

### Osteoporosis Assessment Using DXA and Instant Vertebral Assessment Clay County Hospital Working Together For A Healthier Community Big HealthCare\*\*





## Osteoporosis The Silent Thief



### **The Facts About Osteoporosis**

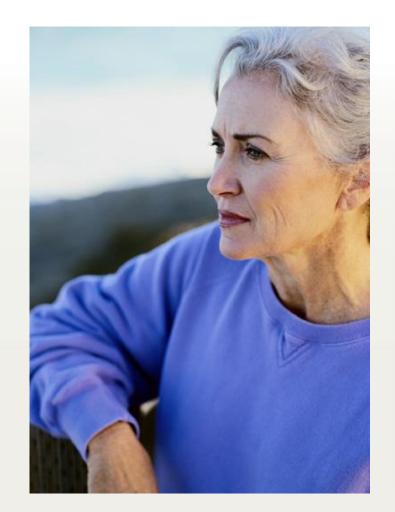
- 1 in 2 women will develop osteoporosis
- 60,000 deaths annually due to complications from osteoporosis
- This is more than breast and cervical cancers combined
  - 40,000 from breast cancer
  - 4,000 from cervical cancer





# The Osteoporosis Epidemic

- Every 3 minutes someone has a fracture due to osteoporosis
- 30 million American women at risk
- 300,000 hip fractures per year
  - 20% mortality within 1 year
  - 50% never regain independence





## What is Osteoporosis?

- Osteoporosis is a systemic skeletal disease characterized by low bone mass and micro architectural deterioration, with a consequent increase in bone fragility with susceptibility to fracture\*
- How is osteoporosis measured?
  - Bone density T-score ≥ 2.5 SD below young normal mean†



\*Consensus Development Conference: Diagnosis, prophylaxis, and treatment of osteoporosis, *Am J Med* 1993;94:646.



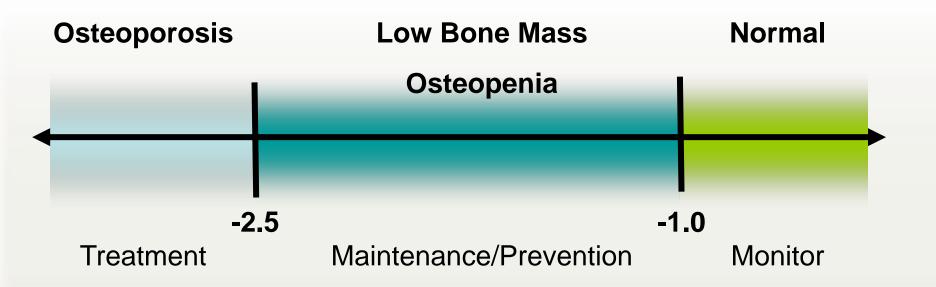
<sup>†</sup>Kanis JA et al, *J Bone Miner Res* 1994;9:1137.

## Who is at Risk?

- Early menopause, surgical menopause
- Low body weight compared to height
- Diet low intake of milk products and lack of vitamin D
- Life-style factors: cigarette smoking, caffeine, alcohol abuse, lack of exercise
- Drugs and diseases, corticoseroid treatment, hyperthyroidism, anorexia nervosa, amenorrhoea, arthritis
- Genetic factors (family history, race)



## Assessing Risk Through BMD Measurement

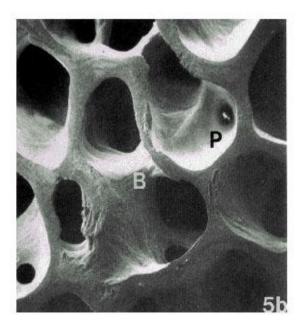


### **Know Your T-Score!**

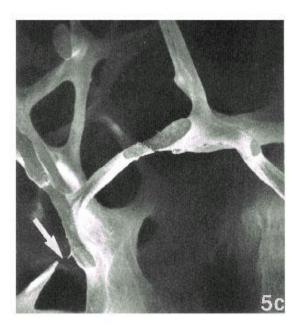


## Normal and Osteoporotic Bone Architecture

#### Normal Bone



#### **Osteoporotic Bone**

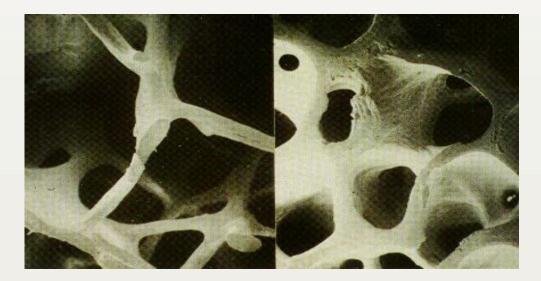


Reproduced from *J Bone Miner Res* 1986;1:15-21 with permission of the American Society for Bone and Mineral Research. © 1986 by Massachusetts Medical Society. All rights reserved.



### **Bone Metabolism**

- Bone is made up of:
  - Trabecular (spongy)
  - Cortical (compact)

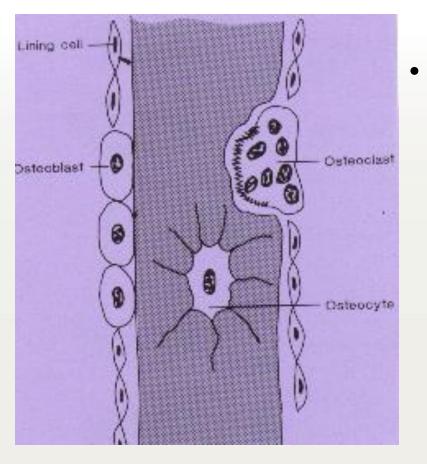


#### Osteoporotic





### **Bone Metabolism**



SKELETAL LIFE AT THE CELLULAR LEVEL

Consists of Two Processes:

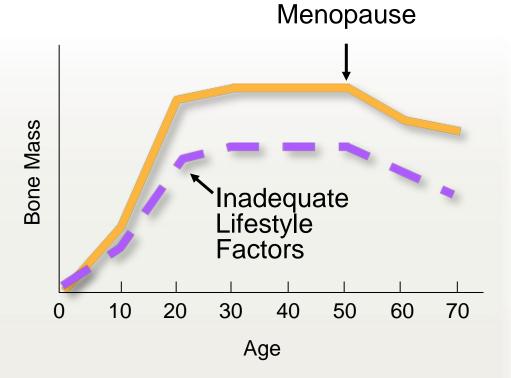
- bone resorption (osteoclasts)
- bone formation (osteoblasts)

#### THE LIVING SKELETON



## **Peak Bone Mass**

- Bone remodeling continues throughout life even after the cessation of growth
- The skeleton reaches peak bone mass between age 25 and 40 depending on the site in the body





#### **Bisphosphonates**

- Alendronate (Fosomax<sup>™</sup> Merck)
  - One weekly dose
  - Slows bone resorption/fracture reduction
  - GI problems/ not absorbed well
  - Generic, 2/08
- Risedronate (Actonel<sup>™</sup> P&G)
  - One weekly dose
  - Slows bone resorption/fracture reduction
  - GI problems/ not absorbed well





#### Bisphosphonates (cont.)

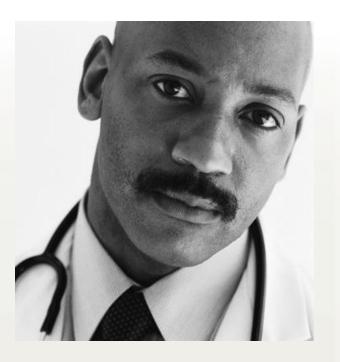
- Ibandronate (Boniva<sup>™</sup> Roche)
  - One Monthly dose (New Quarterly Dose)
  - Slows bone resorption/fracture reduction
  - GI problems/ not absorbed well
- Zoledronic Acid (Reclast<sup>™</sup> Novartis)
  - Once a year infusion
  - Slows bone resorption/fracture reduction of all clinical sites
  - Approved for postmenopausal women only at this time





#### Estrogen

- Maintenance drug
- Reduces risk of cardio-vascular problems / stroke
- Controversy Women's Health Initiative
- Raloxifene (Evista<sup>™</sup> Lilly)
  - SERM designer Estrogen
  - Reduced fracture risk
  - Maintenance drug





- Teriparatide (Forteo<sup>™</sup> Lilly)
  - Injectable pen that requires refrigeration
  - Synthetic parathyroid hormone
  - Yearly treatment (10K / year)
  - Stimulates bone growth
- Calcitonin<sup>™</sup> (Sandoz)
  - Well tolerated
  - Low turnover only



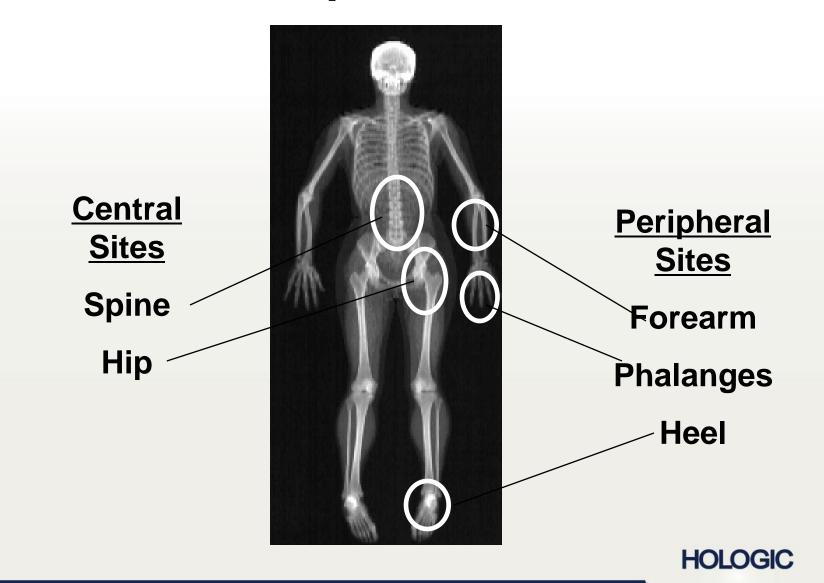




## Osteoporosis Assessment Technology Overview



#### **Central vs. Peripheral Measurements**



#### **Types Of Densitometry Instrumentation**

- 1. Dual Energy X-ray Absorptiometry (DXA)
  - central or peripheral sites (pDXA)
- 2. Single Energy X-ray Absorptiometry (SXA)
  - peripheral sites only low usage
- 3. Quantitative Ultrasound (QUS)
  - peripheral sites only
- 4. Quantitative Computed Tomography (QCT)
  - Central sites or peripheral sites low usage



## Central vs. Peripheral BMD Measurements

- Hip and spine the "Gold Standard" for Diagnosis
- Hip and spine the "Gold Standard" for Monitoring of BMD changes
- Peripheral measurements useful for risk assessment, but not preferred
- Peripheral measurements NOT RECOMMENDED for Monitoring of BMD changes
- BMD and Vertebral Assessment (IVA) is the standard of care



## **DXA: The Gold Standard**

- Detects early bone loss and monitors therapeutic effectiveness
- Measures axial skeletal sites where early bone loss occurs
- High precision (<1.0%)
- Low patient dose
- High-resolution imaging



### Sahara Heel Ultrasound

- Radiation-free
- Dry technology
- Light weight, portable (22 lbs.)
- Rapid assessment (<10 sec)
- Utility:
  - Risk assessment w/o DXA
  - Screening for DXA
  - Ideal for smaller practices





#### Hologic DXA: True Linear Fan-beam Scanning

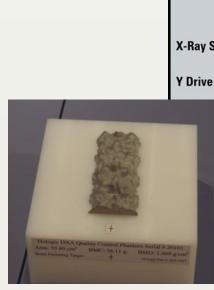




#### Hologic DXA: True Linear Fan-beam Scanning

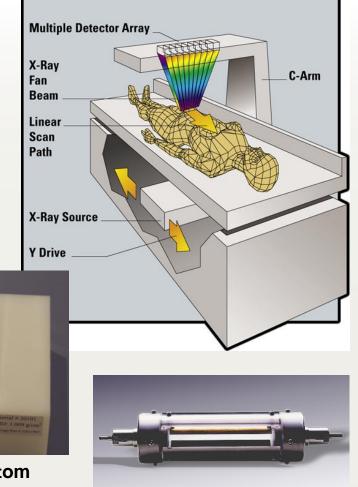
#### **One Pass Technology**

- Single sweep scanning
- CT based acquisition geometry
- Digital image processing for all scan modes
- Continuous calibration
- Anthropomorphic spine phantom



#### **Spine Phantom**

#### FAN BEAM Multiple Detectors



## W.H.O. Classification

#### World Health Organization

T-scores are used to decide whether a patient has reduced BMD consistent with osteoporosis and osteopenia.

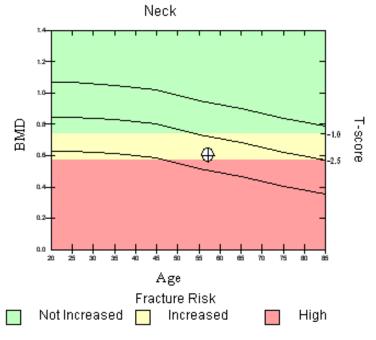
T-score	Classification
T< -1.0 SD	Normal
-1.0 SD <t< -2.5="" sd<="" td=""><td>Osteopenic</td></t<>	Osteopenic
T < -2.5 SD	Osteoporotic

**For every SD of decline, fracture risk increases 2-3x!** —World Health Organization (W.H.O.)



### **BMD Test Results**

- BMD=g/cm<sup>2</sup> of bone mineral
- Z-scores normalize a patient's BMD by assessing the amount of bone loss compared to the expected loss for age-matched peers
- T-scores indicate the amount of bone loss, by quantifying the difference between a patient's BMD at his/her current age, and the peak bone mass for young normals



T-score vs. White Female; Z-score vs. White Female. Source:NHANES

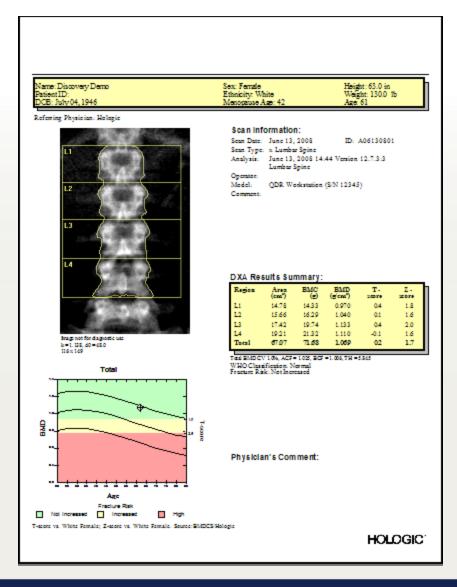


## **Hologic DXA: Femur Report**

Name: Discovery Demo	Sex: Ferrale Height: 63.0 in
Patient D: DCB: July 04, 1946	Ethnicity: White Weight 130.0 fb Menograve Age: 42 Age: 60
Referring Physician: Hologic	10000000000
Actor by Physician. Adding to	Scan Information: Scan Date: January 02, 2007 ID: A01020701 Scan Type: x Left Hip Analysin: January 02, 2007 12:24 Version 12:6.1:3 Left Hip Operator: mab Model: QDR: Workstation (SIN 80000) Comment:
	DXA Results Summary:           Region         Area         BMC         BMD         T.         Z.           (cm)         (c)         (cm)         1000         1000         2000           Neck         453         353         0.754         -0.9         0.4           Total         20.06         25.24         0.668         0.6         0.4           Test SMDCV 10%, ACF=102, BCF=1.066, TH=5.135         WHO Classification: Normal         Fracture Rak. Not Increased
Neck	Physician's Comment:
Not increased Increased High T-score vs. White Female; Z-score vs. White Female; Z-score vs. White Female. Source: SMDCS	INGLANES
	HOLOGIC



## **Hologic DXA: AP Spine Report**







## Hologic The Gold Standard in Osteoporosis Assessment





## BMD and Vertebral Fracture Assessment



#### Why Aren't Vertebral Fractures Commonly Considered in Osteoporosis Assessment?

- Most fractures are asymptomatic
  - <1% of back pain episodes due to Vertebral Fracture (Ettinger, 1996)
- Height loss is difficult to assess
- Radiographs are infrequently ordered
  - Not available at point of care
  - High radiation dose (800 mRem typical)
  - Difficult to identify appropriate candidates
- Only 20 25% of Vfx are recognized clinically (Ensrud 1999)



#### Why is Vertebral Fracture Assessment Necessary?

- Combined BMD/Fracture Assessment is the standard of care
- 20 25% of postmenopausal women have fractures
- 30% of women needing treatment are missed without IVA
- New ISCD Training and Clinical Guidelines
- New WHO Guidelines Require FX Information



## **Clinical Relevance of BMD and IVA**

- Knowledge of the presence of a fracture is a strong indicator of risk
- Often impossible to know that fractures are occurring until it's too late
- The presence of vertebral fracture, combined with BMD, provides superior prediction of fracture risk
- Very low radiation dose (1% of conventional radiographs)
- Captures entire spine in one 10-second scan



## Industry Momentum

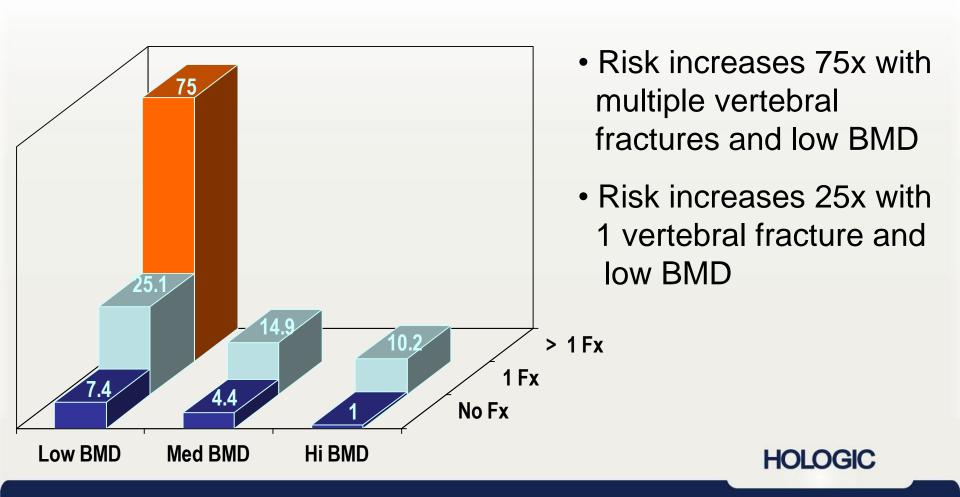
- Approved drugs are now available for prevention and treatment of osteoporosis
- At least 45 companies are currently developing additional therapies
- Increased attention to women's health
- Increased focus on "graying of America"
- Increased focus on disease prevention

A woman is at least <u>3X more likely</u> to comply with hormonal therapy if she has knowledge about her bone mass.

-Silverman, Greenwald et. al Ob/Gyn V89, 1997 3(321-325).



#### Integration of Vertebral Fracture and BMD Improves Risk Assessment



#### National Osteoporosis Foundation Guidelines for Patient Evaluation (1999)

Evaluating Fracture Risk Known Vertebral Fracture? NO **fx:** Bisphosphonates Willing to Consider Treatment? Alendronate Risedronate YES NO Calcitonin ET/HT AGE Parathyroid Hormone Calcium Vertebral Raloxifene Exercise Smoking Cessation > 65 **Fracture: Risk Factors** The key factor NO Calcium Measure Hip in patient BMD Exercise Smoking Cessation evaluation **BMD** Optional

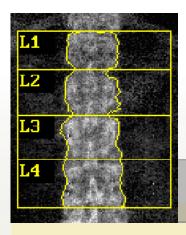
**DGIC** 

# IVA Opportunity Clinical Importance is Accepted

- <u>Prevalence</u>: 20 25% of postmenopausal women have fractures
- <u>Mis-classification</u>: 30% of women needing treatment are missed without IVA
- <u>High Re-fracture Rate:</u> 20% will re-fracture within one year
- <u>Effective Therapies Exist</u>: Treatment reduces fracture risk in these women by 50% in the first year!
- <u>Value in Patient Counseling</u>: Showing the patient a fracture has great value
- <u>Standard of Care :</u> IVA / BMD assessment is the established standard of care



### **Case Study: BMD and IVA**



#### 70 year-old female

- AP spine T-score = -1.0 (osteopenia)
- L2 wedge deformity subsequent to baseline IVA evaluation
- Fracture indicates increased risk, need for more aggressive therapy





## **Clinical Implications**

• If this woman's doctor had been able to identify her first fracture ...

• Perhaps the rest of her fractures could have been prevented







### Instant Vertebral Assessment and Abdominal Aortic Calcifications



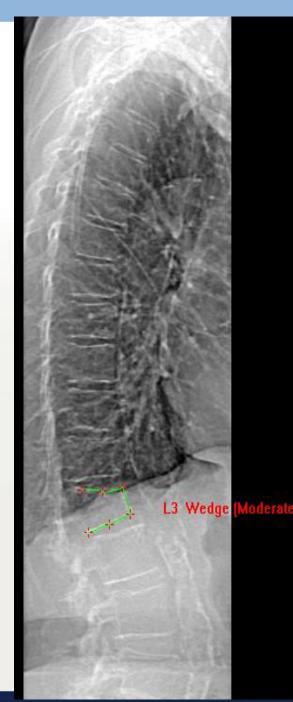
#### **DXA** with IVA HD



- Point of Care
  - Assessment:
    - BMD
    - -VFA
    - Aortic
       Calcification

Global ROI Bone Map	A04100102 fLett Hip	Patient Data         Global         Rol           Scan Date:         04/10/2001 19 30         Rol         Rol           Name:         Smith, Jane A         Bene Map         Image: Sex:         F           Patid         Sex:         F         Venteral         Image: Sex:         F           Birthdate:         02/13/1940         Age:         61         Unes         Image: Sex:         F
Results		Height Weight Results
Results Toolbox	Left Hip Analysis Image not for diagnostic use k=1.136 d0=47.2 t=5.028 TOTAL BMD CV 1.0%	
		C.F. 1.025 1.006 1.000 Include Region Area(cm?) BMC(q) BMD(q)cm?) Exclude
		Neck 545 4.82 0.884
		Troch 12.25 9.04 0.738
		Inter 21.94 23.90 1.069
		TOTAL 39.64 37.75 0.952
Auto Analyze		Ward's 1.13 0.82 0.722 Auto Analyze
	112×111	QDR Workstation SN: 50000
Close	Single Energy	Version 11.1 :3 04/10/2001 19:30 Close

00101 fLumbar Spine	- Patient Data Scan Date: 04/10/2001 19:29
	Name Smith, Jane A Pat Id Sex F Bindate: 02/13/1940 Age 61 Height: Weight Ethnic: White Lumber Spine Analysis Image not or diagnostic use ket 131. dbc4/26. the 727
	TOTAL BMD CV for L1-L4 10%           C.F.         1.025         1.006         1.000           Region         Area(cm?)         BMC(g)         BMD(g/cm?)           L1         13.61         11.77         0.865           L2         14.56         13.25         0.910           L3         15.87         14.50         0.914           L4         18.41         17.13         0.830           TOTAL         62.45         56.65         0.907
116 x 140 Single Energy	QDR Workstation SN 50000 Version 11.1 :3 04/10/2001 19:34
,	Help 04/10/2001 19:



#### AAC and Discovery

#### Improves Patient Health

- Doubles clinical utility of IVA (Osteoporosis and Cardiovascular)
- Performed on target population (> age 55)
- Allows intervention before being symptomatic

#### Improves Practice ROI

- Significant risk factor for further evaluation
- Stress test >> Carotid ultrasound >> CT Calc Scoring >> CT Angio
- AAC > 20x more likely +CA score by CT



#### Abdominal Aortic Calcification New Links to Fracture Risk

Osteoporos Int DOI 10.1007/s00198-006-0255-2

ORIGINAL ARTICLE

Links between cardiovascular disease and osteoporosis in postmenopausal women: serum lipids or atherosclerosis per se?

Y. Z. Bagger • H. B. Rasmussen • P. Alexandersen • T. Werge • C. Christiansen • L. B. Tankó • PERF study group

Received: 18 August 2006 / Accepted: 9 October 2006 © International Osteoporosis Foundation and National Osteoporosis Foundation 2006

#### Abstract

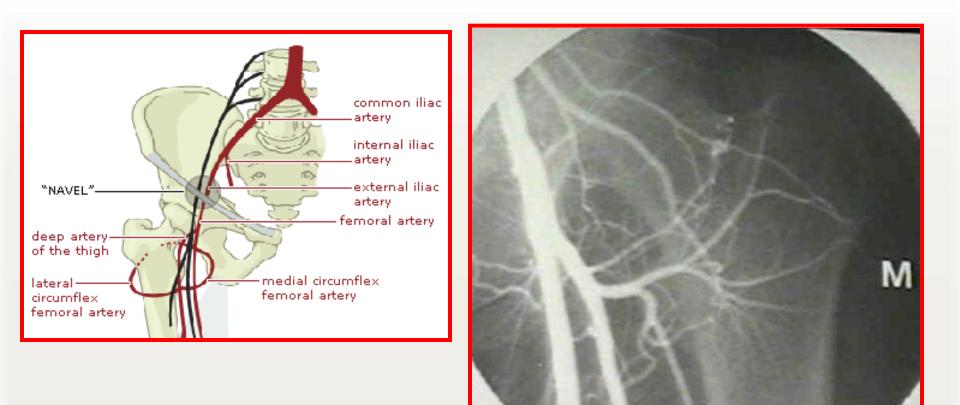
Introduction and hypothesis Epidemiological observations suggest links between osteoporosis and risk of acute cardiovascular events and vice versa. Whether the two clinical conditions are linked by common pathogenic factors or atherosclerosis per se remains incompletely understood. We investigated whether serum lipids and polymorphism in the ApoE gene modifying serum lipids could be a biological linkage.

Methods This was an observational study including 1176

lipid components were independent contributors to the variation in spine or hip BMD. When comparing the women with or without vertebral fractures, serum triglycerides showed significant differences. This finding was however not applicable to hip or wrist fractures. After adjustment for age, severe AC score (≥6) and/or manifest cardiovascular disease increased the risk of hip but not vertebral or wrist fractures. *Conclusion* The contribution of serum lipids to the modulators of BMD does not seem to be direct but rather indirect via promotion of atherosclerosis, which in turn can affect

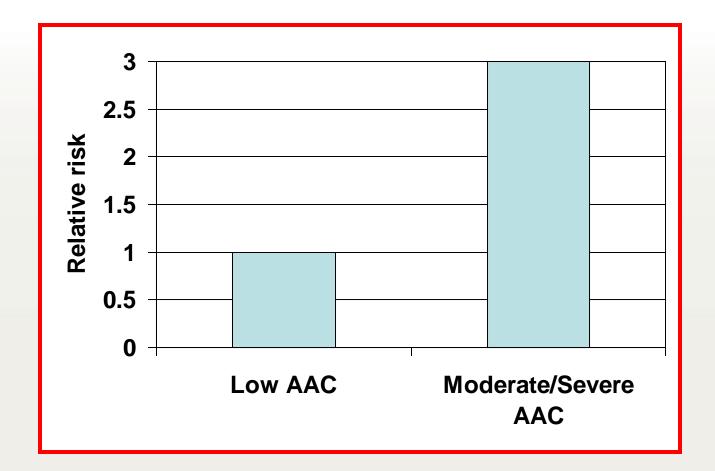
#### GIC

#### Abdominal Aortic Calcification New Links to Fracture Risk





#### Moderate/Severe AAC 3X Risk for Hip Fracture

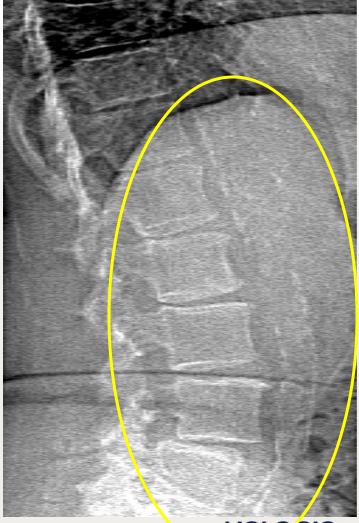




#### AAC Case Study 3

- 76 Year Old Caucasian Female,Weight 135 Ibs.,Current Height 66", 1" Height Loss Since Age 25
- Previous Non-Vertebral FX
- T-Score
  - -1.4 Neck
  - -1.2 Total Hip
  - -0.1 Spine L1-L4

Severe AAC (AAC = 6 on 8 point Scale)





#### Osteoporosis Can Be Prevented!





