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LETTER TO THE EDITOR

Comments on Preti et al: "The clinical role of LASER for vulvar and vaginal treatments in gynecology and female urology: An ICS/ISSVD best practice consensus document"

Dear Editor,

We read with interest the recent review by Preti et al[1] and we welcome the systemic approach to evaluating the safety and efficacy of the use of lasers in treating different pelvic floor disorders and establishing best practice guidelines.

While reviewing the search terms and cited papers, we were surprised to see that some recent studies that we authored, or were aware of, were misrepresented. For example, in the chapter evaluating laser therapies for genitourinary syndrome of menopause (GSM), the article failed to properly cite and discuss the paper authored by Dr Levancini and myself.[2] In the study, we have evaluated the safety and effectiveness of the Er:YAG laser treatment on GSM symptoms in 43 breast cancer survivors and followed them up to 18 months posttreatment. We found that the treatment was effective and safe for the treated population, yet the paper was not included in the discussion of studies on breast cancer survivors in chapter 4.

Dr Preti et al state that the sample size of the majority of available laser studies is small. However, in our long term prospective study[3] of the safety and effectiveness of Er:YAG laser for treating GSM, we included 205 postmenopausal women followed for 24 months (reference 69 in the Preti et al paper). The results enabled us to estimate the average duration of the effectiveness of the laser treatments and to suggest the interval for repeated treatments. Out of these 205 patients, 114 women were also suffering from stress urinary incontinence (SUI) and received an additional SUI laser treatment - the effects of these treatments were not discussed in chapter 5.

Regarding possible side effects, Dr Preti et al state that laser-tissue interactions may lead to serious adverse events. Although we agree with the authors, one needs to keep in mind that LASER is a common name for multiple different wavelengths and treatment modes, some being much safer to use than others. Using the same preset and standardized procedures as reported in the cited laser papers using Er:YAG laser in the Preti et al review, we did not overlook the adverse events, but simply did not encounter them. This is not surprising since the procedure we use is nonablative, leaves the mucosa surface intact and thus does not induce bleeding, bruising or burning of the treated tissues.

The Gaspar et al[4] cohort study on the effect of Er:YAG lasers on GSM was cited in the GSM section. However, Dr Preti and colleagues have failed to include the histological data reported in this paper (analyzed up to 12-months posttreatment) in Section 3.2 that presented the histological effects of laser therapies.

Furthermore, in the chapter evaluating studies for SUI, Dr Preti et al have stated that there have been no published randomized control trials (RCTs). On the contrary, in 2018, Blaganje et al[5] have published the results of the first RCT evaluating the safety and effectiveness of nonablative Er:YAG laser against a sham control for treating SUI.

As we have identified these missing points from these papers "by heart" without doing comprehensive searching and analysis, it is highly probable that other points or papers were missed. We believe that omitting published data brings into question the soundness of the review. Such analyses, to be objective and free of bias, need to be truly comprehensive, especially if resulting in practice recommendations from a highly regarded professional association.

The authors were somewhat unfair comparing the new laser therapies to the controversial mesh surgeries. These are completely different treatments, having different indications, limitations and risk/benefits ratios. Nonablative Er:YAG laser treatments have an intrinsically lower risk profile compared to implantable mesh devices and thus require lower levels of clinical evidence for regulatory approval. All of the published studies so far have found the treatments to be safe and free of serious side effects, resulting in regulatory approval for clinical use in Europe and many other countries. The authors also criticize the fact that a lot of the studies are done in a clinical practice setting, yet long-term safety and effectiveness monitoring is always done through post-market clinical trials, both for drugs and medical devices.

Lastly, we would recommend the authors and readers to put the lack or small numbers of RCTs into perspective —the reviewed laser therapies have started to be introduced only in the last decade. The gap between the initiation of a clinical trial and the publication of

its results is measured in several years. The database clinicaltrials.gov search for the revised indications and "laser" reveals that several RCTs are ongoing for different indications and laser sources. We believe that in the next 5 years, with new clinical research on the way, the picture will be much clearer regarding these treatments. Clinical guidelines should closely follow these developments.

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REFERENCES

1. Preti M, Vieira-Baptista P, Digesu GA, et al. The clinical role of LASER for vulvar and vaginal treatments in gynecology and female urology: an ICS/ISSVD best practice consensus document. *Neurourol Urodyn*. 2019;38:1009-1023.
2. Gambacciani M, Levancini M. Vaginal erbium laser as second-generation thermotherapy for the genitourinary syndrome of menopause: a pilot study in breast cancer survivors. *Menopause*. 2017;24:316-319.
3. Gambacciani M, Levancini M, Russo E, Vacca L, Simoncini T, Cervigni M. Long-term effects of vaginal erbium laser in the treatment of genitourinary syndrome of menopause. *Climacteric*. 2018;21:148-152.
4. Gaspar A, Brandi H, Gomez V, Luque D. Efficacy of Erbium: YAG laser treatment compared to topical estriol treatment for symptoms of genitourinary syndrome of menopause. *Lasers Surg Med*. 2017;49:160-168.
5. Blaganje M, Šćepanović D, Žgur L, Verdenik I, Pajk F, Lukanović A. Non-ablative Er: YAG laser therapy effect on stress urinary incontinence related to quality of life and sexual function: A randomized controlled trial. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 2018;224:153-158.