TREATMENT WITH OSTEOBIOS® IN EARLY POSTMENOPAUSAL PATIENTS AFFECTED BY OSTEOPOROSIS

Liliana Groppa – MD, PhD, professor, Department of Internal Medicine 1, State University of Medicine and Pharmacy „Nicolae Testemiţanu", **Laura Vremiş –** MD, PhD, Department of Internal Medicine1, State University of Medicine and Pharmacy „Nicolae Testemiţanu", **Lealea Chiaburu** –assistant professor, Department of Internal Medicine 1, State University of Medicine and Pharmacy „Nicolae Testemiţanu", **Eugeniu Russu** – assistant professor, Department of Internal Medicine 1, State University of Medicine and Pharmacy, Nicolae Testemiţanu", Chisinau, Moldova.

Background: Osteoporosis is defined as a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fractures *(NIH Consensus Development Panel on Osteoporosis, JAMA 2001, 285: 785-795).*

Osteoporosis is considered one of the most important problems that have an impact on the public health system because of the high costs of osteoporosis fractures. Osteoporosis is one of the main causes of functional disability among the older population. Over the last few decades this problem has become very acute due to an increasing number of the older population throughout the world. Among women over 50 years of age the risk of osteoporosis fracture is comparable to that of breast cancer and to cardiovascular risk. According to the existing data, at least 1 osteoporosis-related fracture occurs in 1 mln of female population within 1 year. According to different epidemiological reports, the incidence of osteoporosis vertebral fractures among women over 60 years of age is between 25% and 60%, and the fracture risk is highly connected with age. Most of the patients older than 45 years of age and affected by hip fractures due to osteoporosis are hospitalized. The femoral neck fractures result in a mortality rate of 2.8% among middle-aged population and of 14%-36% among the elderly population.

Bones are continually undergoing a process of renewal called remodelling throughout one's life period. The peak of the bone mass occurs at the age of 30-35. This process is strongly connected with certain endogenous and exogenous factors. Postmenopausal osteoporosis is a chronic progressive condition where the bone resorption process prevails over the bone formation resulting in a loss of bone mass and an altered bone architecture and strength. The main therapeutic aim is to reduce the fractures risk by interfering with the mechanism of bone remodelling, even if results are not always satisfactory. That is why the possibility of alternative therapies is very welcome.

Materials and methods:

This study has been carried out at the Department of Rheumatology of Clinical Hospital „Sfanta Treime" Department of Internal Medicine 1, State University of Medicine and Pharmacy „Nicolae Testemiţanu", Chisinau, Moldova. Our study has enrolled 70 female patients, diagnosed with postmenopausal osteoporosis. These patients have been randomly divided into 2 groups of study. Group I - 40 women treated with Osteobios, 10 drops 3 times daily and Guna-Fem, 10 drops 3 times a day; Group II – 30 women treated with Calcium, 500 mg/day and Vit D. The study was conducted for 6 months. The inclusion criteria were: female patients who have entered physiological menopause for 2-5 years. The exclusion criteria were: female patients who had entered menopause for more than 5 years, surgical menopause, personal or family history of osteoporosis fracture and secondary osteoporosis.

Both groups have been evaluated from a clinical and paraclinical viewpoints according to a prearranged plan, which included: evaluation of risk factors, clinical and imaging examination, laboratory examination of markers of bone resorption such as alkaline phosphatase and serum Calcium. All these parameters have been evaluated at the base-line 3 and 6 months after the treatment. The imaging methods have included the thoracic spine X-ray to determine the presence of vertebral fractures; the bone density was measured by ultrasound method. These parameters were evaluated at the baseline and 6 months after the treatment.

According to the majority of evaluated parameters, both groups were statistically homogeneous. The average age in Group I was 54,4±1,01 years, and 57,5±0,64 years in Group II. The clinical manifestations assessed in both groups were statistically comparable at the base line: the pain syndrome of thoracic spine was found in 64,3% of the patients belonging to Group I and in 56,8% of the patients belonging to Group II. The pain syndrome of the upper limbs accounted for 29,3% of the patients of Group I and 24,1% of Group II. The pain syndrome of the lower limbs was found in 67,2% of the patients of Group I, and in 49,9% of the patients of Group II. Tender joints have been found in 45,4% of the patients of Group I, and in 37,3% of the patients of Group II.

The bone density was evaluated by using the ultrasound method and was comparable in both groups, T-score was 3,42 SD in Group I, whereas 3,34 SD in Group II. Besides the mineral bone density the standard method of radiological semi quantitative measurement of thoracic vertebras was used, which didn't match any statistically significant differences between the two groups.

Results:

During the treatment administered in our study the following results have been obtained: decrease of pain syndrome in the thoracic vertebras was observed in 43,90% of the patients belonging to Group I, but only in 13,50% of the patients belonging to Group II (Fig.1). The decrease of pain syndrome of the long bones was observed in 41,40% of the patients of Group I, but only in 10,00% of the patients of Group II (Fig.2); the intensity of pain in existing tender joints determined by VAS decreased by 64,4% in Group I and by 34,4% in Group II.

Fig.1:The evolution of axial pain syndrome

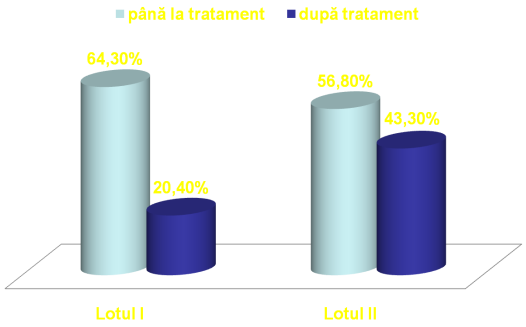
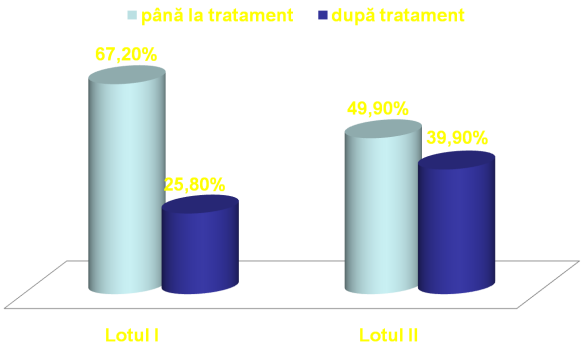


Fig2. The evolution of pain syndrome of the long bones



One of the most important findings was the diminishing of clinical symptoms specific to perimenopausal syndrome, which have been observed in 85% of patients of Group I compared with only 23,3% of Group II, and this fact significantly improved the patients' life quality.

The assessment of biochemical parameters, as bone resorption or bone formation markers showed a decrease of bone-specific alkaline phosphatase by 34 nmol/l in Group I and by 18 nmol/l in Group II. Concerning the assessment of serum Calcium, no differences have been observed.

Radiological assessment: all patients have been assessed by means of radiological exams of the thoracic spine at the base-line and after the treatment we have not observed any aggravation of radiological features in both groups. This fact is probably due to more compelling selection of the patients for study and a short study period. The assessment of bone density in both groups during the treatment have shown insignificant evolution of T score.

The improvement of the patients' life quality, which was measured by SF-36 score, showed to be significant in Group I compared with Group II.

Conclusions: Postmenopausal osteoporosis affects the life quality and the life expectancy of the patients. According to our study, the treatment of patients affected by early postmenopausal osteoporosis and low fractures risk with Osteobios + Guna-Fem to be taken according to the recommended doses, have improved their life quality score and decreased the pain syndrome associated with osteoporosis. So these results may also suggest the possibility of a combined therapy in patients suffering from osteoporosis and high fracture risk.

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