

VNS therapy in bipolar II patients. Project description and preliminary results

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Background: Vagus nerve stimulation (VNS) refers to stimulation of the left vagus nerve at the cervical level. VNS is an established treatment for medically refractory partial onset seizures and has been used in more than 30000 patients. Over the past 10 years, several studies have been conducted to investigate its potential in the treatment of depression and recently the treatment was approved as an adjunct treatment for treatment resistant depression by the FDA. The perspective of VNS as a long-term treatment with the advantage of assured compliance makes it an interesting technique to potentially treat bipolar disorders.

Objective: The present study aims to evaluate the effects of long term vagus nerve stimulation (VNS) in 12 patients with bipolar II and 12 patients with unipolar affective disorder regarding: 1. Affective symptoms, side effects and stimulation tolerance 2. Quality of sleep. 3. Cognitive functioning 4. Gastric accommodation.

Methods:

1. Clinical evaluation by MADRS, YMRS and careful investigation of side effects, weekly the first 8 weeks, thereafter monthly for 1 year.
2. Sleep studies were conducted in the laboratory at baseline and 6 months and 12 months after VNS implantation.
3. F-mri with a battery of cognitive tests at baseline and after 12 months 4. Measures of the gastric vagal tone by balloon dilatation technique at baseline, 6 months and 12 months.

Results: 4 patients have completed 12 months of treatment. The results concerning the affective symptoms, side effects and stimulation record in these patients will be presented. An overall significant treatment effect on depressive symptoms was found in all patients, although the tolerability of the stimulation, side effects and need for additional treatment varied between the patients.

Conclusion: All patients improved after 12 months with VNS therapy, and none wanted to have the device explanted. The treatment was generally well tolerated, although patients had different acceptability to the stimulation-induced side effects. The procedures for the investigations of sleep, f-mri and gastric dilatation were well put up with by the patients and compatible with carrying a VNS device.