

# Radiofrequency in female external genital cosmetics and sexual function: a randomized clinical trial

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## Abstract

**Introduction and hypothesis** Female sexual behavior goes through cultural changes constantly, and recently, some women have shown the desire the ideal genitalia. In this study, we aimed to evaluate clinical responses to nonablative radiofrequency (RF) in terms of its cosmetic outcome in the female external genitalia and its effect on sexual function.

**Methods** A single-masking randomized controlled trial was conducted in 43 women (29 sexually active) who were unsatisfied with the appearance of their external genitalia. The women were divided into an RF group ( $n=21$ , 14 sexually active) and a control group ( $n=22$ , 15 sexually active). Eight sessions of RF were performed once a week. Photographs (taken before the first session and 8 days after the last session) were evaluated by the women and three blinded health professionals by using two 3-point Likert scales (unsatisfied, unchanged, and satisfied; and worst, unchanged, and improved). Sexual function was evaluated using the Female Sexual Function Index (FSFI) and analyzed using the Student *t* test. Women's satisfaction and health professional evaluation were analyzed using the chi-square test and inter- and intragroup binomial comparisons.

**Results** Satisfaction response rates were 76 and 27 % for the RF and control groups, respectively ( $p=0.001$ ). All

professionals found a clinical improvement association in the treated group with RF in comparison with the control group ( $p<0.01$ ). The overall FSFI sexual function score increased by 3.51 points in the RF group vs 0.1 points in the control group ( $p=0.003$ ).

**Conclusions** RF is an alternative for attaining a cosmetic outcome for the female external genitalia, with positives changes in patients' satisfaction and FSFI scores.

**Keywords** Pulsed radiofrequency · Collagen · Female · Urogenital atrophy · Cosmetic

## Introduction

In recent decades, the role of women in the sexual behavior of human beings has undergone significant cultural changes. Especially in Brazil, these changes are associated with the increasing media exposure of female genitals. The desire for ideal genitalia explains the increasing number of cosmetic vaginal procedures, making it one of the 20 most frequently performed surgeries [1]. Reasons for dissatisfaction with the female genital appearance may include flabbiness or sagging skin of the labia majora or increased size of the labia minora [2]. Indications for aesthetic procedures on the genital region is quite controversial in scientific circles, and no conclusions have been made regarding the issue [3–5]. The justification for conducting such cosmetic procedures is grounded on the theory that women's dissatisfaction with their genitals' appearance affects their self-esteem and sexual performance [6, 7]. The feelings of embarrassment regarding sexual function, shame about the appearance of the genital region, anxiety about the sex act, and a strong desire to improve sexual relations are commonly cited as reasons for undergoing genital cosmetic surgeries [8].

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Filling through labioplasty has been the most frequently used procedure for treating labia majora laxity. It consists of an injection of autologous fat or synthetic materials in this region. However, it may cause complications and the need of care in the postoperative period [9]. Currently, the interest in safe and effective noninvasive interventions for rejuvenating tissue, without adverse effects, is increasing [10–12]. One of these techniques is nonablative RF, which is a diathermic process generated by the radiation of an electromagnetic spectrum, resulting in an immediate retraction of existing collagen. It causes the formation of new collagen over time and is thought to change the appearance of the area in which it was applied [10]. An incipient pilot study showed satisfactory results from RF as a treatment for attaining a cosmetic outcome for female external genitalia and the positive effect of RF on sexual function [13].

Owing to the need to assess results of minimally invasive techniques and the use of methodologically appropriate studies, we conducted a randomized clinical trial to evaluate response to nonablative capacitive RF as a treatment for attaining cosmetic outcome on the female external genitalia and the effect of RF on sexual function.

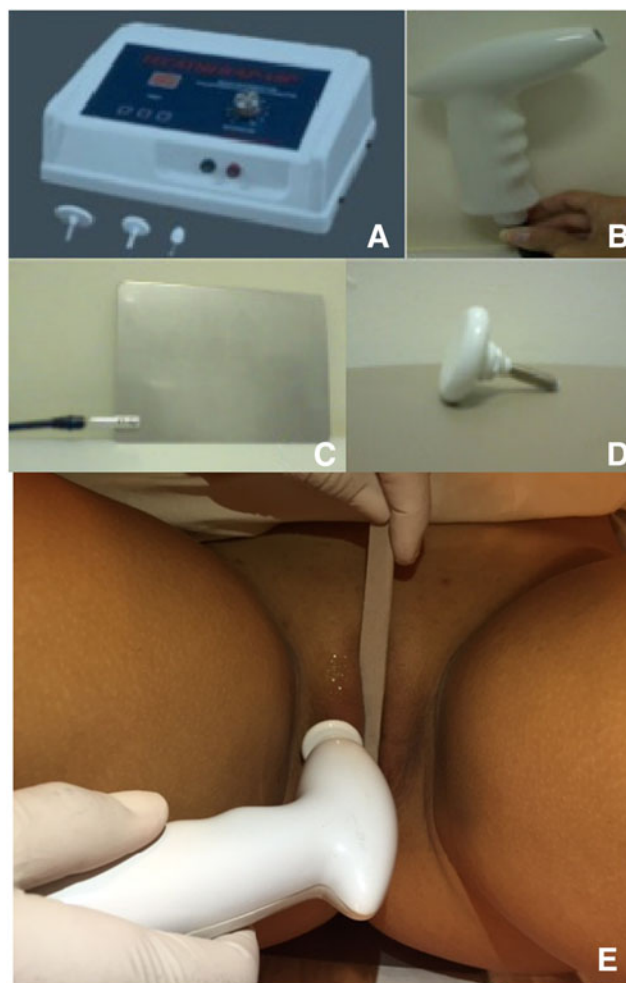
## Materials and methods

The study was approved by the research ethics committee of the Bahiana School of Medicine and Health Ethics and conformed to the standards set by the Declaration of Helsinki. (CAAE: 03449212.3.0000.5544). It was registered at ClinicalTrials.gov (NCT02611791). Informed consent was obtained from all participants.

For this single-masking randomized clinical trial, we collected data during the months of January 2014 through December 2014. Women aged between 18 and 60 years who were unsatisfied with the appearance of their external genitalia and receiving clinical physiotherapy in Bahia, Brazil were included. Pregnant women, women with a copper intrauterine device, and those with skin lesions in the genital region were excluded. Sociodemographic data were collected, and clinical records were reviewed for information about previous surgeries in the genital region, use of hormones, sexual activity, and obstetric history. To assess sexual function, women who were sexually active in the last 4 weeks answered the Female Sexual Function Index (FSFI) questionnaire [14].

The study consisted of 43 women who were divided into two groups by using a random table (<http://www.random.org>) [15]. The RF group comprised 21 women and the control group 22. The women were randomly assigned to the groups by a third person, not a researcher, while guaranteeing allocation concealment. A list of random numbers was available for this third person responsible for doing the assignments.

Eight RF sessions were performed, with an interval of 7 days between each session. RF was applied using a Tecatherap-VIP unit (VIP-Eletromedicina, Argentina) with a monopolar method in which a 2-cm gauntlet and a metal coupling/return electrode located in the sacral region were used (Fig. 1). RF was applied while participants were in the supine position, with legs in the lithotomy position. A water-soluble gel was used for gauntlet coupling and slide. Application on external labia majora was made in the caudal–cranial direction using constant movement and the electrode lightly pressed. During the session, the heat level was monitored verbally and by using an infrared digital thermometer. Intensity was gradually increased. When the temperature reached 39–41 °C, intensity was reduced by 2 points and the procedure maintained for 2 min. Photographs were taken on two occasions—before the initial session and 8 days after the last session—always with the woman in the sitting position with her legs bent. A single photographic machine (10.2 megapixels, in smart-capture mode, without flash; Kodak)



**Fig. 1** a Tecatherap-VIP unit (VIP-Eletromedicina, Argentina); b monopolar gauntlet; c metal coupling/return gauntlet; d 2-cm electrode; e radiofrequency procedure

was used, positioned at a distance of 30 cm from the genital region, and suspended on a 12-cm tripod. Photographs were taken in the same place and under the same lighting condition.

The treatment protocols for the control group were identical, differing only in relation to the RF equipment, which was turned off. A water-soluble gel heated by a resistor was used in order to prevent the women from knowing to which group they belonged. Only the physiotherapist who performed the procedure knew which group the women were assigned to. Genital appearance was assessed based on the woman's qualitative response, which was apart from opinions of the three healthcare professionals: dermatologist, physiotherapist, and gynecologist who were masked regarding the treatment each group received. Based on a 3-point Likert scale, aesthetic results (appearance) were evaluated according to three possible patterns of change in tumescence and number of wrinkles (grooves) in the labia majora: 1 = worsened, 2 = unchanged, 3 = improved. Satisfaction with treatment was subjectively evaluated by the woman only before and 8 days after treatment, according to the 3-point Likert scale as follows: 1 = unsatisfied, 2 = unchanged, and 3 = satisfied. The highest FSFI was considered the best therapeutic response; scores <26 indicated sexual dysfunction. The same researcher evaluated therapeutic response before and 8 days after treatment [14].

A sample calculation was performed by the free statistical calculator, available on [http://www.lee.dante.br/pesquisa/amostragem/calculo\\_amostra.html](http://www.lee.dante.br/pesquisa/amostragem/calculo_amostra.html) [16]. The absolute difference in patient satisfaction was 40 %, with a two-tailed hypothesis, requiring 19 women in each group in order to obtain a statistical power of 80 %, with a significance level of 5 %. A possible loss of 10 % was added.

The Shapiro–Wilk normality test was performed, and the numeric variables age and body mass index (BMI) is represented as mean and standard deviation (SD). The *t* test was used to compare both groups. Categorical variables were represented as absolute frequency and percentage and used in intergroup comparison. The chi-square test was used to analyze race, climacteric, surgery, use of hormonal contraceptives, and satisfaction as assessed by the professionals and women. Fisher exact was used for education, sexual activity, and hormone therapy. The binomial test was used to evaluate women's satisfaction (intragroup). Sexual function, overall FSFI, and scores for each FSFI domain were evaluated using dependent and independent Student *t* tests. Data analysis was performed using the Statistical Package for Social Sciences (SPSS) version 14.0 for Windows; significance level was 5 %.

## Results

The sample consisted of 43 women; seven (5 in the RF group and 2 in the control group) did not complete treatment. The

remaining 36 participants (16 in the RF group and 20 in the control group) completed treatment, of whom 14 in the RF group and 15 in the control group were sexually active in the last 4 weeks (Fig. 2). No significant differences in clinical and sociodemographic variables were found between treatment and control groups (Table 1).

When evaluating clinical improvement regarding labia majora flabbiness, there were differences between the RF and control groups regarding patients' satisfaction after analyzing the photographs. In the RF group, 16 women (76 %) reported being satisfied, and in the control group, only six (26 %) reported being satisfied ( $p=0.001$ ). Evaluations were ratified by the professionals (Table 2).

In the control group, among the 20 women who completed treatment, six (30 %) were satisfied ( $p=0.115$ ). In the intention to treat group, (27 %) remained satisfied ( $p=0.052$ ). In the RF group, the 16 women who completed treatment were 100 % satisfied ( $p\leq 0.001$ ). Of the 21 intention to treat participants, 16 (76 %) were satisfied, with a statistical significance ( $p=0.001$ ; Table 2).

## Sexual function

The RF group experienced a significant increase in sexual function, with an absolute difference of 3.51 points in the absolute mean of the general score compared with the pretreatment score ( $p=0.03$ ). Initially, the mean was  $25.41\pm 6.34$ , which increased to  $28.9\pm 5.1$  at the final moment. Significant increases in the sexual arousal and satisfaction domains were observed in the RF group (Table 3).

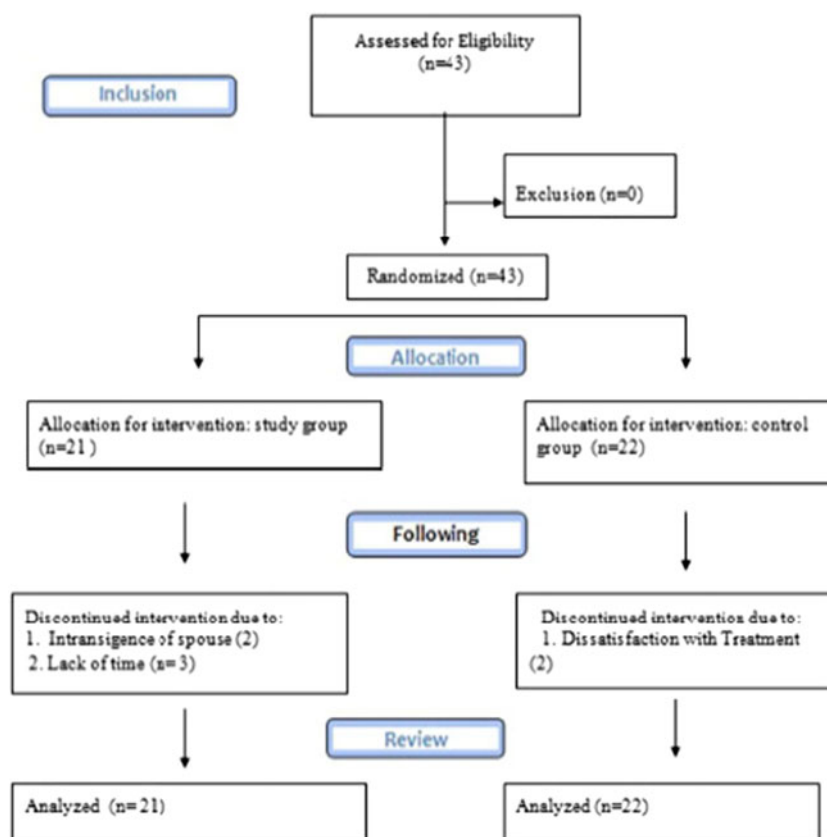
Two participants in the RF group showed a reduction in overall score, one of whom showed a decrease in all domains and the other decreased desire, arousal, and orgasm, as well as having pain, as presented in Fig. 3.

In intergroup analysis, no significant differences in overall and domain FSFI scores were observed between groups before and after RF sessions (Table 3). No participant experienced discomfort during application or any kind of side effects.

## Discussion

RF is an alternative for cosmetic improvement in the female external genitalia, with positive changes in patients' satisfaction when compared with a control group. Response to treatment was satisfactory; that is, 76 % of women in the intervention group who were evaluated for intention to undergo treatment reported satisfaction with the appearance of their genitalia after RF treatment. When only participants in the RF group who completed treatment were evaluated, all achieved improvement. This is due to change in location and appearance, perhaps explained by the mechanism of action of RF on

**Fig. 2** Consolidated Standards of Reporting Trials (CONSORT) Fluxogram



**Table 1** Clinical characteristics and sociodemographic characteristics of radiofrequency and control groups

Variable	Radiofrequency (N=21)	Control (N=22)	<i>p</i> value
Age (years)	41.71 (±8.53)	46.68 (±8.60)	0.065
BMI (kg/m <sup>2</sup> )	25.23 (±4.08)	27.04 (±3.01)	0.116
Climacteric hormone therapy	7 (33.3 %)	13 (59.1 %)	0.091
contraceptive	1 (4.8 %)	4 (18.2 %)	0.345
Pelvic surgery	7 (33.3 %)	3 (13.6 %)	0.126
Race			
White	12 (57.1 %)	12 (54.5 %)	0.864
Mixed	4 (19 %)	6 (27.3 %)	
Black	8 (38.1 %)	9 (40.9 %)	0.710
Education			
Elementary	9 (42.9 %)	7 (31.8%)	
High school	2 (9.5 %)	0(0 %)	
Undergraduate incomplete	11 (52.4 %)	15 (68.2 %)	0.569
Undergraduate complete	2 (9.5 %)	2 (9.1 %)	
	6 (28.6 %)	5 (22.7 %)	

Categorical variables expressed in absolute frequency and percentage. Numeric variables expressed as mean and standard deviation

BMI body mass index

\* $P \leq 0.05$

collagen and elastin fibers, resulting in greater production and reorganization of these structures [17].

In the analysis of the control group's satisfaction in relation to appearance of the labia majora, 27 % of women evaluated who completed the treatment were satisfied with the result. These results may have been due to the Hawthorne effect and thus the placebo effect, where individuals believe they are undergoing an intervention and report satisfaction with the therapeutic responses [18]. Furthermore, it can be explained by hydration, as a heated water, soluble gel was used in these women. Many of these women observed their genitalia more closely, resulting in satisfaction with its appearance.

This positive change was also found in evaluation of photographs by professionals. Enlargement of the labia majora volume associated with the decrease in the number of skinfolds, determined by evaluators, elicited a positive response to genitalia appearance in the RF compared with the control group. This is due to contraction of the existing collagen and formation of new collagen and elastin over time [19, 20].

Cihantimur et al., in a study of women who underwent genital plastic surgery, including 124 participants who underwent the procedure for swelling the labia majora, demonstrated through evaluation of photographs by two health professionals, that appearance of genitalia improved in



**Table 2** Evaluation by patients and professionals in relation to clinical improvement of sagging skin

Evaluation (clinical improvement)	Radiofrequency ( <i>N</i> =21) <i>n</i> (%)			Control ( <i>N</i> =22) <i>n</i> (%)			<i>P</i> value
	Unsatisfied	Unchanged	Satisfied	Unsatisfied	Unchanged	Satisfied	
Patients	0	5 (23.8 %)	16 (76 %)	0	16 (73 %)	6 (27 %)	0.001*
Professionals	Worsened	Unchanged	Improved	Worsened	Unchanged	Improved	
Dermatologist	0	4 (19 %)	17 (81 %)	0	13 (59 %)	9 (41 %)	0.007*
Gynecologist	0	6 (29 %)	15 (71 %)	0	15 (68 %)	7 (32 %)	0.009*
Physiotherapist	0	7 (33 %)	14 (67 %)	0	16 (73 %)	6 (27 %)	0.010*

\**P* ≤ 0.05

>95 % of women 1 year after surgery [21]. That study, as with the study we report here, showed the usefulness of photographs as evaluation tools regarding the outcome of cosmetic procedures in the genital region.

Changes in sexual function may also have influenced the increased satisfaction of the women in our study. Trichot et al., in a descriptive study, reported that of 18 women who underwent labioplasty, 17 (94 %) reported satisfaction with the appearance of their postsurgical genitalia and all reported improvement in sexual function [22]. Alter, in a study of women who underwent genital plastic surgery, reported that the average degree of participant satisfaction after surgery on a scale of 1–10 was 9.2 and that 93 % of women reported improvement in self-esteem and 71 % in sexual function [23]. This fact was confirmed in our study. There was an increase in total FSFI score and domains of satisfaction and arousal after treatment in the RF group. Based on the principle that RF increases local temperature and consequently vascularization of the region, a significant increase in the vaginal lubrication domain was expected but was not found in this study. This may be because RF was applied on the labia majora, not on the vaginal opening. Sekiguchi et al. conducted a study regarding the application of RF on the vaginal opening to improve its general appearance and found an increase in the score for long-term vaginal lubrication domain [24]. Bramwell et al.

conducted a qualitative study of six women who underwent vulvar cosmetic surgeries to improve their sexual life. However, not all participants achieved this objective (number not reported) [25]. This may be because the surgery generated a scar, which might have changed the sensitivity of the region. This is unlike RF, which is a conservative technique. In addition, female sexuality is complex and influenced by several factors, such as general health, interpersonal relationships, reproductive events, cultural factors, and body image [26].

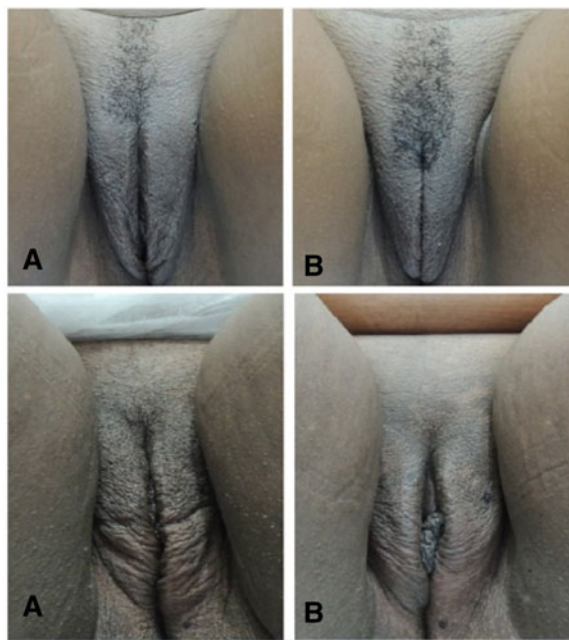
Most studies evaluating sexual function of women who had undergone cosmetic treatments of the vulvar region performed subjective assessments by asking general questions [22, 24], unlike this study, which used an appropriate and validated tool for this purpose. However, our study has limitations. One is the site at which it was conducted, which is a clinical school of physical therapy that treats people with functional disorders. Another is the large number of treatment sessions, which might have led to the high number of participant losses (7 in total). Another important limitation is the absence of a scale for assessment of skin laxity in the female genitalia. The evaluation criteria used in this study was prepared by the authors based on their practical experience, the pathophysiology of sagging skin, and the inability to collect information about the type of hormone therapy women received.

**Table 3** Female Sexual Function Index (FSFI) scores of 14 study group and 15 control group participants using Student's *t* test

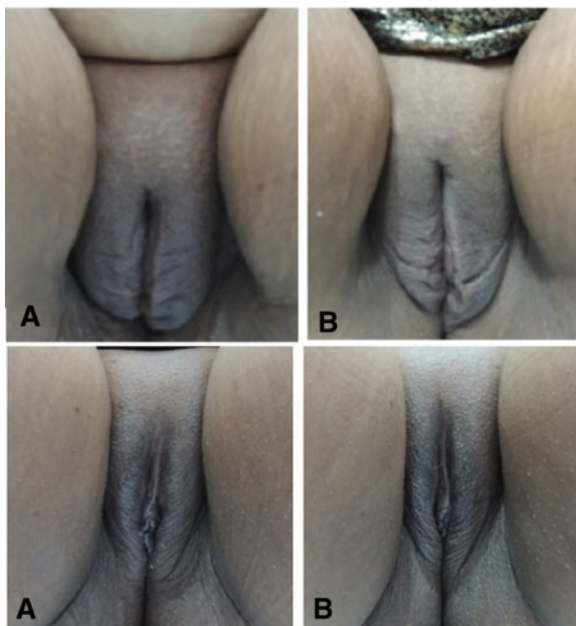
Variable	Study group			Control group			Intergroup (after) <i>P</i> -value
	Initial moment	Final moment	<i>P</i> value	Initial moment	Final moment	<i>P</i> value	
Sexual desire	3.98 ± 1.25	4.24 ± 1.27	0.39	4.04 ± 1.05	4.08 ± 1.16	0.87	0.90
Sexual arousal	4.20 ± 1.32	4.75 ± 0.90	0.05*	4.38 ± 0.94	4.76 ± 1.04	0.11	0.67
Vaginal lubrication	4.56 ± 1.41	5.22 ± 1.05	0.77	4.72 ± 1.58	4.84 ± 1.37	0.67	0.78
Orgasm	4.14 ± 1.29	4.57 ± 1.45	0.17	4.77 ± 1.11	4.77 ± 1.18	1.0	0.17
Sexual satisfaction	4.20 ± 1.55	5.20 ± 1.26	0.02*	5.28 ± 0.71	4.96 ± 1.20	0.24	0.02
Pain	4.31 ± 1.29	4.88 ± 1.00	0.15	4.74 ± 1.16	4.58 ± 1.25	0.38	0.35
General score	25.40 ± 6.34	28.92 ± 5.14	0.03*	27.94 ± 4.36	27.97 ± 5.75	0.97	0.22

*P* ≤ 0.05

## RG



## CG



**Fig. 3** Overall patient satisfaction scores: **a** Before RF, **b** after RF. *RG* radiofrequency group, *CG* control group

There are intentions to perform new research studies involving women, with the objective to evaluate long-term clinical response to RF. These studies are in progress by the same team who conducted the study reported here. Further studies can be conducted to compare clinical response between RF and surgery for filling the labia majora to treat sagging skin in this region.

We can conclude that RF verified improvement in women's satisfaction with the appearance of their external genitalia,

mainly according to their views in general. This can be considered as an alternative, noninvasive treatment that can elicit a positive clinical response in terms of genital appearance and has a positive effect on FSFI sexual score, especially by improving sexual arousal and satisfaction.

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**Compliance with ethical standards**

**Conflicts of interest** None.

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