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A COMPARATIVE STUDY BETWEEN I-GEL AND LMA SUPREME IN SPONTANEOUSLY BREATHING PATIENTS POSTED FOR ELECTIVE BREAST SURGERIES.

Anaesthesiology

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ABSTRACT

Background: Both i-gel™(I-gel) and LMA Supreme™ (Supreme) are new ssupraglottic airway devices. . This study was designed to investigate I-gel in comparison with LMA Supreme.

Material and Methods: One hundred patients in the age group of 18 to 60 years with American Society of Anaesthesiologist physical status I or II undergoing elective breast surgeries were randomly assigned to either I-gel group or Supreme group (50 patients in each group). After induction with propofol the supraglottic airway device was inserted . We assessed the insertion success rate, insertion time, oropharyngeal leak pressure, number of airway manipulations required, haemodynamic parameters and postoperative complications.

Results: The success rate of insertion was same in both the groups. The insertion time of the Supreme LMA was higher than that of I-gel. The oropharyngeal leak pressure in the Supreme group was higher than that in the I-gel group. There were no significant differences in complications.

Conclusion: From our study we concluded that i-gel was a better alternative than LMA supreme.

KEYWORDS

Supraglottic airway devices, i-gel, LMA Supreme

Introduction: Dr. Archie Brain revolutionised the field of anaesthesia and critical care with the introduction of classic laryngeal mask airway in early 1980s. Now we are in the second generation of such devices and they continue to be an essential tool in the anaesthesiologist's armamentarium. These devices have become popular because of their ability to maintain the airway without perturbing the trachea and can be used in patients without muscle relaxation[2].

Both the i-gel™(I-gel) and LMA Supreme™(Supreme) are new, single-use, second-generation Supraglottic Airway Devices (SAD). The i-gel (Intersurgical Ltd., Wokingham, Berkshire, UK) is a latex-free SAD with a non-inflatable cuff and a gastric drain tube. The Supreme (The Laryngeal Mask Company Ltd., St Helier, Jersey, UK) has a curved and rigid airway tube, a drain tube positioned within the centre of the airway tube and a relatively large inflatable cuff made of polyvinyl chloride[24567].

There are many studies comparing i-gel with other SADs that have shown effective clinical performances in adults and children[1678].

Though our studies have been done comparing i-gel with SLMA, we compare the two devices, especially with regards to ease of insertion, insertion time, number of attempts, oropharyngeal leak pressure, haemodynamic parameters and postoperative complications.

Materials and Methods:

This is a prospective, randomized, comparative study and was conducted after obtaining informed consent from the patients. American Society of Anaesthesiologists physical status I and II of either gender aged 18-60 years, with body mass index 18-30 Kgm^{-2}, schedule for elective breast surgeries under general anaesthesia with spontaneous ventilation without muscle relaxation were included. The duration of surgeries were not less than 30 min and not more than 90 min.

We excluded patients from the study with anticipated difficult airway, restricted mouth opening, pregnant females, cervical spine disease, obese with body mass index >30Kg/m^2 and patients with history of regurgitation.

The patients were randomly allocated in two groups (50 in each group) based on the computer generated codes. In Group I I-gel was inserted and in Group S, Supreme LMA was inserted. In the post-anaesthesia care unit, monitoring of the postoperative parameters and the incidence of sore throat were done. All the patients were blinded to the group assigned.

Preoperative evaluation of all the patients were done and baseline vitals were recorded.

The patients were pre-medicated with Inj. Glycopyrrolate 0.2 mg, Inj. Midazolam 0.02mg/kg, and Inj. Fentanyl 2mcg/kg intravenously. All patients were pre-oxygenated with 100% oxygen for 3 minutes.

Induction was done with Inj. Propofol (2-2.5 mg/kg body weight) till the loss of eyelash reflex. Then the patients head was placed in sniffing the morning air position and the device was inserted by a single experienced anaesthesiologist who has the experience of more than 100 Supreme LMA and I-gel insertion. The supraglottic airway device was inserted after lubricating the posterior surface of the cuff with a water based jelly.

Cuff of LMA Supreme was inflated with half of the recommended volume of air and if required in case of inadequate seal, the entire recommended volume of air was used to inflate the cuff. The device was then connected to the breathing circuit and secured after confirming bilaterally equal air entry. Ryle's tube was inserted. An effective airway was confirmed from bilaterally symmetrical chest movement, square waveform on the capnograph and a normal oxygen saturation[2].

Ease of insertion was defined as no resistance to insertion of the device in the pharynx at single attempt.

The oropharyngeal leak pressure was measured after closing the adjustable pressure limiting valve with a fresh gas flow of 3 lit/min and noting the airway pressure at equilibrium or when there was an audible air leak from the throat. The maximum pressure allowed was 40 cm H_2O. The epigastrium was also auscultated when measuring the oropharyngeal leak pressure to detect any air entrainment in the stomach[2].

Manipulations were done in the form of increasing the depth of insertion, giving jaw thrust or chin lift or changing the size of the device if an effective airway was not achieved.

After 3 unsuccessful attempts, the device insertion was abandoned and the patients were given muscle relaxants and intubated with

endotracheal tube.

Maintenance of anaesthesia was done with oxygen, nitrous oxide and propofol infusion with spontaneous respiration.

When the procedure ended, all the patients were ventilated with 100% oxygen during emergence from anaesthesia. The removal of the device was done when the patient was able to open the mouth on command. Then inspection was done for any injury to lips, tongue or teeth and presence of blood stain.

After completion of the procedure, all patients were observed for a period of 24 hours for any complaint of sore throat. In the postoperative period, sore throat was treated with warm saline nebulisation. The occurrence of laryngospasm was treated with 100% oxygen followed by Inj. Succinylcholine 0.25 mg/kg to 1mg/kg. Hiccups were managed by increasing the depth of anaesthesia by increasing the maintenance dose of Inj. Propofol.

RESULTS AND OBSERVATIONS:

The study population consisted of 100 ASA grade I and II patients posted for elective breast surgeries with spontaneous respiration under general anaesthesia without muscle relaxation.

They were divided into two groups of 50 each. Patients in Group I were given I-gel while Group S were given Supreme LMA.

Table1. Division of study population in two groups

Group I	I-gel	N=50
Group S	Supreme LMA	N=50

Statistical analysis was done with Graphpad® Instat3 statistical software. For qualitative data, Chi square test or Fisher exact test was used. Quantitative data was analysed using Student unpaired t-test.

The P value was determined
- P> 0.05 is not significant
- P< 0.05 is significant
- P< 0.001 is highly significant

Following observations were made during this study-

Table2. Demographic characteristics of the patients in the two Groups: Data are expressed as mean+standard deviation for age, height and weight; absolute number for gender and ASA physical status

Category	Group I	Group S	P=Value
Age (in years) Mean+ SD	34.86+11.16	34.72+10.76	0.9492(NS)
Sex Male Female	20 (40%) 30 (60%)	28 (56%) 22 (44%)	0.1093(NS)
Height (meter) Mean+ SD	158.98+6.98	159.18+6.54	0.8828(NS)
Weight (kg) Mean+SD	57.72+6.38	57.58+5.98	0.9101(NS)
ASA physical status I II	27(54%) 23(46%)	33(66%) 17(34%)	0.2206(NS)

Abreviation: SD=Standard Deviation NS=Not significant

p-value was calculated from unpaired t-test for age, height and weight and Chi-square test for sex distribution, ASA Physical status, between the groups.

On statistical analysis the p value was found to be >0.05 which is by conventional criteria, this difference is considered to be not quite statistically significant.

The mean time required for insertion and the mean oropharyngeal leak pressure was compared using Unpaired student's t test.

The Chi-square test was used to compare the ease of insertion, attempts required for insertion, Ryle's tube insertion and the occurrence of adverse events.

Table 3. Comparison of successful insertion time, ease of insertion, insertion attempts, ease of Ryle's tube insertion and oropharyngeal leak pressure

Category	Group I	Group S	P Value
Successful insertion time(in seconds) Mean+SD	24.34+6.60	25.52+7.54	0.4069*
Ease of insertion Yes No	47 (94%) 3 (6%)	46 (92%) 4 (8%)	0.6951@
Insertion attempts 1st attempt 2nd attempt	48 (96%) 2 (4%)	45 (90%) 5 (10%)	0.2396@
Ease of Ryle's Tube insertion Easy Difficult	49 (98%) 1 (2%)	48 (96%) 2 (4%)	0.5577@
Oropharyngeal leak pressure Mean+SD	20.84+3.09	20.60+3.08	0.6981*

*Student t test P>0.05, Not significant.

@Chi-square test P>0.05, Not significant

Table 4: Comparison of complications among the groups.

Variables	Group I	Group S	P value
Coughing	3	6	0.4846
Laryngospasm	0	0	-
Injury to teeth, gum and lip	0	0	-
Sore throat	1	4	0.3588
Blood stains on device	2	3	0.6464
Regurgitation	0	0	-
Aspiration	0	0	-
Gastric insufflation	0	0	-

*Student t test P>0.05, Not Significant

@Chi-square test P>0.05, Not Significant

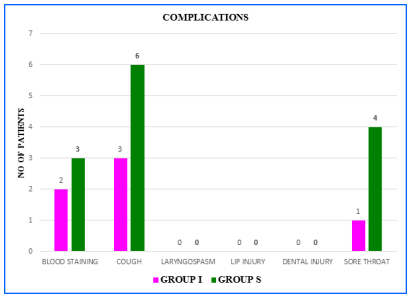

Figure 1: Comparison of complications among the two groups which were statistically not significant. P value >0.05

Table 5: The percentage changes in mean arterial pressure, heart rate and Minimum oxygen saturation.

Variables	Group I	Group S	P value
MAP Mean+SD	30.60+3.99	30.80+3.69	0.7954
HR Mean+SD	35.80+2.92	35.50+3.39	0.6364
SpO2 Mean+SD	98.40+1.16	98.62+1.07	0.3262

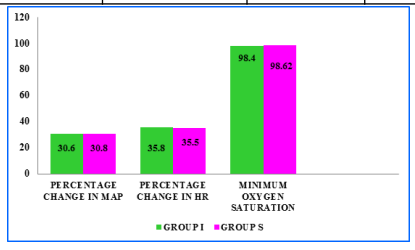

Figure 2: Bar diagram showing the comparison of percentage changes in mean arterial pressure, heart rate and minimum oxygen saturation in the two groups.

On comparison using Chi-square test both the groups had similar changes in mean arterial pressure, heart rate and minimum oxygen saturation and the differences were statistically insignificant (P value >0.05).

DISCUSSION:

This study was undertaken to compare the clinical efficacy of I-gel and Supreme LMA in patients undergoing elective breast surgeries who were on spontaneous ventilation under general anaesthesia without muscle relaxants in a period of one year from 1th August 2018 to 31st July 2019. The demographic characteristics of the study groups in terms of age, sex, gender, height, weight and ASA physical status were comparable between the two groups. In our study, we randomly allocated any one of the two supraglottic airway devices during anaesthesia.

After induction of anaesthesia, the randomized appropriate size device was inserted and we noted the ease of insertion, insertion time and number of attempts of insertion.

In our study, successful positioning of I-gel in single attempt is 96% (48/50) and Supreme LMA is 90% (45/50). The successful positioning of i-gel in second attempt is 4% (2/50) and Supreme LMA is 10% (5/50). There were no failed insertion attempt in our study population and converting to endotracheal intubation was not required. We found that the first attempt success rate was more with I-gel group than Supreme LMA. The statistical analysis was done with Chi-square test which was found to be not significant (P value =0.2396).

In our study population of 50 patients in I-gel group 94% (47/50) of insertion was easy and the airway was secured at first or second attempts and 6% (3/50) were difficult. Insertion of Supreme LMA in 92% (46/50) of patients was easy and 8% (4/50) were difficult. Hence the insertions were easy with i-gel than the Supreme LMA but the difference is insignificant (p value =0.6951).

In our study, oropharyngeal leak pressure was measured to compare the airway sealing pressure of both the devices. On comparison with Unpaired student's t-test between the two groups, the oropharyngeal leak pressure of I-gel (20±3.09 cmH_2O) and the Supreme LMA (20.60+3.08 cmH_2O) were found to be insignificant (P value =0.6981).

In a study conducted by Sunil Kumar T.S[3] et al., comparing clinical performance of LMA Supreme vs. I-Gel in 134 patients, 88% of I-gel and 79% of Supreme LMA were inserted successfully at first attempt and insertion were easy in 92.5% (62/67) of patients in I-gel group where as 89.6% (60/67) were easy with Supreme LMA group.

Teoh WHL [8] et al., studied in 100 patients comparing I-gel with LMA Supreme, 96% of I-gel and 94% of Supreme LMA were successfully inserted at first attempt with same ease of insertion. They found insignificant difference of airway sealing pressures between the Supreme LMA and the I-Gel [mean (SD) 26.4 (5.1) vs 25.0 (5.7) cmH_2O, respectively, p=0.18].

Gabbot et al [9]., in their study on 100 patients, found that the I-gel provides good airway sealing pressure that improved over time due to thermoplastic properties of gel cuff which forms an effective sealing around the larynx after warming to body temperature.

Balasaheb T. G. [2] et al., compared Supreme LMA vs I-Gel in short surgical procedures in a study population of 60 patients, 93.33% (28/30) in i-gel group and 90% (27/30) of Supreme LMA were inserted successfully at first attempt with similar ease of insertion. In their study they found the airway sealing pressure of Supreme LMA (25.73+2.21 cmH_2O) were significantly higher than I-gel (20.0+2.94 cmH_2O) but the differences were clinically insignificant.

In between the two groups, the mean heart rate were comparable but no statistically significant difference was noticed (p value =0.6364). The mean arterial pressure difference were comparable in both the groups which were statistically and clinically insignificant (p value =0.7954). In our study, saturation was maintained within normal range (p value =0.3262) throughout the surgery.

The haemodynamic parameters of our study were in accordance with Balasaheb T. G. [2]et al., Amr M. Helmy [10]et al. And Teoh WHL [8] et al.

Comparing the complications among the groups, we found no cases of laryngospasm, injury to teeth, gum, lip, regurgitation, aspiration and gastric insufflation. There was post extubation coughing in three[6% (3/50)] cases in i-gel group and six [12% (6/50)] cases in Supreme LMA group which were comparable but statistically insignificant (p value =0.4846). The incidence of sore throat were studied 24 hours post extubation among the groups where in i-gel group, single [2% (1/50)] case of sore throat was reported and four [8% (4/50)] cases were reported in Supreme LMA group (p value=0.3588). The patients were comfortable after warm saline nebulisation. Post extubation blood stain on devices were observed 4% (2/50) in i-gel group and 6% (3/50) in Supreme LMA group which were comparable but statistically and clinically insignificant (p value=0.6464).

In our study, gastric tube insertion were found to be easy in 98% (49/50) of patients with I-gel group and 96% (48/50) with Supreme LMA group. The insertion was difficult in 2% (1/50) of patients with I-gel group and 4% (2/50) with Supreme LMA group. Both the groups were comparable but statistically and clinically insignificant (p value=0.5577).

Sunil kumar T. S. [3]et al., in their study comparing clinical performance of LMA Supreme vs I-gel observed that the incidence of sore throat was 11.9% (8/67) patients in Group I and 28.4% (19/67) in Group S. Their result was statistically significant (p value=0.017).

In the study of Mukadder [11] et al., on 105 patients comparing the Proseal, Supreme, and I-Gel SAD in gynecological Laparoscopic Surgeries, found that airway morbidity were more in Supreme LMA group than the i-gel group.

In a study conducted by Chen X [12]et al., comparing the performance of the i-gel™ vs. LMA-S™ a meta-analysis of controlled trials found that sore throat was more in Supreme LMA when compared to i-gel. They also found that the gastric tube insertion was more easier with LMA Supreme than I-gel group. The findings of the above studies were indistinguishable to our studies.

CONCLUSION:

In our study we compared i-gel with LMA Supreme in terms of number of attempts for insertion of device, ease of insertion of the device, haemodynamic parameters and postoperative complications. From our observations, we conclude that, i-gel was better than LMA Supreme in first time insertion success rate and ease of insertion and the incidence of postoperative sore throat was more with Supreme LMA. Therefore, i-gel is a better alternative to LMA-Supreme.

REFERENCES

1. Kim, H. et al. A comparison of i-geltm and lma supremetm in anesthetized and paralyzed children. Korean J. Anesthesiol. 67, 317–322 (2014).
2. Tukaram Govardhane, B., Kulkarni, S. & Parmar, M. A Comparative Study of Supreme LMA Vs I-gel: Two Supraglottic Airway Devices in Short Surgical Procedures. Orig. Res. Artic. MVP J. Med. Sci. 5, 5–11
3. Kumar S, S. T., Beegum S, S. T., Professor, A., Professor, A. & Professor, A. COMPARISON OF CLINICAL PERFORMANCE OF LMA SUPREME VERSUS I-GEL 1.
4. Uppal, V., Gangaiah, S., Fletcher, G. & Kinsella, J. Randomised crossover comparison between the i-gel and the LMA Unique in anaesthetised, paralysed adult patients. (2009).
5. Francksen, H. et al. A comparison of the i-gelTM with the LMA-UniqueTM in non-paralysed anaesthetised adult patients. Anaesthesia 64, 1118–1124 (2009).
6. Theiler, L. G. et al. Crossover comparison of the laryngeal mask supremeTM and the i-gelTM in simulated difficult airway scenario in anesthetized patients. Anesthesiology 111, 55–62 (2009).
7. Ragazzi, R., Finessi, L., Farinelli, I., Alvisi, R. & Volta, C. A. LMA Supreme TM vs i-gel TM- a comparison of insertion success in novices. Anaesthesia 67, 384–388 (2012).
8. Teoh, W. H. L. et al. Comparison of the LMA Supreme vs the i-gelTM in paralysed patients undergoing gynaecological laparoscopic surgery with controlled ventilation. Anaesthesia 65, 1173–1179 (2010).
9. Gabbott, D. A. & Beringer, R. The iGEL supraglottic airway: A potential role for resuscitation? Resuscitation 73, 161–162 (2007).
10. Helmy, A. M., Atef, H. M., El-Taher, E. M. & Henidak, A. M. Comparative study between I-gel and classical laryngeal mask airway in anesthetized spontaneously ventilated patients. Egypt. J. Anaesth. 26, 47–52 (2010).
11. Mukadder, S. et al. Comparison of the Proseal , Supreme , and I-Gel SAD in Gynecological Laparoscopic Surgeries. 2015, (2015).
12. Chen, X., Jiao, J., Cong, X., Liu, L. & Wu, X. A Comparison of the Performance of the I-gel TM vs . the LMA-S TM during Anesthesia : A Meta-Analysis of Randomized Controlled Trials. 8, (2013).