*Comparison of Supraglottic Airway Devices I-Gel and LMA ProSeal for Pediatric Patients**

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Öz

Amaç:
Çalışmamızda pediatrik hastalarda supralottik havayolu gereçlerinden LMA ProSeal ve I-gel kullanımı karşılaştırıldı. Gereç yerleştirme süresi, etkinliği, hemodinami ve komplikasyonlar açısından değerlendirilmesi amaçlandı.
Yöntemler:
Çalışmamız 1-9 yaş arası elektif alt karın cerrahisi geçiren ve vücut ağırlığı 5-20 kg aralığında olan 40 çocuk ile yapıldı. Çocukların vucüd ağırlığına uygun I-gel (Grup I, n = 20) veya LMA ProSeal (Grup L, n = 20) yerleştirildi. Gereç yerleştirme süresi, gereç yerleştirme girişim sayısı, yerleştirme kolaylığı ve komplikasyonlar değerlendirildi. Çıkarıldıktan sonra gereç üzerinde kan varlığı gözlendi.
Arteriyel kan basıncı, kalp hızı, oksijen doygunluğu, hava yolu basıncları ve tidal volüm kaydedildi.
Bulgular:
Gereç yerleştirme girişim sayısı değerlendirildiğinde, gruplar arasında anlamlı bir fark yoktu.
Gereç üzerinde kan varlığı Grup L'de (% 25) Grup I (% 0) ile karşılaştırıldığında anlamlı yüksek bulundu (p = 0.02).
Sistolik kan basıncı ve kalp hızı, cihazın yerleştirilmesinden 1 dakika sonra Grup

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L'de anlamlı derecede yüksek bulundu.
Sonuç: Her iki grupta da girişim sayıları ve girişim süreleri benzerdi. ProSeal LMA kullanılan hastaların %25'inde hava yolu morbiditesi gözlendi ve bu hastalarda gereç yerleştirilmesinin 1. dakikasında hemodinamik yanıt anlamlı derecede yüksekti.

Anahtar kelimeler: *I-gel, Pro-Seal LMA, supraglottik hava yolu cihazları, hava yolu, pediyatrik hava yolu*

Abstract
Objective:
In our study, we aimed to compare the use of the supraglottic airway devices LMA ProSeal and I-gel for pediatric patients in terms of insertion process, efficacy, hemodynamia and complications.
Methods:
Our study was completed with 40 children undergoing elective lower abdominal surgery aged from 1-9 years, with bodyweight 5-20 kg. I-gel (Grup I, n=20) or LMA ProSeal (Grup L, n=20) were inserted appropriate for weight.
The insertion attempts, the insertion duration, ease of insertion and complications were assessed. Presence of blood on the device after removal was monitored.
Arterial blood pressure, heart rate, oxygen saturation, airway pressure and tidal volume were recorded.
Results
When the insertion attempts are assessed, there was no significant difference between the groups. Presense of blood on the device was significantly high in Group L (25%) compared to Group I (0%) (p=0.02).
The systolic blood pressure and heart rate were found significantly high in Group L,1 min after device insertion.
Conclusion: The attempt numbers and insertion durations were similar in both groups. Morbidity of the airway was observed on LMA ProSeal in 25% of cases in Group L. And hemodynamic response, 1 min after device insertion was significant high in GrupL.

Keywords: *I-gel, Pro-Seal LMA, supraglottic airway devices, airway, pediatric airway*

Introduction:

Airways in pediatric patients are different compared to adults, with difficult intubation and difficult ventilation frequently observed and lengthened durations needed for intubation causing rapid hypoxia. Additionally, the effect of trauma occurring in the airway is more dramatic.

Alternative methods to endotracheal intubation may be applied in pediatric patients to ensure airway opening. For this, different supraglottic airway devices are used. While ensuring efficient airway opening, there is a search for possibilities allowing this process to pass in stable and reliable fashion.

LMA (laryngeal mask airway) ProSeal (LMA® ProsealTM Airway, Teleflex®) easily sits in the hypopharynx due to soft silicone (polysiloxane) cuff structure and allows the possibility of stomach aspiration due to the gastric drainage channel.

I-gel (I-gel® supraglottic airway, Intersurgical) is a cuff-free device with thermoplastic elastomer structure designed to sit without compressing the laryngeal and pharyngeal anatomic structures. Similarly, it has a gastric drainage channel for stomach aspiration.

LMA ProSeal and I-gel are used safely in pediatric patients to provide airway patency and ventilation (Mihara T, Asakura A, Owada G, 2017, Ekinci O, Abitagaoglu S, Turan G. 2014)

In our study, we aimed to compare the use of the airway devices LMA ProSeal and I-gel for pediatric patients in terms of insertion process, efficacy and complications.

Methods:

This study received ethics committee permission from Bakırköy Dr. Sadi Konuk Education and Research Hospital Clinical Research Ethics Committee with the decision no. 2017-01-05 and written informed consent from all the parents. It was conducted at Bakırköy Dr. Sadi Konuk Education and Research Hospital Pediatric Surgery from 20.04.2017 to 20.12.2017.

Our study was completed with 40 children undergoing elective lower abdominal surgery aged from 1-9 years, with bodyweight 5-20 kg and ASA I-II. Patients with lung and heart disease, history of gastroesophageal reflux, considered difficult intubation, with pharynx and larynx pathology and undergoing head and neck operations were not included in the study. The study was planned as a prospective, observational study.

Patients with elective operations had routine standard monitoring with electrocardiography (ECG), non-invasive blood pressure (NIBP) and peripheral oxygen saturation (SpO_2). Anesthesia induction used 2.5-3 mg kg^{-1} propofol and 1 mcg kg^{-1} fentanyl.

I-gel (Grup I, n=20) or LMA ProSeal (Grup L, n=20) were inserted appropriate for weight. The volume of air stated on the LMA ProSeal cuff was used to inflate the cuff. Cuff pressure was held at 25-30 mmHg.

Our primer endpoint, the number of attempts required to insert the supraglottic device was recorded.

The insertion duration (duration from end of mask ventilation, inserting the device and beginning manual ventilation until square wave-form capnogram was obtained), ease of insertion (1- no reaction, 2- clenching, retching, 3- alternative airway management) and complications occurring were assessed.

For anesthesia maintenance, controlled mechanical ventilation with 50/50% O_2/air mixture with 2% sevoflurane, tidal volume 7-8 ml kg^{-1}, 12-25 respirations min^{-1} and $ETCO_2$ 35-40 mmHg was ensured.

Patients had systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR) and peripheral oxygen saturation (SpO_2) values recorded before the intervention and 1, 5, 10 and 15 minutes after the intervention.

Peak airway pressure (Ppeak), mean airway pressure (Pmean), inspiration tidal volume (VTI), and expiration tidal volume (VTE) values were recorded before the intervention and 1, 5, 10 and 15 minutes after the intervention. Leak volume (VTI-VTE) and leak ratio (VTI-VTE/VTI) values were calculated.

Statistical analyses used the NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) program. When assessing the study data, the descriptive statistical methods were used (mean, standard deviation, median, frequency, proportion, minimum, maximum). For comparison of quantitative data, the student t-test was used to compare two groups with normally distributed data, while the Mann Whitney U test was used to compare two groups with non-normal distribution of data. The Pearson chi-square test and Fishers exact test were used to compare qualitative data. Significance was assessed at $p<0.05$ level.

Results:

The study was completed from 20.04.2017 to 20.12.2017 at Bakırköy Dr. Sadi Konuk Education and Research Hospital Pediatric Surgery with 40 children including 22.5% female (n=9) and 77.5% male (n=31). The ages of children varied from 1 to 9 years with mean of 5.20 ± 2.35 years. In both groups the age, gender and body weight were similar (Table 1).

Table 1: Distribution of Demographic Data

		Group I (n=20)	Group L (n=20)	p value
Age	*Min - Max (Median)*	2-7 (4,5)	1-9 (6,5)	[a]*0,060*
	Mean±Sd	4,50±1,73	5,90±2,71	
Gender*; n (%)*	*Female*	5 (25,0)	4 (20,0)	[b]*1,000*
	Male	15 (75,0)	16 (80,0)	
Weight (kg)	*Min - Max (Median)*	12-28 (18)	11-25 (18,25)	[a]*0,717*
	Mean±Sd	18,90±4,76	18,38±4,30	

[a]*Student t Test* [b]*Pearson Chi-Square Test*

Comparison of operation duration, anesthesia duration and recovery duration between the two groups were similar (Table 2).

Table 2: Assessment of Operation, Anesthesia and Recovery Duration

		Group I (n=20)	Group L (n=20)	p
Operation Duration (min)	*Min-Max (Median)*	10-60 (20)	5-40 (20)	*0,525*
	Mean±Sd	23,60±10,85	23,68±7,97	
Anesthesia Duration (min)	*Min-Max (Median)*	15-65 (25)	10-45 (27,5)	***0,425***
	Mean±Sd	28,60±10,85	29,09±7,96	
Recovery Duration (min)	*Min-Max (Median)*	10-25 (10)	10-15 (10)	***0,545***
	Mean±Sd	12,20±3,84	11,25±2,24	

Mann Whitney U Test

Our primer endpoint, the number of attempts required to insert the supraglottic airway device (attempt number) was assessed, the number of attempts was similar in both groups (Table 3). When the insertion duration is compared, there was no significant difference observed between the groups (Table 3).

Table 3: Assessment of Insertion Duration and Number of Attempts

		Group I (n=20)	Group L(n=20)	p
Number of Attempts; n (%)	One Attempt	17 (85,0)	13 (65,0)	[a]***0,282***
	Two Attempt	3 (15,0)	6 (30,0)	
	Three Attempt	0	1 (5,0)	
Insertion Duration (sn)	Min-Max (Median	2-35 (25)	5-35 (20)	[b]***0,999***
	Mean±Sd	20,31±12,56	21,00±9,40	

[a]*Pearson Chi-Square Test* [b]*Mann Whitney U Test*

When ease of insertion is assessed (1- no reaction, 2- clenching, retching, 3- alternative airway management), there was no significant difference observed between the groups and no patient required an alternative airway like intubation (Table 4).

Table 4: Assessment of Ease of Insertion

		Group I (n=20)	**Group L (n=20)**	p
Ease of Insertion; *n (%)*	**1**=No Reaction	19 (95,0)	16 (80,0)	***0,171***
	2=Clenching, retching	1 (5,0)	4 (20,0)	
	3=Alternative airway management	0(0)	(0)	

Pearson Chi-Square Test

Presence of blood on the device was significantly high in Group L (25%) compared to Group I (0%) (p=0.024<0.05) (Table 5). Apart from bleeding, no complications were observed (Table 5).

Table 5: Assessment of Complications and Side Effects

		Group I(n=20)	Group L (n=20)	*p*
Presence Of Blood On The Device*; n (%)*	None	20 (100,0)	15 (75,0)	**0,024*
	Present	0	5 (25,0)	
Throat Pain*; n (%)*	None	20 (100)	20 (100)	-
	Present	0 (0)	0 (0)	
Other Side Effects*; n (%)*	None	20 (100)	20 (100)	-
	Present	0 (0)	0 (0)	

**p<0,05*

When the medication doses used in the groups are compared, the propofol amount used in both groups was similar. No patient required neuromuscular blocker.

In Group L, 1 min after device insertion, heart rate measurements were found to be significantly high (p<0,006) . In Group L, 1 min after device insertion, systolic arterial pressure measurements were found to be significantly high (p<0,029).

There was no statistically significant differences observed between DBP, MAP and SpO_2 values measured in the groups before the intervention and 1, 5, 10 and 15 minutes after the intervention.

The Ppeak, Pmean, VTI, VTE, leak volume (VTI-VTE) and leak ratio (VTI-VTE/VTI) values were similar before the intervention and 1, 5, 10 and 15 minutes after the intervention.

Discussion:

Pediatric patients have limited tolerance of hypoxia, and rapid desaturation may be observed causing cardiac effects secondary to hypoxia. After induction, ensuring reliable airway opening in the least amount of time should be the target. It is important to insert the device on the first attempt.

A meta-analysis including 65 randomized controlled trials (RCT) with 5823 participants stated the LMA ProSeal was the most reliable supraglottic airway for children due to high oropharyngeal leak pressure and better success in inserting the device on the first attempt (Mihara T, Asakura A, Owada G, 2017)

A study of 505 patients comparing five different 2nd generation supraglottic airway (SGA) found the first insertion success rate was higher for I-gel with shorter insertion duration (Ekinci O, Abitagaoglu S, Turan G. 2014)

Ekinci et al. (2014) compared I-gel with LMA ProSeal in adult patients and found the first attempt success rate was higher for I-gel with shorter device insertion duration.

In our study the attempt numbers and insertion durations were similar in both groups.

Another important point is ensuring reliable insertion without damaging the airway. Trauma occurring in the airway may cause edema which may lead to aspiration due to the presence of hemorrhage, in addition to limiting the airway.

A study comparing the I-gel, LMA Supreme and LMA ProSeal found throat pain and blood on the device were observed less in the I-gel group (Liew GH, Yu ED, Shah SS, 2016)

Mihara et al. (2017) recommended that in spite of the high oropharyngeal leak pressure and lower observation of blood with the I-gel, the device should be assessed before routine use due to the risk of dysfunction.

In our study, morbidity of the airway was not observed in Group I, with blood observed on LMA ProSeal in 25% of cases in Group L; however, it did not cause any airway edema, stridor, spasm or aspiration.

Additionally, cuff pressure may indirectly cause airway morbidity (throat pain, dysphagia) which has been investigated. A study of 19 cadavers assessed pressure from airway devices and when the maximum volumes recommended by the manufacturers were used, pharyngeal pressure was identified to be very high. Due to tissue compression, indirect trauma may occur; however, it is considered there is no danger as the devices are not used long-term (Ulrich H, Hrska F, Krafft P, 2006)

Due to the I-gel's hard protective section held fixed within the mouth without biting, it complies with the oropharyngeal curve without malrotation. In this way, there is little compression difference between the beginning and end of the operation.

A study comparing LMA ProSeal and I-gel in adult patients including 10 prospective controlled trial (RCT) stated the insertion of the I-gel was easier and less blood stains were observed; however as the LMA ProSeal was recommended as it had higher oropharyngeal leak pressure (Maitra S, Baidya DK, Arora MK, 2016)

A study including 14 RCT compared I-gel and LMA ProSeal and observed the I-gel had less bleeding and shorter insertion time, with less throat pain. However, as the oropharyngeal leak pressure was higher the LMA ProSeal was recommended (An J, Nam SB, Lee JS, 2017)

An RCT comparing I-gel and LMA ProSeal in 60 patients with spontaneous respiration found the insertion of the I-gel was easier, took shorter time and had higher first attempt success rates. The results of the study reported the I-gel was a good alternative to LMA ProSeal (Jadhav PA, Dalvi NP, Tendolkar BA, 2015)

Conclusion:

In the selection of a supraglottic airway device, effective ventilation should be ensured without leaks. At the same time, it is important to insert the device in the shortest time without causing airway morbidity especially in children. In conclusion, we believe the I-gel is an alternative to the LMA ProSeal that does not cause airway trauma and hemodynamic response in pediatric patients.

There is a need for more studies on this topic in pediatric patients.

Ethical Committee: Bakırköy Dr. Sadi Konuk Education and Research Hospital Clinical Research Ethics Committee with the decision no. 2017-01-05

Limitations of the study:

Our study include small population, we think, this study should include more children.

But blood presence on device and the high hemodynamic response at the first minute after insertion is significantly.

There are few studies on children in this topic. This study is important in terms of the development of future studies

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Author contributions: Design of the study : DGM. / Data collections : KZLA. / Data analysis and interpretation : DGM, KZLA, GOH / Critical revision of the article : DGM., GOH.

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