IVC Filters: For Whom, Why and When?

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Disclosures:

- I have no financial conflicts to disclose.
- I do not endorse any specific product or manufacturer.
- I will be discussing some off-label use of medical devices that are otherwise FDA approved for use in the United States at the time of this presentation.
You must clearly explain your problem
Background:

- Venous Thromboembolic (VTE) disease incidence is estimated at 1 per 1000 population in the USA. (10)
- 300,000 new cases of VTE each year. (10)
- So far there has been no definitive evidence published to support the efficacy of or need for IVC filters in treating pulmonary embolism.
IVC Interruption History:

- 1865: Trousseau suggested that Caval interruption could prevent pulmonary embolism. (1)
- 1874: The first femoral vein ligation.
- 1893: The first surgical ligation of the IVC. (2)
- 1963: A plastic clip placed across the IVC during laparotomy. (3)
- 1967: Mobin-Uddin Umbrella, the first percutaneous IVC filter was developed. (4)
Inverted umbrella with six stainless-steel struts covered with a thin heparin-impregnated fenestrated silastic membrane.
Temporary IVC Filters:
IVC Interruption History:

- 1865: Trousseau suggested that Caval interruption could prevent pulmonary embolism. (1)
- 1893: The first surgical ligation of the IVC. (2)
- 1963: A plastic clip placed across the IVC during laparotomy. (3)
- 1967: Mobin-Uddin Umbrella, the first percutaneous IVC filter was developed. (4)
- 1973: Greenfield Filter was developed. (6)
  - Garman Kimmel applied a problem of sludge in pipelines.
Greenfield Filter:
IVC Interruption History:

- 2000: Günther Tulip Filter as the first FDA approved optional IVC filter.
Current IVC Filters (3/12):

- **Simon Nitinol Filter** (Bard Peripheral Vascular, Tempe, AZ, USA).
  - Permanent filter
  - Max IVC size 28mm
  - Introducer size 9F
  - The first nitinol filter FDA approved 1990
Current IVC Filters (3/12):

- **Vena Tech LGM** (B. Braun, Melsungen, Germany).
  - Permanent filter
  - Max IVC size 28mm
  - Introducer size 10F
  - Made out of Phynox (Conichrome)
  - FDA approved 1989
Current IVC Filters (3/12):

- **Vena Tech LP** (B. Braun, Melsungen, Germany).
  - Permanent filter
  - Max IVC size 28mm
  - Introducer size 7F
  - Made out of Phynox (Conichrome)
  - FDA approved 2001
Current IVC Filters (3/12):

- **Titanium Greenfield** (Boston Scientific, Natick, MA).
  - Permanent filter
  - Max IVC size 28mm
  - Introducer size 12F
  - Made out of Titanium
  - FDA approved 1989
  - Stainless steel Over-the-Wire version available since 1995
Current IVC Filters (3/12):

- **Gianturco-Roehm Bird’s Nest** (Cook Medical, Bloomington, IN).
  - Permanent filter
  - Max IVC size 40mm
  - Introducer size 12F
  - Made out of stainless steel
  - FDA approved 1982
Current IVC Filters (3/12):

- **TrapEase** (Cordis, Miami Lakes, FL)
  - Permanent filter
  - Max IVC size 30mm
  - Introducer size 6F
  - Made out of Nitinol
  - FDA approved 2000
Current IVC Filters (3/12):

- **Celect** (Cook Medical, Bloomington, IN)
  - Optional/Temporary filter
  - Max IVC size 30mm
  - Introducer size 7F
  - Made out of Conichrome
  - FDA approved: permanent 2007 and retrievable 2008
  - Retrieval: 95% at:
    - 179 days mean
    - 466 days longest
Current IVC Filters (3/12):

- **Günther Tulip** (Cook Medical, Bloomington, IN)
  - Optional/Temporary filter
  - Max IVC size 30mm
  - Introducer size 11F
  - Made out of Conichrome
  - FDA approved: permanent 2000 and retrievable 2003
  - Retrieval: 94% @ 12 weeks
Current IVC Filters (3/12):

- **G2 and Eclipse** (Bard Peripheral Vascular, Tempe, AZ)
  - Optional/Temporary filter; updated version of Recovery
  - Max IVC size 28mm
  - Introducer size 7F
  - Made out of Nitinol
  - FDA approved: permanent 2005 and retrievable 2008
  - Retrieval: 95% at:
    - 144 days mean
    - 300 days longest
  - Older version Recovery filter was pulled out of market in 2005 for fractures and migrations
Complications with Inferior Vena Cava filter?

- Fracture or Migration of the IVC Filter
- Perforation of Heart, Lung, or Vena Cava
- Hemmorage

Learn more about IVC filter complications and how we can protect your legal rights.
Current IVC Filters (3/12):

- **OptEase** (Cordis, Miami Lakes, FL)
  - Optional/temporary filter
  - Max IVC size 30mm
  - Introducer size 6F
  - Made out of Nitinol
  - FDA approved: permanent 2002 and retrievable 2004
  - Manufacturer recommends retrieval up to 23 days
Current IVC Filters (3/12):

- **ALN Filter** (ALN) Implants Chirurgicaux, Ghisonaccia, France
  - Optional/temporary filter
  - Max IVC size 28mm
  - Introducer size 7F
  - Made out of stainless steel non-ferromagnetic alloy
  - FDA approved: permanent 2008 and retrievable 2008
  - Retrieval: 95% at:
    - 144 days mean
    - 300 days longest
Current IVC Filters (3/12):

- **SafeFlo** (Bard Peripheral Vascular, Tempe, AZ)
  - Optional/Temporary filter;
  - Max IVC size 25mm
  - Introducer size 6F
  - Made out of Nitinol; no hooks design;
  - FDA approved: permanent only 2009;
Current IVC Filters (3/12):

- **Option (Rex Medical)**
  - Optional/temporary filter
  - Max IVC size 32mm
  - Introducer size 5F
  - Made out of Nitinol
  - Retrieval: 92% at:
    - 67 days mean
    - 175 days longest
Current IVC Filters (3/12):

- **Crux Filter** (Crux Biomedical, Menlo Park, CA)
  - Optional/temporary filter
  - Max IVC size 28mm
  - Introducer size 6F
  - Made out of Nitinol
  - Currently undergoing clinical trials
How Is It Done?

- Clinical assessment: verify indications and check for contraindications.
- Choose the access and deployment sites and prep the patient appropriately.
- IVC venogram and appropriate additional venograms.
  - Check for thrombus load in IVC and on the way up there
  - Check for variant anatomy (IVC duplication 0.3%)
  - Measure the size of IVC
- Deploy the IVC filter in the desired location.
- Final venogram for confirmation.
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“Much Ado About…”

- **PREPIC Study (1998 and 2005 follow up) (7,8)**
  - 400 patients with proximal DVT randomized to anticoagulation vs. anticoagulation and IVC filter insertion.
  - In the first 12 days significantly less PE (symptomatic & asymptomatic) in the filter group (1.1% vs. 4.8%, P=0.03).
  - However, after 2 years, there were no significant differences in symptomatic PE or survival between the two groups.
  - In addition, the filter group had a significant higher rate of recurrent DVT (20.8% vs. 11.6%, P=0.02).
  - At 8 years follow up the overall incidence of VTE was similar between the two groups. Patient with filters had more DVT (35.7% vs. 27.5%, P=0.042) but less symptomatic PE (6.2% vs. 15.1%, P=0.008). Mortality and PTS were similar.
“Much Ado About...”

- Problems with PREPIC Study (1998 and 2005 follow up) (7,8)
  - Four different types of permanent filters were placed.
  - Different anticoagulation regimens were used.
  - The study did not include patients with common indication for IVC filter use.
Indications for IVC Filter:

- **American College of Chest Physicians (ACCP):**
  - Not recommended routine use of IVC filters in addition to anticoagulation in patients with DVT or PE.
  - Recommended IVC filter use in patients with proximal DVT and contraindication for anticoagulation.
  - If after IVC filter placement the risk for bleeding resolves a standard anticoagulation is recommended.
  - Not recommended as primary thromboprophylaxis in patients with major trauma or spinal injuries.
    - 2002 the Eastern Association for the Surgery of Trauma (EAST) recommended consideration of prophylactic IVC filters with high risk injuries who cannot be safely anticoagulated (severe closed head, spinal cord, multiple long bones, complex pelvic fractures injuries). (12)
Indications for IVC Filter:

- Controversial indications (9):
  - PE without concurrent proximal DVT, with an absolute contraindication for therapeutic anticoagulation.
    - Use prophylactic doses until therapeutic can be used.
  - Substantial progression of DVT despite full anticoagulation.
  - Recurrent VTE despite full anticoagulation.
    - In both cases try to use more aggressive or different anticoagulation regimen.
  - Massive PE with residual proximal DVT.
  - Extensive DVT or DVT with “floating” clot.
  - DVT in setting of heparin-induced-thrombocytopenia.
Contraindications for IVC Filters:

- Uncorrectable, severe coagulopathy.
- Extensive IVC thrombus.
Complications of IVC Filters:

- **Short-term:**
  - Insertion site hematoma
  - Arterial puncture
  - Contrast reaction
  - Air embolism
  - Pneumothorax/hemothorax
  - Extravascular penetration of wires
  - Arrhythmia
  - Premature or incomplete opening of a device
  - Misplacement (0.7-4.6%) (11)
  - Tilting/angulation (0-56%) (11)
  - Guide wire entrapment
  - Early filter migration
Complications of IVC Filters:

- **Short-term:**
  - Infection at the insertion site
  - Contrast induced renal dysfunction
  - Insertion site thrombosis (1.8-24.7%) (11)
  - Thrombosis in the IVC implantation site (1-24%) (11)
  - Arterio-venous fistula
  - Recurrent PE (2.5-7.7%) (11)
  - Fatal PE (0-4.4%) (11)
Complications of IVC Filters:

- **Long-term:**
  - Increased risk for subsequent DVT
  - Migration: proximal or distal (>10mm 2.9-12%) (11)
  - Perforation of the IVC wall (30-100%) (11)
  - Retroperitoneal hematoma
  - Lumbar pain from impingement
  - Filter fracture (1.5-2.9%) (11)
  - IVC occlusion/thrombosis (1-24%) (11)
Conclusions:

- There is still no final verdict on the use of IVC filters.
- For now the best use of IVC filters is in patients with proximal DVT and possibly in trauma patients with high risk injuries who cannot be anticoagulated safely.
- Preferred use optional/temporary filters and remove them ASAP.
- Use anticoagulation with IVC filters when possible.
Conclusions:

- No proven data to show any specific IVC filter superiority.

- WE NEED MORE DATA, MORE PROSPECTIVE STUDIES, PLEASE !!!
References:


8. PREPIC study group. Eight years follow up of patients with permanent vena cava filters in the prevention of pulmonary embolism. Circulation 2005; 112: 416-422.

References:

