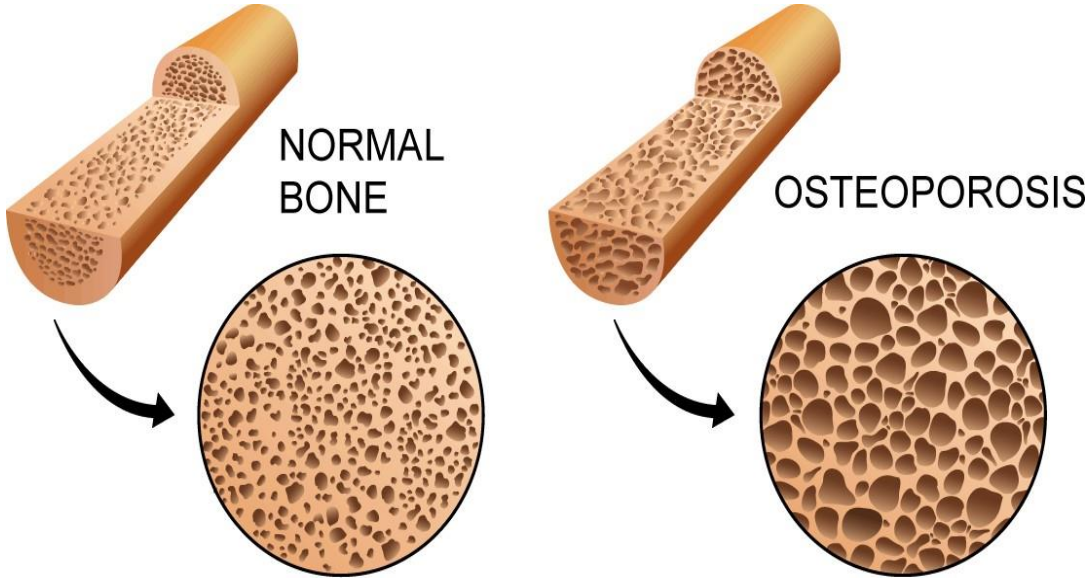
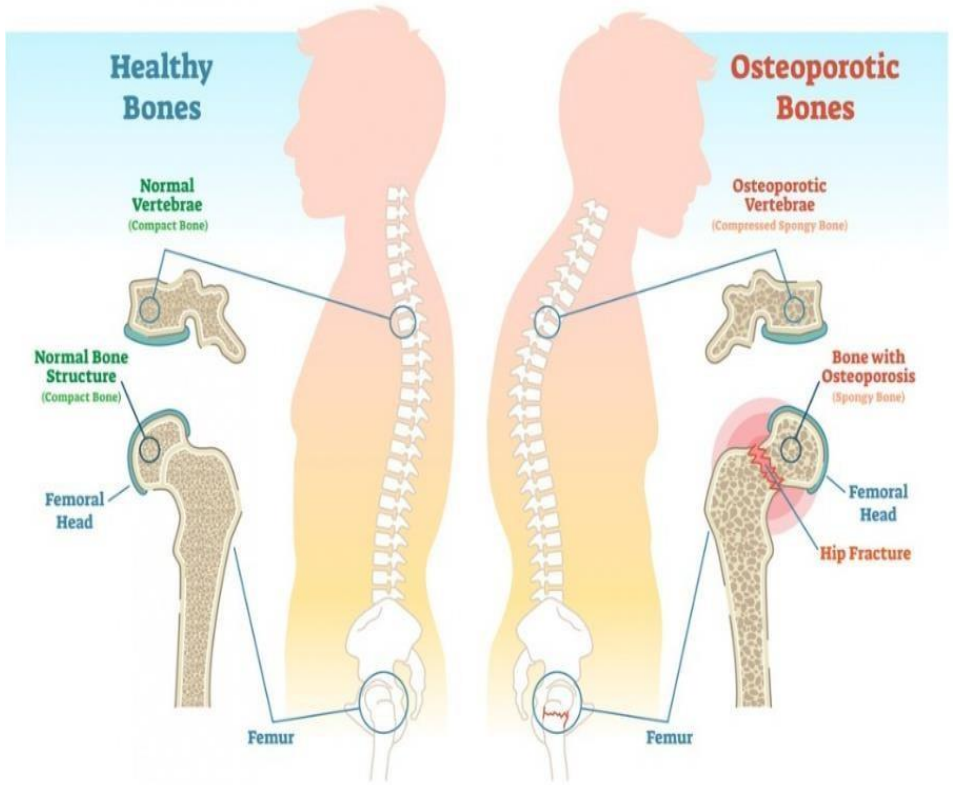
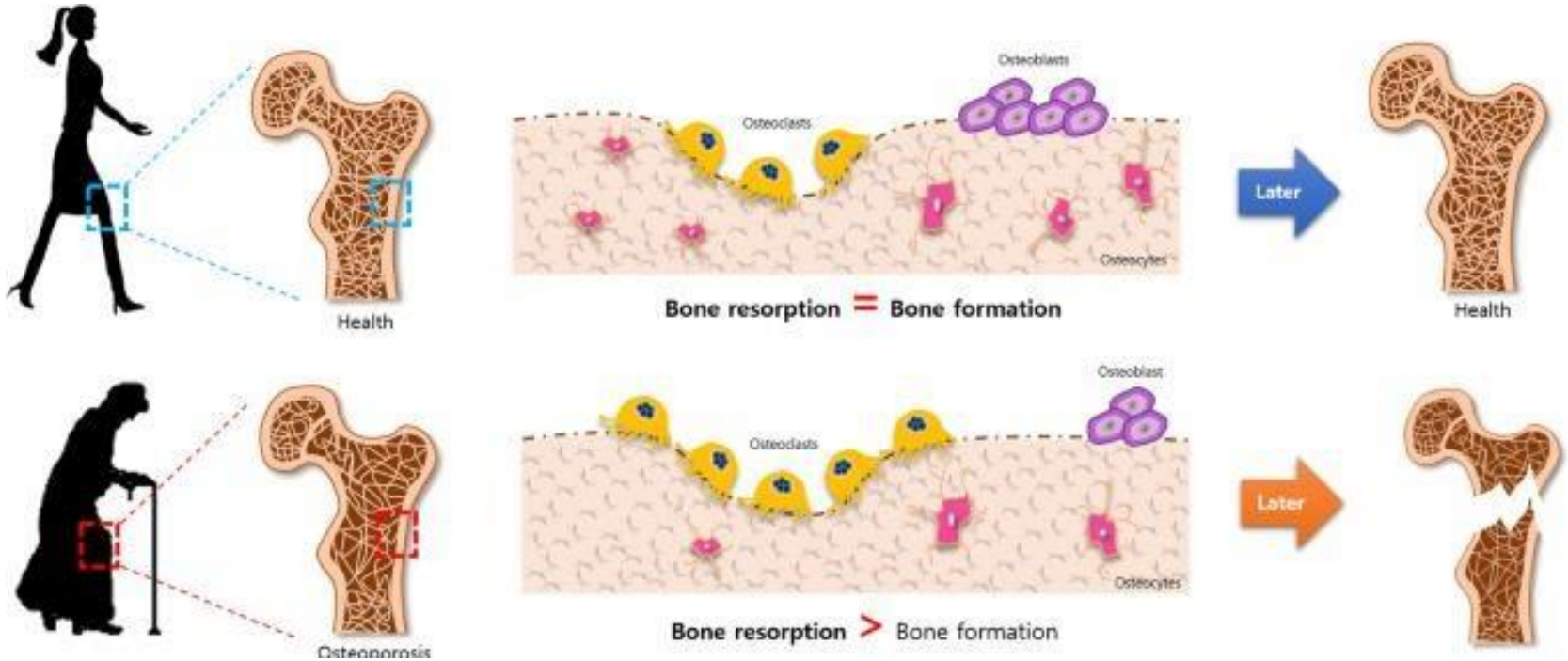

label
البرنامج التدريبي لإعداد الصيادلة

OSTEOPOROSIS





- Osteoporosis typically results from an imbalance between **osteoblasts** (cells that build bone mass) and **osteoclasts** (cells that remove old bone)



Bone Density Test

- A bone density test is the only test that can diagnose osteoporosis before a broken bone occurs.
- This test helps to estimate the density of bones and chance of breaking a bone.
- NOF recommends a bone density test of the hip and spine by a central DXA machine to diagnose osteoporosis.
- DXA stands for dual energy x-ray absorptiometry.

Based on T-scores (T-score indicates that for every standard deviation [SD] below the mean young adult bone mineral density [BMD], fracture risk increases 2-fold)

1. Normal = BMD within 1 SD of the young adult mean.
2. Low bone mass (osteopenia) = BMD 1–2.5 SD below the young adult mean (often seen as T-score between -1 and -2.5).
3. Osteoporosis = BMD at least 2.5 SD below the young adult mean (often seen as T-score of less than -2.5).

B. Guidelines

1. Risk factors for osteoporotic fractures

    a. Female sex

    b. White race

    c. Poor nutrition, long-term low-calorie intake

    d. Early menopause (before age 45 (before age 40 based on AACE/ACE)) or prolonged premenopausal amenorrhea

    e. Estrogen deficiency

    f. Drugs: glucocorticoids, heparin, anticonvulsants, excessive levothyroxine, gonadotropin-releasing hormone (GnRH) agonists, lithium, cancer drugs

    g. Low body mass index (BMI) or low weight

i. Low calcium and vitamin D intake

j. Sedentary lifestyle, decreased mobility

k. Cigarette smoking

l. Alcoholism

m. Dementia

n. Impaired eyesight despite adequate correction

o. Previous fractures

p. History of falls

2. Recommendations

a. Advise patient to avoid smoking and to consume only moderate amounts of alcohol.

b. Encourage regular weight-bearing and muscle-strengthening exercise.

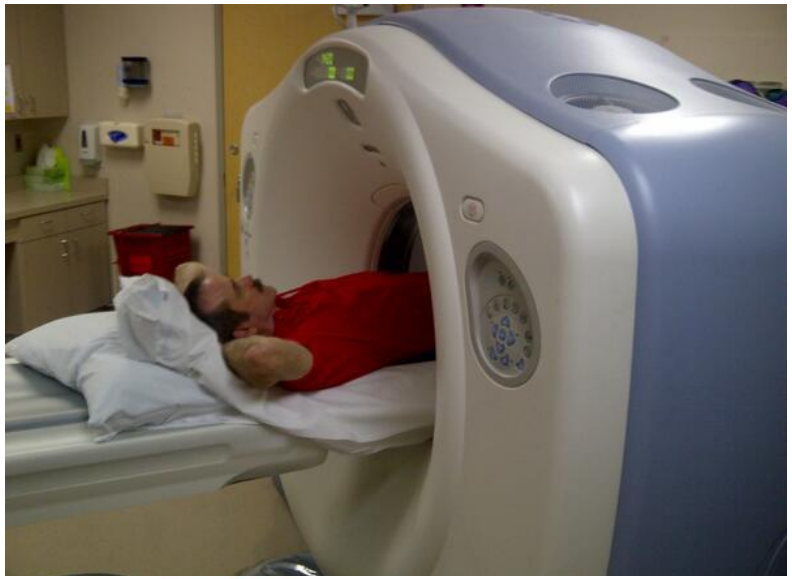
c. Encourage adequate intake of calcium (at least 1000 mg/day) and vitamin D (800–1000 international units/day) according to the NOF guidelines, or 600 international units/day for those younger than 70 years and 800 international units/day for 70 years or older according to the Institute of Medicine (IOM).

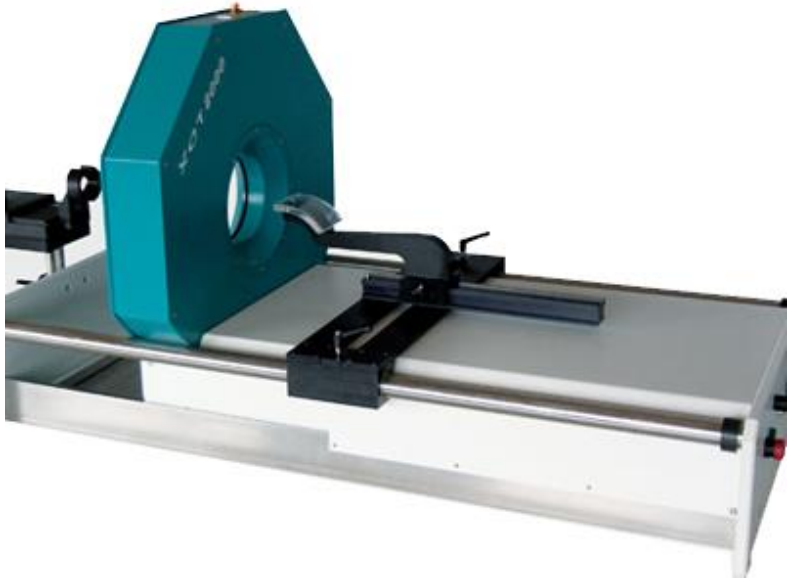
d. Assessment

i. Dual-energy x-ray absorptiometry (DXA): Gold standard, measures hip or lumbar spine BMD

ii. Quantitative computed tomography (QCT): Measures volumetric BMD of lumbar spine

iii. Peripheral DXA (pDXA) and peripheral QCT (pQCT): Not appropriate for monitoring





iv. **Vertebral imaging**: Used to identify vertebral fractures because they are often asymptomatic

(a) All women 70 years or older and men 80 years or older with BMD T-score of –1.0 or less at spine, total hip, or femoral neck

(b) Women 65–69 years and men 70–79 years if BMD T-score is –1.5 or less at spine, total hip, or femoral neck

(c) Postmenopausal women or men 50 and older with the following risk factors

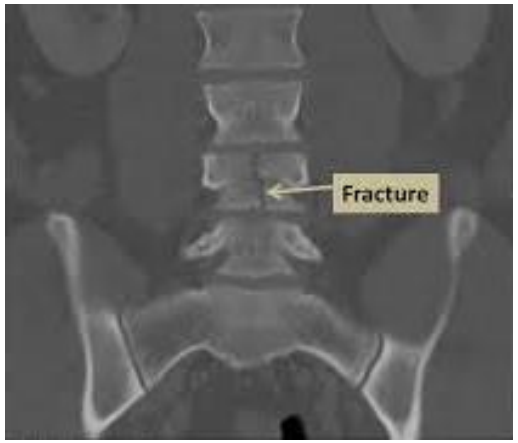
(1) Low-trauma fracture as an adult (age 50)

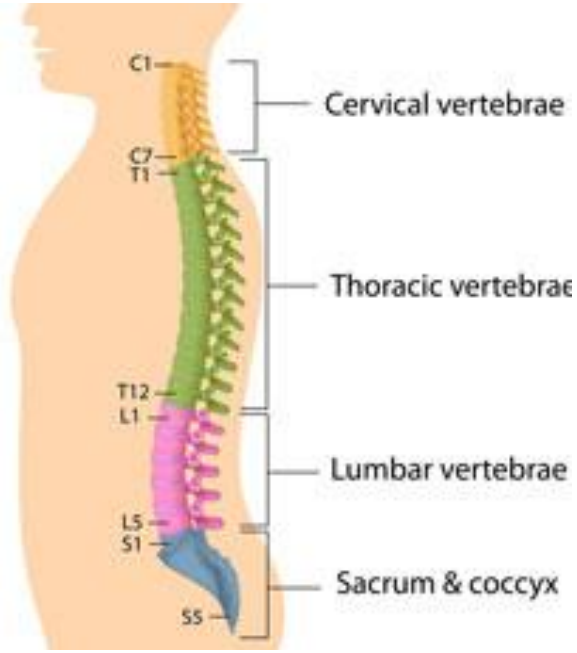
(2) Historical height loss of 4 cm or more (since peak in adulthood)

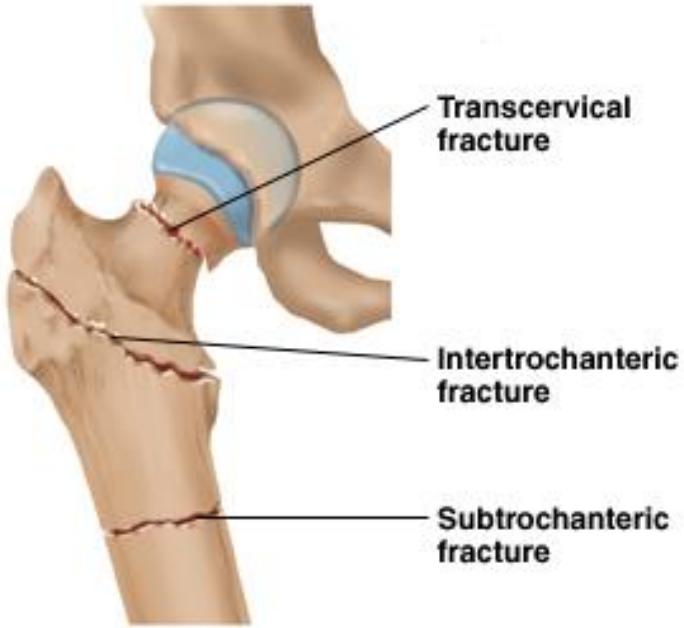
(3) Prospective height loss of 2 cm or more (measured at medical assessments)

(4) Recent or ongoing long-term glucocorticoid treatment

(d) Follow-up needed only if new back pain or further height loss is documented







v. FRAX score (www.sheffield.ac.uk/FRAX/tool.jsp)

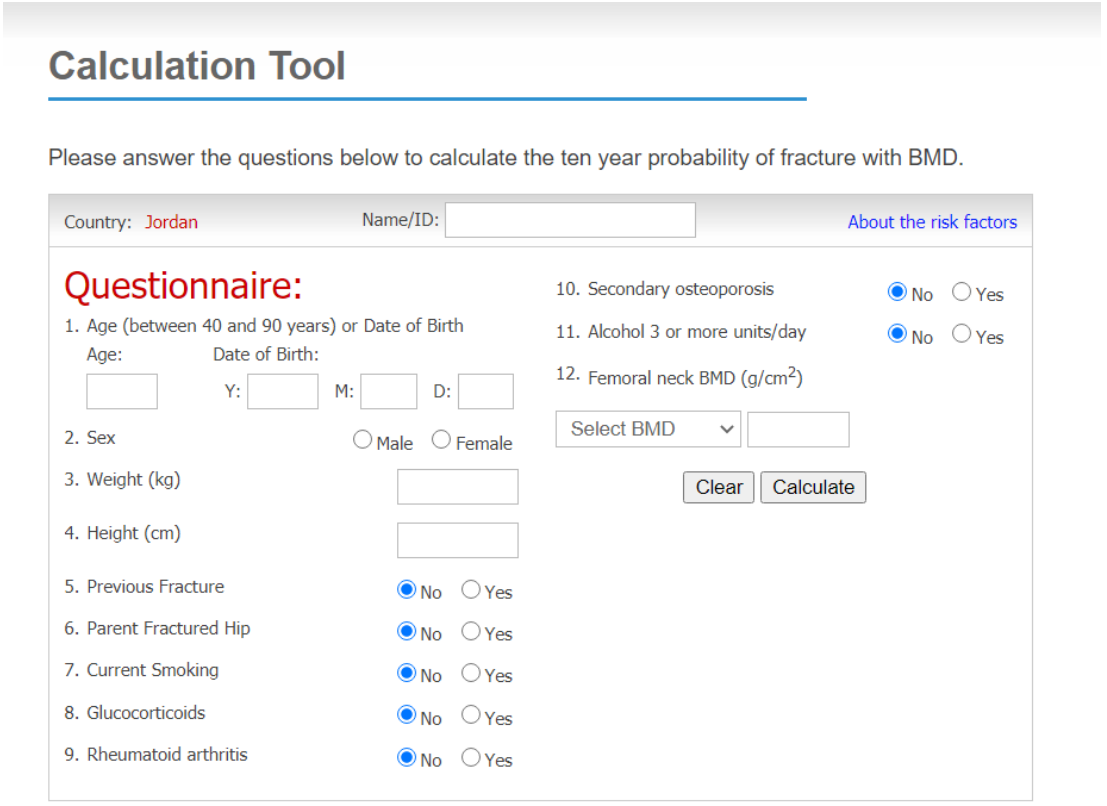
(a) Used to estimate fracture **risk**

(b) Most useful to estimate for patients with **low BMD of hip**

(c) Recommended for postmenopausal women and men 50 years or older but validated in women 40–90 years of age

(d) Useful to determine whether patients with low bone mass (osteopenia) need pharmacologic treatment

(e) Not validated for patients on drug therapy for osteoporosis



Calculation Tool

Please answer the questions below to calculate the ten year probability of fracture with BMD.

Country: Jordan Name/ID: About the risk factors

Questionnaire:

1. Age (between 40 and 90 years) or Date of Birth
   Age: Date of Birth: Y: M: D:
2. Sex — Male / Female
3. Weight (kg)
4. Height (cm)
5. Previous Fracture — No / Yes
6. Parent Fractured Hip — No / Yes
7. Current Smoking — No / Yes
8. Glucocorticoids — No / Yes
9. Rheumatoid arthritis — No / Yes
10. Secondary osteoporosis — No / Yes
11. Alcohol 3 or more units/day — No / Yes
12. Femoral neck BMD (g/cm^2)

Select BMD

Clear Calculate

e. Recommended BMD testing

i. **All women** 65 years and older, **men** older than 70

ii. Men 50–69 years of age with previous fractures or risk factors such as delayed puberty, hypogonadism, hyperparathyroidism, hyperthyroidism, or chronic obstructive pulmonary disease; drugs such as glucocorticoids or GnRH agonists; alcohol abuse or smoking; or other causes of secondary osteoporosis

iii. All postmenopausal women with medical causes of bone loss

iv. Postmenopausal women younger than 65 years with at least one of the following:

(a) Previous fracture after menopause other than skull, facial bone, ankle, finger, or toe; thinness; history of hip fracture in a parent; current smoking; rheumatoid arthritis, alcohol intake of 2 units/day or more.

(b) With any risk factor listed before, Previous fracture not caused by severe trauma after age 40–45

(c) Thinness, family history of spine or hip fracture

(d) Low bone mass (osteopenia) identified radiographically

(e) Starting or taking long-term systemic glucocorticoids for 3 months or longer

Medical causes of bone loss

- Rheumatoid Arthritis and Other Rheumatological Conditions.
- Malabsorption Syndromes.
- Sex Hormone Deficiency (Hypogonadism).
- Primary Hyperparathyroidism.
- Chronic Kidney Disease.
- Chronic Liver Disease.
- Diabetes.
- Chronic Obstructive Pulmonary Disease (COPD)

f. Initiation of drug therapy

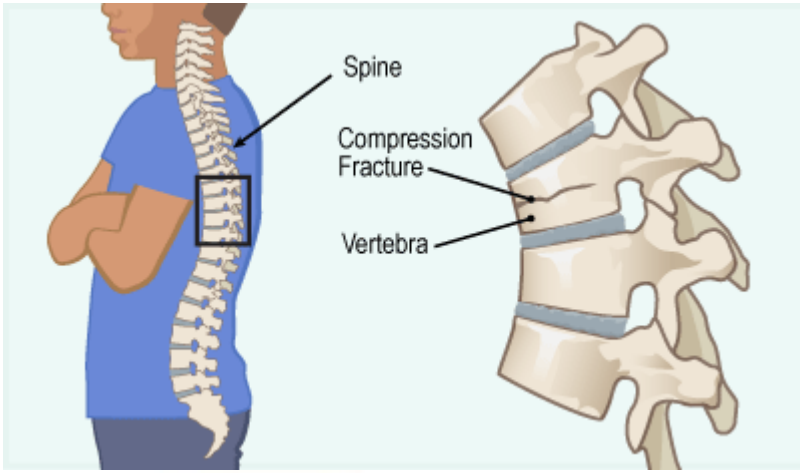
i. If hip or spine fracture

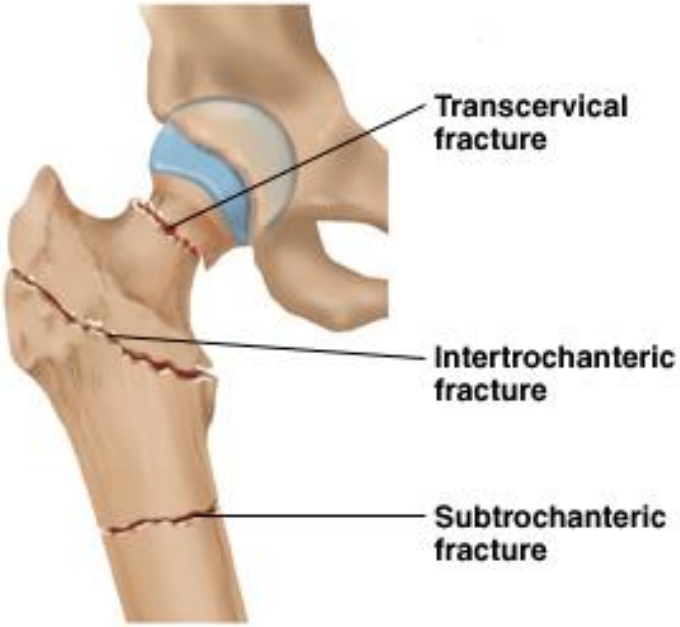
ii. If BMD T-score is −2.5 or below at spine, hip, or femoral neck

iii. If BMD T-score is between −1.0 and −2.5 at the femoral neck or spine and the 10-year probability of hip fracture is 3% or greater or the 10-year probability of major osteoporosis-related fracture is 20% or greater, according to the FRAX system

g. Follow up on BMD-DXA

- Every 2 years.
- Some situations may warrant a follow-up BMD sooner than 2 years.
- The interval may be longer in patients with T-scores in the normal or upper bone mass range who do not have major risk factors.





C. Osteoporosis Treatments

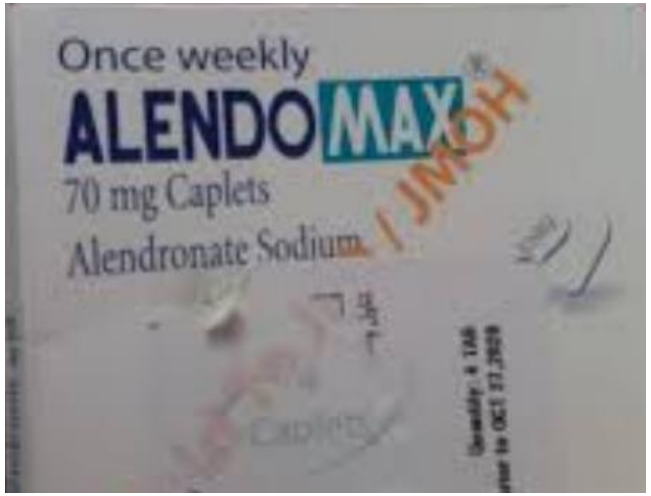
1. Bisphosphonates

a. Alendronate, risedronate, ibandronate, zoledronic acid.

b. Inhibits normal and abnormal bone resorption

c. First-line therapy; exception: ibandronate second-line therapy

d. Efficacy: Reduces vertebral and non-vertebral fractures by 30%–50%.



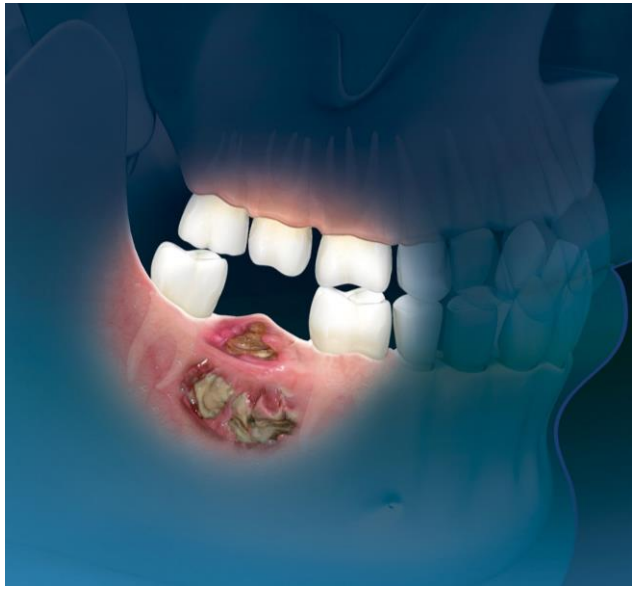
e. Adverse events (not dose-dependent):

i. Gastrointestinal (GI): flatulence, acid regurgitation, esophageal ulcer, dysphagia, abdominal distention, gastritis. To reduce the risk of GI adverse effects, those taking oral bisphosphonates should not lie down for 30–60 minutes after taking the dose.

ii. Miscellaneous: headache, musculoskeletal pain, rash

iii. Laboratory values: Decreases in serum calcium concentrations; decreases in serum phosphorus concentrations in the first month

iv. Osteonecrosis of jaw: Most are associated with dental procedures. Most cases occur in patients with cancer after prolonged therapy. High-dose intravenous administration (usually for cancer-related issues) has a greater risk than oral therapy.



v. Atypical fractures and esophageal cancer: The FDA is monitoring these adverse drug reactions; for now, the recommendation is to continue use as directed by physician.

Drug holidays are controversial; bone density may decrease 5 years after discontinuation of bisphosphonate therapy, but risk of hip fracture stays the same; however, higher risk of vertebral fracture may occur.

(a) American Society for Bone and Mineral Research recommends that, after 5 years of oral bisphosphonate use or 3 years of intravenous treatment, women be reassessed for risk.

(b) Women at a high risk of fractures should continue oral therapy for up to 10 years and up to 6 years with intravenous therapy with intermittent follow-up.

(c) Women whose fracture risk decreased after 3–5 years of use should stop treatment for 2–3 years.

vi. Atrial fibrillation: Possible increased risk of atrial fibrillation but not of stroke or cardiovascular mortality.

f. Drug-food interactions: Wait at least 30 minutes after taking bisphosphonate before taking any medications, food, or drinks except for water.

g. Dosage for osteoporosis

i. Alendronate: 10 mg/day or 70 mg/week; taken for 3 years. Alendronate (daily dose regimen) was shown to decrease vertebral fractures by 47% and hip fractures by 51% in women with previous fractures.

2. Calcium

a. Recommended for all patients with osteoporosis to maintain normal calcium concentrations and to prevent hypocalcemia associated with other drug treatments for osteoporosis

b. Elemental calcium intake: Avoid doses higher than 2500 mg/day; NOF recommends no more than 1200–1500 mg/day.

Higher doses may increase risk of constipation, contribute to kidney stones, and inhibit absorption of zinc or iron.

c. Most common forms: Calcium carbonate (take with food), calcium citrate (take with or without food, may be good option for patients taking antacids or acid-suppressive therapy or for patients with achlorhydria)

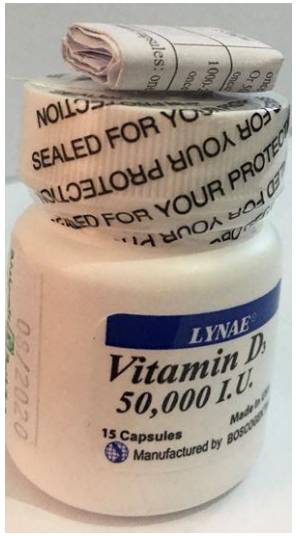
3. Vitamin D

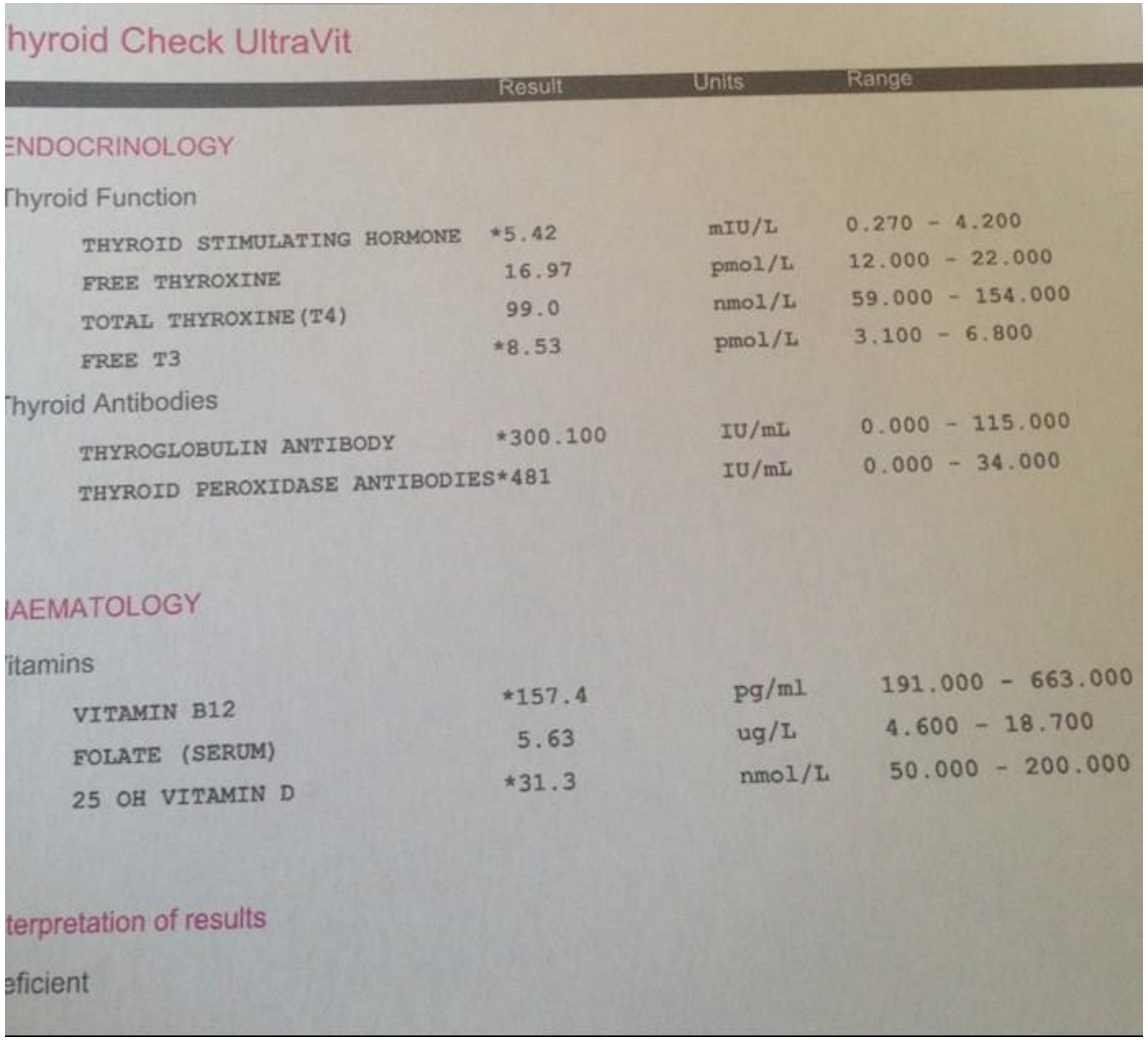
a. Recommended for all patients with osteoporosis; promotes calcium reabsorption.

b. Minimal dose is 800 international units/day for those older than 70 years, 600 international units/ day 70 years of age and younger (IOM recommendations 2010); NOF recommendations are 800–1000 international units/day for those 50 and older.

c. Higher doses of vitamin D may be necessary for those with vitamin D concentrations less than 30 ng/mL.

d. Goal: 30 ng/mL in adults (NOF), although the IOM states that concentrations of 20 ng/mL may be adequate for most of the population



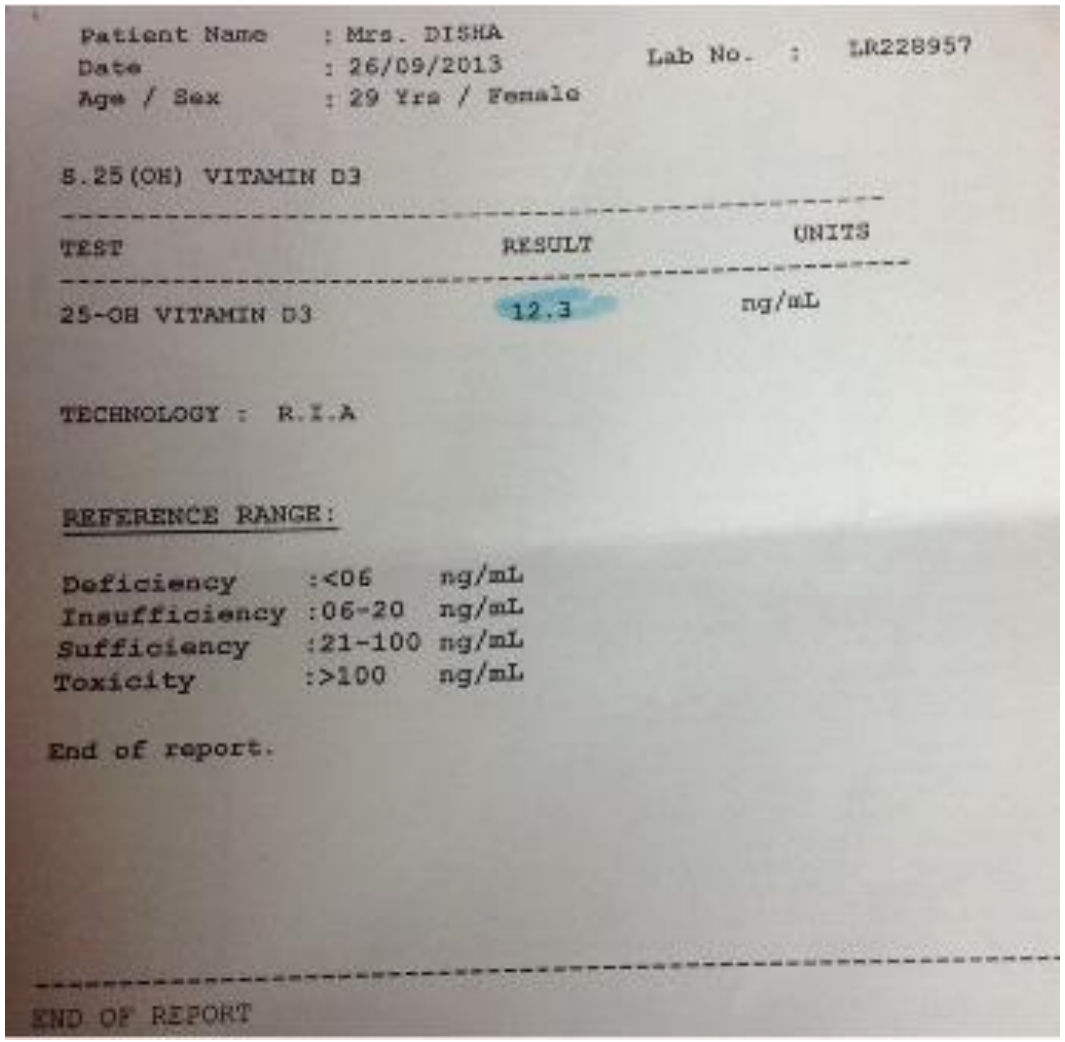


hyroid Check UltraVit

	Result	Units	Range
ENDOCRINOLOGY			
Thyroid Function			
THYROID STIMULATING HORMONE	*5.42	mIU/L	0.270 - 4.200
FREE THYROXINE	16.97	pmol/L	12.000 - 22.000
TOTAL THYROXINE(T4)	99.0	nmol/L	59.000 - 154.000
FREE T3	*8.53	pmol/L	3.100 - 6.800
Thyroid Antibodies			
THYROGLOBULIN ANTIBODY	*300.100	IU/mL	0.000 - 115.000
THYROID PEROXIDASE ANTIBODIES	*481	IU/mL	0.000 - 34.000
AEMATOLOGY			
itamins			
VITAMIN B12	*157.4	pg/ml	191.000 - 663.000
FOLATE (SERUM)	5.63	ug/L	4.600 - 18.700
25 OH VITAMIN D	*31.3	nmol/L	50.000 - 200.000

terpretation of results

eficient



Patient Name : Mrs. DISHA
Date : 26/09/2013
Age / Sex : 29 Yrs / Female
Lab No. : LR228957

S.25(OH) VITAMIN D3

TEST	RESULT	UNITS
25-OH VITAMIN D3	12.3	ng/mL

TECHNOLOGY : R.I.A

REFERENCE RANGE:

Deficiency	:<06	ng/mL
Insufficiency	:06-20	ng/mL
Sufficiency	:21-100	ng/mL
Toxicity	:>100	ng/mL

End of report.

END OF REPORT

4. Selective estrogen receptor modulators

a. Raloxifene (Evista)

i. Indication: Prevention and treatment of osteoporosis in postmenopausal women.

ii. Mechanism: Selective estrogen receptor modulator

(a) Reduction in resorption of bone

(b) Decrease in overall bone turnover

(c) Data suggest estrogen antagonist in uterine and breast tissue.

iii. Efficacy

(a) Reduces the risk of vertebral fractures; reduces vertebral fractures by 30%–50%; has not been shown to decrease hip fractures

(b) Lowers total cholesterol by 7% and LDL by 11%; does not reduce risk of CHD

5. Calcitonin-salmon

a. Inhibition of bone resorption

b. Indicated for treatment of osteoporosis in women who are more than 5 years postmenopause

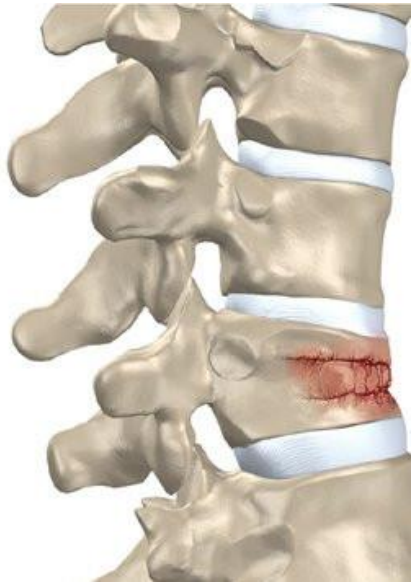
c. Not a first-line drug; useful for bone pain caused by vertebral compression fractures

d. Efficacy: Nasal calcitonin reduces the incidence of new vertebral fractures by 36%

e. Adverse effects

    i. Nasal (10%–12%): Rhinitis, epistaxis, irritation, nasal sores, dryness, tenderness

    ii. Other (3%–5%): Backache, arthralgia, headache



f. Drug interactions: None

g. Dosage: 200 international units/day in one nostril, alternating nostrils daily

    i. 200 international units nasally = 50–100 international units by injection

    ii. 200 international units per actuation, so one bottle will last about 2–3 weeks

h. FDA labeling changes regarding safety in 2014: Malignancies reported to be higher in those treated with calcitonin than in those treated with placebo. Benefits for patient should be discussed with patient and carefully considered.

6. Denosumab (Prolia):

Approved for postmenopausal women with osteoporosis and for men and women with bone loss associated with prostate or breast cancer.

a. Inhibits osteoclast-mediated bone resorption, monoclonal antibody against receptor activator of nuclear factor κ β ligand (RANKL), cytokine essential for formation, function, survival of osteoclasts

b. Considered alternative first-line therapy by AACE guidelines

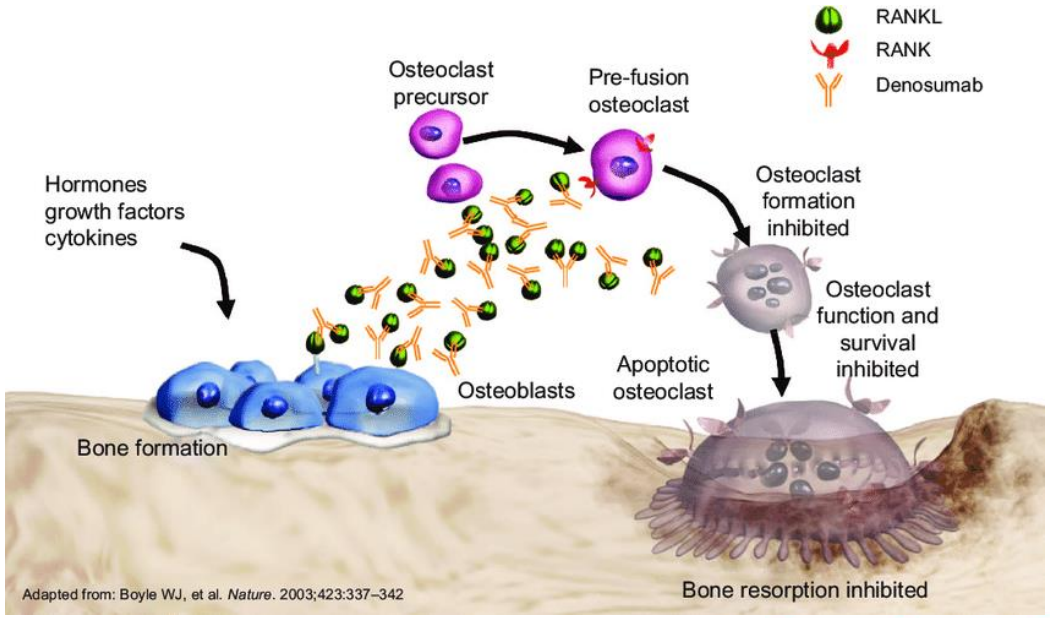
c. Administered as 60 mg subcutaneously every 6 months

d. Not contraindicated in patients with renal dysfunction

e. Efficacy

i. Increased hip (6%) and spine (9%) BMD

ii. Reduced spinal fracture risk by 68%, hip fracture risk by 40%

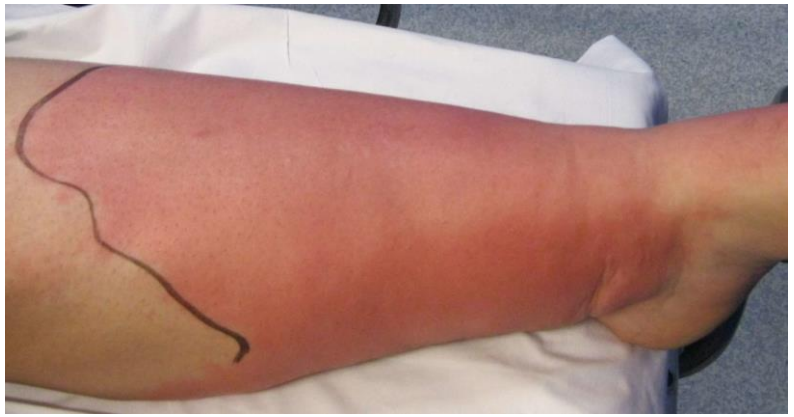


f. Safety issues

i. Possible opportunistic infections, skin infections such as cellulitis

ii. Hypocalcemia: Patients should take calcium and vitamin D together with denosumab; those with impaired renal function are more likely to have hypocalcemia.

iii. The FDA has Risk Evaluation and Mitigation Strategies requirements for this drug (Medication Guide).



7. Lifestyle modifications

a. Weight-bearing exercise that includes walking, tai chi, dancing, and tennis; recommend 30–40 minutes per session most days of the week, if possible; helps maintain bone strength

b. Smoking cessation: Smokers tend to have lower BMD scores than nonsmokers and may reach menopause earlier.

c. Limiting alcohol intake: Affects fall risk, 2 or more units of alcohol per day associated with 20% of falls at home, according to one study. No more than 2 units/day or 7 units/week is recommended.

d. Fall prevention