Microinvasive Treatments in Pelvic Floor Disorders

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Vaginal Energy-Based Devices

In recent years, in-office treatment of genitourinary syndrome of menopause (GSM) and vaginal laxity (VL) using nonsurgical laser-based vaginal devices (LBD) have been introduced worldwide and have been rapidly promoted as both safe and efficacious.

Vaginal EBD treatments are classified as:

1) Ablative:

Ablative lasers burn a grid of tiny holes on the surface tissue, which then induces a healing response, leading to increase in collagen, elastin, and glycogenated cells.

The term microablative is used for a laser device that cause minimal ablation

2) Nonablative lasers and RF :

work by heating up the underlying tissue and increasing heat shock proteins and collagen production without harming the surface

Fractional lasers:

break up the laser energy into thousands of tiny beams to treat only a fraction of the skin in the area, which is aimed to reduce downtime

Fractional lasers can be:

ablative, microablative, or nonablative. The 2 main types of lasers currentl used for the treatment of GSM are the fractional microablative CO2 laser and the nonablative Er:YAG laser.

Target devices were defined as:

all vulvovaginal EBDs applied to treat the conditions listed here, including the following:

Nonablative Er:YAG laser

Fractional microablative CO2 laser

Hybrid—combination of nonablative and ablative approaches

LBD within the context of this committee opinion include light amplification by stimulated emission of radiation:
(LASER). By heating the connective tissue of the vaginal wall to 40–42 °C, these devices induce collagen contraction,
Neo collagenesis, vascularization, and growth factor infiltration that ultimately revitalize and restore elasticity and moisture to the vaginal epithelium

Radiofrequency:

A device that uses RFenergy to heat tissue and stimulate subdermal collagen production in order to reduce the appearance of fine lines and loose skin. The technique induces tissue remodeling and production of new collagen and elastin.
Radiofrequency treatment also causes apoptosis of fat cells, which leads to fat layer reduction in the treated area.

Patients who benefit the most
from energy-based procedures are :
those who have symptoms of mild-to-moderate SUI,
overactive bladder,
vaginal dryness,
Decreased lubrication,
orgasmic dysfunction,
grade 1 prolapse,
and vaginal laxity.
The indications are ever increasing, but more studies are required to evaluate the true breadth of the efficacy of energy-based devices.

I n a July 2018 Safety Communication, the U.S. Food and Drug Administration (FDA) issued a public warning about the use of energy-based devices (EBDs) to perform vaginal rejuvenation or vaginal cosmetic procedures
the agency
has not approved their use for any specific gynecologic indication.

An International
Continence Society/International Society for the Study of Vulvovaginal Disease Best Practice Consensus Statement published in February of 2019 concluded that, based on the currently available literature, laser is not recommended for routine treatment of vaginal atrophy or urinary incontinence unless treatment is part of a well-designed clinical trial or with special arrangements for clinical governance, consent, and audit

Statements That Reached Consensus

Before EBD therapy,

vulvar lesions, vaginal lesions, or cervical pathology should be excluded.
Absolute contraindications to EBD therapy include a current pelvic malignancy, recent pelvic surgery, or an active infection

Pretreatment criteria for EBD therapy may include :

inability to use vaginal estrogen treatment for menopausal dyspareunia, VVA, or vaginal dryness.

Low-dose vaginal estrogen is the most effective therapy for moderate to severe VVA, vaginal dryness, and menopausal dyspareunia, but there are insufficient data to demonstrate the safety of vaginal estrogen for women with breast cancer.

Vaginal moisturizers, lubricants, and topical lidocaine are helpful alternatives, but these may be insufficient to alleviate symptoms. Vaginal energy-based therapies may fill a treatment gap for women who are unable to use low-dose vaginal estrogen.

Patients undergoing EBD therapy should have had a gynecologic examination within 1 year of treatment.

The purpose of a focused gynecologic examination include:
visual inspection of the external genitalia
a speculum examination
bimanual examination
and rectal examination based on symptoms
Cervical cytology with human papillomavirus cotesting based on screening guidelines.

EBD therapy for vaginal and vulvar health should be offered by individuals who have had training in the relevant anatomy and demonstrated clinical competence, judgment, and experience in the full range of treatments of the intended conditions.

Industry standards for proper EBD training for health care providers need to be established.
No industry standards currently exist outlining specific protocols for proper training of health care providers offering EBD services,

In the EBD space:

individual companies develop their own training programs in accordance with the specific products they are marketing, which may not take patient outcomes into account.

Companies must follow FDA-mandated labeling as listed in the IFU (“instructions for use”), which is required in the labeling of all regulated medical devices.

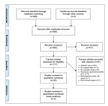
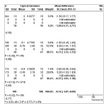
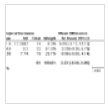
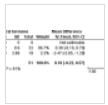
EBD therapy has demonstrated short-term efficacy in addressing medical menopause-related conditions of vaginal atrophy and menopausal dyspareunia.

Use of Er:YAG and fractional CO2 EBD for treatment of GSM/VVA have increased. However, existing clinical studies are limited in their design, with small sample sizes, lack of control groups, short follow-up periods

Placebo-controlled level I data are needed to further explore this topic

Outline

Figures (6)

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Review Article

The Efficacy of Vaginal Laser and Other Energy-based Treatments on Genital Symptoms in Postmenopausal Women: A Systematic Review and Meta-analysis

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ABSTRACT

Methods of Study Selection

The inclusion criteria were all randomized studies, prospective studies with >10 cases, and retrospective studies with >20 cases published in English or French that assessed change in postmenopausal vaginal symptoms and/or sexual function in women after energy-based vaginal treatments. Meta-analyses were performed on randomized data.

Tabulation, Integration, and Results

Of the 989 results retrieved, 3 randomized studies, 16 prospective studies, and 7 retrospective studies were included in the review, representing data from 2678 participants. Pooled data from 3 randomized controlled trials show no difference between vaginal laser and topical hormonal treatments for change in vaginal symptoms (−0.14, 95% confidence interval −1.07 to 0.80) or sexual function scores (2.22, 95% confidence interval −0.56 to 5.00). Furthermore, no difference among vaginal laser, topical hormone, and lubricant was demonstrated in sexual function ($p = .577$). As in our previous review, non-randomized data support energy-based treatments in improving vaginal symptoms, sexual function, and clinician-reported outcomes. No severe adverse events were reported in the included studies. Significant heterogeneity of data arising from differing measures and reported outcomes continues to be an issue, with data remaining low quality, with high risk of bias, and no double-blind or placebo-controlled randomized trials yet reported, although 1 has now completed recruitment.

Conclusion

EBD therapy may be effective for the treatment of lichen sclerosus

Several case series describe success with CO2 laser treatment of lichen sclerosuswhenmedical therapy with topical corticosteroids has failed.

One RCT concluded that Neodymium Nd:YAG laser was more effective in treating lichen sclerosus than topical Corticosteroid.

Further studies, including differing EBDs, are necessary to provide treatment recommendations, duration of
effect, and curative effect

EBD therapies are not known to be effective in the treatment of fecal incontinence.

transanal use of RF energy has been studied in a case series of patients with fecal incontinence, but there was no control group.

This minimally invasive technique appeared to be relatively safe (low rates of mucosal ulceration and delayed bleeding) and demonstrated favorable disease-specific and overall quality of life scores 6 months after treatment.
However, long-term (mean 40 months) results have been disappointing with benefits in only 22% of treated patient

There is no clear definition of labial hypertrophy, and there is lack of evidence on the efficacy of EBD therapy for this condition.

Multiple definitions have been proposed for classification of labial hypertrophy, there is currently no clearly accepted standard,

and there are little data on use of EBD therapy for the treatment of labial hypertrophy

It is unknown if EBD therapy offers better success rates than PFE or midurethral slings for treatment of stress urinary incontinence.

Prospective case series and placebo/sham-controlled studies on EBD have shown conflicting results.
Although there is no evidence that RF offers any significant benefit,

CO2 and Er:YAG laser may help improve symptoms in women with SUI over 3 to 36 months. One randomized trial comparing Er:YAG laser to sham in 114 women with SUI showed improvement of SUI and positive effects on quality of life and sexual function at 3 months.
However, clinical trials comparing EBD therapy with standard of care treatment modalities such as PFE or midurethral slings in women with SUI are lacking.

There are no objective data on the effect of EBD therapy on vulvar or vaginal appearance.

The American Society of Plastic Surgeons advocates for use of RF or laser energy to induce collagen tightening for nonsurgical vaginal rejuvenation based on expert opinion.

Nevertheless, the AUGS EBD writing group is not aware of any long-termcredible studies that have objectively examined the effect of EBD therapy on vulvar or vaginal appearance.

The AUGS EBD writing group reached consensus that the benefits of vaginal fractionated laser therapy used to treat menopausal dyspareunia may last up to 1 year

EBD therapy improves VVA for up to 1 year.
Vaginal CO2 laser therapy has been shown to be effective in treatment ofVVA in several studies up to 20 weeks.
Although there are fewer studies with follow-up of 1 year

There are no comparative cost-efficacy data for EBD therapy versus available medical and surgical therapies for GSM/VVA, vaginal laxity, lichen sclerosus, and other pelvic floor disorders.

It is unknown if there is a cost advantage to attempting medical or behavioral therapies before EBD therapy in the management GSM/VVA, vaginal laxity, lichen sclerosus, or other pelvic floor disorders.

Validated symptoms and quality of life questionnaires, in conjunction with physical examination and diagnostic testing, should be used to assess outcomes of EBD therapy.

The AUGS EBD writing group reached consensus that either new EBD-specific validated questionnaires should be developed or existing questionnaires should be validated for assessing the efficacy of EBD therapy in conjunction with utilization of diagnostic criteria.

Based on short-term published data, EBDs have a favorable safety profile, making them appropriate alternate interventions should efficacy trials prove their benefit.

Based on the Manufacturer and User Facility Device reports:
major adverse events appear to be uncommon, but there are few trials reporting long-term safety outcomes for these relatively new therapies.
the AUGS EBD writing group believes that rigorously designed sham-controlled trials evaluating long-term safety and efficacy need to be performed before widespread adoption of EBDs for various indications.

Some potential adverse events attributable to EBD therapy may include:

increase in vaginal discharge,
vaginal spotting immediately after treatment,
bacterial vaginosis,
urinary tract infection,
and mild discomfort at the sight of treatment.
Possible but rare adverse events include scarring or burning.

The longest published follow-up after Er:YAG is 18 to 24months.

In a study of a 2-week pretreatment with estriol ovules followed with laser therapy, the adverse effects were minimal and transient, affecting 4% of patients, and included transient warmth, edema, and mild to moderate pain.

The effect of EBD therapy on existing cervical pathology or subsequent cervical stenosis is unknown.

The AUGS EBD writing group is not aware of any studies that have looked at this question.

and the practitioner should confirm normal cervical cytology based on ACOG guidelines

There is no evidence to support the use of vaginal EBD therapy for the treatment of pelvic radiation-induced vaginitis, and long-term risks of EBD use in these patients are unknown.

Importantly, a history or previous vaginal/colorectal irradiation is often listed as a contraindication for vaginal EBD therapy by the manufacturers of these devices.

Lasers in Surgery and Medicine

ASLMS

Clinical Reports

Lasers and energy-based devices marketed for vaginal rejuvenation: A cross-sectional analysis of the MAUDE database

Jusleen Ahluwalia MD, Mathew M. Avram MD, JD, Arisa E. Ortiz MD

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an analysis of MAUDE data between October 2015 and January 2019 revealed events affecting 46 patients.

“Pain,” “burning or numbness,” and “scarring or burns” were the most commonly reported adverse events with 33 patients reporting some form of long-term complication profile.

All 3 main forms of EBD therapy: CO2 Laser, Er:YAG Laser, and RF had adverse events reported

The optimal number of treatments for EBD therapy for menopausal dyspareunia, GSM/VVA, or vaginal dryness is unknown.

There is little evidence on the optimal treatment regimen for any particular EBD modality as it pertains to duration, the number, the interval in between, or the total length of treatments. A prospective study of postmenopausalwomen suggests that fractional CO2 therapy alleviates dyspareunia, dryness, and VVA due GSM, and reestablishes sexual function in a dose-response manner. Although subjective improvement on VAS, FSFI, and objective improvement on vaginal cytology and vaginal health index scores were seen after 3 treatments, this report suggests that a fourth or fifth treatment may increase the rate of complete resolution of GSM-related symptoms when assessed 1 month after each treatment. The number of treatments required to achieve and maintain a durable effect is unknown.

There may be a benefit to synergistic therapy with vaginal EBDs and medical therapy (eg, estrogen) for the conditions of menopausal dyspareunia, GSM/VVA, vaginal dryness, and vulvar pain.

But Ideal hormonal pretreatment, concurrent treatment, and posttreatment protocols involving EBD are unknown.

In one study:

patients pretreated with estriol for 2 weeks before Er:YAGlaser therapy showed greater relief of symptoms in the laser compared with estriol alone group at 12 and 18 months.

The synergistic benefit of vaginal EBD therapy with medical therapies such as vaginal estrogen or vaginal nonhormonal moisturizers is unknown in patients with pelvic radiation-induced vaginitis.

The AUGS EBD writing group is not aware of any studies that have looked at this question.

Pelvic irradiation is often listed as a contraindication for vaginal EBD therapy by the manufacturers of these devices

Statements That Did Not Reach Consensus

Relative contraindications to EBD therapy include
vaginal mesh
midurethral sling mesh
prior pelvic irradiation.

Because
there are no studies looking at outcomes in patients with a history of these conditions.

EBD therapy has similar or somewhat better efficacy compared with vaginal estrogen or sham
treatment for GSM/VVA, menopausal dyspareunia, and vaginal dryness.
There are conflicting data on the efficacy and/or superiority of EBD over vaginal estrogen or even sham the treatment of GSM

EBD therapy may be effective in the treatment of OAB and stress urinary incontinence.

RF has not been studied for treatment of OAB.

Very limited comparative data exist on use of RF in the treatment of SUI.

There are multiple observational studies on vaginal CO2 laser in both OAB and SUI that show improvement in quality of life and objective measures.

The majority of the data are short term and lack control groups.

As with the CO2 laser, there are multiple studies that suggest the Er:

YAG laser may be beneficial in the treatment of SUI (less data on OAB), but data are short-term studies with no control groups.

intraurethral Er.YAG for SUI treatment illustrated short-term improvement in symptoms.

Transurethral RF therapy also has been investigated in women with SUI.
One RCT showed no difference between RF and sham in the Incontinence Quality of Life questionnaire at 12 months.

RF has shown promise for treatment of vaginal laxity.

Although several case series and one sham-controlled RCT suggest improvement in vaginal laxity symptoms after RF therapies, there are no standardized anatomical definitions for vaginal laxity,

there is poor understanding of the impact of vaginal laxity on quality of life,

EBD therapy is an effective treatment option for treating medically induced menopausal
dyspareunia, GSM/VVA, vulvar pain or vaginal dryness, or failed conservative
or medical treatment for SUI in cancer patients who are taking or who have previously taken anti-estrogens.
There are no published randomized placebo-controlled trials in this special population

Vaginal RF treatments improve VVA for up to 1 year.

There are no studies on short-term to long-term effect of RF in treatment of VVA.
There are some studies
looking at benefits of RF on sexual satisfaction over 3 to 6 months.
One study has a 12-month follow-up
and shows improvement in sexual satisfaction and VVA.

Vaginal EBD therapy improves vaginal pH and lactobacilli counts for CO2 laser, but other
effects on the vaginal microbiome are unknown.
two prospective study of post menopausa lwomen who underwent micro ablative fractional CO2 treatments also Er: YAG laser experienced a statistically significant improvement in lactobacilli count, normal vaginal flora, and a
decrease in vaginal pH up to 12 months .
however, all patients were pretreated with vaginal estrogen before laser intervention.
Overall, there was insufficient evidence to generate consensus on this statement.

Maintenance therapies may continue to maintain symptom improvement in VVA and vaginal
laxity patients who have undergone effective EBD therapy. Although there are reported studies for treatment of vaginal laxity, most involve single
treatment with no re-treatment nor follow-up beyond 6 months post treatment.

Data on maintenance therapies are, therefore, very limited.

There are no data on the potential additive role of platelet-rich plasma or growth factor to EBD therapy the pelvic floor.

There are limited data on the combined effect of platelet-rich plasma and CO2 laser for treatment of GSM (irritation, dyspareunia, and dryness). Per this study, patients
have higher reported rate of improvement in dyspareunia.
AUGS EBD writing group finds the evidence inconclusive to reach a consensus

CO2 laser or Er:YAG laser combined with vaginal estrogen shows improved outcomes over either CO2 alone or vaginal estrogen alone for the treatment of vaginal atrophy, and
all GSM symptoms:
including burning, dryness, and dyspareunia.

The AUGS EBD writing group did not reach a consensus in support of this statement.

Patient Criteria

There is no evidence-based literature or guidelines that support the inclusion or exclusion of women from receiving EBD therapy.

Health Care Provider Criteria

There is no literature available reporting vulvovaginal EBD therapy outcomes based on physician specialty or level of training. Ultimately, the optimal health care providers are the gynecologists who are comfortable with vaginal conditions.

Efficacy Outcomes

CO2 and Er:YAG have shown promise in the treatment of vulvovaginal atrophy, vaginal dryness, and menopausal dyspareunia with benefits lasting up to 1 year.

Safety Outcomes

Based on short-term data, that vulvovaginal EBD therapies have a favorable safety profile but the longer sequelae of vulvovaginal EBD therapy are unknown.

Treatment Considerations

The optimal number of treatments, the effect of synergistic treatments such as estrogen, and the optimal maintenance therapy regimens using vulvovaginal EBD therapy for various indications need to be elucidated.

Thank you