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A CLINICAL TRIAL COMPARING SUBACROMIAL BURSA INJECTION OF HYALURONIC ACID TO STEROID IN SUBACROMIAL IMPINGEMENT SYNDROME

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Abstract

Objective: To evaluate the effects of subacromial bursa injection in subacromial impingement with hyaluronic acid and compare its outcome results with the corticosteroid.

Method: A total of 88 patients with subacromial impingement were randomised to treatment with subacromial bursa injection, 44 patients underwent subacromial bursa injection with hyaluronic acid (Group A) and other 44 patients (Group B) treated with steroid. Patients were followed up for 24 weeks. Primary outcome was pain on Visual analogue scale (VAS)and secondary outcome measured was Constant Murley score.

Result: Both the groups showed statistically significant improvement in VAS, Constant Murley score and shoulder movement range at 3rd week after the injection. However when comparing the extant of improvement of outcome measures at 24 weeks to the baseline in both groups, it was statistically not significant (P>0.05).

Conclusion: The different outcome measures in both hyaluronic acid and steroid injections groups showed similar results, however steroids produces faster pain relieve compared to the hyaluronic acid.

Keywords: *Shoulder impingement syndrome, Subacromial bursa injection, hyaluronic acid, steroid*

Introduction:

Shoulder pain is very common, it is second most frequent musculoskeletal disorder[1] and shoulder impingement is the leading cause of pain.[2] Initial treatment consist of acetaminophene or low does non-steroidal anti-inflammatory drugs (NSAIDs) in first four to six weeks. When pain relief is insufficient, a subacromial bursa injection of steroid advised for pain control and improvement of shoulder functions.[3-9]

Some guidelines also advocate physiotherapy or manipulative therapy.[10] Crawshaw et al[6] reported that physiotherapy combined with sub-acromial injection give better results than each separately.

A few studies have demonstrated improvement in shoulder pain and functions following the injection of hyaluronic acid alone in sub-acromial bursa.[11-14] The hyaluronic acid is though to work as lubricant[15] and is reported to have an anti-inflammatory effects.[16]

This study aimed to access the efficacy of hyaluronic acid in sub-acromial injection and results were compared with from corticosteroids.

Patients and Methods:

The trial had ethical approval. The study participants, who came to the department of orthopaedics with primary complaint of shoulder pain, were recruited. Thos who met following inclusion criteria were finally considered. (1) All patients, over 18 years of age and had shoulder pain either at rest or at movement. (2) Who had painful arc and positive in Hawkin's test or Neer impingement sign.

The exclusion criteria were follows. (1) Pain for less than six weeks. (2) Prior injection of steroid or hyaluronate in the same shoulder. (3) Allergy to lidocain, steroid or hyaluronic acid. (4) Pregnancy or suspected pregnancy. (5) Dementia or other psychiatric disorder. (6) Tumor. (7) Previous fractures or surgery on shoulder, upper limb or neck. (8) Flexion at shoulder $<100^0$ and external rotation limited by 50% compared with opposite shoulder. (9) Rheumatoid arrhritis, ankylosing spondylitis and polymyalgia. (10) Associated neurological disorder.

A total of 88 patients, who met the inclusion criteria were taken and randomised blindly into two treatment groups with the random block assignment method. All the subjects of both two groups had a sub-acromial injection with either a combination of 2ml lidocain 1% and 2ml hyaluronic acid (Group A) or mixture of 2ml lidocain 1% and 2ml steroid (Metheylprednisolone acetate) (Group B). Injection were repeated if required at three and six weeks, and no further injection were given.

All the injections were administered via a dorsolateral approach, through the interval just beneath the dorsal acromial edge, with the patient sitting up. Administration of all kind of analgesics or anti-inflammatory drugs was stopped starting one week prior to the trial treatment. Patients were instructed for shoulder exercises after injection. No other associated therapy or drugs treatment were allowed.

Subjects were evaluated, before the first injection, three weeks, six weeks, 12 weeks, 18 weeks and at 24 weeks after the treatment start. Primary outcome measure was pain as measured on visual analogue score (VAS). Secondary outcome measure were the Constant Murley shoulder score and active movement range of the shoulder joint were used to access shoulder function of the patient.

Statistical analysis:

All statistical analyses conducted using SPS software V20.0 for windows with t-test, ANOVA and Fisher exact test. Statistical significance was assumed at $P<0.05$.

Results:

A total of 88 patients were enrolled and randomly assigned into two groups, group A and group B with 44 patients in each groups. Group A patients injected with 2ml lidocain 1% and 2ml Hyaluronic acid combination. Group B patients injected with 2ml lidocain 1% and 2ml steroid (methylprednisolone acetate) mixture.

Mean age of the 44 patients in group A was 44.35±9.40 and in group B it was 43.81±8.34. In group A, 16 were male and 28 were female. Whereas 19 were male and 25 were female in group B, and there was no statistically significant difference ($p>0.05$) in age, sex, shoulder affected and pre-injection score between the groups (Table 1).

Change in visual analogue scale (VAS):

There was significant improvement in VAS observed at each follow-up intervals after the sub-acromial bursal injection in both groups ($P<0.05$). Maximum betterment in VAS was observed at six weeks in both groups (Fig 1). However there was a more gain in group A when comparing the degree of improvement at six months to the per-injection in both group, but it was not statistically significant (Table 2)

Change in Constant Murley Score:

For Constant Murley score, there was significant improvement in both

the groups at all stages of observations (P<0.05). Maximum improvement in Constant score was at six weeks after the injection in both groups. Though, there was a larger improvement in group B when comparing intensity of improvement at six months and before sub-acromial injection in both group, but it was not statistically significant (P>0.05) (Table 2, Fig 2).

Change in active range of motion:

A significant recovery in active range of motion of shoulder joint in all planes was observed at all phases of follow up in both group (P<0.05). Maximum gain in the range of flexion, abduction and internal rotation movement of shoulder joint was observed at third week after the injection. External rotation movement showed maximum gain at 12 weeks of follow up. Although, there was a greater improvement in flexion and abduction range of movement in steroid group when comparing the extant of improvement at 24 weeks to the baseline scores in both groups, but it was not statistically significant (P>0.05) (Table 3,Fig 3-6).

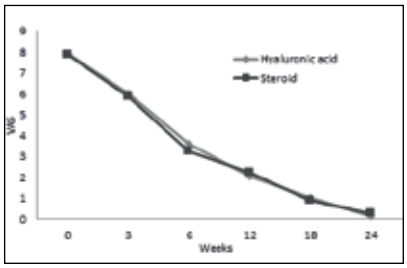

Fig. 1. Figure show the changes of Visual analogue scale (VAS) at different time intervals.

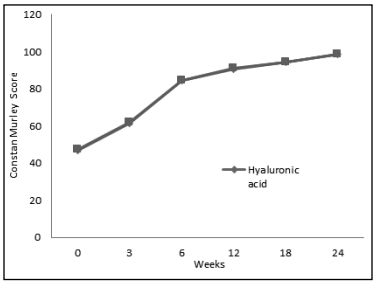

Fig. 2. Figure show the changes of Constant Murley Score at different time intervals.

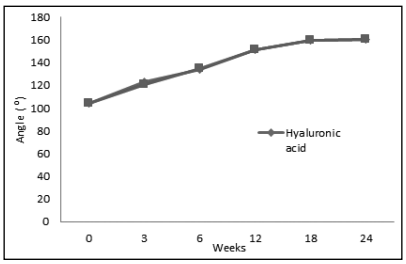

Fig. 3. Figure show the changes of AROM of shoulder flexion at different time intervals.

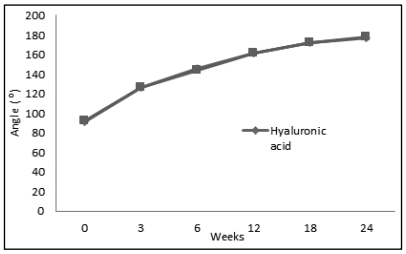

Fig. 4. Figure show the changes of AROM of shoulder abduction at different time intervals.

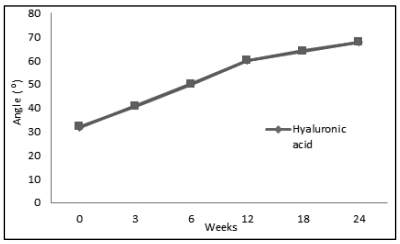

Fig. 5. Figure show the changes of AROM of shoulder external rotation at different time intervals.

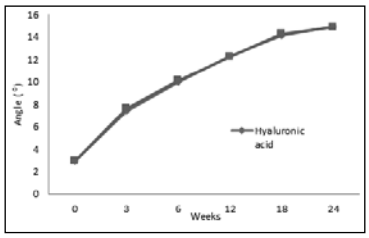

Fig. 6. Figure show the changes of AROM of shoulder internal rotation at different time intervals.

Discussion:

Subacromial bursa injection of steroid is often used for pain relief and function improvement in patients with periarticular shoulder disorders, but there are controversy concerning the number of injection and the dose of steroid.[17-20] As degenerative changes, metabolic and endocrine related adverse effects are of concern in higher dosage,[20,21] studies are seeking to replace steroid with others like hyaluronic acid[11,22,23] or combine it with drugs regimen.

Hyaluronate is glycosaminoglycan, a main component of synovial and it have significant role in joint lubrication. Bursal injection of hyaluronate in osteoarthritis of knee and shoulder joint is being used as one of the treatment method to substitute steroid to relieve joint pain. Hyaluronate also having an anti-inflammatory effects, improving active range of motion of joints, inhibiting the denaturalization of cartilage and normalizing the abnormal joint fluid.[14,15,24-27]

In our trial, when comparing the measurement values at each stages of follow up, both the groups showed significant fast improvement in VAS, Constant Murley score and active range of motion of shoulder joint up to 12 weeks, thereafter it became gradual but progressive (P>0.05).

The steroid injection given better results from start and was slightly better at six to 12 weeks after the injection than hyaluronic acid. Steroids provide faster relieve in pain than hyaluronic acid in the first six weeks. No statistically significant (P>0.05) improvement was observed at 24 weeks of duration after the injection.

Midorika K et al[28] reported on the effectiveness of the hyaluronate and steroid in patients with shoulder disorder, the therapeutic efficacy of

the hyaluronate was equivalent to the steroid group.

Penning et al[29] reported a study of 159 patients with subacromial impingement, treated with subacromial injection using hyaluronic acid, corticosteroid and placebo (NaCl). Patients were followed up to for 26 weeks. They observed no beneficial results from hyalurunic acid injection compared with corticosteroid or placebo injection. Corticosteroid produced a significant reduction in pain in short term (first three to 12 weeks), but in the long term, the placebo injection produced best results.

In this study, we found a beneficial role of corticosteroid injection in short term, but did not find it to be significant different to the hyaluronic acid at mid or long term. During trial, most adverse effects observed were local and mild and concerned increase in pain after injection. There were no infection or allergic reactions to the drugs.

Both hyaluronic acid and steroid injection demonstrate significant pain relief and improvement in shoulder function within three weeks of first dose that sustained for at least 24 weeks. Both the hyaluronic acid and steroid injections showed near equal effects in shoulder functions.

Hence we conclude that injection hyaluronic acid is safe and effective drug in treatment of subacromial impingement of shoulder and might be useful where steroid related adverse effects needs to be avoided.

Table 1. Baseline characteristics of subjects

	Group A (Hyaluronic acid) (n = 44)	Group B (Corticosteroid) (n = 44)	(P – value)
Male : Female	16 : 28	19 : 24	
Mean (SD) age (yrs)	44.35 (9.40)	43.81 (8.34)	0.7763
Shoulder affected			
Dominant (n,%)	40 (90.91)	41 ((3.18)	
Non-dominant (n,%)	4 (9.09)	3 (6.82)	
Duration of complaint			
< 6 weeks	21 (47.73)	18 (40.91)	0.5689
6 – 12 weeks	18 (40.91)	23 (52.27)	
>12 weeks	5 (11.36)	3 (6.82)	
Mean outcome measures			
Visual Analogue Score	7.89 (0.99)	7.86 (0.86)	0.8797
Constant Murley Score	47.07 (5.29)	47.21 (4.27)	0.8917
Mean (SD) range of movement (°)			
Flexion	103.83 (2.22)	103.77 (2.32)	0.9016
Abduction	91.74 (2.65)	92.00 (2.73)	0.6500
External rotation	31.78 (2.74)	32.19 (2.86)	0.4942
Internal rotation	2.93 (1.06)	2.93 (0.91)	0.9999

Table 2. Summary of outcome measures in patients with subacromial impingement and difference in groups by treatment at different times of follow-up

	Hyaluronic acid (A)	Corticosteroid (B)	P - value
Visual Analogue Score			
Baseline	7.89 (0.99)	7.86 (0.86)	0.8797
Week 3	5.98 (1.11)	5.88 (1.10)	0.6723
Week 6	3.61 (1.08)	3.23 (1.17)	0.1171
Week 12	2.04 (0.94)	2.23 (0.90)	0.3365
Week 18	1.02 (0.95)	0.91 (0.65)	0.5281
Week 24	0.13 (0.40)	0.26 (0.49)	0.1765
P - value	<0.0001	<0.0001	
Constant Murley Score			
Baseline	47.07 (5.29)	47.21 (4.27)	0.8917
Week 3	61.59 (5.00)	62.14 (5.31)	0.6182
Week 6	84.65 (5.60)	84.44 (5.66)	0.8615
Week 12	90.72 (3.07)	91.14 (2.96)	0.5153
Week 18	94.26 (2.51)	94.35 (2.46)	0.8655
Week 24	98.65 (1.16)	98.70 (1.21)	0.8436
P - value	<0.0001	<0.0001	

Values are mean (standard deviation), Fisher exact test applied.

Table 3. Shoulder movement range (°) and differences by treatment at different time interval.

	Hyaluronic acid (A)	Corticosteroid (B)	P - value
Movement range of motion (°)			
Flexion			
Baseline	103.83 (2.22)	103.77 (2.32)	0.9016
Week 3	122.96 (4.17)	120.93 (5.44)	0.0529
Week 6	134.26 (6.28)	134.70 (5.24)	0.7221
Week 12	151.00 (5.33)	151.40 (5.93)	0.7401
Week 18	159.48 (2.55)	159.77 (2.01)	0.5552
Week 24	160.22 (2.65)	160.65 (1.62)	0.3615
P - value	<0.0001	<0.0001	
Abduction			
Baseline	91.74 (2.65)	92.00 (2.73)	0.6500
Week 3	126.46 (10.06)	125.86 (8.99)	0.7671
Week 6	145.87 (6.89)	144.19 (7.24)	0.2659
Week 12	161.09 (4.98)	161.58 (5.01)	0.6449
Week 18	171.70 (4.38)	171.95 (4.65)	0.7950
Week 24	176.83 (1.87)	177.67 (2.00)	0.0441
P - value	<0.0001	<0.0001	
External rotation			
Baseline	31.78 (2.74)	32.19 (2.86)	0.4942
Week 3	41.00 (5.19)	40.70 (5.16)	0.7863
Week 6	50.30 (3.48)	50.09 (3.90)	0.7905
Week 12	60.00 (2.27)	60.00 (2.89)	0.9990
Week 18	64.13 (2.47)	63.95 (3.01)	0.7599
Week 24	67.57 (1.06)	67.91 (1.80)	0.2840
P - value	<0.0001	<0.0001	
Internal rotation			
Baseline	2.93 (1.06)	2.93 (0.91)	0.9999
Week 3	7.43 (1.05)	7.65 (1.04)	0.3262
Week 6	10.00 (1.01)	10.14 (0.97)	0.5090
Week 12	12.33 (1.03)	12.23 (1.07)	0.6563
Week 18	14.15 (0.84)	14.26 (0.88)	0.5502
Week 24	14.93 (0.95)	14.88 (1.03)	0.8135
P - value	<0.0001	<0.0001	

Values are mean (standard deviation), Fisher exact test applied.

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