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Introduction

Genitourinary Syndrome of Menopause (GSM): Terminology combines the conditions of vulvovaginal atrophy and urinary tract dysfunction or urethral atrophy. 50% of postmenopausal women are affected by GSM. “GSM is defined as a collection of signs and symptoms associated with decreased estrogen and other sex steroids involving changes to the labia majora/minora, clitoris, vestibule/introitus, vagina, urethra and bladder.”

Changes & Signs include: thinning of the vaginal epithelium, loss of the vaginal folds/rugae, reduced vascularization & vaginal secretion that alter the vaginal bacterial flora, thinning of pubic hair, thinning or fusion of labia, vulvovaginal pallor or erythema/petechiae, introital retraction/stricture, prominence of urethral meatus/caruncle

Symptoms include:

• Genital symptoms: vaginal dryness, burning, irritation/itching
• Urinary symptoms: burning with urination, urinary urgency, recurrent UTI’s, UI
• Sexual symptoms: dyspareunia, light bleeding after intercourse, decreased vaginal lubrication during sexual activity and sometimes shortening and tightening of the vaginal canal

Treatment includes:

• Topical hormonal treatment is considered the gold standard, except for women with history of breast CA, estrogen-sensitive tumors, and thromboembolism
  o Poor compliance is common due to inconvenience of application and c/o of increased vaginal discharge
• Lubricants and moisturizers are another line of self-treatment
• Other treatments include: testosterone, isoflavones (plant estrogens-most common-soybeans), and bioidentical hormones.
• Radiofrequency therapies: heats tissue **
• Laser therapy: ** Currently there are two lasers offered: thermoablative fractional CO2 laser (TACO2L) and nonablative vaginal Erbium YAG laser (VEL)
  o There are studies that suggest that both lasers (CO2-laser and Er:YAG-laser) are safe and have a high efficacy on alleviating vaginal dryness and dyspareunia, as well as restoring the local pathophysiology.
  o There are additional studies that indicate LUTS improvement with CO2-laser
  o There are no studies comparing the 2 laser-technologies for the management of GSM

Aim of Study: “To evaluate the long-term effect of Thermoablative Fractional CO2 laser (TACO2L) as an alternative treatment for early stages of SUI”

Methods

Subjects: 161 Postmenopausal women (age range 45–65 years). Women were prospectively enrolled at the Urogynecology Unit, San Jorge University Hospital, Pereira, Colombia, for 4 months (September and December
2015). The appropriate medical ethics committee and institutional review board approved the study

**Inclusion criteria:** Clinical dx of mild SUI and genitourinary syndrome of menopause

**Exclusion criteria:** Anterior POP-Q stage >1, recurrent lower UTIs, obesity (BMI>35 kg/m2) and patients who could not be classified because of previous surgery

**Treatment**
- There were 4 laser sessions every 30–45 days.
- Name of device: SmartXide2 V2LR fractional microablative CO2 laser system (MonaLisa Touch™;Deka, Florence, Italy**).  
  - MonaLisa Touch is a CO2 & radiofrequency laser with a scanning system (V2LR); used in vulvovaginal ‘rejuvenation’ and genital cosmetic surgery. TACO2L works in 2 ways: microablative effect and thermal effect. A probe delivers laser energy in dots circumferentially and can take about 5 minutes. Recovery time lasts 10-15 days.
- The same laser device parameters were used in all patients.
- After the 4 treatments; yearly check-up/treatment sessions occurred at 12, 24 and 36 months

**Measures at baseline**

**Questionnaire:** Urinary Incontinence Short Form (ICIQ-UI SF) at baseline and at 12, 24 and 36 months after TACO2L treatment

**Objective measures**
- **Punch biopsies** of the anterior vaginal wall (urethrovesical junction) were obtained for histological analysis before and at the end of the treatment protocol. Sections of the blinded biopsy samples were stained for histological analysis at baseline; then 6 weeks and 6 months after treatment
- **PWT:** 1 hour pad weight tests at baseline and at 12, 24 and 36 months after TACO2L treatment

**Results**
- All patients attended the follow-up visits at 12-, 24-, and 36 months.
- Baseline characteristics of the study population are presented in Table 1
- TACO2L treatment was well tolerated, and no side effects were observed during the study period.
- TACO2L significantly improved ICIQ-UI SF scores and 1-h pad weight test results, and the improvements were maintained during the 36 months without any need for further re-intervention.

- **ICIQ-UI SF scores:** treatment resulted in improvements in ICIQ-UI SF scores  
  - 12 months (14.34 ± 2.65 vs. 7.09 ± 1.1, p < 0.001),  
  - 24 months (14.34 ± 2.65 vs. 7.49 ± 0.94, p < 0.001)  
  - 36 months (14.34 ± 2.65 vs. 6.76 ± 0.82, p < 0.001)  
  - Although there was a significant decrease between 24 months and 36 months (p < 0.001) and overall between 12 months and 36 months (p < 0.003)

- **1-h PWT:** Significant changes were recorded in the 1-h pad weight test from baseline  
  - Baseline 9.89 ± 0.57 g  
  - 12 months 3.52 ± 1.89 g,  
  - 24 months 3.55 ± 1.88 g,  
  - 36 months 3.72 ± 2.05 g (all p < 0.001).  
  - There were no differences in the 1-h pad weight test results between the follow-up time points 12 months, 24 months and 36 months (all p > 0.05).

- **“Histological examination** of the vaginal mucosa revealed thicker epithelium, a higher population of intermediate and shedding superficial cells and underlying connective tissue with papillae indenting the epithelium–connective tissue junction. The stroma showed features indicating structural recovery in all patients at 6 weeks”
  - The authors state that their “study demonstrated that an adequate amount of heat is delivered to the deep vaginal epithelium and urogenital structures to generate histologically confirmed structural changes that seem to be related to vaginal trophic intrinsic and extrinsic continence mechanisms of the urethra”
Author Discussion

- The authors’ state the CO2 laser penetrated a depth of not more than 0.6mm. This should only impact the vaginal epithelium and consequently thermal diffusion to structures around the vagina (rectum, bladder and peritoneal cavity) would not be possible.
- Authors state “SUI is characterized by insufficient support of the urogenital tract related to decreased collagen production in the connective tissue. Thermal energy/laser energy or transvaginal use of the thermoablative fractional CO2 laser (TACO2L) is considered a potential strategy to activate collagen and promote elastin formation at the molecular level by generating controlled thermal damage followed by a wound healing response.”
- They clearly state there is still a lack of understanding of the histological changes and that further research using energy lasers for the treatment of SUI is needed.
- This treatment strategy is not recommended in patients with advanced stage POP or for moderate SUI. In these cases the authors only recommend surgical intervention. They conclude that TACO2L is most suitable for patients with GSM and mild SUI; women that have contraindications to surgery; women that want to postpone surgery or simply do not want to undergo surgery.

Strengths

- This is the first long-term study looking at the use of TACO2L for the treatment of mild SUI with yearly check-ups at 12, 24 and 36 months. Other studies report 20 week or 1 year F/U.
- Significant improvements are noted immediately following treatment and maintained 3 years later.
- It was stated there was no conflict
- No funding by manufacturer
- Blinded histological biopsies

Weaknesses

- Need placebo-control study/RCT. But it is interesting to note that histological changes have not been readily documented in placebo trials.
- FDA** has recently stated alerts & warnings concerning energy-based devices like the one used in this study

**July 30, 2018: FDA alerted and warned “patients and health care providers that the use of energy-based devices to perform vaginal rejuvenation, cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.”
https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm

Journal Club Discussion

1. Are your clients asking about or receiving Laser treatments? Any feedback from clients?
2. What recommendations do you make concerning GSM treatment? Lubricants?

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1 Portman DJ, Gass ML; Vulvovaginal Atrophy Terminology Consensus Conference Panel. Epub 2014 Aug 19