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Analysing the efficacy of the I-gel supraglottic airway device in the supine and lateral decubitus positions

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Abstract

Background: The advantages of the I-gel supraglottic airway device include ease and speed of insertion, reduced trauma incidence, an integral bite block, gastric access, a non-inflatable cuff and superior seal pressure. The primary goal of this study was to compare airway leak pressures and the fibreoptic view in the supine and lateral positions. Our secondary aim was to analyse the effects of I-gel insertion on haemodynamic parameters.

Methods: One hundred patients undergoing saturation biopsy due to *prostati*c hyperplasia were recruited to this prospective randomised study. *An* I-gel device was inserted in the supine position. Taking of measurements, patients were placed in the lateral decubitus position. Mean arterial pressure, heart rate, peripheral O_2 saturation and end-tidal CO_2 were recorded before and after insertion. We recorded the number of attempts and insertion time for the I-gel device. Oropharyngeal leak pressures and I-gel device positioning were scored in the lateral decubitus and supine positions.

Results: It was possible to insert the I-gel device in 88 patients on the first attempt. The median time for insertion was 7.97 ± 2.18 sec. The mean arterial pressure and heart rate decreased 1 and 2 min after insertion. Oropharyngeal leak pressure was similar in the supine (27.45 ± 5.37 mm Hg) and lateral decubitus positions (26.04 ± 4.92 mm Hg) ($P > 0.05$). On fibreoptic examination through the I-gel device, the scores of patients were comparable in different positions ($P = 0.542$).

Conclusion: As there was no significant difference in oropharyngeal leak pressure and fibreoptic view, we concluded that the I-gel device may be used safely in both the supine and lateral positions.

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Key words: airway device, I-gel; airway device, insertion; positioning

Supraglottic airway devices (SADs), having various advantages such as ease of fit, haemodynamic stability, positive respiratory mechanics and reduced airway morbidity, have a well-established use [1]. Displacement-related compression or trauma risk is significantly low [2]. The I-gel device is quick, easy and consistently reliable to insert [3]. Its non-inflatable cuff, bite-block and gastric drainage channel are the superior features of the I-gel device [4]. Having up to 30 mm Hg pharyngeal seal leak pressure, it provides as many ventilation characteristics as a tracheal tube can offer [5, 6].

The large oval structure of I-gel allows buccal stabilisation and reduces the risk for axial rotation and malposition [7]. Although such advantages of ventilation with the I-gel device are well documented, the effects of body position changes on the device have not been evaluated.

The efficacy of ventilation with SADs changes according to head and neck positions [8–10]. The primary aim of this study was to compare airway leak pressure and fibreoptic view in the supine and lateral positions. Our secondary aim was to analyse the effects of I-gel insertion on haemodynamic parameters.

METHODS

Following the approval of the Ethics Committee and the securing of patients' written informed consents, 100 ASA 1–3 patients above 18 years of age, undergoing saturation biopsy due to prostatic hyperplasia were included in the study. Exclusion criteria included patients with neck or upper airway pathologies and regurgitation of stomach contents or pulmonary aspiration risk. All the anaesthesiologists were experienced in using the I-gel device.

Although we administered 1–3 mg kg^{-1} propofol and 1 µg kg^{-1} remifentanil iv, we did not use any muscle relaxant. When patients were unresponsive to anterior jaw thrust and their eyelash reflexes disappeared, the level of anaesthesia was considered appropriate for I-gel insertion [11]. In anticipation of having difficulty opening the patient's mouth, gagging or coughing, we administered an additional dose of iv propofol (20 mg).

The I-gel device was inserted according to the manufacturer's instructions. Before insertion, the front and back sides of the device were lubricated with a water-based lubricant. We used adult-size 3, 4 or 5 I-gel devices according to the patients' weight. We recorded the number of attempts and the time required for insertion. When we had problems related to insertion, we applied various adjuvant manoeuvres. We used techniques such as head flexion or extension, or slightly pulling or pushing the device. We recorded any additional manoeuvres. The success of the ventilation was determined based on visible chest movements, a square wave capnogram, the provision of tidal volume expired above 7 mL kg^{-1} and SpO_2 above 95%. When insertion or ventilation failed three times in succession, patients were ventilated using a Laryngeal Mask Airway (LMA) Classic. The I-gel device was inserted in the supine position. Blood pressure, heart rate, SpO_2 and end tidal CO_2 values of patients were recorded before and after insertion. The measurements were repeated in the following 1st and 2nd minutes. The position of the I-gel device was evaluated with a fibreoptic bronchoscope passing through the device. The bronchoscope was pushed forward up to 1 cm proximal of the I-gel device and the obtained glottic view scored as follows [12]: only vocal cords can be seen — 4 points; vocal cords and posterior epiglottis can be seen — 3 points; vocal cords and anterior epiglottis can be seen — 2 points; vocal cords cannot be seen — 1 point.

In order to measure the airway leak pressure, ventilation was halted by closing the anaesthetic circuit to the atmosphere. The rise in the airway circuit was recorded using 5 L min^{-1} fresh gas flow until an audible leak occurred or the airway pressure increased and plateaued. The pressure was allowed to reach 40 cm H_2O at maximum [13]. Afterward, the patients were placed in the lateral decubitus position and after the 1st and 2nd minutes, their haemodynamic data, SpO_2, and CO_2 values were measured and the fibreoptic view was obtained for each patient. Surgery could be commenced only after all these measurements had been completed. The oropharyngeal leak pressure was measured in both positions. Data regarding the presence of blood or secretion on the I-gel device, or the occurrence of any complication, were noted. Patients were followed up during the first postoperative 24 hours to monitor any throat, chin or neck pain.

STATISTICAL ANALYSIS

One hundred patients were considered sufficient for the study when the difference between oropharyngeal leak pressures of the supine and lateral positions was accepted max. 2 mm Hg with a standard deviation of 5 mm Hg, alpha= 0.05, beta = 0.8. The standard effect size was assumed to be 0.40.

Statistical analyses were conducted using the SPSS program version 21.0. The mean, standard deviation, ratio, and frequency values were used for the descriptive statistics of the data. The distribution of variables was tested using the Kolmogorov- Smirnov test. Quantitative data was analysed with the paired-sample t-test and the Wilcoxon test while the qualitative data was analysed using McNemar's test. $P < 0.05$ was considered statistically significant.

RESULTS

One hundred and ten male patients meeting the inclusion criteria were included to the study. Two of them did not give their approval to participate in the study while 8 other patients could not be ventilated efficiently with the I-gel device. In total, data for 100 patients were statistically analysed. The median age was 65 years (range 44 to 84 years) while the median body mass was 81 kg (range 50 to 110 kg). We obtained 24 prostate biopsies from all patients in the lateral decubitus position.

There no significant difference between patients regarding their demographic data (Table 1). The average time required for I-gel insertion was 7.97 ± 2.18 seconds. It was possible to insert the I-gel device in 9 patients on the 2nd attempt, and in 3 patients on the 3rd attempt. The mean arterial pressure and heart rate in the supine position during the 1st and 2nd minutes of the preoperative period was significantly higher than the measurements conducted in the lateral decubitus position ($P < 0.05$). There was no significant difference between two positions in terms of peripheral oxygen saturation and end tidal CO_2 values (Table 2).

While the median oropharyngeal leak pressure was found to be 27.45 ± 5.37 mm Hg in the supine position, it was 26.04 ± 4.92 mm Hg in the lateral decubitus position ($P > 0.05$). The fibreoptic view through the I-gel device did not indicate any difference between two positions ($P = 0.542$, Table 3). Although we identified blood on the I-gel device in

Table 1. Patients' demographics (mean ± SD). No significant differences were confirmed

Age (years)	65.16 ± 7.56
Body mass (kg)	81.28 ± 10.77
Height (cm)	169.5 ± 29.61

Table 2. Comparison of perioperative parameters in supine position (mean ± SD)

		Supine	*P*-value
Mean arterial pressure (mm Hg)	T_1	91.89 ± 16.33	
	T_2	84.35 ± 12.84	< 0.05
	T_3	79.39 ± 13.02	< 0.05
Heart rate (min^{-1})	T_1	78.52 ± 11.44	
	T_2	74.98 ± 11.60	< 0.05
	T_3	73.65 ± 11.77	< 0.05
Peripheral O_2 saturation (%)	T_1	99.00 ± 1.05	0.262
	T_2	98.83 ± 1.08	0.051
	T_3	98.56 ± 1.08	0.183
End tidal CO_2 (mm Hg)	T_1	32.90 ± 2.51	0.128
	T_2	32.43 ± 2.43	0.226
	T_3	31.70 ± 2.49	0.106

T_1: Before induction
T_2: 1. min after insertion
T_3: 2. min after insertion

two patients, once it had been pulled out, we did not come across any other complications. No significant complaint was observed for the presence of throat pain. None of the patients required additional analgesics.

DISCUSSION

In this prospective clinical trial, we analysed the efficacy of the I-gel supraglottic airway device on 100 individuals undergoing prostate biopsy without a muscle relaxant. There was no significant difference in oropharyngeal leak pressure and fibreoptic view when the patient's position was changed from supine to lateral while patients could be ventilated with a sufficient amount of tidal volume.

The I-gel device was well tolerated by patients both during anaesthesia and emergence from anaesthesia. Therefore, using the I-gel device in patients under anaesthesia, both for controlled ventilation and spontaneous breathing, seems to be appropriate. In this study, the successful insertion rate for the I-gel device was 92%, 88% of which was inserted successfully on the first attempt. The I-gel device provided airway approximately in 8 seconds. As the anaesthesiologists taking part in the study comprised experienced anaesthetists using the I-gel device frequently in practice, this factor may have increased the speed and success of insertion. In a previous study carried out with

Table 3. Evaluation of the I-gel device position using fibreoptic bronchoscope passing through the I-gel device

Scores	Supine	Lateral decubitus
1	n = 4 (4.0%)	n = 5 (5.1%)
2	n = 21 (21.2%)	n = 15 (15.2%)
3	n = 44 (44.4%)	n = 49 (49.5%)
4	n = 30 (30.3%)	n = 30 (30.3%)

anaesthetists who were inexperienced in I-gel insertion and who placed the I-gel device after 10 attempts, the median time required for ventilation was reported approximately 15 seconds [11]. However, another study has asserted the contrary by stating that one's experience has no impact, either on the time to achieve ventilation or the success rate of insertion [2]. Nevertheless, as the latter is a manikin study, its results should be supported with more clinical trials before being adopted into clinical practice. On the other hand, the I-gel device was applied both on manikins and patients in another study while the insertion time differed by approximately 3.5 seconds between two groups [14].

While the mean leak pressure was measured at 27.4 mm Hg in the supine position, this figure decreased to 26.0 mm Hg in the lateral decubitus position. However, this decrease did not create any clinical difficulty in ventilation and patients could be continuously ventilated. Patients were evaluated according to the data on sufficiency of tidal volume, appropriate chest movements and stable oxygen saturation. Considering that the mean leak pressure obtained in previous studies from the patients placed in the supine position was 23.7 mm Hg [15] or 20 mm Hg [16], the leak pressure obtained from our study is higher. However, unlike other studies, our study compared the supine and lateral positions. To the best of our knowledge, this is the first study comparing the efficacy of the I-gel device in the supine and lateral decubitus positions regarding patients receiving general anaesthesia without any muscle relaxant. Sanuki *et al.* [8] conducted a study on various head positions. As their 20-patient series indicated that head and neck flexion has more negative effects on ventilation scores as compared to the neutral position, it was argued in the same study that flexion should be avoided for patients ventilated with the I-gel device. In contrast to this study, we did not come across any significant difficulty in ventilating patients receiving a little head and neck flexion in the lateral decubitus position.

The mean arterial pressure and heart rate at 1st and 2nd minutes after I-gel insertion were found to be significantly lower in the supine position. We concluded that it corresponds to the time when sufficient depth of anaesthesia was provided for the patient.

In line with the data in the literature [17], the I-gel device was inserted with a high success rate on the first attempt in our study. Contrary to the suggestion made by Amini and Khoshfetrat [18], we made a third attempt for the patients who could not be ventilated with the I-gel device on the 1st and 2nd attempts. Thus, it was possible to ventilate three patients successfully on the 3rd attempt using the I-gel device. However, all patients who could not be ventilated with I-gel device were ventilated using the Laryngeal Mask Airway Classic; therefore, we did not need to apply another SAD or tracheal intubation. Even though all the anaesthetists were experienced in I-gel insertion, they had more experience with the LMA classic. We believe that their experience with the LMA classic contributed to the successful provision of the airway with the LMA device in patients who could not be ventilated using the I-gel device.

Analysing the fibreoptic view through the I-gel device provided an acceptable view of the vocal cords. The view of vocal cords was at the level of Grade 3 and 4 for 74% of the patients in the supine position and 79% of the patients in the lateral decubitus position. According to the size of these rates we concluded that the I-gel device may be used comfortably in different anatomical positions. On the other hand, there should be further studies including more subjects to properly reflect these data into clinical practice.

LIMITATIONS

This study has some limitations which need to be stated. As the study population was composed of only male patients, it cannot provide information on females. Additionally, although sore throat and discomfort have been reported to be more common in females, there is no evidence supporting the idea that gender affects the success rate or leak pressure [19].

CONCLUSION

The results of the study suggest that the I-gel device is an airway device offering reliable and quick insertion. As there was no significant difference in oropharyngeal leak pressure and fibreoptic view, we concluded that the I-gel device may be used safely in both the supine and lateral positions.

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