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Managing Crohn's Disease Postoperative Recurrence Beyond Prophylaxis: A Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 August 2024 and was last updated on 07 August 2024.

INTRODUCTION

Review question / Objective In patients with Crohn's disease postoperative recurrence which therapy is most efficacious and safe in preventing progression/ curing relapse?

Rationale Although numerous studies have examined the effects of prophylactic therapy on maintaining post-surgery remission, data on treating the established endoscopic POR to prevent clinical relapse are less consistent. This study aims to evaluate the efficacy and safety of different management strategies for POR of CD through a systematic review of the current literature.

Condition being studied Crohn's disease postoperative recurrence defined as an endoscopic Rutgeerts score of I2 or more.

METHODS

Search strategy A comprehensive search of PubMed, Cochrane, and Scopus databases was performed in March 2024. The search strategy included: (post-operative OR postoperative OR "post operative" OR "ileocolic resection" OR "ileo-colic resection" OR "ileocolonic resection" OR "ileo-colonic resection") AND recurrence AND Crohn's AND (biologic OR biologics OR "anti-tumor necrosis factor" OR "anti-tumour necrosis factor" OR anti-TNF OR infliximab OR adalimumab OR vedolizumab OR ustekinumab OR azathioprine OR 5-aminosalicylates).

Participant or population We included studies that met the following eligibility criteria: (1) reporting data on the therapeutic management of established POR after ileocolonic resection in CD, (2) defining POR as RS ≥i2, and (3) study types including case reports, retrospec-tive/prospective studies, and randomized controlled trials (RCTs).

Excluded studies were those referring strictly to prophylaxis of POR and reviews.

Intervention Treatment with any therapy - enteral nutrition, 5-ASA, AZA, MTX, biologics, other drugs.

Comparator N/A.

Study designs to be included Case reports, Retrospective studies, prospective studies, randomised controlled trials.

Eligibility criteria (1) reporting data on the therapeutic management of established POR after ileocolonic resection in CD, (2) defining POR as RS ≥i2, and (3) study types including case reports, retrospec-tive/prospective studies, and randomized controlled trials (RCTs). Excluded studies were those referring strictly to prophylaxis of POR and reviews.

Information sources PubMed, Cochrane, and Scopus databases.

Main outcome(s) The primary outcomes measured were endoscopic and clinical responses. Endoscopic improvement was typically defined as a reduction in the RS with at least 1 point, while clinical remission was measured by the absence of clinical symptoms and need for additional intervention.

Quality assessment / Risk of bias analysis Risk of Bias Assessment: The risk of bias in the included studies was assessed using the Cochrane Risk of Bias tool. This tool evaluates bias across several domains, including selection bias, performance bias, detection bias, attrition bias, and reporting bias. Two reviewers independently assessed the risk of bias for each study, and discrepancies were resolved through discussion or consultation with a third reviewer. Each domain was rated as low, high, or unclear risk of bias.

Strategy of data synthesis Data will be analysed focusing on outcomes (endoscopic/clinical response) , type of trial, intervention (drug vs placebo, drugs vs drug), primary endpoint, secondary endpoint, duration of follow-up, adverse events.

Subgroup analysis A network meta-analysis with the studies that had endoscopic response as an outcome measure.

Sensitivity analysis To assess the robustness of our findings, we performed several sensitivity analyses. These included:

1. **Exclusion of High-Risk Studies**
2. **Model Comparison**: We compared the results using both fixed-effect and random-effects models.
3. **Varying Inclusion Criteria**: We conducted sensitivity analyses by including and excluding studies with different patient populations and prior treatments.
4. **Heterogeneity Assessment**: We performed subgroup analyses based on study characteristics such as type of intervention and outcome measures.
5. **Small Study Effects**: We analyzed the impact of excluding the smallest studies or those with the largest standard errors.

Language restriction English only.

Country(ies) involved Romania.

Keywords postoperative recurrence; Crohn's disease; biologic therapy; infliximab; ustekinumab; azathio-prine; anti-TNF agents; endoscopic remission.

Dissemination plans Medical Journals.

Contributions of each author

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