

# Association of Inferior Vena Cava Filter Placement for Venous Thromboembolic Disease and a Contraindication to Anticoagulation With 30-Day Mortality

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# Disclosures

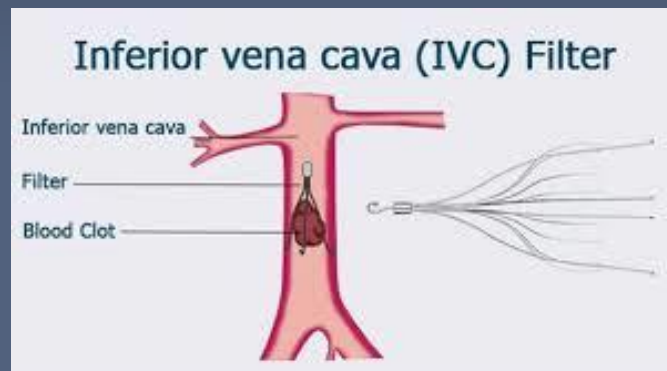
- None

# Background

- Venous thromboembolism (VTE) is the third most common vascular disease after MI and stroke, with ~1 million patients diagnosed with fatal or nonfatal PE annually in the United States and Europe combined.
- IVC filters first received approval by the US FDA in 1976, the year the FDA was assigned by Congress to regulate medical devices.
- IVC filters were approved as class II devices by the FDA, a class of devices that are deemed generally safe, and were approved without the acquisition of data on safety or efficacy.

# Current IVC Filter Use

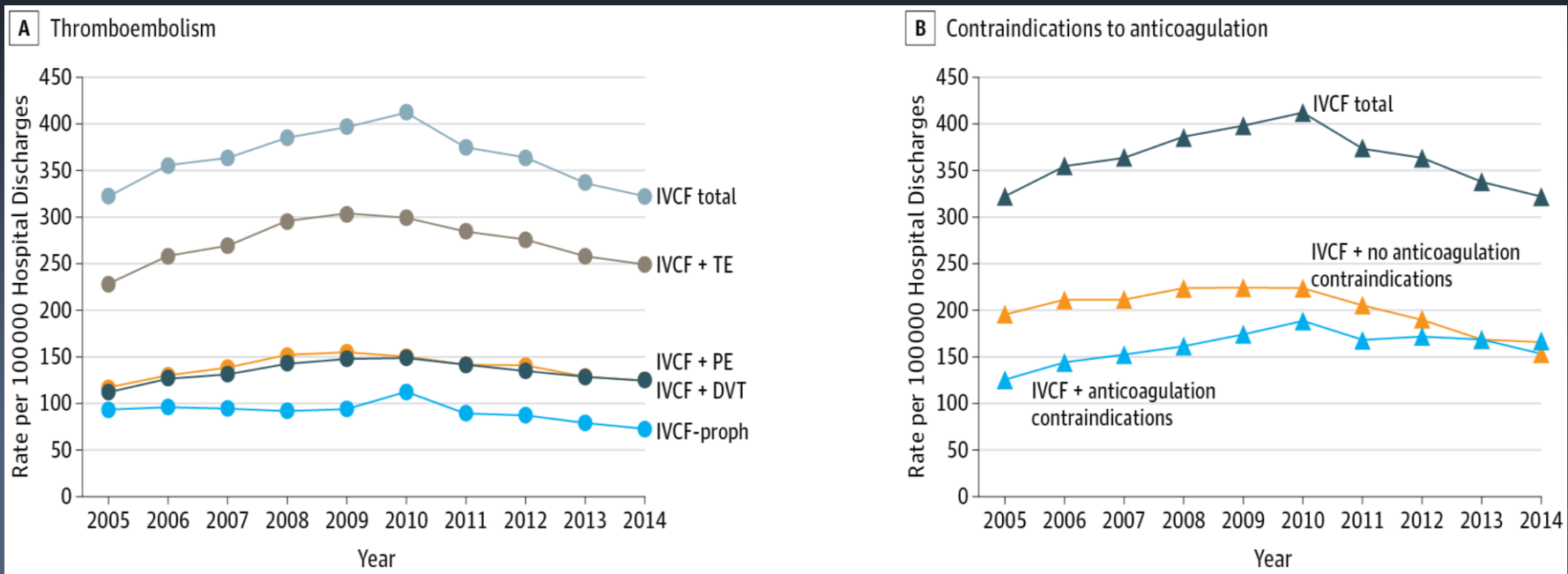
- High-risk patients with PE/DVT
- Patients with PE/DVT and a contraindication to anticoagulation
- Patients without a PE/DVT but with an elevated risk of developing them during a period when they may not be able to receive anticoagulation (prophylaxis)



# U.S. Trends in IVC Filter Placement: 2005-2014

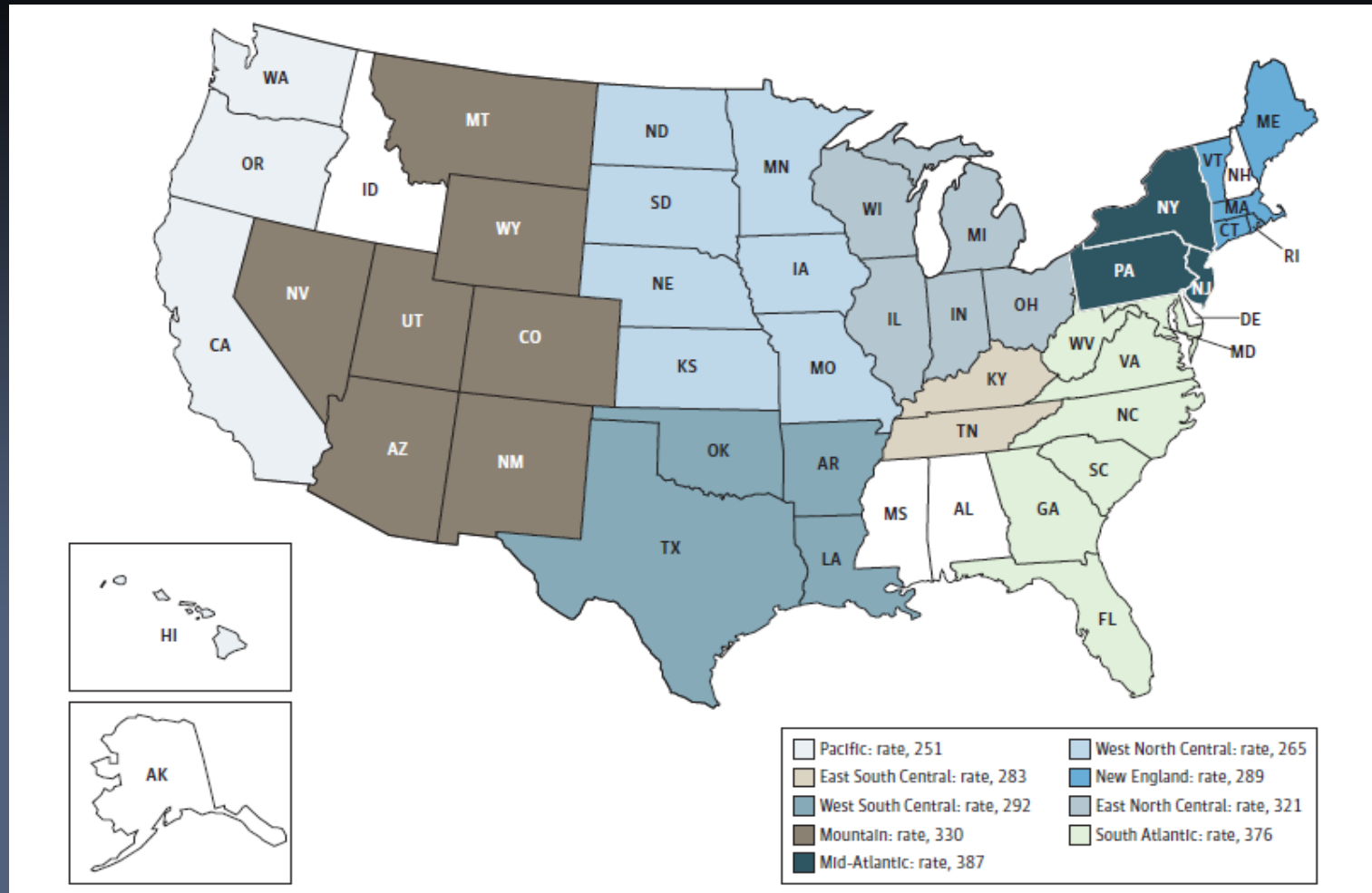
118,000

96,000



JAMA Internal Medicine 2018; 177(12), 1861-1862.

# Geographic Variation in Rates of IVC Filter Placement-2013 (per 100,000 hospital discharges)



JAMA Internal Medicine 2018; 177(12), 1861-1862.

# Evidence Base

Indication	Number of RCTs
No contraindication to anticoagulation	2
Contraindication to anticoagulation	0
Prophylaxis	0

Prevention du Risque d'Embolie Pulmonaire par Interruption Cave (PREPIC) trial, a 1998 study of 400 patients with proximal DVT randomized to receive anticoagulation with or without IVC filters, demonstrated reduced rates of PE at the cost of increased rates of recurrent deep vein thrombosis, without a difference in mortality at 2- or 8-year follow-up.

PREPIC II (2015) did not show a mortality reduction in patients with PE who received a retrievable IVC filter in addition to anticoagulation compared with patients who received anticoagulation alone. The rate of recurrent PE, the study's primary end point, was numerically higher in the group that received IVC filters.

# Society Recommendations for IVC Filter Placement

**Table 1: Potential Indications for Inferior Vena Cava Filter Insertion**

Indication*	Societies that Support this Indication	Societies that Oppose this Indication	Comments
Acute VTE and inability to anticoagulate	ACCP, <sup>7</sup> AHA, <sup>8</sup> SIR, <sup>9,10</sup> ACR <sup>11</sup>	-	-
Anticoagulation failure	AHA, SIR, ACR	-	-
Hemodynamically unstable patients, as an adjunct to anticoagulation	ACCP, SIR, AHA, ACR	-	The intent is to prevent further hemodynamic decompensation
Massive PE treated with thrombolysis or thrombectomy or during thromboendarterectomy	ACCP, SIR, ACR	AHA	-
Prophylaxis in high-risk populations	SIR, ACR	ACCP	Examples of high-risk populations include multi-trauma and spinal cord injury
Mobile thrombus	SIR, ACR	-	-
Iliocaval DVT	SIR, ACR	-	-



# Methods

- Data Source: State Inpatient Databases from CA, FL, NY
- Study Population: Adults with DVT or PE with contraindications to anticoagulation based on ICD-9 codes
- Exposure: IVC filter placement
- Endpoint: 30-day mortality
- Statistical Analysis:
  - Cox proportional hazards model with IVC filter status as a time-dependent variable to adjust for **immortal time bias**-the time before an intervention is performed where all deaths are assigned to the control group.

# Study Population

**132 355** Participants aged  $\geq 18$  y; no missing person identifier; hospitalization with *ICD-9-CM* diagnosis code for PE, DVT, or both; contraindication to anticoagulation; in California (2006-2010), Florida (2006-2012), or New York (2006-2011)

**6325** Excluded

- 599** Hospitalization in prior y with IVC filter
- 41** Missing sex
- 4942** Residence outside the hospital state
- 649** Index hospitalization  $>6$  mo
- 94** Incomplete IVC filter date and time variable

**126 030** Study population

# Selected Patient Characteristics

Characteristics	No. (%)		
	Overall (n = 126 030)	No IVC Filter (n = 80 259)	IVC Filter (n = 45 771)
Male	61 281 (48.6)	38 673 (48.2)	22 608 (49.4)
Age at admission, mean (SD), y	66.9 (16.6)	65.7 (17.1)	69.1 (15.6)
Thromboembolism			
PE and DVT	19 271 (15.3)	9263 (11.5)	10 008 (21.9)
PE only	42 398 (33.6)	32 447 (40.4)	9951 (21.7)
DVT only	64 361 (51.1)	38 549 (48.0)	25 812 (56.4)
Intracranial bleeding	9691 (7.7)	3574 (4.5)	6117 (13.4)
Other major bleeding	71 455 (56.7)	43 216 (53.8)	28 239 (61.7)
Thrombocytopenia	37 624 (29.9)	25 743 (32.1)	11 881 (26.0)
Cranial surgery	5124 (4.1)	1723 (2.1)	3401 (7.4)
Spinal surgery	6331 (5.0)	3651 (4.5)	2680 (5.9)
Metastatic cancer	17 018 (13.5)	9777 (12.2)	7241 (15.8)
Solid tumor without metastasis	24 647 (19.6)	14 035 (17.5)	10 612 (23.2)

# Results: 30-Day Mortality

- When evaluated in a multivariable Cox model with IVC filter placement analyzed as a time-dependent variable to account for immortal time bias, IVC filter placement was associated with an increased hazard ratio of mortality (1.18; 95%CI, 1.13-1.22;  $P < .001$ ).

# One-Year Mortality- Effect of Adjustment for Immortal Time Bias

<b>Cox Proportional Hazards Model</b>						
	Time-fixed analysis			Time-dependent analysis		
	HR	95% CI	P value	HR	95% CI	P value
<b>Death</b>	0.882	0.859- 0.905	<.001	1.216	1.185-1.249	<.001
<b>Propensity Score Matching Model</b>						
	After PS matching			After PS matching adjusted for immortal time bias		
<b>Death</b>	0.875	0.851- 0.901	<.001	1.051	0.019-1.083	0.002

# Conclusion

- After adjustment for immortal time bias and other differences in baseline characteristics, IVC filter placement *was associated with an increased hazard of 30-day mortality.*

# Limitations

- Observational study-hypothesis generating only!
- Administrative data is lacking in granularity
- Coding is designed for billing rather than clinical phenotyping
- Out-of-hospital and out-of-state deaths not captured
- Cause of death is unknown
- Contraindications to anticoagulation were assumed and not verified
- No information on retrievable IVC filters

# Bottom Line

- IVC filters are not parachutes
- There is no high-quality data supporting their efficacy in patients with a contraindication to anticoagulation
- Randomized controlled trials are desperately needed





# Thank You