on 50 adult’s patients who were scheduled for elective non-abdominal surgery lasting less than 2 hours under general anesthesia. Patients were
randomly divided by computer designed lists and then concealed in closed envelopes into 2 equal groups:

1. GA (n=25) in which classic laryngeal mask was used for ventilation.

1. GB (n=25) in which I gel was used for ventilation.

There was no statistical significance difference between the two groups regarding the demographic data shown in table (1).

Table (1): Demographic Data in both cLMA and I gel.

| Group A(n=25)       | Group B(n=25)       | P value |
|---------------------|---------------------|---------|
| Age                 | 35.28±8.94          | 36.2±9.63 | 0.728 |
| BMI                 | 36.41±1.79          | 36.82±2.42 | 0.5   |
| Gender(male)        | 14(56%)             | 10(40%)  | 0.39   |

Ordinal Data are presented as Mean ± SD, while categorical data were presented as number (%). p<0.05 is considered statistically significant. BMI: body mass index, cLMA: classic laryngeal mask airway.

Regarding insertion time and leaking pressure required for both cLMA and Igel, there was Statistically significant difference in either group (Table 2).

Table (2): Data regarding time of insertion and leaking pressure.
|                          | Group A (n=25) | Group B (n=25) | P value |
|--------------------------|----------------|----------------|---------|
| Time of insertion (seconds) | 10(2)          | 9(2.5)         | * 0.01  |
| Leaking pressure         | 18(2)          | 25(6)          | *<0.001 |

Data presented as median and IQR (inter quartile range). *P value < 0.05 is considered statistically significant.

Although time of insertion in group (B) lesser than group (A), 4 attempts of insertion in I gel group were needed in contrast to cLMA that one attempt is done. That was statistically insignificant as showed in table (3).

Table (3): Data regarding number of device insertion attempts.

|          | Group A (n=25) | Group B (n=25) | P value |
|----------|----------------|----------------|---------|
| Easy     | 24(96%)        | 21(84%)        | 0.35    |
| moderate | 1(4%)          | 4(16%)         |         |

Data were presented as number (%). p<0.05 is considered statistically significant.

Concerning hemodynamic monitoring, we recorded a baseline reading of heart rate, systolic blood pressure, diastolic blood pressure and oxygen saturation before insertion of both devices. A second reading was taken after insertion of both devices, just before removal. The fourth reading was recorded 1 min after removal of both devices. There was statistical insignificance regarding all hemodynamic variables and oxygen saturation between both groups as shown in Figures (2, 3, 4 and 5).
Figure 1: Heart rate (beat/min) difference between both groups

Figure 2: Systolic blood pressure (mmHg) difference between both groups.

Figure 3: Diastolic blood pressure (mmHg) difference between both groups.

Figure 4: SaO2 (%) difference between two groups.

18 patients in both groups were have grade 1 by fiberoptic, 7 patients in group (A) and 6 patients in group (B) were have grade 2 and 1 in group (B) has grade 3. That was statistically insignificant as shown in table (4).

Table (4): position assessment by fiberoptic in both groups:

|                  | Group A(n=25) | Group B(n=25) | P value |
|------------------|---------------|---------------|---------|
| Grade 1: clear view of vocal cords | 18(72%)       | 18(72%)       |         |
| Grade 2: only arytenoids cartilages visible | 7(28%)        | 6(24%)        | 0.584   |
| Grade 4: only epiglottis visible | 0(0%)         | 1(4%)         |         |

Data were presented as number (%). p<0.05 is considered statistically significant.
Finally, there was no significant difference in the mean number of postoperative complication rates concerning sore throat, hoarseness of voice, laryngospasm and postoperative blood stain between both devices. Only two cases was reported to have postoperative blood stain and the other case have laryngospasm, Table (5)

Table (5): Data regarding post-operative complications. Table (5) : Data regarding post-operative complications.

|                          | Group A(n=25) | Group B(n=25) | P value |
|--------------------------|--------------|--------------|---------|
| Hoarseness of voice      | 0(0%)        | 0(0%)        | *       |
| laryngospasm             | 1(4%)        | 0(0%)        | 1       |
| Postoperative blood stain| 1(4%)        | 0(0%)        | 1       |

Categorical data were presented as number (%).

*no p value calculated because hoarseness of voice is constant.

Discussion

This study compared between cLMA and I gel regarding insertion success rate, the time of insertion, leaking pressure, and assessment of position by fiberoptic, hemodynamic, Spo2 for each device during insertion and maintenance of general anaesthesia and postoperative complications in obese patients. (14, 15, 16)

Our results regarding time, difficulty of insertion and leaking pressure were the same as the study done by Weber U, et al (17) in which mean insertion time was (18.3s vs. 24.4s) I gel and cLMA respectively, 5 out 50 was difficult in insertion in I gel group but it was 1 in cLMA
group and regarding leaking pressure it was (25.7 cmH2o vs. 17 cm H2o) respectively.

Weber U, et al (17) also showed no statistical significance difference between I gel and cLMA.

Study by Chauhan et al mentioned that in all patients I gel or LMA was inserted within 3 attempts. Mean insertion time for the i-gel was significantly lower than LMA (18) Wharton et al evaluated the performance of i-gel supraglottic airway device in manikins and anesthetized patients. Their results suggest the i-gel is rapidly inserted in both manikins and patients by an inexperienced person and compares favorably to other supraglottic airways available. (19)

Regarding all hemodynamic variables including heart rate, systolic blood pressure, diastolic blood pressure and oxygen saturation, they were compared in both groups and there was statistical insignificance between them.

Regarding assessment of position by fiber optic there was no statistical significance difference between 2 groups, in group (A) there was 18 patients showed grade 1 and 7 patients showed grade 2, in group (B) there was 18 patients showed grade 1, 6 patients showed grade 2 and one patient showed grade 4.

Cattano D., et al (20) found that there was no hoarseness of voice or sore throat complains in both groups.

In contrast to our study Francksen, H., et al (21) showed that fiberoptic position was excellent in I gel airway in lean patient than LMA unique may be due to large sample size rather than us.
Regarding postoperative complications: laryngospasm and postoperative blood stain was complaint in one case in group (A).

Regarding postoperative blood stain Siddiqui, A.S., et al (22) there was 18% of patients of LMA group with blood after removal in contrast to I gel group where none was detected.

Regarding postoperative sore throat, dysphonia Francksen, H., et al (21) showed that postoperative sore throat occur in (7 vs. 8) patients in I gel and cLMA groups respectively, dysphonia occur in (2 vs. 1) patients in I gel and cLMA groups respectively as a moderate symptom, however. It was statistically insignificant.

Limitations:

This study was restricted to patients undergoing non-abdominal elective surgeries with preoperative fasting. Patients who less than 18 years were not included and small sample size also a limitation, Investigators suggest further studies to be done on a wider population scale to achieve our conclusion.

Conclusion

Our main finding in the study was that both supraglottic airway devices; the classic LMA and the I GEL mask are satisfactory devices providing high airway leaking pressures. Although both devices provide high airway leaking pressures, our study revealed that the I gel mask provides a better seal with the glottic aperture and shorter time of insertion than cLMA. Both devices showed also effective ventilation, more hemodynamic stability and no episode of hypoxia with minimal post-operative complications.

Abbreviations
ABP: Arterial blood pressure

ANOVA: Analysis of variance

ASA: American Society of anesthesiologists

ECG: Electrocardiograph

SBP: Systolic blood pressure

Declarations

Ethics approval and consent to participate*: N 34-2017/Ms

(Department of Anesthesia, Cairo University)

Name: Randomized comparative study between classic laryngeal mask airway and I gel Airway in obese patients having BMI 35-40 during elective non-abdominal surgery

Obtained written consent from the participants

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Availability of data and materials

The data that support the findings of this study are available from Cairo University hospitals but restrictions apply to the availability of these data,

Which were used under license for the current study, and so are not publicly
Available. Data are however available from the authors upon reasonable request and with permission of Cairo university

Authors’ contributions

Conception of the idea: A.A., F.I.E, N.H., T.K.

Study design: N.H., T.K., A.A., A.F.A.E, S.O., M.B, A.S, A.A.S

Acquisition of data: A.A., F.I.E.N, A.R.A

Data analysis and interpretation: A.A.

Drafting the article: A.A.,

Revising the manuscript: N.H

Research group leader and supervision of the work: NH. A.A and F.I.E

All authors approved the manuscript and agreed to be accountable for all aspects of the work.

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Figures

Figure 1

Consort flow chart

Figure 2

Heart rate (beat/min) difference between both groups

Figure 3

Systolic blood pressure (mmHg) difference between both groups.
Figure 4

Diastolic blood pressure (mmHg) difference between both groups.

Figure 5

SaO2 (%) difference between two groups.

Supplementary Files

This is a list of supplementary files associated with the primary manuscript. Click to download.

Consort Diagram.docx