DWH Lee 李偉雄
ACW Chan 陳志偉
SKH Wong 黃健鴻
ACN Li 李志毅
TS Sze 施德遜
SCS Chung 鍾尚志

The safety, feasibility, and acceptability of patient-controlled sedation for colonoscopy: prospective study

病人在結腸鏡檢查中自控鎮靜的安全性、可行性及滿意程度：預期性研究

Objective. To assess the safety, feasibility, and acceptability of patient-controlled sedation for elective day-case colonoscopy, and the factors predicting patients' unwillingness to use patient-controlled sedation for colonoscopy.
Design. Prospective, non-randomised study.
Setting. University-affiliated endoscopy centre, Hong Kong.
Participants. Five hundred patients who underwent elective day-case colonoscopy were prospectively recruited from January 2001 to June 2002.
Intervention. Sedation for colonoscopy was a mixture of propofol and alfentanil, which was delivered by means of a patient-controlled syringe pump. Each bolus delivered 4.8 mg propofol and 12 μg alfentanil. No loading dose was used and the lockout time was set at zero.
Main outcome measures. Cardiopulmonary complications, dose of patient-controlled sedation used, recovery time, satisfaction score, delayed side-effects, and the willingness to use the same sedation protocol for future colonoscopy. A multiple stepwise logistic regression model was used to assess which factors might predict unwillingness to use patient-controlled sedation for colonoscopy.
Results. The mean (standard deviation) age of patients was 53.0 (13.9) years. The mean dose of propofol consumed was 0.93 (0.69) mg/kg. Forty-three (8.6%) patients developed hypotension during the procedure. The mean satisfaction score was 7.2 (2.6). Sixteen (3.2%) patients developed delayed side-effects. The median (interquartile range) recovery time was 0 (0-5) minutes. Approximately 78% of patients were willing to use patient-controlled sedation for future colonoscopy if needed. Younger age (<50 years), female sex, a higher mean dose of sedatives used, a lower satisfaction score, and the presence of delayed side-effects were independent factors that were associated with patients' unwillingness to use patient-controlled sedation for colonoscopy.
Conclusion. The use of patient-controlled sedation for elective colonoscopy is safe, feasible, and acceptable to most patients.

目的：評估在選擇性日間結腸鏡檢查中，實行病人自控鎮靜的安全性、可行性及接受程度，以及病人進行結腸鏡檢查時不願意作自控鎮靜的預期因素。
設計：預期非隨機研究。
安排：大學附屬的內窺鏡中心，香港。
參與者：2001 年 1 月至 2002 年 6 月期間， 500 名進行選擇性日間結腸鏡檢查的患者預期參與研究。
療法：結腸鏡檢查進行期間，病人有一個注射器，可自行控制注射丙泊酚及阿芬太尼混合而成的鎮靜劑；每次劑量為丙泊酚4.8毫克及阿芬太尼12微克。並無使用負荷劑量，鎖定時間調較至零。
主要結果測量：心肺併發症、病人自控鎮靜使用的劑量、復原時間、滿意程度得分、延遲出現的副作用，以及日後進行結腸鏡檢查時使用同樣鎮靜治療方案的接受程度。利用多元對數回歸分析，評估預期病人進行結腸鏡檢查時不願意自控鎮靜的因素。
結果：患者年齡中位數（標準差）為 53.0（13.9）歲。丙泊酚的劑量中位數為 0.93（0.69）毫克 / 公斤。43 名（8.6%）患者在過程中出現低血壓。滿意度得分中位數為 7.2（2.6）。16 名（3.2%）患者有延遲出現的副作用。中值（範圍）復原時間為

Key words:
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關鍵詞：
阿芬太尼；
結腸鏡檢查；
輕度鎮靜；
丙泊酚

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North District Hospital, 9 Po Kin Road, Hong Kong:
Department of Surgery
DWH Lee, FRCS, FHKAM (Surgery)
ACW Chan, MD, FHKAM (Surgery)
ACN Li, FRCS, FHKAM (Surgery)
Department of Anaesthesiology
TS Sze, FANZCA, FHKAM (Anaesthesiology)
Department of Surgery, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin, Hong Kong
SKH Wong, FRCS, FHKAM (Surgery)
SCS Chung, MD, FHKAM (Surgery)

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Correspondence to: Prof SCS Chung (e-mail: sydneychung@cuhk.edu.hk)

0（0至5）分鐘。約有78%患者表示日後有需要進行結腸鏡檢查時，願意使用自控鎮靜。研究發現年紀較輕（50歲以下）、女性、使用鎮靜劑量中位數較高、滿意度得分較低，以及出現延遲的副作用，均為病人進行結腸鏡檢查時不願意使用自控鎮靜的獨立因素。

結論：在選擇性結腸鏡檢查時進行病人自控鎮靜是安全、可行及為多數患者接受的。

Introduction

Procedure-related pain and anxiety are two main reasons for the use of sedative medications during colonoscopy. In most endoscopy units, conscious sedation during colonoscopy is achieved by using a combination of intravenously administered benzodiazepine (eg midazolam) and narcotic agent (eg pethidine).[1-4] However, dose-related complications associated with intravenous sedation were shown to account for most of the complications of colonoscopy.[5,6] This finding prompted endoscopists to look for alternative, better sedative methods. Although colonoscopy without the need for sedation has been reported with success, it is not a widely accepted approach.[7,8] The introduction of patient-controlled sedation (PCS) for colonoscopy has provided an alternative sedative method. In randomised controlled trials, PCS was safer and was associated with faster recovery than intravenous sedation.[9-13] Nonetheless, numbers of patients recruited in these studies were small.

In this study, we assess the safety, feasibility, and acceptability of PCS for colonoscopy in a large prospective series of patients who had undergone day-case elective colonoscopy at the North District Hospital. In addition, we examine the factors that may predict the unwillingness of patients in using PCS.

Patients and methods

The study was conducted in a university-affiliated endoscopy unit. Since May 2000, our unit has been using PCS as a sedative protocol available to patients who underwent day-case elective colonoscopy. The use of PCS was approved by the hospital ethics committee, and all patients signed an informed consent for the procedure. The series in this study comprised 500 consecutive patients who received PCS for colonoscopy from January 2001 to June 2002. We selected patients for PCS on the basis of the following criteria: (1) patients were aged between 16 and 75 years; (2) a day-procedure was scheduled; (3) the American Society of Anesthesia (ASA) class was I to III; (4) patients had no history of colectomy; (5) patients had no history of allergy to propofol or alfentanil; and (6) patients had no history of difficult endotracheal intubation for a surgical procedure. During the study period, 30 eligible patients did not enter the study; among them, 25 did not want any sedation and the remainder did not consent to the study.

Patient-controlled sedation was delivered by means of a patient-controlled syringe pump (Graseby 3300 PCA; Graseby Medical Ltd, Hertfordshire, UK) that contained a mixture of propofol (200 mg in 20 mL) and alfentanil (0.5 mg in 1 mL) in a 25-mL syringe. The drugs were delivered in response to a hand-held button. Each bolus (0.5 mL) delivered 4.8 mg propofol and 12 μg alfentanil. No loading dose was used and the lockout time was set at zero. Patients were instructed on the use of the hand-held button before colonoscopy. All patients received supplemental oxygen delivered at 2 L/min by means of nasal prongs during the procedure. Pulse rate and oxygen saturation were continuously monitored, and the blood pressure was recorded every 5 minutes throughout the procedure and recovery period. At the end of the procedure, all patients were monitored in recovery suites until they were fully conscious and oriented, at which point a recovery nurse who was not involved in the procedure administered a questionnaire to assess patient satisfaction. Satisfaction was scored on a 10-cm unscaled visual analog scale, with 0=not satisfied and 10=very satisfied. At 24 to 48 hours after the procedure, the principal investigator, who was unaware of the questionnaire results and other procedural details, telephoned patients to ask about any delayed side-effects of the sedative drugs, and whether patients were willing to use PCS as their sedative method for future colonoscopy if needed.

Standardised bowel preparation before colonoscopy consisted of either polyethylene glycol–electrolyte lavage (Klean-prep; Norgine Ltd, Uxbridge, UK) or sodium phosphate (Fleet Phospho-Soda; CB Fleet Inc, Virginia, US).[14] All colonoscopies were performed by a team of experienced surgical endoscopists that had performed more than 500 similar procedures previously. In addition, all endoscopists had experience with endotracheal intubation. A senior anaesthesiologist was present to teach and supervise the use of PCS at the first week when we first started PCS. Thereafter, the anaesthesiologist would be immediately available on request. The endoscopist who performed the procedure was also responsible for PCS set-up and administration.

Outcome measures included the following: the number of episodes of hypotension (defined as a systolic blood pressure of <90 mm Hg) and desaturation (SaO_2 <90%), dosage of PCS used, recovery time (recovery being defined as haemodynamic stability and satisfactory cognition, as assessed every 5 minutes until the patient was oriented and able to subtract serial 7s from 100), satisfaction score, willingness to repeat the procedure using the same sedative method, and any delayed side-effects of sedative drugs recorded at 24 to 48 hours after the procedure.

Statistical analysis

Parametric summary statistics are presented as the mean (standard deviation [SD]). Nonparametric summary statistics are presented as the median (interquartile range [IQR]). Categorical data were analysed with the Pearson Chi squared test or Fisher's exact test as appropriate. Yates correction for continuity was used when analysing 2x2 tables for homogeneity of proportions with the Chi squared test. The two-sample *t* test was used to test the hypothesis of equality of means, and the Mann-Whitney *U* test was used to test hypothesis of equality of medians. A P value of 0.05 or less was regarded as statistically significant. Factors that might predict patients' unwillingness to use PCS for future colonoscopy were first identified using univariate analysis. Those factors with P values of less than 0.10 were then entered into a stepwise multiple logistic regression. Significant independent factors were considered when the P value is 0.05 or less. Statistical analyses were performed with the Statistical Package for the Social Sciences version 9.0 (SPSS Inc, Chicago, US).

Table 1. Characteristics of 500 patients receiving patient-controlled sedation for colonoscopy

Characteristic	No. (%)*
Mean age (SD) [years]	53.0 (13.9)
Sex (M:F)	247: 253
Indications	
Rectal bleeding	219 (43.8)
Changed bowel habit	108 (21.6)
Surveillance	57 (11.4)
Abdominal pain	46 (9.2)
Constipation	28 (5.6)
Anaemia	14 (2.8)
Others	28 (5.6)
American Society of Anesthesia class	
I	431 (86.2)
II	67 (13.4)
III	2 (0.4)
Mean duration of colonoscopy (SD) [min]	18.8 (13.0)
Complete colonoscopy	470 (94.0)
Polypectomy	119 (23.8)
Mean dose of propofol (SD) [mg/kg]	0.93 (0.69)
Hypotension	43 (8.6)
Suboptimal PCS† delivery	8 (1.6)
Median recovery time (IQR) [min]	0 (0-5)
Mean satisfaction score (SD)	7.2 (2.6)
Admittance to hospital	13 (2.6)
Delayed side-effects	16 (3.2)
Willing to repeat PCS for colonoscopy	392 (78.4)

* Mean (standard deviation [SD]), median (interquartile range [IQR]) where indicated
† PCS patient-controlled sedation

Results

The mean (SD) age of the 500 patients was 53.0 (13.9) years. The male to female ratio was approximately 1:1. The indications and ASA grading of these patients are summarised in Table 1. The mean (SD) duration of colonoscopy was 18.8 (13.0) minutes. We have a 94.0% complete colonoscopy rate and 23.8% polypectomy rate. The mean (SD) dose of propofol used was 0.93 (0.69) mg/kg. Forty-three (8.6%) patients developed hypotension during colonoscopy; among them, five patients required supplemental intravenous fluid to maintain their blood pressure during the remaining procedures, two required cessation of PCS, and the remainder had transient hypotension that did not require further treatment. There was no apnoea or desaturation in this series.

In eight cases, PCS delivery was suboptimal because of kinking in the delivery tubes (n=5) and PCS pump machine failure (n=3). There was no uncontrolled over-delivery in this series. The median (IQR) recovery time was 0 (0-5) minutes. The mean (SD) satisfaction score was 7.2 (2.6). A total of 13 (2.6%) patients were admitted to hospital after colonoscopy: eight patients were admitted because of newly diagnosed cancer that required further investigation; five patients complained of abdominal pain and were admitted for observation. In all, 16 (3.2%) patients complained of minor delayed side-effects after colonoscopy: 10 patients complained of dizziness after discharge, four complained of nausea and vomiting, and

Table 2. Univariate analysis of factors related to unwillingness to use patient-controlled sedation for colonoscopy

Factor	Willing, n=392* No. (%)	Unwilling, n=108* No. (%)	P value
Age <50 years	152 (38.8)	63 (58.3)	<0.001
Female	184 (46.9)	69 (63.9)	0.003
Education			
<Primary	79 (20.1)	24 (22.2)	-
Primary	134 (34.2)	34 (31.5)	-
Secondary	160 (40.8)	40 (37.0)	-
College or university	18 (4.6)	9 (8.3)	-
Postgraduate	1 (0.3)	1 (1.0)	0.432
Previous colonoscopy	113 (28.8)	35 (32.4)	0.470
Mean duration of procedure (SD) [min]	18.7 (12.7)	19.1 (13.9)	0.756
Complete colonoscopy	374 (95.4)	96 (88.9)	0.022
Polypectomy	101 (25.8)	18 (16.7)	0.066
Mean dose of propofol (SD) [mg/kg]	0.87 (0.66)	1.13 (0.76)	0.001
Median recovery time (IQR) [min]	0 (0-5)	0 (0-5)	0.121
Mean satisfaction score (SD)	7.7 (2.2)	5.5 (3.1)	<0.001
Delayed side-effects	9 (2.3)	7 (6.5)	0.056

* Mean (standard deviation [SD]), median (interquartile range [IQR]) where indicated

Table 3. Factors predicting unwillingness to use patient-controlled sedation for colonoscopy

Factor	Odds ratio (95% CI)	P value
Female (vs male)	1.76 (1.08-2.86)	0.023
Age <50 years (vs age ≥ 50 years)	1.90 (1.17-3.07)	0.009
High dose of patient-controlled sedation	1.46 (1.06-2.03)	0.022
Lower satisfaction score	1.39 (1.27-1.49)	<0.001
Delayed side-effect(s)*	3.28 (1.04-10.31)	0.043

* Delayed side-effects mean those occurred 24 to 48 hours after the procedure

two complained of persistent abdominal pain and distension. After some reassurance, none of these patients required further treatment.

In a univariate analysis, an age younger than 50 years (P<0.001), female sex (P=0.003), incomplete colonoscopy (P=0.022), a higher PCS dose used (P=0.001), and a lower satisfaction score (P<0.001) were significantly related to unwillingness to use PCS for colonoscopy (Table 2). Further analysis using a multiple stepwise logistic regression model showed that an age younger than 50 years (odds ratio [OR]=1.90; 95% confidence interval [CI], 1.17-3.07; P=0.009), female sex (OR=1.76; 95% CI, 1.08-2.86; P=0.023), a higher PCS dose used (OR=1.46; 95% CI, 1.06-2.03; P=0.022), a lower satisfaction score (OR=1.39; 95% CI, 1.27-1.49; P<0.001), and the presence of delayed side-effects (OR=3.28; 95% CI, 1.04-10.31; P=0.043) were independent variables predicting patients' unwillingness to use PCS for colonoscopy (Table 3).

Discussion

In randomised controlled trials, PCS provided lighter sedation and hence could shorten recovery period after colonoscopy.[9-13] Little is known, however, about the safety, feasibility, and acceptability of PCS for colonoscopy, especially when this new sedative method is delivered by non-anaesthesiologists. In this study, 500 elective patients received PCS (a mixture of propofol and alfentanil) as their sedative method for colonoscopy. Hypotension was present in 8.6% cases. Nonetheless, most patients experienced only transient hypotension and did not require further treatment. On the other hand, there was no desaturation or apnoea when patients received 2 L/min oxygen supplementation during the procedure. This encouraging result suggests that PCS is safe in terms of cardiopulmonary complications. Short recovery time is a distinct advantage of PCS. Although we did not measure the actual discharge time, the reduced recovery time could possibly reduce the workload of nursing staff to a certain extent with respect to patient monitoring. Since propofol and alfentanil were short-acting drugs, it was conceivable that only a minority of patients would complain of delayed side-effects; in our series, only 3.2% patients complained of minor side-effects after the procedure. Although the PCS delivery system malfunctioned in eight (1.6%) cases, these cases were all related to under-delivery and we did not experience any inadvertent over-deliveries. Overall, we found that PCS was reliable and easy to set up and deliver, even under non-anaesthesiologists' hands.

The majority of patients gave high satisfaction scores. Nonetheless, approximately 22% of patients, when asked 24 to 48 hours after the procedure, were unwilling to use PCS for colonoscopy in the future if needed. Schutz et al[15] reported that 15% of patients were dissatisfied with conscious sedation for colonoscopy and that highly educated patients and those who underwent longer procedures were likely to be dissatisfied with conscious sedation for colonoscopy. In our series, by using a multiple stepwise logistic regression model, we found that younger age, female sex, higher mean dose of PCS, lower satisfaction score, and the presence of delayed side-effects were all independent factors that predicted unwillingness to again use PCS for colonoscopy. Education level and length of procedure, however, were not predictors. This finding might be related to our study population and the relatively short duration for most procedures. Better pre-procedure explanation and use of an appropriate adjunct to sedation might be possible ways to improve patients' willingness and acceptance of PCS for colonoscopy.[16-19]

To conclude, this prospective study has demonstrated that the use of PCS for elective, day-case colonoscopy is safe, feasible, and acceptable to most patients. It is, however, imperative to find ways to improve the willingness and acceptance of using PCS in younger and female patients, patients who require a higher dose of PCS, those who report lower satisfaction scores, and those who experience delayed side-effects.

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