Pulmonary Embolism and DVT

- Estimated 570,000 to 650,000 cases of symptomatic PE each year
- These result in an estimated 200,000 deaths per year
- Anticoagulation is the treatment of choice for most, but . . .
Heparin and Coumadin

- Up to 26% of patients will experience a complication related to anticoagulation.
- As a whole, these anticoagulation related complications have an associated mortality rate of 5 to 12%.
- 3 to 20% of patients will develop a second PE despite therapeutic levels of anticoagulation.
Heparin and Coumadin: Contraindications

- Hx of bleeding complication on anticoagulation
- Known recent bleeding—GI, CNS, etc.
- Recent major trauma or surgery
- Thrombocytopenia—HIT or otherwise
- CNS neoplasm, aneurysm, or AVM
Prevention of PE: Historical Interventions

• Femoral vein ligation
  – Hunter 1874, Homans 1934
  – High morbidity, recurrent PE

• IVC ligation
  – Ochsner, Debakey, O’Neal 1940’s
  – Operative mortality, recurrent PE
  – High morbidity with venous stasis in 33%
IVC Filters: Absolute Indications

• Thromboembolic disease and contraindication to anticoagulation
• Thromboembolic disease and complication related to anticoagulation
• Recurrent thromboembolic disease despite anticoagulation
• Inability to achieve or maintain therapeutic anticoagulation
IVC Filters: Relative Indications

- Iliocaval DVT
- Large, free-floating proximal DVT
- Difficulty establishing therapeutic anticoagulation
- 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 anticoagulant medications
- High risk of complication of anticoagulation (eg, ataxia, frequent falls)
Prophylaxis:
Is there a role for IVC filters?

- The only function of vena cava filters is to prevent clinically significant PE by trapping venous emboli.
- Vena cava filters do not prevent or treat venous thrombosis.
- Vena cava filters are indicated when primary therapy cannot be started, must be stopped, or is insufficient to protect patients from clinically significant PE who are at high risk.
- Filters placed for so-called prophylactic indications do not provide prophylaxis for development of DVT.
Prophylactic Filters

- Usually in the setting of trauma
- Preoperatively in select patients
- Data supporting placement in setting of malignancy
- Cannot receive anticoagulation
- Suffers from one of the following injury patterns:
  - CHI with low GCS Spinal cord injury
  - Pelvic and long bone fractures
  - Multiple long bone fractures
Optional Filters

- Patients with accepted indications for filters plus -
- Well defined short period of risk
- Relatively young age
- Reasonable life expectancy
- Avoidance of anticoagulation for sake of the filter
Non-Permanent Filters: Old Idea

1967:

A New Experimental Approach to Prophylaxis of Pulmonary Embolism

PETER EICHELTEN, M.D.,* AND WORTHINGTON G. SCHENK, JR., M.D.

Department of Surgery, State University of New York at Buffalo and the Surgical Research Laboratories of the Edward J. Meyer Memorial Hospital, Buffalo, New York
IVC filters: Adjunct to Thrombolysis

• Overall risk of PE low
  – <1% in Venous Thrombolysis Registry
• No proven clinical benefit
  – Trapped thrombus common
• Are we brave enough not to place a filter?
  – No.

Mewissen et al  Radiology 1999;211:39
Yamagami et al Br J Radiol 2003;76:712-713
IVC Filters: Contraindications

- Chronically thrombosed IVC
- Inability to obtain direct access to IVC
Decousus et al, NEJM 1998

• Only randomized, prospective study (unblinded)
  – 400 pts with DVT, DVT + PE
  – 200 heparin alone, 200 heparin + filter

• Mortality, recurrent PE at 2 yrs: no difference
Decousus et al, NEJM 1998

- DVT at 2 yrs 20% with filter, 12% without (p<.05)

- PE during first 12 days Rx:
  - 1.1% with filter, no mortality
  - 4.8% no filter, \( \frac{1}{2} \) lethal
  - P < .05
Decousus 8-Year Update

- Circulation
- Recurrent DVT
  - 34.1% filter group
  - 27.3% no filter $P = 0.08$
  - Post-thrombotic syndrome 56% in both groups
- Symptomatic PE
  - 6.2% (2 fatal) in the filter group
  - 15.1% (5 fatal) in the no filter group $P = 0.01$
- No survival benefit with filter
IVC filtration: Historical Interventions

- **Mobin-Uddin Filter**
  - 1\textsuperscript{st} intravascular IVC filter – 1967
  - Placed via a surgical venotomy
  - Percutaneous methods introduced in 1973
  - Recurrent PE rate $<$ 3%; fatal PE rate $<$ 1%
IVC filters: Historical Interventions

• Stainless Steel Greenfield Filter
  – 2\textsuperscript{nd} intravascular IVC filter – 1972
  – Placed via a surgical venotomy
  – Percutaneous methods evolved during the 1980’s
  – Inserted through a 29.5 Fr sheath
  – Crafted of medical grade 316 L Stainless steel
Historical IVC Filters

• Stainless Steel Greenfield filter (cont.)
  – Shape allowed for 89-100% rate of clot trapping
  – Could preserve laminar flow through the IVC despite with up to 70% of the cone filled with thrombus
  – Tilting reduces efficacy of the device (15 degrees)
  – Migration has been seen in up to 39% - caudal
  – Strut perforation of IVC reported
Modern IVC Filters

• Ideal Qualities of IVC Filter
  – Nonthrombogenic, biocompatible
  – Infinite implant lifetime and function
  – Secure fixation
  – High filtering efficiency
  – Ease of insertion/delivery
  – MR compatible
  – Low cost
  – Retrievable
Titanium Greenfield Filter -- 1988

- 12 Fr filter inserted through a 14 OD Fr sheath
- Dimensions: 47mm x 38mm, 0.25 g
- Crafted of Beta III titanium alloy
- Inserted from jugular or femoral approach
- Not inserted over guidewire—tab release
- “Modified” hooks from original design
Modern Greenfield Filter

- Insertion site thrombosis of 8.7%
- Recurrent PE rate of 3.3%
- IVC thrombosis rate of 1%
- Left femoral and internal jugular approaches difficult because of catheter kinking and device tilt
Modern Greenfield IVC Filters

• Over-the-Wire Greenfield Filter -- 1995
  – 12 Fr filter inserted through a 14 OD Fr sheath
  – Filter is designed to be deployed over a 0.035 wire
  – System stabilizes the filter reducing the incidence of tilting
  – Dimensions: 49mm x 32mm
  – Crafted of 316 L stainless steel
  – Inserted from a femoral or jugular approach
Bird’s Nest Filter – 1982

- 14 Fr delivery Sheath
- Dimensions: two V-shaped stainless steel struts connected by four 304 stainless steel wires each 25 cm long.
- Deployed in stepwise fashion “packing” the filter wires in between the first and second set of struts.
- Can be used in IVCs between 28 mm-48mm
Simon Nitinol Filter -- 1990

- Small system with delivery catheter with a 9 Fr OD
- Dimensions: 45mm x 30 mm
- Crafted of Nitinol
- Deployed by unsheathing the device – not over-the-wire
- Inserted from jugular, femoral, or antecubital approach
VenaTech Filter – 1986

- 12 Fr sheath with a 14.6 Fr OD
- LP version uses a 7 Fr sheath with a 9 Fr OD
- Deployed with a pusher – not over-the-wire
- Has side rails with hooklets to provide stabilization and centering
- Dimensions: 38mm x 30 mm
- Crafted of Phynox,
  - non-ferromagnetic alloy
  - MRI-compatible.
- Inserted via from jugular or femoral approach
TrapEase Filter – 2000

- Small system with a 6 Fr delivery catheter with a 8 Fr OD
- Dimensions: vary depending on cava diameter 50mm x 35mm. Can be deployed in cavas up to 30mm in diameter.
- Crafted of laser-cut Nitinol
- Advertised as “idiot proof” because device cannot be deployed backwards
Non-Permanent Filters

- **Temporary**
  - Filter attached to tether
  - Must be removed

- **Retrievable**
  - Self-affixing to IVC wall
  - Permanence is optional

- **Convertible**
  - Self-affixing to IVC wall
  - Device is permanent, but filtration capability is not
Currently FDA approved optional/retrievable filters

- Gunter tulip filter (Cook)
- Celect (next gen Tulip by Cook)
- Optease filter (Cordis)
- Recovery/G-2 filter (Bard)
- ALN Filter (ALN)
Retrievable Filter Types

Tulip  Recovery  G2  OptEase
Gunther Tulip Filter – 2001

- 8.5 Fr introducer sheath
- Dimensions: 45mm x 30mm
- Deployed with release mechanism can be readjusted at the time of deployment
- Crafted of Elgiloy and MRI compatible alloy
- Permanent or retrievable
Gunther Tulip Filter (cont)

- Migration rate very low
- Filter can be retrieved with a loop-snare from jugular
- Approved for 4-6 weeks. Up to 9 months retrieval reported.
Gunther Tulip II (Celect)

- Modification for extended retrieval by opening petals
  - 12 weeks +
- Decreased tilt with longer arms
  - Improve retrievability
- Early reports of penetration of IVC wall.
Tulip Retrieval

4 weeks
Recovery Filter – 2003

- 9 Fr introducer sheath from femoral approach
- Delivery and release similar to Simon Nitinol device
- Crafted of Nitinol alloy but has a dual array of six radial arms and legs.
- The hooklets are designed to allow release of the device even after endothelialization has occurred
- Preliminary studies indicate the device can be removed up to 134 days
Recovery Filter Removal
OptEase (Cordis)

- Nitinol hypotube
- Based on TrapEase
- Inserted from Jugular, femoral of antecubital approach
- 30 mm IVC
- Femoral retrieval with snare
- Removal recommended up to 23 days
  - Probable 4-6 weeks
OptEase Retrieval
Filter Literature

- Limited data on permanent IVC filters

- The available data on optional devices are even more limited than permanent filters

- The few published clinical reports suggest that optional filters, as a group, are associated with equivalent outcomes to permanent devices

- There has never been a clinical study to directly compare optional and permanent filters
Filter Literature

• Percutaneous removal of retrievable filters appears to be a safe procedure with few immediate or late complications

• Currently, lack of published human data on convertible filters

• The benefit of discontinuation of filtration has never been proven

• Until more data are available, permanent caval filtration should always be considered when a filter is indicated
Comparison of IVC Filters

- Majority of data concerning filter use and effectiveness is historical and has not been performed in consistent manner.
- Method of follow-up varies widely
  - Imaging
  - Clinical evaluation
  - Telephone interview
- Duration of follow-up varies widely
  - 2 weeks, 2 months, 2+ years
Comparison of IVC Filters

• To standardize Filter evaluation two values are currently focused upon: Recurrent PE after filter placement and Thrombosis

• Recurrent PE after IVC Filter
  – Clinically symptomatic
  – Infrequent for all IVC filter devices (2 to 5%)
  – True value of this is unknown as the rate of asymptomatic PE is still unknown as is its clinical relevance
  – In this setting must account for PE source: Filter, other medical device, atypical venous source, or even cardiac
  – Tilt of the device should also be factored into the evaluation
Comparison of IVC Filters

- **Thrombosis**
  - Includes IVC and access site thrombosis
  - The rate of IVC thrombosis varies widely 0 to 28%
    - Variablitiy of follow-up
    - Screening of symptomatic vs. all patients
    - Method of follow-up: US, CT, MR, venography
  - The rate of access thrombosis varies from 2 to 35%, much higher for the older devices with larger profile. Lower profile devices have very rarely cause access thrombosis.
Is flow stagnation or turbulence linked to thrombosis and thrombus and/or PE formation?

Hemodynamics: Mobin-Uddin and TrapEase filters versus the Greenfield filter.

Penetration of the IVC by filter hooks or struts is a long-term complication that happens relatively often, though symptomatic penetration is very rare.

When to Retrieve A Filter?

- Risk of symptomatic PE becomes low
  - Patient can be managed with first-line therapy
  - Patient no longer at risk of thromboembolic disease
- Risk of anticoagulation is acceptable
- Risk of filter exceeds benefit
- Life expectancy sufficient to realize benefit from absence of filter
Guidelines for Retrieval

• Filter no longer clinically indicated
• No significant trapped thrombus
• No prior or present thromboembolic disease
  • Prophylaxis with LMWH
  • Negative screening LE duplex
• Prior or present thromboembolic disease
  • Full anticoagulation
• Patient agrees to have filter removed
Filter Retrieval

- Rosenthal et al documented successful retrieval of forty OptEase filters, with one retrieval at 48 days, and all other retrievals performed within 23 days.

- The Jonas study showed that the OptEase filter can be successfully retrieved up to 14 days.

- Hoppe et al, reported Gunther Tulip filters were removed at a mean of 11.1 days with 100% technical and clinical success rates.
Retrievable Vena Cava Filters in Trauma Patients: An AAST multicenter study

- 152 Gunter-Tulip (G-T), 224 Recovery (R), and 37 Optease (Opt).
- Only 22% of filters were retrieved.
- The primary reason filters were not removed was because of loss to follow up (31%).
- 115 patients in whom retrieval was attempted, retrieval failed as a result of technical issues in 15 patients (10% of G-T, 14% of R, 27% of Opt) and because of significant residual thrombus within the filter in 10 patients (6% of G-T, 4% of R, 46% Opt).

UVA experience:

From 2002 to 2006, 386 retrievable IVC filters were deployed at our institution. Only 73 filter retrieval attempts have been made (18%). Of the retrieval attempts, 68 were successful (93%).
<table>
<thead>
<tr>
<th></th>
<th>Number of Attempted Retrievals</th>
<th>Longest Interval for Successful Retrieval</th>
<th>Successful Retrievals</th>
<th>Failed Retrievals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tulip</td>
<td>25</td>
<td>3 months 4 days</td>
<td>24 (96%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Recovery</td>
<td>26</td>
<td>8 months 20 days</td>
<td>26 (100%)</td>
<td>0</td>
</tr>
<tr>
<td>G2</td>
<td>7</td>
<td>3 months 9 days</td>
<td>7 (100%)</td>
<td>0</td>
</tr>
<tr>
<td>OptEase</td>
<td>15</td>
<td>3 months 0 days</td>
<td>11 (73%)</td>
<td>4 (27%)</td>
</tr>
</tbody>
</table>
UVA Experience

• IVC filter retrieval has been largely successful.

• 5 of 73 retrieval attempts were unsuccessful:
  – Hook and filter endothelialization (3).
  – Extensive thrombus which involved the filter, preventing retrieval (1).
  – Filter migration to the right ventricle, where the filter became tangled in the chordae tendinae, preventing retrieval (1).
Complications:

- **Migration greater than 5 mm: 16%**
  - Tulip (8%, 2/25)
  - Recovery (12%, 3/26)
  - G2 (71%, 5/7)
  - OptEase (13%, 2/15)

- **Failed Retrievals: 7%, 5 /73 filters.**
  - Tulip (4%, 1/25)
  - Recovery (0%, 0/26)
  - G2 (0%, 0/7)
  - OptEase (27%, 4/15)

- **IVC penetration: 1 (Tulip)**
- **Bacteremia: 1 (Recovery)**
- **Maldeployment: 2 (1 OptEase, 1 Tulip)**
- **Pain: 3 (2 G2, 1 Recovery)**
Migration occurred with all filter types

• Most migrations occurred in filters with free limb construction (G2 and Recovery)
  – G2 demonstrated migration in 5 of 7 cases, accounting for 5 of the 12 total migrations for all filter types
  – Leading to our institution’s discontinued use of this filter.
Endothelialization of an OptEase retrieval hook
G2 filter which migrated caudally to the common iliac confluence and caused the patient pain, which led to follow-up imaging and retrieval.
The same G2 filter 14 days later, demonstrating migration and presence of a filter limb in the left renal vein (arrow).

G2 filter upon placement in the infrarenal IVC.
Suprarenal IVC filter placed upright position for IVC thrombus.

One day later, filter demonstrates interval tilt, with extension of legs into right renal vein, which caused the patient pain.
OptEase filter, placed at an outside hospital, which migrated to the right ventricle and led to patient shortness of breath and arrhythmia.
Other reported complications

- Incomplete opening
- Filter fracture
- Filter fragment embolization to the lungs
- IVC thrombosis
Buried Hook
Fracture of Filter
Fixed penetration of IVC wall
IVC thrombosis
Conclusions

- Thromboembolic disease can be due to transient risk factors
- Permanent filters have low but real rate of complications
- Optional filters allow protection for limited period of risk
- Physician judgment important for placement
  - Crucial for removal
All Optional/Retrievable filters are FDA approved permanent filters

- Currently no FDA approved temporary filters available in the USA

- Retrieval is approved by FDA as an option in 5 types of filter (since 2002)
Key Points of SIR Consensus report 2006

1. The primary means of therapy and prophylaxis of VTE are pharmacologic
2. No unique indications for optional vena cava filters exist that are distinct from permanent vena cava filters
3. Patients with filters in situ should be managed with pharmacologic methods
4. There are no absolute indications for discontinuation of filtration unless the filter itself is a source of documented major morbidity that will be relieved by retrieval or conversion
5. Discontinuation of filtration should only occur when the risk of clinically significant PE is reduced to an acceptable level
6. The quality of literature on optional vena cava filters is not sufficient to support evidence-based recommendations at this time