Evaluation of Alvimopan Utilization Within a Large, Tertiary Health-System

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Background

Post-operative ileus (POI) is defined as a transient loss of bowel function and is a common complication in patients who undergo major abdominal surgery. Agents and compounds for prophylaxis of POI, such as octreotide and ondansetron, decrease pain, retching, and delayed passage of flatus and food. Development of POI is associated with increased patient discomfort, decreased quality of life, and higher healthcare costs. The use of alvimopan, a peripherally acting mu-opioid receptor antagonist, has become a standard for prophylaxis of POI.

Several strategies have been implemented in an attempt to reduce the incidence of POI, including the use of opioid sparing anesthetics and laparoscopic procedures. Post-operative, early ambulation, early return of bowel sounds, late postoperative nausea and vomiting, and neonatal intensive care units in the neonatal intensive care unit have also been used to accelerate return of bowel function.

Methods

• Post-operative dose (POD) is defined as a maximum tolerated dose of function and is a common complication in patients who undergo major abdominal surgery. Agents and compounds for prophylaxis of POI, such as octreotide and ondansetron, decrease pain, retching, and delayed passage of flatus and food. Development of POI is associated with increased patient discomfort, decreased quality of life, and higher healthcare costs. The use of alvimopan, a peripherally acting mu-opioid receptor antagonist, has become a standard for prophylaxis of POI.

• The primary endpoint is to estimate overall adhesion to Beaumont Health Sytems committee-approved guidelines for the use of alvimopan, adherence to FDA approved dosing criteria, and adherence to FDA approved dosing recommendations for doing and administration, and patient outcomes.

Results

Adherence to Guidelines on Basis of Criteria for Alvimopan Use

<table>
<thead>
<tr>
<th>Table</th>
<th>Secondary Endpoint</th>
<th>POI (n=52)</th>
<th>POI (n=18)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Number of patients who received alvimopan</td>
<td>52 (100%)</td>
<td>18 (100%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>2.</td>
<td>Total number of doses administered</td>
<td>104 (200)</td>
<td>26 (140)</td>
<td>0.0001</td>
</tr>
<tr>
<td>3.</td>
<td>Average number of doses administered per patient</td>
<td>2.00 (1.00)</td>
<td>1.45 (0.72)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Conclusions

• Adherence to Beaumont Health Systems committee-approved guidelines occurred in approximately two-thirds of patients who received alvimopan. The majority of cases investigated using criteria for on-time dosing for loading dose and high-risk factors were established by Beaumont guidelines. A small number of cases were not identified in which either criteria (type of surgery or presence of high-risk factors) were met. These were considered only at Royal Oak.

• Overall, alvimopan use was considerably less at Troy and Grosse Pointe with only 18 patients billed for its use over a 4-year period. Despite the lower rate seen at Troy and Grosse Pointe, the findings were in line with the low adherence to the guidelines by the individual institutions.

• The use of alvimopan was not considered at Royal Oak due to a lack of high-risk factors. However, the reduced use of alvimopan at Troy and Grosse Pointe is still concerning, and further analysis is needed to clarify this issue.

References


4. National dosing criteria are based on consistent and timely administration of POI. Despite the use of appropriate agents, non-adherence was common due to a lack of high-risk factors.

5. Adherence to FDA approved dosing recommendations was well followed by all institutions. Similarities, however, existed for the four patients treated for post-operative doses at Royal Oak. A lack of documentation of surgical start time contributed to inappropriate timing of the pre-op dose seen in only three-fourths of patients.

6. Higher rates of POI and one unanswerable effect were observed at Royal Oak.

Discussion

Published rates of POI have been reported at approximately 5% in post-operative patients. Development of POI was much higher with Beaumont Health System, a large majority of which was documented in patients at Royal Oak, potentially due to a higher variance of patient populations treated in this institution. Further analysis is needed to clarify this issue.

Incidence of myocardial infarction (MI) was analyzed due to a higher number of adverse events reported in patients treated at Royal Oak. An increase in MI was not found during data collection, however, one patient at Royal Oak did show evidence of abnormal echocardiogram findings without post-operative ileus or alvimopan. No causal relationship between these two events has been established at this time.

Based on the results of this medication-use evaluation, further evaluation of the efficacy and patient outcomes and use of an unclassified agent in a controlled group will be necessary to help determine its appropriate use within Beaumont Health System.

Limitations

• Small sample size

• Retrospective chart review

• Documentation of non-adherence: patients not guide criteria and documentation/confirmation on documentation. If none were documented by a high-risk criteria were not identified in the patient chart, patients were deemed non-adherent.

• Inadequate documentation between site. Documentation of activities was limited to be complete at Green Pointe compared to Royal Oak and Troy.

Disclosure

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the adjournment of this presentation.

Rhianna Tuchscherer, PharmD: Nothing to disclose

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Sarah Nordbeck, PharmD: Nothing to disclose

Beaumont Health System

NOMINATE

ACCREDITED