IVC Filters and the Trauma Patient

Stuart M Lyon
Injury 2011
Trauma and venous thromboembolism (VTE)

- Trauma patients have the highest VTE rate of all hospital patients
  » Geerts WH, Chest. 2001;119:132S-175S

- Fatal Pulmonary Embolism (PE) is 3rd most common cause of death in trauma patients who survive >24hrs after injury
Why high VTE in trauma?

• Hypercoaguuable
  - increased thromboplastin
  - reduced fibrinolytic activity
  - circulating catecholamines
  - compliment activation
  - reduced clearance of clotting factors

• Venous endothelium
  - extrinsic coagulation mechanism from direct endothelial trauma
  - remote endothelial trauma?

• Venous stasis
  - prolonged bed rest
  - altered flow dynamics, etc

• Don’t forget to add the medical culprits
  - Co morbidities/ age/ obesity/ pregnancy
  - 1 in 14 trauma patients have a genetic clotting defect
VTE prophylaxis after trauma

• Chemoprophylaxis
  – Low Molecular Weight Heparin often contraindicated
    • Delay of 4 days in 50% of trauma patients
    • Delay of 1 week in 25% of trauma patients
    • 3 fold increase in VTE with delay to LMWH over 4 days
      » Nathens AB, J Trauma. 2007;62:557-562

• Sequential compression devices
  – Efficacy questioned
    » Knudson MM, J Trauma. 1996;41:446-459
  – Contraindicated in 35% due to lower limb injuries
    » Agudelo JF, Orthopedics. 2005;28(10):1164-71

• Monitoring
  – Duplex, clinical, etc
  – Efficacy questioned
What is aim of IVC filter Rx?

Prevent PE!

Reduce morbidity and mortality of PE with acceptable safety and cost benefit profiles?
IVC and Trauma

- PREPIC
- Filter development
  - Birth of the retrievable filter
  - Prophylactic indications/filters
  - Future directions

- State of play IVC filters in Trauma
- Conclusions??
- Where to from here
INDICATIONS

- Contraindication to anticoag.

- Anticoag. failure (10%)
  - Recurrent PE
  - Progressive DVT

- Anticoag. Complication:
  - Major hemorrhage-approx 10-26% risk
  - Heparin induced thrombocytopenia- 5-15%
  - Heparin induced osteoporosis

- Failure of existing filter
**ONE RCT**

- 400 patients with proximal DVT, mean age 72
- Randomised to filter + AC or AC alone

<table>
<thead>
<tr>
<th>Time</th>
<th>Filter grp</th>
<th>AC grp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day1</td>
<td>1.1% PE</td>
<td>4.8% PE</td>
</tr>
<tr>
<td>2yrs</td>
<td>20.8% DVT</td>
<td>11.6% DVT</td>
</tr>
<tr>
<td>8yrs</td>
<td>6.2% PE</td>
<td>15.1% PE</td>
</tr>
<tr>
<td>8yrs</td>
<td>35.7% DVT</td>
<td>27.5% DVT</td>
</tr>
<tr>
<td>8yrs</td>
<td>50.3% PTS</td>
<td>69.7% PTS</td>
</tr>
</tbody>
</table>

- No difference in mortality at 8 yrs
  - Decousus et al. NEJM 1998;338:409
ONE RCT

- 400 patients with prox DVT, mean age 72
- Randomised to filter + AC or AC alone

<table>
<thead>
<tr>
<th>Time</th>
<th>Filter grp</th>
<th>AC grp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day1</td>
<td>1.1% PE</td>
<td>4.8% PE</td>
</tr>
<tr>
<td>2yrs</td>
<td>20.8% DVT</td>
<td>11.6% DVT</td>
</tr>
<tr>
<td>8yrs</td>
<td>6.2% PE</td>
<td>15.1% PE</td>
</tr>
<tr>
<td>8yrs</td>
<td>35.7% DVT</td>
<td>27.5% DVT</td>
</tr>
<tr>
<td>8yrs</td>
<td>50.3% PTS</td>
<td>69.7% PTS</td>
</tr>
</tbody>
</table>

- No difference in mortality at 8 yrs
  - Decousus et al. NEJM 1998;338:409
PREPIC

‘IVC filters in patients with DVT +/- PE protect against longterm development PE without favouring development of PTS’

‘Their insertion is associated with a significant increase in DVT’
IVC filters

- Difficult to deny that filters have a role to play in preventing PE in proximal DVT.
- Can we take high risk groups and give them the advantage of caval interruption without the risks?

= the birth of non permanent filters and prophylactic indications.
INDICATIONS

- High risk PE
- Standard prophylaxis ineffective or CI
Explosion in use of filters

Trends in vena caval interruption

Phillip S. Moore, MD, Jeanette S. Andrews, MS, Timothy E. Craven, MSPH, Ross P. Davis, MD, Matthew A. Corriere, MD, Christopher J. Godshall, MD, Matthew S. Edwards, MD, and Kimberley J. Hansen, MD, Winston-Salem, NC (J Vasc Surg 2010;52:118-26.)

- NIS database
- VCF increased from 52,680 (98) to 104,114 (05)
- Prophylactic VCF for head injury and morbid obesity increased significantly
- Hospitalizations with DVT and PE rose 14% and 59%

“The findings that rates of DVT and PE in hospitalized patients increased significantly from 1998 to 2005 was unexpected.”
FIG 2. Bar graph demonstrating the number of patients reported to the NTDB who had a VCF placed during the interval 1994-2002. Also shown are the number of patients reported to the NTDB who had either a DVT or a PE. When these numbers are divided by the total number of patients reported to the NTDB in each of the years shown, the number of VCF placed annually has increased 340%, whereas the number of DVT or PE reported has increased 246% (Shackford SR, Cook A, Rogers FB, et al. The increasing use of vena cava filters in adult trauma victims: data from the American College of Surgeons National Trauma Data Bank. J Trauma 2007;63:764-9. Reproduced with permission).
FIG 3. Bar graph demonstrating the total number of VCFs placed as reported to the NTDB during the interval 1994-2002. Also shown are the number placed in patients with a diagnosis or complication of either DVT or PE (considered a therapeutic filter) and the number placed in patients without DVT or PE as a complication or diagnosis (considered a prophylactic filter) (Shackford SR, Cook A, Rogers FB, et al. The increasing use of vena cava filters in adult trauma victims: data from the American College of Surgeons National Trauma Data Bank. J Trauma 2007;63:764-9. Reproduced with permission).
Societal guidelines

- EAST = consideration of very high risk patients who are immobilized and cannot receive anticoagulation.
- AC Chest physicians = recommend against primary prophylaxis in trauma patients.
- SAGES = consideration of VCF in morbid obesity undergoing laparoscopic surgery.
Where to stand?

- No RCT for prophylactic filters
- Great variation in societal guidelines
- Fundamentalists on both sides
- Rest of us in a very wide middle
High risk PE, standard prophylaxis ineffective or CI

- Permanent filters?
- Temporary filters?
- Retrievable filters?
- No filters?
- Which patient cohorts?
Who?
Alfred

- CI to clexane > 72 hours and CI to IPC, with one of the following
  - Spinal injury
  - Multiple lower limb fractures
  - Pelvic fractures

- Duplex proven above knee DVT and CI to full anticoagulation
History

Surgical

- Ligation
- Plication
- Clipping
- Stapling

Filter 1967 - Mobin Udin
## Current Filters

<table>
<thead>
<tr>
<th>Filter</th>
<th>Sheath size</th>
<th>Max IVC diam</th>
<th>MRartifact</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS Gr</td>
<td>28Fr</td>
<td>28mm</td>
<td>+++</td>
</tr>
<tr>
<td>Tit Gr</td>
<td>15Fr</td>
<td>28mm</td>
<td>-</td>
</tr>
<tr>
<td>OTW-SSGr</td>
<td>15Fr</td>
<td>28mm</td>
<td>++</td>
</tr>
<tr>
<td>Bird’s Nest</td>
<td>14Fr</td>
<td>40mm</td>
<td>+++</td>
</tr>
<tr>
<td>VenaTech LGM</td>
<td>13Fr</td>
<td>28mm</td>
<td>+</td>
</tr>
<tr>
<td>Vena Tech LP</td>
<td>9Fr</td>
<td>30mm</td>
<td>+</td>
</tr>
<tr>
<td>Simon Nitinol</td>
<td>9Fr</td>
<td>28mm</td>
<td>+</td>
</tr>
<tr>
<td>Gunther Tulip</td>
<td>8.5Fr</td>
<td>30mm</td>
<td>+</td>
</tr>
<tr>
<td>Trapease</td>
<td>8Fr</td>
<td>30mm</td>
<td>+</td>
</tr>
</tbody>
</table>
Temporary Filters

- Three types: recently five
  - Tethered: filter is attached to a catheter.
    - Günther Temporary filter (Cook)
  - Tempofilter® II (Braun)
  - Retrievable/Permanent: the filter is totally implanted.
    - Günther Tulip (Cook)
    - Recovery (Bard)
  - in-situ Thrombolysis: IVC clot lysis
    - ProLyser (Cordis)
    - Antheor (Medi.tech)
    - Protect (BARD)
    - Lysofilter (Braun)
  - Convertible
  - Dissolvable
Tempofilter II

- B. Braun
- 6 wks implantation
- Totally implanted
- Subcut anchoring device
- Migration to RA reported
  - 1 death
Cordis - ProLyser

- Permits in-situ thrombolysis with 3F catheters
- Material: Fluoropolymer
- Dimensions:
  - Filter Diameter
    - Maximum Vena Cava = 35 mm
  - Introducer system
    - Diameter = 7 F / 8.5 F
    - Length = ?
- Access
  - Brachial / Jugular / Femoral
Temporary Vena Cava Filters

Retrievable/Permanent
Endothelialization
Figure 4. Kaplan-Meier analysis comparing the successful retrieval rate profile of the Celect filter to that of the Günther Tulip filter. The probability of successful filter retrievals at time points beyond 12 weeks is greater when the Celect filter is placed (black) versus when the Günther Tulip filter is placed (gray).
### Retrieval window

<table>
<thead>
<tr>
<th>Study Description</th>
<th>Retrieval Window</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early GT clinical and experimental published studies. 1997-2001</td>
<td>14 days max.</td>
<td></td>
</tr>
<tr>
<td>Extended interval for retrieval of Gunther-Tulip filters. JVIR 2004</td>
<td>Mean 43.6 days (1-126)</td>
<td>84%</td>
</tr>
<tr>
<td>Retrievable Gunther Tulip inferior vena cava filter: experience in 317 patients.</td>
<td>Mean 77 days</td>
<td>92%</td>
</tr>
<tr>
<td>JMIRO 2008</td>
<td>128 days (14-267)</td>
<td>93.4%</td>
</tr>
<tr>
<td>Initial experience in 115 patients with the retrievable Cook Celect vena cava</td>
<td>Mean 179 days (5-466)</td>
<td>96.6%</td>
</tr>
<tr>
<td>filter. JMIRO 2009</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short and Long term retrievability of the Celect Vena Cava Filter: Results from</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a multi-institutional Registry. JVIR 2009</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In situ temporary interruption devices

- Convertible
  - Braun
  - Mednova

- Dissolvable
The Novate IVC filter is not approved for commercial distribution and is currently under clinical investigation in Australia.
Efficacy of VCFs in trauma

Data supporting prophylactic VCFs after trauma is limited to historical and/or non-randomised controls

Decrease in number and severity of PE

- Velhamos, J Trauma. 2000;49:140-144
- Sekhram, J. trauma. 2001; 51:1087-1090

“Most studies demonstrate successful efficacy of IVC filters to reduce the incidence of all PE and fatal PE but lack rigorous control groups for comparison.”

Efficacy of prophylactic VCFs

Data supporting prophylactic VCFs after trauma is limited to historical and/or non-randomised controls

**Increase** in PE with increasing prophylactic VCF use


**No change** in PE rate with increasing use of prophylactic VCFs

» Antevil, J Trauma. 2006 Jan;60(1):35-40
» Cherry, J Trauma. 2008 Sep;65(3):544-8
To investigate the effect of prophylactic VCFs on the incidence of PE after major trauma
Methods

• Prospectively collected data
  – The Alfred Hospital Trauma Registry
  – Dept. Radiology VCF Database

• Inclusion criteria:
  – Major trauma patients
    • Injury Severity Score (ISS) > 15
    • Death following injury
    • ICU admission >24hrs requiring mechanical ventilation
    • Injury requiring urgent surgery on admission

• Multivariate logistic regression
  – Covariates derived from a literature review
Results - demographics

- 6,344 patients met inclusion criteria

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>44.2 (21.0)</td>
</tr>
<tr>
<td>Injury Severity Score (ISS)</td>
<td>24.3 (12.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>4645 (73.2)</td>
</tr>
<tr>
<td>Blunt injury</td>
<td>5724 (90.2)</td>
</tr>
</tbody>
</table>

- 511 VCFs (8.1% of total major trauma population)
  - Prophylactic -
  - With DVT -
Results - incidence of PE

- 45 PE (0.71%)
  - 2 fatal PE (0.03%)

- 42 (94%) symptomatic, 3 (6%) incidental findings

- Median time to PE: 9 days (range 0 - 48)
### Results - univariate analysis, PE vs no-PE, significant results

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt; 40 years</td>
<td>2.28</td>
<td>1.21 – 4.28</td>
<td>p=0.010</td>
</tr>
<tr>
<td>Injury severity score (ISS) &gt; 20</td>
<td>2.37</td>
<td>1.23 – 4.59</td>
<td>p=0.010</td>
</tr>
<tr>
<td>Number of injuries to lower extremity</td>
<td>1.25</td>
<td>1.13 – 1.38</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Injury severity to lower extremity</td>
<td>1.31</td>
<td>1.08 – 1.59</td>
<td>p=0.005</td>
</tr>
<tr>
<td>Number of pelvic fractures</td>
<td>1.73</td>
<td>1.05 – 2.86</td>
<td>p=0.031</td>
</tr>
<tr>
<td>Number of lower limb fractures</td>
<td>1.42</td>
<td>1.16 – 1.73</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Number of major operations (&gt;2 hrs)</td>
<td>1.11</td>
<td>1.04 – 1.19</td>
<td>p=0.003</td>
</tr>
<tr>
<td>Central venous catheterisation</td>
<td>3.30</td>
<td>1.84 – 5.93</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>2.79</td>
<td>1.54 – 5.05</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Hospital length of stay hours</td>
<td>1.00</td>
<td>1.00 – 1.01</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Mechanical ventilation hours</td>
<td>1.00</td>
<td>1.00 – 1.002</td>
<td>p=0.012</td>
</tr>
<tr>
<td>Intensive care unit hours</td>
<td>1.00</td>
<td>1.00 – 1.01</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>
# Results - multivariate analysis, PE vs. no-PE

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prophylactic vena cava filter</td>
<td>0.28</td>
<td>0.088 – 0.890</td>
<td>p=0.031</td>
</tr>
<tr>
<td>Number of injuries to lower extremity (AIS)</td>
<td>1.31</td>
<td>1.174 – 1.469</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Central venous catheterisation</td>
<td>3.41</td>
<td>1.879 – 6.172</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

AIS: Abbreviated Injury Scale
“Breakthrough” PE?

- 4 patients with a VCF subsequently developed PE

<table>
<thead>
<tr>
<th>Patient 1</th>
<th>Fatal PE</th>
<th>Chemoprophylaxis</th>
<th>Likely source of PE</th>
<th>Tilt</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>LMWH</td>
<td>Thrombosed right subclavian vein</td>
<td>0</td>
</tr>
<tr>
<td>Patient 2</td>
<td>No</td>
<td>LMWH</td>
<td>Thrombosed left internal jugular vein</td>
<td>0</td>
</tr>
<tr>
<td>Patient 3</td>
<td>No</td>
<td>LMWH</td>
<td>Unknown</td>
<td>8</td>
</tr>
<tr>
<td>Patient 4</td>
<td>No</td>
<td>Nil</td>
<td>Thrombus trapped in filter - dislodged by retrieval catheter</td>
<td>0</td>
</tr>
</tbody>
</table>

LMWH: Low Molecular Weight Heparin
VCF complications

- Data available for 429 of 511 VCFs (84%)

- Major complications - 2.6% (n=11)
  - Non fatal PE (n=4)
  - Contrast reaction (n=1)
  - Filter damaged during deployment (n=1)
  - Deployment above renal veins (n=2)
  - Deployment in lumbar plexus (n=1)
  - Symptomatic vena cava thrombosis (n=1)
  - Post retrieval vena cava narrowing requiring balloon dilation (n=1)

- Minor complications - 21.2% (n=91)
  - Non-major complications
  - VCF tilt / mild vena cava narrowing post retrieval
VCF retrieval rates

- Technical success rate for retrieval - 92%
  - (279 retrievals from 302 attempts)

- Overall retrieval rate - 63% (to date)
  - (279 retrievals from 429 placements)
PE & IVC filter insertion rates in Trauma Patients
Trauma Database

<table>
<thead>
<tr>
<th>Year</th>
<th>IVC Filter</th>
<th>PE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>25</td>
<td>7</td>
</tr>
<tr>
<td>2003</td>
<td>44</td>
<td>5</td>
</tr>
<tr>
<td>2004</td>
<td>111</td>
<td>12</td>
</tr>
<tr>
<td>2005</td>
<td>86</td>
<td>8</td>
</tr>
<tr>
<td>2006</td>
<td>146</td>
<td>13</td>
</tr>
<tr>
<td>2007</td>
<td>107</td>
<td>9</td>
</tr>
<tr>
<td>2008</td>
<td>72</td>
<td>19</td>
</tr>
<tr>
<td>2009</td>
<td>47</td>
<td>20</td>
</tr>
<tr>
<td>2010</td>
<td>79</td>
<td>32</td>
</tr>
</tbody>
</table>
Major Trauma ONLY

PE Incidence & IVC Insertion rate in major trauma [ISS98 >15]

<table>
<thead>
<tr>
<th>Year</th>
<th>IVC in ISS98&gt;15</th>
<th>PE rate in ISS98 &gt;15 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>24</td>
<td>0.79%</td>
</tr>
<tr>
<td>2003</td>
<td>42</td>
<td>0.65%</td>
</tr>
<tr>
<td>2004</td>
<td>98</td>
<td>0.99%</td>
</tr>
<tr>
<td>2005</td>
<td>73</td>
<td>0.68%</td>
</tr>
<tr>
<td>2006</td>
<td>127</td>
<td>0.86%</td>
</tr>
<tr>
<td>2007</td>
<td>86</td>
<td>0.59%</td>
</tr>
<tr>
<td>2008</td>
<td>63</td>
<td>1.37%</td>
</tr>
<tr>
<td>2009</td>
<td>41</td>
<td>1.49%</td>
</tr>
<tr>
<td>2010</td>
<td>41</td>
<td>2.27%</td>
</tr>
</tbody>
</table>
Safety of IVC filters

- Caval thrombus
  Smoot et al, J Trauma April 2010
  Retrospective review 226 trauma patients with IVC filters
  27(12%) had documented thrombus within or below filter
  15(7%) clinically significant thrombus

- Access site thrombosis
  Molgaard et al, Radiology 1992 – femoral thrombosis 35%
  Rosenthal et al, J Vasc Surg 2004 – femoral thrombosis 1%
88 / 102 consecutive patients followed up with average of 4 years

Pelvic or acetabular fractures + preoperative DVT had IVC filters inserted.

No patients readmitted with DVT or PE

7% lower extremity swelling, 1 patient PTS

“filter placement use is not associated with the same long term complications as in patients with thrombosis because of chronic medical comorbidities.”
Filters have changed

- Do we need to retrieve as aggressively as was the original intention?
  - PREPIC VCF’s plagued by high DVT rates
  - But we do not seem to see the same complications
  - Recurrent DVT/ filter thrombosis/ access thrombosis uncommon
  - However, new problems
    - Filter penetration?
    - Filter fractures?
    - Filter migration?
Filter struts outside the IVC wall on CT 85.9%
89.1% removed successfully
No major complications

Animal models suggesting that CT caval penetration of IVC filter reflects a much lower rate of true penetration

Proctor et al, 1993 – all on CT: 0 at laparoscopy
Laborda et al, 2011 - 59.3% CT: 44% laparoscopy
IVC retrieval controversies

Retrievability and follow up

- Large variance (11% to 65%)
- Higher rates of retrieval in ANZ

FDA August 2010; “The FDA is concerned that these retrievable IVC filters, ..., are not always removed once patients risk for PE subsides.”
The Deductive Argument for Retrievable IVC Filters

Deductive Reasoning #1

VTE* causes high mortality → YES

VTE* requires prophylaxis → YES

High-risk trauma patients are at high risk for VTE* → YES

↓

Therefore: High-risk trauma patients require VTE prophylaxis

Deductive Reasoning #2

High-risk trauma patients require VTE prophylaxis → YES

Some high-risk trauma patients cannot have anticoagulation → YES

IVC filters are affective in prevention of PE^ → YES

↓

Therefore: Some high-risk trauma patients will require an IVC filter

Deductive Reasoning #3

Some high-risk trauma patients will require an IVC filter → YES

Permanent IVC filters cause long-term complications → YES

Retrieved IVC filters avoid long-term filter complications → YES

↓

Therefore: Retrievable IVC filters are indicated in high-risk
IVC filters
what do we know?

- Safe
- Efficacy established in proximal DVT were anticoagulation is problematic.
- Probable efficacy in trauma for select groups
What do we not know?

- **DVT/ PE**
  - Increasing incidence?
  - Do PE’s all come from our lower limb DVT?
  - Does ultrasound surveillance work in this cohort?

- **Filters**
  - Which trauma patients to put these in?

- **Retrieval**
  - What are the right retrieval rates and indications?
  - Dissolving filters?
Where to?

- Desperately need better data
  - RCT
  - Large registries
  - Other

- Dissolvable filters/ Convertible