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Home vs Hospital Infusion of Biologic Agents for Patients With Inflammatory Bowel Diseases

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Inflammatory bowel disease (IBD) therapy often requires biologic medications delivered by intravenous infusion.^{1–4} Historically, intravenous infusions of infliximab and vedolizumab in patients with IBD were delivered under direct supervision of clinicians in infusion centers at hospitals or clinics. Recently, intravenous infusions have transitioned into patient homes. Professional societies have differed on their recommendations for biologic home infusions (HI),^{5,6} yet limited data exist on the safety and efficacy of HI programs.^{7,8} Therefore, the primary aim of this study was to compare adverse outcomes (AOs), as defined as a composite of stopping therapy, IBD-related emergency-room (ER) visit, or IBD-related hospitalization, in patients with IBD receiving biologics as HI or at a hospital-based infusion center.

Methods

We conducted a matched retrospective cohort study of patients treated with infliximab or vedolizumab via HI compared with hospital-based infusion (control) between January 1, 2016, and July 1, 2017, at a large tertiary care IBD center. Patients on HI were matched to control subjects based on age, gender, IBD type, infusion medication, and time on therapy before HI or matching. The primary endpoint of AOs was a composite of the following events: stopping biologic therapy, IBD-related ER visit, or IBD-related hospitalization. Secondary outcomes were degree of monitoring assessed by frequency of IBD outpatient clinic visits and laboratory assessments. A time-to-event (survival) analysis for AOs was performed. Kaplan-Meier estimates were used to analyze the cumulative incidence curves compared by log-rank test with censoring of patients who did not have an AO by the end of follow-up. Given variable follow-up times, univariable and multivariable Cox proportional hazards analyses were performed to determine the independent effects of variables associated with AOs.

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Results

Sixty-nine patients (46 infliximab/23 vedolizumab) started HI during the study period and were similar in baseline characteristics to matched control subjects. Most patients (89.9%) in the HI cohort transitioned from an infusion center to HI and the remainder (10.1%) initiated biologic therapy as HI. Median follow-up time was 645 days (interquartile range, 121 days) in control patients and 672.5 days (interquartile range, 134 days) in HI patients.

Patients started on HI were more likely to experience AOs compared with control patients (43.5% vs 21.7%; $P = .006$). Time to AOs was significantly shorter in HI patients than in control subjects (log-rank, 0.008; Figure 1). In univariable analysis (Figure 1) only elevated C-reactive protein at the start of HI and receiving HI were significantly associated with time to AOs. In multivariable analysis controlling for elevated C-reactive protein at the start of HI or match and age, HI (adjusted hazard ratio, 2.30; 95% confidence interval, 1.23–4.31) was the only variable significantly associated with time to AOs. Patients started on HI showed a trend toward stopping therapy within 1 year (20.3% vs 8.7%; $P = .053$) and stopping therapy within the complete follow-up period (27.5% vs 15.9%; $P = .099$) when compared with control patients. Patients on HI had significantly more ER visits following transition to HI compared with control patients (HI 30.4% vs control 7.2%; $P < .001$), but not hospitalizations (HI 17.4% vs control 11.6%; $P = .333$). HI patients on therapy for less than 1 year before the start of HI were significantly more likely to stop therapy than those on stable therapy for more than 1 year (40.6% vs 16.2%; $P = .024$).

Patients persisting on HI ($n = 47$) had significantly fewer IBD clinic visits (1.23 vs 1.75; $P = .018$) than control subjects ($n = 57$) in the year following HI initiation or matching. HI patients were significantly more likely to have 2 or fewer laboratory assessments in the year following HI initiation when compared with control patients (30.4% vs 0%; $P = .0001$).

Discussion

We observed that patients with IBD receiving biologic HI were significantly more likely to have AOs including stopping therapy, IBD-related ER visits, or IBD-related hospitalization than those receiving hospital-based infusions. The increase in AOs was potentially related to a reduced level of monitoring found in HI patients with significantly fewer clinic visits and laboratory evaluations than control patients.

Although our study was limited to 69 patients in both groups, it is the largest to our knowledge in patients receiving HI for management of IBD. Although HI may provide added convenience and possibly decrease costs for some patients, further research is needed to determine its safety, optimal patient selection, and the true cost benefit. Although HI of biologic medications is discouraged by the American College of Rheumatology, no clear guidelines exist in the gastroenterology literature.⁶ Our data, the first of its kind, show an increase in AOs and therapy disruption with AOs and paves the way for larger, prospective studies to inform practice guidelines.

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Conflicts of interest

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Abbreviations used in this paper

AO	adverse outcomes
ER	emergency room
HI	home infusion
IBD	inflammatory bowel disease

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Predictor	Univariable HR [95% CI] for Time to AOs	p-value	Multivariable aHR [95% CI] for Time to AOs	p-value
HI vs control	2.27 [1.22, 4.22]	.010	2.30 [1.23-4.31]	.009
Elevated CRP at the start of HI or match	1.91 [1.03, 3.52]	.039	1.73 [0.93-3.22]	.083
Age at HI or matching (years)	1.02 [0.99, 1.04]	.063	1.02 [0.99-1.04]	.110
Gender (female vs male)	1.12 [0.62, 2.03]	.712		
IBD type (CD vs UC)	1.07 [0.58, 1.97]	.835		
Prior biologic exposure	1.53 [0.85, 2.76]	.158		
HI or matched medication (vedolizumab vs infliximab)	1.06 [0.57, 1.98]	.845		
Concomitant immunomodulator	0.71 [0.37, 1.38]	.318		
Disease duration at HI or matching (years)	1.01 [0.98, 1.04]	.545		
Time on therapy prior to HI or matching (days)	1.00 [0.99, 1.00]	.389		
≥ 1 yr stable therapy prior to HI or matching	0.73 [0.40, 1.31]	.288		

Abbreviations: Adverse Outcome (AO), Confidence Interval (CI), Hazard Ratio (HR), Home Infusion (HI)

Figure 1.

Kaplan Meier curve and predictors for composite adverse outcome of stopping therapy, IBD-related ER visit, or IBD-related hospitalization any time after HI or match. aHR, adjusted hazard ratio; CD, Crohn's disease; CI, confidence interval; CRP, C-reactive protein; HR, hazard ratio; IQR, interquartile range; UC, ulcerative colitis.