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Original Research

A Clinical Comparative Study Of I-Gel And Lts-D In Adult Patients Under Going Elective Non Laproscopic Surgery

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Abstract

Aim: To compare the outcome of I-GEL AND LTS-D in adult patients undergoing elective non laproscopic surgery.
Material and Methods: The present study was conducted on 60 ASA grade I and II patients of either sex between 18 to 60 years of age. The sample size calculated was 30 in each group. Patients were randomly divided using close envelope technique into following two groups of 30 patients in each group i.e. Group A (n=30) = I-GEL and Group B (n=30) =LTSD. We assessed the ease of insertion, attempts and time for insertion, hemodynamic changes and complications.
Results: When compared to LTSD the attempts required to insertion was less for I – GEL, but it was not statistically significant. When compared to LTSD the time required to insertion of I – GEL was less in duration and compared to LTSD, the ease of insertion for I – GEL was easier. Traumatic injury to the airway was less in I – GEL than LTSD. In postoperative adverse events sore throat and hoarseness of voice seen in LTSD was more than I-GEL.
Conclusion: I –GEL was better in view of ease of insertion, placement was rapid, less changes in hemodynamic parameters and also less traumatic to airways than LTSD.

Keywords: I-GEL, LTS-D

Introduction: Airway management is the primary responsibility of the anaesthesiologists to secure, preserve and protect it during induction, maintenance and recovery from anaesthesia. Failure to manage airway can lead to hypoxemia and brain damage. The first supraglottic airway (SGAD) device was introduced in anaesthetic practice in 1988, enabling hands-free airway maintenance without the need for tracheal intubation. Prior to this, the patient was either intubated or a face mask was held on the patients face for a prolonged period of time[1,2].
In the past 10 years, there has been a phenomenal increase in the use of supraglottic airway devices (SGADs) like proseal, I-Gel, laryngeal tube suction device etc. There are broadly two types of SGAD: first generation (classic LMA, Unique, AuraOnce, AuraStraight) and second generation (e.g. i-Gel, LTSD, LMA Pro-Seal, LMA-Supreme, AuraGain)[3]. The aim and objectives of the study are as follows:

Aim: To compare the assessment of I-GEL and LTSD SGAD insertion in adult patients undergoing elective non laparoscopic surgery, in two group of patients (group A I-Gel) (group B LTSD).

Objectives:
1. Assessment of Hemodynamic changes due to pressore response (HR,SPO2,SBP,DBP) during SGAD insertion.
2. Time taken for device insertion
3. Ease of insertion
4. Any other complications during procedure.

Materials And Methods: After approval from the Ethics committee of the institution, the present study was conducted on the patients admitted in the SVBP hospital, affiliated to L.L.R.M. Medical college, Meerut. Patients undergoing elective surgeries were included in the study.
Inclusion criteria:
1. Age- 18 to 60 year
2. ASA grade 1 and 2
3. BMI 18- 25
Exclusion criteria:
1. Patient refusal.
2. Mallampatti grade III and IV

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3. History of bleeding diathesis
4. Significant systemic disease

Allocation of group: A total of 60 patients were randomly allocated into two groups of 30 each i.e. Group A (I-Gel) and Group B (LTSD). I-Gel is a new SGAD with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer and smooth under surface of the device, from the tip of bowl and throughout the entire tube section, allow the device to easily slide along the back of the throat and securely into place. I-Gel has the potential advantages including easier insertion, minimal risk of tissue compression, inbuilt bite block and stable after insertion, it seal the laryngopharyngeal space without any air being insufflated and has a esophageal lumen. The gel like cuff is designed to fit perilaryngeal anatomy. It has the advantage of easier insertion, less tissue trauma and stability. It is a latex free device. The thermoplastic elastomer a soft gel like material is used to make of I – GEL. It is a transparent material. It creates an anatomical seal without an inflatable cuff. So it avoids the compression injury to perilaryngeal structures that can occur with other inflatable device. The noninflattable cuff fits correctly onto the perilaryngeal anatomy. Its cuff tip lies in the opening of the oesophagus. So it separates laryngeal opening from oesophagus. It has drain tube opening at the tip. This Soft gel like design ensures the maintaining of blood flow to the perilaryngeal structures and reduces the neurovascular compression. The proximal end of the cuff contains the epiglottic rest, it avoids the epiglottis from folding / obstruction to the airway. It also prevents upward movement of the device from its position.

The laryngeal tube suction device (LTSD) consist of tube with a two inflatable balloons and one suction port, small esophageal balloon and a large balloon for placement in the hypopharynx. A suction port distal to the esophageal balloon is present, permitting decompression of the stomach. This device can be inserted blindly through the oropharynx into the hypopharynx to create an airway during general anaesthesia and cardiopulmonary resuscitation so as to enable mechanical ventilation of the lungs.

Insertion Technique:

First the cuff is deflated to a smooth spoon shaped shape, posterior mask tip is lubricated, the black line is aligned with patient's nose. Patient's head is kept at sniffing position (in the absence of any contraindications). The LTSD is held at the junction of tube and cuff like a pen and glided against the hard palate along its curvature, until a definite resistance is felt. The index finger is used for guiding the LMA, while the index finger is removed press down the LTSD (using the dominant hand), mask is inflated to maximum volume. These parameters of hemodynamic and pulmonary status were measured on arrival of patient in the operating room: Baseline HR, SBP, DBP, SPO2 and ECG were recorded. Patients were pre-oxygenated with 100% oxygen for 3 minutes and appropriate premedication was given. Patient's induction was performed using volatile anaesthetic agent sevoflurane and after patient was put on NDMR, oxygen, nitrous oxide, isoflurane and positive pressure ventilation. The following parameters H.R, S.B.P, D.B.P, SPO2 and ECG changes were noted at pre-induction as mentioned already and after induction, during I-Gel and laryngeal tube insertion, 5 min after device I-Gel/LTS-D insertion, 15 min after device insertion during intra op, during device removal, and post op. After insertion of I-Gel/LTS-D correct placement is confirmed by auscultation and end tidal carbon dioxide (ETCO2) values. After confirmed subsequent anesthetic management were be continued as per the need of the case.

SCORING SYSTEM

***INSERTION ATTEMPTS**

NO. OF ATTEMPTS	SCORE
ONE (A1)	2
TWO(A2)	1
>TWO	0

***EASE OF INSERTION**

TIME FOR INSERTION	SCORE	EASE OF INSERTION
<30 SECONDS	2	VERY EASY
30-50 SECONDS	1	MEDIUM
>50 SECONDS	0	DIFFICULT

Results: The mean age (years) in Group A (38.4±6.98) and Group B (40.93±8.2) were comparable (p-value = 0.22). The male to female ratio in Group A (16:14) and Group B (10:20) were comparable. Mean attempts in Group A (1.33±0.47) and Group B (1.46±0.50) and p-value (p=0.80). It shows no of attempts non-significantly between the two groups (table 1).

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Table 1: Attempts comparison among the groups

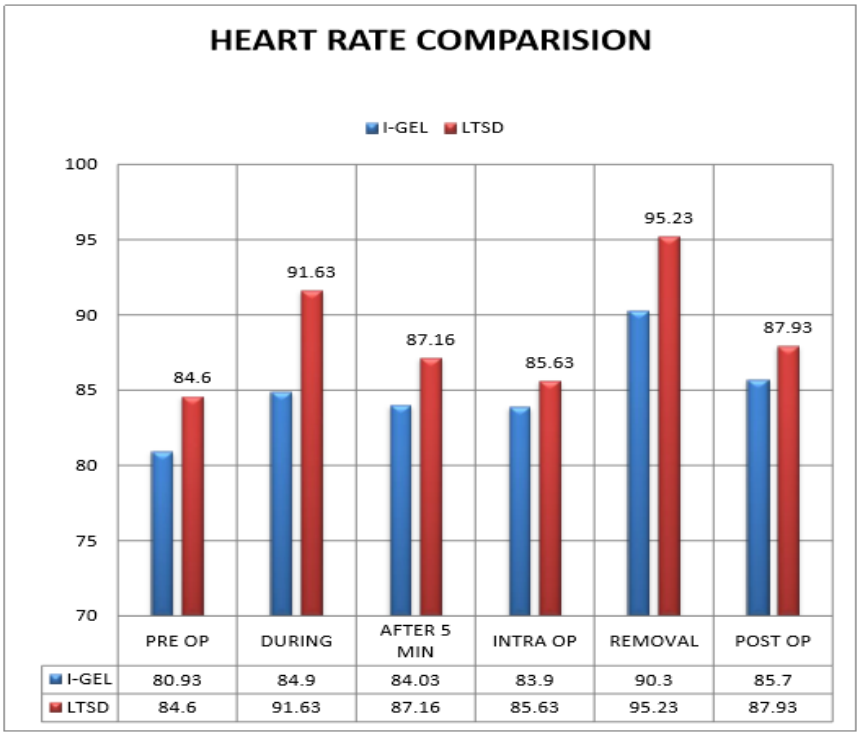
NO.OF ATTEMPTS	I-GEL	LTSD
A1	20	16
A2	10	14
TOTAL	30	30
MEAN	1.33	1.46
SD	0.47	0.50
P' VALUE	0.804	

Mean insertion time (secs) in group A (32.53±7.09) and in group B (39.06±10.102). Mean insertion time was observed to be significantly lower in Group A as compared to Group B ($p<0.00321$). Mean of ease of insertion in group A (1.4±0.49) and in group B (1.33±0.50). Mean of ease of insertion was observed to be significantly lower in Group B as compared to Group A ($p<0.0092$) as shown in table 2.

Table 2: Ease of insertion comparison among the groups

EASE OF INSERTION	I-GEL	LTSD
EASY	13	6
MEDIUM	17	22
DIFFICULT	0	2
TOTAL	30	30
MEAN	1.4	1.33
SD	0.498	0.507
P' VALUE	0.0092	

After induction, in both the groups a slight increase in pulse rate was observed. This trend of increase continued till 5 min post insertion interval. Thereafter, the pulse rate showed a slow decline till 15 min p.i. After 15 min p.i. interval, in both the groups only decimal fractional change in mean p.i. were noticed. At during removal, the mean pulse rate in Group A was 90.30±6.76 bpm as against 95.23±4.24 bpm in Group B. At none of the time intervals, a significant difference between two groups was observed ($p>0.05$) as shown in graph 1.



Graph 1: Comparison of heart rate among the study groups

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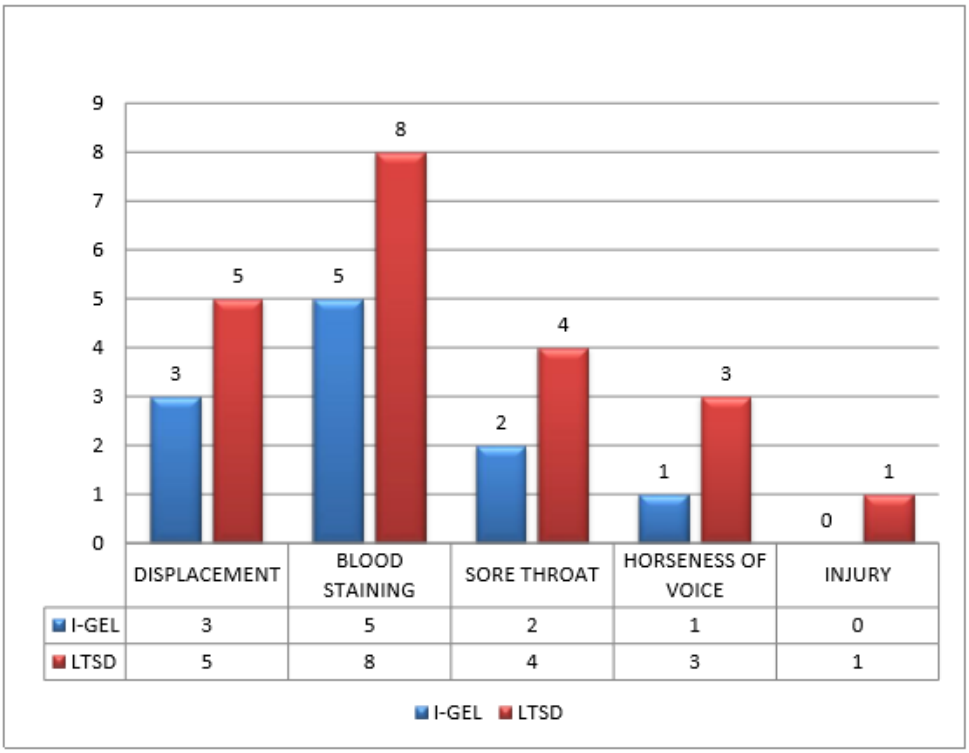
At baseline, the mean SBP in Group A was 122.4±7.490 mm of Hg and 130.73±6.528 mm of Hg in Group B. On comparing the data statistically, no significant difference between two groups was observed (p=0.256). After induction, during the device insertion in both the groups increase in SBP was observed but in group B more increase in SBP in comparison to group A the difference between two groups was significant statistically (p=0.0059). The mean SBP in two groups after 5 min of device insertion slightly lower than at the time of insertion but in group B it significantly higher (p=0.0419) against group A. At 15 min intra op, the difference between two groups was nonsignificant statistically (p=0.604). At the time of device removal, the mean SBP in Group A was 125.70±4.83 mm of Hg as compared to 137±0.0 mm of Hg in two groups, showing significant difference between two groups (p=0.0410) as shown in table 3.

Table 3: Comparison of blood pressure among the groups

BLOOD PRESSURE		I-GEL		LTSD		P'VALUE
		MEAN	SD	MEAN	SD	
PRE OP	SBP	122.4	7.490	130.73	6.528	0.256
	DBP	79.73	5.650	83.46	5.963	0.376
DURING INSERTION	SBP	128.3	5.94	136	6.05	0.0059
	DBP	83.13	6.25	88.53	4.06	0.699
AFTER 5 MIN	SBP	124.0	5.61	131.73	6.05	0.0419
	DBP	81.26	5.61	85.13	4.74	0.0829
INTRA OP (15 MIN AFTER INSERTION)	SBP	123.0	6.20	130.86	5.00	0.0604
	DBP	81.6	5.69	84.86	4.71	0.2232
REMOVAL (AFTER 2 MIN)	SBP	125.7	4.83	137	5.245	0.0410
	DBP	83.4	5.176	89.33	3.33	0.0364
POST OP	SBP	125.1	4.83	132.7	5.34	0.9504
	DBP	82.33	4.844	86.46	3.66	0.287

Complications were less in I-GEL which was significantly less than LTSD (graph 2).



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Graph 2: Comparison of complications among the study groups

Discussion: In this study, there was statistically no significant difference in age (p=0.221), gender and weight (p=0.47). This indicates that the groups were matched on the demographic variables and no bias of demographic variable was found. In our study out of 30 subjects in group A (I-GEL), 20 patients were inserted with device in 1st attempt and 10 in 2nd attempt and in group B (LTSD), 16subjects out of 30 were inserted and 14 subjects in 2ndattempt. First time success rate of insertion is more in I-GEL in comparison to LTSD. The mean attempts in Group A (1.33±0.47) and Group B (1.46±0.50) and p-value (p=0.80). It shows no of attempts non significantly between the two group. Anurag Garg, N.S. Lamba et al[4] reported that first time success rate for insertion of Baska mask was higher than that of seen with I-Gel (94% vs 70%), respectively (P = 0.0033). B Richez et al[1] perfomed a prospective, observational study, they evaluated the I-gel in 71 subjects. Insertion success rate was 97%. Insertion was easy and was performed in first attempt in every patient.

The time taken for insertion was not same in two groups. It was significantly less with I-GEL group with mean time of 32.5 seconds, which is statistically significant (p value = 0.0032), followed by LTSD with mean time 39.066 seconds. In a study conducted by Russo SG[5], insertion times did not differ significantly (i-gel™ 10±5 sec; LMA-S 11±9 sec; LTS-D 14±10 sec; p = 0.173). In a study conducted by Suzzana et al showed insertion time for classic LMA from 35-105 seconds and proseal LMA 25-75. G Amarappa, Vishwanath et al[6] in their study showed that I-gel has better insertion conditions compared to LMA Proseal in terms of ease of insertion, jaw relaxation, number of attempts for insertion, time taken for insertion. The mean duration of insertion of Igel and proseal were 15.90±2.52 and 17.80 ±1.69 seconds respectively, which was statistically significant (p<0.05). Ease of insertion was comparable in two groups which was statistically significant (P'value = 0.0092). Insertion in group A was more easy against group B. A study done by Revi N[7], ease of insertion was more with I gel 96% (24/25) compared to pLMA 80% (20/25) and cLMA 88% (22/25). Ishwer singh and Monika Gupta et al[9] in their study showed that the ease of insertion of I-GEL was easy for 90% of cases (27) and 10% (3) of 51 cases had difficult insertion. The Proseal shows 83.3% cases (25) had easy insertion and 16.7% of cases (5) had difficulty in insertion.

In our study, difference in baseline heart rate, systolic blood pressure, diastolic blood pressure, Spo2 of both the groups was statistically not significant (p value> 0.05).Difference in Heart rate and spo2 during the insertion, after 5 min of insertion, intra -op, after 2mins of removal and post -op in both group was non significant (p>0.05). Systolic Blood pressure (SBP) during the insertion and after 5 min of insertion respectively in group A mean 128.33±5.94,124.06±5.61 and in group B mean (SBP) 136±6.05,131.73±6.05 was statistically significant (p<0.05). But in DBP no significant change was seen. Intra-op after 15 min of insertion non significant change in SBP and DBP of both the groups (p>0.05) was seen. At the time of removal of the devices significant changes in SBP (p=0.041) and DBP (p=0.036) of the two groups was seen, and post-op there was no significant change in SBP and DBP. In our study, we observed that changes in SBP and DBP was more in LTSD receiving group in comparison to I-GEL receiving group and other heamodynamic parameter were not changed significantly. A study done by Dr. Radha et al[9], comparing heamodynamic changes with proseal LMA 73 and classic LMA, which showed more changes in proseal LMA compared to classic, attributing it to the presence of dorsal cuff.

Shin, Won-jung et al[10] did a comparative study of the supraglottic airway I-gel with ProSeal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients. The American Society of Anaesthesiologists physical status I-II patients (n = 167) scheduled for orthopaedic surgery were included in this prospective study. There were no differences in the demographic data and hemodynamic data immediately after insertion of devices among the three groups. In case of displacement after placement, it was 3 with I-GEL compared to 5 in LTSD group. Regarding blood staining, it was less with I-GEL 5 out of 30 patients in comparison to LTAD 8 out of 30 patients. Sore throat complication was 2 with I-GEL and 4 with LTSD group. Hoarseness of voice was seen in 1 with I-GEL and 3 with LTSD group which was more and injury nil with I-GEL group and 1 with LTSD.

Theiler et al[11] analyzed complications associated with the use of I-gel in 2049 patients. They experienced 1.2% incidence of laryngospasm, 3.9% incidence of blood staining on the device, 2 cases of transient nerve damage, and one case of glottic hematoma after uncomplicated device insertion. Pavel Michalek et al[12] had done a study on complications of SGAD's, they found, SLMA, PLMA, I-gel, and LTS-D showed lower incidence of blood staining on removal than SLIPA and the incidence of sore throat and dysphagia following insertion of the LT or LTS II (LTSD) has been reported between 8% and 20%. The LTS-D showed a significantly higher incidence of postoperative sore throat and dysphagia than both the i-gel and SLMA.

Conclusion: With the above study I –GEL was better in view of ease of insertion, placement was rapid, less changes in hemodynamic parameters and also less traumatic to airways than LTSD.

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