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SICUREZZA ED EFFICACIA DELLE APPARECCHIATURE

- Gruppo di lavoro sulle apparecchiature utilizzate nel settore della medicina fisica e riabilitativa
- Magnetoterapia, elettroterapia, energia vibratoria, laser, ultrasuoni, tecar e diatermia

- Definizione della metodica e le sue caratteristiche fisiche
- Effetti biologici
- Effetti clinici e livelli di evidenza scientifica
- Elementi da inserire nel manuale d'uso e parametri da sottoporre a controllo

SICUREZZA ED EFFICACIA DELLE APPARECCHIATURE

Le apparecchiature utilizzate nel settore della medicina fisica e riabilitativa si configurano come dispositivi medici sulla base della Direttiva 93/42/CEE, come da ultimo modificata dalla direttiva 2007/47/CE, recepita in Italia dal D. Lgs. 46/97 e successive modificazioni.

EBM

"È relativamente comune contrapporre il concetto di medicina basata sull'evidenza, come prototipo della buona medicina, a quello di medicina basata sull'opinione, immagine negativa della medicina vecchio stampo. Questo manicheismo non ha ragione di essere."

(Gensini)

Copyright © 2003 Elsevier Published by Elsevier B.V. Research Report

Therapeutic Ultrasound: Clinician Usage and Perception of Efficacy

Lucy S. Chipchase MAppSc, MAPA_and Dorothea Trinkle B Physio (Hons) School of Health Sciences (Physiotherapy), University of South Australia, North Terrace, Adelaide, South Australia 5000, Australia



A mailed questionnaire, employing both open- and closed-ended questions, was distributed to all members of the Australian Physiotherapy Association (South Australian branch) registering an interest in the musculoskeletal field. Questions were asked regarding the usage and perception of the effectiveness of the rapeutic ultrasound. A response rate of 55% was achieved, with a total of 210 questionnaires available for statistical analysis. The results demonstrated that ultrasound is frequently used as an electrotherapy modality by South Australian musculoskeletal physiotherapists. Most physiotherapists perceived ultrasound to be effective in treating localized, superficial conditions, especially when used in conjunction with other treatment techniques and at suitable dosages. However, ultrasound was thought to be most effective in producing a placebo effect. These findings suggest that ultrasound is perceived as an effective treatment tool when applied appropriately. Its placebo quality may contribute to its effectiveness. Further scientific research is warranted to confirm the results. Randomized controlled trials investigating ultrasound's usefulness for muscle strains, scar tissue, bursitis and tendinitis are indicated. The results of this study will be useful for educators and researchers, and suggest that more research into ultrasound applied as part of a treatment package is needed.

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A New Direction for Ultrasound Therapy in Sports Medicine

Stuart J. Warden^{1,2,3}

- 1 Centre for Sports Medicine Research and Education, School of Physiotherapy, The University of Melbourne, Parkville, Victoria, Australia
- 2 Department of Orthopaedic Surgery, Indiana University School of Medicine, Indianapolis, Indiana, USA
- 3 Physiotherapy Department, Centre for Sports Sciences and Sports Medicine, Australian Institute of Sport, Bruce, Australian Capital Territory, Australia

Abstract

Ultrasound therapy is a widely available and frequently used electrophysical agent in sports medicine. However, systematic reviews and meta-analyses have repeatedly concluded that there is insufficient evidence to support a beneficial effect of ultrasound at dosages currently being introduced clinically. Consequently, the role of ultrasound in sports medicine is in question. This does not mean that ultrasound should be discarded as a therapeutic modality. However, it does mean that we may need to look in a new direction to explore potential benefits. A new

Epicondilite:

La terapia fisica sembra migliorare la soddisfazione del paziente nei tempi brevi ma ci sono dati limitati per sostenere la premessa anche a lungo termine

- Ultrasound and iontophoresis are other modalities that are often combined with occupational therapy regimens.
- One study of ultrasound in patients with described functional and pain improvement in 63% of patients compared with 29% of patients in the placebo group (A. Binder *Br Med J* (1985),

Is therapeutic ultrasound effective in treating soft tissue lesions?

A BINDER, G HODGE, A M GREENWOOD, B L HAZLEMAN, D P PAGE THOMAS

Abstract

Of 76 patients with lateral epicondylitis, 38 were randomly allocated to receive ultrasound treatment and 38 placebo. All 76 were given 12 treatments each over four to six weeks. The conditions of 24 patients (63%) treated with ultrasound and 11 (29%) given placebo improved, the difference being significant at the 1% level. Improvement in particular clinical variables (pain score, weight lifting, grip strength) also showed an advantage for the patients given ultrasound treatment. A simple underwater radiation balance showed considerable fluctuation in ultrasonic output, and frequent checks of output were shown to be necessary.

Ultrasound enhances recovery in most patients with lateral epicondylitis. Treatment—Treatment was

Treatment—Treatment was "pulsed" with an on to off ratio of one to four and a frequency of 1.0 MHz. It was given in contact, using Electro Medical Supplies' ultrasonic coupling medium. The space averaged intensity was increased from 1 to 2 W per cm² and treatment time from five to 10 minutes during the course of treatment. Twelve treatments were given (two to three per week) over four to six weeks. A therapist not taking part in giving treatment randomly

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Further treatment—Forty one patients (14 given ultrasound treatment and 27 given placebo) still showed an unsatisfactory outcome at the end of the controlled study and were offered ultrasound (some placebo group patients) or steroid injections, or both (table II). Eight patients either withdrew still complaining of severe disability or required surgery to the elbow; of these, four were housewives, two domestic workers, and two manual workers.

Review at one year—All the patients were re-examined or completed a postal questionnaire at one year. A much lower incidence of recurrence of severe pain (table III) was noted in the patients who responded to ultrasound than those who required steroid injections. Minor or intermittent pain in the elbow was still present in over half the patients.

1: Scand J Rehabil Med. 1991;23(3):115-8.

Pulsed ultrasound treatment in lateral epicondylalgia.

Haker E, Lundeberg T.

Department of Physiology II, Karolinska Institutet, Stockholm, Sweden.

This study was carried out to explore the pain-alleviating effect of pulsed ultrasound in lateral epicondylalgia. Forty-five patients were consecutively assigned at random to two groups for pulsed ultrasound or placebo. The parameters for ultrasound were 1 MHz; 1:4; 1 W/cm2. Each session was for 10 min, two to three times weekly, ten treatments in all. Follow-ups were done after three and twelve months. The statistical analysis showed no significant differences in relation to subjective or objective outcomes between the groups after the treatment period or at the follow-ups. Our results do not support the use of pulsed ultrasound treatment with the chosen parameters in lateral epicondylalgia.

N. Smidt: Corticosteroid injections, physiotherapy, or a wait-and-see policy for lateral epicondylitis: a randomised controlled trial, *Lancet* (2002).

- Our results suggest that corticosteroid injections are the best treatment option in the short-term for patients with lateral epicondylitis.
 - Patients assigned to corticosteroid injections were treated by their doctors with local infiltration of 1 mL triamcinoloneacetonide (10 mg/mL) and 1 mL lidocaine 2%. Max 3
- At longterm follow-up, our findings suggest that physiotherapy becomes the best option, followed by a wait-and-see policy.
 - Physiotherapy consisted of nine treatments of pulsed ultrasound, deep friction massage, and an exercise programme over 6 weeks. Pulsed ultrasound (20% duty cycle) was given with an intensity of 2 W/cm2 for 7.5 minutes per session.

Advance Access publication 22 November 2005

Pulsed <u>low-intensity ultrasound therapy</u> for chronic lateral epicondylitis: a randomized controlled trial

A. P. D'Vaz, A. J. K. Ostor, C. A. Speed, J. R. Jenner, M. Bradley¹, A. T. Prevost¹ and B. L. Hazleman

Methods. Patients with LE of at least 6 weeks' duration were recruited from general practice, physiotherapy and rheumatology clinics, and had to have failed at least one first-line treatment including non steroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injection. Participants were assigned either active LIUS or placebo. Treatment was self-administered daily for 20 min over a 12-week period. The primary end-point was a 50% improvement from baseline in elbow pain measured at 12 weeks using a patient-completed visual analogue scale.

Subjects were randomized and all appliances were identical and appeared to be fully functional. Active devices produced a low-intensity (30 mW/cm²), 1.5 MHz ultrasound signal modulated by an ON/OFF square function. Placebo devices did not emit an ultrasound signal.

Phys Ther. 2006 Jan;86(1):136-40.

Is there evidence that phonophoresis is more effective than ultrasound in treating pain associated with lateral epicondylitis?

Hoppenrath T, Ciccone CD.

Department of Physical Therapy, Ithaca College, Ithaca, NY, USA.

Clinical decision:



Based on the available evidence, we did not include phonophoresis in the treatment regimen for our patient. Even though one systematic review (Trudel et al) suggested that phonophoresis might show beneficial effects for lateral epicondylitis, this suggestion seemed inappropriate based on the results from the studies that actually used phonophoresis. The conclusions of the systematic review by Trudel et al did not seem consistent with the results from the individual studies addressed in that review. Furthermore, no strong evidence was presented in any experimental study to suggest that adding a drug to the coupling medium produced additional benefits compared with the use of US alone.

We therefore decided to implement the regimen described earlier—stretching, strengthening, cross friction massage, and US to the right proximal wrist extensor muscle. Pulsed US (20% duty cycle) was administered based on Cameron 5 using a standard coupling gel at a frequency of 3 MHz and an intensity of 1.0 W/cm 2. In addition to these interventions, we also advised the patient on how to modify to her motorcycle riding style. This advice consisted of maintaining a neutral wrist position at all times. She also was advised to loosen her grip on the throttle to decrease tension as well as stretching her fingers into extension as much as possible on longer rides.

Epicondylitis

- Low-intensity laser therapy has also been used as an adjunctive modality. A randomized controlled trial of laser therapy conducted by in 52 patients failed to show any efficacy of laser therapy over placebo. A Month follow-up. (Basford et al *Arch Phys Med Rehabil* 81 (2000)
 - Participants were irradiated for 60 seconds at 7 sites along the forearm
 - On a 3-times weekly, 4-week schedule
 - Irradiation was performed with a 1.06-m Nd:YAG CW laser with a 5-cm diameter applicator.
 - Subjects were evaluated before the 1st, 6th, and 12th sessions of treatment, as well at 1-month follow-up (28–35d after the last session).

BMC Musculoskeletal Disorders



Research article

Open Access

A systematic review with procedural assessments and meta-analysis of Low Level Laser Therapy in lateral elbow tendinopathy (tennis elbow)

Jan M Bjordal*^{1,2}, Rodrigo AB Lopes-Martins³, Jon Joensen^{1,2}, Christian Couppe⁴, Anne E Ljunggren², Apostolos Stergioulas⁵ and Mark I Johnson⁶

Address: ¹Institute of Physiotherapy, Faculty of Health and Social Sciences, Bergen University College, Moellendalsvn. 6, 5009 Bergen, Norway, ¹Department of Public Health and Primary Health Care, Section of Physiotherapy Science University of Bergen, Kalfarveien 31, 5018 Bergen, Norway, ³Department of Pharmacology, Institute of Biomedical Sciences, University of São Paulo. Av. Prof. Lineu Prestes, 1524, Butantan, 05508-900São Paulo – SP, Brazil, ⁴University of Copenhagen – Institute of Sportsmedicine, Bispebjerg Hospital, Bispebjerg Bakke 23, 2400 Copenhagen NV, Denmark, ⁵Faculty Human Movement & Quality Life, University of Peloponnese, 23100 Sparta, Greece and ⁶Faculty of Health, Centre for Pain Research, Leeds Metropolitan University, Leeds, LS2 8AJ, UK

Email: Jan M Bjordal* - jmb@hib.no; Rodrigo AB Lopes-Martins - rmartins@icb.usp.br; Jon Joensen - jjoe@hib.no; Christian Couppe - ccou0001@bbhregionh.dk; Anne E Ljunggren - elisabeth.ljunggren@isf.uib.no; Apostolos Stergioulas - asterg@uop.gr; Mark I Johnson - M.Johnson@leedsmet.ac.uk

Corresponding author

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Conclusion

The available material suggests that LLLT is safe and effective, and that LLLT acts in a dose-dependent manner by biological mechanisms which modulate both tendon inflammation and tendon repair processes. With the recent discovery that long-term prognosis is significantly worse for corticosteroid injections than placebo in LET, LLLT irradiation with 904 nm wavelength aimed at the tendon insertion at the lateral elbow is emerging as a safe and effective alternative to corticosteroid injections and NSAIDs. LLLT also seems to work well when added to exercise and stretching regimens. There is a need for future trials to compare adjunctive pain treatments such as LLLT with commonly used pharmacological agents.

Br J Sports Med. 2006 Jan;40(1):81-5.

A controlled clinical pilot trial to study the effectiveness of ice as a supplement to the exercise programme for the management of lateral elbow tendinopathy.

Manias P, Stasinopoulos D.

School of Health and Human Sciences, Faculty of Health, Leeds Metropolitan University, Leeds, UK.

METHODS: Patients with unilateral LET for at least four weeks were included in this pilot study. They were sequentially allocated to receive five times a week for four weeks either an exercise programme with ice or the exercise programme alone. The exercise programme consisted of slow progressive eccentric exercises of wrist extensors and static stretching of the extensor carpi radialis brevis tendon. In the exercise programme/ice group, the ice was applied after the exercise programme for 10 minutes in the form of an ice bag to the facet of the lateral epicondyle. Patients were evaluated at baseline, at the end of treatment, and three months after the end of treatment. Outcome measures used were the pain visual analogue scale and the dropout rate.

conclusions: An exercise programme consisting of eccentric and static stretching exercises had reduced the pain in patients with LET at the end of the treatment and at the follow up whether or not ice was included. Further research to establish the relative, absolute, and cost effectiveness as well as the mechanism of action of the exercise programme is needed.



Physiotherapy interventions for shoulder pain (Review) Copyright © 2010 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Main results

Twenty six trials met inclusion criteria. Methodological quality was variable and trial populations were generally small (median sample size = 48, range 14 to 180). Exercise was demonstrated to be effective in terms of short term recovery in rotator cuff disease (RR 7.74 (1.97, 30.32), and longer term benefit with respect to function (RR 2.45 (1.24, 4.86). Combining mobilisation with exercise resulted in additional benefit when compared to exercise alone for rotator cuff disease. Laser therapy was demonstrated to be more effective than placebo (RR 3.71 (1.89, 7.28) for adhesive capsulitis but not for rotator cuff tendinitis. Both ultrasound and pulsed electromagnetic field therapy resulted in improvement compared to placebo in pain in calcific tendinitis (RR 1.81 (1.26, 2.60) and RR 19 (1.16, 12.43) respectively). There is no evidence of the effect of ultrasound in shoulder pain (mixed diagnosis), adhesive capsulitis or rotator cuff tendinitis. When compared to exercises, ultrasound is of no additional benefit over and above exercise alone. There is some evidence that for rotator cuff disease, corticosteroid injections are superior to physiotherapy and no evidence that physiotherapy alone is of benefit for adhesive capsulitis

Am J Sports Med. 2006 Aug;34(8):1247-53. Epub 2006 Apr 24.

Short-term effectiveness of hyperthermia for supraspinatus tendinopathy in athletes: a short-term randomized controlled study.

Giombini A, Di Cesare A, Safran MR, Ciatti R, Maffulli N.

Orth Department of Trauma and Orthopaedic Surgery, Keele University School of Medicine, Thornburrow Drive, Hartshill, Stoke on Trent ST4 7QB, Staffs, England.

METHODS: The authors studied 37 athletes (29 men, 8 women; mean age, 26.7 +/- 5.8 years; range, 19-43 years) with supraspinatus tendinopathy who had had symptoms between 3 and 6 months. Subjects were randomly assigned to 3 groups. Group A (n = 14) received hyperthermia at 434 MHz. Group B (n = 12) received continuous ultrasound at 1 MHz at an intensity of 2.0 w/cm(2) 3 times a week. Group C (n = 11) undertook exercises, consisting of pendular swinging and stretching exercises 5 minutes twice a day every day. All interventions were undertaken for 4 weeks. Subjects were evaluated at baseline, immediately on completion of treatment, and at 6 weeks after the end of the intervention using mean pain score for pain at night, during movement, and at rest on a visual analog scale; pain on resisted movement and painful arc on active abduction between 40 degrees and 120 degrees on a 4-point scale; and Constant score.

Am J Sports Med. 2006 Aug;34(8):1247-53. Epub 2006 Apr 24.

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Giombini A, Di Cesare A, Safran MR, Ciatti R, Maffulli N.

Orth Department of Trauma and Orthopaedic Surgery, Keele University School of Medicine, Thornburrow Drive, Hartshill, Stoke on Trent ST4 7QB, Staffs, England.

RESULTS: Patients who received hyperthermia experienced significantly better pain relief than did patients receiving ultrasound or exercises: group A, 5.96 to 1.2 (P = .03); group B, 6.3 to 5.15 (P = .10); group C, 6.1 to 4.9 (P = .09).

CONCLUSION: Hyperthermia at 434 MHz appears safe and effecti∨e in the short term for the management of supraspinatus tendinopathy.

ESWT (onde d'urto)

- Indicazioni: tendinosi del sovraspinato, epicondiliti e fascite plantare.
- Limiti confronto degli studi: dose di EFD, l'impiego e la tipologia del sistema di focalizzazione, la frequenza ed il tempo di somministrazione, l'impiego o non dell'anestesia.

Lateral epicondylitis

- In the past decade, use of extracorporeal shock wave therapy (ESWT) has been tried as a nonoperative treatment for lateral epicondylitis.
- Inspired by its success in other soft tissue maladies in a randomized prospective study of 100 patients randomly assigned to ESWT or sham control for lateral epicondylitis, reported improvement in both pain and function in 48% of the shock wave group versus 6% in the controls. (Rompe *J Joint Surg* 1996)
- Other studies, however, have shown little benefit compared with other treatments, with morbidity from ESWT including pain, reddening of the skin, hematoma, and swelling
- A recent meta-analysis of studies involving ESWT versus placebo in 9 trials with more than 1000 patients concluded that there was no notable effect of ESWT. (Buchbinder Cochrane Database Syst Rev 2005)

Epicondiliti

- Istologicamente sono evidenti i segni di un processo degenerativo cronico più che infiammatorio acuto, motivo per il quale il riposo e gli antinfiammatori sono inefficaci (Regan et al 1992)
- Numerosi lavori attestano l'efficacia delle ESWT nel trattamento delle epicondiliti(Ko, 2001; Rompe et al 2004, Pettrone et al 2005).
- Altri studi ne sottolineano l'inefficacia (Bryan, Preston 2004; Speed et al 2002).

Epicondiliti

- Secondo una recente review che include 1006 partecipanti in nove lavori randomizzati si riconosce, con il massimo livello di evidenza (Platinum), che le ESWT determinano un beneficio piccolo o nullo sul dolore e sulla funzione rispetto al placebo e, con un livello di evidenza buono (Silver), che le infiltrazioni con steroidi danno risultati superiori rispetto alle ESWT in un lavoro su 93 casi (R Buchbinder et al 2005).
- I risultati sembrano promettenti ed in un lavoro prospettico randomizzato controllato in singolo cieco gli AA di mostrano una riduzione significativa del dolore ed un incremento della forza di presa rispetto al gruppo controllo (Spacca et al 2005).
- I risultati si mantengono a distanza di sei mesi (Spacca et al 2005). E' auspicabile un controllo dei trattamenti a distanza di due anni per verificare l'efficacia terapeutica (Haake et al 2000).

Tendinopatie inserzionali del tendine d'Achille

- I risultati sull'impiego delle ESWT nel trattamento delle tendinopatie inserzionali dell'Achille non sono ancora evidenti.
- Uno studio controllato riconosce risultati positivi a tre mesi dalla esposizione ad ESWT.
- In altri non sono stati evidenziate differenze significative rispetto al gruppo controllo ed in un lavoro si riporta la rottura del tendine in due pazienti di 62 e 65 anni il che raccomanda prudenza nel trattamento di pazienti anziani (Costa et al 2005).

Fascite plantare

- La presenza di edema midollare calcaneare evidenziato attraverso Risonanza magnetica è predittivo di un risultato positivo nel trattamento con ESWT (Maier et al 2000).
- I risultati del trattamento con ESWT a bassa energia sono superiori rispetto alla alta energia e quelli senza anestesia rispetto all'impiego dell'anestesia (Labek et al 2005).
- Il trattamento con ESWT risulta superiore, in studi randomizzati, rispetto al trattamento con procedure non invasive tradizionali ed il risultato si mantiene nel tempo (Wang et al 2006).
- Sec una Cochraine Reviews del 2003 esiste comunque una evidenza conflittuale sui risultati nell'impiego di ESWT (Crawford, Thomson 2003).
- E' evidente che l'impiego di ESWT deve seguire al fallimento di quello non invasivo comunemente utilizzato (Rompe et al 2007).

Tendinosi calcarea

- Secondo un lavoro randomizzato controllato in doppio cieco l'impiego dell'<u>Ultrasuono</u> (frequenza di 0,89 MHz, intensità di 2,5 W/cm², 24 sedute di 15 min) risulta efficace sul dolore e determina la soluzione o la riduzione della calcificazione di spalla in una percentuale di casi significativa come si può ottenere con le WST, ma a costi ben inferiori (Ebenbichler et al 1999).
- Secondo una review recente il trattamento con ESWT delle s. da conflitto della spalla risulta efficace con livelli di moderata evidenza in caso di presenza di calcificazione (Harniman,2004).
- In un lavoro randomizzato in singolo cieco con gruppo di controllo si sottolinea come l'impiego di RSWT sia efficace dopo 4 settimane senza eventi avversi (Cacchio et al 2006). I risultati si mantengono almeno al follow-up di sei mesi.