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A Randomized Comparative Study of Blind versus Ultrasound Guided Glenohumeral Joint Injection of Corticosteroids for Treatment of Shoulder Stiffness

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Background: We prospectively compared the response to blind and ultrasound-guided glenohumeral injection of corticosteroids for treatment of shoulder stiffness.
Methods: A total of 77 patients with shoulder stiffness between April 2008 and March 2012 were recruited. Patients were randomized to receive either a blind (group 1, n=39) or ultrasound-guided (group 2, n=38) glenohumeral injection of 40 mg triamcinolone. The clinical outcomes and shoulder range of motion (ROM) before injection, at 3, 6, and 12 months after injection and at the last follow-up were assessed. The same rehabilitation program was applied in both groups during the follow-up period.
Results: There was no significant difference in demographic data on age, sex, ROM, and symptom duration before injection between groups ($p>0.05$). There were no significant differences in ROM including forward flexion, external rotation at the side, external rotation at 90° abduction, and internal rotation, visual analogue scale for pain and functional outcomes including American Shoulder and Elbow Surgeons score, Simple Shoulder test between the two groups at any time point ($p>0.05$).
Conclusions: Based on the current data, the result of ultrasound-guided glenohumeral injection was not superior to that of blind injection in the treatment of shoulder stiffness. We suggest that ultrasound-guided glenohumeral injection could be performed according to the patient's compliance and the surgeon's preference. Once familiar with the non-imaging–guided glenohumeral injection, it is an efficient and reliable method for the experienced surgeon. Ultrasound could be performed according to the surgeon's preference.
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Key Words: Shoulder stiffness; Glenohumeral joint injection; Corticosteroid; Ultrasound-guided injection

Introduction

Shoulder stiffness is one of the most common and clinically important shoulder pathologies. Glenohumeral corticosteroid injection is an effective treatment modality because of its rapid effect of pain relief, low cost and simplicity of the procedure, which can be performed in an out-patient setting. Hannafin and Chiaia[1)] assessed the effectiveness of early treatment with intra-articular corticosteroids which provides chemical ablation of synovitis, thus limiting the subsequent development of fibrosis and shortening the natural history of the disease. Intra-articular corticosteroid injection accompanied by physiotherapy has been found to be effective in improving shoulder stiffness during the early follow-up period.[2,3)]

To increase the accuracy of intra-articular injection, imaging-guided injection has been recommended.[4-7)] An ultrasound (US)-guided technique was recently introduced for the musculoskeletal system. US-guided injection is being increasingly

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used, especially in shoulder disease, due to lack of radiation exposure and greater accuracy than blind technique. US-guided technique is particularly useful for glenohumeral joint injection because of the unique anatomy and location of this joint, which is deeply surrounded by the peri-articular muscles.

However, the efficacy and effectiveness of this technique have been questioned and controversial results have been reported for a long time. Rutten et al.[8] reported that US-guided glenohumeral joint injection is significantly less time consuming, causes less discomfort to the patient, and obviates the need for radiation and iodine contrast compared with fluoroscopic-guided injection. On the other hand, Porat et al.[9] reported that the accuracy of non-imaging–guided glenohumeral joint injection through the rotator interval is up to 99% on retrospective review of the post-injection magnetic resonance imaging (MRI) sequences. According to Patel et al.,[10] although US-guided injection could potentially reduce unnecessary attempts at glenohumeral placement, it has a disadvantage of being more time-consuming when compared with freehand injection. The purpose of this study was to prospectively compare the clinical outcomes of blind glenohumeral injection with those of US-guided injection of corticosteroids for the treatment of shoulder stiffness. The hypothesis of our study was that the US-guided glenohumeral joint injection of corticosteroid would contribute to improved outcomes in treatment of shoulder stiffness. Glenohumeral joint injection of corticosteroid would contribute to improved outcomes when compared with blind injection.

Methods

Patient Selection

A total of 115 patients with shoulder stiffness between April 2008 and March 2012 were recruited. There was no general agreement on the definition of shoulder stiffness with respect to the range of motion (ROM). The criteria for stiffness was defined as forward flexion (FF) less than 100° of glenohumeral motion, or external rotation less than 30°, or internal rotation (IR) of the back at a level lower than the first lumbar spine junction. Plain radiography for shoulder (true anteroposterior, supraspinatus outlet and axial views) and ultrasonography were performed to determine the secondary cause of shoulder stiffness including rotator cuff tear, calcific tendinitis, osteoarthritis, and fracture. Patients with secondary cause of shoulder stiffness, previous history of operation, or trauma or fracture were excluded from this study. Twenty-one patients were excluded after detection of the primary cause of shoulder stiffness and 4 patients refused to participate in this study. The remaining 90 patients were randomized into 2 groups through computer-generated blocked-randomization to receive either a blind glenohumeral injection of 40 mg triamcinolone (group 1, n=45) or US-guided injection of 40 mg triamcinolone (group 2, n=45) from the same orthopedic surgeon blinded to the clinical evaluation. Informed consent was obtained from all participants and a total of 13 patients discontinued or were lost to follow-up. Data from 77 patients was finally collected (Fig. 1). All procedures related to the study were approved by the Institutional Review Board of the Seoul St. Mary's Hospital, School of Medicine, The Catholic University

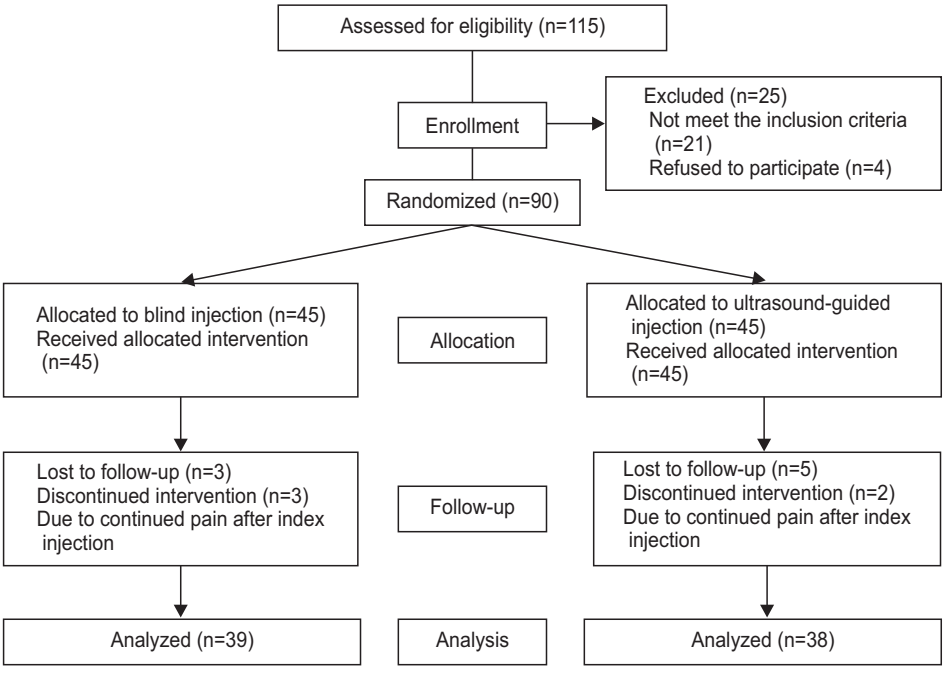

Fig. 1. Flow chart shows the conduct of the study according to Consolidated Standards of Reporting Trials criteria.

Table 1. Demographic Data of Patients

Varaible	Blind injection group	Ultrasound-guided injection group	*p*-value
No. of patient	39	38	
Age (yr)	53.9 (45–76)	57.4 (47–78)	0.15
Sex (male/female)	7/32	11/27	
Underlying diseases			
Diabetes mellitus	3/39	2/38	0.08
Thyroid diseases	1/39	1/38	0.12
Average follow-up period (mo)	16.38	15.36	0.13
Range of motion before injection			
Forward flexion (°)	117.5	127.7	0.07
External rotation at 90° (°)	70.4	73.9	0.52
External rotation at side (°)	64.6	72.7	0.18
Internal rotation	3.96	3.88	0.93

Values are presented as number only or median range.

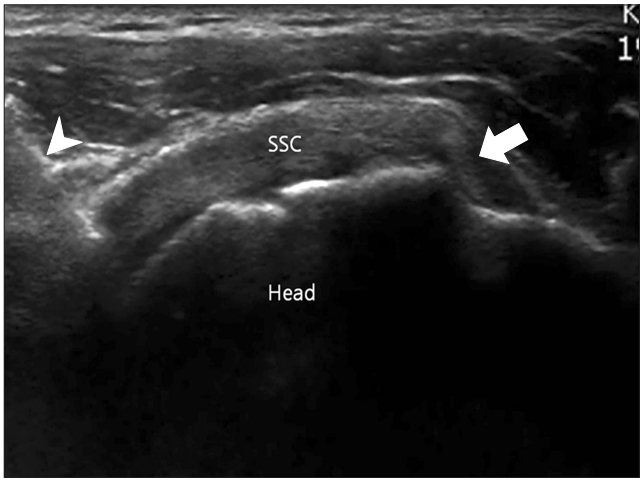

Fig. 2. Ultrasound-guided injection. Needle (arrowhead) was inserted through the subscapularis (SSC) aimed at the medial border of the humeral head (Head) (arrow: biceps tendon).

of Korea (No. KC12RISI0908). There were no significant differences in demographic data on age, sex, mean follow-up period, underlying diseases, and ROM before injection between groups ($p>0.05$; Table 1).

Injection Technique

In both groups, the patients were positioned on a standard gurney with the arm at the side. The field of anterior shoulder from the coracoid process to the anterior tip of the acromion was prepared in a sterile manner. In the blind injection group, the sulcus between the lateral tip of the coracoid and the humeral head was palpated. Then, a 21-gauge×1.5-inch needle on a 3-ml syringe with triamcinolone acetonide 40 mg and 2 ml of 2% lidocaine was inserted in a slightly cephalad direction at the anterior-lateral tip of the coracoid. The needle was slowly advanced while infiltrating the local anesthetic until resistance was lost, indicating intra-articular position.[9] The injection was performed slowly.

The US-guided injection was performed according to Valls and Melloni[5] with a slight modification: Other than performing injection in the supine position, the patient position and preparation were the same as those in the blind injection group. A high-resolution transducer with 12 MHz linear array was used to visualize the needle. After skin and transducer preparation with alcohol and povidone, the needle was inserted at the level of the coracoids, from lateral to medial, aimed at the medial border of the humeral head. When the needle made contact with the articular cartilage of the humeral head, the needle was tilted to position the point of the needle in the articular cavity. The intra-articular position of the needle and fluid infiltration in the shoulder joint was confirmed by ultrasonography (Fig. 2). All procedures were performed by one experienced senior surgeon (Y-S K.) with more than 5 years of experience in performance of US-guided injection at the shoulder joint.

Rehabilitation after Injection

All patients were prescribed the same home-based exercise program for rehabilitation. Starting from the first day after injection, pendulum circumduction and passive shoulder exercises for self-stretching in FF, external rotation and IR in the supine position were recommended until 4 weeks after injection. Pulley exercise was prescribed for achieving advanced further flexion after 4 weeks of injection, and isometric exercise in all planes was recommended. From 8 weeks after injection, thera-band exercise, strengthening exercise for scapular stabilization and

Table 2. Comparison of Range of Motion between Pre- and Postoperative Treatment

Variable	Initial range of motion	Range of motion at last follow-up	*p*-value
Group 1			
Forward flexion (°)	117.5	148.6	0.02
External rotation with 90° abduction (°)	70.4	90.0	0.01
External rotation at side (°)	64.6	87.1	0.01
Internal rotation	4.0	9.8	0.01
Group 2			
Forward flexion (°)	127.7	143.2	0.01
External rotation with 90° abduction (°)	73.9	86.4	0.02
External rotation at side (°)	72.6	83.7	0.04
Internal rotation	3.9	9.4	0.01

Group 1: computer-generated blocked-randomization to receive either a blind glenohumeral injection of 40 mg triamcinolone, Group 2: ultrasound-guided injection of 40 mg triamcinolone.

Table 3. Comparison of Functional Scores between Pre- and Postoperative Treatment

Variable	Preoperative score	Score at last follow-up	*p*-value
Group 1			
Pain VAS	6.9	1.5	0.01
ASES	42.5	91.3	0.01
SST	42.9	83.3	0.02
Group 2			
Pain VAS	6.8	2.2	0.02
ASES	48.1	79.5	0.01
SST	47.9	83.3	0.02

Group 1: computer-generated blocked-randomization to receive either a blind glenohumeral injection of 40 mg triamcinolone, Group 2: ultrasound-guided injection of 40 mg triamcinolone. VAS: visual analogue scale, ASES: American Shoulder and Elbow Surgeons score, SST: simple shoulder test.

advanced muscle strengthening exercise with dumbbells were taught. All listed procedures were recommended until the last visit after 12 months. No limit was imposed on use of the shoulder within a tolerable extent.

Outcome Measurement

Each patient was assessed prospectively before injection as well as at 3, 6, and 12 months after injection and at last follow-up using the American Shoulder and Elbow Surgeons score (ASES) score[11] and simple shoulder test (SST). All assessment data were prospectively collected by a clinical researcher who was blinded to the current study; patients were also blinded during the assessment. The ROM including FF, external rotation at side (ERs), external rotation at 90° abduction and IR of the injected shoulder and the visual analog scale (VAS) for pain (0 representing 'no pain' and 10 representing 'the most severe pain') were evaluated in all patients at each visit. During the assessment of ROM, only glenuhumeral motion was evaluated without scapulohumeral motion by stabilizing the scapula. Internal rotation was evaluated by the tip of the thumb reaching the vertebral level. For the analysis, the vertebral level was numbered serially: 0 for any level below the sacrum and 1 point was added for each level above the sacrum.

Statistical Methods

Sample sizes were calculated, with a significant difference of 2 points in pain VAS between 2 groups. Minimal 2 point difference in 11-point pain numerical system was reported to have clinical significance in a broad population of patients with various musculoskeletal conditions.[12-14] A sample size of 27 patients in each group was required for power of 95% at a type I error of 0.05 with a standard deviation of 2 points.[2,12] Statistical analysis was performed using SPSS software version 12.0 (SPSS Inc., Chicago, IL, USA). A Student's t-test was used to compare the differences between the outcomes of the two groups and a paired t-test was used to compare the differences between the functional evaluation scores before and after the injection in each group. A chi^2 test was used for comparison of the demographic outcome of the 2 groups. A p-value <0.05 was considered statistically significant.

Results

In group 1, there were 7 males and 32 females with an average age of 53.9 years (range, 45–76 years). In group 2, there were 11 males and 27 females with an average age of 57.4 years (range, 47–78 years) ($p=0.77$). The mean follow-up period was 16.4 months in the blind injection group (group 1) and 15.4 months in the US-guided injection group (group 2), respectively.

In both groups, functional scores and ROM assessed after 12 months showed significant improvement compared with those

Table 4. Comparison on Range of Motion

Variable	Group 1	Group 2	p-value
Forward flexion (°)			
Initial	117.5	127.7	0.07
3 months	136.9	141.1	0.26
6 months	142.7	143.2	0.87
12 months	142.1	146.1	0.36
Last	148.6	143.2	0.08
External rotation with 90° abduction (°)			
Initial	70.4	73.9	0.52
3 months	81.9	86.1	0.11
6 months	80.8	84.7	0.42
12 months	88.6	86.7	0.64
Last	90.0	86.4	0.15
External rotation at side (°)			
Initial	64.6	72.7	0.18
3 months	77.6	83.3	0.13
6 months	79.2	82.4	0.58
12 months	87.1	84.4	0.62
Last	87.1	83.6	0.32
Internal rotation			
Initial	4.0	3.9	0.93
3 months	8.4	8.2	0.82
6 months	9.5	8.2	0.28
12 months	9.6	9.7	0.94
Last	9.9	9.4	0.68

Group 1: computer-generated blocked-randomization to receive either a blind glenohumeral injection of 40 mg triamcinolone, Group 2: ultrasound-guided injection of 40 mg triamcinolone.

Table 5. Comparison on Functional Scores

Variable	Group 1	Group 2	*p*-value
Pain VAS			
Initial	6.9	6.8	0.79
3 months	2.8	3.0	0.85
6 months	3.4	2.3	0.32
12 months	3.2	3.0	0.90
Last	1.5	2.3	0.61
ASES			
Initial	42.5	48.1	0.27
3 months	77.4	78.6	0.85
6 months	73.5	77.6	0.69
12 months	72.8	77.6	0.61
Last	91.3	79.5	0.39
SST			
Initial	42.9	47.9	0.47
3 months	75.9	78.5	0.74
6 months	75.0	81.6	0.55
12 months	64.0	78.4	0.34
Last	83.3	83.3	0.94

Group 1: computer-generated blocked-randomization to receive either a blind glenohumeral injection of 40 mg triamcinolone, Group 2: ultrasound-guided injection of 40 mg triamcinolone, VAS: visual analogue scale, ASES: American Shoulder and Elbow Surgeons score, SST: simple shoulder test.

during the initial pre-injection phase ($p<0.05$, Table 2, 3). However, no significant differences were found in ROM including FF, ERs, external rotation at 90° abduction and IR (Table 4, Fig. 3) and clinical outcomes of VAS for pain, ASES, and SST between the two groups at 3, 6, and 12 months after injection and at the last follow-up (Table 5, Fig. 4). No complications were observed during the evaluation period.

Discussion

The current data demonstrated that there were no significant differences between US-guided injection and blind injection in treatment of shoulder stiffness with respect to ROM, pain and functional outcomes. This result is not significantly different from that of many previous studies and some similarities can also be found. Lee et al.[15] evaluated the clinical effect of US-guided intra-articular injection compared with a blind technique in 43 patients with adhesive capsulitis. Triamcinolone was injected posteriorly to the glenohumeral joint for both US-guided and blind injection groups. According to their results, improvement in VAS for pain, ROM, and functional score was significantly greater in the US-guided injection group by the second week after injection. However, there were no further significant differences in improvement between the two groups beyond the third week. Rutten et al.,[16] who compared the accuracy of both anterior and posterior blind injection to that of US-guided injection into the subacromial-subdeltoid bursa using T1-weighted magnetic resonance (MR) scan immediately after injection, reported that the accuracy of blind and US-guided injection was the same and that blind injection is as reliable as US-guided injection. However, they did not compare the clinical outcomes in between groups. Accurate injection into the glenohumeral joint is technically demanding. Performance of glenohumeral injection is more difficult than injections in other parts since the glenohumeral joint is surrounded by bulky muscles and is deeply located. Favorable results have been reported in both anterior and posterior approach of glenohumeral joint injection without guidance of imaging device.[9,17] However, development

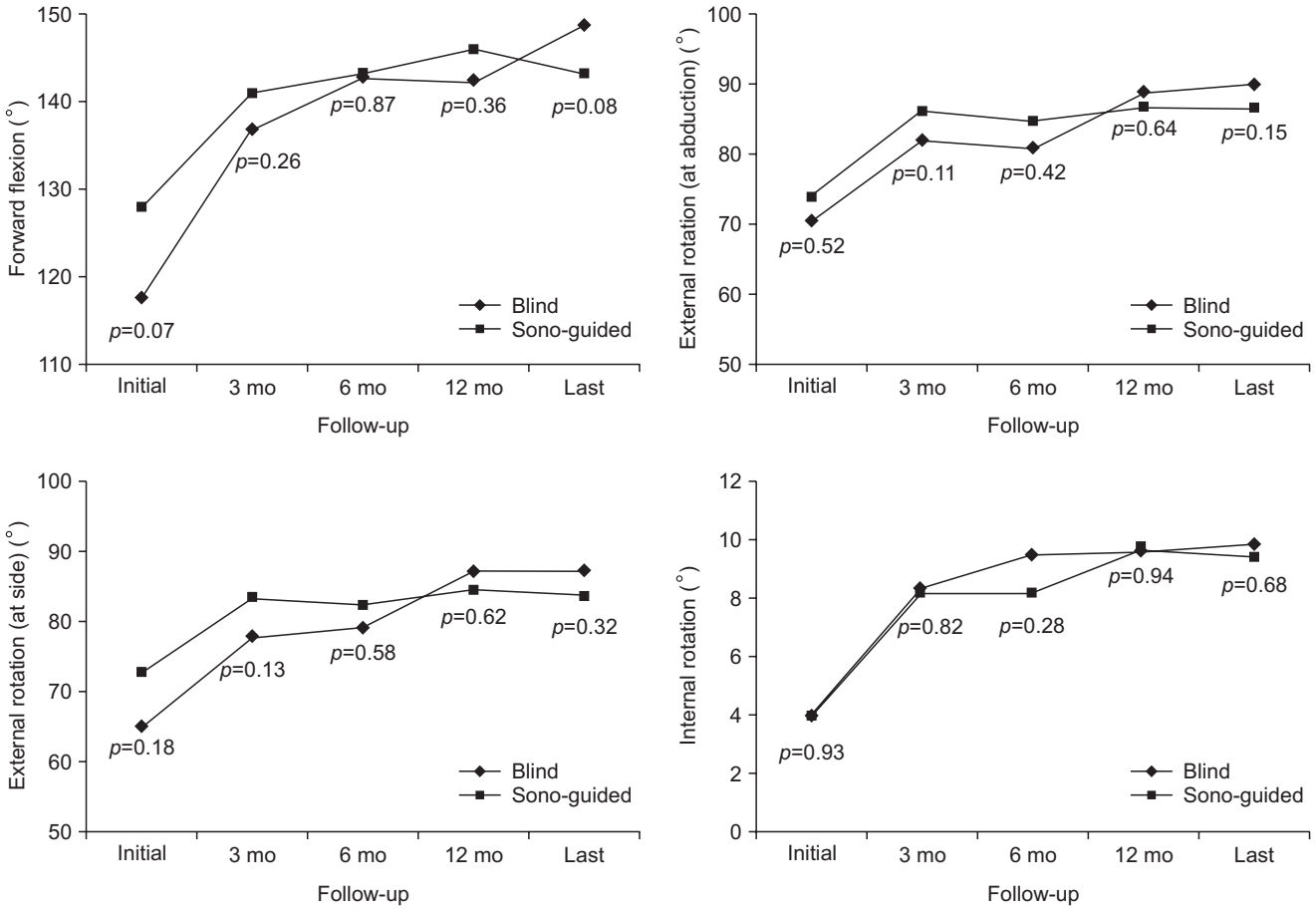

Fig. 3. Range of motion (forward flexion; external rotation at abduction, side; and internal rotation) improved after patients received blind injection and ultrasound-guided injection in the glenohumeral joint. There were no significant statistical differences between the 2 groups at serial follow-up assessments.

of imaging-guided injection technique, such as fluoroscopy or ultrasonography, was recommended for more accurate intra-articular injection.[4,6,8,10,18] In a systematic review,[18] the use of imaging-guided technique improved the accuracy of injection into the glenohumeral joint (95% vs. 79%), subacromial space (100% vs. 63%), and acromioclavicular joint (100% vs. 45%) compared to the non-imaging–guided technique.

Nevertheless, in our study there were no significant differences in clinical outcomes between blind injection and US-guided injection. We can explain this result in two possible ways. First, the corticosteroid might have been injected accurately in the glenohumeral joint in both groups. In this study, blind injection was performed by an experienced orthopedic surgeon who was a shoulder specialist. Second, it may be possible to improve the symptoms and clinical outcomes of shoulder stiffness regardless of the injection site. In a recent prospective randomized comparative study,[12] glenohumeral steroid injection was not superior to subacromial injection in treating primary frozen shoulder. The authors suggested that the stiffness in many shoulder diseases might originate from the subacromial space. In our study, some injections in the blind group might have been placed outside the glenohumeral joint and there is a possibility that subacromial bursitis or inflammation around the glenohumeral joint might be reduced with steroid injection. The etiology and pathophysiology of shoulder stiffness is still unclear and further evaluation is needed.

Some limitations of our study need to be mentioned. First, the number of cases was relatively small. The accuracy of the study would be higher with a larger number of patients. Second, there was no control group receiving other treatments such as placebo injection or medication only. This might have eliminated the possibility of placebo effect that may be responsible for the improvements. Third, there could be inhomogeneity of the rehabilitation program after injection. Because it was a home-based self-exercise program, the degree of passive ROM exercise might be different in each patient. However, we taught our patients to practice the exercises steadily three times a day and encouraged them to continue with the stretching exercise whenever they visited the clinics. Fourth, we did not confirm the needle position during intra-articular injection with the US-guided technique by using imaging modalities other than ultrasonography itself. Additional imaging guidance, such as fluoroscopy or MRI would have

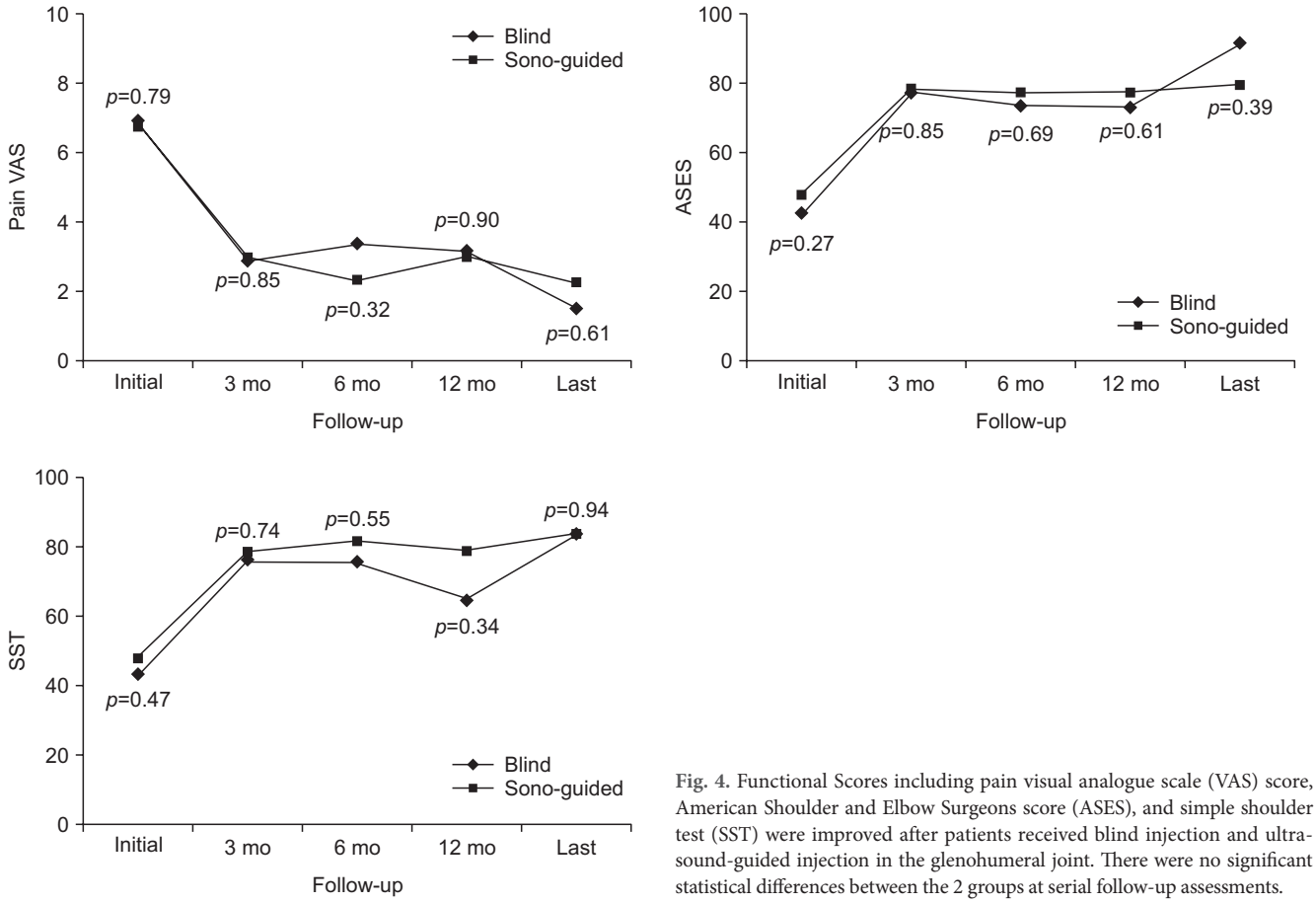

Fig. 4. Functional Scores including pain visual analogue scale (VAS) score, American Shoulder and Elbow Surgeons score (ASES), and simple shoulder test (SST) were improved after patients received blind injection and ultrasound-guided injection in the glenohumeral joint. There were no significant statistical differences between the 2 groups at serial follow-up assessments.

confirmed the position of the needle and the result would have been more reliable as we would be assured that the needle was in the correct position. Fifth, ultrasonography was not accurate enough in detecting glenohumeral lesions such as labral lesions or intra-articular biceps pathologies. Prior MR or computed tomography arthrographic evaluation might have helped to clarify the pathology within the joint and we could have subdivided the patients according to the disease. Finally, assessment within the first month after injection was omitted. Long period of follow-up with low rate of drop-out in this study is a strong point, but evaluation of the shorter period may have been better in isolating the efficacy of corticosteroid injection with a long period of rehabilitation.

Conclusion

The current data demonstrated that the result of US-guided glenohumeral injection did not yield superior results over blind injection in the treatment of shoulder stiffness. We suggest that US-guided glenohumeral injection could be performed according to the patient's compliance and the surgeon's preference. Once familiar with the non-imaging–guided glenohumeral injection, it is an efficient and reliable method for the experienced surgeon. The usage of US could be performed according to the surgeon's preference.

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