Propofol patient-controlled sedation during hip or knee arthroplasty in elderly patients

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Purpose: Little information is available regarding the use of patient-controlled sedation (PCS) among the elderly. This study evaluated the safety and efficacy of propofol PCS among elderly patients undergoing hip or knee arthroplasty.

Methods: Forty patients, aged 65–78 yr, undergoing hip or knee arthroplasty under regional anaesthesia were randomized to receive propofol PCS (dose = 0.3 mg·kg^{-1}, delay = three min; n = 20) or anaesthetist-administered midazolam-fentanyl sedation (n = 20). Sedation, anxiety and discomfort visual analogue scores (VAS) were measured, by an independent observer, preoperatively, immediately at the end of surgery and one hour following admission to the postanaesthetic care unit (PACU). Cognition was evaluated, using an abbreviated Mini Mental Status Examination, preoperatively and in the PACU. Patient satisfaction, based on VAS and a brief questionnaire, was measured in the PACU. The incidence of intraoperative complications was also compared.

Results: Patient satisfaction was high in each group. Sedation and anxiety VAS were similar in each group. A high incidence of pain with drug injection was noted among patients receiving propofol (80%). Transient deeper levels of sedation (6 *vs* 1; $P = 0.05$) were observed more commonly in the propofol PCS group.

Conclusion: Propofol PCS provides effective sedation. Using a propofol dose of 0.3 mg·kg^{-1}, transient episodes of deeper sedation were noted more frequently among patients receiving PCS. These episodes did not require intervention but, suggest that this propofol PCS dose approaches the limit of safety and should be further reduced for some elderly patients.

Objectif : On connaît mal le maniement de la sédation autocontrôlée (PCS) chez les patients âgés. Cette étude visait à évaluer la sécurité et l'efficacité du propofol en PCS chez des patients âgés soumis à une arthroplastie de la hanche ou du genou.

Méthodes : Quarante patients âgés de 65 à 78 ans programmés pour arthroplastie de la hanche ou du genou sous anesthésie régionale étaient répartis au hasard pour recevoir soit la PCS au propofol (dose = 0,3 mg·kg^{-1}, délai = 3 min ; n = 20), soit la sédation au midazolam-fentanyl administrée par l'anesthésiste. Des échelles visuelles analogiques (ÉVA) pour la sédation, l'anxiété et l'inconfort étaient enregistrées par un observateur indépendant, avant l'intervention, immédiatement après la fin de la chirurgie et une heure après l'admission à l'unité des soins postanesthésiques (USPA). La conscience était évaluée à l'aide d'un test abrégé d'évaluation de l'état mental (*Mini Mental Status Evaluation*) avant l'intervention et à l'USPA. La satisfaction du patient, basée sur l'ÉVA et un bref questionnaire, était évaluée à l'USPA. L'incidence des complications peropératoires a aussi été comparée.

Résultats : Dans les deux groupes, la satisfaction des patients était élevée. L'ÉVA de sédation et d'anxiété était identique dans les deux groupes. Une incidence élevée de douleur à l'injection était rapportée dans le groupe propofol (80%). Des épisodes transitoires d'approfondissement de la sédation (6 *vs* 1 ; $P = 0.05$) étaient plus souvent observés dans le groupe propofol.

Conclusion : Le propofol produit une sédation efficace. Avec une dose de propofol de 0,3 mg·kg^{-1}, en PCS des épisodes transitoires d'approfondissement de la sédation ont été observés plus souvent. Ces épisodes n'ont pas nécessité d'interventions mais portent à croire qu'avec cette méthode, la dose administrée approche la limite de sécurité et qu'elle devrait être encore plus faible chez certains patients âgés.

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NUMEROUS studies have reported the use of patient-controlled sedation (PCS) during a variety of procedures performed under local or regional anaesthesia.[1–5] Reports of patient-controlled drug administration have typically involved patients in younger age groups.

Elderly patients being more susceptible to drug-induced complications (e.g., ventilatory depression, confusion) have traditionally been excluded from studies involving patient-controlled drug administration. However, experience at our hospital using PCA for postoperative analgesia among elderly patients has been favourable.[6] Little information is available regarding the safety and efficacy of PCS among the elderly. This randomized, prospective study evaluated propofol PCS during hip or knee arthroplasty performed on an elderly population of patients.

Methods

Following approval of the institutional ethics review board and acquisition of written informed consent, elderly patients (65–79 yr) scheduled to undergo elective hip or knee arthroplasty were randomized to receive propofol PCS or anaesthetist-administered midazolam and fentanyl intraoperative sedation. The PCS parameters consisted of a propofol PCS dose of 0.3 $mg \cdot kg^{-1}$ and a delay interval of three minutes. Basal infusions were not used. Patients randomized to PCS were shown how to use the device and were instructed to use the pump if they felt anxious or wished to be more sedated during their operation. Anaesthetist-administered sedation consisted of 0.5 mg midazolam and 25 μg fentanyl boluses *iv* administered at the discretion of the attending anaesthetist to achieve and maintain sedation at level 2–3 (Appendix A). Anaesthesia was provided to all patients by one anaesthetist (SG).

All patients received supplemental oxygen by face mask. Intraoperative monitoring included ECG, automatic noninvasive blood pressure, continuous pulse oximetry and respiratory rate monitored via capnographic sampling from the mask. Regional anaesthesia consisted of spinal or epidural blocks performed by the attending anaesthetist.

Each study was supervised by an independent research nurse who was present in the operating room during each operation and conducted cognitive function testing, obtained visual analogue scores (VAS) for discomfort, sedation, anxiety and patient satisfaction, recorded drug use and noted complications. Cognitive functioning was evaluated preoperatively and one-hour after arrival in the postanesthetic care unit (PACU) using an abbreviated version of the Mini Mental Status Examination (MMSE). The MMSE has been endorsed[7] as a useful screening test for cognitive impairment in the elderly and the abbreviated version has been reported to contain the MMSE test items with the highest specificity and sensitivity for cognitive impairment.[8,9]

Discomfort, sedation and anxiety VAS (100 mm) were obtained preoperatively (PREOP), immediately at the end of surgery (EOS) and one-hour following arrival in the PACU. Patient satisfaction with each technique was assessed by satisfaction VAS and a brief questionnaire (Appendix B) completed by each patient in the PACU. The questionnaire evaluated the general level of comfort during the procedure and patients' willingness to repeat the procedure using the same technique. Since the success of PCS is directly dependent on patients' responses to the opportunity to administer their own medications, a third question, completed by patients in the PCS group only, evaluated how well they liked the method of self-administration.

Complications noted specifically included haemodynamic instability (systolic BP <85 mmHg), respiratory rate depression (<eight breaths per minute), pulse oximetric desaturation (<90%), pain with drug injection and deep levels of sedation. Patients who complained of discomfort when propofol was injected were treated with lidocaine (20 mg bolus *iv* or the addition of lidocaine to the propofol emulsion: 1 mg lidocaine per 10 mg emulsion). The level of sedation was evaluated at 10 min intervals by the attending anaesthetist based on a five-point scale (Appendix A). Levels of sedation >3 were considered excessive.

Discomfort, anxiety and sedation VAS were expressed as absolute change from preoperative score. Data were analyzed using Fisher's exact test and Student's t-test for unpaired data. A level of $P<0.05$ was accepted as statistically significant.

Results

Forty elderly patients (mean age = 72 yr, range = 65–78 yr) were randomized to receive propofol PCS (n=20) or anaesthetist-administered midazolam and fentanyl sedation (n=20). Regional blocks were adequate in all patients. Each patient completed the surgical procedure satisfactorily. The two groups were similar based on demographic comparisons (Table I).

All patients received intraoperative sedation. The mean doses of sedative drugs administered to patients in each group are shown in Table II. The ratio of successful to total PCS demands was 0.43.

Discomfort, sedation and anxiety VAS were similar for each group (Figure 1). Cognitive function was well preserved in both groups (Table III). Patient satisfaction was high with both sedation techniques based on

TABLE I Demographic Data

Characteristic		*Propofol PCS*	*Midazolam-Fentanyl*
Age (yr)		72.0 ± 4	71.6 ± 4
Sex (M:F)		7:13	10:10
Weight (kg)		80 ± 16	87 ± 15
Height (cm)		166 ± 8	168 ± 10
Surgical procedure (hip: knee arthroplasty)		4:16	5:15
Duration of procedure (min)		95 ± 31	102 ± 25
ASA Physical Status	I	1	1
	II	10	11
	III	9	8

Mean ± SD or number of patients
PCS = patient-controlled sedation
ASA = American Society of Anesthesiologists

TABLE II Intraoperative Sedation Administered and Complications

Characteristic	*Propofol PCS*	*Midazolam-Fentanyl*
Propofol PCS total dose (mg)	190.0 ± 92.3	N/A
Fentanyl total dose (μg)	N/A	165 ± 107
Midazolam total dose (mg)	N/A	2.4 ± 1
PCS demand ratio (%) (successful: total demands)	43.8	N/A
Complications		
Haemodynamic instability	0	0
Pain with injection	16*	1
Respiratory rate depression (RR <8·min^{-1})	6	2
Pulse oximetric desaturation (SpO_2 <90%)	0	0
Sedation ≥level 4[a]	6*	1

Mean ± SD or number of patients
* $P \leq 0.05$ between groups
PCS = patient-controlled sedation
N/A – not applicable
a = based on a five-point sedation scale (Appendix A)

TABLE III Patient Satisfaction and Cognitive Function Test Results

Characteristic	*Propofol PCS*	*Midazolam-Fentanyl*
MMSE Score		
PREOP	12.8 ± 2.3	13.0 ± 1.4
POSTOP	13.1 ± 1.9	13.6 ± 1.2
Satisfaction VAS	94.2 ± 5.4	94.8 ± 5.1
Satisfaction (Score=1–4)		
a) General level of comfort	4 (1)	4 (1)
b) Willingness to repeat sedation technique	4 (2)	4 (1)
c) Satisfaction with self-administration	4 (1)	N/A

Mean ± SD or Median (range)
MMSE = abbreviated Mini Mental Status Examination
VAS = visual analogue score
PCS = patient-controlled sedation

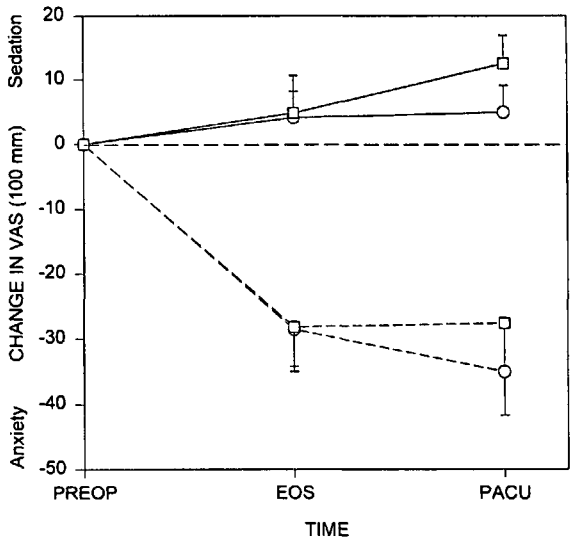

FIGURE Change in sedation (solid lines) and anxiety (dashed lines) visual analogue scores (VAS) for the propofol patient-controlled sedation (PCS) group (open circles) and anaesthetist-administered midazolam-fentanyl group (open squares). Data are plotted as absolute change in VAS from preoperative (PREOP) values measured immediately at the end of the surgical procedure (EOS) and 60 min after arrival in the postanesthetic care unit (PACU). Error bars denote SEM.

the VAS results and the responses to the satisfaction questionnaire (Table III). Satisfaction with self-administration was also very high among the patients who received propofol PCS. All patients in the PCS group liked the method of self-administration with each patient rating the technique as 3 (n=7) or 4 (n=13) on the satisfaction questionnaire (based on a scale of 1–4; Appendix B, question 3).

The incidence of complications associated with sedation is shown in Table II. Discomfort during injection of sedative medications was more prevalent among patients receiving propofol (16 patients with propofol *vs* 1 patient with midazolam, $P<0.00003$). Discomfort associated with injection was remedied with the administration of lidocaine.

Transient respiratory rate depression was observed in six patients in the propofol group and in two patients in the midazolam-fentanyl group ($P=0.12$) following bolus doses of sedative medications (Table II). Episodes of respiratory rate depression were of short duration (< one minute), were not associated with pulse oximetric desaturation and did not require intervention. The mean age of the patients who experienced transient decrease in respiratory rate was 72 yr, (range= 65–78 yr).

Patients receiving propofol PCS achieved deeper levels of sedation more commonly than patients

receiving anaesthetist-administered midazolam and fentanyl. Six patients in the propofol group reached level 4 sedation compared with one patient in the midazolam-fentanyl group (P=0.05) (Table II). None of the patients reached level 5 sedation. In each case, deeper levels of sedation were transient and followed the administration of sedation. The mean age of the group of patients who developed level 4 sedation was 75 yr (range=69–78 yr). Four of the seven patients in this group were 78 yr of age.

Discussion

Sedation and anxiety VAS among patients using propofol PCS were similar to those reported by patients receiving anaesthetist-administered midazolam and fentanyl sedation. Cognitive functioning was equally well preserved with both techniques. Patients were equally satisfied with either technique.

Among elderly patients, propofol administration is commonly associated with injection pain. Using a bolus dose of 0.3 $mg \cdot kg^{-1}$, 80% of the PCS patients in this study complained of pain with drug injection. Since this phenomenon can be remedied effectively with the administration of small doses of lidocaine *iv*, the routine use of lidocaine should be considered during propofol sedation.

More patients in the propofol PCS group were noted to experience deeper levels of sedation transiently following doses of sedative medications. This phenomenon was more common with advancing age since four of seven patients (57%) were 78 years old. These findings support those reported by Grattidge.[2] Using a larger propofol PCS dose (0.7 $mg \cdot kg^{-1}$) among patients ranging in age from 26 to 72 yr (mean=42 yr), Grattidge noted deeper levels of sedation among the older patients and emphasized the need to reduce the PCS dose with advancing age.

Transient depression in respiratory rate was noted among patients in both groups following bolus doses of sedative medication (propofol n=6, midazolam-fentanyl n=2; $P = 0.12$). Although this difference was not statistically significant, the power of the comparison is low (Power = 0.65). With respect to propofol sedation, transient respiratory rate depression has been noted by other investigators. Rosa *et al.*,[10] studying the ventilatory effects of sedative doses of propofol (0.3 and 0.6 $mg \cdot kg^{-1}$) among younger (mean age – 47 yr), healthy (ASA 1) patients, reported that some patients (30%) experienced a transient ("clinically irrelevant") decrease in respiratory rate following propofol boluses. Our observations are consistent with these findings with six of 20 patients (30%) in the propofol group experiencing transient decreases in respiratory rate. Each patient in our study received supplemental oxygen during the operative procedure and clinically significant decreases in oxygen saturation were not observed in either group.

There is no information available regarding the safe PCS dose for elderly patients. In our study, the propofol PCS dose of 0.3 $mg \cdot kg^{-1}$ was selected based on an empiric reduction in the dose used safely among younger patients (0.5 $mg \cdot kg^{-1}$) and experience with the technique.[11] Although this dose was not associated with any clinically serious misadventure, the transient episodes of deeper sedation observed suggest that this dose approaches the upper limit of safety for some elderly patients and that a further dose reduction may be prudent (e.g., 0.3 $mg \cdot kg^{-1}$ for patients 60–69 yr and 0.15 $mg \cdot kg^{-1}$ for patients 70–79 yr). The merit of altering the delay interval has not been investigated. Patient-controlled sedation offers a useful addition to the repertoire of sedation techniques available to the anaesthetist. The technique can be used effectively by elderly patients but, further evaluation to delineate the optimum dose in this patient population is warranted.

Acknowledgments

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Appendix A

Patient Satisfaction Questionnaire

Please help us evaluate your anaesthetic by completing the following questions. We are interested in your honest opinion, positive or negative. We also welcome your comments and suggestions.

CIRCLE YOUR ANSWER

1. How satisfied were you with your pain management and overall level of comfort?

4	3	2	1
very satisfied	mostly satisfied	mildly satisfied or indifferent	quite dissatisfied

2. If you were to have surgery again would you opt for the same method of management?

1	2	3	4
no definitely not	no I don't think so	yes I think so	yes definitely

3. Did you like the method of self-administration of sedative medication?

4	3	2	1
yes definitely	yes I think so	no I don't think so	no definitely not

Appendix B

Sedation Scale

SCORE	CRITERIA
1	Fully awake and oriented
2	Drowsy, eyes open
3	Drowsy, eyes closed but rousable to command
4	Drowsy, eyes closed, rousable to mild physical stimulation
5	Unrousable to mild physical stimulation