ORIGINAL ARTICLE

Local corticosteroid injection in iliotibial band friction syndrome in runners: a randomised controlled trial

P Gunter, M P Schwellnus

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See end of article for authors' affiliations

Correspondence to:
Professor Schwellnus,
UCT/MRC Research Unit
for Exercise Science and
Sports Medicine,
Department of Human
Biology, Faculty of Health
Sciences, University of
Cape Town, Sports Science
Institute of South Africa,
Boundary Road, Newlands
7700, South Africa;
mschwell@sports.uct.ac.za

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Objective: To establish whether a local injection of methylprednisolone acetate (40 mg) is effective in decreasing pain during running in runners with recent onset (less than two weeks) iliotibial band friction syndrome (ITBFS).

Methods: Eighteen runners with at least grade 2 ITBFS underwent baseline investigations including a treadmill running test during which pain was recorded on a visual analogue scale every minute. The runners were then randomly assigned to either the experimental (EXP; nine) or a placebo control (CON; nine) group. The EXP group was infiltrated in the area where the iliotibial band crosses the lateral femoral condyle with 40 mg methylprednisolone acetate mixed with a short acting local anaesthetic, and the CON group with short acting local anaesthetic only. The same laboratory based running test was repeated after seven and 14 days. The main measure of outcome was total pain during running (calculated as the area under the pain versus time graph for each running test).

Results: There was a tendency ($p = 0.07$) for a greater decrease in total pain (mean (SEM)) during the treadmill running in the EXP group than the CON group tests from day 0 (EXP = 222 (71), CON = 197 (31)) to day 7 (EXP = 140 (87), CON = 178 (76)), but there was a significant decrease in total pain during running ($p = 0.01$) from day 7 (EXP = 140 (87), CON = 178 (76)) to day 14 (EXP = 103 (89), CON = 157 (109)) in the EXP group compared with the CON group.

Conclusion: Local corticosteroid infiltration effectively decreases pain during running in the first two weeks of treatment in patients with recent onset ITBFS.

The iliotibial band friction syndrome (ITBFS) can be defined as an inflammatory condition of the lateral aspect of the knee resulting from repetitive friction between the iliotibial band and the lateral femoral condyle. It is a fairly common running injury and accounts for 1.6–12% of all running related injuries.^{1–2} In a recently reported survey of athletes seen at a sports injury clinic, it was the second most common running injury.³ It has also been described in military recruits undergoing training,^{4–8} cyclists,^{4–12} football players,^{12–13} downhill skiers,^{13–14} and weight lifters.¹³

The classic clinical presentation of the injury in runners is that of gradual onset, progressive lateral knee pain. The pain often starts at a predictable distance and is often relieved when the knee is kept in full extension, and is aggravated by repetitive knee flexion, particularly at a 30° angle. This injury eventually forces the athlete to run shorter and shorter distances until virtually no training is possible.

Numerous possible factors contributing to the development of ITBFS have been described: (a) factors that cause repetitive movement of the iliotibial band over the lateral femoral condyle such as a sudden increase in the volume of training and hill training^{15–18}; (b) factors that may increase the tension and thus a frictional force over the lateral femoral condyle such as genu varus,¹⁹ rearfoot varus,² a cavus foot,^{16–20} iliotibial band inflexibility, weakness of the hip abductor muscle group,²¹ abnormal lower limb alignment,²² knee flexion angle at footstrike²³; (c) other intrinsic factors such as an excessive prominence of the lateral femoral condyle,¹⁵ younger age,³ male sex,^{13–17} and ectomorphic and mesomorphic somatotypes.¹⁷ There are, however, few data from well conducted scientific studies to link these factors in a causal relation to the development of ITBFS in runners.

The gross pathology and histopathology of ITBFS has been described in tissue obtained at the time of surgery. Features of chronic inflammation^{12–16} characterise the macroscopic appearance of tissue between the distal iliotibial band and

the lateral femoral condyle. A reddish brown bursal thickening under the iliotibial tract, possibly due to chronic inflammation, has been observed,¹⁶ but a true bursa does not appear to be characteristic of the pathology.^{16–24} These findings have been supported by more recent reports using magnetic resonance imaging to define the pathology in ITBFS.^{25–27} Histological examination of tissue obtained at the time of surgery showed areas of mucoid degeneration of fibroid necrosis.¹² It therefore appears that the pathology of ITBFS is that of an acute inflammatory process resulting from repetitive trauma to the tissues between the iliotibial band and the lateral femoral condyle.¹ If left untreated, the acute inflammatory process continues and can result in the chronic inflammatory response that has been observed at the time of surgery. Surgery is usually performed only in refractory cases.²⁸

The treatment for ITBFS in the early phase (first two weeks) therefore involves management of the local inflammation and pain. It is this time period in the course of the injury that is the focus of this study. After the inflammatory process has been treated, correction of the underlying causes of the injury becomes a priority.

A number of treatment modalities have been suggested for the early phase of treatment of ITBFS. These include rest,^{1–4–12–24–29–31} alternative activity such as pool running,³² reducing the amount and intensity of running,^{16–17} ice,^{1–2–16–17–29–33} stretching,^{1–15–19} massage,^{29–33–34} and oral non-steroidal anti-inflammatory drugs.^{1–4–12–13–16–17–30–33} However, there are very few published randomised controlled trials to support the use of these modalities in the early phase treatment of ITBFS. In only one randomised placebo controlled clinical trial has a combination of an

Abbreviations: ITBFS, iliotibial band friction syndrome; VAS, visual analogue scale

anti-inflammatory/analgesics together with physiotherapy been shown to increase total running time and decrease pain in the first two weeks of treatment.³³

In addition to the treatments already mentioned, it is also popular clinical practice to inject the area between the lateral femoral condyle and the iliotibial band with corticosteroids to reduce the local inflammation.^{1 12 19 29 31 32} However, despite the popularity of this practice, the effect of local corticosteroid injection at the site of tenderness has never been evaluated in a randomised placebo controlled clinical trial.

The aim of this study was to determine whether a single local infiltration of corticosteroid into the area between the iliotibial band and the lateral femoral condyle decreases pain during running in the first two weeks of treatment.

METHODS

Subjects

All male and female runners aged 20–50 attending the sports medicine clinic of a Staff Model Health Maintenance Organisation (Vaalmed) in South Africa, who were diagnosed clinically with ITBFS, were potential subjects. They were all athletes from local running clubs, and were either self referred or referred by their general practitioners.

Approval for the study was obtained from the ethics and research committee of the Faculty of Health Sciences of the University of Cape Town.

Diagnosis of ITBFS was based on history, clinical examination, and special clinical tests. Patients were considered if they presented with pain of recent onset (in the preceding 14 days) on the lateral aspect of the knee during repetitive flexion and extension movements of the knee.

Subjects underwent a full clinical assessment. The following information was obtained: age, weekly running distance, best 10 km running time, pain localisation, degree of pain, medical and surgical history, history of allergies (lignocaine or corticosteroids), and family history.

Criteria for inclusion were that the pain had to be: (1) well localised to the lateral femoral condyle; (2) sharp; (3) characterised by a sudden onset, usually after a specific time (or distance of running); (4) more intense at the stage when the foot comes into contact with the ground during deceleration (when contraction of tensor fascia occurs at 30° knee flexion); (5) worse during downhill running—because there is a reduced angle of knee flexion at foot strike when running downhill and therefore the posterior border of the iliotibial band is in the “impingement zone” over the lateral femoral condyle for a longer period of time²³; (6) relieved by walking with the knee in full extension.

The history was followed by a full clinical examination to confirm the diagnosis of ITBFS and to exclude any contraindications to methylprednisolone administration. MPS performed all the medical assessments. Specific features in the clinical examination considered to be diagnostic were: (1) tenderness of the lateral femoral condyle located 2 cm above the lateral joint line of the tibiofemoral joint; (2) elicitation of pain at 30–40° of flexion when a finger was held on the lateral condyle during flexing and extending of the knee¹⁶; (3) pain on weight bearing on the affected limb at knee flexion of 30–40°. The diagnosis was made on the basis of a classic history and the presence of criterion 1 and at least one of the other two criteria on clinical examination.

Subjects with a confirmed clinical diagnosis of ITBFS were excluded from the study if: (1) the pain was not severe enough to impair running performance; (2) there was an unwillingness to adhere to the period of rest, icing, and abstinence from running during the first 14 days of treatment; (3) the subject had a history of allergy to methylprednisolone acetate or lignocaine.

Forty five runners were screened, but only 18 fulfilled the inclusion criteria. The most common reasons for not including potential subjects were that they were not willing to comply with the protocol and that the pain was not severe enough.

Day 0: screening, familiarisation, and randomisation

Subjects dressed in appropriate running gear including their normal running shoes (which were used for each subsequent test) were familiarised with the treadmill running test. A previously validated³³ treadmill running test was used to measure the amount of pain that subjects experienced during normal running. There was a warm up period of five minutes. During this phase, all the subjects ran on the motorised treadmill at a slow speed equivalent to 7 min/km. A 10 point visual analogue scale (VAS) was used during the test to measure pain experienced during running (fig 1). Subjects were instructed to report the severity of the typical pain on the lateral side of the knee at the site of ITBFS pain at the end of every minute of the test. A chart with the VAS was displayed on the wall in front of the treadmill so that the subject could easily see it while running.

After the warm up period (first five minutes of running), the speed of the treadmill was increased to the subjects' best recent 10 km running speed. This speed was then maintained for 30 minutes or until the pain reached 8 (severe pain) on the VAS. The test was then terminated.

After the treadmill running test had been completed, the subjects were randomly assigned to either the experimental (EXP) or control (CON) group in a single blind (subject blinded but not investigator) fashion. The EXP group (n = 9) received an injection of 40 mg (1 ml) methylprednisolone acetate (Depot-Medrol; Pharmacia and Upjohn, Craighall, Johannesburg, South Africa) mixed with 10 mg (1 ml) 1% lignocaine hydrochloride (Fresenius Kabi, Halfway House, South Africa). The CON group (n = 9) received an injection of 20 mg (2 ml) 1% lignocaine hydrochloride into the space between the lateral femoral condyle and the iliotibial band.

PG used the following technique while injecting the subjects:

- After receiving an explanation of the injection technique, the subject was positioned lying on his/her side with the affected leg on top.
- The knee was flexed to 30° and the point of maximal tenderness (the area to be injected on the lateral femoral condyle) was identified and sterilised using 90% ethanol.
- 2 ml either 1% lignocaine hydrochloride (CON group) or 1 ml methylprednisolone acetate together with 1 ml 1% lignocaine hydrochloride (EXP group) was drawn into a 2.5 ml disposable syringe.
- While identifying the iliotibial band with the thumb of the left hand and sliding it over the posterior border of the

0	No pain
1	
2	Mild pain
3	
4	
5	Moderate pain
6	
7	
8	Severe pain
9	
10	Unbearable pain

Figure 1 Visual analogue scale of pain perception.

iliotibial band, the index finger of the left hand was kept on the area to be injected.

- Approaching from the posterior aspect, the needle was directed at 90° to the long axis of the body and medial to the posterior border of the iliotibial band.
- The needle was advanced until it was under the index finger of the left hand deep to the iliotibial band at the point of maximal tenderness just lateral to the lateral femoral condyle tubercle, and the solution was injected slowly over 15 seconds.
- The subject was then observed for 20 minutes in case of any allergic or other adverse reaction.

Subjects were then instructed not to run for a period of 14 days. They were allowed to continue with work related activities but not any exercise training. They were asked to keep a daily diary, recording any side effects or adverse reactions. They were also instructed to report for a follow up treadmill running test after 7 and 14 days. The only other treatment was self application of ice wrapped in a towel to the area twice daily at 12 hour intervals for 30 minutes.

Subjects were requested to record their perception of pain on the lateral aspect of the knee every evening over the 14 day period in a logbook using the same VAS as was used during the running test.

Days 7 and 14

The subjects were followed up after 7 and 14 days. At each visit, it was established whether the subject had adhered to the initial period of relative rest and if there were any side effects or adverse reactions. The treadmill running test was repeated. After the test on day 7, subjects were again instructed to abstain from running or other athletic activities for the following seven days. The procedure on day 14 was the same as on day 7.

Statistical analysis

The results were analysed by the Department of Statistics at the University of Potchefstroom (Vaal Triangle Faculty). The Stat Advisor package on the mainframe computer was used. The two groups were compared with respect to the following general characteristics: age, weight, height, running history, and training history (best 10 km running time, weekly running distance). The main measures of outcome of the study were total pain experienced during running and daily pain recorded on the VAS.

A graph of pain (VAS units) on the y axis (1–10) was plotted against time run (minutes) on the x axis for each of the three treadmill tests for each subject. The area under the pain versus time curve was calculated as a measurement of the total pain experienced during running in each subject. If the pain became severe (score of 8) and the test had to be terminated, the area of the pain versus time for that subject was calculated using the maximum pain score of 8 for the remainder of the test (until 30 minutes). Total pain experienced during running was compared between the EXP and CON groups on days 0, 7, and 14.

Standard skewness and standard kurtosis were used to establish whether there were any differences in physical characteristics between the two groups. Different tests were then used to establish whether there were any differences in the outcome of the injections in the EXP and CON groups. A *t* test was used to compare the means of the two samples. It was also used to construct confidence intervals for each mean and for the difference between the means. An *f* test was also run to compare the standard deviations of the two samples. The level of significance was established as $p < 0.05$.

RESULTS

Physical characteristics, running, and training history

Table 1 shows the physical characteristics of the subjects in the CON and EXP groups. There were no significant differences in any of the physical characteristics, running history, or training history between the two groups.

Total daily pain

Data from the daily pain recall could not be analysed further in any meaningful way, because virtually all the runners reported no pain every day over the 14 day testing period. It was clear that, for this running population, this measure of outcome was not sensitive enough.

Total pain during running

Figure 2 shows the results of the total pain (pain $\times$ time) experienced during the 30 minute treadmill running test. A significantly greater decrease in total pain was experienced by subjects in the EXP than the CON group in the period from day 7 to day 14 ($p = 0.01$). From day 0 to day 7, there was a tendency to decreased total pain in the subjects in the EXP group during running ($p = 0.07$). There was also a significant improvement in pain during running in the EXP group compared with the CON group in the period day 7 to 14 ($p = 0.01$) (fig 2).

Side effects/adverse reactions

None of the subjects reported any side effects or adverse reactions as a result of either the placebo or the active injection.

DISCUSSION

In this study, the efficacy and safety of injection of methylprednisolone into the area between the lateral femoral condyle and the iliotibial band was evaluated. The only other form of treatment during the study period was ice on the area for 20 minutes twice daily. The results show that local infiltration with corticosteroid decreases pain during running more so than placebo after 14 days in patients with ITBFS of recent onset. Both groups showed improvement in pain during running, which may be attributed to a period of rest and the application of ice. However, the group receiving a local corticosteroid injection had a significantly greater decrease in pain during running than the control group.

The pathology of ITBFS is an inflammation resulting from repetitive mechanical trauma. The inflammation results in pain, mainly during running. This pain can be graded on a VAS and therefore the effectiveness of different treatments can be evaluated. We have previously shown that a functional treadmill running test during which pain was recorded every minute is a valid, effective, and sensitive method of evaluating the effects of different treatments for running related pain.³³ Importantly, this method eliminates recall bias, as pain is recorded while the activity is performed.

This study has a number of limitations. Firstly, the sample size is small. This was because, despite recruiting 45 runners,

Table 1 Physical characteristics and training history of the experimental (EXP) and control (CON) groups

	CON group (n = 9)	EXP group (n = 9)	p Value
Total weekly distance (km)	82.5 (9.3)	83.3 (9.7)	0.87
Best 10 km time (minutes)	46.6 (6.7)	46.8 (6.9)	0.96
Age (years)	28.9 (5.0)	29.0 (6.5)	0.87
Height (cm)	177.9 (11.1)	176.4 (8.3)	0.86
Weight (kg)	70.5 (8.0)	73.3 (7.3)	0.72

Values are mean (SD).

Figure 2 Total pain experienced during running in the control (CON) and experimental (EXP) groups at day 0, 7, and 14. Values are mean and SE. *Significant difference from the value at day 7 ($p = 0.01$).

most who were eligible did not want to refrain from running for the 14 day study period. Recruitment of subjects for this study took in excess of 24 months, highlighting the difficulty in performing these types of controlled trials in the running population.

A second limitation is the short duration of the study. A period of 14 days was selected for the follow up period because the drug used should have shown an effect if the pain were due to an acute inflammatory process. Furthermore, as mentioned, runners were only willing to comply with the request to refrain from running for that period but not any longer. Although an attempt was made to follow up the runners in each group for much longer, there was too large a variability in their return to running, their volume of running, the type of rehabilitation programme, alterations in footwear, and the use of orthoses, all of which form part of the second phase treatment of this condition. Therefore no conclusions on the longer term benefits of the corticosteroid treatment compared with placebo could be made in this group.

In conclusion, the results of this study show that the infiltration of the lateral femoral condyle area deep to the iliotibial tract with corticosteroid decreased pain during running after 14 days. Therefore the practical recommendation for treating runners is that local corticosteroid infiltration is effective and safe in the early (first 14 days) treatment of recent onset ITBFS. However, it must be emphasised that identification and correction of the underlying causes must form part of the management.

Authors' affiliations

P Gunter, M P Schweltnus, UCT/MRC Research Unit for Exercise Science and Sports Medicine, Department of Human Biology, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa

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COMMENTARY

The main value of this study is in providing good scientific evidence that a corticosteroid injection improves the symptoms of ITBFS two weeks later. This confirms a clinical impression among sports physicians and a treatment recommendation that has been suggested (without good evidence) in many previous articles on this condition. However, ITBFS is notorious for not responding to treatment and often becomes chronic or recurrent. The question of whether corticosteroid injections help with the ultimate resolution of the symptoms is not answered (and not claimed to be answered) by the investigators in this study. From a cautionary point of view it could even be argued that, although corticosteroid injections reduce symptoms in the acute phase of the condition, they may actually delay the eventual return to full pain free running because of the longer term effects of cortisone—that is, inhibition of collagen synthesis. Despite these comments, I believe this is a useful study for the reasons given above.

P J Fuller

Lifecare Ashwood Sports Medicine, 330 High Street, Ashwood, Victoria 3147, Australia; peterfuller@sub.net.au