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Keeping CALM in Crohn's Disease: An Exploration of Biomarker Cutoffs & Endoscopic Outcomes

Dr. Wang:

For ReachMD, this is Audio Abstracts, produced in collaboration with the Crohn's & Colitis Foundation. I'm Dr. Xiaohong Wang, and I'm a post-doctoral fellow at the Center for Ultrasound Research & Translation in the Department of Radiology at Massachusetts General Hospital. Today, I'll be reviewing an article published in the Inflammatory Bowel Diseases journal titled "Association of Biomarker Cutoffs and Endoscopic Outcomes in Crohn's Disease: A Post Hoc Analysis From the CALM Study." This article appeared in the journal's special biomarkers issue released in October 2020.

To give you some background, Crohn's disease is an inflammatory bowel disease characterized by chronic inflammation of the gastrointestinal tract. To achieve the goal of mucosal healing, objective biomarkers like C-reactive protein and fecal calprotectin have been reported as potential surrogates of mucosal inflammatory activity. Although prior studies have shown an association between these biomarkers and clinical outcomes, the relationship between biomarker cutoff levels and mucosal improvements has not been fully established. So to learn more about the association of the biomarkers with mucosal healing, the authors of this study used data from the CALM study. CALM was a randomized trial in patients with Crohn's disease that demonstrated improved endoscopic healing when treatment was escalated based on a treat-to-target approach compared to escalation based on symptoms alone.

Using data from the CALM study, CRP and FC levels were retrospectively collected from 244 subjects. The authors then stratified the endoscopic outcomes by CRP and FC levels at week 48 separately, to see if either biomarker was predictive of mucosal healing. In this study, endoscopic mucosal healing was defined by the Crohn's Disease Endoscopic Index of Severity, meaning less than 4 and no deep ulcers. The cutoffs of CRP less than 5 mg/L and FC less than 250 μ g/g was adopted to classify the subjects achieving the primary outcome. Univariate and multivariate regression analyses were also applied to evaluate the predictive performance of the clinical symptoms based on the Crohn's Disease Activity Index in relation to endoscopic outcomes.

Ultimately, the authors found that FC and CRP played significant roles in treatment escalation. Specifically, FC less than 250 μ g/g at week 48 was a reasonable biomarker of improved endoscopic healing with a high odds ratio of 18.4, independent of disease location at baseline. This finding was in alignment with earlier reports on the effectiveness of FC in detecting endoscopic ulcers. However, a small additive effect of CRP was observed when the authors combined it with the FC cutoffs at week 48. Therefore, it would not be indicated as the primary predictor of endoscopic activity. As for the predictive performance, it's important to note that the combination of the biomarker cutoffs and Crohn's Disease Activity Index less than 150 demonstrated value up to 86 percent in predicting endoscopic outcomes. On the other hand, multivariate logistic regression did not show significant contribution of Crohn's Disease Activity Index.

Despite some limitations in this study such as the quantification of FC level above 250 μ g/g, the results of this study still help provide further support for the use of FC as a surrogate marker for mucosal inflammation when implementing a treat-to-target strategy for patients with Crohn's disease. The authors also highlighted the need for identification of specific concentration cutoffs for setting appropriate treatment goals. This could help avoid the risk of side effects from the long-term use of corticosteroids and immunomodulators.

If you're interested in this topic or others on Crohn's disease or ulcerative colitis, the Crohn's & Colitis Foundation's Inflammatory Bowel Diseases Journal provides the most impactful and cutting-edge clinical topics and research findings. For more information on the Foundation, please visit crohnscolitisfoundation.org.

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