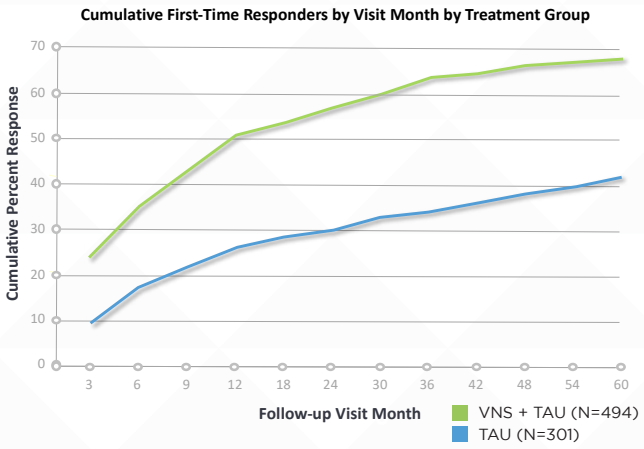
Clinical Highlights: Aaronson ST et al.
Am J Psychiatry 2017;174:640-48

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:

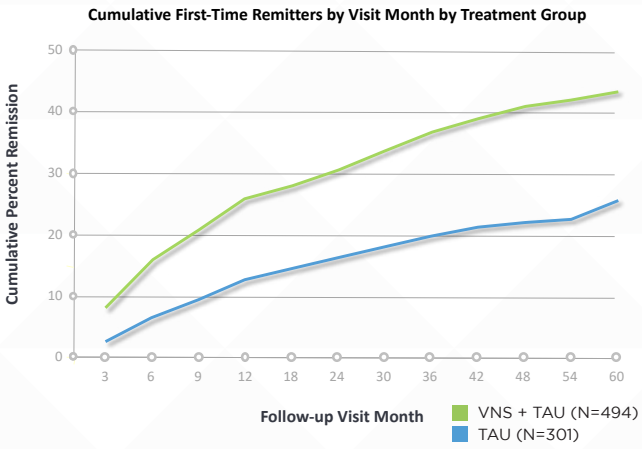
1 VNS Therapy (+ TAU) delivered superior cumulative response and remission rates vs TAU alone over 5 years (p<0.001)

The cumulative **response rate** over 5 years was 67.6% for patients treated with adjunctive VNS Therapy compared to 40.9% for patients treated with TAU alone (p<0.001).



2 Results with VNS Therapy get stronger over time

The cumulative **remission rate** over 5 years was 43.3% for patients treated with adjunctive VNS Therapy compared to 25.7% for patients treated with TAU alone (p<0.001).



3 Reduced rate of suicide compared with Treatment as Usual and reduced all-cause mortality when added to traditional treatment.

- The VNS (+TAU) arm showed a greater reduction in the suicidality profile compared with the treatment-as-usual arm (The difference was statistically significant for QIDS-SR item 12 but not for MADRS item 10).
- All-cause mortality was markedly lower in the VNS (+TAU) arm than in the treatment-as-usual arm.

Variable	VNS + TAU	TAU
Total number 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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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

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 ≥ 50% in baseline Montgomery-Asberg Depression Rating Scale (MADRS) score at any postbaseline visit during the 5-year study. Secondary efficacy measures included remission.

This study was sponsored by LivaNova.

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.

Implant-related adverse events reported by ≥ 5% of patients are listed in order of decreasing occurrence: incision pain, voice alteration, incision site reaction, device site pain, device site reaction, pharyngitis, dysphagia, hypesthesia, dyspnea, nausea, headache, neck pain, pain, paresthesia, and cough increased. Stimulation-related adverse events reported by ≥ 5% of VNS Therapy-treated patients are listed in order of decreasing occurrence: voice alteration, cough increased, dyspnea, neck pain, dysphagia, laryngismus, paresthesia, pharyngitis, nausea, incision pain and headache.

FOR MORE SAFETY INFORMATION, go to https://www.symmetryvns.com/resources.html#manuals

SYMMETRY™

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