

TRANSCUTANEOUS SUBMENTAL ELECTROSTIMULATION THERAPY FOR OBSTRUCTIVE SLEEP APNEA. FIRST CLINICAL RESULTS

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INTRODUCTION In 2001 two different devices for submental transcutaneous electric stimulation therapy for sleep related breathing disorders were introduced to the market in Europe. The IMPERPULS device is used for half an hour during the day and during the whole night. The objective of the present pilot study was to assess the efficacy and safety of the device after 4 weeks of treatment.

METHODS 14 male sleep apneics were treated for at least 4 weeks with the IMPERPULS device. Patients filled in a diary every day including time and duration of use and adverse events. The following parameters were assessed before and after treatment. Daytime sleepiness was recorded using the Epworth Sleepiness Scale (ESS), severity of snoring was measured using a visual analogue scale (VAS) for the bed partners with the end points 0 for no snoring and 10 for excessive snoring. Sleep studies were performed as fully attended polysomnographies in the sleep lab. For statistics the Wilcoxon rang sum test for paired variables was used.

RESULTS Patients were 61.2 (37 to 74) years old. All but one patient used the device as recommended and completed the study. For the remaining 13 patients the mean apnea-hypopnea index was 32.5 (13.5 to 51.5), and was reduced in all but one patient to 21.1 (2 to 38) after treatment in the mean. The differences were statistically significant ($p < 0.05$). Daytime sleepiness was 10.3 (3 to 18) before treatment and decreased not statistically significant to 8.9 (3 to 20) after stimulation therapy. The preoperative severity of snoring was ranked 7.1 (3 to 10). After treatment snoring was significantly improved to 3.4 (0.8 to 7.2) ($p < 0.05$). As complications one allergic reaction to the skin electrodes was noticed. No other adverse events were seen.

DISCUSSION Submental transcutaneous electric stimulation therapy is a save treatment modality for sleep related breathing disorders. The subjective efficacy concerning snoring is superior to the objective efficacy concerning the severity of obstructive sleep apnea. Controlled studies have to show whether electrostimulation therapy might be a good treatment modality for mild OSA and simple snoring.