ISSN:09758309762833. VOL14.ISSUE 08,.2023

AN OBSERVATIONAL STUDY OF THE I-GEL: A NEW SUPRAGLOTTIC AIRWAY DEVICE

Dr. Dharmesh Ladhad[1*], Dr. Avinash Karekal[2], Dr. Milon Mitragotri[3]

[1]Assistant Professor, Department of Anaesthesia, Critical Care and Pain Medicine, Karnataka Institute of Medical Sciences, Hubli, Karnataka.*
[2]Associate Professor, Department of Anaesthesia, Critical Care and Pain Medicine, KLE JGMM Medical College, Hubli, Karnataka.
[3]Assistant Professor, Department of Anaesthesia, Critical Care and Pain Medicine, Karnataka Institute of Medical Sciences, Hubli, Karnataka.

Corresponding Author: Dr. Dharmesh Ladhad

Abstract

Introduction: Anaesthesiologists support the ventilation and oxygenation after the induction of anaesthesia. Traditional methods of ventilation is by the face mask and the tracheal tube. During the last decade, several supraglottic airway devices have been introduced in clinical practice. Supraglottic glottic airway devices have become a standard fixture in airway management, filling the gap between the face mask and the tracheal tube, in terms of both anatomical position and the degree of invasiveness. These devices are positioned outside the trachea but provide hands-free means of achieving gas tight airway.

Materials and Methods: In this study, we included 45 patients of ASA I and II physical status and aged between 18 and 45 years undergoing general and orthopedic surgery after obtaining approval from institutional ethical committee and informed written consent. Patients with anticipated difficult airway, pregnant, obese, with lung diseases, with GERD and those who require surgery in position, other than supine or lithotomy were excluded. The ease of insertion, number of attempts of insertion, time to achieve effective airway, oropharyngeal seal pressure, I-gel Airway stability on neck movements and complications during insertion, maintenance of anaesthesia, during removal of i-gel and in the post operative period were studied.

Results: Present study included 45 patients, of either sex undergoing general surgical procedures. The ease of insertion of i-gel, time for insertion, insertion attempts, device size, airway manipulation, oropharygeal seal pressure and complications were evaluated.

Conclusion: From our study we conclude that I-gel is a simple and easy to use supraglottic airway device, easy to insert with minimal airway manipulations to achieve adequate airway and ventilation. It has a high success rate at first attempt of insertion and 100% success rate without any failure, quickly inserted, has a high oropharyngeal seal

ISSN:09758309762833. VOL14.ISSUE 08,.2023

pressure, stable in various positions of head and neck and there is minimal risk of displacement once properly placed. It's use is associated with minimal complications and morbidity.

Key Words: oxygenation, Lithotomy, morbidity, mortality, supraglottic airway.

INTRODUCTION

Anaesthesiologists support the ventilation and oxygenation after the induction of anaesthesia. Traditional methods of ventilation is by the face mask and the tracheal tube.

During the last decade, several supraglottic airway devices have been introduced in clinical practice. Supraglottic glottic airway devices have become a standard fixture in airway management, filling the gap between the face mask and the tracheal tube, in terms of both anatomical position and the degree of invasiveness. These devices are positioned outside the trachea but provide hands-free means of achieving gas tight airway.[1]

The LMA was the first major supraglottic airway with its initial introduction in 1989 by Dr. Archie Brain. Though initially approved for use as an alternative for face mask and when tracheal intubation was not achievable, it soon enjoyed wide use in surgical cases traditionally managed with tracheal intubation.[2]

The i-gel (Intersurgical Ltd., Wokingham, Berkshire,U.K.) is the new supraglottic airway device invented by Dr. Mohammed Aslam Naseer in 2007 and has anatomically designed non-inflatable, transparent mask, made of thermoplastic elastomer gel, styrene ethylene butadiene styrene(SEBS)[4] which creates an anatomic seal with perilaryngeal structures without causing compression trauma.[3,5]

I-gel is said to have easier insertion, minimal risk of tissue compression and stability after insertion. [6,7] I-gel is currently gaining reputation because of the favourable reports regarding ease of insertion.[8,9]

I-gel ensures a better control of airway than the face mask and avoid the disadvantages of endotracheal intubation like pressor response during intubation[10,11] and sore throat, dysphonia[10] etc. post operatively.
The i-gel can be positioned without direct visualization or administration of neuromuscular blocking agents and the patient can be allowed to breathe spontaneously throughout the procedure.[10,6,8]

By avoiding laryngoscopy and intubation, the amount of anaesthetic drugs administered is reduced and a faster recovery with fewer post operative side effects may be anticipated. With the greater emphasis on day care anaesthesia, these features are desirable.

ISSN:09758309762833. VOL14.ISSUE 08,.2023

The i-gel has been proposed for use during cardiopulmonary resuscitation as it can be inserted quickly and easily.[12,13] Furthermore there is evidence that it is easier to train non-anaesthesiologists to correctly insert i-gels, compared with the conventional supraglottic airway devices, thus making it a potentially useful device for situations such as resuscitation.[10,14,15]

The results of initial clinical trial have shown many advantages of the i-gel. These include high success rate at first attempt, easy insertion, shorter time to achieve effective airway, high seal pressure, stability of device despite changes in position of head and neck and low incidence of adverse events. We undertook this study to evaluate these parameters.

MATERIALS AND METHODS

In this study, we included 45 patients of ASA I and II physical status and aged between 18 and 45 years undergoing general and orthopedic surgery after obtaining approval from institutional ethical committee and informed written consent. Patients with anticipated difficult airway, pregnant, obese, with lung diseases, with GERD and those who require surgery in position, other than supine or lithotomy were excluded. The ease of insertion, number of attempts of insertion, time to achieve effective airway, oropharyngeal seal pressure, I-gel Airway stability on neck movements and complications during insertion, maintenance of anaesthesia, during removal of i-gel and in the post operative period were studied.

Preanaesthetic evaluation included detailed history and through examination. Airway was assessed by Samsoon and Young modified Mallampatti classification. Inter incisor gap, thyromental distance and adequacy of neck movements were assessed, relevant investigations were ordered and their results were noted.

All the patients were given oral alprazolam 0.25mg and ranitidine 150mg both previous night and morning of surgery.

They were kept nil per oral overnight before surgery. On arrival to the operating room 18G venous cannula was secured in non dominant hand and intravenous fluid was started. Monitors were applied which included electrocardiogram, pulse-oximetry, non invasive blood pressure and end tidal carbon dioxide.
Patients were placed supine with head on standard pillow. All patients were given injection midazolam 0.02mg/kg and injection fentanyl 1-1.5µ/kg intravenously 10 minutes prior to induction.

ISSN:09758309762833. VOL14.ISSUE 08,.2023

Following preoxygenation for 3 minutes, general anaesthesia was induced with intravenous propofol 2-2.5mg/kg over 30-40 seconds. Face mask ventilation with nitrous oxide and oxygen in 50 % mixture was done and after optimal conditions for i-gel insertion were achieved, i-gel was inserted according to manufacturer's instructions. No muscle relaxants were administered. If effective airway is not achieved repositioning of the i-gel by increasing depth of insertion, jaw thrust, chin lift or changing the size of the device was done. If effective airway was not achieved after three attempts, alternative technique was used, like cLMA or endotracheal tube.

Insertion:

The back and the sides of the cuff were lubricated with water based jelly. The patient's head was placed in "sniffing the morning air" position and i-gel was grasped along the integral bite block and was introduced into the mouth with its tip directed towards the hard palate. With continuous, gentle push it was glided downwards, backwards along the hard palate until definite resistance was felt. Ease of insertion was recorded. I-gel was connected to breathing circuit and was ventilated manually till spontaneous respiratory efforts resumed. Adequate placement of device was assessed by gently squeezing the reservoir bag and observing the end tidal carbon dioxide waveform and chest movements and lack of gastric insufflation which was determined by epigastric auscultation.[6,8] I-gel was secured by taping the tube over the maxilla.

Oropharyngeal seal pressure was determined by closing the APL valve of the circuit (circle system, DatexOhmedaAestiva/5) at fix gas flow of 5 liters per minute and recording the airway pressure at which gas leaks into the mouth[8,9]. Anaesthesia was maintained on oxygen and nitrous oxide (66%) and halothane (1-2%) with spontaneous ventilation.

Non invasive blood pressure, heart rate, and oxygen saturation were recorded pre induction, during insertion (0 min), 5min, 15min, and every 15 min thereafter and after the removal of i-gel.

Following observation were made:

Size of the i-gel used.

Number of insertion attempts.

Failed insertion/alternative technique for ventilation needed.

Time needed for insertion was noted i.e. from picking up the device to successful ventilation.

Ease of insertion was graded subjectively.[7,8]

Airway manipulations required to aid insertion like jaw thrust, chinlift, increase in depth of anaesthesia or no manipulations needed were noted.

Need for change of device size was noted.

Oropharyngeal seal pressure was determined

ISSN:09758309762833. VOL14.ISSUE 08,.2023

Stability of the device in different head/neck positions was noted
Duration of anaesthesia was noted.
At the conclusion of surgery inhaled anaesthetic was discontinued and patients breathed 100% oxygen during emergence from anaesthesia. The device was removed when the patient was able to open the mouth on command. Airway complications such as presence of blood on device, troublesome secretions, injury to lips, tongue, or teeth were noted. Postoperatively all patients were visited and presence of sore throat and adverse events such as dysphagia and dysphonia were enquired on first operative day i.e. after 24 hours.
A pretested proforma was used to collect the relevant information from each patient. Collected data is presented in terms of no. of patients, mean, standard deviation and percentages.

OBSERVATIONS AND RESULTS

Present study included 45 patients, of either sex undergoing general surgical procedures. The ease of insertion of i-gel, time for insertion, insertion attempts, device size, airway manipulation, oropharygeal seal pressure and complications were evaluated.

Table 1: Patients characteristics

Variables	Value
Age(years)-range(mean ± SD)	18-45 (29.5±8.5)
Weight(kg)- range(mean ± SD)	35-80 (52.3±9.5)
Height(cm)- range(mean ± SD)	135-165 (151.7±7.6)
Gender male/female(number)	21/24
ASA Physical status I/II	43/2

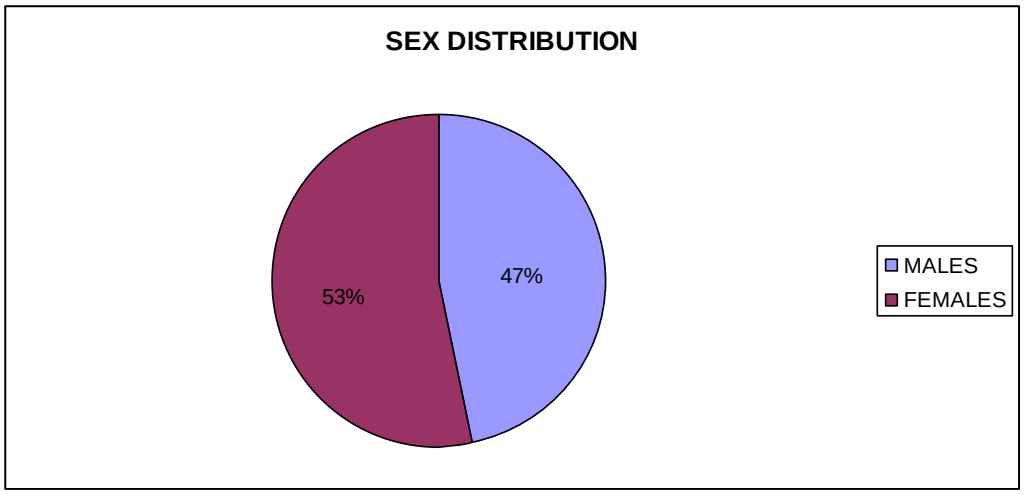

Fig 1: Sex distribution.

ISSN:09758309762833. VOL14.ISSUE 08,.2023

The mean duration of surgery was 39.8±10.9 min (range 30-75min).

Table 2 : Size of i-gel used

Size of i-gel	No. of patients (%)
3	17(37.8%)
4	24(53.3%)
5	04(8.9%)

I-gel size 3 was used in 17 patients (37.8%), size 4 was used in 24 patients (53.3%), size 5 was used in 04 patients (8.9%). In 7 patients, i-gel when first used needed to be replaced to larger size to achieve a better seal and prevent leak.

Table 3: Insertion attempts

No. of attempts	Count (%)
1	37(82%)
2	8(18%)
Total	45(100%)

The success rate at first attempt of insertion was 37/45(82%) patients. In 8/45(18%) patients I-gel was inserted in second attempt.

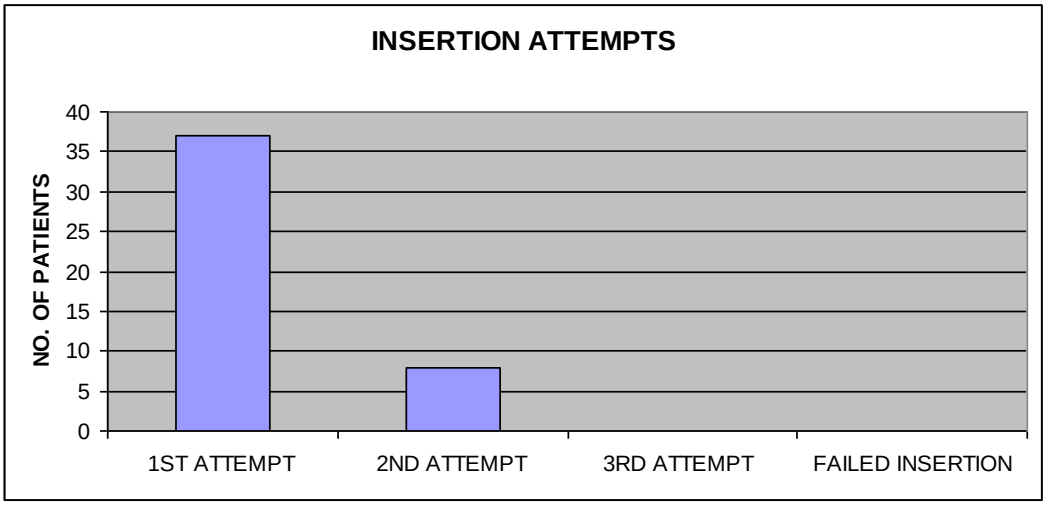

Fig.2: Insertion attempts

Table 4: I-gel insertion time (sec)

No.	Mean	Std. deviation	Minimum	Maximum
45	10.29	4.22	6	25

The mean time for i-gel insertion was 10.29 ± 4.22 sec.(range 6-25 sec).

ISSN:09758309762833. VOL14.ISSUE 08,.2023

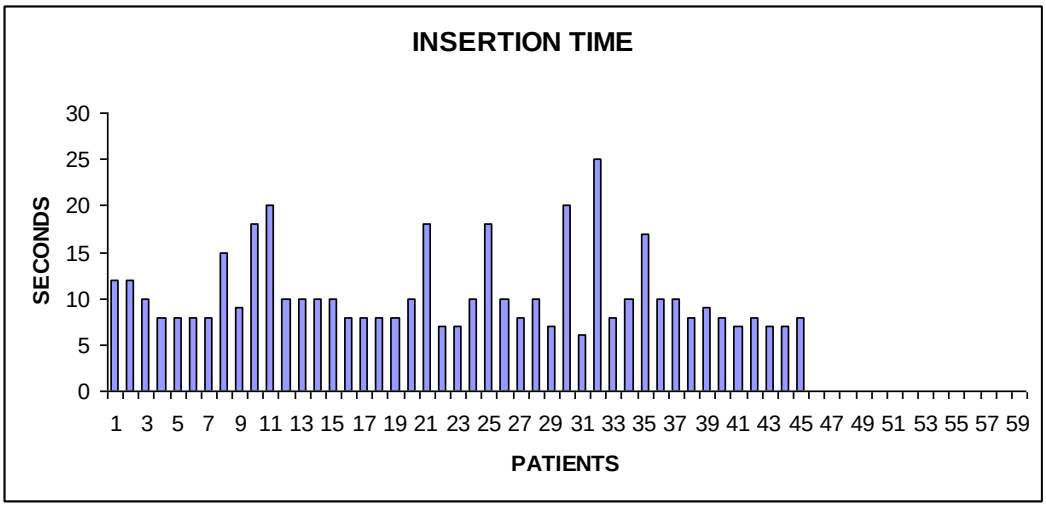

Fig.3: Insertion time

Table 5: Airway manipulations required for i-gel insertion

Airway manipulations	Count (%)
Jaw thrust	7(15.6%)
Chin lift	0
Increasing depth of anaesthesia	1(2.2%)

Out of forty five patients seven patients (15.6%) required jaw thrust for inserting i-gel and increasing depth of anaesthesia was required in one patient (2.2%) for inserting i-gel.

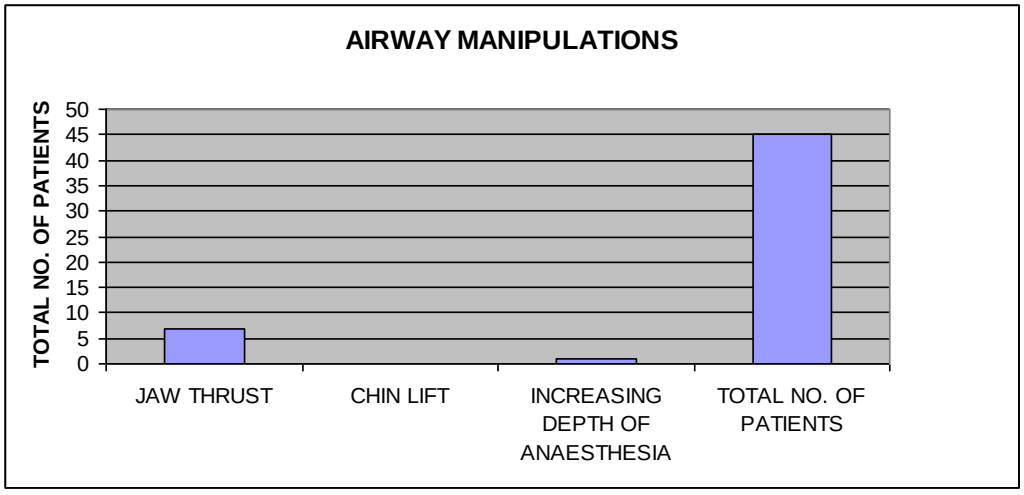

Fig.4: Airway manipulations for i-gel insertion

Changing size of device was needed in seven out of forty five patients (15.6%) to achieve effective airway, as there was leak around the i-gel and inadequate chest movements.

ISSN:09758309762833. VOL14.ISSUE 08,.2023

Ventilation and chest movements were adequate in these patients after changing to larger size of device. There was no leak after changing the device.

Table 6: Ease of i-gel insertion

Ease of insertion	Count (%)
Very easy	36(80%)
Easy	8(17.78%)
Difficult	1(2.22%)
Very difficult	0
Total	45(100%)

I-gel insertion was very easy in thirty six out of forty five (80%) patients. It was easy to insert in eight (17.78%) of patients. Insertion was found to be difficult in one (2.22%) patient. Insertion was possible in 100% of the patients.

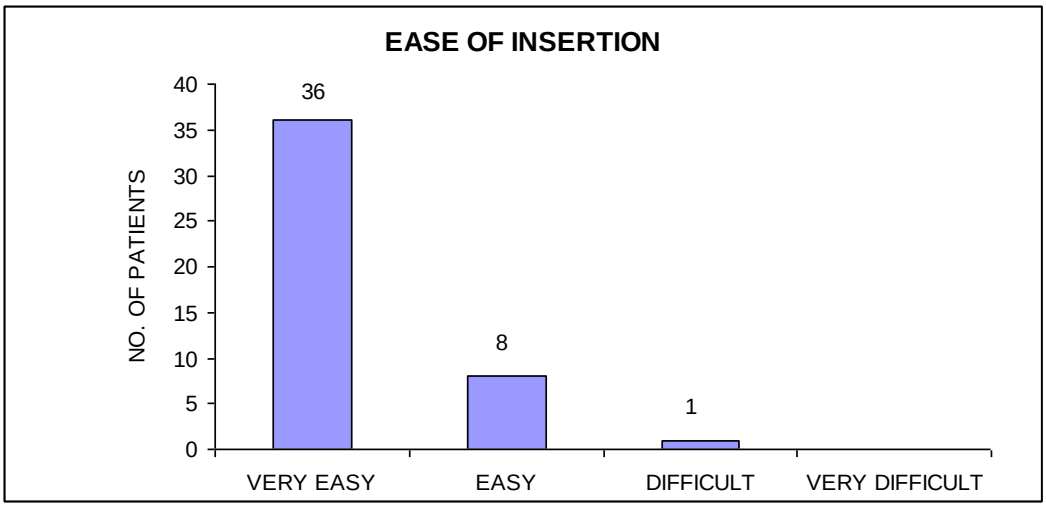

Fig.5: Ease of insertion.

Table 7: Oropharyngeal seal pressure

No.	Mean	Std. deviation	Minimum	Maximum
45	24.57cmH_2O	4.14cm H_2O	17cmH_2O	35cmH_2O

The mean oropharyngeal seal pressure was found to be 24.8± 4.3(range 17-35)cm H_2O.

ISSN:09758309762833. VOL14.ISSUE 08,.2023

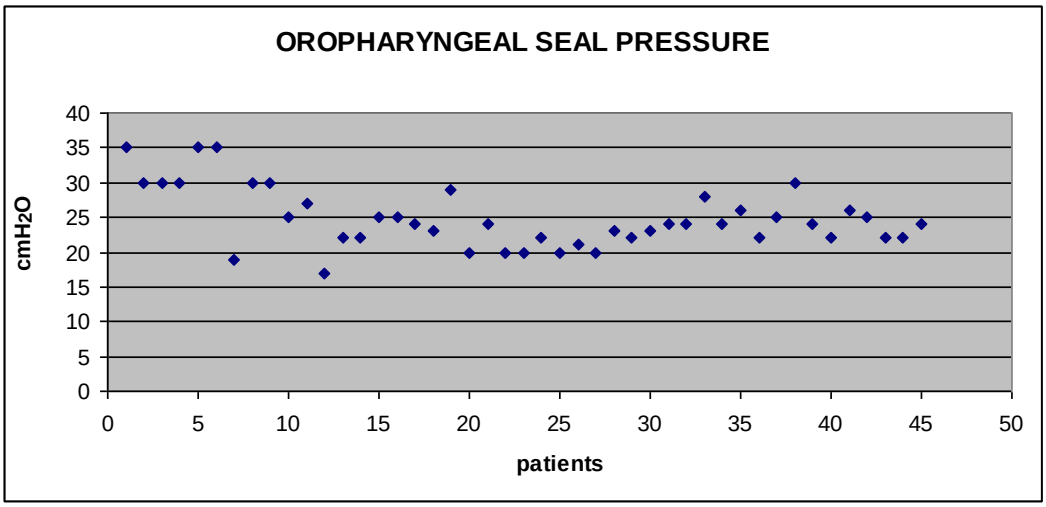

Fig. 6: Oropharyngeal seal pressure.

The incidence of adverse events during perioperative period was low. One patient had hiccups during the recovery period, before removal of i-gel. Anaesthesia was deepened with injection propofol 60mg i.v. Hiccups subsided and later i-gel was removed and ventilation was assisted by holding mask using 100% oxygen. Vitals were stable during the episode and there was no desaturation.

One patient developed partial laryngospasm during maintenance of anaesthesia which was relieved by increasing the depth of anaesthesia. The suspected reason for this event is increased secretions and laryngeal irritation. Two out of forty five patients had sore throat in post operative period which subsided in one day. None of the patients had coughing, gastric insufflation, regurgitation, aspiration, injury to teeth/lip/gum, blood on device, dysphagia or dysphonia.

DISCUSSION

Supraglottic airway devices are increasingly used in anaesthetic practice and cardiopulmonary resuscitation. They provide a perilaryngeal seal with an inflatable cuff and are an alternative to tracheal intubation. I-gel has been shown to be easily inserted, effective airway device and has been easier to insert in comparison to other supraglottic airways in manikins, even by novices. Recent studies support its use during anaesthesia, for spontaneously breathing patients. I-gel has been shown to be associated with low complications and morbidity with its use. Hence, we conducted this study in 45 anaesthetised, spontaneously breathing patients to evaluate the ease of insertion, no. of attempts needed to insert i-gel, time for insertion, oropharyngeal seal pressure, stability of device in different neck positions and any complications associated with the use of i-gel.

We assessed the performance of i-gel following induction of general anaesthesia. In our study patients were in the age group of 18 to 45 years and there were 21 males and 24

ISSN:09758309762833. VOL14.ISSUE 08,.2023

female patients. I-gel size 3 was used in 17/45 patients, size 4 in 24/45 patients and size 5 in 4/45 patients.

Changing size of device was needed in 7/45(15.6%) patients to achieve effective airway, as there was leak around the i-gel and inadequate chest movements. Ventilation and chest movements were adequate in these patients after changing to larger size of device. In all these patients i-gel size was initially selected according to weight based guidelines suggested by the manufacturer but larger size was needed to achieve adequate ventilation without leak. All the 7 patients were males and it may be due to the individual variability and larger body frames of these patients.

C Janakiraman et al in their comparative study between i-gel and cLMA found that 14/50 patients needed larger size of the i-gel due to leak. They suggested that this may be due to the absence of inflatable cuff in i-gel which can be inflated to achieve better seal. They concluded that i-gel is not an acceptable alternative to cLMA with current sizing guidelines.[3]

We found high success rate of insertion of i-gel. It was possible to insert i-gel in one or two attempts in all the patients.

Successful insertion was established in 37/45(82%) patients on the first attempt and the remaining patients i.e. 8/45(18%) on the second attempt. None of the patients needed third attempt and there were no failures. 7 out of the 8 patients who needed second attempt was due to changing device size to larger size to achieve better seal and in 1 patient we needed to increase the depth of anaesthesia and before doing second attempt for insertion.

J.J Gatward et al evaluated i-gel insertion in hundred non paralysed patients with propofol induction. Success on first attempt was achieved in 86/100 patients (86%), on second attempt in 11/100 patients (11%) and third attempt in 3/100 patients (3%).[6]

H.Francksen et al compared i-gel and LMA-uniqueTM insertion in 80 non paralysed and anaesthetized patients with propofol induction. Primary airway was established in 36/40 patients (90%) on first attempt and 4/40 patients (10%) on the second attempt in i-gel group.[27]

Ashish Kannaujia et al conducted a preliminary study on i-gel with propofol induction in 50 patients breathing spontaneously. The success rate at first attempt of insertion was 45/50 patients (90%) and on second attempt 5/50 patients (10%), While none needed third attempt.[9]

Our results are comparable to above studies.

Securing an effective airway was rapid in most of the patients. Mean time of insertion was 10.29±4.22sec (range 6-25) in our study. In 8 patients where we needed second attempt for insertion, needed more time for achieving effective airway.

ISSN:09758309762833. VOL14.ISSUE 08,.2023

J.J Gatward et al evaluated size 4 i-gel airway in 100 non paralysed patients and found mean insertion time of 15 sec (range 5-20 sec).[6]

I - gel insertion was graded as very easy, easy, difficult, very difficult in our study. This was graded subjectively. We found that i-gel insertion was very easy in 36/45 patient (80%), easy in 8/45 patients (17.78%) and difficult in 1/45 patients (2.22%). One patient where we graded insertion was difficult, needed increasing the depth of anaesthesia and also jaw thrust for insertion of i-gel.

B. Richez et al evaluated i-gel in 71women scheduled for gynaecological surgery in observational study and graded insertion as very easy in 66/71(93%) and easy in 5/71(7%).[8]

C Janakiraman et al compared i-gel with cLMA^{TM} in 50 anaesthetised patients breathing spontaneously and scored insertion as easy in 40/50 cases(80%) in igel group.[3]

Gatward JJ et al evaluated the size 4 i-gel airway in one hundred non-paralysed patients and found that the i-gel is easily and rapidly inserted, providing a reliable airway in over 90% of cases.[6]

In our study we also found i-gel insertion is easy as seen in above stated studies.

The mean oropharyngeal seal pressure was found to be 24.8± 4.3(range 17-35) cmH_2O in our study. This higher seal pressure suggests that we can use i-gel for pressure control ventilation. Absence of inflatable cuff means, that theoretically it may be more prone for gas leak during pressure control ventilation. Uppal et al in their study found that there is no significant difference in gas leak between i-gel and tracheal tube when using i-gel with moderate airway pressure.

B. Richez et al in a observational study on 71 women undergoing gynaecological surgery found the mean oropharyngeal seal pressure to be 30±7 cm H_2O. [8]

C. Janakiraman et al in a comparison study between i-gel and cLMA found that the median leak pressure was 20(14-24) cm H_2O for i-gel.[3]

Our results are comparable with above studies.

In our study we found that i-gel was stable in all the positions i.e. when head was on standard pillow, rotated to either side, with chin lift or without standard pillow. This greater stability is primarily related to the anatomical design of the non inflatable cuff. The ridge at the proximal end of mask catches the base of the tongue thus prevents the device from moving and so contributes to the positional stability of the device after placement.[9]

In our study one patient had hiccups during recovery, one patient had partial laryngospasm during maintenance and later developed complete laryngospasm and desaturation and required intubation and recovered uneventfully. The suspected reason for this event is increased secretions and laryngeal irritation.

Two patients had sore throat. None of the patients had coughing, gastric insufflation, regurgitation, aspiration, injury to teeth/lip/gum, blood on device, dysphagia or dysphonia.

ISSN:09758309762833. VOL14.ISSUE 08,.2023

B. Richez et al in their study found only one case of coughing and one mild sore throat.[8]
S. Amini et al reported a low incidence of sore throat and dysphagia in i-gel group, in their study.
Wharton N.M et al reported one case of aspiration and partial regurgitation out of forty anaesthetized patients.
Gatward J.J et al reported one episode of regurgitation but without aspiration. Other complications and side effects were mild and very few. Blood stain was visible on the device in one patient.[6]

CONCLUSION

From our study we conclude that I-gel is a simple and easy to use supraglottic airway device, easy to insert with minimal airway manipulations to achieve adequate airway and ventilation. It has a high success rate at first attempt of insertion and 100% success rate without any failure, quickly inserted, has a high oropharyngeal seal pressure, stable in various positions of head and neck and there is minimal risk of displacement once properly placed. It's use is associated with minimal complications and morbidity.

REFERENCES

1. Understanding anaesthesia equipment; fifth edition. Jerry A. Dorsch, Susan E. Dorsch: pg.462.
2. Clinical anaesthesia; fifth edition. Paul G. Barash:pg. 602.
3. Janakiraman C, Chethan DB, Wilkes AR, Stacey MR, Goodwin N, A randomized crossover trial comparing the I-gel supraglottic airway and classic laryngeal mask airway. Anaesthesia2009;64:674-678
4. Asai T, Liu EH. The i-gel, a new supraglottic airway Masui.2010 Jun;59(6):794-7. (Article in Japanese) .
5. Levitan RM, KinkleWC. Initial anatomic investigations of the i-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia2005;60:1022-26.
6. Gatward JJ, Cook TM, Seller C, Handel J, Simpson T, Vanek V, Kelly F. Evaluation of size 4 i-gel^{TM} airway in one hundred non-paralysed patients. Anaesthesia. 2008;63(10):1124-30.
7. Heuer JF, Stiller M, Gottingen. Observational study of the newly developed supraglottic airway. Der Anaesthesist 2009:58, number 8.
8. Richez, Saltel L, Bankchereau, Torriell R, Cros AM. A new single use suproglottic airway with a non inflatable cuff and an esophageal vent: an observation study of the I-gel. Anaesthesia and Analgesia 2008 Apr;106(4):1137-9
9. Kannaujia Ashish, Srivastava Uma, Saraswat Namita, Mishra Abhijeet. A preliminary study of I-gel: A new supraglottic airway device. Indian Journal of Anaesthesia 2009;53(1):52-56

ISSN:09758309762833. VOL14.ISSUE 08,.2023

10. Uppal V, Fletcher G, Kinsella J. Comparison of the i-gel with the cuffed tracheal tube during pressure controlled ventilation. 2009;102:264-8.
11. Jindal P, Rizvi A, Sharma JP. Is I-gel a new revolution among supraglottic airway devices?--a comparative evaluation. Middle East J Anesthesiol.2009 Feb;20(1):53-8.
12. Weise CHR, Bahn J, Popov AF, Hinz JM, Graf BM. Influence of airway management on ‘no flow time’ in a standardized single rescurer manikin scenario-a comparison between LTS-D and I-gel. Resuscitation 2009;80:100-103
13. Castle N, Owen R, Hann M, Naidoo R, Reeves D. Assessment of the speed and ease of insertion of three supraglottic airway devices by paramedics: a manikin study. Emerg Med J.2010 Nov;27(11):860-3.
14. Soar J.The I-gel supraglottic airway and resuscitation-some initial thoughts. Resuscitation 2007;74:197.
15. J. J. Gatward, M. J. C. Thomas, J. P. Nolan,T. M. Cook. Effect of chest compressions on the time taken to insert airway devices in a manikin. BJA 2008;100:351-6.