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EROS device in the management of female anorgasmia: Prospective study of a series of cases in women in Quindío (Colombia)

Dispositivo EROS en el manejo de la anorgasmia femenina: Estudio prospectivo de serie de casos en mujeres del Quindío

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Resumen

Introducción: La anorgasmia es el retraso persistente, o recurrente o ausencia de orgasmo después de una fase de excitación sexual normal, resultando en dificultades personales o interpersonales. El tratamiento se aborda desde diferentes perspectivas. **Objetivo:** Presentar los resultados de la efectividad y seguridad del uso del dispositivo EROS-CTD en el manejo de la anorgasmia femenina, en un grupo de mujeres del Quindío. **Materiales y métodos:** Estudio de reporte de casos, de tipo observacional, descriptivo, prospectivo, de mujeres intervenidas por trastorno del orgasmo, en Armenia, Quindío, Colombia, en el periodo de 2012 a 2017. **Resultados:** Se intervino 39 mujeres; edad media de 35,1 (DS ± 3,7) años. La anorgasmia primaria fue del 61,53% y la secundaria del 38,36%. El promedio de seguimiento del uso del dispositivo EROS-CTD, fue de 23,7 (DS ± 4,5) meses por paciente. Al finalizar el estudio, la satisfacción global con el uso del dispositivo es del 89,74%, ninguna de las mujeres presentó complicaciones relacionadas con el uso del aparato. **Conclusiones:** La efectividad del tratamiento de la anorgasmia femenina con el dispositivo EROS-CTD, ha beneficiado favorablemente a las mujeres del estudio.

Palabras clave: Efectividad; mujeres; orgasmo; seguridad; terapia. (Fuente: DeCS, Bireme).

Abstract

Introduction: Anorgasmia is the persistent, or recurrent, or absence of orgasm after a normal phase of sexual arousal, resulting in personal or interpersonal difficulties. Treatment is approached from different perspectives. **Objective:** To present the results of the effectiveness and safety of the use of the EROS-CTD in the management of female anorgasmia in a group of women from Quindío. **Materials and methods:** A descriptive, prospective observational study of case reports was carried out with women intervened by orgasm disorder in Armenia, Quindío, Colombia, from 2012 to 2017. **Results:** 39 women were intervened whose average age was 35.1 (DS ± 3.7). Primary anorgasmia was 61.53% and the secondary was 38.36%. The average follow-up of the use of EROS-CTD was 23.7 (DS ± 4.5) months per patient. At the end of the study, overall satisfaction with the use of the device is 89.74%, none of the women presented complications related to the use of the appliance. **Conclusions:** The effectiveness of the treatment of female anorgasmia with EROS-CTD has benefited the women of the study.

Key words: Effectiveness; women; orgasm; safety; therapy. (Source: DeCS, Bireme).

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Introduction

The female orgasm is interpreted as a feeling of happiness and satisfaction after an adequate sexual stimulation. It is also understood as a short term state of intense pleasure that is accompanied by rhythmic contractions of the uterus, anus and muscles of the pelvic floor[1-3]. Orgasmic dysfunction occurs when an orgasm does not take place or it is noticeably delayed[4].

Female anorgasmia refers to the inability of a woman to reach an orgasm after an effective sexual stimulation, i.e., the orgasmic response is blocked upon an appropriate sexual arousal[2,4,5]. It is also defined as the persistent and/or recurrent delay or absence of orgasm following a phase of normal sexual arousal, which results in personal or interpersonal difficulties[6].

A recent literature review shows that nearly 40%-60% of women experience at least one sexual dysfunction event throughout their lifetime[7-9]. This relatively high percentage could be associated with age, education, occupation, consumption of pharmaceuticals, psychological, environmental or cultural factors, religious beliefs, psychological disorders, gynecological surgeries, and physiological dysfunctions (e.g., hormonal, vascular, neurological or anatomical), etc[8,10,11].

While primary anorgasmia is experienced by 5%-28.5% of women[7,8,12], secondary anorgasmia ranges between 6.8%-59.09%[7,8,13,14]. Sexual disorders usually cause difficulties in the couple's relationship; recent studies show that 67% of divorces are related to sexual disorders[12], anorgasmia not being the exception[2,5].

The clitoris and vagina are the female physiological places of sexual stimulation in order to reach an orgasm. Nevertheless, peri-urethral, breast and nipple stimulation as well as erotic mental images and fantasies can induce and influence the appearance of an orgasm[2,5,15].

The clitoris has a significant role in the primary erogenous response of women and, given its anatomy, physiology and embryological origin, its relevance in female orgasm is unquestionable[2,5,15,16]. Specifically, the nervous branches of the pudendal nerve (cavernous, peripheral and dorsal nerve of the clitoris) transmit the sensory stimulation that induces vasocongestion of the clitoral area during sexual arousal[2,15-17] and facilitates the orgasmic response.

Treatment of anorgasmia had been approached from psychoanalytic, pharmacological, and cognitive-behavioral perspectives[3,4,18], among others. Success rates, after therapy, range between 90% (reaching orgasm during masturbation) to 75% (experiencing orgasm during sexual intercourse)[1,19-21]. Cognitive-behavioral therapy to treat anorgasmia focuses on promoting changes in attitudes and sexually relevant thoughts in order to both decrease anxiety and increase the orgasmic capacity and satisfaction. The behavioral exercises that are traditionally prescribed to induce these changes include directed masturbation, sensitive focus, and systematic desensitization. Sexual education, communication skills training, and Kegel exercises are also often included in cognitive-behavioral treatment for anorgasmia[22,23].

EROS *clitoral therapy device* (EROS-CTD), is a small hand-held medical device, made of soft plastic, vacuum-type vibrator. It has the shape of a computer mouse and a cap of the right size to cover the clitoris. When turned on, this device provides a gentle suction of the clitoris, improving the female sexual response because it increases blood flow in both the clitoris and external genitalia. Since there is a better vaginal lubrication, the capacity to experience an orgasm improves too. EROS-CTD has been approved by the US Food and Drug Administration (FDA) since 2000 to treat female orgasm and arousal disorders[2-5, 24-26]. Although the number of participants in current studies has been low, the effectiveness of EROS-CTD has been documented, reporting an improvement of at least 42% in female patients[2,22,27,28].

We proposed to carry out this study after considering all aspects related to female anorgasmia, the lack of non-pharmacological treatment alternatives, and the significantly high number of women with this disorder who have requested assistance at the Sacred Family Sexology Clinic (Armenia, Quindío, Colombia). Our objective is to present results about the effectiveness and safety involved in the use of an EROS-CTD device to treat anorgasmia in women treated at the Sacred Family Sexology Clinic.

Materials and methods

A case report study was conducted, which also was of observational, descriptive, and prospective type. The participants were women treated for orgasmic disorders at the Sacred Family Sexology Clinic of the city of Armenia, Quindío, during January 1, 2012 – October 31, 2017. We applied a consecutive sampling method.

The inclusion criteria were as follows: women aged 18 years and older, sexually active, who attended the Sexology Clinic because of anorgasmia (primary or secondary); their participation in the study was voluntary. The following were the exclusion criteria: pregnancy, menopause, intellectual disability, psychiatric disorders, and vascular diseases.

The EROS device was used in all sexual intercourses and during self- or couple masturbation.

The instrument used for assessing sexual dysfunction was the Female Sexual Function Index-6 (FSFI-6), which is a useful questionnaire for the diagnosis of female sexual dysfunctions; it has a sensitivity and specificity of >94%, with a $p<0.001$[29] and has been validated in Spanish[30]. FSFI-6 consists of 6 questions to measure the desire arousal, lubrication, orgasm, satisfaction and pain during sexual intercourse. Each question is scored from 0 to 5 and the final result is the arithmetic sum of all analyzed domains. A risk criterion of sexual dysfunction is represented by a score of equal to or lower than 19 or when the score of one domain is lower than 3.6. A total score of higher than 19 indicates normal female sexual function[29,31].

Clinical histories from women that fulfilled the inclusion criteria were prepared in order to obtain the studied variables: (i) sociodemographic variables (age, ethnicity, height, weight, body mass index (BMI), marital status, employment, educational level, precedence, religious/spiritual condition); (ii) sexual behavior variables, like beginning of sexual life and common sexual activities (masturbation, oral sex, anal or vaginal intercourse); (iii) average weekly frequency of sexual relations; (iv) time of coexistence as a couple; (v) history of sexual abuse or sexual violence during marriage; (vi) partner with sexual dysfunction; (vii) history of: toxic habits (alcohol consumption or smoking), prescription drug abuse, contraception methods, parity (i.e., number of pregnancies reaching viable gestational age), organic and surgical diseases, depression, family history of sexual disorders, personal history of anorgasmia and treatments received.

In addition to the previous variables, we registered all the answers related to each of the domains covered by the FSFI-6 in a special format designed by the researcher. Sexual dysfunction was assessed through FSFI-6 at the beginning of the study as well as after 6, 12, and 24 months of treatment. The study was conducted for a total period of 2 years.

Ethical considerations

The objectives of the study as well as the purpose of the obtained results were informed to all women who met the inclusion criteria and therapeutic indications. In addition, they had the opportunity to ask questions and have any of their doubts clarified. All patients signed the informed consent form authorizing their participation in the research, and confidentiality of the information was guaranteed. Throughout the study, we followed the ethical standards for good clinical practice established in accordance with the Committee of Human Experimentation, the World Medical Association, and the Declaration of Helsinki[1].

Statistical analysis

The data was analyzed using SPSS version 19 and *Epi* Info version 3.5.1 statistical programs. Qualitative variables were expressed as absolute and relative frequencies (percentages). Numerical variables were presented as averages with standard deviations (SD).

Results

During the analyzed period and from a group of 48 patients, 45 women (93.75%) were included, 3 (6.66%) of which refused to participate in the study. From the remaining 42 women that met the selection criteria, two (4.76%) incorrectly filled out the FSFI-6 form and one (2.38%) withdrew before completing the questionnaire. As a consequence, a total of 39 women (81.35%) who presented orgasmic disorders according to FSFI-6 were considered to carry out the final analysis

The average age of the women included in the study was 35.1 (SD ± 3.7) years old, within a 18-45 range, a median of 35 years, and a variation coefficient of 28%. Most of them were Hispanic (71.79%, n=28), married (38.46%, n=15), from urban areas (79.48%, n=31), had a high school graduate level of education (53.84%, n=21), employed (61.53%, n=24), and

belonged to a contributive health care regime. The average education time period was 10.8 (SD ± 4.8) years. 76.92% (n=15) of the participants had consumed alcohol at least once a week, 48.71% (n=19) had never smoked, and 12.82% (n=5) were current smokers. With respect to other variables, we observed that 61.53% (n=24) of patients belonged to a high socioeconomic stratum and 76.92% (n=27) where Catholic. Finally, the ratio of multiparous to nulliparous women was 2:1. Table 1 summarizes the general characteristics and sociodemographic data of the patients.

In reference to sexual and reproductive health, we found a median of 3 children in terms of parity (2 via cesarean section and 1 vaginal route, per woman) with a range of 0-6 children. The overall prevalence of abortions was 30.76%, 17.94% of which were induced and illegally performed. 84.61% of women had used contraception methods with a predominance of hormonal contraceptives (76.92%), followed by subdermal implant, pills, and injection (27.27%, 24.24% and 21.21%, respectively).

Table 1. General characteristics and sociodemographic data of women with anorgasmia and treated with EROS-CTD

Variable and categories	Population n=39
Age (years) ± SD	35.1±3.7
Weight (Kg) ± SD	62.7±8.1
Height (centimeters) ± SD	158.49±5.28
BMI ± SD	24.6±4.5
Ethnicity %	
Hispanic	71.79
Afrocolombian	28.2
Marital status	
Married	38.46
Common law	25.64
Single	33.33
Socioeconomic stratum %	
High	61.53
Medium	30.76
Low	7.69
Employment %	
Housewife	38.46
Employed	61.53
Education level %	
Elementary	10.25
High school	53.84
Technical	20.51
University	15.38
Origin (area) %	
Urban	79.48
Rural	20.51
Religion %	
Catholic	76.92
Other	23.07

The average age of onset of sexual activity was 16.74 (SD ± 1.29) years old, the median number of sexual partners was 9 (range 1-15), and masturbation age of onset was 12.87 (SD ± 1.35) years old. The average number of weekly sexual intercourse was a median of 2, with ranges of oscillating frequencies between 0-4 encounters per week. The most frequent sexual practice was vaginal intercourse and the least frequent was anal coitus (35.89%); masturbation and oral sex were a common practice in participating women (87.17% and 89.74%, respectively). 23.07% of patients mentioned that they had maintained a stable relationship for 5 years, whereas 38.46% of them reported that their partners had some type of sexual dysfunction. Having an unfaithful partner was reported by 46.15% of participants, while 15.38% of women reported to having been unfaithful themselves. 79.48% of women admitted frequently faking orgasms because of pressure of their partners. Only 10 women (25.64%) reported the use of sexual toys at the beginning of this study. Finally, 100% of participants admitted to being heterosexual.

We observed that 7.69% had pulmonary arterial hypertension (PAH), 10.25% suffered with type 2 diabetes, 12.82% had dyslipidemia, and 3 out of 10 women were receiving hypothyroidism therapy. 15.38% (n=9) of women were hysterectomized, 85.71% of which kept both ovaries, and urinary anti-incontinence surgery was performed in 20.51% (n=8) of them.

The 25-34 years old age group (69.23%) experienced greater difficulties with respect to orgasms, mostly affecting married women (73.33%), from rural areas (75%), with low education level (88%), and with history of abdominal hysterectomy (57.14%).

87.17% (n=34) of participants expressed that anorgasmia negatively affected their sexual performance, reducing their capacity to respond to erotic stimuli and generating an unsatisfying sexual life.

In relation to relevant sexual history, we found sequelae of child sexual abuse in 9 patients (23.07%). In addition, we observed inability to communicate with their partners in 8 patients (20.51%), problems related to intimate partner violence in 7 patients (17.94%), fear of abandonment in 5 patients (12.82%), fear of pregnancy in 4 patients (10.25%), feelings of sexual guilt in 3 patients (7.69%), and

educational factors (illiteracy about human body anatomy and physiology) in 3 patients (7.69%).

79.48% of women reported to having a satisfying relationship with their partners, and 43.58% claimed to be sexually empowered as they felt free to discuss sexual difficulties with their partners. 41.02% of female participants reported having suffered some form of sexual violence throughout their lives, while 10.25% reported sexual abuse by their partners.

The number of women experiencing orgasmic primary and secondary difficulties was 24 (61.53%) and 15 (38.36%), respectively. A total of 18 women (46.15%) had consulted other professionals due to their orgasmic disorders, whereas 21 (53.84%) had never previously sought professional help. From those women that sought help, pharmacological treatment was the most representative with 15 cases (83.33%), which was mainly bupropion and apomorphine. In the same group, none of the treated patients had used sex toys as part of their treatments before the use of the EROS device in this study.

In the series of treated patients, 12 women (66.66%) experienced enhanced erotophilia since they expressed that they had tried to eliminate negative attitudes and prejudices related to sexuality. In regards to sexological treatments, patients were not clear about the applied model. Even though none of the treatments included masturbation training, all patients reported to have performed Kegel exercises upon therapist's recommendation. For this reason, we assume that patient care was not performed by sexology professionals.

At the beginning of the study, the FSFI-6 score in the global population, of the 39 women was 14.37 (SD ± 4,7) points, with a maximum and minimum score of 15.57 and 10.75 points, respectively, and a standard deviation of ± 3.06 points. The average score for the orgasm domain was 1.21 (SD ± 0.9).

A more detailed analysis of the FSFI-6 shows that orgasm is the most fluctuating domain with an initial score of 1.21, followed by desire (2.02 ± 0.7); the only domain with a score higher than 3.6 was pain (Table 2). Women with primary anorgasmia were emphatic in affirming that they had never experienced coital orgasms under other circumstances.

After six months, we noticed an increase in orgasm [2.41 (SD ± 0.6)], with a FSFI-6 score of 17.47 (SD ± 3.9) points. We observed the same tendency after 12 months, with values of 3.79 (SD ± 0.5) and 22.21 (SD ± 3.6) for orgasm and average FSFI-6 score, respectively (Table 2).

At the 24-month time point we observed a significant rise in the orgasm score [4.22 (SD ± 0.5)], with an average FSFI-6 score of 25.21 (SD ± 3.5). The average follow-up time for the usage of EROS-CTD device was 23.7 (SD ± 4.5) months per patient. The detailed scores for each domain included in the FSFI-6 at the beginning and the end of the study are presented in table 2.

Women with partners that actively participated in therapy were the ones that obtained better results among married women. Particularly, this group obtained an average score higher than 4.52 (SD ± 1.27) (93.33%) for the orgasm domain of FSFI-6 after 24 months of treatment. In contrast, the remaining participants reached an orgasm score of 3.65 (SD ± 0.68). Patients with psychological history (e.g., fears, abuse, etc.) had an average score between 3.07 and 4.02, which corresponds to 70.37%. Finally, women with sexual intercourse frequency equal to or higher than two encounters per week displayed an average score higher than 4.54, placing them in the group with the best results.

Table 2. Average of FSFI-6 and its domains

	Beginning	6 months	12 months	24 months
Domains				
Desire	2.02±0.7	2.44±0.6	3.51±0.7	4.13±0.5
Arousal	2.41±0.9	2.93±0.8	3.63±0.6	4.26±0.4
Lubrication	2.45±0.5	2.95±0.7	3.62±0.8	4.31±0.7
Orgasm	1.21±0.9	2.41±0.6	3.79±0.5	4.22±0.5
Satisfaction	2.61±0.8	2.96±0.5	3.85±0.6	4.45±0.6
Pain	3.67±0.9	3.78±0.7	3.81±0.4	3.84±0.8
IFSFA-6 score	14.37±4.7	17.47±3.9	22.21±3.6	25.21±3.5

In reference to masturbation, at the beginning of the study only 30.76% of women did it with a frequency of 1-2 times per week. Nearly 25.64% of the total study population had used erotic toys with the vibrator being the most commonly used device. However, 94.87% of women masturbated 1-2 times per week at the end of the research, 100% of which used a sexual toy and 58.97% practiced with their partner. In addition, 74.35% of participants reported that they enjoyed masturbation more if it was carried out as a couple activity. A success rate of 89.74% was reported for orgasms with solo masturbation, whereas this result decreased to 78.12% in cases of couple masturbation (without coitus).

There was a difference in the response to the use of EROS-CTD during solo masturbation between married, common law and single women (73.3%, 80%, and 84.6%, respectively). In this category, we also observed differences between women that had masturbated for a long time (85.71%) and those that had never tried it before (83.3%).

The following is the orgasmic situation of the patients after the intervention. 28 women (74.35%) were satisfied with their ability to reach orgasms regularly (4-5/5); 7 participants (17.94%) had orgasms less regularly (2-3/5), but they felt satisfaction; and 4 patients (10.25%) had difficulties to reach orgasms (<2/5), but none of them reported problems previous to their participation in the study. The negative perception about the EROS-CTD device was 5.12%.

The success rate (achievement of an orgasm) at the end of the study was 89.74% (n=35). We calculated the ratios reaching orgasm/masturbation and reaching orgasm/with partner (including coitus), obtaining 78.12% and 89.74%, respectively.

Women with secondary anorgasmia exhibited low satisfaction rates (20.83%) compared to those that had primary anorgasmia (53.33%). An even more reduced satisfaction was noted in previously treated women (72.22%), which can be considered a secondary dissatisfaction related to reaching an orgasm with the EROS-CTD device.

During the follow-up we perceived that >79.48% of women had feelings of disgust, annoyance and resentment towards their partners, putting blame on them for the sexual dissatisfaction and anorgasmia due to a lack of sexual resources. None of the women had complications related to the use of the EROS-CT device, demonstrating its safety.

Discussion

Studies conducted in Colombia and other countries have reported that women with orgasmic disorders who were treated for 69 months in sexological consultations showed similar behaviors in relation to sociodemographic variables[8,32-34].

In this study, there was a low percentage (10.25%) of women who were not satisfied with the results obtained with the EROS-CTD device since they did not reach orgasms through coital encounters nor masturbation. Nonetheless, there was a 89.74% overall satisfaction with respect to the use of the device.

We observed a high success rate in reference to reaching orgasm through masturbation (78.12%). However, this frequency is lower than the one reported by Bronselaer *et al*., in Belgium, who indicates that 94% of women reached an orgasm through clitoris stimulation[35]. This difference could be explained by the fact that our study included women already diagnosed with anorgasmia. However, our figures are higher than those reported by Espitia in Colombian populations (47.19%)[8].

A higher frequency of orgasmic dysfunction was found in young women who also were less sexually experienced, which agrees with other studies reporting a prevalence rate of 11% for inhibited orgasm. Guarín-Serrano *et al.,* have described that 24% of a population of university female students from Bucaramanga (Colombia) had never experienced an orgasm and 21% of those that actually had had one experienced difficulties in order reach an orgasm[34]. In this study, we have found a higher percentage of primary (61.53%) compared to secondary (38.36%) anorgasmia.

In our study population, we found that 79.48% of women faked orgasms in order to be at peace with their partners, which is higher than the frequency described by Espitia (58.34%)[8]. Likewise, Muehlenhard and Shippee observed that 67% of university female students in United States had faked orgasms because of pressure from their partners[36]. The same explanation was actually expressed by the women participating in our investigation.

Given that female anorgasmia is a sexual dysfunction that seriously disturbs women's relationships and affects their health and quality of life[2,37,38], it is surprising to observe a lack of studies focused on pharmacological treatment alternatives, such as the EROS-CTD device. In this respect, Schroder *et al.,* have observed statistically significant improvements in all domains of the Female Sexual Function Index (FSFI) in women with an average age of 43.5 years old. After three months of treatment, they noticed that the FSFI score increased from 17 to 29.4 (36 being the maximum score; $p<0.001$)[39]. Similarly, Billups *et al.,* from Boston University, reported a 45% increase in the capacity to reach an orgasm using the EROS-CDT therapy[24].

We identified child sexual abuse, inability to communicate with their partners, and intimate partner violence as the relevant circumstances found to be associated with female anorgasmia. Our findings are consistent with what has been described by IsHa *et al.,* who have indicated that the prevalence and causes of female orgasmic disorders are both abundant and multifactorial[23].

Considering that the orgasm is an indicator of the healthy exercise of the erotic function[2,5] and sexual satisfaction, our results agree with the evidence showing that women with orgasmic disorders have an unsatisfactory sexual life.

The differences found in the use of the EROS-CTD device between married and single women as well as between women who have a longer history of masturbation vs. those who have not could be explained by the existence of a strong influence of both a patriarchal culture and sexual conservatism[2,5]. The latter two elements may have served to discourage the women participating in this study from engaging in these types of practices.

Our comprehensive literature review shows controversial results regarding the use of the EROS-CTD device in women undergoing treatment for anorgasmia[27,28,39,40], but, surprisingly, we registered significantly higher figures (89.74%). Based on the analysis of the FSFI-6 score and its follow-up, we observed satisfactory percentage increases that may be the result of proper guidance and education about the benefits of the device. Another explanation behind this improvement could be that the partners of the female participants were actively involved in the therapy. Finally, the level of acceptance of the EROS-CTD device reported by the participating women is significant as demonstrated by both (i) the relatively low negative perception (5.12%) and (ii) the rejection of the device only expressed by women with deep spiritual and religious roots. The fact that there were no complications related to the use of EROS-CTD, demonstrates the safety of the device.

Some of the limitations of this study were the significantly low number of participants and the inability to follow all participants until the end of the study. Also, the fact that we applied a survey that was not previously validated to assess anorgasmia (because it is a complicated variable to be specifically measured), made it difficult to estimate prevalence of anorgasmia and extrapolate results. Among the strengths of our investigation is that, to the best of our knowledge, this is the first work of this kind done in Colombia. In addition, it is important to mention the long follow-up time and the opportunity to include these women in future studies as positive values of this study.

Conclusions

The effectiveness of the anorgasmia treatment using an EROS-CTD device has favorably benefited our female participants as demonstrated by the high overall satisfaction (89.74%) reported in our study, which is higher than what has been described worldwide.

We think that it is necessary to monitor these patients for a longer period of time and include more patients in future studies to further support our results.

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Conflict of interests
None declared by the authors.

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