

Rhon DI, Boyles RB, et al. One-Year Outcome of Subacromial Corticosteroid Injection Compared With Manual Physical Therapy for the Management of the Unilateral Shoulder Impingement Syndrome. A Pragmatic Randomized Trial. Ann Intern Med 2014;161:161-169.

Design: Randomized clinical trial

Study question: in patients with unilateral shoulder impingement, is there any difference between steroid injection and manual physical therapy for improving shoulder disability?

Population/sample size/setting:

- 98 patients (67 men, 31 women, mean age 41) treated for shoulder impingement syndrome at Madigan Army Medical Center in Tacoma
- Eligible if they had a referral for unilateral shoulder pain from family practice and orthopedic clinics at the Madigan Center; patients were a mix of active duty and retired military and their family members (no copayments for care)
- Exclusion criteria were a history of shoulder dislocation, fracture, or adhesive capsulitis; a history corticosteroid shoulder injection (CSI) or physical therapy for the shoulder pain in the past 3 months, baseline Shoulder Pain and Disability Index (SPADI) score less than 20%, pain of cervical spine origin, systematic or neurologic disease affecting the shoulder, positive rotator cuff lag sign or history of full-thickness rotator cuff tear, pending litigation, or inability to attend physical therapy (PT) for three weeks

Main outcome measures:

- Randomized to two intervention groups: manual PT (n=46) or CSI (n=52)
- Manual PT, which lasted three weeks, consisted of twice weekly sessions of soft tissue and joint mobilizations, manual stretches, contract-relax techniques, and reinforcing exercises, with the details matched to individual requirements; home exercises were prescribed to reinforce the clinic interventions
- CSI was done by a credentialed sports medicine physician who injected 40 mg triamcinolone into the subacromial space; as many as three could be given during the year of the study, but had to be spaced at least one month apart
 - o Patients received printed material on gravity-assisted distraction and oscillatory pendulum exercises
- Patients were allowed to seek additional health care after one month; PT patients could receive steroid injections and CSI patients could receive PT or could have additional steroid injections if they wanted
- Followup was done at 1, 3, 6, and 12 months

- Primary outcome was SPADI score, and the minimal clinically important change was considered to be between 8 and 13 points
 - o Secondary outcomes were the Global Rating of Change (GRC) and the Numerical Pain Rating Scale (NPRS)
 - o A blinded assessor examined the electronic health care records for the use of additional shoulder-related health care resources, including physician visits, MRI, additional steroid injections, and physical therapy visits
- All patients in the CSI group had at least one injection; all but 6 patients in the PT group received the 6 PT sessions in the protocol
- Both groups had improvements in the SPADI of about 50% between baseline and 12 months, but there were no differences in SPADI improvement between the two groups
 - o CSI mean SPADI went from 46.0 to 23.1; mean PT SPADI went from 44.9 to 21.6
 - o The 50% improvements were actually observed in both groups at the 1 month followup assessment; there were no real changes between 1 month and 12 months in the subsequent SPADI scores
- The secondary outcomes of the GRC and the NPRS also improved equally in both groups
- There was a difference in the other secondary outcome of health care usage during the 12 months of followup
 - o Patients in the PT group used less health care than those in the CSI group
 - 37% of the PT patients had shoulder-related visits to their primary care physician; 60% of CSI patients had at least one such visit
 - The PT patients had fewer additional steroid injections than did the CSI group; 20% of PT patients and 38% of CSI patients had at least one additional injection (a first injection for a PT patient and a second injection for a CSI patient)
 - 10 patients in the CSI group and 4 patients in the PT group had additional physical therapy after the end of initial treatment

Authors' conclusions:

- Manual PT and corticosteroid injections produce similar improvement in pain and function beginning at 1 month and continuing through 12 months in patients with unilateral shoulder impingement syndrome
- Manual PT patients used fewer health care resources during the followup visit than did the CSI patients
- There are some limitations in the study; patients were not blinded and there was no standardized definition of the shoulder impingement syndrome

- In addition, the patient enrollment was restricted to patients who had been referred for PT and this may not be representative of all patient with shoulder impingement symptoms

Comments:

- Most sources of bias were controlled, but the exclusion from the analysis of the 6 PT patients who did not receive PT violates the intention-to-treat principle; this is not likely to undermine the conclusions of the study
- Patients had to have a negative lag sign for inclusion in order to exclude a full-thickness tear, but there is some ambiguity in this wording
 - o There are two lag signs: an external rotation and an internal rotation lag sign
 - o It appears that the authors refer to the lag sign described by Rigsby et al 2010; this is an internal rotation lag sign
- The minimal clinically important change value is somewhat confusing: the SPADI is a 100 point scale, and the minimal change is said to be from 8 to 13 points (6% to 10%); on a 100 point scale, where most of the patients had an initial SPADI of on the order of 50, an 8 point change would be closer to 16% and a 13 point change would be closer to 26%
- The health care usage was not a primary outcome, and the study probably cannot be used to claim evidence that PT reduces health care consumption; however, the observation is an interesting one
- The impingement group probably included a mix of bursitis, tendinosis, and partial thickness tears of the rotator cuff; if steroids had an advantage over PT in bursitis patients, where inflammatory mechanisms may be relevant, the study was not set up to detect such differences

Assessment: adequate for some evidence that 6 sessions of manual physical over a three week period are as effective as an injection of 40 mg triamcinolone for relief of symptoms of shoulder impingement symptoms

Reference:

Rigsby R, Sitler M, Kelly JD. Subscapularis Tendon Integrity: An Examination of Shoulder Index Tests. *Journal of Athletic Training* 2010;45(4):404–406