

**A critical appraisal of “Vaginal cone for postmenopausal women  
with stress urinary incontinence; randomized, controlled trial”**

**By**

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## **Abstract**

This term paper attempts to answer a clinical question involving vaginal cones and pelvic floor muscle testing. More specifically, which of these would be most impactful on stress urinary incontinence and should be implemented in a therapy setting. The methods presented in the study are reproducible and are performed in a way that reduces the risk of skewing data. Neither the evaluator nor the patients were blinded, creating a bias issue. The results and discussion are thorough and correctly interpreted. Tables 2 and 3 present accurate information, however a better explanation regarding the intergroup p values being selectively included or excluded would have been beneficial for the readers' understanding. Despite these few shortcomings, this article is regarded as a reputable source of information. An important strength of the article is its numerous references to related studies about the outcome measures and similar tests with results. In the end, it was concluded that both vaginal cones and PFMT are equally efficient at decreasing SUI complications.

**Key words:** vaginal cones, pelvic floor muscle testing, stress urinary incontinence

## **Introduction**

Stress urinary incontinence (SUI) is unintentional urine loss that occurs during physical activity—such as running or coughing—due to pressure being placed on the bladder. Women—particularly post-partum and post-menopausal—are at a much higher risk for developing SUI, with a prevalence between 25-45% worldwide. There are a variety of methods that are used to strengthen pelvic floor muscles which decreases incontinence accidents. Some of these approaches include pelvic floor muscle training and the use of vaginal cones. This article answers the clinical question of which method is most effective at decreasing SUI accidents and would be best implemented in physical therapy practice.

## **Methods**

When searching for articles related to interventions for SUI, I primarily used PubMed and Angelo State's online library. I also attempted to use PEDro, but most of the results on this database were the same as what was already found on PubMed. Keywords “vaginal cones” with the inclusion of “pelvic floor muscle testing” were used, although this yielded only 3 results. After broadening the search by using “vaginal cones” alone, results increased to 99 hits. The clinical question at hand requires both PFMT and vaginal cones, hence the inclusion of both for keywords; however, many the articles that appeared without the inclusion still discussed both methods. Lastly, I placed a limit of only clinical trials by using a filter, which dropped the results back down to a modest 14 results. Before adding this filter, the results were predominantly systematic reviews.

After narrowing my results to 3 relevant articles, I eventually chose the article by V.S Pereira, M.V. de Melo, G.N. Correia and P. Driusso because it was the only article that strictly focused on the two interventions mentioned previously. The other two articles included both PFMT and vaginal cones, but they also included other irrelevant methods that distracted from what my clinical question intended to explore. This article was published in the Climacteric journal, which has an impact factor of 2.264. The article was published in 2012 with the study being conducted at the Federal University of Sao Carlos in Brazil.

## **Results**

### Summary of the study

Those performing the study hypothesized that women who used vaginal cones would show a decrease in urinary incontinence complications than women who have not used these devices. This was a randomized, controlled study with parallel randomization between control, PFMT and vaginal cones. Subjects included postmenopausal Brazilian women with urine leakage the previous month from coughing, sneezing or running and all had similar demographic and clinical characteristics.

### Appraisal of the study introduction

The introduction sufficiently addresses all critical variables mentioned in the article's title and presented the information in a way that was clear, easy to read and concise. The title also specifies that the women tested are postmenopausal. The introduction explains why this subset of women is being targeted for this study instead of simply testing women in general. Women

spend a significant portion of their lives post-menopause, which is when the onset of urinary incontinence is most prevalent. The authors also referenced a systematic review that supported the assertion that vaginal cones are beneficial; however, this review only compared the cones to no treatment. At the end of the introduction, the authors clearly state their hypothesis as well as what they plan to discover.

Despite the introduction's strengths, it's missing pertinent information regarding pelvic floor muscle testing which is the current gold standard that vaginal cones are being compared against. Without sufficient knowledge about PFMT, the readers won't be able to fully comprehend how well the vaginal cones work in comparison and which method is best to use in practice. Furthermore, a more thorough explanation of what vaginal cones are and how they are used would be beneficial. The literature referenced in the introduction are from credible sources with impact factors in respectable ranges. Since this was a study completed in Brazil, a couple of the references were not in English, making it difficult to assess their credibility.

#### Appraisal of the study methods

All three groups in this study had similar sociodemographic, clinical and prognostic characteristics. More specifically, all subjects were female, postmenopausal, have experienced urinary incontinence and were Brazilian. Further comparisons were made about age, BMI, number of deliveries and menopause years. These comparisons showed no significant differences, allowing for fair comparisons between the three interventions. Additionally, all intervention groups were treated similarly, with equal number of therapy session with equal length. Descriptions of both interventions were clear and thorough, including types of contractions, number of contractions, length of contractions and positions in which they were

performed. Specifications were also made to the weight of the cones and even explained the test performed to determine which weight was best for each patient. The authors were also efficient at describing the outcome measures (1-h pad test, pelvic floor muscle contraction pressure evaluation and the KHQ questionnaire), providing references to the protocols, and stating the ICC and SEM numbers which show the validity and reliability of the measures.

A major flaw with this research design was the fact that neither the therapist performing the intervention, nor the participants were blinded, except during the initial evaluation. The article also failed to explain why two women, both of whom were part of the PFMT group, decided to drop out of the study. Since reasons for quitting weren't mentioned, it is unknown whether they left due to complications with the treatment or dissatisfaction with that particular intervention. With the sample sizes within each group were small to begin with (15 subjects per group), losing two participants in one group may skew the data. If the two women who left did so because the intervention wasn't working, it'll make PFMT look more successful than it truly is since the two failed cases were not included. One limitation when replicating this intervention would be finding a physical therapist that is trained in women's health to carry out the testing. Although the outcomes measures were explained in sufficient detail, there could have been more specifics about what pelvic floor muscles were being tested. Additionally, there could have been a better explanation in the statistical analysis section about what each of the named analyses meant.

#### Appraisal of the study results

The authors present the results in an organized manner by referring to each intervention in the same order in each topic's paragraph. The results addressed the hypothesis; however, since

the hypothesis was broad, it was easy to address. Most outcome parameters were discussed in the results section. Both primary outcomes—urinary leakage and muscle pressure—were thoroughly discussed. In the last paragraph, the authors briefly discuss secondary outcomes, such as satisfaction and continuity of training.

Although most outcomes were addressed, there was no reference to the third secondary outcome, quality of life. The tables were easy to understand, except for one aspect. The control group was included for the intergroup p value in the “after treatment” column, but not included in the “6 weeks after the end of treatment” column. This is to show that the difference between treatments and control group are statistically significant while treatment between the two interventions were not significant. Although the values are accurate, the presentation of this information should have been clearer or explained in the literature. At first glance, it looks as if the p values were being skewed with the inclusion or exclusion of the control group.

#### Appraisal of the study discussion

In the discussion, the authors went into more detail about why vaginal cones were thought to be potentially more efficient and mentioned that their hypothesis was incorrect. They also made multiple references to other related studies and compared them to their own results. During these comparisons, they explained differences in results between these studies as well as some variances in methods and why those differences may have led to each study’s result. The authors mention limitations of their study, including the blinding issue mentioned previously as well as the small sample size.

It is claimed that PFMT and vaginal cones both helped the women with incontinence, which is true for most parameters, however table 3’s intragroup p values show that neither of

these groups were statistically significant in “general health.” This indicates slight over conclusion of their findings, although most of their claims are accurate.

## **Discussion**

This study shows that therapists can use either PFMT techniques or the vaginal cone to strengthen pelvic floor muscles and confirms that both interventions show equal improvements in a variety of aspects in comparison to women who were not treated. Areas of improvement included decrease in urinary leakage, increase in muscle pressure, decrease in incontinence impact and decrease in gravity measures. My clinical question sought to discover which intervention was best in reducing urinary incontinence complications. This study did not show which was superior, rather that they are equal.

This article shows evidence that either method would work successfully in the clinical setting. One potential risk of the cone is the continuation of use after therapy sessions. Both interventions have risks of incorrect body mechanics once patients no longer have a therapist providing cues. This study would have a better source of information if the evaluator and patients were blinded, eliminating potential bias from the therapist.

Overall, the authors were thorough in their testing and presentation, making replication of the methods possible. Although there were limitations, the greatest of which was the blinding issue, the rest of the methods were clearly explained, and the results were accurately interpreted. Information presented in this paper can be safely applied to the clinical setting and has been supported by various other studies. Resources to replicate these methods are easily attainable and with the descriptions provided in the paper, therapists with limited knowledge of the women’s health field will be able to perform with little difficulty.

This appraisal concluded that the methods and results of this study are sound and could be reproduced. For future related studies, the blinding issue should be addressed, and more subjects included. Further investigation into related studies would be beneficial for the reader. All said, these interventions would be appropriate and helpful in the clinical setting.