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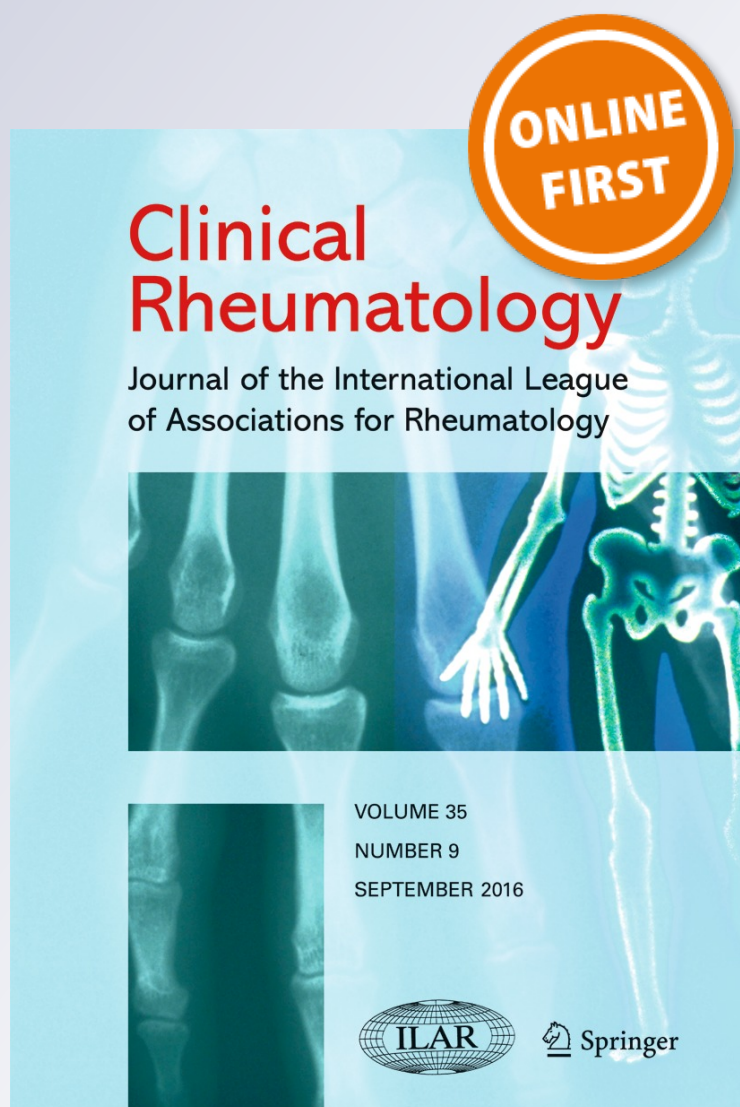
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Comparing the accuracy and efficacy of ultrasound-guided versus blind injections of steroid in the glenohumeral joint in patients with shoulder adhesive capsulitis

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Abstract Shoulder adhesive capsulitis is a condition mainly characterized by a decreased range of motion (ROM), with a lifelong prevalence of 2–5 %. Intra-articular steroid injection is an important treatment in this disease. It has been suggested that ultrasound-guided (US-guided) intra-articular injections are more accurate and effective than blind injections. This randomized clinical trial was designed to compare efficacy and accuracy of US-guided injections versus blind injections of steroid in the glenohumeral joint. Forty-one patients diagnosed with shoulder adhesive capsulitis were included. Patients randomly underwent intra-articular injection either blind or under guidance of ultrasound by a specialist. Immediately after injection, radiograms were obtained to assess the accuracy of injection. Demographic characteristics, their functional status, the severity of pain, and the ROM were gathered and compared between the two groups. Twenty

patients in the US-guided group and 21 in the blind group finished the 4-week period of the study. Improvements in pain, ROM, and functional score after 1 and 4 weeks were more prominent in the US-guided group, but the differences were not statistically significant, except for the changes in extension where the improvements were significantly higher in the US-guided group ($p = 0.01$). The accuracy of injections was also higher in the US-guided group (90 % vs. 76.19 %), but the differences were not found to be significant ($p = 0.24$). US-guided injections can be more accurate and yield better improvements in pain, ROM, and function of the patients, but they cost more and are time-consuming.

Keywords Adhesive capsulitis · Intra-articular injection · Shoulder · Steroid · Ultrasound-guided

Abbreviations

ROM	Range of motion
US-guided	Ultrasound-guided
VAS	Visual analog scale
GH	Glenohumeral
MRI	Magnetic resonance imaging

Introduction

Shoulder pain has a prevalence of 2–5 % in the general population and is more commonly caused by incomplete or complete tears of rotator cuff, subdeltoid or subacromial bursitis, and adhesive capsulitis [1]. Adhesive capsulitis has been defined by the American Academy of Orthopedic Surgeons as “A condition of varying severity characterized by the gradual development of global limitation in active and passive shoulder range of motions, where radiographic findings other than osteopenia are

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absent" [2]. The condition is more common in the fifth and sixth decades of life, and onset before the age of 40 is rare. Women are more often affected than men, and the non-dominant shoulder is slightly more likely to be affected [3].

Steroid injection is commonly used for treating shoulder pain. The target anatomic sites include the glenohumeral (GH) joint, subacromial space, and near the tendon sheaths [4]. Injection can be blindly performed just according to the anatomic landmarks, or it can be done through guidance of imaging modalities such as ultrasound or magnetic resonance imaging (MRI). Other than the imaging guidance, the approach of injection can also affect the accuracy and efficacy of the treatment [5, 6].

Previous studies have reported the accuracy of intra-articular injection in the shoulder joint to be 10 to 46 % [7]. Extra-articular injections can lead to complications such as soft tissue injuries, weakening of the tendons, and skin depigmentation [8]. The risk of these complications, its costs, and the time taken to perform this semi-invasive procedure accentuate the importance of an accurate intra-articular injection in the patients. Although few studies have found no significant relation between response to treatment and the accuracy of injection [9], the majority of surveys conducted on this matter have found higher efficacies of accurate injections compared to inaccurate ones [10, 11]. Accordingly, we aimed to design this clinical trial to compare the efficacy and accuracy of blind injections with ultrasound-guided injections to help reach a consensus regarding the application of imaging modalities as guidance for intra-articular injection in patients with frozen shoulder.

Materials and methods

In this single-blinded randomized clinical trial conducted in Shahid Modarres Hospital in 2015, patients presenting with shoulder pain were evaluated. Through convenience sampling, 41 subjects diagnosed with adhesive capsulitis by two different physical medicine and rehabilitation specialists according to the patients' history and physical examination were enrolled as the study population. Duration of patient's symptoms was at least 3 months. Exclusion criteria included evidence of previous fracture in the shoulder, history of joint inflammatory diseases or any bone disorders, history of surgical procedures in the affected shoulder, history of shoulder physical therapy or injections in the shoulder in the past 3 months, hypersensitivity reactions to steroids, and recurrence of the disease.

Using block randomization method, the patients were divided into two equal-sized groups. Although the sufficient sample size was calculated to be 29, in order to compensate for the subjects dropping out of the study during follow-ups, we included 41 patients.

The 41 patients, 20 subjects in the ultrasound-guided group and 21 in the blind group, completed all the follow-ups of the survey and cooperated until the end of the study.

Data on demographic characteristics of the patients including age, gender, height, weight, and history of diabetes, hypothyroidism, and coronary artery diseases were registered via questionnaire. The rest of the required information for the study was collected by the physical medicine and rehabilitation specialist in three stages: before injection, 1 week after injection, and 4 weeks after injection. The information included severity of the pain according to the visual analog scale (VAS) score [12], functional status of the patients based on the Oxford questionnaire [13], and the maximum range of the six active motions of shoulder (flexion, extension, abduction, internal and external rotation) measured by a goniometer.

All the injections were performed by one physical medicine and rehabilitation specialist with 15 years' experience in his field, different from the physician who measured range of motion of the patients. In the blind group, the posterior approach was practiced and the 25-gauge needle was inserted 2.5 cm lower than the posterolateral aspect of the acromion. First, 1 cm³ lidocaine 1 %, then, 3 cm³ water soluble un-ionized contrast with 1 cm³ distilled water, and finally, 1 cm³ triamcinolone 40 mg/cm³ with 1 cm³ lidocaine 1 % was injected. If the physician felt that the needle is not accurately inserted, he was not allowed to withdraw and re-enter again. In the ultrasound-guided group, injections were performed by the same physical medicine and rehabilitation specialist using an Alpinion E-cube 7 ultrasound device with linear 3–12-MHz probe while the patient was sitting and the affected hand resting his/her thigh. The posterior short-axis approach was practiced, and the needle was inserted in plane relative to the ultrasound probe and medial to the posterior aspect of the head of the humerus (Figs. 1 and 2).

Immediately after injection, patients in both groups underwent plain radiography of the shoulder in anteroposterior and axillary views to assess the accuracy of injection by a radiologist who was blind about the approach of injections. Presence of the contrast medium in the glenohumeral joint was considered as an accurate injection and its presence in the subacromial space or soft tissue as a failed injection. After the injections, all of the patients received naproxen tablet 500 mg BD for 5 days and Codman's exercises were instructed to all of them.

Statistical analysis

Data were entered into SPSS software v.22 [14] and then were analyzed. The efficacy of the two methods was compared based on the pain severity, maximum range of motion, and function of the patient using *t* test and ANOVA test. The accuracy of each method was calculated in percent. The relation between qualitative variables was assessed using chi-squared test.

Fig. 1 The posterior short-axis approach for injection



Results

A total of 41 patients with frozen shoulder were included in the present study. Of these subjects, 21 (51.2 %) were randomly assigned to the blind group and 20 (48.8 %) were put into the ultrasound-guided group. Fifteen subjects (36.6 %) were females, and 26 (63.4 %) were males. Only one of the participants (2.4 %) was left-handed, and the rest were right-handed (97.6 %). In 16 patients (39.0 %), the left shoulder was affected, and in 25 (60.9 %), the right shoulder was affected. Only four (9.7 %) patients were diabetic, 3 (7.3 %) had hypothyroidism, and 7 (17.0 %) mentioned a history of coronary artery

disease. The mean age of the subjects was 58.9 ± 8.9 years with a minimum of 37 and a maximum of 77 years old.

Gender distribution was quite similar between the two groups with 13 males in each group and 8 females in the blind group (38.1 %) and 7 in the ultrasound-guided (US-guided) group (35.0 %) ($p = 0.837$). All the 21 patients in the blind group were right-handed (100 %). Only one of the 20 patients (5.0 %) in the US-guided group was left-handed ($p = 0.3$). In the blind group, 14 subjects (66.7 %) had a problem in their right shoulder and 7 (33.3 %) in their left shoulder. These figures were 11 (55.0 %) and 9 (45.0 %) in the US-guided group ($p = 0.444$). One patient in the blind group (4.8 %) and

Fig. 2 Insertion of the needle in plane relative to the ultrasound probe and medial to the posterior aspect of the head of the humerus



three in the US-guided group (15.0 %) had diabetes ($p = 0.269$). Regarding hypothyroidism, one subject in the blind group (5.0 %) and two in the US-guided group (9.0 %) were positive ($p = 0.531$). Three of the patients in the blind group (15.0 %) and four (20.0 %) in the US-guided group were positive for coronary artery disease ($p = 0.611$). No significant difference was observed between the two groups regarding baseline measurements, except for the shoulder extension which was higher in the blind group (Table 1). No adverse effects occurred after injection in neither of the groups.

The quantitative variables were measured before injection and after 1 and 4 weeks and were compared between the two groups. Only the maximum external rotation after 4 weeks was found to be significantly higher in the US-guided group compared to the blind group ($p = 0.03$). The significance of the changes in these variables was also evaluated in each group separately. Accordingly, the differences in all the variables between each two temporal points were found to be statistically significant except for the changes in internal rotation in the blind group.

Furthermore, the differences between the two groups regarding the changes in the evaluated variables were also assessed. The changes in all the variables were found to be higher in the US-guided group compared to the blind group

although were not significant except for the changes in extension of the shoulder where the differences were significantly higher in the ultrasound group (Table 2). VAS score showed no improvements in only one of the patients who belonged to the blind injection group.

The accuracy of injection in the blind group was 76.19 %, and it was 90.0 % in the US-guided group, but the difference between the two groups was not statistically significant.

Finally, all the quantitative variables including VAS score, range of motion (ROM) measurements, and Oxford score before injection and 1 and 4 weeks after injection along with the changes in these variables after 1 and 4 weeks were compared between the subjects with accurate and inaccurate injections. As presented in Table 3, all the differences were found to be statistically insignificant.

Discussion

Adhesive capsulitis is characterized by gradually increasing pain and restriction of ROM in the affected shoulder. Patients often experience severe limitations in abduction and external rotation of their shoulders. Frozen shoulder is a self-limited disease in most cases but does not resolve completely in some

Table 1 Differences between the two groups regarding baseline characteristics

		Group				<i>p</i> value
		Blind		US-guided		
		Count	<i>N</i> (%)	Count	<i>N</i> (%)	
Gender	Male	13	61.90	13	65.00	0.837
	Female	8	38.10	7	35.00	
Dominant hand	Right	21	100.00	19	95.00	0.3
	Left	0	0.00	1	5.00	
Affected shoulder	Right	14	66.70	11	55.00	0.444
	Left	7	33.30	9	45.00	
Diabetes	Positive	1	4.80	3	15.00	0.269
Hypothyroidism	Positive	1	5	2	9	0.531
CAD	Positive	3	15.00	4	20.00	0.611
		Mean	Std. Dev.	Mean	Std. Dev.	
Age (year)		59.9	11.01	57.8	6.0725	0.46
Height (cm)		167.33	10.81	165.9	10.48	0.66
Weight (kg)		77.28	13.62	77.28	13.62	0.87
BMI (kg/m ²)		27.57	3.98	27.52	6.27	0.97
Chronicity (month)		10.64	11.38	11	6.98	0.28
VAS score		6.66	2.35	7.6	1.5694	0.14
Abduction		93.28	20.58	97.8	24.19	0.52
Flexion		102.	23.04	90.35	19.21	0.087
Extension		55.33	7.786	46.0	16.79	0.027
Internal rotation		79.57	16.32	76.8	21.33	0.64
External rotation		52.81	27.73	54.25	23.52	0.85
Oxford score		24.5	7.31	21.45	6.84	0.16

Table 2 Differences between the two groups regarding changes in outcome variables

	Group	Mean	Std. Dev.	<i>p</i> value
VAS score change after 1 week	Blind	1.9	1.44	0.17
	US-guided	2.65	1.95	
VAS score change after 4 weeks	Blind	3.8	1.93	0.32
	US-guided	4.45	2.187	
Oxford score change after 1 week	Blind	6.66	5.45	0.81
	US-guided	7.0	3.19	
Oxford score change after 4 weeks	Blind	14.33	6.17	0.75
	US-guided	14.90	5.52	
Abduction changes after 1 week	Blind	18.95	14.30	0.57
	US-guided	21.60	15.83	
Abduction changes after 4 weeks	Blind	32.47	12.63	0.71
	US-guided	34.20	17.31	
Flexion changes after 1 week	Blind	12.33	8.98	0.08
	US-guided	20.45	18.90	
Flexion changes after 4 weeks	Blind	24.33	14.77	0.07
	US-guided	33.50	17.75	
Extension changes after 1 week	Blind	2.09	3.71	0.01
	US-guided	10.70	14.53	
Extension changes after 4 weeks	Blind	2.57	4.05	0.01
	US-guided	12.05	15.70	
Internal rotation changes after 1 week	Blind	3.90	6.38	0.16
	US-guided	9.15	15.84	
Internal rotation changes after 4 weeks	Blind	6.28	9.69	0.31
	US-guided	10.75	17.59	
External rotation changes after 1 week	Blind	7.71	8.14	0.06
	US-guided	14.45	13.97	
External rotation changes after 4 weeks	Blind	13.76	12.49	0.05
	US-guided	23.35	17.52	

of patients [15]. No standard approach is available for these patients. Treatment options for this condition include specific exercises, intra-articular injections, arthrographic capsular distention, manipulation of the joint under general anesthesia, and surgical interventions, which are chosen individually for each patient based on his or her condition [16–18]. Injection of steroids in the glenohumeral joint is found to have treatment effects by reduction of inflammation which is one the pathologic processes involved in this disease [19, 20].

In this clinical trial, we included patients with frozen shoulder and compared the two intra-articular injection methods of blind and US-guided injections, considering the accuracy of injection and improvements in patients' pain, function, and ROM. According to the results yielded from this survey, although the improvements were found to be more prominent in the US-guided group, the differences between the two groups were not statistically significant, except for the changes in extension of the shoulder which was significantly higher in the ultrasound group.

Prior to this study, many researches had conducted similar surveys to evaluate this subject. Eustace et al. evaluated the accuracy of blind injections in 38 patients. Based on their results, 14 injections (37 %) were found to be correctly placed.

They also reported better treatment outcomes in subjects with accurate injections compared to those whose injections had failed [7].

Naredo et al. assessed 41 patients with painful shoulders in 2004. They assessed efficacy of blind versus US-guided subacromial injections. They also found a higher improvement in pain and function of the patients injected under ultrasound guidance compared to subjects who were injected according to anatomic landmarks [21]. Considering the pain and function of the joint, Ucuncu et al. also yielded similar results in 2009 and confirmed superiority of US-guided injections; however, they did not find any significant difference with regard to ROM of the affected joint [22].

In 2009, Lee et al. evaluated 43 patients with adhesive capsulitis and showed that the improvement in pain severity, ROM, and shoulder function score was significantly greater in the subjects whose injections were done under guidance of ultrasound by the second week after injection. However, the differences were found to be insignificant after the third week [23].

In 2010, Gokalp et al. aimed to assess the efficacy of MR arthrography using ultrasound guidance instead of fluoroscopy guidance. They performed MR arthrography on 29 patients and reported one failed procedure due to obesity, contrast

extravasation in 12 patients, and one vasovagal collapse. All the needles were found to be accurately placed [24].

In a systematic review by Soh et al. in 2011, the improvements in pain and function of the joint, 6 weeks after injection, were significantly higher in patients with US-guided injections. Common complications such as aggravated pain and thinning and depigmentation of the skin were more prevalent in patients with blind injections, but the differences between the two groups were not significant [11].

In 2010, Hegedus et al. aimed to measure the accuracy of blind intra-articular injections. Of the 103 joint injected in this study, 54 (52.4 %) were found to be accurately injected by fluoroscopy. They also found better improvement of pain in these patients compared to those with inaccurate injections [9].

Ogul et al. assessed the accuracy of US-guided needle placement in 34 patients with shoulder pain in 2012. They evaluated the accuracy via injection of gadolinium and found that 100 % of injections performed under guidance of

Table 3 The differences in all the quantitative variables between accurate and inaccurate injections

	Intra-articular injection				p value
	Negative		Positive		
	Mean	Std. Dev.	Mean	Std. Dev.	
VAS score (initial)	6.7	2.3	7.2	2.0	0.612
VAS score (after 1 week)	4.3	1.4	5.0	2.0	0.292
VAS score (after 4 weeks)	2.6	.5	3.1	1.6	0.137
Abduction (initial)	95.7	25.4	95.4	22.0	0.980
Abduction (after 1 week)	113.7	20.1	116.1	27.3	0.790
Abduction (after 4 weeks)	127.3	20.0	129.1	24.1	0.836
Flexion (initial)	92.6	22.8	97.1	21.9	0.643
Flexion (after 1 week)	115.3	27.9	112.1	22.9	0.782
Flexion (after 4 weeks)	128.0	26.7	124.5	23.1	0.757
Extension (initial)	49.0	8.2	51.1	14.6	0.598
Extension (after 1 week)	55.6	9.7	57.4	6.4	0.650
Extension (after 4 weeks)	56.6	7.1	58.3	5.7	0.571
Internal rotation (initial)	85.1	9.5	76.8	19.9	0.108
Internal rotation (after 1 week)	87.3	7.2	84.1	11.8	0.370
Internal rotation (after 4 weeks)	89.4	1.5	86.1	9.2	0.055
External rotation (initial)	48.3	29.7	54.6	24.8	0.615
External rotation (after 1 week)	61.1	26.9	65.2	18.6	0.714
External rotation (after 4 weeks)	67.1	23.4	72.9	15.9	0.550
Oxford score (initial)	23.1	8.8	23.0	7.0	0.975
Oxford score (after 1 week)	31	8	30	7	0.735
Oxford score (after 4 weeks)	38	9	38	7	0.874
Abduction changes after 1 week	18.00	12.40	20.71	15.54	0.626
Abduction changes after 4 weeks	31.57	13.78	33.68	15.33	0.726
Flexion changes after 1 week	22.71	23.01	14.97	12.98	0.418
Flexion changes after 4 weeks	35.43	24.97	27.44	14.67	0.441
Extension changes after 1 week	6.57	5.74	6.24	12.13	0.912
Extension changes after 4 weeks	7.57	4.96	7.12	13.24	0.879
Internal rotation changes after 1 week	2.14	3.76	7.35	13.06	0.058
Internal rotation changes after 4 weeks	4.29	8.10	9.32	15.00	0.226
External rotation changes after 1 week	12.86	8.15	10.62	12.40	0.560
External rotation changes after 4 weeks	18.86	12.03	18.35	16.54	0.927
VAS score change after 1 week	2.43	1.13	2.24	1.84	0.722
VAS score change after 4 weeks	4.14	1.95	4.12	2.11	0.976
Oxford score change after 1 week	7.71	6.05	6.65	4.13	0.669
Oxford score change after 4 weeks	15.00	8.06	14.53	5.38	0.887

ultrasound were accurately injected in the glenohumeral joint, verifying the accuracy of needle placement [25]. Cicak et al. had conducted a similar survey in 1992 and had reported similar results of a 100 % accuracy in needle placement using ultrasound guidance [26].

Aly et al. conducted a systematic review in 2015, including 13 studies. They reported that in all shoulder injections including injections in the GH joint, subacromial bursa, biceps tendon sheath, and acromioclavicular joint, considering all the efficacy parameters including improvements in pain, function, and ROM of the joint, US-guided injections yielded significantly better results compared to blind injections in short-term follow-ups. Except for the subacromial bursa injections, the accuracy of US-guided injections was also reported to be higher than that of blind injections for all the other sites. The accuracy of US-guided injections for the GH joint was reported to be 93 % compared to 73 % for blind injections [10].

Therefore, the accuracy of US-guided intra-articular injections was found to significantly differ between the mentioned studies, from 37 % reported by Eustace et al. [7] and 52.4 % by Hegedus et al. [9] to 90 % in the present study and 93 % reported by Aly et al. [10]. These differences can be attributed to the operator-dependent nature of the procedure.

The other prominent findings in all of these surveys were the superior effects of US-guided injections on pain, function, and ROM improvements compared to those of blind injections. Although the present study did not find the differences between the two methods to be statistically significant, in almost all of the outcome variables, the improvements were higher in the US-guided group.

In the present survey, all the injections were performed by a physical medicine and rehabilitation specialist with 15 years of experience in this field. Therefore, the fact that the differences between the two methods were found to be insignificant might be due to the experience and accuracy of the attending physician in blind injections of the joint, and so, it is recommended to include multiple physicians with different experience and skill levels in future studies to take this factor into account as well.

In the present study, we performed intra-articular steroid injections in patients with adhesive capsulitis using two methods of blind injection and US-guided injection. In both groups, improvements in ROM, pain, and shoulder function were observed after 1 and 4 weeks from injection compared to baseline. The improvements were found to be more prominent in the US-guided group compared to the blind group, but the differences were not statistically significant except for the changes in extension of the shoulder which was significantly higher in the US-guided group.

As mentioned, the improvements were found to be more prominent in the US-guided group which can be attributed to the effects of ultrasound in the accuracy of intra-articular injections. Despite the higher accuracy of US-guided injections,

the differences between the two groups were not statistically significant. This might be due to the fact that the same experienced physician performed the injections in both groups.

Patients were administered naproxen after injection which is a common practice at our center to relieve post-injection pain in the patients. Although this might have influenced the VAS score results and the lack of significant differences between the two groups might be due to treatment with this drug, but since the drug is short acting, it is unlikely that its effects have influenced the VAS scores after 4 weeks. However, it is suggested that in further studies, patients be kept off analgesics, so that the differences in pain severities be more evident.

US-guided procedures have been shown to be safer than blind injections in several previous studies; therefore, if there are no significant differences between the two methods in terms of efficacy, the safety is a relevant positive aspect for the patients and should not be overlooked.

One of the limitations of the present study is the small sample population and the low power of the survey (80 %). It is suggested that further studies conducted on this subject include a larger sample size to lower the second type error (B).

Conclusion

Overall, our results showed that US-guided injections in adhesive capsulitis are more accurate and might provide more improvement in pain reduction, shoulder ROM, and function in the patients. However, there is no statistically significant correlation between the accuracy of injection and improvement of patients' symptoms. Therefore, considering the slight advantages of US-guided injections, this method might be a better choice for patients with adhesive capsulitis.

Compliance with ethical standards

Disclosures None.

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