

Health Horizons

A FOCUS ON WOMEN'S HEALTH ISSUES



FROM THE OFFICE OF DR. STEVEN R. GOLDSTEIN

SEPTEMBER 2002



A Word From The Doctor

Recently one of my patients went onto the Internet after experiencing her first episode of abnormal vaginal bleeding. By the time she came in, as an add-on emergency, she was convinced it was either cervical or uterine cancer! It is this dissemination of questionable and frightening information that motivated me, sometime ago, to begin this periodic newsletter. It is time to educate my patients about common problems that do not have to produce the anxiety or even panic that I have all too often observed. Knowledge is power! The more educated you are about your body and how it works the better for both of us. After all we are a partnership – a partnership to help ensure your continued health and well-being. There are enough landmines in the fields of our lives without having to deal with any additional burden of ill health. So much of what I concentrate on is promoting wellness and if something does happen then early detection is our main weapon. With most traditional medical approaches a doctor is dealing with advanced disease process and then tries to put out "forest fires". In this office I want to blow out matches or at worst distinguish small brush fires before problems accelerate. Don't put it off - if you or your family are due call us and come and see me. If you have been a patient of mine and insurance problems have forced you to switch doctors, but like so many others you are just not pleased with the change in care "PLEASE" call our office, most of the time we can work out some arrangement.

Steven R. Goldstein, M.D.

After writing three medical text books and working his way up to full professor of Obstetrics and Gynecology at NYU Medical Center, Dr. Goldstein has recently turned to education of the patient. He currently has two books out which might be of interest to you, your friends or your family. The first Could it be ...Perimenopause? describes the unique phase up to a decade before your first hot flash when fluctuating levels of unopposed estrogen, (not the absence of estrogen seen in menopause) can cause some subtle or not so subtle bleeding abnormalities and subtle or not so subtle psychosocial symptoms (sleep disturbances, mood swings, free floating anxiety, inability to concentrate, memory lapses). The other book The Estrogen Alternative: what Every Woman Needs to Know About Hormone Replacement Therapy and SERMs, the new Estrogen Substitutes chronicles this important new category of compounds known as SERMs (Selective Estrogen receptor Modulators), how they were developed, what they can and cannot do, and if they might be right for you.

SPECIAL ISSUE

Please Read Carefully. If you personally are not concerned about HRT (Hormone Replacement Therapy) show this to a friend, family member, or a coworker who is.

Confused about HRT? What's a woman to do?

The recent media blitz about the article in JAMA (Journal of The American Medical Association) needs to be clarified and put in context. FIRST, NONE OF THIS IS NEW!! I have practiced with this knowledge for the last 4-5 years. The purpose of this study was to see if using HRT reduced heart disease. Realize that 10 years ago the feeling that HRT did reduce heart disease was so strong that cardiologists were sending patients to me to be put on hormones to prevent heart attacks. Wyeth (makers of Premarin) petitioned the FDA to change the label to include cardiac prevention. This was based on observational studies that showed women prior to menopause had a fraction of the number of heart attacks of men but after menopause they caught up very quickly, except that those women on hormones retained their protection. These were not randomized placebo controlled blinded trials. (The gold standard of medical research)

The WHI (Women's Health Initiative) was funded by Congress, and administered by The National Institutes of Health (NIH). This portion of it involved more than 16,000 women one half of whom got HRT (Prempro®) and one half got placebo. No one knew which group they were in. The endpoint was heart disease. In addition, they derived information on breast cancer, stroke, blood clots, hip fracture, and colorectal cancers. Every six months the data was reviewed and if the benefits (good effects) or the risks (bad effects) surpassed a pre-agreed upon level of significance, the trial was to be stopped. In the first 2 years, there were more

cardiac events (heart attacks) in the HRT group but the numbers were not conclusive enough to stop the study. A letter however was sent out to all the investigators and participants informing them of this. This came on the heels of HERS study (Heart and Estrogen/Progesterone Replacement Study) where women with heart disease got either placebo or Prempro for an average of 4.1 years, and not only was there no benefit from HRT, there was some actual increased risk in the first year. Thus, when the WHI was stopped this lack of benefit in the heart did not come as a surprise. To put it into context among the women not on HRT (placebo group) the rate of "cardiac events" was 30 per 10,000 women per year. If they were on HRT it went up to 37 per 10,000 women per year. That is an additional seven women per 10,000 or a 29% increase in the relative risk. 29% sounds like a huge number (especially in these trying economic times) but that is 1.29 times the placebo group (baseline). To put this in perspective the increase in relative risk of lung cancer from smoking cigarettes is 12.0 times baseline or 1200 % increase!! Furthermore the study did not sub analyze who is more likely to be in that 7/10,000 women. Many patients think this is random (almost like losing the lottery!) Clearly, a woman with other risk factors (smoker, high cholesterol, high blood pressure, strong family history) has more concern than someone without risk factors! Still if there were MD's giving HRT or patients taking HRT before July of this year for prevention of heart disease then this media blitz was an appropriate wake up call!

What About Breast Cancer?

Several previous studies have shown that long term HRT use is associated with an increased risk of breast cancer. The most recent, prior to this WHI study, found that women who took HRT for more than 4 years had a 40% increase in risk (once again 1.4 times the baseline group). If they took estrogen only, which you can really only do if you have had a hysterectomy, since progesterone prevents pre cancers and cancers of the uterus associated with estrogen only, (which is also referred to as "unopposed estrogen") the increase was only 20%. So, similar to the foreshadowing in heart disease, this 29% increase in breast cancer in WHI also did not occur until 4 years and is NOT NEW NEWS

Other Effects of HRT from WHI

There was a 41% increase in stroke, (8 women per 10,000 per year) a doubling of blood clots, but a 34% decrease in hip fracture, and a 37% decrease in colorectal cancers. This WHI study did not address taking HRT for relief of disruptive menopausal symptoms in order to regain ones equilibrium. (see below) Still it seemed to prove that there is NOT enough long-term benefit to counterbalance long-term risk to advise women to take HRT for PREVENTION OF DISEASE (i.e. maintaining long term health).

So Who Should Take HRT?

In my mind for several years now the indication for HRT has been and continues to be relief of disruptive transitional symptoms – sleep disturbances, hot flashes, etc. I am a male gynecologist. I will never have a hot flash. This however allows me to be totally objective. I have had very articulate capable women whose judgment I trust tell me they felt like they hit a brick wall ("... I couldn't put two intelligent sentences back to back..." "...I couldn't run a meeting..." "... I felt like I was coming out of my skin...") These women CAN and DID benefit from short term HRT use. What is short term? It varies. After 12, 18, 24 months I recommend a weaning of HRT ("taper and washout"). If the symptoms recur, then a patient can resume the medication. If the symptoms do not, she is better off no

longer taking it. If someone doesn't successfully wean off at age 52 or 54 they can try again in a year or two. Over time, most women's symptoms will dissipate.

Was The Choice of HRT (Prempro) the Wrong Brand?

No one can say. There are now several ways to give HRT besides Prempro. In my opinion although different formulations may have somewhat different rates of benefit or risk – I believe that much of them, once metabolized through the liver, are basically similar and I would not expect that merely a different brand would give totally opposite results.

What About Natural Products?

Many herbs or products you can get at the health food store are very estrogenic (Black Cohosh, evening primrose oil, Dong Quai). These are metabolized through your liver as estrogen. You are deluding yourself if you automatically equate "natural" with "risk free." All medicines have their origins in botanicals. These are not regulated by the FDA and the quality control is not nearly as well scrutinized as pharmaceutical products.

The Bottom Line

Women on HRT have to ask "Why am I on this?" If the reason is relief of symptoms then perhaps it is time to consider a trial of "taper and washout", just to see what happens. I have been doing this on long-term users for at least 4-5 years. In my experience about 80% of women who are, 3-4 years into menopause will successfully get off HRT. The others end up back on it but it is for TREATMENT OF SYMPTOMS, disruptive symptoms, and not simply continuing it because no one wants to rock the boat.

Future Role of Serms (Selective Estrogen Receptor Modulators)

Many of you know that I have been involved in studying this new category of drug. The SERMs (currently Evista, although others are in trials) have been out for 5 years and in ran-

domized prospective placebo controlled trials they 1) build and preserve bone density and have thus reduced osteoporotic fractures. 2) significantly reduce breast cancer compared to placebo and 3) in preliminary data, in women with osteoporosis at risk for heart disease, they significantly reduced heart attacks. These drugs may deliver the promise that HRT failed to fulfill, which is, to extend long term women's health. Many women ask why doesn't everybody take them? The problem is they are NOT estrogen. They do not relieve hot flashes, and/or dry vagina. They are best suited for women at least 3-4 years into menopause who no longer have symptoms. They often require some local vaginal estrogen in women who are sexually active.

Still confused? Still concerned. Give Dr. Goldstein a call or come in for a consultation. Remember knowledge is power.

NEWS FLASH:

Italian study shows Goldstein Catheter gives best results with most patient satisfaction.

As many of you know Dr. Goldstein has been a pioneer in saline infusion sonohysterography (SIS)- the technique of putting a little saline into the uterus through a tiny plastic catheter to improve the transvaginal ultrasound diagnosis and reduce biopsies and D&C's up to 79%!! He has developed a catheter known as the Goldstein sonohysterography catheter. A recent Italian study compared four different devices for sonohysterography. While they all had relatively equal diagnostic results the Goldstein Catheter got the highest score for patient comfort and satisfaction. This study and its data is very gratifying to him. Next time you are in ask to see a copy.

Over Active Bladder/ Urinary Incontinence

In the past, the only approach to urine loss (accidents) was surgery. There are now medications available depending on the cause of the problem. Dr. Goldstein has started to do urodynamic testing. It is painless, takes about 10 minutes, and involves measuring pressures in the bladder and urethra. It is totally covered by virtually all insurance including Medicare. If you have urinary issues please bring them to his attention!

**HEALTH HORIZONS will be published three time a year.
If you would like to see a specific health issue addressed, please contact us at:**

**Dr. Steven R. Goldstein, M.D.
Professor of Obstetrics & Gynecology
New York University Medical Center
530 First Avenue, Suite 10N • New York, NY 10016
Phone: 212-263-7416 • Fax: 212-263-6259 • www.goldsteinmd.com**