Bone markers can give answers in 3 months
How long do your osteoporosis patients have to wait?
Determining the severity of a patient’s bone loss

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures of the hip, spine, and wrist.\(^1\)

**Flexible and intelligent solutions**

A bone mineral density (BMD) test is the standard process used to determine a patient's bone health. The most commonly used BMD assay is a Dual Energy X-ray Absorptiometry (DXA) test.\(^2\)

A patient’s DXA result is then compared to the ideal or peak BMD of a healthy 30-year old adult to yield that patient's T-score. A T-score of 0 means that patient is equal to the norm. The more standard deviations below 0, the lower that patient’s BMD score and the higher their risk of bone fracture.\(^2\)

The severity of a low T-score is depicted on this basic scale, where a T-score of -2.5 or lower indicates osteoporosis\(^2\)
Bone is comprised of bone forming cells (osteoblasts and osteocytes), bone resorbing cells (osteoclasts), the osteoid matrix, and inorganic mineral salts. The osteoid matrix is made up of type I collagen (~94%) and non-collagenous proteins. The rigidity of bone is due to the presence of calcium and phosphate in this matrix.\(^3\)

Throughout life, bone is constantly renewed through a two-part process called remodeling, which consists of resorption and formation. During resorption, osteoclasts break down and remove old bone tissue. During formation, new bone is made to replace the degraded bone. After our third decade of life, bone is usually degraded faster than it is formed.\(^4\)

During bone resorption, type I collagen is broken down and the resulting degradation products are released into our circulation. These degradation products, such as C-telopeptide (CTx), are useful bone mineral metabolism markers. Typically there is a decrease in levels of these bone markers within four to six weeks of starting successful anti-resorptive therapy. These levels have been shown to remain reduced for the duration of the therapy.\(^5\)
Why is there a need for bone markers?

Poor compliance and the need for patient management

Bone structural changes are a slow process. Positive changes in bone mineral density that are identified by DXA testing are only apparent two years after starting therapy. Unfortunately, fewer than 50% of patients continue with their osteoporosis therapy for more than one year. Poor compliance compromises efforts to reduce fracture risk.

Why wait for 2 years to determine if your patient management decision was correct?

You and your patients don’t have to wait to determine if treatment is working when you incorporate bone markers into your treatment strategy. By using the Roche Elecsys® β-CrossLaps assay, you can confirm whether or not the prescribed medication worked much sooner than waiting two years for their next DXA scan.

The β-CrossLaps assay quantifies the bone specific degradation products of type 1 collagen-isomerized C-terminal telopeptides (βCTx), which are increased in physiologically or pathologically elevated bone resorption as seen with old age or osteoporosis.

During resorptive inhibiting therapy, the levels of βCTx return to normal. The determination of βCTx in serum is recommended for the monitoring of the efficacy of anti-resorptive therapy since the induced changes can be demonstrated as early as 90 days after the start of therapy. Bone markers can be useful for early therapy monitoring, especially in the first year of treatment when BMD changes do not provide meaningful information. Additionally, monitoring with bone markers may help determine if the patient is taking the medication appropriately or is compliant with treatment. Providing evidence to the patient that therapy is working after three months may increase compliance.

See evidence of successful therapy in one-eighth the time compared to DXA
Diagnosis of osteoporosis

Start of antiresorptive therapy

Measure β-CrossLaps baseline

Bone marker monitoring with β-CrossLaps after 3 months

Significant decrease with β-CrossLaps (>35-55%)

β-CrossLaps results aid in decisions for maintaining therapeutic regimen. Consider monitoring every 6-12 months.

No significant decrease with β-Crosslaps (<35-55%)

β-CrossLaps as adjunct with other clinical information. Ask about compliance & gastrointestinal side effects. Change therapy if necessary.

The efficacy of an antiresorptive therapy can be established through the use of Elecsys® β-CrossLaps bone resorption marker and other clinical information.
David Hevert, MD

David B. Hevert is a board-certified Internist and is the founder of Glades Medical Group in Boca Raton, Florida. The Glades Medical Group services approximately 10,000 patients, many of whom have osteoporosis or osteopenia. For the past twenty-five years, Dr. Hevert has been medical director of a CLIA-certified lab. 

Presently, Dr. Hevert serves as Medical Director to the Louis & Anne Green Memory and Wellness Center at Florida Atlantic University (FAU) in addition to being the Medical Director for Manor Care Rehabilitation Center in Boca Raton. He is also a clinical professor for the Schmidt Medical School at FAU and University of Miami Miller School of Medicine.

Bone health

Before the use of bone markers, clinicians used basic x-ray films and imaging systems such as MRI and CT scans to determine bone health of a patient. Dual energy X-ray absorptiometry, or DXA, (previously DEXA) was designed to measure bone mineral density. A DXA scanner produces a high energy and low energy X-ray beam, which both pass through a patient’s bone. The amount that passes through is measured and the difference between the two beams determines bone density.

β-CrossLaps / Serum CTx

Roche’s β-CrossLaps is an immunoassay used to determine the amount of degradation products, namely CTx, of type I collagen as an aid in assessing bone resorption. The test may be used as an aid in monitoring anti-resorptive therapies in postmenopausal women and people diagnosed with osteopenia.

“Our practice has found CTx to be the best marker through our trials and research. It is easily done, cost-effective, requires no radiation, and can measure changes accurately.”

David Hevert, MD
For patients treated for osteoporosis or osteopenia, CTx should drop at least 25% from baseline 3 to 6 months after the start of therapy. This 25% reduction indicates the treatment is working."  

David Hevert, MD

How β-CrossLaps works

β-CrossLaps is an electrochemiluminescence immunoassay that uses a sandwich complex. This complex is made from a two monoclonal anti-β-CrossLaps antibodies – one is biotinylated and one is labeled with a ruthenium complex. These two antibodies bind to the antigen and then interact with streptavidin-coated microparticles which are magnetically captured by an electrode. When a voltage is applied to the electrode it induces a chemiluminescent emission which is measured. The amount of antigen present correlates with the amount of emission measured.10

Case study

Patient basics and history: 73 year old white female (post-menopausal without HRT)

- Sedentary lifestyle
- Total abdominal hysterectomy
- History of rheumatoid arthritis
- Prior steroid use
- GERD / using proton pump inhibitor (PPI)
- Previous compression fracture of T-10 treated with kyphoplasty

A DXA scan showed osteoporosis of hips and spine, most severe in her spine with a T-score of -4.0. Her labs were normal, except that her vitamin D level was low at 29 ng/mL. Her baseline CTx level was 610 pg/mL.

Treatment was started to increase her calcium levels. This patient had to use calcium citrate because her PPI interfered with the absorption of calcium carbonate. Vitamin D replacement was instituted in order to increase calcium absorption in the GI tract. It was advised that this patient exercise to the best of her ability to increase her weight bearing.

This patient was prescribed the bisphosphonate Atelvia® (Warner Chilcott, Rockaway, NJ) because it is more “GI friendly” and has less gastric irritation, which was beneficial due to her having GERD.

After six months her follow-up CTx level declined to 428 pg/mL, indicating less bone resorption and probable bone regeneration. It was suggested that this patient continue therapy and have a repeat DXA scan in one year.
References

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