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Target-Controlled Infusion versus Intermittent Bolus Administration of Propofol for Sedation in Colonoscopy: A Randomized Controlled Trial

Abstract

Background: Propofol is the preferred sedative agent for colonoscopy, but optimal administration techniques remain debated. This study compared target-controlled infusion (TCI) with intermittent bolus (IB) administration regarding safety, efficacy, and patient satisfaction.

Methods: We conducted a prospective, randomized, single-center study of 100 patients (ASA I-III) undergoing elective colonoscopy. Patients were randomized to receive propofol via TCI (n=50) or IB administration (n=50). Primary endpoints included composite safety outcomes and sedation adjustments. Secondary endpoints comprised propofol consumption, recovery time, and satisfaction scores.

Results: The composite safety endpoint occurred in 18 (36%) TCI patients versus 19 (38%) IB patients ($p=0.836$). However, TCI patients experienced more hypotension (22% vs 8%, $p=0.031$) but less tachycardia (6% vs 20%, $p=0.028$) and desaturation (6% vs 22%, $p=0.008$). TCI required fewer sedation adjustments (median 1 vs 3, $p<0.001$) and achieved higher patient satisfaction scores (8.2 ± 1.4 vs 7.5 ± 1.6 , $p=0.017$). Total propofol consumption was higher with TCI (454.0 ± 110.8 mg vs 305.9 ± 73.1 mg, $p<0.001$), while recovery time was longer (16.5 ± 2.9 min vs 11.9 ± 2.2 min, $p<0.001$).

Conclusion: Both techniques demonstrated comparable overall safety. TCI provided superior sedation stability and patient satisfaction but required higher drug consumption and longer recovery times. Technique selection should be individualized based on patient characteristics and clinical priorities.

Introduction

Colonoscopy remains the gold standard for colorectal cancer screening and surveillance, with over 14 million procedures performed annually worldwide¹. Effective sedation is crucial for patient comfort, procedural success, and future compliance with screening recommendations². Propofol has emerged as the preferred sedative agent due to its rapid onset, short duration of action, and favorable recovery profile³.

The administration technique for propofol significantly influences clinical outcomes. Traditional intermittent bolus (IB) administration, whilst simple and cost-effective, may result in fluctuating plasma concentrations leading to periods of inadequate or excessive sedation⁴. Target-controlled infusion (TCI) systems, utilizing pharmacokinetic models to maintain predetermined plasma concentrations, theoretically provide more stable sedation levels⁵.

Current evidence comparing TCI and IB administration for gastrointestinal endoscopy remains limited and conflicting. Whilst some studies suggest improved hemodynamic stability with TCI⁶, others report increased drug consumption and prolonged recovery times⁷. The European Society of Gastrointestinal Endoscopy (ESGE) guidelines acknowledge both techniques as acceptable for non-anesthesiologist administration of propofol (NAAP)⁸, but provide limited guidance on optimal technique selection.

This randomized controlled trial aimed to comprehensively compare TCI and IB propofol administration for colonoscopy sedation, hypothesizing that TCI would provide superior hemodynamic stability and patient comfort whilst maintaining comparable safety profiles.

Methods

Study Design and Participants

This prospective, randomized, single-center study was conducted between January and December 2023 at a tertiary endoscopy unit. The study protocol received approval from the institutional research ethics committee (Reference: REC-2023-001), and all participants provided written informed consent.

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Inclusion criteria comprised patients aged 18-80 years with ASA physical status I-III scheduled for elective colonoscopy. Exclusion criteria included pregnancy, allergy to propofol or its components, severe cardiac or respiratory disease, body mass index $>35\text{ kg/m}^2$, history of substance abuse, and inability to provide informed consent.

Randomization and Interventions

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Participants were randomized using computer-generated random numbers in sealed opaque envelopes to receive propofol via either TC or IB administration. All patients received standardized monitoring including continuous electrocardiography, pulse oximetry, non-invasive blood pressure measurement, and capnography. Supplemental oxygen (2 L/min) was administered via nasal cannulae.

TCI Group: Propofol was administered using the Marsh pharmacokinetic model with an initial target plasma concentration of $2.0\text{ }\mu\text{g/ml}$, adjusted in $0.5\text{ }\mu\text{g/ml}$ increments to achieve optimal sedation (Modified Observer's Assessment of Alertness/Sedation [MOAA/S] score 2-3).

IB Group: Propofol was administered as initial bolus doses of $0.5\text{--}1.0\text{ mg/kg}$ followed by incremental boluses of $10\text{--}20\text{ mg}$ titrated to achieve identical sedation targets.

All procedures were performed by experienced endoscopists, with sedation managed by trained anesthetic nurses under anesthesiologist supervision, consistent with ESGE guidelines for NAAP⁸.

Outcome Measures

Primary Endpoints: The composite safety endpoint included hypotension (systolic blood pressure $<90\text{ mmHg}$ or $>20\%$ decrease from baseline), tachycardia (heart rate $>100\text{ bpm}$), and oxygen desaturation ($\text{SpO}_2 < 90\%$). Sedation efficacy was assessed by the number of dose adjustments required during the procedure.

Secondary Endpoints: Total propofol consumption, recovery time (procedure completion to MOAA/S score 5), patient satisfaction (11-point numerical rating scale), endoscopist satisfaction (5-point Likert scale), and hemodynamic stability (coefficient of variation for heart rate and blood pressure).

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Statistical Analysis

Sample size calculation, based on a 20% difference in composite adverse events with 80% power and 5% significance level, required 45 patients per group. Allowing for 10% dropout, 50 patients were recruited per group. Continuous variables were analyzed using Student's t-test or Mann-Whitney U test as appropriate. Categorical variables were compared using chi-square or Fisher's exact test. Statistical significance was set at $p < 0.05$.

Results

Participant Characteristics

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One hundred patients were randomized and completed the study protocol. Baseline characteristics were well-balanced between groups. Mean age was 50.7 ± 13.6 years in the TCI group and 53.2 ± 12.6 years in the IB group ($p = 0.340$). The majority of patients were ASA class I or II (88% TCI, 85% IB), with no significant differences in demographic or clinical parameters.

Table 1. Baseline Demographic and Clinical Characteristics

Variable	TCI Group (n=50)	IB Group (n=50)	p-value
Age (years)	50.7 ± 13.6	53.2 ± 12.6	0.340
Weight (kg)	71.9 ± 13.1	74.8 ± 11.3	0.291
Height (cm)	167.9 ± 10.6	168.1 ± 6.5	0.798
BMI (kg/m^2)	25.7 ± 5.1	26.5 ± 4.1	0.324
Male sex, n (%)	25 (50%)	24 (48%)	0.818
ASA Class I/II/III	20/24/6	18/25/7	0.112

Primary Outcomes

The composite safety endpoint occurred in 18 (36%) TCI patients and 19 (38%) IB patients ($p = 0.836$), indicating no significant difference in overall safety. However, analysis of individual components revealed distinct patterns between groups.

11 Hypotension was significantly more frequent in the TCI group (22% vs 8%, $p=0.031$, $OR=3.25$, 95%CI:1.12-9.42). Conversely, tachycardia occurred less frequently with TCI (6% vs 20%, $p=0.028$, $OR=0.26$, 95%CI:0.08-0.85), as did oxygen desaturation (6% vs 22%, $p=0.008$, $OR=0.22$, 95%CI:0.07-0.69).

13 The number of sedation adjustments was significantly lower in the TCI group (median 1 [IQR 0-1] vs 3 [IQR 1-4], $p<0.001$), supporting the hypothesis of improved sedation stability.

Secondary Outcomes

8 Total propofol consumption was significantly higher with TCI (454.0 ± 110.8 mg vs 305.9 ± 73.1 mg, $p<0.001$), representing a 48% increase. When adjusted for body weight, this difference remained significant (6.4 ± 1.6 mg/kg vs 4.1 ± 1.0 mg/kg, $p<0.001$).

17 7 Recovery time was significantly longer in the TCI group (16.5 ± 2.9 minutes vs 11.9 ± 2.2 minutes, $p<0.001$), representing a 39% increase that could impact patient throughput.

Patient satisfaction scores were significantly higher with TCI (8.2 ± 1.4 vs 7.5 ± 1.6 , $p=0.017$), as were endoscopist satisfaction scores (4.3 ± 0.7 vs 4.0 ± 0.8 , $p=0.045$).

Table 2. Primary and Secondary Outcomes

Variable	TCIGroup(n=50)	IBGroup(n=50)	p-value
PrimaryEndpoints			
Compositeadverseevents	18(36%)	19(38%)	0.836
Hypotension	11(22%)	4(8%)	0.031
Tachycardia	3(6%)	10(20%)	0.028
Desaturation	3(6%)	11(22%)	0.008
Sedationadjustments	1(0-1)	3(1-4)	<0.001
SecondaryEndpoints			
Totalpropofoldose(mg)	454.0±110.8	305.9±73.1	<0.001
Recoverytime(min)	16.5±2.9	11.9±2.2	<0.001
Patientsatisfaction	8.2±1.4	7.5±1.6	0.017
Endoscopistsatisfaction	4.3±0.7	4.0±0.8	0.045

HemodynamicStability

TCIdemonstratedsuperiorhemodynamicstability,withsignificantlylowercoefficientof variation for mean arterial pressure (12.3% vs 18.7%, p=0.002) and heart rate (8.9% vs 13.4%, p=0.001). This improved stability translated to more predictable cardiovascularresponsesthroughouttheprocedure.

SubgroupAnalysis

In patients aged “65 years (n=28), TCI benefits were more pronounced, with greater reductions in tachycardia (0% vs 25%, p=0.045) and improved satisfaction scores. Similarly,patientswithASAclassIIIdemonstratedfewercompositeadverseevents with TCI (33% vs 71%, p=0.048).

Discussion

This randomized controlled trial provides comprehensive evidence comparing TCI and IB propofol administration for colonoscopy sedation. Whilst both techniques demonstrated comparable overall safety, they exhibited distinct profiles regarding hemodynamic stability, drug consumption, and patient experience.

Safety and Efficacy

The similar composite safety endpoints between groups confirm that both techniques can be safely administered when appropriate protocols are employed. However, the differential pattern of individual adverse events provides important clinical insights. The increased hypotension with TCI likely reflects more consistent drug delivery achieving sustained plasma concentrations that may predispose to cardiovascular depression⁹. Conversely, the reduced tachycardia and desaturation suggest more effective blunting of sympathetic responses and better respiratory stability¹⁰.

The significantly fewer sedation adjustments required with TCI (median 1 vs 3) provides objective evidence of improved sedation stability. This finding has practical implications for nursing workload and procedural efficiency, particularly in high-volume endoscopy units.

Drug Consumption and Recovery

The 48% increase in propofol consumption with TCI represents a significant economic consideration. This finding is consistent with previous studies and reflects the continuous drug delivery inherent to TCI systems¹¹. However, this increased consumption must be balanced against improved patient satisfaction and reduced adverse events.

The prolonged recovery time with TCI (39% increase) could impact patient throughput, particularly in resource-constrained settings. This finding likely reflects higher cumulative drug exposure and warrants consideration in clinical decision-making.

Patient and Provider Satisfaction

The improved patient satisfaction with TCI, whilst statistically significant, represents a modest absolute difference. However, in the context of patient-centered care and future screening compliance, this improvement may have meaningful clinical significance. Similarly, enhanced endoscopist satisfaction suggests better procedural conditions that could potentially improve examination quality.

Clinical Implications

Our findings suggest that technique selection should be individualized based on patient characteristics and clinical priorities. TCI may be preferred for elderly patients, those with significant comorbidities, or complex procedures where hemodynamic stability is paramount. Conversely, IB administration may be appropriate for routine procedures in healthy patients where rapid turnover is essential.

Limitations

Several limitations warrant acknowledgment. The single-center design may limit generalizability to other clinical settings. The inability to blind the anesthetist could introduce bias, though standardized protocols and objective outcomes help mitigate this concern. Additionally, our study focused on short-term outcomes and did not assess longer-term effects on patient satisfaction or procedure acceptance.

Future Research

Future studies should explore hybrid approaches combining the advantages of both techniques, investigate the role of processed electroencephalography monitoring in optimizing sedation delivery, and conduct comprehensive health economic analyses to guide policy decisions.

Conclusion

This randomized controlled trial demonstrates that both TCI and IB propofol administration are safe and effective for colonoscopy sedation. TCI provides superior hemodynamic stability, reduced adverse events, and improved patient satisfaction, but at the cost of increased drug consumption and prolonged recovery times. The

choice between techniques should be individualized based on patient characteristics, procedural complexity, and institutional resources. These findings contribute important evidence to guide clinical decision-making and support the continued evolution of sedation practices in gastrointestinal endoscopy.

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