Osteoporosis and Spine Health During the Coronavirus Pandemic

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Objectives

• Describe the scope of the problem and morbidity and mortality associated with vertebral compression fractures (VCF)

• Review treatment options for patients with vertebral compression fractures (VCF)

• Discuss the effects of COVID-19 on osteoporosis and fracture care, including vertebral fracture management

• Discuss vertebral augmentation procedures and the recommendations for utilization during the coronavirus pandemic
The Scope of the Problem
Osteoporosis

*Definition:*

Osteoporosis is a systemic disease characterized by weakened and fragile bone tissue, leading to an increased risk of fracture.

- Osteoporosis is underdiagnosed and undertreated.
- Osteoporosis is a chronic disease requiring prolonged treatment.
- It is important to develop a strategy for long-term management to reduce the risk for fracture.
- Osteoporosis medications effectively reduce fracture risk in patients with osteoporosis.

Images Courtesy of Drs. David Dempster & Roger Zambezi.
The Silver Tsunami:
Prevalence of Osteoporosis and Low Bone Mass

Americans Age 50 and Above Affected by Osteoporosis/Low Bone Mass, 2010 to 2030 (projected)

- 54 million of 99 million Americans age 50+ (2010)
- 17% of the ENTIRE U.S. POPULATION (2010)
- Osteoporosis: • 16.2% of adults aged 65 and over
  • 25.7% of women aged 80 and over
- +27% change from 2010 to 2030

Millions

2010  2030

# Lifetime Risk of Fracture at the Age of 50

<table>
<thead>
<tr>
<th>Type of Fracture</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoporotic Fracture&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>46-53%</td>
<td>21-22%</td>
</tr>
<tr>
<td>Hip Fracture&lt;sup&gt;2,3&lt;/sup&gt;</td>
<td>15-23%</td>
<td>5-11%</td>
</tr>
<tr>
<td>Radiographic Vertebral Fracture&lt;sup&gt;4&lt;/sup&gt;</td>
<td>27%</td>
<td>11%</td>
</tr>
<tr>
<td>Clinical Vertebral Fracture&lt;sup&gt;2&lt;/sup&gt;</td>
<td>15%</td>
<td>8%</td>
</tr>
</tbody>
</table>


**NHANES VFA Study 2017<sup>5</sup>**

Vertebral Fracture Prevalence:
- 5% in the 60s
- 10% in the 70s
- 20% in the 80s

Vertebral Fractures are Common in Both Men and Women

European Prospective Osteoporosis Study (EPOS) mean follow-up 3.8 years

Data from the EPOS Study Group, J Bone Miner Res 2002;17:716
Milliman Report: Human Cost of Osteoporotic Fractures

In 2015,
2 MilLLION
Medicare patients suffered
2.3 MILLION
fractures

• 30% of hip fracture patients die within 1 year
• 21% of spine fracture patients die within 1 year
• ~20% of all fracture patients die within 1 year
• 15% of spine fracture as well as all patients suffer one or more additional fractures
  • Hip and spine fractures were most common subsequent fractures

Prior Fracture Increases the Risk of Subsequent Fracture

Prior rib fracture can increase risk of new vertebral fracture by 2.3-fold.

Prior vertebral fracture can increase risk of:
- New vertebral fracture 9.1-fold
- New hip fracture 7.1-fold
- New wrist fracture 2.3-fold

Prior hip fracture can increase risk of new vertebral fracture 1.6 to 5.9-fold.

Prior wrist fracture can increase risk of new vertebral fracture by 37%.

Prior shoulder fracture can increase risk of:
- New wrist fracture by up to 5-fold
- New vertebral fracture by up to 10-fold
- New hip fracture by up to 18-fold

Prior fracture can increase the risk of subsequent fractures by varying degrees, as detailed above.

References:
2020 AACE Diagnosis of Osteoporosis

Establishing a Diagnosis of Osteoporosis

- T-score ≤-2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius
- Low-trauma spine or hip fracture (regardless of bone mineral density)
- T-score between -1.0 and -2.5 and a fragility fracture of proximal humerus, pelvis, or distal forearm
- T-score between -1.0 and -2.5 and high FRAX® (or if available, TBS-adjusted FRAX®) fracture probability based on country-specific thresholds

AACE, American Association of Clinical Endocrinologists; FRAX®, fracture risk assessment tool; TBS, trabecular bone score.
Importance of Vertebral Fractures

- Most common osteoporotic fracture
- Can diagnose osteoporosis
- Indication for pharmacologic treatment
  - “A vertebral fracture is consistent with a diagnosis of osteoporosis even in the absence of a bone density diagnosis and is an indication for pharmacologic treatment”¹,²
- Marker of bone fragility – predicts future fracture risk
- Associated with significant morbidity and mortality

¹. NOF Clinicians Guide [www.NOF.org]. ². AACE Guidelines 2020
Morbidity and Mortality
Fractures Are Associated With Disability and Loss of Independence

Impact of Fragility Fractures at Various Sites (Including Hip, Vertebral, Pelvis, Humerus, Wrist)


Admission to nursing home or long-term care facilities

Non-skeletal clinical sequelae, such as chronic pain, depression, and complications from hospitalization

Inability to perform activities of daily living

Reductions in quality of life, including frailty

Worry about falls, future fracture, and potential for nursing home care, which erodes confidence and damages relationships

Burden on patients and caregivers, including lost workdays and wages
Significant Morbidity From Vertebral Fractures

• Restrictive lung disease
  o Each vertebral fracture can decrease pulmonary function as much as 9% \(^3,4\)
  o Lung function (FVC, FEV1) is significantly reduced in patients with thoracic and lumbar fractures \(^5\)

• GI: constipation, abdominal distention, early satiety, weight loss

• Psychosocial – depression, loss of self-esteem\(^1,6\)

\(^1\) Lyles KW *Am J Med* 1993;94:595-60
\(^3\) Harrison RA *J Bone Miner Res* 2007;22(3):447-57
\(^5\) Schlaich, Osteoporosis Int, 1998, 8: 261-67
Vertebral Fractures Are Associated With Increased Mortality

Adapted from Bliuc D, et al. (2009) JAMA 301(5):513

www.iofbonehealth.org
Mortality Rate Increases with the Number of Prevalent Vertebral Fractures

Adapted from Kado DM, et al. (1999) Arch Intern Med 159:1215

www.iofbonehealth.org
Untreated VCFs Result in A Downward Spiral Associated with Increased Morbidity and Mortality

Consequences are independent of acute fracture pain

Silverman – Bone 1992
Evaluation and Management
COVID-19 and Osteoporosis/Fracture Care

• COVID-19 has impacted multiple aspects of osteoporosis care
• Access issues – clinical care, medication administration
• Change in the paradigm of face-to-face visits
• Telehealth transformed into an essential service
• Rapid expansion of virtual care for diagnosis, intervention, ongoing management
Osteoporosis/Post-Fracture Care During COVID-19

- Importance of continuing therapy in patients with established bone health plans
- In patients with new fracture who “require” DXA and lab tests to initiate therapy – consider alternate options to ensure delivery of care
- DXA may not be needed depending on type of fracture (Hip, Spine) or may be delayed
- Use of online risk calculators to aid in decision making (FRAX, Garvan, others)
VCF Treatment Goals

○ Overall treatment goals:
  - Pain relief/management
  - Maintenance of independence and mobility
    ▪ Early mobilization, including bed transfers, ambulation, ADLs
  - Prevention of future fractures
Treatment of Symptomatic Vertebral Compression Fractures

- Non-surgical Management (NSM): medical management
  - Bed rest (for severe pain)
    - Avoid long-term immobilization and recommend partial bed rest (with periodic sitting and ambulating) only when required and for the shortest periods possible.
    - Leads to bone loss and muscle loss
    - Potential complications – DVT/PE, pressure ulcers, infection
  - Pharmacologic treatment
    - Analgesics
    - Opioids
    - Calcitonin
  - Trunk orthoses/Posture support
    - Use of back braces, corsets, or posture training support devices may provide pain relief by reducing the loads on the fracture sites and aligning the vertebra
    - Long-term bracing may lead to muscle weakness and further de-conditioning
  - Physical Therapy
Comprehensive Management Includes Evaluation and Treatment of Osteoporosis

Patients diagnosed with a VCF must also be evaluated for the underlying condition (osteoporosis)

- Bone density testing (DXA) and/or fracture risk assessment
- Evaluation for secondary causes

A comprehensive treatment plan includes:

- Risk reduction counseling
- Calcium and vitamin D
- Pharmacologic therapy
  - Effective therapies are widely available and can reduce vertebral fractures by ~30-80%
- Physical therapy
- Appropriate exercise once mobility returns
TREAT THE UNDERLYING DISEASE: Osteoporosis Treatment Options

• Anti-remodeling agents *(inhibit bone turnover)*
  o Estrogen
  o Estrogen agonist/antagonists (raloxifene)
  o Tissue specific estrogen complex (estrogen/bazedoxifene)*
  o Bisphosphonates (oral and IV)
  o RANK ligand inhibitor (denosumab)

• Remodeling stimulators *(increase formation and resorption)*
  o Parathyroid hormone receptor activators
    ▪ (teriparatide, abaloparatide)

• Modeling stimulator *(increase formation, decrease resorption)*
  o Sclerostin inhibitor (romosozumab)

ALL SIGNIFICANTLY REDUCE THE RISK OF VERTEBRAL FRACTURES*

*No fracture data with CEE/BZD
The Impact of COVID-19 on Interventional Treatment Protocols
Disclosures

Joshua Hirsch, MD FACR FSIR FSNIS
Consultant: Relievant; Medtronic
Grant/Research Support: Neiman Health Policy Institute
VCF and COVID-19

Retrospective cohort study in Milan, Italy

Methods
▪ Retrospective cohort study in Milan, Italy
▪ Assess vertebral fracture (VF) prevalence and clinical impact in COVID-19 patients
▪ N = 114
  ▪ Patients ≥18 years with a confirmed diagnosis of COVID-19 admitted to ER
  ▪ Patients for whom lateral chest x-rays at ED admission were available
    ▪ Only those that allowed high quality assessment were used for analyses
    ▪ Only x-rays in which T4 to T12 was visible
▪ 65 VCFs detected in 41 patients

Results
▪ Patients with VFs were older and more frequently affected by hypertension and coronary artery disease (P < 0.001, P = 0.007, P = 0.034; respectively).
▪ Thirty-six (88%) patients in VFs+ group compared to 54 (74%) in VFs− group were hospitalized (P = 0.08).
▪ Patients with VFs more frequently required noninvasive mechanical ventilation compared with those without VFs (P = 0.02).
▪ Mortality was 22% in VFs+ group and 10% in VFs− group (P = 0.07). In particular, mortality was higher in patients with severe VFs compared with those with moderate and mild VFs (P = 0.04).

Limitations
▪ Retrospective study, does not allow us to evaluate the timing of VFs
▪ Limited number of enrolled patients due to the huge pressure on EDs, which did not allow lateral chest x-rays to be performed in many patients
▪ Lack of a BMD evaluation or vitamin D level assessment to better characterize bone metabolic status.

EVOLVING Elective procedure environment due to COVID19

- Many state governors have issued executive orders and/or put forth guidance relative to elective procedures
- CMS has published elective procedures recommendations
- Several societies have published elective procedure recommendations

*** Healthcare providers determine what procedures are considered elective.

Regulations & recommendations among the states, CMS, and societies are constantly evolving!
CENTER FOR MEDICAID AND MEDICARE SERVICES (CMS)

On April 7th, 2020 published its modified recommendations for:
• Non-Emergent Services
• Elective Services
• Treatment Recommendations

Decisions remain the responsibility of local healthcare delivery systems, including:

- state and local health officials,
- those clinicians who have direct responsibility for their patients.

*Federally Qualified Health Care/ Rural Health Clinics

**Hospital Outpatient Department

***If a practice can provide only limited well child visits, healthcare providers are encouraged to prioritize newborn care and vaccination of infants and young children (through 24 months of age) when possible (see also CDC guidance for further information): [https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html](https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html)

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ASSR Adult Interventional Procedure Triage Recommendation during COVID-19 Pandemic & PPE Shortage

<table>
<thead>
<tr>
<th>Tiers/Description</th>
<th>Definition</th>
<th>Locations</th>
<th>Procedure Suggestions</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1a</td>
<td>Low acuity procedure/healthy patient Outpatient Procedure Not Life-threatening illness</td>
<td>OBL HOPD ASC Hospital with low/no COVID census</td>
<td>Trigger point, epidural/facet, Sympathetic nerve, and MSK injections, Myelogram, Discogram, MSK radiofrequency ablation procedures, Arthrogram studies</td>
<td>Postpone procedure</td>
</tr>
<tr>
<td>Tier 1b</td>
<td>Low acuity procedure/unhealthy patient</td>
<td>OBL HOPD ASC Hospital with low/no COVID census</td>
<td>Interventional headache procedures</td>
<td>Postpone procedure</td>
</tr>
</tbody>
</table>

*Repeated office calls, 1 ED visit, or prolonged Inpatient Admission.
+ After multi-disciplinary consensus
OBL = Office-Based Laboratory, HOPD = Hospital Outpatient Department, ASC = Ambulatory Surgery Center
Adapted and modified from Sameer Siddiqui MD, FACS, St. Louis University at American College of Surgeons and CMS.
For more information, visit: [https://www.theassr.org/](https://www.theassr.org/)

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<th>Procedure Suggestions</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 2a</td>
<td>Intermediate acuity procedure/healthy patient</td>
<td>HOPD, ASC</td>
<td>Spinal cord / Peripheral Nerve stimulator trial/implantation, Lumbar spinal stenosis decompression/implantation, Basivertebral nerve ablation, SIJ fusion</td>
<td>Postpone procedure/surgery</td>
</tr>
<tr>
<td></td>
<td>Not life threatening but potential for future morbidity and mortality.</td>
<td>Hospital with low/no COVID census</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Requires in hospital stay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 2b</td>
<td>Intermediate acuity procedure/unhealthy patient</td>
<td>HOPD, ASC</td>
<td>Pain pump trial/implantation</td>
<td>Postpone procedure/surgery</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hospital with low/no COVID census</td>
<td></td>
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### ASSR Adult Interventional Procedure Triage Recommendation during COVID-19 Pandemic & PPE Shortage

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<th>Locations</th>
<th>Procedure Suggestions</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 3a</td>
<td>High acuity procedure/healthy patient</td>
<td>OBL, HOPD, ASC, Hospital</td>
<td>Kyphoplasty/Vertebroplasty/Sacroplasty, Epidural/Facet/Interventional Headache injections*</td>
<td>Do not postpone</td>
</tr>
<tr>
<td>Tier 3b</td>
<td>High acuity procedure/unhealthy patient</td>
<td>Hospital</td>
<td>Intrathecal pump / implant infection, Infection drainage, Tumor biopsy/ablation†</td>
<td>Do not postpone</td>
</tr>
</tbody>
</table>

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American College of Surgeons (ACS)

The American College of Surgeons issued guidelines and a checklist to help manage elective procedures.

“Knowing your community’s COVID-19 numbers, including prevalence and incidence rates, as well as local isolation mandates, will help dictate timing of ramp up.”

NASS convened a multidisciplinary task force of orthopedic surgeons, neurosurgeons and PM&R/pain specialists to provide spine-care specific guidance for procedures.
American Society of interventional pain physicians (ASIPP)


VCF MORTALITY RISK

NUMBERS NEEDED TO TREAT

This study was a retrospective database analysis using U.S. Medicare claims data (2005-2014). NNTs were calculated by comparing propensity-score adjusted survival rates for balloon kyphoplasty (BKP), vertebroplasty (VP), and nonsurgical management (NSM) groups between 1 to 5 years following the VCF diagnosis.

Link to AJNR:
http://www.ajnr.org/content/early/2019/12/26/ajnr.A6367

The study reported that to avoid risk of one additional death, the estimated number needed to treat (NNT*) varied, as shown below:

<table>
<thead>
<tr>
<th></th>
<th>BKP vs NSM</th>
<th>VP vs NSM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>14.8 (Year 1)</td>
<td>22.8 (Year 1)</td>
</tr>
<tr>
<td></td>
<td>11.9 (Year 5)</td>
<td>23.8 (Year 5)</td>
</tr>
</tbody>
</table>

~ 15 patients would need to be treated with BKP to avoid one additional death at the end of 1-year follow up relative to those treated with NSM.

~ 23 patients would need to be treated with VP to avoid one additional death at the end of 1-year follow up relative to those treated with NSM.

LIMITATIONS
This population may not be representative of an individual provider’s case mix and therefore may not represent survival probabilities and associated NNTs for that specific practice.

* NNT is a biostatistical term, representing the number of patients that need to be treated to avoid one additional adverse outcome as compared to the control treatment. Mathematically, the NNT is calculated as: NNT = 1 / (Control Event Rate - Experimental Event Rate)
