

Clinical and Electrographic Response to Antiepileptic Drugs in Patients Treated with the RNS System

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SUMMARY

- Typically, it takes many months to know whether a new antiepileptic drug (AED) will improve seizure control
- Electrographic data recorded by the RNS System may be used to assess whether a new AED is likely to improve seizure frequency in as early as one month
- The percentage of patients treated with the RNS System who experienced an additional clinical benefit was higher when clobazam or levetiracetam were started than when lacosamide or pregabalin were started

BACKGROUND

In addition to therapeutic benefits, the RNS System is the only device that provides long-term recordings of neural activity at the seizure focus/foci. Examples of types of data provided by the RNS System include:

- Electrographic recordings of sample baseline, interictal, and ictal activity
- Continuous counts of electrographic events and other epileptiform activity over days, months, and years



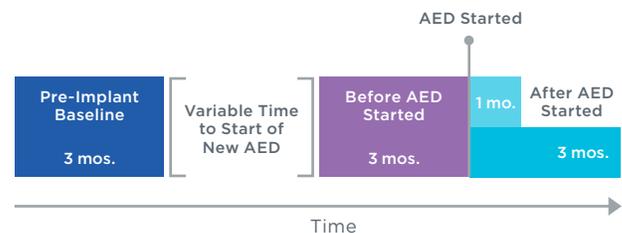
RNS System data terminology used here:

- **Detection counts:** counts of irregular epileptiform activity detected by the RNS System
- **Long episode counts:** counts of a specific type of detection trigger (lasting longer than a pre-specified time period) that often represent electrographic seizures

Histogram showing counts of electrographic events recorded by the RNS System. This information is available to physicians through the PDMS (Patient Data Management System).

METHODS

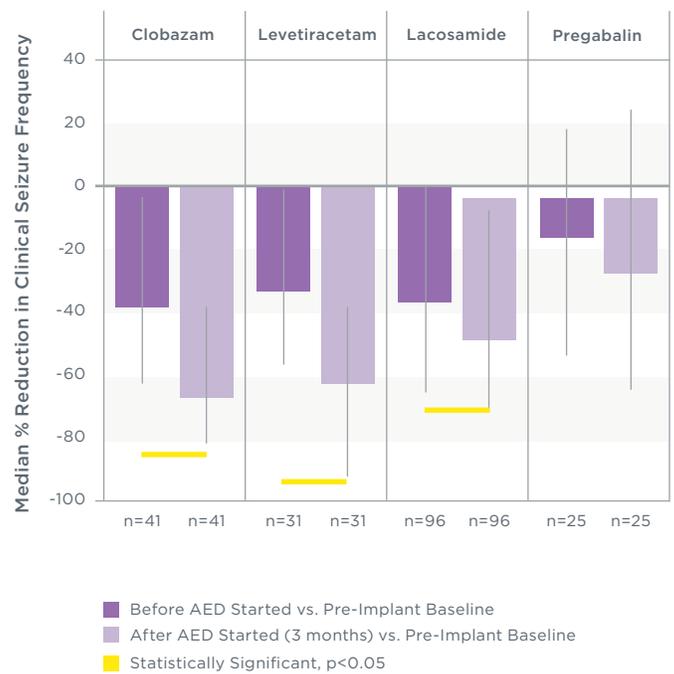
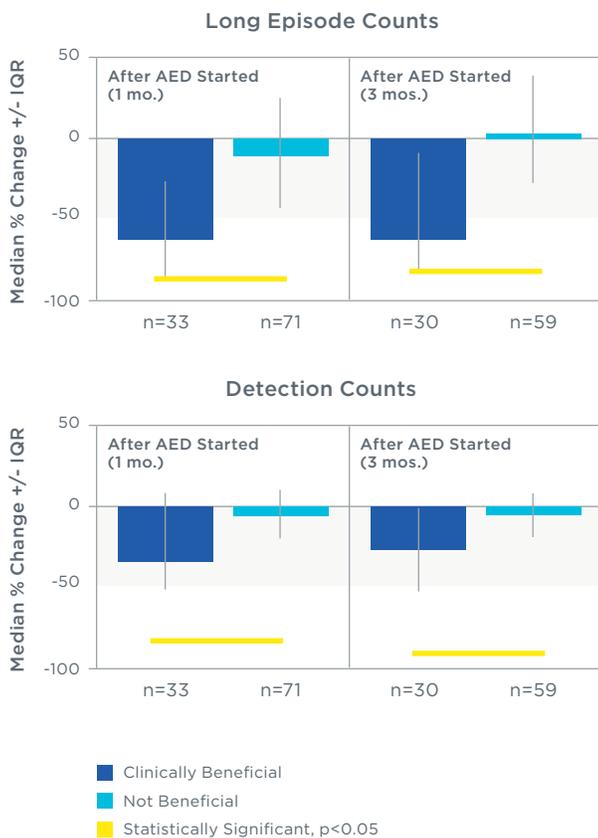
- This study assessed the relationship between the frequency of disabling seizures and electrographic data after starting a new antiepileptic medication
- Of the 230 patients participating in the RNS System long-term treatment (LTT) study, 132 were included in this analysis due to the pre-specified inclusion/exclusion criteria for this analysis
- An AED was categorized as clinically beneficial in a specific patient if it produced a $\geq 50\%$ reduction in clinical seizures above the pre-AED baseline
- RNS System data was analyzed during three periods: 3 months before the AED Start, 1 month after the AED Start, and 3 months after the AED Start





KEY RESULTS¹

- Within the 132 patients, 59 out of the 193 “AED Starts” were determined to be clinically beneficial
- The most commonly added medications were clobazam (Onfi), lacosamide (Vimpat), levetiracetam (Keppra) and pregabalin (Lyrica)
- Clinically beneficial “AED Starts” were associated with significant reductions in detection counts and long episode counts at 1 and 3 months
- Initiation of clobazam or levetiracetam was associated with significant reductions in clinical seizure frequency
- A smaller but still significant reduction in seizures was also noted for lacosamide, but not for pregabalin



ADDITIONAL NOTES

- Detection settings were held stable throughout the evaluation period
- There was a significant reduction in interictal spike rate and total spectral power (1-125 Hz) at 1 and 3 months after “AED Starts” in patients who had a clinically beneficial response. This was not observed at either 1 or 3 months for “AED Starts” that were not clinically beneficial.



SKARPAAS



The RNS System is an adjunctive therapy for adults with refractory, partial onset seizures with no more than 2 epileptogenic foci. See important prescribing and safety information in the RNS[®] System 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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Footnotes

1. This was a retrospective analysis, and was not powered to drive conclusions of clinical significance. N values are small and caution must be taken when interpreting results.