INPLASY PROTOCOL

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EFFECT OF INTRALUMINAL (ENDOANAL AND INTRAVAGINAL) AND SURFACE ELECTRODE PLACEMENT IN THE STIMULATION OF PELVIC FLOOR MUSCLE AMONG WOMEN WITH POST PARTUM ANAL INCONTINENCE: A SYSTEMATIC REVIEW

Mba, CG1; Ibeneme, SC2.

Review question / Objective: What are the effects of intraluminal (endoanal and intravaginal) and surface electrode placement on pelvic floor muscle activity, strength(squeeze pressure), structural dimensions, symptom severity and quality of life in women with postpartum anal incontinence?/ To determine effects of intraluminal (endoanal and intravaginal) and surface electrode placement on pelvic floor muscle activity, strength (squeeze pressure) structural dimensions, symptom severity and quality of life in women with postpartum anal incontinence.

Information sources: Search of the bibliographic database and grey literature, and (ii) the choice of studies for inclusion based on eligibility criteria. Searches involved some combinations of search terms from medical subject headings (MeSH) and keywords with a mix of symbolic logic within the title, abstract and text for the population, intervention, control and outcomes, first in a preliminary or pilot search to determine the sensitivity of the search strategy. Additional searches were made of the reference list of identified studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 November 2022 and was last updated on 05 November 2022 (registration number INPLASY2022110019).

INTRODUCTION

Review question / Objective: What are the effects of intraluminal (endoanal and intravaginal) and surface electrode placement on pelvic floor muscle activity, strength(squeeze pressure), structural dimensions, symptom severity and quality

of life in women with postpartum anal incontinence?/ To determine effects of intraluminal (endoanal and intravaginal) and surface electrode placement on pelvic floor muscle activity, strength (squeeze pressure) structural dimensions, symptom severity and quality of life in women with postpartum anal incontinence.

Rationale: In the management of Postpartum anal incontinence, there is no established protocol especially pertaining to electrode placement and treatment parameters. Most researcher seem to favour endoanal electrode placement. while this may be an effective form of therapy. However, intraluminal electrode placement has been reported to be uncomfortable and painful by most patients and the increased rate of pull-out and reinsertion further worsens the problemand also.women have reported adverse psychological reactions to endoanal placement (Correia et al, 2014). A combination of these factors and the prolonged treatment time averaging 3-6months makes the option less desirable. This underlines the need for a less invasive procedure applicable with the use of surface electrodes in electrical stimulation. However, the question arises on which method provides effective recovery from PPAI. However, it is not known whether the use of surface electrode in the electrical stimulation of the pelvic floor muscles would be more effective with better clinical outcomes than the intraluminal methods. This is also important considering that a previous study (Dumoulin et al 1995) demonstrated that the location of stimulating electrodes and other treatment parameters are of critical importance in obtaining maximal muscles contraction. Therefore a synthesis of evidence from the literature is required to guide practice.

Condition being studied: Postpartum anal incontinence.

METHODS

Search strategy: (anal incontinence) OR (fecal incontinence) OR (post partum anal incontinence) OR (postdelivery anal incontinence)) OR (obstetric anal sphincter injur*)) OR (OASIS)) OR (OASIS)) OR (obstetric anal sphincter ruptur*) AND (electrical stimulation) OR pelvic floor stimulation)) OR (pelvic floor electrical stimulation)) (anal incontinence) OR (fecal incontinence) OR (post partum anal incontinence) OR (postdelivery anal

incontinence)) OR (obstetric anal sphincter injur*)) OR (OASIS)) OR (OASIS)) OR (obstetric anal sphincter ruptur*) AND (electrical stimulation) OR pelvic floor stimulation)) OR (pelvic floor electrical stimulation)).PubMed, CINAHL, EMBASE, Medline, PsycINFO, Cochrane, Health source, Clinicaltrial.gov, Scopus, Web of Science.

Participant or population: Women with postpartum anal incontinence;> 18years but < 45 years who reported anal incontinence 6weeks to 12months postbirth.

Intervention: Pelvic floor electrical stimulation upelvic floor electrical stimulation either as an adjunct or standalone therapy which utilized intraluminal (endoanal or intravaginal) or surface electrode placementpelvic floor electrical stimulation either as an adjunct or standalone therapy which utilized intraluminal (endoanal or intravaginal) or surface electrode placement.

Comparator: Other forms of interventions or sham treatment.

Study designs to be included: Only Random Control Trial studies that highlighted the effects intraluminal or surface electrode placement in the management of PPAI.

Eligibility criteria: 5 In considering duplicate publications from the same study, the most recent or most comprehensive publications were used.

Information sources: Search of the bibliographic database and grey literature, and (ii) the choice of studies for inclusion based on eligibility criteria. Searches involved some combinations of search terms from medical subject headings (MeSH) and keywords with a mix of symbolic logic within the title, abstract and text for the population, intervention, control and outcomes, first in a preliminary or pilot search to determine the sensitivity of the search strategy. Additional searches were made of the reference list of identified studies.

Main outcome(s): Pelvic floor muscle activity, pelvic muscle strength (squeeze pressure), symptom severity, quality of life.

Additional outcome(s): Pelvic muscle structural dimension dimensions.

Data management: The search results were exported to the RefWorks™ manager where the Checks for duplication of the identified studies were done. Using the RefWorks™ manager, the bibliographic records were exported to Microsoft Excel 2007 for organization and sorting of articles according to specific eligibility criteria. The screening was performed in two phases. (FI) (reviewer 1) carried out the first phase of screening based on the title and abstract to spot articles that met the eligibility criteria. The screening results were independently cross-checked by P.S.C. (reviewer 2). The two reviewers then read through the full text of the chosen studies for further screening, using the eligibility criteria. In order to reduce assessor bias, differences in opinions about inclusion or exclusion of any identified study were resolved either through discussion and reflection or by consulting with M.C.G. (reviewer 3). The reasons why studies were excluded were adequately stated, and a description of the study selection procedure.

Quality assessment / Risk of bias analysis:

The quality and risk of bias in the included studies were evaluated using the PEDro scale for quality appraisal of clinical trials [49]. The PEDro scale comprises a 10-item checklist, scored either "yes" or "no" on the internal validity and statistical evidence provided in the study. In evaluating the quality of each study, the "yes" in the checklist are tallied up and scored over 10. The scores for the quality of the study are categorised into three, and defined as follows: high quality (6-10), fair/moderate quality (4, 5), and poor quality (≤ 3). When any study is rated as poor quality, it suggests a possibility that the study has a high risk of bias, while a high-quality study indicates the probability that the study has a low risk of bias. Two reviewers independently adjudged the risk of bias of each of the included studies. Areas of differences were reconciled by discussion and reflection, or in consultation with the third reviewer. The quality appraisal of the quality of the included studies was done after the study selection was done while conducting data extraction and synthesis.

Strategy of data synthesis: Meta-analysis will be conducted where feasible. effects of intraluminal (endoanal and intravaginal) and surface electrode placement on pelvic floor muscle activity, strength, endurance, structural dimensions, symptom severity and quality of life in women with postpartum anal incontinence will be determined by an assessment of all the quantitative study outcomes which have analyzed the effects of these interventions. Analysis and presentation of results will be on a table and validated statistical methods will be used to evaluate the different variables.

Subgroup analysis: As deemed fit for the study.

Sensitivity analysis: As deemed fit for the study.

Language restriction: Studies in other language will not be elligible other than english language.

Country(ies) involved: Nigeria.

Other relevant information: None.

Keywords: postpartum anal incontinence, pelvic floor electrical stimulation, vaginal deliveries, intraluminal electrodes, surface electrodes.

Dissemination plans: GRADE Evidence Table and Descriptive Evidence Table will be drafted and submitted to the WHO Secretariat as stipulated in the Procedures for the Retrieval of Evidence and Summary of Evidence. Review protocol will be registered and published with PROSPERO international prospective register of systematic reviews. Also, a manuscript will be submitted to a peer-reviewed journal for

publication. Conference presentations on the study will be made where necessary.

Contributions of each author:

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