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A COMPARATIVE STUDY BETWEEN I –GEL WITH CLASSICAL LMA IN SHORT SURGICAL PROCEDURE FOR REQUIREMENT OF PROPOFOL

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Abstract

Background and Aims: *Supraglottic airway devices have been established in clinical anesthesia practice and have been shown to be safe and efficient. The objective of this, randomized trial was to compare I-Gel with LMA-Proseal in anesthetized spontaneously breathing patients.* ***Material and Methods:*** *100 patients all asa 1 & 2 undergoing short surgical procedures were randomly assigned to I-gel (Group X) or LMA- Proseal (Group Y). Anesthesia was induced with standard doses of propofol and the supraglottic airway device was inserted. We compared the ease and time required for insertion, airway sealing pressure and adverse events.* ***Results:*** *There were no significant differences in demographic and hemodynamic data. I-gel was significantly easier to insert than LMA-Proseal (P < 0.05) (Chi-square test). The mean time for insertion was more with Group P (41 + 09.41 secs) than with Group I (29.53 + 08.23 secs) (P < 0.05). Although the airway sealing pressure was significantly higher with Group P (25.73 + 02.21 cm of H 2 O), the airway sealing pressure of Group I (20.07 + 02.94 cm of H 2 O) was very well within normal limit (Student's t test). The success rate of first attempt insertion was more with Group I (P < 0.05). There was no evidence of airway trauma, regurgitation and aspiration. Sore throat was significantly more evident in Group P. Conclusion: I-Gel is a innovative supraglottic device with acceptable airway sealing pressure, easier to insert, less traumatic with lower incidence of sore throat. Hence, I-Gel can be a good alternative to LMA-Proseal.*

Keywords: *I –Gel With Classical Lma In Short, Propofol, Classical Lma In Short Surgical Procedure, I –Gel*

INTRODUCTION

The approach of airway has evolved greatly in recent times since development of endotracheal intubation by Mc Evan in 1880 to present day use of modern supraglottic airway devices. The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of facemask. Dr. Archie Brain, a British anesthesiologist, for the first time indroduced the laryngeal mask airway in 1983. C LMA are to provide a clear airway without the need for anesthetist hand to support a face mask. Also, useful when holding a face mask may be difficult due to patient positioning or site of surgery. To overcome the limitations of the classical LMA, a new and cheaper supraglottic airway device I-Gel has been developed. I-gel is made up of thermoplastic elastomer which is soft gel like and transparent .The insertion of these devices require sufficient depth of anesthesia for the relaxation of jaw muscles and suppression of upper airway reflexes such as coughing, gagging and laryngospasm.

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Propofol as sole anesthetic agent is extensively used for the placement of supraglottic airway devices. Dixon‟s up and down method[1] has been successfully used previously to determine the dose of propofol required for insertion of supraglottic devices. A minimum of six crossover points is needed for this method to be used effectively. Our primary aim was to find the dose of propofol required for smooth insertion of Igel in the first attempt and to compare it with the C LMA using Dixon‟s up and down method[1]. We also observed hemodynamic stability and intraoperative and postoperative complications with these doses. We postulated that I gel produces less stimulation to the airway and thus would require lesser dose of propofol than c-LMA.

MATERIALS AND METHODS

The present study was conducted on 100 patients of ASA grade 1 and 2 between 20-60 years of either sex scheduled for elective surgery of less than 45 min.They were randomly divided in two groups, Group X and group Y of 50 patients each. Group X- We inserted c-LMA & Group Y- We inserted I-gel. After obtaining approval of the institutional review board and written informed consent, all patients underwent through preanaesthetic evaluation the day prior to the surgery. Non-consenting patients, pregnant women, lactating mothers, full stomach, surgery in prone position and patient with known allergy to propofol were excluded.
In the operation theater monitors were applied (noninvasive arterial blood pressure, electrocardiogram monitor and pulse oximeter). Basal vitals were recorded.IV cannula was secured and iv fluid was started.Patients were premedicated with injection glycopyrolate 0.004 mg/kg iv, injection ondensetrone 0.15 mg/kg iv, injection fentanyl 2 mcg/kg iv, injection midazolam 0.02mg/kg iv. Patients were preoxygenated for 3 minutes and predetermined dose of propofol was given intravenously beginning with 2mg/kg for the first patient in each group over 30 seconds. I-gel or LMA was inserted 60 seconds after the propofol injection. Patient‟s response was assessed as “movement” or “no movement”.

The term “movement” was defined as resistance in mouth opening, gross purposeful movement, coughing, straining or laryngospasm occurring after insertion of the device or during airway manipulations before an effective airway is established. The term “no-movement” was defined as the absence of bucking or gross purposeful movement after insertion of the device until an effective airway is established.

Both the devices were lubricated with hydrating jelly before insertion. An effective airway and proper placement of the device was judged by a square wave capnography, normal chest expansion and absence of audible leak.The device was connected to the bain‟scircuit and anesthesia was maintained with 50% O_2, 50% N_2O and sevoflurane on spontaneous respiration.

Patients‟s were watched for intraoperative complications like tachycardia, bradycardia, hypotension, hypertension, hypercarbia, aspiration and postoperative complications like coughing, blood stained device, tongue-lip-dental trauma, sore throat, hoarseness of voice. Postoperatively the patients were watched for the incidence of sore throat for 24 hours.

The doses of propofol for each patient were predetermined by modifications of dixon‟s up and down method in each group, The first patient received a dose of 2mg/kg.For the next patient, the dose of propofol was increased by 0.5 mg/kg if the response in the preceding patient was judged as “movement” or decreased by 0.5 mg/mg if response in preceding patient was ”no-movement”. The step size that is 0.5 mg/kg approximates the estimated standard deviation derived from the previous studies. Each patient in the study group received a predetermined dose of propofol depending upon previous patient‟s response.

Response of each paient with the dose used, plotted on the graph, with the patient‟s response on x axis and dosage in mg/kg on y axis. Propofol dose was then determined by calculating the midpoint dose of all independent pairs of the patients using a crossover technique that is “movement” to “no-movement”.ED50 for i-gel and LMA group were determine as the average of the crossover midpoints in each group. We studied 50 patients in each group and obtained 16 to 17 crossover midpoints in both the groups.

STATISTICAL ANALYSIS

All observations were recorded and results were analyzed statistically. Data was expressed as mean and standard deviation for comparing data between two groups, unpaired T- test was used and P value calculated. „P‟ value of <0.05 interpreted as clinically significant, whereas „P‟ value of <0.01 was taken as highly significant.

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This randomized, prospective study was conducted for comparing supraglottic airway devices, classical LMA and I gel in hundred patients. Patients of ASA grade 1 and 2 of age between 20-60 years of either sex were randomly selected and divided into 2 groups, group X(c-LMA) and group y(I-gel) of 50 patients each.

TABLE-1 DEMOGRAPHIC DATA

DEMOGRAPHIC DETAILS		
PATIENT DATA	GROUP X (cLMA)	GROUP Y (I GEL)
NUMBER OF PATIENTS	50	50
AGE(YEARS)	35.30 ± 12.19	32.93 ± 13.47
MALE/FEMALE	32 /18	35 /15
WEIGHT(KG)	49.67 ± 10.57	50.10 ± 8.38
ASA GRADE 1OR2	18 /12	33 /17

Table-1 shows demographic data (age, sex, weight) in patients of both groups. There was no significant difference between two groups with respect to demographic data. (P >0.05)

TABLE-2 EASE OF INSERTION

	GRADE	GROUP –X (CLMA) n=50	GROUP-Y (I-GEL) N=50	P VALUE
EASE OF INSERTION	EASY	37(74%)	47(94%)	0.04
	DIFFICULT	13(26%)	3(6%)	

Table-2 shows that it was easy to introduce device in 74% patients of Group - X (cLMA) and 94% patients of Group-Y (I-Gel) which is significant (p<0.05).

Graph 1 : Propofol dose in each patient with response to LMA group-X

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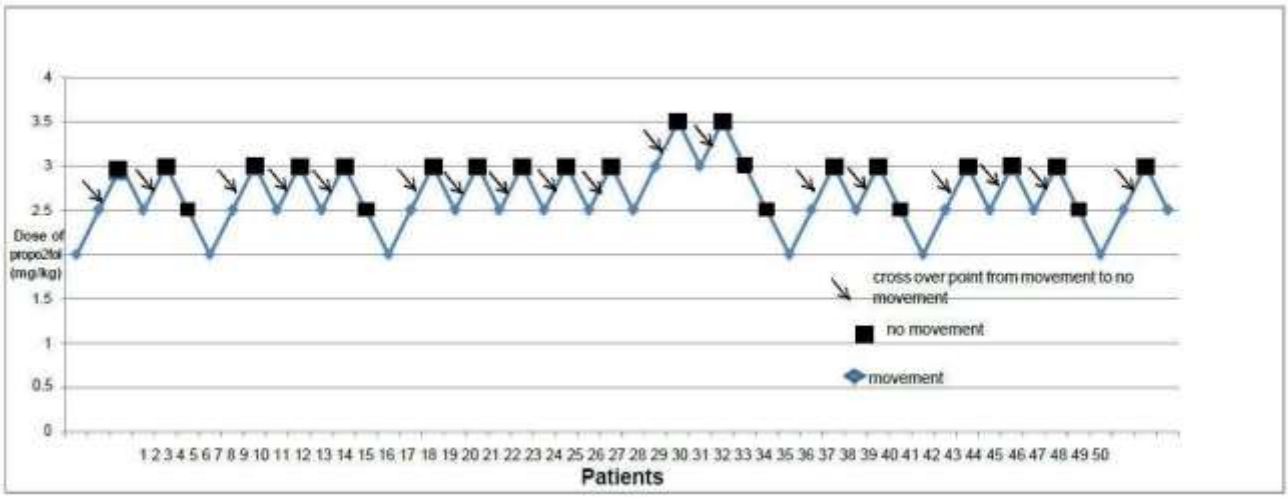

Graph 2 : Propofol dose in each patient with response to I-gel group-Y

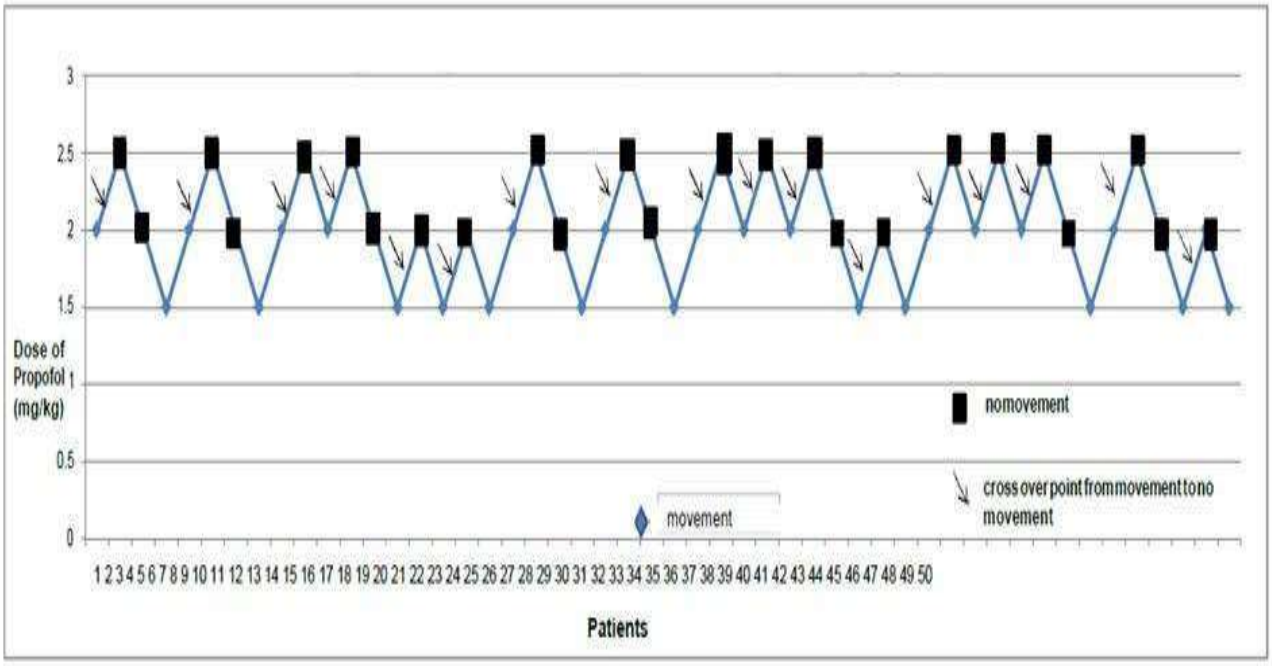

TABLE-3 MANIPULATION REQUIRED DURING INSERTION

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MANIPULATION REQUIRED DURING INSERTION		
	Group-X (cLMA) N=50	Group-Y (I-Gel) N=50
	No of patients (%)	No of patients(%)
Gentle pushing/pulling	5(10%)	2(4%)
Chin lift	3(6%)	0(0%)
Jaw thrust	3(6%)	2(4%)
Head extension/neck Flexion	2(4%)	0(0%)

MANIPULATION REQUIRED DURING INSERTION		
	Group-X (cLMA) N=50	Group-Y (I-Gel) N=50
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GRAPH - 3 : COMPARISION OF MEAN HEART RATE

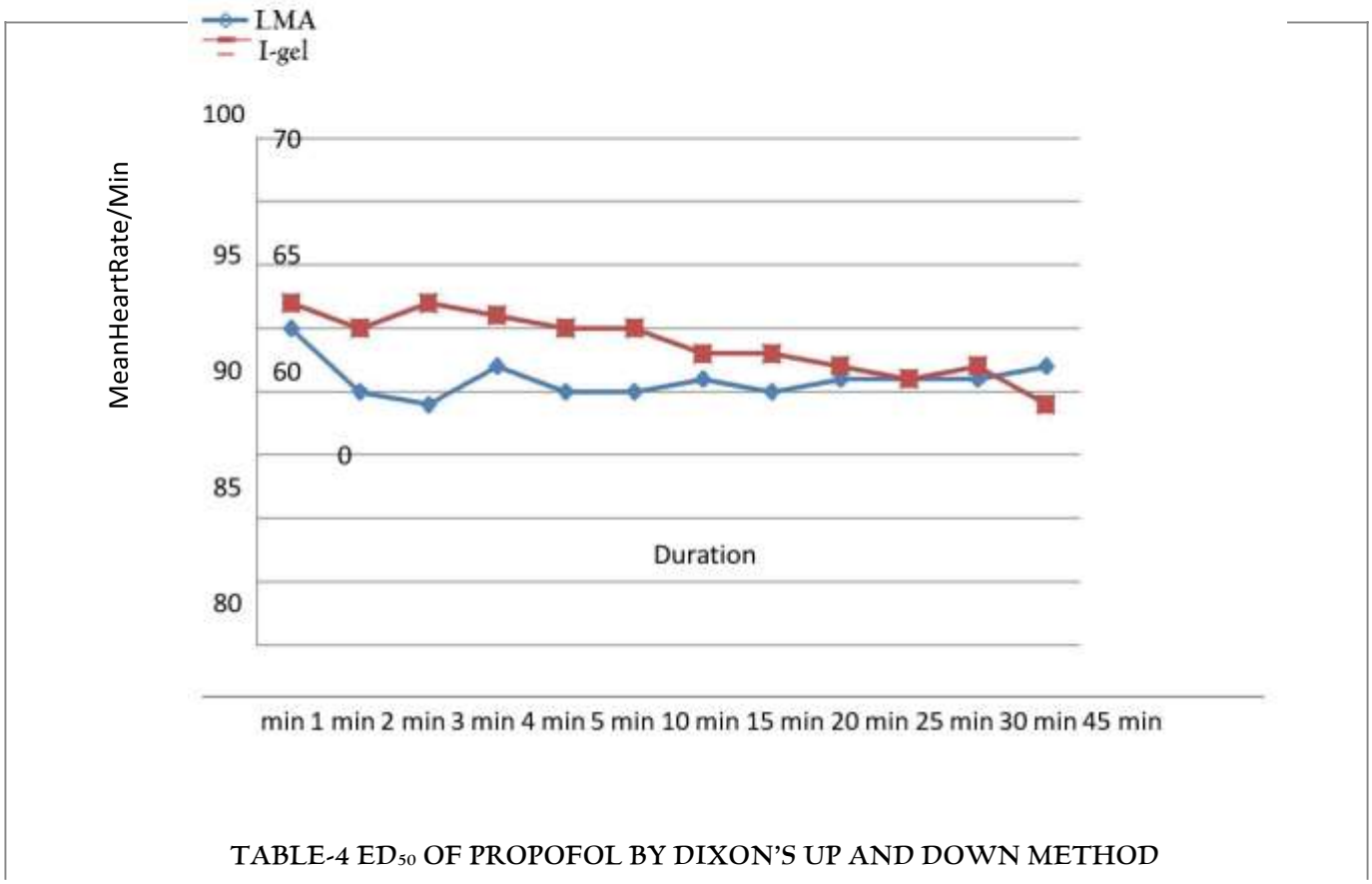

TABLE-4 ED_{50} OF PROPOFOL BY DIXON'S UP AND DOWN METHOD

GROUPS	ED_{50} (mg/kg)
I-gel	2.13 ± 0.35
LMA	2.67 ± 0.37

By students t-test, p value is <0.001.

LMA= laryngeal mask airway. ED = effective dose.

DISCUSSION

Endotracheal intubation has been considered to be the gold standard of care for patients requiring general anaesthesia. But various types of supraglottic devices are good alternative for securing and maintaining a patent airway for surgery requiring general anaesthesia. The LMA represents one of the most important revolutions in the airway management. I-gel is a single use non-inflatable supraglottic airway device. This study is to compare cLMA with i-gel for ease of insertion, dose of propofol and haemodynamic stability. The major finding in this case study was that the propofol requirement for smooth insertion of I-gel was significantly less (p<0.001) than cLMA.

In our study 74% (37/50) patients of group-X (cLMA) and 94% (47/50) patients of group-Y (I- Gel),insertion was done easily without any manipulation. The ease of insertion was more with group-Y (47/50) which was statistically significant. (P=0.0421)

Amr and amin[2] found that the use of propofol at 2.5 mg/kg produced comparable insertion conditions for i-gel compared with thiopentone sodium (7mg/kg). They used fixed dose of propofol 2.5mg/kg for every patients and premedication was not given unlike our study where we used dixons up and down method along with fentanyl 2mcg/kg and midazolam 0.02 mg/kg as premedication.

Tanaka and nishikawa[3] who found propofol requirements after fentanyl for LMA insertion to be 1.42 ± 0.26 (1.15-1.69) mg/kg. Also our criterion of smooth insertion (i.e. the definition of „no movement") may have been relatively strict compared to study conducted by tanaka and nishikawa.

Hui et al[4] reposted that co-administration of alfentanyl -propofol provided better insertion conditions for lma than fentany l-propofol.

In our study at all points of time interval mean heart rates,systolic and diastolic blood pressures were comparable and there was no statistically significant difference between the two groups with p value>0.05. Propofol reduces arterial blood pressure due to reduction in sympathetic tone and direct venodilator effect, as the patients in the LMA group received higher mean dosage of propofol, a steeper fall in blood pressure was expected. However the haemodynamic stability observed in our study can be contributed to the hypotension produced by propofol, which offsetted the pressor responses of LMA.

Amar M helmy et al[5] was found statistically no significant difference between group i-gel and group lma of the study, regarding systolic BP, diastolic BP, heart rates, spo2(%) and etco2 throughout the whole duration of the surgery. Bikramjit das et al[6] in their study they found there were not any significant changes occur in heart rate and mean arterial pressure throughout the study. Data from both the group I-gel and group lma were comparable. Priyamvada gupta et al[7] observed that change in mean arterial pressure, heart rate, and arterial oxygen saturation (spo2)were comparable in both the group I-Gel and group cLMA.
Shin et al[8] also found no difference in haemodynamic data immediately after the insertion of I-Gel, Proseal LMA and cLMA.

In our study, none of the patients had coughing, gagging or bronchospasm/laryngospasm during insertion of the device in any of the group.

Priyamvada gupta et al[7] concluded that statistically significant difference was found between the I-Gel and cLMA groups as regards the assessment after removal of the supraglottic airway device, evidencing that IGel had a lower incidence of complications such as sore throat, blood staining, oral injury, pain on swallowing($p<0.05$).

Amar helmy et al[5] found postoperative complications were not significantly different except nauses and vomiting was significantly higher in LMA group ($p=0.032$)than I-Gel group patients.

Jeevan singh et al[9] shows there were no incidence of major airway obstruction or bronchospasm intraoperatively in i-gel group but there were 2 incidences of major airway obstruction in lma group.

Alireza pournajaflan et al[10] observed that the incidence of postoperative complications was not significantly different between both the group I–gel and group clma.

R F danha et al[11] show that the incidence of postoperative complications in terms of sore throat was seen in 5 of 15 in lma unique group, compared to 3 of 15 in the I-Gel group. This difference was statistically significant, Saturation (spo2) was comparable in both the group I-Gel and group cLMA.

Priyamvada gupta et al[7] concluded that statistically significant difference was found between both the IGel and cLMA groups after removal of the supraglottic airway devices, evidencing that I-Gel had a lower incidence of complications such as sore throat ,blood staining , oral injury, pain on swallowing($p<0.05$).

CONCLUSION

From the present study, We concluded that I-Gel is better alternative supraglottic device than C-LMA in view of ease of insertion, attempts of insertion, manipulations required and postoperative complications. Both the devices were

comparable in view of haemodynamic parameters, spo2, etco2, proper placement of device, failure rates, complications during insertion .In our study the dose of propofol required to insert I-gel is lower than C-LMA.

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