PHILIPPINE SOCIETY for UROGYNECOLOGY & RECONSTRUCTIVE PELVIC SURGERY

Position Statement

NON-SURGICAL VULVOVAGINAL REJUVENATION

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Genitourinary Syndrome of Menopause (GSM) is a term introduced in 2014 by the North American Menopause Society (NAMS) and the International Society for the Study of Women's Sexual Health (ISSWSH)[1] to describe a collection of symptoms and signs associated with estrogen deficiency such as vaginal dryness, irritation, dyspareunia, urinary incontinence, and urinary tract infections. GSM, a condition that affects more than half of menopausal women, significantly affects the woman's quality of life and sexual function.

Management of these symptoms and other pelvic floor disorders have been, and continues to be, extensively researched and published in literature. Various treatment options, ranging from conservative methods (such as non-medical/behavioural or medical therapy) to surgical methods have been described and defined as the standards of care by leading authorities in the field.

With modern medicine leaning towards minimally-invasive treatments, minimally-invasive surgery has been at the forefront of care of various pelvic floor disorders especially for stress urinary incontinence and pelvic organ prolapse. In the past years, the trend towards minimally-invasive methods has been pushed much further with the use of lasers for various gynecologic conditions, specifically for the treatment of GSM. Laser vaginal therapy is being promoted for the treatment of vulvovaginal atrophy (VVA), urinary incontinence, pelvic organ prolapse and even for cosmetic indications. In fact, laser vaginal rejuvenation has become a commonly practiced intervention in spite of the lack of good quality evidence demonstrating long-term effects including safety.

The contention of aesthetic gynecology is to provide comprehensive care to patients in wellness and health. And, nonsurgical vaginal rejuvenation is a natural

extension of that culture. Non-surgical vaginal rejuvenation (NVR) performed by cosmetic and aesthetic surgeons utilizes radiofrequency and/or laser devices to treat vaginal laxity, genitourinary syndrome of menopause (GSM), sexual dysfunction, and stress urinary incontinence (SUI) in spite of only anecdotal evidence of improvement. To date, there are approximately 15 laser companies in the global market advertising laser vaginal treatment as an effective minimally invasive solution for a wide range of pelvic floor/urogynecological disorders. The number of laser procedures for managing important aspects of vulvovaginal atrophy and/or genitourinary syndrome of menopause (GSM), urinary incontinence, and pelvic organ prolapse in the last 3 years has significantly increased worldwide, mainly because of **media advertising and the manufacturer's marketing policy.** Currently, the proposed mechanisms of action of increased collagen production, changes in the angle of the urethra, and increased lubrication due to blood flow are speculative. MUCH OF THE RESEARCH IS BEING DRIVEN BY INDUSTRY as different devices seek to claim a niche within NVR while indications are broad.[2]

A well-executed meta-analysis or systematic review provides the highest level of evidence in the arena of researches or clinical trials. As early as 2015, Singh A et al had suggested that laser application as treatment for urogenital symptoms needs to be very cautiously appraised in view of the lack of robust and qualitative body of data; yet, we have seen little progress in the proper research direction[3]. In previous reports by Salvatore et al and Stefano et al, the authors suggested that pulsed CO2 laser might benefit patients with vulvovaginal atrophy, as clinical and histological data support this hypothesis[4,5]. Despite their recommendation for future randomized trials, evidence to date remains extremely limited. Currently, the predominant evidence available for laser vaginal treatment are prospective observational studies.

In May 2017, Arunkalaivanan et al. conducted a well-designed systematic review of laser therapy as a treatment modality for the relief of symptoms of GSM[6]. Among a total of 165 articles identified in their search, none was a randomized controlled trial (RCT) and none of the 3 observational studies included a control group. Additionally, the lack of RCTs made it difficult to

undertake a meta-analysis, and thus to give any weight to the recommendations from the currently published studies. An important limitation of these short-term studies is that the potential risks of long-term complications, such as scarring, have not yet been addressed or reported. Therefore, assumptions cannot yet be made regarding the applicability or long-term effects of this treatment, whether positive or negative. The authors concluded that although laser therapy seems to be promising, evidence does not allow firm conclusions.

Similarly, Pergialiotis et al. reported on the results of a systematic review on the role of laser vaginal therapy as a treatment option for SUI[7]. This review included 12 studies and a total of 760 patients that underwent laser therapy for SUI. No randomized controlled trials were identified. The authors found that the methodological quality of the reported studies was low, with Oxford Level Evidence 3b and 4. Several limitations including methodological flaws (which render the studies prone to selection, attrition and statistical biases), and the lack of a control group or comparison with other clinically proven treatment modalities (such as pelvic floor exercises, bulking agents or mid-urethral slings); thus prohibiting firm conclusions regarding its use in the treatment of SUI. These studies should base their findings not only on patient satisfaction but also include urodynamic evaluation to enhance their scientific merit, increasing our understanding of whether laser therapy actually benefits women with SUI and identifying the underlying mechanism that is potentially corrected.

Laser vaginal rejuvenation is also described as a surgical technique indicated for sexual dysfunction whether it be from dyspareunia, genital appearance, or vaginal laxity. Studies have shown sexual gratification to be directly related to frictional forces during intercourse with friction directly related to vaginal diameter. NVR (Nonsurgical Vulvovaginal Rejuvenation) aims at reducing the diameter & laxity of the vagina and thus improved sexual functioning. The Vaginal Laxity Questionnaire (VLQ), however, is not a validated scale. An objective, reproducible way or device to measure vaginal laxity or changes after treatment using nonsurgical vulvovaginal rejuvenation does NOT exist. This should have enhanced research and clinical tracking of changes experienced by patients. Moreover, studies comparing NVR to surgical options

like labiaplasty or vaginoplasty along with cost will help inform providers and patients about cost-effectiveness.[8]

Despite the lack of clinical data, laser vaginal rejuvenation and various cosmetic gynecologic procedures have been receiving increased attention with a corresponding increased number of practitioners performing laser vaginal procedures. Not surprisingly, laser vaginal treatment for GSM, sexual dysfunction, urinary incontinence, prolapse, and even cosmetic issues has become a controversial issue among international bodies including the American College of Obstetricians & Gynecologists (ACOG)[9,10,11], Royal College of Obstetrics & Gynecology (RCOG)[12], and the International Urogynecological Association (IUGA)[2,3,6]. Issues of concern include the lack of scientific data on its efficacy, surgical indications, standardization of technique, and complication rates including effects on adjacent organs (urethra, bladder, rectum, pelvic vessels and nerves).

In line with this, the Philippine Society for Urogynecology and Reconstructive Pelvic Surgery (PSURPS), as a professional society, takes a proactive stance in making a responsible scheme of guiding new promising technologies into clinical practice. While acknowledging the potential benefit of laser technology, we also believe that further long-term efficacy and safety data should be obtained (thru large-scale good-quality prospective randomized trials) before fully embracing this new technology and incorporating it into mainstream clinical practice.

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