

Original Article

Safety of Nurse-administered Propofol Sedation Using PCA Pump for Outpatient Colonoscopy in Chinese Patients: A Pilot Study

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BACKGROUND: To determine the safety and effectiveness of nurse-administered propofol sedation using patient-controlled analgesia (PCA) pump in outpatient colonoscopy in a Chinese population.

METHODS: From April to June 2005, 50 consecutive ASA class I or II patients aged 18–65 undergoing outpatient colonoscopy in an endoscopy centre of a regional hospital were prospectively recruited in this study. After a loading dose of 40–60 mg intravenous propofol, a mixture containing 14.3 mg propofol and 35 µg alfentanil were delivered via a patient-controlled syringe pump as bolus dose by an endoscopy nurse under the supervision of an endoscopist during the procedure. Lockout time was set to be zero. We aimed to achieve conscious sedation, with an Observer's Scale for Sedation and Alertness (OSSA) score of 3. The primary outcome measure was complications from sedation, which included hypotension, bradycardia and desaturation. Other outcome measures included onset time, patients' pain score, endoscopists' and nurses' satisfaction on the level of sedation, patients' satisfaction regarding the procedure (measured by 10 cm visual analogue scale), and their willingness to repeat the procedure.

RESULTS: The mean lowest systolic blood pressure and mean arterial pressure (MAP) were 103.2 ± 12.4 mmHg and 78.3 ± 11.0 mmHg, respectively. The mean percentage drop in MAP was $15.7 \pm 11.9\%$. Six patients (12.2%) developed transient hypotension. Three patients (6.1%) had bradycardia. There was no episode of desaturation. The median onset time to reach OSSA score of 3 was 1 minute (range, 0.5–20.5). The OSSA score of 3 could be maintained throughout the procedure. The mean loading dose of propofol was 48.9 ± 6.7 mg. The mean total dosages of propofol and alfentanil given were 124.2 ± 38.1 mg and 184.3 ± 93.7 µg, respectively. Endoscopists, endoscopy nurses and patients were highly satisfied with the sedation. The median pain score was 1 (range, 0–10; 0 = no pain, 10 = very painful), and the mean recovery time was 2.8 ± 2.8 minutes. Most patients (93.9%) were willing to repeat the procedure.

CONCLUSION: Nurse-administered propofol sedation using PCA pump is safe and effective in sedation and pain control in outpatient colonoscopy in a healthy Chinese population. [*Asian J Surg* 2007; 30(4):239–43]

Key Words: colonoscopy, nurse-administered propofol sedation, PCA pump

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Introduction

Propofol has been reported as a choice of sedation for endoscopy in recent years.¹ Its characteristics of rapid onset, short half-life and rapid recovery compared with traditional intravenous sedation are advantageous as a hypnotic agent in the outpatient setting.² Its unpopularity in the past is accounted for by the absence of an antidote, adverse effects of hypotension and severe respiratory depression. In the consideration of safety, propofol used to be administered by anaesthesiologists in Hong Kong. Recent studies have successfully showed that nurse-administered propofol sedation (NAPS) under the supervision of endoscopists without anaesthesiologists is safe and effective.³⁻⁷ In past studies, propofol was delivered by intravenous bolus and titrated against the level of sedation. This requires a demanding technique of drug administration and close patient monitoring. Patient-controlled analgesia (PCA) pump has been used for patient-controlled sedation in colonoscopy in the past. Based on the properties of concise repeated drug delivery and constant time interval between doses with the use of a PCA pump, we propose that it can facilitate NAPS. A new protocol on NAPS using PCA pump has been developed in our endoscopy unit. This pilot study aims to investigate the safety and effectiveness of NAPS by PCA pump in Chinese patients, and its acceptance to endoscopy nurses.

Patients and methods

This study was supported by the Department of Anaesthesia. All endoscopy nurses participating in this study have the Basic Cardiac Life Support (BCLS) certificate and they are familiar with initial airway management by chin lift manoeuvre and oropharyngeal airway insertion. Before the start of this study, endoscopists and endoscopy nurses were trained by a consultant anaesthesiologist through a series of lectures to understand: (1) the properties and technique of propofol delivery; (2) patient monitoring by using the Observer's Scale for Sedation and Alertness (OSSA) score (Table 1); and (3) a reminder on airway management. During the study period, a dedicated senior anaesthesiologist inside the hospital was immediately available for assistance if necessary.

From April to June 2005, 50 consecutive patients aged 18 to 65 undergoing outpatient elective colonoscopy were recruited for the trial with informed consent. Ethical

Table 1. Observer's Scale for Sedation and Alertness

Score	Responsiveness	Eyes
5	Responds readily to name	Clear, no ptosis
4	Lethargic response to name	Glazed or mild ptosis (< 1/2 eye)
3	Responds only when called loudly/repeatedly	Marked ptosis (> 1/2 eye)
2	Responds after mild prodding/shaking	
1	Unresponsive to mild prodding/shaking	

approval was obtained from the clinical research ethics committee of the institution. Exclusion criteria included: (1) American Society of Anesthesiologist (ASA) Class III or above; (2) known allergy to propofol, alfentanil, eggs or soy products; (3) previous colectomy; (4) history of difficult endotracheal intubation.

We aimed to achieve the level of conscious sedation, or moderate sedation/analgesia. Conscious sedation was defined according to the ASA as a state of drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions were required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function was usually maintained. Sedation was considered adequate when the patient only responded to light tactile stimulation.

The patient was monitored by a qualified endoscopy nurse with BCLS certification, in addition to the medical and nursing staff required for the procedure. The nurse provided verbal intercommunication to and from patients with light tactile stimulation throughout the procedure. The level of sedation was assessed every 30 seconds according to OSSA score. The nurse pressed the button of the PCA pump until an OSSA score of 3 was achieved. Propofol (Diprivan®; AstraZeneca, Hong Kong SAR) and alfentanil (Rapifen®; Janssen-Cilag, Hong Kong SAR) were delivered intravenously via a 50 mL-syringe PCA pump (Grabesy 3300 PCA pump; Graseby Medical Ltd., Hertfordshire, UK) by bolus titration. A loading dose of 40–60 mg propofol or 0.8 mg propofol/kg, whichever was the higher, was given 1 minute before the commencement of the procedure. Propofol 20 mL (200 mg) and alfentanil 1 mL (0.5 mg) were mixed in a 50 mL-syringe pump and 1.5 mL of mixture (14.3 mg propofol and 35 µg alfentanil) was delivered in

each bolus with zero lockout time. About 20 seconds was required for completion of each bolus delivery. The nurse stopped drug delivery and informed the endoscopist when (1) an allergic reaction occurred, or (2) the patient developed desaturation with $\text{SpO}_2 < 90\%$, or (3) the patient developed hypotension (systolic blood pressure [SBP] < 90 mmHg) or bradycardia (pulse $< 50/\text{min}$). The nurse informed the patient on the finding of appendiceal opening when the colonoscope reached the caecum. Drug delivery was stopped on withdrawal of the colonoscope.

Hong Kong College of Anaesthesiologists guidelines on sedation were followed.⁸ An anaesthesiologist was available on request during the procedure. The patient's oxygen saturation was continuously monitored by pulse oximeter which was set to alarm when the saturation fell below 90%. Two litres of oxygen were routinely given via nasal cannula. Blood pressure was measured every 3 minutes. In patients with desaturation and reduced respiratory effort, patent airway was maintained by the chin lift manoeuvre and oropharyngeal airway. Colonoscopies were performed by experienced endoscopists who have the experience of 300 similar procedures.

After the procedure, the patient was monitored in the recovery area. Degree of alertness was assessed every 5 minutes according to the OSSA score. When patients had an OSSA score of 5, were haemodynamically stable (SBP > 90 mmHg and pulse $> 50/\text{min}$) and ambulatory, they were regarded as having fully recovered from the procedure.

At the end of the pilot study, a questionnaire was completed by the endoscopy nurses who participated in this study. The usefulness of the PCA pump in NAPS was assessed.

The primary outcome measure was complications arising from sedation, which included hypotension, bradycardia and desaturation. Other outcome measures included propofol onset time, patients' pain score, endoscopists' and nurses' satisfaction on the level of sedation, patients' satisfaction on the procedure, their memory on colonoscopy findings and their willingness to repeat the procedure. All scores were measured using a 10 cm visual analogue scale (0 = unsatisfied, 10 = very satisfied).

Results

From April to June 2005, 50 consecutive patients were recruited for the study; 23 were female and 27 were male. Mean age was 47.6 ± 10.1 years, and 35 patients belonged

to ASA class I and 14 patients belonged to ASA class 2. Eleven patients had previous history of colonoscopy. Indications for colonoscopy included per rectal bleeding ($n = 26$), abdominal pain ($n = 7$), altered bowel habit ($n = 13$), past history of colonic polyp ($n = 4$) and anemia ($n = 1$).

All colonoscopies were completed with no complications. The mean duration of the procedure was 19.0 ± 8.6 minutes. The mean time to reach the caecum was 11.3 ± 5.4 minutes. The mean baseline SBP was 128.0 ± 17.9 mmHg and baseline mean arterial pressure (MAP) was 93.9 ± 13.6 mmHg. The lowest SBP and MAP were 103.2 ± 12.4 mmHg and 78.3 ± 11.0 mmHg, respectively. The mean percentage drop in MAP was $15.7 \pm 11.9\%$. Six patients (12.2%) developed transient hypotension (SBP < 90 mmHg) during the procedure, with the lowest SBP being 78 mmHg. All patients regained normal blood pressure spontaneously on repeated measurement after drug delivery was stopped temporarily. No patients required intravenous fluid resuscitation. Thirteen patients (26.5%) had a greater than 25% drop in MAP. Three patients (6.1%) had bradycardia (pulse $< 50/\text{min}$). There was no episode of desaturation. The mean lowest SpO_2 was $97.0 \pm 2.5\%$. The mean OSSA score at the beginning of the procedure 1 minute after the loading dose was 3.45 ± 1.4 . The median onset time to reach OSSA score of 3 was 1 minute (range, 0.5–20.5 minutes). The OSSA score of 3 could be maintained throughout the procedure. The mean OSSA score from the start of the procedure to the arrival of the colonoscope at the caecum was 3.24 ± 0.57 . The mean OSSA score at the caecum was 2.86 ± 1.18 . The mean loading dose of propofol was 48.9 ± 6.7 mg. The mean total dosages of propofol and alfentanil given were 124.2 ± 38.1 mg and 184.3 ± 93.7 μg , respectively.

We achieved high endoscopists' and nurses' satisfaction on sedation (0 = unsatisfied, 10 = very satisfied). Mean endoscopist's satisfaction score was 7.5 ± 2.4 and mean nurse's satisfaction score was 7.78 ± 2.2 . Mean patient's satisfaction score was 8.6 ± 1.9 and the median pain score was 1 (range, 0–10; 0 = no pain, 10 = very painful). Most patients (46/50, 92%) were willing to repeat the procedure with the same mode of sedation. The mean recovery time was 2.8 ± 2.8 minutes. Of the 50 patients, 38 (76%) could recall the colonoscopy findings. No patients required overnight observation. Seven endoscopy nurses dedicated to NAPS filled in the questionnaire. All of them preferred sedation in colonoscopy. They were competent in patient monitoring and assessment of complications. Most of

them (6 of 7) preferred PCA pump to manual injection for drug delivery. They all agreed that the PCA pump could reduce their burden in NAPS.

Discussion

This is the first study to describe the use of a PCA pump in NAPS. The PCA pump is commonly used in patient-controlled sedation (PCS) in colonoscopy.^{1,9-11} It has several advantages compared with conventional manual bolus titration by syringe injection. First, it can accurately give the same bolus dose repeatedly. Nurses need not pay attention to the dose they inject each time, so human error can be avoided. Second, the time interval between bolus injections is fixed to around 20 seconds by the machine with zero lockout time for drug delivery. This is an ideal window between bolus doses. Nurses who deliver the drug need not count the time before delivering the next dose. Thus, they can comfortably concentrate on the assessment of the patient response and monitoring of blood pressure and SpO₂.

The level of sedation and pain control determine the success of a comfortable colonoscopy. Previous studies in NAPS used a loading dose of 20–50 mg followed by a bolus dose of 10–20 mg propofol without alfentanil (Table 2). Studies in the United States use no analgesia, while studies in Switzerland add 12.5–25 mg meripidine for pain control. In our new protocol, a relatively higher loading dose (mean, 48.9 mg) was used, with an excellent median onset time of 1 minute, just at the beginning of the procedure. The propofol/alfentanil mixture is effective in sedation and pain control. A state of conscious sedation (OSSA score 3) can be kept during the procedure, while a low median pain score of 1 can be achieved. Both the synergistic effect of alfentanil and no-drug-delivery strategy on withdrawal of the colonoscope contributed to the low mean total dose of propofol of 124.2 mg compared with

other studies (Table 2). The latter factor also contributed to a short recovery time.

The potential danger of cardiopulmonary complication in the absence of an antidote makes physicians extremely cautious in the use of propofol without anaesthesiologists. The most life-threatening event is reduced respiratory effort, leading to desaturation and respiratory arrest. Close patient monitoring and strong support from an anaesthesiologist are essential to develop a safe practice of NAPS. This will inevitably increase the demands on resources and manpower. In our protocol, one extra endoscopy nurse with BCLS certification is required in each endoscopy room. Despite the extra cost of NAPS, the favourable outcome of a high quality colonoscopy service can be achieved. If the resources are available, NAPS is a good choice to make colonoscopy a comfortable procedure, with an optimal sedation and a low pain score.

We encountered 12.2% transient hypotension and 6.1% bradycardia. There was no respiratory complication in our series. All patients with hypotension did not require fluid resuscitation. The ultra-short half-life of propofol can readily remedy the disadvantage of there being no antidote. Our result is comparable to previous NAPS studies, with 0–22% hypotension and 0.1–3.7% desaturation.⁴⁻⁸ The addition of alfentanil does not hinder the safety of NAPS, but gives better pain control. NAPS is highly accepted by patients, endoscopists and nurses. Most endoscopists, endoscopy nurses and patients were satisfied with our new protocol of NAPS. In particular, endoscopy nurses appreciate the use of the PCA pump, which can reduce their burden. Most patients (92%) were willing to repeat the procedure with the same mode of sedation.

To conclude, our new protocol using PCA pump in NAPS for outpatient colonoscopy is safe and effective in sedation and pain control with fast recovery in healthy Chinese patients. It is well accepted by patients, endoscopy nurses and endoscopists in Chinese population. Further

Table 2. Dosage of propofol in nurse-administered propofol sedation

	Loading dose (mg)	Bolus dose (mg)	Time interval between doses (sec)	Mean total dose (mg)
Sipe et al ³	20–40	10–20	30–60	218
Kulling et al ⁴	0.5/kg (half in ASA 3/4, age > 70)	10	30–60	157
Heuss et al ⁵	20	10	20	1.93/kg
Walker et al ⁷	30–50	10–20	30–60	210

randomized trial of NAPS versus conventional sedation is worthwhile before commencing routine use of NAPS with PCA pump in outpatient colonoscopy.

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