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Roundtable: Safety and Efficacy Data on New Therapies for Excessive Daytime Sleepiness in Obstructive Sleep Apnea

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Dr. Malhotra:
Hello and welcome. My name is Dr. Atul Malhotra. This session is entitled Roundtable: Safety and Efficacy Data on New Therapies for Excessive Daytime Sleepiness in Obstructive Sleep Apnea. I'm the Research Chief for Pulmonary Critical Care, Sleep Medicine Physiology at the University of California, San Diego. I'm a Professor of Medicine here doing research and patient care related to sleep apnea and other conditions. I'd like to introduce my friend, Dr. Neomi Shah.

Dr. Shah:
Thank you, Atul. My name is Neomi Shah, as Atul mentioned. And I'm in New York City at the Icahn School of Medicine, and I'm a Professor of Medicine and also the System Vice Chair of Faculty Affairs for the Department of Medicine. And it's a pleasure to be here.

Dr. Malhotra:
Great. Thank you. I'd like to learn from your experience in sleep apnea. So if you see a patient on CPAP who has residual sleepiness, what's your thought process?

Dr. Shah:
Yeah. Usually the first thought is, are they using their CPAP enough? And once we've sort of established that, and they are using it to the degree that I'm satisfied, which is usually at least 4 hours, but ideally for the entire sleep duration, if they're residual AHI is less than 5, and I'd established that they're getting enough sleep, I'm looking to see if there are any other potential alternatives that I can offer, either medication is or other behavioral interventions to help improve that.

Dr. Malhotra:
Do you find the downloads quite helpful in that context to assessing those patients?

Dr. Shah:
Absolutely. They're critical.

Dr. Malhotra:
Okay. And do you find other sleep disorders come up with some people that talk about narcolepsy or other conditions that may be coming into play? Or do you find that residual sleepiness is common in sleep apnea with or without, you know, other conditions coming into play?

Dr. Shah:
Yeah, I think insufficient sleep is really the big one that comes up. A lot of times, they're just not sleeping enough. So in terms of sleep disorders, insomnia is a big

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one in the center population here in New York City. So those two are really the main ones that come up.

Dr. Malhotra:
Yeah. And then if you are reaching for pharmacology, what's your thought process there?

Dr. Shah:
So I'm usually reaching for the ones that I'm familiar with, the ones that I was trained with, and so they're typically Modafinil or armodafinil. And I am finding that I'm using solriamfetol more, primarily in my patient population that are on oral contraceptives, because that's a nice one, you don't have to worry about checking all of the different devices or potential oral - OCPs. So that's one of the main features that I reach for solriamfetol. But I'm still very comfortable with using Modafinil or armodafinil just the physical track record.

Dr. Malhotra:
Yeah, I have an issue as well. Modafinil and armodafinil interfere with birth control pills, and they're teratogenics, and kind of call that a double whammy. I'm quite careful about using those drugs in premenopausal women.

Dr. Shah:
Yeah. And up until we had solriamfetol, it was really disappointing to have these conversations and try to figure out which IUD is potentially safe or not safe. You know, OCPs are easier, but the IUDs I've found, you know, I had long conversations with the pharmacists to figure out whether it actually does make a difference or not.

Dr. Malhotra:
Yeah, and that's not really in the skillset of many sleep physicians. It's something I was very familiar with.

Dr. Shah:
More intensive it is, for that round.

Dr. Malhotra:
Yeah, fair enough. Fair enough. And do you have insurance issues getting coverage for the newer medications?

Dr. Shah:
Not usually. I think as long as we established that they've tried these drugs, and they haven't really responded, or there's clear contraindications. We haven't had too many, but it's not like I have hundreds of patients on these new meds. This is obviously still a new area. So most of my colleagues and I are having, you know, very little difficulty getting this approved compared to, for example, Xyrem, or, you know, sodium oxybate, I think that's a much sort of a bigger problem in terms of getting approval, getting the paperwork done.

Dr. Malhotra:
Yeah, agreed. I don't know if it's a referral bias or what, but I see a lot of patients who don't do well with Modafinil, who then come for seeking alternative therapies. And maybe it's just the ones who are happy with Modafinil don't necessarily come to see me. But do you find that as well, that there's a patient switching from one drug to another because of incomplete efficacy?

Dr. Shah:
Absolutely. Absolutely. We see that all the time. And it is very hard because you keep going back and forth between Modafinil or armodafinil, and then went back to sort of the stimulants, which I was never a big fan of.

Dr. Malhotra:
Yeah, agreed. How about with side effects. Have you had much experience with solriamfetol side effects? I've seen some nausea and some headache, but not, you know, in general, they're pretty well tolerated.

Dr. Shah:
Absolutely. Yeah. I haven't seen anything major. I mean, anxiety, headaches, sort of the two main ones that I've seen, but nothing beyond what - nothing where they would have to discontinued this.

Dr. Malhotra:
Yeah. And full disclosure, I was, you know, I was involved in some of the studies. And, you know, the efficacy and safety do look pretty good for these new medications. But, as you say, clinical experience is still early days.

Dr. Shah:
Yeah. And there was a really good meta-analysis in the *Annals of Internal Medicine* that also basically showed the same thing that you just said.

Dr. Malhotra:

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Great, thank you. Thanks for everybody for joining us today. Been a pleasure. Thank you, Dr. Shah, for your insights.

Announcer:
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