Alvimopan Use, Outcomes, and Costs: A Report from the Surgical Care and Outcomes Assessment Program Comparative Effectiveness Research Translation Network Collaborative

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BACKGROUND: Randomized trials have found that alvimopan hastens return of bowel function and reduces length of stay (LOS) by 1 day among patients undergoing colorectal surgery. However, its effectiveness in routine clinical practice and its impact on hospital costs remain uncertain.

STUDY DESIGN: We performed a retrospective cohort study of patients undergoing elective colorectal surgery in Washington state (2009 to 2013) using data from a clinical registry (Surgical Care and Outcomes Assessment Program) linked to a statewide hospital discharge database (Comprehensive Hospital Abstract Reporting System). We used generalized estimating equations to evaluate the relationship between alvimopan and outcomes, and adjusted for patient, operative, and management characteristics. Hospital charges were converted to costs using hospital-specific charge to cost ratios, and were adjusted for inflation to 2013 US dollars.

RESULTS: Among 14,781 patients undergoing elective colorectal surgery at 51 hospitals, 1,615 (11%) received alvimopan. Patients who received alvimopan had a LOS that was 1.8 days shorter ($p < 0.01$) and costs that were $2,017 lower ($p < 0.01$) compared with those who did not receive alvimopan. After adjustment, LOS was 0.9 days shorter ($p < 0.01$), and hospital costs were $636 lower ($p = 0.02$) among those receiving alvimopan compared with those who did not.

CONCLUSIONS: When used in routine clinical practice, alvimopan was associated with a shorter LOS and limited but significant hospital cost savings. Both efficacy and effectiveness data support the use of alvimopan in routine clinical practice, and its use could be measured as a marker of higher quality care. (J Am Coll Surg 2016;222:870–877. © 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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Abbreviations and Acronyms

CHARS = Comprehensive Hospital Abstract Reporting System
ERAS = Enhanced Recovery After Surgery
LOS = length of stay
POI = postoperative ileus
RCT = randomized controlled trial
SCOAP = Surgical Care and Outcomes Assessment Program

More than 330,000 colorectal operations are performed annually in the United States,[1] and approximately 17% of patients will develop a postoperative ileus.[2] Postoperative ileus is estimated to cost the US health care system more than $1.5 billion per year,[3] which does not include the burden placed on patients and their families. Although POI has many potential causes, opioid use is believed to be a key determinant.[4] Alvimopan (Entereg; Merck) is a pharmaceutical—approved by the FDA in 2008—that prevents opioid-induced POI in the setting of colorectal and pelvic surgery. Alvimopan blocks peripheral μ-opioid receptors in the gastrointestinal tract, but has limited systemic absorption and ability to cross the blood-brain barrier and, therefore, still permits opioid-mediated central pain control.[5] Multiple randomized controlled trials (RCTs) have found that alvimopan decreased time to return of bowel function by 5 to 28 hours, depending on the dose.[6-10] In the one RCT that evaluated length of stay (LOS), alvimopan reduced LOS by 24 hours.[9]

There remains considerable interest in determining whether alvimopan is effective in routine clinical practice. Many processes that were standardized and carefully monitored in RCTs to demonstrate efficacy (such as dose and frequency of drug administration and implementation of Enhanced Recovery After Surgery [ERAS]-type programs) might not occur in routine practice, and the drug can appear to be more or less effective than what was initially reported. Concerns about the effectiveness of alvimopan persist, as several well-done observational studies have reported LOS savings of more than 1 day.[11-13] Additionally, some believe that the cost of the drug is excessive and unwarranted, even though it is estimated to be approximately $67.50 per pill or $937.50 for a full course of 7 days of treatment[14] and few patients actually receive the full course. Both of these factors might prevent adoption of alvimopan in routine clinical care.

To address these issues, we sought to evaluate the relationship between alvimopan use and LOS and hospital costs among patients undergoing elective colorectal surgery in Washington state. We hypothesized that alvimopan use would be associated with LOS reduction no more than 1 day, and that alvimopan use would not be associated with higher hospital costs.

METHODS

We performed a retrospective cohort study of all adult patients undergoing elective colorectal surgery from January 1, 2009 to December 31, 2013 at hospitals participating in the Surgical Care and Outcomes Assessment Program (SCOAP). Patients treated before 2009 were excluded, as alvimopan was not approved by the FDA until May 2008. The Surgical Care and Outcomes Assessment Program is a quality improvement and benchmarking collaborative based in Washington state, for which the Comparative Effectiveness Research Translation Network provides research and analytic support.[15,16] This clinical registry collects information about patient demographic characteristics, disease characteristics, management, and outcomes. The Surgical Care and Outcomes Assessment Program data are collected directly from the medical record by trained, audited abstractors using standardized definitions that are available via a secure page at www.SCOAP.org. To obtain hospital cost data, SCOAP cases were linked to the WA Comprehensive Hospital Abstract Reporting System (CHARS), a hospital discharge database that includes data from all public and private hospitals in Washington state, excluding Veterans Affairs and military hospitals. The use of deidentified data does not require review by the University of Washington Human Subjects Division, and the linkage to CHARS was approved by the WA Department of Social and Health Services IRB.

Of patients who had elective colorectal surgery between 2009 and 2013 (n = 15,565), the following sequential exclusion criteria were applied: patients who were missing information about alvimopan receipt ($n_{excluded}$ = 31); patients younger than 18 years ($n_{excluded}$ = 4); individuals who had colorectal surgery listed as a secondary operation ($n_{excluded}$ = 226) or who were designated as having an additional or staged procedure during the same admission ($n_{excluded}$ = 67); those who had undergone a colon resection within the previous 30 days ($n_{excluded}$ = 70); patients with American Society of Anesthesiologists class V ($n_{excluded}$ = 13) or who were intubated ($n_{excluded}$ = 3); and those with American Society of Anesthesiologists class listed as "emergent" ($n_{excluded}$ = 264) or "not applicable" ($n_{excluded}$ = 106), as we could not confirm that these were elective cases.

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