International Urogynecology Journal (2019) 30:1–2
https://doi.org/10.1007/s00192-018-3812-2

EDITORIAL

Academic cosmetic gynecology and energy-based therapies: ambiguities, explorations, and FDA advisories

Bobby Garcia[1] · Jack Pardo[2]

Received: 30 August 2018 / Accepted: 31 October 2018 / Published online: 8 November 2018

What is preprolapse? Similar to prediabetes describing impaired glucose tolerance not yet severe enough to warrant a pathologic diagnosis, preprolapse is a mild defect in pelvic organ support. A concept that is easily conveyed to patients, this term is not yet standardized or widely accepted among urogynecologists. What about vaginal laxity? Here, at least, we have a working precedent of the complaint of excessive vaginal looseness [1]; however, without an objective measure such as the Pelvic Organ Prolapse Quantification System (POP-Q), this also will vary between patients and providers. Energy-based and surgical treatment for these nebulous conditions, along with others too numerous to describe here, have fallen under the umbrella of the mutually ambiguous yet ubiquitous term vaginal rejuvenation. And now, with Pandora's box completely opened, this July, the US Food and Drug Administration (FDA) issued an official warning against energy-based therapy [2].

This notification advises patients against using energy-based devices for vaginal rejuvenation, cosmetic vaginal procedures, or symptoms related to menopause, urinary incontinence, or sexual function. Given the lack of standardization in this budding niche of gynecology, a blanket advisory has been issued for the treatment of a variety of conditions. In order to clearly understand the variables in play, dissection of the previous statement is warranted. Energy-based devices largely fall into two categories: radiofrequency and lasers. Radiofrequency (Thermi Va™) works by volumetrically heating tissue to activate fibroblasts, thereby stimulating production of new collagen resulting in healthier, more elastic tissue. Lasers, on the other hand, are further substratified into CO_2 laser (Mona Lisa™), Erbium:Yag (Intimalase™), and hybrid Erbium:Yag Diode (Diva™), which operate at 10,600 nm, 2940 nm, and 2940 + 1470 nm, respectively. These devices function ablatively and nonablatively to create controlled thermal injury, resulting in immediate contraction, remodeling, and stimulation of new collagen. Irrespective of mechanism, depth of tissue penetration, or relative efficacy, they all aim to alleviate the same conditions.

The most widely accepted use of energy therapy studied to date is the genitourinary syndrome of menopause (GSM). As a syndrome, GSM is defined as a constellation of symptoms afflicting the pelvic organs, such as irritation, dryness, sexual dysfunction, pain, and recurrent vaginal and urinary tract infections. To be clear, first-line therapy of GSM includes the use of moisturizers and lubricants. Second-line therapy for patients with persistent symptoms is vaginal estrogen, as declining levels of this hormone are responsible for the condition in the first place. Energy-based therapies are currently being explored as an alternative or third-line option for patients who decline or are otherwise averse to local hormone therapy. Although far from an established treatment modality for GSM, preliminary data is promising [3], and we must continue to investigate the efficacy of these technologies through further research. The FDA advisory has not removed these devices from the market; rather, it is asking for further evidence to support the claims being made by manufacturers and to help keep both physicians and patients fully apprised of any adverse events.

Under the purview of GSM lies arguably one of the symptoms most affecting quality of life: sexual dysfunction. Here, the old adage "sex sells" holds truer than ever, and we postulate it is chief among the reasons that the aforementioned warning became necessary. Is there a plausible mechanism for improvement of sexual function in women undergoing energy-based therapy? Yes. Remodeling and increased formation of collagen resulting in increased elasticity, coupled with increased blood flow and lubrication to the vaginal epithelium, could potentially result in better sexual function as

✉ Bobby Garcia
bgarc3@lsuhsc.edu

[1] Louisiana State University Health Sciences Center, New Orleans, LA, USA

[2] Urogyn & Cosmetic Gyn, Clinica Ginestetica, Santiago, Chile

measured by objective validated questionnaires. Do we have randomized placebo-controlled data to support this? No. And therein lies the problem. Most of the research is based on nonrandomized, short-term enrollment of small groups of women to demonstrate safety and set a precedent for efficacy. Somewhere along the way—possibly in aggressive marketing of these technologies, reality television, the Internet, or all of the above—information gets misconstrued and lumped into the wastebasket term of vaginal rejuvenation. We are completely in agreement with the FDA that "vaginal rejuvenation is an ill-defined term, as it only fuels the pyres of confusion and misunderstanding.

Energy-based devices are deceptively simple: insert probe, push button, heat tissue. This by no means implies that safety is assured. Each patient, depending on menopausal status, level of genital atrophy, sexual function, and overall health, has an optimal treatment range and a danger zone. This translates to a different treatment time, number of passes, and/or set depth of penetration depending on the type of device used. Similar to the retropubic midurethral sling and the robotic sacrocolpopexy, energy-based therapies come with their own learning curve and require appropriate training. Preconference hands-on workshops have been helpful in giving an overview of these technologies, but we need to go further. A standardized energy-based curriculum would provide a baseline foundation of knowledge and training that could help to decrease the incidence of adverse events.

All this being said, there is a potential role for energy-based cosmetic vaginal procedures after appropriate research documenting safety and efficacy. Will a 45-year-old woman who is a para 3 with a GH = 4 and an overall POP-Q of stage I (preprolapse) complaining of sexual dysfunction benefit from a cosmetic (read: functional) vaginal procedure, such as a colpoperineoplasty or energy-based therapy? The evidence here is largely relegated to anecdotal, single-provider experiences, and a few single-center studies, but the short answer is: potentially. Academic cosmetic gynecology is at such a nascent stage in development that we still lack a standardized terminology; however, this does not preclude the theoretic benefit of these procedures. Rather, it suggests that we need to take a step back to establish uniform definitions and procedural outcomes to eliminate ambiguities, thereby fostering valid and reproducible objective research.

Vaginal energy-based therapy has been around since 2009, and industry's rush to market may have overridden the desire to study the technology, but all is not lost. In fact, this may have been the wake-up call we needed. Although confusion over vaginal laxity abounds, definitions for GSM, stress urinary incontinence, and sexual dysfunction are well established and primed for exploration. Now is the time for rigorous protocols with sham treatment arms for study participants and blinded investigators performing follow-up exams to truly lift the veil on energy-based therapy and determine efficacy. Please see the "Committee Opinion on Laser-based Therapies for the Treatment of Urogynecological Disorders" in this issue of the IUJ for a survey of current evidence available to date. These are very promising technologies, but without objective, validated, and well-designed academic research, we risk losing it all.

Compliance with ethical standards

Conflicts of interest J Pardo serves as a faculty member and consultant of the European Society of Esthetic Gynecology. He serves as a member and consultant of the Scientific Committee and has received acceptance of paid travel expenses and honoraria from the International Association of Gynecology and Sexual Well-being. He has received travel expenses and serves as a consultant for Sciton, Inc. B Garcia, none.

References

1. Haylen BT, Maher CF, Barber MD, et al. Erratum to: an international Urogynecological association (IUGA) / international continence society (ICS) joint report on the terminology for female pelvic organ prolapse (POP). Int Urogynecol J Pelvic Floor Dysfunct. 2016;27(4): 655–84. https://doi.org/10.1007/s00192-016-3003-y.
2. Health C for D and R. Safety Communications - FDA Warns Against Use of Energy-Based Devices to Perform Vaginal "Rejuvenation" or Vaginal Cosmetic Procedures: FDA Safety Communication https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm615013.htm. Accessed August 15, 2018.
3. Tadir Y, Gaspar A, Lev-Sagie A, et al. Light and energy based therapeutics for genitourinary syndrome of menopause: consensus and controversies. Lasers Surg Med. 2017. https://doi.org/10.1002/lsm.22637.