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## Is forgoing chemical venous thromboembolism prophylaxis for women undergoing breast-conserving surgery for breast cancer safe?



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### **KEYWORDS:**

Breast; Cancer; Lumpectomy; VTE; Thromboembolism; Prophylaxis

#### Abstract

**BACKGROUND:** Cancer patients have a 4 to 7 fold increased risk of venous thromboembolism (VTE) vs the normal population. Chest guidelines recommend no chemical VTE prophylaxis for women with a <1.5% risk for VTE. Although the risk of VTE among women undergoing breast-conserving therapy is reported to be low overall, the rate without chemical prophylaxis has not been defined. The objective of the study was to establish the VTE risk among women undergoing breast-conserving surgery (BCS) who did not receive chemical VTE prophylaxis.

**METHODS:** From a prospective breast cancer database, 1,000 consecutive patients who underwent BCS without chemical VTE prophylaxis and with mechanical prophylaxis (support hose and intermittent pneumatic compression devices) were analyzed for VTE occurrence within 30 days postoperatively. Institutional review board approval was obtained.

**RESULTS:** The mean age was  $65.4 \pm 11.7$  years, and mean body mass index was  $27.3 \pm 5.7$ . About 81.9% of the patients were postmenopausal. Median tumor size was 1.1 cm, and 24.7% of patients had lymph node metastases. The 30-day rate of clinically significant VTE was 0% (95% CI 0% to .37%). Hematomas requiring surgical intervention occurred among .6% of patients.

**CONCLUSIONS:** This cohort demonstrates that breast cancer patients undergoing BCS may be safely managed without chemical VTE prophylaxis because the risk with only mechanical prophylaxis is acceptable.

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0002-9610/\$ - see front matter © 2016 Elsevier Inc. All rights reserved. http://dx.doi.org/10.1016/j.amjsurg.2016.09.038 Cancer patients are at an increased risk of venous thromboembolism (VTE) and thrombotic complications due to their hypercoagulable state. VTE typically presents as deep vein thrombosis and/or pulmonary embolism (PE). In general, cancer patients have a 4-7 fold increased risk of VTE as compared with the general population.<sup>1–3</sup> Many studies have shown that the risks of VTE are dependent on the type of malignancy and its stage. For instance, brain and pancreatic cancer patients are at significantly greater risk of developing VTE as compared with patients with breast cancer or prostate cancer.<sup>2</sup>

In a recent National Surgical Quality Improvement Program (NSQIP) analysis conducted by the American College of Surgeons to evaluate the incidence of VTE among women undergoing lumpectomy, mastectomy, mastectomy with reconstruction, and reconstruction, the incidence of VTE was shown to be .13% in the lumpectomy group as compared with .29% in the mastectomy group, .41% in the reconstruction group, and .52% in the mastectomy with reconstruction group (P < .0001).<sup>4</sup> Thus, women undergoing a lumpectomy tend to have a significantly lower risk for VTE as compared with other breast surgery groups. Furthermore, the Chest antithrombotic guidelines recommend mechanical prophylaxis (preferably with intermittent pneumatic compression devices) for general and abdominal– pelvic surgeries that carry less than 1.5% risk of VTEs.<sup>5</sup>

Women with breast cancer who are candidates for breastconserving surgery (BCS) tend to present with early stage malignancy. Theoretically, we would assume that this population would manifest procoagulative effects of cancer to a lesser degree than those who present with later stage disease. Currently, there is no defined VTE prophylaxis regimen for this population in the literature. Consequently, to guide practice, we study the risk of VTE in a cohort of women undergoing BCS who did not receive chemical VTE prophylaxis.

## Methods

Institutional review board approval was obtained for this study. We performed a retrospective review of 1,000 consecutive breast cancer patients who underwent BCS without chemical prophylaxis for VTE. All patients undergoing BCS were considered eligible for no chemical prophylaxis if there was no history of VTE and no history of specific thrombophilic condition. Patients receiving VTE prophylaxis due to these factors were excluded. No formal VTE risk calculation was used. The cohort was retrieved from a prospective breast cancer database at the Mayo Clinic in Arizona. Medical records were seperately reviewed to assure no chemical VTE prophylaxis was received. We analyzed the occurrence of VTE and hematoma requiring surgical evacuation within 30 days postoperatively in this cohort. Furthermore, we included age, body mass index, menopausal status, tumor size, and lymph node status in our analysis. A minimum of 30-days of follow-up for each patient and the capture of any incidence of VTE were assured through a separate review of all medical records. Patients were seen for ongoing care at our multidisciplinary breast center, and all clinical documentation to the 30-day point was reviewed for evidence of VTE event.

VTE was defined a priori as any diagnosis of deep venous thrombosis (DVT) or PE. Patients were not subjected to any specific testing for VTE absence clinical signs or symptoms. Thus, the outcome measured was *clinically evident* VTE.

### Results

Our analysis included 1,000 consecutive women with breast cancer who underwent BCS without VTE chemical prophylaxis. All women received mechanical VTE prophylaxis (support hose and intermittent pneumatic compression devices). The mean age of the population cohort was  $65.4 \pm 11.7$  years. The mean body mass index was  $27.3 \pm 5.7$  kg/m<sup>2</sup>. We found that 81.9% of the patients were postmenopausal. The median tumor size was 1.1 cm, and 24.7% of patients had evidence of lymph node metastases. The 30-day rate of VTE was 0% (95% CI 0% to .37%). Hematomas requiring surgical intervention occurred among .6% of patients.

## Comments

The overall age adjusted incidence of VTE among women in the United States is 105 per 100,000 (.1%).<sup>6</sup> Pharmacologic VTE prophylaxis has been shown to be associated with a decreased incidence of DVT and PE.5,7 Women with breast cancer who are candidates for surgery are at a particular risk of developing the Virchow's triad in the setting of their underlying malignancy and surgery.<sup>7,8</sup> Therefore, early ambulation and application of sequential compression devices have become standard practice. For patients undergoing BCS, the applicable Chest guideline (for moderate-risk general surgery patients) would suggest that if chemical thromboprophylaxis is chosen to be used, it would be with low-molecular-weight heparin, low-dose unfractionated heparin, or fondaparinux.<sup>5</sup> While pharmacologic prophylaxis of VTE has been widely recommended to prevent hypercoagulability, its use is not without risk, particularly bleeding, development of hematoma and heparin-induced thrombocytopenia.<sup>8–10</sup>

Surgery and the presence of a malignant neoplasm are both independent risk factors for developing VTE.<sup>11</sup> The choice of the VTE prophylactic regimen in surgical patients is usually dependent on the type of surgery and the balance between the risk of bleeding and the risk of VTE. BCS is associated with low risks of fatal bleeding and low risks of venous stasis since most women ambulate early. While the Chest guidelines recommend mechanical prophylaxis for abdomino–pelvic surgeries that are associated with less than 1.5% risk of VTEs, pharmacologic prophylaxis is also recommended in the setting of hypercoagulability like malignancy.<sup>5</sup>

The current literature shows that hypercoagulability in patients with breast cancer is seen less often as compared with

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