Rev Bras Anestesiol. 2013;63(5):410-414

REVISTA BRASILEIRA DE ANESTESIOLOGIA

Official Publication of the Brazilian Society of Anesthesiology
www.sba.com.br

SCIENTIFIC ARTICLE

Patient-Controlled Sedation in Orthopedic Surgery Under Regional Anesthesia: A New Approach in Procedural Sedation

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Received on March 22, 2012; accepted on July 16, 2012

KEYWORDS
Analgesia, Patient-Controlled;
Anesthesia, Epidural;
Anesthesia, Spinal;
Conscious Sedation;
Infusion Pump;
Propofol

Abstract
Background and objectives: Regional anesthesia is a commonly used technique in orthopedic procedures. Sedation should reduce the patient's anxiety and fear while increasing regional anesthesia quality. This study evaluated the hemodynamic changes, level of sedation, both patients' and surgeons' levels of satisfaction and potential side effects in patient-controlled sedation using propofol.
Methods: This randomized clinical trial studied sixty ASA physical class I-III patients scheduled for total knee replacement surgery under combined spinal-epidural anesthesia. Patients in Group P (n = 30) received propofol via a patient-controlled analgesia device with the following settings: intravenous propofol bolus dose 400 μg.kg^{-1}, 5-minute lockout interval and no basal infusion. In Group S, we infused saline 150 using the same settings. To determine the level of sedation, we used BIS and Observer's Assessment of Alertness/ Sedation Scale. For all patients, we recorded the number of requests. As the final evaluation, we scored surgeons' and patients' satisfaction on 4-point scales.
Results: Both BIS values and OAA/S scores were lower in Group P than in Group S. Patients' satisfaction was higher in Group P, although there was no significant difference with respect to surgeons' satisfaction between the groups. The number of requests for sedation was significantly higher in Group S. However, most requests were considered unsuccessful.
Conclusion: This study suggests that patient-controlled sedation with propofol can be used efficiently in orthopedic procedures.

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0104-0014/$ - see front matter
http://dx.doi.org/10.1016/j.bjane.2012.07.013

Introduction

Regional anesthesia is a commonly used technique in orthopedic procedures. It offers several advantages, including the maintenance of spontaneous respiration and some patient reflexes such as swallowing and coughing, the provision of analgesia in the postoperative period, low operation costs and shorter hospital stays.[1,2] However, as is frequently seen in orthopedic surgery, the patient who remains conscious during the procedure may be fearful, anxious, and nervous. The easiest way to prevent such situations is to sedate the patient during the operation, which should reduce the anxiety and fear of the patient while increasing the quality of regional anesthesia. However, this is quite difficult to achieve due to different patient expectations regarding level of sedation, different intraoperative conditions, and different pharmacokinetic and pharmacodynamics of the agents used. Procedural sedation, known as monitored anesthesia care, includes methods such as single dose, intermittent or continuous infusions. However, effective sedation is not always possible, resulting in ineffective or deep sedation.[3] Generally, anesthesiologists control the titration of sedation and analgesia for monitored anesthesia care procedures,[4] whereas, in patient-controlled sedation, the patients control their own depth of sedation under the supervision of the anesthesiologist. Once patients can change their levels of sedation in response to stress resulting from the environment and procedures, they are unable to use the device when they reach an adequate level of sedation. Thus, excessive levels of sedation are prevented.[5,6]

This study evaluated the hemodynamic changes, level of sedation, both patients' and surgeons' levels of satisfaction and potential side effects in patient-controlled sedation using propofol.

Material and Method

The Local Ethics Committee granted approval for the study. This randomized clinical trial included sixty ASA physical class I-III patients scheduled for total knee replacement surgery under combined spinal-epidural anesthesia. All patients provided informed consent. We included patients in the trial if they were 53-75 years of age and excluded those that had vertebrae deformities, bleeding diathesis, neurological disorders or an allergy to the studied drug. We allocated the patients randomly to two groups: propofol (Group P) and saline solution (NS) (Group S). Patients in Group P (n = 30) received intravenous (IV) propofol via a patient-controlled analgesia (PCA) device (Abbott Pain Management Provider, Hospira Inc, USA) with the following settings: propofol bolus dose 400 $\mu g.kg^{-1}$, 5-minute lockout interval and no basal infusion. In Group S, we infused NS 150 mL using the same settings.

Prior to the procedure, all patients received 0.9 % NS 10 $mL.kg^{-1}$ IV for prehydration and midazolam 0.025 $mL.kg^{-1}$ IV for premedication. Each patient received detailed instructions for the use of the patient-controlled analgesia device. In the operating room, we applied an electrocardiogram, a non-invasive blood pressure monitor, a pulse oxymeter and BIS device (BIS Vista, Aspect Medical Systems Inc, USA) to each patient. We gave supplemental oxygen at a flow rate of 3 $L.min^{-1}$ via face mask. After local anesthesia, we performed combined spinal-epidural block at L2-4 in the lateral decubitus position and administered levobupivacaine 15 mg to the subarachnoid space. We placed the epidural catheter into the same spaces. We determined sensorial block level by the pin-prick test. When the level of sensorial block reached T10 dermatome, the operation could begin. At the same time, patient-controlled sedation began. To determine the level of sedation, we used the BIS and Observer's Assessment of Alertness/ Sedation Scales (OAA/SS) (Table 1). We recorded mean blood pressure, heart rate, peripheral oxygen saturation, level of sedation and BIS values of patients every 5 minutes in the first 30 minutes and then at 15-minute intervals until 30 minutes after the end of the procedure. We terminated all infusions at the end of the operation. As the final evaluation, we scored surgeons' and patients' satisfaction on 4-point scales. For all patients, we recorded the number of requests. When the device gave the drug it was recorded as a successful request and when the device did not give any drug it was recorded as an unsuccessful request. Specific complications noted included hemodynamic instability (systolic BP < 85 mm Hg), bradycardia (HR < 60.min^{-1}), respiratory rate depression (< 8 breaths per minute), pain on drug injection and nausea or vomiting. Patients who complained of propofol injection pain were treated with lidocaine (20 mg bolus IV). We administered ephedrine 10 mg IV for hypotension and atropine 0.5 mg IV for bradycardia.

We performed a power analysis using Minitab 16 statistical package program for determining this study's sample size. The study was performed with a power of at least 90% for the BIS values. We analyzed data with SPSS (Statistical Package for Social Science, SPSS Inc., Chicago, IL; USA) 11.5 package program (Table 2). We tested compliance with the normal distribution of the data obtained from the measurements with the Shapiro Wilk test. For the characteristics obtained from the measurements, descriptive statistics were connoted in terms of mean± standard deviation or median (minimum-maximum) while categorical variables were connoted in terms of percentages. We used Student's t or Mann Whitney

Table 1 Assessment Scale of Patient and Surgeon Satisfaction.

Score	Scale
0	Bad
1	Moderate
2	Good
3	Very good

Table 2 Demographic Data.

	Group P	Group S	p
Age (year)	64.33 ± 6.34	65.43 ± 7.23	0.534
Body weight (kg)	78.43 ± 6.69	82.07 ± 7.90	0.06
Body height (cm)	164.23 ± 8.76	165.13 ± 8.93	0.695
Duration of operation (min)	91.83 ± 19.14	88.83 ± 16.27	0.603
ASA II	22 (73.3%)	25 (83.3%)	0.347
ASA III	8 (26.7%)	5 (16.7%)	

U test to determine whether there was any statistically significant difference between the data obtained from both groups. We used Repetitive Measurement Variance Analysis or the Friedman test to determine whether there were statistically significant differences between the recurrent measurements conducted on both groups. In cases where we found Repetitive Measurement Variance Analysis or Friedman test results to be significant, we applied the Bonferroni Corrected Multiple Comparison test to determine the time of the measurement which had caused the difference. We presented results related to all intragroup comparisons after Bonferroni Correction. For categorical comparisons, we used Chi-square and Fisher's Definitive test. We accepted a value of $p < 0.05$ as statistically significant.

Results

Patient-controlled sedation with propofol was applied to patients undergoing orthopedic surgery under regional anesthesia. The following results were determined from this study: Both BIS values and OAA/S scores were lower in Group P than in Group S. Patients' satisfaction was higher in Group P. However, there was no significant difference with respect to surgeons' satisfaction between the groups. The characteristics of age, body weight and height, duration of surgery and ASA scores were similar in both groups. The mean propofol dosage used in Group P was 132.87 ± 62.6 mg. We administered no additional sedative drug in group S. There was no statistical difference between the groups in terms of heart rate, mean blood pressure and peripheral oxygen saturation. However, the BIS values and OAA/S scores were lower in Group P than in Group S. Patients' satisfaction scores were higher in Group P in comparison with those in Group S. However, surgeons' satisfaction scores were similar for both groups. While 76.7% of patients complained of injection pain in Group P, there were no complaints from Group S. We saw hypotension and bradycardia in Group P patients at the rate of 16.7% and 13.3%, respectively. In Group S, we observed bradycardia in only 10% of patients. The number of requests for sedation was significantly higher in Group S, but most of these were considered unsuccessful requests (Table 3).

Table 3 Number of Requests.

	Mean ± SD	Minimum	Maximum
Group P			
Successful PCA	4.30 ± 2.10	1	9
Unsuccessful PCA	6.30 ± 5.24	1	22
Total PCA	10.60 ± 6.55	2	27
Group S			
Successful PCA	6.70 ± 2.87	1	13
Unsuccessful PCA	23.33 ± 18.39	2	69
Total PCA	30.03 ± 19.57	3	77

PCA, patient-controlled analgesia/sedation.

Table 4 Side Effects.

	Group P	Group S	p
Bradycardia	4 (13.3%)	3 (10%)	1.000
Hypotension	5 (16.7%)	-	0.052
Nausea	-	-	-
Vomiting	-	-	-
Respiratory depression	-	-	-
Injection pain	23 (76.7%)	-	0.000*

Discussion

Central neuraxial blockade techniques are widely accepted and used with confidence by anesthesiologists. Stress factors in the operating room and ineffective or patchy blocks may result in discomfort and anxiety in patients under regional anesthesia. Thus, a sufficiently sedated and cooperative patient is of great importance in regional anesthesia.[7] Anesthesiologists frequently use sedative and narcotic agents in operating rooms in order to resolve anxiety and fear;[8] however, the different responses of patients to these drugs may result in ineffective or deep sedation. In addition, patients' requests regarding the level of sedation vary dramatically - some patients prefer to be awake during the whole operation, while most prefer deep sedation so as not to remember what happens during the procedure.

Traditionally, the anesthesiologists in monitored anesthesia care perform titration of sedation. However, in patient-controlled sedation, patients are free to control their own levels of sedation. The purpose of patient-controlled sedation is to achieve fast and adequate sedation without risk of overdose.[9] Sedation with propofol has been advocated as an alternative to the more commonly used combination of midazolam and narcotic sedative drugs. Propofol is associated with faster onset and offset of sedation and higher patient satisfaction. Patient-controlled sedation has been advocated to improve titration of sedation with propofol. In a study of elderly patients that underwent cataract surgery, Yun et al. determined that the use of propofol in both anesthesiologist-controlled and patient-controlled sedation reduced anxiety and that patients' satisfaction was higher in the patient-controlled group.[10] Singh et al. applied patient-controlled and anesthesiologist-controlled sedation with propofol to patients during surgery under spinal anesthesia and determined that the patient-controlled model resulted in effective sedation with lower propofol dosage, and that the respiratory depression rate was lower in the same model.[11] Crepeau et al. used propofol in both patient-controlled and anesthesiologist-controlled sedation during colonoscopy and determined that propofol was a highly effective sedative agent in the patient-controlled method.[12]

Wilson et al. determined that propofol and midazolam used in addition to spinal anesthesia resulted in adequate sedation, and that recovery was more rapid with propofol.[13]

Yaddanupi et al. compared propofol and midazolam infusions in elderly patients who underwent urological surgery under spinal anesthesia. With a propofol bolus of $0.4 mg.kg^{-1}$ and $3 mg.kg^{-1}.h^{-1}$ infusion, titration and efficiency of sedation were improved, but resulted in hypotension.[14] Mandel et al. compared propofol-remifentanil and midazolam-fentanyl combinations using the patient-controlled sedation method on patients during colonoscopy, and determined that the propofol-remifentanil combination was superior.[15]

Although patient-controlled analgesia is a commonly used method for orthopedic patients undergoing hip or knee replacement surgery in our hospital, patient-controlled sedation

is not routinely implemented. However, the orthopedic operating rooms allow noise of up to 110 decibels, so it is clear that patient-controlled sedation can be applied easily and safely in orthopedic procedures.

In this study, patient-controlled sedation was applied to patients who underwent knee replacement surgery under combined spinal-epidural anesthesia. The average propofol dosage used in patient-controlled sedation was 132.87 ± 62.6 mg. However, total propofol dosage used in the patient-controlled sedation differs according to the type and duration of the surgery and the patient group. Ganapaty et al. reported average propofol dosage of 190.0 ± 92.3 in knee and hip replacement surgery under regional anesthesia.[16] Crepeau et al. reported 60 mg dosage in patient-controlled sedation for colonoscopy[12] but Ng et al.[17] reported 98 mg dosage. While Yun et al. reported a dosage of 30.1 ± 30.4 mg for patient-controlled sedation in cataract surgery,[10] Janzen et al. reported 40.8 ± 35.9 mg.[18] Ganapaty et al. reported patient-controlled propofol usage as 25 $\mu g.kg^{-1}.min^{-1}$, whereas the present study found it to be 18 $\mu g.kg^{-1}.min^{-1}$. The one-minute propofol dosage used in this study was lower than that reported in the study by Ganapaty and also lower than the 30–60 $\mu g.kg^{-1}.min^{-1}$, which has been suggested for sedation. The authors consider one-minute propofol dosage to be affected by the duration of the operation and midazolam premedication. Nakagawa et al. reported that midazolam premedication reduced the propofol requirement for sedation.[19]

In this study, we used BIS monitoring to determine the level of sedation. Although the sensitivity of BIS in terms of monitoring of the level of sedation has been approved in many studies,[20-22] the issue remains controversial.[23] Therefore, in order to eliminate potential misevaluations, we also used the clinical observational method of OAA/SS to evaluate the level of sedation. BIS values decreased 15 minutes after the beginning of sedation and increased gradually after the termination of sedation. We observed fluctuations in OAA/S scores in parallel to those of BIS values. BIS values remained in the alertness range during the operation and never fell below 80, and no deep sedation episode occurred. High BIS values resulted from high environmental stimuli and the application of the tourniquet. These partly high BIS values did not have a negative effect on the patients' satisfaction as 30% of the patients in Group P classed the method as good while 70% classed it as very good. Another indicator of patients' satisfaction was the number of requests for sedation. In the patient-controlled sedation group, the average number of requests was 10.6 ± 6.5. Successful requests were determined as 40%. The current study's findings are comparable with those of Ganapaty et al., who reported satisfaction and successful request rates as 94% and 43.8%, respectively.[16]

We observed no significant difference in the patients of Group S when compared to initial BIS values, and we determined the requests for sedation as 30.0 ± 19.6 (22% successful). These findings show that the preoperative use of midazolam for premedication is not sufficient for perioperative sedation.

We observed injection pain in 76.7% of patients in Group P. Ganapaty et al reported a rate of 80%.[16] This rate is quite high for the patient-controlled sedation group and should be considered a problem to be resolved.

We observed hypotension in 17% of the patients in Group P. Although no statistically significant difference was found when compared with the patients in Group S, this shows an important side effect to be considered (Table 4). The one-minute propofol dosage in the patient-controlled sedation in the current study was lower than in previous studies. However, the dosages were not adjusted according to the age of the patient. In patient-controlled sedation, propofol dosage should be reduced for elderly patients.

The results of this study determined that propofol reduces BIS values and OAA/S scores does not negatively impact satisfaction levels for patients or surgeons, does not lead to side effects other than injection pain and that midazolam premedication alone is not sufficient for perioperative sedation. These findings suggest that patient-controlled sedation with propofol can be used efficiently in orthopedic procedures and that the routine use of this method will increase patients' comfort under regional anesthesia.

Conflicts of interest

The authors declare no conflicts of interest.

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