

Efficacy of iliopsoas muscle release on respiratory parameters in patients with chronic low back pain: a single blinded, two-groups, pre-test/post-test randomized controlled trial protocol

Eficácia da liberação do músculo iliopsoas sobre os parâmetros respiratórios em pacientes com dor lombar crônica: um protocolo de ensaio clínico controlado randomizado único cego, dois grupos, pré-teste/pós-teste

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ABSTRACT | BACKGROUND AND PURPOSE: Iliopsoas and diaphragm muscle share common attachment at L2 vertebrae, iliopsoas tightness may lead to reduce diaphragm excursion leading to breathing difficulty. Therefore, the present controlled trial will provide evidence on the effect of the iliopsoas muscle release in upgrading respiratory efficiency in patients with chronic low back pain. **METHOD/DESIGN:** A total of thirty-four participants with mechanical chronic low back pain due to hip flexor tightness and having breathing difficulty will be recruited based on selection criteria. It will be randomly allocated into Group A (conservative treatment + iliopsoas myofascial release), Group B (conservative treatment + sham treatment). Both the group will receive the intervention three times a week for three weeks. The outcome measures will be the Roland Morris Disability Questionnaire, Numeric Pain Rating Scale, and diffuse capacity of Lung for Carbon monoxide as outcome measures. **DISCUSSION:** This trial will help identify the effectiveness of iliopsoas release in low back pain and its effect on respiratory parameters. **TRIAL REGISTRATION:** This trial has been prospectively registered at clinclatials.gov (CTRI/2020/04/024661) on 16 April 2020.

KEYWORDS: Carbon monoxide. Diaphragm. Low back pain. Lumbar vertebra. Manipulation.

RESUMO | JUSTIFICATIVA E OBJETIVO: Iliopsoas e o músculo diafragma compartilham fixação comum nas vértebras L2, a contração do iliopsoas pode levar à redução da excursão do diafragma levando à dificuldade respiratória. Portanto, o presente estudo controlado fornecerá evidências sobre o efeito da liberação do músculo iliopsoas na melhoria da eficiência respiratória em pacientes com dor lombar crônica. **MÉTODO / DESENHO:** Um total de trinta e quatro participantes com lombalgia crônica mecânica lombar crônica devido à rigidez dos flexores do quadril, dor lombar crônica e dificuldade respiratória serão recrutados com base nos critérios de seleção e serão alocados aleatoriamente em dois grupos, Grupo A (tratamento conservador + liberação miofascial iliopsoas), Grupo B (tratamento conservador + tratamento simulado). Ambos os grupos receberão a intervenção três vezes por semana durante 3 semanas. As medidas de resultado serão o Questionário de Incapacidade de Roland Morris, a Escala Numérica de Avaliação da Dor e a Capacidade de Difusão do Pulmão, pois o monóxido de carbono será usado como medidas de resultado. **DISCUSSÃO:** Este estudo ajudará a identificar a eficácia da liberação de iliopsoas na dor lombar e seu efeito nos parâmetros respiratórios. **REGISTRO DO ENSAIO:** Este ensaio foi registrado prospectivamente em clinclatials.gov (CTRI / 2020/04/024661), em 16 de abril de 2020.

PALAVRAS-CHAVE: Monóxido de carbono; Diafragma; Dor lombar; Vértebra lombar; Manipulação; manipulação espinhal

Introduction

Low back pain has a high prevalence among musculoskeletal disorders nowadays due to a sedentary lifestyle. The prevalence of chronic low back in the worldwide population is 4.2% in the age group of 24-39 years and 19.6% in the population¹ of 20-59 years of age. Moreover, in the Brazilian sedentary population, the prevalence is 71.5%.² More than 80% of the population experience low back pain after the third decade of their life, with 95% recovering within a few months of onset.³ Chronic pain is the pain that persists consistently for more than twelve weeks or three months and hampers the quality of life.⁴ According to National Health Survey (NHIS), about 22.4 million back pain cases lasted for more than a week within one year.³

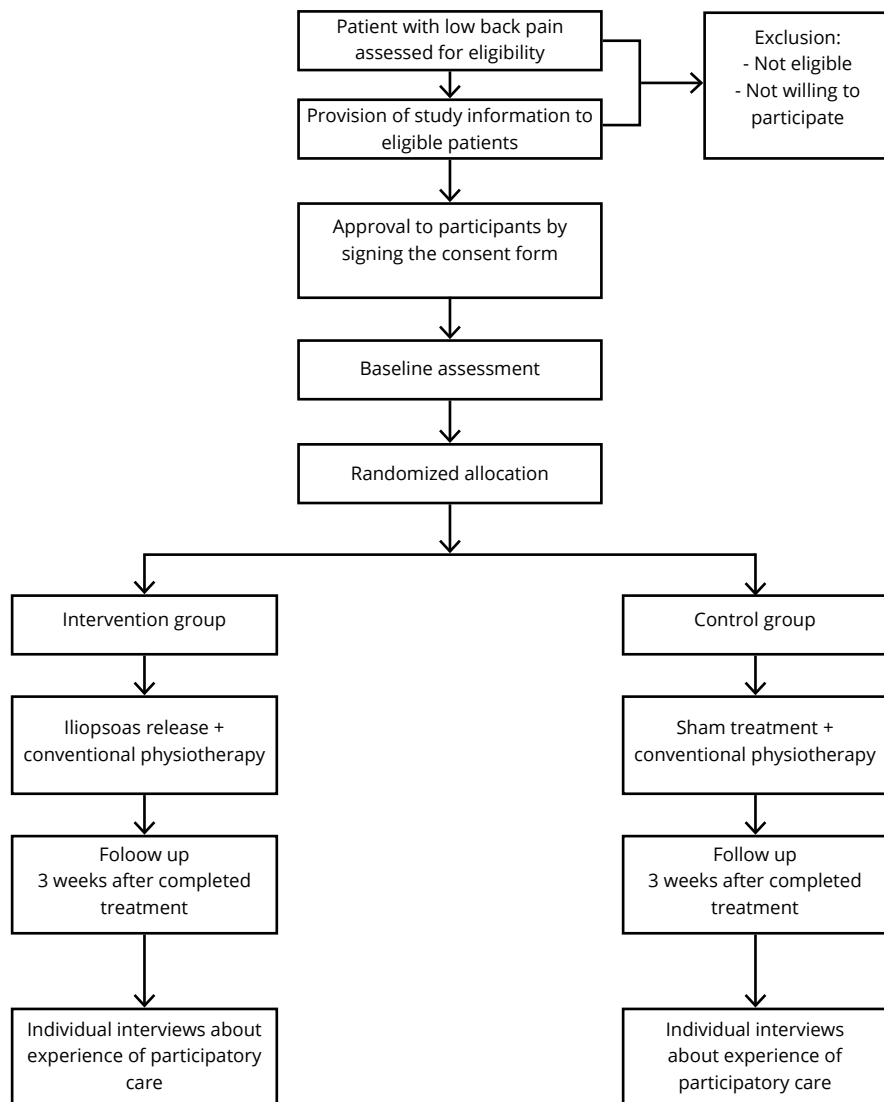
The postural factor may play an important role in the etiology of low back pain. The diaphragm is a key inspiratory muscle that contributes to controlling the posture of the spine. Thus, chronic low back pain that results in reduced postural control. Loading of the diaphragm is reduced in individuals with LBP and activates the proprioceptive feedback, leading to increased diaphragm fatigue.⁵ The core muscles are the primary spine stabilizer that prevents low back pain. The core consists of four main muscles, i.e., transverse abdominals, multifidus, pelvic floor muscles, and diaphragm.⁶ Multifidus are a deep lower back muscle that makes up the back part of the core and is also known as the main postural muscle that helps maintain the spine's erectility. Low back pain's predisposing factor is reduced flexibility, particularly of iliopsoas and hamstring muscles, leading to reflex inhibition of stabilizing musculature of the spine.⁶ Multifidus muscles are broader at the lower lumbar level and narrower at the upper lumbar level. Multifidus muscle covers the facet joints and the most medial paraspinal muscle. Fatty infiltration on the multifidus muscle (posterior compartment) and the iliopsoas muscle (anterior compartment) at the level of L4-L5 is associated with low back pain.⁷

The posterior fascia of the diaphragm at the level of retroperitoneal is divided into four parts. The interfascial plane is a system that integrates the aortic structure, the mediocrura vena cava, the liver, the muscles of the psoas, the lumborum quadratus, the heart region, the phrenic-esophageal tendons, and, ultimately, the kidneys.⁸ Psoas major and diaphragm muscle share a common attachment proximal to T12 vertebrae.⁹ These two muscles have a similar fascial relationship; therefore, any fascial dysfunction in one structure could affect the other's biomechanics.¹⁰ Hip flexor tightness is one of the major causes of back pain. Primary hip flexor iliopsoas is composed of psoas major and iliacus muscle.

A previous study¹¹ conducted to determine the effect of manipulating the thoracic spine, breathing exercises on respiratory parameters in patients with non-specific chronic low backache. The most common cause of reduced respiratory function in patients with chronic low backache is a faulty posture demonstrated by stoop posture and thoracic kyphosis, leading to a decrease in the rib cage excursion because of altered muscle length-tension relationship with posture.¹¹ The results obtained from the study demonstrated improvement in forced vital capacity, chest wall expansion in the patients and concluded that the patients treated with particular treatment of low backache in adjunct with respiratory exercises showed reduced disability due to low backache and enhancement in respiratory parameters. An unpublished study was conducted to determine the correlation between the iliopsoas muscle tightness and respiratory parameters in the patients with chronic low back pain concluded a moderate correlation between the two. Myofascial release is used to enhance function and decrease pain; it involves applying mild pressure stretch to the myofascial complex.¹² However, there is a lack of evidence available that proves the effect of iliopsoas muscle release on the respiratory parameters. Thus, the study's objective is to see the efficacy of iliopsoas muscle release on respiratory parameters in patients with chronic low back pain.

Material and methods

Figure 1. Flow chart of study protocol



This single-blinded, single-center, pre-test post-test randomized controlled trial. The standard protocol items for randomized interventional trials (SPIRIT) were followed, and then CONSORT guidelines will be followed to report the result of the study.¹³

Trial registration

The study has got ethical clearance from Institutional Ethical Committee (IEC) number 1526. This trial has been prospectively registered at Clinical Trial Registry- India (CTRI) number CTRI/2020/04/024661. The Universal Trial Number (UTN) mentioned as U1111-1248-4133. The trial will be conducted in the Physiotherapy Outpatient Department in a tertiary care hospital.

Study design

The proposed study is a single-blinded, two-group, pretest-posttest randomized controlled trial design Fig. 1 demonstrates an overview of the protocol. The consent form will be taken from the voluntary patients before the treatment. The patient will be assured that there will be no harmful effect of the treatment on their health conditions, and the privacy of the patients will be maintained. The primary outcome will be the Numeric Pain Rating Scale (NPRS) and Modified Oswestry Disability Questionnaire (MODQ) to assess the disability's low back pain. The secondary outcome will be Diffusing Capacity of Lung for Carbon monoxide (DLCO).

Recruitment of participants

Forty patients with low back pain will be recruited for the study according to the selection criteria Using purposive sampling. Demographic data such as name, age, gender, occupation, address, a contact number will be taken in a pre-designed Performa¹³ of the patients. The weight and height of each patient will be measured for calculating BMI.

Table 1. Selection criteria for participants

Inclusion Criteria	Exclusion Criteria
1. Age 25-55 years. ¹⁴ 2. Bilateral hip flexor tightness. ¹⁵ 3. Chronic low back pain due to hip flexor tightness (more than 12 weeks). ¹⁶ 4. Both male and female. ¹⁷ 5. Body Mass Index (BMI) 18.5- 24.9. ¹⁸ 6. Numeric Pain Rating Scale (NPRS) \geq 3. ¹⁹	1. Spinal surgeries. ³ 2. Smokers. 3. Infections like tuberculosis and pneumonia. 4. Lumbar radiculopathy. 5. PIVD and anterolisthesis. 6. Recent abdominal surgeries (< 6 months).

Both the males and females¹⁷ of age group 25-55¹⁴ years with hip flexor tightness¹⁵ having body mass index of the 18.5-24.9¹⁸ and NPRS score of \geq 3¹⁹ and back pain due to hip flexor tightness¹⁶ will be included in the study. The patients who are smokers, having infections like tuberculosis, pneumonia, lumbar radiculopathy, PIVD, anterolisthesis, recent abdominal surgeries (<6 months), spinal surgeries³ are excluded from the study.

Randomization

The therapist will perform block Randomization to randomize the patients into two groups (Group A experimental group, n =20, Group B control group, n=20) so that an equal number of patients can be assigned to each group.²⁰ Determination of the block size so that it will be a multiple of the number of groups (block size will be 4, 6, 8 for two groups). Blocks are used for the small sample size. By determining the block size, all possible ways of grouping must be calculated. Block size should be dividable by the number of treatment groups.²¹ Patients will be assigned to the groups using sequentially numbered opaque sealed envelopes to provide allocation concealment.

To minimize the risk of predicting the following eligible patient's treatment assignments, they will be randomly permuted into blocks of 4.

Intervention

Patients will be assessed for iliopsoas muscle tightness using the Modified Thomas test (MTT). A written consent form will be taken from the patient for voluntary participation. Patients will be recruited based on the selection criteria. The patient will be randomly allocated into two groups, i.e., Group A (experimental group), will receive iliopsoas release and conventional physiotherapy, and in Group B (control group), they will receive sham treatment with conventional physiotherapy. Patients will receive nine treatment sessions 30-45 minutes/ day for three weeks, i.e., three days /week on consecutive days.²² Ajimsha MS, Daniel B, Chithra S. Effectiveness of Myofascial release in the management of chronic low back pain in nursing professionals. *J Bodyw Mov Ther.* 2014;18(2):273-81. <http://dx.doi.org/10.1016/j.jbmt.2013.05.007> na página 419 The outcome measures NPRS, MODQ and DLCO will be measured at baseline and on the last day, i.e., after the 10th session. The study's principal investigator will provide the intervention, and the face-to-face mechanism will provide the intervention. Repetitions of the treatment session will be reduced according to the pain severity.

Table 2. Summary of interventions to be given to the patients

Group	Procedure
Group A (Experimental group) Conventional physiotherapy + Iliopsoas muscle release	Patient Position- The patient in a supine lying position on the couch Therapist position – Standing Procedure – For giving myofascial release of iliopsoas muscle therapist will place one hand reinforced by the other hand and fingers pointed perpendicularly over the iliopsoas tendon palpated approximately midpoint of the umbilicus and ASIS of side to be treated. Force applied by the fingers should be mild, and compression and tension will be given in superior direction. Release of the muscle will be provided by the transverse sliding of the psoas fascia. MFR will be given for 2 minutes on each side in every session
Group B (Control group) Conventional physiotherapy +Sham treatment	Patient Position- The patient in a supine lying position on the couch Therapist position - Besides the couch. Procedure- The patient in the control group will be given sham myofascial release, and only the hands will be placed in a similar position as for iliopsoas myofascial release (in the experimental group); no force will be applied.

Group A (Conventional physiotherapy + Iliopsoas muscle release)

The patient will be in the supine lying position, and the therapist will be in a standing position. For giving myofascial release of iliopsoas muscle therapist will place one hand reinforced by the other hand and fingers pointed perpendicularly over the iliopsoas tendon palpated approximately over the midpoint of umbilicus and ASIS of side to be treated. The force applied by the fingers should be mild, and compression and tension will be given in a superior direction; the muscle release will be provided by the transverse sliding of the psoas fascia.²³ MFR will be given for 2 minutes on each side in every session.¹⁴ For conventional physiotherapy treatment, the patient will be in prone lying, moist heat pack for 15 minutes, and Transcutaneous Electrical Current Stimulator of 100ms pulse width, 90 Hz frequency, intensity according to patient tolerance for 15 minutes will be given.

Group B (Conventional physiotherapy + Sham treatment)

The patient will be in a supine lying position on the couch, and the therapist will be beside the couch. It will be given sham myofascial release to the patient, only the hands will be placed in a similar position as given in group A, but no force will be applied. In conventional physiotherapy treatment, moist heat pack for 15 minutes¹⁷ and Transcutaneous Electrical Current Stimulator (TENS) of pulse width with 100ms, frequency 90 Hz, intensity according to patient tolerance for 15 minutes over the lumbar region will be given.²⁴

Outcome measures

Numeric Pain Rating Scale (NPRS)

The NPRS questionnaire is composed of an 11-point scale from 0-10. The patient chooses a most compatible value with the force of pain they have experienced in the last 24 hours. In which "0" means no pain, "10" means intense pain. The NPRS has good sensitivity while producing data that can be statistically analyzed. The patient has to mark the score on the questionnaire according to the pain intensity he/ she is suffering. Cheryl et al. reported that the reliability of NPRS is $r = 0.74$.²⁵

Modified Oswestry Disability Questionnaire (MODQ)

MODQ questionnaire is consisting of 10 items that are associated with different functions. The functions include personal care, lifting, sitting, walking, standing, social life, sleeping, traveling, employment/homemaking (replacement of sex life item). Each item has a 0- 5 score; higher values that represent more disability. Disability score will be obtained by the sum of the score divided by total score (50), and the percentage of disability is calculated by multiplying the obtaining score by 100.²⁶ In a study, Bakers et al. reported that the reliability of MODQ is $r=0.89$.²⁷

Diffusing Capacity of Lung for Carbon monoxide (DLCO)

According to criteria by the American Thoracic Society/ European Respiratory Society, diffusing capacity of the lung for carbon monoxide will be performed using Vmax 22 system (Sensor Medics, Yorba Linda, CA, USA) according to criteria by the American Thoracic Society/ European Respiratory Society.²⁸ DLCO consist of mixture of gases that is carbon monoxide (0.3%), acetylene (0.3%), methane (0.3%), oxygen (21%), nitrogen.²⁹ Diffusion capacity for carbon monoxide (DLCO) will be carried out in Respiratory Medicine OPD. This patient will be prepared for the procedure and his nose will be clipped so that air will not be inhaled or exhaled through the nose; it will be asked that the patient inhale through the mask that is fitted over the mouth, hold the air for 10 sec and then exhale the air in the tube.³⁰

Pulmonary function tests (PFT)

PFT is a breathing test used to evaluate the movement of air in and out of the lungs. The most common forms of PFT are spirometry and diffusion studies, and body plethysmography. Spirometry performed in an upright position can measure the forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), FEV1/FVC. Spirometry is performed by exhaling fully through a mouthpiece, i.e., connected to a machine. A nasal clip will be applied to the patient's nose after normal inspiration to prevent the inhalation and exhalation through the nose, then inspire as much as possible through the mouthpiece hold the breath for 10 seconds after that breath out.³¹

Safety and adverse outcome

The risk of harm to the patient during the session is minimal. Common side effects that can occur due to the physical therapy intervention will be mild soreness, some temporary alteration in the pain level.

Data monitoring

An independent researcher will perform all the statistical analyses and datasets, names of the patients will be kept confidential. A treating physiotherapist will monitor the treatment sessions in each group.

Follow up

The therapist will encourage and inspire the patient to follow up by phone or through mails on specific days, which will be accomplished after one week.

Sample size calculation

The sample size was calculated using the standard formula of sample size estimation, i.e., $2[(z\alpha+z\beta)^2 \times S^2/d]$. In which the value of $z\alpha = 1.96$ and $z\beta = 0.84$. The study included for the estimation of sample size has MCID value of Oswestry Disability Index is 7.5 and the value of $S = 16.6$, so by applying these values in the formula, the calculated sample size was 34. The total sample size of 34 participants and 20% dropout will be taken by which the sample size calculated 40 samples, 20 in each group.²⁰

Data analysis

All data will be analyzed in IBM SPSS 20 (Chicago, IL). The Independent Researcher will complete observable investigations and datasets. The Normality test, Shapiro Wilk, will be used to check the normal distribution of the sample size. Based on the normality, descriptive statistics data will be expressed as mean, standard deviation (SD)¹², or median and interquartile range. A paired t-test or Wilcoxon signed-rank test will be made the within-group comparison, and between groups, the comparison will be made through independent t-test or Mann Whitney U test. For all the analysis p-value will be set as equal to or less than 0.05 as significance.

Discussion

Low back pain is one of the most common worldwide medical complaints that reduces the quality of life, disability, and socioeconomic burden. Low back pain arises or is associate with any anatomical structure includes bones, muscles, intervertebral discs, joints, ligaments. Back pain can either be mechanical or chemical. The presence of low back pain is associated with decreased postural control. The previous literature has shown that core strengthening exercises are effective in mechanical low back pain.¹⁸ The major compressor of the lumbar spine is known as iliopsoas, as it contributes to the spine's stability because of its comprehensive character. The psoas' compression causes segmental stiffness, and increased force of iliopsoas can hinder the spinal health, and this increased tightness of the hip flexor leads to low back pain. Active release of iliopsoas by fascial muscular lengthening technique decreases the tightness of the hip flexor, reduces low back pain, and increases the spine's stability.¹⁵ However, it remains unclear that the release of the iliopsoas is effective in low back pain. Therefore, this experimental trial will help to provide the iliopsoas release impact on respiratory parameters in individuals with chronic low back pain.

This clinical trial's primary goal is to determine the efficacy of iliopsoas release on respiratory parameters in patients with chronic low back pain.

This trial will contribute to the evidence-based use of iliopsoas release in low back pain management. It contemplates the items of checklists for protocol studies to minimize bias, and it was prospectively registered. Data will be published after the study is completed.

Limitations

Firstly, the study will be conducted in a single-center. Secondly, the therapist cannot be blinded, which may unintentionally influence verbal and non-verbal interactions.

Author contribution

Vats S participated in designing the methodology of the study and drafting the manuscript. Kothiyal S designing study, writing, and editing the manuscript. Goyal M participated in the conceptualization, designing the methodology of the study, and reviewing the manuscript.

Competing interests

No financial, legal, or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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