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Article

Usefulness of Polydeoxyribonucleotide in Lateral Epicondylitis Injection Therapy: A New Strategy for a Rapid Pain Reduction and Functional Recovery for Tennis Players

Bruni Danilo [1,*,†], Jacopo Izzi [2,†], Andrea Pantalone [1], Adele Vaccaro [2], Stefano Di Pangrazio [2], Luigi Brizielli [2], Niccolò Fiandanese [1], Andrea Delli Pizzi [2,3,4], Antonia Patruno [1,5], Mirko Pesce [1,5], Teresa Paolucci [6], Giovanni Cannataro [7] and Massimo Caulo [4,8]

[1] Department of Medicine and Aging Sciences, G. D'Annunzio University of Chieti-Pescara, 66100 Chieti, Italy
[2] Unit of Radiology, Santissima Annunziata Hospital, Chieti, Italy
[3] Department of Innovative Technologies in Medicine and Dentistry, G. D'Annunzio University, Chieti, Italy
[4] Institute for Advanced Biomedical Technologies (ITAB), Gabriele d'Annunzio University of Chieti, Italy
[5] UdA—TechLab, Research Center, "G. d'Annunzio" University of Chieti-Pescara, 66110 Chieti, Italy
[6] Department of Neuroscience and Imaging, Section of Diagnostic Imaging and Therapy, Radiology Division, G. D'Annunzio University, Chieti, Italy
[7] Department of Oral, Medical and Biotechnological Sciences, Physical Medicine and Rehabilitation, G. D'Annunzio University of Chieti-Pescara, 66100 Chieti, Italy
[8] Department of Neuroscience, Imaging and Clinical Sciences, "G. d'Annunzio" University of Chieti-Pescara, 66100, Chieti, Italy
* Correspondence: danilo.bruni@unich.it
† These authors contributed equally to this work.

Abstract: Background: This study assesses the efficacy of polydeoxyribonucleotide (PDRN) injection therapy in treating lateral epicondylitis (LE), commonly known as tennis elbow. **Methods:** The study included twelve patients who had persisting pain for more than six weeks and had failed conservative therapy. The patients (M: 7; F: 5; age: 46 ± 12 years old) received three PDRN injections in different sessions over eight weeks. Pain was assessed using the Visual Analogue Scale (VAS) and the Clinical Global Impression-Improvement (CGI-I) scale in five different evaluation times (T0= baseline, up to T4= 6 months after treatment beginning. **Results:** The VAS scores were reduced by an average of 40% at T2 compared to baseline, indicating a significant clinical improvement. The CGI-I scale showed a reduction of at least 3 points between T2 and the baseline visit, which is considered clinically significant. Ultrasound evaluation was also performed to assess tendon trophism, and PDRN was found to have a trophic/reparative effect on the tendon. **Conclusions:** the preliminary data suggest that PDRN injection could be an efficacy treatment for lateral epicondylitis in terms of pain reduction and tendon trophism. Further investigations are warranted to validate these findings and explore the broader applicability of PDRN in tendinopathies.

Keywords: lateral epicondylitis; polydeoxyribonucleotide; injection therapy; Visual Analogue Scale; Clinical Global Impression-Improvement

1. Introduction

Lateral epicondylitis (LE), also known as tennis elbow, is an overuse injury that involves common extensor tendon at the origin of the extensor carpi radialis brevis (ECRB) tendon.

It results from repetitive movement of the wrist such as extension, radial deviation, or forearm supination (i.e. in tennis and padel players or in those professions that require recurrent use of the

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upper limb such as plumber, bartender etc.). It usually occurs in players with poor technique, improper equipment or warm-up, in occasional athletes and after high intensity activity.

Patients affected by tennis elbow refer pain, mainly over the lateral elbow and generally 1 to 3 days after an improper exercise aforementioned. This pain increases with movement and gets better with rest.

In most cases (80 to 90%) patients have a spontaneous recovery within 12 to 24 months.

If recovery doesn't occur, first line therapy is conservative and includes rest, ice after activity, oral or topical non-steroidal anti-inflammatories and rehabilitative therapy as extracorporeal shock wave, ultrasound, laser therapy, and cryotherapy. It may also make use of complementary therapeutic agents such as taping and bracing [1,2].

Injection therapy such as injection of corticosteroids, topical nitrates, botulinum toxin, autologous platelet-rich plasma, dextrose prolotherapy and polydeoxyribonucleotide (PDRN) is often used as a second line. Surgery should be considered after vain prolonged nonoperative management (6 to 12 months) [3] .

Several studies have found that PDRN can be a substitute for corticosteroids because of their anti-inflammatory capabilities [4–6], also avoiding minor adverse event associated with corticosteroids injection such as subcutaneous atrophy and skin depigmentation [7].

PDRN is a compound made up by polymers of deoxyribonucleotides of different lengths, between 50 and 2000 base pairs, and by nucleosides derived from trout sperm. The structure of PDRN consists of a low molecular weight fraction of deoxyribonucleic acid, which is composed of a linear polymer of deoxyribonucleotides connected by phosphodiester bonds, in which the monomeric units are represented by purine and pyrimidine nucleotides. PDRNs have effects on musculoskeletal pain, and in addition they stimulate the regeneration of tendons and ligaments in animal models [8].

These polymers of natural origin have several effects after tissue infiltration, for example it's known that they deeply hydrate the tissues in the short term, so this product creates the ideal environment for the healing of damaged tissue, promoting tendon hydration and lubrication.

Instead, in the long term, PDRNs stimulate damaged or atrophic tissues to increase the production of new collagen and fibers of elastin and a new glycosaminoglycan matrix [9]. So PDRNs could be used to reach pain relief and improving joint function, promoting the physiological regenerative process of the tendons.

In this scenario, as there are still no many studies using PDRNs infiltrative therapy in tennis elbow, we built up a preliminary study with the aim to evaluate the effect of PDRN in terms of pain reduction and tendon trophism in patients with LE.

2. Materials and Methods

This retrospective observational small-N design study was conducted in line with the ethical principles laid down by the latest version of the Declaration of Helsinki [10]. Written informed consent was obtained from all patients enrolled in the study. Twelve patients with clinically and ultrasonographic LE diagnosis were retrieved from our institute's Picture Archiving and Communication System (PACS) between January 2024 and June 2024. They were examined during this period at the ultrasound clinic of the U.O.C. of Radiology, located at the P.O. "SS. Annunziata" of Chieti.

Inclusion criteria were as follows: 1) Persistence of pain (VAS values ≥ 4) for more than 6 weeks; 2) Failure of conservative therapy; 3) Treatment with PDRN; 4) Availability clinical outcome after treatment.

Exclusion criteria were as follows: 1) Treatment with other experimental products done within 6 months prior to enrollment; 2) Known hypersensitivity to the active ingredient and excipients or to other components used in the study; 3) Presence of para-tendinopathy, partial or total tendon rupture, previous tendon surgery; 4) Severe concomitant pathologies (i.e. peripheral neuropathy, autoimmune, inflammatory, severe metabolic and oncological disease); 5) use of systemic or topical steroids in the last 24 weeks, immunosuppressant drugs in the last 3 months, repeated use of non-

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steroidal anti-inflammatory drugs (NSAIDs) in the last week, or occasional use in the last 24 hours; 6) Pregnancy and breastfeeding.

2.1. PDRN Injection Treatment

The procedure has been performed under sterile condition obtained applying antiseptic solution, first alcoholic based and subsequently povidone-iodine based, with friction over the operation site and over surrounding areas using a sterile gauze swab.

The first needling was performed at the osteotendinous junction (OTJ), followed by a PDRN injection at the myotendinous junction (MTJ). During the procedure, the patient was kept in clinostatism with the arm slightly abducted and internally rotated. A 10 ml luer slip syringe containing 5.625x2 mg/6 ml of PDRN was used, along with a thin-gauge needle (typically 25-30G).

Procedure consists of US guided needling over the center of the lateral epicondyle, according to the build of the patient perpendicular to the skin (with adequate subcutaneous fat) or with an angle of 45° (without sufficient subcutaneous fat) to a depth of 1cm to 1.5 cm in the common extensor tendon. The needling was performed with "in plane" approach and with the ultrasound probe positioned along the long axis of the tendon, 15 times during injection of PDRN inside the common extensor tendon at peri-entheseal level, followed by a single injection of PDRN in the myotendinous junction. We performed injections in 3 different sessions, at T0 (first infiltration), T1 (2 weeks from the first injection) and T2 (4 weeks from the first injection). Once the infiltration had been carried out, the dressing was done applying alcoholic antiseptic solution using a sterile gauze swab and then applying a band aid. Therefore, patients were kept under observation for 15 minutes to highlight the onset of any adverse reactions. For the next three days functional rest, an ice pack for 15 minutes every 3 hours and anti-inflammatories as needed were recommended.

2.2. Pain Assessment

2.2.1. VAS

Visual Analogue Scale is a line 10 cm long (0=absence of pain or absence of functional alteration and 10= worse pain or worse functional alteration) [11].

VAS was evaluated, from T0 to T3 (8 weeks from last injection / 3 months from the beginning of the treatment) and at T4 (20 weeks from last injection / 6 months from the beginning of the treatment), on resting conditions and on the degree of interference with daily activities.

2.2.2. CGI-I Scale

Clinical Global Impression-Improvement scale is a 7-point scale that requires the clinician to rate how much the patient's disease has improved or worsened since the baseline visit, at the beginning of the experimental treatment. The investigator can rate the condition of the patient (on average) as:

1) Really much improved
2) Very much improved
3) Slightly improved
4) Not varied
5) Little worsened
6) Much worsened
7) Actually very much worsened

It was evaluated from T0 to T4. A reduction of at least 3 points on the CGI-I scale between the last study visit and the baseline visit is considered clinically significant [12].

2.3. Tendon Trophism

US evaluation has been performed to prove tendinopathy (thickness and micro vascularization assessed by Color/Power Doppler examination) with qualitative assessment performed by a radiologist with at least 10 years of experience.

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PDRN trophic/reparative effect has been evaluated by US, using Epiq Elite (© Koninklijke Philips N.V, Amsterdam, Netherlands) ultrasound platform equipped with an eL 18-4 linear probe (operating frequency 18–4 MHz) and ARIETTA 850 (Hitachi Healthcare®, Tokyo, Japan) ultrasound platform equipped with a Hitachi L 55 linear probe (operating frequency 13–5 MHz). US assessment was performed at T0 and T3 considering tendon thickness (with normal values approximately under 4.2 mm) [13] and level of inflammation (in term of increased micro vascularization) using Color/Power Doppler (CPD) EULAR-OMERACT combined score (Table 1) [14].

Table 1. Definition of severity grades (0-3) for each elementary component and for the EULAR-OMERACT combined score.

Synovitis	SH (grey scale)	Power Doppler (PD)	Combined score * (greyscale SH+PD)
Grade 0 (normal)	No SH independently of the presence of effusion	No Doppler signal	No SH and no PD signal
Grade 1 (minimal)	Minimal hypoechoic SH up to the level of the horizontal line connecting bone surfaces between the metacarpal head and the proximal phalanx	Up to the three signle Doppler spots OR up to one confluent spot and two single spots OR up to two confluent spots	Grade 1 hypoechoic SH and ≤ grade 1 PD signal
Grade 2 (moderate)	Moderate hypoechoic SH extending beyond joint line but with the upper surface concave (curved downwards) or hypertrophy extending beyond the joint line but with the upper surface flat	> Grade 1 but < 50% Doppler signals in the total greyscale background	Grade 2 hypoechoic SH and ≤ grade 2 PD signal; or grade 1 SH and a grade 2 PD signal
Grade 3 (severe)	Severe hypoechoic SH º with or without effusion extending beyond the joint line but with the upper surface convex (curved upwards)	> Grade 2 (> 50% of the total greyscale background)	Grade 3 hypoechoic SH and ≤ grade 3 PD signal; or grade 1 or 2 SH and a grade 3 PD signal

º Independently of the presence of effusion; EULAR-OMERACT, European League Against Rheumatism-Outcomes Measures in Rheumatology; PD, Power Doppler; SH, Synovial Hypertrophy.

3. Results

A population of twelve patients, seven males and five females one of whom treated both epicondyles, aged between 34 and 58 years, underwent our study protocol.

3.1. Pain Assessment

All twelve patients started with an average VAS at rest higher than 8 and an average VAS related to their daily activities higher than 6, except for two patients, in which daily activities have not been influenced by painful symptoms.

Six patients had benefits just 2 weeks after the first infiltration, with an improvement in the VAS, both at rest and related to daily activities, of at least 5 points from the starting value. The same patients, therefore, at T3, declared resolution of the painful symptoms, both at rest and referred to daily activities (VAS=0).

Patient who carried out the treatment on both epicondyles, first the left one and then the right one, on the other hand, showed a reduction in symptoms, at T3, of at least 3 points on the VAS at rest, while VAS during daily activities reduced only 2 points from basal condition.

The other five patients, having a history of usurious work, benefited less from the treatment, showing a reduction in symptoms both at rest and during daily activities of only 1 point on the VAS.

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An average reduction of 40% in VAS scores from the last study visit compared to baseline condition is considered to correlate with a significant clinical improvement for the patient.

3.2. Clinical Assessment

At clinical evaluation, six patients with better resolution of pain similarly showed CGI-I=1 (really much improved) or CGI-I=2 (very much improved).

Patient who treated both epicondyles and two of the five patients with usurious work activity reported a CGI-I=4 (unchanged).

The other three patients with usurious work activity, in contrast, showed slight clinical improvement, with CGI-I=3 (little improvement).

3.3. Tendon Trophism

US monitoring at T0 and T3 was in line with VAS and CGI-I values in those six patients who have benefited from the infiltrative treatment. They showed minimal decreased tendon thickness, the thickest one passed from 5.2 mm to 4.7 mm and the least thickened one passed from 3.5 to 3 mm (average tendon thickness: 4,4 mm; average tendon reduction: 0,5 mm). They also showed minimal decreased micro vascularity on CPD examination (T0: grade 2; T3: grade 1).

The other five patients with usurious work activity and minimal or null changing in VAS and CGI-I values, demonstrated a slight increased tendon thickness, the thickest one passed from 5,6 mm to 8 mm and the least thickened one passed from 5 mm to 6 mm (average tendon thickness: 5,3 mm; average tendon increase: 1,7 mm). It was found also a slight increased micro vascularity on CPD examination (T0: grade 0; T3: grade 2). In addition, in two of those patients was observed at T3 micro fissuring in the deep portion of the tendon.

A discordant finding compared with VAS and CGI-I, however, was found to be in patient evaluated on both upper arms, which showed a decreased tendon thickness (right: 5 mm at T0 to 3.1 mm at T3; left: 6 mm at T0 to 3.3 mm at T3); the doppler signal on both tendons has not changed (grade 0 at T0 and at T3).

4. Discussion

The investigation of the efficacy of injection therapy with polydeoxyribonucleotides (PDRN) for lateral epicondylitis (LE) has shown promising results. Our study demonstrated a substantial reduction in visual analog scale (VAS) scores, with an average decrease of 40% from baseline. This reduction in pain intensity, together with the significant improvements recorded on the Clinical Global Impression-Improvement (CGI-I) scale, suggests that injection therapy with PDRN is very promising as a second-line treatment option for individuals with persistent symptoms who do not respond to conservative measures.

This study contributes to the growing body of evidence supporting the efficacy of PDRN in the management of LE. The observed reduction in VAS scores aligns with the results of previous studies, indicating a significant pain-relieving effect associated with PDRN injection therapy. The improvements recorded on the CGI-I scale further confirm the clinical relevance of these findings. In particular, the impact of PDRN on tendon trophism, as demonstrated by ultrasonography, sets the stage for considering PDRN as a treatment that not only addresses symptoms but also promotes tissue regeneration.

One aspect that deserves discussion is the potential comparability of PDRN with other interventions commonly used for LE. Although our study focused on its efficacy in isolation, future comparative efficacy studies could provide more information on whether PDRN outperforms or complements interventions such as corticosteroid injections, platelet-rich plasma (PRP) therapy, or other emerging modalities. In addition, exploring the optimal timing and combination of interventions could improve overall treatment outcomes for patients with lateral epicondylitis.

Lee and Park's case series mirrors our exploration into PDRN's role in lateral epicondylitis [4]. They evaluated PDRNs as an alternative to corticosteroids, to demonstrate the anti-inflammatory

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effect of PDRN, which reduces the production of pro-inflammatory cytokines IL-1 and IL-6 in favor of anti-inflammatory cytokines, such as IL-10. This has been demonstrated in studies prior to their own, by Kang SH et al. and Squadrito F et al. [8,9].

The sample of our study was heterogeneous in terms of age, gender and work activity but all of them were tennis or padel player at an amateur or competitive level (2-3 game sessions/week); in their case series Lee and Park included two men who were over 50 years old and one of whom had a wearisome work activity and the other had sports elbow pain. In our study, we used the Visual Analog Scale (VAS) and the Clinical Global Impression-Improvement (CGI-I) scale for comprehensive pain assessment; they instead used the numerical rating scale (NRS) and a physical examination, Cozen's test.

Their results, assessed at a single follow-up 2 months after only two PDRN infiltrations, showed an even more significant reduction in pain on the NRS scale than our study, estimated at about 80%. Also, in spite of what we obtained in our study, the reduction in pain was more significant in the patient with strenuous work activity than in the sportsman. In both patients, at two-month follow-up, hypervascularization was completely absent in line with our study. The heterogeneity of our sample, and consequently different degrees of tendinosis, also allowed us to assess the contribution of PDRN to the tendon structure. In Lee and Park's study, in fact, both patients started with a severe tendinopathy.

Although our study provides valuable information on the effectiveness of polydeoxyribonucleotide (PDRN) injection therapy for lateral epicondylitis (LE), it is essential to recognize some limitations. Sample heterogeneity of our study that included participants with different characteristics could impact the generalizability of the findings. The follow-up period was relatively short; extending the observation period could provide a more complete understanding of the long-term effects and duration of PDRN therapy for LE. The lack of a placebo control group in our study design poses difficulties in isolating the specific effects of PDRN, making it difficult to discern whether the observed improvements are solely attributed to the intervention. The need to use standardized scales and clinical tests as well as tendon thickness cut-offs and classification of the degree of vascularization on Doppler may improve the robustness and applicability of findings regarding the use of PDRN in the treatment of lateral epicondylitis.

5. Conclusions

In conclusion, our study suggests that PDRN injection holds promise for effectively reducing pain and improving tendon trophism in lateral epicondylitis. Although encouraging, the results require larger, multicenter studies to validate long-term efficacy and establish PDRN as a standard intervention.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: We encourage all authors of articles published in MDPI journals to share their research data. In this section, please provide details regarding where data supporting reported results can be found, including links to publicly archived datasets analyzed or generated during the study. Where no new data were created, or where data is unavailable due to privacy or ethical restrictions, a statement is still required.

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Suggested Data Availability Statements are available in section "MDPI Research Data Policies" at https://www.mdpi.com/ethics.

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Conflicts of Interest: The authors declare no conflict of interest.

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