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CLINICAL ARTICLE

Sequential screening to predict symptomatic pulmonary thromboembolism after gynecologic surgery in Nara, Japan

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ABSTRACT

Objective: To evaluate a sequential screening method's efficacy in predicting symptomatic pulmonary thromboembolism (PTE) after gynecologic surgery. **Methods:** A prospective study employing a two-stage screening process was conducted among consecutive asymptomatic adults who underwent outpatient evaluation for gynecologic surgery at Nara Medical University Hospital, Japan, between April 1, 2004, and December 31, 2013. Patients with a preoperative plasma D-dimer level greater than or equal to 1.0 µg/mL underwent compression ultrasonography of the lower extremities. The primary outcome measure was postoperative detection of symptomatic PTE. **Results:** Overall, 1729 patients were included. The mean D-dimer level was 1.7 ± 3.3 µg/mL. Compression ultrasonography was conducted among 470 (27.1%) patients with positive D-dimer test results; symptomatic deep vein thrombosis (DVT) was preoperatively detected among 94 (20.0%) of them. Patients with DVT ($n = 94$) had higher D-dimer levels than patients ($n = 1635$) without (7.8 ± 12.8 µg/mL vs 1.1 ± 1.8 µg/mL; $P < 0.001$). Despite anticoagulant therapy, symptomatic PTE was detected postoperatively among two of these 94 patients. Symptomatic PTE was also detected among four of 376 patients with positive D-dimer test results but no evidence of DVT by ultrasonography. No clinical onset of postoperative PTE was observed among 1259 patients with D-dimer levels below the cut-off value. **Conclusion:** The PROVEN screening strategy (Preoperative surveillance using a sequential strategy) was ineffective at predicting postoperative symptomatic PTE.

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1. Introduction

Venous thromboembolism (VTE)—which includes deep vein thrombosis (DVT) and pulmonary thromboembolism (PTE)—is a serious complication associated with gynecologic surgery [1]. The rate of VTE among women undergoing such surgery is high, particularly among those with a gynecologic malignancy, and the overall risk of DVT is estimated at 7%–45% [2]. Of note, the prevalence of proximal DVT is approximately 70% among patients with PTE confirmed by angiography [3]. Therefore, women undergoing major gynecologic surgery should be offered thromboprophylaxis [4–6].

Many imaging modalities are used in the diagnostic algorithm for VTE. Compression ultrasonography (or venous ultrasonographic imaging) is a convenient, reproducible, and highly accurate method for the detection of DVT that has replaced venography in clinical practice [7]. Furthermore, the plasma D-dimer test is an established method for early detection of VTE [8,9].

Over the past decade, the Nara Medical University Hospital in Japan has used a sequential strategy involving plasma D-dimer measurement followed by ultrasonography to preoperatively screen for VTE among patients who have undergone gynecologic surgery. This patient-based screening approach is known as the Programme for VTE Screening Study at Nara, Japan (PROVEN).

The aim of the present study was to determine whether PROVEN is useful for predicting preoperative asymptomatic DVT and postoperative symptomatic PTE.

2. Materials and methods

A single-center prospective study was conducted among consecutive asymptomatic adults who underwent outpatient evaluation for gynecologic surgery in the Department of Obstetrics and Gynecology, Nara Medical University Hospital, between April 1, 2004, and December 31, 2013. The inclusion criteria were age older than 20 years and gynecologic surgery for uterine leiomyoma, endometriosis, pelvic organ prolapse, ovarian cyst, cervical cancer, endometrial cancer, or ovarian cancer. The exclusion criteria were pregnancy or lactation; suspected DVT or PTE; ongoing anticoagulation therapy; mandatory indication for anticoagulation therapy; and geographic inaccessibility to follow-up. The participants' medical records were abstracted for relevant

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ultrasonography, computed tomography, and clinical data, including VTE diagnosed either preoperatively or postoperatively. The study was conducted according to the ethical principles stated in the Declaration of Helsinki, and the protocol was approved by the Institutional Review Board of Nara Medical University. The purpose and details of PROVEN were explained to the patients; written informed consent was obtained before participation.

The PROVEN screen for PTE was a two-stage process (Fig. 1). Patients with a plasma D-dimer level of 1.0 µg/mL or higher subsequently underwent ultrasonography, whereas those with a D-dimer level of less than 1.0 µg/mL did not receive a referral for ultrasonography. All participants were scheduled for surgery and a 3-month follow-up evaluation. Patients who presented with clinical signs of PTE postoperatively underwent enhanced computed tomography of the lungs to diagnose this condition.

All patients received appropriate thromboprophylaxis according to the Japanese VTE guideline recommendations [10]. This guideline stratifies patients into low, moderate, high, and very high risk groups according to their actual VTE risk and recommends optimum VTE prophylaxis for each group. The guideline also recommends early ambulation for low-risk patients (surgical time <30 minutes). The use of graduated compression stockings or intermittent pneumatic compression is recommended for moderate-risk patients undergoing gynecologic surgery for benign disease. For high-risk patients with malignant disease, intermittent pneumatic compression or pharmacological prophylaxis with low molecular weight heparin (4000 IU/day) or low-dose unfractionated heparin (10 000–15 000 units/day) is recommended. Mechanical and pharmacological prophylaxis are recommended if patients with malignant disease have any additional risk factors, including previous VTE or thrombophilia (very high-risk group).

Patients with VTE were treated according to the Japanese VTE guidelines [10]. Conventional anticoagulant therapy was initiated after the diagnosis of DVT. An inferior vena cava filter was placed in patients with proximal DVT or floating DVT for preoperative prophylaxis of PTE.

Quantitative measurement of plasma D-dimer levels was performed two weeks prior to the date of surgery using the AIA-PACK DD immunoassay kit (Tosoh Medics, Foster City, CA, USA). A plasma D-dimer level of less than 1.0 µg/mL was reported to be

sufficient to exclude VTE among patients with a negative D-dimer level without needing to perform ultrasonography [11].

The gold standard for DVT diagnosis in the present study was ultrasonography using vein compression. Imaging was performed on the lower extremities with a 5-MHz transducer connected to a Sonovista-SL MEU 1577 ultrasonographic unit (Mochida Pharmaceutical, Tokyo, Japan). Routine scanning methods for compression ultrasonography were previously established to shorten the time required for examination and ensure consistent conditions during secondary screening [12].

The preoperative incidence of DVT among the participants was determined. The primary outcome measure was the number of patients with symptomatic PTE after undergoing gynecologic surgery.

Participants were registered in a computer system to aid data collection and management. The data were analyzed using SPSS version 11.0 (IBM, Armonk, NY, USA). Differences between the observed results were evaluated using the χ^2 test, whereas differences between the means were evaluated by the *t* test and analysis of variance. A *P* value below 0.05 was considered statistically significant.

3. Results

Of the 1729 patients enrolled, 934 (54.0%) had benign disease and 795 (46.0%) had malignant disease (Fig. 1). A total of 470 (27.2%) patients met the preoperative D-dimer cut-off level for ultrasonography, which was scheduled within 1 week. The preoperative ultrasonography data revealed asymptomatic DVT among 94 (20.0%) of the 470 patients with a positive D-dimer test result, giving an overall prevalence of 5.4% (94 of 1729). The incidence of preoperative DVT was 65 of 795 (8.2%) among patients with gynecologic cancer and 29 of 934 (3.1%) among those with benign disease. Proximal DVT was found among 14 (14.9%) of the 94 patients with DVT.

The incidence of confirmed symptomatic PTE during the postoperative follow-up period was six of 1729 (0.4%) for all participants and six of 470 (1.3%) for those with a positive D-dimer test result. The case histories of the six patients with PTE are shown in Table 1.

Two of these patients presented with DVT preoperatively. Patient 1 had a large uterine leiomyoma weighing 1865 g; she exhibited

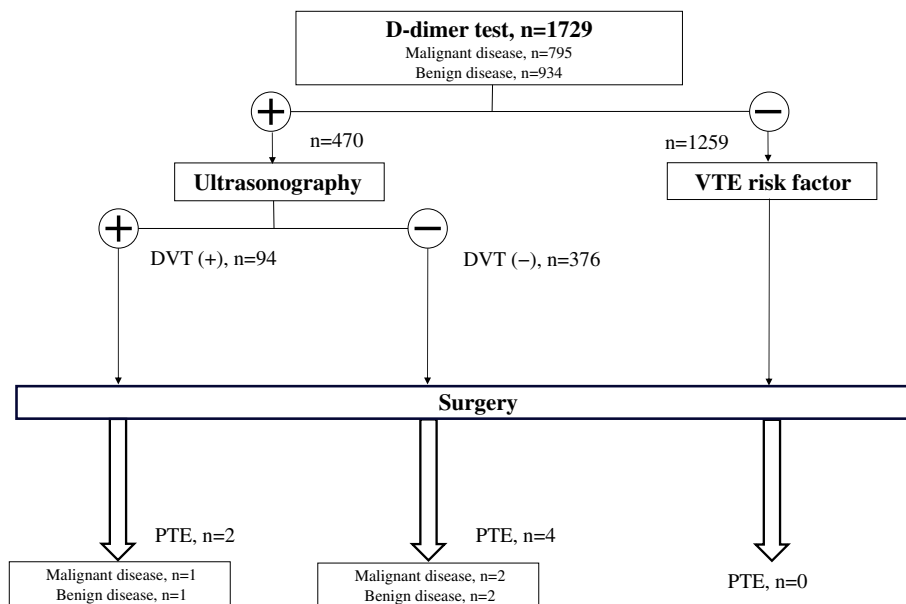


Fig. 1. Flow diagram of the two-point screening strategy for predicting pulmonary thromboembolism after gynecologic surgery. The screening protocol comprised a plasma D-dimer assay followed by compression ultrasonography; the whole-leg strategy comprised whole-leg color-coded Doppler ultrasonography. The plus and negative symbols indicate positive and negative test results, respectively. Abbreviations: VTE, venous thromboembolism; DVT, deep vein thrombosis; PTE, pulmonary thromboembolism.

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