REV COLOMB ANESTESIOL. 2018;46(1):37-41

Colombian Journal of Anesthesiology
Revista Colombiana de Anestesiología
www.revcolanest.com.co

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Wolters Kluwer

Tracheal intubation with I-gel supraglottic device in pediatric patients: a prospective case series

Intubación traqueal con dispositivo supraglótico I-gel en pacientes pediátricos: Serie de casos prospectiva

Keywords: Intubation Intratracheal, Airway Management, Pediatrics, Anesthesia, Ventilation

Palabras clave: Intubación Intratraqueal, Manejo de la Vía Aérea, Pediatría, Anestesia, Ventilación

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Abstract

Introduction: Currently, there are no devices showing an acceptable success rate in blind intubation in pediatrics.

Objectives: The purpose of this particular series of cases is to identify the percentage of successful blind intubations using the I-gel laryngeal mask in children between 2 and 35 kg of body weight, in addition to evaluating seal pressure, fiber optics vision through the device, and reporting the occurrence of complications.

Materials and methods: A prospective case series in pediatrics; patients from 2 to 35 kg.

Results: According to our study, the overall percentage of blind intubation was 23%, while the percentages of ideal and low vision to facilitate the insertion of the bronchoscope into the airway, and then inserting a tracheal tube through the fiber optics was 70%.

Conclusion: We feel that the supraglottic I-gel is not the appropriate device for blind intubation; however, it is an acceptable recommendation to conduct fiber optics intubation.

Resumen

Introducción: No hay un dispositivo en la actualidad que demuestre apropiado porcentaje de éxito de intubación a ciegas en pediatría.

Objetivos: El propósito de esta serie de casos es conocer el porcentaje de éxito de intubación a ciegas a través de la mascara laríngea I-gel en niños pesando entre 2 y 35 kilos, además evaluar la presión de sello, la visión fibroscópica a través del dispositivo y reportar la aparición de complicaciones.

Materiales y Métodos: Serie prospectiva de casos en pediatría, en pacientes de 2 a 35 kilos.

Resultados: En nuestro estudio el porcentaje global de intubación a ciegas fue del 23%, el porcentaje de visión ideal y visión baja, que permiten fácil introducción del broncoscopio en la via aérea y luego a través del fibroscopio introducir un tubo traqueal, fue de un 70%.

Conclusiones: Consideramos que el I-gel supraglótico no es un dispositivo adecuado para intubación a ciegas. Sin embargo tiene

How to cite this article: Zamudio-Burbano MA, Giraldo-Salazar O, Gaviria-Rivera E, Gómez-Castellanos G, Ángel Rodríguez C, Medina Ramírez S, et al. Tracheal intubation with I-gel supraglottic device in pediatric patients: a prospective case series. Rev Colomb Anestesiol. 2018;46:37–41.

Read the Spanish version of this article at: http://links.lww.com/RCA/A4.

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Rev Colomb Anestesiol (2018) 46:1

http://dx.doi.org/10.1097/CJ9.0000000000000007

un valor aceptable para recomendar realizar intubación fibroóptica a través del dispositivo supraglótico I-gel.

Introduction

One of the major challenges in pediatric anesthesia is to maintain the patency of the airway during anesthesia, as, due to the particular anatomical and physiological characteristics of the pediatric population, there are differences between the pediatric and the adult airway,[1] and such differences represent a risk of severe, life-threatening respiratory complications.

While the nonventilation situation is considered rare in pediatrics, the nonintubation event is more frequent. Up to 4.7% of pediatric patients undergoing general anesthesia may present with difficult intubation.[2] Thus, it is desirable to have a device that facilitates blind intubation for salvage of the unexpected difficult airway. The Fastrach laryngeal mask (iLMA) is available for adult intubation and it is the standard of reference; however, the device is not available for children under 30 kg of body weight.

The single use I-Gel supraglottic device has shown a good performance for airway patency in children and adults.[3–6] It has a gastric aspiration canal, a bite blocker, and is a useful conduit for fiberoptic bronchoscopy.[7–9] In adults, it has been described as a blind endotracheal intubation device with a success rate of up to 80%.[10] A prospective series of cases is discussed with the primary goal of establishing the percentage success rate for blind intubation in pediatrics. Secondary outcomes such as insertion times, seal pressure, fiber optics view, and adverse events are also evaluated.

Methods

A prospective case series of 39 patients admitted to the study upon approval by the ethics and research committees of the San Vicente Fundación University Hospital (HUSVF) and the Universidad de Antioquia. The patients included had a bodyweight ranging between 2 and 35 kg, ASA 1 and 2 status, and were scheduled for surgery and/or diagnostic procedures in the operating rooms of the pediatrics department of the HUSVF. Considering that the time to safe apnea could be too short for the tests with the device, patients ASA 3 and higher were excluded, as well as patients classified with a difficult airway; the recommended technique for these patients according to the pediatrics airway team is spontaneous ventilation intubation and flexible fiber optics. Patients not accepted by the treating anesthesiologist and/or for whom the procedure was not approved by their legal guardian were also excluded. The primary outcome was to establish the overall success rate of blind intubation on 3 attempts, using the I-Gel and based on the above-mentioned secondary outcomes.

The patients were recruited by 3 investigators who completed their learning curve of 20 procedures at the simulation laboratory, school of medicine, Universidad de Antioquia.

After giving an explanation to the patients' guardians, obtaining their approval and the approval of the treating anesthesiologist to participate in the study, every patient submitted his/her informed consent.

Fasting was confirmed, the medical record was reviewed, and the physical examination conducted; finally, the procedure was explained. No pre-medication was administered, and the induction of anesthesia was administered according to the anesthesiologist's criterion, ensuring adequate depth of anesthesia based on the absence of eyelid reflex, easy ascending and descending jaw movement, and absence of reaction when applying pressure on both mandibular commissures. Subsequently, a water-based lubricant was used and the I-Gel laryngeal mask was inserted in accordance with the manufacturer's instructions. Upon insertion of the laryngeal mask, the mask was then connected to the semi-closed circuit, fixing the mask to both jaws with micropore, and adequate performance was confirmed based on chest expansion, capnography, and absence of leaks.

The insertion time was measured from the removal of the facial mask to the occurrence of an adequate capnography wave. The mask was inserted by the anesthesiologist or the investigator, and then, the leak pressure was measured by closing the pressure relief valve and opening the flow of fresh gases to 3 l/min. When an audible leak occurred, the pressure gauge measurement on the anesthesia machine was recorded. No pressure increases above 35 cmH_20 were allowed.

Then, the fiberoptic view was evaluated and the scale by Cook and Cranshaw[11] was used, with a High, Ideal, or Low classification. Finally, 3 attempts of blind intubation were conducted, rotating the orotracheal tube in different directions: the first attempt was done with the tube curved against the I-Gel mask; the second attempt rotated the tube 90° clockwise with respect to the I-Gel curvature in case of resistance to passage of the tube in the first attempt. Finally, the last insertion attempt was done at 90° anti-clockwise. In case of successful intubation, the technique described for iLMA was used. In case of failed patient intubation, but if the patient required intubation at any rate, the mask was removed and direct laryngoscopy was performed. The variables and data were recorded, as well as any complications, until the patient was discharged from the post-anesthesia care unit.

Outcomes

The primary outcome was the percentage of successful blind intubations using the I-Gel mask, verifying with the first capnography and effective ventilation. The secondary outcomes were the percentage of successful blind intubations

Table 1. Baseline patient characteristics: 4 groups

Sociodemographic variables				
Mask size	I-gel # 1 (2–5 kg)	I-gel # 1.5 (5–12 kg)	I-gel # 2 (10–25 kg)	I-gel # 2.5 (25–35 kg)
Patients	8	10	10	11
Sex	Male: 5 (62.5%) Females: 3 (37.5%)	Male: 8 (80%) Female: 2 (20%)	Male: 5 (50%) Female: 5 (50%	Male: 8 (72%) Female: 3 (28%)
ASA	I: 0 (0%) II: 8 (100%)	I: 2 (20%) II: 8 (80%)	I: 7 (70%) II: 3 (30%)	I: 8 (72%) II: 3 (28%)
Mean age	1 month	41 months	51 months	103 months

ASA = American Society of Anesthesia Classification of Physical Condition.
Source: Authors.

with the device, differentiating each attempt made, with the same primary outcome method. The proportion of fiberoptic view according to the scale by Cook and Cranshaw[11] was evaluated, seal pressure measurements were taken, and any adverse events were recorded.

Statistical analysis

As this is a descriptive study, the sample size was not estimated and inferential statistics were not used. The qualitative variables are presented as frequencies and proportions, while the quantitative variables are expressed as measurements and standard deviations.

Results

Table 1 summarizes the demographic characteristics of the 39 patients recruited. Nine patients were intubated blindly, representing a global success rate of 23%; in 55% of the cases, intubation was successful at the first attempt, 22% at the second attempt, and 22% at the third attempt. Two patients (12.5%) were intubated with I-Gel, 3 patients (30%) were intubated with #1.5; no patients were intubated with #2, and finally 5 patients (50%) were intubated with #2.5. Considering the secondary end-points, the visualization of the glottic structures using the flexible fiberoptic bronchoscope, according to the classification by Cook and

Table 2. Primary and secondary outcomes

Variable	I-gel # 1 (2–5 kg)	I-gel # 1.5 (5–12 kg)	I-gel # 2 (10–25 kg)	I-gel # 2.5 (25–35 kg)
Blind intubation	1 (12.5%)	3 (30%)	0%	5 (50%)
Success at first attempt	0	1 (33%)	0%	4 (80%)
Success at second attempt	2 (100%)	1 (33%)	0%	0%
Success as third attempt	0	1 (33%)	0%	1 (20%)
Mean seal pressure, cmH_2O	17.5	19.4	20.5	20.8
High glottic view	0 (0%)	5 (50%)	4 (40%)	3 (27%)
Ideal glottic view	3 (37.5%)	1 (10%)	4 (40%)	6 (54%)
Low glottic view	5 (62.5%)	4 (40%)	2 (20%)	2 (19%)
High overall glottic view	29.5%			
Ideal overall glottic view	35.25%			
Low overall glottic view	35.25%			

cmH20 = water centimetres.
Source: Authors.

Table 3. Adverse events report

Adverse events	n (%)
Bleeding	4 (10.2%)
Odynophagia	0 (0%)
Hypoxemia ($satO_2$ <92%)	2 (5.1%)
Laryngospasm	1 (2.6%)
Cardiorespiratory arrest	0 (0%)
Death	0 (0%)
Total	7 (17.9%%)

$satO_2$ = oxygen saturation.
Source: Authors.

Cranshaw,[11] 35.8% of the cases were ideal, and a high view was achieved in 33.3% of the patients. The mean seal pressure measured in average 19.6 cmH_2O (10–35 cmH_2O). See Table 2.

Seven adverse events were reported (17.9%): bleeding at the time of device removal in 4 patients (10.2%), hypoxemia (pulse oximetry <92%) in 2 patients (5.1%), and 1 laryngospasm (2.56%) (Table 3).

Discussion

The percentage success of blind intubation with the I-Gel supraglottic device is low, 23%, consistent with the results of blind intubation trials.[4] If the various groups studied are analyzed separately, the success rate is higher in the group of patients with a body weight between 25 and 35 kg, using the I-gel #2.5 mask. The intubation success in this group may be associated with the similarity of the airway anatomy of these patients and the adult patients. No relationship was found between the fiberoptic view and the blind intubation success. Among the intubated patients, 44.4% had ideal view, 33.3% high view, and 22.2% low view, according to the Cook and Cranshaw scale.[11] The I-Gel laryngeal mask has excellent ventilation rates, 100% of the patients in this group were ventilated, with seal pressures of around 20 cmH_2O, a pressure similar to that reported in clinical trials.[2–6,12]

We believe that one of the strengths of the study was the inclusion of 4 different pediatric populations separated by body weight ranges. Moreover, the goal of blind intubation was a significant clinical outcome, which could improve airway management safety.

Other strengths included the ability to evaluate the fiberoptic vision through the I-gel mask and establish a correlation with the success of the intubation. Moreover, the fact that the investigators did not have a learning curve for blind intubation resulted in mask insertion conditions and intubation attempts that were closer to real-life situations.

We also noticed that the I-gel device is a good intubation guide through the fiberoptic bronchoscope, as the rate of ideal and low view that facilitates access of the fiberoptic bronchoscope through the glottis and insertion into the airway to complete the orotracheal intubation was 70%. This is an acceptable value to recommend the use of the I-gel supraglottic device as a guide for fiberoptic bronchoscopy-based orotracheal intubation. This is in fact the current recommendation.

The limitations we identified in the study were the inclusion of patients classified above ASA II; the size of the balloon-less orotracheal tubes recommended by the manufacturer for each I-gel was usually small for the patient's airway, facilitating the development of leaks in patients achieving a successful intubation. Moreover, none of the patients in the study met the difficult airway criteria; hence, the results in terms of the percentage of successful intubations may not be extrapolated to difficult airways. There was no learning curve for blind intubation in real-life patients, only simulation that could have influenced the device performance.

In summary, we are of the opinion that the I-gel supraglottic device is not a good choice for blind intubation in the pediatric population, particularly sizes 1, 1.5, and 2. The performance improves with the I-gel #2.5 (50% effectiveness); however, it is not as successful as in adults. It is however a suitable device for positive pressure ventilation, with a seal pressure of around 20 cmH_2O and it also helps as a canal for glottis visualization using fiberoptic bronchoscopy, in addition to having a gastric suction canal, except for mask #1.

Acknowledgment

The authors acknowledge the Universidad de Antioquia for the academic endorsement and human resources support, and express their gratitude to the Hospital Universitario San Vicente Fundación for allowing us to conduct this study.

Ethical disclosures

Protection of human and animal subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data: The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent: The authors have obtained the written informed consent of the

patients or subjects mentioned in the article. The corresponding author is in possession of this document.

Funding

The study was financed with the authors' own resources.

Conflicts of interest

The authors have no conflict of interests to disclose with regards to this study. The design, patient recruitment, analysis, and publication are entirely the result of their own personal effort.

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