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Oral Vancomycin Is Associated With Less IBD Therapy Intensification in PSC-IBD

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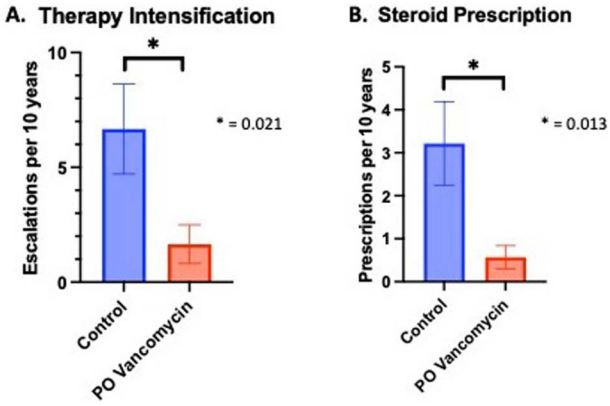
Introduction: Primary sclerosing cholangitis (PSC) is a progressive, cholestatic liver disease. About 70% of patients with PSC have co-morbid inflammatory bowel disease (IBD), typically ulcerative colitis (UC). There is no proven disease-modifying therapy for PSC, though oral vancomycin therapy (OVT) has received considerable interest. Anecdotally, patients with PSC-IBD treated with OVT seemed to have fewer IBD flares. To date, only case reports and a small case series have been published. We aim to determine the impact of OVT on IBD disease activity, estimated by therapy intensification, in patients with concomitant IBD and PSC.

Methods: This was a two-center, retrospective, self-controlled, cohort study. The study population included patients >18 years of age, confirmed diagnosis of PSC and IBD, history of OVT prescribed for the treatment of PSC after their diagnosis of IBD. Time off OVT was defined as any period after IBD diagnosis when the patient was not taking OVT. Therapy intensification was defined as therapy change, dose escalation or steroid prescription. Patients served as their own control, comparing number of therapy intensifications as a composite outcome between periods on and off OVT for the same patient.

Results: 15/22 (68.2%) had less therapy intensification on OVT compared to off OVT. For our primary outcome, there was a significant difference in the number of therapy intensification events when comparing OVT to control periods. The mean number of therapy intensifications per 10 person-years on OVT was 1.7 compared to 6.7 intensifications per 10 person-years when off OVT (P=0.021, Figure 1a). For our secondary outcome, OVT was associated with less frequent steroid prescriptions with 0.6 prescriptions per 10 person-years compared to 3.2 prescriptions per 10 person-years without OVT (P=0.013, Figure 1b). See Table 1 for patient demographics.

Conclusion: To our knowledge, this is the first study to show that OVT use was associated with less therapy intensification in patients with PSC-IBD. OVT was also associated with a decreased rate of steroid prescriptions. These results suggest that OVT could be an effective pharmacologic therapy for controlling IBD in patients with PSC-IBD. Hypothesized mechanisms by which OVT impacts IBD include direct modulation of the microbiota, alteration in bile acid profile, and increases in peripheral regulatory T cells. Further investigation with a prospective pilot study is warranted to confirm these findings.



[1090] **Figure 1.** Comparison of therapy escalation (a) and steroid prescriptions (b) between periods of time on and off OVT per 10 person-years of follow-up.

Table 1. Comparison of baseline demographics and clinical characteristics of patients with less therapy intensification on oral vancomycin therapy (OVT) to those with more intensification on OVT

Characteristic	All patients (n=22)	LI (n=15)	MI (n=7)	*P*-value
Median Age, y (IQR)	23.5 [21.0-28.3]	25.5 [22.0-29.0]	21.5 [19.8-24.5]	0.174
Male, (%)	15 (68.2%)	11 (73.3%)	4 (57.1%)	0.642
Race and Ethnicity, (%)				
Caucasian	11 (50.0%)	8 (53.3%)	3 (42.8%)	0.667
Black	2 (9.1%)	2 (13.3%)	0 (0.0%)	0.526
Asian	2 (9.1%)	2 (13.3%)	0 (0.0%)	0.526
Hispanic	5 (22.7%)	3 (20.0%)	2 (28.6%)	0.999
Other	2 (9.1%)	0 (0.0%)	2 (28.6%)	0.111
IBD, (%)				
Ulcerative colitis	21 (95.5%)	15 (100.0%)	6 (85.7%)	0.318
Proctitis	2 (9.1%)	2 (13.3%)	0. (0.0%)	0.999
Left-sided	4 (18.2%)	2 (13.3%)	2 (33.3%)	0.565
Pancolitis	15 (68.2%)	11 (73.3%)	4 (66.7%)	0.630
Crohn's disease	1 (4.5%)	0 (0.0%)	1 (14.3%)	0.318
Colon only	1 (4.5%)	0 (0.0%)	1 (100.0%)	0.318
Duration of IBD, months (IQR)	129.0 [108.5-184.8]	125.0 [99.3-167.0]	146.0 [110.8-206.0]	0.352
Time off OVT, months (IQR)	48.0 [27.0-80.3]	46.1 [17.0-82.8]	48.0 [31.3-80.3]	0.980
Time on OVT, months (IQR)	88.4 [47.5-102.0]	82.8 [41.8-101.3]	96.0 [63.8-136.3]	0.296
IBD Medications				
Salicylates	14 (63.6%)	9 (60.0%)	5 (71.4%)	0.999
Immunomodulators	5 (22.7%)	3 (20.0%)	2 (28.6%)	0.999
Biologics	2 (9.1%)	2 (13.3%)	0 (0.0%)	0.999
Steroids	4 (18.2%)	3 (20.0%)	1 (14.3%)	0.999
Cirrhosis	7 (31.8%)	5 (33.0%)	2 (28.5%)	0.999

Table 1. (*continued*)

Characteristic	All patients (n=22)	LI (n=15)	MI (n=7)	*P*-value
Compensated cirrhosis	4 (18.2%)	3 (20.0%)	1 (14.3%)	0.999
Decompensated cirrhosis	3 (13.6%)	2 (13.3%)	1 (14.3%)	0.999
Dominant stricture	9 (40.1%)	4 (26.7%)	2 (28.6%)	0.999
Episode of cholangitis	3 (13.6%)	3 (20.0%)	0 (0.0%)	0.523
Charlson Comorbidity Index	0.0 [0.0-1.0]	0.0 [0.0-1.0]	0.5 [0.0-1.0]	0.722

Demographic and Clinical Characteristics, Median [IQR] or N (%).
IBD medications recorded in this table are prior the first prescription of OVT. 5-ASA, aminosalicylic acid; IBD, inflammatory bowel disease; IQR, interquartile range; LI, less intensification; MI, more intensification; PSC, primary sclerosing cholangitis; y, year *P*-value given for comparison of those with less therapy intensification (LI) to those with more therapy intensification (MI).

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Inflammatory Bowel Disease Course May Be Less Severe in Patients After Liver Transplantation for Primary Sclerosing Cholangitis: A National Database Review

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Introduction: Data on the outcomes of inflammatory bowel disease (IBD) post liver transplant (LT) for primary sclerosing cholangitis (PSC) have been reported in small studies in the past. We explored the MarketScan database to investigate the outcomes of IBD in post-LT patients with PSC.
Methods: Adult patients older than 18 years with IBD and PSC who underwent LT between 1/1/2013 and 11/23/2020 were analyzed in the Marketscan claims database. Patients were excluded if they were in the database for less than 3 months pre-LT, had less than 6 months enrollment post-LT, or had HIV/AIDS. IBD outcomes were based on immunosuppresive medications, IBD-related surgery, and IBD-related hospitalizations. McNemar's tests and signed rank test were used.
Results: A total of 178 patients with IBD and PSC with mean age at LT of 46.5±12.5 years, 29.2% female were studied. Median follow up was 29.86 months. Pre-LT 94 (52.8%) patients were on steroids, 90 (50.5%) were on 5-ASA, 35 (19.6%) were on antimetabolites, 20 (11.2%) were on biologics, 1 (0.5%) was on small molecules for IBD and 26 (14.61%) were on transplant medications. Post-LT 159 (89.3%) patients were on steroids, 76 (42.7%) on 5-ASA, 27 (15.1%) on antimetabolites, 11 (6.2%) on biologics, none on small molecules for IBD and 164 (92.13%) were on transplant medications. As expected, more patients were prescribed transplant medications ($P< 0.0001$) and steroids ($P < 0.001$) post-LT as compared to pre-LT. There was a trend toward less 5-ASA and biologics used post-LT ($P=0.06$) for IBD. Eleven (6.2%) patients had IBD-related surgeries pre-LT compared to 7 (3.9%) post-LT ($P=0.45$). The cohort had a median of 1 hospitalization (IQR: 0-3) for IBD pre-LT and a median of 1 hospitalization (IQR: 0-2) post-LT ($P=0.02$, Table 1).
Conclusion: We found that IBD course in the post-LT setting in patients with IBD and PSC may not be as severe as pre-LT, as reflected by a trend in less use of 5-ASA and biologics and less IBD-related hospitalizations. We were unable to tease out the impact of biologics and small molecule medications in these patients due to their limited use in this cohort. This information is useful in management of patients with IBD who are post-LT for PSC in the real-world setting.

Table 1. **Comparison of inflammatory bowel disease (IBD) severity as indicated by immunosuppressive medications, IBD-related surgeries and IBD-related hospitalizations pre and post liver transplant (LT), n=178**

Variable	Pre-LT	Post-LT	*P*-value
Transplant Medications	26 (14.61%)	164 (92.13%)	< **0.0001***
Steroids	94 (52.81%)	159 (89.33%)	< **0.001***
Biologics	20 (11.24%)	11 (6.18%)	0.06**
5-ASA	90 (50.56%)	76 (42.70%)	0.06*
Antimetabolite	35 (19.66%)	27 (15.17%)	0.22*
Small molecules	1 (0.56%)	0 (0.00%)	N/A
IBD surgery (at least one)	11 (6.18%)	7 (3.93%)	0.45**
Strictureplasty	1 (0.56%)	0 (0.00%)	N/A
Colectomy	9 (5.06%)	5 (2.81%)	0.42**
Enterostomy	4 (2.25%)	3 (1.69%)	1.00**
Anal Fistula Surgery	0 (0.00%)	1 (0.56%)	N/A
Incision and Drainage	1 (0.56%)	1 (0.56%)	1.00**
Proctectomy	1 (0.56%)	2 (1.12%)	1.00**
IBD Hospitalizations			**0.02*****
Median (IQR)	1 (0-3)	1 (0-2)	
Range	0-13	0-18	

*McNemar's Test was used.
**Exact McNemar's Test was used.
***Signed Rank Test was used.

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How Does Human Immunodeficiency Virus Affect Outcomes in Patients With Inflammatory Bowel Disease? An Analysis of the National Inpatient Sample Data From 2016 to 2020

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Introduction: The effect of HIV on IBD has been controversial. The remission hypothesis secondary to CD4 count depletion has been hypothesized but not proven yet. The aim of this study is to examine the characteristics and outcomes of IBD patients with HIV and compare them to IBD patients without HIV.
Methods: Patients hospitalized between 2016 and 2020 who were admitted for Ulcerative colitis (UC) and Crohn's disease (CD) were identified using International Classification of Diseases Code,10th Revision Clinical Modification (ICD-10) identified from the Healthcare Cost and Utilization Project databases (HCUP) using the National inpatient sample (NIS). Patients with history of HIV were compared to patients without HIV.
Results: A total number of 410950 patients with history of UC were identified. 1000 patients had a history of HIV. General characteristics are summarized in Table 1. HIV patients were younger, less likely to be covered by Medicare and female constituted lower proportion. Mortality rate and length of stay (LOS) were similar in both groups. Patients with UC and history of HIV were more likely to develop ano -rectal