INPLASY PROTOCOL

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None declared.

Lasers in the treatment of vulvodynia: A scoping review

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Review question / Objective: **What is known from the existing research on the effectiveness of different forms of laser therapy in the treatment of women with vulvodynia? The aim of this scoping review is to appraise the existing published evidence on the effectiveness of different types of laser devices in the treatment of women with vulvodynia.**
Eligibility criteria: **The PCC (Participant, Concept, Context) framework will be used as recommended for scoping reviews. [11]. Participants: This scoping review will consider studies that included women who had had vulvodynia or superficial dyspareunia for at least 3 months.Concept: Literature that describes the use of laser therapy in the treatment of vulvodynia and its effect on pain and function. There will be no restrictions in terms of comparators.Context: Any clinical or research settings and any geographical setting will be considered for inclusion.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 May 2022 and was last updated on 24 May 2022 (registration number INPLASY202250141).

INTRODUCTION

Review question / Objective: **What is known from the existing research on the effectiveness of different forms of laser therapy in the treatment of women with vulvodynia? The aim of this scoping review is to appraise the existing published evidence on the effectiveness of different types of laser devices in the treatment of women with vulvodynia.**

Rationale: **Lasers are a common type of energy-based vaginal/vulvar device [1]. To date, the available literature reviews have focused mainly on the treatment of**

genitourinary syndrome of menopause which is distinct from vulvodynia. To our knowledge, there is no available research review that systematically locates and synthesizes the available evidence on the effects of laser for reducing pain and improving functional outcomes in vulvodynia. Laser treatment may be provided as a modality included in gynaecological or physiotherapy treatment. It is worth noting that the effects of laser differ according to the type of lasers and the parameters selected. Moreover, the lasers tend to differ between settings: those used by medical doctors have parameters and objectives distinct from those used by physiotherapists. Currently, the available evidence on these energy-based devices is separated between the applications in physiotherapy and medical/gynaecological settings. This leads to confusion and difficulties when comparing the methods in use. There is a need to sum up and compare the existing body of evidence relevant to the application of lasers according to the parameters used in the treatment of women with vulvodynia.

Condition being studied: Vulvodynia is an overlooked chronic pain condition affecting the vulval area. It has a prevalence of up to 18% and an ever-increasing incidence [2,3]. The condition and its co-morbidities negatively impact quality of life, and the World Health Organization has recently identified it as a neglected condition that requires immediate attention. This is justified by the fact that effective treatment options for this taboo condition, which is as common as osteoarthritis and fibromyalgia, are still limited [4-6]. This condition also carries a huge economic burden for society, with an annual budget as high as $72 billion in the US [7,8]. The source of the problem is that vulvodynia remains poorly understood, compromising its diagnosis and therapeutic management. The literature suggests potential causes including muscular, hormonal, genetic, inflammatory, and neurogenic factors [9,10]. Laser therapy has gained popularity as it is suggested to target some of these pathophysiological pathways. Conducting a review targeting the efficacy of lasers in women with vulvodynia is needed considering the warning statement issued by the Food and Drug Administration (FDA) and leading scientific societies. They claimed that there is an urgent need to assess the state of evidence on the efficacy of lasers in gynecology in order to inform clinical practice.

METHODS

Search strategy: The proposed scoping review will be conducted in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews [11] and Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) guidelines [12]. The search strategy will aim to locate published studies. Searches will include a combination of medical subject headings and free-text searches for terms related to the cited condition (vulvodynia) and investigated intervention (lasers). An initial limited search of MEDLINE is currently being undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles will be used to develop a full search strategy. Two reviewers will independently screen the titles and abstracts and identify relevant articles that met the inclusion criteria. Full text articles for all the titles that appear to meet the eligibility criteria will be obtained and then assessed for eligibility. Disagreements will be resolved through discussion and a third reviewer will be included if needed. Reasons for exclusion will be recorded.

Participant or population: This scoping review will consider studies that involved women who had had vulvodynia or superficial dyspareunia for at least 3 months.Studies involving women who are minors, pregnant women, or women who had undergone organ or bone marrow transplants will be excluded. Additionally, studies involving women with the following pelvic pain conditions will be excluded: chronic pelvic pain different from vulvodynia, endometriosis, sexually transmitted infections, other vulvovaginal

infections, cancer or former cases of cancer, dermatologic conditions, genitourinary syndrome of menopause (including vulvovaginal atrophy) or deep dyspareunia. Studies involving women with vulvodynia and other pelvic pain conditions will be considered eligible if women meeting our eligibility criteria will constitute at least 75% of the study group.

Intervention: Literature that describes the use of energy-based vaginal/vulvar devices, namely LASERS (light amplification by the stimulated emission of radiation) in the treatment of vulvodynia will be included.

Comparator: Any comparator will be eligible for inclusion, including sham laser, other treatment modalities, or values before treatment for before-and-after studies. Studies including co-interventions will be allowed if applied equally to both the laser and control groups.

Study designs to be included: This scoping review will consider a variety of study designs, including randomized controlled trials, non-randomized controlled trials, and before-and-after studies. In addition, analytical observational studies, including prospective and retrospective cohort studies, case-control studies, and analytical cross-sectional studies, will be considered for inclusion. This review will also consider descriptive observational study designs, including case series, individual case reports, and descriptive cross-sectional studies for inclusion.

Eligibility criteria: The PCC (Participant, Concept, Context) framework will be used as recommended for scoping reviews. [11]. Participants: This scoping review will consider studies that included women who had had vulvodynia or superficial dyspareunia for at least 3 months.Concept: Literature that describes the use of laser therapy in the treatment of vulvodynia and its effect on pain and function. There will be no restrictions in terms of comparators. Context: Any clinical or research settings and any geographical setting will be considered for inclusion.

Information sources: The following bibliographic databases will be searched: Amed, CINAHL, psyInfo and Sportdiscuss, Medline via EBSCO, Embase via Scopus, Cochrane CENTRAL via Cochrane library and ProQuest to locate peer-reviewed, published articles and/or dissertations.

Main outcome(s): Effect on pain and function will be analyzed:
1) pain (e.g., pain intensity during intercourse),
2) functional disability (e.g., sexual function),
3) participants' perceived improvement.

Additional outcome(s): Adverse events (worsening of pain, dropouts) will be analyzed.

Data management: The literature search results will be uploaded into the EndNote software program. Two independent reviewers will extract relevant information from the full texts, including the study sample, subject demographics, treatment details, data collection time points, outcome measures, adverse events, dropouts, and results. The drafted data extraction tool will be modified as needed throughout the review depending on the data extracted from the included studies. Disagreements will be resolved by consensus among reviewers. A third reviewer will be involved if needed.

Quality assessment / Risk of bias analysis: National Heart, Lung, and Blood Institute Study Quality Assessment Tools (NIH quality assessment tools) will be used for critical appraisal of individual studies.

Strategy of data synthesis: Data will be aggregated, and a narrative critical analysis will be performed based on the included studies. Descriptive data will be used to characterize the study population. Summary data for each type of laser treatment will be provided. A narrative report on the findings with relevance to the objectives of this review will be completed.
Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Language: There will be no restrictions in terms of language.

Country(ies) involved: Canada, Poland, Brazil.

Other relevant information: A preliminary search in MEDLINE was conducted and no published systematic reviews or scoping reviews on the topic were identified.

Keywords: Laser therapy, vulvodynia, pain management.

Dissemination plans: Once the data analysis is complete, results will be published in a peer-reviewed journal and presented at relevant scientific conferences.

Contributions of each author:

Author 1 - Małgorzata Starzec-Proserpio - The author developed and prepared the protocol and verified the search methodology. She was involved in the conception and design of the review, she will conduct the acquisition of the data, contribute to the analysis and interpretation of the data, and will write the initial draft of the manucript.
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Author 2 - Marcela Grigol Bardin - The author was involved in the conception and design of the review, she will conduct the acquisition of the data, contribute to the analysis and interpretation of the data, and participate in writing the initial draft of the manuscript.
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Author 3 - Melanie Morin - The author developed and prepared the protocol and verified the search methodology. She was involved in the conception and design of the review. She will conduct the acquisition of the data, contribute to the analysis and interpretation of the data as well as write the initial draft of the manuscript.
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