Sodium Hyaluronate Injections Compared to Local Modalities for the Treatment of Shoulder Impingement Syndrome

Omuz Sıkışma Sendromu Tedavisinde Sodyum Hiyalüronat Enjeksiyonu ile Lokal Modalitelerin Karşılaştırılması

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Summary

Objective: To determine and compare the efficacies of sodium hyaluronate injections and local modalities in patients with shoulder impingement syndrome.
Materials and Methods: Patients (n=50) were treated with subacromial injections of sodium hyaluronate (n=25) once weekly for 3 weeks or a daily program of local modalities (n=25) for 2 weeks. Response to treatment was evaluated with the items of function in the Society of American Shoulder and Elbow Surgeons Basic Shoulder Evaluation Form and pain, activities of daily living and ranges of motion in the Constant-Murley Scale. Patients were questioned about night pain and their global impressions of the treatment. All outcome measures were assessed at baseline and weeks 1 and 5 after treatment.
Results: Society of American Shoulder and Elbow Surgeons Basic Shoulder Evaluation Form and Constant-Murley Scale scores of both groups were significantly improved at week 1 and 5 compared to baseline ($p<0.05$). Comparison of the scores demonstrated an insignificant difference between the two types of treatment ($p>0.05$). Night pain was reduced effectively by both treatments, with no significant difference between the groups. The majority of patients reported that they benefited from the treatment and results were similar in both groups. No side effects were observed.
Conclusion: Sodium hyaluronate injections and local modalities have been found to be similarly effective. Either one of these methods may be included in a treatment program for patients with shoulder impingement syndrome. *Turk J Phys Med Rehab 2008;54:138-42.*
Key Words: Shoulder, impingement, sodium hyaluronate, rehabilitation

Özet

Amaç: Omuz sıkışma sendromlu hastalarda sodium hiyalüronat enjeksiyonu ile lokal modalitelerin etkinliklerini saptamak ve karşılaştırmak.
Gereç ve Yöntem: Yirmibeş hasta 3 hafta boyunca, her hafta 1 kez olmak üzere subakromial aralığa sodyum hiyalüronat enjeksiyonu, 25 hasta ise 2 hafta süreyle lokal modalitelerin uygulandığı bir program ile tedavi edildiler. Tedaviye yanıt, Society of American Shoulder and Elbow Surgeons Basic Shoulder Evaluation Form içindeki fonksiyon parametreleri ve Constant-Murley Skalasındaki ağrı, günlük yaşam aktiviteleri ve eklem hareket açıklığı parametreleri ile değerlendirildi. Hastalar gece ağrısı ve tedavi memnuniyeti açısından sorgulandı. Tüm parametreler tedavi başlangıcı, tedaviden sonra 1. ve 5. haftalarda değerlendirildi.
Bulgular: Tedavi başlangıcına göre 1. ve 5. haftalarda her iki grubun tüm skorları anlamlı düzelmiş bulundu ($p<0,05$). Skorlar karşılaştırıldığında iki tedavi yöntemi arasında anlamlı fark yoktu ($p>0,05$). Gece ağrısı her iki yöntemle de belirgin azaldı ve gruplar arası fark anlamlı değildi. Hastaların çoğunluğu tedaviden yararlandığını bildirdi ve sonuçlar her iki grupta benzerdi. Herhangi bir yan etki gözlenmedi.
Sonuç: Sodyum hiyalüronat enjeksiyonu ve lokal modalitelerin etkinliği benzerdir ve omuz sıkışma sendromu tanılı hastalarda tedavi programı planlanırken seçenekler arasında yer alabilirler. *Türk Fiz Tıp Rehab Derg 2008;54:138-42.*
Anahtar Kelimeler: Omuz, sıkışma sendromu, sodyum hiyalüronat, rehabilitasyon

Introduction

Shoulder impingement syndrome (SIS) is a common cause of chronic shoulder pain and disability (1). It refers to compression of the rotator cuff tendons and subacromial bursa between the humeral head inferiorly and the coracoacromial arch, the anterior third of the acromion, the coracoacromial ligament and the acromioclavicular joint superiorly (2). Accurate diagnosis of SIS depends mainly on the history and physical examination of the patient (3). Among the many tests

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that have been developed for physical examination of the shoulder, Neer and Hawkins tests are considered to be highly efficient in diagnosing SIS (4). A reference standard test, however, is the subacromial injection test (SIT) which is considered positive if marked relief of pain and almost total improvement in passive and/or active shoulder range of motion (ROM) are achieved after an injection of 10 cc of 1.0% xylocain or lidocain into the subacromial space (5). Routine X rays, especially supraspinatus outlet radiographs may also be helpful, and if a tear of the rotator cuff is suspected, additional radiologic studies such as ultrasound, magnetic resonance imaging and finally arthroscopy may be performed (3).

The classification of SIS was first defined by Neer in three stages relating patient age, physical findings, and clinical course (5). Stage 1 is characterized by edema and hemorrhage of the bursa and cuff, usually found in patients who are under 25 years of age. Progression to stage 2 is marked by tendonitis and fibrosis of the rotator cuff, found in patients between 25 and 40 years of age. Further progression of the disorder results in stage 3, which is characterized by bone spurs and partial or full thickness tendon rupture affecting older patients (5).

Other classification systems have emerged in an attempt to categorize SIS according to etiological factors. They can be termed direct or indirect, intrinsic or extrinsic, primary or secondary, and static or dynamic (3,6). There is overlap among these systems and the terminology is not synonymous. Overuse, trauma of the tendons, anatomic variations of the acromion or coracoid process may lead to narrowing of the subacromial space, while glenohumeral or scapulothoracic joint instability, faulty posture or posterior capsule tightness may result in impingement due to "relative narrowing" (1,7).

Initial treatment of SIS should focus on relief of pain through rest, nonsteroidal anti-inflammatory medication and modification of daily activities. Local modalities (LM) including heat, cryotherapy, TENS or ultrasound may also be used. The next step should be an effort to restore normal flexibility through an individualized rehabilitation program. If patients fail to respond favorably to a 4-to 6-week course of therapy, a corticosteroid injection may be used to hasten the recovery process (8).

Recent studies have proposed sodium hyaluronate (HA) as an alternative to steroids for the treatment of painful shoulder disorders (9,10). HA is a naturally occurring polymer found in high concentrations in joints and, being highly viscous, it may function as a lubricant and shock-absorber. Postulated mechanisms of the long-term efficacy of HA include possible action on pain receptors and inflammatory cells (11). It has been successfully used for pain relief and treatment of inflammation in osteoarthritis of the knee and periarthritis of the shoulder (12).

The purpose of this study was to investigate and compare the efficacies of HA injections and LM for the treatment of SIS.

Materials and Methods

This prospective randomized study was conducted on patients with shoulder pain. The study was approved by the local ethical committee. All patients signed an informed consent form before screening and enrollment. Patients who had positive Neer and Hawkins tests underwent SIT and those who reported elimination or marked relief of pain after the test were diagnosed as SIS and included in the study.

Data about sex, age, occupation, duration of pain, hand dominance, affected side and co-existence of diabetes mellitus (DM) were recorded. All patients went through detailed physical examination and routine laboratory tests. Conventional radiography of the chest, cervical spine and shoulder and magnetic resonance imaging (MRI) of the shoulder were performed and evaluated by a radiologist who had experience on imaging the skeletal system, especially shoulder imaging. MRI was aimed at visualizing the acromion shape and changes related to impingement. Zlatkin's (13) classification was used to categorize the stages of SIS on MRI.

Patients were excluded from the study if they had a positive drop arm test, a diagnosis of adhesive capsulitis, calcific tendinitis, severe cervical spondylosis, cervical radiculopathy, partial or complete rotator cuff tear, fracture or dislocation of the shoulder girdle or systemic illnesses such as an inflammatory disease, severe cardiac or chronic pulmonary disease or malignancy.

Fifty patients with SIS were randomly assigned to two groups of different treatment strategies. The first group was given 2 ml injections of 20 mg HA with a molecular weight of 1.2x106 Da once weekly for 3 weeks. Injections were made into the subacromial space through a posterolateral approach. The second group underwent a 2-week program consisting of daily applications of an analgesic current (diphasic and long period modulations of diadynamic current produced by Petdin-101 with an output of 25 W, frequency of 50 Hz) for 10 minutes, superficial heat with infrared lamp for 15 minutes and deep heat (ultrasound with an application dose of 1.5 W/cm^2 produced by Petson-250 with an output of 25 W, frequency of 50 Hz) for 10 minutes.

Both groups were instructed about pendulum exercises and pain-free active assistive ROM exercises and encouraged to perform them at home. Patients were evaluated at baseline, and at the first and fifth weeks after treatment according to the item about functional assessment in the Society of American Shoulder and Elbow Surgeons (ASES) Basic Shoulder Evaluation Form and the items of pain, activities of daily living (ADL), and ROM in the Constant-Murley Scale (CMS). The item about muscle strength assessment was not utilized. Night pain was recorded as present or absent. Patients were also asked to report their impression about how their complaints were affected by the treatment they received by using the terms "worse", "not changed", "better", "much better".

Statistical analysis was made in SPSS for Windows program. Comparisons within each group were made with the Wilcoxon Signed Ranks test, and the Mann-Whitney U test was used to compare the two groups. Comparisons of parametric values were made with the Student t-test. A p value of less than 0.05 was considered significant.

Results

Data for the study were collected between June 2004 and March 2005. The patients were randomly allocated to two groups in which one was treated with HA injections and the other with LM. The groups were well-matched in respect to sex, age distribution, occupation, duration of pain, affected side, dominant side, co-existence of DM, acromion shape, and stages of impingement. Demographic data and patient characteristics are presented in Table 1.

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Night pain was a common complaint in all patients at baseline. At the first week, night pain was present in 40% and 60% of patients who were treated with HA and local modalities, respectively. At the fifth week, only 7 patients (28%) in the HA group and 12 patients (48%) treated with local modalities complained of night pain. The differences between baseline and all time points were significant for both groups. Although HA seemed to be more effective for treating night pain, both treatment methods were statistically similar (Table 2).

Baseline characteristics of patients in both groups in respect to ASES and CMS scores were similar. ASES scores were significantly improved at the first and fifth weeks in both groups. However, the improvement between these weeks was significant only in the HA group. The effect of HA and LM on ASES scores were found to be statistically similar.

CMS scores of the groups were significantly better at both time points compared to baseline. Changes in scores between week 1 and 5 did not reach statistical significance. Comparison of the scores showed that the patients had been similarly benefited by HA injections and LM (Table 3).

Patient global assessment was performed at the first and fifth weeks. No side effects were reported. Most of the patients were satisfied with the treatment they received. No significant difference was found between the groups at both time points with slightly better results in patients treated with HA (Table 4).

Table 1. Demographic data and patient characteristics.

Characteristics	HA (n=25)	LM (n=25)	P value
Sex			
Male	5	6	>0.05
Female	20	19	>0.05
Age			
Mean±SD	50.84±9.45	49.04±10.01	>0.05
Occupation			
None	1	4	
Office worker or light work	6	5	>0.05
Manual labor	18	16	
Duration of pain			
Mean±SD	10.16±11.32	17.79±20.26	>0.05
Affected side			
Left	9	11	>0.05
Right	16	14	
Dominant side			
Left	1	3	>0.05
Right	24	22	
Co-existence of DM	3	5	>0.05
Acromion shape			
Type 1 (Flat)	19	16	
Type 2 (Curved)	4	6	>0.05
Type 3 (Hooked)	2	3	
MR staging			
Stage 0	4	5	
Stage 1	10	9	>0.05
Stage 2	11	11	

Table 2. Statistical analysis of improvement of night pain in and between the groups.

	HA n (%)	LM n (%)	P value
Night pain			
Baseline	25 (100%)	25 (100%)	NS
Wk 1	10 (40%)*	15 (60%)*	NS
Wk 5	7 (28%)†	12 (48%)†	NS

*P<0.05, baseline vs. wk 1
†P<0.05, baseline vs. wk 5
‡P<0.05, wk 1 vs. wk 5
NS, P>0.05, not significant

Table 3. ASES and CMS scores at baseline, weeks 1 and 5, and statistical analysis of the changes of scores in and between the groups.

	HA	LM	P value
ASES score			
Baseline	35.28±9.73	32.48±9.22	NS
Wk 1	41.96±10.06*	42.56±10.09*	NS
Wk 5	46.44±10.12†‡	42.04±12.66†	NS
CMS score			
Pain			
Baseline	3.80±3.31	2.40±2.92	NS
Wk 1	7.40±3.57*	7.00±4.78*	NS
Wk 5	8.60±4.21†	6.40±4.68†	NS
ADL			
Baseline	9.88±3.56	9.72±3.20	NS
Wk 1	13.96±3.58*	14.20±4.31*	NS
Wk 5	15.24±3.24†‡	14.20±4.66†	NS
ROM			
Baseline	19.76±6.35	16.16±4.93	NS
Wk 1	24.72±8.46*	22.24±7.51*	NS
Wk 5	25.60±7.74†	21.60±8.79†	NS
Total			
Baseline	34.44±9.78	28.28±9.20	NS
Wk 1	46.08±14.47*	43.44±14.49*	NS
Wk 5	49.44±13.47†	42.20±16.73†	NS

*P<0.05, baseline vs. wk 1
†P<0.05, baseline vs. wk 5
‡P<0.05, wk 1 vs. wk 5
NS, P>0.05, not significant

Table 4. Comparison of satisfaction with treatment.

Patient satisfaction N (%)	HA	LM	P value
Worse			
Wk 1	1 (4)	3 (12)	NS
Wk 5	1 (4)	5 (20)	NS
Not changed			
Wk 1	4 (16)	3 (12)	NS
Wk 5	2 (8)	2 (8)	NS
Better			
Wk 1	15 (60)	16 (64)	NS
Wk 5	13 (52)	14 (56)	NS
Much better			
Wk 1	5 (20)	3 (12)	NS
Wk 5	9 (36)	4 (16)	NS

NS, P>0.05, not significant

Discussion

A diagnosis of SIS requires the initiation of a rehabilitation program directed toward relief of pain and inflammation, prevention of muscle atrophy, reestablishment of painless ROM, and normalization of kinematics of the shoulder complex. Patient education is particularly important regarding the avoidance of activities that may cause an increase in symptoms. Patients are instructed in pendulum (Codman's) exercises and symptom-limited, active assisted ROM exercises. Isometric strengthening for the external and internal rotators, biceps, deltoid, and scapular stabilizers should also be initiated, with progression to isotonic dumbbell resistance exercises, endurance exercises, trunk exercises and general cardiovascular conditioning in late phases (14). In our study, patients were instructed in pendulum exercises and pain-free active assisted ROM exercises. The exercise program was not carried further during the study in order to avoid interference with the treatments undertaken and also a possible aggravation of symptoms.

Pain control is critical in non-operative treatment of SIS because joint immobilization and functional disability are induced by pain. Local modalities have been advocated by several authors to achieve clinical relief of symptoms in SIS (15,16). Analgesic currents may change the sensitivity of peripheral receptors or free nerve endings responsible for transduction of nociceptive stimuli or block transmission of impulses in afferent nerves conveying nociceptive information (17). Surface-heat agents can be used to alleviate muscle spasm, increase range of motion, and improve tissue healing by increasing blood flow and nutrients to an area. Ultrasound acts as a deep heating agent which can elevate the temperature of periarticular structures and muscle at the bone-muscle interface, resulting in reduction of pain and increase in collagen tissue extensibility (18). Ultrasound and cryotherapy have been found similarly effective in decreasing pain and increasing ROM in frozen shoulder cases (19). Munting compared ultrasound combined with exercise with exercise alone for the treatment of patients with shoulder pain and concluded that ultrasound was beneficial for relief of pain (20). A controversy exists in the literature, however, as there are studies indicating no significant benefit with the use of ultrasound in patients with subacromial impingement (21). A combination of analgesic current, superficial and deep heating agents was found effective in alleviating pain with motion, nocturnal pain and limitations of ranges of motion in a group of patients in our study. The synergistic activity that has been acquired by combining different modalities might have been responsible for this result.

Recent research has revealed various properties of HA which have made it more popular in the treatment of painful disorders of the knee, hip, and shoulder joints. HA provides mechanical protection to tendons, improves local nutrition, restores the properties of the synovial fluid and limits the entry of polymorphonuclear leukocytes from the capillaries of the inflamed synovial membrane to synovial fluid (10). HA has not been associated with detrimental effects such as rotator cuff tear, subcutaneous atrophy, and cartilage destruction, which may occur with corticosteroid injections (9). In a prospective, randomized, double-blind, pilot study with 30 patients who were diagnosed as SIS, steroid and hyaluronate injections were found equally effective with no untoward sequelae (22). A multicenter study involving 70 patients with periarthritis of the shoulder demonstrated that significant increases in joint ranges of motion and improvement in activities of daily living were achieved with HA injections (23). Leardini et al investigated the efficacy of 3 intra-articular injections of HA in patients with painful shoulder disorders and found that there was rapid and significant improvement, with no side effects (10). In accordance with these results, HA has been found to be safe and beneficial in our group of patients also.

Management of SIS can be successfully achieved with conservative care if it is diagnosed early and appropriate treatment is undertaken. Studies have been conducted with various forms of noninvasive methods, which have led to controversial results. Our study is unique in comparing sodium hyaluronate injections with a program of local modalities for the treatment of SIS. Similar effects in improvement of pain, flexibility of the shoulder, and activities of daily living have been observed by both treatment methods at the first and fifth week follow-ups. A major drawback of this study is that both groups went through an exercise program, which rendered it impossible to isolate the effects of the treatments under investigation. Ideally, a group of patients who were treated only with an exercise program should also have been included. Other potential criticisms of the study might be the small size of the patient sample and the short duration of follow-up. Within the limits of this study, we can conclude that sodium hyaluronate and local physical modalities can contribute to alleviation of pain and improvement in limitation of shoulder ROM, and since one is not significantly superior to the other, the physician can make a choice according to his experience with these treatment regimens and the patient's expectations. Another point that the physician has to consider is that HA treatment seems to be more cost-effective because the application of local modalities casts a greater financial burden and is more tiresome for both the patient and the physio- therapist. Future studies in which larger patient populations and control groups are investigated and followed up for longer durations will aid in achieving a more precise conclusion.

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