

The efficiency of transcutaneous nerve stimulation with a new TENS device Salutaris® on Symptomatic Diabetic Polyneuropathy



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Introduction

Symptomatic peripheral neuropathy most common sec. complication

Typical are foot and leg pain

TENS = physical treatment for symptomatic pain disorder

Salutaris[®] has a new technique of power application and specification of the device have been specially target for use by elderly or visually impaired patients

Patients and Methods

According GCP-ICH guidelines and ethical review board approval

Double blind randomised protocol;

19 patients

Evaluation via NTTS-score and VAS

Measurement sensory threshold and micro vascular function after 12 weeks

Device and electrode placement



Parameters: 4 Hz / 280 μ sec, intensity 5mA-70mA
Treatment of both legs at least half an hour per day (no upper limit)

Clinical characteristics of the investigated groups

	TENS Group	Placebo group
N	12	7
Sex (male/female)	6/6	4/3
Age (years)	57,6 ± 8,3	59,4 ± 8,6
Duration of diabetes (years)	15,9 ± 8,3	18,4 ± 11,0
HbA1c (%)	6,6 ± 0,9	6,5 ± 0,7

Statistic analysis

Results in \pm STD.

Comparison: non-parametric methods of statistical analysis

Wilcoxon signed rank test (analysis changes in time)

Mann-Whitney U-test to assess difference between the 2 groups

A p-value <0.05 was considered to be statistically significant

Time course of single parameters of the NTSS-6-score

	TENS			Placebo		
	V1	V2	V3	V1	V2	V3
Lancinating pain	1,58 ± 1,09	0,58 ± 0,86	1,22 ± 1,48	1,19 ± 1,39	1,48 ± 1,46	0,57 ± 1,05
Burning pain	1,19 ± 1,4	0,53 ± 0,86	0,72 ± 1,13	0,76 ± 1,03	1,24 ± 1,34	1,14 ± 1,4
Aching pain	1,42 ± 1,27	1,28 ± 1,14	0,76 ± 1,07	1,67 ± 1,09	1,52 ± 1,24	1,24 ± 1,4
Numbness	2,19 ± 1,05	1,55 ± 1,26	1,86 ± 1,00	1,86 ± 1,47	1,57 ± 1,26	1,47 ± 1,44
Prickling sensation	2,14 ± 0,91	1,33 ± 1,15	1,61 ± 0,97	2,14 ± 0,73	2,14 ± 0,9	1,81 ± 1,11
Allodynia	1,44 ± 1,59	0,53 ± 1,03	0,58 ± 1,12	0	0,14 ± 0,38	0,29 V 0,7

NTTS-6-score= total symptom score

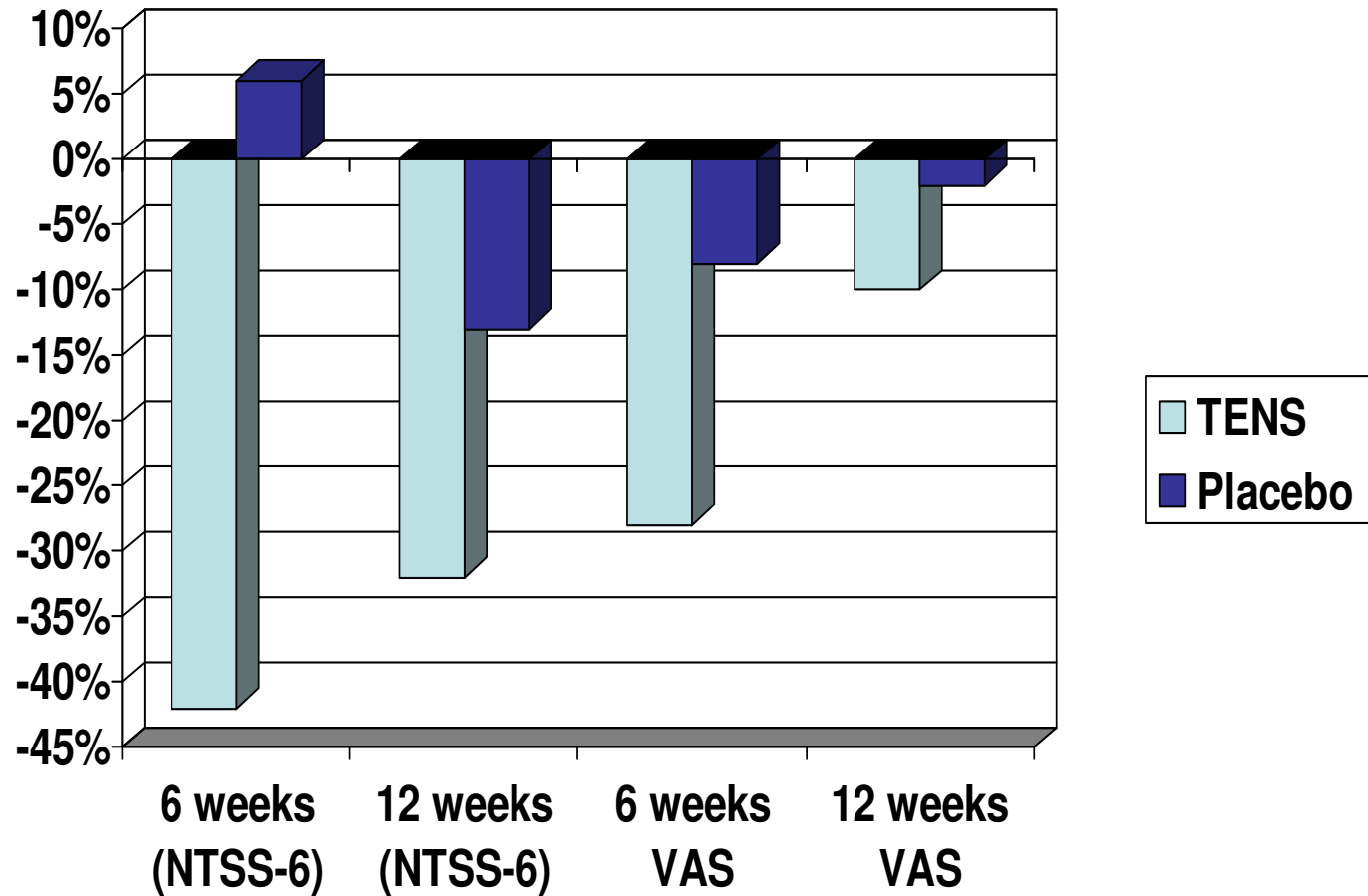
V1: Baseline, V2: after 6 weeks, V3; After 12 weeks

Results

No significant changes placebo group

Significant decrease (= improvement) in
NTSS-6 score in the TENS: 6 weeks -42%
after 12 weeks – 32%

Percent of change of NTSS-6 and VAS after 6 and 12 weeks of treatment



Discussion

The mechanism of TENS induced improvement in naturopathic problems is still not known in detail

Limited number of patients

No effect on neurovascular function could be found

Conclusion

TENS therapy with the Salutaris® device resulted in an improvement of painful symptoms of neuropathy in patients with diabetes mellitus. The treatment procedure was well tolerated and well accepted by the patient and may be safe single or complementary non-pharmacological treatment option in patients with symptomatic diabetic neuropathy.

Conclusion

Further studies with longer periods of treatment and larger patient groups may be necessary to evaluate possible beneficial long-term effects of TENS-therapy on nerve fibre function and the progression of diabetic polyneuropathy

Final questionnaire

70 % of patients in TENS group reported a subjective improvement in symptoms

100 % of the patients in the TENS group recommended this kind of therapy to other patients with comparable symptoms of diabetic neuropathy