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# Stosowanie hormonalnej terapii zastępczej a jakość życia kobiet w wieku około- i pomenopauzalnym

# Hormone replacement therapy and quality of life of women in peri- and postmenopause

#### Streszczenie

**Cel.** Celem pracy było ustalenie, czy przyjmowanie przez kobiety w wieku około- i pomenopauzalnym hormonalnej terapii zastępczej aktualnie lub w przeszłości ma wpływ na obecną jakość ich życia.

Material i metody. Badanie zrealizowano metodą sondażu diagnostycznego, techniką ankiety pocztowej. Narzędzie badawcze stanowiły trzy standaryzowane kwestionariusze: Women's Health Questionnaire (WHQ), WHOQOL-BREF i SF-36. W badaniu wykorzystano również ankietę własnego autorstwa. W roku 2007 wysłano ankietę pocztową do 7875 kobiet w wieku 45-65 lat, mieszkających na terenie województwa lubelskiego. Adresy reprezentatywnej próby mieszkanek województwa lubelskiego w tym wieku otrzymano z Terenowego Banku Danych Urzędu Wojewódzkiego w Lublinie. Otrzymano 2143 listy zwrotne (zwrotność 27,2%). Uzyskane dane poddano analizie statystycznej. Domeny jakości życia ustalone kwestionariuszami WHOQOL-BREF, WHQ i SF-36 przyjęto jako zmienne zależne, natomiast dane na temat stosowania HTZ przez kobiety jako zmienne niezależne.

Wyniki. Nie dowiedziono jednoznacznie pozytywnego wpływu hormonalnej terapii zastępczej na jakość życia kobiet. Nieco lepszą jakość życia wykazano u kobiet przyjmujących HTZ w postaci tabletek doustnych niż u kobiet stosujących HTZ w innych formach. Nie dowiedziono różnic w jakości życia kobiet w zależności od czasu stosowania HTZ. Stwierdzono gorszą jakość życia u kobiet, które podały wystąpienie objawów ubocznych HTZ i u tych, które nie były zadowolone z efektów tego leczenia. Analiza regresji logistycznej wykazała, że stosowanie HTZ miało niezależny wpływ na jakość życia kobiet tylko w jednej domenie jakości życia – w domenie problemy ze snem kwestionariusza WHQ.

### **Abstract**

**Aim.** The aim of the research was to estimate if the women's quality of life depends on present or past taking HRT.

Material and methods. The survey was carried out by means of a survey method, a postal questionnaire technique. Three standardized questionnaires: the WHOQOL-BREF, the Women's Health Questionnaire (WHQ) and the SF-36 were used as research tools. A self-constructed questionnaire was also put into use. The questionnaires were sent to a representative sample of 7,875 women between 45 and 65 years old, living in the Lublin province, in 2007. The mail addresses were obtained from the Local Data Bank of the Lublin Provincial Office. We received 2,143 replies (feedback 27.2 %). The statistical analysis of the obtained data has been performed. The domains of the quality of life defined by the WHOQOL, the WHQ and the SF-36 questionnaires were treated as dependent variables whereas the data on using HRT by women were treated as independent variables.

Results. The positive impact on the quality of life of women taking HRT was not proved unambiguously. Women taking HRT in form of tablets revealed slightly better quality of life than women taking other forms of hormones. There were no statistical differences in the quality of life of women upon the duration of admitting HRT. The worse quality of life was found in women who quoted the appearance of HRT side effects and in women who were dissatisfied with the effects. The multivariate analysis showed that HRT admitting had an irrespective impact on women's quality of life only in one domain – the domain of sleep problems of the WHQ questionnaire.

**Słowa kluczowe:** jakość życia, hormonalna terapia zastępcza.

**Key words:** quality of life, hormone replacement therapy.

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# INTRODUCTION

Recent studies point out to the importance of the quality of life in people of different age groups. The quality of life in peri- and postmenopausal women constitutes a serious public health problem. This is due to current demographic trends in the Polish society of which women in peri- and postmenopausal stages constitute an increasing proportion.

# **AIM**

The aim of the study was to determine whether current or past hormone replacement therapy used by women in menopausal and postmenopausal stages could influence their current quality of life.

# MATERIAL AND METHODS

The study applied a diagnostic survey method realised by means of a mail questionnaire. Research tools included three standardized questionnaires (the Women's Health Questionnaire [WHQ], the WHOQOL-BREF and the SF-36) and the author's questionnaire. The questions concerned the current and past use of hormonal preparations to relieve menopausal complaints, therapy duration, HRT's side effects, women's positive reactions to HRT, as well as their sources of knowledge of the treatment. In 2007 the mail questionnaire was sent to 7,875 women aged 45-65, the residents of the Lublin Voivodeship. The addresses of the representative sample were obtained from the Local Database of the Voivodeship Office in Lublin. The total number of 2,143 questionnaires were answered (27.2% return rate).

The obtained data were subjected to statistical analysis. Quality of life domains measured by the WHOQOL-BREF, the WHQ and the SF-36 questionnaires were treated as dependent variables whereas the data concerning women's HRT use were considered as independent variables. The analysis of qualitative variables was performed using t-Student test for two groups and the analysis of variance when more than two groups were compared. For multiple comparisons the Dunnett T3 test was used. The comparison of two means using t-Student test was preceded by the Levene test for homogeneity of variances. When the variances in both groups differed significantly, a modified test for heterogeneous variances was used. For comparison of more than two means from independent groups a one-way analysis of variance (one-way ANOVA) was applied and preceded by the Levene test for homogeneity of variances. The study also included two strong tests for equality of means - the Welch test and the Brown-Forsythe test. The adopted significance level of p<0.05 displayed statistically significant correlations. The second stage of statistical analysis involved a stepwise logistic regression analysis used to eliminate possible disturbing influence of various independent variables. The values of dependent variables were dichotomized according to the median value.

# RESULTS

At the time the study was conducted, 8.4% of women were using hormone replacement therapy, 16.4% of the respondents were past HRT users and 75.2% had never used the treatment. Statistical analysis of respondents' quality of life depending on HRT use revealed the lowest quality of life in past HRT users. The quality of life of current HRT users was comparable with that of HRT non-users. Statistically significant differences involved: somatic symptoms, memory and concentration, vasomotor symptoms, anxiety and fears, sexual behaviour, sleep problems of the WHQ, physical domain of the WHOQOL-BREF and physical role, general health status, vitality and emotional role of the SF-36 (p<0.05). To sum up, the positive influence of HRT on women's quality of life was not conclusively proved.

From among 531 current or past HRT users, nearly two-thirds (61.2%) were taking it in the form of pills and oral tablets, 34.8% used patches and 4.1% took long-acting injections (the percentages do not sum up to 100% since women had the possibility to choose more than one answer). Statistical analysis of women's quality of life depending on the manner of HRT administration showed higher quality of life in respondents taking oral pills than in those using HRT in other forms. Statistically significant differences were revealed in the following domains: somatic symptoms, anxiety and fears of the WHQ and physical role, vitality and mental health of the SF-36 (p<0.05).

Among the 531 tested women the minimum period of HRT use was 1 month and the maximum one - 33.5 years (arithmetic mean = 4.12 years, standard deviation = 3.89 years). No statistically significant differences in the quality of life in women depending on duration of HRT use were found. In 42.6% of HRT users some side effects of the therapy were observed, 40.9% of the respondents did not suffer from any side effects and 16.6% did not answer the question concerning the occurrence of side effects. The analysis of the quality of life among HRT users depending on the occurrence of side effects revealed a lower quality of life in women who suffered from treatment's side symptoms. Statistically significant differences were shown in seven domains of the WHQ (depressed mood; somatic symptoms; vasomotor symptoms; anxiety, fears; sleep problems, menstrual symptoms and attractiveness), in the physical, psychological and environment domains of the WHOOOL-BREF and nearly in all SF-36 domains (except for the social functioning domain) (p<0.05).

Nearly half (46.0%) of women using HRT were satisfied with the effects of the treatment, 9.2% of the respondents expressed dissatisfaction and the rest did not have a clear opinion on the matter. Statistical analysis of the quality of life in the tested women depending on their satisfaction with the HRT treatment revealed statistically significant differences in all domains of the three standard questionnaires used. The women satisfied with HRT treatment were marked by a decidedly higher quality of life than both those not satisfied with the treatment and the undecided ones (p<0.05).

Women learnt about HRT primarily from mass media (newspapers, magazines, television). This source was indicated by 38.8% of the respondents. Health care workers were the source of information for 32.3% of women, 11.4%

from specialist literature and 6.3% were not aware of HRT treatment at all and found out about this possibility while filling in the survey questionnaire.

Women who indicated specialist literature as the source of their knowledge of HRT had a decidedly higher quality of life. Statistically significant correlations concerned all quality of life dimensions of the standard questionnaires, except for menstrual symptoms of the WHQ. A markedly poorer quality of life was found in women who had no knowledge of HRT treatment prior to filling out the survey questionnaire. Statistically significant differences concerned almost all quality of life domains of the standard questionnaires (with the exception of vasomotor symptoms domain of the WHQ and physical role domain of the SF-36, p<0.05).

Many independent variables were correlated (i.e. age, education, place of permanent residence, professional status, self-assessment of financial situation and living conditions). In order to estimate the influence of these variables on women's quality of life a stepwise logistic regression analysis was conducted. Its results were expressed as the Odds Ratio (OR).

HRT use had independent influence on women's quality of life only in one domain – sleep problems of the WHQ. Current HRT users were characterised by a slightly lower risk of the quality of life reduction (0.89) when compared to past HRT users (OR 1.5) and women who never used HRT (OR 1.0).

# DISCUSSION

The study revealed the lowest quality of life in past HRT users. The quality of life of current HRT users was comparable with that of HRT non-users. These conclusions partially coincide with the findings of Travers and coworkers [1], who analyzed the quality of life of Australian women, aged 50 - 59, depending on HRT use. In their study, past HRT users achieved considerably poorer results in psychological and depression scales of the Green questionnaire than current HRT users and HRT non-users. The study of Skrzypulec and co-workers [2] that involved 190 Polish peri-menopausal women showing symptoms of climacteric syndrome proved a significantly higher quality of life in three SF-36 domains (physical functioning, social functioning and vitality) in women using HRT for at least 3 months in comparison with the control group of nonusers. Another study conducted by the same authors [3], involving 1,007 Polish women aged 45-65, revealed that the use of hormone therapy correlated significantly with lower values of the Kupperman Index in all age groups. In a similar manner, the study of Genazzani and co-workers [4] estimating the quality of life of postmenopausal women in Italy using the WHQ and the SF-36 questionnaires showed higher quality of life of current HRT users as opposed to HRT non-users. The authors found statistically significant differences in the emotional role domain of the SF-36 and in three domains of the WHQ (anxiety, fears; vasomotor symptoms and sexual behaviour). A direct positive influence of HRT on the quality of life of Chinese women measured by the SF-36 was shown in the study conducted by Chiu and co-workers [5]. The study involved 1,250 women, aged 43-77, from the south part of the Chinese island Taiwan. A

clearly positive influence of oestrogen-progesterone HRT on the quality of life of postmenopausal women was proved by Pitkin and co-workers [6]. Their randomized, double-blind, multiethnic study showed a considerable improvement of the quality of life of HRT users in all quality of life domains of the SF-36 and the summary scale of general 15D questionnaire. The observed improvement was statistically significant in comparison with the control group that was receiving placebo, both after 12 and 52 weeks of treatment. The results of the WISDOM (Women's International Study of Long Duration Oestrogen After Menopause) - a largescale, randomized, double-blind study published in the British Medical Journal and concerning the influence of HRT on quality of life of postmenopausal women proved that after a year of HRT use (oral oestrogen-progesterone hormone replacement therapy) statistically significant improvement of quality of life was observed only in 3 WHQ quality of life domains (vasomotor symptoms, sexual behaviour, sleep problems). In the remaining 6 domains no statistically significant differences were found. No differences were also observed in women's quality of life measured by the EQ-5D questionnaire and a visual analogue scale (EQ-VAS) [7]. Nielsen and co-workers [8] who performed a similar study of the quality of life of women aged 40-65 who were taking HRT in the form of nasal oestrogenic preparations (women after hysterectomy) or oestrogen-progesterone (women with preserved uterus) found considerable improvement of the quality of life in HRT users after two years of treatment. Comparison with the control group that was receiving placebo revealed statistically significant differences in four WHQ quality of life domains (vasomotor symptoms, memory and concentration, sleep problems and sexual problems).

This study results are similar to those of our previous research [9] concerning the quality of life in women aged 45-64, the patients in hospitals in Lublin and Zamość. The study estimated women's quality of life using the WHQ and showed that HRT had little impact on the quality of life of the surveyed women.

There also exist studies whose final results are strikingly different from those mentioned above. Lack of improvement of HRT users quality of life estimated using the SF-36 was, for example, reported by Hess and co-workers [10], who surveyed 3,102 middle-aged women in the Unites States (a multi-site study – The Study of Women's Health Across the Nation). Similar conclusions were drawn by Yaffe and co-workers [11], who investigated the quality of life and cognitive functions in American postmenopausal women aged 60-80. Their study revealed neither statistically significant differences in the respondents' quality of life measured by the SF-36 nor significant changes in the cognitive functions evaluated using 7 standardized tests in women after 2 years of ultra-low-dose transdermal oestrogenic replacement therapy use.

In the view of the above it can be stated that the results of the studies concerning the influence of HRT on women's quality of life often contradict each other. Most of the studies merely confirm improvement of quality of life in women with clear-cut menopausal syndrome symptoms.

# CONCLUSIONS

- The positive influence of hormone replacement therapy on women's quality of life has not been conclusively proved.
- A slightly better quality of life was shown in women taking HRT in the form of oral pills than in other forms.
  No differences in quality of life were found depending on treatment duration.
- 3. A lower quality of life was found in women who admitted experiencing HRT side effects and those not satisfied with the treatment results.
- A logistic regression analysis revealed that HRT use had independent influence only on one WHQ quality of life domain that is sleep problems.

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The study was financed as research project from science funds in 2007-2010.

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