

# Applicability of vaginal energy-based devices in urogynecology: evidence and controversy

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## SUMMARY

**OBJECTIVE:** This study aimed to analyze the evidence and controversies about the use of vaginal energy-based devices (laser and radiofrequency) for treatment of genitourinary syndrome of menopause, recurrent urinary tract infection, urinary incontinence, and genital prolapse through a literature review.

**METHODS:** A search of literature databases (PubMed, Medline) was performed for publications in December 2022. Keywords included genitourinary syndrome of menopause, vaginal laxity, vaginal/vulvovaginal atrophy, urinary tract infection, urgency incontinence, frequency, urgency, stress urinary incontinence, genital prolapses AND energy-based devices, AND vaginal laser, AND vaginal radiofrequency, AND CO2 laser, AND Er:YAG laser. Publications in English from the last 7 years were reviewed and selected by the authors.

**RESULTS:** The literature regarding vaginal energy-based devices in the treatment of urogynecological conditions is primarily limited to prospective case series with small numbers and short-term follow-up. Most of these studies showed favorable results, improvement of symptoms with low risk, or no mention of serious adverse events. Consensus statement documents from major medical societies suggest caution in recommending these therapies in clinical practice until more relevant data from well-designed studies become available.

**CONCLUSION:** The potential of the vaginal laser and radiofrequency as a therapeutic arsenal for the evaluated urogynecological conditions is great, but qualified research must be done to prove their efficacy and long-term safety, define application protocols, and recommend the use of these technologies in clinical practice.

**KEYWORDS:** Genitourinary syndrome of menopause. Female urogenital diseases. Urinary tract infection. Urinary incontinence. Genital prolapses AND "laser therapy" AND "radiofrequency therapy".

## INTRODUCTION

Genitourinary syndrome of menopause (GSM) is a common clinical condition, and its symptoms affect about 50% of postmenopausal women, with a great impact on their quality of life. Since the first use of vaginal laser in 2014, there has been growing enthusiasm regarding the use of vaginal energy-based devices (EBD) to treat vaginal atrophy and other associated urogynecological conditions. Several publications describe the potential use of these devices, especially the laser, which demonstrates that their use is already a reality in clinical practice despite limited evidence regarding long-term efficacy and safety<sup>1-4</sup>.

There are three main types of non-surgical (for tissue remodeling) EBD with applicability for vaginal use: micro ablativ fractional CO<sub>2</sub> laser, Er:YAG laser, and temperature-controlled radiofrequency (RF). As they have not yet been recommended

for general use, they are not treatments covered by health insurance or affordable for the general population<sup>3,4</sup>.

In July 2018, the Food and Drug Administration (FDA) issued a public warning about the use of EBD to perform vaginal rejuvenation or vaginal cosmetic procedures because the safety and efficacy for treatment of these conditions have not been established<sup>5</sup>. Some more recent research is disparate from the FDA's safety communication. A review in the American Manufacturer and User Facility Device Experience (MAUDE) database and the Bloomberg Law database showed a low rate of reported side effects or no claims asserting harm from vaginal EBD use, which suggests they have an acceptable safety profile<sup>6-8</sup>.

Through this narrative review of the literature, we aimed to analyze the current evidence for recommending the use of these vaginal EBD in urogynecology, especially in GSM,

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recurrent urinary tract infection (UTI), urinary incontinence, and genital prolapses.

## METHODS

A structured search of literature databases (PubMed, Medline) was performed for all publications, full texts, and abstracts, written in English from January 2015 to December 2022. Keywords included genitourinary syndrome of menopause, female urogenital diseases, urinary tract infection, urinary incontinence, genital prolapses AND “laser therapy” AND “radiofrequency therapy”. The articles were reviewed and selected to present the evidence and discuss each proposed clinical indication.

## RESULTS

A total of 32 studies were selected and analyzed by the authors, of which 14 evaluated the effect of energy-based therapies in GSM, 5 recurrent urinary tract infection, 11 urinary incontinence, and 3 pelvic organ prolapse.

All the studies except five were prospective or retrospective case series without a control group. Most of them were of low quality and had short follow-up and the clinical outcomes measured were subjective.

## DISCUSSION

### Vaginal energy-based devices in the treatment of genitourinary syndrome of menopause

Genitourinary syndrome of menopause (GSM) describes the symptoms and signs resulting from the effect of estrogen deficiency on the female genitourinary tract. Symptoms associated with GSM are highly prevalent, affecting approximately 27% to 84% of postmenopausal women, and can include vaginal dryness, dyspareunia, burning, itching, and dysuria. GSM is generally progressive without effective therapy<sup>1</sup>.

According to the North American Menopause Society (NAMS), the first-line recommended treatment for mild GSM is the use of non-hormonal therapies such as lubricants and moisturizers; gentle vaginal stretching exercises or regular sexual activity can also be recommended. When we face a moderate-severe GSM, it is recommended to start with local estrogen products, which are considered the “gold standard” and the most effective therapy as long as there are no contraindications to its use. Alternative options for those patients for whom estrogenic therapies are not recommended have been studied<sup>2</sup>.

Mension et al.<sup>3</sup> published in 2021 a systematic review on the use of vaginal laser for GSM. A total of 64 studies were available, of which only 10 were controlled intervention studies, and only 4 were considered of good quality. All selected studies had a short follow-up time, less than 6 months, and used three CO<sub>2</sub> laser sessions. One recent publication analyzed in this review was highlighted by Salvatore et al.<sup>9</sup>, in which the CO<sub>2</sub> laser was compared with a placebo (sham-laser) and compared the intensity of vaginal dryness, dyspareunia, sexual desire and satisfaction, urinary frequency, and urinary incontinence through the visual analog scale (VAS), Female Sexual Function Index (FSFI), and Urogenital Distress Inventory (UDI-6). At the end of the 4th month, the incidence of vaginal dryness, dyspareunia, and sexual dysfunction was lower in the laser group compared to the placebo; there was no difference in urinary symptoms, and there were no significant adverse events. Most studies used symptom scores and not objective measures to assess outcomes.

The International Continence Society (ICS) and the International Society for the Study of Vulvovaginal Diseases (ISSVD) elaborated a consensus paper on the use of vaginal laser for the treatment of urogynecological conditions, aiming to bring recommendations for use based on a literature review and pointing out existing evidence until publication (2018). The authors pointed out that there is little known about the histology of vaginal mucosa after laser therapy for vaginal rejuvenation or functional remodeling; what is reported is based on small studies of patients over a short period of time and cannot prove tissue remodeling in fact, ending up not to recommend the use of laser for “vaginal rejuvenation” or indicate it for routine treatment of vulvovaginal atrophy or GSM<sup>10</sup>.

The American Urogynecologic Society (AUGS) provided guidance for the use of vaginal EBD by convening a panel of experts to compile a clinical consensus statement in 2020. In the publication, the authors agreed that the evidence is limited by the scarcity of randomized and controlled studies, in addition to the short follow-up to assess safety and long-term effects. However, the use of laser to treat vaginal atrophy and dyspareunia associated with menopause has shown efficacy for up to 1 year with a favorable safety profile<sup>11</sup>.

Paraiso et al. published in 2020 a multicenter, randomized trial comparing the effect of CO<sub>2</sub> laser with vaginal estrogen cream after 6 months. They included 62 menopausal women with significant vaginal atrophy symptoms and did not find a statistical difference in the score VAS, which evaluated dryness and dyspareunia, as well as in the other analyzed scores FSFI, UDI-6, and Day-to-Day Impact of Vaginal Aging (DIVA). The measurements of vaginal pH and vaginal maturation index

(VMI) with objective data showed statistical differences, with improvement in the group that used estrogen, although baseline and 6-month follow-up VMI data were only available for 34 participants (16 laser, 18 estrogen)<sup>12</sup>.

Another study published in 2022 by Quick et al.<sup>13</sup> evaluated the effectiveness of three CO<sub>2</sub> laser sessions, separated by intervals between 30 and 45 days, for GSM symptoms in 67 women treated for breast cancer. In all, 33 women completed the 2-year follow-up. VAS, UDI-6, FSFI, and Female Sexual Distress Scare Revised (FSDS-R) scores were evaluated. There was an initial improvement in vaginal and urinary symptoms in all indexes after the first 4 weeks of treatment, with a decrease in the improvement in most evaluations after 1 and 2 years. Sexual function was the only area that sustained significant improvement over time. No grade 3 or higher adverse events were identified at the 2-year follow-up.

Regarding the use of vaginal RF for GSM treatment, there are still fewer publications of well-designed, randomized, and long-term studies that assess genitourinary symptoms. Wattanakrai et al. published, in 2021, a prospective, randomized, double-blind study evaluating the effect of RF and PEMF (pulsed electromagnetic field-based device) versus sham for vaginal laxity. They included the Vaginal Laxity Questionnaire (VLQ), the FSFI, perineometer measurements, Brink scores, and vaginal histological analysis. There was an improvement in parameters in the treated group compared to the control group without significant adverse events in both groups, and itching was significantly higher in the sham arm. Histological analysis demonstrated signs of neocollagenesis, neoelastogenesis, and neoangiogenesis. Authors concluded that RF+PEMF was safe and improved all studied parameters at least 12 weeks post-procedures (short-term follow-up)<sup>14</sup>.

The authors agreed that there is no robust scientific evidence to support the widespread use of EBD for the treatment of GSM. On the contrary, the potential benefit and low rate of serious adverse events must be recognized. Well-designed, multicentric, long-term case-control studies are required to further investigate the potential benefits, safety, and efficacy of vaginal EBD therapy for treating GSM. In addition, to establish application or reapplication protocols, it is necessary to define the real cost-benefit ratio of these technologies.

### Vaginal energy-based devices in the treatment of recurrent urinary tract infection

There are no publications, in the reviewed databases, that have specifically analyzed the action of vaginal EBD in preventing UTIs, despite the relationship between GSM and the recurrence of such infections. In postmenopausal women, there is

an impactful transition in vaginal microbiome; lactobacilli concentration and diversity tend to be lower, and pH also usually elevates. All these changes can be correlated to vulvovaginal atrophy and estrogen deficiency<sup>10,15</sup>.

Athanasίου et al.<sup>16</sup>, evaluated vaginal laser therapy with CO<sub>2</sub> in 53 postmenopausal women and demonstrated a decrease in vaginal pH and an increase in the number of lactobacilli. In contrast, another study, published by Becorpi et al.<sup>17</sup>, showed no change in the vaginal microbiome in 20 women after breast cancer treatment who underwent vaginal CO<sub>2</sub> laser sessions but recorded significant changes in the patterns of inflammatory cytokines and immunomodulators in the vaginal epithelium, suggesting that the benefits of laser treatment in this group of patients are related to a possible anti-inflammatory effect.

Sarmento et al.<sup>18</sup>, evaluated the effect of fractional microablative RF on the vaginal microbiota, vaginal pH, and cell maturation of 55 postmenopausal patients. They demonstrated a drop in pH and an increase in the flora of vaginal lactobacilli 30 days after application without serious adverse effects. The short follow-up time, the lack of a control-group, and the failure to assess the UTI rate did not allow for more assertive conclusions.

The potential of the use of vaginal EBD, laser, and radiofrequency in the prevention of UTI recurrence needs to be better evaluated through well-designed studies with this specific purpose.

### Vaginal energy-based devices in the treatment of urinary incontinence

Fistonić et al.<sup>19</sup> conducted the first study on the efficacy and safety of the laser in the treatment of Stress Urinary Incontinence (SUI). They included 73 patients between 18 and 70 years of age with pure SUI not associated with pelvic organ prolapses (POP) who were treated with a single session of Er:YAG laser. In 6 months, only 47 patients remained in the study; 34/47 (72.3%) of patients experienced improvement on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQUI SF), and 18/47 (38.3%) had an ICIQUI SF score=0. Patients who were overweight (body mass index >25 kg/m<sup>2</sup>) and aged over 60 years had the least improvement in the questionnaire. The short-term follow-up, lack of control group, and high loss of follow-up were important limitations.

Gambacciani et al.<sup>20</sup> conducted a non-randomized prospective study with long-term follow-up in 235 patients undergoing vaginal Er:YAG laser. Of these, 114 had SUI and were evaluated with the ICIQUI SF questionnaire, excluding patients with POP. There was a significant decrease in ICIQUI SF scores

after the third month, which remained lower until 12 months after the last application. However, after 18 and 24 months, there was no significant difference compared to baseline values. A total of 96 patients desired to repeat the procedure, and 9 patients remained satisfied after 24 months.

Blaganje et al.<sup>21</sup> published the only prospective randomized controlled trial (RCT) evaluating the effect of the vaginal laser on SUI. In all, 114 premenopausal women were classified into treatment group with Er:YAG laser in a single session and a control group with placebo (sham laser). The primary result was evaluated with the ICIQUI SF questionnaire. Of note, 21.4% of patients in the laser group were dry (ICIQUI SF score=0) after 3 months, when compared to only 3.6% of the control group. Age, BMI, and parity had no effect on the outcome, but severe SUI was a negative predictive factor.

González et al.<sup>22</sup> published the first long-term study of CO<sub>2</sub> vaginal laser in patients with SUI. A case series of 161 postmenopausal women with mild SUI without POP underwent four sessions of micro ablativ CO<sub>2</sub> fractional laser, followed by annual protocol at 12, 24, and 36 months. There was a reduction in ICIQUI SF scores up to 36 months and also a significant improvement in the 1-h pad test.

Few studies have presented an objective evaluation of the improvement of urinary incontinence. Tien et al.<sup>23</sup> consecutively evaluated 28 women with urodynamic SUI. Of them, 39.3% (11/28) had an objective cure with a single session of Er:YAG laser and other 39.3% (11/28) showed improvement. The best results were for mild SUI. Other studies, such as that by Kuszka<sup>24</sup> suggest that laser treatment should be reserved for milder cases.

Another randomized, no-blinded study<sup>25</sup>, of short follow-up, evaluated vaginal CO<sub>2</sub> laser in postmenopausal women with genitourinary syndrome. The effect on SUI was analyzed with the ICIQUI SF questionnaire. In all, 72 patients were classified into three groups: group 1 received three sessions of fractional vaginal CO<sub>2</sub> laser, group 2 received vaginal promestriene, and group 3 received vaginal lubricant. At 14 weeks, there was a reduction in ICIQUI SF scores only in the laser group.

A meta-analysis by Wang et al.<sup>26</sup> investigated the safety and efficacy of the vaginal laser (Er:YAG and CO<sub>2</sub>) for the treatment of SUI. It included 16 studies involving 899 patients, excluding patients with POP, with only 1 prospective RCT<sup>22</sup>. There was an improvement in the ICIQUI SF score up to 6 months and in the 1-h pad test up to 12 months after treatment. Three sessions of treatment achieved a greater improvement compared to the results from 1 or 2 sessions, and no benefit was achieved with more than 3 sessions<sup>19,22,24,27</sup>. The data showed that the laser can be effective in the long term, but only two

studies had follow-up time of up to 24 or 36 months<sup>19,22</sup>. Premenopausal women had a greater chance of sustained results in 2 years<sup>20</sup>, and most studies suggested the need for an annual maintenance session<sup>19,21,27,28</sup>. Only six studies reported side effects, with vaginal discharge being the most frequent, in a small number of patients. There have been reports, even less frequent, of de novo urgency (2 patients), low-intensity pain (6 patients), vaginal itching (3 patients), vulvar discoloration (5 patients), and vaginal bleeding (2). None of the effects required medical intervention.

Regarding RF, the number and quality of studies that evaluate their applicability to SUI are even lower. However, the Brazilian study by Slongo et al. deserves to be highlighted<sup>29</sup>. It was a randomized clinical trial including 117 climacteric women who were classified into three groups: group 1 received three monthly sessions of vaginal micro ablativ RF; group 2 received 12-weekly pelvic floor muscle training (PFMT) sessions; and group 3 received RF+PFMT simultaneously. Assessment at 30 days after treatment using ICIQUI SF demonstrated improvement in all three groups; however, it was significantly greater in the RF+PFMT group than in the RF and PFMT alone groups (p=0.002). Urinary loss in the 1-h pad test decreased by 7.72 g on average after treatments but with no differences between the three groups.

The authors concluded that vaginal EBD may have applicability for SUI, especially for mild cases, but randomized and controlled trials with a greater number of patients are necessary.

### Vaginal energy-based devices in the treatment of genital prolapses

Few studies evaluate the effectiveness of vaginal EBD for the treatment of POP. Most works that evaluate the laser for other conditions exclude patients with POP. Athanasiou et al.<sup>30</sup> compared Er:YAG laser with observation in a randomized prospective study in 30 postmenopausal patients with cystocele or rectocele stage  $\geq 2$ , excluding patients with apical prolapse. In all, 15 patients received three monthly laser sessions, and 15 were observed. No patients in the laser group had objective cure of prolapse (considered stage  $\leq 1$ ); 2/15 had a decrease of 1 point in the prolapse stage, and 2/15 worsened. Pelvic Floor Distress Inventory Questionnaire short-form (PFDI-20) and Pelvic Floor Impact Questionnaire short-form (PFIQ-7) scores did not show statistically or clinically meaningful differences with laser treatment.

Another study evaluated three CO<sub>2</sub> laser sessions in women with postmenopausal genitourinary syndrome and POP stage  $\leq 2$ , observing improvement in PFDI-20, Pelvic Organ Prolapse Distress Inventory, and Urinary Distress Inventory questionnaires,

which evaluated urinary, sexual, and functional symptoms related to prolapses. However, there was no control group, and there was no direct evaluation of the improvement of the prolapse<sup>31</sup>.

Ogrinc<sup>32</sup> demonstrated significant improvement of cystocele grades 2 to 4 with 2 to 5 sessions of Er:YAG laser, with reduction of prolapse to grades 0 or 1 in 85% of cases in 12 months of follow-up. However, this is a single-arm, pilot, and observational study with 61 patients, using only the Baden-Walker scale for POP staging and without the use of validated questionnaires.

The authors concluded that there is no recommendation for EBD in the treatment of genital prolapses.

## CONCLUSION

The lack of quality in studies regarding the use of vaginal laser or radiofrequency for urogynecology raises the

question about whether these therapies provide long-term risk-free benefit. Based on the available scientific evidence, after this literature review, although the vaginal EBD seems promising for select indication at present, it should not be recommended for the treatment of GSM, urinary incontinence, recurrent urinary tract infection, and genital prolapses outside of a research context where patient is aware of efficacy and risks.

## AUTHORS' CONTRIBUTIONS

**ACM:** Data curation, Resources, Writing – original draft.

**LMPPJ:** Data curation, Resources, Writing – original draft.

**LGMT:** Methodology, Supervision, Writing – review and editing.

**CLZR:** Methodology, Supervision, Writing – review and editing.

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