Hospitalization and Surgery Rates in Patients Awaiting Approval of Biologics or Small Molecules for treating Inflammatory Bowel Disease

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Introduction

Advanced IBD therapies including biological agents (infliximab, adalimumab, ustekinumab, golimumab, certolizumab pegol, and vedolizumab) and oral inhibitors (tofacitinib and ozanimod) have become main stays of treatment for moderate to severe Crohn's disease (CD) and ulcerative colitis (UC). Although providers have anecdotal evidence that delays in insurance approval for these treatments might result in adverse outcomes, the rate of hospitalization and surgery during the prior approval process have not been formally evaluated. This study was designed to assess the rate of IBD-related hospitalizations and surgeries in individuals waiting for prior authorization for their advanced IBD therapy.

Methods

To assess the impact of the prior authorization process on clinical outcomes, we obtained IRB approval to evaluate the charts of individuals with IBD treated at the University of Mississippi Medical Center between the dates of 3/1/2019-12/31/2021. Mississippi has not adopted universal Medicaid. During this period, we found 542 individuals who had been started on a biological agent or an oral inhibitor. Using a data collection tool developed in the Harvard system, we identified 182 patients in whom we had complete data set. A complete data set included demographic data, disease variables, past medication history, insurance status, date of decision for medication, date of prior authorization, date of intuition of therapy, and clinical outcomes during the prior authorization period.

Demographics

Table 1. Demographics

	Cohort (N = 182)
Age (years)	
10-19	10
20-29	46
30-39	43
40-49	26
50-59	28
60-69	18
70-79	8
80-89	1
Unknown	2
Gender	
Male	65
Female	117
Race	
White	95
Black/African American	79
Asian	3
Hispanic or Latino	4
Unknown	1

Table 2. Employment and IBD Therapy

	Cohort (N = 182)
Employment Status	
Employed	65
Unemployed	107
Unknown	10
Current IBD Therapy	
Steroids	9
IMM	7
5-ASA	8
Infliximab	10
Adalimumab	23
Golimumab	1
Certolizumab	1
Ustekinumab	66
Vedolizumab	25
Tofacitinib	16

Table 1 and 2. The demographics of the IBD cohort, including employment status and current IBD therapy.

Data

Table 3. Disease Variables

	Cohort (N = 182)
Disease Type	
CD	137
UC	44
IBD	1
CD Phenotype	
Inflammatory	54
Penetrating	37
Stricturing	16
Penetrating & Stricturing	27
CD Location	
Ileal	23
Colonic	31
Ileocolonic	83
UC Extent	
Extensive	31
Left-sided	12
Proctitis	1
History of Surgery	
Yes	71
No	111

Table 3. Disease variables that occur within patients diagnosed with CD and UC.

Table 4. Key Variables Among Biologics/Small Molecules Being Initiated

	Infliximab	Adalimumab	Golimumab	Certolizumab	Ustekinumab	Vedolizumab	Tofacitinib	Overall
Number	7 (3.8%)	28 (15.4%)	2 (1.1%)	0 (0%)	85 (46.7%)	38 (20.9%)	22 (12.1%)	182 (100%)
Payor Status								
Commercial	2 (28.6%)	12 (42.9%)	2 (100%)	0 (0%)	39 (45.9%)	19 (50%)	11 (50%)	85 (46.7%)
Medicare	3 (42.8%)	8 (28.6%)	0 (0%)	0 (0%)	14 (16.5%)	5 (13.2%)	4 (18.2%)	34 (18.7%)
Medicaid	1 (14.3%)	7 (25%)	0 (0%)	0 (0%)	21 (24.7%)	12 (31.6%)	7 (31.8%)	48 (26.4%)
Unknown	1 (14.3%)	1 (3.6%)	0 (0%)	0 (0%)	11 (12.9%)	2 (5.2%)	0 (0%)	15 (8.2%)
Prior 5-ASA Use	3 (42.8%)	13 (46.4%)	0 (0%)	0 (0%)	35 (41.2%)	22 (57.9%)	17 (77.3%)	90 (49.5%)
Prior IMM Use	5 (71.4%)	13 (46.4%)	1 (50%)	0 (0%)	56 (65.9%)	20 (52.6%)	15 (68.2%)	110 (60.4%)
Prior Steroid Use	4 (57.1%)	22 (78.6%)	1 (50%)	0 (0%)	80 (94.1%)	32 (84.2%)	22 (100%)	161 (88.5%)
Prior Biologic/Small Molecule Use	4 (57.1%)	6 (21.4%)	2 (100%)	0 (0%)	73 (85.9%)	17 (44.7%)	10 (45.5%)	112 (61.5%)
Specialty Pharmacy	3 (42.8%)	12 (42.9%)	1 (50%)	0 (0%)	69 (81.2%)	17 (44.7%)	5 (22.7%)	107 (58.8%)
Type of Practice								
Private	0 (0%)	1 (3.6%)	0 (0%)	0 (0%)	11 (12.9%)	2 (5.2%)	1 (4.5%)	15 (8.2%)
Academic	7 (100%)	27 (96.4%)	2 (100%)	0 (0%)	69 (81.25)	36 (94.8%)	21 (95.5%)	162 (89.0%)

Table 4. Key variables amongst the different IBD therapies that were initiated within the patient cohort.

Table 5. Clinical Outcomes While Awaiting Initiation of Biologic/Small Molecule

	Infliximab	Adalimumab	Golimumab	Certolizumab	Ustekinumab	Vedolizumab	Tofacitinib	Overall
Delay Interval	38.6 ± 25.9	41.7 ± 23.0	42 ± 11.8	N/A	40.6 ± 6.1	51.8 ± 17.4	32.4 ± 25.0	43.1 ± 7.1
ED Visits	1 (14.3%)	4 (14.4%)	0 (0%)	0 (0%)	15 (17.6%)	3 (7.9%)	3 (13.6%)	26 (14.3%)
Hospital Admissions	2 (28.6%)	3 (10.7%)	0 (0%)	0 (0%)	17 (20%)	1 (2.6%)	4 (18.2%)	27 (14.8%)
Length of Hospital Stay	13.5 ± 0.98	7.0 ± 3.40	0 (0%)	0 (0%)	13.4 ± 9.8	6 ± 0	3.8 ± 2.0	10.9 ± 6.2
Surgical Intervention	1 (14.3%)	2 (7.1%)	0 (0%)	0 (0%)	9 (10.6%)	1 (2.6%)	2 (9.1%)	15 (8.2%)

Table 5. Clinical outcomes that occurred in IBD patients while awaiting the initiation of IBD therapy.

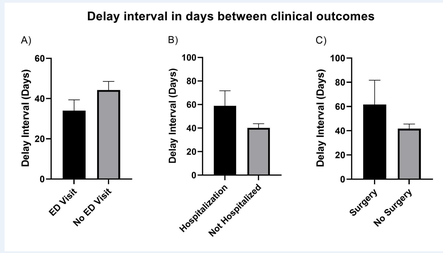

Figure 1. Delay interval, in days, between the clinical outcomes of patients awaiting advanced IBD therapy. **A)** Delay interval for patients making Emergency Department (ED) visits (n=26, 34±5.4 days) and those who did not have an ED visit (n=140, 44±4.2 days). **B)** Delay interval for patients requiring hospitalization (n=27, 59±13 days) and those who did not require hospitalization (n=138, 40±3.6 days). **C)** Delay interval for patients requiring surgery (n=15, 62±20 days) and those who did not require surgery (n=150, 42±3.9 days). Data represented as the mean ± standard error.

Results

Of 182 IBD patients with complete data sets, we found that 64.3% of them had previously been treated with an advanced IBD therapy. Despite this, the average interval between decision and initiation of therapy was 43 days (40 days for commercial insurance, 49 days for Medicare, 45 days for Medicaid, and 42 days for those without insurance.) During the delay, 14.3% of patients had an ED visit, 14.8% were admitted to hospital, and 8.2% of patients required surgical intervention (bowel resections). It should be noted that these delays occurred despite having a full time IBD pharmacist.

Conclusions

During the waiting period for the approval of appropriate, advanced IBD therapies, 15% of patients were hospitalized and 8.2% underwent surgery for their disease. This data suggests that the time to advanced IBD therapy approval probably needs to be shortened to reduce morbidity in this patient population. Further study across multiple institutions will be necessary in order to better address this important issue.

References

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