Short communication

OBSERVATIONAL STUDY COMPARING THE SAFETY AND EFFICACY OF IGEL SUPRAGLOTTIC AIRWAY DEVICE INSERTION IN ANESTHETISED PATIENTS BY ANESTHESIA FACULTY VERSUS RESIDENTS

ABSTRACT

Aims: Successful airway management is the first priority in a variety of emergency care and hospital scenarios. This study was an attempt to compare and find out how quickly a first-time resident can learn to insert an I-gel and secure the airway versus their trained counterparts, thereby proving the effectiveness of this I-gel innovation in airway patency maintenance. **Study design:** Observational study. **Place & Duration of Study:** Department of Anesthesiology, Dr. D.Y. Patil Medical College, Hospital and Research Centre, Dr. D.Y. Patil Vidyapeeth, Pune, Maharashtra 411018 India, from August 2021 to December 2021. **Methodology**: Two groups of 80 patients belonging to ASA grade I and II, aged between 18 to 65 years, including either gender, posted for elective surgery under GA requiring I-gel Supraglottic Airway device (SAD) insertion, with informed consent. The patients underwent I-gel SAD insertion by Anaesthesia Faculty & Anaesthesia Residents respectively. Baseline vital hemodynamic parameters, the time taken for insertion, number of attempts made and the serial heart rate, arterial pressure, SpO2 and respiratory rate noted at the time of insertion and at one, three- and five-minutes following insertion were noted. **Results**: Faculty group outperformed the residents with regards to number of attempts taken and time taken for each attempt, however the numbers in both groups are still comparable with no stark differences. **Conclusions**: There's a very short & easy learning curve for successful i-gel® insertion by novice practitioners as well as paramedical workers, especially during a variety of emergency care and pre-hospital scenarios.

Keywords*: Laryngeal masks; Intubation; Airway management; Cardiopulmonary resuscitation.*

INTRODUCTION

Successful airway management is the first priority in a variety of emergency care and pre-hospital scenarios. 1, 2 Though tracheal intubation remains the gold standard in securing airway, it is a relatively difficult skill to acquire and can prove risky when performed by non-anaesthetic personnel. In contrast supraglottic airway devices are considered relatively safe and easy to use by operators with limited airway management experience. The I-gel^{TM} (Intersurgical Ltd, Wokingham, UK) is a single use supraglottic airway device with a non- inflatable cuff and drain tube, for use in anesthesia during spontaneous or intermittent positive pressure ventilation.

Till date, there has been a dichotomy of views regarding the safe and efficacious use of the various supraglottic airway devices by newly trained physicians or paramedical workers, for achieving successful securing the airway, with minimal training, especially in medical emergencies.

With respect to all the plethora of divergent views regarding the efficiency of the I-gel, our study was an attempt to compare and find out how quickly a first-year resident can learn to successfully insert an I-gel and secure the airway versus their trained counterparts, thereby proving its ease of use & effectiveness in establishing airway patency.

METHODOLOGY

Institute Ethics Committee Clearance was obtained before start of study. Two groups of 80 patients belonging to ASA grade I and II, aged between 18 to 65 years, including either gender, posted for elective surgery under GA requiring I-gel Supraglottic Airway device (SAD) insertion, with informed consent. Patients belonging to ASA grade III-IV, with cardiac, neurological and respiratory diseases, or with full stomach, emergency cases, or patients scheduled for head and neck surgery were excluded from this study. The patients were randomized into two groups (group F and group R) using the equal group random allocation method. We followed the stated guidelines of strengthening the reporting of observational studies in epidemiology (STROBE) for observational cohort studies.

After detailed preanesthetic evaluation & routine investigation, preoperative fasting status (6–8 hrs) was confirmed, 20G intravenous (IV) cannula secured & basic monitors like pulse oximetry, non-invasive blood pressure and standard 3-lead electrocardiography (ECG) was applied. Baseline vital parameters such as heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP), SpO2 and respiratory rate (RR) were recorded.

Premedication Inj. Glycopyrrolate 0.004 mg/kg Inj. Ondansetron 0.1 mg/kg IV, Inj. Midazolam 0.0.2 mg/kg IV and inj. Fentanyl 2µg/kg IV was given & induced with injection propofol 3mg/kg. Face mask ventilation with 100% oxygen, 60% nitrous oxide and 1-1.5 vol% of Sevoflurane until adequate jaw relaxation for device insertion was achieved. The resident volunteers were made to stand at the head end of the patient with each resident volunteer allowed to attempt I-gel insertion using standard techniques, under the supervision of senior anesthesiologist. Each attempt was timed using a stopwatch. Bilateral equal chest rise and a square wave on the capnograph was taken as the end point of a successful insertion. The insertion time is defined as the time from the end of mask ventilation to the commencement of ventilation through I-gel.

If these findings are not present, then the resident is made to re-insert the device. The attempts were considered a failure if effective airway is not attained after three attempts. Then the senior experienced anesthetist took over. The time taken for successful insertion, number of attempts made and the serial heart rate, arterial pressure, SpO2 and respiratory rate were noted at the time of insertion and at one,

three- and five-minutes following insertion. Similar parameters were observed in the Anaesthesia faculty group.

Patients maintained on oxygen and nitrous oxide (50-50%) and sevoflurane (1-1.5 vol%) with spontaneous respiration throughout the procedure as no muscle relaxant will be used. At the end of the procedure, all the patients kept only on 100% oxygen. When the patient is able to open their eyes and follow verbal commands, oral suctioning was done and subsequently the I-gel airway device was removed. Any buccal mucosal, lip and/or teeth injury or blood stain on the device was recorded.

Statistical Analysis:

Continuous variables like Age, Heart Rate, Mean Arterial Pressure are compared across the two groups using unpaired t test. An alpha level of 5% has been taken, i.e., if any p value is less than 0.05 it has been considered as significant. Paired t test is used to compare the two means.

RESULTS AND DISCUSSION:

All forty I-gel insertion attempts were successful on the very first attempt in the anaesthesia faculty group (group F). Whereas, in the resident group (group R), thirty-two I-gel insertion were successful on the first attempt, followed seven successful second attempts & one successful third attempt. None of the residents had a failed third attempts, hence all attempts were considered successful.

I-gel™ (Intersurgical Ltd, Wokingham, U.K.) is a new second generation, single use supraglottic airway device (SAD) with a non-inflatable cuff and a drain tube. (19) The non-inflatable cuff is made of gel-like thermoelastic elastomer, that creates a non-inflatable anatomical seal of the pharyngeal, laryngeal and peri-laryngeal structures. Thus, making I-gel easy to insert and position, useful for anesthesia, cardiopulmonary resuscitation and even acts as a rescue device in cases of failed intubation and ventilation.

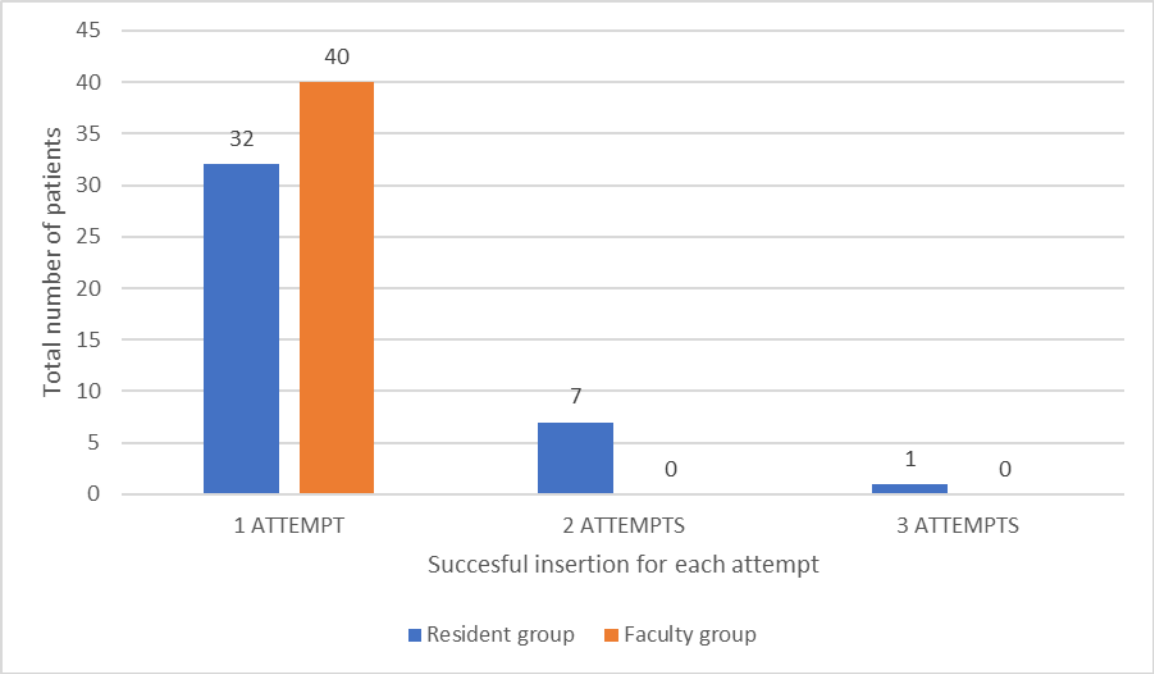
Table 1: Mean age, male to female ratio, mean heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure and respiratory rates in both groups at various intervals.

Parameters		Group F	Group R	P value
Age (years)		36.45 ± 11.56	37.12 ± 14.7	0.15
Gender	Male	24	16	
	Female	26	14	
Mean Heart Rate (beats/minute)	Baseline	82.55±7.42	81.15±8.87	0.441
	During I-gel insertion	79.62±7.67	77.72±9.21	0.321
	1 min after insertion	79.62±6.91	78.15±8.36	0.401
	3 mins after insertion	81.75±6.65	79.87±8.41	0.220
	5 mins after insertion	84.81±5.43	82.11±8.07	0.210

Mean Systolic Blood pressure (mm of Hg)	Baseline	120.8±9.52	124.13±7.93	0.093
	During I-gel insertion	118.01±7.05	118.40±9.41	0.614
	1 min after insertion	116.93±7.04	122.00±8.71	0.44
	3 mins after insertion	118.93±8.84	118.00±8.23	0.622
	5 mins after insertion	121.30±10.10	120.50±7.68	0.691
Mean Diastolic Pressure (mm of Hg)	Baseline	75.90±7.15	79.86±7.61	0.111
	During I-gel insertion	74.80±4.60	71.73±5.20	0.611
	1 min after insertion	75.70±5.50	74.93±7.01	0.54
	3 mins after insertion	76.80±5.84	77.53±6.33	0.59
	5 mins after insertion	79.60±6.51	76.53±5.37	0.271
Mean Arterial Pressure (MAP) (mm of Hg)	Baseline	93.41±6.76	93.61±6.99	0.900
	During I-gel insertion	88.23±5.31	88.25±5.75	0.981
	1 min after insertion	90.64±6.82	90.12±6.05	0.719
	3 mins after insertion	91.87±5.74	91.32±5.10	0.670
	5 mins after insertion	92.30±5.41	92.32±5.64	0.840
Mean Respiratory rate (breathes per minute)	Baseline	16.05±1.21	16.42±1.67	0.064
	During I-gel insertion	15.80±0.96	16.40±1.65	0.062
	1 min after insertion	15.72±0.98	15.60±0.95	0.840
	3 mins after insertion	15.95±1.13	15.55±0.87	0.106
	5 mins after insertion	15.80±0.96	15.57±0.98	0.291
Mean SpO_2 (%)		100	100	100

All the hemodynamic parameters showed little to no changes during I-gel insertion or following one, three- and five-minutes post I-gel insertion in both study groups. This finding is in similar as seen in a study by Jindal P et al, who compared hemodynamic effects of three supraglottic airway devices (SAD) I-gel, LMA and streamlined pharyngeal airway (SLIPA) during general anesthesia with controlled ventilation, with I-gel resulting in least hemodynamic changes during device use.[3]

Graph no. 1: Number of Attempts Taken By Both the Groups



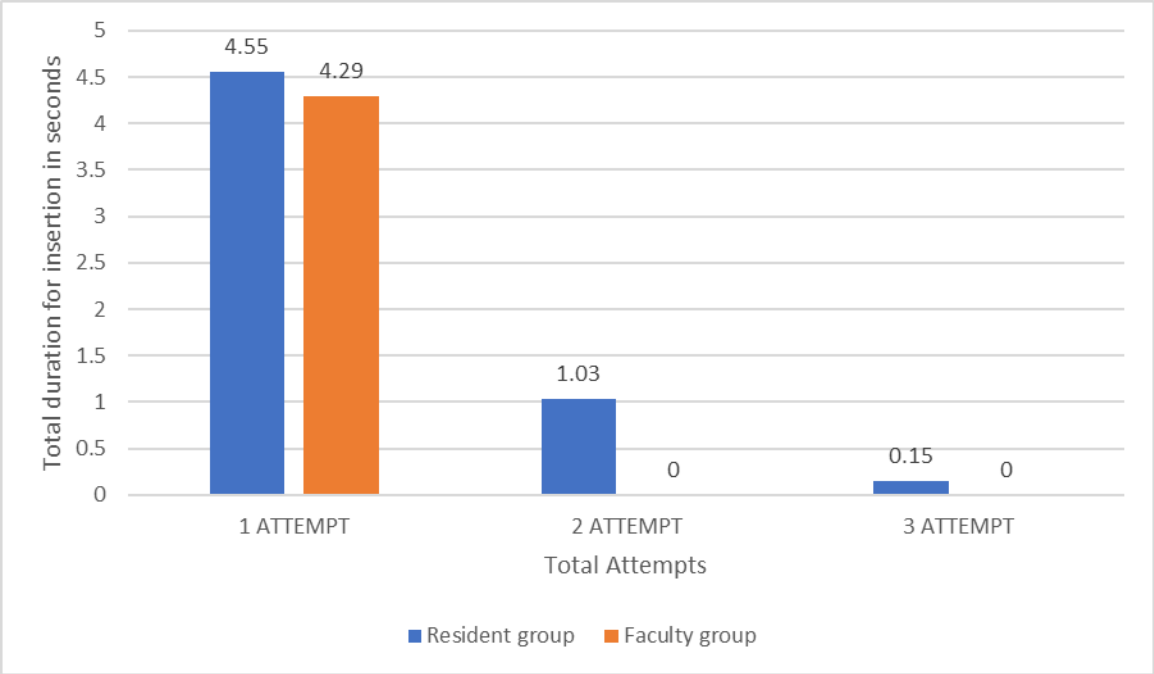
As per the above graph, there were thirty-two successful first attempt insertion and commencement of manual ventilation in the resident group in comparison to all successful first attempt insertion and ventilation in the faculty group.

During our study, all first attempt insertion by the faculty group were successful. In the residents' group, following a tutorial and demonstration of I-gel insertion, in thirty-two cases out of forty, there was successful first attempt I-gel insertion. Followed by seven successful second attempt insertion and only one successful third attempt insertion. This enlightens the ease of I-gel insertion and requirement of virtually no learnt skill or dexterity for successful insertion and positioning for achieving airway patency. In a study carried out by Stroumpoulis K et al, comparing I-gel and classical LMA insertion by experienced and novice physicians in manikins, I-gel performed better than cLMA especially when used by novice physicians.[12]

TABLE 2: Mean Attempt Time Between both the groups

MEAN ATTEMPT TIME	FACULTY	RESIDENTS	T VALUE	P VALUE
1 ATTEMPT	4.29±2.59 seconds	4.55±2.75 seconds	0.435	0.66
2ND ATTEMPT	0	1.03±2.30 seconds	-	-
3RD ATTEMPT	0	0.15 ± 0.96 second	-	-

Graph 2: Mean Attempt Time Taken by Both the Groups:



The average time taken in both faculty and residents' group, from picking up the device to commencement of manual ventilation after first successful insertion was comparably similar, 4.29 seconds and 4.55 seconds respectively, which was not statistically significant. With no events of failed insertion and positioning even after third attempt in either group. Thereby making it safe to say that the use of such an easy to learn device, with virtually no requirement of any advanced skill or training, definitely compares favorably against the skill and experience required to secure airway with tracheal intubation by novice practioners and paramedical staff in both pre-hospital or in-hospital emergency settings.

There were no reports of post I-gel extubation oral mucosal trauma, post operative sore throat or cough or laryngospasm, from either group in our study.

This a single centre study, carried out in a controlled environment with adequate facilities, experienced practitioners and fasted patients, which makes deriving conclusive evidence regarding effective use of I-gel supraglottic airway device by inexperienced practitioners in emergency situations difficult. Thereby necessitating more studies focusing on its effective use in emergency situation, involving patients at a risk of aspiration or with anticipated difficult airway etc., especially by novice practioners to help establish a patent airway.

CONCLUSIONS

I-gel supraglottic airway device is an exceptionally useful tool for both basic as well as advanced airway management. A well-defined preformed shape, no cuff and minimal to virtually no learning curve makes it a good device to secure airway and ensure adequate ventilation and perfusion for the experienced physicians as well as the new recruits.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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ABBREVIATIONS AND SYMBOLS

Symbols & Abbreviations	**Full Form**
ASA	American Society of Anaesthesiologists
cLMA	Classical Laryngeal mask airway
DBP	Diastolic Blood pressure
ECG	Electrocardiography
etc	etcetera
G	Gauge
GA	General Anaesthesia
HR	Heart rate
I.V, or IV	Intravenous
Inj.	Injection
kg	Kilogram

LMA	Laryngeal mask airway
MAP	Mean arterial Blood pressure
mcg Or µg	Microgram
mg	Miligram
SAD	Supraglottic Airway device
SBP	Systolic Blood pressure
SLIPA	streamlined pharyngeal airway
SpO_2	Peripheral Oxygen saturation