SCIENTIFIC ARTICLE

Comparison of the i-gel™ and the Laryngeal Mask Airway Classic™ in terms of clinical performance

Reyhan Polat *, Gözde Bumin Aydin, Jülide Ergil, Murat Sayin, Tuğba Kokulu, İbrahim Öztürk

Department of Anesthesiology, Diskapi Yildirim Beyazit Research and Training Hospital Diskapi, Ankara, Turkey

Abstract
Purpose: The i-gel™ is one of the second generation supraglottic airway devices. Our study was designed to compare the i-gel and the Laryngeal Mask Airway Classic™ with respect to the clinical performance.
Methods: We compared the performance of the i-gel with that of the Laryngeal Mask Airway Classic in 120 patients undergoing urologic surgery during general anesthesia without muscle relaxant with respect to the number of attempts for successful insertion, insertion time, peak airway pressure, incidence of regurgitation, fiberoptic glottic view and postoperative complications. Second generation supraglottic airway devices were inserted by the same anesthesiologist, experienced in use of both devices (>200 uses and first time failure rate <5%). Methylene blue method was used to detect gastric regurgitation.
Results: There was no statistical difference between the two groups regarding the success of insertion of second generation supraglottic airway device ($p = 0.951$). The laryngeal mask insertion time for the i-gel group was significantly shorter than that for the Laryngeal Mask Airway Classic group (11.6 ± 2.4 s versus 13.1 ± 1.8 s [$p = 0.001$]). The fiberoptic glottic view scores for the i-gel group was significantly better than that for the ones for the Laryngeal Mask Airway Classic group ($p = 0.001$). On fiberoptic view, there was no sign of methylene blue dye at any time point in either group. In addition, there was no difference between the groups in patient response regarding the presence of a sore throat when questioned 24 h after the procedure ($p = 0.752$).
Conclusion: Both devices had good performance with low postoperative complications and without occurrence of regurgitation. The i-gel provided a shorter insertion time and a better fiberoptic view than the Laryngeal Mask Airway Classic.
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* Corresponding author.
   E-mail: reyhanp9@gmail.com (R. Polat).

Comparação da máscara laríngea i-gel (i-gel™) com a máscara laríngea clássica (LMA-Classic™) em relação ao desempenho clínico

Resumo

Justificativa e objetivo: A i-gel é um dos dispositivos supraglóticos de segunda geração para o manejo das vias aéreas. Nosso estudo foi projetado para comparar a i-gel™ e a máscara laríngea clássica (Laryngeal Mask Airway Classic™, LMA-C) em relação ao desempenho clínico.

Métodos: Avaliamos os desempenhos de i-gel e LMA-C em 120 pacientes submetidos à cirurgia urológica sob anestesia geral sem relaxante muscular. Comparamos o número de tentativas de inserção bem-sucedidas, o tempo de inserção, a pressão de pico das vias aéreas, a incidência de regurgitação, a visibilidade da glote com o uso de fibra óptica e as complicações no pós-operatório. Os dispositivos supraglóticos de segunda geração foram inseridos pelo mesmo anestesiologista com experiência na aplicação de ambos os dispositivos (> 200 aplicações e taxa de falha na primeira tentativa < 5%). O corante azul de metileno foi usado para detectar regurgitação gástrica.

Resultados: Não houve diferença estatística entre os dois grupos em relação ao sucesso da inserção do dispositivo supraglótico de segunda geração (p = 0,951). O tempo de inserção da máscara laríngea no grupo i-gel foi significativamente menor do que no grupo LMA-C (11,6 ± 2,4 segundos *vs.* 13,1 ± 1,8 segundos, p = 0,001). O escore de visibilidade da glote via fibra óptica do grupo i-gel foi significativamente melhor do que o do grupo LMA-C (p = 0,001). Na visão via fibra ótica, sinais do corante azul de metileno não foram observados em qualquer momento em ambos os grupos. Além disso, não houve diferença entre as respostas dos grupos quando perguntados sobre a presença de dor de garganta 24 horas após o procedimento (p = 0,752).

Conclusão: Ambos os dispositivos apresentaram bom desempenho, com poucas complicações no pós-operatório e sem ocorrência de regurgitação. A máscara laríngea i-gel proporcionou um tempo de inserção mais curto e uma visão via fibra óptica melhor do que a LMA-C.

Introduction

Introduction of Laryngeal Mask Airway (LMA Classic™; [LMA-C] Intavent Orthofix, UK), has changed the practice of maintaining safe airway.[1] Since then, supraglottic airway devices (SGADs) have been used successfully and safely in anesthetic practice with various models, and have undergone rapid development.[2,3] Almost all SGADs, including the LMA-C, use an inflatable cuff to wedge into the upper esophagus and provide a perilaryngeal seal.[4] Accurate positioning and adequate pressure and volume within the cuff are fundamental to achieve optimal function, and to reduce the complications. A limiting factor for the use of SGAD is the lack of airway protection from gastric contents.[5,6] Several SGADs are now marketed that are specifically designed to reduce the risk of aspiration. The i-gel™ (Intersurgical Ltd., UK) is one of the second generation SGADs produced for this purpose. The cuff of the i-gel is constructed from medical-grade thermoplastic elastomer (styrene ethylene butadiene styrene) which does not require inflating the cuff or adjusting intra-cuff pressure. Its design enables a mirrored impression of the pharyngeal and laryngeal structures and provides a perilaryngeal seal without cuff inflation. The potential advantages of the i-gel are easy and rapid insertion and a reduction in the risk of pharyngeal tissue compression due to high cuff pressure. Moreover, it has an inbuilt drainage channel, which allows the insertion of a gastric tube (maximum 14F gauge), to facilitate the eflux of gastric fluid and gas.

This study compares the clinical performance of the i-gel with the LMA-C in terms of insertion time, the number of attempts for successful insertion, peak airway pressure, fiberoptic glottic view, incidence of regurgitation, and post-operative complications which have never been compared in a randomized-prospective study in adults in vivo before.

Methods

This study was conducted between June and September 2013 at Diskapi Yildirim Beyazit Research and Training Hospital. The study (ref: 06/27, date: 12/17/2012) was approved by a local research ethics committee. A total of 120 patients, who underwent urologic surgery in lithotomy position under general anesthesia with ASA physical status I–III (aged 18–70 years, weight 50–90 kg), were assessed and written informed consent was taken from all patients enrolled in the study. Patients with a history of gastroesophageal reflux, hiatal hernia, previous gastric surgery or body mass index (BMI) >35 kg/m^2, and those who take medications for disorders of gastrointestinal motility were excluded from the study. The patients were randomized into two groups (group LMA-C, n = 60, or group i-gel, n = 60) by a computer-generated random number table. The insertion of SGADs was conducted by the same anesthesiologist experienced in the

use of both devices (>200 uses and first time failure rate <5%).

All patients' demographic parameters (gender, age, weight, height and body mass index), and the duration of surgery were recorded. Patients were premedicated with 0.04 mg/kg midazolam iv approximately 30 min before induction of anesthesia. A gelatin capsule containing methylene blue powder (25 mg in lactose and 30 mL of water) was ingested orally in sitting position by the patients 10 min before induction of anesthesia. The gelatin capsule dissolves in water or acidic pH 1–5 solution within 5 min and turns the gastric contents blue.[7,8] Patient heart rate (HR) by a three-channel ECG, noninvasive blood pressure, bispectral index (BIS) (A-200 BIS monitoring system; Aspect Medical systems, BIS XP; Framingham, MA, USA), and pulse oximetry were monitored. Anesthetic management was standardized according to the following protocol. Patients were pre-oxygenated for 2 min, and anesthesia was induced with propofol (2–2.5 mg/kg) and fentanyl (1.5–2 μg/kg). In order to provide consistent conditions, insertion of the SGAD was made when the BIS was below 60. BIS values were kept stable by inhalational anesthesia throughout the study period. Each device was lubricated with a water-based agent and inserted according to the manufacturer's recommendations. Size selection of the i-gel or LMA-C depended on patient's weight in accordance with the guidelines. The LMA-C cuffs were inflated until the air leak sound coming from the mouth ceased (≤45 cm³ air). In order to maintain adequate cuff pressure for LMA-C, cuff pressure was maintained in by using a handheld pressure gauge (VBM Medizintechnik GmbH, Sulz a.N., Germany).

Anesthesia was maintained with 1.5–2% sevoflurane in 50% oxygen–air mixture without using any neuromuscular blockers, and remifentanil infusion was started at a dose of 0.2–0.3 μg/kg/min. Manual bag ventilation was maintained in all patients through a circle system until insertion of SGAD and validation of placement.

In order to insert the SGAD, a maximum of three attempts was made for each group. If it was not possible to ventilate the lungs, the following adjustments were allowed: neck extension or flexion, chin lift, jaw thrust and gentle pushing or pulling of the device. When insertion of both SGAD models failed, the subject was excluded from the study and the airway was maintained by an endotracheal tube. Correct insertion was assessed by proper chest expansion, the presence of a curved CO_2 wave on the capnography, the absence of audible leak, and lack of gastric insufflation. The presence of gastric insufflation was determined by epigastric auscultation. In both groups, insertion success of the SGAD (the number of airway manipulations), time required to establish the airway (the total time from grasping of the device to observing a square wave capnograph trace) and complications such as laryngospasm, apnea, or hiccups were recorded. After obtaining an effective airway, the device was connected to a circle breathing system (Primus, Drager, Lubek, Germany). The lungs were ventilated with a tidal volume of 7 mL kg^{-1}, a respiratory rate of 12 breaths per minute, and *I:E* ratio of 1:2 and peak airway pressure of approximately 12–20 cm H_2O in volume controlled mode. Peak airway pressure values were recorded. After ensuring satisfactory ventilation, the anatomical position of LMA-C and i-gel was assessed using a fiberoptic endoscope (2.8 mm; Olympus, Tokyo, Japan) via the airway tube of the device. The fiberscope was always kept straight (anatomical position) to maintain control over the tip. The tip of the fiberscope was positioned just above the bars of the LMA-C or i-gel. The view via the airway channels was scored as follows: Grade 4, only vocal cords are viewed; Grade 3, vocal cords and posterior epiglottis are viewed; Grade 2, vocal cords and anterior epiglottis are viewed; Grade 1, cords are not viewed but functioning adequately.[9,10]

To prevent false-positive regurgitation, the oropharyngeal cavity was inspected for blue dye. After insertion of SGAD, the presence or absence of blue dye in the bowl was assessed using a fiberscope. Additionally, before SGAD was removed, fiberscopy was repeated again to find out traces of methylene blue in all the patients at the end of the surgeries. After removal of SGAD, the devices used for fiberscopy were inspected visually for trace of blue staining and blood by one of the investigators and the results of these inspections were recorded.

Once surgery was completed, sevoflurane and remifentanil were discontinued. When the patient was able to open his or her mouth following our command, the airway device was removed after pharyngeal suctioning and lifting of the jaw. Then, the patient was given 100% oxygen via facemask for 10 min.

The patients were interviewed in the post-anesthetic care unit by nurses who were blind to study, with respect to the presence of sore throat and dysphagia. When modified Aldrete scores were 10 and above, the patients were transferred to their rooms. Twenty-four hours after surgery, the patients were asked one more time if they had sore throat and dysphagia.

Statistical analysis

The sample size of 55 per group was determined by power analysis; due to the preliminary study results of decrease in insertion time measurements, when delta was assumed to be 1.25 and SD as 2.0, with 90% power and α: 0.05, the sample size (*n*) was calculated to be minimum 55 for each group. Considering a 10% drop-out rate, the number of subjects was calculated to be 60 in each group.

All statistical analyses were performed by using SPSS 15.0 software package (SPSS Inc., Chicago, IL, USA). *T* test for independent samples was used to compare two groups for data with normal distribution and Mann–Whitney *U* test was used for comparing data with non-normal distribution. Yates continuity correction test, Fisher's exact test and Fisher–Freeman–Halton test were used for comparison of qualitative data.

All data were summarized as mean ± SD for continuous variables, numbers and percentages for categorical variables. A $p < 0.05$ was accepted as statistically significant.

Results

Both groups were comparable with respect to age, male-to-female ratio, height, weight, and body mass index. The duration of operations was 48 ± 16.1 min and 47.5 ± 23.5 min for i-gel group and the LMA-C group, respectively ($p = 0.753$) (Table 1).
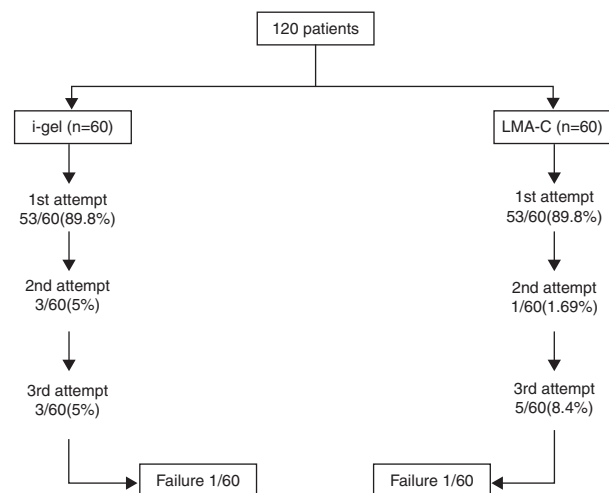
Table 1 Baseline characteristics of patients who underwent anesthesia with the i-gel or Laryngeal Mask Airway Classic (LMA-C). Data are expressed as mean $\pm$ SD.

	i-gel ($n = 59$)	LMA-C ($n = 59$)	p
Age (years)	48 $\pm$ 15	50 $\pm$ 17	0.619
Weight (kg)	77.9 $\pm$ 10.5	75.9 $\pm$ 14.1	0.384
Height (cm)	169.1 $\pm$ 9.9	168. 4 $\pm$ 8.1	0.656
Body mass index (kg/m^2)	27.3 $\pm$ 3.5	26.7 $\pm$ 4.4	0.436
Duration of surgery (min)	48.6 $\pm$ 16.1	47. 5 $\pm$ 23.5	0.753

Table 2 Comparative data for the i-gel and Laryngeal Mask Airway Classic (LMA-C). Data are expressed as number (proportion) or mean $\pm$ SD.

	i-gel ($n = 59$)	LMA-C ($n = 59$)	p
Insertion time (s)	11.6 $\pm$ 2.4	13.1 $\pm$ 1.8	0.001
Peak airway pressure (cm H$_2$O)	12.4 $\pm$ 2.2	12.6 $\pm$ 2.4	0.753
Glottic view[a]			0.001
4	19 (32.2%)	1 (1.7%)	
3	16 (27.1%)	10 (16.9%)	
2	14 (23.7%)	19 (32.2%)	
1	10 (16.9%)	29 (49.2%)	

[a] The glottic view via fiberoptic examination was scored using the following: score 4, clear view of the vocal cords; score 3, only arytenoid visible; score 2, only epiglottis visible; score 1, larynx not visible.

Figure 1 Flow chart of the study, showing the subdivision into groups corresponding to each supraglottic airway device.

In the i-gel group, the SGAD was successfully inserted in 53 patients (89.8%) at the first attempt, in three patients (5.0%) at the second attempt, and in three patients (5.0%) at the third attempt. In the LMA-C group, the SGAD was successfully inserted in 53 patients (89.8%) at the first attempt, in one patient (1.69%) at the second attempt, and in five patients (8.4%) at the third attempt. There were two patients in whom neither the i-gel nor the LMA-C could be inserted. There was no statistical difference between two groups regarding to success of insertion of SGAD ($p = 0.951$) (Fig. 1).

Duration of laryngeal mask insertion time in the i-gel group was significantly shorter than that in group LMA-C.

The mean laryngeal mask insertion times were 11.6 $\pm$ 2.4 s in i-gel and 13.1 $\pm$ 1.8 s in LMA-C group ($p = 0.001$). Three patients in group LMA-C (5.0%) and five patients in group i-gel (8.4%) suffered from hiccups, which was the only complication ($p = 0.717$). No laryngospasm and apnea were observed in any of the patients.

Peak airway pressure values measured by the ventilator were remarkably close for the two groups. The mean peak airway pressures were 12.4 $\pm$ 2.2 cm H$_2$O and 12.6 $\pm$ 2.4 cm H$_2$O in i-gel group and LMA-C group, respectively ($p = 0.753$). The fiberoptic view scores for the i-gel group were significantly better than that for the LMA-C group ($p = 0.001$) (Table 2).

There were no signs of methylene blue dye in fiberoptic view at beginning, after insertion of devices, and just before removal of devices in both groups. Bluish discoloration was not seen after removal of any of the devices.

Blood staining was encountered rarely after removal of the devices in both groups; however, it was comparable between the groups (5 in group i-gel [8.5%] and 3 in group LMA-C [5.1%]) ($p = 0.717$). Postoperative interview revealed a notable incidence of sore throat in both groups. Ten patients of group i-gel (16.9%) and five patients of group LMA-C (8.5%) reported sore throat at the postanesthesia care unit ($p = 0.169$). Also, there was no difference between the groups regarding sore throat at 24 h questioning ($p = 0.752$) (Table 3).

Discussion

Our results demonstrate that i-gel has a similar performance in terms of insertion success, peak airway pressure, the number of manipulations required for adequate positioning, and

Table 3 Side effects observed in study groups.

	i-gel ($n = 59$)	LMA-C ($n = 59$)	p
Signs of regurgitation	0	0	
Blood staining	5 (8.5%)	3 (5.1%)	0.717
Sore throat in PACU	10 (16.9%)	5 (8.5%)	0.169
Sore throat after 24 h	1 (1.7%)	1 (1.7%)	0.752
Hiccups	5 (8.5%)	3 (5.0%)	0.717

LMA-C, Laryngeal Mask Airway Classic.

the number of gastric regurgitation compared with the LMA-C. However, i-gel has advantages over the LMA-C in terms of shorter insertion times and improved fiberoptic views of the glottis.

Our study showed high success rates of insertion with both devices, which is in agreement with data existing in the literature. In Gatward et al.[11] study, they obtained a 86% success rate in i-gel insertion at the first attempt, and the overall insertion success rate was 100%, similar to the LMA-C and the proseal LMA (PLMA). Ali et al.[12] had a success rate of 77% for LMA-C insertion and a success rate of 88.5% for LMA-Supreme at the first attempt in their study. Richez[13] also showed a comparable success rate for placement of the i-gel. In contrast to these studies, in Amini et al.'s study[14] comparing i-gel and intersurgical solus LMA, they found that i-gel group required more interventions on the airway than the intersurgical solus LMA group. They thought it might be because of lack of experience of the anesthesiologists. In our study, i-gel has a similar performance in terms of insertion success compared with LMA-C, and no intervention was required during maintenance of anesthesia. SGADs were successfully inserted in 89.8% of patients at the first attempt in the LMA-C and in the i-gel group. This may be explained by the presence of experienced instructor in placing both SGADs.

Our results demonstrate shorter insertion times for the i-gel compared with the times for LMA-C, probably because of the fact that less flexible stem of the i-gel makes insertion easier and without any need for cuff inflation. Insertion success and shorter insertion times influence the feasibility of SGADs, as determined by Uppal and Amini and colleagues[14,15]; we found that the insertion time was shorter in the i-gel group but we did not find any significant clinical difference in this regard.

Many investigators have demonstrated that there are no significant differences in oropharyngeal leak pressure between the i-gel and LMA-Supreme.[16,17] Chen et al.'s[18] meta-analyses revealed that there were similar oropharyngeal leak pressures during anesthesia between the LMA-Supreme and the i-gel. In some studies, the LMA Supreme is reported to have higher oropharyngeal leak pressure than the LMA-C.[12,17] Although the i-gel does not have an inflatable cuff and thus it is harder to adjust the seal, given Chen et al.'s meta-analyses of oropharyngeal leak pressures of i-gel and LMA-Supreme and various investigators' comparisons of oropharyngeal leak pressures of LMA Supreme and LMA-C, it can be deduced that i-gel might have same or higher amounts of oropharyngeal leak pressure than LMA-C.[12,16–19] Further studies on the most common alternative SGADs suggest that a mean peak airway pressure of more

than 20 cm H_2O increases the risk of leakage with resultant insufficient ventilation and increased risk of aspiration.[20,21] In our study, the i-gel demonstrated similar peak airway pressures (mean 12 cm H_2O) with 7 mL kg^{-1} tidal volume, to the LMA-C and was comparable with the LMA-C in other studies and less than 20 cm H_2O.[22]

In our study, we had better glottic view in i-gel group by fiberscopy and similar results were reported in a cohort study performed by Beringer et al.[23] as well as a number of adult studies.[17,18] We think that the reason for fiberoptic view of glottis not being good enough in LMA-C group might be due to malposition caused by cuff of LMA-C. The fiberoptic view depends on the hypopharyngeal position of the SGAD and whether the epiglottis is folded down during insertion or not. However, it was shown that there is no correlation between fiberoptic view and SGAD's function. The fiberoptic score confirms that the SGAD occupies a favorable anatomical location to ensure unimpeded ventilation, with lower leak pressures and less gastric insufflation.[23]

In many studies that investigate SGAD regurgitation, it has been shown that the presence of SGAD results in a reaction in the pharynx which causes a reflex relaxation at the lower esophageal sphincter as well as a decrease in lower esophageal sphincter pressure.[7,8,24] This mechanism might be more active during superficial anesthesia. Inadequate anesthesia level and inexperience with the SGAD use may increase the risk of regurgitation. Bapat et al.[25] concluded that they did not encounter any regurgitation even in patients with high risk in their study because of an experienced SGAD user. Another study with 280 patients using i-gel demonstrated that three patients suffered from regurgitation and one of them resulted in aspiration. This patient's supraglottic device was replaced by a medical student.[26] Brimacombe[22] has suggested two distinct learning curves in the use of SGAD, and we believe that the high incidence of regurgitation cited in the earlier studies might have occurred during the learning curve. We controlled depth of anesthesia with BIS monitoring, and maintained it at between 50 and 60, with an experienced anesthesiologist placing both SGADs'.

The measurement of hypopharyngeal pH is an another method to detect gastric regurgitation, but hypopharyngeal pH is measured at a single level and thus may not accurately reflect the actual incidence of silent regurgitation.[27] The validity of the methylene blue method to detect regurgitation is questionable, because disintegration of a capsule in the esophagus may lead to a falsely high incidence of regurgitation.[8] In our study, to reduce false positives, the methylene blue capsule was ingested with 30 mL water in the upright position. Also, we visualized oropharynx of the

patients 10 min after the ingestion of the drug in case of false positive blue dye.

Several limitations exist in this study. Firstly, unblinded observers collected all the data. Secondly, the anesthesiologist inserting the SGADs had considerably more experience in inserting the LMA-C and the i-gel and this may have introduced bias in the results. Thirdly, the devices were used in non-obese patients and in those without underlying gastrointestinal system disorders. The results cannot be extrapolated to other groups of patients.

In conclusion, our study demonstrates that both devices had good performance with low postoperative complications and without occurrence of regurgitation. The i-gel provided a shorter insertion time and a better fiberoptic view than the LMA-C.

Conflicts of interest

The authors declare no conflicts of interest.

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