UNIVERSIDADE ESTADUAL PAULISTA
"JÚLIO DE MESQUITA FILHO"
Campus de Presidente Prudente

ANA PAULA COELHO FIGUEIRA FREIRE

TREINAMENTO RESISTIDO COM MATERIAIS ELÁSTICOS EM INDIVÍDUOS COM DOENÇA PULMONAR OBSTRUTIVA CRÔNICA: ASPECTOS FUNCIONAIS E QUALITATIVOS

PRESIDENTE PRUDENTE
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Tese apresentada à Faculdade de Ciências e Tecnologia – FCT/UNESP, Campus de Presidente Prudente, para obtenção do título de Doutor no programa de Pós-graduação em Fisioterapia.

Orientadora: Professora Drª Ercy Mara Cipulo Ramos

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TÍTULO DA TESE: TREINAMENTO RESISTIDO COM COMPONENTES ELÁSTICOS EM PACIENTES COM DOENÇA PULMONAR OBSTRUTIVA CRÔNICA: ASPECTOS FUNCIONAIS E QUALITATIVOS

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Presidente Prudente, 03 de dezembro de 2018

Dedicatória

Ao meu melhor amigo e companheiro de todas as horas, Elton Mendes, seu apoio, amor e carinho foram essenciais neste processo.

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Epígrafe

"Por vezes sentimos que aquilo que fazemos não é senão uma gota de água no mar. Mas o mar seria menor se lhe faltasse uma gota".

Madre Teresa de Calcutá

SUMÁRIO

Apresentação

APRESENTAÇÃO

Este modelo alternativo de tese contempla o material originado a partir da pesquisa intitulada: "*TREINAMENTO RESISTIDO COM MATERIAIS ELÁSTICOS EM INDIVÍDUOS COM DOENÇA PULMONAR OBSTRUTIVA CRÔNICA: ASPECTOS FUNCIONAIS E QUALITATIVOS*" realizada no Laboratório de Estudos do Aparelho Muco-secretor (LEAMS), da Faculdade de Ciências e Tecnologia – FCT/UNESP, campus de Presidente Prudente e financiada pelo Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPQ).

Em consonância com as regras do programa de pós-graduação em Fisioterapia desta unidade, o presente material está dividido nas seguintes sessões:

- **Contextualização inicial**: Introdução e objetivos do tema pesquisado.
- **Artigo científico I**: "Elastic materials promotes similar gains in muscle strength to weight machine equipment in subjects with COPD: A randomized control trial".
- **Artigo científico II**: "Physiotherapists´ perceptions about facilitators and barriers in the use of different tools for resistance training in COPD patients: a mixed-method study".
- **Artigo científico III**: "Body image in patients with COPD and its relation with physical activity levels: An observational study".
- **Conclusões finais**: Obtidas a partir da pesquisa realizada.
- **Anexo I**: Resumo das atividades desenvolvidas no período do doutorado.
- **Anexo II**: Publicação científica resultante do período de internacionalização na Universidade de Sydney, Austrália. **"**Use of 95% confidence intervals in the reporting of between-group differences in randomized controlled trials: analysis of a representative sample of 200 physical therapy trials".

Resumo

RESUMO

Introdução e objetivos: O treinamento resistido para indivíduos com Doença Pulmonar Obstrutiva Crônica (DPOC) se torna uma opção atrativa pois gera menos dispneia, podendo tornar-se mais tolerável do que treinos aeróbios. Os materiais elásticos vêm sendo utilizados em indivíduos com DPOC como uma alternativa aos equipamentos de musculação convencionais. Entretanto, observa-se que a comparação entre diferentes ferramentas de materiais elásticos ainda não foi realizada. Além da investigação de efeitos na força muscular, é pertinente a execução de estudos que realizem avaliações multidimensionais, desta forma acredita-se que análises qualitativas podem ampliar e aprofundar os conhecimentos sobre treinamento resistido no contexto da reabilitação pulmonar. Também são necessárias avaliações que identifiquem comprometimentos de auto estima que podem influenciar na motivação e adesão a programas de treinamento físico. Neste sentido, observa-se um crescente interesse em avaliações sobre a imagem corporal, variável ainda desconhecida em indivíduos com DPOC. Assim os objetivos da tese foram: Analisar os efeitos do treinamento resistido com materiais elásticos nos aspectos funcionais de indivíduos com DPOC. Além disso, analisar quanti-qualitativamente a percepção de fisioterapeutas sobre as barreiras e facilitadores do uso de diferentes ferramentas para treinamento resistido. Por fim, analisar a percepção da imagem corporal em indivíduos com DPOC. **Métodos:** Três artigos científicos foram realizados para responder aos objetivos desta tese, sendo um ensaio clínico randomizado, um estudo com análise qualitativa por meio de grupo focal e o por fim, um estudo observacional transversal. **Resultados:** Os principais achados desta tese foram que materiais elásticos promoveram ganhos de força muscular semelhante aos equipamentos de musculação. Fisioterapeutas identificaram diferentes particularidades para três ferramentas de treinamento resistido em pacientes com DPOC. Por fim, indivíduos com DPOC apresentaram significativa insatisfação com sua imagem corporal. **Conclusões:** Com base nos achados dos três estudos apresentados nesta tese foi possível aprofundar os conhecimentos em diferentes aspectos de treinamento resistido em indivíduos DPOC. Possibilitou-se ampliar achados sobre aspectos funcionais e qualitativos do treinamento resistido nestes indivíduos, além da investigação de comprometimentos ainda pouco conhecidos nesta população, como a insatisfação com a imagem corporal.

Palavras chave: Doença Pulmonar Obstrutiva Crônica; Exercício; Terapia por Exercício.

Abstract

ABSTRACT

Introduction and objectives: Resistance training for individuals with Chronic Obstructive Pulmonary Disease (COPD) is an attractive option as it generates less dyspnea and may be more tolerable than aerobic training. Elastic materials have been used in individuals with COPD as an alternative to conventional weight machine equipment. However, it is observed that the comparison between different tools of elastic materials has not yet been performed. In addition to the investigation of effects on muscle strength, it is pertinent to carry out studies that perform multidimensional evaluations, thus it is believed that qualitative analyzes can broaden and deepen the knowledge about resistance training in the context of pulmonary rehabilitation. Assessments that identify self-esteem commitments that may influence motivation and adherence to physical training programs are also needed. There is a growing interest in assessments about body image, a variable still unknown in individuals with COPD. Thus, the objectives of the thesis were: To analyze the effects of resistance training with elastic materials on the functional aspects of individuals with COPD. In addition, quantitatively analyze the perception of physical therapists on the barriers and facilitators of the use of different tools for resistance training. Finally, we analyze the perception of body image in individuals with COPD. **Methods**: Three scientific articles were performed to answer the objectives of this thesis: a randomized clinical trial, a study with qualitative analysis performing a focal group and the last, a transversal observational study. **Results**: The main findings of this thesis were that elastic materials promoted muscle strength gains similar to weight machine equipment. Physiotherapists have identified different peculiarities for three resistance-training tools in patients with COPD. Finally, individuals with COPD had significant dissatisfaction with their body image. **Conclusions**: Based on the findings of the three studies presented in this thesis, it was possible to deepen the knowledge on different aspects of resistance training in COPD individuals. It was possible to expand on functional and qualitative aspects of resistance training in these individuals, as well as the investigation of compromises not yet well known in this population, such as dissatisfaction with body image.

Key Words: Pulmonary Disease, Chronic Obstructive ; Exercise; Exercise Therapy.

Contextualização

CONTEXTUALIZAÇÃO

A Doença Pulmonar Obstrutiva Crônica (DPOC) é definida como uma doença comum, prevenível e tratável caracterizada por sintomas respiratórios persistentes e limitação do fluxo aéreo devido a anormalidades alveolares ou de via aérea geralmente ocasionada por exposição significativa a partículas ou gases nocivos.[1]

O mecanismo fisiopatológico da DPOC envolve inflamação sistêmica com alterações significativas em nível celular e estrutural que desencadeiam um processo de remodelamento de vias aéreas. A destruição e fibrose das paredes alveolares acabam por promover constrição das vias aéreas, produção de muco e consequentemente obstrução de fluxo aéreo.[2]

Dados sobre a prevalência de DPOC no mundo ainda são conflitantes devido aos diferentes critérios de diagnóstico para a doença e a grande problemática de subdiagnóstico nesta população. Algumas estimativas apontam para 600 milhões de casos em todo mundo, já em outras projeções mais conservadoras este número pode chegar as 326 milhões casos.[3, 4]

A DPOC tornou-se foco constante de atenção devido aos seus altos índices de morbidade e mortalidade.[1, 5] Sabe-se que esta doença é altamente incapacitante e atualmente ocupa a posição de quarta maior causa de morte no mundo, com projeções de atingir o terceiro lugar até o ano de 2020.[6]

As estimativas de aumento do número de casos de DPOC estão relacionadas principalmente a contínua exposição aos fatores de risco para esta doença, como poluição e fumo, além do aumento de expectativa de vida da população mundial.[6] Dessa forma, há uma constante preocupação com o manejo da DPOC a fim de controlar hospitalizações, exacerbações e os altos custos econômicos ocasionados por esta doença.[7] Estes custos podem atingir de 6% até 9% do orçamento total gasto com saúde em países da Europa e Estados Unidos, representando valores que chegam até 38 bilhões de euros. [4]

Somado as alterações e sintomas pulmonares característicos da fisiopatologia da DPOC, estes indivíduos também podem apresentar manifestações extrapulmonares como inflamação sistêmica e extenso prejuízo no sistema muscular decorrente de diversos fatores como uso crônico de corticosteroides, estresse oxidativo, além de redistribuição de fibras musculares com aumento do percentual de fibras do II e redução de fibras tipo I.[8] Essas manifestações resultam em perda da capacidade funcional e de qualidade de vida que impactam diretamente as atividades de vida diária e o nível de atividade física destes indivíduos.[9, 10]

Sabe-se que o descondicionamento físico desencadeia maior dispneia em níveis de esforço físico cada vez menores, o que pode resultar em comprometimentos funcionais e incapacidades ainda mais severos.[11] Além disso, a inatividade física e a disfunção músculo esquelética são alguns dos principais preditores de mortalidade em indivíduos com DPOC.[12, 13]

Frente a este cenário, o exercício físico é altamente indicado pelas principais diretrizes clínicas internacionais, pois além de apresentar sólido nível de evidência científica para o manejo dos sintomas, também melhora da qualidade de vida e aumenta a tolerância ao exercício destes indivíduos.[1, 14, 15] Assim, o exercício físico é considerado um dos principais pilares da reabilitação pulmonar em indivíduos com DPOC.[1]

Os princípios básicos de prescrição de exercício físico em indivíduos com DPOC não se distanciam dos utilizados para indivíduos saudáveis. É necessário que a carga total de treinamento prescrita reflita necessidades individuais e além disso, que exceda a carga habitual realizada em suas atividades de vida diária para que seja efetivo.[15] As principais recomendações de diretrizes clínicas apontam o exercício aeróbio, resistido e de flexibilidade como componentes importantes a serem incorporados no tratamento de indivíduos com DPOC.[14, 15]

Sabe-se que cada modalidade de exercício pode proporcionar diferentes efeitos de acordo com sua especificidade. Neste sentido, pode-se citar particularidades do treinamento resistido nesta população, o qual mostrou-se mais efetivo para ganho de força do que quando comprado ao treinamento aeróbio isolado.[15] Além disso, o treinamento resistido para estes indivíduos se torna uma opção atrativa pois além de proporcionar ganho de força muscular e melhoras no quadro de densidade mineral óssea[15, 16] também gera menos dispneia e um menor consumo ventilatório durante o exercício, podendo tornar esta estratégia mais tolerável do que treinos aeróbios.[16-18]

Diversas ferramentas podem ser utilizadas no treinamento resistido, como equipamentos de musculação, pesos livres e também materiais elásticos que incluem bandas e tubos elásticos.[15, 16] Os materiais elásticos vêm sendo utilizados em indivíduos com DPOC como uma alternativa aos equipamentos de musculação convencionais devido ao seu baixo custo, demanda de menor espaço físico, além de sua portabilidade que pode favorecer o treinamento, inclusive em domicílio.[19-21]

Os materiais elásticos são capazes de aumentar sua tensão linearmente a partir do início da contração até o fim do movimento, o que parece ser menos lesivo para as articulações.[19] Somado a este fato, podem requerer maior ativação muscular e o uso de unidades mais rápidas do sistema neuromotor em comparação com a musculação convencional.[22]

Diferentes estudos já demonstraram efeitos positivos do uso de bandas e tubos elásticos analisados separadamente.[19-21] Além disso, algumas investigações também já apontaram que treinamentos com materiais elásticos, como tubos elásticos, promoveram ganhos semelhantes aos obtidos com equipamentos de musculação, demonstrando que possivelmente os mecanismos de fortalecimento muscular sejam semelhantes entre estas ferramentas analisadas.[19, 20, 23]Entretanto, observa-se que a comparação entre diferentes ferramentas de materiais elásticos ainda não foi realizada.

Acredita-se que investigações que abordem estes aspectos sejam de grande relevância clínica visto que características dos materiais elásticos como espessura, diâmetro e constituição do material utilizado podem influenciar nos efeitos observados e na dinâmica do treinamento.[24, 25] Além disso, uma possível equivalência ou superioridade de efeitos no treinamento com materiais elásticos comparados a equipamentos de musculação, pode favorecer a disseminação e acesso à reabilitação pulmonar, a qual é considerada baixa em todo o mundo.[26-28]

Além da investigação de efeitos na força muscular, é pertinente a execução de estudos que realizem avaliações multidimensionais que levem em consideração os diversos comprometimentos sistêmicos da DPOC, desta maneira pode-se obter uma visão integral dos efeitos deste tipo de intervenção nestes indivíduos. [9]

Os efeitos do treinamento resistido com materiais elásticos vêm sendo estudado sob diferentes aspectos entre eles, funcionais,[19] metabólicos e inflamatórios[29] que são caracterizados como análises quantitativas. Entretanto, observa-se um crescimento significativo em análises que levem em consideração aspectos qualitativos de intervenções com treinamento físico em indivíduos com DPOC.[30, 31]

As análises qualitativas exploram fenômenos complexos da percepção humana com métodos não quantitativos para aprofundar os conhecimentos e promover novas perspectivas de uma determinada intervenção.[32] Esta modalidade de estudo abrange diferentes métodos, sendo um dos mais comuns a realização de entrevistas com grupos focais. Este tipo de análise pode complementar e fortalecer os achados de estudos quantitativos que muitas vezes não são capazes de captar as nuances e a complexidade da perspectiva humana.[32, 33]

Dessa forma acredita-se que a análise qualitativa pode ampliar e aprofundar os conhecimentos sobre treinamento resistido no contexto da reabilitação pulmonar. Estudos já demonstraram a percepção qualitativa de possíveis barreiras e facilitadores encontradas por indivíduos com DPOC que participaram de programas de treinamento resistido.[30, 31] Este conhecimento é essencial para a prática clínica de profissionais que estão envolvidos na supervisão deste tipo de treinamento, visto que a identificação destes fatores pode auxiliar em adaptações necessárias, além de estar diretamente relacionada aos índices de aderência e satisfação dos pacientes a estas intervenções.[31]

Para complementar os achados das análises qualitativas de pacientes, também se faz necessário conhecer a visão de terapeutas que supervisionam o treinamento resistido de pacientes com DPOC e que utilizam diferentes ferramentas para a execução deste tipo de treinamento. É relevante conhecer as vantagens, desvantagens e particularidades dos diferentes materiais utilizados, além das dificuldades vivenciadas por terapeutas no cotidiano do treinamento resistido e como estes aspectos influenciam sua prática clínica.

A seleção da ferramenta utilizada para o treinamento resistido no DPOC, pode depender de diversos fatores como o local no qual será ofertado o treinamento, disponibilidade de recursos, custo, características dos pacientes, e principalmente da percepção do fisioterapeuta que administrará o treinamento sobre as ferramentas a serem utilizadas .[28]

Assim, considerando a importância do treinamento resistido dentro do contexto da reabilitação pulmonar, é relevante conhecer a percepção de fisioterapeutas sobre as barreiras e facilitadores para a utilização de diferentes ferramentas para treinamento resistido em sua prática clínica. Este conhecimento ainda é escasso na literatura e pode auxiliar na disseminação desta modalidade de exercício, além de auxiliar fisioterapeutas na melhor escolha para ofertar o treinamento resistido de acordo com sua realidade e necessidades específicas.

Como abordado anteriormente, sabe-se que a DPOC promove diversas consequências extrapulmonares, sendo considerada uma doença sistêmica.[34] Comprometimentos extrapulmonares da DPOC, podem incluir caquexia,[35] obesidade[36] e adicionalmente comprometimentos psicológicos importantes, como sintomas depressivos, sinais de isolamento, além de perda de auto estima.[37] Acredita-se que estas alterações podem influenciar diretamente na aderência a programas de reabilitação pulmonar e de treinamento físico, influenciando assim na prática clínica fisioterapêutica.[37]

Dessa forma, além de avaliações de aspectos biológicos, funcionais e qualitativos, também são necessárias avaliações que identifiquem comprometimentos de auto estima que podem influenciar na motivação e adesão a programas de treinamento físico, afim de direcionar a melhor abordagem para cada paciente.

Neste sentido, observa-se um crescente interesse em avaliações sobre a imagem corporal em diferentes populações. As análises de percepção da imagem corporal vêm sendo amplamente estudada em adolescentes,[38] idosos[39] e mais recentemente em outras condições crônicas como doentes renais crônicos[40] e pacientes com dor lombar.[41] Entretanto estas análises em indivíduos com DPOC ainda são muito escassas, apesar de consideradas simples, de baixo custo e fácil aplicação.[42]

A imagem corporal pode ser definida como a figura mental que o indivíduo tem sobre suas medidas, contornos, forma de seu próprio corpo além de seus sentimentos e percepções sobre estas características. [42] Assim, a análise da imagem corporal se refere a satisfação que o indivíduo apresenta com seu próprio corpo, sendo considerado uma representação interna de um complexo mecanismo de identidade pessoal relacionada ao formato do corpo, peso tamanho, ou outras características relacionadas à aparência física.[42, 43]

Alterações na percepção de imagem corporal podem influenciar diretamente na qualidade de vida, no sentimento de auto estima e ainda comprometer habilidades funcionais.[44] Desta forma, pode trazer uma visão complementar dos comprometimentos de indivíduos com DPOC. Alguns estudos apontam que os níveis de satisfação com a imagem corporal podem estar relacionados com níveis de atividades física.[43, 45] Este fator torna esta avaliação ainda mais atrativa para indivíduos com DPOC, levando em consideração a relevância do exercício físico para o status de saúde destes indivíduos.

Assim, demonstra-se que diferentes aspectos do treinamento resistido em pacientes com DPOC ainda necessitam ser investigados. É preciso aprofundar conhecimentos em campos quantitativos, qualitativos e complementar a avaliação sobre possíveis comprometimentos de auto estima destes indivíduos. A soma destes achados afeta diretamente a prática clínica de profissionais envolvidos na reabilitação pulmonar, além de promover embasamento científicos para melhores decisões no manejo da DPOC.

OBJETIVOS

Frente a contextualização apresentada os objetivos da presente tese foram:

- Analisar os efeitos do treinamento resistido com materiais elásticos nos aspectos funcionais de indivíduos com DPOC e comparar a magnitude destes efeitos com os de equipamentos de musculação convencionais.

- Analisar quanti-qualitativamente a percepção de fisioterapeutas sobre as barreiras e facilitadores do uso de diferentes ferramentas para treinamento resistido em sua prática clínica.

- Analisar a percepção da imagem corporal em indivíduos com DPOC e investigar as associações destes índices com níveis de atividade física.

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ARTIGO 1

ELASTIC MATERIALS PROMOTES SIMILAR GAINS IN MUSCLE STRENGTH TO WEIGHT MACHINE EQUIPMENT IN SUBJECTS WITH COPD: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Elastic materials have been used as an alternative to weight machine equipment in rehabilitation of subjects with COPD. Whether or not the selection of the elastic materials to deliver training interferes with the magnitude of training responses, remains to be elucidated. The aim of this study to compare the effects of three modalities of resistance training (two using elastic materials and one using conventional weight machine) on peripheral muscle strength in subjects with COPD. Effects on exercise capacity, impact of disease on health status, body composition and daily level of physical activity were investigated as secondary endpoints. Forty eight subjects were randomly allocated into one of the groups: Elastic band group using Theraband® (EBG); Elastic tubes training using Lemgruber® (ETG); and Conventional training with weight machine equipment (CG). Subjects were evaluated before and after 12 weeks of training regarding peripheral muscle strength (dynamometry), impact of disease on health status (COPD Assessment Test, CAT), exercise capacity (6-minute walk test, 6MWT), body composition (bioelectrical impedance), and daily level of physical activities (acelerometry). Inter-group comparison of absolute training effects did not elucidate significant differences between the modalities in muscle strength. Likewise, all training modalities showed similar effects on CAT ($p=0.59$), body composition variables ($p>0.05$ for all) and daily physical activity variables ($p>0.05$ for all). Modalities of resistance training using elastic materials presented similar effects on muscle strength, health status, exercise capacity, body composition and daily level

of physical activity in subjects with COPD. The effects of elastic resistance were similar to conventional resistance training.

Keywords: Exercise; Pulmonary rehabilitation; Resistance training; Elastic materials; Pulmonary disease, Chronic Obstructive; Airflow Obstruction, Chronic; Physical Therapy Specialty;

BACKGROUND

Chronic obstructive pulmonary disease (COPD) is a major cause of chronic morbidity and mortality and is projected to be the third most common cause of death by 2020.[1] The benefits of physical training for these subjects are widely known and considered the cornerstone of pulmonary rehabilitation programs.[2] Large evidence already demonstrated that physical training improves exercise tolerance, dyspnea sensation, functional status and quality of life in subjects with COPD. [2, 3]

Resistance training is a modality that evokes less metabolic load and dyspnea during exercise, which makes training easier to tolerate than endurance training.[4-6] Resistance training promotes significant effects on peripheral muscle strength, exercise capacity and health-related quality of life in chronic obstructive pulmonary disease.[2, 7] Furthermore, reductions in type I fibers, atrophy of type I and II fibers, reduced capillarity, and altered metabolic enzyme levels are observed in patients with COPD and can be significantly improved through resistance training .[8-12] Therefore, resistance training may be considered an important component for rehabilitative interventions in individuals with COPD. [13]

Conventionally, resistance training is delivered using weight machines or free weights (e.g. dumbbells, ankle weights) or using elastic materials (e.g. elastic tubes and elastic bands).[11, 14-16] Elastic materials may be used in subjects with COPD as an alternative to weight machine equipment since the lower costs of the material and less physical space requirement, facilitates its implementation and accessibility to places such home environment.[16 17] This is particularly appealing as elastic materials may be an option for increasing access to pulmonary rehabilitation considered low worldwide.[18-21]

Furthermore, elastic materials are able to increase their tension linearly from the onset of contraction to the end of the movement, which seems to be less damaging to the joints.[22] Added to this fact, they may require more muscle activation and the use of faster units of the neuromotor system compared to conventional weight machine equipment.[22, 23]

Elastic tubes and elastic bands are different tools commonly used in resistance training. [16, 17, 24]They differ in shape (round vs flat), material (latex vs rubber) and thickness. Thus, we believe is still necessary to investigate if these differences may promote different effects after a resistance training protocol. In addition, elastic tubes can be up to four times cheaper than elastic bands, a significant feature that may influence clinical practice especially in low incoming countries.[18]

A few studies already demonstrated positive effects of elastic bands / tubes as training modality in COPD[16, 17, 24]. The equivalence of training modalities including elastic tubing to conventional resistance training is yet at early stages of evidence. Importantly, literature lacks evidence about the equivalence/superiority of benefits from different elastic materials during training.

Therefore, the primary aim of this study was to compare the effects of three modalities of resistance training (two using elastic materials and one using conventional weight machine) on peripheral muscle strength in subjects with COPD. Because COPD is a disease with a large array of systemic manifestations,[25] we also investigated whether training responses of the elastic materials are similar to those already observed in conventional resistance training. Secondary outcomes of this study included effects of training modalities on exercise capacity, the impact of disease on health status, body composition and daily level of physical activity were investigated as secondary endpoints.

METHODS

Sample selection

Subjects were included if had primary diagnosis of COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD I to IV),[26] presented clinical stability (without exacerbations or changes in medications for at least 30 days), did not smoke in the last year and did not present any condition or disease limiting exercise performance. Subjects would be excluded from the analyses if withdrew consent or suffered from an exacerbation episode during the period of the study.

Ethical Aspects

Individuals were informed about research aims and procedures and, upon acceptance, provided an informed consent form. The present study was approved by the institutional review board (CAAE: 46065315.7.0000.5402). The trial was register in the Brazilian Clinical Trials Registry (#RBR-6V9SJJ).

Exp*erimental Design*

This study was a parallel randomized trial and subjects underwent an initial evaluation consisting of medical history with investigation of preexisting comorbidities physical examination, lung function (spirometry), impact of disease on health status (COPD Assessment Test, CAT), exercise capacity (6-minute walk test, 6MWT), body composition analysis (bioelectrical impedance), peripheral muscle strength (dynamometry) and daily level of physical activities (accelerometry).

Random sampling was performed using Microsoft Excel software (Microsoft Office 2007, Microsoft Corporation, Redmond, Washington). Subjects were then randomly allocated using sealed opaque envelopes into one of the three following groups: Elastic band training using Theraband® (EBG); Elastic tubes training (ETG); and Conventional training with weight machine equipment (CG). Upon training completion, subjects were submitted to the same assessments as performed prior to training beginning. Exercise programs and evaluations were conducted in a rehabilitation center always in the morning to avoid circadian variations. All evaluations and randomization steps were performed in a rehabilitation center by a researcher with no contact with the training protocol. Subjects were initially recruited in January of 2015 and the study was concluded in July of 2016.

A detailed description of the assessments is provided below.

Peripheral muscle strength was assessed using an electronic dynamometer (Power Din Standard, CEFISE, Brazil) for the muscle groups: elbow flexors, shoulder flexors / abductors and knee flexors / extensors. Each muscle assessment consisted of three repetitions separated by 1 minute of interval and the best value was used as the maximal muscle strength. Muscle strength was defined as primary outcome of the study. [16]

The COPD assessment test (CAT) was used to measure the impact of the disease on health status. It consists of eight items with scores ranging from 0 to 5. An overall score is calculated by adding individual items' scores. Higher scores indicate more severe health status impairment or a poorer control of COPD.[27]

Lung function measurements were obtained for all subjects at baseline. Spirometry was performed according to the guidelines of the American Thoracic Society (ATS) and European Respiratory Society (ERS) [28] using a portable spirometer (Spirobank-MIR, Italy,). The reference values were specific for the Brazilian population.[29]

The 6MWT was performed according to the ATS/ERS technical standard on field walking test. [30] Briefly, participants were asked to walk indoors on a flat, straight, 30-meter long corridor supervised by a trained researcher. Subjects were encouraged using standard methodology at every minute of the 6MWT. Rest and post-exercise SpO_2 were measured using a pulse oximeter with a finger probe. A modified Borg scale was used to quantify perceived dyspnea and fatigue at the beginning and at the end of the test.[31]

Body fat mass in kilos and percentual, visceral fat area , skeletal muscle mass and skeletal lean mass were measured with octopolar bioimpedance InBody 720 (Biospace, Seoul, Korea). This technology employs eight contact electrodes (two are positioned on the palm and thumb of each hand and the other two on the front part of the feet and on the heels).[32]

Actigraph model GT3X (Actigraph LLC, USA) was used to measure daily levels of physical activities. Actigraph is an activity monitor which measures and records triaxial body acceleration within a frequency range of 0.25 to 2.5 Hz. Recorded data was analyzed using a specific software (ActiLife5, Actigraph). Minutes and percentage of total time that the subjects remained in activities of sedentary, moderate, vigorous and very vigorous intensities were analyzed. Monitors were placed at the waist line and subjects were instructed to wear the equipment 24 hours/day during seven consecutive days (prior to and upon completion of exercise programs).

Training programs offered in ETG, EBG and CG

The training was performed for a 12-week training, 3 times a week. The duration of each exercise session was approximately 50 minutes and every exercise session consisted of an initial warm-up and general stretching followed by resistance training. Prior to the commencement of the training programs, participants were familiarized with the exercises, equipment and elastic bands / tubes. Exercises were conducted under a periodized and progressive design.[24] The movements were performed in the following standardized sequence: shoulder abduction, elbow flexion, shoulder flexion, knee extension and knee flexion. Exercises in all groups followed a design with standardized progression of workload. Patients, however, could increase workload whenever felt comfortable with the workload. Training progression of all muscle groups had a non-linear progression design with the following preset number of sets and repetitions: 1st to 2nd weeks: 2 X 15rep; 3rd to 6th weeks: 3X15rep; 7th to 9th weeks: 3X10rep; 10th to 12th weeks: 3x15rep. Velocity of muscle contractions were controlled by the therapist to last approximately 2 seconds in both concentric and eccentric component of the movement. Between each set of training patients were instructed to rest for two minutes. The criterion to increase workload was based on the number-of-repetitions test (NR) performed at the beginning of each session. Participants performed the NR to verify the maximum number of repetitions they could perform with a given load. The load would be maintained for that session when the maximum number of repetitions performed was the established for each week (considering a variation of ±2 repetitions), it would be otherwise adjusted to achieve the expected number of repetitions stipulated for each week of training. The increment in the ETG and EBG was done by changing the diameter of the tubes/color of the band and/or adding extra tubes/ bands. Increases in the workload for subjects in CG followed the same criterion of ETG with changes in the weights of the machine. This protocol was based on previous studies [24, 33]

Resistance training with elastic resistance (tubing (ETG) and bands(EBG)

Five strengths of elastic tubing were used (#200, #201, #202, #203 and #204) (Lemgruber, Brazil). The estimated cost of the full set of elastic tubing per subject is around US$20 and can be acquired online. Higher numbers indicates larger tube diameters. Tubes #200 (internal/external diameter: 3.0/5.5mm), #201 (internal/external diameter: 4.0/5.5mm), #202 (internal/external diameter:4.0/8.0mm) and #203 (internal/external diameter: 6.0/9.0mm) were used for the upper limbs training. Tubes #203 and #204 (internal/external diameter: 6.0/11.5mm) were used for lower limbs training. The difference in the diameters of tubes explain the amount of resistance provided. A detailed protocol of the mechanical properties of elastic tubing was assessed by Lima et al.[23]

All tubes were connected to a specific chair with length and position adjusted for each trained muscle group.[24] Trained muscle groups were the same as evaluated during the assessments (i.e. knee flexors and extensors, shoulder flexors and abductors and elbow flexors). For the elastic bands (Theraband®, USA), five different colors were used: yellow, red, green, blue and black . The estimated cost of each elastic band Theraband ranges from US$14,99 to US$24,99 (considering each subjects may use 3 to 4 different elastic bands).

Conventional resistance training (CG)

Participants allocated to the CG used a weight machine (Ipiranga®, Brazil). A simple pulley equipment was used for the upper limb training. One-legged open chain knee extension/flexion exercises were conducted on a seated position.

Statistical analysis

Statistical software Prism (GraphPad Software, USA) was used to data analysis. To analyze data distribution Shapiro-Wilk test was used. Paired student's t test or Wilcoxon test was used according to the normality of the data to compare training effects within each group. For comparisons between the three interventions, the absolute variation between the final and baseline values of each variable (absolute delta) was calculated, using a one-way ANOVA test with Tukey post-test or Kruskal Wallis test with Dunn test according to the normality of the data. Since we observed differences in baseline values, adjustment analysis of effects were performed through ANCOVA, using age, CAT, muscle strength (knee extension and knee flexion) as covariates.

Magnitude of differences between group responses was also describe as effect size using Cohen's *d*. The effect size classes were defined according to calculated values d [small ($d \leq 0.2$), moderate ($d = 0.5$) or large ($d \geq 0.8$).[34] The minimal clinically important difference (MCID) of outcomes were calculated and compared between groups using chi-square test. In case of attrition, patients would be invited (whenever possible) to perform the final evaluations, regardless the amount of exercise sessions followed. If they still did not attend the reassessments, an intention-to-treat analysis would be performed carrying forward the last available set of data (baseline values) for final analysis.[35] Data was expressed as mean and standard deviation or median and interquartile range according to the data distribution. The level of significance was set as 5%.

Knee extension force was a priori defined as primary endpoint. Sample size calculation was done based on equivalence of training. Thirty-nine subjects (13 per group) were needed to achieve a power of 80% and expecting a difference of 9.46Kg between groups (data based on pilot study of our group[36]) with a standard deviation of 10.52Kg and taking into account a typical dropout rate of 20%.

RESULTS

Eighty-one subjects were initially screened for inclusion. Forty-eight subjects with COPD were randomized into the 3 training protocols and 40 completed the program. Details of study flow are described in Figure 1 according to CONSORT.[37]

INSERT FIGURE 1

Table 1 shows the baseline characteristics of subjects in the three training groups. As expected, all subjects presented airway obstruction: 4,1% mild (ETG=1 ; EBG=2; CT=0), 37,5% moderate (ETG=6 ; EBG=3; CT=6), 47,9% severe (ETG=1 ; EBG=8; CT=7) and 10,4% very severe (ETG=1 ; EBG=1; CT=3). Subjects also presented low to high impact of COPD according to CAT questionnaire. Regarding body composition, 54% (n=26) of subjects presented altered fat-free mass index[38] and virtually all subjects presented increase in total body fat (n=41; 92,7%). [39] Finally, subjects spent most of the day in sedentary activities. There were no statistically significant differences between groups in none of the investigated variables upon study commencement, except for knee extension that was higher in the EBG when compared to ETG ($p<0.05$).

INSERT TABLE 1

Training effects on muscle function

Improvements in lower and upper limb muscle strength were similar among the three groups. Absolute delta variation (Δ) and the respective 95% confidence interval for inter-group analysis can be observed in Table 2. Intra-group analysis (baseline x final) revealed significant improvements in lower limbs muscle strength in ETG and CG. Upper limbs muscle force was significantly improved from baseline only in EBG ($p<0.05$) (Table 2).

INSERT TABLE 2

A visual analysis of the variation (absolute delta) in muscle strength from baseline in the modalities of training can also be seen Figure 2. The figure shows the variation of change in all movements analyzed in the three modalities of training. Similar variation was observed between groups and no statistical differences were observed in inter group analysis ($p>0.05$)

INSERT FIGURE 2

The effect size calculations on muscle strength showed small to moderate effects between ETG and EBG (Cohen's *d*: 0,14 to 0,53), small effects between ETG and CG (Cohen's *d*: 0,02 to 0,23) and small effects between EBG and CG (Cohen's *d*: 0,06 to 0,46).

Other training outcomes

INSERT TABLE 3

Table 3 reports the results for all others training outcomes with adjustment for the following covariates: muscle strenght, CAT and age. A reduction in CAT scores was observed in all groups, however, a significant difference was only observed in EBG (P=0.04). 57% of subjects in EBG, 38% in ETG and 50% in the CG reached the minimal clinical important difference (MCID) in CAT questionnaire (X^2 test p=0.5789). Between-group comparison, however, did not show statistical significant difference with only small effect sizes (Cohen's *d*: 0.12 to 0.36). 6MWT did not significantly improve from baseline in none of the three groups. Magnitude of changes between interventions were also similar (p=0.189) with effect sizes ranging from 0.08 to 0.51. Similarly, none of the body composition variables changed significantly after interventions ($p>0.05$) with effect sizes ranging from 0.02 to 0.61. Finally, no significant changes from baseline or between interventions were observed in daily physical activity variables ($p> 0.05$ for all). However, we observed large effect size for changes on light activities between ETG and CG (0.87), moderate effect size between ETG and EBG (0.58) and moderate effect size for vigorous activities between ETG and EBG (0.65) and between ETG and CG (0.51).

DISCUSSION

The present study demonstrated comparable gains on muscle force between three resistance training interventions. Also, improvements (or lack thereof) of other investigated outcomes were similar between the three interventions, suggesting mechanisms responsible for training effects might be similar. We believe these findings are relevant since the materials used in the training present significant differences regarding, materials, size and cost, features that can directly influence clinical practice.

Previous evidence demonstrated positive effects of elastic resistance on muscle strength in COPD[17, 40]. The effects observed on muscle strength in both conventional and elastic tubing groups in the present study corroborate previous studies comparing elastic and conventional resistance (weight machine equipment) training.[16, 24] Our results expand on those findings showing that different elastic materials (tubing or bands) can improve muscle strength to a similar extent. This may be fundamental in the clinical choice of the selection of tools to deliver training considering the great discrepancy of costs between the elastic materials and weight machine equipment. The estimated cost of the elastic tubing per patient is US$20,[41] while each elastic band (1,5 meters) costs around $17,00 and patients usually need around 3 to 5 bands for training. Weight machine equipment can be found for up to $1000,00, therefore it is necessary that clinicians consider their own financial and infrastructure reality to choose between the equipment's used in resistance training.

It is also important to notice that we performed an isometric strength evaluation, trough dynamometry, even though we delivered a dynamic execution of training. It could be suggested for future studies to evaluate strength similarly as the participants have trained (e.g. maximum repletion test) since this might be more sensitive analysis for detecting changes.

Previous evidence demonstrated improvements on the impact of disease on health status (CAT questionnaire) following resistance training in COPD.[9] This is in line with the present study as all groups showed numerically reduction in the CAT scores. A statistically significant reduction, however, was obtained only in EBG group. This is not particularly surprising as baseline values of CAT in EBG (deemed medium) were higher than the other two groups (deemed low).[42] Worse baseline CAT values were associated with larger improvements after training.[43] Furthermore, the average reduction in the three groups exceeded the MCID in the test (2 points)[44].

Baseline values of 6-minute walk test in all investigated groups were close to normal values, which is expected as Brazilian subjects present higher walked distances in the test.[45, 46] Thus, anticipated improvements in the test following exercise training are also small. The maintenance of functional capacity may be attributed to the conditioning of peripheral musculature identified by the increase of muscular strength of upper and lower limbs in the three types of physical training. Thus, it is emphasized the importance of resistance training to maintain the functionality of these subjects, since there is compelling evidence highlighting the role of muscular strength in the exercise performance in subjects with COPD. [3, 16, 47]

Studies with body composition analysis gained interest in the COPD population. Casaburi et. al demonstrated that resistance training effects on body composition are less pronounced (or inexistent) compared to resistance training plus testosterone supplementation in subjects with COPD [48]. Changes on body composition are normally associated with rehabilitation programs that include a nutritional component and strict monitoring of the dietary behavior of these subjects.[49] Thus, we believe that lack of changes on body composition observed in our cohort may be partially explained by the lack of a nutritional component in our program.

Subjects with COPD present reduced levels of daily physical activity compared to healthy controls[50]. Daily levels of physical activity were not changed after the training interventions. This is not particularly surprising in COPD as changes on overall physical capacity are not necessarily translated into a more active lifestyle.[51] In fact, strategies to increase levels of physical activity are still being investigated with conflicting, inconsistent or unsatisfactory results[52] ,[51] [53, 54]. Importantly, training regimens did not seem to reduce daily levels of physical activity, suggesting that modalities did not affect negatively on the outcome.

The present study is the first, to our knowledge, to investigate the effects of different types of elastic resistance and conventional training in several clinical aspects in subjects with COPD. This result confirms the initial hypothesis of a potential equivalence of training between the three modalities on muscle force. Interestingly, the effects of modalities were also similar for all investigated secondary outcomes. We believe these findings are clinically relevant since elastic materials may be an effective and inexpensive alternative tool when compared to weight machine equipment for the training of chronic pulmonary subjects.

It is important to notice that the interpretation for the secondary outcomes of this study should be cautious, due to the possibility an underpowered sample. Despite the sample size calculation for the primary endpoint, it is not possible to confirm whether the sample included in the present study has enough power for the effects on any of the secondary endpoints. This aspect is considered a limitation of our study and therefore future studies focusing in these endpoints are recommended.

Furthermore, the lack of a specific nutrition intervention may have potentially interfered with the lack of benefits on body composition in all groups. Future studies with power for outcomes different than muscle force and with a structured nutritional intervention are necessary to confirm our findings on these outcomes.

In conclusion, different modalities of resistance training using elastic materials presented similar gains on muscle strength. These results were comparable to a conventional resistance training in subjects with COPD.

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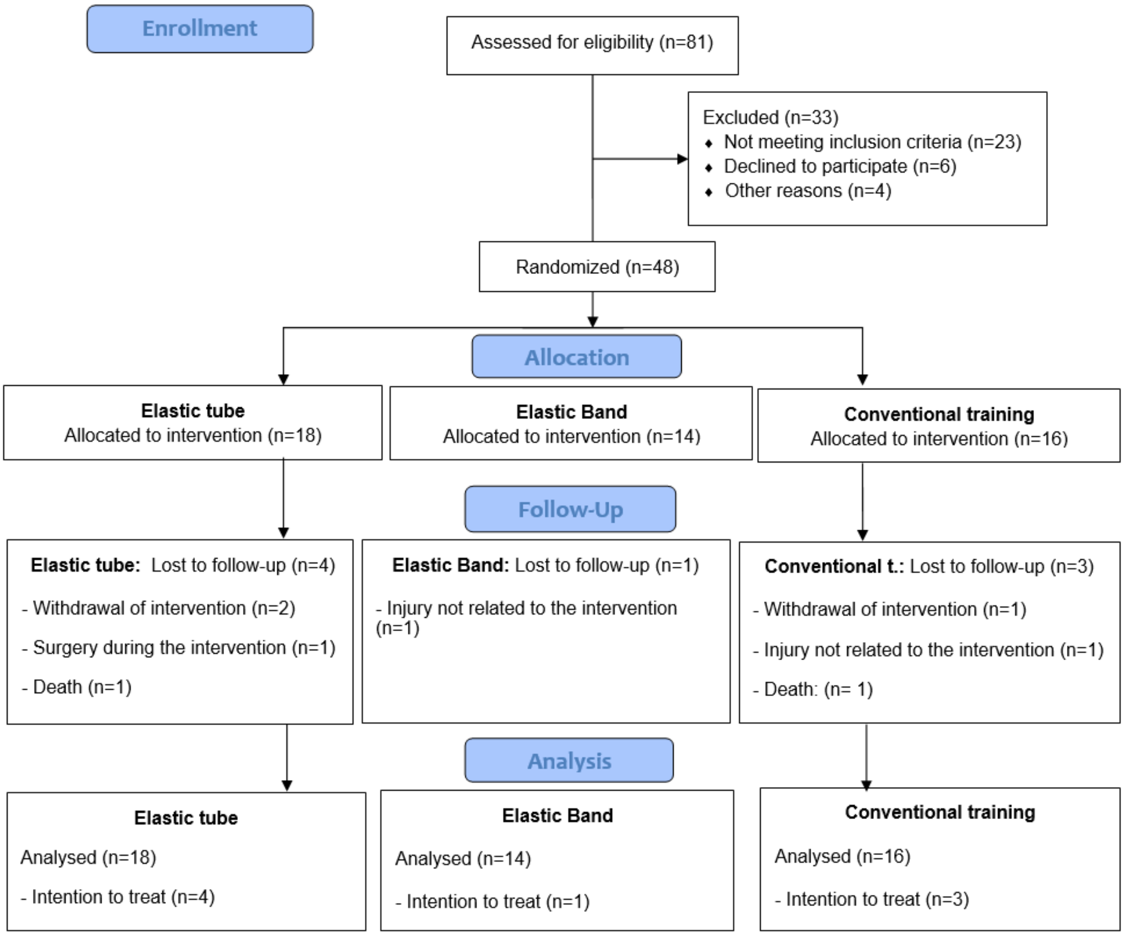

Figure 1 – Flowchart of the study according to CONSORT.

Table 1 – Baseline characteristics of spirometry, muscle strength, clinical symptoms, functional capacity, body composition and daily physical activity. Data expressed as mean and standard deviation.

	Elastic Tubing	Elastic Bands	Conventional resistance Training	p
Caractheristics				
Gender (M/F)	13/5	8/6	10/6	
Age	71.53±6.97	66.46±10.63	64.63±11.49	0.0686
BMI (Kg/m^2)	24.88±4.17	26.53±5.23	25.68±4.40	0.3322
Spirometry				
FVC (l)	2.53±0.81	2.64±0.79	2.43±0.60	0.7434
FVC % predicted	70.88±13.23	75.92±13.21	66.96±13.91	0.1785
FEV_1 (l)	1.41±0.55	1.34±0.51	1.29±0.49	0.8954
FEV_1 % predicted	51.15±16.58	49.91±16.80	45.72±15.59	0.6946
FEV_1/FVC	55.99±13.00	51.09±12.44	54.59±14.56	0.5499
Disease impact on health status				
CAT	20.75±7.22	14.67±7.72	15.56±7.29	0.0638
Functional capacity (m)				
6MWT	468.4±60.22	482.5±134.0	502.9±79.11	0.2181
6MWT (% predicted)	91.54±14.87	93.82±22.69	92.23±14.28	0.5156
Body composition				
Visceral Fat Area (cm^2)	107.4±64.38	111.1±35.92	98.09±31.69	0.4396
Skeletal Muscle Mass (kg)	22.36±6.98	24.17±2.46	25.80±5.29	0.2203
Body Fat Mass (kg)	23.40±12.51	24.49±10.65	22.70±8.17	0.9615
% Body fat	34.74±15.44	34.07±11.76	32.13±9.66	0.7901
Skeletal Lean Mass (kg)	39.41±10.96	42.01±3.97	44.04±8.21	0.2792
Daily physical activity				
% time in sedentary activity	86.3±6.096	83.16±6.65	84.55±5.28	0.4995
% time in light activity	10.88±5.462	12.70±6.27	11.54±4.93	0.6856
% time in moderate activity	2.64±1.84	3.79±1.77	3.65±2.153	0.2119
% time in vigorous activity	0.14±0.09	0.28±0.13	0.21±0.19	0.0515
% time in very vigorous activity	0.03±0.03	0.07±0.05	0.04±0.02	0.1088

BMI: Body Mass Index; FVC: Forced vital capacity; FEV1: forced expiratory volume in the first second; CAT: COPD assessment test; 6MWT: Six minute walking test; kcal: kilocalories; kg: kilograms; l: liters; m: meters; cm: centimeters;*: statistical significance post hoc test between elastic tubing and elastic bands

Table 2 - Peripheral muscle strength in kilograms data at baseline, after resisted physical training and absolute (delta) variation. Data expressed as mean and standard deviation.

	ETG			EBG			CG			
	Baseline	Final	Δ (CI 95%)	Baseline	Final	Δ (CI 95%)	Baseline	Final	Δ (CI 95%)	p intergroup
Elbow flexion	12.4±5.5	13.3±4.6	0.9(-1.6-3.5)	15.4±6.0	18.9±7.7*	3.4(0.05- 6.9)	14.4±5.7	16.8±6.1	2.3 (-0.05 – 4.8)	0.40
Shoulder abduction	7.5±3.7	7.9±3.7	0.45 (-1.1-2.1)	9.4±3.2	11.8±5.14*	2.4(0.06 - 4.8)	7.4±2.7	8.3±3.8	0.8 (- 0.67 – 2.3)	0.24
Shoulder flexion	6.9±3.4	7.4±3.0	0.5 (-1.1 – 2.1)	9.8±4.0	11.2±4.5	1.3(-0.7 - 3.4)	7.9±3.1	8.5±3.7	0.5 (-1.0 – 2.1)	0.74
Knee extension	23.6±8.3	26.7±8.3	3.12 (-1.1 – 7.3)	33.6±10.1	39.4±12	5.8(-0.05 -11.73)	29.1±12.8	34.2±13.4*	5.1 (0.7 – 9.5)	0.66
Knee flexion	18.0±9.0	22.9±8.5*	4.8 (0.7 – 8.9)	27.1±10.2	32.6±10.8	5.4(-0.6 -11.59)	25.2±12.3	31.4±14.7*	6.1 (0.6 – 11.7)	0.77

*= $p<0.05$ in the paired comparisons; ETG: Elastic tubing group; EBG: Elastic Band Group; CG: Conventional resistance training group;

Table 3 – Other Training outcomes data at baseline, after resisted physical training and absolute (delta) variation. Data expressed as mean and standard deviation.

	ETG			EBG			CG			
	Baseline	Final	Δ CI 95%	Baseline	Final	Δ CI 95%	Baseline	Final	Δ CI 95%	p inter group*
Clinical impact COPD										
CAT	20.75±7.22	17.82±9.0	-2.9(-1.01 – 7.64)	14.67±7.72	9.0±5.82*	-5.58 (0.18-10.98)	15.56±7.29	11.44±9.20	-4.12 (-0.13-8.38)	0.460
Functional capacity										
6MWT (m)	455.5±61.69	458.9±65.9	3.35 (-12.56 – 5.85)	482.5±134	497.6±135.5	15.07 (-37.52-7.38)	502.9±79.11	505.0±72.45	2.09 (-18.51 – 14.32)	0.189
6MWT predicted (%)	91.02±14.85	92.64±13.64	1.62 (-5.89-2.66)	93.83±22.70	96.55±24.69	2.72 (-8.45-3.0)	92.54±13.71	94.31±13.44	1.77 (-6.91-3.39)	0.180
Body composition										
Visceral Fat Area	107.4±64.38	88.41±29.45	-18.9(-46.7-8.7)	111.1±35.92	116.1±28.32	5 (-7-16.3)	98.09±31.69	104.1±29.14	6.01(-8-12.5)	0.938
Skeletal Muscle Mass	22.36±6.98	23.15±4.23	0.78(-2.7-4.2)	24.17±2.46	24.79±3.15	0.62 (-2.66-1.42)	25.80±5.29	26.05±5.53	0.25 (-1.2-1.8)	0.752
Body Fat Mass	23.40±12.51	19.80±7.84	-3.6(-8.7-1.4)	24.49±10.65	26.62±8.40	2.13 (-9.0-4.8)	22.70±8.17	23.85±7.59	-0.02 (-3.0-2.9)	0.97
% Body fat	34.74±15.44	30.30±9.38	-4.44(-11.1-2.2)	34.07±11.76	36.31±8.02	2.09(-1.5-5.7)	32.13±9.66	32.97±9.20	1.15(-2.6-2.4)	0.602
Skeletal Lean Mass	39.41±10.96	40.53±6.74	1.12(-4.2-6.5)	42.01±3.97	43.04±5.07	1.12(-4.2-6.5)	44.04±8.21	44.81±8.58	0.77(-1.5-3.0)	0.150
DPA										
% in Sedentary	86.3±6.09	84.35±7.62	-1.9(-4.4-0.72)	83.16±6.65	80.92±8.44	2.2 (-6.9-2.8)	84.55±5.28	80.94±6.086	-3.61(-7.0-0.7)	0.213
% in Light	10.88±5.46	12.87±6.201	1.99 (-6.21-2.23)	12.70±6.27	15.16±8.82	2.46(-3.0-7.6)	11.54±4.93	15.93±6.61	4.09(-0.36-8.0)	0.348
% in Moderate	2.64±1.84	2.60±2.19	0.04 (-1.42-1.50)	3.79±1.77	3.69±1.87	-0.1(-0.72-0.54)	3.65±2.153	2.97±1.83	-0.68(-1.3-0.11)	0.373
% in Vigorous	0.14±0.09	0.14±0.12	0 (-0.08-0.08)	0.28±0.13	0.18±0.15	-0.1(-0.1-0.01)	0.21±0.19	0.12±0.09	-0.09(-0.19-0.03)	0.314
% in Very Vigorous	0.03±0.03	0.03±0.03	0 (-0.02-0.02)	0.07±0.05	0.05±0.07	-0.02(-0.06-0.01)	0.04±0.02	0.03±0.05	-0.01(-0.03-0.02)	0.200

*p value adjusted through ANCOVA considering as covariates: CAT, age, muscle strenght; FEV1 ETG: Elastic tubing group; EBG: Elastic Band Group; CG: Conventional resistance training group;CAT: COPD assessment test; 6MWT: Six minutes walking test; DPA: daily physical activity.

Artigo 2

ARTIGO 2

PHYSIOTHERAPISTS´ PERCEPTIONS ABOUT FACILITATORS AND BARRIERS IN THE USE OF DIFFERENT TOOLS FOR RESISTANCE TRAINING IN COPD PATIENTS: A MIXED-METHOD STUDY

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ABSTRACT

The aim of the study was to quantify and qualitatively analyze the perception of physiotherapists about facilitators and barriers in the use of different types of tools for resistance training in patients with COPD. A mixed model with qualitative analysis developed in a rehabilitation center. Six physiotherapists that performed a randomized clinical were interviewed.The protocol consisted of the evaluation of three types of resistance training: elastic tubes, elastic bands and training with conventional weight machines. After completion of the randomized trial, therapists were invited to participate in a focus group to collect qualitative data. Physiotherapists also answered a quantitative questionnaire containing closed questions. The main outcome measures were the opinion of physiotherapists about the advantages and disadvantages in clinical practice of each of the analyzed tools. The focus group analysis resulted in eight themes: Insecurities regarding load and handling tools, implementation of home based treatment, tools improvements, advantages and disadvantages of tools, incidence of injuries with elastic tools, patient's preferences and particularities of the tools. Physiotherapists pointed out different barriers and facilitators for resistance training. Characteristics of the tools, such as costs, portability, handling and practicality, were cited as factors that influence clinical practice. In the quantitative analysis, no differences were observed when comparing the scores of each instrument. The three tools analyzed are applicable and feasible in the clinical practice of physiotherapists; additionally, they present different characteristics and particularities that should be taken into account, such as cost, clinical applicability, portability and perception of the patient and physiotherapists.

Key words: Pumonary disease; Exercise training, Pulmonary rehabilitation; Physiotherapy; Qualitative methods

BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of morbidity worldwide. It is estimated that by the year 2030, COPD will be the third most frequent cause of death globally.[1] Current international guidelines emphasize the central role of pulmonary rehabilitation in the treatment of COPD.[2] Pulmonary rehabilitation aims to control COPD symptoms, reestablish and improve functional ability, enhance participation in activities of daily life, promote autonomy and improve quality of life among this population.[3]

Exercise training has been considered an essential component of pulmonary rehabilitation programs.[3, 4] Several training modalities have been used, including resistance training, since the muscular weakness found in these patients is associated with prognosis and functionality in these individuals. [2-4] Several tools can be used to improve muscle strength in these patients, such as weight machines, dumbbells, ankle weights and elastic components (e.g. elastic tubes and elastic bands). [5-7]

The selection of the tool that will be used in resistance training may depend on several aspects, such as the location in which the training will happen, availability of resources, cost, portability, patients' characteristics, and also the training and perception of the physiotherapist who will administer the resistance training. [8, 9] Previous quantitative studies reported that patients´outcomes improve when the resistance training is delivered by trained physiotherapists.[10, 11] Nevertheless, physiotherapists´perceptions after delivering such training have not been investigated. It may be important to investigate such perspectives, as while resistance training is beneficial to COPD patients, if therapists are not confident or unwilling to administer it, it may not be an approach that can be routinely incorporated with ease in the clinical setting. Therefore, the aim of the present study was to quantify and qualitatively analyze the perception of physiotherapists about facilitators and barriers in the use of different types of tools for resistance training in patients with COPD.

METHODS

Six physiotherapists that performed a randomized clinical trial at a rehabilitation center located in Presidente Prudente, Brazil were invited and agreed to participate in the present study.

Individuals were previously reported on the research objectives and procedures and, upon acceptance, signed a free and informed consent form, in accordance with the Declaration of Helsinki of the World Medical Association. The present study was approved by the Ethics Committee of São Paulo State University (UNESP) (CAAE: 46065315.7.0000.5402).

The resistance training protocol of the randomized clinical trial consisted of the evaluation of three groups of patients with COPD. The first group performed resistance training with elastic tubes (Lemgruber®, Brazil), the second performed training with elastic bands (Therabanb®, USA) and the third performed training with conventional weight machines (Ipiranga, Brazil).

The intervention occurred between September of 2015 and June of 2016 and lasted 12 weeks, with a frequency of three sessions per week. The same muscle groups (shoulder flexion, elbow flexion, shoulder abduction, knee extension, and knee flexion) were trained in all three types of training, using the same muscle strengthening protocol. Training with bands and elastic tubes was carried out in chairs especially designed for the exercises (containing hooks that allowed the fixing of elastic bands and tubes).[12]

Therapists underwent a training phase prior to the beginning of the training protocol in order to familiarize themselves and standardize sessions using all the tools evaluated in the study. At the beginning of the training patients were randomly distributed among therapists so that all therapists could use the three tools analyzed.

To perform the three types of training, the patients worked with a protocol of maximum number of repetitions in each set. The protocol was based on a previous study of our group.[7, 12]

After completion of the randomized clinical trial, therapists participating in the trial were invited to participate in a focus group to collect qualitative data. The focus groups were lead by the main researcher of the study and conducted using an interview guide containing open-ended questions (Table 1). The moderator was a female, PhD student, with previous training and experience in qualitative research. A second researcher also participated in the interview to take notes.

The focus group was conducted in the rehabilitation center where the therapists worked. The interview was audio-recorded (OLYMPUS / VN-8100PC, Tokyo, Japan) and later transcribed verbatim. Table 1 shows the interview guide used in the focus group. (Insert Table 1)

The focus group lasted approximately 50 minutes. Data were collected until no new information was acquired (data saturation point).[13, 14]

After completion of the focus group, the physiotherapists answered a quantitative questionnaire containing closed questions. We asked the opinion of therapists about the advantages and disadvantages of each of the analyzed tools (elastic tubes, elastic bands and weight training equipment). The questionnaire is presented in Table 2. Finally, therapists were asked to assign a grade from 0 to 10, with 0 being the worst grade, taking into account the general aspects of each tool. (Insert Table 2)

DATA ANALYSIS

Qualitative data were analyzed using content analysis, which is a systematic way of describing phenomena and allow researchers to improve their understanding of data by refining words in fewer categories related to the content.[15] By analyzing the content, it is possible to distill words in less related categories in order to provide knowledge, new insights, representation of facts and a practical guide for action. [15]

The transcripts of the focus groups were analyzed by three independent researchers to identify and classify the categories related to the research question. The analysis was developed by categorizing, organizing and compacting data. After initial analysis, all researchers discussed the differences in the results until consensus was reached (triangulation). The final results were then sent to participants to check whether the findings really reflected their perspectives and points of view. Analyzes were performed and stored in the HyperRESEARCH 3.7.3 program.

To analyze quantitative data, we used Shapiro Wilk test for data normality analysis and then applied Kruskal Wallis test with Dunn post test. Statistical software GraphPad Prism was used and a level of significance was set at 5%.

RESULTS

The six therapists finalized all the proposed evaluation process. All physiotherapists had college degree in Physical Therapy and applied the exercise training with the three tools.

The therapists presented mean age of 23.83 ± 2.04 years old and on average 1.72 ± 1.73 years after end of graduation. In addition, they were working in the pulmonary rehabilitation area for 1.68 ± 1.74 years.

Qualitative Analysis

The interview resulted in eight items, as described below.

1. Insecurities regarding the identification of the load imposed on the patient

Therapists found difficulties in using the elastic tools, especially to determine the accuracy of the initial load imposed on the patient and the load used in the progression of the training. Due to the fact that elastic tools do not present a pre-determined load and their load is variable during the execution of the movements, the quantification of the load totally depended on the perception of the therapist. This factor was seen as a possible barrier to the use of elastic tools.

"*…finding the initial load imposed on the patients to start the training. I believe that after you started too, it's easier for you to do the increment, but starting is more complicated" (Therapist 1)"... incrementing is easier, but finding this initial load has a certain difficulty ..." (Therapist 1)*

Additionally, the difficulty to identify the load exerted by the elastic tools also generated concerns related to the tendency to underestimate or overestimate the load that would be ideal for each patient.

"It is difficult to find out what is the load for the patient, to not to underestimate or overestimate. I think it is easy to overestimate using tube and Theraband. "(Therapist 2)

"We do not know how much resistance each tube offers, according to the stretch of it, it gets complicated ... if we knew ..." oh, this tube has a certain percentage of stretch, offers this resistance, "would be much easier to adjust. Because you would start from a principle that you already know how much you will offer. We still do not know, so we go as we see." (Therapist 3)

"With the tube you do not regulate / adjust, that's it and done. Not there (weight machines), you can gradually increase, I think that is the main advantage." (Therapist 4)

When comparing the elastic tools, they reported greater easiness in identifying the load on the elastic bands, since the band (Theraband) provides the load (in kilograms) according to color and percentage of deformation in relation to the initial movement. Concerning the elastic tubes, it is known that larger diameters offer greater resistance to the patient.

"In fact the biggest advantage in using Theraband over the elastic tube, is that you know the grade of the resistance offered according to the stretch. It's the only difference, the rest is the same. "(Therapist 4)

"In fact, I think the biggest difficulty of the tube is when you start working with it, to understand the load graduation of it, a matter of diameter, but after you get it, I think it is not difficult at all." (Therapist 4)

2. Difficulties regarding handling the resistance tool

Therapists reported greater difficulties regarding the handling of elastic tools when compared to conventional weight machines. Reports on the difficulty of tube and band replacement were frequent.

Therapists reported that more effort is required in the dynamic of the training with elastic tools because frequent changes of elastic resistances on upper limb and lower limb exercises are necessary, since larger diameter tubes or bands of different colors are required for different movements.

"I think the change of tubes also, for different movements, is a bit complicated, both in the tube and in the Theraband ..." (Therapist 1)

"... all the time we have to change ..." (Therapist 5)

"... This changing thing is a lot of effort ... for the therapist is more tiring, more exhausting ..." (Therapist 1)

(regarding weight machines) "... No need to change here, putting and removing, no, you set the load and it is done, finish the set and only change when you change the point of movement. You do not have to spend all the time changing limbs, putting loads, so the practicality of working is a lot better. "(Therapist 4)

One of the therapists also stressed that handling with elastic bands (Theraband) can still be more laborious than tubes.

"Theraband is still more laborious, because it tangles. So to hook it, I think it is harder, tougher, you have to keep opening it. I prefer the tube, I think it is much easier to work with ... "(Therapist 4)

Additionally, a barrier found in the elastic tools was the material that, on certain occasions, provided difficulties during the resistance training sessions.

"..., one of the disadvantages of the elastic tools is that it periodically burst. If the patient is using it, it bursts in the middle of the movement .... (Therapist 4)

Due to these difficulties observed by the therapists regarding the handling of the elastic tools, there was an extended time of each session using these tools when compared to the training performed using conventional weight machines.

"Time is much faster (in weight machine), what we do in one hour using the tube, we do in half hour, 35 minutes using weight machines ..." (Therapist 3)

"And in two patients." (Therapist 1)

3. Implementation of home based treatment

The chair used during the training was designed by the researchers specifically for training with elastic tools. It can be used in the rehabilitation center and also in the patients' home after supervised training. However, some obstacles were pointed out, such as the difficulty that the patient would probably face in performing changes of tubes or bands without assistance, and different loads of the elastic tools.

"... aiming the independence of the patient during training, I think is a bit difficult. Because using weight machine, for example, if the patient had machines like that at home, it would make easier to set the loads. I think the chair is different, the patient needs help from someone at home ... to be changing, otherwise the patient has to get off the chair to put the tube or the band on the hook. So I think that's a harder thing to make the patient independent. "(Therapist 3)

Another indication regarding the use of the elastic tube at home was the possible difficulty in identifying the resistances, and the therapists suggested coloring them.

"I think Theraband is easier for the patient. It is much easier for the patient to know what color he has to put on than to identify the thickness of the tube." (Therapist 6)

Regarding the difficulty in portability of the chair, it was suggested to implant fixed bars in the patients' homes to facilitate the use of the elastic tools, as well as the fixation of handles for better handling of the elastic tools.

"... it does not even need to be a chair ... any fixed bar, any hook that the patient has at home already helps training ..." (Therapist 1)

"... would have to put a handle ..." (Therapist 5)

They also emphasized that despite the difficulties that may occur in the patient's house, elastic tools are the most viable options to continue unsupervised resistance training, which was considered an advantage when compared to weight machines.

"Even though it is difficult for the patient to do the training with the elastic resistance, the patient can continue the training, taking the equipment home, unlike the weight machines ..." (Therapist 1)

In addition to the possibility of using elastic tools at home, it was also pointed out that these tools have the advantage of being used in other environments that do not have conventional weight machine.

"Because you can work with this type of patient in any environment, in your clinic you do not have to have a weight machine ... it is much easier to get the tube and the Theraband and you can take it to any place, health care unit, hospital, patient's house." (Therapist 2)

4. Suggested improvements to the tools

Therapists reported that the use of elastic tube for muscle strengthening in COPD patients is a new method, and they observed some limitations that could be fixed in the future.

"... it's a new thing, too, there's a lot to study, there's a lot of adaptations to make, a lot of questions to improve for the patient and the therapist ..." (Therapist 4)

They also made suggestions on how to make elastic tubes colored, since only tubes of a single color (yellow) were used. The purpose is to make the tubes more attractive to the patients and easier to identify the resistance of different diameters.

"... if it had a color to characterize each tube, for example, the same as on Theraband, blue is 01, green is 02, it would be easier." (Therapist 5)

"I think putting colors on the tubes will make identification easier for those who are starting to use it ..." (Therapist 6)

Improving the portability of the chair, used to fix the elastic tools, and adaptations for the tools were also proposed, since home training is an option.

"... Because it is a chair that you can't take home. I think about its size, we would have to do something more portable." (Therapist 5)

"I think it has to be a chair that folds, I know that is not easy, but a chair that folds, that I can keep it somewhere, and then open it and have some hooks. I think it's the ideal." (Therapist 5)

"... maybe if the (hooks) were a little bigger they would help too." (Therapist 3)

5. Advantages and disadvantages of different tools

The therapists mentioned different points of view when questioned about the preference for tools used in clinical practice. One of the therapists' notes revealed costs of the tools and the similarity in the perception of physical gains.

"... because when you compare with the elastic band, it is much cheaper. With what you spend to assemble a kit (of tubes), you buy only one Theraband. So, in my opinion, there is no difference in gains comparing both, but cost-benefit, certainly the tube. Because practicality is the same." (Therapist 4)

"I think the main advantage is the cost-benefit, ... the easiness of having the tool for training, it is much easier to have the elastic tools, either the tube or Theraband, more the tube because of the value, more than the weight machine. And when you see the gains, the patient can have the same gains as using the weight machine, elastic tools are more interesting." (Therapist 1)

In another point, the therapists mentioned the greater easiness of weight machines in clinical practice.

"Practicality to work. ..., you put the load and it is ready, finish the set and only change load when changing the point of movement. You do not need to change limbs all the time, add weight, so the practicality of working is much higher." (Therapist 4)

"... using weight machines you do not have to change, you just set the weight on the side and that's it, the patient starts to work. I think so, for the therapist is more tiring, more exhausting. Training using weight machines is much faster than tube or Theraband, .." (Therapist 1)

Another facilitator for the use of weight machines was the time spent per patient and the possibility to attend more patients at a time.

"... with weight machines you can attend four ... with the tube it is impossible." (Therapist 5)
" with tube two per hour, if you need to train three, it will be one hour and a half." (Therapist 1)
"... time is much faster, what we did in an hour using the tube, we do in half hour, 35 minutes using weight machines." (Therapist 3)

6. Concerning about the incidence of injuries with elastic tools

Therapists were concerned about the occurrence of injuries during training.

“... but what happened regarding injury, the patient could not use that load with the tube. ... because we do not know how much this tube offers, whether that was the reason or something else or it was coincidence of the patient using the tube. But the patients that got injured, it was not an injury; at the end of the training it was necessary to decrease the load of the tube and Theraband. I did not see this happening when using weight machines.” (Therapist 2)

7. Patient’s preferences regarding different tools

Therapists were asked about their perception of patients' preferences in the three training sessions (i.e. elastic tubes, elastic bands and weight machine equipment). Most therapists observed greater satisfaction with training using weight machines.

"... the thing about being a machine, thinking that it is more expensive, it looks better, they wanted to use weight machines ...” (Therapist 6)

"... in all three tools we had people who did not like, (...). But in general, the one with most acceptance was the weight machine. The tube, in my opinion, was worse than Theraband. I think because it was colored (theraband), it brings for more attention." (Therapist 4)

"I think there's also the acceptance of the patient, ... in private clinics sometimes they'd accept better a clinic that has weight machines than one with tubes." (Therapist 6)

Another observation was about training time.

"It's a matter of time, everyone using elastic tools complained that the patients using weight machines left a long time before. They (elastic resistance) took about 20 - 25 minutes longer." (Therapist 3)

8. Particularities of the tools

The physiological mechanisms of elastic resistance were highlighted, especially about the concentric phase of the exercise.

"So for me the elastic resistance, with tube and Theraband, they control the eccentric phase a lot better, it works a lot better than using the weight machine, it is my perception." (Therapist 4)

Some aspects about the execution of the movements using different tools were pointed out by the therapists, in this topic there were divergences in the responses obtained.

"I think you have to be a little more attentive when the patient is using the weight machine because of the compensation, I think in the chair (used in the training with elastic tools) they compensate less." (Therapist 2)

"When they were doing it on the chair (elastic components), they did not complete the movement, they did not make the complete movement arc and I think when they were using weight machines, they were doing it better." (Therapist 3)

"I think that with the tube you have to be more attentive than with the weight machine considering the arc of movement." (Therapist 1)

Quantitative analysis

In the quantitative analysis, we found that 50% of the therapists considered the gains observed in the patients the main advantage of the elastic tube. For elastic bands, 33.33% of therapists believe that the main advantage was the gains observed in patients, and 33.33% said that the main advantage is its clinical practicality. For weight machines, the main advantage reported was also the gains observed in the patients (Figure 1).

Regarding the disadvantages of each tool, the therapists pointed out difficulties of applicability for elastic tools (tubes and elastic bands). For weight machines, the main disadvantage reported was the cost-benefit. This information can be seen in Figure 2.

Finally, in the last part of the questionnaire, the therapists were asked to assign a score from 0 to 10 (considering 10 the best score) for each tool, taking into account their experience and general aspects of each instrument. Weight machines received the highest score (8.50 ± 1.04), followed by elastic bands (7.83 ± 0.75) and elastic tubes (7.66 ± 0.81), but there was no statistical difference between the three tools ($p = 0.2987$).

DISCUSSION

In the present study we observed that physiotherapists pointed out different barriers and facilitators in the use of three different tools for resistance training in patients with COPD. Characteristics of the tools, such as costs, portability, handling and practicality, were cited as factors that influence clinical practice. In the quantitative analysis, no differences were observed when comparing the scores of each instrument.

The elastic tools have gained space in rehabilitation protocols because they are portable, have low cost and easy maintenance.[16, 17] These instruments allow a larger range of motion with concentric and eccentric muscle contractions.[17] On the other hand, weight machines are less accessible financially, have higher maintenance costs, and require more physical space, which may limit their use in the patients' house.[18] These characteristics were pointed out by the therapists as important aspects that influence clinical practice. The possibility of home use of elastic tools as an alternative was mentioned as a facilitator, in addition to reduction of costs in clinical practice and the perception that these instruments provide similar gains when compared to weight machines.

Studies have demonstrated similar results when comparing weight machines and elastic tools. Ramos et al.[7] observed similar gains in muscle strength and functional capacity when comparing these tools in patients with COPD. In sedentary middle-aged women, the same changes in body composition were also observed when comparing these two types of resistance training.[16] However, qualitative studies demonstrate that the opinion of patients and therapists concerning these tools are still scarce in the literature.

O´Shea et al.[17] offered resistance training with elastic bands, using a protocol similar to the present study, also in patients with COPD. After the intervention, the patients were invited to participate in a focus group. Patients' perceptions, in certain aspects, corroborate with the findings of the present study. The patients of O´Shea's study[17] also reported the rupture of elastic bands during exercise as a negative aspect, besides considering the exercises boring. These aspects were also mentioned by the therapists in our study as possible barriers for the use of elastic tools.

Another situation highlighted by O´Shea et al.[17] was the perception of load exerted by elastic instruments. Some patients showed higher fatigue and reported high intensity as perception of the exercise performed. Similarly, in the present study, therapists expressed some concerns about the imprecision of the load using these instruments. It is important to note that the quantification of load of elastic tools is not clear in the literature. This is due to the different elongation coefficients of elastic components and their modification during the exercise.[18] When an elastic component is used, the tension promoted will linearly increase from the beginning of the contraction up to the end of the range of motion, providing resistance not only in the vertical plane but also throughout the range of motion.[18, 19]

The particularities of elastic tools inhibit the precise determination of load. However, these same aspects are also responsible for requiring greater muscle activation and use of faster motor units.[19] This finding suggests an urgent need to determine specific equations for each type of elastic band to better explain these aspects.

In the quantitative analysis, greater percentage of the physiotherapists mentioned the gains of the patients as the main advantage for the three tools. For disadvantages, the therapists cited the difficulty of applicability as the main weakness of elastic tools and cost-benefit for weight machines. Despite the characteristics observed, no significant differences were observed for the three tools when considering the scores attributed by the physiotherapists. Based on these results, it is noted that solutions for the implementation of pulmonary rehabilitation are necessary, emphasizing low cost alternatives that can increase the offer of this type of program. Alison et al. demonstrated that exercise training using minimal equipment is effective in improving outcomes of functional exercise capacity and health-related quality of life in COPD.[9] Our study present a possible and viable tool for this purpose.

The present study has contributed importantly to a better understanding of facilitators and barriers of resistance training in patients with COPD. This is the first study demonstrating the physiotherapist view about different resistance training tools. These findings may help other professionals to make decisions that influence their clinical practice and may make the treatment of these patients more effective.

Thus, we conclude that qualitatively gains of the patients was the main advantage for the three tools. For disadvantages, therapists pointed the difficulty of applicability as the main weakness of elastic tools and the cost benefit for weight machines. Despite these particularities, no differences between the tools were reported in general aspects demonstrating that that the three tools analyzed are applicable and feasible in clinical practice of physiotherapists.

Ethical Approval: The present study was approved by the Ethics Committee of São Paulo State University (UNESP) (CAAE: 46065315.7.0000.5402).

Conflict of Interest: The authors declare no conflict of interest.

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Table 1. Interview guide used in the focus group.

Qualitative questions
1. Have you ever found difficulties to use elastic tubes and/or elastic bands in clinical practice? If yes, what difficulties?
2. What are the main disadvantages of elastic tubes and/or elastic bands?
3. Is there any difficulty to use weight machines? If yes, what difficulties?
4. Is there any advantage of using elastic tubes and/or elastic bands? If yes, which ones?
5. Is there any advantage of using weight machines? If yes, which ones?
6. During training, what was your perception of satisfaction of the patients about the tolls used?
7. Taking into consideration only the practicality of each tool (not considering costs or benefits), which tool would you use in clinical practice? Why?
8. Taking into consideration the cost-benefit of each tool, which one would you use in clinical practice?

Table 2 – Quantitative questions

Questions – Quantitative questionnaire
Advantages of each tool
1. Satisfaction of the patient
2. Cost-benefit
3. Clinical practicability
4. Portability
5. Gains for the patient
Disadvantages of each tool
1. Injuries in the patient
2. Difficulties using the tool
3. Dissatisfaction of the patient
4. Low gain for the patient
5. Cost-benefit

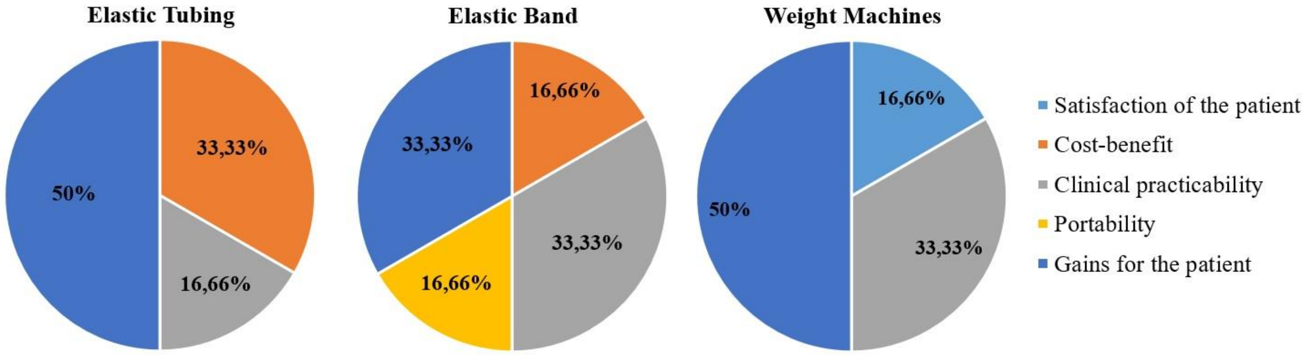

Figure 1 – Quantitative analysis of advantages in each tool used.

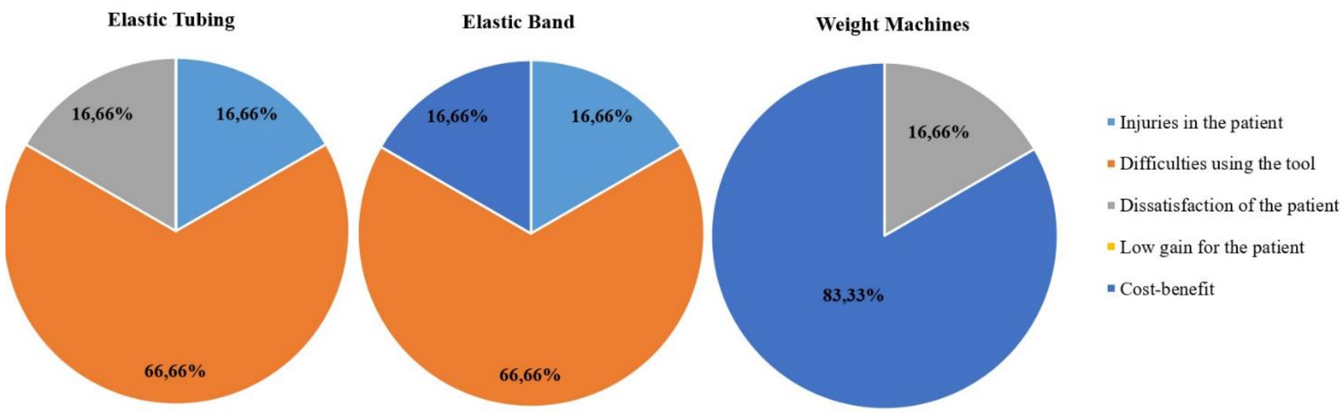

Figure 2 – Quantitative analysis of disadvantages in each tool.

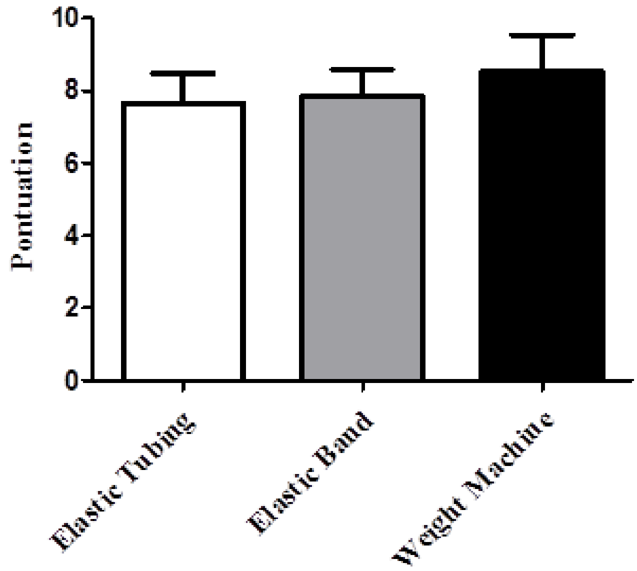

Figure 3 – Scores attributed to each tool by physiotherapists.

Artigo 3

ARTIGO 3

BODY IMAGE IN PATIENTS WITH COPD AND ITS RELATION WITH PHYSICAL ACTIVITY LEVELS, LUNG FUNCTION AND BODY COMPOSITION: AN OBSERVATIONAL STUDY

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ABSTRACT

Background: Body image has been previously defined as the mental figure we have of the measurements, contours, and shape of our body; and the feelings concerning these characteristics. A change in body perception can influence one's feelings of self-worth and further compromise functional abilities. Thus, detection and knowledge of the magnitude of distortions in body image could be important data for clinical evaluation of elderly subjects and patients with chronic diseases such as COPD. **Objectives:** The aim was to assess the body image perception of subjects with COPD. Also, to investigate the association between body image and levels of physical activity in these subjects. **Materials and Methods:** 109 subjects were recruited and divided into a COPD group and elderly subjects without any pulmonary conditions (control group). For this cross sectional study, we performed an initial evaluation and participants were evaluated regarding physical activity level, body image perception (silhouette scale), and determination of body mass index (BMI). Finally, we performed evaluation of lung function (spirometry) and body composition analysis (bioelectrical impedance). **Results:** Both COPD and elderly subjects present alterations in body image, reflecting some level of body dissatisfaction ($p<0,05$). No differences were found when comparing body dissatisfaction between these groups ($p>0.05$). A significant negative correlation ($p<0.05$) was observed between spirometry variables (FVC and FEV_1) and body dissatisfaction only in the control group, reflecting that worse spirometric values are related to greater dissatisfaction with body image. **Conclusion**: No associations between physical activity levels and body image were observed. In conclusion COPD subjects present significant body dissatisfaction, similar to elderly individuals. Furthermore, body image perception in COPD is related to body composition measurements but not to physical activity levels.

KEYWORDS: Body image; Body Composition; Pulmonary Disease, Chronic Obstructive; Exercise, Body fat.

BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) is a progressive and treatable disease with pulmonary and systemic manifestations.[1, 2]The natural course of COPD is complicated by the development of systemic consequences and co-morbidities.[2, 3]For instance, in COPD, skeletal muscle weakness, osteoporosis, and cardiovascular diseases are common.[4-6] Other prevalent manifestations include cachexia, obesity, and psychological impairments.[6-8]

Due to the above conditions, and given the need to make physical changes and lifestyle alterations that result from this chronic condition, the psychological well-being of individuals with COPD can be affected.[9] Additionally, COPD is associated with a high level of psychological distress, such as symptoms of depression, loss of confidence, and isolation that can directly impact on quality of life and even adherence to rehabilitation and exercise programs.[6, 10, 11] Furthermore, COPD subjects must cope with alterations in their health status which may lead to body image disturbance.[9]

Body image has been previously defined as the mental figure we have of the measurements, contours, and shape of our body; and the feelings concerning these characteristics.[12] The component of body image refers to the satisfaction of a subject with their body and has been considered an internal representation of a complex mechanism of personal identity related to body shape, weight, size, or other characteristics related to physical appearance.[12, 13]

A change in body perception can influence one's feelings of self-worth and further compromise functional abilities.[9] Moreover, quality of life may be inextricably related to an individual's view of their own body. [9, 13,14]. Thus, detection and knowledge of the magnitude of distortions in body image could be important data for clinical evaluation of subjects with chronic diseases such as COPD.

Furthermore, some studies indicate that levels of body image satisfaction may be related to physical activity levels in other population.[15, 16] This makes this assessment even more attractive for individuals with COPD, taking into account the relevance of physical exercise to health status of these individuals.[17] Therefore, it is important to understand whether levels of physical activity are associated with body image perception in COPD and if exercise may positively influence this variable, providing valuable information to health care professionals involved in rehabilitation programs.

So far, only one study has addressed body image perceptions in COPD, although related only to cachexia analysis[9] and these kinds of observations in other chronic conditions are very recent and scarce.[18-20]

Thus, considering these facts and the several co-morbidities and manifestations presented by subjects with COPD, it may be valuable to know if these subjects present alterations in body image and if body image can be associated with the level of physical activity in these individuals. Additionally, there is no evidence regarding associations between body image and lung function and body composition in subjects with COPD. This knowledge may be a valuable information to provide a more informative and complete evaluation in these individuals.

The aim of the present study was to assess body image perception of subjects with COPD and compare this with individuals without pulmonary conditions. Furthermore, to investigate the relation between body image and levels of physical activity, lung function and body composition in these subjects.

METHODS

Ethical Aspects

Individuals were informed about the aims and procedures of the study and, upon acceptance, provided an informed consent form. The present study was approved by the institutional review board (CAAE: 46065315.7.0000.5402).

Participants

109 subjects were recruited for this study and divided into a COPD group and elderly subjects without any pulmonary conditions (control group). Participants with COPD were recruited from medical offices and a physiotherapy rehabilitation centre, while participants without pulmonary conditions were invited to participate in the study through local media and telephone invites.

For the COPD group, subjects were included if they had a primary diagnosis of COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD I to IV),[1] and presented clinical stability (without exacerbations or changes in medication for at least 30 days). For the control group, we included individuals with no alterations in lung function according to spirometry.

For both groups participants were only included if they were aged 55 years or more, had not smoked in the previous year, and did not present any condition or disease limiting exercise performance. Subjects were excluded from the analyses if they withdrew consent or did not complete any of the evaluations during the period of the study.

Sample size calculation was carried out based on the study of Laus et al.[21], considering body mass index as the primary outcome. With a standard deviation of 3.5, a difference of 2.5 kg/m^2 with 5% significance, and 80% test power for two-tailed hypothesis, the sample calculation resulted in 35 individuals for each group, totaling 70 individuals for the sample.

Study design

For this cross sectional study, first we performed an initial evaluation consisting of medical history with investigation of pre-existing comorbidities and educational level. Next participants were evaluated regarding physical activity level, body image perception, and determination of body mass index (BMI). Finally, we performed evaluation of lung function (spirometry) and body composition analysis (bioelectrical impedance). A detailed description of the assessments is provided below.

Physical activity level

According to well established methods, the Baecke's questionnaire was used to determine physical activity level. This questionnaire has been previously validated and includes 16 questions covering three scores regarding activity in the previous 12 months: 1) occupational physical activities; 2) physical exercises in leisure; and 3) leisure and locomotion physical activities. The questionnaire also provides a total score [22].

Body image

As described in the literature, the Brazilian version of the silhouette scale was validated previously by Kakeshita et al.[23] and the adult scale was used in the present study. The scale consists of a set of fifteen contour drawings of man and woman presented on cards showing escalating measures, from leaner to wider drawings of silhouettes. The cards represent mean BMIs ranging from 12.5 to 47.5 kg/m^2 and a weight range of 34.03 kg to 144.52 kg, which evaluate body image dissatisfaction. The silhouette scale is a very effective instrument to evaluate the degree of dissatisfaction with body dimensions in the evaluation of the perceptual component of body image.[24, 25]

The method applied consisted of asking the participants to choose one card from the set of cards displayed in ascending order, which would best represent their own body contour at that time, denominated as "Perceived BMI" and "Perceived weight". Then, participants were asked to point out the silhouette with their desired body contour, denominated as "Desired BMI" and "Desired weight". Body dissatisfaction is represented as the difference between perceived and desired BMI and weight. Results are given as a continuous variable, being that the closer to zero, the lower the dissatisfaction. We also calculated the discrepancy between the Perceived and Desired BMI and weight and the real BMI measured by anthropometry.

Body Mass Index

According to well-established methods, BMI consists as the ratio of weight (kg) to height (m) squared. To the determination of weight, we used an electronic and previously calibrated scale (Kratos-Cas, Brazil) with participants wearing light clothes, barefoot, and carrying no heavy objects. Height was determined using a portable anthropometer (Kratos-Cas, Brazil, adjusting with accuracy participant posture before reading the fixed marker.(23)

Lung function

Lung function assessment were determined for all participants at baseline through spirometry and performed according to the guidelines of the American Thoracic Society (ATS) and European Respiratory Society (ERS),[26] using a spirometer (Spirobank-MIR, Italy,). The reference values considered for this study were specific for the Brazilian population. [27]

Body composition analysis

As described previously (26), Fat mass (FM), visceral fat area (VFA), and fat-free mass (FFM) were measured to characterize the sample with an octopolar bioimpedance InBody 720 (Biospace, Seoul, Korea). This technology employs eight contact electrodes (two are positioned on the palm and thumb of each hand and the other two on the front part of the feet and on the heels).[28]

Statistical methods

Graphpad Prism software was used for statistical analysis. Initially, the Shapiro Wilk test was performed to determine data distribution. For the comparison between the COPD group and Control group, the Student t test or Mann Witney test were used according to data distribution. For correlation analysis, Spearman or Pearson analyses were applied, also according data distribution. Data are expressed as mean and standard deviation or median and interquartile range according to data distribution. The level of significance was set as 5%.

RESULTS

109 subjects were assessed for eligibility and after 17 exclusions, 44 (28 males) subjects were included in the COPD group and 48 (13 males) in the Control group. (Figure 1)

In the comparisons of the groups, COPD and control subjects were similar regarding age, weight, BMI, and body composition variables. As expected, COPD subjects presented significantly lower values in all spirometry variables ($p<0.05$), with the exception of Forced Vital Capacity (FVC). (Table 1)

Regarding body image analysis, the comparison in each group showed alterations in body image perception in the COPD and Control groups (Figure 2). Both groups desired significantly lower BMI and weight measures, according to the silhouette scale, demonstrating body dissatisfaction. We also performed a sub analysis comparing de level of dissatisfaction of body image between obese and eutrophic subjects, according to body mass index in both groups. These analyses showed that obese subjects presented a significant higher dissatisfaction with body image than eutrophic subjects in both groups. These findings can be observed in Figure 3. (Figure 3)

The comparison of body dissatisfaction between groups (COPD x Control) was performed through absolute variation (Δ) and showed no significant differences. The COPD and Control groups presented similar alterations in body image. These results can be observed in Table 2. (Table 2)

In the correlation analysis we analysed the association between body dissatisfaction and pulmonary function, physical activity level, and body composition. A significant negative correlation ($p<0.05$) was observed between spirometry variables (FVC and FEV_1) and body dissatisfaction only in the control group, reflecting that worse spirometric values are related to greater dissatisfaction with body image. No associations between physical activity levels and body image were observed. (Table 3)

All measures of body composition were positively correlated with the level of body dissatisfaction in both groups, demonstrating that higher fat levels are related to greater dissatisfaction with body image. The correlations were considered moderate and range from r=0.53 to r=0.75 all with statistical significance (p<0.0001)

DISCUSSION

The main findings of the study showed that both COPD and elderly subjects with no pulmonary alterations present alterations in body image, reflecting some level of body dissatisfaction. However, no differences were found when comparing body dissatisfaction between these groups. We also observed that fat levels are associated with levels of body image perception in both groups; however, associations between body image and pulmonary function were only observed in control group. Additionally, sub analysis showed that obese subjects presented significant higher levels of body image dissatisfaction.

The fact that the images pointed out as desirable were predominantly in smaller BMI and weight ranges in relation to those indicated as the perceived images suggest dissatisfaction with body image, in the sense that both men and women value models of thinness. Body image is an important component of the complex mechanism of personal identity and can be influenced by multifactorial components such as biological, perceptual, cognitive, cultural, and social components. [21] Therefore, the dissatisfaction observed in both groups in this study may be related to different aspects.

First, we know that overweight and obesity have become widespread phenomena whose prevalence is increasing worldwide.[29] The subjects in this study were predominantly overweight or obese (57% in the COPD group and 72% in the Control group) and the correlation analysis showed that individuals with higher fat tissue levels indicated greater body dissatisfaction. Our results also showed that obese subjects, regardless pulmonary condition, presented a higher level of body image dissatisfaction. Condello et al. [15] showed a prevalence of dissatisfaction in overweight and obese adults. Our results are supported by previous studies[21, 30] and present important clinical relevance since they suggest that the analysis of body image perception can play an important role in nutritional supervision.[21]

Considering the social aspect, previous studies have already shown the implications of the "ideal of beauty prescribed by society" and the role played by the media in creating and exacerbating the phenomenon of body dissatisfaction. Television, the internet, and other media represent an important influences in contemporary society and can potentially influence adult stereotypes and body image perception. [31, 32]

Although research on body image in the literature has mainly focused on adolescents and subjects with eating disorders, increasing recognition of the psychosocial problems associated with body disturbance demonstrates the importance to understand the factors influencing body image. This information is still very scarce for COPD subjects.

To our knowledge only one study evaluated body image and COPD subjects, in 1992. Despite being focused on cachexia and using different methods, the results of Byers et al also showed that subjects with COPD present modifications in body image perception related to cachexia. In addition, the authors demonstrated that body dissatisfaction was not related to gender, corroborating with our study.[9]

Our results showed no significant differences in the comparison of body image perception between COPD and elderly subjects. Thus, we could hypothesize that body dissatisfaction may be more strongly related to age than to the disease itself. Previous studies suggest that alterations related to skin flaccidity, loss of brightness and color of hair, and increase in weight, are probable reasons for dissatisfaction and concern with body image among the elderly.[33] In addition, alterations in body image in these individuals may be related to the non-acceptance of the process of functional decline of the organism and to the impossibility of reversal of the aging process.[33, 34]

The significant correlations observed between body image and body composition characteristics (body fat mass, % body fat, and visceral fat area) suggest that the analysis of body image perception could even play an important role in nutritional surveillance, becoming a useful tool in clinical practice through the use of the silhouette scale. This scale is considered to represent a simple, reliable, and fast method of application.[12, 23] Similar results were also found in the study of Laus et al,[21] although the correlations detected by the author used anthropometric measures such as weight and BMI. Our study included more specific and direct measurements of fat tissue as we used an advanced method to analyze body composition (octapolar bioimpedance).

In the present study, we did not observe a direct correlation between physical activity levels and body image perception. We expected to find these associations since it is known that exercise is more often performed for appearance-related reasons and this relation has previously been observed in the elderly population.[15, 16] We believe that more direct measurements of physical activity level such as pedometers or accelerometry would probably be more appropriate than assessment using questionnaires. Previous studies also failed to show this correlation using different questionnaires such as the IPAQ.[21]

The results of this study are clinically relevant since a significant body of data in the literature verified the negative distress caused by body image disturbance, as well as its association with depression symptoms, low self-esteem, and an increased risk of suicide.[35] Meneze et al., showed that it is necessary to identify the reason why elderly people are dissatisfied with their body image, so that it is possible to establish strategies that provide adequate nutritional status, thus generating satisfaction with body image.[33]

Advancements in this area contribute to clinical and nutritional evaluation, prevention of obesity, and consequent improvement in the general incidence of chronic diseases, such as COPD, known to be associated with nutritional status. The use of this instrument at the outpatient level could be effective as an additional tool in the clinical evaluation of people seeking care from health professionals regarding the question of body weight.

It is important to consider that the control group in our study presented significantly more females; these results may influence our results. Although previous studies showed no differences between gender and body satisfaction in adolescents , [21] more studies approaching these results in COPD are still needed.

To our knowledge, the present study is the first to show body image through the silhouette scale contributing greatly to COPD evaluation. Nevertheless, it is not without limitations. First, although a sample size calculation was performed, a larger sample would reflect a stronger experimental design. In addition, the lack of a direct measurement of physical activity level may be considered a limitation and is suggested for future studies.

CONCLUSIONS

COPD subjects present significant body dissatisfaction, this level is similar to elderly individuals. Furthermore, body image perception is related to body composition measurements but not to physical activity levels.

DISCLOSURE OF INTEREST

The authors report no conflict of interest.

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Table 1 – Comparison of demographic characteristics, pulmonary function, physical activity levels, and body composition between COPD and Control groups. Data expressed as mean and standard deviation.

	COPD Group (n=44)	**Control Group (n=48)**	**p-value**
Demographic characteristics			
Gender (Male/Female)	28/16	13/35	0.004*
Age (years)	70.23±10.4	70.1±5.63	0.63
Weight (Kg)	67.45±13.38	68.57±12.72	0.68
Height (meters)	1.62±0.09	1.57±0.08	<0.01*
BMI (Kg/m^2)	26±5.5	27.52±4.69	0.16
Pulmonary function			
FVC (liters)	2.55±0.73	2.86±0.77	0.06
FVC (% predicted)	71.86±13.81	94.74±13.52	<0.01*
FEV_1(liters)	1.31±0.5	2.33±0.61	<0.01*
FEV_1(% predicted)	47.66±14.66	98.85±13.82	<0.01*
FEV_1/FVC	51.51±11.51	81.93±6.38	<0.01*
Physical activity level			
Baecke score	6.58±1.27	7.58±1.41	<0.01*
Body composition			
Body fat mass (Kg)	24.40±11.94	26.57±9.11	0.25
% Body fat	34.35±13.06	38.08±8.22	0.10
Visceral fat area (cm)	106.1±49.32	109.8±31.88	0.45

*BMI: Body Mass Index; FVC: Forced Vital Capacity; FEV_1: Forced expiratory volume in the first second; Kg:kilos; cm: centimeters *: statistical significance $p<0.05$.*

Table 2 –Comparisons of body dissatisfaction (absolute variation) between groups. Data expressed as median, interquartile range 25-75%, and 95% confidence intervals.

	COPD Group (n=44)		**Control Group (n=48)**	
	Median [IQ Range]	95%CI	Median [IQ Range]	95%CI
Δ Perceived and Desired BMI	2.5 [-2.5-11.88]	1.93-7.95	5 [0-10]	3.93-7.52
Δ Perceived and Desired Weight	7.4 [-6.81-34.54]	5.46-22.65	13.61 [0-29.58]	10.58-20.81
Δ Perceived and Real BMI	1.52 [-3.81-5.77]	-2.68-3.23	-0.17 [-2.84-5.45]	-1.2-2.42
Δ Perceived and Real Weight	0.3 [-16.39-12.39]	-8.0-6.23	-9.5[-17.84-4.56]	-11.9-(-0.6)

COPD: Chronic Obstructive Pulmonary disease; BMI: Body Mass Index; IQ: interquartile range; CI: confidence intervals.

Table 3 – Correlation analysis between body dissatisfaction (Perceived and Desired BMI and Perceived and Desired Weight)

	COPD Group (n=44)				Control Group (n=48)			
	Δ BMI		Δ Weight		Δ BMI		Δ Weight	
	r	p	r	p	r	p	r	P
Gender								
Male/Female	-0.06	0.66	-0.06	0.70	-0.26	0.06	-0.23	0.10
Pulmonary function								
FVC	0.001	0.99	0.02	0.88	-0.38	0.0076*	-0.38	0.007*
FVC (% predicted)	-0.06	0.66	-0.05	0.71	-0.25	0.08	-0.26	0.06
FEV_1	0.20	0.1739	0.20	0.165	-0.29	0.0453*	-0.30	0.0386*
FEV1 (% predicted)	0.21	0.16	0.21	0.15	-0.23	0.10	-0.26	0.07
FEV_1/FVC	0.26	0.07	0.27	0.06	0.23	0.11	0.22	0.12
COPD Severity (GOLD)	0.06	0.70	0.06	0.70	-	-	-	-
Physical activity level								
Baecke score	0.14	0.32	0.15	0.30	-0.24	0.09	-0.23	0.10
Body composition								
Body fat mass (Kg)	0.75	<0.0001*	0.74	<0.0001*	0.63	<0.0001*	0.63	<0.0001*
% Body fat	0.56	<0.0001*	0.54	0.0001*	0.61	<0.0001*	0.61	<0.0001*
Visceral fat area (cm)	0.68	<0.0001*	0.66	<0.0001*	0.53	<0.0001*	0.53	<0.0001*

*FVC: Forced Vital Capacity; FEV_1: Forced expiratory volume in the first second; *: statistical significance $p<0.05$.*

Figure 1 – Flowchart of the study.

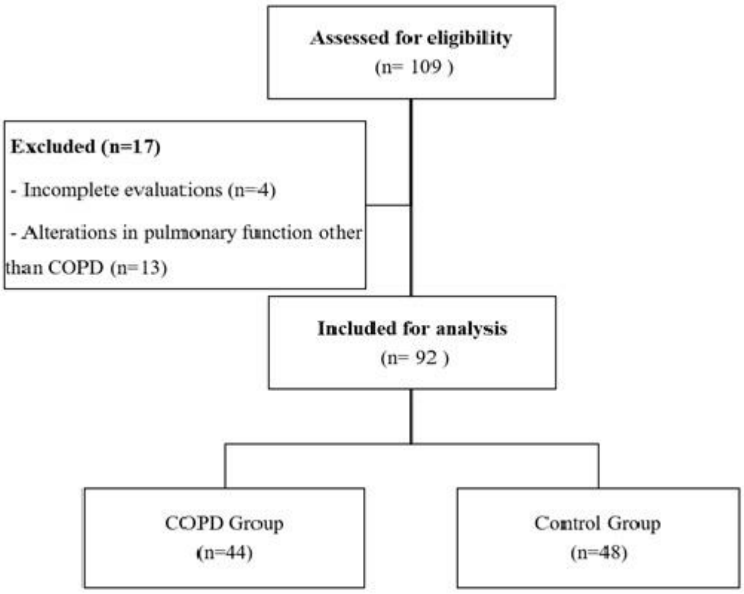
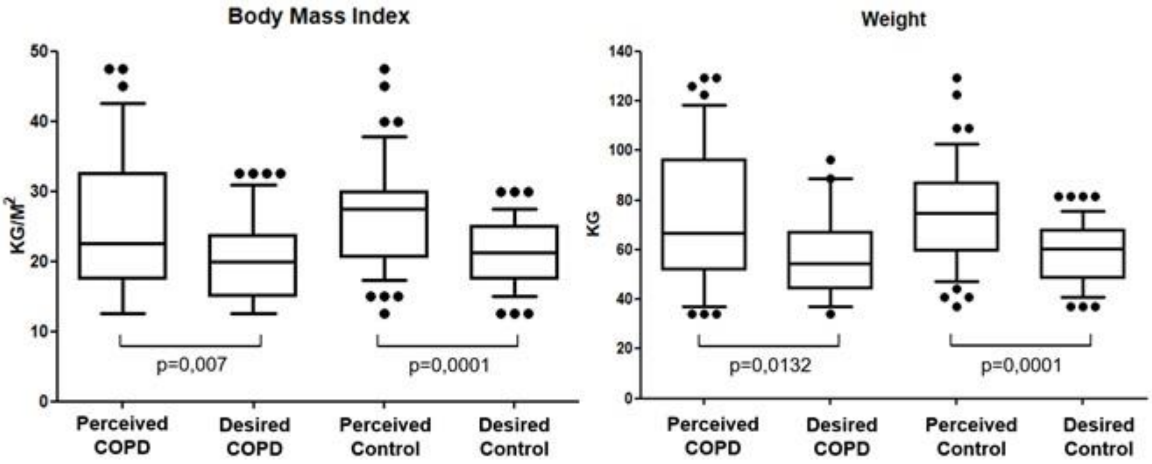
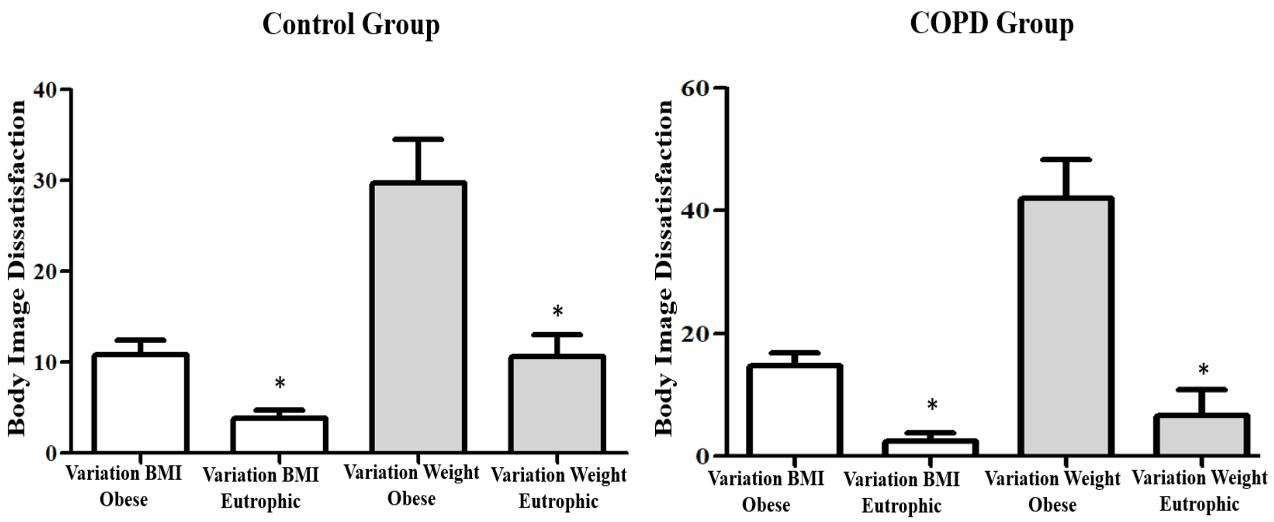


Figure 2 – Comparison of the silhouette scale in each group.



Boxplot expressed as median and 10-90 percentiles.

Figure 3 – Variation between perceived and desired BMI and weight through silhouette scale comparing obese and eutrophic subjects in both groups.



*: statistiscal significance: $p<0.05$

Conclusões finais

CONCLUSÕES FINAIS

Com base nos achados dos três estudos apresentados nesta tese foi possível aprofundar os conhecimentos em diferentes aspectos de treinamento resistido em indivíduos DPOC. Possibilitou-se ampliar achados sobre aspectos funcionais e qualitativos do treinamento resistido nestes indivíduos, além da investigação de comprometimentos ainda pouco conhecidos nesta população, como a insatisfação com a imagem corporal.

Pode-se observar em relação aos aspectos funcionais, que após o treinamento resistido com diferentes ferramentas o ganho de força muscular foi semelhante, demonstrando que tanto materiais elásticos quanto equipamentos de musculação podem ser utilizados na prática clínica de fisioterapeutas que supervisionam treinamento resistido destes pacientes. Já para os desfechos secundários avaliados, como capacidade funcional, impacto da doença no status de saúde, composição corporal e nível de atividade física não foram identificadas mudanças nestes desfechos após um período de 12 semanas de treinamento.

Estes achados demonstram que as ferramentas com materiais elásticos podem facilitar a disseminação deste tipo de treinamento, devido ao seu baixo custo, portabilidade e necessidade de pouco espaço físico.

A presente tese também abordou achados importantes em relação a percepção de terapeutas sobre as diferenças no uso de tubos, bandas elásticas e equipamentos de musculação. Identificou-se que terapeutas apontaram pontos importantes que devem ser considerados no momento de escolha do tipo de ferramenta que será utilizada no treinamento resistido de indivíduos com DPOC, como custos, portabilidade e facilidades na aplicabilidade clínica.

Além disso, fisioterapeutas tem a percepção que tanto componentes elásticos como equipamentos de musculação promovem ganhos funcionais importantes em indivíduos com DPOC. Ainda de acordo com a percepção dos terapeutas, não há diferenças nos aspectos de satisfação na utilização de componentes elásticos e equipamentos de musculação, demonstrando que tubos, bandas e equipamentos de musculação são aplicáveis na prática clínica fisioterapêutica.

Por fim, a presente tese também permitiu uma análise mais profunda sobre comprometimentos de autoestima em indivíduos com DPOC. Foi possível identificar que estes pacientes apresentam uma insatisfação significativa com sua própria imagem corporal, demonstrando que este tipo de avaliação deve ser incluída na prática clínica de profissionais envolvidos em programas de reabilitação pulmonar. Além disso, a imagem corporal mostrou associações significativas com os índices de composição corporal, mas não foi possível estabelecer esta relação com os níveis de atividade física destes indivíduos.

A soma dos achados da presente tese é de importante relevância para embasar e aperfeiçoar a prática clínica de profissionais envolvidos na reabilitação pulmonar de pacientes com DPOC. Foi possível desenvolver e aprofundar conhecimentos em aspectos funcionais, qualitativos e aprimorar os itens de avaliação, como a imagem corporal, destes indivíduos.

____Atividades desenvolvidas no período do Doutorado

ATIVIDADES DESENVOLVIDAS NO PERÍODO DO DOUTORADO

Artigos publicados no período de doutorado

1. FREIRE AP, ELKINS M, RAMOS EMC, MOSELEY A. Use of 95% confidence intervals in the reporting of between-group differences in randomized controlled trials: analysis of a representative sample of 200 physical therapy trials. Braz J Phys Ther. 2018. (Qualis A2, FI:1,69)

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___Produção científica resultante de internacionalização

PRODUÇÃO CIENTÍFICA RESULTANTE DE INTERNACIONALIZAÇÃO

Use of 95% confidence intervals in the reporting of between-group differences in randomized controlled trials: Analysis of a representative sample of 200 physical therapy trials

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ORIGINAL RESEARCH

Use of 95% confidence intervals in the reporting of between-group differences in randomized controlled trials: analysis of a representative sample of 200 physical therapy trials[☆]

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KEYWORDS
Confidence interval;
Clinical trials as topic;
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Abstract
Objectives: To assess the prevalence of the use of 95% confidence intervals in the reporting of between-group differences in randomized controlled trials of physical therapy interventions and to determine if the prevalence is changing over time.
Methods: Observational study, including an analysis of 200 trials from the Physiotherapy Evidence Database: 50 from each of the years 1986, 1996, 2006, and 2016. The primary outcome used was the prevalence of the between-group difference presented with 95% confidence intervals. We also extracted trial characteristics for descriptive purposes (i.e., number of participants, number of sites involved in recruitment, country(ies) of data collection, funding, subdiscipline of physical therapy, publication language and total Physiotherapy Evidence Database score).
Results: Most commonly, the trials were published in English (89%) and classified in the musculoskeletal subdiscipline (23%). The overall prevalence of use of confidence intervals was 29% and there was a consistent increase in reporting between 1986 and 2016, with peak usage in the 2016 cohort (42%). Confidence intervals were more likely to be used in trials that had received funding, were conducted in Europe and Oceania, and in trials with a Physiotherapy Evidence Database score of at least 6/10.

☆ Study was performed at The University of Sydney, School of Public Health, Musculoskeletal Health Sydney.

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Conclusions: Most trials of physical therapy interventions do not report confidence intervals around between-group differences. However, use of confidence intervals is increasing steadily, especially among high-quality trials. Physical therapists must understand confidence intervals so that they can understand a growing number of trials in physical therapy.

Introduction

Clinicians worldwide are implementing a transition to evidence-based practice. One of the main components of evidence-based practice involves clinicians interpreting and critically appraising the evidence for its validity and applicability.[1] When considering whether to use an intervention with a patient, clinicians are encouraged to identify high-quality clinical research (systematic reviews and randomized controlled trials) and to consider its estimate of the size of the treatment effect of the intervention.[1,2]

One of the most common statistical approaches used to detect the effect of interventions involves significance testing.[3] Traditionally, *p*-values are used to interpret the result of significance testing. In general terms, the *p*-value summarizes the compatibility between the observed data and what we would expect to see if all the assumptions used to compute the *p*-value were correct.[4] In the context of testing a between-group difference in a randomized controlled trial, one assumption is the null hypothesis, i.e., the assumption that the study treatment makes no difference to the average outcome. However, there are other assumptions made in calculating *p*-value, such as assumptions about how the data were distributed and how the analysis was conducted. Many people misinterpret the *p*-value as only testing the null hypothesis assumption, but in fact it tests all the assumptions. In a between-group comparison in a trial, the difference between the observed data and what we would expect to see based on all the assumptions is calculated as a *t*-statistic or a Chi-squared statistic. The *p*-value is then the probability that that difference would have been at least as large as its observed value if every model assumption (including the null hypothesis) were true.[4] The *p*-value can be viewed as a measure of how well the observed data fit with the assumptions made, ranging from 0 for poor fit to 1 for perfect fit. Usually, however, the *p*-value is dichotomised into significant or not, based on the 0.05 threshold.

Even when *p*-values are interpreted correctly, they do not portray some crucial information about the magnitude or the clinical relevance of the difference between the groups.[5,6] Thus, a statistically significant finding should not be interpreted on its own to influence clinical practice.[6,7] The *p*-value also provides no information about the uncertainty around the trial's estimate of the effect of the intervention. All such estimates are associated with uncertainty, even if trials are well designed and conducted, because the observed difference is only an estimate of the true effect of treatment derived from the sample of participants in the trial.[8,9]

Confidence intervals have been proposed as an alternative to significance testing reported using *p*-values.[6,10,11] When reporting a trial's estimate of the effect of an intervention, a confidence interval describes the uncertainty around that estimate by defining two values, one on either side of the estimate. Most often the 95% confidence interval is used, meaning that 95% of the time, the true average effect of the intervention (i.e., the effect that the trial is trying to estimate) will fall within the interval between those two numbers. Therefore, the 95% confidence interval is the interval within which we can be 95% confident that the true average effect of the intervention actually lies.[8,9,12,13] Confidence intervals indicate the precision of the estimate. This provides researchers and clinicians with a much more informative view of how much of an effect an intervention had, compared with only observing if there was statistical significance via a *p*-value.[6,7,13]

Many journals[6–11] and reporting guidelines[14–16] have been recommending the use of confidence intervals since as early as 1986. However, only a few studies have investigated how commonly authors report this measure; with 54% in public health trials, and 86% in epidemiology reporting confidence intervals.[17,18] These studies, however, focused on high prestige journals, which may be unrepresentative of journals generally. As a result, the current prevalence of use of confidence intervals and whether the prevalence is changing over time are still unknown. Rigorous evaluation of how between-group differences are reported in a representative sample of trials is required to determine if reporting guidelines and journal editorial policies have been sufficient to shift reporting from *p*-values to treatment effect estimates. The representative sample of trials is also important to assess whether the usage of confidence intervals is increasing over time, because it is plausible that the stance taken by the high prestige journals could gradually filter down to lower prestige journals. This information could be used to promote the uptake of reporting of confidence intervals, which will ultimately assist clinicians to make more-informed decisions in their clinical practice.

One field in which a representative sample of trials can be obtained is physical therapy, because the Physiotherapy Evidence Database (PEDro; www.pedro.org.au) comprehensively indexes trials regardless of the publishing journal.[19,20] Therefore, the first aim of this study was to assess the prevalence of the use of 95% confidence intervals in the reporting of between-group differences in reports of randomized controlled trials of physical therapy

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interventions. The second aim was to determine if the prevalence is changing over time.

Methods

Design

We extracted a random sample of 200 published articles reporting randomized controlled trials: 50 from each of the years 1986, 1996, 2006, and 2016 to form representative samples at regular time points for analysis of change over time. The sample size of 200 was chosen because it gives overall estimates of prevalence that have confidence limits of ±7% or smaller, which we consider to be sufficiently precise estimates to characterize the use of 95% confidence intervals. Random sampling was performed using Microsoft Excel software (Microsoft Office 2007, Microsoft Corporation, Redmond, Washington). The trials were selected from the February 6, 2017 update of PEDro. PEDro was used because it is one of the most complete indexes of trials for an entire profession,[19,20] plus all trials are evaluated for methodological quality and completeness of statistical reporting using the PEDro scale.[21,22]

Eligibility

Because trials were selected from the PEDro database, the eligibility criteria used for indexing trials on that database were by default applied to our cohort of trials. Briefly, the trials must be published in peer reviewed journals and use (quasi-)random allocation to estimate the effects of interventions that are (or could be) part of physical therapy practice in patients.[23] In addition, we included articles that presented a trial's primary analysis, with no restriction by language of publication or area of physical therapy practice. Pilot studies and articles presenting secondary analyses were excluded. Full-text copies of the published articles were acquired and, if cited in the article, any online supplementary material was also obtained.

The small proportion of articles in each of the target years that failed to include a between-group statistical comparison were excluded based on the score for Item 10 of the PEDro scale, prior to random selection of the 50 trials from each year. Also excluded were articles that were still in the process of being indexed on PEDro (i.e., those without complete indexing terms and PEDro scale evaluation).

Data extraction

Bibliometric data, language of publication, subdiscipline of physical therapy (cardiothoracic, continence and women's health, ergonomic and occupational health, gerontology, musculoskeletal, neurology, oncology, orthopaedics, paediatrics, sports, and other), and PEDro scale were downloaded from PEDro. In cases where the trial was classified in more than one subdiscipline, one of the investigators selected the single most relevant subdiscipline for the trial. For the PEDro scale, all trials are double-rated by trained staff/volunteers and any disagreements are arbitrated by a third rater. The PEDro scale has good reliability and validity.[21,22]

Reporting of confidence intervals was extracted from the included trials. Trials were coded as 'yes' if 95% confidence intervals were reported for at least one between-group difference for one outcome. Confidence intervals for other types of analysis (e.g., baseline characteristics, within-group comparisons) were not considered. We also extracted the types of outcomes presented, coded as continuous, dichotomous, or both, and if the trial reported a primary outcome (i.e., the terms *primary*, *principal*, *main* or *key* were used when specifying the outcome). In trials that had more than one primary outcome, we also recorded whether there was any adjustment for multiple comparisons (including Bonferroni, sharpened Bonferroni, Dunn). We also extracted the number of participants, reporting of a sample size calculation, number of sites involved in recruitment, country(ies) where the study was conducted, and if the study was funded. We accepted only funding for the trial, not funding for authors. If funding was not specified, the item was rated as unclear. Two independent reviewers extracted these data, with any disagreements resolved by discussion. When trials were published in languages other than English, two bilingual colleagues for each language extracted the data and resolved disagreements by discussion.

The primary outcome used in our analysis was the reporting of the between-group differences (PEDro item 10) presented with 95% confidence intervals. The trial characteristics used for descriptive purposes were: number of participants, number of sites involved in recruitment (single-centre vs multi-centre), country(ies) of data collection (which were collapsed into continent of data collection), funding, number of primary outcomes, subdiscipline of physical therapy, and total PEDro score (raw score or dichotomized as $\leq$5 and >5).

Data analysis

Trial characteristics and prevalence of the use of confidence intervals were summarized with descriptive statistics. The prevalence of the use of confidence intervals was presented graphically, with stratification by trial characteristics. These characteristics were funding, single/multi-centre, continent, subdiscipline and total PEDro score. These analyses were presented first separately and also for the 200 trials pooled, with weighting applied for the total number of trials published each year.

Each year, a greater number of trials evaluating physical therapy interventions are published than in the preceding year. By sampling 50 trials from each of the four nominated years (1986, 1996, 2006, 2016), we were able to generate representative samples at regular time intervals to examine changes over time. However, analysis of the characteristics of the four cohorts pooled would not be representative of the body of trials of physical therapy interventions because it would over-represent the earlier years. Therefore, we calculated a weighting factor for each publication year, calculated as the total number of trials indexed on PEDro with that publication year divided by the number of trials in that year's sample (i.e., 50). For any pooled analysis,

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Table 1 Summary characteristics extracted from the published reports of the 50 trials randomly selected from 1986, 1996, 2006 and 2016.

Extracted data	1986	1996	2006	2016
Language, n (%)				
English	48 (96)	47 (94)	34 (68)	48 (96)
Others	2 (4)	3 (6)	16 (32)	2 (4)
Subdiscipline, n (%)				
Cardiothoracic	5 (10)	10 (20)	5 (10)	4 (8)
Continence and women's health	8 (16)	5 (10)	7 (14)	7 (14)
Ergonomics and occupational health	0 (0)	3 (6)	0 (0)	2 (4)
Gerontology	1 (2)	7 (14)	6 (12)	1 (4)
Musculoskeletal	15 (30)	5 (10)	12 (24)	13 (26)
Neurology	3 (6)	6 (12)	6 (12)	3 (6)
Oncology	0 (0)	0 (0)	0 (0)	1 (2)
Orthopaedics	3 (6)	2 (4)	2 (4)	6 (12)
Paediatrics	7(14)	6(12)	4 (8)	2 (4)
Sports	0 (0)	4 (8)	4 (8)	6 (12)
Other	8 (16)	2 (4)	4 (8)	5 (10)
Total PEDro score (0–10)				
Median [IQR]	4 [3; 5]	4 [4; 6]	5 [4; 6]	6 [5; 7]*
Randomized participants, median [IQR]	50 [26; 93]	59 [39; 118]	82 [57; 147]	81 [39; 123]
Sample size calculation presented, n yes (%)	1 (2)	7 (14)	13 (26)	32 (64)
Sample size calculated, median [IQR]	40 [40; 40]	104 [36; 200]	120 [69; 179]	89 [48; 173]
Multicenter recruitment, n (%)				
No	26 (52)	20 (40)	28 (56)	25 (50)
Yes	2 (4)	8 (16)	15 (30)	19 (38)
Not specified	22 (44)	22 (44)	7 (14)	6 (12)
Sites involved if multicenter, median [IQR]	20 [17; 22]	14 [3; 52]	7 [4; 17]	3 [2; 8]
Continent, n (%)				
Asia	1 (2)	3 (6)	21 (42)	15 (30)
Europe	27 (54)	20 (40)	12 (24)	17 (34)
North America	19 (38)	24 (48)	14 (28)	9 (18)
South America	1 (2)	0 (0)	0 (0)	2 (4)
Oceania	2 (4)	3 (6)	3 (6)	7 (14)
Funding, n (%)				
Yes	19 (38)	30 (60)	18 (36)	29 (58)
No	27 (54)	18 (36)	30 (60)	17 (34)
Unclear	4 (8)	2 (4)	2 (4)	4 (8)
Primary outcome identified, n (%)	4 (8)	11 (22)	22 (44)	33 (66)
Number of primary outcomes, median [IQR]	4 [1; 9]	2 [1; 7]	1 [1; 2]	1 [1; 2]
Adjustment for multiple primary outcomes, n (%)				
Yes	1 (2)	1 (2)	2 (4)	3 (6)
No	3 (6)	5 (10)	14 (28)	12 (24)
Not applicable	46 (92)	44 (88)	34 (68)	35 (70)
Types of outcomes presented in the trial, n (%)				
Continuous	21 (42)	29 (58)	22 (44)	31 (62)
Dichotomous	2 (4)	0 (0)	8 (16)	1 (2)
Both	27 (54)	21 (42)	20 (40)	18 (36)

IQR, interquartile range.
* Statistical significance between 2016 and each of the other three years (1986, 1996 and 2006), with a one-way ANOVA with Dunn's multiple comparison correction.

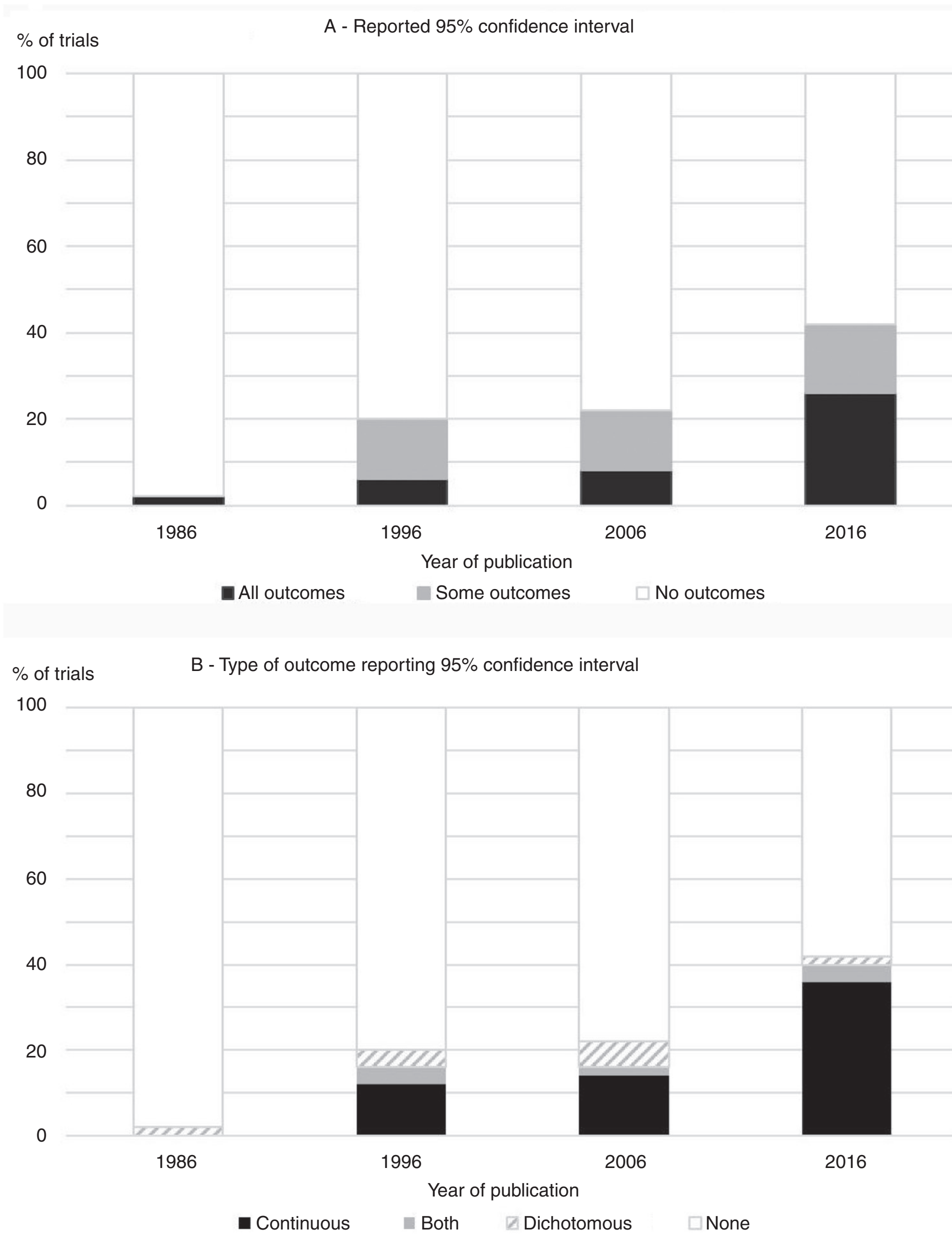

Figure 1 Percentage of trials from each of the four years studied that (A) reported 95% confidence intervals for at least one outcome and (B) reported 95% confidence intervals for continuous and/or dichotomous outcomes.

first the numerator and denominator for each year were multiplied by this weighting factor. Then all the numerators were summed, and all the denominators were summed. The resulting pooled numerator and pooled denominator were scaled down until the denominator equalled the original number of trials entered into the weighted calculation. The re-weighted numerator and denominator were then used to calculate the proportion and its 95% confidence interval. The weighted analyses are more representative of the body of trials indexed on PEDro.

One-way analysis of variance (ANOVA) and Dunn's multiple comparisons post hoc tests were used to compare the total PEDro score over the years. We also performed a Mann–Whitney test to compare data from trials that reported or did not report confidence intervals. A significance threshold of 5% was adopted and GraphPad software was used for analysis.

Results

The February 6, 2017 update of PEDro contained 28,216 trials, of which 3214 were published in 1986, 1996, 2006 or 2016. About 10% of trials were excluded because they were in-process ($n = 156$) or did not report a between-group comparison ($n = 172$). 50 trials were randomly selected from the remaining 170 trials published in 1986, 380 published in 1996, 1099 published in 2006, and 1237 published in

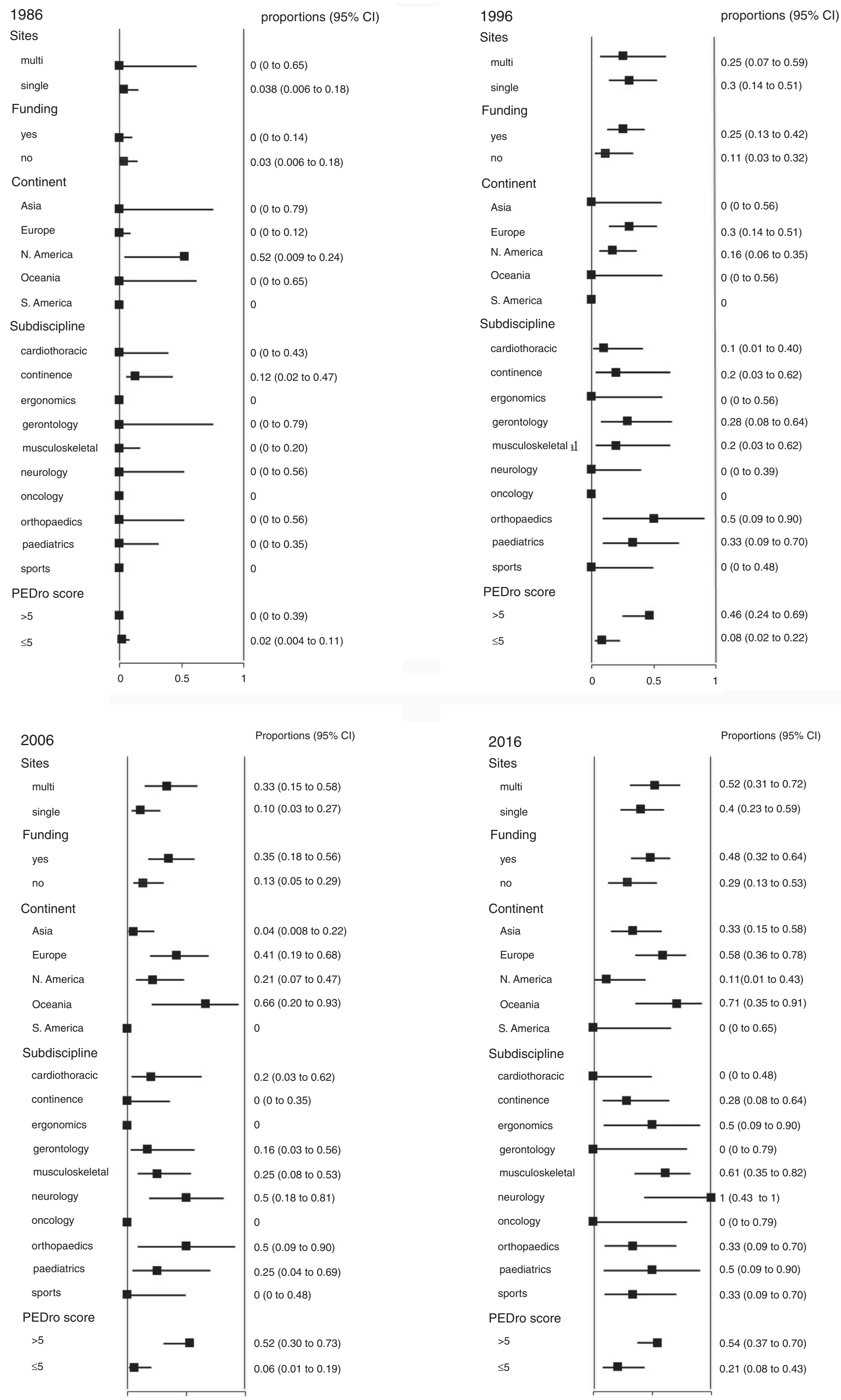

Figure 2 Prevalence of use of confidence intervals (95% CI) among the 50 trials randomly selected from each of the 4 years examined in the study, categorized by site, funding, continent, subdiscipline and total PEDro score.

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2016. The main characteristics of the selected trials are presented in Table 1. Most of the trials were published in English (89%). Other languages were: Chinese ($n = 14$), Dutch ($n = 1$), French ($n = 1$), German ($n = 3$), Japanese ($n = 1$), Korean ($n = 1$) and Spanish ($n = 2$). Majority of trials were classified in the musculoskeletal (23%), continence and women's health (14%) and cardiothoracic (12%) subdisciplines. There was a significant increase ($p < 0.0001$) in methodological quality with time when the 2016 total PEDro scores were compared with the 1986, 1996 and 2006 cohorts. Several of the variables showed consistent increases with time, including the proportions of trials that: included a sample size calculation, had multi-centre recruitment, and specified the primary outcome(s).

The overall prevalence of use of confidence intervals (for at least one outcome) was 29% and the proportion of trials that reported confidence intervals for the between-group comparisons increased consistently between 1986 (2%) and 2016 (42%), as presented in Fig. 1. The increase over time was evident regardless of whether the use of confidence intervals was analyzed as 'use with all outcomes' or 'use with at least one outcome'. In the 1986 cohort, the one trial that reported a confidence interval did so for a dichotomous outcome. From 1996 forward, however, the presentation of confidence intervals was most common for continuous variables (Fig. 1).

We also analyzed the proportion of trials that reported 95% confidence intervals within the following strata: centres involved in recruitment (single-centre vs multi-centre), funding, continent, subdiscipline and total PEDro score (>5 vs ≤5). When these analyses were performed for each year (Fig. 2), few of these factors were consistently associated with the use of confidence intervals. Significant differences occurred between some continents and between some subdisciplines, but these differences were transient and generally disappeared in the most recent cohort. In contrast, several statistically significant differences emerged in the weighted analysis of the pooled cohort (Fig. 3). Confidence intervals were more likely to be used among trials that had received funding than among unfunded trials. Trials conducted in Europe and Oceania were more likely to use confidence intervals than trials conducted in Asia and North America. Neurology trials were more likely to use confidence intervals than cardiothoracic trials. Confidence intervals were more likely to be used among trials with a total PEDro score of at least 6 than among lower quality trials.

The comparisons of number of participants, total PEDro score and number of primary outcomes between trials that did and did not report 95% confidence intervals are presented in Table 2. Trials that reported confidence intervals had some significantly better characteristics than trials that did not report confidence intervals. These significant differences were: greater median number of participants (in the 2006 and 2016 cohorts); higher median PEDro scores (in the 1996, 2006 and 2016 cohorts); and lower median number of primary outcomes (in the 2016 cohort only).

Discussion

This study demonstrated that less than one-third of a representative sample of trials of physical therapy interventions reported confidence intervals for between-group comparisons, with an overall prevalence of 29% in the weighted analysis of the pooled cohort of 200 trials. This prevalence is lower than equivalent analyses in other disciplines; 54% of trials in public health and 86% of trials in epidemiology published in 1982–2000,[18] 74% of journal abstracts in medicine, and 83% of abstracts in epidemiology.[17] This difference may at least in part be due to the fact that the present study used a representative cohort of trials, rather than trials from high prestige journals only. High prestige journals are typically early adopters of reporting initiatives such as the CONSORT Statement.

Despite the low prevalence of the use of confidence intervals overall, this study nevertheless identified several favourable trends among the trials. After only a single trial in the 1986 cohort reported confidence intervals, each subsequent year analyzed showed consistent increases in the proportion of trials that used confidence intervals. There were also progressive increases in the proportion of trials that used confidence intervals for all (as opposed

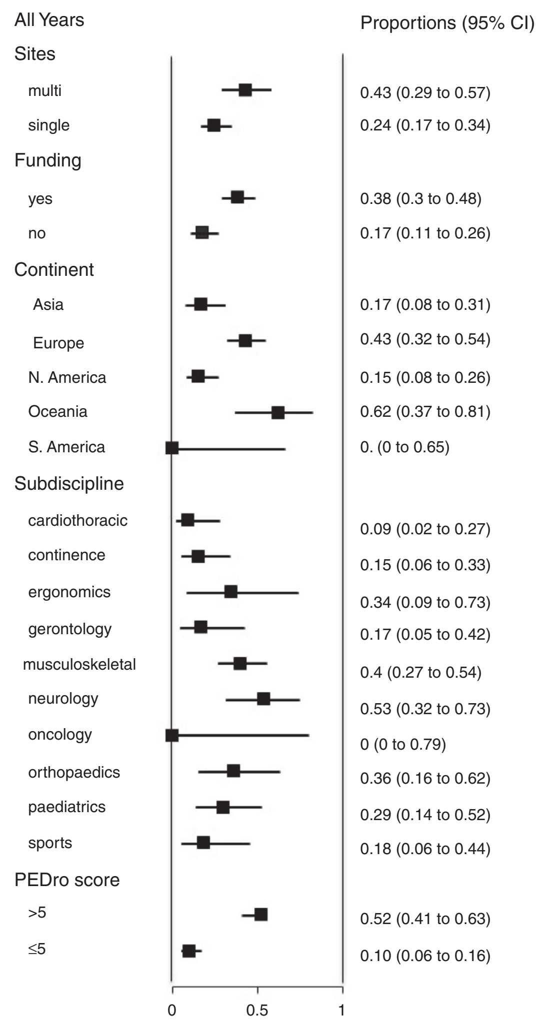

Figure 3 Weighted analysis of the proportion of trials that report 95% confidence intervals (95% CI) for all years combined (200 trials), categorized by site, funding, continent, subdiscipline and total PEDro score. See main text for details of the weighting procedure.

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Table 2 Mann–Whitney test comparisons between the trials that did and did not report 95% confidence intervals for at least one outcome for three characteristics: number of participants, total PEDro score, and number of primary outcomes identified.

Characteristic Year	Reported 95% confidence interval	Did not report 95% confidence interval	*p* value
Number of participants			
1986	49 [49; 49]	50 [27; 94]	N/A*
1996	80 [43; 239]	57 [35; 101]	0.20
2006	108 [80; 248]	75 [44; 131]	0.03
2016	114 [49; 252]	60 [33; 103]	0.008
PEDro score (0–10)			
1986	3 [3; 3]	4 [3; 5]	N/A*
1996	6 [5; 6]	4 [4; 5]	0.004
2006	6 [6; 8]	5 [4; 7]	0.000
2016	7 [6; 8]	5 [5; 7]	0.000
Number of primary outcomes			
1986	0 [0; 0]	4 [1; 9]	N/A*
1996	9.5 [1; 18]	1 [1; 3]	0.49
2006	1 [1; 1]	1 [1; 3]	0.49
2016	1 [1; 1]	2 [1; 3]	0.02

* Not applicable to statistical analysis due to the low number of trials reporting confidence intervals in 1986.

to some) between-group comparisons (Fig. 1). These progressive increases suggest that awareness of the value of confidence intervals is increasing among clinical trialists. Similar trends have been noted outside physical therapy, with the percentage of abstracts with confidence intervals increasing from approximately zero in the mid-1970s to 79% in 2014.[17] Editors and reviewers could refer to these consistent increases over time to show authors who are reluctant to use confidence intervals that their importance is being increasingly recognized. These findings may also convince readers who are unfamiliar with confidence intervals to upskill in this area so that they will be able to understand the growing proportion of trials that are reported using confidence intervals. Authors, reviewers and editors who are unfamiliar with confidence intervals can access several resources online for free, including excellent introductory papers[8,9] and a user-friendly, Excel-based, confidence interval calculator.[24]

We hypothesize that the trend of increased reporting of 95% confidence intervals over time may be due in part to an emphasis on improved reporting of trials (e.g., Item 12a of CONSORT Statement[16] and Items 10 and 11 of the PEDro scale[16,21] encourage reporting of the estimated effect size with its confidence interval). These reporting elements are required for submissions of trials in many healthcare journals. This hypothesized explanation is supported by the concurrent increases in the number of PEDro criteria met by the trials over the same period (Table 1). This explanation is supported by the concurrent improvements in the prevalence of other aspects of design and reporting, such as having an explicit sample size calculation, multi-centre recruitment, and specifying primary outcome(s) (Table 1).

In the weighted analysis of the pooled cohort (Fig. 3), the significant differences in the use of confidence intervals between some strata indicate some groups of researchers that could be particularly encouraged to increase their use of confidence intervals – such as those in the cardiothoracic subdiscipline and those conducting trials in Asia and North America. That encouragement might come from the other two statistically significant associations in Fig. 3. First, higher quality trials are more likely to be reported with confidence intervals, suggesting that skilled researchers realize the value of confidence intervals. Second, funded trials are more likely to be reported with confidence intervals. Although we cannot determine causation in either of these findings, it is possible that a research protocol that indicates that confidence intervals will be reported is seen as more worthy of being funded.

This study had many strengths. The cohorts of trials studied were representatively sampled from a bibliographic database with comprehensive coverage of trials for an entire discipline.[19,20] Sampling of trials was not limited to particular journals and language bias was avoided. Duplicate data extraction based on the full-text version of the articles (not the abstracts only) was used. Quality ratings were based on duplicate ratings with a scoring system that has good reliability and validity,[21,22] and we analyzed whether confidence intervals were used with all or only some of the between-group comparisons reported in each trial.

Study limitations

The study did not analyze whether confidence intervals were presented numerically or graphically, nor how the confidence intervals were used when interpreting the results. Both elements have been evaluated in studies of other disciplines,[18] and could be the focus of future research for physical therapy trials. For example, the validity of any interpretation of the confidence interval provided by the authors could be evaluated in relation to factors like the smallest worthwhile effect. A small number of trial characteristics (number of sites, funding, geographic location, subdiscipline and total PEDro score) were considered for their impact on the use of confidence intervals. The associations between a more comprehensive list of trial characteristics and the reporting of confidence intervals could be evaluated using logistic regression analysis.

Conclusions

A minority of randomized controlled trials of physical therapy interventions are reported with confidence intervals around the between-group differences. This indicates that authors, editors and reviewers should undertake to increase the use of confidence intervals in the reporting of trials. Despite its current low prevalence, the use of confidence intervals has been increasing steadily over the past three decades. Higher quality trials are more likely to report confidence intervals. This suggests that readers of trials need to understand confidence intervals if they are to understand the rapidly growing body of high-quality evidence that uses confidence intervals.

Conflicts of interest

The authors declare no conflict of interest. The authors declare that no reprints are available.

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