

Electrostimulation with FREMS is effective in therapy-refractory painful Diabetic Neuropathy

Ben Imholz, MD, PhD, Jack Heijster, MD

ETZ, Department Internal Medicine, Tilburg-Waalwijk, The Netherlands

ABSTRACT

Neuropathy common complicates Diabetes Mellitus (DM), and often converts from sensory loss to painful neuropathy (pDN). In these patients standard pharmaceutical strategies often are ineffective or cause side-effects.

We assessed the efficacy of Frequency Rhythmic Electro Magnetic neural Stimulation (FREMS) in patients with therapy-refractory pDN in a phase-IV conducted study evaluating the effects of a 2-weeks treatment on 3 months of pain relief. Two validated scorings systems were used; the Neuropathic Pain Symptom Inventory (NPSI), and the EQ-5d quality of Life score.

Upon a call in local newspapers and the internet 307 subjects were screened of which 236 subjects were included with pDN without co-morbidities and unsuccessful medical treatment: 8 subjects cancelled FREMS. So 228 subjects received 10 daily 40 min FREMS stimulations within 2 weeks. FREMS is executed on 2 legs below the knees with 4 pairs of electrodes/leg. The stimulations is unique and differs from conventional treatments in a randomised stimulation with changing frequencies and amplitudes. The results are given as %- changes in NPSI and changes in visual EQ-5D score from baseline to 1 and 3 months after day-1 of treatment.

FREMS induced significant changes in absolute NPSI from baseline to M1 and M3 (ANOVA).

An at least 50% fall in NPSI was seen in 71/228 subjects at M1 and in 68/228 at M3. In 102/228 subjects at M1 or M3. If a 33% fall was considered these data were 102/228; 100/228 and 115/228.

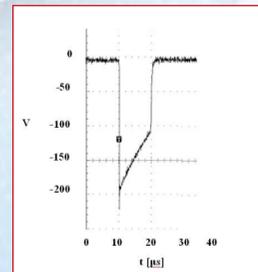
The average EQ-5D visual score (0-100) increased from baseline 53±16 to 62±14 at M1 and 63±16 at M3.

In Clinical practice electro stimulation with FREMS is effective in therapy-refractory pNP. The method needs further investigation but is a promising alternative for difficult to treat patients.

BACKGROUND

- Neuropathy is a common complication in Diabetes Mellitus (DM), it effects 25-50% of diabetic patients and often converts to painful Diabetic Neuropathy (pDN)
- Pharmacological treatments in pDN is insatisfactory in clinical practice.
- FREMS was suggested as an alternative treatment in 2005 (Bosi et al, Diabetologia)

METHODS AND MATERIALS



- Electrostimulation different from TENS.
- Specific large negative Voltage with restphase
- Continuously changing signal (Randomiser)
- Both Legs, 4 channels, 16 electrodes
- 10 days/2 weeks, a 40 min period.
- Stimulation threshold: just not painful

OBJECTIVE

Aim Study:

To assess the efficacy of a standard 10 days/40 min/two-legs/4 channel treatment with FREMS in patients with pDN who did not respond to pharmacological treatment.

Measures of effect:

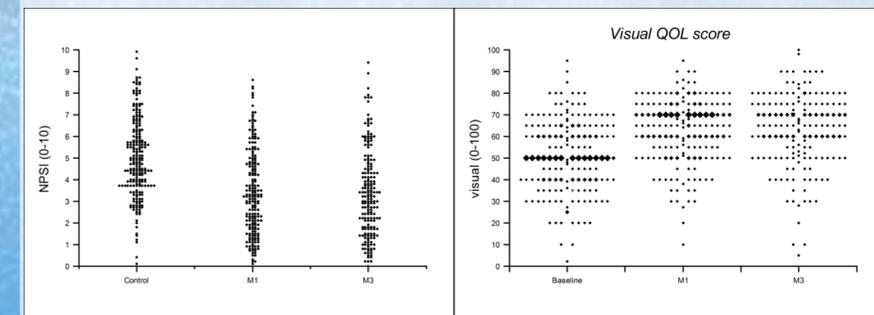
- Neuropathic Pain Symptom Inventory score (NPSI) (12 questions, 10 with 0-10. Score: 0-100 Max)
- EQ-5D Quality of Life (linair 0-100 scale)

Subjects:

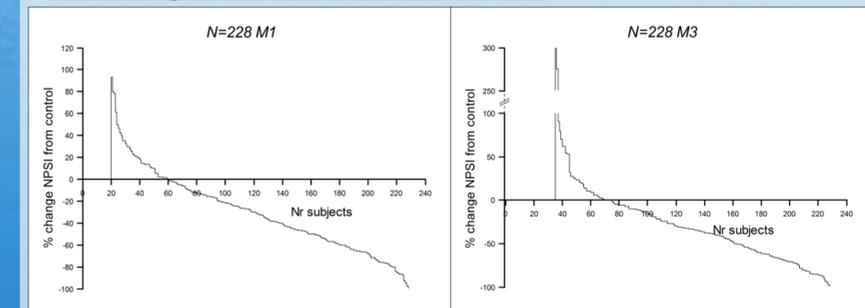
- Responded upon a call in local newspapers and the internet
- N=307 screened
- N=236 subjects eligable, having (clinically) proven pDN without co-morbidities and unsuccessfull medical treatments.
- Data are presented from N=228, 8 subjects canceled their treatment.

RESULTS

Absolute NPSI and visual EQ-5D (N=228)



Percentage fall in NPSI at M1 and M3:



Classical Response (≥50% fall in NPSI)

At M1: 71/228 subjects (31,1%)

At M3: 68/228 subjects (29,8%)

M1 or M3: 102/228 subjects (44,7%)

If a 33% fall is considered clinically relevant:

At M1: 102/228 44,7%; At M3 100/228 (43,8%)

M1 or M3 in 115/228 (50,4%)

CONCLUSION OR DISCUSSION

- FREMS was feasible in patients with painful Diabetic Neuropathy (pDN)
- FREMS electro-stimulation is effective in pain relief assessed with objective scores in patients with therapy-refractory pDN
- This promising therapy needs a blinded head-to-head comparison with alternative electrostimulation (e.g. TENS)