

REAL-LIFE VS TRIAL ACCESS TO BIOLOGICAL THERAPY DIFFERENCES: A 2019-2020 EXPERIENCE IN AN ITALIAN TERTIARY IBD CENTER

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Poster

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A single-center prospective study comparing 134 IBD patients starting biologics found that only 43% of ulcerative colitis and 39% of Crohn's disease patients met eligibility criteria for randomized clinical trials, with trial enrollees showing higher disease activity scores and more extraintestinal manifestations than real-life patients.

KEY POINTS

- Among 72 ulcerative colitis and 62 Crohn's disease patients starting biologic therapy, only 43% and 39% respectively were suitable for potential RCT enrollment based on existing inclusion and exclusion criteria.
- Trial patients had significantly more extraintestinal manifestations, particularly articular, and higher concomitant corticosteroid use (dose ≤ 20 mg/day) compared to real-life patients in both diseases ($p < 0.05$).
- Mean Harvey-Bradshaw Index was higher in trial Crohn's disease patients (9.1) compared to real-life patients (4.8), and trial patients waited longer before accessing biologic therapy.
- In ulcerative colitis, 88% of trial patients had prior biologic exposure versus 29% of real-life patients; in Crohn's disease, prior biologic use was similar between groups (60% versus 45%).
- The authors suggest that discrepancies between clinical practice (which relies on endoscopy and imaging) and RCT enrollment criteria (which use clinical scores like CDAI) may affect generalizability of trial results to real-world populations.

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