Effectiveness of neurodynamic mobilization and MCGILL-type strengthening exercises in patients with piriformis syndrome: study protocol for a randomized controlled trial

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Abstract.

Purpose: Determine the effectiveness of adding a McGill-type strengthening exercise program to neurodynamic mobilization in patients with pyramidal syndrome (PS).

Material and methods: This study has a pre/post experimental design of a randomized single-blind clinical trial that will be carried out in the province of Chimborazo - Ecuador, with a duration of 8 months. The final sample will be formed by 58 patients with a diagnosis of SP who will be randomly assigned to a control group: neurodynamic mobilization and to an experimental group: neurodynamic mobilization plus McGill type strengthening exercises. Both groups will be evaluated before, immediately after and after two months of the intervention phase to determine changes in pain, disability, and range of motion.

Results: The comparison between the evaluations aims to reveal information on the effectiveness of combining neurodynamic mobilization plus McGill-type strengthening exercises, providing valuable information to contribute to the quality assurance of rehabilitation and physical activity behavior throughout rehabilitation patients.

Conclusions: Neurodynamic mobilization plus McGill-type strengthening exercises could reduce pain, improve range of motion and quality of life in patients diagnosed with SP.

Key words: piriformis syndrome, sciatica, neurodynamic mobilization, strengthening exercises.

Introduction

Piriformis syndrome (PS) is defined as the association of signs and symptoms that manifest when there are alterations affecting the mechanosensory relationships between the piriformis muscle and the sciatic nerve as it exits the pelvis. The piriformis muscle originates in the anterior and lateral region of the sacrum to insert through a tendon at the superior end of the greater trochanter, thus delimiting the supra and infrapiriform foramina, through which the sciatic nerve passes on its way to the lower extremity. At this level, the sciatic nerve can present anatomical variations that have been considered an important factor in the etiology of SP(Durrani & Winnie, 1991; Haładaj et al., 2015).

The most frequent symptomatology of PS is deep pain in the gluteal region, which in most cases radiates to the posterior thigh and is accompanied by neuropathic sensations such as numbness, paresthesia, and cramps. The most relevant clinical manifestation is pain on palpation in the region of the piriformis muscle, a clinical sign that is present in all patients diagnosed with this syndrome. Other less relevant manifestations are the patients' complaints that they cannot tolerate sitting or that they feel as if they have sat on their wallet (Hopayian & Danielyan, 2018).

The etiology of SP seems to be conditioned by factors that influence the physiological state of the sciatic nerve in relation to the piriformis muscle. These may be: acute repetitive or overuse trauma and the anatomical variants that the sciatic nerve may present at its exit from the pelvis. (Muñoz Chiamil, 2004). The predominance of SP in patients with chronic low back pain varies between 5 and 36%. SP is often confused with other chronic low back pain disorders, especially because it may present similar characteristics to other pathologies, which causes it to go unnoticed or to be misdiagnosed (Kean Chen &izar, 2004). (Kean Chen & Nizar, 2013; Uttam & Yadav, 2016).

SP has a higher incidence in women on a scale affecting 1 in 6, due to the biomechanics associated with a wider Q angle in this gender (Boyajian-O'Neill et al., 2008).. The population most prone to SP are patients with alterations in the length of the lower extremities, athletes due to overtraining, people who spend a long time in sedentary sitting, patients with hematomas and subsequent perineural scarring between the sciatic nerve and the tissues of the region (Kean Chen & Nizar, 2013)..

There is currently quite a lot of controversy about SP, mainly due to the difficulties in reaching an etiological diagnosis of certainty, which causes the signs and symptoms experienced by patients to be prolonged in time, favoring compensatory or facilitating mechanisms, contributing to lumbopelvic pain and pathological conditions of the sciatic nerve (Kean Chen & Nizar, 2013; Boyajian-O'Neill et al., 2008).. It is important to include the suspicion of SP in the differential diagnosis when there is persistent pain in the gluteal area and it is unrelated to clinical findings in the lumbar spine or the hip (Papadopoulos & Khan, 2004).. The most relevant tests and signs used in the differential diagnosis of SP are the modified FAIR test, which is a combination of the Laségue sign and the standard FAIR test (Kean Chen & Nizar, 2013)Beatty's test, Pace's sign, and Freiberg's sign (Papadopoulos & Khan, 2004; Solheim et al., 1981).

Once SP is diagnosed, conservative treatments may be established that include NSAID treatment, analgesics, physical therapy interventions that commonly use ultrasound, soft tissue mobilization, hot compresses or cold spray and stretching of the piriformis muscle. When conservative treatment fails, more aggressive techniques such as dry needling, analgesic infiltrations, and, in more extreme cases, surgical release of the piriformis muscle may be chosen (Papadopoulos & Khan, 2004; Tonley et al., 2010). Previous studies in patients with SP have used several tools to evaluate the efficacy of treatment in relation to pain, functionality or range of motion (ROM), including the use of scales, questionnaires and instruments such as: the numerical pain scale (NRS), the Oswestry low back pain disability scale (ODI) and the goniometric (Uttam & Yadav, 2016; Tonley et al., 2010; Nazlıkul et al., 2018).

In the last decade, there has been a significant increase in the number of investigations on the effects of neurodynamic mobilization (NDM) applied to musculoskeletal pathologies affecting the mechanosensitive components and the neurobiomechanical behavior of nervous tissue. It appears that NDM techniques are able to disperse intraneural edema, restore pressure gradients, alleviate hypoxia and prevent adhesion of neural tissues with surrounding connective tissues, improving symptoms associated with neuropathic syndromes (Pourahmadi et al., 2019; Plaza-Manzano et al., 2020).

MND is based on joint mobilizations, aimed at sliding, or tensioning the neural tissue with the purpose of increasing the flexibility and tolerance of this tissue to load and movement, which can lead to positive effects on pain, disability and ROM of patients. In relation to the application of neural sliding and tension techniques, it is recommended to dose and execute them considering the degree of irritability of the neural tissue and adjacent musculoskeletal structures (Neto et al., 2017).

Motor control and strengthening exercises have positive effects in addressing compensations secondary to SP, on pain, disability, and ROM (Tonley et al., 2010). On the other hand, there is research, developed by Professor Stuart McGill of the University of Waterloo in Canada, which proposes a group of exercises that aim to achieve an optimal physiological state of the lumbopelvic region, working important points such as stability and coordination. With loads below 3400 Newtons, which is recommended by the National Institute of Occupational Safety and Health of the USA, achieving positive effects on the physiological state of the anterior, posterior and lateral lumbopelvic musculature. (Ghorbanpour et al., 2018)..

Within physical therapy there are numerous techniques, protocols and treatments described for SP. Many practitioners focus on the pain and its distribution rather than its etiology. Therefore, this article describes the study protocol for a randomized controlled clinical trial to determine the effectiveness of adding a McGill-type strengthening exercise program to neurodynamic mobilization in patients with SP. In this context, the following main research question will be addressed:

What is the effect of adding a McGill-type strengthening exercise program to neurodynamic mobilization in patients diagnosed with pyramidal syndrome?

In relation to the main research question, the following hypotheses were developed:

Hi. Neurodynamic mobilization techniques and McGill-type strengthening exercises have beneficial clinical effects on pain, function, and range of motion in patients with piriformis syndrome.

Ho. Neurodynamic mobilization techniques and McGill-type strengthening exercises have no beneficial clinical effects on pain, function, and range of motion in patients with piriformis syndrome.

Material and methods of research

Participants

The number of participants was calculated using a formula to compare two means, using data from a previous similar study (Plaza-Manzano et al., 2020).. The sample size of the study participants was determined by a one-sided test with a confidence level of 95%, statistical power of 80%, precision of 1.0, variance of 1.96, The sample size will be 29 patients in each group, assuming a 15% loss rate in the development of the study. Therefore, the total sample size will be 58 participants.

Participants will be recruited from comprehensive rehabilitation clinics associated with Neurofit Ec, in the province of Chimborazo, Ecuador. To be eligible to participate in this study, patients must meet the following criteria: (1) Age between 18 and 65 years; (2) Pain, dysesthesias and/or paresthesias radiating from the lumbar region through the gluteal area and posterior aspect of the thigh to the knee of more

than 12 weeks' duration; (3) Pain in the lumbopelvic region, on sitting, standing or lying down for more than 15 to 20 minutes; (4) Hyperesthesia over in the region of the sacroiliac joint, greater sacrocygeal notch and/or piriformis muscle; (5) Medical diagnosis of SP and/or positive result on three of the following five tests: Modified FAIR, Beatty, Laségue, Pace and Freiberg. Exclusion criteria are: (1) Acute low back pain and/or acute lumbar radiculopathy; (2) Having received treatment for low back pain by strengthening exercises in the last 6 months; (3) Cauda equina syndrome; (4) Inflammatory, infectious or tumor diseases; (5) Osteoporosis; (6) Severe vascular disease; (7) Pregnancy.

Eligibility criteria for physical therapists who will perform the intervention are: (1) A qualification or certification related to MND and therapeutic exercise; (2) A minimum of three years of experience with group therapeutic exercise treatments (e.g., aquatic therapy, medical Nordic walking, or back school). Clinic staff will inform patients about the content, design, and eligibility criteria of the study during the welcome event at the start of the rehabilitation program. Individuals interested in participating must provide written informed consent. Participants will not receive any financial compensation for their participation in the study. Participants will be distributed by simple randomization, which will be done through the order of patient enrollment. The 100% of the sample will be mixed in an envelope so that later a person, external to the research, will remove from the envelope 50% of the participants, who will form part of the control group, and the remaining 50% will form part of the experimental group.

The study will be conducted in accordance with the Declaration of Helsinki. Participation in the study is voluntary. Written informed consent will be obtained from all participants. Participants may withdraw from the study at any time without giving a reason and without any individual inconvenience for subsequent physiotherapeutic care.

Methods

For this study, an experimental pre/post randomized single-blinded clinical trial design is proposed. The study is registered in the clinical trial database of Neurofit Ec (CEINF00012) and approved by the research ethics committee of the Integral Physical Rehabilitation Center (N°5/2022 date of approval May 23, 2022). It has undergone external peer review by the research group of Bolivar State University.

Procedure

The intervention stage will last 6 weeks. During this time, 3 physiotherapy sessions per week will be given to each patient (Efstathiou et al., 2015), both in the control group (Table 1) and in the experimental group (Table 2). The application of the techniques at this stage will be with a progressive dosage under the tolerance,

degree of effort and irritability of each patient. For this reason, three phases will be established for each intervention group, and in each phase the number of techniques will be increased, as well as the degree of intensity according to the response and tolerance of the patients to them.

Patients in the control group will receive MND techniques. The time and number of repetitions of these techniques will vary according to each patient, and will be applied up to a maximum of 5 minutes for the passive neural gliding technique (TPDN) and a maximum of 10 repetitions for the passive neural tension technique (TPTN) (Boudier-Revéret et al., 2017).. In the first phase TPDN will be applied, in the second phase TPDN will be combined with TPTN and in the third phase TPTN will be applied exclusively.

TPDN aims to promote the sliding of the sciatic nerve in relation to the piriformis muscle. For this, the TPDN will be initiated by placing the patient in the supine position and the physiotherapist will make the following contacts: the caudal hand will make contact behind the leg and near the heel, and the cranial hand will make contact in front of the knee. Before executing the technique, the degree of pain and neural resistance will be evaluated. To do this, the patient's hip will be slowly brought into flexion (keeping the knee in extension) until the maximum pain-free range of motion is reached. At this point in the range, a joint mobilization will be performed in which the movements of hip flexion with knee flexion and knee extension with hip extension will be combined simultaneously (Coppieters & Butler, 2008). (Coppieters & Butler, 2008).

TPTN aims to place tension by stretching the sciatic nerve, progressively adding more range of motion in hip flexion and keeping the knee in extension. (Coppieters & Butler, 2008).

Patients in the experimental group will receive MND techniques plus a McGill-type muscle strengthening exercise program. These interventions will be applied in each of the phases. The time and number of repetitions of these techniques will vary according to the patient's response and tolerance, and will be applied up to a maximum of 5 minutes for TPDN and a maximum of 10 repetitions for TPTN (Boudier-Revéret et al., 2017).. The McGill-type strengthening exercises will be applied progressively in each phase and the degree of effort and the number of repetitions will be increased with a maximum of 12 repetitions for each exercise with a rest interval of 1 minute between exercises (Ghorbanpour et al., 2018)..

The McGill type strengthening exercises consist of three exercises: Curl-up, Side plank and Birddog:

Curl-up: the patient will be in the supine position with one leg in flexion and the other in extension to maintain lordosis of the lumbar spine. In the first phase the

patient will be asked to slowly lift the head, in the second phase the patient will be asked to slowly lift the head and neck and in the third phase the patient will be asked to slowly lift the head, neck and shoulders until the scapulae are detached from the support surface (Barbado et al., 2019).

Side plank: the patient will be in lateral decubitus. In the first phase, the patient will be asked to rest on the elbow, the hip and place the knees in 90º flexion. From this position, the patient will be asked to try to lift and maintain the hip towards the ceiling with the objective of being in two points of support (elbow and knee) forming a short bridge. In the second phase, the patient will be asked to lean on the elbow and the outer edge of the foot, and to lift the hip towards the ceiling forming a long bridge. In the third phase, the patient will be asked to lean on the elbow and outer edge of the foot forming a long bridge, and to elevate and hold the lower extremity on the upward side towards the ceiling (Barbado et al., 2019).

Birddog: the patient will be in a quadrupedal position. In the first phase, the exercise will be performed in a three-support posture with one leg elevated. In the second phase, the classic birddog position will be performed with two supports (one leg and one contralateral arm elevated). In the third phase, starting from the two-point stance. At these points, the knee and/or arm will be supported on an unstable surface using a Bosu (Barbado et al., 2019).

Statistical Analysis

Prior to statistical analysis, as much information as possible will be collected on each patient. Subjective information will be collected through anamnesis and clinical history. The objective data will be obtained through the physical examination, including the tests proposed to determine the dependent variables of this research, such as the NRS scale to quantify pain and the ODI to determine the influence on functionality and disability. In addition, goniometric measurement will be used to determine the ROM of flexion, adduction, abduction, internal and external rotation of the hip.

The data collected in this research will be processed through SPSS version 26.0 statistical software to obtain the main data of central tendency, as well as for dispersion measures such as standard deviation. The Kolmogorov-Smirnov test will be used to identify the normality of the sample and the t-student test for independent samples.

Results of the study

Scales, questionnaires, and goniometric measurement will be collected through three evaluations. The first assessment is at the initial stage and is intended to determine the patient's pain, degree of disability and ROM prior to the intervention. The second evaluation will be performed immediately after the intervention to

determine the immediate effect on pain, functionality, and ROM, both for the control group and the experimental group. The last evaluation is the follow-up of the two intervention groups two months after the end of the intervention stage to determine the effect on pain, function, and ROM of adding a McGill-type strengthening exercise program to the MND.

Discussion

Our study evaluates the implementation and effects of neural mobilization combined with McGill-type strengthening exercises, contributing to quality assurance in physical rehabilitation on pain, range of motion and disability that patients diagnosed with SP may present.

Several operational challenges should be considered in the execution of this study. First, recruitment of study participants because of the number of unexpected dropouts. Therefore, it may be necessary to extend the recruitment period to reach our sample size.

Second, the content of the intervention could be influenced by the personal characteristics and social-communicative skills of the respective physical therapist delivering the intervention. Therefore, the physical therapists are required to adhere to the structure and content of the study. In addition, only two physical therapists are responsible for the intervention and control group, respectively, thus minimizing bias.

There are strengths in the design of this study. We expect that the combination of quantitative and qualitative data collection will not only identify the potential effects of the study (outcome quality) but also highlight potential difficulties and shortcomings during the implementation of the intervention (process quality).

In addition, the 8-week follow-up will provide data on the mid-term efficacy of the study after the intervention. Finally, the different scales and questionnaires measuring the outcome of the study will allow determining the effectiveness of the intervention.

Since the physical therapists at the clinic are responsible for delivering the intervention, this study is limited to a single-blind design. Although both the intervention and control groups are organized as closed groups, in theory, the blinding of participants could be compromised through communication between the groups during the hours set aside for the intervention by social conditions, labors, and other factors specific to each patient. In addition, the study-specific information provided to patients during the welcome could cause selection bias and additional recruitment of participants would be required. Finally, due to clinic-specific operating procedures, patient randomization and group assignment should be performed several days in advance.

Finally, based on the results of the planned study, implementations of the intervention protocol could be developed for future research.

Conclusions

Neurodynamic mobilization plus McGill-type strengthening exercises can provide very important information to improve the approach to pyramidal syndrome, contributing to protocols that focus on pain, range of motion and quality of life.

Authors' contribution

DMGH, SMOP, and JGOM were responsible for the conception and overall design of this study. All authors developed the study design. FBA and CLTN were responsible for the sample size calculation and statistical design of the study.

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Conflict of interest

The authors declare that it has no competing interests.

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Table 1

Control group intervention

Intervention		***Procedure***	***Weather***
Neurodynamic techniques.	Phase 1	Passive neural gliding technique. The objective is to alternately slide the sciatic nerve in the thigh in a cranial and caudal direction: - Starting position: patient in supine decubitus. - Contacts: caudal hand contacts behind the leg near the heel and the cranial hand contacts in front of the knee. - Hip flexion is applied slowly with the knee extended. - Pain and neural resistance are identified. - When the maximum range of pain-free hip flexion is reached, hip flexion is increased and at the same time knee extension is reduced. Knee extension is then extended and hip extension is reduced (Boudier-Revéret et al., 2017)..	The control group intervention will be applied 3 days per week, for 6 weeks (Efstathiou et al., 2015).. The neural gliding technique will be applied for up to 5 minutes and neural tension for up to 10 repetitions, respecting the patient's pain and tolerance (Boudier-Revéret et al., 2017)..
	Phase 2	Passive neural sliding technique + passive neural tension technique.	
	Phase 3	Passive technique of neural tension. It is achieved by modifying the longitudinal dimension of the musculoskeletal continent of the nervous system through passive movements of the selected body segments: - Patient in supine decubitus. - Contacts: caudal hand contacts the sole of the foot, cranial hand contacts in front of the knee. - Hip flexion, knee extension and dorsal flexion of the foot are performed. (Coppieters & Butler, 2008).	

Table 2

Experimental group intervention			
Intervention		*Procedure*	*Weather*
- **Neuro dynamic techniques** - **McGill exercises**	Phase 1	- Passive neural gliding technique (Boudier-Revéret et al., 2017).. - Curl-up: from the starting position, flexion is performed by initially raising the head. - Side plank: short bridge (Barbado et al., 2019). - Birddog in three-legged stance with one leg elevated.	The intervention of the experimental group will be applied three days a week for six weeks. (Montenegro, n. d.). The neural gliding technique will be applied for up to 5 minutes and neural tension for up to 10 repetitions, respecting the patient's pain and tolerance (Boudier-Revéret et al., 2017).. The McGill-type strengthening exercises will be applied with 10 repetitions for each exercise with a rest interval of 1 minute between exercises (Ghorbanpour et al., 2018)..
	Phase 2	- Passive neural gliding technique (Boudier-Revéret et al., 2017).. - Passive neural tension technique (Boudier-Revéret et al., 2017).. - Curl-up: from the starting position, flexion is performed by raising the head and neck. - Side plank: long bridge (Barbado et al., 2019). - Birddog: classic posture with two supports, with one leg and one contralateral arm elevated. (Barbado et al., 2019).	
	Phase 3	- Passive neural tension technique (Boudier-Revéret et al., 2017).. - Curl-up: from the initial position, flexion is performed by raising the head, neck and shoulders until the scapulae are released. - Side plank: bridge with single leg support. (Barbado et al., 2019). - Birddog: two-point birddog pose with the knee and/or arm on an unstable surface. (Barbado et al., 2019).	

Abbreviations

SP	Piriformis syndrome
MND	Neurodynamic mobilization
ROM	Range of motion
TPDN	Passive neural sliding technique
TPTN	Passive neural tensioning technique

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