Perioperative Pharmacologic Prophylaxis for Venous Thromboembolism in Colorectal Surgery

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BACKGROUND: To determine the effectiveness of pharmacologic prophylaxis in preventing clinically relevant venous thromboembolic (VTE) events and deaths after surgery. The Surgical Care Improvement Project recommends that VTE pharmacologic prophylaxis be given within 24 hours of the operation. The bulk of evidence supporting this recommendation uses radiographic end points.

STUDY DESIGN: The Surgical Care and Outcomes Assessment Program is a Washington State quality improvement initiative with data linked to hospital admission/discharge and vital status records. We compared the rates of death, clinically relevant VTE, and a composite adverse event (CAE) in the 90 days after elective, colon/rectal resections, based on receipt of pharmacologic prophylaxis (within 24 hours of surgery) at 36 Surgical Care and Outcomes Assessment Program hospitals (2005–2009).

RESULTS: Of 4,195 (mean age 61.1 ± 15.6 years; 54.1% women) patients, 56.5% received pharmacologic prophylaxis. Ninety-day death (2.5% vs 1.6%; p = 0.03), VTE (1.8% vs 1.1%; p = 0.04), and CAE (4.2% vs 2.5%; p = .002) were lower in those who received pharmacologic prophylaxis. After adjustment for patient and procedure characteristics, the odds were 36% lower for CAE (odds ratio = 0.64; 95% CI, 0.44−0.93) with pharmacologic prophylaxis. In any given quarter, hospitals where patients more often received pharmacologic prophylaxis (highest tertile of use) had the lowest rates of CAE (2.3% vs 3.6%; p = 0.05) compared with hospitals in the lowest tertile.

CONCLUSIONS: Using clinical end points, this study demonstrates the effectiveness of VTE pharmacologic prophylaxis in patients having elective colorectal surgery. Hospitals that used pharmacologic prophylaxis more often had the lowest rates of adverse events. (J Am Coll Surg 2011;213: 596–603. © 2011 by the American College of Surgeons)

Venous thromboembolism (VTE) is the second most common postoperative complication,[1] and one of the most common preventable causes of in-hospital death.[2-4] To prevent VTE, the American College of Chest Physicians generates evidence-based guidelines every 4 years.[3,5] Current guidelines recommend that, unless otherwise contraindicated, heparin-based pharmacologic prophylaxis be administered to prevent deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients undergoing major abdominal surgery. This recommendation, with the specification that VTE pharmacologic prophylaxis be given within 24 hours of the operation, has been adopted by the Surgical Care Improvement Project (SCIP) initiative as a "pay for performance" initiative. The bulk of evidence supporting this recommendation uses an end point of VTE events determined by radiolabeled fibrinogen uptake or venography rather than clinically relevant VTE (symptomatic DVT and symptomatic or fatal PE). In part because of the use of radiographic end points and concerns about bleeding risk, there has been skepticism about the wider use of VTE pharmacologic prophylaxis in patients having surgery.[6-8] Skeptics note that as many as 66% of patients who get a VTE have received appropriate pharmacologic

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Abbreviations and Acronyms

CAE = composite adverse event
CHARS = Comprehensive Hospital Abstract Reporting System
DVT = deep venous thrombosis
OR = odds ratio
PE = pulmonary embolism
SCIP = Surgical Care Improvement Project
SCOAP = Surgical Care and Outcomes Assessment Program
VTE = venous thromboembolism

prophylaxis[9] and, in at least one center, despite increasing use of pharmacologic prophylaxis, the rate of symptomatic VTE on the surgical service actually increased during a 10-year period.[10] These concerns might explain why the rate of use of pharmacologic prophylaxis is highly variable despite the SCIP mandate.[11-14]

Given the relative paucity of VTE studies using clinical end points and the unclear effectiveness of pharmacologic prophylaxis in community practice settings, we performed an observational, comparative effectiveness evaluation across most Washington State hospitals. The study is based in Washington State's Surgical Care and Outcomes Assessment Program (SCOAP), a prospectively gathered clinical registry and quality improvement activity now implemented at nearly all statewide hospitals where surgery is performed (n = 55).[15] The purpose of this study was to evaluate the relationship between the use of pharmacologic prophylaxis and clinical VTE in patients having elective colorectal surgery and to determine the relationship between increasing hospital use of pharmacologic prophylaxis and outcomes.

METHODS

Study design

This study was approved by the University of Washington Human Subject Review Committee and the Washington State Department of Health. A prospective cohort study was conducted using the SCOAP in-hospital clinical registry linked to hospital administrative discharge database, and the state's vital records system. SCOAP draws data from the medical record by trained, audited abstractors using standardized definitions (http://www.scoap.org/documents/index.html). The Washington State Comprehensive Hospital Abstract Reporting System (CHARS) includes administrative information on all hospitalizations and patient identifiers that allows for tracking of subsequent hospitalizations. SCOAP index cases were linked to CHARS to identify patients who were rehospitalized at any center after a SCOAP index admission and to the vital status registry to determine if they had died. The CHARS dataset also contains ICD-9 procedure and diagnosis codes. Records of inpatient hospitalization between the fourth quarter of 2005 and first quarter of 2009 at 36 SCOAP hospitals (Appendix 1, online only) were used to assess outcomes for patients undergoing elective colon/rectal resections.

Variable definitions

Patient risk factors

SCOAP records were used to obtain sociodemographic characteristics, clinical comorbidities, and operative details. We used the Deyo modification of the Charlson Comorbidity Index to calculate a weighted index of comorbid conditions for each patient.[16] Scores range from 0 to 3+, where 0 indicates the absence of comorbid conditions and the score was truncated at ≥3.

Duration of operation

Anethesia record and operating room log were used to identify the operating room incision and end times. Duration was measured from incision to final wound closure.

Type/method of operation

Operation type was specified as right hemicolectomy, left hemicolectomy, low anterior resection, abdominal perineal resection, total abdominal colectomy, colostomy takedown, and perineal proctectomy. Method of operation was specified as laparoscopic, open, laparoscopic converted to open, and laparoscopic/hand-assisted.

Use of pharmacologic prophlaxis

VTE pharmacologic prophylaxis administration was obtained by directed chart review of all patients. SCIP criteria were used to define the use of pharmacologic prophylaxis, specifically chemical agents administered 24 hours before or after the operative start time in a patient not otherwise contraindicated for use.[17] Acceptable pharmacologic prophylaxis included unfractionated heparin, low molecular weight heparin (ie, enoxaparin, dalteparin, or tinzaparin), and synthetic factor Xa inhibitor (ie, fondaparinux). Use of warfarin was not counted as acceptable as defined by SCIP criteria.[18] Use of agents that did not conform to SCIP criteria (eg, sequential pneumatic compression devices) was also recorded.

Outcomes

Given recent evidence that the risk of operation-related VTEs does not return to baseline for 12 weeks,[19] the primary outcomes were 90-day death rate, new VTE diagnosis or VTE-related intervention, as well as the composite of these adverse events (CAE). Complication potentially related to the use of VTE pharmacologic prophylaxis (intra-