
Design: Randomized clinical trial

Study question: In the setting of rotator cuff tendinopathy, is an injection of platelet-rich plasma superior to an injection of saline?

Population/sample size/setting:
- 40 patients (13 men, 27 women, mean age 48) treated for rotator cuff tendinopathy at the Turkish Armed Forces Rehabilitation Center in Ankara
- Eligible for inclusion if they were age 18 to 70, had pain in the shoulder or lateral deltoid area, exacerbated with overhead-throwing activity, more than 3 months of symptoms, pain on palpation of the insertion of the cuff in the proximal humerus, rotator cuff tendinosis or partial tear on MRI
  - A positive Neer impingement sign, manifested as at least a 50% relief of pain following 5 ml of subacromial 2% lidocaine) was also required for inclusion
- Exclusion criteria were full-thickness tear on MRI, medical comorbidity such as arthritis or a bony lesion, systemic disease such as diabetes, hepatitis, or coagulopathy, hemoglobin level <11g/dL, platelet level <150,000/microliter, pregnancy, and recent (6 week) steroid injection or NSAID use in past week

Main outcome measures:
- Randomization was to PRP (n=20) or saline (n=20) with concealment of allocation
  - PRP was obtained by drawing 54 ml of blood and mixing with 6 ml of citrate, centrifuging to obtain a platelet level 4 times that in whole blood, and injecting 5 ml prepared by a nurse who covered the syringes and hubs with an opaque band to ensure blinding of the injections, which were all done by the same clinician
- Injections were done under ultrasound guidance with infiltration technique depending on whether the patient had tendinopathy alone or had a partial thickness tear
- After injection, all patients had the same standard rehabilitation program, refraining from overhead throwing and rotatory movement of the shoulder for 2 days, followed by a 3 week physical therapy exercise program followed by a home-based program focusing on isotonic strengthening and stretching exercises for a further 3 weeks; the entire exercise program lasted 6 weeks
- Main outcome was the Western Ontario Rotator Cuff Index (WORC), which was converted to a scale from 0 to 100%, where 100% is the best possible score
A 17% increase in the WORC was considered to be the clinically relevant difference, and was the basis for the sample size calculation.

Secondary scores were the Shoulder Pain and Disability Index (SPADI), pain VAS, and passive ROM using goniometry; a blinded researcher assessed all outcomes.

Both groups had marked improvements between baseline and the 3 week, 6 week, 12 week, 24 week, and 1 year followup:

- For WORC, the PRP group had a baseline score of 34.6 and a 1 year score of 84.6; the saline group had a baseline WORC of 29.9 and a 1 year score of 79.7
- For SPADI, the PRP group had a baseline score of 77.5 and a 1 year score of 14.6; the saline group had a baseline of 78.2 and a 1 year score of 15.4
- For VAS, the PRP group had a baseline of 80 and a 1 year score of 7.5; the saline group had a baseline of 90 and a 1 year score of 10

Both groups had equal improvements in outcome scores; PRP was not superior to saline.

Authors’ conclusions:

- PRP in a single injection was not superior to saline injection for chronic rotator cuff tendinopathy
- Exercise, which was done in both groups, may account for most of the considerable improvement in pain and function which was observed over the course of one year
- It is possible that multiple injections of PRP could have an effect not obtained with a single injection; however, PRP was not “ineffective” in this study; it simply did not provide any added benefit over that obtained by exercise

Comments:

- Methodologically this had most of the hallmarks of a high quality study; the randomization and blinding controlled serious threats to internal validity; the primary outcome was clearly specified, and a minimal clinical difference was used to calculate the sample size
- Most of the patients were women, even though the study was done in an Armed Forces health facility; the distribution of patients in terms of active duty or dependents of active duty may have been of interest, but its omission is not a threat to the validity of the study

Assessment: High quality study with good evidence that in the setting of rotator cuff tendinopathy, a single dose of PRP provides no additional benefit over saline injection when the patients are enrolled in a program of active physical therapy.