ORIGINAL ARTICLE

Electronically monitored single-use patient-controlled analgesia pumps in postoperative pain control

Michael Zimmermann, MD
Karin Friedrich, MD
Rolf Kirchner, MD

ABSTRACT

The present study was performed to establish whether analgesic consumption in the first four postoperative hours is a suitable basis for selecting the demand dose and predicting the likely analgesic requirement over the next 20 hours with single-use patient-controlled analgesia (PCA) pumps, and to establish whether this method provides effective pain control.

Forty-two patients who had undergone a laparotic gynecological procedure (hysterectomy) were given an electronic PCA pump (Abbott Lifecare, Abbott Laboratories, Abbott Park, IL) for four hours (phase I) with a demand dose of 1 mg piritramide and a lockout period of five minutes for dose titration. Piritramide's potency is comparable with that of morphine. The patients then received single-use PCA pumps (Baxter Infusor/Watch, Baxter, Deerfield, IL) for the next 20 hours (phase II) with a demand dose of 0.75 mg in Group A and 1.5 mg in Group B, depending on whether more or less than 10 mg pritramide had been consumed in phase I. A specially designed electronic recorder was used to measure the exact amount consumed and number of demands. Patients experiencing pain were free to receive additional piritramide at any time as rescue medication; however, these patients were withdrawn from the study.

Ninety percent of the patients in group A said they were satisfied with or undecided as to the level of analgesia. The corresponding figure in group B was 95 percent. Piritramide consumption was significantly higher in group B than in group A. There were no significant differences between the groups regarding demographic data or duration of surgery, nor did either of these two parameters affect postoperative piritramide consumption. Significant alleviation of pain and improvement in visual analog scale scores from phase I [group A, 4.7 (range, 2.0 to 6.8); group B, 4.6 (range, 3.0 to 8.3)] to phase II [group A, 3.1 (range, 0.4 to 5.2); group B, 3.2 (range, 0.4 to 6.0)] was achieved in both groups. A significant difference in analgesic consumption up to 18 hours postoperatively was seen after dose titration. In the first four hours, the rate of successful demands was significantly higher in group A (80.9 percent) than in group B (40.9 percent). The number of successful demands was comparable in the two groups during phase II (A, 98.8 percent; B, 94.5 percent).

In summary, total opioid consumption during the first four hours after operation showed two groups of patients with significantly different needs for piritramide (< 10 mg per 4 hours or > 10 mg per 4 hours). Two different dose regimes were applied using a high and a low bolus size in the following 20 hours. We concluded that effective pain control without respiratory depression was achieved with single-use PCA pumps. Opioid consumption varied significantly, whereas pain levels did not.

Key words: postoperative analgesia, patient-controlled analgesia, single-use, demand-dose, acute analgesia

INTRODUCTION

Patient-controlled analgesia (PCA) is a highly effective means of providing postoperative pain management.[1] Patients can control their own individual analgesic requirements, thus enhancing user acceptance and satisfaction.[2,3] With proper monitoring, the method is also a safe means of handling strong opioids.[1,4-6] Routine use of electronically controlled PCA pumps is limited by the expense and technical problems involved,[7] and also a lack of available pumps. The need for improved postoperative pain management is amply documented in a number of national and international studies.[8-15] Mechanically operated single-use PCA pumps without electronic recording and control therefore constitute a rational alternative.[16,17] Because of their construction, the demand dose can only be adjusted with systems of this type when filling the pumps, and the lockout period is fixed at a set level. Also, because the demand dose is essential to successful PCA[18-20] and the postoperative analgesic requirement may vary greatly,[2] the present study was performed

to establish whether the postoperative analgesic requirement during the first four hours after surgery established using an electronic PCA pump accurately predicts the analgesic requirement during the subsequent 20 hours and can be used as a basis for setting the demand dose. Another objective of the study was to establish whether single-use PCA pumps provide effective analgesia with no added risk of respiratory depression.

METHODS

A total of 42 American Society of Anesthesiologists class I/II female patients undergoing abdominal hysterectomy were included in the study. Ethics committee approval from our institutional review board was obtained beforehand and written informed consent was obtained from all patients. Patients displaying opioid intolerance, suspected alcohol or drug dependency, analgesic abuse, or inability to understand the method were excluded from participation. All patients were instructed in the method on the day before surgery. The participants were taught how to operate both PCA pumps and when to administer a dose. A demonstration was also shown. The night before surgery, patients received oral premedication with diazepam of 5 to 10 mg. Midazolam 7.5 mg p.o. was administered on the day of surgery before transport to the operating room. General anesthesia was inducted by intravenous injection of pancuronium (1 mg), fentanyl (3 to 5 µg per kg), thiopental (3 to 5 mg per kg), and succinylcholine (1 mg per kg). The patients were intubated and ventilated with 0.5 to 1.5 vol% enflurane or isoflurane and O_2/air (FiO_2 = 0.35). After the surgical procedure, patients were wheeled to the recovery room and connected to an electronic PCA pump (Abbott Lifecare, Abbott Laboratories, Abbott Park, IL) containing pritramide (1 mg per mL, demand dose 1 mg, lockout period 5 min, maximum dose in 4 h = 30 mg). Pharmacological data on piritramide are comparable to those of morphine; its potency is 0.7 of that of morphine. The pharmacological duration of action is six hours. In our study, piritramide consumption was recorded over the four-hour period. According to the findings of Lehmann,[21] the average accumulated piritramide dose within four hours was 8.52 mg in postoperative pain with on-demand pumps. In relation to the type of operation, and to have objectives, we had to fix a certain quantity of opioid consumption from which patients received a low or high demand dose. Patients were allocated to one of two groups on the basis of piritramide consumption over the first four postoperative hours (< 10 mg or > 10 mg) and the demand dose for the subsequent 20-hour period delivered via the single-use PCA pump (0.75 mg or 1.5 mg per demand dose) was set based on these data. The only way that opioid consumption can be altered in single-use PCA pumps is to change the demand dose by the concentration of the administered opioid. Patients who had a higher opioid consumption in phase I were expected to continue this demand in phase II. Patients who had lower opioid requirements in phase I were also expected to have similar demands in phase II.

Group A received piritramide 0.75 mg per demand dose; group B received piritramide 1.5 mg per demand dose. The severity of pain was documented every four hours on the basis of a visual analog scale (VAS, range 0 to 10). A short infusion of piritramide 15 mg as rescue medication was available at any time to patients requiring additional pain relief, who were then withdrawn from the study. The single-use PCA pumps for phase II were from the Baxter Infusor/Watch line (Baxter, Deerfield, IL). The system was filled with piritramide 30 mg in 20 mL of 0.9 percent saline (group A) or with piritramide 45 mg in 15 mL of 0.9 percent NaCl (group B). The pumps were used without a basal infusion, in compliance with the recommendations in the literature on preventing risks and side effects of PCA therapy.[3,22-28] The Baxter systems have a default lockout period of six minutes. The fixed demand dose was set at 0.5 mL. The frequencies and times of demands and doses during the 20-hour observation period were documented on a dedicated electronic recorder; this allowed us to determine each patient's exact piritramide consumption. The patients were monitored continuously during the first four hours in the recovery room and the subsequent 20 hours in the postoperative intermediate care unit (electrocardiogram, blood pressure, pulse oximetry). SaO_2 levels were recorded every two hours. Patients exhibiting oxygen saturation below 95 percent on pulse oximetry were administered oxygen at a rate of 3 L per hour through a nasal tube. The number of such episodes and saturation levels below 90 percent were recorded. Other safety parameters according to the study protocol were spontaneous reports of nausea and episodes of vomiting. The patients were asked to rank the severity of their pain at intervals of no greater than four hours on the basis of the VAS used.

Patient demographics, duration of surgical procedure, and postoperative piritramide consumption were described as means with standard deviations and compared statistically with the U test. Incidences were compared by Chi-square analysis. The data concerning piritramide consumption were compared between the two groups (A/B) and among the two phases (I/II) with the Wilcoxon test. Also used were nonparametric tests for unpaired probes (comparison of groups) with the Wilcoxon test and paired probes (comparison of phases) with the Wilcoxon test. Continuous quantitative parameters were investigated by a correlation coefficient. A t-test was used to show any deviation from 0 of the correlation coefficient. The level of significance was $p < 0.05$.

Table 1. Piritramide use, patient satisfaction, reported side effects, and oxygen saturation			
	Group A (n = 20)	**Group B (n = 20)**	**Statistics**
Piritramide (mg in first four hours postoperative)	6.5 ± 2.6	13.6 ± 2.9	$p < 0.05$
Piritramide (mg in subsequent 20 hours)	16.5 ± 8.9	25.2 ± 14.3	$p < 0.05$
Patient evaluation of treatment effectiveness (percent)			
Satisfied	16 (80)	17 (85)	ns
Undecided	2 (10)	2 (10)	ns
Dissatisfied	2 (10)	1 (5)	ns
Patient side effects			
Nausea	8	3	$p < 0.05$
Vomiting	0	1	ns
Pulse oximetry (first four hours postoperative)			
$SaO_2 < 95$ percent	12	17	ns
$SaO_2 < 90$ percent	0	0	ns
Pulse oximetry (subsequent 20 hours)			
$SaO_2 < 95$ percent	1	2	ns
$SaO_2 < 90$ percent	0	0	ns
Statistics on piritramide use from U1-test and on incidences from Chi-square test; ns, not significant.			

RESULTS

The results of 40 of the original 42 patients were assessable. In one patient's case, the nursing staff threw away the counting module by mistake; in another case, the nurse forgot to open the three-way valve on the indwelling cannula after changing the drip at night. The latter patient required piritramide infusion for pain and was withdrawn from the study. The remaining 40 patients were allocated according to the stated criteria into two groups, depending on whether their piritramide consumption in phase I was more or less than 10 mg (demand dose: group A, 0.75 mg; group B, 1.5 mg). After the first four hours, it was possible to distinguish one group of patients with an average opioid consumption of piritramide of 6.5 ± 2.6 mg and another with a significantly higher consumption of 13.6 ± 2.9 mg (Table 1). There were 20 patients in either group. The two groups did not differ in demographics or duration of surgical procedure (Table 2).

Over the next 20 hours, cumulative consumption was significantly lower in group A (16.5 ± 8.9 mg) than group B (25.2 ± 14.3 mg) ($p < 0.05$). Figure 1 shows the exact time curve of piritramide demand. It can be seen that the difference between the two groups was significant only up to 18 hours postoperatively. No difference at all was discernible after 20 hours. The number of successful dose demands was twice as high in group A (80.9 percent) than in group B (40.9 percent) during phase I. There was no difference between the two groups in terms of the number of successful demands during the subsequent 20 hours (group A, 98.8 percent; group B, 94.5 percent). Significant alleviation of pain from phase I to phase II was achieved in both groups, with VAS in group A of 4.7 (range, 2.0 to 6.8) and 3.1 (range, 0.4 to 5.2) and in group B of 4.6 (range, 3.0 to 8.3) and 3.2 (range, 0.4 to 6.0) in the two phases, respectively.

Figure 2 shows that the patients in both groups were similar regarding severity of pain. There were no significant differences at any time. Only two patients in group A and one patient in group B were unsatisfied with the analgesic regimen. Eighty percent of patients in group A and 85 percent in group B said pain relief had been good (Table 1). Thus, the two groups did not differ significantly in this respect.

Table 1 also shows the observed side effects. The incidence of nausea differed significantly ($p < 0.05$) between

Table 2. Demographic data of patients and anesthesia			
	Group A (n = 20)	**Group B (n = 20)**	**Statistics**
Age (yr)	48.0 ± 8.0	48.0 ± 9.4	ns
Weight (kg)	66.0 ± 12.2	65.0 ± 12.9	ns
Operation duration (min)	133.0 ± 61.0	138.0 ± 59.0	ns
ns, not significant.			

group A (eight patients) and group B (three patients). Vomiting was seen in only one patient (group B). Decline in oxygen saturation measured by pulse oximetry to levels below 95 percent in the first four hours was seen in 12 patients in group A and 17 in group B. In the subsequent 20 hours, oxygen saturation measured below 95 percent was seen in only one patient in group A and two in group B. Saturation levels below 90 percent were not observed in any patient.

DISCUSSION

We found a significant correlation between analgesic consumption in the first four hours after laparotomy and consumption over the subsequent 20-hour period. Single-use PCA systems may represent an alternative to purchasing expensive electronically controlled PCA pumps. The only adjustable variable with single-use PCA pumps is the demand dose. The demand dose appears to be of greater significance for pain relief than adjustment of the lockout period.[2]

Because of their construction, currently available single-use PCA systems allow the demand dose to be set only when filling the pump. However, because the analgesic consumption in the initial postoperative phase may vary greatly,[2] we used an electronic PCA pump in this study to determine the precise individual analgesic requirement and use this as a basis for setting the demand dose for subsequent pain control with the single-use PCA system.

Sources in the literature[19] recommend use of the opioid amount needed in the recovery room as a basis for determining the following day's analgesic requirement for adjustment of conventional postoperative analgesia. On the basis of our own studies on postoperative opioid requirements, we decided on a study design with piritramide use in the first four postoperative hours as a cutoff point for allocating patients to one of two groups (low/high analgesic requirements).

Analysis of time curves showed that differences in dosing behavior persisted up to 18 hours after surgery. The results support the observations of other authors[18,29,30] who propose further graduations in the demand dose in the quest for optimum PCA therapy. Previous studies using single-use PCA pumps mention a single uniform level of 1 mg morphine per demand dose.[31,32] Limitation of demand dose and lockout period to a single standard level for all patients regardless of the type of surgery, gender, and body weight greatly limits the therapeutic potential of PCA pumps, thereby reducing the effectiveness of PCA therapy.

Our study results also corroborate those of other authors[18,19,30] in identifying considerable interindividual variation in analgesic requirements, which can best be addressed by providing individually adjusted demand doses. The specially designed recorder used in this study enabled us to determine the exact dosage behavior of patients using single-use PCA pumps after dose titration. The results showed a large percentage of successful demands by patients in group A (80.9 percent) on the basis of the uniform demand dose of piritramide 1 mg during the first four hours. However, demand failure was much higher in group B, with only 40.9 percent successful demands. During phase II, with different demand dose levels (group A, 0.75 mg; group B, 1.5 mg), there was no longer any difference between the groups regarding the rate of successful demands (98.8 percent and 94 percent, respectively).

Unlike the analysis of dosing behavior, evaluation of severity of pain by VAS disclosed no significant difference between the two groups. Use of the PCA pumps according to the stated regimen brought about continuous pain relief over a 24-hour period in both groups, while piritramide consumption was significantly higher in group B (1.5 mg demand dose) than in group A up to the 18th postoperative hour. Patient assessment of the effectiveness of pain control showed that only two patients in group A and one in group B were dissatisfied with the chosen procedure, showing that 90 percent and 95 percent of patients in each group, respectively, were satisfied with the method or were undecided.

Nausea was reported by eight patients in group A (low

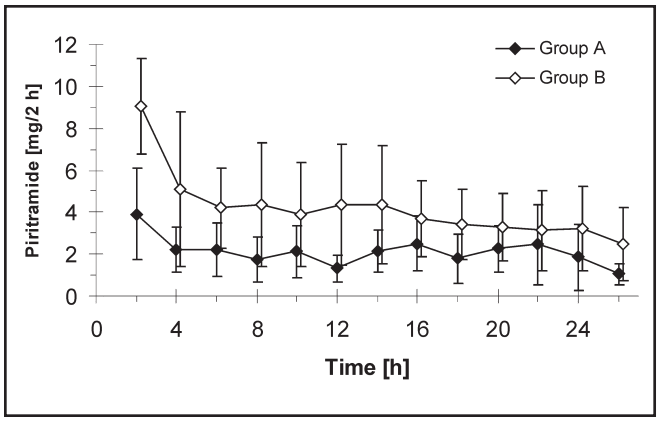

Figure 1: Piritramide consumption (average ± standard deviation) was significantly higher in group B than in group A up to the 18th postoperative hour.

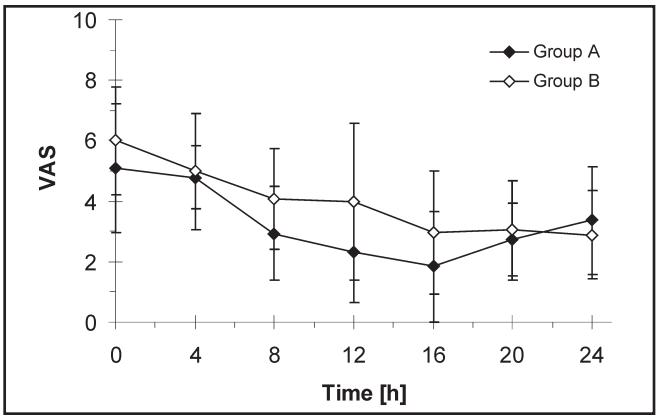

Figure 2: The level of change in the visual analog scale pain scores (VAS, range 0 to 10, average ± standard deviation) was the same in both groups.

demand dose) and three patients in group B. This contrasts with earlier studies in which nausea was more usually associated with higher opioid doses.[1] This observation may be attributable to slightly higher vigilance in the lower-demand dose group; our hypothesis is that the smaller amount of opioid consumption by this group causes lower blood levels of the medication, resulting in the higher vigilance. Interestingly, nausea and vomiting have the same incidence in morphine and piritramide treatment.[33]

One very important aspect in assessing the safety of an analgesic procedure using opioids is the potential to cause respiratory depression. Therefore, all the patients in this study were monitored by pulse oximetry throughout the entire period of observation. Oxygen saturation below 95 percent was seen during the first four hours in 12 patients from group A and 17 from group B. These patients were administered oxygen through a nasal tube. During phase II, oxygen saturation levels below 95 percent were seen in only one patient in group A and two in group B. There were no cases of oxygen saturation below 90 percent. The method thus appears to be safe under the conditions described here.

The results of our study confirm the hypothesis that use of an electronic PCA pump in the first four hours after laparotomy provides a suitable basis for predicting the analgesic requirement during the subsequent 20 hours and can be used to set a fixed demand dose to be administered by single-use PCA pumps. Dose titration can also be performed by manual means in clinical practice (e.g., in the recovery room).[34] Single-use PCA systems provided effective and safe postoperative analgesia in our study. Thirty-one to 75 percent of patients receiving standard analgesia on general wards report severe postoperative pain.[9] The postoperative pain control method presented here seems more effective than the previously described standard ward procedures. Direct costs are higher with the PCA, however, in contrast to standard intramuscular injections.[35]

Titration of the individual opioid requirement enabled us to identify and provide optimum postoperative care for two patient groups with significantly different postoperative piritramide consumption. The patients in both groups were able to steadily reduce their pain with the selected fixed demand dose. None of the patients with a PCA pump required rescue medication. Single-use pumps are not equipped with any kind of alarm function; therefore, dose titration is important to give patients a safe bolus size of opioids. Respiratory depression did not occur in any patient on either regimen during the study.

Single-use PCA pumps are small pumps requiring no main electricity supply or maintenance, which we tested for suitability in a postoperative setting. The pumps are user friendly, with little potential for error in administration. We divided the patients in our study into low- and high-analgesia groups based on prior dose titration and set them up with single-use PCA pumps, which were primed to provide demand doses of piritramide 0.75 mg or 1.5 mg according to group. In this study, we used a dedicated electronic recorder, which gave us important information on the use of those pumps in the postoperative period. Our data indicate that effective 24-hour pain relief was achieved in both patient groups. Based on this, we believe that single-use PCA pumps are suitable for use in conjunction with or as an alternative to electronic pumps and, as such, represent a useful addition to the postoperative pain control armamentarium.

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Michael Zimmermann, MD, Department of Anaesthesiology, Intensive Care, and Pain, Johann-Wolfgang-Goethe University, Frankfurt/Main, Germany.
Karin Friedrich, MD, Department of Anaesthesiology, Intensive Care, and Pain, Johann-Wolfgang-Goethe University, Frankfurt/Main, Germany.
Rolf Kirchner, MD, Department of Anaesthesiology, Intensive Care, and Pain, Johann-Wolfgang-Goethe University, Frankfurt/Main, Germany.

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