SHORT COMMENTARY: LASER VERSUS SHAM FOR GENITOURINARY SYNDROME OF MENOPAUSE: A RANDOMISED CONTROLLED TRIAL

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Short Commentary: Laser versus Sham for Genitourinary Syndrome of Menopause: a Randomised Controlled Trial

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Genitourinary Syndrome of the Menopause (GSM) refers to the symptoms and signs associated with changes in the lower urinary and urogenital tracts following the menopause and is known to affect between 10-40% of postmenopausal women, increasing to 66% by the age of 75 years, although only 25% seek medical help.

Systemic Hormone Replacement Therapy (HRT) may not offer symptomatic improvement in vaginal symptoms and therefore vaginal oestrogen therapy remains integral in the management of women with GSM. The available evidence clearly supports the safety and efficacy of vaginal oestradiol (Vagifem, Estring) and oestriol (Ovestin) although the use of vaginal oestrogen therapy remains controversial following breast cancer and other hormonal dependent tumours. The current consensus opinion suggests that vaginal oestrogen therapy may be used after the failure of non-hormonal treatments in women with a history of oestrogen dependent breast cancer including those taking tamoxifen and they may be considered in women taking aromatase inhibitors after shared decision making with patient, gynaecologist and oncologist (ACOG Consensus Statement, 2021). However, there remains an unmet clinical need for non-hormonal alternative therapies.

Fractionated CO_2 Laser therapy for the treatment of GSM may offer an efficacious and safe alternative to hormonal therapy and the mechanism of action has been clearly documented using histological studies (Salvatore et al, 2018) supported by clinical data demonstrating a meaningful improvement in Health-Related Quality of Life (HRQoL) in affected individuals (Fillipini, 2020). These prospective cohort studies are also supported by sham trials (Salvatore et al, 2021) and systematic reviews and meta-analyses (Pitsouni et al, 2017; Fillipini et all, 2022).

However these results are not supported by animal studies (Makova et al, 2021) and two recently reported prospective randomised trials (Li et al, 2021; Page et al, 2022) which have shown no difference between active and sham treatment arms. This raises the question about how these data should be interpreted in clinical practice and whether there is a role for CO_2 laser therapy in the treatment of GSM. Current guidelines (RCOG, 2022) suggest that laser therapy may have a role but at present laser therapy should only be used as part of a clinical trial.

Is laser therapy 'the emperor's new clothes' or a meaningful advance in therapy for GSM? The dichotomy of the available evidence would suggest we need more evidence for high quality clinical studies.