SCIENTIFIC ARTICLE

COMPARATIVE EFFECTIVENESS OF ULTRASOUND GUIDED INTRATENDINOUS PROLOTHERAPY INJECTION WITH CONVENTIONAL TREATMENT TO TREAT FOCAL SUPRASPINATUS TENDINOSIS: RANDOMISED CONTROL STUDY

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ABSTRACT

Background:
Even though supraspinatus tendinosis is a common problem, there is not much literature on treatment of supraspinator tendinosis with direct tendon injectables compared to other tendinosis such as lateral epicondylitis.

Objective:
To conduct a randomised controlled study on the efficacy of dextrose prolotherapy injection for focal supraspinatus rotator cuff tendinosis via outcomes such as functional score, range of movement and real time ultrasound parameters.

Material and Methods:
12 adult patients (mean age 60 years) with focal supraspinatus tendinosis were recruited into the study after they had less than 30% improvement in functional (DASH) scores after one month of physiotherapy following initial presentation. Regional intensity in decibels within of tendinosis vs normal tendon, trace area of tendinosis, calcification, partial tears and Doppler flow within the area of focal tendinosis were recorded at first visit and at the end of 12 weeks by two radiologists in the 12 patients. 7 patients had 0.5 -1.0mls of prolotherapy injection (12.5% Dextrose, 0.5% Lignocaine) injected into the area of tendinosis under ultrasound guidance. The remaining 5 patients continued standard physiotherapy with no intervention performed.

Results:
Prolotherapy group show significant improvement in abduction using Mann-Whitney U Test (p=0.030). No significant improvement in functional score after 12 weeks between both groups using Fisher-Exact test (p=0.364). Pain reduction of 57.1% of patients in injection group and 25% of patients in control group
after 12 weeks, 71.4% of patients in the prolotherapy have improvement in sleep with p=0.027 using Fisher-Exact test. The intensity of area of tendinosis increases at the end of treatment with p=0.009 (Mann-Whitney U Test). However no significant difference in intensity change of tendinosis between prolotherapy group and control group using Mann-Whitney U Test (p=0.927).

**Conclusion:**

Ultrasound guided intratendinous prolotherapy injections significantly improves patient’s range of abduction, reduce pain and improves sleep within 12 weeks in this study when compared to conventional physiotherapy management. This study introduces for the first time a detailed protocol for grading of tendinosis and standardization of imaging the tendinosis using standardisations of bony landmark and probe positioning technique.

**Keywords**: Prolotherapy, Supraspinatus tendinosis, Range of movement, Ultrasound, Intensity, Tendon healing
Introduction

Shoulder pain is an important condition of the upper extremity occurring in approximately 15/1000 patients per year in the outpatient primary care setting. Currently the known regenerative injection-based therapies which have been used in supraspinatus and other tendinosis, in particularly lateral epicondylitis are: Platelet rich plasma (PRP), Autologous Blood and Prolotherapy. Types of prolotherapy include dextrose, phenolglycerine-glucose (P2G) and sodium morrhuate. The objective of this study is to study the role of dextrose prolotherapy and the ultrasound changes pre- and post-injection.

Materials and Methods

12 patients participated in this randomised controlled prospective study and were randomly divided into two groups (7 patients in prolotherapy group and 5 patients in control group). Inclusion criteria included focal supraspinatus tendinosis confirmed on ultrasound and failure of functional score to improve more than 30% after 1 month of conventional treatment after first attendance to our sports medicine outpatient clinic. Exclusion criteria included mechanical cause of shoulder pain, full-thickness tendon tears, autoimmune diseases, patients on anticoagulant, congenital or acquired platelet dysfunction abnormality/disorder, haemoglobin level less than 10g/L and/or platelet count less than 100,000/uL, corticosteroid injection within the past 6 weeks and self-reported immuno-compromised status.

Functional score using the Disability of Arm and Shoulder (DASH) Score and physical examination for range of shoulder movement were performed by the sports medicine physician at recruitment to study and after 12 weeks.

Patients in the prolotherapy treatment group were seen and treated with 1 to 2 injections of 0.5 to 1ml mixture of 12.5% Dextrose Solution and 0.5% Lignocaine in bacteriostatic water into area of painful focal
tendinosis under ultrasound guidance at one week interval according to relieve of symptoms. Patients in both groups continued to get standardised physiotherapy regime and mechanical loading for 12 weeks.

Ultrasound parameters assessed were such as intensity area of tendinosis (dB), area of tendinosis on cross section (mm2), length of partial tears (if present), presence of calcification, periostitis of adjacent greater tuberosity, doppler flow within area of focal tendinosis, subacromial bursitis and dynamic impingement.

**Results**

There were 14.3% (1 patient) of patients in prolotherapy group and 40% (2 patients) of patients in control group who show significant improvement at 12 weeks (Table 1). There was no significant difference in the improvement of functional score between these 2 groups using the Fisher-Exact test (p=0.364).

There were 57.1% of patients in prolotherapy group who showed significant reduction in pain score while in the control group was 25% (Table 1). However, there was no significant difference of pain score in both groups using the Fisher-Exact test and p value was 0.247. There was significant difference in sleep improvement between both groups using the Fisher-Exact test and p value was 0.027 (Table 1). 62.5% of patients in prolotherapy group improved in sleep score while no patients improved in the control group.

There was significant improvement in shoulder abduction in prolotherapy patients compared to the control group using Mann-Whitney U Test with p value of 0.030. Range of abduction of patients in the prolotherapy group increased with a mean of 20.0° while the mean range of patients in the control group decreased with a mean of 12.0° (Figure 2).
Figure 2

Boxplot comparing difference in degree of abduction between prolotherapy and control group at baseline and at 12 weeks (p value = 0.030).
Table 1
Comparison DASH, pain and difficulty to sleep between prolotherapy and control group at baseline and at 12 weeks.

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Significant Improvement (%)</th>
<th>P-value (Fisher-Exact)</th>
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<tr>
<td></td>
<td>Baseline</td>
<td>12 weeks</td>
<td></td>
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<tr>
<td>DASH Score</td>
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<tr>
<td>Prolotherapy</td>
<td>60.14</td>
<td>43.89</td>
<td>14.3%</td>
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<tr>
<td>Control</td>
<td>56.86</td>
<td>46.68</td>
<td>40.0%</td>
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<tr>
<td>Pain Score</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Prolotherapy</td>
<td>3.29</td>
<td>1.86</td>
<td>57.1%</td>
</tr>
<tr>
<td>Control</td>
<td>3.20</td>
<td>2.40</td>
<td>20.0%</td>
</tr>
<tr>
<td>Difficulty to Sleep Score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolotherapy</td>
<td>3.29</td>
<td>2.15</td>
<td>71.4%</td>
</tr>
<tr>
<td>Control</td>
<td>2.20</td>
<td>2.60</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

There was no significant difference in improvement of the ratio intensity of tendinosis to normal tendon from baseline to 12 weeks between both groups using the Mann-Whitney U and p value was 0.93. However, there was significant increase in the intensity of the area of tendinosis from baseline and at 12 weeks when both groups are combined using Mann-Whitney U and p value was 0.009 (Figure 3).

The other ultrasound parameters did not show significant difference between the prolotherapy and control group. There were also no significant correlation between ultrasound parameters with functional and pain score.
Discussion

There is significant reduction of pain score in prolotherapy patients with improvement of movement such as abduction. In a study on prolotherapy in knee osteoarthritis, there were similar results which was 40% decrease in pain post 12 months dextrose prolotherapy injections and improvement of movement which is flexion of 14°. (1, 2). In our study with reduction of pain particularly in the prolotherapy group, these patients were able to lie on affected shoulder during sleep and thus sleep is improved. Prolotherapy improve sleep and therefore will improve quality of life of patients.

Significant improvement in abduction was noted in prolotherapy patients compared to the control group. Movement is very important for patients in activities of daily living. A simple action such as flicking on a light switch will be made possible with improvement of abduction and forward flexion.

Increase of intensity of tendinosis in both groups regardless of treatment, suggest area of tendinosis regional intensity measurements of the hypoechoic abnormal tendon increases to near similar normal intensity with treatment in both groups. This suggests remodeling of the tendon. A study on autologous blood injection for lateral epicondylitis showed the median echogenicity of the tendon significantly increased to near normal-like tendon appearance as well(3).

There is no significant correlation of ultrasound parameters and function. Zeisig et al (4) and Connell et al (3) also reported decreased structural defects on ultrasound, though these were not reliably correlated with clinical gains.
Conclusion

Dextrose prolotherapy was clinically effective and safe in the treatment of pain with joint movement limitation. It is advocated for patients who want faster improvement in shoulder abduction, pain and improvement in sleep. We hope our study forms the base for earlier intervention and not waiting for conditions to be deemed recalcitrant which is usually after 4-6 months of conventional therapy.

Figure Legend

Figure 1
Longitudinal sonographic image obtained using 5-17–MHz linear array transducer after insertion of 21-gauge needle shows tip of needle located in area of tendinosis with prolotherapy injected (*).

Figure 2
Boxplot comparing difference in degree of abduction between prolotherapy and control group at baseline and at 12 weeks (p value = 0.030).

Figure 3
Intensity measurement of tendinosis (a) and normal tendon (b) at baseline which was 5.56 dB and 19.50 dB respectively giving a ratio of 0.26. Intensity measurement of tendinosis (c) and normal tendon (d) at 12 weeks after injection which was 20.07 dB and 28.97 dB respectively giving a ratio of 0.70 which showed increase in ratio. Transverse sonographic image of the supraspinatus tendon at baseline (a, b) and at 12 weeks (c, d) at same section showing almost similar humeral head diameter (+). The tendinosis measured with continuous trace (b) on cross section is almost not visible at 12 weeks (d) marked with (*).
COMPETING INTEREST

None declared.

TRIAL REGISTRATION

Study is registered under Current Controlled Trials (UK) and given International Standard Randomised Controlled Trial Number (ISRCTN) of 43520960.

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Reference