

**TITLE:** CURRENT STATE ANALYSIS OF DISEASE MONITORING PRACTICES AFTER INITIATION OF ADVANCED THERAPIES IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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**CATEGORY:** Immunology, Microbiology and Inflammatory Bowel Diseases (IMIBD)

**SUBCATEGORY/DESCRIPTORS:** IBD: Disease Activity Assessment and Monitoring

**ABSTRACT BODY:**

**Background:**

Advanced therapies (AT) are effective for inducing remission in inflammatory bowel disease (IBD). A treat-to-target (T2T) approach with close monitoring of symptoms and inflammation is crucial to optimize outcomes. This study investigates the current state of T2T monitoring practices after AT initiation and risk factors for suboptimal monitoring for IBD patients at a large tertiary care center.

**Methods:**

This retrospective cohort study included adults with IBD initiated on AT with at least one year of follow-up after initiation at a large, academic tertiary care center between 2018 and 2023. Time to first gastroenterology (GI) encounter with symptom assessment, endoscopy, fecal calprotectin test, and imaging were summarized via Kaplan-Meier survival analysis. Multivariable logistic regression evaluated potential risk factors for lack of monitoring practices. Clinical remission was defined as a Harvey–Bradshaw Index <5 or a Simple Clinical Colitis Activity Index <3. Having any form of monitoring was defined as having a clinical remission assessment, fecal calprotectin test, endoscopy or imaging.

**Results:**

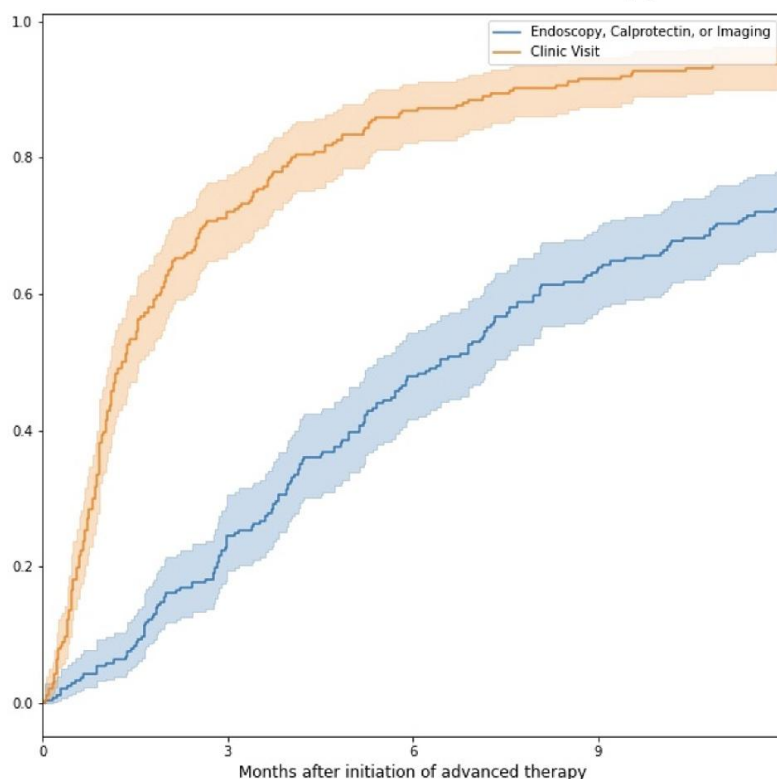
Among the 236 included patients, the mean age was 43.8 years (standard deviation [SD] 16.5), 50.0% were female, 61.4% were White, and 44.5% had Crohn's disease. By week 52, 93.6% had a GI encounter with symptom assessment (mean 11.9 weeks; SD 14.0), and 72.5% had inflammation assessed via endoscopy, calprotectin, or imaging (mean 29.9 weeks; SD 17.7) (Figure 1). By week 52, 47.5% of patients achieved clinical remission. Among those who did not achieve remission, 27.4% had their AT increased, 10.5% had their AT switched, and 6.5% had their AT stopped. In multivariable models (Table 1), being followed by an IBD specialist was significantly associated with timely clinical remission assessment (odds ratio [OR] 20.75,  $p < 0.01$ ) and having any form of monitoring (OR 5.53,  $p < 0.01$ ). Longer disease duration was inversely associated with assessment of clinical remission (OR 0.96,  $p = 0.04$ ). Living 20-40 miles from clinic was inversely associated with having any form of monitoring (OR 0.20,  $p = 0.01$ ). Older age was associated with having any form of monitoring

(OR 1.06,  $p=0.02$ ). Patient sex, race, ethnicity, IBD type, and extra-intestinal manifestations were not associated with monitoring practices.

### Conclusions:

Symptom and inflammation assessments were commonly performed after AT initiation, although T2T monitoring practices can be improved. Patients followed by IBD specialists were more closely monitored and more likely to be assessed for clinical remission after AT initiation. Travel distance adversely affected timely disease monitoring. Given these observed factors, quality improvement measures could include development of computerized reminders for providers and protocols that leverage remote monitoring and use of local third-party clinical laboratories.

**Figure 1: Time to first GI visit with symptom assessment and inflammation assessment after advanced therapy initiation**



**Figure 1:** Kaplan-Meier survival analysis depicting time to first gastroenterology encounter with symptoms assessment (N = 221) and time to first inflammation assessment via endoscopy, fecal calprotectin test, or imaging (N=171) within one year after advanced therapy initiation.

| Table 1: Predictors of treat-to-target monitoring practices after advanced therapy initiation |              |   |       |                                 |       |
|---|--------------|---|-------|---------------------------------|-------|
| Variables   |              | Outcome: assessment of clinical remission |       | Outcome: any form of monitoring |       |
|   |              | OR (CI)                                   | P     | OR (CI)                         | P     |
| Age (years)   |              | 1.03 (1.00-1.06)                          | 0.08  | 1.06 (1.01 - 1.11)              | 0.02  |
| Sex   | Female       | 0.57 (0.27-1.21)                          | 0.14  | 1.36 (0.52 - 3.56)              | 0.54  |
| Race  | White        | Reference                                 |       | Reference                       |       |
|   | Black        | 0.47 (0.09 - 2.54)                        | 0.38  | 0.19 (0.03 - 1.12)              | 0.07  |
|   | Asian        | 0.65 (0.17-2.43)                          | 0.52  | 1.49 (0.27 - 8.23)              | 0.65  |
|   | Other        | 0.73 (0.28 - 1.95)                        | 0.53  | 0.95 (0.26 - 3.45)              | 0.94  |
| Ethnicity   | Hispanic     | Reference                                 |       | Reference                       |       |
|   | Non-Hispanic | 1.39 (0.43 - 4.56)                        | 0.58  | 0.94 (0.20 - 4.40)              | 0.94  |
|   | Unknown      | 0.61 (0.12 - 2.99)                        | 0.54  | 0.35 (0.04 - 2.75)              | 0.32  |
| Distance (miles)  | 0-20         | Reference                                 |       | Reference                       |       |
|   | 20-40        | 0.53 (0.20 - 1.38)                        | 0.19  | 0.20 (0.06 - 0.69)              | 0.01  |
|   | >40          | 0.87 (0.34 - 2.26)                        | 0.78  | 0.57 (0.16 - 2.02)              | 0.38  |
| IBD type  | CD           | Reference                                 |       | Reference                       |       |
|   | UC           | 2.15 (0.99 - 4.66)                        | 0.05  | 1.30 (0.47 - 3.58)              | 0.61  |
| Disease duration  |              | 0.96 (0.93 - 1.00)                        | 0.04  | 0.98 (0.92 - 1.04)              | 0.51  |
| Extra-intestinal manifestations   |              | 1.36 (0.57 - 3.23)                        | 0.49  | 0.71 (0.25 - 2.05)              | 0.53  |
| IBD specialist  |              | 20.75 (8.89 - 48.46)                      | <0.01 | 5.53 (1.89 - 16.19)             | <0.01 |

**Table 1:** Multivariable regression analysis for having a formal assessment of clinical remission and any form of monitoring (formal clinical remission assessment, endoscopy, fecal calprotectin test, or imaging) within one year after advanced therapy initiation when adjusted for age, sex, race, ethnicity, distance of patient residence from clinic, IBD type, disease duration, presence of extraintestinal manifestations (EIM), and whether they were followed by an IBD specialist versus general GI physician.