Complex balneo-physiatric treatment in fibromyalgia: A pilot study

J Jerabek, A Bordon, R Pineda

Citation

Abstract
19 patients meeting CDC criteria for fibromyalgia (FM) were treated. The treatment consisted of warm water hydrotherapy performed in bathtub with hydrojets, dry CO2 bathes, pulsed magnetotherapy, ultrasonotherapy applying capsaicin ointment and manual techniques for 2 weeks. All the mayor fibromyalgia impact questionnaire, McGill short questionnaire and additional variables improved at high statistical significance level. Up to date the worst improvement period lasted for 4 months. The most difficult cases were those, where cervical spondylitis was diagnosed together with FM. The mechanism of action of factors applied is discussed.

INTRODUCTION
Fibromyalgia (FM) has been defined as rheumatic disease characterized by at least 3 months lasting pain in all 4 body quadrants with at least 11 from 18 specific points painful to palpation with force of about 4 kp (1). Alarming results in NMR imaging were published (2) about cortical gray matter hypodensity and degeneration with severity correlated to the fibromyalgia duration resembling premature brain aging. Similar changes were observed in striatum (3). A lot of papers have appeared showing hypoperfusion in thalamus, cuadate nucleus and anterior cingulate cortex (4-7). The pharmacological treatment in spite of great effort is not quite satisfactory. It seems that physiatric approach is better (8,9,10,11,12,13), and above all balneology with more complex and intensive treatment gives more long-lasting results (14,15,16,17,18). The problem with balneological treatment is its high price (20) and necessity to stay for a couple of weeks in a specific place with given climatic and geological features that differ significantly. That means that at any spa approaches are different and hardly can be compared.

Physiatric procedures generally applied are based mainly on active exercising. However, for a FM patient physical activity quite common for healthy person represents an overload followed by amplification of pains. If exercising is not led by especially trained persons knowing well the pathology and patients limits the results may be catastrophic. This fact explains reported low adherence to exercising (21). We decided to apply a selection of 5 passive cheap and simple procedures derived from european balneological practice to prove if those may improve patients conditions as a preparation for consequent active treatment.

The study was performed as open as except of ultrasound no one of factors applied can not be even single blinded. Form those reasons this study should be understood as pilot one showing certain possibilities only.

Moreover, we wanted to verify whether unpublished results from Czech and Slovak spas might be repeated in harder climate zone without corresponding natural resources. Form those reasons this study should be understood as pilot one showing certain possibilities only.

LOCALIZATION AND CLIMATE
San Pedro is localized in subtropical zone of Misiones Province in the NE of Argentinean territory with geographical coordinates: 26°50' S and 54°15' W, 505 meters above sea level. The climate is continental subtropical with average winter temperature 17 °C (range 0 - 28 °C), summer average temperature 25 °C (range 15 - 40 °C). Humidity varies from 30% up to 100% with marked season, day-to-day and daily instability.
PATIENTS AND METHODS

19 outpatients, 3 males (M) and 16 females (F) meeting the CDC criteria for the fibromyalgia (1).

Age (years): 23 - 62, median 41, lower quartile (LQ) 30, upper quartile (UQ) 48.

Professions: 5 rural workers (F), 2 drivers (M), 1 carpenter (M), 1 cashier (F), 1 teacher (F), 2 nurses (F), 1 cosmetologist (F), 1 accountant (F), 1 administrative worker (F), 1 shop owner (M), 2 housewives, 1 retired (F).

Disease history (years elapsed since the FM was diagnosed): 1 - 37, median 5, LQ 2.5, UQ 9.5. Note: the female patient with the largest history had been diagnosed as FM in Switzerland before the CDC definition.

Allodyniae were reported by 5 patients, in 4 of them in lower extremities, in 1 in shoulders and upper back region.

Periarticular edemas were observed in 2 women, in both the cases around wrists.

Comorbidities: in all the rural workers severe spondylitis in lumbar spine was found. Where the intellectual work prevailing degenerative changes were localized in cervical spine. One patients (F) suffered from treated hypothyroidism and one female was treated by hormonal substitution due to menopause. The “pure” FM, without other diagnosticable pathology we saw in the accountant (30 years) and in the shop owner (42 years).

All of the patients were hypotonics. Regardless of their ages the blood pressure did not exceed 120/80 mmHg.

All the patients except the retired one continued with their daily work activities.

Inclusion criteria: patients meeting FM criteria.

Exclusion criteria: any pathology corresponding to counterindications to any of physiatric procedures applied.

Therapy applied in order and doses:

1. Hydrotherapy in a bathtub with 6 hydrojets (diameter of 25.4 mm, 3 on each side) commercially available at any hardware shop in Argentina, water temperature 33 - 38 °C, daily step up 1 °C, 20 minutes. The water to hydrojets was driven by one pump with P=750W.

2. CO₂ dry bath for 20 minutes. The patient immediately after the water bath entered in a polyethylene bag with volume 300 liters and sat down at the chair. The bag was tied up around patient's neck and inflated with industrial CO₂. The patient remained in the bag for 20 minutes.

3. Pulsed magnetotherapy was applied using ULTICARE LT99 device (http://www.magnetotherapy.com) provided with 4 coils of size 18 x 8 cm in belt localized along the vertebral column from occiput down to the lumbar part. The pulse shape was roughly asymmetrically triangular with dB/dt 3T.s⁻¹ ; -1.2 T.s⁻¹, respectively.

Figure 1
Figure 1: Magnetic pulse shape on the coil surface.

Figure 2
Figure 2: Spatial distribution of the magnetic field around the applicator - longitudinal section. Blue dotted lines represent the force lines, blue full lines are the equipotential lines, white dot-dashed line shows symmetry plain of the applicator. The fourth coil omitted.
The device was fed up with 12 V DC source. Patients were in supine position covered with a blanket. Regimen used - the 1st week 8 Hz, during the 2nd one 16 Hz. Exposures lasted 20 minutes each.

4. Ultrasonotherapy/phonophoresis was applied with Sonotherp 880 (Meditea, Buenos Aires, Argentina) on tender point zones, \( f = 1 \text{ MHz}, P = 3 \text{W/cm}^2 \), continuous regimen, device head 5 cm diameter, using capsaicin ointment commercially available as the contact medium, 1 minute to each point/area, dynamic regimen. Capsaicin ointment was applied at the very beginning on anterior surface of the forearm to check possible allergic reaction.

5. Classical massages of back an neck regions and postisometric relaxation of neck muscles were applied. In cases of cervical and/or lumbar spondylitis manual tractions were added. The zones of peripheral alodyniae were not treated.

All the procedures were performed once a day from Monday to Friday for two weeks.

Every patients was informed in details about the therapy he/she would meet and all of them agreed. Except of tender points testing all the procedures applied are painless, no one of them is invasive and no one of them brings risks. Moreover, during the whole time of all the procedures the patients were guarded. The study was supervised by the Health Care Department of the Municipality of San Pedro.

**DATA COLLECTION AND EVALUATION.**

For evaluation of patients’ conditions McGill short questionnaire, visual analogue scale (VAS 100mm) of pain with pain diagrams (\( r_2 \)), Fibromyalgia Impact Questionnaire (FIQ) (\( r_3 \)) adapted for local rural conditions, myofascial pain questionnaire (\( r_4 \)) were used at the beginning and at the end of the treatment. In all the cases we preferred VAS instead of whole-number scales. In the pain diagrams number of spontaneous pain areas were counted as well as planimetry of them was performed using as data the total planimetered area.

Number of tender points (TP) was counted and pressure for pain provocation was estimated in scale: pain on touch - 3 , pain provoked with pressing of approx. 2 kp - 2, pain provoked with pressing of 4 kp - 1, no pain - 0.

In addition, in order to verify possible effects on other FM symptoms we asked if: sleep disturbances, light, noise and climate intolerance, cephalea, abdominal pains, irritable bowel, vesico-urethral syndrome, temporomandibular dysfunction, dizziness, memory disorders muscular spasms, “fog in the head”, restless legs, ears and vision disorders (e.g. tinnitus, blurred vision) and nausea and vomit were present. Those variables we evaluated as yes/no.

The statistical analysis for differences was performed from data collected before and after the treatment using non-parametrical tests. Man-Whitney test was used for numeric data, while for yes/no data Yates corrected \( \chi^2 \) test was used. Probability level \( p<0.05 \) was chosen as limiting. Program Statistica 4.5 (Statfoft, Tulsa OK, USA) was used.

**RESULTS.**

A comparison of data obtained at the beginning and the end are summarized in figures 4. - 7.
Complex balneo-physiatric treatment in fibromyalgia: A pilot study

DISCUSSION

LOCALIZATION AND CLIMA.

San Pedro, Misiones, Argentina is localized in zone very unfavorable regarding fast changes (in hours) in temperature, humidity and wind directions. The climatic and season factors play a significant role in balneological treatment (24). Although we had a small number of patients it seems that those factors did not affect results. However, we can not conclude definitely this question.

PATIENTS GROUP

Although data collection started in December 2004 we treated only 19 persons for complete ignorance about the disease in the zone.

Our group is very inhomogeneous regarding to age, disease duration, profession and social level. The only common feature was presence of required symptoms. The comorbidities, above all the axial skeleton degenerative changes, in certain patients very pronounced, do not explain widespread pains and their severity and/or other symptoms.

From patients histories in 12 cases patients reported permanent stress situations (at work and/or in family), in 2 cases no trigger situations were found, in 2 cases long-lasting virosis was reported as a point of FM onset, 1 case had a motorcycle accident with cervical spine trauma, in 1 case the fall from a ladder harvesting fruits was mentioned and in 1 case the disease started after an appendectomy.
PROCEDURES

Hydrotherapy is always recommended in FM and is highly appreciated by patients as can be read in various FM patients fora. It is known that it has myorelaxant effect that persists if the therapy is repeated (53) although the mechanism is not sufficiently explained. The analgesic effect might be explained by vast receptor area stimulation by whirling warm water acting as Melzack gate blocker due to large perception area stimulation.

We want to stress out the importance of step-up approach and not to exceed the temperature 38 °C as too hot water sometimes recommended might bring circulation collapse in already hypotonic patients.

CO₂ dry bath method might be seen in (36,37) . It has been proven that CO₂ easily penetrates through wet skin and enters in the circulation (38) . Strong and fast vasodilatation effect depends on increase of NO formation (38) due to direct action on K⁺-ATP dependent channels activation in vessel wall (39) . Moreover, due to Bohr effect not only vasodilatation but augmented tissue oxygenation appears as well.

It is known that hypercapnia causes vasodilatation while hypocapnia acts as vasoconstrictor of cerebral vessels (40) with marked effects in brain stem, cerebellum and thalamus.

In Czech and Slovak spas CO₂ baths (both dry or in carbonized natural waters) have been used as a part of rehabilitation procedures in vascular pathologies and their consequences, conditions after cerebrovascular accident including.

The magnetotherapy is rather controversial point. Problem is, that the term “magnetotherapy” is understood as any therapeutic use of magnetic fields, regardless of their parameters. It is quite different if static magnetic field is used or sinusoidal or pulsed one. Very few articles describe the time and space distributions of the fields used. Neither the applicator shape nor size. A great deal of works exists confirming positive results in vast areas of pathologies (41) . There is a study (41) where an effect in the FM with static magnetic field was positive, while in other study (42) the analgesic effect was not confirmed. Other study shows benefits in FM pain with pulsed magnetic field in a single exposure (43) . Recent work (44) shows benefit of repeated application of pulsed magnetic fields with B = 400 T applied daily for period of one week for 40 minutes daily. Repeated transcranial magnetic stimulation (rTMS) shows analgesic effects in FM (45,46) .

Chronic exposures to magnetic fields of various types in industry clearly showed strong parasympathetic activation (47-49) . As vagus nerve stimulation (VNS) with implanted device has been described as beneficial in chronic pain conditions (49-52) and increases in both acute and chronic application improvement in thalamic blood flow (53,54) , magnetotherapy thus might serve as a contactless option.

Time varying magnetic fields induce electric currents in any matter exposed. Their magnitude depends above all on magnetic field dB/dt and matter conductivity. We estimate with our device the currents induced in various CNS areas according to the equation:

\[ I = \frac{r}{2} . \frac{dB}{dt} . \sigma \]

where:

- \( I \) = current density in A/m²
- \( r \) = radius of the area exposed
- \( dB/dt \) = velocity of magnetic flux density change in T/s [Tesla/second]
- \( \sigma \) = tissue conductivity in S [Siemens]

Calculating in this way the maximum current density induced in the plane perpendicular to magnetic field force lines. We can roughly estimate taking about 0.1 S that in the area of thalamus 6 mA/m² are induced that means about 4 - 6 A in the zone itself. This, although very weak stimulation, might activate midbrain periaqueductal gray matter descending inhibition of spinal nociceptive input. The current densities that might be reached with device we used were more or less comparable with direct currents that passed through tissues with various conductivities during transcranial direct electrostimulation. Positive effects of cerebral electrostimulation in FM are described in (55,56). A laboratory base for use of magnetic fields in the FM might be a fact that magnetic fields reduce glutamate toxicity blocking NMDA receptors (57,58) and amplifying effects were found in enzymatic reactions involved in neurotransmitters formation (59). There is a great pool of works from 60 and 70 stressing out the effects of magnetic fields in vasodilatation (60) . rTMS causes vasodilatation in thalamus (61) that is apparently frequency dependent (61) . It was shown that while 1 Hz repetition frequency causes impairment in cerebral perfusion, 20 Hz repetition frequency had opposite effect. Those results correspond to older work (62) , showing that pulsed magnetotherapy with f = 2 Hz (Bmax = 8 mT, 20
minutes, applicator localized in the posterior cervical zone, a single exposure) caused immediate vasodilatation in trunk and extremities of healthy persons that disappeared switching off the generator while frequency of 50 Hz had caused first vasoconstriction followed by 2 hours lasted strong vasodilatation it the same zones and head. Measurements were performed by thermographic camera.

Glutamate is considered as the main excitatory molecule in pain transmission and perception. If not removed from the synaptic gap, it turns from excitatory to toxic molecule due to opening of NMDA receptors allowing continuous entry of Ca\(^{2+}\) ions that cause postsynaptic membrane structural changes and activate enzyme systems that may lead up to apoptosis. It is interesting that astroglia surrounding synapses in spinal cord under ischemic conditions is unable to remove glutamate from synaptic gap in the spinal cord. Moreover, it was proven that the pain after an abdominal operation causes long lasting vasoconstriction in spinal cord zone. That might mean that just in spinal centers the aberrant pain perception starts and perpetuates with spreading up to higher centers where similar mechanism might be considered. It might be concluded that vasodilatation caused by any factor would be welcomed.

Ultrasound belongs among the most traditional instrumental methods in physiatry. The analgesic effect due to nerve conduction slowing down is well known as well as warming up of deep tissue layers leading to capillary vasodilatation. Moreover, in phonophoresis was proven as suitable method for enhanced locally applied drugs penetration through the skin.

As analgesic injections are considered to be applied either to trigger points in myofascial pains and/or maximum pain regions, thus the phonophoresis seems to be suitable procedure combining both physical and pharmacological pain killing effects. We decided to use capsaicin ointment for to its availability, low price and sale over-the-counter and proven analgesic effects.

Manual methods are the golden standard in physical medicine for any musculoskeletal pathology. A mere fact that someone “puts hands on” is very powerful tool in physical medicine. According to review there is no doubt about powerful analgesic effect of massages. In addition, in decrease of P-substance is described. According to the Melzack gate theory the pain reduction may be explained by non-nociceptive nerve receptors stimulation in vast areas. Massages performed once a day for three weeks have been proven to improve significantly FM symptoms.

Placebo effect in such a complex therapy as well as in any balneological procedures is doubtless and high. A systematic review about this topic and its clinical importance above all in painful conditions treatment has been published.

The following table summarizes main effects of our complex treatment:

**Figure 8**

Table 1: Effects of procedures applied.

<table>
<thead>
<tr>
<th>Method</th>
<th>Circulation</th>
<th>Periarticular receptors</th>
<th>Oxygenation</th>
<th>NMDA channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whirling warm water</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Cold dry bath</td>
<td>yes</td>
<td>??</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Ultrasound-phonophoresis</td>
<td>yes</td>
<td>??</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Massage</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>

Although in the past years researchers in FM are concentrated mainly to CNS there is a pool of dates of muscular functional and morphological changes reviewed. Interesting data can be found in about correlation of thiobarbituric acid reactive (TBARs) compounds in plasma with severity of symptoms. It may be speculated that TBARs are generated form either primarily damaged muscle tissue or due to relative muscle overload in persons passing long time hypomobility due to pains and fatigue. In any case, hypoperfusion of muscles should be taken into account.

There is a hypothesis pointed to this direction. It is logic that careful circulation improvement should reduce the FM pains.

Summarizing this point, we bet on both circulation improvement and analgesic effect in the CNS as well as in periphery. We believe that depressed neurotransmitters production might be improved. Unfortunately having no tools to investigate this point we can only speculate.

We can not discriminate which of procedures applied is more or less important than the others. Any of them contributes in certain degree and all of them have vasodilatating effect. But the question was not to decide what is more important, we simply tried to verify if a complex of simple, safe and cheap procedures might bring positive results perhaps due to mutual potentiation.

**RESULTS**

Although the number of patients is small, surprisingly high statistical significances in mayor parameters have been
reached. As most important result, save pain reduction, is sleep improvement and general improvement in the morning pain as well as rigidity.

We found rather problematic those patients who had severe cervical spine osteochondritis or even spondylitis and passed already 50 years. Whereas after the 3rd or 4th exposure we saw beneficial effects in majority of patients, cervical spondylitis present postponed the effect onset up to 7 days.

In spite of that this study have not had the fix end point date and we are still going on collecting data, we can say that at worst pain and other symptoms relief duration was 4 months due to decompensation of cervical spondylitis in 1 patient. In most of patients pain relief we saw about 8 - 9 months. However, 2 patients have had lost their symptoms for 3 and 2.5 years, respectively. With respect to that we dare hypothesize that even complete restoration of pathological may be expected if toxic glutamate toxicity is reduced or eliminated due to possible recuperation of pathologic morphology of postsynaptic membrane. Simply said, we dare say that our procedures might initiate autorecuperative processes that are for certain unknown reason stopped.

We have not had any patient without any positive response neither any patient impaired.

CONCLUSIONS

It appears that the studied balneo-physiatric pentathlon might be widely used prior the exercising program starts. All the methods are simple, non invasive and safe and widely used in European spas. Some of them - bathes in warm water, CO₂ dry bathes and magnetotherapy might be used even at patients' homes by themselves.

We believe that in spite of small number of patients we have proven that it works.

References
15. Moses SW, David M, MD2, Goldhammer E , Tal A, Sukenik S. The Dead Sea, A Unique Natural Health Resort. IMAJ 2006;8:483-488
fribromyalgia patients. Medicine & Science in Sports & Exercise, Suppl. 2006; 38(5):426
42. Kirchner A, Stefan H, Bastian K, Birklein F. Vagus nerve stimulation suppresses pain but has limited effects on neurogenic inflammation in humans. Eur J Pain. 2006;10(5):449-455
44. Henry TR, Bakay RA, Pennell PB, Epstein CM, Votaw JR. Brain blood-flow alterations induced by therapeutic vagus nerve stimulation in partial epilepsy: II. Prolonged effects at high and low levels of stimulation. Epilepsia. 2004;45(9):1064-1070
49. Kavaliers M, Osenkop KP. N-methyl-D-aspartate (NMDA) involvement in the mediation of differential effects of acute and repeated exposures to extremely low frequency magnetic fields on opioid analgesia. BEMS 22nd Annual Meeting 2000, Abstract Book pp.252-253


Author Information

Jiri Jerabek, Ph.D.
former invited professor of physiatry at San Martín University

Analía Bordon
private general practitioner

Rosario Maria Pineda
physiotherapy student at San Martín University