

Comparison of Three Levels of Target Controlled Infusion of Propofol to Assess Ease of Insertion of I-Gel

Shubham Shukla¹, Ashok Kumar Sharma², Rishiraj Sanjay³, Shishir Agrawal⁴,
Teena⁵, Vivek Kumar⁶

1, 5, 6- Vivekananda polyclinic and institute of medical sciences, Lucknow

2- Asian hospital, Faridabad

3- Batra hospital & medical research hospital, New Delhi

4- Apollomedics Hospital, Lucknow

Corresponding author- Ashok Kumar Sharma, Senior consultant, Asian hospital,
Faridabad

Abstract: Propofol is fast acting IV agent with favorable profile for inducing and maintaining total IV anaesthesia. It provides smooth and rapid induction and obtunds upper airway reflexes readily and imparts suitable condition for I- Gel insertion. Target Controlled Infusion (TCI) System is an IV drug delivery system containing pharmacokinetic model of a drug. TCI System delivers precisely the amount of drug required to achieve concentration as selected by anaesthesiologist, and then continue to infuse the agent at a proportionate rate to maintain it. This study was done to determine the most appropriate effect site concentration of propofol for easy insertion of I-gel without significant hemodynamic compromise.

Material and Methods:

A prospective double blind randomized controlled trial was conducted in a tertiary care hospital over a period of one year. ASA status I or II, aged 18 to 60 years, undergoing short duration (<1 hr) elective surgeries under general anesthesia were enrolled. TCI effect site concentration of 2.5mcg/ml, 3.5mcg/ml and 4.5mcg/ml were used in Group-I, II, III respectively. Successful insertion of I gel in three groups were compared by Fischer exact or contingency Chi-square test. Pre induction and post induction hemodynamic parameters were compared using ANOVA test.

Results:

Number of attempts of I gel insertion in group I was higher as compared to group II and group III. I gel was inserted in first attempt in maximum patients of group III. Incidence of cough and gag reflex was least in group III, where cough reflex was in 3 patients. Whereas in group I, it was in 6 patients. Relaxed jaw was found in maximum number of patients of group III. Incidence of movement was maximum in patients of group I, during insertion of I gel. Increase in mean arterial blood pressure and heart rate was significantly low in group III during insertion of I gel ($p < 0.05$).

Conclusion:

I gel was inserted in first attempt in maximum patients in group with higher effect site concentration of propofol (group III). Incidence of untoward responses like cough, gag, movement, rigidity of jaw decreased from group I to III.

Keywords: Propofol, TCI, I gel, effect site concentration.

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I. Introduction

I-gel is second generation supraglottic airway device used for short surgeries under general anaesthesia. Propofol provides smooth and rapid induction and obtunds upper airway reflexes readily and thus imparts suitable conditions for insertion of LMA^{1,2}.

It needs sufficient depth of anaesthesia during insertion to prevent untoward events of coughing, gagging and laryngospasm. Target controlled infusion device provide anaesthesia by controlling the calculated concentration of drug in the central compartment to achieve and maintain the desired blood concentration³. Diprifusor TCI system contain the Diprifusor (controller and software, including the pharmacokinetic model for propofol only) integrated within a syringe pump⁴. The anaesthesiologist enters a target plasma concentration based on knowledge of pharmacokinetic- pharmacodynamic relationship of drug and the desire effect as well as

on the individual response of the patient. The computer calculates the infusion rate and transmits it to the pump which then delivers drug to the patient at a desired rate.

Targeting the effect-site concentration shortened the time of loss of consciousness compared with the targeting plasma concentration without causing hypotension⁵.

In our study we compared three groups of patients using effect site concentration of 2.5 mcg/ml, 3.5mcg/ml and 4.5mcg/ml of propofol respectively for insertion of I gel.

II. Material and Methods

After approval of the hospital ethics committee, 90 adult patients of either sex, of ASA status I or II, aged 18 to 60 years, undergoing short duration(< 1hr) elective gynecological, orthopedic and urology surgeries under anesthesia(muscle relaxant was not used) were studied in this randomized double blinded study protocol.

Exclusion Criteria-

1. Difficult airway (MP grade III/ IV, mouth opening<2.5cm)
2. BMI> 30 kg/m²
3. Risk of aspiration
4. Upper respiratory tract symptom
5. Cervical spine disease.

TCI effect site concentration of propofol 2.5 mcg/ml, 3.5 mcg/ml, 4.5mcg/ml were used in Group I, group II, Group III respectively. Baseline vital parameters were recorded of all groups and patients were premedicated with midazolam (30mcg/kg) and fentanyl (1mcg/ kg). Propofol was administered by computer assisted TCI according to group chosen. Appropriate size I gel inserted as effect site concentration was achieved; arterial pressures, heart rate, EtCO₂, SpO₂ were monitored every minute for first 10 minutes and then every 5 minutes. Neuromuscular blocking drugs were not used. Failure in insertion of I- gel in three attempts in 30 second was excluded from study. Responses were monitored and classified - jaw relaxation (rigid/ relaxed), movement (bucking, gross purposeful movement/no movement), apnea (present/ absent), coughing (present/absent), gagging (present/absent), laryngospasm (present/absent) and number of attempts (1, 2, 3).

Proportion of successful insertion of I-gel in three groups was compared by Fischer exact or contingency Chi square test. Changes in hemodynamic parameters between pre and post induction were compared using ANOVA test.

III. Results and Observation

Written informed consent was obtained from ninety adult patients fulfilling the inclusion criteria scheduled to undergo short duration surgery under general anaesthesia. The difference in mean age of patients of Group I, Group II, Group III were 40.53±10.51, 39.63±9.17 and 41.20±8.96 respectively and were not found to be significant statistically. Patients of above three groups were found to be statistically comparable for weight, gender, ASA grade distribution and Mallampatti grade distribution (p>0.05).

Table-1 - Number of Attempt (1, 2, 3)

Groups(n=30)	I	II	III
Group I	16	13	1
Group II	25	5	0
Group III	28	2	0

Comparing the three groups, I- gel insertion was achieved in single attempt in 16, 25, 28 patients of group I, II and III respectively. Similarly second attempt was required in 13, 5 and 2 patients in respective groups. Third attempt required in 1 and 5 patients in group I and II respectively. (p < 0.05)

Table -2- Incidence of Cough and GAG reflex

Groups		I	II	III
Cough reflex	Absent	24	27	29
	Present	6	3	1
GAG reflex	Absent	19	25	29
	Present	11	5	1

Incidence of cough and GAG reflex decreased by increasing target concentration. Comparing the three groups, cough and gag reflex was present in minimum patients in group III (p<0.05).

Table-3- Jaw condition

Groups (n =30)	Relaxed	Rigid
Group I	13	17
Group II	24	6
Group III	28	2

Incidence of jaw rigidity decreased by increasing target concentration and jaw rigidity was significantly higher ($p<0.05$) in group I.

Table -4- Incidence of apnea and movement

Groups		I	II	III
Apnea	Absent	29	28	25
	Present	1	2	5
Movement	Absent	25	28	29
	Present	5	2	1

Incidence of apnea increased by increasing target concentration of propofol and was highest in group III (5 patients) which was significant as compared to group I and II ($p<0.05$). Movements (bucking and gross purposeful muscular movements) was significantly higher in group I i.e. in 5 patients as compared to other groups ($p<0.05$).

**Table -5- Changes in mean blood pressure (mm Hg)
(Mean±SD)**

Groups (n=30)	Baseline value	After premedication	At target level	On I-gel insertion
Group I	88.0 ±5.9	83.0±5.7	78.9±5.3	81.3±5.5
Group II	94.1±5.4	90.3±5.5	84.3±5.4	88.1±5.4
Group III	90.3±6.8	86.0±6.6	71.9±4.9	77.0±4.9

Preoperative and after premedication mean arterial blood pressure in all groups were comparable ($p<0.05$). Fall in blood pressure was significant in group III after achieving target level of propofol ($p<0.05$). Increase in mean blood pressure during I-gel insertion was observed in all groups, but the increase in group III was significantly low ($p<0.05$).

**Table -5- Changes in heart rate (per minute)
(Mean±SD)**

Groups (n=30)	Baseline value	After premedication	At target level	On I-gel insertion
Group I	76.2 ±9.41	73.9±8.76	70.23±7.6	72.0±8.0
Group II	78.7±8.37	76.4±8.01	70.93±7.4	73.8±7.6
Group III	76.1±7.48	73.7±7.9	63.8±6.8	66.0±6.8

Fall in heart rate was significant in group III after achieving target level of propofol ($p<0.05$). Increase in heart rate during I-gel insertion was observed in all groups, but the increase in group III was significantly low ($p<0.05$).

IV. Discussion

The target concentration is based on knowledge of the pharmacokinetic-pharmacodynamic relationship of the drug and desired effect, as well as on the individual responses of the patient⁶. Russell et al found that target controlled infusion resulted in more rapid induction of anaesthesia and allowed earlier insertion of LMA.⁷

I-gel is a recently introduced device which is promoted as a simpler, faster and safer supraglottic airway device. I- Gel is popular for spontaneous breathing patients undergoing minor surgical procedure. Adequate effect site concentration of propofol provides smooth induction and obtunds upper airway reflexes and thus imparts suitable condition for I-gel insertion without cardio-respiratory compromise. Hence, the present study was planned to determine what is the appropriate effect site concentration of propofol for easy insertion of I-gel without significant hemodynamic compromise.

For this purpose, a prospective randomized-controlled study was carried out. To ensure that there is no induced bias owing to randomization, the age, gender, grade of surgery, anthropometry (weight, height and BMI), type of surgical procedure and baseline hemodynamic were also found to be statistically matched, i.e., the three groups(30 patients in each) did not have any induced bias owing to randomization.

Wakeling et al⁸ found that effect site concentration correlates better with clinical effects and adequate depth is achieved faster if we target effect site concentration⁹.

In our study we used 3 levels of effect site concentration of propofol for ease of insertion of I-gel with minimal cardio-respiratory depression. We used 30 mcg/kg midazolam and 1mcg/kg fentanyl as premedication with effect site concentration of propofol 2.5, 3.5, 4.5 mcg/ml in groups I, II and III respectively. The ease of insertion of I-gel increased with increase in target concentration of propofol. Incidence of untoward responses like cough, gag, movement and rigidity of jaw decreased from group I to III. The incidence was significantly higher in group I and in group II and III were statistically similar.

We found that the fall in mean blood pressure was significantly higher in group III with 4.5mcg/ml similarly to Biak et al results. We found the fall in heart rate in all the groups but it was significantly higher in group III as compared to other groups¹⁰. Similar decrease in heart rate was found by Matilde et al¹¹.

In our study we found group 3.5 mcg/ml as optimum TCI concentration. Similar study conducted by Kodaka et al who found cp50 of LMA insertion as 3.24mcg/ml¹². In another study kodaka et al found EC50 LMA to be 3.14mcg/ml¹³.

Kim SH and colleagues compared the effect-site of 3.5 $\mu\text{g}\cdot\text{mL}^{-1}$ propofol in insertion of different supraglottic devices.¹⁴

Casati et al reported EC50 LMA to be 4.3mcg/ml but they did not use any premedication and targeted the plasma concentration¹⁵.

Goldsiff et al found that midazolam reduces the requirement of propofol for insertion of LMA 16.

Our study gives an indicative TCI effect site concentration 3.5mcg/ml as most appropriate for inserting I-gel without undue adverse effects.

V. Conclusion

On the basis of the study we conclude that TCI (effect site concentration) of 3.5 mcg/ml of propofol provides smooth insertion of I-gel. At this effect site concentration, incidence of cough, gag reflex, rigidity of jaw and gross purposeful movement & bucking were minimal with minimal hemodynamic variation.

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1. Consultant 2.Consultant 3. Senior Consultant 4. Senior Consultant 5. DNB resident 6. DNB resident.

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