The Osteoporosis Challenge: Closing the Treatment Gap
DISCLOSURES - NONE
Discussion Today

- Decline in DXA screening – Decreasing diagnosis
- Hip fractures – Increasing trend
- Vertebral fractures – Missed opportunities
- Fracture Liaison Service – The solution
- Bisphosphonates – Adverse Effects
- Physician-Patient discussion: The shared decision making process
Lot of Questions! And Discussions!

Unsure if we have the perfect answer yet..
Osteoporosis - Epidemiology

- **Prevalence**
  - Over 10 million US adults have osteoporosis.
  - Over 34 million US adults have low bone density.

- **Sex Differences**
  - 80% of US osteoporosis patients are females.
  - 28-47% prevalence of osteopenia in adult males and females is approximately the same.

- **Vitamin D Deficiency**
  - Affects 8% of US adults (age 20+ years).
  - 3x higher in females than males.
  - 24% of US youth (age 11-18 years).
  - More common in females than males.

- **Lifetime Risk of Osteoporosis Related Fractures**
  - Direct costs associated with osteoporosis related fractures in 2005: $17 billion.

Endocrine Facts and Figures, Endocrine Society, 2016
FIGURE 1. Unadjusted rate of total osteoporotic fracture, myocardial infarction, stroke, and breast cancer hospitalizations. OF = osteoporotic fracture; MI = myocardial infarction.
DXA - Screening

Reimbursement Rates

DXA Office Providers

Percent of Women Tested

This area represents 2.2 million fewer women tested over five years.

Courtesy: Peter M. Steven, PhD (2015)
DXA - Diagnosis

Percent of Women Diagnosed with Osteoporosis

Percent of Hip Fractures with No Prior Osteoporosis Diagnosis

Age-Adjusted Hip Fractures per 100,000 Older Women

8,024 additional hip fractures over two years

Direct Research LLC, Medicare PQPS Master Files and Medicare 5 Percent Sample LDS SAP, analysis by Peter M. Steven, PhD.

Courtesy: Peter M. Steven, PhD (2015)
What is happening in Utah?

- DXA testing of elderly women peaked in 2008 at 12.9%
- By 2013, testing of women 65+ years declined by 12.5%
- Payment cuts resulted in the loss of 22 DXA physicians (10%)
- From 2011 to 2013 there were 4,481 fewer DXAs, which likely resulted in:
  - 37 additional hip fractures
  - 7 additional hip fracture related deaths
  - $1,483,790 in estimated additional costs to Medicare
Hip Fractures
Complications

- **Mortality**
  - 30% (at 1 year)

- **Morbidity**
  - Significant functional loss
  - 50% of survivors are permanently incapacitated
  - 20% of survivors require long-term nursing home care

- **Economic burden**
  - 10 million USD/year
Question (MOC)

What percent of US older patients are treated with any osteoporosis medication within 3 months of hospitalization for a non-traumatic hip fracture?

1) 70%
2) 50%
3) 30%
4) 10%
Hip Fracture – Post Hospitalization

Oral Bisphosphonates

Year (quarters)

Percentage


US Medicare
US Commercial
Korea
Spain

Kim SC, AJM 2015
Vertebral Fractures – Missed Opportunities

Normal

Biconcave (codfishing) deformity

Wedge fracture

Compression fracture
A fracture predicts fracture better than BMD

1 fracture + low BMD: 25X

>1 fractures + low BMD: 75X

“More than 2/3rd are silent”
Serious Consequences

- Back pain
- Loss of height
- Deformity (Kyphosis, protuberant abdomen)
- Reduced pulmonary function
- Diminished quality of life
- Dependence on pain medication
- Depression
- Increased mortality
“Drugs’ causing jawbones to rot and thighbones to snap in two”

Fearing Drugs’ Rare Side Effects, Millions Take Their Chances With Osteoporosis

By GINA KOLATA   JUNE 1, 2016
Prevalence of bisphosphonate use among females and males aged 55 years and older

Jha S, JBMR, 2015
US Google search of the term “Fosamax”

Relative Search Activity

ONJ  AFF

A. Fib

A  B  C  D

Jha S, JBMR, 2015
<table>
<thead>
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<tbody>
<tr>
<td>N</td>
<td>4,704</td>
<td>6,700</td>
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<tr>
<td>PDC up to 6 months, mean ± SD</td>
<td>0.73 ± 0.28</td>
<td>0.72 ± 0.29</td>
</tr>
<tr>
<td>% of patients with</td>
<td></td>
<td></td>
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<tr>
<td>PDC ≥0.75</td>
<td>59.98</td>
<td>58.70</td>
</tr>
<tr>
<td>0.5 ≤ PDC &lt;0.75</td>
<td>16.92</td>
<td>16.61</td>
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<tr>
<td>0.25 ≤ PDC &lt;0.5</td>
<td>12.77</td>
<td>12.51</td>
</tr>
<tr>
<td>PDC &lt;0.25</td>
<td>10.33</td>
<td>12.18</td>
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<tr>
<td>PDC up to 1 year, mean ± SD</td>
<td>0.70 ± 0.30</td>
<td>0.67 ± 0.31</td>
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<tr>
<td>% of patients with</td>
<td></td>
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<tr>
<td>PDC ≥0.75</td>
<td>57.65</td>
<td>52.90</td>
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<tr>
<td>0.5 ≤ PDC &lt;0.75</td>
<td>16.01</td>
<td>17.59</td>
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<td>0.25 ≤ PDC &lt;0.5</td>
<td>13.27</td>
<td>12.77</td>
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<tr>
<td>PDC &lt;0.25</td>
<td>13.07</td>
<td>16.74</td>
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PDC: proportion of days covered
Osteonecrosis of the Jaw (ONJ)

Definition

- Exposed bone in the maxillofacial region that does not heal within 8 weeks after identification by a health care provider
- Exposure to an antiresorptive agent and
- No history of radiation therapy to the craniofacial region
Epidemiology

- 2/3 in mandible

- Prevalence
  - PO: 0% to 0.04% (majority being below 0.001%)
  - IV: 0% to 0.348% (majority being under 0.005%)

- Incidence
  - PO: 1.04 to 69 per 100,000 patient-years
  - IV: 0 to 90 per 100,000 patient-years

Khan, JBMR 2015
Pathophysiology

- Infection
- Suppression of bone turnover
- Vascularity (anti-angiogenic)
- Genetic predisposition
Prevention

- Completion of necessary oral surgery prior to initiation
- Use of antibiotics before and/or after the procedure
- Antimicrobial mouth rinsing
- Appropriate closure of the wound following tooth extraction
- Maintenance of good oral hygiene

Khan, JBMR 2015
Atypical Femoral Fracture (AFF)

- **Hypothesis:** Over-suppression of bone remodeling could impair the repair of micro damage
- **Transverse** (not spiral) fractures of femoral diaphysis or in subtrochanteric region
- May begin with stress reaction or stress fracture of lateral femoral cortex (arrow)

Shane E, JBMR 2010
Atypical Femoral Fracture (AFF)

- Often bilateral
- Prodromal pain in thigh or groin in 70%
- Can occur in untreated patients, but increased incidence in patients on bisphosphonates > 5 years, often in combination with other drugs, especially steroids or estrogen

Shane E, JBMR 2010
FDA safety update - 2012

- Be aware of the possibility of AFF in patients on bisphosphonates
- Evaluate any patient who presents with new groin or thigh pain
- Discontinue potent antiresorptive medication in patients with AFF
- Periodically reevaluate the need to continue bisphosphonate therapy, particularly in patients treated for 5 years or more
Risks associated with bisphosphonate use and other health outcomes

Adler RA, JBMR 2016
Fracture Liaison Service

- Specific Osteoporosis protocols for staff working in emergency rooms, inpatient wards, and orthopedic units
- Health education of patients/families
- Alerts to primary care physician for evaluation
- Assessment of clinical risk factors
- Investigation for secondary causes
- BMD testing
- Treatment initiation (pharmacologic and non-pharmacologic)
- Monitoring and follow-up
Fig. 1 Structure of a typical fracture liaison service. MTF minimal trauma fracture, f/u follow-up, LMO local medical officer, BMD bone mineral density.
<table>
<thead>
<tr>
<th>Study name</th>
<th>Refractures (control)</th>
<th>Refractures (intervention)</th>
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<tbody>
<tr>
<td>Lih et al. [34]</td>
<td>31</td>
<td>157 at 35.2 months</td>
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<tr>
<td>Dell et al. [32]</td>
<td>2,510 (expected hip fractures)</td>
<td>1,575</td>
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<tr>
<td>Majumdar et al. [44] and Morrish et al. [55]</td>
<td>No numbers</td>
<td>No numbers</td>
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<td>Boudou et al. [38]</td>
<td>–</td>
<td>14</td>
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<td>Langridge et al. [29]</td>
<td>–</td>
<td>129</td>
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<tr>
<td>McLellan et al. [31]</td>
<td>–</td>
<td>468</td>
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Ganda K, Osteo Int, 2013
Conclusion

- Greater effectiveness with increasing intensity of the intervention

- Cost-effectiveness improves with intensity of the intervention

- Significant improvement in closing the care gap in osteoporosis management

“Room for improvement definitely exists”

Ganda K, Osteo Int, 2013
The Shared Decision Making Process

- Discussion between physician and patient
- Fracture risk
- Indication for treatment
- Benefits of treatment
- Harms of treatment
- Cost of treatment
- Patient values and preference
Call to action to address the crisis in the treatment of Osteoporosis

- Osteoporotic fractures have serious health consequences
- Fewer individuals at high risk for osteoporotic fractures are being treated
Action to Change!

- Health professional education programs and continuing medical education programs to expand education
- Governmental organizations (health, public health, research, elected groups) to increase focus and support for programs to reach the highest risk patients
- Insurers (private and public) to cover the most effective services
- Health systems and medical practices to adopt and use quality measures
University of Utah

- Collaboration with primary care physicians, geriatricians, hospitalists, ER physicians, orthopedic surgeons, radiologists, physical therapists, and home health care

- The Osteoporosis and Metabolic Bone Health Program - initiated in February 2016 with collaboration with the University Rehabilitation and Wellness Clinic

- In-hospital Fracture Liaison Service - initiated in November 2016 in collaboration with the Hospitalist Service
"Your x-ray showed a broken rib, but we fixed it with Photoshop."