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EXAME DAS FUNÇÕES SENSORIAIS E MUSCULARES DO ASSOALHO PÉLVICO (EFSMAP): DESENVOLVIMENTO, CONFIABILIDADE E VALIDAÇÃO PARA MULHERES COM INCONTINÊNCIA URINÁRIA

Belo Horizonte
Escola de Educação Física, Fisioterapia e Terapia Ocupacional/UFMG
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Área de concentração: Desempenho Funcional Humano

Linha de pesquisa: Estudos do Desempenho Motor e Funcional Humano

Orientadoras: Profa. Dra. Elyonara Mello de Figueiredo

Profa. Dra. Rosana Ferreira Sampaio

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PARECER

Considerando que a Tese de Doutorado de **FERNANDA SALTIEL BARBOSA VELLOSO**, intitulada **"FUNÇÕES MUSCULARES DO ASSOALHO PÉLVICO EM MULHERES COM INCONTINÊNCIA URINÁRIA"** defendida junto ao Programa de Pós-Graduação em Ciências da Reabilitação, nível doutorado, cumpriu sua função didática, atendendo a todos os critérios científicos, a Comissão Examinadora **APROVOU** a Tese de doutorado, conferindo-lhe as seguintes indicações:

Nome do Professor (a)/Banca	Aprovação	Assinatura
Professora Dra. Rosana Ferreira Sampaio	Aprovada	[illegible]
Professora Dra. Marilene Vale de Castro Monteiro	aprovada	Marilene V.C. Monteiro
Professora Dra. Renata Noce Kirkwood	Aprovada	[illegible]
Professor Dra. Ana Paula de Melo Ferreira	Aprovada	[illegible]
Professor Dra. Patrícia Driusso	APROVADA	[illegible]

Belo Horizonte, 28 de fevereiro de 2018.

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ATA DE NÚMERO 74 (SETENTA E QUATRO) DA SESSÃO DE ARGUIÇÃO E DEFESA DE TESE APRESENTADA PELA CANDIDATA **FERNANDA SALTIEL BARBOSA VELLOSO** DO PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO.

Aos 28 (vinte e oito) dias do mês de fevereiro do ano de dois mil e dezoito, realizou-se na Escola de Educação Física, Fisioterapia e Terapia Ocupacional, a sessão pública para apresentação e defesa da Tese de Doutorado intitulada **"FUNÇÕES MUSCULARES DO ASSOALHO PÉLVICO EM MULHERES COM INCONTINÊNCIA URINÁRIA"**. A comissão examinadora foi constituída pelos seguintes Professores Doutores: Rosana Ferreira Sampaio, Marilene Vale de Castro Monteiro, Renata Noce Kirkwood, Ana Paula de Melo Ferreira e Patrícia Driusso, sob a Presidência da primeira. Os trabalhos iniciaram-se às 14h com apresentação oral da candidata, seguida de arguição dos membros da Comissão Examinadora. Após avaliação, os examinadores consideraram a candidata ***aprovada e apta a receber o título de Doutora após a entrega da versão definitiva da Tese***. Nada mais havendo a tratar, eu, Marilane Soares, secretária do Colegiado de Pós-Graduação em Ciências da Reabilitação dos Departamentos de Fisioterapia e de Terapia Ocupacional da Escola de Educação Física, Fisioterapia e Terapia Ocupacional, lavrei a presente Ata, que depois de lida e aprovada será assinada por mim e pelos membros da Comissão Examinadora. Belo Horizonte, 28 de fevereiro de 2018.

Prof. Dra. Rosana Ferreira Sampaio ____________

Prof. Dra. Marilene Vale de Castro Monteiro ____________

Prof. Dra. Renata Noce Kirkwood ____________

Prof. Dra. Ana Paula de Melo Ferreira ____________

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“Uma vez que a iniciativa científica envolve a comunicação da informação entre indivíduos, é importante compreender os elementos centrais que fundamentam essa comunicação.”

Jaccard e Jacoby, 2010, p. 18

RESUMO

Introdução: As funções musculares do assoalho pélvico (FMAP) são um alvo importante da abordagem fisioterapêutica a mulheres com disfunções do assoalho pélvico (DAP), dentre elas a incontinência urinária (IU). O treinamento de força e resistência dos músculos do assoalho pélvico (TMAP), é o tratamento de primeira linha para mulheres com incontinência urinária (IU) uma vez que esses músculos desempenham papel fundamental, tanto na sustentação dos órgãos pélvicos, quanto no mecanismo de continência urinária. No entanto, para que seja possível treinar força e resistência musculares, outras funções tais como capacidade de contração e adequada coordenação são fundamentais. O exame de todas as FMAP possibilitaria identificar quais funções musculares são relevantes para quais mulheres. A partir daí, a prescrição da dose de treinamento específica para cada paciente seria possível, ampliando o espectro de mulheres que se beneficiaria do tratamento conservador. Apesar de existir uma vasta literatura sobre FMAP em mulheres, a variedade de termos utilizados para descrever essas funções musculares e a variação nos métodos de mensuração impedem o agrupamento de dados e o avanço do conhecimento científico na área. Além disso, comprometem a comunicação entre pesquisadores, profissionais de saúde e as próprias mulheres. O desenvolvimento de um exame das FMAP mais relevantes para mulheres com DAP, que apresente definições conceituais e operacionais claras, válidas e reprodutíveis, contribuirá para a comunicação interprofissional, para o agrupamento de dados científicos e de serviços e para a prescrição de TMAP que seja dose-específico para cada mulher. **Objetivos**: O objetivo desta tese foi desenvolver, testar a reprodutibilidade e a validade de um exame das FMAP para mulheres com DAP, com os seguintes objetivos específicos: 1) identificar quais são as FMAP de mulheres mais investigadas na literatura e a terminologia utilizada nessa investigação; 2) propor o uso de terminologia padronizada para as FMAP de acordo com a Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF) da Organização Mundial da Saúde (OMS); 3) desenvolver o exame das FMAP a partir das informações identificadas nos objetivos 1 e 2, e testar a reprodutibilidade das medidas propostas nesse exame; 4) testar a validade de constructo do exame proposto para mulheres com DAP. **Métodos**: Para cumprir os objetivos acima, esta tese foi composta de quatro estudos. *Estudo 1*: Revisão sistemática da literatura, em

que três revisores independentes fizeram buscas nas bases PUBMED, CINAHL, LILACS e SCIELO de estudos observacionais que investigaram quaisquer FMAP de mulheres com e sem DAP, publicados em inglês, espanhol e português no período entre 2005 e 2017. A análise da qualidade metodológica dos estudos incluídos foi feita por meio de questionário padronizado para estudos observacionais. Os dados sobre as FMAP investigadas e sobre terminologia utilizada foram extraídos sob a forma de *termos*, *definições conceitual* e *operacional* das FMAP, e sintetizados de acordo com palavras-chave, ideias-chave e instrumentos-chave, respectivamente. Todas as etapas foram realizadas por dois pesquisadores independentes e os dissensos foram resolvidos com um terceiro pesquisador. *Estudo 2*: Processo de lincagem dos termos relativos às FMAP identificados no estudo 1 com a CIF/OMS, de acordo com regras padronizadas de lincagem. A frequência de ocorrência dos *termos* e definições operacionais (instrumentos) relativos às FMAP foi reportada e a porcentagem de concordância entre os avaliadores foi calculada. Dois pesquisadores independentes fizeram a vinculação dos conceitos à CIF. As discordâncias foram discutidas com um terceiro examinador por meio de discussão aberta. *Estudo 3*: Estudo metodológico que desenvolveu e testou a confiabilidade do Exame das Funções Sensoriais e Musculares do Assoalho Pélvico (EFSMAP), a partir da identificação das funções musculares mais relevantes/frequentes, da adequada terminologia para descrevê-las e dos instrumentos válidos, confiáveis e acessíveis para mensurar essas funções, originados dos resultados dos estudos 1 e 2. As FMAP foram examinadas por palpação e manometria vaginal (Peritron®). A confiabilidade das medidas foi testada por dois pesquisadores que examinaram as participantes em um intervalo de 10 a 20 minutos (análise interexaminador) e um avaliador examinou novamente as participantes em um intervalo de uma semana (análise intraexaminador). As funções mensuradas foram as funções sensoriais: *Propriocepção* (código CIF/OMS: b260) e *Dor localizada* (assoalho pélvico) (b28018); e as funções musculares e relacionadas ao movimento: *Tônus de músculos isolados e grupos de músculos* (b7350), *Controle de movimentos voluntários simples* (contração e relaxamento) (b7608), *Coordenação de movimentos voluntários* (b7602), *Reflexos de movimentos involuntários* (tosse) (b755), *Força de músculos isolados e de grupos de músculos* (b7300) e *Resistência muscular* (duração e repetições) (b7408). Foram calculados o percentual de concordância, índices de Kappa (K) e Kappa ponderado linear (Kw), limites de concordância e Coeficiente de Correlação Intraclasse (CCI). *Estudo 4*: Estudo metodológico que testou a validade de constructo da EFSMAP utilizando-se o procedimento *known groups method*, por meio da comparação de um grupo de mulheres com DAP com queixa prioritária de IU, com outro de mulheres sem IU. Duas fisioterapeutas previamente treinadas examinaram as participantes de acordo com o EFSMAP. A sensibilidade e a especificidade das variáveis categóricas foram calculadas. Para as variáveis ordinais e contínuas, foram calculadas as curvas *Receiver Operating Characteristic* (ROC) e estabelecidos pontos de corte para estas funções, baseados na maior soma obtida entre sensibilidade e especificidade. **Resultados**: *Estudo 1:*- Foram incluídos 64 estudos na revisão sistemática. Todos apresentaram *termos* e *definições operacionais*, mas apenas 29.7% deles apresentou definição conceitual. Cento e noventa e seis *termos* diferentes foram utilizados para se referir à FMAP. De acordo com similaridades na terminologia, foi possível agrupar 161 deles em 26 termos, deixando 35 termos não agrupados. Assim, 61 FMAP com distintas terminologias foram identificadas na literatura, não sendo, portanto, possível identificar quais as FMAP mais frequentemente investigadas na literatura. *Estudo 2:* Dos termos utilizados na literatura para descrever as FMAP, 93,8% puderam ser lincados à seis funções musculares descritas no capitulo 7 da CIF e apenas doze termos (6,25%) não estavam incluídos na CIF. A porcentagem de concordância na lincagem foi de 73,2%. As FMAP mais investigadas, em ordem decrescente, foram: *Força* (25,6%)*, Reflexo* (21,9%), *Resistência* (17,2%)*,Controle* (14,1%)*, Coordenação* (9,9%) e *Tônus* (4,2%)*.* Vários instrumentos foram utilizados para medir as FMAP. A palpação vaginal foi o único método utilizado para quantificar todas elas. A manometria vaginal foi o instrumento mais utilizado para medir *Força* (40,9%), e o segundo mais utilizado para medir Resistência (36,4%), sendo que o manômetro Peritron® foi utilizado em 60% das vezes para medir *Força* e em 75% delas para medir *Resistência*. *Estudo 3:* Os resultados obtidos nos estudos 1 e 2 permitiram identificar quais são as funções mais relevantes de serem avaliadas em mulheres com e sem DAP, bem como os instrumentos acessíveis mais utilizados mundialmente para esse fim. Assim, o Exame das Funções Sensoriais e Musculares do Assoalho Pélvico, o EFSMAP, for proposto. Para os testes de confiabilidade das medidas do EFSMAP, participaram 30 mulheres com e sem DAP a partir da queixa de IU, com média de idade de 51,2 (14,7) anos. Os índices de reprodutibilidade intra e interexaminador do EFSMAP foram bons a excelentes (ex.: Kw=0,67; 95%CI=0.40-0.94 para *Tônus*; CCI=0.97; 95%CI=0.92-0.99 para *Resistência*-duração) para a maioria das funções. A concordância foi substancial para a maioria das FMAP testadas. No entanto, não identificamos bons índices de confiabilidade intraexaminadores para as funções Dor e Tônus. *Estudo 4:* Da validação de construto do EFSMAP participaram 182 mulheres (grupo IU=91; grupo sem IU=91), pareadas por idade [mediana de 50,9(26-91)anos e 46,0(27-87)anos, respectivamente]. O EFSMAP apresentou índices excelentes (95,6%) a bons (acima de 70%) de especificidade, mas baixos índices de sensibilidade (abaixo de 60%) para as funções *Controle* (contração e relaxamento), *Dor* (presença) e *Coordenação*. Inversamente, a função *Reflexo* (tosse) apresentou sensibilidade alta (82,6%), mas baixa especificidade (37,4%). O *Tônus* não diferenciou os grupos de mulheres com e sem IU. *Força* e *Resistência* (duração) diferenciaram os dois grupos (área sob a curva>0,70). Os pontos de corte para a *Força* medida pela Escala de Oxford Modificada foi de 3; pela manometria foi de 45,9 cmH2O e para *Resistência* foi de 6,5 segundos na palpação vaginal. **Conclusão**: Há grande variação na terminologia para as FMAP. A lincagem dos termos usados para descrever as FMAP à terminologia da CIF/OMS mostrou-se viável e válida, sendo possível estabelecer linguagem consensual e com fundamentado referencial teórico. Esse processo culminou na organização do EFSMAP, um exame para avaliação das funções sensoriais e musculares do assoalho pélvico para mulheres com DAP. Este mostrou-se confiável para mulheres com DAP com queixa prioritária de IU. Para tal, é recomendado que se tenha clareza das *definições conceitual* e *operacional* das FMAP e que se faça treinamento prévio dos examinadores. O EFSMAP teve sua validade de constructo atestada, uma vez que a maioria das FMAP testadas foi diferente entre mulheres com DAP com queixa prioritária de IU quando comparadas àquelas sem IU. O EFSMAP foi mais específico do que sensível para diferenciar essas mulheres. Também, os pontos de corte estabelecidos para as funções *Força* e *Resistência* podem guiar os fisioterapeutas a definir mais claramente suas metas e propor estratégias terapêuticas mais efetivas e de menor custo para mulheres com DAP. Desta forma, o EFSMAP pode ser utilizado em pesquisas científicas e na prática clínica, proporcionando: a) uma ferramenta que utiliza terminologia clara, padronizada, universal e com referencial teórico sólido sobre funções sensoriais e musculares válidas para o assoalho pélvico, favorecendo a comunicação e o avanço científico na

área; b) uma ferramenta que permite a identificação confiável e válida das deficiências sensoriais e musculares do assoalho pélvico mais relevantes de serem avaliadas e reabilitadas em mulheres com DAP; c) um ponto de partida para o desenvolvimento de avaliação fisioterapêutica global focada na funcionalidade da mulher e não na doença.

Palavras-chave: assoalho pélvico, músculos, disfunções do assoalho pélvico, incontinência urinária, terminologia, classificação internacional de funcionalidade incapacidade e saúde, reprodutibilidade, validade.

ABSTRACT

Introduction: Pelvic floor muscle functions (PFMF) are important targets for the physical therapy interventions for women with pelvic floor dysfunctions (PFD), including urinary incontinence (UI). Pelvic floor muscle training (PFMT) is recommended as first line treatment for those women, as pelvic floor muscles (PFM) are part of the continence mechanism and support pelvic organs. Nevertheless, to train muscle strength and endurance other muscle functions, such as ability to contract and coordination are mandatory. The examination of all PFMF would allow the identification of which are the relevant functions for which women. Then, it would be possible to set a dose specific physical therapy approach for the patient, expanding the range of women who would benefit from the the conservative treatment. Albeit there is a large number of studies about PFM in women, the variety of terms used to describe those functions, as well as the variation in their measurement methods prevents data gathering and the advance in scientific knowledge in the field. Also, it compromises communication among researchers, health care professionals and the women themselves. The development of an exam of the relevant PFMF for women with PFD, that presents clear, valid and reproducible conceptual and operational definitions will contribute to interprofissional communication, to scientific and service data gathering and to the prescription of a dose-specific rehabilitation program for each woman. **Aims**: The goal of this thesis was to develop, test reproducibility and validity of a pelvic floor muscle evaluation for women with PFD with the following specific aims: 1) to identify which are the most investigated PFMF in women and the adopted terminology regarding *terms*, *conceptual* and *operational definitions*; 2) to propose the use of a universal and standardized terminology based on International Classification of Functioning, Disability and Health (ICF) from World Health Organization (WHO); 3) to develop the PFMF exam based on information identified in aims 1 and 2 and test reproducibility of the exam; 4) to test construct validity of the exam for women with PFD.

Methods: To answer those aims, this thesis is constituted of four studies. *Study 1*: Systematic literature review, in which three independent reviewers took part and retrieved observational studies investigating any PFMF of women with or without PFD, published in English, Spanish or Portuguese, from 2005 to 2017 in PUBMED, CINAHL, LILACS and SCIELO. The risk of bias was assessed by a questionnaire on quality of observational studies. Data on terminology was extracted as *terms*,

conceptual and *operational definitions* of PFMF, and synthesized according to *key-words*, *key-ideas*, and *key-operationalization* respectively*.* All steps were carried by two independent researchers and disagreements were discusses with a third researcher. *Study 3*: Methodological study to develop and test the reproducibility of the Pelvic Floor Sensory and Muscle Function Exam (EFSMAP-*Exame das Funções Sensoriais e Musculares do Assoalho Pélvico*) proposed from the identification of the most relevant PFMF, from the adequate terminology used to describe those functions and from valid, reliable and accessible instruments to measure them. Those information emerged from studies 1 and 2. PFMF were evaluated by vaginal palpation and manometry (Peritron®). For interrater analysis, two raters evaluated participants in a 10 to 20 minute interval. Intrarater analysis was conducted by one rater in a one week interval. Main outcomes were sensorial functions: *Proprioceptive* (ICF code: b260) and *Pain* (b28018); muscle and movement functions: *Tone* (b7350) *Control* (contraction and relaxation) (b7608), *Coordination* (b7602), *Involuntary movement reaction* (cough) (b755), *Power* (b7300) and *Endurance* (duration and repetitions) (b7408). Percent agreement, Kappa (K) and linear weighted Kappa (Kw), limits of agreement and Intraclass Correlation Coefficient (ICC) were calculated. *Study 4*: Methodological study. The known groups method procedure was used to test construct validity of the EFSMAP by comparing a group of women with PFD, mostly UI with a non-IU. Two previously trained physical therapists examined women according to the EFSMAP. Sensitivity and specificity were calculated for categorical data. For ordinal and continuous variables, *Receiver Operating Characteristic* (ROC) curves were calculated and the cutoff points for those functions were set based on the highest sum of sensitivity and specificity. **Results**: *Study 1 -* Sixty-four studies were included in the systematic review. All studies presented *terms* and *operational definitions* of PFMF, but only 29.7% presented *conceptual definitions* of those *terms*. One hundred and ninety six different *terms* referred to PFMF. According to similarities in terminology, 161 PFMF could be grouped into 26, but the other 35 were left ungrouped. Therefore, a total of 61 PFMF with different terminology were identified in the literature. *Study 2* - 93.8% of the terms used to describe the PFMF could be linked to six neuromusculoskeletal and movement-related functions, described in chapter 7 of ICF. Twelve functions (6.25%) were found to be not covered by the ICF. Percentage agreement in independent linking was 73.2%. The most investigated PFMF were, consecutively, *Power of isolated muscles and muscle groups* (25.6%), *Involuntary movement reaction functions* (21.9%), *Endurance of muscle groups* (17.2%), *Control of simple voluntary movements* (14.1%), *Coordination of voluntary movements* (9.9%) and *Tone of isolated muscles and muscle groups* (4.2%). There was a wide variation in instruments used to measure PFMF. Vaginal palpation was the only method employed to measure all six PFMF investigated. Vaginal manometry was the most used instrument to measure *Power* (40.9%), and the second most frequently used to measure *Endurance* (36.4%). Peritron® was the most used manometer (60% of the times to measure *Power* and 75% to measure *Endurance*). *Study 3* - Data obtained in studies 1 and 2 allowed the identification of the most relevant PFMF to be investigated in women with and without UI, along with the most used and accessible instruments to measure them. Thereby, the Pelvic Floor Sensory and Muscle Function Exam - EFSMAP - emerged. Thirty women with PFD, mainly IU, and without UI took part to the reliability study, with mean age of 51.2 (14.7) years. Intra and interrater reproducibility indices of the EFSMAP were good to excellent (e.g.: Kw=0.67; 95%CI=0.40-0.94 for *Tone*; ICC=0.97; 95%CI=0.92-0.99 for *Endurance*-duration) for most functions. Reproducibility indexes for the functions *Pain* (presence and intensity) and *Tone* (right) were poor. Agreement was substantial for most PFMF measured. *Study 4 -* For the construct validity study, 182 women (91 in UI group, and 91 in non-UI), paired by age, volunteered. Median age was 50.9, 26-91 years and 46.0, 27-87years, respectively. *Control* (contraction and relaxation), *Pain* presence, and *Coordination* had excellent (95.6%) to good specificity indexes (above 70%), but low sensitivity

(below 60%). Conversely, *Involuntary movement reaction* during cough had high sensitivity (82.56%), but low specificity (37.36%). *Tone* did not distinguish those groups. *Strength* and *Endurance* (duration) distinguished women with UI from those with no UI, with area under the ROC curve above 0.70. Cutoff values were 3 in Modified Oxford Scale, 45.9cmH2O in vaginal manometry for *Strength*; and 6.5 seconds in vaginal palpation for *Endurance*. **Conclusion**: A large variation in PFMF terminology was identified. Linking PFMF to ICF terminology was found to be feasible and valid towards a standardized and universal language based on *terms* and *conceptual definitions* anchored on a sound theoretical framework. This process allowed the organization of the EFSMAP, an exam fostered to evaluate sensory and muscle function of the pelvic floor for women with PFD. This exam was proved to be reproducible for women with PFD, mainly with UI complaints. To reach reproducibility, it is recommended that the *conceptual* and *operational definitions* be as clear as possible and that the raters be systematically trained. Also, the EFSMAP presented construct validity, as most tested functions distinguished women with UI from those without UI. The exam was more specific than sensitive for discriminative purposes. The cutoff values for *Strength* and *Endurance* may guide physical therapists to set treatment goals towards a more effective and lower cost therapeutic program for those women. Therefore, the use of the EFSMAP both in research and in clinical setting, can provide to the professionals who deal with women's health field: a) a tool that adopts a clear, standardized and universal language on pelvic floor sensory and muscle functions and it is founded on a sound theoretical framework, fostering communication and advance in the field; b) a tool that allows a reliable and valid identification of sensory and muscle impairments in those functions that are relevant to be assessed in women with UI, and rehabilitated as well; c) a starting point to the development of a thorough physical therapy assessment focused on women's functionality, rather than on the disease.

Key-words: pelvic floor, muscle, urinary incontinence, terminology, international classification of functioning disability and health, reproducibility, validity.

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LISTA DE ABREVIATURAS E SIGLAS

95%CI - *95% confidence interval*

AP - Assoalho Pélvico

ATLA - Arco Tendíneo do Levantador do Ânus

CAPES - Coordenação de Aperfeiçoamento de Pessoal de Nível Superior

CCI - Coeficiente de Correlação Intraclasse

CI - *Confidence Interval*

CID - Classificação Internacional de Doenças

CIF - Classificação Internacional de Funcionalidade, Incapacidade e Saúde

CPR - *Clinical Prediction Rules*

CVM - Contração Voluntária Máxima

DAP - Disfunções do Assoalho Pélvico

EFSMAP – Exame das Funções Sensoriais e Musculares do Assoalho Pélvico

EMG - Eletromiografia

EMG - *Electromyography*

EOM - Escala de Oxford Modificada

FMAP - Funções Musculares do Assoalho Pélvico

GRAAS - *Guidelines for Reporting Reliabilty and Agreement Studies*

IA - Incontinência Anal

IC - Intervalo de Confiança

IC95% - Intervalo de Confiança de 95%

ICC - *Intraclass Correlation Coefficient*

ICF - *Classification of Functioning, Disability and Health*

ICIDH - Classificação Internacional de Deficiências, Incapacidades e Limitações

ICIQ-UI-SF - *The International Consultation Incontinence Questionnaire-Short Form*

ICS - *International Continence Society*

IU - Incontinência Urinária

IUE - Incontinência Urinária de Esforço

IUGA - *International Urogynecological Association*

IUM - Incontinência Urinária Mista

IUU - Incontinência Urinária de Urgência

K - Estatística Kappa

Kw - Kappa Linear Ponderado

MAP - Músculos do Assoalho Pélvico

MEEM - Mini Exame do Estado Mental

MLA - Músculo Levantador do Ânus

MOS - *Modified Oxford Scale*

MRI - *Magnetic Ressonance Imaging*

MVC - *Maximum Voluntary Contraction*

OMS - Organização Mundial de Saúde

PFD - *Pelvic Floor Dysfunction*

PFM - *Pelvic Floor Muscle*

PFMF - *Pelvic Floor Muscle Function*

PFSMF – *Pelvic Floor Sensory and Muscle Function*

PFMT - *Pelvic Floor Muscle Training*

POP - Prolapso de Órgãos Pélvicos

POP - *Pelvic Organ Prolapse*

POP-Q - *Pelvic Organ Prolapse Quantification System*

PRISMA - *Preferred Reporting Items for Systematic Reviews and Meta-Analyses*

PROSPERO - *Interrnational Prospective Register of Systematic Reviews*

QV - Qualidade de Vida

RM - Ressonância Magnética

ROC - *Receiver Operating Characteristics*

RPC - Regras de Predição Clínica

SUS - Sistema Único de Saúde

TMAP - Treinamento dos Músculos do Assoalho Pélvico

UFMG - Universidade Federal de Minas Gerais

UI - *Urinary Incontinence*

US - Ultrassom

US - *Ultrasound*

VRP - *Vaginal Resting Pressure*

WCPT - *World Confederation for Physical Therapy*

WHO - *World Health Organization*

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PREFÁCIO

Esta Tese de Doutorado foi elaborada de acordo com as normas estabelecidas pelo Colegiado do Programa de Pós-Graduação em Ciências da Reabilitação da Universidade Federal de Minas Gerais (UFMG). Sua estrutura compreende quatro capítulos. O primeiro capítulo contém a introdução, em que se contextualiza o objeto de estudo e apresenta os objetivos geral e específicos da Tese. No segundo capítulo estão descritos os métodos e materiais utilizados em cada um dos quatro estudos da Tese. O terceiro capítulo apresenta os resultados da tese, sob o formato de artigos. O primeiro estudo, denominado “Terminology of pelvic floor muscle function of women with and without urinary incontinence: a systematic review of the literature” e o segundo estudo, denominado “Linking pelvic floor muscle function to the International Classification of Functioning, Disability and Health” estão formatados conforme as normas do periódico *Physical Therapy Journal*, sendo que o Artigo 1 foi submetido e aceito com revisões no referido periódico em 08 de janeiro de 2018 (Anexo A). O 3º estudo é intitulado “Reliability and agreement of the Pelvic Floor Sensory and Muscle Function Exam-EFSMAP: a methodological study”, e o 4º estudo é intitulado “The Pelvic Floor Sensory and Muscle Function Exam – EFSMAP based on ICF/WHO terminology: a construct validity study”. Estes dois últimos artigos foram formatados conforme as normas do periódico *British Journal of Obsetrics and Gynaecology – BJOG*. O quarto capítulo compreende as considerações finais desta Tese. Em seguida, estão indicadas as referências, anexos e apêndices.

1. INTRODUÇÃO

1.1 Assoalho pélvico

O termo assoalho pélvico (AP) se refere a um conjunto de estruturas dispostas em camadas que, juntas, fecham distalmente a pelve. A camada cranial corresponde ao peritônio visceral, a camada média é composta, primordialmente, de tecido muscular estriado esquelético envolto pela fáscia endopélvica, e a camada distal corresponde à pele da vulva, escroto e períneo (MOORE; AGUR; DALLEY, 2013)(ASHTON-MILLER; DELANCEY, 2007). O AP está relacionado diretamente a três órgãos e age como uma unidade, suportando as vísceras pélvicas, dando passagem ao reto, uretra e vagina (por meio do hiato urogenital) e também funcionando como mecanismo esfincteriano (CORTON, 2009; MESSELINK et al., 2005). Portanto, deficiências do AP influenciam mais de uma função (urinária, anal, vaginal e/ou sexual) ao mesmo tempo e podem contribuir para a ocorrência de disfunções do assoalho pélvico (CORTON, 2009).

1.2 Disfunções de assoalho pélvico

Disfunções de assoalho pélvico (DAP) são um termo aplicado a uma variedade de condições clínicas que incluem a incontinência urinária (IU), anal (IA), prolapso de órgãos pélvicos (POP), outras anormalidades de enchimento e esvaziamento do trato urinário baixo, disfunções defecatórias e sexuais e várias síndromes dolorosas como as dores pélvicas (SUNG; HAMPTON, 2009)(BUMP; NORTON, 1998; HAYLEN et al., 2010). Em função da estreita relação entre o AP e estruturas pélvicas diretamente relacionadas à função sexual, vesical e intestinal, essas disfunções geralmente co-ocorrem e são bem documentadas na literatura. A frequência da co-ocorrência de DAP varia entre 6% e 80%, a depender de quais disfunções estão sendo investigadas (LAWRENCE et al., 2008; SUNG; HAMPTON, 2009). Isoladamente, a IU é a mais prevalente das DAP, atingindo entre 13,1% e 64,4% da população; seguida de POP (2,9 e 49,9%); e IA (2,2% e 24%) (SUNG; HAMPTON, 2009). A grande variabilidade nas taxas de prevalência é decorrente de como as variáveis são definidas, operacionalizadas e em que populações são estudadas (SUNG; HAMPTON, 2009).

1.2.1 Incontinência urinária – definição, impacto e fatores de risco

A IU é definida como a perda involuntária de urina e é classificada, a partir de sinais e sintomas e do estudo urodinâmico, em pelo menos três subtipos: a) incontinência urinária de esforço (IUE): em que a perda urinária ocorre em situações de esforço, como tosse, atividades físicas e levantamento de peso; b) incontinência urinária de urgência (IUU): perda involuntária de urina precedida por um desejo imperioso para urinar (urgência miccional), frequentemente associada a contrações involuntárias do músculo detrusor da bexiga; e, c) incontinência urinária mista (IUM): perda urinária aos esforços e em situações de urgência (HAYLEN et al., 2010).

A IU impõe elevados encargos financeiros sobre os sistemas de saúde. Estima-se que os custos com as incontinências, nos Estados Unidos sejam de, aproximadamente, US$12,4 bilhões de dólares/ano, sendo o cuidado de rotina responsável por 70% dos custos (SUNG; HAMPTON, 2009). No Brasil, uma estimativa de custos com o tratamento de IU do serviço de uroginecologia da Universidade Federal de São Paulo (baseada na perspectiva da fonte pagadora pública) com exames diagnósticos, tratamentos cirúrgico, fisioterapêutico (1ª consulta) e gastos pessoais com limpeza de roupas, absorventes e medicamentos no ano de 2007, somou um total de R$481.557,43/ano (ARAÚJO, 2009).

A IU afeta negativamente a qualidade de vida (QV) de mulheres, interferindo no bem-estar físico, nos aspectos psicológicos e sócio-econômicos (KWON et al., 2010). A idade, tipo de IU, número de episódios de perda urinária, peso corpóreo, estresse e comportamento de busca por ajuda são fatores que influenciam a QV, sendo a gravidade dos sintomas de IU o mais crítico (KWON et al., 2010; MONZ et al., 2005). As mulheres incontinentes, frequentemente, desenvolvem estratégias para lidar com os desconfortos deles decorrentes. Uma revisão sistemática que buscou investigar as percepções sobre a IU em mulheres em diferentes grupos étnicos e sociais, mostrou que alguns comportamentos são comuns entre a maioria deles. A redução na ingestão líquida, o uso restrito de roupas, a limitação na realização de atividades diárias, como práticas esportivas e de lazer, e a restrição na participação social são alguns exemplos (SIDDIQUI et al., 2014).

Levando-se em conta a alta prevalência de IU na população mundial, os custos elevados e a morbidade, essa condição de saúde é hoje considerada um problema de saúde pública (KWON et al., 2010) (MILSON et al.,2009).

As causas e os fatores de risco para a ocorrência de IU são multifatoriais. Bump e Norton propuseram um modelo biomédico baseado em aspectos sócio-demográficos e clínicos para delinear as causas e os fatores de risco para a ocorrência de DAP, incluindo-se a IU (BUMP; NORTON, 1998). Este modelo considera a existência de cinco fatores: predisponentes (raça, anatômicos, neurológicos, *musculares*, tecido conectivo e genéticos), incitantes (parto, lesão nervosa, *muscular*, tecidual, cirurgia, radiação), promotores (constipação, obesidade, cirurgia, tabagismo, comorbidades, medicação, infecção, ciclo menstrual, menopausa), intervenientes (comportamental, farmacológico, cirurgia, equipamentos) e descompensadores (envelhecimento, demência, mobilidade reduzida, ambiente, medicação). A condição muscular aparece em dois momentos no modelo proposto, indicando sua relevância para o mecanismo de continência e de suporte de órgãos pélvicos.

1.2.2 O assoalho pélvico e o mecanismo de continência

1.2.2.1 Estrutura do assoalho pélvico

A manutenção da continência e a micção dependem de mecanismos de controle complexos que requerem a interação orquestrada entre a anatomia pélvica, o controle neural e os hábitos comportamentais aprendidos (FOWLER, 2006). Para a continência é preciso que os mecanismos que aumentam a pressão de fechamento intra-uretral estejam funcionando adequadamente para superar o aumento de pressão intravesical (SHAH et al., 2014). As estruturas muscular, fascial e ligamentar do assoalho pélvico contribuem, juntamente com a mucosa vaginal e o contorno dos órgãos pélvicos projetados sobre as paredes vaginais, para gerar tensão passiva no canal uretral, suportar as vísceras pélvicas e favorecer o mecanismo de continência (ASHTON-MILLER; DELANCEY, 2007).

O mecanismo de continência consiste de uma *unidade esfincteriana* (incluindo-se a uretra com três camadas (mucosa, submucosa e muscular dispostas em dois sentidos: circunferencial e longitudinal) e a inervação alfa adrenérgica do colo vesical), de um *sistema de suporte*, que consiste de tecidos conectivos entremeados por músculos lisos e dos músculos estriados do músculo levantador do ânus (MLA) (DELANCEY, 2010), bem como da integração com aferências e eferências neuronais complexas (SHAH et al., 2014).

Tendo como foco a contribuição da condição muscular para o mecanismo de continência, a seguir estão descritos, em detalhes, a unidade esfincteriana e o sistema de suporte, do qual os músculos fazem parte.

Unidade esfincteriana

A uretra é uma estrutura composta de três camadas que consistem de músculos estriados, lisos, tecido conectivo, um plexo submucoso ricamente vascularizado e um epitélio de revestimento. Essas estruturas criam tensão na parede da uretra mantendo-as coaptadas, favorecendo o seu selamento. Trinta e três por cento dessa tensão de coaptação decorre da ação de músculos estriados, 28% de fatores vasculares e 39% de músculos lisos e tecidos conectivos (DELANCEY, 2010).

A pressão de fechamento uretral máxima é o parâmetro de fechamento uretral que parece mais contribuir para a continência urinária (DELANCEY, 2010). O elemento dominante do esfíncter uretral é o músculo estriado esfincteriano, disposto circularmente na porção média da uretra e, em forma de cinta, no seu terço distal. Este esfíncter é entremeado por algumas fibras musculares lisas, circunda uma camada de músculo liso longitudinal e também o núcleo vascular da mucosa. Funcionalmente, os músculos uretrais mantêm a continência por meio: a) de uma alça em formato de U no nível do colo vesical originada do músculo liso detrusor que circunda a uretra proximal, favorecendo o fechamento do seu lume; b) do esfíncter estriado logo abaixo do colo vesical que, devido à sua composição majoritária de fibras musculares do tipo I (contração lenta), são adequadas para manterem contração constante; c) por meio do recrutamento dos músculos estriados do esfíncter uretrovaginal (esfíncter uretral propriamente dito associado ao MLA) e do compressor da uretra, que fecham o lume uretral, estes localizados distalmente na uretra (ASHTON-MILLER; DELANCEY, 2007).

Sistema de suporte

O sistema de suporte uretral e da parede vaginal distal é intrincadamente conectado. A uretra é fundida, em sua maior parte, à parede vaginal anterior. Também, as estruturas que determinam a posição uretral e vaginal são as mesmas. Os principais componentes desse sistema de suporte são a parede vaginal, propriamente dita, a fáscia endopélvica, o arco tendíneo da fáscia pélvica e o MLA recoberto por sua fáscia. O MLA é componente da camada profunda dos músculos do assoalho pélvico (MAP) (ASHTON-MILLER; DELANCEY, 2007; CORTON, 2009).

A *fáscia endopélvica* é uma camada de tecido conectivo denso que circunda a vagina e fixa-se bilateralmente a cada arco tendíneo, disposto lateralmente à pelve (ASHTON-MILLER; DELANCEY, 2007). Ela ocupa o espaço entre o peritônio membranáceo, paredes e o assoalho muscular da pelve não ocupado pelos órgãos pélvicos e é contínua com a fáscia de revestimento do abdome (fáscia transversal fáscia ílio-psoas) e interrompida pela fusão desta com o periósteo do osso do quadril e a face posterior do corpo do púbis (MOORE; AGUR; DALLEY, 2013). A fáscia endopélvica é formada por duas lâminas, as fáscias parietal e visceral da pelve. A diferença entre elas está relacionada à localização anatômica e às características histológicas e funcionais (MOORE; AGUR; DALLEY, 2013).

O *arco tendíneo* do levantador do ânus (ATLA) é uma condensação da fáscia parietal superior endopélvica cobrindo a superfície medial do músculo obturador interno (fáscia obturatória), e sobre o qual parte do MLA se insere (sua porção iliococcígea) (CORTON, 2009). O ATLA de cada lado da pelve se fixa ao osso púbico ventralmente e à espinha isquiática, dorsalmente, e tensiona a uretra, como os cabos de uma ponte em suspensão, elevando-a, juntamente com a parede vaginal anterior. Sua estrutura começa como uma faixa fibrosa no osso púbico e vai se tornando uma aponeurose larga no sentido dorsal até a espinha isquiática, a medida que se funde com a fáscia endopélvica, onde se conecta com o MLA (ASHTON-MILLER; DELANCEY, 2007; MOORE; AGUR; DALLEY, 2013).

Os *músculos do assoalho pélvico* (MAP) estão localizados na camada média do assoalho pélvico (Figura 1) e são divididos em, pelos menos, três outras camadas: profunda, média e superficial, que apresentam funções distintas. Enquanto as camadas profunda e média estão mais relacionadas aos mecanismos de continência, a camada superficial está, primordialmente, associada às funções sexuais (ASHTON-MILLER; DELANCEY, 2007). A camada profunda é constituída dos músculos coccígeo e MLA. Para o mecanismo de continência e suporte dos órgãos pélvicos, o MLA é estrutura fundamental. É composto de três regiões: porção iliococcígea, relativamente achatada e horizontal que se expande de um lado da parede pélvica até a outra; a porção pubovisceral, se origina no osso púbico bilateralmente e se fixa às paredes dos órgãos aos quais tangencia (uretra, vagina e reto) e ao corpo perineal. Este músculo (pubovisceral) tem outras três subdivisões: puboperineal (que se insere no corpo perineal), pubovaginal (se insere nas paredes vaginais) e puborretal. Este forma uma alça circundando posteriormente o reto, passando logo acima do esfíncter anal externo e se insere no púbis contralateral (ASHTON-MILLER; DELANCEY, 2007; CORTON, 2009; KEARNEY; SAWHNEY; DELANCEY, 2004). O MLA é recoberto por uma camada superior e outra inferior de fáscia endopélvica, que, nessa região, recebe o nome de fáscia superior e inferior do MLA, respectivamente. Todas essas estruturas descritas acima, em conjunto, são denominadas de diafragma pélvico (ASHTON-MILLER; DELANCEY, 2007).

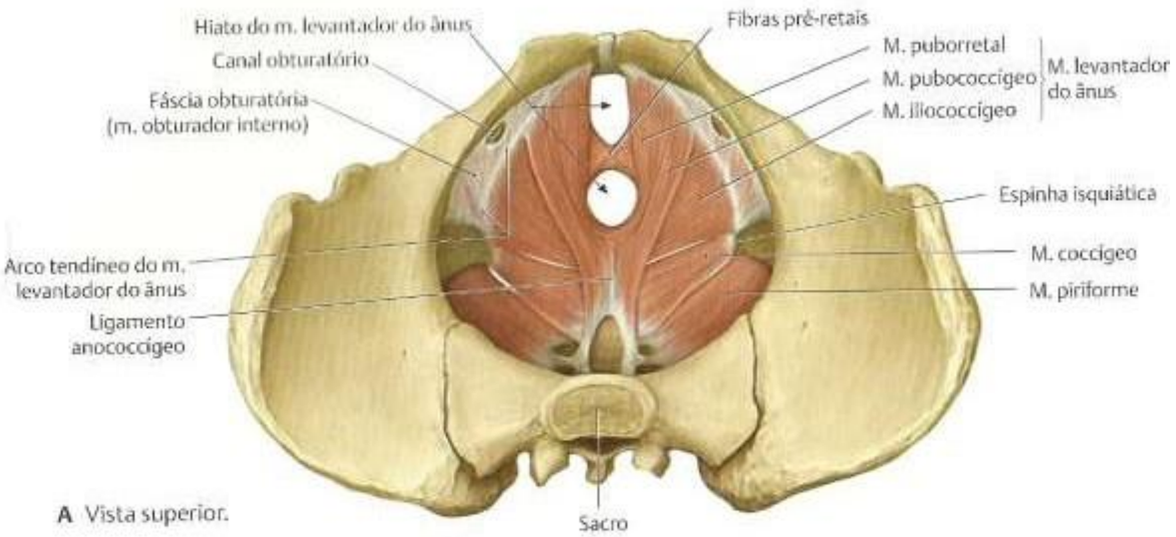

Figura 1 - Vista superior dos músculos do assoalho pélvico (MAP). Observar a íntima relação da camada muscular profunda recoberta pela fáscia do músculo levantador do ânus (MLA), composto pelos músculos pubovisceral (medial), iliococcígeo (lateral) e puborretal (inferiormente) (não representado na figura), com o músculo obturador interno, por meio do espessamento de sua fáscia, formando o arco tendíneo do levantador do ânus (ATLA), sobre a qual o MLA se insere. Fonte: Gilroy AM et al., Atlas de Anatomia. Rio de Janeiro: Guanabara Koogan ltda. 2008 p. 141

A camada média dos MAP é composta pelos músculos transverso profundo do períneo e esfíncter uretral externo. E, finalmente, a camada superficial é composta pelos músculos isquiocavernoso, bulboesponjoso, transverso superficial do períneo e esfíncter anal externo (Figura 2) (ASHTON-MILLER; DELANCEY, 2007; KEARNEY; SAWHNEY; DELANCEY, 2004).

A Figura 3 mostra a intrincada relação entre as estruturas do assoalho pélvico que contribuem para a ação esfincteriana e para o suporte dos órgãos pélvicos.

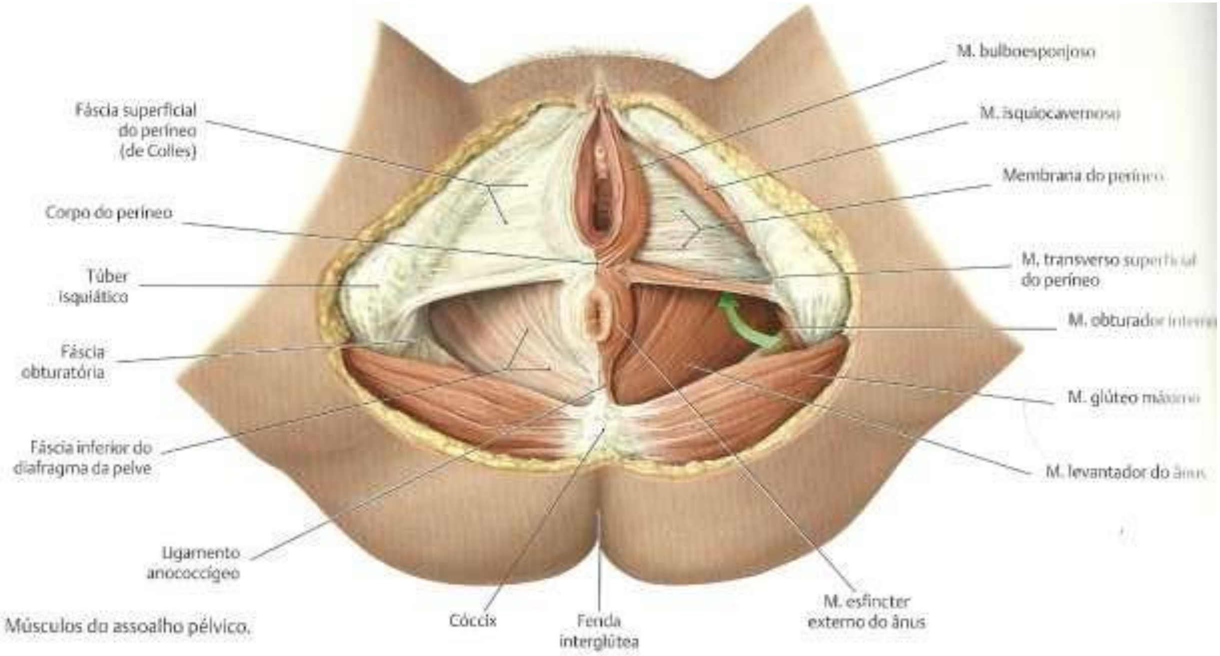

Figura 2 - Camada superficial dos músculos do assoalho pélvico (MAP) formada pelos músculos bulbocaverno, isquiocavernoso, transverso superficial do períneo e esfíncter anal externo. Cranialmente localizada encontra-se a camada profunda dos MAP, sendo possível visualizar os músculos puborretal e ileococcígeo que compõem o músculo levantador do ânus (MLA), recoberto por fáscia endopélvica. Fonte: Gilroy AM et al., Atlas de Anatomia. Rio de Janeiro: Guanabara Koogan ltda. 2008 p. 136

Figura 3 – Vista lateral da estruturas uretral e muscular do assoalho pélvico. BC representa o músculo bulbocavernoso; CU, compressor da uretra, D, detrusor (músculo liso de compõe a parede vesical); LA, músculo levantador do ânus; US, esfíncter uretral; UVS, esfíncter uretrovaginal. O músculo puborretal foi removido para fins didáticos. Fonte: Ashton-Miller e DeLancey. Functional anatomy of pelvic floor, 2007.

1.2.2.2 Função muscular do assoalho pélvico

Funcionalmente, a atividade basal normal do MLA nas mulheres mantém o hiato urogenital fechado, contribui para a continência urinária e anal e evita prolapsos, pois comprime a vagina, uretra e reto contra o osso púbico no sentido cefálico (ASHTON-MILLER; DELANCEY, 2007; CORTON, 2009). A contração voluntária máxima do MLA favorece ainda mais compressão sobre o terço médio da uretra, da vagina e reto, mais distalmente, contra o osso púbico e, mais proximalmente, contra o aumento da pressão hidrostática abdominal. A contração do músculo bulbocavernoso e das fibras ventrais do iliococcígeo aumentam apenas um pouco a força de compressão desenvolvida pelos músculos pubovisceral e puborretal. Isso ocorre porque o primeiro desenvolve pouca força e o segundo está localizado muito dorsalmente para ter algum efeito intravaginal. A contração das fibras médias e dorsais dos músculos iliococcígeos elevam a parte central do assoalho pélvico posterior, mas pouco contribuem para a força muscular dos MLA quando mensurada via intravaginal, porque eles não agem circunferencialmente (ASHTON-MILLER; DELANCEY, 2007).

Uma rede de suporte sob a uretra e colo vesical, dada pela parede vaginal anterior e tecidos conectivos que à fixam aos ossos pélvicos (porção pubovaginal do MLA e ligamentos cardinal e uterossacro) fornece um ponto de apoio firme contra o qual a uretra é comprimida durante aumentos de pressão intra-abdominal. Esse mecanismo permite manter a pressão de fechamento uretral maior que os aumentos súbitos de pressão vesical. Tanto no repouso, quanto no esforço, o MLA, em interação com a fáscia endopélvica, contribui para manter o fechamento do hiato urogenital ao resistir às cargas inerciais decorrentes da aceleração visceral e dos aumentos de pressão abdominal que ocorrem durante as atividades cotidianas que requerem o recrutamento dos músculos da parede abdominal e diafragma. (ASHTON-MILLER; DELANCEY, 2007). Durante a tosse, por exemplo, há aumento da pressão intra-abdominal da ordem de 150cmH_2O e um deslocamento da uretra no sentido caudal em 10mm no plano sagital. Devido à incompressibilidade do conteúdo abdominal, a parede abdominal e o AP se alongam levemente. Este último deve, então, desacelerar o momento causado pelos órgãos abdominais no sentido inverso e manter o suporte dos órgãos pélvicos e a continência (ASHTON-MILLER; DELANCEY, 2007; DELANCEY, 2010).

As evidências científicas a partir da revisão sistemática de ensaios clínicos aleatorizados conduzida por Bo e et al., 2012, indicam que o treinamento dos MAP (TMAP) é efetivo para o tratamento de mulheres com IU (BO, 2012), sendo recomendado como abordagem de primeira linha para essas mulheres (DUMOULIN; HAY-SMITH, 2014)(BO, 2012)(ABRAMS et al., 2005). Apesar de ainda se desconhecer o regime ótimo de TMAP em mulheres com IU, aquelas que o realizam têm 17 vezes mais chance de relatar cura/melhora do que aquelas do grupo controle (DUMOULIN; GLAZENER; JENKINSON, 2011). A lógica biológica para o efeito do treinamento baseia-se em dois princípios: (a) na contração muscular em momentos que antecedem o aumento de pressão intra-abdominal. A realização de uma manobra de contração dos MAP prévia à e durante a tosse (“The Knack”) se mostrou efetiva para evitar a perda urinária (MILLER; ASTHON-MILLER; DELANCEY, 1998); e (b) no treino de força visando a melhora do padrão de ativação muscular ou a hipertrofia muscular para aquelas mulheres que tem capacidade de contrair os MAP voluntariamente. A força muscular se correlaciona diretamente com a rigidez deste tecido (DELANCEY, 2010). O termo rigidez refere-se à resistência oferecida pelo tecido quando se tenta deformá-lo, por exemplo, durante a palpação (LATASH e ZATSIOROSKY, 2016). O aumento da rigidez tecidual (tecidos muscular e conectivo) decorrentes do treinamento muscular favorece o suporte das vísceras pélvicas, prevenindo a descida perineal e, subsequentemente, a redução das perdas urinárias (DUMOULIN; GLAZENER; JENKINSON, 2011). O TMAP é, basicamente, focado em treino de força e resistência musculares (DUMOULIN e JEAN, 2014).

No entanto, cerca de 30 a 45% das mulheres não é capaz de contrair os MAP mesmo depois de terem sido instruídas a respeito da correta contração (BO e SHERBURN, 2005; VERMANDEL et al., 2015; TALASZ et al., 2008). Portanto,
quase a metade das mulheres não se beneficiaria de tratamento efetivo para IU. A habilidade de se elevar ativamente o AP sem gerar aumento de pressão intra-abdominal e enrijecer o AP, para promover a função esfincteriana e o suporte de órgãos pélvicos, é pré-requisito para que o TMAP seja implementado. Essa habilidade requer uma combinação de fatores relativos às funções musculares, a seguir descritos:

a) interdigitação dos filamentos de actina e miosina para gerarem tensão no repouso;

b) deslizamento desses filamentos em uma contração voluntária, gerando o encurtamento dos sarcômeros (KNUTTGEN; KRAEMER, 1987) e, consequentemente, o encurtamento das fibras musculares;

c) tensão ótima de fáscias e ligamentos (THOMPSON et al., 2007) para, em conjunto com a contração muscular, oferecerem rigidez tecidual contra a qual a uretra é comprimida para fechamento de seu lume (ASHTON-MILLER; DELANCEY, 2007);

d) habilidade de se contrair prioritariamente os MAP sem aumento da pressão hidrostática abdominal (THOMPSON et al., 2007);

e) integridade neural (SHAH et al., 2014); etc. Portanto, essas informações apontam para a necessidade de se investigar a contribuição outras funções musculares, além de força e resistência, para o mecanismo de continência.

1.3 Terminologia e função muscular do assoalho pélvico - Termos, definição conceitual e operacional

Dada a relevância das funções musculares do AP (FMAP) para o mecanismo de continência e suporte de órgãos pélvicos é importante investigar como essas funções se comportam em mulheres com e sem IU para, por exemplo, identificar que mulheres estão mais propensas a desenvolver IU e para se estabelecer abordagens preventivas e terapêuticas mais efetivas. Uma revisão sistemática com o objetivo de avaliar estudos sobre FMAP (denominadas pelos autores de “PFM activation and strength components”) e informar sobre o comportamento dessas funções em mulheres com IU, mostrou que tanto a ativação do assoalho pélvico, registrada por eletromiografia, quanto os componentes de força, medidos por dinamometria ou manometria vaginal, influenciam positivamente a continência urinária. No entanto, os autores encontraram uma grande variedade de terminologia, bem como de procedimentos e instrumentos de mensuração (definições operacionais) das FMAP, o que impossibilitou o agrupamento de dados e a realização de meta-análise (LUGINBUEHL et al., 2015).

Assim, para que seja possível avançar no conhecimento científico, e disseminação da prática baseada em evidência, é preciso promover a comunicação efetiva entre os profissionais de saúde e o público de interesse a partir do uso padronizado da terminologia. Neste sentido, as definições conceitual e operacional dos termos utilizados para nomear os conceitos, devidamente ancorados em um referencial teórico consistente são fundamentais (PIERCE et al., 2015)(KAZDIN; NOCK, 2003).

Terminologia se refere ao “conjunto de termos específicos ou sistemas de palavras numa disciplina particular, nomenclatura” (HOLANDA, 2010). *Termos* se referem ao uso de palavra ou frase utilizada de forma clara e definida para designar um conceito ou algum assunto em particular (HOLANDA, 2010; OMS/ OPAS, 2003). A *definição conceitual* está relacionada ao significado de certas palavras ou termos e especifica o que deve ser quantificado. Já a *definição operacional* refere-se à mensuração do conceito a partir de, por exemplo, a especificação dos componentes-chave da definição conceitual e estabelece como medir um conceito (JACCARD; JACOBY, 2010). A definição operacional engloba tanto a *medida* de desfecho (instrumento utilizado para medir o desfecho) quanto a *mensuração* do desfecho (procedimentos detalhados de como a medida é feita)(FAWCETT, 2007). Por exemplo, força (que é um *termo* que nomeia uma função muscular) é *conceitualmente definida* como a capacidade de um músculo gerar força (KNUTTGEN; KRAEMER, 1987). A *medida* de desfecho de sua *definição operacional* pode ser a dinamometria, manometria ou palpação vaginal (BO et al., 2015). Tendo-se optado pela palpação vaginal, a Escala de Oxford Modificada (EOM) pode ser usada para categorizar o desfecho (BO et al., 2015). E a *mensuração* do desfecho consiste dos procedimentos para proceder a mensuração, ou seja, em posicionar a mulher em supino com os joelhos apoiados sobre um rolo de espuma e os quadris abduzidos e rodados lateralmente. À mulher é solicitada a contração máxima dos MAP como se tentasse segurar gases ou conter a urina, sem o uso de musculatura sinergista (BO et al., 2015).

A definição baseada na operacionalização das variáveis, embora seja lógica, objetiva e direta, conforme requer a ciência (JACCARD e JACOBY, 2010), conduz ao operacionismo. Este refere-se a abandonar a definição conceitual e restringir a ciência à definição operacional. O problema do operacionismo é que quando a forma de se mensurar um conceito se torna sinônimo do conceito em si, toda vez que se modifica o método de mensuração, cria-se um novo conceito. O resultado é a proliferação de definições, o que impede a comunicação clara e efetiva entre profissionais e pesquisadores, o agrupamento de dados e, por consequência o avanço da ciência (JACCARD; JACOBY, 2010).

Dentro desse panorama, ainda há a variação no conteúdo da informação de saúde, ou seja, do referencial teórico em que está baseado o conceito. Esta variação ocorre quando a informação é coletada dentro do mesmo domínio, mas estruturada em referenciais teóricos distintos. Por exemplo, a função muscular tônus pode ser conceitualmente definida sob a perspectiva neurofisiológica, como o nível basal de atividade eletromiográfica; ou sob a perspectiva mecânica, como a sensação de resistência oferecida pelo segmento corpóreo de uma pessoa quando se pede o relaxamento completo e o clínico move o membro de forma lenta ao longo de sua amplitude de movimento (LATASH; ZATSIORSKY, 2016). De fato, ambas as perspectivas informam sobre tônus. Apesar de cada uma ser válida, é fundamental que os constructos estejam ancorados em um referencial teórico para a definição apropriada de como mensurá-los (JACCARD e JACOBY, 2010). Assim, a apresentação clara da definição conceitual considerada permite a identificação do referencial teórico que embasa o trabalho em questão, facilita a comunicação, portanto deveria ser mencionada.

Em 2005 a *International Continence Society* (ICS) propôs um documento visando padronizar a terminologia das funções e disfunções dos músculos do assoalho pélvico e favorecer a comunicação a esse respeito (MESSELINK et al., 2005). A padronização é baseada no modelo etiológico de sinais e sintomas de saúde/doença e define o diagnóstico da condição muscular como músculos hiperativos, normais, hipoativos ou não funcionantes a partir da combinação dos sinais relativos à capacidade de contração e relaxamento dos MAP, com os sintomas das DAP (MESSELINK et al., 2005). O documento menciona os termos *voluntary contraction, voluntary relaxation, involuntary contraction, involuntary relaxation, non-contracting pelvic floor, non-relaxing pelvic floor*, e *non-contracting* + *non-relaxing pelvic floor*, para se referir às FMAP. Estes termos parecem pouco esclarecedores para guiarem a avaliação, diagnóstico e raciocínio clínico para proposição da conduta fisioterapêutica. Além disso, o documento informa que não é apropriado usar outros termos que não contração e relaxamento dos MAP para se referir a suas funções, ressaltando que "muscle tone" não pode ser medido, e que o termo "force" e outros relacionados como "strength", "power", endurance" e "exhaustion" ainda não são aplicáveis à prática clínica.

Recentemente em 2016, a ICS publicou um *joint report* em conjunto com a *International Urogynecological Association* (IUGA) sobre a terminologia para a conduta conservadora e não farmacológica de DAP, incluindo-se aqui a atualização do documento sobre terminologia publicado em 2005. A partir de metodologia de *brain storming*, os autores listaram os termos mais frequentemente descritos na literatura sobre FMAP. Eliminaram alguns termos contidos no documento anterior e reorganizam outros. Chegaram a uma lista de 16 termos, sendo classificados sob o título "sinais das FMAP". Neste nível encontram-se descritos os termos como "Normal PFM contractile function", "muscle tone", "stiffness", "spasm", "cramp", "trigger point" e "muscle action characteristics". Incluídos sob este último item estão descritos outros dez termos, como "muscle strength", "muscle power", "maximal voluntary contraction", "co-contraction", "antagonistic contraction", "sinergistic contraction", "coordination", etc. (BO et al., 2016). Embora mais abrangente, as informações parecem redundantes e pouco claras com relação às FMAP relevantes de serem avaliadas em mulheres com DAP para a prática do fisioterapeuta.

Tendo em vista que o foco da terminologia para funções musculares proposta pela ICS/IUGA é baseada no modelo médico de sinais e sintomas usados para se referir a doenças e que os documentos apresentam alguns termos e definições que são poucos claros e parecem se sobrepor, a presente tese toma como referência a nomenclatura da Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF). Esta foi proposta pela Organização Mundial de Saúde (OMS) e buscou, a partir dessa classificação, entre outros aspectos, estabelecer linguagem padronizada para favorecer a comunicação sobre saúde e assistência à saúde de forma universal entre diversos países, profissionais de saúde, pesquisadores, elaboradores de políticas públicas e população em geral (OMS/ OPAS, 2003). A CIF é baseada na perspectiva holística bio-psico-social, ao invés de em sinais e sintomas de doenças. A classificação oferece termos específicos e definições conceituais a partir do significado compartilhado[1] descritos na literatura para codificar a saúde e os estados a ela relacionados. A CIF não define como medir os conceitos, ou seja, não estabelece as definições operacionais. Para isso, é preciso o uso de testes padronizados descritos na literatura especializada. Mas sim, ela permite delinear os conceitos relevantes de serem medidos, por exemplo, na avaliação fisioterapêutica. . Por exemplo, *função muscular* é um componente fundamental para o movimento humano, objeto de estudo do fisioterapeuta. Na CIF, está conceitualmente definida como “funções fisiológicas exercidas pelos músculos”. E, sob este componente estão identificadas funções musculares como força e resistência (OMS/OPAS, 2003) que também apresentam suas definições conceituais específicas.

Por meio de sua linguagem padronizada, a CIF fornece um sistema para a codificação de informações sobre a saúde e é complementar à Classificação Internacional de Doenças (CID) para estabelecer o impacto da doença sobre a funcionalidade do indivíduo. É organizada em componentes da funcionalidade e incapacidade, a saber: componente *corpo* (subdividido em dois domínios[2]: *estrutura* e *função do corpo*); componente *atividade e participação* (domínios áreas da vida, como tarefas e ações), e componente de fatores contextuais (*ambientais*: influências externas sobre a funcionalidade/incapacidade; e *pessoais*: influências internas sobre esses aspectos). Estes *componentes* são organizados em capítulos. Cada capítulo representa um *domínio* que apresenta classes e subclasses, denominadas de *categorias*, que são as unidades de classificação. As *subclasses* representam um detalhamento da informação contida em cada classe.

O código da CIF é composto por letras e números. O domínio *estrutura do corpo* é codificado na CIF em códigos compostos por números precedidos da letra *s*; *função do corpo* é identificado pela letra *b* precedendo os números; para *atividade e participação a letra é d*, fatores ambientais é identificado pela letra *e*; e os *fatores pessoais* não apresentam codificação específica. A quantidade de números contida no código se refere ao número de *classes/subclasses* que aquela *categoria* apresenta. Ou seja, quanto mais números, mais detalhada/precisa é a informação. Por exemplo, o código *b7*300 se refere ao componente *b função do corpo*, descrito no capítulo 7 onde estão descritas e classificadas as *Funções Neuromusculares e Relacionadas ao Movimento*, à classe b730 *Funções relacionadas à força muscular e* à subclasse *b7300 Força de músculos isolados e de grupos de músculos*. Neste capítulo ainda estão listadas outras categorias, a seguir descritas: b710 *Funções relacionadas à mobilidade das articulações*; b750 *Funções relacionadas à estabilidade das articulações*; b720 *Funções de mobilidade óssea*; b730 *Funções relacionadas à força muscular*; b740 *Funções de resistência muscular*; b750 *Funções relacionadas ao reflexo motor*; b760 *Funções relacionadas ao controle de movimentos voluntários*; b770 *Funções relacionadas ao padrão de marcha*; b780 *Sensações relacionadas aos músculos e funções de movimentos*; b798 *Funções neuromusculoesqueléticas* e *relacionadas ao movimento, outras especificadas;* e b799, *não especificadas*.

As funções musculares são interdependentes e se organizam num espectro contínuo representado na figura 4, de acordo com alguns critérios em comum entre elas. O esquema parte dos reflexos simples, involuntários e estereotipados, até à ação voluntária e coordenada com relação à presença de estímulos desencadeadores, tempo de resposta, número de sinapses neurais, características da ação e às estruturas neuronais envolvidas (LATASH e ZATZIORSKY, 2016.

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[1]Significado compartilhado (*shared meaning*) refere-se à conceptualização subjacente conforme representada em nossas mentes que coincide com os símbolos externamente visíveis utilizados para a comunicação em relação a esses conceitos (JACCARD E JACOBY, 2010).

[2]Domínios referem-se a conjuntos práticos e significativos de funções relacionadas à fisiologia, estruturas anatômicas, ações, tarefas ou áreas da vida (CIF/OMS, 2001).

REFLEXO		**AÇÃO VOLUNTÁRIA**
sempre	**Relacionado a um estímulo**	algumas vezes
curto	**Tempo de resposta**	longo
poucas	**Sinapses**	muitas
simples	**Ação**	complexa
estereotipado	**Resposta**	variável
medula espinal	**Estruturas neuronais**	cérebro

Figura 4 - Ilustração representando o *continuum* das funções musculares partindo-se dos reflexos até os movimentos voluntários de acordo com alguns critérios em comum. (traduzido de LATASH E ZATZIORSKY, PAG 101)

Assim, para que um músculo seja capaz de executar uma ação em um padrão coordenado de movimento, formando sinergias com outros músculos, e também gerar força muscular e ser capaz de manter a contração por o tempo apropriado em resposta à demanda funcional, é necessário que funções musculares mais elementares, como o tônus e a capacidade de contrair e relaxar voluntariamente os músculos estejam íntegras (LATASH; ZATSIORSKY, 2016).

1.4 Avaliação e diagnóstico das funções musculares do AP

Se, por um lado, está evidente que o TMAP é efetivo para o tratamento de mulheres com IU, a busca pela resposta de qual seria o melhor regime de treinamento para quais mulheres persiste (DUMOULIN; GLAZENER; JENKINSON, 2011). No entanto, a definição da estratégia terapêutica apropriada requer o estabelecimento de um diagnóstico fisioterápico claro e preciso a partir da avaliação. Trata-se a *avaliação* fisioterápica de um processo continuamente efetuado no transcurso do tratamento, pelo qual o fisioterapeuta coleta dados do paciente/cliente por meio de entrevista e exame físico para desenvolver o raciocínio clínico (“Description of Physical Therapy”, 2007). O *diagnóstico* fisioterápico é decorrente do processo de avaliação e refere-se à identificação da presença de (potenciais) deficiências, limitações e restrições e dos fatores de contexto que influenciam as incapacidades identificadas. A partir do diagnóstico, é possível traçar a *estratégia* ou *conduta fisioterápica*, ou seja, definir o conjunto de recursos e técnicas fisioterapêuticas a serem utilizados (se cinesioterapia, eletroterapia, treino funcional, técnicas de proteção e reparo tecidual, orientações ao paciente, etc.) para prevenir, minimizar ou eliminar as deficiências nas estruturas e funções do corpo, limitações nas atividades e restrições na participação social. Em outras palavras, a estratégia fisioterápica visa promover a funcionalidade do indivíduo, que representa o foco da de atuação do fisioterapeuta(WCPT, 2007).

Sendo a avaliação e o diagnóstico os pontos de partida para a definição da conduta terapêutica, uma revisão recente das diretrizes para guiar a prática clínica na abordagem diagnóstica e terapêutica da IU apontou para a importância do exame físico, incluindo a avaliação das funções musculares do assoalho pélvico (FMAP). Três das sete diretrizes incluídas no estudo recomendam essa avaliação. No entanto, essas recomendações são baseadas em estudos cujos benefícios e riscos não justificam a generalização da recomendação ou em opinião de *experts* (SYAN; BRUCKER, 2015).

Algumas escalas e esquemas de avaliação das FMAP, cuja definição operacional se baseia na palpação vaginal, já foram previamente propostas, como a escala de Brink, escala de Ortiz, Escala de Oxford Modificada (EOM) e o esquema PERFECT (LAYCOCK; JERWOOD, 2001; ORTIZ; NUNEZ, 1996; SAMPSELLE; BRINK; WELLS, 1989). Todas estas escalas tem como foco o exame de duas funções musculares: força e resistência. Em 2009, Hove et al., propuseram um esquema baseado na terminologia proposta pela ICS e o testaram quanto à sua validade aparente e confiabilidade intra e interexaminador (HOVE et al., 2009). O esquema considera outras funções musculares como a capacidade de contração, relaxamento e a resposta dos MAP a uma perturbação, como a tosse. Refere-se a essas e outras funções musculares, como força e resistência, mas também a sinais observáveis da contração e relaxamento dos MAP, como elevação uretral, fechamento do hiato do levantador do ânus e movimento para dentro do períneo. Ou seja, apresenta níveis diferentes de análise de uma mesma função muscular que não levantam informações adicionais que possam orientar a prática clínica. Assim, incluídos no esquema encontram-se 18 itens que devem ser observados e percebidos pela palpação vaginal durante o exame das FMAP, tendo alguns a terminologia da ICS, e outros propostos pelos autores. Embora o exame tenha apresentado validade aparente atestada por um esquema Delphi de discussão entre especialistas sobre o seu conteúdo, e boa reprodutibilidade interexaminador para 10 dos 18 itens, apenas três deles tiveram confiabilidade intraexaminador. Os autores concluíram que seus resultados indicam a necessidade de refinamento do esquema de avaliação antes de ser implementado na prática clínica (HOVE et al., 2009).

Desta forma, é necessário avançar no estudo do diagnóstico das FMAP tendo como foco, não a doença, a partir de sinais e sintomas, mas sim a funcionalidade, a partir da identificação de que aspectos da estrutura e função do corpo, da atividade e participação e dos fatores de contexto são relevantes de serem investigados em mulheres com DAP. A partir do paradigma da funcionalidade, e tendo como ponto de partida as funções musculares do assoalho pélvico, é importante responder as seguintes perguntas:

a. Quais são as funções musculares investigada na literatura especializada?
b. As FMAP são descritas na literatura por meio de terminologia padronizada?
c. Quais são as FMAP relevantes em mulheres que contribuem para a continência urinária?
d. Quais são os parâmetros funcionais das FMAP a serem atingidos durante o treinamento dos MAP de mulheres com IU?

Essas informações podem fornecer subsídios científicos para recomendações mais robustas para a prática clínica. Por exemplo, pode ser possível: 1) identificar quais funções musculares devem ser priorizadas durante a avaliação e a reabilitação em mulheres com IU; 2) estabelecer parâmetros objetivos para guiar intervenções fisioterapêuticas dose específicas, mais efetivas e de menor custo (JETTE, 2017); 3) estabelecer critérios de alta e/ou redirecionamento da estratégia terapêutica; e 4) identificar as mulheres sob risco de desenvolver IU do ponto de vista muscular.

A IU é a DAP mais prevalente entre as mulheres, influencia negativamente sua qualidade de vida e representa elevado custo financeiro para o sistema de saúde e para as pacientes, desta forma, é considerada um problema de saúde pública (SUNG E HAMPTON, 2009; ARAUJO et al., 2009; KWON et al., 2010; SIDDIQUI et al., 2014). Embora seja de causa multifatorial, os MAP são parte do mecanismo de continência e seu treinamento é considerado tratamento de primeira linha de IU, já que aquelas que o fazem tem 17 vezes mais chances de cura/melhora da IU (DUMOULIN; GLAZENER; JENKINSON, 2011; DUMOULIN; HAY-SMITH,

2014). Também, as escalas de avaliação das funções musculares do assoalho pélvico descritas na literatura são focados em avaliar força e resistência (LAYCOCK; JERWOOD, 2001; ORTIZ; NUNEZ, 1996; SAMPSELLE; BRINK; WELLS, 1989),
sendo que quase 40% das mulheres não é capaz de sequer contrair os MAP adequadamente. O instrumento que avalia outras funções musculares não apresentou bons índices de confiabilidade intraexaminador e teve apenas a validade aparente testada. Apresenta níveis diferentes de análise de uma mesma função muscular que não adicionam informações à prática clínica. Sua terminologia é baseada naquela proposta pela ICS, no entanto, adiciona outros termos não reportados pela ICS (HOVE et al., 2009). Além disso, a terminologia da ICS é focada em sinais e sintomas e não na funcionalidade humana. Tendo como referencial teórico o paradigma da funcionalidade com foco na abordagem holística bio-psico-social na qual se baseia a CIF/OMS, compreender as deficiências das funções do corpo de mulheres com DAP, em especial, daquelas relacionadas aos músculos do assoalho pélvico é o ponto de partida para se estabelecer uma avaliação fisioterapêutica focada no indivíduo e não na doença. A avaliação conduz ao diagnóstico fisioterápico e, a partir daí, é possível traçar a conduta fisioterápica, também com foco na funcionalidade, de forma mais apropriada e efetiva.

O paradigma holístico ainda permite identificar os passos futuros para se traçar uma avaliação fisioterápica global. Deve-se buscar compreender o comportamento de outras estruturas e funções do corpo relacionados à postura e movimento humanos nessa população; bem como a inserção da mulher com DAP nas atividades e na participação social e os fatores de contexto que influenciam a funcionalidade dessa mulher.

1.5 Objetivos

1.5.1 Objetivo geral

Desenvolver o Exame das Funções Sensoriais e Musculares do Assoalho Pélvico (EFSMAP) a partir da literatura especializada e da terminologia da CIF/OMS, testar a confiabilidade e validar o EFSMAP para mulheres com disfunções do assoalho pélvico.

1.5.2 Objetivos específicos

1.5.2.1 Identificar as funções musculares do assoalho pélvico mais investigadas na literatura e como são mensuradas/operacionalizadas, por meio de uma revisão sistemática da literatura;

1.5.2.2 Investigar a consistência no uso da terminologia das funções musculares do assoalho pélvico na literatura especializada identificando os termos, definição conceitual e operacional dessas funções musculares;

1.5.2.3 Lincar a terminologia encontrada na literatura especializada com a terminologia da Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF) da Organização Mundial da Saúde (OMS);

1.5.2.4 Desenvolver um Exame de Funções Sensoriais e Musculares do Assoalho Pélvico (EFSMAP) a partir dos objetivos 1, 2 e 3;

1.5.2.5 Testar a reprodutibilidade intra e inter-examinadores do EFSMAP;

1.5.2.6 Testar a validade do EFSMAP para mulheres com disfunções do assoalho pélvico.

2. MATERIAIS E MÉTODOS

2.1 Artigo 1

Trata-se de estudo de revisão sistemática da literatura sobre as FMAP investigadas em mulheres com IU. Esta revisão foi conduzida conforme as diretrizes do *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) (LIBERATI et al., 2009) e foi registrada no *Interrnational Prospective Register of Systematic Reviews* (PROSPERO) do *National Institute for Health Research* sob o número 2016:CRD42016045260

Dois revisores trabalharam de forma independente em todos os passos do presente estudo e um terceiro revisor foi consultado para discussão de discordâncias e consenso entre os dois primeiros investigadores.

As buscas foram realizadas nas seguintes bases de dados eletrônicas: PUBMED, CINAHL, LILACS e SCIELO, no período de 2005 a agosto de 2017. As bases foram selecionadas por serem as principais de referência para disseminação das publicações relativas às FMAP e Fisioterapia. O ponto de corte para o início das buscas em 2005 foi estabelecido por ser o ano da publicação do 1º documento da ICS sobre a padronização de terminologia das funções e disfunções dos músculos do assoalho pélvico (MESSELINK et al., 2005). As listas de referência dos estudos incluídos também foram rastreadas para possível seleção de artigos para esta revisão.

A estratégia de busca para a base PUBMED constou de quatro grupos de palavras-chave e descritores MeSH: a) *structure (pelvic floor, muscle*); b) *function* (*weakness, strength, force, power, tonus, stiffness, relaxation, contraction, control, ability, endurance, coordination*); c) *health condition* (*urinary incontinence*); d) *population* (*female AND humans*). Para as bases SCIELO, LILACS and CINAHL as palavras "*pelvic floor*" AND *"musc*"* foram usadas. A busca foi focada na sensibilidade para garantir a recuperação de artigos relevantes sobre FMAP. A estratégia de busca completa encontra-se no Apêndice A.

Foram incluídos estudos observacionais exploratórios que avaliaram FMAP e mencionaram esta informação no título, resumo ou objetivos do estudo de mulheres com e sem IU, publicados em português, inglês e espanhol. Estudos que apresentaram dados de homens e mulheres de forma separada também foram incluídos.

Foram excluídos estudos de revisão (sistemática, narrativa ou protocolo), metodológicos (confiabilidade, validade e de desenvolvimento de métodos), ensaios clínicos e protocolos, diretrizes práticas/clínicas, cartas ao editor, resumos de conferências, padronizações. Estudos que tratassem de outras DAP que não IU e entre mulheres com outras condições de saúde associadas, como acidente vascular encefálico, esclerose múltipla, câncer pélvico, em populações de gestantes ou mulheres que tiveram parto nos últimos 12 meses, atletas, crianças, cadáveres e animais. Também, estudos em que a mensuração das FMAP foi feita via uretral ou anal/retal foram excluídos.

Os dados foram extraídos e registrados em uma tabela contendo as seguintes informações: desenho do estudo, população e características dos participantes (idade, paridade e DAP), tamanho da amostra e FMAP (termo, definição conceitual e definição operacional e dados quantitativos).

Os *termos*, *definição conceitual* e *definição operacional* foram extraídos conforme definidos na introdução desta tese. As informações foram extraídas exatamente conforme citadas pelos autores dos estudos incluídos. O nome da variável foi citado como termo representando a função muscular, quando este não era apresentado. Quando mais de um termo foi utilizado para se referir à mesma função, todos eles foram extraídos. Também, quando um termo foi operacionalmente definido por mais de uma *medida de desfecho* (por exemplo, palpação vaginal e manometria) ou *mensuração de desfecho* (por exemplo, supino, de pé, etc), o termo foi incluído tantas vezes quanto foram os resultados quantitativos fornecidos pelas diferentes definições operacionais. Os dados quantitativos foram extraídos para fins metodológicos apenas, pois, quando não estavam reportados na seção de resultados do artigo, as informações sobre terminologia das FMAP não foram extraídas. Também, informações relativas a outros domínios de função do corpo não primariamente relacionados à função muscular e definidos no capítulo 7 da CIF/OMS não foram extraídas (como ângulo de medida uretral via ultrassonográfica ou via teste do cotonete, teste de interrupção de urina, escalas de depressão ou qualidade de vida).

O risco de viés dos estudos incluídos foi avaliado por meio de um questionário desenvolvido para avaliar a qualidade de estudos observacionais

(PRINS et al., 2002). Este instrumento é baseado na “informatividade” (descrição clara do referencial teórico e objetivos), “validade externa e interna”. Foram feitos ajustes no questionário, como previamente realizado por outros autores (HOFMEESTER et al., 2015) conforme a seguir: a) adicionando-se uma questão relativa à *confiabilidade* dos instrumentos, *termos* e *definição operacional* das FMAP; b) substituindo o termo *doença* por *função*; c) excluindo-se as seguintes questões que não se aplicam aos objetivos do presente estudo: “Does the method to select and invite participants is clearly described?” e “Is the period covered by the measurement instrument specified?”. A questão adicionada sobre confiabilidade foi pontuada positivamente quando os autores testaram a confiabilidade de seus instrumentos e mensurações no estudo em questão ou em um estudo prévio, em que pelo menos um dos autores fez parte. Os procedimentos para pontuação das demais questões encontram-se descritos em PRINS et al., 2002.

As seguintes regras foram utilizadas para sintetizar os dados. Os *termos*, *definições conceitual* e *operacional* foram organizados conforme uma ordem de agrupamento em três níveis. Considerando que *termos* são o ponto de partida para se estabelecer um sistema conceitual (JACCARD; JACOBY, 2010), o primeiro grupo foi definido a partir daí e a frequência absoluta em que os *termos* foram encontrados na literatura foi descrita. Um termo-chave (isto é, um termo em comum entre vários usados para nomear uma dada FMAP) guiou o agrupamento neste nível. Por exemplo, “strength” foi o termo-chave que gerou um grupo incluindo termos como “perineal muscle strength”, “pelvic floor contraction strength”, “strength at maximum voluntary contraction”, “strength peak pressure”, e assim por diante.

Já que *termos* similares podem não representar conceitos semelhantes, um segundo nível de grupamento foi estabelecido a partir das *definições conceituais*. Cada *definição conceitual* (sempre que presente) ligada ao seu termo, foi agrupada com outras *definições conceituais* semelhantes pela identificação de ideias-chave. Por exemplo, “presence and intensity of a voluntary muscle contraction” foi agrupada com “vaginal pressure or muscle force during the performance of a voluntary PFM contraction”, e “sustained PMF contraction” foi agrupada com “the point of isometric fatigue where the muscle contraction could no longer be maintained at a certain level”.

O terceiro nível de agrupamento foi definido a partir das *definições operacionais*. Os grupos de instrumentos de medida descritos por (BO et al., 2015) foram usados para agrupar informações neste nível conforme a seguir: observação visual (p.ex. “inward or downward movement of perineum”, “visible co-activity of other muscles”), palpação vaginal [p.ex. “Modified Oxford Scale (MOS)”, “Brink scale”], manometria vaginal (p.ex. “Perina®”, “Peritron®”, “PFX2® perineometer”), eletromiografia (EMG) (p.ex. vaginal ou abdominal), dinamometria de assoalho pélvico (p.ex. “speculum by Morgan’s”, “by Dumolin’s”), ultrassom (US) (p.ex. transabdominal or transperineal), e imagem por ressonância magnética (RM).

Os resultados foram apresentados de acordo com o *termo* usado para descrever FMAP e, na sequência, de acordo com a *definição conceitual* e *operacional*.

2.2 Artigo 2

Trata-se este estudo de um processo de lincagem das FMAP identificadas na revisão sistemática (Artigo 1) com a terminologia da CIF/OMS, conforme regras padronizadas de lincagem desritas por CIEZA et al., 2016. A partir da lincagem, buscou-se identificar as funções musculares mais frequentemente investigadas na literatura e que instrumentos foram os mais utilizados para mensurar essas funções.

O processo de lincagem é baseado em dez regras, que levam em consideração o objetivo do estudo e a definição operacional dos desfechos, conforme descritas a seguir: REGRA 1 - adquirir bom conhecimento dos fundamentos conceituais e taxonômicos da CIF/OMS; REGRA 2 - identificar o propósito da informação a ser vinculada (*Conceito principal*); REGRA 3 - identificar *Conceitos adicionais* contidos na informação que complementam o *Conceito principal*; REGRA 4 - identificar e documentar a perspectiva da informação (se *capacidade, desempenho, apreciação/ponderação* ou *necessidade/dependência*) ao vinculá-la à CIF; REGRA 5 - identificar e documentar a categorização das *opções de resposta*; REGRA 6 - vincular todos os *Conceitos principais* (os mais relevantes) e *adicionais*, com a categoria mais precisa da CIF/OMS; REGRA 7 – usar os códigos (8) “outra categoria ou (9) “categoria da CIF não especificada” conforme definido na CIF; REGRA 8 - se a informação fornecida pelo *Conceito principal* não for suficiente para tomar uma decisão sobre a categoria mais precisa da CIF, classificar o conceito como *nd (*“não definível”); REGRA 9 - se o *Conceito principal* não estiver contido na CIF, mas é claramente um fator pessoal, atribuir este conceito à *fp* (fatores pessoais); REGRA 10 - se o *Conceito principal* não estiver contido na CIF, classificar como conceito *nc* (“não coberto”) (CIEZA et al, 2016).

Assim, para a aplicação das regras, as seguintes informações foram extraídas dos estudos e organizadas em uma tabela, conforme proposta por Cieza, 2016: *Nome do instrumento; Instruções/orientações ao participante para mensurar o conceito; Opções de resposta, Classificação das opções de resposta (intensidade, duração, frequência, confirmação ou concordância, atributos qualitativos), Conceito principal, Conceitos adicionais, Categoria da CIF dos Conceitos principal e adicional* e *Anotações*.

Identificar os *Conceitos principais e adicionais* (regras 2 e 3) é o ponto de partida para vincular qualquer fonte de informação de saúde à CIF. Para evitar aplicação de regras de um modo muito rígido, não considerando o contexto/objetivo em que a informação foi coletada e levando à má interpretação e a uma vinculação incorreta dos conceitos, foi utilizada uma abordagem interpretativa, baseada nos objetivos do estudo (CIEZA et al., 2016).

Algumas FMAP identificadas na revisão sistemática precisaram ser agrupadas para o processo de vinculação e as variações nos procedimentos de mensuração (*mensuração do desfecho*) foram descritas como *Conceitos adicionais*. Por exemplo, Sapsford et al., 2006 and 2008, mediram a atividade eletromiográfica dos MAP em três posturas diferentes: “sentada postura relaxada e apoiada”, “sentada postura ereta sem apoio”, “sentada com coluna bastante ereta e sem apoio”. O *Conceito principal* considerado foi: atividade EMG dos MAP durante contração voluntária e o *Conceito adicional* foi: manutenção da posição corporal. Desta forma, as 196 FMAP iniciais da revisão sistemática foram agrupadas em 192 para o processo de vinculação.

Dados não relativos às funções FMAP, tais como estruturas musculares que não sejam MAP, posturas e atividades relacionadas à mobilidade, função sexual, funções respiratórias e etc, foram extraídas como *Conceitos adicionais*.

Para categorizar as *opções de resposta* dos instrumentos, sempre que escalas ordinais derivadas de informações qualitativas foram utilizadas, estas foram categorizadas como *atributos qualitativos*. Foi este o caso de instrumentos como Escala de Brink, Escala de Ortiz e EOM (SAMPSELLE et al., 1989; ORTIZ e NUNES, 1996, LAYCOCK e JERWOOD, 2001).

A lincagem com a CIF foi realizada por duas revisoras independentes, a primeira pesquisadora (FS) (fisioterapeuta, doutoranda em Ciências da Reabilitação e especialista em Saúde da Mulher com 14 anos de experiência na área); e a pesquisadora assistente (APGMG) (fisioterapeuta e mestranda em Ciências da Reabilitação). As divergências foram discutidas em diálogo aberto para consenso com a terceira pesquisadora e coordenadora do projeto (EMF), professora do Programa de Ciências da Reabilitação da UFMG com 20 anos de experiência em Ciências do Movimento e Saúde da Mulher (EMF) (FAYED et al., 2011). O percentual de concordância foi calculado e os resultados foram apresentados sob a forma de síntese narrativa. A frequência de ocorrência das funções investigadas e dos instrumentos utilizados foi computada.

2.3 Artigo 3

Trata-se de estudo metodológico para testar a confiabilidade e concordância intra e inter-examinadores do Exame das Funções Sensoriais e Musculares do Assoalho Pélvico (EFSMAP) que emergiu a partir da revisão sistemática e do processo de lincagem das FMAP com a terminologia da CIF/OMS. Este estudo foi conduzido de acordo com a Declaração de Helsinki e aprovado pelo Comitê de Ética da UFMG sob o parecer de número CAAE 44534615.5.0000.5149 (Anexo B), todos os participantes assinaram o consetimento de consentimento livre e esclarecido (Apêndice B). O documento de *Guidelines for Reporting Reliabilty and Agreement Studies* (GRAAS) (KOTTNER et al., 2011) foi utilizado para guiar a escrita do presente estudo.

Mulheres com e sem IU com idade igual ou acima de 18 anos, originárias de um serviço secundário público de ginecologia e da comunidade compuseram uma amostra de conveniência para este estudo. Mulheres virgens, grávidas, que tiveram aborto ou parto nos últimos 12 meses, que estavam no período menstrual, que apresentavam sintomas de infecção urinária e/ou vaginal, que foram submetidas a cirurgias pélvicas nos últimos cinco anos, que não compreendiam as orientações das pesquisadoras sobre a avaliação do assoalho pélvico e aquelas que recusaram a assinar o consentimento informado foram excluídas. As mulheres acima de 60 anos responderam ao Mini Exame do Estado Mental (MEEM) (Anexo C) e aquelas com alterações cognitivas detectáveis por este instrumento, considerando-se os pontos de corte de acordo com a escolaridade, foram excluídas (BERTOLUCCI et al., 1994). Para as medidas feitas utilizando-se o instrumento de manometria vaginal, a mulher deveria ser capaz de contrair os MAP ao comando e o canal vaginal deveria permitir a introdução da sonda do manômetro. Mulheres avaliadas entre Janeiro e Junho de 2016 participaram deste estudo.

O tamanho da amostra necessário para atingir índice de confiabilidade de 0,80 para variáveis contínuas, com poder estatístico de 80% e valor de alfa de 0,05, foi de 23 mulheres (KRAEMER; THIENIANN, 1987).

As FMAP relevantes de serem medidas, bem como os instrumentos utilizados para medir estas funções foram selecionados considerando dois estudos prévios (Artigo 1 e Artigo 2). As informações originadas desses estudos foram organizadas em um exame de avaliação dos MAP e culminaram com a elaboração do EFSMAP (TAB.1). A tabela 1 contém os termos que nomeiam as funções sensoriais (propriocepção e dor) descritas no Capítulo 2 (Funções sensoriais e dor) e as FMAP de acordo com o Capítulo 7 (Funções neuromusculoesqueléticas e relacionadas ao movimento) da CIF/OMS, com suas respectivas definições conceituais e operacionais.

As aferências são importantes fontes de informação para promover ações musculares e relacionadas ao movimento otimizadas (LATASH e ZATSIORSKY, 2016). Portanto, as funções sensoriais *propriocepção* e *dor* foram incluídas no esquema. Além disso, a presença de dor pode interferir na capacidade para contrair voluntariamente os músculos e no desenvolvimento da força (LOVING 2014; REISSING 2005). Embora a *pressão vaginal de repouso* não seja uma função muscular e também não está incluída na codificação da CIF, é um parâmetro frequentemente medido nos estudos de avaliação dos MAP como protocolo para utilização da manometria vaginal (BO; FINCKENHAGEN, 2001; FRAWLEY et al., 2006a; QUARTLY et al., 2010), portanto foi mensurada.

Para encorajar o uso deste exame na prática clínica, os instrumentos definidos para serem utilizados foram baseados naqueles simples e acessíveis e também nos mais frequentemente descritos na literatura científica. Tratam-se de instrumentos já validados para medir a força e a resistência dos MAP (BO et al., 1990; BO; SHERBURN, 2005; FRAWLEY et al., 2006; MESSELINK et al., 2005).

As funções são apresentadas a seguir utilizando-se os termos da CIF e seus respectivos códigos*: Função proprioceptiva* (b260), *Dor* localizada (b28018), *Tônus* (b7350), *Controle do Movimento Voluntário Simples* (contração) e (relaxamento) (b7608), *Coordenação do Movimento Voluntário* (b7602), *Reflexo de Movimento Involuntário* (tosse) (b755), *Força* (b7300), *Resistência muscular* (duração e repetições) (b7408) (Tabela 1). As funções foram operacionalizadas por meio da observação visual, palpação e manometria vaginal (Peritron®, CardioDesign PTY LTD – Australia). A manometria é um método válido para avaliar a força e a resistência dos MAP, desde que seja observado o movimento para dentro (no sentido cranial) da sonda e a contração dos músculos do assoalho pélvico sem o uso de sinergistas (Bo et al., 1990). O tempo de duração da contração na palpação e na manometria vaginal (este medindo-se o tempo de sustentação acima de 60% da CVM) foi registrado por meio de um cronômetro. Uma calculadora portátil foi utilizada para calcular 60% do valor da contração voluntária máxima (CVM) para quantificar a função *Resistência* (duração) por manometria vaginal (QUARTLY et al., 2010). A razão para se utilizar este ponto de corte é por corresponder a 12 contrações máximas repetidas, recomendado pelas diretrizes de atividade física do *American College of Sports Medicine* para o treinamento de resistência em adultos saudáveis (HASKELL et al., 2007), conforme previamente proposto por Quartly et al., 2010.

O treinamento dos examinadores e a coleta de dados foram realizados em seis etapas: 1ª) primeira rodada de discussão entre os examinadores; 2ª) primeira rodada de treinamento do esquema de avaliação por meio de estudo piloto com 10 participantes; 3ª) segunda rodada de discussão para esclarecer dúvidas e barreiras para as mensurações; 4ª) segunda rodada de treinamento do esquema de avaliação com outras 16 participantes; 5ª) terceira rodada de discussão sobre dúvidas; 6ª) avaliação final de 23 voluntárias para os testes intra e inter-examinadores incluídas neste estudo.

As participantes eram convidadas entre as mulheres que aguardavam nas salas de espera para o atendimento de ginecologia de rotina do Instituto Jenny de Andrade Faria do Hospital das Clínicas da UFMG, entre aquelas que estavam em fila de espera para o atendimento de fisioterapia devido à IU, entre as que eram encaminhadas pelo serviço de uroginecologia e de fisioterapia do referido instituto ou entre aquelas provenientes da comunidade externa ao Instituto. Todas as participantes foram instruídas sobre a estrutura, localização e função dos MAP, utilizando-se figuras anatômicas ilustrativas da pelve e órgãos pélvicos, e foram informadas sobre os procedimentos da entrevista e exame físico. Em seguida, as voluntárias responderam a um questionário de informações sociodemográficas e clínicas sobre funções urinárias, sexuais e defecatórias; recreação e lazer; hábitos alimentares e de ingestão líquida e medidas antropométricas (peso e altura). Posteriormente, as mulheres foram submetidas à avaliação conforme o EFSMAP, em sala reservada para este fim. A ficha de avaliação contendo as informações coletadas na entrevista e EFSMAP estão apresentadas nos Apêndices C e D.

As mulheres foram posicionadas em litotomia e o estadiamento de prolapsos dos órgãos era registrado por meio do esquema *Pelvic Organ Prolapse Quantification System* (POP-Q) (BUMP et al., 1996). Para a realização do EFSMAP, as voluntárias foram posicionadas em supino com flexão, abdução e rotação lateral dos quadris e flexão de joelhos de forma relaxada com os joelhos apoiados em um rolo com 30 cm de diâmetro e 70 cm de comprimento. As participantes foram instruídas a contrair os MAP como se tentassem interromper o fluxo de urina ou segurar gases, sem contrair os músculos sinergistas, como abdome, glúteos e adutores. Sempre que a contração dos MAP era realizada apenas com o uso de musculatura sinergista, esta informação era registrada e as voluntárias eram classificadas como apresentando deficiência na função de *Coordenação.* Os passos para a avaliação das FMAP seguiram uma ordem lógica, conforme apresentada na Tabela 1.

Para a confiabilidade e concordância inter-examinador, ambos os examinadores avaliaram as voluntárias no mesmo dia, com um intervalo de 10 a 20 minutos entre as avaliações e em ordem aleatória. Para a confiabilidade e concordância intra-examinador, a segunda avaliação foi realizada uma semana após a primeira, no mesmo período do dia em que aconteceu o exame prévio. Os procedimentos foram idênticos aos utilizados nos testes inter-examinador. As medições/classificações foram conduzidas de forma independente e mascarada pelos examinadores.

Para a avaliação das FMAP, sempre que a função *Controle (contração)* na palpação era classificada como “ausente” e a força graduada como “zero” ou “um” na EOM, as funções *Controle (relaxamento), Coordenação, Resistência (duração* e *repetições*) foram classificadas como "ausência de contração" e as medidas por palpação e manometria vaginal dessas funções não eram possíveis de serem realizadas. Sempre que isto ocorreu ou quando a mulher não tolerava a introdução da sonda no canal vaginal, a manometria vaginal não era realizada. Nestes casos, para o exame das FMAP por meio de manometria vaginal, novas participantes foram incluídas até que o tamanho calculado para a amostra fosse alcançado.

Tabela 1: Definições conceituais e operacionais do Exame das Funções Sensoriais e Musculares do Assoalho Pélvico (EFSMAP) conforme vinculação prévia com a terminologia da CIF/OMS.

Função	Definição Conceitual	Definição Operacional	Escala	Comando verbal
b260 Função proprioceptiva	Função sensorial que permite sentir a posição relativa das partes do corpo (OMS/OPAS, 2003).	Palpação digital vaginal: Examinador pressiona as paredes vaginais posterior (sobre o reto), laterais (posições 5h e 7h de um relógio) e anterior (sobre a uretra) e solicita que a mulher informe o sentido da pressão.	**Ausente**: não identifica os sentidos da pressão - anotar qual(is) parede(s) vaginal(is). **Presente**: identifica os sentidos da pressão.	"Eu vou pressionar assim (realiza pressão em uma parede vaginal) e você vai me dizer se estou pressionando para cima (apontar o sentido), para baixo (idem), para a direita (idem) ou para a esquerda (idem)"
b28018 Dor localizada	Sensação desagradável sentida em uma ou várias partes específicas do corpo que indica lesão potencial ou real de alguma estrutura (OMS/OPAS, 2003).	Palpação digital vaginal: Examinador exerce pressão digital sobre as paredes vaginais laterais, anterior e posterior e solicita que o paciente informe a presença de dor (MESSELINK et al., 2005). Em caso afirmativo, solicita-se que a paciente gradue a intensidade da dor (KATZ; MELZACK, 1999).	**Ausente**: Sem relato de dor **Presente**: Relata dor (anotar em qual(is) parede(s) vaginal(ais) **Escala de Classificação Numérica** (0-10)	"Eu vou pressionar as paredes da sua vagina e você vai me informar se sente alguma dor ou desconforto." "Qual a intensidade da dor/desconforto?"
b7350 Tônus muscular	Tensão presente nos MAP quando palpados no estado máximo de relaxamento que o indivíduo consegue atingir (LATASH; ZATSIORSKY, 2016).	Palpação digital vaginal: Examinador pressiona os ventres musculares do puborretal, alternadamente à direita e à esquerda (posições 7h e 5h de um relógio). Manobra repetida 3 vezes com os MAP relaxados após 3 contrações voluntárias (se possível) dos MAP (UNGER et al., 2014).	**Baixo**: músculo oferece mínima resistência à pressão (muito deformável; ou músculo não palpável devido à atrofia muscular por hipoestrogenia). **Normal**: músculo oferece alguma resistência à pressão (deformável). **Aumentado:** músculo rígido (pouco ou não deformável).	"*Respire fundo, solte o ar, contraia o períneo e pare de contrair (repetir essa sequência 3 vezes) Agora solte a contração e mantenha-se tranquila enquanto eu examino."

Continua...

b7608 Controle de movimentos voluntários simples (*contração*)	Capacidade de contrair os músculos do assoalho pélvico ao comando (LAYCOCK; JERWOOD, 2001).	<u>Inspeção</u> O examinador observa o movimento do períneo em resposta à contração (MESSELINK et al., 2005). <u>Palpação (bi)digital vaginal:</u> Examinador posiciona os dedos sobre os ventres musculares do puborretal, (posições 7h e 5h de um relógio)** e sente a resposta muscular à contração (MESSELINK et al., 2005).	<u>Inspeção:</u> **Presente:** quando observa-se o deslocamento cranial do centro tendíneo do períneo. **Ausente:** nenhum movimento do centro tendíneo do períneo é observado. <u>Palpação:</u> **Ausente:** Sem contração palpável dos músculos do assoalho pélvico. **Presente**: Aumento inequívoco da tensão muscular.	"*Respire fundo, solte o ar e contraia os músculos do períneo como se fosse segurar o xixi, evitando prender a respiração ou usar abdome, bumbum e/ou coxas, e depois pare de contrair."
b7608 Controle de movimentos voluntários simples (*relaxamento*)	Capacidade de relaxar os músculos do assoalho pélvico sob comando após uma contração (LAYCOCK; JERWOOD, 2001).	<u>Palpação (bi)digital vaginal</u>: Examinador sente a redução na tensão muscular à solicitação do relaxamento (MESSELINK et al., 2005).	**Ausente**: Nenhum relaxamento é sentido; a contração persiste, mesmo após o comando *"pare de contrair"*. **Parcial/lento**: Os MAP não retornam ao seu estado de repouso ou o fazem de modo lento. **Presente**: Os MAP retornam rápida e completamente ao seu estado de repouso. **ATENÇÃO:** Sempre que a função *Controle* (contração) for classificada como <u>ausente</u>, esta função não pode ser avaliada.	"Respire fundo, solte o ar e ontraia os músculos do períneo como se fosse segurar o xixi, e depois pare de contrair."
b7602 Coordenação dos movimentos voluntários	Ativação dos músculos corretos em tempo e intensidade corretos para uma desenvolver uma ação específica. (TURVEY, 1990)	<u>Palpação (bi)digital vaginal + inspeção:</u> O Examinador sente o aumento da tensão muscular e inspeciona o padrão respiratório e o uso de outros músculos durante a contração dos MAP: abdome, coxas e glúteos.	**Presente:** Contração dos MAP sem o uso de músculos sinergistas. **Ausente:** Contração dos MAP concomitante à contração visível de músculos sinergistas mais frequentemente observados: abdome, adutores, glúteos, respiratórios e valsava. **ATENÇÃO:** sempre que a função "Controle" na contração for classificada como ausente, a coordenação não poderá ser avaliada e deve ser registrada como NA (não se aplica)	"Respire fundo*, solte o ar e ontraia os músculos do períneo como se fosse segurar o xixi, evitando prender a respiração ou usar abdome, bumbum e/ou coxas, e depois pare de contrair."
b755 Reflexo (reação) de movimento involuntário (tosse)	Contração muscular em resposta a uma perturbação (LATASH E ZATSIORSKY, 2016).	<u>Palpação digital vaginal</u>: Examinador sente a resposta à solicitação de uma tosse intensa (MESSELINK et al., 2005).	**Ausente:** Não se sente contração muscular em resposta à tosse. **Presente:** Sente-se contração muscular evidente à direita e/ou esquerda da parede vaginal.	"Dê uma tosse forte."

Continua...

b7300 Força muscular	Força máxima que um musculo ou grupo de músculos pode gerar a uma específica velocidade de contração (CIRPIANI E FALKEL; 2007)	Palpação (bi)digital vaginal: Examinador identifica a intensidade da tensão muscular gerada pela contração assim como o deslocamento do dedo no canal vaginal. (LAYCOCK; JERWOOD, 2001).	**Escala de Oxford Modificada (EOM)** (LAYCOCK; JERWOOD, 2001): **0** Ausência de contração palpável. **1** Esboço de contração. **2** Percebe-se aumento de tensão sem elevação perceptível. **3** Aumento da tensão muscular caracterizada por elevação do ventre muscular e da parede posterior da vagina. Observa-se visualmente movimento para dentro do períneo e ânus. **4** Aumento da tensão muscular e boa contração estão presentes e são capazes de elevar a parede posterior da vagina contra resistência (pressão digital aplicada na parede posterior da vagina). **5** Forte resistência pode ser aplicada à elevação da parede posterior vaginal; o dedo do examinador é comprimido e sugado para dentro da vagina (como um bebê sugando o dedo).	"Contraia os músculos do assoalho pélvico com o máximo de força que conseguir sem usar bumbum, barriga e coxas ou prender a respiração."
		Manometria vaginal (Peritron[TM]): Sonda vaginal é coberta com preservativo não-lubrificado e pequena quantidade de gel à base de água é colocada na ponta da sonda. O manômetro é calibrado em zero antes da introdução da sonda na vagina. É introduzida no canal vaginal até que sua parte central esteja à 3,5cm do introito. Registra-se a pressão obtida durante o repouso (pressão vaginal de repouso). A calibração é feita novamente em zero e a mulher é solicitada a realizar três CVM com um minuto de repouso entre cada uma. O maior valor encontrado é registrado. (FRAWLEY et al., 2006b).	**Cm H_2O**	

Continua...

b7400 Resistência muscular (duração e repetições)	Capacidade de sustentar uma contração ou realizar um número de contrações até que ocorra fadiga ou degradação do movimento (CIPRIANI; FALKEL, 2007).	<u>Palpação (bi)digital vaginal:</u> Examinador sente o tempo de sustentação da contração máxima ou próxima da máxima. Uma queda consistente e marcada da intensidade da contração e/ou o início explicito do uso de músculos sinergistas são os pontos de corte para o registro da sustentação da contração muscular (LAYCOCK; JERWOOD, 2001). <u>Palpação (bi)digital vaginal:</u> Examinador sente o número de repetições da contração sustentada que a mulher é capaz de realizar. Os intervalos entre as contrações correspondem ao tempo de um ciclo respiratório (aproximadamente 4-5 segundos) O ponto de corte do número de repetições é qualquer sinal de fadiga muscular, como redução explícita da intensidade da contração, contração irregular ou relaxamento lento após a contração. Após identificar esses sinais, o examinador repete mais uma vez a contração, sem intervalo de repouso, para confirmar os sinais de fadiga (LAYCOCK; JERWOOD, 2001)	**Segundos** **Número** de contrações repetidas **ATENÇÃO:** Sempre que a função Controle – capacidade de *contração* (b7600) for <u>ausente</u> ou a função Força (b7300) for graduada como *ausente*, esta função não pode ser avaliada.	“Contraia os músculos do assoalho pélvico com força e mantenha essa contração pelo máximo de tempo que conseguir sem usar bumbum, barriga e coxas ou prender a respiração. Segure a contração, segure, segure.” Idem ao comando anterior, acrescido de: “Pare de contrair, respire fundo, solte o ar, contraia de novo e segure, segure, segure.”

Nota:*“Respire fundo”: comando que objetiva direcionar o foco da mulher para o seu corpo, de modo a favorecer a percepção corporal; ** Esta posição do dedo foi utilizada em todos os testes de palpação do canal vaginal, salvo indicação contrária.

Estatística descritiva (média, desvio padrão, frequência, mínimo e máximo) foi utilizada para descrever as variáveis, conforme apropriado. Para a análise da confiabilidade das variáveis contínuas foi calculado o Coeficiente de Correlação Intraclasse (CCI), modelo (2,1) para o teste interexaminador; e o modelo (3,1) para o teste intraexaminador. Os limites de concordância foram calculados conforme Bland e Altman, 1986, para testar a dispersão dos dados.

Para as variáveis categóricas e ordinais, o percentual de concordância e a estatística Kappa (K) e Kappa linear ponderado (Kw) foram utilizados para computar os erros de medidas e a confiabilidade, respectivamente (KOTTNER et al., 2011).

Os coeficientes de confiabilidade e concordância foram analisados como descritos por Portney and Watkins, 2009 (valores de CCI acima de 0,75 indicam boa confiabilidade e abaixo de 0,75 moderada ou baixa confiabilidade). Para concordância e índices Kappa, valores acima de 80% representam concordância excelente; acima de 60%, nível de concordância substancial; entre 60% e 40% concordância moderada e abaixo de 40% baixa concordância (LANDIS; KOCH, 1977; PORTNEY, LESLIE G; WATKINS, 2009).

O nível de significância estatística foi estabelecido em 5%. A análise foi realizada utilizando os softwares SPSS versão 19 e o VassarStats © disponível em http://vassarstats.net/kappa.html.

2.4 Artigo 4

Este é um estudo metodológico para testar a validade de constructo do EFSMAP que foi previamente testado quando à confiabilidade e concordância, atingindo bons índices de reprodutibilidade (Artigo 3). O presente estudo foi conduzido de acordo com a Declaração de Helsinki e aprovado pelo Comitê de Ética da UFMG sob o parecer de número CAAE 44534615.5.0000.5149 (Anexo B), todos os participantes assinaram o termo de consentimento livre e esclarecido (Apêndice B).

Trata-se de amostra de conveniência, cujos critérios de inclusão e exclusão e os procedimentos para coleta de dados e aplicação do EFSMAP foram descritos na seção Materiais e Métodos do Artigo 3. As mulheres que fizeram parte do estudo de validade foram avaliadas no período entre Julho de 2016 e Abril de 2017.

Durante a coleta de dados sócio-demográficos e clínicos, as mulheres responderam, sob a forma de entrevista, ao questionário *International Consultation Incontinence Questionnaire-Short Form* (ICIQ-UI-SF) (Anexo D). Este foi aplicado para identificar a presença de IU nas participantes e, a partir daí, definir os dois grupos de comparação (mulheres com IU e sem IU). O ICIQ-UI-SF é amplamente utilizado tanto na prática clínica quanto em pesquisas e é válido para avaliar a frequência, volume, gravidade e impacto da IU na qualidade de vida do indivíduo (AVERY et al., 2004; KLOVNING et al., 2009). Este questionário foi validado e transculturalmente adaptado para o português brasileiro (TAMANINI et al., 2004). Seu escore varia de zero (0) (ausência de IU) a 21 (maior impacto da IU na qualidade de vida). Em relação à gravidade da IU, o escore total do ICIQ-UI-SF seguiu a categorização proposta por (KLOVNING et al., 2009) em uma escala de quarto graus para descrever a população estudada, conforme a seguir: leve (1-5), moderada (6-12), grave (13-18) e muito grave (19-21).

Duas examinadoras previamente treinadas e que conduziram o estudo de confiabilidade do EFSMAP (Artigo 3) coletaram os dados das participantes de forma independente.

O cálculo amostral baseou-se na diferença entre a FMAP *Força*, medida por meio de manometria vaginal (Peritron®), ao comparar mulheres com e sem IU, pois essa função apresentou o menor tamanho do efeito (d=0,419) (THOMPSON et al., 2006a) dentre todos as outras FMAP testadas: *Força* (medida por palpação vaginal utilizando a Escala de Oxford Modificada – EOM), *Resistência* (duração) (THOMPSON et al., 2006b), *Controle* (contração) e *Coordenação* (GONTIJO, 2012). Para alcançar poder estatístico de 80% e nível de significância de 5%, foram necessárias 182 mulheres (91 mulheres no grupo com IU e 91 no grupo sem UI). As mulheres foram pareadas por idade, já que o envelhecimento está relacionado à sarcopenia e afeta o desempenho muscular (COOPER et al., 2013; FRONTERA et al., 2000), incluindo-se os MAP (ASHTON-MILLER; DELANCEY, 2007). Os softwares *G3Power* e *OpenEpi* foram utilizados para calcular o tamanho da amostra de variáveis contínuas e dicotômicas, respectivamente.

A normalidade dos dados foi testada por meio do teste Kolmogorov-Smirnoff. Estatística descritiva foi realizada para as variáveis (média, desvio padrão, mediana, intervalo interquartílico, frequência, mínimo e máximo) conforme apropriado. Os testes Qui-quadrado de Pearson e Exato de Fischer foram utilizados para testar a diferença entre os grupos em relação às variáveis categóricas e o teste de Mann-Whitney, para as variáveis contínuas.

O procedimento *known methods group* foi utilizado para testar a validade de constructo (PORTNEY, LESLIE G; WATKINS, 2009) do EFSMAP. Este método fornece evidências para justificar a validade de constructo por meio de teste que é capaz de discriminar/diferenciar os indivíduos que sabidamente apresentam uma característica específica ou condição de saúde, no caso do presente estudo, mulheres com IU, daquelas que não a apresentam. Os valores de sensibilidade e especificidade, com seus respectivos intervalos de confiança de 95%, foram calculados para as variáveis categóricas. Valores acima de 0,70 foram considerados satisfatórios como representativos de bons índices de sensibilidade e especificidade (FARR; SHAPIRO, 2000; VAN DER SCHOUW; VERBEEK; RUIJS, 1992). As curvas *Receiver Operating Characteristic* (ROC) foram calculadas para as variáveis ordinais e contínuas (PORTNEY, LESLIE G; WATKINS, 2009). Os pontos de corte foram calculados de acordo com a maior soma de sensibilidade e especificidade (FARR; SHAPIRO, 2000; VAN DER SCHOUW; VERBEEK; RUIJS, 1992). A presença de IU foi utilizada como padrão de referência para predizer um teste positivo. O nível de significância estatística foi estabelecido em 5%. A análise foi realizada utilizando-se o software SPSS versão 21.

3. RESULTADOS

3.1 Artigo 1 - Terminology of pelvic floor muscle function of women with and without urinary incontinence: a systematic review of the literature.

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ABSTRACT

Background: Pelvic floor muscle functions (PFMF) are targets of the physical therapy interventions for women with urinary incontinence (UI). However, possible variations in PFMF terminology might hamper communication among researchers and health care professionals of Women's Health.

Objective: To investigate the terminology of PFMF regarding clear *terms*, *conceptual* and *operational definitions*.

Data sources: PUBMED, CINAHL, LILACS and SCIELO.

Study eligibility criteria: Observational studies investigating any PFMF of women with or without UI, published in English, Spanish or Portuguese, published from 2005 to 2017.

Study appraisal, data extraction and synthesis methods: The risk of bias was assessed by a questionnaire on quality of observational studies. Data on terminology was extracted as *terms*, *conceptual* and *operational definitions* of PFMF, and synthesized according to *key-words*, *key-ideas*, and *key-operationalization* respectively. Consistencies and variations were identified for the most frequently PFMF investigated.

Results: Sixty-four studies were included and a low risk of bias was identified. All studies presented *terms* and *operational definitions* of PFMF, but only 29.7% presented *conceptual definitions* of those *terms*. One hundred and ninety six different *terms* referred to PFMF. According to similarities in terminology, 161 PFMF could be grouped into 26, but the other

35 were left ungrouped. Therefore, a total of 61 PFMF with different terminology were identified in the literature.

Limitations: Only observational studies were included.

Conclusions and implications of key findings: A large variation in PFMF terminology was identified, precluding data gathering and meta-analysis. The lack in the use of standardized terminology delays the progress of scientific knowledge and evidence based practice dissemination. Efforts towards a consensual terminology are necessary.

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INTRODUCTION

Effective communication among health care professionals, researchers, policymakers and target audience, by means of a standardized terminology drives the progress on scientific knowledge and evidence based practice dissemination.[1,2] The International Continence Society (ICS) has been making significant and ongoing efforts towards standardization on pelvic floor muscle function (PFMF) and dysfunction terminology to “enable effective communication by investigators performing pelvic floor muscle (PFM) studies”.[3] The ICS, in 2005, has published a document proposing a standardization for terminology of pelvic floor muscle function and dysfunction based on signs and symptoms.[3] Recently, a joint report of the ICS and the International Urogynecological Association (IUGA) updated the former document and presented terminology of 16 “PFM function signs”, including 10 “muscle action characteristics”.[4] The results of the ICS endeavor for adopting a standardized terminology for PFMF, to this date, remains unknown. In this regard, a recent systematic review investigating PFM activation and strength in women with urinary incontinence (UI) concluded that “a high variation of testing procedures, measurements methods and terminology, as well as definitions of the evaluated PFM”, hindered the possibility of gathering data and meta-analysis.[4] Thus, although PFMF of women with UI have been largely investigated in the literature[5–14], a clear PFMF terminology seems not to be observed.

Terminology refers to a system of terms belonging to a particular science or art.[15] Standardized terminology requires clear *terms*, *conceptual* and *operational definitions* of a particular subject (i.e., the PFMF). Since the PFM are skeletal muscles, they should have similar functions as other skeletal muscles. Muscle function refers to the physiological functions of muscles, such as strength, endurance and tone,[16] which are *terms* used to name some of the skeletal muscle functions. *Term* refers to a word or phrase used in a definite or precise sense in some particular subject.[17] *Conceptual definition* states what one means by the use of particular words, or *terms*,[18] and specifies WHAT needs to be evaluated, or measured.[18] *Operational definition* refers to the measurement of the concept. *Operational definition* states HOW to measure a concept[18] and it encompasses both the *outcome measure* (standardized instruments to measure the concept) and the *outcome measurement* (detailed procedures of how the measurement is taken).[19] For example, strength (a *term*) is *conceptually defined* as the capacity of a muscle to generate force,[20] and its *operational definitions* are vaginal dynamometry, manometry and palpation as well as their respective procedures to proceed with the measurement (Table 1).[21]

Since concepts are the building blocks for all thinking, gathering data require a conceptual system to organize them.[18] Thus, identifying consistencies in the use of the *terms* and *conceptual definitions* of the PFMF, as well as how they are measured (i.e. *operational definition*), would contribute to effective communication, data gathering and advances in the evidence-based approach to women with UI. Therefore, this systematic review was conducted to investigate if the terminology of PFMF is accomplished by the use of clear *terms*, *conceptual* and *operational definitions*.

METHODS

This systematic review was conducted following PRISMA guidelines[22] and registered *a priori* at PROSPERO under the no. 2016:CRD42016045260 (http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42016045260).

Data Sources and Searches

Literature searches were done in the following electronic bibliographic databases: PUBMED, CINAHL, LILACS and SCIELO, from 2005 to August, 2017. These databases comprise the majority of biomedical journals published in English, Spanish and Portuguese. LILACS and SCIELO are the main databases on biomedical literature for Latin America and Brazil respectively. Therefore, we found relevant/necessary to investigate how information on PFMF terminology is presented in our continent due to public health policy issues. The cut off year of 2005 was chosen according to the year of publication of the ICS report on terminology standardization on PFMF and dysfunctions.[3] Studies from the reference list of the included studies were also retrieved.

For the PUBMED search, four groups of MeSH descriptors and respective key-words were used according to: a) structure (pelvic floor, muscle); b) function (weakness, strength, force, power, tonus, stiffness, relaxation, contraction, control, ability, endurance, coordination); c) health condition (urinary incontinence); d) population (female and humans). For Scielo, Lilacs and CINAHL "pelvic floor" AND "musc*" were the key-words used. The search strategies were focused on search sensitivity in order not to miss any relevant articles on PFMF. No search to grey literature was performed. The full search strategy is presented as supplementary data in eAppendix (available at xxxx).

Study Selection

The focus of observational studies is on the phenomenon itself (i.e. the PFMF), rather than on manipulation of the phenomenon (PFMF as an outcome) as in experimental studies.[23] Therefore, only observational studies were included, as they would have higher chances to present clear conceptual and operational definitions of the PFMF. Observational studies regarding any PFMF mentioned either in title, abstract or in study aims were retrieved. Since UI is one of the most investigated and prevalent pelvic floor dysfunction in women, the study population was comprised of women with or without UI. Studies that presented data from both men and women, but stated results separately by sex were also included. Studies published in English, Spanish or Portuguese were retrieved, as the researchers were fluent on those languages. Exclusion criteria along with detailed inclusion criteria are depicted in Table 2. A librarian with FS and EMF collaboration developed the search strategy. FS and APGM performed independently the search strategy, studies' identification, eligibility and inclusion, and data extraction. FS and ROV worked independently in studies' quality assessment. Data analysis and synthesis were thoroughly reviewed by the project coordinator's EMF. Disagreements in all steps were managed through discussion with a third reviewer (EMF). Two reviewers worked independently in all steps of the present study and disagreements were managed through discussion with a third reviewer.

Data Extraction

Data was extracted and registered in a template previously pilot-tested, according to: study design, population and participants' characteristics (age, parity, pelvic floor dysfunctions), sample size, and PFMF (*term*, *conceptual* and *operational definitions* and quantitative data). Age and parity are mentioned as the major (and non-reversible) aspects that influence PFMF.[24–27] As women get older (from 15 to 80 years of age), there is a sevenfold decrease in the number of striated muscle fibers within the ventral wall of the urethra.[26,27] In addition, parity is recognized to cause striated muscle injury due to mechanical work on a muscle in a lengthening contraction, causing it to stretch.[24,25,27] It is also important to mention age and parity were the only two variables present in all studies reviewed and, therefore, they were used as sample characterization.

We have extracted the exact *terms*, *conceptual* and *operational definitions* of the PFMF used by authors of the included studies, as defined in the introduction section of this paper. When no *term* was stated, we have selected the variable name as the *term*. When more than one *term* was used to refer to the same or to similar *concepts*, we have extracted as many *terms* as stated by authors in the whole text. Also, when one *term* was *operationally defined* by more than one instrument (e.g. vaginal palpation and vaginal manometry) or procedure (e.g., supine, sitting, standing), the *term* was included as many times as there were different operational definitions that yielded different quantitative results. Data regarding the PFMF terminology were not extracted if quantitative data regarding PFMF were not presented in the study´s results section. Thus, quantitative data of PFMF was extracted only for methodological purposes. Data regarding domains not primarily related to muscle function, defined in the chapter 7 of the International Classification of Functioning, Disability and Health (ICF) from World Health Organization (WHO), 2001[16], as body functions were not extracted (i.e. urethral angle measured by ultrasound or cotton swab test, urinary interruption test, depression scales and quality of life).

Quality Assessment

To the best of our knowledge, there is no consensus on instruments to assess bias of observational studies. Therefore, we built the following rationale to select an appropriate tool to assess the quality of the studies included: 1st) the instrument must address the threats to studies' internal, external and statistical validities; 2nd) the instrument should address terminology issues such as conceptual and operational definitions; 3rd) the instrument should have been previously used in the pelvic floor literature. The unique instrument that accomplished those criteria found in the literature was the Prins' questionnaire.[28]

That instrument is based on studies' *informativity* (the description clarity of study theoretical framework and aims), *external* and *internal validities*. We have tailored this questionnaire, as previously done in a recent systematic review,[29] by: a) adding a question on the completeness of data on instruments reliability, PFMF *terms* and *operational definitions*; b) exchanging the term disease by function; and, c) exclusion of the following questions that did not apply to the aims of the present study: *"Does the method to select and invite participants is clearly described?"* and "*Is the period covered by the measurement instrument specified?"*. The added question on reliability was positively scored when the authors ran a reliability test to collect their own data or had done it in a previous study, in which at least one of the authors participated. The procedures used to score the other questions are fully described in Prins et al., 2002.[28]

Data Synthesis and Analysis

Data synthesis was done according to the following set of rules. *Terms*, *conceptual and operational definitions* were grouped according to a clustering order, in three levels. Since *terms* are the starting point to establish a terminology system,[18] the first clusters were set at this level and the absolute frequency in which *terms* were found was described. A key-term (i.e., a common *term* among the ones used to name a given PFMF) guided the clustering at this level. For example, “strength” was the key-term that generated a cluster including *terms* such as: “perineal muscle strength”, “pelvic floor contraction strength”, “strength at maximum voluntary contraction”, “strength peak pressure”, and so on.

Since similar *terms* might not present similar concepts, a second level clusters were set at *conceptual definitions*. Every conceptual definition (whenever presented) linked to its *term*, was clustered with other similar *conceptual definitions*, by the identification of key-ideas. For example, “presence and intensity of a voluntary muscle contraction” was clustered with “vaginal pressure or muscle force during the performance of a voluntary PFM contraction”, and “sustained PMF contraction” was clustered to “the point of isometric fatigue where the muscle contraction could no longer be maintained at a certain level”.

The third level clusters were set at *operational definitions.* The groups of measurement tools described by Bø et al.,[21] were used to set clusters at this level as follows: visual observation (e.g. inward or downward movement of perineum, visible co-activity of other muscles), vaginal palpation [e.g. Modified Oxford Scale (MOS), Brink scale], vaginal manometry (e.g. Perina®, Peritron®, PFX2® perineometer), electromyography (EMG) (e.g. vaginal or abdominal), pelvic floor dynamometry (e.g. speculum by Morgan’s, by Dumolin’s), ultrasound (US) (e.g. transabdominal or transperineal), and magnetic resonance image (MRI).

Results were presented according to the *term* used to describe PFMF, and then, according to the *conceptual* and *operational definitions* onwards.

RESULTS

Study selection

A total of 2364 studies were retrieved and after duplicates removal, 2042 remained for further analysis. Inclusion and exclusion criteria lead to exclusion of 1972 studies, resulting in 70 final records eligible for full-text review. From those, ten were excluded and four additional studies, identified by reference list search, after analysis, were also included, leading to 64 studies. A PRISMA flow diagram depicted in Figure 1 summarizes this pathway.

Studies characteristics and participants

Overall, 9762 women were investigated in the 64 cross-sectional studies (supplementary material listed in eAppendix available at xxxxx) that comprise the present systematic review**.** Fifty nine studies were prospective [9–13,30–62,24,63,25,64–72,26,73–80] and 5 retrospective.[81–85] Twenty six studies (40.6%) included women with UI compared with women without UI, [11,12,14,36–39,46,53–57,61–63,65–68,69,70–72,76,79] 21 (32.8%) investigated only women with UI, [10,13,26, 29,30, 33, 34,35,37,41,44,48,49,54,65,67,78,80,82–84] and 17 (26.6%) included only women without UI.[28,27,31,32, 36,42,43,47,51,55,56,58,62,65,73,72,79] Participants' age ranged from 21.0 to 78.2 years among women with UI and from 22.0 to 53.1 years among women without UI. Mean parity varied from 0 to 3.8 births in the UI women and from 0 to 2.8 in the women without UI.

Quality assessment and synthesis of results

A low risk of bias of the reviewed studies was identified. More than 53 (82.2%) studies presented adequate information concerning *informativity* and *external validity.* In relation to *internal validity*, 78 (40.6%) of the 196 studies that investigated PFMF scored in questions relative to the presence of reliability testing, and 57 (29.7%) on *conceptual definition* (Tab 2). Detailed information on study methodology analysis is listed in eAppendix (available at xxx).

The synthesis of the data retrieved is presented in table **3**. Overall we have identified 196 *terms* mentioned as PFMF. Although all *terms* were *operationally defined*, c*onceptual definition* was present in only 29.7% of the studies reviewed. Based on key-terms we could group 161 *terms* into 26, leaving the other 35 *terms* ungrouped (described as "other terms" in Table 4, leading to 61 PFMF with different terminology. Also different *terms* were used to refer to the same PFMF in the same studies (i.e., "PFM constriction and elevation of the vaginal wall", "strength of PFM contraction" and "ability to contract PFM"[48,60,67] "strength" and "force"[45]; "levator ani muscle strength" and "ability to contract"[52], "maximum voluntary contraction", "voluntary contraction" and strength".[11] All the *terms* used to name PFMF are described in Figure 2 and Table 4. The first seven *terms* most investigated comprised 52.8% of all PFMF investigated, therefore, they were presented in details.

The most frequently investigated PFMF was "strength" (35 times in 24 studies).[10,14,26,28,29,34,35,40,40,45,41,48,55,54,59,60,65,67,74,76,77,80,81,84] Although the key-term strength appeared consistently, this function was named differently in the studies (e.g., pelvic floor strength, contraction strength, perineal muscle strength). This PFMF was *conceptually defined* only in 5 studies and in addition, 3 different concepts were used. It was *operationally defined* by means of 12 different instruments that were grouped[21] into 3 categories, vaginal palpation, vaginal manometry and vaginal dynamometry (Tab. 3).

"PFM contraction" was the 2nd most frequently investigated PFMF (13 times in 13 studies).[11,12,26,28,39,43,45,53,54,70,77,79,75] This function was also named differently in the studies (e.g. voluntary PFM contraction, PFM contraction and relaxation, maximal PFM contraction). PFM contraction was *conceptually defined* in 2 studies, according to the ICS terminology[3], and *operationally defined* by 9 different instruments that were grouped into 6 categories:[21] visual observation, vaginal palpation, vaginal manometry, vaginal EMG, transperineal US and MRI (Tab. 3)

"PFM activity" was the 3rd most investigated PFMF (13 times in 6 studies).[14,30,58,,69,78,68] This function was also named differently among studies (e.g., activity of PFM, resting/functional bioelectrical activity of PFM, PFM activity during passive and active ankle position). None of these studies presented *conceptual definition*, a finding that also occurred for the 5th ("muscle activation patterns"), 6th ("vaginal pressure") and 7th ("vaginal closure force") most frequently investigated functions. PFM activity was *operationally defined* by 4 different instruments, that were grouped[21] into 2 categories: vaginal EMG and transabdominal US (Tab. 3).

Endurance was the 4th most investigated PFMF (12 times in 10 studies).[9,11,30,38,49,53,57,59,75,81] This function was named consistently among studies. Only 3 studies presented a *conceptual definition* to this *term*. It was *operationally defined* by 6 different instruments grouped[21] into 2 categories: vaginal palpation and vaginal manometry (Tab. 3).

Although 7 studies[11,12,47,48,60,67,84] stated that have adopted ICS terminology[3], during analysis of these studies we observed variations such as the use of "PFM contraction during coughing" to refer to the ICS *term* "involuntary contraction"[60], the use of "slow twitch", "fast twitch" and "rest tone"[12], and "co-contraction visible", "inward movement perineum", "urethral lift" and "strength"[11] that were not found in the ICS terminology.

DISCUSSION

Main findings

This systematic review aimed to investigate if terminology used for PFMF studies of women with and without UI is standardized. A large variety of *terms*, *conceptual* and *operational definitions* used to describe PFMF was observed. Frequently, these *terms* were not followed by a *conceptual definition*, different *operational definitions* were used to measure similar *terms*, and the same *operational definition* was used to measure different *terms*. Discussion of factors influencing this inconsistency is presented.

PFM strength was the most frequently PFMF investigated, probably due to its importance to urethral lift and closure in continence maintenance.[86,27] However the variety of *terms* used in combination with the *term* strength suggests different meanings that should be clarified by their concepts. In addition, *conceptual definitions* differed among each other, none of them comprised the actual *conceptual definition* of muscle strength, and one definition did not comprise strength but endurance. Therefore both the *term* and the *conceptual definition* were neither clear nor consensual among studies. PFM strength was either *operationally defined* by vaginal palpation, dynamometry or manometry. Since muscle strength is the muscle force generation capacity[16,20] the direct method to *operationally define* it is pelvic floor dynamometry.[87] However, this instrument is not available to the majority of physical therapists around the world, especially to those in clinical settings. On the other hand, vaginal palpation is a method widely used and easy to apply in clinical practice. Still, different scales were used to quantify strength: Brink, Ortiz and MOS, leading to non-comparable results. Manometry was also often described as the *operational definition* of PFM strength. Thus, the variety of *terms* used to refer to strength associated with the lack of clear *concept* and diversity on methods to *operationalize* it indicate that, even to the most frequently investigated PFMF, data gathering and meta-analysis are not feasible.

Conceptual definitions were lacking to four (“PFM activity”, “muscle activation patterns”, “vaginal pressure” and “vaginal closure force”) of the seven most investigated PFMF. If *conceptual definitions* were presented in more studies, it could be possible to cluster the 196 variables into a lower set of *terms*. For instance, “muscle activation patterns or synergies” could have been grouped with “trunk and PFM EMG”, “co-contraction”, “simultaneous contraction of levator ani and gluteus maximus” and with “PFM and abdominal muscle activity”, since all of these *terms* typically intend to measure synergies between PFM and other muscles such as abdominal, gluteus and trunk muscles. Also, “reflex”, “involuntary muscle contraction”, “anticipatory PFM contractions” and “automatic activation of PFM” could have been *termed* equally considering that these functions share a common element, that is, the PFM contraction preceding/during a rise in intraabdominal pressure. However, these functions could not be gathered because, when present, the studies differed in *conceptual* and *operational definitions* of those *terms*. Moreover, there were studies that even used distinct *terms* to refer to the same PFMF being investigated,[11,45,48,52,60,67] adding more puzzling to the PFMF terminology.

Those results characterize an approach called operationism, in which the focus of the description of the PFMF is on the measurement instead of on the concept, on “WHAT is to be measured”.[18] Once the concept being measured becomes synonymous to the measurement outcomes, even small changes in method produce a new concept.[18] The result of operationism is a thriving of *terms* and *definitions* that hinder effective communication, data gathering and reduce the feasibility of generalization beyond that investigation, restricting the conclusions from each particular study to its particular methodology.[18] The impact of operationism in the PFMF terminology was demonstrated in a previous systematic review’s on PFMF[4] that investigated PFMF strength, focusing on strength’s *operational definition* (EMG and dynamometry), but could not gather data nor run a meta-analysis due to the “large variation on outcome measure, outcome measurements and terminology”. Furthermore, operationism’s emphasis on HOW to measure variables leads to loss of focus on what is relevant to be measured. For example, the 2nd most investigated function, “PFM contraction”, was *operationally defined* by six different methods: visual observation, vaginal palpation using MOS, vaginal manometry, vaginal EMG, transperineal US and MRI. Clearly, these methods measure different aspects of "PFM contraction", or even different PFMF. While visual observation detects the contraction of PFM, US and MRI equally allow to do so, but in a more detailed level, since they inform the position and displacement of pelvic structures.[21] Vaginal palpation with MOS allows grading the presence and, additionally, the intensity of "PFM contraction", that is, the ability to contract and strength. Finally, vaginal manometry measures vaginal pressure during rest or during PFM contraction and, in this last case, also expresses strength, whereas vaginal EMG measures the neuromuscular activity of PFM during rest and contraction.[21] Combined, these results indicate that the identification of what is the relevant/consensual information regarding "PFM contraction" is not a straightforward task, and needs clarification.

In contrast, the 4th most investigated function, "endurance", was the only PFMF that was consistently conceptualized. Only two different *operational definitions* were used to measure the sustained PFM contraction. This result indicates that there is a consensus in the terminology of this function, suggesting that it is possible to use standardized terminology for PFMF.

From the 64 studies reviewed, only seven reported the use of ICS standardized terminology[3]. Furthermore, only one study actually has used the exact term recommended. These results pose a question on the validity of this terminology and points out the need for a terminology anchored on sound theoretical foundation that allows a deeper comprehension of the PFMF across disciplines.

Recommendations for future work

More than the demand for a standardized terminology, the present results indicate redundancy in the PFMFs investigated and suggest a deeper reflection on the PFMF that are relevant to research and to clinical practice. A sound theoretical foundation should support that reflection allowing a deeper comprehension of PFMF beyond signs and symptoms of diseases, as recommended by the WHO[16]. Next, consensual *terms* should be pointed to name these PFMF. These *terms* should, then, be followed by clear *conceptual definitions.* Lastly, consensual *operational definitions* should be set, allowing communication, data gathering and progress in science knowledge.

Methodological quality

Most studies included in this review presented adequate external validity and informativity, but internal validity was fair, mainly due to measurements' reliability and *conceptual definition* issues. The usefulness of measurement in research and in the clinical decision making process depend on the extent to which one can rely on data accuracy and meaningfulness to indicate a characteristic or performance.[23] Thus, validity and reliability are compulsory for data collection, and authors should not only considering the reliability stated by others, but ensuring reliability of their own measurements.[23]

Strengths and limitations

To our knowledge this was the first unabridged systematic review with a sensitive literature search strategy investigating the terminology of PFMF among women with and without UI ever since ICS published the Report on Standardization of Terminology of PFMF and Dysfunction. Differently from previous study,[4] the present review investigated PFMF terminology, regardless of *operational definition*. Thereby, a large number of studies were included, allowing synthesis of a broad set of information on PFMF. Also, we have used a comprehensive synthesis method based on fundaments of terminology by means of identifying clear *terms*, *conceptual* and *operational definitions.* The results show that past and current terminology are not consistent, indicating the need to build and implement PFMF standardized terminology.

This review included only observational studies since these should offer foundations to build scientific knowledge on PFMF. Grey literature was not included once we expected large variation in terminology in the primary literature. Although PFMF were synthesized by consensus among three investigators, it would be possible that, if performed by other researchers, some numerical variation in PFMF clusters could occur. However, the conclusion regarding the large variation in PFMF terminology would still be observed.

CONCLUSION

Although literature on PFMF of women with and without UI is plentiful, a large variety of *terms*, *conceptual* and *operational definitions* were observed. The majority of the existing definitions were based on operationism, leading to a proliferation in *terms* and *concepts*, preventing data gathering, effective communication among health-care professionals and scientific community, hindering science and clinical practice to progress. The results presented pose an urgent need to build and adopt a standardized terminology encompassing the different disciplines, akin areas, researches and policymakers in order to increase understanding on PFMF of women with UI and hopefully to provide higher quality of health care.

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TABLES

Table 1: Definition of terms, conceptual and operational definitions with examples.

Table 2: Inclusion and exclusion criteria for title and abstract screening, and full-text evaluation.

Table 3: Quality assessment analysis of included studies

Table 4: Summary of *terms, conceptual* and *operational definitions* of PFMF used in the reviewed studies.

Table 1: Definition of terms, conceptual and operational definitions with examples

Term	Definition	Example
Term	A word or phrase used in a definite or precise sense in some particular subject.	Strength
Conceptual definition	What one means by the use of particular words, or terms, and specifies WHAT needs to be evaluated, or measured.	Capacity of a muscle to generate force
Operational definition	The measurement of the concept. Operational definition states HOW to measure a concept. This definition includes both the standardized instrument (outcome measure) and the detailed procedures of how the measurement is taken (outcome measurement)	Outcome measure: Vaginal manometry using Peritron® Outcome measurement: Vaginal probe was covered with a non-lubricated condom and a small amount of water-based gel was placed on the tip of probe. Peritron was calibrated to zero before probe insertion into vagina. The probe was inserted into vaginal canal until its central part was at 3.5cm of the introitus. A measurement was taken during rest (vaginal resting pressure-VRP). Calibration was again set to zero and a measurement on maximal voluntary contraction (MVC) was taken. Three contractions were performed, with a 1 minute rest between them. The highest score on display was registered

Table 2: Inclusion and exclusion criteria for title and abstract screening, and full-text evaluation.

CATEGORY	INCLUSION	EXCLUSION
Design	Descriptive (cross-sectional and longitudinal) studies	Reviews (systematic or narrative and protocols), methodological (reliability-validity and methodology development), clinical trials aimed at investigating intervention effects, clinical trial protocols, practice/clinical guidelines, letters to editor, conference abstracts, standardizations.
Participants	Women with urinary incontinence (UI) either clinically or urodynamically diagnosed.	Other pelvic floor dysfunctions and did not present data on UI, with additional health conditions (such as stroke, multiple sclerosis, pelvic cancer), in pregnant women or in the post-partum period (up to 12 months), athletes, children, men, cadavers and animals.
Comparison	Women without UI	-
Outcome	Pelvic floor muscular functions (PFMF) (weakness, strength, force, power, tonus, stiffness, relaxation, contraction, control, ability, endurance, coordination) investigated as a dependent variable.	PFMF measured either via anal canal or via urethra.

Table 3: Quality assessment analysis of included studies

Number of studies	**64**
Number of PFMF/variables measured in all studies	**196**
Informativity n (%)	
1.Clear theoretical introduction with relevant references to support the research question?	53 (82.8%)
2. Aims of the study clearly described?	57(89.1 %)
External validity n (%)	
3. Are inclusion and exclusion criteria specified?	53 (82.8%)
4. Is the method of data collection properly described?	170 (86.7%)
5. Is the response rate >70%, or is the information on nonresponders sufficient to make inference on the representativeness of the study population?	55 (85.9%)
6. Are important population characteristics relative to outcome specified?	58 (90.6%)
7. Are outcome results presented by mean and standard deviation or similar?#	189 (96.4%)
Internal validity n (%)	
8. Are the data prospectively collected?	57 (89.1%)
9. Is a term/concept of the outcome stated? *†	196 (100%)
10. Is a conceptual definition of the outcome stated? †	57 (29.7%)
11. Is an operational definition of the outcome stated?* †	196 (100%)
12. Is the measurement instrument validated? †	179 (91.3%)
13. Is the measurement instrument tested for reliability in the study?* †	78 (40.6%)

*Included items in the assessment tool proposed by Prins et al., 2001, to fit the present study aims

† Some studies investigated more than one PFMF, thus count and percentage values are relative to the total number of PFMF.

Table 4: Summary of *terms, conceptual* and *operational definitions* of PFMF used in the reviewed studies.

Key-term relative to PFMF (n)	**Conceptual Definiton**	**Operational Definition**
1. Strength (37) • Strength (16) • PF strength (3) • PFM strength (3) • Contraction strength (4) • Strength of PFM (1) • Perineal muscle strength (2) • PFM strength contraction (1) • PF contraction strength (2) • Strength of the PFM contraction(2) • Strength at maximum voluntary contraction (1) • Voluntary PFM contractile strength(1) • Strength peak pressure (1)	Presence and intensity of a (maximum) voluntary muscle contraction (+ vaginal pressure or muscle force during the performance of a voluntary PFM contraction)	**Vaginal palpation**: Ortiz Scale,[10,28,60] MOS,[81] Brink Scale (pressure felt by examiners fingers);[67] **Vaginal manometry**: Perina (Quark,Brazil),[60] Peritron 9300(Cardio-Design, Austrália)[10,34]
	Elevation or vertical displacement of the examiner´s finger during the performance of a voluntary PFM contraction	**Vaginal palpation**: Brink scale (fingers pulled anteriorly and/or in)[67]
	Duration of contraction during the performance of a voluntary PFM contraction	**Vaginal palpation**: Brink scale (duration of contraction)[67]
	-	**Vaginal palpation**: MOS,[14,26,29,45,74,75,80,84] Amaro Scale,[35,36] Brink Scale (pressure felt by examiners fingers),[65] Ortiz Scale;[54] **Vaginal manometry:** PFX2 perineometer (Cardio-Design, Australia),[29] perineometer DM01,[36] Instrument not specified,[35] Peritron (Cardio-Design, Austrália),[14,26,40,55,77,36] Custom vaginal pressure sensor,[52] Kroman;[48] **Pelvic floor dynamometry:** [59]
2. PFM contraction (13) • Voluntary PFM contraction (5) • PFM contraction and relaxation (3) • PFM contraction (2) • Maximal PFM contraction (2) • Perineal contraction (1)	Voluntary contraction means that the patient is able to contract the PFM on demand (from ICS, 2005)	**Transperineal US:** Kretz Voluson 730 Expert system (GE Healthcare, USA) [83]
	-	**Visual observation**: [77,80] **Vaginal palpation**: MOS,[50] **Vaginal manometry**: Custom vaginal pressure sensor,[52] Peritron 9300(Cardio-Design, Austrália);[32,41,74] **Transperineal US**: E8 ultrasound system (GE

		Healthcare, USA[11]; HDS Sono 5000 CT (Philips, Netherlands) [74]; ES500 (Ultrasonix, Canada)[46] **Vaginal EMG:** probe with two metal sensors (Everyway Medical Instruments Co, Taiwan)[27] **MRI:** 1.5-T super conductive magnet unit (Vision, Siemens Corp., Erlangen, Germany) [43]
3. PFM activity (13) • PFM activity (resting, mean max contraction (3) • Activity of PFM (during shoulder flexion and extension, bladder empty/full) (3) • Resting/functional bioelectrical activity of the PFM (2) • PFM activity during passive and active ankle position (2) • PFM activity prior to loading perturbation (1) • PFM activity in response to loading (1) • PFM activity with bladder filling (1)	-	**Vaginal EMG:** Life-care vaginal probe PR-02 (Everyway Medical Instruments Co, Taiwan)[30] Periform (NEEN HealthCare, England),[68,69] Feminscan EMG vaginal probe (Mega Electronics, Finland) + adjustable angle platform;[58,78] **Transabdominal US:** Acoustic Imaging Performa Ultrasound (GE Medical, USA)[14]
4. Endurance (12) • Endurance (9) • PFM endurance (2) • Static PFM endurance (1)	Sustained (maintained) PMF contraction	**Vaginal palpation:** [10], PERFECT Scheme[49]; **Vaginal manometry:** Custom vaginal pressure sensor[52]; Peritron 9300(Cardio-Design, Austrália)[10]
	-	**Vaginal palpation:** [80] **Vaginal manometry:** Peritron (Cardio-Desing, Australia); [26,34,55,74] **Vaginal palpation**:[12,45] PERFECT scheme[26]
5. Vaginal pressure (11) • Vaginal pressure during/at rest (2) • Vaginal pressure during valsalva (2) • Intra vaginal pressure (2) • Vaginal pressure during PFM contraction (2)	-	**Vaginal manometry**: Peritron 9300 (Cardio-Design, Austrália);[14,31,34,42,75] **Vaginal palpation**: MOS;[47,52] **Vaginal EMG + vaginal manometry**: Femiscan (Mega Electronics, Finland) with two air-filled pressure transducers mounted on the vaginal probe[53]

• Vaginal rest pressure (1) • Vaginal squeeze pressure during maximum voluntary contraction (1) • Vaginal pressure amplitude during coughing (1)		
6. Muscle activation patterns (or synergies) (11) • Muscle activation pattern (during rest/contraction/valsava/from levator ani and gluteus maximus (4) • Muscle activation synergies of the PFM (supine/sitting/standing) (3) • Activity of synergistic muscles (PFM rest/PFM activity) (2) • Contraction pattern of deep and superficial PFM (1) • Patterns of muscle activation during PFM contraction (1)	-	**Pelvic floor dynamometry:** Verelst dynamometer;[66] **Vaginal manometry:** Custom vaginal pressure sensor;[72] **Vaginal EMG + abdominal EMG + vaginal manometry**: Octopus Cable Telemetric Systems ((Bortec Electronics, Canada)and a Medilec amplifier surface EMG of PFM and abdominal muscles (Oxford Instruments, UK) + pressure transducer in the posterior fornix of vagina;[75] Custom vaginal pressure sensor (Mega Electronics Ltd., Finland) + EMG of abdominal muscles (Bortec Electronics, Canada)[62] **Vaginal EMG + abdominal EMG:** vaginal surface EMG sensor (VS0 2000) (Haynl-Elektronik Corp., Germany) + gluteus maximus EMG (Haynl ST-2001M, Haynl-Elektronik Corp., Germany);[43] Myosystem 1400 (vaginal surface electrode 02 + surface electrodes on abdominus muscles) (Everyway Medical Instruments Co, Taiwan) [30]
7. Vaginal closure force (8) • Vaginal closure force at rest (3) • Vaginal closure force during maximum voluntary contraction (3) • Vaginal closure force augmented/augmentation (2)	-	**Pelvic floor dynamometry**: Instrumented vaginal speculum described by Morgan et al., 2005,[61] Vaginal speculum described by Dumoulin et al., 2004, [71] Custom instrumented vaginal speculum[79]
8. Reflex (7) • Reflex of PFM contraction (2) • Levator reflex (2) • Clitorial reflex (2) • Reflex PFM contractile strength (1)	Contractile strength during coughing	**Vaginal manometry:** Custom vaginal pressure sensor in cmH_2O;[52] **Transperineal US**: Volustron 730 (GE Healthcare, USA)[82]

9. Tone (6) • Resting PF tone (1) • Resting tone (1) • PFM tone (1) • Tonus at rest of levator ani and gluteus maximus (1) • Rest tone (1) • Tone of the fibrous center of the perineum (1)	The resting level of tension in a muscle that, when at appropriate levels, allows a muscle to make an optimal response to voluntary or reflexive commands	**Vaginal palpation**: [81]
	Baseline EMG signal in µV at maximal muscle relaxation	**Vaginal EMG:** Vaginal surface EMG sensor (VS0 2000) (Haynl-Elektronik Corp., Germany) [43]
	-	**Pelvic floor dynamometry:** speculum as described by Morgan et al., 200;7[59] **Vaginal EMG**: Myomed 932 (Enraf Nonius, the Netherlands) with a vaginal probe V.M.P (Bioparc, Netherlands),[13] MyoTrace 400 (Noraxon Inc., USA);[27]
10. Force (4) • Active force (2) • Passive force (2)	Anteroposterior (and left-right) force at rest and at maximum voluntary contraction	**Pelvic floor dynamometry**: Stainless steel specular dynamometer[39]
11. Voluntary relaxation (3) • Voluntary relaxation (1) • Voluntary PFM relaxation (1) • Ability to relax the muscles (1)	It means that the patient is able to relax the PFM on demand, after a contraction has been performed (from ICS, 2005)	**Vaginal palpation**: [12,81]
	-	**Vaginal EMG**: Myomed 932 (Enraf Nonius, the Netherlands) with a vaginal probe V.M.P (Bioparc, Netherlands),[13] MyoTrace 400 (Noraxon Inc., USA);[27]
	Movement (contraction) of pelvic floor structures during coughing.	**Transperineal US:** Voluson 730 or Philips HD 11 (Philips, USA)[38,82]
	Resting contractile activity of PFM	**Pelvic floor dynamometry**: Verelst dynamometer[70]

	Maximum active force was calculated as total force, measured during maximal voluntary contraction, minus the passive force at the corresponding diameter.	**Pelvic floor dynamometry**: Verelst dynamometer[70]
12. Correct contraction (3) • Correct PFM contraction (1) • Able to contract PFM correctly (1) • Correct technique of PF contraction (1)	Inward pressure or upward traction on the examining finger in the vagina, without accompanying significant valsava, abdominal or gluteal squeeze.	**Vaginal palpation**: [40,36] Brinks Scale[37]
13. Involuntary contraction (3) • Involuntary contraction (1) • Involuntary muscle contraction (1) • Involuntary PFM contractions during coughing (1)	Muscular contraction before and during a rise in intra-abdominal pressure in order to prevent incontinence	**Vaginal palpation:** [12,44,65]
14. Fast (3) • Fast twitch (2) • Fast fibers (1)	Number of fast-twitch: corresponds to measure contractility of fast muscle fibers determined after two minutes of rest. It is noted the number of rapid contractions of a second without compromising intensity (maximum ten times).	**Vaginal palpation:** PERFECT Scheme[49]; **Vaginal manometry:** Perina (Quark, Brazil)[49]
	-	**Vaginal EMG**: Myomed 932 (Enraf Nonius, the Netherlands) with a vaginal probe V.M.P (Bioparc, Netherlands)[13]
15. PFM function (3) • PFM function (2) • Levator function (1)	Maximum contraction of PFM	**Vaginal palpation**: Ortiz;[33] **Vaginal manometry**: Kroman KG40[33]
	-	**Vaginal palpation**: MOS[82]

16.PFM and abdominal muscle activity (3)	-	**Vaginal EMG and abdominal EMG:** Periform probe (NEEN HealthCare , England) + disposable Ag/AgCl surface electrodes placed on abdominal mucles + flexible ruler[63,73]
17.Antecipatory PFM contraction (3)	-	**Transperineal US:** 2D US (EUB-52-Hitachi Medical Corporation, Tokyo)[50]
18. Cocontractions (2) • Cocontractions visible (1) • Cocontractions of the PFM and abdominal muscles (1)	Cocontractions of the PFM and abdominal muscles during coughing and at the beginning of a forced expiration	**Vaginal palpation and espirometry**: MOS + espirometry (Micro Medical SuperSpiro, UK)[56]
	Extra-pelvic muscle activity is the contraction of muscles other than those that comprise the pelvic floor, for example, the abdominal, gluteal and adductor muscles.	**Vaginal palpation**:[12]
19. Involuntary relaxation (2) • Involuntary muscle relaxation (1) • Involuntary relaxation (1)	Relaxation that takes place when the patient is asked to strain as if defecating (from ICS, 2005)	**Vaginal palpation:** [12]; **Vaginal EMG**: Myomed 932 (Enraf Nonius, the Netherlands) with a vaginal probe V.M.P (Bioparc, Netherlands)[13]
20. Repetitions (2) • Repetitions (1) • PF repetitions (1)	Repeat the contractions kept: they correspond to the number of contractions with satisfactory supports (five seconds), which can be performed after a rest period of four seconds between them. The number achieved without compromising the intensity is recorded (maximum of ten repetitions).	**Vaginal palpation**: PERFECT Scheme[49]
	-	**Vaginal palpation**:[45]

21. Slow (2) • Slow fibers (1) • Slow twitch (1)	-	**Vaginal EMG**: Myomed 932 (Enraf Nonius, the Netherlands) with a vaginal probe V.M.P (Bioparc, Netherlands)[13] **Vaginal manometry**: Perina (Quark, Brazil)[49]
22.EMG activation level (2)	-	**Vaginal EMG + abdominal EMG**: Custom modified Femiscan surface EMG probe (Mega Electronics Ltd, Finland) + Delsys™ DE 2.1 surface electrodes (Delsys, USA)[11]
23.Maximum pressure at upper/lower sensor (2)	Pressure at the upper sensor at maximum voluntary contraction/ Pressure at the lower sensor at maximum voluntary contraction	**Vaginal manometry:** Custom vaginal pressure sensor[72]
24.Trunk and PFM EMG with bladder full/empty (2)	-	**Abdominal EMG + Vaginal EMG**: Trunk muscle EMG and vaginal EMG with Periform intravaginal probe electrode (NEEN HealthCare , England)[64]
25.Automatic activation of PFM (2)	-	**Vaginal manometry and espirometry**: Peritron 9300(Cardio-Design, Australia) and Portex EzPAP (Smiths Medical ASD Inc., USA)[32]; **Transperineal US**: MyLab25 (Biosound Esaote, USA)[32]
26. Stiffness (2) • Active stiffness (1) • Passive stiffness (1)	Change in force (ΔF) divided by change in diameter (Δd), that is, (ΔF\Δd), and is expressed as N\mm, Resistance to enlogation (strech).	**Pelvic floor dynamometry**: Verelst dynamometer[70]
Other terms (35)		
27. Abdominal muscle activities during PFM contraction	-	**Abdominal EMG:** Biopack student labs-EMG B(Biopack, USA)[42]
28. Accessory muscle	Observation of gluteus, adductors, abductors contractions during PFM contraction	**Visual observation + vaginal palpation:** [54]
29. Awareness of PFM contraction	-	**Visual observation + vaginal palpation:** [49]

30. Bilateral symmetry of beams	-	**Visual observation + vaginal palpation:** [49]
31. Change in levator hiatus during transversus abdominis contraction	Change in levator hiatus opening dimensions and muscle length shortening during transversus abdominis contraction	**Transperineal 4D US:** E8 ultrasound system (GE Healthcare, Norway)[57]
32. Constriction and elevation of the vaginal wall/Strength of PFM contraction/Ability to contract PFM (3 *terms* for the same function)	The ability to perform a voluntary muscle contraction resulting in a ciruclar closing of vagina, urethra, and anus and in a cranio-ventral movemnet of the perineum and upward movement of the pelvic organs (ICS,2005)	**Vaginal palpation:** MOS[44]
33. Constriction and elevation of the vaginal wall/Strength of the PFM contractions (2 *terms* for the same function)	-	**Vaginal palpation:** MOS[56]
34. Constriction and elevation of the vaginal wall/Ability to contract/Voluntary contraction (3 *terms* for the same function)	-	**Vaginal palpation:** MOS[65]
35. Contraction duration	-	**Vaginal manometry:** Peritron(Cardio-Design, Austrália)[40]
36. Contraction number	-	**Vaginal EMG:** Custom modified Femiscan surface EMG (Mega Electronics Ltd, Finland) [11]
37. Direction and magnitude of PF displacement during maximum voluntary contraction	-	**Translabial 2D US:** MyLab25 (Biosound Esaote, USA)[32]
38. Inward movement perineum	-	**Vaginal palpation:**[12]
39. Levator ani muscle strength/Ability to contract (2 *terms* for the same function)	-	**Vaginal palpation**: Ortiz scale[48]
40. Levator closure	-	**Vaginal palpation:**[12]

41. PFM lengthening	This motion is distinct from the relaxation that occurs immediately after muscle contraction and represents the elongation of the PFMs beyond their baseline, “as if you are trying to initiate urination.”	**Vaginal palpation:**[81]
42. Muscle activation contributions to PVW pressure	-	**Vaginal EMG + vaginal manometry simultaneously:** customized Femiscan probe (Mega Electronics Ltd, Finland)[53]
43. PF and abdominal muscle EMG amplitudes during coughing	-	**Abdominal EMG + vaginal EMG:** Delsys™ D.E.2.1 (Delsys Inc., USA) + Femiscan™ vaginal probe (Mega Electronics Ltd., Finland)[53]
44. PFM contraction during coughing	-	**Visual observation + vaginal palpation**:[56]
45. PFM coordination	Normal muscle recruitment patterns during abdominal and pelvic floor tasks with submaximal efforts.	**Transperineal ultrasound + vaginal EMG:** Periform (NEEN HealthCare , England)[51]
46. PFM EMG amplitude	-	**Vaginal EMG:** Periform vaginal EMG probe (NEEN HealthCare , England)[47]
47. PFM function X expiratory function	-	**Vaginal palpation + spirometry:** MOS + Spirometry (Micro Medical SuperSpiro, Kent, UK)[56]
48. Power	Muscle strength: assessing the presence and intensity of voluntary muscle contraction	**Vaginal palpation:** PERFECT Scheme as stated by Bo e Larsen, 1992- Ortiz Scale[49]
49. Pressoric activation	-	**Vaginal manometry:** Endovaginal probe - Biofeedback equipment (not specified)[54]
50. Quick flick contractions	-	**Vaginal EMG + abdominal EMG:** Myo Trace 400 (Noraxon U.S.A. Inc.)[27]

51. Rate of PVW pressure generation	-	**Vaginal manometry:** customized Feminscan vaginal probe (Mega Electronics Ltd, Finland)[53]
52. Simultaneous contraction of the LA and GM	Any contraction of the GM recorded bilaterally as well as only on the right or left muscle side at the same time with voluntary contraction of the LA was defined as simultaneous contraction of the LA and GM measured by s-EMG	**Vaginal EMG:** VS0 2000 (Haynl-Elektronik Corp., Germany)[43]
53. Strength/Force (2) (2 *terms* for the same function)	-	**Vaginal manometry:** Peritron 9300 (Cardio-Design, Austrália)[41]
54. Sustained contraction	-	**Vaginal EMG + abdominal EMG**: Myo Trace 400 (Noraxon Inc., U.S.A.)[27]
55. Time of PFM contraction	-	**Vaginal manometry:** DM01 perineometer (Dynamed, Brazil) + and chronometer[36]
56. Timing of peak PVW pressure generation in relation to peak PF and abdominal muscle EMG	-	**Vaginal EMG + vaginal manometry simultaneously**: customized Feminscan (Mega Electronics Ltd, Finland)[53]
57. Trunk muscle EMG amplitude (timing)	-	**Abdominal EMG:** Delsys Bagnoli-8 EMG amplification system (Delsys, USA)[47]
58. Urethral lift	-	**Vaginal palpation:**[12]
59. Use joint lumbosacral	-	**Visual observation + vaginal palpation**: [49]
60. Use muscle parasite	Usage of adductors and gluteus muscles as well as the influence of the lumbosacral joint during this contraction	**Visual observation + vaginal palpation**: [49]
61. Maximum voluntary contraction/Voluntary contraction/Strength (3 *terms* for the same function)	Voluntary contraction means that the patient is able to contract the PFM on demand (from ICS, 2005)	**Vaginal palpation**: ICS scale[12]

EMG: electromyography; MOS: Modified Oxford Scale; PFM: pelvic floor muscle; PVW: posterior vaginal wall; US: ultrasound

FIGURES LEGENDS

Figure 1: PRISMA flow diagram summarizing pathway of included studies.

Figure 2: Frequency distribution of the *terms* used to describe PFMF in the reviewd studies.

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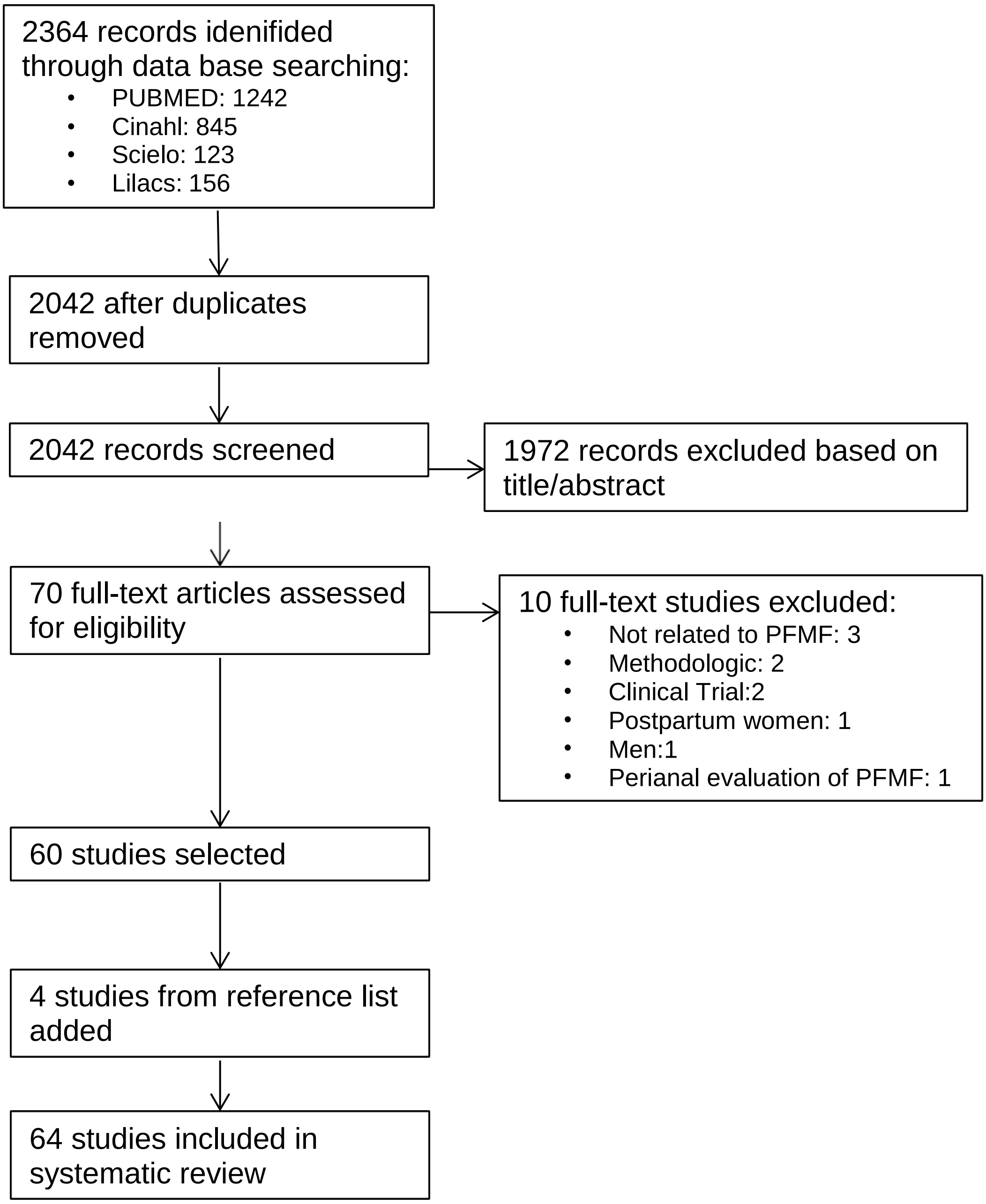
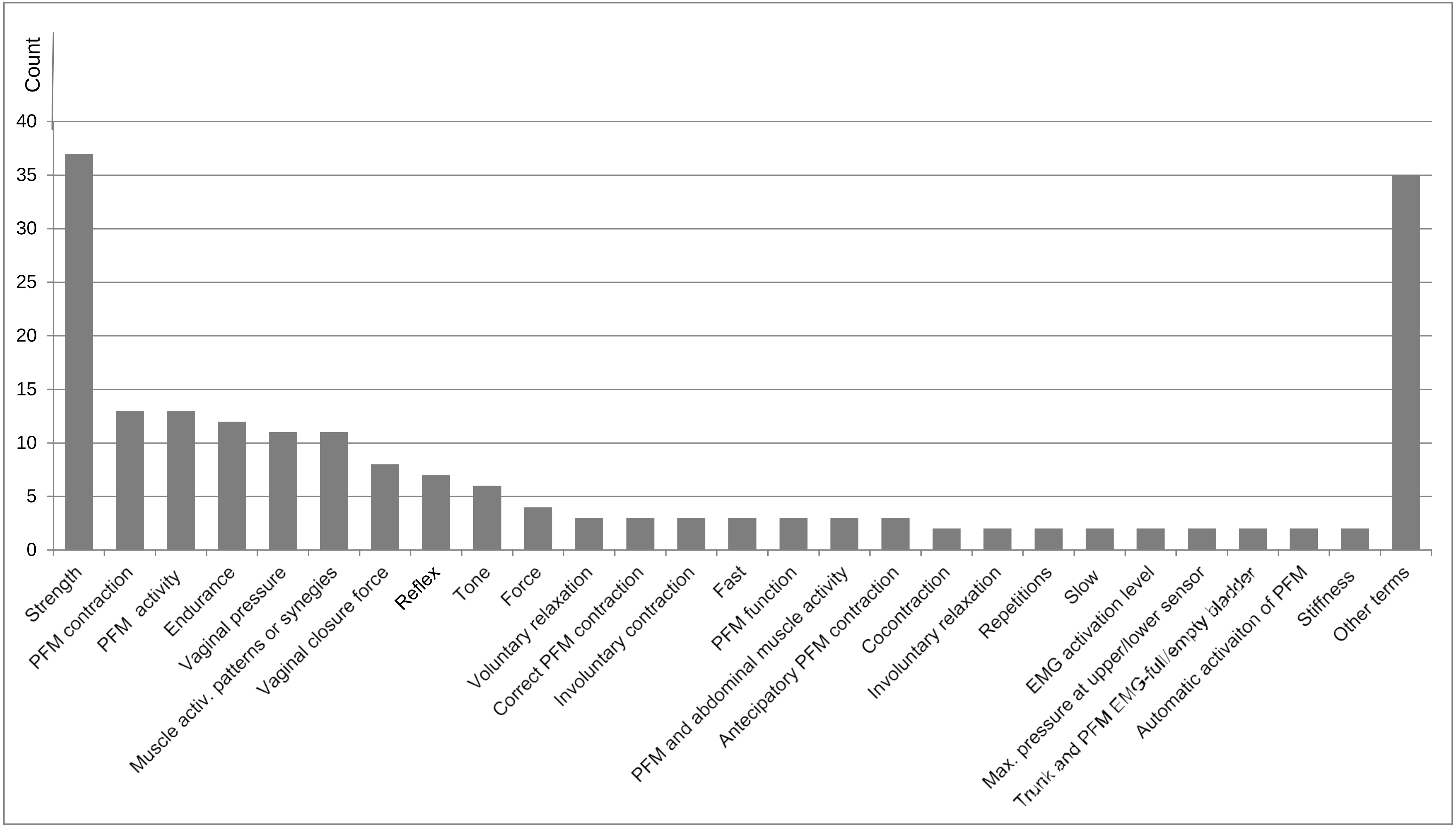


Figure 2: Frequency distribution of the *terms* used to describe PFMF in the reviewed studies.



3.2 Artigo 2 -Linking pelvic floor muscle function terminology to the International Classification of Functioning, Disability and Health.

Fernanda Saltiel, Ana Paula Gonçalves Miranda-Gazzola, Rayane Oliveira Vitória, Rosana Ferreira Sampaio, Elyonara Mello Figueiredo

ABSTRACT

Background: pelvic floor muscle functions (PFMF) are associated with the functions of the pelvic organs, therefore are important to individuals with pelvic floor dysfunctions. The lack of consensual terminology of those functions hampers communication and hinders the advance in scientific knowledge. A previous systematic review on PFMF terminology held by our study group*, has identified 196 different terms referring to PFMF. Also, there was a lack of conceptual and operational definitions of those functions. A standardized terminology, properly anchored in consistent theoretical framework, is crucial to effective communication among health care professional in the area of pelvic floor dysfunctions and public of interest, favoring data gathering, advance in scientific knowledge and dissemination of evidence-based practice. **Aims:** this study aimed to identify a valid and theoretical sound terminology to the PFMF, by: a) linking the PFMF terminology previously identified, to the terminology of the International Classification of Functioning, Disability and Health (ICF); b) to identify which are the most investigated PFMF; and c) to map which are the most used instruments to evaluate those functions. **Methods:** This is a secondary analysis study from a systematic review on PFMF terminology held by our group. The 196 PFMF terms were linked to the ICF terminology according to standardized linking rules from Cieza et al, 2016. Two researchers independently performed the linking process. Disagreements were solved by open dialogue with a third researcher. Percent agreement on linking between raters was calculated. The frequency of appearance of PFMF terms and concepts, as well as their operational definitions were also computed. **Results:** This is a secondary analysis study from a systematic review on PFMF terminology held by our group*. The 196 PFMF terms were linked to the ICF terminology according to standardized linking rules from Cieza et al, 2016. Two researchers independently performed the linking process. Disagreements were solved by open dialogue with a third researcher. Percent agreement on linking between raters was calculated. The frequency of appearance of PFMF terms and concepts, as well as their operational definitions were also computed. **Conclusions:** Linking the PFMF previously identified in the literature to the ICF terminology was feasible and valid. Its use allowed gathering the PFMF data previously identified in the literature to objectively identify the PFMF mostly investigated and how they were operationalized. The use of this terminology will

improve communication, foster data gathering and the advance in scientific knowledge towards more precise assessment, diagnosis and therapeutic approaches for impairments in PFMF among women with pelvic floor dysfunctions.

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INTRODUCTION

The advance in scientific knowledge and dissemination of evidence based practice depends upon effective communication among health care professional and public of interest. [1] To accomplish that, it is necessary to use standardized terminology, with clear conceptual and operational definitions, properly anchored in a consistent theoretical framework. [2] Systematic reviews on terminology in various fields have shown a variety of terms and definitions, preventing clear and unambiguous communication. [3–8] The same is true for studies on pelvic floor muscle functions (PFMF), which are associated with the functions of the pelvic organs, therefore are important to individuals with pelvic floor dysfunctions. Since 2005, the International Continence Society (ICS) has been working on standardization of terminology of PFMF and dysfunction. [9] Recently, they have updated the standardization document in a joint report with the International Urogynecology Association (IUGA), based on etiological perspective of signs and symptoms of diseases. Despite those efforts, Luginbuehl et al., 2015,[10] in a systematic review investigating “pelvic floor muscle activation and strength components” that influence urinary continence in women, concluded that the lack of clarity and the diversity of terms to name and to measure PFMF lead to heterogeneity in results, refraining authors from running a meta-analysis and drawing relevant conclusion.

Recently, our research group carried out a systematic review investigating terminology, conceptual and operational definitions on PFMF of women with and without UI. [11] We have identified 196 different terms to refer to PFMF, that were grouped, according to similarities in conceptual and operational definitions into 26 terms, but other 35 were left ungrouped. Therefore, we have identified 61 different terms in the literature referring to PFMF. [11] Also, PFMF terminology is based on operationism that is, focusing on the description of how to measure the PFMF, instead of on what to measure.[12] This approach leads to a proliferation of terms and definitions that hinder data gathering, reduce the feasibility of generalization beyond that investigation, and ultimately bounds communication and scientific progress.

The World Health Organization (WHO) has proposed, in 2001, the use of the International Classification of Functioning, Disability and Health (ICF).[13] This multipurpose classification provides a functional based theoretical framework to establish, among other objectives, a common language for describing health and health-related states to improve communication among different users. ICF is based on the holistic, bio- psycho-social approach rather than on signs and symptoms of diseases, that encompasses the components *body structure and function*, *activity and participation*, and *contextual factors* (personal and environmental, although personal factors are not coded in ICF). Each component consists of various chapters of ICF, which, in turn, are organized into categories that represent the units of classification. The ICF coding system encloses letters, indicating the ICF component, followed by numbers, indicating the categories. It offers specific terms and conceptual definitions from shared meanings described in the literature to code health and health related states. For instance, in the *body functions* component, there is a domain in which terms and conceptual definitions relative to the *neuromusculoskeletal and movement-related functions* (Chapter 7), such as *power*, *endurance* and *tone*, are listed. ICF does not bring into discussion how to measure concepts. To do so, it is necessary to use standardized tests described in specialized literature. Instead, the ICF allows delineating the relevant concepts to be measured in all domains that comprise human functionality (*body function and structure, activity and participation* and *contextual factors*), guiding a thorough Physical Therapy assessment.[13] Also, ICF is already translated into all languages spoken in the countries that are WHO members.[13] Therefore, the use of ICF terminology may enlighten the literature on PFMF, fostering communication and the gathering of data for scientific work and health related services to individuals with pelvic floor dysfunctions.

In order to link health and health-related states to ICF, scientific community has published linking rules,[14–16] a standardized method for connecting outcome measures to the ICF classification. A systematic review has identified more than 100 articles published in 58 peer reviewed journals across 50 areas that used the linking rules to connect health information to ICF, indicating that the linking process is a useful tool to apply the ICF classification in research.[17]

Thereby, an overlooked, but relevant aspect to promote the advance in knowledge towards more precise assessment, diagnosis and therapeutic approaches for impairments in PFMF among women with pelvic floor dysfunctions is to set a standardized language. Since the pelvic floor muscles are skeletal muscles, we hypothesized that the ICF classification offers a valid terminology to the PFMF. Thus, the aims of this study were a) to link the PFMF terminology previously identified in the literature to the ICF classification; b) to identify which are the most investigated PFMF terms; and c) to map which are the most used instruments to evaluate those functions.

Matherials and Methods

In this study we linked PFMF identified in a previous systematic review conducted by our study group[11] to the ICF terminology following the 10 standardized linking rules proposed by Cieza et al., 2016.[16] The linking process was carried out independently by two researchers (FS, APGMG) from the Post-Graduation Program in Rehabilitation Sciences of the *Universidade Federal de Minas Gerais*, Brazil. As suggested by Fayed in 2011, the linking results were compared for agreement. Doubts and disagreements were solved by open dialogue with a third researcher, the project's coordinator (EMF). All the researchers were physical therapists specialized in Womens' Health and with knowledge on theoretical and taxonomical contents of the ICF. Raters were trained to implement the linking rules.

According to the standardized linking process,[16] the following information were extracted from the included studies: *Name of the instrument, Verbatim health information (wording of item or instruction), Response options, Classification of response options, Main concept, Additional concepts, ICF category of Main Concept, and Annotation*. The PFMF studies previously identified[11] were linked to the most precise ICF category, using an interpretative approach based on a combination of information from the study aims (that guided the identification of the *Main concepts*), the *Instruments* used to measure the variables, the *Response options*, and the *Verbatim instructions* given to the participants. This interpretation is important to avoid applying rules not considering the context/purpose in which the information was collected. [16]

From the original systematic review on PFMF terminology,[11] some terms were merged before the linking process; the situations in which PFMF were measured was linked as *Additional concepts*. For example, Sapsford et al., 2006[18] and in 2008[19], measured PFM activity using electromyography (EMG) during three different sitting postures: slump supported, upright unsupported, and very tall unsupported. These measurements yielded three different quantitative results and were extracted as three PFMF in the systematic review. For the linking process, they were merged into one most relevant meaningful concept (the *Main concept)*, that is the "PFM activity" during a voluntary contraction, with three *Additional concepts* regarding the maintenance of body position (sitting slump supported; sitting upright unsupported; sitting very tall unsupported). Thus, the 196 initial PFMF terms identified in the systematic review were resumed into 192 terms that were, then, linked to the ICF terms. This was the case for Sapsford 2008[19]; Sapsford 2006[18]; Thompson et al. 2006b[23]; 2006c[24]. Data other than movement and muscular functions related to pelvic floor, such as muscle structures other than PFM, posture, mobility related activities, sexual function, respiratory functions were linked to ICF as *Additional concepts*.

Ordinal scales that presented qualitative description of their grades were classified in the *Response option* item as *Qualitative attributes*. This was the case of the Ortiz[20], Modified Oxford[21] [21]and Brink[22] scales.

Percentage agreement on ICF categories among raters was calculated. Frequency of occurrence of the investigated PFMF, as well as the instruments used to measure them was registered. Results were presented as a narrative synthesis.

Results

Regarding *Main concepts*, overall, 180 (93.8%) of the 192 PFMF terms were all linked to the ICF component *body function* in chapter 7-neuromusculoskeletal and movement-related functions. Concerning *Additional concepts,* 72 were identified. They were either linked to the ICF components: a) *activity and participation* in chapter 4-mobility (25 terms; 34.5%); b) *body function* (27 terms; 37.5%) in chapter 4-functions of the cardiovascular, haematological, immunological and respiratory systems; chapter 5-functions of the digestive, metabolic and endocrine systems, and chapter 6: genitourinary and reproductive functions; c) *body structure* (20 terms; 27.7%) in chapter 7-structures related to movement. No terms were linked to contextual factors. Percentage agreement between raters was 73.2%. For 26.8% of the categorizations it was necessary a discussion round with a third researcher for consensus. Twelve functions (6.25%) were classified as not covered by the ICF.[23,25–32]

Ninety PFMF terms were linked to the *muscle function* domain under the *body function* component as follows: 49 terms were linked to *Power of isolated muscles and muscle groups* [23,24,26,28,33–68] coded in ICF as b7300; 33 terms were linked to *Endurance of muscle groups* (b7408) [23,26,29,33,36–39,42–44,47,50–53,55,58,62,67,69,70] either specified at duration (28 times) or repetition (5 times) of contraction; and eight functions were linked to *Tone of isolated muscles and muscle groups* (b7350) [40,48,57,59,63,64,68] (Table 1).

Other ninety PFMF terms were linked to the *movement function* domain under the *body function* component as follows: 43 were linked to *Involuntary movement reaction functions* (b755) [19,24,28,30,32,35,41,46,48,49,51,54,55,71–80]. Twenty two terms were linked to *Control of simple voluntary movements* (b7608) during contraction [23,24,27–30,35,37,38,43,55,62,67,71,75,81–83] and five during relaxation [30,48,55] . Lastly, nineteen terms were linked to *Coordination of voluntary movements* (b7602) (Table 1).

Therefore, the most frequently PFMF terms related to the *Main concepts* were linked to six ICF terms in the *body function* component as follows: *Power of isolated muscles and muscle groups* (25.6%), *Involuntary movement reaction functions* (21.9%), *Endurance of muscle groups* (17.2%), *Control of simple voluntary movements* (14.1%), *Coordination of voluntary movements* (9.9%) and *Tone of isolated muscles and muscle groups* (4.2%).

In regard to the *Additional concepts,* the term *Power* was linked to the *activity and participation* component of ICF as follows: *maintaining a body position* (d415) was linked 3 times [28,65,68], and sexual function (b640-related to *body function* component) was linked once. [37] *Tone* was once linked to *maintaining a body position* (d415). [65] *Involuntary movement reaction* was linked to the following *Additional concepts*: *maintaining a body position* (d415) (7 times),[18,19,28,51,71,77] *respiratory functions* (b440 and b450-*body function* component) mainly during *cough* (23 times) [28,41,46,49,51,54,73,75,84]; and *catching* (d4455-*Activity and Participation* component) (3 times). [28,78] *Coordination* was linked mostly with *trunk muscles* (s7601-*body structure* component) (15 times),[24,25,27,29,45,52,55,56,66,80,85–87] *maintaining a body position* (d415) (8 times);[25,27] and *Muscles of tight* (s75002-*body structure component*) (5 times). [29,52,55] *Control* during contraction and during relaxation were, each, linked with *Additional concepts* 3 times. Control during contraction was linked to *maintaining a body position* (d415) [27,28,81]; while *Control* during relaxation was linked to *defecation functions*-b5258 (twice) and *urination function*-b6200 once); both related to the *body function* component) [30,48,84]

Instruments used to measure the PFMF linked to *muscle functions* domain listed in chapter 7 of the *body function component* are presented in Table 2. For measuring *Power*, the most used instrument was vaginal manometry (20 times), mainly using the Peritron 9300 (CardioDesign, Australia) (12 times);[26,28,31,35,42–45,53,67,83] followed by vaginal palpation (17 times) using Modified Oxford Scale (15 times).[24,33,34,38,41,44,46–49,54,60,65,75,80,83] *Endurance* (PFM contraction duration) was mostly measured by vaginal palpation (16 times) using Oritz scale (6 times);[29,36,44,50,52,58,69] followed by sustained contraction registered in seconds (4 times);[38,39,44,47] and by vaginal manometry, using the Peritron 9300 (Cardio design, Australia) (9 times).[26,33,42–44,53,55,67,83] *Endurance* (repetitions) was mostly measured by vaginal palpation (3 times) by registering the number of repeated contractions as proposed in the PERFECT scheme (twice).[29] *Tone* was measured by pelvic floor dynamometer (7 times), mostly using Morgan´s dynamometer (4 times);[57,59,63,68] and vaginal palpation (once).[48]

Instruments used to measure the PFMF linked to *movement functions* domain described in chapter 7 of the *body function component* were as follows: for *Involuntary movement reaction* (mostly measured during a perturbation caused by a cough), transperineal US was used 9 times (4D-US Volustron 730-GE Healthcare, USA- this being used 6 times[73,41]); ensued by vaginal EMG coupled to vaginal manometry (5 times);[70] and by vaginal palpation (4 times).[46,54,55,75] *Control* during contraction was measured using vaginal palpation (5 times) either adopting MOS[29,38,43,75] or using Brink scale.[62] *Control* during relaxation was registered by visual observation and vaginal palpation (twice).[48,55] *Coordination* during MVC was measured by visual observation (4 times)[29,52]; and by visual observation combined with vaginal palpation (twice).[55,85] The complete linking table is displayed as a supplementary material listed in eAppendix (Apêndice eletrônico F).

Discussion

Main findings

This study aimed at linking outcomes relative to the PFMF previously identified in a literature review to the ICF classification. Also, to identify what are the most investigated PFMF terms and the instruments used to measure them. The majority of the PFMF (93.8%) could be linked to the ICF. Furthermore, by using the ICF standardized linking rules we could reduce the 196 PFMF terms used in the specialized literature into six terms: *Power*, *Involuntary movement reaction, Endurance, Control, Coordination* and *Tone.* These terms are familiar to physical therapists of any field since these are functions of any skeletal muscle. Furthermore, the conceptual definitions of these muscular and movement related functions are also presented in the ICF classification.[13] As hypothesized, the ICF offers the necessary consensual terminology to the PFMF. Therefore, we recommend the use of this terminology to favor communication among researchers, clinicians, policy makers, health care users and foster advance in knowledge.

However, one aspect of ICF terminology needs attention. The term *Power* to express *the force generated by the contraction of a muscle or muscle group*[13], may not be the most appropriate as *Power* is the product of force and velocity.[88] The term strength is more appropriate than the definition presented in the ICF classification instead of power as strength is defined as the maximal force a muscle or muscle group can generate at a specified angle[88] and it is what effectively is intended to be measured during the PFMF assessment. In fact, there is a variation in the use of these terms in the ICF as in the Portuguese version, for example, the term used is strength (*força)*, not power (*potência*).

To link PFMF to the most precise ICF category, we have used the interpretative approach that combines information from the *Main concepts*, the *Instruments*, the *Response options*, and the *Verbatim instructions.*[16] Due to this combination, some functions were considered as *not covered*, although the *Main Concept* suggests that the linking was possible. For instance, PFMF were linked to the term *Tone* if they had in their *Verbatim instructions* “to maintain PFM relaxed during measurements”, combined with the *Instruments,* either dynamometer or vaginal palpation, which are methods with face validity[60,64,68,89] to register the tension present in the resting muscles and the resistance offered when trying to move the muscles passively.[13] When the instrument used to measure that function was vaginal EMG,[23–25,27,28,30,32] which measures only the neurophysiological aspect of the muscle tone (the resting neuromuscular activity of the muscle),[90,91] or vaginal manometry,[23,24,26,28,65] which might capture some aspect of tone, but is also related to the size of the levator hiatus and vaginal laxity,[92] it was linked as *not covered*. Also, the study that used vaginal palpation performed over perineum body [29], instead of over the deep PFM belly via the vaginal canal was also linked as *not covered*. For the functions *Coordination* and *Control* during contraction, although *Verbatim instructions* were similar, the linkage process considered how measurements were registered, either focusing on the synergistic muscles recruited during PFM contraction, or solely on the perineum movement or sensing the contraction during palpation, respectively.

Power was the most investigated PFMF, followed by *Involuntary movement reaction, Endurance, Control, Coordination* and *Tone.* Again, it is important to note that in the ICF the conceptual definition of *Power* is actually strength. Also, from the interpretative linking rules, we found that the most investigated PFMF in the literature refer to strength, not to power. Nevertheless, we are using the term *Power* as it is in the English version of the ICF classification. Since the muscular function *Power* requires recruiting as many fibers in the muscle as possible for the purpose of developing force,[88] it is likely that *Power* is the ultimate expression of all other muscle functions. In women, a strong contraction helps kinking urethra against pubic bone and prevents urine leakage, for instance, during a rise in intra-abdominal pressure.[93] Possibly for those reasons, *Power* was the most investigated PFMF. Nevertheless, in order to develop *Power*, the muscle needs eutrophic and interdigitated fibers, generating tension at rest, expressing the muscle *Tone* function. Also, it must shorten its muscle fibers during a voluntary contraction,[88] expressing the *Control*. In the case of the PFM, it must contract in priority to other synergistic muscles, such as the abdominal, gluteal and adductors, requiring some degree of Coordination to accomplish that.[9,94] Furthermore, the PFM must relax thoroughly (*Control*), allowing micturition, defecation, sexual intercourse and ideally, parturition. *Involuntary movement reaction* of the PFM is also important to counteract subtle increases in intra-abdominal pressure during coughing for example. These aspects highlights that muscle functions are interdependent in a continuum of actions, posing equivalent importance to functions other than *Power*/strength. However, researchers have drawn much attention to *Power*/strength and *Endurance* leading the other PFMF under investigated. Thus, researchers and clinical physical therapists should be aware of the importance to study all PFMF in order to design specific therapeutic approaches to rehabilitate PFM impairments that might vary among women with pelvic floor dysfunctions.

Interestingly, the second most investigated PFMF was the *Involuntary movement reaction,* which expresses the involuntary contraction of PFM in response to a perturbation, such as coughing,[28,41,46,49,51,54,55,61,70,73] during the maintenance or changing of a body posture[18,19,32,71,74,77,79] or during a load catching task.[28,78] That function was put into evidence ever since Asthon-Miller and DeLancey, in 1998[95], found that a contraction of the PFM just prior the increase in abdominal pressure during coughing reduced the volume of leakage of urinary incontinent women.[95] Thus, *Involuntary movement reaction* is a clinically relevant function and to teach women to perform a PFM contraction before any rise in intra-abdominal pressure, such as during cough, lifting a weigh or changing a body position is recommended.

PFMF were mostly investigated by: 1) observing interaction of PFM contraction in relation to the environment (*activity and participation*), either during the maintenance of a body position (lying, sitting, standing, with anterior, neutral or posterior pelvic tilt), or during load catching tasks; 2) observing interaction of PFM contraction in relation to other physiological *body functions* related to respiratory functions (mainly during cough), or in relation to the contraction of other *body structures*, such as the trunk and tight muscles (abdominal, gluteal and adductor muscles); or 3) observing PFM relaxation in relation to other physiological *body functions,* such as defecation and urination. Those information mean that PFM are important structures as they function in alignment with various other body structures and physiological functions, and interact with the environment in order to promote women's functionality.

There was a wide variation of instruments used to measure PFMF. The majority of instruments are valid to measure the PFMF, as previously observed by Saltiel et al., 2018. However, two aspects deserve attention. First, vaginal palpation was the only method employed to measure all six PFMF investigated. This is encouraging, once palpation is a low cost and an easy to perform physical examination.[9] Although requires training (as every assessment method), it is readily available in clinical setting. This is especially important to primary health care and in developing countries in which the access to technology is limited. The second most used instrument was vaginal manometry. It is a valid method as long as *Control* during contraction and *Coordination* are not impaired.[94] Second, the use of the Ortiz scale. This scale was designed to classify PFMF considering "objective perineal function" (but not clearly defined in the original article[20]), which might be related either to *Control* or *Power*, and the duration of the sustained contraction (*Endurance*). As the duration of the sustained contraction is more distinctly provided in the scale, we linked the PFMF graded by Ortiz scale to *Endurance* (duration), even when authors' intention was to measure *Power*. Using a single scale to measure more than one PFMF blurs conclusions concerning physical therapy PFM assessment, diagnosis and treatment. Researchers and clinicians should be aware when interpreting results originated from Ortiz scale. We believe every PFMF should be evaluated and measured separately.

Strengths and limitations

To the best of our knowledge this was the first study that linked outcomes from the PFMF to the ICF classification. We used a standardized methodology to connect health information to ICF based on 10 revised linking rules, which has been shown to be useful for describing and comparing information worldwide across different aspects of clinical practice and scientific interests.[17]

Furthermore, most of the PFMF identified in the literature were linked to ICF. In the case this terminology be adopted by scientific community to refer to PFMF, our results are promising, as communication can be improved among researchers, clinicians, policy makers, health care users and foster advance in knowledge.

Also, as previously said, ICF framework is based on the holistic, bio-psycho-social approach rather than on signs and symptoms of diseases, that is, it is focused on the individual, not on the disease. As such, ICF points to what is relevant to be assessed as far as human functionality is concerned, guiding the elaboration of a physical therapy assessment and approach both focused on functionality. This study identified the relevant PFMF to be evaluated in women with PFD, which were linked to the ICF component *Body function*. It represents the first step to build a global physiotherapeutic assessment of women with PFD that should further include additional domains of functionality, such other *Body functions and structures,* as well as *Activity and Participation* and *Contextual factors* that are relevant to be assessed in that population. Those information may more effectively guide therapeutic goals and treatment.

Some flaws exist in the study. As this was the first study that intended to link PFMF identified in literature by means of a systematic review to ICF terminology, open discussion rounds among raters were required to identify the actual authors' context/purpose concerning the *Main concepts*. Thus, we decided to register only whether raters agreed or were in doubt in relation to PFMF categorization to ICF. This allowed us to calculate percentage agreement, but not a kappa statistics.

PFMF linked to ICF terminology were originated only from observational studies, as this was an inclusion criteria adopted in the systematic review from which PFMF terms were extracted for the linking process.

Conclusion

Linking PFMF to the ICF classification was feasible and valid. Most PFMF could be linked, thus converting the original 196 terms into six PFMF terms from the muscle and movement related functions described in ICF chapter 7 of *body function* component. As ICF provides a uniform language anchored on functionality instead of on signs and symptoms of diseases the results are encouraging, as they may favor the development of a global physiotherapeutic assessment for women with PFD focused on functionality. Also, they may improve communication among researchers, clinicians policy makers, health care users and foster advance in scientific knowledge on pelvic floor dysfunctions.

The most investigated functions were, consecutively, *Power*, *Involuntary Movement Reaction*, *Endurance*, *Control*, *Coordination*, and *Tone*. Muscle functions are interdependent and represent a continuum to muscle action. Thus, all functions must be studied separately, both concerning assessment and intervention aspects.

Various instruments were used to measure those functions and none but vaginal palpation tested all PFMF. Although vaginal palpation requires training of the examiner's ability to palpate the pelvic floor, it is an easy to use and a low cost method. This information is of major importance for physical therapists in clinical settings, especially for those involved in primary health care assistance, as well as in developing countries in which technology is not readily available.

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Table 1: Summary of the linking of the pelvic floor muscle functions to the ICF.

References	Main concept: what is this information about?	Name of instrument or other identifier	Verbatim health information	ICF category of main concept
Fitz et al., 2016; Chevalier et al., 2014; Kitani et al., 2014; Langoni et al., 2014; Walt et al., 2014; Gameiro et al., 2013; Tibaek et al., 2014; Barbosa et al., 2013; Chamochumbi et al., 2012; Dietz et al., 2012; Friedman et al., 2012; Gameiro et al., 2012; Jácomo et al., 2012; Kim et al., 2012; Talasz et al., 2012; Underwood et al., 2012; Unger et al., 2012; Capson et al., 2011; Jones et al., 2010; Knorst et al., 2011; Maddill et al., 2010a; Martin et al., 2010; Quartly et al., 2010; Talasz et al., 2010; Slieker-ten Hove et al., 2009; Maddill et al., 2009; Morgan et al., 2009; Souza et al., 2009; DeLancey et al., 2008; Dietz & Shek, 2008; Talasz et al., 2008; FitzGerald et al., 2007; Trowbridge et al., 2007; Verelst & Leivseth, 2007; Frawley et al., 2006; Maddil & McLean, 2006; Thompson et al., 2006a; Thompson et al., 2006b; 2006c; Amaro et al., 2005; Morgan et al., 2005.[23,24,26,28,31,33–64,66–68,83]	Muscle strength; Intensity of the pelvic floor muscles contraction on demand; Vaginal squeeze pressure during PF maximum voluntary contraction; PFM function; Strength; PFM strength; PFM active anteroposterior and left-right strength; Levator function; PFM strength/peak pressure; Perineal muscle strength; Contraction strength; Vaginal pressure during PFM contraction; Strength of PFM contraction; Intravaginal pressure; Voluntary PFM muscle contraction; LAM strength; Voluntary PFM contractile strength; Pressoric activation; MVC; Intravaginal pressure amplitudes; PF contraction strength; Augmented vaginal closure force; Vaginal pressure or muscle force; Vaginal closure force during MVC; Active force; Active stiffness; Maximum pressure at the upper/ lower pressure sensor; Maximal PFM contraction-squeeze pressure; Max and mean vaginal squeeze pressure.	**Vaginal palpation**: MOS; ICS scale; Brink scale **Vaginal manometry**: Peritron 9300; PFX 2_Pelvic floor exerciser biofeedback; perineometer (Kroman KG40); Perineometer DM01; "perineometry"-Instrument details not stated; Laborie Medical Technologies perineometer; "biofeedback equipment" (not stated); Perina 996-2; Modified EMG Femiscan with manometric measures from abdominal and vaginal pressure ballon; **Vaginal dynamometer**: stainless steel specular dynamometer; intravaginal device that measured data in transverse plane **Vaginal EMG + vaginal manometry**: custom modified Femiscan (Mega Electronics, Kuopio, Finland) **Transabdominal US**: Acoustic Imaging Performa ultrasound unit (GE Medical) with a 3.5-MHz curved array transducer.	Overall instructions were to lift and squeeze the PFM as hard as possible.	b7300 **Power** of isolated muscles and muscle groups
Chamochumbi et al., 2012; Morgan et al., 2009; Unger et al., 2009; DeLancey et al., 2008; Trowbridge et al., 2007; Verelst & Leivseth, 2007; Morgan et al., 2005.[40,48,57,59,63,64,68]	PFM passive force; Resting pelvic floor tone; PFM tone; LAM function/vaginal closure force at rest; Passive force; Passive stiffness; Resting vaginal closure	**Vaginal dynamometer**: Stainless steel specular dynamometer; instrumented vaginal speculum; intravaginal device that measured data in transverse plane. **Vaginal palpation**	Overall instructions were to maintain PFM relaxed during measurement.	b7350 **Tone** of isolated muscles and muscle groups

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Fitz et al., 2016; Sacomori et al., 2015; Langoni et al., 2014; Tibaek S et al., 2014; Walt et al., 2014; Barbosa AMP et al., 2013; Gameiro et al., 2013; Friedman et al., 2012; Gameiro et al., 2012; Underwood et al., 2012; Jácomo et al., 2011; Knorst et al., 2011; Virtuoso et al., 2011; Madill et al., 2010a; Martin et al., 2010; Slieker-ten Hove et al, 2009; Souza et al., 2009; FitzGerald et al., 2007; Thompson et al., 2006a; Amaro et al., 2005.[26,29,33,36–39,42–44,47,50–52,55,62,67,69,83]	Muscle endurance; Muscle function of pelvic floor/Objective perineal function/strength; PFM function; Static PFM endurance; Endurance; PF contraction strength; Time of PFM contraction; Contraction duration; Perineal muscle strength/duration; PFM endurance; Contraction strength; LAM strength/ ability to contract, Power; Endurance; Perineal muscle functions/Fast fibers ; Slow fibers; PFM endurance; Strength/objective perineal function/muscle strength of PF; Strength/Functional pelvic assessment; PF strength/duration of contraction; Vaginal squeeze pressure measurement/endurance; Perineal muscle strength/muscle force/ perineal contraction; Perineal muscle strength/holding period	**Vaginal palpation**: PERFECT; Ortiz; Amaro grade; no specific scale, Brink scale **Vaginal manometry**: Peritron; Perineometer DM01 + chronometer; Perina 996-2; pressure sensor (Laborie Medical Technologies	Overall instructions were to sustain PFM contraction as long as possible.	b7408 **Endurance** of muscle groups (duration)
Underwood et al., 2012; Virtuoso et al., 2011; Quartly et al., 2010; Madill et al., 2009.[29,47,53,56]	PF repetitions; Number of fast twich; Repeat the contractions kept; Endurance; Contraction number in 30 sec;	**Vaginal palpation**: no specific scale, PERFECT **Vaginal manometry**: Peritron 9300; **Vaginal EMG + manometry**: A custom modified Femiscan™ +surface EMG probe	Overall instructions were to repeat PFM contractions.	b7408 **Endurance** of muscle groups (repetitions)
Halski et al., 2014; Kim et al., 2014; Kitani et al., 2014; Yang et al., 2013 Dietz et al., 2012; Talasz et al., 2012; Capson et al., 2011; Talasz et al., 2010; Madill et al., 2010a; Madill et al., 2010b; Chen et al., 2009; Slieker-ten Hove et al, 2009; Jones et al., 2010; Sapsford et al., 2008; 2006; Talasz et al., 2008; Smith et al., 2008; Devreese et al., 2007; Smith et al., 2007a; Smith et al., 2007b; Thompson et al., 2006b; 2006c; Chen et al., 2005.[18,19,23,24,28,32,35,41,46,49,51,54,55,61,70–74,76–79]	Resting bioelectrical activity of the PFM in forward and backward pelvis inclination; Vaginal contraction pressure during valsava; Automatic activation of PF muscle; Reflex PFM contraction; Reflex contraction of the levator ani; Levator reflex/ timing; Clitoral reflex during cough; Timing of clitoral reflex movement; Involuntary PFM contractions in coughing; Intra vaginal + PFM EMG amplitude + trunk muscle EMG amplitude during cough/valsalva; EMG activation timing + intravaginal pressure and trunk muscle EMG in load catching task; Cocontractions of PFM and abdome during coughing; Reflex PFM contractile strength; Intravaginal pressure	**Vaginal EMG:** vaginal probe PR-02 + Myosystem 1400; 9021L0203 vaginal sponges **Vaginal manometry + Transabdominal US**: Peritron 9300 + ultrasound equipment HDI 5000 with a linear probe transducer **Vaginal manometry**: Peritron 9300 **Transperineal US**: MyLab25 with a 2.5- to 5-MHz curvilinear transducer; 4D-US Volustron 730; 2D US; HDS Sono 5000 CT **Vaginal palpation** **Vaginal EMG + vaginal manometry + trunk muscle EMG**: Periform + Peritron + trunk surface EMG **Visual observation + suprapubic palpation + expirometry**	Overall instructions were to cause a body perturbation either maintaining PFM relaxed or contracted such as changing pelvis or body position, coughing or performing a valsalva manoeuvre.	b755 Involuntary movement **reaction**

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	rise time during coughing; Vaginal pressure amplitudes during coughing; Patterns of muscle activity during coughing; PFM and the abdominal muscles contributions to the generation of PVW pressure; Rate of PVW generation; PFM activity during active and passive ankle position; Automatic dynamic function of the PFM during a cough; PFM and abdominal muscle activity; Onset time of superficial and deep PFM activity; Timing and amplitude of postural activity of the PF, abdominal, and erector spinae muscles EMG onsets; PF and abdominal muscle activation under intrinsic and extrinsic perturbations; Vaginal pressure during Valsava; PFM activity in different postures	**Visual observation + suprapubic palpation** **Vaginal EMG + vaginal manometry**: Femiscan with two air-filled pressure transduceres mounted on the vaginal probe + EMG of abominal muscle **Vaginal EMG + abdominal EMG**: Periform probe + disposable Ag/AgCl surface electrodes placed over abdomen **Vaginal EMG + Abdominal EMG + Force plate**: Periform intra-vaginal probe electrode and surface EMG of abdominal muscles **Vaginal EMG + adjustable angle plataform**: Feminscan + plataform		
Halski et al., 2014; Henderson et al., 2013; Slieker-ten Hove et al., 2009; Madill et al., 2009; Madill & McLean L, 2008; Madill & McLean, 2006; Thompson et al., 2006b; 2006c; Kim et al., 2012; Chmielewska et al., 2015; Martin et al., 2010; Virtuoso et al., 2011; Soljanik et al., 2012; Junginger B et al., 2010.[23–25,27,29,45,52,55,56,66,71,85–87]	Activity of synergic muscle at different orientations of pelvis; Able to contract PFM correctly; Co-contraction visible; Muscle activation timing; Patterns of muscle activation during PFM contraction; Synergic muscle pattern according to posture; Accessory muscle; Awareness of PFM contraction; Use of muscle parasite; Use of joint of lumbosacral motion; Muscle activation pattern at MCT; Simultaneous contraction of LA and GM; PFM co-ordination.	**Abdominal EMG**: Biopack student labs-EMG **Visual observation** **Visual observation + vaginal palpation**: Brinks scale. **Vaginal EMG + abdominal EMG**: Myo Trace 400 with vaginal probe and self-adhesive electrodes **Vaginal EMG + vaginal manomety + abdominal EMG**: custom modified Femiscan and surface EMG of rectus abdominus, external oblique, internal oblique and transversus abdominus **Vaginal EMG + abdominal EMG + Transabdominal US**: Periform intra-vaginal probe and Surface EMG and US with a 3.75 MHz curved linear array transducer **Visual observation + vaginal palpation + vaginal EMG + gluteal EMG**: Vaginal surface EMG sensor **MRI:** functional MRI with a (1.5-T superconductive magnet unit.	Overall instructions were to contract PFMF either performing a MVC, or a sustained contraction while synergistic muscle contraction was observed.	b7602 **Coordination** of voluntary movements (postural challenges)

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Slieker-ten Hove et al, 2009 Bo et al., 2009; Talasz et al., 2008; Gameiro et al., 2013; Tibaek S et al., 2014; Gameiro et al., 2012; Soljanik et al., 2012; Arab et al., 2011; Capson et al., 2011; Virtuoso et al., 2011; Steensma et al., 2010; Halski et al., 2014; Kitani et al., 2014; Zalm et al., 2008; FitzGerald et al., 2007; Thompson et al., 2006a; Thompson et al., 2006b; 2006c; Amaro et al., 2005.[23,24,27–30,35,37,38,43,55,61,62,67,71,81–83,96]	Voluntary muscle contration; Levator hiatus dimensions from rest to correct contraction; Ability to contract/voluntary contraction; Correct PFM contraction PF displacement during MVC. ; Correct PFM contraction; Voluntary PFM contraction; Perineal muscle contraction; PFM contraction and relaxation; PFM contraction; PFM EMG amplitude + trunk muscle EMG amplitude in MVC; Bilateral symmetry of beams; voluntary PFM contraction; Fast twitch; Slow twitch.	**Visual observation + vaginal palpation.** **Visual observation.** **Vaginal palpation**: MOS, Brink scale; no specific scale. **Vaginal EMG:** Vaginal probe PR-02; Myomed 932 with a vaginal probe 2mm; Periform. **Vaginal manometry + Transabdominal US**: Peritron and US Philips HDS Sono 5000 CT. **Transabdominal US**: GE E8 ultrasound system with 4–8 MHz curved array 3D/4D ultrasound transducer. **Transperineal US**: 2-dimensional TP B-mode USI using MyLab25 with a 2.5- to 5-MHz curvilinear transducer (CA621); diagnostic ultrasound imaging unit set in B-mode with a 3.5 MHz curved array transducer; GE Kretz Voluson 730 expert system and a RAB 4-8 MHZ; Philips HDS Sono 5000 CT. **MRI:** functional MRI with a (1.5-T superconductive magnet unit.	Overall instructions were to contract the PFM either performing a MVC or a sustained contraction with the intention to lift the perineum	b7608 **Control** of simple voluntary movements (contraction)
Unger et al., 2014; Slieker-ten Hove et al, 2009; Zalm et al., 2008.[30,48,55]	Voluntary relaxation; Involuntary relaxation; PFM lengthening; Voluntary PFM relaxation to baseline;Involuntary. relaxation/straining potential	**Visual observation + vaginal palpation** **Vaginal palpation** **Vaginal EMG:** Biopac	Overall instructions were to relax PFM after a contration or to perform a strong push.	b7608 **Control** of simple voluntary movements (relaxation)

Continua...

Chmielewska et al., 2015; Walt et al., 2014; Soljanik et al., 2012; Capson et al., 2011; Virtuoso et al., 2011; Zalm et al., 2008; Thompson et al., 2006b; 2006c; Frawley et al., 2006; Chen et al., 2005.[23–32]	Ability to relax the muscles; Resting tone vaginal resting pressure; Tonus at rest from LA; PFM EMG amplitude + trunk muscle EMG amplitude during rest; Tone of the fibrous center of the perineum; Rest tone; Muscle activation pattern during rest; Vaginal pressure during rest; PFM resting activity	**Vaginal EMG + abdominal EMG**: Myo Trace 400 + vaginal probe with two metal sensors **Vaginal manometry**: Peritron 9300 **Visual observation + vaginal palpation + vaginal EMG + MRI**: vaginal surface EMG sensor and MRI 1.5-T superconductive magnet unit. **Vaginal EMG**: Periform; Myomed 932 with a vaginal probe 2mm; Femiscan. **Vaginal palpation** **Vaginal EMG + abdominal EMG + Transabdominal US**: Periform intra-vaginal probe + Surface EMG (abdominal muscles) + US with a 3.75 MHz curved linear array transducer. **Vaginal manometry + transabdominal US**: Peritron + US	Overall instructions were to maintain PFM relaxed during measurements.	nc (not covered)*

Legend: EMG: Electromyography; GM: Gluteus maximums; LA: Levator ani; LAM: Levator ani muscle; MCT: Maximal contraction tonus; MOS: Modified Oxford Scale; MRI: Magnetic resonance imaging; MVC: Maximum voluntary contraction; PF: Pelvic floor; PFM: Pelvic floor muscle; PVW: Posterior vaginal wall; US: Ultrasound.

Note: Although some *Main concepts* suggest the linking was possible, it is important to note that it was considered the interpretative approach that combines the *Main concepts*,*Instruments*, *Response options* and *Verbatim information*, as detailed in *e*Appendix 1.

Table 2: Instruments used to measure pelvic floor muscle functions category

PFMF	% of investigation	Frequency*	Instrument
b7300 **Power** of isolated muscles and muscle groups	25.6%	20	**Vaginal manometry**: Peritron 9300 (12 times)(Cardio design-Australia)[26,28,31,35,42–45,53,67,83] "perineometer" (twice)(Kroman trademark [36,50] PFX 2_Pelvic floor exerciser biofeedback (CardioDesign – Australia)[34]; Perineometer DM01 [37]; "perineometry" (Instrument details not stated;[39]); Laborie Medical echnologies, France [70]; "biofeedback equipment" (not stated) [52]; Perina 996-2 (Quark - Brazil) [58]
		17	**Vaginal palpation**: Modified Oxford Scale (15 times) [24,31,33,34,38,41,44,46–49,54,60,75,80,83]; ICS scale [84] ; Brink scale [62]
		9	**Pelvic floor dynamometer**: Morgan's dynamometer (6 times) [57,59,63,68]; Verelst & Leivseth (twice) Verelst & Leivseth, 2007 [64]; Montreal dynamometer Chamochumbi et al., 2012 [40]
		2	**Vaginal EMG + vaginal manometry**: (custom modified Femiscan-Mega Electronics, Kuopio, Finland) [56,66]
		1	**Transabdominal US**: Acoustic Imaging Performa ultrasound unit (GE Medical, USA) [31]
b7350 **Tone** of isolated muscles and muscle groups	4.2%	7	**Pelvic floor dynamometer:** Morgan's dynamometer (4 times) [57,59,63,68]; Verelst & Leivseth dynamometer [64]; Montreal dynamometer Chamochumbi et al., 2012[40]
		1	**Vaginal palpation**: [48]
b7408 **Endurance** of muscle groups (duration)	17.19%	16	**Vaginal palpation**: Ortiz Scale (6 times) [29,36,44,50,52,58,69]; time in seconds of sustained contraction (4 times) [38,39,44,47]; Amaro scale (twice) [37,67]; Brink scale[62], PERFECT scheme [29]
		12	**Vaginal manometry**: Peritron 9300 (Cardio design, Australia) (9 times) [26,33,42–44,53,55,67,83]; Perineometer DM01 + chronometer [37]; Laborie Medical Technologies, France) [51]; Perina 996-2 (Quark, Brazil) [29]
b7408 **Endurance** of muscle groups (repetitions)		3	**Vaginal palpation**: PERFECT scheme (twice)[29]; number or repeated contractions [47]
		1	**Vaginal EMG + manometry**: A custom modified Femiscan™ (Mega Electronics, Kuopio, Finland) surface EMG probe [56]
		1	**Vaginal manometry**: Perina 996-2 (Quark, Brazil) [29]

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b755 Involuntary movement **reaction** (ankle positon)	21.9%	2	**Vaginal EMG**: Feminscan (Mega Electronics, Finland) + ajustable angle plataform [32,74]
b755 Involuntary movement **reaction** (balance, bladder fullness, eyes open and closed)		1	**Vaginal EMG + Abdominal EMG + Force plate**: EMG endovaginal (Periform intra-vaginal probe electrode - NEEN HealthCare , England) and surface EMG of abdomen; force plate (Kistler, Amherst, NY) [76]
b755 Involuntary movement **reaction** (catching)		1	**Vaginal EMG**: Periform (NEEN HealthCare , England) [28]
		1	**Vaginal manometry**: Peritron (Cardio Design, Australia) [28]
		1	**Vaginal EMG + abdominal EMG**: Periform intra-vaginal probe + pairs of ag\agcl surface electrodes over abdomen and arm muscles [78]
b755 Involuntary movement **reaction** (cough)		9	**Transperineal US:** 4D-US Volustron 730 (6 times) (GE Healthcare, USA) [41,73]; Transperineal US: 2D US (3 times) (EUB-52-Hitachi Medical Corporation, Tokyo)[49]
		5	**Vaginal EMG + vaginal manometry**: Femiscan (Mega Electronics, Finland) two air-filled pressure transduceres mounted on the vaginal probe + EMG of abominal muscle (5 times) [70]
		4	**Vaginal palpation**: (4 times) [46,54,55,75]
		3	**Vaginal manometry**: Femiscan (Mega Electronics, Finland) with two air-filled pressure transduceres mounted on the vaginal probe [51] (twice); Peritron (Cardio Design, Australia)[28]

		1	**Visual observation + suprapubic palpation**: [54]
		1	**Vaginal EMG**: Periform (NEEN HealthCare , England) [28]
b755 Involuntary movement **reaction** (forced expiration)		1	**Visual observation + suprapubic palpation + expirometry** (Micro Medical SuperSpiro, UK) [54];
		1	**Vaginal manometry**: Peritron 9300 (Cardio design, Australia) [35]
		1	**Transperineal US**: MyLab25 (Biosound Esaote, USA) with a 2.5- to 5-MHz curvilinear transducer (CA621) [35]
b755 Involuntary movement **reaction** (valsava)		2	**Vaginal EMG + Transabdominal US**:A periform intra-vaginal probe (Neen HealthCare) + Surface EMG (abdominal muscles) + US with a 3.75 MHz curved linear array transducer (Toshiba Capasee model SSA 220A) [24,80]
		2	**Vaginal manometry + transabdominal US:** Peritron (Cardiodesign, Australia, Model 9300 V) +US HDS Sono 5000 CT (Philips, Netherlands) [24,80]
		1	**Vaginal EMG**: Periform (NEEN HealthCare , England) [28]
		1	**Vaginal manometry**: Peritron (Cardio Design, Australia) [28]
		1	**Vaginal manometry + Transabdominal US**: Peritron 9300 + ultrasound equipment HDI 5000 (Philips, USA) with a linear probe transducer [72]
b755 Involuntary movement **reaction** (postural challenge)		3	**Vaginal EMG + abdominal EMG**: Periform probe (NEEN HealthCare, England) +Pairs of Ag/AgCl surface electrodes for trunk muscles [79] ; Vaginal EMG + abdominal EMG: Periform probe (NEEN HealthCare , England) + disposable Ag/AgCl surface electrodes placed over abdomen [18,19]
		2	**Vaginal EMG**: Vaginal probe PR-02 (Everyway Medical Instruments Co-Taiwan) + Myosystem 1400 (Everyway Medical Instruments Co, Taiwan) [71]; Vaginal EMG: 9021L0203 vaginal sponges (Dantec Medtronic, USA)[77]

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b7602 **Coordination** of voluntary movements (MVC)	9.9%	4	**Visual observation** [29,52]
		2	**Visual observation + vaginal palpation**: Brinks scale [85]; [55]
		2	**Vaginal EMG + Transabdominal US**: periform intra-vaginal probe (Neen HealthCare) + Surface EMG (abdominal muscles) + US with a 3.75 MHz curved linear array transducer (Toshiba Capasee model SSA 220A)[23,24]
		1	**Magnetic ressonance imaging**: funtional MRI (Soljanik et al., 2012)
		1	**Vaginal EMG + abdominal EMG**: Myo Trace 400 (Noraxon U.S.A. Inc.), vaginal probe with two metal sensors (Everyway Medical Instruments Co), self-adhesive electrodes (silver/silver chloride) [25]
		1	**Abdominal EMG**: Biopack student labs-EMG (Biopack, USA) [45]
		1	**Vaginal EMG + vaginal manomety:** A custom modified Femiscan™ (Mega Electronics, Finland) surface EMG probe was designed to simultaneously measure PFM EMG and proximal and distal vaginal pressure[56]
		1	**Vaginal EMG + vaginal manomety + surface EMG of abdomen**: Modified EMG Femiscan (Mega Electronics, Finland) (abdominal and vaginal pressure ballon) [66]
		1	**Vaginal EMG+ transperineal US**: endovaginal probe Periform (NEEN HealthCare, England) + transperineal US using a Logiqp US (Medical , USA) [87]
		1	**Visual observation + vaginal palpation + vaginal EMG + gluteal EMG**: vaginal surface EMG sensor (VS0 2000, Haynl-Elektronik Corp., Scho¨nebeck, Germany) +The surfaceareas of LA (LAA), FI (FIA) and GM (GMA) were evaluated using MRI.[27]

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b7602 **Coordination** of voluntary movements (postural challenges)		1	**Vaginal EMG + vaginal manomety**: A custom modified Femiscan (Mega Electronics, Finland) surface EMG probe was designed to simultaneously measure PFM EMG and proximal and distal vaginal pressure [86]
		1	**Abdominal EMG**: disposable self-adhesive Ag/AgCl snap alectrode for surface Emg application in abdomen [71]
b7602 **Coordination** of voluntary movements (repeated contraction + sustained contraction)		2	**Vaginal EMG + abdominal EMG**: Myo Trace 400 (Noraxon U.S.A. Inc.), vaginal probe with two metal sensors (Everyway Medical Instruments Co), self-adhesive electrodes (silver/silver chloride) [25]
b7608 **Control** of voluntary movement (contraction)	14.1%	5	**Vaginal palpation**: (3 times) [29,37,38] ; Modified Oxford Scale [75]; Brink scale [62]
		4	**Transperineal US**: Elevator or depressor - direction of the movement of bladder neck during contraction Philips HDS Sono 5000 CT [83]; 2-dimensional TP B-mode USI using MyLab25 (Biosound Esaote, Indianapolis, Indiana) with a 2.5- to 5-MHz curvilinear transducer (CA621)[35]; ultrasound imaging unit set in B-mode (Ultrasonix-ES500, Canada) with a 3.5 MHz curved array transducer was used for ultrasound measurement 9 [81]; GE Kretz Voluson 730 expert system and a RAB 4-8 MHZ (GE Healthcare, USA) [82]
		4	**Vaginal EMG**: Vaginal probe PR-02 (Everyway Medical Instruments Co-Taiwan) + Myosystem 1400 [71]; Periform (NEEN HealthCare , England) [28]; Vaginal EMG: the pelvic floor function was assessed quantitatively by biofeedback registration (Myomed 932 ...vaginal probe 2mm V.M.P Bioparc) (twice) [30]
		3	**Visual observation + vaginal palpation:** (3 times) [55]
		2	**Visual observation** : [43,67]

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		2	**Vaginal manometry + Transabdominal US**: Peritron (Cardiodesign, Australia, Model 9300 V) + transabdominal US Philips HDS Sono 5000 CT (Philips, USA) [23,24]
		1	**Transabdominal US**: GE E8 ultrasound system (GE Healthcare, Oslo, Norway) with 4–8 MHz curved array 3D/4D ultrasound transducer (RAB 4–8 l/obstetric) [96]
		1	**MRI**: functional[27]
b7608 **Control** of simple voluntary movements (relaxation)		1	**Visual observation + vaginal palpation:** [55]
		1	**Visual observation:** [48]
b7608 **Control** of voluntary movement (relaxation during straining)		1	**Visual observation + vaginal palpation**: [55]
		1	**Vaginal EMG:** (Bioparc, Netherlands)[30]
b7608 Control of voluntary movement (relaxation during urination)		1	**Vaginal palpation:** [48]

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nc-not covered (all measurement performed during rest)		3	**Vaginal EMG**: Periform (NEEN HealthCare , England) [28]; Myomed 932 (Enraf Nonius, the Netherlands) with a vaginal probe 2mm (Bioparc, Netherlands); [30] Femiscan (Mega Electronics, Finland)[32]
		3	**Vaginal manometry**: Peritron 9300 (Cardio design, Australia)[26,28,31]
		2	**Vaginal EMG + abdominal EMG**: Myo Trace 400 (Noraxon U.S.A. Inc.), vaginal probe with two metal sensors (Everyway Medical Instruments Co, Taiwan), self-adhesive electrodes (silver/silver)[25]
		2	**Vaginal EMG + Transabdominal US**: Periform intra-vaginal probe (Neen HealthCare) + Surface EMG (abdominal muscles) + US with a 3.75 MHz curved linear array transducer (Toshiba Capasee model SSA 220A, Japan)[23,24]
		1	**Vaginal palpation:**[29]
		1	**Visual observation + vaginal palpation + vaginal EMG + MRI**: vaginal surface EMG sensor (VS0 2000, Haynl-Elektronik Corp., Schonebeck, Germany). The surface areas of levator ani, fossa isquioanalis and gluteus maximus were evaluated using MRI 1.5-T superconductive magnet unit (Vision , Siemens Corp., Erlangen,Germany). [27]

Note: Some authors have measured the same function using more than one instrument. Legend: EMG: electromyography; US: ultrasound; 4D- fourth dimensional; MRI: magnetic resonance imaging

3.3 Artigo 3 - Reliability and agreement of the Pelvic Floor Sensory and Muscle Function Exam-EFSMAP: a methodological study

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ABSTRACT

Objective: To test intra and interrater reliability and agreement of the Pelvic Floor Sensory and Muscle Function (EFSMAP-Exame das Funções Sensoriais e Musculares do Assoalho Pélvico) based on the ICF/WHO framework and terminology, measured by worldwide accessible instruments among women.

Design: Prospective crossectional study.

Setting: Secondary care gynaecology unit and community.

Sample: A calculated sample of 23 women with and without pelvic floor dysfunction aged over 18 years.

Methods: Pelvic floor sensory and muscle function were evaluated by vaginal palpation and manometry (Peritron®). For interrater analysis, two raters evaluated participants in a 10 to 20 minute interval. Intrarater analysis was conducted by one rater in a one week interval.

Main outcomes: Sensory functions: *Proprioceptive* (b260) and *Pain* (b28018); muscle and movement functions: *Tone* (b7350) *Control* (contraction and relaxation) (b7608), *Coordination* (b7602), *Involuntary movement reaction* (cough) (b755), *Strength* (b7300) and *Endurance* (duration and repetitions) (b7408).

Results: Intra and interrater reproducibility indices of the EFSMAP were good to excellent (e.g.: Kw=0.67; 95%CI=0.40-0.94 for *Tone*; ICC=0.97; 95%CI=0.92-0.99 for *Endurance*-duration) for most functions. Although reliable in interrater analysis, the functions *Pain* (presence and intensity) and *Tone* (right) showed no intrarater reliability. Agreement was substantial for most PFMF measured.

Conclusion: The EFSMAP was focused on human functionality, presents a clear terminology and conceptual definition; and it adopts worldwide and accessible instruments. The exam was reproducible for most functions once conceptual and operational definitions were clearly stated and raters were systematically trained. The EFSMAP could foster communication among health care professionals and help to improve PFMF diagnosis and to set a dose specific rehabilitation program.

Funding: None.

Key-words: pelvic floor muscle, pain measurement, psychometrics, reliability, agreement.

Tweetable abstract

A simple pelvic floor sensory and muscle function exam based on ICF/WHO is reproducible and can be used clinically.

INTRODUCTION

Physical therapy evaluation of the pelvic floor muscle functions (PFMF) is one relevant aspect of the assessment of women with pelvic floor dysfunctions. It is necessary for the physiotherapeutic diagnosis of muscle and movement related functions to appropriately set the treatment targets that are specific to the woman. Diagnosis includes identifying the presence of impairments on the structure and the function of pelvic floor muscles (PFM),[1] Sensory function is related to the functions that the body senses, such as sensing the relative position of body parts (proprioceptive function) and pain (sensation of unpleasant feeling in some body part).[2] Muscle function refers to the physiological functions of muscles, such as power, endurance and tone.[2] Integrity of PFMF and adjacent structures (fascial and ligamentar tissues) are important mechanisms to maintain urinary and faecal continence, as well as pelvic organ support.[3] Pelvic floor muscle training (PFMT) is the first line treatment for women with urinary incontinence (UI) and is proven to minimize initial stages of pelvic organ prolapse (POP).[4] However, to design a patient-oriented rehabilitation program, a consensual, and reproducible PFMF assessment, is mandatory.

Some PFMF evaluation scales and “schemes” based on vaginal palpation have been previously proposed,[5] such as the Brink scale,[6] Ortiz Scale,[7] Modified Oxford Scale [8,9] and the PERFECT scheme [9] All of these scales and schemes focus evaluation in two PFMF: strength/power and endurance. In 2009 Slieker ten-Hove et al., proposed a scale based on International Continence Society (ICS) terminology and considered additional PFMF, such as the ability to contract, relax and the response of PFM to a perturbation. The instrument is mostly focused on signs and symptoms of diseases, not on human functionality. The scale organized the PFMF into observable signs of incontinence and PFM contraction and relaxation, yielding 18 items to be registered during PFMF evaluation.[10] Aiming at human functionality, instead of on the disease, helps the physical therapist to identify which are the relevant aspects of human characteristics that should be assessed and targeted at as functionality is the utmost goal of a rehabilitation process.[2] Although Slieker et al., 2009, found good reliability indexes for intrarater analysis for most signs of all PFMF measured (10 out of 18 tested items), only threeof them showed interrater reliability. These results indicate that a refinement in the PFMF evaluation scheme is needed before its adoption in clinical settings.[10]

Reproducibility refers to reliability and agreement aspects.[11] Reliability refers to the ability of an instrument to distinguish individuals in the face of measurement error,[11] or the “extend to which clinicians can rely on data”.[12] Agreement estimates the measurement error in repeated measurements, identifying how close the results of those measurements are.[11] Reproducible data on PFMF allows the progress towards a better understanding on PFMF behaviour, by means of information grouping to identify, for instance, which are their reference parameters; to define the dose of a rehabilitation intervention and to establish physical therapy discharge criteria.[4,13]

Also, a uniform terminology on PFMF is lacking and it is based on operationism [14,15], which induces a proliferation of concepts and terms that hinder data gathering, reduce the feasibility of generalization beyond that investigation, and ultimately bounds communication and scientific progress.[16] A systematic review of PFMF [14] conducted by our study group identified relevant investigated PFMF terms in literature among women with and without UI, as well as the most used instruments to measure them. As terminology was not uniform, we proposed a linking process of those PFMF to the International Classification of Functioning, Disability and Health (ICF) terminology[17] according to well-established linking rules.[18] Those results supported the evidence for content validity of a PFMF assessment exam that we currently propose, based on a theoretical framework based on functionality, on a consensual terminology, on shared meanings of conceptual definitions and on a set of clinically accessible and worldwide mostly reliable and valid operational definitions.[2,16] As not all of those operational definitions were assessed for reproducibility and validity in literature, we intend to test the intra and interrater reliability and agreement of the PFMF exam (Exame das Funções Sensoriais e Musculares do Assoalho Pélvico-EFSMAP) based on the ICF/WHO terminology and measured by worldwide accessible instruments among women with and without urinary incontinence and other PFD.

METHODS

This is a prospective crossectional methodological study to test intrarater and inter-rater reliability and agreement of the EFSMAP. It was conducted in accordance with the Declaration of Helsinki, all subjects gave written informed consent, and the study was approved by the Ethic Committee of *Universidade Federal de Minas Gerais* (UFMG-Brazil) under the number CAAE 44534615.5.0000.5149. This study was written according to the *Guidelines for Reporting Reliabilty and Agreement Studies* (GRAAS).[19]

Participants

A convenience sample of women older than 18 years, with or without UI and other PFD recruited from public secondary gynaecology unit and from the general community were included. Women who were virgo, pregnant, those who have had an abortion or have given birth in the last 12 months, were in their monthly period, showed symptoms and sings of vaginal and/or urinary infection, had undergone pelvic surgery in the last five years, those who did not understand the researchers orientations on pelvic floor evaluation and those who refused to sign the informed consent were excluded. For vaginal manometry measurements, women' vaginal canal had to allow probe insertion. Participants were evaluated from January to June in 2016.

The sample size of 23 subjects was established according to a reliability index of 0.80 for continuous variables, a 80% statistical power and a 0.05 alpha value.[20]

Main outcomes: EFSMAP, operational definitions and instruments

The relevant PFMF to be measured, as well as the procedures and instruments used to measure those functions were selected from a previous systematic review on PFMF terminology and a study that linked this terminology to the ICS.[14,17] Those information were organized into the EFSMAP (Figure 1).The respective PFMF terms according to chapter 7 (neuromusculoskeletal and movement-related functions) of the ICF/WHO,[2] along with their conceptual and operational definitions are presented in Table 1.

To encourage the use of the EFSMAP worldwide among different clinical settings, the measurement of PFMF were based on accessible and user-friendly instruments, which have been previously reported as valid for rating pelvic floor *Strength* and *Endurance.*[21–24] As sensory inputs are important to provide information to regulate optimal muscle and movement actions,[25] the sensorial functions proprioception and pain were included in the

Figure 1: Pelvic Floor Sensory and Muscle Function Exam (EFSMAP-Exame das Funções Sensoriais e Musculares do Assoalho Pélvico)

Examinator:________________________ Date:__________ Time of the day:________		
Positioning	( ) Supine with lower limbs over supporting roll ( ) Supine with lower limbs flexed no support ( ) Supine ( ) Lithotomy ( ) Lateral decubitus ( ) Standing	
INSPECTION		
Control (contraction) (b7608)	( ) absent ( ) present	
PALPATION		
Number of fingers	( ) 1 ( ) 2	
Proprioceptive function (b260)	( ) yes ( ) no	
Pain in pelvic floor muscles (b28018) (NRS - 0 to 10)	( ) no ( ) yes Right:_______Left:_______	
Tone (b7350)	Right ( ) low ( ) normal ( ) high	Left ( ) 1 low ( ) 2 normal ( ) 3 high
Control (contraction) (b7608)	( ) absent ( ) present	
Control (relaxation) (b7608)	( ) absent ( ) complete ( ) partial/slow	
Involuntary movement reaction (cough) (b755)	( ) absent ( ) present	
Coordination (b7602)	( ) present ( ) absent ( ) abdominals ( ) gluteus ( ) adductors ( ) respiration ( ) other:__________________	
Strength (b7300)	Oxford modified scale:________	
Endurance (duration) (b7408)	__________seconds	
Endurance (repetitions) (b7408)	__________times	
VAGINAL MANOMETRY		
Resting vaginal pressure	__________________________ cmH_2O	
Strength (b7300)	__________________________ cmH_2O	
Endurance (duration) (b7408) 60% of MVC:____________	__________________________seconds	

Legend: NRS- numeric rating scale; MVC: maximum voluntary contraction

exam. Pain is also relevant as it may impairs voluntary contraction and strength development.[26,27] Vaginal resting pressure is not a muscle function and it is not covered by ICF. However, it is a frequently measured parameter in PFM assessment studies as a protocol to use vaginal manometry, [22,28,29] thus, it was also included. The functions are presented using ICF terms and their respective ICF codes as follows: *Proprioceptive function* (b260), *Pain (*b28018)*, Tone* (b7350); *Control of*

Simple Voluntary Movement (contraction) and *(relaxation) (b7608)*, *Coordination of Voluntary Movement* (b7602), *Involuntary Movement Reaction* (cough) (b755), *Strength* (b7300), *Endurance* (duration and repetitions) (b7408). We understand that the most appropriate term to refer to the to the muscle function related to the force generated by the contraction of a muscle or muscle groups is *Strength*, and not *Power*, as it is stated in ICF. The shared meaning for *Power* is the product of force and velocity[20] and it is not what effectively has been measured in most PFMF studies.[21–24] Thus, from now on, we will adopt the term *Strength* instead of *Power* to refer to function coded under b7300 in ICF. Terms, conceptual and operational definitions of all functions are presented in Table 1. Functions were evaluated by means of visual observation, palpation and vaginal manometry using Peritron® (CardioDesign PTY LTD – Australia). Manometry is a valid method to assess PFM strength as long as simultaneous observation of an inward movement of the probe and no contraction of synergistic muscles is observed.[23]

A pocket calculator was used to compute a 60% value of the Maximal Voluntary Contraction in order to register *Endurance* (duration)[29] by manometry and a chronometer was used to register the time in seconds the contraction was sustained. The rationale for using that level of contraction is that it corresponds to 12 repeated maximum contractions, which falls into the range recommended by the American College of Sports Medicine´s physical activity guidelines to endurance training for healthy adults.[30]

Procedures

Raters' training and data collection were done in a six step process: 1st) first round discussion among raters; 2nd) first round assessment training through a pilot study with 10 participants; 3rd) second round discussion to clear doubts and barriers to mensuration; 4th) second round assessment training through a pilot study with other 16 participants; 5th) third round discussion on doubts; 6th) evaluation of 23 patients for inter-rater and intrarater testing included in this study.

Participants were instructed on the structure, site and function of the pelvic floor muscle (PFM), using illustrative anatomic figures of pelvis and pelvic organs and informed on the interview and physical examination procedures. PFM assessment was performed in a private room and measurements/ratings were conducted independently by each rater. Then, volunteers answered a sociodemographic and clinical questions on urinary, sexual and defecation functions, recreation and leisure, eating and drinking habits, and anthropometric measurements (height and weight) were taken. Subsequently, women had their pelvic floor muscles evaluated by vaginal digital examination, followed by vaginal manometry. Participants were lithotomy positioned and pelvic organ prolapse staging was measured using the POP-Q schema.[31] Then, they layed in supine position with flexion, abduction and lateral rotation of hips and knees flexed in a relaxed way as knees were supported by a foam roll measuring 30cm in diameter, and 70cm length. Women were instructed to contract the PFM as if they were trying to stop urine flow or hold gases, without the contraction of other synergistic muscles. Coordination was rated as impaired if PFMF were performed only with the use of synergistic muscles during examination.

For inter-rater reliability and agreement, both raters examined volunteers in the same day within a 10 to 20 minute interval between assessments in a random order. Steps of PFMF exam followed the logic order for testing muscle function as presented in Table 1. For intra-rater reliability and agreement, the second evaluation was set one week apart from the first one, at the same period of the day the previous exam had been performed. The procedures were identical to ones for inter-rater test.

For PFMF evaluation, whenever *Control* (contraction) on palpation was rated as absent and *Strength* was rated as 0 or 1 in Modifed Oxford Scale (MOS), the functions *Control* (relaxation), *Coordination*, *Endurance (duration)* and *(repetitions)* were rated as “no contraction” and measurements by vaginal palpation and manometry of those functions were not performed. Whenever this happened or women did not tolerate probe introduction into vaginal canal, vaginal manometry was not performed. In those cases, new participants were included for vaginal manometry evaluation until sample size was reached.

Table 1: Conceptual and operational definitions of sensory function, pain, muscle and movement related function measurements based on ICF/WHO terminology as linked by Saltiel et al., 2018.[17]

Function	Conceptual definition	Operational definition	Scale
b260 Proprioceptive function	Sensory functions of sensing the relative position of body parts.[2]	Digital vaginal palpation: Examiner inserted one finger in vaginal canal and posed it over the medial aspect of vagina corresponding to level of deep PFM and pressed on anterior, posterior and right and left lateral vaginal walls and asked woman to inform the direction of pressure felt.	**Absent**: pressure directions not identifiable. **Present**: pressure directions identified. State directions felt.
b28018 Pain Sensation	Sensation of unpleasant feeling indicating potential or actual damage to some body structure. [2]	Digital vaginal palpation: Finger position as described above, examiner pressed on anterior, posterior and right and left lateral vaginal walls and asked woman to inform the presence of pain. In case of affirmative answer, the woman was asked to grade its intensity.	**Absent:** No pain is felt. **Present:** There is pain or discomfort. **Numeric Classification Scale** (0 to 10)
b7350 Muscle tone	Tension felt over PFM during palpation in the most relaxation state in which women can voluntarily reach [25].	Digital vaginal palpation: Examiner inserted one finger in vaginal canal and posed it over the medial aspect of deep pelvic floor muscles anterior to anorrectal junction (separately on the left and then on the right sides of vaginal canal) and performed a slow compression over PFM. This maneuver was repeated three times after 3 pelvic floor voluntary muscle contractions in order to locate muscle and to refrain muscle from tixotropy.[32]	**Low**: no or minimum resistance to pressure offered by muscle (very deformable; or not palpable muscle due to muscular atrophy as in hypoestrogenism). **Normal**: tissue offers some resistance to stretch, but it is easily deformable. **High**: muscle offers high resistance to deformation or cannot be deformed.
b7608 Control of simple voluntary movement (contraction)	Ability to contract the PFM on demand [33]	Vaginal (bi) digital palpation: Examiner inserted one or two fingers in vaginal canal (depending on its natural aperture) and posed it over the medial aspect of deep PFM (simultaneously on the left and right sides)* and felt muscle response to contraction on demand.[9]	Visual observation: **Present**: Inward movement of perineum (in cranial direction) is observed **Absent**: no inward movement of perineum Palpation: **Absent**: No contraction of pelvic floor muscles is palpable. **Present**: Unequivocal increase in muscle tension during contraction is felt.

Continues...

b7608 Control of simple voluntary movement (relaxation)	Ablity to relax pelvic floor muscles on demand after a contraction has been performed. [9]	Vaginal (bi) digital palpation: Examiner felt muscle response to relaxation on demand.[24]	**Absent**: no relaxation is felt. Contraction persists even after the command “stop contracting” **Partial/Slow:** Pelvic floor muscles do not return to their resting state or do it in a slow manner. **Present**: Relaxation is felt as a termination of the contraction.The pelvic floor muscles should return fast and completely to their resting state *Whenever *Control* (contraction) (b7608) was classified as absent, this function could not be evaluated.
b7602 Coordination of voluntary movement	Activation of correct muscles in adequate time and intensity to perform a specific action.[34]	Vaginal (bi) digital palpation: + visual observation of abdomen, breathing pattern, tight and buttocks: Examiner felt contraction and the use of other muscles.	**Present:** No muscles other than PFM contracted on demand **Absent:** Contraction of PFM together with other muscles. We have targeted at the frequently observed synergies: abdominal (other than transversus abdominis muscle), gluteal, tight adductors, respiratory, or Valsava maneuver.
b755 Involuntary movement reaction function (cough)	Muscular contraction in response to a perturbation.[25]	Vaginal (bi) digital palpation: Examiner felt muscle response to a strong cough on demand.	**Absent:** No contraction is felt when a strong cough is performed. **Present:** a contraction is clearly felt under examining finger, either on left or right sides of vaginal canal.
b7300 Strength	Capacity of a muscle to generate force. [20]	Vaginal (bi) digital palpation: Examiner felt intensity of the muscle tension during contraction under the examining finger and movement of the finger.[9]	**Modified Oxford Scale (MOS)** (Laycock & Jeerwood, 2001):[9] **0** No discernible muscle contraction. **1** A flicker or pulsation is felt under the examiner's finger. **2** An increase in tension is detected, without any discernible lift. **3** Muscle tension is further enhanced and characterised by lifting of the muscle belly and also elevation of the posterior vaginal wall. **4** Increased tension and a good contraction are present which are capable of elevating the posterior vagin… Continues... resistance (digital pressure applied to the posterior vaginal wall). **5** Strong resistance can be applied to the elevation of the posterior vaginal wall; the examining finger is squeezed

Continues...

		Vaginal manometry (Peritron™: Vaginal probe was covered with a non-lubricated condom and a small amount of water-based gel was placed on the tip of probe. Peritron was calibrated to zero before probe insertion into vagina. The probe was inserted into vaginal canal until its central part was at 3.5cm of the introitus. A measurement was taken during rest (vaginal resting pressure-VRP). Calibration was again set to zero and a measurement on maximal voluntary contraction (MVC) was taken. Three contractions were performed, with a 1 minute rest between them. The highest score on display was registered. [22]	and drawn into the vagina (like a hungry baby sucking a finger) [9] **Cm H_2O**
b7408 Endurance (duration)	Ability to sustained muscle contraction of isolated muscle groups for the required period of [35].	Vaginal (bi) digital palpation: Examiner felt the time (in seconds) the subject sustained the maximum or near maximum contraction. The consistent and marked drop in muscle contraction intensity and/or intermittent contractions and/or use of synergistic muscles were the cutt-off point to terminate this evalulation. [9] Vaginal manometry (Peritron™): After registering the MVC, a 60% value of such score was computed. Women were asked to sustain contraction as long as they could without using synergistic muscles. Time in seconds above 60% was registered. This was done 3 times with a 1 minute rest between trials and the highest value was registered.[29]	**Seconds**

Continues...

b7408 Endurance (repetitions)	Ability to perform a set of contractions until fatigue occurs.[35]	Vaginal (bi) digital palpation: Examiner felt the number of sustained contraction that the woman was able to perform. Interval between contractions corresponds to a breathing cycle (approximately 4-5 sec). Repetitions cut-off point is any fatigue sign, such as explicit reduction in contraction intensity, irregular contraction or slow relaxation after contraction.[9]	**Number of repetitions**

Note:*This finger position was used in all vaginal canal palpation tests, unless otherwise specified.

End.

Data analysis

Descriptive statistics was performed for each variable (mean, standard deviation and frequency, minimum and maximum as appropriate). Intraclass Correlation Coefficient (ICC) was used for inter-rater reliability (ICC 2,1) and intrarater (ICC 3,1) analysis were used. Limits of Agreement were used to test data dispersion.[36]Percent agreement, Kappa statistics and linear weighted Kappa were used to compute measurement error and reliability of categorical and ordinal variables, respectively.[12]Reliability and agreement coefficients were analysed as described by Portney and Watkins, 2009,[12] (ICC values above 0.75 infer good reliability and those below 0.75 of poor to moderate reliability). For agreement and Kappa, values above 80% represent excellent agreement; above 60% substantial levels of agreement; from 40% to 60% moderate agreement; and below 40% poor to fair agreement.[37] Statistical significant level was set at 5%. Analysis were done using SPSS version 19 and VassarStats © available at http://vassarstats.net/kappa.html.

RESULTS

Participants

The study sample comprised of 30 participants. Twenty three women took part on the visual observation and vaginal palpation assessment. Seven women were either not able to contract PFM or did not tolerate vaginal probe insertion and were excluded from the vaginal manometry evaluation. Thus, other seven women were included to fulfil the sample size for vaginal palpation.

Women's mean age was 51.2 (14.7) years. Average of education level was 10.8 (5.3) years. Thirty tree percent of participants declared to be white, 4.3% indian, 40.4% were brown and 14.9% were black. Most women were married (56.1%). Body mass index in average was 27.7cm/m^2 with a range varying from 17.8 to 42.8 cm/m^2. Average number of pregnancies, deliveries and abortion were 3.3 (0-11), 2.7(0-11), 0.7(0-4), respectively. Fifty two percent of women vaginally delivered, 14% went through cesarean section, 12% underwent both and 8% instrumentally delivery. Approximately 6% had no PFD, 71.9% had urinary incontinence, 41.8% reported some unspecific pelvic pain, 35.7% had flatal incontinence, 28.6% complained of constipation,[38] 26.8% complained of dyspareunia, 17.5 had recurrent urinary tract infection, 16.1 complained of faecal incontinence.[39] POP stage were as follows: 0=18.6%, I=44.2%, II=32.6, III=4.7%, IV=none.

Results of intra and interrater reliability and agreement are presented in tables 2 and 3. High values of coefficient of variation (Table 3) show the sample heterogeneity.

Table 2: Reliability and agreement parameters for interrater and intrarater evaluations for categorical and ordinal variables included in the Pelvic Floor Sensory and Muscle Exam (EFSMAP): *Control* (contraction and relaxation), *Proprioceptive* function, muscle *Tone*, *Pain*, *Coordination* and *Strength*

Pelvic floor functions	**INTERRATER (n=23)**		**INTRARATER (n=23)**	
	Reliability (95%CI)	**Agreement (CI95%)**	**Reliability (CI95%)**	**Agreement (CI95%)**
Visual observation				
b7600 Control of simple voluntary movement (contraction)	K=1.00 (1.00-1.00)	1.00 (0.89-1.00)	K=0.83 (0.52-1.00)	0.96 (0.78-1.00)
Vaginal palpation				
b260 Proprioceptive function	K=1.00 (1.00-1.00)	1.00 (0.89-1.00)	K=1.00 (1.00-1.00)	1.00 (0.83-1.00)
b7352 Muscle tone (Right)	Kw=0.78 (0.61-0.94)	0.85 (0.70-0.94)	Kw=0.22 (0.00-0.58)	0.64 (0.43-0.81)
b7352 Muscle tone (Left)	Kw=0.68 (0.50-0.86)	0.75 (0.59-0.87)	Kw=0.67 (0.40-0.94)	0.80 (0.59-0.92)
b28018 Pain in body part (PFM)	K=0.77 (0.56-0.98)	0.90 (0.75-0.97)	K=0.43 (0.07-0.78)	0.72 (0.50-0.87)
b7600 Control of simple voluntary movement (contraction)	Kw=0.84 (0.54-1.00)	0.98 (0.85-1.00)	Kw=1.00 (1.00-1.00)	1.00 (1.00-1.00)
b7600 Control of simple voluntary movement (relaxation)	Kw=0.68 (0.39-0.97)	0.89 (0.72-0.97)	Kw=0.91 (0.73-1.00)	0.96 (0.76-1.00)
b7602 Coordination of voluntary movement (vaginal palpation + visual observation)	K=0.88 (0.71-1.00)	0.94 (0.80-0.99)	K=0.67 (0.37-0.96)	0.83 (0.62-0.95)
b755 Involuntary movement reaction function (cough)	Kw=0.71 0.42-0.99 ()	0.83 (0.61-0.94)	Kw=0.77 (0.46-1.00)	0.92 (0.73-0.99)
b7300 Strength (MOS)	Kw=0.78 (0.68-0.89)	0.70 (0.54-0.83)	Kw=0.91 (0.80-1.00)	0.88 (0.68-0.97)

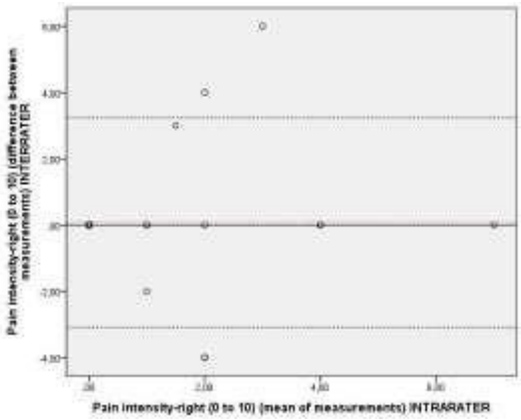
Legend: CI= confidence interval of 95%; K = Kappa coefficient; Kw = Weighted Kappa coefficient; PFM: Pelvic floor muscle; MOS: Modified Oxford Scale

Table 3: Descriptive analysis of measurement differences and reliability for interrater and intrarater measurements for continuous variables included in the Pelvic Floor Sensory and Muscle Exam (EFSMAP): *Pain*, vaginal resting pressure, *Strength* and *Endurance*. (N=30)

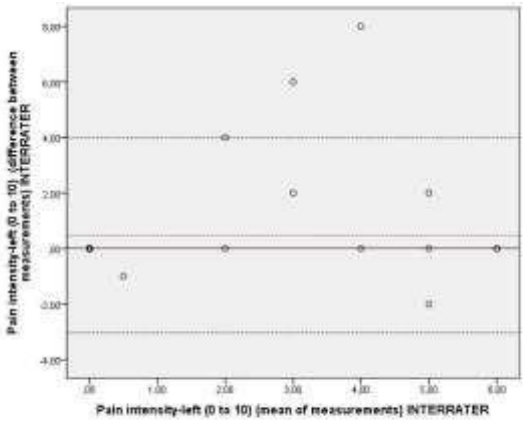
Functions	Rater 1/ 1st Rating Mean(SD)	CV	Rater 2/ 2nd Rating Mean(SD)	CV (%)	ICC (95% CI)	Mean difference (SD)	Limits of agreement *LowerL.*	*UpperL.*	P value
VAGINAL PALPATION									
Interrater (n=23)									
b28018 Pain intensity (right)	0.86 (1.74)	202.0	0.80 (1.77)	221.5	0.57 (0.32-0.75)	0.08 (1.58)	-3.08	3.23	0.765
b28018 Pain intensity (left)	0.84 (1.81)	215.6	1.38 (2.40)	174.2	0.66 (0.45-0.81)	0.48 (1.75)	-3.03	3.98	0.095
b7401 Endurance (duration)	5.85 (4.65)	79.4	6.16 (5.05)	81.9	0.82 (0.69-0.90)	0.01 (3.02)	-6.02	6.04	0.652
b7408 Endurance (repetitions)	4.36 (2.23)	51.2	4.32 (2.63)	60.7	0.81 (0.56-0.92)	0.16 (1.50)	-2.84	3.16	0.980
Intrarater (n=23)									
b28018 Pain intensity (right)	0.86 (1.74)	202.0	0.92 (1.70	184.0	0.07 (-0.32-0.44)	-0.27 (2.65)	-5.56	5.02	0.609
b28018 Pain intensity (left)	0.84 (1.81)	215.6	0.96 (1.72)	179.1	0.48 (0.12-0.73)	0.04 (1.77)	-3.49	3.57	0.911
b7401 Endurance (duration)	5.85 (4.65)	79.4	5.00 (3.81)	76.1	0.80 (0.58-0.91)	0.70 (2.17)	-3.65	5.05	0.189
b7408 Endurance (repetitions)	4.36 (2.23)	51.2	5.0 (2.31)	46.2	0.76 (0.48-0.90)	0.53 (1.68)	-2.83	3.88	0.144
VAGINAL MANOMETRY									
Interrater (n=23)									
Vaginal resting pressure (cmH2O)	32.71 (9.72)	27.9	31.65 (7.66)	22.6	0.84 (0.66-0.93)	-0.72 (4.19)	-9.10	7.66	0.419
b7300 trength (cmH2O)	37.53 (19.81)	52.8	38.97 (19.81)	50.2	0.93 (0.85-0.97)	-0.71 (7.71)	-16.12	14.71	0.635
b7401 Endurance (duration) (sec)	7.59 (10.24)	134.9	8.0 (11.77)	147.1	0.95 (0.89-0.98)	-1.46 (3.49)	-8.44	5.52	0.052*
Intrarater (n=23)									
Vaginal resting pressure (cmH2O)	32.71 (9.72)	27.9	30.85 (9.08)	29.4	0.80 (0.56-0.92)	-0.84 (5.56)	-11.97	10.29	0.517
b7300 Strength (cmH2O)	37.53 (19.81)	52.8	34.33 (13.34)	38.9	0.89 (0.73-0.96)	-1.31 (7.23)	-15.78	13.16	0.440
b7401 Endurance (duration)	7.59 (10.24)	134.9	5.00 (5.27)	105.5	0.97 (0.92-0.99)	-0.16 (1.42)	-3.01	2.69	0.650

Legend: CV: coefficient of variation; *borderline statistically significant difference.

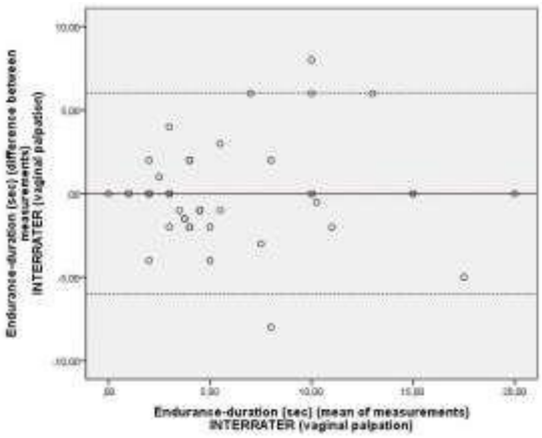
1a)



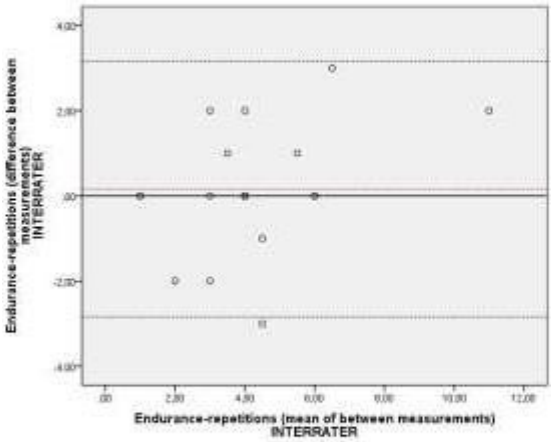
1b)



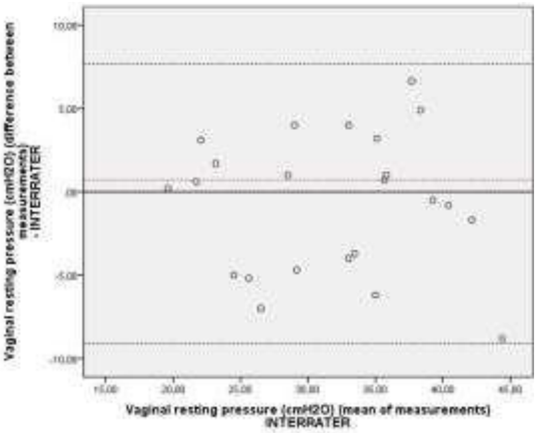
1c)



1d)



1e)



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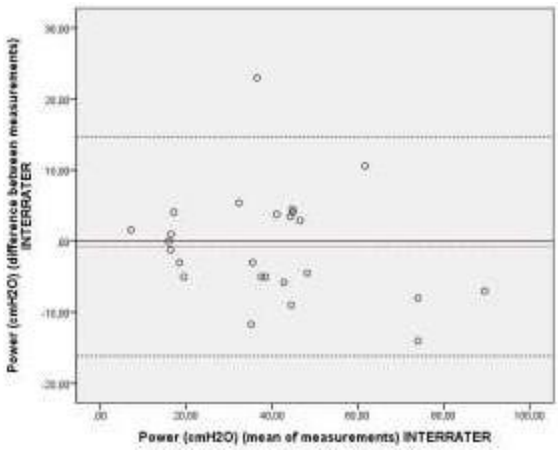


1g)

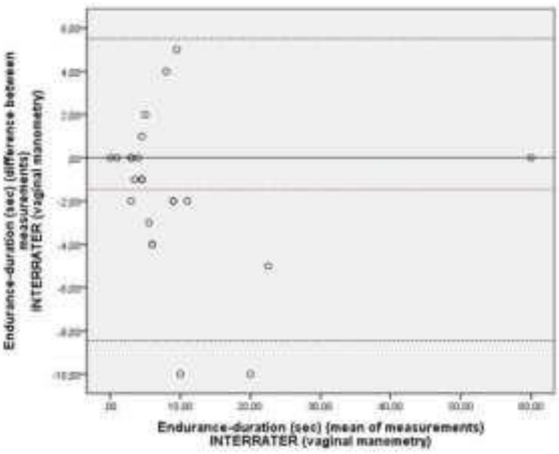
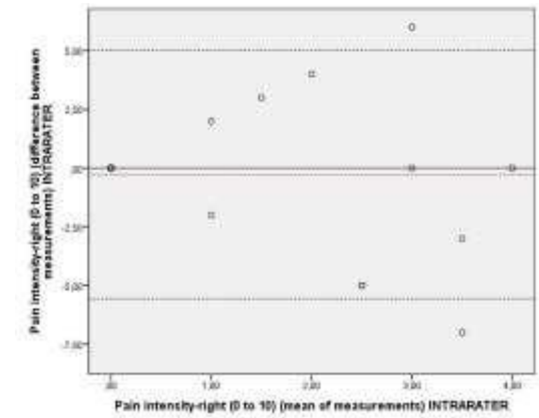
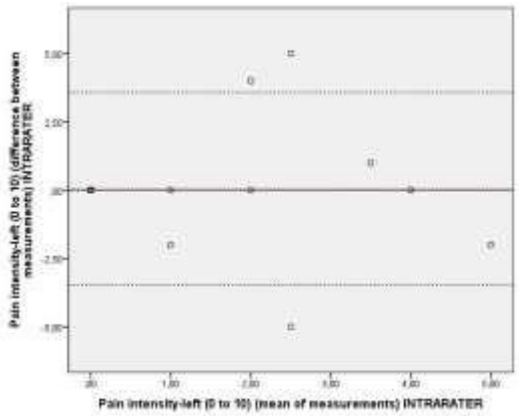


Figure 2: Bland–Altman plots showing interrater agreement analysis. The differences between raters are plotted against each individual means for the two tests. The mean difference and random error lines forming the 95% limits of agreement are presented for the functions measured by vaginal palpation: a) *Pain* (right), b) *Pain* (left), c) *Endurance* (duration), d) *Endurance* (repetition); and measured by vaginal manometry: e) vaginal resting pressure, f) *Strength*, g) *Endurance* (duration)

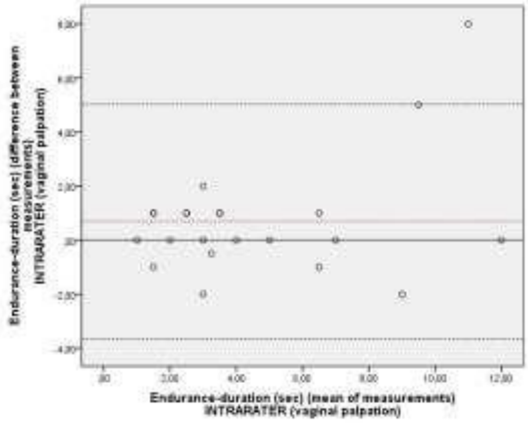
2a)



2b)



2c)



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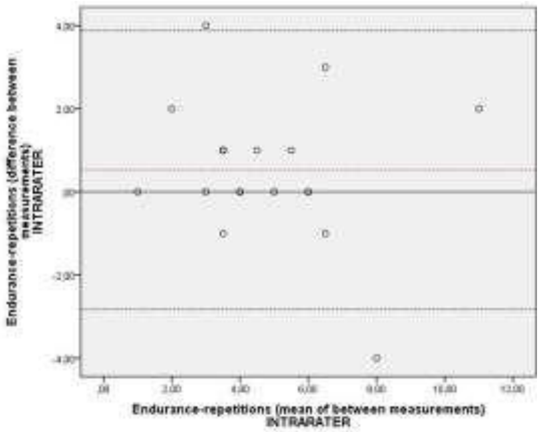

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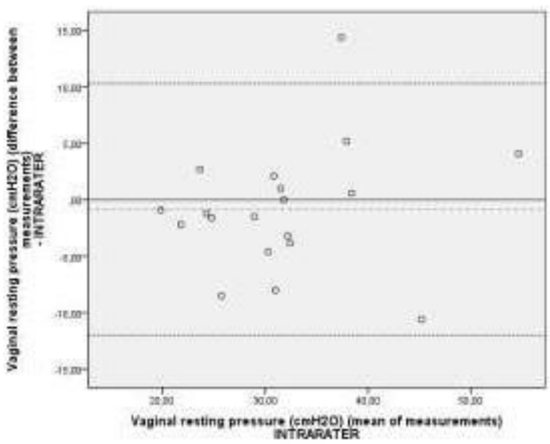
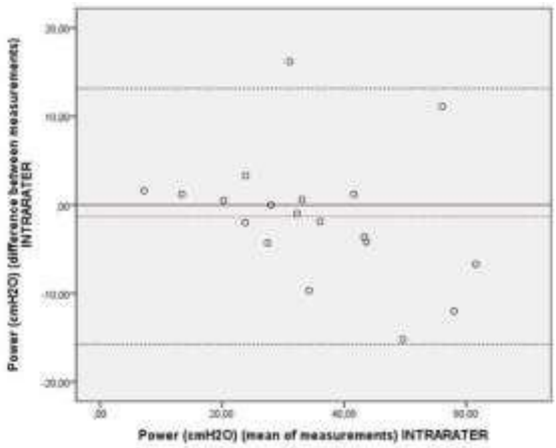


2f)



2g)

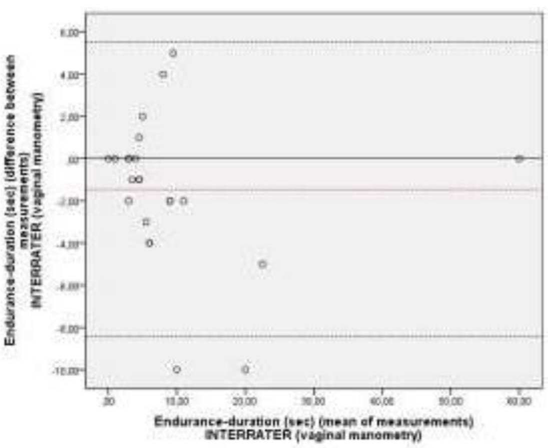


Figure 3: Bland–Altman plots showing intrarater agreement analysis. The differences between the ratings are plotted against each test mean for the two exams. The mean difference and random error lines forming the 95%limits of agreement are presented for the functions measured by vaginal palpation: a) *Pain* (right), b) *Pain* (left), c) *Endurance* (duration), d) *Endurance* (repetition); and measured by vaginal manometry: e) vaginal resting pressure, f) *Strength*, g) *Endurance* (duration)

Reliability analysis

For interrater reliability all Kappa coefficient values related to sensory, pain and PFM function varied from 0.68 [*Control* (relaxation) and muscle *Tone*] to 1.0 [*Control* (contraction) on visual observation and *Proprioceptive function*] and were statistically significant. These results indicate good to perfect reliability for the tested functions.[37] For the intrarater reliability analysis all but the functions *Pain, Pain* intensity and muscle *Tone* (right) did reach statistical significance with good to excellent indices of reliability, varying from 0.67 [muscle *Tone* (left)] to 1.00 [*Proprioceptive function* and *Control* (contraction) during vaginal palpation] (Table 2).

Interrater and intrarater ICC of the muscle functions *Strength, Endurance (duration), Endurance (repetitions)* and of the variable vaginal resting pressure showed good to excellent consistency,[12] (Table 3) varying from 0.84 to 0.97 and were statistically significant. The *Pain* intensity (right) measured using a numerical scale varying from 0 to 10 showed moderate reliability in interrater analysis (ICC=0.57, 95% CI=0.32-0.75) and no reliability in intrarater analysis (0.07, 95% CI=-0.32-0.44).

Agreement analysis

For the functions measured by categorical scales, agreement was good to excellent, varying from 0.75 for the muscle *Tone* (left) to 1.00 [*Control* (contraction) during visual observation and *Proprioceptive function*] in interrater analysis. In intrarater analysis percent agreement was also good to excellent (0.72 for *Pain* to 1.00 for *Proprioceptive* function).

Results from Bland-Altman analysis showed a good agreement both in intra and interrater testing, as in most cases the mean differences (bias) were close to zero and very few values were beyond the limits of agreement (Figures 2 and 3). No statistical significance in mean difference was found, as shown in Table 3 for interrater and intrarater analysis. However, a borderline p value (p=0.052) was found for differences in means in interrater analysis for the function *Endurance* (duration) measured by vaginal manometry.

For both intra and interrater analysis of the *Pain* intensity (right) mean differences increased as measurement values increased (Figures 2a and 3a). This was also observed for *Strength* measured by vaginal manometry in intrarater analysis (Figure 3f).

DISCUSSION

Intra and interrater reliability and agreement indices of most functions assessed by the EFSMAP showed to be good to excellent for most functions tested. The functions *Pain* and intensity and muscle *Tone* were reliable in the interrater but not in the intrarater analysis.

Strengths and limitations

This study proposed a thorough, accessible and free language barrier PFMF exam, which was previously content validated by means of a systematic review on PFMF and linked to ICF/WHO terminology following well established rules.[18] As it was shown to be reproducible, this exam allows PFMF accurate measure, which may guide the setting-up of a dose specific, thus, more effective, rehabilitation program. Also, an exam based on a universal language may foster communication among scientific community and health care professionals who deal with women´s Health.

Due to the heterogeneity of the studied sample, results from reliability indices are accurate, as instruments were able to discriminate individuals. Nevertheless, a sample with mild to no pain was unsatisfactory to evaluate the reliability and agreement indices of a numeric rating scale for pelvic floor muscle pain.

Interpretation

Some studies lack reliability (bellow 40% reliability) either in inter or intrarrater analysis for the functions *Control* (contraction and relaxation), *Coordination*, *Involuntary movement reaction* (cough), *Strength* and *Endurance,* [27,28,40] using similar operational definitions as we did. For instance, Slieker-ten Hove, 2009,[10] found no reliability for *Control* (relaxation) in interrater analysis (Kw=0.17, 95%CI=0.01-0.38). Bo and Finkenhagen, 2001,[28] found a poor K=0.37, SEM=0.16 for *Strength* (measured by vaginal palpation using MOS). On the other hand, other authors stated good to excellent indices when testing reliability of *Control* (contraction), *Strength* (vaginal palpation and manometry) and *Endurance*[10,22,26,27,32,41–43] varying from a Kw=0.64, 95%CI=0.46-0.81 for *Control* (contraction) function in interrater analysis[10] to an ICC=0.98, 95%CI=0.95-0.99 for *Strength* in intrarater analysis using a vaginal manometer.[41] Taken together, results indicate that it is possible to achieve good indices of reliability of most PFMF either measured by vaginal palpation or by vaginal manometry. Clearly specifying PFMF conceptual and operational definitions and systematically training raters are the steps to be taken to grant reliability. Nevertheless, we understand that there is a learning curve to reach expertise as we have achieved those results after three rounds of discussion, training and examining a sample of 26 women with distinct clinical and demographic characteristics before collecting data for this study.

Since PFMF is first line treatment for PFD, such as UI,[4] and a dose specific intervention is critical to contribute to its effectiveness,[13] a thorough evaluation of PFMF is mandatory. As vaginal palpation and manometry are relatively worldwide accessible and easy-to-use instruments, efforts should be made to grant their reliable application in clinical practice to guide physiotherapeutic interventions aiming to improve therapeutic results.

Although *Pain* (presence and intensity) and *Tone* were reliable in interrater analysis, there was no reliability during intrarater testing for the *Pain* intensity and *Tone* (right). Few authors have investigated those functions using similar operational definitions as ours and also found contradictory results. Albeit the presence of *Pain* had good indices of intra and interrater reliability (Kw=0.79, 95%CI=0.60–0.87 and Kw=0.85, 95%CI=0.76–0.91, respectively) in one study[10] the intensity of *Pain*, measured by an 11 point numeric rating scale in other study,[42] showed controversial results varying from no (ICC= 0.22, p=0.31 for intrarater analysis) to good reliability (ICC=0.69, p=0.01) depending on the site of PFM (whether posterior, anterior, left or right) and on the rater who conducted the examination.[42] As observed in our sample, their participants reported low indices of pain intensity (0.24[42] X 0.97 ours, in a 0 to 10 numeric rating scale), which may have underscored the ability of a pain scale to discriminate pain in a population with mild symptoms. This may also implies that pain is an unstable parameter, although an important one, and it should be monitored. A symptomatic sample should be tested to study reliability of a pain scale to rate pelvic floor muscle pain intensity.

For the function muscle *Tone*, while some authors [26,27,32] have found moderate to good reliability indices in intra and interrater analysis, (for instance, r_s=0.70 to1.0 for intrarater; and r_s=0.70 to 0.80 for interrater, Loving 2014), others have found fair to no reliability in the scales used to measure it by vaginal palpation. [27,42] Kavvadias et al., 2013[42] found no intra (same day) (ICC=0.10, p=0.34 and 0.13, p=0.30); or interrater reliability in a seven to 10 day interval (ICC=0.03, p=0.45 and 0.-0.36, p=0.92). Instead of a 3 point scale, as we have proposed, it is likely that they have used an 11 point scale. Authors were not clear on how measurement was scored, nor conceptually defined muscle *Tone*. Loving et al., 2014,[26] have used a six point scale with good reliability indices. Thus, a scale with fewer categories may improve reliability. Also, the time lag between the 1st and the 2nd rating matters. Different from us, they gave a one day interval between intrarater analysis. As we intended to control for rater recall bias we have used a longer period (1 week apart) and this may have affected the results. It is possible that, similarly to *Pain*, *Tone* behaviors as an unstable muscle function and one week interval between tests might have allowed participants to change. *Tone* might also be a reflection of the myofascial force transmission (propagation of muscle tension that affects other structures),[44,45] coming from adjacent myofascial structures that are spontaneous and constantly being self-regulated in order to keep balance in a dynamic musculoskeletal system. [46,47] An imbalance in that mechanism may lead to an increase or decrease in myofascial tone or impairs coordination, supporting the occurrence of several musculoskeletal conditions [46] such as ankylosing spondylitis in lumbar vertebrae, possibly due to excessive force concentration and inefficiency in force transmission.[47] In that sense, although muscle tone seems to be a labile marker of muscle impairment, it is a critical one and it should not be neglected. Instead, it must be tracked over a period of time to uncover muscle and movement behavior and shortcomings related to pelvic floor.

Agreement was substantial for most PFMF measured by vaginal palpation (over 60%). That is, that method present low measurement error as raters mostly agreed when rating PFMF. However, visual inspection of data showed an increase in *Pain* intensity (right side of PFM) and *Strength* (vaginal manometry) mean differences as their values increased. This may be due either to the low accuracy in measuring women with more pain and stronger by those instruments, potentially underestimating the highest scores and overestimating the lower scores; or to the heterogeneity of the studied sample. A study with a homogeneous sample can put these hypotheses to test.

The *Endurance* (repetitions) showed a bias in interrater analysis with a borderline p value of the difference in measures from raters. Thereupon, for evaluative purposes, *Endurance* (repetitions) seems not to be a good parameter as a follow-up measure, unless it is measured by the same rater.

CONCLUSION

The EFSMAP based on ICF/WHO terminology herein proposed to assess PFMF of women with and without UI and other PFD was soundly based on scientific literature and used worldwide accessible and easy-to-use instruments. The exam was shown to present good indices of reliability and agreement for most PFMF tested. To grant those indices, it is necessary to have clear conceptual and operational definitions and raters shall be systematically trained. Intrarater reproducibility of the functions *Pain* and *Tone* should be tested in a moderate to severe symptomatic population and in a time interval shorter than one week. The EFSMAP can be used for discriminative and evaluative purposes for most PFMF. In clinical practice it could help to improve PFMF diagnosis and to guide setting up a dose specific and, thus, more effective rehabilitation program.

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Disclosure of interests

None. Full disclosure of interest available online as supporting information.

Contributions to authorship

EMF and FS conceived the idea and designed the study; FS and APM supervised participants and collected data; EMF and FS performed the data analysis; EMF, FS and GFV wrote the manuscript. All authors read and approved the final version.

Details of ethics approval

The Ethics Review Board of the Federal University of Minas Gerais State approved the study protocol in July, 28, 2015 (ETIC 44534615.5.0000.5149).

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3.4 Artigo 4 - The Pelvic Floor Sensory and Muscle Function Exam – EFSMAP based on ICF/WHO terminology: a construct validity study

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ABSTRACT

Objective: To test construct validity of the Pelvic Floor Sensory and Muscle Function Exam (EFSMAP-*Exame das Funções Sensoriais e Musculares do Assoalho Pélvico*) based on ICF/WHO terminology by investigating its ability to distinguish women with urinary incontinence (UI) from those without UI.

Design: Methodological study

Setting: Secondary care gynaecology unit and community.

Sample: 182 women (91 with–UI group; and 81 with no UI–non-UI group) aged over 18 years.

Methods: The known groups method procedure was used to test construct validity of the EFSMAP. Two previously trained physical therapists evaluated women's pelvic floor sensory and muscle function by vaginal palpation and manometry (Peritron®).

Main Outcome Measures: Sensitivity and specificity of the following pelvic floor sensory and muscle function: *Proprioception*, *Pain*, *Tone, Involuntary movement reaction* (cough), *Control* (contraction and relaxation), *Coordination*, *Strength* and *Endurance* (duration and repetitions).

Results: *Control* (contraction and relaxation), presence of *Pain*, and *Coordination* had excellent (95.6%) to good (above 70%) specificity indexes but low sensitivity (below 60%). Conversely, *Involuntary Movement Reaction* during cough had good sensitivity (82.56%), but low specificity (37.36%). *Tone* did not distinguish groups (sensitivity: 61.54% and specificity: 53.85%). *Strength* and *Endurance* (duration) distinguished groups, with area under the ROC curve above 0.70. Cutoff values were 3 in Modified Oxford Scale, 45.9cmH2O in vaginal manometry; and 6.5 seconds in vaginal palpation for *Endurance*.

Conclusions: The EFSMAP presented construct validity, as most tested functions distinguished women with UI from those without UI. The cutoff values for *Strength* and *Endurance* may guide physical therapists to set treatment goals towards a more effective and lower cost therapeutic programs for those women. Last, as the exam is based on a functionality framework, it is the starting point to guide Physiotherapists onto what aspects of human movement and behaviour should be assessed in women with pelvic floor disorders.

Funding: None

Keywords: muscle function assessment, pelvic floor, urinary incontinence, validity, sensitivity, specificity

Tweetable abstract: The Pelvic Floor Sensory and Muscle Function Exam based on ICF/WHO is valid to distinguish women with urinary incontinence (UI) from those with no UI.

INTRODUCTION

Measurement validity is related to appropriateness, meaningfulness and usefulness of an instrument to measure what it intends to measure.[1,2] Construct validity is the focus of validity [1,2] and allows to answer the question: “is the test capable of discriminating among individuals with and without certain traits?”.[1] To define the appropriateness of an instrument to measure a construct, it is necessary to clearly define the abstract concept that represents the construct.[1] In this case, a theoretical foundation for defining the construct is mandatory. Thus, content validity, which is the definition of the content universe that represents a particular construct, is the first step to set construct validity.[1]

Function of the pelvic floor muscles (PFM) are a largely investigated construct in women, as the integrity of pelvic floor muscles and adjacent structures (fascial and ligamentar tissues) are involved in the mechanisms of urinary and faecal continence, and in the support of pelvic organs.[3] Muscle function refers to the physiological functions of muscles, such as strength and endurance. Pelvic floor muscle training (PFMT) is the first line for the treatment of urinary incontinence (UI) and is proven to minimize initial stages of pelvic organ prolapse (POP).[4] Thus, an adequate assessment of those functions is needed to establish an individual dose of rehabilitation intervention.

Some validated functions of PFM assessment scales and “schemes” based on vaginal palpation have been previously proposed.[5–9] Those scales are focused on the investigation of strength and endurance. A more complete scheme, based on 18 observable signs of PFM contraction and relaxation, included assessment of other functions, such as ability to contract, relax and the response of PFM to a perturbation, was proposed by Hove et al., 2009.[10] The scheme presented face validity, however showed low interrater reproducibility indexes for most items investigated. It is based on International Continence Society (ICF) terminology,[11] nevertheless reports additional terms not provided by ICS. Also, it focuses on the disease signs and symptoms framework,[10] and not on the functionality perspective, which is the focus of the Physical therapy approach.[12]

A previously systematic review of the functions of PFM in women with and without UI conducted by our study group found 61 terms, a variety of operational definitions, and a lack of conceptual definitions on those functions.[13] Hence, we organized a linking process of those terms according to the International Classification of Functioning, Disability and Health (ICF)[14] from World Health Organization (WHO) based on well-defined linking rules.[15] It was possible to convert the 61 terms into six muscle and movement related functions described in the Chapter 7 of ICF/WHO, as follows: *Tone*, *Involuntary Movement Reaction*, *Control*, *Coordination, Strength* and *Endurance*. These were the relevant functions to be assessed in women with UI. The valid instruments used to measure those functions were also identified.[16] Those above mentioned steps set the content validity of the pelvic floor sensory and muscle functions (PFSMF) evaluation developed by our research team, which was named as the Pelvic Floor Sensory and Muscle Function Exam (EFSMAP-*Exame das Funções Sensoriais e Musculares do Assoalho Pélvico*). As reliability is a prerequisite to validity,[1] we, then, managed a reliability and agreement study of the exam and found good indices of reproducibility for most functions of PFM.[17] Therefrom, this study investigates the construct validity of the EFSMAP to determine if the proposed exam is capable of distinguishing women with urinary incontinence (UI) from those without UI.

METHODS

Design, participants and settings

This was a methodological study to test construct validity of the EFSMAP previously developed by our study group, which was previously proven to be reproducible.[17]. It was conducted in accordance with the Declaration of Helsinki, all subjects gave written informed consent, and the study was approved by the Ethic Committee of *Universidade Federal de Minas Gerais* (UFMG-Brazil) under the number CAAE 44534615.5.0000.5149.

A convenience sample of women with and without UI over 18 years of age, from public gynaecology secondary units and from the community was included in this study. Virgo, pregnant women, those who have had an abortion or have given birth in the last 12 months, were in their monthly period, showed symptoms and sings of vaginal and/or urinary infection, had undergone pelvic surgery in the last five years, those who could not understand the orientations for pelvic floor evaluation and those who refused to sign the informed consent were set as exclusion criteria. Women were evaluated from July 2016 to April 2017.

Procedures

Two physical therapists, specialists in women's health, who were previously trained in the EFSMAP, collected data independently. In a private room, women were instructed on structure, site and function of the PFM, using illustrative figures and were informed about interview and physical examination procedures.

Then, volunteers answered a sociodemographic and clinical questions on urinary, sexual and defecation functions, recreation and leisure, eating and drinking habits. The ICS terminology for pelvic floor dysfunction (PFD)[18] and Rome III criteria[19] were used to set PFD and constipation definitions, respectively. Anthropometric measurements (height and weight) and pelvic organ prolapse quantification, usinig POP-Q[20] were taken. Subsequently, women went through PFSMF vaginal digital examination, followed by vaginal manometry. Description of terms, conceptual and operational definitions and procedures were fully reported in Saltiel et al, 2018c[17] as suggested by Messelink 2005.[11]

Outcome measures

The EFSMAP was proposed considering the muscle functions identified in two previous studies (a systematic review on PFM function and a linking process to ICF/WHO terminology) of our research group as the most frequent evaluated functions among women with and without UI.[13,16] The exam was tested for reliability and agreement, reaching good indices of reproducibility.[17] The PFSMF are presented below using ICF/WHO terms and their respective ICF codes: *Pain (*b28018)*, Tone* (b7350), *Control of Simple Voluntary Movement* (contraction) *and (relaxation) (b7608)*, *Coordination of Voluntary Movement* (b7602), *Involuntary Movement Reaction* (cough) (b755), *Strength* (b7300), *Endurance* (duration) and (repetitions) (b7408) (all measured by visual observation combined with vaginal palpation); *Strength* (b7300) and *Endurance* (duration) (b7408) (measured with a vaginal manometry device: Peritron ™ -CardioDesign PTY LTD - Australia). Vaginal resting pressure seems not to directly reflect a PFM function, but it was measured as part of the protocol to use vaginal manometry .[21]

The international Consultation Incontinence Questionnaire-Short Form (ICIQ-UI-SF)[22] was used to identify the presence of UI in the sample and to set the two comparing groups (UI group and non-UI group). The ICIQ-UI-SF is widely used in research and clinical setting and it is validated to assess frequency, volume, severity and impact on quality of life of people with UI.[22,23] It was validated and cross-cultural adapted to Brazilian Portuguese.[24] ICIQ-UI-SF score varies from 0 (no UI) to 21 (the highest impact of UI in quality of life). In relation to UI severity, the ICIQ-UI-SF total score was categorized into a four severity scale as follows in order to describe the studied sample: slight (1–5), moderate (6–12), severe (13–18) and very severe (19–21).[23]

Data analysis

The sample size calculation was based on the difference between the PFM functions *Strength*, measured by vaginal manometry (Peritron®), when comparing women with and without UI, as that function showed the lower effect size (d=0.419)[25] among all other tested: *Strength* (measured by vaginal palpation using Modified Oxford Scale–MOS), *Endurance* (duration),[25] *Control of Voluntary Movement* (contraction) and *Coordination of Voluntary Movements*.[26] To reach a statistical power of 80% and a 0.05 level of significance, 182 women (91 women in UI group; and 91 in the non-UI group) were necessary. Women were paired by age, as aging is related to sarcopenia and known to affect muscle performance.[27,28] Softwares G3Power and OpenEpi were used to calculate sample size of continuous and dichotomous variables, respectively. Data were tested for normality using Kolmogorov-Smirnoff test. Descriptive statistics was performed for each variable. Qui-square Pearson, Fischer exact test were used to test differences between groups on socio-demographic and clinical characteristics of categorical variables and Mann-Whitney for continuous variables. The known groups method procedure was used to test construct validity[1] of the EFSMAP. This method provides evidence to support construct validity by means of a test that can distinguish individuals who are known to have a specific characteristic or health condition, in this case, UI, from those who do not. Sensitivity and specificity values, with their respective 95% confidence intervals, were calculated for the categorical PFSMF. A value above 0.70 was considered satisfactory as representative of good indices of sensitivity and/or specificity.[29,30] Receiver Operating Characteristic (ROC) curves were calculated for the numeric PFSMF variables.[1] Also, the cutoff points based on the sensitivity and specificity of those functions measured by ROC curves were selected according to the highest sum of sensitivity and specificity.[29,30] The presence of UI was used as reference standard to predict a positive test. Statistical significance level was set at 0.05. Analyses were performed using SPSS version 21.

RESULTS

Study participants

Participants were enrolled in the study until sample size was reached. Overall 182 women participated in this study, 91 had no UI and 91 had UI. As 22 women presented impairment in the function *Control* (contraction), in those it was not able to measure the functions *Control* (relaxation), *Coordination*, *Strength* and *Endurance*. Thus, sample size for those functions was comprised of 160 women. Also, it was not possible to introduce the manometer in the vaginal canal of four women, leaving 156 for analysis of *Strength* and *Endurance* measured by vaginal palpation. Data did not have a normal distribution ($p<0.004$). Median age was 50.9(26-91) years for UI group and 46.0(27-87.0) years for non-UI group ($p=0.126$). Women from UI group had lower education level [8.0(0.0-21.0) x 16.0(0.0-23.0) years] ($p<0.001$). Most women from UI group were brown (53.9%), while in the non-UI group, most women were white (59.3%) ($p<0.001$). In both groups, most women were married (50.5% x 56.7%, $p=0.26$).

In relation to clinical characteristics, women in UI group had higher body mass index (BMI) [27.2(18.3-53.4) x 23.3(17.2-40.1)cm/m^2] ($p<0.001$), more deliveries [2.0(0.0-12.0) x 2.0(0.0-8.0)] ($p=0.004$) and were less engaged in regular physical activity (33.0% x 71.4%, $p<0.001$). Fifty two percent of them complained of mixed urinary incontinence symptoms, 27% had stress UI and 21% complained of urgency incontinence. Symptoms intensity were as follows: 11%(n=10) slight, 38.5%(n=35) moderate, 39.6%(n=36) severe, and 11%(n=10) very severe UI. Most women in UI group also had more complaints of lumbo-pelvic pain (60.4% x 38.5%, $p=0.005$), recurrent urinary tract infections (25.3% x 6.6, $p<0.001$), bowel functional constipation (31.9% x 9.9%, $p<0.001$), flatal (43.3% x 13.3%, $p<0.001$) and faecal incontinence (11.0% x 0.0%, $p=0.002$). Dispareunia in sexually active women (n=152) were similar in both groups (26.4% x 15.4%, $p=0.205$). POP staging was 0=7.5%, I=46.3%, II=41.3% and III=5% for the UI group and 0=32.9%, I=32.9%, II=34.1%, III=0.0% for the non-UI group, with the former presenting higher stages of prolapse ($p<0.001$). No women had a stage IV in POP-Q.

Data relative to PFSMF characteristics for both groups are presented in Table 1. Women in UI group present more *Pain* (presence and intensity). *Tone* was found to have a borderline statistically significant difference between groups ($p=0.053$) when analysed considering only two categories. The functions *Control* (contraction), *Involuntary Movement Reaction* during cough and *Coordination* were more frequently impaired in UI group. The functions *Strength*, *Endurance* (duration), either measured by vaginal palpation or vaginal manometry showed lower scores in the UI group ($p<0.001$). There was no statistical significant difference in vaginal resting pressure between groups ($p=0.069$).

Table 1: Pelvic floor sensory and muscle function (PFSMF) characteristics in the total sample and comparison between groups (n =182)

	Total sample (n=182)	IU (n=91)	No IU (n=91)	p-value
	VAGINAL PALPATION			
(b28018) Pain presence				
Yes	60 33.0%	39 42.9%	21 23.1%	**0.007***
No	122 67.0%	52 57.1%	70 76.9%	
(b28018) Pain intensity				
Median (P25 - P75)	0.0 (0.0 - 8.0)	0.0 (0.0 -	0.0 (0.0 - 5.5)	
(b7350) Tone (2 categories)				
Altered	98 53.8%	56 61.5%	42 46.2%	0.053*
Normal	84 46.2%	35 38.5%	49 53.8%	
(b7350) Tone (3 categories)[1]				
Normal	84 46.7%	35 39.3%	49 53.8%	0.149*
Low	23 12.8%	13 14.6%	10 11.0%	
High	73 40.6%	41 46.1%	32 35.2%	
(b7608) Control (contraction)				
Absent	22 12.1%	18 19.8%	4 4.4%	**0.002***
Present	160 87.9%	73 80.2%	87 95.6%	
(b7608) Control (relaxation)				
Absent/Parcial/Slow	58 36,3%	32 43,8%	26 29,9%	0,067*
Present	102 63,8%	41 56,2%	61 70,1%	
(b755) Involuntary movement reaction (cough)				
Absent	128 72.3%	71 82.6%	57 62.6%	**0.004***
Present	49 27.7%	15 17.4%	34 37.4%	
(b7602) Coordination (n=160)				
Absent	52 32,5%	30 41,1%	22 25,3%	0,033*
Present	108 67,5%	43 58,9%	65 74,7%	
(b7300) Strength (Modified Oxford Scale)				
0	7 (3.8%)	6 (6,6%)	1 (1.1%)	**<0.001*** **
1	16 (8.8%)	12 (13.2%)	4 (4.4%)	
2	39 (21.4%)	26 (28.6%)	13 (14.3%)	
3	61 (33.5%)	33 (36.3%)	28 (30.8%)	
4	34 (18.7%)	9 (9.9%)	25 (27.5%)	
5	25 (13.7%)	5 (5.5%)	20 (22.0%)	

continues...

(b7408) Endurance (number of repetitions) (n=160)				
Median (P25 - P75)	4.0 (0.0 - 5.0)	4.0 (3.0 - 5.0)	3.0 (3.0 - 5.0)	0.486*
(b7408) Endurance (duration-seconds) (n=160)				
Median (P25 - P75)	5.0 (3.0 – 7.7)	3.0 (2.0 - 6.0)	7.0 (4.0 - 10.0)	**<0.001***
VAGINAL MANOMETRY				
Vaginal resting pressure (cm H2O) (n=156)				0.069*
Median (P25 - P75)	31.1 (24.7 – 36.2)	30.2 (23.8 – 35.0)	32.7 (26.6–37.6)	
(b7300) Strength (cm H_2O) (n=156)				
Median (P25 - P75)	39.1 (24.3 – 58.1)	29.6 (20.9 – 44.4)	51.0 (32.0 – 71.2)	**<0.001***
(b7408) Endurance (duration-seconds) (n=156)				
Median (P25 - P75)	4.0 (2.0 – 6.0)	3.0 (2.0 – 5.0)	4.0 (3.0 – 7.7)	**0.047***

* Pearson Qui-square **Fischer´s Exact Test, *** Mann-Whitney test; P25=Percentile 25; P75=Percentile 75; [1]Two women with divergent ratings in left and right sides of pelvic floor muscles were excluded from analysis, SD: Standard Deviation, MOS: Modified Oxford Scale, UI: Urinary incontinence group, No-UI: group without urinary incontinence.

Construct validity of EFSMAP in women with UI

Sensitivity and specificity values of PFSMF measured by categorical variables are presented in Table 2. For the *Proprioceptive* function (b260), as there was low variability in this sample (only one women had impairment in that function-*data not shown*), it was not possible to calculate the sensitivity and specificity rates.

Control (contraction) presented excellent specificity index, indicating that 95.60% of women with no UI were able to contract PFM. Nevertheless, sensitivity was as low as 19.78%. That is, only 19% of women with UI are not able to contract PFM. *Control* (relaxation) presented moderate specificity (70.11%).

Pain and *Coordination* presented a reasonable value of specificity but low indices of sensitivity. Most (75.92%) women in the non-UI group had no pain during vaginal palpation. Sensitivity was low (42.86%), indicating that more than a half of women with UI also had no pain. For *Coordination*, specificity was as high as 74.71%. That percentage of women with no UI were able to contract PFM in a coordinated manner. Sensitivity was low (41.10%). That is, approximately 41% of women in the UI-group have impairment in *Coordination*, but the other 59%% of women in UI-group do not have impairment in *Coordination*.

On the opposite, although *Involuntary Movement Reaction* during cough had low specificity (37.36%, indicating a high percentage of false positives = 62.64%), it presented good indices of sensitivity, with 82.56% of women with UI who do not contract PFM during cough.

The functions *Tone* and *Control* (relaxation) did not present good indices of sensitivity or specificity.

Table 2: Sensitivity and specificity with their respective 95% confidence interval of pelvic floor sensory and muscle functions (PFSMF) measured by categorical variables.

Pelvic floor muscle function	Value	95%CI
Pain		
Sensitivity	42.86%	[33.18%; 53.11%]
Specificity	76.92%	[67.28%; 84.38%]
Tone		
Sensitivity	61.54%	[51.27%; 70.87%]
Specificity	53.85%	[43.66%; 63.72%]
Control (contraction)		
Sensitivity	19.78%	[12.89%; 29.11%]
Specificity	95.60%	[89.24%; 98.28%]
Control (relaxation)		
Sensitivity	43.84%	[33.05%; 55.24%]
Specificity	70.11%	[59.81%; 78.72%]
Involuntary movement reaction (cough)		
Sensitivity	82.56%	[73.20%; 89.14%]
Specificity	37.36%	[28.12%; 47.62%]
Coordination		
Sensitivity	41.10%	[30.53%; 52.55%]
Specificity	74.71%	[64.67%; 82.67%]

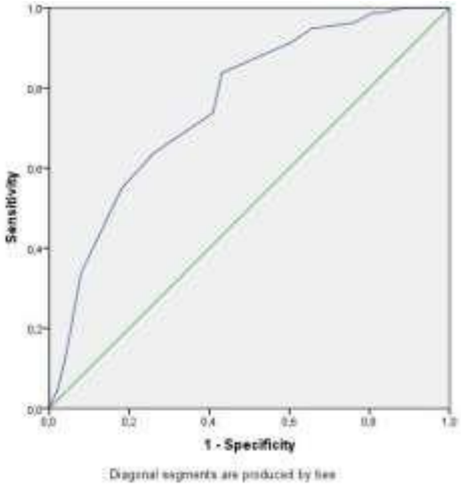
Table 3: Area under de ROC curve for *Pain* intensity, *Strength* (vaginal palpation and manometry) and *Endurance* (duration) by vaginal palpation in relation to the presence of urinary incontinence (UI)

Pelvic floor muscle functions	Area under the ROC curve	95% CI Lower limit	95% CI Upper limit
VAGINAL PALPATION			
Pain intensity (mean)	0.607	0.525	0.689
Endurance (duration)	0.760	0.688	0.832
Strength (Modified Oxford Scale)	0.721	0.641	0.801
VAGINAL MANOMETRY			
Vaginal resting pressure (cm H_2O)	0.599	0.509	0.689
Strength (cm H_2O)	0.721	0.641	0.801
Endurance (duration)	0.593	0.502	0.684

ROC: Receiver Operating Characteristics; CI: confidence interval

The functions *Strength,* measured either by vaginal palpation or manometry, and *Endurance* (duration), measured by vaginal palpation, had the area under the ROC curve above 0.70 and the lower limit of the confidence interval above 0.60. Thus, those are functions that can discriminate women with UI from those with no UI. Conversely, the functions *Pain* intensity, *Endurance* (duration) measured by vaginal manometry had the area under the ROC curve below 0.70, indicating that those functions do not distinguish women with UI from those with no UI.

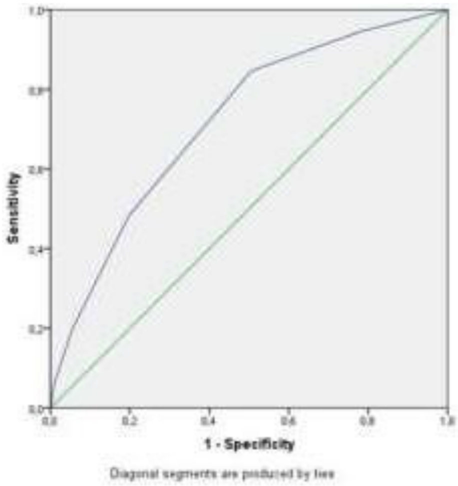
1a)



Endurance (duration) seconds	Sensitivity	Specificity	Sum
0.5	5.0%	97.7%	1.027
1.5	15.0%	95.5%	1.105
2.5	33.8%	92.0%	1.258
3.5	55.0%	81.8%	1.368
4.5	63.8%	73.9%	1.376
5.5	73.8%	59.1%	1.328
6.5*	**83.8%**	**56.8%**	**1.406**
7.5	91.3%	39.8%	1.310
8.5	95.0%	34.1%	1.291
9.5	95.0%	33.0%	1.280
11.0	96.3%	23.9%	1.201
12.5	98.8%	19.3%	1.181
13.5	98.8%	18.2%	1.169
14.5	98.8%	17.0%	1.158
16.5	100.0%	11.4%	1.114...

* Cutoff for highest combination of specificity-sensitivity

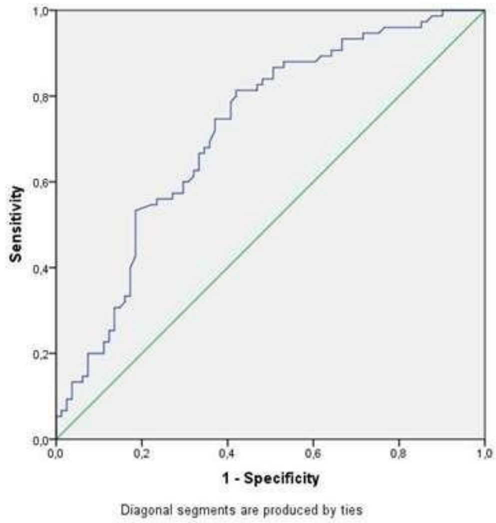
1b)



Strength (MOS)	Sensitivity	Specificity	Sum
.50	6.6%	98.9%	1.055
1.50	19.8%	94.5%	1.143
2.50	48.4%	80.2%	1.286
3.50*	**84.6%**	**49.5%**	**1.341**
4.50	94.5%	22.0%	1.165
6.00	100.0%	0.0%	1.000

MOS: Modified Oxford Scale; *Cutoff value with highest sum of sensitivity + specificity

1c)



Strength (cm H_2O)	Sensitivity	Specificity	Sum
...28.65	45.3%	81.5%	1.268
28.85	46.7%	81.5%	1.281
29.30	49.3%	81.5%	1.308
29.80	50.7%	81.5%	1.321
30.50	53.3%	81.5%	1.348
31.05	54.7%	77.8%	1.324
31.45	54.7%	76.5%	1.312
31.90	56.0%	76.5%	1.325
32.10	56.0%	74.1%	1.301
32.50	56.0%	72.8%	1.288
...			
41.75	69.3%	64.2%	1.335
42.10	72.0%	63.0%	1.350
42.35	74.7%	63.0%	1.376
43.35	74.7%	60.5%	1.352
44.30	74.7%	59.3%	1.339
44.45	76.0%	59.3%	1.353
44.60	77.3%	59.3%	1.366
44.85	78.7%	59.3%	1.379
45.40	80.0%	58.0%	1.380
45.90	**81.3%**	**58.0%**	**1.394**
46.50	81.3%	56.8%	1.381
47.20	81.3%	55.6%	1.369
47.65	81.3%	54.3%	1.357
47.95	81.3%	53.1%	1.344
48.75	82.7%	53.1%	1.358

*Cutoff value with highest sum of sensitivity + specificity

Figure 1: ROC curves with cutoff points for sensitivity and specificity for distinguishing women with UI from those with no UI, respectively, for 1a) for Endurance (duration) during vaginal palpation; 1b) Strength (Modified Oxford Scale) during vaginal palpation; and 1c) Strength (cmH_2O) during vaginal manometry.

Figure 1 presents the cutoff point for the functions *Endurance* and *Strength* considering the highest sum for sensitivity and specificity.[29,30] Sensitivity for *Endurance* (duration) (Fig 1a) measured by vaginal palpation as 83.8% and specificity was 56.8%. That is, women with UI had *Endurance* (duration) below 6.5 seconds in 83.8% of the cases and women with no UI had *Endurance* above 6.5 seconds in 56.8% of the times.

For *Strength* measured by vaginal palpation (Fig. 1b), the optimal cutoff point that balances sensitivity and specificity is the score of 3.5 in MOS, with 84.6% sensitivity and 49.5% specificity. As, there is no half point in the MOS scale, the value immediately below it (that is, 3) was considered as the cutoff point for *Strength*. This indicates that 84.6% of women with UI scores 3 or less in MOS when measuring *Strength* function. The other 15.4% with UI score higher than that. Specificity was lower (49.5%), indicating that most women (50.5%) with no UI also have a score lower than 3.5 in MOS.

For *Strength* measured by vaginal manometry the cutoff point lays on 45.9cmH_2O for a sensitivity of 81.3% and a specificity of 58.0%. That is, women with UI have PFM *Strength* lower than that value in 80.3% of the cases. And, 58% of women with no UI have *Strength* above that value.

DISCUSSION

Main findings

The EFSMAP presented construct validity, once *Strength* and *Endurance*, and also *Control* (contraction and relaxation), *Involuntary Movement Reaction* (cough), *Coordination* and *Pain* presence are relevant functions to be investigated as they distinguish women with UI from those without UI. The functions *Control* (contraction), *Pain* presence, and *Coordination* presented excellent to good specificity indexes, but low indices of sensitivity. Oppositely, *Involuntary Movement Reaction* during cough had good sensitivity, but low specificity. *Strength* and *Endurance* (duration) distinguished women with UI from those with no UI. Cutoff values were 3 in MOS scale, 45.9cmH2O in vaginal manometry for *Strength*; and 6.5 seconds during vaginal palpation for *Endurance* (duration), as they corresponded to the most balanced points between sensitivity and specificity of those measures. The function *Tone* was neither sensitive, nor specific to distinguish women with UI from those with no UI. *Proprioceptive* function could not be tested due to the low variability in the sample.

Strengths and Limitations

To our knowledge this is the first study to test the construct validity of a PFSMF exam based on a universal terminology of musculoskeletal and movement functions proposed by WHO and on the functionality theoretical framework proposed by the ICF/WHO[14]. The exam proved to be valid for pelvic floor muscle functions other than *Strength* and *Endurance* to distinguish women with UI from those without UI. The EFSMAP was developed from a sound scientific literature foundation. The bases were a systematic review[13] and a linking process to ICF terminology[16], held by our study group which aimed to identify the PFM functions studied among women with UI and the worldwide accessible instruments reported to measure those functions. Also, the exam was reliable to measure those functions with good intra and interrater reproducibility indexes.[17] We used a comparison group, which was paired by age. This allowed us to compare the groups by controlling for that confounder, as age clearly affects muscle structure and function, and consequently, its functional performance.[27,28] Albeit women in the UI group were statistically different from those in non-UI group concerning the frequency of occurrence of other PFD, the co-occurrence of PFD is frequent and well described in literature[31,32], which favours external validity of our results.

There are some limitations in the study. We used a convenience sample from one gynaecologic secondary care centre and from the surrounding community, which may restrict study's generalisability. Selection bias might have occurred as PFM evaluation requires participant to inform on genital health and to allow for the examination of that region, which is a taboo for some women. Thus, only those with PFD demands or, in opposition, those women with no cultural taboo traits at all might have consented participation. Raters who collected the socio-demographic and clinical characteristics also rated the PFSMF, thus they were not blinded against which group women belonged to. Last, characteristics in both groups were different concerning demographic and clinical aspects, such as the number of deliveries and BMI, which might represent confounding factors.

Interpretation

Muscle functions are interdependent in a continuum of actions, posing equivalent importance to *Strength* and *Endurance, and also to Control* (contraction and relaxation) and *Coordination,* which are the precursors for a strong and lasting muscle contraction.[33] Slieker-ten Hove et al., 2009[10], face validated a digital scheme based on the International Continence Society (ICS) terminology in which other functions of PFM were also considered.[10] They found good indices of intrarater reliability, but low indices of interrater reliability.[10] The present study went further.

While face validity is the least precise approach for documenting a test's validity [1], construct validity is the pivotal element in a validity study.[2] This study documented construct validity by testing the discriminant ability of the exam. The EFSMAP presented content and construct validity, indicating that *Strength* and *Endurance* are valid to differentiate women with UI from those without UI, and that *Control* (contraction and relaxation), *Involuntary Movement Reaction* during cough and *Coordination* were important functions to be investigated as well. The results on reliability indices were good both for intra and interrater analysis, as stated in a previous study of our study group.[17] The proposed exam is based on a universal terminology set into the ICF developed by WHO, that ought to be adopted by WHO member countries, as the international standard to describe and measure health and disability. [34] The ICF is a classification formulated from a functionality perspective, rather than from the disease context of the biomedical framework. Functionality is the focus of the physiotherapeutic assessment and intervention[12], thus it should be pursued by physicalhterapists to guide their practice. Last, using ICF terminology to describe PFSMF disrupts the language barrier, once ICF is already translated into all languages spoken in the 195 countries that are WHO members.[35]

Specificity was high in most studied PFMF. A highly specific test properly identifies most women who do not have a health condition, in this case, UI. Thus, most women with no UI do not present impairment of PFMF.[1] This is the case for the functions *Control* (contraction and relaxation), *Pain*, and *Coordination as* most women with no UI have those PFMF intact. This indicates that, in order to promote urinary continence, one must target at those functions to grant their integrity.

Conversely, a highly sensitive test properly identifies most women who do have UI.[1] Therefore, in women with UI, it is most likely that the measured PFSMF are impaired. *Involuntary movement reaction* during cough showed high sensitivity. This means that most women with UI are not able to contract PFM during a perturbation, such as cough. So, it is a function to be rehabilitated in those women. However, teaching every woman to contract PFM during a perturbation will not grant continence, as specificity was low.

For the function *Endurance* (duration) and *Strength* during vaginal palpation, the best match between sensitivity/specificity, with specificity showing higher indices, was reached for the cutoff point of 6.5 seconds and 3 point in MOS scale, respectively. When measured by vaginal manometry, *Strength* cutoff point was set at 45.9cmH_2O. Those values can be taken as reference parameters for physical therapists when setting rehabilitation targets for those functions aiming at continence. High values of both specificity and sensitivity are preferable to award more accurate tests.[1] The imbalance in sensitivity/specificity of the PFMF assessments for women with UI may be due to the fact that the continence mechanism does not depend exclusively on the PFMF. UI is a multifactorial health condition and risk factors other than pelvic floor muscle condition contribute to its occurrence, such as age, gender, race, childbirth and obesity.[20,32] Also, structures and other functions related to human posture and movement, woman's engagement in activity and social participation, as well as personal and environmental contextual factors interact to contribute to her functionality or disability.[14,36,37] Thus, as part of the validation process, other modifiable factors related to body structure and function, as well as the demands imposed on women by the contextual factors, should be further tested in a multivariate or partitioning analysis to support the development of Clinical Prediction Rules (CPR).[1,38,39] Those are tools that aid clinicians in decision-making, by the clustering of three or more clinical relevant and reliable (especially in interrater analysis) variables.[1,38,40] CPR are largely used by physicians to help diagnosis, prognosis and treatment likely response in various health conditions[39,41–44] and are currently being incorporated into the physical therapy practice.[45–47]

Yet, PFM training is first line treatment for UI.[4] Thus, to identify which are the PFM that distinguish women with UI from those with no UI seems to be reasonable as the starting point to design a dose specific rehabilitation intervention.[48] Pelvic floor muscle *Pain* along with the muscle functions: *Control* (contraction and relaxation), *Involuntary movement reaction* during cough and *Coordination* should be first improved in women with UI. Posteriorly, the cutoff points identified for *Strength* and *Endurance* functions in this study can guide physical therapists to set their treatment goals, in order to promote a more effective, and possibly, lower cost therapeutic program. Further, that knowledge may feed the development of CPRs that can drive clinicians onto more accurate physiotherapeutic diagnosis, prognosis and likely response to UI treatments. This study starts to put a light into that matter.

CONCLUSION

The EFSMAP was valid to distinguish women with UI from those with no UI. *Strength* and *Endurance*, but also *Control* (contraction and relaxation), *Involuntary Movement Reaction* (cough), *Coordination* and *Pain*, are relevant PFSMF that should be investigated in women. Cutoff values were identified for *Strength* and *Endurance* (duration) that may guide physical therapists to set their treatment goals to promote a more effective and lower cost therapeutic program for women with UI.

As part of the validation process, PFSMF could further be tested along with other UI risk factors, and also with other impairments in structures and functions related to human posture and movement, and with the woman's contextual factors, in a multivariate analysis to develop Clinical Prediction Rules (CPR). Ultimately, those procedures would help clinicians to decision-making in relation to physiotherapeutic diagnosis, prognosis and also UI treatment.

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Disclosure of interests

None. Full disclosure of interest available online as supporting information.

Contributions to authorship

EMF and FS conceived the idea and designed the study; FS and APM supervised participants and collected data; FS coordinated database organization and conference, EMF and FS performed the data analysis; EMF and FS wrote the manuscript. All authors read and approved the final version.

Details of ethics approval

The Ethics Review Board of the Federal University of Minas Gerais State approved the study protocol in July, 28, 2015 (ETIC 44534615.5.0000.5149).

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4. CONSIDERAÇÕES FINAIS

Esta tese foi composta de quatro estudos e desenvolveu o Exame das Funções Sensoriais e Musculares do Assoalho Pélvico (EFSMAP) para mulheres com DAP. O exame foi elaborado a partir da investigação das funções musculares relevantes de serem avaliadas em mulheres com DAP com queixa prioritária de IU. A identificação dessas funções foi realizada por meio de revisão sistemática, que conferiu validade de conteúdo ao exame proposto. A terminologia para descrição das FMAP avaliadas no EFSMAP foi lincada com aquela proposta pela CIF/OMS e, assim, foi possível identificar as definições operacionais mais frequentemente utilizadas para mensurar as FMAP. O EFSMAP foi, posteriormente, testado quanto à sua reprodutibilidade e validade de constructo, apresentando bons índices de confiabilidade e foi válido para diferenciar mulheres com IU daquelas sem IU. Desta forma, o EFSMAP apresenta clara, válida e universal para descrever as FMAP, favorecendo a comunicação entre profissionais de saúde que atuam na área de Saúde da Mulher. É confiável e válido para mulheres com DAP, prioritariamente IU e, portanto, pode ser utilizado em pesquisas científicas e na prática clínica.

Os pontos principais de cada um dos estudos que compõem esta tese estão apresentados a seguir. Os resultados da revisão sistemática indicaram uma abundância de estudos a respeito de FMAP em mulheres com e sem DAP, e, igualmente, uma variedade de termos e definições operacionais para se referir a essas funções. Menos da metade dos estudos apresentaram a definição conceitual das funções que foram mensuradas. Isso indica que a maioria das definições existentes é baseada no operacionismo, ou seja, na definição operacional. Essa abordagem conduz à proliferação de termos e conceitos sobre FMAP, o que impede o agrupamento de dados, a comunicação efetiva entre pesquisadores e profissionais de saúde e, consequentemente, o avanço na ciência e na prática clínica. Essas informações indicaram a necessidade do uso de terminologia padronizada para favorecer a comunicação e a compreensão de como se comportam as FMAP nessas mulheres.

A proposta do uso de terminologia padronizada descrita na CIF/OMS sobre as funções do corpo, como é o caso das funções musculares, pareceu apropriada, já que a classificação fornece linguagem uniforme e é estruturada na perspectiva bio-psico-social, que considera não só a estrutura e função do corpo, mas os diversos aspectos que compõem a funcionalidade humana. Também, sendo o Brasil país membro da OMS, se vê impelido a utilizar a referida classificação por força da resolução 54.21/2001 da OMS, que determina que seus países membros adotem-na, incluindo sua nomenclatura; e, posteriormente, da resolução 52/2012 do Conselho Nacional de Saúde do Ministério da Saúde do Brasil, que estabelece que a CIF seja adotada no Sistema Único de Saúde (SUS) e na Saúde Suplementar. A CIF é traduzida para todos os idiomas adotados em seus 195 países membros, o que elimina a necessidade de tradução da terminologia usada para descrever funções musculares do assoalho pélvico, favorecendo ainda mais a comunicação mundialmente.

Em seguida, procedeu-se a lincagem dos termos encontrados na literatura sobre FMAP com aqueles descritos na CIF/OMS. O processo de lincagem foi realizado seguindo-se regras previamente validadas e revisadas e mostrou-se viável e válido, uma vez que a maioria das informações relativas às FMAP (196 originalmente no estudo de revisão sistemática) pode ser vinculada à CIF e convertidas em seis funções musculares e relacionadas ao movimento descritas no capítulo 7 da referida classificação. Por meio dessa lincagem, foi possível identificar as funções relevantes de serem investigadas em mulheres com e sem IU, a saber: *Força*, *Reflexo de movimento involuntário*, *Resistência*, *Controle* (contração e relaxamento), *Coordenação* e *Tônus*. Também foi possível mapear as definições operacionais (instrumentos) utilizadas para mensurar as funções: manometria vaginal, por meio do Peritron®, para mensurar as funções *Força* e *Resistência*; e palpação vaginal, para mensurar todas as FMAP. Embora a palpação vaginal não seja o método mais acurado para se detectar pequenas mudanças nas FMAP, como é o caso da *Força* muscular, é um método simples, acessível e de baixo custo. Trata-se de informação importante para a prática clínica do fisioterapeuta, especialmente para aqueles que atuam no nível primário de assistência à saúde; e em países em desenvolvimento, em que o acesso à tecnologia e a instrumentos mais sofisticados são restritos. Portanto, os resultados do processo de lincagem das FMAP com a CIF são encorajadores, uma vez que podem aprimorar a comunicação entre os diversos profissionais de saúde, pesquisadores e elaboradores de políticas públicas que lidam na área de Saúde da Mulher.

A organização das informações sobre FMAP a partir da revisão sistemática e da lincagem da terminologia com a da CIF permitiu a validação de conteúdo de um exame padronizada das FMAP, intitulado Exame das Funções Sensoriais e Musculares do Assoalho Pélvico (EFSMAP). Esse exame pode ser adotado na pesquisa e, especialmente, na prática clínica de fisioterapeutas. O passo seguinte foi atestar sua reprodutibilidade. Os resultados indicaram bons índices de confiabilidade e concordância para, praticamente, todas as funções. Para atingir esses índices, é fundamental definir claramente tanto do ponto de vista conceitual, quanto operacional, as funções musculares a serem mensuradas e treinar sistematicamente os examinadores. As funções *Dor* e *Tônus*, na avaliação intraexaminador, não apresentaram reprodutibilidade, possivelmente porque a amostra apresentava sintomas leves de dor no primeiro caso. No segundo caso, não há instrumentos padrão-ouro para a mensuração do tônus dos MAP e o método ainda mais apropriado para tal, e que considera tanto seu componente viscoelástico, quanto muscular, é a palpação. No entanto, parece pouco sensível para detectar pequenas mudanças de estado. Além disso, o tônus relaciona-se à transmissão de tensão entre estruturas neuromusculares que mudam seu estado e se ajustam continuamente para manter o sistema musculoesquelético em equilíbrio para exercer uma ação ou atividade. Também, o aumento de rigidez muscular, que pode ser sentido durante a palpação para registro do tônus, acontece como mecanismo de proteção no caso de dor. Assim, é provável que, dadas as características da amostra, com poucos relatos de dores na pelve, o tônus tenha efetivamente mudado ao longo de uma semana. Portanto, testar essas funções em uma população sintomática e num intervalo de tempo mais curto pode ser útil para se aprofundar a investigação sobre a confiabilidade intraexaminador dessas funções. Ainda assim, o EFSMAP mostrou boa reprodutibilidade e pode ser útil para direcionar a avaliação, aprimorar o diagnóstico das FMAP em mulheres com e sem IU e outras DAP, já que elas co-ocorrem. Também, o diagnóstico dele decorrente pode guiar o estabelecimento de programas de reabilitação dose específicos, tornando-os, possivelmente, mais efetivos.

Como passo seguinte à confirmação da reprodutibilidade, o EFSMAP foi testado quanto à validade de constructo e mostrou-se capaz de diferenciar mulheres com IU daquelas sem IU. Não só as funções *Força* e *Resistência* se mostraram relevantes de serem investigadas nessa população, mas igualmente *Controle* (contração e relaxamento), *Reflexo* (tosse), *Coordenação* e *Dor*. Esses achados mostram a importância de se considerar o *continuum* de funções musculares e não apenas ter como foco de avaliação, e também de reabilitação, a *Força* e *Resistência* musculares. Para ser capaz de treinar *Força* e *Resistência* musculares, visando promover o fechamento uretral contra a sínfise púbica em uma contração intensa e sustentada, principalmente durante aumentos de pressão intra-abdominal, antes é necessário que a mulher seja: a) capaz de contrair e relaxar os MAP; b) realizar essas ações de forma coordenada, sem usar músculos sinergistas. Sabe-se que 30 a 40% das mulheres não é capaz de realizar contração muscular com *Controle* e/ou de forma *Coordenada*, portanto, estas não se beneficiariam do TMAP, que é pautado no treino de *Força* e *Resistência*. Para essas mulheres, estratégias terapêuticas apropriadas devem ser adotadas, para torná-las aptas a, posteriormente, treinar *Força* e *Resistência* musculares e promover o fechamento uretral. Ensaios clínicos devem ser conduzidos com essa finalidade.

Também, os pontos de corte identificados no estudo de validade para as funções medidas por escalas ordinais e contínuas (*Força* e *Resistência*) podem guiar os fisioterapeutas no estabelecimento de objetivos do tratamento para promover programas terapêuticos mais efetivos e, possivelmente, de menor custo.

O EFSMAP foi mais específico do que sensível para diferenciar mulheres com IU daquelas sem IU. Ou seja, o exame é capaz de dizer que as mulheres que não tem IU, em sua maioria, não apresentam deficiência de funções musculares. No entanto, é pouco sensível para identificar que as mulheres com IU sempre apresentarão deficiência das funções sensoriais e musculares do assoalho pélvico. Isso significa que outros fatores, que não as FMAP, contribuem para o mecanismo de continência. Assim, como proposta de continuidade do processo de validação, e tendo em vista que o foco de atuação do fisioterapeuta é a funcionalidade humana, as FMAP relevantes deveriam, futuramente, ser testadas em modelos multivariados incluindo-se outros fatores de risco modificáveis para IU. Por exemplo, aqueles relacionados à estrutura e função do corpo, como a obesidade e a constipação e outras incapacidades relacionadas à postura e movimento humanos, como a postura da pelve e a qualidade do mecanismo de estabilização lombo-pélvico. Em um próximo passo, as atividades e a participação social realizadas por mulheres com DAP, bem como os fatores de contexto que poderiam interferir na sua funcionalidade, deveriam ser investigados. Essas informações seriam utilizadas para desenvolver Regras de Predição Clínica (RPC). Em última análise, esses procedimentos auxiliariam na condução da avaliação e diagnóstico, e na tomada de decisão clínica para o tratamento fisioterapêutico, estando todos estes passos focados na funcionalidade da mulher com IU e não na condição de saúde em si. Esta tese representa o ponto de partida para se buscar a compreensão, abrangente e em profundidade, da avaliação e abordagem fisioterapêuticas de mulheres com IU e outras DAP.

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ANEXOS

Anexo A – COMPROVANTE DE SUBMISSÃO DO ARTIGO 1

De: Physical Therapy <onbehalfof@manuscriptcentral.com>
Data: seg, 8 de jan de 2018 às 19:05
Assunto: FW: Manuscript PTJ-2017-0577; Terminology of pelvic floor muscle.... ADDITIONAL REQUEST
Para: <elyonaramf@gmail.com>

Dear Dr Figueiredo,
In addition to the below revision requests, please upload original editable versions of your figures when you submit your revised manuscript. Thank you!

Dear Dr. FIGUEIREDO:

Thank you for submitting your paper to PTJ. We have now completed our review, and I am pleased to be able to accept your manuscript, contingent on some revisions, for publication in PTJ.

The reviewers and I agree that this paper addresses an important topic, is well written, and is of interest to PTJ readers. The reviewers have provided specific guidance for your revision. I am summarizing their most significant concerns, as well as my own, below:

1) I agree with Reviewer 1 that additional explanation of and rationale for the inclusion and exclusion criteria for studies in the review would be informative. Please address this in your revisions.

2) Reviewer 1 notes, and I agree, that it would be helpful for the authors to include a brief rationale for the selection of databases included in the search in their revisions.

3) I agree with Reviewer 2 that, in the "Methods", the authors should indicate which of the two reviewers performed the various steps in the review process. Please address this in your revisions.

4) I agree with Reviewer 2 that a rationale for use of the tool that was selected to assess bias is needed. This should be addressed in your revisions.

5) Reviewer 2 notes the need for additional sociodemographic descriptors of the study samples. In your revisions, please indicate whether additional indicators were available for inclusion in the review. If so, please provide the rationale for the choice of descriptors that were included.

NEXT STEPS:

On receipt of your revised manuscript, only I will examine it to determine whether it is ready for copyediting prior to publication.

PTJ Manuscript Central has assigned you an automatic deadline of 09-Mar-2018. Please contact karendarley@apta.org if you think you will need more time.

HOW TO PREPARE AUTHOR RESPONSES:

• In a separate letter that accompanies the revised paper, please respond to each item noted by the Reviewers and as noted above, explaining how you addressed our requests or criticisms. In order to expedite the processing of the revised manuscript, please be as specific as possible in your response to the reviewer(s). Please rewrite the reviewer's question/comment and respond below it, so that each response can be easily evaluated during the re-review process. If you believe that any of the requests are unwarranted, please explain why.

• In the manuscript, highlight the changes that you have made by using boldface font. Do not use the "Track Changes" feature.

• A masked AND unmasked copy of your revised manuscript must be uploaded (not including "Perspectives" articles) as Microsoft Word (.doc) files.

INSTRUCTIONS FOR SUBMITTING A REVISION:

• Go to PTJ Manuscript Central (http://mc.manuscriptcentral.com/ptjournal), login to your Author Center, and click on "Manuscripts With Decisions."

• Under "Actions," click on "Create a Revision," which is located on the line next to your most recent manuscript number. If you don't see a "Create Revision" link, that might mean that your revision due date has expired. To reactivate the "CREATE a Revision" link, contact karendarley@apta.org. Please DO NOT SUBMIT YOUR REVISED MANUSCRIPT AS A NEW MANUSCRIPT AND GENERATE A NEW MANUSCRIPT NUMBER. Doing so will delay the process.

OR, you can click the following link to go directly to the first page for creating your revision:

*** PLEASE NOTE: This is a two-step process. After clicking on the link, you will be directed to a webpage to confirm. ***

https://mc.manuscriptcentral.com/ptjournal?URL_MASK=c4874e5c6b78450d816140b72f03f756

Please Note:

The "Create a Revision" instructions above only apply during initial access to the revision. For subsequent access to your revised manuscript submission, click on the "Revised Manuscripts in Draft" link on the left side of the screen after you log into your Author Center, then scroll down to the bottom of the screen and click "Continue Submission."

IMPORTANT: Your original files are available to you when you upload your revised manuscript. Please delete any redundant files before completing the submission.

QUESTIONS?

Please don't hesitate to contact me at RaschE@cc.nih.gov if you have any questions. We look forward to seeing this paper published.

Sincerely,

Elizabeth K. Rasch, PT, PhD
Editorial Board Member

Alan M. Jette, PT, PhD, FAPTA
Editor in Chief
PTJ

Anexo B – APROVAÇÃO DO COMITÊ DE ÉTICA EM PESQUISA - UFMG

UNIVERSIDADE FEDERAL DE MINAS GERAIS
COMITÊ DE ÉTICA EM PESQUISA - COEP

Projeto: CAAE – 44534615.5.0000.5149

Interessado(a): Profa. Elyonara Mello de Figueiredo
Departamento de Fisioterapia
EEFFTO - UFMG

DECISÃO

O Comitê de Ética em Pesquisa da UFMG – COEP aprovou, no dia 28 de julho de 2015, o projeto de pesquisa intitulado **"Funções dos músculos do assoalho pélvico como preditoras de disfunções do assoalho pélvico"** bem como o Termo de Consentimento Livre e Esclarecido.

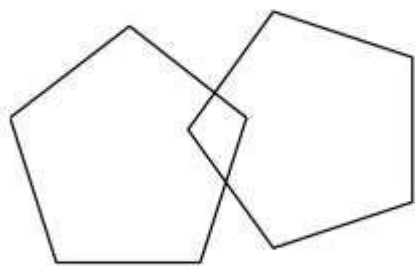
O relatório final ou parcial deverá ser encaminhado ao COEP um ano após o início do projeto através da Plataforma Brasil.

Profa. Dra. Telma Campos Medeiros Lorentz
Coordenadora do COEP-UFMG

Av. Pres. Antonio Carlos, 6627 – Unidade Administrativa II - 2º andar – Sala 2005 – Cep:31270-901 – BH-MG
Telefax: (031) 3409-4592 - e-mail: coep@prpq.ufmg.br

Anexo C – MINI EXAME DO ESTADO MENTAL (MEEM)

Orientação temporal (5 pontos)	Qual a hora aproximada? Em que dia da semana estamos? Que dia do mês é hoje? Em que mês estamos? Em que ano estamos?
Orientação espacial (5 pontos)	Em que local estamos? Que local é este aqui? Em que bairro nós estamos ou qual é o endereço daqui? Em que cidade nós estamos? Em que estado nós estamos?
Registro (3 pontos)	Repetir: CARRO, VASO, TIJOLO
Atenção e cálculo (5 pontos)	Subtrair: 100-7 = 93-7 = 86-7 = 79-7 = 72-7 = 65
Memória de evocação (3 pontos)	Quais os três objetos perguntados anteriormente?
Nomear 2 objetos (2 pontos)	Relógio e caneta REPETIR (1 ponto)
REPETIR (1 ponto)	“Nem aqui, nem ali, nem lá”
” Comando de estágios (3 pontos)	Apanhe esta folha de papel com a mão direita, dobre-a ao meio e coloque-a no chão
Escrever uma frase completa (1 ponto)	Escrever uma frase que tenha sentido
Ler e executar (1 ponto)	Feche seus olhos
Copiar diagrama (1 ponto)	Copiar dois pentágonos com interseção Fonte



Fonte: Fonte: Brucki SMD, Nitrini R, Caramelli P, Bertolucci PHF, Okamoto IH. Sugestões para o uso do mini-exame do estado mental no Brasil. Arq Neuropsiquiatr. 2003; 61(3B):777-81.

Anexo D – INTERNATIONAL CONSULTATION ON INCONTINENCE QUESTIONNAIRE – SHORT FORM (ICIQ-UI-SF)

Muitas pessoas perdem urina alguma vez. Estamos tentando descobrir quantas pessoas perdem urina e quanto isso as aborrece. Ficaríamos agradecidos se você pudesse nos responder ás seguintes perguntas pensando no que você tem passado, em média, NAS ÚLTIMAS 4 SEMANAS

1. Com que frequência você perde urina?

Nunca ( ) 0
Uma vez por semana ou menos ( ) 1
Duas ou três vezes por semana ( ) 2
Uma vez ao dia ( ) 3
Diversas vezes ou dia ( ) 4
O tempo todo ( ) 5

2. Gostaríamos de saber a quantidade de urina que você pensa que perde.

Nenhuma ( ) 0
Uma pequena quantidade ( ) 2
Uma moderada quantidade ( ) 4
Uma grande quantidade ( ) 6

3. Em geral quanto que perder urina interfere em sua vida diária? Por favor, circule um número entre 0 (não interfere) e 10 (interfere muito)

0 1 2 3 4 5 6 7 8 9 10

ICIQ score: Soma de 1+2+3 = ______________

4. Quando você perde urina? (por favor, assinale todas as alternativas que se aplicam a você)

Nunca ( )
Perco antes de chegar ao banheiro ( )
Perco quando tusso ou espirro ( )
Perco quando estou dormindo ( )
Perco quando estou fazendo atividades físicas ( )
Perco quando terminei de urinar e estou me vestindo ( )
Perco sem razão óbvia ( )
Perco o tempo todo ( )

OBRIGADO POR TER RESPONDIDO ÀS QUESTÕES

Fonte: Tamanini JTN et al. Validação para o português do “International Consultation on Incontinence Questionnaire - Short Form” (ICIQ-SF). Rev Saúde Pública 2004;38(3):438-44

APÊNDICES

Apêndice A – ESTRATÉGIA DE BUSCA DA REVISÃO SISTEMÁTICA

PUBMED

("Pelvic Floor"[Mesh] OR "Pelvic Floor Disorders"[Mesh] OR "pelvic floor"[All Fields]) AND (("muscles"[MeSH Terms] OR "muscles"[All Fields] OR "muscle"[All Fields])) AND ("Muscle Weakness"[Mesh] OR "Muscle Strength Dynamometer"[Mesh] OR "Muscle Strength"[Mesh] OR "Muscle Hypertonia"[Mesh] OR "Muscle Hypotonia"[Mesh] OR "Muscle Relaxation"[Mesh] OR "Muscle Tonus"[Mesh] OR "Muscle Contraction"[Mesh] OR tonus[All Fields] OR tone[All Fields] OR stiffness[All Fields] OR force[All Fields] OR strength[All Fields] OR strengthening[All Fields] OR "maximum voluntary contraction"[All Fields] OR ("power (psychology)"[MeSH Terms] OR "power"[All Fields] OR endurance[All Fields] OR resistance[All Fields] OR (sustained[All Fields] AND contraction[All Fields]) OR ("fatigue"[MeSH Terms] OR "fatigue"[All Fields]) OR coordination[All Fields] OR timing[All Fields] OR ("cough"[MeSH Terms] OR "cough"[All Fields]) OR ("cough"[MeSH Terms] OR "cough"[All Fields] OR "coughing"[All Fields]) OR co-contraction[All Fields] OR control[All Fields] OR ("awareness"[MeSH Terms] OR "awareness"[All Fields]) OR "ability"[All Fields]) OR ("physical therapy modalities"[MeSH Terms] OR ("physical"[All Fields] AND "therapy"[All Fields] AND "modalities"[All Fields]) OR "physical therapy modalities"[All Fields] OR "physiotherapy"[All Fields]) OR "physical therapy modalities"[All Fields] OR PFMT[All Fields] OR ("rehabilitation"[Subheading] OR "rehabilitation"[All Fields] OR "rehabilitation"[MeSH Terms]) OR knack[All Fields]) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms])

Limits: Language (portuguese, english, spanish); Population: (female, human)

SCIELO, LILACS AND CINAHL

“Pelvic floor” AND musc*

Apêndice B –TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

A senhora está sendo convidada a participar da PESQUISA “FUNÇÕES DOS MÚSCULOS DO ASSOALHO PÉLVICO COMO PREDITORAS DE DISFUNÇÕES DO ASSOALHO PÉLVICO”. A incontinência urinária (perda de urina sem querer) e a incontinência anal (perda de fezes e/ou gases sem querer) são problemas de saúde bastante comuns, especialmente entre mulheres mais velhas. Prejudicam a qualidade de vida dessas mulheres e impõem custos elevados aos serviços de saúde.

Vários são as causas que ajudam a acontecer este problema, entre eles o apoio dos órgãos contidos na pelve, como a bexiga, vagina, útero e reto (parte final do intestino) feito pelos músculos que fecham a saída da pelve. Estes músculos são chamados de músculos do assoalho pélvico (MAP) e suas funções são exercidas por meio da sua contração e relaxamento. Quando contraem, fecham a uretra, vagina e ânus e evitam o escape de urina e fezes e auxiliam durante o ato sexual. Quando relaxam, permitem a eliminação da urina, fezes e gases. Portanto, quando não funcionam adequadamente, podem levar a perda de urina e/ou de fezes e gases.

O tratamento que não requer cirurgia e/ou uso de medicamento mais adequado para essas perdas é o treinamento dos de músculos do assoalho pélvico sob a supervisão de um fisioterapeuta.

Para se estabelecer o tratamento apropriado para cada pessoa, é importante que se conheçam informações sobre como estes músculos funcionam em mulheres que tem perda urinária, de fezes e/ou de gases e naquelas que não apresentam essas perdas. Apesar de avanços dos estudos sobre o assunto, ainda faltam informações e conhecimento a esse respeito na área de saúde.

Objetivos

Este estudo tem como objetivos investigar as funções dos músculos do assoalho pélvico em mulheres com e sem incontinência anal e incontinência urinária para identificar como estes músculos se comportam nessas mulheres e também identificar os fatores que mais favorecem a ocorrência e a intensidade das perdas.

Procedimentos

A avaliação consiste de duas partes: entrevista e avaliação física. Na entrevista a senhora responderá a um questionário contendo informações sobre dados pessoais e sobre sua saúde.

Na avaliação física, a senhora terá os músculos avaliados por meio de toque na região vaginal e anal. Esta avaliação é semelhante à feita pelo ginecologista, em que a senhora irá se deitar em uma maca e posicionará seus joelhos e quadris dobrados com um rolo sob os joelhos. A pesquisadora, utilizando luvas e gel a base de água, irá palpar sua região vaginal e anal e lhe pedir contrações dos músculos.

Como parte da avaliação física também será usado um aparelho, denominado perineômetro, que consiste de duas sondas, uma para medida da pressão de contração dos músculos ao redor de sua vagina (que mede 3,5cm de comprimento e 2,5 cm de espessura) e outra, para registro da pressão anal (que mede 2cm de comprimento e 1,5cm de espessura). Cada uma das sondas será coberta com um preservativo descartável que será lubrificado com gel a base de água antes da sua inserção na vaginal e ânus.

A avaliação anal será realizada apenas caso haja necessidade. Você será informada a esse respeito.

Desconfortos e riscos

Como serão necessárias várias medidas dos músculos do assoalho pélvico e, portanto, a palpação repetida da região vaginal e anal, a senhora pode se sentir constrangida. Importante destacar que esta avaliação será feita dentro da rotina do Serviço de fisioterapia do ambulatório Jenny Faria e com uso de técnicas validadas e confiáveis por fisioterapeuta especialista em Saúde da Mulher. E será utilizada uma sala reservada para este fim. Em caso de constrangimento ou desconforto além dos habituais para estes tipos de procedimentos, as avaliações serão interrompidas. Portanto, faremos tudo para deixá-la à vontade e o exame poderá ser interrompido, caso necessite.

Benefícios esperados

Este estudo irá fornecer as características de como funcionam os músculos do assoalho pélvico de mulheres com e sem incontinência urinária e anal nas diferentes fases da vida. E também irá permitir conhecer a relação destas funções com a ocorrência e a intensidade das perdas de urina, fezes e gases. Estas informações são essenciais para definir as estratégias para a prevenção e o tratamento desses problemas de saúde. A senhora receberá informações sobre como estes músculos funcionam e instruções de como realizar exercícios específicos para tratar o seu problema ou evitar que ele ocorra no futuro, caso não apresente queixas.

Métodos alternativos existentes

Em associação a estas orientações, a senhora continuará o acompanhamento médico e fisioterapêutico de rotina nos Serviços de Ginecologia e Fisioterapia nas Disfunções do Assoalho Pélvico do Instituto Jenny de Andrade Faria. Conforme avaliação médica, outros tratamentos, como o uso de medicamentos e/ou a cirurgia, lhe serão propostos.

Participação, sigilo e privacidade

A sua participação neste estudo é voluntária e não está prevista qualquer forma de ressarcimento de valores ou indenização porventura gastos pela senhora para participação nesta pesquisa.

A senhora pode esclarecer suas dúvidas em qualquer etapa da pesquisa e tem a liberdade de recusar ou retirar seu consentimento em participar da pesquisa sem qualquer prejuízo a sua assistência de saúde no Hospital das Clínicas/UFMG. Todas as informações obtidas serão anotadas e transcritas para elaborar o laudo do estudo, sendo mantida sua identidade em sigilo para fins de atividades didáticas, publicações científicas e apresentações em congressos.

Responsabilidade

A fisioterapeuta pesquisadora Fernanda Saltiel Barbosa Velloso e a fisioterapeuta chefe do Serviço de Fisioterapia nas Disfunções do Assoalho Pélvico do Instituto Jenny de Andrade Faria, Elyonara Mello Figueiredo, são as responsáveis por esta pesquisa. A senhora irá receber uma via deste termo de consentimento e a outra via ficará com as pesquisadoras. Caso precise esclarecer qualquer dúvida sobre o estudo, favor entrar em contato com a pesquisadora responsável, Fernanda Saltiel Barbosa Velloso, pelo telefone (31)98085008.

Em caso de duvidas éticas, a senhora poderá entrar em contato com o Comitê de Ética em Pesquisa da UFMG localizado à Av. Antônio Carlos, 6627. Unidade Administrativa II – 2º andar – sala 2005, Campus Pampulha, Belo Horizonte, MG – Brasil, CEP: 31270-901 e/ou pelo telefone (31) 34094592.

Consentimento

Declaro que li e entendi as informações acima. Todas as minhas dúvidas foram esclarecidas satisfatoriamente e eu recebi uma via deste formulário de consentimento assinado, para guardar.

_______________________________________ __________________
Assinatura do participante do estudo Data da assinatura

Nome: ____

Endereço:____

Telefone:__________________________________

CI:______________________CPF:____________________DN:___/___/___

____
Assinatura da pessoa que conduziu a discussão do consentimento

____
Nome legível da pessoa que conduziu a discussão do consentimento
(Letra de forma)

Apêndice C – FICHA DE AVALIAÇÃO SÓCIO-DEMOGRÁFICA E CLÍNICA

GRUPO: (   ) IU   (   ) comparação No. Participante:________
Data da avaliação:___/___/____Avaliador:________________
Nome:____CPF:_______________
Telefone:__________________________Número HC:__________________________
Endereço:____
Cor da pele: (1) branca, (2) amarela, (3) indígena, (4) parda, (5) preta.
Estado matrimonial: (1) solteira (2) casada (3) união estável (4) separada
(5) viúva
Escolaridade: (1) analfabeto ou sabe escrever o nome;
(2) alfabetizado:_____anos estudados
Ocupação:____
Data de nascimento:_____/_____/_______Idade:____________
Diagnóstico clínico:(0   ) SEM QX (1   ) IUE   (2) IUU   (3) IUM   (4) IA   (5) POP (6) DPC (7) constipação intestinal
História obstétrica: G____P_______A____Peso maior RN:_____________
DUM:___/___/______
Menopausa:___/___/______Terapia de reposição hormonal: (0) não (1) sim
Peso:___________Altura:__________IMC:__________
Cirurgias pélvico-abdominais prévias:______________________________________
Data da última cirurgia:_____/_____/______
Queixa principal:____

Sintomas urinários:
Sintomas de infecção do trato urinário de repetição:
(0) não (1) sim (2) dor (3   ) desconforto para urinar (4   ) urina fétida
Número de infecções em 12 meses?________________
Sintomas de obstrução urinária: (0) não (1) sim: (2) esvaziamento incompleto (3) esforço para urinar (4   ) jato urinário fraco (5) gotejamento pós-miccional
Noctúria: (0) não (1) sim no de vezes:_________Freq micção/dia:_________
Situações de perda: (0) Não (1) tosse (1) espirro (1) riso (1) correr (1) pular
(1) ativ. sexual (1) carregar peso (1) mudar de decúbito (1) emoção;
(1) água/frio (1) subir/descer escadas
Urgência: (0) não (1) sim   Urge-incontinência: (0) não (1) sim
Uso protetor: (0) não (1) sim   Tipo:________________Quantidade:___________
ICIQ: 1.________2.___________3.__________Total:___________

Sintomas intestinais
Constipação intestinal (≥2 sintomas nos últimos 3 meses, iniciados há 6 meses)
Frequência evacutatória menor do que 3x/semana; (0) não (1) sim
Esforço evacuatório em mais do que 25% das evacuações; (0) não (1   ) sim
Sensação de evacuação incompleta em mais do que 25% das evacuações;
(0   ) não (1) sim
Manobras manuais para facilitar a evacuação em mais de 25% das evacuações;
(0) não (1) sim
Sensação de obstrução anorretal em mais de 25% das evacuações;
(0   ) não (1) sim
Fezes duras ou em cíbolos em mais de 25% das evacuações;   (0) não (1) sim

Incontinência fecal: (0) não (1) sim
incontinência flatos: (0) não (1) sim
Percepção (desejo de defecação e distinção fezes/gases): (1) sim (0) não
Consistência das fezes perdidas: (1) líquidas (2) sólidas (3) pastosas
Situações de perda fecal: (0) não (1)tosse(1) espirro (1) riso(1) correr
(1) pular(1) ativ.sexual (1)carregar peso (1) mudança de decúbito
(1) emoção (1) subir/descer escadas (1) Outros:___________________
Uso de protetores: (0) não (1) sim; Tipo?______________Quantos/dia:________
Diarréia Crônica (1) sim (0) não
Uso de laxantes, lavagem, supositório, alimentação ou outro: (1) sim (0) não

Sintomas vaginais
Dispareunia: (0) não (1) sim
Lassidão vaginal: (0) não (1) sim
Gases vaginais: (0) não (1) sim
Sensação de peso na vagina: (0) não (1) sim
Sensação de bola na vagina (0) não (1) sim

Sintomas de dor
(0) não (1) sim:
(1) Dor vesical (2)Dor uretral (3) Dor vulvar (4)Dor vaginal
(5) Dor perineal (6)Dor pélvica cíclica (menstrual) (7) Neuralgia pudenda
(8) Dor na pelve não associada às anteriores (9) Dor lombo-pelvica

Outras condições de saúde: ____
Medicação:____

Hábitos de vida
Tosse crônica: (0) Não (1) Sim
Tabagismo: (0) não (1) sim no. Cigarros/dia:________
Etilismo: (0) não (1) social (2) diário
Ingestão de cafeína: (0) não (1) sim quantidade:_____________
Ingestão de bebidas gaseificadas: (0) não (1) sim quantidade:______________
Atividade física regular: (0) Não (1) Sim
Qual:_______________Freq/semana:_______

POP-Q:_______________________

Aa (+3 – 3) cm	Ba (+3 – 3) cm	C cm
gh cm	pb cm	Tvl cm
Ap (+3 – 3) cm	Bp (+3 – 3) cm	D cm

Apêndice D – EXAME DAS FUNÇÕES SENSORIAIS E MUSCULARES DO ASSOALHO PÉLVICO (EFSMAP)

Examinador:_________________________Hora:_________		
Posicionamento	(1)Supino apoio MMII no rolo (2) supino (3) litotomia (4) lateral (5) de pé (6) Supino fl MMII sem rolo	
INSPEÇÃO		
Controle (contração) (b7608)	( ) 0 ausente ( ) 1 presente	
PALPAÇÃO		
No. Dedos	( ) 1 ( ) 2	
Função proprioceptiva (b260)	( ) 1 sim ( ) 0 não	
Dor localizada (b28018) (ECN 0 a 10)	( ) 0 não ( )1 sim D:________E:________	
Tônus (b7350)	D ( ) 1 baixo ( ) 2 normal ( ) 3 alto	E ( ) 1 baixo ( ) 2 normal ( ) 3 alto
Controle (contração) (b7608)	( ) 0 ausente ( ) 1 presente	
Controle (relaxamento) (b7608)	( ) 0 ausente ( ) 1 completo ( ) 2 parcial/lento	
Reflexo de movimento involuntário (tosse) (b755)	( ) 0 ausente ( )1 presente	
Coordenação (b7602)	( ) 1 presente ( ) 0 ausente (1) abdominais (2) glúteos (3) adutores (4) respiração (5) outros:____________	
Força (b7300)	Escala de Oxford Modificada:_________	
Resistência (duração) (b7408)	___________segundos	
Resistência (repetições) (b7408)	___________vezes	
MANOMETRIA VAGINAL		
Pressão vaginal de repouso	____________cmH_2O	
Força (cmH_2O) (b7300)	____________cmH_2O	
Resistência (duração) (b7408)	____________segundos	