

SERMs - A NEW CHOICE OF THERAPY

Long term use of hormone replacement therapy (HRT) decreases the risk of osteoporosis and cardiovascular disease (see Developments), but compliance is low and many women stop treatment during the first year, primarily due to side effects such as bleeding, and because of the fear of breast cancer. Although the benefit/risk ratio of HRT is highly favourable, alternatives to HRT would be welcomed by those women who cannot or prefer not to take HRT.

Selective oestrogen receptor modulators (SERMs) are a class of compounds that have been developed with the aim of retaining the beneficial effects of HRT without some of the side effects. Several SERMs are currently under clinical investigation including raloxifene, droloxifene, idoxifene and levomelexifene.

Results of a recent phase III trial showed that raloxifene significantly increased bone mineral density at all skeletal sites by 1 to 3 %, in contrast to placebo which resulted in a moderate but significant bone loss¹. Serum total and LDL cholesterol decreased significantly under raloxifene, while HDL cholesterol and triglycerides were not significantly altered. Treatment was well tolerated and the incidence of adverse events did not differ between groups. Ultrasound evaluation showed that raloxifene did not stimulate the endometrium and, therefore, the concomitant use of a progestin is unnecessary. This study suggests that raloxifene could play an important role in the management of postmenopausal women. As there is no evidence that raloxifene decreases the incidence of hot flushes, it is not an alternative to HRT for the treatment of menopausal symptoms. A large clinical trial in over 7,000 women with vertebral osteoporosis will assess the efficacy of raloxifene in decreasing fracture risk and should provide information on a possible decrease in breast cancer incidence.

Raloxifene has been approved by the American Food and Drug Administration for the prevention of postmenopausal osteoporosis and has been submitted to the European Agency for the Evaluation of Medicinal Products.

Professor Pierre Delmas
EFO President

¹ Delmas PD et al: Effects of Raloxifene on Bone Mineral Density, Serum Cholesterol Concentrations, and Uterine Endometrium in Postmenopausal Women. *N Engl J Med* 1997;337(23):1641-1647



HRT BENEFITS BOTH HEART AND BONE

Besides being an established treatment for osteoporosis, postmenopausal hormone replacement therapy (HRT) is effective in decreasing the risk of cardiovascular disease. Coronary heart disease is the leading cause of death among women in industrialised countries and is an important cause of illness in later life. Studies in women indicate that high-density lipoprotein (HDL) cholesterol is the most powerful serum lipid predictor of the risk of coronary heart disease, with higher levels being strongly protective. It has also been reported that low density lipoprotein (LDL) cholesterol and Lp(a) lipoprotein are also powerful, independent predictors of cardiovascular disease with high levels indicating increased risk.

The effects of HRT (estrogen plus progestin) in lowering serum lipid levels in postmenopausal women with high cholesterol were recently compared to those of conventional lipid lowering therapy (simvastatin)¹. Both HRT and simvastatin had beneficial effects in lowering LDL cholesterol and raising HDL cholesterol. However, there was a marked reduction in Lp(a) lipoprotein levels with HRT whereas simvastatin had no significant effect. This unique beneficial effect of HRT on Lp(a) lipoprotein levels indicates that HRT may be an effective alternative treatment to conventional lipid-lowering therapy.

According to a large study of over 60,000 postmenopausal women, taking HRT for up to 10 years can lower death rate from all causes by 37%². Women with coronary risk factors benefited the most with a drop in mortality rate of 49%. For reduction in cardiovascular risk and effective fracture prevention, HRT needs to be taken long term. Current compliance is poor with 90% of women stopping HRT after the second year of treatment. Although remaining on HRT for more than 5–10 years has recently been shown to be associated with a small but significant increase in breast cancer risk², the recognised benefits to heart and bone should be carefully considered before rejecting the HRT option.

¹ Darling G et al: Estrogen and progestin compared with simvastatin for hypercholesterolemia in postmenopausal women. *N Engl J Med* 1997;337:595-601

² Grodstein F et al: Postmenopausal hormone therapy and mortality. *N Engl J Med* 1997;336(25):1769-Darling 1775



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Letter from the Editor



Dear Readers,

The fundamental importance of early diagnosis cannot afford to be ignored any longer. It is a disgrace to our healthcare systems that bone mineral density measurements are underutilised and not universally reimbursed. Under-diagnosis has been highlighted throughout this edition of EFFO News and we hope that it will soon be the focus of health care authorities at all levels.

1997 was a busy year for EFFO and marked the official recognition of osteoporosis as a serious health care threat at the European Union level. In 1998 we must ensure that osteoporosis does not remain the under-diagnosed and under-treated disease that it is today.

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

EARLY DIAGNOSIS - THE KEY TO PREVENTING FRACTURES

Although early detection is critical for the prevention of fractures, many patients are still not having osteoporosis diagnosed until they have already suffered multiple fractures. The assessment of bone mineral mass is central to early diagnosis and the most widely accepted method is bone mineral density (BMD) measurements by dual energy X-ray absorptiometry (DXA). But, despite the fact that BMD measurements are as effective at predicting fracture as blood pressure is in predicting stroke, they are still not widely available to those at risk.

Recent EFFO feedback indicates that BMD measurements are not reimbursed in certain European countries. These countries (Belgium, Bulgaria, France, Hungary, Ireland, Norway, Poland, Portugal, Romania, and Spain) are not only at odds with the other countries in Europe but also with most of the other developed nations of the world which provide full, or at least partial, reimbursement. Indeed in the USA, the current trend is to extend the reimbursement policy; Medicare has recently broadened coverage for BMD measurement and eliminated age restrictions.

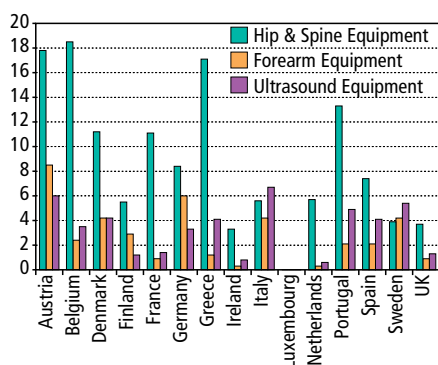
Besides non-reimbursement, other factors can affect the current under-utilisation of BMD measurements. The low availability of bone densitometers in some countries (e.g. Sweden

and UK), restriction in authorised personnel to perform measurements in others (e.g. Italy), or extremely low reimbursement prices (e.g. Germany) also have a detrimental effect.

BMD measurements are recognised as being an effective means of measuring bone loss to assist the physician in the selection and treatment of patients for hormone replacement therapy and anti-resorptive drug therapies. Treatment decisions, based on BMD, have been shown to lead to a reduction in fracture and a reduction in hospitalisations. Recent results from the spinal fracture arm of the Fracture Intervention Trial showed that patients treated with alendronate had a reduction in hospital admittance by 20% compared to the placebo group.

We now know who is most at risk of developing osteoporosis, we have the knowledge to identify them and we have a range of preventive medicines. However, despite these facts, many patients at significant risk of osteoporosis are not having their BMD measured and are therefore not receiving early diagnosis and thus preventive treatment. It will require governments and healthcare providers to address these issues to ensure that osteoporosis can be largely eradicated as a significant health threat. This will, in turn, result in significant long-term savings to governments.

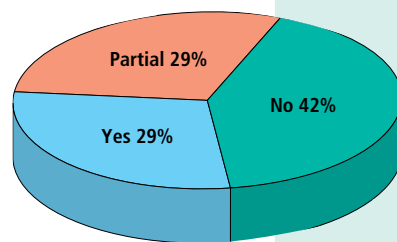
An estimate of Bone Densitometry Equipment (units/million population) in the EU as of mid 1997



Acknowledgement: Thanks to the Bone Density Equipment Manufacturers for providing the data

Many countries have insufficient bone densitometry units

Reimbursement of bone densitometry in Europe



- Partial: Austria, Denmark, Italy, Lebanon, Sweden, Turkey, UK
- No: Belgium, Bulgaria, France, Hungary, Ireland, Norway, Poland, Portugal, Romania, Spain
- Yes: Czech Republic, Finland, Germany, Greece, Slovakia, Switzerland, The Netherlands

Many countries do not reimburse for BMD measurements



Parallel sessions at the European Congress on Osteoporosis

EUROPEAN CONGRESS ON OSTEOPOROSIS: MEETING THE NEEDS OF THE SCIENTIFIC AND PATIENT COMMUNITIES

The next European Congress on Osteoporosis in Berlin, September 11-15, 1998 will run both a scientific programme (organised by EFFO and

IFSSD) and the 4th Worldwide Conference of Osteoporosis Patient Societies. There will also be a Public Education day on September 12. Organised by EFFO in conjunction with Bundeselbsthilfeverband für Osteoporose e.V., Deutsches Grünes Kreuz and the Kuratorium Knochengesundheit, these events should complement the scientific programme and enable both the scientific and patient communities to exchange ideas and information.

For further information contact EFFO secretariat, Pavillon F, Hôpital E. Herriot, F69437 Lyon Cedex 03, France (Tel+33 472 1174 72, fax +33 472 117 494, E-mail effolyon@net.asi.fr).

EFFO SIGNS FIRST CONTRACT WITH THE EUROPEAN COMMISSION

EFFO has recently signed its first contract with the European Commission. This official recognition and funding from the EC means that EFFO can better ensure that osteoporosis will not remain the under-diagnosed, under-treated and poorly supported disease that it is today. EFFO's agreement with the EC includes the development of the EFFO information database and web site, the launch of the European Union Report – Osteoporosis Action for Prevention, and the dissemination of its findings

and recommendations. EFFO appreciate recognition and support by the EC which provides a tool to improve healthcare in Europe.

EUROPEAN EDUCATIONAL GRANTS FOR PATIENT SOCIETIES

EFFO has a number of grants available to enable member patient societies to undertake educational projects. These projects should aim to increase awareness and understanding of osteoporosis, and motivate people to take action to prevent, diagnose and treat this disease. Funding may be requested to cover translation, design, print or production costs or other costs necessary to fulfil the project aim. The total amount allocated to these grants is 45,000 ECU.

These new educational grants represent the increasing support for patient societies and all suitable projects will be considered. The deadline for project submissions is March 31, 1998. Request an application form NOW from Mary Fraser, EFFO secretariat, Pavillon F, Hôpital E. Herriot, F69437 Lyon Cedex 03, France (Tel+33 472 1174 72, fax +33 472 117 494, E-mail effolyon@net.asi.fr).

Euro News

OPPORTUNITIES FOR OSTEOPOROSIS RESEARCH FUNDING

The EU Research Framework programmes have been running since 1982. They have been the biggest single research programmes of the European Union and consist of several individual sub-programmes. According to the treaties the Framework programmes aim to improve the quality of life of the European citizen by developing the European science base which is seen as fundamental to improving the competitiveness of European industry.

Each Framework programme runs for four years - with the Fifth Framework Programme running from 1998 until 2002. The legislative process for the Fifth Framework Programme is that of co-decision between Parliament and Council. For the first reading, the proposal had to pass through the Committee for Research, Technological Development and Energy and then the plenary. At the time of going to press, the proposal was at the Committee stage and it was forecast that the proposal would pass through the plenary during the December Strasbourg session.

The amended proposal will then be passed to the Council. It is thought that the Council will try to arrive at a common position by the end of February 1998. Following the Council common position the amended proposal will pass back to the Parliament for a second reading before returning to the Council who will try to reach an agreement by the end of June 1998.

Funding opportunities for scientists conducting research into osteoporosis will probably be contained in an amendment to the original Commission proposal - that is, in an "ageing and disability" key action section. Most of these opportunities will be available for projects which give a European added value and in collaboration with organisations situated in other EU member states. At this early stage in the legislative process, the exact amount of money available for research under this key action is not yet known.

Dr Gordon Adam

Member of the European Parliament and vice-chairman of the Committee for Research, Technological Development and Energy.

EFFO'S ROLE & COMMENT

EFFO, via Dr Jonathan Reeve, a member of EFFO's Scientific Advisory board, and Mary Fraser, Executive Director, has been actively involved in the consultation process.

EFFO is anxious that the Fifth Framework Research Programme should appropriately address the health problems, including osteoporosis, that arise from an increasingly ageing European population. Research funding from the EU is essential to address these health priorities. In order to achieve this the Commission should have an ongoing dialogue with interested charities, such as EFFO.

Lobbying

US PUBLIC POLICY LEADERSHIP FORUM

As part of its ongoing campaign to reduce the tragic personal and financial consequences of osteoporosis, the US National Osteoporosis Foundation (NOF) held its second annual Public Policy Leadership Forum in June 1997. The Forum brought together citizens dedicated to making osteoporosis a priority on the national health care agenda and prepared them for meetings with Members of Congress.

Programme topics included an osteoporosis research update and a Federal legislation update. Meetings took place with federal legislators and the petitions were delivered to Congress.

The petition campaign, which also ran in 1996, set 3 goals:

- To increase funding for biomedical research
- To launch a national prevention education campaign
- To ensure health insurance coverage of bone mass measurement tests

While fully supporting the NOF petition campaign, EFFO believes that two further points should be made.

- Osteoporosis is a treatable disease
- Governments should help support groups to flourish

PATIENT LEADERS CALL FOR GLOBAL ACTION

The expanding osteoporosis patient movement was represented by over 100 delegates from 32 countries at the 3rd Worldwide Conference of Osteoporosis Patient Societies.



3rd Worldwide Conference of Osteoporosis Patient Societies

The conference was warmly hosted by the Norsk Osteoporoseforening (Norwegian Osteoporosis Society) in Oslo at the end of September 1997. Demonstrating their commitment to working as a global and growing alliance to improve quality of life for osteoporosis sufferers everywhere, the patient society leaders signed a pledge to increase the awareness and knowledge of osteoporosis. This pled-

ge was also signed by Dr N. G. Khaltav on behalf of the World Health Organization.

Sonja Rembo, president of the National Osteoporosis Patient Society of Sweden announced the pledge to "ensure that people everywhere are fully aware of the causes of osteoporosis, the risks of fractures associated with this disease, and the ways in which it can be prevented, detected and treated". She also emphasised in her announcement that osteoporosis remains "an under-diagnosed, under-treated and poorly supported disease".

In concurrence, Professor Arpo Aromaa, who is conducting a one-year study of the epidemiology knowledge base on osteoporosis, described the "extraordinary lack of meaningful and use-

ful information about the incidence, prevalence and seriousness" of osteoporosis. He continued by saying that there was "too little relevant research information on the prevention of osteoporosis, which is unfortunate considering the massive potential health burden of the disease, and how this will increase in the future". However, the first steps in assimilating incidence data have already been taken. The EVOS and subsequent EPOS studies have shed a welcome light on fracture incidence in Europe.

Patient society leaders from all five continents attended this conference to reinforce the importance of a collaborative effort against osteoporosis. Such a strong alliance should result in better osteoporosis management around the world.

New Services

"TOGETHER WE ARE STRONG" – 10 YEARS SELF-HELP IN OSTEOPOROSIS

The Bundesselbsthilfverband für Osteoporose/Federal Association of Osteoporosis Self-Help Groups (BfO) celebrated its 10th anniversary in September 1997 with a programme of lectures, shows and demonstrations which informed and entertained some hundred participants. Dr Johanna Hammerl used the clinical picture of bones from Merovingian skeletons from the early Middle Ages to illustrate that osteoporosis is not a modern disease, tips for bone healthy food were given during the cookery demonstration, and the audience enthusiastically participated in a group exercise class.

The event's special guest was Thomas Reiter, European Space Agency astronaut, who descri-



Astronaut Thomas Reiter encouraging osteoporosis patients to fight their disease.

bed his bone-related experiments on the space station "MIR". Every day he and his fellow cosmonauts had carried out an exercise programme to prevent the bone mineral loss caused by weightlessness in space.

The BfO's extensive self-help group programme was presented in a round of talks. With just under 200 self-help groups and more than

10,000 members the BfO has been able to help thousands of osteoporosis sufferers during the last decade. Since the foundation of BfO, self-help groups have been scientifically proved to play an important role in the management of the osteoporosis patient. By offering many services from emotional support, information about the disease, assistance in coping with everyday problems, rehabilitation measures to the procedures necessary to receive a pension, self-help groups can help osteoporosis sufferers to cope with their disease. Osteoporosis patients can easily become isolated however the leisure time and exercise activities offered by self-help groups can effectively counteract this and improve patients quality of life. BfO's commitment to patient support has already helped many osteoporosis sufferers and will hopefully help many more.

Dr. Dietmar Krause

Deutsches Grünes Kreuz on behalf of BfO

Fundraising

THE IMPORTANCE OF A FUNDRAISING BASE

The Fundraising Seminar at the 3rd Worldwide Conference for Osteoporosis Patient Societies was an enlightening and productive session. Fundraising is unsurprisingly an ongoing issue, but one particular problem for national osteoporosis societies throughout the world is the establishment of their fundraising base.

Due to the nature of osteoporosis, the lack of statistics, and the relatively recent recognition

of the problem, many new osteoporosis societies are founded by medical experts. But, as much of fundraising is based on networking and most doctors are committed elsewhere, these new societies tend to start out from a weak fundraising base.

New societies should strive to find a balance between members from the medical profession and members who can contribute their status, wealth and influence, preferably right from the

beginning. By ensuring that a society has wealthy and influential representatives e.g. public relations specialists, health insurance company managers and retired politicians with good cross-party networks, the initiatives generated by the medical component of the Board will have more chance of being funded and carried out. The goals of a new society should encompass, not only medical progress, but also education at all levels, fundraising and the influencing of decision makers.

Valerie Pakenham Keady

Brakeley Europe, Fundraising & Management Consultants