Anti-inflammatory and combined anti-inflammatory/analgesic medication in the early management of iliotibial band friction syndrome

A clinical trial

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Summary

Forty-three athletes presenting with unilateral iliotibial band friction syndrome (ITBFS) were randomly divided into three groups for the first 7 days of treatment (placebo-controlled, double-blind): 1 — placebo ($N = 13$); 2 — anti-inflammatory medication ($N = 14$) (Voltaren; Geigy); and 3 — analgesic/anti-inflammatory combined medication ($N = 16$) (Myprodol; Rio Ethicals). All subjects rested from day 0 to day 7 and all groups received the same physiotherapy outpatient treatment programme from day 3 to day 7. On days 0, 3 and 7 the subjects performed a functional treadmill running test (maximum 30 minutes) during which they reported pain (scale 0 -10; 0 = no pain, 10 = unbearable pain) each minute. Total running distance, total running time and the area under the pain v. time curve was calculated. Daily 24-hour recall pain scores were also recorded. The 24-hour recall pain scores decreased significantly for all the groups over the treatment period. This method of assessing efficacy of treatment therefore failed to show differences between groups. In contrast, during the running test only group 3 improved their total running time and distance from day 0 to day 7, whereas in all the groups the area under the pain v. time curve decreased from day 0 to day 7. All the other groups improved total running time and running distance from day 3 to day 7. All three treatment modalities are effective in the early treatment of ITBFS but physiotherapy in combination with analgesic/anti-inflammatory medication is superior. A functional running test, which is more sensitive than conventional pain-recall methods in assessing efficacy of treatment in this type of clinical trial, is described.

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Iliotibial band friction syndrome (ITBFS) is a well-described overuse injury of the knee.[1-8] It is commonly seen in distance runners (4 - 7% of lower extremity injuries),[4,8] but has also been described in military recruits,[1,9] weight lifters,[4] downhill skiers[4] and athletes engaged in circuit training.[4] The anatomy of the iliotibial tract,[10] and the clinical presentation of ITBFS have been well described.[1-8,11]

The postulated mechanism of injury in ITBFS is repetitive friction of the iliotibial band as it moves over the prominent lateral femoral epicondyle during flexion/extension movements of the knee.[4,6] This frictional movement may be exacerbated by factors such as training errors,[6] genu varus,[7] cavus foot,[11] leg length discrepancy,[7] road camber[7] and hard running shoes.[7] The pathology of ITBFS is inflammation under the iliotibial tract over the lateral epicondyle. This has been confirmed by macro- and microscopic findings.[4,6]

The management of ITBFS is based on correction of the underlying factors that exacerbate the injury, decreasing activity, stretching the iliotibial band,[5] treatment of the inflammation and a gradual return to activity. In a small group of patients surgery is indicated.[2]

The inflammatory process can be treated with rest, ice, oral anti-inflammatory medication, physiotherapy or local steroid injection.[3,6,8,11,12] It is important to treat the inflammation to reduce the risk of permanent damage with scarring.[2]

The use of non-steroidal anti-inflammatory drugs (NSAIDs) to decrease the inflammatory process in sports injuries has been well described.[13,14] Despite their widespread use, vey few well-conducted clinical trials on the use of these drugs in sports injuries have been reported. The major limitations of these previously reported studies are poorly defined populations;[15–23] severity of the injuries not well defined;[16,17,19,20] not conducted as double-blind studies;[17,24] and measures of therapeutic response being subjective.[15–17,19–24] Furthermore, most studies have been conducted on acute injuries and only one study[17] has documented the use of NSAIDs in overuse injuries.

Although conservative treatment with NSAIDs appears to alleviate the symptoms associated with ITBFS after a few days,[1,12] there are no well-controlled clinical trials to substantiate this. Furthermore, no studies have been conducted to evaluate the use of physiotherapeutic modalities alone or in combination with anti-inflammatory medication in the treatment of ITBFS. The use of combined analgesic/anti-inflammatory medication has also not been compared to anti-inflammatory medication alone in the management of sports injuries.

The primary aim of this study was to compare the use of physiotherapeutic modalities alone or in combination with anti-inflammatory medication (Voltaren; Geigy) or analgesic/anti-inflammatory medication (Myprodol; Rio Ethicals) in the early treatment of ITBFS. A secondary aim was to establish a functional and sensitive test that could be used to assess the efficacy of treatment of sports injuries to the lower limb.

Patients and methods

Patients presenting with unilateral ITBFS were recruited from two sports injury clinics over a period of 9 months (April 1989 - December 1989). The two clinics were the Sports Injury Clinic at the University of Cape Town Sports Centre and the Biokinetic Centre at 1 Military Hospital, Voortrekkerhoogte.

Only patients over the age of 18 years with a confirmed clinical diagnosis of unilateral ITBFS were included in the study. Pregnant patients, those with a history of hypersensitivity to anti-inflammatory or analgesic medication, those with peptic ulcer disease, asthma, haematological disease, hepatic or renal disease, previous knee surgery, and those on concomitant medical therapy were not included in the study.

Each patient was examined and the diagnosis of unilateral ITBFS was made using the following diagnostic criteria: (*i*) history of pain on the lateral aspect of the knee during running;[1,6,8] (*ii*) tenderness over the lateral femoral condyle;[3,4,7] (*iii*) tenderness over the lateral femoral condyle aggravated at 30° of the knee flexion;[2] and (*iv*) normal examination of the knee joint.

The severity of the condition was assessed by grading the pain experienced during running as follows:[7] grade 1 — pain after the run but not restricting the distance or the speed of running; grade 2 — pain during the run but not restricting the distance or the speed of running; grade 3 — pain during the run and severe enough to restrict distance or speed; and grade 4 — pain severe enough to prevent running. Only patients complaining of grade 3 or 4 pain were included in the study.

Written informed consent was obtained from all the patients according the guidelines suggested by the American College of Sports Medicine.[25] The study was approved by the Ethics and Research Committee of the Faculty of Medicine of the University of Cape Town. A running history, which included the following details, was obtained from all the patients: years of running; duration of symptoms; weekly training distance; and average training speed.

Forty-nine patients were entered into the trial and randomly divided into three treatment groups (groups 1, 2 and 3) for the first 7 days of treatment. Three subjects each from groups 1 and 2 were excluded from the final results. The reasons for exclusion were: incomplete follow-up (4); severe side-effects (1); and refusal to comply with the physiotherapy treatment programme (1). The final number of subjects was forty-three.

All the groups received treatment as outpatients. The treatment consisted of rest, ice (twice daily local application) and medication from day 0 to day 7. From day 3 to day 7 they also received physiotherapy. The physiotherapy at the two centres was the same. There were thus two distinct phases in the treatment programme: day 0 to day 3 (rest, ice and medication alone) and day 3 to day 7 (added physiotherapy). The physiotherapy programme consisted of daily stretching of the iliotibial band,[5,26] daily ultrasonography[12] to the tender area, and transverse frictions to the area on days 3, 5 and 7. The value of transverse frictions in this injury is not documented but was included on the basis of anecdotal evidence that it might be effective.

Medication was given for the 7-day period in a double-blind, placebo-controlled fashion as follows: group 2 received 50 mg diclophenac sodium 3 times a day with meals. The tablets were packed into capsules indistinguishable from the capsules used by the other groups; group 3 received a similar capsule containing 400 mg ibuprofen, 500 mg paracetamol and 20 mg codeine phosphate 3 times a day; and group 1 received a placebo capsule 3 times a day. Compliance was monitored by counting the capsules remaining in the containers on day 7. The code with the identity of the capsules handed to each patient was revealed only after the analysis of all the data was completed.

The efficacy of the treatment was assessed by two methods: (*i*) conventional daily pain recall on a scale,[27–29] and (*ii*) a functional treadmill running test.

On the first visit the patient was familiarised with the pain scale used for the daily pain recall and the treadmill running test. The pain scale was a visual analogue scale from 0 to 10 where 0 represented no pain and 10 unbearable pain.[27] Patients were instructed to record their pain experienced at rest, during walking and overall pain every day on a pain report form. The decrease in reported pain was compared in the three groups.

The treadmill running test was performed on day 0, day 3 and day 7. The subjects were dressed in running shorts and vests and wore the same running shoes for all tests. The running speed was the same for each test on the 3 days for each subject and was selected for each subject on the basis of their average daily training speed. A walking test was used for those subjects who were unable to run. The gradient of the treadmill was 0° for all the tests. The tests were always performed at the same time of day (morning) and on the test day the subjects were requested not to take their morning dose of the medication until after the test was completed.

The test was preceded by a warm-up of 1 minute brisk walking. During the test subjects were asked to report each minute on the pain they experienced and it was discontinued if the pain was of such a severity that it would normally decrease the running speed or distance of a runner (7 - 8 on the pain scale) or after 30 minutes of running. The subjects were free to stop at any time but all complied with the running test protocol as outlined above. The speed and distance run was also recorded every minute.

The pain grading was plotted against time (minutes) for each subject on days 0, 3 and 7. The area under the pain v. time curve was calculated from the graphs using the minimum time the subject could run on any of the 3 days (usually day 0). This area is an indication of the total pain experienced during that time. These data were then compared between the three groups and within groups over the 7-day period.

The adverse effects of the medication were assessed on the 3rd and 7th day by a personal interview conducted by the

principal investigator. The following information was obtained: description of symptoms; duration and severity of symptoms (mild, moderate or severe); the relationship of symptoms to the medication; and the management.

Statistical analysis

Statistical analysis was performed by the Institute for Biostatistics of the South African Medical Research Council using the BMPD package on the ISM 4381 mainframe computer. Between-group comparison for physical characteristics, running history, area under the pain/time curve, total running time, total distance run, and daily reported pain was obtained by one-way analysis of variance, after testing that there was no sex-by-group interaction. Significant change over time (from days 0 - 3, days 0 - 7 and days 3 - 7) for the variables within groups was estimated by Wilcoxon's signed-rank test. The level of significance was established at $P < 0,05$, since this is considered a probing experiment. The test level was not adapted according to Bonferroni for the number of comparisons being made.[30]

Results

Table I summarises the age, height, weight and running history of the subjects in each group. There were no significant differences between groups for years of running, average weekly training distance or training speed. In particular, the grade and duration of the injury at the onset of the study was similar in all three groups.

TABLE I. PHYSICAL CHARACTERISTICS AND TRAINING HISTORY

Variable	Group	Mean ± SD
Age (yrs)	1	22 ± 5
	2	24 ± 6
	3	22 ± 2
Mass (kg)	1	74 ± 5
	2	72 ± 6
	3	68 ± 7
Height (cm)	1	181 ± 3
	2	181 ± 6
	3	178 ± 4
Years of running (yrs)	1	10 ± 5
	2	5 ± 5
	3	6 ± 6
Duration of symptoms (wks)	1	6,8 ± 7,1
	2	6,1 ± 8,1
	3	7,4 ± 13,1
Running distance/wk	1	44 ± 29
	2	48 ± 33
	3	39 ± 14
Training speed (min/km)	1	4,9 ± 0,3
	2	4,6 ± 1,0
	3	4,6 ± 0,8
Injury grade at presentation	1	3,2 ± 0,4
	2	3,1 ± 0,3
	3	3,3 ± 0,5

No significant differences were observed between groups.

The mean daily pain scores recorded for overall pain over the treatment period in each group is depicted in Fig. 1. Pain scores at rest and during walking displayed a similar pattern and are therefore not shown. The initial mean scores in all three groups decreased in the first 2 days, then were associated with an increase on day 3 followed by a decrease to day 6. There was a significant decrease in pain scores in all three groups from day 0 to day 2, day 0 to day 6 and day 3 to day 6 (Fig. 1).

The results of pain recorded during the treadmill running test are shown in Figs 2, 3 and 4. The value for pain (area under the pain v. time curve) for the three groups (Fig. 2) was not significantly different between the groups on any of the days. However, there was a significant decrease in the values from day 0 to day 3 for group 3 only. From day 3 to day 7 there was a decrease in the values for groups 1 and 3 but not group 2 and from day 0 to day 6 there was a significant decrease in all three groups.

The total distance run did not differ significantly on each of the test days between the groups (Fig. 3). In all three groups the total distance run did not change significantly from day 0 to day 3 but did increase significantly from day 3 to day 7. However, only in group 3 was running distance significantly increased from day 0 to day 7.

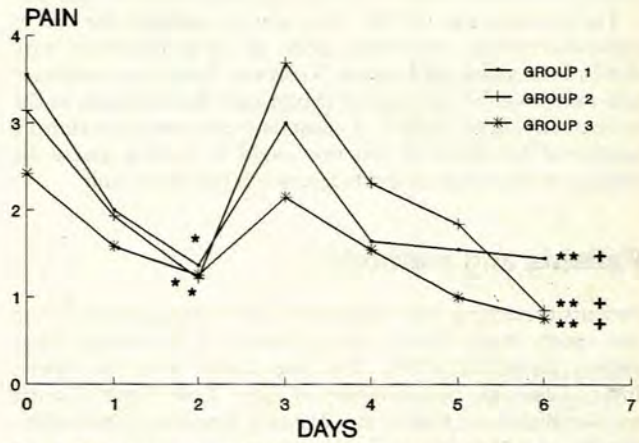

Fig. 1. The mean overall daily pain recorded in each group. Significant differences ($P < 0,05$) are indicated as follows: day 0 - 2 *; day 0 - 6 **; and day 3 - 6 +.

Total running time did not differ significantly between groups on each of the test days (Fig. 4). Group 1 showed a significant reduction in running time from day 0 to day 3. The running time was improved significantly in all the groups from day 3 to day 7 but only group 3 showed a significant improvement from day 0 to day 7.

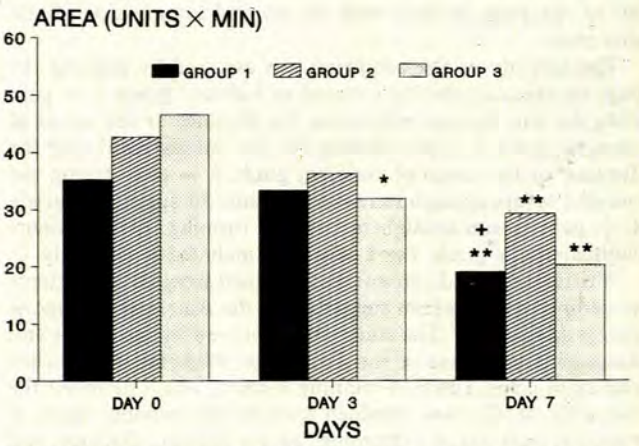

Fig. 2. The pain experienced during running (area under the pain v. time curve) for the three groups on day 0, 3 and 7. Significant differences are indicated as follows: day 0 - 3 *; day 0 - 7 **; and day 3 - 7 +.

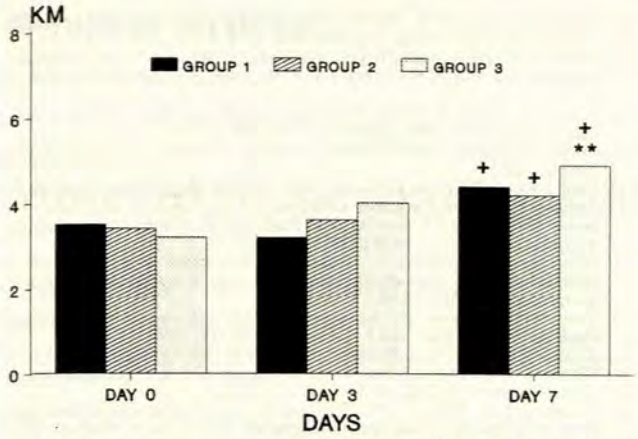

Fig. 3. Total distance run on each of the test days for the three groups. Significant differences are indicated as follows: day 0 - 3 *; day 0 - 7 **; and day 3 - 7 +.

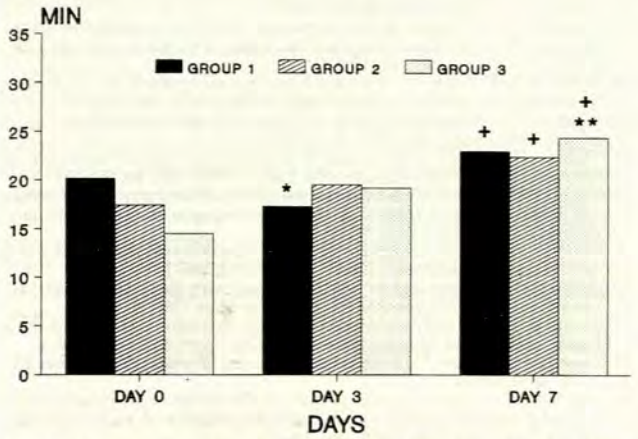

Fig. 4. Total running time on each of the test days for the three groups. Significant differences are indicated as follows: day 0 - 3 *; day 0 - 7 **; and day 3 - 7 +.

The side-effects associated with medication are reported for the three groups in Table II. The incidence (side-effects/week) was 38%, 28% and 23% for groups 1, 2 and 3, respectively. The most common side-effects were headache and nausea. Only 1 subject withdrew from the study because of severe nausea (group 3).

Discussion

Clinical studies to evaluate the effectiveness of different anti-inflammatory medications in sports injuries are mostly vague, conflicting and difficult to interpret because: (*i*) a wide variety of different injuries are usually studied; (*ii*) the severity of injuries often differ; and (*iii*) they rely on very subjective criteria to measure the outcome of treatment.[14] ITBFS is a well-defined, specific injury in which the severity can be graded accurately on the basis of the symptoms.[7] Its pathology is an inflammatory process[4,6] resulting in pain as the main symptom. This injury is therefore an ideal 'model' that can be used to study the effectiveness of different anti-inflammatory or analgesic medications or both.

The principal findings of this study were that ITBFS is best treated in the 1st week by a physiotherapy programme together with combined analgesic/anti-inflammatory medication. Treatment with physiotherapy alone was more effective than when combined with anti-inflammatory medication although both did result in improvement of the condition. In addition, a successful and sensitive functional test is described, which evaluates the effectiveness of treatment in a lower extremity overuse sports injury.

In this study the usual method of daily pain record assessment showed a significant decrease in pain over the treatment period in all three treatment groups. The only exception was the pain recorded at rest in group 3. Based on this traditional method of assessing outcome the effectiveness of the three treatment protocols were similar.

In contrast the novel functional treadmill running test described here did demonstrate differences in the response to treatment in the three groups. Only group 3 showed a significant improvement in running time and distance run from day 0 to day 7. The values for pain on different days decreased significantly for all the groups over the 7 days, perhaps indicating that it is less sensitive than running time or running distance in assessing outcome.

The positive effect of adding physiotherapeutic modalities (ultrasonography and transverse frictions) to the treatment programme is suggested by this study. Total running time and total distance run were improved in all three groups from day 3 to day 7. The values for pain from day 3 to day 7 were also improved in groups 1 and 3 but not group 2. The beneficial effect of rest alone from day 3 to day 7 was not studied and can therefore not be excluded as an additional factor to explain improvement from day 3 to day 7.

The only medication that had an early effect on the functional test was the combined analgesic/anti-inflammatory agent where the pain values decreased from day 0 to day 3. Daily pain

TABLE II. ADVERSE EFFECTS REPORTED IN EACH GROUP

Group	Incidence	Severity	Relationship	Symptoms
1	**38% (5/13)**	**Mild**	**Unrelated**	**Nausea**
		Mild	**Probable**	**Headache**
		Mild	**Unrelated**	**Fatigue**
		Mild	**Probable**	**Abdominal pain**
		Mild	**Unrelated**	**Dizziness**
2	**28% (4/14)**	**Mild**	**Probable**	**Nausea**
		Moderate	**Unrelated**	**Headache**
		Moderate	**Probable**	**Headache**
		Moderate	**Unrelated**	**Headache**
3	**23% (4/17)**	**Mild**	**Definite**	**Headache**
		Moderate	**Probable**	**Sore throat**
		Moderate	**Definite**	**Nausea**
		Severe	**Definite**	**Nausea***

* Significant enough to withdraw from the study.

scores decreased in all the groups during this period but significant differences were not observed between the groups.

The reason for the better performance of the combined analgesic/anti-inflammatory medication is not clear. The most likely explanation is that a greater analgesic effect is achieved, which would blunt the pain experienced during running and other daily activities. However, it must be noted that the running test was performed without the morning dose of the medication and would have been at least 10 hours after the last dose. The dose of anti-inflammatory drug administered was 50 mg 3 times a day — the recommended dose. A low dose could therefore not account for its relatively poor performance.

Although the mean number of years of running was higher in group 1 than in the other two groups (not statistically higher), it is most unlikely that this could account for differences in treatment outcome. There is no evidence to indicate that years of running affects prognosis in ITBFS.

The incidence of adverse effects was similar in all three groups indicating that they were probably not related to the medication. It must be noted that 1 subject on combined analgesic/anti-inflammatory medication withdrew because of severe nausea. The other adverse effects were mild and did not affect the treatment outcome.

In summary, this study demonstrates that physiotherapy (ultrasonography and cross friction) together with combined analgesic/anti-inflammatory medication is the most effective early treatment for athletes presenting with ITBFS. In addition, a functional treadmill running test is described, which is more sensitive than conventional pain recall methods in assessing efficacy of treatment in this type of clinical trial.

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