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A Brief Discussion of the Withdrawal of Opioids with Vagus Nerve Stimulation

Douglas Bremner*

Department of Psychiatry and Behavioral Sciences, Emory University School of Medicine, Washington Dc, USA

DESCRIPTION

The Food and Drug Administration (FDA) approved a percutaneous form of Vagus Nerve Stimulation (VNS) for the treatment of opioid withdrawal symptoms in 2017. This was based on the findings of an open-label study of 73 patients with OUD that showed a significant reduction in opioid withdrawal symptoms within 1 hour. Lack of sham control and objective measures of withdrawal symptoms, including physiological measures of sympathetic nervous system activation, limited this study. The researcher turned on the device at the beginning of each application and held the output voltage at 0 V until an audible beep was heard and the Light Emitting Diode (LED) was illuminated. Stimulation intensity was then increased from 0 V to the maximum level that the participant could painlessly tolerate using a scroll switch. Stimulation intensity was reduced if participants experienced pain during stimulation. Stimulation was automatically terminated 120 seconds after initiation of administration. To ensure double-blinding, participants were randomly assigned to active tcVNS or sham stimulation groups using simple randomization. A neutral party matched the stimulation devices to the participants' identification numbers. The manufacturer prenumbered active tcVNS and simulated pacing devices that appeared and performed identically, with the only difference being the pacing waveforms. As a result, both researchers and participants were blinded to stimulus type during the screening, clinical interview, and data collection process. De bonding occurred only during active *vs.* fake data analysis. Differences in survey scores between the active and sham groups were compared before and after stimulation to examine the effects of tcVNS on the progression of perceived withdrawal symptoms, craving, pain, anxiety and distress. Responses after the second neutral video were used to define the baseline for VAS and SUDS measurements, as this was the final condition of the pre-stimulation protocol. Differences were calculated by subtracting baseline measurements from measurements taken after the final protocol. It should be noted that the post-protocol COWS and NRS pain measurements were taken immediately after the final VAS and SUDS surveys, meaning that the measurements used as minuen correspond to the same time point. All statistical tests were performed with device group as the independent variable and desired outcome as the dependent variable. For normally and non-normally distributed variables, unpaired t-tests or Mann-Whitney U tests were used to compare survey responses. An unpaired t-test, one for each participant, was used to compare heart rate responses. A mixed model with random intercept per participant was used to compare heart rate responses, one for each condition and participant. These mixed models were fitted in R using the lme 4 package, and P values were calculated using Satterthwaite degrees of freedom. All statistical tests were two-sided and had a significance level of 0.05. No serious side effects were observed or reported. When stimulation amplitudes were initially set higher than the participant could comfortably receive for 2 minutes, there were general complaints of uncomfortable muscle contractions. These concerns were alleviated by reducing the stimulation amplitude. After stimulation, one participant reported feeling dizzy. However, it is unclear whether this was due to tcVNS or a random withdrawal symptom. The participant quickly subsided and continued the protocol without further complaints.

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Corresponding author: Douglas Bremner, Department of Psychiatry and Behavioral Sciences, Emory University School of Medicine, Washington Dc, USA; E-mail: jdbremn@emory.edu

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