

THE FIRST CLINICAL TRIAL OF
PAIN@GONE
IN HUNGARIAN MEDICAL PRACTICE

INTRODUCTION:

The **PAIN@GONE** pen is a new pain relief device which has lately become available in Hungary. The piezo-electronic crystal placed in the product works by producing a high voltage, low frequency pulse for a brief period. (15,000 V, 0.006mA, 1-2 Hz). Clicking on the painful area, the device transmits electrical impulses to the skin surface and then to the body's pathway for pain relief.

The technical system of the device is the clinically proven and uses Transcutaneous Electric Nerve Stimulation - TENS, based on the Gate Control Theory of Melzack and Wall, 1965. Electrical stimulation activates endorphins in the hypothalamus and plays a major role in pain relief.

In Hungary, we have carried out a short-term clinical study on **PAIN@GONE** in October 2004.

OBJECTIVE OF STUDY:

To determine the effectivity of the **PAIN@GONE** pen on chronic pain associated with different types of illnesses via changes in VAS and overall effectiveness as a treatment.

Patients:

2 groups

Group 1: patients with spinal pain, lower or upper limb pain
average age 61,62 years (31/76), 8 patients: 1 male, 7 female

Group 2: Patients with different types of chronic pain (fibromyalgia, arthrosis of the finger, arthrosis of the knee and PHS) average age 49,57 years (27/79), 7 patients: 3 male, 4 female

COURSE OF STUDY:

15 patients with chronic pain were involved in the study.

After informing them about the technical system and use of device the patients were asked to take part in the trial.

Selected patients took part in an 8 or 15 days long treatment. During the treatment they were allowed to use the device independently, day-by-day, and as many times as they pleased.

Before the start of the first trial, patients had to indicate the average strength of their pain on that day using the VAS scale. Similarly, pain was measured on the 8th day and then again on the 15th day. In addition, recordings were made of how many times the patient used the pen, the effectivity of single treatments and the overall treatment satisfaction using the pain-gone pen together with common pain-relief medications.

During the course of treatment, pain relief drugs were not withdrawn from patients, and recordings were made of the amount of supplementary medications taken.

Usage of the **PAIN®GONE** pen was left up to individual patients and the number of treatments was recorded. Patients estimated the effectiveness of each treatment in a percentage value and recorded their values in daily patient diaries.

At the end of the treatment our patients marked their overall satisfaction with the device on a scale from 1 to 5.

RESULTS:

According to their disease the patients were selected into two groups.

In the **first group** (group 'A') we examined patient suffering from chronic pain in the low back. In Group 'A' 1 man and 7 women were involved. The average age was 61/62 years (median 64; 76/31). At the beginning of the treatment the VAS was 60.125, (median 57.5; 80/31). Average frequency distribution of device's daily use was 3.72 times (median 4.5, 73/1.66). Average effectiveness of certain treatments was 71.783 (median 80; 100/10). On the 8th day of study average value of VAS was 30 (median 27.5; 94/4), on the 15th day 21 (median 14.5, 55/0). 50 percent of patients provided information about the 15 days long treatment. Reason for lack of providing information was due to the difficulty in reaching patients.

The second group, (Group 'B') consisted of patients suffering chronic pain from different conditions such as fibromyalgia, finger-arthritis, knee-arthritis, PHS, and visceral radiating pain. In this group 3 men and 4 women were involved. Average age is 49.57 (median 49, 79/27).

At the beginning of the treatment the VAS result was 52.57 (median 51; 83/20). Average frequency distribution of device's daily use was 4.22 times (median 5.6; 21/1.18). Average effectiveness of certain treatments was 46.22 (median 37.21; 92.77/10). On the 8th day of study average value of VAS was 37.85 (median 46; 64/15), on the 15th day 24 (median 18; 45/15). 57.14 percent of patients provided information about the 15 days long treatment. Patients not providing information made the decision of not taking part in the further study.

CHANGES OF VAS VALUES AT CERTAIN GROUPS:

In the first week measurements on the 10 cm pain scale showed that pain in Group 'A' members improved 50.1%. By the end of the second week the improvement was 65.07 percent. Calculating with data of patients who provided information in the second week only, the results did not vary significantly.

In Group 'B' the first week's results showed pain relief improvement of 28.0 %, second week resulted in a 54.34 % improvement of pain. Within this group B, separate analysis the data of patients treated for two weeks gave different results: first week's improvement was 30.72 %, second week, 46.36 %.

Our patients' overall satisfaction was 3.61 on a five-grade scale.

CONCLUSION:

According to results, we came to the conclusion that the device is an effective pain relief for most of the examined patients. About half of patients in both groups experienced pain relief that was more than 50% effective. Pain relief was more significant in patients with radiating spinal pain.

In conclusion, we have established the effectiveness of using **PAIN@GONE** pen is an effective device for chronic pain suffering patients and, thus, a potent supplementary treatment device for locomotor disease. Because it is handy and easy to use, it can contribute to a improvement in the quality-of-life for patients who respond well to treatment.

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