Menopause: The Journal of The North American Menopause Society
Vol. 14, No. 2, pp. 216-222
DOI: 10.1097/01.gme.0000233169.65045.b1

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Changing use of hormone therapy among minority women since the Women's Health Initiative

Ira M. Helenius, MD, MPH, Deborah Korenstein, MD, and Ethan A. Halm, MD, MPH

Abstract

Objective: There has been a significant shift in the use of hormone therapy (HT) among nonminority women since the publication of results of the Women's Health Initiative (WHI). Little is known about how the WHI results affected minority populations. This survey measured patterns of HT use among inner city women after publication of the WHI results, identified factors involved in the decision to continue or discontinue HT, and characterized the symptom burden and the experience of women who attempted to discontinue HT.

Design: We conducted a cross-sectional survey of 101 English- and Spanish-speaking women in an inner city general internal medicine clinic from August 2003 to April 2004. All women had been taking HT at the time of the publication of the WHI results. The survey included questions on patient-reported experience with HT, symptoms of menopause, and use of alternative treatments.

Results: Overall, 101 of 142 (71%) eligible women agreed to participate. The mean age of participants was 60 years; 43% were African American and 46% were Hispanic. The mean duration of HT use was 9.6 years. Three quarters (74%) had heard about the WHI findings, and 87% had attempted to stop taking HT after their publication. The most common reason for attempting to stop HT was concern about an increased risk of cancer or a general increase in risk to health. Of those who stopped HT, the vast majority (85%) reported vasomotor symptoms, and 26% restarted HT, mostly to treat those symptoms.

Conclusions: Nearly all minority women in this small sample attempted to stop HT use after the results of the WHI were published. Restarting HT for treatment of symptoms was common.

Key Words: Minority women – Hormone therapy – Women's Health Initiative.

The use of hormone therapy (HT) has changed dramatically since the results of the Women's Health Initiative (WHI) were made public in July 2002.[1] As a result of the WHI's conclusions, HT changed from being a medication commonly prescribed for its health benefits to one that is cautiously prescribed for treatment of moderate to severe menopausal symptoms and not recommended for prevention of cardiovascular disease.[2-5]

Multiple studies have shown that the conclusions drawn from the WHI quickly spread to the public and affected the use of HT.[6-15] According to one national telephone survey, 64% of women had heard about the WHI findings from physicians or the news media within 1 month of the publication.[10] Ettinger et al[11] surveyed predominantly nonminority women in a large managed care plan in California and found that 93% had heard about the new findings and 56% had attempted to stop HT in the 6 to 8 months after publication of the WHI findings.[11] Pharmaceutical sales studies showed that prescriptions for Prempro dropped by 66% in the year after publication of the

Received February 17, 2006; revised and accepted June 1, 2006.

From the Division of General Internal Medicine, Mount Sinai School of Medicine, New York, NY.

Funding/support: This work was funded by grant CFDA 93-895 from the Health Resources and Services Association.

Financial disclosure: None reported.

Address correspondence to: Ira M. Helenius, Division of General Internal Medicine, Box 1087, Mount Sinai School of Medicine, One Gustave L. Levy Place, New York, NY 10029. E-mail: Ira.Helenius@mssm.edu.

WHI results.[13] These studies showed that the WHI findings were quickly disseminated to patients and caused a significant shift in the use of HT in the United States.

However, little is known about how the WHI results affected minority populations. Before the WHI, African American and Hispanic women were less likely to be given HT than white women.[16,17] Women of low income and nonwhite race were also known to receive less counseling about HT.[18,19] Furthermore, studies showed that African-American women tended to use family and friends as sources of information about HT and menopause, whereas white women predominantly relied on the media.[20,21] After publication of the WHI findings, socioeconomically disadvantaged women were found to be less informed about HT and more confused about the information they had received.[10] However, in an analysis of the utilization trends of HT use among women in the Pennsylvania Medicaid Program, nonwhite women had rates of discontinuation of HT similar to those for white women after publication of the WHI findings.[6]

In this survey, we evaluated the ways in which the WHI findings were disseminated to inner city African American and Hispanic women in New York, NY, and how the news affected HT usage. We examined the patterns of HT use and the decision-making process regarding continuation of HT in these minority, inner city women. We also explored the symptom burden and other experiences of the women who attempted to discontinue HT.

METHODS

Study setting and participants

This survey was conducted at a large urban general internal medicine clinic that predominantly serves East "Spanish" Harlem in New York City. Women who had been taking any type of postmenopausal hormone (including conjugated equine estrogens [CEE], CEE/medroxyprogesterone acetate, and transdermal estrogen in this patient sample) at the time of publication of the WHI results (July 7, 2002) were eligible for the survey.

Eligibility was determined by a multistep process. On the days of the study, the principal investigator reviewed the charts of all patients scheduled for visits in the general medicine clinic. Paper medication lists and progress notes from visits during the spring and summer of 2002 were used to identify potential participants. If the medication list or the progress notes indicated that a patient was taking HT around the time of publication of the WHI results that patient was deemed potentially eligible. Potential participants who came to their scheduled appointment were approached and asked to take part in the survey. Once the patient agreed to take part in the survey, eligibility was confirmed by patient self-report of hormone use before July 2002. Patients who were cognitively impaired were excluded. Patients were interviewed in English or Spanish by trained bilingual research staff. Interviews were completed between August 2003 and April 2004. The institutional review board of Mount Sinai School of Medicine approved the study.

Survey domains

All participants were asked about their history of HT use before the WHI, the current status of their HT use, and their knowledge of new information about HT. Questions concerned reasons for starting HT, type of hormone used, hysterectomy status, time since menopause, whose idea (doctor's, patient's, or shared) it was to start taking HT, and sources of new information about HT. Demographic information was determined by self-report, with race/ethnicity categorized as Hispanic/Latina, black/African American, white/Caucasian, or other. Participants were asked to rate their general health status as excellent, very good, good, fair, or poor.

For most questions the participant was asked to choose from a list of possible answers, including "other." However, when asking women their reasons for starting and stopping HT and about the information they had heard about the WHI, we used open-ended questions, to which answers were recorded verbatim. Responses were then coded into categories. The category of "general increase in risk to health" was created during the coding process to encompass answers such as "I was doing myself more harm than good," "hormones damage women," and "there are too many risks."

Women who had stopped or attempted to stop were asked about their reasons for stopping and method of stopping and about symptom burden after stopping. Participants were specifically asked about nine symptoms (hot flashes, fatigue, insomnia, memory loss, mood swings, feelings of depression, vaginal dryness, vaginal itching and irritation, and loss of libido). Participants were asked, "After stopping the hormones did you have more [fill in specific symptom] than while you were taking the hormones?" Those who answered "yes" were asked to rate their symptom as either "mild," "moderate," or "severe," a scale similar to that used in other menopausal symptom

TABLE 1. *Patient sociodemographics, clinical characteristics, and patterns of hormone therapy use (N = 101)*

Mean age, y (SD; range)	60 (6.2; 45-76)
Identification	
Hispanic/Latina	46%
Black/African American	43%
Other	6%
White/Caucasian	5%
Level of education	
<High school	43%
High school or GED	29%
Some college	21%
Graduated college	7%
Living without partner	80%
Unemployed	81%
General health	
Fair/poor	59%
Excellent/very good/good	41%
Self-reported history	
Osteoporosis	21%
Myocardial infarction	9%
Cerebrovascular accident	8%
Deep vein thrombosis	8%
Breast cancer	2%
Years since menopause	
>10 y	61%
5-10 y	28%
1-4 y	11%
<1 y	0%
Main reason to originally start HT	
Vasomotor symptoms	47%
Hysterectomy	22%
Disease prevention	10%
Other menopausal symptoms	9%
Doctor's recommendation	8%
Other	5%
History of hysterectomy	67%
Type of HT	
CEE	62%
CEE + MPA	32%
Other	6%
Years since starting HT mean (SD)	9.6 (6.6)
Information heard from the WHI[a] (n = 75)	
Increased risk of cancer	62%
Increased risk of CAD/CV disease	12%
General increase in risk to health	12%
Other	14%
Sources of information (n = 75)[a]	
Television	51%
Doctor	34%
Newspaper/magazine	32%
Friends and family	29%
Radio/Internet	11%
HT use since WHI	
Successfully stopped HT	64%
Unsuccessfully stopped (restarted HT)	23%
Continued HT	13%
Main reason to attempt to stop HT (n = 88)	
Increased risk of cancer	28%
General increase in risk to health	22%
Do not need HT any more	18%
Medication side effects	11%
Risk of CAD/CVD	4%
Other	16%
Whose idea it was to stop (n = 88)	
Doctor's	47%
Patient's own	36%
Decided together	16%

GED, general education diploma; HT, hormone therapy; CEE, conjugated equine estrogen; MPA, medroxyprogesterone acetate; WHI, Women's Health Initiative; CAD, coronary artery disease; CVD, cardiovascular disease.
[a]More than one answer possible.

surveys.[22,23] Women with symptoms after stopping HT were asked about alternative treatments, including prescription medications and "natural or herbal" remedies. Participants rated the effectiveness of these treatments as "very helpful," "a little helpful," or "not at all helpful." Women who had successfully stopped taking HT were asked if they wish they could continue taking HT, answering either "yes, a lot," "yes, a little," or "no, not at all."

Analysis plan

The primary survey findings are presented with simple descriptive statistics. We used the chi-squared statistic and the Fisher exact test to identify factors associated with stopping HT. Candidate predictors were age, race/ethnicity, education, primary language, self-rated general health, years since menopause, reason for starting HT, hysterectomy status, type of hormone used, number of years taking hormones, knowledge about the WHI findings, whose idea it was to stop, reason to stop HT, method of stopping, type of doctor involved in decision to stop, and number of symptoms after stopping. A low power to detect differences due to the size of the survey was taken into account in the analysis phase. Two-sided P values of 0.05 or less were considered significant. All analyses were performed using SPSS software, version 12.0 (Chicago, IL).

RESULTS

Between August 2003 and April 2004, 142 eligible women were approached, and 101 agreed to participate (71%). The interviews took place a mean of 18 months (range, 13-22 months) after publication of the WHI results. Characteristics and patterns of HT use of the respondents are shown in Table 1. The mean age of the women was 60 years (range, 45-76 years). Forty-three percent identified themselves as African American and 46% as Hispanic/Latina. Twenty percent of interviews were conducted in Spanish. Two thirds of the patients were poor (household income <$15,000/year), and more than half perceived their general health as "fair" or "poor."

Participants had been using HT for a mean of 9.6 ± 6.6 years (range, 2-31 years), and 61% had been postmenopausal for more than 10 years. Sixty-two percent had taken estrogen alone, and 32% had taken combined estrogen and progestogen. The most common reasons for having started HT were vasomotor symptoms (47%) and hysterectomy (22%). Seventy-nine percent said that it had been the doctor's decision to start HT, 12% said the decision had been shared between patient and doctor, and 9% said it had been their own decision.

Almost three quarters (74%) of the women had heard new information about the risks and benefits of female hormone pills for menopause since July 2002. An increase in cancer risk from HT was the most commonly reported new information (62%), whereas only 12% reported hearing about the risk of cardiovascular disease. The women reported getting information about HT from multiple sources. Half of the women had learned about the WHI findings on television, 34% from their physician, and 32% from reading newspapers or magazines.

Overall, 87% of women had attempted to stop HT after publication of the WHI findings. Three quarters of those who attempted to stop were successful, and one quarter restarted HT. The most common primary reason given for stopping or attempting to stop was an increased risk of cancer or a general increase in risk to health. Only 4% said the main reason they stopped HT was because of increased cardiovascular risk. Doctors initiated the idea to stop in 47% of patients, and patients initiated it in 36%. Twenty-two percent of doctors involved in the decision to stop were gynecologists, whereas 78% were other providers, including general internists, nurse practitioners, oncologists, cardiologists, and surgeons. Tapering HT was the method of stopping in 26%; 74% stopped "cold turkey." Fifteen percent of participants had made more that one attempt to stop HT.

The majority (85%) of women experienced symptoms after stopping HT (Fig. 1). The mean number of symptoms reported was 3.8 (SD, 2.8), and most symptoms were moderate or severe. Sixty-three percent of women who had symptoms had discussed the symptoms with their doctors. Prescription medications, such as selective serotonin/norepinephrine reuptake inhibitors and vaginal estrogens, were given to 27% of women who stopped HT, and 18% used natural or herbal remedies (soy products or combination over-the-counter menopause treatments). At the time of the interview, 37% of those who had successfully stopped, 34% of those who had restarted HT, and 23% of those who had not stopped HT stated that they had experienced severe menopausal symptoms during the 2 weeks before the interview.

Most patients (90%) said the prescription medications were helpful or very helpful, and 44% said the herbal/natural remedies were helpful or very helpful. One in four women (26%) restarted HT after stopping, primarily because of vasomotor symptoms (91%). Of the 65 women who were not taking hormones at the time of their interview, 41% wished that they could continue to take hormones.

Thirteen percent of participants had not attempted to stop HT after publication of the WHI findings. Half of these women said that they had considered

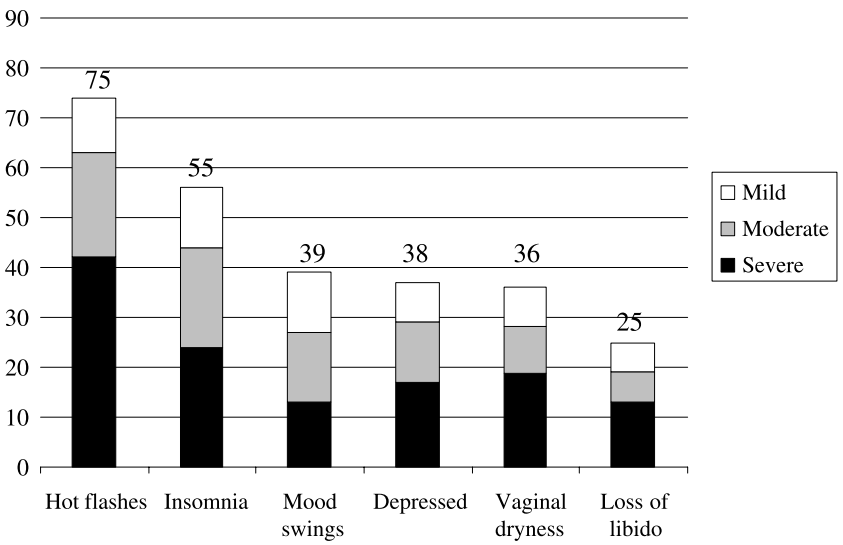

FIG. 1. Percentage of women who experienced menopausal symptoms.

stopping HT but had chosen to continue for a variety of reasons. The most common reason to continue was the fear that menopausal symptoms would be too severe without hormones.

The only patient characteristic that was statistically associated with successful stopping was the original reason for starting HT. Those who had started HT for menopausal symptoms were less likely to stop successfully than were women who had started HT for other reasons (65% vs 85%, $P = 0.026$). No other patient characteristics were associated with successful stopping. Factors examined included age, ethnicity, education, self-perceived health status, time since menopause, hysterectomy status, type of hormone used, number of years taking hormones, knowledge about the WHI, method of stopping HT, whose idea it had been to stop HT, the reason for stopping HT, and the number of symptoms after stopping.

As expected, we found that women who had spoken to their doctors about their symptoms after stopping HT were more likely to use either prescription or natural/herbal medications than women who had not spoken to their doctors (57% vs 14%, $P < 0.001$). No other characteristics predicted use of other treatments for menopausal symptoms.

Stopping HT versus continuing HT was not associated with patient sociodemographics, time since menopause, number of years taking hormones, self-perceived health status, hysterectomy status, type of hormone used, knowledge regarding the WHI, or type of doctor involved in decisions.

DISCUSSION

In this survey, we found that minority women who were taking HT were deeply affected by the results of the WHI. Almost all women in this inner city sample attempted to stop taking HT after publication of the WHI results. The most common reason stated for stopping was the increased risk of cancer and a general increase in risk to health. Very few women mentioned the risk of cardiovascular disease as a reason for stopping, even though the lack of reduction of cardiovascular risk was a major finding in the WHI trial. Moderate and severe withdrawal symptoms were exceedingly common in those who stopped HT, and more than one quarter of women restarted HT to relieve these symptoms.

Our results differ somewhat from the results of surveys in predominantly nonminority populations. Seventy-four percent of the women in our sample said yes when asked if they had "heard anything about the new information on the risks and benefits of female hormone pills for menopause since July 2002." Ettinger et al[11] surveyed a group of 670 predominantly nonminority women 6 to 8 months after publication of the WHI results and found that 93% of their sample knew "about the overall results about HT from a research study called 'The Women's Health Initiative.'"[11] In a national telephone survey completed a few weeks after publication of the WHI results, 64% of women who had used or were using HT were aware of the study findings.[10] The differences between these studies may be due to the timing of the surveys and populations sampled.

The percentage of women who attempted to stop HT after the WHI results is significantly higher (87%) in our study than in surveys done in other populations. Rates of patients attempting to stop HT in other studies have ranged from 26% of women in a large (n = 6,007) German population-based survey to 56% in a survey of 670 Kaiser Permanente members and 58% in 734 New Zealanders.[7,11,12] Furthermore, studies of pharmaceutical sales show that there was a 66% drop in annual sales of Prempro in the year after publication of the WHI results.[13]

The significant difference between rates of attempting to stop HT in our survey compared with those in other larger studies may be due to multiple factors. Timing of our survey probably played a key role. We assessed HT use 13 to 22 months after the WHI results were published, whereas the other studies surveyed patients between 6 to 12 months afterward. Women in our survey probably had more chances to hear physicians' and media messages about the risks of HT. Our survey data do not provide any insight as to whether inherent differences between minority and nonminority populations may also have affected the rates of stopping HT. Potential differences in trust in the medical establishment and levels of risk adversity should be topics of further research.

Nearly all women (85%) in our survey experienced significant vasomotor or other menopausal symptoms after stopping HT. Forty-two percent reported "severe" vasomotor symptoms. The survey done by Grady et al[24] showed that only 31% of women who stopped HT reported "very" or "extremely" troublesome vasomotor symptoms. The disparity between our study and that of Grady et al may be due to differences in rates of menopausal symptoms in various ethnic groups. Previous studies have shown that African American women are more likely to experience hot flashes compared with white American women.[20] However, data showing no difference in

the prevalence of various menopausal symptoms in Hispanic versus white women also exist.[25] Another potential explanation for the high rate of symptoms after stopping HT is that the women in this sample may have had an uncommonly high burden of menopausal symptoms. This is supported by the fact that 47% were taking HT for menopausal symptoms, which is a high rate compared with the rate in a large 1997 survey of a population in which only 20.9% were taking HT for menopausal symptoms.[26] Furthermore, the disparity between symptom burden in our survey and in the study of Grady et al could also be explained by somewhat different item and response wording.

Rates of restarting HT were strikingly similar in our survey and others. Twenty-six percent of our sample restarted HT after attempting to stop. Lawton et al[12] found that 31% of those who attempted to stop HT had restarted the medication by 6 months after the WHI results were published. Heitman et al[7] found that 23% had restarted HT after 1 year, and another large survey showed that 26% resumed taking hormones after attempting to discontinue.[24]

In our sample, the only predictor for restarting HT in our survey was having started HT for symptom relief. This is presumably because symptoms of menopause almost always returned once HT was discontinued. Similarly, in a univariate analysis Grady et al[24] found that women who started HT for reasons other than health promotion were more likely to restart HT than those who had started for health promotion. Their multivariate analysis showed that the strongest predictor of restarting HT was the development of troublesome withdrawal symptoms.

We did not find that women who had an intact uterus were more likely to discontinue HT compared with women who had undergone hysterectomy. This result was surprising. Given that our survey was conducted before the publication of findings from the estrogen-only arm of the WHI, we expected women with hysterectomies to be less likely to discontinue HT. The data available during our survey showed only that the risk of combination CEE/medroxyprogesterone acetate outweighed the benefits and included no information on outcomes for women with hysterectomies taking estrogen alone. Our results may indicate that the minority women and their physicians were applying the negative news about combined CEE/medroxyprogesterone acetate to all forms of HT. In contrast to our findings, Barber et al[8] and Ettinger et al[11] showed that predominantly nonminority women who had undergone hysterectomies were significantly less likely to attempt to stop HT.

Several limitations of our survey are worth noting. First, our inner city, minority patients were recruited from a single large general internal medicine clinic at an urban university teaching hospital. Although the sociodemographics of the patients in our study are similar to those of other clinic attendees in New York City, the generalizability of our results to minority women in other locations and settings is unknown. Our survey gives only a snapshot of how the results of a large and influential trial were understood by our sample of inner city, minority women in New York. Second, our sample size is modest, which limits the generalizability and power to detect weak associations. The lack of association between patient characteristics and outcomes may be a result of low power, not necessarily a true lack of association. Third, the participation of 71% may introduce bias. However, lower participation rates have been reported previously in minority populations.[27] Finally, all information was based on patient self-report and therefore may not be completely reliable. However, this is an approach used in similar published studies.[7,8,10,11]

CONCLUSIONS

The results of this survey provide insight into how a landmark change in women's health messages penetrated an inner city community. The minority women in our sample were widely aware and deeply affected by the results of the WHI. Compared with larger studies of nonminority women, more women in this sample attempted to stop their HT after publication of the WHI findings and reported more symptoms after stopping HT. Clinicians should be aware of the high rates of menopausal symptoms among minority women who discontinue HT. Further research should be conducted to determine whether minority populations respond differently than nonminority populations to other highly publicized clinical trial results.

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