

GETTING THE FACTS STRAIGHT – ONJ with bisphosphonate use

Australia's leading osteoporosis experts have joined forces today to clarify several misconceptions about ONJ with bisphosphonate use, after a story on national TV last week. Bisphosphonates – a class of drugs designed to treat bone diseases such as osteoporosis, and in much stronger doses, in cancer to prevent the complications when it spreads to the bone.

Concerned by the story, the Australian and New Zealand Bone & Mineral Society (ANZBMS) and Osteoporosis Australia have united to set the record straight on a number of factual errors cited by the program, which have the potential to cause serious alarm, unrest and adversely affect many Australians taking bisphosphonates to prevent osteoporosis and fractures.

According to Professor Sambrook, during the past week there have been many reports of patients ceasing bisphosphonate treatment altogether. "If patients stay off this medication for any prolonged period, we will see an increase in the number of fractures that could have been prevented, as well as deaths, since many of the serious fractures like hip and spine fractures, are associated with increased death rates.

"This could have serious implications for many patients who stop therapy that they really need. So we wish to set the record straight," said Professor Sambrook.

"Firstly, it is important to note the clear distinction between the use of bisphosphonates for treating osteoporosis and cancer, which was unfortunately blurred by the *7:30 Report*.

"Bisphosphonates are used in low oral doses to treat osteoporosis and prevent fractures. In contrast, in cancer patients they are used in very high IV doses in life and death situations, usually with the aim of helping to prevent the spread of cancer to the bone and other skeletal complications of cancer," Professor Sambrook said.

"Not uncommonly in cancer sufferers but in rare cases with osteoporosis, bisphosphonates can interfere with the normal bone healing of the jaw, resulting in ONJ, or death of the bone. However the risk of this rare side-effect can be significantly reduced by good dental care."

According to Professor Sambrook, people with osteoporosis have a very low risk of developing ONJ (as low as one in 10,000 and possibly as low as one in 100,000). "Those most at risk include the elderly who have established dental disease."

Another factually incorrect point was that calcium and vitamin D is sufficient to effectively treat osteoporosis in 50 per cent of patients.

"Calcium and vitamin D may be sufficient to treat very mild cases of osteoporosis, but certainly not sufficient to treat moderate or severe cases of osteoporosis," said Professor Sambrook.

"To have given the impression that you can reap the benefits of bisphosphonates in cancer and avoid the risk of ONJ with just calcium supplements alone, is appalling and reflects how the story blurred these issues. To potentially mislead cancer sufferers in this way is simply unacceptable and must be corrected urgently."

The ANZBMS and OA wish to urgently clarify the following two points:

more#

1. **Bisphosphonates may prevent life threatening complications such as the spread of cancer to bone in cancer sufferers and this benefit must be weighted against any risk; and**
2. **Calcium and vitamin D are not sufficient alone to prevent osteoporosis in moderate or severe cases where agents including bisphosphonates have been shown to be significantly more effective.**

The report also incorrectly stated that bisphosphonates were listed by the Howard Government on the Pharmaceutical Benefits Scheme (PBS) last year. "They have been available for 10 years," said Professor Sambrook. "In fact the Government extended their indication last year from patients who had already sustained a fracture to include prevention of fractures in older patients with very low bone density who had not yet fractured, on the basis of sound scientific evidence for their effect."

Professor Sambrook cites several clinical papers containing proven, established facts that were also not mentioned in the final story.

"Other established statistics left out include the fact that one in five patients who sustain a hip fracture due to osteoporosis will die within six months. Or that many trials with bisphosphonates show they can reduce the risk of fracture by 50 per cent. Or that in a recent, large trial of 8,000 patients treated for osteoporosis with either a bisphosphonate or placebo (dummy drug) for three years, one case of ONJ occurred with the bisphosphonate and also one in the placebo group – i.e. no increased risk was seen.

Ms Judy Stenmark, CEO of Osteoporosis Australia, says it's important to note that around 2.2 million Australians are estimated to have osteoporosis, while only around 300,000, or about 10 per cent, are being treated for the disease with bisphosphonates.

"So it could be argued that we are effectively under-treating the disease."

Professor Peter Ebeling, Medical Director of Osteoporosis Australia, has cautioned people using bisphosphonates not to panic. "There are side-effects associated with every drug and those concerned should ask their doctor as a matter of urgency to weigh up the benefits of using bisphosphonates versus their potential risks."

For more information about bisphosphonates for the treatment of osteoporosis, see your doctor or visit www.anzbms.org.au or www.osteoporosis.org.au.

ends#
