**EFFECTS OF AN OVER-THE-COUNTER LACTIC-ACID CONTAINING INTRA-VAGINAL DOUCHING PRODUCT ON THE VAGINAL MICROBIOTA**

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**Abstract**

Background: Lactic-acid containing intra-vaginal douches are marketed as vaginal hygiene products that support optimal vaginal pH balance. We report the effect of an over-the-counter intra-vaginal lactic-acid douche on the vaginal microbiota (VM).

Methods: Through advertisements 25 healthy women were recruited, aged 18-36 years, in 2015-2017. Participants were followed over 3 menstrual cycles and instructed to douche 3x week during cycle 2. Participants completed questionnaires at baseline, kept daily diaries to report douching, menses and sex, self-collected vaginal swabs almost daily and measured vaginal pH mid-cycle. We assessed the VM by 16SrRNA gene sequencing and tested for *Candida albicans* by PCR at four time-points.

Results: Participants had a median age of 24 years [IQR: 22-29], were mostly Dutch-Caucasian (88%), and 60% used combined oral contraceptives. VM was assessed for a median of 44 vaginal swabs [IQR: 41-50] per participant. At baseline, 21 participants had *Lactobacillus*-dominated VM (*Lactobacillus crispatus* (n=14), *L. iners* (n=6), or diverse *Lactobacillus* species (n=1)) and 4 participants had VM consisting of diverse anaerobes (dysbiosis). In multinomial logistic regression models, having dysbiosis was more likely in the second and third cycle, compared to the first cycle, after adjusting for menses (OR=1.4 (95% CI: 0.9-2.1) and OR=1.7 (95% CI: 0.9-3.1), respectively), though not significantly so (p=0.376). Douching did not affect vaginal pH (p=0.943). Menses increased the odds for having dysbiosis 1.7 fold (95% CI: 1.0-2.8), while douching during menses increased the odds 2.6 fold (95% CI: 1.0-6.5), compared to not menstruating (p=0.099). Participants were more likely to test positive for *C. albicans* after cycle two, compared to cycle one (OR = 3.0 (95% CI: 1.2 – 7.2); p=0.017).

Conclusion: This lactic-acid douche did not significantly affect the VM composition or vaginal pH but increased odds for vaginal dysbiosis when douching during menses as well as the odds for *C. albicans* infections.

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**Abstract summary**

Over-the-counter lactic-acid containing douches did not significantly affect the vaginal microbiota composition or vaginal pH. However, increased odds for vaginal dysbiosis and *Candida albicans* infections were observed,as studied in 25 women who were followed for 3 months and instructed to douche 3x a week during the second month.

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