Comparison of lornoxicam with tramadol in patient-controlled analgesia after gynecological surgery

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Summary

Background: The aim of this study was to compare the effects of lornoxicam and tramadol in patient-controlled analgesia (PCA) after gynecological surgery.

Methods: Forty-four patients were randomly allocated to one of two groups after elective gynecological surgery. Patients in group I (n = 22) received IV tramadol, and group II patients (n = 2) received IV lornoxicam with a PCA pump. A visual analogue scale (VAS) (0 = no pain, 10 = worst pain), hemodynamic parameters and side-effects were assessed before starting the infusion (baseline), at the 15th and 30th min, 1st, 2nd, 3rd, 4th, 6th, 8th, 12th, 18th, 24th, 36th and 48th hour thereafter, and results were compared.

Results: Adequate analgesia was achieved in both groups. VAS values in the tramadol group were lower than those of lornoxiacam at the 15th and 30th minute, 1st, 2nd, 4th, 6th, 8th and 12th hour measurements ($p < 0.05$). Eight patients (36.3%) in group I and six patients (27.2%) in group II suffered from nausea ($p > 0.05$).

Conclusions: Tramadol and lornoxicam may be used for pain control after gynecological surgery via PCA. However, we conclude that tramadol has better analgesic efficacy than lornoxicam during the first 12 hours postoperatively.

Key words: Postoperative analgesia; Patient-controlled analgesia; Tramadol; Lornoxicam.

Introduction

Treating pain after surgery is important for both patient comfort and to minimize complications [1]. Although many clinicians are aware of this fact, pain after surgery continues to be a problem, and many patients continue to experience distressing pain postoperatively [2]. There have been many investigations addressing different drugs and methods to achieve the best analgesia. However, there is no one consensus on the best drug regimen to be used for pain control after surgery.

Patient-controlled analgesia (PCA) is an effective analgesic method, and is used widely all over the world to control pain after surgery [3]. Opioids still remain the mainstay of postoperative pain management after major surgical procedures. Being a synthetic opioid agonist, tramadol has been used widely in PCA for pain relief after surgery [4-6]. Non-steroidal anti-inflammatory drugs (NSAIDs) may also be used as analgesic in postoperative pain control to reduce the side-effects of opioids [7]. Lornoxicam, a new NSAID, has been shown to be as effective as morphine and meperidine after surgery in some studies [8-11]. The aim of this study was to investigate and compare the effects of lornoxicam with that of tramadol using PCA for postoperative pain control after gynecological surgery.

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Methods

Following institutional ethics committee approval and with informed patient consent, 44 ASA (American Society of Anesthesiologists) physical status I and II patients undergoing gynecological surgery were included in the study. Patients were randomly assigned to have either tramadol (Group I) or lornoxicam (Group II) postoperatively through a PCA device. Patients were instructed how to use a Baxter PCA pump prior to surgery, and were informed about the measurements to be done postoperatively together with a visual analogue scale (VAS). Patients with any contraindication to regional anesthesia, with a history of allergies, and those unable to understand the use of PCA were not included in the study.

Patients were not premedicated. Anesthesia was induced with fentanyl (1 μg kg^{-1}) and propofol (1-2 mg kg^{-1}), and maintained with isoflurane 0.6-1.5% in a mixture of nitrous oxide 65% and oxygen 35%. Neuromuscular blockade was achieved by vecuronium bromide (0.1 mg kg^{-1}, IV) and maintained by bolus administration (0.03 mg kg^{-1}) at 30 min intervals. At the end of surgery, patients were extubated after antagonism of residual neuromuscular block with neostigmine (0.06 mg kg^{-1}) and atropine (0.02 mg kg^{-1}). No opioids were administered during the last 30 minutes of the operation.

Patient-controlled analgesia was provided to all patients with a standard PCA pump (Baxter AP-2, Round Lake, IL, USA) when the patients complained of pain after extubation. Analgesic solutions were prepared as 100 ml saline solutions in all groups in a double-blind fashion by one of the authors (H.K.) not taking further part in data collection. The solution contained 5 mg ml^{-1} tramadol (Contramal, Grunenthal, Germany) in group I and 0.8 mg ml^{-1} lornoxicam (Xefo, Abdi Ibrahim, Istanbul) in group II. Patients in group I received intravenous tramadol with a continuous infusion rate of 5 mg hr^{-1} after a bolus dose of 20 mg. The loading dose was 20 mg and the lock out time was 20 minutes. Group II patients received intravenous lornoxicam

with the continuous infusion rate of 0.8 mg hr^{-1} after a 3.2 mg of bolus dose. The loading dose was 3.2 mg and the lock out time was 20 minutes in this group.

Pain relief was evaluated using VAS (0 = no pain, 10 = worst pain) just before starting the PCA (baseline), and at the 15th min, 30th min, 1st hour, 2nd hour, 3rd hour, 4th hour, 6th hour, 8th hour, 12th hour, 18th hour, 24th hour, 36th and 48th hour thereafter, together with the sedation score, noninvasive arterial blood pressure, heart rate, respiratory rate, and peripheral oxygen saturation. Untoward effects such as hypotension (blood pressure < 90 mmHg), bradycardia (heart rate < 45 bpm), heart burn, headache, nausea and vomiting, urinary retention or incontinence, pruritis, and bleeding were noted when they appeared. The degree of sedation was measured by using a five-point scale (0 = awake and alert, 1 = weak sedation, tendency to sleep, 2 = mild sedation, easy to wake up when spoken to, 3 = moderately sedated, easy to wake up when slightly shaken, and 4 = deeply sedated and difficult to wake up when shaken). Meperidine (1 $mg.kg^{-1}$, IM) was given for additional analgesia in the case of inadequate pain relief.

Statistical analysis was performed using the statistical package for social sciences (SPSS, Chicago, IL, USA) for windows (version 9.0). The Wilcoxon test was used for data analysis within groups. The Mann-Whitney U test was used to compare the results between groups. A p value of < 0.05 was considered to be statistically significant. Results are presented as mean (SD) or median (range).

Results

Characteristics of patients were similar in both groups (Table 1) as were the baseline VAS values ($p > 0.05$). Adequate analgesia was achieved in both groups within 15 minutes of application in the tramadol group and within 30 minutes in the lornoxicam group, and continued for 48 hours. The VAS values were highest at the first measurement (baseline), and lowest at the 48th hour measurement in both groups. The analgesia achieved with tramadol was higher than that of lornoxiacam which was statistically significant at the 15th min, 30th min, 1st hour, 2nd hour, 4th hour, 6th hour, 8th hour, and 12th hour measurements ($p < 0.05$). Patients were found to be moderately sedated at baseline measurements in both groups, and the baseline sedation levels were not different between groups. Sedation was decreased through the end of the study, and the decrease was faster in the tramadol group. Patients in the lornoxicam group were found to be more sedated at the 1st, 2nd, and 4th hour measurements ($p < 0.05$) (Table 2).

There were no significant differences within and between groups in hemodynamic changes. Hypotension and bradycardia were not seen in any group. Eight patients (36.3%) in group I and six patients (27.2%) in group II suffered from nausea, and were treated with metoclopromide ($p > 0.05$). None of the patients vomited. No patient developed respiratory complications and SpO_2 did not decrease below 90% in any patient. We did not observe any other complications in any patient.

Table 1. — *Demographic data of the patients (mean ± SD).*

	Tramadol Group (n = 22)	Lornoxicam Group (n = 22)
Age (year)	52.3 ± 3.7	52.6 ± 4.4
Weight (kg)	62.4 ± 11.3	65.7 ± 10.2
Height (cm)	162.1 ± 4.36	161.3 ± 5.43

Table 2. — *Visual analogue scale and sedation scores of patients in both groups (mean ± SD).*

	Tramadol Group (n = 22)		Lornoxicam Group (n = 22)	
	VAS	Sedation	VAS	Sedation
Baseline	9.25 ± 1.01	3.68 ± 0.56	9.81 ± 0.39	3.41 ± 1.06
15th Minute	6.95 ± 1.63*	3.09 ± 0.81	8.95 ± 0.99§	3.32 ± 0.89
30th Minute	5.50 ± 1.63*	2.22 ± 0.75*	7.68 ± 0.64*§	2.77 ± 0.93*
1st hour	3.70 ± 1.86*	1.40 ± 0.79*	6.68 ± 0.99*§	1.95 ± 0.85*§
2nd hour	2.00 ± 2.05*	0.50 ± 0.80*	5.22 ± 1.57*§	1.41 ± 0.66*§
4th hour	1.20 ± 2.04*	0.13 ± 0.46*	3.90 ± 2.09*§	0.73 ± 0.88*§
6th hour	0.70 ± 1.83*	0.09 ± 0.42*	2.54 ± 2.30*§	0.41 ± 0.79*§
8th hour	0.55 ± 1.79*	0.09 ± 0.42*	1.72 ± 2.20*§	0.32 ± 0.64*
12th hour	0.20 ± 0.52*	0.54 ± 0.21*	1.27 ± 1.95*§	0.27 ± 0.63*
18th hour	0.35 ± 0.36*	0.00*	0.90 ± 1.68*	0.14 ± 0.47*
24th hour	0.15 ± 0.30*	0.00*	0.68 ± 1.24*	0.00*
36th hour	0.14 ± 1.34*	0.00*	0.40 ± 0.85*	0.00*
48th hour	0.10 ± 0.30*	0.00*	0.18 ± 0.39*	0.00*

VAS: Visual analogue scale; *$p < 0.05$, compare to control value; § $p < 0.05$, between groups.

Discussion

The main finding of this study is that we achieved adequate analgesia with both drugs in all patients. Tramadol has been studied extensively for postoperative analgesia previously. Aygün *et al.* [12] compared tramadol with fentanyl using PCA for pain control after gynecological surgery, and reported similar efficacy for both drugs. Tramadol has been mostly compared with morphine in PCA. In a study intravenous tramadol was compared with morphine for post-thoracotomy pain control, and found to have similar effects on pain relief [13]. Pang *et al.* [14] also compared tramadol with morphine in patient-controlled analgesia after surgery, and reported similar analgesic efficacy with a higher rate of nausea in the tramadol group.

In a study lornoxicam was compared with morphine for postoperative pain control in microsurgical lumber disk operations, and found to be as effective as morphine in total pain relief [10]. We previously demonstrated that lornoxicam used intramuscularly has similar analgesic efficacy after cardiac surgery as diclofenac sodium which is a much weaker drug than morphine [15]. Ilias *et al.* [11] compared intravenous bolus doses of tramadol with lornoxicam for pain control after hysterectomy operations, and reported lornoxicam to be as effective as tramadol. To the best of our knowledge, our study is the first to compare the analgesic efficacy of lornoxicam with that of tramadol in patient-controlled analgesia, using no additional drug or technique. Here in this study we report a better analgesic efficacy achieved with tramadol during the first postoperative 12 hours than lornoxicam, and a similar rate of nausea in both groups.

NSAIDs were thought to have serious side-effects.

Griffin *et al.* [16] concluded that NSAIDs should not be used routinely in postoperative analgesia because of their side-effects. On the other hand, Hyninen *et al.* [7] suggested substituting opioids by other drugs in postoperative pain control after cardiac surgery. Tramadol also has very important adverse effects such as respiratory depression, sedation, nausea and constipation. In our study we did not observe any serious side-effects in either group. This may be due to the short duration of time in the course of the study. Nevertheless, these results show that these two drugs may be used safely in pain control after gynecological surgery.

In conclusion, both tramadol and lornoxicam can be used for pain control after gynecological surgery via PCA. Comparing these two drugs we conclude that tramadol used with a PCA device is more effective than lornoxicam during the first 12 hours postoperatively, and neither drug is superior to the other where side-effects are concerned.

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