Comparison of Ultrasonic Therapy, Sodium Hyaluronate Injection and Steroid Injection in the Treatment of Peri-arthritis Shoulder

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Abstract

Peri-arthritis (PA) shoulder is a common cause of shoulder pain and disability. The optimum management of peri-arthritis shoulder has been the subject of great debate, particularly since the condition tends to resolve spontaneously over months to years leaving behind stiff shoulder.

Objectives of this study was to prospectively evaluate the comparative efficacy of intra-articular steroid (methylprednisolone) injection, intra-articular sodium hyaluronate injection and deep heat in patients with peri-arthritis shoulder who were also taught a simple home exercise programme.

A total of 75 subjects were enrolled in the study. Patients of peri-arthritis of shoulder joint were randomly assigned to three groups: Inj. sodium hyaluronate 20mg (group1), inj. methylprednisolone 40mg (group2), ultrasonic therapy (group3). Evaluation was done at 3 weeks, 6weeks and 12 weeks and 24 weeks after starting the treatment.

Outcomes were determined by the assessment of subjective and objective parameters viz. shoulder pain and disability index (SPADI), range of motion. All three groups showed improvement with respect to time. Steroid group and sodium hyaluronate group showed significant improvement as compared to other ultrasonic group (p=0.02) with respect to shoulder pain and disability index and range of motion. Improvement in pain was equal with all three types of treatment..

Key words : **Ultrasonic therapy, sodium hyaluronate injection, steroid injection, peri-arthritis shoulder, shoulder pain and disability index.**

Introduction:

Peri-arthritis (PA) shoulder is a common but poorly understood syndrome of painful shoulder stiffness. In 1992, the American Shoulder and Elbow Surgeons Society, defined by consensus that PA shoulder is a condition of uncertain aetiology characterised by significant restriction of both active and passive shoulder motion that occurs in the absence of a known intrinsic shoulder disorder[1]. The prevalence of PA shoulder in general population is slightly greater than two per cent[2]. The condition still remains an enigma as to the correct origin, tissue involvement, causation, mechanism and the ideal form of treatment. Although PA of shoulder joint is generally considered to be a self-limiting condition that can be treated with physical therapy, the best treatment has been the subject of extensive investigation[2-5]. The types of treatment have included benign neglect, oral corticosteroids, injection of corticosteroids, physical therapy exercises, deep heat modalities, suprascapular nerve block, manipulation under anaesthesia, and arthroscopic and open release of the contracture. Recent studies have emphasised the effectiveness of surgical management of recalcitrant shoulder stiffness. Many of these studies have been flawed because they have lacked objective and subjective outcome criteria. Corticosteroid therapy was suggested in 1955 by Crisp and Kendall[6]. Since then, there have been many reports of uncontrolled experience with local corticosteroids. The reported

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results cover the entire gamut from no benefit to dramatic improvement. Extensive research has been conducted on sodium hyaluronate (HA), a major component of connective tissue. HA relieves pain and has metabolic effects on articular cartilage, synovial tissue, and synovial fluid. The use of intra-articular injection of HA in the treatment of osteo-arthritis knee is well documented but its role in the treatment of PA shoulder is recently gaining interest[7-9]. Though, a few studies (only three studies available) have shown beneficial effects but no study has been reported from India to document its benefits. There is little evidence to support the use of any of the common interventions in managing PA shoulder. Measurement of outcome varies widely between various clinical trials, and the reliability, validity, and responsiveness of these outcome measures are not established The purpose of the present study was to evaluate, prospectively, the comparative efficacy of: intra-articular steroid injection, intra-articular sodium HA injection and deep heat in combination with a standard exercise programme for the management of idiopathic PA. Outcomes were determined by the assessment of subjective and objective parameters viz. shoulder pain and disability index (SPADI) and range of motion (ROM).

Material and Methods:

This prospective study was conducted in the Department of Physical Medicine and Rehabilitation, VMMC and Safdarjang Hospital, New Delhi on outpatients, from May 2007 to May 2008. Patient included were over 18 years age, symptomatic for at least one month, with limitation of both active and passive shoulder motion of >25% in at least 2 directions (abduction, flexion, external rotation, internal rotation) as compared with normal values with or without pain and with a normal anteroposterior radiograph of the glenohumeral joint. Patients having restriction of the joint motion due to other cause including inflammatory, degenerative, infectious, cerebrovascular accident, history of surgery, dislocation, fractures or shoulder trauma, clinical evidence of reflex sympathetic dystrophy, history of injection in the involved shoulder during the preceding six months, history of allergy to steroid and sodium HA or having any cervical pathology or diabetics were excluded from the study. The study was approved by institutional review board and all the subjects gave their informed consent prior to participate in the study. All the patients were evaluated using a questionnaire and clinical examination. Demographic factors included in the questionnaire were age, sex, religion, state of domicile, socio-economic status and occupation. Detail medical history was taken with attention directed at the identification of relevant co-morbidities, recording history of shoulder disorder, including duration of shoulder pain and shoulder restriction. Physical examination of shoulder included, active and passive ROM. Shoulder pain and disability index was recorded. Routine investigations included complete haemogram and blood sugar level. Simple randomisation by computer generated permuted block of 25 patients each using SPSS for windows version 10 was done. Single blinding was done. Pre and post intervention assessment of cases was done by independent observer (a fellow postgraduate student). Participants were randomised to the following three treatment groups: group1, inj. sodium HA (20mg) given weekly by anterior approach for three weeks with home exercise programme; group 2, inj. methylprednisolone (40mg) given weekly by anterior approach for three weeks with home exercise programme; group3, Ultrasonic therapy of 1.5w/cm^2 daily for seven minutes for three weeks with home exercise programme.

Intervention

On the day of randomisation, all injections were given through 1.5 inch, 21 gauge needle by the same physician using a standard sterile injection technique. The patients were placed in a sitting position with their arm in internal rotation and a needle was inserted 1 cm lateral to the tip of coracoid process. This was followed by injection of either sodium HA (20mg) or methylprednisolone acetate (40mg/ml). Magnetic resonance imaging (MRI) confirmation of the injection site was done in a few patients to ensure that they were in the gleno-humeral space. Patients randomised to receive supervised ultrasonic therapy started their programme on the same day with ultrasonic therapy daily for 3 weeks (1.5w/cm^2 for 7 minutes). All patients participating in the study were taught a simple, 10-minute exercise programme to be done at home twice daily. They consisted of pendulum exercises, auto-assisted, active ROM and stretching exercises in the planes of flexion, abduction, external rotation, and internal rotation (hand behind back).Participants were asked to cease non-steroidal anti-inflammatory. The patients were re-evaluated at 3 weeks, 6 weeks, 12 weeks, and 24 weeks after initial visit. On each visit, investigator completed the SPADI score, measured active and passive ROM and noted any adverse reactions.

Follow-up and assessment of outcome

The patients were evaluated at 3 weeks, 6 weeks, 12 weeks, and 24 weeks. On each visit, investigator completed the SPADI score, measured active and passive ROM and noted any adverse reactions. Data was analysed with SPSS for windows version 10. Mean values and proportions of patients at baseline were compared on the Fisher's exact tests/chi-square tests. For continuous variables, the 3 groups were compared using two ways ANOVA and Benforroni comparison test. The results were considered significant at 5% level ($p<0.05$).

Results:

Between May 2007 and May 2008, 75 subjects were enrolled in the study, with 25 subjects in the corticosteroid group, 25 in the sodium HA group and 25 in the ultrasonic therapy group (UST). Out of the 75 patients, 4 patients in the corticosteroid group, 5 in the HA group and 5 in the UST group, did not return for follow-up visits.

Demographic data

Patients included in the study ranged from 35 to 85 years of age; mean age being 54.49±10.84 (Fig 1). Patients had no significant difference of age in the three groups (p=0.55).Out of 61 patient 35 were males (57.4%) and 26 (42.6%) were females (Fig 2). Sex distribution was similar in all the three groups (p=0.95). Forty (65.6%) patients had involvement of left shoulder whereas 21(34.4%) had right side involvement. After receiving treatment for PA shoulder, 26 patients out of 61 reported few side-effects. In steroid group, out of 21 patients, 20 (95%) patients reported increased pain (mild pain) at the injection site for an average duration of 4 days after receiving injection. In HA group, only 3 (15%) patients out of 20 reported side-effects like increased pain at the side of condition. In UST group, 3 (15%) patients out of 20 reported increased pain (Fig 3).

Response to treatment

At three weeks interval, total pain scores showed improved in all three groups with steroids showing more improvement (differences between groups not significant, p=0.08). At six weeks interval, steroids showed more improvement followed by HA and UST (differences not significant, p=0.55). At 12 weeks interval total Pain scores had improved with HA and Steroids showing significant improvement over UST, p=0.038. (Table 1).

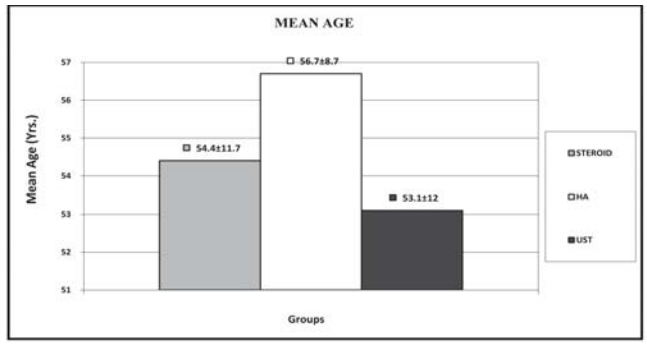

Fig 1- *Mean Age of Patients in Different Groups*

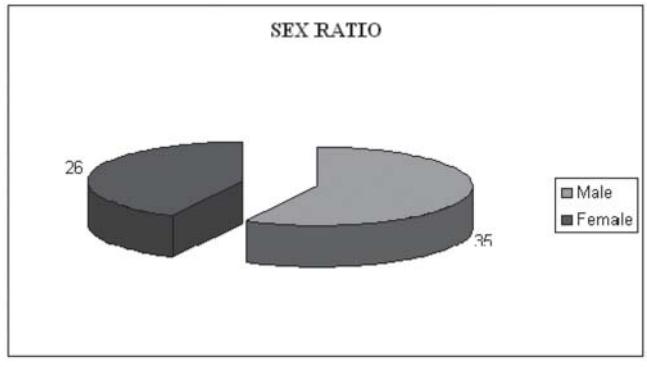

Fig 2- *Sex Distribution*

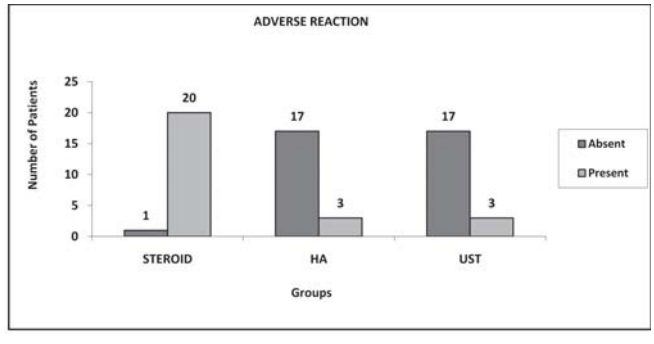

Fig 3- *Adverse Reaction to Treatment (mild pain)*

At 24 weeks interval differences between groups were not significant in all three groups (p=0.461).

All the three groups showed significant improvement on disability score with respect to time, ($p<0.001$).) except in HA group where no significant difference was seen from 0 to 3 weeks (p=0.07) and in UST group from 3 weeks to 6 weeks (0.30). At 3 weeks HA showed more improvement followed by UST and steroid respectively, but the differences between groups were not significant at this level (p=0.99). Six weeks after randomisation HA and steroids showed significant improvement over UST (p=0.03). Twelve weeks after enrollment, HA and steroid groups showed significant improvement over UST therapy (p=0.03). Twenty-four

weeks after enrollment, HA and steroid groups showed significant improvement over UST (p=0.02) (Table 2).

With respect to SPADI, all the three groups showed significant improvement with time (p=0.001) except in UST group from 3 weeks to 6weeks (p=0.1), and from 6weeks to 12 weeks (p=0.20). HA and steroid groups showed significant improvement as compared to UST group at 6 weeks, 12 weeks and 24 weeks respectively. (Table 3). The total active and passive ROM increased in all groups compared with baseline values. The HA group and steroid group had greater improvement than the ultrasonic group.

Discussion:

PA shoulder is a rheumatologic enigma[7]. Precise definition varies. Response to the many recommended treatments is often capricious. Average age of patients in our study was 54.49 years and range from 35 to 85 years which matches favourably with the studies done by Winters *et al*[10] and Van der Windt *et al*[11]. Number of males outnumbered (57.4%) females (42.6%) in our study contrasting sharply with the studies done by Dacre *et al*[12], Shaffer *et al*[4] and Calis *et al*[7]. Sixty-five per cent patients had involvement of left shoulder and 5% patient had bilateral involvement. Various studies have shown involvement of dominant extremity to be

Table 1: *Improvement in Pain Score (Mean Value ± SD)*

Improvement in Pain Score from baseline				
Group	**P1 (P3w-P0)**	**P2 (P6w-P0)**	**P3 (P12w-P0)**	**P4 (P24w-P0)**
Steroid injection	18.4(±7.9)	20.4(±7.2)	26.9(±8.3)	33.2(±11.3)
HA injection	10.3(±3.3)	19.2(±5.50)	31.3(±10.2)	35.7(±8.85)
US therapy	12.1(±4.5)	16.4(±5.2)	21.3(±7.3)	31(±10.3)

P0=Score at 0 week, **P3w**=Score at 3 weeks, **P6w**=Score at 6 weeks, **P12w**=Score at 12weeks, **P24w**=Score at 24 weeks.

Table 2: *Improvement in Disability Score (Mean Value± SD)*

Improvement in Disability Scores from baseline				
Group	**D1**(D3w-D0)	**D2** (D6w-D0)	**D3** (D12w-D0)	**D4(**D24w-D0)
Steroid injection	7.8(±3.3)	20.3(±7.3)	32.3(±11.3)	45.8(±13.5)
HA injection	9(±3.39)	25.5(±7.8)	36(±11.3)	44.7(±13.5)
US therapy	7.8(±2.6)	12.8(±4.2)	17.5(±4.2)	35.7(±12.2)

D0=Score at 0 week, **D3w**=Score at 3 weeks, **D6w**=Score at 6weeks, **D12w**=Score at 12weeks, **D24w**=Score at 24weeks.

Table 3: *Improvements in SPADI Score*

	Improvement in SPADI Score			
Group	**T1** (T3w-T0)	**T2**(T6w-T0)	**T3** (T12w-T0)	**T4** T24w-T0
Steroid injection	20(±7.54)	31.3(±11.3)	45.53(±13.5)	60.76(±15.7)
HA injection	14.85(±5.4)	34.38 (±11.5)	51.77(±15.76)	61.85(±17.5)
US therapy	15.31(±6.54)	22.47(±6.76)	29.77(±10.7)	51.3(±12.9)

T0=Score at 0 week, **T3w**=Score at 3 weeks, **T6w**=Score at 6weeks, **T12w**=Score at 12weeks, **T24w**=Score at 24 week

more than non-dominant extremity[10, 13] whereas a few studies have shown the opposite trends. There seems to be no consensus regarding the extremity involved. In steroid group after receiving injection, 95% of patients reported few side-effects that include increased pain (mild pain) at the injection site for an average duration of 4 days. This finding matches with that of Van der Windt *et al*[10] who also found mild adverse reactions, mainly increased pain after treatment by more than 50% of the patients. In their study, adverse reactions to corticosteroids were particularly frequent in women that include facial flushing and irregular menstrual bleeding. Our patients reported no such side-effects. Eustace *et al*[14] also reported that patients complain of some degree of discomfort after injection.

Though it is a self limiting disease, it leaves behind stiff, shoulder. Although the natural history of PA shoulder is of ultimate resolution, this may not be complete. In a prospective study of 41 patients with five to ten year's follow-up Reeves[3] (1976) found that 39% had full recovery, 54% had clinical limitation without functional disability, and seven per cent had functional limitation. Shaffer *et al*[4] (1992) showed that 50% of his 61 patients with PA shoulder had some degree of pain and stiffness seven years after onset of the disease. Our findings with respect to pain score match with that of Carette *et al*[15] who compared the efficacy of a single intra-articular corticosteroid injection, a supervised physiotherapy programme, a combination of the two, and placebo in the treatment of PA shoulder. They found that at 12 months, the 4 groups did not differ significantly with respect to pain confirming the notion that PA shoulder has a favourable natural history with respect to pain. They also concluded that a single intra-articular injection of corticosteroid administered under fluoroscopy combined with a simple home exercise programme is effective in improving shoulder pain and disability in patients with adhesive capsulitis. Adding supervised physiotherapy provides faster improvement in shoulder range of motion. When used alone, supervised physiotherapy is of limited efficacy in the management of PA shoulder. Bulgen *et al*[13] evaluated intra-articular steroids, mobilisations and ice therapy against control. Steroid injection improvement pain and range of movement in the early stages though in the long term all the modalities had same effect. There appears to be little place for physiotherapy alone, and, if used, it should not be continued for more than four weeks. Dacre *et al*[12] compared steroid injections and physiotherapy for the painful stiff shoulder, the local steroid injections being as effective as physiotherapy alone or a combination. So far only three earlier studies have compared the effect of sodium HA with other treatment regimens. Calis *et al*[7] compared the effects of HA, steroid and physical therapy modalities with a fourth group serving as control and found best results with physical therapy modalities which is in sharp contrast to our results. In another study by Rovetta *et al*[9] where he compared the effect of intra-articular injections of HA plus steroid with steroid and physiotherapy alone, the results indicated an improvement of pain and joint motion after 6 months in all patients, especially in patients treated with HA. Another study by Itokazu *et al*[8] showed similar results. Many reports of uncontrolled experience with local corticosteroids and physiotherapy have shown conflicting results. None of these studies attempted to assess the accuracy with which the steroids were injected.

Limitation of study:

Though our study clearly establishes superiority of intra-articular steroid and sodium HA in the treatment of PA shoulder, many issues remain unclear about intra-articular injections–number of injections needed, the stage of disease at which injections should be administered, the most effective corticosteroid, and the most effective dosage. HA injections have low reaction profile but bigger studies of longer durations are needed to establish its place in routine treatment of PA shoulder.

Conclusion:

In conclusion, intra-articular injection of steroid and HA combined with a simple home exercise programme were equally effective in improving shoulder pain and disability. Deep heat is significantly inferior to intra-articular injection of steroid and HA. Intra-articular injection of steroid is a cost effective treatment for PA shoulder.

What we already knew and what we have learned from this article

PA or frozen shoulder is a common but poorly understood syndrome of painful shoulder stiffness. There are variety of treatments available, most common being use of therapeutic exercises along with some deep heating modality. We have clearly shown in the study that though deep heat is also an effective treatment modality but it is significantly inferior to intra-articular injection of steroid

and sodium HA. We already knew that steroid is effective treatment for PA shoulder along with therapeutic exercises as many previous authors have shown but efficacy of sodium HA in improving pain and disability was established by our study.

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References:

1. Zuckerman J D, Cuomo F. Frozen shoulder in the shoulder: a balance of mobility and stability, 1993: 253-67.
2. Binder AI, Bulgen DY, Hazleman BL, Roberts S. Frozen shoulder: a long-term prospective study. *Ann Rheum Dis* 1984; **43:** 361-4.
3. Reeves B. The natural history of the frozen shoulder syndrome. *Scand J Rheumatol* 1975; **4:** 193-6.
4. Shaffer B, Tibone JE, Kerlan RK. Frozen shoulder: a long-term follow-up. *J Bone Joint Surg Am* 1992; **74:** 738-46.
5. Lee PN, Lee M, Haq AM, Longton EB, Wright V. Periarthritis of the shoulder: trial of treatments investigated by multivariate analysis. *Ann Rheum Dis* 1974; **33:** 116-9.
6. Crisp EJ, Kandall PH. Treatment of periarthritis shoulder with hydrocortisone. *BMJ*, 1955; **1:** 1500-144.
7. Calis M, Demir H, Ulker S, *et al*. Is intraarticular sodium hyaluronate injection an alternative treatment in patients with adhesive capsulitis? *Rheumatol Int* 2006; **26:** 536-40.
8. Itokazu M, Matsunaga T. Clinical evaluation of high-molecular-weight sodium hyaluronate for the treatment of patients with periarthritis of the shoulder. *Clin Ther* 1995; **17:** 946-55.
9. Rovetta G, Monteforte P. Intraarticular injection of sodium hyaluronate plus steroid versus steroid in adhesive capsulitis of the shoulder. *Int J Tissue React* 1998; **20:** 125-30.
10. Winters JC, Sobel JS, Groenier KH, Arendzen HJ, Meyboom-de Jong B. Comparison of physiotherapy, manipulation, and corticosteroid injection for treating shoulder complaints in general practice: randomised, single blind study. *BMJ* 1997; **314:** 1320-5.
11. Van der Windt DA, Koes BW, Deville W, Boeke AJ, De Jong BA, Bouter LM. Effectiveness of corticosteroid injections versus physiotherapy for the treatment of painful stiff shoulder in primary care: randomized trial. *BMJ* 1998; **317:** 1292-6.
12. Dacre JE, Beeney N, Scott DL. Injections and physiotherapy for the painful stiff shoulder. *Ann Rheum Dis* 1989; **48:** 322-5.
13. Bulgen DY, Binder AI, Hazleman BL, Dutton J, Roberts S. Frozen shoulder: prospective clinical study with an evaluation of three treatment regimens. *Ann Rheum Dis* 1984; **43:** 353-60.
14. Eustace JA, Brophy DP, Gibney RP, Bresnihan B, Fitz Gerald O. Comparison of the accuracy of steroid placement with clinical outcome in patients with shoulder symptoms. *Ann Rheum* 1997; **56:** 59.
15. Carette S, Moffet H, Tardif, *et al*. Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder: a placebo-controlled trial. *Arthritis Rheum* 2003; **48:** 829-38.