Chapter 5


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Abstract

Objective: The aim of this study was to investigate the psychometric properties of the items concerning sexual functioning of the Gynaecologic Leiden Questionnaire (LQ), which consists of items for postoperative morbidity for women with cancer.

Methods: The total study sample consisted of 198 subjects: 66 patients treated for cervical cancer, 66 patients with sexual complaints and 66 subjects from the general population.

Results: By means of factor analysis three subscales were derived: Female Sexual Complaints (FSC), Female Sexual Function (FSF) and Female Orgasm (FO). The reliability of the subscales appeared to be satisfactory. The scores on the three subscales differentiated well between the patients treated for cervical cancer, patients with sexual complaints and the subjects from the general population. Furthermore, the subscales were sensitive to change within the patients treated for cervical cancer. The convergent and divergent construct validity of the Gynaecologic LQ was investigated using other validated instruments measuring sexual functioning, sexual dissatisfaction, marital distress, general life distress and psychological distress. The Gynaecologic LQ subscales were found to represent relatively independent constructs.

Conclusions: The results support the reliability and psychometric validity of the Gynaecologic LQ in the assessment of sexual functioning and vaginal changes in gynaecological cancer patients.
Chapter 5

The Gynaecologic Leiden Questionnaire: psychometric properties

Introduction

Diagnosis and treatment of gynaecological cancer are very likely to have a negative impact on the sexual function of the patient (1-6). It is known that women who have been treated for cervical cancer by radical hysterectomy with pelvic lymphadenectomy (RHL) have persistent vaginal changes that compromise sexual activity and result in considerable distress. Changes or problems that have been described are diminished lubrication, a narrow and short vagina, dyspareunia and sexual dissatisfaction (1-7). Therefore, the treatment of cancer should not only be evaluated with regard to survival. The complications and personal implications of the disease and treatment should also be assessed. To obtain an impression of the impact of a given treatment on a patient’s quality of life and to understand the patient’s perception of symptom severity, self-report questionnaires may give more informative answers (8). Over the last decades several questionnaires have been developed to diagnose dimensions of female sexual dysfunction (9;10). Lately, Jensen et al. showed the results of the validation of the Sexual function-Vaginal changes Questionnaire (SVQ), that was developed to investigate sexual and vaginal problems in gynaecological cancer patients (11).

For the Dutch language area however, until recently (12) no questionnaire was available that focuses on sexual and vaginal problems due to disease and treatment specific for gynaecological cancer patients. We developed a 21-items Dutch self-report questionnaire, the Gynaecologic Leiden Questionnaire (LQ), which is the first Dutch list consisting of items for sexual function, voiding- and bowel problems for women with gynaecological cancer. The items of the Gynaecologic LQ were based on the items to assess sexual function, voiding- and bowel problems of a non-validated questionnaire which has been successfully used in rectal cancer studies (13). Clarity of formulation was assessed by presenting the scale items to patients treated for early stage cervical cancer. The final version of the Gynaecologic LQ consists of one item for weariness, one item for lymph edema, 11 items for sexual functioning, 6 items for voiding and 2 items for bowel problems. The aim of this study is to investigate the psychometric properties of the items concerning sexual functioning of the Gynaecologic LQ.

Methods

Study population

The study involved three subject groups: 1) patients with a history of a RHL for the treatment of cervical cancer stage I-IIa, (oncology group (ONCO)); 2) patients of an out-patient clinic of sexology (female sexual dysfunction group (FSD)); 3) subjects from the general population (control group (CONTROL)). The data from the prospective study of Pieterse et al.(7) were used for the ONCO group. This group consisted of consecutive patients who stayed at the department of gynaecology to undergo a RHL for early stage cervical cancer at the Leiden University Medical Centre (LUMC). They were asked to
complete the Gynaecologic LQ before, 3, 12 and 24 months after the operation (7). For the validation of the Gynaecologic LQ we used the Gynaecologic LQ that was completed 12 months after the operation. Sixty-six women who completed the Gynaecologic LQ after 12 months of follow-up were included. The FSD group consisted of women with a sexual problem who solicited for therapy at an out-patient clinic for sexology of a university medical hospital. The women completed the questionnaires at the end of the first visit. Sixty-six consecutive women with sexual complaints, matched for age with the ONCO group, were included. All the women had a heterosexual relationship.

For the CONTROL group the data from the prospective study of Pieterse et al. (7) were used. This group consisted of employees from the hospitals and relatives and friends of these employees. Sixty-six women were selected. The CONTROL group was matched for age and marital status with the ONCO group ($\chi^2=0.04$, $p=.849$). Demographic data of the three groups are given in Table 1.

The Gynaecologic LQ

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>ONCO (n=66)</th>
<th>FSD (n=66)</th>
<th>CONTROL (n=66)</th>
<th>Chi-square $^1$</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age n,(%)</td>
<td></td>
<td></td>
<td></td>
<td>$\chi^2=7.97$</td>
<td>0.436</td>
</tr>
<tr>
<td>21-30</td>
<td>8(12)</td>
<td>11(17)</td>
<td>9(14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>26(39)</td>
<td>29(44)</td>
<td>26(39)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41-50</td>
<td>25(38)</td>
<td>15(23)</td>
<td>25(38)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>51-60</td>
<td>6(9)</td>
<td>11(17)</td>
<td>6(9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;60</td>
<td>1(2)</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living together n,(%)</td>
<td></td>
<td></td>
<td></td>
<td>$\chi^2=24.33$</td>
<td>0.000</td>
</tr>
<tr>
<td>With a partner</td>
<td>46(70)</td>
<td>66(100)</td>
<td>47(71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without partner</td>
<td>20(30)</td>
<td>0</td>
<td>19(29)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Demographic characteristics of ONCO group (patients treated for cervical cancer), FSD group (out-patients with sexual complaints) and CONTROL group (subjects from the general population). $^1$Observed two-tailed significance. Statistical significance at a level of $p<0.05$.  

The current study investigated only the psychometric properties of the items concerning sexual functioning of the Gynaecologic LQ. The 11 items cover aspects of sexual satisfaction, sexual desire, orgasm, lubrication and pain (see attachment). Items covering treatment specific problems e.g. short or narrow vagina and dry vagina were also included. An inherent problem in the development of questionnaires on sexuality is that not all participants had a partner and that not all the participants were sexually active. For the analysis two questions were excluded because they were not answered on a 5 point Likert scale (item 1 “sexual active lately?”, yes/no and item 10 “numbness labia or thigh?”, yes/no). A higher score on a particular item indicates higher endorsement of the dysfunction or problem measured. Therefore, items 2, 3, 4, 5 and 6 were recoded.

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The Dutch version of the Gynaecologic LQ was translated into English by three independent persons. A consensus translation of each was translated into Dutch by a native Dutch speaker. On the basis of differences between the original and retranslated versions of the questionnaires, some additional changes were made in the English translation (see attachment).

**Measures used for construct for validation**

Only in the FSD group, data for the divergent and convergent construct validity were collected. The following measures were used:

- **The Female Sexual Function Index (FSFI)** (10). The FSFI is a multidimensional self-report questionnaire for assessing sexual function in women (10). The FSFI consists of 19 items that assess sexual desire, arousal, lubrication, orgasm, satisfaction and pain. The psychometric qualities of original FSFI (10;14;15) and the Dutch FSFI translation (16) were found satisfactory to good. A higher score means a better sexual function.

- **The Female Sexual Distress Scale (FSDS)** (17). The FSDS is a 12-items self-report questionnaire that is developed to assess sexuality related personal distress. Overall the FSDS seems a valid and reliable measure for assessing sexuality related personal distress in women (17). The reliability and psychometric validity of the Dutch FSDS is excellent (16). Higher scores indicate more sexual dissatisfaction.

- **The Golombok Rust Inventory of Sexual Satisfaction (GRISS)** contains 28 items and covers the most frequently occurring sexual complaints of heterosexual persons with a steady partner. Seven subscale scores can be derived: anorgasmia, vaginismus, (in)frequency of sexual contact, sexual non-communication, dissatisfaction, non-sensuality, and avoidance of sex. For the current study we only used the anorgasmia and vaginismus subscales of the GRISS. The psychometric qualities of original GRISS (18;19) and the Dutch version were found to be satisfactory (20;21). Higher scores indicate more problems.

- **The Maudsley Marital Questionnaire (MMQ)** is a 20-items self-report instrument measuring dissatisfaction with the general relationship, with the sexual relationship, and dissatisfaction with life in general. For the current study we only used the subscales general relationship and dissatisfaction with life in general. The MMQ has shown good reliability and validity (22). The psychometric qualities of the Dutch version of the MMQ were also found to be satisfactory (23). Higher scores represent larger dissatisfaction.

To measure psychological distress, the **Symptom Checklist-90 (SCL-90)** (24) was used. The Dutch version of the SCL-90 (25;26) was used as an index of psychological distress. The psychometric qualities of the Dutch version were found to be satisfactory. Higher scores represent greater psychological distress.

**Statistical analysis**

Exploratory principle component analysis was conducted on the items of the Gynaecologic LQ in the ONCO and FSD groups. The Kaiser criterion (27) was used to determine the number of components. According to the Kaiser criterion, only components whose eigenvalues are larger than 1 are considered
where a multi-componential solution resulted, simultaneous components analysis (28) was used to identify the optimal dimensional structure in the different subgroups. This analysis tries to establish component weights such that the components optimally summarize the variables in each group. Based on the components, subscales were constructed. The internal consistency was calculated using Cronbach’s alpha in the ONCO group, the FSD group and the CONTROL group. The stability of the Gynaecologic LQ was assessed by calculating the test-retest reliability in CONTROL group. To test the discriminant validity of the Gynaecologic LQ-subscals between the three subject groups, univariate comparisons were made by means of one-way analysis. The sensitivity to change was assessed by a repeated analysis of variance in the ONCO group.

The divergent and convergent construct validity were studied using a higher order principal components analysis with varimax rotation of the scores on the Gynaecologic LQ subscales together with the scores on (subscales of) standardized psychometric instruments measuring theoretically related constructs (complaints): sexual functioning (FSFI), sexual dissatisfaction (FSDS), marital and general life maladjustment (MMQ), and psychological distress (SCL-90).

Results

Preliminary analysis

Prior to analysis, all variables were examined for missing values and fit between their distributions and the assumptions of multivariate analyses. The majority of the item score of the Gynaecologic LQ in the CONTROL group was very low, resulting in positively skewed distributions. For seven out of 9 items the median was category one, indicating that on these seven items at least 50% of the subjects in the CONTROL group only used the first of the five available response categories. This can be explained by the fact that these subjects in the CONTROL group did not have any complaints. Therefore, we decided to exclude the CONTROL group from the factor structure analysis.

Since item 4 (orgasm during masturbation) did not correlate with any of the other Gynaecologic LQ items (<.35) (29), item 4 was also excluded from the further analysis.

1 The original version of the Dutch Gynaecologic LQ consisted of one item with a 6-point Likert scale (item 5) and one item with a 4-point Likert scale (item 2). To obtain uniform weights of the individual items on a subscale, we recoded the answering formats of item 2 and 5. For item 5, two answer formats “Less than once a month” and “Approximately once a month” were added together and the score of item 2 was multiplied with 5/4. In the final version of the Gynaecologic LQ, the answer format “always” was added to item 2.
Explorative principal component analysis was conducted on the 8 items of the Gynaecologic LQ in the ONCO and FSD groups. On the basis of the Kaiser criterion (30), a three-component solution was obtained in both groups. A three-component simultaneous components analysis (28) was conducted to find the components weights with which the components optimally summarized the variables in the two subject groups. The total amount of variance explained by component 1 was 43% in the ONCO group and 30% in the FSD group. For component 2 the total amount of variance was 17% in the ONCO group and 23% in the FSD group. The total amount of variance explained by the third component was in both subject groups 13%. The total amount of variance explained by the components resulting from the simultaneous components analysis was 71% for the ONCO group and 65% for the FSD group. These percentages differed not more than 1.0% from the variance accounted for by the separate principal component analyses in the two subject groups. Thus it may be concluded that the same combinations of variables can be used in both subject groups to describe the data adequately. The loading of the individual items on the three common components in the ONCO and FSD group are shown in Table 2. Items with a loading on one component exceeding 0.55 and a difference between loadings on the three components of at least >0.10 in the two subject groups were considered to belong to a subscale. The first subscale consisted of item 7 (Do you experience vaginal dryness during sexual intercourse?), 8 (Do you experience your vagina as too tight or too short during sexual intercourse?) and 9 (Is sexual intercourse painful to you?). This was interpreted as reflecting Female Sexual Complaints (FSC). The

<table>
<thead>
<tr>
<th>Gynaecologic Leiden Questionnaire (LQ) items</th>
<th>ONCO</th>
<th>FSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component 1: Female Sexual Complaints (FSC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Do you experience vaginal dryness during sexual intercourse?</td>
<td>0.739</td>
<td>0.578</td>
</tr>
<tr>
<td>8 Do you experience your vagina as too tight or too short during sexual intercourse?</td>
<td>0.884</td>
<td>0.825</td>
</tr>
<tr>
<td>9 Is sexual intercourse painful to you?</td>
<td>0.890</td>
<td>0.850</td>
</tr>
<tr>
<td>Component 2: Female Sexual Function (FSF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Do you feel sexual desire?</td>
<td>0.693</td>
<td>0.766</td>
</tr>
<tr>
<td>3 Do you notice that your vagina becomes lubricated (“wet”) during sexual arousal?</td>
<td>0.717</td>
<td>0.754</td>
</tr>
<tr>
<td>5 Do you have sexual contact with a partner?</td>
<td>0.754</td>
<td>0.692</td>
</tr>
<tr>
<td>11 How satisfied are you with your present sexual life?</td>
<td>0.785</td>
<td>0.706</td>
</tr>
<tr>
<td>Component 3: Female Orgasm (FO)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Do you reach orgasm during sexual intercourse?</td>
<td>0.703</td>
<td>0.720</td>
</tr>
</tbody>
</table>

Table 2. Component loadings of the individual items of the Gynaecologic Leiden Questionnaire on the three components resulting from the simultaneous components analysis in the ONCO group (patients treated for cervical cancer) and FSD group (out-patients with sexual complaints).
The Gynaecologic Leiden Questionnaire: psychometric properties

second subscale included item 2 (Do you feel sexual desire?), 3 (Do you notice that your vagina becomes lubricated (“wet”) during sexual arousal?), 5 (Do you have sexual contact with a partner?) and 11 (How satisfied are you with your present sexual life?), and was considered to represent Female Sexual Function (FSF). The third subscale only consisted of item 6 (Do you reach orgasm during sexual intercourse?) and represent Female Orgasm (FO).

Reliability

For the internal consistency the ONCO group, the FSD group and the CONTROL group were used. Since subscale FO consists of only one item, only the consistency of subscales FSC and FSF were assessed. The Cronbach’s alpha values (Table 3) of the subscales FSC and FSF were sufficient in our ONCO group (≥0.70) (31). The correlation-coefficients between test and re-test, ranging from 0.78 to 0.93, were never more than 0.20 lower than Cronbach’s Alpha of a subscale (31). These results indicate that the Gynaecologic LQ subscales have appropriate levels of stability over a period of 2.8 weeks of time (SD= 1.7; range: 1 - 8 weeks).

As an internal criterion for the validity of the three subscales, interscale correlations were computed in the three groups and ranged from 0.0 to 0.53. For the purpose of interpretation |0.10|< r < |0.30| is considered as small, |0.30| < r < |0.50| as medium and r > |0.50| as large (32). These results indicate that the Gynaecologic LQ subscales do not measure totally independent constructs.

No significant associations were found between the Gynaecologic LQ subscales on the one hand and age or ‘living with a partner’ on the other. Therefore, it can be concluded that the Gynaecologic LQ subscales scores are independent of biographic variables.

Discriminant validity

The power of the Gynaecologic LQ subscales to discriminate between different groups of subjects was investigated within the three study groups. As can be seen in Table 4, the Gynaecologic LQ subscales proved to differentiate between the three groups. The women treated for cervical cancer (ONCO) scored significantly higher on the FSF, FSC and FO subscales than women from the general population.
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Chapter 5

Sensitivity to change

To test if the Gynaecologic LQ subscales change in the theoretically proposed direction following an intervention the data from the prospective study of Pieterse et al. (7) were used. Sixty-two of the 66 patients of the ONCO group completed the 24 months follow-up and were included in the analysis. The differences in the subscale scores were analysed at three time moments: before the RHL and 12 months and 24 months after the treatment.

Before the RHL all three subscales score significantly lower than 12 months (p<0.01) and 24 months after the treatment (FSC, p<0.01; FSF, p<0.01; FO, p=0.037). The scores of the three subscales did not significantly differ 12 and 24 months after the treatment (p>0.5). These findings are in line with the results of the prospective study of Pieterse et al. (7) in which the patients reported significantly less sexual complaints before than after the RHL. Moreover, sexual dysfunction was reported up to 24 months of follow-up. Only item 'orgasm during sexual intercourse' that formed the subscale FO, never reached significantly difference over time in that study (7).

Construct validity

A principal components analysis suggested a four-component solution that accounted for 72% of the total variance (Table 5). We found that the first component accounted for 31% of the variance and interpreted it as sexual dysfunction. High loadings were found on this component for the FSF and the five FSFI subscales arousal, desire, satisfaction, lubrication and orgasm. The second component, accounting for 18% of the total variance, is interpreted as sexual pain disorder. High loadings on this component were found for the FSC, the GRISS subscale vaginismus and the FSFI subscale pain. The third component, accounting for 13% of the total variance, is interpreted as psychological distress. High

<table>
<thead>
<tr>
<th>Subscale</th>
<th>ONCO Mean (SD)</th>
<th>FSD Mean (SD)</th>
<th>CONTROL Mean (SD)</th>
<th>F-ratio</th>
<th>Post-hoc-tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSC(n=58)</td>
<td>2.2(1.1)</td>
<td>2.9(1.1)</td>
<td>1.4(0.5)</td>
<td>38.59*</td>
<td>CONTROL&lt;ONCO&lt;FSD</td>
</tr>
<tr>
<td>FSF(n=58)</td>
<td>2.6(0.8)</td>
<td>3.5(0.7)</td>
<td>1.9(0.6)</td>
<td>73.77*</td>
<td>CONTROL&lt;ONCO&lt;FSD</td>
</tr>
<tr>
<td>FO(n=58)</td>
<td>2.9(1.3)</td>
<td>3.9(1.3)</td>
<td>1.7(0.9)</td>
<td>48.80*</td>
<td>CONTROL&lt;ONCO&lt;FSD</td>
</tr>
</tbody>
</table>

Table 4. Untransformed mean, standard deviation (SD) and transformed F ratios for the scores on the Female Sexual complaints (FSC), the Female Sexual Function (FSF) and Female Orgasm (FO) in ONCO group (patients treated for cervical cancer), FSD group (out-patients with sexual complaints) and CONTROL group (subjects from the general population).* All p-values were <0.01, statistical significance at a level of p<0.05.
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loadings on this component were observed for the SCL-90 total score, the MMQ subscale scores for general life maladjustment and relationship maladjustment and the FSDS. The fourth component, accounting for 11% of the total variance, is interpreted as orgasm disorder. High loadings were found on this component for the FO, the FSFI subscale orgasm and the GRISS subscale anorgasmia. These results indicate that the Gynaecologic LQ subscales represent relatively independent constructs.

Discussion

The aim of the present study was to investigate the psychometric properties of the items concerning sexual functioning of the Gynaecologic LQ.

Component analysis of the Gynaecologic LQ in patients treated for cervical cancer and patients with sexual complaints yielded a three-component solution. Three items appeared to contribute to component 1, the subscale Female Sexual Complaints (FSC). Four items contribute to component 2, the subscale Female Sexual Function (FSF) and only one item formed component 3, the subscale Female Orgasm (FO) (Table 2).

The internal consistency was sufficient. The stability was good for all three subscales. The scores on the three subscales were overall not associated with age or ‘living with a partner’. The convergent and divergent validity of the Gynaecologic LQ was good, since the 3 subscales corresponded with subscales measuring similar complaints and discriminated from subscales measuring other (psychological)
problems. The scores from the three subscales appeared to differentiate between patients treated for cervical cancer, patients with sexual complaints and subjects from the general population. Furthermore, the subscales were sensitive to change within the patients treated for cervical cancer.

To get insight in the morbidity after RHL in our own population, the Gynaecologic LQ was developed since no other validated Dutch list existed. We already used the Gynaecologic LQ in a prospective study (7) in which it was concluded that women after RHL for early stage cervical carcinoma were associated with adverse effects mainly on sexual functioning. The findings were in line with the literature (2-4;33;34). It is expected that our new developed nerve-sparing modification of the RHL (35) will lead to less postoperative morbidity. The validated LQ will be used as a tool to compare the nerve-sparing RHL with the conventional RHL.

Since the Gynaecologic LQ is a Dutch self-report questionnaire, an English version would need to be tested in English speaking populations to check the reliability and validity. However, the scoring system of the Gynaecologic LQ is not very easy in use. Our suggestion would be to simplify the scoring system of the Gynaecologic LQ by using a uniform Likert scale and that a higher score on all items indicates higher endorsement of the dysfunction or problem measured. In this way the Gynaecologic LQ will be more comfortable to do measurements with.

In conclusion, the results of the current study support the reliability and psychometric validity of the Gynaecologic LQ in the assessment of sexual functioning and vaginal changes in gynaecological cancer patients. The validated Gynaecologic LQ is the first developed Dutch questionnaire which can be used to assess sexual function for women with gynaecological cancer. In an era where quality of life is considered of major importance in the evaluation of cancer treatment, instruments like these are essential tools to improve our treatment modalities for cancer patients.
References

(28) Ten Berghe JMF, Kiers HAL. Simultaneous Components Analysis in two or more populations (in Dutch). Nederlands Tijdschrift voor Psychologie 1990; 45:221-226.


Attachment

The Gynaecologic Leiden Questionnaire

Sexual activity can include masturbation or sexual contact with a partner. When thinking of sexual contact with a partner, please do not only think of sexual intercourse, but also consider other ways of making love that you or your partner experience as sexually arousing.

1. Have you been sexually active lately?
   1. Yes
   2. No

2. Do you feel sexual desire?
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always

3. Do you notice that your vagina becomes lubricated (“wet”) during sexual arousal?
   0. No sexual activity
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always

4. Are you able to reach an orgasm during masturbation?
   0. No masturbation
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always
5. Do you have sexual contact with a partner?
   1. No
   2. Approximately once a month
   3. A few times a month
   4. Approximately once a week
   5. A few times a week

The following questions ask about sexual intercourse. If you never engage in sexual intercourse, please continue with question number 10.

6. Do you reach orgasm during sexual intercourse?
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always

7. Do you experience vaginal dryness during sexual intercourse?
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always

8. Do you experience your vagina as too tight or too short during sexual intercourse?
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always

9. Is sexual intercourse painful to you?
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always
10. Do you experience numbness of your labia and/or the inner sides of your tights?
   1. Never
   2. Seldom
   3. Sometimes
   4. Often
   5. Always

11. How satisfied are you with your present sexual life?
   1. Very satisfied
   2. Satisfied
   3. Not satisfied/ not dissatisfied
   4. Dissatisfied
   5. Very dissatisfied.