



PRP versus steroids in a deadlock for efficacy: long-term stability versus short-term intensity—results from a randomised trial

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Abstract

Purpose A popular choice for lateral epicondylitis (LE), corticosteroid injections have been associated with prominent side effects, which has led to the conception of modalities like platelet-rich plasma (PRP). This randomised trial aimed to evaluate and compare the 6-week, 3-month and 1-year outcomes with PRP and corticosteroid injections in LE. We hypothesised that PRP would prove more effective in relieving pain and improving function.

Methods At the sports medicine unit of our tertiary care teaching centre, 80 patients with LE were randomised into either receiving PRP (group A) or corticosteroids (group B) injections. Pre-injection visual analogue scale (VAS), disabilities of the arm, shoulder and hand (DASH) score, Mayo elbow performance score (MEPS) and grip strength score (GSS) were recorded. Common extensor origins were identified and infiltrated with 3 ml of either PRP or corticosteroid (triamcinolone in 2% xylocaine) using a peppering technique. Follow-up scores and extent of pain relief were recorded and compared.

Results At 6 weeks, there were greater improvements in group B versus A in mean VAS (13.8 vs. 44.5; $p < 0.001$), DASH (64.2 vs. 53.3; $p < 0.001$), MEPS (88.0 vs. 74.5; $p = 0.004$) and GSS (89.3 vs. 73.4; $p = 0.039$). These scores showed a reversed pattern at 3 months when group A outcomes superseded group B (VAS $p = 0.002$; DASH $p < 0.001$; MEPS $p = 0.002$; GSS $p = 0.045$). At 1-year follow-up, group A continued to enjoy better pain relief and function (VAS $p = 0.024$; DASH $p < 0.001$; MEPS $p = 0.009$; GSS $p = 0.028$).

Conclusions Albeit corticosteroid injections show good short-term results at 6 weeks, patients receiving PRP injections fare better at 3 and 12 months.

Keywords Elbow injections · Corticosteroid injections · Platelet-rich plasma injections · Pain relief · Elbow function · Handgrip strengths

Introduction

The commonest cause of upper limb pain, lateral epicondylitis (LE), annually affects 4–7 patients per 1000, mostly between 45 and 54 years [1]. Significant associations include dominant limbs (90%), sporting activities (“tennis elbow”),

increasing age, body mass index (> 25), low social support, shoulder and wrist conditions, corticosteroid therapy and smoking [2]. Both inflammatory and degenerative (angiofibroblastic degeneration—tendinosis) pathologies have been implicated at the wrist-extensor origins (most commonly, the extensor carpi radialis brevis (ECRB) origin) [3]. A pragmatic clinical approach most often clinches the diagnosis which usually responds to conservative therapy (including local injections) [4].

Among injections, corticosteroids (CS) have been most widely espoused (60% studies), followed by botulinum toxin, autologous blood and platelet-rich plasma (PRP). Notwithstanding this, a consensus on the optimal injection is lacking. Questionable efficacy (beyond 8 weeks), post-injection tendon ruptures, joint pain, skin changes, subdermal atrophy, facial flushing and hyperglycaemia associated with CS injections have raised a few eyebrows [5–7]. The

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anti-inflammatory action of CS in suppressing a supposedly non-inflammatory process has also come into question [3].

Of proposed alternatives, autologous blood has been bedeviled with pain, reaction, and practical inconvenience of injecting 10–15 ml blood locally. A more plausible alternative, PRP, can augment the reparative process by delivering high concentrations (3–4 times) of the bioactive component of whole blood, viz. platelet through small (2–3 ml) infiltrations [5, 8–11]. Despite success, PRP use has been limited (12% of all elbow injections) by a paucity of randomised studies. Even fewer have evaluated and compared 1-year results of PRP and CS injections in LE [5, 12].

With the above in mind, this study aimed to measure the efficacy of PRP in LE and to compare the results with local CS injections in a randomised manner. It was hypothesised that PRP injections would prove more effective than CS injections in improving pain and function at 1-year follow-up.

Methods

With a prior institutional ethics committee approval (vide letter no. EC/06/16/1024), this prospective study assessing outcomes of LE managed by PRP (group A) and CS (group B) injections was conducted from July 2016 to June 2017 at the sports medicine unit of our tertiary care teaching centre. The randomised trial was conducted in accordance with the design and principles of the Consolidated Standards of Reporting Trials (CONSORT).

Trial design

A randomised (equal 1:1 randomisation), parallel-group, controlled design, which is the gold standard for evaluating the comparative efficacy of > 1 therapeutic interventions, was adopted. No changes were made to any of the methods throughout the trial.

Participants

Eighty patients aged 18–55 with diagnosed lateral epicondylitis, unresponsive to conservative therapy for > 3 months, were randomly recruited in each group (CS and PRP) after obtaining informed consents. Differential diagnoses of elbow pain (cervical radiculopathy and osteochondritis dissecans) and systemic conditions (rheumatoid disorders and diabetes) were excluded.

Study settings and details of interventions

All injections were performed as office outpatient procedures under strict aseptic conditions by a single senior

fellowship-trained surgeon well versed in shoulder and elbow sports medicine surgery.

Pre-injection preparation

Patients were kept anti-inflammatory-analgesic-free for 2 weeks (to allow for relative washout of the drugs), and pre-injection scores were noted (Fig. 1).

PRP preparation

Out of 20 ml whole venous blood, 18 ml was transferred into 4 red-capped plain tubes (labelled 1, 2, 3 and 4) with 4.5 ml each, and 2 ml was used for cell counts. Two-spin centrifugation was adopted with the first at 160 g for 12 min at room temperature [17]. The sample segregated into three layers—upper plasma, middle buffy coat and lower red cell layer. Supernatant plasma and buffy coat from each tube (total 10–12 ml) were pipetted onto another set of red-capped plain tubes labelled A and B (5–6 ml per tube) under laminar flow. A second spin at 460 g for 18 min was then provided at room temperature. Platelet pellets were collected at the bottom of each tube. Around 3 ml of platelet-poor plasma was discarded, and roughly 2 ml of plasma with platelet pellets was thoroughly mixed in each tube. The final PRP thus obtained was around 4 ml and was transferred from both tubes into one plain tube labelled “PRP”, stored for 15 min at room temperature, and subjected to a platelet count (Fig. 2).

Injection technique

On a 90° flexed elbow and pronated forearm (passively stretched ECRB allowed clearer identification), the common extensor origin was identified, painted and draped. Bony landmarks (lateral epicondyle, supracondylar ridge, olecranon and radial head) were palpated; a 22G needle was introduced along the supracondylar ridge (proximal to lateral epicondyle) and gently advanced into the undersurface of the ECRB and the common extensor tendon using a peppering technique: single skin penetration and 10–20 tendon penetrations (without emerging from the skin). Repetitive puncturing of degenerating tissues, first described in 1964 for LE, initiates bleeding into tissues and hastens healing [18]. 3 ml of PRP and 40 mg triamcinolone with 2% xylocaine were injected in groups A and B (controls), respectively (Fig. 2).

Post-injection and rehabilitation protocol and follow-up

Sterile dressings were removed 2 days later. Discharged after a brief 30-min rest, all patients followed standardised rehabilitation (limb rest—3 days, need-based cold fomentation and oral paracetamol). Additional requirements were noted on subsequent office visits. Gentle range of movement

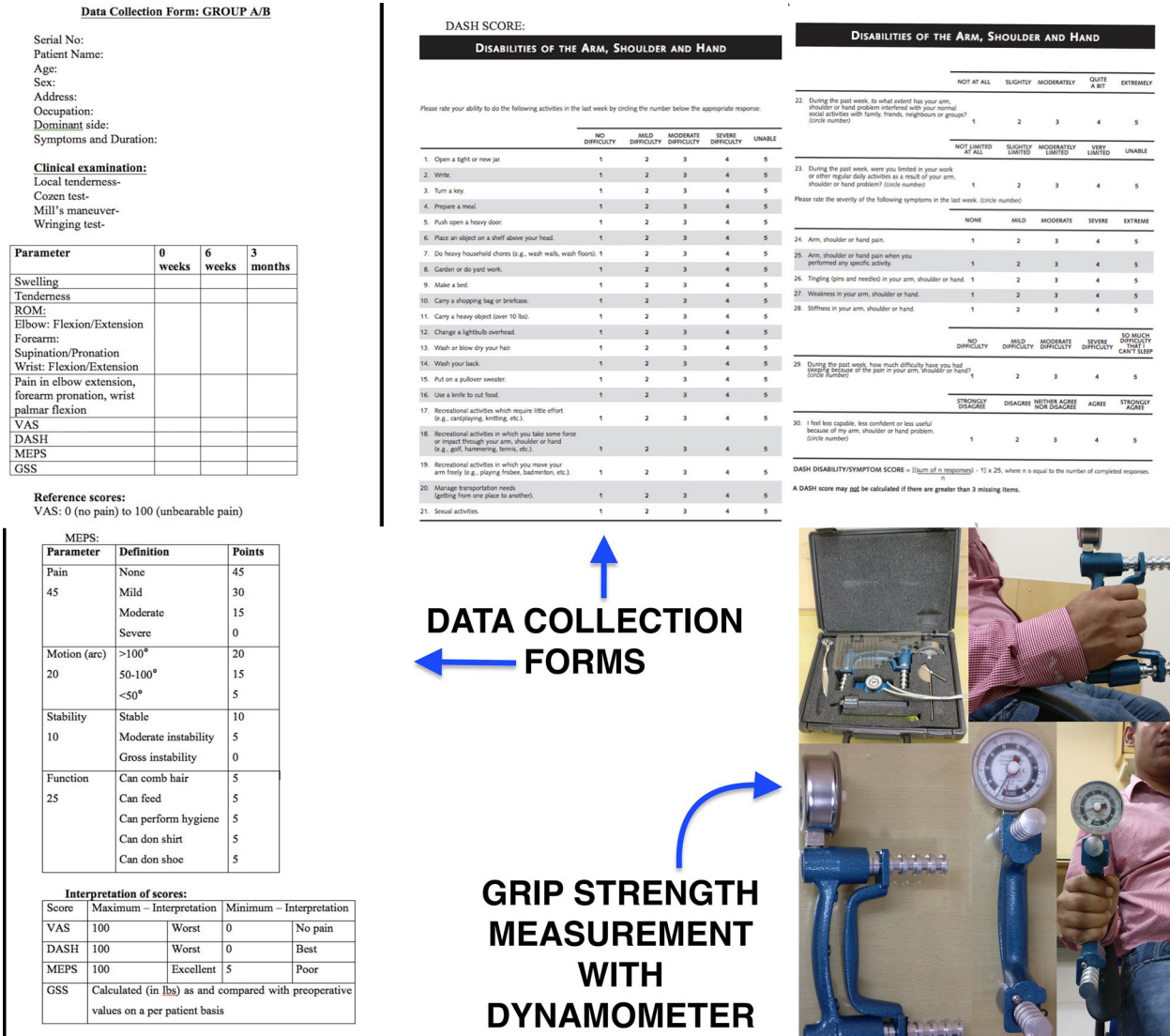


Fig. 1 Data collection form and grip strength measurement with dynamometer

(ROM) and isotonic exercises were prescribed after a week. Resistive training of wrist extensors using TheraBand (THERABAND Akron, OH) and rotator cuff and periscapular muscle exercises were started at 3 weeks. Follow-up clinical scores were recorded and compared at preoperative 6-week, 3-month, and 12-month visits (details below). Complete relief from initial symptoms was enquired for and responses were recorded.

Primary and secondary outcomes

A change in visual analogue scale (VAS) before and after the injections was recorded and was the primary outcome of the present study. As secondary outcomes, the disabilities of the arm, shoulder and hand (DASH) score, Mayo elbow performance score (MEPS) and grip strength score (GSS) obtained

on a hydraulic hand dynamometer (BASELINE, NY, USA) were recorded onto a data collection form [14, 15] (Fig. 1). In addition, the serum and PRP samples of group A before and after PRP preparation, respectively, were subjected to platelet counts. Also, requirements of pain-relief medications and the feeling of “complete relief from pain” were measured in both groups following the injections.

Measuring GSS

Using the Southampton protocol for grip strength measurement, the patient’s midpronated forearm was positioned on an armchair (wrist neutral and overhanging) [16]. The participant was made to squeeze the hydraulic hand dynamometer (BASELINE, NY, USA) for as long and as tightly as possible or until the maximum reading (in lbs) had appeared.

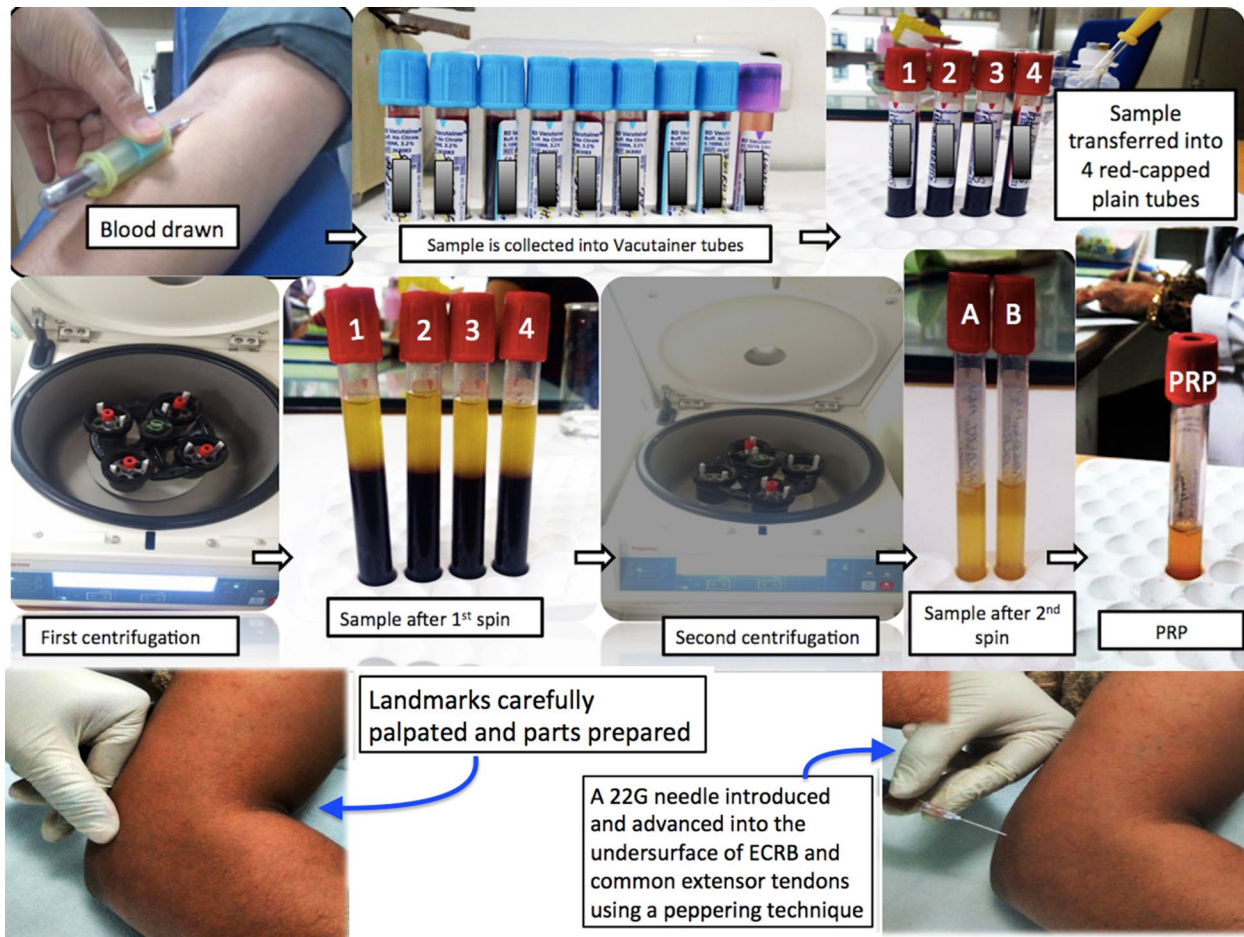


Fig. 2 Steps of PRP preparation and injection

The patient was asked to relax. Two further readings were similarly obtained at 10-min intervals, and mean values were computed as the GSS (Fig. 1).

Sample size calculation

Mean VAS, the primary outcome variable, for groups A (1.6) and B (2.8) (from published literature), was employed to calculate the sample size [13]. Initially calculated at 66 (power 90%, $\alpha=0.05$, $s\sim 1.5$), assuming a 20% dropout rate, the total sample size was finally set as 80 (40 per group).

Randomisation sequence generation, allocation concealment, implementation and blinding

A computer-generated random sequence was utilised, and letters “A” (PRP) and “B” (CS) placed in identical, opaque, sealed and stapled envelopes by an independent researcher (not involved with the care of the patients) to minimise selection bias. The allocation sequence was concealed from the surgeon, and the envelopes were only opened at the time

of allocation of intervention. To prevent subversion of the allocation sequence, the details of the patients (name, date of birth and hospital number), once allocated, were recorded on each envelope and its containing card and stored in a safe isolated locker for later correlation and verification. The need for patient identification during blood withdrawal for PRP injections made the study a non-blinded one.

Statistics

The primary endpoint was a change in the VAS at 6-week, 3-month and 1-year intervals. Secondary endpoints included the changes in DASH, MEPS and GSS measured at similar intervals. The Statistical Package for the Social Sciences (SPSS v.20) was utilised, and continuous variables were compared using the Student’s *t* test. Nominal, categorical data between the groups were analysed with the Chi-square test or Fisher’s exact test as appropriate. Non-normally distributed continuous variables were compared using the Mann–Whitney *U* test ($p < 0.05$ considered significant).

Results

Participant flow, losses, recruitment

All 80 patients deemed eligible for the study between July 2016 and June 2017 were randomly allocated into groups A and B of equal size ($n = 40$ each) based on the allocation procedure described. There were no losses to follow-up (Fig. 3).

Baseline data

Among 46 ladies and 34 men ($p = 0.11$), the overall mean age was 40.8 years. Both groups were comparable in terms of age, involved sides, hand dominance, duration of symptoms and occupation. No dropouts made all patients available for follow-up (Table 1).

Outcomes

Mean pre-injection (0-week) VAS for both groups was similar ($p = 0.285$) (Table 2). Mean platelet concentrations



CONSORT Flow Diagram

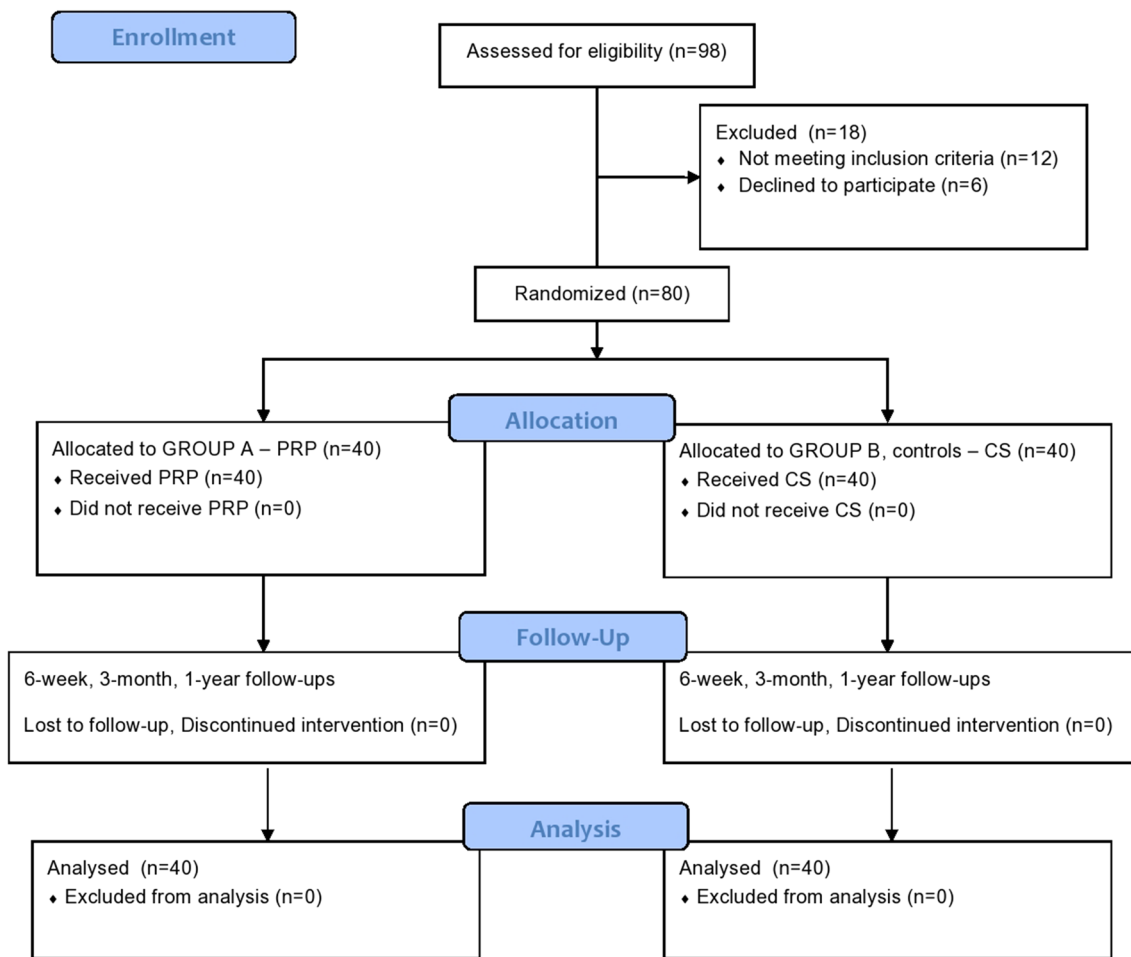


Fig. 3 Study protocol and pre- and post-injection scores of groups A and B

Table 1 Demographic data

Variable	Overall	Group A (PRP)	Group B (CS)	<i>p</i> value
Age (mean)	40.8	42.4	39.4	0.31
Gender				
Women	46	21	25	0.09
Men	34	22	12	
Side				
L	18	10	8	0.59
R	62	30	32	
Dominance				
L	7	3	4	0.69
R	73	37	36	
Duration of symptoms in weeks (mean)	15.9	15.2	16.5	0.30
Occupation				
Vigorous manual (M)	18	10	8	0.59
Non-manual (NM)	62	30	32	

in the whole blood and the prepared PRP in group A patients were $193.1 \times 10^3/\mu\text{L}$ and $823.3 \times 10^3/\mu\text{L}$, respectively, with an approximate 4.3-fold increase in the concentration following PRP preparation. Cold compress and/or paracetamol tablets were needed for 80% group A patients (~ 3 days) for pain versus 25% in group B ($p = 0.001$). At 6 weeks, greater ($p < 0.001$) improvement in mean VAS was seen in group B (13.75) versus group A (44.5), which, however, reversed at 3 months (4 in group A versus 22.75 in group B; $p = 0.002$) (Table 2, Fig. 4).

Similar improvements were observed in mean DASH scores with comparative baseline values ($p = 0.417$), greater improvements in group B at 6 weeks ($p < 0.001$) but group A better at 3 months post-injection ($p < 0.001$). Likewise, data for mean MEPS and GSS, along with VAS and DASH scores, demonstrated identical patterns on follow-up (Table 2, Fig. 4). “Complete relief of pain” at 6 weeks in patients of groups A and B was seen in 5% and 55%, respectively ($p = 0.001$). The values, however, reversed at 3 months and were, respectively, 65% and 30% ($p = 0.027$). At 3 months, the number of recurrences in groups A and B was 2 (5%) and 10 (25%), respectively ($p = 0.012$). No major adverse effects were reported in any patient.

At 1-year follow-up, the trend of significantly better performance and scores with PRP injections continued to prevail (VAS $p = 0.024$; DASH $p < 0.001$; MEPS $p = 0.009$; GSS $p = 0.028$) (Table 2). When asked about complete pain relief, 85% and 20% patients of groups A and B, respectively, answered “yes” ($p < 0.001$).

Table 2 Pre- and post-injection scores

Parameter	Group A (PRP)	Group B (CS)	<i>p</i> value
<i>Pre-injection scores</i>			
VAS			
Mean score	81.00	77.50	0.285
s	8.52	11.64	
DASH			
Mean score	87.15	85.90	0.417
s	5.72	3.68	
MEPS			
Mean score	49.50	54.00	0.185
s	9.85	11.19	
GSS			
Mean score	67.70	58.9	0.239
s	24.34	22.13	
<i>6-week scores</i>			
VAS			
Mean score	44.50	13.75	<0.001
s	17.31	19.66	
DASH			
Mean score	64.15	53.25	<0.001
s	2.91	2.85	
MEPS			
Mean score	74.50	88.00	0.004
s	12.34	15.51	
GSS			
Mean score	73.35	89.30	0.039
s	24.46	25.60	
<i>3-month scores</i>			
VAS			
Mean score	4.00	22.75	0.002
s	5.98	22.33	
DASH			
Mean score	35.10	44.75	<0.001
s	3.08	3.09	
MEPS			
Mean score	97.25	85.50	0.002
s	4.72	15.04	
GSS			
Mean score	109.20	90.55	0.045
s	32.26	24.09	
<i>12-month scores</i>			
VAS			
Mean score	2.50	13.50	0.024
s	5.50	1.84	
DASH			
Mean score	31.65	40.10	<0.001
s	3.87	8.03	
MEPS			
Mean score	98.25	89.75	0.009
s	4.67	12.62	

Table 2 (continued)

Parameter	Group A (PRP)	Group B (CS)	<i>p</i> value
GSS			
Mean score	112.75	92.30	0.028
s	31.52	24.68	

Discussion

Findings of the present study indicate significant improvement in pain (VAS, DASH, MEPS) and function (DASH, MEPS, GSS) following injection therapy for LE. The hypothesis of superior pain relief and functional improvement with PRP injections compared to CS injections at 1-year follow-ups proved true. The effectiveness, in all aspects, was observed to be more rapid in onset with CS injections, while PRP injections had a slower, yet more well sustained impact.

Mean ages of 42.4 and 39.6 years in groups A and B, respectively, were comparable with previously published literature (mean age = 43) [9, Table 3]. More women (57.5% statistically insignificant) were possibly seen due to local societal framework wherein most household chores (washing

and wringing clothes, cutting, chopping and peeling vegetables, carrying heavy, grocery-laden bags) have been conventionally and predominantly performed by women [19]. Such activities naturally predispose to repetitive elbow stresses, microtrauma, both relevant for the initiation and propagation of LE.

Popular among 71% fellowship-trained upper limb surgeons, steroid elbow injections are being presently interrogated after reports incriminating them in delayed healing have surfaced. A questionable impact of anti-inflammatory properties in an essentially non-inflammatory pathology has also impelled scientists to discover newer and safer modalities [5, 7, 8]. Recently, attention has been garnered by a relatively underutilised eligible surrogate, PRP [5]. Among its 4 varieties [viz. pure and leucocyte PRP and pure and leucocyte platelet-rich fibrin (PRF)], L-PRP is presently most suited for LE [10]. Teeming with essential growth factors [platelet-derived growth factor, transforming growth factor-β, insulin-like growth factor and epidermal growth factor], activated platelets from PRP reinforce and intensify repair. An ensuing chain reaction effectuates cellular proliferation, recruitment, differentiation, angiogenesis and collagen-1 synthesis that augments tensile strengths of traumatised tendons [11].

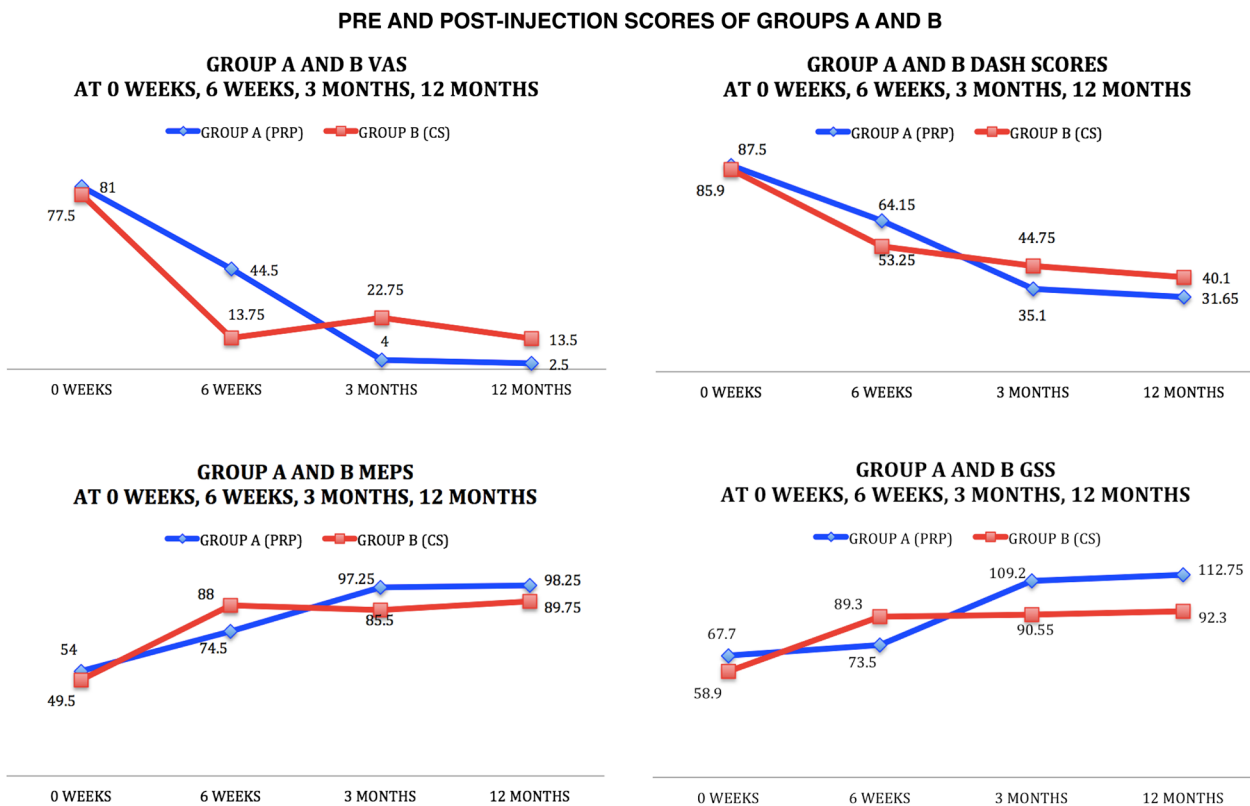


Fig. 4 Pre and post-injection scores in groups A and B

Table 3 Evidence table comparing randomised studies of PRP versus CS

Author	Yr	Des	N	Mean age (yrs)	Score	F/U	Inference	Cx
Seetharamaiah et al. [7]	2013–15	RT	90; 30 each PRP, CS, saline (placebo)	NA, 20-50	VAS, FPS	3 m, 6 m	Better pain relief (6 m)—PRP	Hypopigmentation 13/30, subdermal atrophy 3/30 in CS
Khaliq et al. [26]	2015	RT	102; 51 each PRP, CS	33.9	VAS	NA	Better pain relief—PRP	NA
Yadav et al. [13]	2012–14	RT	60; 30 each PRP, CS	36.7	VAS, dynamometer DASH	3 m	Better pain relief—PRP	–
Lebiedziński et al. [20]	2009–11	RT	99; 53 ACP, 46 CS	50.5	DASH	1 yr	Better results (1 yr)—ACP	–
Gautam et al. [27]	2011–2012	RT	30; 15 each PRP, CS	NA, 18-60	VAS, DASH, modified Mayo score, HGS	6 m	Biological healing—PRP; Short-term, symptomatic relief, tendon degeneration—CS	–
Krogh et al. [5]	2009–10	RT, blinded	60; 20 each PRP, CS, saline (control)	45.4	PRTEE, U/S changes	3 m	Single PRP or CS injection not superior (pain and disability) at 3 m; Dec short-term pain (1 m), colour Doppler activity, tendon thickness versus PRP and saline—CS	–
Peerbooms et al. [25]	2006–08	RT, double-blinded	100; 51 PRP, 49 CS	47	DASH	1 yr	Better pain relief and function—PRP	PRP; 3 surg, 2 CS reinj CS; 6 sx, 1 CS reinj 6 PRP reinj
Present study	2016–17	RT	80; 40 each PRP, CS	40.8	VAS, DASH, MEPS, GSS	1 yr	CS; short-term, short-lasting, PRP; slower onset, longer lasting	None

Yr year, Des study design, N number of patients, F/U follow-up, Cx complication, RT randomised trial, PRP platelet-rich plasma, CS corticosteroid injections, NA not available, VAS visual analogue scale, FPS facial pain scale, DASH disabilities of arm, shoulder and hand, ACP autologous conditioned plasma, HGS hand grip strength, dec decrease, inc increases, sx surgery, reinj reinjection, PRTEE Patient-Rated Tennis Elbow Evaluation

A Polish randomised study elucidated prolonged pain relief and better function with PRP vis-a-vis steroids for LE at 1 year after intervention [20, Table 3]. Gossen et al. also observed sustained improvements 2 years after PRP injections [21]. Our findings are in agreement with the above as PRP recipients displayed gratifying outcomes at 1 year. The above-mentioned papers, however, did not evaluate an essential component of hand function, the grip strength, as an outcome measure. This has a pivotal role in hand functioning

and is potentially impaired in LE and ECRB tendinopathies. Poor handgrip strength can (with slower force development and electromechanical delays) stall reaction times, imperil recurrence and engender substandard quality of life [22, 23]. In the present study, reliable improvements in GSS of group A patients translated into a substantial role of PRP in ameliorating the important hand function in LE patients.

Yadav et al. recently reported better VAS, QuickDASH and grip strength in 60 LE patients randomised between

receiving PRP and CS injections, which is in line with our results. Nonetheless, by including another, elbow-specific score (namely the MEPS) in the present study (accounting for elbow pain, motion stability and function), it was possible to more convincingly demonstrate the implications of PRP and CS injections [13, Table 3]. Also, we differed from the above study as peppering was employed, which enables wider penetration and delivery of active products of PRP and reparative apparatus [18]. Perhaps contributory to successful outcomes observed in the present study, routine peppering should be performed for extra-articular injections in chronic tendinopathies [21].

In 90 LE patients randomly allocated to PRP, CS and saline injections, Seetharamaiah and colleagues reported significantly better outcomes and fewer complications at 6 months with PRP. The authors did acknowledge the lack of sample size calculation from their methodology to be a limitation along with only VAS and facial pain scale (FPS) being used to record results. In contrast, patients from the present study demonstrated additional improvements in function with PRP that could be illustrated with betterment of 4 different scores at 1 year after injection [7, Table 3]. In the above study, although the authors did record serum and PRP-platelet levels, the values and eventually utilised concentrations were not mentioned in the results. Our observed 4.3-fold (mean) increase in platelet concentration in PRP post-preparation (from $193.1 \times 10^3/\mu\text{L}$ to $823.3 \times 10^3/\mu\text{L}$) was within the recommended range of optimum levels for use in promoting healing [24]. This is one singularly important parameter (that we found to be associated with good outcomes) has been overlooked by many in published literature.

Most authors in their studies, in fact, have looked at one or two scoring systems as the outcome measure (for instance, the DASH score), which despite exhaustive evaluation of functional abilities, does not take into account quality of pain relief, grip strength, ROM and stability that are accounted for by the VAS, MEPS and GSS [20, 25, 26, Table 3]. By including these in the present study, the initial (6 weeks) success of CS injections and eventual (12 months) superiority of PRP injections were more convincingly determined (Table 3).

Gautam et al. addressed certain deficiencies in methodology of existing literature by incorporating patient-reported measures such as the VAS, DASH, modified Mayo score and hand grip strength. The authors, however, randomised a relatively small sample (15 for each group), followed up patients for 6 months only and have again not mentioned details about grip strength measurement. In the same study, it took 6 months for PRP to overtake CS in terms of improvement in clinical score. Platelet concentrations at injection have neither been measured nor mentioned in their text [27, Table 3]. This is a cardinal, often underplayed determinant of successful outcomes

in PRP recipients. Concentrations between $500 \times 10^3/\mu\text{L}$ and $1000 \times 10^3/\mu\text{L}$ most positively influence tendon healing through cellular proliferation, migration, collagen and matrix metalloproteinase production as per experimental and clinical studies [24]. While lower concentrations can have a suboptimal impact, excessively high platelet levels negatively and paradoxically influence cell growth and prove counterproductive [28]. Such a discrepancy could have been behind the delayed response observed by Gautam et al. In contrast, group A patients of the present study received measured amounts of PRP injections (mean concentration $823.3 \times 10^3/\mu\text{L}$) which was perhaps the reason for better VAS, DASH, MEPS and GSS scores of group A versus B at 3 months and 12 months versus 6 months in the aforementioned paper [27].

The strengths of the present study include a prospective, randomised controlled design, single-surgeon technique (reducing performance bias) and consideration of a diverse variety of primary and secondary outcome variables. Among a few limitations, a lack of blinding could have induced observer bias when evaluating outcomes. Blinding was not feasible due to the need for confirmatory verification of blood products in group A patients. Also, sealed envelopes could have potentially resulted in subversion of the allocated sequences through randomisation. This was, however, prevented through meticulous and confidential record-keeping. The risk of confounding factors present between both groups was addressed, at least partially, by randomisation and having discrete inclusion and exclusion criteria and similar demographic variables among both groups. Further reduction of these factors could have been best addressed by matching or performing injections in either arm of same patients (bilateral cases).

The present study has attempted to update existing practice of elbow surgery through a design commensurate with high level of evidence (randomised controlled trial). Although ultrasonographic measurements of tendon thickness were not done for financial constraints, persuasive 3-month and 1-year clinical outcomes across 4 scores with PRP injections serve as strong clinical proof of their impact on LE. CS injections, on the other hand, show encouraging results early on, while their efficacy fades beyond few weeks of injecting. Further trials with larger numbers can possibly reiterate these findings and consolidate the role of PRP in the current practice.

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Compliance with ethical standards

Conflict of interest Prateek Kumar Gupta, Ashis Acharya, Vishesh Khanna, Sirshendu Roy, Kamini Khillan and Senthil Nathan Sambandam declare that they have no conflicts of interest.

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