Real-World Utilization of Top-Down and Step-Up Therapy and Initial Costs in Crohn's Disease

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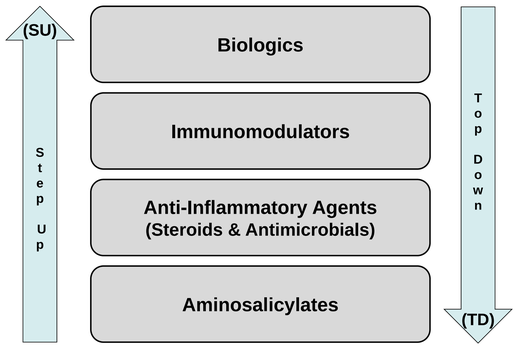
Background

- Crohn's disease (CD) is an inflammatory bowel disease (IBD) characterized by relapsing intestinal inflammation and gastrointestinal tissue damage
- Top-down (TD) and step-up (SU) describe treatment strategies for initiating pharmacologic therapy for CD.[1-2]
  - Step-up (SU) therapy initiates with oral anti-inflammatory agents.[3-5]
  - Top-down (TD) therapy initiates with biologics or immunomodulators.[3-5]
- The real-world utilization and short-term medical costs associated with these treatment strategies are not well described.

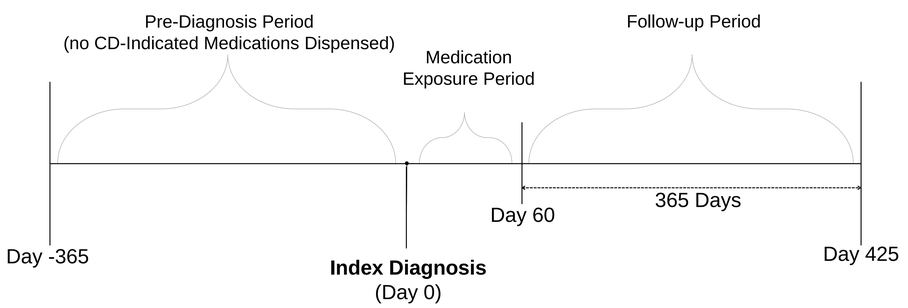


Objective

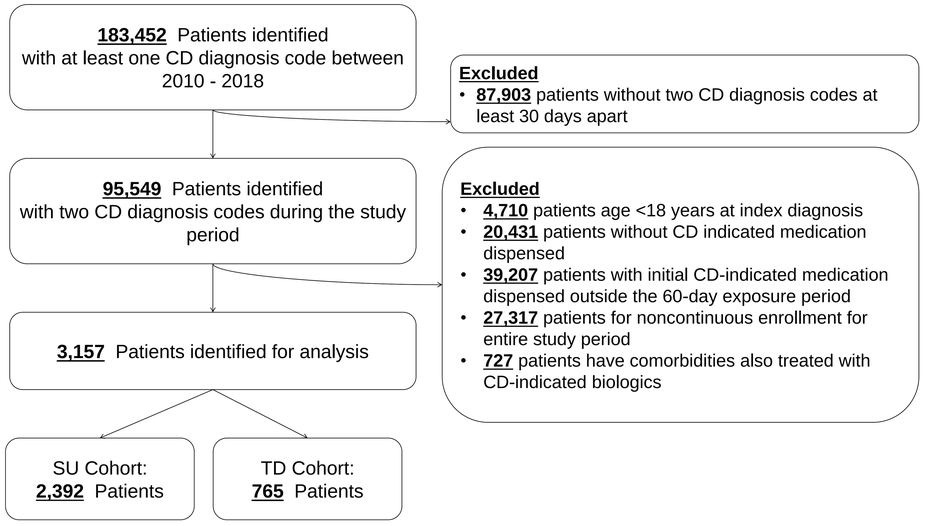
This research examined the prevalence of TD therapy use over time and first-year direct medical expenditures among patients initiating CD medication treatment with SU as compared with TD therapy in a commercially insured population.

Methods

- Retrospective, cohort study using de-identified Optum Clinformatics® Data Mart from 2010 to 2018
- Study Population: adult patients with CD (ICD9: 555.x, ICD10: K50.x) newly initiated on medication therapy. Identified by:
  - no CD-indicated medication dispensed in the one-year pre-diagnosis period
  - having at least two ICD codes for CD in any setting at least 30 days apart within the follow-up period[6-8]
  - a CD-indicated medication dispensed during the 60-day medication exposure period
- Statistical analysis: a joinpoint regression was conducted to determine the statistical significance of differences in the use of TD and SU therapy over time. A generalized linear model was used to quantify the differences in adjusted mean first-year CD-specific, direct non-pharmacy medical costs between utilizers of TD and SU therapy.



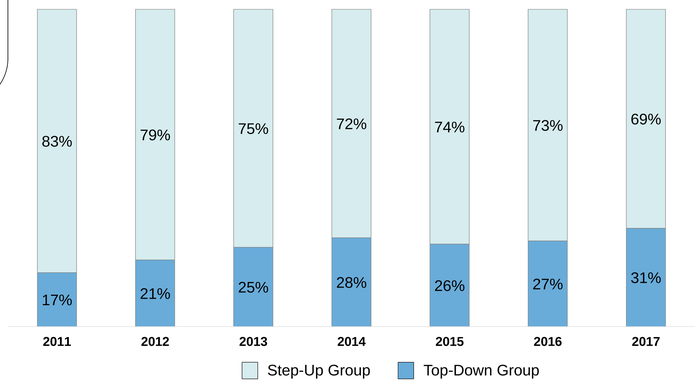
Results



	SU Group	TD Group	Significance
n	2,392	765	
Sex			
Female (n, %)	1,316 (55.0)	380 (49.7)	p=0.0099
Male	1,076 (45.0)	385 (50.3)	
Age at Diagnosis			
Age, Years (mean, SD)	48.9 (18.9)	39.7 (17.0)	p<0.0001
Disease Location (ICD 9/10 Code)			
Small Intestine (555.0, K50.0) (n,%)	832 (34.8)	253 (33.1)	p<0.0001
Large Intestine (555.1, K50.1)	585 (24.5)	134 (17.5)	
Small and Large Intestine (555.2 K50.8)	601 (25.1)	301 (39.4)	
Unspecified (555.9, K50.9)	374 (15.6)	77 (10.1)	
Payer Type			
Commercial (n, %)	1,770 (74.0)	674 (88.1)	p<0.0001
Medicare, Age < 65	91 (3.8)	21 (2.8)	
Medicare, Age ≥ 65	531 (22.2)	70 (9.2)	
Elixhauser Index			
Score (mean, SD)	2.24 (2.5)	1.65 (2.1)	p<0.0001
Score: 0 (n, %)	666 (27.8)	250 (32.7)	p<0.0001
Score: 1-2	924 (38.6)	349 (45.6)	
Score: ≥3	802 (33.5)	166 (21.7)	
GI-Related Hospitalization Prior to Diagnosis			
Prior Hospitalization (n, %)	216 (9.0)	62 (8.1)	p=0.4317
CD-Related Surgical Procedures Performed Within 60 Days Following Index Diagnosis			
Procedure Performed (n, %)	1,388 (58.0)	470 (61.4)	p=0.0951
First-Year Costs			
All-cause Cost (mean $, SD)	34,898 (88,168)	51,359 (66,988)	p<0.0001
CD-Specific Direct Cost	11,765 (24,752)	32,664 (32,570)	p<0.0001
CD-Specific Medical Costs	4,616 (16,731)	11,653 (26,031)	p<0.0001
CD-Specific Medication Costs	7,025 (12,560)	21,011 (21,074)	p<0.0001
First-year Utilization			
CD-Specific Medical Utilization (mean visits, SD)	6.42 (9.9)	14.35 (13.0)	p<0.0001
CD-Specific Prescription Medication Utilization (mean prescriptions, SD)	6.97 (6.3)	11.53 (7.2)	p<0.0001

CD: Crohn's disease; ICD: International Classification of Diseases; SD: Standard deviation; SU: Step-up; TD: Top-down

- We identified 3,157 patients newly initiating medication therapy for CD: 2,392 (75.8%) patients treated with SU therapy and 765 (24.2%) treated with TD therapy.
- The use of TD therapy over the study period increased from 17% in 2011 to 31% in 2017.
- TD therapy was also associated with a 149.8% ($1,230) higher adjusted average per-patient first-year CD-direct medical costs compared with SU therapy (adjusted ratio of cost for TD compared to SU: 2.498, 95% CI: 2.12, 2.95).



Conclusion

- In patients newly initiating medication therapy for CD, use of TD therapy increased between 2010 and 2017 and was associated with higher first-year non-drug medical expenditure.
- These findings align with the strategy of initiating TD therapy in patients with a higher disease burden.
- A limitation of this research was the lack of data on disease severity, which can influence initial treatment decision
- Further research is needed to determine long-term overall healthcare costs and clinical outcomes associated with SU and TD strategies in a real-world setting.

Disclosures

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