

Effectiveness and safety of expanded perioperative thromboprophylaxis in complex gynecologic surgery☆☆☆



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HIGHLIGHTS

- We examine VTE rates before and after a uniform change in practice.
- Expanded prophylaxis resulted in a decreased VTE rate (6.7% to 2.7%).
- There was no significant difference in bleeding or infection complications.

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ABSTRACT

Objective. To determine the effectiveness and safety of an expanded perioperative venous thromboembolism (VTE) prophylaxis strategy in women undergoing complex gynecologic surgery.

Methods. We performed a cohort study of 527 patients undergoing major surgery at a single institution over a thirty-month interval during which the gynecologic oncology service implemented an expanded approach to VTE prophylaxis. We compared rates of VTE pre- and post-intervention as well as bleeding and infectious complications.

Results. Prior to the intervention, there were 23 VTE events in 345 patients (rate of 6.67%): 8 deep vein thromboses (DVTs) and 15 pulmonary emboli (PEs). Post-intervention, there were 5 VTE events in 182 patients (2.7%): 3 DVTs and 2 PEs (RR = 0.4, $p = 0.056$). Time-to-event analysis showed a significantly higher incidence of VTE events in the pre-intervention time frame compared to the post-intervention period ($p = 0.049$). There were no significant differences in bleeding or infection complications between groups.

Conclusions. Implementation of a perioperative VTE prophylaxis protocol was safe, feasible and resulted in a clinically significant reduction in symptomatic VTE. Preoperative single-dose unfractionated heparin for all patients, combined with two weeks of thromboprophylaxis in gynecologic cancer patients, may decrease VTE events without increasing bleeding or infection.

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1. Introduction

Venous thromboembolism (VTE), consisting of deep venous thrombosis (DVT) or pulmonary embolism (PE), remains common and

potentially fatal. VTE affects up to 2 million people in the United States, with an annual incidence of 200,000–400,000. It is the proximate cause of death in up to 100,000 each year [1–3]. Gynecologic surgical patients, especially those with malignancy, have an elevated risk: without prophylaxis, rates of VTE are as high as 35%. Even with prophylaxis, clinically significant PEs are found in 5–18% of women undergoing complex pelvic surgery [4–6]. Preoperative lower extremity screening is not useful, in part because many gynecologic oncology patients with postoperative PEs have no evidence of DVT pre- or post-operatively [7].

Both immediate and extended perioperative pharmacologic prophylaxis with low molecular weight heparin decrease rates of VTE and of hospital readmission in medical and surgical patients with

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malignancy [8,9]. The American College of Chest Physicians (ACCP) and the American College of Obstetricians & Gynecologists (ACOG) recommend unfractionated heparin, low molecular weight heparin, or unfractionated or low molecular weight heparin combined with pneumatic sequential compression devices (SCDs) for patients at moderate or high risk who undergo gynecologic surgery, with extended prophylaxis for 2–4 weeks after discharge [10].

Despite ample guidelines, adherence continues to be suboptimal, ranging in published series from 39–59% [11–13]. While inpatient post-operative VTE prophylaxis has gained acceptance, the use of preoperative or extended prophylaxis has been inconsistent and/or infrequent except in certain orthopedic [14] and cancer populations [15]. Potential concerns with perioperative anticoagulation include perceived risks for wound infection or hematoma, surgical blood loss, and concomitant increased hospital lengths of stay [16].

In 2010, in response to higher-than-expected rates of VTE (as defined by hospital-specific American College of Surgeons National Surgery Quality Improvement Program (NSQIP) data), the Hospital of the University of Pennsylvania launched an initiative to adopt the use of a *preoperative* dose of thromboprophylaxis consistently. In patients undergoing pancreatic surgery at this institution, VTE incidence decreased from 17.6% to 2.76% following implementation of this protocol [15]. Here, we report how expanded thromboprophylaxis affected VTE incidence among our patients undergoing surgery on the gynecologic oncology service.

2. Methods

Institutional review board approval was obtained to perform a prospective cohort study of consecutive patients undergoing major abdominal surgery by the gynecologic oncology service over a thirty-month interval. A protocol was developed in 2010 at the Hospital of the University of Pennsylvania to encourage the routine use of preoperative thromboprophylaxis for high-risk patients. This protocol included a mandatory checklist to be completed by the attending physician prior to surgery that included the questions “1) Heparin use prior to induction in operating room? (yes/no), 2) dosage of subcutaneous unfractionated heparin injection? (5000 units vs. 7500 units based on weight), and 3) intermittent sequential compression devices (SCDs) to be applied in operating room? (yes/no).” The nursing preoperative checklist for safety was expanded to include a mandatory review of the form along with administration of prophylaxis as ordered. Current ACCP guidelines were distributed and posted in patient care areas to assist faculty with the determination of the appropriate regimen.

Prior to this intervention, all patients on the gynecologic oncology service (regardless of cancer status) received dual inpatient prophylaxis consisting of perioperative SCDs and subcutaneous heparin three times daily beginning 6 h after surgery; they received neither the preoperative dose nor the extended thromboprophylaxis after hospital discharge. In February of 2010, the Division of Gynecologic Oncology initiated the above VTE prophylaxis regimen of a dose of pre-operative subcutaneous unfractionated heparin given to all patients undergoing major abdominal surgery on the operating room table prior to the time of anesthesia induction. Patients undergoing exploratory laparotomy received an epidural prior to induction for postoperative pain relief; for these patients, the heparin dose was given 15 min later. This pre-operative dose was combined with dual inpatient prophylaxis (consisting of SCDs and subcutaneous heparin). Patients wore SCDs while in bed and initially received subcutaneous unfractionated heparin three times daily. If hemodynamically stable, cancer patients were transitioned to daily dosing of low molecular weight heparin (LMWH) on the evening of postoperative day 1. Patients with malignancy were discharged with up to 14 days of prophylactic dosing of low-molecular weight heparin (Fig. 1). Insurance coverage was arranged and patients' acceptance of co-pay for extended prophylaxis was documented by social work services prior to discharge; providers assessed compliance with the regimen at each patient's two-week postoperative visit.

“Complex gynecologic surgery” was defined as all major surgery performed by the Division of Gynecologic Oncology requiring an inpatient stay during the designated time frame. Systematic chart abstraction was performed for all patients who underwent surgery by our gynecologic oncology service from January 2008 through July 2010. Charts were reviewed of patients undergoing surgery within a 24-month period prior to the new VTE prophylaxis regimen change as well as 6 months following the change. All charts were reviewed for follow-up for at least one year following surgery. Primary outcomes were: 1) incidence of symptomatic, clinically significant VTE as documented at postoperative clinic visits or readmission before and after the regimen change and 2) post-operative bleeding or infections. The post-operative time period was defined as 90 days.

To aid in the clarification of the complexity of surgery, we assigned each individual patient a Caprini score (CS) using the Caprini Risk Assessment Model (RAM), which has recently been validated for gynecologic oncology surgery [12]. Comorbidities and perioperative risk factors accounted for within this scoring system include age, malignancy, surgery > 45 min, family history of VTE, prior personal history of VTE, thrombophilia, chronic pulmonary disease, body mass index (BMI), and history or recent stroke or hip, pelvis or leg fracture. Scores were then calculated into a Caprini risk category as follows: *low* (0–1 point,

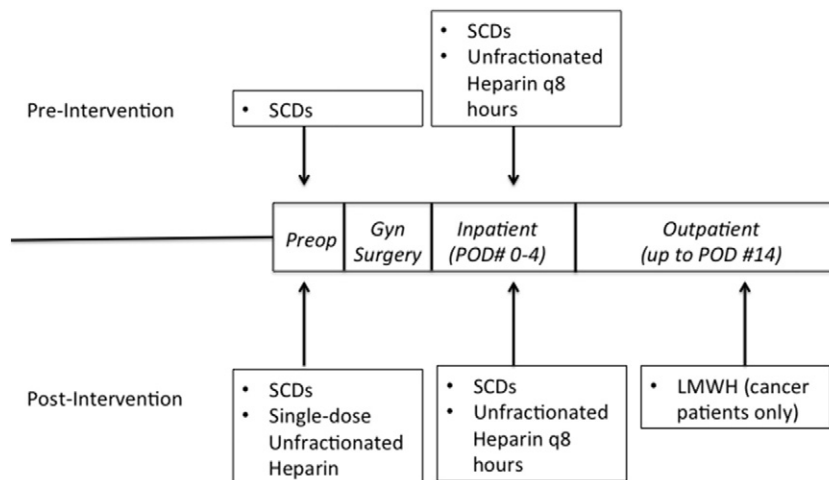


Fig. 1. Schematic of intervention strategy. SCDs = sequential compression devices, Preop = preoperative dose given in operating room prior to anesthesia induction and surgery; POD = postoperative day; LMWH = low molecular weight heparin.

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