



# OSTEOPOROSIS NEWSLETTER

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Editor

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Inside this issue:	
Clinical Research	2
Chocolate and Bone Density	2
Quality of Life	3
Recipe File	4

## Reclast Approved by FDA

Reclast® was approved by the US Food and Drug Administration (FDA) on August 17, 2007 as the first and only once-yearly treatment for postmenopausal osteoporosis. In the Pivotal Fracture Trial, involving more than 7,700 women, Reclast® was shown to increase bone strength and reduce fractures in areas of the body affected by osteoporosis, including the hip, spine and non-spine (i.e. hip, wrist, arm, leg, rib). The study showed that Reclast® reduced the risk of spine fractures by 70% and hip fractures by 41%.

In a study with 2127 patients, infusions of zoledronic acid were first administered within 90 days

after surgical repair of a hip fractures. There was a 35% risk reduction of any new clinical fracture with zoledronic acid and a 28% reduction in deaths from any cause compared to the placebo group.

The Recurrent Fracture Trial found that Reclast® reduced the risk of all types of new clinical fractures by 35% compared to placebo. The risk of new spine fractures was reduced by 46% and new non-spine fractures (such as hip, wrist, arm, leg, rib) by 27%.

The active ingredient in Reclast® is zoledronic acid. It is administered by infusion for 15 minutes. Reclast® belongs

to a class of drugs called bisphosphonates which includes Actonel, Boniva, Fosamax and others.

One of the benefits of a once-yearly infusion is that it may have better patient compliance than a daily, weekly or monthly schedule. One of the challenges of the medical profession is the low compliance rate for osteoporosis medication. Fractures, especially hip fractures, increase mortality, reduce patient quality of life and are a major expense.

### References

Lyles, KW + 18 others Zoledronic acid and clinical fractures and mortality after hip fracture. N Engl J Med 2007, 357:1799-1809.  
[www.novartis.com](http://www.novartis.com) Search Reclast 9/21/07.

**B.O.N.E.S. SUPPORT GROUP**  
will meet on  
**March 11th**  
**Oakwood Auditorium**  
**6209 Mineral Point Road**  
**Madison**

1:30-2:30 p.m.

Questions? Call  
**265-6410**  
for information.

## Next B.O.N.E.S. Support Group Meeting

**Adaptations for Daily Living with Osteoporosis** is the topic of our monthly B.O.N.E.S. meeting on March 11<sup>th</sup>. Our speaker will be Mindy Wiseman

who is an occupational therapist at Care Wisconsin.

Care Wisconsin is a nationally recognized leader in health care

management and innovative high-touch care for older adults with severe and disabling chronic conditions.

# Osteoporosis Clinical Research

2

Diane Krueger, Research Program Mgr

The Osteoporosis Clinical Research Program had a productive 2007. Enrollment for our study comparing the effect of vitamin D<sub>2</sub> with that of vitamin D<sub>3</sub> was completed in October followed by three pharmaceutical-sponsored osteoporosis treatment trials in November and December. Preliminary results of the vitamin D study should be available in April.

Dr. Karen Hansen completed pilot work to evaluate the effect of vitamin D on calcium absorption. Our thanks to all who have or continue to participate in our studies.

Dr. Binkley also received a grant this past year to investigate how response to vitamin D fortified food differs by age and ethnicity in women. Recruitment for women 75 or over in the Madison area will start in February. Additional study populations will include rural Wisconsin (Ashland) and Native American women in northern Minnesota.

Dr. Hansen will soon begin evaluating the impact of acid blocking medications on calcium absorption.

Additionally, three studies evaluating new approaches to osteoporosis treatment are slated to start in February or March. One will study controlled-

release Actonel, investigating a formulation that would not require fasting when dosing. A second study will investigate a new class of medications; cathepsin K inhibitors, for which phase 2 data is promising. A large world-wide study is being initiated to assess fracture reduction efficacy. Finally, our program is participating in a study to determine if the medication Forteo reduces back pain in patients with chronic pain from a vertebral fracture.

We are very excited about the 2008 projects and the coming results from our 2007 studies. Again, we thank everyone for their support of our program.

## Chocolate Consumption and Bone Density

A new study discussed in the American Journal of Clinical Nutrition, investigated the relationship between chocolate consumption and bone density and strength. 1001 randomly selected women, age 70-85 were selected from the general population to participate in a study of calcium supplementation. A questionnaire was used to determine the frequency of chocolate intake: 1 time/week,

1-6 times/week, 1 time/day.

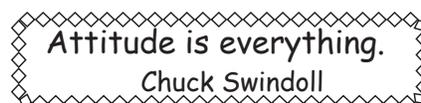
Older women who ate chocolate less than once a week had significantly stronger (3.1%) bones than those who consumed it more often. Calcium supplementation had no effect on the results.

Additional studies are needed to confirm the results of this study.

When eating chocolate, one needs to consider that the health benefits may be offset by the sugar, fat and calories. Maybe we want to consider eating chocolate occasionally rather than frequently even if it isn't easy.

### Reference

Hodgson, Jonathan, etc. Chocolate consumption and bone density in older women. American J of Clinical Nutrition 2008, 87:175-180.



### Quality of Life References

- Gold, DT The clinical impact of vertebral fractures: quality of life in women with osteoporosis. Bone 1996, 18:185S-189S.  
Hallal, J RN, DNSc Life satisfaction in women with postmenopausal osteoporosis of the spine. Health Care for Women 1991, 12:99-110.  
Van Vort, WB, MD; Rubenstein, M, MD; Rose, RP Osteoporosis with pathologic hip fractures in major depression. J of Geriatric Psychiatry and Neurology 1990, Vol 3.  
Wendlova, J Why does depression develop in complicated osteoporosis? Bratisl Lek Listy 2006, 107 (5): 197-204.

Osteoporosis has obvious physical and functional consequences including physical deformity, restricted range of motion and pain. What are not so obvious are the psychosocial results. This article discusses the impact of these results on the quality of life in women with osteoporosis. Please note that not all women with osteoporosis experience psychological problems.

## Psychological Impact of Osteoporosis

**Anxiety** Anxiety may come before a woman knows if she has osteoporosis. She may fear fractures, deformity, pain and restricted activity. The anxiety may start or increase after the first fracture. Anxiety may contribute to feelings of stress. Anxiety about falling and having fractures may lead to inactivity which compounds the problem because the woman doesn't have the benefit of exercise to relieve the stress, increase strength and keep her body flexible. Regular weight-bearing exercise is very important for strong bones. Knowledge of how to be active and exercise safely may decrease anxiety and give a woman confidence to be active.

**Depression** There are various levels of depression. As time passes a woman with osteoporosis may have additional fractures, pain and limited mobility. As she becomes isolated and dependent on others, she may become depressed. Sometimes, physicians recognize depressive symptoms and recommend a trial of an antidepressant. This depression usually responds well to treatment. Unfortunately, the symptoms may be seen as the result of normal aging and the woman may experience continuing emotional difficulties.

Another level is major depression. Major depression may contribute

to decreased bone density. When a woman becomes sedentary and does not exercise, her bones will weaken. She may eat little resulting in insufficient nutrients, especially calcium and vitamin D. Excess use of substances may be implicated in osteoporosis and is especially prevalent in the psychiatric population. The alteration of endocrine function is associated with major depression. Hypercortisolism is observed in a high proportion of patients with major depression and is a known risk factor for osteoporosis. Elevation of cortisol levels and decreased levels of physical activity may exacerbate osteoporosis in depressed individuals. Early therapy may improve physical condition and quality of life.

**Self-esteem** As women watch themselves shrink, have body changes, have limited activity and perhaps become more isolated, their self-image and self-esteem also shrink. Two specific aspects of osteoporosis seem to influence the loss of self-esteem: 1. the obvious physical changes including height loss, kyphosis (stooped-over posture and Dowager's hump) and abdominal protrusion; and 2. the functional limitations including the inability to carry out usual activities and participate in social activities.

## Social Factors

**Social Support** (relationships with other people and the support they provide) Most social relationships are based on the concept of reciprocity – you do something for me and I'll do something for you. While immediate return on an emotional investment may not be critical in relationships with close relatives, reciprocity is typically essential to the survival of relationships outside of the family. Sadly, osteoporosis can create a permanent imbalance

of this reciprocity by causing a shift in the ratio of giving and getting support. Osteoporotic women are often handicapped by physical impairments that reduce their ability to provide help or support to family members or friends. Friends are willing to meet the needs of acute illness but once the fracture begins to heal, friends can tire of being givers. Ongoing assistance can be stressful for family members.

**Social Roles** Some of the most important aspects of adult self-perception are social roles – the positions that people hold in their families, work environments and communities. All adults hold multiple social roles. For example, a woman with osteoporosis may be a wife, mother, secretary, bridge player, friend, gardener and volunteer. All women derive great emotional satisfaction from filling their roles well and they can also feel great embarrassment and frustration when their physical and functional capabilities are limited. Giving up a social role can be depressing and can increase isolation and decrease activity which can further limit the ability to continue her social roles.

## Conclusion

The impact of osteoporosis on an individual varies considerably. On the physical side, some individuals will have low bone mass but very little evidence of osteoporosis while others will have noticeable body changes and several fractures with lots of pain. On the psychosocial side, some individuals will be able to continue their life with some activity limitations while others may have major challenges. Some studies suggest that one's attitude and outlook on life before and after osteoporosis diagnosis has a significant impact on one's quality of life.

See page 2 for references.

# RECIPE FILE

Here is a delicious way to enjoy your vegetables on a cold winter day.

## Minestrone

4 cups vegetable broth	1 can (15 oz) stewed tomatoes
1 small onion, chopped	1 can (6 oz) seasoned tomato paste
1 stalk celery, thinly sliced	1 can (15 oz) pinto beans
1 green pepper, coarsely diced	1 pkg (10 oz) mixed frozen vegetables
1 zucchini, coarsely diced	½ cup macaroni, uncooked
2 medium carrots, peeled, thinly sliced	½ tsp dried basil
4 small red potatoes, coarsely diced	Salt and ground pepper to taste

Add broth and fresh vegetables to a 6 quart pot or crock pot. Cover and bring to a boil. Reduce heat; cook 10 minutes. Add stewed tomatoes, tomato paste and macaroni. Cover; cook 10 minutes. Add remaining ingredients. Cover; cook 30 to 45 minutes or until macaroni is tender and minestrone is

heated through. Serves 4 to 6.

Be creative. Use this recipe to get started, but feel free to substitute, add or delete ingredients. You might want to add turkey, chicken or beef and change broth to chicken or beef.