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FLÁVIA BLASECK SORRILHA

AVALIAÇÃO CRÍTICA DAS DIRETRIZES DE PRÁTICA CLÍNICA PARA O TRATAMENTO DA INCONTINÊNCIA URINÁRIA EM MULHERES: REVISÃO SISTEMÁTICA

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Dissertação apresentada à Banca Examinadora do Programa de Pós-Graduação em Ciências Farmacêuticas da Universidade de Sorocaba, como exigência parcial para obtenção do título de Mestre em Ciências Farmacêuticas.

Orientadora: Profa. Dra. Cristiane de Cássia Bergamaschi

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Aprovado em:

BANCA EXAMINADORA

_____
Profa. Dra. Cristiane de Cássia Bergamaschi
Universidade de Sorocaba (UNISO)

_____
Profa. Dra. Daniela Oliveira de Melo
Universidade Federal de São Paulo (UNIFESP)

_____
Prof. Dr. Marcus Tolentino da Silva
Universidade de Sorocaba (UNISO)

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RESUMO

A incontinência urinária é queixa comum em mulheres em todo o mundo, causa de sofrimento e custos significativos para indivíduos e para a sociedade. As diretrizes são importantes veículos de influência para a prática clínica. Sociedades locais, nacionais e internacionais adotam o processo de identificação de áreas clínicas relevantes, elaboração de questões clínicas específicas, revisão das evidências aplicáveis e formulação de recomendações, que os prescritores e pacientes devem seguir. Esta revisão sistemática avaliou o rigor do desenvolvimento e a transparência das diretrizes de prática clínica a respeito dos tratamentos para incontinência urinária em mulheres. As seguintes bases de dados foram consultadas: Biblioteca Cochrane (Cochrane Controlled Register of Trials - CENTRAL), MEDLINE (via Ovid); EMBASE (banco de dados *Excerpta Medica*, via Ovid); *Web of Science* e Scopus. Bancos de dados específicos de CPGs também foram pesquisados. Revisores, em triplicata e independentemente, avaliaram a qualidade das diretrizes por meio do instrumento *Appraisal of Guidelines for Research & Evaluation* (AGREE II). A classificação priorizou o domínio 3 (rigor do desenvolvimento), considerando-se: alta (escore>60%), moderada (escore 30-60%) ou baixa qualidade (escore<30%). Os resultados foram verificados quanto às discrepâncias e decididos por consenso. Dos 9 documentos avaliados, 3 não foram recomendados para uso. As classificações foram: alta qualidade metodológica (n=5); qualidade moderada (n=2); baixa qualidade (n=2). Os domínios com as pontuações mais altas foram: escopo e finalidade (média=91,4%) e clareza de apresentação (média=89,5%). Os domínios independência editorial (média=52,2%) e aplicabilidade (média=36,8%) foram os de menor pontuação. As intervenções não farmacológicas foram as mais reportadas pelos documentos: intervenções de estilo de vida (n=8), treinamento ou reeducação vesical (n=8) e treinamento dos músculos do assoalho pélvico (n=8). A maioria dos documentos são confiáveis pois apresentaram alto rigor de desenvolvimento, entretanto, a independência editorial e a aplicabilidade representam domínios que precisam ser descritos ou melhor reportados. Estes achados podem orientar profissionais de saúde e formuladores de políticas de saúde na escolha das diretrizes para tratamento da incontinência urinária em mulheres.

Palavras-chave: Incontinência urinária. Diretrizes de prática clínica. Revisão sistemática.

ABSTRACT

Urinary incontinence is a common complaint in women around the world, causing suffering and significant costs for individuals and society. The guidelines are important vehicles of influence for clinical practice. Local, national and international societies adopt the process of identifying relevant clinical areas, formulating specific clinical issues, reviewing applicable evidence and formulating recommendations that they believe that should used by prescribers and patients. This systematic review assessed the rigor of development and the transparency of clinical practice guidelines (CPG) regarding treatments for urinary incontinence in women. The following databases were consulted: Cochrane Library (Cochrane Controlled Register of Trials - CENTRAL), MEDLINE (via Ovid); EMBASE (Excerpta Medica database, via Ovid); Web of Science and Scopus. CPG-specific databases were also searched. Reviewers, organized in triplicate and independently, assessed the quality of the guidelines using the Appraisal of Guidelines for Research & Evaluation (AGREE II) instrument. The classification of the CPG prioritized the domain 3 (rigor in development), considering: high (score>60%), moderate (score 30-60%) or low quality (score<30%). The results were checked for discrepancies and decided by consensus. The interventions have been described. Of the 9 CPGs evaluated, 5 were of high methodological quality, 2 of moderate quality and 2 of low quality, with 3 documents not recommended for use. The domains with the highest scores were scope and purpose (mean=91.4%) and clarity of presentation (mean = 89.5%). The domains of editorial independence (mean=52.2%) and applicability (mean=36.8%) were those with the lowest score. The interventions most cited by CPG were non-pharmacological: lifestyle interventions (n =8), bladder training or re-education (n=8) and pelvic floor muscle training (n=8). The study concluded that most of the documents are reliable because they showed high development rigor, however, editorial independence and applicability represent domains that need to be described or better reported. These findings can guide health professionals and health policy makers in choosing guidelines for the treatment of urinary incontinence in women.

Keywords: Urinary incontinence. Clinical practice guidelines. Systematic review.

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LISTA DE ABREVIATURAS E SIGLAS

ACP	*American College of Physicians*
ACOG	*The American College of Obstetricians and Gynecologists*
AGREE	*Appraisal of Guidelines for Research & Evaluation*
AMB	Associação Médica Brasileira *(Brazilian Medical Association)*
AUA	*American Urological Association*
CPG	C*linical Practice Guidelines* (Diretrizes de Prática Clínica)
CNGOF	*French College of Gynecologists and Obstetricians*
EAU	*European Associate of Urology*
ICS	*International Continence Society*
INCA	Instituto Nacional do Câncer (*National Cancer Institute*)
IOM	*Institute of Medicine da National Academy of Sciences*
NICE	*National Institute for Health and Care Excellence*
PRISMA	*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*
SOGC	*Society of Obstetricians and Gynecologists of Canada*
UI	*Urinary Incontinence*
SUI	*Stress Urinary Incontinence*
UUI	*Urgent Urinary Incontinence*
MUI	*Mixed Urinary Incontinence*
WHO	*World Health Organization*

SUMÁRIO

1 APRESENTAÇÃO

A incontinência urinária tem consequências multidimensionais e negativas na qualidade de vida das mulheres. Frequentemente é um sintoma subdiagnosticado pelos profissionais da saúde e negligenciado pelos indivíduos que acabam por não procurar tratamento por vergonha, medo da cirurgia ou ideia equivocada de que se trata de um problema inerente ao envelhecimento ou a gestação, e dentre outras situações.

As diretrizes de prática clínica (*Clinical Pratice Guidelines* – CPG) são importantes veículos de influência para as sociedades locais, nacionais e internacionais que seguem suas recomendações. A preocupação relacionada a elaboração destes documentos motivou o desenvolvimento de instrumentos que avaliam sua qualidade.

Entre os instrumentos disponíveis, o *Appraisal of Guidelines for Research and Evaluation* (AGREE) foi publicado em 2003 por um grupo de desenvolvedores e pesquisadores de diretrizes internacionais, a AGREE Collaboration, com objetivo de avaliar a qualidade das diretrizes.

Conhecer a qualidade metodológica destes documentos pode garantir o uso de informação adequada, desde que seja elaborada com metodologias apropriadas. Este conhecimento é importante para profissionais da saúde e gestores de políticas de saúde na escolha das diretrizes para a recomendação na prática clínica, por contribuir para o desenvolvimento de documentos de alta qualidade e informar a respeito das recomendações existentes das diferentes intervenções. Os resultados observados, poderá também identificar áreas-chaves para pesquisas futuras.

Este trabalho avaliou as diretrizes de prática clínica quanto ao rigor do desenvolvimento e sua transparência de acordo com o instrumento AGREE II e identificou, nestes documentos, as recomendações de intervenções para a incontinência urinária em mulheres.

O AGREE II, atualizado em 2009, foi o instrumento escolhido para a avaliação dos documentos. Amplamente usado, oferece uma avaliação abrangente, rápida e consistente para as diretrizes de prática clínica.

Para maior clareza e organização, este trabalho foi estruturado em: Referencial teórico, Objetivos, Resultados e Considerações finais. O tópico “Referencial teórico” define a incontinência urinária, apresenta sua prevalência, diagnóstico e tratamentos

disponíveis. O tópico “Objetivos” faz referência aos objetivos “primário” e “secundários” traçados por esse estudo.

Optou-se pelas normas do Programa de Pós-graduação em Ciências Farmacêuticas, o qual consiste em descrever os seus produtos no item “Resultados”. Desta forma, o item foi estruturado com as produções científicas desenvolvidas de acordo com os objetivos do estudo, sendo apresentados dois artigos científicos (ANEXO A)

O **artigo 1** refere-se ao protocolo do estudo publicado no periódico *Medicine Journal*: *“Critical appraisal of clinical practice guidelines for treatment of urinary incontinence: protocol for a systematic review”.*

O **artigo 2** é intitulado: *“Critical appraisal of clinical practice guidelines for treatment of female urinary incontinence: systematic review”*.

O tópico “Considerações finais” discorre sobre os achados e conclusões da presente dissertação.

As referências desta dissertação estão em uma lista única e final.

2 REFERENCIAL TEÓRICO

2.1 Incontinência urinária

A *Internacional Continence Society* (ICS) define a incontinência urinária como a queixa de perda involuntária de urina e que pode ser um dos sintomas relatados pelo paciente e/ou cuidador, ou um sinal observado na presença de disfunções de trato urinário inferior [1].

Esse problema pode acometer pessoas de ambos os sexos, em todas as faixas etárias, independentemente de níveis sociais e econômicos. Atinge negativamente a qualidade de vida e compromete o bem-estar físico, emocional, psicológico e social [2].

Na literatura existente, as informações sobre prevalência da incontinência urinária divergem, principalmente, quanto a população amostral e na aferição das perguntas. Isso dificulta a obtenção mais conclusivas sobre a prevenção e tratamento para o problema [3,4]. Acredita-se que a incontinência urinária é mais frequente em mulheres e tende a aumentar com o envelhecimento, mas sua prevalência na população feminina é muito variável, chegando a 69% de acordo com alguns estudos [5,6].

As mulheres representam maior número, comparada aos homens, devido aos fatores de risco para o desenvolvimento de sintomas da incontinência urinária que incluem gestação, trauma do assoalho pélvico após o parto vaginal, menopausa, histerectomia, obesidade, infecção do trato urinário, comprometimento funcional e ou cognitivo, tosse crônica e constipação intestinal [7].

Segundo um estudo concluído no Brasil, 84% da população com 40 anos ou mais tem pelo menos um sintoma de disfunção de trato urinário inferior, incluindo a incontinência urinária [8]. A prevalência da incontinência urinária entre a população idosa estudada foi de 11,8% entre os homens e de 26,2% entre as mulheres [9].

A incontinência urinária pode ser dividida de acordo com sua etiologia em: neurogênica, quando decorre de alguma lesão neurológica, como o acidente vascular cerebral, esclerose múltipla, lesão medular e outros; e a não-neurogênica que abrange os sintomas de insuficiência do esfíncter uretral, hiperatividade detrusora ou decorrentes de cirurgias [10].

Dentre os tipos de incontinências urinárias não-neurogênicas, a perda de urina pode estar associada a alguns sinais e sintomas, e classifica-se em três tipos principais:

i) a incontinência urinária de esforço, que ocorre o vazamento de urina a esforços físicos como o tossir, rir ou espirrar, ou exercício físico; ii) a incontinência urinária de urgência, que acontece quando a bexiga se contrai inadequadamente e há um forte desejo repentino de urinar, sem tempo hábil para anulação e o vazamento pode ocorrer a caminho do banheiro; iii) a incontinência mista que combina sintomas de incontinência urinária de esforço e de urgência [11].

Quanto à classificação, cerca de 50% dos pacientes apresentam sintomas da incontinência urinária de esforço, 14% apresentam a incontinência urinária de urgência e 32% representam a forma mista da doença, combinando tanto sintomas de esforço quanto de urgência[12]. Em um estudo conduzido na Alemanha e Dinamarca, respectivamente, 48,3% e 46,4% das mulheres abordadas relataram algum episódio de incontinência urinária [13].

O diagnóstico deve partir de uma avaliação centrada nos sinais e sintomas do paciente para determinar a presença e natureza da disfunção e os fatores contributivos, incluindo uma história abrangente, um exame físico focado (quando necessário e apropriado) e testes laboratoriais, a fim de definir o diagnóstico e excluir condições não relacionadas que podem exigir atenção [14].

O treinamento muscular do assoalho pélvico é a primeira linha para o tratamento conservador da incontinência urinária em mulheres. Outros tratamentos incluem cinesioterapia, terapias comportamentais, treinamento da bexiga, uso da eletroestimulação e dispositivos mecânicos (por exemplo, pessários de continência)[15].

Os medicamentos anticolinérgicos, o estrogênio e intervenções cirúrgicas, incluindo a colposuspensão e *slings* uretrais, e a injeção de toxina botulínica tipo A se tornam outras opções quando os sintomas persistirem após tentativa de manejo com tratamentos ativos [16].

Considerando a variabilidade dos tratamentos encontrados, é necessário que os profissionais de saúde adotem as diretrizes de prática clínica como norteadores para decisões clínicas junto a seus pacientes.

2.2 Diretrizes de prática clínica

Segundo o *Institute of Medicine da National Academy of Sciences* (IOM), as diretrizes de prática clínica são declarações que incluem recomendações dirigidas a melhorar o atendimento ao paciente, informadas por revisão sistemática de evidências e avaliação dos benefícios e desvantagens das alternativas de atendimento [17]. Essa definição oferece distinção entre as diretrizes e outras formas de orientação clínica procedentes do desenvolvimento como, por exemplo, os consensos, aconselhamento especializado e critérios de uso apropriados.

As diretrizes são importantes veículos de influência para a prática clínica. Sociedades locais, nacionais e internacionais adotam o processo de identificação de áreas clínicas relevantes, formulação de questões clínicas específicas, revisão das evidências aplicáveis e formulação de recomendações que acreditam que os médicos e seus pacientes devam seguir [18]. Entretanto, para garantir confiabilidade, elas devem ser desenvolvidas sistematicamente por grupos de pessoas com habilidades, perspectivas e conhecimentos baseados na melhor evidência disponível [19].

A implementação de diretrizes de prática clínica traz melhores resultados para uma determinada população, já que se propõe a desenvolver a qualidade da assistência prestada com a padronização das condutas frente a problemas clínicos específicos [20,21]. Além disso, contribuem para as decisões dos profissionais de saúde, exercendo papel importante para a gestão e regulação dos sistemas de saúde [19].

As diretrizes de prática clínica são elaboradas por organizações variadas, como sociedades clínicas especializadas, grupos de defesa de doenças, agências federais e locais, planos de saúde ou empresas comerciais. O propósito de sua elaboração é o de atender diferentes contextos, padronizando condutas em clínicas e/ou hospitais e orientando políticas públicas de saúde [18].

Os principais objetivos para a elaboração de diretrizes de prática clínica estão descritos a seguir [20]:

- Melhorar a qualidade dos cuidados em saúde e resultados para o paciente;
- Diminuir danos e riscos do tratamento;
- Diminuir variação da prática clínica entre os profissionais;

- Disseminar as melhores recomendações obtidas por evidências avaliadas sistematicamente;
- Aumentar a confiança das decisões médicas pela utilização de critérios padronizados;
- Reduzir custos e melhorar a relação custo-benefício das intervenções;
- Dispor de recomendações para áreas de incertezas clínicas;
- Facilitar a educação, treinamento e desenvolvimento profissional contínuo;
- Poupar tempo dos profissionais ao resumir os dados dos estudos publicados;
- Promover a ética médica ao proporcionar clareza, transparência e informações; aos pacientes;
- Informar gestores, financiadores e formuladores de políticas;
- Facilitar a compreensão de questões clínicas complexas para residentes, estudantes, gestores, financiadores, pacientes e sociedade.

Embora a aceitação da importância de empregar uma abordagem baseada em evidências para a tomada de decisões clínicas esteja em crescimento, em muitas áreas, a prática ainda não foi acolhida [22].

Em muitas especialidades e locais, o uso dos diretrizes de prática clínica ainda não é adotado. Sem boas evidências de pesquisa, a tomada de decisão clínica, seja em diagnóstico ou tratamento, faz-se inconsistente [23]. A elaboração destes documentos é um processo complexo e que envolve muitos procedimentos necessários para a publicação final.

Devido à complexidade, o custo e o tempo envolvido no desenvolvimento, o Ministério da Saúde elaborou, em 2016, uma diretriz metodológica que detalha as etapas do desenvolvimento das diretrizes de prática clínica, sumarizadas no Quadro 1.

Quadro 1 - Etapas sumarizadas para elaboração das diretrizes de prática clínica, segundo o Ministério da Saúde

Definição do tema
Delimitação do escopo
Definição das perguntas PICOS
Construção de estratégia de busca
Seleção dos artigos identificados
Avaliação da qualidade dos estudos selecionados
Avaliação da qualidade do corpo de evidências para cada pergunta PICOS
Elaboração e graduação de recomendações pelo Sistema GRADE
Redação do texto das diretrizes
Submissão à revisão externa ou consulta pública, quando aplicável
Redação e publicação da versão final das diretrizes após revisão
Difusão, disseminação e implementação das diretrizes
Monitoramento e avaliação da implementação
Atualização periódica da diretriz

Fonte: Diretrizes metodológicas: elaboração de diretrizes clínicas Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Gestão e Incorporação de Tecnologias em Saúde. Brasília; Ministério da Saúde; 2016. 95 p. Livro ilus, tab, graf. Monografia em Português | Ministério da Saúde | ID: mis-37636. Disponível em: <http://bvsms.saude.gov.br/bvs/publicacoes/diretrizes_metodologicas_elaboracao_diretrizes_metodologicas.pdf> Acesso em: 08 ago.2019

A transparência no processo de desenvolvimento de uma diretriz clínica inclui o relato de quais evidências foram obtidas, revisadas e qual a força de recomendação; ou seja, a confiança nos achados. Desenvolvedores destes documentos devem ser abertos a grupos externos e à população [24].

Uma diretriz clínica de boa qualidade deve ser cientificamente válida, utilizável e confiável. Os potenciais vieses que podem ocorrer ao longo do desenvolvimento devem ser abordados de forma adequada, além da validação interna e externa e a viabilidade na prática das recomendações, itens que podem definir a qualidade destes documentos[25].

Tem-se observado variabilidade nas diretrizes de prática clínica. Entre os itens que contribuem para isso estão: recomendações conflitantes, desinteresse pelas preferências

dos pacientes, baixa qualidade das evidências implícitas às recomendações, falta de transparência dos métodos (especialmente no que se refere à procedência das recomendações e à determinação de seus pontos fortes) e gerenciamento inadequado de eventuais conflitos de interesse [26].

Quando os documentos fornecem orientações diferentes, é provável que os desenvolvedores não estejam certos quanto ao processo de desenvolvimento, esclarecendo algumas das fraquezas observadas na elaboração das diretrizes de prática clínica. Neste caso, é contundente apurar quais e o porquê das lacunas ou contradições destes documentos [27]. Sendo assim, é imprescindível que métodos mais eficientes sejam aplicados na construção e implantação para o fortalecimento da prática clínica baseada em evidências [20].

O desenvolvimento de diretrizes de prática clínica deve ser realizado por um grupo multidisciplinar, com representação de profissionais relevantes e a participação de pacientes, prestadores de cuidados e organizações voluntárias apropriadas [28].

O desenvolvimento por grupos multidisciplinares, aumenta a probabilidade de que todas as informações científicas relevantes serão identificadas e avaliadas criticamente, a possibilidade de que problemas práticos na aplicação das diretrizes sejam identificados e abordados, e o senso de envolvimento entre o público e as orientações [18].

É recomendado que os elaboradores das diretrizes de prática clínica compreendam o contexto de aplicação das recomendações, uma vez que fatores como preferência dos pacientes, aplicabilidade das recomendações, custos, e outras características específicas (equipamentos, profissionais especialistas) possam influenciar na adesão das recomendações. Ainda assim, o documento deve apontar seu público alvo e o contexto clínico no qual será aplicado. Deste modo será possível definir o escopo, as evidências a serem utilizadas e a composição do documento [29].

O processo de atualização é importante e garante a confiabilidade nas recomendações, visto que muitas áreas possuem alta produção de evidência científica e as diretrizes são documentos “vivos” e devem evoluir conforme as novas evidências que emergem para que sua credibilidade não seja prejudicada [20]. O documento precisa ser atualizado se a maioria das recomendações estiver desatualizada, com novas evidências

demonstrando que as intervenções recomendadas são inadequadas, ineficazes ou substituídas por novas intervenções [20].

2.4 Instrumento AGREE II

O desenvolvimento sistemático por grupos de pessoas com habilidades, perspectivas e conhecimento baseados na melhor evidência disponível pode garantir maior confiabilidade das diretrizes de prática clínica. Uma equipe internacional de desenvolvedores e pesquisadores de diretrizes, elaborou um instrumento genérico para avaliar e relatar o processo de desenvolvimento. Com base em métodos rigorosos, o resultado dos esforços da colaboração foi a criação, em 2003, do *Appraisal of Guidelines for Research and Evaluation* (AGREE), ferramenta composta por 23 itens distribuídos por seis domínios relacionados à qualidade das informações disponíveis nas diretrizes [20].

O instrumento AGREE aborda a variabilidade na qualidade e avalia o rigor metodológico e a transparência no desenvolvimento das diretrizes de prática clínica. O Consórcio AGREE refinou o Instrumento original para criar o novo AGREE II, lançado oficialmente em 2010. O Consórcio também modificou significativamente o guia do usuário e o manual de treinamento (Quadro 2).

Quadro 2 - Domínios e itens do *Appraisal of Guidelines for Research and Evaluation* (AGREE II)

Domínio 1	**Escopo e Finalidade**
Item 1	O(s) objetivo(s) geral(is) da diretriz encontra(m)-se especificamente descrito(s).
Item 2	A(s) questão(ões) de saúde coberta(s) pela diretriz encontra(m)-se especificamente descrita(s).
Item 3	A população (pacientes, público, etc.) a quem a diretriz se destina encontra-se especificamente descrita.
Domínio 2	**Envolvimento das Partes Interessadas**
Item 4	A equipe de desenvolvimento da diretriz inclui indivíduos de todos os grupos profissionais relevantes.
Item 5	Procurou-se conhecer as opiniões e preferências da população-alvo (pacientes, público, etc.)
Item 6	Os usuários-alvo da diretriz estão claramente definidos.
Domínio 3	**Rigor do Desenvolvimento**
Item 7	Foram utilizados métodos sistemáticos para a busca de evidências.
Item 8	Os critérios para a seleção de evidências estão claramente descritos
Item 9	Os pontos fortes e limitações do corpo de evidências estão claramente descritos.
Item 10	Os métodos para a formulação das recomendações estão claramente descritos.

Item 11	Os benefícios, efeitos colaterais e riscos à saúde foram considerados na formulação das recomendações.
Item 12	Existe uma relação explícita entre as recomendações e as evidências que lhe dão suporte.
Item 13	A diretriz foi revisada externamente por experts antes da sua publicação
	Um procedimento para atualização da diretriz está disponível.
Domínio 4	**Clareza da Apresentação**
Item 14	As recomendações são específicas e sem ambiguidade.
Item 15	As diferentes opções de abordagem da condição ou problema de saúde estão claramente apresentadas.
Item 16	As recomendações-chave são facilmente identificadas.
Domínio 5	**Aplicabilidade**
Item 17	A diretriz descreve os fatores facilitadores e as barreiras para sua aplicação.
Item 18	A diretriz traz aconselhamento e/ou ferramentas sobre como as recomendações podem ser colocadas em prática.
	Foram consideradas os potenciais implicações quanto aos recursos decorrentes da aplicação das recomendações.
Item 19	A diretriz apresenta critérios para o seu monitoramento e/ou auditoria.
Domínio 6	**Independência Editorial**
Item 21	O parecer do órgão financiador não exerceu influência sobre o conteúdo da diretriz.
Item 22	Foram registrados e abordados os conflitos de interesse dos membros da equipe que desenvolveram a diretriz.
	Avaliação Global da Diretriz Clínica
Item 23	Classifique a qualidade global dessa diretriz

A ferramenta foi projetada para avaliar a qualidade das diretrizes no âmbito da saúde oferecendo assim, orientações sobre o desenvolvimento destes documentos e orienta quais informações específicas devem ser relatadas [20].

Os domínios do AGREE II incluem questões metodológicas relevantes para o desenvolvimento de diretrizes e relatórios, mas não avaliam a adequação ou validade clínica das próprias recomendações. Mesmo com a necessidade de um desenvolvimento rigoroso e relatórios explícitos, as recomendações podem não refletir os melhores resultados em saúde para pacientes e populações [20,30].

Uma vez que há crescente número de desenvolvimento de diretrizes de prática clínica, o instrumento AGREE II fornece uma estrutura para alcançar consenso sobre princípios metodológicos. Além de avaliar as diretrizes de prática clínica, o instrumento pode ser utilizado para propiciar a qualidade e disponibilizar uma estratégia metodológica

consistente para descrever as informações devem ser incorporadas nestes documentos[30].

2.5 Revisão sistemática

As revisões sistemáticas são o padrão de referência para sintetizar evidências nos cuidados de saúde. Devido ao seu rigor metodológico, são usadas para apoiar o desenvolvimento de diretrizes de prática clínica e informar a tomada de decisão clínica[31].

A questão de pesquisa a ser investigada deve ser clara e objetiva, a fim de estruturá-la segundo os componentes PICO: **população,** que especifica qual será a população incluída nos estudos; **intervenção,** definindo qual será a intervenção a ser investigada; **controle,** estabelecendo um comparador (se aplicável); **desfecho,** que é proveniente de um desfecho clínico ou um desfecho substituto procurado [32]. Em geral, estes itens compõe a estrutura de revisão sistemática de intervenção.

Para melhor responder à questão de pesquisa, é interessante definir também o tipo de desenho de estudo que será considerado para a apresentação das evidências sobre as intervenções [33]. Desta maneira, definiu-se que o método utilizado para a busca dos documentos incluídos neste estudo, seguiria os mesmos passos de uma revisão sistemática.

3 OBJETIVOS

3.1 Objetivo primário

Avaliar as diretrizes de prática clínica quanto ao rigor do desenvolvimento e sua transparência de acordo com o documento AGREE II e identificar, nestes documentos, as intervenções para a incontinência urinária em mulheres.

3.2 Objetivos secundários

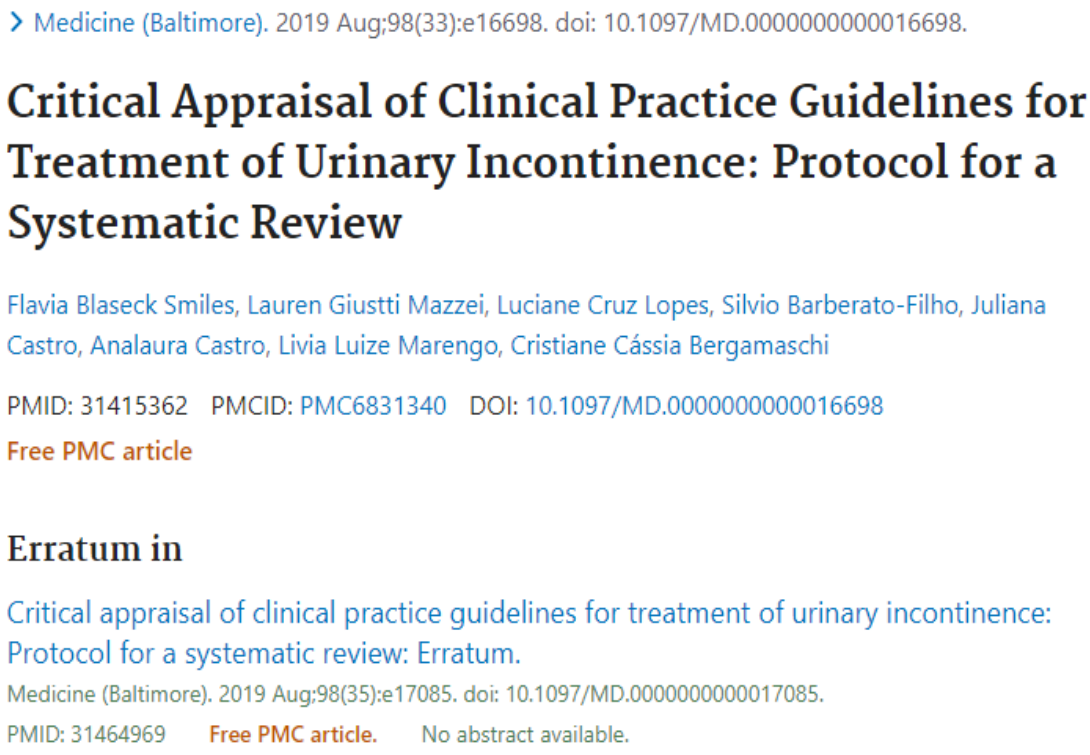
- Caracterizar as diretrizes com relação ao local, ano de publicação e instituição responsável pelo seu desenvolvimento;
- Avaliar o rigor do desenvolvimento e a transparência destes documentos, por meio do instrumento AGREE II;
- Identificar, com base nos domínios do instrumento AGREE II, os itens associados com a qualidade metodológica dessas diretrizes;
- Informar as recomendações fornecidas pelas diretrizes de prática clínica, de acordo com as especificidades dos tipos de incontinência;
- Identificar lacunas nas evidências atuais para serem incorporadas em novas diretrizes e fazer recomendações para pesquisas futuras.

4 RESULTADOS

Esta dissertação é apresentada no formato de artigo científico, elaborado conforme as recomendações do Programa de Pós-Graduação em Ciências Farmacêuticas da Universidade de Sorocaba.

O **artigo 1** é referente ao protocolo do estudo publicado no periódico "*Medicine*": *"Critical appraisal of clinical practice guidelines for treatment of urinary incontinence: protocol for a systematic review"* (doi: 10.1097/MD.0000000000016698).

O **artigo 2** é referente ao artigo "*Critical appraisal of clinical practice guidelines for treatment of urinary incontinencein women: systematic review*" e será submetido a periódico a ser definido.



› Medicine (Baltimore). 2019 Aug;98(33):e16698. doi: 10.1097/MD.0000000000016698.

Critical Appraisal of Clinical Practice Guidelines for Treatment of Urinary Incontinence: Protocol for a Systematic Review

Flavia Blaseck Smiles, Lauren Giustti Mazzei, Luciane Cruz Lopes, Silvio Barberato-Filho, Juliana Castro, Analaura Castro, Livia Luize Marengo, Cristiane Cássia Bergamaschi

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Erratum in

Critical appraisal of clinical practice guidelines for treatment of urinary incontinence: Protocol for a systematic review: Erratum.

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PMID: 31464969 Free PMC article. No abstract available.

4.1 Artigo 1

Full-title: Critical appraisal of clinical practice guidelines for treatment of urinary incontinence: protocol for a systematic review
Short-title: Critical appraisal of guidelines for urinary incontinence

Authors: Flávia Blaseck Sorrilha MsC student[a], Lauren Giustti Mazzei MsC[a], Luciane Cruz Lopes PhD[a], Silvio Barberato-Filho PhD[a], Juliana Pedroso Moraes Vilela Castro PhD Student[a], Analaura Pedroso Moraes Vilela de Castro BS[a], Lívia Luize Marengo PhD Student[a], Cristiane de Cássia Bergamaschi PhD[a*]

Author affiliations
[a]Graduate Program in Pharmaceutical Sciences, University of Sorocaba, Sorocaba, São Paulo, Brazil

∗**Corresponding author:**
Flávia Blaseck Sorrilha
E-mail: flaviablaseck@gmail.com
Universidade de Sorocaba (UNISO)
Rodovia Raposo Tavares, Km 92.5, Sorocaba, São Paulo, 18023-000, Brazil
Phone/Fax: 15 15 2101 7104

ABSTRACT

BACKGROUND Urinary incontinence is a common complaint in all parts of the world, cause of distress, as well as significant costs for both individuals and society. The aim of this study will be to evaluate the rigor of the development of clinical practice guidelines and to identify the recommendations of interventions for urinary incontinence in women.

METHODS In this systematics review, clinical practice guidelines will be identified using a prospective protocol through a systematic search of: MEDLINE (via Ovid); Excerpt Medical Database (EMBASE, via Ovid); Web of Science and Scopus. Specific databases of guidelines for clinical practice will also be searched (National Institute for Health and Care Excellence, American Urological Association, and others). Reviewers, independently and in duplicate, will assess the quality of the guidelines using the Appraisal of Guidelines Research and Evaluation (AGREE II). The results will be checked for discrepancies. Differences between the scores equal to or greater than two will be considered as discrepant and the final result will be decided by consensus. A comparison of the recommendations of interventions and information about the level of evidence, the degree of recommendation, the level of agreement and the level of acceptance will be described. This step will also be done independently and in duplicate, and the result will be decided by consensus. The results will be presented in tables and the descriptive statistics will be calculated for all domains of the AGREE II instrument as mean (standard deviation) and median (interquartile range).

RESULTS: The results derived from this study will increase the knowledge about the development of recommendations guidelines for urinary incontinence of high methodological rigor. This study may also identify key areas for future research.

CONCLUSION: This study may guide health professionals, policy makers and health policy managers in choosing the guidelines for recommendation in clinical practice.

PROTOCOL REGISTRATION: PROSPERO - CRD42018116517

Abbreviations: EMBASE = Excerpt Medical Database; AGREE = Appraisal of Guidelines for Research and Evaluation; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PROSPERO = International Prospective Register of Systematic Reviews.

Keywords: Urinary incontinence, Health planning guidelines, Systematic review.

1 INTRODUCTION

Urinary incontinence is a common complaint in all parts of the world, a cause of distress, as well as significant costs for individuals and for society [34]. It has been associated with significant physical morbidity, loss of independence, decreased quality of life and participation in social and domestic activities [35]. The classification of urinary incontinence varies according to the patient's symptoms. Urge incontinence is present when there is a report of involuntary leakage associated or immediately preceded by a sudden need for emptying without the ability to delay [36]. The involuntary effort leakage complaint performed on some type of activity is considered as stress urinary incontinence. When there is involuntary leakage associated with urgency and effort, urinary incontinence is classified as mixed [37].

The prevalence among types of urinary incontinence varies among countries. It is estimated that women are more affected than men, and between 10% and 55% with ages between 15 and 64 years are affected, with the highest prevalence of stress urinary incontinence [38]. The number of women with urinary incontinence tends to increase along life expectancy, especially in middle age, when cases become more prevalent [39].

The history of urinary incontinence is fundamental to the planning of the clinical process and should be the first step in the evaluation, informing details about the type, moment, severity and other symptoms, allowing the categorization of the disease [40]. Although history provides pertinent data on urinary incontinence, it is often the case that the diagnosis is not complete, since urinary symptoms may be similar, so physical examination is required as part of urogynecologic evaluation of the patient [41].

Treatment options for urinary incontinence may be surgical or conservative. In clinical practice, non-surgical therapies are the first line of treatment, including behavioral therapy with strategies for re-education of the bladder, training of pelvic muscle tone, biofeedback, electrical stimulation, vaginal cones, control of intake of caffeine and pharmacological treatment, varying according to each case or type of urinary incontinence [42–44]. Due to numerous options of treatments, many professional organizations have developed guidelines to help clinicians treat patients with urinary incontinence [45].

Guidelines are important vehicles of influence for clinical practice. Local, national and international societies adopt the process of identifying relevant clinical areas,

formulating specific clinical issues, reviewing applicable evidence, and formulating recommendations that doctors and their patients should follow [46].

To ensure reliability, clinical practice guidelines should be systematically developed by groups of people with skills, perspectives and knowledge based on the best available evidence [47]. With the elaboration of these documents, the concerns related to their quality increased [48–50].

The Appraisal of Guidelines for Research & Evaluation (AGREE II) Instrument aims to address the variability in the quality of clinical practice guidelines, that is, assesses the methodological rigor and transparency with which the guideline is developed. Developed by an international group, first published in 2003 and updated in 2009, AGREE II has been widely used, offering a comprehensive, rapid and consistent assessment of clinical practice guidelines [51].

No systematic review performed the critical appraisal on the development of clinical practice guidelines for the treatment of urinary incontinence. Success in implementing recommendations should be related to the use of appropriate methodologies and rigorous strategies in the guideline development process [52]. The present study will evaluate the rigor of the development of clinical practice guidelines and will identify, in these documents, the recommendations of interventions for urinary incontinence in adults.

2 METHODS

2.1 Protocol and registration

This study will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-P) [31]. The systematic review was register in the International Prospective Register of Systematic Reviews (PROSPERO) database (protocol number: PROSPERO - CRD42018116517), available in (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=116517). Ethical approval is not required because this is a literature-based study.

2.2 Study design

This systematic review of clinical practice guidelines for adult urinary incontinence interventions will be undertaken to assess the methodological quality in their development and the recommendations of the interventions, available in those documents.

2.3. Eligibility criteria

2.3.1 Inclusion criteria

Guidelines for clinical practice and consensus (if applicable) describing interventions for treatment of adults (age ≥18 years) with urgency, stress or mixed urinary incontinence, even if the document reports one or more types of incontinence, will be included. We will consider the documents published from 2009 onwards (date of publication of the latest version of AGREE II), and restricted to English, Portuguese, Spanish and French.

2.3.2 Exclusion criteria

Specific clinical practice guidelines for the treatment of urinary incontinence due to neurological or oncological traumas will be excluded. If there is another more up-to-date version of the guideline; the available version is incomplete or contains only a summary of the information; the document is the translation of a guideline published in another language; and if there is a consensus guideline, evidence summary or algorithm; will be excluded.

2.4. Measured outcomes

The methodological quality of clinical practice guidelines for interventions for urinary incontinence in adults will be evaluated; the scores of each domain associated with the methodological quality of the guidelines will be identified; and the recommendations provided by the guidelines will be described and compared.

2.5 Selection of studies

2.5.1 Search methods

The following electronic databases will be searched: MEDLINE (via Ovid); EMBASE (Excerpta Medical Database, via Ovid); Web of Science; and Scopus.

Specific databases for clinical guidelines will be searched, for example: ECRI Institute (www.guidelines.ecri.org) European Association of Urology (www.uroweb.org), NICE (www.nice.org.uk), American College of Physicians (www.acponline.org), American Urological Association (www.auanet.org), Brazilian Society of Urology (www.sbu-sp.org.br), Canadian Agency for Drugs and Technologies in Health (www.cadth.ca), Canadian Medical Association (www.cma.ca), and others.

2.5.2 Other Search Features

The reference list of eligible studies, review studies and secondary studies will be checked by reviewers in order to identify other possible guidelines. For guidelines published only in summary or where important information is missing, we will try to search complete information by contacting the authors.

2.5.3 Search strategies

The key words will be used according to the terms of the Medical Subject Headings (MeSH) to identify relevant studies. The isolated terms and their entry terms will be identified and will be crossed to perform the search, being adapted for each database. The terms used will be: (Guideline OR Guidelines OR Practice Guideline OR Health Planning Guidelines OR Health Planning Guidelines OR clinical practice guidelines OR best practice OR best practices) AND (Urinary Incontinence OR Incontinence, Urinary OR Urinary Incontinence Urge OR Urinary Reflex Incontinence OR Incontinence, Urinary Reflex OR Urinary Urge Incontinence Urinary Urge Incontinence OR Urge Incontinence OR Incontinence, Urge OR Urinary Incontinence, Stress OR Urinary Stress Incontinence OR Incontinence, Urinary Stress OR Stress Incontinence, Urinary OR Lower Urinary Tract Symptoms OR Female Urogenital Diseases OR Urologic Diseases OR Urination Disorders OR Urological Manifestations). The search strategy will be adapted to each database.

2.6 Determination of eligibility

Duplicates will be removed by one of the reviewers. Reviewers (LLM and APMVC, LGM and JPMVC, FBS and SB-F), in pairs and independently, will assess whether abstracts and titles meet the eligibility criteria.

The eligibility of the guidelines will be confirmed after reading the full text by the same reviewers and independently. Discrepancies will be solved by consensus and a third reviewer (CCB or LCL) will be able to assist in the final decision if necessary. In case of duplicate publication, the most up-to-date guideline will be used. All documents related to the guidelines (cited as supplemental documents, summaries of recommendations and others) will be searched manually by one or two reviewers.

2.7 Data extraction

The information will be added to an Excel® worksheet and the same reviewers, in pairs and independently, will be the extraction of the date. The discrepancies will be resolved by consensus. If cannot be resolved through discussion, will be referred to a third reviewer (CCB or LCL). Previously, the reviewers will be calibrated by extracting at least three documents of different levels of quality and will reach consensus. The results will be discussed with another reviewer, previously trained. This procedure should occur until the reviewers are able to extract the data.

The following data will be extracted: number of authors, year of publication, update time, organizations (government, medical society, university or other), type of guideline (formulated, adapted, updated or revised), country of development, type (diagnosis, prevention, pharmacological and non-pharmacological treatment, and/or other), type of urinary incontinence, treatments described, target population, design of studies included (systematic review, consensus, overview of systematic reviews, and/or other), methods of recommendation formulation (consensus, not mentioned, others) and methods of classifying the quality of evidence (GRADE, Oxford, not mentioned, or other).

2.8 Quality assessment of clinical practice guidelines

The quality of each guideline will be evaluated using the Appraisal of Guidelines for Research and Evaluation - AGREE II. The translated and validated version of AGREE II for the Portuguese language (Brazil) will be used. The tool consists of twenty-three items covering six quality domains, scored with a Likert scale of 1 (totally disagree) to 7 (totally agree) for each. The six areas are: a) scope and objective, b) involvement of stakeholders, c) rigor of development, d) clarity of presentation, e) applicability and f) editorial independence[13]. The same pairs of reviewers will conduct the quality assessment of the

guidelines and the difference of two or more scores for each item will be considered as discrepant. The final score will be decided by consensus and if there is no consensus, another reviewer will help in the final decision.

The quality of each guideline will be calculated for each domain, according to the AGREE II User Manual. The six domains are independents and the scores should therefore be calculated as the sum of the individual items in each domain. Then, the total obtained will be presented as a relation percentage to the maximum possible score for each domain. The evaluation will be conducted using the "My AGREE PLUS" platform. Previously, a training will be done to use the AGREE II instrument according to the following steps: a) study the AGREE II User Manual, the AGREE II validation article in Brazil and a guideline to choose; b) register on the "My AGREE PLUS" platform and complete the AGREE II Training Tools (https://www.agreetrust.org); c) calibration of the reviewers as previously described.

2.9 Description and comparison of the recommendations of the interventions

The study will describe and compare the recommendations of intervention: pharmacological, conservative (such as behavioral therapy with strategies for re-education of the bladder, training of pelvic muscle tone, biofeedback, electrical stimulation, vaginal cones and others) and/or surgical using selected guidelines, respecting the particularities of the treatment of these diseases.

For the recommendations of the description and comparison of the intervention, the level of evidence supporting them will be found. The information will be collected in relation to this level of evidence, the degree of recommendation, the level of agreement and the level of acceptance.

This step will also be done in duplicate and independently by all reviewers. The information will be verified and, if there is no consensus, another reviewer will assist in the final decision.

2.10 Data synthesis

The results will be presented in descriptive tables. Descriptive statistics will be calculated for all AGREE II domains as mean (standard deviation) and median

(interquartile range). Graphs will be plotted when needed. The level of significance will be 5%. Statistical analysis will be conducted using the STATA software (version 14.2).

3 DISCUSSION

This study will identify guidelines of high-quality clinical practice describing interventions for urinary incontinence or the possible flaws observed in these articles. The results observed may guide the development of recommendations guidelines for urinary incontinence of high methodological rigor. Success in implementing recommendations should be related to the use of appropriate methodologies and rigorous strategies in the guideline development process.

A description of the available recommendations on interventions and evidence supporting them contributes to the choice of treatment for urinary incontinence in adults. Thus, the results of this study can subsidize patients, health institutions, health policy makers, choose higher quality guidelines, inform on the existing recommendations of the different interventions and identify gaps in current evidence and make recommendations for future research.

The method of this review includes explicit eligibility criteria, comprehensive and extensive database research, independent and paired evaluation for study selection. Nevertheless, the fact of the present study will be limited to subjective analysis of the AGREE II instrument may be a limiting factor.

The results of the research can be submitted for publication in scientific journals of high impact, peer reviewed and also published in national and international conferences.

Author contributions

FBS is the principal investigator and led the writing of the manuscript. CCB is the project managers and coinvestigators and contributed to the writing and revision of the manuscript. LCL, SB-F, JPMVC, APMVC, LLM, LGM are coinvestigators and contributed to the writing and revision of the manuscript. All authors read and approved the final manuscript.

Conceptualization: Cristiane de Cássia Bergamaschi, Flávia Blaseck Sorrilha
Methodology: Cristiane de Cássia Bergamaschi, Flávia Blaseck, Luciane Cruz Lopes e Silvio Barberato-Filho.
Project administration: Cristiane de Cássia Bergamaschi.
Writing – review & editing: Flávia Blaseck Sorrilha, Cristiane de Cássia Bergamaschi, Lauren Giustti Mazzei, Luciane Cruz Lopes, Silvio Barberato-Filho, Juliana Pedroso Moraes Vilela Castro, Analaura Pedroso Moraes Vilelade Castro, Lívia Luize Marengo
Writing – original draft: Flávia Blaseck Sorrilha, Cristiane de Cássia Bergamaschi

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Conflict of interest: The authors have no conflicts of interest to disclose.

5.2 Artigo 2

Full-title: Critical appraisal of clinical practice guidelines for treatment of urinary incontinence: systematic review

Authors: Flávia Blaseck Sorrilha Msc[a], Lauren Giustti Mazzei Msc[a], Luciane Cruz Lopes PhD[a], Silvio Barberato-Filho PhD[a], Juliana Pedroso Moraes Vilela Castro PhD[a], Analaura Pedroso Moraes Vilela de Castro BS[a], Claudia Marcela Vélez PhD[b], Cristiane de Cássia Bergamaschi PhD[a*]

Author affiliations

[a]Graduate Program in Pharmaceutical Sciences, University of Sorocaba, Sorocaba, São Paulo, Brazil

[b]University of Antioquia, Medellin, Antioquia, Colômbia

∗**Corresponding author:**

Cristiane de Cássia Bergamaschi

E-mail: cristiane.motta@prof.uniso.br

Universidade de Sorocaba (UNISO)

Rodovia Raposo Tavares, Km 92.5, Sorocaba, São Paulo, 18.023-000, Brazil

Phone/Fax: 55 15 2101 7104

ABSTRACT

OBJECTIVES This systematic review evaluated the rigor of the development of clinical practice guidelines (CPG) and described the interventions for urinary incontinence (UI) in women.

METHODS The searched sources were MEDLINE (via Ovid); Excerpt Medical Database (EMBASE, via Ovid); Web of Science, Scopus and specific databases of CPG (National Institute for Health and Care Excellence, American Urological Association, and others). Reviewers, organized in triplicate and independently, selected the studies and assessed the quality of the guidelines using the Appraisal of Guidelines Research and Evaluation (AGREE II), instrument which contains 6 domains for classification. The classification of the CPG prioritized the domain 3 (developmental rigor) considering: high (score>60%), moderate (score 30-60%) or low quality (score<30%). The results were checked for discrepancies and decided by consensus. The interventions have been described. The results were presented by descriptive statistics.

RESULTS Of the 9 CPG evaluated, 5 were of high methodological quality, 2 were of moderate quality and 2 were of low quality. Three documents not recommended for use. The domains with the highest scores were scope and purpose (mean=91.4%) and clarity of presentation (mean=89.5%). The domains of editorial independence (mean=52.2%) and applicability (mean=36.8%) were those with the lowest score. The most citeds interventions in CPGs were the non-pharmacological, such as lifestyle interventions (n=8), bladder training or re-education (n=8) and pelvic floor muscle training (n=8).

CONCLUSION Most guidelines showed high rigor in development, however, editorial independence and applicability were domains that need to be improved in these documents. Conservative interventions are the most reported by the guidelines. These findings can guide in choose of guidelines for treatment of urinary incontinence.

Keywords: Urinary incontinence, Clinical practice guidelines, Systematic review.

1 INTRODUCTION

Urinary incontinence is a common complaint in all parts of the world, a cause of distress, as well as significant costs for individuals and for society [40]. It has been associated with significant physical morbidity, loss of independence, decreased quality of life and participation in social and domestic activities [41].

The classification of urinary incontinence varies according to the patient's symptoms. Urge incontinence is present when there is a report of involuntary leakage associated or immediately preceded by a sudden need for emptying without the ability to delay [53]. The involuntary effort leakage complaint performed on some type of activity is considered as stress urinary incontinence. When there is involuntary leakage associated with urgency and effort, urinary incontinence is classified as mixed [43].

It is estimated that urinary incontinence affect more women than men and between 10% and 55%, with ages between 15 and 64 years; and the highest prevalence of stress urinary incontinence [43]. The number of women with the disease tends to increase along life expectancy, especially in middle age, when cases become more prevalent [5].

Treatment options for urinary incontinence may be conservative or surgical. Non-surgical therapies (surgical) are the first line of treatment, including behavioral therapy with strategies for re-education of the bladder, training of pelvic muscle tone, biofeedback, electrical stimulation, vaginal cones, control of intake of caffeine and pharmacological treatment, varying according to each case or type of urinary incontinence [44,46,47]. Due to numerous options of treatments, many professional organizations have developed guidelines to help clinicians treat patients with urinary incontinence.

Clinical practice guidelines (CPG) are documents that include recommendations for optimizing patient care and are based on systematic review and the assessment of the benefits and harms of different health care options. To ensure reliability, these documents should be systematically developed by groups of people with skills, perspectives and knowledge based on the best available evidence [49]. With the elaboration of these documents, the concerns related to their quality increased [49,50,54].

The Appraisal of Guidelines for Research & Evaluation (AGREE II) Instrument addresses the variability in the quality of guidelines, that is, assesses the methodological rigor and transparency with which the document is developed. Created by an international

group, first published in 2003 and updated in 2009, AGREE II has been widely used [35]. The instrument consists of 23 items and is divided into six domains: scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence.

Success in implementing recommendations should be related to the use of appropriate methodologies and rigorous strategies in the guideline development process [52]. In the literature searched, no systematic review performed the critical appraisal on the development of CPG for the treatment of urinary incontinence. Then, this study evaluated the rigor of the development of guidelines and will identify, in these documents, the recommendations of interventions for urinary incontinence in women.

2 METHODS

2.1 Protocol and registration

This study was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [55]. The systematic review was register in the International Prospective Register of Systematic Reviews (PROSPERO) database (protocol number: PROSPERO - CRD42018116517) - Appendix 1.

2.2 Study design

This systematic review of CPG for treatment of urinary incontinence in women assessed the methodological quality in their development and the recommendations of the interventions, available in those documents.

2.3 Eligibility criteria

Inclusion criteria

CPGs and consensus (if applicable) describing interventions for treatment of women (age ≥ 18 years) with urgency, stress or mixed urinary incontinence, even if the document reports one or more types of incontinence, were included. We considered the documents published from 2009 onwards (date of publication of the latest version of AGREE II), and restricted to English, Portuguese, Spanish and French.

Exclusion criteria

Specific CPG for the treatment of urinary incontinence due to neurological or oncological traumas were excluded. If there is another more up-to-date version of the guideline; the available version was incomplete or contained only a summary of the information; the document was the translation of a guideline published in another language; and if there was a consensus guideline, evidence summary or algorithm; they were excluded.

2.4 Measured outcomes

The methodological quality of CPG for interventions for urinary incontinence in women was evaluated; the scores of each domain associated with the methodological quality of the guidelines were identified; and the recommendations provided by the guidelines will be described and compared.

2.5 Selection of studies

Search methods

The following electronic databases were searched: MEDLINE (via Ovid), EMBASE (Excerpta Medical Database, via Ovid), Web of Science and Scopus.

Specific databases for clinical guidelines were searched: ECRI Institute (www.guidelines.ecri.org) European Association of Urology (www.uroweb.org), NICE (www.nice.org.uk), American College of Physicians (www.acponline.org), American Urological Association (www.auanet.org), Brazilian Society of Urology (www.sbu-sp.org.br), Canadian Agency for Drugs and Technologies in Health (www.cadth.ca), Canadian Medical Association (www.cma.ca), Agency for Healthcare Research and Quality (www.guidelines.gov), The Scottish Intercollegiate Guidelines Network (www.sign.ac.uk), Guidelines in Practice (www.guidelinesinpractice.co.uk), Guidelines International Network (www.g-i-n.net), Chilean Ministry of Health (www.gob.cl), Institute for Clinical Systems Improvement (www.icsi.org), Colombian Ministry of Health and Social Protection (www.minsalud.gov.co), GuíaSalud Portal (guiasalud.es).

Other search features

The reference list of eligible studies, review studies and secondary studies were checked by reviewers in order to identify other possible guidelines. For guidelines

published only in summary or where important information is missing, we tried to search complete information by contacting the authors.

Search strategies

The key words were selected according to the terms of the Medical Subject Headings (MeSH) to identify relevant studies. The isolated terms and their entry terms were identified and crossed to perform the search, being adapted for each database. The search strategy was adapted to each database and is available in Appendix 2.

Determination of eligibility

Duplicates were removed by one of the reviewers (FBS). Reviewers (LLM and APMVC, LGM and JPMVC, FBS and SBF), in pairs and independently, assessed whether abstracts and titles were eligible. The eligibility of the guidelines was confirmed after reading the full text by the same reviewers and independently. Discrepancies were solved by consensus and a third reviewer (CCB or LCL) assisted in the final decision, if necessary. In case of duplicate publication, the most up-to-date guideline was used. All documents related to the guidelines (cited as supplemental documents, summaries of recommendations and others) were searched manually by one or two reviewers.

Data extraction

The information was added to an Excel® worksheet and the same reviewers, in pairs and independently, extracted the date. The discrepancies were resolved by consensus and a third reviewer (CCB or LCL) assisted in the final decision, if necessary. Previously, the reviewers were calibrated by extracting at least three documents of different levels of quality and reached consensus. The results were discussed with another reviewer, previously trained. This procedure should occur until the reviewers were able to extract the data.

The following data were extracted: number of authors, year of publication, organizations (government, medical society, university or other), country of development, type of urinary incontinence, type (diagnosis, prevention, pharmacological and non-pharmacological treatment, and/or other), treatments described, target population,

methods of recommendation formulation (consensus, not mentioned, others) and methods of classifying the quality of evidence (GRADE, Oxford, not mentioned).

2.6 Quality assessment of clinical practice guidelines

Instrument

The quality of each guideline was evaluated using the Appraisal of Guidelines for Research and Evaluation - AGREE II. The tool consists of twenty-three items covering six quality domains, scored with a Likert scale of 1 (totally disagree) to 7 (totally agree) for each. The six areas are: a) scope and objective, b) involvement of stakeholders, c) rigor of development, d) clarity of presentation, e) applicability and f) editorial independence.

Training

Previously, the reviewers (APMVC, CCB, FBS, JPMVC, LCL, LGM and SBF) conducted the training on the use of the AGREE II instrument, according to the following steps: a) study the AGREE II User Manual, the AGREE II Validation Article in Brazil and a guideline to be chosen; b) register on the "My AGREE PLUS" platform and complete the AGREE II Training Tools (https://www.agreetrust.org); and c) calibration of reviewers, as previously described.

Evaluation

The same reviewers, in triplicate and independently, assessed the CPGs through the use of the AGREE II instrument, in the six domains for classification. The evaluation was performed using the "My AGREE PLUS" platform and the total obtained was presented as a percentage of relationship with the maximum possible score for each domain. The scores for each item were checked for discrepancies. For discrepancies >2 points, the final result decided by consensus of the evaluators.

There is no validated method for guideline quality rating as the AGREE II instrument does not define minimum domain scores or cross-domain scoring standards to differentiate between high and low quality guidelines [52].

This study adopted the overall guidelines quality metric used by Molino *et a*l. [56] (Chart 1). The domain 3 has been prioritized to classify overall quality as it assesses methodological rigor during the development of CPG. To differentiate the quality of the

guidelines from other domain scores, the classification used was high (score>60%), moderate (score 30-60%) or low quality (score<30%) which still considered levels from A to C, according to the score of the other domains.

In addition to the twenty-three items that make up the assessment, the instrument provides two general assessments in which the evaluators say they would recommend the CPG using the same scale of 1 to 7 points. However, this information is a subjective analyses [57].

Chart 1 - Quality of clinical practice guidelines according to domain scores base in domains

Rigor of development score (domain 3)		
High (>60%)	***Moderate (30-60%)***	***Low (<30%)***
High A (in 2 other domains with score >60%)	**Moderate A** (in 2 other domains with score >60%)	**Low A** (in 2 other domains with score >60%)
High B (in 2 other domains with score 30-60%)	**Moderate B** (in 2 other domains with score 30-60%)	**Low B** (in 2 other domains with score 30-60%)
High C (in 2 other domains with score <30%)	**Moderate C** (in 2 other domains with score <30%)	**Low C** (in 2 other domains with score <30%)

2.7 Description and comparison of the recommendations of the interventions

The study described the interventions informed by the guidelines in categories: conservative treatments (with pharmacological and non-pharmacological options) and non-conservative treatments (surgical options).

Subsequently, information will be collected regarding the level of evidence, the degree of recommendation, the level of agreement and the level of acceptance. This step will also be carried out in duplicate and independently by all reviewers. The information will be verified and, if there is no consensus, another reviewer will assist in the final decision.

2.8 Data synthesis

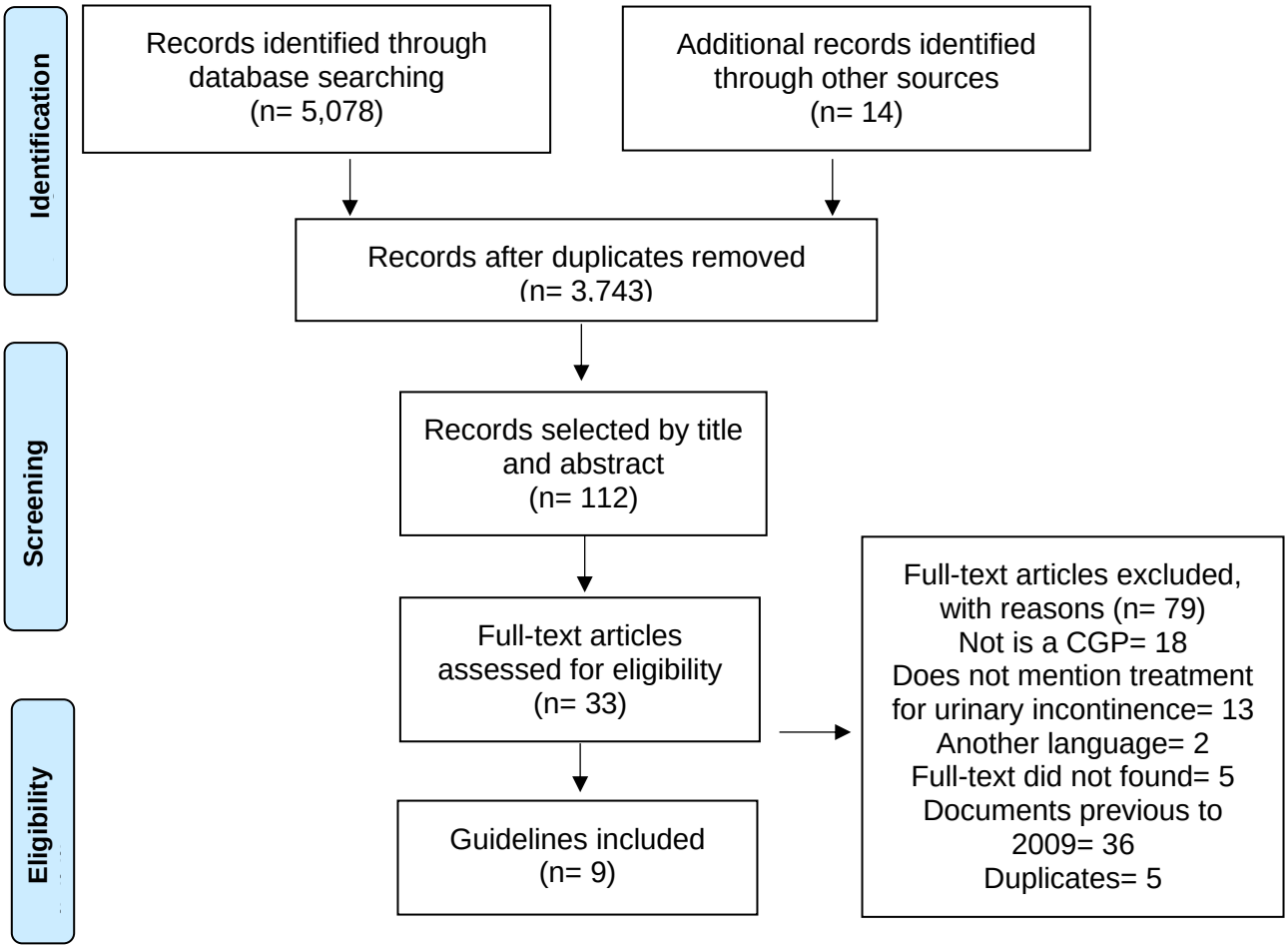
The results were presented by descriptive statistics and calculated for all domains of the instrument, following the AGREE II User Manual.

The scores for each domain were calculated separately, and refer to the maximum percentage obtained by the guidelines.

3 RESULTS

The search strategy retrieved 5,078 records, of which 33 were considered for full-text screening. Nine met eligibility criteria and were evaluated using AGREE II (Figure 1).

Figure 1 - **Flowchart for literature search and study selection**



Nine CPG were evaluated in total, most of them published between 2015 and 2019: American College of Physicians (ACP), Brazilian Medical Association (AMB), American Urological Association (AUA), French College of Gynecologists and Obstetricians (CNGOF), Cortesse, European Associate of Urology (EAU), National Institute for Health and Care Excellence (NICE), World Health Organization (WHO) and Society of Obstetricians and Gynecologists of Canada (SOGC).

The target population of adult women portraying the three types of urinary incontinence. The origin of the documents was distributed between countries in North America, South America and mainly Europe, organized mostly by medical associations or societies and which did not report external funding. The treatments reported in most documents covered both conservative and non-conservative types and described pharmacological and non-pharmacological options (Table 1).

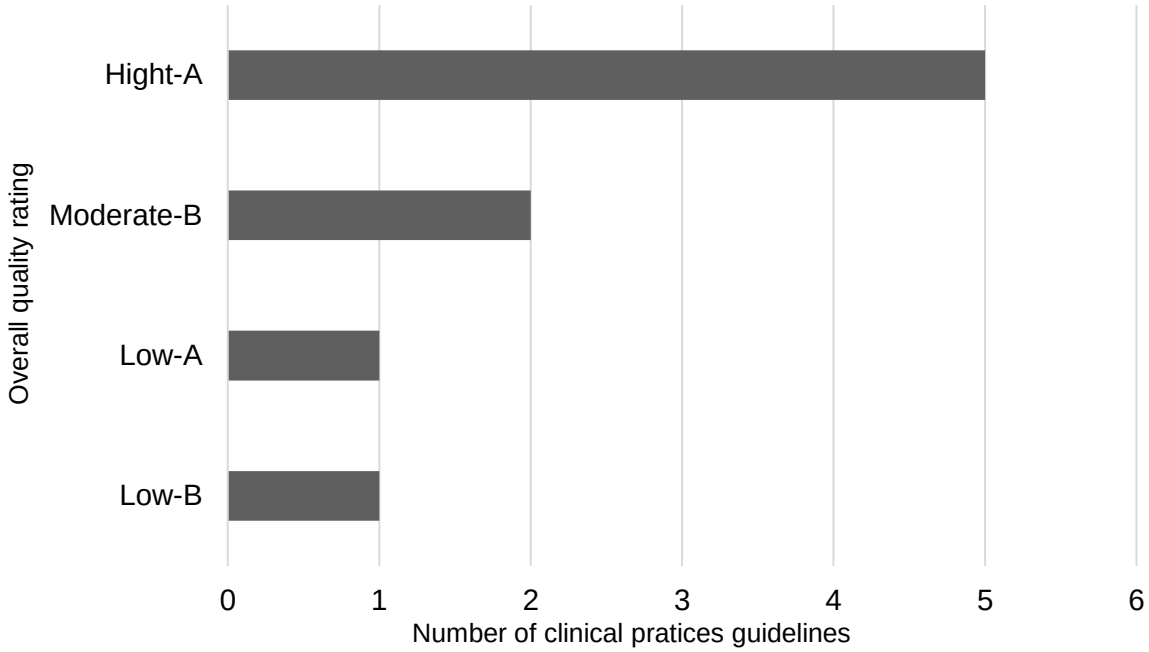
Table 1 - Characteristics of clinical practice guidelines included (n= 9)

CPG	Number of authors	Guidelines developer	Country/ continent	External financing	Population	Gender	Types of UI
ACP, 2014	6	medical associations/ societies	USA	No	adults and ederly	female	SUI, UUI, MUI
AMB, 2014	15	medical associations/ societies	Brazil	No	adults	female	SUI
AUA, 2017	19	medical associations/ societies	USA	No	adults and ederly	female	SUI, UUI, MUI
Cortesse, 2016	5	NR	France	No	adults	female	SUI
CNGOF, 2010	16	medical associations/ societies	France	No	adults and ederly	female	SUI, UUI, MUI
EAU, 2019	12	medical associations/ societies	Europe	No	adults and ederly	female and male	SUI, UUI, MUI
NICE, 2019	24	govern	UK	No	adults and ederly	female	SUI, UUI, MUI
SOGC, 2017	14	medical associations/ societies	Canada	No	adults and ederly	female	SUI, UUI, MUI
WHO, 2017	22	govern	UK	yes	adults and ederly	female and male	SUI, UUI, MUI

Note: ACP: American College of Physicians; AMB: Brazilian Medical Association; AUA: American Urological Association; CNGOF: French College of Gynecologists and Obstetricians; EAU: European Associate of Urology; NICE: National Institute for Health and Care Excellence; SOGC: Society of Obstetricians and Gynecologists of Canada; WHO: World Health Organization; UK: United Kingdom; USA: united States of America; UI: urinary incontinence; SUI: stress urinary incontinence; UUI: urgency urinary incontinence; MUI: mixed urinary incontinence.

The methodological quality score of the nine evaluated CGP were calculated, five (56%) classified as high quality (A), two (22%) as moderate quality (B), and two (22%) as low quality (A and B) (Figure 2).

Figure 2 - Classification of clinical practice guidelines according to domain scores



The overall classification of CPG ranged from 33.0% to 100.0%, with an average of 68.1%. “Scope and purpose” and “clarity and presentation” domains received the highest scores, average of 91.4% and 89.5%, respectively.

Most CPG were recommended without modification (4 out of 6 CPG recommended). The applicability of the domains (average=36.7%) and editorial independence (average=52.2%) were those that obtained the lowest score among the evaluated documents, in addition to having greater divergence between the documents, since some of them do not describe these topics while others scored high. Three CPG were not recommended for use: French College of Gynecologists and Obstetricians (CNGOF), Society of Obstetricians and Gynecologists of Canada (SOGC) and Cortesse, 2016. (Table 2)

Table 2 - Quality scores (%) of included clinical practice guidelines using AGREE II

	Domain 1: Scope and purpose	**Domain 2:** Stakeholder involvement	**Domain 3:** Rigor of development	**Domain 4:** Clarity of presentation	**Domain 5:** Applicability	**Domain 6:** Editorial independence	**Overall guideline assessment** Classification	Recommendation
ACP, 2014	100.0	74.1	95.8	100.0	19.4	100.0	83.3	Yes
AMB, 2014	88.9	53.7	58.3	96.3	13.9	0.0	58.0	Yes with modification
AUA, 2017	96.3	67.0	83.3	100.0	52.8	58.3	77.8	Yes with modification
Cortesse, 2016	55.6	33.3	22.2	68.5	0.0	30.6	33.0	No
EAU, 2019	98.1	61.1	92.4	98.1	65.3	63.9	83.3	Yes
CNGOF, 2010	90.7	50.0	56.9	51.9	12.5	25.0	44.4	No
NICE, 2019	100.0	100.0	100.0	100.0	100.0	94.4	94.4	Yes
SOGC, 2017	92.6	64.8	14.6	90.7	0.0	0.0	38.9	No
WHO, 2017	100.0	100.0	97.9	100.0	95.8	97.2	100.0	Yes
Average ± SD	90.3 ± 14.6	67.1 ± 22.0	69.1 ± 32.9	88.2 ± 18.1	40.0 ± 37.3	52.2 ± 40.2	68.1 ± 25.0	-

SD: standard deviation; ACP: American College of Physicians; AMB: Brazilian Medical Association; AUA: American Urological Association; CNGOF: French College of Gynecologists and Obstetricians; EAU: European Associate of Urology; NICE: National Institute for Health and Care Excellence; WHO: World Health Organization; SOGC: Society of Obstetricians and Gynecologists of Canada.

Description of domains (Figures 3 to 11)

Domain 1: Scope and purpose

Eight CPG evaluated obtained high scores (88.9 to 100.0%) for this domain. Only one document obtained a low score (55.6%), whose main reason was that the population was not specifically described, including inclusion and exclusion criteria.

Domain 2: Stakeholder involvement

Only three CPG scored above 60% and the average score was lower for domain 1 (item 5 - sought to know the opinions and preferences of the target population: patients, public, etc.?). This item scored the lowest among the other CPG, with unclear descriptions of how the views and preferences of the target population were considered.

Domain 3: Rigor of development

Five CPG had high scores in this domain (83.3 to 100.0%). Two CPG had moderate scores (58.3 and 56.9%) and the other two low scores (22.2 and 14.6%). Among the documents with moderate scores in this domain, the items with the lowest scores are related to the lack of detail in the strategy adopted, to search for evidence and the lack of information about the external review process prior to publication and the document update procedure.

Domain 4: Clarity of presentation

Eight CPG received high scores for this domain (68.5 to 100%). The CPG that received the moderate evaluation (51.9%) was due to the fact that the recommendations do not gain prominence in the text, nor are they arranged in tables or presented in flow charts.

Domain 5: Applicability

This domain had the lowest average score (40.0%), with high variations (0 to 95.8%). Five CPG scored low for this domain (0 to 19.4%), as they did not have an implementation section, nor tools and resources to facilitate implementation (summary documents, checklists and algorithms, links to step-by-step manuals) Nor did they mention criteria for monitoring the implementation of the recommendations and the CPG impact assessment was not provided.

Domain 6: Editorial independence

The evaluation of this domain was the one with the highest variability among the CPGs (0 to 100%), with the second lowest mean among the scores (52.2%). Three CPG received low ratings because they did not provide an explicit statement about

funding body and influence on the content of the guideline and often lacked information on potential conflicts of interest from members of the development group.

Figure 3 - Domain scores of American College of Physicians

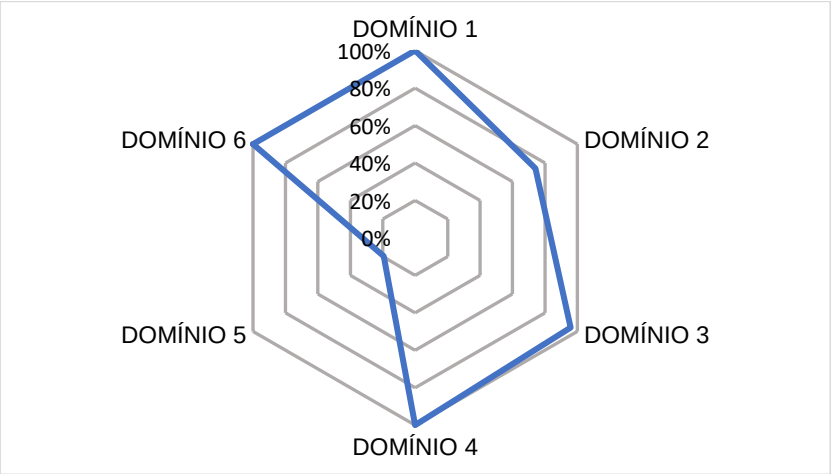


Figure 4 - Domain scores of Brazilian Medical Association

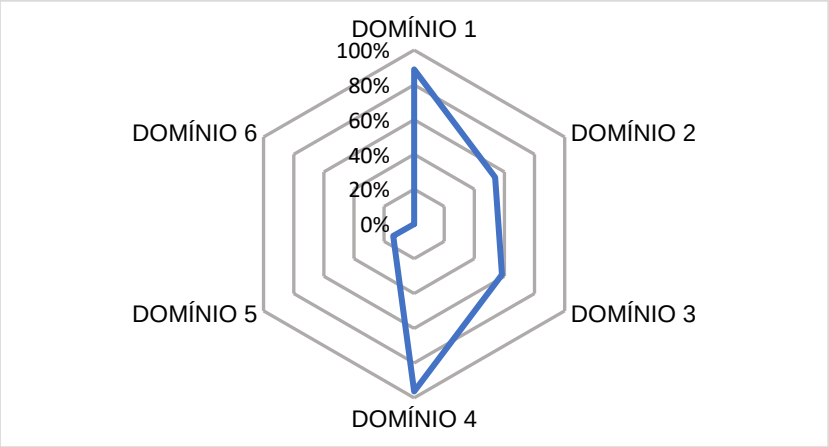


Figure 5 - Domain scores of American Urological Association

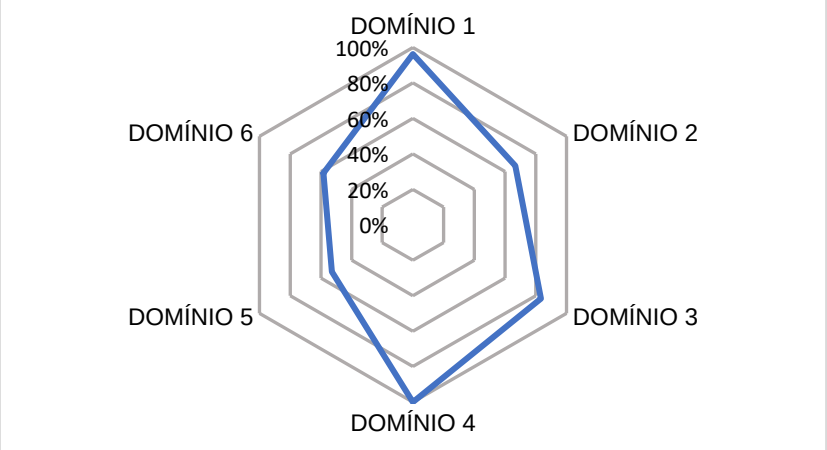


Figure 6 - Domain scores of Cortesse

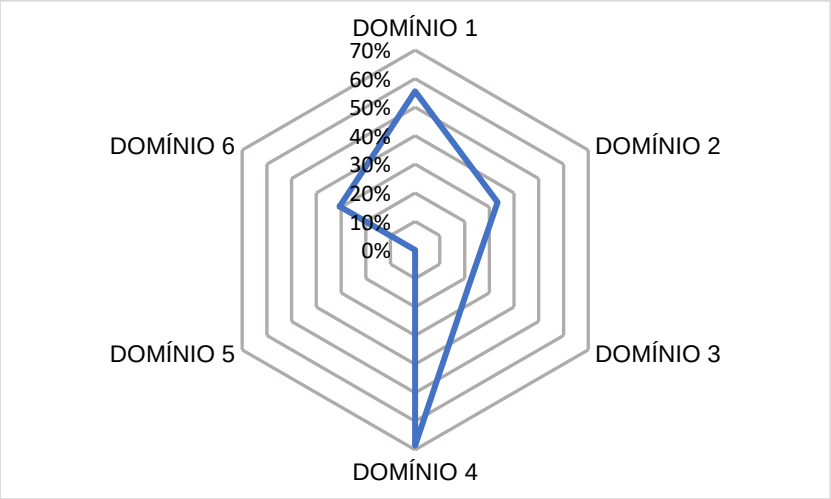


Figure 7 - Domain scores of European Associate of Urology

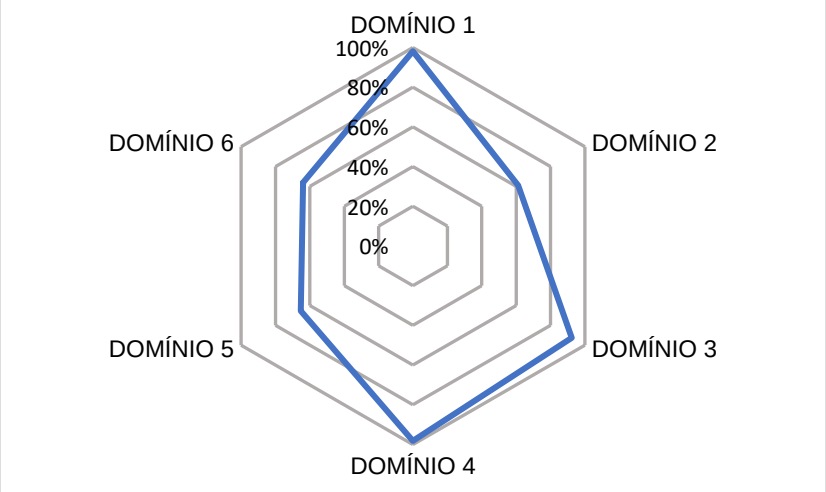


Figure 8 - Domain scores of French College of Gynecologists and Obstetricians

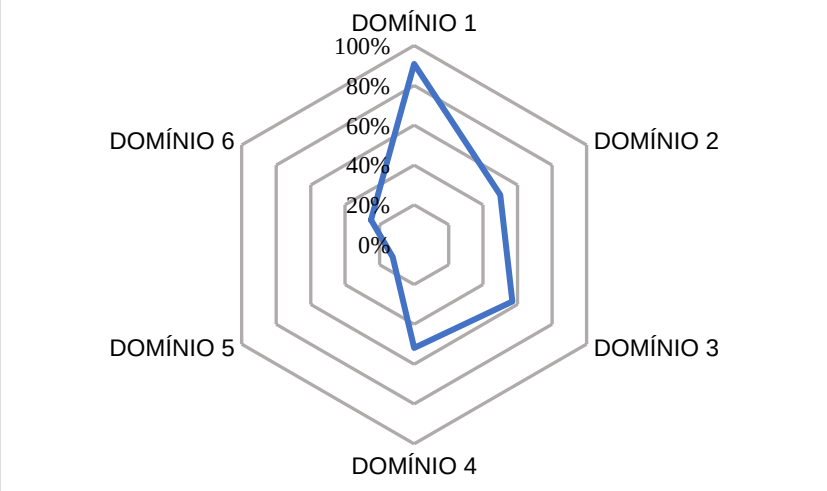


Figure 9 - Domain scores of National Institute for Health and Care Excellence

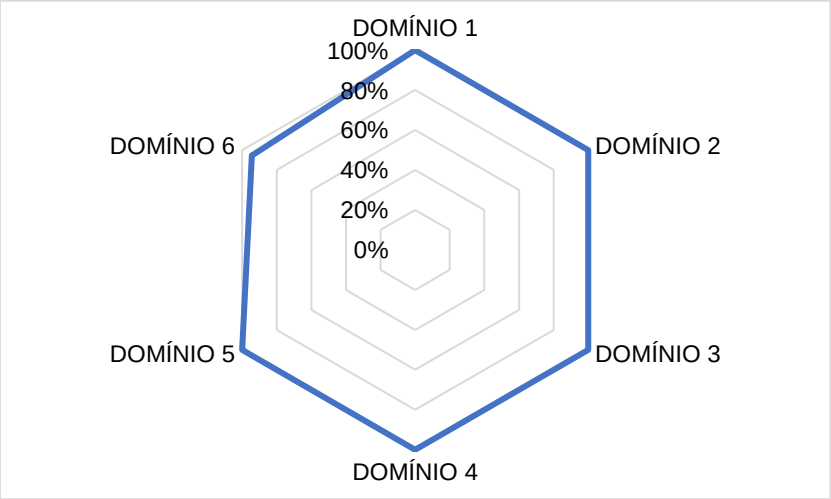


Figure 10 - Domain scores of SOGC

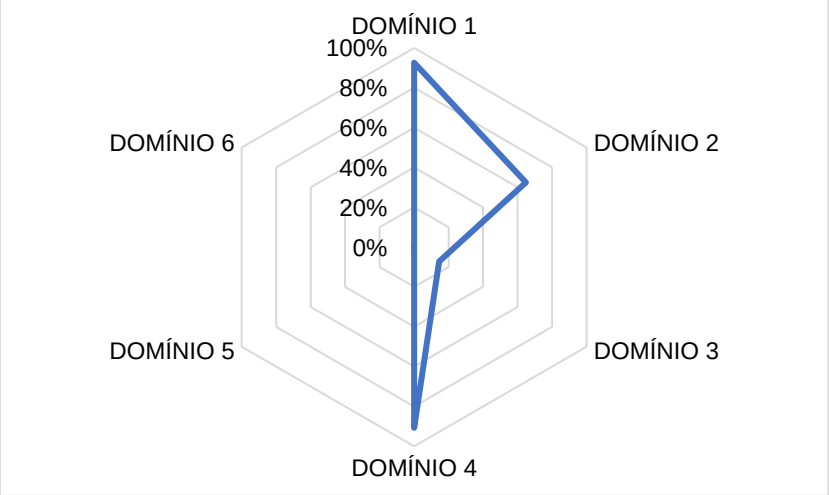


Figure 11 - Domain scores of World Health Organization

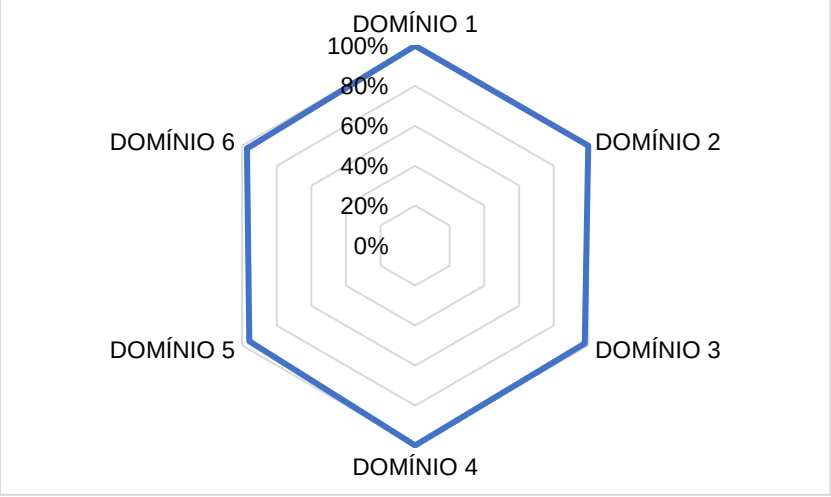


Table 3 aimed to describe the interventions reported by the guidelines, without, however, taking into account the recommendation for use. It most of them reported both conservative and non-conservative treatments, with a greater number of options for non-pharmacological treatments. The main non-pharmacological treatments reported were lifestyle interventions (n=8 guidelines), bladder training or re-education (n=8) and pelvic floor muscle training (n=8). Estrogen (n=4) and duoloxetine (n=4) were the drugs most cited among the CPG.

One CPG was restricted to describing only non-pharmacological interventions (WHO, 2017). The WHO guideline was the subject of the scope question, the non-pharmacological interventions and their interventions aimed at the elderly population. The document Cortesse (2016) reported only non-conservative interventions, but aimed to treat stress urinary incontinence related to pelvic organ prolapse.

The most cited surgical interventions were sling implantation and colposuspension (n=7), while sacral nerve, peri-urethral injection and adjustable compression device interventions were cited in only one study.

Table 3. Description of the types of treatments provided by the clinical practice guidelines

Clinical Pratice Guidelines	ACP, 2014	AMB, 2014	AUA, 2017	Cortesse, 2016	CNGOF, 2010	EAU, 2019	NICE, 2019	WHO, 2017	SOGC, 2017
Type of UI reported	1,2,3	1	1,2,3	1	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3
Conservative treatments									
Non-pharmacological treatments									
Bladder training or re-education	●	●	●		●	●	●	●	●
Catheter						●	●		●
Complementary therapies	●								
Containment products			●			●	●		●
Control of fluid intake		●				●	●		
Electro-stimulation	●	●			●	●	●		●
Pelvic floor muscle training	●	●	●		●	●	●	●	●
Treatment of comorbidities		●				●	●		
Obesity control	●	●			●	●	●		
Physical exercises	●				●	●	●		●
Reduced caffeine		●				●	●		●
Smoking control						●	●		●
Pharmacological treatments									
Alphablockers									NR
Anticolinergics/antimuscarinic									NR
Oxybutynin	●				●		●		
Propiverine	●								
Solifenacin	●								
Tolterodine	●								
Trospium	●								
Darifenacin	●								
Fesoterodine	●								
Beta 3-Adrenoceptor agonists	●					●			NR
Solabegron	●								
Mirabegron	●					●			

Hormone								
Estrogen (oral)	●				●	●	●	
Estriol (intravaginal)	●				●		●	
Other muscle relaxants								
Desmopressim					●	●	●	
Duloxetine	●				●	●	●	
Baclofen								●
Botulinum Toxin A							●	
Non conservative treatments								
Surgical treatment								
Adjustable compression device						●		
Artificial urinary sphincter				●		●		
Colposuspension		●	●	●	●	●	●	●
Cystplasty						●	●	
External compression devices			●			●		
Peri-urethral injection						●		
Sacral nerve						●		
Sling		●	●	●	●	●	●	●

UI: urinary incontinence; 1: stress urinary incontinence; 2: urgency urinary incontinence; 3: mixed urinary incontinence; ACP: American College of Physicians; AMB: Brazilian Medical Association; AUA: American Urological Association; CNGOF: French College of Gynaecologists and Obstetricians; EAU: European Associate of Urology; NICE: National Institute for Health and Care Excellence; WHO: World Health Organization; SOGC: Society of Obstetricians and Gynaecologists of Canada. NR: not reported (specified the class, but not the drugs).

4 DISCUSSION

Summary of main results and comparison of findings with the literature

Considering the importance of CPG as propagators of recommendations on health care, this study evaluated the quality of 9 documents, published in the last 10 years, about urinary incontinence, mainly those aimed at the adult female population. The documents were developed mainly in Europe, by medical associations or societies, without external funding. Four of 6 CPG were recommended without modification [45,58–60] and one third were not recommended for use according to overall guideline assessment [61–63].

In general, domains 1 “scope and objective” and 4 “clarity and presentation” received the highest scores, received the highest scores, demonstrating that most documents are in accordance with the population studied, as well, with the recommendations for proper use of interventions. Then, the guidelines provided a concrete and accurate description of which option is appropriate in the situation and population group, as reported by the body of evidence.

Most of the guidelines were also concerned with domain 3 “rigor of development”, which was prioritized to classify the quality of documents, considering the importance of a clear description of the methods used to formulate the recommendations. The guidelines should describe details about systematics methods for search of evidences, information about the external review process and the procedure for updating documents [35]. In some cases, searches for additional documents were necessary, as the strategies were described in separate documents or in an appendix to the guideline.

In view of this pre-established criterion for domain 3, five CPG were classified of high quality [45,58,60,64,65]**.** The most deficient items in this area refer to the search strategy, the methods of formulating the recommendations, how the final decisions were made and the procedure for updating the guideline.

The domain 5 “applicability” and domain 6 “editorial independence” were the ones with the lowest score among the evaluated documents. Five CPG scored low quality for “applicability” as they did not have an implementation section or tools and resources to facilitate implementation. They too didn’t mention the criteria for monitoring the implementation of the recommendations and the impact assessment

these documents. Three CPG received scored low quality for “editorial independence” domain because they did not provide an explicit statement about funding body and influence on the content of the guideline and/or lacked information on potential conflicts of interest from members of the development group.

The “applicability” domain can be improved to encourage members who develop guidelines to reflect on possible barriers to implementing recommendations. CPG must present a synthesis of the evidence, but also translate scientific knowledge for application in clinical practice and in health systems [66].

The interference of the editorial board can also influence the development process of guidelines. The conflict of interest can be minimized, if considered to be of little relevance, by making a record during the drafting and publication process. A clear statement about the editorial decision process that indicates a lack of influence from the guidelines developers would also increase confidence them [52,67].

The heterogeneity between the scores for domains can be observed in the CPG not recommended. Cortesse et al. (2016) [63] presented a low score (<60%) for most domains, except for “clarity of presentation”. SOGC (2017) [62] presented problems mainly with the domains “rigor of development”, “applicability” and “editorial independence” and CNGOF (2010) [61] mainly with the domains “applicability” and “editorial independence”.

In the search carried out, we did not find a systematic review similar to ours. A protocol was published in 2019 aiming at a critical evaluation of the CPG for the diagnosis and treatment of urinary incontinence [68]. Although there is similarity in the studied disease, this protocol only intends to include studies for stress urinary incontinence, published in English and Chinese languages.

Another systematic review used the same assessment tool (AGREE II) to critically assess the development of these CPG in non-neurogenic overactive bladder and urinary incontinence [69]. This study included the NICE guideline [59] which also got better in all domains, with the highest scores, being the “clarity of the presentation” (97%) and the “editorial independence” (95%), in addition to the recommendation of use by all reviewers, result similar to the present study.

The EAU CPG was too evaluated in systematic review [45] and followed with the best performance in the “clarity of the presentation” (97%) and “scope and objective” (87%). These results also coincide with the assessment made in our study, in which we obtained 98.1% in both domains. It is worth mentioning that the CPG included in

the above-mentioned, are older versions than those included in this study; however, the updates of these documents did not change the methodological issues of their development.

Regarding the description of treatments for urinary incontinence, it was observed that most CPGs included conservative options, mainly non-pharmacological treatment, in their recommendations. The most mentioned options were lifestyle interventions, bladder training or re-education and training of the pelvic floor muscles.

It has been found that lifestyle interventions, behavioural treatment, pelvic physiotherapy (pelvic floor muscle training, electro stimulation, biofeedback) or devices for containment and leakage are generally the treatments most prescribed initially, in the treatment of urinary incontinence [59,60,70,71]. In view of the information collected, it was observed that conservative therapies are the first line of treatment, as they present the least risk of damage.

The importance of considering these types of treatments can be seen in a systematic review of randomized or quasi-randomized clinical trials in women with stress, urgent or mixed urinary incontinence. The review included 31 trials involving 1,817 women from 14 countries [72]. Most clinical trials recommended attempting conservative treatment before invasive therapy.

If the first-line of treatment lifestyle, behavioural and physical therapies are ineffective in treating of urinary incontinences, a variety of pharmacological agents will be available, depending on the specific symptoms of the incontinence [73]. The most common pharmacological options are oral estrogen, duloxetine, desmopressin and antimuscarinics.

Systematic review that included 98 individual studies evaluating 150 interventions (conservative and non-conservative) observed that patients with urinary incontinence who were treated with antimuscarinics, had an average cure rate of 49%, depending on the medication used [74]. However, these drugs can cause a number of side effects, such as dry mouth, gastrointestinal disorders, including constipation and flatulence, taste disorders, blurred vision, dry eyes, drowsiness, dizziness, fatigue, difficulty urinating, palpitations and skin reactions [75–78]. In view of the information collected, it is convenient to state that conservative therapies are the first line of treatment, as they present the least risk of harm [46].

For non-conservative interventions, surgical options for implantation of colposuspension and sling are the most cited options among CPG. Retropubic

colposuspension surgery, considered the gold standard in the treatment of this condition for decades, gave way to slings, described in 1996, showing a very satisfactory result [79].

Although the impact of the vast majority of incontinence conditions is predominantly social, when not treated properly, severe conditions such as renal failure, recurrent urinary tract infection and the need for bladder reconstruction surgery may be necessary.

The development and implementation of CPG in low and middle-income countries can be challenging for their health systems due to difficulties in applying evidence from other countries that may be inappropriate for local contexts, including disease epidemiology, patient needs, resources variables or restrictions in health budgets.

Health managers and professionals may face difficulties in ensuring that the recommendations are applied due to possible shortages of resources to optimize economic results and improve the lives of patients living with morbidity.

Another difficulty faced by these countries is the limited resources for conducting research and developing guidelines for clinical practice that explore local issues. To fill this gap, they end up adopting guidelines from other countries, which may reflect recommendations that are not applicable to different health systems and are inappropriate for local implementation.

The treatment of urinary incontinence will depend on the type and severity, in addition to the underlying causes, and there may often be a need for a combination of interdisciplinary approaches.

Strengths and limitations of study

The fact of the present study to be limited to subjective analysis of the AGREE II instrument may be considered. Although all reviewers have received full training in this rating system and are familiar with the AGREE II user manual, this score can result in different interpretations by them. These differences were minimized through consensus, which consisted of discussing the items considered to be outliers and reaching an agreement with the smallest possible difference.

According to the AGREE user manual, documents must be independently evaluated by at least two and ideally, four reviewers. This study included the evaluation of three reviewers, who examined the CPG independently, after calibration. The

training and content allows users backgrounds to understand and use the AGREE II tool.

The calibration was carried out with the evaluation of three different CPG, in addition to the discussion for each discrepancy between the reviewers. This training process allowed the evaluators to understand and become familiar with the instrument, minimizing possible mistakes in the interpretation of the process.

It is important to note that the method of this review includes explicit eligibility criteria, a comprehensive and extensive database search and specific sites have been undertaken. The selection of studies was carried out in pairs, independently and the full texts were carefully checked so that we were sure that it was a CPG. The evaluation of CGPs quality which makes the study an important exploratory survey, as it pointed out high-quality documents eligible and pointed out flaws in the elaboration.

Generalization of the findings regarding the implications for clinical practices and research, their perspectives and recommendations

The potential benefits of CPG are as important as the quality of their development [35]. Consequently, the use of methodologies for the design process is essential to create reliable recommendations for its users. Success in implementing recommendations should be related to the use of appropriate methodologies and rigorous strategies in the guideline development process.

This study identified high-quality CPG that can subsidize patients, health institutions, health policy makers for the treatment of urinary incontinence in women; as well contribute to the development of high-quality guidelines, identifying the flaws observed in these documents; and inform on existing recommendations for different interventions. It does not correspond to a complete analysis of each CPG, but it summarizes some of the similarities and differences in its development.

The guidelines described conservative (pharmacological and non-pharmacological) and surgical interventions for urinary incontinence, demonstrating that non-pharmacological interventions are the first choice for the treatment of urinary incontinence. This review of guidelines also highlighted the existing agreement between treatments and although, it is satisfactory for the target population to know that these documents reach the same conclusions.

Evidence-based CPG may indicate interventions that offer the greatest benefit and least chance of harm to health, and may also generate greater efficiency in the

allocation of resources. If the evidence is limited, this does not necessarily imply that there is no role for intervention in question, but a recommendation cannot be made based on the available evidence.

This finding of this study can guide health professionals and health policy managers in choosing guidelines for treatment of urinary incontinence in women, contribute to the development of high-quality guidelines, and inform about existing recommendations from different interventions.

This is the first study to assess the quality of the methodology used for the development of CPGs for the treatment of urinary incontinence. We believe that it can help healthcare professionals in their decisions, based on the quality of the documents and in the search for better care for their patients. It can also serve as a valuable resource for the development of high-quality CPGs and public health policies related to urinary incontinence in women.

5 CONCLUSION

Most of the guidelines had high rigor of development, however, editorial independence and applicability were items that need to be improved in these documents. This finding can guide health professionals and health policy managers in choosing guidelines for treatment of urinary incontinence in women, contribute to the development of high-quality guidelines, and inform about existing recommendations from different interventions.

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Conflict of interest The authors have no conflicts of interest to disclose.

6 CONSIDERAÇÕES FINAIS

Embora o impacto da maioria dos quadros de incontinência urinária seja predominantemente social, quando não tratada adequadamente, esta condição pode gerar quadros graves como insuficiência renal, infecção urinária de repetição e necessidade de cirurgia da reconstrução da bexiga podem ser necessárias. Desta forma, verifica-se a importância de haver documentos de qualidade que orientem para o tratamento desta condição.

Os CPG são documentos informativos que incluem recomendações dirigidas a otimizar o cuidado prestado ao paciente. Devem ser construídos com base em estudos de revisão sistemática das evidências científicas que orientam sobre os benefícios e danos de diferentes opções/intervenções no cuidado à saúde.

Conhecer a qualidade metodológica dos diretrizes pode garantir o uso de informação adequada. O presente estudo sumarizou semelhanças e diferenças no desenvolvimento de CPG para o tratamento da incontinência urinária em mulheres. Os achados demonstraram que a maioria dos CPG apresentou alto rigor de desenvolvimento e domínios como “independência editorial” e “aplicabilidade” necessitam ser aprimorados nesses documentos.

O tratamento da incontinência urinária dependerá do tipo e da gravidade, além das causas subjacentes, podendo muitas vezes, haver necessidade de combinar abordagens interdisciplinares. Observou-se que o tratamento de primeira linha inclui mudanças de estilo de vida e comportamentais, bem como treinamento de força do assoalho pélvico e treinamento da bexiga. A terapia medicamentosa é útil no tratamento de incontinência que não responde a outras terapias não farmacológicas. As opções não conservadoras se fazem necessárias quando não há resposta adequada aos tratamentos ou em casos mais graves.

De posse destes achados, os profissionais de saúde e gestores de políticas de saúde podem se orientar para a escolha de diretrizes para o tratamento da incontinência urinária em mulheres. Além disso, o estudo demonstra em quais domínios estes documentos podem ser melhorados, a fim de desenvolver diretrizes de alta qualidade.

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APÊNDICE 1: REGISTRO PROSPERO

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PROSPERO
International prospective register of systematic reviews

Methodological quality and transparency of clinical practice guidelines for the non-pharmacological to urinary incontinence: systematic review

Flavia Sorrilha

Citation

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Review question

Which are the methodological quality and the transparency of clinical practice guidelines for the non-pharmacological to urinary incontinence?

Searches

The articles will be identified by searching the following bibliographic databases: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Excerpta Medica Database (EMBASE), Web of Science and Virtual Health Library, without language restrictions and status of publication. Databases specific to clinical guidelines will be searched: Australian Clinical Practice Guidelines (clinicalguidelines.gov.au), European Association of Urology (www.uroweb.org), National Institute for Health and Care Excellence (www.nice.org.uk), Guidelines International Network (g-i-n.net), National Guideline Clearinghouse (guidelines.gov), American Urological Association (www.auanet.org), Brazilian Society of Urology (www.sbu-sp.org.br), Ministry of Health of Brazil (saude.gov.br), Canadian Agency for Drugs and Technologies in Health (cadth.ca), Canadian Medical Association (cma.ca), Chilean Ministry of Health (bibliotecaminsal.cl/guias-clinicas-auge/), Colombian Ministry of Health and Social Protection (http://gpc.minsalud.gov.co/gpc/SitePages/default_gpc.aspx), Institute for Clinical Systems Improvement (icsi.org), Portal GuíaSalud (guiasalud.es), Scottish Intercollegiate Guidelines Network (sign.ac.uk).

The search strategy will be comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings) and keywords. Guidelines will be identified too by searching by reviewing the bibliographies of key papers. For guidelines published only in summary or where important information is missing, we will seek complete information by contacting the authors.

Types of study to be included

Clinical practice guidelines

Condition or domain being studied

Urinary incontinence

Participants/population

Should have been specified by the guideline as adult women (age ? 18 years) with stress urinary incontinence, urgency or mixed, independent if the document reports one or more types of incontinence.

Intervention(s), exposure(s)

Non-pharmacological interventions for urinary incontinence in adult women.

Comparator(s)/control

Not applicable.

Context

Primary health care services (e.g. outpatient clinics).

Main outcome(s)

The methodological quality and transparency of the clinical guidelines of non-pharmacological interventions for urinary incontinence; and the identification of the scores of each domain associated with the methodological quality of the guidelines.

Additional outcome(s)
The description and comparison of the recommendations provided by the guidelines according to the type of disease.

Data extraction (selection and coding)
The reviewers, working in pairs, will independently extract the data, using standardized and pretested data extraction forms with accompanying instructions. Disagreements will be resolved by consensus, and if there is no consensus, a third reviewer may assist in the final decision. Previously, the reviewers will be calibrated by extracting at least three documents, and then they will reach consensus. This procedure should occur until the reviewers are able to extract the data.

Risk of bias (quality) assessment
The quality of each guideline will be evaluated using the Appraisal of Guidelines for Research and Evaluation (AGREE II), which is a tool of twenty-three items and covers six quality domains, namely: a) scope and objective, b) stakeholder involvement, c) rigor of development, d) clarity of presentation, e) applicability and f) editorial independence. Two reviewers will conduct the quality assessment of the guidelines and the difference of two or more scores for each item will be considered as discrepant. The final score will be decided by consensus and if there is no consensus, another reviewer will help in the final decision.

Strategy for data synthesis
The results will be presented in descriptive tables. Descriptive statistics will be calculated for all AGREE II domains as mean (standard deviation) and median (interquartile range). Graphs will be plotted when needed. The level of significance will be 5%. Statistical analysis will be conducted using STATA (version 14.2software).

Analysis of subgroups or subsets
Not applicable.

Contact details for further information
Flávia Sorrilha
flaviablaseck@gmail.com

Organisational affiliation of the review
Universidade de Sorocaba
www.uniso.br

Review team members and their organisational affiliations
Ms Flavia Sorrilha. Universidade de Sorocaba

Collaborators
Dr Cristiane Bergamaschi. Universidade de Sorocaba

Type and method of review
Systematic review

Anticipated or actual start date
13 July 2018

Anticipated completion date
01 April 2020

Funding sources/sponsors
None

Conflicts of interest

Language
English, Portuguese-Brazil

APÊNDICE 2: ESTRATÉGIA DE BUSCAS NAS BASES DE DADOS

As estratégias de buscas foram aplicadas nas seguintes bases de dados: MEDLINE (Ovid); Cochrane Library (Central Register of Controlled Trials – CENTRAL); EMBASE (Excerpta Medical Database, Ovid); Web of Science e Scopus.

Quadro 4 - Estratégia de busca utilizada na Medline (27/09/18)

1 Guideline.mp. or exp GUIDELINE/	(97217)
2 Guidelines.mp.	(357737)
3 Practice Guideline.mp. or exp Practice Guideline/	(28046)
4 Health Planning Guidelines.mp. or exp Health Planning Guidelines/	(4026)
5 clinical practice guidelines.mp.	(10073)
6 Practice Guideline Care.mp.	(1)
7 best practice.mp.	(11213)
8 best practices.mp.	(10105)
9 Urinary Incontinence.mp. or exp Urinary Incontinence/	(37715)
10 Incontinence, Urinary.mp.	(199)
11 Urinary Incontinence, Urge.mp. or exp Urinary Incontinence, Urge/	(858)
12 Urinary Reflex Incontinence.mp.	(0)
13 Incontinence, Urinary Reflex.mp.	(0)
14 Urinary Urge Incontinence.mp.	(145)
15 Urge Incontinence.mp.	(2401)
16 Incontinence, Urge.mp.	(910)
17 Urinary Incontinence, Stress.mp. or exp Urinary Incontinence, Stress/	(10663)
18 Urinary Stress Incontinence.mp.	(1163)
19 Incontinence, Urinary Stress.mp.	(2)
20 Stress Incontinence, Urinary.mp.	(10)
21 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	(419087)
22 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20	(38492)
23 21 and 22	**(989)**

Quadro 5 - Estratégia de busca utilizada na EMBASE (27/09/18)

1 Guideline.mp. or exp practice guideline/	(505095)
2 Guidelines.mp. or exp practice guideline/	(715465)
3 Practice Guideline.mp.	(352907)
4 Health Planning Guidelines.mp.	(55)
5 clinical practice guidelines.mp.	(13909)
6 best practice.mp.	(17773)
7 best practices.mp.	(13932)
8 1 or 2 or 3 or 4 or 5 or 6 or 7	(762521)
9 Urinary Incontinence.mp. or exp urine incontinence/	(72035)
10 Incontinence, Urinary.mp.	(380)
11 Urinary Incontinence, Urge.mp. or exp urge incontinence/	(6411)
12 Urinary Reflex Incontinence.mp.	(1)
13 Incontinence, Urinary Reflex.mp.	(0)
14 Urinary Urge Incontinence.mp.	(272)
15 Urge Incontinence.mp.	(7592)
16 Incontinence, Urge.mp.	(217)
17 Urinary Incontinence, Stress.mp. or exp stress incontinence/	(20800)
18 Urinary Stress Incontinence.mp.	(1632)
19 Incontinence, Urinary Stress.mp.	(2)
20 Stress Incontinence, Urinary.mp.	(16)
21 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20	(72508)
22 8 and 21	**(2735)**

Quadro 6 - Estratégia de busca utilizada na Web of Science (27/09/18)

#1 TÓPICO: (Guideline) OR TÓPICO: (practice guideline) OR TÓPICO: (Guidelines) OR TÓPICO: (Health Planning Guidelines) OR TÓPICO: (clinical practice guidelines) OR TÓPICO: (best practice) OR TÓPICO: (best practices) (632.621)
#2 TÓPICO: (Urinary Incontinence) OR TÓPICO: (urine incontinence) OR TÓPICO: (Incontinence, Urinary) OR TÓPICO: (Urinary Incontinence, Urge) OR TÓPICO: (urge incontinence) OR TÓPICO: (Urinary Reflex Incontinence) OR TÓPICO: (Incontinence, Urinary Reflex) OR TÓPICO: (Urinary Urge Incontinence) OR TÓPICO: (Urge Incontinence) OR TÓPICO: (Incontinence, Urge) OR TÓPICO: (Urinary Incontinence, Stress) OR TÓPICO: (stress incontinence) OR TÓPICO: (Urinary Stress Incontinence) OR TÓPICO: (Urinary Stress Incontinence) OR TÓPICO: (Stress Incontinence, Urinary) (34.493)
#3 #2 AND #1 **(1.222)**

Quadro 7 - Estratégia de busca utilizada na Cochrane (27/09/18)

#1 Guideline	(11700)
#2 practice guideline	(9199)
#3 Guidelines	(25370)
#4 Health Planning Guidelines	(1062)
#5 clinical practice guidelines	(12031)
#6 best practice	(8091)
#7 best practices	(1795)
#8 #1 or #2 or #3 or #4 or #5 or #6 or #7	(34306)
#9 Urinary Incontinence	(5405)
#10 urine incontinence	(2035)
#11 Incontinence, Urinary	(5405)
#12 Urinary Incontinence, Urge	(848)
#13 urge incontinence	(1004)
#14 Urinary Reflex Incontinence	(84)
#15 Incontinence, Urinary Reflex	(84)
#16 Urinary Urge Incontinence	(848)
#17 Urge Incontinence	(1004)
#18 Incontinence, Urge	(1004)
#19 Urinary Incontinence, Stress	(2237)

#20 stress incontinence	(2548)
#21 Urinary Stress Incontinence	(2237)
#22 Incontinence, Urinary Stress	(2237)
#23 Stress Incontinence, Urinary	(2237)
#24 #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23	(6102)
#25 #8 and #24	**(375)**

Quadro 8 - Estratégia de busca utilizada na Scopus (27/09/2018)

(TITLE-ABS-KEY (guideline) OR TITLE-ABS-KEY (practice AND guideline) OR TITLE-ABS-KEY (guidelines) OR TITLE-ABS-KEY (health AND planning AND guidelines) OR TITLE-ABS-KEY (clinical AND practice AND guidelines) OR TITLE-ABS-KEY (best AND practice) OR TITLE-ABS-KEY (best AND practices) AND TITLE-ABS-KEY (urinary AND incontinence) OR TITLE-ABS-KEY (urine AND incontinence) OR TITLE-ABS-KEY (incontinence, AND urinary) OR TITLE-ABS-KEY (urinary AND incontinence, AND urge) OR TITLE-ABS-KEY (urge AND incontinence) OR TITLE-ABS-KEY (urinary AND reflex AND incontinence) OR TITLE-ABS-KEY (incontinence, AND urinary AND reflex) OR TITLE-ABS-KEY (urinary AND urge AND incontinence) OR TITLE-ABS-KEY (urge AND incontinence) OR TITLE-ABS-KEY (incontinence, AND urge) OR TITLE-ABS-KEY (urinary AND incontinence, AND stress) OR TITLE-ABS-KEY (stress AND incontinence) OR TITLE-ABS-KEY (urinary AND stress AND incontinence) OR TITLE-ABS-KEY (incontinence, AND urinary AND stress) OR TITLE-ABS-KEY (stress AND incontinence, AND urinary)) **(2,567)**

ANEXO A: ORIENTAÇÕES PARA APRESENTAÇÃO DE TESES DO PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS FARMACÊUTICAS DA UNIVERSIDADE DE SOROCABA

As dissertações/teses do Programa de Pós-Graduação em Ciências Farmacêuticas da Universidade de Sorocaba (PPGCF-Uniso) poderão ser apresentadas em dois formatos: o tradicional ou em formato de artigo(s) científico(s).

Os trabalhos de investigação que possam resultar em patentes poderão ser apresentados na forma convencional, a critério do grupo de pesquisadores envolvidos, reservadas as particularidades exigidas em relação ao sigilo.

O formato tradicional segue o padrão descrito nas normas do “Manual para normalização de trabalhos acadêmicos” da Universidade de Sorocaba.

As dissertações entregues no formato de artigo científico têm como exigência a publicação ou, no mínimo, a submissão prévia de pelo menos um artigo em revista científica com classificação mínima Qualis/Capes B2 (de acordo com a categorização da WebQualis mais recente, na data do envio/publicação) e podem ser inseridos no idioma e na formatação estabelecida pelo(s) respectivo(s) periódico(s). Os demais artigos podem não ter sido submetidos ainda.

As teses entregues no formato de artigo científico têm como exigência a publicação ou, no mínimo, a submissão prévia de pelo menos dois artigos em revista científica com classificação mínima Qualis/Capes B2 (de acordo com a categorização da WebQualis mais recente, na data do envio/publicação) e podem ser inseridos no idioma e na formatação estabelecida pelo(s) respectivo(s) periódico(s). Os demais artigos podem não ter sido submetidos ainda.

Para aclarar membros da banca que desconhecem esta versão alternativa da dissertação/tese recomenda-se anexar este documento no final das versões encaminhadas aos membros da banca.

A dissertação/tese no formato de artigo(s) científico(s) deverá possuir os elementos apresentados no Quadro 1.

Elementos textuais	1. Introdução ou apresentação: trata-se da parte inicial do texto com formulação clara e simples do tema investigado, constando a delimitação do assunto tratado, sua relevância e justificativa.
	2. Revisão de literatura: quando a revisão de literatura for concebida como artigo de revisão, este item deverá ser incluído no item resultado(s).
	3. Objetivos: geral e específico
	4. Material e Métodos (opcional). Quando parte dos resultados não for apresentada no formato de artigo, este item deverá ser incluído após os objetivos específicos. Quando o autor quiser apresentar o(s) método(s) de forma mais detalhada do que no artigo, este item pode também ser apresentado em separado.
	5. Resultados (pode ser apresentado no formato de artigos): deve(m) ser inserida(s) a(s) cópia(s) de artigo(s) derivado(s) da dissertação, previamente publicados, submetidos ou não para publicação em revistas científicas. Sugere-se que cada artigo seja antecedido de uma breve apresentação seguida dos elementos de identificação do artigo (autores, título, revista de publicação, volume, páginas). Os artigos anexados poderão ser apresentados nos formatos exigidos pelas revistas, as quais os artigos foram publicados e/ou submetidos. Parte dos resultados pode ser apresentada em separado dos artigos, quando conveniente.
	6. Discussão (opcional): O autor pode ampliar a discussão dos resultados, quando conveniente.
	7. Conclusão ou Considerações finais: esta parte deverá conter a conclusão do trabalho ou as considerações do autor sobre os resultados alcançados frente aos objetivos propostos.
Elementos pós-textuais	8. Referências: Devem seguir as normas do “Manual para normalização de trabalhos acadêmicos” da Universidade de Sorocaba. Não devem ser inseridas as referências apresentadas nos artigos.
	9. Apêndices (Opcional)
	10. Anexos (Opcional)

ANEXO B: DECLARAÇÃO DE POTENCIAIS CONFLITOS DE INTERESSE

Autores:
Flávia Blaseck Sorrilha
Cristiane De Cassia Bergamaschi Motta

1. Você já aceitou de uma instituição, que pode se beneficiar ou se prejudicar financeiramente, algum dos benefícios abaixo?

a) Reembolso por comparecimento a eventos na área de sua pesquisa

Não / Não

b) Honorários por apresentação, consultoria, palestra ou atividades de ensino

Não / Não

c) Financiamento para redação de artigos ou editorias

Não / Não

d) Suporte para realização ou desenvolvimento de pesquisa na área

Não / Não

e) Recursos ou apoio financeiro para membro da equipe

Não / Não

f) Algum outro benefício financeiro

Não / Não

2. Você possui apólices ou ações de alguma empresa que possa de alguma forma ser beneficiada ou prejudicada?

Não / Não

3. Você possui algum direito de propriedade intelectual (patentes, registros de marca, royalties)?

Não / Não

4. Você já atuou como perito judicial?

Não / Não

5. Você participa, direta ou indiretamente, de algum grupo citado abaixo cujos interesses possam ser afetados pela sua atividade?

a) Instituição privada com ou sem fins lucrativos

Não / Não

b) Organização governamental ou não-governamental

Não / Não

c) Produtor, distribuidor ou detentor de registro

Não / Não

d) Partido político

Não / Não

e) Comitê, sociedade ou grupo de trabalho

Não / Não

f) Outro grupo de interesse

Não / Não

6. Você poderia ter algum tipo de benefício clínico?

Não / Não

7. Você possui uma ligação ou rivalidade acadêmica com alguém cujos interesses possam ser afetados?

Não / Não

8. Você possui profunda convicção pessoal ou religiosa que pode comprometer o que você irá escrever e que deveria ser do conhecimento público?

Não / Não

9. Existe algum aspecto do seu histórico profissional, que não esteja relacionado acima, que possa afetar sua objetividade ou imparcialidade?

Não / Não

10. Sua família ou pessoas que mantenha relações próximas possui alguns dos conflitos listados acima?

Não / Não

Confirmamos que todas as informações declaradas são verdadeiras e completas. Comprometemo-nos a informar se houver qualquer mudança em algumas das questões desta declaração que possa influenciar o interesse durante o desenvolvimento das atividades do Programa de Pós-Graduação em Ciências Farmacêuticas – Nível Mestrado da Universidade de Sorocaba.

Sorocaba, 18 de Fevereiro de 2020.

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Profa. Dra. Cristiane de Cássia Bergamaschi Motta
Orientadora - Universidade de Sorocaba (UNISO)

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Flávia Blaseck Sorrilha
Estudante de Pós-Graduação em Ciências Farmacêuticas - curso de Mestrado
Universidade de Sorocaba (UNISO)