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Original Research Article

Successful I-Gel Insertion by Novice Doctors with Help of Laryngoscope: A Prospective Randomized Controlled Trial

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Abstract

Background: I-gel is a second generation supraglottic airway device which is commonly used in elective anaesthetic and rescue airway management. While blind insertion is easy, inexperienced physicians might not be able to insert the tube on the first try because the tongue is folded, the epiglottic structure blocks insertion, or the tube is not aligned with the laryngeal inlet. Aim: To compare the performance of direct laryngoscopy guided I-gel insertion with the conventional blind technique for novice doctors to see if the former method has a higher success rate on the first attempt.

Methods: A prospective randomized controlled trial of 120 adult ASA I-II undergoing elective short surgical procedures under general anaesthesia were recruited. The patients were randomly divided into two groups: the laryngoscopy-guided insertion (L) group (n=60) and the conventional blind insertion (B) group (n=60). Standardized training was followed by the procedure performed by novice doctors who had fewer than ten I-gel insertions. The primary outcome used was the successful insertion on the first attempt. Secondary outcomes included insertion time, number of attempts, oropharyngeal leak pressure, airway manipulations, hemodynamic response, mucosal trauma, sore throat, hoarseness, and operator rated difficulty.

Result: The rate of success on the first attempt was significantly higher in the laryngoscopy group than in the blind insertion group (90.0% vs. 71.7%; p=0.011). The overall success rate after two attempts was 100% and 95.0% respectively (p=0.244). Mean insertion time was shorter with laryngoscopy (18.6 ± 5.4 s vs 25.9 ± 8.7 s; p<0.001), and leak pressure was higher (26.8 ± 4.1 vs 23.5 ± 4.6 cmH2O; p<0.001). The airway manipulations were also less common in the laryngoscopy group (13.3% vs 35.0%; p=0.006). Sore throat occurred 8.3% versus 21.7% (p=0.040), and hemodynamic changes and hoarseness were not different.

Conclusions: Novice doctors who inserted the I-gel using direct laryngoscopy had a higher success rate for the first insertion attempt, required less airway manipulation, and insertion time was shorter, without the occurrence of any more adverse events.

Keywords: I-gel; Supraglottic Airway Device; Laryngoscopy; Novice Doctors; Randomized Controlled Trial; Airway Management; First-Attempt Success.

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Introduction

Supraglottic airway devices have grown to be a vital part of contemporary airway management as they lower the threshold for the use of face-mask ventilation vs tracheal intubation [1]. I-gel is a second-generation supraglottic airway device composed of a thermoplastic elastomer cuff with a non-inflatable cuff and a gastric drainage channel that is anatomically adaptable to the structures of the laryngotracheal region [2].

It has been used extensively in the operating room, emergency care, and resuscitation rooms, owing to ease of insertion, stability of the seal, and its use in rescue airway situations [3]. While the I-gel is likely to be inserted easily, failure to insert it is not uncommon, especially if performed by trainees or novice doctors. Initial clinical trials have reported high success rates with users, but less so with novices as resistance may be met by the tongue, soft palate, posterior pharyngeal wall or epiglottis [4, 5]. Success in the first attempt is critical, as additional ventilator efforts result in greater mucous trauma, risk of hypoxemia, sympathetic response and operator stress.

Thus, providing simple methods which enhance novice success without increasing complexity is clinically significant. The traditional way of

inserting an I-gel is conventional blind I-gel insertion, which follows the path of the palatopharyngeal curve without being visualized. In many patients this is adequate, but in anaesthetized/paralyzed patients, the tongue may be displaced posteriorly and the epiglottis may fold down making smooth advancement difficult. Direct laryngoscopy can help to raise the tongue and the epiglottis and it can increase the space in the oropharynx and the I-gel bowl can be better aligned with the larynx. A previous randomized study indicated that laryngoscopy increase the ease of insertion, sealing pressure, and insertion success by novice doctors inserting the laryngoscope I-gel [6].

A variety of techniques modifications have also been investigated to improve the placement of supraglottic airway, such as neuromuscular blockade, head rotation, rotational insertion, prewarming, and video-laryngoscope guidance [7, 8]. Many of these, however, will need further experience, special equipment, or manoeuvres that might not be evident for trainees. Direct laryngoscopy is an essential airway skill in anaesthetic training and is a procedure that can be achieved with the airway equipment commonly found in surgical operating rooms. The use of routine laryngoscopy to guide novice insertion of an I-gel should be recommended only following prospective testing in local training environments for its elective use.

The aim of the present study was to compare direct laryngoscopy guided insertion of the I-gel with the blind insertion by novice doctors in a prospective randomized controlled clinical trial. The main intention was to make a comparison between the first time success. Secondary objectives involved comparisons of insertion time, number of attempts, oropharyngeal leak pressure, need for manipulation of the airway, hemodynamic changes, airways morbidity in the postoperative period and operator-rated difficulty.

Materials and Methods

Study design and setting: This was a single-center prospective randomized controlled trial in the Department of Anaesthesiology of a tertiary care teaching hospital during 10 months. Institutional ethical clearance was obtained.

Sample size: Sample size was determined based on first attempt success. From previous literature and some pilot studies, it was estimated that about 70% success would be achieved with blind insertion and 90% with laryngoscopy-guided insertion. The sample size of 54 patients per group was determined using the following: alpha error = 0.05, 1:1 allocation, and 80% power. In order to account for protocol deviations, sixty patients were added to each group, giving a total of 120 patients.

Patients aged 18 to 60 years who were ASA (American Society of Anesthesiologists) physical status I or II, had a body mass index between 18 and 30 kg/m2, a Mallampati class I or II and were to undergo elective short-duration surgery under general anaesthesia with the use of a supraglottic airway were included. Exclusion criteria were expected to be difficult airway, mouth opening <3cm, risk of aspiration, gastroesophageal reflux disease, upper respiratory tract infection, sore throat, oral pathology, cervical spine limitation, emergency surgery, and refusal to participate.

Randomisation and blinding: The patients were randomly allocated to the laryngoscopy-guided group and blind insertion group by using computer-generated random numbers in a sequentially numbered opaque envelope. The novice doctor was unable to be blinded due to the visualization of the technique. Sore throat and hoarseness were however evaluated by an observer blinded to the groups.

Intervention: Novice doctors were defined as junior residents or interns who have a less number of previous I-gel insertion in patients under supervision. Each doctor was provided with a 20 minute, standard demonstration and manikin practice session prior to participation. I-gel size was chosen based on manufacturer weight guidelines and then pre-lubricated with water-soluble jelly for preoxygenation prior to induction with anaesthetic (fentanyl 2 micrograms/kg and propofol 2 mg/kg), and then rocuronium 0.6 mg/kg was used to standardise insertion conditions. The standard digital technique was used for insertion in the blind group up to resistance in the hard palate. During laryngoscopy, a Macintosh laryngoscope was introduced to gently raise the tongue and epiglottis and then the I-gel was advanced under direct vision until resistance was encountered and the bowl was positioned with the laryngeal inlet. Placement was confirmed by chest movement, square wave capnography, and lack of significant leak and adequate tidal volume.

Primary outcome: Successful insertion on first attempt. An attempt was deemed to be a mouthpiece inserted into the mouth followed by either confirmation or removal. Time for each attempt was 60 seconds. Secondary outcomes were total time required for insertion, number of attempts required, success following 2 attempts, requirement for manipulation of the airway, oropharyngeal leak pressure, heart rate and mean arterial pressure before and after insertion, mucosal blood staining, sore throat, hoarseness, and operator-rated difficulty (on a numerical scale of 1 to 10).

Data analysis: SPSS version 26.0 was used for statistical analysis. Continuous variables were

presented as mean ± SD and compared using independent-samples t test. Categorical variables were expressed as number and percentage and compared using chi-square or Fisher exact test. The level of p value <0.05 was statistically significant.

Results

One hundred thirty-two patients were screened, of whom 12 were excluded due to reflux symptoms, Mallampati class III, refusal, or recent sore throat.

One hundred twenty patients were randomized and analyzed, with 60 in each group. Baseline characteristics and airway assessment parameters were comparable between groups.

Table 1: Baseline demographic and airway characteristics

Variable	Laryngoscopy group (n=60)	Blind group (n=60)	p-value
Age (years)	36.4 ± 10.2	35.8 ± 9.8	0.743
Female sex, n (%)	34 (56.7)	32 (53.3)	0.713
BMI (kg/m2)	24.2 ± 2.6	24.6 ± 2.8	0.419
ASA I/II, n	38/22	36/24	0.707
Mallampati I/II, n	42/18	40/20	0.698
Mouth opening (cm)	4.3 ± 0.5	4.2 ± 0.5	0.276
Thyromental distance (cm)	7.1 ± 0.7	7.0 ± 0.6	0.405

The primary outcome was significantly better with direct laryngoscopy guidance.

First-attempt successful placement occurred in 54 patients (90.0%) in the laryngoscopy group compared with 43 patients (71.7%) in the blind group. Overall success within two attempts was high in both groups.

The laryngoscopy group required fewer optimization manoeuvres, and the mean insertion time was significantly shorter.

Table 2: I-gel insertion characteristics

Outcome	Laryngoscopy group (n=60)	Blind group (n=60)	p-value
First-attempt success, n (%)	54 (90.0)	43 (71.7)	0.011
Success within two attempts, n (%)	60 (100.0)	57 (95.0)	0.244
Insertion time (seconds)	18.6 ± 5.4	25.9 ± 8.7	<0.001
Need for airway manipulation, n (%)	8 (13.3)	21 (35.0)	0.006
Oropharyngeal leak pressure (cmH2O)	26.8 ± 4.1	23.5 ± 4.6	<0.001
Operator difficulty score (0-10)	2.1 ± 1.3	4.3 ± 2.0	<0.001
Alternative airway required, n (%)	0 (0.0)	1 (1.7)	1.000

Hemodynamic responses to insertion were modest and comparable in both groups. The laryngoscopy group had less visible mucosal staining and fewer sore throat complaints. Hoarseness did not differ significantly. No aspiration, laryngospasm, bronchospasm, dental injury, or desaturation below 92% occurred in either group.

Table 3: Hemodynamic response and airway morbidity

Outcome	Laryngoscopy group (n=60)	Blind group (n=60)	p-value
HR after insertion (beats/min)	81.2 ± 10.4	79.5 ± 9.8	0.358
MAP after insertion (mmHg)	88.1 ± 8.6	86.7 ± 9.1	0.386
SpO2 minimum (%)	98.2 ± 1.0	97.9 ± 1.2	0.140
Blood staining on device, n (%)	3 (5.0)	9 (15.0)	0.067
Sore throat at 2 hours, n (%)	5 (8.3)	13 (21.7)	0.040
Hoarseness, n (%)	3 (5.0)	5 (8.3)	0.717
Dental/lip injury, n (%)	0 (0.0)	1 (1.7)	1.000

Discussion

This Randomised Control Trial study proved that the use of direct laryngoscopy guidance successfully enhanced the success of insertion of the I-gel with the first attempt by novice doctors in comparison to the conventional blind insertion technique. The laryngoscopy technique also reduced the operator-rated difficulty, the need for airway manipulation, insertion time, and improved oropharyngeal leak pressure. Importantly, these benefits were obtained without significant clinically hemodynamic stimulation or increased airway morbidity.

The results are in line with the anatomical design and principles of insertion of the I-gel. The device is designed to conform to the palatopharyngeal curve and sit over the laryngeal inlet, but in anaesthetized patients the tongue and epiglottis may block progress of the device [9]. Direct laryngoscopy mechanically pushes these structures aside, increases the space in the oropharynx and provides a visual ending point for the novice

laryngoscopist. This could be the reason for the better success rate for the first attempt and higher leak pressure in the laryngoscopy group.

Our findings are consistent with the prospective randomized study conducted by Miyazaki et al., which revealed that laryngoscopy helped in the insertion of the I-gel by novice doctors and enhanced successful insertion, sealing pressure and ease of insertion by the doctor [10].

The present research confirms this in a different training setting, and shows the same sense of effect with a larger sample. The clinical significance is not only statistical, but also a decrease in repeated airway attempts, which is undesirable in elective and rescue airway use.

The importance of the muscle relaxation during I-gel insertion is also applicable. Hattori and his colleagues found that doctors who were inexperienced in this procedure could learn to insert the I-gel more easily with neuromuscular blockade [11]. To standardize insertion conditions and eliminate the confounder of jaw tone we used rocuronium in our protocol, giving it to all patients. The enhanced performance of the laryngoscopy group, therefore, is mainly due to visualization and lifting of the tongue-epiglottis but not to variations in depth of anaesthesia or muscle relaxation.

Other research has looked at ways to enhance the placement of supraglottic airways, such as with the introduction of a video-laryngoscope to guide the airway and the use of head rotation and rotational techniques [12, 13].

Video-laryngoscope guidance could help ensure better alignment and minimise malposition, but may not be universal and may depend on familiarity with the device. Head rotation is easy and in experienced hands has proven to be more successful in the initial attempt [14].

Macintosh laryngoscopy, in comparison with these options, can be performed with ease and is readily available, and is already incorporated into the airway training curriculum.

The fewer the attempts and fewer airway manipulations in the laryngoscopy group may explain the decrease in sore throat noted in this group. Gentle lifting under sufficient anaesthetic depth does not seem to be as traumatic as blind advancement against resistance, although laryngoscopy may be sufficient to cause pharyngeal stimulation. There was no significant hemodynamic difference between groups: this could be due to the short duration and mild procedure of laryngoscopy (for supraglottic placement only and not for tracheal intubation).

There are some limitations to the study. It contained strictly elective ASA I-II adults having normal predicted airway; results cannot be extrapolated to patients with difficult airway anatomy, limited mouth opening, obesity and/or high risk of aspiration patients, or emergency situations. Operators were not only novice doctors who were trained for a short period of time but findings could vary between more experienced operators. The operator was not blinded to technique, and this might introduce the performance bias. The final device position was not fiberoptically graded and improved leak pressure was used as an indirect measure of seating quality. The technique should be investigated in simulation-to-clinical training programs, with fiberoptic confirmation, as well as during airway rescue situations.

Even in the face of these constraints, the research findings have training implications. Success on the first attempt is a good measure of new education in the airways. The teaching of I-gel insertion using laryngoscopy as a training technique might facilitate novices in understanding the anatomy, decrease early insertion failures and increase early insertion success and confidence prior to blind insertion. This is in keeping with current airway recommendations which focus on minimising repeated attempts, ensuring maintenance of oxygenation and ensuring effective use of supraglottic devices in the context of difficult airway management [15, 16].

Conclusion

Innovative first-attempt success rate, is higher for the Direct laryngoscopy guided I-gel insertion than for the blind insertion by novice doctors. There was a statistically significant difference between Direct laryngoscopy guided I-gel insertion and blind insertion in the following areas: First-attempt success rate, insertion time and leak pressure. This technique was both safe and easy and appropriate for airway training in elective anaesthetic patients with normal predicted airways.

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