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GENITOURINARY SYNDROME OF MENOPAUSE SYMPTOMS AND QUALITY OF LIFE QUESTIONNAIRES: ARE THEY REPEATABLE AND CORRELATED?

Hypothesis / aims of study

Studies investigating genitourinary syndrome of menopause (GSM) are lacking uniformity in symptoms evaluation [1]. For this reason, the US Food and Drug Administration (FDA) recommended the use of the Most Bothersome Symptom (MBS) questionnaire in 2003 which investigates the symptoms' severity and identifies the most important symptom for women with GSM [2]. Another interesting questionnaire, the Atrophy symptom questionnaire, assesses the impact of GSM symptoms on quality of life (i.e. activities of daily living and sexuality) [3]. However, the repeatability of these questionnaires has never been assessed. Moreover, the relationship between GSM symptoms and their impact on post-menopausal quality of life has never been studied, nor the relationship between the MBS questionnaire and the Atrophy symptom questionnaire. Therefore, the aims of this prospective study were 1) to assess the test-retest repeatability of the MBS questionnaire and the Atrophy symptom questionnaire and 2) to explore the relationship between the MBS questionnaire and the Atrophy symptom questionnaire.

Study design, materials and methods

Community-dwelling women aged 55 years and older with GSM were recruited for this prospective test-retest cohort study from a mother study on older women with urinary incontinence. To be included in this study, participants had to present at least two of the following signs: *petechiae, absent rugae, decreased elasticity* and *friability of the vaginal wall*. Subjects with dermatological diseases of the vulva, important prolapses (POPQ>2), radiation for gynecological cancer or vaginal or urinary infection within the previous 3 months and who were taking antiestrogenic medication were excluded. Dosage of systemic and local hormonal therapy medication had to be stable for six months to ensure symptoms stability.

One evaluator administered the questionnaires twice (at T1 and T2) two weeks apart. The MBS questionnaire is composed of four common GSM's symptoms (vaginal dryness, vaginal itching/irritation, dysuria and dyspareunia) and participants have to rate each of these symptoms on a 4-point scale (0=not present, 1=mild, 2=moderate or 3=severe). Then, women have to select a single symptom as the MBS. According to the FDA, the evolution of this specific symptom is the one to consider after treatment or intervention [2]. The Atrophy symptom questionnaire has four items assessing the impact of GSM's symptoms on activities of daily living and one item on sexual activity. In sexually active women, this item assesses the impact of dyspareunia on intercourse and sexual satisfaction. Each of the five items is rated on a 4-point scale (0=none, 1=mild, 2=moderate and 3=severe). For the total score, the individual items' scores are summated and divided by five in sexually active women or by four in non-sexually active women.

Agreement between test and retest responses to items of the MBS questionnaire was observed by graphical analysis of paired differences and the weighted Kappa (κ) statistic. Test-retest repeatability of the Atrophy symptom questionnaire was assessed using paired t-test and intraclass correlation coefficient (ICC). Finally, Pearson correlation coefficient was computed to assess the correlation between MBS item's severity and the Atrophy symptom questionnaire total score.

Results

A total of 20 women aged between 57 and 82 years old (68.1 ± 7.1 years old) were recruited with a mean parity of 1.7 ± 1.1 delivery and a mean BMI of 26.7 ± 4.6. Thirteen were sexually active, one was taking systemic hormonal therapy, four were taking local hormonal therapy and two used a non-hormonal vaginal moisturizer.

MBS questionnaire: Observed agreement between T1 and T2 for the MBS questionnaire symptoms' severity ranged from 60% to 80%, and Kappa's strength of agreement was fair to substantial (Table 1). For the severity of the selected MBS symptom item, observed agreement of 85% was obtained with a substantial Kappa's strength of agreement (0.751 ± 0.132; $p < 0.001$)(Table 1).

Table 1. Rated severity of MBS questionnaire items

MBS questionnaire items	Observed agreement n(%)	Higher severity observed at T2 n(%)	Lower severity observed at T2 n(%)	Kappa (κ) ± SE	P value
Vaginal dryness	13 (65%)	6 (30%)	1 (5%)	0.489 ± 0.152	< 0.001
Vaginal itching/irritation	12 (60%)	7(35%)	1 (5%)	0.444 ± 0.155	0.001
Dysuria	16 (80%)	2 (10%)	2 (10%)	0.394 ± 0.240	0.045
Dyspareunia	14 (70%)	4 (20%)	2 (10%)	0.589 ± 0.125	< 0.001
MBS symptom	17 (85%)	2 (10%)	1 (5%)	0.751 ± 0.132	< 0.001

Atrophy symptom questionnaire: There was no significant difference between T1 and T2 for the Atrophy symptom questionnaire total (T1 mean=0.76 ± 0.30, T2 mean=0.83 ±0.37; p=0.203). Based on the ICC results, excellent repeatability was obtained (0.81 (95% CI 0.54-0.92); p <0.001).

Correlation between questionnaires: There was a strong, positive correlation between the selected MBS item's severity and the Atrophy symptom questionnaire total score for the two measurements sessions (T1: r=0.572; p=0.008, T2: r=0.620; p=0,004).

Interpretation of results

MBS questionnaire: Results from this test-retest study indicates a substantial agreement of the MBS item's severity in the MBS questionnaire between measurements sessions. Being able to reproduce the MBS item's severity from the questionnaire is of major importance as FDA recommended its use to evaluate change following an intervention, in women with GSM. Looking at each specific item of the MBS questionnaire, agreement obtained was fair for the vaginal dryness, the vaginal itching/irritation, and the dysuria symptoms and was substantial for the dyspareunia symptom. The non-concordant answers seem to be related to a higher rating of GSM's symptoms' severity at T2, mostly for the vaginal dryness and the vaginal itching/irritation symptom items. Those results may be related to women's misunderstanding the meaning of vaginal dryness and vaginal itching/irritation compared to the meaning of dyspareunia.

Atrophy symptom questionnaire: For the Atrophy symptom questionnaire, results obtained in this study indicates excellent repeatability according to the ICC values.

To our knowledge, this is the first study assessing the test-retest repeatability of the MBS questionnaire and the Atrophy symptom questionnaire.

Correlation between questionnaires: A strong positive correlation was found between the MBS item's severity and the Atrophy symptom questionnaire total score. These results appear to support the relationship between higher severity of GSM's symptoms and higher impact on activities of daily living and sexuality (intercourse and sexual satisfaction). Of note, no other study was found in the literature that investigated the relationship between these questionnaires or other questionnaires looking at the same content. Only correlations between GSM's symptoms' severity and physical findings were assessed previously (observed signs, pH and maturation value), with various results.

Concluding message:

The MBS and the Atrophy symptom questionnaires have repeatable outcomes and correlated between each other in women with GSM. Therefore they appear to be good outcome measures to assess GSM symptoms and QOL in this population.

References

1. Weber, M. A., et al. (2015). "Assessment of vaginal atrophy: a review." International Urogynecology Journal 26(1): 15-28.
2. Food and drug administration (2003) Guidance for Industry Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms - Recommendations for Clinical Evaluation, The Division of Drug Information (HFD-240) Center for Drug Evaluation and Research, Rockville, MD, http://www.fda.gov/cder/guidance/index.htm.
3. Davila, G. W., et al. (2003). "Are women with urogenital atrophy symptomatic?" American Journal of Obstetrics and Gynecology 188(2): 382-388.

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