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The effectiveness of extra-corporeal shock wave therapy in calcifying tendinitis of the of the shoulder

Summary

Calcifying tendinitis of the supraspinatus is a common and often symptomatic disorder. It progresses in three distinct stages. Treatment depends on the stage of progression of the disorder and on pain.
Chronic disorders of the locomotor system have benefited in recent years from the new treatment of applying extra-corporeal shock waves. A controlled, open trial in 1999 compared two different types of instrument emitting extra-corporeal shock waves (ESWT) in 40 sports patients suffering from chronic shoulder pain for more than 6 months associated with calcifying tendinitis. All of the treatments which had been administered previously had been ineffective.
During this study we found that symptoms improved in 83% of patients. All were able to restart physical activities without either restriction or pain. Seventeen per cent of patients made no improvement.
Based on their findings, the authors considered that this new type of treatment was effective in the treatment of chronic refractory tendon disease of the shoulder with calcification. They considered, however, that further investigations were required to refine our knowledge about the effects of this treatment, particularly on the possible long term side effects.

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Introduction

Calcification of the rotator cuff is one of the common causes of painful shoulder. This disorder which was previously known as *calcifying scapulo-humeral peri-arthritis (SHP)* is now known by the name *calcifying tendinitis*, which seems to be closer to the progressive and transient nature of the disorder.
According to Welfing, the radiological incidence of rotator cuff calcification ranges from 2.7% to 20% in asymptomatic shoulders. The calcification is located mostly in the supraspinatus, although it is not unusual to find concomitant involvement of several tendons. This disorder mostly affects women and sedentary jobs appear to be more at risk [2].

Pathogenesis

Some workers have attributed the cause of calcifying tendinitis to degenerative disease associated with age and repeated trauma to the tendon, causing degeneration and then necrosis of the collagen fibres, followed by calcification [3]. This hypothesis does not appear to be confirmed clinically as calcifying tendinitis is not particularly more common in manual workers than in a control population. Furthermore, a post-mortem study did not find the incidence of degenerative rotator cuff to be higher in the dominant arm [4]. Several pathogenic explanations have been put forward, depending on the stage of progression of the disorder [5].

Pre-calcification stage:
The site of future calcification undergoes fibro-cartilaginous transformation, which is predisposed to by local hypoxia or genetic factors such as an increased incidence of HLA A1, as described by Sengar et al. [6]. These authors suggested that this fibro-cartilaginous zone contained chondrocytes in a more or less metachromatic matrix, which is usually avascular. This has been shown in ultra-structural studies.

Calcification stage:
At this stage, hydroxyapatite crystals are deposited in the vesicles in the extra-cellular matrix. Greater crystal deposition is seen after these vesicles have fused. The fibro-cartilaginous tissue is gradually eroded by the calcium deposits.
Under electron microscopy, these deposits appear as round structures containing mostly rectangular crystals.

Biochemical analysis has shown that these are crystals of apatite, which however, have a different configuration from conventional hydroxyapatite crystals. In particular, they are larger.

The resorption stage:
This stage follows a period of inactivity lasting varying times, or an attack of intense pain. Micro-vascularisation is seen to develop at the periphery of the calcium deposits. The calcifications are surrounded by macrophages and giant cells, which gradually phagocytose the crystals. The crystals then take on the appearance of a chalky emulsion [7].

The post-calcification stage:
The space left by dissolution of the calcifications is rapidly invaded by granulation tissue. Maturation of this tissue leads to scarring, in which the collagen fibres and fibroblasts are aligned along the axis of the tendon.

Clinical appearances

Less than 50% of people with radiologically visible calcification of the rotator cuff present with a symptomatic shoulder. Symptoms correlate partly with the stage of progression of the disease.

Chronic pain in the calcification stage:
Chronic pain is of variable severity and does not restrict movement of the arm. The patient is able to localise the point of maximum pain, which is generally found anteriorly in front of the head of the humerus. The pain often irradiates to the insertion of the deltoid muscle and also into the arm and neck. Pain is worse at night, particularly if the patient is lying on the affected side. Clinically, a painful arc is found between 70 and 110° of abduction. The painful symptoms may last for months.

Acute pain in the resorption phase:
Acute pain in the resorption phase generally causes severe functional limitations. Pain is such that active or passive mobilisation is either difficult or impossible.
In the absence of treatment, these symptoms disappear after about 10 days and are often associated with radiological disappearance of the calcification.
A pattern of sub-acute pain may transiently worsen a background of chronic pain indicating an unsuccessful attempt at resorption. The calcifications may also disappear spontaneously without painful symptoms, as shown by a 10 year radiological follow up, in 9% of the cases which were monitored.

Chronic pain in the repair phase:
Mild and relatively non-incapacitating chronic pain may persist during the repair stage. This pain precedes the reorganisation of the fibrous scar in the tendon [5].

Radiological appearances:
Standard PA (posterior-anterior) radiographs of the shoulder must be performed in internal and external rotation, in the neutral position, together with lateral X-rays of the cuff. Both shoulders should be investigated because of the high incidence of bilateral involvement. Calcifications of the supraspinatus are seen in external rotation or neutral position and those of the infraspinatus in internal rotation. Subscapular calcifications are rarer. The lateral cuff view allows these calcifications to be clearly localised.
During the calcification phase, the deposits appear as round or ovular homogeneous deposits of different sizes. During the resorption phase, the calcifications take on a more heterogeneous or even cloudy appearance. Their contours are imprecise. They may resorb more or less completely, moving downwards into the sub-achromio-deltoid bursa.
It should be noted that MRI investigation may misdiagnose these calcifications as the same signal is obtained as is obtained from a normal tendon.

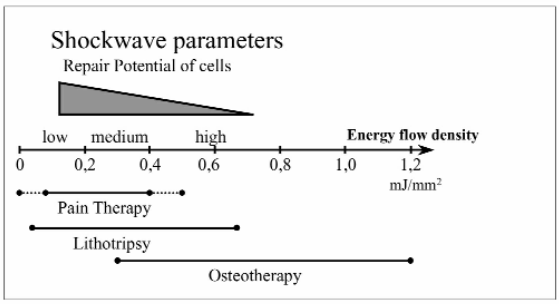

Figure 1: Summary table showing the action of extra-corporeal shock waves as a function of the energy flow applied.

Treatment

It is the stage of progression of the disorder which will dictate treatment. During the formation phase, anti-inflammatory treatment is often combined with re-education. This approach is often inadequate and requires additional intra-articular infiltrations with a corticosteroid solution, which provide relatively complete control of pain by blocking the inflammatory process. These intra-articular infiltrations are commonly used during the acute phase. Radio-guided puncture associated with lavages to attempt to dissolve and aspirate the calcifications may also be used. Surgery is only very rarely offered, if the disorder is resistant to medical treatment.

The place of extra-corporeal shock wave therapy (ESWT): Application of extra-corporeal shock waves is a new technology, the use of which is derived from the fields of urology and surgery, mostly to treat renal, urinary tract or biliary tract calcifications. This method was introduced into orthopaedics in 1991 by Valchanou and Michallov for the treatment of delayed consolidation and pseudarthrosis [8]. From 1992, application of extra-corporeal shock wave was used successfully in the treatment of tendon disorders, particularly in calcifying tendinitis of the shoulder [9, 10]. We have had a Sonocur Plus (Siemens) lithotriptor since the spring of 1998 and the Swiss Dolor-Clast instrument (EMS) since April 1999. These two lithotriptors are equipped with an extra-corporeal shock waves delivery system optimised for application in the field of orthopaedics-traumatology. These two systems are different in that one uses magnetic fields (Sonocur Plus) and the other uses mechanical energy (Swiss Dolor-Clast) to produce the shock waves. The Sonocur Plus instrument is equipped with an ultrasound, which allows applications to be better adjusted. The severity of pain is used to guide treatment with the DolorClast.

Materials and methods

Forty patients suffering from chronic calcifying tendinitis of the shoulder for more than 6 months were treated in an open study. All patients gave their written consent. Conventional treatments used in this type of tendon disorder had failed in all of the patients. These consisted mostly of cold applications, stretching, proprioception, ultrasound and depot infiltrations of corticosteroid. The diagnosis of calcifying tendinitis had been made on clinical and radiological bases.

Th end points used were pain at rest, pain at night and pain during sports, quantified by a visual analogue scale (0-10) and global satisfaction, also indicated by a score of 0-10.

Materials and Methods:

• Sonocur Plus	• Swiss Dolor Clast
- Patients: 16	- Patients: 24
- Age: 42,2 ± 8	- Age: 47,9 ± 12
- Duration: 6,4 ± 5	- Duration: 8,25 ± 4
- 5 men	- 9 men
- 11 women	-15 women
- Number of sessions:	- Number of sessions:
- 6,1 ± 1,1	- 7,8 ± 1,3

Table 1: Clinical details

This evaluation was performed at the start and end of treatment, and again 2 months after treatment had finished.

Treatment was administered with the Sonocur Plus instrument to 16 patients. This instrument provides an 8 level, adjustable energy flow density of 0.04 mJ/mm^2 to 0.5 mJ/mm^2, enabling the acoustic waves to penetrate from 0 to 50 mm. Twenty-four patients were treated with the Swiss DolorClast. This instrument provides an energy flow density of 0.02 mJ/mm^2 to 0.1 mJ/mm^2, allowing acoustic waves to penetrate from 0 to 35 mm.

In each case, the shock wave was delivered in the form of impulses, with a range of between 1 and 5000 impulses/session. The impulse frequency was 1 to 4 Hz for the Sonocur Plus and 1 to 15 Hz for the Swiss DolorClast.

Table 1 summarises the expected effects of treatment as a function of energy flow by type of instrument.

In accordance with the manufacturer's instructions, we applied 1500 impulses per session at a frequency of 2 Hz during one session per week in the 16 patients treated with the Sonocur Plus instrument. The 24 patients treated with the Swiss DolorClast received 2000 impulses per week at a frequency of 4 Hz. In each case, the intensity of application was adjusted as a function of how well it was tolerated by the patient.

The statistical analysis was based on mean and standard deviation values for parametric data, and examining intra-group changes by analysis of variance (Anova). The level of significance was set at 0.05.

Results

The clinical characteristics of our patients are summarised in *table 1*. There were 14 men and 26 women, average age 45 years old. Symptoms had lasted for an average of more than 6 months and patients had been unable to undertake their preferred sport (golf, tennis) usually for the same period. Results were classified as being good or excellent in more than 83% of patients. Seven patients (17%) did not

respond to treatment. Pain was exacerbated in 3 cases and no improvement was seen in 4 cases.

Table 2 shows the improvements in the parameter global satisfaction, which includes the reduction in pain at rest and at night ($p = 0.001$). The 33 patients who responded to treatment restarted their sports without pain or discomfort. The level of satisfaction was maintained in the review 2 months after treatment had finished.

There were no significant differences between the results obtained from the 2 instruments.

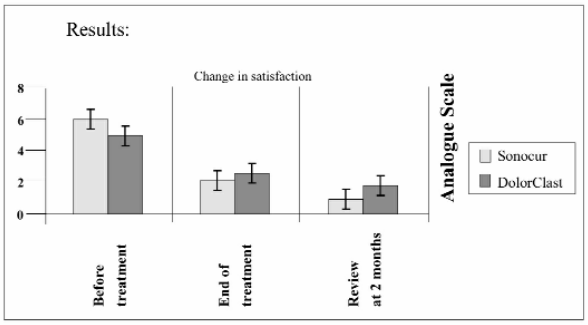

Table 2: Changes in global satisfaction (pain at rest, pain at night, sports activities). The improvement in these parameters was statistically significant ($p = 0.001$). Improvement was greater with the Sonocur, although this difference was not statistically significant.

Discussion

The treatment of chronic calcifying tendinitis of the shoulder is less than satisfactory using conventional measures. For sportsmen suffering from this condition, their quality of sports is reduced because of pain and the fact that conventional treatments are ineffective. Intra-articular injections of depot corticosteroid are often effective. These may not, unfortunately, be repeated indefinitely. Extra-corporeal shock wave therapy, used in 40 cases of chronic refractory calcifying tendinitis which was resistant to treatment, produced excellent results; only 17% of the patients were not cured or considerably improved by treatment. The effect of therapy was sustained as the positive effect on pain was still present two months after the end of treatment and the subjects were not limited in their normal sports practice. Application of this type of wave therefore appears to be potentially particularly useful. Our results confirm those of previous studies, including Rompe et al. [10]. The disorder had lasted for 25 months in this study and the shock waves were applied under plexus anaesthesia. Results were assessed via the Constant score. The average score improved from 43 before starting treatment to 78 twelve weeks after the end of treatment. Calcifications had either disappeared or reduced in volume in 57% of cases.

More recently, W. Brunner et al. reported results in 167 patients treated with the same type of therapy. Here again, improvement, as quantified by the satisfaction scale, was approximately 80% [11].

Application of extra-corporeal shock waves is rapidly effective; pain resolves significantly after the 3rd session, frequently following an acute increase in pain. We insisted on complete abstinence from sports during treatment. The patients were allowed to gradually restart their sporting activities as soon as the final application session had been completed. If treatment was effective, the patients were able to restart their sports activities without any functional difficulty or adjuvant medication.

We did not find any significant side effects, apart from an initial increase in pain, which was reported by most patients, together with local redness at the application site. This corroborates published findings [8, 10]. These secondary reactions are analogous to those seen during use of the ultrasound.

The better results obtained with the Sonocur Plus are explained by the fact that with this instrument, the lesion may be identified in advance by ultrasound, enabling the treatment to be better focussed. This instrument, which is also more powerful that the Swiss Dolor-Clast, provides greater penetration and therefore reaches more deep lying calcifications.

The mechanisms of action of extra-corporeal shock wave therapy has still not been explained. Some analogies exist with conventional ultrasound, such as the cavitation effect observed behind the shock wave. It has been postulated that it may have analgesic activity by inhibiting nociceptive fibres and by lysis of calcified scarring in muscular and tendon structures. This latter hypothesis is attractive and may partly explain the effects of extra-corporeal shock waves. The work performed by Amauroux et al. [12] showed that chronic tendon disorders of the epicondyls are associated with progressive scarring of the fibro-cartilage at the tendon-bone junction. These authors offer this pathogenic mechanism to explain the development of overload epocondyl disorders. The destructive activity of extra-corporeal shock waves on calcified deposits may be explained by an increase in local circulation, produced by shock wave therapy. Ultrasounds performed 24 hours after application invariably show a pronounced inflammatory reaction around the application zone. The increase in circulatory flow and inflammatory reaction produced by the shock wave therapy may reduce local necrosis. These hypotheses, however, need to be confirmed.

Clinically, therefore, our observations following extra-corporeal shock wave therapy show that it produces clinically satisfactory results. We believe that it is important for further work to be performed, particularly double-blind trials, to confirm our clinical results together with fundamental studies to improve our understanding of the mechanism of action of this new therapy.

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