

New acoustic wave therapy improves quality of life in patients with multiple sclerosis and chronic cerebrospinal venous insufficiency



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A Multiple Sclerosis patient with chronic cerebrospinal venous insufficiency (CCSVI) treated by acoustic waves, modulated in frequency and power of the Dreno-MAM® device, showed a progressive improvement in motor coordination, resistance to work, muscular power and rigidity, and distal microcirculation. Life quality, chronic fatigue, and clinical severity questionnaires EDSS show marked improvements with a follow-up of two years. We suggest that the method could be also used in the chronic fatigue syndrome and other neurological diseases such as Parkinson or Meniere syndrome. Analyses on statistically robust samples are in progress to validate such impressive result obtained by this non-pharmacological and non-invasive treatment.

KEY WORDS: Acoustic waves, Chronic cerebrospinal venous insufficiency, Multiple sclerosis

Introduction

Upon chronic cerebrospinal venous insufficiency (CCSVI) definition multiple sclerosis has become also a vascular correlated disease¹⁻². All symptoms and clinical manifestations are being re-evaluated and considered in view of a possible prevention of its evolution and complications. In CCSVI patients with MS the mechanical-

postural aspect is very frequent³ and the assessment of the cerebro-spinal fluid (CSF) must be increased to understand the effects of both treatments of spinal manipulative chiropractic therapy and this new physical therapy, obtaining often very positive, not yet predictable, results on pain and gait. The acoustic wave MAM® device is effective in reducing or eliminating acute or chronic pain, by its acoustic waves modulated in frequency and power, already at the first session in about 90% of patients⁴. The tender areas are treated by wave trains for a total of 12 sec per session. The standard cycle consists of four weekly sessions. Up to day the rationale of the mechanism of action is based on the hypothesis that such particular sound could re-activates the neuromuscular spindles of those fibres that are blocked in contracture. With such device and with the described additional set (see below), we started treating first the patients with water retention, based on the fact

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that such peculiar acoustic stimulation modulated in power and frequency could act also on the small vessels and increased the drainage of the lymphatic system. The preliminary clinical results were very positive, with an effect detectable already at the first session on reduction of the lower limbs fatigue and increase in diuresis. After few other sessions we had the volumetric reduction of the lower limbs, the increase of resistance to work and improvement or disappearance, already from the first cycle (10 sessions), of the peripheral vasospasm with warming-up of the extremities by contact thermography assessment. Many subjects, treated by the same application, reported an increase of the muscular power in the period following the cycle. On the basis of such outcomes, we started this treatment on patients with Multiple Sclerosis. We reasoned as follows: such a strong effect on the tissue drainage could also improve the conduction of the peripheral nervous fibres either by an anti-edema effect, or by an effect on microcirculation, which was evident in the treated subjects. Notably, the presence of the passage of CSF in the lymphonodal and lymphatic system, both peripheral and at the neck level, has been studied since 1935⁵.

Case History

We report a case of forty-six year old woman affected by multiple sclerosis and CCSVI, non-smoker, who had practiced artistic gymnastics. The remote pathological anamnesis was as follows: epilepsy at age 11-14; car accident with neck whiplash at the age of 28; Multiple Sclerosis diagnosis at the age of 30, started with hypoesthesia of the right hand; clinical wellness for about 10 years; at the age of 41, upon hormonal stimulation, signs of fatigue and ataxia with slow, progressive worsening and mononucleosis; at 42 abortion (3rd month) and onset of treatment for hypothyroidism; at 43 worsening of the motor and urinary symptoms, she refused interferon treatment, she got diagnosis of CCSVI and underwent venous angioplasty of the jugular veins followed by an improvement of the motor symptoms; at 44 for clinical worsening she had two cycles of Dreno-MAM® treatment; at 45 she had a third cycle of Dreno-MAM® at 46 she had the fourth cycle.

Treatment, outcome and follow-up

The Dreno-MAM® device comes from the MAM® device used for pain treatment. The implementation by an additional set of eight transducers allows the transmission of the acoustic MAM® wave (modulated in power and frequency 0-2 bar, 0-50 Hertz) on predetermined areas and with a specific sequence for the different pathologies. In case of CCSVI with Multiple Sclerosis, the sequence follows this order: posterior, ante-



Fig. 1: Illustration of the Dreno-MAM device.

rior, feet, trunk. The additional set is composed by probes of different size and a timer that sends every 10 sec a sequence of acoustic waves, for a total of 10 min of treatment for each target area bilaterally. The posterior area includes: the sacral, the gluteal region, and the popliteal fossa. The anterior area includes: the inguinal and the medial region above and below the knee. The foot area includes: the foot arches and the big toe. The area of the trunk includes: the supra-clavicular region, the axillary region and the lower trapezius (Fig. 1).

This sequence and the points of application aims to soundproofing the areas where there are more packages of lymph nodes draining the upper and lower limbs.

The first cycle of Dreno-MAM® was carried out in May-July 2012, bi-weekly for a total of 10 sessions. After the first session there was complete disappearance of the motor symptoms of rigidity, ataxia and physical resistance to work for about 30 min. Such effect was evident also after the three following sessions, while it attenuated as an immediate post-treatment effect although the duration of the progressive improvement continued for the whole week. A marked reduction of asthenia related to the summer warm weather was also reported (anamnesic assessment).

The second cycle of Dreno-MAM® was carried out in November-February 2013, bi-weekly, for a total of 24 sessions. At the end of the cycle an increase of physical strength and motor coordination in gait (stairs without support, physical exercises for 10 min) was reported. The neurological visit ascertained an objective improvement and the disappearance of nystagmus.

In March 2013, the patient was forced into a physical activity of bending and lifting weights for about four hours with disappearance of the clinical results.

The third cycle of Dreno-MAM® was carried out in April-July 2013, bi-weekly, for a total of 24 sessions. An optimal recovery of the motor function was reported: the patient could climb stairs without support, had good gait control and physical strength, fluidity of motor coordination and physical power (she could wear shoes with heels, play beach tennis, and make long walks). Recovery from physical exhaustion occurred in about 20 min. For

TABLE I - Outcome of the questionnaire pre (30-04-2013) and post (26-07-2013) the third cycle of Dreno-MAM® treatment. EDSS results post the third and fourth cycle.

	Pre-treatment score	Post-treatment score
MSIS-29	73	49
FSS	3	2
MEM	14	7
EDSS	4	3

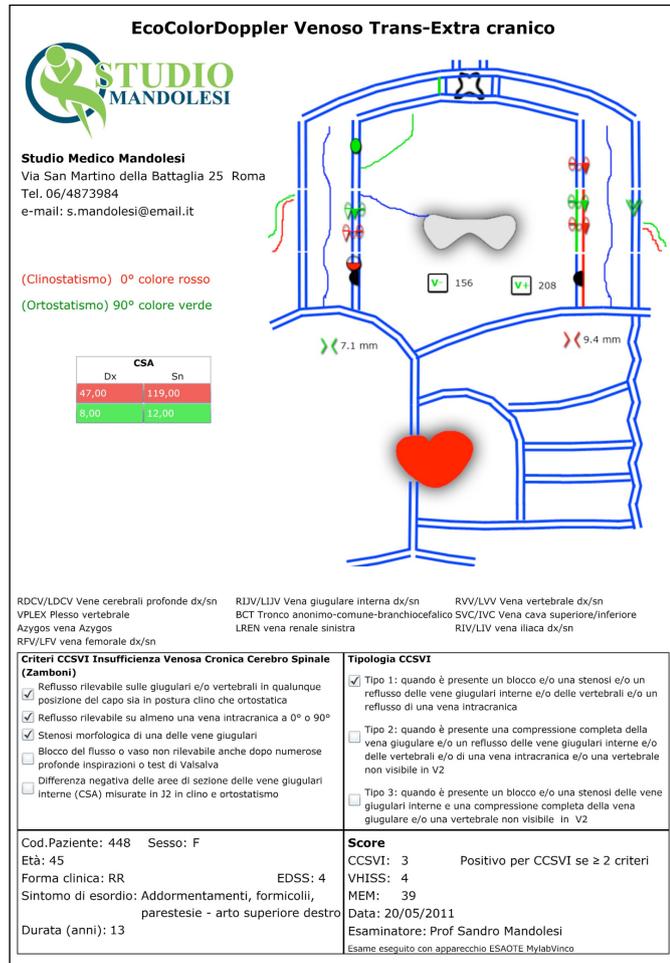


Fig. 2: Morphological Hemodynamic Map (MEM) scheme representing the pattern of ECD venous cerebrospinal drainage, the CCSVI types, the hemodynamic severity score, and the patient data.

one month, in the mid period of the cycle, she stopped assuming drugs for the urinary urgency. The distal vasospasm disappeared and warm feet re-appeared. At the beginning and at the end of the third cycle the patient underwent questionnaires on quality of life (MSIS-29), on chronic fatigue (FSS), and on clinical symptoms (MEM test), and on the Expanded Disability Status Scale (EDSS) as well as a control by her neurologist (Table I).

The fourth cycle of Dreno-MAM® was carried out in April-May 2014, bi-weekly, for a total of 10 sessions with more increased result on EDSS compared to the last outcome.

In Fig. 2 we present the map of the EcoColorDoppler assessment², which identifies the presence of a CCSVI (score > 2).

Discussion

The positive clinical outcome of this case supports our hypothesis that the treatment with Dreno-MAM® acts strongly at peripheral level on the lymphatic tissue drainage, microcirculatory balance, and muscular systems stimulation, perhaps with the effect to activate also a better drainage of the cerebro-spinal system⁶. Life quality, chronic fatigue, and clinical severity questionnaires show marked improvements with a follow-up of two years.

The efficacy of the each cycle is long-lasting, more than four months by clinical anamnestic assessment, therefore we hypothesise that it could re-activate the lymphatic and micro-circulatory systems that in this case could be insufficient for tissue homeostasis. We suggest that the method could be also used in the chronic fatigue syndrome and other neurological diseases such as Parkinson. Analyses on statistically robust samples are in progress to validate such impressive result obtained by this non-pharmacological and non-invasive treatment.

Riassunto

Un paziente con Sclerosi Multipla ed insufficienza venosa cronica cerebrospinale (CCSVI) trattato con le onde acustiche, modulate in frequenza e potenza del dispositivo Dreno-MAM®, ha mostrato un progressivo miglioramento della coordinazione motoria, della resistenza al lavoro, della potenza muscolare e rigidità, e della micro-circolazione distale. I questionari sulla qualità di vita, stanchezza cronica, e gravità clinica (EDSS) hanno fatto rilevare sensibili miglioramenti con un follow-up a due anni. Si suggerisce che il metodo potrebbe essere utilizzato anche nella sindrome da fatica cronica e altre malattie neurologiche come il Parkinson o la sindrome di Meniere. Analisi su campioni statisticamente significativi sono in corso per validare tale notevole risultato ottenuto da questo trattamento non farmacologico e non invasivo.

References

- Zamboni P, Galeotti R, Menegatti E, et al: *Chronic cerebrospinal venous insufficiency in patients with multiple sclerosis*. J Neurol Neurosurg Psychiatry, 2009; 80:392-99.

2. Valdueza JM, Doepp F, Schreiber SJ, et al: *What went wrong? The flawed concept of cerebrospinal venous insufficiency*. Journal of Cerebral Blood Flow & Metabolism, 2013; 33, 657-66.
3. Mandolesi S, Manconi E, Niglio T, d'Alessandro A, Orsini A, Mandolesi D, Fedele F: *Incidence of anatomical compression of the internal jugular veins with full block of their flow in patients with chronic cerebro-spinal venous insufficiency and multiple sclerosis*; Minerva Medica 21st Eurochap-IUA; 2013.
4. Mandolesi S, Galeandro AI, Mandolesi D, Squillino F.: *Il MAM (Modulatore Acustico Muscolare) nella terapia del dolore flebologico*. XXIX Congresso nazionale SIAPAV. Minerva Cardioangiologica 2007; 55(suppl.1 al N 6) :167-68.
5. Speransky AD: *A Basis for the Theory of Medicine*, New York, 1935.
6. Koh L, Zakharov A, Johnston M: *Integration of the subarachnoid space and lymphatics: Is it time to embrace a new concept of cerebrospinal fluid absorption?* Cerebrospinal Fluid Res, 2005; 2:6.