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Title

Prolotherapy vs epidural steroid injections for lumbar pain radiating to the leg: Results of a randomized controlled trial

Priority 1 (Research Category)

Musculoskeletal and rheumatology

Presenters

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Abstract

CONTEXT Chronic low back pain referred to the leg (CLBP-L) is common in primary care, debilitating, and expensive. Routine care includes epidural steroid injection (ESI), the effectiveness of which is often limited. Dextrose prolotherapy (DPT) is an emerging non-opioid regenerative injection technique reported to decrease pain and improved function in several non-cancer pain conditions, but is not well studied in CLBP-L. OBJECTIVE We conducted a randomized effectiveness trial comparing prolotherapy with ESI for CLBP-L. STUDY DESIGN/ANALYSIS Unblinded randomized controlled effectiveness trial; analysis by intention to treat. SETTING/POPULATION/INTERVENTION Outpatient participants with CLBP-L received lumbosacral care: either 3 monthly ESI injections under fluoroscopy, or up to 5 monthly DPT injection sets under ultrasound guidance. The Primary outcome was the change in leg pain score on a 0-10 numerical rating scale (NRS) pain scale; its minimal clinical important difference is 2 points. The secondary outcome was change in function on the Oswestry Disability Index; its minimal clinical important difference is 10 points. Both were assessed at 1,3, 6, and 12 months after final injection. RESULTS 104 participants (53% female; 58±15 years old; BMI 28±5kg/m², 19±23 months CLBP-L) were randomized (55 prolotherapy, 49 ESI) and analyzed. No baseline differences existed between groups. Prolotherapy outperformed ESI in NRS pain score improvement at 6 (3.1±2.9 vs 1.1±2.2 points; p<0.001; 95% CI [1.2-3.1],) and 12 (3.0±2.8 vs 1.3±2.6 points; p = 0.002; 95% CI [0.7-2.7]) months. Oswestry-based function score improvements also favored the prolotherapy group at 6 (16±19 vs 5±18 points; p =.001; 95% CI [4.0-18.5]) and 12 (16±20 vs 8±19 points; p=.04; 95% CI [0.4-15.7]) months. There were no adverse events. CONCLUSIONS Among participants with CLBP-L, prolotherapy resulted in statistically significant and clinically meaningful improvement of pain and function compared with ESI at one year after treatment completion. Prolotherapy may be appropriate care for carefully selected patients who have failed other therapy.

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