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## Treatment of Vaginal Discharge Syndromes in Community Practice Settings

Announcer:

Welcome to CME on ReachMD. This activity, entitled "Treatment of Vaginal Discharge Syndromes in Community Practice Settings," is provided by Omnia Education and is supported by an independent educational grant from BD Life Sciences.

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Dr. Caudle:

Vaginal infections are among the most common reasons why women in the United States seek medical care. These infections are typically characterized by discharge, itching, or odor. Although vaginal discharge symptoms are common, diagnosis of bacterial vaginosis, or BV, vulvovaginal candidiasis, or VVC, and trichomonas vaginalis, or TV, is not standardized. As a result, diagnostic approaches and the suitability of treatment for vaginal discharge syndromes in community practices remain inadequate.

This is CME on ReachMD, and I'm your host, Dr. Jennifer Caudle. And joining me to discuss this issue is Dr. Sharon Hillier. Dr. Hillier, welcome to the show.

Dr. Hillier:

Hi, Jennifer, it's really great to be with you today.

Dr. Caudle:

Excellent. So, Dr. Hillier, why don't we get started. Could you discuss the prevalence and causes of vaginal discharge syndromes and whether or not they are associated with any adverse sequelae?

Dr. Hillier:

Bacterial vaginosis is extremely common in the US, affecting about 30% of reproductive-age women. By comparison, trichomonas vaginalis, or trich, is less common with an estimated prevalence in the United States of only about 3%. But what these two have in common is that they are both associated with several adverse reproductive health sequelae, including increased susceptibility to other sexually transmitted infections, including HIV. Women with BV or trich are also about twice as likely to have or get pelvic inflammatory disease, which I think most people know can cause tubal infertility. In addition, both BV and trich have been linked with increased rates of preterm birth, and BV has been linked with infections of the amniotic fluid, so there really are a range of reproductive health sequelae for these 2 infections. *Candida* is the major cause of vulvovaginal candidiasis, and although this condition is not linked with as many adverse health sequelae as BV or trich, it's still common. It's estimated that 3 of 4 women in the United States will have vulvovaginal candidiasis at least once in their lives, so all together these 3 infections, BV, trich and VVC, add up to trouble for many women.

Dr. Caudle:

Excellent. Now, with that background, what does the CDC, or Centers for Disease Control and Prevention, recommend as point-of-care testing for vaginal discharge syndromes in community settings? And can you also tell us about the sensitivity and specificity of the various recommended tests?

Dr. Hiller:

The Centers for Disease Control guidelines rely heavily on the provision of point-of-care tests to make the diagnosis of BV, trich, and yeast. However, as good as point-of-care testing is in terms of convenience, in the case of vaginitis, it relies on several steps, each of which takes time in the doctor's office and may not be available in many office settings, which are quite busy.

Thus, although we talk about point-of-care testing for vaginitis, it's really not a single point-of-care test. It's a series of multiple steps, each of which provides different clues to the diagnosis.

For trich, the biggest problem with the point-of-care testing is that it's inherently insensitive. Studies have clearly demonstrated that even with a careful look under the microscope, this method is only about 50% sensitive. There are excellent nucleic acid amplification tests available, but evaluation of women for this sexually transmitted pathogen is just not as frequently performed as it is for gonorrhea and chlamydia.

For BV, it's a little different. A diagnosis is based on a combination of having a pH of greater than or equal to 4.7, plus seeing clue cells on the saline wet mount, plus a positive amine odor test. This series of tests, if performed well, can detect more than 80% of BV cases, so it's more sensitive than wet mount for yeast and trich, but it's much less accurate when women have mixed vaginal infections, which does happen. There are now 2 nucleic acid amplification tests which have been approved and cleared by the Food and Drug Administration for diagnosis of BV, and both of these are quite sensitive and specific, but the downside is they're not point-of-care tests.

Finally, vulvovaginitis is also difficult to diagnose using the KOH wet mount because it's relatively insensitive, so many women who have symptoms which are likely caused by *Candida* will not have yeast buds or pseudohyphae visually present on the microscopic slide, so again, about half of cases are missed.

Dr. Caudle:

Excellent. Now, let's turn to your recent publication in *Clinical Infectious Diseases* in which you and your colleagues focus on the diagnosis and treatment of vaginal discharge syndromes in community settings. Could you tell us about your primary objectives and the major findings?

Dr. Hiller:

The primary objective of our study was to assess how women with vaginal discharge syndromes were being evaluated in community practice settings and to see whether or not they were receiving the appropriate treatment. A second objective was to assess how often women came back with those same symptoms in the following 3 months. We enrolled 300 symptomatic women across 8 community practice sites in the Pittsburgh region. Women were evaluated by whatever the local standard practice was for that clinic, but we asked the clinicians to fill out a form telling us how they evaluated the women who presented with vaginal symptoms that day. We also collected vaginal swabs to do standard laboratory testing for BV, trich, and yeast using 2 different sets of lab-based tests. Importantly, we also received IRB approval and had an informed consent to do a medical record extraction so that we could see which treatments were prescribed in the week after the initial visit and whether or not women returned with recurrent symptoms in the next 90 days. So we enrolled women—average age was around 30, most were nonpregnant, and 38% had vaginitis treatment within the past month.

We found that point-of-care tests were really infrequently performed. Only 15% of women had a vaginal pH test, only 20% had the potassium hydroxide whiff test, and only 17% had any microscopic exam of the vaginal fluid under a microscope. We also found when we looked that the most important finding was that many women received the wrong treatment. Of the 170 women having a lab-diagnosed cause of vaginitis, half received 1 or more inappropriate prescriptions. The second important lesson from this study was that many women had none of the infections that caused vaginitis. Of the 120 women without any of these infections, one-third were still prescribed antibiotics or antifungal. And an important lesson we learned was that empiric treatment without infections caused 3 times more repeat visits in the subsequent 3 months. Overall, our study found that 40% of women having vaginitis symptoms received inappropriate treatment.

Dr. Caudle:

For those of you who are just tuning in, this is CME on ReachMD. I'm Dr. Jennifer Caudle, and I'm joined by Dr. Sharon Hillier to discuss best practices for identifying and managing women with suspected vaginal discharge symptoms.

So, Dr. Hillier, in your recent article, you and your colleagues concluded that over 40% of women with symptoms of vaginal discharge syndrome received inappropriate care within a community practice setting—that's actually what you were just discussing with us—and that many women without infections nonetheless received empiric treatment. What practice changes are needed to improve upon our current suboptimal care for vaginal discharge syndromes?

Dr. Hillier:

We have excellent nucleic acid amplification tests that are available commercially, and maybe it's time to consider whether we need to

move away from requiring an in-clinic visit and point-of-care tests towards more accurate nucleic acid amplification tests. One idea I've been thinking about for some time is moving to a model in which women who call for an appointment due to symptoms of vaginitis being asked to come to the clinic and self-collect vaginal swabs. These self-collected swabs would then be sent to a laboratory for testing. And fortunately, both of the FDA-cleared systems that are very good for diagnosis of vaginitis have validated the use of patient-collected swabs, which means we know that patient-collected swabs provide just as good of results as clinician-collected swabs. So that means that once these swabs were self-collected and sent out, the woman could then be treated for the right condition. And importantly, if she has no condition, no diagnosed condition, she could be counseled that she should discontinue the use of over-the-counter antifungals or other home remedies, which could be exacerbating the symptoms, and could be counseled, potentially, if persistent symptoms that continue to plague her, that she could be referred to an expert in vulvar and vaginal conditions. And in that way, we would avoid overuse of the antibiotics and antifungals and more appropriately refer women who need that next step of expert evaluation.

In the end, while accurate diagnostic testing is more expensive than point-of-care testing, we really will need economic modeling data to clarify whether the cost associated with misdiagnosis, unneeded treatments, and extra clinical visits don't outweigh the extra cost of nucleic acid amplification tests.

Dr. Caudle:

Excellent. Well, unfortunately, we are near the end of today's discussion, and in the time remaining, perhaps you can describe the most important takeaways for your colleagues. More specifically, what do we need to take into our offices or clinics with regard to improving the level of care for suspected vaginal discharge syndromes?

Dr. Hillier

There are 3 takeaway lessons. First, in many community health settings, point-of-care tests are really not being done, so if you're working in a setting where you cannot conduct point-of-care tests routinely, you really should recognize that you may not be prescribing the right treatments. The second lesson is that empiric treatment is not without harm. Women without infections who received treatment in our study were 3 times more likely to come back with symptoms again in the subsequent 3 months, so overtreatment actually carries risk. And finally, we are not really serving women well. It's time to identify better strategies which respect our patients by providing accurate diagnoses and effective treatments for their vaginitis symptoms. For all of us who have a commitment to women's health, we need to identify better clinical pathways which meet women's needs.

Dr. Caudle:

Well, thank you. And with those comments in mind, I want to give you an extra thank you. I'd like to thank my guest, Dr. Sharon Hillier, for helping us to better understand how to improve our diagnosis of vaginal discharge syndromes and to treat them appropriately.

Dr. Hillier, it was great speaking with you today.

Dr. Hillier:

It was a pleasure to be with you as well.

Announcer:

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