EM ADVANCES

Efficacy, safety and patient satisfaction of propofol for procedural sedation and analgesia in the emergency department: a prospective study

Peter J. Zed, BSc, BSc(Pharm), ACPR, PharmD, FCSHP;[*] Riyad B. Abu-Laban, MD, MHSc;[†] Winnie W.Y. Chan, BSc(Pharm);[‡] David W. Harrison, MD[§]

ABSTRACT

Objective: We evaluated the efficacy, safety and patient satisfaction with the use of propofol for procedural sedation and analgesia in the emergency department (ED).

Methods: All patients receiving propofol for procedural sedation and analgesia in the ED between December 1, 2003, and November 30, 2005, were prospectively assessed. Propofol was administered using a standardized protocol, which included an initial dose of 0.25–0.5 mg/kg followed by 10–20 mg/minute until sedated. Efficacy was evaluated using procedural success rate, recovery time and physician satisfaction. Adverse respiratory effects were defined as apnea for more than 30 seconds or an oxygen saturation of less than 90%. Hypotension was defined as systolic blood pressure < 90 mm Hg or > 20% decrease from baseline. Patient and physician satisfaction were determined using 5-point Likert scales.

Results: Our study included 113 patients with a mean age of 50 (standard deviation [SD] 19) years; 62% were male. The most common procedures were orthopedic manipulation (44%), cardioversion (37%), and abscess incision and drainage (13%). The mean total propofol dose required was 1.6 (SD 0.9) mg/kg. Procedural success was achieved in 90% of cases and the mean patient recovery time was 7.6 (SD 3.4) minutes. No patient (0%, 95% confidence interval [CI] 0%–3%) experienced apnea; however, 1 patient (1%, 95% CI 0%–5%) experienced emesis, which resulted in an oxygen saturation < 90%. Nine patients (8%, 95% CI 4%–15%) experienced hypotension and 7 (6%, 95% CI 3%–12%) experienced pain on injection. All patients were very satisfied (92%, 95% CI 85%–96%) or satisfied (8%, 95% CI 4%–15%), and 94% (95% CI 88%–98%) reported no recollection of the procedure. The majority of physicians were very satisfied (85%, 95% CI 77%–91%) or satisfied (6%, 95% CI 3%–12%) with the sedation and the conditions achieved.

Conclusion: When administered as part of a standardized protocol, propofol appears to be a safe

*Clinical Coordinator, Department of Pharmacy and Pharmacotherapuetic Specialist–Emergency Medicine, Queen Elizabeth II Health Sciences Centre, *Associate Professor, College of Pharmacy and Department of Emergency Medicine, Dalhousie University, Halifax, NS, *(at the time of study completion) Pharmacotherapeutic Specialist–Emergency Medicine, CSU Pharmaceutical Sciences, Vancouver General Hospital (VGH), *Clinical Associate Professor, Faculty of Pharmaceutical Sciences and Associate Member, Division of Emergency Medicine, University of British Columbia (UBC), Vancouver, BC, †Attending Physician and Research Director, Department of Emergency Medicine, VGH, †Scientist, Centre for Clinical Epidemiology and Evaluation, Vancouver Coastal Health Research Institute, †Scholar, Michael Smith Foundation for Health Research, †Assistant Professor, Division of Emergency Medicine, UBC, Vancouver, BC, ‡Staff Pharmacist, CSU Pharmaceutical Sciences, VGH, Vancouver, BC, §Attending Physician, Department of Emergency Medicine and Director, Hyperbaric Unit, VGH, §Clinical Associate Professor, Division of Emergency Medicine, UBC, Vancouver, BC

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and effective agent for performing procedural sedation and analgesia in the ED, and is associated with high patient and physician satisfaction.

Key words: propofol, procedural sedation, analgesia, emergency department

RÉSUMÉ

Objectif : Nous avons évalué l'efficacité et l'innocuité de propofol ainsi que la satisfaction des patients quant à son utilisation pour des sédations-analgésies procédurales en salle d'urgence (SU).

Méthodes : Tous les patients à qui l'on a administré du propofol lors d'une sédation-analgésie procédurale en SU entre le 1er décembre 2003 et le 30 novembre 2005 ont été évalués prospectivement. Propofol a été administré selon un protocole normalisé qui comprenait une dose initiale de 0,25 à 0,5 mg/kg suivie d'une dose de 10 à 20 mg/min jusqu'à sédation. L'efficacité a été évaluée en fonction du taux de réussite procédural, du temps de récupération et du taux de satisfaction du médecin. Les effets indésirables respiratoires étaient définis comme suit : apnée pendant plus de 30 secondes ou saturation en oxygène inférieure à 90 %. L'hypotension était définie par une pression artérielle systolique inférieure à 90 mm Hg ou une baisse supérieure à 20 % par rapport aux valeurs initiales. La satisfaction du patient et du médecin était déterminée selon des échelles de Likert en 5 points.

Résultats : Notre étude comptait 113 patients dont l'âge moyen était de 50 ans (écart-type [ET] de 19); 62 % étaient des hommes. Les actes médicaux les plus communs étaient la manipulation orthopédique (44 %), la cardioversion (37 %) ainsi que l'incision et le drainage d'abcès (13 %). La dose moyenne totale de propofol requise était 1,6 (ET 0,9) mg/kg. Le succès procédural a été atteint dans 90 % des cas, et le temps moyen de récupération des patients était de 7,6 (ET 3,4) minutes. L'apnée n'est survenue chez aucun patient (0 %, intervalle de confiance [IC] à 95 %, 0 à 3 %). Cependant, un patient (1 %; IC à 95 %, 0 à 5 %) a vomis, ce qui a occasionné une saturation en oxygène inférieure à 90 %. Neuf patients (8 %; IC à 95 %, 4 à 15 %) ont fait de l'hypotension et sept (6 %; IC à 95 %, 3 à 12 %) ont ressenti une douleur au moment de l'injection. Tous les patients étaient très satisfaits (92 %; IC à 95 %, 85 à 96 %) ou satisfaits (8 %; IC à 95 %, 4 à 15 %), et 94 % (IC à 95 %, 88 à 98 %) ont signalé qu'ils n'avaient aucun souvenir de l'acte médical. La majorité des médecins étaient très satisfaits (85 %, IC à 95 %, 77 à 91 %) ou satisfaits (6 %, IC à 95 %, 3 à 12 %) en ce qui a trait à la sédation et aux conditions procédurales.

Conclusion : Lorsque propofol est administré selon un protocole normalisé, il semble être sécuritaire et efficace lors de sédations-analgésies procédurales en SU. Son utilisation est associée à un taux de satisfaction élevé, tant chez les patients que chez les médecins.

Introduction

A number of painful procedures that require procedural sedation and analgesia are performed in the emergency department (ED).[1] It is considered inhumane to perform such procedures without interventions to minimize pain and anxiety for patients.[1–4] Some of these procedures include cardioversion, reduction of orthopedic fractures and dislocations, and abscess incision and drainage. Pharmacologic agents are used to perform the procedure under optimal conditions of sedation, amnesia, anxiolysis and analgesia.[3]

The ideal agent for procedural sedation and analgesia in the ED should have a rapid onset of action, a duration of action sufficient for the procedure and an offset that allows rapid recovery with minimal adverse effects.[1,5] Although no perfect agent currently exists, a number of agents are in current use. For example, benzodiazepines, (midazolam) in combination with opioids (fentanyl), ketamine and, most recently, etomidate have been used for procedural sedation and analgesia in the ED.[6–13] When titrated properly, such agents can allow these short-duration procedures to be completed without difficulty. Unfortunately, these agents have been associated with adverse effects and prolonged sedation, which can result in prolonged ED stays.[12–15]

Propofol is a sedative–hypnotic frequently used in the induction and maintenance of anesthesia[16] that has recently gained increased attention for procedural sedation and analgesia in the ED in both adult and pediatric patient populations.[17–30] Propofol infusions are often used to sedate mechanically ventilated patients in the intensive care unit (ICU), and have been extensively investigated for a variety of uses in ambulatory patients, including procedural sedation during regional anesthesia, surgery and diagnostic procedures.[31–36] Its rapid onset of action and amnesic properties, coupled with smooth and rapid recovery, make propofol an appealing agent for procedural sedation and

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analgesia in the ED setting. However, adverse effects such as hypotension, respiratory depression, apnea and pain on injection have been reported.[37–39] Despite widespread use in the ED, there has been controversy regarding the use of this agent, and the optimal dosing strategy and administration approach has not been clearly established.[40–43]

The purpose of our study was to evaluate the efficacy, safety and patient satisfaction of propofol for procedural sedation and analgesia in the ED of a large tertiary care teaching hospital.

Methods

Study design

We conducted a prospective, observational study of a consecutive series of patients who received propofol for procedural sedation and analgesia over a 2-year period. The study was coordinated by the Research Division of the Vancouver General Hospital (VGH) Department of Emergency Medicine in conjunction with the Pharmaceutical Sciences Clinical Service Unit. Ethical approval was obtained from Clinical Research Ethics Board at the University of British Columbia, with waiver of explicit consent.

Study setting and population

The VGH is a 700-bed adult tertiary referral centre and the lead teaching hospital affiliated with the University of British Columbia. The ED has an annual census of approximately 62 000 visits and is staffed by physicians who are board certified in emergency medicine by the Royal College of Physicians and Surgeons of Canada.

All patients receiving propofol for procedural sedation and analgesia in the ED during a 2-year period between December 1, 2003, and November 30, 2005, were included. Propofol is stocked in a locked narcotic drawer with sign-out procedure, and its use is restricted to attending emergency physicians, allowing complete case identification. Patients who received propofol for procedural sedation and analgesia more than once during the study period were entered as discrete events.

Study protocol

Data were prospectively obtained using a standardized procedural sedation and analgesia monitoring form already in use at VGH. All procedures were performed in a room with the necessary equipment for both the procedure and emergency resuscitation. A minimum of 3 people were present at the bedside for all procedures requiring procedural sedation and analgesia, including, but not limited to

1. an attending emergency physician who was responsible for assessing and monitoring the patient, ordering all medications and, at times, performing the procedure;
2. a registered nurse who was responsible for establishing intravenous (IV) access, patient monitoring, administering medication, and completing the standard procedural sedation and analgesia monitoring form; and
3. a respiratory therapist who was responsible for monitoring the adequacy of ventilation and oxygenation throughout the procedure and for administering supplemental oxygen, if used.

An emergency medicine resident was also present during some procedures, working under the supervision of the attending emergency physician. Another specialist and a pharmacist were also present for some procedures.

Peripheral IV access was obtained in all patients and supplemental oxygen was administered at the discretion of the treating physician. Propofol was administered to all patients using a standardized protocol of 0.25–0.5 mg/kg by slow IV infusion (over 60 s), followed by 10–20 mg/minute IV until adequate sedation was achieved. Individual doses and times of propofol administration were recorded on the procedural sedation and analgesia form. Individual times were recorded to the nearest minute based on the wall clock in the procedure room. Owing to pain on injection associated with propofol, 10 mg of 1% or 2% lidocaine without epinephrine was administered by IV push 30 seconds prior to propofol administration at the discretion of the physician. The use of fentanyl was also permitted at the discretion of the treating physician.

Measures

All data were recorded using the standardized procedural sedation and analgesia monitoring form. Preprocedure assessments included demographic information, medical history, medications, American Society of Anesthesiology (ASA) physical status classification,[4] and time of last oral and solid intake. All medications and doses used were recorded throughout the procedure. Using the modified Ramsey sedation score,[44] the depth of sedation was determined at baseline, throughout the procedure and until the patient returned to baseline mental status, as per institutional protocol. All patients had continuous monitoring of heart rate, respiratory rate and oxygen saturation. A blood pressure cuff obtained measurements every 3 minutes throughout the procedure, followed by every 5 minutes for 15 minutes. Following the completion of the procedure, patients were monitored for activity, breathing, circulation and level of consciousness according to predefined parameters (Box 1). Adverse events were also evaluated until recovery.

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Outcomes

Efficacy outcomes included procedural success rate, recovery time and overall satisfaction with the procedural conditions. Recovery time was defined as the interval between the last dose of propofol and a recovery score of at least 7 (Box 1) as recorded on the procedural sedation and analgesia form. Physicians were asked by the nurse to rate their overall satisfaction with procedural conditions on a 5-point Likert scale using the terms "very satisfied," "satisfied," "neutral," "unsatisfied" and "very unsatisfied."

Safety outcomes were respiratory and hemodynamic status, pain on injection, nausea and vomiting. Respiratory compromise was defined as apnea for more than 30 seconds or an oxygen saturation of less than 90%. Hemodynamic compromise was defined as an absolute systolic blood pressure of < 90 mm Hg or decrease from baseline of > 20%. Major complications were predefined to be aspiration, bag-valve-mask ventilation, intubation, blood pressure or heart rate interventions, unplanned hospital admission and death.

Patient satisfaction was determined after the patient had returned to baseline mental status. Patients were questioned by the nurse about recall ("Do you remember the procedure?") and asked to rate their overall satisfaction on a 5-point Likert scale using the same terms as above.

Data analysis

All data were entered into an Excel spreadsheet for analysis (Microsoft Corp, Redmond, Wash.). Categorical data are presented as proportions with 95% confidence intervals (CIs) (Stata, Version 5.0, Stata Corp., College Station, Tex.). Continuous data are presented as means with standard deviations (SDs).

Box 1. Recovery criteria (total score ≥ 7 before discharge)

Activity
- 0 = unable to lift head or extremities voluntarily or on command
- 1 = lifts head spontaneously and moves extremities voluntarily or on command
- 2 = able to ambulate without assistance

Breathing
- 0 = apnea
- 1 = dyspnea or shallow, irregular breathing
- 2 = able to breathe deeply and cough on command

Circulation
- 0 = systolic blood pressure < 80 mm Hg
- 1 = systolic blood pressure < 100 mm Hg
- 2 = systolic blood pressure within normal limits for patient

Consciousness
- 0 = not responding or responding only to painful stimuli
- 1 = responds to verbal stimuli but readily falls asleep
- 2 = awake, alert and oriented × 3

Results

A total of 113 patients received propofol for procedural sedation and analgesia during the study (Table 1). The mean age of subjects was 50 (SD 19) years, and 62% were male. The most common procedures performed were orthopedic manipulations for fractures or dislocations (44%), cardioversion (37%), and abscess incision and drainage (13%). Baseline systolic blood pressure and diastolic blood pressure were 128 (SD 23) mm Hg and 74 (SD 14) mm Hg, respectively. The mean heart rate was 96 (SD 34) beats/minute .

The mean propofol dose was 113 (SD 62) mg (1.6 mg/kg, SD 0.9 mg/kg). Lidocaine was frequently administered prior to propofol, but fentanyl was not (Table 2). Mean times to achieve adequate sedation, mean procedure duration and mean recovery time were 5.8 (SD 3.6) minutes, 1.8 (SD 2.4) minutes and 7.6 (SD 3.4) minutes, respectively. Overall, 102 (90%) procedures were successfully completed. The following procedures were not successfully completed: hip reduction (4), cardioversion (3), elbow reduction (2), shoulder reduction (1) and incarcerated hernia reduction (1).

Table 1. Patient characteristics, *n* = 113

Characteristic	No. (and %) of characteristics*	95% confidence interval
Mean age (and SD), yr	50.2 (18.8)	NA
Mean weight (and SD), kg	71.8 (14.7)	NA
Sex		
Female	43 (38.1)	29.1%–47.7%
Male	70 (61.9)	52.3%–70.9%
ASA class		
I	81 (71.7)	62.4%–79%
II	31 (27.4)	19.5%–36.6%
III	1 (0.9)	0.2%–4.8%
Procedure		
Orthopedic manipulation	50 (44.2)	34.9%–53.9%
Cardioversion	42 (37.2)	28.3%–46.8%
Abscess incision and drainage	15 (13.3)	7.6%–21.0%
Chest tube insertion	3 (2.7)	0.6%–7.6%
Incarcerated hernia	1 (0.9)	0.2%–4.8%
Foreign body removal	1 (0.9)	0.2%–4.8%
Sutures	1 (0.9)	0.2%–4.8%

SD = standard deviation; NA = not applicable; ASA = American Society of Anesthesiologists.
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No patient (0%, 95% CI 0%–3%) experienced apnea for more than 30 seconds; however, 1 patient (1%, 95% CI 0%–5%) breathing room air experienced oxygen desaturation < 90% during emesis and recovered after supplemental oxygen administration. Nine patients (8%, 95% CI 4%–15%) had an episode of clinically insignificant hypotension that required no intervention. The mean blood pressure change from baseline, compared with the lowest measured blood pressure during the procedure, was systolic blood pressure 117 (SD 20) mm Hg (Δ –12, SD 14 mm Hg) and diastolic blood pressure 66 (SD 13) mm Hg (Δ –8, SD 14 mm Hg). Seven patients (6%, 95% CI 3%–12%) experienced pain on injection. No patients experienced a major complication.

In 94% (95% CI 88%–98%) of the patients there was no recall of the procedure. All patients were very satisfied or satisfied with their procedure, and physician satisfaction was also very high (Table 3).

Discussion

This study demonstrates that a standardized protocol for procedural sedation and analgesia with propofol in the ED provides safe and effective conditions with high patient and physician satisfaction.

The pharmacologic profile of propofol offers many advantages for ED procedural sedation and analgesia. Its onset of action is rapid and predictable, and its duration of action is short, allowing patients to return to baseline level of consciousness within 5–15 minutes, possibly facilitating earlier discharge from the ED. Adverse effects such as hypotension, respiratory depression, apnea and pain on injection can complicate the administration of propofol.[37–39] The hemodynamic effects are related to dose and speed of administration. A higher incidence of hypotension has also been associated with advanced age, female sex, poor physical status and concomitant use of opioids or benzodiazepines.[37] Respiratory depression and apnea also appear to be dependent on dose and rate of propofol administration.[31–37]

The use of propofol for procedural sedation and analgesia in the ED is controversial.[40–43] Proponents argue that with proper titration and monitoring propofol facilitates safe and effective procedural sedation and analgesia when administered by a trained emergency physician. Critics point to a scarcity of evidence in the ED setting. In recent years, a number of ED-based studies have reported the safety and efficacy of propofol.[24–30,45,46] These studies have demonstrated that proper patient selection and drug titration can minimize the incidence of hemodynamic and respiratory complications. Our study confirms these findings in that our relatively conservative administration protocol resulted in no cases of apnea, 1 case of hypoxia with emesis and 9 cases of clinically insignificant reductions in blood pressure.

Several reasons may explain the low complication rate in our study, compared with others evaluating propofol for procedural sedation and analgesia, despite the total administered dose of 1.6 mg/kg being similar to previous studies. First, the administration protocol recommends careful titration of propofol to the desired effect, minimizing the possibility of oversedation and subsequent respiratory compromise. The initial 0.25–0.5 mg/kg dose is recommended to be administered over 60 seconds, and subsequent doses dispensed at 10–20 mg/minute. Bolus administration of propofol has been associated with hemodynamic and respiratory compromise.[31–37] Second, the initial dose of propofol in our study was lower than in previous reports, which typically used 1 mg/kg. While our propofol titration may require longer to achieve the desired level of sedation, we feel it also reduces the likelihood of

Table 2. Medications used during the procedure, *n* = 113

Drug	No. (and %) of patients	Mean (and SD) dose, mg
Propofol	113 (100.0)	113 (62.0)
Lidocaine	88 (77.9)	10.6 (4.0)
Fentanyl	19 (16.8)	0.11 (0.06)

SD = standard deviation.

Table 3. Patient and physician satisfaction with procedure, *n* = 113

Level of satisfaction	No. (and %) of patients	95% confidence interval	No. (and %) of physicians	95% confidence interval
Very satisfied	104 (92.0)	85.4%–96.3%	96 (85.0)	77.0%–90.1%
Satisfied	9 (8.0)	3.7%–14.6%	7 (6.2)	2.5%–12.4%
Neutral	0 (0.0)	NA	4 (3.5)	1.0%–8.8%
Unsatisfied	0 (0.0)	NA	5 (4.4)	1.5%–10.0%
Very unsatisfied	0 (0.0)	NA	1 (0.9)	0.2%–4.8%

NA = not applicable.

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oversedation, especially in patients who do not require 1 mg/kg of propofol (which was the case for 18% of our study population). Third, only 1 in 6 of our patients received fentanyl, an agent associated with increased respiratory and cardiovascular complications when administered concurrently with propofol. Despite the fact that a majority of patients did not receive any supplemental analgesic, only 6.2% of patients experienced procedural recall, confirming the potent amnestic effect of propofol. In addition, the high rate of patient satisfaction achieved in our study also argues that concomitant analgesia with opioids may not be necessary when propofol is used. Fourth, most patients (82%) received supplemental oxygen administration during the procedure. The administration of supplemental oxygen may have masked transient respiratory depression in some cases or have allowed some patients to tolerate respiratory depression for several minutes. The use of oxygen during such procedures is controversial and our protocol left this decision to the discretion of the physician. Finally, careful patient population selection also likely contributed to our low complication rate. In our institution, this selection is at the discretion of the attending emergency physician. We believe that both careful dosing titration and patient selection are critical to minimize the risk of hemodynamic compromise and periods of prolonged apnea when using propofol for procedural sedation and analgesia.

Limitations

Our study had some limitations that should be considered in the interpretation of our results. First, the noncomparative nature of this study precludes any conclusion regarding the relative efficacy and safety of propofol compared with other commonly used agents. Second, our relatively small sample size may have precluded the detection of rare adverse effects. Third, although our lack of mandated opioid use may have contributed to a lower complication rate, we recognize that oligoanalgesia may be a problem and we acknowledge that some underadministration of analgesia may have occurred. Like virtually all studies in this area, we only followed patients until their discharge from the ED; thus, we could not evaluate the issue of hyperalgesia on the day following the procedure.[47] However, since most of the procedures we performed were not typically associated with significant postprocedural pain, we suspect that hyperalgesia is minimally, if at all, relevant to most of the patients we studied. Finally, we did not evaluate the interrater reliability of our tool to evaluate patient and physician satisfaction.

Conclusion

Using a standardized administration protocol in a setting such as we describe, propofol appears to be a safe and effective agent for performing procedural sedation and analgesia in the ED, and it is associated with high patient and physician satisfaction.

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Correspondence to: Dr. P.J. Zed, Queen Elizabeth II Health Sciences Centre, Department of Pharmacy – Halifax Infirmary, Rm. 2417, 1796 Summer St., Halifax NS B3H 3A7; peter.zed@dal.ca