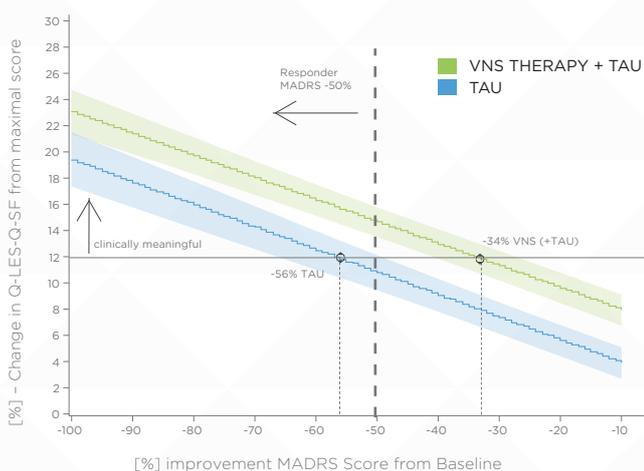




Chronic Vagus Nerve Stimulation Significantly Improves Quality of Life in Treatment-Resistant Major Depression

Key Take Away:

- VNS Therapy (+ TAU) demonstrated a statistically significant greater improvement in quality of life than TAU.**



VNS Therapy (+ TAU) patients could achieve a clinically meaningful increase in QOL when the MADRS drop from baseline is at least **34%**.

The TAU patients achieved the same increase when the MADRS drop from baseline is much bigger (**at least 56%**).

- VNS Therapy (+TAU) demonstrated significant advantages in not only the mood domain, but also multiple other functional domains.**

Q-LES-Q-SF subscale	VNS + TAU	TAU
Mood	1.00 (0.92-1.07)	0.74 (0.65-0.83)
Household Activities	0.80 (0.73-0.88)	0.54 (0.45-0.63)
Family relationships	0.54 (0.45-0.62)	0.35 (0.25-0.44)
Leisure activities	0.83 (0.75-0.91)	0.54 (0.44-0.64)
Ability to function	0.89 (0.82-0.96)	0.62 (0.54-0.71)
Overall well-being	0.92 (0.84-0.99)	0.68 (0.59-0.78)



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

Study Summary:

Objective:

To compare quality-of-life (QOL) change associated with treatment as usual (TAU, any antidepressant treatment) versus adjunctive vagus nerve stimulation treatment (VNS + TAU) in a population of patients with treatment-resistant depression (TRD) for 5 years.

Method:

Self-reported QOL assessments, using the Quality of Life Enjoyment and Satisfaction Questionnaire Short Form (Q-LES-Q-SF), were gathered in a multicenter, longitudinal registry (January 2006 – May 2015) comparing the antidepressant efficacy of VNS + TAU versus TAU in TRD. All depressed patients (N=599), with either unipolar or bipolar depression, met DSM-IV-TR major depressive episode criteria and failed at least 4 adequate antidepressant trials. The Montgomery-Asberg Depression Rating Scale (MADRS) was administered by blinded raters. Q-LES-Q-SF scores in the treatment arms

were compared via linear regression; linear regression was employed to compare QOL differences with percent decrease in MADRS. A sub analysis comparing Q-LES-Q-SF functional domain change was performed. Measures included remission.

Results:

328 VNS + TAU and 271 TAU patients with TRD were compared. On average, VNS + TAU demonstrated a significant, comparative QOL advantage over TAU (as demonstrated via non overlapping 95% confidence bands) that began at 3 months and was sustained through 5 years and was reinforced using a clinical global improvement measure. Patients receiving VNS + TAU, but not TAU alone, demonstrated a clinically meaningful QOL improvement (34% MADRS decrease). Exploratory post hoc sub analysis demonstrated that VNS + TAU had a significant advantage in multiple Q-LES-Q domains.

Conclusion:

Compared to TAU, adjunctive VNS significantly improved QOL in TRD, and this QOL advantage was sustained. Further, TRD patients treated with VNS experienced clinically meaningful QOL improvements even with depression symptom reduction less than the conventional 50% reduction used to ascribe “response”.

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.

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