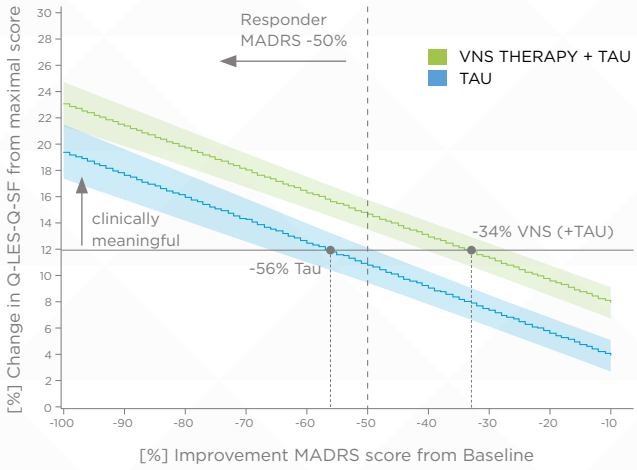
Clinical Highlights: Conway CR et al. J Clin Psychiatry 2018;79:18m12178.

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

## Key take away:

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




**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 clinically meaningful increase in Q-LES-Q-F percent max score when the MADRS drop from baseline is much higher **(at least 56%).**

**2 VNS Therapy (+TAU) demonstrated significant advantages in not only the mood domain, but also multiple other functional domains. (Estimated change in Q-LES-S-SF domain score from baseline with 95% confidence interval at 50% MADRS change from baseline.)**

| Q-LES-Q-SF subscale | VNS + TAU | TAU |
|---|---|---|
| Mood | 1.00 (0.92-1.07) | 0.74 (0.65-0.83) |
| Household Activities | 0.8 (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) |

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## 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 From (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 anti-depressant 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 avantage 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.

**This study was sponsored by LivaNova.**

### 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".**


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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 www.symmetryvns.com/resources.html#manuals**

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