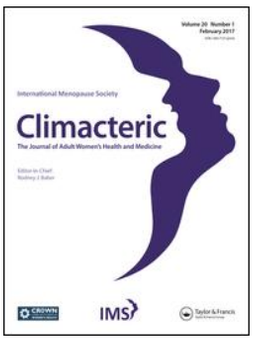

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No vaginal estrogen therapy arm in an RCT trial on genitourinary syndrome of menopause is a concern

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LETTER TO THE EDITOR

No vaginal estrogen therapy arm in an RCT trial on genitourinary syndrome of menopause is a concern

Flint *et al.*[1] are to be congratulated for formulating a randomized controlled trial (RCT) in the management of genitourinary syndrome of menopause (GSM). However, the exclusion of vaginal estrogen as a treatment arm in the trial is disruptive to the natural course of evidence-based medicine, disingenuous to the current evidence surrounding the treatment of GSM, and places participating women at risk of not receiving vaginal estrogen therapy as the current gold-standard treatment for GSM[2,3]. The only published RCT comparing vaginal estrogen and a carbon dioxide laser[4] is not referenced by the authors and demonstrated that the estrogen group had improved scores on the vaginal health index, a lower rate of dyspareunia on the validated self-completed Female Sexual Function Index, and a lower rate of pain post treatments when compared to the carbon dioxide vaginal laser[5]. The trial, by excluding vaginal estrogen as a first-line treatment option, unduly promotes the role of laser therapy for this condition to participants and readers, and is counter-intuitive to the recent action of the Food and Drug Administration in forcing the laser manufacturers to remove any assertions of efficacy or safety of this therapy for the treatment of GSM in promotional material[6]. This methodological problem could be easily addressed with the inclusion of an estrogen arm in the trial.

Furthermore, the authors declare no conflict of interest in the trial; however, both recruiting institutions in this trial are also listed on ClinicalTrials.gov as participating sites in an RCT comparing Fotona YaG vaginal laser therapy and sham treatment for stress urinary incontinence (SUI)[7]. This SUI trial is co-sponsored by Fotona, a company whose YaG laser therapy product also forms one arm of the current study protocol[7]. The authors' research collaboration with Fotona is a potential conflict of interest that should be declared to the readers.

Conflict of interest No potential conflict of interest was reported by the authors.

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References

1. Flint R, Cardozo L, Grigoriadis T, Rantell A, Pitsouni E, Athanasiou S. Rationale and design for fractional microablative CO_2 laser versus photothermal non-ablative erbium:YAG laser for the management of genitourinary syndrome of menopause: a non-inferiority, single-blind randomized controlled trial. *Climacteric* 2019;21:306–10
2. North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause* 2013;20:888–902
3. Faubion SS, Sood R, Kapoor E. Genitourinary syndrome of menopause: management strategies for the clinician. *Mayo Clin Proc* 2017;92:1842–9
4. Cruz VL, Steiner ML, Pompei LM, et al. Randomized, double-blind, placebo-controlled clinical trial for evaluating the efficacy of fractional CO2 laser compared with topical estriol in the treatment of vaginal atrophy in postmenopausal women. *Menopause* 2018;25:21–8
5. Buttini MJ, Maher C. The first published randomised controlled trial of laser treatment for vaginal atrophy raises serious questions. *Med J Aust* 2018;209:376–7
6. Federal Drug Administration. FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication. 2018. Available from: https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm [last accessed 8 Dec 2018]
7. O'Reilly B, The efficacy and safety of Fotona Smooth® Device for the treatment of stress urinary incontinence. 2017. Available from: https://clinicaltrials.gov/ct2/show/NCT03098992?recrs=ab&cond=Female+Stress+Incontinence&draw=2&rank=11 [last accessed 25 Feb 2019]

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