The comparison of ProSeal and I-gel laryngeal mask airways in anesthetized adult patients under controlled ventilation

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ABSTRACT

الأهداف: مقارنة نتائج إدخال الأنبوب المعدي من حيث الوقت، وسهولة ونسبة نجاح الإدخال، وضغط التسرب الهوائي، ومضاعفات العملية بين قناع مجرى الهواء الحنجري برو سيل (ProSeal) وأي جيل (I-gel).

الطريقة: أُجريت هذه الدراسة في قسم الجراحة، مستشفى هايدارباسيا نومون، إسطنبول، تركيا وذلك خلال الفترة من نوفمبر 2013م إلى إبريل 2014م. وقد شملت هذه الدراسة 80 مريضاً ممن تبلغ أعمارهم مابين 6-18 عاماً والذين يخضعون لعملية اختيارية غير طارئة. لقد قمنا بتقسيم المشاركين في الدراسة عشوائياً إلى مجموعتين وهما مجموعة برو سيل ومجموعة أي جيل. وقم قام أخصائي واحد بإدخال أداة مجرى الهواء فوق المزمارية. وقمنا خلالها بتسجيل كلاً من وقت إدخال الأداة، ودرجة الصعوبة أثناء الإدخال، وكذلك صعوبة إدخال الأنبوب المعدي، والتسرب الهوائي، بالإضافة إلى مضاعفات العملية.

النتائج: لقد كان معدل وقت الإدخال في مجموعة أي جيل أقل بصورة واضحة من الناحية الإحصائية من مجموعة برو سيل (أي جيل: 3±8 مقابل برو سيل5±13 دقيقة). وكان معدل نجاح إدخال الأنبوب في مجموعة أي جيل (100% من المحاولة الأولى) أعلى من المعدل الذي أحرزته مجموعة برو سيل (82.5% من المحاولة الأولى). بالإضافة إلى ذلك فقد كان معدل نجاح تثبيت الأنبوب المعدي أعلى في مجموعة أي جيل (92.5% من المحاولة الأولى) منه لدى مجموعة برو سيل (72.5% من المحاولة الأولى). فيما لم يختلف تسرب مجرى الهواء بين المجموعتين.

الخاتمة: أظهرت الدراسة بأن نتائج قناع مجرى الهواء الحنجري أي جيل قد كانت أفضل من نتائج برو سيل وذلك من حيث الوقت، وسهولة الإدخال، ومعدل نجاح إدخال الأنبوب الأنفي المعدي، ولذلك فإنه يمكن اعتبارها كطريقة أفضل لمثل هذه العمليات.

Objectives: To compare the insertion time, ease of device insertion, ease of gastric tube insertion, airway leakage pressure, and complications between the laryngeal mask airway (LMA) ProSeal (P-LMA) and I-gel (I-gel) groups.

Methods: Eighty patients with age range 18-65 years who underwent elective surgery were included in the study. The study took place in the operation rooms of Haydarpaşa Numune Hospital, Istanbul, Turkey from November 2013 to April 2014. Patients were equally randomized into 2 groups; the I-gel group, and the P-LMA group. In both groups, the same specialist inserted the supraglottic airway devices. The insertion time of the devices, difficulty during insertion, difficulty during gastric tube insertion, coverage of airway pressure, and complications were recorded.

Results: The mean insertion time in the I-gel group was significantly lower than that of the P-LMA group (I-gel: 8±3; P-LMA: 13±5 s). The insertion success rate was higher in the I-gel group (100%, first attempt) than in the P-LMA group (82.5%, first attempt). The gastric tube placement success rate was higher in the I-gel group (92.5%, first attempt) than in the P-LMA group (72.5%, first attempt). The airway leakage pressures were similar.

Conclusion: Insertion was easier, insertion time was lower, and nasogastric tube insertion success was higher with the I-gel application, and is, therefore, the preferred LMA.

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Laryngeal mask airways (LMA) represent a good alternative to endotracheal intubation in suitable cases. The LMAs are used to provide ventilation, or to ease the insertion of an endotracheal tube (TT) in difficult airways, but they are also becoming more frequently used to reduce TT associated complications.[1] In particular, the recently developed models of LMAs, which include a gastric tube, have become more commonly preferred in anesthesia applications.[2] The I-gel (I-gel) (Intersurgical Ltd, Workingham, UK) has a latex-free, non-inflatable, gel-like, thermoplastic elastomeric cuff that provides easy coverage by properly fitting the anatomy of the supraglottic region and also involves a gastric tube; therefore, it has become more frequently used in patients under general anesthesia and receiving positive pressure ventilation.[3] It has been reported that the single-use, inflatable cuff-free I-gel can be inserted more easily and has a reduced morbidity rate.[4,5] It is recommended in emergency cases requiring intubation, and particularly in airway management of cases experiencing cardiopulmonary arrest.[6] Another supraglottic airway device that enables gastric aspiration is the LMA ProSeal (Laryngeal Mask Company Ltd, Berkshire, UK). Since it is a semi-rigid device with an inflatable cuff, it has been reported to cause mucosa and nerve damage in the supraglottic region, sore throat, and hoarseness due to the cuff pressure.[7]

The present study aimed to compare the I-gel and the LMA ProSeal (P-LMA) with respect to the duration of insertion, ease of insertion, airway pressure leakage, gastric tube insertion success ratio, and complications.

Methods. This prospective study was initiated after being approved by the Haydarpasa Numune Training and Research Hospital Clinical Trials Ethics Committee. The study was designed according to the principles of the Helsinki Declaration, and all patients were informed and provided written consent. The study took place in the operating rooms (general surgery, urology, and orthopedic) of Haydarpaşa Numune Hospital, Istanbul, Turkey from November 2013 to April 2014.

Eighty adult patients, aged between 18 and 65 years who were American Society of Anesthesiology I-II, and for whom an elective surgery under general anesthesia was planned, were included in the study. The study was carried out by 2 specialists, a planner and an implementer. The patients were randomized by a computer program and divided into 2 groups of 40 patients: I-gel group (n=40), and P-LMA group (n=40). The information that was numerated by the planning specialist was transferred to the implementing specialist in a sealed envelope. For both models, the implementing specialist determined the size of the LMA to be used based on the patient's weight (>50 kg, No. 3; 50-80 kg, No. 4; and 80-100 kg, No. 5). Patients who were planned to undergo a long-lasting operation (3 hours and greater), obese patients (BMI>35), patients with a risk of difficult airways (Mallampati 3 and 4), patients with a history of difficult intubation, patients with lung, or heart failure, complaints of sore throat, and an oral or pharyngeal pathology, and those with a risk of nausea, vomiting, or aspiration were excluded from the study. After vascular access was established, infusion was initiated with 0.9% serum physiological and premedication with midazolam 0.05 mg/kg intramuscular was administered 30 minutes before the induction of anesthesia. The patients were transferred to the operating room and routine monitoring was performed. Following the hemodynamic measurements, pre-oxygenation was carried out using 100% O_2. Anesthesia was induced with IV administration of 5 mg/kg Pentothal, 1 mcg/kg fentanyl, and 0.1 mg/kg vecuronium. After eyelash reflex loss was confirmed, LMAs were placed using a lubricant gel as recommended by the manufacturers.

The LMA placement was initiated after adequate ventilation was confirmed by confirming the CO_2 wavelength by a capnograph, and the duration between initiation of the LMA placement and achieving adequate ventilation was recorded as the duration of insertion. The cuff of P-LMA was inflated until the leakage sound disappeared. The level of airway leakage pressure was identified by increasing peak inspiratory pressures until the leakage sound was heard, and the level was recorded.

An experienced anesthesiologist inserted all LMAs. Ease of insertion was evaluated based on a 5-dimensional scale (easy - 1; somewhat easy - 2; difficult - 3; very difficult - 4; impossible - 5). Cases where adequate ventilation was not achieved with 2 insertions were considered unsuccessful insertions. An alternative airway device was used in those cases (I-gel, P-LMA, or TT). The ease and success of insertion, as well as the complications seen during insertion (blood spread on the LMA cuff, lip, teeth or pharynx trauma, nausea, vomiting, laryngospasm, bronchospasm, cough, hoarseness, or sore throat) were recorded.

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Anesthesia was maintained using desflurane 3% in 4 liter (L) gas flow (50% O_2/N_2O). Remifentanil was administered intravenously at a dose of 0.5 mcg/kg/min. Tidal volume and respiration frequency were set to 8 ml/kg and 12/min. Air leakage to the stomach was monitored with a stethoscope. The end tidal carbon dioxide ($ETCO_2$) was maintained at approximately 35 mm Hg. A tube was inserted for gastric drainage. The stomach was aspirated. The number of insertion attempts and the ratio were recorded. The patient's age, weight, height, gender, and Mallampati score were recorded.

Statistical analysis. Statistical analyses were performed by NCSS (Number Cruncher Statistical System) 2007 & PASS (Power Analysis and Sample Size) 2008 Statistical Software (NCSS, LLC, Kaysville, Utah, USA). The sample size for the total number of the patients of the study was n=80, Power 0.80, β: 0.20 and α: 0.05. Study data were evaluated by descriptive statistical methods (mean, standard deviation) and one-way ANOVA test was used to compare the normally distributed parameters between groups. Student's t-test was used to analyse demographic data. The Tukey honest significant difference (HSD) test was used to detect the group causing the difference. The Kruskal Wallis test was used to compare the parameters that did not fit a normal distribution between the groups and Mann-Whitney U-test, a post hoc analysis was used in which I-gel was compared with the P-LMA group. The significance level was established at $p<0.05$.

Results. Data acquired from all 80 patients participating in the study were evaluated (LMA was successfully inserted in all patients). No statistically significant difference was discovered between the 2 groups with respect to the demographic data, pre-operative assessment criteria, and the type of surgical procedure (**Table 1**).

The duration of insertion was significantly shorter in the I-gel group (8±3 sec) compared with the P-LMA group (13±5 sec) (p=0.015). The success of insertion was higher in the I-gel group compared to the P-LMA group. Ease of insertion assessments demonstrated that the I-gel could be more easily inserted than the P-LMA (p=0.039) (**Table 2**).

The rate of gastric tube insertion was higher in the I-gel group compared with the P-LMA group. Airway leakage pressure was similar between the 2 groups (**Table 2**). The only recorded post-operative complication was sore throat. The rate of sore throat was significantly higher in the P-LMA group than the I-gel group (**Table 2**).

Table 1 - Demographic data, preoperative assessment criteria, and types of surgical interventions among patients included in a study in Turkey.

Variables	I-gel (n=40)	P-LMA (n=40)	*P-value
Age, years (mean ± SD)	42.46 ± 3.21	42.06 ± 3.59	0.2753
Weight, kg (mean ± SD)	72.23 ± 3.85	65.86 ± 3.21	0.1667
Height, cm (mean ± SD)	168.13 ± 2.19	162.33 ± 2.23	0.4613
ASA I-II-III, n	13/18/9	11/21/8	
Gender: Female/male, n	31/9	29/11	
Body mass index, kg/m² (mean ± SD)	24.7 ± 0.92	24.3 ± 0.77	0.1765
Mallampati score, 1/2 (n)	17/23	20/20	
Duration of anesthesia, minutes (mean ± SD)	96.3 ± 3.2	87.9 ± 3.7	0.50
Types of surgical intervention			
Transurethral prostate resection	21	16	
Inguinal hernia repair	7	9	
Arthroscopy	7	8	
Breast surgery	5	6	

*Student t-test, ASA - American Society of Anesthesiology, P-LMA - laryngeal mask airway ProSeal

Table 2 - Insertion data, duration of insertion, and complications with laryngeal mask airways and gastric tube among patients included in a study in Turkey.

Variables	I-gel	P-LMA	*P-value*
	n (%)		
Duration of insertion, seconds (mean ± SD)	8 ± 3	13 ± 5	0.015
Insertion success			0.026
First attempt	40 (100)	33 (82.5)	
Second attempt	0	7 (17.5)	
Ease of insertion			0.039
Easy	34 (85)	29 (72.5)	
Somewhat easy	6 (15)	9 (22.5)	
Difficult	0	2 (5.0)	
Very difficult	0	0	
Impossible	0	0	
Gastric tube insertion			0.034
First attempt	37 (92.5)	29 (72.5)	
Second attempt	3 (7.5)	4 (10.0)	
Unsuccessful	0	7 (17.5)	
Airway leakage pressure	32.4 cm H_2O	35.1 cm H_2O	0.623
Complication rate	3 (7.5)	7 (17.5)	0.001

*Kruskal Wallis test, Mann-Whitney U-test. P-LMA - laryngeal mask airway ProSeal

Discussion. Comprehensive knowledge of the characteristics of alternative airway devices becomes more crucial in achieving airway control in patients at risk of difficult ventilation or intubation. Although it is not very common, it is recommended to keep an alternative airway device in the region where anesthesia is administered in the case of any possible risk of difficult intubation.[8,9] A rather new airway device, the I-gel, was compared in the present study with the P-LMA, which allows gastric drainage. The I-gel was found to be superior to the P-LMA with respect to the duration and ease of insertion, as well as the ease of gastric tube insertion, and the rate of complications. However, no difference was seen between the 2 devices with respect to the airway pressure leakage.

Lee e al[10] compared the duration of insertion of the I-gel with conventional LMA, and discovered that the I-gel can be inserted in a shorter time. They suggested that this finding is related to the flexibility of the I-gel. In a study performed by Tokgöz et al,[11] the duration of insertion of the I-gel was reported to be shorter than the P-LMA. They argued that this difference was due to the time spent to inflate the cuff of the P-LMA. Fernández et al[12] suggested that the shorter duration of insertion is an indicator of the I-gel's suitability to the oropharyngeal anatomy, as well as due to the absence of additional procedures such as cuff inflation. Similarly, the duration of insertion was found to be shorter with I-gel in the present study, and the authors believe that this might be explained by the absence of cuff as well as the gel-like structure of the I-gel.

Schmidbauer et al[13] compared the I-gel and P-LMA in cadaver models and found the ease of insertion to be similar between the 2 devices. In the studies performed by Bamgbade et al[14] with more than 300 patients, and by Gatward et al[4] with 100 patients who did not receive any myorelaxant, the I-gel was concluded to be more easily inserted than the P-LMA. Beylacq et al[15] performed a comparative study in which the insertions were performed by inexperienced individuals, and they found out that the I-gel could be inserted by 100% of the practitioners, while the P-LMA could be inserted by 80%. Studies regarding the ease of insertion report that the I-gel presented better results than the P-LMA,[2,16] while there are also some studies reporting that the 2 methods are similar.[3,17] The present study revealed that the I-gel can be inserted more easily and successfully. Successful insertion was achieved in 100% of cases on the first attempt in the I-gel group, while the rates in the P-LMA group were 82.5% and 17.5% for the first and the second attempts.

Studies regarding the ease of insertion of the gastric drainage tube involve an equal number of studies reporting P-LMA to be superior to the I-gel, and finding the 2 devices to be similar.[17] In a very limited number of studies, insertion with the I-gel was found to be easier than with the P-LMA.[6] Among the researchers comparing the gastric tube insertion and drainage, Beylacq et al[15] reported that both procedures are performed more easily with the I-gel than with the P-LMA. In the present study, the rates of insertion on the first attempt were 92.5% for the I-gel, and 72.5% for the P-LMA. While the I-gel was 100% successful on the second attempt, this rate was 82.5% for the P-LMA.

Bordes et al[7] suggested that high leakage pressure and low peak inspiratory pressure should be targeted to achieve safe ventilation with a laryngeal mask and in their study, they found P-LMA to be more advantageous than both the conventional LMA and the I-gel with respect to high leakage pressure and low inspiratory pressure. Schmidbauer et al[13] reported in their study performed on cadavers that the P-LMA can resist the esophageal pressure better than the I-gel can; however, it applies more pressure on the anatomical structures, as it has a cuff and impairs physiological functions. Beylacq et al[15] concluded that the I-gel and P-LMA are similar to each other, but superior than the conventional LMA in terms of leakage pressure and peak pressure. Similarly, no significant difference was observed between the 2 devices in terms of airway leakage pressure in the present study.

Researchers comparing the complications associated with the use of the I-gel and the LMA underline that the problems such as blood on device (trauma), sore throat, cough, postoperative hypoxia, and nerve damage are more commonly encountered by the LMA.[18,19] In the present study, we noted only sore throat as a postoperative complication, the rate of which was significantly higher with the P-LMA.

In the present study, we concluded that a rather new supraglottic airway device, the I-gel, is a good alternative to the P-LMA since it can be inserted faster and easier, it allows easier insertion of the nasogastric catheter, and results in fewer complications.

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