

Treat the Very Elderly for Low Bone Density

BY KERRI WACHTER
Senior Writer

NEW ORLEANS — Very elderly Americans are rarely assessed and treated for low bone density and osteoporosis despite significant potential benefits, experts said at the annual meeting of the International Society for Clinical Densitometry.

"It's the oldest old, those over age 85," whose numbers are increasing most dramatically. "In fact, people over 100—the

centenarians—are the fastest growing group of Americans," said Neil Binkley, M.D., of the University of Wisconsin, Madison.

Bone loss happens faster in the very elderly than in the less elderly, resulting in higher prevalence rates of osteoporosis, hip fractures, and other serious fractures, said Michael McClung, M.D., of the Oregon Osteoporosis Center, Portland.

Yet despite these risks, the rates of bone density screening go down as age increases,

Dr. Binkley said. "We aren't doing a very good job of paying attention to elderly patients," Dr. McClung agreed.

The very elderly tend to fall into two groups: the ambulatory and reasonably healthy and nursing home residents, who tend to be in poor health and not ambulatory. Virtually all nursing home residents have osteoporosis or low bone density and a very high risk of fractures. Yet these patients rarely receive even calcium and vitamin D supplementation.

The cost of withholding such basic interventions is huge. For the current population of roughly 1,600,000 nursing home residents, the cost of hip fractures is about \$700 million per year, assuming an annual hip fracture rate of 2.3% and a cost of \$18,500 per hip fracture.

In deciding how to care for these patients, it's helpful to divide them into three groups, Dr. Binkley said. Some patients come to nursing homes for terminal care and these patients probably won't benefit from osteoporosis treatment. A number of patients come to nursing homes for rehabilitation following a hip fracture and these people should be treated for low bone density and osteoporosis.

The third group poses the real treatment challenge: long-term care patients who are in nursing homes because of cognitive decline or the need for help with daily living tasks. There are no data on the effectiveness of treatments for this type of patient. "The easy answer might be that we ensure that they have adequate calcium intake and give them vitamin D," Dr. Binkley said.

Vitamin D supplementation, in particular, "is an incredibly cost-effective way to intervene," Dr. McClung agreed. Vitamin D deficiency is very common in the elderly, even in those who still have good mobility. "The older we get, the more dependent we are on higher levels of vitamin D to maintain calcium homeostasis."

Six Tips to Prevent Fractures

- ▶ Measure bone density and diagnose osteoporosis in this age group.
- ▶ Think beyond age: General health and frailty may be better predictors of fracture risk.
- ▶ Bisphosphonates actually work quickly, and patients will see a benefit.
- ▶ Anticipate vitamin D deficiencies: High doses are acceptable in this population.
- ▶ Age is not a barrier to drug response.
- ▶ Drugs are not the only interventions: Exercise, tools for daily living, and training to prevent falls are effective as well.

Sources: Dr. Binkley, and Dr. McClung.

Dr. McClung added that in his own clinic, individuals over the age of 70 are given a 50,000-U dose of vitamin D taken once a month. Study results have suggested that 400 IU of vitamin D per day may not be adequate for many older individuals.

Although a number of drugs have been shown to reduce fracture risk in osteoporotic patients, most of the trials have not involved patients over the age of 80.

Given the lack of supportive data, deciding whether to use bisphosphonates in nursing home residents, however, is tricky.

"My approach, in the absence of data, is to utilize cognition," Dr. Binkley said. He asks patients if this type of treatment is feasible in their living situation, and he inquires about their desire to take the drug, and how their family feels about the approach. If the responses are favorable, he prescribes a bisphosphonate. ■

ORTHOVISC® High Molecular Weight Hyaluronan

BRIEF SUMMARY. Please see full prescribing information.

INDICATIONS

ORTHOVISC® is indicated in the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics, e.g. acetaminophen.

CONTRAINDICATIONS

- Do not administer to patients with known hypersensitivity (allergy) to hyaluronate preparations.
- Do not administer to patients with known allergies to avian or avian-derived products (including eggs, feathers, or poultry).
- Do not inject ORTHOVISC® in the knees of patients with infections or skin diseases in the area of the injection site or joint.

WARNINGS

- Do not concomitantly use disinfectants containing quarternary ammonium salts for skin preparation as hyaluronic acid can precipitate in their presence.
- Transient increases in inflammation in the injected knee following ORTHOVISC® injection have been reported in some patients with inflammatory osteoarthritis.

PRECAUTIONS

General

- Strict aseptic injection technique should be used during the application of ORTHOVISC®.
- The safety and effectiveness of the use of ORTHOVISC® in joints other than the knee have not been demonstrated.
- The effectiveness of a single treatment cycle of less than 3 injections has not been established. Pain relief may not be seen until after the third injection.
- The safety and effectiveness has not been established for more than one course of treatment.
- **STERILE CONTENTS.** The pre-filled syringe is intended for single use only. The contents of the syringe should be used immediately after opening. Discard any unused ORTHOVISC®. Do not re-sterilize.
- Do not use ORTHOVISC® if the package has been opened or damaged.
- Store ORTHOVISC® in its original package at room temperature (below 77°F/25°C). DO NOT FREEZE.
- Remove joint effusion, if present, before injecting ORTHOVISC®.
- Only medical professionals trained in accepted injection techniques for delivering agents into the knee joint should inject ORTHOVISC® for the indicated use.

ADVERSE EVENTS

ORTHOVISC® was investigated in 3 randomized, controlled clinical studies conducted in the U.S. An integrated safety analysis was conducted, pooling the ORTHOVISC® groups from the 3 studies and pooling the control groups, which were either intraarticular saline injections or arthrocentesis. In the integrated analysis, there were 562 patients in the groups treated with ORTHOVISC® (434 receiving 3 injections and 128 receiving 4 injections), 296 in the group treated with physiological saline, and 123 in the group treated with arthrocentesis.

Adverse events occurring at >5% of the overall integrated population included: arthralgia (12.6% in the ORTHOVISC® group, 17.2% in the saline group, and 0.8% in the arthrocentesis group); back pain (6.9% in the ORTHOVISC® group, 12.2% in the saline group, and 4.9% in the arthrocentesis group); and headache NOS (12.1% in the ORTHOVISC® group, 16.6% in the saline group, and 17.9% in the arthrocentesis group). Injection site adverse events (including erythema, edema, pain and reaction NOS) occurred at rates of 0.4%, 0.9%, 2.5% and 0.2%, respectively, in the ORTHOVISC® group, compared to 0.0%, 0.3%, 2.0%, and 0.7% in the saline group and 0.0%, 0.0%, 0.8% and 0.8% in the arthrocentesis group.

Local adverse events reported on a by-patient basis for the combined ITT populations of the three studies are presented in Table 1.

Table 1
Local individual adverse events reported on a by-patient basis for the combined ITT populations of the three studies.

Adverse Event	ORTHOVISC N = 562	Saline N = 296	Arthrocentesis N = 123
Any Adverse Event	349 (62.1%)	204 (68.9%)	65 (52.8%)
Injection site erythema	2 (0.4%)	0 (0%)	0 (0%)
Injection site edema	5 (0.9%)	1 (0.3%)	0 (0%)
Injection site pain	14 (2.5%)	6 (2.0%)	1 (0.8%)
Injection site reaction NOS ¹	1 (0.2%)	2 (0.7%)	1 (0.8%)
Pain NOS ¹	14 (2.5%)	11 (3.7%)	1 (0.8%)
Arthralgia	71 (12.6%)	51 (17.2%)	1 (0.8%)
Arthritis NOS ¹	4 (0.7%)	5 (1.7%)	0 (0%)
Arthropathy NOS ¹	5 (0.9%)	3 (1.0%)	0 (0%)
Baker's cyst	2 (0.4%)	2 (0.7%)	0 (0%)
Bursitis	6 (1.1%)	6 (2.0%)	2 (1.6%)
Joint disorder NOS ¹	2 (0.4%)	0 (0%)	0 (0%)
Joint effusion	2 (0.4%)	1 (0.3%)	1 (0.8%)
Joint stiffness	3 (0.5%)	2 (0.7%)	0 (0%)
Joint swelling	4 (0.7%)	2 (0.7%)	1 (0.8%)
Localized osteoarthritis	5 (0.9%)	1 (0.3%)	1 (0.8%)
Aggravated osteoarthritis	2 (0.4%)	0 (0%)	1 (0.8%)
Knee arthroplasty	3 (0.5%)	2 (0.7%)	0 (0%)

Notes: ¹NOS = Not otherwise specified.

ORTHOVISC® is a registered trademark of Anika Therapeutics, Inc.

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Distributed by:

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Double-Dose Vitamin D Prevents Falls

BY TIMOTHY F. KIRN
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SEATTLE — Vitamin D supplementation at twice the dose usually recommended for elderly individuals decreased falls in nursing home residents by 71%, Douglas P. Kiel, M.D., said at the annual meeting of the American Society for Bone and Mineral Research.

The usual dose of vitamin D recommended for bone health in elderly individuals is 400 IU a day. Vitamin D supplementation has been shown to decrease falls, but it is not certain if the usual dose is adequate for providing this benefit, said Dr. Kiel, director of medical research at the Hebrew Rehabilitation Center for Aged, Boston.

Dr. Kiel and his colleagues randomly assigned 125 elderly residents at a long-term care facility to one of four daily dosages of vitamin D, ranging up to 800 IU.

After 5 months, falls were reduced only among those who took the highest dose,

Dr. Kiel noted in a poster presentation.

There were 9 falls among the 23 individuals who took 800 IU of vitamin D daily, compared with 31 falls among the 25 patients assigned placebo, 37 falls among 26 individuals who took 200 IU, 33 falls among 25 individuals who took 400 IU, and 41 falls among 25 individuals who took 600 IU.

The number of individuals who fell was also significantly reduced. Only 5 individuals taking 800-IU fell, compared with a range from 11 to 15 in the lower-dose and placebo groups.

Those figures translate into a three- to fourfold decrease in risk of falling for those who took the 800-IU dose of vitamin D, Dr. Kiel said.

Almost three-quarters of the individuals were already taking a multivitamin containing 400 IU of vitamin D, which could mean that the threshold dosage for preventing falls could be as high as 1,200 IU, Dr. Kiel noted.

The study subjects had a mean age of 89 years, and 72% were female. ■