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

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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].

The prevalence of painful stiff shoulder was 4.3% in diabetic patients compared 0.5% of the general medical patients[9]. Adhesive capsulitis was seen in 17.9% diabetics compared to 7% in non-diabetics[10]. 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' age[12].

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 therapy[25-28] and acupuncture[29].

To date, a number of systematic reviews have evaluated the effectiveness of conservative treatment in shoulder disorders[30-36]. 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 review[50] 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 patients[51]. Adding manual therapy to usual medical care was found to accelerate recovery in patients with shoulder dysfunction and pain[52].

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, 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 findings58,59 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 VAS[61].

Shoulder pain and disability index (SPADI)- for assessing pain and functional limitation in shoulder pain patients. Roach et al[66] developed the Shoulder Pain and Disability Index in the year 1991. It is the shoulder-specific self report measure studied extensively for its psychometric properties[67]. 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]. Responsiveness[68] 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 validity[69] 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 validity[70]. 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 use[71]. Total SPADI score was taken for analysis and not the pain and disability subscale scores since factorial analysis did not support so earlier[72].

Manual therapy evaluation of impairment: Examination was based on a multistructural approach[73]. 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 reasoning[75].

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 Vaughn[76] 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 ratings[77]. 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 pain[78]. 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 test[79] (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 impairment[82] was considered when there was a presence of neuropathic symptoms like dysesthesia, paresthesia, hyperesthesia, allodynia during nerve palpation[83] and/or percussion (Tinel's sign). Presence or elicitation of subjective symptoms during neurodynamic testing84 where the responses were altered with structural differentiation[85] manoeuvres were considered positive neurodynamic test findings[86]. 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 identified[87]. 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 CON solidated Standards of Reporting Trials Consort 2010 flowchart[90] 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,

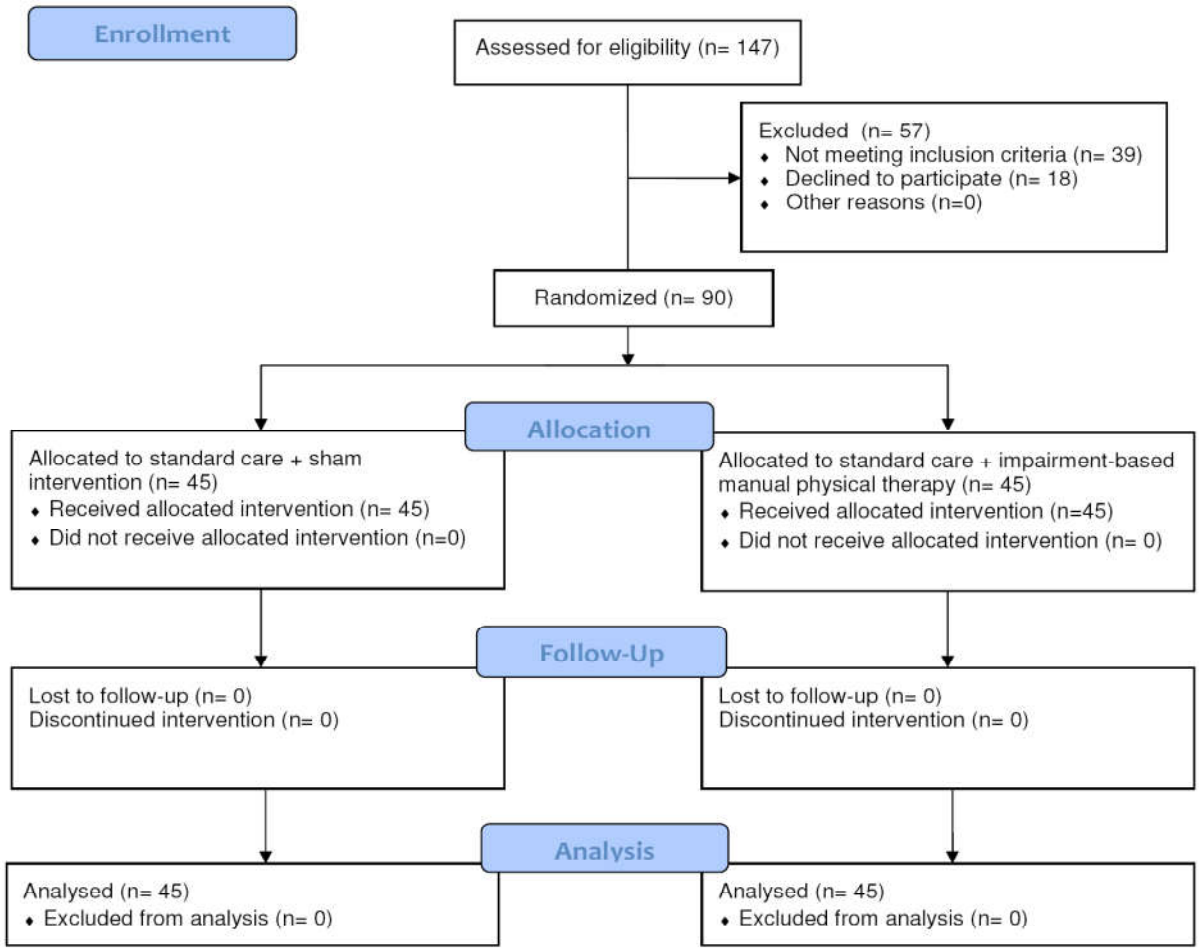

Fig.1: Consort flow chart showing the flow of study participants.

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 al[55] 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 effects[91]. 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 mobilization[99] were used as indicated by examination findings and dictated by therapist's clinical reasoning process[100].

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 sets[102]. Motor control training began with scapular control exercises emphasizing on lateral rotation than elevation,[103] and rotator cuff co-activation using mental imagery[104] 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 massage[83]. 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 Maitland[98] and later integrated into neural mobilization by Butler[105] 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 techniques[106].

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 control[107] and analgesics (oral NSAIDs[17] and topical diclofenac sodium[20] 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 determination[112]

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 al[66] 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-Smirnof 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 ± .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 ± .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 ± .76**
Shoulder Functional Test Battery- SFTB	6.60 ± 1.35**

All mentioned values are mean ± 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 ± .78 points in the sham-control group. See figure-2

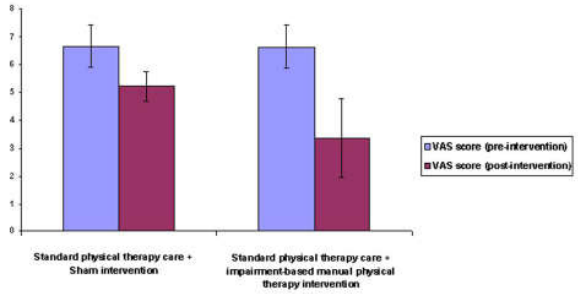

Fig. 2: Between-group comparison of visual analogue scale (VAS) scores pre-post intervention.

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.

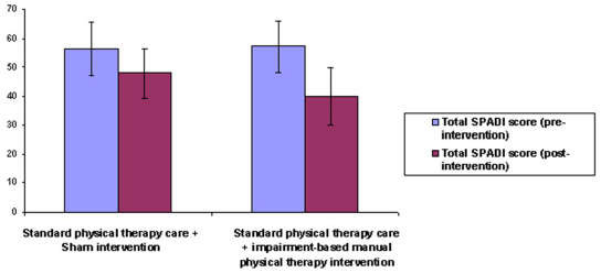

Fig.7: Between-group comparison of shoulder pain and disability index (SPADI) scores pre-post intervention

Discussion:

Similar studies

Our study results were similar to studies of Bergman et 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. 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 setup[115]. Another study[112] 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 points[58] and 3 points[61] 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 rules[127]. 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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A Study to Compare the Effect of Bicycle Ergo Meter & Treadmill Training on Blood Pressure & Heart Rate in Post Menopausal Hypertensive Females

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Abstract

Aims and Objectives: The aim of research is to compare the effectiveness of aerobic exercise tranning on treadmill and bicycle ergometer on physiological parameter in hypertensive post menopausal womens. **Methodology:** A sample of 30 hypertensive post menopausal subjects were recruited for this experimental study. The subjects were randomly divided in to 2 groups Group A (Treadmill exercise) and Group B (Bicycle ergometer). The exercise session of 30 minutes with intensity set at 60%-65% of the reserve heart rate according to the Karvonen method for 4 week5 training session/week. Data collected in the form of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Heart Rate (HR) every pre & post exercise session. **Results:** Comparing of SBP of Group A and Group B at 4 weeks of aerobic training is significance. Comparison of SBP variable has significance difference between the two groups. **Discussion:** Results of our study explained that aerobic exercise training on treadmill and bicycle ergometer showed the significant lowering effect SBP & DBP but not on HR variable for both group. Treadmill exercise is much more impressive in decreasing systolic blood pressure (SBP) with significant change as compare to bicycle ergometer. **Conclusions:** Aerobic physical activity should be considered an important component of lifestyle modification for prevention and treatment of high blood pressure in post menopausal females.

Keywords: SBP; DBP; HR; Treadmill exercise; Bicycle ergometer.

Introduction

Menopause is a cessation of monthly cycles or menstrual cycles of female and characterized by stoppage of regular menstrual cycle more than 1 year. Menopause usually happens in mid life (45-55 yr of age), signaling end of fertile phase of women life. It is to related conditions like mood swings, hot flashes, obesity & high blood pressure. More than 1 in 3 women are postmenopausal are affected by cardio vascular disease and is the primary cause of death among women of postmenopausal age[1].

Menopause starts as function of ovaries begin to change the ripening & release of ovum become unpredictable, ovulation starts to skipped, gradually ovaries almost completely stop producing progesterone & estrogens hormones.A natural or physiological menopause is that which occurs as a part of a woman's normal aging process.

This causes an increase in circulating follicle stimulating hormone (FSH) and luteinizing hormone (LH) levels as there are a decreased in producing estrogen. This decrease in the production of estrogen leads to the perimenopausal symptoms

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of hot flashes, insomnia and mood changes, as well as post-menopausal osteoporosis and vaginal atrophy[2].

Menopause increases risk of high blood pressure. Clinical studies have proved that, once other factors are eliminated, the menopause does indeed place women at a higher risk of developing high blood pressure. During the menopause women experience a dramatic decrease in levels of the hormone estrogen. It is thought that this hormone plays a protective role in maintaining healthy blood pressure, and when it declines suddenly, high blood pressure can be the result[3].

Menopause women's systolic pressure can go up by an average of about 5mm Hg, due to the decrease in estrogen levels. Estrogen withdrawal during menopause has a detrimental effect on metabolism and brings changes in body fat distribution. From a gynoid to an android pattern, reduced glucose tolerance, abnormal plasma lipids, increased blood pressure, increased sympathetic tone, endothelial dysfunction and vascular inflammation[4].

Life style modification in the form of regular physical activity is considered a cornerstone in the prevention and management of hypertension and keeping menopause women physically and mentally fit. Epidemiological studies indicate that greater physical activity or fitness is associated with a lower blood pressure (BP), and meta-analyses of randomized controlled trials have shown that chronic dynamic aerobic endurance training is able to reduce BP[5].

It is well known that exercise plays a vital role in physical fitness, it also helps in keeping blood pressure normal. Aerobic exercise may have a potential role in blood pressure management of long-term-treated hypertensive. So we have done this study to reduce hypertension in postmenopausal females, to provide them easy aerobic exercise regime which can further improve their quality of life.

The aim of study is to compare the effect produced by aerobic exercise in reducing the blood pressure by on treadmill & bicycle ergometer in post menopausal females with hypertension. The purpose of this study is to provide a better treatment regime for the post menopausal females for lowering down their elevated B.P and to create awareness about the risk of hypertension.

Methodology

Research design & sampling

Total 100 subjects were screened for this experimental study and 30 subjects were selected as per inclusion criteria and exclusion citeria. All subjects were divided in two equal 15 subjects/ group Treadmill Group A and Bicycle ergometer Group B by randomization method. Dependent variables of this experimental study were SBP,DBP,HR.Independent variables of this experimental study were Treadmill exercise and Cycle ergometer exercise.

Inclusion criteria

Postmenopausal women with age 45–55 yr old and no natural menses for at least 1 yr

Blood pressure should be Stage 1 hypertension >130/99 mm Hg monitored for continuously three days

Women should be physically capable of exercise; participants must be able to exercise safely at the required doses[6].

Exclusion criteria

Significant any disorders including arrhythmias, myocarditis, cardiomyopathy, congestive heart failure, heart disease etc[7].

Bmi should taken and obesity should considered.

Equipments used

- Treadmill, Model –T 7000
- Cycle ergometer, Model –R8000
- Digital Sphygmomanometer, Model no CH-432B[8].

Procedure

The exercise session consisted of 30 minutes of aerobic exercise on treadmill/ cycle-ergometer and 5 minutes of warm-up and cool-down. Exercise intensity was set at 60%-65% of the reserve heart rate according to the Karvonen method. Entire training period for both the groups is designed for

4 week aerobic exercise with 5 training session/ week. Blood pressure and heart rate is taken every pre & post exercise session[9].

Data Analysis

Data analysis is performed by the SPSS11. the significant level is set at p-value ≤0.05.with confidence level 95%, t- test is used for inter group and one way ANOVA for intra group analysis.

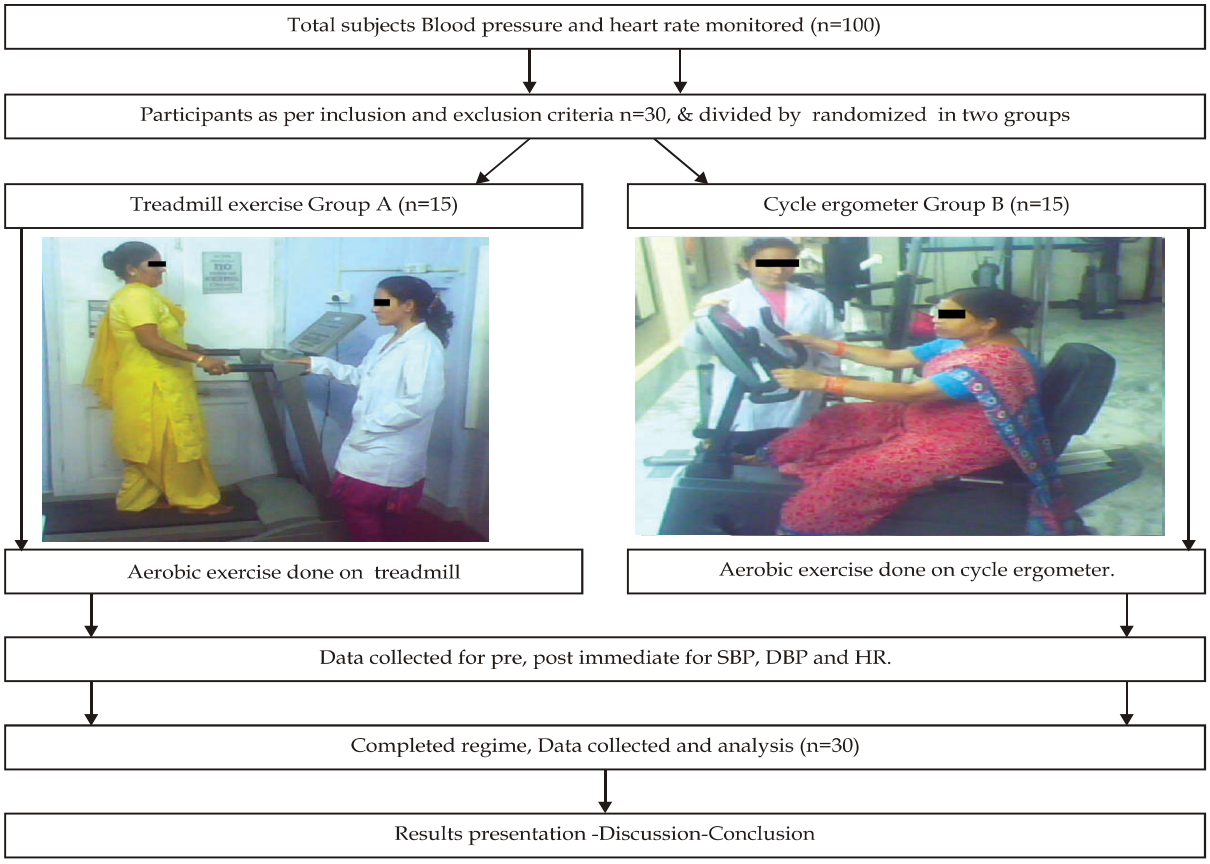


Fig. 1: Research flow chart.

Research flow chart

Result

Table 1: Comparison of mean values of SBP at Pre interval between 1st week, 2nd week, 3rd week and 4th week within Group A and Group B.

Treadmill exercise Group A				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1st week	142.20	5.44	9.56	P <0.05
2nd week	139.73	14.14		
3rd week	134	10.68		
4th week	130	8.01		
Cycle ergometer exercise Group B				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1st week	143.06	6.61	7.91	P < 0.05
2nd week	138.80	8.34		
3rd week	135	6.32		
4th week	134	8.30		

Table 2: Comparison of mean values of SBP at Post interval between 1st week, 2nd week, 3rd week and 4th week within Group A and Group B.

Treadmill exercise Group A				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	135.26	11.21	9.46	P < 0.05
2nd week	134.27	11.14		
3rd week	131.66	7.39		
4th week	122.86	8.00		
Cycle ergometer exercise Group B				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	136.93	13.31	7.29	P < 0.05
2nd week	133.20	9.17		
3rd week	131.60	7.41		
4th week	127.13	6.96		

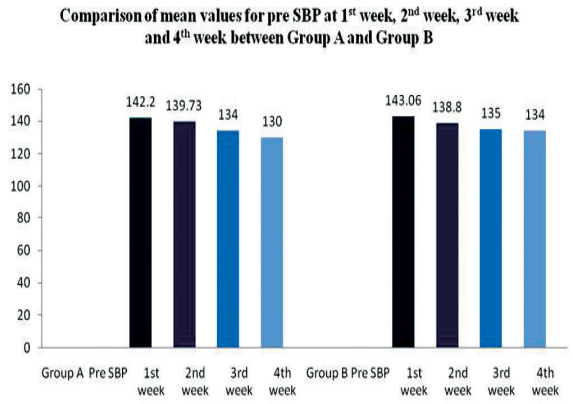


Table 3: Comparison of mean values of DBP at Pre interval between 1st week, 2nd week, 3rd week and 4th week within Group A and Group B.

Treadmill exercise Group A				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	86.06	6.45	1.816	P <0.05
2nd week	85.00	10.47		
3rd week	84.00	6.65		
4th week	82.33	8.36		

Cycle ergometer exercise Group B

Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	86.20	10.21	2.814	P < 0.05
2nd week	85.00	8.11		
3rd week	85.00	10.82		
4th week	84.5	7.27		

SBP After four weeks	**Mean**	**SD**	**F value**	**P value**
Treadmill exercise Group A	130	8.01	3.47	P<0.05
Cycle ergometer exercise Group B	134	8.30		

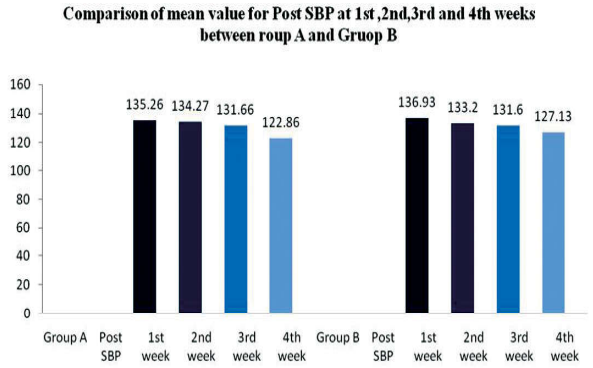
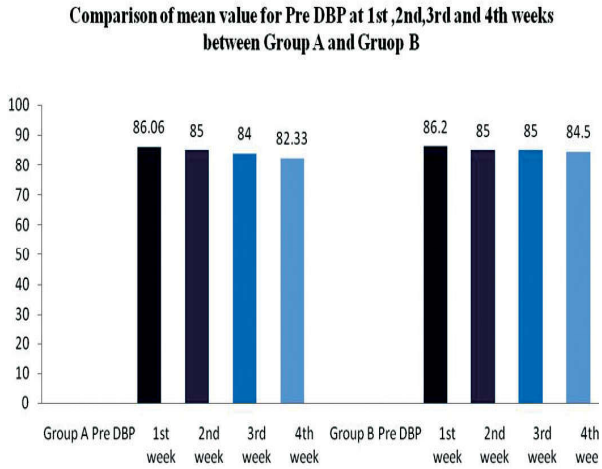


Table 4: Comparison of mean values of DBP at Post interval between 1st week, 2nd week, 3rd week and 4th week within Group A and Group B.

Treadmill exercise Group A				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	85.00	7.80	4.123	P <0.05
2nd week	81.66	7.26		
3rd week	80.86	7.44		
4th week	79.86	6.78		

Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	84.73	10.03	1.995	P < 0.05
2nd week	84.66	4.56		
3rd week	82.93	7.44		
4th week	81.00	7.06		

DBP After four weeks	**Mean**	**SD**	**F value**	**P value**
Treadmill exercise Group A	79.86	6.78	-2.948	P >0.05
Cycle ergometer exercise Group B	81.00	7.06		



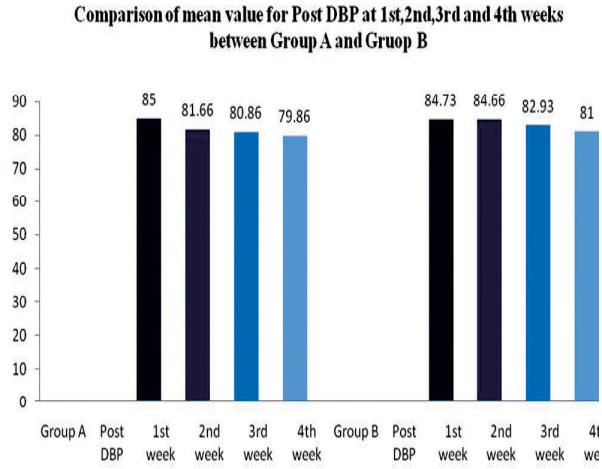


Table no 6: Comparison of mean values of HR at Post interval between 1st week, 2nd week, 3rd week and 4th week within Group A and Group B.

Treadmill exercise Group A				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	86.00	8.21	0.498	P <0.05
2nd week	85.06	12.52		
3rd week	84.53	10.92		
4th week	83.86	9.17		
Cycle ergometer exercise Group B				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	86.73	10.31	0.208	P < 0.05
2nd week	86.00	9.58		
3rd week	85.46	9.14		
4th week	84.86	9.67		

Table no 6: Comparison of mean values of HR at Post interval between 1st week, 2nd week, 3rd week and 4th week within Group A and Group B.

Treadmill exercise Group A				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	85.66	9.65	2.96	P <0.05
2nd week	84.93	10.70		
3rd week	84.06	7.69		
4th week	83.53	8.45		
Cycle ergometer exercise Group B				
Pre SBP	**Mean**	**SD**	**F value**	**P value**
1nd week	86.20	5.93	0.588	P < 0.05
2nd week	85.86	5.98		
3rd week	84.53	9.17		
4th week	84.13	7.31		

Discussion

The important findings of our study are that, the aerobic exercise reduces the blood pressure. After four weeks of aerobic excise we found that blood pressure has reduced with significant changes in the mean of systolic & diastolic blood pressure in both the groups. There is slight reduction in heart rate by aerobics exercise training in both the groups but not significant.

First important finding of our study is that while doing aerobic exercise on treadmill in four weeks significantly reduced systolic blood pressure up to 11.97mmhg. Aerobic exercise on cycle ergometer in four weeks significantly reduced systolic blood pressure upto9.8 mmhg. Aerobic exercise on treadmill seems to be much benefiting and significance as compare to cycle ergometer. A result of our study shows that SBP and DBP was reduced in first few weeks of training but not up to statistically significant level. It reduced significantly in 3rd & 4th week of our study.

Timothy S.& T-M Asikainen etal. have studied on post-menopausal women with aerobic exercise training done on treadmill for 40-45 min 3 days a week at 70-75% of maximum heart rate for 12 weeks. They found that systolic blood pressure was reduced approximately 8mmhg[7,10].

T.Sai etal. examined the effects of regular exercise on blood pressure in 20 and 60 years old adults. The exercise program consisted of 10 minutes of warm up, 30 minutes of treadmill walking or jogging, and 10 minutes of cool down 3 times per week for 10 weeks. Blood pressure was statistically significantly reduced up to 13.1 mm Hg in the exercise group at 10 weeks[11].

Dubbert, P M etal. did a study on endurance exercise in mild hypertension on treadmill with intensity of 50-60% of maximal heart rate, for 40 min 3 days a week up to 36 weeks. They found that systolic blood pressure was significantly reduced[12].

Emmanuel G. Ciolac etal have demonstrated that Exercise intensity with 60% of the reserve heart rate on Cycle ergometer was able to decrease the SBP up to 8.6 mmhg[13].

Another study by Peter F. Kokkinos, Ph.D etal also supports the reduction of systolic blood pressure by aerobic exercise done on cycle ergo meter . They observed a significant reduction in Systolic blood pressure by 7 mm Hg and 6 mm Hg after 16 and 32 weeks of exercise, respectively[14].

Second finding of present study is that diastolic blood pressure was also reduced significantly up to 5.14mmhg on treadmill and up to 3.73 mmhg on cycle ergometer. There was no significance difference between two group on the bases of reduction in DBP .

Timothy S.& T-M Asikainen etal, studied that post-menopausal women age with aerobic exercise training on treadmill reduced significantly to diastolic blood pressure up to 5mmhg .Treadmill exercise was done for 40-45 min 3 days a week at 70-75% of maximum heart rate for 12 weeks[7,10].

Tsai et al. in 2004 examined the effects of regular exercise on blood pressure in adults. The exercise program consisted of 10 minutes of warm up, 30 minutes of treadmill walking or jogging, and 10 minutes of cool down 3 times per week for 10 weeks. Diastolic blood pressure was statistically significantly reduced up to 6.3 mm Hg in the exercise group at 10 weeks[11].

Moreira W.D,Fuchs.F.D etal studied the effect

of different intensities of aerobic exercise on cycle ergometer for 10 weeks at 20% & 60% of their maximum work load .They noted the reduction in DBP up to 6.8 mmHg. Peter F. Kokkinos, Ph.D etal also demonstrated the reduction in DBP up to 7 mm Hg in the patients who exercised[14,15].

Seamus P. Whelton etal did meta-analysis of randomized, controlled trials was conducted to determine the effect of aerobic exercise on blood pressure & concluded that aerobic exercise reduces blood pressure in both hypertensive and normotensive persons. An increase in aerobic physical activity should be considered an important component of lifestyle modification for prevention and treatment of high blood pressure[16].

Third finding of our study was that there was decrease in heart rate of 2.13 beats/miniute by treadmill and 0.63 beats/minute by cycle ergometer, in 4weeks of aerobic exercise training, but it was not statistically significant. Kevin D Monahan etal, conducted a intervention study for 3 month aerobic exercise in the form of walking . They explained that cardiovagal tonicity take time to shows its results in sedentary middle-aged and older healthy people[17].

Result of our study suggests that aerobic exercise done on treadmill & cycle ergometer both reduced blood pressure. Aerobic exercise on treadmill seems to be better as compare to cycle ergometer because walking is an activity of daily living and it requires less co-ordination, muscle fatigueness. Walking also involves action of large muscle group so produces more aerobic stress on heart & hence improve vagal strength. Therefore treadmill exercise is more effective in lowering both systolic & diastolic BP than the aerobic exercise done by cycle ergometer[18,19].

Thus it can be sumrised the importance of physical activity in treatment of hypertension. that regularly performed aerobic exercise for long period of time induces adaptations in the cardiac autonomic nervous system. Aerobic exercise training leads to enhanced vagal activity at rest, which may contribute in part to decrease the blood pressure in long period of exercise training in post menopausal women.

Conclusion

Low levels of cardio respiratory fitness are associated with high risk of cardiovascular disease (CVD) and all-cause mortality and improvements in fitness are associated with reduced mortality risk. Among women in the postmenopausal age range, 30% report no physical activity at all, and the prevalence of inactivity progressively increases with age[20].

Regular physical activity makes positive contributions to health and well-being. The consensus recommended dose described in guidelines is perhaps most clearly presented as obtaining 30 min of moderate-intensity physical activity. Aerobic physical activity should be considered an important component of lifestyle modification for prevention and treatment of high blood pressure in post menopausal females.

Aerobic exercise done by treadmill effectively lowers blood pressure & prevents hypertension. Results of this study showed that early postmenopausal women could benefit from 30 minutes of daily moderate walking on treadmill and cycle ergometer . Aerobic exercise helps to lower high blood pressure by normalizing biochemical, neural and hormonal changes in the blood vessel walls induce an acute and long-term blood vessel relaxation.

Both techniques have their advantages and limitations but treadmill instrumental exercise seems to be better and more effective in reduction of hypertension especially in post menopausal females.

Relevance in clinical practice

Women after menopause face many changes that may lead to loss of health-related fitness (HRF), especially if sedentary. Results of this study elaborate that early post menopausal sedentary females could benefit from 30 minute of daily moderate walking which is feasible & can be incorporated in daily life.

Lifestyle modification in form of aerobic exercise is an important strategy for the prevention and treatment of high blood pressure. It also cut the cost and side effect pharmacologic therapy. Exercise is now relevant for early postmenopausal women and should be routinely performed in order to improve exercise capacity as a preventive measure in subjects with high BP. This can be a informational study that will provide awareness of risks of high blood pressure in postmenopausal women .

Future study

The research can be further extended by taking large sample size, different age group and for long period of time.

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Original Article

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A Study to find the Effect of Posterior Anterior Vertebral Mobilization on Blood Pressure and Heart Rate in Prehypertensive Subjects

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Abstract

Aims and Objectives: The aim of research is to compare the effectiveness of thoracic versus cervical mobilization on physiological parameter in prehypertensive subjects. ***Methodology:*** A sample of 30 prehypertensive subjects were recruited for the study. The subject were randomly divided in to 2 groups Group A (Cervical Mobilization) and Group B (Thoracic mobilization group). Grade III posterior anterior vertebral mobilization, single sitting was given for both the group for 60 sec at each level of spinous process from C2-C7 and T1 to T5. Data collected for pre, post immediate and post 30 min for Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Heaert Rate (HR). ***Results:*** Comparing of SBP of thoracic and cervical group at pre mobilization, post immediate mobilization and post 30 min mobilization is significance. ***Discussion:*** Results of our study explained that when we compare the systolic blood pressure (SBP) variable for cervical group and thoracic mobilization showed the significant lowering effect. Diastolic blood pressure variable, Heart rate variable did not achieve significant level of mean change between the both groups. ***Conclusions:*** So it is concluded that thoracic mobilization is much more impressive in decreasing systolic blood pressure (SBP) with significant change as compare to cervical mobilization.

Keywords: SBP,DBP,HR ,Thoracic Mobilization and Cervical mobilization.

Introduction

Blood pressure is the force exerted on your artery walls as blood flows through your body. Medical associations has given a term called prehypertension which is defined as chronically elevated high blood pressure with systolic blood pressure (SBP) of 130 mmhg or greater and diastolic blood pressure (DBP) of 80mmhg or greater[1].

Prehypertension on long term may lead to hypertension (HTN) and it is the one of the leading cause of death in world. This can be controlled by exercises ,life style modifications and antihypertensive drugs. However, as a result of high cost, multiple adverse results and reduced adherences of antihypertensive drugs, life style modifications and exercises are being of interest for high BP treatment. Some studies have demonstrated that with a single bout of endurance training BP is reduced up to 22 hours of post training[2,3].

Physicalinactivityisamajorriskforcardiovascular disease, and persons who are less active and less fit have a 30% to 50% greater risk for high BP8 .Laura P svetkey et al. has found the beneficial effects of life style modification as a nonpharmacological treatment for prehypertension[4].

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Posterior anterior vertebral mobilization reduces BP in patients with mild to moderate essential hypertension and is now recommended to lower BP in such patients. Posterior anterior vertebral mobilization reduces the risk of injury and cardiac complications and makes exercise feasible for most patients. These factors along with the low cost, absence of side effects, and additional cardiovascular benefits, make the use of mobilization to lower BP appealing[5].

Mobilization is a commonly used passive, skilled,manuel therapy technique applied to vertebral joint and related soft tissue at varying speed and amplitude using physiological or accessory motion for therapeutic purpose. The speed and amplitude could range from a small amplitude force at high velocity.

Posterior anterior vertebral mobilization involves passive rhythmic and repetitive movement within a range of motion or against a restrictive barrier and improves physiological motion of joint. Mobilization is technique that is claiming to be used in variety of condition. It is a gentle technique where the force and amplitude can be controlled depending on response of tissue and severity of condition been treated. Passive movement of the vertebral column is used commonly in the management of spinal dysfunction[6,7].

High blood pressure is the major risk factor for coronary artery disease. That's why it is so important to control prehypertension and make awareness of the risk of prehypertension and hypertension. Therefore this study is design to provide the importance of health life and will create awareness about the risk of prehypertension[8].

The purpose to select this study is to find out the effect of posterior anterior vertebral mobilization on blood pressure and heart rate ,and how does it help in reducing it .To find out better treatment regime with low cost, absence of side effects, and additional cardiovascular benefits, make the use of mobilization to lower BP appealing. Result of this will help in formation of a better and different treatment idea in the form of manual therapy protocol for hypertensive subject.

The aim of the study was to compare the effect of cervical and thoracic mobilization on blood pressure in prehypertension subjects. Mobilization treatment regime with low cost, absence of side effects, and will be able to lower BP with additional cardiovascular benefits.

Methodology

Dependent variables of this experimental study were SBP, DBP, HR. Independent variables of this experimental study were thoracic mobilization and cervical mobilization.

Inclusion criteria

- Age group between 20 to 30 years.
- No drug history.
- Hemodynamiclly stable.
- Male subject with prehypertensive group 120 to 139mmhg and with DBP 80 to 89 mmhg monitored continuous for three days.

Exclusion criteria

Male subject with hypertensive group SBP >140 and DBP> 90 Subject with any musculoskeletal disorder, dizziness on mobilization , individual performing regular exercise, subject who is not co-operative, Subject having pain at spinal level or general body were not included.

Equipments used

Polar heart rate monitor,Model-T 31[9]

Sphygmomanometer, citizen, Accuracy-pressure +/- 3mmhg, Pulse =/-5% of reading.

Procedure

Total 30 subjects as per inclusion criteria out of 200 subjects screened were included for this

experimental study .All subject were divided in to 2 groups, 15 subjects in the Cervical mobilization group A and 15 subjects in the Thoracic mobilization group B. Grade III posterior anterior vertebral mobilization, single sitting was given for both the group for 60 sec at each level of spinous process from C_2-C_7 and T_1 to T_5. Blood pressure, and heart rate were recorded prior and after mobilization[10].

Data analysis

Data analysis is performed by the SPSS11. the significant level is set at p-value ≤0.05.with confidence level 95%, t- test is used for inter group analysis. One way ANOVA is used for intra group analysis.

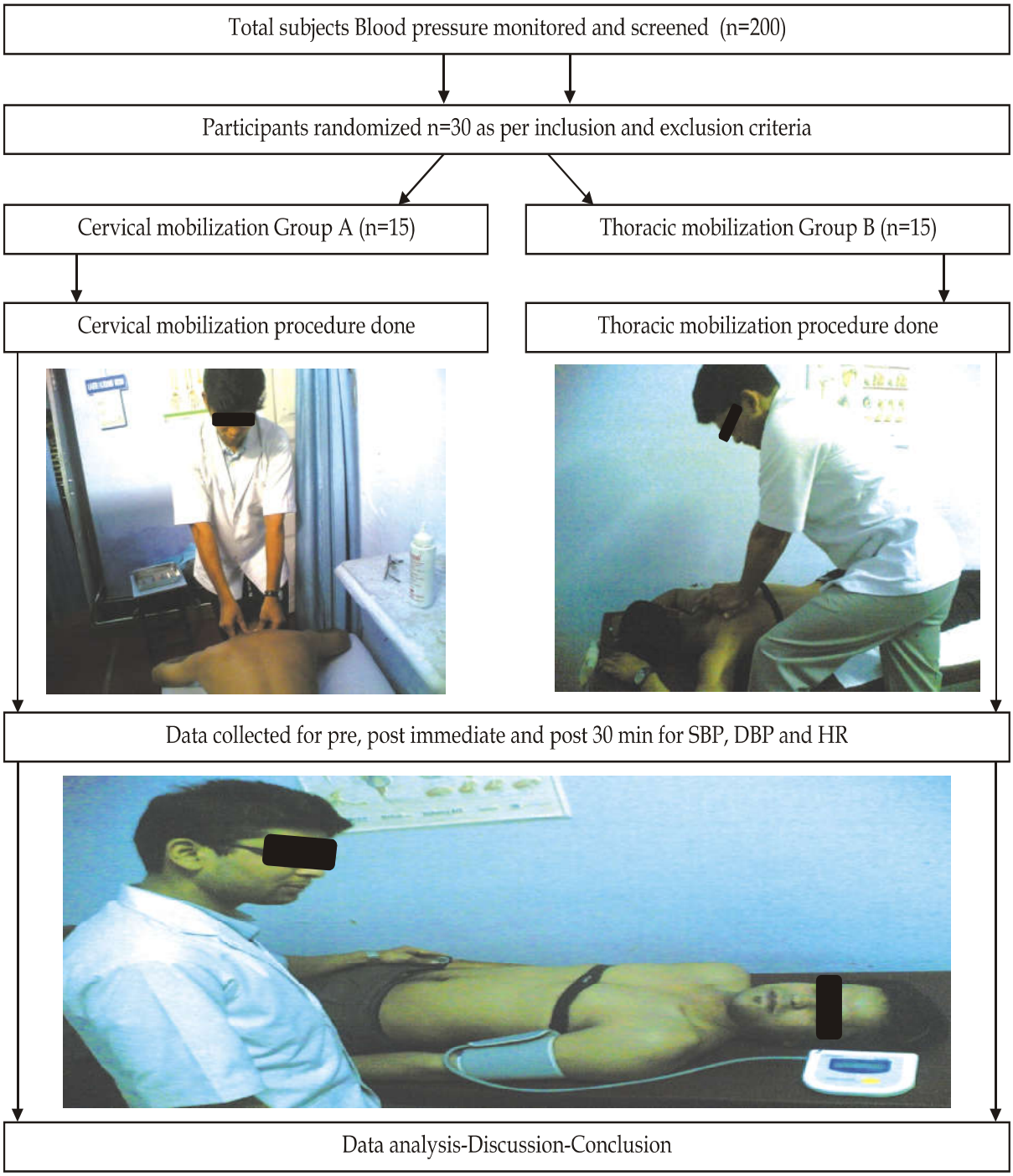


Fig. 1: Procedure Flow chart.

Result

Table 1: Comparing of HR at pre mobilization, post immediate mobilization and post 30 minute mobilization of cervical group A.

Heart Rate	Cervical Group-A		F value	P value
	Mean	SD		
Pre	81.26	4.94		
Post	83.73	5.22	1.083	P > 0.05
Post 30 min	83.33	4.57		

Table 2: Comparing of HR at pre mobilization, post immediate mobilization and post 30 minute mobilization of thoracic group B.

Heart Rate	Thoracic Group B		F value	P value
	Mean	SD		
Pre	80.26	6.30		
Post	81.53	5.11	0.545	P > 0.05
Post 30 min	79.46	4.88		

Table 3: Comparing of DBP at pre mobilization, post immediate mobilization and post 30 minute mobilization of cervical group A.

DBP	Cervical Group		F value	P value
	Mean	SD		
Pre	77.06	5.28		
Post	74.40	4.08	1.799	P > 0.05
Post 30 min	78.33	7.49		

Table 4: Comparing of DBP at pre mobilization, post immediate mobilization and post 30 minute mobilization of thoracic group B.

DBP	Thoracic Group-B		F value	P value
	Mean	SD		
Pre	80.80	4.95		
Post	82.86	4.70	2.116	P > 0.05
Post 30 min.	79.46	3.96		

Table 5: Comparing of SBP at pre mobilization, post immediate mobilization and post 30 minute mobilization of cervical group-A.

SBP	Cervical Group-A		F value	P value
	Mean	SD		
Pre	131.93	3.63		
Post	127.53	5.18	4.090	P > 0.05
Post 30 min.	130.53	3.94		

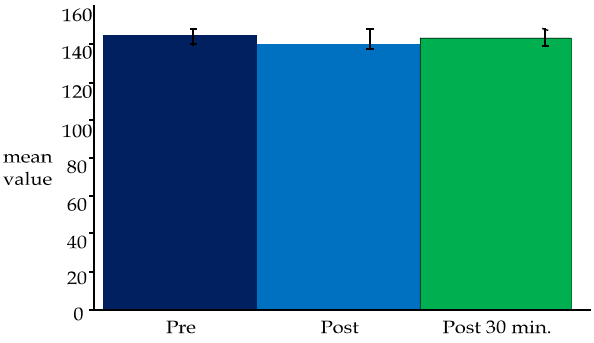


Table 6: Comparing of SBP at pre mobilization, post immediate mobilization and post 30 minute mobilization of thoracic group B.

SBP	Cervical Group-A		F value	P value
	Mean	SD		
Pre	133.66	6.21		
Post	129.73	5.52	5.186	P > 0.05
Post 30 min.	127.00	5.31		

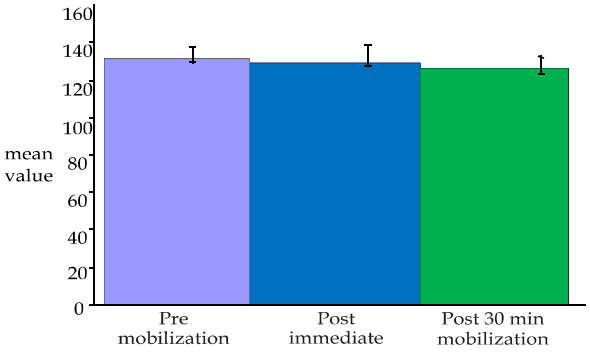


Table-7: Comparing of SBP of thoracic and cervical group at pre mobilization, post immediate mobilization and post 30 min mobilization.

SBP	Thoracic Group B		Cervical Group A		T value	P value
	Mean	SD	Mean	SD		
Pre mobilization	133.66	6.21	131.93	3.63	0.932	P > 0.05
Post immediate mobilization	129.73	5.52	127.53	5.18	1.125	P > 0.05
Post 30 min mobilization	127.00	5.31	130.53	3.94	-2.067	P < 0.05

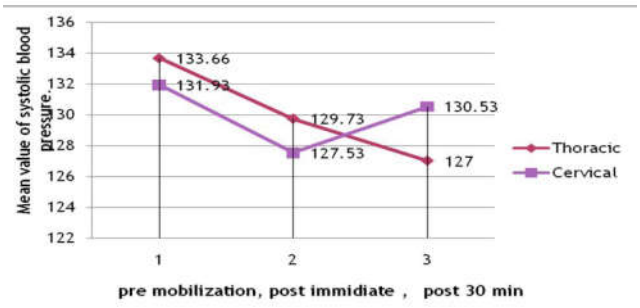


Table 8: Comparing of DBP of thoracic and cervical group at pre mobilization, post immediate mobilization and post 30 min mobilization.

Heart Rate	Thoracic Group B		Cervical Group A		T value	P value
	Mean	SD	Mean	SD		
Pre mobilization	80.26	6.30	81.26	4.94	-0.483	P > 0.05
Post immediate mobilization	81.53	5.11	83.73	5.22	-1.165	P > 0.05
Post 30 min mobilization	79.46	4.88	83.33	4.57	-2.238	P < 0.05

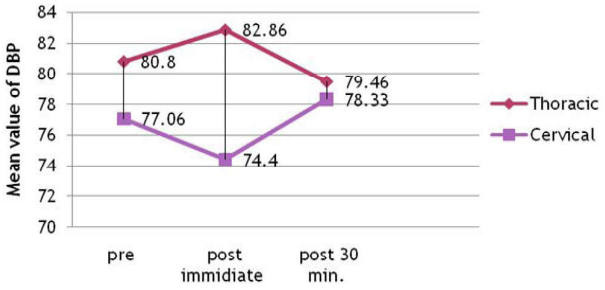
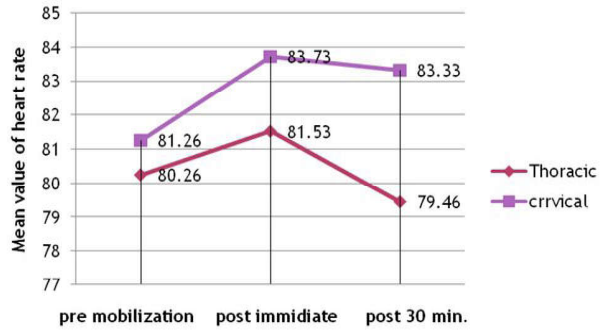


Table-9: Comparing Mean and SD of HR of thoracic and cervical group at pre mobilization, post immediate mobilization and post 30 min mobilization.

DBP	Thoracic Group B		Cervical Group A		T value	P value
	Mean	SD	Mean	SD		
Pre mobilization	80.80	4.95	77.06	5.28	1.995	P>0.05
Post immediate mobilization	82.86	4.70	74.40	4.08	5.264	P>0.05
Post 30 min mobilization	79.46	3.96	78.33	7.49	0.518	P<0.05



Discussion

The first important finding of our study shows that vertebral mobilization on comparing the heart rate variability of thoracic mobilization and cervical mobilization didn't showed significant change although there were very slight changes on pre mobilization to post 30 min mobilization on short term goal but not significant. McKnight ME et al. and Budgell Bet al. has reported in their study that asymptomatic subjects received mobilization to the cervical and thoracic showed no significant difference between group with respect to heart rate after the mobilization[6,11].

Results of our study shows that the comparison of diastolic blood pressure showed not much change at initial state .There was little changes noted which went back to its previous state post 30 min mobilization. Therefore there were no significant changes noted in DBP both in cervical and thoracic mobilization groups. Reis MS etal. has explained in their study that mobilization of cervical, lumber & thoracic level has its own effect but there was significant changes in thoracic level manipulation like difference in systolic blood pressure however diastolic blood pressure, pulse, heart rate and respiratory rate could not achieved significant value[12].

Next important finding of our study is that thoracic and cervical mobilization found to be impressive in decreasing systolic blood pressure (SBP) with significant change. Fichera AP et al. have also demonstrated that manipulation of the cervical and thoracic vertebrae reduces moderate hypertension. McGee D. et al. Founded that in his case study of a 46-year-old woman's rapid decrease in blood pressure following initial chiropractic adjustment[13,8].

Yates RG et al. has also founded that manipulation of the thoracic spine significantly reduces blood pressure in patients with elevated blood pressure. Both systolic and diastolic blood pressure decreased significantly in the adjusted group. No significant changes occurred in the placebo or control groups. Adjustments were delivered to segments T-1 to T-5[14].

Results of our study demonstrated that thoracic mobilization is much more impressive in decreasing systolic blood pressure (SBP) with significant change as compare to cervical mobilization. Tran AT et al. conducted randomized controlled trail on asymptomatic subject for mobilization. There was difference between groups with respect to blood pressure or heart rate after the mobilization[15].

Emmanuel Yung, PT et al. suggested that anterior Posterior spinal pressure caused a statistically significant physiologic response that resulted in a minor drop in vasodepressor and statistically significant reduction in systolic BP after the procedure[7].

Michel Silva Reis et al. explained that autonomic

imbalance is dominated in prehypertensive subjects. The autonomic imbalance characterized by sympathetic hyperactivity at rest and an inability to appropriately respond to physiological stressors. The mobilization technique significantly reduces pain as well as it was able to improve SBP quantified by an increased vagal activity and cardiac autonomic modulation. One session of Maitland spine mobilization was able to acutely improved the blood pressure regulation and HRV[16].

Results of our study concluded that when we compare the systolic blood pressure (SBP) variable for cervical group and thoracic mobilization showed the significant lowering effect. Diastolic blood pressure variable ,Heart rate variable did not achieve significant level of mean change between the both groups . McGuiness J et al. founded in their study that manipulation of the cervical and thoracic vertebrae reduces moderate systolic blood pressure[17,18].

In summary our result suggested that thoracic mobilization is important strategy as compare to cervical mobilization for prevention and treatment of prehypertension. Cervical mobilization seems not to be doing any help in treatment strategy for prehypertension subjects.Thoracic mobilization found out to be better, positive and helpful result then cervical mobilization in normalizing prehypertension.

Conclusion

Thoracic and cervical mobilization both reduces systolic blood pressure with significant value but not diastolic blood pressure; even heart rate not achieved significant level. Thoracic mobilization found to be impressive in decreasing SBP with significant change as compared to cervical mobilization.

Result of this study signifies a simple and easy treatment regime for individuals with prehypertension and will help them in preventing hypertension. This result of this study provide a informational for society about the new treatment for autonomic dysfunction correction in prehypertension. Result of this will create a awareness about the risks of high blood pressure and provide a base line indication to promote another's study in prehypertensive treatment field.

Clinical Relevance

Prehypertension is common and has clinical and public health significance in sedentary life style population. Treatment strategies emphasized nonpharmachological lifestyle interventions in all patients. Our study showed significant changes in blood pressure with cervical and thoracic mobilization. Mobilization will help in prevention of prehypertension to hypertension by effectively lower BP and expected to reduce CVD morbidity and mortality.

Future study

Spinal mobilization appears to be effective in producing a temporary reduction in blood pressure immediately after treatment. The effect of such treatment in reducing blood pressure over a period of days or weeks is unknown and warrant further investigation.This research in future can be extended by taking large sample size and long term treatment goal. The age and gender group can be change to find out effectiveness of the sample protocol normal subjects with precaution.

Conflict of interest: There is no conflict of interest related to this clinical research among all authors.

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Original Article

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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.

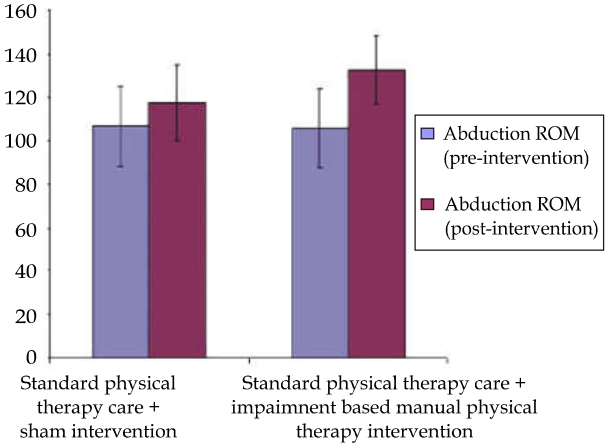

Fig. 3: Between-group comparison of shoulder abduction active range of motion pre-post intervention.

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.

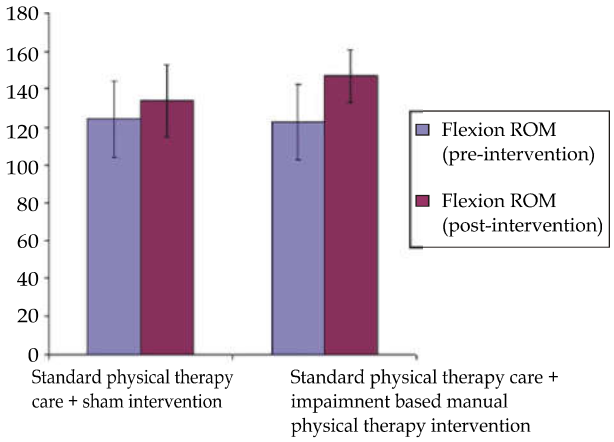

Fig. 4: Between-group comparison of shoulder flexion active range of motion pre-post intervention.

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.

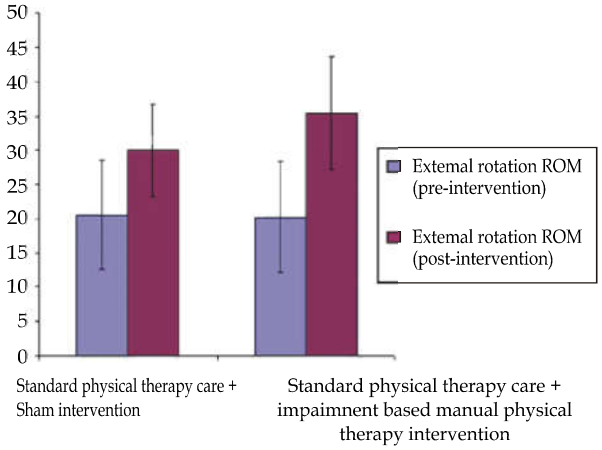

Fig. 5: Between-group comparison of shoulder external rotation active range of motion pre-post intervention.

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.

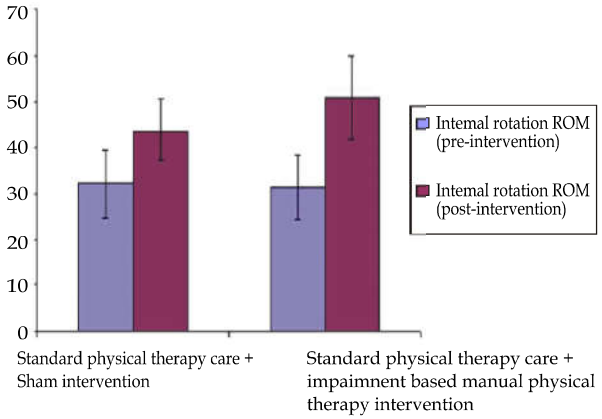

Fig. 6: Between-group comparison of shoulder internal rotation active range of motion pre-post intervention.

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.

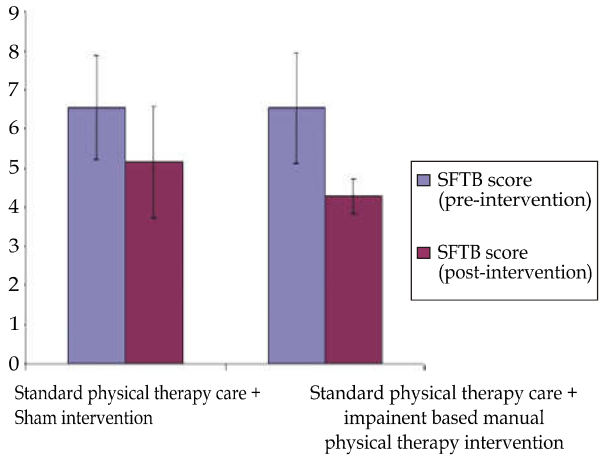

Fig. 8: Between-group comparison of shoulder abduction functional tests battery (SFTB) scores pre-post intervention.

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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