RADIAL SHOCK WAVE THERAPY IN PATIENTS WITH LATERAL EPICONDYLITIS

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ABSTRACT
Introduction: Lateral epicondylitis, or “tennis elbow”, is a relatively common disorder. Various therapeutic modalities have been tried in an attempt to manage the disorder but neither the conservative methods nor the surgical options have proved to be beneficial so far. During the past decade in the USA and European countries and the past several years in Bulgaria, the shock wave therapy (focused and radial) has been introduced as a method of choice in the treatment of chronic tendynopathies. The aim of the present study was to make quantitative assessment of the effect of radial shockwave therapy in patients with lateral epicondylitis.

Patients and Methods: The study included 16 patients with lateral epicondylitis (9 males, 7 females, mean age 47.2 ± 2.3 yrs) of mean duration of 15.06 ± 4.06 months. We used the BTL-5000 radial shockwave therapy equipment and performed 5 procedures (one per week). The total number of shocks was 2500, the pressure was 2 Bars: 1500 shocks of 5 Hz frequency followed by 500 shocks of 10 Hz frequency were applied locally on the lateral epicondyle and 500 shocks of 2 Bar pressure and 5 Hz frequency were applied along the muscles near the insertion. The patients were evaluated 5 times: before treatment, immediately after the end of treatment and at 3, 6 and 12 months of follow-up. Pain was assessed at rest, on palpation and by the Thomsen test using a visual analogue scale (VAS). The patient-rated tennis elbow evaluation (PRTEE) questionnaire was used to assess the patients’ pain, functional condition and limitations in performing specific activities, as well as for the overall self evaluation.

Results: We found significant difference (p < 0.05) between the mean pain scores (at rest, on palpation and by Thomsen test) before treatment and these scores obtained immediately after treatment, the decrease sustained at 3, 6 and 12 months. VAS showed decrease from 3.75 ± 0.49 before therapy to 2.44 ± 0.39 after treatment, to 1.94 ± 0.46 at 3 months and to 0.69 ± 0.38 at one year at rest, from 7.44 ± 0.38 before therapy to 4.69 ± 0.51 after treatment, to 3.56 ± 0.40 at 3 months and 1.46 ± 0.56 at one year at palpation, and from 5.87 ± 0.46 before therapy to 3.5 ± 0.29 after it, to 2.5 ± 0.40 at 3 months and 1 ± 0.38 at one year in the Thomsen test.

The pain, function and the total score as assessed on the patient-rated scale (PRTEE) also showed statistically significant improvement (p < 0.05) after completion of therapy and over the whole follow-up. Total score decreased from 56.75 ± 2.34 before therapy to 39.38 ± 3.96 after treatment, to 27.53 ± 3.7 at 3 months and to 13.69 ± 4.48 at one year.

Conclusion: Based on the results of this preliminary study we could recommend the radial shock wave therapy in the treatment of lateral epicondylitis of more than 6 months duration if the condition is recalcitrant to other conservative methods of treatment.

Key words: lateral epicondylitis, tennis elbow, radial shock wave therapy

INTRODUCTION
Lateral epicondylitis, or so called “tennis elbow”, is a relatively common disorder with a prevalence rate of 1-3%. It is characterized by pain and tenderness over the lateral epicondyle of the humerus and pain on resisted dorsiflexion of the wrist. It peaks in prevalence between the ages of 40 and 50; between 30 and 60 years of age the prevalence can be as great as 19%.¹³ The condition affects men and women equally, but some authors have reported...
more severe and prolonged course of the disorder in women. The etiology and pathogenesis of the disorder still remain unclear, although polyetiological genesis is assumed implicating many predisposing factors such as age, chemical, vascular, hormonal and hereditary factors. Most frequently the disorder is a result of over-exertion and muscle imbalance. Histological studies point to a degenerative process rather than inflammation at the origin of the extensor carpi radialis brevis muscle.\(^4,5\) Although the condition is generally referred to as “tennis elbow”, tennis causes the disorder in only 5% of all cases.\(^6\) It tends to occur in subjects whose occupation or activities are associated with excessive, repetitive, monotonous movements of the wrist beyond the neutral position.

Lateral epicondylitis is relatively easy to diagnose but hard to manage. Various therapies have been advocated but none (both conservative and surgical modalities) have proved to be consistently effective. Reviewing the results of a number of research studies Johnson et al. draws the conclusion that the following interventions are probably helpful for lateral epicondylitis: watchful waiting, topical NSAIDs, corticosteroid injections (with a short-term effect), kinesitherapy, iontophoresis with NSAIDs and ultrasound therapy.\(^7\) The following interventions are possibly helpful: oral NSAIDs, tennis elbow braces, topical glyceryl trinitrate, acupuncture, botulinum toxin type A injection and surgical treatment. Laser therapy has been found to be dubiously effective.\(^7\) The availability of such a great number of methods of treatment suggests that the optimal therapeutic behaviour for lateral epicondylitis has not been found yet which necessitates further research into it looking for new modern methods.

During the past decade in the USA and European countries and the past several years in Bulgaria, the shockwave therapy (focused and radial) has been introduced as a method of choice in the treatment of chronic tendinopathies. Extracorporeal shock wave therapy (ESWT) is a relatively new therapeutic modality which uses high-energy sound waves with a steep pressure rise (0.01 \(\mu\)s), short duration (10 \(\mu\)s) and high peak pressure (> 500 Bar or 100 MPa). The generators producing focused shock waves are based on electrohydraulic, electromagnetic or piezoelectric principle. The different studies on the effect of extracorporeal shock wave therapy in the treatment of lateral epicondylitis have demonstrated contradictory results.\(^8\)

Recently radial shock wave therapy (RSWT) has become popular for the treatment of insertionites and different tendinopathies such as tennis elbow, plantar fasciitis and calcifying tendonitis of the shoulder. In radial shock wave therapy the shock waves are generated on a pneumatic principle. They are propagated radially, as the focal point of energy is achieved on the top of the applicator and it decreases when penetrates in depth (up to 3 cm), which is in contrast to focused extracorporeal shockwave therapy in which the focal point of energy is centred in the target zone. The peak pressure in RSWT is lower than that in focused ESWT – 0.1-1 MPa. Radial shock waves have longer rise time (50 \(\mu\)s) and duration (200-2000 \(\mu\)s).\(^9\) Radial shock wave therapy can be compared to low-energy and medium-energy focused extracorporeal shock wave therapy with energy density (\(EFD\)) respectively – up to 0.08 mJ/mm\(^2\) and up to 0.28 mJ/mm\(^2\). As the application of high energy shock waves results in different soft tissue damages as demonstrated by experimental studies in animals, low- and medium-energy impacts are recommended in the treatment of tendinopathies in humans.\(^10\) We therefore can assume that radial shock wave therapy could be efficient in the treatment of tennis elbow.

AIM

The aim of the present study was to make quantitative assessment of the effect of radial shock wave therapy in patients with lateral epicondylitis.

PATIENTS AND METHODS

The study included 16 patients with lateral epicondylitis (9 men, 7 women, mean age - 47.2 ± 2.3 yrs) of mean duration of 15.06 ± 4.06 months (range 6 to 36 months).

Inclusion criteria were: more than 6 months’ duration, failed previous conservative treatment that included NSAIDs, physical therapy, local corticosteroid injections and orthopedic braces. Patients were excluded if they had a history of coagulation status disorders, inflammation and malignancy, were younger than 18 years, were pregnant, had a pacemaker implanted, and if they had received local corticosteroid injections within the previous 6 weeks.

The patients were haphazardly enrolled in the study when they actively requested medical treatment because of long-term complaints, with already specified diagnosis of lateral epicondylitis and failure of the conservative treatment.
**THERAPEUTIC METHODOLOGY**

We used a BTL-5000 equipment for radial shockwave therapy that works on a pneumatic principle. An air pressure-accelerated projectile hits the applicator placed on the skin. We applied 5 procedures, one procedure per week. The total number of impulses was 2500, the pressure was 2 Bars: 1500 impulses of 5 Hz frequency followed by 500 impulses of 10 Hz frequency were applied locally on the lateral epicondyle and 500 impulses of 2-Bar pressure and 5-Hz frequency were applied along the muscles, near the insertion.

**FOLLOW-UP METHODS**

The patients were evaluated 5 times: before treatment, immediately after the end of treatment, 3 months, 6 months and 12 months after the end of treatment.

We used a visual analogue scale to assess the pain at rest, on palpation and at resisted wrist extension (Thomsen test); the visual analogue scale ranged from 0 (no pain) to 10 (maximal pain). Thomsen test was performed at a starting position, the hand flexed up to 60° at the shoulder joint, the elbow extended and the wrist extended at 30°. Function was assessed using the “patient-rated tennis elbow evaluation” (PRTEE) questionnaire which includes a pain scale of 5 items to quantify pain at various movements and a function scale (evaluation of the limitations in functional activity – 6 items to rate the amount of difficulty in performing specific activities and 4 items - for some usual activities). The best result for a total score was 0; the worst result was 100, e.g. higher score indicates stronger pain and functional disability.

**STATISTICAL ANALYSIS AND STUDY DESIGN**

The statistical analysis was performed using SPSS v. 13 and MS EXCEL: analysis of frequency distributions, descriptive statistics and Student’s t-test to prove that therapy has an effect, the level of the error was \( p \leq 0.05 \).

**RESULTS**

The analysis of the results showed statistically significant differences between the mean scores of pain evaluation (at rest, on palpation and at Thomsen test) before treatment and the mean scores after therapy was completed. The same finding concerned the mean scores of pain assessment (at rest, on palpation and at Thomsen test) which were calculated at 3, 6 and 12 months after completion of therapy. Statistically significant difference was not found between the status immediately after treatment and the mean pain scores at 3 months after treatment, although the mean values of pain were lower at three months compared to the results immediately after the end of therapy. The mean scores of pain at different moments of study sample assessment are shown in Table 1 and Fig. 1.

Analysis of the results for pain scores on the patient-report scale also demonstrated statistically significant difference between pain scores before treatment (29.19 ± 1.2) and the pain scores after administration of radial shock wave therapy (19.56 ± 2.05). The improvement (lower mean scores) was sustained at 3, 6 and 12 months of follow-up study.

Significant differences were found between the mean function scores on the patient-report scale immediately after completion of treatment and the scores at baseline. Improvement (absence of difficulties) was found in the performance of specific activities and in the performance of certain everyday activities (PRTEE). The t-test demonstrated

**Table 1. Mean scores of pain on the visual analogue scale before and after treatment**

<table>
<thead>
<tr>
<th></th>
<th>At rest (n = 16) mean ± SEM</th>
<th>On palpation (n = 16) mean ± SEM</th>
<th>By Thomsen test (n = 16) mean ± SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>3.75 ± 0.49</td>
<td>7.44 ± 0.38</td>
<td>5.87 ± 0.46</td>
</tr>
<tr>
<td>Immediately after treatment</td>
<td>2.44 ± 0.39</td>
<td>4.69 ± 0.51</td>
<td>3.5 ± 0.29</td>
</tr>
<tr>
<td></td>
<td>t</td>
<td>2.10</td>
<td>4.36</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>p &lt; 0.05</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>3 months after treatment</td>
<td>1.94 ± 0.46</td>
<td>3.56 ± 0.40</td>
<td>2.5 ± 0.40</td>
</tr>
<tr>
<td></td>
<td>t</td>
<td>2.7</td>
<td>7.08</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>p &lt; 0.05</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>6 months after treatment</td>
<td>1.5 ± 0.48</td>
<td>2.56 ± 0.54</td>
<td>1.69 ± 0.60</td>
</tr>
<tr>
<td></td>
<td>t</td>
<td>3.28</td>
<td>7.41</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>p &lt; 0.05</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>12 months after treatment</td>
<td>0.69 ± 0.38</td>
<td>1.46 ± 0.56</td>
<td>1 ± 0.38</td>
</tr>
<tr>
<td></td>
<td>t</td>
<td>4.94</td>
<td>8.84</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>p &lt; 0.05</td>
<td>p &lt; 0.05</td>
</tr>
</tbody>
</table>
statistically significant differences over the whole period of follow-up (3, 6, and 12 months). The total score that summarises the results for pain score and function score on the scale also demonstrated statistically significant difference between values immediately after treatment and those before the treatment. The demonstrated beneficial therapeutic effect – post-treatment improvement vs. baseline status – was sustained throughout the follow-up study. The results are presented in Table 2 and Fig. 2.

**DISCUSSION**

Lateral epicondylitis is managed predominantly conservatively with surgical interventions necessary only in 7.3% of all cases. The existing conservative methods of treatment, however, are not entirely effective. The focused extracorporeal shock wave therapy is promising, although there have been research studies that report contradictory results. Some researchers report dubious results as to the efficiency of this method when compared with results in a placebo group.12-15 These studies, however, have certain

| Table 2. Mean pain score, function score and total score as measured by the patient-rated tennis elbow evaluation scale (PRTEE) before and after treatment |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| | Mean pain score *(n = 16)* | Mean function score *(n = 16)* | Mean total score *(n = 16)* |
| | mean ± SEM | mean ± SEM | mean ± SEM |
| Before treatment | 29.19 ± 1.2 | 26.31 ± 1.48 | 56.75 ± 2.34 |
| After treatment | 19.56 ± 2.05 | 17.56 ± 1.91 | 39.38 ± 3.96 |
| t | 6.89 | 3.62 | 3.78 |
| p | p < 0.05 | p < 0.05 | p < 0.05 |
| 3 months after treatment | 14.75 ± 1.98 | 12.75 ± 2.11 | 27.5 ± 3.7 |
| t | 8.95 | 5.26 | 6.67 |
| p | p < 0.05 | p < 0.05 | p < 0.05 |
| 6 months after treatment | 11.94 ± 2.38 | 9.25 ± 2.14 | 20.88 ± 4.33 |
| t | 6.76 | 6.56 | 7.29 |
| p | p < 0.05 | p < 0.05 | p < 0.05 |
| 12 months after treatment | 7.38 ± 2.40 | 6.30 ± 2.10 | 13.69 ± 4.48 |
| t | 8.16 | 7.76 | 8.52 |
| p | p < 0.05 | p < 0.05 | p < 0.05 |
disadvantages. Haake et al. used local anesthesia which can modify the tissue effect of the shock wave therapy, may interfere with hyper-stimulation analgesia and can make it difficult to localize the procedure on the area of maximum tenderness. Speed et al. applied moderately strong dose shock wave therapy administered once a month for three months. Chung administered ESWT in patients, who had not been treated previously by any other modality, at a relatively acute stage of the disorder and had a shorter follow-up study.

Other authors reported significant improvement in relation to pain and functional activity in patients who had received focused extracorporeal shock wave therapy in comparison with a control group, the effect being sustained over a more extended follow-up. Different protocols were applied in those studies: low- and medium- energy shock waves; one procedure monthly, one procedure weekly; with and without anesthesia. The applied dose was also of great importance as it has already been demonstrated that the effect of treatment depends on it.

The radial shock wave therapy as administered herein has its advantages as it is comparable with low-intensity focused extracorporeal shock wave therapy and makes it possible on the basis of patient’s feedback to localize the therapeutic procedure on the most painful zone, because it is not necessary to apply local anesthesia. This can explain the advantages and the positive effect of the treatment in our study, which is consistent with that reported by Petrone et al., who used low-intensity focused shock wave therapy without local anesthesia.

In the available literature, Spacca et al. are the only researchers that investigate the effect of radial shock wave therapy in patients with lateral epicondylitis. The authors reported results which are similar to the results of our study – improvement in relation to pain and functional activity which were preserved for 6 months after treatment completed.

In our study we followed up the therapeutic effect for 1 year; our study protocol was different, too – we administered radial shock wave therapy once a week for 5 weeks. The fact that most of our patients had complaints for more than 10 months with no improvement or had only a temporary effect as a result of other conservative methods they received, excludes the possibility of spontaneous recovery with time as observed by other researchers.

The modern scale for self assessment (PRTEE) we used allowed us to assess more particularly the status of a patient caused by lateral epicondylitis because the modified scale developed by MacDermitt JC is more adequate in comparison with other scales used by other researchers: Disabilities of the arm, shoulder and hand (DASH) and Roles and Maudsley’s scale for nonspecific evaluation of the functional activity.

The mechanisms of the effect of extracorporeal shock wave therapy have not yet been fully clarified. Experimental studies on the Achilles tendon of rabbits and rats demonstrated that it induces neovascularisation with early release of angiogenesis markers (vascular endothelial growth factor VEGF and the proliferating cell nuclear antigen PCNA) at the site of the tendonal insertion. Low-intensity treatment accelerates the process of healing as TGF-β1 and insulin-like growth factor (IGF-I) play an important role in the stimulation
of cell proliferation and tissue regeneration. More recent studies reported that shock wave therapy provoked enzyme and non-enzyme intermediated synthesis of nitrogen oxide, which may well account for the method’s efficiency in the treatment of different tendinopathies.

The analgesic effect of the therapy is explained by the hyper-stimulation induced by the shock waves with activation of the afferent fibres of a smaller diameter. They transfer the stimulus to the cells of the gray substance zone near the aqueduct which activates the serotonergic system and the latter modulates the transmission of the pain impulse to the posterior horn of the spinal cord. This raises the pain threshold. In this respect researchers seem to implicate the mechanisms of the gate control theory.

The lower levels of calcitonin gene-related peptide (CGRP) in the dorsal roots ganglions in rats may also explain the analgesic effect of the shock wave therapy. It has been associated also with the role of substance P, as it has been demonstrated that the substance is considerably decreased at 6 weeks after administration of shock wave therapy in comparison with controls.

In a future study we plan to compare the obtained results with the design of auto-control by including a control group on a placebo treatment as well as to follow-up the dynamics of the therapeutic effect in the course of time.

CONCLUSIONS

We are yet unable to draw any definitive conclusions, but on the basis of the preliminary results of the present study demonstrating statistically significant decrease of pain, improvement of function and easier performance of everyday activities at therapy’s completion, an effect which increases at 3 months and is sustained up to 6 and 12 months after discontinuation of therapy, we advise that radial shock wave therapy can be used in the management of lateral epicondylitis of more than 6 months’ duration if it has been recalcitrant to other conservative therapeutic modalities.

In comparison with focused extracorporeal shock wave therapy, radial shock wave therapy is easier to administer and less expensive; it obviates the need to have instrumental guidance of the energy stream and any preprocedural anesthesia and this allows clinicians to target precisely the area of maximum tenderness on the basis of the patient’s feedback. Radial shock wave therapy is better tolerated by patients and has fewer adverse effects.

REFERENCES

ЭФФЕКТ РАДИАЛЬНОЙ УДАРНО-ВОЛНОВОЙ ТЕРАПИИ НА ПАЦИЕНТОВ С ЛАТЕРАЛЬНЫМ ЭПИКОНДИЛИТОМ

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ВВЕДЕНИЕ: Латеральный эпикондилит или т.н. „тенnis локоть” сравнительно часто встречаемое заболевание. Исследованы различные средства лечения, однако ни консервативные, ни оперативные методы показали постоянные и обещающие результаты. В последнее десятилетие в США и в Европе, а у нас в последние 2-3 года, ударно-волновая терапия (фокусированная и радиальная) находит все большее применение при лечении пациентов с хроническими тендинитами.

Цель: Настоящее исследование ставит себе целью сделать количественную оценку эффекта лечения латерального эпикондилита с помощью ударно-волновой терапии.

ПАЦИЕНТЫ И МЕТОДЫ: В исследование включено 16 пациентов с латеральным эпикондилитом – 9 мужчин и 7 женщин. Средний возраст пациентов 47.2 ± 2.3 г; давность жалоб – 15.05 ± 4.06 мес. Авторы использовали аппарат для радикальной ударно-волновой терапии, BTL – 5000, 5 процедур (одна в неделю); общее число импульсов – 2500, давление - 2 бар: 1500 импульсов частотой 5 Гц, вслед за ними 500 импульсов частотой 10 Гц локально на латеральный эпикондилит, 500 импульсов с давлением 2 бар и частотой 5 Гц по ходу мышц вблизи инъекции. Пациенты оценены пятикратно: до, непосредственно после окончания лечения, 3 мес, 6 мес и 12 мес. позже. Боль оценивалась в пике, при пальпации, при тесте Thomsen по визуально-аналоговой шкале (BAШ). Использовали The patient-rated tennis elbow evaluation (PRTEE) Questionnaire для оценки боли, функционального состояния и ограничений при проведении определенных деятельности, как и для целостной самооценки.

РЕЗУЛЬТАТЫ: Анализ данных показывает статистически значимое уменьшение (p < 0.05) между средними стоимостями оценки боли (в пике, при пальпации, при тесте Thomsen) до лечения по сравнению с результатами непосредственно после терапии. Этот результат удерживается на 3-й, 6-й и 12-й мес. БАШ показывает изменение в средних стоимостях: в пике: 3.75 ± 0.49 до лечения, 2.44 ± 0.39 непосредственно после лечения, 1.94 ± 0.46 на 3-й мес., 0.69 ± 0.38 на 12-й мес.; при пальпации: 7.44 ± 0.38 до лечения, 4.69 ± 0.51 после лечения, 3.56 ± 0.40 на 3-й мес., 1.46 ± 0.56 на 12-й мес.; при тесте Thomsen: 5.87 ± 0.46 до лечения, 3.5 ± 0.29 непосредственно после лечения, 2.5 ± 0.40 на 3-й мес. и 1.00 ± 0.38 на 12-й мес. Боль, функция и тяжелая оценка по шкале самооценки пациентов (PRTEE) также показывает статистически значимое (p < 0.05) улучшение после проведенной терапии по всему периоду прослеживания. Общая оценка изменяется – от 56.75 ± 2.34 до лечения до 39.38 ± 3.96 после окончания лечения, 27.53 ± 3.7 на 3-й мес. и 13.69 ± 4.48 на 12-й мес. прослеживания.

ЗАКЛЮЧЕНИЕ: Результаты этого предварительного исследования доказывают основание рекомендовать применение ударно-волновой терапии при лечении латерального эпикондилита. Изменение боли, наблюдаемое через 6 мес, неподдающееся другим консервативным методам лечения.