

Quality of Life and Mood in Patients with Medically Intractable Epilepsy Treated with Targeted Responsive Neurostimulation

MEADOR KJ, ET AL. EPILEPSY BEHAV. 2015 APR;45:242-7

SUMMARY

- Patients treated with the RNS[®] System showed statistically significant improvements in all quality of life domains, including seizure worry, cognition, mental health, and physical health.
- Improvements were seen in patients with mesial temporal and neocortical seizure onsets.
- Significant group improvements in mood were also observed.

METHODS

Study Design: Data from the blinded period and open label period of a randomized, controlled, double-blinded pivotal trial with follow up at 1 and 2 years.

Population: 191 patients¹. Subset analyses in patients with seizure onsets only in the mesial temporal lobe (n=95) or only in the neocortex (n=81).

Mood: Assessed with the Beck Depression Inventory II (BDI-II) and the Profile of Mood States (POMS).

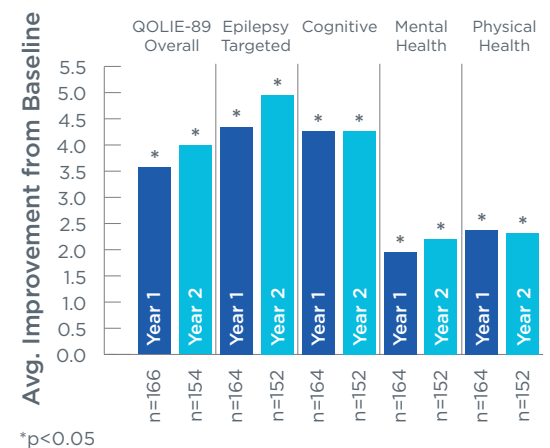
Quality of Life: Assessed with the QOLIE-89, with the following subdomains:

- Epilepsy Targeted: Seizure worry, medication effects, health discouragement, etc.
- Cognitive: Attention, concentration, language, memory.
- Mental Health: Emotional well-being, energy, social support, etc.
- Physical Health: Pain, physical function, role limitations, etc.

KEY RESULTS

Quality of Life (QOL)

Statistically significant group improvements in the overall score and in all domains of QOL at 1 and 2 years after implant.





Mood

BDI-II

- Significant improvements in total score at Years 1 (p=0.036) and 2 (p=0.008)

POMS

- Significant improvements in total score at Year 2 (p=0.04)
- Significant improvements in Confusion (p=0.029), Fatigue (p=0.002), and Tension (p=0.003) subscales at Year 2.

ANALYSES BY REGION OF SEIZURE ONSET²

Neocortical Onset Patients (n=81)

- 51% reported clinically meaningful³ improvements in overall QOL, with 15% reporting declines.
- Statistically significant improvements were seen in:

Overall Score (p<0.001)
Epilepsy-Targeted (p<0.001)
Cognition (p=0.001)
Mental Health (p=0.01)
Physical Health (p=0.01)

MTL Onset Patients (n=95)

- 41% reported clinically meaningful³ improvements in overall QOL, with 16% reporting declines.
- Statistically significant improvements were seen in:

Overall Score (p=0.002)
Epilepsy-Targeted (p<0.001)
Cognition (p<0.001)

ADDITIONAL OBSERVATIONS

- Changes in QOL and in mood were not correlated with changes in clinical seizure frequency.
- Changes in QOL were not different across patients who had increases, decreases, or no change in anti-seizure medications.

Footnotes

1. 18 yrs. or older, refractory to 2 or more AEDs and with no more than 2 foci localized by diagnostic testing
2. At 2 years
3. A “clinically meaningful change” on the QOLIE-89 is defined as a change of ≥ 5 points (1/2 of a standard deviation).



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.

©2015 NeuroPace, Inc. All rights reserved. NeuroPace® and RNS® are registered trademarks of NeuroPace, Inc. NP 150062 Rev 1 / Rev. date: 2015-10