

ESTE ES EL MANUSCRITO FINAL, DESPUES DE LAS REVISIONES, QUE FUE REMITIDO A LA REVISTA Y ACEPTADO PARA SU PUBLICACIÓN

The impact of menopausal symptomatology, sociodemographic status and knowledge of menopause on women's quality of life

Background: A high percentage of menopausal and perimenopausal women suffer symptoms that deteriorate their quality of life (QoL) significantly. Many studies have focused on the relationship between menopausal symptoms and QoL, yet the results obtained have been inconclusive. The aim of this study is to evaluate the impact of the symptoms of menopause, sociodemographic variables and knowledge of menopause on women's QoL.

Method: Sociodemographic and clinical data was collected from interviews of 453 women in Madrid, and they also completed questionnaires related to menopausal symptomatology (MRS, MENQOL), knowledge of menopause and QoL.

Results: Although dependent on the assessment techniques, all the tools used indicated that more than half of the women studied suffered menopausal symptomatology: interview (59.1%), MENQOL (69.2%) and MRS (65.1%). Stronger symptoms were related to a worse QoL, being psychosocial/psychological and urogenital/sexual symptomatology, and educational level and knowledge about menopause the most strongly related to this parameter ($R^2= 0.287$ for MENQOL; $R^2= 0.390$ for MRS). Taking into account the main menopausal symptoms in Europe, psychosocial and sexual symptoms are also found to be strongly related to QoL.

Conclusion: Menopausal symptomatology is frequent and intense, deteriorating women's QoL. While psychosocial and somatic/physical symptoms are the most frequent and intense, psychosocial/psychological and urogenital/sexual are those that

best predict the individual's QoL. Educational level and knowledge about menopause are also related to a better QoL.

Key words: menopause; climacteric symptomatology; quality of life; psychosocial variables.

Introduction

Natural Menopause is defined by the World Health Organization (WHO) as the “permanent cessation of menstruation resulting from the loss of ovarian follicular activity”¹. Important and significant effort has been done to define and clarify the terminology used during the menopause period. In that way, the World Health Organization (WHO) and the International Menopause Society (IMS) suggested to avoid the use of climacteric to define the whole stage of menopausal period and limit it only to the stage, which marks the transition between the reproductive stage to the non-reproductive one². While they are not the same, the term *menopausal symptomatology* is often used to indicate *climacteric symptomatology*, and the instruments used to assess the latter often include the term menopause (not climacteric) in their names. However, in the same line, The Stages of Reproductive Aging Workshop (STRAW) propose several stages independent of ages; these stages vary in length and they are different between each other due to menstrual cycle changes. In this article, *menopause* and *menopause symptomatology* will refer to the period between the stages -3a, -3b, -2, -1, 1a, 1b, 1c and 2. This period comprises the stages from the late reproductive stage (Stage-3a), when menstrual cycles remain regular, follicle counts are low and only subtle changes can show up due to antimüllerian hormone (AMH), to late post menopause stage (Stage +2)³.

Women around the world suffer from symptoms during the menopausal period regardless of ethnic origin, race or socio-demographic factors^{4,5} as it is interpreted and experienced distinctly in different cultures and context^{6,7}. Although it was considered a disease in the 1990’s by medical instances and pharmacologically treated with estrogen therapy⁸, nowadays menopause is regarded worldwide as a natural process in women’s lives, according to Menopause Societies. However, in certain societies and cultures where women are motivated to remain youthful and attractive, menopause represents the symbol of aging and loss of beauty. The beginning of certain symptoms related to

these stages is likely to not only affect their quality of life (QoL), but also the differential construction of their own identity as women^{3,9,10}.

Menopausal symptoms can be very challenging to treat, with at least 30% of menopausal women suffering from symptoms that are frequent and bothersome^{10,11,12,13,14,15}. Previous studies in Spain showed that symptoms of menopause can vary widely, yet hot flashes and psychological reactions are very frequent^{3,16,17,18}. Hence, an individual's QoL during this period is a great concern, for themselves, for healthcare services and for society as a whole^{19,18}.

The interest in studying the impact of the climacteric period on QoL has increased in the last two decades^{20,21,22,23,24} and while there has been significant effort to create accurate questionnaires to measure the QoL of menopausal women^{25,26}, there is still little data available from Spain. Educational level, socioeconomic status, working status and family support are all thought to influence the experience of menopause and climacteric^{27,28}. However, the data available are not consistent and while some studies reveal a strong relationship²⁹, others do not^{30,31}. In Spain, few studies have addressed the relationship between menopausal symptomatology and QoL^{32,33}. Although knowledge of menopause has been related to a better perception on it and a better QoL³⁴, studies in Spain do not consider it. Thus, the aim of this study was to assess the relationships among menopausal symptomatology, sociodemographic conditions, knowledge of menopause and QoL.

Methods

Sampling and procedure

A cross-sectional study was carried out by collecting data from 500 women. As there are 66.4585 women in Madrid aged 45 to 60³⁵, we estimated a sample of 384 women would achieve a 95% confidence level with an acceptable error of 5%. However, we decided to extend the sample to 500 participants, thereby reducing the margin of error to 4.38%. Of these, 9.4% were not Spanish speakers and they were therefore excluded from the final sample (N=453). The study was carried out on 45–60 year old women, excluding women with premature menopause (younger than 40 years of age), those with medically or surgically induced menopause, and women who used hormone replacement therapy.

The sample was recruited by 41 trained Psychology students over the course of one year in three different areas of the Autonomic Community of Madrid (45.6% coming from the metropolitan area, which corresponds to the distribution of the population in this region) by incidental sampling. An incidental sampling researcher determined which individuals deliberately formed part of the sample, pick the cases considered to be typically representative of the population. Trained Psychology students recruited women among their acquaintances (mothers, aunt, friends, neighbour...).

For the recruitment process and application of the instruments, the authors trained a group of Psychology students from Universidad Complutense de Madrid. They observed and responded in person to questions while the research participants filled out the questionnaire. The assessment protocol took 20 to 25 minutes to complete.

The study meets the requirements of Declaration of Helsinki. All participants were volunteers and informed the research participants about the aim of the study, the anonymity of the data and the possibility of leaving the study whenever they wanted. All

women signed an informed consent. Participants' confidentiality was guaranteed by omitting personal information. Approval was obtained from the Research Ethic Committee of the Faculty of Psychology (Universidad Complutense de Madrid).

Sociodemographic and clinical information was collected in a sociodemographic and clinical *ad hoc* questionnaire that had been previously tested in a pilot study on 20 women for suitability and clarity. The participants gave their marital, employment, socioeconomic and educational status, following Spanish criteria³⁵. The socioeconomic status was classified in 6 levels: High (>50.000€), medium-high (44.001-50.000), medium (36.001-44.000€), medium-low (28.001-36.000€), low (20.001-28.000€) and very low (\leq 20.000€).

After that, the female participants filled out the remaining questionnaires under supervision and with the help of one of the trained Psychology students.

Measures

The MENQOL (Menopause Quality of Life Scale)²⁶ and MRS (Menopause Rating Scale)²⁵ were used to gather general information about menopausal symptomatology.

Relationships exist between these two scales and in particular: the physical and vasomotor domain of MENQOL is related to the somatic domain of the MRS; the psychosocial domain in MENQOL is related to the psychological domain in MRS; and the sexual domain of MENQOL is related to the urogenital domain in the MRS. We use both in order to get a broader piece of information and to verify if they can predict QoL equally. We used the versions of these questionnaires adapted and validated for the Spanish population.

*Menopause Quality of Life Questionnaire (MENQOL)*²⁶. This questionnaire consists of a total of 29 items evaluated using a Likert-scale. Each item assesses the impact of one of four domains experienced over the last month: vasomotor ($\alpha = 0.826$), psychosocial ($\alpha = 0.814$), physical ($\alpha = 0.872$) and sexual ($\alpha = 0.671$). The items are rated as present or not (scored 1 or 0) and if present, the intensity is evaluated on a scale of 1 (mild, scored 2) to 6 (extremely intense, scored 8). The total score for each subscale is the mean of their items and the total score is the sum of the subscales. Thus, the higher the score, the more severe the symptoms. In this study the internal consistency coefficient was $\alpha = 0.91$. As no cut-off point was defined for the Spanish population, in this study, we established the mean for each subscale, which was calculated and codified as follows: 0 (no symptoms), 1-3 (low intensity), 4-5 (middle intensity) and >5 (high intensity).

*Menopause Rating Scale (MRS)*²⁵. This scale is comprised of 11 items divided into three subscales: somatic ($\alpha = 0.61$), psychological ($\alpha = 0.86$), and urogenital ($\alpha = 0.67$). The total $\alpha = 0.85$. In this study the internal consistency coefficient was $\alpha = 0.86$. Each item is graded by the subjects from 0 (not present) to 4 (very severe) and the score of each subscale is the sum of the scores of its items. The total score is the sum of the three subscales. Thus, the higher the score, the more severe the symptoms. No cut-off point for these scales has been defined for Spanish populations, so, in this study, we established the mean for each subscale, which was calculated and codified: 0 (no symptoms), <2 (low intensity), 2-3 (middle intensity) and >3 (high intensity).

To study QoL, the *Quality of Life for women aged from 45 to 64 Scale (QoLW)*³⁶, a general questionnaire of QoL in menopause was employed. The QoLW contains 22 items assessed using a Likert scale of 1 to 5, which collect information about: physical symptoms; anxiety and depression; sexuality; and social and family support (five subscales). The questionnaire provides an overall QoL score as the sum of all the

subscales. A higher score indicates a poorer QoL. The QoLW also provides information about the individual's knowledge of menopause (QoLW0), whereby 1= well informed and 5= poorly informed, so a higher score indicates a worse knowledge. This scale was used in prior publications (Larroy, Marín, Gutierrez, 2015)³⁷ and albeit the psychometric analyses carried out, the scale remains unpublished. In our study, internal consistency was adequate (α' = 0.89).

The data was analyzed using IBM/SPSS v. 22.0, and the results are expressed as frequencies and percentages for qualitative variables, and also as measures of central tendency and dispersion (mean and standard deviation) for quantitative variables. We also used a multiple lineal regression model, in which we adjusted for the sociodemographic and clinical variables, which showed statistical significance in the univariate analysis. Also, we used a multiple lineal regression model for the MRS main menopause symptoms in Europe^{38,39,40} in order to examine their relationship and their potential predictable value.

Results

The descriptive analysis of the sociodemographic data collected from all the subjects is presented in Table 1. The majority of the women were married (72.0%) and the 53.2% of the subjects had 2 children. Regarding the socio-economic status, 60.3% belong to the middle class and 44.2% stated that they had completed University studies.

When the clinical information was assessed, a descriptive analysis of the interviews revealed that 59.1% of women in the sample felt uncomfortable and suffered climacteric /menopausal changes, indicating that they had suffered symptoms for between 0 to 160 months (26.1 ± 55). Intermittent menstruation was referred by 41.2% of women and 69.7% had experienced amenorrhea for 3 months or more (31.2 ± 41.1 months; range 0–160). Moreover, 11.0% had sought medication or other aids to help relieve symptoms, of whom 43.6% use pills with isoflavone concentrate, as women under hormone therapy were excluded) and 19.8% herbs or other natural solutions, as food control (as not to eat spicy food; to include more dairy, etc.). When the questionnaires were analyzed, the percentage of women suffering symptoms that were of moderate to severe intensity was apparently even higher: MENQOL 69.2% and MRS 65.1% (see Table 2).

A multiple linear regression model was generated in order to establish the relationship between menopausal symptomatology (MENQOL and MRS subscales) and the QoLW. In addition, educational and socioeconomic level, age, and knowledge of menopause were analyzed to study if any of these variables could explain the changes in QoL. A positive relationship between the psychosocial subscales and QoL was evident in MENQOL ($\beta=0.49$, $t=8.58$, $p<0.001$; Table 3), as higher scores in the psychosocial subscale were associated with higher scores in the QoLW, indicative of a worse QoL. A similar result was observed for the sexual subscales ($\beta=0.119$, $t=2.424$, $p=0.014$). A positive relationship between knowledge of menopause and QoLW was evident

($\beta=0.129$, $t=2.993$, $p=0.003$). In this case, model 1 of the regression explains 28% of the QoL, with $R^2=0.287$.

In relation to the MRS subscales (see Table 3), the psychosocial scales ($\beta=0.531$, $t=11.292$, $p<0.0001$) and urogenital scale ($\beta=0.116$, $t=2.691$, $p=0.007$) were positively related to QoL. Educational level exhibits a negative relationship with QoL ($\beta=-0.083$, $t=-2.107$, $p=0.036$), with high QoLW scores revealing a worse QoL and the higher educational levels associated with a better the QoL. The knowledge of menopause was also positively related to QoL ($\beta=0.097$, $t=2.454$, $p=0.015$), this second model predicting the QoL by 39% ($R^2=0.390$).

In relation to the MRS, also main menopausal symptoms in Europe^{39,40} (hot flushes, sweating, depression, anxiety, irritability, sexual and sleep problems) were analyzed as potential predictors of QoL (see Table 4). Anxiety ($\beta=0.199$, $t=2.936$, $p=0.004$), sexual problems ($\beta=0.127$, $t=2.354$, $p=0.018$), irritability ($\beta=0.189$, $t=2.877$, $p=0.004$), depressive mood ($\beta=0.218$, $t=3.194$, $p=0.002$), were positively correlated to the QoLW scores. This relationship explained 35% of the QoL ($R^2=0.351$). Educational level exhibits a negative relationship with QoL ($\beta=-0.103$, $t=-2.057$, $p=0.041$), with high QoLW scores revealing a worse QoL and the higher educational levels associated with a better QoL. The knowledge of menopause was also negative related to QoL ($\beta=-0.124$, $t=-2.605$, $p=0.010$), this second model predicting the QoL by 37% ($R^2=0.373$). Time since menopause doesn't seem to predict QoL.

Discussion

In this study, we have evaluated the factors that influence the relationships between menopause symptoms and QoL. A high percentage of women in the menopause period (-3a-3b,-2,-1,1a,1b,1c and 2)³, suffer from psychological, physical and/or sexual symptoms. While this appeared to be the case in 59.1% of individuals in the interviews, the questionnaires reveal a higher percentage of women suffer from menopause symptomatology, reaching 69.2% of the cohort in the MENQOL scale and 65.1% in the MRS. These figures were consistent with the results of previous studies using these tools^{41,42}.

Interesting results were obtained regarding the prevalence and intensity of specific symptoms. The data from MENQOL and MRS indicated that physical/somatic and psychosocial/psychological symptoms are those most frequent and intense in our sample. Physical and somatic symptoms might be related to age, as well as to menopausal hormone changes. As humans (men and women) grow older, they suffer more fatigue, muscle pain and sleep disturbances, although hormonal change is probably not the only factor responsible for these symptoms⁴³. Hence, the results of psychological symptomatology are also likely to be relevant in this regard, as highlighted in some^{16,31} but not all studies²⁸. Such differences might reflect cultural differences or the use of different questionnaires²⁰. Indeed, we found some small differences in the prevalence of the same symptoms when assessed by MENQOL or MRS. Although both of these tools indicate that physical/somatic and psychosocial/psychological symptoms were the most intense, their prevalence varied depending on the questionnaire used.

Relationship between menopause symptoms and QoL still remain unclear. Our findings show up that in general, the stronger the symptomatology, the worse the QoL, revealed in QoLW, supporting other studies carried out in different countries^{28,44,45,46,47}. Women who suffer more menopausal symptoms report a worse QoL and as menopausal

symptoms augment, the QoL impairs, as witnessed using both MENQOL and MRS questionnaires. Other studies find a litter impact on QoL⁴⁸ or did not find this relationship in all the QoL domains⁴⁹. It is important to highlight that psychosocial/psychological symptomatology (sexual problems, depression, anxiety and irritability) is the most relevant factor to explain QoL. These symptoms appear to be very prevalent in the sample, albeit less than physical/somatic symptoms. Moreover, psychological symptoms explain the individual's QoL better than any other physical or urogenetical symptoms also included in the analysis. As such, health professionals (e.g., gynaecologists) should pay special attention to any psychological symptoms that women may exhibit and consider possible referral to a psychologist who can properly assess the impact of climacteric symptoms on a woman's QoL, as well as the possible appearance of a psychological disorder, or rather a simple disturbance.

This relationship between psychosocial symptomatology and QoL seems to be mediated by knowledge about menopause and the level of education. Age and time since the last menstruation were included not showing a significant influence. These results support other studies where a poor understanding and ill-informed opinions regarding menopause is related to worse QoL²⁸. It is likely that psychological symptoms might be modulated by improving an individual's understanding of the menopause, leading to a better QoL. Simple changes in everyday life can improve the menopause experience, such as relaxation or physical exercise^{17,21}. Thus, it is necessary to implement educational programs that improve women's knowledge about the climacteric and menopause, and to explain to them or show them how to cope with the symptoms. At a relatively low cost to governments and health services, these activities will result in better health and QoL for a large number of climacteric women.

Finally, we found that MRS subscales and, specifically, sexual problems, irritability, anxiety, mood problems (assessed by MRS) were more sensitive to predict QoL than

MENQOL subscales. Considering that MRS is also shorter and easier to correct, we would recommend the use of this questionnaire, especially for prevalence studies in which a large amount of women is interviewed.

As strengths of the study we can point out the fact that it was carried out on a large and representative sample of the climacteric women in the Autonomic Region of Madrid. In addition, this study utilized structured questionnaires that have been validated for Spanish populations, and these instruments were employed by professionals and students trained in their use. Finally, previous studies have not provided a large amount of data regarding the issues addressed here, and the data available has usually come from interviews and general questionnaires answered by gynaecologists. Thus, the information provided in this study is new and perhaps more accurate, given that it was obtained from climacteric women themselves.

One of the main limitations of this study is that it may not be generally applicable to a large range of nationalities due to different experiences of climacteric in different countries or cultures. Nevertheless, the data are clearly applicable to Spanish women and probably, for other western populations as well. Another limitation is that the study only collected data on natural menopause and it is likely that the related symptoms will vary in surgical or induced menopause. Moreover, the relatively high educational level among our subjects might affect to the external validity.

In summary, Spanish women live many years under a climacteric state and they may therefore suffer symptoms over a considerable proportion of their life, a mean of two years and on occasions more than ten. This is a good reason to design and implement specific programs that aim to relieve climacteric symptoms, and to improve women's QoL during this period. Psychoeducational programs would appear to be necessary, and perhaps for many women such interventions would be sufficient to improve and maintain

their QoL. Gynecologists, endocrinologists, menopause clinicians and any doctor who receives female patients in this condition, should consider the evaluation of the menopause symptomatology in order to detect symptoms that can be treated by different techniques or drugs, but may affect different spheres of their physical and psychological well-being, and exert a significant impact on their quality of life. The results of this study suggest that a good knowledge of menopause is related to a better quality of life, so providing information to the patient individually or through psychoeducational programs may significantly improve their quality of life.

Compliance with Ethical Standards

Conflict of interest: The authors declare that they have no conflict of interest..

Ethical approval: This study was approved by the Ethics Committee of the Faculty of Psychology of the Complutense University of Madrid. All the procedures involving human participants were carried out in accordance with the ethical standards of our institutional and/or national research committees, and with the 1964 Helsinki declaration and its later amendments, or comparable ethical standards.

Informed consent: Informed consent was obtained from all the individual participants prior to their enrolment on this study.

Funding No external funding was obtained to carry out this study.

Table 1. Characteristics of the sample

Table 2 Prevalence of symptomatology of the MENQOL and MRS subscales, depending on their intensity

Table 3. Multiple Lineal Regression model between MENQOL, MRS, sociodemographics and QoLW

Table 4. Multiple Lineal regression model between most prevalent MRS symptoms, sociodemographics and QoLW

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Table 1. Sociodemographic characteristics of the sample

	N	%
Marital status (N=452)		
Married	326	72.0
Lives with partner	17	3.8
Separated or divorced	48	10.6
Single	49	10.8
Widowed	12	2.6
Number of children (N=438)		
None	45	10.3
1	94	21.4
2	233	53.2
3	52	11.9

4	14	3.2
Working status (N=444)		
Unemployed	112	25.2
Civil servant	119	26.8
Employed worker	108	24.3
Self-employed	105	23.7
Socioeconomic status (N=451)		
High	20	4.5
Medium-high	74	16.4
Medium	272	60.3
Medium-low	58	12.8
Low	20	4.5
Very low	7	1.5
Education level (N= 453)		
University	200	44.2
Skill training	12	2.6
Secondary school	179	39.5
Primary school	58	12.8
None	4	0.9
Knowledge about menopause (N=446)		
Very good	82	18.3
Good	214	48.0
Medium	115	25.8
Little	30	6.8
None	5	1.1

Table 2 Prevalence of symptomatology of the MENQOL and MRS subscales, depending on their intensity

	N	Not present		Low Discomfort		Moderate Discomfort		High Discomfort	
		(%)	N	(%)	N	(%)	N	(%)	N
MENQOL									
Vasomotor	447	1.6	7	41.2	185	35.6	159	21.6	96
Psychosocial	448	0.9	4	24.7	111	51.2	230	23.2	104
Physical	449	0.7	3	23.8	107	50.8	228	24.7	111
Sexual	445	4.5	20	31.8	142	40.0	178	23.7	105

MRS									
Somatic	452	7.3	33	22.6	102	48.7	220	21.4	98
Psychosocial	451	10.9	49	25.9	117	41.7	188	21.5	97
Urogenital	451	21.6	97	17.0	77	39.6	179	21.8	98

Table 3. Multiple Lineal Regression models between MENQOL and MRS subscales, sociodemographics and QoLW

	β	t	Sig.
F = 21.681; p < 0.001 R ² = 0.287			
Model 1			
QoLW			
MENQOL. Vasomotor	-0.040	-0.853	0.394
MENQOL. Psychosocial	0.49	8.585	<0.001
MENQOL. Physic	-0.093	-1.567	0.118
MENQOL. Sexual	0.119	2.460	0.014
Educational level	-0.056	-1.283	.200
Socioeconomic	-0.070	-1.613	.108
Age	.076	1.787	.075
Knowledge menopause	.129	2.993	0.003
F = 41.774; p < 0.001 R ² = 0.39			
Model 2			
QoLW			
MRS. Somatic	0.002	0.044	0.965
MRS. Psychosocial	0.531	11.292	<0.001
MRS. Urogenital	0.116	2.691	0.007
Educational Level	-0.083	-2.107	0.036
Socioeconomic Level	-0.050	-1.287	0.199
Age	0.050	1.244	0.214
Knowledge menopause	0.097	2.454	0.015

Note: Model 1= MENQOL Vasomotor; MENQOL psychosocial; MENQOL Physic; MENQOL Sexual; Educational level, Socioeconomic, age, Knowledge of Menopause
Model 2 = MRS Somatic; MRS Psychosocial; MRS Urogenital; Educational level, Socioeconomic, age, Knowledge of Menopause.

Table 4. Multiple Linear regression models between MRS main symptoms, sociodemographics and QoLW

	β	t	Sig.
F = 25.03; p < 0.001			
R ² = 0.351			
Model 1			
QoLW			
Hot flush, sweating	0.009	0.176	0.860
Sleep problems	0.006	0.119	0.905
Depressive mood	0.218	3.194	0.002
Irritability	0.189	2.877	0.004
Anxiety	0.199	2.936	0.004
Physical and mental exhaustion	-0.006	-0.103	0.918
Sexual problems	0.127	2.354	0.018
F = 16.444; p < 0.001			
R ² = 0.373			
Model 2			
QoLW			
Hot flush, sweating	0.010	0.195	0.846
Sleep problems	0.018	0.349	0.727
Depressive mood	0.186	2.755	0.006
Irritability	0.182	2.793	0.006
Anxiety	0.212	3.167	0.002
Physical and mental exhaustion	-0.010	-0.179	0.858
Sexual problems	0.136	2.519	0.012
Educational Level	-0.103	-2.057	0.041
Socioeconomic Level	-0.018	-0.374	0.709
Age	0.041	0.791	0.430
Knowledge menopause	0.124	2.605	0.010
Time since the last menstruation	-0.030	-0.566	0.572

Note: Model 1= Hot flush, sweating, Sleep problems, Depressive mood, Irritability, Anxiety, Physical and mental exhaustion, Sexual problems; Model 2 = Model 1 + Educational level, Socioeconomic, age, Knowledge Meno., time since last menstruation