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Analgesic efficacy of APS (Action Potential Simulation). Pilot study of the patients with chronic pain due to musculoskeletal disorders

Abstract

Background and aims. Pain in musculoskeletal disorders is common medical problem, however frequently difficult to treat. That is why different methods of physical therapies have been tried with the controversial results. APS-therapy (Action Potential Simulation) falls under the broad definition of MET (Microcurrent Electrical Stimulation). MET may be a useful treatment for many pain-related disorders, providing fast relief of symptoms. The aim of this pilot clinical study was to investigate the analgesic efficacy of APS--therapy in chronic pain due to musculoskeletal disorders.

Methods. The study involved 12 patients with musculoskeletal disorders who suffered from chronic pain. Each patient received treatment for 3 weeks' time. APS-therapy was administered for a period of 16 minutes, 5 times a week. Treatment was given by portable unit, that generated an APS waveform (monophasic, pulse width 800 ms, frequency 150 Hz and intensity 0.5–1.5 mA). NRS (Numerical Rating Scale) evaluation was performed for 3 days of pre-treatment period, before each treatment which reflected the pain situation of the previous 24 h, and once daily for 2 weeks after treatment.

Results. The initial mean NRS in pre-treatment period was 5.53 (SD = 1.94), decreased after APS-therapy to 3.45 (SD = 1.4) ($p = 0.002$) and even more to 2.56 (SD = 1.23) in the post-treatment period ($p = 0.0003$). Mean pain intensity decreased significantly after 11 sessions and remained on the same level up to 2 weeks of post-treatment observation.

Conclusion. APS-therapy may be an effective method of nonpharmacological treatment of chronic pain in muscoskeletal disorders.

Key words: APS-therapy, musculoskeletal disorder, chronic pain

Introduction

Electrotherapy is useful for treating a variety of clinical conditions. Indeed, it may be the main or complementary method for treating many pain related disorders, providing fast relief of symptoms. APS-therapy (Action Potential Simulation) falls under the broad definition of MET (Microcurrent Electrical Stimulation). This type of electrical modality uses an electrical current of less than 1 mA, which is measured in the microamperage range. The APS--therapy produces current that is claimed to stimu-

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late an action potential in the neuron. According to the Arndt-Schultz Law weak stimuli increase physiological activity [1]. Investigation into the physiological mechanisms involved has shown that these subthreshold currents cause the following effects: changes in cell wall permeability, increase of the intracellular concentrations of Ca^{2+} and adenosine triphosphate (ATP) production, stimulation of protein synthesis and increase of fibroblast activity [2]. The APS device was invented and designed by G.A. Lubbe in 1991 in South Africa, and marketed in 1994 even without published studies in peer-reviewed journals [2]. Nowadays there is scarcity of published literature of APS therapy. A controlled trial using APS-therapy and TENS (Transcutaneous Electrical Nerve Stimulation) to treat the pain of osteoarthritis of the knee was reported by Berger [3]. In this study electrotherapy (APS and TENS) proved to be beneficial in the relief of stiffness and pain, especially occurring at night [3]. Other authors who studied the usage of APS therapy in chronic and acute post-traumatic pain conditions (low back pain, tennis elbow, sports injuries, shoulder pain, arthritis) indicate that APS therapy produces 40––80% pain relief after 5–15 treatment sessions [4–7].

The aim of this pilot study was to investigate the analgesic efficacy of APS-therapy in chronic pain due to musculoskeletal disorders.

Methods

The study protocol was accepted by the Ethics Committee of the Nicolaus Copernicus University, Collegium Medicum Bydgoszcz in Poland. Before the trial each patient was examined by the physician and signed an informed consent. The inclusion and exclusion criteria are presented in the Table 1. The study involved 12 patients with musculoskeletal disorders who suffered from chronic pain. The demographic and clinical data of investigated subjects are presented in the Table 2. Each patient received three weeks treatment. The APS-therapy was administered for a period of 16 minutes, 5 times a week. The treatment was given by portable unit, that generated APS waveform. Technical specifications of the APS therapy device and information about stimulation parameters and electrodes placements are presented in the Table 3. NRS (Numerical Rating Scale) evaluation was performed for 3 days of pre-treatment period, before each treatment which reflected the pain situation of the previous 24 h and once daily for 2 weeks after treatment.

On 24th day of treatment the patients were asked to estimate the level of satisfaction in seven degrees scale (from –3 to 3) — Satisfaction Scores.

Statistical analysis was made using a licensed version of statistical software STATISTICA PL 5.0 for Windows. Distribution of variables by Kolomogorow-Smirnow test was abnormal, therefore non-parametric statistical tests were chosen. The results were calculated as median NRS score value for respective day of the investigation and presented in Figure 1. Moreover, for every study phase for each subject the mean of NRS score value was calculated. The statistical significance of difference between values calculated for each day of the study (Fig. 1), as well as for every study phase (Table 4) was estimated using one way ANOVA method with 38 repetitions and Scheffe post hoc test. The final results were presented as the median and 95% CI (confidence interval).

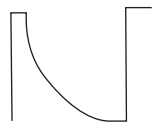
Table 2. Patients characteristics

Total number of patients	12
Gender	
Male	3
Female	9
Age (median ± 95% CI)	26 ± 21.9–40.3
Clinical diagnosis	
Degenerative Joint Disease	9
Painful Shoulder Syndrome	1
Rheumatoid Arthritis	2
Medication	
Anti-inflammatory	1
Analgesics	2
No medication	9

Table 1. Patients inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Patients with chronic pain due to musculoskeletal disorders	Cardiac pacemaker
Average pain intensity not less than 3 measured in NRS	Epilepsy
Patients able to estimate pain intensity	Inflamed or infected skin in planned electrodes placement
Patients, which signed an informed consent	Thrombosis in anticoagulants treatment period
Patients over 18	Pregnancy

Table 3. Procedure parameters

Stimulation parameters	Wave form — APS	Electrodes placements
Frequency = 150 Hz Pulse width = 800 ms Intensity = 0.5–1.5 mA Treatment duration = 16 min		Two channels, electrodes were placed to surround the target area

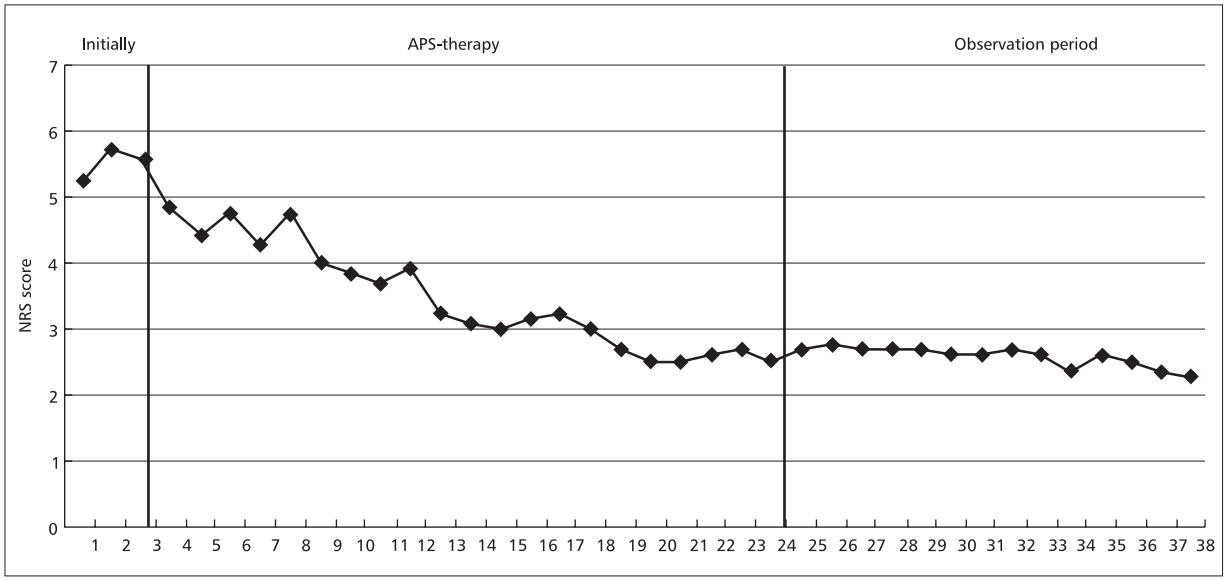


Figure 1. The intensity of pain in NRS score in following days and phases of the investigation, ANOVA; F (37.407) = = 14.12; $p < 0.001$

Table 4. The medians and 95% CI of mean NRS score values observed in individuals within respective study phases as well as the levels of improvement of NRS score values in respective phases of investigation (n = 12)

Parameter	Pre-treatment period (1)	APS-therapy period (2)	Post-treatment period (3)
Median of mean NRS values	5.5 ± 4.3 to 6.8	3.45 ± 2.56 to 4.34*	2,36 ± 1.77 to 3.35*#
Delta1–2 (median ± 95%CI)		–2.07 ± –3.19 to –0.95	
Delta1–3 (median ± 95%CI)			–2.97 ± –4.21 to –1.73
Delta 2–3 (median ± 95%CI)			–0.90 ± –1.27 to –0.52

Statistical significance in Scheffe post hoc, in ANOVA analysis F (2.22) = 22.17, $p < 0.001$); *$p < 0.01$ in comparison between initial values and treatment or observation period, #$p < 0.001$ in comparison between APS treatment period and post-treatment observational period

Results

The median values of NRS score within respective days of the study were presented in Figure 1. The effect of applied therapy was significant in estimation by one-way ANOVA method [F (22.22) = = 22.17; $p < 0.001$]. In comparison to NRS score values obtained within three days of the pre-treatment period, after 11 days of APS therapy pain intensity significantly decreased (Table 4). The effect of therapy was maintained for the subsequent ten days of the APS therapy, as well as within 14 days of post-treatment observation period (Fig. 1).

The median of the means NRS score values obtained within the pre-treatment period, within 14 (21)-days long APS therapy and during 14-days long observation period are presented in table 4. In comparison to the initial value, the NRS score after APS therapy and after observation period were significantly lower, in average by 36% and 51%, respectively. Pain intensity was also significantly lower during post-treatment observation period in compari-

son to APS-treatment period (in average by 27%) (Table 4).

The median of Satisfaction Score after 21-days long APS therapy in seven degrees scale (from –3 to 3) was 2 (95% CI 1.2–2.2). 11 patients found the treatment satisfactory (Satisfaction Scores between 1 and 3), one patient didn't notice any changes (Satisfaction Score = 0). During the treatment no side effects were observed.

Discussion

Many patients suffering from pain due to musculoskeletal disorders are treated with pharmacotherapy only. However, physical methods like electrotherapy should be considered more frequently as a therapeutic option. Our study suggests that APS-therapy can be used as an alternative to drugs or complementary methods for chronic pain management . We showed that APS-therapy significantly decreased pain due to different musculoskeletal disorders. Furthermore, this kind of treatment is cheap and causes no side effects. Another advantage of this method is the fact that the treatment session takes a very short time (approximately 16 minutes once a day for 3 weeks) and in many cases can be applied by the patient himself at home. To compare, the TENS (transcutaneous electrical nerve stimulation) takes a few hours a day [8]. Besides it is worth mentioning that on the contrary to TENS, APS is a causal treatment of pain. Increase of ATP generation after microcurrent stimulation in rat skin models was reported by Cheng [9]. ATP plays an essential role in the inter-body communication (generation of nerve impulses for communication and control purposes), muscle contraction (e.g. during walking, breathing etc.), nerve conduction, transport, growth, etc. That is the reason that APS therapy can be used in pain relief, breakdown of inflammation and wound healing.

Moreover the patients were satisfied with the effects of the treatment what can be noticed in the Satisfaction Scores.

Our study gives the rational reason for further randomized controlled trials with placebo group which should more accurately assess analgesic efficacy of APS-therapy.

Conclusion

APS-therapy may be an effective method of non-pharmacological treatment of chronic pain in musculoskeletal disorders.

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