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Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review and meta-analysis protocol

Abstract

Aim: To identify, critically appraise and synthesise the best current evidence on the use of vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum.

Background: The vaginal use of cones or balls is a pelvic floor muscle training method that aims to enhance muscle performance and thereby prevent or treat urinary incontinence. Nonetheless to date, no systematic review has focused on the effectiveness of these devices specifically during the postpartum period.

Design: Quantitative systematic review with potential meta-analysis

Methods: The review will be undertaken by searching 14 scientific databases (including PubMed and CINAHL, without date restriction) and the world-wide web; experts will also be contacted for published and unpublished data. Included studies must be randomised or quasi-randomised trials and have female participants until one year after childbirth. The intervention will be compared to no treatment, placebo, sham treatment or active controls. Outcome measures will relate to pelvic floor muscle performance or urinary incontinence. Studies will be selected, “risk of bias” assessed, and data extracted by two reviewers independently. Following inter-reviewer agreement of included studies, data will be checked after entry into systematic review processing software. If appropriate, data will be synthesised by meta-analysis; if this is not possible, a narrative review only will be undertaken.

Discussion: The information gained from this systematic review will help midwives, nurses, other health professionals and women after childbirth decide how to promote female pelvic floor health and in defining further areas of study.

Why this systematic review is needed

- As childbearing challenges pelvic floor integrity, postpartum pelvic floor health is an important issue in maternity health care
- The vaginal use of cones or balls by women post partum raises the question of their effectiveness and evidence about it
- This is the first systematic review to focus specifically on the use of vaginal cones for pelvic floor muscle training in the postpartum period

Keywords (according to MeSH terms)

Postpartum Period, Pelvic Floor, Urinary incontinence, Health Promotion, Review, Midwifery, Nursing, Postnatal care

INTRODUCTION

Pelvic floor health is an important issue for childbearing women worldwide, and the impact of postpartal pelvic problems on women's lives can be considerable. O'Reilly's *et al.* (2009) and Buurman and Lagro-Janssen's (2013) interviewees felt distressed by and ashamed about their pelvic problems, which negatively affected their intimate relationships and social activities. As well as feeling uninformed and being reluctant to approach healthcare workers with their pelvic problems themselves, they described healthcare workers as not being sensitive enough to the topic. Midwives and nurses as key professionals in this period of a woman's life need to be able to deal effectively with this issue, and thus, this systematic review aims to provide all health care workers with information to be more knowledgeable and proactive in promoting pelvic floor health.

The pelvic floor seals the inferior opening of the bony pelvis. It contributes to the body's voiding and continence mechanisms, and, in the female, supports the pelvic organs (Ashton-Miller *et al.* 2001, Ashton-Miller & DeLancey 2007). It does so by its muscles (mainly the levator ani), nerves and connective tissue, and any impairment of these structures can lessen the pelvic floor's ability to accomplish the necessary tasks.

Childbearing challenges pelvic floor integrity. During pregnancy, the changes in the hormones progesterone and relaxin lead to tissue softening, and the growing uterus requiring space as well as the physiological weight gain lead to mechanical changes (Baessler & Schüssler 2008). During vaginal birth, the pelvic floor suffers mechanical trauma by (over)stretching, and there might even be tissue rupture and/or biochemical (ischaemic) damage (DeLancey & Ashton-Miller 2007, Baessler & Schüssler 2008).

This pelvic floor impairment by childbearing may or may not lead to clinical symptoms (Baessler & Schüssler 2008). One symptom indicative of a deficient pelvic floor is stress urinary incontinence, an involuntary loss of urine on effort or physical exertion or on sneezing or coughing (International Continence Society 2013). Meyer *et al.* (1998) and Lukacz *et al.* (2006) give a prevalence of stress urinary incontinence after childbirth of 3% to 36% (depending on mode of delivery) and 15% respectively; other studies, not differentiating between types of urinary incontinence, give a prevalence of urinary incontinence after childbirth of 9.3% to 38% (Brown & Lumley 1998,

Mørkved & Bø 1999, Glazener *et al.* 2001, Burgio *et al.* 2003). Other possible symptoms of pelvic floor impairment are perineal descent, pelvic organ prolapse or anal incontinence (Baessler *et al.* 2008).

Background

Pelvic floor muscle training is an effective conservative (non-surgical) treatment method for stress urinary incontinence due to impaired pelvic floor muscles generally (Dumoulin & Hay-Smith 2010) and also around the time of childbirth (Boyle *et al.* 2012). In the sense of secondary prevention, pelvic floor muscle training can also aim at enhancing performance of pelvic floor muscles in women after childbirth without urinary incontinence symptoms. It is then used to forego stress urinary incontinence (or other pelvic floor impairment symptoms) later in life. Therefore, pelvic floor muscle training should be a routine recommendation to all women during postpartum care (Abrams *et al.* 2010, The Joanna Briggs Institute 2011).

Training thereby means to learn to volitionally perform a correct pelvic floor muscle contraction (motor learning) and to enhance the pelvic floor muscles' strength and endurance (strength training) (Bø & Mørkved 2007, Bø & Aschehoug 2007, Laycock 2008). The theory behind this is twofold (Bø 2004). First, it is assumed that women learn to consciously pre- and co-counteract abrupt increases in intra-abdominal pressure by an effective contraction (called "the knack" by Miller *et al.* 1998). This improves urethral closure pressure by bringing the urethra upwards and forward against the pubic symphysis, thereby clamping it by the increasing mechanical pressure and thus preventing leakage. Second, it has been suggested that strength training enhances hypertrophy (growth), tone and stiffness of the pelvic floor muscles and connective tissue, which in turn elevates these urethral support structures within the pelvis. This limits descent of urethra and bladder neck and facilitates a more effective automatic co-contraction during intra-abdominal pressure rises.

Different approaches to pelvic floor muscle training exist (Baessler *et al.* 2008). One pelvic floor muscle training method consists in the vaginal use of cones or balls. These devices can be cylinders either conical at one end or rounded at both ends, or ball-shaped, and they come in different weights (to be increased during training) and sizes (Bø & Aschehoug 2007). According to Bø (2007), their assumed working mechanism consists of reflexive or voluntary contractions of the pelvic floor muscles to prevent the inserted cones/balls from slipping out, thus enhancing pelvic floor muscle strength. Additionally, sensory (by feeling pressure from the cone) and kinesthetic (by feeling the cone move downwards) biofeedback teaches women to identify their pelvic floor muscles so they are enabled to contract them consciously (Chiarelli & Moore 2008). Vibrating vaginal balls provide further stimulation by vibrations caused by a loose inner ball when the woman is moving (Glavind 2001). It is also possible to use the cones/balls as a resistance device during voluntarily contracting and releasing the pelvic floor muscles around them (Bø 2007, Arvonen 2001).

Rationale

Although the effect of pelvic floor muscle training by cones or balls might differ in women after childbirth because of the physiological changes during the childbearing period, no systematic review to date has focused on the vaginal use of cones or balls specifically during the postpartum period. A Cochrane review looked into the effectiveness of cones or balls for urinary incontinence and included postpartum women (Herbison & Dean 2013). Another Cochrane review by Boyle *et al.* (2012) and a systematic review by Mørkved and Bø (2014) looked into the effectiveness of pelvic floor muscle training during and after pregnancy and included cones amongst other forms of training. Urinary incontinence was used as a primary outcome in all three reviews; studies having solely considered pelvic floor muscle strength as an outcome in continent women were excluded from the Cochrane reviews, whereas the use of this outcome is not made explicit in Mørkved and Bø (2014). Pelvic floor muscle strength in continent women as an outcome was used in a systematic review on the prevention of pelvic floor dysfunction around childbirth by Harvey (2003). However, this review also only included cones amongst other pelvic floor muscle training methods, it excluded studies on the treatment of urinary incontinence, and it would now be useful to search for more recent articles to update this review's findings.

Thus, a quantitative systematic review is needed which focuses on (1) the vaginal use of cones or balls as a pelvic floor muscle training method (2) in the postpartum period, and (3) uses both pelvic floor muscle performance and urinary (in)continence as primary outcomes to estimate effectiveness of device use. Such a systematic review is proposed here.

THE REVIEW

Aim

The aim of this quantitative systematic review is to identify, critically appraise and synthesise the best current evidence on the use of vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum.

Objectives

The objective of this systematic review is to compare the effectiveness of vaginal balls or cones for improvement of pelvic floor muscle performance and urinary continence in the postpartum period to no treatment, placebo, sham treatment or active controls. A secondary objective is to gather information on effect on perineal descent or pelvic organ prolapse, adverse effects, and economical aspects.

Research question

The research question has been developed by using the PICO (population – intervention – comparison – outcome)-framework outlined by the Cochrane Collaboration (O`Connor *et al.* 2011):

Does the vaginal use of cones or balls by women in the postpartum period improve performance of the pelvic floor muscles and urinary continence, compared to no treatment, placebo, sham treatment or active controls?

Design/Methodology

This is a quantitative systematic review with a potential meta-analysis on the basis of the guidance on systematic reviews of interventions by the Cochrane Collaboration (Higgins & Green 2011).

Inclusion/exclusion criteria

Inclusion and exclusion criteria have been developed on the basis of the PICOS (PICO plus study design)-scheme of the PRISMA Statement (Liberati *et al.* 2009). The types of participants, interventions, comparisons, outcome measures and study designs included in and excluded from this systematic review are listed in the following.

Types of participants

- Women up to 1 year after childbirth at the time of beginning the intervention, of any parity, mode of birth and birth injuries, with or without urinary incontinence, will be included.
- Pregnant women, women with anal incontinence or major genitourinary/pelvic morbidity will be excluded.

Types of intervention

Vaginal use of cones or balls.

Inclusion criteria:

- cone or ball use of any frequency and duration, and of any method (combined with exercises or not)
- cones or balls of any form, size, weight or brand
- any method of instruction (advised by any health practitioner or self-taught by information material).

Types of comparison

Comparison could be done against physiological restitution (no device or treatment), placebo, sham treatment or any form of pelvic floor muscle training, e.g. physiotherapy individually or in group, or pelvic floor muscle exercises at home.

Types of outcome measures

Primary:

Either one or both of these:

- pelvic floor muscle performance (e.g. strength, endurance), determined using a valid and reliable measure, e.g. vaginal squeeze pressure or participant reported improvement
- urinary (in)continence, determined using a valid and reliable measure, e.g. quantified symptoms or urodynamics.

Secondary:

- perineal descent or pelvic organ prolapse as assessed by standardised clinical methods
- adverse effects, e.g. discomfort or pain during or after the intervention, or vaginitis, as determined in each of the included studies
- health economics, e.g. cost of interventions or teaching time, as determined in each of the included studies.

Outcomes should be measured immediately after the intervention. If longer-term follow-up data are available, these will also be analysed.

Types of study designs

Randomised and quasi-randomised controlled trials with individual or cluster randomisation and parallel design will be included. Blinding of participants is not possible for this intervention.

Search methods

Databases, reports, experts and the world-wide web will be sources for published and unpublished data and for information on ongoing projects. Bibliographic databases to be searched can be seen in table 1. The search strategy prepared for PubMed, comprising searches for synonymous textwords and subject headings and their combination by Boolean operators, is given in table 2. In addition to the focus on cones and balls, search terms for the intervention have been collected with a wider view on pelvic floor muscle exercises in general. This was done not to miss articles mentioning the relevant terms only in their full text but not in title and abstract (and in any other of the fields searched by an [all fields]-search in PubMed), which was found to be the case for literature identified in preliminary searches. For the same reason, study design is not included in the search strategy. This PubMed search strategy will be adapted according to the search functions and complexity of each database.

The references of selected trial reports or similar reviews will be screened to identify further relevant studies. Authors of included studies will be asked if they know of relevant work. The Bielefeld Academic Search Engine (BASE) and Google Scholar will help search the world-wide web, and the web sites of the International Continence Society (ICS) and cone or ball manufacturers will be screened. There will be no language or publication period restrictions. Search protocols will be maintained. The search is planned to take place between 26 February and 23 December 2014.

Studies will be searched and selected by the first (CO) and second (JC) reviewer independently screening titles and abstracts of the citations found in searches. Studies will be included if they fulfil the above defined PICOS. Disagreements will be resolved by consensus, and if further clarification is needed, the third reviewer (CM) will be consulted. The PRISMA flow chart (Liberati *et al.* 2009) will be used to document the selection process.

Quality appraisal

Included studies will be assessed for risk of bias by the first and second reviewer independently using the “Risk of bias assessment tool” of the Cochrane Collaboration (Higgins *et al.* 2011a). Domains to be considered are random sequence generation, allocation concealment, blinding of personnel and outcome assessment (blinding of participants is not possible with this intervention), completeness of outcome data and reporting, and other sources of bias. Assessment within domains will be made for each main outcome. Possible bias will be described and judged into the categories low, unclear and high risk of bias, according to the criteria laid out by Higgins *et al.* (2011a). Specific to cluster-randomised trials, recruitment bias (individuals having been recruited to the trial after randomisation of clusters), baseline imbalance and loss of clusters will be considered (Higgins *et al.* 2011b). Attempts will be made to contact the authors of studies for clarification of incomplete information. Assessments made by reviewers will be compared and disagreements will be resolved by consensus. If further clarification is needed, the third reviewer will be consulted.

Risk of bias will be presented in a table for each study and its outcomes, and across studies by description in the results section and in a “Summary risk of bias” graph and table. Sensitivity analysis will investigate risk of bias. Overall risk of bias will be summarised in a “Summary of findings” table, and magnitude and direction of possible bias for specific outcomes across studies will be discussed.

Data abstraction

Data will be extracted from selected studies using a piloted standard data extraction form adapted from the data extraction form templates of The Cochrane Pregnancy and Childbirth Group (2013) and The Cochrane Editorial Resources Committee (2013). This will include specific details on study characteristics concerning methodology, participants, intervention, comparison and analysis, as well as results and conclusions. Attempts will be made to contact the authors of studies for clarification of incomplete information or to obtain any missing data. Data will be extracted by the lead reviewer and cross checked by the second reviewer.

Data Synthesis

Quantitative analysis will be performed using the analysis software Review Manager (RevMan) 5.3.4 (The Cochrane Collaboration 2014), seeking appropriate statistical expert advice. To ensure correctness, all data will be entered into RevMan 5.3.4 by the lead reviewer and cross checked by the second reviewer. Data used will be at the

aggregate (study) level. Unit of analysis will be the participating woman in individually randomised trials and any unit used in cluster-randomised trials.

Cluster-randomised trials will be analysed alongside individually randomised trials if the authors have used an appropriate method of data analysis to account for clustered data in their published analysis. If the authors have not analysed their data to account for clustering effects, a re-analysis will be performed, or, if the necessary information is not available, inflated standard errors will be calculated for such data prior to any meta-analysis undertaken during this review (as in accordance with Higgins *et al.* 2011b). Inclusion or exclusion of cluster-randomised trials in a sensitivity analysis will consider possible differences between the intervention effects as an effect of study design.

Effect sizes for dichotomous data will be expressed as either risk ratio (RR) or risk difference (RD) with corresponding 95% confidence intervals (CI), and by the number needed to treat (NNT) if there is a statistically significant reduction in RD. Effect sizes for continuous data will be expressed as differences in means (MD) or standardised differences in means (SMD) with their standard errors. Ordinal data will be either dichotomised and treated as dichotomous data or treated as continuous data, depending on the data characteristics.

Studies will be examined for clinical heterogeneity (diversity in relation to participants, intervention, comparison), and for statistical heterogeneity. If the studies appear to be too clinically heterogeneous (as assessed by professional judgement), no meta-analysis will be performed, but the study data will be descriptively discussed and presented. If clinically homogenous, statistical heterogeneity between studies will be assessed by visual inspection of the forest plot and by calculation of the χ^2 and I^2 statistic. Interpretation of the I^2 statistic will follow Deeks *et al.* (2011), judging $I^2 > 50-60\%$ as substantial heterogeneity.

The implications of these findings for the use of meta-analysis will be as follows:

- 1) If quantitative data are found to be statistically sufficiently homogenous, the fixed effects model will be used for pooling in statistical meta-analysis.
- 2) If data are found to be statistically heterogeneous, depending on the degree, there will be either (i) no pooling of data but the quantitative data will be discussed, with findings being presented in a descriptive form. Or (ii) the random effects model will be used for pooling and the source of heterogeneity will be assessed by identification of the methodological differences between studies and by sensitivity and subgroup analyses.

The following sensitivity analyses are planned (subject to available data):

- use of a fixed or random effects model to determine pooled effect measures
- comparing different ways of dealing with ordinal data
- comparing inclusion or exclusion of cluster-randomised trials

- comparing inclusion or exclusion of quasi-randomised trials
- comparing inclusion or exclusion of studies with different levels of risk of bias
- comparing inclusion or exclusion of studies with suspected selective outcome reporting bias thought to introduce serious bias (if missing outcome data could not be provided)
- deleting each single study in turn.

The following subgroup analyses are planned (subject to available data):

- women with urinary incontinence compared to women without urinary incontinence
- use of non-vibrating cones or balls compared to vibrating balls
- different duration of device use.

If at least ten (Sterne *et al.* 2011) trials are found, a funnel plot with visual inspection and possible use of statistical tests to evaluate the plot will be used to assess the possibility of publication bias.

Ethical considerations

No ethical issues are attached to this systematic review.

Validity and reliability/rigour

Criteria having been used in the compilation of this systematic review protocol and the present report correspond to the PRISMA Statement (Liberati *et al.* 2009).

Methodological issues follow those laid out in the Cochrane Handbook (Higgins & Green 2011).

DISCUSSION

There are some operational difficulties anticipated in performing this quantitative systematic review and possible meta-analysis. Amongst the issues to consider at study and outcome level are the limitations of measurement tools. Responsiveness, validity and reliability of different pelvic floor muscle performance or urinary incontinence measures are critically discussed by different authors (Bø & Sherburn 2005, Bø *et al.* 2007, Moore & Karantanis 2008). Lack of adherence to pelvic floor muscle training interventions is common (Alewijnse *et al.* 2007), and a high number of withdrawals has been identified as a challenge in studies on the topic (Herbison & Dean 2013). The nature of the intervention makes blinding of participants to group allocation impossible, potentially leading to performance bias by device users themselves or to detection bias (overestimation of effect) in self-rating by users.

Considering the review level, the available literature might be sparse, reporting bias may be present, and studies found might be of small sample size. Reporting in the

literature with respect to methodological details or data might be of insufficient quality, and information seeking by contacting authors might not yield the desired result. Trials might be clinically heterogeneous in relation to participants, intervention and choice of comparison group. They might use different measurements of pelvic floor muscle performance or urinary continence which might render them difficult or impossible to compare. The identified issues might limit the practicability of performing a meta-analysis.

The novel aspect of this quantitative systematic review lies in being, to the authors' knowledge, the first one to look at the vaginal use of balls or cones specifically during the postpartum period, and with both pelvic floor muscle performance and urinary continence as primary outcomes to estimate effectiveness of device use. The information gained from this systematic review will be useful for midwives, nurses, other health practitioners and women after childbirth to help with promotion of pelvic floor health. It will also be useful for research to define further areas of study, and in particular to design an experimental investigation into the topic by CO.

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Table 1: Databases to be searched

<p><u>For published reports:</u></p> <ul style="list-style-type: none"> • Cochrane Central Register of Controlled Trials (CENTRAL) • PubMed • Embase • Maternity and Infant Care Database • CINAHL • PEDro • POPLINE • AMED • Index Medicus for the South-East Asian Region (IMSEAR) <p><u>For grey literature:</u></p> <ul style="list-style-type: none"> • Conference Proceedings Citation Index • ProQuest Dissertations & Theses Full Text <p><u>For citation searching:</u></p> <ul style="list-style-type: none"> • SCOPUS • Web of Science • “cited by”-link in databases <p><u>For ongoing studies:</u></p> <ul style="list-style-type: none"> • WHO International Clinical Trials Registry Platform (ICTRP)

Table 2: PubMed search strategy

<p>Filter: Humans</p> <ol style="list-style-type: none"> 1. post part* OR postpart* OR post natal* OR postnatal* OR "lying in" OR puerper* OR childbirth* OR birth* OR deliver* OR "Postpartum Period"[Mesh:NoExp] 2. cone* OR ball OR balls OR beads OR Kegel exerciser* OR weight* OR device* OR aid OR "aids" OR "Resistance Training"[Mesh] (beads and Kegel exerciser are synonyms found for balls, weight is sometimes used for cone/ball) 3. "pelvic floor" OR "pelvic hammock" OR pelvic muscle* OR "pelvic musculature" OR vaginal muscle* OR "vaginal musculature" OR circumvaginal muscle* OR "circumvaginal musculature" OR perivaginal muscle* OR "perivaginal musculature" OR levator OR pubococcyge* OR "pelvic diaphragm" OR perine* OR Kegel OR "Pelvic Floor"[Mesh] OR "Perineum"[Mesh] 4. train* OR exercis* OR educat* OR re-educat* OR reeducat* OR rehabilitat* OR restor* OR conditioning OR "Exercise"[Mesh:NoExp] OR "Exercise Therapy"[Mesh:NoExp] OR "Rehabilitation"[Mesh:NoExp] OR "Education"[Mesh:NoExp] 5. 3 AND 4 6. 2 OR 5 7. "pelvic floor" OR "pelvic hammock" OR pelvic muscle* OR "pelvic musculature" OR vaginal muscle* OR "vaginal musculature" OR circumvaginal
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- muscle* OR "circumvaginal musculature" OR perivaginal muscle* OR "perivaginal musculature" OR levator OR pubococcyge* OR "pelvic diaphragm" OR perine* OR "Pelvic Floor"[Mesh] OR "Perineum"[Mesh]
8. performance OR strength* OR "pressure" OR endurance OR tone OR toning OR tonus OR function* OR "activity" OR force OR "power" OR contraction* OR contractility OR stiffness OR "Muscle Strength"[Mesh:NoExp] OR "Physical Endurance"[Mesh:NoExp] OR "Muscle Tonus"[Mesh] OR "Muscle Contraction"[Mesh:NoExp]
9. 7 AND 8
10. "urinary stress incontinence" OR "stress urinary incontinence" OR urinary incontinen* OR urine incontinen* OR stress incontinen* OR effort incontinen* OR "involuntary urination" OR "leaking of urine" OR "leakage of urine" OR urinary leak* OR urine leak* OR urinary continen* OR "Urinary Incontinence"[Mesh]
- 11.9 OR 10
- 12.1 AND 6 AND 11

Explanation:

- unless indicated as search for a Medical Subject Heading by [Mesh], terms are searched as textwords by [all fields]
- NoExp = no explosion used for Medical Subject Heading
- * = truncation
- speech marks are used to prompt a phrase search and an only [all fields]-search respectively