FREMS for painful Diabetic Neuropathy; results of 3 treatments in 1 year

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Abstract

FREMS is useful as a specific form of electro stimulation in patients with painful diabetic neuropathy when they do not respond to conventional therapy (abstract submitted ADA 2016).
FREMS differs from TENS in aspect of the signal; it has 2 phases. A high-negative in voltage short-lasting spike (up to -300V lasting from 10-100 µs) is followed by a resting phase of low voltage and long duration (0,9-999 ms). The overall effect is an improvement of the microcirculation.
To evaluate the perseverance of the effect we aimed to treat 100 patients with classical response to FREMS treatment characterized by a fall in pain of at least 50% from baseline evaluated by the Neuropathic Pain Symptom Inventory (NPSI). We present data of the first 53 patients followed for one year.
The average results of the 53 (69 in Poster) subjects is shown in the figure as %-changes from control (defined as 100% pain) depicted at months 1,3,6,8,10 and 12 after the first day of FREMS treatment. Three FREMS treatments of 2 weeks were given at T=0, T=4 and T=8 months (represented by green squares at timeline). The curve is smoothened (cubic spline).
At the same time points quality of life (QOL) was assessed by the EQ-5D questionnaire as visual scores from 0-100.
The study shows that in patients characterized by a classical response to FREMS the average response persists during 1 year follow up when FREMS is given at 4 months intervals with a gradual and significant increase in QOL.

Background

- Frequency Rhytmic Electro Magnetic neural Stimulation (FREMS) was effective - defined by an et least 50% fall in pain - in about one-third of patients with painful diabetic neuropathy not treated with conventional treatment (ADA abstract 591-P)
- We investigated the effect of repeated treatments with FREMS in these subjects using 3 consecutive treatments during one year of follow-up

Methods and Materials

For FREMS see Poster 591-P

Patient Selection:
•Selected from group receiving one 2 weeks cycle of FREMS, assessed by:
•Neuropathic Pain Symptom Iventory (NPSI):
•Eq-5D QOL score
•Patients were selected for repeated treatments when the effect of the first FREMS treatment resulted in a decrease of NPSI at M1 and/or M3 by at least 50%

FREMS treatments (period of 10 days):
At start first treatment (M0), second period after 4 months (M4) and third period after 8 months (M8)

Treatment Effect
•Neuropathic Pain Symptom Inventory (NPSI) and
•Quality of Life Scores (Qol-EQ-5D) scores at Control (Co) 1 month (M1), 3 months (M3), 6 months (M6), 8 months (M8), 10 months (M10) and 12 months (M12)

Data of 69 subjects is presented:
•The group consisted of 31 male and 38 female subjects, average age 63±8 yrs and 64±10 yrs respectively.
•Average duration of DM was 13±10 yrs, the average duration of pDN 8±6 yrs.
•DM medication:
Oral only: 45; Insulin/Oral: 23 and no medication 1

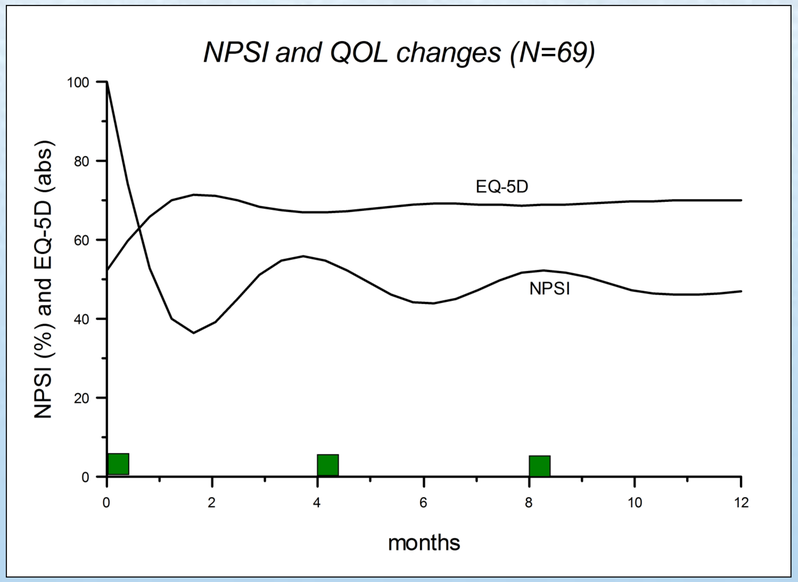
Data analysis:
•Average respons presented N=69 for NPSI and QOL
•Number of Scores with a classical score (≥50% NPSI)/subject counted

Objective

To assess the efficacy of the FREMS treatment in at first succesfull patients during a total of one year of treatment at a typical 4 months treatment interval.

Results

Results of average responses in our 69 subjects



Results of #classical response in our 69 subjects:

•M1, M3, M6, M8, M10 and M12 in 69 subjects respresent 414 datapoints (dp)
•9 missing values (2.2%)
•Classical response (an at least 50% fall in NPSI) in 238/405 dp (59%)
•Clinical relevant response (1/3 relief in pain): in 313/405 dp (77%)

Conclusion or Discussion

- In 69 subjects with therapy refractory painful Diabetic Neuropathy repeated electro-stimulation with FREMS shows a persisted average 50% fall in subjective painscore during 1-year follow-up accompanied by a stable 40% increase in QOL-score (see figure)
- During the observation period 50% of painscores reached the classical threshold; clinically relevant decreases in pain were seen in over 70% of observations.

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