Journal of Applied Cosmetology

ISSN 2974-6140 (online) ISSN 0392-8543 (print)

Case Series

Use of bipolar radiofrequency in combination with hyaluronic acid filler in the treatment of vaginal atrophy induced sexual dysfunction in cancer survivors: a case series

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Keywords: *vaginal atrophy, sexual dysfunction, cancer survivors, bipolar radiofrequency, hyaluronic acid filler*

Received: 05 January 2024
Accepted: 16 February 2024

ISSN 2974-6140 (online) ISSN 0392-8543 (print).

DISCLOSURE: **ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.**

ABSTRACT

Cancer is not only the leading cause of mortality but also has serious negative consequences related to the sexual, mental, and social life not only of the patients themselves but also of their families. Among women who survived cancer, treatment consequences and sexual dysfunctions are serious problems affecting sexual well-being. The aim of this article was to evaluate the effectiveness of the use of non-hormonal bipolar radiofrequency in combination with hyaluronic acid filler in the treatment of vaginal atrophy-induced sexual dysfunction in cancer survivors. We described 3 cases that reported beneficial results with bipolar radiofrequency in combination with hyaluronic acid filler in the treatment of vaginal atrophy-induced sexual dysfunction in cancer survivors. The validated tool, The Female Sexual Function Index (FSFI), before and after treatment was used to assess the progress and effectiveness of the method used. The procedure used for each patient consists of 4 sessions. During the first one, a treatment using bipolar radiofrequency and hyaluronic acid filler injection was performed. The following 3 sessions with intervals – between 3 to 4 days were only RF treatments. Our case series showed that combined therapy of hyaluronic acid and bipolar radiofrequency was effective and significantly improved overall sexual function (FSFI). The treatment turned out to be safe and painless with no side effects.

INTRODUCTION

Sexual dysfunction is a serious problem among women who have survived cancer and is one of the most common and disturbing side effects of treatment. In general, cancer treatment can not only potentially but negatively impact women's physical and sexual function. The course of treatment itself causes stigmatization and trauma, is associated with discomfort, fear, and pain, and has a negative impact on sexual desire, arousal, and orgasm. Patients may experience sexual dysfunctions, which may additionally worsen body image, lower self-esteem, depression, and sexual satisfaction, which results in reduced quality of life (1-3).

Sexual dysfunctions may be caused by changes in hormonal balance or the need to remove reproductive organs. Hysterectomy carries a high risk of loss of sexual pleasure; ovariectomy reduces estrogen secretion and, consequently, reduces vaginal lubrication (4). Vulvectomy changes the appearance and function of the genitals. Chemotherapy causes decreased libido, fatigue, and temporary or permanent menopause. Radiotherapy may damage vaginal tissues, nerves, or blood vessels, leading to vaginal atrophy, vaginal stenosis, and loss of tissue elasticity (5, 6). Painful sexual intercourse, dyspareunia, or vaginal dryness are the most common sexual problems reported by cancer patients. Other issues include bleeding after coitus, decreased sexual activity, limited ability to achieve sexual arousal and orgasm, and reduced sensitivity of the genital organs (7-9). Another factor that negatively affects the improvement of the quality of life of women who survived cancer is insufficient or lack of information, support, or treatment options for these diseases. This is despite the common occurrence of sexual dysfunction associated with cancer therapy. We often observe symptoms of urogenital syndrome in breast cancer survivors, such as those occurring during menopause. In both cases, they are a common cause of sexual dysfunction, negatively affecting the quality of life and sexual health (10).

A practical approach to selecting the appropriate treatment for sexual dysfunctions in women with cancer should focus on eliminating the symptoms of urogenital syndrome, as well as improving the quality of life, sexual well-being, and psychological comfort. However, both areas intersect and influence each other. There are plenty of techniques and treatments related to sexual dysfunction in female cancer survivors; one of them is the one presented in this case report. The aim of this case series is to evaluate the effectiveness and safety of bipolar radiofrequency (RF) therapy in combination with the injection of hyaluronic acid filler crosslinked

with poly (ethylene glycol) diglycidyl ether (PEGDE-HA) as a non-hormonal treatment of vaginal atrophy induced sexual dysfunction in cancer survivors.

CASE REPORT

We describe 3 cases that reported beneficial results with bipolar radiofrequency Sectum (Berger & Kraft Medical Sp. z o.o., Warsaw, Poland) in combination with hyaluronic acid filler 28 mg/ml HA hydrogel crosslinked with polyethylene glycol diglycidyl ether (Neauvia Intense Rose, Matex Lab S.A., Geneva, Switzerland) in the treatment of vaginal atrophy induced sexual dysfunction in cancer survivors. Following the principles of the Helsinki Declaration, all patients received information about the product and procedure and signed an informed consent form for the procedure and use of their data for scientific purposes.

Patient 1:

- 48 years old premenopausal;
- 2 normal vaginal delivery (NVD);
- history of endometrial cancer treated with surgery, chemotherapy, and radiotherapy;
- presenting complaint (PC);
- reduced sexual sensation due to vaginal dryness secondary to cancer treatment.

Patient 2:

- 55 years old perimenopausal;
- previous ovarian cancer treated with surgery and chemotherapy;
- 3 caesarean births;
- presenting complaint (PC);
- dyspareunia, vaginal dryness, urge incontinence, and a reduction in labia majora (LM) volume.

Patient 3:

- 60 years old postmenopausal;
- history of breast cancer treated with chemotherapy and hormonal therapy;
- 2 caesarean births;
- presenting complaint (PC);
- dyspareunia, vaginal dryness, and minor reduction in the LM volume.

The validated tool, The Female Sexual Function Index (FSFI), before and after treatment was used to assess the progress and effectiveness of the method used. The FSFI is a widely accepted, global evaluation used in female sexual medicine trials (11).

The FSFI is a very convenient tool used to assess female sexual medicine trials, using a 19-item questionnaire divided into six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain, which evaluate the current state of a woman's sexual function (11). The results obtained from individual domains combine to give a total score in the range of 2–36, where a score of 26 or less may indicate the occurrence of FSD - female sexual dysfunction.

Hyaluronic acid filler used in the procedure

Our product contains 28 mg/ml of HA crosslinked with PEGDE, glycine, and L-proline (Neauvia Intense Rose, Matex Lab S.A., Geneva, Switzerland). PEGDE, as a cross-linking agent, influences the rheological behavior of hyaluronic acid hydrogels, improving elasticity and swelling ratios. For hyaluronic acid cross-linked, lower swelling rates for PEGDE-HA have been observed compared to BDDE cross-linked fillers in in-vitro and in-vivo tests (12, 13). PEGDE-HA also seems to offer considerable advantages in the field of fillers

for aesthetic use, both in terms of safety and efficacy and patient and doctor satisfaction. This filler was also described in the literature on aesthetic gynecology procedures, where it demonstrated effectiveness and a high safety profile (14).

Radiofrequency (RF) was used in the procedure.

Radiofrequency was performed using a bipolar Sectum RF device (Berger & Kraft Medical Sp. z o.o., Warsaw, Poland) with a disposable 360-degree gynecological applicator. The Sectum device is an electrosurgical generator. It cuts, coagulates, and treats human tissues with a high-frequency electric current that converts to thermal energy. Sectum can be optionally provided with body, face, and gynecology applicators designed to treat tissues by heating them with a high-frequency current. The applicators transfer the energy generated by the Sectum device to the patient via a set of metal electrodes (15). The gynecological treatment protocol using the Sectum RF device consists of four sessions performed three to four days apart. Each session includes treatment of the vulvar area and intravaginal (16).

Treatment procedure

The procedure used for each patient consists of 4 sessions. A treatment using Sectum RF and PEGDE-HA injection was performed during the first one. The following 3 sessions with intervals – between 3 to 4 days were only RF treatments.

Session 1 involves administering PEGDE-HA through an injection using an 18G cannula to the subcutaneous tissue of labia majora (between tunica dartos and a fibrous layer of an adipose sac). During the procedure, the depth of injection plays a crucial role, as accessing too deep structures may result in administering the filler to the adipose sac, thus disrupting its effect. Before starting the procedure, the injection site was thoroughly disinfected and anesthetized. Local anesthesia of approximately 2 ml of 2% lidocaine was administered along each labia in a single injection. To gain access to the labia, a 16G needle was first used, and then the filler was administered using an 18G cannula to the lower pole of the labia.

A linear, upward application mode was followed. PEGDE-HA was administered along the entire length of the labia in a way that allowed for a natural shape. The preparation administration was divided into 4 parts: one-quarter of the syringe at the upper pole, two-quarters at the middle, and one-quarter at the lower pole. Between 1 to 2 ml of PEGDE-HA was injected into each labia majora. The next step was the treatment of the vulva and vaginal canal with a Sectum RF device. For vulva treatment, energy was generated continuously, and the doctor made circular movements with the handpiece on the skin of the vulva for 10 minutes. Sectum RF device energy settings were adjusted each time to the patient's feedback (comfortable or uncomfortable). Usually, the settings were in the range of 5-10 W. When performing the procedure vaginally, the applicator was placed in the vaginal canal behind the hymenal ring, and the RF was exposed to the vaginal walls over a length of about 10 cm for about 9 minutes. In the case of intravaginal application, the energy settings were higher and in the range of 15–20 W, but they were also adjusted to the patient's feedback. Unlike the Sectum procedure for the entire vulvar area, in the vaginal treatment the current was released in "pulse mode", which eliminates the need to move the applicator constantly. To have an even effect on the vaginal wall, the entire area was virtually divided into three 3 cm sections. The tip of the applicator was placed in each section for 3 minutes. An important issue affecting the course and safety of the treatment was the mandatory use of gel intended for Sectum RF treatments, which the manufacturer provided. Sessions 2-4 were Sectum RF treatments performed the same way described above, and the intervals between the sessions were 3 to 4 days (14, 16).

RESULTS

In all 3 described patients, an interview and a physical examination were performed. The patients were instructed about the procedure using hyaluronic acid and the RF device. After signing informed consent and consent to photographic documentation, they completed the Female Sexual Function Index (FSFI) questionnaire.

Patient 1 was injected with 1 ml of PEGDE-HA filler in each LM, Patient 2 was injected with 2 ml of PEGDE-HA Filler in each LM, and Patient 3 was injected with 1.5 ml of PEGDE-HA filler in each LM. All three patients had 4 sessions of bipolar RF treatment in the labia area and intravaginally (Fig. 1).

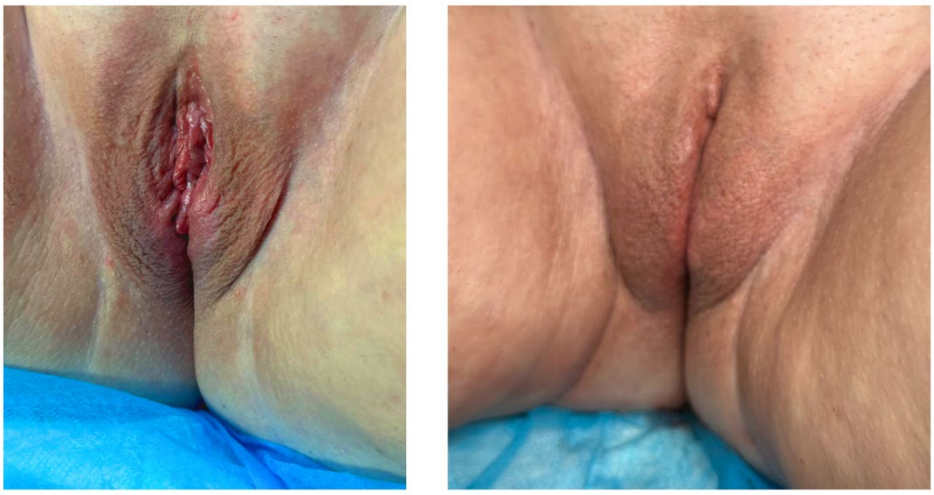

Fig. 1. *Patient 1 - before and after 4 session treatment pictures.*

In the FSFI questionnaires completed by the patients, they assessed the current state of sexual functions (over the last 4 weeks) in terms of desire, arousal, lubrication, orgasm, satisfaction, and pain.

Patients 1, 2, and 3 had improvement of the FSFI from 27 to 31.5, from 13.7 to 30.1, and from 19.2 to 30, respectively (Fig. 2). Patient 2 also noticed improvement in urge incontinence. Significant improvement in FSFI was noted in all three patients; an average FSFI score rose from 19,9 to 30,5.

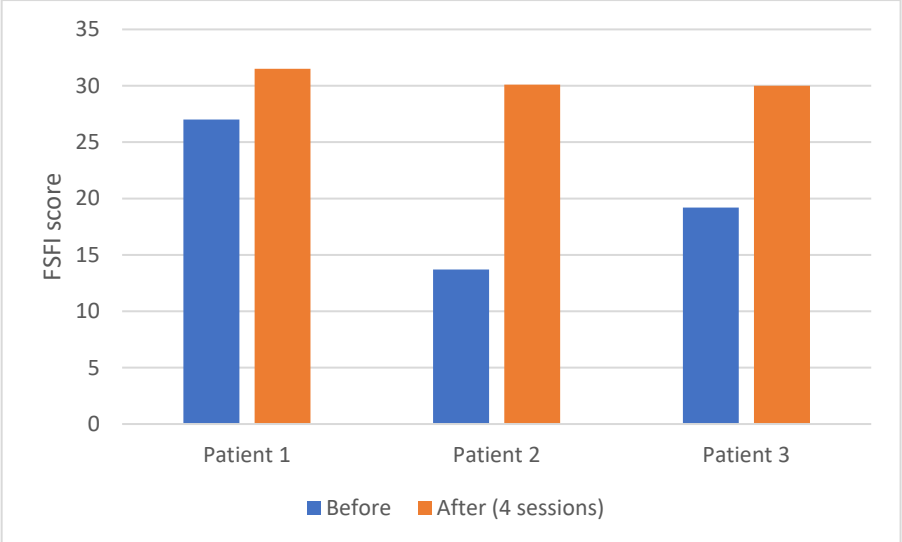

Fig. 2. *FSFI score for individual patients before procedures and after follow-up visits.*

DISCUSSION

There is no doubt that cancer patients are exposed to sexual and health problems during or after treatment, and given the high survival rate of cancer patients and the importance of women's sexuality throughout their lifespan, this issue should receive greater attention. As sexual dysfunction becomes an increasingly common side effect of cancer treatment, gynecologic oncologists need to include a comprehensive sexual health assessment as a routine part of the treatment of such patients from the first visit. Especially when there are various methods of restoring women's sexual health and sexual activity after cancer treatment. For the treatment of mild symptomatic GSM, recommendations are to use long-acting vaginal moisturizers. In cases of moderate to severe VVA or in those who do not respond to treatment with low-dose topical estrogens, systemic replacement is considered the standard. However, systemic estrogen replacement is not always effective in significantly improving the symptoms of vaginal dryness, so topical treatment with vaginal estrogens is best indicated (17-19). It is also noticeable that an increasing number of women undergo invasive surgical procedures, vaginoplasty, labiaplasty, and other cosmetic procedures of the genital organs. Such methods are more effective than Kegel exercises or physical therapy (20-22). Surgical procedures can provide a much better and longer-lasting final result. Still, the results of surgical vaginoplasty must be weighed against the much more significant risks associated with any surgery performed in this region. Recovery time is longer, and there is a risk of scar formation or nerve damage leading to dysesthesia (23, 24). In our case series, combined treatment with injection of PEGDE-HA and Sectum RF significantly improved all domains assessed in FSFI. Over the past years, there has been an increase in the usage of energy-based devices for the treatments of sexual dysfunction, VVA, and GSM, as well as to improve the appearance of external genitalia. In line with the cases we described, the use of radiofrequency for the treatment of Vaginal laxity, sexual dysfunction, and genitourinary syndrome of menopause (GSM) has shown promising treatment outcomes (25-27).

Our case series of three patients in whom bipolar radiofrequency and PEGDE-HA injections were used simultaneously proved to be effective and safe. Both the visual results and the patients' assessment were similar to the publication by Kolczewski et al., in which they were the first to describe this type of combination therapy (16).

The presented case series provides further evidence for the clinical utility and direction for additional evaluation of combination treatments. Since this is a case series with a small number of patients, further studies are required to evaluate the short and long-term effects of the combined treatment of hyaluronic acid and radiofrequency.

List of abbreviations

HA - hyaluronic acid
PEGDE - poly (ethylene glycol) diglycidyl ether
BDDE - butanediol diglycidyl ether

Declarations

Authors' contributions: Nabil Elmahdawi
The author contributed solely to the article.
Availability of data and materials: The data presented in this publication is available upon request from the corresponding author. The data are not publicly available due to privacy restrictions.
Financial support and sponsorship: none.
Conflicts of interest: the author declares no conflicts of interest.
Ethical approval and consent to participate: not applicable. Medical documentation analysis. The study was conducted in accordance with the Declaration of Helsinki.

Consent for publication: informed consent was obtained from the subject involved in the report. Written informed consent has been obtained from the patient to publish this paper.

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