Research Article

Impact of Clinical Pharmacists in the Inflammatory Bowel Disease Clinic

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Abstract

Background: Limited evidence exists regarding pharmacist involvement and impact in inflammatory bowel disease (IBD) interdisciplinary clinic care models. The purpose is to describe pharmacist utilization in an interdisciplinary IBD clinic and evaluate clinical impact on patient quality of life. **Methods:** This was a retrospective cohort study comparing outcomes in patients with Crohn's disease initiated on therapy when the implementation of pharmacy services began (Early Phase) to the expansion of pharmacy services (Recent Phase). The primary outcome compared the proportion of patients referred to a pharmacist and those achieving a Harvey-Bradshaw Index (HBI) reduction of ≥3 points after therapy initiation. **Results:** 50 patients were included in the Early Phase and 43 patients in the Recent Phase. Utilization in pharmacy referrals increased from 48% (n = 24) in the Early Phase to 72% (n = 31) in the Recent Phase ($P = 0.03$). The proportion of patients achieving a HBI reduction of ≥3 points increased from 35% (n = 14) in the Early Phase to 51% (n = 18) in the Recent Phase ($P = 0.23$). Results also found a greater proportion of patients remaining steroid free in the Recent Phase compared to the Early Phase (50% vs 63%; $P = 0.01$) and C-reactive protein (CRP) improved significantly in the Recent Phase (−11) compared to (−3) in the Early Phase ($P = 0.006$). **Conclusion:** The utilization of pharmacists in an interdisciplinary IBD clinic increased and showed to impact patient care through improving symptom relief as seen by the achievement rate of the HBI score reduction, reducing steroid use after therapy initiation, and making clinically significant interventions.

Keywords

Crohn's disease, interdisciplinary, pharmacists

Key Messages

1. Crohn's disease is an autoimmune, incurable disease this is primarily managed with biologic therapy with goal to induce and maintain remission.
2. Clinical pharmacists have shown to improve outcomes in other chronic disease, but limited evidence exists to support an interdisciplinary approach and/or clinical pharmacist impact in the management of patients with Crohn's disease.
3. An interdisciplinary approach can improve patient quality of life and clinical outcomes including symptoms scores like the HBI, reduce the need for steroids, and improve inflammatory markers.

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Introduction

Inflammatory bowel disease (IBD) is an autoimmune, incurable, relapsing, and remitting intestinal disease that consists of conditions including Crohn's disease and ulcerative colitis.[1] Each year IBD accounts for 700,000 physician visits, 100,000 hospitalizations, 119,000 cases of disabilities, and more than $1.7 billion in costs to the health care system.[2] Approximately 1.6 million Americans are affected by IBD and 785,000 are affected by Crohn's disease.[3] Crohn's disease can involve any point of the gastrointestinal tract from the mouth to the anus.[3] This creates a wide spectrum of clinical presentations in which Crohn's disease can present, therefore disease activity becomes important in monitoring disease severity and changes in symptoms after therapy initiation.

Crohn's disease is stratified into remission, mild, moderate, or severe disease. The impact of disease burden is measured by clinical symptoms and quality of life experienced by the patient. This is important as the two main goals in Crohn's management include clinical and patient reported remission and endoscopic remission. The gold standard for evaluating clinical symptoms in randomized controlled trials is the Crohn's Disease Activity Index (CDAI).[4] One of the modified versions of the CDAI is the Harvey-Bradshaw Index (HBI). The HBI is used more commonly in practice as it only requires one day of patient entries vs the seven days required in the CDAI.[5] The HBI has been found to correlate with the CDAI. In PRECiSE 3 the HBI was used to measure Crohn's disease activity and clinical response was defined as a reduction in HBI of 3 points or more and remission as a score of 4 points or less.[5] The American Journal of Gastroenterology recommends the use of biologics and immunomodulators to induce and maintain remission in patients with moderate to severe Crohn's disease.[4] Additionally, guidelines state therapy should show maximal improvement within 12-16 weeks of initiation.[4] Although proven to be effective in the management of Crohn's disease, therapy requires extensive monitoring, education, and follow-up.

Specialty medications like the ones used to manage Crohn's disease are high-cost medications.[6] In 2019 infliximab and vedolizumab were within the top 25 drugs by expenditures in nonfederal hospitals.[6] Administering intravenous biologics in the ambulatory care setting reimbursement is directly tied to the cost and administration of the medication and therefore improves reimbursement.[6] Specialty pharmacists have helped lead the way in assisting with coordination of outpatient infusions, as well as facilitating prior authorizations and financial assistance to improve medication access and adherence.[7]

There is no evidence to support the direct clinical impact pharmacists may have in an inflammatory bowel disease clinic but there is evidence to support pharmacists improving medication acceptance and adherence rates.[1] The unpredictability of Crohn's disease makes adherence challenging.[8] Nonadherence occurs in 45% of Crohn's disease patients and leads to increased rates of relapse and health care utilization.[1] One study evaluated the effects of having one personalized IBD pharmacist adherence and medication counseling visit at baseline on nonadherent patients initiating IBD therapy. The study's main focused on intentional nonadherence which is defined as the deliberate decision to stop maintenance medications due to not understanding the necessity of the medication or other concerns including side effects or cost.[1] The study found pharmacist medication counseling reduces nonadherence from 100% to 44.4%.[1] Although pharmacists have shown to improve adherence in an IBD clinic, there is currently no evidence on the clinical outcomes pharmacists may have when incorporated in an IBD clinic.

Clinical pharmacy services were incorporated in 2018, including medication education and monitoring, serving as a liaison for specialty medications, and providing program support for drug information and formulary management. We sought to investigate how pharmacist utilization in the IBD clinic impacted the management of Crohn's disease. The purpose of this study is to describe pharmacist utilization in an academic medical center interdisciplinary IBD clinic and evaluate clinical impact on patient quality of life.

Materials and Methods

Study Population

This was a retrospective cohort study comparing patients with a listed diagnosis of Crohn's disease newly prescribed Crohn's therapy when the implementation of pharmacy services began (Early Phase) in November 2018 to April 2019 and continuation of pharmacy services (Recent Phase) in November 2021 to April 2022. All patients with diagnosis of Crohn's disease, age 18-89, seen from 11/1/2018 to 4/30/2019 and in 11/1/2021 to 4/30/22 and prescribed one of the following biologics: infliximab, adalimumab, certolizumab, ustekinumab, or vedolizumab were eligible for inclusion. To be eligible for inclusion, patients also had to have HBI scores pre- and post-therapy initiation. Patients were excluded if they were less than 18 or greater than 89 years of age, pregnant, prisoners, or if they initiated one of the following biologics: tofacitinib, upacitinib, or ozanimod.

Outcomes

The purpose of this study was to describe pharmacist utilization in an academic medical center interdisciplinary IBD clinic and evaluate clinical impact on patient quality of life.

The primary outcome of this retrospective analysis was to compare the proportion of patients referred to a clinical pharmacist and those achieving a HBI reduction of ≥3 points at 6 months after Crohn's therapy initiation between patients in

the Early Phase and those in the Recent Phase. Only those with a HBI ≥3 were included for statistical analysis when comparing the proportion of patients achieving a HBI reduction of ≥3 points. Secondary outcomes included comparing the change in disease severity as defined by HBI, remission was defined as a HBI <5 and severe disease was defined as a HBI >16. Other secondary outcomes included total patients on target dose/maximally tolerated dose of azathioprine, changes in SIBDQ (Short Inflammatory Bowel Disease Questionnaire) score, composite of ED visits, hospitalizations, surgical procedures related to Crohn's disease, changes in PHQ-9 score, total corticosteroid use, and up to date vaccine status. Subgroup analysis was performed on patients seen in the pharmacist-run clinic to describe interventions made by the clinical pharmacists.

Data Collection

Patients with a listed diagnosis of Crohn's disease and newly prescribed Crohn's disease therapy in the Early Phase (11/1/2018 to 4/30/2019) and compared to the Recent Phase (11/1/2021 to 4/30/2022) via a query from the Information warehouse, as appropriate. Data was collected retrospectively from existing medical records (the Integrated Health Information System, IHIS) using a data collection form.

Data collected included patient characteristics (sex, age, and race), insurance status, duration of disease, and therapy prescribed at the time of study inclusion. Additional data included azathioprine dose, smoking status, HBI score, SIBDQ score which is a disease-specific health-related quality of life tool used in Crohn's disease (higher score indicates higher quality of life) and PHQ-9 score which is a tool that helps assess depression, CRP, erythrocyte sedimentation rate (ESR), fecal calprotectin, Hepatitis A, B, and C battery, tuberculosis (TB) status, corticosteroid therapy, dual energy X-ray absorptiometry (DEXA) completion of required vaccinations, referrals to clinical pharmacy, ED/hospitalizations related to Crohn's, and surgical procedures related to Crohn's disease. Interventions made by clinical pharmacist were also collected.

Statistical Analysis

Demographic and clinical characteristics were analyzed using descriptive statistics. Discrete data was presented as count (n) and frequency (%) and compared using χ^2 tests or Fisher's exact tests. Continuous data was summarized as mean/standard deviation (SD) and compared using Student's t tests or U rank sum tests where appropriate. The potential associations between primary endpoints and demographic/clinical factors were analyzed for correlation. All statistical tests were two-sided, and the significance level was set at alpha = 0.05.

Results

Initially, 438 patients were screened the Early Phase and 464 patients in the Recent Phase. Of those, 50 patients were included in the Early Phase and 43 patients in the Recent Phase. The majority of patients not meeting inclusion criteria were due to missing a HBI score pre- or post-therapy initiation, or therapy not being newly initiated. Figure 1 is a flow chart summarizing inclusion and exclusion of patients. Prior to going into the results will note the limitations of utilizing *P*-values to analyze statistical significance includes but is not limited to inability of *P*-values to measure the size of an effect or the importance of the result therefore proper and transparent analyzation of the data has been completed to make appropriate inferences.

Baseline characteristics (Table 1) were similar between both the Early Phase and Recent Phase except there were slightly more patients at baseline considered to be in remission (HBI score <5) at 50% (n = 25) in the Early Phase compared to 44% (n = 19) in the Recent Phase; and there were no patients in the Early Phase that were considered to have severe disease activity compared to 2 (5%) in the Recent Phase.

For the primary outcomes, referrals to pharmacy increased from 48% (n = 24) in the Early phase to 75% (n = 31) in the Recent Phase (P = 0.03). The proportion of patients achieving ≥3 reduction in the HBI improved from 35% (n = 14/35) in the Early Phase to 51% (n = 18/51) in the Recent Phase (P = 0.23). Figure 2 describes the proportion of patients achieving ≥3 point reduction in the HBI and the proportion of patients referred to clinical pharmacists.

When comparing secondary outcomes the change in the HBI, the mean change in the HBI was greater in the Recent Phase −2.1 (5) compared to the Early Phase group −0.6 (3) (P = 0.10). The proportion of patients achieving remission or a final HBI <5 improved from 16% in the Early Phase to 23% in the Recent Phase. The improvement in the SIBDQ scores and PHQ-9 scores were not found to be statistically significant. The mean improvement in the SIBDQ scores were 3 points in the Early Phase group compared to 4 points in the Recent Phase (P = 0.40) and the mean improvement in the PHQ-9 scores were 0 in the Early Phase compared to 1 in the Recent Phase (P = 0.63). Health care utilization rates were low in both groups although there was greater proportion of patients in the Early Phase visiting the 1-2 ED times compared to the Recent phase (30% vs 16%).

Corticosteroid use after therapy initiation was significant. There was a greater proportion of patients in the Early Phase that were prescribed corticosteroids after therapy initiation compared to the Recent Phase (48% vs 35%) and a greater proportion of patients in the Recent Phase remaining steroid free compared to the Early Phase (63% vs 50%) as seen in Figure 3. This represents a 26% relative increase observed in the proportion of patients remaining steroid free after therapy initiation in the Recent Phase. The change in Fecal calprotectin and ESR from baseline to 6 months although greater in

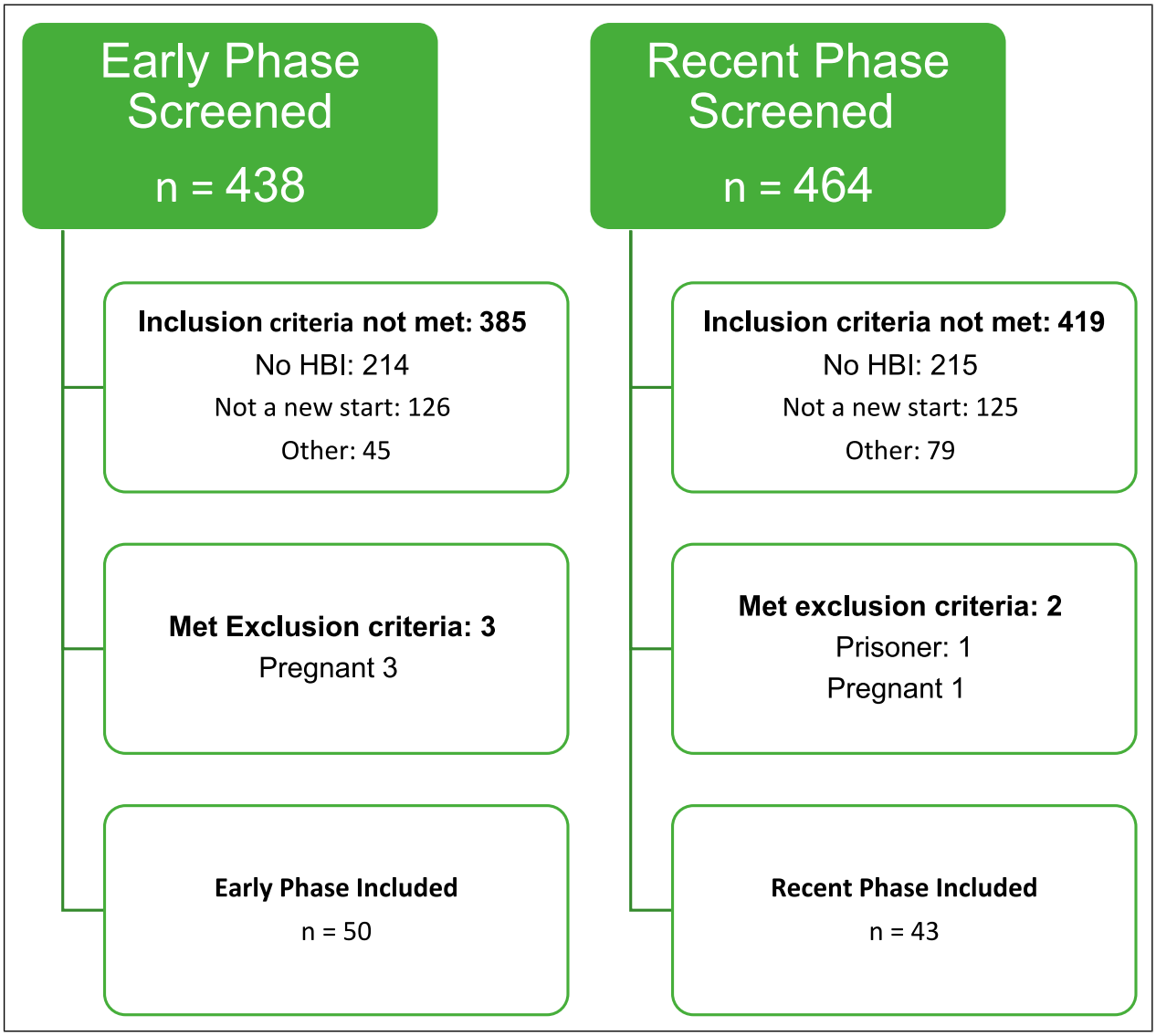

Figure 1. Showing the breakdown of the inclusion and exclusion of patients.

the Recent Phase was not found to be statistically significant compared to the Early phase as shown in Figure 4. On the other hand the change in CRP was not only greater it was also found to be statistically significant in the Recent Phase compared to the Early Phase (−11 vs −3; $P = 0.006$) as shown in Figure 4.

Other secondary outcome compared the achievement of target dose vs max tolerated dose of azathioprine. Majority of patients in both the Early phase and Recent phase group achieved target doses of Azathioprine (82% vs 78%) ($P = 0.99$). In both the Recent Phase and Early Phase there was a low proportion of patients that discontinued azathioprine (11% vs 9%). Patients with Crohn's disease taking biologic therapy undergo routine monitoring for opportunistic injection such as tuberculosis and hepatitis B. After 6 months nearly 100% of patients in both groups had completed TB quants and Hepatitis Battery. Other safety parameters include being up to date on vaccines and DEXA scans. The mean number of vaccines recommended during the follow-up was relatively unchanged among those patients in the Early Phase compared to those in the Recent Phase. Lastly in those patients due for DEXA scans at baseline most had completed them at follow-up.

The subgroup analysis which assessed those patients referred to clinical pharmacy had 22 patients in the Early Phase compared to 28 in the Recent Phase. Figure 5 depicts the reasons for referral. The only reason for referral in the Early Phase was for injection training. In the Recent Phase there was an increase in reasons for referral including not only injection training but also for new medication education, education on available therapy prior to drug initiation, and medication monitoring (P=<0.001). There were more interventions per patient in the Recent Phase compared to the Early Phase (5 [2.2] vs 4 [0.9]; $P = 0.05$).

Table 1. Demographic and Clinical Characteristics of the Study Population. Baseline Characteristics Values are Mean ± SD, n (%). *P* Values ≤0.05 Were Considered Statistically Significant. Abbreviation HBI, Harvey Bradshaw Index.

	Early Phase (n = 50)	Recent Phase (n = 43)	*P*-Value
Mean age, y (SD)	38 (15)	37 (16)	0.75
Male, n (%)	30 (40)	17 (40)	0.99
Ethnicity, n (%)			
Caucasian	43 (86)	36 (84)	0.94
A. American	4 (8)	5 (12)	
Hispanic	2 (4)	2 (4)	
Other	1 (2)	--	
Smoking status, n (%)			
Never	37 (74)	28 (65)	0.35
Former	7 (14)	11 (26)	
Current	6 (12)	4 (10)	
Insurance status, n (%)			
Medicare	4 (8)	5 (12)	0.80
Medicaid	10 (20)	10 (23)	
Commercial	36 (72)	28 (65)	
Therapy at inclusion, n (%)			
Infliximab	13 (26)	12 (28)	0.08
Vedolizumab	10 (20)	7 (16)	
Ustekinumab	16 (32)	17 (40)	
Adalimumab	9 (18)	7 (16)	
Certolizumab	1 (4)	---	
Mean age diagnosed, y (SD)	28 (12)	29 (16)	0.83
HBI, n (%)			
<3	10 (20)	8 (19)	0.99
≥3	40 (80)	35 (81)	0.99
<5 (remission)	25 (50)	19 (44)	0.73
5-7 (mild activity)	13 (26)	11 (26)	0.99
8-16 (moderate activity)	12 (24)	11 (25)	0.99
>16 (severe activity)	0 (0)	2 (5)	0.21
On azathioprine, n (%)	11 (22)	9 (21)	0.99
Therapy at inclusion, n (%)			
Infliximab	13 (26)	12 (28)	0.08
Vedolizumab	10 (20)	7 (16)	
Ustekinumab	16 (32)	17 (40)	
Adalimumab	9 (18)	7 (16)	
Certolizumab	1 (4)	---	

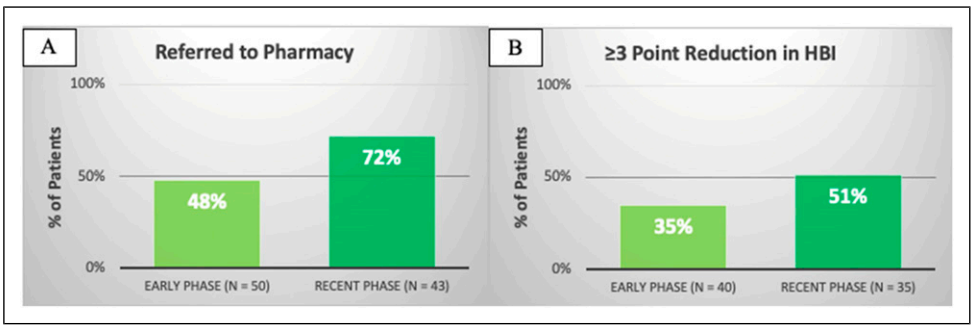

Figure 2. Demonstrates the (A) proportion of patients referred to clinical pharmacists and (B) proportion of patients achieving a ≥3 point reduction in HBI in the early phase compared to the recent phase.

Beyond medication education there were many interventions made by the clinical pharmacist as shown in Figure 6 but the most common interventions included vaccine counseling, immunomodulator monitoring, placing orders for providers and facilitating medication access. Facilitating medication access included coordinating medication assistance applications between patients and outpatient providers, submitting prior authorizations, coordinating approvals for outside and in house infusion, and assisting with formulary management. The mean number of visits in both groups was 2 but the total number of visits nearly doubled in the Recent Phase compared to the Early Phase group (68 vs 38).

Discussion

The findings in this study demonstrated the growth and value clinical pharmacists have in an IBD clinic. This study showed with the increase in clinical pharmacist utilization there was also a clinically significant improvement in the HBI, patients remaining steroid free, and inflammatory markers. Although not statistically significant, there was a 46% relative increase observed in the proportion of patients achieving ≥3 point reduction in the HBI. Lack of statistical significance was maybe due to having a small sample size or not matching the groups at baseline, this is the first study evaluating the impact clinical pharmacists can have on symptom control in patients with Crohn's disease. Although our study did not specifically evaluate adherence, a previous prospective multi-center study showed improvements in adherence and medication acceptance rates after only one pharmacist counseling session.[1] In our study the average visits with a clinical pharmacist was found to be 2 in both the Early Phase and Recent Phase but the total visits with a pharmacist nearly doubled in the Recent Phase compared to the Early Phase. The clinically significant improvement in the HBI can be a reflection of the increase in pharmacist utilization by both providers and patients as it can show closer and more frequent monitoring leads to better adherence and symptom control.

The benefits of increased pharmacist utilization can also be seen in the greater proportion of patients in the Recent Phase remaining steroid free after therapy initiation and a statistically significant improvement in CRP when compared to the Early Phase. Improvements in inflammatory markers and symptom control are valuable markers as short-term treatment goals per the guidelines include symptomatic response and normalization of CRP; improvement in inflammatory markers also serve as important indicators of therapy efficacy. The greater proportion of patients remaining steroid free and improvements in CRP can be related to improved access to the health care team. Patients in the Recent Phase had nearly double the amount of pharmacy visits compared to the Early Phase. Patients having more access to the pharmacist and the care team likely helped reduce barriers to medications. Although this study did not measure barriers or other factors impacting medication access the most common interventions made by the clinical pharmacist was medication coordination. By pharmacists being able to successfully reduce barriers to therapy by submitting prior authorizations to insurance, scheduling outside and in house infusions, and coordinating medication assistance enrollment likely contributed to the improvement in medication access and subsequently limiting steroid use and improving inflammatory markers. A recent retrospective study evaluating outcomes of patients referred to pharmacists showed an improvement in medication access. [7] There were 1800 referrals of patient needing to start IBD

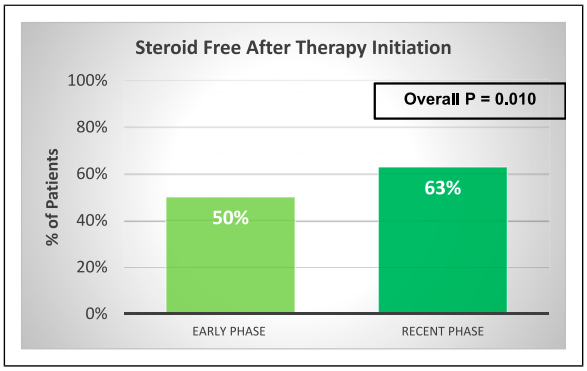

Figure 3. Summarizes the proportion of patients initiated on corticosteroids after therapy initiation and the proportion of patients remaining steroid free in the early phase compared to the recent phase.

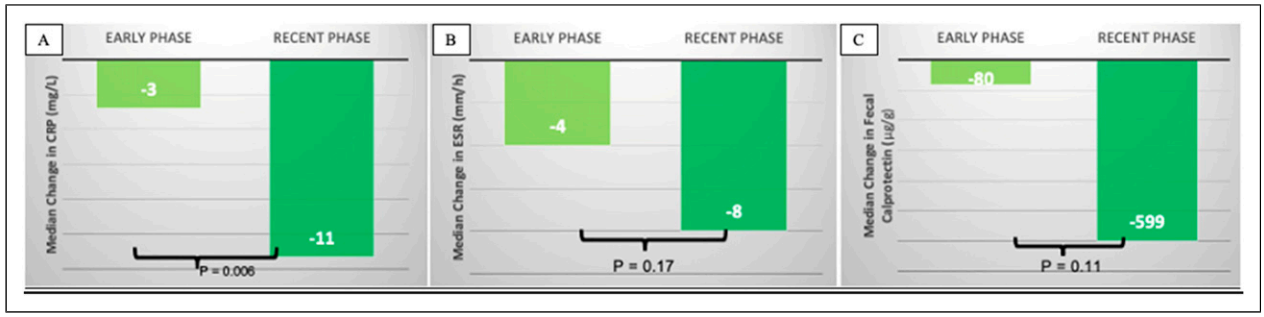

Figure 4. Summarizes the changes in inflammatory markers. (A) Shows improvement in CRP, (B) ESR, and (C) Fecal Calprotectin with respective *P*-values.

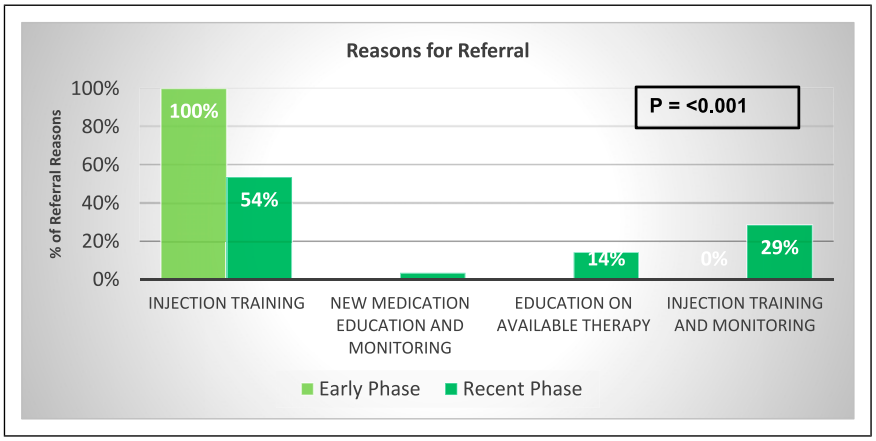

Figure 5. Compared reasons for referrals to clinical pharmacists. Early Phase only had one reason for referral compared the Recent phase.

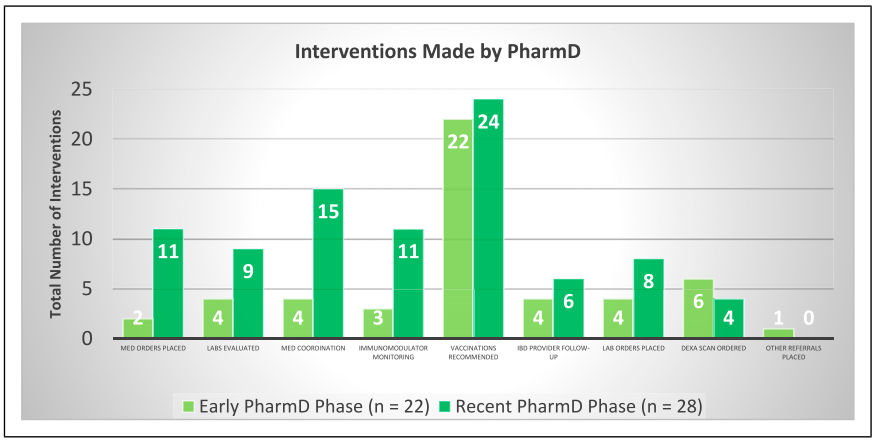

Figure 6. Summarized the interventions made by the clinical pharmacist. The most common interventions were vaccine counseling, medication coordination, immunomodulator monitoring, and placing medication orders.

therapy and 98% of those patients referred to a clinical pharmacist successfully initiated on intended therapy. Our study showed the integration of clinical pharmacists in an IBD center can lead to not only improvements in medication access but improvements in patient care and access to the health care team.

Our study not only helped show the clinical impact pharmacists can have in an IBD center it also helped describe the scope of their clinical interventions. A recent retrospective study evaluating outcomes of patients done at the University of Chicago Medicine, Inflammatory Bowel Disease Center evaluated interventions made when patients were referred to a pharmacist.[7] The most predominant interventions made were prevention of loss in therapy, patient education, and lab recommendations. Similarly, our study found the most prevalent interventions were medication education, medication coordination to avoid lapse or delay in therapy, along with vaccine counseling medication monitoring, and placing medication orders. As the pharmacy services grew along with the relationship with the providers there was a greater variability in referral type and therefore an increased ability to make further clinical interventions along with medication education. Not only were pharmacists helping with injection training they were also helping educate on available therapy prior to initiation and monitoring medications.

Limitations included the potential for selection bias in the sample selection and limited sample size primarily due to missing a HBI score either at baseline or follow-up. Obtaining a HBI score is not always feasible as it is a patient score test therefore not always easily completed at each visit. Thus, not all those who were seen in clinic were represented in the study and it is possible that further impact was not seen in the results of the study. The small sample size also created a large standard deviation in the Recent Phase leading to insignificant results that would be improved with a larger sample size. Additionally, both the Early Phase and Recent Phase were not matched based on disease severity leading to a potential confounding factor as there were more patients in the Early Phase that were in remission at baseline compared to the Recent Phase.

Conclusions

The introduction of pharmacists was successful in impacting patient care in the ability to improve symptom relief, reducing

the use of steroids after Crohn's therapy initiation, and making clinically significant interventions. The success was likely contributed to by an increase in pharmacist utilization. The results of this study provide an example for other institutions to implement pharmacy services into IBD clinics to help improve patient quality of life, improve medication access, help patients stay up to date on vaccines and lab monitoring, and ultimately optimize patient care.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Summary

Limited literature exists to support pharmacist utilization in an interdisciplinary inflammatory bowel disease care model. Crohn's disease requires specialty medications like biologics to induce and maintain remission. Pharmacist utilization can improve clinical outcomes and patient quality of life.

IRB Statement

The following research has received IRB approval from the Office of Responsible Research Practices at the Ohio State University. Study ID: 2022H0403.

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