Clinical Highlights: McAllister-Williams RH et al.
Int J Bipolar Disord 2020;8:13 doi: 10.1186.

The effects of vagus nerve stimulation on the course and outcomes of patients with bipolar disorder in a treatment-resistant depressive episode: a 5-year prospective registry

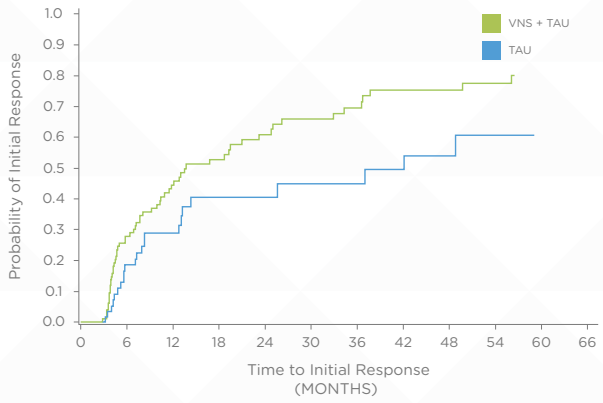
Key Take Away:

1 VNS Therapy (+ TAU) had significantly greater cumulative response rates vs TAU alone over 5 years in patients with DTD bipolar depression.

The cumulative **response rate** at 5 years was **63%** for adjunctive **VNS** Therapy compared to **39%** for **TAU** (p<0.001).

NNT **4**

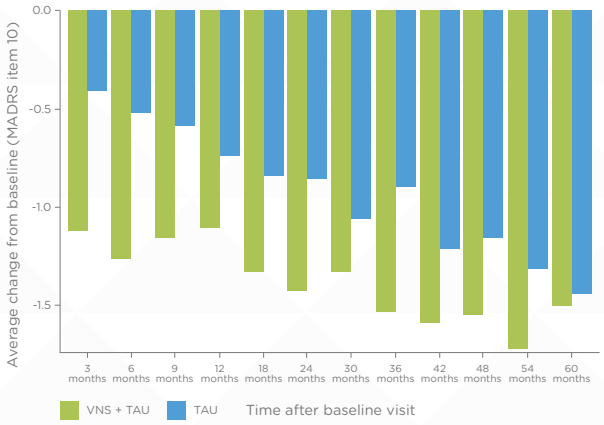
2 VNS Therapy (+TAU) delivered faster on-set of antidepressant response vs TAU and responses with VNS Therapy (+ TAU) were longer in duration than in patients receiving TAU alone.



Time to Initial Response was significantly shorter for VNS Therapy (+ TAU) than for TAU alone.
Median Time to Initial Response (p=0.03):

- VNS + TAU: 13.7 months
- TAU: 42.1 months

3 The mean reduction in suicidality score across the study visits was significantly greater for VNS Therapy (+ TAU) compared to patients receiving TAU alone. (p<0.001)



A total of 34% (33/97) in the VNS + TAU group and 13,6% (8/59) in the TAU group were severely suicidal at baseline based on MADRS (score ≥4 on MADRS item 10).

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Study Summary:

Objective:
To compare illness characteristics, treatment history, response and durability, and suicidality scores over a 5-year period in patients with treatment-resistant bipolar depression participating in a prospective, multicenter, open-label registry and receiving Vagus Nerve Stimulation Therapy (VNS Therapy) plus treatment-as-usual (VNS + TAU) or TAU alone.

Method:
Response was defined as ≥ 50% decrease from baseline Montgomery–Asberg Depression Rating Scale (MADRS) total score at 3, 6, 9, or 12 months post-baseline. Response was retained while MADRS score remained ≥ 40% lower than baseline. Time-to-events was estimated using Kaplan–Meier (KM) analysis and compared using log-rank test. Suicidality was assessed using the MADRS Item 10 score.

Results:
At baseline (entry into registry), the VNS + TAU group (N = 97) had more episodes of depression, psychiatric hospitalizations, lifetime suicide attempts and higher suicidality score, more severe symptoms (based on MADRS and other scales), and higher rate of prior electroconvulsive therapy than TAU group (N = 59). Lifetime use of medications was similar between the groups (a mean of 9) and was consistent with the severe treatment-resistant nature of their depression. Over 5 years, 63% (61/97) in VNS + TAU had an initial response compared with 39% (23/59) in TAU. The time-to-initial response was significantly quicker for VNS + TAU than for TAU ($p < 0.03$). Among responders in the first year after implant, the KM estimate of the median time-to-relapse from initial response was 15.2 vs 7.6 months for VNS + TAU compared with TAU (difference was not statistically significant). The mean reduction in suicidality score across the study visits was significantly greater in the VNS + TAU than in the TAU group ($p < 0.001$).

Conclusion:
The patients who received VNS + TAU included in this analysis had severe bipolar depression that had proved extremely difficult to treat. The TAU comparator group were similar though had slight-ly less severe illnesses on some measures and had less history of suicide attempts. Treatment with VNS + TAU was associated with a higher likelihood of attaining a response compared to TAU alone. VNS + TAU was also associated with a significantly greater mean reduction in suicidality.

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, prickling 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

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