IVC Filter Complications

EDWARD J AROUS, MD MPH
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
DISCLOSURE

• I have no conflict of interest in relation to this presentation.
Understand the limitations of current literature on the role of IVC filters.

Understand complications associated with vena cava filters.

Appreciate methods employed to remove embedded filters and efforts to improve timely filter retrieval.
PULMONARY EMBOLISM

- Venous Thromboembolism (VTE) is estimated to affect 1:1000.
- Approximately 600,000 cases of PE in the US annually, believed to contribute to 200,000 deaths.
- For most situations, VTE is effectively managed with anticoagulation.
ANTICOAGULATION

- First line treatment for VTE
- Associated with decreased risk of recurrence of DVT and PE, and reduced mortality

- In scenarios where anticoagulation is ineffective, contraindicated, or results in bleeding complications, then vena cava interruption is recommended.
NORMAL VENOUS ANATOMY

- External jugular vein
- Subclavian vein
- Brachiocephalic vein
- Internal jugular vein
- Superior vena cava
- Hepatic veins
- Right renal vein
- Testicular or ovarian vein
- Median sacral vein
- Suprarenal vein
- Left renal vein
- Inferior vena cava
- Common iliac vein
- Internal iliac vein
- External iliac vein
- Saphenous vein
- Deep femoral vein
- Femoral vein
ABNORMAL VENOUS ANATOMY

• IVC Transposition (0.2-0.5%)
  – Left-sided IVC drains into the left renal vein
  – Then crosses to the right and continues cephalad in the normal, right-sided, position
  – Still a candidate for IVC filter (although, may consider suprarenal position for more accurate positioning)
ABNORMAL VENOUS ANATOMY

- **IVC Duplication (0.2%)**
  - Duplicated IVC
  - Right-sided IVC drains right iliac and right renal veins
  - Left-sided IVC (typically smaller) drains left iliac and left renal veins. Then crosses over into the right-sided vena cava.

- Requires filter placement in each vena cava, or in the suprarenal vena cava.
ABNORMAL VENOUS ANATOMY

- IVC Agenesis (0.0005-0.1%)
  - Absence of the infrarenal segment of the IVC

- Filter placement in an enlarged azygos vein has been described.
VENA CAVA INTERRUPTION

- 1784: Ligation of the Femoral Vein
- 1846: Rudolf Virchow proposed pulmonary emboli originated from lower extremity thrombosis
- 1868: Armand Trousseau proposed creating physical barrier preventing migration of emboli from LEs to pulmonary circulation
- 1893: Ligation of the IVC to prevent PE
- Multiple other attempts at interrupting the femoral vein and IVC
  - Partial interruption with plastic clips, plication, or staplers
HISTORY OF IVC FILTERS

- 1846: Rudolf Virchow proposed pulmonary emboli originated from lower extremity thrombosis
- 1934: John Homans standardized femoral vein ligation for prevention of PE in context of DVT
- 1943-1945: Oscner, DeBakey and O’Neil proximalized ligation to level of IVC
HISTORY OF IVC FILTERS

• Series of attempts at IVC filtration:
  – Harp-string grid filter
  – IVC plication using sutures/staples
  – Serrated/channeled clips to external IVC wall

• 1967: Mobin-Uddin umbrella filter: Silastic membrane attached to six stainless-steel spokes anchored in the vena cava
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MOBIN-UDDIN UMBRELLA FILTER

• 1967 – First procedure for transvenous “partition” of the IVC no longer requiring general anesthetic using Mobin-Uddin IVC umbrella

• Silastic Membrane with a hole to allow continuous blood flow

• Associated with high rate of IVC thrombosis → Discontinued
IVC FILTER PLACEMENT
TECHNICAL ASPECTS

• Methods of Insertion
  - IVUS
  - Fluoroscopy

• Jugular vs. Femoral Insertion

• Permanent vs. Retrievable
So How is a Filter Placed?

1. Common femoral or internal jugular vein access, sheath is inserted and venogram is performed. Consider IVUS.
2. Guidewire is advanced beyond the renal veins.
3. IVC filter is deployed between the IVC bifurcation and lowest renal vein (most often right renal vein).
US guided venous access, introduction of J wire and 7 or 8.5 Fr sheath by Seldinger technique

Vena cavagram to outline L and R renal veins, assess IVC
Delivery of filter to infrarenal IVC

Unsheathing of filter

Unhooking of filter

Sheath pulled back releasing the legs of the filter but filter still not unhooked.

Filter unhooked.
Inferior vena caval filter models


## Types of inferior vena cava filters

<table>
<thead>
<tr>
<th></th>
<th>Maximum IVC diameter (mm)</th>
<th>Manufacturer</th>
<th>Required sheath size</th>
<th>Insertion sites</th>
<th>Material</th>
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<tr>
<td><strong>Non-retrievable</strong></td>
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<tr>
<td>Titanium Greenfield</td>
<td>28</td>
<td>Boston Scientific</td>
<td>12F</td>
<td>Jugular, femoral</td>
<td>Titanium</td>
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<td>Boston Scientific</td>
<td>12F</td>
<td>Jugular, femoral</td>
<td>316 stainless steel</td>
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<td>Vena Tech LP</td>
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<td>B. Braun Medical</td>
<td>9F</td>
<td>Jugular, femoral</td>
<td>Phynox*</td>
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<td>B. Braun Medical</td>
<td>12F</td>
<td>Jugular/femoral single system</td>
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<td>Bard</td>
<td>9F</td>
<td>Jugular, femoral, subclavian, antecubital</td>
<td>Nitinol (Ni-Ti)</td>
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<tr>
<td>TrapEase</td>
<td>30</td>
<td>Cordis (J&amp;J)</td>
<td>6F</td>
<td>Jugular, femoral, antecubital</td>
<td>Eligloy*</td>
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<td>Cook</td>
<td>12F</td>
<td>Jugular, femoral</td>
<td>304 stainless steel</td>
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<td><strong>Retractable</strong></td>
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<td>G2X with RECOVERY Cone</td>
<td>28</td>
<td>Bard</td>
<td>7F</td>
<td>Jugular, subclavian, femoral</td>
<td>Nitinol (Ni-Ti)</td>
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<td>OptEase</td>
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<td>6F</td>
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<td>Gunther tulip</td>
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<td>Cook</td>
<td>8.5F</td>
<td>Jugular, femoral</td>
<td>Conichrome*</td>
</tr>
<tr>
<td>Cook Celect</td>
<td>30</td>
<td>Cook</td>
<td>7F (II), 8.5F (F)</td>
<td>Jugular, femoral, Uniset</td>
<td>Conichrome*</td>
</tr>
<tr>
<td>Option</td>
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<td>6.5F</td>
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<td>Nitinol (Ni-Ti)</td>
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<td>ALN International</td>
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Data from:
STATE OF THE EVIDENCE

First randomized trial published in 1973*

100 patients with femur fractures and no DVT
   41 received prophylactic filters (pyelographic guidance)
   59 control group

PE 10% vs 32%
   Diagnosed on chest x-ray

Mortality 10% vs 24%

STATE OF THE EVIDENCE

PREPIC*
(Prevention du Risque d'Embolie Pulmonaire par Interruption Cave)

Benefits and risks of prophylactic filter placement in addition to anticoagulation (AC) in patients with proximal DVT who were considered high risk for PE.

- Randomized 400 patients to permanent filter/no filter and LMWH/UFH.

*Initial beneficial effect of vena cava filters at 12 days (1.1% vs 4.8%), counterbalanced by excess of recurrent DVT at 2 years (20.8% vs 11.6%).
  - Filter thrombosis rate was 8.9%.
  - Mortality was not changed.

STATE OF THE EVIDENCE

At 8 year follow-up, the risk of pulmonary embolism remained reduced, but that of DVT increased, with no change in survival.*

Associated with filter thrombosis in 46% (26/57).

Systematic use of permanent filters in patients with proximal DVT cannot be recommended

*The PREPIC Study Group. Eight year follow-up of patients with permanent vena cava filers in the prevention of pulmonary embolism. Circulation 2005;112:416-422
PREPIC-2*

Efficacy and safety of retrievable vena cava filter placement in addition to AC compared to AC alone for prevention of PE recurrence in patients with PE and high risk of recurrence.

- Randomized 399 patients (2006-2012).
- Filter removal mandated at 3 months.

No benefit observed in terms of PE recurrence or mortality.

*Effect of a retrievable inferior vena cava filter plus anticoagulation vs anticoagulation alone on risk of recurrent pulmonary embolism. A randomized clinic trial. JAMA, 2015;313(16):1627-1635.
CRITICISM OF PREPIC TRIALS

Designed to study filters in addition to anticoagulation, not as second line therapy in those not candidates for anticoagulation.

DVT rates masked by large proportion of patients who were continued on anticoagulation at 2 years.
CLINICAL INDICATIONS FOR IVC FILTERS

- Systemic anticoagulation is the therapy of choice for venous thromboembolism
- Without anticoagulation, the risk of PE is high, and potentially fatal in as many as 25% of patients
  - Consider vena cava filter in these patients
  - Resume anticoagulation as soon as possible
CLINICAL INDICATIONS FOR IVC FILTERS

Evidence-Based Guidelines:

• Documented VTE with contraindications to anticoagulation
• Documented VTE with complications of anticoagulation
• Recurrent VTE despite therapeutic anticoagulation
CONTRAINDICATIONS TO ANTICOAGULATION

- Need for major surgery
- Intracranial hemorrhage
- Pelvic/retroperitoneal hematoma
- Ocular injury
- Solid intra-abdominal organ injury
- Uncorrected coagulopathy/coagulation disorder
- Peptic ulcer disease
PROPHYLACTIC FILTERS

Uncertainty in determining true contraindication to anticoagulation

Historical bias against use of chemoprophylaxis due to concern for increased perioperative bleeding risk
  - Are these risks overstated?
  No increase in ICH in brain injury patients placed on pharmacologic prophylaxis*

CLINICAL INDICATIONS FOR IVC FILTERS

Relative Expanded Indications:

- Poor compliance with anticoagulation
- Free-floating iliocaval thrombus
- Renal cell carcinoma with renal vein extension
- Venous thrombolysis
- Documented VTE with limited cardiopulmonary reserve
- Recurrent PE complicated by pulmonary hypertension
- Documented VTE in cancer or burn patient
- VTE prophylaxis in high-risk surgical, medical, or trauma patient
Contraindications to IVC Filter Placement:

- Chronically occluded vena cava
- Vena caval anomalies
- Inability to access the vena cava
- Vena cava compression
GREENFIELD IVC FILTER

• Prevents PE while:
  (1) Maintaining caval patency
**GREENFIELD IVC FILTER**

- Prevents PE while:
  1. Maintaining caval patency
  2. Prevents LE venous stasis
GREENFIELD IVC FILTER

• Prevents PE while:
  – Maintaining caval patency
  – Facilitates lysis of embolic thrombus within the filter
GREENFIELD IVC FILTER

- Greenfield Filter Registry (20-year review)
  - 4% recurrent pulmonary embolism rate
  - 95% caval patency rate
GREENFIELD FILTER DESIGN

Design Goals:

- High filtering efficiency without impediment to flow
- Single trapping level and conical design providing highest filtering:flow volume ratio

![Graph showing cross-sectional area blocked vs depth of filter filled]
GREENFIELD FILTER DESIGN

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IVC Filter

• Original transvenous filters were placed in the operating room through open jugular vein access.
  – Original Greenfield Filter

• Newer technologies facilitate percutaneous approach
**TYPES OF IVC FILTERS**

1. **Permanent filter**: designed for intentional permanent lifelong filtration. Designed to maximize fixation *(FDA approved)*

2. **Temporary filter**: No means of fixation to IVC wall, tethered to wire/catheter protruding through skin. *(not approved)*

3. **Convertible filter**: Can be altered to non-filtration form by removal of filter portion in staged fashion. *(not approved)*

4. **Optional/Retrievable filter**: Similar to permanent filter with additional removal capacity using image-guided techniques within device-specific time interval. *(FDA approved)*
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EXAMPLES OF FDA-APPROVED IVC FILTERS

A Boston Scientific Greenfield Filter
B Cook Medical Bird’s Nest Filter
C Vena Tech LP Filter
D Bard Simon Nitinol Filter
E Bard Recovery G2 Filter
F Cook Medical Günther Tulip Filter
G Cook Celect Filter
H Cordis OPTEASE Filter
I Argon Option Elite Filter
J Crux VCF
K ALN Optional Filter

Many other IVC filters on the market. Including multiple types from a single manufacturer.
Retrievable Filters

- Began to appear on the market in the 1990s.
- Specifically designed to have a less secure implantation in order to facilitate retrieval
RETRIEVABLE FILTERS

• In 1999, the FDA downgraded the risk of IVC filters from class III to class II, thereby permitting manufacturers to achieve market approval more readily under the assumption that new filters are substantially equivalent to other legally marketed devices.

• Allowing retrievable filters to be marketed as ‘permanent filters with an option for retrieval’
  • Inaccurately reflects the discrepancy in design
FDA APPROVAL

• As a consequence, a number of retrievable IVC filters were submitted to the FDA and approved as permanent filters with an option for retrieval.

• Since then, there are have been multiple reports demonstrating significant complications:
  – Vena caval penetration
  – Filter embolization
  – Recurrent VTE
  – Caval thrombosis
Assumption: retrievable devices offer advantage of short term protection and obviating long term retention of a foreign body.

Threshold for filter placement plummeted despite evidence that these filters are infrequently removed.

250,000 filters were placed in the United States (2012)
- 1300 fold increase in 30 years.
- 25 times the number placed in five European countries with comparable population size.
- Fatal VTE were similar in the USA and Europe.
• In 2010, the FDA disclosed that retrievable IVC filters had been associated with more than 900 adverse events.
TIMING OF RETRIEVAL

- FDA Quantitative Decision Analysis: risk-benefit cross-point favored removal between 29-54 days after implantation.

RETRIEVABLE IVC FILTERS

• Indications: No randomized data comparing permanent vs. retrievable IVC filters. Current data inadequate to develop set of clear indications
  – Decision thus based on intent to discontinue filtration:
    • How long VTE protection required versus risk of initiating AC therapy?
• Retrieval Timing: the longer the filter in place, the harder the retrieval
  – 99% successful retrieval at 1 month, 37% success at 1 year
**Retrievable IVC Filters**

- **General Indications for Retrievable Filters:**
  1. No present/expected indication for permanent filter
  2. Risk of clinically significant PE is low
  3. Return to high-risk VTE is not anticipated
  4. Life expectancy long enough to benefit from filter removal
  5. Filter removed safely
COMPLICATIONS: PERMANENT VS RETRIEVABLE FILTERS

- Unlike retrievable IVC filters, the safety and efficacy of permanent Greenfield filters is well established.
- Long-term patency of >3,000 consecutive patients is 98%.

RETRIEVABLE FILTERS

- Risks of temporary IVC Filters have been recently discussed among mainstream media.
- >9,000 lawsuits allege that various types of filters have perforated or fractured
  - C.R. Bard & Cook Medical face the largest number of cases (~4,000 each).
RETRIEVABLE FILTERS

• Single-institution review of patients with a Bard Recovery filter by non-contrast CT revealed 21% incidence of filter arm fracture or migration.

• Increased incidence of limb perforation of the vena cava over time.

RETRIEVABLE FILTERS

- The risk of temporary IVC filter complications is linearly related to the duration of time on the market.

COMPLICATIONS OF RETRIEVEABLE FILTERS

• 44-year retrospective review of 9002 patients with 15 types of filters demonstrated 19% incidence of caval penetration.
• Not limited to 1 filter manufacturer
• 50 Gunther Tulip and 27 Celect filters had an 86% caval perforation of at least one filter component on CT scan.¹
• Smaller IVC filter diameters and longer indwell times have higher rates of IVC penetration, regardless of the manufacturer.²

TECHNICAL CONSIDERATIONS DURING RETRIEVAL

• Venocavagram to screen for retrieval-related problems:
  – Filter thrombus
  – Strut integrity

• Access site for retrieval dependent on filter specifications
  – Trans-femoral
  – Trans-jugular
  – Bi-directional

• Abort retrieval if filter fails to release from IVC with “modest” tension

• Fall-back techniques: balloon angioplasty hooks from IVC, bronchoscopic forceps to directly grasp filter hooks, etc.
HOW OFTEN ARE FILTERS RETRIEVED

• Little evidence exists to show that temporary IVC filters are being retrieved routinely.

• Single-center reviews have reported a 90.6% success rate\(^1\), but this is not achieved uniformly.

• Systematic review found an average retrieval rate of 34%.\(^2\)

Overall risk of complications with IVC filter placement is 5-10%.

Access-site Related:
  - Minor wound hematoma secondary to rapid resumption of anticoagulation therapy
  - Access site thrombosis (10% frequency in common femoral vein)
  - Rates similar to those for central venous catheterizations
COMPLICATIONS OF IVC FILTER PLACEMENT - EARLY

- Filter Misplacement (frequency 4% with use of guidewire)
COMPICATIONS OF IVC FILTER PLACEMENT - EARLY

- Filter Misplacement (frequency 4% with use of guidewire)
COMPLICATIONS OF IVC FILTER PLACEMENT - LATE

- Filter Tilt
COMPlications of IVC Filter Placement - LATE

- Filter Tilt
COMPPLICATIONS OF IVC FILTER PLACEMENT - LATE

- Filter fracture → embolization of foreign body
  - Retrievable filters should be removed as soon as possible
COMPLICATIONS OF IVC FILTER PLACEMENT - LATE

- Filter migration → embolization of foreign body
  - Retrievable filters should be removed as soon as possible
COMPLICATIONS OF IVC FILTER PLACEMENT - LATE

- Filter migration
COMPPLICATIONS OF IVC FILTER PLACEMENT - LATE

• Filter/IVC Thrombosis
  – Incidence is 10%, often asymptomatic due to collateral formation, may lead to post-thrombotic syndrome
COMPLICATIONS OF IVC FILTER PLACEMENT - LATE

Video courtesy Stephan Wicky van Doyer, MD FSIR
COMPPLICATIONS OF IVC FILTER PLACEMENT - LATE

• Caval penetration (often inconsequential)

• Potentially Lethal Complications (extremely rare):
  – Device migration into pulmonary artery
  – Device migration into right ventricle

• No need for retrieval unless patient develops an arrhythmia or tricuspid insufficiency
POST-IVC FILTER PULMONARY EMBOLISM

• Pulmonary embolism reported to occur 2% - 4% of IVC filter recipients
  – Source of thrombi outside filtered flow
    • Upper extremity
    • Right atrium
  – If occurs, obtain fluoroscopic venogram to screen for thrombus adhered to filter
    • If positive for small thrombus: thrombolytic therapy
    • If positive for large thrombus: tandem filter deployment in suprarenal IVC
• Retrospective review of IVC filter use in 978 pts at BU and BMC

• 679 retrievable IVCFs placed
  - 58 (8.5%) retrieved
  - 18.3% of attempts unsuccessful

• 74 (7.8%) had VTE with filter in place (25 PEs)
  - 89.4% in pts not anticoagulated

• Many filters inserted after period of highest bleeding risk

• 237 (24.9%) of patients d/c’d on anticoagulation
FILTER RETRIEVAL

Only 8.5% retrieved

Figure 3. Number of days until attempted retrieval among successfully removed inferior vena cava filters. The middle line indicates the median of 122 days. The dots are scattered upward so that they do not overlap.

18.3% failed retrievals
- Filter embedded in IVC – n=8
- Protrusion through blood vessel – n=3
- Abnormal position – n=2
- Thrombus within filter – n=1
Cost-effectiveness of prophylactic (EAST 2002) vs. therapeutic (ACCP 2008) IVCF in very-high-risk trauma patients

Emily L. Spangler, MD, a Ellen D. Dillavou, MD, b and Kenneth J. Smith, MD, c Pittsburgh, Pa
(J Vasc Surg 2010;52:1537-45.)

- Cost-effectiveness of prophylactic (EAST 2002) vs. therapeutic (ACCP 2008) IVCF in very-high-risk trauma patients
- Hypothetical cohort: 46yo trauma pt, meeting EAST definition of high-risk
- Used base case and sensitivity analysis to determine cost-effectiveness
- Prophylactic IVCF more costly and less effective than therapeutic
MEDICO-LEGAL IMPLICATIONS
MEDICO-LEGAL IMPLICATIONS

National public interest increased significantly
10,000 Google searches in 2015.

Allegation: “defective design, misrepresentation in marketing, and failure to warn doctors and patients”

Details of settlements in individual suits has not been made public.*

MEDICO-LEGAL IMPLICATIONS

- Geographical variation in filter placement.
- Filter use greatest in the Northeast and lowest in the West.
- Implantation is directly related to number of paid malpractice insurance claims and annual liability premiums, and lowest where population is least insured*.

WHERE DO WE GO FROM HERE?

Establishment of Dedicated IVC Filter clinic

- Address loss to follow up

- Transfer responsibility of filter retrieval away from referring physicians and patients to the interventionist.

- Coordinated care results in improved retrieval rates*.

- No difference in retrieval success rate (97% vs 94%) when comparing IVC filters that were in place for less versus more than 6 months^.

- $$: Use of optional filters is financially advantageous only if 41% of the filters are removed&.

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* Minocha J et al. Improving inferior vena cava filter retrieval rates: impact of a dedicated inferior vena cava filter clinic


WHERE DO WE GO FROM HERE?

Define Who Would Benefit From Filter Placement/Retrieval

Many patients labeled as contraindication to anticoagulation are anticoagulated shortly after filter placement, questioning utility.

Predicting the Safety and Effectiveness of Inferior Vena Cava Filters (PRESERVE)
- Jointly sponsored by SIR and SVS
PRESERVE Trial

• Multicenter non-randomized open label study to determine the safety and effectiveness of commercially available IVC filters (both temporary and permanent) in individuals who require mechanical prophylaxis against PE.