Editorial

Complementary and alternative medicine in fibromyalgia: yes or no?

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The treatment of fibromyalgia (FM) is largely debated. Due to its complex nature, successful treatment of chronic pain requires addressing behavioural, cognitive and affective processes. Evidence shows that pharmacological treatment with Food and Drug Administration (FDA)-approved drugs (milnacipram, pregabalin and duloxetine) may not be very effective and can cause a number of adverse events.

Moreover, the recommendations issued by the European League Against Rheumatism (EULAR) point out the need for a multimodal approach, combining pharmacological and non-pharmacological interventions (1).

Therefore:

- What are the most useful non-pharmacological approaches?
- Can we take care of our complex FM patients using only conventional medicine?
- Is there any chance of obtaining good results with unconventional therapies?

Complementary and Alternative Medicine (CAM) is a group of diverse medical and healthcare interventions, practices, products, or disciplines that are not generally considered part of conventional medicine (2). CAM includes traditional Chinese medicine (including acupuncture), biofeedback, stress-control exercises and other body-mind practices such as qi gong, tai chi and yoga. These practices, products and disciplines are extremely heterogeneous and efficacy has been demonstrated only for some of them (3-5).

Over 100 million Europeans currently use CAM, with one fifth using it on a regular basis. One fifth of CAM users would opt for a CAM-including health care (6). In the European Union, CAM is provided by 160,000 non-medical practitioners and 146,000 medical practitioners (7).

CAM is more popular among patients than among their physicians. A study carried out in the United States showed that 23% of patients with a musculoskeletal problem contacted an osteopathic physician (8). In France, patients with chronic musculoskeletal disorders mainly consulted physicians who offered alternatives to conventional medicine (9). Moreover, although acupuncture was originally practiced in China only, it is now used worldwide. According to a recent report, 103 out of 129 countries now recognise the use of acupuncture as an effective treatment (10).

- Could CAM be one of the options for the treatment of patients affected by FM
- What are the most common points of view regarding this debate?

The efficacy of CAM still has to be proved

CAM efficacy has been investigated through randomised controlled trials (RCTs) only on few occasions. Most papers focused on CAM are only anecdotal reports, open studies or clinical trials which were, however, poorly designed (small population size, incorrect or absent randomisation, no main outcome specified, doubtful use of placebo). A study published by Shang *et al.* analysed the effect of biases in trials evaluating homoeopathic and conventional treatments (11). They concluded that biases are present in placebo-controlled trials evaluating both homoeopathy and conventional medicine. Nevertheless, when taking into account these biases in the analysis, while only weak evidence was shown for a specific effect of homoeopathic remedies, strong evidence for specific effects of conventional interventions was demonstrated. This finding is compatible with the notion that the clinical effects of homoeopathy are placebo effects.

On the other hand: the long-lasting effectiveness of conventional medicine is partially proved

Many well-conducted randomised controlled trials (RCTs) have been carried out in FM patients to evaluate the effect of conventional drugs on pain, depression, non-restorative sleep and other FM symptoms (12). Efficacy is often limited. Moreover, most of these RCTs have a major bias: the follow-up is usually quite short (weeks or months). FM, in fact, is a long-lasting disease, requiring long-lasting treatments. A short-term study does not evaluate treatment efficacy and safety in the long term.

CAM is also often criticised for an absence of standardisation. This is true: the efficacy of CAM is not always proven by RCTs. The scientific method, defined as a method of inquiry based on empirical and measurable evidence subject to specific principles of reasoning, is not easily applicable to CAM. CAM practices, as a matter of fact, are person-centred and tailored to each individual: the same symptoms are effectively treated with different interventions in different patients.

Finally, placebo effect should not be repudiated, as it can indeed be considered as an actual therapeutic effect, based on the influence of mental processes (stronger involvement in the treatment, expectations, hope) on neurophysiology, resulting in beneficial changes.

CAM can have adverse effects

People believe that CAM is completely safe; therefore it is often self-administered. Actually, many herbal medicines used in traditional Chinese medicine and in homoeopathy have a significant pharmacological activity and, thus, potential adverse effects. *Ginkgo biloba* leaf extract interacts with aspirin and warfarin. St. John's wort (*Hypericum perforatum*) interacts with cyclosporine and with substrates of the drug efflux transporter *p*-glycoprotein, and decreases fexofenadine plasma concentration. Acupuncture and manual therapies, such as chiropractic and osteopathy, if not well performed, can cause serious adverse events.

Public awareness about the possibility of adverse effects of CAM should be enhanced (13).

On the other hand: people believe that conventional medicine has too many adverse effects

Patients affected by FM are not satisfied with the safety and efficacy of conventional medicine. They are often afraid of taking drugs for a long time and worry about the risk of adverse events. Often, they are active workers and are afraid of not being alert during their working day as a result of the side effects of their medications.

Moreover, clinical practice shows a high variability in terms of patients' compliance. Analgesic drugs are generally well tolerated, but not always effective. On the other hand, Tramadol should be used with caution due to the risk of abuse and dependence and to the possibility of opiate withdrawal symptoms with discontinuation. RCTs testing antidepressants such as amitryptiline, duloxetine and fluoxetine showed frequent withdrawals due to mild adverse events (12).

CAM products, practices and practitioners are not regulated

The lack of control leads to a circulation of non-tested and ineffective products. Moreover, CAM products can be easily purchased without a prescription, even on the Internet. Self-administration of treatments can imply an underestimation of the disease, a worsening of the symptoms, a higher percentage of adverse events or unwanted treatment interactions and a poorer prognosis. On the contrary, conventional drugs are tested and dose-standardised, and require medical intervention with treatment prescription and monitoring.

However, some physicians persist in using CAM without a precise knowledge of the underlying disease, thus delaying a precise diagnosis and a proper initiation of an effective conventional treatment.

On the other hand: lack of regulation of CAM products, practices and practitioners acts against the appropriate use of CAM

CAM can be beneficial, but it is often prescribed incorrectly, as a result of a lack of experience and awareness of possible side effects. Moreover, the practice of CAM by professionals who lack certifications can compromise the perception of these treatments by the institutions, delaying the acceptance of such techniques. Furthermore, the absence of product control is a real problem: it leads to the circulation of poor quality, adulterated or counterfeit products that can consequently be ineffective.

In conclusion, in the last few years a great deal of progress has been made in FM management with conventional treatments. Nevertheless, patients are concerned about safety and efficacy: side effects are frequently reported and symptom relief can be limited, especially in long-term treatments. Moreover, patients often request a good therapeutic relationship based on trust, empathy, compassion and responsiveness to individual needs and values: a person-centred medicine (14) that could be facilitated by the use of CAM practices. In addition, pain, the cornerstone of FM, is first of all an experience that can be moderated in a negative way by depression and anxiety and in a positive way by social support, comprehension and active coping.

Through mechanisms that are not yet well understood, possibly including placebo effect, CAM seems to ameliorate FM symptoms such as pain, fatigue, sleeplessness, irritable bowel disease and depression.

As stated also by the World Health Organization (WHO) in the recent programme "Traditional Medicine Strategy 2014–2023" (10), a global strategy to foster safe and effective use of CAM through the regulation of products, practices and practitioners is needed.

Rheumatologists may therefore obtain good results from an integration of conventional and CAM treatments for the management of FM patients, in order to achieve further goals in FM control and constantly improve patients' quality of life.

References

1. CARVILLE SF, ARENDT-NIELSEN S, BLIDDAL H *et al.*: EULAR evidence-based recommendations for the management of fibromyalgia syndrome. *Ann Rheum Dis* 2008; 67: 536-41.
2. The national center for complementary and alternative medicine agency of the US National institutes of Health 3rd strategy plan

2011-2013, NIH Publication no. 11-7643. USA Feb 2011.
3. European Information Centre for Complementary & Alternative Medicine [web site]. (http://www.eiccam.eu/home.php?il=1&l=eng)
4. IANNUCCELLI C, MANNOCCI F, GUZZO MP *et al*.: Complementary treatment in fibromyalgia: combination of somatic and abdominal acupuncture. *Clin Exp Rheumatol* 2012; 30 (Suppl. 74): S112-6.
5. MADDALI BONGI S, DEL ROSSO A, DI FELICE C *et al*.: Rességuier method and Qi Gong sequentially integrated in patients with fibromyalgia syndrome. *Clin Exp Rheumatol* 2012; 30 (Suppl. 74): S51-8.
6. BAPTISTA AS, VILLELA AL, JONES A, NATOUR J: Effectiveness of dance in patients with fibromyalgia: a randomized, single-blind, controlled study. *Clin Exp Rheumatol* 2012; 30 (Suppl. 74): S18-23.
7. VON AMMON K, FREI-ERB M, CARDINI F *et al*.: Complementary and alternative medicine provision in Europe – first results approaching reality in an unclear field of practices. *Forsch Komplementmed* 2012; 19 (Suppl. 2): 37-43.
8. SUN C, DESAI GJ, PUCCI DS, JEW S: Musculoskeletal disorders: does the osteopathic medical profession demonstrate its unique and distinctive characteristics?, *JAOA* 2004; 104: 151-5.
9. ROSSIGNOL M, BÉGAUD B, AVOUAC B *et al*.: Who seeks primary care for musculoskeletal disorders (MSDs) with physicians prescribing homeopathic and other complementary medicine? Results from the EPI3-LASER survey in France. *BMC Musculoskeletal Disorders* 2011; 12: 21.
10. WHO Traditional Medicine Strategy: 2014-2023.
11. SHANG A, HUWILER-MÜNTENER K, NARTEY L *et al*.: Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet* 2005; 366: 726-32.
12. DI FRANCO M, IANNUCCELLI C, ATZENI F *et al*.: Pharmacological treatment of fibromyalgia. *Clin Exp Rheumatol* 2010; 28 (Suppl. 63): S110-6.
13. NIGGEMANN B, GRÜBER C: Side-effects of complementary and alternative medicine. *Allergy* 2003; 707-16.
14. ROBERTI DI SARSINA P, ALIVIA M, GUADAGNI P: Traditional, complementary and alternative medical systems and their contribution to personalisation, prediction and prevention in medicine-person-centred medicine. *EPMA J* 2012; 3: 15.