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SUMMARY

Preliminary observations on the effects of oral administration of homeopathic remedies in women suffering from postmenopausal osteoporosis are reported. Patients were monitored using Computerized Bone Mineralometry (CBM) before and after 6 and 12 months of therapy. A small number of patients were treated with allopathic drugs with very poor results. Osteobios orally administered is a homeopathic remedy with statistically significant results and without any negative side effects.

KEY WORDS

POST-MENOPAUSAL OSTEOPOROSIS, HOMEOPATHIC THERAPY, ALLOPATHIC THERAPY, ULTRASOUND COMPUTERIZED BONE MINERALOMETRY

PRELIMINARY REPORTS ON COMPLEX HOMEOPATHIC THERAPY IN PATIENTS SUFFERING FROM POST-MENOPAUSAL OSTEOPOROSIS

INTRODUCTION

Osteoporosis is a pathology characterized by an alteration in the physiological balance between the deposit and reabsorption of the organic and inorganic material of the bone tissue. Very often this pathological sphere develops in women as a result of seemingly spontaneous or surgically-induced menopause – under these circumstances the trabecular rather than the compact bone tissue is affected, the main occurrence of the former being due to a deficiency in or absence of estrogen (*Dambacker, Rueeggsegger, 2*). Unfortunately, the osteoporotic process is sometimes subjectively silent for years and, therefore, a large quantity of bone tissue is lost **without** the patient displaying precise symptomatology. Often the occurrence of bone fractures is the time when a painless osteoporotic condition is identified by accident. A small number of patients complain of an intense or diffuse bone pain which is difficult or impossible to control pharmacologically, and which continues day and night; this algic condition prevents sleep, reduces the appetite, and compels the sufferers to isolate themselves from others and even drives them to desire death (*Riva*

Sanseverino, 5). From a psychological point-of-view, this dramatic symptomatology, which is mainly observed in young women undergoing surgically-induced menopause, should give the doctor cause for concern – both because if these patients undergo radical intervention they suddenly lose some reproductive organs, therefore causing them social and family problems (for which no solution has been established), and because elderly patients in seemingly spontaneous menopause complain of enormous existential problems. With regard to fractures, in particular, the gradual reduction in bone mass involves an enormous risk of fracturing for vertebral bodies with a subsequent increase in morbidity and mortality (*Burger et Al., 1*). Vertebral fractures are of medical interest not only because they cause pain, kyphosis and height reduction, but also because they are the **precursor** of subsequent non-vertebral fractures, regardless of bone mineral density (*Leichter et Al, 3*). A recent multicentric study (*Lieberman, 4*) showed that bone density improves when *alendronate* is administered, although it is not tolerated by the majority of patients as it causes frequent, undesired, collateral gastrointestinal disorders. Finally, we should point out that in me-

nopausal patients a progressive deficiency (at first) and an absence (subsequently) of the ovarian secretion of estrogens occurs, which, in perimenopausal states, could inhibit less and less the production of **parathormone**, with a consequent osteolytic effect. In menopausal women, parathyroid hormone exacerbates osteolysis, a process that triggers osteoporosis - the impoverishment of the organic and inorganic material of the bone tissue. Full and exhaustive literature on this argument was published in *Lunar News*, 1998, 1: 1-29. The number of drugs and hormones used for the treatment of post-menopausal osteoporosis has been and continues to be extremely large. This is because, up till now, a single drug to treat this syndrome does not exist and menopausal women often do not tolerate the drugs prescribed; consequently they halt prematurely the treatment.

PRELIMINARY OBSERVATIONS AND AIM OF THE RESEARCH

In a previous publication (*Riva Sanseverino*, 5) this therapeutic problem was evaluated using uncomputerised bone mineralometry (BM) as a test, and a cocktail of allopathic drugs as a treatment (calcitonin, vitamin D and products containing Calcium), often accompanied by monthly parenteral administrations of androgens. The therapeutic results were negative or barely satisfactory and, above all, they were not definitive as the therapy would have had to continue for a long time – after 3-4 years the patients became **resistant** to the therapy and **intolerant** to calcitonin.

On the basis of this, it seemed opportune to examine whether the administration of a **single** homeopathic/homotoxicolo-

gical remedy could produce positive, and above all, better results, **without** causing negative side effects.

STUDY METHODOLOGY

Two Groups of patients in good internistic conditions were included: *Group A* was treated with homeopathic/homotoxicological remedies and *Group B* was treated with allopathic drugs, which were preferred by the patients for personal reasons. *Group A* comprises **68 patients** – 43 were examined using *Ultrasound Bone Mineralometry (BM)* which only gave readings for the mineralisation state of the bone tissue; the results obtained for these 43 patients will be described in a subsequent publication (*Riva Sanseverino, Castellacci*, 6). The other 25 patients underwent *Computerized Bone Mineralometry with Ultrasound (CBM)* which gave readings on the mineralisation and profile of the trabecular bone, and, therefore, on the **risk of fracture**. The preliminary results obtained for these 25 patients are the subject of this publication. The 43 patients above mentioned were moved into a new Group which is going to be studied.

Group B comprises **176 patients** – 170 were treated with allopathic drugs producing modest results (*Riva Sanseverino, Castellacci*, 6); the remaining 6 were examined using the same procedure employed for the patients in Group A. **31 patients** (25 from *Group A* and 6 from *Group B*) initially underwent *Computerized Bone Mineralometry* – before the study started, it was ensured that the patients had not been undergoing any other form of pharmacological therapy for **at least 6 months**. The densitometry values were recorded and monitored again 6 and 12 months after the beginning of the first therapeutic treatment. – The instrument used to establish simple Bone Mineralometry (BM) uses an ultrasonic source of energy which measures the speed of wave propagation via the bone tissue (AD-SoS parameter, *Amplitude Dependent Sound Speed*); *Computerised Bone Mineralometry (CBM)*, used for the 25 patients who are the

Figure 1

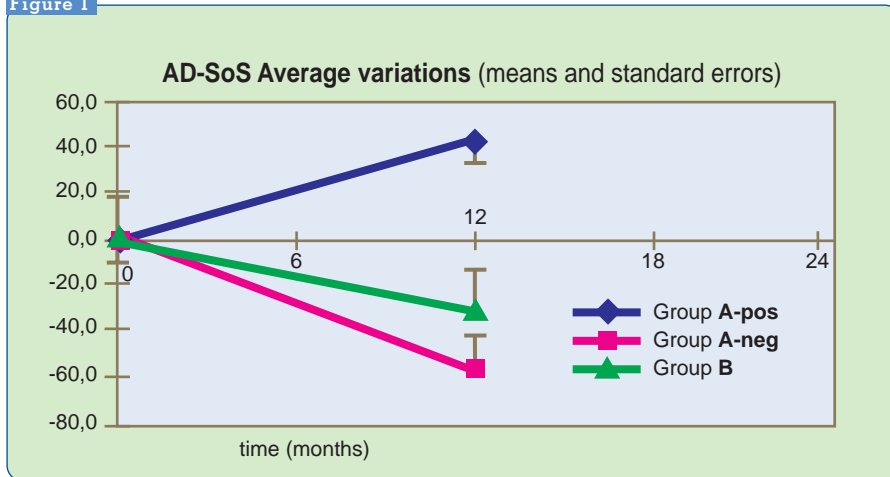


Figure 2

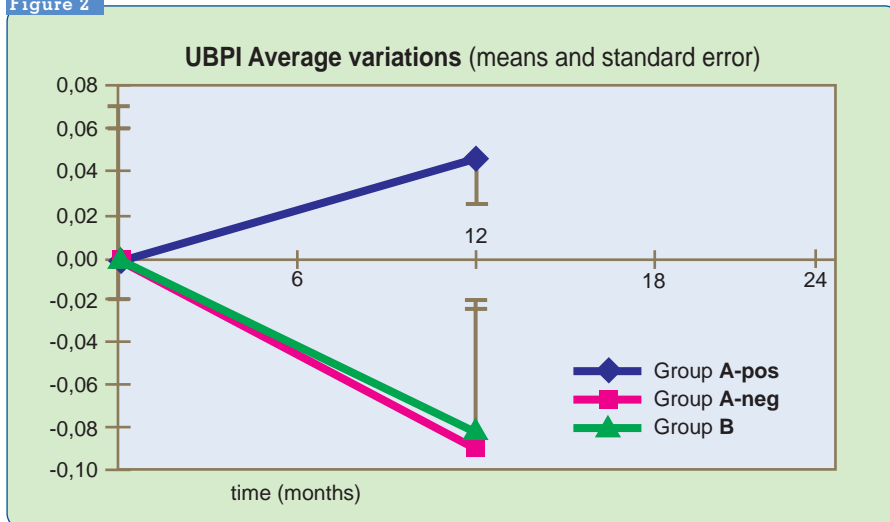


Figure 3

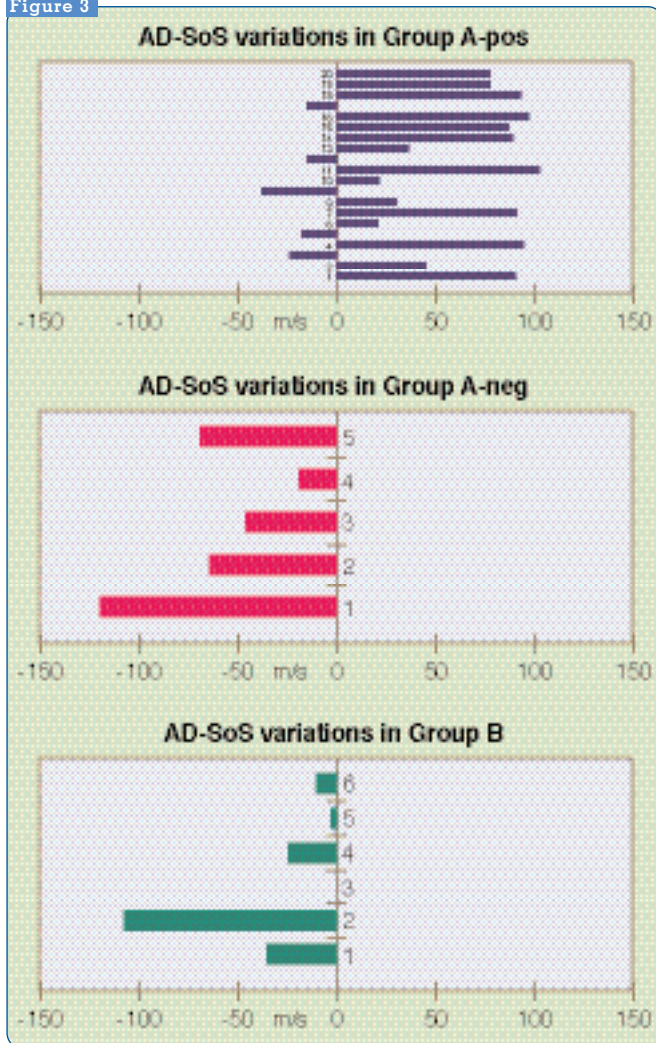
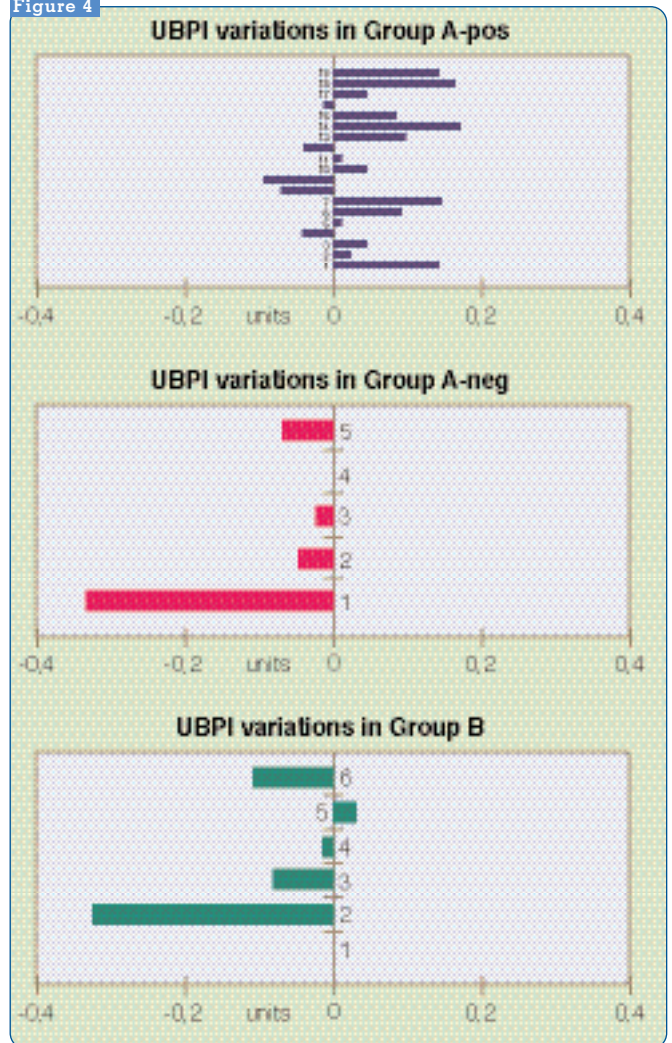


Figure 4



subject of this study, also measures the trabecular bone profile, which, as we have already mentioned, is an indication of the estimated risk of bone fracture (UBPI parameter, *Ultrasound Bone Profile Index*). Both instruments are produced by IGEA (Carpi – Modena - Italy). An average or serious level of post-menopausal osteoporosis is established on the basis of a parameter known as a *T-score* – an average level of osteoporosis would rate a *maximum T-score* of -3.0 and a serious level would rate a more negative *T-score* than -3.0 .

► *Group A* were treated with a complex homeopathic drug known as **Osteobios** [*Os suis D10, D30, D200; Calcium carbonicum/phosphoricum/fluoricum D12, D30, D200; Glandula parathyroidea suis D10, D30, D200; Calcitonin D6; Master Aminoacid Pattern (MAP)*

D3], produced by Guna Laboratories, Milan. Osteobios was administered per os (20 drops in a little water three times a day on an empty stomach, for 6 consecutive months). The CBM was carried out again and as the readings gave positive indications it was felt that they could still be improved upon, it was decided to continue with the therapy for further 6 months. The patients who had a more negative *T-score* than -3.0 were initially treated with a cocktail of **Os suis-Injeel + Calcium carbonicum-Injeel + Calcium phosphoricum-Injeel + Calcium fluoratum-Injeel** (-Heel, Baden Baden) and **Oligoel No 8 (Magnesium)** i.m. three times a week for 6 consecutive weeks. The injection was carried out in equal parts (half cocktail) in each gluteus muscle. The patients then completed the treatment of up to 6 and 12 months in total using Osteobios.

► *Group B* were treated with allopathic drugs: *Sodium alendronate*, 1 tablet a day for 6 consecutive months or *Raloxifene*, 1 tablet a day, every other month for 6 months in total.

RESULTS

Firstly we want to point out that the objective of identifying a **single remedy** solving the problem of multiple and diverse administrations has been achieved in this study. This homeopathic/homeotoxicological remedy is known as **Osteobios**. The quantitative analysis of data was carried out on 25 patients who were monitored using CBM (TABLE 1).

We should point out that Group A was divided into 2 subgroups: **A-pos** (20 patients) and **A-neg** (5 patients), whose results after

12 months are shown in (TABLE 1).

The following conclusions were drawn from analyses of the data at 6 and 12 months after the beginning of the homeopathic therapy:

- after 12 months, Group A-pos showed a **significant increase** in bone tissue **mineralisation**; of the 20 patients in this Group, 5 did not display the increase recorded for the other 15; however, their algic symptomatology has disappeared and their general conditions have improved. These 5 patients, therefore, were also included in Group A-pos (more long-term treatments were predicted for these patients).
- Group A-neg showed a worsening, which was probably due to incorrect execution of the therapeutic protocol, as emerged from the monitoring. The negative result in the 6 patients of Group B who underwent allopathic therapy is not surprising: it is in keeping with that obtained in our previous trial (*Riva Sanseverino*, 5) and in the one currently underway (FIGURES 1, 3).

We can make similar observations for the second parameter studied in this research (profile of trabecular tissue indicated by the initials UBPI) – **the fracture risk only decreases in Group A-pos** (FIGURES 2, 4).

CONCLUSIONS

Analyses on the effectiveness of complex homeopathic drugs data (*versus* allopathic drugs as well) with regard to the loss of bone mass in patients suffering from osteoporosis during seemingly spontaneous menopause, have enabled us to reach the following conclusions: the most positive results for the recovery of bone mass were seen in the patients in Group A-pos, whilst the worst results were seen in patients in Group A-neg. Group B also showed negative variations in the parameters which express the mineralisation and quality of bone tissue, although the average reduction in AD-SoS and UBPI were slightly less evident than those observed in Group A-neg. The fact that in the *average* variations, the standard error is always lower than the variation, would indicate the **marked statistical significance of the results**, even if it is thought necessary to carry out the same trial on a numerically more representative sample.

▶ One last consideration – we have managed to identify a single complex homeopathic drug (**Osteobios**), which can improve both the mineralisation and the quality of bone tissue. This would appear to solve the problem of administering several drugs. Furthermore, the correct application of the therapeutic protocol corroborates the positive results obtained in Group A-pos and the negative ones obtained in Groups A-neg and B, in addition to those published in the Literature.

References

1. BURGER H., VAN DAELE P.L.A., ALGRA D. et Al. – Vertebral deformities as predictors of non-vertebral fractures. *Brit. Med. J.*, **1994**, 309: 991-992.
2. DAMBACHER M.A., RUEEGSEGGER P. – Evaluation of osteoporosis treatment strategies. First Osteoporosis Workshop for European Meridional Countries, Istanbul, **1987**, May 4-5.
3. LEICHTER I., MARGULIES J.Y., WEINREB A. et Al. – The relationship between bone density, mineral content and mechanical strength in the femoral neck. *Clin. Orthop.*, **1982**, 163: 272-281.
4. LIBERMAN U.A., WEISS S.R., BROELL J. et Al. – Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal osteoporosis. *The New England J. Med.* **1995**, 333: 1437-1443.
5. RIVA SANSEVERINO E. – Intensive medical and physical treatment of osteoporosis with the aid of oxygen-ozone therapy. *Europ. Med. Phys.*, **1988**, 24: 199-206.
6. RIVA SANSEVERINO E., CASTELLACCI P. – Il trattamento dell'osteoporosi postmenopausale: rimedi omeopatici versus allopatrici corrispondenti di riferimento. *La Medicina Biologica*, future publication.

Article's reference

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Table 1

Bone mass alterations expressed as variation of supersonic waves propagation speed through the trabecular bone, determined by CBM, after 12 months of therapy.

Group A-pos:	
- variations AD-SoS	= + 46 ± 11 m/s
- variations UBPI	= + 0.05 ± 0.02 units
Group A-neg:	
- variations AD-SoS	= - 60 ± 19 m/s
- variations UBPI	= - 0.09 ± 0.07 units
Group B:	
- variations AD-SoS	= - 31 ± 18 m/s
- variations UBPI	= - 0.08 ± 0.06 units