

Study investigates harmonization of assays for β -CTX

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Bone turnover markers, and specifically bone resorption markers, are commonly used to monitor patients' response to pharmacological treatment and adherence.

In 2011, the Joint Committee on Bone Marker Standards of the International Osteoporosis Foundation (IOF) and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) designated Procollagen type I N-propeptide (PINP) and the C-terminal telopeptide of type I collagen (β -CTX) in blood as reference bone turnover markers for bone formation and bone resorption, respectively, in osteoporosis. However, the effective clinical implementation of these recommendations requires the standardization/harmonization of the different commercial assays.

In its latest publication, published in the journal 'Calcified Tissue International', the IFCC-IOF joint Committee has carried out a multicentre evaluation of C-terminal telopeptide of type I collagen (β -CTX) with the current assays used in clinical laboratories. For the study, four centers (Athens GR, Copenhagen DK, Liege BE and Sheffield UK) collected serum and EDTA plasma samples from 796 patients presenting to osteoporosis clinics.

The study derived regression equations for the interconversion of β -CTX results assayed on serum and plasma specimens, and between Roche cobas e, IDS iSYS immunoassay platforms and IDS manual ELISA. The study findings and recommendations include:

- Significant variation was found between the individual centers;
- No useful regression equation could be calculated to harmonize results obtained with the different platforms, mainly because of the large between-center variations;
- Until harmonization is achieved, the IFCC-IOF Committee recommends measuring β -CTX by the same assay on EDTA plasma, especially for research purposes in large pharmacological trials where samples can be stored for long periods before they are assayed;
- It is recommended that patients are followed by the same method

and that laboratories identify the assay used for β -CTX determination on their protocols.

Lead author, Professor Etienne Cavalier, Chair of the IFCC-IOF Committee of Bone Markers (C-BM), stated, "The ability to monitor bone remodeling markers and in particular β -CTX would be beneficial in the follow-up of patients undergoing treatment. However, the results of this study show that challenges persist given the large within- and between-assay variation for β -CTX measurement, particularly in serum. As we continue to work towards harmonization, we hope that our recommendations will be helpful, and that our findings will serve to inform further research towards the harmonization of β -CTX values between assays. We insist on the importance of using EDTA plasma over serum for β -CTX measurement to improve short and long-term stability as well as harmonization of the results."

Professor Nicholas Harvey, Chair of the IOF Committee of Scientific Advisors added, "Together with IFCC, the International Osteoporosis Foundation looks forward to the important next steps which will lead to reliable reference ranges across assays and thus greater capacity for these measures to inform both clinical care and research. The project demonstrates the huge value of such international collaborations in setting the state of the art to improve [bone](#) health globally."

More information: A Multicenter Study to Evaluate Harmonization of Assays for C-Terminal Telopeptides of Type I Collagen (β -CTX): A Report from the IFCC-IOF Committee for Bone Metabolism (C-BM), *Calcified Tissue International* (2021). [DOI: 10.1007/s00223-021-00816-5](#)

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