Transcript Details
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The Impact of Menopausal Hormone Therapy on Patients & Clinicians

Narrator: Welcome to Clinician's Roundtable on ReachMD. The following activity, titled "The Impact of Menopausal Hormone Therapy on Patients and Clinicians" was recorded at Omnia Education's Women's Health Annual Visit.

Your host is Dr. Thomas Wright, Jr.

Dr. Wright:

On today's program, we'll focus on current clinical practice recommendations for the treatment of menopause-related symptoms, and the effects of hormone therapy on various health conditions throughout a woman's life.
This is ReachMD and I am Dr. Thomas Wright. Joining me is Andrew Kaunitz, Professor and Associate Chair of the Department of Obstetrics and Gynecology at the University of Florida College of Medicine, where he also serves as Director of Menopause and Gynecologic Ultrasound Services at Southside Women's Health.
Dr. Kaunitz, thank you for joining our program today.

Dr. Kaunitz:
Happy to be here.

Dr. Wright:
To start, can you explain what misperceptions regarding the safety of hormone therapy persist and why?

Dr. Kaunitz:
The Women's Health Initiative, which was this largest clinical trial ever sponsored by the National Institutes of Health, the initial findings were published in the summer of 2002 from the WHI. WHI enrolled women of a broad age range, from 50 to 79, and yet we know that the women coming to us, for instance, for treatment of menopausal symptoms, are women from their late 40s to early-to-mid 50s. Few of us in this room have seen a woman in her 60s or 70s come to us to initiate treatment for hot flashes or other related menopausal symptoms. And yet, we enrolled women aged 50 to 79. The median age at which we enrolled women in this massive clinical trial was 66 years of age. So, when the findings came out, the initial findings in 2002 were published in the journal JAMA, and generated tremendous anxiety among, not only clinicians, but women in the U.S. and worldwide. The findings showed small elevation in risk of breast cancer, heart disease, stroke, and yet these findings applied to the entire study, women again, aged 50 to 79. These small elevated risks, particularly that with respect to breast cancer and heart attack, created tremendous anxiety. The number of women using hormone therapy in the U.S. and worldwide plummeted, and remains very low in the U.S. and in other parts of the country. it's only more recently, it's only in the last 5 or so years, we've seen recent publications from the WHI looking at age stratification, Dr. Wright.
And when we just look at what I call the clinically relevant age, which is women within the first 10 years of menopause, those women, hormone therapy, in fact, was very safe. We did not see any elevation in risk of heart attack. And it allows us, including guidelines recently published from the North American Menopause Society, our 2017 Hormone Therapy Position Statement says very clearly that for age-appropriate women, women within 10 years of the onset of menopause, with bothersome menopausal symptoms like hot flashes, hormone therapy is appropriate.

Dr. Wright:
Right. It's a very different message than what people, even currently, talk about. A second question that I have for you today is, how does the safety of estrogen- progestin therapy, we call that EPT, compare with that of estrogen-only therapy, or ET?

Dr. Kaunitz:

Something we learned from this large clinical trial, where we randomized of some 16,000 women with an intact uterus to EPT versus placebo, and about 9,000 women post hysterectomy to ET versus placebo, we learned that there are differences in terms of the impact of EPT and ET. Specifically, there appears to be a small, but apparently real, elevation in risk. In fact, we saw that there was a between 1.2 and 1.3, a small elevation in risk, of being diagnosed with invasive breast cancer in women randomized to EPT versus placebo. I counsel all of my patients, who have an intact uterus and they're thinking of starting hormone therapy for vasomotor symptoms, I'll counsel them regarding this small elevated risk of breast cancer with EPT. And one way of counseling women, a quantitative or evidence-based approach would be to say, "In Women's Health Initiative, there was less than one additional case of breast cancer diagnosed per thousand users." And I might add that some women will say, "Well any increased risk, it's not for me," I'm not going to prescribe this. Other women will say, "Is that all they're talking about? Is that all that's worrying women, because that's not a big elevation in risk." But we have to recognize our patients don't always appreciate describing risks in a quantitative fashion. So qualitatively, we can use other examples that some women may understand better. I'll also say, if it's appropriate, the elevated risk of breast cancer with hormone therapy use is similar to that of moderate alcohol consumption. It's a little bit more than that associated with one glass of wine with dinner a few nights a week, and a little less than that associated with two glasses of wine with dinner a few times a week, and that may help put this in perspective. There seems to be an elevated risk; it is a small elevation in risk.

Dr. Wright:
Just as an aside, many of the epidemiologists that I work with, and we do lots of large screening studies, they generally assume anything which has a relative risk of under 2 to be marginal, at best. It's really, for clinical significance, they'd like to see something over 2.

Dr. Kaunitz:
Sure.

Dr. Wright:
So 1.2/1.3 would be really borderline of significance.

Dr. Kaunitz:
Absolutely. Even in a large clinical trial, because we can't totally rule out the possibility that there was some un-blinding in the women with an intact uterus who, after all, were more likely to bleed on hormone therapy than on placebo therapy. So, there was the potential that participants or study investigators could have, to a small degree, become un-blinded. Could this have explained the small elevation in risk, or is this biologic cause and effect? I don't know, but I do counsel women, and I would encourage you out there, listening in, to counsel women that estrogen-progestin therapy, longterm, is associated with a small elevation in risk of being diagnosed with breast cancer. In contrast, when we prescribe estrogen-only therapy to women post hysterectomy, WHI clarified, but other studies have also clarified, that we do not see, I'll repeat, we do not see an elevation of risk of breast cancer with use of estrogen-only therapy. And that was very clear with WHI where, in fact, we saw a statistically reduced risk with conjugated equine estrogen, which is the estrogen used in WHI, and this reduction in risk was found to persist 13 years after use of study medications.

Dr. Wright:
What about coronary heart disease? We've been talking about breast cancer. What about coronary?

Dr. Kaunitz:
So, the biggest concern that women have, in terms of outcomes with hormone therapy, clearly is invasive breast cancer; but heart attack was also in the headlines in 2002, with that JAMA article, and was very frightening. Overall, there was a small elevated risk of a heart attack; however, again, it's all about age. And when we look at the younger subgroup, women within 10 years of the onset of menopause, or women up to age 60, who are randomized to hormone therapy or placebo therapy, there was definitely no elevated risk of heart attack. If anything, there was a lower risk of being diagnosed with a myocardial infarction, and a lower risk of dying from coronary heart disease. So, when we prescribe systemic hormone therapy to appropriate candidates, that is younger menopausal women, women up to age 60, initiating hormone therapy for bothersome symptoms, we do not elevate risk of coronary heart disease.

Dr. Wright:
Great. What do the NAMS guidelines say regarding patient safety and preferred administration routes for hormone therapy?

Dr. Kaunitz:
Thank you for giving me an opportunity to talk more about NAMS. So, NAMS is a multidisciplinary organization of over a thousand physicians, over 2000 clinicians including physicians, nurse practitioners, nurse midwives, psychologists. It's very international. We have Canadian, we have Mexican, and South American, European, Asian and African members, that all come to our annual meeting. And it's an organization devoted to educating colleagues about menopause. And we issued our updated 2017 guidance regarding hormone therapy earlier this year, Dr. Wright.

Dr. Wright:
Excellent. So, what do they say about patient safety and preferred administration routes for hormone therapy?

Dr. Kaunitz:
So, Women's Health Initiative only looked at oral estrogen or estrogen-progestin. It did not examine other routes of estrogen or hormone administration. And yet, we know that from observational studies, many observational studies conducted in North America and Europe, that patch estrogen, or transdermal estrogen, compared with oral estrogen does not appear to have an impact on risk of venous thromboembolism, or VTE, DVT, pulmonary embolism. And so, NAMS mentions in its guidance that although we don't have randomized, controlled data comparing oral and transdermal route of administration, it is reasonable, based on observational evidence, that in women at higher risk for VTE, and that, in general, is women with higher BMI, because BMI is clearly an independent risk factor for VTE. So, overweight, and particularly obese women, in my practice, I almost exclusively use transdermal or patch estrogen as opposed to oral estrogen when treating menopausal symptoms.

Dr. Wright:
That's great. Does NAMS have a position on the use of compounded bioidentical hormone therapy?

Dr. Kaunitz:
NAMS and others have done surveys recently .More than 2 million women are currently using compounded hormone therapy in the U.S., and few of those women are aware that it is not FDA approved. We have seen cases of endometrial cancer reported in women using compounded estrogen and compounded progesterone cream, of which the absorption is variable and limited and often not sufficient for endometrial protection. We have seen that compounded--practitioners who sell compounded hormone therapy to their patients, which is characteristically not covered by insurance, will often recommend salivary and serum hormone level testing, and yet, for instance, NAMS recommends that routine assessment of serum hormone levels is not a routine part of menopausal practice. And furthermore, salivary hormone levels do not correlate whatsoever with serum. So we, along with the American College of OB/GYN and FDA, do not recommend routine use of compounded hormone therapy. They're not standardized; the safety, the quality, the dosage delivered. None of this is standardized or placed under surveillance as it is for FDA-approved formulations. And we have excellent bioidentical, or natural, estrogen and progesterone formulations. I mentioned earlier, oral estradiol, that's natural estradiol. That's what I use when I prescribe oral estrogen to my patients; $4 a month, natural bioidentical oral estrogen. Micronized oral progesterone is available as a generic and at 100 and 200 mg doses. It should be taken at night, because it makes women sleepy. And also, many of the vaginal estrogen formulations I mentioned this morning, including estradiol cream, the estradiol tablets, and the estradiol ring, are all natural bioidentical, but importantly, FDA-approved formulations.

Dr. Wright:
And non-compounded.

Dr. Kaunitz:
These are not compounded. These are standardized, monitored, FDA approved. And, as I tell my patients, "I don't sell any medications or hormones; all I sell is my expertise, if I have any, and you will have to go to the pharmacy to get your medications. We don't dispense any of them here."

Dr. Wright:
Thank you very much, Dr. Kaunitz. It's been a pleasure having you here today on ReachMD.

Dr. Kaunitz:
Thank you, Dr. Wright.

Narrator:
This has been an episode of Clinician's Roundtable on ReachMD, provided in partnership with Omnia Education.
Thank you for listening.