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Eleveld versus Schnider TCI Model for Propofol Sedation in Outpatient Colonoscopy: A Randomized Trial

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Abstract

Introduction: Outpatient colonoscopy is commonly performed under sedation, and propofol is frequently selected because of its rapid onset and short recovery profile. Target-controlled infusion (TCI) may improve dosing precision, but the comparative performance of the Eleveld and Schnider models during outpatient colonoscopy remains insufficiently defined. This study compared the Eleveld and Schnider TCI models for propofol sedation in patients undergoing outpatient colonoscopy.

Patients and Methods: This randomized, participant- and assessor-blinded, parallel-group controlled trial included 36 adults aged 20-65 years with ASA physical status I-III and BMI <30 kg/m2 who underwent elective outpatient colonoscopy. Participants were allocated to receive propofol using either the Eleveld or Schnider TCI model. The initial effect-site concentration was 2 µg/mL and was titrated by 0.5 µg/mL until a BIS value of 70 was achieved. The primary outcome was induction time, defined as the time from propofol infusion initiation to BIS 70. Secondary outcomes were mean propofol consumption, number of effect-site concentration adjustments, post-procedural agitation assessed using RASS, and recovery time to GCS 15.

Results: The Eleveld model was associated with shorter induction time than the Schnider model (4.03 ± 0.81 vs 5.32 ± 0.98 minutes; p <0.001) and lower propofol consumption (92.47 ± 28.29 vs 119.24 ± 31.56 µg/kg/min; p = 0.011). Recovery time was also shorter in the Eleveld group (5.27 ± 1.71 vs 7.88 ± 1.94 minutes; p <0.001). The number of effect-site concentration adjustments and post-procedural agitation did not differ significantly between groups.

Conclusion: The Eleveld TCI model was associated with faster induction, lower propofol consumption, and faster recovery than the Schnider model during outpatient colonoscopy, with comparable sedation adjustment requirements and post-procedural agitation. These findings suggest that the Eleveld model may improve sedation efficiency in this setting, although larger studies are needed to confirm its clinical and safety advantages.

Keywords: Colonoscopy; Drug delivery systems; Pharmacokinetics; Propofol; Sedation

Introduction

Colonoscopy is an important diagnostic and therapeutic procedure for lower gastrointestinal disease, particularly for colorectal cancer screening and early intervention.[1,2] The increasing use of outpatient colonoscopy has strengthened the need for sedation strategies that provide patient comfort, procedural efficiency, and rapid recovery. Despite its clinical value, colonoscopy may cause discomfort and anxiety, making sedation an important component of care.[3,4]

Propofol, an intravenous hypnotic agent, has emerged as the sedative of choice for endoscopic procedures because of its rapid onset, predictable recovery, and favorable safety profile.[5,6] Administering propofol, however, requires careful titration to balance adequate sedation with minimal adverse events, such as hypotension, bradycardia, and respiratory depression. Conventional methods, including intermittent bolus and continuous infusion via syringe pumps, often lead to fluctuating plasma concentrations, increasing the risk of over- or under-sedation.[7,8]

Target-controlled infusion (TCI) systems were developed to improve the precision of intravenous anesthetic administration by using pharmacokinetic and pharmacodynamic models to estimate plasma or effect-site concentrations, tailored to patient-specific factors such as age, body mass, and sex.[9,10] Among propofol TCI models, Schnider and Eleveld are commonly used. The Schnider model was developed from an adult population and uses covariates such as lean body mass, offers rapid onset and tight control in standard adult populations but may be less reliable in elderly or obese patients.[10,11] In contrast, the Eleveld was developed from a broader dataset and incorporates covariates including fat-free mass, potentially providing more adaptable sedation across different patient groups, although its induction may be slower and initial overshoot is possible.[12,13]

Despite the widespread adoption of both models, direct comparative studies evaluating the efficacy and safety of Eleveld versus Schnider TCI during outpatient colonoscopy remain limited. Most available literature assesses these models in surgical or intensive care settings, with varying patient demographics and procedural requirements, leaving a gap in knowledge regarding their relative performance in endoscopic sedation. Therefore, this study aimed to compare induction time, propofol consumption, effect-site concentration adjustments, recovery time, and post-procedural agitation between the Eleveld and Schnider TCI models during outpatient colonoscopy.

Patients and Methods

This randomized, participant- and assessor-blinded, parallel-group controlled trial was conducted at the Endoscopy Unit of a central general hospital in Bali, Indonesia, between July and August 2025. Ethical approval was obtained from the Udayana University Ethical Clearance Commission on July 20, 2025 (approval number: 2131/UN14.2.2.VII.14/LT/2025). Written informed consent was obtained from all participants before enrollment.

The sample size was calculated based on a previous study by Cuiabano et al. (2022) evaluating TCI propofol for colonoscopy sedation and expecting a clinically significant difference in induction time between the Eleveld and Schnider models, the sample size was calculated using an

alpha (α) of 0.05 and a statistical power of 80%. Anticipating a large effect size (Cohen's d = 0.98) based on pilot data/literature, a minimum sample size of 18 patients per group (total n=36) was determined to be sufficient. No dropouts occurred during the study, resulting in a final analysed sample of 36 patients.

Participants were recruited consecutively until the required sample size was achieved. Eligible participants were adults aged 20-65 years, of both sexes, with American Society of Anesthesiologists (ASA) physical status I-III and body mass index (BMI) <30 kg/m2 who were scheduled for elective outpatient colonoscopy. Patients were excluded if they had allergy to any sedative drug used in the study, neurodegenerative or psychiatric disorders, significant cardiovascular or hepatic dysfunction, chronic sedative use, or obstructive sleep apnea.

Participants were randomly assigned in a 1:1 ratio to the Eleveld or Schnider group using a computer-generated randomization sequence prepared by an independent statistician. Allocation concealment was maintained using sequentially numbered, sealed, opaque envelopes prepared by a third party not involved in recruitment, clinical care, or data collection. The envelopes were opened by the attending anesthesiologist only after eligibility had been confirmed and written informed consent had been obtained

Participants and outcome assessors were blinded to group allocation. The attending anesthesiologist could not be blinded because the assigned TCI model had to be selected and patient parameters had to be entered into the B. Braun Perfusor Space IITM system. Outcome measurements, including BIS threshold timing, propofol consumption, effect-site concentration adjustment, Richmond Agitation-Sedation Scale (RASS) assessment, and recovery evaluation, were performed by an independent trained assessor who was blinded to group assignment and had no access to the TCI interface.

Table 1. Baseline Characteristics of Study Participants

Characteristic	TCI-Eleveld (n=18)	TCI-Schnider (n=18)	*p*-value
Age, years (median, range)	57 (31–65)	56 (40–65)	0.937[M]
Male, n (%)	8 (44.4)	7 (38.9)	0.735[C]
Female, n (%)	10 (55.6)	11 (61.1)	0.735[C]
ASA I, n (%)	5 (27.8%)	5 (27.8%)	
ASA II, n (%)	9 (50%)	9 (50%)	1.000[C]
ASA III, n (%)	4 (22.2%)	4 (22.2%)	
BMI, kg/m² (mean ± SD)	23.89 ± 2.97	23.26 ± 3.39	0.563[T]
Procedure duration, min (mean ± SD)	26.44 ± 8.76	27.33 ± 8.49	0.759[T]

[M]Analysis of the variables was performed using the Mann-Whitney U test; results were considered significant if $p \leq 0,05$

[C]Analysis of the variables was performed using the Chi-square test; results were considered significant if $p \leq 0,05$

[T]Analysis of the variables was performed using the Independent T-test; results were considered significant if $p \leq 0,05$

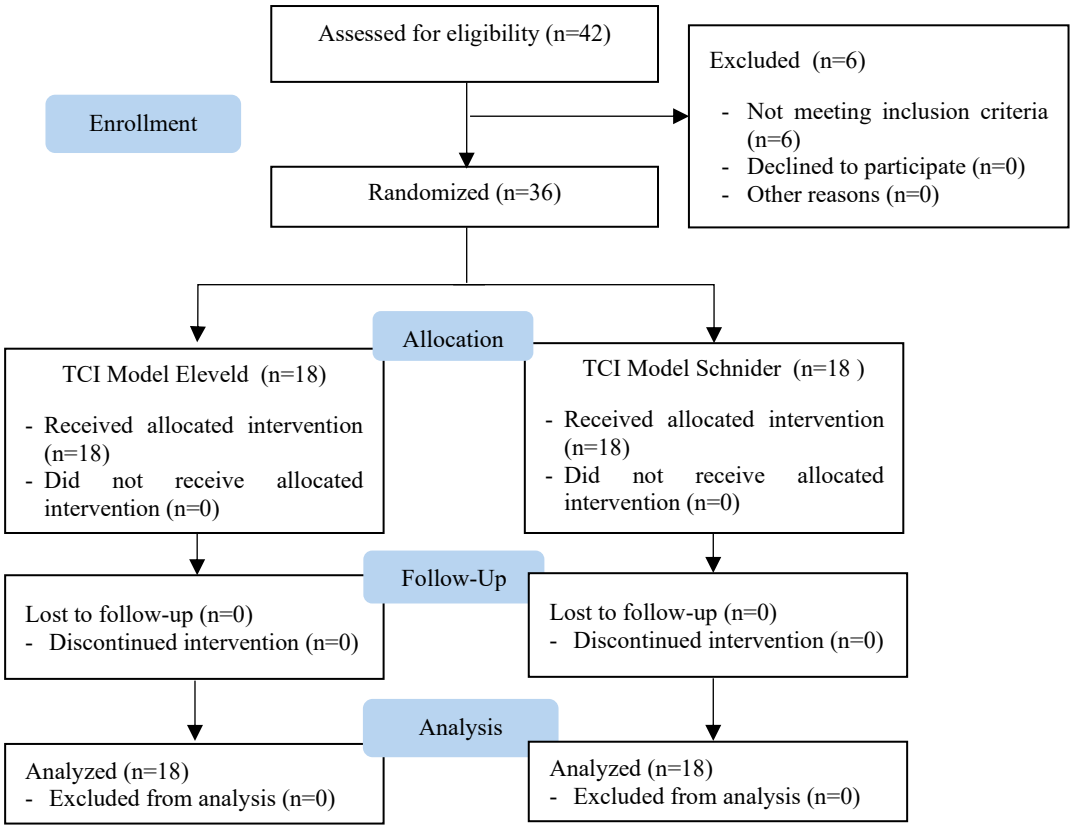

Figure 1. CONSORT Flow Chart

In the endoscopy unit, all participants received standard monitoring, including non-invasive blood pressure, electrocardiography, pulse oximetry, and Bispectral Index (BIS) monitoring. Supplemental oxygen was administered at 3 L/min through a nasal cannula throughout the procedure. Fentanyl 1 µg/kg was administered intravenously before propofol infusion. Propofol sedation was delivered using the assigned TCI model. In both groups, the initial effect-site concentration was set at 2 µg/mL and titrated in 0.5 µg/mL increments until a BIS value of 70 was achieved. During the procedure, effect-site concentration adjustments were made if BIS deviated outside the target range of 65-75 for more than 30 seconds or if clinical signs of inadequate sedation or over-sedation occurred.

The primary outcome was induction time, defined as the interval from initiation of propofol infusion to achievement of BIS 70. Secondary outcomes were mean propofol consumption (µg/kg/min), number of effect-site concentration adjustments, post-procedural agitation assessed using RASS, and recovery time, defined as the interval from cessation of propofol to GCS 15.

Predefined rescue protocols were used for adverse respiratory or hemodynamic events. Respiratory depression, defined as peripheral oxygen saturation <90% or respiratory rate <8 breaths/min, was managed with jaw-thrust maneuver, increased supplemental oxygen flow, or temporary cessation of the TCI pump until spontaneous ventilation recovered. Hypotension, defined as a decrease in mean arterial pressure >20% from baseline, was treated with a 250-mL intravenous fluid bolus and, if persistent, intravenous ephedrine 5-10 mg. Bradycardia, defined as heart rate <50 beats/min, was treated with intravenous atropine 0.5 mg.

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA). Data normality was assessed using the Kolmogorov-Smirnov test. Normally distributed continuous variables were presented as mean ± standard deviation and compared using the independent-samples t-test. Non-normally distributed variables were presented as median (minimum-maximum) and compared using the Mann-Whitney U test. Categorical variables were presented as frequency and percentage and compared using the Chi-square test or Fisher exact test, as appropriate. Statistical significance was set at $p < 0.05$.

Results

A total of 42 patients scheduled for elective outpatient colonoscopy were assessed for eligibility. Six patients were excluded because they did not meet the inclusion criteria. The remaining 36 participants were randomized equally into the Eleveld and Schnider groups, with 18 participants in each group. All randomized participants received the allocated intervention and were included in the final analysis. No protocol deviations, dropouts, or losses to follow-up were reported. Baseline demographic and clinical characteristics, including age, sex, BMI, ASA physical status, and procedure duration, were comparable between groups (Table 1).

The primary outcome, induction time, was significantly shorter in the Eleveld group than in the Schnider group (4.03 ± 0.81 vs 5.32 ± 0.98 minutes; $p < 0.001$). Mean propofol consumption was also significantly lower in the Eleveld group than in the Schnider group (92.47 ± 28.29 vs 119.24 ± 31.56 μg/kg/min; $p = 0.011$). Recovery time was significantly shorter in the Eleveld group than in the Schnider group (5.27 ± 1.71 vs 7.88 ± 1.94 minutes; $p < 0.001$). The median number of effect-site concentration adjustments did not differ significantly between the Eleveld and Schnider groups (3 [range, 1–6] vs 2 [range, 0–6]; $p = 0.710$). Post-procedural agitation occurred in one participant in each group (5.6% vs 5.6%; $p = 1.000$). The comparison of clinical outcomes between groups is presented in Table 2.

Table 2. Test of Normality

Variable	Kolmogorov – Smirnov Statistic	*p*-value[K]
Age	0.136	0.91
BMI	0.09	0.200
Procedure duration	0.089	0.200
Induction time	0.093	0.200
Mean Propofol Consumption	0.110	0.200
Effect-Site Concentration Adjustments	0.173	0.008
Recovery time	0.108	0.200

[K] The Kolmogorov-Smirnov test was used to assess normality; data were considered normally distributed if $p > 0,05$

Discussion

This study showed that the Eleveld TCI model provided faster induction, lower propofol consumption, and shorter recovery time than the Schnider model during outpatient colonoscopy sedation. Both models required a comparable number of effect-site concentration adjustments and showed similarly low rates of post-procedural agitation. These

findings suggest that the Eleveld model may offer greater dosing efficiency without compromising sedation stability in this outpatient setting.

The shorter induction time observed with the Eleveld model may be explained by differences in the pharmacokinetic and pharmacodynamic structures of the two models. The Eleveld model was developed using a broader and more heterogeneous population dataset and incorporates covariates such as age, sex, weight, height, and fat-free mass to estimate propofol distribution and clearance.[12,13] This structure may allow more individualized prediction of effect-site concentration and faster achievement of the intended sedation depth. In contrast, the Schnider model was developed from a more limited adult population and uses lean body mass as one of its key covariates, which may reduce its adaptability across varying patient characteristics.10 Previous comparative data in endoscopic sedation also reported shorter induction with the Eleveld model, supporting the direction of the present findings.[14] Although the absolute difference in induction time was modest, it may be relevant in high-volume outpatient endoscopy units, where small reductions in induction time can influence workflow efficiency.

Table 3. Clinical Variables

Outcome	TCI-Eleveld (n=18)	TCI-Schnider (n=18)	*p*-value (CI*)	Effect Size**
Induction time, minute (mean ± SD)	4.03 ± 0.81	5.32 ± 0.98	<0.001^{T} (-2.156 – -0.658)*	-1.429
Mean propofol consumption, µg/kg/min (mean ± SD)	92.47 ± 28.29	119.24 ± 31.56	0.011^{T} (-1.574 – -0.201)*	-0.893
Effect-Site concentration adjustments, times (median, range)	3 (1–6)	2 (0–6)	0.710^{M} (0.870 – 1.000)*	-0.062
Recovery time, minute (mean ± SD)	5.27 ± 1.71	7.88 ± 1.94^{T}	<0.001^{T} (-2.161 – -0.689)*	-1.433
Post procedural agitation, n (%)	1 (5.6)	1 (5.6)	1.000^{F}	

*95% Confidence Interval; **Effect size value based on Cohen's D; ^{T}Analysis of the variables was performed using the Independent T-test; results were considered significant if $p \leq 0,05$.
^{M}Analysis of the variables was performed using the Mann-Whitney U test; results were considered significant if $p \leq 0,05$. ^{F}Analysis of the variables was performed using the Fisher's Exact test; results were considered significant if $p \leq 0,05$.

This finding may be partly explained by the pharmacokinetic and pharmacodynamic differences between the two models. The Schnider model was developed from a relatively limited adult population and uses fixed compartmental assumptions with lean body mass as an important covariate. These characteristics may reduce its flexibility in predicting effect-site propofol concentrations across patients with varying physiological profiles. In contrast, the Eleveld model was developed from a broader population dataset and incorporates individual covariates, including age, weight, height, sex, and fat-free mass, to estimate propofol distribution and clearance.[10,15,16] This more individualized structure may allow more adaptive prediction of effect-site concentration, thereby contributing to faster achievement of the target BIS level and more efficient propofol use. In outpatient sedation, such differences may be practically relevant because even modest reductions in induction time and drug exposure can support smoother procedural workflow, although this study did not directly measure room turnover or operational efficiency.

The lower propofol consumption in the Eleveld group (92.47 μg/kg/min vs. 119.24 μg/kg/min in the Schnider group) supports the concept that a more individualized pharmacokinetic model may reduce unnecessary drug exposure while maintaining adequate sedation depth. This finding is clinically relevant because higher cumulative propofol doses may increase the risk of dose-related adverse effects, including hypotension, respiratory depression, and delayed recovery.[17] This result is consistent with findings from previous studies showing that the Eleveld model's more individualized dosing approach leads to a more efficient use of propofol while maintaining adequate sedation levels14. The Eleveld model incorporates individual physiological covariates, including age, weight, height, sex, and fat-free mass, allowing more adaptive estimation of propofol distribution and clearance. This may reduce unnecessary dose overshoot and improve dosing efficiency compared with the Schnider model, which uses a more limited pharmacokinetic structure. Despite this lower propofol requirement, the number of effect-site concentration adjustments was comparable between groups, indicating that both models were able to maintain sedation within the intended BIS-guided target range after adequate sedation had been achieved. Therefore, the main advantage of the Eleveld model in this study appears to be related to induction efficiency and lower drug requirement rather than superior intra-procedural sedation stability. This distinction is important because it suggests that the Eleveld model may be more efficient, while the Schnider model remains clinically usable for maintaining stable sedation during outpatient colonoscopy.[10,12,14]

Both TCI models required similar numbers of effect-site concentration adjustments during sedation (3 vs. 2, $p = 0.710$), indicating that both systems were effective in maintaining stable sedation with minimal need for titration. This result suggests that, although Eleveld is more efficient in terms of induction and drug consumption, both models can achieve comparable levels of sedation stability. The similarity in adjustment requirements between the two models aligns with the findings of other studies, which suggest that both Schnider and Eleveld models are equally capable of maintaining sedation

during a range of procedures, including those requiring relatively deep sedation like colonoscopy.[18]

Recovery time was also shorter in the Eleveld group (5.27 ± 1.71 min vs. 7.88 ± 1.94 min in the Schnider group). This may be related to lower propofol exposure and more efficient effect-site targeting during the procedure, resulting in less residual sedative effect after cessation of infusion. This finding supports the notion that more accurate effect-site targeting with the Eleveld model allows for a quicker return to full consciousness and may reduce the overall time spent in the recovery room19. Quicker recovery times also enhance patient satisfaction and operational efficiency, making Eleveld an ideal choice for outpatient colonoscopy and similar procedures. The relationship between cumulative propofol dosage and recovery duration is well-established; lower total doses promote faster drug elimination from the body, thereby shortening the recovery phase. The Schnider model calculates the induction bolus based on distribution to the central (plasma) compartment, but often lacks precision in predicting effect-site concentrations—particularly in elderly patients or those with extreme body mass indices, who represent common demographics in colonoscopy. Consequently, anesthesiologists must frequently adjust target concentrations or administer supplemental boluses. In contrast, the Eleveld model is derived from a larger, more diverse database and utilizes a more sophisticated algorithm, enabling it to predict how propofol distributes into tissues and reaches therapeutic effect-site (brain) concentrations with greater accuracy and efficiency. Because the Eleveld group utilizes propofol more efficiently and at a lower cumulative dose, patients naturally regain consciousness faster, facilitating a prompter transfer to the recovery room and, ultimately, timely discharge home.[19]

Post-procedural agitation was rare and similar between groups. This suggests that both Eleveld and Schnider models provided acceptable emergence quality when sedation was guided by BIS monitoring and titrated using a standardized protocol. The low agitation rate may also reflect the advantage of TCI-based propofol administration, which allows more stable plasma or effect-site concentrations than intermittent bolus techniques.[7] Thus, although the Eleveld model showed advantages in induction, drug consumption, and recovery time, both models appeared comparable in terms of sedation stability and immediate emergence profile

This study has several limitations. First, the sample size was relatively small and the study was conducted at a single center, which may limit generalizability. Second, the study included patients aged 20–65 years with BMI <30 kg/m²; therefore, the findings cannot be directly extrapolated to elderly, obese, or higher-risk populations, even though these groups are often central to discussions of TCI model performance. Third, the anesthesia operators could not be blinded because the selected TCI model had to be entered manually into the infusion system. Although participants and outcome assessors were blinded, operator awareness may still have influenced titration behavior. Fourth, this study focused mainly on short-term procedural outcomes and did not assess detailed cardiorespiratory adverse events, discharge readiness, patient satisfaction, endoscopist satisfaction, or cost-effectiveness. Finally, fentanyl was

used as an adjunct in both groups, which may have influenced propofol requirements and recovery profile, although the same protocol was applied to all participants.

Conclusion

Eleveld TCI model was associated with faster induction, lower propofol consumption, and shorter recovery time than the Schnider model during outpatient colonoscopy sedation, while maintaining comparable sedation stability and emergence quality. These findings suggest that the Eleveld model may be an efficient option for propofol TCI sedation in outpatient endoscopy, particularly in settings where time efficiency, rapid recovery, and optimized drug use are important. The lower propofol requirement may also offer potential safety advantages by reducing dose-related adverse effects, although this study was not powered to assess differences in clinical complications. Therefore, while the Eleveld model appears promising for outpatient colonoscopy sedation, larger multicenter studies involving broader patient populations and more comprehensive safety, recovery, patient satisfaction, and workflow outcomes are needed to confirm whether these advantages translate into meaningful clinical and operational benefits.

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Conflict of Interest

The author(s) report no conflict of interest.

Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Author's Contributions

Conceptualization: AW. Methodology: MW and TA. Investigation: AW, MW, and TA. Data curation: AW, IGAMWK. Formal analysis: AW and MW. Writing – original draft: AW and MW. Writing – review & editing: AW, IGAMWK and MW. Supervision: MW. All authors approved the final manuscript.

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