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Absence of Complications with the Use of Non-Ablative Erbium and Hybrid Semi-Ablative Erbium/Diode Vaginal Laser; Experience After 9 Years

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ABSTRACT

Vaginal laser (VL) for the treatment of vaginal hyperlaxity syndrome, vaginal atrophy, genitourinary syndrome and stress urinary incontinence has been in use for more than a decade. Despite this extensive experience, certain institutions are still prejudicial towards VL, due to the notion that VL can cause serious injuries to patients. This notion is not consistent with the large amount of data on adverse events collected over a period of 9 years by our medical center. During this period, 1743 laser sessions with non-ablative erbium laser and semi-ablative erbium-diode hybrid laser were carried out with patients being monitored for self-limited side effects and complications. Cumulatively, 147 cases of side effects with spontaneous resolution were observed, without a single complication due to laser treatment. We argue that when performed by trained professionals with good quality equipment, VL may be considered a highly safe treatment modality.

Key words: Vaginal Laser, Vaginal Laser complications.

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I. INTRODUCTION

Vaginal laser treatment was introduced in the first decade of this millennium with an objective to perform restorative treatments similar to those used on the face for decades. A paper by Dr. Adrian Gaspar [1] marked the beginning of a new era in gynecology. Since then, laser devices for vaginal use by various manufacturers have spread throughout the world. Alongside more invasive treatments such as diode laser-assisted colpoperineoplasty [2] and diode laser labiaplasty [3], several studies have reported the effectiveness of non-invasive VL treatments for genitourinary syndrome of menopause [4] and for vaginal relaxation syndrome [5-6]. In addition to these anticipated outcomes, some studies also reported an improvement of stress urinary incontinence (SUI) [7-8]. Therefore, VL has been attracting more attention from the scientific community in recent years, which is reflected in numerous publications in different medical journals and presentations on international congresses and symposiums throughout the world. However, it has been argued that these studies mostly do not represent a high enough quality of evidence and that additional well-designed, controlled studies with standardized laser settings and therapeutic protocols, long durations of follow-up, consistent outcome evaluations, and comparisons of laser-therapy to placebo or other treatment modalities are needed. Furthermore, some medical societies are reluctant to endorse this treatment modality due to fear of safety issues based on an FDA (Food & Drugs Administration) warning letter from 2018 [9] about energy-based devices for vaginal rejuvenation association with "numerous cases of vaginal burns, abnormal scars, dyspareunia and chronic pain". In this warning the FDA encourages "those who have had an adverse effect associated with the use of these devices to inform the FDA through its Safe Information and Adverse Events Program."

VL treatments have been performed at our medical center since 2013. To date, numerous patients were successfully treated and the resulting data demonstrating high compliance and high patient satisfaction was published in several case series [10-11]. Importantly, every patient undergoing laser procedure at our medical center is monitored for potential adverse events. The objective of this study was to analyze the data on adverse events collected over a period of 9 years and thereby contribute to the understanding of VL safety.

II. MATERIALS AND METHODS

Data on adverse events was collected from records of patients treated with one or more sessions of VL over a period of 9 consecutive years. All were patients who sought improvement of stress urinary incontinence, hyperlaxity or genitourinary syndrome of menopause, alone or in combination. All patients were offered an alternative treatment depending on their goal; pelvic floor physiotherapy, surgery, or vaginal estrogen. Many of the estrogen-deficient patients received local estrogen treatment before and after their

treatment. During the relevant 9-year period, two different lasers were used for VL therapy. An 2940 nm Er:YAG laser (Fotona Smooth™ xs, Fotona, Ljubljana, Slovenia) was used in the first 5 years (Laser 1) and a Fractionated Hybrid Erbium/Diode Laser with wavelengths 2940 nm/1470 nm respectively (DivA, Sciton, Palo Alto, Ca, USA) in the last 4 years (Laser 2).

During the studied period, 635 sessions were carried out consecutively with Laser 1, from May 2013 to May 2018) and from June 2018 to May 2022, 1108 sessions with Laser 2. We analyzed the data on adverse events collected from patients treated with both Laser 1 and Laser 2 together, because comparison between groups was not the aim of this paper. Collectively, 1743 procedures were performed. We expressed the frequency of each adverse event reported by the patients as a fraction of the total number of procedures.

All patients signed a detailed informed consent before treatment. This consent specified all the possible complications that can occur with the laser, including the most severe ones described by the FDA in its warnings. This is a retrospective study of patients treated with informed consent in the last 9 years, so submission to an Ethics Committee was not necessary.

The ages of the patients ranged in both groups from the 20s (generally women with hypermobility and/or mild to moderate stress urinary incontinence who had not yet fulfilled their reproductive desire) to women 70 or older. 90% of patients were in the age segment between 40 and 55 years.

The possible complications specified in the patient's informed consent document that were subsequently analyzed were the following:

- Edema (swelling) of the vaginal mucosa.
- Excessive pain during or after treatment.
- Hives (itching).
- Vaginal bleeding.
- Burning sensation.
- Infection and/or reactivation of symptoms of genital herpes virus infection.
- Local or systemic allergic reaction to topical preparations.
- Scarring: hypertrophic and non-hypertrophic
- Burns: superficial to full thickness
- Extensive tissue destruction
- Ulceration
- Induced bruising or petechiae formation
- Severe edema

III. RESULTS

The frequency of adverse events is summarized in Table 1.

Table 1: Frequency of adverse events reported by patients treated with VL therapy, presented as a cumulative number of reported side effects/complications (n) and as a fraction (%) of the total number of procedures (1743).

Self-limited side effects	**n**	**(%)**
Edema	0	0.00
Excessive pain during the procedure	8	0.46
Pruritus- Transient Urticaria	35	2.00
Vaginal Bleeding	87	5.00
Sensation of vaginal burning	15	0.86
Infection and/or activation of genital herpes	0	0.00
Allergic reaction to topical anesthesia	2	0.11
Cumulative	147	8.43

Complications	**n**	**%**
Abnormal hypertrophic or non-hypertrophic scarring	0	0
Burn: Superficial to Full Thickness	0	0
Extensive tissue destruction	0	0
Ulceration	0	0
Symptomatic bruising and/or petechiae	0	0
Severe Edema	0	0
Claim or Medical-Legal action due to complications	0	0
Cumulative	0	0

IV. DISCUSSION

During the analyzed period, not a single mild, moderate, or severe complication was observed in any of the 1743 VL procedures. There was not a single case of claim, either informal or legal, due to any complication. There were only a few reports of side effects such as vaginal bleeding during treatment (5%), which resolved spontaneously immediately after the end of treatment. Of these, almost all cases occurred in patients with vaginal atrophy who had a thin vaginal mucosa. Patients with pain and vaginal itching sensation were treated with non-steroidal analgesics such as paracetamol. The two cases of allergic reaction were managed with oral antihistamines. Excessive pain during treatment generally manifested itself in patients undergoing laser treatment with higher energy. In these cases, the common approach is to stop the procedure temporarily and resume with decreased intensity. There was not a single patient whose treatment could not be completed due to pain. Therefore, our data show the VL procedures are safe.

These results are in agreement with a study that analyzed the data on adverse events collected from 43095 patients from various centers performing VL procedures

[12], which concluded that VL carries a very low risk profile, as the reported adverse effects were mild to moderate, transient in nature and occurred with very low frequencies. To compare the safety of VL with more invasive treatment modalities, an extensive analysis would be necessary due to the numerous different medical indications that the VL enables. Nevertheless, VL may be superior in terms of the safety profile for some indications. For example, one study comparing VL and tension-free vaginal tape treatment for SUI stated that while the effectiveness of both is comparable, the incidence of de novo urgency at 1 year after TVT is reported to be 22.2%, whereas VL is not reported to generate de novo urgency or any serious major adverse events [13]. A study treating 16 SUI patients with a bulking agent [14] reported an even higher frequency of adverse events; namely 62.5% for urinary tract infections, 31% for urine retention, 12.5% for de novo urge and urgency incontinence and 6% for nocturia, although these high frequencies may to an extent reflect the small sample used in the study. A systematic review assessing the effectiveness of surgical interventions as treatment for urinary incontinence in the elderly population concluded that complication rates varied between 1% and 26%, mainly bladder perforation, bladder emptying disturbances, and de novo urge [15].

Overall, based on the patients treated at our medical center, we can argue that the worst case scenario of VL treatments is not an injury, but merely not obtaining the desired result. Although assessment of efficacy of VL treatment is not the scope of this paper, in our experience good results are obtained in approximately 85% of patients if the patient is correctly evaluated and selected. As the main task of a physician is to comply with the phrase attributed to Hippocrates that states "primum non nocere" (first do no harm), it is of great importance to review and publish clinical experiences with the use of intravaginal lasers and possible complications. With more data available to the public, there will be fewer unsupported views about the safety of VL treatments and less prejudice about their efficacy.

V. CONCLUSIONS

In our 9-year experience with the use of two different laser devices for vaginal use, we have not observed any complications associated with the laser treatment. Although more randomized studies and double-blind studies evaluating the use of intravaginal laser are needed to ascertain its usefulness in the pathologies for which it is indicated, we argue that this treatment modality does not pose safety issues, provided that the equipment used is obtained from a reliable company and that the operator is properly trained to indicate and perform the procedure.

DISCLOSURE

The author is currently a speaker for Sciton Inc. company for its Diva (Laser 2) intravaginal device. The author does not have and did not have any commitment with the company Fotona (Laser 1).

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