VAGUS NERVE STIMULATION (VNS) USE IN PATIENTS WITH EPILEPSY AND MENTAL RETARDATION

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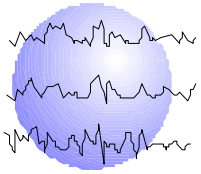

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REVISED ABSTRACT

RATIONALE

Among individuals with epilepsy who are cognitively challenged (IQs of <75), intractability is a problem in up to 45% (Steffenburg AA. Epilepsia 1998;39:767-775). Multiple medical problems, behavioral problems and/or an inability to express themselves result in a thorough evaluation process. Families, guardians and care staff have been reluctant to pursue invasive aggressive therapies including the VNS. In order to make treatment decisions, our community has requested data regarding how this population fares with this treatment.

METHODS

We retrospectively reviewed all our adult patients with IQs < 75 who were implanted with the VNS between 11/97 and 06/02. History, seizure frequency and severity, medications, post-op course, generator settings, reports of Quality of Life (QoL), and alertness were tabulated.

RESULTS

Fifty-six patients between the ages of 19-52 years were implanted under general anesthesia: 21 mild/borderline (MB), 13 moderate (MO), 22 severe/profound (SR). Nine batteries have been replaced; 2 turned off. There were 3 uncomplicated superficial post-op skin infections. One had prolonged hoarseness for several months post-implant. There were no serious complications. Staff/families trained/learned how to use the magnet without problems. Two patients died 2+ years after implant: 1 SR with SUDEP and 1 MO with aspiration pneumonia/sepis. Medications were not held constant through the time periods. Duty-cycles used were: “Routine” (5 min off/30 sec on) 27% MB, 30% MO, 38% SR; “Intermediate” cycles were used: 23% MB, 38% MO, 5% SR; and “Rapid” cycles (7 sec on/0.2 min off) were used: 46% MB, 30% MO, 43% SR. Fifty-one percent of the whole group had at least a 50% improvement in seizure frequency; 12% were 90-100% controlled; 6 had no clear change; 24% had such variable rates of seizure occurrence that the response rate was not clear. In MB, 63% had > 50% seizure decrease and 21% had variability. In the MO group, 31% had > 50% seizure decrease and 38% had variability. In the SR group, 57% had > 50% seizure decrease and 20% had variability. In 44% seizures were described as shorter, less intense, having shorter postictal recovery times, or were improved by the use of the magnet in 34%.

CONCLUSION

Patients with mental retardation of any severity who have refractory epilepsy can benefit from VNS with decreased frequency and severity of seizures at rates equivalent to the general refractory population, tolerate the procedure and the stimulations well, and also achieve improved alertness and function contributing to QoL and improved care.

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RATIONALE

Intractable or refractory epilepsy is a problem in up to 30% of patients who present with epilepsy and do not respond to initial medications[1]. Up to 45% of individuals who are cognitively challenged may be intractable[2]. Treatment options for refractory epilepsy need to be utilized in this population.

In addition, these individuals may also have difficulty in expressing themselves, thus making it difficult to evaluate their medical problems, symptoms and pain experiences, emotional problems, and behavioral issues. This limitation has resulted in caretakers, guardians and families being hesitant to pursue aggressive invasive therapies including the VNS. Nonetheless, individuals with retardation in institutions have responded well to the VNS[3]. In order to help others make informed treatment decisions, we responded to requests from our community to evaluate how patients with mental retardation and disabilities fared through the surgical implantation process and what the results were in this population in our practice.

METHODS

We retrospectively reviewed all our adult patients with IQs < 75 who were implanted with the VNS between 11/97 and 6/2002. History, seizure frequency and severity, medications, post-op course, generator settings, reports on Quality of Life (QoL), and alertness were tabulated.

DISCUSSION

As a group, mentally retarded individuals achieved success rates equivalent to reported rates of patients in the literature[4]. Surprisingly, the SR group did just as well as the less impaired group in tolerating the implantation and achieving seizure reduction. The MO group was less predictable. This group, however, was a smaller cohort and had a higher percentage of variability in monthly baseline seizure counts (38% compared to 19% MB, 20% SR) which made it more difficult to determine response with respect to seizure decrease.

Seizure counts, response to medications, adverse events, awareness of symptoms and pain are considerations that challenge the caregivers and medical team working with individuals who are cognitively challenged. Higher IQ levels seem to imply that more information may be available to the caregivers/medical team and that the patients may be more participatory in their care. Less patient involvement makes the guardian, parent or caregivers more responsible evaluation of the patient's treatment, comfort, and therapeutic response.

This group of adult patients with medically retractable epilepsy includes cognitively challenged patients who have failed surgeries, and who have migrational abnormalities. There was distinct benefit from VNS implantation with decreased frequency and severity of seizures and with the additional ability to interrupt and change seizure pattern. This was obtained safely without any long-term sequelae. Improved alertness and improved function led to reports of improved QoL and social-vocational opportunities and more independent living scenario.

RESULTS

Fifty-six cognitively impaired patients between 18 and 52 years of age were implanted under general anesthesia. Twenty-two were mild/borderline range (MB); 13 were moderately impaired (MO); and 21 were severely to profoundly impaired (SR) (Figure 1). Two have been turned off, although one patient keeps his magnet settings on. One had prolonged hoarseness for several months post-implant. There were no serious complications. Staff and family members, and patients when able, learned how to use the magnet without difficulty. Two patients died more than two years after implant: one of SUDEP and one after massive sepsis secondary to aspiration and pneumonia. Medications were not held constant during the evaluation period.

No patients had serious problems with anesthesia or post-operative pain. Acetaminophen with or without codeine, or non-steroidal anti-inflammatory agents were effective to control pain. Early complaints were primarily stimulus induced: cough, throat irritability, or lump in the throat. Other complaints were temporary hiccups, decreased appetite, and facial numbness. There were three local skin infections, none of which became serious, systemic or required explant. There were no prolonged or persistent complaints. One patient developed hallucinations after three years that did not resolve with medication changes (discontinuation of levetiracetam and oxcarbazepine), there was a history of schizophrenia in a brother.

Nine patients have had Model 100 units replaced due to "high hours" having been on rapid duty cycles. Three of these patients had clearly begun to lose seizure control as the battery life wore out.

Fourteen patients had prior surgical interventions with inadequate clinical response (Table 2). Of those with Lennox-Gastaut Syndrome, 57% had a decrease of 50% or more. Of the six with resective surgeries, 16% are seizure free and 16% have some response. The one patient with hemispherectomy has the unit turned off and continues to deteriorate.

Figure 2 shows the distribution of duty cycles. The choice of duty cycle is a "clinical choice" based on an estimate of patient response at the time of a clinic visit. Two patients clearly worsened, going from intermediate to rapid cycle, and were re-adjusted downward.

Figure 3 illustrates the decrease in seizures in the three groups of cognitive impairment. The MB and SR groups did equally well. Sixty-three percent of the MB group had a worthwhile response (between 50-100% decrease); 31% of the MO group; and 57% in the SR group had a decrease in seizures overall greater than 50%. As a whole group, 51% responded with a 50% or greater decrease (Figure 6).

The housing situation (Table 3) changed for eight patients (14%), enabling an improvement in independence and life style or emancipation from watchful parents who felt more comfortable.

Patients were also described as being more alert and functioning better. This occurred frequently prior to any noted change in seizures (see Figure 4). This change in alertness led to more environmental involvement at home and school/work programs. Caregivers, families and patients were asked how they felt about having the device and were pleased with the outcome. There was no difference between groups.

Nineteen (34%) felt the magnet interrupted or changed the seizure characteristics. Forty-four percent felt that seizures were shorter, less intense or had shorter post-ictal recovery times. This occurred independently of change in absolute seizure counts.

CONCLUSION

The decision to utilize the VNS as a therapeutic modality in the population that is cognitively challenged is encouraged. Improvements in alertness, function and seizure control may maximize life opportunities. This is a safe and effective therapeutic option.

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3. Gates JR, Huf R, Frost M. Vagus nerve stimulation for patients in residential treatment facilities. *Epilepsy & Behavior* 2:563-67; 2001.
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Table 1

Co-Diagnoses

	n
Migrational Abnormalities	4
Lennox-Gastaut	7
Tuberous Sclerosis	1
Diffuse Atrophy	4
Bilateral MTS	3
Childhood Infection	2
Rasmussen's	1
PKU	1
Head Injury	1
Prader Willi	1
S/P Tumor Resection & Radiation	1

Table 2

Previous Surgeries

	n
Corpus Callosum Section	7
Focal Resections ± Subpial Transection	5
Temporal Lobectomy	1
Hemispherectomy	1

Table 3

Living Situations

	n
Stable Group Home	29
Able to Leave Parental Home to Group Home	4
Independent Apartment from Parental Home	3
Remain in Initial Single Home Situation	18
Able to Return to Family Home	1
Unknown	3

Figure 1

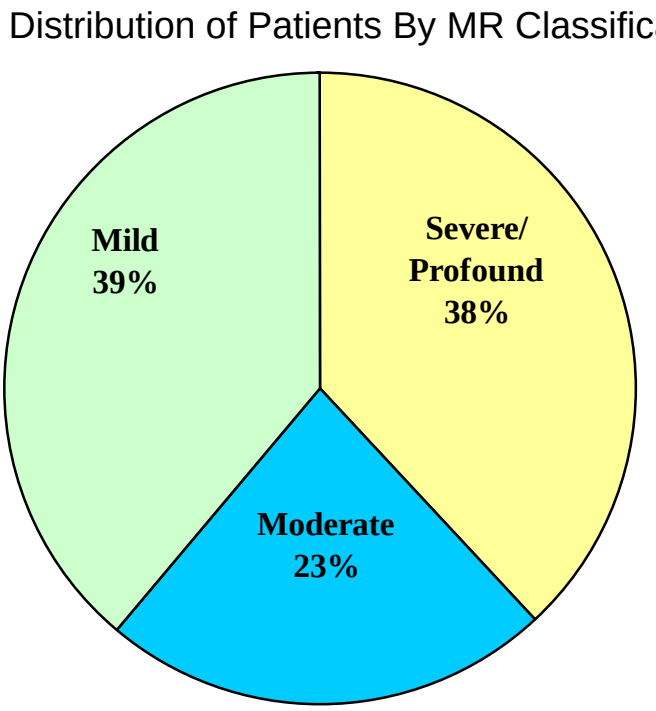

Figure 2

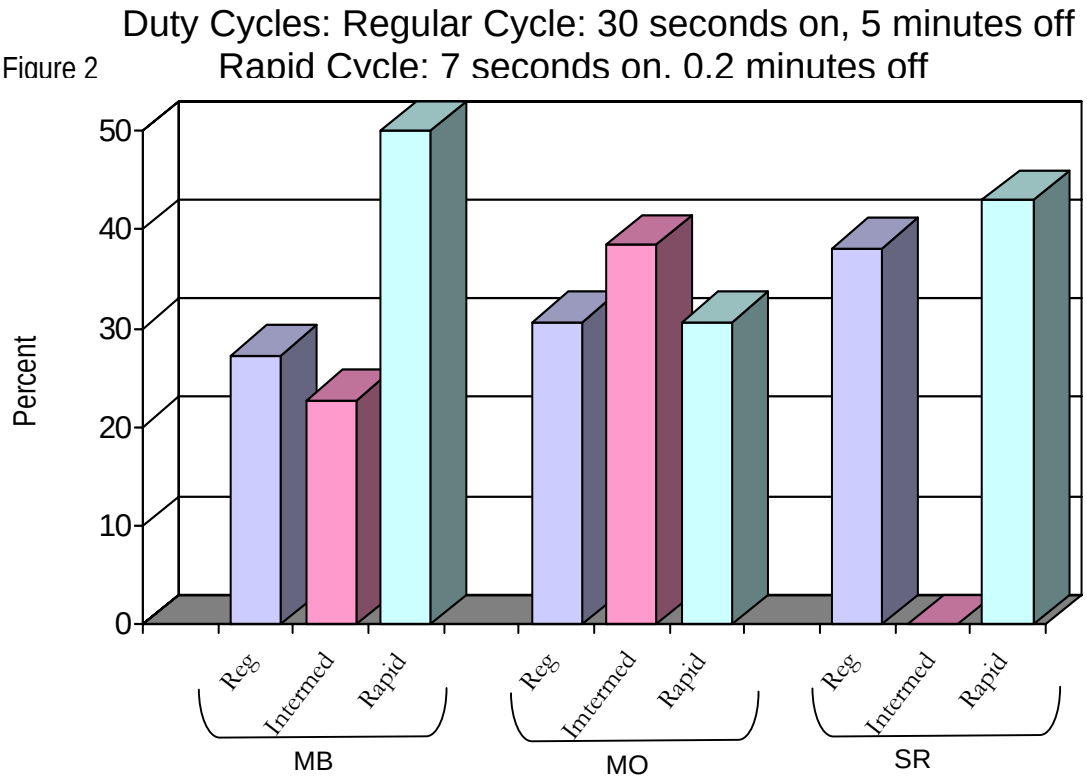

Figure 3

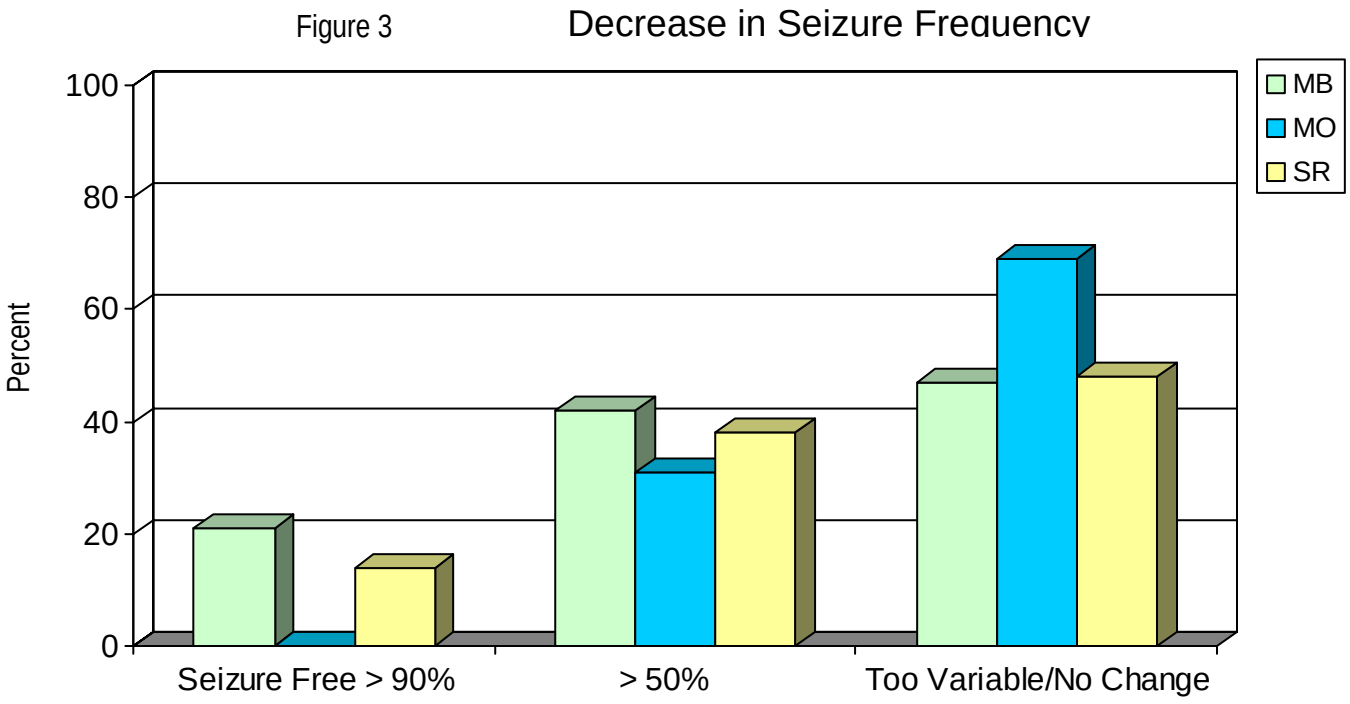

Figure 4

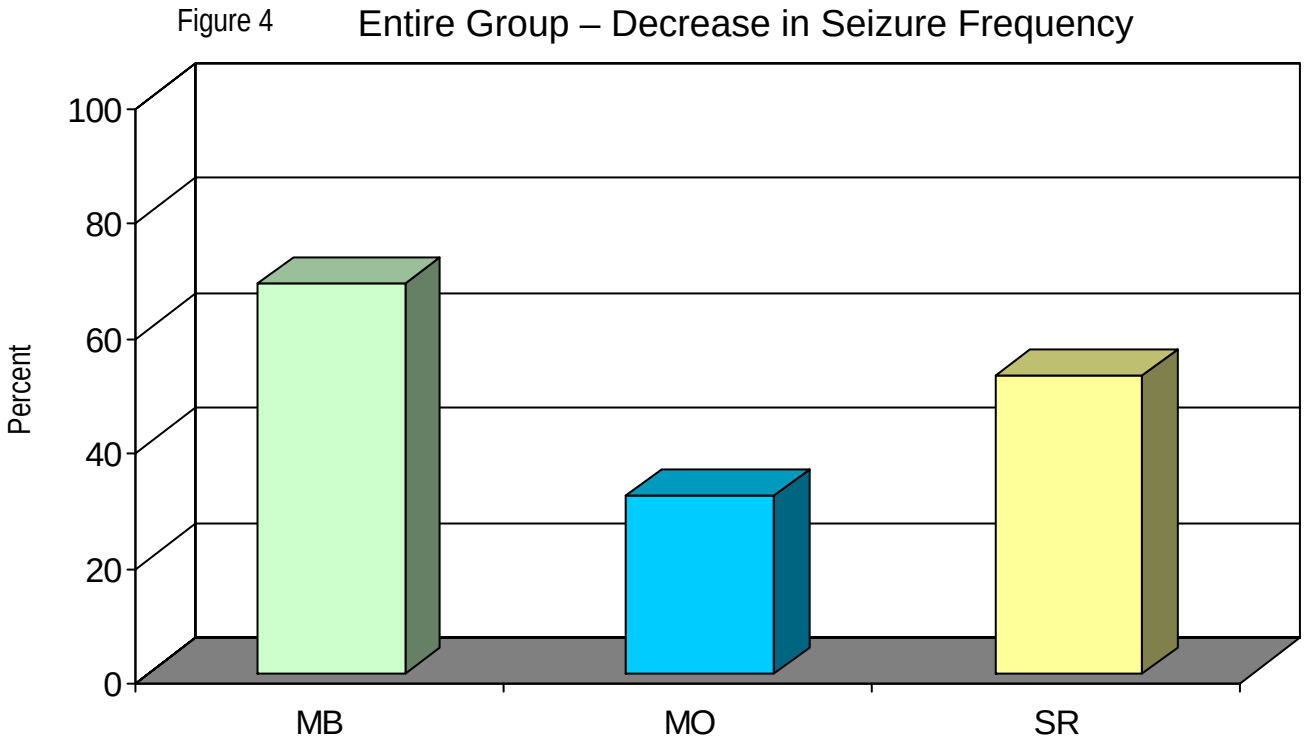

Figure 5

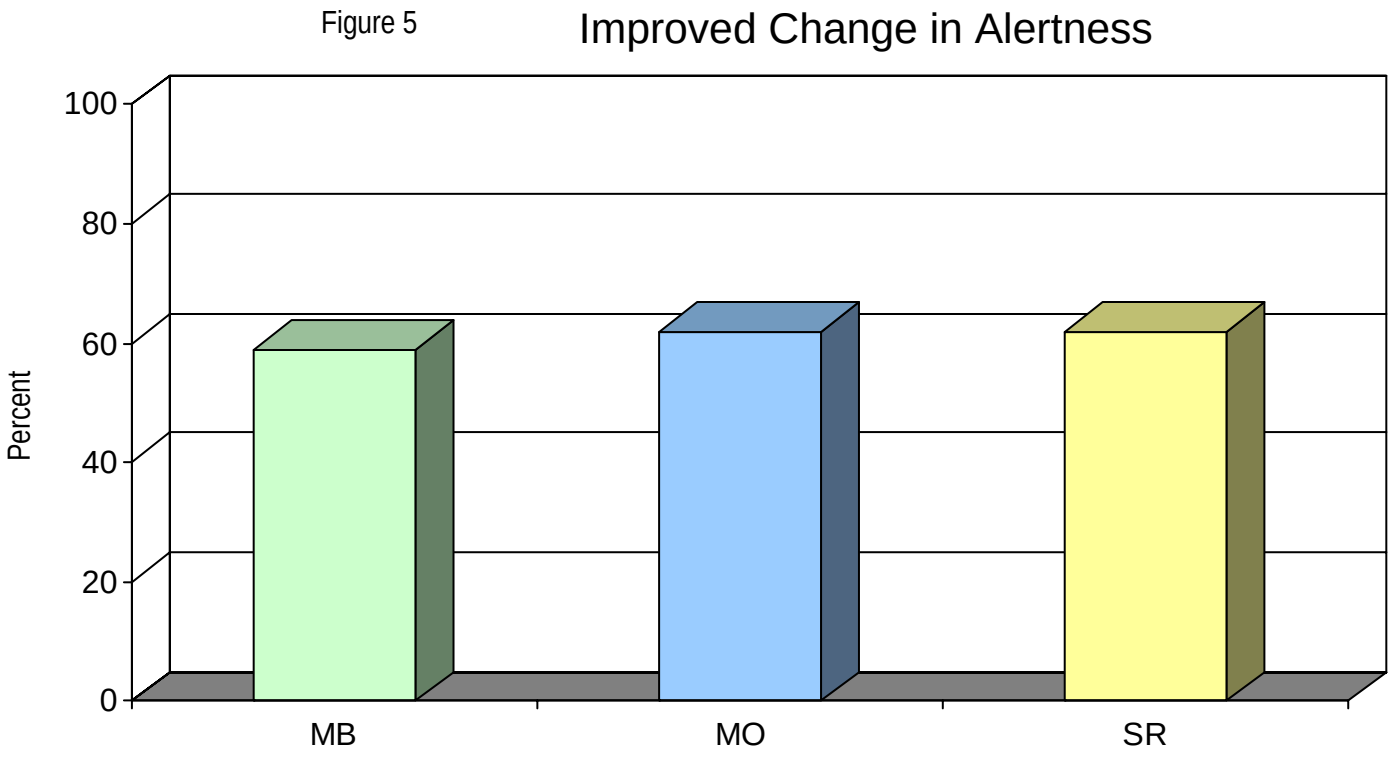

Figure 6