



BIPHOSPHONATES – IMPORTANT AGENTS FOR OSTEOPOROSIS MANAGEMENT

Biphosphonates, synthetic compounds characterised by a P-C-P bond, were first discovered in the middle of the last century. Previously known for their industrial use as anti-scaling agents, the biological effects of biphosphonates were first described in 1968 with particular emphasis on their action in bone. By substituting the hydrogens on the C atom, a variety of biphosphonates were synthesised, each of them with its own distinct characteristics. About a dozen biphosphonates have been tested in humans and six of them, alendronate, clodronate, etidronate, ibandronate, pamidronate, tiludronate, are commercially available today.

Their main characteristic is their ability to inhibit bone resorption and this effect varies greatly from compound to compound. The decrease of resorption is followed by a decrease in formation resulting in a smaller turnover. This leads to a reduction in bone loss in conditions with a negative bone balance, both in animal and man. The administration of these compounds often results in an actual increase of calcium balance. These two effects lead to an improvement in the biomechanical characteristics of the skeleton.

Biphosphonates have been successfully used in conditions such as osteoporosis, tumour bone disease, and Paget's disease. The compounds are administered either orally or parenterally, continuously as well as intermittently. When given in large amounts, biphosphonates can inhibit normal and ectopic mineralisation, because of their inhibitory effect on calcium phosphate crystal formation. This property is used clinically, although only with moderate success, to prevent abnormal calcification and ossification, such as after hip surgery or in certain generalised calcifying conditions. Biphosphonates have low toxicity and the main side effect is a certain gastrointestinal intolerance, especially with the newer more potent compounds. Therefore the latter need to be ingested with sufficient fluid.

Biphosphonates present a most interesting development in the field of treatment of bone diseases and it is probable that we are only at the beginning of a new area of therapy.

Professor Herbert Fleisch
Treasurer, EFO



NEW HEAD FOR WHO & A NEW FOCUS

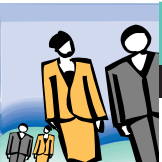


Gro Harlem Brundtland,
new head of WHO

Former Norwegian prime minister, Gro Harlem Brundtland was nominated as the new Director-General of WHO in January this year. Brundtland, a medical doctor, should be particularly aware of osteoporosis and related problems as the prevalence of osteoporosis fractures in Norway is amongst the highest in the world.

One of the first challenges for Brundtland will be the development of a global strategy for prevention and control of noncommunicable diseases, for example osteoporosis, within the framework of the renewed WHO health-for-all policy. Noncommunicable diseases were recently recognised by the WHO Executive Board as being a major source of human suffering and increasing health care costs worldwide. Concerned by the latest increases in related deaths and disease, the Executive Board of WHO recently endorsed the proposed framework for the integrated prevention and control of non-communicable diseases. This framework includes the provision of public health services and the major involvement of health and medical professions in improving the health of individuals and communities.

The Executive Board of WHO has requested the Director-General to "solicit the support of nongovernmental organisation and other international agencies by creating a forum for the exchange of experiences and results of research". The proposed global strategy and a timetable for its implementation is planned for submission in 1999 to the Executive Board and the Health Assembly. With Dr Brundtland at the helm, osteoporosis should benefit from this new focus and finally receive the attention it requires from senior health care officials and politicians around the world.



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Letter from the Editor



Dear Readers,

Co-ordinated action is required to balance out the inequities in osteoporosis health care. Only about 6% of osteoporosis sufferers in the UK and less than 20% of sufferers in Germany receive treatment. Four out of 5 German sufferers still remain untreated. Current treatment rates throughout Europe are unacceptable and we must strive to offer each and every osteoporosis patient appropriate treatment and care.

Yours sincerely,

Professor Helmut Minne

EFFO Mission

- To support national osteoporosis societies in order to maximise their effectiveness
- To increase the awareness and understanding of osteoporosis
- To motivate people to take action to prevent, diagnose and treat osteoporosis

This year World Osteoporosis Day will gain from the timely launch of the Report on Osteoporosis in the European Community - Action for Prevention on June 10 1998. A launch meeting/press conference in the European Parliament in Brussels with 300 attendees will undoubtedly increase multi-level awareness of osteoporosis to coincide with World Osteoporosis Day which occurs just two weeks later on June 24 1998.

The report contains important recommendations which particularly apply to policy makers and national politicians but are also relevant to health care professionals across the globe. The implementation of the first recommendation is crucial to prevent an osteoporosis epidemic.

Recommendation 1:

The European Union and the governments of the 15 member states, especially policy makers and national politicians, should explicitly adopt osteoporosis prevention as a major health care

WORLD OSTEOPOROSIS DAY 1998

Building Strong Bones and Preventing Fractures

Summary Report on Osteoporosis in the European Community – Action for Prevention

Health

Employment & social affairs

European Commission

Report on Osteoporosis in the European Community – Action for Prevention

target and establish awareness campaigns. Prevention of osteoporosis should be a major priority in the ongoing health promotion, education and training of health care professionals.

This recommendation is vital to equalise the standard of osteoporosis diagnosis, treatment and care throughout Europe. Bone density is still not reimbursed in many European countries, support groups are scarce, Hormonal Replacement Therapy is not reimbursed in France and the majority of osteoporosis medications are not reimbursed in Italy. It is the patient who suffers due to these gross variants in health care policies and establishing a standard of health care for all is imperative to avoid unnecessary suffering and health care costs.

Europe is not alone in neglecting the osteoporosis problem, many countries are only just beginning to realise the threat which osteoporosis poses to their ageing populations. However, there is an increase in national osteoporosis patient oriented societies with new societies being recently founded in Russia and the Middle East. The formation of a united force against osteoporosis will result in a far brighter future for potential, and actual, osteoporosis sufferers across the world.

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CLINICAL TRIALS DIRECTIVE – EU LEGISLATION IN THE MAKING

The current European environment encourages pharmaceutical research and the development of innovative medicinal products which has proved advantageous to both patients and health care professionals.

Clinical trials have been at the forefront of this progress but the globalisation of the pharmaceutical industry has meant that standards for clinical trials need to be compatible with international standards. Good Clinical Practice (GCP) guidelines, established in 1990, have been undergoing an ongoing process of harmonisation within the forum of the International Conference on Harmonisation (ICH). Since January 1997, the internationally harmonised GCP has been incorporated into clinical practice within the European Community. However, such guidelines are not binding, and a supportive legislative framework is required.

Each Member State has either legislative and/or administrative provisions relating to the commencement of a clinical trial. However, when a 'multi-centre' trial spans across more than one member state, this one trial must comply with different national provisions resulting in delays of up to nine months.

A proposal for a European Parliament (EP) and Council Directive to reinforce existing practice

and harmonising procedures for clinical trials is currently being reviewed by both institutions. This legislative proposition is designed to build on the existing experience of the Member States, ensuring the same level of patient protection and scientific standards, but with the rationalisation of the documentary and administrative procedures involved in multi-centre trials.

After a meeting with patients' groups, the European Federation of Pharmaceutical Industries and Associations (EFPIA) commented that "elements of the proposed directive will help to ensure a consistent implementation of the internationally agreed ICH GCP guidelines" but expressed concern about the "complex and conflicting procedures to be fulfilled prior to commencing a clinical trials" and suggested clearly defining overall time limits to avoid unnecessary delays to patients.

The official opinion of the Economic and Social Committee endorsed the approximation of provisions, "on condition that this does not in practice create further bureaucratic or admin-

istrative obstacles but promotes high-quality pharmacological research in the EU". The Committee also expressed the encouraging view that the "EU must remain a magnet for trials and innovation, as this will help to improve health protection".

NEW EU HEALTH POLICY PUBLICATION

The European Public Health Alliance has recently published "Public health and the EU: an overview, 1997". A comprehensive guide to EU health policy developments this overview includes interesting chapters on "Older people" and "Food and nutrition". To order this fascinating new publication and for further information contact:

The European Public Health Alliance, Tel: +32 2 230 3056, Fax +32 2 231 0990, e-mail: epha@club.innet.be.

EFFO Update

FROM BONE CELLS TO PATIENTS – A NETWORK FOR PROGRESS

The 1998 European Congress on Osteoporosis organised by EFFO and IFSSD, will take place from September 11 to 15 in Berlin, the new cosmopolitan hub of Germany. With easy access by road and rail, delegates from Eastern Europe should particularly benefit from this Central European location. This major congress caters for all audiences, from the scientific community to the general public. By combining the best scientific information with the needs of osteoporosis patients, effective solutions will not only be discovered but carried out.

Scientific Programme

Running from September 11 to September 15, with 8 sessions, the scientific programme will survey the cutting edge of osteoporosis research. Productive and extensive discussions are predicted after lectures such as "Global evaluation of fracture risk" and "Nutrition in the treatment of osteoporosis". In addition, 34 oral presentations, 3 poster sessions, and

satellite symposia organised by the health care industry should provide in-depth information on all aspects of the disease.

Consensus Conference

A Consensus Conference on Clinical Guidelines for Diagnosis and Treatment of Osteoporosis organised by EFFO and NOF will take place on September 15, following the scientific programme. Such consensus conferences play a major role in establishing standards in the developing osteoporosis arena. Topics to be addressed include "the patient perspective", "the dilemma of clinical guidelines" and a presentation of the Report on Osteoporosis in the European Community – Action for Prevention.

Public Education Day

In parallel to the scientific programme, a Public Education Day will be held on September 12. Over 1,000 participants are expected to attend this which aims to heighten public awareness about osteoporosis. The preliminary programme includes risk factor assessments, advice on nutrition and sport, osteoporosis support group information and information on medi-

cations. Recommendations from the newly produced Report on Osteoporosis in the European Community-Action for Prevention will be presented to participants.

4th Worldwide Conference of Osteoporosis Patient Societies, September 13–14

Organised by EFFO and the three German osteoporosis patient oriented societies, this conference brings the osteoporosis patient movement together in a common purpose to raise awareness of osteoporosis as a public health issue. Over 100 participants are expected to attend and there will be ample opportunities for the exchange of ideas and information. Workshops are planned including "Getting the basics right – how to get started", "Lobbying – how to get more mileage out of the Report on Osteoporosis in the European Community", and "Communications – creating wake-up communications".

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TARGETING GROWING BONES

National osteoporosis societies in Lebanon, Spain and Germany have their eye on the future and have recently concentrated on educating school children about osteoporosis prevention.

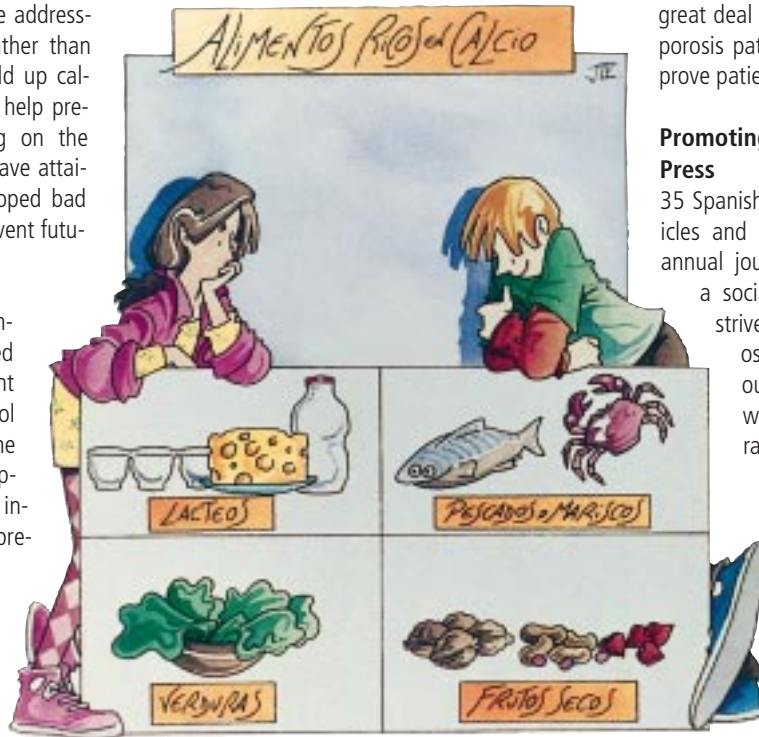
Most educational materials are addressed to the general public rather than school children who need to build up calcium and grow healthy bones to help prevent future problems. Focusing on the younger generation before they have attained peak bone mass, and developed bad nutritional habits, should help prevent future cases of osteoporosis.

The Lebanese Osteoporosis Prevention Society (LOPS) has succeeded in adding "Osteoporosis Treatment and Prevention" to the high school curriculum with the support of the Centre of Education and Development. The educational materials introduce the disease and how to prevent it from an early age. LOPS hopes that, by improving awareness among children, future generations should be able to protect their bones and maintain adequate levels of calcium.

The Fundacion Hispana de Osteoporosis y Enfermedades Matabolicas (FHOEMO) in Spain have produced a booklet and slide presentation suitable for schools entitled "Growing up healthily for fracture-free bones". Full of de-



FHOEMO brochure for growing teenagers



Good food choices for adolescents

tailed information and appealing to adolescents, this publication should heighten awareness of osteoporosis to this crucial age group.

The Kuratorium Knochengesundheit has produced a cookbook "Cooking for strong bones" aimed at school children. Full of information on how to cook calcium rich food with appropriate illustrations and easy-to-follow recipes, "Cooking for strong bones" should help many German school children attain peak bone mass in their own kitchens.

Widening the Education Net

Osteoporosis patients often require a great deal of care and rehabilitation, the burden of which usually falls on nurses. FHOEMO in Spain has been leading the way in establishing standards for osteoporosis care by offering educational courses to nurses, as well as doctors. Their annual "Course for Nurses", now in its 6th year with the next course in November 1998, encompasses a wide range of topics including "Social repercussions of fractures", "Bone and diet", "Exercise and osteoporosis" and "Prevention of falls". They also publish a guide for health professionals which is given to nurses at the course. By focusing on nurses, who spend a

great deal of time with individual osteoporosis patients, FHOEMO hopes to improve patient care.

Promoting Osteoporosis in the Press

35 Spanish journalists entered their articles and broadcasts for the FHOEMO annual journalist award. The winner was a social affairs journalist who has strived to prevent, inform and help osteoporosis patients throughout his career. Second and third were a scientific journalist and a radio presenter.

Recommendation for Future Services

All of these services stress the importance of Recommendation 7 in the Report on Osteoporosis in the European Community – Action for Prevention, to "Promote national patient

and scientific societies by providing financial support and helping them to publicise their cause throughout the European Union". The implementation of this recommendation would ensure that national osteoporosis societies could offer a multitude of valuable services to the general public and osteoporosis community.

Osteoporosis Guide produced by FHOEMO & SEIOMM for health professionals.

