

THE EFFECT OF PULSE RATE CHANGES ON CLINICAL OUTCOME IN SACRAL NEUROMODULATION

Hypothesis / aims of study

To evaluate the effect of pulse rate changes on clinical response in patients with sacral neuromodulation (SNM) treatment.

Study design, materials and methods

Patients with suboptimal response to SNM were included in this pilot study. The effect of four different pulse rates (5.2Hz, 10Hz, 21Hz and 40Hz) was evaluated. Each test period lasted 6 days. To diminish carry-over effect, stimulation was turned off for 24 hours between each test period. In the last days of each test period, a 3-day voiding diary and questionnaire were filled out. The questionnaire consisted of 7 visual analogue scale (VAS) scores, ranging between 0 (worst) and 100 (best) and was used to evaluate micturition in general, voiding frequency, flow, urgency, emptiness of bladder, bladder control and the feeling of being dry. The clinical response was compared between the four pulse rates. Because only patients with a good, yet suboptimal response to SNM were included, a change of at least 20% compared to baseline was considered a clinically significant change.

Results

Fifty patients were included, 40 women and 10 men. The mean age was 55.5 years (SD 12.3). Twenty-nine (58%) patients had overactive bladder, 9 (18%) had chronic urinary retention, and 12 (24%) had both overactive bladder and urinary retention. Statistical analysis showed no significant difference between the four different pulse rates in any of the VAS scores of the questionnaire. Differences in voiding diary results between the 4 pulse rates for the whole study group were also non-significant. The results of individual voiding diary analysis are shown in table 1, with improvement or worsening for each pulse rate setting.

When patients were asked to choose the 'best' and 'worst' pulse rate based on subjective experience, 45 of the 50 patients responded (table 2), whereas the other 5 did not notice any difference between the pulse rates.

At baseline, 15 patients reported having some stimulation related pain or discomfort. Ten of these patients (67%) reported pain relief during the study with at least one pulse rate setting. This was reported 6 times with 5Hz, 6 with 10Hz, 5 with 20Hz and 7 with 40Hz.

Interpretation of results

In this pilot study, we did not find a significant difference in clinical outcome for the 4 different pulse rates. However, on individual basis, patients appear to benefit from changing the pulse rate setting regarding both treatment efficacy and stimulation related pain. Further research is going on to evaluate the optimal algorithm for pulse rate changes in order to improve efficacy of reduce side effects of SNM.

Concluding message

Evaluating the whole patient group, none of the four pulse rates in this study appears to have a significantly different effect on clinical outcome. Nevertheless, a tailor-made approach for optimizing treatment efficacy by changing the pulse rate proves to be useful.

Table 1. Results of voiding diary analysis, with the number of patients shown that responded to the different pulse rate settings. Improvement or worsening was defined as 20% or more difference in their relevant voiding diary parameters compared to baseline.

Pulse rate	Improvement	No difference	Worsening
5Hz	20	16	14
10Hz	20	20	10
21Hz	23	13	14
40Hz	25	12	13

Table 2. Best and worst pulse rates chosen by individual patients, based on subjective experience.

	5Hz	10Hz	21Hz	40Hz
Best	15	14	4	12
Worse	7	4	11	7

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Medical Ethical Committee of the Maastricht University Medical Centre
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes