IVC Filters and the IVC Filter Clinic

Northwestern Medicine
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ARIN August 2015
• Inferior Vena Cava
  • A major blood vessel that returns blood from the lower body to the heart.
  • Structurally dynamic
**IVC Filter**

- A small piece of metal that can be put in the IVC to prevent blood clots in the legs from traveling to the lungs.
Venous Thromboembolism (VTE)

Diagnosis of DVT/PE: Deep Vein Thrombosis/Pulmonary Embolism

According to the CDC:

- As many as 900,000 people could be affected (1 to 2 per 1,000) each year
- 60,000-100,000 Americans die of DVT/PE
- 10-30% of people die w/in 1 month of diagnosis
- Sudden death is the first symptom for 25%
- Leading cause of preventable hospital death and maternal mortality in the U.S.
Pulmonary Embolism

Among People with DVT ½ will have long term complications – post-thrombotic syndrome (swelling, pain, discoloration)

-PE Complications- Pulmonary Hypertension

1/3 will have recurrence w/in 10 years

5-8% of U.S. population has one of several genetic risk factors

- Family history
- Antiphospholipid antibody syndrome
- Factor V Leiden - Lupus Anticoagulant
- Prothrombin G20210A
- Elevated Factor VIII, IX, XI
- Protein C or S deficiency
- Antithrombin deficiency
- Sickle Cell Trait

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Who is at Risk for DVT/PE in the hospital?

- **Low Risk <10% if no prophylaxis given**
  - Mobile patients undergoing minor surgery
  - Medical patients who are fully mobile

- **Moderate Risk 10-40% if no prophylaxis given**
  - General surgery patients
  - Patients having gynecologic or urologic surgery
  - Medical patients who are sick or on bed rest
Who is at Risk for DVT/PE?

**High Risk 40-80% without prophylaxis**
- Patients undergoing hip or knee surgery
- Patients with major trauma or spinal cord injury

**Cancer Patients**
Are at increased risk (by 4-7 fold) because of:
- Malignancy – hypercoagulable state
- Increased immobility
- Certain treatments- chemo, hormone replacement, angiogenesis inhibitors
- Surgery
- Location of Cancer- Very high risk (stomach/pancreas)
- 20% of patients with VTE are cancer patients
- 15% of cancer patients develop VTE during their illness
Additional Patient Populations at Increased Risk

- Extended Car/plane trips
- Hormone replacement therapy 2-4 fold increase
- OCP 3-6 fold increase
- Genetics
- Smokers
- Nursing or rehab facilities
- Obesity 2-3 fold increase, bariatric surgery
- Neuro/Spine
- Pregnancy & Post-Partum period 4-14 fold increase risk
  - 1.7 events per 1000 pregnancies
Virchow’s Triad

**HYPERCOAGULABLE STATE**

- Malignancy
- Pregnancy and peri-partum period
- Oestrogen therapy
- Trauma or surgery of lower extremity, hip, abdomen or pelvis
- Inflammatory bowel disease
- Nephrotic syndrome
- Sepsis
- Thrombophilia

**VASCULAR WALL INJURY**

- Trauma or surgery
- Venepuncture
- Chemical irritation
- Heart valve disease or replacement
- Atherosclerosis
- Indwelling catheters

**CIRCULATORY STASIS**

- Atrial fibrillation
- Left ventricular dysfunction
- Immobility or paralysis
- Venous insufficiency or varicose veins
- Venous obstruction from tumour, obesity or pregnancy

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Symptoms of PE/DVT and Diagnosis

• Symptoms
  - DVT - edema, pain, warmth in one leg
  - PE - cough, shortness of breath, chest pain, palpitations, wheezing

• Diagnosis
  • DVT
    • Based on risk factors
    • Blood Test - D-Dimer
    • Duplex US
    • Contrast Venography
  • PE
    • Chest X-Ray
    • EKG
    • ABG - Blood Test
    • VQ scan
    • CTA
    • Pulmonary Angio
Veins of the Lower Legs

- **Deep Veins** - 95% of venous return
  - Soleal sinusoids
  - Tibial veins
  - Popliteal veins
  - Femoral veins

- **Superficial veins** - 5% of venous return
  - Dorsal venous foot arch
  - Great saphenous
  - Small saphenous
  - Posterior arch
  - Perforator veins
  - Giacomini vein
  - Additional tributaries
Veins of the Lower Legs

- Common iliac vein
- Internal iliac vein
- External iliac vein
- Inguinal ligament
- Femoral vein
- Great saphenous vein (superficial)
- Popliteal vein
- Tibial vein
- Lesser saphenous vein
- Greater saphenous vein
Coagulation Cascade
Anticoagulation

- **Aspirin** – 81mg used in multiple myeloma patients
- **Vitamin K antagonist**: Coumadin
- **Xa inhibitor**: Rivaroxaban (Xarelto) or Apixaban (Eliquis)
- **Direct Thrombin Inhibitor**: Dabigatran (Pradaxa), Bivalirudin (Angiomax), Argatroban
- **Thienopyridine antiplatelet agents**: Clopidogrel (Plavix), Ticlopidine (Ticlid)
- **Glycoprotein IIB/IIIa inhibitors**: Abciximab (Reopro), Eptifibatide (Integrilin), Tirofiban (Aggrastat)
- **LMWH**: Dalteparin (Fragmin), Tinzaparin (Innohep), Fondararinux (Arixtra), Enoxaparin (Lovenox)
- **SQ Heparin**
When Would A Filter Be Placed?

• **Classic Indications:**
  - Contraindications or complications to A/C
  - Inability to achieve or maintain therapeutic A/C
When Would A Filter Be Placed?

- **Extended Indications:**
  - Recurrent VTE despite adequate A/C
  - Iliocaval DVT
  - Large Free floating proximal DVT
  - Difficulty establishing therapeutic A/C
  - Massive PE treated with thrombolysis/thrombectomy
  - Chronic PE treated with thromboendarterectomy
  - Thrombolysis for iliocaval DVT
  - VTE with limited cardiopulmonary reserve
  - Recurrent PE with filter in place
  - Poor compliance with A/C meds
  - High risk of complication of A/C (falls, ataxia, etc)
When Would A Filter Be Placed?

• **Prophylactic Indications:**
  - Trauma patient with high risk of VTE
  - Surgical patient at high risk of VTE
  - Medical condition with high risk of VTE
Types of Filters

• Permanent
  - Permanent Contraindication to anticoagulants
  - Complication or inability to achieve therapeutic dose to anticoagulants
  - Elderly
  - Poor prognosis – survival < 6 months
  - Patients with fall risk
  - Patients that are not compliant

• Optional
  - Risk of VTE is temporary
  - Contraindication to anticoagulation is temporary
  - Massive PE-treated with thrombolysis
  - Temporary Fall risk
  - Can leave in permanently or be removed
Decision for Permanent vs Optional filter Placement

• Each patient referred for an IVC filter in IR is evaluated for Permanent vs. Optional Filter placement
• Data suggests optional filters may have higher complication rates then permanent filters and are more expensive
• Northwestern Radiology IVC Filter Clinic-Likelihood of retrieval calculator

• Likelihood that an optional filter becomes permanent: -----%
  - Age
  - Male?
  - History of VTE?
  - Presence of malignancy?
  - VTE with AC failure?
  - Presence of neurologic disease?
  - VTE with AC complication?
  - High-risk VTE?
  - Prophylaxis?

Permanent and Optional Filters

- **B Braun** Vena Tech Permanent Filter
- **Cook Gunther Tulip** Retrievable Filter
- **Cook Celect** Retrievable Filter
- **ALN** Optional Filter
Permanent and Optional Filters

Birdsnest
Cook Medical

Greenfield Filter
Meditech-Boston Scientific

OptEase
Cordis Endovascular

Bard Denali Filter

Crux
Volcano Corporation
Benefits of IVC Filters

• **Benefits:**
  - Only method to prevent PE if unable to receive AC
  - Minimally invasive procedure with a short recovery period
  - Effective in preventing PE (98%)
  - Optional filters can be easily removed or replaced
Risks of IVC Filters

• Contrast reaction/induced renal dysfunction
• Arrythmia
• Air Embolism
• Pneumothroax/hemothroax
• Extravascular penetration of guide wire
• Incomplete opening
• Tilting
• Misplacement
• Guide wire entrapment
• Filter migration/embolization (heart/pulmonary artery)
• Filter Fracture
• Insertion site bleeding/Thrombosis
• AV fistula

• Increased risk of subsequent DVT
• Symptomatic penetration outside of IVC
  • (aorta, ureter, bowel, nerve, pancreas)
• Symptomatic IVC occlusion
• Vena Caval stenosis
• PE
Placing the Filter

- Placed in Interventional Radiology
- Through Right IJ or Femoral Vein
- place, location
- Venacavagram done-look for clot in IVC,
  - Size of IVC, variant anatomy
- Deploy filter straight- infra-renal
84yo Male with B DVT-filter placed before surgery
Nickel allergy

- **All Currently Available Retrievable IVC filters contain Nickel**
  - Most comprised of Nitinol (Nickel-Titanium) contains 56% Nickel
    - Examples: Denali, G2, Optease, Option, Crux
  - Conichrome (cobalt-chromium-nickel-molybdenum-iron) contains 15.4% Nickel
    - Examples: Tulip, Celect
  - Phynox (cobalt-chromium-nickel-molybdenum-iron) contains 15-18%
    - Examples: VenaTech
  - Stainless Steel 10-14% Nickel
    - Examples: Bird’s Nest, Greenfield
- **Only Filter without Nickel**: Greenfield Beta III titanium Alloy (titanium-molybdenum-zirconium-tin)- Permanent IVC filter
• Started January 2009
• 2 Interventional Radiologists
• 1 RN Clinical Coordinator

• Why was filter clinic started?
  - Consult Service
  - Patient Follow Up
  - Increase retrieval rates
  - Patient and Medical Staff Education
  - Research
FDA warnings
First Date Issued August 9, 2010

- **Recommendations/Actions:**
  - **FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.**
    - “Since 2005, the FDA has received 921 device adverse event reports involving IVC filters, of which 328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforation of the IVC, and 56 involved filter fracture. Some of these events led to adverse clinical outcomes in patients.”
    - “FDA encourages all physicians involved in the treatment and follow-up of IVC filter recipients to consider the risks and benefits of filter removal for each patient. If a patient has a retrievable IVC filter that should be removed based on his or her individual risk/benefit profile, the primary care physician and/or those providing ongoing patient care should refer the patient for IVC filter removal when feasible and clinically indicated.”
FDA warnings

Updated Safety Communication May 6, 2014

- Recommendations and actions have not changed
- FDA activities updated
  - developed a quantitative decision analysis to assess whether there is a time period during which the risk of having an IVC filter in place is expected to outweigh the benefits.
    - suggested that if the patient’s transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.
  - requiring collection of additional clinical data for currently marketed IVC filters in the United States.
    - PRESERVE study (PREdicting the Safety and Effectiveness of InferioR Vena Cava Filters)
    - 522 studies by manufacturers postmarket surveillance
IVC Filter Clinic

• **Forming the clinic:**
  - Creating a database
  - Coordinator to follow patients
  - Creating a website
  - Business cards/letterhead
  - Clinic space
  - Creating patient education pamphlets

• **Getting the word out:**
  - Speaking at Grand Rounds
  - Speaking at Patient Support Groups
  - Contacting referring physicians personally
  - Presentations at conferences
  - Publications in Journals
IVC Filter Clinic

• **Referral Services**
  - Medicine
  - Critical Care
  - Neuro
  - Ortho
  - Urology
  - Rehab
  - Oncology
    • Gyn onc
    • Heme onc

• **Clinic Numbers**
  - Total Filters Placed approx 250 per year
  - Permanent Filters Placed approx. 35%
  - Optional Filters approx. 65%
  - Filters Removed between 55-74%
  - Optional filters kept permanent between 20-43%
  - Placed at OSH-Referred for removal- increasing referrals
IVC Filter Clinic

- **Pre-Clinic Period**
  - 2001-2008
  - 369 Optional Filters Placed
  - 108 retrieved
  - 29% retrieval rate

- **Published articles and SIR presentations**
  - *Improving Inferior Vena Cava Filter Retrieval Rates: Impact of a Dedicated Inferior Vena Cava Filter Clinic* - Minocha, Jeet, MD, et al. JVIR 2010
IVC Filter Clinic-Database

Excel Spreadsheet

- Information we are following:
  - Name, age, sex of patient
  - Hx of Thromboembolic episodes, complication or contraindication to a/c, prophylaxis
  - Malignancy, misc risk factors
  - Filter Indication: date and method of primary diagnosis
  - Type of filter, date placed, IR MD that placed filter, date follow up needed, date removed, complications with removal,
  - Discharge date, a/c on d/c?, type of A/C
  - Referring service, ordering and primary physician
  - Notes on follow up
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Follow Up

- **See patient pre-placement**- contact info given, pt ed.
- **2 week follow up**- IR RN – evaluate patient progress
- **2-6 weeks post** – IR MD or RN coordinator contacts patient's primary MD, APN, PA to discuss removal over email or phone
- **Additional On-Going Follow up**- Send letter to patient's home, call OSH doctors, SNF, emergency contact numbers, etc.
- CT, LE Doppler, labs, patient seen in IVC Filter clinic if indicated –before scheduling retrieval
- Filter removal scheduled in IR
- Follow up visit for difficult retrievals or fractured filter left behind- 1month post-retrieval
Follow Up Letter to Physicians

Dear Dr REFERRING PHYSICIAN,

Your patient, NAME, had an optional inferior vena cava (IVC) filter placed in the Interventional Radiology Department at Northwestern Memorial Hospital on DATE. The indication for IVC filter placement was REASON.

When IVC filtration is no longer indicated, I would like to attempt to remove your patient’s filter device. Please let me know when you feel PATIENT NAME is a candidate for IVC filter retrieval. I can contact the patient directly and schedule the procedure at HIS/HER convenience. I will follow up with you after the procedure.

Please let us know if you have any questions.

Thank you,
Dear ______________,

You had an optional inferior vena cava (IVC) filter placed in the Interventional Radiology Department at Northwestern Memorial Hospital on ______. This filter was placed because you had a blood clot found in your legs and your lungs. We would like to remove this IVC filter when you no longer need it. This is usually done once you are on blood thinning medication at a therapeutic dose or it is determined you no longer have blood clots in your legs. Please discuss the IVC filter with your doctors to see when you may be able to have this removed. If you or your doctor have any questions about this please give me a call. When you are ready for the filter to be removed please call me and I will schedule this for you.

Thank you,
Filter Retrieval

• Done in Interventional Radiology department
• Almost identical to filter placement procedure – remove from Right IJ unless OptEase filter (hook at the bottom)
• Moderate sedation used for retrieval
• Vena Cava gram-evaluate tilt, penetration, thrombus
• Recovery 1 hour after procedure
• Done as an outpatient procedure
• Pre-Removal Check:
  - Lower Extremity Duplex Exam
  - Current therapeutic A/C
  - CBC with plt, CMP, PT/INR check
Typical Filter Retrieval
Typical Filter Retrieval
Failed Retrievals.....

- If significant clot found in filter
- Endothelialized in IVC
- Fibrin Sheath

Filling defect – Thrombus in filter

Hook embedded in IVC
unable to capture to remove

Fibrin Sheath around Hook-
unable to capture to remove
More reasons for Failed Retrievals….

• Legs outside IVC-hitting nerves, organs, causing abdominal pain
• Leg in Spine- vertebral body causing back pain
• Fractured Legs- unable to remove fractured leg without surgery if outside IVC
  - Some may not be harmful
  - Can monitor for migration with CT
• Filter in place greater than 6 months
• Tilted filter – unable to grab hook

Ancillary Techniques

- Excimer Laser – training and use
- Forceps
- SOS Omni Selective Catheter
- Ansel Sheath
- Loop Snare

Spectranetics Corporation
Filter Retrievals – Ancillary Techniques

30yo male filter placed prophylactically April 2012 after a motorcycle accident. He had no follow up to remove his filter. Starting Nov. 2014 pt had back pain radiating to his testicles. Had extensive urology work up and was on pain medication. On CT Found filter fractured with prong into L2-L3 disc space.
Filter Retrievals – Ancillary Techniques
Filter Retrievals – Ancillary Techniques

29yo OptEase filter placed January 2014 after pelvic mass removal sx, had left ileofemoral DVT. She had a failed removal at OSH due to the filter being tilted. Not able to grasp the hook to remove the filter. Patient on Xarelto.
Filter Retrievals – Ancillary Techniques
Filter Retrievals – Ancillary Techniques

Filter Retrievals – Ancillary Techniques
Filter Retrievals – Ancillary Techniques

75 yo male s/p R THA complicated by DVT/PE. Transferred to NMH from OSH after aborted IVC filter removal – wire and microcatheter entanglement into OptEase filter.
Filter Retrievals – Ancillary Techniques
Filter Retrievals – Ancillary Techniques

34yo female filter placed prophylactically before gastric bypass surgery November of 2008 for a history of PE in 2007. No one followed up about removing the filter with her. In March 2015 she started to have right flank pain and it was found that the filter had multiple prongs extending beyond the IVC lumen 1 into the L3 vertebral body, and some abutting the duodenum and right ureter. She was hospitalized for pain r/t the filter. Failed removal at outside hospital.
Filter Retrievals – Ancillary Techniques

74yo female with IVC filter placed 4-5yrs ago for DVT/PE while on coumadin. Since the filter was placed she had pancreatitis 4 times in 2014. She was referred by her PCP who felt some filter struts maybe near the pancreas causing the repeated pancreatitis.
Filter Retrievals – Ancillary Techniques
Filter Retrievals – Removing Permanent Filters

62yo female with Simon Nitinol filter placed 2010 found to have struts outside of the IVC extending into the duodenum and L common iliac vein. On Venogram saw all lower segment filter struts were outside the IVC and the filter was tilted posteriorly.
Filter Retrievals – Removing Permanent Filters

22 yo F had filter placed prophylactically after a diving accident, C6 injury, paraplegic in August 2012. Patient having abdominal pain, Nausea, and vomiting and had been to several doctors for workup. Mother called to refer her for IVC filter removal. On CT in Feb 2015 fractured filter seen with a strut in the liver- hepatic vein branch.
Filter Retrievals – Removing Permanent Filters
Filter Retrievals – Removing Permanent Filters
Research

• Lots of questions to be answered???
  - Follow up-Long Term
  - Indications for Permanent vs. Optional filters
  - Permanent Filters and Long Term Prophylaxis
  - When to Retrieve Optional Filters
  - New Types of Filters

• SIR Panel and Research Agenda-2009
  • prophylactic use of filters in trauma patients was considered the leading clinical research topic
  • Listed 33 different research topics listed
  • Highest basic science priority- study of filters in the IVC over time

Research

• **Research Challenges**
  • Devices change too rapidly for long-term study
  • Differences in devices are poorly understood
  • Technical aspects of clinical practice vary
  • Lack of validated models for testing devices in vivo, in vitro, and virtual
  • Constant evolution of indications for filter placement with new devices
Research at Northwestern

• Industry Sponsored Clinical Trials
• PRESERVE Study - Predicting the Safety and Effectiveness of Inferior Vena Cava Filters to start 2015
• Chart Reviews:
  • A Prospective Review of Excimer Laser-Assisted IVC Filter Retrieval
  • A Prospective Chart Review Study on the Impact of a Dedicated IVC Filter Clinic in the Department of Interventional Radiology in the Placement and Retrieval of IVC Filters
IVC Filter clinic card and website

IVC Filter Clinic
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References

Please contact me for more references if needed

Thanks everyone 😊

Questions ???????