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Trends in vena cava filter insertions and "prophylactic" use

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ABSTRACT

Background: Prophylactic vena cava filter (VCF) use in patients without venous thromboembolism is common practice despite ongoing controversy. Thorough analysis of the evolution of this practice is lacking. We describe trends in VCF use and identify events associated with changes in practice.

Methods: Using the National Inpatient Sample, we conducted a retrospective observational study of U.S. adult hospitalizations from 2000 to 2014. Trends in prophylactic VCF insertion were analyzed both across the entire study population and within subgroups according to trauma status and type of concurrent surgery. Annual percentage change (APC) was calculated, and trends were analyzed using Poisson regression.

Results: Among 461,904,314 adult inpatients (median [interquartile range] age, 58.1 [38.5-74.3] years; 39.6% male), the incidence of VCF insertion increased rapidly at first (from 0.19% to 0.35%; APC, 11.2%; 95% confidence interval [CI], 10.3%-12.2%; $P < .001$), then at a slower rate after the publication of the Prévention du Risque d'Embolie Pulmonaire par Interruption Cave 2 (PREPIC2) trial in 2005 (from 0.35% to 0.42%; APC, 4.4%; 95% CI, 2.8%-6.0%; $P < .001$), and it began decreasing after the 2010 Food and Drug Administration (FDA) safety alert (from 0.42% to 0.32%; APC, −5.5%; 95% CI, −6.5% to −4.6%; $P < .001$). The percentage of total VCFs that had a prophylactic indication increased quickly before publication of the PREPIC2 trial (APC, 19.5%; 95% CI, 17.9%-21.0%; $P < .001$), increased at a slower rate after publication in 2005 (APC, 4.4%; 95% CI, 2.6%-6.2%; $P < .001$), and dropped after the FDA safety alert, stabilizing at 18.5% for the last 3 years (APC, −0.3%; 95% CI, −2.2% to 1.7%; $P = .8$). Subgroups most associated with prophylactic VCF insertion were operative trauma (odds ratio [OR], 10.9; 95% CI, 10.2-11.7), orthopedic surgery (OR, 4.7; 95% CI, 4.3-5.2), and neurosurgical procedures (OR, 3.9; 95% CI, 3.6-4.2). All groups except orthopedic surgery experienced a deceleration in prophylactic VCF growth after the publication of PREPIC2. Meanwhile, the FDA safety alert was associated with a decrease in prophylactic VCF insertions for all groups except other major surgery.

Conclusions: Whereas publication of the PREPIC2 trial led to a deceleration in prophylactic VCF insertion growth, the FDA alert had a bigger impact, leading to declining rates of prophylactic VCF use. Further investigations of prophylactic insertion of VCF in trauma, orthopedic, and neurosurgical patients are needed to determine whether current levels of use are justified. (J Vasc Surg: Venous and Lym Dis 2018;■:1-7.)

Keywords: Vena cava filter; Venous thromboembolism; Pulmonary embolism; Deep vein thrombosis; FDA; Food and Drug Administration; NIS; National Inpatient Sample

Venous thromboembolism (VTE), which includes pulmonary embolism (PE) and deep venous thrombosis (DVT), is the third most common cause of cardiovascular illness.[1] In the inpatient setting, where the majority of patients have more than one risk factor for VTE, PE is the single most common cause of preventable hospital-related death.[2] Physicians must consider various options to prevent PE, including mechanical prophylaxis by vena cava filter (VCF). However, the indications for and benefit of VCF insertion have long been controversial.[3-6] Recent debates have centered on so-called prophylactic VCFs, the insertion of VCFs in high-risk patients without prior VTE. Although prophylactic VCFs are routinely used, especially in high-risk patients with contraindications to pharmacologic anticoagulation, there are conflicting guidelines regarding this practice.[7]

Since 2000, major developments in VCF technology, research, and guidelines have occurred. First, the Food and Drug Administration (FDA) began approving VCFs for retrievable use in July 2003, which is widely believed to have permitted excessive VCF use.[8,9] Second, the FDA issued a safety alert in 2010 that recommended removal of retrievable VCFs as soon as mechanical PE

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prophylaxis can be discontinued.[10] In addition, three major professional societies have issued guidelines pertaining to VCFs between 2000 and 2014. Finally, several landmark studies on VCFs, including Prévention du Risque d'Embolie Pulmonaire par Interruption Cave 2 (PREPIC2), an 8-year follow-up to the first-ever randomized controlled trial that showed no survival benefit to VCFs, were published.[11,12] In light of these events and ongoing debate about the role of prophylactic VCFs, we analyzed national trends in VCF insertion from 2000 to 2014. Objectives were to describe trends, to identify events that associated with changes in the trend, and to quantify their impact.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of inpatient health data from the National Inpatient Sample
- **Take Home Message:** Analysis of trends in prophylactic vena cava filter (VCF) insertion in the U.S. adult population from 2000 to 2014 revealed that the annual percentage change in VCF insertion increased before and after publication of the Prévention du Risque d'Embolie Pulmonaire par Interruption Cave 2 (PREPAC2) trial, dropped after the 2010 Food and Drug Administration safety alert, and stabilized for the last 3 years. Operative trauma, orthopedic surgery, and neurosurgical procedures are most associated with prophylactic VCF insertion (odds ratios of 10.9, 4.7, and 3.9, respectively).
- **Recommendation:** The authors recommend further investigation of prophylactic VCF insertions in trauma, orthopedic, and neurosurgical patients to determine whether current levels of use are justified.

METHODS

Data source. The National Inpatient Sample (NIS), part of the Healthcare Cost and Utilization Project (HCUP), was used to obtain data from 2000 to 2014. The NIS is the United States' largest publicly available database that covers hospitalizations across all payer types.[13] In addition to the patient's age, sex, and race and hospital characteristics (size, location, teaching status, and region), the database includes procedures and discharge diagnoses coded according to the *International Classification of Diseases, Ninth Revision* (ICD-9) for each hospitalization. Because the NIS is a nationally representative sample of hospitalizations, weights are provided to create national estimates.

Study population. Our study population included all NIS hospitalization records of patients aged 18 years and older from 2000 to 2014, representing a total of 461,904,314 hospitalizations. Diagnoses of PE and DVT were identified by searching all diagnosis codes within a given hospitalization for the respective ICD-9 codes (Supplementary Table I, online only). We identified VCF insertion using the ICD-9 procedure code 38.7.[3,9,14] Concurrent neurosurgical procedure, orthopedic surgery, major abdominal surgery, and other major surgery were identified according to the HCUP Clinical Classification Software procedure code categories.[9,15] We used Clinical Classification Software diagnosis codes and E-codes to identify hospitalizations with trauma. Because some hospitalizations included multiple types of concurrent procedures, hospitalization type was assigned in a mutually exclusive but hierarchical order of operative trauma followed by neurosurgical procedures, orthopedic surgery, major abdominal surgery, other major surgery, nonoperative trauma, and hospitalizations with no major surgery. Version 3.7 of HCUP's comorbidity software was used to identify 29 comorbidities based on diagnosis codes.[16] This study is not considered human subject research and was exempted from Institutional Review Board approval and informed consent.

Statistical analysis. National estimates accounted for the NIS design by using NIS stratum, clustering, and trend weights. Trends in VCF insertion, DVT, and PE were examined using Poisson regression. Joinpoint regression analysis was used to test for natural turning points in these trend lines.[17] We tested for up to four turning points using Joinpoint Regression Program version 4.5.0.1 (Statistical Research and Applications Branch, National Cancer Institute, Bethesda, Md). Turning points found in the general VCF trend line were compared with relevant guidelines, regulations, and publication of landmark evidence. The effect of these turning points was tested on subgroup VCF trends with a Poisson regression. These interventions were used to divide the study period into intervals across which differences in the population of patients receiving VCF were compared (Supplementary Table II, online only). The Rao-Scott χ^2 test was used for categorical variables and the *t*-test for continuous variables. Factors associated with VCF insertion and prophylactic VCF insertion were assessed with multivariable logistic regression controlling for 42 covariates including the patient's demographics and comorbidities, concurrent surgery type, hospital volume, teaching status, location, region, and year of hospitalization (a complete list of covariates is presented in Supplementary Table III, online only).[18] All statistical analysis was conducted using SAS 9.4 software (SAS Institute Inc, Cary, NC). $P < .05$ (two sided) was considered statistically significant.

RESULTS

Trends in hospitalizations with VTE diagnoses. The trend of hospital PE incidence had only one natural turning point, found in the first quarter of 2009. PE incidence increased from 0.46% of all admissions at the start to 0.95% by the first quarter of 2009 (annual