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Randomized, double-blind, placebo-controlled clinical trial for evaluating the efficacy of fractional CO_2 laser compared with topical estriol in the treatment of vaginal atrophy in postmenopausal women

Cruz VL, Steiner ML, Pompei LM, Strufaldi R,
Fonseca FLA, Santiago LHS, Wajsfeld T, Fernandes CE
ABC School of Medicine, São Bernardo do Campo, São Paulo – Brazil.

Abstract

Objective

The aim of the study was to evaluate efficacy of fractional CO_2 vaginal laser treatment (Laser, L) and compare it to local estrogen therapy (Estriol, E) and the combination of both treatments (Laser + Estriol, LE) in the treatment of vulvovaginal atrophy (VVA).

Methods

A total of 45 postmenopausal women meeting inclusion criteria were randomized in L, E, or LE groups. Assessments at baseline, 8 and 20 weeks, were conducted using Vaginal Health Index (VHI), Visual Analog Scale for VVA symptoms (dyspareunia, dryness, and burning), Female Sexual Function Index, and maturation value (MV) of Meisels.

Results

Forty-five women were included and 3 women were lost to follow-up. VHI average score was significantly higher at weeks 8 and 20 in all study arms. At week 20, the LE arm also showed incremental improvement of VHI score (P=0.01). L and LE groups showed a significant improvement of dyspareunia, burning, and dryness, and the E arm only of dryness (P<0.001). LE group presented significant improvement of total Female Sex Function Index (FSFI) score (P=0.02) and individual domains of pain, desire, and lubrication. In contrast, the L group showed significant worsening of pain domain in FSFI (P=0.04), but FSFI total scores were comparable in all treatment arms at week 20.

Conclusions

CO_2 vaginal laser alone or in combination with topical estriol is a good treatment option for VVA symptoms. Sexual-related pain with vaginal laser treatment might be of concern.