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Target-controlled propofol infusion versus single-bolus propofol for I-gel insertion: A prospective randomized study in India

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Abstract:

Propofol TCI delivers drug to a set effect-site concentration, unlike bolus dosing, which can cause cardiovascular and respiratory depression. Therefore, it is of interest to compare the propofol TCI (Schnider model, 6 µg/mL, n=60) with a 2.5 mg/kg bolus (n=60) for I-gel insertion in 120 ASA I-II patients. TCI gave better jaw relaxation (83% vs. 58%; p=0.001) and insertion quality (80% vs. 55%; p=0.003). TCI also used less propofol (116 vs. 157 mg; p<0.001) and preserved hemodynamics better, with no ephedrine rescue versus 15% in the bolus group. Thus, TCI offers superior insertion conditions and hemodynamic stability at the cost of longer induction (124 vs. 54 sec).

Keywords: Target controlled infusion, propofol, I-gel, supraglottic airway, Schnider model, hemodynamic stability, induction of anesthesia

Background:

The I-gel (Intersurgical, Wokingham, UK) is a second-generation supraglottic airway device fabricated from thermoplastic elastomer (styrene-ethylene-butadiene-styrene) that forms a non-inflatable anatomical seal of the perilaryngeal structures without requiring cuff inflation [1]. Its integrated gastric channel offers an early warning of regurgitation and allows nasogastric tube passage, making it a versatile choice for elective procedures of short to moderate duration. Successful insertion requires adequate depth of anesthesia to achieve jaw relaxation and suppress upper airway reflexes. Propofol has emerged as the preferred induction agent for supraglottic airway device insertion owing to its pronounced inhibitory effect on pharyngeal and laryngeal reactivity [2]. The conventionally recommended induction dose of 2.5 mg/kg, however, results in a transient peak blood concentration of approximately 8–10 µg/mL, which is associated with dose-dependent cardiovascular and respiratory depression including apnea in up to 25–35% of patients [3]. Target controlled infusion (TCI) is a computer-controlled drug delivery system that titrates infusion rates using validated pharmacokinetic models to achieve a user-defined plasma or effect-site concentration [8, 9]. By avoiding the high peak plasma concentrations inherent to bolus dosing, effect-site TCI can theoretically reduce cardiovascular depression while maintaining adequate depth of anesthesia [4]. The Schnider pharmacokinetic model incorporates age, height, total body weight and lean body mass, making it particularly suitable for diverse patient populations. The effect-site concentration at which I-gel insertion is achievable in 50% of adults (EC₅₀) has been reported to be in the range of 4–8 µg/mL depending on premedication and concomitant opioid use [5]. Several studies comparing TCI with bolus propofol for laryngeal mask airway (LMA) insertion have demonstrated reduced propofol

requirements and better hemodynamic stability with TCI [6], but comparisons specifically involving the I-gel remain limited. Therefore, it is of interest to report the TCI propofol at a C_{et} of 6 µg/mL with a standard bolus dose of 2.5 mg/kg, describing their effects on ease of I-gel insertion, propofol consumption, induction time and hemodynamic responses.

Materials and Methods:

Institutional review board approval was obtained from Manipal Hospital, Bangalore, prior to study commencement. Written informed consent was obtained from all participants. The study was conducted between December 2015 and May 2017. This was a prospective, randomized, comparative study. Patients aged 18–60 years, ASA physical status I or II, with body weight not exceeding 85 kg, scheduled to undergo elective surgical procedures of duration not exceeding one hour (dilatation and curettage, superficial lump excision, lower ureteric stone removal, or external anal surgeries) under general anesthesia using I-gel as the supraglottic airway were eligible for inclusion. Exclusion criteria were: risk of pulmonary aspiration, BMI > 35 kg/m², anticipated or previous difficult airway with mouth opening < 3 cm, upper respiratory tract infection, hypertension, or New York Heart Association (NYHA) functional class III or above. Sample size was calculated which reported an easy LMA insertion rate of 72% with bolus propofol. Assuming a clinically significant difference of 33% (p₁ = 72%, p₂ = 48%), with 80% power and 95% confidence interval (α = 0.05, β = 0.20), the calculated sample size was 60 patients per group, totalling 120 patients. The formula used was: $N = (Z_{\alpha/2} + Z_{\beta})^2 \times [P_1(1-P_1) + P_2(1-P_2)] / (P_1 - P_2)^2$. Patients were allocated using a computer-generated random number table into two equal groups of 60: Group 1 (TCI) received propofol administered by a Fresenius Kabi TCI pump using the Schnider pharmacokinetic

model at a target Cet of 6 µg/mL, with the infusion stopped once the calculated effect-site concentration reached 6 µg/mL; Group 2 (Bolus) received propofol 2.5 mg/kg administered intravenously over 30 seconds. All patients underwent pre-anesthetic evaluation the day before surgery. Patients were cannulated with a 20-gauge intravenous catheter connected to a syringe pump via a 1.4 mL extension tube in the arm contralateral to the blood pressure cuff. Intraoperative monitoring included electrocardiography, scenography, noninvasive blood pressure and pulse oximetry. Following preoxygenation with 100% oxygen for 3 minutes, all patients received fentanyl 2 µg/kg IV and lignocaine 1 mg/kg IV (to reduce propofol injection pain) prior to induction. I-gel size was selected based on patient weight. The device was lubricated with water-based gel and inserted 15 seconds after loss of verbal contact in the bolus group, or when the predicted Cet reached 6 µg/mL in the TCI group. Patient movement was defined as coughing, straining, bucking, laryngospasm, or gross purposeful movement occurring at or within 1 minute of I-gel insertion. An additional propofol dose of 30 mg was administered for any movement and insertion was reattempted after 30 seconds. Hypotension (systolic BP < 90 mmHg) was treated with IV ephedrine 6 mg bolus.

Outcome measures:

Primary outcomes:

- [1] Jaw relaxation, assessed using Muzi's score (1 = fully relaxed; 2 = mild resistance; 3 = resistance but could be opened).
- [2] Insertion quality score (1 = full mouth opening, no movement; 2 = partial mouth opening, slight gagging, finger movements; 3 = difficult mouth opening, coughing, gross limb movements).
- [3] Number of attempts required for successful I-gel insertion.

Secondary outcomes:

- [1] Total propofol dose (mg) required for induction.
- [2] Induction time: time from start of propofol infusion to end of I-gel insertion (seconds).
- [3] Hemodynamic parameters: heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) at baseline, post-induction and at 1, 3, 5 and 10 minutes after I-gel insertion.

Statistical analysis:

Continuous data are expressed as mean ± standard deviation (SD). Categorical data are expressed as number (%). Between-group differences for continuous variables were analyzed using the independent Student's t-test; categorical variables were compared using the Chi-square or Fisher's exact test, as appropriate. Within-group hemodynamic changes over time were assessed using multiple paired t-tests with Bonferroni's correction ($p < 0.01$ considered significant after correction). A two-tailed $p < 0.05$ was considered statistically significant for between-group comparisons. All analyses were performed using standard statistical software.

Results:

All 120 enrolled patients completed the study. The two groups were comparable in age, sex distribution, weight, height and BMI (Table 1). Pre-operative airway assessments, including Mallampati grading, thyromental distance, inter-incisor distance and neck mobility, did not differ significantly between groups. Jaw relaxation was significantly superior in the TCI group: a Muzi's score of 1 (fully relaxed) was recorded in 83% of TCI patients versus 58% of bolus patients ($p=0.001$). Correspondingly, an insertion quality score of 1 was achieved in 80% of TCI patients versus 55% of bolus patients ($p=0.003$). Despite these differences in insertion quality parameters, the first-attempt success rate was not statistically different between groups (90% TCI vs. 96.6% bolus; $p=0.143$). No failed insertions occurred in either group (Table 2). Mean propofol dose for induction was significantly lower in the TCI group (116 ± 11 mg vs. 157 ± 29 mg; $p<0.001$). Induction time was significantly longer in the TCI group (124 ± 24 sec vs. 54 ± 15 sec; $p<0.001$). The number of patients requiring an additional propofol dose (8 vs. 15; $p=0.104$) and the incidence of movement during insertion (8 vs. 6; $p=0.57$) did not differ significantly between groups (Table 3). Within both groups, heart rate showed a significant decline from 1 to 10 minutes after I-gel insertion compared with baseline (Bonferroni-corrected $p<0.01$). Between groups, heart rate was significantly lower in the TCI group at all post-insertion time points (Table 4). No intervention was required for bradycardia in either group. Both groups exhibited a significant intra-group decline in SBP from post-induction through 10 minutes post-insertion ($p<0.01$ after Bonferroni correction). Between groups, SBP was significantly higher in the TCI group at all post-induction time points (Table 5). No patient in the TCI group required vasopressor support; 15% of patients in the bolus group required a single dose of IV ephedrine 6 mg for hypotension. Both groups showed a significant intra-group decline in DBP from post-induction through 10 minutes ($p<0.01$ after correction); however, there was no significant between-group difference in DBP at any time point. MAP was significantly lower in the bolus group at the post-induction time point and at 5 minutes post-insertion ($p=0.01$ and $p=0.02$, respectively); differences at other time points were not significant.

Table 1: Demographic and airway parameters

Variable	TCI Group (n=60)	Bolus Group (n=60)	P-value
Age (years)	38 ± 10	38 ± 12	0.89
Gender (M:F)	28:32	29:31	0.85
Weight (kg)	67 ± 7	65 ± 11	0.11
Height (cm)	162 ± 8	160 ± 7	0.13
BMI (kg/m ²)	26 ± 3	25 ± 3	0.26

Values are mean ± SD or number (%). BMI: body mass index.

Table 2: I-Gel insertion characteristics

Parameter	TCI Group (n=60)	Bolus Group (n=60)	P-value
Muzi's score 1 (fully relaxed)	50 (83%)	35 (58%)	0.001
Muzi's score 2 (mild resistance)	8 (13%)	25 (41%)	-
Muzi's score 3 (resistance)	2 (3%)	0 (0%)	-
Insertion quality score 1	48 (80%)	33 (55%)	0.003
Insertion quality score 2	12 (20%)	27 (45%)	-
First-attempt success	54 (90%)	58 (96.6%)	0.143

Values are number (%). Muzi's score: 1 = fully relaxed, 2 = mild resistance, 3 = resistance. Insertion quality score: 1 = full mouth opening/no movement, 2 = partial opening/slight gagging.

Table 3: Propofol requirements and induction characteristics

Parameter	TCI Group	Bolus Group	P-value
Propofol dose (mg)	116 ± 11	157 ± 29	< 0.001
Induction time (sec)	124 ± 24	54 ± 15	< 0.001
Patients requiring extra propofol	8 (13%)	15 (25%)	0.104
Movement during insertion	8 (13%)	6 (10%)	0.57

Values are mean ± SD or number (%).

Table 4: Heart rate (beats/min) - between-group comparison

Time Point	TCI Group (bpm)	Bolus Group (bpm)	P-value
Baseline	81 ± 14	86 ± 15	0.12
Post-induction	79 ± 13	83 ± 13	0.18
1 min post-insertion	71 ± 11*	77 ± 10*	0.002
3 min post-insertion	69 ± 11*	74 ± 10*	0.01
5 min post-insertion	65 ± 15*	75 ± 11*	< 0.001
10 min post-insertion	69 ± 12*	77 ± 12*	0.001

Values are mean ± SD. *Significant within-group change from baseline after Bonferroni correction ($p < 0.01$). bpm: beats per minute.

Table 5: Systolic blood pressure (mmHg) - between-group comparison

Time Point	TCI Group (mmHg)	Bolus Group (mmHg)	P-value
Baseline	140 ± 19	135 ± 17	0.098
Post-induction	116 ± 15*	105 ± 30*	0.006
1 min post-insertion	111 ± 15*	101 ± 12*	< 0.001
3 min post-insertion	103 ± 11*	96 ± 11*	< 0.001
5 min post-insertion	104 ± 11*	99 ± 10*	0.004
10 min post-insertion	109 ± 13*	102 ± 18*	0.037

Values are mean ± SD. *Significant within-group change from baseline after Bonferroni correction ($p < 0.01$).

Discussion:

This randomized controlled study shows that propofol TCI using the Schnider pharmacokinetic model at a CET of 6 µg/mL provides superior jaw relaxation and insertion quality conditions for I-gel placement compared with the conventional 2.5 mg/kg bolus technique. These superior insertion conditions were achieved with a statistically and clinically meaningful reduction in propofol dose (26% less) and with better hemodynamic stability, as reflected by higher post-induction SBP and MAP and an absence of vasopressor requirements in the TCI group. The significantly longer induction time observed in the TCI group (124 ± 24 sec vs. 54 ± 15 sec) is a predictable consequence of effect-site targeting pharmacokinetics. When propofol is administered as a rapid bolus, a high initial blood concentration creates a steep blood-brain concentration gradient, producing rapid onset of unconsciousness. In contrast, TCI titrates drug delivery to gradually raise the effect-site concentration to the target level, inherently taking longer. Similar findings were reported by Ragazzi *et al.* (147 sec TCI vs. 103 sec bolus) [9]. Researchers found propofol requirements of 110 mg (TCI) vs. 153 mg (bolus) significantly lower induction doses with TCI compared with manually controlled infusion in a large multicentre study [10]. The mechanism relates to the avoidance of unnecessary overshoot: by targeting the effect site, the TCI system administers only the dose required to reach and maintain C_{et} 6 µg/mL, avoiding the surplus delivered by weight-based bolus dosing that accounts for pharmacokinetic variability. Jaw relaxation, assessed using Muzi's score, was significantly better

in the TCI group, with a greater proportion of patients achieving complete jaw relaxation (83% vs. 58%; $p=0.001$) and an optimal insertion quality score (80% vs. 55%; $p=0.003$). This may be attributed to the more stable effect-site concentration achieved with TCI compared with the rapidly declining plasma concentration following bolus induction. Although insertion conditions were superior with TCI, first-attempt I-gel success rates were comparable between groups ($p=0.143$), consistent with the findings of Jang *et al.* for LMA insertion [11]. However, unlike their study, which reported no difference in insertion quality, our results favored TCI, possibly because the cuffless I-gel is more dependent on optimal jaw relaxation and anesthetic depth than the inflatable LMA. TCI also provided superior hemodynamic stability, with better preservation of systolic blood pressure and mean arterial pressure, lower heart rates during the first 10 minutes after I-gel insertion and no requirement for ephedrine compared with 15% of patients in the bolus group. These findings support the pharmacodynamic advantage of effect-site targeting, which avoids the high plasma peaks and abrupt cardiovascular depression associated with bolus administration. Similar observations have been reported by Peacock *et al.*, who demonstrated less hypotension with slower propofol infusion rates [12] and by Vale *et al.* [13], who showed that cardiovascular depression develops more gradually than hypnotic effects during effect-site TCI. The lower heart rate observed with TCI likely reflects more consistent sedation and reduced sympathetic stimulation during airway manipulation [14, 15].

Conclusion:

Propofol TCI using the Schnider pharmacokinetic model at C_{et} 6 µg/mL provides significantly superior jaw relaxation and I-gel insertion quality compared with the standard 2.5 mg/kg bolus technique, with a clinically meaningful reduction in total propofol consumption and better hemodynamic stability. First-attempt insertion success rates are comparable between the two techniques. TCI should be considered the preferred induction method for I-gel placement, particularly in patients for whom hemodynamic stability is a priority.

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