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The Local Addition of Tenoxicam Reduces the Incidence of Low Back Pain after Lumbar Epidural Anesthesia

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Background: **Postepidural backache is a common postoperative complaint after lumbar epidural anesthesia. Useful interventions to decrease the incidence of postepidural backache would be helpful.**

Methods: **We performed a prospective, randomized, double-blind study to compare the effect of local addition of tenoxicam on the incidence of postepidural backache after nonobstetric surgery. One thousand unpremedicated ASA physical status I or II patients scheduled for hemorrhoidectomy were assigned randomly to tenoxicam or control groups. Patients in the control group received 25 ml lidocaine, 2%, with epinephrine 1:200,000 epidurally and 4 ml lidocaine, 1%, for local skin infiltration. Patients in the tenoxicam group received 25 ml lidocaine, 2%, with epinephrine 1:200,000 epidurally and 4 ml lidocaine, 1%, with tenoxicam (2 mg) 1:2,000 for local skin infiltration. Patients were interviewed at 24, 48, and 72 h postoperatively using a standard visual analog scale for evaluation of postepidural backache. A patient was considered to have postepidural backache when the postoperative visual analog scale score was higher than the preoperative score.**

Results: **The incidence of postepidural backache in patients in the control group for the 3 days were 22.8%, 17.4%, and 9.2%, all of which were significantly more frequent than observed in the patients in the tenoxicam group (6.8%, 4.0%, and 1.2%, $P < 0.01$). There was a significant association between backache and multiple attempts at epidural needle insertion.**

Conclusion: **In summary, the local addition of tenoxicam reduced the incidence and severity of postepidural backache. (Key words: Centroneuraxial blockade; hemorrhoidectomy; secondary backache.)**

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LOW back pain is a common postoperative complaint after any type of anesthesia. The incidence of postepidural backache after obstetric delivery is between 30% and 45%,[1,2] and the incidence of immediate postoperative backache after nonobstetric surgery is 2–31%.[3,4] Postoperatively, patients frequently associate postepidural backache with epidural anesthesia administered for the operation. Wilkinson[5] recommended the use of field-block anesthesia to prevent postepidural backache, but the technique was not simple and the result was unsatisfactory. Conversely, systemic nonsteroidal antiinflammatory drugs (NSAIDs) have been used widely to treat low back pain. Minor analgesic effects of locally applied NSAIDs also have been reported in animal and clinical studies.[6,7] Nevertheless, no randomized, double-blind study of local effects of NSAIDs on prevention of postepidural backache after nonobstetric surgery has been reported.

Tenoxicam is a newer-generation drug-of-choice NSAID for parenteral administration. The purpose of this prospective study was to compare the incidence of postepidural backache for 3 days in patients undergoing hemorrhoidectomy during epidural anesthesia with and without local addition of tenoxicam.

Materials and Methods

After obtaining Institution Ethics Committee approval and written, informed consent from the patients, 1,000 unpremedicated, ASA physical status I or II patients scheduled for hemorrhoidectomy were included in this prospective study from May 1994 to September 1997. Patients with a history of severe low back injury or surgery, treatment with NSAIDs, or emotional disorder

were excluded from the study. Patients were assigned to one of two groups according to a table of random numbers. Control group patients received 25 ml lidocaine, 2%, with epinephrine 1:200,000 epidurally and 4 ml lidocaine, 1%, for local skin infiltration. Patients in Tenoxicam group received 25 ml lidocaine, 2%, with epinephrine 1:200,000 epidurally and 4 ml lidocaine, 1%, with tenoxicam 1:2,000 for local skin infiltration. The solution for local anesthesia was prepared with or without 10 mg tenoxicam injected into a vial of 20 ml lidocaine, 1%, by anesthetics according to the groups. Both the anesthesiologist who performed epidural anesthesia and the investigator who evaluated the patients pre- and postoperatively were blinded to the group assignment.

The first step of standard technique for epidural anesthesia was local skin infiltration with 1% lidocaine in a depth up to 3.0 cm with a 23-gauge needle (B-D; Becton Dickinson Worldwide Inc., Singapore). In this way, skin, subcutaneous tissue, part of the interspinous ligaments, part of the periosteum, and part of the muscle were infiltrated by local anesthetic agents. The next step was to identify epidural space with a 17-gauge Tuohy needle *via* a midline approach with loss of resistance to air through the area in which the test solution was injected. The blocks were performed with patients lying in the left lateral knee-chest position, and all epidural anesthetics were administered by the same anesthesiologist through needles at L4-5 or L5-S1 interspace. Epidural catheters were not inserted. Postoperatively, patients received intramuscular pethidine (0.5 mg/kg, every 4 h as needed in the first 24 h) for surgical pain and took warm sitz baths for anal wound care on the first postoperative morning.

In the initial preoperative evaluation, patients were asked about a history of low back pain and were evaluated using the standard visual analog scale (VAS). The VAS consisted of a 10-cm line labeled with "no backache" at 0 and "most intensive backache imaginable" at 10. Patients were interviewed again at 24, 48, and 72 h postoperatively by an independent blinded investigator. The postoperative interviews were postponed at least 2 h if patients had received pethidine within 1 h. Patients were asked to stand at attention and flex the spine to touch the toes while keeping their knees straight. If any low back discomfort was noted, it was recorded using the VAS score. If the postoperative VAS score was higher than the preoperative score, the patient was recorded as having postepidural backache. Postepidural backache was defined as mild (<3), moderate (3–7) or severe (>7) based on the VAS score.

Table 1. Demographic Data

	Control Group	Tenoxicam Group
n	500	500
Gender (M/F)	302/198	317/183
Age (yr)	33.7 ± 16.2	32.2 ± 18.3
Weight (kg)	66.0 ± 22.7	67.8 ± 20.8
Height (cm)	163.7 ± 12.1	165.9 ± 11.5

Age, weight, and height are expressed as mean ± SD. No significant differences were noted.

Statistical Analysis

Parametric data were analyzed using the unpaired Student's *t* test and the chi-squared test was used for nonparametric data. Associations between variables were evaluated using logistic regression or log-linear analysis. Differences were considered statistically significant when $P < 0.05$.

Results

There were no significant differences in age, body weight, body height, and gender ratio between the two groups (table 1). One hundred twenty-eight (25.6%, 71 men and 57 women) control-group patients and 34 (6.8%, 21 men and 13 women) tenoxicam-group patients had postepidural backache at some time during the 3 days studied. This overall incidence was significantly different between the two groups ($P < 0.01$). In control group patients, incidence at 24, 48, and 72 h was 22.8%, 17.4% and 9.2%, respectively, all of which were significantly higher than seen in tenoxicam-group patients (6.8%, 4.0%, and 1.2%; $P < 0.01$). Fourteen (9 men and 5 women) control-group patients had no complaint of postepidural backache in the initial 24 h interview, but low back pain was recorded in the following interview. This phenomenon was not seen in tenoxicam-group patients. Stepwise multiple logistic regression showed that age, body weight, body height, and gender were not significant factors in predicting the occurrence of postepidural backache.

There were also significant differences in postoperative VAS-score distribution between control-group and tenoxicam-group patients with postepidural backache (table 2). More patients in the control group than in the tenoxicam group had mild or moderate pain. Local supplementation with tenoxicam not only decreased the

Table 2. Severity of Postepidural Backache (Total Number)

	Group I	Group II	Result
Mild (VAS <3)	44	28	$P < 0.05$
Moderate (VAS 3–7)	83	6	$P < 0.01$
Severe (VAS >7)	1	0	NS

VAS = visual analog scale; NS = no significant difference.

incidence and severity of postepidural backache, but also shortened its duration (table 3).

There was a significant association between postepidural backache and multiple attempts at epidural needle placement in control-group patients ($P < 0.05$). There was also a significant difference ($P < 0.05$) in log-linear regression between control-group and tenoxicam-group patients if multiple attempts at epidural needle placement occurred (table 4).

Analgesic consumption for surgical wound pain was not different between patients with and without postepidural backache or between groups (table 5). No specific complications were noted during the hospital stay. At follow-up, local skin wound infection or hematoma at the epidural needle puncture site had not developed in any patient.

Discussion

The current study showed that prophylactic local administration of a small dose of tenoxicam (2 mg) reduced the incidence of postepidural backache after epidural anesthesia for hemorrhoidectomy. Low back pain is a common postoperative complaint after regional anesthesia. The incidence of postepidural backache after delivery or nonobstetric surgery has been reported to be between 2% and 45%.[1–4] In our control group, in which patients underwent hemorrhoidectomy during epidural anesthesia, the incidence of postepidural backache was 25.6%, which was comparable to that in previous reports. Four types of low back pain may be differentiated: local, referred, radicular, and that arising from secondary

Table 4. Correlation between Attempts at Lumbar Epidural Needle Placement and Postepidural Backache

	Control Group	Tenoxicam Group
Single attempt		
Backache	45	15
No backache	326	299
Multiple attempts		
Backache	83	19
No backache	46	167

there were significant differences between groups ($P < 0.05$) and attempts at epidural needle insertion ($P < 0.05$).

(protective) muscle spasm.[8] The cause of backache associated with centroneuraxial blockade might be a result of localized trauma, leading to aseptic periostitis, tendonitis, inflammation of the ligaments, and osteochondritis. Postepidural backache usually is characterized by marked tenderness of the lumbar spinous area, therefore, the major type of low back pain after lumbar epidural anesthesia will usually be local or secondary. Fourteen (2.8%, 9 men and 5 women) control-group patients had no complaint of postepidural backache in the initial 24 h interview, but low back pain was recorded in the following interview. This phenomenon did not occur in the tenoxicam group. We suspect that these late-onset cases reflect a more gradually developing local inflammation with associated muscle spasm. Local tenoxicam prevented such cases of late-onset backache, suggesting that local antiinflammatory action is valuable.

Wilkinson[5] described the use of field-block anesthesia to prevent backache after lumbar puncture. The field-block anesthetized the recurrent spinal nerves, which innervate the interspinous ligaments and muscles. Although the incidence after this block is comparable to that which we found, this block is not a simple procedure and could not prevent aseptic periostitis, inflammation of ligaments, and osteochondritis.[9]

Tenoxicam is a newer-generation drug-of-choice NSAID in the oxicam group. It is a highly hydrophilic prostaglandin synthesis inhibitor with a peripheral pharmacodynamic action, therefore lacking central effects.[6]

Table 3. Severity of Postepidural Backache by Days

	Control Group			Tenoxicam Group		
	Day 1	Day 2	Day 3	Day 1	Day 2	Day 3
Mild (VAS <3)	30	36*	31†	28	16*	6†
Moderate (VAS 3–7)	83†	51†	15†	6†	4†	0†
Severe (VAS >7)	1	0	0	0	0	0

VAS = visual analog scale. Significant difference between groups: * $P < 0.05$, † $P < 0.01$.

Table 5. Consumption of Pethedine (mg/kg)

	Control Group	Tenoxicam Group
Backache	0.79 ± 0.45	0.86 ± 0.51
No backache	0.81 ± 0.43	0.85 ± 0.47

There were no significant differences between groups.

It is almost entirely eliminated by linear metabolism.[6] The recommended systemic dose of tenoxicam for postoperative pain is 20–40 mg intravenous or intramuscular every 24 h. The smaller dose of tenoxicam in the current study (2 mg) was chosen to provide a dose without systemic side effects. In contrast to our study, the minor analgesic effects of locally applied NSAIDs have been reported in previous animal studies and clinical studies: injection of acetylsalicylic acid, indomethacin, or acetaminophen into the inflamed paws of rats attenuated nociception responses[10]; topical lysine acetylsalicylate reversed the hypersensitivity of the joint-capsule receptors in rats with polyarthritis[11]; subcutaneous administration of indomethacin reduced the second phase of formalin response in rats[12]; and local indomethacin blocked heat-induced sensitization of C-fiber polymodal nociceptors in a rabbit-ear preparation.[13] Topical acetylsalicylic acid, salicylic acid, and indomethacin suppress pain from experimental tissue acidosis in the skin of human volunteers.[14] Topical NSAIDs are valuable for short-term treatment of acute musculoskeletal pain and inflammation,[15] and locally applied aspirin and acetaminophen were effective for controlling pain in the early postoperative period after third-molar surgery.[16] The addition of ketorolac to intravenous regional anesthesia with lidocaine improved pre- and postoperative analgesia after arm and hand surgery,[17] and finally, wound infiltration with 30 mg ketorolac was more effective than 60 mg intramuscular ketorolac after inguinal herniorrhaphy.[7] Systemic NSAIDs on their own may also produce adverse side effects, such as gastric bleeding, renal impairment, or increased bleeding, caused by inhibition of platelet activity.[18] None of these effects were observed in our study, and local skin wound infection or hematoma at the epidural needle puncture site did not develop in any patient. Conversely, systemic NSAIDs have been used widely to treat low back pain. Nevertheless, no randomized, double-blind study of local effects of NSAIDs on prevention of postepidural backache after nonobstetric surgery has been reported.

In conclusion, the local addition of small dose tenoxicam (2 mg) is effective in reducing the incidence, duration, and severity of postepidural backache, particularly after multiple attempts at needle placement. Complications because of systemic tenoxicam administration were not found in this dosage.

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