The use of a plasma generator (Plexr) to treat the symptoms of vulvar and vaginal atrophy (VVA).

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Abstract

The aim of the study was to evaluate the safety and efficacy of Plexr device in the treatment of vulvar and vaginal atrophy (VVA).

The study included women with dyspareunia and symptoms of dryness or pruritus vulvitis. Evaluation was performed at the beginning of the study and 4 weeks after treatment. A visual analogue scale (VAS) was used to evaluate: the degree of vaginal pain, burning, itching, dryness and dyspareunia. Questionnaires were administered to measure the vaginal health index (VHI) before treatment and after completion of the study, while participants' satisfaction was measured on a 5-point Likert scale (1 = very dissatisfied, 5 = very satisfied).

One treatment session was performed. Results were assessed at baseline and 1 month after treatment. 39 women (mean age 47.2 ± 6.3 years) took part in the study. The average improvement in visual analogue scale results for all symptoms was statistically significant at the endpoint. The overall average improvements were respectively: perceived pain 3.2 (± 2.9), pruritus 1.6 (± 1.5), dryness 3.9 (± 2.5), dyspareunia 2.3 (± 3.3) . Also the improvement of the vaginal health index between before and after the treatment was statistically significant ($p < 0.0001$).

The results obtained indicate that Plexr is a good therapeutic option in the treatment of VVA symptoms. Treatment with Plexr can improve genito-genital symptoms and clinical symptoms.

Introduction

Vulvar and vaginal atrophy (VVA) is considered a common and chronic disease, as well as progressive with age. Almost 50% of menopausal women report symptoms associated with decreased estrogen levels [1]. The most common symptoms of the genital system include dryness, edema, vaginal pain and related dyspareunia [2]. Due to the lack of estrogen, a thinning of the vaginal mucosa occurs, the mucous membrane is less hydrated and therefore leads to discomfort during sexual intercourse and even dyspareunia. According to Kinsberg's study, these symptoms affect sexual satisfaction of 59% of the women who took part in the survey, and almost a quarter (23%) of them also reduced libido and overall quality of life [3].

Plexr is a wireless device that generates plasma. Plasma is one of the four fundamental states of matter, together with solid, liquid and gaseous. Plasma can be produced by heating a gas or by subjecting it to a strong electromagnetic field, applied by means of a laser or microwave generator. This energy decreases or increases the number of electrons, creating positive or negative charged particles called ions, which involve the dissociation of molecular bonds. The ionization of the gases contained in the air is obtained by an electric discharge. Plexr transfers the concentrated heat directly to the treated skin tissues, without direct contact with them. The operating principle is based on the potential difference between the device and the patient's skin. This difference generates a small electric arc that causes the sublimation of the corneocytes contained in the superficial part of the skin, without affecting the tissues located below the treated area. Plasma is an excellent method for creating new collagen fibers. The device was created for the purpose of performing non-surgical blepharoplasty. It can also be used to remove skin lesions, keloids, scars, wrinkles, perform facelifts and can also be very useful in treating acne scars.

Vaginal dryness is a common symptom in the perimenopausal period and is usually one of the many symptoms reported by women suffering from vaginal and vulvar atrophy. It is estimated that about 15% of women in the perimenopausal period and up to 57% of post-menopausal women experience this symptom. [4,5]

Current therapeutic approaches in the treatment of vaginal mucosal atrophy include local therapies or hormone replacement therapy. The organization of the North American Menopause Society (NAMS) in 2013 published a position stating that non-hormonal therapies relieve symptoms of low intensity and general estrogen therapy is the most effective treatment for moderate and severe symptoms. [4]

Laser treatment may be a non-hormonal alternative in the treatment of VVA. These treatments are performed using a CO2 laser or Er: YAG laser, through which they perform ablation and coagulation of tissue of the vagina and vulva that stimulate the formation of new collagen fibers and increased vascularization, thus interrupting the process of atrophy [5].

So far, however, there are no official non-pharmacological protocols for the treatment of vaginal and vulvar atrophy. The latest FDA stance on the use of laser therapy and

radiofrequency has further increased the confusion. This is why it is so important to carry out further research to demonstrate the effectiveness of these treatments and safety for patients.

Materials and methods

The study was conducted from November 2016 to September 2017 at a private gynecology clinic in Warsaw, Poland. During this period, 39 perimenopausal women were enrolled for the study. All patients participated in the study voluntarily, after having performed a medical examination and signed the consent form for treatment. Inclusion criteria were: dyspareunia, dryness, vaginal pain, burning and itching. The exclusion criteria were: previous use of formulations based on systemic or topical estrogens. All patients were previously informed about the design of the study.

The procedure was performed in the clinic and required only local anesthesia. The treatment started after 40 minutes from the application of local anesthesia, carried out with an ointment containing lidocaine and tetracaine. Vaginal canal treatment was performed using a gynecological speculum and the Plexr handpiece with the lowest power (white). Treatment continued until the vaginal wall and vulva were covered with sublimation points (evidence of vaporization of the tissue). The procedure was one-off. Patients were advised to avoid sexual activity and to use the tampon for at least 7 days after treatment. It was also advised to use a cream with zinc oxide to accelerate tissue regeneration.

All patients were prospectively enrolled in the study after gynecological examination and evaluation of VHI (Vaginal Health Index) and VAS (Visual Analogic Score) of the subject and of the subject's symptoms. The VHI is a scale that is used to evaluate, among others, proper vaginal hydration, volume of the liquid, pH and epithelial structure. Each of the five parameters can be evaluated by a score from 1 (worst condition) to 5 (best condition). The result can therefore be between 5 and 25. The signs and symptoms of the VAS have been assessed subjectively by the patients. The following parameters were assessed: vaginal dryness, burning, pruritus, pain during intercourse and vaginal pain. Patients were asked to rate their symptoms by scoring 1 (best condition) to 10 (worst condition).

All patients were reexamined using VHI and VAS one month after the end of treatment. One month after the end of treatment, patients were asked to assess their satisfaction with the effects

of the 5-point Likert procedure (5 = very satisfied, 1 = very dissatisfied). Treatment was considered satisfactory when the patients were very satisfied or satisfied with the procedure.

Statistical analysis

Statistical analysis of the VHI and VAS results was performed using the Wilcoxon classification test, assuming a value p <0.001 as statistically significant.

Results

The study group consisted of 39 women in the perimenopause period; the average age of the patients was 47.2 years (minimum 45 years - maximum 61 years). All women completed the study because no significant adverse effects were observed.

The subjective evaluation (VAS) of the symptoms - dryness, itching, vaginal pain and dyspareunia - was 6.9; 3.2; 4.7; and 5.3. Vaginal dryness (mean VAS 6.9) and pain during intercourse (mean VAS 5.3) were the most severe symptoms observed in this group of patients. On the other hand, vulvar pruritus (mean VAS 3.2) was considered the least severe for patients. At the end of treatment, all baseline VAS results showed a statistically significant improvement (p <0.0001) in relation to the value of 3; 1.6; 1.2; 2. The results are presented in Figure 1.

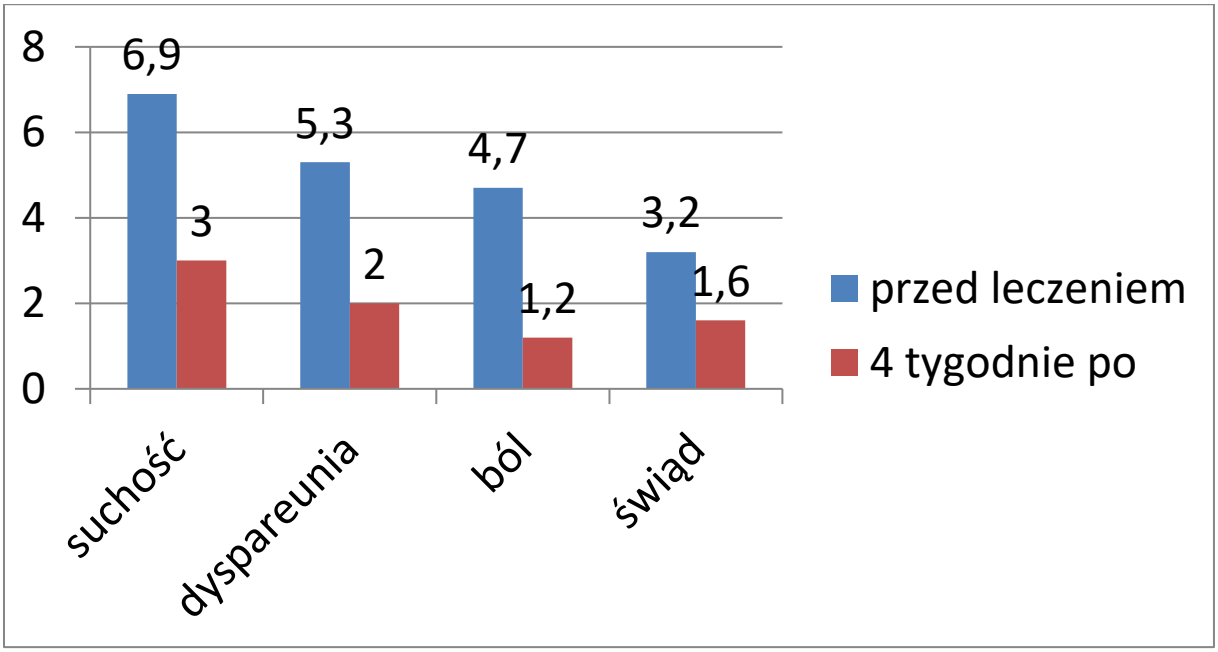

Figure 1. Mean value of VAS assessment of symptoms of vaginal atrophy and vulva before starting treatment and 4 weeks after completion (p <0.0001)

The average vaginal health index score before treatment was 8.97 (minimum 5 - maximum 17). During the final evaluation one month after Plexr treatment, the mean value of VHI showed a statistically significant improvement of the value at 17.28 (minimum 14 - maximum 22 (p <0.0001) (Figure 2).

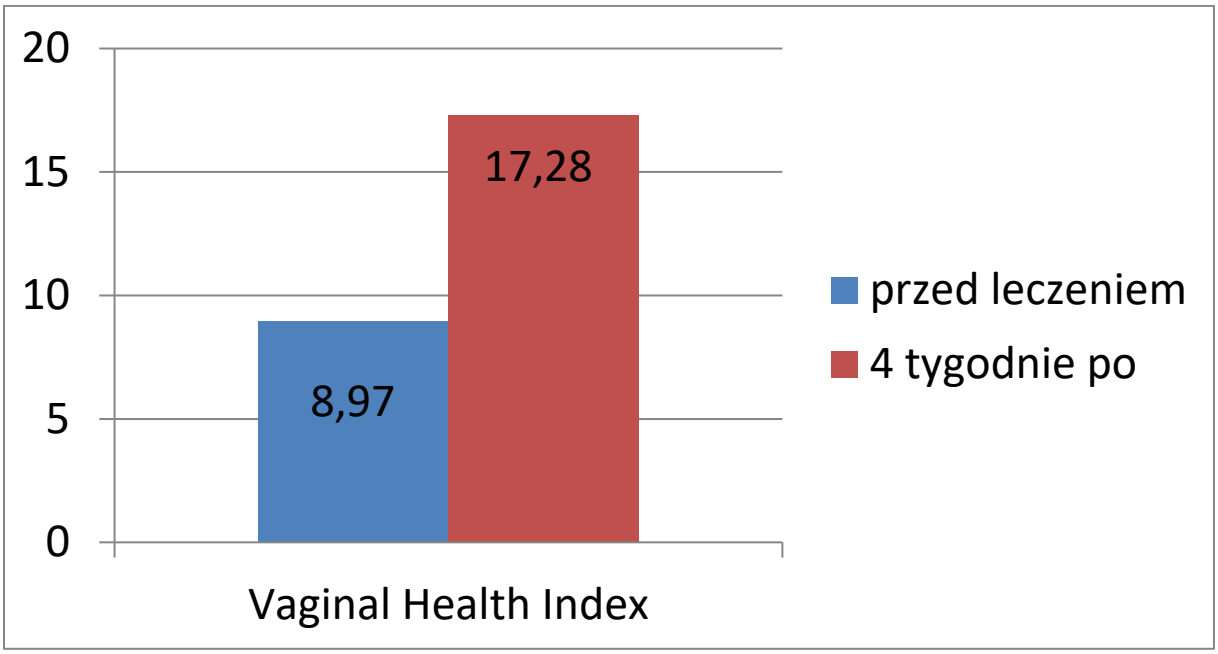

Figure 2. Vaginal health index (VHI) before and after treatment (p <0.0001).

According to the 5-point Likert scale, a satisfaction rate of 95% of patients was achieved. Most of the patients undergoing treatment were satisfied with the result. On a 5-point scale, 64% assessed the effects of treatment with a score of 5 (very satisfied). No patient evaluated the treatment with a score lower than 3. (Figure 3)

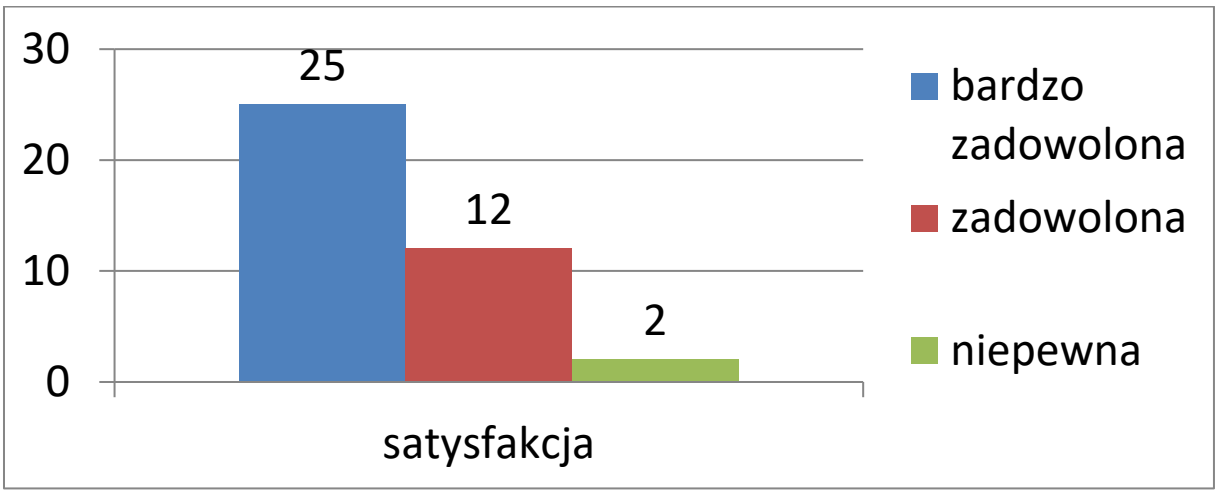

Figure 3. Satisfaction of patients with treatment according to the Likert scale.

None of the patients reported serious side effects associated with treatment.

Discussion

In the treatment of perimenopausal symptoms, vaginal estrogen appears to relieve symptoms more effectively than non-hormonal gels. Hormone replacement therapy can also be used, however, 10% -20% of women may also have symptoms while taking estrogen [8]. Furthermore, many women prefer not to use hormone therapy because of side effects or contraindications [9].

Lasers have long been considered a precise and controllable treatment method to rejuvenate the skin through tissue ablation resulting in collagen regeneration and remodeling. [10] In gynecology the C02 laser is also used to alleviate the symptoms associated with sclerofascial lichen, with good results [11]. Furthermore, the regenerative effect on the remodeling of collagen has been used in the treatment of atrophy of the urogenital system, due to the decrease in estrogen levels. The CO2 laser is able to restore the pH of the vaginal mucosa by releasing glycogen and acid mucins from the epithelium. [12] Plexr seems to work with a similar mechanism. The induced heat, the thermal remodeling with the formation of new collagen fibers and also an effect on neoangiogenesis can certainly reduce the discomfort. Simultaneous constriction of the lips is smaller and their clearing after treatment can be a further advantage of the device. At the same time, the lack of side effects can lead to the assertion that Plexr may be an alternative to pharmacological and non-pharmacological treatment of vaginal and vulvar atrophy symptoms.

Conclusion

1. Plexr is a good option for the treatment of VVA symptoms

2. Treatment with Plexr can improve genital-genital symptoms and clinical symptoms associated with decreased estrogen levels.

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