Long-Term Outcomes of Treatment with Responsive Brain Stimulation in Adults with Refractory Partial Seizures

† HECK CN, ET AL. EPILEPSIA. 2014 MAR;55(3):432-41
‡ BERGEY GK, ET AL. NEUROLOGY. 2015 FEB 24;84(8):810-7

SUMMARY

- Patients treated with the RNS® System experience substantial seizure reductions that continue to improve over time.
- At 6 years, patients achieved a 66% reduction in seizures and reported significant improvements in quality of life.
- The risk of infection was 3.5% per neurostimulator procedure.

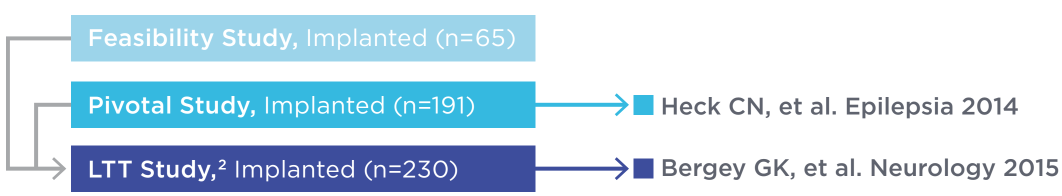
METHODS

Study Design: 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 5.4 years.

Population: 256 patients[1] representing 1,389 patient implant years.[‡]

Effectiveness Outcomes: Seizure reduction and quality of life

Safety Outcomes: Serious adverse event (SAE) rates

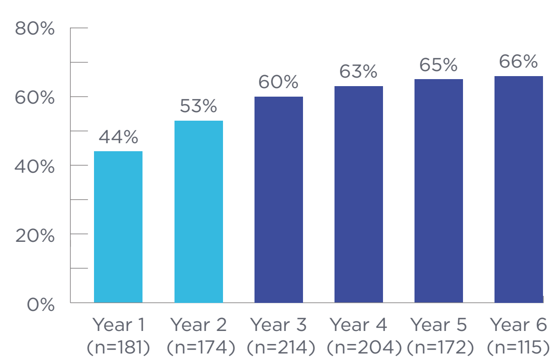


KEY RESULTS

Long-Term Efficacy[‡]

- **66% median seizure reduction**[3] at 6 years
- **59% responder rate** at 6 years
- **At least one seizure-free period lasting**
  - ≥3 months = 37% of patients
  - ≥6 months = 23% of patients
  - ≥1 year = 13% of patients
- **Significant improvements in QOL** ($p<0.01$), including improvements in cognition and decreases in seizure worry.

Median Seizure Reduction

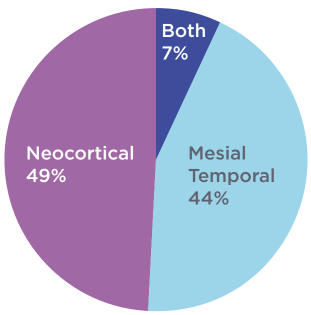


Long-term Safety[‡]

- **SUDEP rate**[4] (probable or definite) was **2.3 per 1,000** patient stimulation years (CI 0.9–6.1).
- **3.5% infection rate**[5] per neurostimulator procedure. All infections were superficial soft tissue infections. There were no meningitis or parenchymal infections, and no chronic neurologic or medical consequences.
- **2.7% intracranial hemorrhage rate**[6] with no persistent, clinically significant neurologic sequelae.

PATIENT CHARACTERISTICS[‡]

Region of Seizure Onset[‡]



Among mesial temporal patients:

- 28% unilateral
- 72% bilateral

Among neocortical patients:

- 45% temporal (non-mesial)
- 38% frontal
- 13% parietal
- 4% occipital

History

- 32% had prior treatment with vagus nerve stimulation (VNS)
- 34% had prior treatment with epilepsy surgery
- 65% had prior localization with intracranial monitoring

ADDITIONAL OBSERVATIONS

- 97% of patients chose to continue treatment by enrolling in the LTT Study.[‡]
- Efficacy results were not due to patient drop-out: the responder rate was 60% using a last observation carried forward analysis.[‡]
- There was no relationship between adjustments in AEDS and seizure outcomes.[†,‡]

Footnotes

1. 18 yrs. or older, refractory to 2 or more AEDs and with no more than 2 foci localized by diagnostic testing
2. Study ongoing, interim results as of Nov 01, 2013
3. Data represents number of patients who have reached that time point as of Nov 01, 2013.
4. Data on file, as of Sept 2015. Presented at American Neurological Association Annual Meeting, Chicago 2015.
5. Device related serious adverse events not due to seizure-related head trauma
6. Serious adverse events, not seizure related

Heck Bergey

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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