Treatment of AAA in the Endovascular Era

Richard L. McCann MD
Duke Medical Center
Famous People with AAA

- Albert Einstein
- Conway Twitty
- Lucille Ball
- Nelson Rockefeller
- George C. Scott
- Charles DeGaulle
- Bob Dole

- N=50,000/yr, 13th leading cause of death
History

- **Matas (1860-1957)**
  - 98 total cases
  - 25 restorative (2.4 % mortality)

- **Dubost 1951**
  - first successful graft
History

- Voorhees 1952
  - fabric graft (Vinyon N)
- Ochsner 1966
  - endoaneurysmorrhaphy
- Parodi 1991
  - first AAA endograft
- Moore (EVT-Ancure) 1995 - 1999
  Fogarty (AneuRx)
Epidemiology

- **age**
  - M > 70, F > 80

- **gender**
  - M:F 4:1

- **race**
  - W:AA 4:1

- **genetics**
  - mother 50%, father 20%
Key Clinical Data

- 5 cm rule
  - Olmsted Co Data
- mortality
  - 2.1%, 4.2%, 7.3%
- morbidity
  - cardiac, pulmonary
- consequences of rupture
  - 95% mortality, 50% if operation
Key Clinical Data

- **UK Small Aneurysm Trial**
  - NEJM 346:1445-52, 2002
  - Multicenter randomized trial 4.0-5.5 cm AAA (U/S) early surgery vrs watchful waiting
  - No long term (8yr) aneurysm survival benefit, but lower overall mort. Attributed to lifestyle change e.g. smoking
  - 5.5 % operative mortality
Key Clinical Data

Aneurysm Detection And Management

- VA Cooperative Study Group
- NEJM 346:1437-44, 2002
- Multicenter Randomized 4.0-5.4 cm AAA early open surgery vrs watchful waiting
- N=569 open (92.6% had repair) 567 surveillance (61.6% had repair)
- No survival advantage for preemptory repair
- Midas comment
Incisions for endovascular AAA repair
Endovascular Operation

- **Approved**
  - Ancure (Guidant)
  - AneuRx (Medtronic)
  - Excluder (Gore)
  - Zenith (Cook)
  - Powerlink (Endologics)
  - Talent (World Medical)

- **Seeking Approval**
  - Lifepath (Edwards)
  - Trivascular (Boston Scientific)
  - Aptus (staple)
Endovascular Operation

- Failed
  - Vanguard I-IV (Meadox, William J. von Liebig)
  - Corvita (Pfizer)
## Major Differences

<table>
<thead>
<tr>
<th>Approach</th>
<th>Pre-op evaluation</th>
<th>Follow-up</th>
<th>Resource utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td>Minimal (U/S)</td>
<td>Minimal</td>
<td>Concentrated</td>
</tr>
<tr>
<td>Endovascular</td>
<td>Extensive (CAT, 3D, Agram)</td>
<td>Unlimited (Q 6 mos CAT)</td>
<td>Extended</td>
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</table>
## Major Differences

<table>
<thead>
<tr>
<th></th>
<th>Conventional</th>
<th>Endovascular</th>
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<tbody>
<tr>
<td>LOS</td>
<td>11 days</td>
<td>2 days</td>
</tr>
<tr>
<td>ICU</td>
<td>4.5 days</td>
<td>0.5 days</td>
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<tr>
<td>Anesthesia</td>
<td>GOT</td>
<td>Regional</td>
</tr>
<tr>
<td>Convalescence</td>
<td>120 days</td>
<td>10 days</td>
</tr>
<tr>
<td>Pt Satisfaction</td>
<td>88%</td>
<td>98%</td>
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</table>
Key Clinical Data

- **D**utch **R**andomized **E**ndovascular **A**neurysm **M**anagement **T**rial (NEJM 352:2398-405, 2005)
  - Multicenter randomized open vrs endo
  - N= 351; AAA>5cm
  - Perioperative (30 day) survival advantage of endo not sustained at two years
  - 2 y survival 89.6 open, 89.7 endo
  - Comment: no disadvantage of endo
<table>
<thead>
<tr>
<th>BRAND</th>
<th>COMPANY</th>
<th>DESIGN</th>
<th>STENT</th>
<th>FABRIC</th>
<th>DISTINCTION</th>
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</thead>
<tbody>
<tr>
<td>Ancure®</td>
<td>Guidant</td>
<td>unibody</td>
<td>hooks body unsup- ed</td>
<td>PET polyester</td>
<td>best clinical results</td>
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<tr>
<td>AneuRx®</td>
<td>Medtronic</td>
<td>bi-modular</td>
<td>Nitinol exo-skeleton</td>
<td>polyester</td>
<td>easiest to insert</td>
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<tr>
<td>BRAND</td>
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<td>----------------------------------</td>
</tr>
<tr>
<td>EXCLUDER</td>
<td>W L GORE</td>
<td>MODULAR</td>
<td>NITINOL</td>
<td>ULTRA THIN PTFE</td>
<td>LOW PROFILE</td>
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<tr>
<td>ZENITH</td>
<td>COOK</td>
<td>TRIMODULAR, LONG BODY</td>
<td>STEEL</td>
<td>PET</td>
<td>SUPRA RENAL FIXATION</td>
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<tr>
<td>POWERLINK</td>
<td>ENDOLOGIX</td>
<td>UNIBODY</td>
<td>COBALT CHROMIUM SINGLE WIRE CAGE</td>
<td>THINWALL PTFE FREE FLOATING FROM STENT</td>
<td>LONG UNIBODY SINGLE INCISION, NO MIGRATION</td>
</tr>
<tr>
<td>BRAND</td>
<td>COMPANY</td>
<td>DESIGN</td>
<td>STENT</td>
<td>FABRIC</td>
<td>DISTINCTION</td>
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<td>---------------------------------</td>
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<tr>
<td>Lifepath®</td>
<td>Edwards</td>
<td>Tri-modular</td>
<td>Elgiloy®</td>
<td>polyester</td>
<td>Hybrid self &amp; balloon expand</td>
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<tr>
<td>Talent®</td>
<td>World Medical /Medtronic</td>
<td>Bi-modular</td>
<td>Z stent</td>
<td>Polyester</td>
<td>Supra-renal fixation Thoracic model</td>
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<tr>
<td>MEG</td>
<td>TBA</td>
<td>Uni-femoral</td>
<td>Palmaz</td>
<td>ePTFE</td>
<td>One size fits most</td>
</tr>
<tr>
<td>Aptus</td>
<td>Aptus</td>
<td>trimodular</td>
<td>nitinol</td>
<td>pet</td>
<td>Staple fixation</td>
</tr>
</tbody>
</table>
APTUS ENDOSYSTEMS
APTUS ENDOSYSTEMS
APTUS ENDOSYSTEMS
Making the Diamond
Confirm Renal Location
Measure Contra Length
Completion
Customized Design

Extensive selection of individual components provides physicians with the ability to customize each AAA graft to patient’s anatomy.

Investigational device, limited by federal (U.S.A.) law to investigational use.
Built on our proven Zenith® platform, the Zenith® Fenestrated AAA Endovascular Graft offers customized solutions for an expanded range of AAA patients.

Investigational device, limited by federal (U.S.A.) law to investigational use.
GORE EXCLUDER® Endoprosthesis
For the Treatment of
Infrarenal Abdominal Aortic Aneurysms

- First implantation in 1997
- FDA approved in November 2002
- 15,000 Devices implanted through May 2004
- 3 Ruptures worldwide (all due to Type I endoleaks)
GORE EXCLUDER® Endoprosthesis

Implant and Deployment Steps

- Deliver the Trunk-Ipsilateral Leg Endoprosthesis through an 18 Fr Introducer sheath

- Utilizing a 18 Fr x 30 cm long introducer sheath, withdraw the introducer sheath to the white shaft marker on the delivery catheter.

- Ensure accurate proximal and rotational position*

- Deploy the endoprosthesis utilizing the GORE SIM-PULL Delivery System

- Inflate balloon to seat the aortic end of the endoprosthesis

- Cannulate the Contralateral Trunk (leg hole) with a guidewire

* Positioning of the gold markers can be achieved by rotating the Trunk-Ipsilateral delivery catheter no more than 180° in either direction. Do not rotate the Trunk delivery catheter beyond 360° to avoid delivery system damage and/or premature deployment.

⚠️ Attention, See Instructions for Use
GORE EXCLUDER® Endoprosthesis

Implant and Deployment Steps

- Deliver the Contralateral Leg Endoprosthesis through a 12 Fr / 18 Fr Introducer sheath
- Withdraw sheath back to white delivery catheter marker
- Ensure proper position of proximal end of device
- Deploy the endoprosthesis utilizing the GORE SIM-PULL Delivery System
- Inflate balloon to seat the ends of the endoprosthesis
- Insert and deploy Aortic and Iliac Extenders if needed
- Perform angiography to confirm exclusion of the aneurysm

⚠️ Attention, See Instructions for Use
GORE EXCLUDER® Endoprosthesis

4-Year Clinical Update*
U.S. Pivotal Trial Data

Summary of Conversion, Death, Aneurysm-Related Death, and Rupture

<table>
<thead>
<tr>
<th></th>
<th>Conversion</th>
<th>Death¹</th>
<th>Aneurysm-Related Death</th>
<th>Rupture</th>
<th>Aneurysm Size Increase²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>%</td>
<td>#</td>
<td>%</td>
<td>#</td>
</tr>
<tr>
<td>Perioperative (&lt; 30 days)</td>
<td>0 (0%)</td>
<td>3 (1.3%)</td>
<td>3 (1.3%)</td>
<td>0 (0%)</td>
<td>N/A</td>
</tr>
<tr>
<td>1 year</td>
<td>0 (0%)</td>
<td>14 (6.0%)</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
<td>6 (3.1%)</td>
</tr>
<tr>
<td>2 year</td>
<td>3 (1.4%)</td>
<td>16 (7.4%)</td>
<td>1 (0.5%)</td>
<td>0 (0%)</td>
<td>16 (9.8%)</td>
</tr>
<tr>
<td>3 year</td>
<td>1 (0.5%)</td>
<td>12 (6.2%)</td>
<td>0 (0%)</td>
<td>0³ (0%)</td>
<td>29 (22.1%)</td>
</tr>
<tr>
<td>4 year</td>
<td>5 (3.1%)</td>
<td>9 (5.6%)</td>
<td>1 (0.6%)</td>
<td>0 (0%)</td>
<td>36 (33.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>9 (3.8%)</td>
<td>54 (23%)</td>
<td>6 (2.6%)</td>
<td>0 (0%)</td>
<td>56 (23.8%)</td>
</tr>
</tbody>
</table>

¹ Deaths are reported in the interval in which they occurred.
² Change in maximum aneurysm diameter of ≥ 5 mm from 1 month baseline.
³ One rupture occurred in the Feasibility Study in a subject with an untreated Type I endoleak.
4 Subjects that experienced aneurysm size increase in multiple intervals are counted only once.

* Site Reported Data Through May, 2004
Surveillance

- Current protocol
  - CTA @ 1,6,12,q12months--lifetime
  - Duplex, MRI used less frequently
    - Contrast reaction
    - Steel stents obviate MRI
MicroElectrical Mechanical Systems
Rapid Miniaturization of Sensor Technology

AAA
30 mm

CHF
14 mm

Hypertension
5 mm

[Images of sensor technology devices]
Implant Procedure
The EndoSure™ AAA Wireless Pressure Sensor
Stent Graft Challenges – Need For EndoSure Sensor

- Angiography provides subjective images which are not definitive about existence, location or type of leak
- Stent Grafts continue to present a long-term risk of leaking which increases over time
- Patient compliance to current surveillance is questionable
Regulatory Status

- On October 28, 2005 CardioMEMS received written authorization from the FDA to market the EndoSure AAA Pressure Sensor.
- 510 k # K050939
- Classification: Type II
- Product Code: NQH
- Extended to TAA March 2007

(Letter on file at CardioMEMS)
Type 1 & 3 endoleaks transmit high pressure

Type 2 & 4 endoleaks transmit variable pressure
Advantages

- Acute
- Measures most important metric—pressure
- Confirms successful sac exclusion
- Reduced radiation and contrast load
Advantages

- Chronic (potential)
- Better compliance
- More frequent surveillance
- Decreased contrast and radiation dose
- Direct therapy for type II leaks
Disadvantages

• Cost ~ $4000
• Frequent denials
• Requires thrombus free lumen
• 14 fr sheath
• Poor deployment precision
• Signal integrety in chest
Sensor Accuracy

Catheter vs. EndoSensor Correlation

Catheter (mm Hg) vs. EndoSensor (mm Hg) correlation with a P-value of <0.05.
Results:

Intraoperative Sac Pressure Ratio

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>Balloon</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P</strong>&lt;0.001</td>
<td>1.02±0.23</td>
<td>0.63±0.31</td>
<td>0.36±0.24</td>
</tr>
</tbody>
</table>

*P<0.001

**P<0.001
Summary

1.02 ± 0.23

0.63 ± 0.31

0.36 ± 0.24

0.19 ± 0.14

0.12 ± 0.08

* p<0.001

** p<0.001

*** p<0.001
Results:

Stent Graft Sac Pressure

<table>
<thead>
<tr>
<th>Sac Pressure Ratio</th>
<th>GORE</th>
<th>COOK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.13±0.11</td>
<td>0.26±0.14</td>
</tr>
</tbody>
</table>

P<0.007
Future EVAR Surveillance Protocol

- Monthly-Biannual wireless pressure sensing
- Abdominal Radiography every 6 months to detect graft migration, component separation, stent fractures
- CT and/or angiogram only if abnormality detected by pressure sensor or X-ray
CardioMEMS in Type I Leak

- 73 yo Female
- 5.3 cm AAA (↑ 1 cm in 6 mos)
- Smoker
- Caretaker of Down’s child
- Gore Excluder planned
Excluder Deployment

Short neck

Pre-Exclusion
Post deployment

No change in pulse pressure
Proximal leak
Proximal cuff

Pulse pressure drop
CardioMEMS example

- 83 YO Extent II TAAA
- Lives alone, son ER MD
- RLQ pain, aneurysm tender
- 8.5 Cm TAAA
- Normal ECHO, carotid U/S
MEMS

Pre exclusion

91/45 (71) <46>

Post exclusion

0.60

91/64 (76) <27>
1 MONTH POST OP
The care of patients with an abdominal aortic aneurysm: The Society for Vascular Surgery practice guidelines

Elliot L. Chaikof, MD, PhD, David C. Brewster, MD, Ronald L. Dalman, MD
Michel S. Makaroun, MD, Karl A. Illig, MD, Gregorio A. Sicard, MD, Carlos H. Timaran, MD
Gilbert R. Upchurch Jr, MD, and Frank J. Veith, MD, Atlanta, Ga, Boston, Mass, Palo Alto, Calif, Pittsburgh, Penn, Rochester, NY; St. Louis, Mo, Dallas, Tex, Ann Arbor, Mich, and Cleveland, Ohio

DEFINITION OF THE PROBLEM

Purpose of these guidelines

The Clinical Practice Council of the Society for Vascular Surgery charged a writing committee with the task of updating practice guidelines, initially published in 2003, for surgeons and physicians who are involved in the preoperative, operative, and postoperative care of patients with abdominal aortic aneurysms (AAA). This document provides recommendations for evaluating the patient, including risk of aneurysm rupture and associated medical co-morbidities, guidelines for selecting surgical or endovascular intervention, intraoperative strategies, perioperative care, long-term follow-up, and treatment of late complications.

Decision making related to the care of patients with AAA is complex. Aneurysms present with varying risks of rupture and patient specific factors influence anticipated life expectancy, operative risk, and the need to intervene. Careful attention to the choice of operative strategy, as influenced by anatomic features of the AAA, along with optimal treatment of medical co-morbidities is critical to achieving excellent outcomes. Moreover, appropriate postoperative patient surveillance and timely intervention in the case of a late complication is necessary to minimize subsequent aneurysm-related death or morbidity. All of these clinical decisions are determined in an environment where cost-effectiveness will ultimately dictate the ability to provide optimal care to the largest possible segment of the population. Currently available clinical data sets have been reviewed in formulating these recommendations. However, an important goal of this document is to clearly identify those areas where further clinical research is necessary.
Pre-test

- 65 yo male patient with 6.2 cm AAA, favorable anatomy for EVAR. DMI 5 years ago. No chest pain or SOB. Is able to cut his grass. Stress test shows no reversible ischemia and EF 47%. Cath shows 50% in LAD bridging large D1 and total RCA lesions (anatomically challenging PCI)

- A. PTCA with DES and EVAR in one year (stop plavix 10 days preop)

- B. PTCA with BMS and EVAR in 4-6 weeks (continue plavix)

- C. CABG/ Open AAA combination operation

- D. CABG followed by EVAR in 4-6 months

- D. EVAR –medical Rx of CAD
Pre-test

- 65 yo male 5.5 cm AAA with 10 mm X 28 mm angulated neck. AAA found during cath during which DES placed in LAD for USA, now pain free.

- A. OSR 4-6 weeks, stop plavix 10 days.
- B. OSR 4-6 weeks, convert plavix to ASA only (325 mg)
- C. EVAR on plavix
- D. OSR in one year, stop plavix 10 days.
AAA Guidelines (“‘DUH’s’”) 

- AAA patients need PE to assess for femoral/popliteal aneurysms
- Patients with active cardiac disease (unstable angina, decompensated CHF, severe valve disease should be treated before EVAR/OSR
- AAA should have EKG before EVAR/OSR
- If patient has indication for betablockers they should take them
AAA Guidelines ("DUH’s")

- Reimplantation of a patent IMA should be considered under circumstances that suggest an increased risk of colonic ischemia.
- Immediate repair is recommended for patients that present with documented aneurysm rupture.
AAA Guidelines (‘‘DUH’s’’)

- Patients with renal insufficiency should be hydrated before exposure to contrast.
  - Type, route, volume, duration, timing, not defined
  - Little/no evidence for manitol, allopurinol, vit C, vit E, mucormyst
- Patients with new abdominal or back pain and pulsatile mass should have a CAT scan
AAA Guidelines

- Mortality of OSR affected by
  - Specialty (GSU 76% higher)
  - Surgeon Volume (low 40% higher)
  - Hospital Volume (low 30% higher)
AAA Guidelines (debatable)

- Non-invasive stress test for patients with 3 or more risk factors
  - CAD, CHF, CVA, DM, CRI, poor (or unknown) functional status
- CABG/PCI before EVAR/OSR
  - Acute MI, USA, stable angina & LM or 3v dz
  - Asx or stable c 2VD (LAD) and ischemia or EF <0.5
AAA Guidelines (debatable)

- Screening
  - Q 60 mos  AAA 2.6-2.9
  - Q 36 mos  AAA 3.0-3.4
  - Q 12 mos  AAA 3.5-4.4
  - Q  6 mos  AAA >4.5
AAA Guidelines (debatable)

- Tube grafts are preferred over bifurcated
- EVAR OK for high risk patients unfit for OSR
- Central Venous Access (but **NOT** S-G Cath) is recommended during OSR
- OK to cover both hypogastrics in high risk for OSR
Controversies not addressed

- Frequency/ type of surveillance after EVAR
- Surveillance after OSR
- Treatment of type II leaks
- Influence of 3-D reconstruction on EVAR
- Cost of OSR vrs EVAR
- Use of blood products/salvage in OSR
- DVT prophylaxis
- Anesthesia for EVAR