AN OPEN NON - COMPARATIVE STUDY OF PARENTERAL PIROXICAM IN THE MANAGEMENT OF PATIENTS WITH ACUTE LOW BACK PAIN

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An open non-comparative study of parenteral Piroxicam in the management of patients with Acute low back pain.

Summary:

PFIZER's recently introduced parenteral formulation of a non steriodal anti-inflamatory analgesic, Piroxicam (feldene) was asseyed in the mangement of acute low back pain. Forty patients were admitted into the trial. The visual analogue scales VAS I and VAS II were employed in the assessment of the onset, efficacy and tolerance of the drug. At the close of the trial, it was concluded that this drug has a rapid onset, is well tolerated, has little side effects and is very efficacious in the treatment of acute low back pain.

Introduction:

Piroxicam, (Feldene) a non steriodal anti-inflammatory agent has been very successful in the treatment of chronic inflamatory disease such as Rheumatoid arthritis, ankylosing spondylitis and for acute conditions affecting muscles, tendons, tendonsheaths and bursae. It was first introduced ten years ago following extensive trials of the oral form and is now in use in more than ninety countries (1, 2) where it is now registered. Published evidence indicate that piroxicam is useful in the treatment of acute musculoskeletal disorders. (1,2,3,4,5,6). The drug is available as capsules of 10 and 20 mgs for oral use as well as suppository. Pfizer has developed a parenteral formulation of Piroxicam consisting of 20 mg per mililitre in 2 percent benzyl alchol for use by deep intramuscular injections. The present study assess the efficacy and tolerance in the management of disorders in which it is desirable to use the parenteral route. Such indications would include patients with sprains, tendinitis and low back pain where a rapid onset of action with immediate relief of the pain would be required, as well as patients who are vomiting or in whom the oral route would otherwise be contraindicated.

Method:

Forty patients were enrolled in the study with a history of low back pain of sudden onset or recent onset of not more than three days. Eight of these were having recurrance of acute low back pain. Pregnant women, patients having Osteoarthritis, ankylosing spondylitis, osteoporosis, congenital malformations, tumours or who had a history of allergy or were receiving steriods, tranquilizers, hypnotics, or other nonsteriodal anti-inflamatory drugs were excluded from the study. The only other auxillary treatment permitted during the trial was the application of heat, bed rest, joint immobilisation and exercise.

Patients received a loading dose of forty milligrams (40mg in 2ml) Piroxicam parenteral by deep intramuscular injection on the first day; followed by daily injections of twenty milligrams (lml) starting from day two up to day nine. Both the patient and the investigator kept records from which evaluation of the analgestic efficacy, time of onset, tolerance and any adverse effects were made. The patients used a visual analogue scale (VAS) in which the pain intensity was self rated on a four point scale. (Table 1) .

The extent of pain relief was scored on a five point visual analogue scale (Table II) patients rated their pain severity shortly before the administration of intramuscular piroxiam. They also scored themselves on the five point pain relief scale on the degree of relief obtained after the injection at five, ten and thirty minutes, one,six and twelve hours on days one, two and three.

The investigator made anamnestic assessment of the patients tenderness on pressure, restriction to mobility (planter flexion) and Lasegues sign (when present) also on a four point visual analogue scale as in Table 1.

The extent of relief obtained was scored on a five point scale using the VAS II just immediately before the next injection. Both the paitents and the investigator made global assessment of tolerance and effectiveness at the conclusion of treatment using the criteria set out on Table III.

Side effects were recorded when voluntered or specifically asked for when not. In particular chest pain, chills, dizziness, fever, headaches, sweating, nausea, vomiting, abdominal pain and local pain were sort for. Mid stream urinalysis, Haemoglobin level, white cell count and Erythrocyte sedimentatim rates were obtained for every patient before the commencement of the trial and 24 hours after the treatment ended.

Results:

Forty patients were admitted into the trial. There were twenty-seven males and fourteen females. Their ages ranged from sixteen to fifty-five years (Figure 1)

The aggregate of the pain severity scores for all forty. Patients was III on day 1. It had fallen to 57 by day 2 and 3 by day 9 (Table IV)

On the fifth day, one person withdrew having fully recovered. Similarly, six and five persons withdrew on days seven and eight respectively. Only twenty-eight persons continued to the end of the trial. The sum of the pain relief on the first, second and third day is shown on Table V.

Thirty-six patients had detectable levels of tenderness on exertion of pressure. Eleven patient had significant limitations to movement and eighteen had positive lasegues sign. The results obtained following treatment with Piroxicam on the analogue scale (using VAS II) are shown on Table VI, VII and VIII.

Tolerance and effectiveness of the drug was assessed as excellent by twenty-eight patients, good by ten and moderate by two patients. None said it was poor. The investigator assessed it as excellent in twelve patients, good in twenty-three, moderate in five and poor for no patient.

Three patients complained of local pain at the site of injection on the first day but not subsequently. There were no instances of nausea, vomiting or other side effects. Midstream Urinalysis haemoglobin estimations and white cell counts remained the same at the beginning as at the conclusion of the trial. The Erythrocyte sedimentation rates were raised in five patients at the start but showed a drop in 3 of the conclusion of trial. Fig.

Discussion:

Following the injection of forty milligrams of piroxicam, the severity of pain showed a decrease within five to ten minutes. The decrease continued exponentially till the nineth day from a total of one hundred and eleven initially to only three as scored by three different patient with slight pain. Pain relief was noticed as early as five minutes by two persons and ten minutes by eighteen persons on day one. Pain relief was maximum at six hours and remained the same till the next injection twenty-four hours later. The extent of pain relief increased exponentially with each dose of piroxicam. Table IV demonstrates clearly this increase in the degree of pain relief obtained by patients.

By the fifth day, one person had achieved complete relief of his pain that he withdrew from the trial. Similarly,six and five persons obtained complete relief by days seven and eight respectively, and did not think it necessary to continue. By the nineth day, the sum of the pain relief scored for all rose from eight-eight; after ten minutes to two hundred by the third day. There were thirty-six persons with tenderness, twenty-three severe, scoring a total of nineth-two points on the first day. By the fifth day, there were only twenty-eight, four of these still severe. By the nineth day, one person still had severe tenderness, two mild and one slight which persisted at the close of the trial. Eleven persons with limitation of movement (nine, severe) scoring thirty-one points showed marked recovery following the first dose of Piroxicam.

By the fourth day, there was no further limitation of movement in three patients. By the fifth day, only three persons still had detectable limitations to movement. One patient with recurrent attacks of acute low back pain had slight pain scoring one point on days seven and continued so till after the conclusion of the trail.

Also of eighteen persons with positive lasegues sign (sixteen severe) scoring a total of 52 points on the first day only one was still positive scoring one point by the conclusion of the trial. Side effects were insignificant as only three persons complained of pain locally following the injection of the drug on the first day and this did not recure. There were no adverse effects on the body biochemistry as there was no change in the results of urinalysis, haemoglobin and white cell count. Only three people showed a fall in the raised ESR. The efficacy of this drug is lowing the ESR as an indix of inhibting tissue inflamation needs further investigation.

Conclusion:

Piroxicam is very effective in the treatment of Low Back pain. When administered parenterally, pain relief is noted as early as ten minutes. By thirty minutes, most persons have obtained significant pain relief. The drug is effective in abolishing all the physical signs associated with acute low back pain of musculoskeletal origin. Tenderness, limitation to movement and positive lasegues sign are effectively abolished. It has very little side effect and can be safely administered to all age groups. It is very well tolerated. Neither the patients nor the investigator rated its efficacy as poor whereas twenty-eight patients rated it as excellent, ten as good and two as moderate in the relief of Low Back Pain. Parenterally, Piroxicam is recommended in the treatment of acute low pain since it has very minimal side effect, its action is of rapid onset and it has a very potent analgestic effect.

TABLE 1

VISUAL ANALOGUE SCALE OF PAIN INTENSITY

Rating	Score
No pain	0
Slight Pain	1
Moderate Pain	2
Severe pain	3

TABLE II

VISUAL ANALOGUE SCALE OF PAIN RELIEF

Rating	Score
No Relief	0
Little relief	1
Moderate relief	2
A lot of relief	3
Complete relief	4

TABLE III

VAS FOR ANAMNESTIC ASSESSMENT

Rating	
Poor	0
Moderate	1
Good	2
Excellent	3
	4

TABLE IV

PAIN SEVERITY SCORE

	DAYS								
	1	2	3	4	5	6	7	8	9
3	31	5	4	4	3	1	1	-	-
2	9	7	6	4	4	6	3	1	
1	-	28	29	29	26	27	10	11	3
0	-	-	1	3	6	15	18	16	25
TOTAL	III	57	53	49	43	35	21	13	3

TABLE V

SUM OF PAIN RELIEF SCORE

DAY	TIME 5min	10min	30min	1hr	6hrs	12hrs
1	2	24	37	26	50	56
1	2	41	45	71	74	81
3	13	18	50	50	54	62
TOTAL	17	88	132	147	178	200

TABLE VI VAS II

ANALOGUE SCALE OF TENDERNESS

Number of patients

Day	1	2	3	4	5	6	7	8	9
3	23	11	9	7	4	3	3	1	1
2	10	18	19	12	10	3	1	3	2
1	3	7	5	10	14	8	6	3	1
0	-	-	3	7	9	21	19	17	20
TOTAL	29	76	70	55	46	23	17	12	8

TABLE VII

ANALOGUE SCALE OF LIMITATION TO MOVEMENTS

Number of Patients

Day	1	2	3	4	5	6	7	8	9
3	9	6	1	-	-	-	-	-	-
2	2	3	5	2	1	-	-	-	-
1	-	2	2	3	2	2	1	1	1
0	-	-	3	3	2	1	-	-	-
TOTAL	31	26	15	7	4	2	1	1	1

References:

1. Broggen R. N., Heel R C, Speight TM, Avery G. S. Piroxicam; A review of its Pharmacological properties and Therapeutic Efficacy. Drugs 1981; 22:165-187.
2. Gunther R, Egy D, Herold M. Efficacy and Safety of Piroxicam and Indomethacin in the treatment of Musculoskeletal Disorders. Z. Rheumatol 1979 38: 330-334.
3. Nussdorf R. t. Piroxicam and Acute Musculoskeletal Disease. A double blind 14 day study comparing Piroxicam Phenylbutazone R. Soc. Med. International Congress and Symposium Series No. 1, 1983 93-95.
4. Sahilli G., Tuccimei U., Cannistra F.M., Comparative Study with Piroxicam and Ibuprofen versus placebo in the supportive treatment of minor sports injuries. Joint Med. Res. 1980, 8:265-269.
5. Hess H. Rothaar J., Thiel W., Therapy of acute sports injuries with a new antiarthritic agent Piroxicam, proceedings of a symposium malaga spain; Excerpta medical 1980, 73-77
6. Filho J. L. Multicentre study of piroxicam in the treatment of acute musculoskeletal disease involving 3011 patients. Fur. J. Raheum Inflam 1983, 199-125.