The prevalence of the Neglected Sexual Side Effects (NSSEs) after early prostate cancer treatment and the role of a questionnaire in its diagnosis: A Scoping Review Protocol

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Protocol

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Abstract

Background: Early prostate cancer (PCa) treatment interventions may leave men with debilitating sexual side effects. These side effects may remain permanent, often undiagnosed and undermanaged. The objective of this study is to map the evidence about the prevalence, and use of questionnaires, related to the neglected sexual side effects (NSSE) after PCa treatment.

Methods: This systematic scoping review's search strategy will involve the following electronic databases: PubMed, Science Direct and Google Scholar. Following title searching, two-independent reviewers will conduct screening of abstracts and full articles.

Eligibility criteria will guide the screenings. Data will be extracted from the included studies, and the emerging themes will be analysed. The review team will analyse the implications of the findings concerning the research question and aim of the study. The Mixed Method Appraisal Tool (MMAT) will be employed for quality appraisal of included studies.

Discussion: We anticipate finding a small number of studies about the prevalence and questionnaire use for NSSE after early PCa treatment. The study findings will be disseminated through publication in a peer-reviewed journal, peer presentations, as well as presentations at relevant conferences.

Background

Prostate cancer (PCa) is a major cause of disease and mortality among men and it is the second most common cancer affecting men on a global scale (1). Early PCa or localized PCa is cancer contained within the prostate described as being stage I or II on the tumour-node-metastasis system (2). Early PCa treatment consisting of surgery or radiotherapy, either through external beam radiotherapy or brachytherapy, results in side effects including sexual dysfunction. Other common side effects could include both pain and incontinence (1). Sexual dysfunction from PCa treatment is common regardless of whether the treatment modality included surgical or non-surgical interventions. Sexual dysfunction was found to increase during each year of follow-up after the initial intervention and it affects an average of 50% of patients within 5 years of receiving treatment (3).

Most men generally recover from pain and incontinence after PCa surgery but sexual dysfunction often remains untreated leaving them with long-lasting and debilitating sexual dysfunction (1). Specific conditions related to sexual dysfunction are common after PCa treatment. The conditions include orgasm-associated incontinence, urinary incontinence during sexual stimulation, altered perception of orgasm, orgasm associated pain, penile shortening, and penile deformity (1, 4, 5). These conditions are collectively referred to as the “Neglected Sexual Side Effects” (NSSE) and the symptoms are reportedly prevalent in 20–93% of post prostatectomy patients (1).

Only a fifth of the men who had been diagnosed with PCa will ever discuss issues related to sexual dysfunction with their health care practitioners (HCP) (6). A questionnaire may be useful as a non-

threatening strategy to initiate such a discussion and allow the patient to indicate their presenting symptoms. Two validated questionnaires, the Expanded Prostate Cancer Index Composite (EPIC)(7) and International Index of Erectile Function (IIEF)(8) were recommended for use in this context in 2015 (9).

Reason for this review

While the EPIC and IIEF both help to stimulate the conversation around general urinary function, they do not address the NSSE after PCa treatment. There is currently a lack of evidence about the availability of a possible questionnaire to specifically address the NSSE after PCa treatment. It is therefore important to conduct a systematic scoping review to improve our understanding on the prevalence of NSSE and to highlight knowledge gaps on the role of questionnaires in the assessment of the NSSEs.

Methodology

A systematic scoping review will be conducted to map the evidence on

A systematic scoping review will be conducted to map the evidence on

i. the prevalence of NSSE after early treatment PCa, and
ii. summarise literature on the use of questionnaires in the assessment of NSSE after early treatment for PCa.

The scoping review will follow the five steps described by (10) that included the following;

1. Identifying the research question
2. Identifying relevant studies
3. Study selection
4. Charting the data
5. Collating, summarizing and reporting on the data

Quality assessment of each of the included primary studies will be done as directed by (11)

Identifying the research question

This review aims to identify current academic literature on the NSSE after men have undergone early treatment for PCa.

The research questions are as follows:

- What is the prevalence of NSSE after early treatment for PCa?
- Which questionnaires are being used to assess NSSE after early treatment for PCa?

Eligibility criteria

The Population Concept Context (PCC) framework will be used to determine the eligibility of the research question as illustrated in Table 1

Table 1
The PCC framework

Criteria	Determinants
Population	Men who received surgical and non-surgical treatment following early PCa diagnosis
Concept	Neglected sexual side effects (NSSE)
Context	Prevalence of NSSE Questionnaire use to assess NSSE

Identifying relevant studies

This scoping review will include original research of any study design that has been published in peer-reviewed papers. To identify the studies an electronic search will be conducted using the Pubmed, Science Direct and Google Scholar databases. We will also include relevant studies found in citations and reference lists of included articles. The search will include publications available in English and published between January 2009 and December 2019.

Boolean terms (AND, OR) and Medical Subject Headings (MeSH) will be used as indicated in Table 2. The search results will be captured on an Excel spreadsheet where the duplicates will be removed. The selected studies will be screened against the eligibility criteria. The study search strategy was piloted to determine the appropriateness and feasibility of conducting this study, and the results are represented in Table 2.

Table 2
Pilot database search results

Keyword search	Date of search	Search Engine used	No. of publications retrieved
(*Orgas* OR Penil* OR Climacturia (MeSH Terms) OR Dysorgasmia (MeSH Terms) OR anejaculation (MeSH Terms) OR Peyronie OR neglected AND [prostate cancer (MeSH Terms) OR Prostatectomy (MeSH Terms)]*	1 September 2019	Pubmed	152

Study selection

A specific set of eligibility criteria was developed to ensure that relevant studies contain the appropriate results according to our research question.

The results of all three databases will be combined into one Excel spreadsheet after applying the search parameters. The eligibility criteria were developed to ensure that selected studies contain relevant information to answer the review questions.

The inclusion criteria

Only primary studies that present evidence on:

- The prevalence of NSSE after 3early stage PCa treatment
- The use of questionnaires to assess NSSE after early stage PCa treatment
- Original studies available in English and published between 1 Jan 2009-31 December 2019.

The exclusion criteria

The coping review will exclude:

- Review articles
- Non-peer reviewed articles (e.g. books, magazines, policy briefs etc.
- Commentaries, editorials, programme evaluations and letters.
- Literature on sexual dysfunction not relating to the prevalence and questionnaire use after early PCa treatment.
- Studies outside the period of interest and studies not available in English.

The primary investigator will conduct a comprehensive search and screening of the study titles from the above-mentioned databases. All the relevant studies with appropriate titles will be extracted and entered into an Excel spreadsheet for processing. All duplicates will be removed before the titles are screened. The abstracts of the eligible studies will be reviewed by two reviewers. This will be followed by full text screening by both reviewers of the qualifying articles to apply the inclusion and exclusion criteria. Any discrepancies in reviewers' results during the abstract and /or full text screening stage will be resolved by discussion until resolved. If needed, a third reviewer will be used to settle discrepancies. The screening result will be reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) chart (12).

Charting the data

The information will be extracted and organized using a data charting form. Data will be processed so that the relevant information can be summarized to answer the research questions. The data charting tool as illustrated in Table 3 will be used by a second reviewer to validate all the information.

Table 3 Data charting form included information on:

Author, date and reference

Aims and research questions

Geographical setting

Study Population

Study design

Number of participants

Period post PCa investigated

Prevalence of NSSE

Reported use of Questionnaire

Quality of the study

Quality Appraisal

An electronic version of the Mixed Method Appraisal Tool (MMAT) (13) will be adapted to assess the quality of the included studies. The study designs included in this scoping review will include qualitative, quantitative descriptive and mixed methods studies. The specific criteria to determine the appropriateness of each included study is outlined in Appendix 1.

Two reviewers will assign a score to assess each article that will assess the appropriateness of the study aims and its relevance for inclusion on the review. The overall quality for each included study will be calculated according to the following MMAT guidelines (score = number of criteria met/total score in each domain). 1 point will be given for each question and a total score out of 5 will be calculated. This will be represented as a percentage which correlates to the quality of the included studies. (Appendix 1)

The results will use the following descriptors.

- Very poor quality (20%) where minimal criteria is met
- Poor quality (40%) where less than half the criteria is not met
- Fair quality (60%) where just more than half the criteria is met
- Good quality (80%) where most of the criteria is met
- Excellent quality (100%) all criteria are met

The overall quality of a combination of components cannot be more than its weakest component when it comes to mixed methods studies, making the overall score equal to the lowest scoring component (13).

Collating, summarizing and reporting on the data

The findings of this scoping review will be analysed using a content analysis approach of the themes emerging from the extracted data. The themes will be collated to answer each research question. The

review team will discuss findings, resolve issues and finalise findings. The review team will analyse the implications of the study findings in how they relate to the study aims and further research in the field.

Discussion

PCa constitutes a global public health burden (14) and surgical and non-surgical interventions are routinely administered (15). Men who receive treatment for early stage PCa are often unaware of the debilitating, long-lasting side effects following the treatment (4). Sexual function has been identified as the quality of life domain most strongly associated with outcome satisfaction after prostate cancer treatment (16). With most research in the field of PCa focused around incontinence and erectile dysfunction, the NSSE remain understudied and neglected (1, 17). This review will report on the prevalence of the NSSE after early PCa treatment.

Only two studies have been published on the NSSE related to PCa treatment (5, 18). There is also no current valid and reliable questionnaire being used in the field of the NSSE after early PCA treatment. Such a questionnaire would assist health care practitioners to screen for possible NSSEs in patients who had undergone treatment for early PCa.

A review of the literature related to the prevalence and use of questionnaires in the NSSE after PCa treatment may help to inform future clinical practice around the NSSE in PCa survivors.

Abbreviations

PCa: Prostate cancer, HCP: Health care practitioner, NSSE: Neglected sexual side effects, EPIC: Expanded Prostate Cancer Index, IIEF: International Index of Erectile Function, MMAT: Mixed Method Appraisal Tool

Declarations

Ethics approval and consent to participate

Full ethical clearance was obtained from the University of KwaZulu-Natal, School of Health Sciences Research Committee (Biomedical Research Ethics Committee) with registration no: BREC/00000478/2019

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

PR conceived the study and participated in the design involved in drafting and finalising the manuscript. JvW participated in the design of the study, drafting the manuscript and revising it critically providing final approval of the version to be published.

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Guarantor of the review

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Supplementary Files

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- Appendix1.docx
- BMCWAIVERREQUEST2020.pdf
- PRISMAPchecklistPRoschercompleted.pdf