

Non-steroidal anti-inflammatory drugs fail to enhance healing of acute hamstring injuries treated with physiotherapy

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The effects of two non-steroidal anti-inflammatory drugs (NSAIDs), meclofenamate and diclofenac, in combination with physiotherapy modalities on the rate of healing of acute hamstring muscle tears were studied in a double-blind, placebo-controlled trial. Forty-four of the 75 patients with this injury recruited were assessed and randomly allocated to one of three treatment groups: meclofenamate (100 mg 3 times a day), diclofenac (50 mg 3 times a day) and placebo. All patients received the same intensive physiotherapy treatment over the 7-day treatment period. Patient assessments were performed on days 1, 3 and 7 of the 7-day study period and included pain assessment (visual analogue scale), swelling measurement (thigh circumference measurement at the site of the muscle tear) and isokinetic muscle performance testing. Treatment produced a significant improvement in all measurements in all groups, but there was no difference in any measurement between groups. However, when only the more severe injuries were analysed, the reported pain score at day 7 was significantly lower in the placebo group than in either the meclofenamate group or the diclofenac group ($P < 0,05$). Hence this study did not find any additive effect on the healing of acute muscle injuries when meclofenamate or diclofenac was added to standard physiotherapeutic modalities. The study therefore does not support the use of NSAIDs in the treatment of acute hamstring muscle injuries.

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Almost half of all sporting injuries involve the musculo-tendinous unit.¹ Of these, acute muscle injuries are the most common.² There have been few well-controlled studies to

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determine the optimal management of these injuries or the role of non-steroidal anti-inflammatory drugs (NSAIDs) in the management of these injuries.³⁻⁶ The possibility that these agents might be contraindicated in the acute early treatment (within 4 days of injury) of these injuries has been raised by a number of recent studies. For example, Almekinders and Gilbert² provided histological and biomechanical evidence that NSAIDs delayed muscle regeneration following acute muscle injury.

Despite these findings, which might reasonably be expected to constrain the use of NSAIDs, these agents are widely used in the treatment of these and other sports-related injuries in South African athletes.⁴

As we could not locate any previous study performed with sufficient control to quantify objectively the role of NSAIDs in acute, sports-related muscle injuries, we used a placebo-controlled, double-blind trial to determine whether two commonly used NSAIDs, meclofenamate and diclofenac sodium, influence the rate of healing of acute sports-related muscle tears treated according to standard physiotherapy practice.

Materials and methods

Patients who had sustained acute sports-related tears of the hamstring or quadriceps groups of muscles and who were first seen within 48 hours of injury, were assigned to the trial. Those with known sensitivities to aspirin or to NSAIDs, or with a previous history of peptic ulceration, haematopoietic disease or bronchospasm were excluded from the trial. Those who had received any prior treatment or medication were excluded and no concomitant treatment was allowed. Of the 75 patients recruited initially, 44 sustained hamstring injuries and only these were studied. All patients were informed of the nature of the trial and signed a consent form before commencing with assessment and treatment. The study was approved by the Ethics and Research Committee of the Faculty of Medicine of the University of Cape Town. Patients were referred to either 1 Military Hospital, Voortrekkerhoogte, Pretoria or 2 Military Hospital, Wynberg, Cape Town for assessment and treatment. Two centres were used to facilitate more effective patient recruitment.

Treatment and assessment techniques were standardised as far as possible throughout, as were calibration procedures for the isokinetic testing (muscle performance testing) equipment. All physiotherapists (two at 2 Military Hospital, two at 1 Military Hospital) were carefully instructed in the therapy that was to be administered and how this was to be done. Standard calibration procedures laid down by the manufacturers (Cybex Division of Lumex, NY) were performed regularly on the two machines that were used.

Provision was made for patients to withdraw from the study for any of the following reasons: voluntary withdrawal, protocol violation, drug intolerance or serious illness.

Drug administration

Patients were randomly allocated to 1 of 3 groups. Group 1 ($N = 13$) received two 50 mg meclofenamate capsules and two identical diclofenac placebo capsules 3 times per day for 7 days. Group 2 ($N = 17$) received two 25 mg diclofenac capsules and two identical meclofenamate placebo

capsules 3 times per day for 7 days. Group 3 ($N = 14$) received two identical diclofenac placebo capsules and two identical meclofenamate placebo capsules 3 times per day for 7 days. The trial was performed double blind and the random code, held by the pharmaceutical company overseeing the trial, was broken only after completion of the trial. Patient compliance was controlled by counting the remaining capsules in the containers at the end of the treatment period.

Experimental procedures

Pain test

Patients were asked to assess their pain on days 1, 3 and 7 in five ways, using a visual analogue scale. Day 1 is that of the first visit, i.e. 0 - 48 hours after injury. The values for pain on the scale ranged from 0 to 10 (0 — no pain; 10 — unbearable pain) for: (i) pain experienced in the previous 24-hour period; (ii) pain on movement. The patient was positioned on his side to eliminate gravity and was asked to flex and extend the knee through the maximum available range of movement; (iii) pain on walking 10 metres (recorded as 10 if not able to do so); (iv) pain on running 10 metres (recorded as 10 if not able to do so); and (v) pain on palpation of the affected area.

The five pain scores were added together for each day and recorded as a total pain score. The result was that three total pain scores were recorded for each patient during the study, one for each assessment day. Median values for the total pain score were then obtained for each group.

Swelling test

Swelling was measured with a metric plastic tape-measure. Circumferential measurements were taken of each leg with the patient in the prone position. The site of maximum pain was determined by palpation of the affected leg. The distance from this circumferential measurement to the popliteal crease was recorded. This was done so that measurements could be taken at the same sites during subsequent visits and a measurement at the corresponding anatomical site on the opposite leg could be taken for comparison.

On each assessment day, three measurements were taken at the site of injury on the affected leg and at the corresponding site on the unaffected leg. The mean of the three readings for each leg was calculated on each assessment day. A ratio was then calculated for each assessment day by dividing the mean value for the affected leg by the mean value for the unaffected leg.

Isokinetic muscle test

Isokinetic muscle function was tested with a Cybex II dynamometer and data reduction computer (Cybex Division of Lumex, NY). This system provides an accurate measure of isokinetic muscle performance⁷ in terms of force development and endurance.

The patient was placed in the sitting position with knees and hips flexed to 90°. The axis of rotation of the lever arm of the Cybex was positioned opposite the medial femoral

condyle which is the axis of rotation of the knee joint. The distal end of the lever arm was secured to the patient via a shin pad placed just proximal to the malleoli. Thigh and shin pad straps were tightened within comfortable limits to eliminate unwanted movement, such as hip extension, and to ensure that the lower leg and the lever arm of the Cybex machine moved as one. The unaffected leg was always tested first; practice runs of five repetitions at each speed ($60^{\circ}.\text{sec}^{-1}$ and $240^{\circ}.\text{sec}^{-1}$) were allowed to enable the patient to become accustomed to isokinetic exercise. No verbal encouragement was given to the patient.

Isokinetic muscle strength of hamstrings and quadriceps muscles was tested first with 5 maximal reciprocal contractions for each leg at $60^{\circ}.\text{sec}^{-1}$. Data were measured as peak torque and expressed in Newton metres.

The endurance of the hamstring muscles was measured during 25 reciprocal contractions at a speed of $240^{\circ}.\text{sec}^{-1}$. Endurance was expressed as: (i) total work, performed during 25 contractions and expressed in joules; (ii) torque acceleration energy (joules), which is a measure of the energy expended in the first 0,125 ms of torque production; and (iii) average power (watts), which is the total work performed in the 25 contractions, divided by the total contraction time.

Both legs were tested on each of the three assessment days. A ratio was obtained for each measurement in each patient on each assessment day. This was done by dividing the value obtained in each category for the affected leg by the value obtained for the unaffected leg.

Physiotherapy treatment

All patients received the same physiotherapy treatment on all 7 days of the study. This treatment commenced after assessment on day 1, i.e. within 48 hours of injury, and stopped when the patient was fully recovered. The treatment comprised rest, ice, compression and elevation (RICE), continuous ultrasound therapy and deep transverse friction massage⁸ given on alternate days and only commencing 48 hours after injury. Patients were instructed to rest from all sporting activity for the duration of the study, to apply ice to the injury for periods of 20 minutes three times a day and to elevate the injured limb as often as possible. An elastic compression bandage was applied to the injured thigh for the first 48 hours after injury, or the remaining part thereof. Ultrasound was given continuously for 5 minutes daily with a 1 MHz sound head, at a dosage of 1 W.cm^{-2} commencing after the first 48 hours of injury. Rehabilitative exercise comprised stretching exercises for the hamstring muscles, isometric contractions (10 contractions held for 5 seconds 3 times per day) in the first 3 days after injury and aerobic exercise including swimming, running, or static cycling for 20 minutes a day starting on the third day after injury. Patients were encouraged to stretch and exercise at least three times a day. As this was a multicentre study, physiotherapists at the various centres were shown exactly what treatment to give in order for all patients to receive standard treatment.

Statistical methods

All analyses were performed using analysis of variance (ANOVA).

In order to nullify the restrictions at the upper and lower ends of the measures, the transformation formula described by Cox⁹ was used to correct for this. Therefore, instead of ratio values as described above, the following formula was used:

$$x = \frac{100}{1} \times \frac{\text{affected leg value} - \text{unaffected leg value}}{\text{unaffected leg value}}$$

$$y = \log \frac{x + 0,5}{100,5 - x}$$

Mean values were then calculated for these y-values in each assessment and plotted on the y-axis of the graph.

The acceptance level of $P < 0,05$ was used in all tests performed.

Severe injury analysis

Severe injuries were also assessed separately, as was done by Van Marion.¹⁰ For purposes of analysis, injury severity was determined as follows:

1. Patients were grouped according to their injury severity determined at the initial visit. The injury was subjectively assessed as mild, moderate or severe and assigned the values 1, 2 or 3 respectively. The same person at each centre performed these assessments.

2. Patients were grouped according to objective injury severity criteria as follows: hamstring peak torque at day 1 had to be less than 60% that of the normal leg. This test was selected because its high resistance makes it the most difficult test to perform after an acute muscle injury; the total pain value at day 1 had to be greater than 25, i.e. give an average greater than 5 out of 10 for each category; the value of severity at day 1 (see above) had to be equal to or greater than 2. For inclusion in the study, all three of the above criteria had to be met.

The variance in severity was determined between the three subgroups, by means of the Bartlett criteria. The two-way ANOVA was repeated on the severe injury subgroup.

Limitations

Because of the difficulty experienced in recruiting patients directly after injury, there was a wide discrepancy in the time which elapsed between injury and the first assessment in each case. 'Day 1' was regarded as the first assessment day although 48 hours might have elapsed since injury. These time discrepancies between the groups were analysed with the one-way ANOVA test and these data are presented in Table I.

Table I. Height, weight, injury severity, age and gender of three groups of subjects with acute hamstring injuries (mean \pm SD)

	Meclofenamate	Diclofenac	Placebo
Weight (kg)	80,8 \pm 12,1	79,7 \pm 11,9	77,2 \pm 7,8
Height (cm)	180,7 \pm 7,9	175,4 \pm 9,5	178,9 \pm 7,0
Injury severity (units)	1,8 \pm 0,7	1,9 \pm 0,6	1,7 \pm 0,7
Age (yrs)	33,8 \pm 10,6	31,8 \pm 9,9	30,7 \pm 7,9
Gender			
Male	13	16	14
Female	0	1	0
Injury to assessment	30,7	29,9	30,9
Time lapse (hrs)	15,3	13,0	12,1

Mild injuries = 1; moderate injuries = 2; severe injuries = 3.

There were no differences between groups with regard to time elapsed between injury and assessment. The same assessment was performed on the severe injury subgroup and again no differences were shown.

While the investigators went to great lengths to standardise physiotherapy treatment and its application, there were obviously variables in this regard which are difficult to avoid. These differences do, however, exist in the clinical situation.

Results

Subject characteristics

Between 1 January 1987 and 1 June 1989, 75 patients were admitted to this study. Of these, 15 were subsequently excluded for protocol violation or non-compliance prior to data analysis. Of the 60 patients who completed the study, 21 patients received meclofenamate, 19 diclofenac and 20 placebo.

There were 13 hamstring injuries and 8 quadriceps injuries in the meclofenamate group, 17 hamstring and 2 quadriceps injuries in the diclofenac group and 14 hamstring and 6 quadriceps injuries in the placebo group. In the severe-injury subgroup there were 6 patients in the meclofenamate group, 6 in the diclofenac group and 5 in the placebo group. In the non-severe-injury subgroup there were 7 patients in the meclofenamate group, 9 patients in the placebo group and 11 in the diclofenac group. Only 1 female patient was admitted to the study; she received diclofenac. As the number of quadriceps injuries was not evenly distributed between the groups, only data from the hamstring injuries were analysed.

The average weights and heights of the patients with hamstring injuries were very similar, as were their ages and the severity of their injuries (Table I).

Reported adverse effects

Thirteen of the 44 patients (29%) reported an adverse effect of medication taken during the study (Table II). None of these adverse effects warranted any reduction or alteration in medication, or any withdrawals from the study. The adverse events were mainly gastro-intestinal in nature. No patient reported more than one adverse effect.

The frequency of reported adverse effects was more than 100% higher in the treatment groups than in the placebo group.

Table II. Adverse events reported by three groups of subjects with acute hamstring injuries treated with NSAIDs or placebo

	Meclofenamate (N = 13)	Diclofenac (N = 17)	Placebo (N = 14)
Stomach cramps	1	1	0
Drowsiness	2	3	1
Diarrhoea	1	1	0
Headache	0	1	0
Dry mouth	1	0	0
Increased frequency of stools	0	0	1
Total	5	6	2

Pain

All groups showed a steady reduction in pain over the 7 days of the trial (Table III). There were no statistically significant

differences in reported pain scores between groups at any time after injury. However, there may be a trend for values to be lower in the placebo group than in either of the drug groups, and this issue may warrant further investigation.

Swelling

No significant differences were found in the rate of swelling reduction between the three groups (Table III).

Table III. Pain and swelling scores in three groups of patients with acute hamstring injuries treated with NSAIDs or placebo

	Day 1		Day 3		Day 7	
	Median	SD	Median	SD	Median	SD
Pain units						
Meclofenamate	24,4	9,0	15,3	9,0	7,9	6,6
Diclofenac	26,8	10,0	17,8	8,7	8,8	7,7
Placebo	25,4	12,2	12,6	8,3	3,9	3,3
Swelling units						
Meclofenamate	1,008	0,020	1,002	0,012	0,995	0,009
Diclofenac	1,002	0,024	0,998	0,020	0,994	0,018
Placebo	1,007	0,018	1,004	0,015	0,998	0,013

Muscle function testing

Fig. 1 shows that there was no difference between groups in either absolute values or the rate of recovery of hamstring peak torque, average power or total work done on days 1, 3 or 7 of the study. No differences were found after the transformation formula was applied.

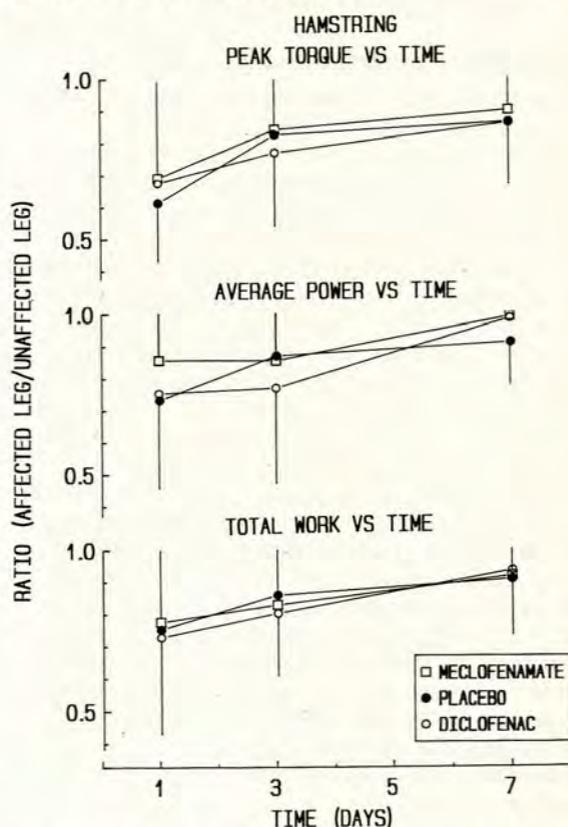


Fig. 1. Ratios for peak torque (top), average power (middle) and total work (bottom) measured during maximal isokinetic exercise of the hamstring muscles of the affected/unaffected legs of three groups of subjects treated with NSAIDs or placebo. Note that there were no significant differences between groups.

Analysis of severe injuries

The variance in severity within the three severe injury subgroups was similar. Subjects with severe hamstring injuries who received placebo demonstrated a steeper reduction in pain at day 7 than did subjects in either of the drug-treatment groups (Fig. 2).

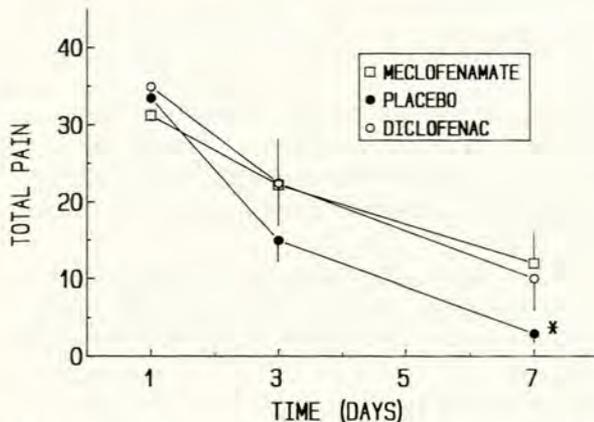


Fig. 2. Changes in total pain scores in three groups of subjects with severe acute hamstring injuries treated with NSAIDs or placebo. Note that pain scores were significantly lower in the placebo group than in the meclofenamate group on day 7.

There were no other significant differences in any parameters between the three groups with severe injuries.

Discussion

It is important that any therapy used in medical management should be thoroughly evaluated before it is used routinely. This applies as much to the use of NSAIDs in sports-related trauma, including acute muscle tears, as to the use of any other form of medical therapy.

Yet, despite the widespread use of NSAIDs, recent reviews^{5,11} have found that of 43 studies over the past 16 years that evaluated their value in the management of sports injuries, only 8^{10,12-18} met scientific criteria for objectivity, i.e. they dealt with a single injury type and included a placebo-control group. Only 3 of these studies,^{14,15,17} which have used objective measures to evaluate treatment outcome, have demonstrated a significantly beneficial effect of NSAIDs. On this basis, a number of reviewers have concluded that NSAIDs are no more effective than placebo in the management of acute sports injuries.^{10,12,13,19,20}

On the other hand, concern has been expressed about possible detrimental effects of NSAIDs on acute muscle injuries. Laboratory experiments have shown that although NSAIDs reduce swelling and inflammation, they may also delay muscle regeneration for the first 4 days and slow down the clearance of cellular debris.^{2,3} However, Dahners *et al.*²¹ showed that although piroxicam increased ligament strength during the early healing phase, there was no effect on the strength of either healed or normal ligament.

In addition these drugs are used widely despite their adverse effects; these were also evident in this study (Table II).

Accordingly, the most important finding of this study was that recovery from acute hamstring injury measured as the reduction of pain and swelling and the normalisation of muscle strength and endurance was not different in groups receiving accepted physiotherapy management with or without NSAIDs. This was true for all injuries and also for the more severe injuries when analysed separately.

In contrast, when only severe injuries were considered, reduction in pain was greatest in the placebo group with the result that the total pain score was significantly lower in the placebo group than in the group receiving meclofenamate at day 7 (Fig. 2). This is a particularly remarkable finding, given the strong analgesic properties of both the NSAIDs used in this study. One possibility, most obvious in more severe injuries, is that NSAIDs delay recovery,^{2,3} and that this delay is shown in a more prolonged return to pain-free function, despite the extra analgesia provided by these agents.

These results therefore provide no compelling evidence that NSAIDs were of additional value in the management of acute muscle trauma. This was also the conclusion of Huskisson *et al.*²² and Almekinders and Gilbert,² who found no evidence that the use of NSAIDs enhanced the healing of soft-tissue injuries.

In contrast, standard physiotherapy treatment which included the use of rest, ice application, compression bandaging and elevation of the injured area for the first 24 - 48 hours after injury,^{23,24} ultrasound therapy,^{7,25-28} deep friction massage^{8,29,30} and intensive rehabilitation including stretching and strengthening exercises^{7,22,27,31-34} was associated with rapid recovery of function within 7 - 10 days.

In conclusion, this study found that intensive but conventional physiotherapy effected a rapid reduction of pain in acute hamstring muscle injuries and that NSAIDs had no additional measurable effect on the rate of reduction of pain or swelling in these injuries. Such treatment may, however, have delayed the pain recovery in those with the most severe injuries.

Accordingly, we suggest that in view of the cost, adverse effects and risks of delayed healing,² NSAIDs should not be prescribed routinely for acute muscle injuries until such time as convincing evidence for their efficacy in this condition becomes available. In the interim it would seem that conventional physiotherapy remains the treatment of choice for this condition.

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