

ABSTRACT OF CO.ME.TA M.S.A.D. STUDY CO.ME.TA. M.S.A.D. STUDY (Coprime Trial Analysis Muscle-Skeletal Apparatus Disease) USE OF A COPRIMED-ARIA MEDICAL DEVICE AS A THERAPEUTIC COMPONENT IN THE TREATMENT WITH *MANU MEDICA* VERTEBRAL MANIPULATIONS IN PATIENTS WITH CHRONIC OR RECURRENT ASPECIFIC LUMBAGO. Dr. Renato Villammar CENTRO FISIOTERAPICO CEMES Gruppo Data Medica

DEFINITION OF NON-SPECIFIC LUMBAGO

Localised pain in the spine is a very frequent symptom and the lumbar tract is among the segments that are most affected in this type of disorder. It has been calculated that about 80% of people suffer from or have experienced lumbago, which affects both sexes equally, with a peak incidence for the female sex after 60 years and for the male sex after 40 years. In most cases (80%-90% depending on the case) these are so-called non-specific or idiopathic forms, resulting from functional alterations secondary to abnormal stress or faulty poses or postures. Generally, non-specific lumbago has a benign prognosis, with spontaneous resolution in 75% of cases after about 4 weeks from onset and in 95% of cases after three months in studies with a follow-up of at least six months, but the rate of relapse is high (70-90%) and after two years it has been calculated that in 44% of cases it becomes chronic, being the first cause of disability in people under 45 years of age and the third cause among older age groups. In the light of these considerations, lumbar pain is a highly topical problem with a significant medical and economic impact.

MATTRESS AND BACK PAIN: For years, orthopaedists have advised those suffering from back pain to sleep on mattresses as hard as boards, but without having great scientific evidence on the soundness of their advice. A recent clinical study in 2003 (3) showed that the ideal mattress against back pain is one of medium hardness, even better if it adapts to the body. This was confirmed by another study in 2006 (4) which showed that sleeping on a new mattress compared to a mattress that is at least 5 years old, improves sleep quality by 62% and reduces back pain by 55.3%. Chronic lumbago and sleep problems are closely related to the quality of the mattress on which you sleep. In chronic lower back pain, sleep changes are significant. In another study in 2006 (5), the scores of the assessment scales used were worse in patients sleeping on hard orthopaedic mattresses ($p=0.001$). It is therefore clear that changing the mattress in general and using medium-hard mattresses in particular, are associated with a reduction in pain and an improvement in daily activities. It has been shown that people suffering from back pain and sleeping on a flat mattress have a higher muscle activity of the erector spinae muscle and a faster heart rate than people sleeping on conventional mattresses. (3). It is therefore likely that a mattress of medium hardness will cause a change in muscle function and pressure distribution during bedtime.

MATERIALS AND METHODS: Based on the findings in the literature on the correlation between lumbago and alteration of night rest, we conducted a case control study to assess the therapeutic efficacy of a class I medical device called "Coprime Aria", on spontaneous and induced pain symptoms, on disabilities and on the use of pharmacological and physiotherapy in patients with chronic low back pain (duration more than six months) or recurrent low back pain (duration less than six months, but with previous attacks). The aim of the study was to verify the reduction of pain symptoms, disability and quality of sleep in patients treated with *manu medica* manual mobilizations who slept with the coprime-aria, compared with a homogeneous control group of patients always treated with manipulations but who slept on their mattress, for a period of 4 months. A total of 20 patients, evaluated and enrolled at the CEMES Outpatient Centre in Padua, were admitted to the study between November 2009 (01.11.2009) and February 2010 (26.02.2010). The T1 follow-up took place between 15.07.2010 and 20.08.2010. The end of the study was on 15.09.2010. After filling out and signing an informed consent, all patients were assessed with X-rays of the lumbar spine in the following projections: anterior posterior, laterolateral and oblique for the assessment of the lateral foramina. Patients with vertebral pain due to intervertebral disc herniation, radiculopathy, narrow lumbar spinal canal syndrome, spondylolysis and spondylolisthesis were excluded from the study and therefore could not be treated with vertebral manipulations. All subjects were female and aged between 26 and 48 years (average = 40 years). About 88% of subjects reported pain for more than 6 months and 78% of subjects reported pain for a year or longer. Patients were randomly divided into two groups: Group A; composed of 10 subjects who were given the Coprime Aria to be placed between the sheet and the bed mattress. Group B; composed of 10 subjects who slept on their mattresses and were instructed not to change it for the duration of the study. All 20 patients were treated with *manu medica* manipulation of the lumbar spine according to the technique of Dr. R. Maigne for 6 consecutive weeks with frequency of one weekly treatment. The Aria (Coprime) mattress topper is a Class I medical device consisting of two Tibetan goose down mattress toppers joined together at the ends. Inside, there is a hygroscopic chamber that allows great breathability and thermoregulation and therefore can be used even during the summer, because it reduces the stagnation of sweat and moisture on skin. The initial exam (T0) consisted of a complete medical history and a medical check-up. Pain was evaluated with the VAS visual analogue scale (in mm where 0 = no pain and 100 = maximum pain imaginable), the quality of daily life was measured by means of the "Oswestry Low Back Pain Disability Questionnaire" scale, which represents a well-known system for measuring lumbago disability frequently used in clinical trials (Pain=5 points; Disability=45 points). It consists of ten sections on everyday activities that may be affected by lumbago: the first allows a specific description of the pain, all the others concern the limitations due to lumbago in daily life including sleep. In detail, these are the

items and scores of the latter. The follow-up of the patients (T1) took place 4 months after the end of the recruitment, always with the same scales of pain and functional assessment and the index of satisfaction and comfort given by the Coprimed was also surveyed.

RESULTS: The processing of the data, given the small number of patients, was calculated with the mean of the values recorded and allowed us to measure an improvement, in both groups treated, both in the pain and disability index. However, the patients who slept with the Coprimed-Aria reported better values than the control group both in pain reduction on the VAS scale and on the Oswestry Low Back Pain Disability Questionnaire scale and in particular in the item regarding night rest. All patients expressed a maximum score as an index of satisfaction and comfort of the mattress topper, except for one who stated at the time of the follow-up that she did not use it during the summer, because she said it was too hot.

CONCLUSIONS: The findings of this study show that the use of the Coprimed-Aria can be considered a valuable supplement to the treatment of spine pain in individuals with chronic or recurrent low back pain, although the mode of action on musculoskeletal pain is not yet fully understood. What should be highlighted is certainly the high degree of satisfaction expressed by patients in terms of comfort and the clinical demonstration that it improves the quality of sleep. Considering that we spend about a third of our life on a mattress, it is not a utopia to think that this should be our most important investment.