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## Decision-making for the treatment of climacteric symptoms using the Menopause Rating Scale

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#### ABSTRACT

*Objective:* The Menopause Rating Scale (MRS) is one of the most frequently used instruments to evaluate menopausal symptoms; however, no cut-off score is given that would indicate the need for treatment. Our goal was to determine such a cut-off score on the MRS, using as a standard a woman's own perception of her need for treatment in relation to the severity of her symptoms.

*Material and methods*: The sample comprised 427 healthy women aged 40–59 years who were not taking hormonal treatment. Based on the concept of quality of life, we considered that the patient required treatment if she herself believed that she required it, on the basis of the severity of at least one of her menopausal symptoms. To obtain an optimal MRS cut-off score associated with the need for treatment, an ROC curve analysis was performed.

*Results*: The symptoms rated "very severe" on the MRS (i.e. that most require treatment) were physical and mental exhaustion (95.8% of women) and muscle and joint discomfort (95.1%). In total, 378 women (88.5%) considered that their symptoms required treatment. The ROC curve analysis determined that the optimal cut-off score on the MRS to indicate the need for treatment would be 14 (area under the curve 0.86, p < 0.0001). This score achieved 76.5% sensitivity and 83.6% specificity. With this cut-off score, 97.1% of the women who considered that they required treatment for at least one of their symptoms would be treated. There was concordance of more than 90% between this cut-off score and a score of 4 (i.e. a rating of "very severe") for any of the symptoms on the scale.

*Conclusions:* An MRS score  $\geq 14$  indicates the need for treatment for climacteric symptoms. In clinical practice, a score of 4 for any of the MRS items could be taken to indicate the need for treatment.

#### 1. Introduction

The 2017 Position Statement of the North American Menopause Society (NAMS) considers that menopausal hormonal therapy (MHT) is "the most effective treatment for vasomotor symptoms (VMS) and the genito-urinary syndrome (GSM) of menopause" [1]. The intensity of climacteric symptoms varies in different women, from light disturbances not requiring treatment to severe symptoms which greatly reduce quality of life. The Position Statement of the NAMS does not state when it is desirable to initiate MHT; while it does say that "bothersome VMS" can be taken to indicate the need for treatment, it does not go on to define "bothersome".

The "Revised Global Consensus Statement on Menopausal Hormone

Therapy" produced by the International Menopause Society states that "the option of MHT is an individual decision in terms of quality of life and health priorities as well as personal risk factors such as age, time since menopause and the risk of VTE, stroke, ischemic heart disease and breast cancer. MHT should not be recommended without a clear indication for its use" [2]. However, it does not define the meaning of "a clear indication for its use".

The US Food and Drug Administration (FDA) defines health-related quality of life as "the patients' evaluation of the impact of a health condition and its treatment on daily life" [3]. Similarly, the UK National Institute for Health and Care Excellence (NICE), in a Clinical Guideline, defines a complaint as severe when it 'interferes with a womańs physical, emotional, social and material quality of life' [4]. Thus,

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considering the concept of quality of life, the decision to prescribe MHT should take account of the perception of the patient regarding the severity of her climacteric symptoms. That is, it is the patient who should decide whether treatment is needed.

Different instruments have been designed for the recognition and measurement of the impact of climacteric symptoms on quality of life. The Menopause Rating Scale (MRS) is an instrument with known psychometric properties, that has been validated in several languages and that is the most extensively used around the world to evaluate the severity of symptoms associated with menopause [5]. However, although this instrument is used worldwide, some caution is warranted in interpreting scores, since the prevalence of climacteric symptoms can differ across countries because of genetic, sociocultural and lifestyle factors [6]. While a total score of 17 or more on the MRS is stated to indicate "severe symptomatology", no cut-off score is given that could be taken as an objective indication of the need for treatment. It would be ideal to determine such a cut-off score for this instrument.

The goal of our study was to find a cut-off score on the Menopause Rating Scale which would allow us to make a better decision regarding the need to start treatment, using as a standard the woman's own perception of the severity of her symptoms.

#### 2. Subjects and methods

#### 2.1. Participants

A group of 500 women aged 40–59 years, with self-reported normal health, defined as their capacity to perform all their routine activities [7], were asked to complete the MRS. All the participants were companions of patients attending the Diagnostic Center, Hospital Barros Luco, Santiago de Chile.

We used the statistics program Epi Info 7.2 to calculate the sample size, with an expected frequency of severe climacteric symptoms of 40% [8], with a total population of 150,000 women aged 40–59 years [9] and an acceptable maximum error of 5% and with 95% confidence. With these parameters we concluded that the minimum sample size was 369 women. Five hundred women were surveyed, in case it was necessary to eliminate some cases due to incomplete data and also to perform subgroup analyses. The principal inclusion criterion was adequate health to perform routine activities and the principal exclusion criteria were mental deficiency that prevented a woman from understanding the questionnaire, and the use of oral contraceptives or MHT.

#### 2.2. Instrument

The validated Spanish version of the MRS was used [10]. It is a questionnaire composed of 11 items (symptoms), divided into three domains:

- Somatic hot flushes, excessive perspiration; heart discomfort; sleep problems; muscle and joint discomfort (items 1–3 and 11, respectively)
- Psychological depressive mood; irritability; anxiety; physical and mental exhaustion (items 4–7, respectively)
- Urogenital sexual problems; bladder problems; vaginal dryness (items 8–10, respectively).

For each item, the women assigns a score of 0–4 for the intensity of the symptom (0, absent; 1, mild; 2, moderate; 3, severe; 4, very severe). The score on a particular domain corresponds to the sum of the values obtained for each item of the subscale. The total MRS score is the sum of the scores obtained in each domain. Based on the concept of quality of life, which includes the woman's perception of the severity of the symptomatology, to evaluate the need to prescribe MHT, we additionally asked with every MRS question: "Do you believe that the severity of this particular symptom requires treatment?" We considered

that the patient required treatment if she answered yes in relation to any of the 11 items of the MRS.

#### 2.3. Statistical analysis

Data analysis was performed using the IMB SPSS 21 statistical package. Results are presented as means  $\pm$  standard deviations, percentages and odds ratios (with 95% confidence intervals, CI). To obtain the optimal MRS cut-off score to indicate the need for treatment, receiver operator characteristic (ROC) curve analysis was performed (SPSS 21). The optimal cut-off score was determined by plotting for each score the true-positive rate (sensitivity) against the false-positive rate (1-specificity), and ascertaining when the maximum accuracy (sensitivity plus specificity) was achieved. In addition, cut-off values were assessed based on the maximum values of the Youden Index (calculated as sensitivity + specificity-1) and the minimum values of the square root of [(1 – sensitivity)2 + (1 – specificity)2], which indicates the minimum distance from the upper-left corner to the value on the ROC curve [11,12].

#### 2.4. Ethics

This study was approved by the Comité de Ética del Servicio de Salud Metropolitano Sur, Santiago, Chile, according to the Helsinki Declaration [13]. All participants gave informed consent for the use of their data to perform clinical studies, maintaining confidentiality.

#### 3. Results

Of the 518 women invited to participate in this study, 500 (96.5%) agreed to do so. We eliminated a further 48 women because they used oral contraceptives and 25 because they used MHT. As shown in Table 1, the mean age of the remaining sample of 427 women was  $50.5 \pm 5.4$  years; most of them had a low level of education; 84.3% attended public health services; 68.9% had a stable partner; 63.7% were postmenopausal; 17.6% used psychotropic drugs; and 18.7% had a previous psychiatric consultation.

In Table 2 shows the ratings for the different climacteric symptoms included on the MRS. The symptoms most commonly rated "very severe" (i.e. a score of 4 on the MRS) were muscle and joint discomfort (42.9% of all women), followed by physical and mental exhaustion (33.7%), depressive mood (33.3%) and sleep problems (31.1%).

#### Table 1

Characteristics of the women in the study (n: 427).

Variable	Means $\pm$ SD or Number of women (percentage; IC 95%)
Age (years)	50.5 ± 5.4
Total time in education (years)	$11.0 \pm 3.3$
Attending public health services	360 (84.3; 80.8–87.6)
With a stable partner (%)	294 (68.9; 64.6–73.1)
With sexual activity (%)	296 (69.3; 64.9–73.5)
Premenopausal (%)	60 (14.1; 10.8–17.3)
Perimenopausal (%)	95 (22.2; 18.5–26.5)
Postmenopausal (%)	272 (63.7; 59.3–68.1)
Hysterectomy (%)	63 (14.8; 11.5–18.3)
Bilateral oophorectomy (%)	22 (5.2; 3.0–7.3)
Use of psychotropic drugs (%)	75 (17.6; 14.3–21.1)
Previous psychiatric consultation (%)	80 (18.7; 15.2–22.5)

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