Early Biologic Treatment versus Conventional Step-Up Treatment for the Management of Ulcerative Colitis: Comparative Clinical Effectiveness, Cost-Effectiveness, and Guidelines
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Acknowledgments:

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.
Research Questions

1. What is the clinical effectiveness and safety of early biologic treatment compared with conventional step-up treatment for the management of ulcerative colitis?

2. What is the cost-effectiveness of early biologic treatment compared with conventional step-up treatment for the management of ulcerative colitis?

3. What are the evidence-based guidelines on the use of biologics for the management of ulcerative colitis?

Key Findings

No relevant literature was identified regarding early biologic treatment compared with conventional step-up treatment for the management of ulcerative colitis.

Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2013 and November 14, 2018. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.
Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Population</th>
<th>Adults and pediatric patients with active moderate to severe UC who have not been treated with immunosuppressants or biologics (may or may not have been treated with aminosalicylates or steroids)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Biologics: adalimumab, infliximab, vedolizumab, golimumab given in the context of an early initiation algorithm</td>
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<tr>
<td>Comparator</td>
<td>Q1-2: Conventional management sequence (“step-up”) typically consisting of giving steroids, then switching to immunosuppressants when remitting or not responding, and then switching to biologics if not responding to previous drugs</td>
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<tr>
<td>Outcomes</td>
<td>Q1: Clinical effectiveness based on:</td>
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<tr>
<td></td>
<td>Q2: Cost-effectiveness</td>
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<td></td>
<td>Q3: Guidelines</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines</td>
</tr>
</tbody>
</table>

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations, or evidence-based guidelines were identified regarding early biologic treatment compared with conventional step-up treatment for the management of ulcerative colitis.

References of potential interest are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.
Randomized Controlled Trials
No literature identified.

Non-Randomized Studies
No literature identified.

Economic Evaluations
No literature identified.

Guidelines and Recommendations
No literature identified.
Appendix — Further Information

Previous CADTH Reports


Systematic Reviews and Meta-Analyses

Population Insufficiently Defined – Disease Severity Unknown/ Naïveté to Biologic/ Immunosuppressant Use Unknown


Randomized Controlled Trials - Population Insufficiently Defined – Naïveté to Biologic or Immunosuppressant Use Unknown


Non-Randomized Studies

Mixed Population


Population Insufficiently Defined – Disease Severity Unknown/ Naïveté to Biologic/ Immunosuppressant Use Unknown


Economic Evaluations

Not Compared to Conventional Management


Population Insufficiently Defined – Disease Severity Unknown/ Naïveté to Biologic/ Immunosuppressant Use Unknown


Guidelines and Recommendations

*Population Insufficiently Defined – Naïveté to Biologic Unknown*


*Information on Aminosalicylates and Steroids*


Clinical Practice Guidelines

*Methods Not Systematic*


Unspecified Methodology


Subsequent-Entry Biologics


Mixed Populations - Position Statements
