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Menopause Reimagined: The Role of Hormonal IUDs in Perimenopausal Care

Announcer:
You're listening to *Advances in Women's Health* on ReachMD. Here's your host, Dr. Mary Katherine Cheeley.

Dr. Cheeley:
Welcome to *Advances in Women's Health* on ReachMD. I'm Dr. Mary Katherine Cheeley, and joining me to discuss how hormonal IUDs can help protect endometrial health in perimenopausal patients is Dr. Mary Jane Minkin. She's a Clinical Professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at Yale School of Medicine, and the Co-Director of the Sexuality, Intimacy, and Menopause Program at Smilow Cancer Hospital in New Haven, Connecticut. Dr. Minkin, thanks for being here today.

Dr. Minkin:
Oh, Dr. Cheeley, thank you so much for the kind invitation to join you. A pleasure being here.

Dr. Cheeley:
So let's start with a little bit of background. Can you help us understand the historical context behind the use of menopausal hormone therapy and the impact of that black box warning on prescribing practices?

Dr. Minkin:
Well, unfortunately, a black box warning did appear—or some people just call it the box warning, officially—on hormone therapy shortly after the release of the preliminary batch of data from the Women's Health Initiative back in 2002. This was a large study, for those people don't know about it. It was not designed to study everything about hormones; it was basically designed to evaluate if estrogen therapy helps prevent heart disease. That was the real game plan in this whole study.

And they were looking at a few other issues along the way, and what the study ended up doing was being called before it was officially finished, because of some adverse events that happened. And the adverse events that they were concerned about was, did the combination of estrogen therapy with progestin therapy, which was needed to protect the lining of the uterus—so that's a very important concept that we need to talk about here—did the addition of progestin to estrogen therapy increase the risk of breast cancer? Did that expose women to breast cancer?

And indeed, what the study showed was that this safety data and a monitoring board said, "Yeah, there was a very, very slight increased risk of breast cancer in the women taking estrogen plus synthetic progestin therapy," and the WHI study was halted early. And then subsequently, very shortly thereafter—within the year—folks started saying, "Well, maybe we should put warning things on boxes of hormone therapy to say, oh, this is dangerous stuff for women."

And basically, again, once women in the United States heard any mention of the word breast cancer, it became, "No, we're not going to do this. This is something we're definitely not interested in." And the use of estrogen therapy plummeted.

Now, of course, it was nice that we basically had a lifting this summer of the boxed warning about the use of estrogen. It originally started as removing the black box warning from vaginal estrogens, but then subsequently the black box warnings were removed from a combination of the systemic estrogens, not just vaginal estrogens.

Dr. Cheeley:
Yeah, so tell me a little bit more about that. I know that the black box warning, like you mentioned, was taken out this summer. How do you think that information has gotten to patients? How do you think that they're hearing about it, or changing that tide? How's that occurring?

Dr. Minkin:
Well, I think they're hearing about it because they're showing up in the office, so they must be hearing some good news about it.

And one thing that I can tell you is, I give a fair amount of talks, and the talk that I've put together now to bring awareness and teach young folks about these issues—the title that I'm using is Menopause: From Forbidden to Favorite Topic, and that's what we're seeing. I mean, this was a topic that nobody cared about, and now we've got all these younger women interested in this topic, because they're also realizing that they don't have to feel miserable, that maybe it is okay to feel good.

And we do explain to people why we can't just give them estrogen. Many of these young women come in looking for estrogen, and it's very nice, I'm happy to give you estrogen, but you got a uterus in there. And guess what the uterus is designed to do? So we've got to protect the lining of the uterus from just giving you estrogen, and we've got to give you some progesterone or progestin in some form. But we can give it to you in a local therapy, which we can place in the uterus. It lasts for a long time. Basically, we know the progestin protection given with levonorgestrel-coated IUD lasts for five years. The contraception protection goes on for about eight years—that we've known for quite a while—which is great.

And one of the problems in perimenopause is that, fortunately or unfortunately, women are still making some estrogen in a sporadic fashion. And I'm giving them estrogen on top of that. So I may be giving them the setup for a lot of bleeding, because estrogen is basically—as one of my good friends comments—the former chair at University of Colorado, Dr. Nanette Santoro, uses the example of saying that estrogen is like fertilizer and progesterone is the lawn mower, as far as, basically, taking care of the lining of the uterus, and that we have to mow that lawn if we're going to grow the grass. And I think it's a beautiful analogy, and I think it makes sense to most people.

Dr. Cheeley:
Yeah, talk to me a little bit more about that. So treat me like I'm your resident, or like I'm that youngin' that you're going to teach. Why does it matter? Why is it important to have that endometrial protection for women who are getting systemic estrogen if they're perimenopausal?

Dr. Minkin:
Okay, I can give you historical perspective, because I'm old, and that's a definite advantage of being old. When I was a little girl—this is true—we didn't give progesterone to people; we gave them just estrogen. And to be honest, there were very few people who got uterine cancer. People, and some of the youngins' think, "Oh, all these people were dying of uterine cancer." They were not, but we did have a few cases of uterine cancer.

And it really wasn't until the 1970s—and remember that the first estrogen product was approved in the United States in 1942, which is even older than I am. Yes, 1942. So anyway, for many years, people just gave estrogen unopposed. And then when they saw this increased number of women developing uterine cancers, they had the bright idea, "Well, how does nature keep us from getting cancer of the lining of the uterus from our ovaries making estrogen?" Well, the ovaries are smart. They make progesterone also, because when they're trying to prepare that lining of the uterus for a baby, we got to prepare it, and that's where the progesterone comes in.

So then people had the bright idea, "Well, let's sort of follow Mother Nature and give some progesterone cyclically, just like our ovaries do, and help clean out the lining of the uterus." Great. That was very nice, except then you got a period, and that wasn't so much nice. That was not the good part. Getting the uterus clean was good. So anyway, folks started fooling around with, "Well, maybe we can give progesterone or progestins in the first place." We did not use natural progesterone, and we would give progestin, basically to prevent people from getting periods. We'd give them a small dose of progestin on a daily basis, which would prevent the growth in the first place. And then ladies were happy they didn't have to get periods.

But unfortunately, a couple things happened. This is all nice when this is predictable and stuff like that, but perimenopause is not predictable, so you end up with people bleeding all the time, and that's not a good thing.

So one of the nice advances that was also going on concomitantly, as the same time as all the rest of this stuff, was the development of an IUD that was coated with levonorgestrel, which is a good, active progestin. And folks discovered that if you coated the IUD with this levonorgestrel, you could actually prevent the growth of the lining in the uterus in the first place, which was very nice. And the other nice benefit was it made for nicer periods, or even better, no periods.

And then folks had the brilliant idea. "Well, this is very nice, this is nice for protecting the lining of the uterus, and this is nice for keeping us from getting pregnant." Because, of course, the developments were as contraceptive, and we were giving people local progestin to basically make a hostile environment in the lining of the uterus, and even more important, in the cervical mucus, for keeping the sperm from getting up inside, which is very nice if you don't want to get pregnant. But then folks had the bright idea, "Well, when we give

estrogen therapy, we might grow the lining of the uterus. So what if we put this progestin in the middle of the lining of the uterus? Maybe it'll protect it." And lo and behold, it did.

Dr. Cheeley
For those just tuning in, you're listening to *Advances in Women's Health* on ReachMD. I'm Dr. Mary Katherine Cheeley, and I'm speaking with Dr. Mary Jane Minkin about the role of hormonal IUDs in endometrial protection for perimenopausal patients.

So Dr. Minkin, let's jump back in. Let's look at the current clinical guidance. The American College of Obstetrics and Gynecology recognizes the role of hormonal IUDs in providing endometrial protection for the patients that we're talking about. How is that guidance being applied today in clinical practice?

Dr. Minkin
I think it's being widely applied because certainly— and one of the things, again, to go back to the fact that I'm old—we used to have very high rates of hysterectomies. A lot of women had hysterectomies.

And, of course, as we get older, we develop things like adenomyosis. We develop things like fibroids, including submucous fibroids, all of which lead to bleeding. And people started realizing that we can not only help control the bleeding, but we can help control the excessive growth of the endometrium on spontaneous things. People ended up with endometrial hyperplasia on their own, and then folks had the bright idea, "Why don't we use this when people get estrogen therapy?" Because we have to protect the lining of the uterus there, and it's a lot nicer for many people to use local therapy than systemic therapy.

So what if we use these intrauterine devices coated with progestin? We can achieve a very good level of progestin locally without giving them a systemic progestin. And many women just don't like these synthetic progestins. They get sore breasts. They get irritable. They get headaches. They get mad at me. And these are not good things. And that if we can get rid of these side effects and we can protect the lining of the uterus, well, that's great.

Dr. Cheeley
Yeah, so talk to me about your patients who are over 40, and you're talking to them about an IUD. Because the thought, like you mentioned, is they were originally created for contraception. So help me understand how you talk to your 40 plus-year-old patients about IUDs, not necessarily being used for contraception—although, to your point, perimenopausal women are still at risk of getting pregnant, so that is part of the magic there. But how is that part of their hormone therapy plan that they have for their menopausal symptoms?

Dr. Minkin
The key thing is I always try to explain physiology to a patient, because if the patient understands why we want to do something and why we would suggest this is a good idea for her, she's going to be a lot happier, and she's going to be a lot more compliant with the therapy. She's going to think about it as an option for and say, "Gee, this makes sense." Okay?

So these are all very important concepts, and I think if you explain this to patients, you can say, "I can give you local therapy, okay, as opposed to systemic therapy." And when does somebody get sore breasts? Is she going to get sore breasts from putting some progestin in the lining of her uterus? No, she doesn't, because the amount that's absorbed is very small. We have studies showing very, very limited absorption—not none, but very limited. But if we can give her extra progestin where she needs it, which is right on the lining of the uterus, we can really help prevent the overgrowth there and manage her menopause and perimenopause quite effectively without giving her systemic side effects.

Dr. Cheeley
So what key considerations should clinicians keep in mind when they're integrating hormonal IUDs into their practice?

Dr. Minkin
Well, there are a few things you need to know. You need to know what women are concerned about. And of course, again, I don't want to dump on social media, but there's a lot of stuff in social media about how you're going to die if you do this, why not do the other thing, and you're going to have a lot of pain. And do people who have IUDs get pain when the IUD is inserted? Yes, you can have some pain, but there are ways to mitigate that pain. We can give our patients, if you want, blocks, or you want to use different kinds of TENS therapies, or things like that. There are all these other options that we have for patients.

And again, I also tell anybody I'm putting in an IUD for, "Listen, if at any point you say stop, we stop." And that's it. We're not going to torture you. We'll say stop. So I think we can get over the pain and the discomfort.

And then we can tell them, "Okay we're going to do this," and again, you have to inform them, "I'm not going to stop your bleeding tomorrow. I don't want you to call me in a week and say I'm bleeding." You know what, you're going to be bleeding. If you're bleeding heavily, I've got to know about it. But you're not going to be guaranteed instant amenorrhea. For the first few months, you're going to

have some bleeding, and it may be unpredictable. So I want you to have a few pads or tampons with you just to make sure.

But what's good is, within a few months, those periods start to get a lot lighter and maybe disappear altogether. And most people are pretty happy about that. Now, again, one thing that I do always go over with a patient is that if you are somebody who's still getting periods on a reasonably regular basis, I may be stopping your periods. Now, most people say, “What, are you crazy?” And “Not having a period is good.” Some women do want a period, and if they do want a period, I don't want to give them an IUD that’s a levonorgestrel-coated IUD, because they may stop getting periods, and that may not make them happy. But then again, if you have any consequence, you can go in and take out the IUD. So, say, if you don't like it, if you're having more cramps—"My cousin Susie six times removed had an IUD put in, and she was miserable and horrible”—if you're miserable, we'll take it out. Don't worry.

But you have to discuss these things and respect the patient's concerns, because they're legitimate concerns, and you want to make sure that she's comfortable with the right decision. I mean, this is a term that came about long after I was practicing: shared decision-making. And when the term came about, I was like, “I hate this term. It's stupid.” And people said, “You of all people, why are you saying that?” And I said, “Well, because that's called being a good doctor.” Shared decision-making is being a good provider, a good practitioner. You're saying you have to tell the patient what's going on. Yes, you want to discuss physiology, but you have to say, “This is what I'm going to do now, and this is why, and this is important.” And it's a decision between the two of you. It's not your own decision to say, “This is what you're going to get.” I think that's very important.

Dr. Cheeley
I think so too. This has been such a great discussion. I have really enjoyed it. Thank you so much, Dr. Mary Jane Minkin, for joining me to discuss hormonal IUDs and how they can play a supportive role in endometrial health in perimenopausal patients. It was so lovely chatting with you.

Dr. Minkin
Oh. Thank you very much.

Announcer:
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