IVC Filter Registry Update
(i.e., PRESERVE)
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Pulmonary Emboli

Indications for Vena Cava Filters According to the FDA
• **All vena cava filters are cleared by the FDA only for the prevention of recurrent PE when anticoagulation fails**

Trends in Filter Use
• Reviewed National Hospital Discharge Survey database, patients with DVT, PE, and vena cava filters (VCF)
  - 2,000 VCF in 1979
  - 49,000 VCF in 1999
  - 45% of VCF in patients with DVT alone
  - 36% in patients with PE
  - 19% had neither Dx; “presumably were at high risk”
  - The use of VCF was more frequent in northeastern states than in western states (p = 0.01)


2010
Societal Response to FDA Communication

• Discussions between members of the
  • Society of Interventional Radiology (SIR),
  • The Society for Vascular Surgery (SVS), and
  • The FDA
  began in November, 2010, and we
• Defined questions (see next slide), and
• Considered the best method to answer questions
  • RCT versus other, considering
    • Scope
    • Participants
    • Logistics (including funding)

2010-2011
FDA’s Questions

• Include:
  – What are the types and rates of adverse events (AE) associated with permanent and retrievable filters?
  – Are there device designs or materials that are more prone to those AE?
  – What are the most common AE associated with off label use?
  – What is the rate of prophylactic (vs. on-label) IVCF placement?
  – What is the proportion of permanent to retrievable filters being implanted?

2010-2012
Options

• RCT is inadequate to address complicated landscape (devices, indications, variable use, etc.)
• Registries, e.g., the MAUDE database, have no denominator
• Need a prospective study with definitions
  – Subject population (demographics - Who? Why?)
  – Device(s)
  – Goals (e.g., prophylaxis vs standard indication)
  – Terms (e.g., DVT, migration, perforation)
  – Methodology (e.g., imaging at X time point)
  – Outcomes (e.g., freedom from complication)

Prospective Study = PRESERVE

• FDA, SIR and SVS, with input from representatives of other societies and from vena cava filter manufacturers, drafted the PRESERVE protocol, directed toward the evaluation of the safety and effectiveness of IVCF, and to answering the FDA’s other questions as well
• That study was presented to the FDA on August 10, 2012

PRESERVE 2013-2014

• SIR and SVS formed a joint foundation, the "IVC Filter Study Group Foundation" a 501(c)(3) not-for-profit entity which sponsors and oversees PRESERVE
• The IVCFSFG chose New England Research Institutes (NERI) as CRO
• Working with NERI, the IVCFSFG steering committee completed the protocol
• The FDA approved the PRESERVE IDE
**PRESERVE**

**Supporting Manufacturers & Devices**
- ALN Implants Chirurgicaux
- Argon Medical Devices, Inc./Rex Medical
- B. Braun Interventional Systems, Inc.
- Bard Peripheral Vascular, Inc.
- Cook Incorporated
- Cordis Corporation
- Volcano Corporation
- ALN Vena Cava Filters
- Option Elite Retrievable Vena Cava Filter
- VenaTech LP Vena Cava Filter
- DENALI Vena Cava Filter System
- Günther Tulip VCF
- OptEase/TrapEase VCF
- Crux Vena Cava Filter

**Trial Leadership**

Sponsor: IVC Filter Study Group Foundation
- Society of Interventional Radiology
- Society for Vascular Surgery

Steering Committee:
- David Gillespie, MD, Co-Chair
- Matthew Johnson, MD, Co-Chair
- Jeanne Laberge, MD
- James Spies, MD
- Rodney White, MD

Contract Research Organization:
- New England Research Institutes, Inc.

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**PRESERVE October 2, 2015**

- A core lab has been selected
  - NERI is working with the ACR to use TRIAD to anonymize images presented to core lab
- 60 sites selected
  - 7 sites have both budget & IRB complete
  - 1 site has completed site training
- Case report forms have almost been finalized
- Enrollment of the first PRESERVE subject anticipated to occur this month

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**PRESERVE Methods**

- Prospective, multicenter, single-arm clinical trial of adults (≥ 18 years of age) in whom IVCF are clinically indicated
- Primary endpoints
  - Safety = freedom from major complications
  - Effectiveness = freedom from PE
- ~2100 subjects will be enrolled, with a minimum of ~300 subjects per filter type

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**Table 1: Time and Event Schedule for Trial**

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- Subjects whose filters are removed will be evaluated 1 month following removal
Start-up Status

60 Sites Selected
- Specialty Distribution as Contact PI
- 36 Interventional Radiologists as Contact PIs
- 18 Vascular Surgeons as Contact PIs
- 1 Trauma Surgeon as Contact PI
- 5 Undetermined Contact PIs
- Fairly Even Geographic Distribution across the US
- Equitable Distribution of Sites using Filters from Participating Manufacturers

Activation Status

2 Sites Activated!
- 2 Sites Activated last week

58 Sites in various stages of Start-up
- 11 Sites – Have both IRB approval and Executed CTA, minor outstanding items for activation remain
- 29 Sites – Have IRB approval, awaiting executed CTA and minor outstanding items
- 12 Sites – Have executed CTA, awaiting IRB approval and minor outstanding items
- 6 Sites – Still awaiting IRB approval, CTA execution, training, and regulatory document collection

Enrollment Status

First Patient In – 13/Oct/2015!

4 Patients Enrolled as of 09/Nov/2015

Visit our public website for more information:
www.preservetrial.com