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□ 원 저 □

Propofol Patient-Controlled Sedation Using WalkMed (Medex Inc, USA) Infusion Pump in Dental Patients

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Abstract

치과 환자에서의 WalkMed사(Medex Inc, USA)의 자가통증조절기를 이용한 Prorofol 자가진정조절법

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연구배경: 일반적으로 자가통증조절기가 자가진정조절을 위해 적합한 것으로 알려져 있다. 그러나 이 장치들은 몇몇 진정제 투여 시 너무 긴 최소 폐쇄간격을 가지고 있다. WalkMed사(Medex Inc, USA)의 자가통증조절기는 폐쇄간격을 0으로 설정할 수 있으며 30 ml/h로 추가용량을 투여할 수 있다. 이번 연구에서는 환자 개개인의 요구에 맞추어 환자의 진정을 조절하기 위하여 위 장치를 이용한 propofol 자가진정조절기의 가능성를 조사하였다.

방법: Propofol과 전산 프로그램된 WalkMed 주입장치를 이용한 자가진정조절법이 치과치료를 받는 24명의 건강한 환자에게 시행되었다. Propofol 지속 주입량은 2 mg/kg/h로, 추가용량은 5 mg으로 조절되었으며 최소 폐쇄간격은 0으로 설정하였다. Ketoloac 30 mg이 통증 조절을 위하여 진정법 시행 전에 근주되었다.

결과: 진정법 시행 동안 주입된 propofol의 평균량은 3.4 mg/kg/h이었으며 평균 추가용량은 1.6 mg/kg/h이었다. 시간 당 추가용량에는 많은 변이가 있었다(0-32). 모든 환자는 진정법 시행 동안 완전한 각성상태였으며 이러한 진정법에 만족하였다. 진정법과 관련된 주요한 합병증은 관찰되지 않았다.

결론: WalkMed사의 자가통증조절기를 이용한 propofol 자가진정조절법이 치과 치료를 받는 환자들에게 유용하게 사용될 수 있다. **(JKDSA 2001; 1: 16～20)**

Key Words: Infusion pumps; Patient-controlled sedation; Propofol.

INTRODUCTION

Patient-controlled analgesia (PCA) has been known for a safe and effective analgesic method. As patient-controlled sedation (PCS) uses the same pharmacological concepts of PCA, PCS was modified from PCA. In PCS, a patient titrates the dose of sedatives rather than analgesics but

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most of sedatives have longer onset and action time compared to analgesics.

Many different kinds of infusion devices have been used for PCS. However, these devices often have minimum lockout time, which may be too long for some sedatives (Hamid et al, 1996). For 'true' PCS, no lockout should be used, which means that the amount of drug available is restricted only by its concentration and the time taken to infuse each dose (Cook et al, 1993).

The WalkMed® PCA ambulatory infusion pump (Medex Inc, Duluth, GA, USA) is a popular PCA device in the world. The flow rate of the WalkMed® is 30 ml/h, which is relatively low compared to other commonly used PCS machines, but it is able to set no lockout time. We thought a delay mechanism in the infusion rate and the possibility of no lockout time setting of WalkMed® may prevent over-sedation by preventing over administration of bolus doses under true PCS. Therefore we may use this machine safely and satisfactorily in PCS. As far as we are aware, this is the first report of PCS using the WalkMed® PCA device.

Propofol has a rapid onset time, and leads to an early and clear recovery after stopping its administration. It also allows us to control the consciousness level easily. Recently these advantages have made propofol a popular choice for sedation.

In this study, propofol was infused without a lockout time using the WalkMed®. We examined the feasibility of propofol PCS using this machine in order to control patient's anxiety in accord with the individual patient's requirements.

MATERIALS AND METHODS

Twenty-four healthy patients (ASA PS 1 or 2) presenting for dental procedure were studied. Patients aged less than 10 and over 65 were excluded from this study, as were those with pre-existing cardiovascular or respiratory illness. After midnight NPO, all patients arrived in the operating room with an intravenous catheter inserted. Following acquisition of written informed consent, ketorolac 30 mg was given intramuscularly to control pain during sedation. Local anesthesia with local infiltration of 2% lidocaine solution mixed with 1 : 100,000 epinephrine was performed before dental procedure. All patients received 5 L/min of oxygen via nasal prong during the procedure.

Propofol PCS was performed using the WalkMed®. The machine was set to deliver a continuous dose of 2 mg/kg/h without propofol loading dose, and a bolus dose of 5 mg over 1 minute. We set also the maximum number of bolus doses of 25/h without lockout time. Patients were told to press the bolus button as often as they needed to relieve discomfort.

The level of consciousness was estimated with bispectral index (BIS) and a five-point sedation scale (Table 1). Complications were observed, including hemodynamic instability (over 30% changes than control), ventilatory depression (RR $<$ 10/min), arterial oxygen desaturation (SpO_2 $<$ 95%) and oversedation (sedation score was 4 or 5 or BIS $<$ 70). Postoperative drowsiness (recovery time $>$ 30 min), nausea and vomiting were also noted.

After dental procedure, we examined satisfaction criteria (Table 2).

Statistical analysis was performed using Pearson product moment correlation analysis, and linear regression was used to evaluate the relationship among total infused propofol per hour versus sedation duration, patient age and

Table 1. Sedation Score

1. Fully awake and oriented
2. Drowsy, eyes open
3. Eyes closed but responds promptly to verbal commands
4. Eyes closed, rousable on mild physical stimulation
5. Eyes closed, unrousable on mild physical stimulation

Table 2. Patient Satisfaction Criterion

Very satisfied
Satisfied
Dissatisfied
Very dissatisfied

Table 3. Clinical Characteristics

Patient's number	24
Age (years)	27.4 ± 15.4
Gender (M : F)	13 : 11
Weight (kg)	61.5 ± 13.2
Height (cm)	169.0 ± 7.9

Values are expressed as mean ± SD.

Table 4. Operative Procedures Performed during Sedation

Operation name	Case number
Teeth extraction	16*
Cyst enucleation	6*
Flap surgery	1
Ankylosis release	1
Incision and drainage	1

*: Teeth extraction and cyst enucleation were performed in one patient.

Table 5. Propofol Administration during Patient-controlled Sedation

Duration of infusion (min)	58.0 ± 13.7
Total dose (mg/kg/h)	3.4 ± 0.87
Total demand dose (mg/kg/h)	1.4 ± 0.87
Total demand number (/h)	15.1 ± 8.75

Values are expressed as mean ± SD.

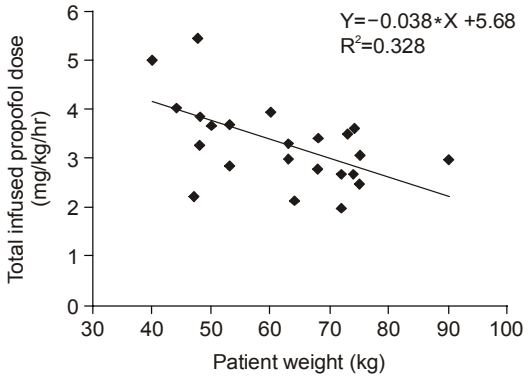

Fig. 1. Scatter plot of total infused propofol doses versus patient weight. The negative correlation was found to be statistically significant (p = 0.003).

body weight. Differences were considered to be statistically significant at the $p < 0.05$.

RESULTS

All patients participating in this clinical study completed the surgical procedure satisfactorily. Table 3 summarizes clinical characteristics. The most common dental procedure was surgical extraction of wisdom teeth or impacted teeth (Table 4). There was great variation in the infused bolus doses (Table 5), and no significant correlation was found between total infused propofol dose per hour and sedation duration (p = 0.43). There was also no correlation between total infused propofol dose per hour and patient age (p = 0.09). However, there was a significant correlation between total infused propofol per hour and body weight (Fig. 1).

All patients were under 1 to 3 state of sedation score during dental procedure. Patient satisfaction criteria were high (Very satisfied, 22, Satisfied, 2). There were no clinically significant intraoperative side effects such as hemodynamic instability (over 30% changes than control), ventilatory depression (RR < 10/min), arterial oxygen desaturation (SpO_2 < 95%), oversedation (BIS < 70), postoperative drowsiness (recovery time > 30 min), nausea or vomiting.

DISCUSSION

Conscious sedation with propofol appears to be gaining popularity in a wide variety of clinical applications. Patients have different sensitivities to sedative drugs and different preferences with respect to the level of sedation required during a procedure. These individual preference and tolerance may make it difficult to provide optimal sedation for each patient. It is well known that PCS provides a satisfactory level of conscious sedation and a high level of patient satisfaction (Osborne et al, 1994; Dell and Cloote, 1998).

Rudkin et al firstly described the use of PCS using propofol in 23 patients undergoing surgical extraction of the third molars (Rudkin et al, 1991). They used a modi-

fied Graseby PCA device to deliver minimum lockout time of one minute. In recent reports, the common PCA devices used in PCS are Graseby PCA delivery system (Pac-Soo et al, 1996; Thorpe et al, 1997; Zacharias et al, 1998), and the Ohmeda 9000 syringe pump (Osborne et al, 1994). The Graseby PCA device (Graseby Medical Ltd, Watford, UK) has been used to deliver sedatives at a rate of either 100 ml/h or 200 ml/h (Thorpe et al, 1997) and the Ohmeda 9000 pump (Ohmeda, West Yorkshire, UK) used at a delivery rate of 1200 ml/h. Compared with these two devices, the flow rate of the WalkMed® is 30 ml/h. Therefore, the bolus dose of 5 mg of propofol has an infusion time of 1 min, which is relatively low. The long delivery time coupled with no lock out time means that patients are receiving an interrupted infusion, rather than an intermittent dose of sedative (Dell, 1996).

Propofol PCS bolus doses are generally 5 to 10 mg. For conscious sedation, propofol should be administered at the rate of 0.6 to 3 mg/kg/h, either alone or in combination with an opiate (Mackenzie and Grant, 1987; Smith et al, 1994). The maximum dose per hour of WalkMed® is 30 ml (i.e. 300 mg of propofol). This value is converted to 4.3 mg/kg/h of propofol in the case of a patient with a body weight of 70 kg. This means that the WalkMed® is adequate to provide conscious sedation, which allows the patient to maintain verbal contact and retain the ability to control the delivery system. In this study, ketorolac was also used intramuscularly at the beginning of sedation. The rationale being that by using drugs of two different pharmacological classes, the dose of each drug can be reduced and side effects are minimized. Ketorolac is a useful analgesic adjunct for the multimodal management of pain (Reuben et al, 1998). It has been reported to provide better and longer-lasting postoperative pain relief than morphine. It also has fewer side effects than the narcotic analgesics and causes notably less sedation, nausea, and respiratory depression (Morrison and Repka, 1994). Although we were unable to demonstrate to what extent the use of ketorolac allowed the propofol dose to be reduced, we believe that the combined use of these drugs improved the quality of sedation because of the analgesic effect of ketorolac.

Propofol is a lipid-soluble anesthetic agent, therefore, it is expected to have a prolonged effect in obese patients. In this study, a negative correlation was found between the total quantity of propofol infused per hour and the patient's body weight, which agrees with the results of other studies (Grattidge, 1994), and means that a reduction of propofol dose is needed in obese patients. However, no significant correlation was found between total infused propofol per hour and patient age or sedation duration. Even when the sedation period extended to about 1 hour, it was found that there was no need to reduce the propofol dose in normal patients.

The objective measurement of the level of consciousness is difficult during sedation. In recent years, the bispectral index (BIS) has been developed. This index quantifies the nonlinear relationships between the EEG component waves, and analyzes their frequency and amplitude (Leslie et al, 1994). BIS is the only commercially available technology using EEG parameters, which has proven to be useful clinically. In this study, BIS was monitored in 8 patients. They were found to have 80-98 of BIS score during PCS, which means that patients were under condition of light sedation or alert state (Liu et al, 1997).

The most frequently reported side effect of propofol administration is pain at the injection site (Lyons et al, 1996). In this study, we managed this pain with an injection of 1 to 2 ml of 1% lidocaine. Propofol may induce respiratory depression (Blouin et al, 1993) and hypotension, which are related to vasodilation (Muzi et al, 1992; Robinson et al, 1997). However, no such problems were observed in this study because we used proper monitoring devices and pre-sedation hydration with balanced salt solution.

CONCLUSION

This investigation shows that propofol PCS using a WalkMed® PCA device with ketorolac and local anesthesia provided good conscious sedation for dental procedures. The dosage regimen used in this study, a continuous dose of 2 mg/kg/h without propofol loading dose, a bolus dose of 5 mg without lockout time, proved

to be a safe and effective for achieving true PCS.

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