NEUROPACE

Mesial Temporal

Brain-responsive Neurostimulation in Patients with Medically Intractable Mesial Temporal Lobe Epilepsy

GELLER EB, ET AL. EPILEPSIA. 2017 JUN; 58(6): 994-1004

SUMMARY

- The median percent seizure reduction was 70% and responder rate was 66% in most recent 3 months using last observation carried forward (LOCF) analysis.
- Twenty-nine percent of patients experienced at least one seizure-free period of 6 months or longer and 15% experienced at least one seizure-free period of 1 year or longer.

METHODS

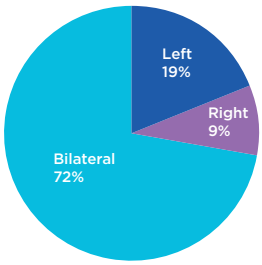
Study Design:[1] Prospective data from the open label period of a randomized, controlled, double-blinded pivotal trial and a long-term treatment (LTT) trial with average follow up of 6.1 years.

Population: 111 patients[2] with mesial temporal lobe epilepsy, representing 671 patient implant years.

Outcome Measures: Median percent change in seizures compared to baseline and the responder rate. To control for possible effects of patient withdrawal, last observation carried forward (LOCF) analyses were performed. Safety was assessed by reported adverse events (AE's).

PATIENT CHARACTERISTICS

Seizure Onsets



Demographics (mean ± SD):

- Duration of epilepsy: 19.8 yrs ± 12.7
- Number of AEDs at enrollment: 2.7 ± 1.1
- Baseline seizures/month: 15.1 ± 25.0 (median = 7.7)

History:

- 12% had prior treatment with epilepsy surgery
- 24% had prior treatment with vagus nerve stimulation (VNS)
- 54% did not have prior localization with intracranial monitoring
- 55% had mesial temporal sclerosis

KEY RESULTS

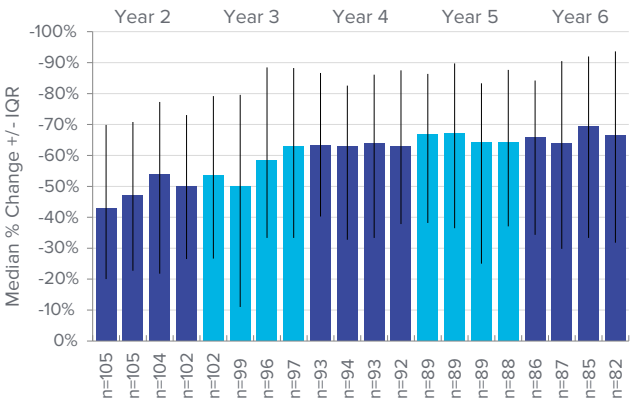
Long-term Seizure Reduction

- 70% median seizure reduction (LOCF)
- 66% responder rate (LOCF)
- At least one seizure-free period lasting
  - ≥3 months = 45% of patients
  - ≥6 months = 29% of patients
  - ≥12 months = 15% of patients

Long-term Safety

- The overall rate of SAEs due to infection was 0.03 per patient implant year
- 2.7% hemorrhage rate with no neurologic sequelae

Median % Change in Seizure Frequency



OUTCOMES BY CLINICAL CHARACTERISTICS

There was no difference in seizure response for patients with the following clinical characteristics.

	Yes	No	P-value
Prior intracranial monitoring	Median % reduction: 74.5% Responder rate: 66.7% | LOCF n=48	Median % reduction: 67.6% Responder rate: 65.5% | LOCF n=58	p=0.15
Mesial temporal sclerosis	Median % reduction: 60.6% Responder rate: 60.3% | LOCF n=58	Median % reduction: 75.6% Responder rate: 72.9% | LOCF n=48	p=0.42
Bilateral MTL onsets	Median % reduction: 67.9% Responder rate: 64.5% | LOCF n=75	Median % reduction: 72.5% Responder rate: 70.0% | LOCF n=30	p=0.97
Prior epilepsy surgery	Median % reduction: 72.5% Responder rate: 91.7% | LOCF[3] n=12	Median % reduction: 69.6% Responder rate: 62.8% | LOCF n=95	p=0.54
Prior VNS	Median % reduction: 56.8% Responder rate: 63.0% | LOCF n=27	Median % reduction: 74.1% Responder rate: 67.1% | LOCF n=78	p=0.78

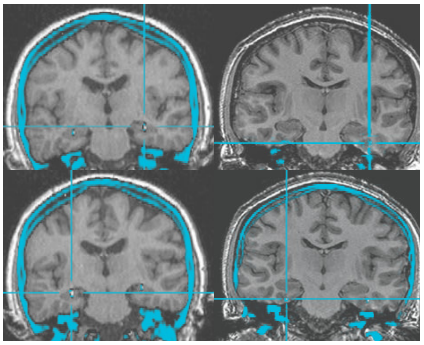
LEAD PLACEMENT OBSERVATIONS

Common lead placement approaches

- Depth leads only (N= 76)
- Depth and cortical strip leads (N=29)
- Cortical strip leads only (N=6)

Outcomes similar when leads placed within and adjacent to hippocampus[4]

- In hippocampus (n=31)
  - 77.8% median seizure reduction
  - 67.7% responder rate
- Outside of hippocampus (n=31)
  - 60.2% median seizure reduction
  - 61.3% responder rate



Footnotes

1. Retrospective analysis of ongoing prospective study, with data cutoff of November 1, 2014. The study was not powered to drive conclusions of clinical significance. N values are small and caution must be taken while interpreting results.
2. 18 yrs. or older, refractory to 2 or more AEDs and with no more than 2 foci localized by diagnostic testing.
3. Small n
4. Sixty-two of the subjects had coregistered preoperative MRI and postoperative CT images with sufficient resolution for localizing the depth leads. The co-registered images were reviewed by two independent neurosurgeons who categorized a depth lead as within the hippocampus if at least two of the four electrode contacts were in the hippocampus, and outside of the hippocampus if more than two of the four contacts were not in the hippocampus.

GELLER

Rx Only

See important prescribing and safety information in the RNS® System labeling. This is intended as supplementary information and should be used in conjunction with the labeling. Refer to the labeling for a description of the RNS® System and its components, indications for use, contraindications, warnings, cautions, adverse events and instructions for use. The manuals are available at www.NeuroPace.com.

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