Long-term Experience of VNS in Lennox-gastaut Syndrome at 24 Months from the CORE-VNS Registry

Abstract number : 2.249
Submission category : 4. Clinical Epilepsy / 4C. Clinical Treatments
Year : 2024
Submission ID : 907
Source : www.aesnet.org
Presentation date : 12/8/2024 12:00:00 AM
Published date :

Authors :
Presenting Author: Paul Lyons, MD, PhD – Virginia Commonwealth Epilepsy Program

James Wheless, BScPharm, MD, FAAP, FACP, FAAN, FAES – LeBonheur Children's Hospital
Ryan Verner, PhD – LivaNova PLC (or a subsidiary)
Jose Ferreira, MD – Pediatric Epilepsy and Neurology Specialists, Tampa, Florida, USA
Kore Liow, MD – University of Hawaii at Manoa
James Valeriano, MD – Allegheny General Hospital
Gholam Motamedi, MD – Medstar Georgetown University Hospital
Kathryn Nichol, PhD, MS, MBA – LivaNova PLC

Rationale: The epileptic encephalopathies associated with Lennox Gastaut Syndrome (LGS) have a long-term effect on patients and caregivers. LGS patients have intractable epilepsy that is difficult to treat with conventional pharmacological and non-pharmacological therapies. Vagus nerve stimulation (VNS) is a neuromodulation option to help manage the seizures associated with LGS.

Methods: Participants were enrolled into a prospective, multicenter, multinational observational registry- CORE-VNS (NCT03529045). The registry collected data on seizure and non-seizure outcomes following treatment with VNS, which includes those receiving VNS. For this analysis, participants were identified as having a documented LGS diagnosis and receiving initial VNS implants. Baseline seizure frequency data (collected from seizure diaries) and patient-reported outcome measures, such as quality of life (1 question Likert scale) and quality of sleep (Pittsburg Sleep Quality Index [PSQI] or Children's Sleep Habit Questionnaire [CSHQ]) were collected at 3, 6, 12, 24, and 36 months. The 24-month outcomes are compared to the pre-implant baseline and presented here.

Results: Sixty (60) participants in the CORE-VNS registry had a diagnosis of LGS and received an initial implant of VNS. The population was geographically diverse, with 31.7% European, 26.7% from the Americas, and 26.7% from the Western Pacific. The median age at implant in this study was 11.79 years (range 2.2 to 47.6) with only 26.7% diagnosed with LGS being ≥18 years of age. Most of the participants had severe cognitive impairment (70%). The LGS participants failed a median of 6 anti-seizure medications (ASMs) (range 2 to 17), and 83.3% had not undergone epilepsy surgery. In those with LGS, the responder rate (≥50% reduction in

seizure frequency) at 24 months for focal seizures was 66.7% and 47.4% in those with generalized seizures. Twenty percent of all participants experienced a ≥80% reduction in total seizure frequency. The median seizure frequency reduction at 24 months was -74.8% for focal and -43.3 for generalized seizures, respectively. Most subjects reported improvement in quality of life at 24 months (52.08%; n=25/48 non-missing) or no change (35.42%; n=17/48 non-missing). Overall sleep quality was not changed on either the PSQI or CSHQ. VNS was well-tolerated, with only 9 of 60 participants (15.0%) reporting at least 1 treatment-emergent adverse event, primarily cough, dysphonia, and oropharyngeal pain.

Conclusions: The LGS participants who received adjunctive VNS therapy to help manage seizures were predominantly severely cognitively impaired children. Seizure response to VNS was healthy, with many participants achieving a >50% reduction in seizures. VNS reduced focal and generalized seizures associated with LGS. At 24 months, the quality of life improved in over half of the study participants.

Funding: The CORE-VNS Study is Funded by LivaNova, PLC.

Clinical Epilepsy