

Effects of Impairment Based Manual Physical Therapy on Pain and Disability Diabetic Frozen Shoulder: A Part 1 of Randomized Clinical Trial

Mohd Javed Iqbal¹, Senthil P Kumar²

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Abstract

Purpose: To assess the efficacy of impairment-based manual physical therapy compared to sham conservative treatment for painful stiff shoulder in diabetic subjects.

Relevance: Adhesive capsulitis or painful stiff shoulder is a common condition among diabetes mellitus (DM) subjects. Effects of manual therapy techniques have been widely studied in the literature but not as integrated impairment-based manual therapy techniques.

Participants: Ninety patients of age (54.14 ± 12.85 years), both gender (41 male, 49 female) were selected on convenient sampling. Subjects were selected based on following: Physician diagnosed type-II DM of at-least two years duration; complaint of shoulder pain and stiffness (> 3 months duration); ability to understand and cooperate for instructions of tester.

Methods: The subjects then were randomized to receive either of two interventions- sham intervention + standard care and experimental intervention + standard care. The sham control group received drugs for glycemic control, analgesics for shoulder pain, active mobilization exercises to shoulder girdle and shoulder joint. The experimental group received in addition, impairment-based manual therapy comprising of joint mobilization, neurodynamic mobilization, myofascial release and trigger point therapy. The treatment session was of one hour duration on five sessions (one session per week) for total study duration of five weeks. Patients were instructed to perform home programme once daily and were given patient log to ensure compliance. Data was collected twice- pre and post intervention by an independent blinded observer.

Analysis: The two outcome measures (shoulder pain and disability index- SPADI, and pain intensity on visual analogue scale- VAS) were analyzed using students' t-test at 95% confidence interval by SPSS 11.5 for Windows.

Results: The experimental group showed statistically significant improvements post treatment in both the outcomes. The pre-post mean differences for SPADI (17.28 ± 3.18), and pain on VAS (3.29 ± 1.4) was significant ($p < .05$) in favor of experimental group.

Conclusions: Impairment-based manual physical therapy in addition to standard physical therapy care was better than standard physical therapy care combined with sham intervention to relieve pain and disability in type-2 diabetes mellitus patients with painful stiff shoulders.

Implications: Inclusion of impairment-based manual physical therapy should be considered based on clinical examination findings of articular, myofascial and neural tissue impairments through their contribution to shoulder pain and dysfunction in patients with type-2 diabetes mellitus. Further studies are warranted with large, population-based, multicenter, multinational trials on patients with idiopathic shoulder pain and dysfunction or in other clinical states following trauma, rupture, dislocation or surgery.

Keywords: Shoulder Dysfunction; Rehabilitation; Physical Therapy.

Author Affiliation: ¹Assistant Professor, Department of Physiotherapy, Faculty of Allied Health Sciences, Integral University, Lucknow, 226026 India, ²Chief Instructor, Academy of Orthopedic Manual Physical Therapists, Bangalore, Karnataka 560058 India.

Corresponding Author: Senthil P Kumar, Chief Instructor, Academy of Orthopedic Manual Physical Therapists, Bangalore, Karnataka 560058 India.

Email: Prof.senthil.p.kumar@gmail.com

Introduction

Shoulder pain is the third most common complaint for a visit to a physical therapist, next only to back pain and neck pain¹. The estimated prevalence of shoulder pain in general population ranges from 1% to 4% and from 31% to 48% among patients with musculoskeletal complaints². Shoulder pain was present in 25.7% of diabetic patients compared with 5.0% of general medical patients. 7% of

patients with shoulder pain report complaints of both pain and stiffness³ which necessitates clinical nomenclature of “painful stiff shoulder” as put forward by Bunker⁴ instead of terms such as adhesive capsulitis or frozen shoulder^{5,6}.

The prevalence of painful stiff shoulder was 4.3% in diabetic patients compared 0.5% of the general medical patients⁹. Adhesive capsulitis was seen in 17.9% diabetics compared to 7% in non-diabetics¹⁰. Diabetes mellitus is by far the most common comorbid condition to painful stiff shoulder with an estimated incidence of 10-37%¹¹. The extent and severity of dysfunction and range of motion limitation in adhesive capsulitis was independently associated with duration of diabetes than from the patients’ age¹².

Conservative treatments aimed at relieving pain and improving range of motion of shoulder include medications like NSAIDs,¹⁷ oral steroids or prednisolone,^{18,19} diclofenac sodium,²⁰ corticosteroid injections,^{21,22} dynamic splinting,²³ continuous passive motion,²⁴ physical therapy²⁵⁻²⁸ and acupuncture²⁹.

To date, a number of systematic reviews have evaluated the effectiveness of conservative treatment in shoulder disorders³⁰⁻³⁶. Manual therapy techniques primarily focus on three tissue components where they can be grouped as under; articular, myofascial and neural. Articular techniques studied in shoulder pain population comprised of mobilizations with movements, oscillatory joint mobilizations of cervical spine, scapula and glenohumeral joint, and application of manipulative thrust to thoracic spine. Myofascial techniques like trigger point therapy for infraspinatus, subscapularis, upper trapezius and gross myofascial release for the upper quarter like arm-pull were also described in literature. Neurodynamic techniques for arm pain secondary to shoulder problems include the neurodynamic mobilization techniques of sliders and tensioners for nerves around the shoulder and arm. Manual physical therapy when added to supervised exercise programme in shoulder impingement syndrome patients was found to be better in improving range of motion, strength and function when compared to exercise alone^{48,49}.

Recent systematic review⁵⁰ concluded in favor of manual physical therapy in the management of painful shoulder conditions and the findings of improved range of motion and decreased pain was observed across the reviewed studies. Another systematic review suggested combining manual therapy with exercises for better long-term pain

improvements in shoulder impingement syndrome patients⁵¹. Adding manual therapy to usual medical care was found to accelerate recovery in patients with shoulder dysfunction and pain⁵².

The aim of our study was to observe the efficacy of impairment-based manual physical therapy intervention for painful stiff shoulder condition in type-II diabetes mellitus subjects. We hypothesized that impairment-based manual physical therapy when added to standard physical therapy would be better to relieve pain, improve range of motion and improve shoulder function than standard physical therapy care with sham intervention in these patients.

Materials and methods

Study design and ethical approval

Observer-blinded randomized sham-controlled clinical trial. The study conduct was approved by Institutional Ethics Committee and was registered at Clinical Trials Registry-India under UTRN 022104848-130120101648203.

Subjects

Medically diagnosed stable type-2 diabetes mellitus patients of either gender of age group 18-65 years were recruited by convenient sampling from two locations- outpatient treatment unit of physiotherapy department of multispecialty teaching hospital (screened by a physician experienced for 20 years) and a primary healthcare hospital (screened by a physician experienced for 25 years) between July 2008 and December 2009. All patients were required to give written informed consent and consented patients were then screened for their suitability in participating in the study by inclusion and exclusion criteria.

Inclusion criteria

symptoms of unilateral or bilateral shoulder pain and restriction of motion for at least 6 months duration; ability to understand written and spoken English and fill the SPADI questionnaire; and, stage-1 or stage-2 adhesive capsulitis as described by Kelley et al⁵⁵.

Patients with atleast five of the eight following Delphi Consensus Criteria⁵⁶ reported by Walmsley et al for adhesive capsulitis; (1) night pain, (2) increase in pain with rapid/ unguarded movements, (3) uncomfortable to lie on affected side, (4) pain aggravated by movement, (5) onset age greater than 35 years, (6) global loss of active

and passive ROM on examination, (7) end-of-range pain in all directions, and (8) global loss of passive glenohumeral joint movement and;

(9) Minimum total score 3 with atleast score of 1 per item for the three items- hand behind neck(0-4), hand to opposite scapula backwards(0-4), hand to opposite scapula forwards(0-3) on Shoulder Function-related Tests Battery (SFTB) studied by Yang and Lin⁵⁷.

Exclusion criteria

History of trauma, surgery or systemic disorders and diseases, or received any form of treatment for shoulder complaints within the past 6 months and patient's voluntary disapproval or withdrawal from participation in the study.

Demographic information (age, sex, involved side) of all patients was collected, as well as duration of diabetes and shoulder symptoms.

Outcome measures

Four primary outcome measures were assessed before and after the treatment duration. They are; Visual analogue scale-VAS (0-10) for pain intensity. Pain intensity was measured on a 10cm line (0-10), where 0 indicated "no pain" and 10 indicated "pain as bad as it could be". Current pain intensity, as well as best and worst pain intensity since onset of symptoms, was collected. Subjective pain intensity ratings were averaged from current, best, and worst pain score for each subject because this method was recommended earlier for better reliability and validity of findings^{58,59} which also best suited our sample. The minimum clinically important difference (MCID) for VAS was 1.2 ± 0.3 at 95% confidence interval.⁵⁸ Patients with greater pain intensity required greater change to be clinically important⁶⁰ and hence roughly a 36% change was meant to be a clinically significant change for the VAS⁶¹.

Shoulder pain and disability index (SPADI)- for assessing pain and functional limitation in shoulder pain patients. Roach et al⁶⁶ developed the Shoulder Pain and Disability Index in the year 1991. It is the shoulder-specific self report measure studied extensively for its psychometric properties⁶⁷. The SPADI is a 13-item joint- specific measure of shoulder disability. The questionnaire consists of 2 subscales based on domains of pain (5 items) and function (8 items). Higher scores indicate higher levels of disability. It has shown high responsiveness to detect change following an initial episode of shoulder pain for a spectrum of shoulder conditions. The internal consistencies of

the SPADI total and subscales of pain and function ranged from 0.86 to 0.95, and it has demonstrated moderate test-retest reliability of total and subscale scores (ICC = 0.64 to 0.66)⁶⁶. Responsiveness⁶⁸ of SPADI was shown to be clinically useful with a minimum detectable difference of 17 points on total 0-100 score with an ICC of .89 for test-retest reproducibility. Construct validity⁶⁹ of the SPADI was studied comparing to sickness impact profile and was shown to be more responsive among the two. SPADI was shown to have high factor, construct and longitudinal validity⁷⁰. Discriminant validity of SPADI to differentiate between patients-improved versus worsened- was shown to be high, together with its good responsiveness, was thus recommended for its clinical use⁷¹. Total SPADI score was taken for analysis and not the pain and disability subscale scores since factorial analysis did not support so earlier⁷².

Manual therapy evaluation of impairment: Examination was based on a multistructural approach⁷³. After the therapist assessed selective tissue tension tests as described by Cyriax,⁷⁴ a thorough manual examination for presenting impairments were identified and then related to symptom reproduction and subjective history to arrive at a probable pattern-recognition based on clinical reasoning⁷⁵.

Articular examination

Articular impairment was considered as a presence of restricted mobility during passive physiological and/or passive accessory examination or joint play testing. The four cardinal principles- positioning, stabilization, mobilization and comfort, as explained by Stevenson and Vaughn⁷⁶ were followed throughout the joint play testing and joint mobility assessments. Joint mobility testing was graded by using a seven-point scale. Its reliability was shown to be moderate to good for intra-tester and fair to moderate for inter-tester ratings⁷⁷. The cervical and thoracic spine, and the joints of the shoulder complex were thus evaluated by an orthopaedic manual physical therapist with seven years experience.

Myofascial examination

Myofascial impairment was considered as a presence of myofascial tightness, tenderness and/or trigger points associated with palpable taut band, muscle twitch with jump sign or referred pain⁷⁸. Manual palpation with fascial stretch, muscle contraction and/or muscle stretch was done to confirm the tissue involved. Scapular and

glenohumeral motor control evaluation using scapular assistance test⁷⁹ (scapular force couple), dynamic rotator stability test (internal vs external rotator force couple),⁸⁰ and dynamic relocation test (rotator cuff force couple)⁸¹ was done to ascertain associated stability dysfunction.

Neural tissue examination

Neural tissue impairment⁸² was considered when there was a presence of neuropathic symptoms like dysesthesia, paresthesia, hyperesthesia, allodynia during nerve palpation⁸³ and/or percussion (Tinel's sign). Presence or elicitation of subjective symptoms during neurodynamic testing⁸⁴ where the responses were altered with structural differentiation⁸⁵ manoeuvres were considered positive neurodynamic test findings⁸⁶. Evaluation of neural tissue mechanosensitivity was done to interpret the observed movement dysfunction associated with patient's pain. Two types of

neural dysfunctions slider and tensioner were identified⁸⁷. Evaluation was done using upper limb neurodynamic test-1 or median neurodynamic test since it was shown to be associated with shoulder girdle movement dysfunction^{88,89}.

Treatment allocation

The procedure using CONSORT solidated Standards of Reporting Trials Consort 2010 flowchart⁹⁰ is outlined in figure-1. Included patients were randomly assigned to receive either of the two interventions- sham intervention and standard physical therapy care or experimental intervention and standard physical therapy care using block randomization. The allocation method was concealed using sequentially numbered sealed opaque envelopes. Both the interventions were provided by a treating orthopaedic manual physical therapist trained and experienced in orthopaedic manual physical therapy (OMPT) for eight years,

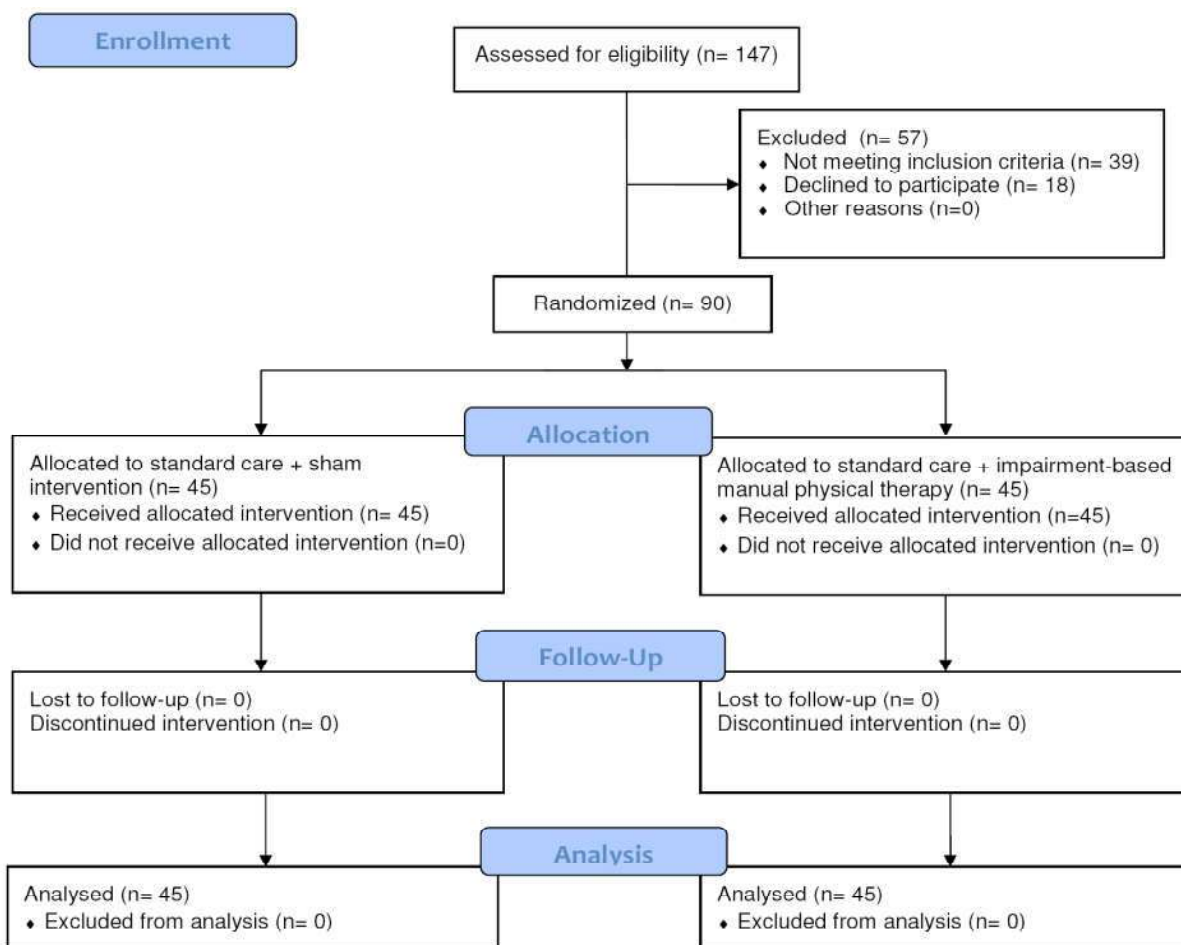


Fig.1: Consort flow chart showing the flow of study participants.

who was not blinded to the procedures. By nature, manual physical therapy is an open-label treatment for which no patients, general practitioners, nor can manual therapist be blinded. To optimize blinding, the research assistants, who are responsible for the outcome measurements, were blinded for the allocated treatment. Also, patients were instructed not to inform the research assistants or the general medical practitioner about the received treatment.

Standard physical therapy care + sham-control group

Standard physical therapy care as described by Kelley et al⁵⁵ and comprising of active mobilization exercises for cervical spine, thoracic spine, shoulder girdle and glenohumeral joint; Codman's pendular exercises, wall-climbing exercises for shoulder elevation through abduction and flexion; and strengthening to shoulder muscle groups initially being isometric later progressing to isotonic. Sham intervention consisted of the therapist applying manual contact and forces similar to actual manual physical therapy intervention but performed in a way not to induce any potential therapeutic effects⁹¹. Example, the lesser grades of mobilization was applied at other than the levels identified as hypomobile. Hand contact was done for glenohumeral glides but glides were not applied. Hand contact was done on muscles with trigger points simulating superficial massage with light strokes. Passive movements of shoulder or elbow and/or wrist were done separately instead of in combination for sham neurodynamic intervention^{92,93}.

Standard physical therapy care + impairment-based manual physical therapy group

The experimental group received standard physical therapy intervention following which impairment-based manual physical therapy was given which comprised of the following techniques;

Articular Mobilization techniques

Mobilization with movement (MWM) techniques,⁹⁴ Cervical lateral glide,⁹⁵ selective posterior capsular stretching,⁹⁶ coracohumeral ligament stretching,⁹⁷ scapular mobilization, end-range mobilizations for restricted glenohumeral movements,^{75,98} manipulative thrust for thoracic extension mobilization⁹⁹ were used as indicated by examination findings and dictated by therapist's clinical reasoning process¹⁰⁰.

Myofascial techniques

Gross myofascial release technique (arm pull),¹⁰¹ followed by specific local release of longitudinal, transverse and oblique fascial stretches around the trigger point, and ischemic compression at 7/10 VAS for 30 secs, 5 reps, 2 sets¹⁰². Motor control training began with scapular control exercises emphasizing on lateral rotation than elevation,¹⁰³ and rotator cuff co-activation using mental imagery¹⁰⁴ and dynamic stability training using DRST and DRT reported by Magarey and Jones^{80,81}.

Neural tissue techniques

Nerve massage was given to the mechanically sensitized peripheral nerve along its course first in the transverse direction and then in the longitudinal direction. The nerve found tender on manual nerve palpation was chosen for application of nerve massage⁸³. Nerve massage was done for suprascapular nerve, median nerve, radial nerve and ulnar nerve respectively. Neurodynamic mobilization comprised of nerve slider and/or nerve tensioner techniques according to the type of neural dysfunction (slider or tensioner dysfunctions)⁸⁵. The mobilization grades III and IV originally described for peripheral joints by Maitland⁹⁸ and later integrated into neural mobilization by Butler¹⁰⁵ was used and frequency of. 5Hz for the neurodynamic techniques. Care was taken to avoid holding the neurodynamically sensitized position to more than 10 secs during the tensioner techniques¹⁰⁶.

The total treatment duration in a single intervention session for both the groups were for 60 min per shoulder. Treatments consisted of one session per week for total study duration of five weeks per patient. Patients in both groups received a home programme of exercises administered in standard physical therapy care. Patients were given a log to ensure compliance with the home programme, which was again verified by the tester on subsequent visits during the study period.

Other interventions

The two physicians at either of the two study locations, administered medications for glycemic control¹⁰⁷ and analgesics (oral NSAIDs¹⁷ and topical diclofenac sodium²⁰ gel) for shoulder pain. All patients in addition received dietary advice,¹⁰⁸ lifestyle modification,^{109,110} and regular physical activity^{109,111} (walking) prescription as part of their routine treatments for diabetes in both the locations. The prescription patterns were maintained the same for both the treatment groups in both the

study locations. The two physicians were blinded to the intervention group of the patient.

Data collection

Outcome assessment was done by an assessor blinded to the patient's intervention group before the commencement of the intervention and after the completion of the intervention. Outcome assessment did not require much training for administration for our chosen outcomes and hence was not given. Same assessor measured pre and post-intervention for all the subjects.

Adverse effects if any were to be reported by patients on subsequent visits, which were also analyzed for between-group comparison.

Data analysis

Sample size determination¹¹²

The sample size for this study was based on a predetermined 15-point difference between groups in the reduction on the SPADI total score. Power calculations indicated that a sample of 90 participants (45 per group) would provide an 80% probability of detecting a 15 ± 24 points, with an alpha of .05, and an estimated loss to follow-up of 10%. The minimum important clinical difference earlier reported by Roach et al⁶⁶ was 13 points on the SPADI total score.

Baseline demographic characteristics

Age, gender, duration of diabetes, duration of shoulder symptoms and side of involved shoulder were analyzed using descriptives and compared for between-group homogeneity using independent t-test for data with normal distribution (verified by Kolmogorov-Smirnov test) and Mann-Whitney U test for non-normal and qualitative data.

Between-group and within-group comparisons

The four outcome measures were analyzed using students' t-test at 95% confidence interval using SPSS 12.0.1 for Windows.

Results

Of the 147 patients who were screened for eligibility, 90 patients fulfilled the study criteria and were then randomized. Of the 57 patients excluded-18 declined to participate due to their personal reasons to follow the study schedule and follow-

up; 9 had a history of trauma to the symptomatic shoulder; 13 had a history of cervical spondylosis; 12 had peripheral neuropathy, and 5 had peripheral vascular disease.

Overall demographic characteristics

A total of 90 medically diagnosed type-II diabetes mellitus patients of either gender (41 men, 49 women) with age 54.14 ± 12.85 years and average diabetes duration of 4 ± 1.11 years were thus recruited into our study. They had complaints of shoulder pain and restricted shoulder movements for $2.28 \pm .66$ years. The side of involvement was right (31 patients), left (53 patients) and 6 patients had bilateral shoulder involvement. The overall sample characteristics are provided in table-1.

Table-1: Combined sample characteristics (patient demographics and baseline clinical findings) in the study.

Characteristic of study sample	Descriptive value
Total Number of patients, N	90
Gender	41 men; 49 women
Age	54.14 ± 12.85 years**
Duration of type-2 diabetes	4 ± 1.11 years**
Duration of shoulder symptoms	$2.28 \pm .66$ years**
Side of involved shoulder	Right(31); Left (53), Bilateral (6)
SPADI Total score	56.82 ± 8.92 **
Abduction ROM	106.28 ± 18.02 **
Flexion ROM	123.54 ± 19.84 **
External rotation ROM	20.42 ± 7.98 **
Internal rotation ROM	31.85 ± 6.97 **
Visual analogue scale- VAS (0-10cm)	$6.65 \pm .76$ **
Shoulder Functional Test Battery- SFTB	6.60 ± 1.35 **

All mentioned values are mean \pm SD unless stated in numbers directly.

Key terms: SPADI- shoulder pain and disability index; ROM- range of motion (in degrees); VAS- visual analogue scale (points).

Test for homogeneity between-groups:

Comparison of groups for homogeneity showed both groups were comparable in terms of all the study measures. The comparison of patient demographics and baseline outcome measures between the two treatment-groups are outlined in table-2.

Table-2: Individual sample characteristics (patient demographics and baseline clinical findings) and their comparisons.

Groups Variables	Control group N= 45	Experimental group N= 45	Level of significance, p value
Age (years)	54.27 ± 14	54 ± 11.93	.95 (NS)
Duration of Diabetes (years)	4.05 ± 1.16	3.94 ± 1.08	.76 (NS)
Duration of shoulder symptoms (years)	2.38 ± .69	2.17 ± .63	.35 (NS)
Gender ^a Male (female)	20 (25)	21 (24)	.236 (NS)
Side of involved/ affected shoulder- ^a Left, right, bilateral	29,13,3	24,18,3	.773 (NS)
SPADI (Total score) pre-treatment	56.41 ± 9.26	57.25 ± 8.82	.786 (NS)
Abduction ROM pre-treatment (degrees)	106.72 ± 18.22	105.82 ± 18.36	.885 (NS)
Flexion ROM pre-treatment (degrees)	124.22 ± 20.26	122.82 ± 19.97	.838 (NS)
External rotation ROM pre-treatment (degrees)	20.55 ± 8.02	20.29 ± 8.19	.925 (NS)
Internal rotation ROM pre-treatment (degrees)	32.22 ± 7.32	31.47 ± 6.79	.755 (NS)
VAS pre-treatment (degrees)	6.66 ± .76	6.64 ± .78	.941 (NS)
SFTB pre-treatment (degrees)	6.55 ± 1.33	6.64 ± 1.41	.845 (NS)
SPADI (Total score) post-treatment	47.91 ± 8.59	39.96 ± 9.77	.015 (S)
Abduction ROM post-treatment (degrees)	117.33 ± 17.34	132.47 ± 15.95	.011 (S)
Flexion ROM post-treatment (degrees)	133.83 ± 18.99	146.94 ± 13.81	.027 (S)
External rotation ROM post-treatment (degrees)	30 ± 6.8	35.41 ± 8.28	.042 (S)
Internal rotation ROM post-treatment (degrees)	43.83 ± 6.86	50.94 ± 9.06	.012 (S)
VAS post-treatment	5.22 ± .54	3.35 ± 1.41	.000 (S)
SFTB post-treatment	5.16 ± 1.42	4.29 ± .46	.022 (S)

NS-not statistically significant at p<.05, S-Statistically significant at p<.05

All comparisons done using independent t-test unless mentioned.

A: comparisons done using Mann-Whitney U test.

Key terms: SPADI: shoulder pain and disability index; ROM-range of motion (in degrees); VASvisual analogue scale (0-10 cm); SFTB-shoulder functional tests battery.

Between-group analysis of pre-post change in outcome measures

Detailed results for all outcome measures are shown in table-3.

Table 3: Between-group comparison for measured changes in outcome measures.

Group Outcomes	Control group	Experimental group	P-value
SPADI (Total score)	8.5 ± 4.07	17.28 ± 3.18	.00*
VAS	1.44 ± .78	3.29 ± 1.4	.00*

Statistically significant at p<.05

All comparisons done using independent t-test.

Key terms: SPADI shoulder pain and disability index; VAS- visual analogue scale (0-10 cm).

VAS score

The experimental group had a statistically significant ($p < .05$) change of 3.29 ± 1.4 points decrease in averaged VAS pain scores compared to the change of $1.44 \pm .78$ points in the sham-control group. See figure-2

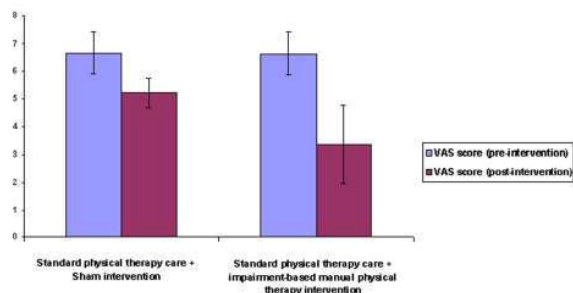


Fig. 2: Between-group comparison of visual analogue scale (VAS) scores pre-post intervention.

SPADI (Total score)

The experimental group had a statistically significant ($p < .05$) change 17.28 ± 3.18 points decrease in total SPADI score compared to the change of 8.5 ± 4.07 points in the sham-control group. See figure-7.

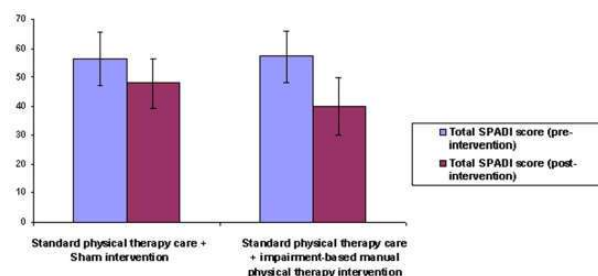


Fig.7: Between-group comparison of shoulder pain and disability index (SPADI) scores pre-post intervention

Discussion:

Similar studies

Our study results were similar to studies of Bergman et al¹¹³ and Bergman et al¹¹⁴. The first study¹¹³ compared manual therapy to usual care in shoulder pain and dysfunction population while the second,¹¹⁴ between manual therapy and usual medical care in shoulder pain patients. Both the studies used only thoracic spine and ribcage manipulation and mobilization techniques for the manual therapy group whereas we used a combination of manual techniques to address articular, myofascial and neural tissue impairments associated with shoulder pain and dysfunction. The earlier authors found improvements in shoulder pain and function after 12 weeks. Our study is

the first of its kind reporting significant treatment effects in five weeks. The interventions integrated into our treatment methods were joint mobilization and exercises both of which were found to have a high positive likelihood for pain reduction and improved function in patients with adhesive capsulitis in an out-patient physical therapy setup¹¹⁵. Another study¹¹² which found no added effect of manual therapy when compared to advice and exercise used passive mobilization techniques alone which was likely to address predominantly the articular impairments of the shoulder pain and dysfunction patients.

Effect size of our findings

The combined impairment-based manual physical therapy (IBMPT) intervention could possibly be responsible for the magnitude of the treatment effect measured in all the study outcomes. The pre-post decrease in the SPADI total score noted in the experimental group was 17 points which was higher than minimum clinically important difference (MCID) of 15 points reported earlier for the SPADI^{66,68,112}.

The VAS scores for pain intensity decreased in the experimental group to as much as by 3.2 points which is again much higher than the MCID of 1.3 points⁵⁸ and 3 points⁶¹ described earlier.

Relationship between changes in study outcomes

The corresponding change in the study outcomes was evident when we found a significant correlation of the pre-post change between the measures. Our secondary analysis showed that decrease in SPADI (total score) was positively associated with ROM improvements for abduction ($r = .717$), flexion ($r = .600$), external rotation ($r = .423$), and internal rotation ($r = .345$). The SPADI decrease was also positively associated with VAS improvements ($r = .645$). Change in VAS was positively associated with improvements in ROM abduction ($r = .572$) and ROM external rotation ($r = .346$). The VAS decrease was also positively associated with reduction in SFTB score ($r = .375$).

The basis of manual physical therapy was not just with regard to interventions but also with regard to diagnosis. The emphasis needs to be placed on patient-based evidence that links individual patient characteristics to characteristics derived at the group level; one way to achieve this is to continue on the avenue of developing clinical prediction rules¹²⁷. On those lines, an impairment-based

manual physical therapy (IBMPT) approach would be justified. There is scope for developing clinical prediction rules to identify responders to IBMPT among patients with painful stiff shoulders, and being tested across multiple locations and across diverse patient populations.

Conclusion

Impairment-based manual physical therapy in addition to standard physical therapy care was better than standard physical therapy care combined with sham intervention in type-2 diabetes mellitus patients with painful stiff shoulders.

Further validation of this study's findings could be warranted in the future with large multi-center trials to derive clinical prediction rules for this subgroup of patients who are likely to benefit from manual therapy techniques.

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