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Is there evidence-based practices of laser therapy in lateral epicondylitis patients?

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Abstract. Laser treatment is noninvasive, painless, and can be easily administered in primary care settings for a wide range of conditions. Lateral epicondylitis represent an overuse tendinopathy of wrist extensor, and limited evidence on the efficacy of different therapeutic modalities has been shown. The objective of the present review is to consider the recent laser therapy interventions for subjects affected by lateral epicondylitis compared with other physical or electrophysical modalities of treatment, taking into consideration the scientific benefits of the systematic reviews (SRs) and the need of implementation of the Shared decision making (SDM).
Key words: *laser therapy, lateral epicondylitis, evidence-based practice*.

Evidence based practice in physical therapy, rehabilitation and sports medicine

For sports medicine and rehabilitation clinicians, researchers, and policymakers to properly engage in evidence-based practice (EBP), they need a sophisticated understanding of its background, methods, and limitations. Of note is that most definitions of EBP contained in the literature of various rehabilitation disciplines do contain language pertaining to patient values. Such language is absent from the Sackett (1) definition and most early characterizations of evidence-based medicine EBM. This omission may have contributed to the persistent criticism that EBP values the results of clinical research to the exclusion of other information relevant to clinical decision making (2).

Patient preferences, based on their unique values and wants, have presumably always helped inform EBM. However, significant development of effective aids (eg, means to educate patients so they can make informed choices) to facilitate joint decision making between clinician and patient has really only occurred relatively recently. The importance given to the clinician's own experience and expertise, academic learning, and continuing education (CE), as well as cost issues and societal values, has varied over time and still differs across societies and health care systems.

At present, RCTs are considered among the most valid for generating information about treatment efficacy (3). But RCTs produce evidence based on aggregated group data obtained under highly controlled conditions. Therefore, RCTs cannot account for the complex set of extraneous factors present in any given research participant or predict the treatment effect for every individual. Individuals, not groups, are the foci of rehabilitation. The RCT's inability to produce such detailed information means that its application to rehabilitation research may be limited (4), and practice-based evidence (PBE) designs are to be preferred, certainly in the initial phases of evidence development (5).

No single research design is superior to all others for addressing most research questions. Consequently, reliance on 1 or even a few mainstay designs to provide rehabilitation research data will not provide the field with complete, generalizable information to guide diagnosis, treatment, and prognosis. In an era with multiple available research designs, each with its own strengths and weaknesses (6), the systematic reviews SRs and meta-analyses have gained prominence as a means of evaluating and synthesizing volumes of research findings that were derived using different methods. This process allows clinicians and researchers to become better consumers of available research so they can identify findings that will be of optimum use in their daily practice. Indeed, including a wide range of research designs in SRs and meta-analyses has been recommended to fill in gaps in the field's understanding of a variety of pertinent issues (7).

However, SR methodologists and authors have emphasized publication bias: the tendency of published studies to have positive findings (ie, providing support for the hypothesis), while investigations with negative findings linger in desk drawers, especially if lacking sufficient power.51 This bias results from a preference of authors, peer reviewers, and editors to publish studies with positive findings, especially intervention studies. The end result is that the published literature contains a high percentage of type I errors: a claim is made (based on sample results) that there is support for the hypothesis, but this claim does not reflect reality.

To avoid these biasing effects when drawing conclusions, authors of SRs should do their best to find studies in the gray literature - dissertations, reports, technical notes, white papers, or other documents produced and published by governmental agencies, research institutions, and other groups that are not distributed by commercial publishers and (commonly) not indexed in bibliographic databases. They even should try to track down unpublished studies by contacting experts in the area of the review. The creation of trials registries such as ClinicalTrials.gov was occasioned exactly by the danger of publication bias—the potential that most studies showing no effect of interventions, or even more harm than benefit, would not be available in making health care decisions. For individual clinicians, attempting to track down gray literature, let alone unpublished studies, is nigh impossible. That is the first reason that they rely on SRs and other EBP resources to access evidence (8).

Secondly, EBP often disregards factors that should play a role in clinical decision making. In its initial stages, EBM indeed held research evidence (or specifically RCT-produced evidence) to be the only factor to be considered in making decisions on the care of individual patients. As indicated above, in the EBP canon patient preferences and clinician experience and expertise are now explicitly allowed to also impact clinician decisions; it must be noted that there, as of yet, is no clear pathway on how the 3 should be integrated, or what should be done if they clearly contradict one another (9).

I was found that, in making decisions on what is the best in health care, eliminating bias is impossible, and that the best approach is to be aware of bias, put in place mechanisms to minimize or balance biases (10) and to make values and value judgments explicit, as in the GRADE approach (11).

EBP adherents in vain pointed out the confusion between proof of lack of effectiveness and lack of proof of effectiveness on the part of the policymakers who denied reimbursement for particular treatments—for example, cognitive rehabilitation. For those treatments or other procedures that truly have been shown to unequivocally have no effect or even to be harmful (eg, bloodletting), denial of reimbursement is a reasonable step. For old or new treatments that have not yet been shown to be effective, a "wait, study it, and see" attitude is prudent. One thing that EBP certainly has contributed to is a better understanding of the value and limitations of the evidence produced by individual studies, and the need to evaluate a body of evidence relevant to a particular procedure.

Regarding our study's issues, the main question to be debated is: what are the effects of laser therapy for tennis elbow / lateral epicondylitis compared with other physical or electrophysical modalities of treatment?

Method

Considering the benefit of SRs to clinicians and that The International Network of Agencies for Health Technology Assessment (12) often base it's activity on or incorporate SRs, the need of implementation of Shared Decision Making (SDM) (which can reduces the asymmetrical power between the therapist and the patient, improves patient satisfaction, treatment adherence, health outcomes, all of these benefits improving the quality of health care) (13), we constructed our analyze on laser therapy efficiency in LE based on these statements.

Results

Effects of laser therapy on Tennis elbow / lateral epicondylitis

Nowadays, the epicondylitis etiology is thought to be structural overuse of the extensor carpi radialis brevis muscle (ECRB) which leads to micro trauma and finally primary tendinosis of the ECRB, with or without involvement of the extensor digitorum communis instead of inflammation (14). Current laser-treatment methods focus mainly on reducing pain, increasing strength and (above all) improving the quality of life of patients rather than directly treating inflammation (14). But more recently, the pulsed neodymium-doped yttrium aluminum garnet (Nd:YAG) laser, a form of high-intensity laser therapy (HILT), was introduced to the field of physical therapy. This laser works with high peak power (3 kW), and a wavelength of 1,064 nm, and is considered to be a nonpainful and noninvasive therapeutic modality. Studies have documented the anti-inflammatory, anti-edematous, and analgesic effects of the HILT Nd:YAG laser, justifying its use in patients with pain issues/ therapy of pain (15, 16). HILT uses a particular waveform with regular peaks of elevated amplitudes and durations of time between them to decrease thermal accumulation phenomena, and it is able to rapidly induce photochemical and photothermic effects in the deep tissue. These photochemical and photothermic effects of HILT may stimulate collagen production within the tendons and increase the blood flow, vascular permeability, and cell metabolism; thus, they help to repair damaged tendons and remove painful stimuli.

Laser therapy versus plyometric exercises

In the high-quality study of Stergioulas et al (17) a significant benefit was found in favor of the laser treatment group on short term. A total of 50 patients were randomized into 2 groups: (i) group A (n = 25) was treated with a 904 nm Ga-As laser, frequency 50 Hz, intensity 40 mW and energy density 2.4 J/cm(2), plus plyometric exercises, and (ii) group B (n = 25) that received placebo laser plus the same plyometric exercises. During 8 weeks of therapy, patients of the 2 groups received 12 sessions of laser or placebo, 2 sessions per week (weeks 1 to 4) and 1 session per week (weeks 5 to 8). Pain at rest, at palpation on the lateral epicondyle, during resisted wrist extension, middle finger test, and strength testing was evaluated using visual analog scale (VAS). Also, the grip strength, the range of motion (ROM) and weight test were evaluated. Parameters were determined before treatment, at the end of the 8th week course of treatment (week 8), and 8th (week 8) after the end of treatment. Relative to group B, group A had (i) a significant decrease of pain at rest at the end of 8 weeks of the treatment ($p < 0.005$) and at the end of following up period ($p < 0.05$), (ii) a significant decrease in pain at palpation and pain on isometric testing at 8 weeks of treatment ($p < 0.05$), and at 8 weeks follow-up ($p < 0.001$), (iii) a significant decrease in pain during middle finger test at the end of 8 weeks of treatment ($p < 0.01$), and at the end of the follow-up period ($p < 0.05$), (iv) a significant decrease of pain during grip strength testing at 8 weeks of treatment ($p < 0.05$), and at 8 weeks follow-up ($p < 0.001$), (v) a significant increase in the wrist ROM at 8 weeks follow-up ($p < 0.01$), (vi) an increase in grip strength at 8 weeks of treatment ($p < 0.05$) and at 8 weeks follow-up ($p < 0.01$), and (vii) a significant increase in weight-test at 8 weeks of treatment ($p < 0.05$) and at 8 weeks follow-up ($p < 0.005$). The authors concluded that these findings suggested that the combination of laser with plyometric exercises was more effective treatment than placebo laser with the same plyometric exercises at the end of the treatment as well as at the follow-up.

HILT laser therapy versus splinting

A recent prospective, randomized, controlled, assessor-blinded trial (2015) investigated the effects of high-intensity laser therapy (HILT) in patients with LE and to compare these results with those of a brace and placebo HILT (18). HILT and brace groups showed significant improvements for most evaluation parameters (pain scores, grip strength, disability scores, and several subparts of the short-form 36 health survey (physical function, role limitations due to physical functioning, bodily pain, general health, and vitality)) after treatment (after 4 and 12 weeks). Furthermore, comparison of the percentage changes of the parameters after treatment relative to pretreatment values did not show a significant difference between HILT and brace groups. Authors concluded that both HILT and splinting are effective physical therapy modalities for patients with LE in reducing pain and improving disability, quality of life, and grip strength. The results of this study revealed that pulsed Nd:YAG laser therapy (HILT) is as effective as brace therapy (not superior, but neither inferior) in the treatment of these patients with respect to decreased pain and disability and improved quality of life. In addition, HILT was applied once a day for 15 days (15 min daily) during a period of 3 weeks, while brace groups used lateral counterforce brace for a longer time (4 weeks and only removed during sleep and bathing). This may also show that HILT has an advantage in treatment duration (only 15 min a day) compared to brace therapy (during all day and removed during sleeping), which could be an advantage in terms of patient’s comfort, compliance to treatment, and quality of life.
Furthermore, studies on the effectiveness of splinting in LE also have shown conflicting results. Cochrane database systematic review found that no definitive conclusions can be drawn concerning effectiveness of orthotic devices for the treatment of LE (19). But, in a meta-analysis, Borkholder et al. reported one Sackett

level 1b study and ten Sackett level 2b studies that offer early positive, but not conclusive, supporting the effectiveness of splinting lateral epicondylitis (20).

Short and long term HILT laser therapy in LE

A recent study (2015) investigated the short and long-term effects of high-intensity laser therapy (HILT) in lateral epicondylitis (LE) patients (21). The authors applied HILT for 5 sessions per week for 2 weeks, 10 sessions in total. LE patients were evaluated before, right after, and 6 months following HILT intervention post-treatment using visual analogue scale for pain (VAS) during activity and resting. Disabilities of the Arm, Shoulder, and Hand (DASH) Score and hand grip strength test (HGST) were used. The participants of the present study were also evaluated using Short-Form 36 (SF-36) before and 6 months after the treatment. Out of the 30 patients, 8 were male and 22 female with a mean age of 47.2± 9.7. The activity and resting VAS, DASH, and HGST scores revealed statistically significant improvement (p= 0.001) following treatment. Whereas VAS activity, DASH, and HGST scores increased after treatment until post-treatment 6 months significantly (p=0.001), VAS resting scores remained stable (p= 0.476). A statistically significant improvement was also evident in the physical and mental components of SF-36 scores following treatment until post-treatment 6 months compared to pre-treatment scores (p =0.001). In conclusion, the results of the present study suggest that *HILT* is a reliable, safe, and effective treatment option in LE patients in the short and long term considering pain, functional status, and quality of life.

Laser therapy versus other physical modalities of treatment

In a Systematic Review made by Dingemanse et al (2014) (22) has been analyzed the evidence for the effectiveness of electrophysical modalities for treatment of medial and lateral epicondylitis. A total of 2 reviews and 20 RCTs were included, all of which concerned LE. Different electrophysical regimes were evaluated: ultrasound, laser, electrotherapy, ESWT, TENS and pulsed electromagnetic field therapy. Moderate evidence was found for the effectiveness of ultrasound versus placebo on mid-term follow-up. Ultrasound plus friction massage showed moderate evidence of effectiveness versus laser therapy on short-term follow-up. On the contrary, moderate evidence was found in favor of laser therapy over plyometric exercises on short-term follow-up. For all other modalities only limited/conflicting evidence for effectiveness or evidence of no difference in effect was found. The authors concluded that potential effectiveness of ultrasound and laser for the management of LE was found.

Non-surgical approaches to treatment of lateral epicondylitis (including laser therapy)

Another SR was realized in 2014 to examine randomized, controlled trials of non-surgical approaches to treatment of lateral epicondylitis (23). Fifty-eight articles met eligibility criteria: (1) a target population of patients with symptoms of lateral epicondylitis; (2) evaluation of treatment of lateral epicondylitis with the following non-surgical techniques: corticosteroid injection, injection technique, iontophoresis, botulinum toxin An injection, prolotherapy, platelet-rich plasma or autologous blood injection, bracing, physical therapy, shockwave therapy, or laser therapy; and (3) a randomized controlled trial design. *Bracing with a proximal forearm strap or wrist extension splint, however, seems to provide little to no additional benefit when combined with physical therapy.* Early studies of laser therapy did not show an effect of treatment whereas more recent investigations did show substantial improvement for patients treated with laser therapy over those who received placebo therapy. These beneficial effects were most apparent at 1 to 4 months of follow-up. The authors concluded that therapies that do not include injection, such as bracing, PT, or ESWT, do not appear to provide substantial benefit in terms of pain relief or improved function.

Swedish systematic review on LE conservative management

In a 2012 Swedish systematic review, published by Institutionen för Hälsovetenskap, has been analyzed the Conservative Interventions for Lateral Epicondylalgia (24). The authors concluded a limited scientific basis for that self-rated health did not increase in use of orthotics in acute pain of lateral epicondylalgia. For intervention of subacute pain, the authors found a moderately strong scientific basis that pain decreases in use of elbow mobilization and a limited scientific basis was found that pain decreases in use of cervical manipulation and orthotics. In case of long-lasting pain a limited scientific basis was found that pain decreases in use of laser therapy. Regardless of pain stage, it was concluded a moderately strong scientific basis for positive effect in use of elbow mobilization and a limited scientific basis for positive effect of laser therapy, physical exercise and cervical manipulation. It was also concluded a limited scientific basis for no effect of orthotics and TENS, regardless of pain stage.

Clinical evidence in tennis elbow / LE using GRADE approach

Bisset at al (25) conducted a systematic review that aimed to answer the following clinical question: What are the effects of treatments for tennis elbow?

In this systematic review they present information relating to the effectiveness and safety of the following interventions: acupuncture, autologous whole blood injections, corticosteroid injections, combination physical therapies, exercise, extracorporeal shock wave therapy, iontophoresis, low-level laser therapy, manipulation, non-steroidal anti-inflammatory drugs (oral and topical), orthoses (bracing), platelet-rich plasma injections, pulsed electromagnetic field treatment, surgery, and ultrasound.

Orthoses/bracing - the authors find that on the following symptoms the effects are:

- ✓ Pain **-** if compared with combination physical therapies, orthoses (bracing) may be less effective at 6 weeks at improving pain in people who have pain as their main complaint (very low-quality evidence).
- ✓ Global improvement **-** Compared with corticosteroid injection, orthoses (splint or elbow band) may be less effective at increasing the proportion of people who rate their global improvement as "good" or "excellent" at 2 weeks, but not at 6 or 12 months (low-quality evidence). Compared with physiotherapy, orthoses may be less effective at improving patient satisfaction scores at 6 weeks (low-quality evidence).
- ✓ Functional improvement - Compared with physiotherapy, orthoses may be more effective at improving the ability to perform daily activities at 6 weeks (low-quality evidence). Note - they found no direct information from RCTs about whether orthoses are better than no active treatment.

Laser therapy - the authors find that on the following symptoms the effects are:

- ✓ Pain relief - Compared with sham treatment/other non-laser interventions Low-level laser therapy (LLLT) seems more effective at reducing pain after treatment at up to 2 months, but seems no more effective at reducing pain at 3 months in people with tennis elbow (moderate-quality evidence).
- ✓ Global improvement - Compared with sham treatment/other non-laser interventions LLLT seems more effective at increasing global improvement after treatment at up to 2 months, but seems no more effective at increasing global improvement at 3 to 12 months in people with tennis elbow (moderate-quality evidence).
- ✓ Functional improvement **-** Compared with sham treatment/other non-laser interventions LLLT seems more effective at improving pain-free grip strength after treatment up to 2 months, but seems no more effective at improving pain-free grip strength at 3 to 12 months in people with tennis elbow (moderate-quality evidence).

*Clinical guide***.** Overall, conflicting data and heterogeneity between RCTs suggests that caution should be taken in drawing conclusions regarding the effects of LLLT. However, it seems that LLLT using a 904- nm wavelength applied directly over the tendon area may be effective in reducing pain and improving functional outcomes in the short term in people with tennis elbow.

Discussion and conclusions

To date, a standardized, universally accepted program for LE treatment has not been established. Various nonsurgical modalities have been described, none of them being general effectively. Bracing (orthoses) provided little, or at all, benefits; furthermore, compared with physiotherapy or corticosteroid injection was less effective concerning pain and patient satisfaction scores.

There is a variety of applications related to LLLT or HILT dosage and no of sessions (ranging between 7/8-10 to 15). The superiority of HILT over LLLT has been proved, given that HILT is able to reach and stimulate the larger and/or deeper areas; accordingly, during HILT therapy, significantly greater energy might be transferred into tissue compared to LLLT (26).

When comparing with other therapies, laser therapy demonstrated its beneficial effects especially on long-term follow-up.

We also consider significant to mention that in most of EU countries: UK, Romania, Italy, Czech Republic, Bulgaria, Germany e.g. the laser therapy is covered by National public Insurance Agencies. The current situation may pave the road for other risk-free alternatives such as laser therapy, which has appeared to provide clinically relevant changes in several randomized placebo-controlled trials. Moreover, from the findings of a recent Norwegian Health Technology Assessment Report, laser therapy was given potential of becoming at least twice as effective as NSAIDs, if applied with optimal dose and energy (> 2.5 Joule per point for 810-30 nm, and > 0.6 Joules per point for 904 nm, and at least 3 points irradiated). Although the number of laser trials is still smaller than for NSAIDs, the unequivocal scientific findings so far, has earned laser therapy a top spot in levels of evidence and treatment recommendations for knee osteoarthritis issued by the Norwegian Drug Agency. Laser therapy is also reimbursed in the physiotherapy program of the National Health Insurance Agency, and is slowly becoming one of the standard therapies for knee osteoarthritis pain in Norway.

Therefore, as for many other health situations in which there's not one clearly superior course of treatment, the health care team's skills and patient shared decision making can ensure that medical care better aligns to patients' needs and modern new therapeutically approaches.

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