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Autologous US-guided PRP injection versus US-guided focal extracorporeal shock wave therapy for chronic lateral epicondylitis: A minimum of 2-year follow-up retrospective comparative study

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Abstract

Purpose: To compare the efficacy of two independent groups of patients treated with ultrasound (US)-guided extracorporeal shock wave (ESW) therapy and with US-guided injection of platelet-rich plasma (PRP) for chronic lateral epicondylitis (LE) with a minimum of 2-year follow-up. **Methods:** We retrospectively evaluated 63 patients treated for chronic LE (31 patients with autologous US-guided PRP injection and 32 patients with US-guided focal ESW therapy) from 2009 to 2014. All the patients were evaluated by means of Roles–Maudsley (RM) score, quick Disabilities of Arm, Shoulder, and Hand (QuickDASH) score, visual analogic scale (VAS) and patient-rated tennis elbow evaluation (PRTEE) to retrospectively assess the pain relief, level of activity, the self-reported function and subjective satisfaction at minimum of 2-year follow-up. **Results:** Both US-guided autologous PRP injection and US-guided focal ESW administration proved effective in chronic LE with significant improvement in the QuickDASH, VAS, RM and PRTEE scores ($p < 0.0001$). No adverse effects or complications were recorded in any groups. No differences were found in recurrence rate and final results of the QuickDASH, VAS, RM and PRTEE scores between the two groups ($p > 0.05$). The mean time between treatment and symptom resolution was significantly shorter for the PRP treatment ($p = 0.0212$); furthermore, the mean time to return to the normal activities was quicker for PRP group ($p = 0.0119$). **Conclusion:** Both PRP injection and ESW therapy are feasible and safe options for the treatment of chronic LE with low risk of complications and with good long-term follow-up results. US-guided PRP injection has quick efficacy when compared with US-guided focal ESW therapy.

Keywords

extracorporeal shock wave therapy, lateral epicondylitis, platelet-rich plasma injection, tennis elbow

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Introduction

Lateral epicondylitis (LE) is a painful condition of the elbow, resulting from a non-inflammatory tendinopathy along the extensor origin of the lateral epicondyle.[1] It affects 1–3% of the adult population and most commonly presents in the fourth and fifth decades of life, with equal prevalence among males and females.[2] Multiple aetiologies have been proposed, including micro-tears between the

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tendon origin of extensor carpi radialis brevis (ECRB) and the periosteum of the lateral epicondyle that lead to both inflammation and degenerative changes.[3] It has been demonstrated that the common extensor origin of the lateral epicondyle region is vulnerable to micro-traumatic events from eccentric loading and overuse because of its poor vascular supply.[4] Patients report pain and tenderness on the lateral aspect of the elbow with weakness in wrist extension and impairment of the gripping activities. A wide variety of therapies have been proposed (i.e. rest, physical therapy, non-steroidal anti-inflammatory medication, bracing and local injection) but the choice of the best treatment is still debated.[1–3] In case of failure of conservative measures, in 5–15% of patients surgery is required and the reported success rate of surgery is 85%.[5]

Extracorporeal shock waves (ESWs) are transient pressure oscillations that propagated in three dimensions and directly stimulate the healing, neovascularization and suppression of the activity of nociceptors on the target tissue. ESW treatment can increase the neovessels at the normal tendon–bone junction through the release of growth factors, transforming growth factor (TGFβ-1) and Insuline-like growth factor (IGF-I).[6] Clinical application of ultrasound (US)-guided focal ESW demonstrated good short- to mid-term results for the treatment of LE.[7–9]

On the other hand, several major preclinical and clinical studies have examined the role and therapeutic effects of platelet-rich plasma (PRP) in the treatment of soft tissue pathologies and other musculoskeletal disorders.[10–12] Platelets contain more than 300 bioactive cytokines and growth factors that operate via paracrine and autocrine mechanisms to coordinate cellular communication. Platelets also release vasoactive substances such as serotonin, calcium, histamine, and adenosine via their dense granules.[11]

Although the fullness of literature of studies focused on the conservative treatment of LE, there are no paper comparing the long-term efficacy and the clinical outcome of the focal ESW therapy and PRP injection.

The aim of this study was to compare the efficacy of two independent groups of patients treated with US-guided ESW therapy and with US-guided injection of PRP for chronic LE with a minimum of 2-year follow-up.

Materials and methods

We retrospectively evaluated 63 patients (63 elbows) treated for chronic LE (31 patients with autologous US-guided PRP injection and 32 patients with US-guided focal ESW therapy) at our institution, from February 2009 to October 2014. Inclusion criteria were (1) symptoms of LE for more than 6 months and magnetic resonance imaging (MRI) and/or US diagnosis of tendinosis of ERCB tendon; (2) persistence of pain and function impairment refractory to rest, ice, sling and pharmacological therapies (local or systemic non-steroidal anti-inflammatory drugs (NSAIDs) and/or analgesic drugs); (3) persistence of symptoms after previous physical therapies (Laser, Tecar, TENS and US); and more than 6 months elapsed between the selected treatment and previous therapies.

Patients in treatment using anti-inflammatory drugs/pain killers, steroids or anticoagulant, cardiac pacemaker carriers, previous injections, surgery or fractures of the affected elbow, systemic diseases, history of epilepsy, congenital or acquired deformities of the upper limb, history of neurologic or musculoskeletal disorders that might affect grip strength, active/previous infection in the site of treatment, open wounds or skin ulcers, history of any blood disorder, haemoglobin <11 g/dL, haematocrit <33%, and platelet count outside of the normal range of 150 to 400 × 1000/μL and pregnant or lactating women were excluded. Patients with less than 24-month follow-up were excluded as well.

In all cases, diagnosis was verified before the treatment by means of clinical tests, that is, a painful local palpation at the humeral epicondyle and positive Cozen's and middle finger's tests. Furthermore, the sonographic evaluation of the elbow with high-frequency probe (18-6 MHz linear transducer) was performed in all patients in order to confirm the diagnosis.

Patients were seated in a chair with the arm flexed at 90° and the antero-medial forearm resting on an examination bed. The common extensor origin from the lateral humeral epicondyle was examined in longitudinal and axial planes. The sonographic assessment was made with systematic evaluation of tendon echotexture, overall tendon thickness and neovascularity as previously described by Clarke et al.[13]

US inclusion findings were structural changes in the common extensor origin (tendon thickening, hypoechogenicity and diffuse heterogeneity) and blood flow changes or neovascularity.

Tendinosis was defined as thickening and heterogeneous echotexture of tendon with the presence of Doppler hyperaemia in common extensor origin. Negative findings on both grey scale and Doppler US conclusively excluded diagnosis of LE. Patients diagnosed with myofascial pain, posterior interosseous nerve entrapment and partial tears of common extensor origin were excluded.

The patients were free to choose their treatment modality (PRP or ESW) based on their confidence and disposal, being informed and conscious of the advantage/disadvantage of each treatment and always upon written informed consent.

For patient treated with PRP injections, a blood sample of 450 mL was taken from the patients and treated by the Department of Transfusion Medicine. The blood underwent a standardized protocol of preparation, which consisted of three centrifugations (Hettich Zentrifugen®; Hettich Lab technology, Tuttlingen, Germany): the first at 3550 r/min for 12 min, the second at 1100 r/min for 10 min and the last at 2600 r/min for 20 min; the final

product was then filtered and frozen (–80°C) in four shares for cryopreservation.

The platelet concentration in this type of PRP was 2–3 times greater than the blood platelet count (range 250,000–900000/μL, mean 600,000/μL), which is considered to be moderately elevated. Moderately elevated platelet concentration seems to induce optimal biological benefit, with lower platelet concentrations leading to suboptimal effects and higher platelet concentrations to inhibitory effects. During their preparation, leucocytes were filtered and their concentration in the final product was low (<1000/μL).

Our institute protocol provides four 3-mL injections of PRP once a week for each patient. The injection was always performed in sterile conditions and under US guide. We decided to use the sonography to better assess the soft tissue target and because the manual injection of the ECRB tendon often lacks accuracy with only 30% of reported hit target tissue.[14]

For patients belonging to the ESW group, focal ESW were administered by means of an electromagnetic generator equipped with in-line US guidance in order to increase the reliability and effectiveness of the treatment (Minilith SL1, Storz®, Tagerwilen, Switzerland).

In accordance with the literature[15,16] and International Society for Medical Shock wave Treatment guidelines,[17] ESWs were administered during 3–4 weekly sessions, depending on the symptom's initial severity and symptoms modification during treatment.

The repetition frequency of shock wave pulses was 4 Hz, and the machine was set on a low to medium energy level compatible with patients' pain tolerance. A low energy level (0.03–0.07 mJ/mm^2) in the first session, and then medium energy level (0.08–0.13 mJ/mm^2), if tolerated, during the following sessions was considered the standard protocol. A total of 1000 impulses were administered for each session. The US guide was used to focalize the ESW pulses at the muscle origin and muscle–tendon junction of the ECRB, which are both involved in the pathogenesis of the LE. Coherence with the localization of pain generally complained by the patient was verified during the ESW administration. This specific setting protocol was demonstrated to be effective in the treatment of recalcitrant LE in a previous studies.[8,9]

No local anaesthetic was used to prevent a possible negative interaction. Patients were advised to rest, apply ice and avoid unnecessary efforts for 24–48 h after the treatment session. Acetaminophen was recommended as an analgesic, if needed, but patients were instructed to abstain from taking NSAIDs during the treatment and for 2 weeks after the last injection in order to prevent possible negative interaction with the mechanism action of PRP. Patients were also instructed to stop sports activity or heavy physical work during the treatment time. Physical therapy was not prescribed after treatment, and a gradual return to normal recreational, working and sport activities was then allowed.

Table 1. RM score.

Results	Point	Interpretation
Excellent	1	No pain, full movement and activity
Good	2	Occasional discomfort, full movement and activity
Fair	3	Some discomfort after prolonged activity
Poor	4	Pain-limiting activities

RM: Roles–Maudsley.

All the included patients were evaluated by means of Roles–Maudsley (RM) score,[18] quick Disabilities of Arm, Shoulder, and Hand (QuickDASH) score,[19] visual analogic scale (VAS)[20] and patient-rated tennis elbow evaluation (PRTEE)[21] to retrospectively assess the pain relief, level of activity, the self-reported function and subjective satisfaction at long-term follow-up. The RM score is a subjective functional score ranging from 1 to 4 where 1 correspond to pain-free full movement and activity and 4 to poor painful function with limitation of daily activities (Table 1).

The QuickDASH represents a validated self-reporting questionnaire consisting of 11 questions (from the 30 items of the original version), investigating symptoms and functional tasks. Like the extended version, the QuickDASH score ranges from 0 (no disability) to 100 (extreme disability). The VAS indicates the subjective feeling of pain, with 0 indicating no pain and 10 indicating the worst pain that the patient has ever had. The PRTEE is 15-item questionnaire designed to measure forearm pain and functional disability in patients with tennis elbow. The score ranges from 0 (best score) to100 (worst score).

Pretreatment data relative to RM, quickDASH, PRTTE, VAS and clinical tests were available for all patients, consulting medical records and values were compared with those obtained at last follow-up (LFU).

Subjective satisfaction was investigated through patients self-assessing to one of four satisfaction categories (i.e. very satisfied with the outcome, satisfied, partially satisfied and unsatisfied). A specifically created questionnaire was further used in order to investigate eventual therapies tried before the treatment in study, time before symptom remission after treatment, time prior to go back to usual activities, need to retreatment or reinjection.

Recurrence was defined as persistence of pain or symptom relapse with return to normal activities, work and/or sport activities, need of reinjection/retreatment and recurrence of symptoms after minimum of 6 months after administered therapy.

The continuous variables between the two-paired groups were compared using the nonparametric Student's t test or the Wilcoxon signed-rank test. The continuous variables between two-unpaired groups were compared with Mann–Whitney U test. The categorical variables of two independent groups were compared with the two-tailed Fisher's exact test. A $p < 0.05$ was considered statistically significant.

Table 2. Demographic data of each treatment group.

Type of treatment	No. of elbows	Gender (male/female)	Risk factors (professional or sport activities)	Main duration of symptoms (months)	Mean age (years ± SD)	Age (range)	Follow-up (months ± SD)	Follow-up (range)
PRP	31	18/13	14	8.3 ± 4.3	46.3 ± 10.1	18–69	44.5 ± 11.9	25–67
ESW	32	13/19	12	7.9 ± 5.1	50.4 ± 7.3	31–65	40.0 ± 5.1	24–45

PRP: platelet-rich plasma; ESW: extracorporeal shock wave.

Results

Sixty-nine patients with LE diagnosis met the inclusion criteria of the study, 6 of them were not disposable to participate or were untraceable for a total of 63 investigated patients (63 elbows).

Thirty-one patients were treated with autologous US-guided PRP injections and 32 with US-guided ESW administration (Table 2). Twenty-six patients in the series were considered at risk of LE for both their manual and sport activities.

The mean age was 48.5 ± 8.7 years (range, 18–65), and the mean follow-up was 42.1 ± 9.1 months (range, 24–67 months). No differences were found between the demographic characteristics of the two different treatment groups ($p > 0.05$). The QuickDASH, VAS, RM and PRTEE scores before the treatment and at LFU for both treatment groups are reported in Table 3. Statistical analysis of data demonstrated that both US-guided autologous PRP injection and US-guided focal ESW administration demonstrated effective in chronic LE with significant improvement in the QuickDASH, VAS, RM and PRTEE scores ($p < 0.0001$) as shown in Figure 1.

Nevertheless, no differences were found for the final results of the QuickDASH, VAS, RM and PRTEE scores between the groups ($p > 0.05$). No differences were found in recurrence rate between the two groups (6.5% in the PRP group and 15.6% in the ESW group, $p > 0.05$). No adverse effects or complications subsequent to treatment administration were recorded in both groups.

The mean time between treatment and symptoms resolution was 1.1 ± 0.9 months (range, 0.5 – 6) for the PRP treatment and 1.7 ± 1.1 months (range, 0.5–4) for ESW therapy ($p = 0.0212$); furthermore, the mean time to return to the normal activity of daily living was 0.8 ± 1.4 months (range, 0–6) for PRP group and 1.5 ± 0.6 months for ESW therapy (range, 0–3) ($p = 0.0119$).

Two patients (6.4%) in the PRP group and four patients (12.5%) in the ESW group were unsatisfied but no differences were found ($p > 0.05$), instead 88.9% of the patients were satisfied and very satisfied with the chosen treatment. Among patients treated with ESW therapy, one patients had resolution of symptoms in the second session of therapy and was satisfied at the LFU. Three patients (4.8%) required surgical treatment (one in the PRP group and two in the ESW group) for failure of conservative measures. Outcome features of the two treatment groups are listed in Table 4.

Discussion

Various conservative measures have been proposed as suitable alternatives to surgical intervention for chronic tennis elbow. Unfortunately, no guidelines are available for the treatment of chronic LE. For many years, injection of corticosteroid has been the preferred treatment of patients with recalcitrant LE.

Earlier studies suggested greater benefits of corticosteroid injection compared to NSAIDs, but the same cohort of patients demonstrated no difference in pain control and outcomes at 12 months.[22] More recent studies suggested that corticosteroid injections demonstrated only short-term relief and that these patients may have more pain and dysfunction at longer follow-up compared to other patients treated with conservative measures.[23,24] Smidt et al.[24] showed high frequency of relapse and recurrence with corticosteroid injection for LE because the inhibitor processes of cortisone may lead the intra-tendinous injection to deleterious long-term effects with permanent structural changes and tendon atrophy. Furthermore repeated preoperative steroid injection have been recently identified as significant risk factor for revision in case of surgical treatment of LE.[25]

When considering treatment modalities for patients with LE, researchers have begun to examine the role of biological therapies for LE management in an attempt to optimize the local environment for tendon healing and to promote its potential regeneration. Inflammation processes can in fact provoke the release of cytokines and growth factors from platelets, leucocytes, macrophages and other inflammatory cells. These growth factors promote neovascularization and chemotaxis of fibroblasts and tenocytes and stimulate fibroblast and tenocytes proliferation and neo-synthesis of collagen.[26] These processes are based on the mechanism of action of both PRP injection and ESW therapy.[6,9,27]

Peerbooms et al.[28] compared a single PRP injection and corticosteroid injection in patients who failed non-operative measures and demonstrated significant pain reduction and increased function with PRP injection therapy. Authors obtained 73% of success rate, nevertheless the PRP properties were different: Local anaesthetics and epinephrine have been added, leucocyte concentration were not clearly specified and therapeutic protocol was different (all included patients received only one PRP injection). These features could justify the differences in final results if compared with the present study.

Table 3. Mean values and standard deviations of pretreatment and LFU QuickDASH, VAS and RM scores of the two treatment groups of patients.[a]

Group	QuickDASH pre-	QuickDASH LFU	*p* Value	VAS pre-	VAS LFU	*p* Value	RM pre-	RM LFU	*p* Value	PRTEE pre-	PRTEE LFU	*p* Value
PRP	65.1 ± 10.5	5.5 ± 9.5	**<0.0001**	8.4 ± 1.1	0.9 ± 1.6	**<0.0001**	3.7 ± 0.5	1.3 ± 0.7	**<0.0001**	60.1 ± 5.6	15.9 ± 4.1	**<0.0001**
ESW	57.4 ± 20.2	3.3 ± 7.4	**<0.0001**	8.0 ± 1.3	0.8 ± 1.8	**<0.0001**	3.8 ± 0.4	1.4 ± 0.8	**<0.0001**	61.6 ± 10.4	14.2 ± 4.9	**<0.0001**

LFU: last follow-up; QuickDASH: quick Disabilities of Arm, Shoulder, and Hand; VAS: visual analogic scale; RM: Roles–Maudsley; PRTEE: patient-rated tennis elbow evaluation.
[a]Boldface values indicate *p* values < 0.05.

Mishra et al.[11] published a prospective randomized controlled trial of 230 patients and highlighted a meaningful improvement in the clinical outcome in patients treated with leucocyte-enriched PRP for LE after 24 weeks. The success rate of this study was 82.1%, but both the PRP preparation and the therapeutic protocol were different.

The non-standardized PRP preparation and composition do not help in the comparison between the different PRP products being delivered to patients. A precise, stepwise and detailed description of the preparation protocol is required to allow comparison among studies and provide the reproducibility of this therapeutic application.[29]

Systematic reviews that had evaluated the effectiveness and reliability of ESWT for the treatment of LE have been published with diverging results.[30] ESW therapy demonstrated positive results in some studies.[7,16] On the other hand, some other studies did not find superiority to ESW if compared with placebo.[15,30]

Positive effect of ESW therapy on LE have been demonstrated by some authors to reduce the necessity of surgery.[15,31] ESW therapy (1000 impulses of 0.08 mJ/mm^2) represented an effective method to decrease pain in chronic tennis elbow. Authors showed how the low-energy shock wave treatment led to alleviation of pain and improvement in function in 90% of their 50 patients with chronic tennis elbow with 91% of resolution of symptoms in patients with LE after treatment. Wang et al.[9] demonstrated significant improvement in pain, functional scores, grip strength and range of motion among patients treated with 1000-impulse protocol compared with the control group.

From our opinion, to obtain good results with the ESW therapy for the treatment of LE, it is necessary to accurately select the patients and to use focused ESW therapy. This therapy has the maximal energy to reach the focus that is located deeper into the soft tissues and the US guide is used to identify the target tissue with less missing rate. However, there is a need for high-quality studies comparing the results of the focused and radial ESW therapy in chronic LE.[32]

Biological impact of the shock waves on target tissues are the up-regulation of proliferating cell nuclear antigen (PCNA), collagen type I, collagen type III and TGF-β-1 gene expression, followed by an increases in nitric oxide (NO) production, TGF-β-1 release and collagen synthesis. Moreover, shock waves can stimulate tenocyte proliferation and collagen synthesis. These data supported that tenocyte proliferation is mediated by early up-regulation of PCNA and TGF-β-1 gene expression, endogenous NO release and synthesis and TGF-β-1 protein and then collagen synthesis.[26]

In the present study, PRP injection and ESW therapy both lead to significant improvement in pain, function and return to normal activity in patients with chronic LE, with a minimum of 2-year follow-up. Although this improvement was comparable in both treatment groups for RM, quickDASH, PRTEE and VAS, the US-guided PRP injections

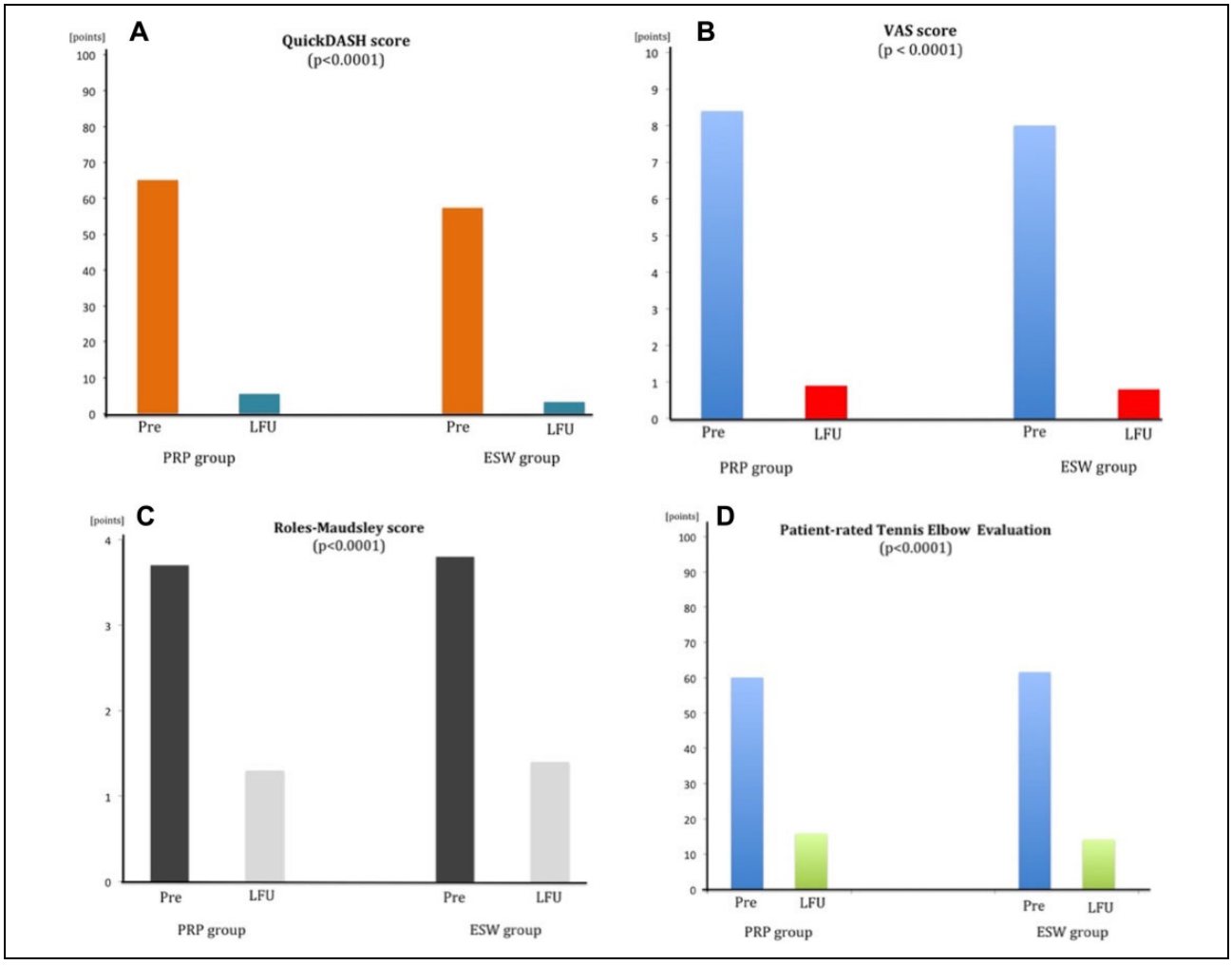

Figure 1. Graphic illustration of pretreatment and at LFU QuickDASH (a), VAS (b), RM (c) and PRTEE (d) scores of the two treatment groups of patients. LFU: last follow-up; QuickDASH: Quick Disabilities of Arm, Shoulder, and Hand; VAS: visual analogic scale; PRTEE: patient-rated tennis elbow evaluation; RM: Roles–Maudsley.

Table 4. Clinical features and *p* values indicating no statistically significant differences of the two treatment groups of patients.

Results	PRP	ESW	*p* Value
Adverse effects	0	0	1
Recurrence	2	5	0.426
Unsatisfied patients	2	4	0.672
Surgical treatment	1	2	0.202

PRP: platelet-rich plasma; ESW: extracorporeal shock wave.

showed early remission of symptoms and faster return to normal activity if compared with ESW therapy. To the best of our knowledge, there are no study comparing the long-term efficacy of these conservative treatments.

Several limitations could be underlined in this work. First, it is a non-controlled retrospective study on limited population of patients. Second, there is also a large variability in patients' features and about symptom history and previous conservative treatments. Third, the absence of MRI and/or sonographic imaging evaluation at the LFU to demonstrate the soft tissue differences before and after treatment. Finally the high satisfaction rate of the present study could be justified because the patient self-selected their treatment modality. With these limitation, however, this is a single-centre study with two groups of patients with homogeneous diagnosis treated with standard protocols and mid-term follow-up of at least 2 years.

Conclusion

PRP injection and ESW therapy both are feasible and safe options for the treatment of chronic LE with low risk of complications and with acceptable mid-term follow-up results. Longer term randomized comparative studies are necessary to determine more objectively the correct definition of the first-line treatment for ESW and PRP injections.

Declaration of conflicting interests

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