

Effect of Intra-articular Triamcinolone vs Hyaluronate Injection in Zygapophyseal Joint Arthropathy: A Prospective Randomized Controlled Trial

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ABSTRACT

Objective: To compare the effect of triamcinolone with hyaluronate injection in low back pain due to zygapophyseal joint arthropathy.

Materials and methods: This was a prospective, single-blind, randomized controlled trial. Twenty-nine subjects were randomly assigned to receive bilateral L3-S1 zygapophyseal joint injections with triamcinolone or hyaluronate (HA). Pain (visual analog scale) and disability (Oswestry Disability Index, ODI) scores were evaluated at 1, 4, and 12 weeks.

Results: No significant intergroup differences in outcomes were noted in 29 subjects. For triamcinolone/HA (baseline; 1 month; 3 months; and 6 months), visual analog scales were as follows: 77.07/76.14; 62.93/63.71; 43.47/43.14; and 44.27/59.57, respectively. ODI scores were as follows: 52.53/52.71; 37.60/37.14; 23.73/23.71; and 41.07/50.57, respectively.

Conclusion: The response of patients with chronic low back pain suggestive of lumbar zygapophyseal joint arthropathy was almost similar to triamcinolone or hyaluronate injection. Triamcinolone showed both short- and long-term improvement in both short- and long-term pain and function.

Keywords: Hyaluronic acid, Triamcinolone, Zygapophyseal joint.

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INTRODUCTION

Superior and inferior facets of adjacent vertebrae form lumbar facet joints whose arthropathy results in pain in the lower back also known as lumbar facet syndrome. The capsule of these posteriorly located joints are richly innervated. Any change in normal anatomy and functioning or disruption of biomechanics cause damage to hyaline cartilage, collectively called arthropathy of facet joints. Pain may arise solely due to this or concomitantly with a degenerative or injured lumbar disk, fracture, or ligamentous injury. It is more severe at the L4 to L5 level and with advancing age and progressive intervertebral disk disease.^{1,2} Patients often complain of generalized or lateralized spinal pain, provoked with spinal extension and rotation, from either a standing or a prone position. Relief with partial lumbar flexion is common. In the lumbar spine, these joints may refer pain into the buttock or posterior thigh but rarely below the knee.³⁻⁵ Neurological symptoms, such as lower extremity weakness, numbness, and paresthesias, are uncommon. Although no portion of the examination has been shown to definitively correlate with the diagnosis of a facet joint disorder, the physical examination can be helpful in elevating the clinician's level of suspicion for this diagnosis.^{6,7} In the absence of coexisting pathologic processes, such as lumbar radiculopathy, strength, sensation, and deep tendon reflexes should be normal. Patients with lumbar facet joint arthropathy may experience difficulty with prolonged walking, stair climbing, twisting, standing, and prone lying. Fluoroscopy-guided, contrast-enhanced, anesthetic intra-articular or medial branch blocks are considered the "gold standard" for the diagnosis of a painful lumbar facet joint.⁸⁻¹⁰ Differential diagnosis includes internal disc disruption, myofascial pain syndrome, nerve root compression, radiculopathy, spondylolysis or spondylolisthesis, lumbar stenosis, spondylosis, and sacroiliac joint dysfunction. Initial treatment emphasizes local pain control with oral analgesics and nonsteroidal

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anti-inflammatory drugs, ice, topical creams, local blind periarticular corticosteroid injections, and avoidance of exacerbating activities. Spinal manipulations and acupuncture may also reduce local pain. Temporary wearing of corsets and limited activity may be used. Physical therapy may include modalities to control pain (e.g., ice, heat, ultrasound), traction, instruction in body mechanics, flexibility training (including hamstring stretching), articular mobilization techniques, core strengthening, generalized conditioning, and restoration of normal movement patterns. Critical assessment of the biomechanics of specific activities may be job related (e.g., sitting at a desk, carpentry work, driving) or sports related (e.g., running, cycling) is important. This assessment can result in prevention of recurrent episodes of pain because changes in a technique or activity may reduce the underlying forces at the joint level. Simple ergonomic measures that act to support the lumbar spine during sitting and standing may reduce the occurrence of low back pain from the facet joints. These measures include proper chair height and design, properly designed work table, and adjustable chair

supports. While standing, the addition of a footrest, pads, and the ability to change body position routinely may reduce low back pain. Intra-articular, fluoroscopy-guided, contrast-enhanced facet injections are considered essential in treatment of a painful facet joint.¹¹⁻¹⁴ Recent data suggest that medial branch blocks may be the preferred method for diagnosis of facet joint pain.^{13,15,16} If the facet joint is found to be the putative source of pain, a medial branch neurotomy may be desirable.¹⁷⁻¹⁹

STUDY OBJECTIVES

To compare the effect of injection of hyaluronate sodium (HA) and triamcinolone (TA) in improving low back pain in diagnosed arthropathy of lumbar facet joint.

STUDY DESIGN

This prospective, single blinded, randomized controlled trial (RCT) was conducted between December 2017 and February 2019 at a tertiary care center of North India.

STUDY POPULATION AND CRITERIA

Subjects were recruited from both outpatient and inpatient of tertiary care center. Inclusion criteria include low back pain without any radiation beyond knee, tenderness in midline, painful lateral rotation and hyperextension, and degeneration of facet joints evident radiologically. Patients with history of drug abuse, alcohol, mental illness, noncompliance, intra-articular steroid or previous surgery, any allergy, degenerative disease, infection, malignancy, or deficient immunity were excluded. Written informed consent was taken and ethical committee has approved this study.

MATERIALS AND METHODS

Demographic information, height, weight, and duration of pain were generated from all subjects. The outcome parameters used were visual analog scale (VAS) and Oswestry disability index (ODI). Baseline data on disability (ODI) and pain were obtained. Randomization was done using computer-generated random number tables. Patients were randomized to either triamcinolone group (group I) or HA group (group II). On scheduled date, L3 to L4, L4 to L5, and L5 to S1 facet joints were injected bilaterally with study medications fluoroscopically using standard technique every time by the same resident. Patients of group I received 1 mL of triamcinolone (10 mg/mL of kenacort), and patients in group II received 1 mL of HA-KEM (6 mg of hyaluronic acid per prefilled syringe), 6 mL volume in each joint in each patient. Follow-up was done at 1 week, 4 weeks, and 12 weeks after the procedure, and outcome parameters were assessed in each visit. Instructions were given to subjects to not change their any concurrent medical or physical therapy that was taken before commencement of this study.

RESULTS

A total of 30 subjects (15 males and 15 females) were included in this study of which one female left study in between taking consent. Subjects were having mean age of 34.07 ± 5.49 and mean weight of 67.59 ± 7.36. At baseline, mean duration of low back pain was 29 months, mean pain score of VAS was 76.62 ± 2.73, and a mean ODI score was 52.62 ± 3.43. Mean age of each group was 34.53 ± 5.53

and 33.57 ± 5.61 for group I and group II, respectively. Subjects in group I were 53.3% males and 46.7% females, while in group II they were 50% of both sexes. Baseline variables were not found to be significantly different (Tables 1 to 4).

Measures of outcome such as pain (VAS) and disability (ODI) in the two groups showed no difference that was statistically significant. The score of VAS was (group I and group II, respectively): baseline—77.07 ± 3.01 and 76.14 ± 2.41, at first week—62.93 ± 2.37 and 63.71 ± 3.22, second week—43.47 ± 4.93 and 43.14 ± 3.82, third visit—44.27 ± 3.01 and 59.57 ± 1.40. The ODI scores were (group I and group II, respectively): Baseline—52.53 ± 2.88 and 52.53 ± 2.88, first visit—37.60 ± 2.29 and 37.14 ± 2.80, second visit—23.73 ± 2.25 and 23.71 ± 2.58, and third visit—41.07 ± 1.28 and 50.57 ± 2.77 (Figs 1 and 2).

Intergroup analysis of outcome measures revealed that although significant improvement was seen in both VAS and ODI at first and second visit, but they were almost comparable to baseline level at third visit. The final outcome improvement was more significant in group I when compared to group II. Due to development of neurological claudication, single subject was

Table 1: Age distribution of patients studied

Age in years	Group T	Group H	Total
<30	2 (13.3%)	3 (21.4%)	5 (17.2%)
30-40	11 (73.3%)	9 (64.3%)	20 (69%)
41-50	2 (13.3%)	2 (14.3%)	4 (13.8%)
Total	15 (100%)	14 (100%)	29 (100%)
Mean ± SD	34.53 ± 5.53	33.57 ± 5.61	34.07 ± 5.49

p = 0.646, Not significant, Student t test

Table 2: Gender distribution of patients studied

Gender	Group T	Group H	Total
Female	7 (46.7%)	7 (50%)	14 (48.3%)
Male	8 (53.3%)	7 (50%)	15 (51.7%)
Total	15 (100%)	14 (100%)	29 (100%)

p = 0.858, Not significant, Chi-square Test

Table 3: Weight (kg) distribution of patients studied

Weight (kg)	Group T	Group H	Total
<60	1 (6.7%)	2 (14.3%)	3 (10.3%)
60-70	9 (60%)	7 (50%)	16 (55.2%)
71-80	5 (33.3%)	5 (35.7%)	10 (34.5%)
Total	15 (100%)	14 (100%)	29 (100%)
Mean ± SD	67.73 ± 7.81	67.43 ± 7.12	67.59 ± 7.36

p = 0.914, Not significant, Student t test

Table 4: Duration distribution of patients studied

Duration	Group T	Group H	Total
<12	0 (0%)	0 (0%)	0 (0%)
12-24	13 (86.7%)	12 (85.7%)	25 (86.2%)
>24	2 (13.3%)	2 (14.3%)	4 (13.8%)
Total	15 (100%)	14 (100%)	29 (100%)
Mean ± SD	20.27 ± 7.40	19.71 ± 5.25	20.00 ± 6.35

p = 0.820, Not significant, Student t test



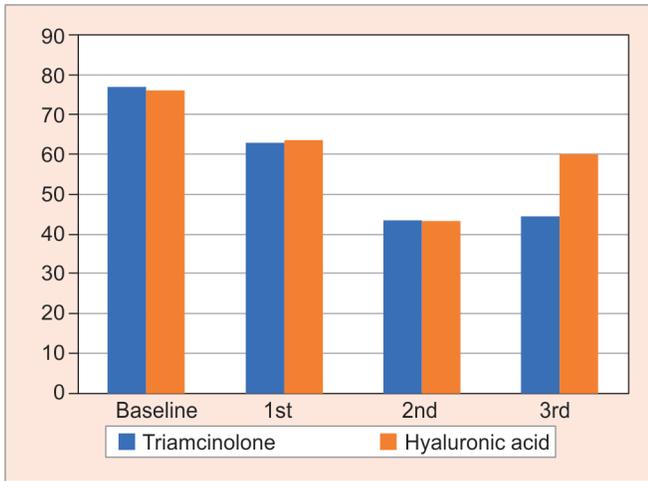


Fig. 1: Variation of VAS among two groups at subsequent visits

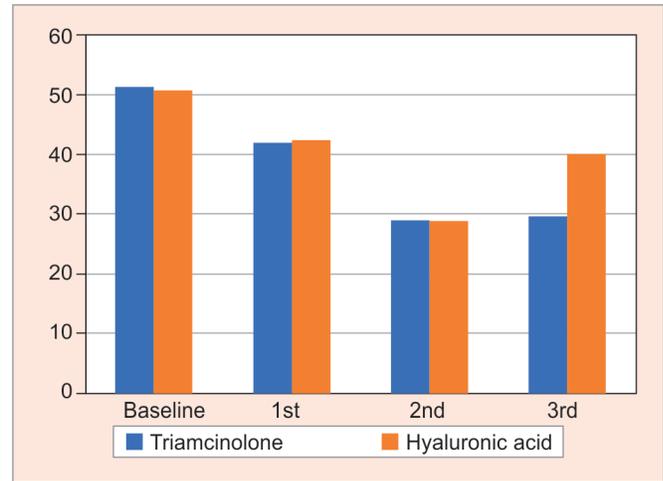


Fig. 2: Variation of ODI among two groups at subsequent visits

withdrawn from the study due to noneligibility. There was no complication in other subjects who underwent intervention.

DISCUSSION

This study clearly showed that treatment of HA injection in zygapophyseal joint arthropathy revealed no difference in improvement of disability or pain that was statistically significant, in comparison to commonly performed standard treatment of corticosteroid injection. However, analysis in a group itself (in both groups) showed that both groups attained short-term functional and pain improvement, although the improvement in long term is better with triamcinolone. Fuchs et al. in their study²⁰ compared intra-articular triamcinolone with HA and concluded that improvement in pain and function was found in both groups (shown by multiple questionnaires). Their study also revealed that improvement in pain and function was almost equal or better in HA group. Similarly, Cleary et al.²¹ in their study found no improvement that was significant after injections of HA in 13 patients they studied. DePalma²² et al. studied injections of Synvisc intra-articularly for low back pain. Significant relief was found from baseline to 6 months in terms of VAS, ODI, SF 36, finger to floor distance, tolerance, and satisfaction, but most of the effect disappeared in 12 months. Although HA was approved for osteoarthritis²⁰ of knee joint only by Food and Drug Administration, arthritis of hip²³ and MCP of thumb,²⁴ ankle,²⁵ shoulder,²⁶ and sacroiliac joint²⁷ are also benefitted by HA visco supplementation. In terms of safety, HA injection is superior to steroid injection due to less or almost no risk of increased blood sugar, suppression of cortisol, or osteoporosis.²⁸ Many previously conducted studies on zygapophyseal arthropathy pain showed some benefit with HA. However, further trials are required for giving a concrete evidence for good clinical recommendation.

STUDY LIMITATIONS

Our study has drawn advantage by taking previously defined facet joint arthropathy injection criteria and randomization. This study could have been more precise if a large cohort was taken with long follow-up period. Relying only on clinical criteria for diagnosing facet joint arthropathy pain is another limitation of this study. Dual comparative blocks²⁹ is recommended for diagnostic confirmation

by research standards. Some study subjects who had all clinical features consistent with facet arthropathy might not have met recommended research criteria. We hid this possibility which can be our study limitation. There must be a third group to serve as control intervention (with injection of normal saline). This would have better differentiated the effect of Triamcinolone from HA. Similarly, some improvement in both groups must have been due to concurrent treatment such as nonsteroidal anti-inflammatory drugs or exercises. Lastly, any confounding effect due to any changes in concurrent treatments cannot be ruled out even after repeatedly instructing the participants.

CONCLUSION

In comparing TA vs HA injections in facet joint arthropathy, no statistically significant differences were found in relief of pain or improvement in function. Comparison of HA injection in a single group showed only statistically significant benefit for short term in pain and function when compared to baseline level. While comparison of Triamcinolone injections in a single group showed statistically significant improvement in both pain and function.

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