Effect of the Association of Pelvic Floor Muscles and Inspiratory Muscles Training in Women With Stress Urinary Incontinence Resulting From Chronic Obstructive Pulmonary Disease: Protocol Study

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Research Article

Keywords: Chronic Obstructive Pulmonary Disease, Stress Urinary Incontinence, Pelvic Floor Muscle Training

Posted Date: October 30th, 2024

DOI: https://doi.org/10.21203/rs.3.rs-5283135/v1

Additional Declarations: No competing interests reported.

Abstract

Stress Urinary Incontinence is a prevalent issue among women with Chronic Obstructive Pulmonary Disease (COPD), primarily due to the increased intra-abdominal pressure from chronic coughing. This study proposes a novel protocol combining Pelvic Floor Muscle Training (PFMT) and Inspiratory Muscle Training (IMT) to address SUI in women with COPD. The research aims to evaluate the effectiveness of this combined intervention in reducing urinary leakage and dyspnea, thus improving the quality of life for these patients. The study is a randomized, double-blind clinical trial with 64 female participants, aged 18 to 65, who have both COPD and SUI. Participants are divided into an intervention group and a control group, with assessments conducted before and after a five-week treatment period. The primary outcome measured is the daily incidence of urine leakage episodes, while secondary outcomes include functional capacity tests, muscle strength measurements, and various clinical and sociodemographic profiles. Interventions include low to moderate intensity resistance exercises for inspiratory muscles and pelvic floor muscles, progressively increased based on patient progress. The intervention group undergoes IMT with the PowerBreathe device at 50% of their maximum inspiratory pressure, while the control group is set at 10% without modifications. The expected outcomes are a significant reduction in urinary leakage and improved respiratory function, highlighting the potential of this non-invasive and comfortable intervention. The study aims to fill a gap in the literature by providing evidence on the efficacy of combined PFMT and IMT in treating SUI in women with COPD, thereby offering new insights and tools for clinical practice and future research.

Introduction

Urinary Incontinence (UI) continues to be a worldwide problem that affects adult women across different cultures and races. As defined by the International Continence Society, UI is a condition in which there is involuntary loss of urine, being considered a social problem and can seriously compromise the physical, psychological and even social and economic well-being of individuals and their families (LALLEMAND et al., 2021). Among the types of UI, Stress Urinary Incontinence (SUI) is defined as the complaint of involuntary loss of urine when exerting effort, sneezing or coughing (LIM et al., 2018).

Specifically, the discomfort caused by SUI is a unique problem that has been present in individuals with Chronic Obstructive Pulmonary Disease (COPD). Information on the impact of SUI on quality of life is absent from the extensive literature on COPD (HRISANFOW; HÄGGLUND, 2013). SUI in individuals with COPD is largely unexplored in clinical research and often underestimated in clinical practice. Although the involuntary loss of a small amount of urine during coughing, for example, is among the most plausible causes of SUI in patients with COPD, its importance has been questioned by some researchers. (BATTAGLIA et al., 2019).

Patients with obstructive ventilation disorders, such as Chronic Obstructive Pulmonary Disease (COPD), Asthma, Cystic Fibrosis and Bronchiectasis, constitute a population at risk for SUI due to the frequency of episodes of increased intra-abdominal pressure due to symptoms of chronic cough.

Currently, there is Level 1 evidence (recommendation A) that PFMT should be the first therapeutic option for SUI in women. Commonly, women with SUI who undergo PFMT have eight times more chances of recovery compared to control groups without treatment (DUMOULIN; CACCIARI; HAY-SMITH, 2018). Therefore, TMAP minimizes episodes of UI in women with SUI and in those with any form of UI.

As for dyspnea, which is present in people with COPD, it is a symptom that worsens the general health of patients with COPD (HIGASHIMOTO et al., 2020). These patients face limitations in exercise capacity due to several factors, such as ventilation, gas exchange, cardiovascular diseases(BEHNIA et al., 2017) and dysfunctions in peripheral muscles (SANSEVERINO et al., 2018).Inspiratory muscle dysfunction is equally prevalent in these patients and is linked to dyspnea and decreased exercise capacity(ROCHA et al., 2017).

In this context, Inspiratory Muscle Training (IMT) is emphasized as an efficient intervention in cardiorespiratory management, providing advances in physical performance and alleviating dyspnea in patients with different stages of the disease (PUHAN et al., 2016). As a pulmonary rehabilitation strategy, IMT enhances respiratory capacity and, therefore, improves conditioning.(BORGE et al., 2014).

Therefore, SUI and urinary symptoms are prevalent in patients with COPD, affecting quality of life. Despite this, both clinicians and researchers rarely investigate them. (BATTAGLIA et al., 2019).This highlights that, together, SUI and COPD are dual challenges for healthcare professionals. Thus, there is a need for further investigation into the relationships between COPD and SUI in order to clarify the underlying mechanisms and to develop appropriate prevention and treatment strategies.

If the association of IMT with PFMT proves effective in reducing urinary loss and dyspnea in women with SUI and COPD, it could be a new tool to improve results through this treatment. This study can be useful because it has few and controlled adverse effects and, due to its non-invasive approach, it can be more comfortable for patients to adopt. Considering these assumptions, this study will investigate the effects of a protocol with IMT associated with PFMT, when compared to a placebo protocol, in women with COPD who present SUI.

Methods

Study design and recruitment

This study protocol followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

Election criteria

The study will recruit women using the following criteria: (1) Age 18 to 65, (2) clinical diagnosis of COPD (3), diagnosis of SUI (4), good cognitive conditions (with a score above 19 for illiterate and above 22 for those literate through the Mini Mental State Examination - MMSE) and verbal, and (5) who agree to

participate in the research, after reading, understanding and signing the Free and Informed Consent Form - ICF.

Volunteers will be excluded from the research with unstable COPD, with more than four hospital admissions due to COPD in the current year, with some gynecological surgical procedure , with low cognition or a Mini Mental State Examination (MMSE) score below 19 points for illiterate women and below 22 for literate women, and those who request their withdrawal or give up on the research.

Interventions

Firstly, before the care begins, a meeting will be held with each volunteer to carry out assessments (anamnesis, gynecological assessment and cardiorespiratory assessment) and application of tests and questionnaires. The treatment will last 5 weeks, with an average duration of 50 minutes for each session, twice a week.

Both groups will perform inspiratory muscle training with low to moderate intensity resistance exercises associated with exercises to strengthen the pelvic floor muscles.

Training intensities during exercises will be progressively increased during the course of the program based on the evolution of the treatment. For this, the Borg scale classifications for the sensation of dyspnea will be used.

IMT in both groups will be performed with the PowerBreathe device (Powerbreathe Plus® Medic NCS). The training intensity in the intervention group and control group will initially be set at a load of approximately 50% of the patients' maximum inspiratory pressure (PImax). This initial load will be increased continuously and gradually to the highest tolerable intensity during each of the supervised sessions, while the control group will be set at 10% of the initial MIP and will not be modified throughout the intervention period. The use of Powerbreathe will be used in a protocol with the following exercises:

Sit/stand	3 sets with 10 repetitions
Abduction/adduction of upper limbs using load (0.5kg – 1kg) -	3 sets with 10 repetitions
Stationary walking on the *step*	3 series lasting 30 seconds
Lateral abduction/adduction using light resistance elastic	3 sets with 10 repetitions

For the treatment of SUI, the exercises described below will be performed, in which the contraction of the PFM (Pelvic Floor Muscles) will be performed according to the “E” of PERFECT:

In the supine position, the therapist will request and instruct the volunteer to perform a bridge, they will be asked to elevate the pelvis and perform contractions of the PFM	2 sets with 8 repetitions of contraction
Sitting on a Swiss ball, breathing exercises will be performed, associating the anterior and posterior pelvic tilt with the contraction maintained under the therapist's commands.	2 sets with 4 repetitions
Sitting in a chair, the volunteer will be instructed to contract the PFM and maintain the contraction when standing. The exercise will be sitting and standing up	2 sets with 8 repetitions
While standing, the patient will be instructed to walk around the room counting 10 steps. With each step in front of her, she will perform and maintain the contraction of the PFM from the removal of the foot from the ground to the landing of the same foot upon touching the ground.	Carrying out 10 steps

Results

All assessments will be carried out by a researcher previously trained in the instruments and procedures for collection, to minimize risks of bias. The study variables will be measured on the day of assessment and at the end of treatment (5 weeks). The primary outcome will be the assessment of the daily incidence of urine leakage episodes. The secondary results will be the variables analyzed through the clinical and epidemiological profile of the study participants.

The sociodemographic and clinical questionnaire developed for this research will address sociodemographic and clinical characteristics, will have 16 variables studied, namely, age, gender, family income, place of residence, illnesses, marital status, lifestyle habits and addictions, among other variants (GOUVEIA, 2011).

Measurement of Heart Rate, Respiratory Rate, Blood Pressure and Peripheral Oxygen Saturation will be carried out to measure vital signs. The left upper limb will be standardized for collecting Blood Pressure data and the index (second finger) homolateral to the previous measurement to check the Heart Rate.

Stabilometry will assess postural balance by quantifying postural oscillations in the orthostatic position on the force platform, which involves monitoring the displacements of the center of pressure (CP) in the lateral (X) and anteroposterior (Y) directions. The signals will be captured on the platform using three charge transducers, present on the surface of the platform and recorded by a microcomputer attached to the platform, using the EMGSystems do Brasil software – registered trademark. The data will be processed and sent to the database for subsequent statistical analysis.

The six-minute walk test (6MWT) is a simple test that objectively assesses the volunteer's functional capacity. This test requires a 30m walking distance, a stopwatch, a lap counter and two cones to mark

the turning points. The patient's heart rate, blood pressure and oxygen saturation are measured before and after the exam (DU et al., 2017).

Electromyography will evaluate motor control by quantifying biological signals resulting from muscular electricity during its action, using a four-channel device. The MAP and diaphragm will be evaluated.

Heart Rate Variability will check the heartbeats through the analysis of the RR complex, in any modality. Heartbeat monitoring will be carried out using a Frequency Meter, by sending the heart rate (HR) to a specific monitor, which is saved in computer memory and analyzed using software (Protainer ®).

Functional Kinesiological Ultrasonography will evaluate diaphragmatic function, pelvic floor muscles (ischiocavernosus , bulbocavernosus , superficial transverse perineum and others) and bladder. A high-resolution ultrasound, Mindray ® Z5, with a linear (7.5 MHz) and convex (3.5 MHz) transducer will be used, which will be used according to the protocol suggested bySantana e colaboradores (2020).

Respiratory Muscle Strength will be measured by measuring maximum respiratory pressures, both inspiratory and expiratory (PImax and PEmax), based on the residual volume (RV) and total lung capacity (TLC), respectively, using a manovacuometer (Critical®), scaled in cmH_2O as the unit of pressure. A clip occluding the nasal orifice will be used to measure three measurements, the largest of which will be recorded. The MIP and MEP values found will be compared with these: MIP : y= -0.49 (age) + 110.4 / MEP : y= -0.61 (age) + 115.6.

Spirometry is a lung function test that measures the air that is exhaled and inspired. There are three basic related measurements: volume, time and flow. Spirometry is objective, non-invasive, sensitive to changes and reproducible. It is performed to detect the presence or absence of lung disease, quantify lung involvement, monitor the effects of occupational/environmental exposures and determine the effects of medications (LANGAN; GOODBRED, 2020).

The pelvic floor muscle assessment (PFM) will be performed through bidigital vaginal palpation, in which disposable gloves will be used to prevent contamination during care. Vaginal palpation is a valid and widely used technique in the literature (SILVA, 2020), according to the perception of contractile activity related to the Modified Oxford Scale (domains from zero to five, in which zero: absence of muscular response; 1: outline of a contraction without sustained; 2: presence of low intensity, but sustained contraction; 3: moderate contraction, felt as an increase in intravaginal pressure, which compresses the examiner's fingers with a small cranial elevation of the vaginal wall; with elevation of the vaginal wall towards the pubic symphysis; 5: strong contraction, firm compression of the examiner's fingers with movement towards the pubic symphysis) (DRIUSSO; BELEZA, 2018).

The *pad test* refers to the placement of an absorbent to quantify urine loss by comparing the weight of that absorbent before and after a period of one hour. During this period, the volunteer will undergo a protocol for water intake and activities of daily living. Based on the difference in weight of the initial and final absorbent, urinary losses are classified as: insignificant or continent loss (when the final weight of

the absorbent is up to one gram (g); slight loss (1.1 to 9.9 g); moderate loss (10 to 49.9 g); severe loss (over 50 g)(MATA et al., 2021).

Biochemical markers of oxidative stress will be collected through laboratory evaluation of the samples, checking the concentration parameters of Malondialdehyde (MDA), Glutathione (GSH) and Myoperoxad (MPO), before the first day, halfway through the treatment and after the last day of service.

Study Period								
	Recruitment	Allocation	Post allocation (weeks)					Outcomes
Timepoint			**1**	**two**	**3**	**4**	**5**	
Recruitment								
Selection criteria	X							
TCLE	X							
Allocation		X						
Interventions								
Group control			X	X	X	X	X	
Intervention Group			X	X	X	X	X	
Assessments								
Sociodemographic Questionnaire	X						X	
Vital signs	X						X	
Stabilometry	X						X	
6MWT	X						X	
Electromyography	X						X	
HR variability	X						X	
Ultrasound	X						X	
Vacuum manometer	X						X	
Spirometry	X						X	
MAP Assessment	X						X	
Pad test	X						X	

Sample size

The sample of this study will be of the simple random probabilistic type, through the use of a statistical program to calculate the same GPOWER ® with effect size f (30%), α err prob (5%) and Power (1-β err prob) (80%), inferring 64 people. It will be divided into two groups: Control Group (CG) and Intervention Group (IG) with 32 volunteers in each group.

Recruitment

A controlled, randomized, double-blind clinical trial will be carried out with a quantitative approach carried out between December 2023 and July 2024 at the Universidade Federal Delta do Parnaíba – UFDPar, in the city of Parnaíba. To recruit volunteers, there will be publicity through social media, in addition to the dissemination of leaflets in Basic Health Units, clinics and offices.

Randomization, allocation and blinding.

To avoid the carry -over effect, two independent groups will be randomized (IG: intervention group and CG: control group). Therefore, participants will be allocated to these groups using the *Random program Allocation* (version 2.0). Training will be carried out for two members regarding assessment and intervention; It will be decided to standardize the same location for evaluation and treatment. Randomization and hidden allocation will be used for selection . This selection will be carried out by a member external to the project, without prior knowledge of the research and its objectives. After allocation, this person will place the results in an envelope to ensure allocation confidentiality (SNOOZE), which will only be opened after statistical analysis. There will also be blinding of the study (the evaluator, the statistician and the volunteers will not have access to the identification of the groups). The selection of volunteers will take place after completing an evaluation form including the anamnesis, the MMSE and the ICF.

Data collect

Data will be collected at the GPFAT Laboratory at the Federal University of Delta do Parnaíba in Parnaíba in Piauí, Brazil.

Statistical analysis

The data will be entered into a database using the Epi Info program (version 6.04d, Centers for Disease Control and Prevention , USA), and then SPSS software (version 23.0) was used to infer the data, using descriptive statistics with mean ± standard deviation for continuous variables; frequency and percentage for categorical variables.

It should be noted that for the use of statistical tests, the normality of the variables will initially be checked, using the Kolmogorov -Smirnov test, followed by the choice of the most appropriate test for them. Therefore, the chi -square association tests (x^2), independent t , ANOVA with Bonferroni post *hoc* and confidence interval will be used (PAGANO; GAUVREAU, 2006). For a better analysis of the data that presented predictive values, the percentage difference of the mean in relation to the baseline values

will be chosen. The nominal significance level will be defined as $p \leq 0.05$ and the data will be expressed in table form .

Data monitoring

This study will not involve participants with life-threatening or harmful interventions; therefore, the creation of a data monitoring committee will not be necessary.

Scratchs

This research may bring risks, such as: dyspnea, pain, exacerbation of COPD symptoms, decrease in SPO_2, general discomfort, however, if participants report any discomfort, they will receive all necessary support as requested by the Mobile Customer Service (SAMU), referral to the Physiotherapy clinic, the city's reference hospital or the psychology sector of the aforementioned University.

Furthermore, participants will be guaranteed absolute confidentiality regarding the information offered and anonymity, without any risk or harm to their activities within the group of participants, as well as the right to withdraw from participating in the research at any time. In addition to maintaining the choice of treatment for those who were selected to the control group after carrying out the research, their rights are guaranteed.

The data obtained will be used on a strictly scientific basis , aiming to contribute to the formation and dissemination of scientific knowledge .

Ethics and disclosure

The research will be carried out following the ethical principles of Resolution No. 466/12 of the National Health Council (CNS) (BRASIL, 2013), respecting the four basic references of bioethics: “autonomy, non-maleficence, beneficence and justice”, with its approval by the Ethics Committee in Research from the Federal University of Delta do Parnaíba, with opinion number 5,949,708 and submission on the ReBEC platform .

The researcher will explain the objectives and steps of carrying out the research to those volunteers who meet the work inclusion criteria. Then, those who accept to participate in the study will be provided with the TCLE to sign it.

Discussion

COPD emerges as a disabling disease, with a notable presence in the female population. Surprisingly, its prevalence has equaled that of men since 2008, in part attributed to the increase in tobacco consumption among women globally and exposure to biomass fuels (GUT-GOBERT et al., 2019). Furthermore, women diagnosed with COPD may present with SUI as a concomitant symptom, with the majority undergoing conservative or pharmacological treatments.

In a bibliographic survey, a gap was observed, as no studies were identified that addressed specialized physiotherapeutic interventions or that associated inspiratory muscle training with PFM training in women diagnosed with COPD and SUI. Nor do these investigations elucidate correlations, variations and respective outcomes, such as changes in heart rate, blood pressure, inflammatory markers, respiratory functionalities and capacities, urodynamic parameters, sexual function, among others.

Patients with obstructive pulmonary diseases are a population at risk for UI due to the high frequency of increased intra-abdominal pressure due to chronic cough (AIGON; BILLECOCQ, 2018). This statement can be proven through studies, for example, an Australian group that explored the prevalence of UI in participants with COPD and showed a prevalence of 39% compared to 17% in control groups (BURGE et al., 2017). An Italian study (MAGGI et al., 2001)also showed that the presence of COPD is a risk factor for UI in elderly women. In addition, other research (JACKSON et al., 2004)identified COPD as a risk factor in elderly women.

Incontinence affects women more than men, and there is a significantly higher proportion of women with UI who have abstained from activities to seek help more frequently for incontinence. In relation to men, women seem to suffer more frequently from stress UI, as the loss of urine during coughing in women with SUI may be related to different motor controls, an example of this is insufficient urethral closure and stress UI that are associated with bladder hypermobility with or without insufficient function of urethral sphincter activity. (HRISANFOW; HÄGGLUND, 2011)

A recent prospective study (BUTTON et al., 2019)was carried out to determine the prevalence of UI, related risk factors and the effects of UI in a specialized physiotherapeutic treatment in women with chronic lung diseases. A total of 134 participants were enrolled, 27 of them with COPD and the others with other respiratory conditions. In conclusion, the research showed that 59% of women with COPD reported episodes of SUI.

Conclusions

The results of this trial can be very useful in the treatment of people with SUI. Furthermore, this protocol is important for health professionals to have access to the effectiveness of this research as well as its availability for future protocols. It is hoped that it will be possible to carry out a measurable and reproducible study, in which it will be possible to identify the improvement in SUI. The aim is also to reduce the daily incidence of episodes of urine loss in both groups.

Declarations

Financing

Piauí Research Support Foundation (FAPEPI).

Declaration of Interest

The authors report no declarations of interest.

Author Contribution

TS Barbosa contributed to the conception, design and acquisition of the study, analysis and interpretation of data and writing of the manuscript.JLP Santos contributed to the conception, design and acquisition of the study, analysis and interpretation of data and writing of the manuscript.GPM Gouveia contributed to the conception, design and acquisition of the study, analysis and interpretation of data and review, preparation of versions of the manuscript, critical review of the content and approval of the final version

COLLABORATORS TS Barbosa contributed to the conception, design and acquisition of the study, analysis and interpretation of data and writing of the manuscript. JLP Santos contributed to the conception, design and acquisition of the study, analysis and interpretation of data and writing of the manuscript. GPM Gouveia contributed to the conception, design and acquisition of the study, analysis and interpretation of data and review, preparation of versions of the manuscript, critical review of the content and approval of the final version

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