Balancing the Benefits and Risks of Osteoporosis Therapy

December 6, 2011

National Osteoporosis Foundation
National Osteoporosis Foundation
Participate in Osteoporosis Support Groups

NOF has support groups across the country to provide support and information for people affected by osteoporosis. NOF depends on volunteers like you to serve as support group leaders. To find out if there is a support group in your area or learn how you can start a support group, e-mail request@nof.org.
Just like our mothers’ and grandmothers’ pearls are precious, so are our bones. Order your Pearls of Strength® bracelets today – the perfect holiday gift.

New this year, we added a Me&Ro designed “love” charm to our white and black bracelets. $25 for each bracelet with charm

Proceeds benefit NOF’s Generations of Strength Campaign.

To order, call (800) 231-4222 or visit www.nof.org
For the first time, we have an opportunity to work together to protect our mothers, fortify our daughters and guarantee a lifetime of strength, independence and happiness for ourselves. And it all starts with a conversation.

Visit [nof.org/startaconversation](http://nof.org/startaconversation) to join the discussion and help spread the word to prevent osteoporosis for generations to come.
Mission Statement

The National Osteoporosis Foundation is the leading consumer and community-focused health organization dedicated to the prevention of osteoporosis and broken bones, the promotion of strong bones for life and the reduction of human suffering through programs of public and clinician awareness, education, advocacy and research.
Today’s Presenter

E. Michael Lewiecki, MD
Balancing the Benefits and Risks of Osteoporosis Therapy

E. Michael Lewiecki, MD
New Mexico Clinical Research & Osteoporosis Center
Albuquerque, NM
What Is Osteoporosis?

Osteoporosis is a condition where the bones become weak and can break from a minor fall or activity that would not normally cause a bone to break.
Consequences of Fractures

- Pain
- Disability
- Loss of height
- Increased risk of death
- Loss of independence
Diagnosing Osteoporosis

- Bone density testing
  - DXA
  - T-score
- Previous fracture as an adult
  - Having a fracture greatly increases the risk of another fracture
Fracture Risk

- Having osteoporosis increases the chances of a bone breaking
- Uncertainty
  - Not everyone with osteoporosis will break a bone
  - Some people who do not have osteoporosis by bone density testing will break bones
Prevention and Treatment of Osteoporosis

• For everyone: good nutrition and healthy lifestyle
  – Calcium
  – Vitamin D
  – Weight-bearing and muscle-strengthening exercise
  – Avoid falling, smoking, and excess alcohol

• For some people: prescription medications
Treatment is recommended for postmenopausal women and men age 50 and older who have:
- Low bone density according to a bone density test AND certain risk factors that suggest an increased chance of breaking a bone
  - FRAX® can help identify these individuals
- Osteoporosis according to a bone density test
- Broken a hip or bones in the spine
Medications for Osteoporosis

- Bisphosphonates
  - Alendronate (Fosamax®, generic versions)
  - Risedronate (Actonel®, Atelvia™)
  - Ibandronate (Boniva®)
  - Zoledronate (Reclast®)
- Calcitonin (Miacalcin®, Fortical®)
- Denosumab (Prolia®)
- Estrogen
- Raloxifene (Evista®)
- Teriparatide (Forteo®)
Considerations with Medications

• Benefits
  – Prevent bone loss
  – Improve bone strength
  – Reduce risk of broken bones

• Risks
  – Possibility of side effects
Risk: Chance of Something Bad Happening

- Life is risky
- Everything we do has risk
- Not doing anything may also be risky
- What is frightening to one person may not be to another
“People are disturbed, not by things, but by the view they take of them.”

Epictetus

Greek Stoic philosopher

(AD 35 - AD 135)
Definition of Risk

“The probability of loss of that which we value.”

Risk = Hazard + Outrage
Undesirable medical occurrence that is CAUSED by taking a medication
Learning about Side Effects

- Strong evidence: randomized placebo-controlled clinical trials showing a statistically significant difference between something bad happening with treatment compared to not taking treatment
  - Establishes causality
  - Limited by small number of participating patients
  - Short period of observation
  - May not identify very rare events
  - May not apply to other people and circumstances
Learning about Side Effects

• Weak evidence: reviews of healthcare claims databases, national registries, case reports, anecdotes, news media
  – May identify very rare events
  – Does not establish causality
Understanding Side Effects

• Could it happen to me?
• Is it caused by the drug or just coincidence?
• How common is it?
• How serious is it?
• How frightening is it?
• What is the risk of not taking the drug?
• How does the risk of side effects compare to the benefits of treatment?

Beware of unreliable sources of information
Risk Perspective for Patients and Physicians

<table>
<thead>
<tr>
<th>Technical (physicians &gt; patients)</th>
<th>Personal (patients &gt; physicians)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health statistics</td>
<td>Anecdotes</td>
</tr>
<tr>
<td>Randomized controlled trials</td>
<td>Case reports</td>
</tr>
<tr>
<td>Medical journals</td>
<td>Mass media</td>
</tr>
<tr>
<td>Expert recommendations</td>
<td>Friends and family</td>
</tr>
</tbody>
</table>
Gap in Understanding Risk

- Virtually no correlation between the ranking of hazards by experts and the ranking of the same hazards by how upsetting they are to the public.

- Many risks make people furious even though they cause little harm, and others kill many without making anybody mad.

- Risk communication is a scientifically based discipline that confronts these dilemmas.

Adapted from Covello VT, Sandman PM. http://www.psandman.com/articles/covello.htm.
Risk Communication

“The study and practice of collectively and effectively understanding risks.”

Industry: crisis management for malfunctioning or contaminated products
Government: natural disasters, bioterrorism, nuclear threats
Public health officials: epidemics
Physicians: every day for every patient, osteoporosis

Obstacles to Effective Risk Communication

- Uncertainty, complexity, incompleteness of data
- Distrust of experts, government, industry
- Selective reporting by news media
- Statistical illiteracy

Adapted from Covello VT, Sandman PM. http://www.psandman.com/articles/covello.htm.
• TV news report of December 11, 2007
• Described cases of osteonecrosis of the jaw (ONJ) in patients taking bisphosphonates

Sambrook PN et al. MJA. 2010;193:154–156.
Problems with ABC News Report

• Failed to distinguish between oncology and osteoporosis settings with ONJ
• Failed to give estimate of absolute risk
• Errors/omissions later retracted
• Pharmaceutical claims database review showed decrease of ~30,000 bisphosphonate prescriptions over the next 9 months
• Consequences: 70 hip fractures, 60 other fractures, and 14 deaths that might have been prevented

Sambrook PN et al. MJA. 2010;193:154–156.
Statistical Literacy

• Basic competency in understanding healthcare statistics for patients and physicians
  – Benefit vs harm with treatment
  – Magnitude of risk – relative vs absolute
  – Time frame – lifetime vs finite time period
  – Population at risk – you or someone else

• Learning to live with uncertainty
  – No certainty with any intervention
  – Nothing has zero-risk
Statistical Illiteracy is Common

• Patients
• Politicians
• Healthcare journalists
• News services
• Physicians
### Statistical Literacy Test

<table>
<thead>
<tr>
<th>Question</th>
<th>High School Graduates (n =131)</th>
<th>College Graduates (n = 103)</th>
<th>Post-graduate Degree (n = 62)</th>
<th>Physicians at Grand Rounds (n = 85)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convert % to proportion: 1% = x in 1000</td>
<td>56%</td>
<td>79%</td>
<td>82%</td>
<td>91%</td>
</tr>
<tr>
<td>Convert proportion to %: 1 in 1000 = x%</td>
<td>23%</td>
<td>30%</td>
<td>27%</td>
<td>75%</td>
</tr>
<tr>
<td>How many heads in 1,000 coin flips?</td>
<td>62%</td>
<td>87%</td>
<td>86%</td>
<td>100%</td>
</tr>
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Adapted from Gigerenzer G et al. Psychological Science in the Public Interest. 2008;8:53-96.
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<tbody>
<tr>
<td>Convert % to proportion: 1% = x in 1000</td>
<td>10 in 1000</td>
<td>56%</td>
<td>79%</td>
<td>82%</td>
<td>91%</td>
</tr>
<tr>
<td>Convert proportion to %: 1 in 1000 = x%</td>
<td>0.1%</td>
<td>23%</td>
<td>30%</td>
<td>27%</td>
<td>75%</td>
</tr>
<tr>
<td>How many heads in 1,000 coin flips?</td>
<td>500</td>
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<td>87%</td>
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<td>100%</td>
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Adapted from Gigerenzer G et al. Psychological Science in the Public Interest. 2008;8:53-96.
Decision Aids

- Supplementary material to help make “close call” decisions that involve consideration of benefits, harms, and scientific uncertainty
- Review of 55 randomized clinical trials
  - Decision aids improved patient knowledge, created accurate perceptions of benefits and harms, reduced difficulties with decision making
  - Stronger effect when probabilities measured quantitatively than qualitatively

Comparison of Risk: Icon Array Graph

<table>
<thead>
<tr>
<th></th>
<th>10-Year risk of fracture without treatment</th>
<th>10-Year risk of fracture with treatment</th>
</tr>
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<tbody>
<tr>
<td>Proportion</td>
<td>4 in 10</td>
<td>2 in 10</td>
</tr>
<tr>
<td>Probability</td>
<td>40%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Part-to-whole icon array graph
Comparison of Risks: Risk per 100,000

- Any Fragility Fracture (1) 2668
- Hip Fracture (1) 387
- Anaphylaxis from PCN Shot 32
- Death by MVA 11
- Death by Murder 6
- ONJ- Osteoporosis Patient 0.7
- Death by Lighting Strike in NM 0.6

(1) Women age 65-69 from Swedish National Bureau of Statistics and database of Olmsted County, MN, USA

Comparison of Risks: 10-year Probability

72 year-old woman with FN T-score = -3.0

Includes 0.01% Atypical Femur Fracture Risk
Includes 0.5% Atypical Femur Fracture Risk

Models for Making Clinical Decisions

• Paternalism
  – Physician has all relevant information and is the sole decision maker
• Independent choice
  – Physician presents “the facts” and the patient makes all decisions
• Shared (participatory)
  – Physicians and patient share information, discuss options, and reach collaborative decision
  – Physician may offer recommendation that patient chooses to accept or reject
Challenges in Shared Decision Making

- Physicians typically spend less than 1 minute out of a 20 minute office visit discussing treatment and plans (1)
- Informed decision making occurs in only 9% of office visits (2)
- Physicians ask patients if they have questions in <1/2 of office visits (2)
- Patients recall only a fraction of the information presented (3)

Benefits of Risk Communication

- Patients have better understanding of
  - Disease (fractures and their consequences)
  - Benefits of therapy (reduced fracture risk)
  - Potential harms of therapy (side effects)
- Reduced mistrust and fear
- Better collaboration between physician and patient
- Possible improved persistence and compliance with therapy
- Greater reduction in the burden of osteoporotic fractures
Summary

• Wise healthcare decisions for osteoporosis require a full understanding of fracture risk, consequences of fracture, magnitude of benefit and potential harm of therapy.

• Risk communication is a two-way street: physicians and patients must listen to each other and appreciate all concerns.

• Shared decision making is the process of negotiating a treatment plan that is acceptable to the physician and patient.
We will now answer questions submitted by the audience during this webinar.

**Please note:** NOF is unable to provide you with medical advice. For questions about your specific condition, please talk to your healthcare provider.

We are only able to answer questions related to exercise and the topics covered in today’s presentation.
National Osteoporosis Foundation

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E-mail: Request@nof.org
Please take a few minutes to complete the evaluation for this webinar.