

System Information Therapy in the Management of Pain: A Pilot Study

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Abstract— Dealing with pain is an important daily part of current medical practice. Biophysical methods by use of medical devices (such as Med Select 729 in this trial) allows to perform very personalized treatment using endogenous signals of the patient leading to the definition of a System Information Therapy (SIT) approach. An open labeled clinical trial was designed to assess the effectiveness of a biophysical treatment compared to a common anti inflammation drug (ibuprofen) and compared to placebo. Methods: patients has been divided in three groups: **Group 1** System Information Therapy patients receiving two steps of treatment by the Med Select 729 medical device: 1st step delivered with a program called regulation therapy with recording of endogenous input signals at the painful region and delivery of therapeutic output signals at systemic level by mean of an electromagnetic mattress on which the patient lied — 2nd step delivered with the program called pain therapy: recording endogenous input signals at the painful region and delivery of therapeutic output signals at the pain site, moreover a copy of therapeutic signals has been recorded on a commercial available aqueous system (Nomabit Base). **Group 2** Pharmacological therapy: receiving ibuprofen 600 mg twice a day for 10 days. **Group 3** Placebo group: receiving only Nomabit Base solution as placebo. A total of 66 patients was enrolled: 26 in System Information Therapy group (17 f, 9 m), 23 in the pharmacological group (11 f, 9 m); 17 in the placebo group (12 f, 5 m). Evaluation of follow up was performed by a visual analogue scale at the beginning, after one week, after one month, and after three months. After one week biophysical therapy shows similar effect than ibuprofen and after one month the statistical significance was $\chi^2 = 12.153$ with $p < 0.02$. In conclusion the biophysical therapy protocol demonstrated the same effectiveness than usual pharmacological therapy with ibuprofen at first week reaching statistical significance after one month of administration and maintaining the effect at tree month. System information therapy seems, therefore, to be an effective and safe method in the management of pain in current medical practice representing a possible resource especially for patients with chronic disease and multiple comorbidities in order to reduce drug overload.

1. INTRODUCTION

Practitioners has to cope daily with many kind of pain related diseases. Pain usually expresses maladaptive response to stress. Stress can be defined as a condition or state in which a perceived discrepancy between afferent stimuli and a well-defined range of allostasis activates adaptive responses trying to reduce this possible discrepancy. Allostasis describe the dynamic adaptive process aimed to keep stability while coping with both internal of external challenges. Allostasis describe the dynamic adaptive process aimed to maintain the most effective condition of the whole organism at any moment: therefore it is intrinsically time varying according to different combinations of both inner and external conditions. Allostatic load is the sum of allostatic response exciding physiological attitude of the organism at a certain time. Allostatic load occur when activation of allostatic response are continuously settled [1–3]. Pain is part of almost any adaptive response in the acute diseases yielding a fastening in recovery of allostasis. Pain is part of the maladaptive responses in chronic diseases leading to a worsening of allostatic load and slowing recovery [4–6]. In this framework it is clear that coping with pain has to be considered not only from a symptomatic viewpoint but also from a systemic perspective [7–10]. Biophysical methods by use of electro-medical devices allows to deliver treatment using endogenous electromagnetic signals and is therefore consistent with the developing concept of personalized medicine [11, 12]. In the last decays a progressive fall

of reductionism had led to the concept of Systems biology and, only very recently, to the concept of Systems Medicine. In the framework of Systems Medicine it is clear that some features and behaviour of the system as a whole are not the sum of the single parts but arise from emergent characteristics due to the complexity of living organisms. Consistently with the raising concept of System Medicine [7–10] is raising the concept of System Information Therapy [13] as an integrative clinical tool able to allow the treatment of patients with biophysical methods operating at once by endogenous and external electromagnetic signals. Indeed living organisms are endogenously producing electromagnetic signals and make fruitful use of them in the coordination of their internal processes and in cell to cell coordination [14–16]. On the other hand the clinical use of electromagnetic therapies has long history with evidence of anti-inflammatory effects of electronic signals [17]. System Information Therapy approach allows to achieve at once a systemic and a local effect [18] leading to a reduction of allostatic load as clinically detectable by evaluation of fluctuating asymmetry, a clinical marker of stress [19], as reported in a previous study [20]. In this pilot study we also implemented the transfer of electromagnetic signals to an aqueous system in agreement with previous finding on cellular, bacterial, plants and human models [21–26]. The idea of performing a single treatment with biophysical therapy making at the same time a record of the signals on a commercial available aqueous system allows to perform a single treatment in a single day and to continue the treatment by the daily sublingual administration of drops of the recorded aqueous solution (a commercial available aqueous solution of micro elements: Nomabit Base). This could also provide support to the feasibility of the Electro Magnetic Information Transfer (EMIT) through aqueous system [26] in clinical use.

2. METHODS

A pilot clinical trial was designed to assess the effectiveness of a biophysical treatment recorded on an aqueous system compared to a common anti inflammation drug (ibuprofen) and compared to placebo. A total of 66 patient (40 females and 26 males) was enrolled in the study, that was performed in the respect of the declaration of Helsinki, upon delivery of an informed consent. 66 patients was divided into 3 groups as follow: 26 in the Biophysical therapy group (17 f, 9 m), 23 in the pharmacological group (11 f, 9 m); 17 in the placebo group (12 f, 5 m). Visual Analogue Scale (VAS) score was recorded at the beginning, after one week, after one month.

2.1. Group 1

Group 1 was the System Information Therapy group and was treated by a 2 step protocol using a commercial available electro-medical device Med Select 729 (by Wega, Germany). Meanwhile a copy of the output therapeutic signals were recorded on a commercial available aqueous system (Nomabit Base) placing the solution into a special output coil built-in for this purpose in the Med select device. The aqueous solution of Nomabit Base was self-administered daily to the patient in order to allow the therapeutic information recorded to be delivered once a day. The drops were taken according to a weekly plan starting on Monday with a single drop and raising of one drop a day up to 6 drops on Saturday, no therapy was taken on Sunday and then the protocol started again from one to six drops during each following week.

2.2. Group 2

Group 2 was the Pharmacological therapy group: ibuprofen 600 mg twice a day, on full stomach, for 10 days, was administered to each patient of this group.

2.3. Group 3

Group 3 was the Placebo group. The patients of this group was receiving only Nomabit Base solution as placebo, therefore not placed into the Med Select to be selectively recorded, and administered with the same protocol as in the System Information Therapy group.

3. RESULTS

Evaluation and follow up was performed by a Visual Analogue Scale (VAS) at the beginning, after one week, and after one month. Criteria of evaluation of VAS self-rating modification in the follow up was the following: Reduction ≥ 2 Points in VAS score was considered as improved; Reduction = 1 Points in VAS score was considered as unchanged; Reduction ≤ 0 Points in VAS score was considered as worsen. After one week System Information Therapy shows similar effect than ibuprofen as reported in Figure 1.

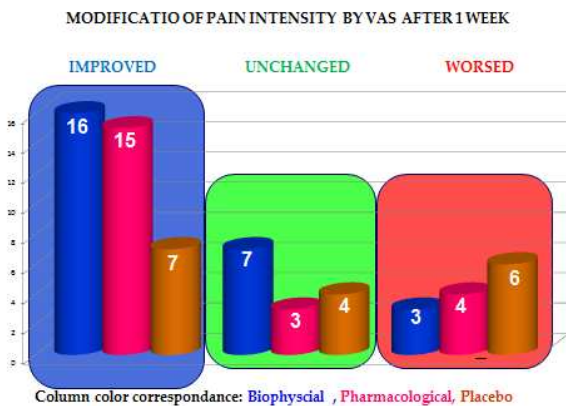


Figure 1.

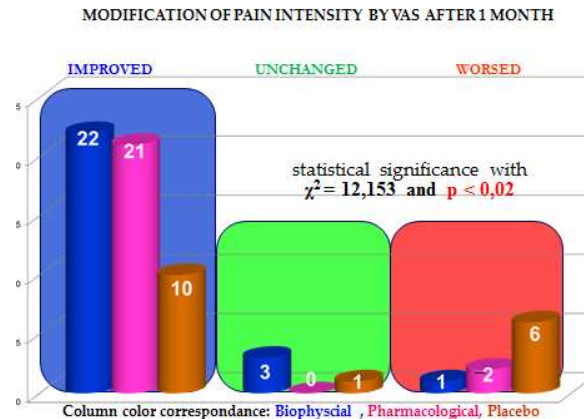


Figure 2.

Data reported after one month reach a statistical significance with $\chi^2 = 12.153$ and $p < 0.02$ as showed in Figure 2 demonstrating that biophysical therapy is as effective as pharmacological treatment with ibuprofen in respect to placebo in the management of pain.

4. DISCUSSION

System Information Therapy demonstrated to be an effective and efficient method in pain relief according to the modification of self-rating of pain collected by mean of the Visual Analog Scale VAS. System Information Therapy showed the same effectiveness of the non-steroidal anti-inflammatory drug Ibuprofen administered in the dose of 600 mg. twice a day in respect to the use of a placebo. System Information Therapy and Ibuprofen were efficient in pain rating reduction as reported at the first follow up assessment after one week while placebo was not as reported in Figure 1. System Information Therapy and Ibuprofen was efficient also in pain rating reduction at the second follow up assessment after one month while placebo was not. A complete statistical significance is achieved by both Biophysical and Pharmacological group in respect to placebo at the end of the first month with $\chi^2 = 12.153$ with $p < 0.02$ (Figure 2). The available data suggest that Biophysical therapy mimic the dynamics of the Pharmacological treatment and is long lasting in their effects. Interestingly a very low amount of worsen cases was reported in the biophysical group and especially no side effect was referred. Moreover many patients of the Biophysical group reported feeling of a general relaxation following the treatment as presumably to be due to a systemic effect of the biophysical therapy besides the effect on pain. Importantly the use of a single recording procedure during the System Information Therapy allowed to perform a unique treatment of the patient, lasting only 20 minutes, saving time and cost due to repetition of the treatment. Biophysical treatment therefore was time effective and cost effective. The treatment fulfill the requirement to be considered as a personalized medication because the pattern of signals are recorded on the site of the pain, such pattern of endogenous electromagnetic signal being unique for any single person at any single time, this way the procedure is actually tailored on the patient. Moreover the recording of the output signals on the aqueous system, a commercial available solution of micro elements Nomabit Base (by NAMED, Italy) is consistent with the previous findings [21–26] and demonstrate the clinical feasibility of such a procedure as a useful integrative tool in general practice as reported by further studies in agreement with the hypotheses that aqueous system could be able to record, store, and transfer biophysical active information to biological targets [27–30]. Further clinical trials are certainly requested to confirm and widen the data presented in this preliminary pilot study and someone are already in process to better define the clinical areas besides pain in which a biophysical strategy could improve quality of life to the increasing number of patients with chronic diseases and multiple comorbidities that require to be treated effectively and safely reducing the number of drugs to be used especially for the management of pain. Biophysical therapies could help to manage some symptoms related to no life-threatening diseases reducing global allostatic load and therefore cooperating to reduce total morbidity and mortality as reported from successful aging studies [31, 32].

5. CONCLUSION

In this pilot study on the management of pain in general practice System Information Therapy demonstrated the same effectiveness than an usual pharmacological therapy with ibuprofen, in respect to placebo. The effectiveness was already disclosed at the end of first week reaching statistical significance after one month of treatment. System Information Therapy should therefore be considered as an effective and safe method in the management of pain in current medical practice.

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