Original Article

A Comparison of the Efficacy and Tolerability of Lornoxicam and Diclofenac Sodium in Patients with Acute Postoperative Pain after Spinal Surgery

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ABSTRACT

Spinal fusion surgery causes severe postoperative pain, hampering reconvalescense. Nonsteroidal anti-inflammatory drugs are used in the management of postoperative pain to avoid the adverse effects associated with opioids. Lornoxicam use is increasing for postoperative pain management. However, lornoxicam has not been studied for use in pain management after spinal surgery. In the present study, analgesic efficacy and tolerability of lornoxicam and diclofenac sodium were compared in post operative spinal surgery patients. This single blinded, randomized, prospective comparative study of lornoxicam (8 mg) versus diclofenac (75 mg) was conducted at Stavya Spine Hospital, Ahmedabad, Gujarat. 47 patients were enrolled in the study. After spinal surgery, 23 patients received diclofenac sodium and 24 patients received lornoxicam. Pain were assessed at baseline (0 min), 15 mins, 30 mins, 45 mins, 60 mins, 90 mins, 120 mins, 180 mins, 240 mins, 300 mins, and 360 mins by visual analog scale of 10 points. Adverse events were recorded for both groups. Laboratory safety parameters were measured before and after 24 hrs of surgery. The pain relief score were significantly (<0.001) reduced at measured time points as compared to baseline for both groups. However, difference ($p < 0.05$) between lornoxicam and diclofenac treated groups for pain relief score were found only at 30 mins and 300 mins after drug administration. Lornoxicam has slightly greater efficacy than diclofenac in acute post operative pain with similar tolerability and safety. Thus, lornoxicam is a better alternative for diclofenac in acute post operative after spinal surgery.

Keywords: Acute Postoperative Pain, Spinal Surgery, Lornoxicam, Diclofenac.

INTRODUCTION

Postoperative pain is a common form of acute pain. The management of acute postoperative pain poses a significant challenge in surgical specialities. The problem of acute postoperative pain is widespread, with approximately 40% of all surgical patients experiencing moderate-severe acute postoperative pain[1]. Although acute postoperative pain is a frequent and often expected occurrence after surgery, the issue of unnecessary patient suffering and discomfort, heightened acute postoperative pain can significantly delay ambulation, lengthen hospital stay, increase the number of unanticipated hospital admissions and contribute to mental decline[2-5]. In the long-term, severe acute postoperative pain is a risk factor for the development of chronic post-surgical pain[6]. Effective postoperative pain relief improves patient satisfaction and may decrease morbidity and reduce mortality[7,8].

Opioid analgesics are often used to manage postoperative pain but are associated with a high incidence of adverse effects (AEs) such as nausea, vomiting, constipation, oversedation, and respiratory depression.[9,10]. Nonsteroidal anti-inflammatory drugs (NSAIDs) provide effective analgesia for acute pain after minor and major surgery as a substitute for or as an adjunct to opioid analgesia[11,12].

Lornoxicam is a nonselective NSAID of the oxicam class with analgesic, anti-inflammatory, and antipyretic properties[13]. Its inhibitory effects on cyclooxygenases in peripheral tissues decrease prostaglandin production and its effects on endogenous dynorphins, b-endorphin levels also promote its central analgesic and anti-inflammatory effects.[14] Recent studies also suggested a pre-emptive role for lornoxicam[15,16]. The drug has a short plasma elimination half-life, of approximately 4 to 6 h. This short plasma half life may in part be responsible for the lornoxicam's reduced incidence of adverse effects[15]. Because of this, it is suitable in the postoperative period for acute pain [16,17]. It has been reported that Intravenous Patient Controlled Analgesia (IV PCA), with lornoxicam is as effective as opioid analgesics for postoperative pain management[18-20]. In the postoperative setting, lornoxicam has been well tolerated[21-23], with tolerability profile similar to diclofenac[22] but superior to that of indomethacin[23].

Diclofenac (cyclooxygenase 1 and cyclooxygenase 2 inhibitor) is being used conventionally for many years for postoperative pain relief. It is known to accumulate in inflamed tissue where its concentration is maintained much higher than in plasma for many hours. It also has active metabolites that act as analgesic[24-27]. However, there are only a few studies available in literature comparing post operative analgesic effects of lornoxicam and diclofenac. Therefore, the present study was substantiated to evaluate the analgesic efficacy and safety of lornoxicam and diclofenac in acute postoperative pain after spinal surgery.

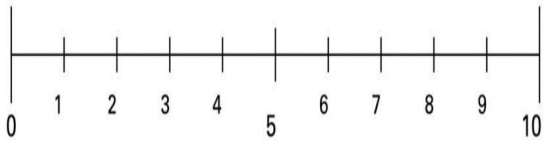
MATERIALS AND METHODS

Patients and Methods

This single-blinded, randomized, prospective comparative study of lornoxicam versus diclofenac was conducted for 3 months (From January to March 2012) after obtaining approval from institutional ethical committee in patients undergoing spinal surgery at Stavya Spine Hospital and Research Institute, Ahmadabad. Patients (male or female) aged between 18-70 years, not taken analgesics 12 h prior to spinal surgery and experienced score >5 points on a 10 points visual analogue scale [VAS] at first perception of pain after

completion of spinal surgery, without history of hypersensitivity of analgesics were included for the study. Patients with a history of, or active or suspected gastrointestinal ulcers or bleeding or asthma, who have previously shown hypersensitivity reactions (e.g. asthma, urticaria or acute rhinitis) or hepatic inflammation to aspirin or other NSAIDS, history of hemorrhagic diathesis and history of confirmed or suspected cerebrovascular bleeding, patients using serotonin selective reuptake inhibitors, monoamine oxidase inhibitor, anti-platelets, anti-coagulant and steroids patients using any within 2 weeks of surgery, with SGPT (> 2 x ULN) and serum creatinine elevations, patients who have taken intra- or post-operative analgesics and pregnant or lactating women were excluded from the study.

Inform consents were taken from all enrolled patients. Laboratory investigations and clinical examination were performed before spinal surgery and at the end of study (24 hrs.) for the safety purpose. The demographic details of patients, including age, gender, and type of spinal surgery were recorded. 40 patients were randomly divided in to two groups. The anesthetic technique was standardized among the two anesthesiologists. All patients were premedicated with Inj. glycopyrrolate 0.2mg and Inj. fentanyl (2mg/kg). Anesthesia was induced with Inj. propofol (1.5mg/kg). Orotracheal intubation was facilitated with Inj. isoflurane (0.1mg/kg). Anesthesia was maintained with Inj. isoflurane in a partial mixture nitrous oxide and oxygen and Inj. vacuronium 0.02mg/kg when necessary. No local anesthetics or any medications with a possible coanalgesic effect were administered intra- or 48 hours after surgery. On the day of surgery one group had received single dose intravenous diclofenac sodium injection (75mg/3 ml) and second group was treated with single dose IV lornoxicam injection IV (8mg/2 ml). Pain was assessed by Visual Analogue Scale (VAS) of 10 point at baseline after surgery. If pain greater than 5 point on 10 point scales VAS then drug was administered and time for drug administered was recorded as baseline. Pain was assessed after every 15 mins, 30 mins, 45 mins, 1 h, 1.5 h, 2 h, 3 h, 4 h, 5 h and 6 h on VAS scale after drug administration. The VAS is 0-10 point non-graduated scale, stretching from "no pain" to "pain as bad as it could be" and commonly used tool in research and clinical practice, and its reliability and validity in pain assessment has been clearly demonstrated[28].



Visual analog scale (VAS)

Pain intensity difference [0-10] was also measured. Blood pressure, pulse and temperature were recorded at baseline, 30 mins, 1hrs, 3 h, and 6 h after administration of drug and at end of study (24 h). As a rescue analgesic tramadol and paracetamol were given to the patient.

Statistical analysis

Statistical analyses were performed using SPSS and PRISM software. Results are presented as mean (SD) ± SEM. One way ANOVA was used to compare measured data (VAS) between the two groups. Unpaired Student t test was used to compare measured data (VAS) between the two groups. A P value <0.05 was considered statistically significant.

RESULTS

A total 47 patients who underwent spinal surgery at Stavya Spine Hospital were included during period from February 2012 to April 2012. Out of 47 patients, 7 patients were excluded from study due to need of rescue analgesics. 40 patients were randomly divided in to two groups, 20 patients treated

with lornoxicam and remaining 20 patients treated with diclofenac. Demographic data of study patients are shown in Table 1. There were no differences between the groups in term of age and weight of patients. Out of them 26 (65%) female and 14 (35%) were male patients. 5 patients were found in the age group of 18 to 40 years, 27 patients were found in the age group of 41 to 60 and 8 patients were found in the age group of 61 to 70. In present study mean age was observed in lornoxicam group and diclofenac group as 51.35 ± 2.38, 52.80 ± 2.23 respectively.

Need of the Rescue analgesics

Table 3 shows the percentage of patient required Tramadol (100mg) as rescue analgesics. Rescue analgesic required in lornoxicam group and diclofenac group was 20% and 15% respectively.

Incidence of Adverse effect

The incidence of adverse event did not differ between both groups. The side effects were mild in nature and resolved. Nausea was noted in 1 (4%) patient in both groups. Vomiting was noted in 1 (4%) patient in diclofenac group (Table 3).

Safety parameter

Hemoglobin and platelet count were reduced significantly after surgery but not abnormal reduction of hemoglobin and platelet count were observed after surgery in both groups. Significant rise in total WBC counts were observed in both groups though it was in normal range. No significant changes in SGPT and serum creatinine were observed in both groups (Table 4).

DISCUSSION

Postoperative pain causes marked distress and anxiety and is a major factor that affects recovery from anesthesia and surgery. Despite major improvements in understanding of acute pain pathophysiology over the past decade, approximately 80 percent of patients undergoing surgical procedures experience mild to severe postoperative pain[29]. Both diclofenac[24,26,27] as well as lornoxicam[18,30-39] have been used as analgesic for post operative pain relief in various surgical procedures. These drugs have been used either individually or in combination with others using different rescue drugs in different studies. However, there are only a few studies available in literature where the post operative analgesic effects of these drugs have been compared after surgery[40-44].

Daglar et al. (2005)[40] studied the comparison of the effects of lornoxicam versus diclofenac in pain management after cardiac surgery in a single blind randomized study. The study included 40 adult patients who were randomly assigned to either receive lornoxicam 8 mg intramuscularly 8 hourly or diclofenac 75mg intramuscular 12 hourly for 48 hours. No significant group difference in mean pain relief scores was found at any point in both groups.

Sener et al (2008)[41] in a prospective, randomized, placebo controlled double blind study compared the efficacy of lornoxicam with diclofenac, ketoprofen and dipyrone for relief of acute postoperative pain in patient undergoing septoplasty. They used lornoxicam 8mg twice daily and diclofenac 75 mg twice daily. There was no significant difference among the remaining lornoxicam and diclofenac groups.

Kidd et al. (1996)[42] compared the efficacy and tolerability of lornoxicam and diclofenac in the treatment of patients with osteoarthritis over 12 weeks and assessed the efficacy and tolerability of lornoxicam over a followup period of 40 weeks. Results of their study showed that Lornoxicam 4 mg tid and 8 mg bid were as effective as diclofenac 50 mg tid for the treatment of osteoarthritis. There

was no significant difference in tolerability of these regimens.

Herrmann & Geertsen (2009)[43] compared efficacy and tolerability of lornoxicam with placebo and diclofenac reported in 164 acute sciatica/lumbo-sciatica patients using randomized double blinded multicentre study. They reported that lornoxicam and dicolfenac had similar analgesic effect. Incident and severity of adverse effects were comparable. Overall tolerability was rated very good by 93% of patients.

Result of the present study also showed that lornoxicam and diclofenac treatments produced significant and comparable postoperative analgesic effect for 6 hrs in spinal surgery patients. However, lornoxicam produced significantly greater analgesic effect at 30 mins and 300 mins after treatment as compared to diclofenac group. The need of rescue analgesics was in diclofenac and lornoxicam treatment groups in our study was similar as reported in a study conducted on patients of septoplasty.[42] No significant differences were demonstrated with regard to tolerability and the incidence of adverse events between the two groups. In the present study, lornoxicam showed high tolerability and less gastrointestinal toxicity as compared to the other oxicams[45,46]. Laboratory measurements showed no evidence of renal damage in any group.

It is concluded that pain after spinal surgery may be treated with either diclofenac or lornoxicam. Lornoxicam has slightly greater efficacy than diclofenac in acute post operative pain with similar tolerability and safety. Therefore, further studies are required to compare the efficacy and safety of these drugs in postoperative analgesia with large number of spinal surgery patients. Thus, lornoxicam is a better alternative for diclofenac in acute post operative after spinal surgery.

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Table 1. Patient Demographic Data

Variable	Lornoxicam group	Diclofenac group
No. of patients	20	20
Gender(male/female)	8/12	6/14
Age	51.35 ± 2.38	52.80 ± 2.23
Weight	66.65 ± 2.33	65.52 ± 2.26

Table 2. Comparison of VAS score and pain intensity difference between the Lornoxicam and Diclofenac groups

Assessment time (min)	Lornoxicam (8 mg i.v.)		Diclofenac (75 mg i.v.)	
	VAS (score)	Pain intensity difference	VAS (score)	Pain intensity difference
0 (Baseline)	9.8 ± 0.14	0	9.7 ± 0.16	0
15	8.65 ± 0.23**	1.15 ± 0.22*	9.15 ± 0.21**	0.55 ± 0.19*
30	6.9 ± 0.29*#	2.9 ± 0.29**#	7.9 ± 0.16*	1.8 ± 0.16**
45	6.2 ± 0.3*	3.6 ± 0.28**	6.75 ± 0.23*	2.95 ± 0.21**
60	5.15 ± 0.28*	4.65 ± 0.27**	5.9 ± 0.22*	3.8 ± 0.21**
90	4.45 ± 0.24*	5.35 ± 0.25**	4.65 ± 0.21*	5.05 ± 0.25**
120	3.95 ± 0.21*	5.85 ± 0.23**	4.2 ± 0.16*	5.5 ± 0.21**
180	3.35 ± 0.15*	6.45 ± 0.21**	3.8 ± 0.12*	5.9 ± 0.19**
240	2.9 ± 0.14*	6.9 ± 0.20**	3.2 ± 0.12*	6.5 ± 0.19**
300	2.4 ± 0.15*#	7.4 ± 0.23**	2.75 ± 0.10*	6.95 ± 0.19**
360	2.25 ± 0.16*	7.55 ± 0.25**	2.5 ± 0.12*	7.2 ± 0.21**

Each value expressed as Mean ± SEM. *p <0.001, **p<0.05 as compared to baseline (one way ANOVA) #p<0.05, as compared to Diclofenac (Lornoxicam group v/s Diclofenac group by unpaired T test)

Table 3. Incidence of Adverse effect and need of the Rescue Analgesics

Adverse effects	Lornoxicam group	Diclofenac group
Nausea	1(4%)	1(4%)
Vomiting	-	1(4%)
Need of rescue analgesics in number of patients	4 (20 %)	3 (15 %)

Table 4. Comparison of safety parameter between the Lornoxicam and Diclofenac groups

	Lornoxicam		Diclofenac	
	Before surgery	After 24 hrs.	Before surgery	After 24 hrs.
Hb gm/dl	13.165 ±0.3700	11.395 ± 0.40*	13.1 ± 0.27	12.09 ± 0.28*
PC/cmm	281200 ±15590	239100±15140*	319100±14450	271400±15820*
TWC/cmm	8201 ± 476.5	10380 ± 513.3*	7087 ± 316.8	9145 ± 549.7*
SGPT IU/L	24.61 ± 1.783	27.05 ± 1.900	26.9 ± 1.25	28.31 ± 1.23
Serum creatinine mg/dl	0.817 ± 0.039	0.814 ± 0.046	0.785 ± 0.038	0.805 ± 0.041

Each value express as Mean ± SEM *P<0.05 as compared to before surgery (paired T test) Where Hb-hemoglobin, PC-platelet count, TWC-total WBC count, SGPT- serum glutamate pyruvate transaminase.