Comparing patient-reported outcome measures for pain in women with pelvic floor disorders pre- and post-surgical management: A systematic review protocol

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Research Article

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Abstract

Background: Pelvic floor disorders including stress urinary incontinence and/or pelvic organ prolapse affect more than 50% of Australian women. Pelvic floor disorders cause a wide range of symptoms including painful urination, constipation and lower back pain. Previous surgical treatment may also affect the presence of pelvic symptoms, including pelvic pain, vaginal pain and dyspareunia which can lead to poor health-related quality of life. Patient-reported outcome measures are an important way of examining the health-related quality of life of women with pelvic floor disorders pre- and post-surgery, however, there are very few patient-reported outcome measures measuring this important domain of pelvic or vaginal pain. This paper aims to identify and compare patient-reported outcome measures for pain in women with a pelvic floor disorder in the existing literature, as well as to explore and highlight the gaps regarding the development and validation of a pain instrument. This review also aims to describe the modes and methods for administration of the instruments.

Methods: This review will be conducted based on the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols guideline and checklist. Ovid MEDLINE, Ovid Embase, CINAHL Plus and Ovid PsychInfo databases as well as the grey literature will be searched for studies that use, develop or implement patient-reported outcome measures for pain as an HRQoL outcome in adult women with a pelvic floor disorder pre- and post-surgery. Studies reporting on the psychometric properties of patient-reported outcome measures will be included. An independent researcher will screen the title and abstracts of the studies. Two independent researchers will undertake full-text review and any disagreements will be resolved through discussion and consensus. The final selected studies will undergo data extraction, qualitative analysis and synthesis.

Discussion: The findings of this review will assist with the development and validation of new pain-specific patient-reported outcome measures for women with pelvic floor disorder in the registry or clinical practice.

Trial registration: CRD42022319663

Introduction

Pelvic floor disorders (PFDs) involve the dysfunction of musculo-fascial support to pelvic organs that traverse the pelvic floor leading to complications [1]. These complications include pelvic organ prolapse (POP) and stress urinary incontinence (SUI). POP is the downward displacement of the pelvic organs accompanied by displacement of the vaginal wall that internally covers those organs [2, 3] SUI is, the involuntary loss of urine during physical activities [4]. Up to 50% of women in Australia experience SUI and 9% are symptomatic for POP [5], with a 20% lifetime risk of needing a pelvic floor reconstructive procedure [6]. It is expected that there will be a 34% increase in the number of women who experience PFDs by 2030 [7].

Most women with PFDs are recommended to have conservative treatments (i.e. pelvic floor exercises), however, such treatment may not be effective or provide insufficient relief to patients due to the patient's poor adherence to the treatment and barriers including difficulty accessing pelvic floor physiotherapists, motivation, cultural beliefs, stigma, lack of self-care and lack of patient-centred physio programs [8]. These may be some of the reasons why so many women go on to have surgery. In Australia, since 1998, around 25% of pelvic floor reconstructive procedures involve using a mesh product, with approximately 150,000 mesh devices implanted [7]. Procedural failure to control POP or SUI is an inherent risk of these pelvic floor surgical procedures. Adverse events including chronic pelvic pain, erosion of the mesh into the vagina, and post-surgery pain are not rare which can lead to poor health-related quality of life (HRQoL) outcomes [9, 10].

Australasian Pelvic Floor Procedure Registry

Clinical quality registries aim to systematically monitor the quality of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information [11, 12]. The Australasian Pelvic Floor Procedure Registry (APFPR) was developed in 2019 to monitor the safety and quality of care for PFD surgical procedures that involve POP and SUI using an opt-out approach for patient reporting [13]. APFPR has been established to address this need and captures several patient-reported outcomes. Literature reviews to date have not identified a suitable PROM measuring pain as an HRQoL outcome.

The APFPR does not have a PROM that measures pain as an HRQoL outcome. Given the population-level data that will be collected by the APFPR, the addition of a pain PROM will be important in understanding the quality of life of women who undergo surgery for their PFDs, to identify the surgical devices and procedures that produce the best holistic outcomes for women. Furthermore, a pain PROM for the registry will be vital in providing an additional patient perspective of their condition pre- and post-surgery.

Rationale

PROMs are an essential method for examining the HRQoL of women with PFDs by capturing women's perceptions of their health [14]. There are several generic and condition-specific PROMs with specific domains that have been developed to measure HRQoL, however, these PROMs do not focus on pelvic or vaginal pain, which is important in identifying pain in women with a PFD [15]. There is yet to be an instrument that specifically covers domains such as location, duration, and the onset or sensation of pain among women who have had surgical treatment for their PFD [16].

Materials and methods

This systematic review protocol has been developed as per the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guideline/checklist (supplementary material 1) [17]. A detailed description of the population, intervention, comparison and outcome of the systematic review is outlined in Table 1. The protocol was registered in the Prospective Register of Ongoing Systematic

Reviews (PROSPERO) (registration number: CRD42022319663). Any amendments to the protocol will be submitted to PROSPERO to establish a record of any changes and will be reported in the final published systematic review.

Table 1
Population, intervention, comparison, and outcome (PICO) of systematic review

Population	**Adult women (aged 18 years and above) with a PFD (i.e. POP, SUI) pre- and post-surgery or symptoms related to previous surgical treatment of these conditions)**
Intervention(s)	PROMs measuring pain in PFD patients
Comparison	Not applicable
Outcome(s)	PROMs used to measure pain as HRQoL outcome in PFDs, pain as PROM domain, psychometric properties of PROMs, modes and methods of PROMs administration, PROMs collection settings, frequency of data collection and PROMs reporting and analysis.

Eligibility criteria

Studies will be selected according to the criteria outlined below.

Type of participants:

- Studies examining adult women aged 18 years and above with pelvic pain associated with PFD (including POP, SUI or their treatment) pre- and post-surgery and of any ethnic background, will be included. Studies will be excluded if they examine male or female participants under the age of 18 and any other conditions other than PFDs, including endometriosis, interstitial cystitis, ovarian vein syndrome etc.

Type interventions:

- Studies that use, develop or implement PROMs that measure pain in PFDs or have pain as a PROM domain will be included.

Type of comparators:

- Studies without a comparator will be considered for inclusion.

Type of outcomes:

- Studies will be included if they investigate PROMs that measure pain as an HRQoL outcome, including registries; psychometric properties of PROMs; modes and methods of PROMs administration; PROMs collection settings; frequency of collection; and PROMs data reporting and analysis.

Type of studies:

- Quantitative and qualitative studies will be included. Mixed methods studies, clinical registry reports, audits and randomised controlled trials will also be included. Unpublished manuscripts, dissertations, conference proceedings and meeting abstracts will not be included in the review.

Information sources

This systematic review will search the following electronic databases: Ovid MEDLINE, Ovid Embase, CINAHL Plus, and Ovid PsycINFO. Grey literature will also be searched. Reference lists of the included studies and systematic reviews will also be examined during the review. References will be checked for forward citation tracking. The searches will be limited to publication in English language.

Search strategy

An initial search on Google Scholar, PubMed and other grey literature will be undertaken to find relevant search terms. A combination of medical subject headings (MeSH), Embase subject headings (Emtree) CINAHL headings and PsycINFO thesaurus subjects along with keywords, and free text terms will be used, and draft search strategies for the databases will be developed by a researcher (SSH). Database search strategies will be developed using subjects and free text terms relating to Concept A – PROMs and HRQoL; Concept B – PFDs, POP and SUI and Concept C – pain. A research librarian (LR) will then assist with refining and finalising the search strategies. A draft search strategy for Ovid MEDLINE is included in supplementary material 2.

Ethics

Ethics approval

was not sought after for this study because the data to be collected cannot be linked to individuals.

Study screening and selection

Studies found from searching the databases will be imported into Endnote to remove any duplicates. The remaining studies will then be exported into Covidence to undergo screening based on eligibility criteria. The first stage of screening comprising screening of studies by their title and abstract will be conducted by an independent researcher (SSH). Full texts of potentially eligible studies will be retrieved, read and assessed for inclusion by two independent researchers (SSH, RR). Any disagreements occurring between the researchers will be resolved through discussion and consensus. Studies finally selected for inclusion after the full-text screening will undergo data extraction.

Data extraction

Data extraction will be performed independently by two reviewers (SSH, RR), and any discrepancies in the data extract will be resolved by discussion and reaching consensus, and if necessary, discussion with a

third reviewer. Evidence from the data extracted will be populated into a Microsoft Excel spreadsheet. The types of data to be extracted are listed in Table 2.

Table 2
Data extraction items of included studies

Category	Items
Bibliographic information	• Author • Publication year • Title
Study characteristics	• Study design • Study setting • Country • Study population, sample size
PROM characteristics	• Name of PROM • Type of PROM (generic, specific) • PROM domains • Instrument developed/development in progress • Purpose of PROM • PROM collection setting
PROM administration and data collection/analysis	• Models and method of PROM administration (interview, paper, online) • PROM response rates • PROM data reporting and analysis • Frequency of data collection
PROM properties	• Psychometric properties of PROM (construct validity, content validity, internal consistency, reliability, responsiveness)

Risk of bias (quality assessment)

Two researchers (SSH, RR) will independently assess the risk of bias and methodological quality of each of the studies using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) risk of bias checklist for PROMs [18]. Discrepancies will be resolved through discussion. All questions answered for the sections on the checklist regarding PROM development, content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity and responsiveness will be rated as ‘very good’, ‘adequate’, ‘doubtful’, ‘inadequate’ or ‘NA’.

Data management

The search will be carried out in the databases mentioned above and then loaded into EndNote X8 software, management software for references that allows the identified references to be organized into different electronic databases. All the results will be inserted in a single EndNote folder, and the duplicated studies will be identified and removed. After the duplicate removal, the research results will be loaded onto Covidence, a software that assists the article trials, database extraction, and cooperation among multiple assessors.

Analysis

A descriptive synthesis of the results aligned with the outcomes of this review will be performed. A table with a summary of study characteristics from the data extracted will be presented. This will include basic information about the PROM, for example, the name, type, whether PROM is in use/implemented/developed/development in progress and type of PROM (generic/specific); the context in which the PROM was used, how the PROM was administered, and the data reporting and analysis of the PROM. Such information will then be used to compare the instruments. In this review, a subgroup analysis of the psychometric properties of the PROMs as well as the strengths and limitations of each instrument will be undertaken and presented in a second table. A quantitative synthesis will not be undertaken because the outcomes assessed by the included studies will be different.

Discussion

This systematic review aims to identify and compare PROM for pain or pain as a PROM domain in women with a PFD pre- and post-surgery as well as to capture studies examining mesh removals and implications or native tissue repair, based on their context, modes or methods of administration and psychometric properties in the current literature. The review also aims to explore and highlight the gaps of PROMs in the current research. To our knowledge, this systematic review will be the first to compare the use of PROMs measuring pain as an HRQoL outcome in women affected by PFDs. Results from this paper will help to establish whether the current PROMs for PFDs are appropriate and feasible to measure pain and potentially identify the need for a pain-specific PROM for PFDs, particularly in the registry or clinical setting.

Abbreviations

APFPR	Australasian Pelvic Floor Procedure Registry
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
Emtree	Embase subject headings
HRQoL	Health-related quality of life
MeSH	Medical subject headings
PFD	Pelvic floor disorder
PICO	Population, intervention, comparison and outcome
POP	Pelvic organ prolapse
PRISMA-P	Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
PROM	Patient-reported outcome measure
PROSPERO	Prospective Register of Ongoing Systematic Reviews
SUI	Stress urinary incontinence

Declarations

- **Ethics approval and consent to participate:** Ethics approval is not appropriate and thus not required for this study.
- **Consent for publication:** Yes
- **Availability of data and materials:** Not applicable
- **Competing interests:** None declared
- **Funding:** This work has been supported by the Australian Government Research Training Program (RTP) Scholarship (award/grant number: N/A).
- **Authors' contribution:** SSH registered the protocol with PROSPERO and draft the first manuscript which was reviewed by all authors. Constructive feedback was provided by RR, SA, HOC and LR and incorporated into the final version of the paper. All the authors read and approved the final version of the protocol.
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Supplementary Files

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