Pain Med. Author manuscript; available in PMC 2012 Sep 1.

Published in final edited form as:

Pain Med. 2011 Sep; 12(9): 1406–1413.

Published online 2011 Aug 3. doi: 10.1111/j.1526-4637.2011.01203.x

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3173600/

PMCID: PMC3173600

NIHMSID: NIHMS305993

PMID: 21812908

Safety and efficacy of vagus nerve stimulation in Fibromyalgia: A Phase I/II proof of concept trial

Gudrun Lange, PhD, Malvin N. Janal, PhD, Allen Maniker, MD, Jennifer FitzGibbons, APN, Malusha Fobler, BA, Dane Cook, PhD, and Benjamin H. Natelson, MD

Author information Copyright and License information Disclaimer

Abstract

Objective

We performed an open label Phase I/II trial to evaluate the safety and tolerability of vagus nerve stimulation (VNS) in patients with treatment-resistant fibromyalgia (FM) as well as to determine preliminary measures of efficacy in these patients.

Methods

Of 14 patients implanted with the VNS stimulator, 12 completed the initial 3 month study of VNS; 11 returned for follow-up visits 5, 8 and 11 months after start of stimulation. Therapeutic efficacy was assessed with a composite measure requiring improvement in pain, overall wellness, and physical function. Loss of both pain and tenderness criteria for the diagnosis of FM was added as a secondary outcome measure because of results found at the end of 3 months of stimulation.

Results

Side effects were similar to those reported in patients treated with VNS for epilepsy or depression and, in addition, dry mouth and fatigue were reported. Two patients did not tolerate stimulation. At 3 months, five participants had attained efficacy criteria; of these, two no longer met widespread pain or tenderness criteria for the diagnosis of FM. The therapeutic effect seemed to increase over time in that additional participants attained both criteria at 11 months.

Conclusions

Side effects and tolerability were similar to those found in disorders currently treated with VNS. Preliminary outcome measures suggested that VNS may be a useful adjunct treatment for FM patients resistant to conventional therapeutic management but further research is required to better understand its actual role in the treatment of FM.

Fibromyalgia (FM) affects 3.4% of women and 0.5% men in North America (1). Despite this prevalence, only three medications are currently approved for its use. Anecdotal data among FM practitioners suggest that many patients, however, continue to suffer pain which interferes substantially with their physical function and quality of life.

We evaluated the possibility that periodic stimulation of the left vagus nerve by Vagus Nerve Stimulation [VNS] throughout the 24 hr day might be a safe, tolerable, and useful adjunct treatment for patients reporting continued severe pain despite receiving current best medical management. Three observations guided the reasoning for undertaking this trial: first, experimental studies suggested that afferent vagal stimulation may modulate descending serotonergic and noradrenergic neurons to reduce pain (2); second, VNS has FDA approval for treatment resistant epilepsy and depression – disorders which have been treated by similar medicines as those used to treat FM (3;4) and third, VNS appeared to decrease pain perception in patients with treatment-resistant depression (5). To test our hypothesis, we initiated a Phase I/II safety and tolerability trial of VNS in a cohort of FM persons with continued substantial pain complaints despite medical treatment. While the primary purpose of this "proof of concept" trial was to assess the safety and tolerability of VNS in FM, we also collected preliminary data assessing potential treatment efficacy.