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Efficacy of Infliximab Dose Escalation in Patients With Refractory Immunotherapy-Related Colitis: A Case Series

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INTRODUCTION: Immune checkpoint inhibitor (ICI)-related colitis (rICl) is a frequent complication of ICI use in cancer. Treatment approaches have been adapted from the treatment of inflammatory bowel disease (IBD), including the use of infliximab (IFX) for patients with rICl refractory to corticosteroids. The efficacy of IFX dose-escalation in patients not responding to standard dose IFX, a common practice in patients with severe IBD, has not been reported in rICl.

METHODS: We describe a retrospective study of patients treated with IFX dose escalation (i.e. 10mg/kg dose) after failure of standard dose IFX (5 mg/kg) dose for rICl at a tertiary care center in New York City between 2016 and 2020. Clinical response was defined as improvement in diarrhea to <3/6.

RESULTS: Ten patients were treated with high dose IFX for refractory rICl. High dose IFX was started after a median of 2 (IQR 2-4) doses of standard dose IFX for non-response (n=2) or incomplete response (n=8). Five (50%) patients had a clinical response to high dose IFX after a median of 4 (IQR 3-6) days. Five (50%) patients were refractory to high dose IFX and were treated with Vedolizumab (n=5) and/or fecal microbiota transplantation (n=2). Patients were followed for a median 457 (IQR 325-567) days from initiation of ICI therapy. No adverse events attributed to IFX were observed in any of the patients.

CONCLUSION: In this series of patients with rICl refractory to standard dose IFX, high dose IFX was successful in inducing response in 50% of patients. Prospective studies are needed to further elucidate the role and optimal dosing of IFX in rICl.

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Real World Experience of Ustekinumab for Pediatric Crohn’s Disease

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INTRODUCTION: Ustekinumab (UST) is a humanized monoclonal antibody against interleukins 12 and 23, and is approved for moderate-to-severe Crohn’s disease (CD) in adults. There are increasing reports on the off-label use of UST in pediatric CD which have demonstrated efficacy and safety. The purpose of this study was to describe our real-world experience with the use of UST in pediatric CD.

METHODS: This was a retrospective review of all pediatric patients #18 years initiated on UST from Jan 2017 to Apr 2019. Data collection included demographics, prior biologics, UST therapy, and disease activity scores using the pediatric Crohn’s disease activity index (shPCDAI). Clinical response was defined as improvement in diarrhea to <3/6.

RESULTS: We identified 12 pediatric CD patients treated with UST for a median of 11.4 months (IQR 6.9-17.1). Mean age was 15 ± 2.6 years, 6 were male, and median CD duration was 2.7 years (IQR 1.2-4.4). All were biologic-experienced and were put on UST as second line in 4 patients, third line in 7 patients, or fourth line therapy in 1 patient. Ten patients were started on UST due to refractory disease, and were changed to UST due to infliximab-induced psoriasis. Baseline median shPCDAI score was 32.5 (IQR 28.8-33.0). Currently, 10 patients remain on UST therapy and 2 have discontinued. At last clinic follow-up, obtained at a median of 8.9 months (IQR 7.8-11.6), 7 of 10 were in clinical remission and median shPCDAI score was 10 (IQR 1.23-17.5).

CONCLUSION: Our data suggest that ustekinumab is effective in the treatment of pediatric CD, even in the setting of refractory disease. Further studies are warranted to determine the place in therapy for ustekinumab among other biologics.

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Response to Biologics and Healthcare Utilization in Bio-Naive Ulcerative Colitis Patients

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INTRODUCTION: Biologics have been shown to effectively reduce the risk of hospitalizations, emergency department (ED) visits, and surgical interventions in inflammatory bowel disease (IBD) patients. Still, at least one-third of patients do not have an initial or sustained response to these therapies. Infliximab (IFX) and vedolizumab (VDZ) are considered first-line biologics for the treatment of moderate-to-severe ulcerative colitis (UC). The purpose of this study was to evaluate the association between early clinical response and healthcare resource utilization (HRU) in bio-naive UC patients initiated on IFX or VDZ.

METHODS: This was a retrospective review of all bio-naive UC patients started on IFX or VDZ as first-line therapy at a large gastroenterology private practice from Jan 2017 to Apr 2019. Data collection included demographics, biologic therapy, disease severity, and HRU. Clinical response was defined as a reduction in partial Mayo score (pMayo) of ≥ 2 at 14 weeks compared to baseline. Patients were classified as “responders” or “non-responders” based on their clinical response at 14 weeks. HRU was defined as HRU-related ED visits, hospitalizations, and/or surgeries within 1 year of biologic initiation.

RESULTS: We identified 65 bio-naive UC patients initiated on IFX or VDZ during the study period: mean age 45 ± 15.2 years, male gender 36 (55%), median disease duration 1.8 years (IQR 0.6-5.6), IFX 32 (49%), VDZ 33 (51%). Fifty-eight (89%) patients had moderate-to-severe UC at baseline, with a median pMayo of 6 (IQR 5-7). At 14 weeks, there were 37 (57%) responders and 28 (43%) non-responders. Response and non-response rates were similar between IFX and VDZ. We captured a total of 23 HRU events in 13 patients within 1 year of biologic initiation. Of these, 4 responders experienced 6 HRU events and 9 non-responders experienced 17 HRU events. Non-responders had an increased risk of HRU compared to responders (OR 3.91 [95% CI 1.06-14.49], P = 0.03). At one year, biologics were discontinued in a total of 21 (32%) patients, including 4 responders and 17 non-responders. Non-responders were more likely to discontinue biologics compared to responders (OR 11.63 [95% CI 3.20-41.67], P < 0.001).

CONCLUSION: Our data suggest that clinical response to biologic induction may reduce long-term healthcare resource utilization and lower discontinuation rates. Efforts should be focused on achievement of early clinical response and biologic therapy optimization in cases of non-response.