The Pendulum Swings: Prescribing Hormone Replacement Therapy 13 Years After the Women’s Health Initiative Study

By John Fisch — August 2, 2015

It has been 13 years since the publication of the Women’s Health Initiative (WHI) studies in 2002 that examined the role of menopausal hormone replacement therapy (HRT) in the prevention of cardiovascular disease. It can be argued that never before or since has a medical study generated such controversy by the media and scientific community. To this day, the results are still being debated, reinterpreted and in many cases misinterpreted.

Estrogen was initially prescribed for vasomotor symptoms in the 1960s; by the end of the decade it was heralded as a fountain of youth, allowing women to maintain their femininity indefinitely. The pendulum swung the other way in the mid 1970s, when it was discovered that the use of estrogen alone increased the risk of uterine cancer. In the 1980s however, HRT use once again rose, as the addition of progestin reduced the risk of endometrial cancer and observational studies showed a decreased risk of CHD. Since women who took HRT lived longer, a protective effect was assumed and estrogen was prescribed to many older women without menopausal symptoms for cardioprotection. In 2002, the WHI the largest controlled trial of HRT ever performed was published. Overnight, the use of HRT declined dramatically. Not only did the study fail to show the anticipated protective effect against CHD, but it also showed increased risk of stroke, blood clots and breast cancer.

One of the biggest criticisms of the study was that, while the age of women studied ranged from 50 to 79, the mean age was 63, and that women who were younger and symptomatic with menopausal symptoms the group that was most likely to use HRT was excluded from the study. Unfortunately, results from the study showing the negative effects in the older age group were publicized as pertaining to all women at all ages, no matter how long they took HRT. This is false and misleading, but is still regarded as gospel by many women and their primary care providers. Upon reanalysis of the WHI, there was no increased risk of CHD in women age 50-59, and no increased risk of breast cancer in women using HRT for 5 years or less. Additionally, in women
who had had a hysterectomy and used estrogen alone suffered no increased risk of breast cancer after 7 years of use. In fact, women who were 50-59 and used estrogen alone had lower rates of CHD and reduced all-cause mortality. This information has not prevented patients from regularly proclaiming that they won’t use estrogen because it causes breast cancer, or patients who are on HRT being told by their PCP they need to stop taking it because it is bad for their health.

The pendulum now appears to be swinging the other way in favor of judicious use of HRT. There is now a critical mass of data supporting a timing hypothesis that suggests that starting HRT early in menopause is safe and effective while starting it late in life has no protective effect and has a higher risk/benefit profile. In addition, whereas the women in the WHI took one dose of HRT orally, newer formulations in lower doses and delivery options such as transdermal have enabled physicians to individualize treatment and provide HRT in the lowest effective dose for the shortest period of time necessary.

The challenge for gynecologists like myself will be educating patients and physicians alike about the true benefits and risks of HRT. In the coming years, major new studies will be published looking at HRT in younger menopausal women. Hopefully soon the pendulum can finally stop swinging and patients and physicians alike will have a much clearer idea of who should use HRT and who should not.

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