LOSING HEART: THE ESTROGEN DILEMMA - RETHINKING HEALTH RESEARCH FOR MIDLIFE WOMEN

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Although menopause has historically been viewed as time of ill-health, the medical definition of menopause as a disease was established in 1966 with the simultaneous marketing of synthetic estrogen to relieve all menopausal symptoms and to keep women looking young and beautiful. Over the next 30 years many new benefits were linked to estrogen use, the two most compelling being substantial reductions in osteoporosis and cardiovascular disease risks. The latest research on postmenopausal estrogen use reveals that the benefits of estrogen on heart health were overstated and that earlier studies were confounded by biased samples. Notwithstanding this new finding, medical practice guidelines continue to promote estrogen as the treatment of choice for postmenopausal women. This paper traces the research and marketing of synthetic estrogen and I argue that the pharmaceutical industry in tandem with physicians have proselytized the benefits of estrogen even though the robustness of research findings have been challenged, consumer compliance has been relatively low, and there are many adverse health effects associated with estrogen use. It is time for medical researchers to rethink the biomedical model of menopause and develop new research guidelines that embrace the precautionary principle and treat menopause as a natural process in a woman’s life cycle.

Menopause is the cessation of menstruation, an anticipated physiological event (the average age being 51). Yet, the medical profession has historically characterized menopause as a time of ill health when women undergo personality and behavioral changes (Deutsch, 1944; Freud, 1961; Tilt, 1857; Wilson, 1966). For example, throughout the nineteenth century, menopause was described as a gradual “loss of feminine grace” (Tilt, 1857). Since a woman’s worth and value were directly related to reproduction and sexual attractiveness, menopausal women were viewed as “useless and repulsive” (Tilt, 1857, p. 8; Mitchinson, 1991, p. 95). To treat this “final incurable ill… ‘the death of the woman in the woman’ ” (Ehrenreich & English., 1973, p. 21), physicians offered a range of bizarre remedies such as bandaging of limbs, placing leeches behind the ear, blood letting (Tilt, 1857) and castration – the surgical removal of the ovaries (Currier, 1897 cited in Delaney, Lupton & Toth, 1988).

Largely influenced by Freud (1961), menopause in the first half of the twentieth century was not classified as a disease but rather a time when women became neurotic. As such, menopausal women were frequently prescribed sedatives to keep them calm and controlled. This view largely prevailed until the mid 1960s, when pharmaceutical companies began an aggressive marketing campaign promoting estrogen as the wonder drug to treat symptoms associated with menopause. They boasted that Estrogen Replacement Therapy (ERT) could allay all menopausal symptoms caused by decreased levels of estrogen. The underlying premise of their marketing campaign was that menopause is a hormone deficiency disease and that the woman’s body needs estrogen in the same fashion a diabetic needs insulin (Wilson, 1966).

Over the following thirty years, many more benefits were attributed to estrogen use, including substantial risk reductions in developing osteoporosis – thinning of bone mass (Lindsay et al., 1978) and heart disease (Stampfer et al., 1991). The medical establishment world-wide, convinced of the efficacy of estrogen, implemented practice guidelines that recommended all menopausal women receive hormonal treatment, preferably for life (SOGC, 1994; Rovira & Trinxet, 1993; Tosteson, 1993). But, recent research has indicated that, in fact, there are no cardiovascular benefits associated with estrogen use (Hulley et al., 1998) and that synthetic estrogen can even increase the risk of coronary disease in women with pre-existing heart conditions (WHI HRT Update, 2001). Notwithstanding these new findings, estrogen-prescribing practices, for the most part, remain unchanged (Petitti, 1998; Mitka, 2001).

In this paper, I trace the history of the medicalization of menopause through the marketing of synthetic estrogen from 1966 until the present. I show that the medical profession and pharmaceutical companies, in spite of consumer resistance and in spite of research that has been repeatedly proven to be flawed and incomplete, continue

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to promote estrogen as the drug of choice for menopausal women (and beyond). Based on these findings I argue that we need to rethink the biomedical model of menopause and develop new research guidelines that embrace the precautionary principle and that treat menopause as a natural process in a woman’s life cycle.

THE PROOF: THE MEDICALIZATION OF MENOPAUSE

Synthetic estrogen was first introduced in 1943 and is marketed today as “Premarin”. Premarin takes its name from its source – an extraction of pregnant mares’ urine. Not in wide use until the 1960s, estrogen surged in popularity after a gynecologist, Robert Wilson, published a book titled Feminine Forever (funded by numerous pharmaceutical companies). His audience was menopausal women. Wilson saw menopause as a time when women become shrill, irritable and out of control and as such, “a major medical problem in modern society:

What for example, can the poor doctor make of a woman who complains to him of nervousness, irritability, anxiety, apprehension, hot flushes, nigh sweats, joint pains, melancholia, palpitations, crying spells, weakness, dizziness, severe headache, poor concentration, loss of memory, chronic indigestion, insomnia...? (Wilson, 1966, p. 42)

Wilson identified a total of 26 symptoms related to menopause. His success in promoting estrogen, however, was the exploitation of women’s fear about losing their youthful attractiveness. Women at menopause are, he wrote, “condemned to witness the death of their womanhood” (1966, p.42) but, with estrogen, they continue to be “romantic, desirable and vibrant” (p. 66); they “after all, have the right to remain women [and] should not have to live as sexually neutered for half their lives” (p. 42).

Based on case studies from his own medical practice, Wilson argued that the harmful behaviours associated with the symptomatic menopausal woman also had far-reaching effects on her family. Quoting a husband who accompanied his wife during a medical consultation, Wilson portrays a disturbing caricature of the menopausal wife who does not use estrogen therapy (1966, p. 93): “She is driving me nuts. She won’t fix meals. She lets me get no sleep. She picks on me all the time. She makes up lies about me. She hits the bottle all days. And we used to be happily married”. Wilson “rescued” this distressed husband by prescribing estrogen to his wife and, as he predicted, harmony was restored to their household.

Sales of estrogen skyrocketed until two studies, published in the New England Journal of Medicine linked the use of postmenopausal estrogen to increasing rates of endometrial carcinoma or the cancer of the lining of the uterus (Smith et al., 1975; Ziel & Finkle, 1975). In 1977 action was taken by the FDA to warn women about the causal relationship between ERT and cancer. But, it was not until 1979, four years after the estrogen-cancer link was established, that the consensus conference on ERT, organized by the National Institute of Health (NIH), alerted women to the risks of ERT and the need for alternative remedies (NIH, 1979). By 1980, researchers agreed that the risk of cancer could be increased three to sixfold by using estrogen. To lower that risk, doctors began to prescribe synthetic progesterone (progestin) in conjunction with estrogen; progesterone induces a monthly withdrawal bleed, believed to regularly slough off cells with malignant potential. The combination of estrogen and progesterone is referred to as Hormone Replacement Therapy (HRT).

Although estrogen was initially marketed to relieve symptoms associated with hormonal fluctuations that coincide with cessation of menses, throughout the 1980s and the 1990s new benefits were claimed for estrogen, including protection from osteoporosis and cardiovascular disease. Advocates of HRT claimed that it reduced the risk of hip fractures (Lindsay et al., 1978) and heart disease (Stampfer et al., 1991), the leading cause of death among post-menopausal women, by up to 50%.

Estrogen has conclusively been shown to slow down the rate of bone loss that begins with menopause. Lindsay and her colleagues (1978), in an impressive double-blind crossover study spanning eight years, found that HRT in combination with a calcium supplement of 1,500 milligrams a day resulted in increased bone mass. This research has been validated in numerous other studies (Christiansen, 1990; Henderson, Paganini-Hill & Ross, 1991).

The introduction of heart disease, the leading cause of death for both men and women in North America, into the HRT debate is relatively new, first appearing in the mid 1980s with mixed outcomes (Barrett-Connor, 1987; Stampfer et al., 1985; Wilson, Garrison & Castelli, 1985). But, two studies published in 1991 turned around the thinking about the widespread benefit of estrogen in the post-menopausal years (Henderson et al., 1991; Stampfer et al., 1991). Henderson’s research group (1991) studied over 8,000 women in a southern California retirement community and found that women who used estrogen for 15 years “had a reduced mortality from all categories of
acute and chronic arteriosclerotic disease and cerebrovascular disease” (p. 74). The most noted research, the Nurses’ Health Study (Stampfer et al., 1991) - a longitudinal survey that followed 48,470 postmenopausal women to determine the relationship between estrogen and coronary artery disease - revealed that nurses on estrogen had a 50% reduction in their risk of heart attack. These findings were so impressive and compelling that HRT gained support in the medical community for routine use in menopausal women. For example, the Canadian Society of Obstetricians and Gynecologists’ policy guidelines for treatment of menopausal women in 1994 recommended, “that every Canadian woman should have individualized care, and should be offered the benefits of Hormonal Replacement Therapy” (SOGC, 1994, p. 1649).

And so, the definition of menopause as a disease was medically established and the medicalization of menopause was born. Zola (1983) coined the term medicalization to refer to a process of legitimating the medical control and management over an area of life, typically by asserting and establishing dominance of a medical interpretation of that area. The medical profession claims and labels illnesses so that medicine can control and subsequently “legitimate the expense of medical care for that disease” (Freund & McGuire, 1995, p. 183); newly established disease categories are financially lucrative as funding for research and treatment is readily available.

Over the past century, science has uncritically accepted and reinforced the predominant myths about women’s biology (Coney, 1994; Ehrenreich & English, 1973, 1978; Hubbard, 1983). Coney’s work on the medical exploitation of menopausal women illustrates this point:

Medicine is meant to be neutral and detached, but in this case science reinforces negative social attitudes… It legitimizes the social prejudices by providing a “scientific” base for them… The current medical model of menopause is neither scientific nor neutral. It is ideological (Coney, 1994, p. 65).

The role of the doctor treating menopausal women is to “try to tailor the patient to fit better into her circumstances” (Greer, 1992, p. 121). Feminist scholars, therefore, argue that the continued medical reinforcement of negative stereotypes is a means by which patriarchal power and control over older women is maintained (Coney, 1994; Kaufert, 1980; Kaufert & Gilbert, 1986, Kaufert & McKinlay, 1985; MacPherson, 1981; 1985; 1993; Voza, 1993). Such negative images have serious repercussions in the day-to-day lives of middle-age women; their body image, relationships, and even participation in the workforce may all fall victim to these misogynist representations:

Medicine stands between biology and social policy, between the “mysterious” world of the laboratory and everyday life. It makes public interpretations of biological theory; it dispenses the medical fruits of scientific advance. Biology discovers hormones; doctors make public judgements on whether “hormonal imbalances” make women unfit for public office (Ehrenreich & English, 1973, p. 5).

The medical model of menopause, which depicts women as “naturally disadvantaged”, has far reaching implications in that it promotes institutionalized ageism and sexism (MacDonald & Rich, 1991) and, for this reason, women’s biology cannot be viewed in a vacuum exclusive of social and political influences.

THE PHARMACEUTICAL INDUSTRY

Menopause is big business and pharmaceutical companies are key players in constructing menopause as a disease. They are the primary beneficiaries of hormonal treatment, making huge profits through the sale of the drugs they manufacture for its treatment (Coney, 1994). Indeed, synthetic estrogen was a financial success from the time it was first marketed. From 1967 to 1975, sales of estrogen tripled (Seaman & Seaman, 1977) and in 1975, physicians wrote 28 million prescriptions. The pharmaceutical company, Wyeth-Ayerst, boasted impressive profits “as a result of its market dominance and the low cost of goods” (MacPherson, 1985, p. 16).

Estrogen’s success was in large part due to an aggressive advertising campaign by the powerful pharmaceutical corporations. Borrowing themes from Wilson’s Feminine Forever (1966), menopausal women were portrayed in medical journals as old looking and out of control. Wilson’s images of the menopausal woman as a nuisance to herself and her family were used to persuade physicians to prescribe estrogen and to “manage” such women. Examples of advertising captions read: “Help keep her this way”; “… the menopausal symptoms that bother him most”. Not only do these ads portray menopausal woman as irksome to her family, but her destructive presence
affects everyone she meets. One two-page ad makes this point. The first page shows a bus driver who is frustrated and distraught. The caption says: “he is suffering from estrogen deficiency”. On the second page is a “menopausal” woman standing on the same bus, with bulging eyes, flared nostrils and raging: “she is the reason why” the bus driver is so harassed. The accompanying text continues:

Behind the long suffering man is a suffering woman. She may be suffering from any one or more of a multitude of symptoms… apart from the more obvious sign of estrogen deficiency and through no fault of her own she makes life miserable for everybody she comes in contact with.

If we consider the number of aging changes that take place in the body after estrogen deficiency begins it would be logical to treat all women… Estrogen is as essential to health as a well balanced diet (Canadian Family Physician, 1973, pp. 91-2).

But, profits were short-lived once women were notified of the cancer risks and stopped using estrogen. Even though the risks of endometrial cancer were erased by taking another hormone – progestin – and new benefits of estrogen use were introduced such as reduced risk of developing osteoporosis, compliance continued to be substantially lower than in the 1970s and profits did not meet the projected goals of the pharmaceutical companies (Love, 1997). Furthermore, the pharmaceutical companies were confronted with new challenges in the 1980s. A changing political and social climate resulted in increased consumer health awareness, in large part due to AIDS activists and the women’s movement. These groups challenged traditional doctor/patient relationships and demanded more involvement and information in their treatment. Thus, as the baby boomers were approaching menopause, they challenged the hegemonic medical beliefs that at midlife, women are old and that menopause is a disease.

The pharmaceutical industry may have recognized a new approach was needed that would reflect the lifestyle of the up and coming menopausal generation. In tandem with new research linking synthetic estrogen use with decreased risk of heart disease, a new advertising campaign was introduced, one in which the menopausal woman was portrayed as sophisticated and elegant and the texts were rewritten to address the changing times. Many of these ads appropriated feminist language of the women’s liberation movement in the 60s and 70s:

Is it right for a woman to suffer needlessly with hot flashes, sweats and sleepless nights?
Is it right to allow estrogens to become depleted through the menopausal years?
Is it right that a woman be denied the chance for an improved quality of life? (Canadian Family Physician, 1984, p. 137)

Although by the early 1990s the dominant image was no longer that of a woman as “out of control”, the themes of age continued to loom large. One ad promoting the estrogen patch shows a beautiful, slim, refined woman standing on a marble floor at the foot of a winding staircase. Stylishly dressed, wearing pearls, she stands proud and confident. However, cast over the stairs in a shadow-like manner is a clock, a reminder of biology as destiny. The intent of this ad is designed to appeal to a woman’s sense that at menopause, with the help of estrogen, she need not be old. Thus, the pharmaceutical industry has refashioned midlife women as dignified and attractive. The trend in the recent years is to characterize menopausal women as youthful, beautiful, energetic and, most recently, angelic. Menopausal women are either walking dogs, climbing mountains, or involved in rigorous exercise programmes to promote bone health. Having moved from one extreme to another, many of the women in present-day advertisements look to be at most thirty-five (Coney, 1994). The catch, of course, is that women have to comply with the prescribing practices of their physicians who “know” the merits of estrogen.

Regrettably, profits continue to motivate these industries, rather than genuine shifts in their attitudes towards aging. The marketing of menopause continues to generate large profits for pharmaceutical companies. Sales of estrogen in 1991 reached 750 million dollars (Sheehy, 1992) and, 850 million dollars in 1995 (Love, 1997). Since 1997, synthetic estrogen generated more prescriptions than any other drug in the United States and, in 2000, Wyeth - Ayerst earned 1.9 billion dollars from estrogen products (Kellosalmi & Basile, 2001). Should most women over the age of 50 use HRT, as the medical profession recommends, the profits for the pharmaceutical companies would be even higher.

Consumer Resistance: The Risks

The success of any marketing programme lies in consumer participation. Yet, midlife women have not complied with their physicians’ prescribing practices in ways the drug companies had hoped. According to Coney
(1994), 30% of postmenopausal American women in the early 1990s used hormones, compared to 10% in Britain and Australia. In Canada, there was less compliance than in the United States, as only 11.4% of women over the age of 50 who received prescriptions filled them (Journal SOGC, 1994). Although HRT use increased throughout the 1990s (Connelly, Richardson & Platt, 2000; Townsend, 1998), the focus of scores of articles in medical journals was on low compliance rates and strategies to better promote HRT. For instance, the researchers of a retrospective longitudinal analysis of 26,718 American women wrote: “Noncompliance with HRT in the general population is higher than that reported in randomised clinical trials…Increased efforts to improve long-term HRT compliance are urgently needed” (Faulkner et al., 1998, p. 226). Similar concerns about improving HRT compliance have been expressed worldwide (in Canada, Pilon, Castilloux & LeLorier, 2001; in Sweden, Li et al., 2000; in the U.K., Sturdee, 2000, p. 9; in the Netherlands, van Seumeren, 2000 and in Turkey, Karakoc & Erenus, 1998).

The most common reasons women offer why they stop using hormone therapy are: unpleasant side effects such as menstrual-like bleeding and breast pain (Hochner-Celniker, 1999), fear of cancer (Li et al., Lobo, 1999), weight gain (Li et al., 2000; van Seumeren, 2000) or because the medication was ineffective (Kaufert, 1993). Of those women who used hormones, almost half discontinued medication within the first two years (Sturdee, 2000; Hochner-Celniker, 1999; Kaufert, 1993; Klein & Dumble, 1994).

Proponents of estrogen recognize both its short and long-term side effects. Estrogen can induce disease of the liver and gallbladder; women on estrogen, for example, have a 38% greater risk of having biliary tract surgery than women not taking estrogen (Simon et al., 2001). Estrogen may also cause a rise in blood pressure, depression and retinal thrombosis – a clot in the blood vessels of the eye (Henkel, 1992; Prior, 1992). As well, there is evidence that shows an increased risk of venous thromboembolic disease (VTE) with postmenopausal estrogen use (Daly et al., 1996; Jick et al., 1996).

The more vexing question appears to be the relationship between estrogen and breast cancer. Prior to 1995, the few studies available were inconsistent and controversial in their findings (Bergkvist et al., 1989; Steinberg et al., 1991) and physicians were reluctant to admit a connection between increased estrogen use and breast cancer. However, in 1995, the Nurses’ Health Study showed that the risk of breast cancer among estrogen users was significantly higher than previously thought – women who take estrogen between five and nine years have an over 40% increase in their risk of developing breast cancer (Colditz et al., 1995). Since then, a collaborative reanalysis of epidemiological studies (see Breast cancer, 1997) found that women who used estrogen for five years had a 35% increased risk of developing breast cancer, the risk further increasing with prolonged use.

By 1998, the link between estrogen and breast cancer was less contentious, yet the medical community remained committed to the benefits of estrogen and minimized the significance of the breast cancer risk, arguing that heart disease, not breast cancer, is the leading cause of death for women. But, many women continued to be seriously concerned about using hormones because of the increased risk of breast cancer (Lobo, 1999). This concern may help explain why the compliance rate of women taking hormones was low. For many women, the difficulty lay in trying to apply the general risks and benefits to their individual situation. For example, a woman who had no family history of heart disease or osteoporosis may be more reluctant to take a drug that reduced the risk of getting a disease for which she already had a reduced risk. In this instance, the woman’s risk for developing breast cancer may have been greater than her risk of heart disease. Given the variability of individual susceptibilities, such concerns were not misplaced.

For now, explanations of why most postmenopausal women choose not to ever use hormone therapy are speculative. One possible explanation is, contrary to popular myth, not all women suffer at menopause (McKinlay & Jeffrey, 1974; McKinlay & McKinlay, 1973; Neugarten et al., 1963). Although most women experience hot flashes and other menopausal-related symptoms, they feel these symptoms to be minor irritants that do not need treatment. Since the 1970s, critics of the biomedical model of menopause have claimed that research on menopause is based on a faulty hypothesis – menopause is a disease needing medical intervention (Kaufert & Gilbert, 1986; MacPherson, 1985; McKinlay & McKinlay, 1973; 1986; Prior; 1992; Voda, 1993). Instead, they stressed that menopause is a “normal” phase in a woman’s life and most menopausal women are physically and psychologically healthy. For example, McKinlay and McKinlay (1973; 1986) criticized the biomedical approach for solely selecting samples from doctors’ practices instead of women randomly drawn from the general population. Indeed, their research on 2,500 menopausal women showed that, in contrast to medicine’s archetypical menopausal woman having limited health capacities, the “typical” menopausal woman was neither ill nor “a high utilizer of health care” (McKinlay, McKinlay & Brambilla, 1987, p. 110). Hence, they “underscored” the importance of more research on menopause utilizing samples of healthy women.

One other possible explanation why menopausal women resist hormone therapy may be rooted in the harsh
lessons of women’s gynecological history. Although only a minority of women, and their babies, suffered the adverse effects of thalidomide and diethylstilbestrol (DES), most women are aware of the harm that was caused. At the time these medications were prescribed, many doctors spoke confidently and convincingly of their safety. Many of these doctors were genuine and sincere in their professional beliefs; tragically, history proved them wrong. Throughout the 1990s, menopausal women were confronted with assurances of safety and health benefits even though the research has established that there are numerous health risks associated with postmenopausal estrogen use. Perhaps, then, women are suspicious of medicine and distrust the information disseminated by drug companies and physicians.

The Skeptics

Over the last thirty years, while proponents of HRT promoted the benefits of estrogen, there were many scholars who questioned the validity of the research. Yen (1986), for example, argued that only a small percentage of women are truly at risk for osteoporosis, yet estrogen treatment is recommended for all women. Voda (1993) also posited that women after menopause “do not need estrogen replacement therapy to prevent osteoporosis” and went one step further by saying that it is contraindicated in many postmenopausal women:

The lack of valid and reliable predictive methods to identify who should receive some form of prophylactic therapy for osteoporosis currently poses a major dilemma. For those women who would benefit from estrogen, acceleration in bone loss would have occurred before definitive evidence of entry into the menopausal transition (Voda, p. 176).

Other research questioned the effect of long-term estrogen use on bone health later in life (Felson et al., 1993). A meta-analysis, spanning studies on osteoporosis, found that women under the age of 75 taking estrogen for at least 10 years had, on average, 11.2% higher rates of bone density compared to non-users. However, the difference between users and non-users, in women older than 75 who took estrogen for similar amounts of time, was diminutive: 3.2% higher in women who used estrogen. The study concluded that long-term estrogen therapy “may have little residual effect on bone density among women 75 years of age and older, who have the highest risk of fracture” (p. 1141).

Furthermore, according to Vines (1993), it is unclear whether fractures in the elderly were solely attributed to lower levels of estrogen. She pointed out that, in Britain, older women living in the 1990s were two times more likely to fracture their hips compared to the same-age women thirty years earlier, “a change that is impossible to link to any change in oestrogen levels” (p. 133). Instead, she ascribed this change to a decline in routine exercise, poorer eating habits and less time being spent in the sun (p. 56).

Similarly, critical researchers questioned the validity of the Nurses’ Health Study linking estrogen to reduced risks of heart disease, as it was neither randomised nor blinded (Prior, 1992; Vandebroucke, 1991; Wolfe, 1992). For example, women who used estrogen were overall healthier than those who did not. They, on the whole, were leaner, physically more active and smoked less than non-estrogen users. Ironically, the group of researchers who ran the Nurses’ Health Study, in an earlier study, found that being overweight could account for 70% of a woman’s risk for heart disease (Manson et al., 1990).

Vandebroucke (1991) and Wolfe (1992) also made the argument that, although estrogen reduces the risk of cardiac death, the more “important” question is estrogen’s relationship to total mortality. In the Nurses’ Health Study, “when women with pre-existing disease (cancer and coronary heart disease) were removed from the analysis, the mortality rates were similar in both groups” (Vandebroucke, 1991, p. 834). A related question was examined in a meta-analysis published in the Annals of Internal Medicine (Grady et al., 1992). Researchers compared the life expectancy of women who took HRT to the life expectancy of the matched sample of women who did not take HRT. Women on HRT and progestin had a life expectancy of 83.8 years, compared to 82.8 years for women who did not take the medication.

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2 Thalidomide was prescribed to pregnant women in the 1960s to help with nausea. The “thalidomide” children were frequently born with either partial limbs or without limbs. DES was frequently prescribed to women between 1940 and 1960 to prevent miscarriages. Daughters whose mothers took DES are at higher risk for vaginal cancer and other gynecological disorders. The mothers themselves are now at higher risk for breast cancer.
Of note, the researchers of the *Nurses’ Health Study*, in an earlier research study (Stampfer et al., 1985), also observed that estrogen use substantially reduced the risks of coronary artery disease. But, these findings were contradicted by one of the research projects emanating from the highly esteemed Framingham Heart Study⁴. The data showed that, overall, women using estrogen did not have lower mortality but they had “increased rates for myocardial infarction particularly among the estrogen users who smoked” (p. 1038). Yet, in spite of this knowledge, Stampfer and colleagues (1991) failed to adjust their clinical trials for lifestyle factors.

Many retrospective studies on HRT in the early 1990s were confounded by socio-economic status and education. Even supporters of estrogen therapy to prevent heart disease admitted that their research was biased by these factors (Schrott et al., 1994). For example, the participants in the Postmenopausal Estrogen/Progestin Intervention trials (900 women taking various forms of estrogen) were described as being:

- more highly educated and [having] higher incomes than the average woman and consequently, may observe healthier lifestyles. Thus, lipid levels, particularly the TG [triglycerides] and HDL-C, appear to be significantly affected by exercise, body weight and distribution, and income and education (Schrott, 1994, pp. 161-162).

The relationship between socio-economic factors and health determinants are well documented in the literature (Burke et al., 1992; Frank & Mustard, 1994). For example, persons of lower economic status have a higher risk of death “from heart disease, strokes, smoking and nonsmoking related cancers, gastrointestinal disease, accidents and suicides (Frank & Mustard, 1994, p. 8). As for education, women who do not finish high school have a 50% greater risk of heart attacks than college graduates (Barrett-Connor, 1993). Overall, research on Hormone Replacement Therapy throughout the 1990s failed to seriously address the issue of collinearity – the difficulty of differentiating between the effects of independent variables such as, lifestyle and socio-economic status.

Kaufert (1993) forewarned that we must be careful how we interpret the data from the *Nurses’ Health Study* when assessing who truly benefits from HRT. She raised many valid questions such as: what is the risk of developing heart disease for women who are neither white, nor middle class and can we safely use HRT to medically manage women with thyroid conditions or chronic diseases such as multiple sclerosis? In short, she questioned whether the HRT data was sufficiently robust to definitively identify the positive relationship between estrogen use and heart health. The answer to these questions, we know now, is, no! (Herrington et al., 2000; Hulley et al., 1998)

**New Findings**

The findings of the Heart and Estrogen/progestin Replacement Study (HERS), a randomized control trial of 2,763 postmenopausal women with pre-existing heart conditions, reported in the *Journal of American Medical Association* (*JAMA*), revealed that there was no reduction of coronary heart disease events with the use of HRT (Hulley et al., 1998). Of more concern, there was a significant 52% increase in coronary events among HRT users, compared to those in the placebo group. This study is pivotal in that it challenges the “heart” of the HRT marketing campaign.

In an editorial that appeared in the same issue of the *JAMA*, Petitti (1998) commented that “these findings are a sobering reminder of the limitations of observational research, the incompleteness of current understanding of the mechanisms of vascular disease, and the dangers of extrapolation” (p. 650) The beneficial effect of estrogen on heart disease is that estrogen has a lipid-lowering effect. Lipid lowering drugs (non-estrogenic) have been shown to “prevent CHD events in persons free of coronary disease (primary prevention), as well as those who have coronary disease (secondary prevention)” (p. 650). Even though estrogen can reduce lipids, it does not appear to be beneficial in reducing coronary disease occurrences in women with pre-existing conditions. Petitti also acknowledges what feminist social scientists have been arguing, that earlier studies linking the benefits of HRT use to heart health needed to be viewed “cautiously” because “women with healthy behaviours...may selectively use postmenopausal hormones” (p. 650). Notwithstanding these findings, Petitti concludes that patients should not stop using hormone therapy, as there are many other positive benefits – on bones and menopausal symptoms – that have been established. Curiously, such risks as breast cancer still pale in the HRT decision-making equation.

Further proof that estrogen did not benefit menopausal women with pre-existing heart disease was

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⁴ A longitudinal study – since 1948 – of American men and women to identify cardiovascular risk factors and “the effect of estrogen use on morbidity from cardiovascular disease in 1,234 postmenopausal women” (Wilson et al., 1985, p. 1038).
published in the New England Journal of Medicine two years later (Herrington et al., 2000). In this study, 309 menopausal women, who were diagnosed with coronary atherosclerosis, were either given HRT or a placebo for three years, on average. There was no significant difference found between the HRT and placebo groups and the researchers concluded that HRT should not be prescribed with the expectation of coronary benefits. More recently, the participants in the Women’s Health Initiative (a 15 year study that examines “the major causes of death, disability and frailty in postmenopausal women”) were told that healthy women “during the first two years [of estrogen use experience]…a small increase in the number of heart attacks, strokes, and blood clots” (WHI HRT Update, 2001).

Based on the above reported findings, the American Heart Association (AHA) now recommends that HRT should not be offered for secondary prevention of heart disease (pre-existing heart condition) (Mosca et al., 2001). As well, the AHA suggests that HRT should not “be initiated for the sole purpose of primary prevention of CVD” until further research results are available (p. 502). At the same time, however, they are not advocating that HRT be taken out of the menopause equation all together but, instead, “‘it can weigh into the decision; it just shouldn’t drive the decisions for women without heart disease’” (Mitka, 2001, p. 907).

Taking Precaution

The biomedical definition of menopause is implicitly rooted in an ideology that links hormones to health. But, medical claims about this linkage have proven to be dubious. Its osteoporosis-reducing effect may have been overstated. As well, synthetic estrogen is clearly not the magic bullet researchers had boasted in matters of heart disease protection. The research, designed to measure estrogen’s effect on heart health, ended up only measuring the relationship between lifestyle choices, socioeconomic status and heart health. At the same time, the evidence that linked hormones to adverse health risks - namely increased risk of developing breast cancer, venous thromboembolic events (Daly et al., 1996; Jick et al., 1996) and strokes (Mosca et al., 2001) – was either ignored or understated.

Throughout the 1990s, in response to women’s concerns over breast cancer, physicians compellingly argued that heart disease, not breast cancer, is the leading cause of death and, for that reason, the elevated breast cancer risk associated with estrogen use was minimized. Even though the estrogen equation has lost heart, estrogen continues to be recommended as the treatment of choice for most menopausal women. Once again, scientists and physicians blindly accept this drug and fail to investigate and weigh the evidence that suggests that estrogen is not beneficial, possibly even harmful.

The history of estrogen use is marked by controversy, in large part because the scientific research has been incomplete and the samples of midlife women who used estrogen were biased. In spite of poorly designed research, the findings were promoted as scientifically sound. It is time that we turn around our thinking on what is a good starting point for research on midlife women’s health. A new approach is required based on the precautionary principle, a concept that advocates that harm should be prevented before it occurs (Steingraber, 1998). Both public and private interests should take a better-safe-than-sorry approach in contrast to waiting “until damage is proven before action is taken” approach (p. 270). From this perspective, the current evidence on HRT conveys sufficient cause not to recommend HRT use until it can be unequivocally demonstrated that HRT will have a beneficial influence on postmenopausal women’s health. As things stand now, post-menopausal women are partaking in an uncontrolled experiment and they run the risk of future harm to their health. History’s harsh lessons should be heeded, not repeated.

More fundamentally, it is also time to reject the disease model of menopause that views midlife as a time of doom and gloom, when women are continuously confronted with impending health disasters. Women, as a result, become preoccupied with death, not life, and “menopause means you wake up overnight an alarmingly diminished person” (Gullette, 1997, p. 185). Research that is situated in a biomedical model, according to Voda (1993, p. 189), “does not seek answers to how women can most healthily live their lives; rather it seeks to cure women of being women.”

Over thirty-five years have passed since Robert Wilson published Feminine Forever and promoted estrogen use as the wonder drug to treat women’s menopause. Since then, many benefits have been ascribed to estrogen use; the most impressive one linked estrogen use to reduced risk of heart disease, the leading cause of death among older women. The reality today is that we have come full circle. The benefits ascribed to postmenopausal estrogen use are no different than those touted in the late 1970s; estrogen can help allay the symptoms associated with menopause and can help reduce bone loss. But, this does not mean we have not learned much about synthetic estrogen. We have! In spite of physicians’ repeated promises of estrogen’s safety, we have learned that there are many adverse effects associated with exogenous estrogen use. Estrogen increases the risk of breast cancer, stroke, VTE, and in
women who have pre-existing heart problems, estrogen can exacerbate coronary events. We have learned that, in spite of the proselytizing determination of the pharmaceutical companies to promote estrogen, women’s compliance rates have been low. Finally, we have learned that even though there are more adverse health risks than benefits associated with estrogen use, estrogen therapy continues to be routinely recommended for “healthy” menopausal women. The truth is that Canadian women today are expected to live to the age of 81, on average five years longer than their male physicians. Most of these women will never use estrogen therapy and will live their older years in good health.

Hence, what we still need to learn is more about the experiences of healthy women going through menopause, exactly what feminist scholars have been advocating for since the 1970s. As Greer (1992) points out, if “we do not know enough about the well woman” how can we “understand what has gone wrong with the sick one”(p.143). For all these reasons, it is urgent that biomedical researchers shift their research paradigms on midlife women’s health from a disease model to one that views menopause as a stage in life.
REFERENCES


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