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Effects of Impairment Based Manual Physical Therapy on Range of Motion and Function in Diabetic Frozen Shoulder: Part 2 of A Randomized Clinical Trial

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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 co-operate 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 45 min 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 (range of motion- ROM, shoulder functional tests battery- SFTB) 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 all the four outcomes. The pre-post mean differences for shoulder abduction ROM (26.64 ± 7.36 degrees), shoulder external rotation ROM (15.11 ± 3.75 degrees), SFTB score (2.35 ± 1.41 points), 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 improve range of motion and shoulder function in type-2 diabetes mellitus patients with painful stiff shoulders.

Keywords : Shoulder dysfunction, rehabilitation, physical therapy

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Introduction

Shoulder pain is the third most common complaint for a visit to a physical therapist, next only to back pain and neck pain[1]. The estimated prevalence of shoulder pain in general population ranges from 1% to 4% and from 31% to 48% among patients with musculoskeletal complaints[2]. 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 stiffness[3] which necessitates clinical nomenclature of "painful stiff shoulder" as put forward by Bunker[4] instead of terms such as adhesive capsulitis or frozen shoulder[5,6].

Manual therapy was shown to be effective in earlier studies when used as technique-based research and not as impairment-based. Impairment-based manual physical therapy would then be very effective in such situations but not yet studied in this population of painful stiff shoulder. 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 atleast 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 al[55].

Patients with atleast five of the eight following Delphi Consensus Criteria[56] 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 Lin[57].

Exclusion criteria

History of trauma, surgery or systemic disorders and diseases, 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

Two outcome measures were assessed before and after the treatment duration. They are; Standard universal goniometer, for measuring shoulder active range of motion in degrees with patient in standing position. The movements assessed were abduction, flexion, external rotation and internal rotation.

Shoulder functional tests battery[57] consisting of three functional movements (hand to neck, hand to opposite scapula, hand to scapula) scored on a grading of 0-4 with a maximum score of 11 for maximum limitation of shoulder function. Shoulder functional tests battery (SFTB) includes three function-related tests:

1. Hand to neck- shoulder flexion and external rotation;
2. Hand to scapula- shoulder extension and internal rotation; and.
3. Hand to opposite scapula- shoulder horizontal adduction.

Total score of SFTB ranges from 0-11. A score of zero indicates normal and minimum abnormal score is a total score of 3. The scale had excellent reliability (kappa = .83-.90) for use in clinical practice[73].

Manual therapy evaluation of impairment

Examination was based on a multistructural approach and the detailed description based upon articular, myofascial and neural impairment was given in part-1 of this study.

Treatment allocation

The procedure using consolidated Standards of Reporting Trials consort 2010 flowchart[90] is outlined in Part-1 of this study.

Standard physical therapy care + sham-control group

Standard physical therapy care as described by Kelley et al[55] is provided in part-1 of this study.

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 articular, muyofascial and neural techniques as described in Part-1 of this study.

Data collection: Outcome assessment was explained in part-1 of this study.

Data analysis: As provided in part-1 of this study.

Results

Of the 147 patients screened, the flow of participants is provided in part-1 of this study.

The overall sample characteristics are provided in table-1 and baseline comparisons for heterogeneity was provided in table-2 both are available in part-1 of this study.

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
Abduction ROM	10.61 ± 3.63	26.64 ± 7.36	.00*
Flexion ROM	9.61 ± 4.4	24.11 ± 9.90	.00*
External rotation ROM	9.44 ± 3.53	15.11 ± 3.75	.00*
Internal rotation ROM	11.61 ± 10.34	19.47 ± 8.69	.02*
SFTB	1.38 ± 1.09	2.35 ± 1.41	.03*

*- statistically significant at p<.05

All comparisons done using independent t-test.

Key terms: OM- range of motion (in degrees); SFTB- shoulder functional tests battery.

Shoulder active range of motion

Abduction

The experimental group had a statistically significant (p<.05) change of 26.64 ± 7.36 degrees increase in shoulder abduction active range of motion compared to the change of 10.61 ± 3.63 degrees in the sham-control group. See fig. 3.

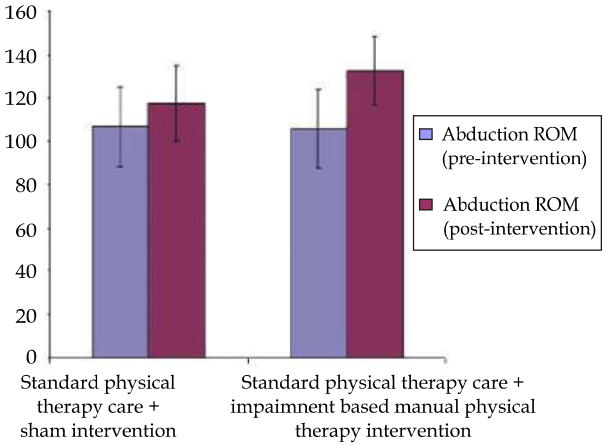

Fig. 3: Between-group comparison of shoulder abduction active range of motion pre-post intervention.

Flexion

The experimental group had a statistically significant (p<.05) change of 24.11 ± 9.90 degrees increase in shoulder flexion active range of motion compared to the change of 9.61 ± 4.4 degrees in the sham-control group. See figure-4.

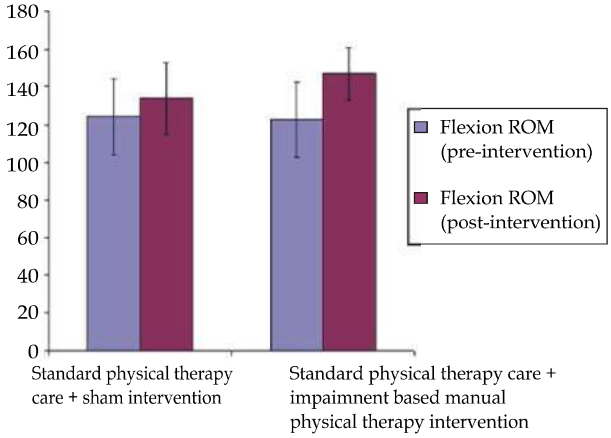

Fig. 4: Between-group comparison of shoulder flexion active range of motion pre-post intervention.

External rotation

The experimental group had a statistically significant ($p<.05$) change of 15.11 ± 3.75 degrees increase in shoulder external rotation active range of motion compared to the change of 9.44 ± 3.53 degrees in the sham-control group. See figure-5.

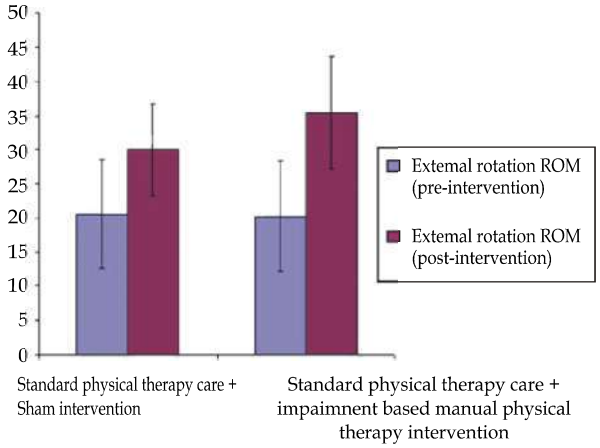

Fig. 5: Between-group comparison of shoulder external rotation active range of motion pre-post intervention.

Internal rotation

The experimental group had a statistically significant ($p<.05$) change of 19.47 ± 8.69 degrees increase in shoulder internal rotation active range of motion compared to the change of 11.61 ± 10.34 degrees in the sham-control group. See figure-6.

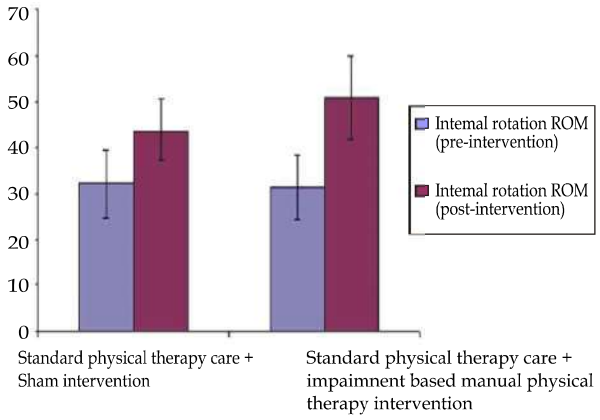

Fig. 6: Between-group comparison of shoulder internal rotation active range of motion pre-post intervention.

SFTB

The experimental group had a statistically significant ($p<.05$) change of 2.35 ± 1.41 points increase in shoulder abduction active range of motion compared to the change of 1.38 ± 1.09 degrees in the sham-control group. See figure-8.

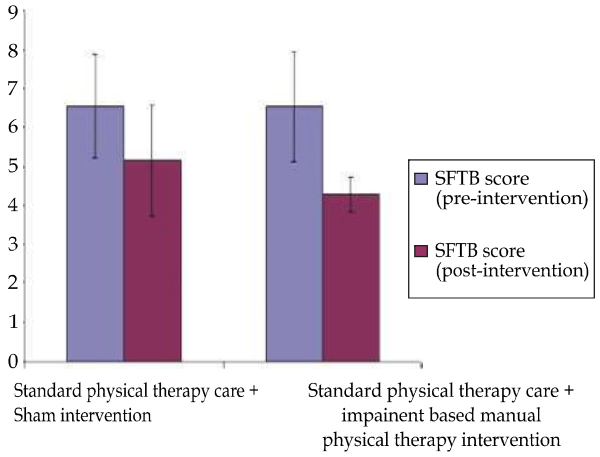

Fig. 8: Between-group comparison of shoulder abduction functional tests battery (SFTB) scores pre-post intervention.

Discussion

Similar studies

Our study results were similar to studies of Bergman et al[113] and Bergman et al.[114] The first study[113] 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. 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.

Limitations of our study

Our study sample though statistically acceptable, a total of 90 participants, were studied from a single geographical location, which may limit external applicability of its findings. Larger population-based multi-center trials are necessary before drawing definitive conclusions based on our findings.

Significance of our study

Using factorial analysis of physical examination findings, they[114] reported improvements in shoulder pain and shoulder mobility in their patients following the use of manual therapy. In our study, we explored the effects on SPADI and SFTB in addition to pain and mobility measures.

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.

Conclusion

Impairment-based manual physical therapy in addition to standard physical therapy care was better than standard physical therapy care combined with sham intervention for improving range of motion and shoulder function in type-2 diabetes mellitus patients with painful stiff shoulders.

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