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QoL Matters: Brain Stem Stimulation in Patients With Unipolar Depression

Announcer:

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Dr. Sankar:

This is CME on ReachMD, and I am Dr. Raman Sankar. Joining me today is Dr. Scott Aaronson.

Dr. Aaronson, can you talk about VNS for the management of treatment-resistant depression, or TRD?

Dr. Aaronson:

Thank you, Dr. Sankar. VNS has been available for the treatment of difficult-to-treat depression for a long time, but there has not been sufficient insurance company support for this. On the basis of this, we were able to get the Centers for Medicare and Medicaid to agree to fund a large multicenter study called RECOVER to compare efficacy of VNS in people with very difficult-to-treat depression.

As it turned out, when we looked at the patient population, average number of treatment failures was 13 treatment failures for this population. Folks were randomized to either getting a VNS device implanted and turned on or getting a VNS device implanted. And we followed people in this double-blind part of the study for 12 months, and we're continuing to follow these people out for another 4 years.

We're now coming out with that initial 12 months of study. And what we find is that, particularly in quality of life and functionality, we find a significant improvement between the folks who had the device in and on and the folks who just had the device without it being turned on. We also are now finding in some of the 2-year data that there is very good durability in folks who have had a meaningful improvement in quality of life, functionality, or depression continue to preserve that to a very, very high extent.

The other thing that we learned is that for this difficult-to-treat population, depression markers may not be as important as quality-of-life and functionality issues, that we don't seem to see as much separation between the on and the off group with some of the typical depression markers as much as we do with the quality-of-life markers.

Curiously, though, where we saw the best separation was a CGI score, Clinical Global Impression score from the treating clinician who was blinded to the treatment protocol. But not surprisingly, experienced psychiatrists can recognize when their patients are having a meaningful improvement in their illness.

So we're coming up with not merely important evidence for efficacy of VNS in a very, very sick population, but we're also developing new methods of looking at outcomes in folks who have been ignored by the psychiatric field for so many years, people with multiple treatment failures. And so going forward, we're hopeful that we're going to be able to touch a larger number of people who we have not had adequate interventions for.

Dr. Sankar:

Thank you, Dr. Aaronson. This is very consistent with my understanding of the pathophysiology. I think one of the great things about

this kind of peripheral stimulation of the vagus nerve is being able to access both the raphe nucleus and the locus coeruleus indirectly without the invasive procedures in the brain and yet be able to steadily release norepinephrine and serotonin in a pulsatile fashion, which is very, very consistent with pharmacotherapy, however, without the baggage of side effects we see with many of those medications.

So it has been a great learning activity and a wonderful micro discussion. I thank you.

Announcer:

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