Aims: The findings are limited about the long-term effects of treatment with vaginal cones in women with stress urinary incontinence (SUI). The aim of this study was to investigate the long-term effects of vaginal cones and pelvic floor muscle training in post-menopausal women with SUI. Methods: This randomized controlled trial included 45 post-menopausal women with SUI. They were randomly allocated in three groups: vaginal cones (VC, n = 15), pelvic floor muscle training (PFMT, n = 15), and control group (CG, n = 15). Women in VC and PFMT groups were treated for 6 weeks with twice weekly sessions. Women in VC group carried out the pelvic floor muscle strengthening with vaginal cones. The CG did not receive any treatment during the corresponding time. Women were evaluated before treatment, at the end, 3 and 12 months after treatment completion for primary outcome (urinary leakage) and secondary outcomes (pelvic floor muscle strength, quality of life, satisfaction with treatment, and continuity of training).

Results: There was a significant decrease of urinary leakage in the VC and PFMT group comparing values at the end of treatment, 3 and 12 months to baseline values. There were no differences between VC and PFMT group in primary outcome in any evaluations.


Key words: conservative treatment; female urinary incontinence; pelvic floor muscle training; vaginal cones
previous treatment for UI or hormone therapy, ongoing urinary tract infections, cognitive or neurological disorder, inability to perform the proposed procedures. 

For the safety of patients, the presence of uncontrolled hypertension was also considered an exclusion criterion because isometric exercises, as pelvic floor muscle training, can increase both systolic blood pressure and diastolic blood pressure. 

All participants provided informed consent and were instructed about the study protocol. Forty-nine potential participants were screened and 45 met the criteria. They were allocated according to a computer-generated randomization list in three groups: vaginal cones (VC, n = 15), pelvic floor muscle training (PFMT, n = 15) and control group (CG, n = 15). Participants were randomly assigned following simple randomization procedures (computerized random numbers) to VC, PFMT, or CG group. A researcher not involved in the data collection or analyses created the randomization list. Allocation was concealed in sequentially numbered, sealed, opaque envelopes. Immediately after collecting baseline data, the physical therapist opened the allocation envelope, which contained the participant’s group.

**Treatment Protocol**

The treatment protocol was carried out as outpatient activities under the supervision of the same physical therapist that carried out the evaluations. The treatment for the VC and PFMT groups consisted of 12 sessions, with two 40 min sessions per week and total of 6 weeks of treatment. During the sessions, participants received instructions about anatomy of the pelvic floor muscles and continence mechanisms and carried out exercises to strengthen the pelvic floor muscles in supine, sitting, and standing positions. The difficulty degree progressed according to the positions adopted, increasing the number of repetitions and time of sustained contraction. An average of 100 contractions were performed per session, with phasic contractions, lasting 3 sec with 6 sec of rest, and tonic contractions, lasting 5–10 sec followed by 10–20 sec of rest. To minimize muscle fatigue, resting time was rigidly observed in all sessions and the time of sustained contraction was slowly increased. At the beginning of the treatment, the time of sustained contraction was the same recorded for each woman during the initial evaluation. For both groups, the time of sustained contraction was increased by 1 sec per week up to 10 sec.

Women of VC group performed the pelvic floor muscle strengthening with vaginal cones during the whole session. Five vaginal cones (Femcone, Quark Medical Products, Piracicaba, Brazil) of the same volume and size, and weight varying from 20 to 100 g were used. The cone was inserted into the vagina in the supine position by a trained physical therapist. Treatment was initiated with the cone with which the patient was able to walk for 1 min without expelling it. In each session, a new test was performed in order to progress the weight of the cone used. After treatment completion, participants were instructed about the importance of exercises and received a booklet consisting of written instructions and illustrations for continuation of pelvic floor muscle exercises at home twice a week. As the purpose of this study was to investigate whether the results would remain with the simple exercises at home, the VC group carried out the exercises at home without the vaginal cone. The CG did not receive any treatment during the corresponding treatment time. Afterwards, CG subjects were evaluated and referred to physical therapy treatment.

Outcome Measurements and Follow-Up

Only one not blinded experienced physical therapist performed evaluations of the three groups. Initially, all women went through a complete physical examination and an interview regarding their thorough medical history. Women were evaluated before treatment, at the end, 3 and 12 months after treatment completion for primary outcome (urinary leakage) and secondary outcomes (pelvic floor muscle strength, quality of life, satisfaction with treatment and continuity of training). Women in the CG carried out a similar evaluation just before and after the corresponding time of treatment but were not asked about satisfaction with treatment. The primary investigator carried out a prior evaluation of the test–retest reliability. Ten women with UI were tested on two occasions, separated by 1 week, to determine the intraclass correlation coefficients (ICC) and standard errors of measurement (SEM) for all variables.

The 1-hr pad test was carried out to evaluate urinary leakage according to the protocol proposed by Abrams et al. The participants were instructed to place a pad previously weighed on a precision balance Denver APX200 (precision of 0.0001 g. Denver Instrument, Bohemia, NY) and then drink 500 ml of water. After 30 min, they started performing a series of provocative exercises and at the end of 1 hr, the pad was removed, reweighed and the urinary loss was calculated. The ICC and the SEM for this variable were 0.99 and 0.45 g.

To evaluate the pelvic floor muscle strength, a Perina Stim device (Quark Medical Products) was used, graded from 0 to 60 cmH 2O and supplied with a vaginal probe. Participants were positioned in supine, with hip and knee flexion. The vaginal probe was inserted into the vagina and the device was calibrated. Then, participants were asked to perform three 3-s maximum perceived effort contractions of pelvic floor muscles. The participants were instructed not to use abdominal, gluteal and/or hip adductor muscles during the contractions and carry out the “inward and up” movement. The contractions were considered valid only when this pelvic floor muscle movement could be observed. The ICC and SEM were 0.97 and 0.53 cmH 2O, respectively.

For the assessment of quality of life, the KHQ was used. This questionnaire consists of 30 questions, divided into nine individually scored domains. Because it is a long questionnaire, three broad domains related to UI were chosen. These domains (ICC; SEM) are: general health (0.79; 8.69), incontinence impact (0.82; 13.33), and severity (0.91; 7.60). The total score ranges from 0 to 100 and a score of 100 represents the worst possible quality of life, and 0 represents the best possible quality of life.

In the follow-up evaluations, the women were asked if they performed the pelvic floor muscles exercises at home with the same frequency of that carried out during the supervised treatment. The participants answered “yes” or “no” to the question: “Did you carry out the pelvic floor muscle exercises twice a week every week since you finished the treatment?”

Statistical Analyses

All statistical analyses were performed using Statistica software (version 7.0, StatSoft, Inc., Tulsa, OK). To test data distribution in each group, the Shapiro Wilk test was used. As the majority of data did not show normal distribution, nonparametric tests were used. The intragroup analysis in the three evaluations was carried out with the Friedman tests. Pair wise comparisons were carried out with the Wilcoxon signed-rank test if the overall difference was statistically significant.
For the intergroup analysis before and after treatment, the Kruskal–Wallis tests were used. Pair wise comparisons were made with the Mann–Whitney test to compare the groups. This same test was carried out for the follow-up evaluation because only two groups (VC and PFMT) composed the analysis. Differences were considered significant when the P-value was <0.05. To measure the practical significance of the data, the effect size and the confidence interval were calculated. The effect sizes were considered mild if values were smaller than 0.20; moderate if values were between 0.25 and 0.75, and large when values were over 0.80.\(^\text{18}\)

**RESULTS**

Among the 45 women who started treatment, two women of the PFMT group (11.7%) and two women of the CG (11.7%) did not complete the treatment or did not perform the final evaluation due to family health problems and were excluded from the sample. Forty-one participants completed the study and were included in the analysis (Fig. 1). There were no significant differences between groups in terms of demographical and clinical characteristics (Table I).

There was a significant decrease of urinary leakage in the VC group when comparing values at the end, 3 and 12 months after treatment (all \(P < 0.001\); effect size \(-0.96; 95\%\) confidence interval from 0.65 to 6.65) to baseline values. A similar behavior was verified for the PFMT group (all \(P < 0.001\); effect size \(-0.93; 95\%\) confidence interval from 0.46 to 6.52). In the intergroup analysis, there was a significant difference only in the evaluation post-treatment between VC group and CG (\(P < 0.001\)) as well as between PFMT group and CG (\(P < 0.001\); Table II). In the analysis of the pelvic floor muscle strength, a significant increase in the VC (\(P < 0.01\); effect size 2.96; 95\% confidence interval from 23.25 to 42.01) and PFMT (\(P < 0.01\); effect size 2.09; 95\% confidence interval from 17.24 to 38.76) groups were verified when comparing values at the three evaluations after treatment to baseline values. There was also a significant reduction in pelvic floor muscle strength in VC and PFMT groups when comparing values after treatment and 12 months later (\(P = 0.03\) and \(P < 0.01\), respectively). The intergroup analysis showed statistical differences between VC group and CG (\(P < 0.001\)) as well as between VC group and PFMT group when comparing values after treatment and 12 months later (\(P < 0.01\); Table II).

**DISCUSSION**

After treatment completion, we verified improvement in urinary leakage, in pelvic floor muscles strength and in quality of life of post-menopausal women with SUI in response to treatment with and without the use of vaginal cones. Three months after treatment completion, we observed maintenance of the results in VC and PFMT groups. But after 12 months, a decrease of the pelvic floor muscle strength was observed in both treatment groups; nonetheless, this decrease was not great as to match baseline values. These results disagree with the only study found that evaluated the long-term results of vaginal cones. Gameiro et al.\(^\text{5}\) also treated incontinent women with and without the use of vaginal cones and they found equal benefit between the two treatment types on urinary leakage, number of used pads and pelvic floor muscle strength. However, after 6 and 12 months
they observed the maintenance of the results of urinary leakage and pelvic floor muscle strength, which disagrees with our results. Despite some similarities, the heterogeneity of populations and intervention protocols may explain the disparity of results. Gameiro et al.\(^5\) treated women with symptom of predominant SUI but 50% also presented urge incontinence. Moreover, their protocols consisted of one 40-min session per week over a 12-week period, and women continued using vaginal cones during the follow-up period.

It is generally accepted that neural factors play an important role in muscle strength gains in the first 8 weeks of training. In this period of training is observed a gain in muscle strength without muscle hypertrophy. An increase in muscular strength without noticeable hypertrophy is the first line of evidence for neural involvement in acquisition of muscular strength.\(^19\) As this study involves 6 weeks of treatment, possibly the strength gain observed can be justified by the presence of neural changes, such as changes in the motor units recruitment. Moreover, it is known that after the strength gain resulting from muscle training, maintenance of muscle strength occurs with continued exercise. According to Kraemer,\(^20\) exercises for muscle contraction with a weekly frequency of once or twice are able to act in the maintenance of previous strength gains obtained by a strength training program. However, the total disruption of the exercise may lead to a muscle strength reduction of about 5–10% per week.\(^21\)

In the present study, 53.3% of VC women and 53.8% of PFMT women continued performing the exercises at least twice a week, with a similar percentage between the two groups. A decrease of the exercises continuation percentage is observed as the years of follow-up of women who received supervised treatment without the use of vaginal cones increase. Alewijnse et al.\(^22\) found that 67% of women continued the exercises after a year, while Bø et al.\(^23\) evaluating women 15 years after the end of treatment found that only 28% of patients had persisted in performing the exercises.

It is known that the continuation of the pelvic floor muscles training takes time and motivation. Thus, it may be influenced by barriers such as lack of discipline, time and energy, stressful situations and difficulties in integrating exercises in daily life,\(^22\) and therefore cannot be considered as dependent on the type of treatment. The initial hypothesis that women treated with use of vaginal cones would have better outcomes has not been confirmed, possibly because, in the follow-up period, participants were instructed to perform exercises

**TABLE II. Values and Intragroup and Intergroup Analysis of Urinary Leakage and Pelvic Floor Muscle Strength for the Three Groups Before, After Treatment, 3 and 12 Months After the End**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Pre (g)</th>
<th>Post (g)</th>
<th>3 months (g)</th>
<th>12 months (g)</th>
<th>Intragroup P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary leakage (g)</td>
<td>VC</td>
<td>2.2 (1.1, 18.3)</td>
<td>0.14 (0.1, 0.2)(^a)</td>
<td>0.3 (0, 1.5)(^a)</td>
<td>0.2 (0, 2.6)(^a)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>PFMT</td>
<td>1.9 (1.0, 15.2)</td>
<td>0.2 (0.1, 0.3)(^a)</td>
<td>0.1 (0, 0.9)(^a)</td>
<td>0.1 (0, 1.2)(^a)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>1.9 (1.1, 16.4)</td>
<td>2.2 (0, 14.9)</td>
<td>—</td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Intergroup P-value</td>
<td>VC</td>
<td>0.58</td>
<td>&lt;0.001</td>
<td>0.16</td>
<td>0.27</td>
<td></td>
</tr>
<tr>
<td>Strength (cmH(_2)O)</td>
<td>VC</td>
<td>10.3 (4, 38)</td>
<td>48.0 (16.7, 60)(^ab)</td>
<td>48.7 (15, 60)(^a)</td>
<td>34.7 (7, 60)(^ac)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>PFMT</td>
<td>10.7 (2.7, 43.3)</td>
<td>28.0 (16, 60)(^ab)</td>
<td>37.3 (15, 60)(^a)</td>
<td>15.3 (7, 60)(^ac)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>9.3 (7, 16)</td>
<td>9.0 (7, 17)</td>
<td>—</td>
<td>—</td>
<td>0.18</td>
</tr>
</tbody>
</table>

Data presented as median (minimum, maximum).

\(^a\)Differences versus pre (Friedman tests).

\(^b\)Differences versus control group (Kruskal–Wallis tests).

\(^c\)Differences versus post (Friedman tests).

**TABLE III. Values of the KHQ Domains for the Groups**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Pre (c)</th>
<th>Post (c)</th>
<th>3 months (c)</th>
<th>12 months (c)</th>
<th>Intragroup P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General health</td>
<td>VC</td>
<td>25.0 (0, 75)</td>
<td>25.0 (0, 50)</td>
<td>25.0 (0, 50)</td>
<td>25.0 (0, 50)</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>PFMT</td>
<td>25.0 (0, 75)</td>
<td>25.0 (0, 50)</td>
<td>25.0 (0, 50)</td>
<td>25.0 (0, 25)</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>50.0 (0, 75)</td>
<td>25.0 (0, 75)</td>
<td>—</td>
<td>—</td>
<td>0.14</td>
</tr>
<tr>
<td>Intergroup P-value</td>
<td>VC</td>
<td>0.14</td>
<td>0.71</td>
<td>0.55</td>
<td>0.15</td>
<td></td>
</tr>
<tr>
<td>Incontinence impact</td>
<td>PFMT</td>
<td>100.0 (0, 100)</td>
<td>33.3 (0, 67)(^ab)</td>
<td>0.0 (0, 33)(^ac)</td>
<td>0.0 (0, 100)(^a)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>33.3 (0, 100)</td>
<td>0.0 (0, 67)(^ab)</td>
<td>0.0 (0, 33)(^ad)</td>
<td>0.0 (0, 33)(^ae)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intergroup P-value</td>
<td>VC</td>
<td>0.22</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>Severity measures</td>
<td>PFMT</td>
<td>60.0 (20, 100)</td>
<td>6.7 (0, 60)(^ab)</td>
<td>6.7 (0, 20)(^ad)</td>
<td>7.0 (0, 40)(^abce)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>40.0 (20, 100)</td>
<td>46.7 (20, 100)</td>
<td>—</td>
<td>—</td>
<td>0.27</td>
</tr>
<tr>
<td>Intergroup P-value</td>
<td>VC</td>
<td>0.41</td>
<td>0.01</td>
<td>0.12</td>
<td>0.03</td>
<td></td>
</tr>
</tbody>
</table>

Data presented as median (minimum, maximum).

\(^a\)Differences versus pre (Friedman tests).

\(^b\)Differences versus control group (Kruskal–Wallis tests).

\(^c\)Differences versus PFMT group (Kruskal–Wallis tests).

\(^d\)Differences versus post (Friedman tests).

\(^e\)Differences versus 3 months (Friedman tests).
without the vaginal cones. Hence, during follow-up, the biofeedback effects afforded by the vaginal cones\textsuperscript{6} would not be present during training and any benefits achieved by the VC group would indicate advantages of the treatment with vaginal cones gained during the period of supervised treatment.

The assessment of quality of life is recommended by the ICS as a supplement to clinical measures of UI.\textsuperscript{3} Treated groups showed improvement on the quality of life in incontinence impact and severity domains. Significant differences were observed between VC and PFMT group after 3 months in the incontinence impact domain and after 12 months in the severity measures domain, with the presence of scores indicating better quality of life for the PFMT group. This finding may be related to the presence of lower values for urine leakage average in this group, although that difference was not significant.

The main limitation of our study was that the therapist who carried out the evaluation and treatment was not blinded and this could have influenced the results. The small sample size is other limitation of this study. A larger sample size could have altered some of the results of the study. However, despite the small sample size, the calculation of effect size showed that the treatment had a large effect on clinical variables. Moreover, we must consider that a longer treatment may have shown differences in the results of VC and PFMT groups. Therefore, further research is required before definite conclusions could be drawn.

CONCLUSION

Treatments with and without vaginal cones can promote positive long-term effects on urinary leakage, pelvic floor muscle strength, and quality of life in post-menopausal women with SUI.

REFERENCES