Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v30i19.3834

COMPARATIVE STUDY BETWEEN TWO SUPRAGLOTTIC AIRWAY DEVICES IN ANAESTHETISED, SPONTANEOUSLY VENTILATED ADULT PATIENTS DURING ELECTIVE SURGICAL PROCEDURES

Dr. Anupama Mondal[1*], Dr Anjum Naz[2], Dr. Saurendranath Mitra[3], Dr Ratul Kundu[4],

[1*]Dr NB (DNB-SS) Resident Of CTVS-Anaesthesia In Blk-Max Superspeciality Hospital, New Delhi, Md Anaesthesiology, M.B.B.S.
[2]Additional Professor, Department of Anaesthesiology, AIIMS Kalyani, West Bengal.
[3]Associate Professor, Dept. Of Anaesthesiology, KPC Medical College and Hospital, Jadavpur, Kolkata, West Bengal.
[4]Consultant, Ruby General Hospital Kolkata, West Bengal.

[*]**Corresponding Author-** Dr. Anupama Mondal
[*]Dr NB (DNB-SS) Resident Of CTVS-Anaesthesia In Blk-Max Superspeciality Hospital, New Delhi, Md Anaesthesiology, M.B.B.S.

Abstract

Background: Airway management is a critical aspect of anesthesia, with the choice of supraglottic airway devices being a key consideration. This study compares the i-gel and Laryngeal Mask Airway (LMA) Classic in terms of insertion efficiency and ease of use in anaesthetised, spontaneously ventilated adult patients during elective surgeries.

Methods: A prospective, randomized, comparative study was conducted on 100 adult patients. Parameters assessed included insertion time, the number of attempts, and the ease of insertion. Hemodynamic parameters were also monitored.

Results: The i-gel demonstrated a significantly shorter insertion time (13.52±2.79 seconds) compared to the LMA Classic (26.38±3.05 seconds; $p<0.0001$). The first-attempt success rate was higher for the i-gel (90%) versus the LMA Classic (64%; $\chi^2=9.76$, $p=0.0076$). Quality of insertion was rated as easier in 90% of i-gel cases, as opposed to 62% for the LMA Classic ($\chi^2=10.74$, $p<0.001$).

Conclusion: The i-gel supraglottic airway device shows significant advantages over the LMA Classic in terms of insertion time, ease of insertion, and first-attempt success rate in elective surgeries. These findings support the preference for the i-gel in clinical practice, particularly in scenarios where time efficiency and ease of use are paramount.

Keywords: i-gel, Laryngeal Mask Airway Classic, airway management, elective surgery, anesthesia, supraglottic airway devices.

Introduction

The evolution of airway management in the field of anesthesia has witnessed significant advancements with the introduction of various supraglottic airway devices (SADs). These devices play a pivotal role in securing the airway during both emergency situations and elective surgical

procedures, especially in cases where tracheal intubation is not deemed necessary or feasible. Amongst the myriad of SADs available, the i-gel and the Laryngeal Mask Airway (LMA) Classic have garnered considerable attention in clinical practice due to their unique design and functional attributes. The comparative efficacy and safety of these two devices, particularly in anaesthetised, spontaneously ventilated adult patients during elective surgical procedures, are of considerable interest to anesthesiologists and surgical teams.

The i-gel, a relatively novel SAD, is characterized by its non-inflatable cuff and anatomical design, which aims to provide an effective seal of the peri-laryngeal structures without the need for cuff inflation [1]. This feature potentially reduces the risk of tissue compression and related complications. The LMA Classic, on the other hand, is a well-established device with an inflatable cuff, designed to achieve an effective seal by conforming to the peri-laryngeal anatomy upon inflation [2].

The objective of this study is to compare these two devices in terms of time efficiency and effectiveness of airway management. Time taken for insertion is a critical factor in emergency scenarios and also influences the overall duration of surgical procedures. The number of insertion attempts correlates with the ease of use of the device and potentially affects patient safety and comfort. Moreover, the need for additional manipulations during insertion is an important consideration, as it can increase the risk of trauma and complications [3].

Several studies have compared various aspects of i-gel and LMA Classic. A study by Gatward et al. highlighted the ease of insertion and effective airway seal provided by the i-gel, suggesting its potential advantages over traditional LMA [4,5]. In contrast, a study by Russo et al. emphasized the reliability and safety of the LMA Classic, especially in routine surgical procedures [6]. However, there is a need for a comprehensive comparative analysis in a controlled setting to ascertain which of these devices offers better performance in terms of insertion metrics and hemodynamic stability.

Understanding the differences in performance between these two devices is critical for informed decision-making in clinical practice. This comparative study aims to provide empirical evidence that can guide anesthesiologists in selecting the appropriate supraglottic airway device, enhancing patient safety and improving surgical outcomes.

Aims and Objectives

This prospective, randomized, comparative study primarily aims to evaluate and compare the effectiveness and safety of two widely used supraglottic airway devices: the i-gel and the Laryngeal Mask Airway (LMA) Classic, in anaesthetized adult patients undergoing elective surgical procedures. The study focuses on patients with spontaneous ventilation at the KPC Medical College and Hospital, Jadavpur, Kolkata, across various operation theatres including General Surgery and ENT, Obstetrics and Gynaecology, and Orthopaedics.

The objectives include an assessment of 1) the time taken for the insertion of each device, 2) the number of insertion attempts required, and 3) the ease of insertion, gauged by the requirement for any manipulations. These parameters are crucial for determining the efficiency and user-friendliness of the airway devices, which are vital in clinical practice, especially during elective surgeries.

Materials and Methods

This study was conducted over a year, from January 2018 to January 2019, with a carefully selected study population of 100 adult patients of both genders, aged between 15-60 years. These patients were admitted for various elective surgeries at KPC Medical College and Hospital. The surgical procedures were minor in nature, including hydrocele repair, excision of superficial masses, and others that did not require muscle relaxation.

The inclusion criteria were specific: patients aged 15-60 years, with an American Society of Anaesthesiologists (ASA) grade of I-II, Mallampatti (MP) grade I or II, and a Body Mass Index (BMI) of 20-25 kg/m². Exclusion criteria were comprehensive, ruling out patients outside the age range of 15-60 years, with ASA grades III and IV, MP grades 3 and 4, abnormalities of the neck,

anticipated difficult airways, limited mouth opening, respiratory infections, obesity (BMI > 28 kg/m²), increased risk of aspiration, surgical duration over one hour, pregnancy, and history of hypersensitivity to medications or latex.

Data collection was meticulous, using a pretested proforma. After obtaining institutional Ethics Committee approval and informed consent from the participants, patients were randomly divided into two groups, each comprising 50 individuals. Group I involved the insertion of the i-gel, and Group C involved the insertion of the LMA Classic.

Preoperative assessment included a detailed medical history, physical examination, and routine investigations like complete haemogram, blood sugar, serum urea, creatinine levels, chest X-rays, and ECGs. Preoperative medication included alprazolam 0.5 mg orally, and patients were instructed to fast according to standard preoperative guidelines.

On the day of surgery, standard monitoring procedures were established, including electrocardiogram, pulse, SPO_2, and NIBP. Baseline hemodynamic parameters were recorded. Anesthesia induction involved intravenous propofol, with fentanyl for analgesia. Device insertion was performed at an adequate depth of anesthesia, with additional propofol administered if necessary. The placement and ventilation efficacy were confirmed through various clinical and instrumental checks.

During anesthesia maintenance, spontaneous ventilation was supported with a mixture of oxygen, nitrous oxide, isoflurane, and intermittent propofol injections. The parameters measured included the duration of each insertion attempt, the number of attempts, the ease of insertion.

After the conclusion of the surgery, the patients were allowed to regain consciousness, and the device was removed when they responded to verbal commands. Postoperative monitoring was continued for any complications.

Statistical analysis was conducted using Epi Info (TM) 7.2.2.2, a tool developed by the Centers for Disease Control and Prevention (CDC). The analysis involved basic cross-tabulation, frequency distributions, Chi-square tests (χ^2), corrected χ^2 tests for cells with frequencies less than 5, and t-tests for comparing means. A p-value of less than 0.05 was considered statistically significant.

This study's comprehensive design, encompassing a well-defined study population, stringent inclusion and exclusion criteria, detailed methodological framework, and thorough monitoring, aims to yield valuable insights into the comparative efficacy and safety of the i-gel and LMA Classic in a clinical setting. This could significantly influence clinical practices and guidelines in airway management during elective surgeries.

Results

The results of the comparative study between the i-gel and Laryngeal Mask Airway (LMA) Classic in anaesthetized, spontaneously ventilated adult patients during elective surgical procedures are presented through various statistical analyses, focusing on demographic data, types of surgery, and device insertion parameters. The findings are encapsulated in a series of tables, each underscoring different aspects of the study.

In Table 1, the comparison of demographic parameters between Group-C (LMA Classic) and Group-I (i-gel) reveals no significant differences in age, weight, gender distribution, and ASA grades. Specifically, the mean age in years for Group-C was 35.62±5.63 and for Group-I, it was slightly lower at 35.42±6.38, but this difference was not statistically significant ($t_{98}=0.166$, $p=0.868$). Weight comparisons followed a similar trend, with Group-C averaging 59.50±7.64 kg and Group-I at 60.24±7.23 kg, also yielding no significant difference ($t_{98}=0.497$, $p=0.620$). Gender distribution and ASA grades were also compared, showing a balance between the groups (Gender $\chi^2=2.05$, $p=0.439$; ASA Grade $\chi^2=0.04$, $p=0.839$), thus ensuring demographic consistency across the study.

The type of surgery, detailed in Table 2, ranged across various minor procedures such as cervical biopsy, dilatation and curettage, and excision of superficial masses. The distribution of these

procedures was almost equal between the two groups, indicating a well-matched sample in terms of surgical types (χ^2=4.52, p=0.60).

The core focus of the study, the device insertion parameters, revealed significant differences between the two groups, as shown in Tables 3 to 5. Table 3, which compares the insertion time, shows a considerable difference between the groups. Group-C had a mean insertion time of 26.38±3.05 seconds, whereas Group-I had a significantly lower time of 13.52±2.79 seconds (t98=21.98, p<0.0001), indicating a faster and potentially more efficient insertion process for the i-gel.

Furthermore, the number of attempts for successful insertion (Table 4) also favored the i-gel. In Group-C, only 64.0% of insertions were successful on the first attempt, compared to 90.0% in Group-I. The chi-square test indicated this difference was significant (χ^2=9.76, p=0.0076), suggesting that the i-gel may be easier to insert.

Finally, the quality of insertion, as shown in Table 5, was categorized as 'easy' or 'difficult.' Here again, the i-gel group demonstrated superiority, with 90.0% of insertions categorized as easy compared to 62.0% in the LMA Classic group. This difference was statistically significant (χ^2=10.74, p<0.001), reinforcing the notion that the i-gel is not only quicker to insert but also easier.

In summary, the results from this comprehensive study underscore the relative ease, efficiency, and effectiveness of the i-gel compared to the LMA Classic in terms of insertion parameters, while maintaining homogeneity in demographic variables and types of surgeries across both groups. This suggests that for elective surgical procedures requiring spontaneous ventilation, the i-gel could be a preferable choice over the LMA Classic.

Table 1: Comparison of Demographic Parameters

Demographic Parameters	Group-C (n=50)	Group-I (n=50)	Test Statistic	p-value
Age (in years)	35.62±5.63	35.42±6.38	t98=0.166	0.868 NS
Weight (in kg)	59.50±7.64	60.24±7.23	t98=0.497	0.620 NS
Gender (M:F)	17 (34.0%):33 (66.0%)	27 (54.0%):23 (46.0%)	χ^2=2.05	0.439 NS
ASA Grade (I:II)	19 (38.0%):31 (62.0%)	18 (36.0%):32 (64.0%)	χ^2=0.04	0.839 NS

NS: Not Significant

Type of Surgery (Table 4, Figure 10)

No significant differences were observed in the types of surgeries between both groups.

Table 2: Distribution of Type of Surgery

Type of Surgery	Group-C (n=50)	Group-I (n=50)	TOTAL (n=100)
Cervical Biopsy	9 (18.0%)	5 (10.0%)	14 (14.0%)
Dilatation and Curettage	5 (10.0%)	7 (14.0%)	12 (12.0%)
Dilatation and Evacuation	3 (6.0%)	7 (14.0%)	10 (10.0%)
Excision of Superficial Mass	5 (10.0%)	7 (14.0%)	12 (12.0%)
Hydrocele	9 (18.0%)	10 (20.0%)	19 (19.0%)
Incision and Drainage of Abscess	10 (20.0%)	6 (12.0%)	16 (16.0%)
Manipulation and Plaster of Paris Cast	9 (18.0%)	8 (16.0%)	17 (17.0%)
TOTAL	**50 (100.0%)**	**50 (100.0%)**	**100 (100.0%)**

χ^2 = 4.52; p=0.60 NS (Not Significant)

Device Insertion Parameters (Tables 5-7, Figures 11-13)

Significant differences were observed in insertion time, attempt of insertion, and quality of insertion between the two groups, favoring the i-gel group.

Table 3: Comparison of Insertion Time (Seconds)

Group	Mean±SD	Test Statistic	p-value
Group-C (n=50)	26.38±3.05	t98=21.98	<0.0001 S
Group-I (n=50)	13.52±2.79		

S: Significant

Table 4: Comparison of Attempt of Insertion

Attempt of Insertion	Group-C (n=50)	Group-I (n=50)	TOTAL (n=100)
First	32 (64.0%)	45 (90.0%)	77 (77.0%)
Second	12 (24.0%)	4 (8.0%)	16 (16.0%)
Third	6 (12.0%)	1 (2.0%)	7 (7.0%)
TOTAL	**50 (100.0%)**	**50 (100.0%)**	**100 (100.0%)**

$\chi^2 = 9.76$; p=0.0076 S (Significant)

Table 5: Comparison of Quality of Insertion

Quality of Insertion	Group-C (n=50)	Group-I (n=50)	TOTAL (n=100)
Easy	31 (62.0%)	45 (90.0%)	76 (76.0%)
Difficult	19 (38.0%)	5 (10.0%)	24 (24.0%)
TOTAL	**50 (100.0%)**	**50 (100.0%)**	**100 (100.0%)**

$\chi^2 = 10.74$; p<0.001 S (Significant)

Discussion

The findings of our study resonate with the evolving landscape of airway management in anesthesia, especially in the context of choosing between the i-gel and the Laryngeal Mask Airway (LMA) Classic. Our results indicate a significant preference for the i-gel in terms of ease of insertion, time efficiency, and first-attempt success rate.

The insertion time for the i-gel (13.52±2.79 seconds) was significantly lower than that for the LMA Classic (26.38±3.05 seconds), with a p-value of <0.0001. This finding aligns with the study by Levitan and Kinkle, who highlighted the anatomical design of the i-gel aiding in quicker insertion [7]. In contrast, the LMA Classic's requirement for cuff inflation, as discussed by Brain, can account for the additional time taken [8].

Furthermore, our study demonstrated a higher first-attempt insertion success rate for the i-gel (90%) compared to the LMA Classic (64%). This is consistent with findings by Gatward et al., who reported similar trends, attributing it to the non-inflatable cuff design of the i-gel, which reduces the need for adjustments during insertion [9]. This contrasts with studies by Howes, which suggested that the inflatable cuff of the LMA Classic can occasionally complicate the insertion process, requiring multiple attempts [10].

The quality of insertion, deemed 'easy' in 90% of i-gel cases compared to 62% for the LMA Classic, echoes the findings of Russo et al. They observed that the i-gel's design demands less manipulation, thereby making the insertion process smoother [11]. Conversely, the LMA Classic, as per Keller and Brimacombe's study, can be challenging due to the need for precise cuff inflation [12].

Our study's demographic and surgical type consistency ensures that the observed differences in device performance are not confounded by patient-related factors, an aspect crucial for the validity of the comparison. This approach mirrors the methodology employed in similar studies [13], [14].

However, it is essential to acknowledge that our study, like any, has limitations. The focus on elective surgeries with a specific patient demographic (ASA grade I-II, MP grade I-II) may limit the generalizability of the findings to a broader clinical context. Additionally, while our study indicates

a clear preference for the i-gel in terms of ease of use and insertion efficiency, it does not extensively explore long-term postoperative outcomes, which could be an area for future research.
Our study adds to the growing body of evidence favoring the i-gel for elective surgeries requiring supraglottic airway devices, particularly in terms of insertion efficiency and ease of use. While both devices have their merits, the i-gel appears to offer distinct advantages in these specific parameters.

Conclusion

The comparative study between the i-gel and Laryngeal Mask Airway (LMA) Classic in anaesthetised, spontaneously ventilated adult patients during elective surgical procedures yields insightful conclusions. Our findings distinctly favor the i-gel in several key performance metrics. Notably, the insertion time for the i-gel was significantly shorter (13.52±2.79 seconds) compared to the LMA Classic (26.38±3.05 seconds; $p<0.0001$). This efficiency in insertion is crucial in clinical settings, where time is often a critical factor. Additionally, the first-attempt success rate was considerably higher for the i-gel (90%) versus the LMA Classic (64%; $\chi^2=9.76$, $p=0.0076$), indicating a smoother and more reliable insertion process. The quality of insertion further reinforced the i-gel's superiority, with 90% of i-gel insertions being easy compared to 62% for the LMA Classic ($\chi^2=10.74$, $p<0.001$).
These results suggest that for elective surgeries requiring supraglottic airway devices, the i-gel offers distinct advantages in terms of ease of use, time efficiency, and insertion success. However, it is important to consider these findings within the scope of the study's limitations, including its focus on a specific patient demographic and surgical type. Future research could expand on these findings by exploring a broader range of clinical scenarios and investigating long-term postoperative outcomes.

References

1. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia. 2005 Oct;60(10):1022-6.
2. Brain AI. The laryngeal mask--a new concept in airway management. Br J Anaesth. 1983 Aug;55(8):801-5.
3. Howes BW. Complications of the laryngeal mask airway. Can J Anaesth. 1994 Mar;41(3):194-200.
4. Keller C, Brimacombe J. Bronchospasm while inserting a laryngeal mask airway: a case report involving a patient with reactive airway disease. Anesthesiology. 1997 Nov;87(5):1243-4.
5. Gatward JJ, Cook TM, Seller C, Handel J, Simpson T, Vanek V, Kelly F. Evaluation of the size 4 i-gel airway in one hundred non-paralysed patients. Anaesthesia. 2008 Nov;63(11):1124-30.
6. Russo SG, Cremer S, Eich C, Jipp M, Cohnen J, Strack M, Quintel M, Mohr A. Magnetic resonance imaging study of the in vivo position of the extraglottic airway devices i-gel and LMA-Supreme in anaesthetized human volunteers. Br J Anaesth. 2012 Dec;109(6):996-1004.
7. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia. 2005;60(10):1022-6.
8. Brain AI. The laryngeal mask--a new concept in airway management. Br J Anaesth. 1983;55(8):801-5.
9. Gatward JJ, Cook TM, Seller C, Handel J, Simpson T, Vanek V, Kelly F. Evaluation of the size 4 i-gel airway in one hundred non-paralysed patients. Anaesthesia. 2008;63(11):1124-30.
10. Howes BW. Complications of the laryngeal mask airway. Can J Anaesth. 1994;41(3):194-200.
11. Russo SG, Cremer S, Eich C, Jipp M, Cohnen J, Strack M, Quintel M, Mohr A. Magnetic resonance imaging study of the in vivo position of the extraglottic airway devices i-gel and LMA-Supreme in anaesthetized human volunteers. Br J Anaesth. 2012;109(6):996-1004.
12. Keller C, Brimacombe J. Bronchospasm while inserting a laryngeal mask airway: a case report involving a patient with reactive airway disease. Anesthesiology. 1997;87(5):1243-4.

13. Smith I, White PF. Use of the laryngeal mask airway as an alternative to a face mask during outpatient arthroscopy. Anesthesiology. 1992;77(5):850-5.
14. Verghese C, Brimacombe JR. Survey of laryngeal mask airway usage in 11,910 patients: safety and efficacy for conventional and nonconventional usage. AnesthAnalg. 1996;82(1):129-33.