

Vaginal Energy-Based Devices

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Abstract: This clinical consensus statement on vaginal energy-based devices (EBDs) reflects statements drafted by content experts from the American Urogynecologic Society's EBD writing group. The American Urogynecologic Society's EBD writing group used a modified Delphi process to assess statements that were evaluated for consensus after a structured literature search. A total of 40 statements were assessed and divided into 5 categories: (1) patient criteria, (2) health care provider criteria, (3) efficacy, (4) safety, and (5) treatment considerations. Of the 40 statements that were assessed, 28 reached consensus and the remaining 12 did not. Lack of evidence was among the main reasons that vulvovaginal EBD treatment statements did not reach consensus.

Key Words: energy-based devices, laser, vaginal laxity, vaginal/vulvovaginal atrophy, dyspareunia, overactive bladder, urgency incontinence, frequency, urgency, stress urinary incontinence, fecal incontinence, lichen sclerosis, vulvodynia/vestibulitis/vulvar pain sexual dysfunction, radiofrequency, CO₂ laser, Er:YAG

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In 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.¹ The statement highlighted the imprecision of the term “vaginal rejuvenation” and emphasized that, although the FDA is aware that devices such as lasers are used for a variety of surgical applications, the agency has not approved their use for any specific gynecologic indication. Health care providers who subspecialize in female pelvic medicine and reconstructive surgery are positioned to evaluate and manage genitourinary syndrome of menopause (GSM) and vulvovaginal atrophy (VVA), and some of these clinicians deliver patient services using the EBDs that are discussed in the FDA Safety Communication. The vulvovaginal EBD devices that will be addressed in this document include laser and radiofrequency (RF) devices.

Concurrent with the FDA's Safety Communication, a December 2018 International Urogynecological Association Writing Group Opinion summarized the small, but growing, body of evidence as well as concerns about vulvovaginal EBD.² This document explored evidence for the use of laser-based devices for GSM, vaginal laxity, and stress urinary incontinence. 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.³ The American Urogynecologic Society (AUGS) found it timely to provide guidance by convening a panel of experts to compile a clinical consensus statement (CCS). In the absence of strong level I evidence, this CCS was created based on rigorous criteria to compile the most important agreed upon expert opinion statements supported by the available literature as it pertains to the use of vulvovaginal EBDs. In contrast to clinical practice guidelines, which are based primarily on high-level evidence, clinical consensus statements are more applicable to situations where evidence is limited or lacking, yet there are still opportunities to reduce uncertainty and improve quality of care by providing evidence-based treatment approaches to care. Systematic reviews in the literature were considered as part of this document. Consensus was sought using explicit methodology to identify areas of agreement and disagreement.

BACKGROUND

There is considerable variability in the level of peer-reviewed support for use of various vulvovaginal EBD devices across a

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.

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number of indications for which these devices have been advertised. This variability creates meaningful challenges for health care providers in their efforts to counsel patients, inhibits patients from making informed decisions about their care, and misrepresents potential treatment outcomes. The AUGS supports efforts to assist clinicians in helping patients understand their evidence-based treatment options in general, and this consensus statement is a part of that larger effort. Accordingly, the purpose of this CCS is to convey the AUGS EBD writing group's findings concerning specific statements related to use of specific vaginal EBD technologies (eg, fractionated CO₂ laser, Er:YAG laser, hybrid laser, RF) for the treatment of specific indications (eg, vaginal dryness, dyspareunia, lichen sclerosus). This information will facilitate clinicians' efforts to educate and empower patients to fully engage in shared decision making with their health care team.

METHODS

The vaginal EBD topic was proposed by the AUGS Board of Directors. A formal proposal was reviewed for feasibility and importance by the AUGS Publications Committee and recommended to the Board for further development. This CCS was developed using established methods as detailed below to reach consensus on vulvovaginal EBD treatments.⁴

A call for applications for participation in the AUGS EBD writing group was issued to the AUGS membership. Applications, including conflicts of interest, were reviewed and a writing group chair was identified. The chair identified a co-chair to assist with task management and manuscript writing. The members of the writing group were chosen with input from the AUGS Publications Committee from the pool of applicants and by invitation to ensure a wide range of expertise. A consultant from the AUGS Publications Committee served as a resource and liaison to the AUGS EBD writing group, and administrative support was provided by AUGS.

A structured literature review was conducted by an information specialist to identify current evidence regarding the indications, treatment considerations, and clinical outcomes for vulvovaginal EBD treatment approaches. The literature search was started in November 2018 and concluded in January 2019. The search conducted by the librarian included randomized controlled trials (RCTs), systematic reviews, clinical trials, and practice guidelines publications in English from PubMed (MEDLINE), National Guideline Clearinghouse, CMA Infobase (Canada), NHS Evidence (United Kingdom), NICE (United Kingdom), SIGN (Scotland), New Zealand Guidelines Group, TRIP database, Guideline International Network (GIN), EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, AMED, Web of Science, BIOSIS Citation Index, CAB Abstracts, and AHRQ. For example, the PubMed search for practice guidelines included the following terms:

(energy-based device OR energy-based therapy OR lasers OR laser-based OR radiofrequency OR lasers, gas OR rejuvenation)

AND

(menopause OR menopause OR genitourinary syndrome of menopause OR (vaginal AND [laxity OR dry OR dryness OR itch]) OR urinary incontinence, stress OR ([incontinence OR Dyspareunia OR Dyspareunia OR Dysuria [mesh] OR Dysuria OR sexual function] AND [female OR woman OR women OR vaginal OR female]) OR ([vaginal OR Vulvovaginal] AND atrophy) OR "Lichen Sclerosus et Atrophicus" OR Lichen Sclerosus OR white spot disease.

OR ("Pelvic Organ Prolapse" OR Pelvic Organ Prolapse OR "Fecal Incontinence" OR Fecal Incontinence OR Bowel

Incontinence OR Fecal Soiling OR Labial hypertrophy OR "Vulvodynia" OR Vulvodynia OR "Vulvar Vestibulitis" OR Vestibulitis OR Vulvar pain OR ("Prolapse" OR prolapse OR "Urinary Tract Infections" OR Urinary tract infection OR "Urinary Incontinence, Urge" OR Urge incontinence OR Frequency incontinence) AND (female OR women OR vaginal OR female)) OR Pelvic radiation)

Publication Dates: No limit

Limit: "Practice Guideline" OR "Practice Guidelines as Topic" OR "practice guideline" OR "practice guidelines."

The search of all databases mentioned yielded 511 articles. The initial title results were screened by the chair and the librarian to remove duplicates or references not relevant to vaginal EBD treatment. The 406 remaining search abstract results were screened by the chair and 3 writing group members to focus on the pertinent articles. Ultimately, 206 articles were retained to inform this CCS.

The AUGS EBD writing group outlined the scope of the CCS before initiating the Delphi process. The following conditions were identified as potential indications for which vulvovaginal EBD is currently used: vaginal dryness/lack of lubrication, vaginal laxity, vaginal/VVA, dyspareunia, overactive bladder (OAB) (urge incontinence, urinary urgency, and frequency), stress urinary incontinence (SUI), fecal incontinence, dysuria, lichen sclerosus, prolapse, urinary tract infection, labial hypertrophy, vulvodynia/vestibulitis/vulvar pain, pelvic irradiation, and sexual dysfunction.

Vaginal EBD treatments are classified as ablative and nonablative in their mechanism of action. Nonablative lasers and RF work by heating up the underlying tissue and increasing heat shock proteins and collagen production without harming the surface. 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.⁵

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

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 currently used for the treatment of GSM are the fractional microablative CO₂ laser and the nonablative Er:YAG laser.⁵

Target devices were defined as all vulvovaginal EBDs applied to treat the conditions listed previously, including the following:

- Nonablative Er:YAG lasers: A solid-state infrared light laser whose active laser medium is erbium-doped yttrium aluminum garnet (Er:YAG), which typically emits light with a wavelength of 2.94 μm.⁵
- Fractional microablative CO₂ laser: A CO₂ laser that produces a beam of continuous infrared light with the principal wavelength bands centering on 9.4 and 10.6 μm.

Hybrid—combination of nonablative and ablative approaches

- Hybrid fractional lasers: A laser device that applies tunable nonablative (1.47 μm) and ablative (2.94 μm) wavelengths to the same microscopic treatment zone.⁵ This allows for simultaneous ablation and coagulative effects.

Other—current based EBD devices

- Radiofrequency: A device that uses RF energy 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.⁵

The AUGS EBD writing group considered inclusion of ultrasound devices that are currently being introduced to the market but ultimately decided against their inclusion because of the paucity of literature on these devices.

Each AUGS EBD writing group member selected a category for which she/he developed a list of questions to be considered for inclusion in the Delphi process. More than 100 of these statements were evaluated with a modified Delphi survey method, and were further refined by the writing group (Table 1).

A list of 42 questions was ultimately developed. Each member of the writing group ranked each question in order of importance and provided a draft statement for each of his or her top 5 ranked question choices. Statements were grouped into 5 categories: (1) patient criteria, (2) health care provider criteria, (3) efficacy outcomes, (4) safety outcomes, and (5) treatment considerations.

Based on topic rankings, the AUGS EBD writing group chair and co-chair developed the first Delphi survey which consisted of 40 statements. A Web-based software (www.surveymonkey.com) was used to administer confidential surveys to writing group members. Survey questions used a 5-point Likert scale derived from the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) grid as seen in Table 2.⁶ Consensus was defined as 80% or more of the members voting in agreement. A total of 100% survey completion by the AUGS EBD writing group was required.

The statements that reached consensus as well as the statements that did not reach consensus were assigned to the AUGS EBD writing group members to provide a brief rationale, supported by published literature where available. The AUGS EBD writing group members were asked to limit their comments to a short paragraph and, where applicable, these comments were further refined by the chair and the co-chair to fit the writing format.

RESULTS

A total of 40 statements were reviewed by the AUGS EBD writing group members at the first Delphi Round with 23 statements reaching consensus. The 17 statements that did not reach consensus were discussed to clarify ambiguities and consider whether revisions were needed, or if the statement should be omitted in the second round. Of these, 10 were omitted and 7 statements were revised and included in the second Delphi survey. In the second round, 5 statements reached consensus and the remaining 2 did not. It was determined that all statements that did not reach consensus were because of absence of evidence rather than

TABLE 1. Sample Topic Questions and Associated Draft Consensus Statements

| Topic Question | Draft Consensus Statement |
|--|--|
| What are the contraindications to EBD therapy? | Relative contraindications to EBD therapy include transvaginal mesh or midurethral sling mesh or prior pelvic irradiation. |
| What are the criteria for EBD therapy for menopausal dyspareunia, VVA, or vaginal dryness? | Pretreatment criteria for EBD therapy may include inability to use vaginal estrogen treatment for menopausal dyspareunia, VVA, or vaginal dryness. |

TABLE 2. Survey Grading for the Web-Based Delphi Method

| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|----------------|-------|---------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 |

Consensus was defined $\geq 80\%$ of the members voting positively, including both strong and weak agreement combined (from GRADE methodology).

ambiguity in wording, lack of clarity, or other factors. In summary, 28 statements reached consensus and 12 did not.

The results within each predefined category are listed below with statements achieving consensus organized by categories of (1) patient criteria, (2) health care provider criteria, (3) efficacy, (4) safety, and (5) treatment considerations (Tables 3–7). This is followed by statements that did not reach consensus and their accompanying brief rationales and percentile agreements (Table 8).

1. Patient Criteria

Three of the 4 statements in this category reached consensus (Table 3). There was 100% agreement among the EBD writing group that before any vulvovaginal EBD therapy, vulvar lesions, vaginal lesions, or cervical pathology should be excluded with absolute contraindications, including a current pelvic malignancy, recent pelvic surgery, or an active infection (Statement Q1). It was also unanimous that potential indications may include inability to use vaginal estrogen treatment for menopausal dyspareunia, VVA, or vaginal dryness (Statement Q3a). Consensus was reached that patients should have a gynecologic examination within the preceding year before initiating vaginal EBD therapy (Statement Q4).

2. Health Care Provider Criteria

Both statements in this category reached consensus (Table 4). All AUGS EBD writing group members agreed that EBD therapy for vaginal and vulvar indications 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 (Statement Q5). It also was noted that industry standards for proper EBD therapy training for health care providers need to be established (Statement Q6).

3. Efficacy Considerations

Thirteen statements achieved consensus, whereas 8 did not (Table 5). Results were categorized as long, medium, and short term. Long term was considered as more than 3 years, medium term as between 1 and 3 years, and short term as less than 1 year.

Genitourinary Syndrome of Menopause

Consensus was reached that CO₂ and Er:YAG have shown promise in the treatment of VVA, vaginal dryness, and menopausal dyspareunia (Statement Q13). For patients experiencing vaginal atrophy and dyspareunia associated with medical menopause, it was also agreed that EBD therapy has demonstrated short-term efficacy (Statement Q7). The benefits associated with fractional laser treatment for menopausal dyspareunia last up to 1 year (Statement Q20), and CO₂ and Er:YAG laser may improve VVA for 1 year (Statement Q22a). The AUGS EBD writing group agreed that EBD therapy has a beneficial effect on sexual function in the short term, whereas longer duration is unknown (Statement Q18).

TABLE 3. Statements That Reached Consensus: Patient Criteria

| | % Agreement |
|--|----------------|
| <p>Q1. 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. The AUGS EBD writing group is not aware of any evidence-based literature or guidelines that support inclusion or exclusion of women from receiving EBD therapy. However, clinical trials on EBD have typically excluded women with history of vulvovaginal lesions, cancer, or recent history of active lesions, infections, or pelvic surgery.⁷⁻¹⁰</p> | 100 |
| <p>Q3a. 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.¹¹ 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.</p> | 100 |
| <p>Q4. Patients undergoing EBD therapy should have had a gynecologic examination within 1 year of treatment. The purpose of a focused gynecologic examination, which can include visual inspection of the external genitalia, a speculum examination, bimanual examination, and rectal examination, is to assess underlying gynecologic pathology based on symptoms and patient history. Cervical cytology with human papillomavirus cotesting can also be performed based on screening guidelines. Importantly, any underlying active infection can be identified and appropriately treated according to evidence-based and evidence-informed guidelines. This type of evaluation and examination should be conducted before EBD based on clinical expert opinion.¹²</p> | 89 |

Patient Body Image

It was agreed that there are no long-term objective data on the effect of EBD therapy on vulvar or vaginal appearance (Statement Q19). Also given that there is no widely accepted definition of labial hypertrophy and there is a lack of evidence on the efficacy of EBD therapy for this condition (Q12a). Concomitant with this lack of standardization in the field of cosmetic gynecology, the AUGS EBD writing group could not find any objective data illustrating the effect of EBD therapy on vulvar or vaginal appearance (Q19).

Comparative Interventions and Cost-Effectiveness

It was unanimous among AUGS EBD writing group members that validated symptom and quality of life questionnaires in conjunction with physical examination findings should be used to quantify the efficacy of EBD therapy (Statement Q27). After completion of the literature search, the AUGS EBD writing group did not encounter any substantial information on the cost-efficacy of vulvovaginal EBD therapy (Statements Q23 and Q24).

Other

Energy-based device therapy may be effective for the treatment of lichen sclerosus (LS) (Statement Q9).

The AUGS EBD writing group was in consensus that the overall efficacy of EBD therapy compared with pelvic floor exercise (PFE) or midurethral slings for the treatment of stress urinary incontinence has not yet fully been elucidated (Statement Q16). There was consensus that EBD therapy is not known to be effective in the treatment of fecal incontinence (Statement Q11).

4. Safety Considerations

All 6 drafted statements on the safety of vulvovaginal EBD therapy achieved consensus (Table 6). Serious adverse events have been reported with the use of EBD therapies; however, these incidents are relatively infrequent in the short term when used to treat women with menopausal dyspareunia, VVA, or vaginal dryness (Statement Q33a). The AUGS EBD writing group largely agreed that, based on short-term data, EBD therapies have a favorable safety profile (Statement Q28), but the long-term sequelae of vulvovaginal EBD therapy are unknown (Statement Q30). Some potential adverse

TABLE 4. Statements That Reached Consensus: Health Care Provider Criteria

| | % Agreement |
|--|----------------|
| <p>Q5. 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. There is no literature available reporting EBD outcomes based on physician specialty or level of training. In the United States, medicolegally, any physician with a medical license or their supervised nurse practitioners can potentially perform these laser-based procedures.² Nevertheless, the AUGS EBD writing group agreed that 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.</p> | 100 |
| <p>Q6. 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, as is the case for all other medical devices that are used to treat female pelvic floor disorders. 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.</p> | 90 |

TABLE 5. Statements That Reached Consensus: Efficacy Outcomes

| | % Agreement |
|---|----------------|
| <p>Q7. EBD therapy has demonstrated short-term efficacy in addressing medical menopause-related conditions of vaginal atrophy and menopausal dyspareunia.</p> <p>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, and/or nonstandardized outcome improvement measures. Despite these limitations, published studies suggest that EBD improves the condition of vulvovaginal tissues among menopausal women, and associated symptoms of vulvar and vaginal atrophy and/or menopausal dyspareunia for up to 1 year.^{13–15} Placebo-controlled level I data are needed to further explore this topic.</p> | 90 |
| <p>Q9. EBD therapy may be effective for the treatment of lichen sclerosus.</p> <p>Several case series describe success with CO₂ laser treatment of lichen sclerosus when medical therapy with topical corticosteroids has failed. One RCT concluded that Neodymium Nd:YAG laser was more effective in treating lichen sclerosus than topical corticosteroid.¹⁶ Further studies, including differing EBDs, are necessary to provide treatment recommendations, duration of effect, and curative effect.⁵</p> | 80 |
| <p>Q11. EBD therapies are not known to be effective in the treatment of fecal incontinence.</p> <p>Studies of treatment of fecal incontinence with CO₂ or Er:YAG lasers have not been performed. However, 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.¹⁷ However, long-term (mean 40 months) results have been disappointing with benefits in only 22% of treated patients.¹⁸</p> | 80 |
| <p>Q12a. There is no clear definition of labial hypertrophy, and there is lack of evidence on the efficacy of EBD therapy for this condition.</p> <p>There is anatomic variability of the labia minora and majora in terms of length, width, and symmetry. Although multiple definitions have been proposed for classification of labial hypertrophy,^{19–23} there is currently no clearly accepted standard, and there are little data on use of EBD therapy for the treatment of labial hypertrophy. One RCT evaluated nonablative RF on the external genitalia to assess cosmetic and sexual function outcomes.²⁴ Forty-three women were randomized to 8 weekly treatments of either RF or heated resistor placebo. Outcomes were assessed with the Female Sexual Function Index (FSFI) and photography evaluation by the subject and 3 blinded health care providers. Both patients and health care providers noted significant improvement in “labia majora flabbiness” in the RF group versus placebo. Although a therapeutic effect was demonstrated, quantification is difficult to characterize because of a lack of widely accepted definitions and standardized objective outcome measures.</p> | 100 |
| <p>Q13. EBD therapy has shown promise in treatment of VVA, vaginal dryness, and menopausal dyspareunia.</p> <p>Limited evidence shows potential benefit for the treatment of the conditions of VVA and the symptoms of vaginal dryness and menopausal dyspareunia. Research on efficacy is limited by a very small number of short-term clinical trials and one published RCT in which fractional CO₂ laser, vaginal estriol, and a combination of the 2 were compared in a randomized, sham- and placebo-controlled trial of 45 postmenopausal women. No treatment was superior to another, and the study was not designed to assess noninferiority.⁷ In a parallel cohort study, the Er:YAG laser was compared with vaginal estriol in a nonrandomized, nonblinded trial in 50 postmenopausal women. Symptom assessment by visual analog score (VAS), Vaginal Maturation Index, and vaginal biopsy showed a variety of outcomes and limited a strong conclusion.²⁵ Overall, most published articles are small, short case series that measure a variety of outcomes.</p> | 90 |
| <p>Q16. It is unknown if EBD therapy offers better success rates than PFE or midurethral slings for treatment of stress urinary incontinence.</p> <p>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,²⁶ CO₂ and Er:YAG laser may help improve symptoms in women with SUI^{27,28} 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.²⁹ However, clinical trials comparing EBD therapy with standard of care treatment modalities such as PFE or midurethral slings in women with SUI are lacking.²⁷</p> | 90 |
| <p>Q18. EBD has a positive effect on sexual function in the short term. The medium- and long-term duration is unknown.</p> <p>In one study of fractional CO₂ laser with placebo vaginal cream, estriol with sham laser, or laser + estriol, with assessments at 8 and 20 weeks, the latter group had significant improvement of total FSFI score (and individual domains of pain, desire, and lubrication). The placebo group showed significant worsening of the pain domain, but FSFI total scores were comparable in all treatment arms at week 20.⁷ In a second study of fractional CO₂ laser, FSFI and frequency of sexual intercourse increased starting 1 month after the last laser treatment. The positive effect on sexual function after laser treatment remained unchanged throughout the 12 months of follow-up.³⁰ In a study of premenopausal women with vaginal laxity randomized to either RF therapy or sham therapy, statistically significant improvements in overall sexual function were noted at 6 months based on improved FSFI scores and decreased female sexual distress scores in the RF group.³¹</p> | 80 |
| <p>Q19. There are no objective data on the effect of EBD therapy on vulvar or vaginal appearance.</p> <p>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.³² Nevertheless, the AUGS EBD writing group is not aware of any long-term credible studies that have objectively examined the effect of EBD therapy on vulvar or vaginal appearance.^{24,33}</p> | 90 |

Continued next page

TABLE 5. (Continued)

| | % Agreement |
|--|----------------|
| <p>Q20. The benefits from vaginal fractionated laser therapy used to treat menopausal dyspareunia last up to 1 year. 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. In a prospective observational study, patients treated with a fractionated CO₂ laser experienced significant improvements in dyspareunia at 3 months, with efficacy maintained at 12 months.¹⁴ Several other prospective case series have shown similar benefits for dyspareunia at 1 year, with a few studies suggesting that benefits persist up to 2 years.^{34–36}</p> | 90 |
| <p>Q22a. EBD therapy improves VVA for up to 1 year. Vaginal CO₂ laser therapy has been shown to be effective in treatment of VVA in several studies up to 20 weeks. Although there are fewer studies with follow-up of 1 year, there appear to be similar findings of multiple independent case series of unique patient populations.^{14,29,37} The only published randomized trial comparing laser with hormonal treatment has a follow-up period of 20 weeks.⁷ A higher proportion of studies of Er:YAG laser therapy focus on its use in treatment of urinary incontinence, and there are no randomized trials of the Er:YAG laser for VVA. As with CO₂, there are multiple independent series of patients showing improvements in VVA after Er:YAG laser therapy lasting up to 1 year,³⁵ including one cohort study in which results are compared with a control group of patients who used vaginal estriol ovules for 8 weeks at the beginning of the study.²⁵</p> | 89 |
| <p>Q23. 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. No studies have been reported to determine cost-effectiveness of EBD therapies. Furthermore, there is no current standard of pricing for these therapies. For example, some protocols advocate for one treatment versus 3 treatments to achieve a therapeutic result, resulting in differences in cost.</p> | 100 |
| <p>Q24. 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. The AUGS EBD writing group is not aware of any published reports on the cost advantage or disadvantage of trialing standard therapies before EBD initiation for the conditions of GSM/VVA, vaginal laxity, LS, or other pelvic floor disorders.³⁸</p> | 90 |
| <p>Q27. 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.</p> | 100 |

events attributable to EBD therapy may include an increase in vaginal discharge, spotting, bacterial vaginosis, urinary tract infection, and rarely the development of scarring or burning (Statement Q29). Members concurred that the effect of EBD therapy on existing cervical pathology or the development of cervical stenosis is unknown and lacks evidence (Statement Q31), and there is currently no evidence to support the use of vaginal EBD therapy for the treatment of pelvic irradiation-induced vaginitis (Statement Q32).

5. Treatment Considerations

Four of the 7 drafted statements reached consensus (Table 7). The optimal number of treatments for vulvovaginal EBD therapy for various indications has not yet been clearly elucidated (Statement Q34a). Although there may be a synergistic benefit of EBD therapies with vaginal estrogen for the treatment of vaginal dryness and menopausal dyspareunia (Statement Q36), this symbiotic effect has not been studied in all populations such as women with pelvic irradiation-induced vaginitis (Statement Q40), and more research is needed to draw further conclusions (Statement Q36).

DISCUSSION

The recent widespread interest in EBD therapies despite a striking paucity of level I evidence represents a growing demand for effective, safe, and noninvasive therapies for a wide range of difficult to treat vaginal conditions. Each technology (RF [460 kHz], CO₂ laser [10.6 μm], Er:YAG laser [2.94 μm], and Hybrid laser [2.94 + 1.47 μm]), although all technically classified as an energy-based intervention, operates in nuanced but distinct fashion, if not by a completely different mechanism of action. Each device employs variable factors such as differences in the

depth of tissue penetration, amount of energy delivered, and tissue application time making direct outcome comparisons difficult. In addition to the differences in technology, different studies may use the same technology differently (for example, the studies that use CO₂ laser may not be using this specific technology in the same exact manner), limiting the ability to compare. To further compound matters, EBD therapies have been used to treat a litany of pelvic floor conditions, at times based on relatively scant data.

Patient Criteria

The AUGS EBD writing group was not aware of any evidence-based literature or guidelines that support the inclusion or exclusion of women from receiving EBD therapy. However, clinical trials on EBD have typically excluded women with a history of vulvovaginal lesions, cancer, or recent history of active lesions, infections, or pelvic surgery.^{7–10} To appropriately screen for pathology, it was agreed that all patients should have a focused gynecologic examination, which can include visual inspection of the external genitalia, a speculum examination, bimanual examination, and rectal examination within 1 year of initiating treatment. In addition, cervical cytology with human papillomavirus cotesting should be performed according to guidelines. This type of evaluation and examination should be conducted before EBD therapy based on clinical expert opinion.¹² One potential indication for EBD therapy includes either inability or unwillingness to use moisturizers, lubricants, or vaginal estrogen for the treatment of menopausal dyspareunia or VVA. The clinical consensus on the use of vaginal estrogen⁶⁴ is based on short-term clinical trials, larger observational studies, and expert opinion regarding the minimal systemic absorption of estrogen.¹¹ However, there is no prospective evidence to support the safety of long-term vaginal estrogen use, and the

TABLE 6. Statements That Reached Consensus: Safety Outcomes

| | % Agreement |
|--|----------------|
| <p>Q28. Based on short-term published data, EBDs have a favorable safety profile, making them appropriate alternate interventions should efficacy trials prove their benefit.</p> <p>Although adverse events with the use of EBD therapies have been reported through the Manufacturer and User Facility Device Experience (MAUDE) database and in the literature,³⁹ major adverse events appear to be uncommon. Short-term evidence suggests that EBDs have a favorable safety profile, but there are few trials reporting long-term safety outcomes for these relatively new therapies.⁵ This statement reached consensus with the understanding that 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.</p> | 80 |
| <p>Q29. 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 that have been reported include scarring or burning.</p> <p>Various adverse effects, although typically minor and infrequent, have been reported in studies that have included small numbers of patients who have been followed up, in most cases, for 1 year or less.^{1,2,9,40} Long-term adverse events are not well studied or understood.</p> | 90 |
| <p>Q30. The long-term sequelae of EBD therapy is unknown; however, short- and medium-term data on safety are promising.</p> <p>The longest published follow-up after Er:YAG is 18 to 24 months. 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.²⁵ Other studies have reported no serious adverse events, with less than 3% discontinuing treatment because of adverse events. These adverse events were not clearly specified except for one patient reporting discomfort after the first laser treatment.³⁵</p> | 90 |
| <p>Q31. The effect of EBD therapy on existing cervical pathology or subsequent cervical stenosis is unknown.</p> <p>The AUGS EBD writing group is not aware of any studies that have looked at this question. Because the effect of EBD therapy on cervical pathologies or stenosis remains unknown, the practitioner should confirm normal cervical cytology based on ACOG guidelines.⁴¹</p> | 100 |
| <p>Q32. 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.</p> <p>There is no literature on the use of vaginal EBD therapy in populations of women who have previously undergone pelvic irradiation. Importantly, a history or previous vaginal/colorectal irradiation is often listed as a contraindication for vaginal EBD therapy by the manufacturers of these devices.</p> | 90 |
| <p>Q33a. Serious reported adverse events related to EBD therapy are infrequent in the short term when used to treat women with menopausal dyspareunia, VVA, or vaginal dryness.</p> <p>FDA encouraged reporting of any EBD complications through the MAUDE database. Although the total number of patients (the denominator) who have received EBD therapies is unknown, an analysis of MAUDE data between October 2015 and January 2019 revealed events affecting 46 patients.⁴² "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. Given the inherent limitations to a voluntary data system like MAUDE, it is not possible to estimate the incidence of EBD complications. Nonetheless, the AUGS EBD writing group agreed that although serious adverse events have been reported, they appear to be infrequent in the short term in the context of treatment for menopausal dyspareunia, GSM/VVA, and vaginal dryness.</p> | 100 |

FDA has declined to remove the Black Box warning from vaginal estrogen products.⁶⁵ The conflicting advice about the safety of vaginal estrogen leads many women to seek nonhormone alternatives.

Notably, a consensus could not be reached as to the role of EBD treatment in patients with midurethral slings, vaginal mesh, or prior pelvic irradiation. Although anecdotally patients with mesh have been subsequently treated with EBD therapy for various indications listed in this consensus article, there are little data in the literature to provide supportive evidence.

Health Care Provider Criteria

Discussion of this topic largely focused on the qualifications necessary to operate and treat patients with vulvovaginal EBD therapy. Although 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. In the United States, medicolegally, any physician with a medical license or their supervised nurse practitioners or physician assistants can potentially perform these energy-based procedures.² Nevertheless, the AUGS EBD writing group agreed that 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. These are the qualities that urogynecologists possess, and these make them a uniquely better choice to provide the needed services to afflicted women.

In addition, no industry standards currently exist outlining specific protocols for proper training of health care providers offering vulvovaginal EBD therapy services, as is the case for other medical devices that are used to treat female pelvic floor disorders.⁶⁴ 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. The AUGS EBD writing group largely agreed that industry standards must be established.

Efficacy Outcomes

This section was centered on GSM, patient body image (lichen sclerosis and vulvar appearance), and comparative interventions and

TABLE 7. Statements That Reached Consensus: Treatment Considerations

| | % Agreement |
|---|----------------|
| <p>Q34a. The optimal number of treatments for EBD therapy for menopausal dyspareunia, GSM/VVA, or vaginal dryness is unknown.</p> <p>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 postmenopausal women 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.⁴³ The number of treatments required to achieve and maintain a durable effect is unknown.</p> | 89 |
| <p>Q36. 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. The optimal medical therapy regimen and sequence in relation to the EBD treatment is not known.</p> <p>Ideal hormonal pretreatment, concurrent treatment, and posttreatment protocols involving EBD are unknown. In one study, patients pretreated with estriol for 2 weeks before Er:YAG laser therapy showed greater relief of symptoms in the laser compared with estriol alone group at 12 and 18 months.²⁵ In another study, patients showed the greatest improvement in the laser plus estrogen arm versus laser alone or estrogen alone in a small pilot of 45 patients over 20 weeks.⁷</p> | 89 |
| <p>Q39. More studies are needed to determine if combining EBD therapy with medical therapy for the condition of menopausal dyspareunia may improve outcomes more than either therapy alone.</p> <p>There is a paucity of literature regarding combining medical therapy with EBD. There is one small RCT that came to the conclusion that CO₂ vaginal laser in combination with topical estriol is a good treatment option for VVA symptoms.⁷ Although vaginal EBD devices may be appropriate therapy for menopausal dyspareunia, more studies are needed to show their superiority to medical therapy in improving patient outcomes.</p> | 100 |
| <p>Q40. 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.</p> <p>The AUGS EBD writing group is not aware of any studies that have looked at this question. Therefore, the synergistic effect of EBD and vaginal estrogen or moisturizers is unknown in patients with radiation-induced vaginitis. Pelvic irradiation is often listed as a contraindication for vaginal EBD therapy by the manufacturers of these devices and “Relative contraindications to EBD therapy include... prior pelvic irradiation” did not reach consensus.</p> | 100 |

cost-effectiveness. The AUGS EBD writing group found that CO₂ and Er:YAG have shown promise in the treatment of VVA, vaginal dryness, and menopausal dyspareunia with benefits lasting up to 1 year.^{13–15} Vulvovaginal EBD therapy may ultimately be effective for the treatment of lichen sclerosus¹⁶; well-designed trials involving placebo treatment and RCTs are needed to show the benefits.

It was agreed that there are no long-term objective data on the effect of EBD therapy on vulvar or vaginal appearance. The AUGS EBD writing group unanimously agreed that validated symptom and quality of life questionnaires in conjunction with physical examination findings should be used to quantify the efficacy of EBD therapy and that more randomized placebo-controlled and comparative clinical trials are needed for treatment of SUI. There is a knowledge gap on cost-efficacy of vulvovaginal EBD compared with existing treatments for conditions discussed.

Safety Outcomes

The AUGS EBD writing group agreed, based on short-term data, which vulvovaginal EBD therapies have a favorable safety profile, but the longer sequelae of vulvovaginal EBD therapy are unknown. The effect of EBD therapy on existing cervical pathology or the development of cervical stenosis is unknown, and there is currently no evidence to support the use of vaginal EBD therapy for the treatment of pelvic irradiation-induced vaginitis.

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.

RESEARCH NEEDS

In summary, this CCS was created based on rigorous criteria to compile the most important agreed upon expert opinion statements supported by the available literature as it pertains to the use of vulvovaginal EBDs. In general, the AUGS EBD writing group reached consensus that research on GSM/VVA is limited due to diversity of various EBD modalities and protocols, lack of educational and credentialing standards, the lack of standardized research definitions for the presence and the severity of various conditions, and the lack of validated tools to assess symptoms, physical examination changes, and diagnostic tests. The AUGS EBD writing group proposed that furthering research for menopausal vulvovaginal symptoms will likely require large, randomized placebo-controlled trials, sham-controlled trials, or active comparator trials against vaginal estrogen. Having estrogen as an effective treatment provides both an ethical argument and scientific justification for noninferiority trials. Placebo-controlled trials can be smaller and provide clearer evidence. Placebo-controlled trials could be conducted in women for which estrogen is refused or relatively contraindicated, such as for breast cancer survivors using aromatase inhibitors.⁶⁶ Still larger and longer trials or registries will be required to gather sufficient safety information. If efficacy and safety are clearly established, the frequency and interval of required treatments will need to be established in order to understand the treatment burden and costs that women may experience with these modalities.

Similar considerations will need to be made for all the conditions and symptoms that vulvovaginal EBDs may address. For GSM, vaginal EBD therapies may address vaginal dryness and dyspareunia, but it is possible that they have no effect on recurrent urinary tract infections. For stress incontinence, there are many effective treatments with a variety of attributes to consider as

TABLE 8. Statements That Failed to Reach Consensus

| Category | Statements That Did Not Reach Consensus | % Agreement |
|-------------------|---|-------------|
| Patient criteria | Q2. Relative contraindications to EBD therapy include vaginal mesh or midurethral sling mesh or prior pelvic irradiation. The AUGS EBD writing group discussed potential contraindications of EBD therapy that are not covered in the literature and could not reach a consensus about whether relative contraindications to EBD therapy should include transvaginal mesh or midurethral sling mesh or prior pelvic irradiation because there are no studies looking at outcomes in patients with a history of these conditions. Indeed, most of EBDs have listed these conditions in the exclusion criteria. | 60 |
| Efficacy outcomes | Q8. 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 for the treatment of GSM. Two published reports aimed to answer this question. One RCT compared CO ₂ laser to both vaginal estrogen and combined laser + estrogen. The study was not powered to establish noninferiority or to have multiple comparisons, thereby failing to estimate the placebo effect. ⁷ Completed in 2018, the Velvet trial compared vaginal estrogen and laser therapy for GSM. An abstract slated for publication suggested that at 6 months, both arms showed comparable efficacy and high patient satisfaction. ⁴⁴ Also, a small prospective cohort comparing Er:YAG laser treatment and estrogen for GSM-related symptoms demonstrated greater improvement in symptoms at 18 months in the laser-treated group. ²⁵ | 70 |
| Efficacy outcomes | Q10. 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. ⁴⁵ There are multiple observational studies on vaginal CO ₂ laser in both OAB ⁴⁶ and SUI ³⁶ that show improvement in quality of life ⁴⁷ and objective measures. The majority of the data are short term and lack control groups. As with the CO ₂ 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. ^{48,49} | 60 |
| Efficacy outcomes | Q14. EBD therapy has shown promise for treatment of SUI. Although there are no RCTs assessing the efficacy of Er:YAG for SUI, prospective cohort studies evaluating intraurethral ⁵⁰ and intravaginal ^{48,51} treatment illustrated short-term improvement in symptoms. Transurethral RF therapy also has been investigated in women with SUI. One RCT ⁴⁰ showed no difference between RF and sham in the Incontinence Quality of Life questionnaire at 12 months. Future research should incorporate the use of RCTs with a placebo group to evaluate EBD on SUI. | 70 |
| Efficacy outcomes | Q15. RF has shown promise for treatment of vaginal laxity. Although several case series and one sham-controlled RCT ⁸ suggest improvement in vaginal laxity symptoms after RF therapies, ^{31,52-56} there are no standardized anatomical definitions for vaginal laxity, there is poor understanding of the impact of vaginal laxity on quality of life, ^{57,58} and there are a relative paucity of well-designed clinical trials evaluating the use of RF technologies for the specific indication of vaginal laxity. | 70 |
| Efficacy outcomes | Q17. 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 antiestrogens. There are no published randomized placebo-controlled trials in this special population. Two retrospective case series using the CO ₂ laser and 2 prospective series using the Er:YAG laser showed short-term benefits. The CO ₂ laser was studied retrospectively in breast cancer survivors and several VVA symptoms improved (demonstrated by VAS). ⁵⁹ For the Er:YAG laser, breast cancer survivors have reported improvements in VAS for vaginal dryness and dyspareunia that persisted somewhat after 18 months. ⁶⁰ These small studies failed to differentiate between early surgical menopause, chemotherapy-induced menopause, and the potential differential effects on vaginal mucosa related to tamoxifen, raloxifene, and aromatase inhibitors. Although published studies show promise for this population, RCTs are needed to demonstrate efficacy. | 70 |
| Efficacy outcomes | Q21a. 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. ⁶¹ One study has a 12-month follow-up and shows improvement in sexual satisfaction and VVA. ^{53,55} | 70 |
| Efficacy outcomes | Q25. Vaginal EBD therapy improves vaginal pH and lactobacilli counts for CO₂ laser, but other effects on the vaginal microbiome are unknown. One prospective study of postmenopausal women who underwent microablative fractional CO ₂ treatments experienced a statistically significant improvement in lactobacilli count, normal vaginal flora, and a decrease in vaginal pH. ⁶² Patients treated with Er:YAG laser also experienced statistically significant improvements in the Vaginal Maturation Index and decreased vaginal pH values up to 12 months after treatment; however, all patients were pretreated with vaginal estrogen before laser intervention. ²⁵ Overall, there was insufficient evidence to generate consensus on this statement. | 30 |

Continued next page

TABLE 8. (Continued)

| Category | Statements That Did Not Reach Consensus | % Agreement |
|--------------------------|---|-------------|
| Efficacy outcomes | <p>Q26. The Vaginal Laxity Questionnaire is a validated tool that can be used to measure improvement in laxity after vaginal EBD treatment.</p> <p>The article that originally reported on this instrument designed it for their study without validation.³¹ Several subsequent studies used this questionnaire, still without validation.^{54,55} Studies to validate this or other tools to objectively measure vaginal laxity are recommended.</p> | 67 |
| Treatment considerations | <p>Q35. Maintenance therapies may continue to maintain symptom improvement in VVA and vaginal laxity patients who have undergone effective EBD therapy.</p> <p>Although there are reported studies^{51,54,55} of RF for treatment of vaginal laxity, most involve single treatment with no re-treatment nor follow-up beyond 6 months posttreatment. The studies of CO₂ laser for VVA usually involve more than one treatment session, but as with RF for laxity, these studies have limited follow-up. Most do not follow patients longer than 12 months^{15,47}; those that do have only a small percentage of the original patient population returning for evaluation beyond 18 months.²⁵ Data on maintenance therapies are, therefore, very limited.</p> | 78 |
| Treatment considerations | <p>Q37. There are no data on the potential additive role of platelet-rich plasma or growth factor to EBD therapy the pelvic floor.</p> <p>Data on this statement are limited to one study. 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 on combined platelet-rich plasma and EBD have higher reported rate of improvement in dyspareunia, as well as evidence of histological changes suggestive of beneficial tissue and collagen remodeling⁶³; however, the AUGS EBD writing group finds the evidence inconclusive to reach a consensus.</p> | 11 |
| Treatment considerations | <p>Q38a. CO₂ laser combined with vaginal estrogen shows improved outcomes over either CO₂ alone or vaginal estrogen alone for the treatment of vaginal atrophy.</p> <p>One study compared postmenopausal women receiving 8 weeks of treatment with estriol ovules versus laser treatment with Er:YAG laser, and followed them for 12 months. A significant reduction of all assessed GSM symptoms with improvement in vaginal maturation value and a decrease of pH were observed, with the improvement in all endpoints being more pronounced and longer lasting in the laser group.²⁷ Another study randomized women to CO₂ laser + estriol treatment or laser + placebo treatment or estriol + sham laser treatment. At 20 weeks, the first 2 groups had significant improvement in all GSM symptoms, including burning, dryness, and dyspareunia. Moreover, an increase of pain was measured in the second group.⁷ The AUGS EBD writing group did not reach a consensus in support of this statement.</p> | 78 |

comparators. The scientific and ethical considerations for research design are more complex than for menopausal vulvovaginal symptoms. Midurethral sling surgery is effective but invasive compared with vaginal EBD therapies. In contrast, pelvic floor exercises are less effective and noninvasive compared with vaginal EBD therapies but require ongoing effort by the woman. The effectiveness, durability, and adverse outcomes of incontinence surgery have been well established in multiple studies involving thousands of women.

The conditions of labial hypertrophy and vaginal laxity seem to be important for some women, but all research in this clinical area is limited due to the lack of definitions of symptoms, signs, and conditions as well as validated instruments to assess outcomes, such as we have for urinary incontinence.⁶⁷

SUMMARY

Clinical consensus statements are largely reserved for practice guidelines that lack grade A level evidence in their support. All statements that did not reach consensus were because of lack of evidence (see Table 4).

The absence of consensus on many statements about EBD therapy practices currently in clinical use without preliminary scientific evidence exposes a significant knowledge gap about the efficacy and safety profile of the vulvovaginal EBD therapies, their indications, contraindications, maintenance regimens, comparison with available current treatments, and long-term benefits.

The information from this CCS will facilitate clinicians' efforts to educate and empower patients to engage in shared

decision making with their care team, but much more research is needed. Ultimately, the health care providers will need to demand level I evidence before recommending therapies to the patients, as the patients will be in a disadvantage to make decisions without properly conducted research that shows clear long-term safety and efficacy. This CCS document will also be instrumental in educating the general AUGS audience about the current state of the art, the level of evidence available, and in identifying the knowledge gap as to what further studies are needed.

DISCLAIMERS

This document was developed by the American Urogynecologic Society. This document reflects clinical and scientific advances and expert opinion as of the date issued, and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Its content is not intended to be a substitute for professional medical judgment, diagnosis, or treatment. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient.

This clinical consensus statement highlights the areas of agreement and more importantly the absence of consensus on many statements about vaginal energy-based therapy practices currently in clinical use without preliminary scientific evidence which exposes a significant knowledge gap about the efficacy and safety profile of the vulvovaginal energy based therapies, their indications, contraindications, maintenance regimens, comparison with available current treatments, and long-term benefits.

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