Factors driving treatment escalation in Crohn’s disease in the CALM trial


1Medical University of Vienna, Vienna, Austria, 2University of Calgary, Calgary, Canada, 3Imelda General Hospital, Bonheiden, Belgium, 4AZ Delta Roeselare-Menen, Menen, Belgium, 5Presidio Columbus, Fondazione Policlinico Gemelli Università Cattolica, Rome, Italy, 6Service de Gastroenterologie et Nutrition Clinique, Nice, France, 7Université de Nice-Sophia-Antipolis, Nice, France, 8Istituto Clinico Humanitas, Milan, Italy, 9University of California San Diego, La Jolla, USA, 10University Hospital Schleswig-Holstein, Kiel, Germany, 11Academic Medical Center, Amsterdam, The Netherlands, 12AbbVie AB, Solna, Sweden, 13AbbVie Inc., North Chicago, USA, 14Icahn School of Medicine at Mount Sinai, New York, USA

Background: Patients with Crohn’s disease (CD) from the tight control (TC) management group of CALM, whose treatment was escalated based on clinical symptoms and biomarkers (CD Activity Index [CDAI], C-reactive protein [CRP], faecal calprotectin [FC] and/or prednisone use), achieved better endoscopic outcomes than patients whose treatment was escalated based on CDAI and prednisone use only. The majority of decisions to escalate in the TC group included FC followed by CRP, CDAI, and prednisone use, however, a detailed algorithm of treatment decisions based on the four criteria has not been described. This analysis reports treatment escalation decisions in the TC group in more detail.

Methods: A total of 122 patients naïve to biologics and immunosuppressants with or without prior prednisone use were randomised to the TC group. At randomisation, patients received treatment with adalimumab (ADA) induction 160/80 mg and then 40 mg every other week (EOW) if they met at least one criterion, i.e., CDAI ≥150, CRP ≥5 mg/l, FC ≥250 µg/g, and prednisone use. At 12, 24, and 36 weeks after randomisation, patients, who met at least one of the CDAI, CRP, FC, or prednisone criteria were escalated consecutively to the next treatment option (ADA 40 mg every week [EW], followed by ADA 40 mg EW+2.5 mg/kg azathioprine). Patients who did not meet a treatment escalation criterion were to stay at the same treatment. CDAI, FC, CRP and prednisone use were assessed one week before randomisation and treatment escalation. Dose escalation criteria were summarised and reported as observed in all patients who met escalation criteria at each time point.

Results: Over 70% of patients who qualified to receive ADA at randomisation met three to four criteria (Table). After randomisation, approximately 50% or more patients were escalated to the next treatment option based on one criterion, FC was the most frequent single reason of escalation followed by CRP and CDAI at 12 and 24 weeks. At 36 weeks, there were fewer escalations to which FC, CRP, and CDAI contributed equally. Among two reasons for escalation, the FC+CRP combination was the most prevalent. Overall, prednisone use was the least frequent criterion for escalation.

Conclusions: The data from CALM suggest that biomarkers are important for guiding treatment decisions in patients with early CD after their symptoms are controlled by treatment. These results underscore the importance of monitoring biomarkers along with clinical symptoms to achieve better clinical and endoscopic outcomes.


Clinical characteristics, associated malignancies and management of primary sclerosing cholangitis in inflammatory bowel disease patients: A Spanish nationwide study based on the ENEIDA registry


1Hospital Universitario de Fuenlabrada, Department of Gastroenterology, Fuenlabrada, Spain, 2Hospital Donostia/Instituto Biodonostia, Universidad del País Vasco UPV/EHU, Department of Gastroenterology, Donostia-San Sebastian, Spain, 3Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas (CIBERehd), Spain, Spain, 4Hospital Clínico de Barcelona, Department of Gastroenterology, Barcelona, Spain, 5Hospital Universitario de Cruces, Department of Gastroenterology, Baracaldo, Vizcaya, Spain, 6Hospital Universitario Clinic de