# **Original Article**

# Comparison between lornoxicam quick-release and parecoxib for post-operative analgesia after laparoscopic cholecystectomy: A prospective randomized, placebo-controlled trial

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## Abstract

**Background:** Non-steroidal anti-inflammatory drugs (NSAIDs) are valuable for post-operative pain as they reduce the use of opioids. Cyclooxygenase-2 inhibitors and traditional NSAIDs can be used. This is a prospective, randomized, placebo-controlled trial to study the efficacy and the safety of the oral administration of lornoxicam quick release tablets versus intravenously administered parecoxib for the management of pain after laparoscopic cholecystectomy (LC).

**Materials and Methods:** One hundred and eight patients, American Society of Anesthesiologists I-II, were randomized to either group A (n = 36): Lornoxicam quick-release 8 mg PO, group B (n = 36): Parecoxib 40 mg intravenous (IV) or group C (n = 36) placebo, for post-operative analgesia, 30 min before the operation and 12 and 24 h post-operatively. All patients received a standard dose of meperidine 1 mg/kg intramuscularly before the incision and post-operatively as rescue analgesia, when visual analog scale (VAS) pain score was >4. Pain at rest and on movement was assessed at 20 min, 3, 6, 12, 18 and 24 h post-operatively. Total meperidine administration and adverse events were also recorded.

**Results:** There were significantly lower VAS pain scores at 20 min, 3, 6, 12 and 18 h at rest or with movement in the lornoxicam quick release and parecoxib groups compared with the placebo group. The number of patients requiring rescue analgesia (meperidine) was significantly higher in the placebo group (P = 0.001). The average dose of meperidine administered was significantly higher in the placebo group, both at 20 min (P = 0.013/0.007) and 24 h (P = 0.037/0.023) post-operatively. VAS scores and meperidine requirements were similar in patients who received lornoxicam or parecoxib.

**Conclusions:** Parecoxib 40 mg IV and lornoxicam quick-release 8 mg PO every 12 h are equivalent adjuvant analgesics with a greater efficacy than placebo for post-operative analgesia in patients undergoing LC.

Key words: Laparoscopic cholecystectomy, lornoxicam, parecoxib, post-operative analgesia

# Introduction

Post-operative analgesia with a combination of agents and techniques (multimodal analgesia) is currently recognized as the most effective practice in pain management.<sup>[1,2]</sup> Pain after laparoscopic cholecystectomy (LC) is usually managed with opioids. Several studies have demonstrated that the use

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Access this article online			
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	<b>DOI:</b> 10.4103/0970-9185.119144		

of opioids is associated with adverse effects.<sup>[3]</sup> Non-opioid analgesics are increasingly being used in the perioperative period.<sup>[4-6]</sup>

Non-steroidal anti-inflammatory drugs (NSAIDs) can be valuable assets as they reduce the use of opioids.<sup>[7-9]</sup>

Lornoxicam quick-release is available in a special formulation with altered pharmacokinetic properties. Due to a patented dissolution technique (Hafsuld Nycomed Pharma, AG), lornoxicam is released and made ready for absorption faster than the standard formulation.<sup>[10]</sup>

Due to the short elimination half time and rapid onset of action, lornoxicam quick-release is an ideal candidate for the treatment of acute pain. Reduction of post-operative pain with lornoxicam was demonstrated in gynecological, orthopedic, abdominal and dental surgery with a recommended dose of 16 mg daily.<sup>[11-15]</sup> Cyclooxygenase-2 (COX-2) inhibitors are not associated with the various side-effects of NSAIDs and they can be used more often. Parecoxib is a parenterally administered inactive prodrug that undergoes rapid amide hydrolysis *in vivo* to the pharmacologically active COX-2 inhibitor valdecoxib. The intravenous (IV) dose of parecoxib for post-operative analgesia varies from 20 mg to 80 mg, depending on the type of surgery.<sup>[16,17]</sup> Most of the studies, compare agents which are given parenterally (IV or intramuscularly [IM]). Considering the rapid onset of action of lornoxicam quick release, we proposed to study its efficacy when compared with a parenterally administered agent as potent as parecoxib, in seemingly equipotent doses. There are few studies, which compare an agent, which is administered orally to a parenteral one.<sup>[10]</sup>

The primary endpoint of the study was to compare the efficacy of parecoxib IV and lornoxicam PO as well as and the differences in pain scores at rest and on movement compared with placebo. Secondary objectives of this study included the need for rescue analgesia, meperidine consumption and side effects.

# **Materials and Methods**

This single site, double-blind, placebo-controlled, parallel groups randomized clinical trial on the evaluation of the efficacy and the safety of PO administration of lornoxicam quick release tablets versus IV administered parecoxib for the management of pain after LC was conducted from April 2008 to May 2010. The study protocol, patient information sheet and informed consent form were reviewed and approved by the Ethics Committee of the hospital. All patients provided written consent prior to participation. The principles of the Declaration of Helsinki and its amendments were followed.

One hundred eight (American Society of Anesthesiologists I-II [ASA I-II] risk criterion) patients scheduled for elective LC under general anesthesia were enrolled in this prospective randomized trial.

Patients with a history of allergy to aspirin-like drugs or sulphonamides, bronchial asthma, liver or renal dysfunction, peptic ulcer disease, bleeding disorder, pregnancy, substance abuse and chronic pain were excluded from the study.

The statistician provided a computer generated randomization list, which assigned participants in a 1:1:1 ratio to one of the 3 treatment groups: Lornoxicam quick-release 8 mg PO, parecoxib 40 mg IV or placebo, for post-operative analgesia, 30 min before the operation and then at 12 h and 24 h post-operatively. All patients received a standard dose of meperidine 1 mg/kg IM before the incision and 12.5 mg IV post-operatively as rescue analgesia, when pain score according to the visual analog scale (VAS) 0-10 was > 4. After they were transferred to the ward, patients were given 1 mg/kg meperidine IM as rescue analgesia, at a maximum dose every 4 h.

All study medications were prepared by a study-coordinator who was in cooperation with an oversight committee and then distributed to investigators. All investigators were blinded of the treatment type. The study-coordinator functioned only in the capacity of study co-ordination and did not participate in patient testing or medication administration. Placebo medications were designed to be indistinguishable from treatment medications and were administrated in the same time frame and fashion as treatment medication for all treatment groups.

Anesthesia administration followed a standardized procedure. The night before the operation patients were instructed to take pantoprazole 40 mg PO and bromazepam 1.5 mg PO. Upon entering the operating room, electrocardiogram leads, non-invasive blood pressure and pulse oximetry monitors were applied. After establishing IV access, patients were given Midazolam 0.035 mg/kg, Dehydroperidol 0.5 mg, Granisetron 3 mg and a single prophylactic dose of pantoprazole 40 mg. General anesthesia was induced with propofol 2 mg/kg, remifentanil 1 µg/kg, followed by rocuronium 0.6 mg/kg, to facilitate tracheal intubation. Mechanical ventilation was adjusted to maintain partial pressure of end-tidal carbon dioxide between 35 mmHg and 45 mmHg. Hemodynamic parameters, such as blood pressure and heart rate, were maintained within 20% of pre-operative values by adjusting anesthetic depth, fluid replacement and vasoactive drugs. Anesthesia was maintained with oxygen in nitrous oxide (1:1)and sevoflurane 2-3% end-tidal concentration, in conjunction with remiferitanil as a continuous infusion 5-10  $\mu$ g/kg/h. At the end of the operation, remifentanil infusion and anesthetic gases were discontinued and replaced by oxygen only and residual neuromuscular block was antagonized with the use of neostigmine (2.5 mg) in the case that two responses of the abductor pollicis muscle could be seen in the "train of four test." All surgical operations were performed by experienced laparoscopic surgeons using a standardized technique with 2 10-mm and 2 5-mm trocars. All patients were in the anti-trendelenburg position with left tilt and maximum pneumoperitoneal pressure at 12 mmHg.

After the screening and enrolment, patients were assessed prior to surgery and then at the time that patient was transferred to the post-anesthesia care unit (T0), usually 20 min after tracheal extubation and then after 20 min, 3, 6, 12, 18 and 24 h post-operatively. Pain intensity was assessed at rest and with movement, by an investigator blinded to the specific patient analgesia group, using the VAS scale, where 0 represented "no pain" and 10 "the worst possible pain."

The safety and tolerability of the study treatments were assessed using spontaneously reported adverse events, the premature discontinuation from the study due to adverse events and monitoring of Electrocardiograph, vital signs, hematology and blood biochemistry during the study.

Patient demographics and VAS ratings are represented as means with standard deviations. Statistical analysis of VAS pain scale scores was performed using the Wilcoxon signed ranks test (2 tailed). The Kruskal-Wallis test was used to analyze meperidine dosages. A P value of < 0.05 was considered to be statistically significant. The analysis was performed using the SPSS<sup>®</sup> Base 13.0 for Windows.

Sample size was calculated using three groups for an ANOVA analysis, with an Alpha score = 0.05, statistical power of 80%, having the measurable treatment effect (effect size) of 1.0, with an assumed standard deviation  $\approx \pm 1.0$  (0.999). This produced a sample size of 36 members per group, for a total of 108 study subjects.

# Results

One hundred eight patients were enrolled in the study, but nine patients withdrew as the surgery was rescheduled. Patients were assigned, via a computer-generated randomization list provided by the statistician to one of three groups in a 1:1:1 basis.

The patients' baseline characteristics and information regarding the type and duration of surgery are illustrated in Table 1. There were no significant differences between the treatment groups regards to age, weight, gender, ASA risk qualification and the duration of surgery. Pain scores as measured by the investigators post-operatively are shown in Tables 2 and 3.

Overall, pain ratings were low and showed a similar decreasing pattern over time [Figure 1]. At rest, patients showed significantly lower values compared to controls at all time points, lornoxicam (20 min P = 0.001, 3 h P = 0.003, 6 h P = 0.023, 12 h P = 0.001, 18 h P = 0.014, 24 h P = 0.008) or parecoxib (20 min P = 0.003, 6 h P = 0.033, 18 h P = 0.012).

With movement, time points of 20 min, 3 h, 6 h and 12 h after surgery, controls had significantly higher pain scores [Figure 2] compared to the treatment groups; lornoxicam (20 min P = 0.006,) or parecoxib, (3 h P = 0.003, 6 h P = 0.001 12 h P = 0.004).

Meperidine consumption at 20 min (P = 0.013/0.007) and 24 h (P = 0.037/0.023) was significantly higher in the control group.

The number of patients requiring rescue analgesia with meperidine [Figure 3] was significantly lower in both treatment groups, compared to the placebo group (P = 0.001/0.001) Table 4.

A total of three patients (9%) in group A, 2 in group B (5.6%) and 2 in group C (6.7%) had minor gastric events, such as epigastric pain, nausea and vomiting, during the first 6h post-operatively. Blood loss was not significant in all groups and no patient needed a blood transfusion.

Table 1: Baseline patient characteristics*					
Group**	Lornoxicam (n=36)	Parecoxib (n=36)	Placebo (n=36)		
Age (years)	62.4±4.2	64.1±5.8	63.2±4.6		
Weight (kg)	74.8±10.5	$72.9 \pm 11.0$	73.7±10.0		
ASA (I/II)	20/16	20/16	19/17		
Gender (male/female)	19/17	16/20	20/16		
Surgical time (minutes)	55±16	59±19	58±19		

\*Demographic data and duration of surgery are expressed as mean±SD or as number of patients, no significant differences were noted between the groups, \*\*Lornoxicam (p.os), parecoxib (iv), saline (iv, placebo), ASA=American Society of Anesthesiologists

Time	Treatment	N	VAS-painscore	P value
20 min	Lornoxicam	36	$4.48 \pm 2.27$	0.001*
	Parecoxib	36	$4.19 \pm 2.72$	0.003*
	Placebo	36	$5.90 \pm 1.24$	
3 h	Lornoxicam	36	$4.15 \pm 1.97$	0.023*
	Parecoxib	36	$4.00 \pm 2.46$	0.579
	Placebo	36	4.17±1.64	
6 h	Lornoxicam	36	$3.52 \pm 1.60$	0.023*
	Parecoxib	36	$2.64 \pm 1.66$	0.033*
	Placebo	36	$3.73 \pm 1.57$	
12 h	Lornoxicam	36	$2.45 \pm 1.66$	0.001*
	Parecoxib	36	$2.28 \pm 1.63$	0.078
	Placebo	36	$3.33 \pm 1.52$	
18 h	Lornoxicam	36	$2.28 \pm 1.59$	0.014*
	Parecoxib	36	$1.75 \pm 1.34$	0.012*
	Placebo	36	$2.63 \pm 1.35$	
24 h	Lornoxicam	36	$1.73 \pm 1.61$	0.008*
	Parecoxib	36	$1.31 \pm 1.21$	0.055
	Placebo	36	$2.13 \pm 1.43$	

\*Wilcoxon signed ranks with 2-tailed  $\alpha$ =0.05,VAS=Visual analog scale (0-10)

## Discussion

LC is one of the most frequently performed the same day surgeries, where tissue injury is minimal. LC has been associated

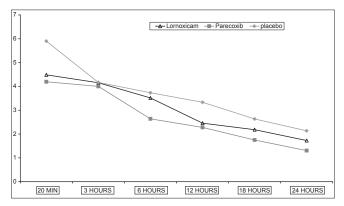


Figure 1: Visual analog scale scores at rest

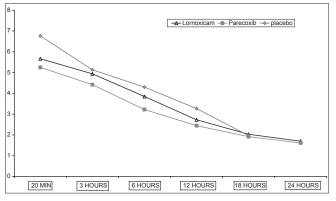
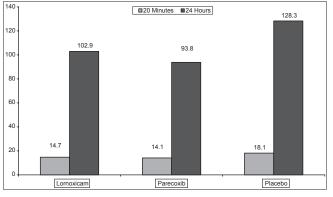
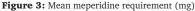


Figure 2: Visual analog scale scores with movement





with incisional, visceral and shoulder pain.<sup>[18]</sup> Previous studies have shown that pain associated with LC is not always well-managed and there is a 70% incidence of post-operative nausea and vomiting.<sup>[19]</sup> These complications are associated with the use of opioids, which can affect the recovery process and delay the patient's discharge from the hospital,<sup>[20]</sup> due to their adverse events including, nausea, vomiting, sedation, bladder dysfunction and respiratory depression.<sup>[21,22]</sup> Therefore, it has been suggested that opioids be used sparingly in patients undergoing ambulatory surgical procedures.<sup>[23]</sup>

This has made non-opioid analgesics, such as NSAIDs, local anesthetics and specific COX-2 inhibitors, increasingly popular for the management of post-operative pain.<sup>[5]</sup> The concept of balanced analgesia suggests that a combination of opioid and non-opioid analgesic agents will enhance the analgesic efficacy and reduce potential side effects after surgery.

For the purpose of this study, the combination of a standard dose of meperidine with either lornoxicam quick-release 8 mg PO every 12 h or parecoxib 40 mg IV every 12 h, were used for the management of post-operative pain in patients with

Time	Treatment	N	VAS-painscore	P value
20 min	Lornoxicam	36	$5.67 \pm 2.07$	0.006*
	Parecoxib	36	$5.25 \pm 2.03$	0.001*
	Placebo	36	6.77±1.79	
3 h	Lornoxicam	36	$4.94 \pm 1.43$	0.234
	Parecoxib	36	$4.42 \pm 2.06$	0.003*
	Placebo	36	$5.13 \pm 1.94$	
6 h	Lornoxicam	36	$3.85 \pm 1.50$	0.064
	Parecoxib	36	$3.22 \pm 1.53$	0.001*
	Placebo	36	$4.30 \pm 1.39$	
12 h	Lornoxicam	36	$2.73 \pm 1.23$	0.115
	Parecoxib	36	$2.44 \pm 1.71$	0.004*
	Placebo	36	$3.27 \pm 1.41$	
18 h	Lornoxicam	36	$2.03 \pm 1.02$	0.955
	Parecoxib	36	$1.92 \pm 1.27$	0.157
	Placebo	36	$1.97 \pm 1.19$	
24 h	Lornoxicam	36	$1.70 \pm 1.05$	0.878
	Parecoxib	36	$1.61 \pm 1.27$	0.739
	Placebo	36	$1.87 \pm 1.13$	

\*Wilcoxon signed ranks with 2-tailed  $\alpha$ =0.05,VAS=Visual analog scale

Table 4: Meperidine requirement					
Group	Α	В	С	P value A-C/BC	
	Lornoxicam mean±SD	Paracoxib mean±SD	Placebo mean±SD		
Patients with meperidine need <i>N</i> (%)	15.0±45.5	17.0±47.2	$27.00 \pm 90.0$	0.001*/0.001	
Meperidine requirement 20 min (mg)	$14.7 \pm 4.9$	$14.06 \pm 4.3$	$18.08 \pm 6.3$	0.013*/0.007	
Meperidine requirement 24 h (mg)	102.9±37.4	93.8±40.3	$128.30 \pm 48.6$	0.037*/0.023	

Kruskal-Wallis test=Meperidine dose 20min and 24h significantly higher in control group, SD=Standard deviation

LC. The primary goal was to compare the efficacy of both agents as adjuvant analgesics after LC taking into account the intensity of pain using the VAS scale and the need for rescue analgesia during the first 24 h. The secondary goal was to compare the adverse events of the analgesic agents.

We found that both parecoxib 40 mg IV every 12 h and lornoxicam 8 mg PO every 12 h reduced pain intensity at rest and on movement at 20 min, 3, 6, 12 and 18 h post-operatively compared with placebo. However, the rescue analgesia with meperidine was still required in a high percentage of patients in both groups.

Parecoxib has been reported as an agent, which could significantly reduce the post-operative opioid consumption after LC.<sup>[17]</sup>

In a study, Parecoxib 40 mg IV, 30-45 min pre-operatively followed by oral valdecoxib 40 mg reduced opioid requirements and provided superior pain relief as well as improved patient global evaluation after LC.<sup>[24]</sup> Papadima *et al.*<sup>[25]</sup> compared the efficacy of a single dose of parecoxib IV or lornoxicam IV for pain management after LC, where both agents were equal analgesic and both were more efficacious than placebo.

In our study, we chose to compare parecoxib IV with lornoxicam PO, since no other studies have been published comparing these two agents after LC.

On the other hand, lornoxicam PO has been evaluated in pain management and it is found to be effective at treating moderate to severe acute post-operative pain and adverse events did not differ significantly from placebo.<sup>[26]</sup>

In another study, quick-release lornoxicam versus placebo was evaluated for acute pain management after dental implant surgery. The study found that lornoxicam is effective in post-operative acute pain control and has a high safety profile with no reported adverse events.<sup>[27]</sup> Møller *et al.*,<sup>[28]</sup> evaluated the analgesic efficacy of quick-release versus standard lornoxicam for pain after third molar surgery and they reported a faster onset and superior analgesic effect than lornoxicam IV.

There are no studies evaluating the efficacy of lornoxicam quick release PO for pain management after LC. An orally administered agent like lornoxicam quick—release could be a significant asset to post-operative analgesia.

Our data showed that both parecoxib IV and lornoxicam PO reduced meperidine consumption compared with placebo. They also reduced pain at rest and on movement at all-time points post-operatively until 18 h compared with placebo. However, rescue analgesia with meperidine was still required in both study groups.

In conclusion, lornoxicam quick-release PO and parecoxib IV every 12 h are both valuable adjuvant analgesics for post-operative analgesia after LC with a greater efficacy than placebo. Furthermore, an agent orally administered with such a rapid action as lornoxicam quick-release PO is a useful tool in the hands of the anesthetists, which may be particularly useful in ambulatory surgeries, such as LC.

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**How to cite this article:** Kouroukli I, Zompolas V, Tsekoura V, Papazoglou I, Louizos A, Panaretou V. Comparison between lornoxicam quick-release and parecoxib for post-operative analgesia after laparoscopic cholecystectomy: A prospective randomized, placebo-controlled trial. J Anaesthesiol Clin Pharmacol 2013;29:485-90.

Source of Support: Nil, Conflict of Interest: None declared.

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