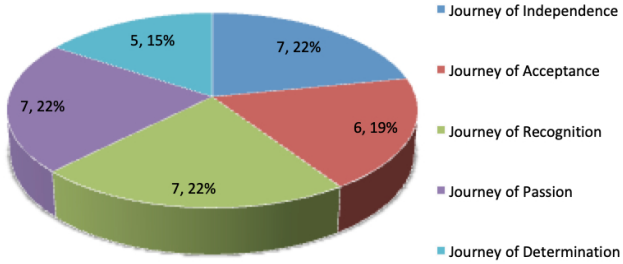
Table. Demographics of Patients with IBD Who Participated in Interviews

	Patients (N = 32)	Percentage
Disease by Gender		
Crohn's Disease		
Female	11	34.4%
Male	6	18.8%
Ulcerative Colitis		
Female	8	25.0%
Male	5	15.6%
Indeterminate Colitis		
Female	2	6.3%
Age Range		
18-24	12	37.5%
25-44	9	28.1%
45-64	5	15.6%
65+	6	18.8%
US Region		
Midwest	11	34.4%
East	6	18.8%
South	8	25.0%
West	7	21.9%
Location		
Suburban	16	50.0%
Urban	13	40.6%
Rural	3	9.4%

IBD Patient Experience Journeys
(Based on Analysis of Qualitative Interviews)



Listed as n. %

PHOTOVOICE AS A TOOL TO IMPROVE PATIENT - PROVIDER COMMUNICAITON IN INFLAMMATORY BOWEL DISEASE CLNIIC: A PILOT OF FEASIBILITY STUDY

Ksenia Gorbenko, Alexa Riggs, Sydney Phlegar, Brooke Koeppel, Marla Dubinsky, Ryan Ungaro, Laurie Keefer

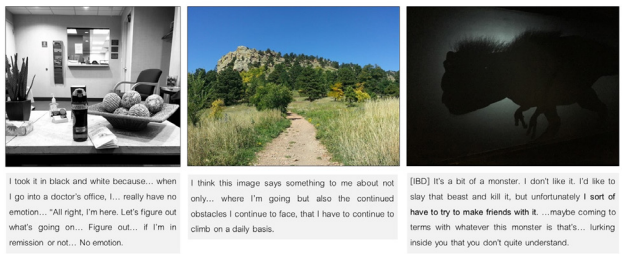
Introduction: The emotional health of patients with IBD has been difficult to elucidate in routine IBD care, but is critical to medication adoption, adherence and self-management. Patients often are unsure how to communicate their preferences and concerns to their providers in ways that could directly inform shared decision making. Photovoice is an established research methodology used to give vulnerable patients a voice through alternative communication strategies, but has not been previously used in IBD.

Aim: Our goal was to determine the acceptability and feasibility of developing a communication tool using photovoice in an IBD clinic. The ultimate goal is to adapt Photovoice to facilitate doctor – patient communication around treatment and wellness goals in the clinic setting.

Methods: We recruited patients at a single tertiary care IBD center in 2019 to participate in a pilot Photovoice study. Patients received a digital camera, training on basic usage and 10 disease specific prompts focused on goals/strategies they used to manage IBD. For example, "What is the most important thing for your doctor to know about you?" Patients then participated in in-depth interviews where they shared the photos they took and described rationale for their photo choice. The interviews lasted approximately one hour and were audio recorded and professionally transcribed. Three analysts coded transcripts for themes using qualitative analysis software QSR NVivo 11. Subsequently, five physicians were recruited and also participated in in-depth interviews to gauge provider feasibility of incorporating Photovoice into clinical practice.

Results: Fifteen patients were enrolled, median age 28 IQR (24–40), 66% women, 86% white. Three patients (20%) identified as Hispanic and six (40%) identified as Ashkenazi Jewish. Fourteen transcripts were available for analysis (9 patient and 5 providers). A total of 87 photos were taken and reviewed with patients, with a subset of 15 photos reviewed with physicians. The general themes from patients were physical and psychological aspects of disease, logistical/practical aspects, and future with IBD. Physician response was overwhelmingly supportive of incorporating Photovoice into clinical practice and suggested several ways to incorporate: 1. As discrete parts of visits to foster goal-setting and identify patient priorities. 2. Displayed in the hallways of the clinic to foster community among patients. 3. As part of electronic medical records or as prompts in the waiting room to generate referrals to other resources like psychotherapy, social work and diet consults.

Conclusions: Photovoice is a feasible methodology for patients with IBD and acceptable to providers to use in a clinical setting. Photovoice may help providers identify patient concerns and tailor their communication and enhance approaches to shared decision making.



POLYSUBSTANCE USE IN INFLAMMATORY BOWEL DISEASE

Kaleb Bogale, Kent Vrana, Wesley Raup-Konsavage, Vonn Walter, August Stuart, Shannon Dalessio, Walter Koltun, Nana Bernasko, Andrew Tinsley, Emmanuelle Williams, Kofi Clarke, Matthew Coates

Background: Polysubstance Use (PSU), the use of two or more substances of abuse, has been associated with increased risk for development of psychiatric conditions and early death compared to both monosubstance use or no substance use. The vast majority of clinical research on prescription or recreational drug consumption in patients with inflammatory bowel disease (IBD), including both Crohn's disease (CD) and ulcerative colitis (UC), has focused on use of individual substances. We evaluated the incidence and impact of PSU in IBD and assessed potential predisposing factors in this setting.

Methods: We performed a retrospective analysis using a consented IBD natural history registry from a single tertiary care referral center between 1/1/2015–8/31/2019. Demographics, endoscopic severity (using Mayo endoscopy sub-score for UC and Simple Endoscopic Score for CD), totals and sub-scores of surveys (Harvey-Bradshaw Index, Simple Clinical Colitis Activity Index, Hospital Anxiety and Depression Scale, Short IBD Questionnaire) assessing for symptoms (abdominal pain, fatigue, anxiety/depression, gas, diarrhea, rectal bleeding, and fecal urgency), substance use (tobacco, alcohol, marijuana, cocaine, methamphetamine, heroin, opiates, or benzodiazepine), and antidepressant or anxiolytic medication were abstracted. PSU was defined as concurrent use of two or more non-prescription drugs or substances, and healthcare resource utilization was defined as any IBD-related imaging, emergency room visit, hospitalization, or surgery over the prior 12 months. We computed descriptive statistics and performed contingency table analyses in order to identify associations between PSU and a variety of demographic and clinical characteristics. Multivariable logistic regression models were fit incorporating the clinical factors described above.

Results: 315 consecutively enrolled IBD patients (166f:149m; 214 CD and 101 UC) were included. Sixty-six patients (21.0%) were polysubstance users. Of these patients, 40.9% had moderate to severe disease activity, 47.0% had extra-intestinal manifestations (EIM), and 36.4% demonstrated an anxious or depressed state. EIM and antidepressant or anxiolytic use were positively associated with PSU on bivariate analysis (Table 1) and multivariable analysis (Table 2).

Conclusions: PSU is common in IBD, including both CD and UC. Interestingly, disease activity, IBD therapy type, and IBD-related symptoms were not associated with PSU. EIM and antidepressant or anxiolytic use were the only statistically significant predictors of PSU among patients with IBD in the multivariable logistic regression models. Our study represents the first evaluation of PSU within IBD and reinforces the importance of appropriate substance use screening among IBD patients, particularly among those with EIM and antidepressant or anxiolytic use.

Table 1. Clinical Characteristics of Polysubstance Use in Inflammatory Bowel Disease

Variable	Total (n=315)	Polysubstance Use (n=66)	No Polysubstance Use (n=249)	Odds Ratio	95% Confidence Limits		P Value
Gender [female (%)]	166 (52.7%)	34 (51.5%)	132 (53.0%)	0.942	0.547	1.621	0.890
IBD subtype (CD/UC)	214 / 101	46 / 20	168 / 81	0.902	0.501	1.624	0.769
Moderate or Severe Inflammation (%) (on endoscopic evaluation)	118 (37.5%)	27 (40.9%)	91 (36.5%)	1.2	0.691	2.092	0.568
Extra-Intestinal Manifestations (%)	108 (34.3%)	31 (47.0%)	77 (30.9%)	**1.97**	**1.138**	**3.440**	**0.0193**
Anxiety or Depression (%)	131 (41.6%)	24 (36.4%)	107 (43.0%)	0.759	0.432	1.329	0.400
Antidepressant or Anxiolytic Use (%)	112 (35.6%)	35 (53.0%)	77 (30.9%)	**2.51**	**1.451**	**4.385**	**0.00130**
Steroid Use (%)	167 (53.0%)	37 (56.1%)	130 (52.2%)	1.17	0.677	2.016	0.678
Mesalamine Use (%)	71 (22.5%)	13 (19.7%)	58 (23.3%)	0.808	0.412	1.585	0.621
Immunomodulatory Use (%)	75 (23.8%)	13 (19.7%)	62 (24.9%)	0.74	0.378	1.447	0.420
Biologic Use (%)	150 (47.6%)	31 (47.0%)	119 (47.8%)	0.968	0.562	1.666	1.00
Fatigue (%)	270 (85.7%)	55 (83.3%)	215 (86.3%)	0.791	0.377	1.660	0.554
Abdominal Pain (%)	206 (65.4%)	46 (69.7%)	160 (64.3%)	1.28	0.712	2.298	0.468
Diarrhea (%)	117 (37.1%)	29 (43.9%)	88 (35.3%)	1.43	0.826	2.488	0.201
Fecal Urgency (%)	218 (69.2%)	52 (78.8%)	166 (66.7%)	1.85	0.973	3.544	0.0715
Rectal Bleeding (%)	125 (39.7%)	27 (40.9%)	98 (39.4%)	1.07	0.614	1.854	0.888
Healthcare Resource Utilization (%)	220 (69.8%)	50 (75.8%)	170 (68.3%)	1.45	0.779	2.708	0.291

Note: CD = Crohn's disease, UC = ulcerative colitis.

Table 2. Multivariable Logistic Regression Model, Polysubstance Use in Inflammatory Bowel Disease.

Variable	Odds Ratio	95% Confidence Limits		P Value
Gender [female (%)]	0.8192	0.4501	1.491	0.514
Age	1.005	0.9859	1.025	0.607
IBD Subtype (Ulcerative Colitis)	0.7017	0.3508	1.404	0.317
Moderate or Severe Inflammation (on endoscopic evaluation)	1.346	0.7155	2.532	0.357
Extra-Intestinal Manifestations	**1.973**	**1.075**	**3.622**	**0.0284**
Anxiety or Depression	0.5937	0.3049	1.156	0.125
Steroid Use	0.863	0.4514	1.65	0.656
Antidepressant or Anxiolytic Use	**2.628**	**1.452**	**4.757**	**0.00142**
Mesalamine Use	0.8762	0.3991	1.924	0.742
Immunomodulatory Use	0.574	0.2743	1.201	0.1407
Biologic Use	0.8554	0.4656	1.571	0.615
Fatigue	0.5329	0.2147	1.323	0.175
Abdominal Pain	1.445	0.7015	2.977	0.318
Diarrhea	1.41	0.7288	2.727	0.308
Fecal Urgency	2.052	0.9461	4.452	0.0688
Rectal Bleeding	0.9243	0.4849	1.762	0.811
Healthcare Resource Utilization	1.303	0.6277	2.704	0.478

SELF-COMPASSION IN ADOLESCENTS AND YOUNG ADULTS WITH INFLAMMATORY BOWEL DISEASE: RELATIONSHIP OF SELF-COMPASSION TO PSYCHOLOGICAL AND PHYSICAL OUTCOMES

Nicole Neiman, Ann Ming Yeh, Rachel Bensen, Elvi Sanjines, Anava Wren

Background: Adolescents and young adults (AYA) with Inflammatory Bowel Disease (IBD) are at increased risk for poor psychological and physical well-being. Self-compassion (i.e., understanding and acceptance towards oneself) has been associated with better psychological and physical outcomes in AYA with chronic health conditions. There is limited research exploring self-compassion in AYA with IBD.

Aims: To examine: 1) the reliability of a Self-Compassion Scale (SCS-SF), and 2) how self-compassion relates to physical (i.e., pain interference, fatigue) and psychological (i.e., stress, anxiety, depression) outcomes in a sample of AYA with IBD.

Methods: This study was a collaboration with ImproveCareNow, and all procedures were approved by Stanford's Institutional Review Board. Study participants included 85 AYA (mean=18 yrs) with IBD (52% Crohn's; 55% female; 61% White). Participants completed a one-time online survey. The internal reliability of SCS-SF was a = 0.88, indicating high internal consistency. Hierarchical linear regression (HLR) analyses examined the unique contribution of self-compassion to pain interference, fatigue, physical stress, psychological stress, anxiety, and depression after controlling for significant demographic and medical variables (sex, IBD diagnosis, mental health diagnosis).

Results: The overall HLR models were significant for all dependent variables. For physical outcomes, the overall model examining pain interference was significant ($F(3, 72) = 4.517$; $P = 0.003$), with sex, IBD diagnosis, and mental health diagnosis accounting for 13% of the variance in pain interference. Self-compassion accounted for an additional 20% of the variance in pain interference over and above demographic/medical variables. For psychological outcomes, the overall model examining anxiety was significant ($F(3, 73) = 15.54$; $P < 0.001$), with sex, IBD diagnosis, and mental health diagnosis accounting for 33% of the variance in anxiety. Self-compassion accounted for an additional 46% of the variance in anxiety over and above demographic/medical variables. HLR also demonstrated that self-compassion was a significant independent predictor of pain interference (b = -0.30, $P = 0.015$), fatigue (b = -0.38, $P = 0.001$), psychological stress (b = -0.51, $P = < 0.001$), anxiety (b = -0.41, $P = < 0.001$), and depression (b = -0.59, $P = < 0.001$). Participants reporting higher levels of self-compassion had less pain interference, fatigue, stress, anxiety, and depression.

Conclusion: Preliminary results suggest self-compassion may be an important factor in explaining the variability of key physical and psychological outcomes among AYA with IBD. Research should investigate self-compassion in diverse IBD populations, and explore if feelings of kindness and acceptance towards oneself can be a protective factor for AYA by supporting positive coping and adjustment to IBD.

THE EVALUATION OF SERUM SEROTONIN LEVEL AMONG PATIENTS WITH CROHN'S DISEASE AND ITS IMPACT ON QUALITY OF LIFE

Marcin Sochal, Piotr Bialasiewicz, Agata Gabryelska, Renata Talar-Wojnarowska, Jakub Fichna, Bartosz Szmyd, Ewa Malecka-Panas

Background and aims: Serotonin affects intestinal physiology, mood, as well as circadian rhythm. Moreover, serotonin has proinflammatory function. Therefore, the aim of this study was to investigate the role of serotonin in clinical severity of Crohn's Disease (CD) and its effect on pain and sleep quality.

Methods: Fifty-nine CD patients (34 in exacerbation and 25 in remission according to the Harvey-Bradshaw Index-HBI) and 25 health control individuals(HC) were recruited. Sleep quality was assessed by the Pittsburgh Sleep Quality Index (PSQI) and subjective severity of pain by the Visual Analog Scale (VAS). Seventeen patients were treated with anti-TNF-α induction therapy for 14 weeks.

Results: Serotonin level was higher in CD (145.12ng/mL, IQR:98.14–179.25) compared to HC (87.52ng/mL, IQR:70.04–129.39; p=0.002) and in exacerbation of CD (157.66ng/mL, IQR:111.94–197.64) compared to remission (122.33ng/mL, IQR:83.28–163.67; p=0.029). Serotonin level with cut-off point of 92.45 ng/mL is useful for distinguishing participants with CD from HC (sensitivity: 78%, specificity: 60%, positive predictive value: 82%). Positive correlation between serotonin and HBI (r=0.279, p=0.032) and severity of diarrhoea (r=0.260, p=0.047) were found. Serotonin does not correlate with PSQI (r=0.152, p=0.168), but correlates with presence of sleep fragmentation for example by getting up to use the bathroom (joined 5b-5j PSQI questions; r=0.270, p=0.039). Correlations between serotonin and VAS were also obtained (r=0.220, p=0.045). Moreover, serotonin level significantly decreased after anti-TNF-α therapy (192.35ng/mL, IQR:150.36–225.56 vs. 121.11ng/mL, IQR:91.28–188.87; p=0.006). The study was funded by National Science Centre, Poland (#2018/31/N/NZ5/03715).

Conclusions: Serotonin level correlates with the severity of CD and decreases after anti-TNF-α therapy. It is associated with sleep fragmentation, which may be caused by diarrhea.

Therapeutic Drug Monitoring

ANTI-TNF PHARMACOKINETICS AND RESPONSE TO THERAPY IN PEDIATRIC ACUTE SEVERE ULCERATIVE COLITIS (THE ARCH STUDY)

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Background and Aims: 25% of children hospitalized with acute severe ulcerative colitis (ASUC) rescued with infliximab (IFX) at labeled dosing undergo a colectomy prior to discharge. Our aim was to determine whether IFX pharmacokinetics (PK) are associated with treatment response in pediatric ASUC.

Methods: We prospectively enrolled hospitalized pediatric patients initiating IFX for ASUC or IBD-U (PUCAI ≥65) at 7 North American centers and followed for 26 weeks in this pilot and feasibility cohort study. Serial IFX levels (Prometheus Biosciences, Inc.) were obtained and individual PK parameter estimates, such as volume of distribution, clearance (CL), elimination half-life ($T_{1/2}$) and IFX exposure (area under the concentration-time curve) were estimated using Bayesian methodology. The primary outcome was Day 7 clinical response (CR-D7, PUCAI <35). Key secondary outcomes were Week 8 clinical remission (CR-W8, PUCAI <10) and Week 26 corticosteroid-free clinical remission (CFR-W26).

Results: 38 participants (mean age 14.5 years, 50% female, 95% UC, 87% extensive/pancolitis) were treated with IFX at a mean higher than labeled dosing of 9.9 [9.3,10.3] mg/kg, and 16% received an early second dose 4–6 days after the first infusion. CR-D7, CR-W8, and CFR-W26 were achieved in 71%, 55%, and 41%, respectively. Only one participant (2.7%) underwent colectomy by week 26. Using 304 IFX level measurements, we developed a novel pediatric population PK model for IFX in ASUC that incorporated albumin, antibodies to IFX, CRP, and height to characterize the PK profile for participants. The median IFX $T_{1/2}$ was 5.8 [4.2,7.0] days at Day 7 and lengthened to 7.4 [5.4,8.4] days by Week 26 (P=0.014), but notably remained below the median 10.8 [8.6, 15.4] days reported in a randomized controlled trial of IFX for moderate to severe pediatric UC (Fig. 1). IFX exposure was not associated with CR-D7, CR-W8, or CSR-W26. More rapid IFX CL at Week 26 was significantly associated with inability to achieve CFR-W26 (P=.013). This finding was in line with a higher, but not statistically significant, median trough IFX level nearest Week 26 in those with (19.5 [13.6, 30.3]) versus without (14.2 [6.0, 21.3] µg/ml) CFR-W26 (P=.13) (Fig. 2).

Conclusion: At the higher than standard IFX dosing used to treated children with ASUC in this observational study, we observed a lower colectomy rate compared to prior studies but did not observe a positive association between IFX exposure and clinical outcomes. Albumin, CRP, height, and ATI were associated with IFX PK and incorporated into a new pediatric ASUC PK model. Initial 10 mg/kg IFX dosing may be sufficient to optimize early outcomes in pediatric ASUC. Additional studies are needed to determine if sustained intensification of maintenance IFX regimens