An Interventional Randomized Study to Evaluate a new Supraglottic Airway Device (I-gel) in Comparison with the Classical LMA

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Abstract: Background: This prospective, randomized controlled clinical trial was done to compare the newer supraglottic airway device (SGD) I-gel with the LMA-classic.

Materials and methods: Sixty adult patients of 18-60 years age group were enrolled. The patients were randomly divided into two groups, in group 1, I-gel and in group 2, LMA-C was inserted. Both group evaluated regarding the hemodynamic stability, ease of insertion, number of attempts and airway manipulations required during insertion, time required for insertion of the SGD and adverse events occurring intra-operatively and post-operatively.

Result: I-gel is better than LMA in all parameters measured with fewer complications.

Conclusion: I-Gel can be used as a better alternative to the LMA-C.

Keywords: Randomized controlled trial, I-Gel, LMA-Classic, supraglottic airways

Introduction:

Supraglottic devices are useful advent in the airway management, filling a niche between the facemask and tracheal tube in terms of both the anatomical position and the degree of invasiveness. It is easy to insert them blindly into the hypopharynx to form a seal around the larynx and have an important role in the management of difficult intubation and failed intubation. Laryngoscopy and muscle relaxation are not necessary for the insertion of supraglottic device. As it avoids invasion of vocal cords, incidence of injury inside the oral cavity and the occurrence of sore throat also decreases. These devices are better tolerated than the tracheal tube at 'lighter' levels of anaesthesia and have minimal cardiovascular response. They can be inserted in awake as well as anaesthetized patients with or without using muscle relaxant. The I-Gel is a new, single use, non-inflatable supraglottic airway for use in anaesthesia during spontaneous or intermittent positive pressure ventilation. The shape, softness and contours accurately mirror the perilaryngeal framework itself and create the perfect fit. As it has no inflatable cuff, it has several potential advantages including easier insertion, minimal risk of tissue compression, stability after insertion and an integrated gastric channel is provided for gastric suction for passage of nasogastric tube to empty the stomach. The objective of our study was to compare two supraglottic devices, classic LMA and I-Gel for ease of insertion, position within the airway, ease during mechanical ventilation, hemodynamic parameters before, during and after insertion and postoperative complications in anaesthetised patients undergoing elective surgical procedures.

Materials and methods:
Sixty patients of either sex in the age group of 18-60 years were selected randomly. Patients were divided into two groups comprising of thirty patients each and comparison was made between LMA-C Classic and I-Gel supraglottic device. In group 1, I-gel and in group 2, LMA-C was inserted. The hemodynamic stability, ease of insertion, number of attempts & time required for insertion and airway manipulation required for insertion were
noted. After insertion, pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, SpO2 & EtCO2 were noted at different time intervals. Anesthesia was maintained with 66% N2O with O2 and isoflurane 0.5 - 1% and muscle relaxation was provided with vecuronium. Insertion of nasogastric tube was done through the gastric channel of the I-gel using appropriate size of nasogastric tube.

Adequacy of oxygenation was determined as SpO2 >95% and adequacy of ventilation was defined as EtCO2 between 30-40 mmHg. At the end of surgery, neuromuscular blockade was reversed with Neostigmine 50 mcg/kg and Glycopyrrolate 8 mcg/kg IV. After suctioning from the hypopharynx and once the consciousness was regained, patients were asked to open their mouth and device was removed after the protective reflexes had returned.

The devices were examined for the presence of blood on it and any adverse events occurring post-operatively were noted. The statistical analysis was done using EPI INFO software using the "two tailed students 't' test for unequal variance." the difference was considered to be statistically significant when p<0.05 and highly significant when p<0.01.

Results:
The demographic data of both the groups was comparable. In both the groups pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure remained below the baseline values and remained lower in the I-Gel group compared to the LMA-C group throughout the observation period.

A significantly higher pulse rate was noted in LMA-C group at 3 min following insertion as compared to the I-Gel group (p<0.05). The difference in mean systolic blood pressure was significant at 1 & 3 min after insertion (p<0.05) and in mean diastolic pressure, it was significant at 5 min after insertion (p<0.05), where it was higher for the LMA-C group. The MAP was comparable in both the groups throughout the observation period (p>0.05).

There was no statistically significant difference in SpO2, EtCO2 and they remained within normal limits (p>0.05), chest compliance and ease of IPPV were adequate in both the groups.

The insertion of the I-Gel required less attempts and less airway manipulation as compared to LMA-C. Insertion of I-gel was possible in single attempt in all 30 patients whereas, in the LMA-C group it was possible in 27 patients while 2 patients required 2 attempts and 1 patient required 3 attempts for insertion. Manoeuvres for airway manipulation like jaw lift, adjusting head and neck position and twisting, rotating or reinsertion of the device were not needed in 20 patients of I-Gel group and one manoeuvre was needed in remaining 10 patients. In the LMA-C group, 6 patients did not require any airway manipulation, 17 patients needed one, 2 patients needed two and 1 patient needed three manoeuvres. I-Gel was easy to insert in 100% patients as compared to 78.33% patients in LMA-C, I-Gel required less time for insertion (8.26±2.88 sec) as compared to the LMA-C (25.13±31.71 sec).

One patient of the I-Gel group developed bradycardia (pulse< 60/min) intra-operatively. I-Gel insertion was associated with less post-operative complications like sore throat (3.33%) as compared to the LMA-C (20%). I-Gel did not show staining of device with blood and tongue, lip or dental trauma whereas; it was seen in 13.33% and 10% of the patients of the LMA-C group respectively. None of the patients in the I-Gel group experienced cough, hoarseness of voice and vomiting whereas, it was seen in 6.66%, 3.33% and 6.66% of the patients of the LMA-C group respectively.

Conclusion:
Thus it can be concluded from the study that the I-gel is easy to insert with less airway manipulations, requiring less time and attempts for insertion, maintaining better hemodynamic stability following insertion and causing less post-operative complications compared to the LMA-C.

The I-Gel can be used as a better alternative to the LMA-C.

Key Words:
randomized controlled trial, I-Gel, LMA-Classic, supraglottic airways

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