Assessing the Uptake of Core Outcome Sets in Randomized Controlled Trials for Inflammatory Bowel Disease

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INTRODUCTION

Increasing prevalence and significant medical expenses associated with Inflammatory Bowel Disease (IBD) necessitate high-quality clinical research to evaluate treatment effectiveness. Randomized control trials (RCTs) provide robust evidence, but the diversity of outcomes used in these trials poses challenges in summarizing outcomes for systematic reviews. The lack of outcome standardization limits comparability and hinders therapeutic advancements. Core Outcome Sets (COS) have been established to improve the comparability of outcomes across studies. This study analyzes the uptake of COS in IBD clinical trials before and after its publication.

METHODS

- We searched through ClinicalTrials.gov on June 26, 2023 for RCTs evaluating outcomes in patients with IBD.
- The COMET Initiative COS database was used to identify an IBD COS for uptake analysis, which consisted of 4 outcome domains.
- Studies were analyzed to assess COS uptake before and after its development.
- An interrupted time series analysis was conducted to assess the adoption of the COS before and after its publication.

RESULTS

- Of the 3,205 articles originally screened, 177 trials were included in our final sample for analysis.
- Most frequently measured outcomes were change in bowel symptoms (88.1%, 156/177), pain or discomfort (83.1%, 147/177), and disease activity and remission (82.5%,146/177).
- No trial reported on colorectal cancer, only 1.1% (2/177) measured overall survival, and 8.5% (15/177) measured cause of death.
- The uptake of COS over time showed non-significant results.

Table 1. Frequency of Outcome Uptake

Core Outcome	Yes n (%)
Symptoms, function, and quality of life	
Change in bowel symptoms	156 (88.1%)
Missing planned activities	76 (42.9%)
Night symptoms	57 (32.2%)
Pain or discomfort	147 (83.1%)
Energy and fatigue	75 (42.4%)
Feel anxious or depressed	78 (44.1%)
Overall control over IBD	109 (61.6%)
Weight	94 (53.1%)
Fistula symptoms (only applicable to Crohn's patients)	19 (21.8%)
Disutility of care	
Steroid use	64 (36.2%)
Occurrence and impact of complication from an IBD intervention	69 (39.0%)
Healthcare utilization	
Time spent in hospital	43 (24.3%)
Survival and disease control	
Presence of anaemia	57 (32.2%)
Disease activity and remission	146 (82.5%)
Colorectal cancer	0 (0%)
Overall survival	2 (1.1%)
Cause of death	15 (8.5%)

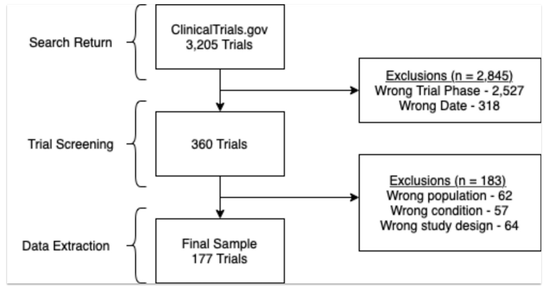

Figure 1. Flowchart of Study Inclusion

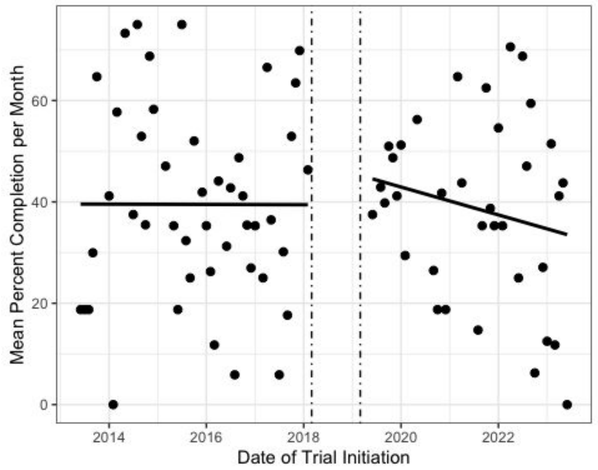

Figure 2. Mean Percent Completion vs Date of Trial Initiation

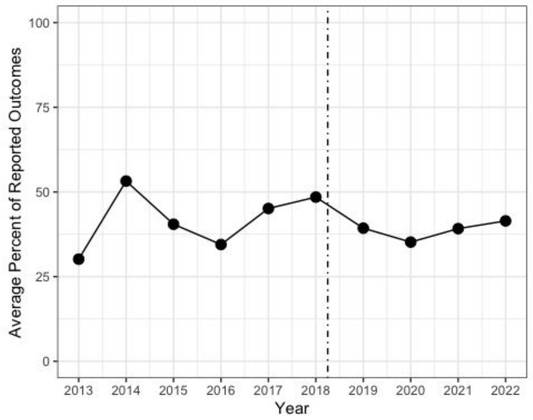

Figure 3. Average Percent of Reported Outcomes Per Year

CONCLUSION

Our study revealed that there were no significant differences in the adherence to COS in IBD clinical trials, both before and after the publication of the IBD COS. Notably, the only consistently measured outcomes across the trials were ‘bowel symptoms’, ‘pain or discomfort’, and ‘disease activity and remission’. No other outcome was measured in more than 62% of the RCTs in our sample. We speculate that previous patterns observed regarding COS adherence might have been influenced by regulatory agency endorsements and we suggest that further research be conducted to explore this relationship. Additionally, we recommend that trialists make more efforts to implement COS in their clinical trials. By better integrating COS into their research, trialists can enhance the standardization and comparability of outcomes across studies in the field of IBD.

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REFERENCES