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Update on Treatment Options for Narcolepsy

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[CHAPTER 1 – Narcolepsy Treatment Evolution]

Dr. Kushida:
As clinicians, we often prescribe therapies based on safety, efficacy, and tolerability, and we factor in potential comorbidities and drug-drug interactions. What we sometimes don’t have an opportunity to address is how it’s critically important to weigh the likelihood of patient adherence with the various therapies. In this program, we’re going to look at new treatments for narcolepsy that are on the horizon and talk about how a shared decision-making approach is crucial to ensure we’re selecting the right therapy for each patient to meet their individual needs.

This is CME on ReachMD, and I’m Dr. Clete Kushida.

Dr. Krahn:
And I am Dr. Lois Krahn.

Dr. Kushida:
Welcome. In this first chapter, we’ll discuss how our clinical strategies have evolved as our treatment options for narcolepsy have begun to expand. There has been a lot of exciting news in the field of sleep medicine and there are still more new therapies on the horizon. So let’s just dive right in.

So, Lois, can you discuss some of the latest developments in the management of narcolepsy?

Dr. Krahn:
Yes, my pleasure. This has been an incredibly active and exciting time for the treatment of narcolepsy. For more than 50 years, we have been treating patients with narcolepsy primarily with stimulant medications like methylphenidate and amphetamine. Then we had agents like modafinil and armodafinil. But more recently, we’ve had a whole slew of new medications: solriamfetol, the histamine agonist, and pitolisant, as well as the oxybate therapies, where we have more options than we ever had before.

So for our patients, this gives us more options than we’ve ever had to be able to understand a patient’s specific needs, look at the choices, and select a medication or a group of medications that really should allow them to have the best possible outcomes.

My hope is that by having more treatments, that the patients will be more motivated to seek out treatment so that we’ll have an opportunity to use these new agents for their benefit.

Dr. Kushida:
In Chapter 2, we’ll be discussing the latest information on oxybate treatments for narcolepsy, so please stay tuned.

[CHAPTER 2 – Sodium Oxybate Advances]

Dr. Krahn:
In the first chapter, we covered the evolution of treatments for narcolepsy. In Chapter 2, we'll be discussing the oxybate therapies and ways to optimize outcomes even though we don't really have head-to-head comparisons of treatment efficacy. Clete, can you touch upon the latest efficacy and safety data on emerging oxybate therapies? Then I'll jump in and relate this to how we can address our patient needs.

Dr.Kushida:
Thank you, Lois. Sodium oxybate has a well-established safety and efficacy profile. Although it is the same main molecule or active ingredient, there are different formulations. Sodium oxybate is considered a standard of care treatment according to the American Academy of Sleep Medicine since 2007. There are several different formulations, as I mentioned. One is sodium oxybate; there's also lower-sodium or mixed-salt oxybate. On the horizon, there's a no sodium oxybate. So XW10172 is a novel, patented analog of oxybate. It doesn't contain sodium or other cations and was designed to deliver the $GABA_B$ agonist oxybate.

On the horizon, also, is FT218. It's currently being reviewed by the FDA, and it's a once-a-night sodium oxybate formulation. The implication of this medication is to not have to wake up in the middle of the night when a patient has a sleep disorder and is already experiencing sleep pressure.

Now there were some studies that were presented this past year at the American College of Chest Physicians Meeting, or CHEST, and here are a few of the key highlights.

One of these studies, the pivotal phase 3 REST-ON clinical trial of FT218, or the once-nightly treatment, was associated with a statistically significant improvement compared to placebo on mean sleep latency, as shown by the results of the Daytime Maintenance of Wakefulness Test, which is a measure of excessive daytime sleepiness.

A significantly greater proportion of the participants who received once-nightly sodium oxybate compared to placebo experienced increased mean sleep latency change from baseline which ranged from greater than or equal to 5 minutes to 30 minutes. The improvement was evident as early as week 3 at the 6-g dose and increased with a 7.5-g dose at week 8 and the 9-g dose at week 13. The most common adverse drug reactions with once-nightly sodium oxybate at 9 g were enuresis, dizziness, and vomiting.

Lastly, the third study, was the utility of discrete choice experiment in evaluating treatment preferences among patients with narcolepsy. So a discrete choice experiment evaluated drivers of patient preference for sodium oxybate and demonstrated that dosing frequency was the single most important attribute of a narcolepsy treatment, with once-nightly dosing significantly more preferred than twice-nightly dosing on a *P* value of 0.001. The number of nightly doses was also the most important driver observed of taking the medication exactly as directed and reduced anxiety and stress, with once-nightly dosing preferred over twice-nightly dosing.

Dr. Krahn:
We're in a great situation where we have more options and more information than ever before. It is too bad that we don't have a direct comparison so that these are side-by-side trials where we really know which medication is better for a certain patient. But we certainly have more information than we ever did before and more treatment options.

In the past, many narcolepsy specialists and sleep specialists have primarily looked at the presence or absence of excessive daytime sleepiness, the omnipresent symptom of narcolepsy, or the degree that cataplexy interferes with functioning when selecting a medication. I think with these new options in oxybate therapy, clinicians can more so also pay attention to disruptive nighttime sleep and scary, vivid dreams. Because in particular, those symptoms respond well to some of these new options in the oxybate family. So as a clinician treating patients, it is tremendously powerful to have a larger tool kit with more options to select from.

Dr.Kushida:
Thank you, Lois. Completely agree. Oxybate safety is well established since it's FDA approval in 2002. Safety is always important because we should include appropriate evaluation of patients for comorbidities and cardiovascular disease risk factors as part of a standard workup. And it's also important for providers to always address risk evaluation and mitigation strategies as appropriate.

Dr. Krahn:
Before we wrap up, Clete, can you provide us with one key takeaway from this chapter?

Dr. Kushida:
Yes, So sodium oxybate efficacy and safety is well established. There are 3 new preparations of oxybate either available or on the horizon. And one of them, once-nighty sodium oxybate, has been shown to be effective in improving objective daytime sleepiness and cataplexy with the benefit of strong patient preference for once-nightly dosing, as demonstrated by a discrete choice experiment.

Dr. Krahn:
Thank you. In Chapter 3, we will be talking about how we can better meet our patient needs by shared decision-making and switching therapies in order to give them the best possible outcome. Stay tuned.

[CHAPTER 3 – Matching Patient Needs]

Dr. Kushida:
For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Clete Kushida, and here with me today is a true expert in the field of sleep medicine, Dr. Lois Krahn. We're just about to delve deeper into shared decision-making in narcolepsy.

Welcome, in the first and second chapters, we briefly discussed some of the latest data on the efficacy and safety of treatments for narcolepsy. Lois, can you start off Chapter 3 for us by reviewing how we can use these data to meet our patients' needs through shared decision-making and switching medications?

Dr. Krahn:
Thank you. It is really an exceptional time to be caring for patients with narcolepsy. We have patients who have many different needs. They perhaps live with their parents, live in a dorm, live with roommates. And now for the first time, we can really take the opportunity to understand a person's sleeping situation and select a medication that really meets their needs. For example, some patients and their parents are very uncomfortable with a medication sitting around until the middle of the night. They don't know what may happen to that medication, and now we have options that we didn't have before. So it's a very exciting time, but it gives us the opportunity to better understand our patients' situation and then select a medication that truly has the chance to work well for them. You know, in the past, we've focused on excessive daytime sleepiness, cataplexy, disrupted sleep, and dreams, and we can continue to do all of that, but we can go even further now to better understand the sleep environment and the circumstances of the patient and select something that will work for them and is likely to work well.

I am very heartened to have this new information and have a greater selection of medications to use for patients with narcolepsy. You know, as for many physicians, I have patients of many different ages with many different needs. I certainly have older patients who have a number of medical comorbidities where we do need to be aware of their cardiovascular status, we need to be aware of their salt intake, and it's great to now be able to factor in those issues and those risks and be able to select a narcolepsy treatment that is expected to be as well tolerated as possible. On the other end of the age spectrum, we have patients who are just becoming independent, who are moving out of their parents' home into a dormitory or another group living situation or living with roommates. In that setting, many patients and their families are concerned about having a second dose sitting out where it might be accessible to others, and having a formulation of oxybate therapy where that is not necessary is really going to make some of those decisions easier.

Of course, we have the older medications that have been available for longer. They have their own issues, but as a clinician, as I talk to my patients and their families, I just warmly welcome having more things that we can consider that we can use as a single agent to treat a patient's narcolepsy or perhaps combine in order to treat the different symptoms. Our patients present with sleepiness, cataplexy, disturbed sleep, vivid dreams, so there are a lot of things we need to consider, and now we have more tools to be able to match with what, really, we expect a patient will do best with.

Dr. Kushida:
Thank you, Lois. Definitely agree.

As clinicians, we will need to be able to counsel patients about switching medications, and it almost goes without saying that when the goal of treatment is mutually agreed upon, there will be better outcomes. Generally, providers should consider variables that may impact adherence to medication regimen. And these include important factors such as patient preference, dosing schedule, side effect profile, efficacy, tolerability, and alcohol and food, as well as a dosing regimen.

So this has been great. Before we wrap up, Lois, can you provide us with one last key takeaway?

Dr. Krahn:
Yes, my pleasure. You know, Clete, I appreciate how many points you've made and just talking about the different factors that need to be considered. It is important to know your patient well in order to understand their sleep lifestyle. But now for the first time, we have more options than ever before to be able to address the specific circumstances of a patient and be able to treat their narcolepsy and do so successfully.

Dr. Kushida:
Thank you, Lois.

Unfortunately, that's all the time we have today. So I want to thank our audience for listening in and also especially thank you, Dr. Lois Krahn, for joining me, for sharing all of your valuable insights and expertise. It was terrific speaking with you today.

Dr. Krahn:
Well, and I would like to say thank you. You know, I'm very committed to doing all we can to help clinicians and patients understand their treatment options, so I appreciate the opportunity to talk with you today.

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