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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Hypoactive Sexual Desire Disorder: Advances in Diagnosis and Treatment

Narrator:
Welcome to CME on ReachMD. This activity entitled, Hypoactive Sexual Desire Disorder, Advances in Diagnosis and Treatment, is provided by Omnia Education. Your host is Dr. Shira Johnson. Dr. Johnson will speak with Dr. Anita Clayton, who is the David C. Wilson Professor and Chair of the Department of Psychiatry and Neurobehavioral Sciences at the University of Virginia in Charlottesville, Virginia. Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements, as well as the learning objectives. This CME activity is supported by an independent medical educational grant from Valeant Pharmaceuticals.

Dr. Johnson:
Hypoactive sexual desire disorder, or HSDD, is the most common female sexual dysfunction. About 10% of premenopausal women in the U.S. are believed to have this condition. HSDD is consistently underdiagnosed and undermanaged, due to the lack of adequate communication between physicians and patients on this topic. This is CME on ReachMD and I'm Dr. Shira Johnson. Today's discussion, with Dr. Anita Clayton, will focus on the symptoms of HSDD and their impact on a patient's quality of life. We'll also talk about the components for a comprehensive sexual history, the tools for screening and diagnosing HSDD, and the therapeutic modalities available for this condition. Dr. Clayton, welcome to the program.

Dr. Clayton:
Thank you.

Dr. Johnson:
So, tell us, how common is hypoactive sexual desire disorder and what are the typical presenting symptoms of a woman with HSDD?

Dr. Clayton:
So, really, the short definition of HSDD is distressing low sexual desire. And this lack of motivation for sexual activity, may be manifested by decreased or absent spontaneous sexual thoughts or fantasies, decreased or absent response of desire to erotic queues or stimulation, an inability to maintain interest through sexual activity, and a loss of desire to initiate or, more so, participate in sexual activity. And that might include some behavioral responses like avoidance of situations that might be interpreted as suggesting she does want to participate in sexual activity, or might be likely to lead to sexual activity. So, if someone has any of these manifestations, and they're distressed or bothered by it, then I think that we could say that they have hypoactive sexual desire disorder. As for the prevalence rate, a very large epidemiological study that involved over 31,000 U.S. women showed a rate of HSDD of about 10%, and a rate of just over 5% for arousal disorder, and slightly less than 5% prevalence for orgasmic disorder. There's some overlap so that about half of women who have HSDD, potentially have arousal disorder or orgasmic disorder. Also, about 40% of women with HSDD have comorbid depression, and that should be addressed before acknowledging that this is HSDD.

Dr. Johnson:
So, sexuality-related topics are often difficult, not just for patients to raise with their clinicians, but also for clinicians to even bring up with their patients. Are there strategies and tips you can share with us that will allow both sides to feel comfortable initiating a discussion?

Dr. Clayton:

I think practice is really, really important, because this is such a sensitive topic, both for patients and clinicians. And sometimes clinicians are fearful that patients may believe that they're being seductive or overly provocative or intrusive, but still, the provider really needs to broach the subject. Imagine how much harder it is for the patient to bring it up. Broaching the subject is a lot easier, though, if assessment of sexual functioning is really a part of the routine exam. Whether that's a reproductive health exam, a general medical screening, or annual general exam, or related to the questions pertaining to lifestyle issues that patients usually don't bring up, do they eat a healthy diet, how much alcohol do they consume, do they smoke, we could tie sexual functioning into those types of questions. Another way to introduce the topic of sexual health is to utilize a clinical questionnaire like the Decreased Sexual Desire Screener, or we can begin with a question where we say something like, "Many women with a…" and you want to use a descriptor that's appropriate for the individual, so, let's say, "Many women who are going through the menopause" or "Many women after childbirth…… have concerns about their sexual functioning. Do you have any complaints?" And then you can follow this up when you hear about complaints with, "Tell me more".

Dr. Johnson:
How do you assess the impact of HSDD on the patient, his or her partner, and on their relationship?

Dr. Clayton:
Yes, this is really important to consider early on in an evaluation for HSDD. In most relationships, there's a discrepancy in the level of desire between the two partners. One person tends to have higher desire than the other. But, really, without distress in the person with low desire, there is no HSDD. And the partner's distress is not a determinant of HSDD, but it does then impact on the relationship. It's also important to remember that HSDD can impact the relationship and the relationship can impact the level of sexual desire. So, it's really important to determine which came first. If the relationship problems appear to be a cause of the low sexual desire, then the interpersonal difficulties must be addressed first. On the other hand, the impact of HSDD on the relationship might be manifested as the distress that we need to evaluate for. And that might include symptoms like sadness, worry, anger, frustration, or sense of loss of emotional intimacy. And the partner may also have feelings in response to the woman's diminished sexual desire. For example, they might be concerned she's no longer in love, or is no longer attracted to her partner, or fear that she's having sex with someone else. Additionally, partner sexual dysfunction may contribute to low sexual desire in your female patient.

Dr. Johnson:
Dr. Clayton, what type of physical exam should be performed to assess for HSDD and can this be done by any primary care provider?

Dr. Clayton:
Well, the truth really is, is that what's going on with HSDD occurs above the neck, and so, no physical exam is really necessary for the diagnosis of HSDD. But remember, I said that about 50% of women with HSDD have a comorbid other sexual disorder. In particular, that might be an arousal disorder, and that might specifically be more common in women who are peri- and post-menopausal. So, in those women, a focused physical exam may be important for determining problems with genital arousal, particularly genitourinary syndrome of the menopause or if sexual pain is a problem, because certainly people's desire goes down if they're experiencing pain with sexual activity. And if they are having arousal problems or sexual pain, these must be addressed before turning your attention to the low sexual desire.

Dr. Johnson:
Dr. Clayton, what screening instruments are available to help clinicians diagnose HSDD?

Dr. Clayton:
The FDA required the development of a screening tool for HSDD when the first medication was being developed for treatment of HSDD, and we developed the Decreased Sexual Desire Screener, or DSDS. This is a validated, 5-item questionnaire that the patient completes first, and it's used to assess symptoms of generalized, acquired HSDD, and also to assess for potential causes of low sexual desire. The first 4 questions utilize yes/no responses to evaluate level of desire for sex, decrease from the prior satisfactory level of desire, the bother or distress related to the decreased sexual desire, and a wish on the part of the woman that the level of desire would improve. The 5th question is a checklist of potential modifiable causes of HSDD. So, things like medical or psychiatric illness, substance use including medications, partner issues, and the comorbidity of other sexual dysfunctions. So, if any of these are identified, then the clinician must determine whether they think that they have a significant impact on the woman's level of desire, and recommend interventions.

Dr. Johnson:
There is currently only one FDA-approved agent for treating HSDD which is flibanserin. Can you provide an overview of this agent in terms of its clinical trial base, and what these studies demonstrated in terms of efficacy and potential side effects?

Dr. Clayton:

Flibanserin is a non-hormonal, centrally acting, oral, serotonin agonist and antagonist, dosed at 100 mg daily at bedtime. Efficacy was established in three 6-month pivotal trials that involved over 3500 women, and these trials demonstrated statistically-significant and meaningful improvement, according to the patient, compared to placebo on all three endpoints. And those endpoints were: an increase in the level of sexual desire, a decrease in distress, and an increase in the number of sexually satisfying events as determined by the woman. Approximately 50% of women with HSDD respond to flibanserin. And it may take up to 8 weeks for efficacy to be evident, although many women experience significant improvement very quickly in the first week or two. The most common adverse events in pre-menopausal women are: dizziness which occurred in less than 10% of the women; and then in decreasing order: somnolence, nausea, and fatigue. And when we look at these rates and correct them for placebo, they're very similar to those seen with other CNS-active agents. Most of these side effects were considered mild and transient, and they were actually mitigated with bedtime dosing. So, if the drug made you feel sleepy, some women might consider that a good thing if they were taking it at bedtime, but it wouldn't be such a good thing if they were taking it in the morning. In the trials also, discontinuation due to side effects was about double the rate with flibanserin as compared to placebo 13% with flibanserin and 6% with placebo. So, flibanserin was found to be effective and safe in the treatment of generalized acquired HSDD in pre-menopausal women.

Dr. Johnson:
Flibanserin also has a required risk evaluation and mitigation strategy program attached to its prescribing. Can you explain the details of this and what it means for the patient, prescriber, and pharmacist?

Dr. Clayton:
Yes. Flibanserin labeling has a boxed warning with alcohol contraindicated. This is based on the results of an alcohol-challenged study that was required by the FDA that was done in 24 subjects. These subjects were randomized to drink grain alcohol equivalence of a half a bottle of wine or a full bottle of wine in 10 minutes on an empty stomach at 10 a.m. So, a pretty strong challenge. They then took flibanserin or placebo, and what they found was an increase in sedation, syncope, and hypotension in the flibanserin treatment group. However, alcohol use did not increase such adverse events over placebo in those three large registration trials I mentioned, with data from over 3500 women, 60% of whom self-reported alcohol use at study enrollment. Alcohol use was not systematically tracked across the 6-month studies, however. A post-approval risk evaluation and mitigation program, or REMS program, is available online, and that's at addyirems.com. And for anyone who wants to prescribe flibanserin or if pharmacies are going to dispense it, that program must be reviewed and a test completed so that the provider is certified in prescribing flibanserin. And that is so that the provider and the pharmacy are sure that they have consented the patients to avoid alcohol while taking flibanserin.

Dr. Johnson:
Given everything we talked about today, what would you say the future looks like for potential pharmacologic therapies for HSDD?

Dr. Clayton:
There are some exciting potential treatments that are being studied. One is bremelanotide which is probably the closest to submission to the FDA, having recently completed positive Phase III trials. And this is a melanocortin receptor agonist that's thought to enhance dopamine and norepinephrine function which are excitatory in desire. Differences between bremelanotide and flibanserin include that bremelanotide is not given daily, but is taken on an as-desired basis before sexual activity. It's administered with a subcutaneous injection with an auto-injector, and it does not have an interaction with alcohol. Another potential non-hormonal agent is a combination treatment of the antidepressants bupropion and trazodone. So, working again, to enhance the excitatory neurotransmitters and diminish the inhibitory neurotransmitter serotonin. And hormonal products such as transdermal testosterone have been tested and found effective in post-menopausal women, although not approved yet in the United States.

Dr. Johnson:
I want to thank Dr. Clayton today for helping us get a clearer picture of HSDD. From the impact of this condition on the patient's quality of life, to the diagnostic and therapeutic modalities currently available. Dr. Clayton, it was great to have you on the program.

Dr. Clayton:
Thank you. I was happy to be here.

Narrator:
This has been CME on ReachMD. This activity is sponsored by Omnia Education and supported by an educational grant from Valeant Pharmaceuticals. To receive your free CME credit, or to download this segment, go to ReachMD.com/CME. Thank you for listening.