PFD WEEK 2018
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Advancing Female Pelvic Medicine and Reconstructive Surgery

Short Oral 62: Comparison of Vaginal Laser Therapy to Vaginal Estrogen Therapy (VeLVET) for women with Genitourinary Syndrome of Menopause (GSM)

Friday, October 12, 2018

02:51 PM - 02:56 PM

Hyatt Regency Chicago - Grand Ballroom EF

Objective:

To compare 6-month efficacy and safety for treatment of vaginal dryness/GSM in women undergoing fractionated C02 vaginal laser therapy to women using estrogen vaginal cream.

Methods:

This multicenter, randomized trial compared fractionated C02 laser to estrogen cream at 6 institutions. We included menopausal women with significant vaginal atrophy symptoms based on a VAS bother score > 7. We excluded women with prolapse >Stage 2, recent pelvic surgery, prior mesh surgery, active genital infection, history of estrogen sensitive malignancy, and other autoimmune conditions. The primary outcome was the VAS vaginal dryness score. Secondary outcomes included evaluation of vaginal atrophy (vaginal health index [VHI], vaginal maturation index [VMI]), QoL symptoms (day-to-day impact of vaginal aging questionnaire [DIVA]), assessment of sexual function (female sexual function index [FSFI], patient report of sexually activity), and urinary symptoms (urogenital distress inventory [UDI-6]). Adverse events and patient global impression of improvement (PGI-I) and satisfaction were also assessed. 85 subjects/group were required for this non-inferiority trial (90% power, 15% dropout) and an intention-to-treat analysis was performed with logistic regression adjusting for baseline differences.

Results:

±± 4.6 kg/m^2 and the majority were Caucasian (91.4%). Demographics did not differ between groups except the laser group was less parous [0 (range 0-4) vs 2 (0-6), p=0.04]. A summary of 6-month outcomes is in Table 1. On PGI, 85.8% of laser patients rated their improvement as “better or much better” and 78.5% reported being either “satisfied or very satisfied” compared to 70% and 73.3% in the estrogen group; this was not statistically different between groups. 10 adverse events (AE) were either mild or moderate and included vaginal bleeding, pain, and/or discharge, breast tenderness, UTI, migraine, and abdominal cramping. AE’s did not differ between groups. On logistic regression, mean difference in FSFI scores was no longer statistically significant; and, VMI scores remained higher in the estrogen group (adj p-value 0.02); although, VMI data were only available for 34 subjects (16 laser, 18 estrogen). Due to changes in regulatory requirements, enrollment was halted prior to study completion.

Conclusions: At 6-months, fractionated C02 vaginal laser and vaginal estrogen treatment resulted in similar improvement in GSM symptoms as well as urinary and sexual function. Overall, 70-80% of patients were satisfied or very satisfied with either treatment and there were no serious adverse events. Funded by a grant from the Foundation for Female Health Awareness (

www.femalehealthawareness.org).ClinicalTrials.gov identifier: NCT02691936

Table 1. 6-Month Outcome Measures VELVET trial

Outcome	Fractionated C02 laser N=28	Conjugated estrogen cream N=30	P value
Mean difference VAS score			
Dryness	-5.48 ± 2.68	-5.76 ± 2.48	0.67
Itching	-1.84 ± 3.01	-1.24 ± 2.96	0.45
Irritation	-3.29 ± 3.73	-3.49 ± 3.19	0.87
Dysuria	-1.4 ± 2.89	-2.11 ± 2.85	0.36
Mean difference VHI	0.87 ± 0.7	1.17 ± 0.93	0.07
Mean difference DIVA	-4.38 ± 3.1	-3.57 ± 3.15	0.32
Mean difference VMI^	3.9 ± 30.6	25 ± 22.6	0.04*
Mean difference FSFI†	-5.57 ± 7.67	-2.17 ± 6.13	0.03*
Mean difference UDI	-6.25 ± 12.24	-10 ± 16.43	0.34
% sexually active	53.6 (15)	50 (15)	0.79
% resume activity	71.4 (20)	63.3 (19)	0.51

*statistically significant at P ≤ 0.05
^remained statistically significant after controlling for confounding factors
†no longer statistically significant after controlling for confounding factors

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