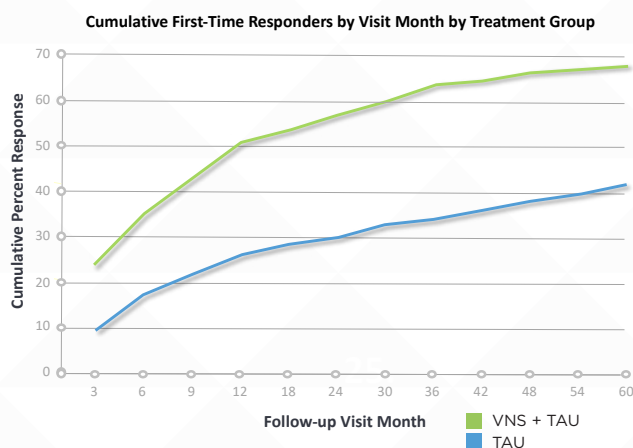


A 5-Year Observational Study of Patients With Treatment-Resistant Depression Treated With Vagus Nerve Stimulation or Treatment as Usual: Comparison of Response, Remission, and Suicidality

Key Take Away:

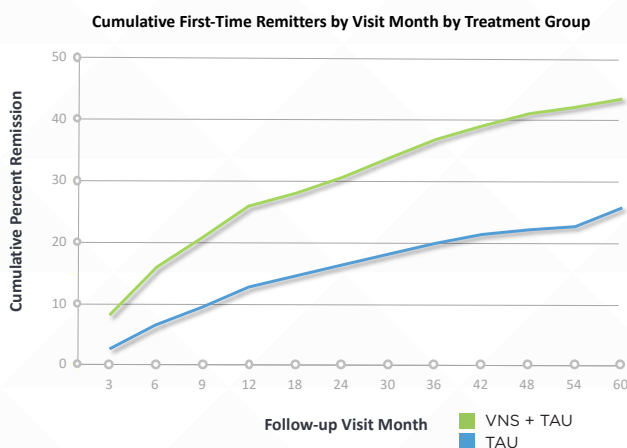
1 VNS Therapy (+ TAU) delivered superior response and remission rates vs TAU alone over 5 years

The cumulative response rate at 5 years was **67.6%** for adjunctive VNS Therapy compared to **40.9%** for TAU ($p < 0.001$).



2 Results with VNS Therapy (+ TAU) get stronger over time

The cumulative remission rate at 5 years was **43.3%** for adjunctive VNS Therapy compared to **25.7%** for TAU ($p < 0.001$).



3 VNS Therapy (+ TAU) reduced suicidal ideation, rate of suicide, and all-cause mortality when added to traditional treatment

- Adjunctive VNS therapy showed a greater reduction in the suicidality profile compared with TAU.
- All-cause mortality was markedly lower for patients with VNS Therapy (+ TAU) than for patients with TAU.

Variable	VNS + TAU	TAU
Total nr of deaths	7	8
All-cause mortality / 1.000 pt years	3.53	8.63
Suicides	2	2
Suicides / 1.000 pt years	1.01	2.20



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Study Summary:

Objective:

The Treatment-Resistant Depression Registry investigated whether adjunctive vagus nerve stimulation (VNS) with treatment as usual in depression has superior long-term outcomes compared with treatment as usual only.

Method:

This 5-year, prospective, open-label, nonrandomized, observational registry study was conducted at 61 U.S. sites and included 795 patients who were experiencing a major depressive episode (unipolar or bipolar depression) of at least 2 years' duration or had three or more depressive episodes (including the current episode), and who had failed four or more depression treatments (including ECT). Patients with a history of psychosis or rapid-cycling bipolar disorder were excluded. The primary efficacy measure was response rate, defined as a decrease of $\geq 50\%$ in baseline Montgomery-Asberg Depression Rating Scale (MADRS) score at any postbaseline visit during the 5-year study. Secondary efficacy measures included remission.

Results:

Patients had chronic moderate to severe depression at baseline (the mean MADRS score was 29.3 [SD=6.9] for the treatment-as-usual group and 33.1 [SD=7.0] for the adjunctive VNS group). The registry results indicate that the adjunctive VNS group had better clinical outcomes than the treatment as-usual group, including a significantly higher 5-year cumulative response rate (67.6% compared with 40.9%) and a significantly higher remission rate (cumulative first-time remitters, 43.3% compared with 25.7%). A subanalysis demonstrated that among patients with a history of response to ECT, those in the adjunctive VNS group had a significantly higher 5-year cumulative response rate than those in the treatment as-usual group (71.3% compared with 56.9%). A similar significant response differential was observed among ECT nonresponders (59.6% compared with 34.1%).

Conclusion:

This registry represents the longest and largest naturalistic study of efficacy outcomes in treatment-resistant depression, and it provides additional evidence that adjunctive VNS has enhanced antidepressant effects compared with treatment as usual in this severely ill patient population.

The VNS Therapy System is indicated for the treatment of chronic or recurrent depression in patients that are in a treatment-resistant or treatment-intolerant major depressive episode.

The most commonly reported side effect from the implant procedure is infection. The most commonly reported side effects from stimulation include voice alteration, pricking feeling in the skin, shortness of breath, sore throat and increased coughing. VNS Therapy is well-tolerated and side effects were less noticeable over time.

FOR MORE SAFETY INFORMATION, [CLICK HERE](#)