ABENFISIO

ARTIGO DE REVISÃO

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PHOTOBIOMODULATION ON PERINEAL PAIN AND HEALING PROCESS FOLLOWING EPISIOTOMY: A SYSTEMATIC REVIEW PROTOCOL

FOTOBIOMODULAÇÃO NA DOR PERINEAL E NO PROCESSO DE CICATRIZAÇÃO APÓS EPISIOTOMIA: UM PROTOCOLO DE REVISÃO SISTEMÁTICA

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AK Rocha: Conception and design of the study, acquisition, analysis, and interpretation of data, article drafting, critical revision regarding important intellectual content, and final approval of the version to be submitted.
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ABSTRACT

Introduction: Photobiomodulation (PBM) is a widely used modality in clinical practice during the puerperal period. Nevertheless, no systematic reviews have examined the impact of this intervention on perineal pain and healing outcomes in women after episiotomy. Objective: To investigate the effects of PBM on perineal pain intensity and the healing process in women during the immediate postpartum period. Method: A systematic review will be conducted with a view to performing a meta-analysis, if feasible. An electronic search of six databases will be conducted (PubMed, PEDro, SciELO, LILACS, Cochrane Library, and EMBASE), followed by a manual search. Studies will be evaluated according to the Population, Intervention, Comparison, and Study design (PICOS model), including women in the immediate postpartum period who were treated with PBM or other conservative treatments, to evaluate their effects on perineal pain intensity and the perineal healing process, based on Randomized Controlled Trials (RCTs). The risk of bias will be assessed using the Cochrane RoB 2 for RCTs, and the quality of evidence will be investigated using the GRADE approach. The meta-analysis will be performed using Review Manager 5.4 software. Results: This study presents a methodological protocol for a systematic review of RCTs, followed by a meta-analysis. The aim will be to analyze the effects of PBM on perineal pain intensity and the healing process in women during the immediate postpartum period using validated instruments. Conclusion: The results will provide scientific evidence regarding the intervention, thereby supporting conservative treatment decision-making.
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Keywords: Episiotomy, Pain, Photobiomodulation, Rehabilitation.

RESUMO

Introdução: A Fotobiomodulação (PBM) é uma modalidade amplamente utilizada na prática clínica durante o puerpério. No entanto, nenhuma revisão sistemática examinou o impacto dessa intervenção na dor perineal e nos resultados de cicatrização em mulheres após episiotomia. Objetivo: Investigar os efeitos da PBM sobre a intensidade da dor perineal e o processo de cicatrização em mulheres durante o período pós-parto imediato. Método: Será realizada uma revisão sistemática com o objetivo de realizar, se possível, uma metanálise. Será realizada uma busca eletrônica em seis bases de dados (PubMed, PEDro, SciELO, LILACS, Biblioteca Cochrane e EMBASE), seguida de uma busca manual. Os estudos serão avaliados de acordo com o desenho População, Intervenção, Comparação e Estudo (modelo PICOS), incluindo mulheres no pós-parto imediato, tratadas com PBM ou com outros tratamentos conservadores, para avaliar seus efeitos sobre a intensidade da dor perineal e o processo de cicatrização perineal com base em Ensaios Clínicos Randomizados (ECRs). O risco de viés será avaliado usando o Cochrane RoB 2 para ECRs, e a qualidade da evidência será investigada usando a abordagem GRADE. A metanálise será realizada com o software Review Manager 5.4. Resultados: Este estudo apresenta um protocolo metodológico para uma revisão sistemática de ECRs, seguida de uma metanálise. O objetivo será analisar os efeitos da PBM sobre a intensidade da dor perineal e o processo de cicatrização em mulheres durante o período pós-parto imediato, usando instrumentos validados. Conclusão: Os resultados facilitarão a aquisição de evidências científicas sobre a intervenção, facilitando, assim, a tomada de decisões sobre tratamentos conservadores.
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INTRODUCTION

Perineal trauma affects millions of women, with a prevalence of around 91% in nulliparous women and over 70% in multiparous women, with a potentially significant impact on daily activities, psychological well-being, sexual function, and overall quality of life[1-3]. Perineal trauma should be identified early, and when third- and fourth-degree lacerations are diagnosed, they should be corrected quickly by an experienced surgeon. First- and second-degree traumas are typically treated conservatively, with a primary focus on pain management and monitoring of the healing process[3-6].

The American College of Obstetricians and Gynecologists (ACOG) recommends that screening and pain management for women in the immediate postpartum period be conducted on an individual basis to identify and address the primary causes of postpartum complications. Regarding the pelvic floor, the presence of perineal discomfort and the status of urinary and/or fecal incontinence should be evaluated to guide routine puerperal care and professional care when necessary[1,7].

Conservative therapies, including drug analgesia, cryotherapy, and transcutaneous electrical stimulation, can effectively relieve perineal pain and discomfort[8-12]. Recently, studies have been conducted to verify the potential of Photobiomodulation (PBM) to enhance the healing process during the postpartum period[12].

PBM is defined as the therapeutic application of light-emitting sources, including Light Amplification by Stimulated Emission of Radiation (LASER) and Light-Emitting Diodes (LEDs), to a biological system to induce a photochemical process, primarily within mitochondria. This process stimulates energy production as Adenosine Triphosphate (ATP), which can enhance cellular metabolism and elicit effects such as analgesia and wound regeneration[11-13].

Regarding tissue repair, PBM can hinder the inflammatory process by using nonionizing radiation and inducing nonthermal responses. These benefits are promoted by the red (600–700 nm) and near-infrared (770–1200 nm) wavelengths. These spectra have been the subject of the most extensive research to date, while other types of light have been comparatively understudied[11-13]. The benefits of using light in PBM are contingent on multiple variables, including the energy dose used[12-16]. The effects of LEDs have recently been studied, with one study showing that their application can promote analgesic effects that induce peripheral neural blockade, suppress central synaptic activity, modulate neurotransmitters, reduce muscle spasms and interstitial edema, improve local circulation, and exert anti-inflammatory effects [17]. Some studies have indicated that the amount of energy supplied by PBM to tissues ranges from 3 to 8.8 J/cm^2[12,14-17].

Kymplová et al.[18] studied the effects of PBM on episiotomy patients and observed that women exposed to PBM had minimal secondary complications during treatment for episiotomies. Santos et al.[14] found that a PBM group was superior to a Placebo Group (PG) at 24 and 48 hours after PBM application, although no improvement was observed during the first 2 hours of application. Regarding the healing

process, the PBM group showed improvement after 15–20 days, while the PG group's conditions worsened.

Alvarenga et al.[15] demonstrated that perineal pain intensity was statistically higher in the PBM group at the first evaluation after PBM and after the third evaluation than in the PG, and healing the process improved after the application of PBM; however, there was no significant difference between the groups regarding perineal healing process after PBM. Despite promising results, the authors proposed using alternative parameters and a larger sample size in future investigations[12-18].

East et al.[19] found that women who had undergone vaginal delivery and conservative pain relief therapies experienced reduced perineal pain; the concurrent administration of analgesic therapies demonstrably diminished the need for pharmacological intervention, and the greater the perineal trauma, the greater the perineal pain intensity. A reduced intensity of postoperative pain was observed among women who underwent cesarean delivery with PBM. Furthermore, Frederice et al.[16] observed decreased pain in women with pelvic floor myofascial dysfunction, which had positive repercussions for sexual function following the application of PBM.

A low-cost, low-risk therapeutic option with minimal adverse effects that could reduce perineal pain intensity and stimulate the healing process during the postpartum period would be beneficial for avoiding the administration of opioids to lactating women and the associated risks for infants, mitigating the complications that increase costs for health systems, and reducing negative effects on women's quality of life[1,3,5,11,12,20,21].

PBM has been employed in numerous health-related fields and has been the subject of extensive investigation by physiotherapy professionals[11,12]. In women's health physiotherapy, post-birth massage can be used as an adjunctive therapy for perineal pain management in clinical practice. Among postpartum analgesic treatments, PBM is distinguished by its noninvasive nature, ease of application, and safety for postpartum women[12,21-23].

This study aims to establish a protocol for a systematic review of Randomized Controlled Trials (RCTs), followed by a meta-analysis. Thus, using validated instruments, we will analyze the effects of PBM on perineal pain intensity and the healing process in women during the immediate postpartum period.

METHOD

Eligibility criteria

Inclusion criteria

The protocol for this systematic review was registered under PROSPERO registration number CRD42024523811. For the study, the eligibility criteria will accord with the Population, Intervention, Comparator, Outcome, and Study (PICOS) design model. Studies will be included if they evaluate postpartum women (P) undergoing PBM (I) compared to other conservative treatments (C) and evaluate their effects on perineal pain intensity and the healing process (O) through RCTs (S)[24,25]. This systematic review will be developed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis for the Protocol (PRISMA-P)

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for Enhancing the Quality and Transparency of Health Research (EQUATOR) network[24]. To meet the aims of this study, a systematic review will be carried out using the Cochrane RCTs methodology, following the precepts and recommendations of the RoB tool 2[26,27].

Exclusion criteria

Case studies, crossover studies, gray literature, and studies that do not present separate groups or details of the appropriate protocol will be excluded from this analysis.

Outcome measures

Primary outcomes

The primary outcomes will be the effects of PBM on postpartum perineal pain intensity, assessed using scales such as the Visual Analog Scale (VAS), Visual Numerical Scale (VNS), and Numerical Rating Scale (NRS), as well as validated questionnaires.

Secondary outcomes

Secondary outcomes will include evaluations of the healing process, assessed using the Reedness, Oedema, Ecchymosis, Discharge, and Approximation (REEDA) Scale and the Scar Size Scale (Peri-Rule™ Ruler).

Literature search strategies

The search will be conducted by six databases: PubMed Central (PMC)/MEDLINE, Physiotherapy Evidence Database (PEDro), Scientific Electronic Library Online (SciELO), Latin American and the Caribbean Literature on Health Sciences (LILACS), Central Cochrane Library, and Excerpta Medica DataBASE (EMBASE). Thereafter, a manual screening will be conducted to identify studies involving the previously mentioned interventions.

The Medical Subject Headings (MeSH) and search descriptors will be as follows: “pelvic diaphragm,” “perineum,” “pelvic floor,” “pelvic floor diseases,” “pelvic floor disorders,” “episiotomy,” “postpartum period,” “postnatal care,” “parturition,” “natural childbirth,” “obstetric labor complications,” and “labor complications.” These will be associated with intervention terms (“light therapy,” “photobiomodulation therapy,” “LLLT,” “light,” “phototherapy,” “laser therapy,” and “laser”) and terms related to study design (“randomized controlled trial,” “controlled clinical trial,” “randomly,” and “RCT”).

The search will be conducted by AKR with assistance from an institution librarian, using standard Boolean operators and symbols. Each search term will be combined with the intervention terms (photobiomodulation or light therapy and its variations, and other terms), the terms for the health state studied (childbirth or postpartum), and then with the terms for the chosen study type and design for analysis. The primary search terms will include “perineum,” “photobiomodulation,” and “randomized control trial”. The terms mentioned above will be searched using MeSH or search descriptors, with appropriate changes for each database.

Data collection and analysis

Study selection

In this study, two independent reviewers (AKR and TC) will manually screen the studies collected from the databases in the following order: title, abstract, and full reading. All studies potentially eligible for inclusion in the systematic review will be selected for full reading. In the event of disagreement, a third reviewer will be consulted.

The primary search will cover December 2023 to December 2024. The results of the database search will be imported into Mendeley Reference Management 2.67.0 software[28]. These programs or software support the collaborative screening of titles,

abstracts, and full texts. Likewise, for each search strategy, two reviewers will evaluate the studies retrieved from the databases for full reading, and in the event of disagreement, the third reviewer will be consulted again. After screening, the results will be saved and documented in a flowchart, as recommended by the PRISMA Statement[26].

The following characteristics will be extracted from the studies: title, author, year, objectives, participant age of, groups, number of participants per group, study duration, follow-up period, primary and secondary measures, results, PBM parameters, number of applications, and application techniques. The excluded studies will be tabulated and presented according to the model in Table 1.

Table 1. Characteristics of the studies

Title/ author/ year	Objectives	Number of participants per group	Groups and average age	Duration of study and follow-up	Primary and secondary measures	PBM parameters used for each study	Number of applications	Application techniques	Results for each outcome measure
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-

Legend: Inclusion table for the systematic review and meta-analysis of clinical trials to evaluate the effects of PBM on women during the immediate postpartum period.

Case-crossover, noncomparative, noncontrolled, observational cohort, case-control, cohort, cross-sectional, and single-group observational studies will be excluded. Additionally, the abstracts, opinion articles, integrative mixed methods studies, systematic reviews, and gray literature, as well as studies stated to have objectives not to review RCTs that focus on pain relief and the evaluation of the healing process or have been previously treated using any treatment in the study population, will be excluded. The excluded studies will be tabulated and presented according to the model in Table 2.

Table 2. Studies excluded and reasons for exclusion

First author Author/ Year	Title	Reason for exclusion
-	-	-
-	-	-

Legend: Table of excluded studies for the systematic review and meta-analysis of RCTs to evaluate the effects of PBM on women during the immediate postpartum period.

Methodological quality, risk of bias, and statistical analysis

In this study, the methodological quality and risk of bias will be assessed using the Cochrane Handbook for Systematic Reviews of Interventions. This assessment tool considers the following domains: allocation generation, allocation concealment, blinding (of participants and researchers), blinding of the assessment of results, presence of incomplete data, reporting bias, and other types of bias[27].

The risk of bias will be analyzed for each study using the ROB 2 tool. Two independent evaluators will conduct the initial evaluation, and a third evaluator will be consulted to break any ties in scores[26,27]. In the event of uncertainty regarding whether the risk-of-bias criteria have been met, the authors of this study will contact the authors of the uncertain study to request further clarification of the methodology and data[26,27].

To compare the studies, odds ratios mean differences, or standardized mean differences will be calculated. In the event of missing data, we will attempt to contact the principal investigators to obtain pertinent information.

The results of the interventions will be presented in summary form and will include the calculation of odds ratios for dichotomous outcomes (with 95% confidence intervals), mean differences for continuous outcomes, or standardized mean differences for outcomes measured using incompatible scales (with 95% confidence intervals). Given the heterogeneity of results across a limited number of existing studies, we will conduct a meta-analysis. The 95% confidence intervals and two-sided p-values for each outcome will be provided. All analyses will be conducted using Review Manager (RevMan) software, including meta-analyses comprising more than two studies, illustrated using forest plots[29,30-33].

To assess heterogeneity among the studies, we will evaluate the effect measures using the X^2 test and the I^2 statistic[30,31]. An I^2 value greater than 50% will be considered to indicate significant heterogeneity, with ranges as follows: low heterogeneity between 0% and 40%, moderate heterogeneity between 30% and 60%, heterogeneity between 50% and 90%, and high heterogeneity between 75% and 100%[31]. The subgroups of stratified meta-analyses will be analyzed using estimates of heterogeneity according to study quality, study populations, intervention logistics, and intervention content[31-33].

Quality of evidence

The overall effectiveness of treatment and improvement in individuals with perineal pain intensity will be assessed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, and the quality of the evidence presented in the studies will be analyzed[33,34]. To assess the quality of the evidence, two authors will evaluate each outcome measure through discussion and consensus. The data will be grouped for the meta-analysis and narrative analysis will be used, following the GRADE criteria, to evaluate each analytical grouping. The GRADE approach is used to assess the limitations, inconsistencies, indirect evidence, inaccuracies, and publication bias of reviewed studies and to classify the levels of evidence as high, moderate, low, or very low[33,34].

RESULTS

The studies included in this systematic review are expected to demonstrate that PBM has positive effects on reducing perineal pain and accelerating the healing process in women who have undergone episiotomy in the postpartum period. The results may indicate improved local inflammatory signs, reduced edema, increased maternal comfort, and faster functional recovery compared with conventional conservative treatments.

Furthermore, the synthesis of the evidence may reveal that PBM is a safe, non-invasive, and potentially effective intervention for managing perineal complications in the postpartum period. However, heterogeneity among the studies is also expected, particularly regarding the parameters used in PBM, such as wavelength, dosage, frequency, and treatment duration.

DISCUSSION

The period immediately following childbirth is critical for women's health because it is a time when complications can arise, affecting the quality of life of puerperal women. Such complications may include pelvic floor dysfunction (e.g., urinary and/or anal incontinence) and sexual dysfunction, among other conditions[1-6,12,36].

Complications following vaginal delivery are particularly prevalent among primiparous women[2,3,6,17-19,35]. Perineal trauma affects approximately 9 of 10 women who experience vaginal delivery[3,4,5,7,35]. Greater than second-degree perineal trauma has been identified as a risk factor for the development of urinary and/or fecal incontinence, as well as for reduced quality of life among women one year after childbirth[2,6].

Therefore, it is crucial to enhance clinical care with the objective of reducing such risks and mitigating the complications associated with vaginal delivery. This is particularly important in light of the potential benefits of physical resources that can reduce healthcare costs while enhancing healing from perineal pain and improving quality of life for women in the immediate postpartum period[3,5,6,12,35]. It is plausible that conservative interventions may prove advantageous for postpartum women. The results of PBM are generally positive, in part due to its ease of implementation and potential to reduce healthcare costs[12,16,21-23].

PBM is a widely used therapeutic option in clinical physiotherapy practice, particularly in the context of urogynecological dysfunction. Nevertheless, the currently available evidence is insufficient to justify the use of PBM with complete confidence, which is why this study will be conducted.

Among the potential limitations of this study are differences in energy delivery protocols, doses, application techniques, and application intervals across studies, which will make comparisons difficult. Furthermore, studies unpublished at the time of the initial search and those not designed as RCTs may be missed during the review.

This systematic review protocol will facilitate a systematic investigation of RCTs to provide robust evidence regarding PBM for professionals working in clinical practice with women during the puerperal period.

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