

New Diagnostic Instrument for Sexual Function Assessment in Menopausal Women: Libido Scoring System

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Abstract

Objective: Libido is a subjective issue involving several aspects, including desire, pleasure, sexual life, intercourse, erection, ejaculation, orgasm, happiness, clitoral or penile sensation and others. Sexuality can be measured through patient-doctor interviews as well as through self-completing questionnaires. It is important that such questionnaires should be simple and easy for the patient to complete. The aim of the present study was to evaluate the validity and reliability of a new instrument, which involves four questions on four domains; orgasmic function, coital frequency, sexual desire and self sexual interest (masturbation).

Materials and Methods: The libido scoring system (LSS) was developed in 1997 and applied on 238 natural menopausal women by self completion of questionnaires. Conventional methods and LSS results were compared with Cronbach α and correlation coefficient in order to examine the validity and reliability. Furthermore subgroup analyses were performed for evaluating the inter and intraobserver variability of LSS (kappa statistics).

Results: The scoring system was applied on the participants with a return rate of 100%. Upon reliability analysis, the Cronbach α coefficient was found to be 0.83 and the kappa values of total scores were 0.67 and 0.77, respectively for inter and intraobserver variability analysis. The Index of Female Sexual Function (IFSF, Kaplan et al. 1999) which is the most widely used diagnostic test, was taken as the golden standard to assess sexual function and the matched total score results of LSS revealed a correlation coefficient of 0.96 ($p < 0.001$).

Discussion: Our results imply that this simple test, namely the LSS, provides a reliable measure for routine clinical practice or trial purposes. Nevertheless, validity and reliability of this instrument need to be further investigated on larger groups of women.

Keywords: sexuality, libido, score, menopause

Özet

Menopozal Kadınlarda Yeni Bir Seksüel İşlev Ölçme Skalası: Libido Skorlama Sistemi

Amaç: Cinsel istek, haz, cinsel yaşam, ilişki, ereksiyon, ejakülasyon, orgazm, mutluluk, klitoral ve penil duyarlılık ve daha birçok komponenti olan libido oldukça sübjektif bir konudur. Cinsel fonksiyon doktor-hasta sorgulamaları ile ölçülebildiği gibi hastaların kendi doldurdıkları bir soru formu ile de ölçülebilir. Ancak bu sorgulama hem anlaşılır ve basit hem de doldurulması kolay olmalıdır. Çalışmamızın amacı yeni geliştirdiğimiz ve orgazm, cinsel ilişki sıklığı, cinsel istek ve kendi kendine cinsel tatmin (masturbasyon) konularını içeren 4 sorudan oluşan sorgulama sisteminin geçerliliğini ve güvenilirliğini araştırmaktır.

Materyal ve Metot: Libido skorlama sistemi (LSS) ilk kez 1997 yılında geliştirilmiş olup, geçerlilik ve güvenilirlik testleri, doğal menopoza girmiş kadınlarda ($n=238$) kendi kendine doldurma yöntemi ile uygulanmıştır. Konvansiyonel yöntemlerle LSS sonuçları Cronbach α ve korelasyon katsayıları karşılaştırılmıştır. Gözlemciler arası ve gözlemci içi değişkenliği araştırmak için LSS altgruplar üzerinde uygulandı. (kappa istatistiği)

Sonuçlar: Sorgulamanın yapıldığı katılımcılarda formlar başarı ile uygulanmış olup (geri dönüşüm %100) güvenilirlik analizinde Cronbach α katsayısı 0.83 bulunurken gözlemciler arası ve gözlemci içi değişimin kappa değerleri sırasıyla 0.67 ve 0.77 bulunmuştur. Kadın cinsel fonksiyon değerlendirmesinde en sık kullanılan altın standart test olan "Index of Female Sexual Function" (IFSF, Kaplan et al. 1999) bizim skorlama sistemimiz ile karşılaştırıldığında korelasyon katsayısı 0.96 bulundu ($p < 0.001$).

Tartışma: Çalışmamızdan elde ettiğimiz veriler bu basit testin (LSS) klinik pratikte ve çalışmalarda kolay uygulanabilir ve güvenilir bir test olduğunu ortaya koymuştur. Bununla birlikte skorlama sisteminin daha geniş gruplarda geçerlilik ve güvenilirlik çalışmaları yapılmasına gerek vardır.

Anahtar sözcükler: cinsellik, libido, skor, menopoz

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Introduction

Quality of life (QoL) is an important concept that reflects the women’s feelings and function. The menopausal transition in women often brings along mood alterations, sleeplessness, hot flushes, and sweating, sexual dysfunction, the impact of which may be noteworthy on the QoL. The relative contribution of androgens and estrogens of female sexual function is controversial (1).

Sexual activity in women involves interest and motivation, ability to become aroused and achieve orgasm, the pleasure of the experience and subsequent personal satisfaction. All components of the female sexual experience are interdependent and thus impairment of any specific aspect may affect others. Sexual problems experienced by women include; low interest or motivation to engage in sexual activity (Libido), diminished capacity for vaginal lubrication and arousal, difficulty achieving/or absent orgasm, and/or painful intercourse (2).

Low libido, decreased wellbeing, blunted motivation and fatigue are listed as major features of the proposed syndrome of female androgen deficiency. However, defining and elucidating this issue has been problematic. First, the symptoms are vague and difficult to operationalize, and all can occur in other conditions, such as major depressive disorder. In addition, there is no consensus on the definition of low sexual interest (libido) levels. This lack reflects difficulties with assays and insufficient studies establishing the normal ranges of libido levels in different life phases. Thus, no cut-off level for a normal range of libido has been agreed on. What is known from the studies of libido assessment in women of different ages and at different endocrine phases of life is that pronounced age-related and partner-related changes exist in this issue (3).

The Princeton Consensus Conference in 2002 defined female androgen deficiency as consisting of a pattern of clinical symptoms in the presence of decreased bioavailable testosterone and normal estrogen status. Besides decreased libido, changes in sexual function include decreased sexual receptivity and pleasure. As in men, decreased androgens may cause a

diminished sense of well-being and unexplained fatigue and loss of energy. Vasomotor instability and decreased lubrication can occur even if the patient is adequately estrogenized. Decreased muscle strength and bone loss may also occur (4).

Libido is a subjective issue in men and women involving several aspects, including desire, pleasure, sexual life, intercourse, erection, ejaculation, orgasm, happiness clitoral or penile sensation and others. Sexuality can be measured through patient-doctor interviews as well as through self-completing questionnaires. It is important that such questionnaires should be simple and easy for the patient to complete (5).

In contrast to the burgeoning data on men, clinical trials on sexual dysfunctions in women are few despite of the fact that sexual dysfunctions are likely more common in women than in men. Currently there are no medications approved for treatment in women, and there are limited data on drug efficacy or psychological efficacy in well-controlled studies (6).

In the present study, we evaluated the validity and reliability of a new instrument, which involves four questions on four domains; orgasmic function, coital frequency, sexual desire and self sexual interest (masturbation). The purpose of this study was to investigate: (a) the observer’s (inter and intra) agreement, (b) the comparison with a golden standard instrument and (c) the diagnostic efficacy in detecting women with low libido, when untrained residents assess the sexual function of postmenopausal women.

Materials and Methods

The libido scoring system (Table 1) was developed in 1997 in Turkish language and till now applied on natural menopausal women (n =238) by self completing questionnaires to examine the validity and reliability. A hundred of them were concomitantly questioned by another diagnostic tool accepted to be the gold standard to evaluate the diagnostic accuracy of this newly developed test. To assess the inter-and intraobserver variability LSS was applied on 49 and 55 of the subjects respectively. The flow-chart of the study is demonstrated in Figure 1.

| Item/Score | 0 | 1 | 2 | 3 |
|--------------------------------|----------------|----------------|------------------------|------------------------|
| Sex Frequency | None | ≤ once a week | Twice a week | > twice a week |
| Masturbation | Does not | | | Does |
| Who starts the sexual activity | Always partner | Mostly partner | Mostly herself/himself | Always herself/himself |
| Orgasm | Never | Sometimes | Frequently | Always |
| Total Scoring | | | | |
| 0-2 scores: Loss of libido | | | | |
| 3-4 scores: Low libido | | | | |
| 5-7 scores: Good Libido | | | | |
| 8-12 scores: High Libido | | | | |

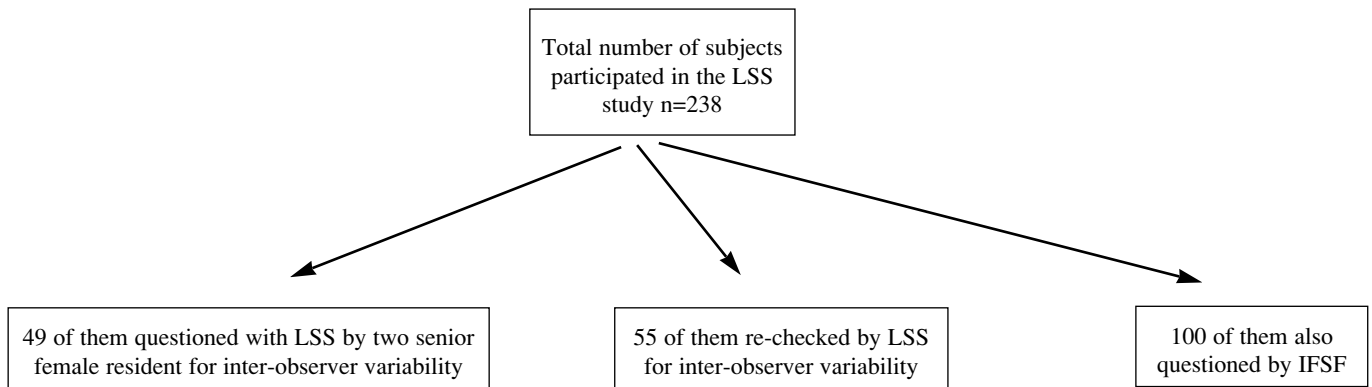


Figure 1. Flow chart of subjects participated in the study.

This new test (LSS) can be measured through patient-doctor interviews as well as through self-completing questionnaires which involves four questions on four domains; orgasmic function, sexual action frequency, and self sexual interest (masturbation). People were requested to ask themselves for questions to fill-out the self completed questionnaire; Each question has to be answered by choosing the most appropriate answer item.

1. What is your sexual action frequency? (Sexual action means: to do intercourse with your partner or masturbation by yourself)
2. Do you do masturbation? (self sexual satisfaction by stimulating yourself)
3. If you have a partner, who starts the sexual activity? (Who asks for or implies to do for the first)
4. Do you reach orgasm by yourself and/or with your partner?

To compare this new diagnostic instrument with the most widely used diagnostic tool; Index of Female Sexual Function (7), 100 of the participants are asked to complete both questionnaires after year 2000. The forward/backward method was employed to ensure conceptual equivalence of IFSF score for Turkish version. This reference score was translated from English to Turkish by two independent professional translators who were native Turkish language speakers. A backward translation (from Turkish to English) was performed by a professional translator, English native speaker and bilingual

in the target language. The time period to complete those tests and each item results and total scores were recorded.

Because the most widely used questionnaire (IFSF) is not a head-to-head instrument for matched comparison of LSS, the appropriate questions have been chosen to compare the results according to their ability of sexual assessment performance. Four questions of IFSF have been used for matched comparisons. Question number 3 matched for frequency of sexual activity, question number 4 matched for initiator of sexual activity and question number 8 is for orgasm and question number 9 is for masturbation. In the IFSF, answers pointed out on 5 or 6 domains and matched with LSS domains are summarized in Table 2.

The return rate was 100%, because the procedure was performed in the menopause polyclinic in a routine fashion. The demographic characteristics of the subjects are shown in Table 3. Subjects were postmenopausal according to their serum

| Table 3. Demographic characteristics of participants (n=238) | |
|--|----------|
| | Mean±SD |
| Age (years) | 52.4±4.6 |
| Age at menopause (years) | 49.1±3.1 |
| Time since last menstrual period (years) | 3.3±2.4 |
| BMI (kg/m ²) | 26.2±5.3 |

| Table 2. IFSF question numbers and matched answers in LSS | | | | |
|---|--------------|--------------------------|-------------------------------|-----------|
| IFSF Quest#3 | IFSF Quest#4 | IFSF Quest#8 | IFSF Quest#9 | LSS match |
| 0 | | Almost never/never | Very low/none at all Low | 0 |
| 1-2 3-4 | | A few times Sometimes | | 1 |
| 5-6 | | Most times | | 2 |
| 7-10 11+ | | Almost always/always | Moderate High Very high | 3 |

gonadotrophins (FSH or LH > 20 IU/mL), estrogen levels (E2 < 50 pg/mL) and the period since last menstrual period (> 6 months). Exclusion criteria were; known systemic disease, diabetes, thyroid dysfunction, known psychiatric disorder, systemic medication which may affect mood or libido. Each subject was learnt to reach menopause spontaneously and they were all married with an husband (monopartner sexual relationship established according to patient’s testimony).

Two weeks on the average from the first test, without any medication, 59 of the participants (59/238) were invited to the polyclinic again to self-complete LSS to analyze the intraobserver variability. In the last statistical analyses the results were calculated by using mean value of intra-observer variability scores.

Doctor-patient interview type application was used to evaluate the inter-observer variability. For this purpose, a subgroup of postmenopausal patients (n=45/238) were questioned by two female, senior resident doctor, to establish the inter-observer variability. In the last statistical analyses the results were calculated by using mean value of inter-observer variability scores.

For statistical analysis all data were recorded on SPSS version 11.5 and evaluated. The mean and standard deviation at each time-point were calculated for all parameters. For internal consistency of LSS, cronbach alpha were used. Kappa values were calculated for inter and intra observer variability and IFSS score results were compared with LSS via Pearson correlation coefficient. Probability at the level of 0.05 was accepted to be the statistical level of significance.

Results

Unanswered question rate was 2.3% for IFSF and 1.3% for LSS and the time required for the completion of each tests were 10.7±5.6 and 4.6±3.4 minutes, respectively (p<0.05). The distribution of the item results are revealed in Figures 2-7 and Table 4.

| Table 4. Mean and standard deviation (SD) distributions of each item results in LSS* | | |
|--|--------|--------|
| | Mean | SD |
| 1. FREQ | 1.6555 | 0.8611 |
| 2. MAST | 0.6176 | 1.2156 |
| 3. INITIAL | 0.6891 | 0.7603 |
| 4. ORGASM | 1.2899 | 1.1746 |
| 5. TOTAL | 4.2521 | 3.3381 |

*Heads in first line translated from Table 1.

In the correlation matrix (Table 5) the highest correlation was found between orgasm and initiation of sexual activity items (r=0.82) which is proceeded by orgasm and masturbation items (r=0.7). Inter-item correlations mean was 0.57. Interclass

| Table 5. Correlation matrix of items in LSS | | | | |
|---|--------|--------|---------|--------|
| | FREQ | MAST | INITIAL | ORGASM |
| FREQ | 1.0000 | | | |
| MAST | 0.3614 | 1.0000 | | |
| INITIAL | 0.3964 | 0.6196 | 1.0000 | |
| ORGASM | 0.5247 | 0.7074 | 0.8195 | 1.0000 |

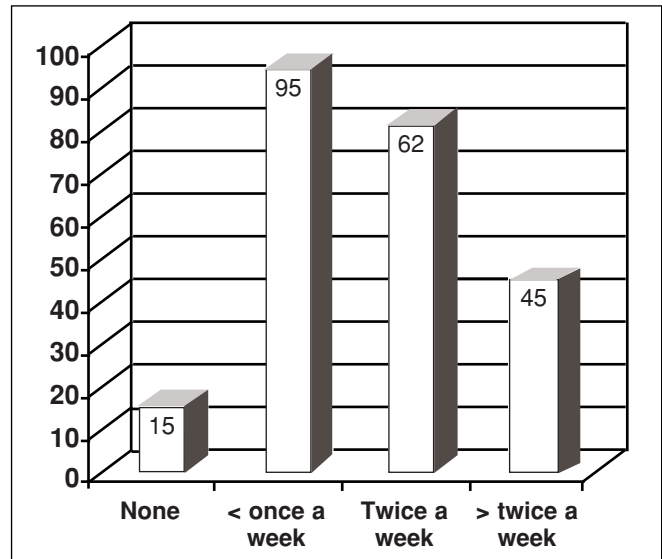


Figure 2. Sex frequency distribution of 238 postmenopausal women.

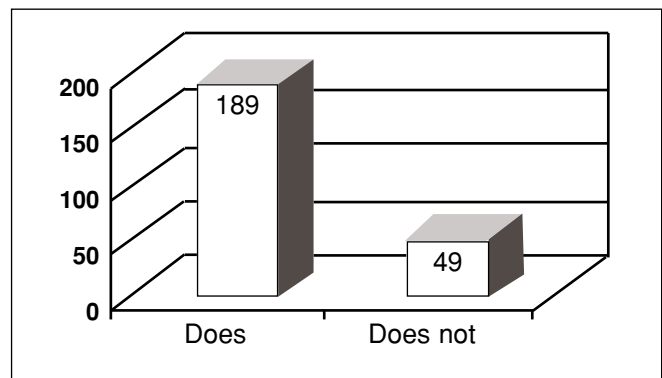


Figure 3. Masturbation distribution of 238 postmenopausal women.

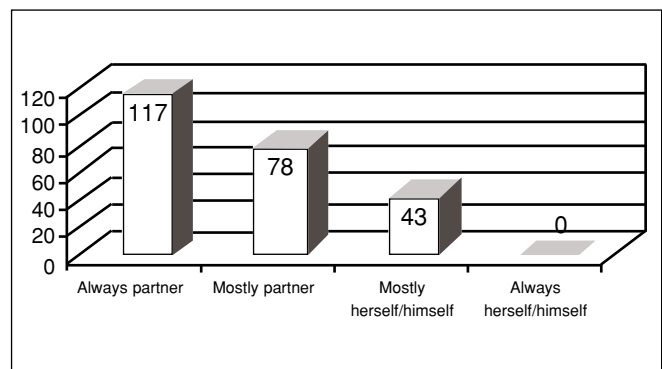


Figure 4. "Who starts the sexual activity" distribution of 238 postmenopausal women.

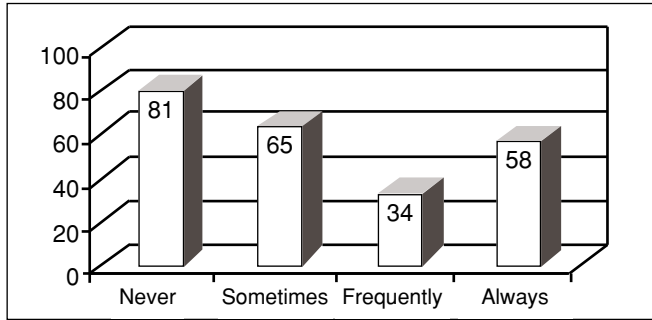


Figure 5. Orgasm distribution of 238 postmenopausal women.

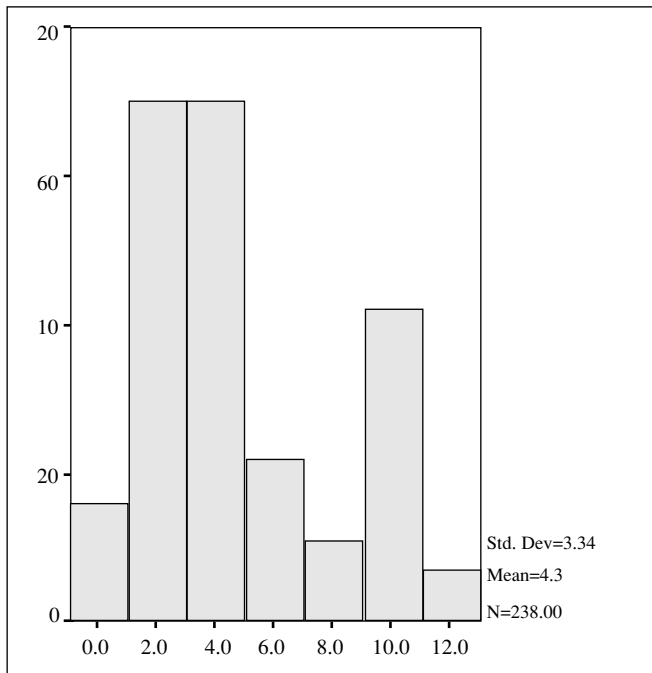


Figure 6. Total score distribution of subjects.

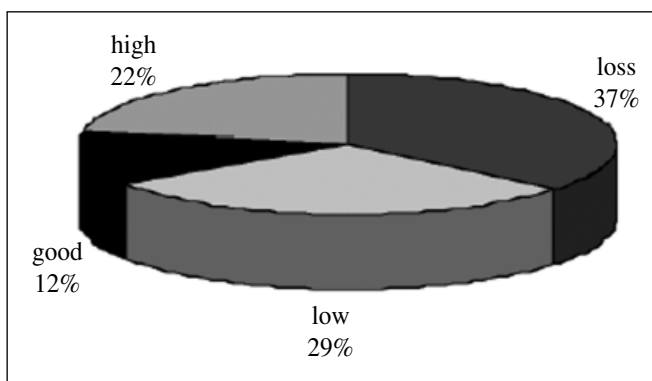


Figure 7. Libido level distribution of patients according to LSS.

correlation coefficient (ICC) in two-way mixed effects model (consistency definition) was evaluated and single rater ICC value was 0.55 (95% CI 0.49-0.61 $p<0.001$) and average of raters coefficient was 0.83 (95% CI 0.79-0.76). Cronbach α coefficient was 0.83.

Intraobserver (n=49) variability of frequency, masturbation, initiation of sexual activity, orgasm and total scores' kappa values were found to be $\kappa=0.755$, $\kappa=1$, $\kappa=0.827$, $\kappa=0.748$ and $\kappa=0.673$, respectively ($p<0.001$). Intraobserver (n=55) variability of frequency, masturbation, initiation of sexual activity, orgasm and total scores' kappa values were found to be $\kappa=0.782$, $\kappa=1$, $\kappa=0.97$, $\kappa=0.949$ and $\kappa=0.769$, respectively ($p<0.001$). IFSF and LSS matched agreement (n=100) of frequency, masturbation, initiation of sexual activity, orgasm and total scores' kappa values were found to be $\kappa=0.758$, $\kappa=0.852$, $\kappa=0.676$, $\kappa=0.944$ and $\kappa=0.553$, respectively ($p<0.001$). Correlation between total scores of matched diagnostic instruments (IFSF and LSS) was evaluated and Pearson correlation coefficient revealed $r=0.961$, $p<0.001$.

Discussion

The need for an easy and reliable sexual function assessment test was emphasized in the review of the literature. Sex therapy centers always use detailed analyses of couples to establish the source of problem. For research purposes, some drugs may alter the libido in either direction, or some phases of lifetime; menopausal status, after prostatectomy or hysterectomy operations, researchers uses an instrument to measure the sexual function properly. One should keep in mind that, questionnaires have to be applicable to the target population according to their cultural, educational, ethnic and religious structure (8,9).

Schover and LoPiccolo analyzed to determine the prevalence of desire phase sexual dysfunctions and the effectiveness of treating them with behavioral sex therapy. When cases were rediagnosed with a multi-axial problem-oriented system, increases in both the prevalence of desire phase problems and of male low sexual desire were observed from 1974-1981. Their data suggested that wives display more extreme patterns of sexual avoidance than do husbands in couples seeking sex therapy. Outcome statistics on marital adjustment, overall sexual satisfaction, the frequency of intercourse and masturbation, and patterns of initiation of sexual activity reveal significant positive changes after treatment. These changes are not due to nonspecific factors and are maintained at follow-up. Sex therapy was equally successful for male-centered vs. female-centered problems, for low sexual desire vs. aversion to sex, and for global or lifelong dysfunctions vs. the more recent or situational ones. Post treatment gains reflect a minimally adequate sexual relationship, however, rather than an optimal degree of intimacy and pleasure (10).

Vestergaard et al. evaluated 1006 early postmenopausal women aged 45-58 years, randomized to Hormonal replacement therapy (HRT) (n=502) or no HRT (n=504) in an open label trial. In this study, 5th year results with modified Greene scale, libido (0.48 ± 0.05 vs. 0.59 ± 0.05 , $P=0.08$) was not changed between groups (11).

Circulating testosterone in women declines during the late reproductive years such that otherwise healthy women in

their 40s have approximately half the testosterone level as women in their 20s. Despite this, research showing the benefits of androgen replacement has been limited to the postmenopausal years. In view of the known premenopausal physiological decline in testosterone, Goldstat et al. have evaluated the efficacy of transdermal testosterone therapy on mood, well-being, and sexual function in eugonadal, premenopausal women presenting with low libido. Testosterone therapy resulted in statistically significant improvements in the Sabbatsberg Sexual Self-Rating Scale [+15.7 (95% CI, +6.5 to +25.0), $P = 0.001$] compared with placebo (12).

It is confusing and rather heterogeneous in the literature to find different instruments and different cut-off levels in the application of libido assessment. It may hasten the interpretation of the results and yield difficulties to perform head to head comparisons. Some of the scales have only one item to ask the libido level which may open to discussion and some have more than 50 questions to assess the sexual function.

Since 1952 the Kupperman index has served as an indicator for climacteric symptoms. This index, original at that time, has been widely criticized in recent years. After worldwide criticism it was finally reduced to two true symptoms, namely hot flushes and genital atrophy. The so-called psychosomatic symptoms which are essential for the quality of life, insomnia, nervousness and depression, were largely disregarded. In 1994, an expert group of German, Austrian and Swiss members published a new score (Menopause Rating Scale) selectively adopting most of the symptoms of the Kupperman index and adding the missing symptoms such as alteration of libido, urological complaints and vaginal dryness. In contrast to the Kupperman index, the Menopause Rating Scale presented here registers every single symptom individually in a numerical and graphic way without any multiplication factor. Thus, an individual profile of each patient can be established. This new score may be completed by the physician or by the patient. An improvement in therapy can be rapidly recognized by means of the score as well as by the graphic presentation (13).

In this research, the shorter version of sexual function assessment questionnaire has been validated in a Turkish population of menopausal women, with results sustaining the use of LSS to investigate QoL in Turkish postmenopausal women population. In this study the item-scale correlations used to evaluate item-internal consistency, exceeded the minimum accepted value of 0,30 for all items. The item discriminant validity was measured by the scaling success rate that is the percentage of times item correlated scale score in the instrument. In particular for LSS questions, the correlation between an item and its hypothesized scale always exceeded correlations with other scales. Also the reliability of scale scores was excellent. Cronbach alpha coefficient was 0.83 [for group comparisons, a minimum value of 0.5 (12,13) to 0.7 (14) is generally recommended].

The perception of QoL is significantly modified during peri/postmenopausal period (15,16) Hormone replacement therapy can be used to reverse or improve climacteric symptoms, and to maintain the physical and psychological functioning of the postmenopausal women (17-21).

These results imply that this simple test provides a reliable measure for routine clinical practice or trial purposes. Nevertheless, validity and reliability of the instrument need to be further investigated.

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