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Treatment of Vulvo-vaginal atrophy (VVA) using vaginal dilators in addition to usual treatment: a randomized control trial

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Conflict of interest & Disclosure

- No conflict of interest declared
- JP & AJ: no disclosures
- SR Disclosures
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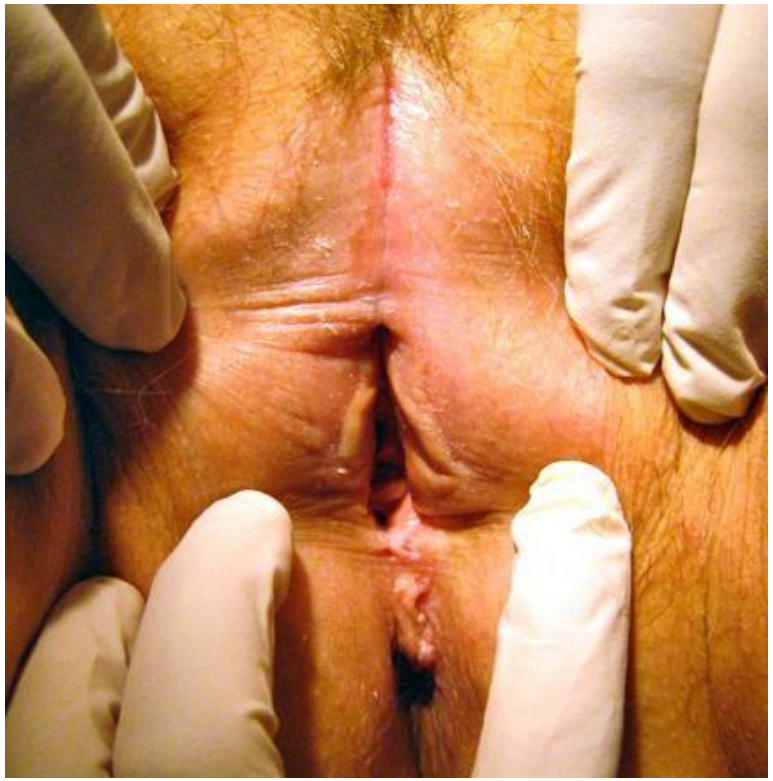
Overview of VVA/GSM

- **VVA or GSM**: under-reported
- Associated with decreased estrogenization
- **Symptoms**: dryness, irritation, and soreness, dyspareunia, urinary frequency and urge incontinence.
- **The standard treatments**: MHT or topical estrogens, DHEA, ospemifene (SERM).
- **Additional treatments (controversial)**: fractionated CO_2 laser, vaginal dynamic radiofrequency, hyaluronic acid



External genitalia show scarce pubic hair, diminished elasticity, and turgor of the vulvar skin, decreased introital moisture, and fusion of the labia minora. *Courtesy of Aron Schuftan, MD.* From Uptodate.

Study Objectives

- Primary objective : Evaluate the efficacy of vaginal dilators as an addition to SoC in premenopausal or menopausal women.

- Broader Scope : Evaluate women with contraindications to MHT who experience VVA symptoms.

Study Design & Methods

- **Design**: Monocentric pilot RCT evaluating SoC (MHT, lubricants, moisturizers) (control group) to SoC + vaginal dilators (test group).
- **Population**: Peri- and postmenopausal women with VVA, including breast cancer survivors.
- **Procedures**: Assessments at baseline, at 4 & 12 weeks
- **Measures** : VVA severity , dyspareunia, VHI, FSFI, and VAS (for vaginal dryness, vaginal and/or vulvar irritation/itching, and pain during sexual intercourse).

Vaginal Dilator Use and Instructions

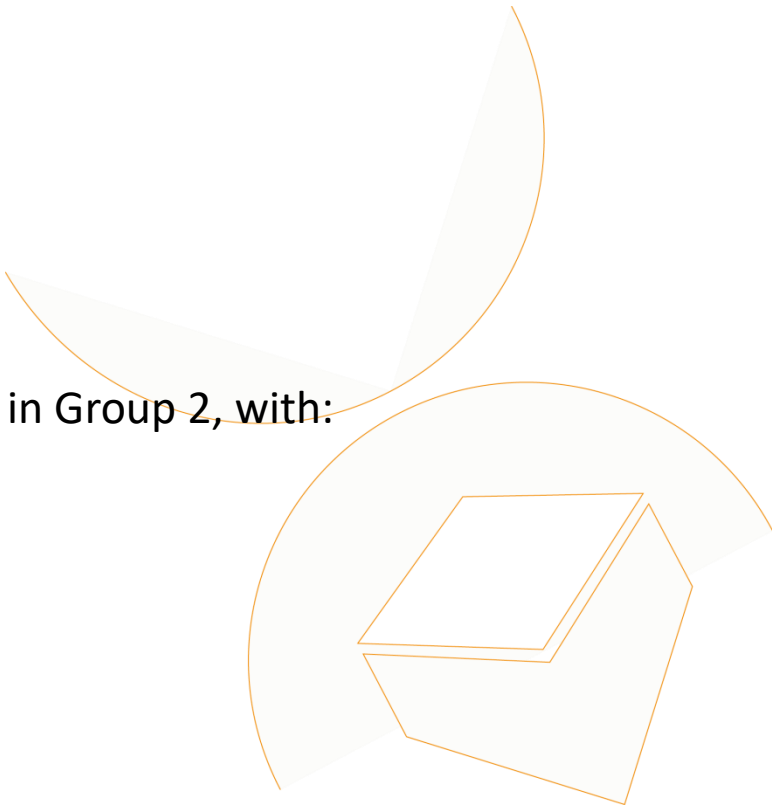
Vaginal Dilator:

- A silicone medical device for gradual stretching
- The kit includes dilators of progressively larger sizes

Statistical Analysis and Power

- **Statistical Analysis**:
- Differences at baseline, 4 weeks, and 12 weeks will be tested using:
  - Two-sample t-test
  - Mann-Whitney test

- **Statistical Power:**
- Assuming a 20% improvement in Group 1 and 40% in Group 2, with:
  - $p < 0.05$ (type I error)
  - 80% power (type II error),
  - 160 patients needed across both groups.



Study Phases & Current Status

- **Phase 1**:

Ongoing pilot study evaluating feasibility at CHU St-Pierre.

- **Phase 2** :

Multicenter study to include a sufficient number of patients.

Aim to involve Belgian physicians specialising in menopause.

Next steps

WHO WILL PARTICIPATE TO THE STUDY ?

ETHICAL APPROVAL OF OTHER CENTERS

UNIFORMIZATION OF PROTOCOLS

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References

- Bachmann GA, Nevadunsky NS. Diagnosis and treatment of atrophic vaginitis. Am Fam Physician. 2000 May 15;61(10):3090-6.

- Nappi RE, Kokot-Kierepa M. Women's voices in the menopause: results from an international survey on vaginal atrophy. Maturitas. 2010 Nov;67(3):233-8.

- Mortensen OE, Christensen SE, Løkkegaard E. The evidence behind the use of LASER for genitourinary syndrome of menopause, vulvovaginal atrophy, urinary incontinence and lichen sclerosus: A state-of-the-art review. Acta Obstet Gynecol Scand. 2022 Jun;101(6):657-692.