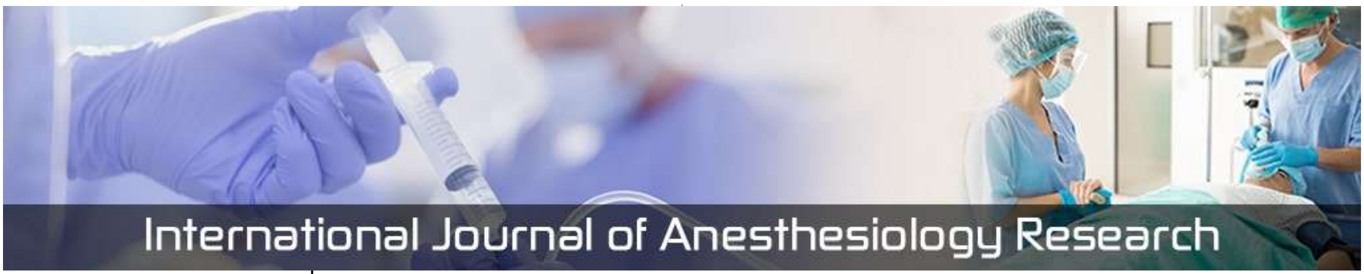

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The effect of head rotation on leak pressure of I-gel masks in paralyzed and anesthetized patients

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Abstract

Background: Supraglottic airway devices are very popular in lieu of tracheal intubation for patients who are under general anaesthesia. Of all these devices, oropharyngeal leak pressure is a useful variable in determining proper positioning, functions and comparison between devices. The I-gel device is used widely thanks to its structure and effectiveness; still, the effects of changes in the head and neck position on this device are studied insufficiently.

Objective: To assess the impact of fixed head and neck rotation on oropharyngeal leak pressure and examine the safety of the I-gel in the lateral head position.

Method: This prospective single group comparative study was carried out in Baghdad Teaching Hospital from the 1st of October to the 1st of June 2022. The patients selected for the study were sixty patients posted for elective surgeries under general anesthesia. Collectively, standardized anesthesia was started with the patient in supine position and the I-gel device was placed in neutral position. Subsequently, only the head was turned in the lateral position for the same parameters including peak airway pressure, leak airway pressure, ETCO2, ventilation scores and fiberoptic views.

Results: Out of 60 patients, 77 percent of the respondent was males, 33.3 percent of the patients was below 30 years old. Leak airway pressure, peak airway pressure and ETCO2 did not show any difference when patient position was changed from neutral to lateral in our study; thus, P= 0.594, P-0.117, and P=0.064 respectively. Likewise there was no significant difference in the ventilation scores and fiberoptic views between the two positions.

Conclusion: This study examines the head and neck rotation from the neutral to lateral position and has shown no compromise on the performance or safety of the I-gel device. The insignificant interconditions changes of measured parameters: leak airway pressure, peak airway pressure, ETCO2, ventilation scores, and fiberoptic views indicate that the I-gel device is dependable during head rotation.

Keywords: I-gel, leak pressure, head rotation, airway management, supraglottic airway device.

Introduction

Anaesthesia is one of the most sensitive procedures in surgical operations, and therefore airway care is one of the most important values in anaesthetic practice since the well-being of the patients depends on it throughout the operations. The upper respiratory system includes several essential structural structures with a of important duties implementing in breathing plus oxygenation. The buccal mucosa surrounds the oral cavity abutted by lips in front, oropharynx in rear, hard and soft palates on upper section and tongue / floor of mouth on the lower section. It shall be noted that upper and lower teeth together with the periodontium form a base or structure of the oral cavity [1]. The oropharynx is a particular area of the muscular structure of human ingestion and digestion, recognised as an essential part of the upper respiratory tract located behind the oral cavity. This include; base of tongue, soft palate, tonsils and the pharyngeal walls, from the uvula to the hyoid bone [2]. It is a cartilaginous structure situated behind the oropharynx the larynx is a structurally and developmentally intricate organ. The principal functions of the cuff are to protect from aspiration into the lower respiratory tract as well as to support phonation. As part of this structure, the cricoid, thyroid, and epiglottis cartilages, as well as the intrinsic muscles have been recognized. Collectively, these cartilages and muscles play the following roles: Structural role and functional role [3-5]. The largest cartilage in the group is the cricoid cartilage that protects the vocal cords and gives the standard appearance of the Adam's apple [6-9]. What could also be observed is that the cricoid cartilage play a major role of forming the inferior portion of the laryngeal skeleton.

Airway management has change significantly over the decade mostly due to development of new SADs. These devices offer a valuable option in general anesthesia, in cases where tracheal intubation is difficult, providing means for ventilation, and oxygenation. It is most useful in emergency situations and in patients that have anatomically challenging airways [11, 12]. SADs are general categorized into first and second generation devices. First generation equipment include the use of a simple airway tubes such as the larynaral mask airway without features aimed at minimizing aspiration. Second generation, like the ProSeal LMA and I-gel contains more newer features like gastric drainage port and epiglottis blockers which both increase safety and efficacy [13-17]. Among these, the I-gel is especially unique because of the innovative design, which was launched in 2007: the mask has a soft, gel-like, non-inflatable cuff made of thermoplastic elastomer. This design does not require cuff inflation to hold tight against the patient's limb, therefore preventing complications consequent to high cuff pressures and compression trauma [24-26]. Moreover, the I-gel is designed with a gastric drainage tube to reduce aspiration and has been designed to allow direct fiberoptic intubation making it ideal for both normal and emergent airway management [27-29].

The I-gel has numerous advantages like easy to slip into place, has minimal effects to the hemodynamic status of patients and decreased incidence of adverse effects such as sore throat, laryngospasm and change in voice [30-35]. Despite the above advantages, researchers have questioned its performance during head and neck positional changes especially in the lateral plane. Such positional changes may change airway mechanics, which may impact parameters that are of paramount importance when using devices, namely oropharyngeal leak pressure which is a direct measure of the position and sealing ability of both the device and the airway [34]. An evaluation of the effects that head and neck rotation have on the aspects of functionality of the I-gel is a crucial aspect of enhancing the utility of this piece of clinical equipment. This study will determine the impact of head and neck rotation on oropharyngeal leak pressure and also seeks to compare the safety and efficiency of the I-gel during general anaesthesia.

Patients and Method

Study design and setting: The present study was a comparative prospective single group study in Baghdad Teaching Hospital / Baghdad / Iraq from the first of October 2021 to the first of June 2022.

Scientific considerations

The study has been suggested and from then on endorsed by the Scientific Council of Anesthesia and Intensive Care of the Arabic Board of Medical Specializations. Following the objectives and the research methodologies used in this study have been explained in detail.

Study population

Sampling: In the current study patients of sixty age and below, of both sexes with the diagnosing disease and who were to undergo elective surgical operation and were to be under general anaesthesia were conveniently sampled.

Inclusion criteria

1. Age of 18-60 years old.
2. Aspirin Administration in American Society of Anesthesiologists (ASA) physical status I and II patients

Exclusion criteria

1. Potential aspiration include patients with history of OSA, possibly have a full stomach also history of GERD.
2. Any neck problem or restriction of neck movement in any direction.
3. Nonspecific upper respiratory tract infection.
4. Any disease, sore or ulcers in the mouth or pharynx.
5. BMI > 35 kg/m2.
6. Head and neck surgery.

Intervention and data collection

A proper history taking and examination were done before addition to the operating room, including:

1. They include the age, sexual reproduction, and history of chronic disease, history of any present illness and the cause of the operation.
2. Analysis of the weight of the patients.
3. Evaluation of the ASA classification.
4. Patients were assessed for Mallampati score by oropharyngeal examination.

In the theater two IV cannulas were inserted, invasive blood pressure, pulse oximetry and ECG were done. This went on and even during the postoperative observation in the recovery ward.

All the patients, gave 8 mg of dexamethasone (IV) and 4 mg of ondansetron (IV). besides, low plasma colloid osmotic pressure (PCOP) was also confirmed, in conjunction with crystalloid fluid (approximately 10 ml/kg) as needed for each patient. Routine intraoperative anaesthesia was with Fentanyl 2 Mcg/kg as analgesia and Propofol 1.5-2.5 mg/kg (IV) (sleeping dose), and atracurium 0.5 mg/kg.

Lungs were then mask ventilated with 3-5% sevoflurane in oxygen for 3 minutes thereafter, a single experienced I-gel mask was placed and size of I-gel depended on body weight of the patient.

Once confirmation was made on the correct location of the device, the impact of different head and neck angles on the device was analyzed. The starting landmark was considered neutral when the external ear canal was at the top of the shoulder and the ear-eyed line from the external ear canal to the superior orbital margin was also vertical; the patient was then turned to maximal rotation to the left side.

In position change, supraglottic airway device was maintained constantly in at neutral position for the subject. Cuff pressure was also kept below 60 cm H2O in the study.

The PAW and LAW were measured at a set of 10 mL, Kg tidal volume in each position as well. Objective measurements were taken right after one minute following head and neck position manipulation.

LAW was set up when the anaesthesia circle breathing system was connected in a bag or in manual position with the final pressure limit valve closed and the continuous gas flow of 3L/minute (GE S/5 anaesthesia delivery system).

Airway pressure was gradually increased (but was not to go over 40 cm H2O) until it leaks and can be heard of the humming sound heard over the mouth or by listening the sound produced thru the stethoscope positioned laterally over the thyroid cartilage. The changes in the safety margin for ventilation with position change were also determined by calculating the differences between the mean LAW and mean PAW (LAW-PAW). The ventilation score was scored from 0 to 3 based on three criteria: no leakage with an airway pressure of 15 cm H2O, bilateral chest excursions with a peak inspiratory pressure of 20 cm of H2O, a square wave capnogram each of which is scored 0 or 1. Therefore if the three has been met then the ventilation score was 3. The specialists observed fibreoptic views. Fibreoptic views were obtained by passing a fibreoptic scope through the airway tube to a position 1 cm proximal to the end of the tube and scored using the Brimacombe score (1: According to the proportion provided by three observers, it was graded as follows: 1: vocal cords cannot be identified 2: only vocal cords plus part of anterior epiglottis, 3: both vocal cords and posterior epiglottis, and 4: only vocal cords are seen [39].

Statistical analysis

All data was inputted and analyzed using the statistical package of social science (SPSS) version 22. These measures of descriptive statistics were presented in forms of frequencies and were used to delineated characteristics of the participants. The inter-group comparison was done using t-test and Chi-Square test. A p level of less than 0.05 indicated statistical significance.

Results

The study was carried out with the participation of sixty patients in total. A little more than half of the participants were male (51.7%), while females made up 48.3% of the sample. This was shown by the gender distribution of the survey participants. In terms of age, around 33.3% of the patients were younger than 30 years old. This is a significant percentage on the whole. Twenty-seven percent of the remaining patients were between the ages of thirty and forty-nine, twenty-three percent were between the ages of forty and forty-nine, and sixteen percent were beyond the age of fifty. A summary of these demographics may be found in Table 3.1, which can be seen below.

Table 3.1: Gender and age distribution of the patients

Gender and Age		N	%
Gender	Male	31	51.7
	Female	29	48.3
Age (years)	<30	20	33.3
	30-39	16	26.7
	40-49	14	23.3
	≥50	10	16.7

Regarding BMI, more than half of the patients had overweight (51.7%), while 6.6% of them were obese (Figure 3.1)

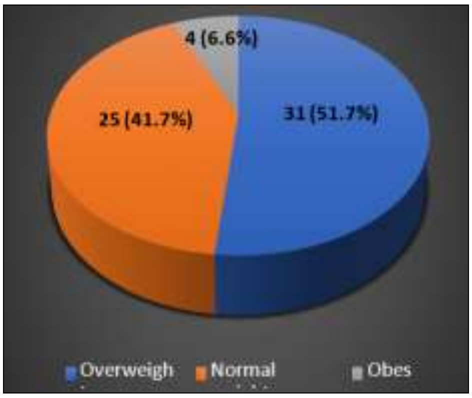

Fig 3.1: Distribution of the body mass index

The inguinal hernia was the most common cause of surgery followed by haemorrhoid, while mastectomy was the last one, as shown in figure 3.2.

Most of the enrolled patients had Mallampati and ASA scores of grade one, as shown in table 3.2.

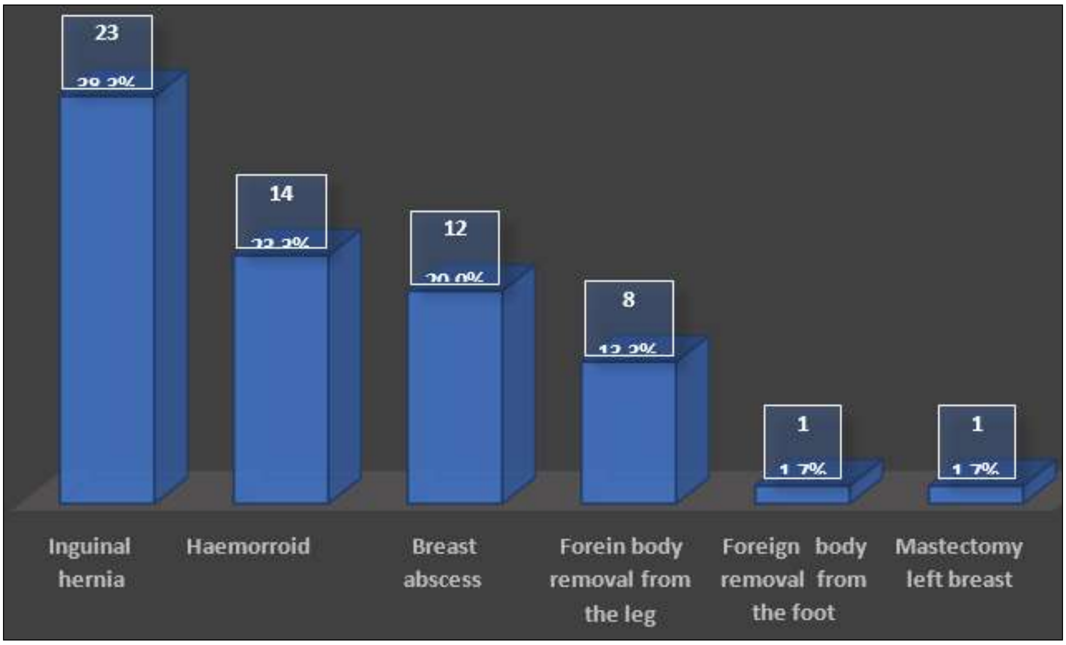

Fig 3.2: Types of surgery

Table 3.2: Mallampati score and American Society of Anesthesiologists score of the patients

Examinations		N	%
Mallampati score	1	33	55.0
	2	27	45.0
American Society of Anesthesiologists	I	41	68.3
	II	19	31.7

The was no significant difference between the neutral and lateral rotation positions regarding the LAW (P-value=0.594), PAW (P-value=0.117), and end-tidal carbon dioxide (EtCO2) (P-value=0.064), as shown in table 3.3.

T-test

No significant differences were obtained in the ventilation score and fiberoptic view between the neutral and lateral rotation positions, as shown in table 3.4

Table 3.3: Distribution of the parameters according to the studied positions

Parameters	Neutral position	Lateral head rotation	P-value
	Mean (±SD)	Mean (±SD)	
Leak airway pressure	20.95 (±1.3)	20.68 (±1.04)	0.594
Peak airway pressure	17.73 (±1.4)	17.9 (±1.1)	0.117
LAW-PAW	2.95 (±1.3)	2.81 (±1.3)	0.306
EtCO2	29.93 (0.98)	29.57 (1.6)	0.064

Table 3.4: Association between ventilation score and fiberoptic view and the position of the I-gel

Parameters		Neutral position	Lateral head rotation	P-value
		N (%)	N (%)	
Ventilation score	2	5 (8.3)	5 (8.3)	0.100
	3	55 (91.7)	55 (91.7)	
Fiberoptic views	2	2 (3.3)	1 (1.7)	0.682
	3	6 (10.0)	5 (8.3)	
	4	52 (86.7)	54 (90.0)	

Chi-Saure test

Fig 3.3: Fibreoptic view

Discussion

Supraglottic airway devices are now employed in more numerous clinical settings than any other application. They are also useful to specialists in anesthesia care to special care babies because they are easy to use. In recent past, currently available 2nd generation market shares were significantly higher and therefore the possibility of practicing on them in clinic is higher. However, several of these devices have not been subjected to systematic real time clinical testing hence efficiency and safety information is scarce [14]. This study was among other studies that were conducted to assess the efficacy and safety of Supraglottic airway devices in variable situations. The main finding of the current study was that there was no statistical significance between the PAW and LAW in the neutral and lateral rotation positions out of the supine position. Similarly the results were found on similar lines by Sandeep *et al.* in their study done in. In India [40]. This concurred with another study that was done by Sanuki, *et al.* in Japan which found it out that Effective ventilation with an I-gel can be performed in patients in whom the head and neck are extended or rotated- [41]. Jun *et al.* also stated that the positioning of the head to either side did not cause any impact on ventilation in patients in the programme of elective surgery under general anaesthesia with an I-gel mask [42]. However, Shreyasi *et al.* observed that the ventilatory performance of the I-gel reduces when the head and neck is extended, right or left laterally flexed and right or left rotated during the procedure in spontaneously breathing patients under general anaesthesia using pressure support ventilation with PEEP. (43) In the present research, EtCO2 was not differential between the neutral and lateral rotation positions. On this, I concur with another study that was conducted by *et al.* Sandeep in India [40]. The same observation was made by Sanuki *et al.* [41] who conducted another study in Japan. The other discovery of the current study was the lack of significant difference between the two study postures in the ventilation score and the fiberoptic views. Similar findings were also presented in other study conducted in India, as well as another study done in another state. [40] This concurred with another study that was conducted in Japan by Sanuki *et al.* [41]. The recent systematic review and meta-analysis was designed to investigate the impact of change in head and neck position on supraglottic airway devices and demonstrated rotation of the head and neck did not affect the performance of supraglottic airway devices [44].

Conclusion

The performance and safety of I-gel were not affected by head and neck rotation from neutral to lateral as there were no significant differences between the two positions regarding LAW, PAW, EtCO2, ventilation score, and fiberoptic views.

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