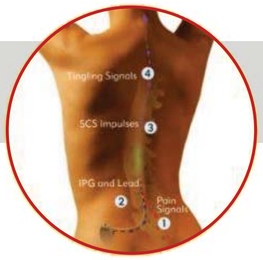


# Objective measurement of pain levels in patients with radicular pain treated by spinal cord stimulation

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## 1 Background and Goal of Study

Although pain induces changes in autonomic parameters, the extent to which these changes correlate with the experience of pain remains under debate. In a recent study [1], we have shown that a combination of multiple autonomic parameters, rather than each parameter by itself, successfully differentiated between four categories of experimental pain intensity in healthy subjects.

The present study tests the ability of a similar combination of autonomic parameters to differentiate between intensities of clinical pain in patients with chronic pain.

## 2 Material and Methods

Thirty three patients with chronic radicular (neuropathic) pain in one lower extremity and permanent spinal cord stimulator (SCS) participated in the study. Patients were requested to rate the intensity of their radicular pain on numerical pain scale (NPS, 0-100) twice, at a random order: either thirty minutes after turning the SCS on first, and then - two hours after turning it off, or vice versa (figure 1). For the purpose of this study, a difference of 15 NPS points or greater between the two ratings (stimulator "on" and "off") was regarded as an "effective SCS" .

Photoplethysmogram (PPG) and skin conductance (SC) were recorded twice with SCS on and off, simultaneously with the subjective pain ratings. Each recording lasted for 120 sec with the use of the PMD-100™ (Medasense Biometrics, Israel, figure 2). The following autonomic parameters and their derivatives were extracted: PPG wave amplitude, PPG wave amplitude variation, pulse rate (PR) interval, PR variability and SC fluctuations. Non-Linear regression was used to combine the parameters and to differentiate between intensities of the radicular pain with “SCS on” and “SCS off”. Paired t-test was used for statistical analyses.

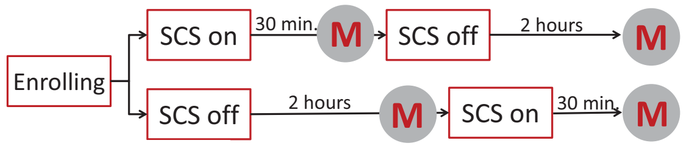



**Figure 1: study design**

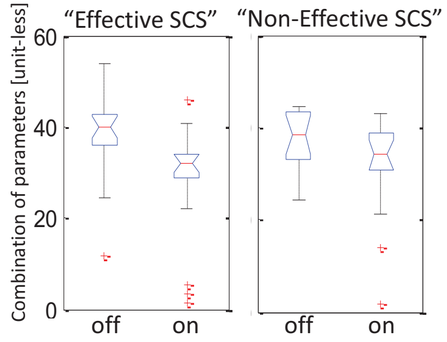
**Figure 2: PMD-100™**

## 3 Results

Eighteen patients reported an “effective SCS” (NPS reduced from 71±17 to 31±21, p<0.001) while fifteen reported “non effective SCS” (NPS = 68±27 with “SCS off” and 60±27 with “SCS on”, p=0.44). No statistical difference was found between groups in NPS during “SCS off” state (p=0.74).

For the “effective SCS” group, the combination of the parameters, but not each parameter alone, showed significant difference (p=0.002) between the “SCS on" and the “SCS off“ states (Table 1; Figure 3), in concordance with the recorded pain ratings (Table 1). For the “non-effective SCS” group none of the parameters showed a significant change.

**Figure 3: Combination of parameters**




— represents median values; ⌶ represents the 25th and 75th percentiles; | whiskers extend to extreme data points (5% and 95%) not considered outliers; + represents outliers.

**Table 1**

| Parameter | “Effective SCS” (N=18) | | | “Non-effective SCS” (N=15) | | |
|---|---|---|---|---|---|---|
| | “SCS Off” mean [SD] | “SCS ON” mean [SD] | *p* val | “SCS Off” mean [SD] | “SCS ON” mean [SD] | *p* val |
| PR variability | 0.78 [0.85] | 0.49 [0.43] | 0.09 | 1.9 [3.4] | 1.6[2.1] | 0.50 |
| PR | 75.09[12.6] | 75.3[13.22] | 0.88 | 79.9[10.5] | 77.48[8.6] | 0.14 |
| PPG wave amplitude | 7.8 [8.7] | 4.9[4.3] | 0.10 | 18.9 [34.1] | 15.3[20.8] | 0.47 |
| PPG wave amplitude variation | 6.4[10.6] | 1.6[2.2] | 0.07 | 1.4[4.9] | 0.15[0.31] | 0.34 |
| SC fluctuations | 2.9 [2.9] | 3.4 [3] | 0.14 | 5.46 [5.55] | 6.3 [5.5] | 0.94 |
| **Combination of physiological parameters** | 41.8 [15.7] | 28.2[12.5] | **0.002** | 38.6 [10.9] | 31.5[11] | 0.13 |
| **Patient pain ratings (NPS 0-100)** | 70.8 [17.2] | 30.6 [21.1] | **<0.001** | 68.3 [26.8] | 59.7 [26.6] | 0.44 |

*p<0.008 is considered significant due to multiple comparisons (Bonferroni correction).*

## 4 Conclusions

These preliminary findings suggest that autonomic-based multi-parameter assessment differentiate between intensities of chronic clinical pain.

**Literature** [1] Treister R et al. Pain®. 2012 Sep. 153(9): 1807-14.