Ultrasound guided versus landmark guided corticosteroid injection in patients with rotator cuff syndrome: Randomised controlled trial

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ABSTRACT

Objective: Impingement syndrome is the most common differential in a patient presenting to an orthopaedic OPD with shoulder pain. Impingement syndrome is often managed with subacromial corticosteroid injection, which can be instilled using either landmark guided (LMG) approach or with the assistance of ultrasound (US). This study was envisaged to enquire whether ultrasound assistance improves the accuracy, efficacy or safety profile of the injection.

Methods: 60 patients of rotator cuff syndrome underwent diagnostic ultrasound. They were randomly assigned to receive subacromial injection of 2 ml (40 mg/ml) methylprednisolone and 2 ml of 1% lignocaine combination either by US assistance (n=30) or using LMG assistance (n=30). The patients were evaluated before injection and on follow up visits at day 5, week 3, week 6 and 3rd month by a single assessor. The assessor was blinded of the treatment group to which patient belonged. Clinical assessment included demographic and clinical data, accuracy of injection, VAS (0–100) for pain, Constant score with goniometer evaluation of range of motion, patient's self assessment proforma and post injection side effects if any.

Results: Initial demographic, clinical and US findings in the groups exhibited no significant differences. The accuracy of US guided injections (100%) was more when compared from LMG injection (93.3%). Both VAS and Constant score showed significant improvement following steroid injection up to 3 months of follow up. However the differences in the two groups were not significant suggesting comparable efficacy of the two approaches. (Mean VAS score decrease: 27.23 for US and 25.16 for LMG, $p < 0.05$; Mean constant score change: 14.73 for US and 15.00 for LMG, $p < 0.05$). The safety profile in both groups was comparable.

Conclusion: Although US guided injections have a higher accuracy of drug placement in the subacromial bursa, there is no difference in terms of clinical outcomes or safety profile of either of the method. Hence US guided injections seems to be unjustified, when compared to equally efficacious and cost effective LMG steroid injection

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1. Introduction

Shoulder disorders are common in general practice with an incidence of 12–25 per thousand per year.^{1,2} The differential diagnosis of shoulder pain in adults mainly include partial or complete rotator cuff tear, calcific tendinitis, adhesive capsulitis, impingement syndrome and nerve entrapment syndromes of

which one of the most common differential diagnosis is the rotator cuff syndrome³ (RCS). Bodin et al.⁴ reported that prevalence rates of RCS in males and females are 6.1% and 7.3% respectively.

Most patients with a rotator cuff syndrome (RCS) can be treated conservatively with combinations of activity modification, physical therapy, NSAIDs and supplementation with corticosteroids injections. Subacromial corticosteroid injection is a useful therapy especially if activity modification and medications are ineffective for pain relief. Landmark guided (LMG) approach for subacromial corticosteroid injections (CSI) for rotator cuff pathologies have a variable success rate of 30–80%.⁵ However, this can not be generalised as various factors such as local anatomy, peripheral fat

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distribution, Body mass index (BMI), different length needles used and expertise of the clinician determines the chances of accurate placement of needle in subacromial bursa. Subacromial placement of drug can be made by radiological assistance of ultrasound (US), CT and MRI. However, the radiological assistance comes with the drawbacks of added cost, requires more expertise and time.

Few studies have tried to investigate the requirement of radiological assistance in placing the subacromial-subdeltoid injections. These studies have given conflicting results.^{5–9} A recent systematic review by Soh et al.¹⁰ reported paucity of randomised control trials on image guided versus LMG steroid placement and recommended further studies. In this study we aim to investigate whether the use of US improves the accuracy of steroid placement in subacromial- subdeltoid space vis-à-vis LMG injection and if so whether there is a significant difference in clinical outcome and safety in the two defined groups.

2. Material & methods

Our study was a randomised clinical controlled trial. We recruited 60 patients of RCS presenting to the orthopaedic OPD in Guru Teg Bahadur Hospital, Delhi from October 2012–December 2013. We included patients who were at least 18 years old with following features: History of shoulder pain for at least two months that has been not satisfactorily responsive to a trial of oral medication and physical therapy for at least last one month, history of night pain, pain on overhead abduction, less than 50% reduction in glenohumeral range of motion in not more than one direction of external rotation, internal rotation or abduction or positive impingement test.

We excluded patients with history of inflammatory joint disease, significant trauma, periarticular arthritis, allergy to contrast agents, previous history of steroid injection in the same shoulder. Patients with symptomatic acromioclavicular arthritis, full thickness rotator cuff tear, pregnant patients and those who did not wish to participate in the study were also excluded.

Baseline parameters like age, sex, BMI, side of shoulder involved, duration of symptoms, diurnal or nocturnal pain and occupational requirements of the patients were recorded. Detailed history was obtained from the patients. Relevant physical

examination was done including the specific clinical tests such as Neer's impingement sign, Hawkins-Kennedy test, Jobe's empty can test, lift-off test, belly press test, painful arc test and drop arm test. Routine investigations (haemogram, white blood counts, blood sugar level, erythrocyte sedimentation rate, RA factor, serum uric acid level and C reactive protein) were done. X-ray of the affected shoulder in true antero-posterior view was done to exclude fracture, glenohumeral osteoarthritis, osteonecrosis and other bone conditions. Patients were explained home based shoulder rehabilitation program. Both active and passive range of motion of both the shoulders was measured in flexion, extension, internal and external rotation using a goniometer. VAS score and baseline constant score were evaluated before subacromial steroid injection by a single orthopaedic surgeon. Patients were asked to continue home exercise program. All the patients included in the study underwent a US evaluation as per the diagnostic criteria.¹¹ All diagnostic US scans were performed by a single radiologist within one week of clinical evaluation. Within 10 days of US evaluation, the patients were randomly allocated to receive US guided or LMG injection based on random number sequence. The clinician who performed the randomisation was blinded of the clinico-radiological assessment of the patients.

2.1. Interventions

All the procedures were performed under strict sterile and aseptic conditions.

2.1.1. Group 1 (ultrasound guided, USG)

A single experienced radiologist performed the US imaging using the Phillips HD 7 US machine with 7–10 MHz multi frequency broad band transducer. Intradermal drug testing with lignocaine was performed 30 min prior to the procedure. A 10 ml syringe connected to 5 cm, 21 Gauge needle was prepared with 2 ml of 40 mg/ml Methylprednisolone Acetate suspension mixed and 2 ml of 1% lignocaine. Patient was seated with the affected arm in hyperextension and internal rotation with elbow bent and back of the hand resting against the lower back. Needle with syringe containing methylprednisolone-lignocaine mixture was inserted parallel to the transducer in a semi oblique plane from the anterior side of the shoulder (Fig. 1). The bevelled side facing the transducer, the needle was advanced under the real time US assistance till the tip of the needle appeared in subacromial bursa (Fig. 2). Rotation of the bevelled side of the needle by 180° was

Fig. 1. Clinical photograph depicting advancement of needle to right subacromial bursa under US guidance.

Fig. 2. US image depicting needle shadow in subacromial bursa.

Fig. 3. US image depicting swollen subacromial bursa after injection.

done for confirmation of the tip positioning. The preparation was instilled and the bulging of subacromial bursa ascertained in the real time imaging (Fig. 3).

2.1.2. Group 2 (landmark guided, LMG)

A single orthopaedic surgeon neither involved in recording clinical assessment of the patients, nor in the randomisation of the patients performed all the LMG injections. Intradermal skin testing

Fig. 4. Clinical photograph depicting landmark guided injection in left subacromial bursa.

Fig. 5. Fluoroscopic image depicting dye in subacromial bursa.

with lignocaine and iohexol was performed 30 min prior to procedure. A 10 ml syringe connected to 5 cm, 21 gauge needle was prepared with 2 ml of 40 mg/ml Methylprednisolone Acetate suspension mixed, 2 ml lignocaine and 2 ml of radio opaque non- ionic contrast media iohexol (1-N, 3-bis (2,3-dihydroxypropyl) –5- [N – (2, 3-dihydroxypropyl) acetamido-2,4,6 triiodobenzene-1, 3-dicarboxamide). The patient's skin was sterilised with spirit. Access to the subacromial space was achieved using the lateral approach to the subacromial space, inserting the needle just inferior to the midlateral aspect of the acromion, with the needle angled slightly cephalad, passing through the deltoid muscle, and directed medially and slightly anterior to the subacromial bursa (Fig. 4). Care was taken to avoid injection directly into the tendons of the rotator cuff. Correct placement of the drug in the subacromial subdeltoid space was confirmed by the fluoroscopic assessment under the C arm within 10 min of the injection (Fig. 5). Patients were observed for development of drug allergy due to iohexol. Accuracy of correct instillation of Methylprednisolone-Lignocaine-Iohexol combination was assessed by a senior radiologist.

All the patients were prescribed a 5 day course of antibiotics for prevention of injection induced subacromial bursitis.

2.1.3. Follow up

Follow Up visits were scheduled on day 5, 3rd week, 6th week and 3rd month from the day of injection. Patients were evaluated by the same clinician who evaluated the patient prior to the injection. Constant score and VAS score were evaluated and documented. The clinician was blinded of the clinico-radiological findings of the patient and the treatment group to which the patient belongs. On each follow up visit, patients were reinforced to continue home exercise program consisting of shoulder abduction and pendulum exercises. Patients were not prohibited

Table 1

Patients' demographic and clinical characteristics.

	USG	LMG	p-value
Age (yrs), mean (SD)	44.53 (9.2)	42.03 (9.9)	>0.05
Sex, number (%)			
Male	13 (43.3)	20 (66.6)	>0.05
Female	17 (56.6)	10 (33.3)	
Smoking status, number (%)			
Smokers	18 (60)	20 (66.6)	>0.05
Non-smokers	12 (40)	10 (33.3)	
Occupational demand, number (%)			
Heavy weight	22 (73.3)	16 (53.3)	>0.05
Light weight	8 (26.6)	14 (46.6)	
Constant score, mean (SD)	63.9 (7.889)	58.90 (9.204)	>0.05
VAS, mean (SD)	52.93 (1.910)	48.13 (11.515)	>0.05

LMG: Landmark guided; USG: Ultrasound guided, VAS visual analogue scale, SD: Standard deviation.

Table 2
US Findings.

Diagnosis	Group 1	Group 2	Total
SS Tendinitis	22	18	40
SS Partial Tear	13	25	38
IS Tendinitis	4	1	5
IS Partial Tear	3	1	4
SB Tendinitis	3	2	5
SB Partial Tear	2	1	3
Biceps Tendinitis	2	3	5
SA SD Bursitis	2	5	7
ACCL Involvement	0	0	0
Impingement	30	30	60
B T Subluxation	0	0	0
B T Rupture	0	0	0
GH Effusion	0	0	0
TM partial tear	0	0	0

SS: Supraspinatus, SB: Subscapularis, SA SD: Subacromial Subdeltoid, ACCL: Acromioclavicular, GH: Glenohumeral, TM: Teres Minor, B T: Biceps Tendon.

from the use of analgesics or using the affected shoulder during follow up period.

2.2. Statistical analysis

To obtain comparisons between and within groups, Repeated Measure ANOVA followed by Tukey's test was used. A *p* value less than 0.05 was considered significant. The data was entered in MS Excel worksheet. The statistical software used was SPSSv 20.0.

3. Results

There were no significant differences between the two groups for age, sex, occupational demands, smoking status, baseline VAS score or constant score (Table 1) and US pathologic findings (Table 2). In group 1, all 30 injections were instilled in the desired subacromial bursa making it 100% accurate. In group 2, only two LMG injections could be instilled partially in the subacromial bursa as observed by fluoroscopy done after the CSI. Rest 28 were accurately instilled into the desired subacromial space making the LMG injection 93.3% accurate.

In group 1, the differences in constant score and VAS score between Day 0 to Day 5 (mean difference 12.9 & 27.93 respectively) and between day 0 and 3 month (mean difference 14.73 & 27.23) was also found to be statistically significant ($p < 0.05$). The difference of constant score & VAS score between day 5 and week 3, week 3 and week 6 or between 6 week and 3 month were not statistically significant ($p > 0.05$). In group 2, the difference in

Fig. 6. Comparison of trends in CS. **Fig. 7.** Comparison of trends in VAS score.

constant score and VAS score between day 0 and day 5 (mean difference 12.9 & 27.83) and between day 0 and 3 month (mean difference 15.0 & 25.16) was found to be statistically significant ($p < 0.05$). The difference of constant score & VAS score between day 5 and week 3, week 3 and week 6 or between 6 week and 3 month were not statistically significant ($p > 0.05$) (Tables 3 and 4, Figs. 6 and 7)

None of the 60 patients reported of any side effect following methylprednisolone injections hence supporting the safety profile of steroids in the subacromial bursa. None of the patients developed allergic reaction to lignocaine or iohexol.

Table 3
Constant score at day 0, day 5 (5D), week 3 (3W), week 6 (6W) and 3rd month (3mn).

	CS 0D		CS 5D		CS 3W		CS 6W		CS 3mn	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group I (n = 30)	63.90	7.889	76.80	8.861	78.57	8.657	78.53	8.740	78.63	8.227
Group II (n = 30)	58.90	9.204	71.80	8.548	72.70	7.598	73.10	7.434	73.90	7.160
Total (n = 60)	61.40	8.499	74.30	8.631	75.63	8.087	75.81	8.048	76.266	7.674

Table 4
VAS score at day 0 (0D), day 5 (5D), week 3 (3W), week 6 (6W) and 3rd month (3mn).

	VAS 0D		VAS 5D		VAS 3W		VAS 6W		VAS 3mn	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group I (n = 30)	52.93	11.910	25.00	13.463	22.67	12.647	22.40	10.682	25.70	13.044
Group II (n = 30)	48.13	11.515	20.30	8.619	20.23	8.419	20.87	8.669	22.97	9.412
Total (n = 60)	50.53	11.864	22.65	8.619	21.45	10.722	21.63	9.676	24.33	11.361

4. Discussion

Corticosteroid injections have a proven role in management of patients with RCS. Various studies^{12–18} have supported the role of subacromial steroid injection in patients with RCS. The variables compared in the two subgroups were VAS and Constant scores.

In group 1 (US Guided), the mean baseline Constant score was 63.90 and at 3 months follow up it was 78.63 (mean increase of 14.73). In group 2 (LMG), the mean Constant score from baseline of 58.9 improved to 73.90 (mean increase of 15.0). Ucuncu¹⁹ performed a study in which no specific shoulder pain cases were taken which showed Mean increment of 32.2 in US guided group and 12.2 in other group whereas this study was about specific rotator cuff syndrome.

Zufferey et al.²⁰ stated that clinical difference is evaluated at a difference of 16 to 20 points in Constant Score. In our study 11 patients in group 1 and 12 patients in group 2 achieved more than 16 points increment at 3 months follow up when compared from the baseline. There was no statistical difference in number of responders and non responders.

Constant score is reliable in following patient progress after surgery, injury or conservative treatment.²¹ The score is easy to use and has low inter- and intra observer errors.²² Soh et al.¹⁰ reported Constant score as a validated scale for measuring shoulder function. Ucuncu et al.¹⁹ used Constant score and VAS scores as outcome measures for comparison of LMG and US guided subacromial CSI in patients with shoulder pain. Karthikeyan et al.¹⁸ also used Constant score as a primary outcome measure to establish efficacy of CSI in patients with rotator cuff syndrome.

VAS as an outcome measure has been used in previous studies to compare US guided and LMG injections.^{19,23,24} Ucuncu et al.,¹⁹ achieved mean decrease of 34.9 in US group and 7.1 in LMG group in VAS scale of 0–100. Naredo et al.²⁵ achieved mean difference of 4.0 in US guided group and 2.2 in LMG in VAS scale of 0–10. In our study we observed that 18 patients (60%) in group 1 and 16 patients (53.3%) in group 2 achieved $\geq 50\%$ reduction at 3 months follow up. There was no statistical difference in number of responders and non responders. Naredo et al.²⁵, reported that one out of 20 patients in landmark group and 11 out of 21 patients in US guided group achieved $\geq 50\%$ reduction in VAS score following steroid injection. The patients with painful shoulder were included in their study. Ucuncu et al.,¹⁹ reported 7 patients of 30 in LMG group and 25 patients of 30 patients in US guided group achieved $\geq 50\%$ reduction in VAS scores at 6 week follow up following subacromial steroid injection in patients with shoulder pain.

Both groups in our study showed statistically significant improvement in both Constant score and VAS score following subacromial steroid injections. However the intergroup differences of both the scores were not significant. The result portrays ultra sound assisted steroid injections have comparable clinical outcomes as landmark guided subacromial injections.

Subacromial steroid injections are routinely performed by orthopaedic surgeons on an outpatient basis. These injections can be performed with help of LMG approach. Over the past few years, there has been a recent trend in assistance of imaging such as US in guiding the placement of subacromial steroid injections. US is safe and accurate technique for guiding aspiration and infiltration that ensures more accurate placement of delivery of drug.¹⁸ US guided injections allow direct visualisation of the needle in real time in the subacromial bursa. However, performance of an accurate shoulder US examination requires a skilled and experienced operator with very good knowledge of shoulder anatomy, US scanning technique and normal imaging findings²⁶. US imaging comes at an additional burden on the existing manpower and increases the cost of treatment.

5. Conclusions

In our study we found US guided injection to be more accurate, however, it did not provide any significant advantage in terms of clinical outcome or safety profile when compared to patients receiving steroid injections using LMG approach. However, it was found that combining exercise with CSI improves the effectiveness of injection. We conclude that in subacromial impingement secondary to rotator cuff disease, clinical outcome and safety profile of US guided CSI and LMG CSI are comparable. Hence additional cost and requirement of skilled manpower needed for US guided injections not only increases the overall health burden on an economically deprived health set up in developing countries like ours, but also seems to be unjustified to equally efficacious and cost effective LMG CSI.

Conflict of interest

The authors have none to declare.

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