Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/m1x9bb92

COMPARISON OF TARGET-CONTROLLED INFUSION AND MANUAL INFUSION OF PROPOFOL FOR COLONOSCOPY SEDATION IN ANESTHESIOLOGY TRAINEES

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ABSTRACT
Propofol is often used to sedate patients during colonoscopy, but its possible side effects on the heart and breathing are still worrisome. The aim of this study was to see if using target-controlled infusion (TCI) of propofol results in superior sedation quality for novice anesthesiology trainees than using manually controlled infusion (MCI). Initially, eighteen residents started training with TCI in one group and MCI in the other, finishing with TCI in their second month and MCI in their first. At the end of every month, the last two patients treated were picked for review. Both patients and doctors using the procedure gauged how much they were satisfied with the sedation, using a visual scale called VAS. Other important points we measured were heart rate (HR), mean arterial pressure (MAP), oxygen saturation (SpO_{2}) and how long recovery took. Baseline patient characteristics were the same in both the TCI and MCI groups. There was a clear difference in endoscopists' satisfaction, with TCI receiving ratings of 81.3±7.2 compared to 74.2±9.5 for MCI (P=0.003), but no difference was found with patients. Hemodynamic stability in the TCI group was reflected by a lower maximum MAP and a higher minimum MAP, compared to the MCI group. In addition, the TCI group had better lowest SpO2 results. Studies have observed that people given propofol using TCI get better faster than those using MCI. Giving sedation via target-controlled infusion is considered more effective and safer for anesthesia residents performing colonoscopies.

Key words: Propofol sedation, Target-controlled infusion (TCI), Manual infusion, Colonoscopy sedation Anesthesiology training

INTRODUCTION
Often, colonoscopy is carried out to screen for colorectal problems. Doctors use sedation and/or pain medication for almost all colonoscopies [1,2] and suitable sedation can make the procedure more comfortable [3,4]. The amount of sedation for endoscopy is called minimal, moderate or deep according to what is needed and doctors say moderate sedation is the lowest level acceptable for colonoscopies [5,6]. Many both anesthesiologists and non-anesthesiologist practitioners find propofol sedation, with or without adjunct opiates, to be the preferred approach because it starts working rapidly and its effects are short lived [7–9]. Despite this, the impact of cardiovascular and breathing issues remains an important problem for using benzodiazepines in endoscopic sedation [10,11]. While propofol can be given as a bolus or as a continuous injection, its effects in different people bring up worries about safety during colonoscopy [12]. TCI uses mathematical models of drug absorption to administer intravenous anesthesia according to each patient's age, gender and body mass index. Research shows that TCI is associated with faster recovery and more steady

values of cardiovascular and respiratory parameters than manually controlled infusion (MCI) [13,14]. appropriate training in endoscopic sedation helps keep patients safe and should be provided to both anesthesiologists and anyone in non-anesthesiology roles. The study was designed to assess how well TCI and MCI methods worked for sedation during residents' training years.

MATERIAL AND METHODS

Study design

In 2011 and 2012, 18 anesthesiology residents taking part in training were randomly assigned to complete a prospective study. Everyone in the study was in the middle of a three-year training program. The residents had learned about general anesthesia in orthopedic and general surgery before working rotations in the endoscopy unit. Students were taught both the theory and practice of sedation during an endoscopy procedure called target-controlled infusion (TCI) and manually controlled infusion (MCI). Both kinds of training were assigned randomly to the residents using a computer program that placed nine randomly selected residents in each group. During the first month, the TCI group sedated patients using TCI, while the MCI group sedated patients with MCI for colonoscopy. Collected data came from the last two colonoscopy patients of the month for study and assessment. The second month saw the groups change their sedation approach: those who had been using MCI before now tried TCI and the reverse held true for the TCI group. In addition, information from the two patients in the last group treated in the second month was obtained. How patients fared each month was analyzed to check if the training was having the desired result (Figure 1). All aspects of the procedures were directed by senior attending anesthesiologists. The inclusion criteria were that patients had been scheduled for elective colonoscopy by the endoscopist, were aged 18 years or over and were ASA physical status 1 or 2. Those with morbid obesity, a high risk airway, known heart issues, high blood pressure, acute or chronic liver or kidney failure and those who received long-term anesthetics or opioids were excluded. Blinded to each group's assignment, a single endoscopist performed every colonoscopy. Local approval of the study protocol was obtained from the Ethics Committee and each patient was given written information and provided their own consent.

Sedation Protocol

People who needed the procedure were asked to seal their bowel overnight and use bowel preparation. Before starting the procedure, the standard monitors were attached and they measured electrocardiography, SpO_2 and non-invasive blood pressure. A flow rate of 2 L/min oxygen was given to the patient through nasal cannula. Propofol was delivered to patients by pump and via a TCI monitor, connected to an intravenous line to keep all involved unaware of the study drugs. A small amount of fentanyl (2 μg/kg) was given slowly at first, followed by the main injection of propofol given to each group based on their treatment. The group given propofol used Module DPS TCI with the Marsh pharmacokinetic model. The target plasma concentration was originally set to be 3.0 μg/ml and was adjusted in sarectl by 0.2 μg/ml when the patients showed changes on the OAAS scale. In this group, we first gave propofol as a 1.5 mg/kg bolus and then we maintained infusion at 6 mg/kg/h using a normal microinfusion pump. Small extra amounts of propofol were given when necessary in boluses of 0.5 mg/kg. Members of the research team roused the patients following their colonoscopies and only discharged them after they had a Modified Aldrete Score of 9 or more.

How Results are Completed

The quality of sedation was assessed using a VAS rating of 100 mm by both those performing the endoscopy and the patients. HR, SpO_2 and BP were each measured every three minutes while the procedure was being done. Respiratory and cardiovascular stability was determined by noting the maximum and minimum HR, MAP and minimum SpO_2 measured. Severe events were considered

when SpO_2 was less than 90, HR less than 50 or MAP was below 55 mmHg. Recovery time was estimated as the interval from finishing the propofol infusion to the patient being fully oriented.

Statistical Analysis

All statistical tasks were performed using IBM SPSS Statistics version 20.0. Results for continuous variables are given as mean ± standard deviation; Student's t-test is used for comparing normally distributed data. To study categorical data, the chi-square test was applied. For this study, a p-value under 0.05 was considered significant statistically.

RESULTS

Table 1. Demographic data of the patients.

Groups	TCI (n=36)	MCI (n=36)	P value
Age (years)	45.2 ± 8.1	43.7 ± 7.4	0.321
Gender (M/F)	20 / 16	22 / 14	0.732
Height (cm)	171.5 ± 6.8	168.9 ± 7.3	0.412
Weight (kg)	67.3 ± 11.2	64.8 ± 9.9	0.298
BMI (kg/m²)	23.0 ± 2.6	22.4 ± 2.8	0.455
ASA score (1/2)	24 / 12	25 / 11	0.851
Baseline heart rate (bpm)	71.4 ± 7.9	74.2 ± 8.1	0.178
Baseline blood pressure (mmHg)	86.7 ± 8.6	87.9 ± 9.1	0.657
Procedure time (min)	28.1 ± 9.2	26.8 ± 8.0	0.489

Table 2. Quality and safety assessment of colonoscopy sedation.

Groups	TCI (n=36)	MCI (n=36)	P value
VAS score of endoscopist	83.7 ± 6.5	76.9 ± 8.3	0.002
VAS score of patients	78.5 ± 7.1	77.3 ± 6.9	0.542
Lowest HR (bpm)	67.8 ± 5.4	65.9 ± 6.5	0.157
Highest HR (bpm)	86.4 ± 6.8	88.2 ± 7.9	0.221
Lowest MAP (mmHg)	74.3 ± 7.1	69.0 ± 7.5	0.003
Highest MAP (mmHg)	96.7 ± 6.2	101.4 ± 7.9	0.007
Lowest SpO2 (%)	97.9 ± 1.8	96.1 ± 2.7	0.006
Recovery time (min)	8.6 ± 2.1	10.7 ± 2.9	<0.001

Figure 1:Patient Demographics: TCI vs MCI Groups

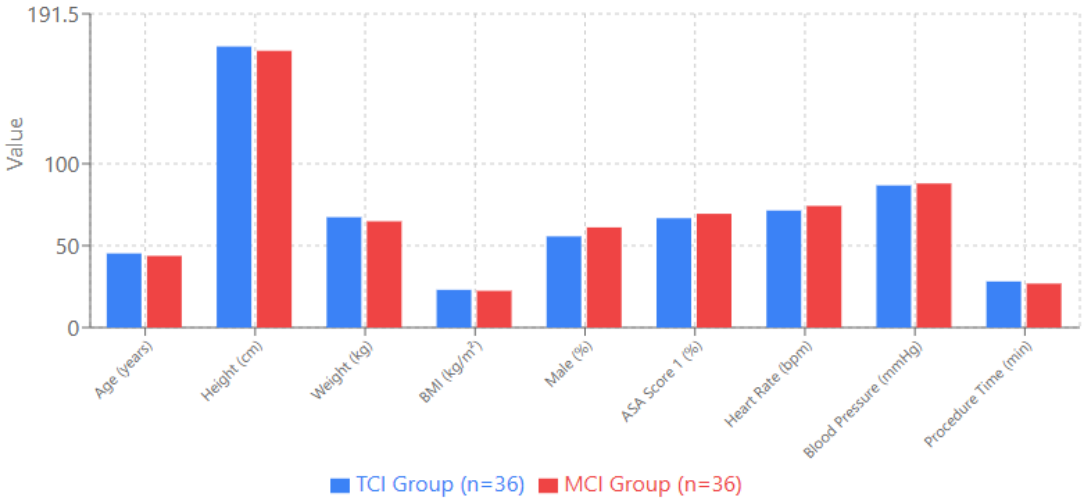
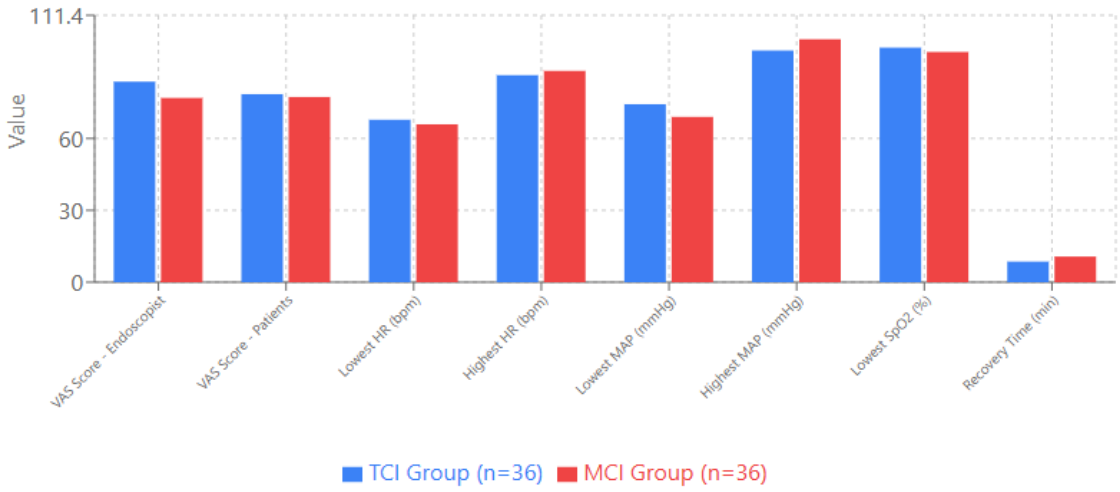


Figure 2: Colonoscopy Sedation Quality and Safety Assessment



The groups showed similar demographics in patients undergoing colonoscopy with sedation, as shown on Table 1. The average age among patients in the TCI group was 45.2 ± 8.1 and among those in the MCI group it was 43.7 ± 7.4, but the difference in ages was insignificant (p=0.321). Groups were matched by gender with 20 males and 16 females assigned to the TCI group and 22 males and 14 females assigned to the MCI group (p=0.732). All participants had the same height, weight and BMI levels, so there wasn't much variation to affect the results of the sedation. ASA physical status classification showed no statistical difference in the number of patients with ASA scores 1 or 2 between groups (p=0.851). Heart rate and blood pressure remained similar before sedation, confirming that everyone's heart condition was very close at the start. Procedure times were very close which shows that the procedure was not more complex for one patient over the other. Results related to quality and safety during sedation are summarized in Table 2. TCI offered better procedural conditions than MCI, as endoscopists reported higher satisfaction with TCI, measured by VAS (p=0.002). Scores for how patients were satisfied did not differ greatly between groups (p=0.542). TCI patients had more stable hemodynamic control, as their lowest mean arterial pressure average was 74.3 ± 7.1 mmHg, compared to 69.0 ± 7.5 mmHg in the others (p=0.003) and their peak mean arterial pressure average was 96.7 ± 6.2 mmHg vs. 101.4 ± 7.9 mmHg in the other group (p=0.007). Higher oxygen saturation levels in the TCI group (97.9% ± 1.8%) proved that respiratory safety was higher. TCI anesthesia allowed patients to regain consciousness about two minutes quicker than MCI sedation (p<0.001), showing that TCI is efficient. In general, these results indicate that TCI offers the best sedation, helps make heart and lung functions more stable and speeds up patient recovery after colonoscopy.

DISCUSSION

TCI was shown in the study to help anesthesiology trainees achieve better sedation results, based on how satisfied the endoscopists were with the procedures. Patients given propofol using targeted controlled infusion (TCI) showed less change in cardiovascular and respiratory activity than those who had manual infusion (MCI). Those treated with TCI recovered more quickly than those treated with MCI. Both endoscopist and patient satisfaction were chosen as main outcomes to judge sedation quality, since neither knew which type of propofol was being used. Although some previous studies had senior anesthesiologists involved, it is difficult to fool them about the type of anesthetic [16,17] which may bring bias into the decision. There was little difference in patient satisfaction between TCI and MCI, but more endoscopist satisfaction suggests that TCI makes the procedure technically simpler. Also, using pharmacokinetic models, TCI proved to be more effective, allowing patients to wake more quickly after propofol was turned off than in MCI. There

is still a major concern with cardiovascular and respiratory depression during propofol sedation for endoscopy when residents or non-anesthesiologist staff are involved [8,18]. Even so, anesthesiologists and non-anesthesiologists still choose propofol because it has a quick onset and generates a short recovery time [19–21]. Keep in mind that relaxing the patient enough to reduce stress should not cause other problems. Furthermore, after a bolus dose, the highest amount of propofol in the blood might be more than double the regular level within 10 minutes, whereas continuous infusion allows the blood to accumulate a little bit at a time [22]. The inconsistent plasma levels linked to MCI could be responsible for why MCI increases heart and respiratory issues. Pharmacokinetics with propofol are greatly affected by a patient's age, sex and body mass index, but these factors are usually overlooked in MCI. For this reason, doctors may need to change the dose depending on the patient's needs, but this can be hard for trainees with less practice. Similarly, TCI maintains a more reliable amount of drug in the blood which lowers the chance of harmful events.

CONCLUSION

All in all, TCI of propofol leads to more effective sedation than MCI among anesthesiology residents managing colonoscopies. Thanks to TCI, endoscopists were more satisfied and both the endoscopist's blood flow and respiration remained more stable. The results from the data indicate that TCI ensures greater stability in MAP, with both lower maximum values and higher minimum MAP and leads to higher oxygen saturation levels than MCI. TCI's use of pharmacokinetic modeling may be responsible for the stronger stability of vital signs, since it considers a person's unique characteristics such as age, gender and body mass. This keeps the plasma levels stable and more accurate which reduces chances of heart and lung problems that often follow sedation. Moreover, those given sedation with TCI generally regained consciousness sooner than those given MCI sedation. Fast recovery matters greatly in hospitals, where handling patients one after another is vital. Patient satisfaction was similar in TCI and MCI groups, but a greater percentage of trained endoscopists using TCI reported being more satisfied. This suggests that TCI makes the procedure simpler and more efficient for them, especially during their training. The results point out that training in the use of sedation medications should be provided to anesthesiologists and to staff not only engaged in anesthesiology. Those lacking experience, for example, in this study group, might have trouble handling the changing drug levels that are typical in MCI, perhaps resulting in unsafe events. Alternatively, TCI delivers drugs more consistently and protects against any risks of sedation, since it holds plasma levels steady which is key for those new to this field. These findings suggest that TCI should be included in anesthesia training so that patients undergoing colonoscopy get better care, treatment and a safer recovery. The fast acting nature and quick drop in sedation from propofol, plus the excellent control TCI provides, promise a better way to optimize sedation at work. Next, more studies ought to examine how TCI improves outcomes and whether it can be used in a variety of sedation methods in the clinic. All in all, TCI makes colonoscopy sedation safer, improves its effectiveness and saves time for anesthesiology residents.

REFERENCES

1. Cohen LB, Wecsler JS, Gaetano JN, et al. Endoscopic sedation in the United States: results from a nationwide survey. Am J Gastroenterol. 2006;101:967–74. doi: 10.1111/j.1572-0241.2006.00500.x. [DOI] [PubMed] [Google Scholar]
2. Porostocky P, Chiba N, Colacino P, et al. A survey of sedation practices for colonoscopy in Canada. Can J Gastroenterol. 2011;25:255–60. doi: 10.1155/2011/783706. [DOI] [PMC free article] [PubMed] [Google Scholar]
3. Radaelli F, Meucci G, Sgroi G, Minoli G. Technical performance of colonoscopy: the key role of sedation/analgesia and other quality indicators. Am J Gastroenterol. 2008;103:1122–30. doi: 10.1111/j.1572-0241.2007.01778.x. [DOI] [PubMed] [Google Scholar]

4. Triantafyllou K, Sioulas AD, Kalli T, et al. Optimized sedation improves colonoscopy quality long-term. Gastroenterol Res Pract. 2015;2015:195093. doi: 10.1155/2015/195093. [DOI] [PMC free article] [PubMed] [Google Scholar]
5. Igea F, Casellas JA, Gonzalez-Huix F, et al. Sedation for gastrointestinal endoscopy. Endoscopy. 2014;46:720–31. doi: 10.1055/s-0034-1377561. [DOI] [PubMed] [Google Scholar]
6. Lichtenstein DR, Jagannath S, Baron TH, et al. Sedation and anesthesia in GI endoscopy. Gastrointest Endosc. 2008;68:815–26. doi: 10.1016/j.gie.2008.09.029. [DOI] [PubMed] [Google Scholar]
7. Wehrmann T, Triantafyllou K. Propofol sedation in gastrointestinal endoscopy: a gastroenterologist's perspective. Digestion. 2010;82:106–9. doi: 10.1159/000285554. [DOI] [PubMed] [Google Scholar]
8. Singh H, Poluha W, Cheung M, et al. Propofol for sedation during colonoscopy. Cochrane Database Syst Rev. 2008;2008:CD006268. doi: 10.1002/14651858.CD006268.pub2. [DOI] [PMC free article] [PubMed] [Google Scholar]
9. Shen XC, Ao X, Cao Y, et al. Etomidate-remifentanil is more suitable for monitored anesthesia care during gastroscopy in older patients than propofol-remifentanil. Med Sci Monit. 2015;21:1–8. doi: 10.12659/MSM.891183. [DOI] [PMC free article] [PubMed] [Google Scholar]
10. Rex DK, Overley C, Kinser K, et al. Safety of propofol administered by registered nurses with gastroenterologist supervision in 2000 endoscopic cases. Am J Gastroenterol. 2002;97:1159–63. doi: 10.1111/j.1572-0241.2002.05683.x. [DOI] [PubMed] [Google Scholar]
11. Kim EH, Lee SK. Endoscopist-directed propofol: pros and cons. Clin Endosc. 2014;47:129–34. doi: 10.5946/ce.2014.47.2.129. [DOI] [PMC free article] [PubMed] [Google Scholar]
12. Cohen LB. Endoscopy: Can computer-aided personalized sedation bridge troubled waters? Nat Rev Gastroenterol Hepatol. 2011;8:183–84. doi: 10.1038/nrgastro.2011.31. [DOI] [PubMed] [Google Scholar]
13. Moerman AT, Herregods LL, De Vos MM, et al. Manual versus target-controlled infusion remifentanil administration in spontaneously breathing patients. Anesth Analg. 2009;108:828–34. doi: 10.1213/ane.0b013e318198f6dc. [DOI] [PubMed] [Google Scholar]
14. Muller T, Ludwig A, Biro P. Two distinct application habits for propofol: an observational study. Eur J Anaesthesiol. 2010;27:265–69. doi: 10.1097/EJA.0b013e3283354736. [DOI] [PubMed] [Google Scholar]
15. Sun Y, Liu C, Zhang Y, et al. Low-dose intramuscular dexmedetomidine as premedication: a randomized controlled trial. Med Sci Monit. 2014;20:2714–19. doi: 10.12659/MSM.891051. [DOI] [PMC free article] [PubMed] [Google Scholar]
16. Fanti L, Gemma M, Agostoni M, et al. Target Controlled Infusion for non-anaesthesiologist propofol sedation during gastrointestinal endoscopy: The first double blind randomized controlled trial. Dig Liver Dis. 2015;47:566–71. doi: 10.1016/j.dld.2015.03.003. [DOI] [PubMed] [Google Scholar]
17. Chiang MH, Wu SC, You CH, et al. Target-controlled infusion vs. manually controlled infusion of propofol with alfentanil for bidirectional endoscopy: a randomized controlled trial. Endoscopy. 2013;45:907–14. doi: 10.1055/s-0033-1344645. [DOI] [PubMed] [Google Scholar]
18. Shah B, Cohen LB. The changing faces of endoscopic sedation. Expert Rev Gastroenterol Hepatol. 2010;4:417–22. doi: 10.1586/egh.10.43. [DOI] [PubMed] [Google Scholar]
19. Birk J, Bath RK. Is the anesthesiologist necessary in the endoscopy suite? A review of patients, payers and safety. Expert Rev Gastroenterol Hepatol. 2015;9:883–85. doi: 10.1586/17474124.2015.1041508. [DOI] [PubMed] [Google Scholar]
20. Dumonceau JM, Riphaus A, Aparicio JR, et al. European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates, and the European Society of Anaesthesiology Guideline: Non-anesthesiologist administration of propofol for GI

endoscopy. Endoscopy. 2010;42:960–74. doi: 10.1055/s-0030-1255728. [DOI] [PubMed] [Google Scholar]
21. Redondo-Cerezo E, Sanchez-Robaina A, Martinez Cara JG, et al. Gastroenterologist-guided sedation with propofol for endoscopic ultrasonography in average-risk and high-risk patients: a prospective series. Eur J Gastroenterol Hepatol. 2012;24:506–12. doi: 10.1097/MEG.0b013e328350fcbd. [DOI] [PubMed] [Google Scholar]
22. Fan SZ, Yu HY, Chen YL, Liu CC. Propofol concentration monitoring in plasma or whole blood by gas chromatography and high-performance liquid chromatography. Anesth Analg. 1995;81:175–78. doi: 10.1097/00000539-199507000-00036. [DOI] [PubMed] [Google Scholar]