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Electromyographic parameters for treating pelvic floor disorders in pregnant and postpartum women: A review protocol

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Study Protocol Article Template

Electromyographic parameters for treating pelvic floor disorders in pregnant and postpartum women: A review protocol

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Writing – review & editing: Alethéa Cury Rabelo Leitão, Elizabel de Souza Ramalho Viana.

Abstract

Electromyography is a widely used instrument in clinical practice to evaluate and treat pelvic floor disorders in pregnant and postpartum women. The objective of this study is to analyze the scientific evidence on the electromyography parameters used for treating pelvic floor disorders in pregnant women in any gestational week and postpartum women up to 12 months after delivery. A systematic review will be performed in online databases (Scopus, Medline, Pedro, Scielo and Pubmed) of randomized controlled experimental studies and quasi-experimental studies, in English, Portuguese or Spanish, which used electromyography as an intervention for treating pelvic floor disorders in pregnant or post-childbirth women up to 12 months after birth. Risk of bias assessment will be performed using Cochrane group tools. The Rob 2.0 tool will be used for experimental studies and the Robins-I tool for non-experimental studies. The protocol was registered in PROSPERO (nº.433510). The quality of the evidence will be analyzed using the GRADE System Methodological Guide and the systematic review structure will be performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Introduction

Description of the condition

It is consensus that the risk factors for developing pelvic floor disorders in women are related to the pregnancy and delivery period[1]. The pelvic floor of these

women will be overloaded during pregnancy due to enlargement of the gravid uterus from anatomical and physiological changes[2]. Therefore, some women may develop pelvic floor disorders (PFD), such as urinary and fecal incontinence and pelvic organ prolapse[3].

Perineal, connective tissue, and muscle rupture or weakness may occur after delivery, which may cause fecal and urinary incontinence, pelvic organ prolapse, sexual dysfunction, and pain syndromes [3]. The literature shows that 50% of women lose some support functionality of the pelvic floor muscles (PFM) due to childbirth, and these injuries increase by an average of 20% in women who had vaginal delivery [4].

Pelvic floor muscle training (PFMT) is the first-line treatment for dysfunctions of this musculature [5]. This treatment is based on increasing strength, endurance, maintaining muscle contraction for a long period of time, muscle coordination, adherence to and motivation for the training program [6]. [7]

Electromyography can be an adjunct to pelvic floor muscle training for treating urinary disorders in pregnant and postpartum women.

Description of the intervention

There are several methods for evaluating and treating the functionality of the pelvic floor muscles, such as: digital palpation, manometry, ultrasound, electromyography and magnetic resonance imaging [6][5][8]

A 2021 meta-analysis with more than four thousand women found that the use of electromyography combined with conservative treatment of the pelvic floor muscles has better results than the isolated treatment[1]

Another 2019 meta-analysis with 1,104 studies did not demonstrate that conservative treatment with electromyographic biofeedback offers a better intervention alternative for the treatment of this urinary incontinence [9]. In other words, it did not find significant differences in the findings when compared with other interventions for the same treatment objective[9][5].

How the intervention will work

Electromyography can be used alone or in combination with conservative treatment. It allows indicating the activity of the pelvic floor muscles in relation to rest during contraction and during relaxation[10][9].

Clinical studies have evaluated the bioelectric activity of this muscle group using electromyography[11]. This resource has been used as an adjunct to conservative training and enables the physiotherapist to correctly and objectively observe the contraction and relaxation of the pelvic floor muscles. Therefore, it facilitates neuromuscular learning and performs rehabilitation more assertively[9][10].

So far, more recent reviews which analyzed the effectiveness of conservative treatment with and without electromyography in relation to pelvic floor strength, urinary incontinence score and quality of sexual life excluded pregnant and postpartum women from the intervention groups to analyze these effects, leaving this gap in the literature on this population[12][13][14].

Knowledge about data on frequency, intensity and type of muscle contraction can determine goals and therapeutic conduct more assertively. The electromyographic parameters of the pelvic floor muscles guide the health professional in choosing the best strategies for the successful treatment of PFM

disorders in pregnant and postpartum women. However, due to the scarcity of studies in this population, a systematic investigation of the literature on the conducts carried out and their effects so far is necessary.

Why is this review important?

It is important to have a better understanding of the electromyography parameters most used in treating pelvic floor muscle disorders in pregnant and postpartum women. Identifying electromyography data can be a reference for elaborating pelvic floor rehabilitation procedures, and thereby contribute to the prevention and treatment of dysfunctions. Furthermore, previous systematic reviews have not analyzed the most appropriate therapy for this population when using EMG alone or in combination in this population.

Materials and Methods

Protocol and guidelines

This review will be conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Prisma guidelines[15]. The protocol will be registered with PROSPERO and will be carried out between August 2023 and October 2024.

Type of studies

The review will include randomized controlled experimental studies (RCTs) and non-experimental studies (nRCTs), in English, Portuguese or Spanish, using

electromyography in pregnant or postpartum women for evaluating or treating pelvic floor dysfunctions which analyzed baseline tone, contraction and relaxation capacity.

Type of participantes

Studies including pregnant women (at any gestational week) and postpartum women (up to 12 months postpartum) with MAPM who were treated with EMG will also be considered.

Type of interventions

In addition, studies which used electromyography as an instrument, in isolation or in combination, for evaluating or treating of pelvic floor muscle dysfunctions that describe the parameters used in the therapy of these women will also be included.

Type of outcome mensures

Primary results

1. Baseline pelvic floor muscle tone
2. Maximum voluntary contraction of the pelvic floor muscles
3. Sustained contraction of the pelvic floor muscles
4. Functionality of the pelvic floor muscles (contraction-relaxation coordination capacity)
5. Functionality of the pelvic floor muscles (ability for rapid contractions)

Secondary results

6. Types of electromyographic equipment
7. Patient positioning during the intervention

8. Limitations of the chosen therapy
9. Types of Female Pelvic Floor Dysfunction More
10. Adverse events

Electronic database

1. Cochrane Central Register of Controlled Trials (CENTRAL)
2. MEDLINE (Pubmed)
3. Banco de Dados de Evidências em Fisioterapia (PEDro)
4. Scopus
5. Web of Science
6. Scielo
7. US National Institutes of Health, Register of Continuous Trials, ClinicalTrials.gov (www.clinictrials.gov);

The strategy on the terms used in each database can be found in Appendix S1.

Searching other resources

Reference checking of primary studies will be done manually and review articles will be added to the reference.

Selection of studies

Two independent authors (ACRL and SORL) will analyze the articles by titles and abstracts at the first moment. Eligible studies will be read in full and data extracted for inclusion. The exclusion reasons for the studies will also be analyzed

one by one. Disagreements regarding articles were resolved by a third author by casting vote (ESRV).

Duplicate studies will be identified and excluded. Studies involving men, children or non-pregnant women will also be excluded from the eligibility process and detailed in the Guideline Prisma flowchart.

Data extraction and management

The authors will extract the characteristics below from the included studies:

1. Participants: pregnant women in any gestational phase or postpartum women up to 12 months after delivery, postpartum time, mean age, gestational week, floor dysfunction for treatment, sample inclusion and exclusion criteria, and sample description.
2. Intervention: type of electromyographic equipment, types of electrodes, type of comparator equipment (if any), use of combined therapy (if any), intervention time, electromyographic parameters used, description of alternative interventions (placebo, no intervention or other intervention).
3. Method: study design, session time, follow-up time, study location, patient positioning, PFM functionality assessment method, treatment method.
4. Results: primary and secondary studies that evaluated electromyographic parameters for treating pelvic floor muscle dysfunctions.
5. Notes: authors, year of publication, funding of studies, and notable conflicts of interest among authors

Two authors (ACRL and SORL) will perform the initial data extraction from the included studies after reading the full text and within the inclusion criteria. A

“Summary of included studies” table will be created, informing the total number of studies. In case of disagreements in the extraction of data, a meeting will first be held for consensus on the extraction, and in the persistence of doubt, a third author will be deciding by the casting vote (ERSV). The review author (ACRL) will transfer the summarized data to the Systematic Reviews management program (RevMan 2014) in order to generate the study report and analysis of heterogeneity and the possibility of meta-analysis of the data.

In case of lack of important data to perform the analysis, one of the review authors will contact you to provide details of the study in question. A professional fluent in the English language or Google Translator will assist in the translation of other published languages in case of doubts. The main results will be carefully reanalyzed by the study authors after translation.

Assessement or risk of bias in the included studies

Two independent authors (ACRL and SORL) will analyze the risk of bias of experimental studies using the Rob 2.0 tool and for non-experimental studies the Robins-I tool. Disagreements will be resolved by consensus or involving a third review author (ESRV).

The Rob 2.0 tool is structured in five domains that have “signaling questions” with the possibility of answers in: “yes”, “probably yes”, “probably not”, “no”, “no information'” and “not applicable”. Definitive “yes” and “no” answers often indicate that robust evidence is available. The “not applicable” option is only available for questions with a non-mandatory answer. The final score of the responses

determines the risk of bias for each domain: “high risk of bias”, “low risk of bias” or “unclear”[16]

The ROBINS-I tool evaluates seven domains of bias, classified by: low risk of bias, moderate risk of bias, severe risk of bias, critical risk of bias or no information. The result for the final analysis of each component of the domain is based on the answers to the guiding questions and tables that support the judgment of bias in each domain.[17]

Another bias: the ROBINS-I tool also allows for ranking the overall risk of bias, which receives the least favorable ranking among the assessed risks for the assessment tool’s domains.

Evidence quality assessment

The evidence quality will be analyzed using the GRADE tool[18]. The structure of the systematic review will follow the recommendation of the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the protocol is registered in the PROSPERO database, the international prospective register of systematic reviews in health and social care (www.crd.york.ac.uk/prospero).

Assessment of bias during the systematic review

The review must be conducted according to this protocol and any adjustments can be justified in the “Difference between protocol and review” tab in the systematic review session.

Effect treatment measures

Dichotomous data: the odds ratios (ORs) and their associated 95% confidence intervals (CIs) will be used to determine the value of dichotomous data.

Continuous data: will be evaluated using standardized mean differences (STDs) and their corresponding 95% CIs using the Mantel-Haenzel method.

In case of a difference between means, the standard mean can be used for studies that analyzed the same result using different methods. P-values less than 0.05 will be considered statistically significant in all cases.

Issues related to a single analysis

Data analyzed in the study may be analyzed using a single analysis on the outcomes found. Meta-analysis may be used for randomized studies only if the data are justified for doing so.

Lost data

The authors of the present study will be able to contact the authors of the articles listed for data analysis in order to resolve doubts or request numerical data that were not made explicit in the body of the text or which were not found in the Register of Continuous Tests, ClinicalTrials.gov (www.clinictrials.gov). There are cases where only the abstract of the study contains the information, however, in the course of the text it does not. The failure of contacts and loss of entered data cause serious bias and this will be considered in the GRADE system.

Evaluation of heterogeneity

If great heterogeneity is identified between the studies, the possible causes of the data discrepancy can be evaluated using specific sub-groups for analysis. If it is not possible to analyze the subgroup, the qualitative analysis will be summarized and presented in tables.

Evaluation of the risk of bias

The funnel chart can investigate reported biases. Symmetry of the funnel plot can be visually evaluated and explored.

Synthesis of the data

A random effects model and sensitivity analysis with a fixed model can be used for subgroup analysis and data heterogeneity. It is suggested to follow the results below for subgroup analysis:

1. Electromyographic parameters for the treatment of APMD
2. Limitations of the chosen therapy

The following results will be used in subgroup analyzes:

1. Functionality of the pelvic floor muscles
2. Most common types of female pelvic floor dysfunction
3. Adverse events

Statistical analysis for analysis of subgroup interactions will be analyzed using the Rev-Man tool.

Sensitivity analysis

A sensitivity analysis will be conducted to obtain a solid conclusion and to evaluate the stability of the results. All analyses will be performed using STATA SE 14.0. The sensitivity analysis may explore the influence of the quality of results. This can be assessed by excluding studies at high risk of bias.

Discussion

From an evaluation and analysis of the studies that will be systematically reviewed, it is intended to analyze the variation of the protocols tested, methods, terminologies used, as well as definitions of the evaluation of electromyography

components of the pelvic floor and their characteristics. In addition, the analysis of the selected studies on the heterogeneity level of the results is also an objective. The publication of findings may expose gaps in information about the intervention and the standardization of interventions, in addition to comparing results and conclusions between studies.

The publication of this protocol will serve as a reference for elaborating protocols in the rehabilitation of the pelvic floor, identification of the most common dysfunctions, quality of intervention and outcomes, thus contributing to the care and monitoring of these pregnant and postpartum women.

Acknowledgements

None

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Supporting information

S1 Checklist. PRISMA-P (Preferred Reporting Items for Systematic review and Meta

Analysis Protocols) 2015 checklist: Recommended items to address in a systematic review protocol.(DOC)

S1 Appendix.(DOCX)

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