Inferior Vena Cava Filters:
A Love /Hate (Mostly Hate) Relationship

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The Problem of the “Con-Position”
I am NOT:
• Against New Ideas
• Against New Therapies
• Against Endovascular Therapies

Disclosures
Lack of Political Correctness

Non Thinking!
Mistaken thinking
Wishful Thinking

“Lemming” Behavior
Misuse of the Bully Pulpit
Why Filters: PE Happens

• About 200,000 deaths/year secondary to PE
Many are perhaps preventable

IVC Filters and Bariatric Surgery

• Bariatric Outcomes Longitudinal Database
• 73,921 subjects
• Mandated clinical pathways to prevent VTE
• Risk VTE in 90 days: 0.42%
• 626 patients with IVC filters
  -increased risk of VTE with IVC filter
  -hazard ratio 7.66, 95% CI 4.55-12.91


Trauma Prophylaxis

• Eastern Association for Surgery for Trauma (EAST):
  -High risk injuries precluding thromboprophylactic Rx
  -Level 3 recommendation

• Michigan Trauma Registry*
  -803 prophylactic IVC filters in 39,456 patients (2%)
  -Hospital variation (0.6 TO 9.6%) in filter use.
  -No variation in mortality by quartile use of filters.
  -Increased DVT with prophylactic filter (OR 1.83; 95% CI 1.15 – 2.93)

*Ann Surg 2015; 262: 577-85

Filters for Prophylaxis

• American College Chest Physicians (ACCP)
  -"We do not recommend the use of an IVC filter as thromboprophylaxis, even in patients at high risk for VTE."
IVC Filters

(Increasing Utilization)

- 1979: 2000 filters
- By 1990: >120,000 Greenfield filters had been placed
- 2000: 50,000/yr
- 2009: >130,000/yr

Complications Vena Cava Filters

- Misplacement
- Thrombosis
- Migration
- Fracture
- Penetration
- Ineffective
  - mortality
  - PE prevention
- Inducing VTE

Misplaced filter secondary to Renal Vein Variant

Right Hepatic Vein Filter
Deployment Errors

Intracardiac Filter: Premature unsheathing led to ensnarement in the right atrium

Thrombosis: IVC Filter / Vena Cava / Iliac Veins

IVC Filters

• 29 year old male with a perforated duodenum from an IVC filter.
• 4 unit drop in Hematocrit
• Infected, disrupted infrarenal aorta discovered at exploration.
• Treated with rifampin soaked Dacron aortic interposition graft

IVC Filters

(FDA Warning: Posted August 9, 2010)
• Since 2005 there were 921 adverse event reports:
  - 328 migrations
  - 146 embolizations of device components
  - 70 IVC perforations
  - 56 filter fractures
IVC Filters
(Mobin Uddin Filter)
• First IVC filter
• Developed in late 1960s
• Initial favorable reports
• Late reports:
  -50% IVC occlusion rate
  -High rate of PE
  -Migration

(Volvic Greenfield Filter)
• Introduced in 1973
• 1981 report:
  -156 patients
  -119 patients followed
  -3% PE rate
  -5% IVC occlusion
  -No migration

(Kimray-Greenfield Filter: 1988 report)
• 469 patients
• 146 long-term follow-up (mean 43 months)
• 190 lost to follow-up
• 133 died (33%)
• 4% PE rate (17 fatal, 9 nonfatal)
• 4% IVC occlusion
• 44% with post thrombotic syndrome

*Arch Surg 1981; 116: 1451-1456
*Surgery 1988; 104: 706-712
### IVC Filters

*(Kimray-Greenfield Filter: 1988 report*)

- Served as evidence for efficacy of IVC filters
- Likely would not be sufficient evidence by modern standards:
  - Half the patients lost by either death or LTFU
  - No control group
  - No follow-up imaging

*Surgery 1988; 104: 706-712

### IVC Filters

*(Literature)*

- More than 600 reports
- Virtually all retrospective analysis of single institution case-series
- Only ONE randomized, controlled trial

### IVC Filters

*(PREPIC Study: Prevention du Risque d'Pulmonarie par Interruption Cave)*

- Published in 1988
- 400 consecutive patients with acute proximal DVT with or without PE
- Considered ‘high-risk’ by their physicians

### IVC Filters

*(PREPIC Study)*

- One of two types of anticoagulation
- With or without addition of a vena cava filter
IVC Filters (PREPIC Study: Two-year Results)

- No mortality difference with or without filter
- Filter patients: 10% higher DVT rate (95% CI, 11.6% to 20.8%)
- Nonstatistically significant reduction in PE, p=0.16

IVC Filters (PREPIC Study: Eight-year Results)

- ↓ in symptomatic PE in the filter group
  -6.2% vs. 15.2% (p =0.008)
- ↑ in DVT in the filter group
  -35.7% vs. 27.5% (p= 0.04)
- No difference in mortality

IVC Filters (PREPIC Study: How was PE determined?)

- Annual phone calls:
  - Questioned for symptoms suggestive of VTE
  - Imaging recommended based on answers
- Therefore not just symptoms drove patients to hospital
- Is discovering a condition evident only on probing a valid patient-centered outcome?

IVC Filters (PREPIC Study: What Has Happened)

- Weak findings of the PREPIC study and no other randomized trials has permitted great variation in the use of filters.
  - Guidelines
  - "Judgment"
  - Financial motivation
  - Industry
**PREPIC2 Study**

- Randomized trial of retrievable IVC filters with anticoagulation vs anticoagulation alone.
- Acute symptomatic PE with leg DVT and RV dysfunction and/or pulmonary hypertension
- Filter + AC group, n=200
- AC only, N=199
- 193 filters with 153/164 retrievals
- Filter + AC group: Recurrent PE in 6 (3%, all fatal)
- AC only: Recurrent PE in 3 (1.5%, 2 fatal)

*JAMA 2015; 313:1627-635*

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**IVC Filters**

*(Guidelines)*

- American college of Chest Physicians
- American Heart Association
- British Committee for Standards in Hematology
- Thrombosis Interest Group of Canada

Only consensus is placement in patients with VTE and a contraindication to anticoagulation!

**IVC Filters**

*(Guidelines: No Consensus)*

- VTE despite anticoagulation
- Patients with recent VTE who must have anticoagulation held for surgery
- Patients with proximal DVT and poor cardiac reserve
- Patients with free-floating DVT
- Primary prevention in high-risk patients

**IVC Filters**

*(How Did We Get Where we Are?)*

- Benefits: Difficult to prove
- Complications: Are now obvious:
  - Bird’s Nest: 0.34% procedural deaths
  - VenaTech: 22% IVC occlusion at 5 years
  - Bard Retrieval: 16% risk stent fracture
  - Overall 19% cava vena penetration rate*

*Circulation 2015; 132:944-952*
IVC Filters
(How Did We Get Where we Are?)

- U.S. Food and Drug Administration (FDA) approval process for vena cava filters:
  - all filters approved through the 510 (k) process for devices
  - **NOT** based on safety
  - **NOT** based on efficacy
  - Based on similarity to an existing product

IVC Filters
Conclusions: Why I dislike IVC Filters

- It is unclear why IVC filters were ever approved.
- There is no consensus on the use of IVC filters.
- There is no proof IVC filters save lives or are even remotely cost effective.
- There is clear evidence IVC filters can cause harm.

Questions?
Columbia River, Oregon
IVC Filters

(FDA MedWatch Safety information and Adverse Event Reporting Program)

• On line:  [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

• Phone: 1-800-332-1088 to request form

• Fax: 1-800-FDA-0178