Early Versus Delayed Initiation of Vedolizumab in Ulcerative Colitis: Treatment Response in the Real World (RALEE)

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Introduction

- Patients with newly diagnosed ulcerative colitis are often prescribed corticosteroids, immunomodulators, and/or 5-aminosalicylates.
- Delayed initiation of biologic therapy may increase complications and consequent costs.
- Evidence suggests that patients with ulcerative colitis experience significant morbidity and treatment burden before the initiation of biological therapy.
- Data are lacking on the effects of early biologic therapy in patients with ulcerative colitis.
- RALEE aimed to investigate the effect of early versus delayed initiation of vedolizumab on treatment outcomes and medical costs using administrative data sets.
- Here, we report the impact on treatment response in patients with ulcerative colitis.

Methods

- Adult patients with ulcerative colitis were identified from MarketScan data.
- Eligible patients were categorized into one of five treatment pathways.
- Logistic regression was used to evaluate the association between treatment pathway and response.

Results

- Treatment response was defined as no occurrence of any of the following events within 60 days after vedolizumab initiation:
  - New concomitant use of corticosteroids
  - Inflammatory bowel disease-related surgery
  - Increased administration of vedolizumab
  - Vedolizumab treatment discontinuation
  - Vedolizumab treatment switch

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall cohort (N = 1,342)</th>
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</thead>
<tbody>
<tr>
<td>Age at first diagnosis, years, median</td>
<td>43.0</td>
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<tr>
<td>Sex, N (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>685 (51.0)</td>
</tr>
<tr>
<td>Female</td>
<td>657 (49.0)</td>
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<tr>
<td>Payer type, N (%)</td>
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<tr>
<td>Commercial</td>
<td>1,294 (96.4)</td>
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<tr>
<td>Medicare</td>
<td>48 (3.6)</td>
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<tr>
<td>Year of diagnosis, N (%)</td>
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<tr>
<td>2017</td>
<td>1,160 (86.4)</td>
</tr>
<tr>
<td>2018</td>
<td>182 (13.6)</td>
</tr>
</tbody>
</table>

Conclusion

- Patients with ulcerative colitis are more likely to respond to treatment if vedolizumab is initiated within 30 days after diagnosis than if delayed until after corticosteroids, immunomodulators, and/or 5-aminosalicylates.
- These findings are consistent with clinical guidelines that recommend use of vedolizumab for induction of remission in patients with moderately to severely active ulcerative colitis.
- Further analyses of remission, healthcare resource utilization, and associated medical costs are underway.

References