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# Optimizing Breast Health: Managing Fibrocystic Breast Changes and Mastalgia

NARRATOR:
Welcome to CME on ReachMD. This segment, “Optimizing Breast Health: Managing Fibrocystic Breast Changes and Mastalgia is sponsored by Omnia Education and supported by an educational grant from BioPharmX.

Your host, Dr. Brian P. McDonough. Dr. McDonough will speak with Dr. Lee Shulman from Northwestern University in Chicago, IL; Dr. Shawna Willey from MedStar Georgetown University Hospital in Washington, DC and Susan Wysocki, WHNP, FAANP from Washington, DC.

Dr. Shulman has disclosed that he is a consultant for Bayer, Teva, Merck, Sequenom Inc., Shionogi, and Pfizer. He also serves on the commercial Interest speakers’ bureau for Bayer, Teva, Merck, Shionogi and Watson.

Dr. Shawna Willey has disclosed that she receives consultant fees from Genomic Health, Genetech,

and BioPharmx; and is part of the Commercial Interest Speakers Bureau for Genomic Health, Genetech, and Medtronic

Susan Wysocki has disclosed that she is on the commercial interest speakers' bureau for Teva, Merck, Novo-Nordisk, Watson, and Pfizer. She has also discloses that she is a consultant for Johnson and Johnson, Shionogi, and Church and Dwight.

Dr. McDonough has nothing to disclose.

This CME activity is supported by an independent educational grant from BioPharmX.

After listening to this activity, participants should be better able to:

- Confidently identify and evaluate patients who show symptoms of fibrocystic breast disease/mastalgia
- Demonstrate an understanding of various treatment options for management of fibrocystic breast disease/mastalgia

Since this online Panel Discussion was initially launched last year here on ReachMD, there have been noteworthy updates to share with you. Regarding educational outcomes… looking retrospectively at Omnia Education's analysis of the knowledge and practice gaps associated with diagnosis and management of fibrocystic breast changes, cyclic mastalgia, and general breast health management during the course of our educational activities in 2014 and 2015, we continue to identify gaps among all learners. In the interest of improving practitioner knowledge, proficiency, and patient outcomes we are presenting you an updated version of Optimizing Breast Health: Managing Fibrocystic Breast Changes and Mastalgia.

Dr. Brian McDonough:
Joining me today are Dr. Lee Shulman, Dr. Shawna Willey, and Susan Wysocki. Welcome to the program.

Susan Wysoki: Thank you.

Dr. Lee Shulman: Thanks very much for having us.

Dr. Shawna Willey: Yeah. Thank you.

Dr. Brian P. McDonough:
I'll start with Dr. Shulman. What are the common breast problems that typically cause women to seek a physician's help?

Dr. Lee Shulman:
Clearly women are very concerned about breast health. In fact, you could potentially even make the argument that they are over concerned about breast health. Fear of breast cancer is something that is ubiquitous in our society, tends to increase as a woman ages, and as a result almost any change in her breast well-being could lead her to seek a physician's help. But when we take a look and break down those issues that lead a woman to consult a clinician regarding something with breast health, invariably there are two major things. The first is pain, something that is different than the pain or discomfort that a woman may perceive on a chronic basis and obviously, the second thing is a lump or bump or something that wasn't there or perhaps something that may have been there but has changed. Those are really the two most common overall breast problems that really lead a woman to make an appointment with her health provider to seek some sort of assessment, and for the most part to seek reassurance that everything is okay and it is not a malignancy.

Dr. Brian P. McDonough:
Susan, what is the approach with evaluating women complaining of breast pain?

Susan Wysoki:
First of all, I echo Dr. Shulman's assessment of the things that are most likely to bring a woman into a clinician's office. Pain or a lump, you know, certainly when it comes to breast pain that's really quite common and so there's a lot of reassurance that needs to be done in terms of letting women know that pain with oral contraceptives, pain with breastfeeding, pain with cyclical changes are quite common. So reassurance for me is important. In terms of lumps and bumps and all those things, it's important for women to understand that breast tissue is lumpy to start with and that understanding or getting to know what their lumps and bumps are helps them to identify when those lumps and bumps change. The last thing is that no clinician should ever ignore a woman who says that something has changed and she's concerned about it. That's very important.

Dr. Brian P. McDonough:
That is a really important point. I agree that when you see a patient you want to make sure that you listen to what they have to say and take it seriously because they obviously have some thought there's something that's bothering them. Others have comments about that point?

Dr. Lee Shulman:
I'll also echo Susan's statement. I remain shocked with how many patients I see on a regular basis who have come to see me because their clinicians, and I'm going to even say women's healthcare providers, have been dismissive about something that they have been informed about. “Don't worry about it. Wait a few weeks. Wait a few months.” Now, I don't think any of us as busy healthcare

providers wants to be jumping through hoops. It's sort of the cry wolf situation, but I cannot agree with Susan more that there is no issue that doesn't at some point require an assessment, perhaps not that same day or even in the next day, but being dismissive of pain or what is truly unbelievable is dismissive of a new or change in the breast contour that is appreciated by the patient. The evaluation assessment isn't very long and I understand that all of us have stresses and pressures with getting patients through our office but it just boggles my mind that there are still so many women out there who are being dismissed by their clinicians about true and real clinical issues that really require assessment.

Dr. Brian P. McDonough:
All good points. I want to turn, if I could now, to Dr. Shawna Willey and I wanted to ask you what exactly is mastalgia and what is its relationship to fibrocystic breast issues.

Dr. Shawna Willey:
Well, mastalgia if you take it at the root word is pain in the breast. Some people use the term mastadynia, but it's a very common breast condition most commonly seen in pre-menopausal women is, what I always say to my patients, what reminds them that they have breasts which reminds them that they could have cancer and makes them fearful of having cancer. Fibrocystic breast changes is also very common and mastalgia is associated with fibrocystic breast changes but they don't necessarily always occur together. Again, when we talk about these symptoms, they tend to occur in pre-menopausal women and they are very common. Most women have felt at some point in their life some tenderness or some pain in their breasts. If you talk to women, you can elicit what their history is with it and you can figure out with them when they're feeling it and whether or not it seems to be associated with lumps as we've talked about, something that should be evaluated, whether it needs to have further evaluation with imaging, whether it seems to be cyclic. These are all things we as clinicians need to evaluate when women present with breast pain.

Dr. Brian P. McDonough:
Dr. Shulman, I want to follow up on that point. Do you think physicians are doing a good job with this because you alluded to the fact sometimes we push people along or we don't listen. Are we overall doing a good job? Are there things we could do to make it better?

Dr. Lee Shulman:
You know, once that patient does get into the office, I think most clinicians do a great job, taking a history, doing their physical exam, and then providing the kind of imaging that may be required based on the symptoms, the presentation, the overall health status of the patient, so I think once the patient is able to access, I think the good amount of education about breast health that's out there in the

professional community as well as the lay community, has provided the basis for that assessment. You could, in fact, argue that perhaps there are too many women getting imaging studies. I think that's for another program, but I think for the most part the patient presenting with symptoms, once they get into the office I think is being evaluated appropriately.

Dr. Brian P. McDonough:
One of the things I was just thinking of, Susan, is that we're talking about mastalgia and fibrocystic breast changes. Just how common are these problems? Its clear women are coming and they have these questions. Is it extremely common? How often do we see these things?

Susan Wysoki:
Yeah, actually they're very common. They're common with cyclic changes and with menstrual cycles. I think what Dr. Shulman was just talking about with pre-menopausal women is that because the cyclic changes are different and women are more sensitive at that age category to, you know, could this be something that's cancer, you know. I said before there's some reassurance that needs to be made about common changes that aren't related to cancer but there also needs to be a vigilance on what the woman says is different in not just the cyclical changes but different for her in general. That's an important distinction.

Dr. Brian P. McDonough:
I'm getting the sense, in fact the distinct sense, in this case when we talk about these problems it's clear with these conditions it's very important that we get good histories and that there's a great conversation back and forth between the provider and the patient.

Susan Wysoki:
Absolutely. Not only a great conversation between the provider and the patient but also the provider making sure that they pay attention to insist a time when you would send someone for a mammogram or an ultrasound or some other way of evaluating this both in terms of reassuring her and in making sure that there isn't a problem.

Dr. Brian P. McDonough:
Shifting gears a little bit but really getting a little deeper into this topic. Dr. Shulman, I wanted to ask you are there different types of mastalgia, different types of fibrocystic breast changes, and if there are maybe you could describe them for us.

Dr. Lee Shulman:
I think they pertain obviously to the reproductive aged woman and it was mentioned a little bit earlier, you essentially can divide breast pain and mastalgia into cyclical and non-cyclical pain. Cyclical

referring to breast discomfort that many women feel with the ebb and flow of their endogenous hormones connected with menses, connected with certain hormonal contraceptive use. Some could argue, and I think I would agree with them that such cyclical pain is as much physiological as it is concerning with regard to disease. We consider cyclical pain or should consider it in a completely different concept than non-cyclical pain. This is clearly pain that is not associated with the menstrual cycle or with hormonal use. For both reproductive age women, while again it's something that's an important part of the history, perhaps in particular for the post-menopausal woman who has no such physiological issues, it is the non-cyclical pain that should raise at least an eyebrow and a little bit more concern.

I wanted just to reiterate what was said earlier. I used the word reassurance at the beginning of the presentation on purpose because the vast majority of women who present with a symptom, with a bump or a lump or a mass or pain, do not have cancer. It's important that be at the forefront of the assessment of the patient. That being said, once we have in fact ruled out cancer or anything bad, unfortunately I think a lot of clinicians perhaps drop the ball. Well, you don't have cancer. We're all done. That essentially leaves that woman with pain or discomfort or other things and I think clinicians have to be more aware that we need to address those particular concerns once we have ruled out the serious problems.

Dr. Brian P. McDonough:
So there are definitely things where there might be a perception out there that there's some sort of, for lack of a better term, people thinking oh that's really something I don't want to talk about or should be ashamed of, when we really shouldn't be talking in those terms. It's something physiologic.

Dr. Lee Shulman: Correct.

Dr. Brian P. McDonough:
Okay, let me continue. You mentioned those different changes and the types and I wanted to ask Dr. Willey what are the causes of mastalgia and these fibrocystic breast changes? How do you make a definitive diagnosis? And we'll get to it at the end: how do you exclude malignancy, most important of all?

Dr. Shawna Willey:
Well, when a woman presents with breast pain of course we've talked about you need to take a history, you need to know the age of the patient, you need to know where they are in the menstrual cycle and try to elicit whether there is any hormonal influence or variation that has an effect on their breast pain. We generally divide the patients up into pre-menopausal/post-menopausal. Women who are menstruating often have a cyclic nature but sometimes they don't. If they have a cyclic nature to their

breast pain, we do consider that physiologic and oftentimes predictable. Sometimes it's very reassuring to women if you can point out to them where they're going to experience pain if they're going to and that it will be a normal part of their cycle. Early pregnancy is a time when we notice breast pain and woman are very familiar with that type of pain associated with early pregnancy. People who have cysts, dilated ducts, you can often have focal pain in the region of those structural abnormalities, but I always tell my patients that pain is really not a good discriminator and I think there are some old wives tale out there that say well if it hurts it can't be cancer. For the most part that's true, but it's not an absolute. So it really is incumbent on us as healthcare providers, as we've talked about, to make sure the patient doesn't have cancer, to make sure that they have support and reassurance about a symptom that they've presented with, and that they felt strongly enough about that they needed to see a provider. Sometimes I will ask the patient to keep a pain dairy and to jot down every day of the month how severe the pain is, where they started their period, you know, just to kind of see if there's a pattern to it. If it's age-appropriate, imaging is necessary to exclude malignancy but as I think Dr. Shulman alluded to, we don't want to be doing mammograms on 25 year old women who present with breast pain. That would be a misuse of mammograms and falsely reassuring possibly. So we need to lend support but we also need to be assured. We as the providers need to be reassured that that patient does not have cancer because breast cancer is the most common malignancy in women and when you have a malignancy that has a 12 percent occurrence in the population you really have to look at each patient as they may be harboring a malignancy, rule that out first, and then provide reassurance, treatment, and follow-up. Sometimes observation is appropriate management for a patient if you've ruled out malignancy first.

Dr. Brian P. McDonough:
If you're just tuning in, you're listening to CME on ReachMD, the channel for medical professionals. I'm your host, Dr. Brian McDonough and today I am speaking with Dr. Lee Shulman, Dr. Shawna Willey and Susan Wysocki. We're talking about fibrocystic breast changes and mastalgia.

Dr. Shulman, let me turn to you at this point. Is there a current standard of care for women with mastalgia and fibrocystic breast changes, and if not, why don't we have one?

Dr. Lee Shulman:
Unfortunately it's an easy question to answer and the answer is no we don't have one. I think part of the reason why we don't have one is because mostly of the physiological nature of the majority of breast pain especially that occurs in the pre-menopausal population and then the pain, obviously non-cyclical, that tends to occur in the post-menopausal population where that pain is inadvertently associated with something of concern like cancer or a benign mass. So I think through all of this there has been the obvious attention to ruling out malignancy. That is unfortunately sort of compounded by

the fact that until recently we have had a wide variety if interventions that have been shown to treat mastalgia but have not been very well tolerated. There has been one particular regimen, Danazol, which has been a highly androgenic compound for which I would doubt that anybody would use for the treatment of mastalgia. So we're left with a lot of clearly tolerable regimens like Lupron and Tamoxifin and Raloxifine, sort of anti-estrogenic formulations, and then compounded with the fact that outside of nonsteroidals and perhaps for the actual pain itself and then oral contraceptives and hormonal contraceptives to diminish ovulation and also the physiological effects.

I hate to say it but I think the mindset has been this is a physiological change, take an aspirin and sort of call me in the morning, as inappropriate and as ridiculous as that is, but I think that's why we're here today to talk about this. Not only is there in fact been some movement in this particular field, I think it gives us the opportunity to address what is the far more common issue with breast health which is mastalgia and not breast cancer.

Dr. Brian P. McDonough:
I think that is a good point and I'm glad we're talking about it because I think it is important. Dr. Willey, what are the knowledge deficits that prevent having this meaningful management strategy we're talking about? Obviously mastalgia is an issue and we've got these concerns, but again, there seem to be these deficits that perhaps many of us as providers have.

Dr. Shawna Willey:
I think you're absolutely right. We get to the point where we've ruled out cancer in our own minds and we've reassured the patient and yet they still have pain. We have knowledge deficits in the medical literature. We don't really have good, non-toxic treatments for breast pain. Historically, pain medication: ibuprofen, aspirin, Tylenol, don't work well for this kind of pain. Caffeine reduction has been one of the things that has been tried. But again, if you look at trials that have tried to study it in a controlled way, that's not really very effective for very many women. The problem with breast pain is that some of these things work for some women but if you really study them in a controlled way, we don't have good studies to really advocate for one treatment versus another. As Dr. Shulman mentioned, the drugs that we do know work which tend to lower the estrogen effect on the breast tissue, tend to be more toxic, have higher side effects and typically are not things that women want to take on a prolonged basis because of the side effect profile of the drugs.

Dr. Brian P. McDonough:
Interesting. Dr. Shulman let me take that another step about the treatments that are out there. What are some of the treatments that are out there that can be helpful. Things that maybe, again, we as physicians don't know a whole heck of a lot about?

Dr. Lee Shulman:
Well, I think we've got the old school which I'm sort of happy that a lot of people kind of know about because, as I said, they tend to be clearly interventions that have clear clinical usefulness for clinical issues other than breast pain, but because of their side effect profile it's clearly something that most of us would not consider using, and I would dare say even for a woman with considerable breast pain. Again, if things like Tamoxifen and Raloxifine which are selective estrogen receptor modulators and have an anti-estrogenic effect of the breast. We've got Lupron and gomatotropin-releasing hormone GNRH agonists which provide a chemical menopause similar to the effect of Danazol, again a highly androgenic compound. That's sort of what's out there. You then have the second tier which is to inhibit ovulation and again, our hormonal contraceptives do a good job of that. But I think perhaps the first tier, as Dr. Willey mentioned, is nonsteroidals or general analgesics that can provide really adequate pain relief for a wide array of women who have, I'll say, mild-to-moderate physiological breast pain.

There is, unfortunately, a considerable number of women who have more than mild-to-moderate pain for whom contraceptive use is even not desired or inappropriate and who clearly would not do well with some of the third-tier or the more severe issues. In a sense the good news is the very recent availability of what turns out to be a rather fascinating intervention which is iodine. The iodine story is interesting insofar as iodine is something that most of us clinicians don't think about because iodine is rather ubiquitous in our diet. It was placed there to prevent goiter and that's done a very good job of doing that. But it turns out that that level of which we consume iodine in our diets and with your supplements, while it's fine for thyroid function, turns out it may not be fine for other organic function.

Work done in the 70's and progressing really until the late 2000's has shown clearly that as we've increased iodine consumption, and clearly well below toxic levels, we have found an excellent impact on breast pain. Small, placebo-controlled trials have demonstrated its effectiveness and ongoing studies have shown its safety. It's now available as an over-the-counter regimen and I think this now provides a wonderful, non-hormonal second option after nonsteroidal and analgesic interventions.

Dr. Brian P. McDonough:
It is amazing how these things come up and how you discover these things and yeah, as I hear, they are getting good results and that's fascinating as well.

I want to turn, Susan, to the role of the Affordable Care Act that might have on a woman's ability to learn the facts about mastalgia and fibrocystic breast changes and maybe help them become self-advocates for better outcomes than currently exist.

Susan Wysoki:

The Affordable Care Act is going to allow women to have access to this kind of care so if they have a question about mastalgia, pain, lumps, bumps, they should be able to get access to this care without a copay and I think that's critical.

Dr. Brian P. McDonough:
One last question I have for you and it's kind of a broad one. Don't feel you have to speak but if you have something you want to say, certainly it would be great at this point. Is there something we didn't discuss that each of you would like to briefly mention as we're about to wrap it up and we get close to the end of the program? Something that you think's important to bring up?

Dr. Shawna Willey:
I would like to say we are talking about a phenomenon or an entity that occurs to at least 70 percent of women at some point in their lives and such a common thing has very poor treatment and very little research behind it. I echo what Dr. Shulman said with the molecular iodine. This is something that has some promise for women who suffer from mastalgia. So I think this is although not a life-threatening health problem, it's a health problem that affects a great majority of women and I think it's been vastly undervalued and kind of poo-pooed by medical professionals as a major concern for women.

Dr. Lee Shulman:
You know, I couldn't agree with Dr. Willey any more. I think she just hit it out of the park as far as I'm concerned. We have women come in with breast pain. They are maybe inappropriately evaluated with imaging and other things and then most of these women are left with take a couple of Tylenol. Just be thankful you don't have cancer. And for something that is so genuinely ubiquitous in our population amongst all ethnic and socioeconomic levels, it is in a sense about time that we have something other than incredibly (and I'll use the word toxic) toxic interventions that may have potential benefit for, again not for a life-threatening problem but for a life-altering problem. In our zeal to rule out cancer, we forgot that there's still a patient who is having a problem and that problem which brought her into the office has not been appropriately addressed. Hopefully now as we go forward with hopefully some more studies on this molecular iodine, we'll have a safe, reliable, effective, and I don't want to say organic because clearly it's an inorganic compound, but a well-tolerated compound that will provide the relief of the breast pain for women who have it.

NARRATOR:
In this current educational activity, “Optimizing Breast Health: Managing Fibrocystic Breast Changes and Mastalgia,” we have made mention of initial study data suggesting that molecular iodine (now commercially available OTC as Violet®) may be a useful treatment for fibrocystic breast changes and cyclic mastalgia. This patented formulation is now in an ongoing, multi-center, randomized, placebo-

controlled clinical study intended to further define its value to patients with fibrocystic breast changes and cyclic mastalgia.

We look forward to continuing our breast health education initiatives in 2016 by providing to you, our learners, with information that continues to help optimize care to your patients. Our purpose is to further improve learner knowledge; to improve practice habits; and to improve patient outcomes for those who suffer with fibrocystic breast changes or cyclic mastalgia.

This segment of 'CME on ReachMD' is sponsored by Omnia Education and supported by an educational grant from BioPharmX. To receive your FREE CME credit or to download this segment, go to reachmd.com/cme. Thank you for listening.