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VNS: Beyond Seizure Control

Announcer:

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Dr. Aaronson:

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

Dr. Sankar, can you discuss the safety and efficacy of VNS?

Dr. Sankar:

Gladly, Dr. Aaronson. The VNS has been now in use for almost 25 years and has a long-established record of both efficacy and safety. The seizure control gradually improves over time. Usually, most patients can achieve anywhere from 50% to 55% reduction of seizure with some of them achieving considerably more than that. And the quality-of-life improvement involves both reduction in seizures, as well as, in some patients, there has been a reduction on medication, which secondarily leads to quality-of-life improvement, because one of the big contributors to adverse quality of life are the medication side effects.

In addition, patients also find the protection from SUDEP and the improvement in mood to be reassuring, and that probably contributes to the quality of life as well.

In terms of adverse events and safety, it is very rare to have an infectious complication. It is probably helped by the fact that VNS involves only a peripheral placement and no brain surgery. And in terms of the adverse events, many of them that are presented in standard presentations, come from the initial pivotal clinical trials that were used to obtain approval by the FDA.

But during those trials 25 years ago, people were routinely using a 30 Hz stimulus with a 500 μ s pulse width and often went to currents as high as 3.5 mA. What we have learned over the years is we do not need such a strong signal. So we find that the adverse events, such as hoarseness, coughing, etc., or even discomfort, have substantially been reduced with modern approaches to programming. In general, a lower pulse width, the lower frequency, and lower current density, all of which should reduce the side effects. And so we generally use, in the modern VNS devices, preprogrammed settings so we are able to, in fact, do the dose titration without even the patient having to come to the clinic for each visit. And we do that in very small increments, and we pause at a relatively low stimulus rate, so that the adverse events can be minimized.

Dr. Aaronson:

I'll just add some more commentary about my experience with VNS. And within my clinic, we've done about 100 implantations of VNS for people with difficult-to-treat depression.

The most common side effects that we'll see in this cohort of folks is there will be some voice alteration when the device is going off, because the pigtails from the battery that are wrapped around the vagus nerve are wrapped around the vagus nerve right where the recurrent laryngeal comes off the vagus nerve, and so we're going to get some leakage of that signal over to the recurrent laryngeal. So

you'll get changes in vocal quality. And sometimes you'll get people feeling that they're having difficulty taking a deep breath because of the interference with the vocal cords.

That said, of the 100 or so implantations that we've done, we've only done 3 explantations, which is important because what we're actually capturing with that is both the tolerability of this treatment as well as the efficacy. One of the most important things that you can see is that people will vote with their feet, and the fact that more people aren't asking to be explanted really means that they're tolerating it.

And the other comment on that is that a lot of the people who want to be reimplanted once the battery dies out, which will generally, in my experience, be anywhere between 6 and 9 years after initial implantation, is a lot of people who wind up getting lost to follow-up, come back when the battery runs out because they're clear that there has been enough meaningful benefit that they've lost without getting that stimulation.

I'm going to wrap it up today. And I thank Dr. Sankar again for a wonderful discussion. And thank you all for listening.

Dr. Sankar:

Thank you, Dr. Aaronson.

Announcer:

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