

were reported in 2018 US\$ per patient per month and compared between treatment groups overall, and for biologic-naive and -experienced (≥ 1 pre-index biologic therapy for CD) subgroups, using mean cost differences (MCD) obtained from weighted two-part models. **Results:** The 599 (117 biologic-naive) UST-treated and 589 (172 biologic-naive) VDZ-treated patients who met eligibility criteria were similar in sex (54% and 57% female), mean age (41 ± 14 and 44 ± 14 years), time since diagnosis (42 ± 33 and 46 ± 35 months), and Charlson comorbidity index (0.4 ± 1.0 and 0.6 ± 1.1). Disease location, follow-up duration, and prior therapies and surgeries were also comparable. Characteristics were similar in biologic-naive and -experienced patients. Mean weighted time on treatment was 11.4 and 12.1 months in UST- and VDZ-treated patients. Mean weighted total healthcare costs per patient per month were higher with UST vs VDZ (MCD=\$5051), driven by total index drug costs (MCD=\$4946; **Table**). Cost differences were consistent in biologic-naive and -experienced patients (total cost MCD=\$4466 and \$4836, both $P < 0.01$). **Discussion:** Characteristics of UST- and VDZ-treated patients in real-world settings were comparable. In this population of patients receiving maintenance treatment for CD, index drug costs make UST treatment substantially more costly than VDZ. Further comparison of healthcare outcomes in patients treated with UST vs VDZ is warranted.

Weighted healthcare costs per patient per month with UST vs VDZ (2018 US\$)				
	Mean Cost		MCD	P Value
	UST	VDZ		
Total*	12510	7460	5051	<0.01
All-cause medical costs ^b	1864	1740	123	0.69
Inpatient	896	850	47	0.86
Emergency department	128	146	-17	0.58
Outpatient	345	745	94	0.44
Pharmacy costs ^b	345	364	-19	0.64
Total index drug costs	10302	5356	4946	<0.01
Medical	1013	5073	-4060	<0.01
Pharmacy	9289	283	9006	<0.01
CD-related medical costs	1257	1154	103	0.70

*All cause-medical costs + pharmacy costs + total index drug costs
^bExcluding index drug costs.

Sa1750

WOULD K50* BY ANY OTHER NAME SMELL SO SWEET? A SYSTEMATIC REVIEW OF CLAIMS-BASED CROHN'S DISEASE CASE DEFINITIONS

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Background: The acceptance of real-world data (RWD) in biomedical research has created opportunities to explore thousands, and sometimes, millions of individuals in a single study. The 21st Century Cures Act created a framework to evaluate real-world evidence (RWE) to help support the approval of new indications for already approved drugs. Crohn's disease (CD) is an ideal condition to consider for RWE approvals. RWE for CD will depend upon the accuracy of the claims. We performed a systematic review to identify studies that calculated CD diagnostic accuracy. **Methods:** We combined the concepts of study design ("population-based cohort study" or administrative or ICD or claims), validation and study population (Crohn's or "inflammatory bowel disease") to identify potentially relevant RWD articles in Embase and PubMed. No year of publication or language restrictions were applied. Title/abstract and full-text screening was performed using Covidence software. Eligible articles reported on CD separately from UC; used codes to define CD; reported the number of CD patients; and included CD as the study population or provided validation for the CD case definition. Dual-independent data extraction was performed using the "data comparison" function in REDCap. At all phases of review and extraction (title/abstract, full-text and data extraction), two authors independently reviewed each article and a third author adjudicated the disagreements. **Results:** We identified 21 studies that performed chart reviews of patients and calculated the diagnostic accuracy of the coding-based case definitions. An additional 175 studies cited a validation study and 149 studies did not calculate diagnostic accuracy nor cite a validation study. International Classification of Diseases 9th revision was the most common coding system used to identify cases. Diagnostic accuracy that included at least 2 encounters (inpatient or outpatient) for CD and a minimum duration of follow-up (range 1-5 years) had the best diagnostic accuracy (Sensitivity: 89-95%; Specificity: 86-90%). Without the follow-up requirement, 2 encounters yielded 72-91% positive predictive value (PPV); the PPV for a single encounter was as low as 18%. Countries with validation studies included Canada, Denmark, Italy, South Korea, Sweden, United Kingdom, and the United States. There is no validation of Medicare, Medicaid or any commercial claims databases in the United States and no inclusion of ICD-10 codes. **Conclusion:** The diagnostic accuracy for CD is highest when 2 encounters are combined with a minimum duration of follow-up. A single encounter for CD should not be used unless supported by a validation study. Without validation, the RWE patient population may be a combination of CD and other conditions. This preventable misclassification could prevent truly effective drugs from being approved for CD patients.

Sa1751

COMPARATIVE EFFECTIVENESS OF HIGH-DOSE INFlixIMAB VS. CYCLOSPORINE IN ACUTE SEVERE ULCERATIVE COLITIS

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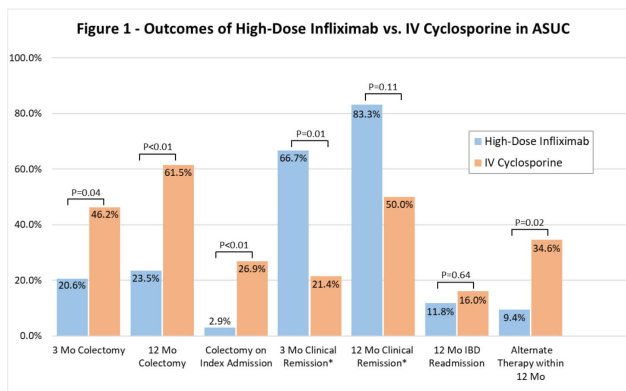
Background: Patients with inflammatory bowel disease (IBD) hospitalized with acute severe ulcerative colitis (ASUC) refractory to steroids require salvage therapy with infliximab (IFX) or cyclosporine (Cys). Two randomized controlled trials have shown equivalent efficacy of these therapies, but these studies used IFX at 5mg/kg dosing. Given the high inflammatory burden in ASUC, there is evidence to suggest that IFX at a higher induction dose of 10 mg/kg may be beneficial. In this study, we compared the clinical effectiveness of high-dose IFX with Cys in hospitalized ASUC patients. **Methods:** We performed a retrospective chart review of all patients admitted to an academic medical center between January 2015 and June 2019 requiring salvage therapy for steroid-refractory ASUC. Patient demographics, disease characteristics, and UC treatment history were recorded. The primary outcome was colectomy rate at 3- and 12-months. Secondary outcomes were clinical remission at 3- and 12-months, and readmission and/or requirement for alternate IBD therapy within 12-months. **Results:** We identified 60 patients hospitalized with steroid-refractory ASUC. 53% were male with a median age of 31 years. 34 (57%) received high-dose IV IFX 10mg/kg and 26 (43%) received Cys 2mg/kg. Between treatment groups, there were no differences in duration of disease, proportion with extensive colitis, or baseline albumin. Patients treated with IFX had a higher baseline C-reactive protein (CRP) (83 vs. 33 mg/dL, $P < 0.001$). Patients treated with Cys had higher rates of prior medical therapy, most notably biologics (9% vs. 92%, $P < 0.001$; Table 1). Patients treated with IFX had lower rates of colectomy at 3- and 12-months, less requirement for alternate IBD therapy within 12-months, and higher rates of clinical remission at 3-months (Figure 1). On univariate analysis, extensive colitis ($P = 0.02$), prior biologic use ($P < 0.01$), CRP ($P = 0.02$) and Cys use did not (OR: 0.62, 95% CI 0.05-7.55). **Conclusion:** Patients hospitalized with ASUC treated with high-dose IFX had lower rates of 3- and 12-month colectomy and higher rates of 3-month clinical remission than those treated with Cys. However, in our cohort, Cys patients had higher rates of prior biologic use, indicating more treatment-refractory disease. Further randomized control studies with improved power are required to compare inpatient high-dose IFX with Cys.

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Table 1: Patient Demographics, Disease Characteristics and Treatment History*

	High Dose IFX (N=34)	Cyclosporine (N=26)	P-value
Demographics			
Male	19 (55.9)	13 (50.0)	0.77
Age, years, median (IQR)	31.0 (25.0, 39.25)	30.5 (24.0, 44.3)	0.93
Disease Characteristics			
Duration of disease, years, median (IQR)	2.5 (1.0, 7.0)	5.5 (2.0, 10.3)	0.09
Prior IBD admission	7 (20.6)	10 (38.5)	0.13
Extensive colitis	22 (74.7)	15 (57.7)	0.58
CRP on admission, mean \pm SD	82.5 \pm 78.6	32.8 \pm 35.2	<0.001
Albumin at induction	3.0 \pm 0.5	3.2 \pm 0.5	0.34
Prior Treatment History			
5-ASA	34 (100.0)	24 (92.3)	0.18
Corticosteroids	24 (70.6)	26 (100.0)	<0.01
Immunomodulators	5 (14.7)	15 (57.7)	<0.01
Biologic therapy	3 (8.8)	24 (92.3)	<0.001
Number of prior biologics, mean \pm SD	0.1 \pm 0.4	2.0 \pm 1.0	<0.001

*All numbers represented as N (%) unless otherwise indicated.



*Clinical remission defined as a total score of 2 or less on the partial Mayo score (range: 0 to 9) or total Mayo score (range: 0 to 12) and no subscore greater than 1 (range, 0 to 3) on any of the Mayo scale components.

Sa1752

POSTOPERATIVE CROHN'S DISEASE RECURRENCE BASED ON GUIDELINE CONCORDANT RISK STRATIFICATION

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Background: Postoperative Crohn's disease (CD) recurrence is common and current guidelines recommend preoperative risk stratification to guide prophylactic biologic therapy utilization. Few data have corroborated the quantified risk and validated the proposed stratification. We aimed to assess the risk of postoperative recurrence (POR) by guidelines risk category and the impact of biologic therapy on recurrence. **Methods:** CD patients who underwent ileocecal resection between 1992-2019 were identified at two tertiary referral centers. Patients were divided into groups with high risk features (smoking, age <30 yrs, and ≥ 2 prior surgeries) and low risk features (nonsmokers, age >50 years old, resection