

PIRPROFEN IN TREATMENT OF NON-ARTICULAR RHEUMATISM IN PAKISTANI OUTPATIENTS, A MULTICENTRE STUDY

Pages with reference to book, From 265 To 268

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Abstract

This study was conducted by 50 leading family physicians and consultants scattered throughout Pakistan to evaluate efficacy and tolerability of Pirprofen in non-articular rheumatism in Asian populations.

A total of 199 subjects suffering from soft tissue rheumatism completed 2 weeks therapy.

Evaluation of patient's condition was made on days 0, 7 and 14, seven target symptoms and signs were evaluated on four point scale (i.e. absent, mild, moderate or severe). At the end of two weeks of treatment each patient gave his own evaluation of the effectiveness of treatment and physician made his final assessment.

Pirprofen was found to be an efficacious drug in treatment of soft tissue rheumatism in Pakistani patients, and its tolerability compared well with other non-steroidal anti-inflammatory drugs. Marked response to treatment was found in each of 7 signs and symptoms studied even after only one week of treatment. This is particularly encouraging as these were precisely the signs and symptoms that would have kept a person from work, or prevented him from performing without restrictions his routine day to day activities.

In this study the rapid onset of analgesic effect and improvement of symptoms with low incidence of side effects establishes Pirprofen as a drug of choice for treatment of soft tissue rheumatism (JPMA 38:265 , 1988).

INTRODUCTION

Pirprofen (Rengasil), a non-steroid anti-inflammatory drug, was first presented to the medical community in 1979. Numerous studies have since confirmed its efficacy and tolerability as being equal to or better than piroxicam¹, naproxen², pentazocine³, indomethacine⁴, ibuprofen⁵ and ketoprofen⁶. Pirprofen has been found effective in the treatment of pain from osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, oral surgery, malignancy, primary dysmenorrhoea, and acute gout. In spite of the large number of these studies, it is evident that most of the information available is from studies done with Western populations.

Although some studies have examined the efficacy of pirprofen in both non-articular and articular disease^{7,8} most others have concentrated solely on the latter (eg., osteoarthritis, rheumatoid arthritis, ankylosing spondylitis). However, in many parts of Asia, pain from nonarticular disease (i.e. soft tissue rheumatism) is just as important and probably commoner in the family physician's clinic. It also represents a significant socio-economic burden, as this collection of ill-defined symptoms prevents large numbers of people from performing their day-today activities efficiently, either at work or at home, and often for weeks. This study was therefore, carried out to see if marked improvement of such signs and symptoms of soft tissue rheumatism could be obtained with short courses of pirprofen in Asian patients attending outpatient clinics.

SUBJECTS AND METHODS

The subjects were patients at outpatient clinics of 50 leading family physicians and consultants scattered throughout Pakistan. They were of either sex, aged over 15 years, and had presented for soft tissue rheumatism which was non-articular in origin.

Patients in whom diagnosis was accompanied by bone injuries (e.g. , fractures), lacerations or large haematomas were excluded, as were women intending to get pregnant, already pregnant or still lactating. Patients with heart failure, diabetes, asthma, peptic ulcer, severe liver or renal disease were also excluded. For the duration of the study, patients were not allowed to receive concomitant physiotherapy, intra-articular steroid injections, or any other analgesics.

Patients who fulfilled the above criteria received Pirprofen 400mg twice a day.

A total of 199 subjects (101 males and 98 females) aged 15 to over 60 years completed 2 weeks therapy. The patients were clinically examined by the doctor concerned on day 0, and a follow-up clinical assessment was conducted after treatment had been administered for seven and 14 days, with the following signs and symptoms assessed by both doctor and patient:

- Pain at rest
- Pain on movement
- swelling
- local tenderness
- functional impairment (subjective)
- limitation of movement (clinical)
- sleep disturbed by pain

Each of the above was classified according to severity (i.e, absent, mild, moderate or severe), and comparison of the findings after one and two weeks treatment respectively allowed the injury to be classified as cured, improved, unchanged, or worsened. Side effects were also recorded. At the end of two weeks of treatment, the patient gave his own evaluation on the effectiveness of the treatment and the physician then finally assessed the therapeutic results.

RESULTS

One hundred and ninety nine patients were included in the study.

TABLE-I. Age distribution of 199 Subjects.

Age Group	n	%	
20 yrs	7	3	younger n = 96 age group % = 49*
21 - 30 yrs	44	22	
31 - 40 yrs	45	23	
41 - 50 yrs	53	27	older n = 101 age group % = 51*
51 - 60 yrs	34	17	
60 yrs	14	7	
Unspecified	2		1
Total	199		100

* % of Patients in younger and older Age Groups:
Ignores the 2 Subjects with unspecified Ages.

Table I shows the age distribution of the patients.

The duration of symptoms prior to entry of patients to study is indicated in Table II.

TABLE -II. Duration of Symptoms prior to entry to Study.

Duration	n	% *
Acute (less than 1 month)	68	36
Short term (1 - 2 months)	33	17
Chronic (3 - 12 months)	88	47
Unknown	10	

TABLE III. * Distribution of Patients in diagnostic Sub-Group.

Soft tissue rheumatism of vertebral musculature (tension, neck, lumbago, cervical syndrome).	49
Soft tissue rheumatism of shoulder region (Frozen shoulder, humeroscapular periarthrits).	35
Other soft tissue rheumatism (myositis, tendomyositis, bursitis,).	76
Soft tissue Rheumatism (un-specified)	37

Table III shows the distribution of patients in the Diagnostic Sub-groups. The response of each of the 7 signs and symptoms studied after 1 and 2 weeks is illustrated in Figure

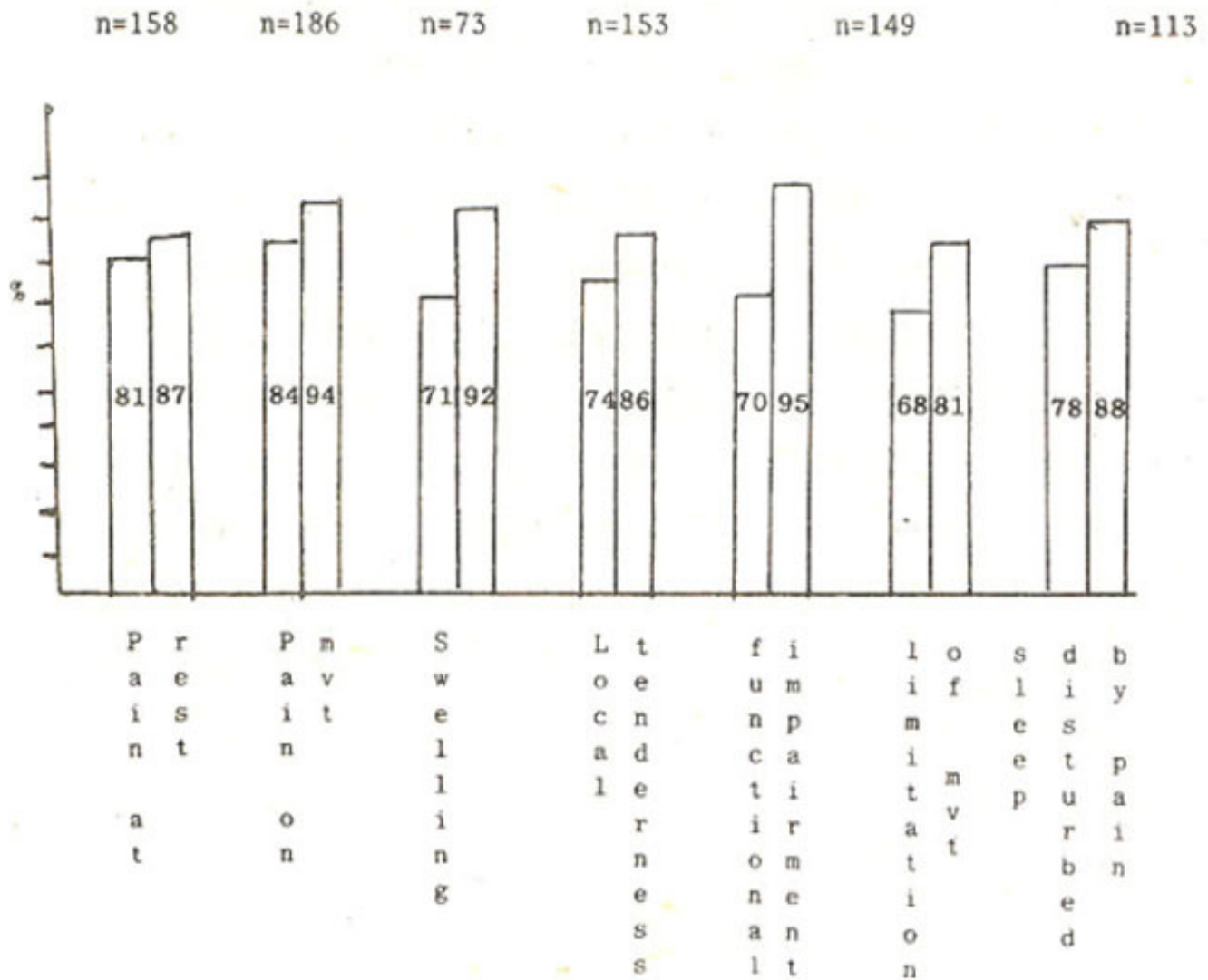


Figure. Response of each of the 7 signs and symptoms studied after 1 and 2 weeks.

(as % of patients showing). Effectiveness of Rengasil in improvement or abolition of each of 7 signs and symptoms, after 1 and 2 weeks (left and right bars of the pairs respectively).

After one week of treatment, there was an improvement in all the parameters measured.

SNmptoms showing most rapid improvement were pain at rest and pain on movement which had either improved or the patients were symptom free.

Effectiveness of Pirprofen 400 b.d. in the treatment of soft tissue rheumatism in different sites of pain, assessed by the physician after 2 weeks of treatment is shown in Table IV.

***TABLE – IV. The effectiveness of the medicine as assessed by Physicians in different diagnostic Sub Groups.**

Site of pain	n	Effective
Back Musculature	49	93.8
Shoulder Region	35	94.2
Others : specified (e.g. , Myositis, Tendomyositis, bursitis etc)	76	89.4
Other, unspecified	37	89.1

Pirprofen was found to be the most effective in soft tissue rheumatism of vertebral musculature (94% of all cases).

DISCUSSION

This study shows that when Pirprofen was used to treat soft tissue rheumatism in outpatients in Pakistan, the drug was effective in over 88-90%, of all cases (as assessed by the physician and patient respectively). This compares favourably with the results of other studies of the use of Pirprofen in the treatment of other painful conditions conducted in non-Asian patients.²⁻⁸ This open clinical study confirms the results of controlled trials that were mainly conducted in hospitals under double blind conditions.^{4,5} It also compares well with the efficacy of other non-steroid anti-inflammatory drugs¹⁻⁶. Of the 7 signs and symptoms monitored, the earliest to improve were pain at rest and pain on movement (81% and 84% respectively either better or asymptomatic after one week only). Forty Six percent of those with sleep disturbed by pain initially, were totally untroubled during sleep after only 1 week of treatment. Other signs and symptoms responded more slowly, with 73%, 71% and 70% response after 1 week in local tenderness, swelling and subjective functional impairment, respectively. Slowest to respond was clinical judgement of limitation of movement, with only 68% showing response after 1 week. This was expected because limitation of movement at a joint may be the result of fibrosis from chronic inflammation, a feature that is not reversed by relief of acute inflammatory process. This trend continued with treatment, with approximately a further half of all non-responders improving within each symptom group during the second week of treatment. As predicted, limitation to movement was again the least responsive of all 7 signs and symptoms even after the second week of treatment.

TABLE – V. Efficacy of Pirprofen in the Treatment of Soft Tissue Rheumatism : Global impression by Physicians and Patients.

	Effective
Physicians (n = 189)	87.9
Patients (n = 183)	89.7

The results thus indicated an excellent relief of pain and symptoms within a week, and either improvement in, or total freedom from, functional impairment in 92% of patients after 2 weeks. This is of particular importance because these same signs and symptoms are precisely those that prevent patients from participating fully in their day-to-day activities.

TABLE – VI. Distribution of 42 Cases of unwanted effects with Pirprofen 400 mg. b.d.

Unwanted effects	n	reported severity
Epigastric pain/burning	19	mild
Gastritis (prolonged symptoms)	6	mild
Nausea	4	mild
Diarrhoea	1	mild
Dryness of mouth	2	mild
Burning sensation in hand	1	mild
Skin rash	2	mild
Tinnitus	1	mild
Palpitations	2	mild
Dizziness	2	mild
Vertigo	2	mild
TOTAL	42	42

The unwanted effects of drug were minimal and mild and none of the patients had to discontinue medication due to side effects.

In this study the rapid onset of analgesic effect and improvement of symptoms with low incidence of side effects establishes Pirprofen as a drug of choice for treatment of soft tissue rheumatism.

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