Long-term Outcomes After Switching to CT-P13 in Pediatric-Onset Inflammatory Bowel Disease: A Single-Center Prospective Observational Study

Ben Kang, MD, MS,[*,†,‡] *Yoon Lee, MD, MS,*[§] *Kiwuk Lee, MD,*[‡] *Young Ok Choi, MS,*[‡] *and Yon Ho Choe, MD, PhD*[‡]

Background: The relatively high cost and patent expiry of infliximab, an anti–tumor necrosis factor monoclonal antibody used in inflammatory bowel disease (IBD), has led to the development of biosimilar versions of the reference product (RP). This study investigated the long-term efficacy, safety, pharmacokinetics, and immunogenicity of CT-P13 after switching from infliximab RP in pediatric-onset IBD patients.

Methods: In this prospective observational study, patients with pediatric-onset IBD receiving maintenance infliximab RP were followed for 1 year after continuing infliximab RP (RP maintenance group) or switching to CT-P13 (CT-P13 switch group). Primary end points were the proportion of patients continuously receiving infliximab and the proportion achieving persistent remission—corticosteroid-free sustained clinical remission without dose intensification—at 1 year.

Results: Thirty-six patients were recruited to the RP maintenance group and 38 to the CT-P13 switch group. At 1 year in the RP maintenance group and CT-P13 switch group, 86.1% (31/36) and 92.1% (35/38) patients had continuously received infliximab (P = 0.649), and 77.8% (28/36) and 78.9% (30/38) patients experienced persistent remission (P = 1.000), respectively. There were no statistically significant differences in any measures of disease activity, pharmacokinetics, or immunogenicity between the time of switch and 1-year postswitch in the CT-P13 switch group. Twenty-seven adverse events occurred in the maintenance group and 30 in the switch group.

Conclusions: Switching from maintenance infliximab RP to CT-P13 did not result in any significant differences in efficacy, pharmacokinetics, or immunogenicity in patients with pediatric-onset IBD, and no unexpected safety issues occurred, supporting findings from randomized controlled trials.

Key Words: biosimilar, children, inflammatory bowel disease, infliximab, switching

Inflammatory bowel disease (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), is commonly diagnosed in adolescents or young adults, with around 1 in 4 patients receiving a diagnosis before the age of 20 years.[1] A significant increase in the incidence of IBD in the pediatric population has occurred over the last few decades, with rates varying across populations.[2] Pediatric-onset IBD typically presents with a more severe phenotype than adult-onset disease, and its symptoms may include growth retardation and delayed onset of puberty, in addition to age-independent symptoms such as abdominal pain, diarrhea, rectal bleeding, and weight loss.[1, 3] Early and effective treatment is therefore especially important in this group of vulnerable patients.[4, 5]

Infliximab is an anti–tumor necrosis factor (anti-TNF) monoclonal antibody used in the treatment of pediatric CD and UC, usually after conventional therapies have failed. As with many biologics, the relatively high cost and patent expiry of infliximab has led to the development of less expensive biosimilar versions. CT-P13 (infliximab-dyyb; Remsima, Inflectra [CELLTRION, Incheon, Republic of Korea]) is a biosimilar of the infliximab reference product (RP; Remicade) that has been approved in countries worldwide for all indications held by the RP, including pediatric and adult CD and UC. In accordance with regulatory guidelines on biosimilars,[6, 7] approval of CT-P13 was based on extensive comparisons with the infliximab RP in nonclinical studies and 2 randomized controlled trials performed in adults with rheumatoid arthritis and

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From the *Department of Pediatrics, Kyungpook National University School of Medicine, Daegu, Republic of Korea; †Crohn's and Colitis Association in Daegu-Gyeongbuk (CCAiD), Daegu, Republic of Korea; ‡Department of Pediatrics, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea; §Department of Pediatrics, Korea University College of Medicine, Seoul, Republic of Korea.

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Address correspondence to: Yon Ho Choe, MD, PhD, Department of Pediatrics, Samsung Medical Center, Sungkyunkwan University School of Medicine, 81 Irwon-ro, Gangnam-gu, Seoul, 06351, Republic of Korea (i101016@skku.edu).

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