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ORIGINAL ARTICLE

Postoperative pain management after inguinal hernia repair: lornoxicam versus tramadol

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Abstract
Background In this randomized and prospective study, we compared the analgesic effects of lornoxicam and tramadol in patients after inguinal hernia repair.
Methods A total of 160 patients were assigned in a randomized manner into two groups. Group L received 8 mg lornoxicam i.v. at the end of the operation, followed by 8 mg 12 h after the operation. Group T received 1 mg/kg tramadol at the end of the operation and every 6 h up to 24 h postoperatively. The visual analog scale (VAS) score was assessed at 0, 2, 4, 8, 12, and 24 h after surgery.
Results All patients completed the study. All vital signs were within normal ranges. The mean VAS score in Group L and in Group T was 21.66 ± 14.64 and 19.75 ± 11.82, respectively. No significant differences were found between groups with respect to VAS score. Eight (10%) patients in Group T had nausea.
Conclusion Lornoxicam 8 mg i.v. and b.i.d., tramadol 1 mg/kg at the end of the surgery and every 6 h up to 24 h after inguinal hernia repair provided rapid and effective analgesia and was well tolerated.

Keywords Lornoxicam · Tramadol · Inguinal hernia repair · Postoperative pain

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Introduction

Postoperative pain not only causes considerable distress to the patient, but it also contributes to prolonging recovery time and may adversely affect patient outcome [1]. Postoperative pain management has received increased attention in recent years because of the development of new techniques and drugs for its treatment and increased understanding of the underlying pathophysiology of acute pain [2]. Inguinal hernia repair is one of the most common and continues to be one of the most painful ambulatory surgeries, with almost half of patients suffering moderate to severe pain after inguinal hernia repair [3].

The aim of this study was to evaluate whether lornoxicam administration is associated with lower pain scores at 24 h compared to tramadol in patients for inguinal hernia repair.

Methods

We studied 160 consecutive patients for elective unilateral inguinal hernia repair in a double blind, randomized study. Approval was given by the Hospital Ethics Committee and informed written consent was obtained from all patients. The surgical techniques were open hernia repair with or without extirpation of the hernial sac. Anulorrhaphy or a tension-free herniorrhaphy (Lichtenstein) with insertion of a polypropylene mesh was used for indirect inguinal hernia. A tension-free herniorrhaphy (Lichtenstein) with insertion of a polypropylene mesh was used for a direct inguinal hernia. The Lichtenstein operation was performed as described by Amid, using 2-0 polypropylene to secure the mesh. We used a 7.5 × 15-cm polypropylene mesh that was trimmed to match the size of the inguinal floor, if necessary. After closure of the external oblique and Scarpa's fascia, the skin

was closed with a running 3-0 polyglactin. Patients were not included if they had a history of daily intake of any analgesics, known upper gastrointestinal bleeding, hyper sensitivity to lornoxicam or other nonsteroidal anti-inflammatory drugs (NSAIDs) and tramadol, any bleeding disorder, or if they were unable to cooperate. Operation for recurrent hernia was excluded, as the tissue trauma would be expected to be greater than for first repairs. The patients were not receiving any premedication and all patients were operated under general anesthesia.

At the end of the surgery, the patients were randomly allocated to one of two groups according to a computer-generated table of random numbers. The study drug was prepared and labeled by the anesthetist. One group received lornoxicam (Group L) i.v. 8 mg at the end of the surgery and at 12 h after surgery, and the other group received tramadol (Group T) i.v. 1 mg/kg at the end of the surgery and every 6 h up to 24 h postoperatively. Patients were not receiving rescue analgesia protocol. Pain intensity was assessed using a visual analog scale (VAS) (0 = no pain; 100 = most severe pain imaginable). The nurses on the ward were taught to use the VAS to determine the intensity of pain and they were blinded to the study group. Pain intensity was evaluated at 0, 2, 4, 6, 8, 12, and 24 h after surgery. The hemodynamic parameters systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR) and peripheral oxygen saturation (SpO_2), and respiratory rate (RR) were recorded before operation and 0, 2, 4, 8, 12, and 24 h postoperatively by nurses of the Pain Management Team. Patient satisfaction was assessed using a five-point numerical scale from 0 to 4 (0 = extreme discomfort to 4 = perfect) at 12 and 24 h postoperatively. Sedation was also assessed using a five-point scale, with 0 = alert and 4 = deep sleep at 0, 2, 4, 8, 12, and 24 h postoperatively. Side effects related to drugs were recorded by self-reporting and were treated as necessary.

The risk of a statistical type one or type two error was set, respectively, at $\alpha = 0.05$ and $1 - \beta = 0.80$. The effect size value was accepted at 0.55 (GPower Version 2; Franz Faul & Edgar Erdfelder). Consequently, the adequate inclusion number was determined to be 80 patients in each study group (a total of 160 patients).

The data are presented as mean values with their standard deviations. Analysis of demographic data was performed by the Chi-square test. Student's *t*-test was used to evaluate age, weight, duration of surgery, and VAS score between the two groups. *P*-values less than 0.05 were considered to be statistically significant.

Results

One hundred and sixty patients completed the study. Complete data were obtained on all patients. There were no differences between the two groups with respect to demographic variables and duration of surgery (Table 1). There were no statistically significant differences in the hemodynamic parameters SBP, DBP, HR and SpO_2, RR, patient satisfaction, and sedation with respect to the distribution of surgical procedures (direct vs. indirect hernia repair) between the two groups (Figs. 1, 2, and 3). The VAS scores were similar between the two groups at 0, 2, 4, 8, 12, and 24 h after surgery (Fig. 4). None of the patients in either group suffered allergic reactions. In Group T, eight (10%) patients complained of nausea. This was treated with antiemetics and they completed the study as normal. The mean 24-h consumption of tramadol was 281.94 ± 33.44 (240–400) mg and for lornoxicam it was 16 mg. Postoperative bleeding at the surgical site was not seen in any patient. Postoperative pain after inguinal hernia repair was treated successfully. According to the patients, the global evaluation between the two groups was not different at 12 and 24 h after surgery.

Discussion

The provision of adequate postoperative pain treatment is not only important from a humanitarian perspective, but it has also been shown to improve postoperative recovery and

Table 1 Demographic characteristics and surgical data of patients

Variable	Group T	Group L	*P*-value
Age (years)	25.60 ± 11.20	23.91 ± 9.08	0.495
Weight (kg)	70.34 ± 8.34	71.59 ± 9.96	0.575
Duration of operation (min)	90.25 ± 17.35	88.12 ± 14.56	0.458
ASA physical status (I/II)	75/5	76/4	0.493
Direct/indirect	53/27	48/32	0.325

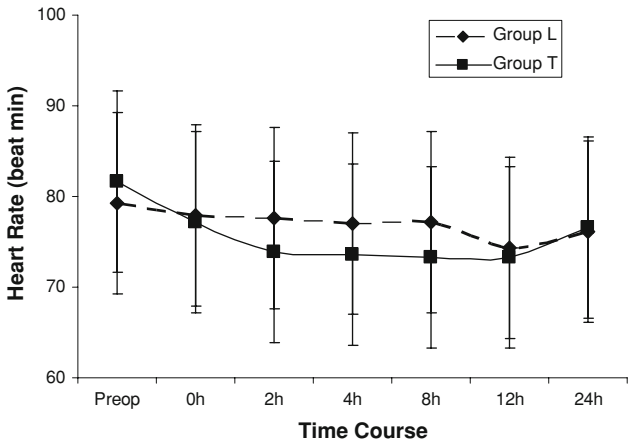

Fig. 1 Perioperative changes in heart rate. Values are mean ± SD

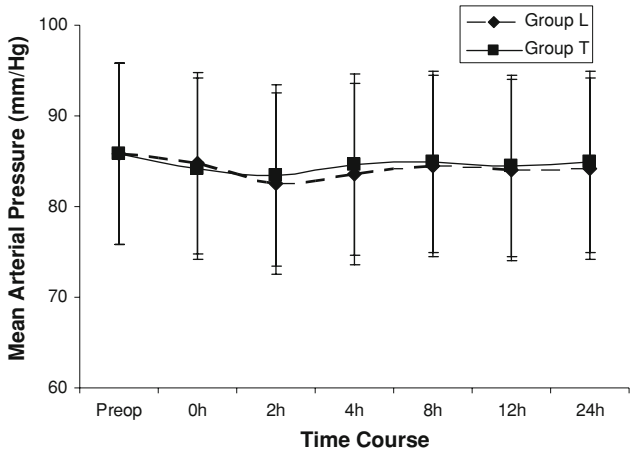

Fig. 2 Perioperative changes in mean arterial pressure. Values are mean ± SD

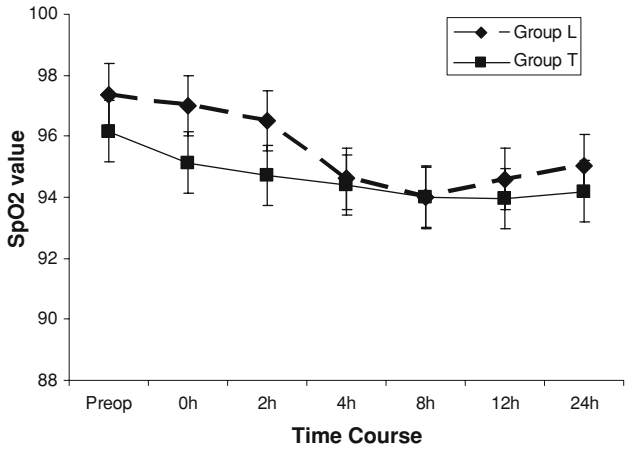

Fig. 3 Perioperative changes in SpO_2. Values are mean ± SD

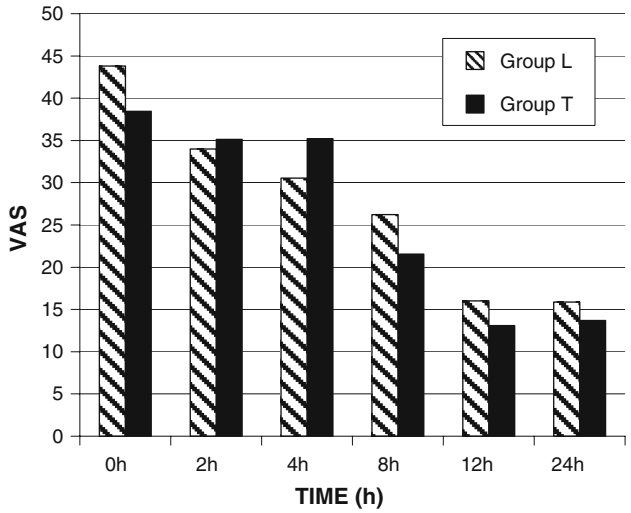

Fig. 4 Visual analog scale (VAS) pain scores during the first 24 h after surgery. There were no significant differences by analysis of variance (ANOVA): 0 h, $P = 0.273$; 2 h, $P = 0.839$; 4 h, $P = 0.417$; 8 h, $P = 0.081$; 12 h, $P = 0.096$; 24 h, $P = 0.126$

outcome [4]. Unsatisfactorily treated postoperative pain is one of the most common complications after surgery and leads to some pathophysiological changes. Also, poor pain control leads to the development of chronic pain.

Today, even with the availability of a variety of potent analgesics, postoperative pain management still a routine problem in day surgery. Traditionally, the management of postoperative pain has focused on the intramuscular administration of opioid analgesics on an 'as required' basis [5]. Injectable NSAIDs have recently become more alternative and useful agents in postoperative pain treatment. NSAIDs do not cause sedation, respiratory depression, reduce intestinal motility, or have significant hemodynamic effects [6, 7].

Lornoxicam is a new NSAID belonging to the oxicam class with analgesic, anti-inflammatory, and antipyretic properties; the plasma half-life time is 3–5 h [8]. Tramadol, a synthetic opioid of the aminocyclohexanol group's μ-opioid receptor agonist—deriving part of its effect by inhibiting the reuptake of norepinephrine and 5-hydroxytryptamine in the central nervous system—offers a similar analgesic potential to opioids. Because of tramadol's low affinity for μ-opioid receptors, there is a lack of sedative and respiratory depressive effects at the clinical level and this makes it potentially suitable for analgesic use after surgery [9–12].

In vitro experimental studies have demonstrated that lornoxicam is more than 100 times more potent than tenoxicam and 40 times more potent than piroxicam in its ability to inhibit cyclooxygenase. In an animal model of analgesia, lornoxicam was approximately three times more potent than piroxicam and ten times more potent than tenoxicam [13].

McGrath et al. [3] reported 5,703 patients' pain profiles after day surgery during the first 24 h who had undergone inguinal hernia repair ($n = 152$) and having moderate pain after surgery. This large study showed us that postoperative pain is still a problem for patients. McHugh and Thoms [14] found the incidence of severe pain to be 21% in 48-h post ambulatory surgery in 99 patients. Beauregard et al. [15] reported a 40% incidence of moderate to severe pain in patients who had undergone knee arthroscopy and gynecological laparoscopy.

Several placebo-controlled studies have shown that NSAIDs reduce postoperative pain and the use of additional analgesics after inguinal hernia repair [16, 17]. Nørholt et al. reported that the analgesic efficacy of i.m. lornoxicam at doses ≥4 mg was superior to placebo, and doses ≥8 mg was at least as effective as i.m. morphine 20 mg in patients who had undergone surgical removal of the mandibular third molar. Tolerability of i.m. injections

of lornoxicam 4, 8, 16, and 20 mg was found to be without any side effect [5]. Staunstrup et al. [18] found that 16 mg of lornoxicam had a superior analgesic effect compared to 100 mg of tramadol following arthroscopic reconstruction of the anterior cruciate ligament using the patella bone–tendon–bone technique.

Rosenow et al. [19] reported that the administration of lornoxicam 8 mg intravenously was as effective as pethidine 50 mg intravenously in relieving moderate to severe after postlaminectomy pain.

Unsatisfactorily treated postoperative pain is one of the most common complications after surgery and leads to some pathophysiological changes. Also, poor pain control leads to the development of chronic pain.

Karaca et al.'s [20] study suggested that tramadol and lornoxicam may be used for pain control after gynecological surgery as a patient-controlled analgesia. One of the main reasons in avoiding NSAID consumption for postoperative pain treatment is the fear of causing bleeding [21]. NSAIDs cause bleeding because of their inhibition of cyclooxygenase and thrombocyte aggregation. The most common adverse effects of tramadol are nausea, vomiting, dizziness, and sweating, with an overall incidence of 1–6% [22]. We found an incidence of nausea of 10% in Group T. We did not observe any respiratory or cardiovascular depression or excess sedation in both groups.

In conclusion, effective pain management is an important component of post-surgical care. Current therapeutic strategies for the management of postoperative pain management are mostly dependent on opioid analgesics and NSAIDs. As in the present study, lornoxicam and tramadol were better tolerated. Lornoxicam 16 mg and 1 mg/kg tramadol every 6 h up to 24 h postoperatively gave same analgesia for postoperative pain management after inguinal hernia repair without any major side effects, and both drugs can be safely used in postoperative pain management after inguinal hernia repair.

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