

Comparitive Study of I-Gel Vs Supreme LMA in Anaesthetised Patients on Spontaneous Ventilation

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Abstract

The aim of this study is to study and compare two supraglottic airway devices I-gel and supreme laryngeal mask airway, in anaesthetised adult patients with spontaneous ventilation, with respect to Ease of insertion, Number of insertion attempts and Haemodynamic changes like heart rate, mean arterial pressure, Systolic and diastolic blood pressure.

Keywords: I-Gel; Supreme LMA; Haemodynamics; Heart Rate; Blood Pressure.

Aim of the Study

To study and compare two supraglottic airway devices I-gel and supreme laryngeal mask airway, in anaesthetised adult patients with spontaneous ventilation, with respect to

- Ease of insertion .
- Number of insertion attempts .
- Haemodynamic changes like heart rate, mean arterial pressure, Systolic and diastolic blood pressure.

Materials and Methods

The study was conducted on 60 adult patients who were scheduled for elective surgery under general anaesthesia, requiring endotracheal intubation. The approval for the study was obtained from the Institutional Ethics Committee and informed consent was obtained from all patients.

Inclusion Criteria

Patient selected for the study were:

- Patients aged between 15 -60 years
- American Society of Anaesthesiologists (ASA) grade I-II
- Mallampatti (MP) grade 1 and 2
- Body Mass Index (BMI) between 20 -25kg/m²
- Scheduled for elective surgeries

Exclusion Criteria

- Age <15 years and > 60 years
- ASA III and IV
- MP 3 and 4
- Patients having any abnormality of the neck, anticipated difficult airway
- Mouth opening \leq 2 cm
- Upper respiratory tract infections

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- History of obstructive sleep apnea
- Obese patients with BMI >28kg/m²
- Patients with increased risk of aspiration
- Duration of surgery >1hr.

They were randomly allocated into 2 groups. i-gel and supreme LMA group with 30 patients.

Methodology

Procedure

The patients will be divided into 2 groups, of 30 each, in a random, single blinded manner. A detailed medical history, complete physical examination and routine investigations will be done for all the patients. IV line will be secured, the patients will be premedicated with Inj Metaclopramide 10 mg, i.v., Inj Glycopyrolate 0.2 mg, Inj Fentanyl 2mcg/kg and Inj. Midazolam 0.05mg/kg i.v just before induction. Monitoring of pulse, NIBP, ECG will be done. Baseline values of HR and MAP will be recorded. After preoxygenation for 3 minutes, anaesthesia will be induced with Propofol 2 mg/kg i.v. Induction of anaesthesia will be confirmed by loss of verbal contact with the patient, loss of eyelash reflex and relaxation of the jaw. If coughing, gagging or body movement occurred during insertion, a further dose of Propofol 0.5 mg/kg will be given to achieve an adequate depth of anaesthesia.

The size of the device is decided by anaesthetist based on patient's body weight and manufacturer's recommendation, size 3 for patients weighing between 30-50 kgs, size 4 for patients between 50 -90 kgs. For Supreme-LMA, size 3 for patients 30 to 50 kg, size 4 for patients 50 to 70 kg will be used as per manufacturer's recommendation.

The following parameters will be measured.

- Heart rate, mean arterial pressure, Systolic and diastolic blood pressure. at baseline, after insertion of device, during surgery and at the end of surgery after removal of device.
- Number of insertion attempts

At the end of the operation, anaesthetic agents will be discontinued, allowing smooth recovery of consciousness. The device will be removed after the patient regains consciousness spontaneously and responds to verbal command to open the eyes.

If it is not possible to insert the device or ventilate through it, two more attempts of insertion will be allowed. If placements had failed after three attempts, the case will be excluded from the study and the patient will be intubated and this case will be considered as a failed attempt.

After securing the device, spontaneous ventilation will be maintained using O₂ (33%)+N₂O (66%)+ intermittent Inj. Propofol. Ventilation will be judged to be optimal if there is adequate chest expansion and stable oxygenation, SpO₂ not less than 95%.

Results

Among the total cases, 56% of the cases were males and 44% were females in i Gel group. In the supreme LMA group, 53% of the cases were males and 47% were females (Table 1).

It is evident that both the groups had a majority of males. With the P Value being > 0.05, both the groups are statistically insignificant with regard to gender.

Among the total cases, In i Gel group 23% belong to the age group 15-30 years, 43% belong to 31-45

Table 1: Gender

Gender	I Gel	%	Supreme LMA	%	P value
Male	17	56	16	53	0.801
Female	13	44	14	47	
Total	30	100	30	100	

Table 2: Age

Age (in years)	I Gel	%	Supreme LMA	%	P value
15 - 30	7	23	6	20	0.541
31 - 45	13	43	14	47	
46 - 60	10	33	10	33	
Total	30	100	30	100	
Mean	37.90	-	38.47	-	
SD	12.32	-	11.60	-	

Table 3: BMI

BMI (kg/m ²)	I Gel	%	Supreme LMA	%	P Value
< 20	13	43	14	47	0.359
20 - 25	17	57	16	53	
Total	30	100	30	100	
Mean	22.47		23.12		
SD	6.49		6.12		

Table 4: ASA Classification

	I Gel	%	Supreme LMA	%	P Value
ASA I	22	73	15	50	0.539
ASA II	8	27	15	50	
Total	30	100	30	100	

Table 5: MPC Classification

MPC	I Gel	%	Supreme LMA	%	P Value
MPC I	15	50	14	47	0.145
MPC II	15	50	16	53	
Total	30	100	30	100	

Table 6: Type of Surgeries

Type of Surgeries	I Gel	%	Supreme LMA	%	P value
Kwire	7	23	6	20	0.09
Incision and drainage	10	33	12	40	
Fibroadenoma breast	5	17	5	17	
Puerperal sterilization	8	27	7	23	
Total	30	100	30	100	

Table 7: No of Attempts

No of Attempts	I Gel	%	Supreme	%	P Value
1st attempt	21	70	LMA	77	0.601
2nd attempt	9	30	23	23	
Total	30	100	7	100	

Table 8: Heart Rate-Post Intub Ation

Heart Rate	I G el	%	Supreme	%	P Value
70 - 80	8	27	LMA	23	0.021
81 - 90	14	46	7	50	
91 - 100	8	27	15	27	
Total	30	100	8	100	
Mean	86.27	-	30	-	
S.D.	3.47	-	84.15	-	

years and 33% belong to 46-60 years. In Supreme LMA group, 20% belong to the age group 15-30 years, 40% belong to 31-45 years and 40% belong to 46-60 years.

It is evident from the table that in both the groups the majority of the age group who underwent minor surgeries lies between 31-45 years.

With the P Value being > 0.05, both the groups are statistically insignificant with regard to age.

In the present study, patients in which iGel was

used the BMI lesser than 20 kg/m² was seen in 43% and percentage of patients with BMI between 20 - 25 kg/m² was 57%. In the supreme LMA cases, the BMI lesser than 20 kg/m² was seen in 47% and 53% of the patients had BMI between 20-25 kg/m².

Patients with BMI greater than 25 kg/m² have been excluded from the study.

With the P Value being > 0.05, both the groups are statistically insignificant with regard to BMI.

The percentage of patients who were assessed under ASA I in the iGel group were 73% and 27% were assessed under ASA II classification. Whereas in the Supreme LMA group, the patients assessed according to ASA classification I and II were equally distributed.

With the P Value being > 0.05, both the groups are statistically insignificant with regard to ASA Classification.

With regard to the MPC Classification, the percentage of patients assessed under MPC I and MPC II was equal in the iGel group. In the Supreme LMA group, 47% of the patients were assessed under MPC I and 53% were assessed under MPC II.

With the P Value being > 0.05, both the groups are statistically insignificant with regard to MPC classification.

Incision and drainage (I & D), Fibroadenoma breast and Puerperal sterilization.

It is significant from the above table that incision and drainage was done in majority of the patients. 33% in the iGel group and 40% in Supreme LMA group.

With the P Value being > 0.05, both the groups are statistically insignificant with regard to the type of surgeries.

In the present study, iGel was placed in the first attempt 70% (n - 21) and 30% (n -9) in the second attempt. In the Supreme LMA group, the instrument was placed in the first attempt in 77% (n -23) and placed in the second attempt in 23% of the cases.

With the P Value being > 0.05, both the groups are statistically insignificant with regard to the number of attempts in inserting the instrument for securing the airway.

In the present study, 27% of the patients had heart rate between 70 - 80 beats per min(bpm), 46% of the cases were between 81-90 bpm and 27% of the cases were between 91-100 bpm among the iGel cases.

With regard to the cases used with Supreme LMA, 23% of the patients had the heart rate between 70-80 bpm, 50% of the cases were between 81-90 bpm and 27% of the cases were between 91-100 bpm.

With the P Value being < 0.05, there was a statistical significance with regard to heart rate post intubation with iGel and supreme LMA. Also it is evident that iGel group is better compared to the supreme LMA group.

In this study, 27% of the patients had the systolic blood pressure between 110-120, 40% of the patients had between 121-130 and 33% of the patients had between 131-140 among the iGel group.

With regard to the patients used with Supreme LMA, 22% of the patients had the systolic blood pressure between 110 - 120, 42% of the patients had between 121-130 and 36% of the patients had between 131-140.

It is evident that majority of the patients included in this study had systolic blood pressure ranging between 121-130.

In this study, 23% of the patients had the systolic blood pressure pre intubation between 110 - 120, 33% of the patients had between 121-130 and 44% of the patients had between 131-140 among the iGel group.

With regard to the patients used with Supreme LMA, 30% of the patients had the systolic blood pressure between 110-120, 37% of the patients had between 121-130 and 33% of the patients had between 131-140.

Table 9: Systolic Blood Pressure

SBP (mm/Hg)	I Gel	%	Supreme LMA	%
110 - 120	8	27	7	22
121 - 130	12	40	13	42
131 - 140	10	33	10	36
Total	30	100	30	100
Mean	124.41		123.52	
SD	4.25		4.62	

Table 10: Systolic blood pressure - pre intubation

SBP	I Gel	%	Supreme LMA	%	P Value
(mm/Hg)	7	23	30	30	
110 - 120	10	33	9	37	
121 - 130	13	44	11	33	
131 - 140	30	100	10	100	0.584
Total	125.41	-	30	-	
Mean	3.14	-	123.52	-	

It is evident that majority of the patients included in this study had systolic blood pressure - pre intubation ranging between 121-130.

With the P Value being > 0.05 , there is no statistical significance with regard to systolic blood pressure - pre intubation.

In this study, 23% of the patients had the systolic blood pressure Post intubation between 110-120, 33% of the patients had between 121-130 and 44% of the patients had between 131-140 among the i Gel group.

With regard to the patients used with Supreme LMA, 30% of the patients had the systolic blood pressure between 110-120, 37% of the patients had between 121-130 and 33% of the patients had between 131-140.

It is evident that majority of the patients included in this study had systolic blood pressure-post intubation ranging between 121-130.

With the P Value being < 0.05 , there is a statistical significance with regard to systolic blood pressure - post intubation.

In this study, 40% of the cases had the Diastolic blood pressure between 71-80, 40% of the cases had between 81-90 and 20% of the cases had between 91-100 among the i Gel group. With regard to the

patients used with Supreme LMA, 37% of the cases had the diastolic blood pressure between 71-80, 40% of the patients had between 81-90 and 23% of the patients had between 91-100. It is significant that majority of the patients included in the study had diastolic blood pressure 81-90.

In this study, 43% of the cases had the Diastolic blood pressure pre intubation between 71-80, 37% of the cases had between 81-90 and 20% of the cases had between 91-100 among the i Gel group. With regard to the patients used with Supreme LMA, 40% of the cases had the diastolic blood pressure between 71-80, 37% of the patients had between 81-90 and 23% of the patients had between 91-100.

It is significant that majority of the patients included in the study had diastolic blood Pressure pre intubation 71-80.

With the P value being > 0.05 , there was a statistical significance with regard to diastolic blood pressure pre intubation. Also it is evident that i Gel group is better compared to the supreme LMA group based on the mean calculations.

In this study, 37% of the cases had the Diastolic blood pressure post intubation between 71 - 80, 40% of the cases had between 81 - 90 and 20% of the cases had between 91-100 among the i Gel group. With regard to the patients used with Supreme LMA, 33%

Table 11: Systolic blood pressure - post intubation

SBP (mm/Hg)	I Gel	%	Supreme LMA	%	P Value
110 - 120	8	23	9	30	
121 - 130	11	33	12	37	
131 - 140	13	44	8	33	
Total	30	100	30	100	0.022
Mean	126.51		127.25		
SD	3.46		3.62		

Table 12: Diastolic blood pressure

DBP	I Gel	%	Supreme LMA	%
71 - 80	12	40	11	37
81 - 90	12	40	12	40
91 - 100	6	20	7	23
Total	30	100	30	100
Mean	83.41	-	85.52	-
SD	4.25	-	4.62	-

Table 13: Diastolic blood pressure - pre intubation

DBP	I Gel	%	Supreme LMA	%	P Value
71 - 80	13	43	11	40	
81 - 90	11	37	12	37	
91 - 100	6	20	7	23	
Total	30	100	30	100	0.321
Mean	83.41	-	85.52	-	
SD	4.25	-	4.62	-	

Table 14: Diastolic blood pressure-post intubation

DBP	I Gel	%	Supreme LMA	%	P Value
71 - 80	11	37	10	33	0.026
81 - 90	12	40	12	40	
91 - 100	7	23	8	27	
Total	30	100	30	100	
Mean	83.41	-	85.52	-	
SD	4.25	-	4.62	-	

Table 15: Mean arterial pressure

MAP	I Gel	%	Supreme LMA	%	P Value
71 - 80	11	37	10	33	0.014
81 - 90	12	40	12	40	
91 - 100	7	23	8	27	
Total	30	100	30	100	
Mean	84.12	-	82.52	-	
SD	10.25	-	09.67	-	

Table 16: Complications

Complications	I Gel	%	Supreme LMA	%	P Value
Sore throat	8	27	LMA	23	0.699
Blood stain	7	23	7	30	
Laryngospasm	6	20	9	17	
Pharyngealspasm	3	10	5	10	
Mucosal injury	6	20	3	20	
Total	30	100	6	100	

of the cases had the diastolic blood pressure between 71-80, 40% of the patients had between 81-90 and 27% of the patients had between 91-100.

It is significant that majority of the patients included in the study had diastolic blood Pressure post intubation 81-90.

With the P Value being < 0.05, there was statistical significance with regard to diastolic blood pressure post intubation. Also it is evident that iGel group is better compared to the supreme LMA group based on the mean calculations.

In this study, 37% of the patients had the Mean arterial pressure between 71- 80, 40% of the patients were between 81-90 and 23% of the patients were between 91-100 in the iGel group.

With regard to the patients used with Supreme LMA, 33% of the patients had the Mean Arterial Pressure between 71-80, 40% of the patients were between 81-90 and 27% of the patients were between 91-100. It is evident that majority of the patients had MAP between 81-90 in both the groups.

With the P Value being < 0.05, both the groups are statistically significant with regard to mean arterial pressure. Also it is evident that iGel group is better compared to the supreme LMA group based on the mean calculations.

Among the total cases, 23% had sore throat, 30% had blood stain, 17% had laryngospasm, 10% had pharyngealspasm, and 20% had mucosal injury in the iGel group. In the Supreme LMA group, 27% had sore throat, 30% had blood stain, 23% had laryngospasm, 20% had pharyngealspasm, and 10% had mucosal injury.

There is no statistical significance with regard to complications encountered in the placement of iGel and supreme LMA.

Discussion

The study was conducted in Sree Balaji Medical college and hospital with 60 patients. Out of which 30 patients were intubated with iGel and Supreme LMA was used in 30 patients. These supraglottic devices were used in minor procedures. The majority of the patients included in this study were in the age group of 31 to 45 years.

In our study, we found that i-Gel may be more useful than the supreme LMA for controlled ventilation and this was both statistically significant and clinically relevant. We found that the i-Gel was slightly easier to insert compared to Supreme LMA but the clinical relevance of the difference is not

known. Moreover, time to achieve an effective airway was similar between the two devices.

The first attempt and overall insertion success rates were similar between groups. Richez et. al. [13] carried out one of the earliest studies to evaluate the I-gel. They found that insertion success rate was 97%. Insertion was easy and was performed at the first attempt in every patient. I-gel is easily and rapidly inserted, providing a reliable airway in over 90% of cases. This disagrees with other studies that have shown a high success rate with both devices. No complete failure occurred in the I-Gel group. Acott [22], assessed the use of I-gel as an airway device during general anesthesia. In accordance with our results, they reported that a single insertion attempt was required in the majority of patients and all the insertion times recorded were less than 10 seconds. Similar results were obtained in study done by Gatward et. al. [23], who evaluated size 4 I-gel airway in 100 non-paralyzed patients and found that first insertion attempt was successful in 86% of patients, the second attempt in 11% of patients and the third attempt in 3% of patients. Our study has a number of limitations. First, our study was conducted in non-paralysed patients, hence our findings may be less applicable to paralysed patients. However, there is indirect evidence from mucosal pressure studies that pharyngeal muscle tone is similar in paralysed and non-paralysed patients. Second, both devices were inserted by anaesthesiologist. Therefore, our results may not be applicable to inexperienced users.

Jindal et. al. [21] reported hemodynamic stability with both LMA and I-gel devices, with no statistically significant difference between both devices, which is inconsistent with our findings. In our study, there is change in heart rate, systolic and diastolic blood pressure and mean arterial pressure while inserting the supreme LMA as compared to i-gel. One of the most important parameters to be compared between both supraglottic devices was postoperative complications. It was estimated that difference between S-LMA and I-gel regarding postoperative complications was not statistically significant except nausea and vomiting which was significantly higher in S-LMA due to high incidence of gastric insufflation. Consistent with our results, no major complications associated with I-gel have been described to date. Protection against aspiration is probably comparable with LMA family. Minor complications like sore throat, sore tongue were reported.

During maintenance of anaesthesia the airway was clear throughout the operation for most of the cases. One patient developed mild laryngospasm and the other patient had sore throat. No conclusions can be

drawn about the incidence of these complications due to the small numbers involved. There was minimal blood-staining with both the devices. Postoperative sore throat was also similar to both supraglottic airway devices. There are some limitations of the present study. Firstly, we studied only low risk patients assessed under ASA I and II who had normal airways, secondly not obese.

Conclusion

In conclusion, both LMA and I-Gel cause significant alteration in the hemodynamic status of the patients, and SpO₂. The postoperative complications are significantly different among both LMA and I-Gel patients. Insertion of I-Gel is significantly easier and more rapid than insertion of LMA. Leak pressure is significantly higher with I-gel than with LMA and thus incidence of gastric insufflation is significantly lower with I-gel.

References

1. Peppard SB, Dickens JH. Laryngeal injury following short term. *Ann Otol Rhinol Laryngol*, 1983;pp.327-30. [PubMed: 688183].
2. Jayashree S. Laryngeal mask airway and its variants. *Indian J Anaesth*, 2005;49:275-80.
3. Asai T, Murao K, Shingu K. Efficacy of the laryngeal tube during intermittent positive pressure. *Anaesthesia*, 2000;pp.1099-102. [PubMed: 11069337].
4. Levitan RM, Kinkle WC. Initial anatomic investigations of the Igel airway. A novel supraglottic airway without inflatable cuff. Initial anatomic investigations of the Igel. *Anaesthesia*, 2005;pp.1022-6. [PubMed: 16179048].
5. Practice guidelines for management of the difficult airway. An updated report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. *Anesthesiology*. 2003. pp.1269-1277.
6. Shorten GD, Opie NJ, Graziotti P, et al. Assessment of upper airway anatomy in awake, sedated, and anaesthetised patients using magnetic resonance imaging. *Anaesth Intensive Care*. 1994;p.165-169.
7. Williams PJ, Bailey PM. Comparison of reinforced laryngeal mask airway and tracheal intubation for adenotonsillectomy. *Br J Anaesth*, 1993;pp.30-33.
8. McClune S, Regain M, Moore. Laryngeal mask airway for caesarean section. *Anaesthesia*. 1990;pp.227-228.
9. Nanji GM, Maltby JR. Vomiting and aspiration pneumonitis with the laryngeal mask airway. *Can J Anaesth*, 1992;39:446-447.

10. Wharton NM, Gibbison B, Gabbott D, Haslam GM, Cook TM. I-gel insertion by novices in manikins and patients. *Anaesthesia*, 2008;63:991-5.
 11. Gatward JJ, Cook TM, Seller C, Simpson T, Vanek V, Handel J, Kelly F. Evaluation of the i-gel airway in 100 patients. *Anaesthesia*, 2008;63:1124-30.
 12. Gibbison B, Cook TM, Seller C. Case series: protection from aspiration and failure of protection from aspiration with the i-gel airway. *Br J Anaesth*, 2008;100:415-17.
 13. Schmidbauer W, Bercker S, Volk T, Bogusch G, Mager G, Kerner T. Oesophageal seal of the novel supralaryngeal airway device I-Gel in comparison with the laryngeal mask airways Classic and ProSeal using a cadaver model. *Br J Anaesth*, 2009;102:135-9.
 14. Verghese C, Ramaswamy B. LMA-Supreme-a new single-use LMA. With gastric access: a report on its clinical efficacy. *Br J*. 2008;101:405-10.
 15. O'Connor CJ Jr, Stix MS. Bubble Solution Diagnoses Proseal™ Insertion into the Glottis. *Anesth Analg* 2002;94:1671-2.
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