

The Effectiveness of Platelet-Rich Plasma Injections in Gluteal Tendinopathy

A Randomized, Double-Blind Controlled Trial Comparing a Single Platelet-Rich Plasma Injection With a Single Corticosteroid Injection

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Background: Gluteus medius/minimus tendinopathy is a common cause of lateral hip pain or greater trochanteric pain syndrome.

Hypothesis: There would be no difference in the modified Harris Hip Score (mHHS) between a single platelet-rich plasma (PRP) injection compared with a corticosteroid injection in the treatment of gluteal tendinopathy.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: There were 228 consecutive patients referred with gluteal tendinopathy who were screened to enroll 80 participants; 148 were excluded (refusal: $n = 42$; previous surgery or sciatica: $n = 50$; osteoarthritis, $n = 17$; full-thickness tendon tear, $n = 17$; other: $n = 22$). Participants were randomized (1:1) to receive either a blinded glucocorticoid or PRP injection intratendinously under ultrasound guidance. A pain and functional assessment was performed using the mHHS questionnaire at 0, 2, 6, and 12 weeks and the patient acceptable symptom state (PASS) and minimal clinically important difference (MCID) at 12 weeks.

Results: Participants had a mean age of 60 years, a ratio of female to male of 9:1, and mean duration of symptoms of >14 months. Pain and function measured by the mean mHHS showed no difference at 2 weeks (corticosteroid: 66.95 ± 15.14 vs PRP: 65.23 ± 11.60) or 6 weeks (corticosteroid: 69.51 ± 14.78 vs PRP: 68.79 ± 13.33). The mean mHHS was significantly improved at 12 weeks in the PRP group (74.05 ± 13.92) compared with the corticosteroid group (67.13 ± 16.04) ($P = .048$). The proportion of participants who achieved an outcome score of ≥ 74 at 12 weeks was 17 of 37 (45.9%) in the corticosteroid group and 25 of 39 (64.1%) in the PRP group. The proportion of participants who achieved the MCID of more than 8 points at 12 weeks was 21 of 37 (56.7%) in the corticosteroid group and 32 of 39 (82%) in the PRP group ($P = .016$).

Conclusion: Patients with chronic gluteal tendinopathy >4 months, diagnosed with both clinical and radiological examinations, achieved greater clinical improvement at 12 weeks when treated with a single PRP injection than those treated with a single corticosteroid injection.

Registration: ACTRN12613000677707 (Australian New Zealand Clinical Trials Registry).

Keywords: platelet-rich plasma; gluteal tendinopathy; leukocyte

Tendinopathies constitute the most common reason for consultation with a primary care physician and make up 30% of all musculoskeletal consultations.²⁰ Tendinopathy of the gluteus medius or minimus tendons is a major cause of lateral hip pain or greater trochanteric pain syndrome. It is more

than 4 times more common in women and is the most prevalent of all lower limb tendinopathies.¹⁰ High levels of dysfunction have been found in people with gluteal tendinopathy who fail nonoperative treatment,³⁷ including less full-time employment, higher pain levels, and poorer quality of life.¹³ This has been equated with the disability of severe osteoarthritis of the hip¹³ in which the economic effect has been estimated at 4400 Euros per patient (US\$4707)³⁴ in indirect costs, having a major economic effect.

Fearon et al¹⁴ identified that the diagnosis of greater trochanteric pain syndrome can be confirmed by a clinical

history of lateral hip pain localized to the greater trochanter, pain with activities such as walking and stair climbing, and pain lying on the affected side at night. Positive clinical signs include tenderness at the greater trochanter and localized lateral hip pain with flexion, abduction, and external rotation (FABER) testing.¹⁴ Both ultrasound and magnetic resonance imaging can reliably predict the presence of gluteal tendinopathy and tears.^{3,23,24} Patients with both clinical signs and symptoms as well as the radiological appearance of gluteal tendinopathy can be regarded as having symptomatic disease involving the gluteal tendons.

Although physical therapy may be considered a first-line treatment for tendinopathy, 2 recent reviews of treatment modalities for gluteal tendinopathy have found that there is little evidence to support physical therapy or an exercise program for gluteal tendinopathy.^{2,19} Other interventions including analgesics and nonsteroidal anti-inflammatory drugs have also failed to provide a long-term benefit.^{28,33,38} Today, glucocorticoid injections are still considered to be one of most popular injection therapies for pain relief in many clinics, despite controversies regarding the use of glucocorticoid injections for the treatment of tendinopathy. Several studies have shown that glucocorticoid injections provide short-term benefits from 12 to 26 weeks^{31,33} but no long-term benefit.⁶

Another commonly used injection modality in tendinopathy is platelet-rich plasma (PRP), but inconsistent outcomes of PRP have been reported. There have been numerous studies attempting to determine the best injection treatment, with varied, contradictory, and inconclusive results.^{††}

Considering the lack of high-level clinical evidence on injection modalities for treating gluteal tendinopathy, we have designed a double-blind, randomized controlled study to compare the effectiveness of glucocorticoid and PRP. Our hypothesis was that there would be no difference in the modified Harris Hip Score (mHHS) between a single intratendinous PRP injection compared with a corticosteroid injection in the treatment of gluteal tendinopathy.

METHODS

Trial Design

This trial is a single-site, double-blind, prospective, parallel-group randomized controlled clinical trial, submitted August 2012 to the Australian New Zealand Clinical Trials Registry

(ACTRN12613000677707) and approved by the Epworth HealthCare Human Research Ethics Committee (57412). The participants, clinical investigator (treating physician), and investigators examining the data were blinded to the treatment allocation and results until the end of the study after statistical analysis. Informed consent was obtained and CONSORT (Consolidated Standards of Reporting Trials) guidelines followed. No changes were made to the trial design after commencement.

Participant Selection

Eligible participants were aged 18 to 80 years, male or female with a history of gluteal tendinopathy of greater than 4 months and having lateral hip pain, pain with activity such as walking and stair climbing, and pain lying on the affected side at night. The clinical signs on examination included tenderness over the greater trochanter. Radiological confirmation of the diagnosis of grade 2 to 3 tendinopathy (no tear) was made using ultrasound and magnetic resonance imaging. We classified the tendon pathological abnormalities as follows with reference to the gluteus medius and minimus: grade 1, bursitis only; grade 2, tendinopathy of one or both tendons; grade 3, partial-thickness tear; and grade 4, full-thickness tear of either tendon.

Participants were excluded if they had full-thickness tears (grade 4) demonstrated radiologically, had previous hip or tendon surgery, had a history of breast cancer, were taking warfarin (blood thinners) at the time of the procedure, had back surgery within the last 12 months, had a history of recent sciatica, or had a cortisone injection within the previous 6 weeks.

Randomization

Assignment to a treatment group was determined by an independent statistician using a computer-generated, fixed-block randomization scheme, allowing for 80 participants after screening and informed consent. This was electronically locked and accessible only by the single allocator. A unique trial patient identification number was allocated simultaneously with treatment allocation. Allocation concealment was ensured, as the allocation remained electronically locked after allocation and only the code given to the laboratory preparation technician at the time of trial substance preparation.

††References 7, 11, 17, 18, 22, 25, 29, 32, 35, 36.

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Interventions

All participants had approximately 55 mL of blood withdrawn from the cubital fossa to ensure blinding. PRP was prepared using the GPS III kit (Zimmer Biomet) according to the manufacturer’s instructions, and corticosteroid was prepared by mixing Celestone Chronodose (Merck Sharpe & Dohme, Australia) with saline to the same volume. No buffering or activating agents were added, and the resultant syringe was covered with tape to blind the injector and the participant to the contents. Local anesthetic was administered, and then 6 to 7 mL of trial substance (PRP or corticosteroid) was injected into the affected area of the tendon in 5 to 6 passes using ultrasound guidance.

Both groups had the same 12-week unsupervised rehabilitation program with directed activity modification after treatment without the engagement of clinical physical therapists. In the first 4 weeks, participants were instructed to avoid all aggravating activities including walking for exercise, stairs, squats, lunges, and abduction exercises. At 6 weeks, they were instructed to begin a progressive walking program, which also included the use of stairs, return to the gymnasium, and other sports. At 12 weeks, there were no limitations on activity.

Outcome Measures

The primary outcome measure was a pain and functional assessment: the mHHS. The mHHS used as our primary outcome measure was completed by the participants at baseline and 2, 6, and 12 weeks. The mHHS is the Harris Hip Score (HHS) without the physician-reported range of motion component. This retains the pain and function components including daily activities (stairs, use of public transport, sitting, and managing shoes and socks) and gait (limp, support needed, and walking distance).³⁰ There has been shown to be no meaningful difference between the HHS and the mHHS.¹² This score has been widely used in other hip pathological changes such as replacement surgery and hip arthroscopic surgery in patients of the same age and has been found to reflect patient satisfaction.¹

The patient acceptable symptom state (PASS) reflects the point at which patients feel well.²⁶ This reflects the score that a participant would achieve when he or she has clinically recovered and requires no further treatment. The PASS score at which patients considered their status to be satisfactory at 12 months has been found to be 74 for the mHHS.⁴ We defined a PASS score of 74 to reflect an improvement representative of clinical recovery. The minimal clinically important difference (MCID) for the mHHS has been shown to be 8 points.²¹ Clinical reviews were performed at 6 and 12 weeks.

Statistical Analysis

A power analysis determined the total sample size to be 72 (36 in each group) based on the hypothesis that there would be no difference in the mHHS between a single intratendinous PRP injection compared with a corticosteroid injection in the treatment of gluteal tendinopathy. To account for a 10% dropout rate at 12 weeks, 80 participants were recruited to the study.

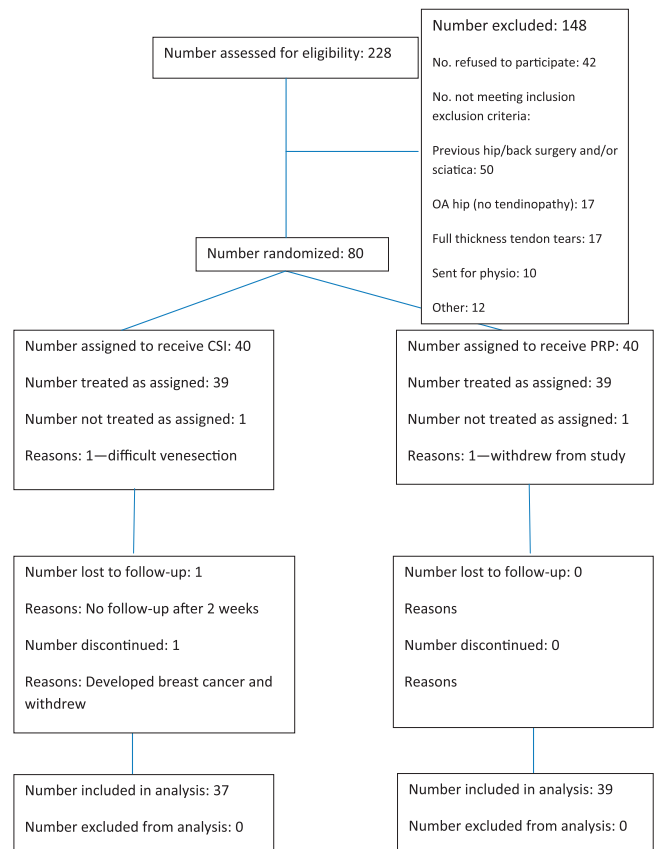


Figure 1. Flow diagram of platelet-rich plasma (PRP) trial in gluteal tendinopathy. CSI, corticosteroid injection; OA, osteoarthritis.

The treating/assessing clinicians and participants were blinded to the treatment. The results were entered on a locked Excel spreadsheet (Microsoft), coded, and analyzed blinded. Statistical analysis was conducted on an intention-to-treat basis using STATA version 13 (StataCorp). Treatment comparisons were based on the mHHS at 12 weeks, with significance at $P < .05$. Standard t tests with equal variance were performed at 12 weeks.

RESULTS

Participants

During the recruitment period (May 2013 to May 2015), 228 patients were assessed. Figure 1 shows the flow of participants through the study. One hundred forty-eight participants were excluded because of ineligibility criteria. A standardized physical therapy program had been ineffective before enrollment in all of these participants. The enrollment period was extended for 1 month to meet the target recruitment of 80 participants. Participants were randomly assigned to the PRP injection group ($n = 40$) or the corticosteroid injection group ($n = 40$). One participant in each group was not treated as assigned: 1 because of a difficult blood draw and 1 because of withdrawal. Two participants were lost to follow-up in the corticosteroid

TABLE 1
Patient Characteristics^a

	Corticosteroid Group (n = 40)	PRP Group (n = 40)
Age, mean (range), y	59.7 (23-78)	60.3 (23-76)
Sex, n (%)		
Male	2 (5)	6 (15)
Female	38 (95)	34 (85)
Body mass index, mean \pm SD (range), kg/m ²	26.96 \pm 4.33 (18.8-39.5)	28.42 \pm 4.58 (20.0-43.9)
No. of previous corticosteroid injections, n (%)		
0	21 (52.5)	13 (32.5)
1	14 (35)	19 (47.5)
2	3 (7.5)	6 (15)
≥ 3	2 (5)	2 (5)
Mean \pm SD	0.65 \pm 0.83	0.98 \pm 0.97
Previous physical therapy, n (%)	40 (100)	40 (100)
Grade of tendinopathy, ^b n (%)		
1	24 (60)	20 (50)
2	9 (22.5)	6 (15)
3	7 (17.5)	14 (35)
4	0 (0)	0 (0)
Mean \pm SD	1.6 \pm 0.7	1.8 \pm 0.9
Baseline mHHS, mean \pm SD (range)	54.15 \pm 10.88 (32-71)	53.77 \pm 12.88 (23-77)

^amHHS, modified Harris Hip Score; PRP, platelet-rich plasma.

^bTendinopathy: grade 1, bursitis only; grade 2, tendinopathy of one or both tendons; grade 3, partial-thickness tear; and grade 4, full-thickness tear of either tendon.

group; 37 participants in the corticosteroid group and 39 in the PRP group were available for analysis at 12 weeks.

The baseline patient characteristics and mHHS data are shown in Table 1. The groups showed similar baseline data relative to mHHS, sex, body mass index (BMI), age, duration of symptoms, and previous cortisone injections. In accordance with the prevalence of this condition, there were more female than male participants recruited.

Primary Outcome

Table 2 shows the mean mHHS at baseline and 2, 6, and 12 weeks for the groups and the 12-week values for the MCID and PASS. The end of the follow-up period was September 2015. The mean mHHS at 2 weeks was 66.95 \pm 15.14 for the corticosteroid group versus 65.23 \pm 11.60 for the PRP group and at 6 weeks was 69.51 \pm 14.78 for the corticosteroid group versus 68.79 \pm 13.33 for the PRP group. The mean mHHS improved significantly at 12 weeks in the PRP group, with a mean score of 74.05 \pm 13.92, compared with the corticosteroid group, with a mean score of 67.13 \pm 16.04. This was statistically significant ($P = .048$). These data are shown graphically in Figure 2. The proportion of participants who achieved the MCID of a change in score from baseline of more than 8 points at 12 weeks was 21 of 37 (56.7%) in the corticosteroid group and 32 of 39 (82%) in the PRP group ($P = .016$).

Secondary Outcome

The participants' ability to return to normal activities can be measured by the PASS score. This reflects the point at which the mHHS improvement correlates with clinical recovery. At

this point, the participants have resumed normal activity and are unlikely to require further treatment. The proportion of participants who achieved an outcome score of ≥ 74 at 12 weeks was 17 of 37 (45.9%) in the corticosteroid group and 25 of 39 (64.1%) in the PRP group ($P = .11$). There was no correlation between the outcome and BMI, duration of symptoms, or number of previous corticosteroid injections.

Compliance With Rehabilitation Program

All participants were compliant with the 12-week unsupervised rehabilitation program. This was reviewed at 6 weeks at which further instructions relating to the progressive walking program and return to other activity were outlined. No protocol deviations were recorded relating to noncompliance of the rehabilitation program.

Adverse Events

There were no treatment-related significant adverse events in either group. Treatment-related minor adverse events occurred in both groups and generally related to posttreatment localized soreness within 48 hours.

DISCUSSION

This study compared the change in pain and function measured by the mHHS in participants treated with a single PRP injection compared with a corticosteroid injection in gluteal tendinopathy. The results showed a statistically significant improvement in patients treated with PRP over 12 weeks. The corticosteroid group showed good improvement

TABLE 2
Outcomes at Various Time Points^a

	Baseline	2 wk	6 wk	12 wk
mHHS, mean ± SD				
Corticosteroid group	54.15 ± 10.88	66.95 ± 15.14	69.51 ± 14.78	67.13 ± 16.04
PRP group	53.77 ± 12.08	65.23 ± 11.60	68.79 ± 13.33	74.05 ± 13.92
P value				.048
PASS score ≥74, n (%)				
Corticosteroid group				17/37 (45.9)
PRP group				25/39 (64.1)
P value				.11
MCID >8 points on mHHS, n (%)				
Corticosteroid group				21/37 (56.7)
PRP group				32/39 (82.0)
P value				.016

^aMCID, minimal clinically important difference; mHHS, modified Harris Hip Score; PASS, patient acceptable symptom state; PRP, platelet-rich plasma.

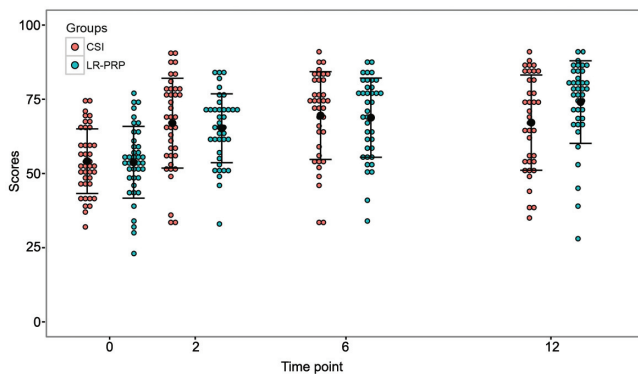


Figure 2. Graph of modified Harris Hip Score (mHHS) values at 0, 2, 6, and 12 weeks.

to 6 weeks, but their subsequent scores declined as compared with the PRP group.

The use of PRP has been controversial in the management of tendinopathy as trials have shown variable results.^{††} In a recent meta-analysis that included 18 studies (1066 participants), significant positive outcomes were seen in those treated with highly cellular leukocyte-rich PRP (LR-PRP) preparations. There was good evidence to support the use of a single injection of LR-PRP under ultrasound guidance in tendinopathy.¹⁵ This study provides further evidence for the use of LR-PRP in gluteal tendinopathy using LR-PRP produced by the GPS III kit.¹⁶ Treatment with PRP provides a successful nonsurgical management option that is more effective than corticosteroid injections and is less invasive than surgical treatment.

The demographic data shown in Table 1 show the groups to be well randomized with no significant differences between the groups. A mean age of 60 years and a 9:1 ratio of female to male are consistent with previous findings of a higher ratio of female patients.² The BMI was similar in the corticosteroid

and PRP groups (mean, 26.96 ± 4.33 and 28.42 ± 4.58, respectively), contrary to our expectation that patients with a higher BMI may be represented in this group. To ensure the group had chronic tendinopathy, the minimum duration of symptoms was 4 months. The mean duration of symptoms was 15.25 ± 12.52 for the corticosteroid group and 14.78 ± 12.33 for the PRP group. Almost half (47.5%) of the participants had symptoms longer than 12 months, suggesting that the natural history of chronic gluteal tendinopathy is not to resolve over 12 months.

In line with the World Medical Association’s Declaration of Helsinki⁹ that the benefits, risks, burdens, and effectiveness of a new intervention must be tested against the best current proven intervention, the currently accepted treatment for gluteal tendinopathy, a corticosteroid injection, was used as a control in this study.^{2,28} Thirty-four participants (42.5%) had not had a previous corticosteroid injection, and only 13 (16.2%) had ≥2 injections before entry in the study. A subgroup analysis found that there was no difference in the outcome for patients who had more previous injections. Although this would suggest that there is no long-term detrimental effect on the tendon from corticosteroid injections, we had few participants who had more than 2 injections, and the outcome may be different with a larger number of injections.

Physical therapy has been used as a first-line therapy for gluteal tendinopathy, despite no evidence for its efficacy.² All the participants in this study had failed previous physical therapy interventions, and further physical therapy was avoided because it was not considered an evidence-based treatment for this study. The results of this study can be attributed directly to the biological response to the injection treatment received by the participant.

The results shown in Table 2 show that the corticosteroid group improved up to 6 weeks but then began to decline. The mHHS of 54.15 ± 10.88 at baseline improved to 69.51 ± 14.78 at 6 weeks and then dropped to 67.13 ± 16.04 at 12 weeks. However, as the increase in the SD shows, there was a lot of variation in the outcome in this group. Our study confirms previous studies, findings that cortisone

††References 7, 11, 17, 18, 22, 29, 32, 35, 36.

injections are effective for less than 3 months.^{27,28,31,33} By contrast, the PRP group showed a consistent progressive improvement compared with the corticosteroid group, with scores of 53.77 ± 12.08 at baseline to 74.05 ± 13.92 at 12 weeks ($P = .048$).

The strength of this study is that we are able to recruit only participants with chronic tendinopathy of greater than 4 months. Some previous studies have included participants with acute reactive pathological changes, thus including participants who may recover with physical therapy alone or with no additional treatment.^{5,7,11} The power calculation of the sample size has been adequate to provide statistical significance, and there were only 2 participants lost to follow-up at 12 weeks. The limitations of this study are the short duration of follow-up, the use of corticosteroid as a control, and the inability to determine the economic effect of the treatment.

While the use of corticosteroid as a control is controversial in longer term studies,⁸ the use of corticosteroid as a control compared with placebo, local anesthetic, or saline injections did not affect the outcome of similar trials.¹⁵ The 3-month follow-up was chosen based on a meta-analysis of previous studies showing that the effectiveness of corticosteroid was maximal at 2 to 6 weeks and that the effect of PRP was emerging at 12 weeks and continued to show a trend of improvement out to 12 months.¹⁵ The 12-week point would therefore be the first point at which the groups would be likely to diverge, as has been found in our study. A longer duration than 12 weeks would be likely to suffer from dropout in the control group. An open-labeled follow-up has demonstrated that the result from the PRP is sustained at 1 to 2 years as anticipated and that the corticosteroid group continues to decline (unpublished data).

CONCLUSION

Patients with chronic gluteal tendinopathy of greater than 4 months, diagnosed with both clinical and radiological examinations, achieved greater clinical improvement at 12 weeks when treated with a single PRP injection than those treated with a single corticosteroid injection.

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