Can balneotherapy represent a useful option for fibromyalgia syndrome? Results from a double blind randomized clinical trial

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Background: Fibromyalgia Syndrome (FS) is a syndrome characterized by chronic widespread pain and associated with sleep disturbance, depression, fatigue, and cognitive dysfunction. The aim of study was to assess the efficacy and tolerability of Balneotherapy (BT) in patients with primary FS.

Methods: In a prospective, randomized, controlled, double-blind trial with a 6-month follow-up, 100 patients with FS were randomized to receive a cycle of BT with a highly mineralized sulfate water (BT Group) or with tap water (Control Group). Clinical assessments were performed 7 days before enrollment, at the time of enrollment, after two weeks, and after 3 and 6 months. The Primary Outcome Measures were the change on patient's assessment of global pain on a Visual Analogue Scale (VAS) and Fibromyalgia Impact Questionnaire total score (FIQ-Total) from baseline to month 6. Secondary Outcomes included Widespread Pain Index (WPI), Symptom Severity Scale Score (SS), Short Form Health Survey (SF-12), State-Trait Anxiety Inventory (STAI) and Center for Epidemiologic Studies Depression Scale (CES-D). The main analysis for efficacy and safety was an intent-to-treat (ITT) analysis. The Kolmogorov-Smirnov test was applied to verify the normality distribution of all quantitative variables and the student t-test to compare sample data. All the statistical analysis were performed using the SPSS statistical software, version 10.

Results: In BT Group, we observed a significant improvement of VAS and FIQ total score at the end of the treatment that persisted until 6 months, on the contrary, no significant differences were found in Control Group. The differences between the two groups were significant for primary parameters at each time point. Similar results were obtained for the other secondary outcomes except for the STAI outcome. Adverse events were reported by 10 patients in BT group and by 22 patients in Control Group. The side effects in BT Group were transient and of light intensity.

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Conclusions: Our results support the evidence of the long-term effectiveness and safety of BT in patients with FS.

Trial registration: ClinicalTrials.gov, http://www.clinicaltrials.gov, date of registration: September 4, 2015, NCT02548065. The present trial was retrospectively registered.

Key words: Balneotherapy, Fibromyalgia Syndrome, Double-blind Study, Spa Therapy