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Original article

Autologous Platelet Rich Plasma (PRP) in the treatment of elbow epicondylitis and plantar fasciitis: medium to long term clinical outcome

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Abstract

*Background and aim***:** Platelet-Rich-Plasma(PRP) is a popular biological therapy especially used to regenerate different musculoskeletal tissues by releasing growth-factors and cytokines promoting cell proliferation, chemotaxis, differentiation, and angiogenesis. The *aim* was to evaluate the clinical effectiveness and safety of PRP for Lateral-Epicondylitis (LE) of the elbow and Plantar-Fasciitis (PF). *Methods:* A retrospective study was conducted including patients treated with a single topic autologous-PRP-injection between 1-1-2009 and 7-18-2019 for LE or PF at our institution; patients operated for the same problem, patients refusing the study or not traceable were excluded. Patients were assessed with VAS for pain and clinical scales. *Results:* 33 patients were treated with PRP and 13 (8F, 5M) included: 4LE and 9PF for a total of 16 cases. The average pain level was 0.61±0.63: 1±1.41 for LE and 0,44±0 for PF. No significant side effect was reported. 4 PRP-treatments failed: 2LE and 2PF. OES and PRTEE gave excellent results for elbow. Average foot scores were AOFAS 98.2±5 and FADI 91.3±1. Patients were stratified and compared according to plantar arch conformation, follow-up length, healing time, time from diagnosis to PRP-treatment, therapies before PRP (physiotherapy, steroid infiltration or shock-waves), risk factors (standing work, sport, age, sex). *Conclusions:* As in other studies, our results do not allow to draw sufficiently valid conclusions regarding the effectiveness and safety of PRP in the treatment of LE and PF: in particular the statistical significance is limited by the small sample size. PRP can be chosen as a non-first-line treatment for LE and PF.

Key words: PRP, Platelet Rich Plasma, epicondylitis, plantar fasciitis, regenerative medicine, growth factors.

Introduction

Plantar fasciitis (PF) is a common musculoskeletal problem characterized by pain in the heel. It is often described as an overload of the plantar fascia[1] but the pathophysiology remains poorly understood. Pain is the most important clinical manifestation and is intensified by prolonged weight bearing, obesity, and increased activity. It is estimated that about 10% of the population may be affected by this pathology.[2] The highest risk of occurrence of PF is at 40 to 60 years of age, with no significant difference in sex distribution.[3] Diagnosis of PF is mainly clinical. In terms of treatment, various methods have been used including nonsteroidal anti-inflammatory drugs, corticosteroid injections, and non drug approaches, such as heel pads,

arch supports, plantar fascia stretching exercises, extracorporeal shock wave therapy, and even surgical treatment. Platelet Rich Plasma (PRP) has been suggested as an alternative treatment.

Lateral Epicondylitis (LE), commonly known as tennis elbow, is one of the most common musculoskeletal soft tissue injuries in adults. It is characterized by elbow pain increased with wrist extension. LE appears to be a very common disease, the incidence is estimated at 1 to 3% in the general population. [4] The prevalence appears to be increased in the working age population.[5] It typically occurs between 35 and 55 years.[6] Any activity that involves overuse of the wrist extensor or supinator muscles may be a risk factor even if in most cases of lateral epicondylitis, no obvious underlying etiology can be identified.[7] A segment of the population that is particularly affected is that of sportsmen at both a competitive and non-competitive level. About 50% of tennis players, especially at the amateur level, are affected by this pathology during their life, but they represent only 10% of the total cases of LE.[8] The treatment of lateral epicondylitis includes rest, nonsteroidal anti-inflammatory medication, stretching, physical therapy, shock wave therapy, botulinum toxin injection, corticosteroids injection and PRP.

Platelet Rich Plasma (PRP) is a bioactive form of autologous whole blood with a platelet concentration greater than baseline. The PRP can be used in different areas for the regeneration either of soft tissues or bone.[9] Dohan's study[10] proposed a classification of these preparations based on the different platelet concentration and their various biologic characteristics,[11] because for example a more elevate concentration could favor the formation of a thicker fibrin net, so it may lead to different clinical effects.[12] The PRP is said to improve tissues healing via local injection of growth factors and recruitment of reparative cells.[13,14] The beneficial effect of PRP is attributed to its high concentrations of growth factors: PDGF, VEGF, EGF, PF-4, IGF-1, TGF-β.[15,16] The PRP can be made following different preparation protocols. The use of PRP in LE and PF is usually reserved for second-line treatment, after the failure of initial conservative therapies and therefore in patients who have not benefited from previous treatments.[17,18] The effectiveness of the PRP in these pathologies is still being debated.[7,19,20]

The **purpose** of this study was to evaluate the clinical effectiveness and safety of PRP in the treatment of lateral epicondylitis and plantar fasciitis.

Materials and Methods

Study design: a retrospective observational study was conducted according to the STROBE statement for cohort studies.[21]

Inclusion criteria: patients treated by local PRP injection for PF or LE at the Department of Orthopedics and Traumatology of the "AUO Maggiore della carità" hospital of Novara (Italy) from 1st of January 2009 to 18th of July 2019 were included. Patients were retrieved through the surgical registries of our institution. Bilaterally affected patients were counted twice.

Exclusion critera: patients who did already have surgery in the same anatomical site and for the same problem and patients not accepting participation in the study or not traceable.

Preparation of PRP: all our patients were treated with a single local PRP injection obtained following the same preparation protocol (BIOMET biologics nSTRIDE® APS preparation kit).

Outcomes: the primary outcome for both PF and LE was pain assessed with Visual Analogue Scale (VAS).[22]

Secondary outcome was disability assessed by Quick-DASH[23] for LE and FADI[24] for PF. The functional outcome was measured by the Italian validated American Orthopaedic Foot & Ankle Society (AOFAS)[25] score for foot and by Patient-Rated Tennis Elbow Evaluation (PRTEE) [26] and Oxford Elbow Score (OES)[27] for elbow.

Patients were classified in 7 foot-types depending on plantar arch evaluated by podoscope: normal arch, high arch (3 degrees) and flat foot (3 degrees).

The time to return to normal activities and work after treatment was also evaluated as an indirect index of possible complications and the time required to reach a therapeutic effect.

Patients were asked for feedback with binomial yes/no form about satisfaction for treatment.

The possible adverse effects reported and attributable to the PRP inoculation, the absence of a therapeutic effect and the requiring of subsequent surgery or other interventions were considered as failure.

Age, sex, duration of symptoms and different therapies undertaken before this treatment were also recorded.

We carried out a descriptive *statistical analysis* of the sample evaluating the mean, the median and the standard deviation and stratifying the patients according to some variables.

Results

Sample description

Of the 33 patients treated with PRP 13 were included: 4 with diagnosis of LE, 1 of which bilateral, and 9 with PF, 2 of which with bilaterality. Therefore 16 cases, 11 PF and 5 LE, were evaluated in 13 patients, 8 females and 5 males. (Table 1)

Of the 9 patients with PF, 2 (22.5%) were affected on left side, 5 (50%) on right side and 2 (22.5%) bilaterally.

Failures

2 patients in the LE (3 elbows) and 2 in the PF group (3 feet) were unsuccessful with PRP. (Table 2)

One of the patients attended surgery at the elbow after PRP failure, but still with unsuccess and thus was operated again with a Nirschl complete procedure (excision of ERCB tendon and epicondyle drilling); the other patient, with bilateral epicondylitis, had full recovery after local corticosteroid injection therapy associated with physiotherapy.

Of the 2 patients not healed from PF with PRP, none did attend surgery. One had remission of symptoms after multiple cycles of focal extracorporeal shock waves, while the other, who had a bilateral involvement, was still suffering from the pathology. (Table 2)

After further exclusion of the failed patients, the remaining were evaluated for pain and functional outcomes.

Pain

The mean VAS score for pain was 0.61 (SD 0.63) for the total sample, 1 (SD 1.41) for LE and 0.44 (SD 0) for PF. (Table 3)

Table 1. Sample description.

Sample Description			
	Total (PF+LE)	**Plantar Fasciitis (PF)**	**Lateral Epicondylitis (LE)**
Included patients N	13 (8F, 5M)	9	4
Included cases N	16	11	5

Table 2. PRP failures and subsequent treatments with outcome.

PRP Failures		
	Lateral Epicondylitis	**Plantar Fasciitis**
Patients N	2	2
Cases N	3	3
Therapeutic interventions post PRP Failure		
Surgery	1	0
Shock Waves	0	2
Glucocorticoid Injection + Physiotherapy	1	1
Outocomes		
Healed	1	1
Unhealed	1	1

Table 3. Primary outcome pain expressed in VAS score, after exclusion of failed patients.

Pain (VAS)			
	Total (PF+LE)	**Plantar Fasciitis (PF)**	**Lateral Epicondylitis (LE)**
Pain (mean ± SD VAS)	0.61 ± 0.63	0.44 ± 0	1 ± 1.41

Elbow clinical outcomes

Elbow scores for the 2 remaining successful patients (2 cases) were: OES 48 (best possible) for both and PRTEE zero (best possible) for both.

Foot clinical outcomes

- AOFAS: mean 98.2, median and mode 100, SD 5.11;
- AOFAS-F (function): mean 49.7, median and mode 50, SD 3.33;
- AOFAS-P (pain): mean 38.7, median and mode 40, SD 3.33.
- FADI: mean 91.3, median and mode 104, SD 1.12;
- FADI-A (activity): mean 87.3, median and mode 88, SD 0.77;
- FADI-P (pain): mean 15.7, median and mode 16, SD 0.70. (Table 4)

4 patients showed a normal plantar arch with a mean AOFAS of 97 and FADI of 103.5, 4 patients a high arch with AOFAS 97.5 and FADI 102.7, and zero a flat foot. (Table 4)

Patients were also classified depending on follow-up length: the 4 patients treated before 2011 had FADI 103.5, FADI-pain 16 and FADI-activity 87.5; the 4 patients treated after 2011 had FADI 102.7, FADI-pain: 15.5, FADI-activity: 87.2. (Table 4)

Of the 8 cases treated with PRP for PF (excluding failures), the healing time was greater than or equal to one year in 7 cases and less than one year in 1. (Table 5)

Time from diagnosis to PRP treatment was one year or more in 7 patients (FADI 101, FADI-activity 87, FADI-pain 14) and lower than one year in one patient (FADI 103.4, FADI-activity 87.7, FADI-pain 16). (Table 4)

Table 4. Plantar fasciitis' outcome. FADI P = pain disability, FADI A = evaluation of the impact on daily activity.

PLANTAR FASCIITIS' Evaluation Scales						
	FADI			**AOFAS**		
	Tot.	**Activity**	**Pain**	**Tot.**	**Function**	**Pain**
Average	91.3	87.3	15.7	98.2	49.7	38.7
Median	104	88	16	100	50	40
Mode	104	88	16	100	50	40
SD	1.12	0.77	0.7	5.11	3.33	0.70
Time between diagnosis and PRP	**FADI Tot**	**FADI A**	**FADI P**			
> 1 Year (N 7)	101	87	14			
< 1 Year (N 1)	103.4	87.7	16			
Time of Follow-Up (> or < 9 years)	**FADI Tot**	**FADI A**	**FADI P**			
Treatment before 2011 (N 4)	103.5	87.5	16			
Treatment after 2011 (N 4)	102.7	87.2	15.5			

Table 5. Plantar Fasciitis Patients' Data.

PLANTAR FASCIITIS			
Patients N			9
Cases N			11
Failures N(%)			3 /11 (27%)
Pain VAS			0.44 ± 0
Foot	**Cavus**	**Normal**	**Flat**
N	4	4	0
AOFAS	97.5	97	
FADI	102.7	103.5	
Healing Time	**≥1 Year**	**< 1 Year**	
Number	7	1	
Satisfied	**Yes**	**N0**	
N	7	4 (3 failures +1)	

Table 6. AOFAS and FADI scale values for each single pre-PRP treatment.

PF TREATMENTS BEFORE PRP			
Physiotherapy	**N**	**AOFAS**	**FADI**
Yes	6	95	103
No	2	100	103,5
Glucorticoides	**N**	**AOFAS**	**FADI**
Yes	8	98,2	91,3
No	0	—	—
Shock Waves	**N**	**AOFAS**	**FADI**
Yes	4	97,5	103
No	4	97	103,2

PF cases were compared with FADI and AOFAS scales depending on whether they were treated before PRP respectively with physiotherapy, steroid infiltrations or shockwaves. (Table 6) Six patients had undergone at least one course of physiotherapy and reported an average AOFAS score of 95 and FADI of 103 against AOFAS 100 and FADI 103.5 for the 2 non-physiotherapy cases. All 8 cases received at least one therapeutic cycle with local corticosteroid injection before PRP treatment. In the 4 cases treated with shock-waves cycles before PRP were recorded the following scores: AOFAS 97.5 and FADI 103.2; while in the 4 not treated with shock-waves: AOFAS 97 and FADI 103.2. (Table 6)

Patients have been stratified according to risk factors for PF: sex, standing work, predisposing sports. (Table 7)

- Three patients were exposed to a standing work activity and the following scores were recorded: AOFAS 100, FADI 104 (AOFAS-pain 40, FADI-pain 16). Five patients non-exposed: AOFAS 95.6, FADI 102.6 (AOFAS-pain 38, FADI-pain 15.6).

- 5 patients played predisposing sports. In this exposed group the following scores were recorded: AOFAS 100, FADI 103.6 (AOFAS-pain 40, FADI-pain 16); non-exposed AOFAS 92.6, FADI 102.3 (AOFAS-pain 36.6, FADI-pain 15.3).

- Patients were divided by age in 2 groups: over 45 years (3 patients): AOFAS 96.6, FADI 103; under 45 years: AOFAS 97.6, FADI 103.2 (AOFAS-pain 35, FADI-pain 15).

- Patients were divided also by sex: 2 males and 5 females. In male group scores are: AOFAS 95, FADI 102.5 (AOFAS-pain 35 and FADI-pain 15). In female group, the scores recorded are: AOFAS 98, FADI 103.3 (AOFAS-pain 40 and FADI-pain 16). (Table 7)

Table 7. Scores for each single risk factor

RISK FACTORS				
	AOFAS Tot.	**FADI Tot.**	**AOFAS Pain**	**FADI Pain**
Work				
Standing (N3)	100	104	40	16
Not standing (N5)	95,6	102,6	38	15,6
Sport				
Athlete (N5)	100	103,6	40	16
Not Athlete (N3)	92,6	102,3	36,6	15,3
Age at PRP				
< 45 (N5)	97,6	103,2	40	16
> 45 (N3)	96,6	103	36,6	15,3
Sex				
Male (N2)	95	102,5	35	15
Female (N5)	98	103,3	40	16

Discussion

Musculoskeletal injuries represent a challenging problem for traumatology and sports medicine, as they are among the most common causes of severe long-term pain and physical disability.

For this reason, it is commonly accepted that a quick mobilization associated with specific rehabilitation and physical therapies facilitates an adequate structural resolution of the lesion. Also PRP injections may favour this process. PRP is a biological blood product obtained from the patient, which has anti-inflammatory and pro-regenerative functions. It has been demonstrated that PRP is able to induce proliferation and differentiation of cells and facilitate angiogenesis.

Nevertheless, literature is not clear about the PRP real therapeutic efficacy.[17,19,28,29,30,31]

For this reason, although LE and PF are not sporadic in the general population, in this study only few cases were treated with PRP therapy.

All these patients, for both pathologies, were refractory to systemic and local pharmacologic treatments and to physical therapies; all were treated following the same operative protocol with a single local injection of PRP obtained with the same procedure. Authors believe that in this cohort of patients the use of PRP could be an effective alternative before surgery and that the results could describe the real efficacy of this treatment.

No patients reported significant negative effects related to PRP injection; in the worst case the treatment did not obtain a therapeutic effect. This is in accordance with other authors[13,28] who reported that PRP is a secure treatment and has not significant adverse effects except for rash and pain around the site of injection.[32,33]

DASH scale, as well as the quick-DASH version[23,34] and the Mayo Elbow Performance Index (MEPI)[35] are usually used for the evaluation of the elbow's pathologies, but authors decided not to use this latter scale because 2 of the 4 sections of MEPI are not appropriate in the lateral epicondylitis, with the risk to negatively affect the outcomes.

Other evaluation scales such as the SF-12[36] and SF-36[37] were initially considered for assessment, but they were discarded because they are characterized by a low specificity.

The primary outcome of both pathologies in this study was the evaluation of pain with the VAS.[22,38]

Secondarily, specific scales for each pathology were used in order to assess disability and functional evolution.

The overall average score for the VAS in PF was 0,44 /10. This score shows a good regression of the pain. This result can be explained by the elevated time in follow-up and by the typical natural evolution of these pathologies: they are characterized in fact by restricted time frame.[17,8]

The LE patients had still good but worse results with an average score of 1 /10. It could be explained by the elevated number of failures in proportion of the small number of patients in this group and by other concurrent conditions and diseases.

Similar considerations may be done for both groups of pathologies regarding the functional scores. In fact, if we split the PF group according to the treatment's year, before or after 2011, we have a less favourable average score in the group with shorter follow-up.

The time between the use of PRP and healing is at least one year in most of patients. This is in accordance with the PRP's therapeutic rationale in which there is a regenerative effect mediated by the growing factors.[12,13] This effect is more lasting, but more diluted over time, than other alternative therapeutic options. [8,17]

Our subjects, who did not have a PRP's failure, expressed a general satisfaction for PRP therapy, being only one unhappy for this treatment.

The total number of PRP's failures was 4 out of 13 subjects: 2 in LE and 2 in PF.

One of this failures, that was treated bilaterally with PRP for PF, had a diagnosis of fibromyalgia: the literature reports a possible correlation between fibromyalgia and PF or with other foot pathologies which heal with higher difficulties.[39] Furthermore symptoms could be referred more to fybromialgia than to PF itself. The other PF failure was treated with 3 cycles of shock waves and afterward healed.

As regard to the two LE failure, one underwent surgery without success, and the other, that had been treated with PRP bilaterally, healed after further corticosteroids injections and physiotherapy.

Patients had an average time of more than one year between diagnosis and treatment with PRP, because nowadays PRP is still considered a second line treatment in no responding cases. All subjects before PRP treatments, had a combination of corticoids injection and physical therapies.[8]

Our patients were treated with PRP in a temporal arc of ten years and this long follow up may have leaded to overrate the outcome score obtained in our patients, knowing that these pathologies can be self-limiting.[17,8]

Unfortunately our small sample size affects statistical significance and this is a common problem with other PRP studies as well.[13]

Another limitation is the lack of pre-treatment comparison scores with the consequent impossibility of defining a precise variation in the degree of pain[22] and disability.

Moreover the heterogeneity of the patients in terms of clinical condition and stage of the disease at the time of treatment adds to the heterogeneity of the follow-up time between treatment and evaluation.

Curiously, in our case study two out of the four patients who went through failure of PRP therapy had bilateral involvement, and this could be attributable more to a lack of systemic response rather than a topical one.

Conclusions

As in other studies our results do not allow to draw sufficiently valid conclusions regarding the effectiveness and safety of PRP in the treatment of elbow epicondylitis and plantar fasciitis: in particular the statistical significance is limited by the small sample size.

Anyway our study, despite its limits, still gives an idea of the outcome of PRP treatment which is in line with results reported in literature.

PRP can be chosen as a non-first-line treatment for LE and PF.

To better evaluate the clinical effectiveness and safety of PRP it would be interesting and desirable to compare the pre-treatment evaluation scores with those observed at scheduled times after treatment with either PRP or other in a Randomized Controlled Trial with a larger sample of homogeneous patients.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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