

**Kim WM Lee HG, et al. A Randomized Controlled Trial of Intra-Articular Prolotherapy Versus Steroid Injection for Sacroiliac Joint Pain. J Alternative Complementary Med 2010;15:1285-90.**

**Reviewed, no change to conclusions, May 2017**

Design: Randomized clinical trial

Population/sample size/setting:

- 48 patients (14 men, 34 women, mean age 60) treated for chronic SI joint pain in a university anesthesiology department in Korea
- Eligibility criteria were 2 or more months of pain in the buttock, groin, or thigh, with physical examination tenderness just below the posterior superior iliac spine and either a positive Patrick or Gaenslen test
  - o Patients who had these signs received an injection of 2.5 ml of 0.25% bupivacaine ; if the pain intensity decreased by at least 50%, the patient was diagnosed as having confirmed SI joint pain and was eligible for randomization and continuation in the study
- Exclusion criteria were cancer, fractures, inflammatory arthritis, infection, unresolved workers' compensation claims or litigation, fibromyalgia, and pregnancy

Main outcome measures:

- 50 patients were randomized to either prolotherapy with 2.5 ml of 25% dextrose plus 0.25% bupivacaine (n=24) or to a steroid injection with 40 mg triamcinolone plus 2.5 ml of 0.125% bupivacaine (n=26)
- Analgesics previously taken by the patients were discontinued before any injections were given
- Up to three injections could be given every other week; however, if the patient responded with a 90% reduction in pain to an injection, further scheduled injections were canceled
- After the procedure, analgesia was provided with tramadol/acetaminophen (Ultracet), and 7 days of tizanidine were prescribed for all patients
- Injections were done under fluoroscopic guidance which confirmed the intra-articular position using an arthrogram
- A physician unaware of the patient treatment assessed the two main outcomes of Numerical Rating Scale (NRS) for pain and the Oswestry scale for disability, beginning before and 2 weeks after the completion of the final treatment injection
- One patient in each group dropped out of the study; 48 patients provided outcome data for analysis
- In the immediate term, steroid injection was more effective than prolotherapy; an average of 1.5 injections were required for 90% relief in the steroid group, but an average of 2.7 injections were required for the prolotherapy group to report 90% relief

- At the 2 week follow-up point, all patients in both groups had at least 50% reduction in pain and significant improvements in the Oswestry
- The main outcome was the proportion of patients who sustained pain relief without analgesics during 15 months of follow-up, which was considered to have occurred if pain did not recur; when pain did recur, this recurrence was defined as the “event” which formed the basis for a survival analysis
- Although the steroid group had faster relief of pain than the prolotherapy group, the prolotherapy group response was longer-lasting
  - o At 6 months, the continued positive response was reported by 63.6% of the prolotherapy group and for 27.2% of the steroid group
  - o At 10 months and again at 15 months, persistent pain relief was reported in 58.7% of the prolotherapy patients and in only 10/2% of the steroid patients
  - o Median survival time was 3 months for the steroid group, but could not be calculated for the prolotherapy group, since more than 50% remained pain-free at the end of the 15 month observation period
- No serious complication was reported in either group during follow-up

Authors’ conclusions:

- Intra-articular prolotherapy provided significant relief from SI joint pain, and its effects lasted longer than a steroid injection of the same joint
- The patients were required to show a response to a local anesthetic injection prior to being randomized; this increased the specificity of the enrollment to patients likely to have the SI joint as a pain generator
- Intra-articular SI joint injection may have some beneficial effects on the ventral structures of the joint, which are inaccessible to ligament prolotherapy and radiofrequency denervation
- The prolotherapy group required more injections than the steroid group, indicating that the therapeutic effect may take longer to appear
- Intra-articular prolotherapy with 5% dextrose water diluted to 2.5% may be useful for the long-term relief of SI joint pain

Comments:

- Blinding appears to be satisfactory at the 2 week point, when a blinded physician assessed the pain and disability scores, but it is not stated when the code was broken; if it continued for the 15 months of the follow-up, that would make the results less susceptible to bias
  - o There is no reason to assume that the follow-up was not blinded for the entire 15 months; the point is not made explicitly
- It is not clear that this is a study of the same kind of prolotherapy that has been previously studied, since it is an intra-articular injection under fluoroscopic guidance and is not aimed at the joint ligaments, which is the usual assumed target of other prolotherapy studies
- There appears to be a misprint at the top of the first column of page 1289, which should read that the spread of the drug allows it to reach the ventral SI structures, not the dorsal structures

- Sustained pain relief appears to have been defined as continued relief without analgesics; this is not clearly defined, since it is not clear whether an occasional aspirin or acetaminophen would count as an analgesic use which would define recurrence of SI joint pain
  - o Although the definition of recurrence of pain is lacking, the definition should have been the same for prolotherapy and steroid groups
- Fluoroscopic guidance of intra-articular injections is likely to have been an important part of the procedure for both injection groups, and may not always be practical

Assessment: Adequate for some evidence that intra-articular prolotherapy of the SI joint under fluoroscopic guidance with 2.5% dextrose provided longer pain relief than steroid injection of the same joint