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.

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 summed 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 intra-class 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

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

Disclosures
Funding: Réseau québécois de recherche sur le vieillissement grant, Québec, Canada. Fond de recherche du Québec en santé fellowship, Québec, Canada. Clinical Trial: Yes Public Registry: No RCT: No Subjects: HUMAN Ethics Committee: Le Comité d’éthique de la recherche de l’Institut universitaire de gériatrie de Montréal Helsinki: Yes Informed Consent: Yes