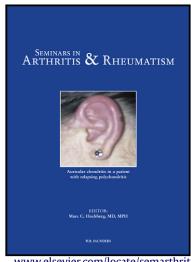
# Author's Accepted Manuscript

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# Ultrasound-guided versus blind subacromial-subdeltoid bursa injection in adults with shoulder pain: a systematic review and meta-analysis

Tao Wu Dr.

Inflammation of the subacromial-subdeltoid (SASD) bursitis is a common cause of shoulder pain and functional disability<sup>[1]</sup>. SASD bursitis is regarded as the nonstenotic impingement of the shoulder. It is often secondary to lesions in the tendinous cuff<sup>[2]</sup>. The patient suffering from SASD bursitis frequently complains of pain with any movement of the shoulder, but especially with abduction. Although there has been a debate about the effectiveness of local corticosteroid injections for patients with shoulder pain<sup>[3][4]</sup>, SASD bursa injection of corticosteroids is an effective therapy for SASD bursitis or symptomatic subacromial impingement<sup>[5]</sup>.

Shoulder Corticosteroids injections have traditionally been done 'blind' (anatomical landmark guided injections) or image guidance (fluoroscopy or ultrasonography)<sup>[6]</sup>. Several meta analysis have been shown the improved accuracy of shoulder girdle injections by ultrasound guided approach<sup>[7][8][9]</sup>. But there are no previous review evaluated the effectiveness of the injections based on the different locations of the SASD bursa injection. Also it is more controversial whether accuracy of needle placement has a significant impact on long fellow-up clinical outcome in SASD bursa injection<sup>[10]</sup>. To assess the effectiveness of this procedure, multiple clinical trials with heterogeneous design have reported conflicting outcomes.

Therefore, we conducted this systematic review and meta-analysis to summarize the current evidence and evaluate the clinical effectiveness of ultrasound-guided SASD bursa injection for shoulder pain patients. This systematic review and meta-analysis aimed to assess the effectiveness of ultrasound-guided versus blind (landmark-guided) corticosteroid SASD bursa injection in adults with shoulder pain. Outcome measures for effectiveness included change in pain and function scores. It was the hypothesis of this

study that the Ultrasound-guided (USG) SASD bursa injection is more effective in clinical outcomes than landmark-guided (LMG) technique in patients with shoulder pain.

#### Methods

This systematic review of randomized controlled trials was performed according to the current recommendations of the Cochrane Collaboration<sup>[11]</sup> and reported using the criteria of the PRISMA statement<sup>[12]</sup>.

Search strategy

The searches were performed on PubMed, Ovid MEDLINE, Ovid EMBASE, Ovid Cochrane CENTRAL, Web of Science, Google Scholar, and Scopus from database inception through on March 27, 2015. Key search terms were blind, landmark, anatomical, image-guided, ultrasound, fluoroscopy, steroid injection, subacromial-subdeltoid bursa, subacromial, random allocation, randomized controlled trial (RCT) and clinical trial. Each concept used a combination of controlled vocabulary (MeSH and EMTREE) combined with text words for each database which uses subject heading (PubMed, MEDLINE, EMBASE, CENTRAL). Web of Science and Scopus depend primarily on text words alone.

Inclusion and exclusion criteria

We included randomized controlled trials (RCTs) comparing the clinical effectiveness of USG and LMG SASD bursa or subacromial injection in shoulder pain patients. Anatomical target locations include SASD bursa or subacromial space. Outcomes of interest included pain, function, range of motion and proportion of participants with overall improvement. Exclusion criteria were case reports, technical reports, pilot and uncompleted studies, studies with no data analysis and/or power analysis, acromioclavicular or glenohumeral injection.

Study selection

Once all relevant full-text papers had been gathered, the reference lists of each eligible paper were scrutinized by two reviewers (Y.D., T.W.) for any omitted studies.

Each search was imported into an EndNote (Thomson Reuters Research Soft), a bibliographic database manager, and duplicates removed. All conflicts were discussed and resolved with a third author (J.H.). The reference sections of all articles were used to identify additional relevant articles.

Data collection process and Outcome measures

Following selection of all relevant articles, two authors (Y.D., T.W.) extracted all data into a pre-constructed data table. The following data was extracted: author, year published, study location, sample size, patient characteristics (gender, age), injection approach, fellow up period and outcomes. The outcome measures collected were the decreased VAS and SDQ scores, the increased shoulder function scores and shoulder abduction motion range, and the effective rate at 6 weeks after injection. Shoulder functional outcome measurements used instruments such SFA score<sup>[13]</sup>, constant score<sup>[14]</sup> and physical function<sup>[15]</sup>.

## **Statistical Analysis**

All analyses were performed using the generic inverse variance method (Rev Man 5.3, The Cochrane Library). Statistical heterogeneity was quantified using the I<sup>2</sup> statistic and the chi-square-based test. The decreased VAS and SDQ scores, increased shoulder function scores and shoulder abduction motion range at 6 weeks after injection between USG and LMG groups were expressed in terms of the weighted mean difference or Std mean difference with a 95% confidence interval (CI) evaluation. For summarizing the effective rate (frequency of effective number), the risk ratio (RR) was used. We used the Cochrane Risk of bias tool to assess the methodological quality of the included RCTs in terms of sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias [11]. The significance level was defined as P value lower than 0.05.

#### Results

We identified 305 articles, seven RCTs were eligible for this review (Figure 1), with a total of 445 adult patients <sup>[13,14,15,16,17,18,19]</sup>. Characteristics of the enrolled studies are described in Table 1.

#### Clinical outcomes

1. The decreased VAS and SDQ scores at 6 weeks after injection

Six studies assessed pain using a pain score <sup>[13,14,15,17,18,19]</sup> and two assessed SDQ score <sup>[15,18]</sup> at 6 weeks after injection. The analysis indicated a statistically significant decreased VAS and SDQ score difference between USG and LMG groups at this follow-up period in favour of USG (MD 1.19, 95% CI [0.39, 1.98], P = 0.003 & MD 5.01, 95% CI [1.82,8.19], P=0.02, respectively, Fig 2,3).

2. The increased shoulder function scores and shoulder abduction degree at 6 weeks after injection

Four studies assessed increased shoulder function  $^{[13,14,15,18]}$  and two assessed increased shoulder abduction motion range  $^{[14,16]}$  6 weeks after injection. This indicated a statistically significant difference between the groups, with greater improvement reported of shoulder function scores and shoulder abduction motion range in the USG group (SMD 0.89, 95% CI [0.56, 1.23], P < 0.001 & MD 32.69, 95% CI [14.82, 50.56], P<0.001, respectively, Fig 4,5).

#### 3. The effective rate

Two studies compared the effective rate difference between ultrasound-guided and landmark injection groups  $^{[14,17]}$ . More effective rate was also reported with USG group and the difference was statistically significant (risk ratio = 1.6, 95% CI [1.02, 2.50], p=0.04, Figure 6).

#### 4 Quality of included studies

The studies reported low risk of bias in terms of sequence generation, incomplete outcome data, and selective outcome reporting. However, some studies (3/8) did not report blinding of participants and personnel and some (2/8) are high risk of other bias,

including limited by the single follow-up visit at week 6. Patients were not blinded to the injection technique and this may have resulted in some bias particularly for purely subjective assessments such as VAS. The risk of bias for shoulder function assessment in terms of blinding outcome assessment was judged to be of low risk in 7 studies. In summary, the risk of bias within the studies was medium due to potential publication bias and unknown quality (Fig 7, 8).

#### Discussion

The purpose of this study was to assess whether there is a difference in the clinical and functional outcomes of USG vs LMG SASD bursa injections in adults with shoulder pain based on the current evidence base. A total of 8 RCTs were included in our meta analysis. The results showed that USG SASD injections were more efficient than the LMG injections. USG injections significantly decreased the VAS and SDQ scores, and increased shoulder function, shoulder abduction motion range at 6 weeks after injection.

SASD bursitis, regarded as the nonstenotic impingement of the shoulder is a common cause of anterior shoulder pain. Painful arc syndrome develops when there is a loss of clearance or normal gliding mechanism of the walls of the subacromial bursa between the coracoacromial arc above and the humeral head below. Ultrasound has proven to be an effective tool in the diagnosis of SASD bursitis<sup>[20]</sup>. SASD bursitis is observed under the sonogram as a hypoechoic region correlating with an effusion between the deltoid muscle and supraspinatus. Local injection of steroid suspension into the SASD bursa may be needed if conventional therapy including physical modality or anti-inflammatory medications is failed. The key point of the technique lies in that the needle tip should be accurately placed into the SASD bursa to achieve the ideal clinical outcomes and reduce local complications<sup>[21]</sup>.

In clinical practice, injection treatment of SASD is frequently done by palpation of the acromion by the thumb, and the needle slides blindly under it in a horizontal approach<sup>[22]</sup>. However, physicians using the blind injections can never be sure about the

depth of the inserted needle. Also the accuracy rate of LMG injections is poor especially in obese patients with no obvious landmark. Potential side effects of blind injection include necrotizing fasciitis, a deleterious effect on intra-articular cartilage, or tendon degeneration, which may lead to late rupture of the rotator cuff and subcutaneous atrophy<sup>[23]</sup>.

The US-guided SASD bursa injection technique has become increasingly popular because of its several advantages<sup>[13]</sup>. US provides fast and less invasive real-time monitoring during needle placement with no risk of radiation exposure. US machine is also much more affordable, acceptable to patients, and available than machine like fluoroscopy or computed tomography/magnetic resonance scanner.

To our knowledge, this is the first meta-analysis to assess outcome of SASD bursa injections guided by ultrasound vs. Landmark. The recent Cochrane review reported no significant improvement in effectiveness with US-guided injections<sup>[24]</sup>. However, the limitations in that study is obvious that there was considerable heterogeneity in the included trials, and the authors did not perform the analysis based on the injection location. So we included the study that specially involved patients for SASD bursa or subacrominal injection. Also, the biceps tendon sheath injection and glenohumeral joint injection were excluded. We required image-confirmed needle placement in SASD bursa in order to ensure precision.

The limitation of this study is the relatively small sample size in each group. The results should be interpreted with some caution due to the limited number of studies and small sample sizes available for review. More adequately-powered and well-executed RCTs are required.

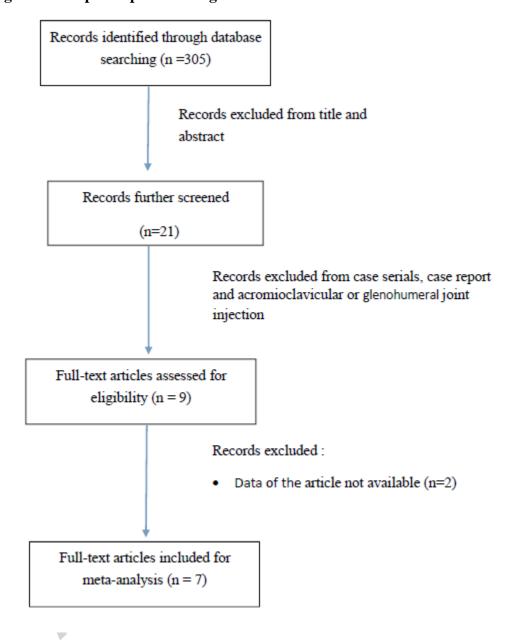
#### **Conclusions**

The meta-analysis in this study provides evidence that ultrasound-guided corticosteroid injections potentially offer a significantly greater clinical improvement over blind SASD injections in adults with shoulder pain. Therefore, we believe that the US-guided SASD injection technique can be a useful treatment that leads to improvements in patients with SASD bursitis.

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Fig-1 Flow of participants through trial



## Fif-2 Forest plot of the decreased VAS scores at 6 weeks after injection

	US- guided			Landmark				Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI Year	IV, Random, 95% CI		
Esperanza Naredo 2004	3.49	2.13	21	0.71	0.82	20	15.0%	2.78 [1.80, 3.76] 2004	<del></del>		
Faik Ucuncu 2009	4	1.7	30	2.2	0.9	30	16.9%	1.80 [1.11, 2.49] 2009	<del></del>		
Zufferey P 2012	3.7	1.4	27	2.4	1.4	29	16.6%	1.30 [0.57, 2.03] 2012	<del>-</del>		
Dogu B 2012	3	1.86	23	2.04	1.22	23	15.4%	0.96 [0.05, 1.87] 2012			
LIN-FEN HSIEH 2013	3.07	1.39	46	3.46	1.25	46	17.7%	-0.39 [-0.93, 0.15] 2013	<del></del>		
Aamir Saeed 2014	4.66	0.94	44	3.72	1.08	46	18.4%	0.94 [0.52, 1.36] 2014	-		
Total (95% CI)			191			194	100.0%	1.19 [0.39, 1.98]	•		
Heterogeneity: Tau <sup>2</sup> = 0.86	6; Chi² =	43.76	df = 5	(P < 0.0	00001)	; I <sup>2</sup> = 89	<del></del>	-4 -2 0 2 4			
Test for overall effect: Z = 2.92 (P = 0.003)									-4 -2 0 2 4		



Fig-3 Forest plot of the decreased SDQ scores at 6 weeks after injection

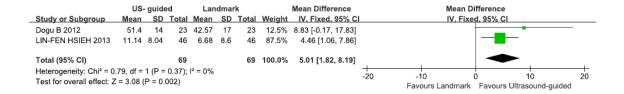




Fig-4 Forest plot of the increased shoulder abduction degree at 6 weeks after injection

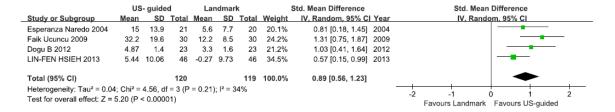




Fig-5 Forest plot of the increased shoulder function scores at 6 weeks after injection

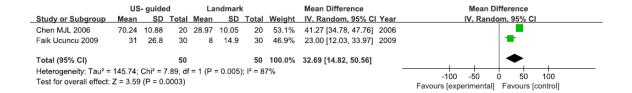




Fig-6 Forest plot of the effective rate comparation

	US- gu	ided	Landmark Risk Ratio				Risk	Ratio				
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl			M-H, Fix	ed, 95% CI		
Faik Ucuncu 2009	12	24	6	18	39.3%	1.50 [0.70, 3.23]			_		_	
Zufferey P 2012	17	27	11	29	60.7%	1.66 [0.96, 2.87]						
Total (95% CI)		51		47	100.0%	1.60 [1.02, 2.50]				<b>~</b>		
Total events	29		17									
Heterogeneity: Chi <sup>2</sup> = 0.04, df = 1 (P = 0.83); $I^2 = 0\%$								0.2	0.5	1 2		10
Test for overall effect: Z = 2.05 (P = 0.04)										Favours U	S-guided	



**Table 1** The characteristics of the enrolled studies for comparing US-guided vs. Landmark guided SASD bursa injection

First author	Publish	Country	Sample size USG/LG (n)	Diagnosis Impingement	Randomization Prospective	Duration of symptoms (months) Mean	
Esperanza Naredo	2004	Spain	21/20	Syndrome; subacromial-subdeltoid	randomized study	duration: 10.2 months	
				bursitis; rotator cuff lesions,	0	>	
Chen MJL	2006	Taiwan	20/20	Subacromial bursitis	Not mention	> 1months	
		Turky	30/30	Impingement Syndrome;	Prospective randomized study	> 1months	
Faik Ucuncu	2009			subacromial-subdeltoid	study		
				bursitis; rotator cuff lesions			
Zufferey P	2012	Switzerland	27/29	Bursitis; Fluid or synovitis	Randomized controlled trial.	Mean duration: 5.5	
1	1		23/23	Subacromial	Double-blind,	months >3	
Dogu B	2012	Turkey		impingement syndrome	randomized study	months	
LIN-FEN HSIEH	2013	Taiwan	46/46	Chronic subacromial bursitis	Rndomized, and singleblind study	> 1 months	
Aamir Saeed	2014	Ireland	44/46	Subacromial impingement syndrome	Randomized single-blinded prospective study	Mean duration: 4.7 months	

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