Efficacy and safety of external Trigeminal Nerve Stimulation: An experience in 8 patients with drug-resistant epilepsy

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Purpose

There is preliminary evidence that external Trigeminal Nerve Stimulation (eTNS) is safe and may be effective in reducing seizures in patients with drug-resistant epilepsy (1-3). The aim of this study is to describe the outcome of a series of 8 patients with drug-resistant epilepsy treated with eTNS.

Methods

Patients with drug-resistant epilepsy treated with eTNS in our epilepsy unit were retrospectively evaluated. Stimulation intensity was increased up to the maximum tolerated level. We analyzed tolerability and efficacy (measured as reduction in seizure frequency and responder rate, defining responders as those experiencing a ≥ 50% reduction in seizure frequency). Only seizures with impaired consciousness and/or motor component were accounted for. We compared seizure frequency during a 12-week period before eTNS initiation (pre-eTNS period) with seizure frequency during an early evaluation period (weeks 1-12) and a late evaluation period (weeks 13-24).

Results

Table 1. Clinical characteristics of patients and eTNS parameters

Patient	Age	Age at onset	Epilepsy type	Seizure type(s)	Number of previous AEDs	Number of current AEDs	Intensity range (mA)	Stimulation Hours/day	Seizure frequency* (pre-eTNS period)	Seizure frequency* (early evaluation period)	Seizure frequency* (late evaluation period)
1	52	20	Focal symptomatic (postraumatic)	Complex Partial	5	3	3.4-4.6	10-11	2	3	2.5
2	47	12	Focal cryptogenic	1. Simple partial 2. Complex partial	5	3	3.8-4.6	8	1.66	2.33	2.33
3	16	7	Cryptogenic Lennox-Gastaut syndrome	1. Tonic/atonic 2. Atypical absences	10	4	4.6	12-14	50	66.7	33.3
4	27	0	Symptomatic Lennox-Gastaut syndrome (hypothalamic hamartoma)	1. Atypical absences 2. Tonic-myoclonic 3. Generalized tonic-clonic	12	5	2.8-4.4	10-16	38	38	23
5	50	47	Focal symptomatic (resected meningioma)	1. Simple partial 2. Complex partial	5	3	1.8-3	8-10	2	0.33	0
6	13	7	Progressive myoclonic epilepsy	1. Atypical absences 2. Myoclonus	11	3	3.6-6.4	13	1260	65	9
7	12	0	Focal symptomatic (MCD, hemispherectomy)	1. Bilateral asymmetric tonic 2. Focal clonic	12	3	4.4	11-13	252	252	-
8	53	11	Cryptogenic Lennox-Gastaut syndrome	Atypical absences	11	3	4-5	10-14	3	3	-

*Number of seizures per period of 28 days, MCD = Malformation of cortical development

Non-responders → Incomplete responders → Responders

Results

- Mean age at time of eTNS initiation: 34 [12-53] years.
- Median number of seizures in the 12 week pre-eTNS period: 20.5 [2-1260]/month.
- Four patients presented symptomatic or cryptogenic focal epilepsy, three patients had Lennox-Gastaut syndrome and one patient had progressive myoclonic epilepsy.
- Two patients discontinued eTNS due to lack of efficacy at 12 and 18 weeks.
- Retention rate was high (5/8 or 62.5% patients continue after 6 months).

Fig 1. Responder rate and reduction in seizure frequency (number of seizures/28 days) during the early and late evaluation period

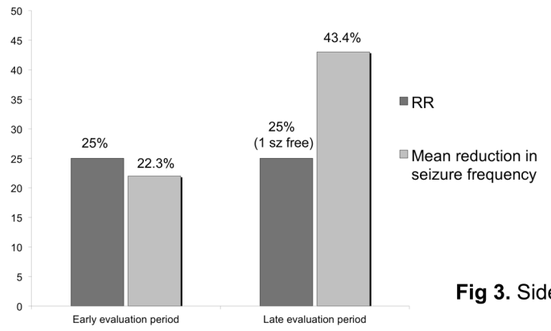


Fig 2. % Change in seizure frequency by subject in the early and late evaluation periods

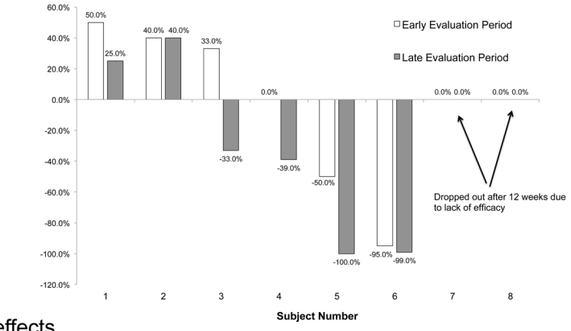
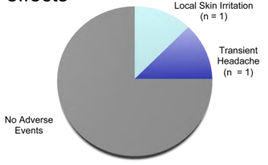


Fig 3. Side effects



Conclusions

eTNS resulted in improvement in 50% of our series of highly drug-resistant patients: 2/8 were responders (and were seizure free or almost seizure free) and another 2/8 were incomplete responders (33.3 and 39.5% reduction in seizure frequency during the late evaluation period). Efficacy improved over time. No relevant side-effects were observed.

References

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