

The Medicalization of Menopause

By Kathleen O'Grady

A media frenzy erupted recently when the news broke that an American federal study of hormone replacement therapy (HRT) was halted midway because study participants were at a significantly increased risk for breast cancer, heart attack, stroke and blood clots. The Women's Health Initiative (WHI), funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health, did something rare in the scientific world: they stopped their clinical trial for HRT 3 years before the scheduled study conclusion because their preliminary findings demonstrated that the serious health risks associated with the long-term use of combined estrogen plus progestin greatly outweigh any health benefits.

But the study results were no surprise to the many women's health organizations who have been following the questionable methods used to promote the prescription of HRT to healthy midlife women. Short-term use of HRT has been documented in a variety of studies as a useful treatment for alleviating the temporary symptoms associated with the onset of menopause, such as hot flashes, night sweats and vaginal dryness. However, long-term use of HRT (more than 5 years), and the practice of prescribing HRT to healthy women – those not experiencing severe menopausal symptoms – is another matter. The WHI results are only the latest in a long series of studies demonstrating that long-term use of HRT should be considered only with extreme caution.

Yet for more than a decade, healthy women have been advised by medical practitioners and medical advisory bodies to take HRT when they reach menopause as a means to prevent heart disease and osteoporosis. Some of the more dubious pharmaceutical marketing and advertisements for HRT insinuate even more sensationalistic claims, leading women to believe that HRT reduces the signs of aging, cures depression and incontinence, prevents the onset of Alzheimer's disease, and much more. In other words, HRT has been touted as the miraculous 'wonder drug' for midlife women. But somehow the science got lost along the way.

The last decade has seen an accumulated medicalization of menopause from a natural stage of a woman's life to an 'ailment' or 'disease' requiring a pharmaceutical 'fix'. Not incidentally, this occurred at precisely the moment when millions of baby-boom women across North America began entering midlife. The direct beneficiaries of the HRT-craze have been the pharmaceutical companies who have turned HRT into a multi-billion dollar industry. Wyeth, the makers of Premarin, the largest selling HRT formula in the US, sold US\$2.07 billion in Premarin prescriptions last year alone, making it the company's best-selling drug.

But the losers of the HRT craze have been precisely those midlife women who were supposed to benefit from the health claims associated with HRT. The latest WHI study results are clear: the relative risks for long-term HRT (combined estrogen plus progestin for more than 5 years) constitutes a whopping 41% increased risk for strokes; 29%

increased risk for heart attacks; a doubled risk for blood clots; a 22% increased risk for cardiovascular disease; and a 26% increased risk for breast cancer (numbers cited from the WHI study site: www.nhlbi.nih.gov/new/press/02-07-09.htm).

Some media reports have downplayed the relative risks by citing the actual number of women at increased risk and, at a glance, these numbers do appear meager; According to the WHI study, only 8 more women in 10,000 will have breast cancer, 7 more, a heart attack, 8 more a stroke, and 18, blood clots because of long-term HRT use. But when these numbers are evaluated with respect to the millions of women in North America currently on HRT, the result is in the range of tens of thousands of women at an increased risk. No wonder women are sitting up and taking notice. And the question that is on everyone's mind: how could healthy women have been encouraged to take HRT for so long?

The confusion surrounding HRT comes from a combination of millions of dollars being spent on marketing hype and a poor evaluation of the scientific data. For many years observational studies were used to tout the benefits of HRT and were employed as part of the pharmaceutical push to market long-term HRT use for preventative measures (and not simply as a temporary relief for menopausal symptoms, such as hot flashes). But observational studies and clinical experience are so called 'soft data' in the world of science – they are interesting, but too open to bias to constitute the necessary 'proof' of the efficacy and safety of a medication required before it is put into widespread use. For this, only randomized, double-blind controlled clinical trials – the gold standard for health research – can produce credible results.

WHI constitutes the first mass-scale controlled trial to address the long-term risks and benefits associated with HRT use for healthy women. In other words, the practice of prescribing healthy women HRT came *before* the medical evidence that should have underpinned HRT prescription guidelines. Other large clinical trials examining long-term HRT use have examined the practice of prescribing HRT to women with heart disease, such as the Heart and Estrogen/Progestin Replacement Study (HERS), and the Estrogen Replacement in Atherosclerosis (ERA) trial, which found that HRT does not reduce the risk of heart disease for midlife women, but as in the case of the HERS study, actually *increases* the risk for heart disease.

Over the years, these studies, and a large number of other, smaller trials, have shown long-term constant HRT to be good for preserving bone mass, but have also linked HRT to a long list of possible health risks, including breast cancer, gall bladder disease, cardiovascular disease, venous thromboembolism, biliary disease and more. Yet despite the troubling results from these shorter-term trials and the trials conducted on women with heart disease, HRT has continued to be routinely prescribed and recommended as a method of health preservation.

It would simply be too easy to lay the blame solely at the feet of the big pharmaceutical companies who can perform an important function in our health services, but who are also, we should never forget, in the business of turning a 'healthy' profit for themselves.

Rather, what needs to be addressed in this current HRT crisis – and it is a crisis, with millions of women across North America on some form of HRT regimen, and with breast cancer rates continuously on the rise – is the logic of prescribing medications that have not yet been tested thoroughly in extensive clinical trials to otherwise healthy women.

Who shall stand up and take the blame for letting ‘soft science’ and marketing triumph over sound medical research? Where were our independent medical organizations and governing bodies to sound the alarm? There have been more than enough warnings now that long-term HRT use comes with serious health consequences for midlife women, and that any benefits from HRT are more than outweighed by the risks. We can only hope for a revision of the medical and pharmaceutical guidelines that have perpetuated the promotion of HRT to healthy women in light of this new study. But one question remains: *why has it taken so long?*

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