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Vaginal cone for postmenopausal women with stress urinary incontinence: randomized, controlled trial

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Key words: PELVIC FLOOR MUSCLE, POSTMENOPAUSAL WOMEN, URINARY INCONTINENCE, VAGINAL CONES

ABSTRACT

Objective To investigate the effect of vaginal cones and pelvic floor muscle training (PFTM) in postmenopausal women with stress urinary incontinence.

Methods This randomized, controlled study included postmenopausal women, who complained of stress urinary incontinence. Forty-five women were allocated to three groups: a group given therapy with vaginal cones ($n = 15$), a group receiving therapy with PFTM ($n = 15$), and the control group ($n = 15$). Subjects in the intervention groups were treated for 6 weeks with twice-weekly sessions of 40 min. Women in the vaginal cone group carried out the pelvic floor muscle strengthening with vaginal cones. The control group did not receive any treatment during the corresponding time. They were evaluated before, at the end of treatment and 6 weeks after treatment completion for primary outcomes (1-h pad test for urinary loss and pelvic floor muscle pressure) and secondary outcomes (quality of life with King's Health Questionnaire, satisfaction with treatment, and continuity of training).

Results For urinary leakage, there were statistical differences between the treated groups and the control group at the end of treatment and 6 weeks after treatment (all $p < 0.01$; effect size: vaginal cone group −0.97; PFMT group −0.96). The same behavior was shown for treatment with pelvic floor muscle pressure (all $p < 0.01$; effect size: vaginal cone group −2.58; PFMT group −1.68). There were no differences between the vaginal cone and PFMT groups in any of the evaluations. In outcomes for quality of life, significant differences were observed for incontinence impact and gravity domains when both treated groups were compared with the control group after treatment. Both groups reported similar satisfaction levels and the vaginal cone group demonstrated lower training continuity.

Conclusion Based on this study, there were similar positive results for treatment with the vaginal cone and pelvic floor muscle training for urinary leakage, pelvic floor muscle pressure and quality of life for postmenopausal women with stress urinary incontinence after 6 weeks.

INTRODUCTION

Urinary incontinence (UI) is defined as any involuntary loss of urine[1] and shows a higher incidence among women. It is estimated that the prevalence may vary between 25 and 45% worldwide, and stress urinary incontinence (SUI) is the most common form[2]. This dysfunction is responsible for multiple effects on the mental and social well-being of women, affecting significantly their quality of life[3]. Its high incidence, coupled with the psychological, social and economic impacts, makes UI a troubling health condition[4].

It has been shown that women have a higher prevalence of UI during the menopausal period, with 70% of them relating the onset of symptoms with the cessation of menstruation[5]. Furthermore, the increase in life expectancy means that women spend more than one-third of their lives in the postmenopausal period[6] and the prevalence of UI in women in this period has been increasing, reaching to between 26.2 and

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35% of Brazilian women[7]. Given this situation, the need for adequate treatment to reduce the impact of UI in women in this period is clear. Currently, the International Continence Society (ICS) recommends physical therapy as the first treatment option for SUI[1]. Different therapies are used for physical therapy, having as their main objective the strengthening of the pelvic floor muscles[8]. Among them, pelvic floor muscle training using vaginal cones, as proposed by Plevnik[9], seems to be effective for preventing a sense of slipping out, inducing a contraction of the pelvic floor muscles. However, the results of studies using vaginal cones are still inconclusive, since the evidence that vaginal cones are more effective than pelvic floor muscle training is limited[10].

In a systematic review, Herbison and Dean[10] found that treatment with vaginal cones is beneficial when compared to no active treatment. However, there is no consensus on the superiority of using these devices when compared to other treatments[10]. Thus, the purpose of this study was to investigate the short-term effect of vaginal cones and pelvic floor muscle training in postmenopausal women with SUI. It was hypothesized that women treated with vaginal cones would demonstrate better results when compared to treatment without these devices and no treatment.

MATERIALS AND METHODS

This was a randomized, controlled study, with parallel randomization (1 : 1 : 1), performed from April 2009 to April 2010 at the Laboratory for Assessment and Intervention on Women's Health, Federal University of São Carlos. The local ethics committee approved the study (report #180/2008), which is in agreement with the Declaration of Helsinki. The women were recruited through newspaper and website advertisement. This study included postmenopausal women, defined by the absence of vaginal bleeding for 12 months[7], with at least one episode of urine leakage during the previous month. One standard question about SUI was used to determine patient eligibility. The question is part of the King's Health Questionnaire (KHQ) scale of urinary symptoms[11]. This is a reliable instrument, validated in Brazilian Portuguese[12] and specific for women with UI. The question was 'Do you lose urine with physical activities such as coughing, sneezing, running?'. Only women who answered 'yes' to the question were recruited. Exclusion criteria also included previous treatment/surgery for UI or hormone therapy, ongoing urinary tract infections, cognitive or neurological disorder, uncontrolled hypertension, and inability to perform the proposed procedures[13].

All participants signed an informed consent and were instructed about the study protocol. A total of 49 potential participants were screened and 45 met the criteria (Figure 1). They were allocated according to a computer-generated randomization list into three groups: a group given therapy with vaginal cones (VC) ($n = 15$); a group receiving therapy with pelvic floor muscle training (PFTM) ($n = 15$); and the control group ($n = 15$). For the allocation, a researcher not involved in data collection or analysis developed a randomization schedule and produced 45 consecutively numbered, sealed, opaque envelopes containing each participant's allocation. Immediately after collecting baseline data, the evaluator opened the allocation envelope, which contained a paper on

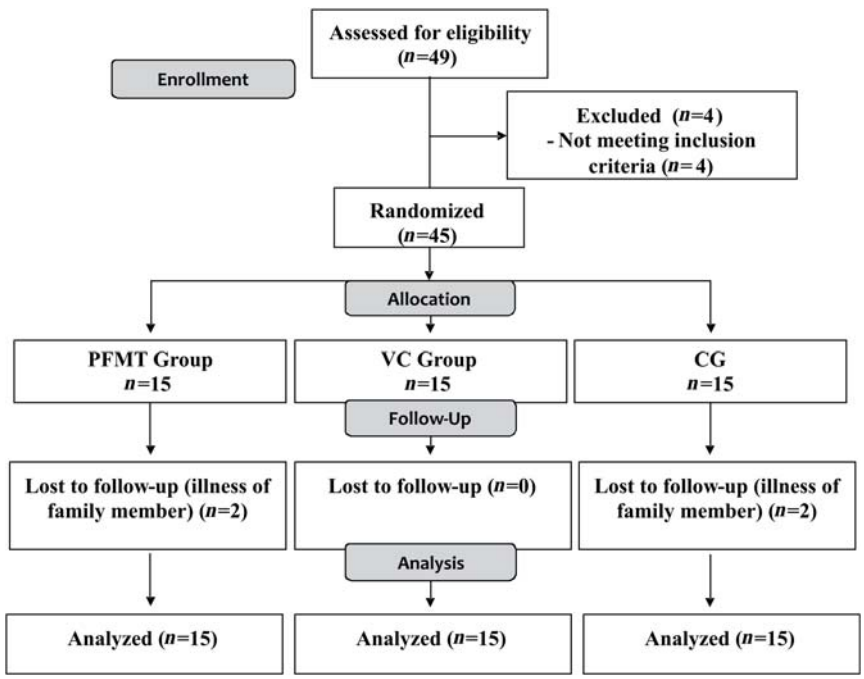

Figure 1 Flow diagram of the study. VC, vaginal cone; PFMT, pelvic floor muscle training; CG, control group

which was written 'pelvic floor muscle training', 'vaginal cone' or 'control' group. Therefore, all participants were allocated to one of the three groups.

Outcome measurements

Only one unblinded experienced physical therapist performed all evaluations of the three groups. Initially, all women went through a complete physical examination and an interview regarding their thorough medical history. The VC and PFMT groups were evaluated before the treatment, at the end of treatment and 6 weeks after the treatment for primary outcomes (urinary leakage and pelvic floor muscle pressure) and secondary outcomes (quality of life, satisfaction with treatment, and continuity of training). The women in the control group carried out a similar evaluation just before and after the corresponding time of treatment but they were not asked about satisfaction with treatment. The primary investigator carried out a prior evaluation of the test–retest reliability. Ten women with SUI 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-h pad test was performed to evaluate urinary leakage according to the protocol proposed by Abrams and colleagues[14]. The women were instructed to wear a pad which had been previously weighed on a precision balance (Denver APX200, precision of 0.0001 g, Denver Instrument, Denver, USA) and then drink 500 ml of water. After 30 min, they started performing a series of provocative exercises and, at the end of 1 h, the pad was removed, reweighed and the urinary loss calculated. The ICC and the SEM for this variable were 0.99 and 0.45 g.

The evaluation of the pelvic floor muscle contraction pressure was carried out by the perineometer Perina Stim (Quark Medical Products, Piracicaba, Brazil), graduated from 0 to 60 cmH_2O and equipped with a vaginal probe. The women were positioned in the supine position, with hip and knee flexion. The vaginal probe was inserted approximately 3.5 cm into the vaginal cavity and the device was calibrated. Then, the women were verbally instructed and motivated to perform three pelvic floor muscle contractions each of 3 s with maximum perceived effort. The women were also instructed to avoid using the abdominal, gluteal and hip adductor muscles during the contractions and carry out the 'inward and up' movement. Only when this pelvic floor muscle movement was seen were the contractions considered valid[15]. The mean of three contractions was used for analysis. 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 gravity (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[11].

At the end of the treatment and after a further 6 weeks, women in the VC and PFMT groups were questioned regarding their satisfaction with treatment. The only two response options available were 'satisfied' and 'dissatisfied'. Answering 'satisfied' indicated that the patient did not want a different treatment. Answering 'dissatisfied' indicated that the patient wanted a different treatment from the initial one[16]. In the follow-up evaluation (6 weeks after the treatment), the women were also asked if they performed the exercises at home with the same frequency as that of the exercises carried out during the supervised treatment.

Treatment protocol

During the first session, all women were taught to contract the pelvic floor muscles correctly, and this was assessed by vaginal palpation. Moreover, a physical therapist provided explanations about the anatomy of the pelvic floor muscles and lower urinary tract, physiology, and continence mechanisms.

The treatment protocol was carried out under the supervision of the same physical therapist that carried out the evaluation. Treatments for both VC and PFMT groups consisted of 12 individual sessions, with twice-weekly sessions of 40 min each. The total time of both treatments was 6 weeks. During each session 100 contractions were performed on average, composed of phasic contractions held for 3 s with 6 s of rest as well as tonic contractions, held for 5–10 s followed by 10–20 s of rest[17]. The pelvic floor muscle contraction was carried out in the supine, sitting and standing positions. The degree of difficulty progressed according to the positions adopted, the number of repetitions, and the time of sustained contraction. Women in the control group carried out no treatment during the time corresponding to the 6-week treatment, being re-evaluated after this time. Subsequently, they were referred for physiotherapy treatment.

Women in the VC group carried out the pelvic floor muscle strengthening with vaginal cones. For treatment, five vaginal cones were used (Femcone, Quark Medical Products, Piracicaba, Brazil) of the same volume and size, with weight varying between 20 and 100 g. The cone was inserted into the vagina with the woman in the supine position by a trained physical therapist. In each session, a test was performed to determine the weight of the cone for proper pelvic floor muscle training. For the initial test, the lightest vaginal cone was introduced by the therapist. The patient was instructed to walk for a minute. If the cone was kept inside the vagina of the patient, the cone weight was progressively increased in order to find the maximum weight that could be maintained inside the vaginal canal without it slipping out. The selected cone was used during all the exercises for that session. In each session, a new test was performed in order to increase the weight of the cone used[18].

At the end of both treatments, the women were instructed about the importance of exercises and received a booklet

consisting of written instructions and illustrations for continuation of exercises at home twice a week. The VC group carried out the exercises at home without the vaginal cone. The control group did not receive any orientation or treatment during the corresponding treatment time. Afterwards, control group subjects were evaluated and referred for physical therapy treatment.

Statistical analysis

All statistical analyses were performed using Statistica software (version 7.0, StatSoft Inc., Tulsa, OK, USA). All data were analyzed by intention to treat. To test the normal distribution of data in each group, the Shapiro–Wilk test was used. As the majority of data did not show normal distribution, non-parametric 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 the analysis was composed of only two groups (VC and PFMT). Differences were considered significant when the p value was <0.05. To measure the clinical significance of the data, the effect size and the confidence interval were calculated for primary outcomes. 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[19].

RESULTS

Forty-five participants were included at the intention-to-treat analysis (Figure 1) but two women of the PFMT group did only six and eight sessions, respectively, and discontinued treatment. There were no significant differences between the groups in terms of demographical and clinical characteristics (Table 1). The severity and type of prolapse were comparable among the groups. One woman in each treatment group and two control group patients had anterior wall prolapse grade I, according to the classification recommended by the ICS[1].

There was a significant decrease in urinary leakage in the VC group when compared with the values at the end ($p<0.001$; effect size −0.97; 95% confidence interval (CI) 0.76–6.0) and 6 weeks after treatment ($p<0.001$) and the values at baseline. The same behavior was shown for the PFMT group ($p<0.001$ and $p=0.001$, respectively; effect size −0.96; 95% CI 0.74–5.98). In the intergroup analysis, there was a significant difference only in the evaluation after treatment between the VC group and the control group ($p<0.001$) as well as between the PFMT group and the control group ($p<0.001$) (Table 2).

Table 1 Demographic and clinics characteristics of the study participants ($n=45$). Data are given as mean (standard deviation)

	Vaginal cone group ($n=15$)	*PFMT group* ($n=15$)	*Control group* ($n=15$)
Age (years)	66.33 (10.86)	63.0 (10.73)	62.92 (9.24)
Schooling (years)	9.33 (2.55)	9.98 (4.17)	10.02 (3.35)
Body mass index (kg/cm^2)	27.89 (1.93)	25.65 (2.79)	26.04 (1.84)
Number of deliveries	3.06 (1.16)	2.26 (1.09)	2.81 (1.32)
Vaginal delivery	2.40 (1.41)	1.40 (1.29)	2.13 (1.46)
Menopause (years)	15.93 (9.76)	14.47 (10.10)	13.42 (9.12)
Urinary symptoms (years)	3.46 (3.04)	3.67 (3.69)	3.73 (3.36)

PFMT, pelvic floor muscle training

In the analysis of pelvic floor muscle pressure, a significant increase in pelvic floor muscle pressure was shown in the VC group ($p<0.001$; effect size 2.58; 95% CI 22.23–40.43) and in the PMFT group ($p<0.001$; effect size 1.68; 95% CI 12.86–33.76) when comparing the values at the end and 6 weeks after treatment with the values at baseline. The intergroup analysis showed statistical differences between the VC group and the control group ($p<0.001$) as well as between the PFMT group and the control group ($p<0.001$) only after treatment (Table 2). For both variables, there were no differences among treated groups in any of the evaluations. In the control group, no differences were observed between the evaluations for any variable.

A significant reduction in the scores was shown at the end and 6 weeks after treatment in the VC and PFMT groups for incontinence impact (both $p=0.001$) and gravity measures (both $p<0.001$). Similarly, in the PFMT group, a significant reduction was observed at the end and 6 weeks after treatment for incontinence impact ($p=0.005$ and $p=0.003$) and gravity measures. Significant differences were observed in the intergroup analysis for incontinence impact and gravity measures domains (all $p<0.01$) when both treated groups were compared with the control group after treatment (Table 3).

Regarding reported satisfaction, 14 of 15 (93.3%) of the VC group subjects and 12 of 13 (92.3%) of the PFMT group subjects showed that they were satisfied with treatment. After 6 weeks from the end of treatment, the same result was found for the two groups. In follow-up evaluation, three of 15 (20%) of the VC group subjects and one of 13 (7.7%) of the PFMT group subjects reported that they did not perform the exercises with a minimum frequency of twice per week. There were no complaints of adverse effects due to the treatment from either group.

DISCUSSION

The benefits of strengthening pelvic floor muscles with the use of vaginal cones have been proposed by the possibility of

Table 2 Values and intragroup and intergroup analyses of urinary leakage and pelvic floor muscle pressure for the three groups before, after treatment and 6 weeks after the end of treatment. Data are given as mean (standard deviation).

Groups	*Before treatment*	*After treatment*	*6 weeks after the end of treatment*	*Intragroup p value*
Urinary leakage (g)				
VC group	7.36 (8.76)	0.27 (0.36)*†	0.36 (0.38)*	<0.001
PFMT group	3.70 (4.35)	0.29 (0.31)*†	0.19 (0.27)*	<0.001
Control group	3.87 (5.56)	3.65 (4.94)	–	0.19
Intergroup *p* value	0.91	<0.001	0.10	
Pressure (cmH_2O)				
VC group	12.60 (13.86)	43.24 (16.28)*†	43.29 (18.54)*	<0.001
PFMT group	12.55 (9.20)	35.22 (18.96)*†	37.38 (18.18)*	<0.001
Control group	11.42 (5.13)	11.91 (5.57)	–	0.18
Intergroup *p* value	0.76	<0.0.01	0.54	

*, Differences vs. before treatment (Friedman tests); †, differences vs. Control group (Kruskal–Wallis tests)
VC, vaginal cone; PFMT, pelvic floor muscle training

providing sensory-motor biofeedback[18]. It is possible that this sensory-motor biofeedback could maximize the neural gains as the greatest activation and synchronization of the motor units[20]. Therefore, the use of vaginal cones would provide a rapid gain in muscle strength[21] by neural mechanisms, followed by muscle hypertrophy in response to resistance training with progression of the cone weight. Considering these possible physiological mechanisms, it has been hypothesized that the use of vaginal cones could have advantages when compared to other modalities for treatment of UI[10]. However, contrary to our initial hypothesis, the VC and PFMT groups demonstrated similar results for primary and secondary outcomes, indicating that muscle strengthening with and without the use of vaginal cones seem to be effective for treatment of SUI.

Similarly to the results shown in the present study, there is some evidence suggesting that vaginal cones and pelvic floor muscle training have equal benefit on the outcomes of urinary leakage, number of pads used and muscle strength[18,22–24]. However, Bø and colleagues[15] found better results for the pelvic floor muscle training group on the outcome of urinary leakage when compared to electrical stimulation, vaginal cones, and no treatment for SUI. On the other hand, Arvonen and colleagues[25] showed a greater reduction in urinary leakage in the treatment group with use of vaginal cones.

The heterogeneity of populations and intervention protocols may explain the disparity of results, making it difficult to compare them[10]. The results of Bø and colleagues[15] and Arvonen and colleagues[25] are similar because they treated women with an average age of about 50 years and both studies measured urinary leakage through the pad test with a standardized bladder volume. However, the different protocols of these studies also may explain the differences found. Bø and colleagues[15] instructed the women in the PFMT group to carry out contractions three times a day, every day, and then weekly sessions of 45 min with supervision, and the women in the VC group were told to carry out the exercises for 20 min each day. Moreover, Arvonen and colleagues[25]

Table 3 Values of the King's Health Questionnaire domains for the groups. Data are given as mean (standard deviation)

Groups	*Before treatment*	*After treatment*	*6 weeks after the end of treatment*	*Intragroup p value*
General health				
VC group	35.0 (20.7)	28.33 (18.6)	25.0 (13.6)	0.053
PFMT group	33.34 (18.09)	30.01 (16.90)	23.33 (6.45)	0.32
Control group	40.01 (18.4)	33.34 (18.09)	–	0.17
Intergroup *p* value	0.16	0.79	0.34	
Incontinence impact				
VC group	75.56 (32.0)	22.24 (20.6)*†	17.78 (17.2)*	<0.001
PFMT group	55.82 (39.32)	17.76 (24.7)*†	7.69 (14.6)*	<0.001
Control group	59.98 (33.81)	57.84 (29.48)	–	0.39
Intergroup *p* value	0.39	0.001	0.32	
Gravity measures				
VC group	56.47 (23.9)	17.35 (22.5)*†	8.02 (9.8)*	<0.001
PFMT group	41.33 (25.47)	15.11 (23.0)*†	5.91 (6.26)*	<0.001
Control group	46.67 (24.16)	45.80 (23.09)	–	0.21
Intergroup *p* value	0.43	0.01	0.67	

*, Differences vs. before treatment (Wilcoxon test); †, differences vs. Control group (Mann–Whitney tests) VC, vaginal cone; PFMT, pelvic floor muscle training

instructed both treatment groups to conduct exercises at home and supervised sessions lasting 30 min three times a week. These authors also used vaginal balls, and not vaginal cones as in the other studies. Therefore, the format of the device may have changed the result.

Castro and colleagues[22] and Gameiro and colleagues[18] found similar results to the present study with the implementation of protocols of 45 and 40 min, respectively, similar to the present study. However, Castro and colleagues[22] treated women three times per week for 6 months while patients in the study by Gameiro and colleagues[18] underwent treatment once weekly, for 12 weeks. Thus, the results show that treatment with and without the use of vaginal cones when performed one, two or three times a week may be effective in reducing urinary incontinence in women with SUI.

Although other studies have investigated the use of vaginal cones in women and found similar results, the effects of the pelvic floor muscle strengthening in the specific population of postmenopausal women have not been investigated. This population has a high incidence of lower urinary tract dysfunction, possibly resulting from the sum of the effects caused by the reduction of endogenous estrogen production in the postmenopausal period and aging[6]. Further studies are needed to clarify the real contribution of changes due to advanced aging and the postmenopausal period, individually or together, for the greatest number of lower urinary tract dysfunctions in postmenopausal women. However, the results of the present study showed that, regardless of the structural changes in those women, vaginal cones and pelvic floor muscle training may provide benefits for SUI symptoms in women after menopause.

The benefits of the SUI treatment by vaginal cones and pelvic floor muscle training remained after 6 weeks, possibly by continued exercise without supervision. Despite the VC group being treated with the vaginal cone device and it being expected to show greater motivation for treatment[10], the group showed lower adherence to unsupervised exercise. This finding may be a consequence of the need to carry out the exercises without this device, which would reduce the motivation for the exercises.

Treated groups showed similar improvement in the quality of life in intergroup analysis. The assessment of quality of life is recommended by the ICS as a supplement to clinical measures of UI[26]. However, the presence of a high standard deviation in all evaluations and all groups demonstrates the subjectivity of the assessments of quality of life[3]. This is because it is known that suffering and the range of difficulties are related not only to age, ethnicity and religion but also to each individual's perception of and response to the incontinence[27].

The main limitation of our study was that the therapist that carried out the evaluation and treatment was not blinded and this could have influenced the results, consciously or not. Also, it cannot be ignored that a larger sample size could have altered some of the results of the study. When the power analysis was performed taking into account only the outcome of urinary loss for the treated groups, a low power was found (9%). Therefore, further research is required before definite conclusions can be drawn. However, despite the small sample size, the calculation of effect size showed that the treatment had a large effect on clinical variables. Future studies should also perform follow-up for periods exceeding 1 year to verify the maintenance of long-term gains.

In conclusion, this study verified similar positive results for treatment with vaginal cones and pelvic floor muscle training for urinary leakage, pelvic floor muscle pressure and quality of life for postmenopausal women with SUI. The group receiving pelvic floor muscle training showed greater adherence to unsupervised exercise. Thus, both treatments appear to be effective for treatment of stress urinary incontinence in this population. The low power may be one explanation for the lack of difference between the treated groups.

Conflict of interest The authors report no conflict of interest. The authors alone are responsible for the content and writing of the paper.

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