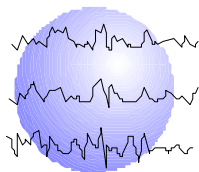


VAGUS NERVE STIMULATION FOR PATIENTS IN RESIDENTIAL TREATMENT FACILITIES

Michael Frost, MD
Roger Huf, MD
John Gates, MD



This paper has been prepared specifically for:

American Epilepsy Society Annual Meeting
Philadelphia, PA

November 30 – December 5, 2001

Please consider this information to be preliminary findings.

Minnesota Epilepsy Group, P.A.[®]
225 Smith Avenue N., Suite 201
St. Paul, MN 55102
Phone: (651) 241-5290
Fax: (651) 241-5248

REVISED ABSTRACT

This analysis compared the effectiveness of VNS therapy among patients with intractable seizures: a group living in residential treatment facilities (RTFs) with a group not living in RTFs (non-RTF). Among a constant cohort of patients with baseline, 3-month, and 12-month data, the RTF group had significantly ($P < 0.05$) larger numbers of patients with generalized seizures, previous callosotomy, psychiatric disorders, behavioral problems, and Rett's syndrome. Median seizure reductions after 3 months were 33% in the RTF group and 49% in the non-RTF group ($P < 0.001$); after 12 months, 50% (RTF) and 56% (non-RTF). After both 3 and 12 months, alertness, mood, postictal recovery, and cluster seizures improved in more than a third of patients in both groups. Because VNS therapy does not interact with medications and is delivered automatically, it should be seriously considered for patients with intractable epilepsy and who reside in RTFs.

Epilepsia 42 Suppl. 7 :203 (Abst. 2.325), 2001

RATIONALE

Patients who live in residential treatment facilities (RTFs) often have complex behavioral, emotional, physical, and cognitive challenges that are exacerbated by medically refractory seizures. This analysis compared the effectiveness of vagus nerve stimulation (VNS) among patients who had intractable seizures and lived in (RTFs) with similar patients who did not live in RTFs (non-RTF).

METHODS

Data Source: VNS Patient Outcome Registry

Patient Selection Criteria:

- ❖ Patients who lived in RTFs
- ❖ Patients who did not live in RTFs
- ❖ Constant cohort of patients with baseline, 3-month, and 12-month data

Comparisons:

- ❖ Baseline demographics
- ❖ Median reductions in seizure frequency, and quality of life at 3- and 12-month follow-up

Statistical Analyses

- ❖ Changes over time and differences between treatments were compared with non-parametric methods for ordinal data including the two-sample test and Wilcoxon two-sample test.
- ❖ The signed rank test was used to measure changes within groups.
- ❖ Statistical significance was assumed when $p \leq 0.05$.

RESULTS

Demographics:

- ❖ Constant cohort of 776 patients
- ❖ 86 patients in the RTF group
- ❖ 690 patients in the non-RTF group

RTF group had a significantly ($p<0.05$) larger number of patients

- ❖ generalized seizures
- ❖ previous callosotomy
- ❖ psychiatric disorders
- ❖ behavioral problems
- ❖ neurological defects
- ❖ cognitive challenges
- ❖ Rett's syndrome

Median seizure reductions after 3 months ($p<0.001$)

- ❖ 33% in the RTF group
- ❖ 49% in the non-RTF group

Median seizure reductions after 12 months (similar)

- ❖ 50% in the RTF group
- ❖ 56% in the non-RTF group

Quality of life improved in more than a third of patients in both groups after both 3 and 12 months of VNS therapy

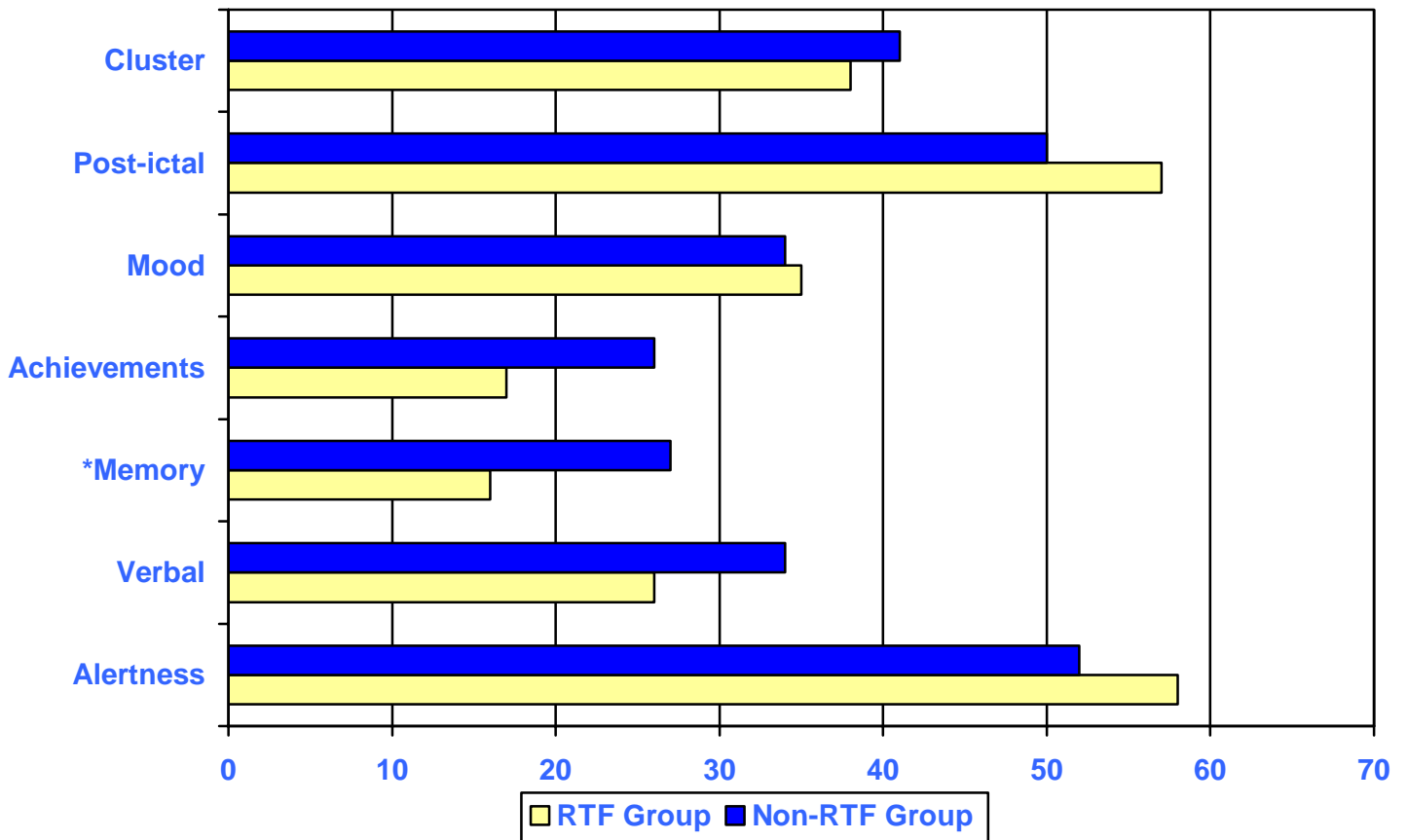
- ❖ alertness
- ❖ mood
- ❖ postictal recovery
- ❖ cluster seizures

CONCLUSIONS:

Reductions in Seizure Frequency:

- ❖ 3-month follow-up: statistically significant difference (greater reduction among non-RTF patients)
- ❖ 12-month follow-up: reductions were similar in both groups
- ❖ Because VNS therapy does not interact with medications and is delivered automatically, it should be seriously considered for patients who live in RTFs and have medically intractable epilepsy

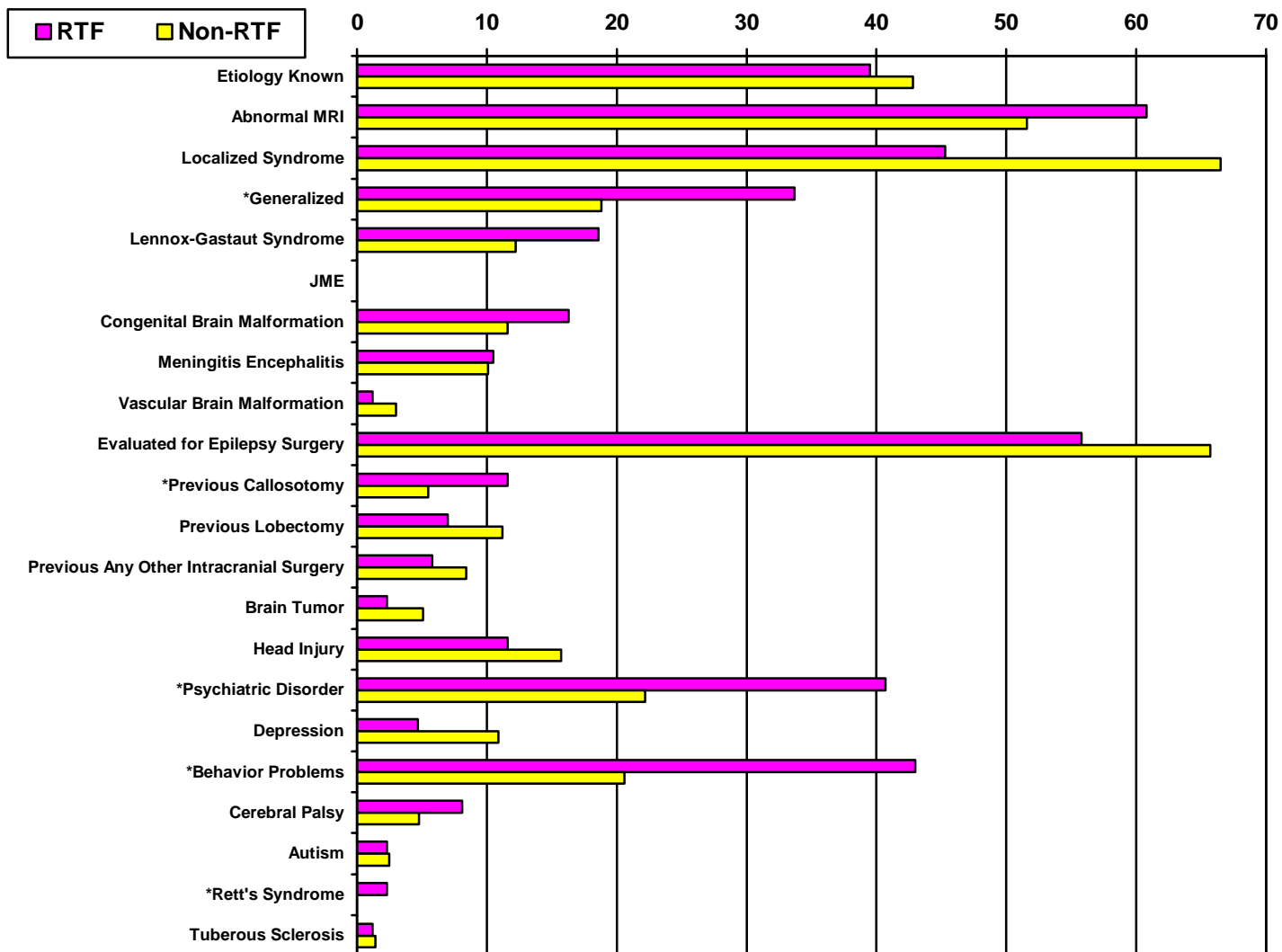
Quality of Life: Percentage of Patients Reported as “better” or “much better”



*Statistically significant differences ($P \leq 0.05$)

Figure 2

Medical History: Percentage Reported as “YES”



*Statistically significant differences (P<=0.05)

Figure 3

Change in Seizure Frequency: Percent of Respondents

