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Clinical outcomes of platelet rich plasma injection in management of chronic tendinopathies

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Abstract
Platelet-rich plasma (PRP) is a biologic treatment derived from blood products, and containing concentrated growth factors, which are thought to reduce inflammation and promote healing. PRP has been described as a general term for therapy lacking standardization in its composition and administration. This study was a prospective, comparative, single blind study, carried out at Department of Orthopedic Surgery, BSMMU, Dhaka, Bangladesh from January to June 2023 with a follow up of 6 months. After institutional review board approval and informed written consent from patients, this prospective case controlled clinical study was carried out in 60 patients. A total of 60 patients presenting with complaint of chronic tendinopathy, who did not respond to conservative treatment for 3 months, were included in the study. The age group varied form 18 years to 70 years with the mean age of 44 years. Incidence of fracture was observed maximum between 30- 50 years of age. Among male were 73.3% and female were 26.7%. Mean age of male patient's was 42.39±6.14 year. Mean age of female patient's was 41.89±5.6 year. We encounter total twenty-two-22 patients of lateral- epicondylitis, ten-10 medial-epicondylitis, fifteen-15 rotator cuff tendinopathy and thirteen-13 patients of Achilles tendinopathy. In this study PRP prepared by drawing blood from patient, centrifuging it, PRP (3 to 10 times of the whole blood) will be injected over pathological tendon site over maximum point of tenderness, followed by immobilization of the part for 3 days, followed by eccentric loading exercise for 6 weeks and results assessed clinically, visual analogue scale at regular interval. PRP injections will be widely accepted by the patient as prepared from patients own blood and risk of adverse effect is minimal. Moreover, during degranulation, platelets release various cytokines and growth factors (vascular endothelial growth factors, platelet derived growth factors, transforming growth factors B, Insulin like growth factor 1 and hepatocyte growth factors) which promote angiogenesis, tissue remodeling, and wound healing Tendinopathies are chronic affections of the attachments of muscles to the bones.

Keywords: Clinical outcomes, of platelet rich plasma, chronic tendinopathies

Introduction
Platelet-rich plasma (PRP) is a biologic treatment derived from blood products, and containing concentrated growth factors, which are thought to reduce inflammation and promote healing [1, 2]. PRP has been described as a general term for therapy lacking standardization in its composition and administration [3]. Multiple treatments are available for chronic tendinopathies including those of the lower extremities with conservative therapies including physiotherapy and/or systemic pharmacotherapy for pain [4-6]. Chronic, or persistent, tendinopathy is a common disorder that is characterized by pain and loss of function, [1] and has been described as accounting for 30% of musculoskeletal conditions [1]. Chronic tendinopathies represent a range of conditions, based on the location of the affected tendon, with chronic tendinopathies of the lower extremities occurring in the hip (e.g., gluteus), knee (e.g., patella), Achilles, and/or plantar fascia [5, 7, 8]. Chronic tendinopathies of the lower extremities can cause pain, swelling, and can interfere with the activities of daily life (Including performance in exercise and sport), as well as quality of life [1]. Tendinopathy refers to a triad of pain, swelling and decreased activity.

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Tendon related injuries are classified as tendinitis during acute inflammatory process and tendinosis when the healing become chronically impaired, clinicians are increasingly using the term tendinopathy to refer tendon disorders without a specific pathology, and chronic tendinopathy for cases that are refractory to conventional treatment. Common tendinopathies are epicondylitis, rotator cuff tendinopathy, patellar tendinopahy, achilles tendinopathy These have traditionally been treated conservatively by activity restriction, nonsteroidal anti-inflammatory drugs, physical therapy and judicious use of orthotics. Unresponsive patients are being treated by locally acting steroid injections with varied results. Surgical options are used sparingly when indicated. Platelet rich plasma has been tried by various researchers with the aim of a biological cure with minimal side effects and has shown promising results. Sports related injuries among professional and recreational athletes are increasingly encountered and diagnosed and demand a quick return to preinjury level of sporting activities [9]. "Orthobiologics", refers to the use of biological substances to help musculoskeletal injuries heal quicker. They are used to improve the healing of fractured bones and injured muscles, tendons and ligaments and are derived from substances that are naturally found in body [10]. The incidence of chronic tendinopathies, in general, has been on the rise and is thought to be associated with greater participation in recreational exercise and sports among middle-aged individuals [4]. While no Canadian data on the incidence or prevalence of chronic tendinopathies in the lower extremities were identified, a survey of Canadian adults indicated the knee and leg as the third and fourth most common sites of chronic pain [11]. Notably, it has been suggested that tendinopathies of the lower extremities may respond differently to treatment than those of the upper extremities, based on factors associated with the central nervous system [5]. The substances include bone grafts, autologous blood, platelet-rich plasma (PRP), autologous conditioned serum and stem cells [10]. Bone grafts act by their osteoinductive, osteoconductive and osteogenic properties to stimulate new bone formation and have no effect on the healing of muscles, tendons and ligaments [12]. On the other hand, autologous blood, PRP and autologous conditioned serum deliver growth factors to the diseased areas to stimulate the repair process [13-15]. Platelet-rich plasma (PRP) is defined as a sample of autologous blood with concentrations of platelets above baseline values [16].

Materials and Methods

This study was a prospective, comparative, single blind study, carried out at Department of Orthopedic Surgery, BSMMU, Dhaka, Bangladesh from January to June 2023 with a follow up of 6 months. After institutional review board approval and informed written consent from patients, this prospective case controlled clinical study was carried out in 60 patients. All patient needed to undergo anterior-posterior (AP) and lateral radiographs as well as ultrasound and MRI to identify swelling, tears, calcification in tendon, bursae, muscle and bone. The patients were assessed pre procedure and post procedure in form of range of movements, pain, tenderness, joint stiffness and early mobilization. After thorough pre procedure evaluation and required investigations, patients meeting the following inclusion criteria were included in the study.

Inclusion criteria

All patients presenting with chronic tendinopathies like rotator cuff tendiopathy, epicondylities, achilles tendinopathy who have failed to improve even after three months of conservative management as outlined above. Men and women between 18 and 70 years of age with tendinopathy for >3 months not resolved with conventional treatment that include epicondylitis, rotator cuff tendinopathy, Achilles tendinopathy

Exclusion criteria

Patients having sensory or neurologic complaints affecting the specified region. Platelet disorder, coagulation disorder, pregnancy, major systemic illness like diabetes, rheumatoid arthritis, fibromyalgia, autoimmune disorders, any condition required strict antiplatelet or anticoagulation therapy, drop out case.

Pre-injection assessment and preparation: Patients with platelet count less than 1 lakh per millimeters were deferred for 3 weeks and were advised treatment for underlying cause of thrombocytopenia. The deferred patients were not taken for platelet rich plasma preparation till they achieved normal platelet count. Patients having thrombocyte count more than 1 lakh per millimeter were accepted for platelet rich plasma preparation. Patients blood was taken from ante-cubital vein preferably from left, in tri-sodium citrate vacutainer (3.8%) under sterile precautions directly from vein to vacutainer without opening the vacutainer. Autologous blood was collected in four vacutainer vials (approx. 12 ml) for unilateral tendinopathy. The initial separation of plasma was done by standing method (vial was left in standing position for 1hour). After 1hour the vacutainer vials were spun at speed of 1600 round per minute for duration of one minute. Platelet rich plasma (PRP) was seen as the top layer in vial vials followed by yellow buffy coat rich in white blood cells and red blood cell sediment at the bottom. One vial of every patient was used to check quality of platelet rich plasma. Plasma which contained platelet count more than 2.5 times of the patient‟s blood platelet counts were accepted for injection. This used vial was discarded. One cm plasma of (approx. 0.8-1 ml) which was just above yellow buffy layer was taken from by opening the top cork in a sterile 10 ml syringe and used for injection. Approx 1ml of platelet rich plasma was mixed with 0.5ml lignocaine and used for injection in one tendon. Usually, four vial for bilateral and two vials for unilateral cases were adequate. However, one to two excess vials preferred were to maintain plasma volume adequacy for injection even in situation error in preparation of plasma, such as hemolysis due mechanical injury to red blood cell during blood withdrawal from patient.

Platelet rich plasma Injection: The affected part was cleaned with savlon and painted povidineiodine anddrapped. Approx. 1.5 ml of mixture of platelet rich plasma and lignocaine was injected in at maximum tender point for epicodylitis and Achilles tendinopathy, and 1 cm below the angle of acromion for RCT. The injection was given with 22 G needle over the part via a peppering technique (single skin entry, partially withdrawing the needle, redirecting and making multiple penetrations to the seath). After injection the part were immobilized for 3 days with appropriate splints & patients were advised to avoid weight bearing sports activity such as running or jumping and heavy works such as lifting of heavy weights for at least four weeks. Nonsteroidal anti-inflammatory drugs were usually avoided because these drugs may interfere in post injection inflammatory healing process.

Pre-injection pain assessment: Visual Analogue Score (VAS) was used to assess pain before injection. All post injection patient were regularly reassessed clinically and for pain improvement with VAS and return to sports activity and heavy work at 1 month, 3month and 6month post injection.

Data Analysis: Data analysis was performed using SPSS version 21. Values are presented as Mean± Standard deviation and standard error of mean. Categorical and Continuous variables were compared using appropriate tests. $p<0.05$ is considered statistically significant. Adjusted odds ratio and 95% confidence interval (CIs) will be computed for significant factors.

Results

A total of 60 patients presenting with complaint of chronic tendinopathy, who did not respond to conservative treatment for 3 months, were included in the study. The age group varied form 18 years to 70 years with the mean age of 44 years. Incidence of fracture was observed maximum between 30- 50 years of age. Among male were 73.3% and female were 26.7%. Mean age of male patient's was 42.39±6.14 year. Mean age of female patients was 41.89±5.6 year. We encounter total twenty-two-22 patients of lateral-epicondylitis, ten-10 medial-epicondylitis, fifteen-15 rotator cuff tendinopathy and thirteen-13 patients of Achilles tendinopathy. In this study, 40 (66.6%) affected patients belong to right side and 20 (33.4%) affected patients to left side. Most common activity levels in male patients were heavy or longstanding and in female patients were sedentary. There are no significant differences of mean in male and female pain score groups at Pre-injection level. There was no significant mean difference in pre-injection pain scores on basis daily activity level (p-value>0.05). Mean visual analogue scores of all affected patients at 1 month, 3 month, and 6 month post-injection follow up showed improvement. Mean visual analogue score of all lateral epicondylitis at pre injection, at 1 month, 3 month, and 6 month post-injection were 7.55, 6.29, 3 and 1.05 respectively. There was no significant mean difference in male and female patients pain score. These were no significant mean difference in right and left side pain scores. Satisfactory improvements were shown in 84% of tendinopathies at 6 month follow up on basis of VAS. Satisfactory and unsatisfactory improvement patients had similar profile like age, weight. Mean visual analogue score of all medial epicondylitis at pre injection, at 1 month, 3 month, and 6 month post-injection were 7.88, 5.77, 2.88 and 1.44 respectively. These values show deceased post injection values.

Table 1: Age distribution of the study patients (n=60)

Age	N	%
18-30 yrs	10	16.6
31-40 yrs	15	25.0
41-50 yrs	20	33.3
51-70 yrs	15	25.0

Table 2: (VAS) for lateral epicondylitis

		Mini-score	Maxi-score	Mean	SD
VAS	Pre-Injection	6	9	7.55	.7838
	1-MonthPost-Injection	3	8	6.29	1.2628
	3-MonthPost-Injection	0	6	3	1.878
	6-MonthPost-Injection	0	6	1.05	1.696

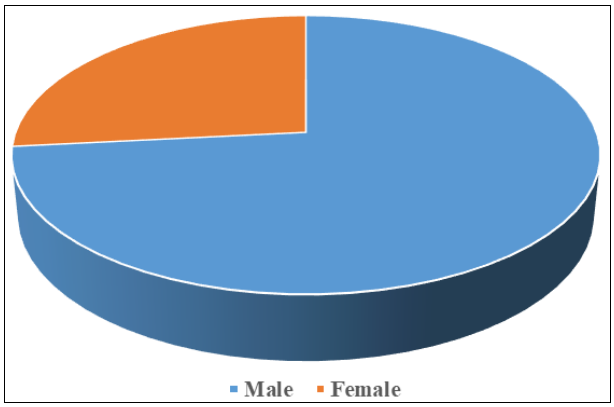

Fig 1: Sex distribution of the study patients.

Table 3: Descriptive Statistics: Visual analogue pain score (VAS) for medial epicondylitis

		Mini-core	Maxi-score	Mean	SD
VAS	Pre-Injection	7	9	7.88	.6009
	1-MonthPost-Injection	4	7	5.77	0.9444
	3-MonthPost-Injection	0	5	2.88	1.833
	6-MonthPost-Injection	0	4	1.444	1.589

Table 4: Descriptive Statistics: Visual analogue pain score (VAS) for RCT

Visual analogue pain score		Minimum score	Maximum score	Mean	SD
VAS	Pre-Injection	8	9	8.25	0.425
	1-MonthPost-Injection	5	7	5.75	0.753
	3-MonthPost-Injection	2	5	3.58	0.792
	6-MonthPost-Injection	0	5	1.25	1.764

Mean visual analogue score of all rotator cuff tendinopathy at pre injection, at 1 month, 3 month, and 6 month post-injection were 8.25, 5.75, 3.58 and 1.25 respectively. These values show deceased post injection values.

Table 5: Descriptive Statistics: Visual analogue pain score (VAS) for AT

		Minimum score	Maximum score	Mean	Std. Deviation
VAS	Pre-Injection	7	9	8	0.447
	1-MonthPost-Injection	4	7	5.54	0.82
	3-MonthPost-Injection	0	4	3.09	1.136
	6-MonthPost-Injection	0	4	1.27	1.555

Mean visual analogue score of all Achilles tendinopathy at pre injection, at 1 month, 3 month, and 6 month post-injection were 8, 5.54, 3.09 and 1.27 respectively. These values show deceased post injection values.

Mean visual analogue score of all tendinopathies at pre injection, at 1 month, 3 month, and 6 month post-injection were 7.88, 5.72, 3.14 and 1.22 respectively. These values show deceased post injection values.

There was significant difference of mean visual scores of pain in all chronic tendinopathy.

In this study arbitrarily we assumed patient with visual analogue pain score equal or less than 3 as satisfactory improvement of pain.

On basis of Visual analogue pain score, satisfactory improvement of pain at 1 month, 3months and 6month post injection were observed in 4%, 50% and 84% of tendinopathies respectively.

Table 6: Visual analogue pain score (VAS) for all tendinopathies in our study

		Minimum score	Maximum score	Mean	Std. Deviation
VAS	Pre-Injection	6	9	7.88	0.6590
	1-MonthPost-Injection	3	8	5.72	0.990
	3-MonthPost-Injection	0	6	3.14	1.49
	6-MonthPost-Injection	0	6	1.22	1.61

Table 7: mean visual analogues pain score

Mean visual analogues pain score		Mean diff.	T value	p-value
Pre-Injection	1-Month post-injection	2.16	14.45	.0000
Pre-Injection	3-Month post-injection	4.74	24.5	.0000
Pre-Injection	6-Month post-injection	6.6	28.1	.0000
1-Month post-injection	3-month post-injection	2.58	10.09	.0000
1-Month post-injection	6-Month post-injection	4.5	16.7	.0000
3-month post-injection	6-Month post-injection	1.92	8.34	.0000

Table 8: Percentage of tendinopathie in which satisfactory improvement occurred

(%) of patients in which satisfactory improvement of pain			
	1-month post-injection	3-month post-injection	6-month post-injection
Visual analogue pain score	4%	50%	84%

Discussion

Despite the variability of the findings in the literature summarized in this review, there may be potential for clinical effectiveness of PRPi, given that some of the findings summarized herein have demonstrated effectiveness. Specifically, 1 MA of 3 primary studies assessing pain in the Achilles tendon demonstrated a statistically significant improvement in patients who received PRPi as compared to placebo [17]; and another MA of 3 primary studies investigating the comparative effectiveness of PRPi versus steroids in patients with chronic tendinopathy of the hip demonstrated a clinical improvement in patients who received PRPi [18]. It may be that advances in the technology of platelet-rich therapies, such as platelet-rich fibrin [19] and plasma gel [20] could hold promise for clearer or more consistent improvement in clinical outcomes among musculoskeletal conditions. Chronic tendinopathies are common clinical problem with many available treatment modalities. Traditional treatments include rest, analgesics and physiotherapy. Injections, particularly corticosteroids, are given in very acute situations and for cases unresponsive to conservative methods. Corticosteroids offer a quick fix for pain relief in the acute phase but have limited effect in chronic cases with a significant fraction of patients having relapse and recurrence [21]. In chronic cases, surgery is the last resort with very unpredictable results. Recent years have seen an increase in the use of PRP in various clinical situations like epicondylitis, rotator cuff, patellar and calcaneal tendinopathies, and proximal plantar fascitis. This study was designed to evaluate the efficacy of PRP therapy for chronic tendinopathy. PRP contains a more concentrated number of platelets than does whole blood. The rationale for using PRP is to increase tendon regenerative abilities with a high content of cytokines and cells, in hyper-physiologic doses, which should promote cellular chemotaxis, matrix synthesis, and proliferation [22]. Degranulation of the alpha granules in platelets releases many different growth factors that can play a role in tissue regeneration processes. PRP represents a treatment option for many foot and ankle pathologies, including tendinopathy (Achilles, pe-roneal, posterior tibial, flexor hallucis longus, anterior tibial) and chronic ligamentous injury, such as plantar fasciitis [23]. Visual Analogue Scale (VAS) measure amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. Operationally a VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end. A total of 60 patients presenting with complaint of chronic tendinopathy, who did not respond to conservative treatment for 3 months, were included in the study. The age group varied form 18 years to 70 years with the mean age of 44 years. Incidence of fracture was observed maximum between 30- 50 years of age. Among male were 73.3% and female were 26.7%. Mean age of male patient's was 42.39±6.14 year. Mean age of female patient's was 41.89±5.6 year. Mishra *et al.* [24] in their study of PRP for lateral epicondylitis taken 15 patients of average age 48.1 yrs showed decreased VAS score (0-100) from 80.3 to 43.4 (4wk) to 32.0(8wk) to 5.7 (6 months). In their study of PRP for lateral epicondylitis showed results of decreased vas score >25% in 96% of patients at 1year. Peerbooms *et al.* [25] conducted a RCT with 100 patients lateral epicondylitis, 51 of whom received PRP injection and 49 received corticosteroid injections and reported better improvement with PRP over a period of 1 year. Gosens *et al.* [26] followed up these patients for the subsequent year and reported a sustained improvement with PRP use in comparison to corticosteroids. Thanasas *et al.* [27] have also shown encouraging results for PRP use compared to ABI in resistant tennis elbow patients. Randelli *et al.* [28] conducted an uncontrolled pilot study of PRP augmentation along with arthroscopic rotator cuff repair. In their 14 patients injected with PRP activated with thrombin at the tendon footprint after repair, they reported statistically significant improvements in VAS. Owens *et al.* [29] reported modest improvement in functional outcome in 10 patients who had received PRP injection for mid substance Achilles tendinopathy. Monto *et al.* [30] reported clinical success in 28 out of 30 patients with recalcitrant Achilles tendinosis. The improvement noted was in the AOFAS score and the MR architecture of the tendon. The present series also shows significant improvement in VAS in consecutive follow up at 1 month, 3 month, and 6 month of duration for lateral epicondylitis medial epicondylitis and rotator cuff tendinopathy and Achilles tendinopathy. Differences between mean pain score on follow up were statistically significant in every follow up interval. These results are comparable to previous studies. It was assumed, that patients with visual analogue pain score equal or less than 3. On the basis of Visual analogue pain score, satisfactory improvement of pain were observed in 4%, 50% and 84% of tendons at 1 month, 3month and 6month post injection respectively. At final follow up (at 6 month) approx. 84% of patient who received

PRP in injection showed satisfactory improvement of pain. There are some limitations of the study that should be considered. This study did not include any control group for comparison of PRP injection result. Studies with control group of proven treatment modality would be required to further validate efficacy of PRP. In this study PRP preparation was done with ordinary technique. Further Studies with better PRP preparation technique would be required to further validate efficacy of PRP.

Conclusion

The results of this study indicate that PRP injection has a role to play in the management of chronic tendinopathies. This technique was efficient in approximately 84% affected patients at 6-month follow-up. PRP is simple to acquire and prepare and is also cost effective. Hence it provides satisfactory intermediate and long-term results in term of pain relief. It seems a safe clinical procedure. Indeed, we had no reported side effects. However larger data set and longer follow up are required to conclude definitive role of PRP. We believe that these initial encouraging results now warrant further investigation, in particular with the use of a prospective randomized controlled trial (RCT).

Conflict of Interest

Not available

Financial Support

Not available

Reference

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