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KEY WORDS: I-GEL, LMA-SUPREME, Laparoscopic surgery

INFLATABLE V/S PRE-SHAPED CUFF OF SUPRAGLOTTIC AIRWAY DEVICES IN LAPAROSCOPIC SURGERY

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ABSTRACT

BACKGROUND: LMA–Supreme and I-Gel are two novel 2nd generation supraglottic airway devices with gastric access.-

AIM: We evaluated safety and efficacy of I-Gel (Pre-shaped cuff) versus LMA-Supreme (inflatable cuff) as ventilatory devices for providing adequate seal in patients undergoing gynaecological laparoscopic surgery with controlled ventilation.

METHODS: A prospective randomized single blind study was conducted in 90 ASA I/II adult female patients of 20-50 years ,weighing 40-70 kg, undergoing surgery of less than 2 hours of duration under general anaesthesia. They were randomly allocated into the group S (LMA-Supreme, n=45) and group I (I-Gel, n=45). Study device was inserted as per manufacturer's recommendation. Effective airway insertion time, ease and number of attempt of insertion, gastric tube insertion time, oropharyngeal leak pressure, respiratory and hemodynamic parameters, and complications were recorded. Statistical analysis was done using student t test.

RESULTS: 97% LMA-Supreme and 91% I-Gel were successfully inserted on first attempt with effective insertion time of 17.13+/-3.15 seconds and 18.86+/-3.30 seconds respectively ($p<0.05$). Oropharyngeal leak pressure(OLP)and inspired-expired tidal volume difference were 27.04+/-1.29 cm of H20;15.68+/-6.61 ml in group S and 26.22+/-1.86 cm of H2O;21.48+/-8.45ml in group I, respectively($p<0.05$).Gastric tube insertion time was 22.95+/-5.02 seconds in group S whereas 34.42+/-10.10 seconds in group I. Other parameters were comparable.

CONCLUSION: Both LMA-Supreme and I-Gel are safe and effective ventilatory devices in patients undergoing gynaecological laparoscopic surgery in Trendelenburg position with controlled ventilation; but LMA –Supreme is easy to insert and provide better airway seal pressure than I-Gel.

INTRODUCTION:

The success of Classic Laryngeal Mask Airway (LMA) since its introduction by Dr.Archie Brain in 1981 in resuscitation and anaesthesia has led to introduction of several supraglottic airway devices (SADs).Their wide spread use has revolutionized airway management scenario in modern anaesthetic practice. As the era of minimally invasive day care laparoscopic surgeries advances, it poses new challenges for safety and efficacy of supraglottic airway devices. Laparoscopic surgeries demand controlled ventilation with an airway device, which provides adequate oropharyngeal leak pressure to prevent aspiration and can provide effective ventilation in presence of altered pulmonary mechanics due to creation of pneumoperitoneum and Trendelenburg position.[1] Second generation supraglottic airway devices(I-Gel ,LMA-Supreme)have been designed with integrated gastric channel to protect again aspiration risk and are increasingly being used in laparoscopic surgery. (NAP4 recommends its use as a standard of care[2]).LMA-Supreme (LARYNGEALMASK COMPANY,UK,APRIL2007, Latex free material) is elliptical, anatomically curved airway tube having inflatable cuff with reinforced tip, epiglottic fins,integral bite block and gastric access permitting larger size gastric tube.I-Gel(INTERSURGICAL LIMITED, WOKINGHAM, UK , JANUARY 2007, material: thermoplastic elastomer) is an anatomically designed airway device having pre-shaped cuff ,integral gastric channel, epiglottic blocking ridge, buccal cavity stabilizer and moulding features. Many studies have proved safety of second generation SADs in laparoscopic surgery against gold standard technique [3],[4],[5],[6].Choice of any supraglottic device primarily depends on its safety profile. Safety and efficacy of SADs are better justified by clinical indicator of airway seal such as oropharyngeal leak pressure (OLP)[7],[8]. So, we compared the inflatable cuff of LMA-Supreme against pre-shaped I-Gel cuff with primary aim being oropharyngeal leak pressure and secondary aims like insertion characteristics and airway morbidity. It might provide an opportunity (though not the necessity) for supraglottic airway devices to take an ever larger role in modern airway management and might add to their safety profile.

MATERIALS AND METHOD:

After the approval of Scientific Research and Ethical Review Committee a total of 93 adult female patients undergoing elective gynaecological laparoscopic surgery of less than two hours duration were randomly selected from our institute, Shri Sayajirao General Hospital, Vadodara to compare the clinical performance of I-Gel versus LMA-Supreme.Three cases were withdrawn from our study when they were switched over to endotracheal intubation for airway management.Out of this two cases were withdrawn because of breakage of LMA-Supreme(at junction of bite block and fixation tab) during insertion only. Similar complication was also reported by B.Simon et al[9]. Third was withdrawn because of excessive leak with I-Gel despite being selected as per recommendation. It may be argued that the non-inflatable pre-shaped cuff and gel-like material of the I-Gel theoretically renders it more susceptible to airway leaks if the wrong size is chosen and the anatomical fit is not correct. It was a prospective, randomized; single blind interventional clinical study carried out from January 2014 to December 2014.Randomization was done by computer generated random number sequence. Patients were allocated into two groups(Group S/Group I) as per randomization sequence kept in opaque envelope. Sample size was calculated using the parameter "Mean difference between expired and inspired tidal volume(airway seal leak)" from the reference study.[10] It was 21.5+/-15.2ml(mean+/-SD), 31.2+/-23.5ml (mean+/-SD) for LMA-Supreme and I-Gel respectively. Effect size: 9.7,Standardized effect size :0.63,according to table 6A (Ref: Designing in clinical research,3rd edition, by Dr. Stephen B Hulley and co-authors) sample size calculated using t-test to compare means of continuous variable with two sided confidence interval (alpha error of 0.05): 95%, power of the study (beta error of 0.02) : 80%. So minimum sample size was 45 patients per group.Total 93 patients were recruited for the study.

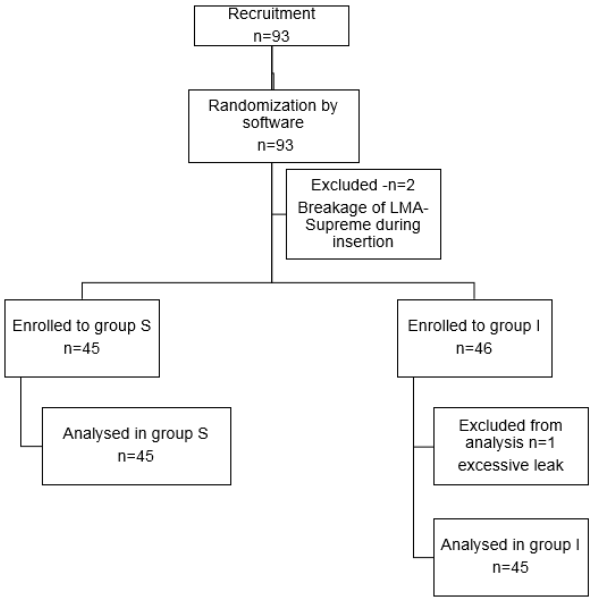

Figure 1:Consort chart

Patients included in the study were adult female patients of 20-50 years, weighing 40-70kg with Mallampati grading (MPG) I/II, ASA: I/II, undergoing elective gynaecological laparoscopic surgery, duration of surgery less than two hours and patients who are able to give written and informed consent. Patients excluded from the study were patients with difficult airway (MPG III/IV), gastroesophageal reflux, cervical spine and known respiratory diseases, preoperative sore throat, pregnancy, morbid obesity and unwillingness to participate in the study. After preanaesthetic evaluation; Injection Glycopyrrolate 0.2 mg, Injection Ondensetron 4 mg, Injection Fentanyl 1mcg/kg injected intravenously as a premedication in fasted patients 15 minutes prior to induction. After pre use check of study device, back and side of the cuff was lubricated. After preoxygenation for three minutes with 100% oxygen using closed circuit and face-mask ventilation, all patients were induced with intravenous injections of Propofol 2- 2.5mg/kg and Vecuronium bromide 0.1mg/kg of loading dose. After assessing adequate jaw relaxation; study device of appropriate size(LMA-Supreme:#3=30-50kg;#4=50-70kg;I-Gel:#3=30-60kg;#4=50-90kg) was inserted as per group selected. (Group I/Group S). Cuff was inflated with air to achieve adequate ventilation in Group-S. Both the device were fixed after proper placement which was confirmed by square wave capnography, bilateral equal chest movements and air entry on auscultation, bite block lying between the teeth, Suprasternal notch test[10](A gel plug is to be placed on proximal 1 cm of gastric drain outlet and gently tapping on suprasternal notch causes the gel to pulsate. This confirms the tip's position behind the cricoid cartilage), passage of orogastric tube easily through drain tube, absence of gastric insufflations by auscultation over epigastrium and audible leak on gentle IPPV. Oropharyngeal leak pressure measured after five minutes of establishing airway after closing expiratory valve of breathing system at a fixed fresh gas flow of oxygen at three litres per minute without nitrous oxide and noting the airway pressure when there was audible air leak from the throat/by auscultation over thyroid cartilage. The maximum pressure allowed was 40 cm of H_2O.The epigastrium was also auscultated when measuring leak pressure to detect any air entrapment in stomach[11].Gastric tube of appropriate size (12, 14 French in Group-I and S respectively) was passed through the gastric channel after lubrication with jelly. (All airway insertions were supervised by senior anaesthetist and performed by anaesthesia trainee experienced with at least 10 LMA-Supreme and I-Gel insertion before the commencement of the study).

Patients were maintained with oxygen and nitrous oxide (50 : 50), Injection Vecuronium bromide 0.025 mg/kg intravenously, sevoflurane (adjusted to maintain adequate depth of anaesthesia and hemodynamic as per discretion of attending anaesthetist) and volume controlled positive pressure ventilation (closed circuit, Dragger Fabius Plus) with tidal volume of 8-10 ml/kg , respiratory rate of 10-16 /minutes, fresh gas flow at the rate of three litters per minute so as to maintain oxygen saturation >95% and end tidal carbon dioxide between 35-45 mmHg.Parameters studied were; *effective airway insertion time (*Time taken from device first entering the mouth to the appearance of first square capnography wave), *ease and number Of attempts for insertion of device, gastric tube insertion time (* Time taken from the gastric tube's first entering the gastric drainage channel to 64 centimetre depth of insertion),*respiratory parameters like* oropharyngeal leak pressure(OLP), airway pressure just before creation of pneumoperitoneum and 30 minutes after creation of pneumoperitoneum, inspired tidal volume, expired tidal volume and difference between inspired and expired tidal volume at 30min after creation of pneumoperitoneum[10]. Pneumoperitoneum pressure was kept between 12-14 mm of Hg.Perioperatively heart rate, blood pressure, oxygen saturation and end tidal carbon dioxide values were observed.

Due care was taken during pneumoperitoneum. At the end of surgery, standard criteria were followed for reversal of neuromuscular blockade with Neostigmine 50 mcg/kg and Glycopyrrolate 10 mcg/kg intravenously and for removal of device. Patients were monitored for intra-operative complications like desaturation (oxygen saturation <95%), audible air leak (set tidal volume is not delivered, air leak heard at mouth, airway pressure > 40cm of H_2O, oropharyngeal leak pressure <20 cm of H_2O) regurgitation/ aspiration (desaturation with audible air leak/fall in end tidal carbon dioxide value/fluid in the tube with pH<2.5), arrhythmias and bronchospasm/ laryngospasm. Complications like blood staining of device, any tongue or lip injury, nausea/ vomiting, cough/sore throat (constant pain or discomfort in the throat independent of swallowing) were observed for 24 hrs postoperatively.

RESULTS:

Data presented in mean ±SD form. Analysis of variance (ANOVA) of the data for the various parameters was done using student's paired t- test for intra-group comparison, unpaired t-test for intergroup comparison for quantitative data and chi-square test for qualitative data. The test for significance was done using Medcalc statistical software. The significance of ANOVA was judged as follows-

p> 0.05 not significant, < 0.05 significant,< 0.01 highly significant.

Both the groups; Group I and Group S were comparable to each other with respect to age, weight, height, ASA grade, type and duration of surgery. In our study 41(91%) I-Gel and 44(97%) LMA-Supreme was successfully inserted on first attempt as per subjective scale used for ease of insertion of airway device. 37(80%) I-Gel and 44(97%) LMA-Supreme scored **grade 1 (easy to insert)** whereas 7(17%) I-Gel and 1(3%) LMA-Supreme insertion was **not so easy (grade 2)** and one I-Gel (3%) was **difficult** to insert **(grade 3).** In **grade 2** out of 7 cases of I-Gel; 3 cases required removal and reinsertion with little increase in depth, whereas 3 cases required jaw thrust manoeuvre and in one case it only required adjustment in head and neck position. Thus, according to our study result LMA-Supreme was easier to insert and had a shorter effective airway insertion time than the I-Gel [12],[13],[14],[15].

Though Oropharyngeal leak pressure was significantly higher with LMA-Supreme,OLP for both devices were higher than maximum peak airway pressure achieved after pneumoperitoneum. Mean inspiratory tidal volume, mean

expiratory tidal volume and ventilator rate were comparable between both the groups. Difference between inspired and expired tidal volume(air leak) was 6 ml more in Group I,which was statistically significant. Intraoperative hemodynamics were stable and comparable between both the groups throughout the study. Postoperatively, we observed 5 cases(11%) of transient sore throat in form of irritation in group S and 3 cases (6%) in group I which were not troublesome, persisted for two hours and did not require any treatment.No any other airway related complication including aspiration were noted.

Table 1-Demographic Data:

	GROUP I	GROUP S	P VALUE
Age(Years)	27.17+/-4.21	26.66+/-3.64	0.540
Height(Cm)	150.48+/-1.82	150.64+/-1.96	0.689
Weight(Kg)	52.93+/-6.22	53.44+/-6.82	0.711
Duration Of Surgery(Minutes)	65+/-14.02	67.22+/-13.03	0.438
ASA(I:II)	39:06	37:08	
Type of surgery: Diagnostic Hysterolaparoscopy/ Laparoscopic Cystectomy/ Laparoscopic Myomectomy/ Laparoscopic Salpingectomy	38 (84%)/ 06 (13%)/ 01 (3%)/00	37 (82%)/ 05 (11%)/ 01 (3%)/ 02(4%)	

Table 2-Insertion and Respiratory characteristics:

PARAMETERS	GROUP I	GROUP S	P VALUE
Effective Airway Insertion Time(Seconds)	18.86+/-3.30	17.13+/-3.15	0.0127
Ease Of Insertion Of Device: Easy/Not So Easy/Difficult	37(82%)/8(17%)/1(2%)	44(97%)/1(3%)/0	0.02/0.02/0.5
Number Of Attempts Of Insertion Of Device : 1st/2nd/3rd	41(91%)/4(8%)/0	44(97%)/1(3%)/0	0.23/0.30
Gastric Tube Insertion Time(Seconds)	34.42+/-10.10	22.95+/-5.02	<0.0001
Ease Of Gastric Tube Insertion Grade 1/Grade 2/Grade 3	40(88%)/05(12%)/00	44(97%)/01(3%)/0	0.1/0.1
Number Of Attempts Of Gastric Tube Insertion $1^{st}/2^{nd}/3^{rd}$	44(97%)/01(3%)/00	45(100%)/00/00	0.2/0.5
Oropharyngeal leak pressure(cm of H2O)	26.22+/-1.86	27.04+/-1.29	0.0171
Mean airway pressure(cm of H2O) Before pneumoperitoneum	13.95+/-1.87	14.57+/-2.21	0.154
Mean airway pressure(cm of H2O) After pneumoperitoneum	22.51+/-2.02	23.17+/-2.11	0.133
Mean Inspired Tidal Volume(Ml)	504.66+/-44.75	514+/-52.54	0.366
Mean Expired Tidal Volume(Ml)	483.17+/-43.2	498+/-53.34	0.150
Mean Ventilator Rate(/Min)	12.08+/-0.41	12.04+/-0.29	0.594
Mean Difference Between Inspired And Expired Tidal Volume(Ml)	21.48+/-8.45	15.68+/-6.61	0.0005
Intra-group p value	<0.01	<0.01	-

#Refer to Foot note

DISCUSSION:

The primary finding of the study were that supraglottic airway devices with both inflatable and pre-shaped cuff were equally effective in providing positive pressure ventilation in adult patients undergoing gynaecologic laparoscopic surgery, but airway seal is slightly better with LMA-Supreme(inflatable cuff).Though preliminary studies have demonstrated adequate seal of both I-Gel[17],[18],[22],[23,24],[25],[26] as well as LMA-Supreme[17],[18],[19],[20],[21],OLP and Leak fraction are important indicator of adequate seal and gas leakage with SGD[27].

Oropharyngeal leak pressure for any SGDs indicates feasibility of positive pressure ventilation, likelihood of successful SGD placement and airway protection from aspiration.It is also an important clinical indicator to compare efficacy and safety of different SGD especially in presence of high airway pressure like laparoscopic surgery, obesity etc . Oropharyngeal leak pressure(OLP) depends on several factors like use of muscle relaxation, type of controlled ventilation, method of assessment etc[7].We used muscle relaxant with controlled ventilation which allows lower airway pressure and better patient-machine synchrony while avoiding displacement of SGD because of tone of oropharyngeal muscle.In our study also mean airway pressure even after pneumoperitoneum remained below OLP in both groups minimizing the chances of aspiration.[6],[16],[10],[19] We measured oropharyngeal leak pressure using audible noise method/auscultation method[11].There was no air leak into the stomach or gastric insufflations in any of our patients at the leak pressure. In our study mean oropharyngeal leak pressure was higher with LMA-supreme (27.04+/-1.29 cm of H2O) as compared to I-Gel (26.22+/-1.86 cm of H2O);which was statistically significant.Higher seal pressure of LMA-Supreme may be due to deep bowl and larger surface area.[18] On the other hand, the I-Gel has soft gel like pre-shaped cuff made up of thermoplastic elastomer, which fits snugly onto the pharyngeal and perilaryngeal framework resulting in lesser pharyngo- laryngeal morbidity because of lesser neurovascular compression trauma[22].Almost similar OLP of LMA-Supreme was reported by several studies in adults[6],[10],[12],[16],[29],[30],[31] with highest being 36.1 cm of H2O reported by Sean et al[32] .The average OLP of I-GEL reported by other authors is also consistent with our results.[17],[26],[29]. In contrast, W. H. Teoh et al[10] and Suhitharan et al[6] showed higher OLP of LMA-Supreme than I-Gel but difference was statistically insignificant. Though OLP of I-Gel was lower; it was adequate to provide safe and effective ventilation. It may be supported by the fact that I-Gel is made up of thermoplastic elastomer which gradually adapts to the body temperature and so its seal may improve over time [26]. In contrast to our study;Thieler et al reported better seal of I-Gel than LMA-Supreme[15] .We found a statistically significant difference between expired and inspired tidal volume with I-Gel compared to LMA-supreme with air leak being 6ml more in group I as compared to group S.[10] Despite of statistically significant greater air leak with I-Gel, its performance was not affected clinically as we found comparable oxygenation, ventilation and delivery of anaesthetic gases throughout surgery without any difficulty. Apart from safety and efficacy,clinical performance of SGDs also depends on ease of insertion and pharyngo-laryngeal morbidity.High first attempt success rate and ease of insertion underlines potential of SGDs as rescue device in case of unanticipated

difficult airway. In our study, LMA –Supreme have statistically significant shorter insertion time and easy insertion, while first attempt success rate was statistically insignificant between both devices.

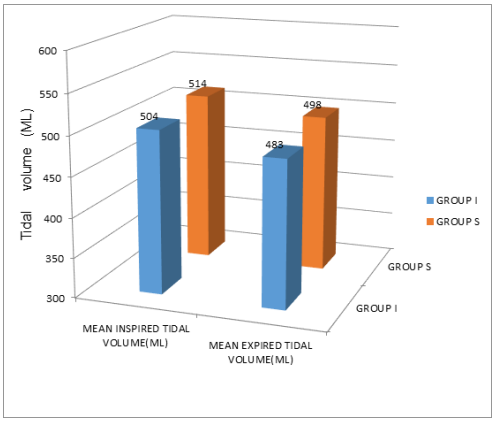

Figure 2: Difference of inspired and expired tidal volume

As argued by Raggazi et al and Theiler et al, reason for better performance of the LMA-Supreme might be that the bulky design of the I-Gel makes its insertion less predictable and tongue size more influential requiring additional manoeuvres. Timmerman et al [14] suggested that LMA-Supreme offers greater rigidity as compared with the Proseal LMA. Therefore, it is easier to insert without placing the index finger in the patient's mouth and repositioning is possible without the need for complete reinsertion. We also agree with their argument that anatomically curved shaft of LMA-Supreme similar to the LMA Fastrach is responsible for short insertion time. Gastric tube insertion was faster with LMA-Supreme as compared to I-Gel,which was highly significant in our study. Smaller aperture of the gastric access port of I-Gel offers little resistance to insert the gastric tube and smaller size gastric tube was required in I-Gel compared to LMA-Supreme[6],[10],[30]. Shorter gastric tube insertion time favors the use of device in case of emergency airway management done in view of high aspiration risk.

Our Study has a few limitations:

We did not use manometer to measure oropharyngeal leak pressure which might have obtained more accurate results. Measurement of the leak pressure at the end of surgery was also not done for either of the airway device. It could have perhaps added important information as reports have emerged that the seal of the I-Gel seems to improve over time due to the thermoplastic cuff's warming to body temperature.[28]

Intra-operative cuff pressure monitoring was also not done in our study. However nitrous oxide diffusion is less in LMA with polyvinyl chloride based cuff [28]. We had not done fiberoptic evaluation to assess the anatomical position of the I-Gel and LMA- Supreme in relation to the vocal cords for two reasons. First, we wanted this study to reflect our clinical practice and high surgical turnover. It was deemed not clinically and logistically feasible to perform endoscopy in all cases. Second, there is evidence that the device with suboptimal fiberoptic view can be used atleast as satisfactory ventilatory device in difficult airway,which is important clinically. It is also impossible to blind the airway operator to the device used hence there is a potential for bias. We studied clinical performance of the device in non-obese women with normal airway and in less than two hours duration of surgery so the results cannot directly be extrapolated to other type of patients, long duration surgery and patients with MPG III/IV.

Thus, both airway devices are safe and efficacious to use in laparoscopic surgery with Trendelenberg position, but ease of insertion and oropharyngeal seal are slightly better with LMA-Supreme.

[Foot note: - EASE OF INSERTION OF DEVICE[10]: [Grade 1-easy-No manoeuvre* required, Grade 2-not so easy-One manoeuvre* for correct placement of device with/without reinsertion, Grade 3-difficult-More than one manoeuvre* for correct placement of device with reinsertion (MANOEUVRE*: adjusting head and neck position, gentle modification in depth of insertion, applying jaw/chin lift and changing the size of device.)

INSERTION FAILURE[10] :>3 attempts were considered as insertion failure.]

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