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Research Article

New Fanwise Subacromial Corticosteroid Injection Technique for Shoulder Impingement: A Preliminary Prospective Single-Arm Clinical Trial

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Abstract

Background: Subacromial (SA) corticosteroid injections (CSI) are a common treatment for shoulder pain. The SA bursa and rotator cuff are often implicated, however, efficacy of SA CSI has been questioned. Outcome variability may be due to patient selection and CSI methodology.

Objective: To examine clinical variables associated with success following fanwise SA CSI over a 6-week follow-up.

Methods: Twenty-nine participants, mean age 58.4 ± 11 years, were included from consecutive convenience sample of patients scheduled for fanwise SA CSI. Participants were evaluated using shoulder clinical tests pre- and post-CSI. Numeric Pain Rating Scale (NPRS) and Shoulder Pain and Disability Index (SPADI) changes were assessed. Friedman and Mann-Whitney tests assessed mean changes with SPADI and NPRS. Fisher's exact test and univariate regression calculated variables associated with success 1- and 6-week post-CSI.

Results: 86% of participants with mean pain duration of 12 ± 32.4 months achieved minimal detectable change (MDC) for SPADI (total) score at 6-week follow-up. Significant improvements were found for mean SPADI (total) score change, reducing from 49.58 ± 17.29 to 10.22 ± 8.16 and 13.20 ± 11.82 at 1- and 6-week follow-up, respectively ($p<0.001$). No variables predicted success with SPADI (total) score at six weeks ($p>0.200$). Mean average NPRS improved from 3.76 ± 1.86 pre-CSI to 1.59 ± 1.62 and 2.10 ± 2.09 at 1- and 6-week follow-up, respectively.

Conclusion: Simple selection of variables, including absence of movement limitations suggestive of adhesive capsulitis and negative Spurling test, with presence of lateral shoulder pain and high rate of positive Hawkins-Kennedy and Neer impingement tests, resulted in 86% success rate following SA bursa CSI at 6-week follow-up.

Keywords: *shoulder impingement syndrome, bursitis, injections, shoulder, pain, steroids*

Introduction

Shoulder pain is commonly treated with corticosteroid injections (CSI) by a variety of providers, including orthopaedists, rheumatologists and family physicians [1]. Subacromial impingement syndrome (SIS), involving the subacromial (SA) bursa and rotator cuff, is a frequent diagnostic label for shoulder pain [2,3]. Subacromial bursa and

rotator cuff histopathology are directly associated with pain through the presence of inflammation, hypertrophy and hyperplasia [2]. Furthermore, the SA bursa has been shown to be particularly susceptible to pain secondary to physical stress and an extensive sensory nerve supply [4]. However, it has been suggested that SA CSI is not efficacious despite widespread use [1,5]. Patient selection, extent of rotator cuff injury and CSI methodology may contribute to outcome variability [1].

Differentiating specific SIS pain sources using shoulder clinical tests is difficult due to complex regional anatomy, tissue confluences, and similarities between shoulder pathology clinical presentations [6-8]. Systematic review articles have previously reported the substantial need to investigate clinical testing accuracy for shoulder pathology [9,10]. However, no single shoulder clinical test should guide clinical decision making and the construct of alternative approaches is warranted [10,11]. Diagnostic imaging can be used as a supplement following a thorough clinical examination, however, asymptomatic pathology may exist, leading to unnecessary healthcare resources [6].

A diagnostic local anaesthetic injection is considered a reference standard test for identifying a pain source when compared to other diagnostic testing approaches [6,12]. A positive anaesthetic response (PAR) from a diagnostic anaesthetic block suggests the therapeutic value for SA CSI. Cadogan et al compared clinical variables against a diagnostic local anaesthetic injection into the SA bursa to identify variables predictive of PAR [6]. Although other structures near the SA bursa may have been exposed to the anaesthetic agent, the findings support using positive clinical predictors, in addition to clusters of tests, as a method for considering a subacromial pain source if an anaesthetic block is not readily available [2,3]. This can improve clinical decision-making guidelines, including the use of SA CSI for shoulder pain alleviation [6].

Multiple directional approaches for SA CSI have been described [13,14]. Lateral approaches have been found to be most accurate for targeting the SA bursa [15]. Corticosteroid injections can also be performed with palpation or image guidance. One recent systematic review found a greater benefit with pain and functional outcome using image guidance, however, further well-executed randomized trials were recommended [16]. Static SA CSI, with no movement of the injection needle, and fanwise SA CSI, using pull-back and redirection, are two infiltration techniques intended to target the SA bursa in clinical practice [17,18]. Corticosteroid injection accuracy and targeting multiple SA bursa areas is an important consideration as a particular location of shoulder pain may be generated from areas that occupy a larger range of anatomical boundaries [6,19].

To our knowledge, the fanwise technique has not been investigated in participant outcomes with lateral shoulder pain, a location considered to arise from SIS [20]. The Shoulder Pain and Disability Index (SPADI) minimal detectable change (MDC) has previously been used to determine responsiveness following SA CSI [21]. Therefore, the objective of this study was to identify demographics, clinical variables and clinical tests associated with a successful response following fanwise SA CSI over a six-week post-CSI period in participants with lateral shoulder pain.

Methods

Participants

The Texas Tech University Health Sciences Center Institutional Review Board granted approval for this research study and the trial was registered NCT02686671.

Two investigators performed the following clinical tests to determine inter-examiner reliability using nine patients with lateral shoulder pain from a local physical therapy outpatient clinic: (1) shoulder flexion, external rotation, abduction and internal rotation passive ROM; (2) Spurling test; (3) Hawkins-Kennedy test; (4) Neer impingement test; (5) painful arc of abduction; and (6) Pull Test, which has been proposed as an SIS clinical test to differentiate SA bursitis from rotator cuff conditions [22,23]. Following reliability testing, 29 participants were included from a consecutive

convenience sample of 38 patients scheduled for fanwise SA CSI between the periods of January 2017 and February 2018. Past medical history was screened for inclusion and exclusion criteria.

For inclusion, the following criteria were: (1) age 18 to 80 years; (2) one or more positive shoulder clinical tests out of the following: Hawkins-Kennedy test, Neer impingement test, and painful arc of abduction; (3) lateral shoulder pain between 2/10 and 10/10 on Numeric Pain Rating Scale (NPRS) during resisted shoulder abduction; and (4) SPADI (total) score greater than or equal to 20 [12,24,25].

For exclusion, the following criteria were: (1) large three-dimensional limitation with any passive range of motion (ROM) of the shoulder as compared to the contralateral side, to rule out adhesive capsulitis; (2) shoulder surgery within the last six months; (3) CSI to the involved shoulder within the past three months; (4) systemic inflammatory condition; (5) radiculopathy during cervical spine active ROM; (6) cervical spine pain as a primary complaint (7) lateral shoulder pain reproduction during Spurling test; (8) inability to undergo a follow-up phone call; (9) neurological disorders that would prevent clinical test performance and (10) pregnancy by self-report [26-28].

Study design

A non-randomized, exploratory study, with repeated measures for pain and disability, was conducted to identify variables associated with successful fanwise SA CSI in participants with lateral shoulder pain.

Power analysis

Calculations conducted with G*Power statistical software, considering an α level set at 0.05, power 1-β set at 0.8 and large effect size of 0.6 to assess differences in magnitude of change with SPADI (total) score, led to a sample size of 25 to detect a significant difference based on SPADI (total) score minimal detectable change (MDC) of 18 points [21,29]. Therefore, 38 participants were recruited to allow for attrition during data collection and follow-ups, leading to 29 participants included in data analysis.

Testing sequence

Each participant read slide presentation printouts explaining study procedures followed by informed consent and medical history questionnaire. A pre-CSI pain questionnaire for average and current shoulder pain (NPRS) and SPADI were then completed to identify changes over the follow-up period.

Prior to their scheduled fanwise SA CSI as part of their plan of care, each participant within a private treatment room underwent a series of cervical and shoulder clinical tests similar to those performed during the reliability portion of testing by Investigator 1. For the first two tests, participants exhibiting three-dimensional limitations of passive ROM within any plane indicative of adhesive capsulitis and/or a positive Spurling test were excluded from the study. If passive ROM and Spurling test were negative, the following shoulder clinical tests were performed with at least one required to be positive to participate further: (1) Hawkins-Kennedy test; (2) Neer impingement test; and (3) painful arc of abduction. Next, the Pull Test, involving comparison of shoulder pain produced between resisted shoulder abduction alone at 0° shoulder abduction and resisted shoulder abduction simultaneous with manually performed humeral long-axis traction by the investigator was performed. Force level for resisted shoulder abduction alone was measured using a dynamometer (Chatillon® DF II Series Digital Force Gauge). For resisted shoulder abduction with traction, traction force was applied at mid-humerus level by one of the investigator's hands. The traction amount was determined by the maximum sulcus distance obtained between the lateral acromion and humerus monitored by the investigators' thumb of the other hand, with no inferior movement of the shoulder girdle detected. The participant was instructed to push outward from their distal humerus into the chest of the investigator positioned adjacent for this portion of the Pull Test. Maximum resisted shoulder abduction, with force level recorded, was the final test performed (Figure 1).

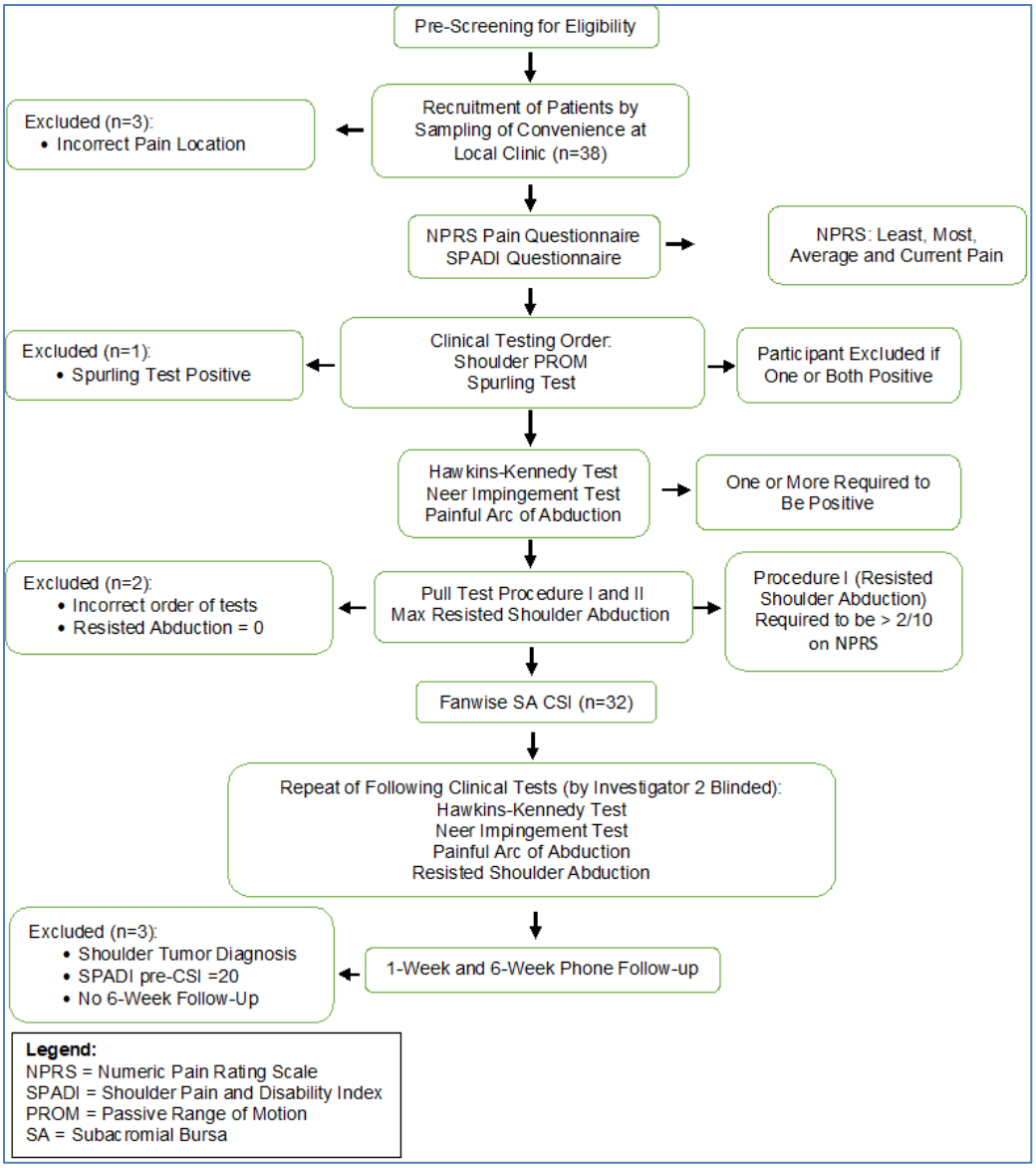

Figure 1: Flow chart of the study

Following clinical testing, each participant underwent fanwise SA CSI (Figure 2) using a blind lateral approach performed by a pain medicine physician or physician assistant with over 30 years of experience [30]. For the CSI, a standard solution consisting of 9cc of 0.25% bupivacaine with 1:200,000 epinephrine and 40 mg of triamcinolone (Kenalog®) was administered using a 9 cm 22- or 25-gauge needle [31-33]. Manually performed humeral long-axis traction was performed by a medical assistant when a patient was unable to relax, which can affect the entry point into the AHI (Figure 2) [18].

Approximately 30-minutes post-CSI (to allow for anaesthetic to take effect and post-injection vital signs to be charted by a medical assistant), Investigator 2 performed the previous series of shoulder clinical tests in the same order except for shoulder passive ROM and Spurling test, which were not performed. The Pull Test was not performed, however, resisted shoulder abduction alone was included as a test to compare with the pre-CSI result. The second investigator was blind to the results of pre-CSI testing with exception of force applied during resisted shoulder abduction pre-CSI, with a similar force used for resisted shoulder abduction post-CSI to identify pain level change.

Maximum resisted shoulder abduction was performed last with force and pain level recorded. One-week and six-week phone follow-ups were conducted post-CSI. Each participant was allowed to continue their current physical therapy regimen if applicable.

Figure 2. Fanwise subacromial corticosteroid injection performed on participants: needle infiltration involves partial pull-back and re-direction (**2A**) with humeral traction (**2B**) applied if necessary

Statistical analysis

Data were analyzed using SPSS software (version 20.0). Descriptive statistics were used to record demographic characteristics, NPRS and SPADI scores.

Inter-examiner reliability was assessed using kappa and percent agreement. Friedman test, with Wilcoxon signed-ranks test for pairwise comparisons, was used to determine if SPADI (total) score and average NPRS demonstrated significant changes over time. Effect size (r) was calculated to determine the magnitude of the difference for each pairwise comparison [34,35]. Mean differences (Mann-Whitney) in average NPRS and SPADI (total) score for positive and negative Pull Test groups were analyzed for follow-up periods. Effect size estimates of variance (r^2) were calculated to identify the percentages of variability in the dependent variables (SPADI, NPRS) explained by each Pull Test group [35,36].

Fisher's exact test was calculated to evaluate dichotomous variable association, including clinical test outcomes, gender, and hand dominance, with SPADI (total) score one-week and six-week post-CSI. Univariate regression was used to determine if demographics, clinical variables and clinical tests were predictive of successful response one-week and six-week post-CSI ($p \leq 0.200$). Sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios, and odds ratios were calculated for shoulder clinical tests.

Results

Nine participants age 61 ± 8.2 years with lateral shoulder pain were included in reliability testing. Percentage of agreement for Pull Test [positive (NPRS ≥ 2 decrease) or negative (NPRS ≤ 1 decrease)] between the two investigators was 89% with kappa (κ) of 0.78. Percentages of agreement for identifying a positive or negative test result for Spurling test and passive ROM testing for adhesive capsulitis were 100%.

Twenty-nine participants (12 males, 17 females; 58.4 ± 11.0 years) were included in final data analysis. Demographic data are presented in Table 1. Nine participants were excluded from final data analysis for the following reasons: SPADI total score less than 20 (1); positive Spurling test (1); resisted shoulder abduction pain level less than 2/10 (1); incorrect location of lateral shoulder pain (3); incorrect order of clinical tests (1); alternate diagnosis requiring

emergency medical care prior to the six-week follow-up (1); inability to complete the six-week follow-up (1). Pre- and post-CSI clinical testing results are presented in Table 2.

Table 1. Participants' Demographic Characteristics (2017-2018)

Demographic Information	**Mean (SD)**	**Range**
Age, years	58.4 (11.0)	37-78
Height, m	1.7 (0.1)	1.5-2.0
Weight, kg	84.3 (22.8)	49.4-145.2
BMI	28.3 (5.6)	20.6-44.1
Symptom duration, weeks	53.0 (129.4)	1-720
Number of PT Sessions[a]	2.3 (2.9)	
	n (%)	
Male gender, n (%)	12 (41)	
Right hand dominant, n (%)	28 (97)	
Dominant arm affected, n (%)	15 (52)	
No. undergoing PT, n (%)	16 (55)	
Smoker, n (%)	2 (7)	

BMI: Body Mass Index; PT: Physical Therapy
[a]Not all participants underwent PT

Table 2. Pre-CSI and Post-CSI Clinical Testing Results (2017-2018)

	Pre-CSI		**Post-CSI**	
Clinical Test	***n* = 29**		***n* = 29**	
Hawkins-Kennedy Test[a], *n* (+)	28		10	
Neer Impingement Test[a], *n* (+)	26		0	
Painful Arc of Abduction[a], *n* (+)	7		5	
Resisted Abduction, *n* (+)	29		4	
Pull Test[b], *n* (+)	16			
NPRS Levels	**Mean (SD)**	**Range**	**Mean (SD)**	**Range**
Resisted Abduction, NPRS	4.93 (1.73)	2-10	0.59 (1.21)	0-5
Pull Test[b], NPRS	2.72 (2.80)	0-9		
Maximum Resisted Abduction[c], NPRS			1.24 (1.68)	0-6
Force (Dynamometer)	**Mean (SD)**	**Range**	**Mean (SD)**	**Range**
Resisted Abduction, lb.	14.14 (7.59)	2.80-31.60	14.21 (7.61)	2.90-31.30
Maximum Resisted Abduction, lb.	17.93 (10.60)	2.60-49.00	20.50 (10.44)	4.40-50.20

ROM: Range of Motion; NPRS: Numeric Pain Rating Scale; (+): Positive Test Only
[a]NPRS not recorded; [b]Not performed after injection; [c]Not recorded before injection

90% of participants demonstrated significant improvement based on SPADI (total) score MDC at one-week follow-up and 86% at six-week follow-up. 78% of participants demonstrated minimal clinically important difference (MCID) (≥ 2 decrease in average pain level) at one-week follow-up and 63% at six-week follow-up. Two participants did not achieve MCID for average pain level due to NPRS ≤ 1/10 prior to CSI. 100% of participants achieved MCID for shoulder resisted abduction post-CSI, decreasing from a mean pain level of 4.93 to 0.59.

Friedman test showed significant improvement for SPADI (total) score (p<0.001) and average pain level (p<0.001) between pre-CSI and one- and six-week follow-up periods for the entire sample. Post-hoc analysis with Wilcoxon signed-rank test with Bonferroni correction produced significance at alpha <0.017. Significant differences were found for SPADI (total) score pre-CSI to the one-week (p<0.001, r=-0.618) and six-week (p<0.001, r=-0.618) follow-up, but no difference between the one-week and six-week (p=0.2259, r=-0.159) follow-up. Significant differences were found for average pain level from pre-CSI to the one-week (p<0.001, r=-0.529) and six-week (p<0.001, r=-0.449) follow-up, but no difference between the one- and six-week (p=0.2046, r=-0.167) follow-up.

The Pull Test resulted in 16 positive (NPRS ≥ 2 decrease) and 13 negative (NPRS ≤ 1 decrease) tests pre-CSI. Mean pain level was 4.93 ± 1.73 during resisted shoulder abduction alone and 2.72 ± 2.80 with resisted shoulder abduction and traction applied together during pre-CSI clinical testing. 81% achieved MDC for positive Pull Test group and 92% achieved MDC for negative Pull Test group regarding SPADI (total) score at six-week follow-up. Table 3 provides mean SPADI (total) score and NPRS changes from pre-CSI to the one-week and six-week follow-ups for entire sample and positive and negative Pull Test groups.

Table 3. SPADI and NPRS Pre-CSI and Follow-Up Scores (2017-2018)

	Entire Sample		**Positive Pull Test Group**		**Negative Pull Test Group**	
SPADI	**Mean (SD)**	**Range**	**Mean (SD)**	**Range**	**Mean (SD)**	**Range**
***Pre-CSI*:**						
Total Score	49.58 (17.29)	23.08-88.46	46.39 (19.01)	23.08-88.46	53.49 (14.69)	23.85-83.08
***One-Week Follow-Up*:**						
Total Score	10.22 (8.16)	0.00-35.45	11.28 (10.01)	0.77-35.45	8.90 (5.16)	0.00-15.38
***Six-Week Follow-Up*:**						
Total Score	13.20 (11.82)	0.00-47.69	15.10 (13.19)	0.00-47.69	10.87 (9.91)	0.00-27.27
NPRS						
***Pre-CSI*:**						
Average	3.76 (1.86)	1-8	3.50 (2.16)	1-8	4.08 (1.44)	2-7
***One-Week Follow-Up*:**						
Average	1.59 (1.62)	0-7	1.63 (1.82)	0-7	1.54 (1.39)	0-4
***Six-Week Follow-Up*:**						
Average	2.10 (2.09)	0-10	2.25 (2.49)	0-10	1.92 (1.55)	0-6
SPADI: Shoulder Pain and Disability Index; NPRS: Numeric Pain Rating Scale						

Mann-Whitney test showed no significant mean differences at pre-CSI, one-week and six-week follow-up periods in SPADI (total) score and current and average NPRS between positive and negative Pull Test Procedure II groups (p>0.05). Effect size estimate of variance (r^2) with SPADI (total) score for pre-CSI, one-week and six-week follow-up

periods were 0.062, 0.001 and 0.035, respectively. Effect size estimate of variance (r^2) with average NPRS for pre-CSI, one-week and six-week follow-up periods were 0.058, 0.001 and 0.001, respectively. Current NPRS pre-CSI demonstrated a r^2 value of 0.017.

Fisher's exact test results produced one variable showing success based on SPADI (total) score. Negative painful arc of abduction showed association with success at one-week follow-up (p=0.0096). Univariate regression analysis resulted in no variables predicting fanwise SA CSI success (p>0.200). Contingency cell counts with diagnostic accuracy analyses for shoulder clinical tests are listed in Table 4.

Table 4. Diagnostic Accuracy of Clinical Tests (2017-2018)

Success at One Week[a]	**Contingency Cell Counts**				**Diagnostic Accuracy**						
Clinical Test:	**TP**	**FN**	**FP**	**TN**	**Sn (%)**	**Sp (%)**	**PPV**	**NPV**	**(+) LR**	**(-) LR**	**OR**
Pull Test	13	13	3	0.5	50.00	14.28	81.25	3.70	0.58	3.50	0.17
Hawkins-Kennedy Test	25	1	3	0.5	96.15	14.28	89.29	33.30	1.12	0.27	4.17
Neer Impingement Test	23	3	3	0.5	88.00	14.28	88.46	14.28	1.03	0.81	1.28
Painful Arc of Abduction	4	22	3	0.5	15.38	14.28	57.14	2.20	0.18	5.92	0.03
Success at Six Weeks[a]											
Clinical Test:	**TP**	**FN**	**FP**	**TN**	**Sn (%)**	**Sp (%)**	**PPV**	**NPV**	**(+) LR**	**(-) LR**	**OR**
Pull Test	13	12	3	1	52.00	25.00	85.71	7.69	0.69	1.92	0.36
Hawkins-Kennedy Test	25	0.5	3	1	98.03	25.00	89.29	66.67	1.31	0.08	16.67
Neer Impingement Test	23	2	3	1	92.00	25.00	88.46	33.33	1.23	0.32	3.83
Painful Arc of Abduction	6	19	1	3	24.00	75.00	85.71	13.64	0.96	1.01	0.95

TP: True Positive; FN: False Negative; FP: False Positive; TN: True Negative; Sn: Sensitivity; Sp: Specificity; PPV: Positive Predictive Value; NPV: Negative Predictive Value; LR: Likelihood Ratio; OR: Odds Ratio

Discussion

This is the first study to our knowledge to report follow-up changes in pain and disability in participants with SIS and lateral shoulder pain treated with only one fanwise SA CSI, resulting in an 86% success rate at six-week follow-up. This is difficult to compare to other studies due to variations in protocol including injection technique and outcome measure used. However, Fawcett et al. reported a mean success rate of 63.6% based on SPADI (total) score MDC at the six-week follow-up [38]. In contrast to our study, diagnostic ultrasound to identify SIS severity sub-groups and guided CSI were conducted within a larger sample size, leading to a range of success levels depending upon diagnosis.

To our knowledge, an 86% success rate based on SPADI (total) score MDC is the highest obtained compared to previous research reports. History-taking and clinical testing were geared toward excluding those participants with adhesive capsulitis, positive Spurling test, and worker's compensation claims, which could explain the high success rate reported in the present study. However, previous studies have incorporated similar criteria for inclusion and exclusion [13,39,40].

Improvement in mean SPADI (total) score for our study did not appear to be affected by variables such as pain chronicity. Previous studies investigating patients with shoulder pain duration of three months or more have reported mean improvements of 14% and 24% at six-week follow-up periods [13,39]. Improvements from 46% at baseline to 23% and 25% at one- and three-month post-CSI, respectively, were reported in a population with a mean pain duration of 6.5 months. However, participants were permitted to receive more than one CSI [40]. Mean SPADI (total) score improvement for our study, with a mean pain duration of 12 months, was 36.3%, decreasing from 49.6% pre-CSI to 13.2% at six-week follow-up.

Our main purpose was to investigate the ability of clinical variables to forecast one- and six-week follow-up responses for patients with lateral shoulder pain following fanwise SA CSI. Due to a high success rate for participants in this study, identifying variables statistically associated with level of responsiveness to SA CSI was difficult as many participants demonstrated a large improvement with pain and disability. Therefore, variables were identified which represented a common theme among a majority of participants. These variables included the presence of lateral shoulder pain, negative adhesive capsulitis testing and a high rate of positive Hawkins-Kennedy and Neer impingement tests.

It has been previously suggested that a significant decrease in pain, or complete resolution of pain, with Pull Test pointed to the SA bursa as a pain generator [22,23]. Our study did not support this assumption as participants with positive and negative Pull Tests did equally well following fanwise SA CSI. One potential explanation is the anatomical layout of the AHI. Our study was not diagnostic for specific AHI tissue conditions, however, influences between the SA bursa and rotator cuff should be noted. Due to confluences and potential communication between structures, isolated involvement of an intended target cannot be assumed with fanwise SA CSI [6].

Fanwise CSI may serve as a contributor to the high rate of success for this study. This technique has been described in medical texts; however, to our knowledge it has not been investigated directly or compared against a static approach [17]. There are variations in volume of anaesthetic and corticosteroid used in previous studies. However, no significant differences for pain and outcome measure results have been found for 4 cc compared to 9 cc of anaesthetic and 20 mg compared to 40 mg of triamicinolone acetonide [31,32]. Based on fanwise SA CSI outcomes observed, future randomized clinical trials comparing this CSI technique with others over long-term follow-ups are warranted to identify if significant improvements can be maintained.

Limitations of the study include no diagnostic imaging used for participants. This may have impacted accuracy for CSI, therefore, future studies using ultrasound are recommended to identify if this may have contributed to the large success rate due to multiple subacromial structures influenced by the solution. Shoulder pain mechanism for onset and cervical pain histories were not intensively reported and may have influenced those participants not achieving SPADI (total) score MDC or pain level MCID.

Conclusion

Simple clinical selection of demographics, pain characteristics and clinical tests, including absence of limitations of movement suggestive of adhesive capsulitis, negative Spurling test and no worker's compensation claim, with the presence of lateral shoulder pain and high rate of positive Hawkins-Kennedy and Neer impingement tests, resulted in superior SA bursa CSI outcomes with 86% success at six-week follow-up.

Declarations/Acknowledgements

1. This study protocol was approved by the Texas Tech University Health Sciences Center Institutional Review Board. IRB Number L16-047
2. Trial was registered at ClinicalTrials.gov Identifier: NCT02686671
3. The authors of this manuscript have no financial affiliation (including research funding) or involvement with any commercial organization that has a direct financial interest in any matter included in this manuscript.

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