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Current Pharmacologic Approaches to Managing Pediatric Narcolepsy

Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. Maski:

There are a number of FDA approved drugs for pediatric narcolepsy. Traditional stimulants were one of the first medications approved for the treatment of daytime sleepiness with pediatric narcolepsy, and include, amphetamine medications as well as methylphenidate, sodium oxybate, and low salt. Oxybate were more recently approved for the treatment of pediatric narcolepsy, specifically symptoms of daytime sleepiness and cataplexy.

And the most recently approved is petant, which was approved for the treatment of daytime sleepiness in pediatric narcolepsy for children age six and above. In 2021, the American Academy of Sleep Medicine presented their clinical practice guidelines for the treatment of central nervous system disorders of hypersomnia somnolence pediatric patients with narcolepsy did not have a lot of data available for review at that time, but based on that data it was advised that clinicians could use modafinil as well as sodium oxybate for the treatment of narcolepsy symptoms in pediatric patients.

These were given conditional reviews based on the strength of the evidence and the treatments might be best for specific populations. The approval of petant was based on this randomized controlled trial, which was recently published in The Lancet Neurology journal. Based on this data patients who are enrolled in this study had a significant improvement in narcolepsy symptoms based on the Ullanlinna narcolepsy severity scale which includes a measure of cataplexy as well as other symptoms of narcolepsy and compared to placebo, there was a 6.3 improvement on the scale with petant and only a 2.6 improve point improvement in the placebo group. And the results were statistically different in terms of the severity of daytime sleepiness. on that scale, the petant group, improved their treatment by 5.5 points, and placebo group had an improvement of 2.1 points.

And again, the difference was statistically significant in terms of the side effects of these medications. the traditional stimulants are of a controlled substance. oftentimes this limits how much medication can be delivered per month in many states. And there's a lot of scrutiny course, of over controlled substance use and specifically misdirection of stimulants. However, the treatments are available and, side effects that people need to be aware of are irritability, headaches, insomnia, GI upset, the potential for increase in blood pressure or hypertension, cardiac arrhythmias, anxieties and psychosis. medications such as lisdexamfetamine might be used off label as an extend version of an amphetamine. And the similar side effects are also there, but hyperhydrosis, skin rash and dry mouth have also been reported. Treatments of the modafinil, class medications are associated with headache, nausea, nervousness, insomnia, and specifically these medications are not approved for children, under 17 years of age, simply because there were some case reports of Steven-Johnson syndrome and psychosis in the pediatric populations.

If they are used in, in a teenage population, counseling certainly needs to be present about interactions with oral contraceptives as modafinil based medications can reduce the efficacy of those treatments. And so if adolescents are, sexually active, they need to use

barrier protection as well, or, or switch to a copper IUD. The oxybate has been studied in a randomized controlled study in pediatric narcolepsy, because of, potential of very severe interactions with alcohol or other sedating substances. they're, they're part of the risk mitigation program. so side effects could in that need to be counseled on are the development of sleep disordered breathing, both central and obstructive sleep apnea hypoventilation.

Presentation of depression suicidality which was reported rarely, but was present, worsening psychosis. And, the counseling on driving safety really needs to go in for, the adolescent population. There should be at least a minimum of six hours before driving from the second dose of twice nightly oxybate. Certainly once nightly, oxybate is more convenient to patients on their care providers, but currently not FDA approved for pediatric narcolepsy. And there's now a low salt version of oxybate, which has similar profile of the sodium oxybate, but has less salt, essentially putting perhaps less risk for development of hypertension or increasing blood pressure. The side effects of petant based on the clinical trial I had presented it included headaches, insomnia, irritability, anxiety, nausea, all within less than 10%. I think the thing to make sure there's monitoring for if there's other SSRI or SNRI use for treatment of say, depression or cataplexy, there's the potential for prolonged QTC pro intervals with, mixing petso and other treatments of cataplexy include antidepressants listed here.

All have very similar side effects. There's the potential for serotonin syndrome suicidality, weight gain, sexual dysfunction. And, the monoamine class also has the potential for anticholinergic effects. in essence, when we're using these medications, we're oftentimes thinking through what's the patient's symptoms, what's the insurance coverage? We try to tailor the medication or the treatment regimen to the patient based on both the severity, the frequency of symptoms and potential for adherence as well as convenience. And so this is a nice graph that basically, this is a nice cartoon that basically shows, how a European cohort of experts use medication management which I think is a nice guide as well for us. So, if daytime sleepiness is the unique or main severe symptom, monotherapy is advised with medications, such as modafinil, peton or sofe in adults in the pediatric population, Peton, traditional stimulants might be considered in excess if the patient presents with daytime sleepiness and cataplexy monotherapy is preferred. So an oxybate, I'd either twice nightly or once nightly certainly could be discussed in the adult population. Peton is also approved for cataplexy in this country, so that could be considered as well. And then various combinations of therapy, if there's the presentation of daytime sleepiness, ca taplexy, as well as disrupted nighttime sleep monotherapy with an oxybate either twice nightly or once nightly would be advised. But obviously combination therapies could also be considered.

Well, this was a brief, but great discussion. Hopefully you can put some of these tips into your practice tomorrow. And thank you again for your listening.

Announcer:

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