Kesikburun S, Tan AK, et al. Platelet-Rich Plasma Injections in the Treatment of Chronic Rotator Cuff Tendinopathy: A Randomized Controlled Trial With 1-Year Follow-up. Am J Sports Med 2013;:2609-2616.

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