

Unwelcome Complication of EVAR?

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Presenter Disclosure Information

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Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

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- Acist Medical Systems Grant; and
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<u>**Patents</u></u> -- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure</u>**

Aneurysms are Common

- In a large US study
 - --.7% in women
 - -- 3.9% in men
- If we screen all men between 65 and 75 years of age, for each 20th person, will detect one aneurysm...but this only picks up 29.9% of potential ruptures

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• What about siblings?

Aneurysms are Common

Siblings

11% incidence-- 17% of brothers-- 6% of sisters



Abdominal Aortic Aneurysm Rupture

Annual Risk of Rupture <5 cm 1-2% >5-6 cm 10% >6 cm 25%





AAA Surgical Repair



Abdominal Aortic Aneurysm Scope of Problem

- 40,000 surgical repairs annually
- Operative mortality 1-5% in good surgical risk patients
- Operative mortality >10% in higher risk surgical candidates
- Significant operative morbidity: 15-30% incidence of major post operative complications





EVAR



Endovascular Aneurysm Repair



 1990 implanted the first Aortic Stent Graft in a highrisk pt with a symptomatic AAA

- Pt survived and died of pancreatic cancer nine years later
- 1991 Reported initial clinical results

• When patients undergo EVAR of AAA, there are increased rates of graft related complications and reinterventions (by a factor of 3-4) and EVAR is more costly

N. Engl J Med 2010; 362:1863-1871. The United Kingdom. EVAR Trial Investigators.





















A 47 year old white male presented with infra-renal abdominal aortic aneurysm that was symptomatic

• His CT angiogram revealed a very proximal left interior iliac artery and a dissection of the left common iliac artery.





Figure 1 -- Angiogram showing abdominal aneurysm with left common and external iliac dissection. Note the proximal takeoff of the left internal iliac artery.





Figure 2 -- Large arrow showing chronic dissection of left common iliac artery. Small arrow showing proximal take-off of left internal iliac artery.





Figure 3 -- Selective angiogram of the left internal iliac artery.



Figure 4 -- Angiogram of left internal iliac artery post coil placement.



Figure 5 -- Final result post endograft placement. Note there is no flow noted in the left internal iliac.



EVAR













Post Implant Syndrome

- Back pain
- Fever
- 50% of cases
- 2-3 days (up to 7)
- Negative cultures
- No increase in white blood count
- Usually benign



Endoleak

- Fix at the time of procedure
- Don't convert to open repair





Red arrows indicate blood flow.

N Eng J Med 338;5, January 31, 2008, p. 499





Figure 100-13 Important collateral pathways for the sigmoid colon and pelvis. IMA, inferior mesenteric artery; SMA, superior mesenteric artery. (From Bergman RT, Gloviczki P, Welch TJ, et al: The role of intravenous fluorescein in the detection of colon ischemia during aortic reconstruction. Ann Vasc Surg 6:74, 1992.)

AAA Endovascular Repair Follow Up

- 1 month CT
- 6 month CT
- 12 month CT
- 18 month CT
- Yearly CT

What about MRI or Abdominal Ultrasound?





Red arrows indicate blood flow.

N Eng J Med 338;5, January 31, 2008, p. 499

Type I Leak All should be treated

- Extension cuff with noncompliant balloon
- When close to renal artery and persists a Palmaz stent
- Distal leaks can be repaired usually with extension limbs or cuffs (sometimes to the external iliac with coil embolization to the hypogastric)





Fig. 9 Nitinol stent frame of the Aptus device in the infrarenal aorta. Endostaples can be seen affixing the graft to the vessel wall.



















Juxtarenal: Zenith[®] Fenestrated




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CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.

Type II Leak

- Extension cuff with noncompliant balloon
- If persistent and greater than 5mm growth after implant should be treated
- TLA needle cyanoacrylate glue







Type II Endoleaks: What's new

- Type II endoleaks with aneurysm sac growth are not benign and should be treated by endovascular embolization.
- Current imaging modalities have improved the detection of type II endoleaks, but further improvements are still needed.
- Endograft explanation and open conversion is still required in some EVAR patients.
- Future innovations in next-generation endograft design should focus on eliminating the occurrence of type II endoleaks.

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Type III endoleak due to separation of the contralateral leg from the main body (a, b) treated by insertion of a stent graft (c).

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Type III Leak

- Leak should be treated with a bridging endograft
- Relining if room between the renal arteries and bifurcation of the original endograft



Type IV Leak

Heparin offUsually no Rx



TYPES, ETIOLOGY, AND TREATMENT OF ENDOLEAKS

Туре	Etiology	Treatment
1	Attachment Site	PTA, Balloons, Stents
2	Collaterals	Embolization
3	Graft Failure	Graft Repair
4	Pourosity	No Treatment Needed







Figure 101-8 Freedom from aneurysm rupture after endovascular aneurysm repair in patients categorized according to endoleak: with isolated type II endoleak, with type I or type III endoleak, and without endoleak. (From Van Marrewijk C, Buth J, Harris PL, et al: Significance of endoleaks after endovascular repair of abdominal aortic aneurysms: The EUROSTAR experience. J Vasc Surg 35:461-473, 2002.)

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Abdominal Aortic Aneurysm Surveillance

- In patients with small aneurysms
- After endograft
- After open repair
- Many of these patients have renal insufficiency











BUSINESS/FINANCIAL DESK | June 17, 2003, Tuesday Medical Concern Will Halt Sales Of Artery Device Linked to Deaths

By MELODY PETERSEN (NYT) 746 words Late Edition - Final, Section C, Page 1, Column 5

ABSTRACT - Guidant Corp to stop selling device that helps treat weakened abdominal aorta after admitting it concealed thousands of problems linked to product; says 18,000 patients who already have device are safe because problems center on system used to insert it, not device itself; says it will continue to support those patients over years; group chairman Jay Graf says potential liability from dozen suits filed on behalf of patients who died or were injured by device is 'manageable' because product liability insurance will help pay costs (M)



Arizona Medical Systems Four devices developed to deal with common complications of EVAR











Catheter Introducer System Patent # 7,166,088 Issue Date 1/27/07



























Common Iliac: Zenith® Branch Iliac Endovascular Graft

• Bifurcated Branch





Not available for sale in the U.S.

Common Iliac: Zenith® Branch Iliac Endovascular Graft





Not available for sale in the U.S.

Common Iliac: Zenith® Branch Iliac Endovascular Graft

Helical Branch












































Aneurysms

• 1st successful of Freeman is rusm repair was in 1951 if Freeman is Never Beren popular iliac vein graft Harles Dubost used an aortic homograft to Environment replace the aneurysm

• 1st Complete Repair Occurred September 2, 1954 -- Michael DeBakey

SUBJECTED TO LEVEL 1 EVIDENCE

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OPEN REPAIR

Does Require In the proposition Up and Surveil 110
518 Aave Endoleaks or Pseudoaneur JRns
Only 64% Fully Archylatory Post Open RWOULD NOT HAVE IT AGAIN



Endoluminal Stent-Graft Demonstrated Advantages

- Minimally invasive surgery
- Reduced morbidity and ?mortality
- Less blood loss/need for transfusion
- Shorter hospital stay
- Quicker recovery time

Patient Preferred Treatment



CONCLUSION

- Endograft repair of abdominal aortic aneurysm should be considered in all patients who present with a significant AAA
 The results appear to be relatively safe
- Endoleaks and late complications can occur, but can usually be managed effectively non-surgically