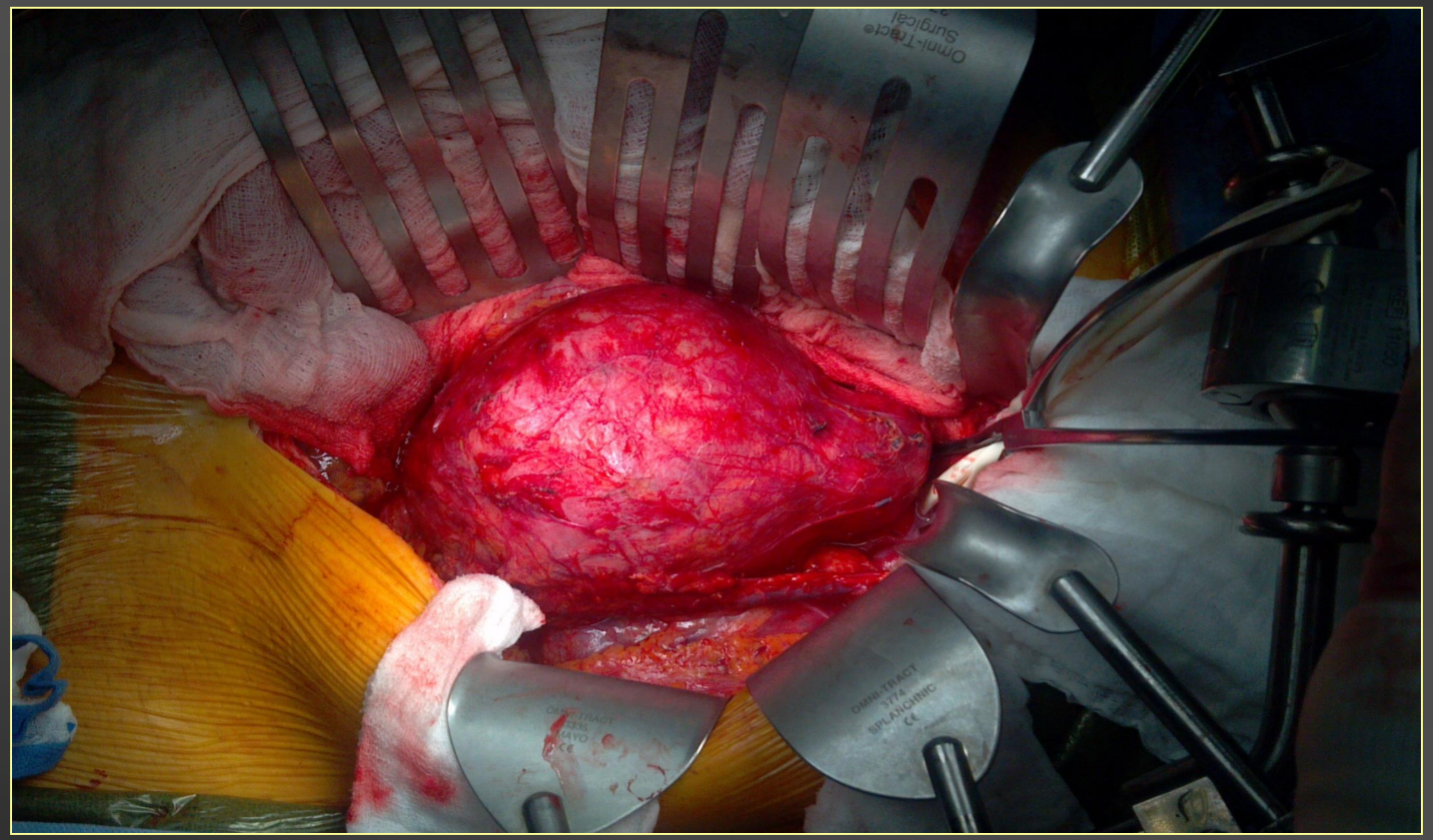
Lesson from the Past:
Open Repair Has a Role, but it is Second Line Treatment



Andres Schanzer, MD

December 17th, 2021
Critical Issues, Paris, France

Disclosures

- Cook Medical, Phillips Imaging, Cryolife
  - Research grants
  - Case proctor
  - Consult

All compensation goes to UMass Memorial Foundation and none to me personally.

Abdominal Aortic Aneurysm

- Epidemiology*
  - 16,000 deaths annually in U.S.
  - 13th leading cause of death in U.S.
  - 10th leading cause of death in men >55

*Dartmouth Atlas of Health Care, 2009.

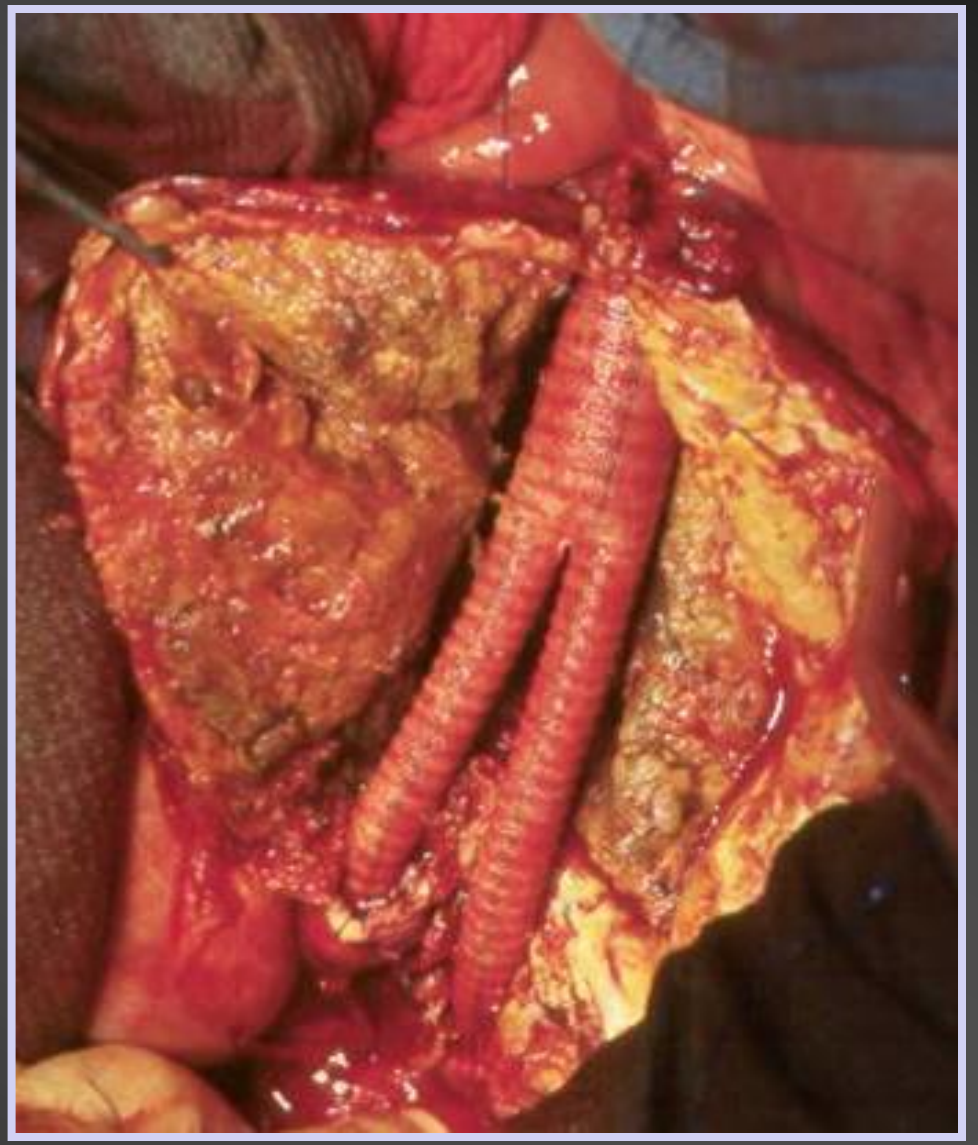
Natural History

- Expansion followed by rupture
  - 0.2-0.4 cm per year expected*

*UK Small Aneurysm, Lancet 1998; ADAM, NEJM, 2002.

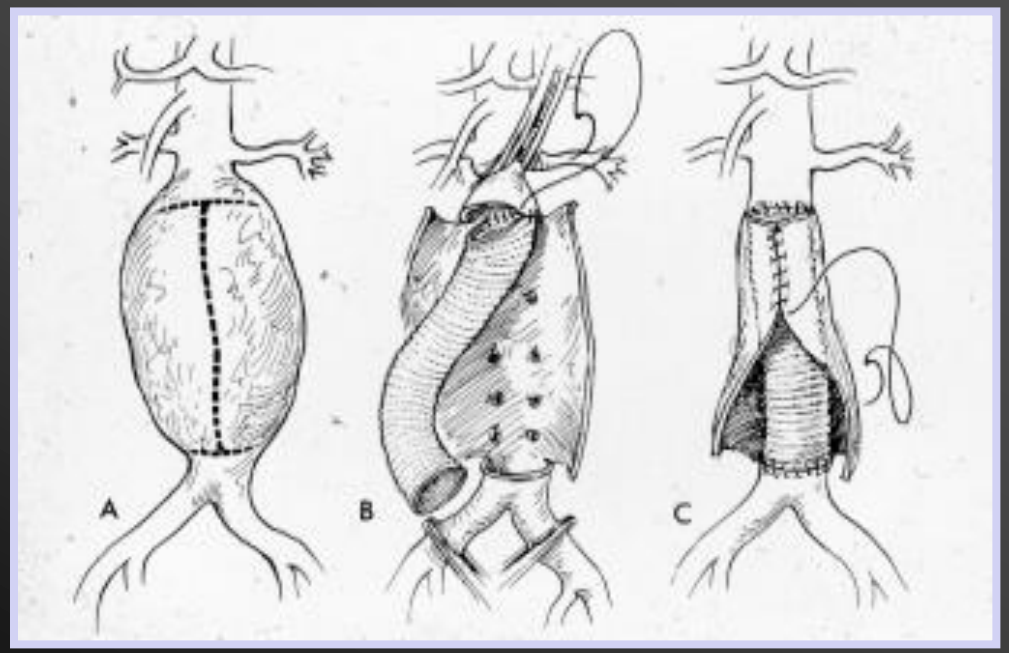
Open Repair

- Direct exposure
  - Transabdominal, retroperitoneal
- Proximal and distal control
- Prosthetic graft sutured to normal artery



Results of Open Repair

Effective and Durable



BUT...

- 5-10% mortality in population-based studies
- 15-30% significant morbidity
- Recovery 2-3 months
- High risk patients often denied repair

AAA Operative Mortality

	n	#Pts	Op Mortality
Single-Center Reports	7	2162	2.1%
Multicenter Reports	5	10,366	4.2%
Population Based Reports	3	9,681	7.3%

5.4% in >22,000 pts with non-ruptured AAA

J Endovasc Surg 1997;4:232

Transformative Moment

1991

Original articles

Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, *Buenos Aires, Argentina, and San Antonio, Texas*

1991

PubMed.gov
US National Library of Medicine
National Institutes of Health

PubMed

Advanced

Display Settings: Abstract

Send to:

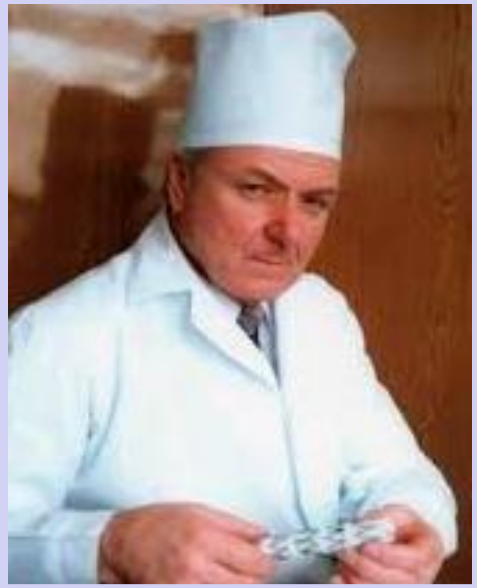
Grudn Khir. 1988 Nov-Dec;(6):84-6.

[A case of distant transfemoral endoprosthesis of the thoracic artery using a self-fixing synthetic prosthesis in traumatic aneurysm].

[Article in Russian]

Volodos' NL, Karpovich IP, Shekhanin VE, Troian VI, Iakovenko LF.

PMID: 3220297 [PubMed - indexed for MEDLINE]



CLINICAL OBSERVATION

Transfemoral, Endovascular Stented Graft Repair of an Abdominal Aortic Aneurysm

Juan C. Parodi, MD; Michael L. Marin, MD; Frank J. Veith, MD

Endovascular aortic graft implantation is a new procedure for the repair of arterial aneurysms. We report on the first such case successfully performed in the United States. A 76-year-old man with severe oxygen-dependent pulmonary insufficiency, coronary artery disease, and recurrent ventricular tachyrhythmia was also diagnosed as having a 7.5-cm infrarenal abdominal aortic aneurysm. Because of the high risks associated with conventional surgical repair, consent was obtained for compassionate use of an experimental device. Using local anesthesia, a 22-mm Dacron prosthesis was inserted under fluoroscopic guidance through an open, left transfemoral route. Completion arteriography demonstrated aneurysm exclusion. No blood transfusion was required and there were no perioperative complications. Further technical refinements and clinical trials will be required prior to the broad implementation of this technique.

(Arch Surg. 1995;130:549-552)

In the United States, >80% of infrarenal elective repairs of AAA are performed utilizing EVAR*

*Lederle et al, NEJM, 2012.

CONTEMPORARY REVIEWS

American Heart Association | American Stroke Association.

Two Decades of Endovascular Abdominal Aortic Aneurysm Repair: Enormous Progress With Serious Lessons Learned

Andres Schanzer, MD; Louis Messina, MD

The modern open surgical management of abdominal aortic aneurysm (AAA) has changed little since its inception in the 1950s. Endoaneurysmorrhaphy, first described by Rudolph Matas in 1888, involved ligating the branches of an aneurysm from within the aneurysm sac. Approximately 25 years later at the beginning of the 20th century, Alexis Carrel received the Nobel Prize for demonstrating the feasibility of suture repair of arteries and perfecting an anastomotic technique to join 2 vessels. With these techniques established, an AAA could be repaired by anastomosis of a synthetic conduit to the aorta just proximal and distal to the AAA, thereby preserving antegrade blood flow.[1] Dubost was the first to marry these 2 techniques in 1952, with the first report of a successful open AAA repair with homograft replacement.[2] Aside from the development of various different types of conduit materials, open AAA repair has remained largely unchanged through to the present day.

the treatment strategy underlying EVAR is completely different than that of open surgical repair. During open repair, the aorta and iliac arteries are clamped, thereby increasing aortic resistance and inducing pelvic and lower-extremity ischemia; the aneurysm is opened; branch vessels are suture-ligated; the aortic aneurysm is replaced with a prosthetic graft; clamps are removed; and blood flow is restored to the pelvis and lower extremities. During EVAR, the aneurysm is left intact, but all blood flow is excluded from the aneurysm by catheter-based deployment of a stent graft, without the necessity to transiently occlude the aorta (Figure 1).

Just as the treatment strategy underlying EVAR is entirely different from that of open AAA repair, the modes of failure also are entirely different. Because the AAA is left intact after EVAR, the patient remains at risk of AAA rupture should flow to the aortic aneurysm sac persist. This phenomenon of persistent flow into an aortic aneurysm sac, despite stent graft place-

*Schanzer et al, JAHA, 2011.

The NEW ENGLAND JOURNAL of MEDICINE

CLINICAL PRACTICE

Management of Abdominal Aortic Aneurysms

Andres Schanzer, M.D., and Gustavo S. Oderich, M.D.

This Journal feature begins with a case vignette highlighting a common clinical problem. Evidence supporting various strategies is then presented, followed by a review of formal guidelines, when they exist. The article ends with the authors' clinical recommendations.

A 64-year-old man presents to his primary care physician for a routine physical examination and is found to have a palpable, midepigastric, pulsatile mass. He reports no abdominal or back pain and can easily climb two flights of stairs. His medical history is notable for well-controlled hypertension and hypercholesterolemia. He reports no family history of aneurysms, but he has smoked one pack of cigarettes per day since he was 16 years of age. Ultrasonographic examination reveals an infrarenal abdominal aortic aneurysm measuring 5.7 cm in its largest diameter. How should this case be further evaluated and managed?

*Schanzer et al, NEJM, 2021.

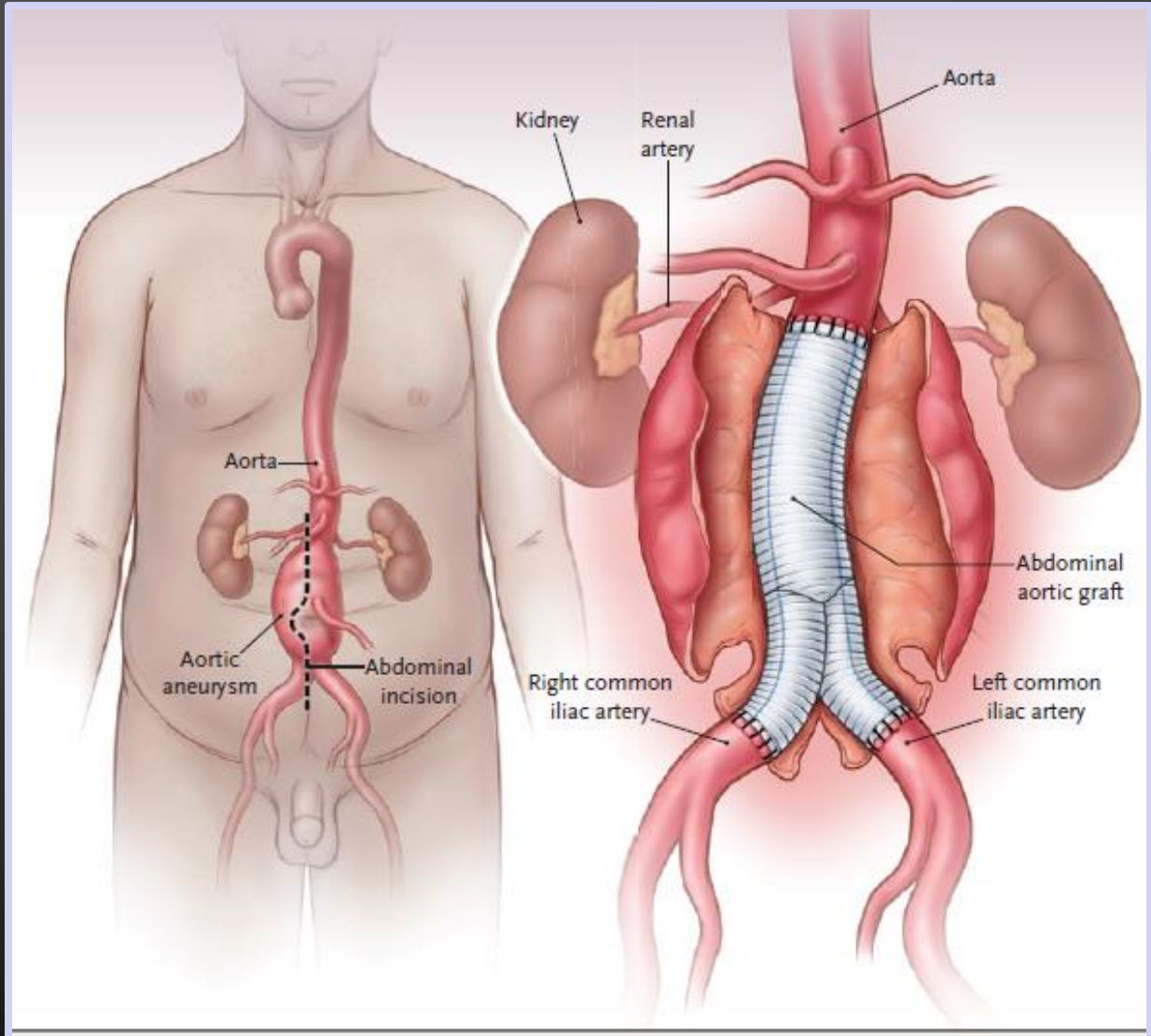


Figure 1. Open Repair of an Infrarenal Abdominal Aortic Aneurysm.
In this procedure, a laparotomy is performed, the aorta is cross-clamped above and below the aneurysm, and a prosthetic graft is sewn in place of the aneurysm.

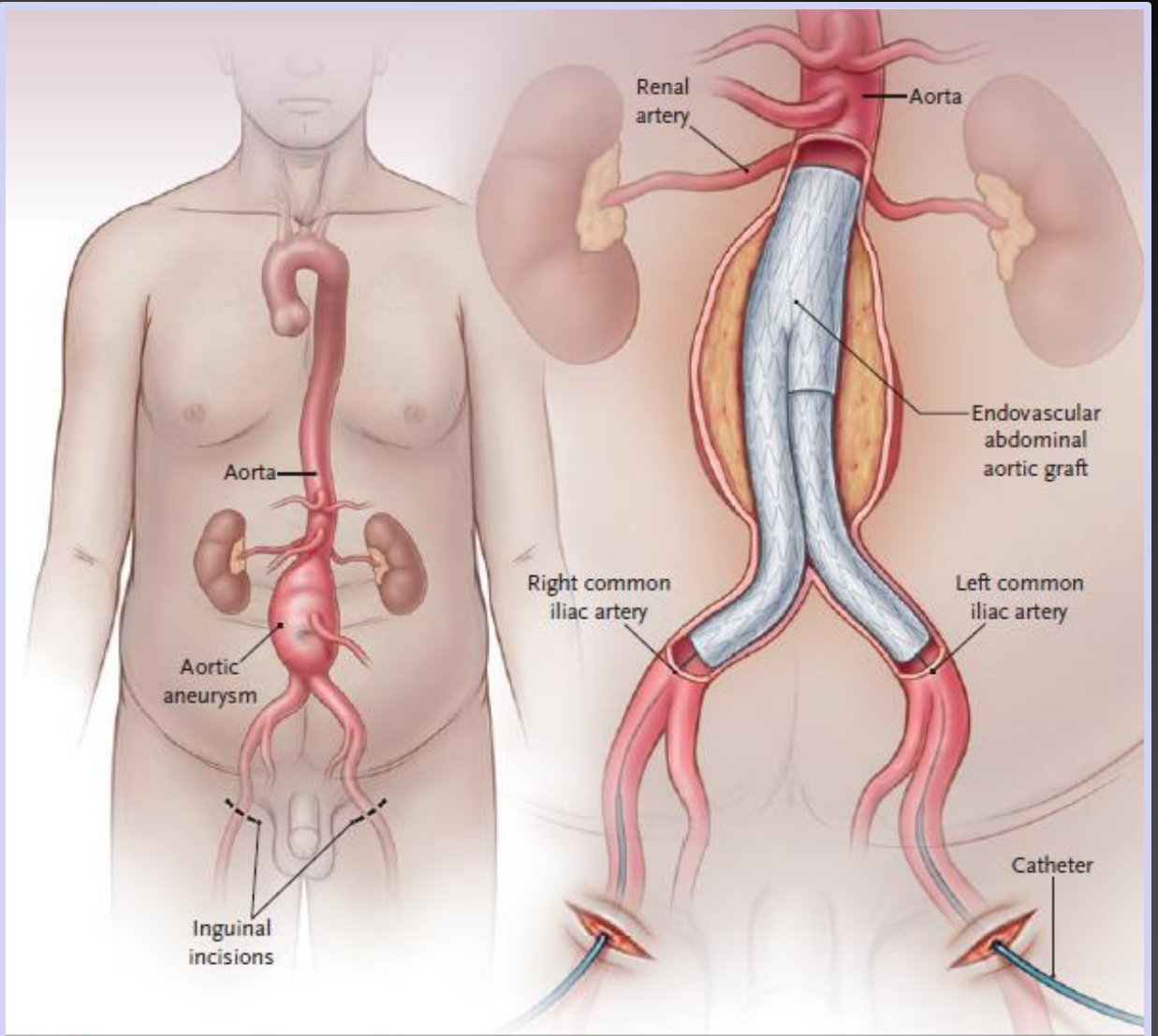


Figure 2. Endovascular Repair of an Infrarenal Abdominal Aortic Aneurysm.
Percutaneous femoral artery access is obtained or small incisions are made to expose the femoral arteries for the purpose of introducing stent grafts, under radiologic guidance, to exclude blood flow to the aneurysm.

*Schanzer et al, NEJM, 2021.

EVAR versus Open RCTs

	DREAM trial		EVAR trial I	
	EVAR	**Open**	**EVAR**	**Open**
Mean operative time (min)	↓	151	↓	205
Mean estimated blood loss (mL)	↓	1654	n/r	n/r
Mean blood products transfused	0.0 units	0.44 units	16 mL	896 mL
Mean length of intensive care unit stay (days)	↓	3	↓	2.4
Mean overall length of stay (days)	↓	13	↓	15.7
Perioperative mortality (%)	↓	4.6	↓	4.7

DREAM Trial: *NEJM*, October, 2004

EVAR Trial: *Lancet*, September 2004

Long-Term Outcome of Open or Endovascular Repair of Abdominal Aortic Aneurysm

Jorg L. De Bruin, M.D., Annette F. Baas, M.D., Jaap Buth, M.D., Monique Prinssen, M.D., Eric L.G. Verhoeven, M.D., Philippe W.M. Cuypers, M.D., Marc R.H.M. van Sambeek, M.D., Ron Balm, M.D., Diederick E. Grobbee, M.D., and Jan D. Blankensteijn, M.D., for the DREAM Study Group*

ABSTRACT

BACKGROUND

For patients with large abdominal aortic aneurysms, randomized trials have shown an initial overall survival benefit for elective endovascular repair over conventional open repair. This survival difference, however, was no longer significant in the second year after the procedure. Information regarding the comparative outcome more than 2 years after surgery is important for clinical decision making.

METHODS

We conducted a long-term, multicenter, randomized, controlled trial comparing open repair with endovascular repair in 351 patients with an abdominal aortic aneurysm of at least 5 cm in diameter who were considered suitable candidates for both techniques. The primary outcomes were rates of death from any cause and reintervention. Survival was calculated with the use of Kaplan–Meier methods on an intention-to-treat basis.

RESULTS

We randomly assigned 178 patients to undergo open repair and 173 to undergo endovascular repair. Six years after randomization, the cumulative survival rates were 69.9% for open repair and 68.9% for endovascular repair (difference, 1.0 percentage point; 95% confidence interval [CI], −8.8 to 10.8; P=0.97). The cumulative rates of freedom from secondary interventions were 81.9% for open repair and 70.4% for endovascular repair (difference, 11.5 percentage points; 95% CI, 2.0 to 21.0; P=0.03).

CONCLUSIONS

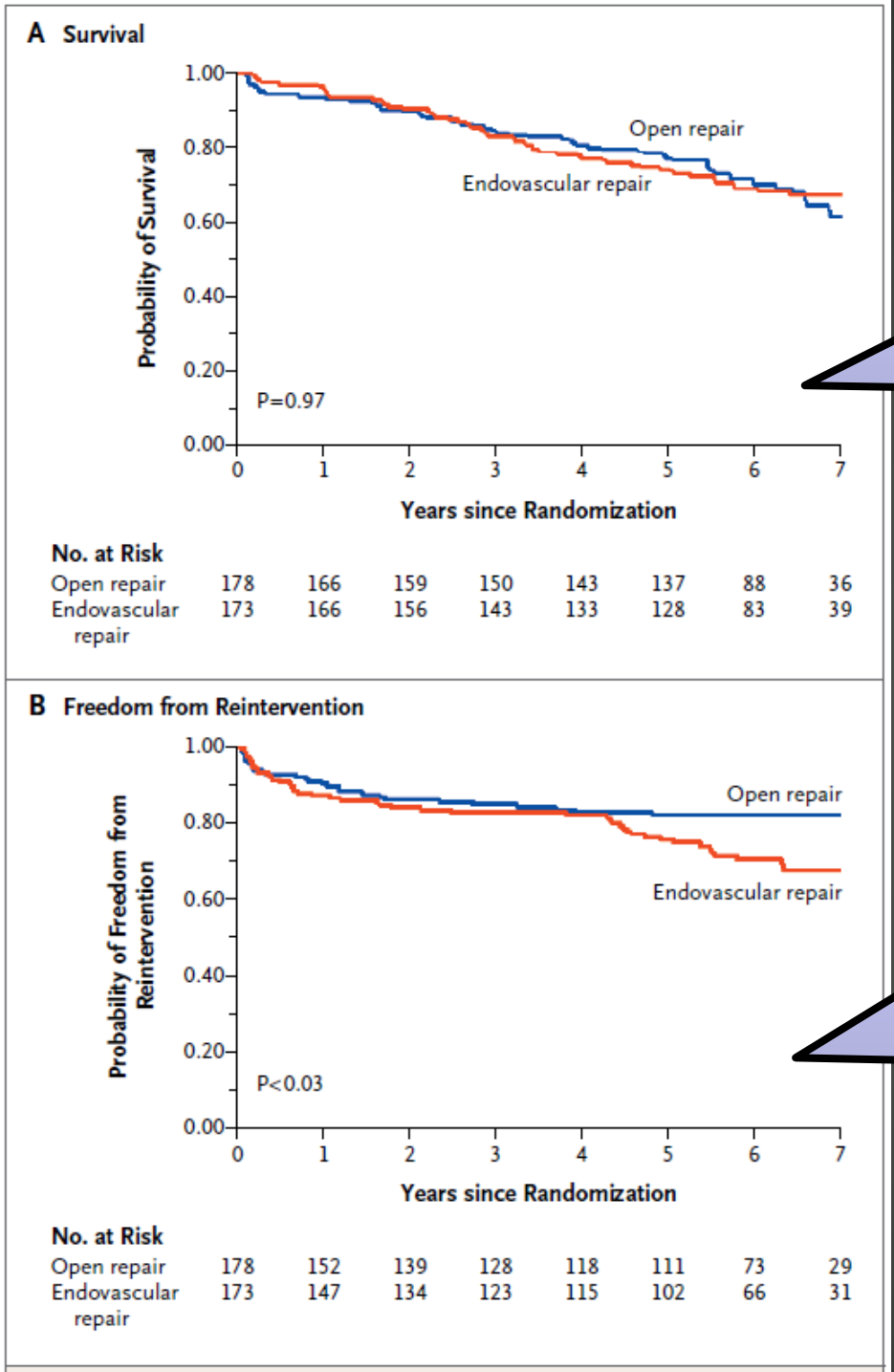
Six years after randomization, endovascular and open repair of abdominal aortic aneurysm resulted in similar rates of survival. The rate of secondary interventions was significantly higher for endovascular repair. (ClinicalTrials.gov number, NCT00421330.)

From the Department of Surgery, Vrije Universiteit Medical Center, Amsterdam (J.L.D.B, J.D.B.); the Julius Center for Health Sciences and Primary Care, University Medical Center, Utrecht (A.F.B., M.P., D.E.G.); the Department of Surgery, Catharina Hospital, Eindhoven (J.B., P.W.M.C., M.R.H.M.S.); the Department of Surgery, Academic Hospital, Groningen (E.L.G.V.); the Department of Surgery, Erasmus Medical Center, Rotterdam (M.R.H.M.S.); and the Department of Surgery, Academic Medical Center, Amsterdam (R.B.) — all in the Netherlands. Address reprint requests to Dr. Blankensteijn at the Department of Surgery, VU Medical Center, P.O. Box 7057, 1007 MB Amsterdam, the Netherlands, or at j.blankensteijn@vumc.nl.

Drs. De Bruin and Baas contributed equally to this article.

*The members of the Dutch Randomized Endovascular Aneurysm Repair (DREAM) study group are listed in the Appendix.

N Engl J Med 2010;362:1881-9.



"…similar rates of survival…"

"…increased rates of reintervention…"

Endovascular versus Open Repair of Abdominal Aortic Aneurysm

The United Kingdom EVAR Trial Investigators*

ABSTRACT

BACKGROUND

Few data are available on the long-term outcome of endovascular repair of abdominal aortic aneurysm as compared with open repair.

METHODS

From 1999 through 2004 at 37 hospitals in the United Kingdom, we randomly assigned 1252 patients with large abdominal aortic aneurysms (≥5.5 cm in diameter) to undergo either endovascular or open repair; 626 patients were assigned to each group. Patients were followed for rates of death, graft-related complications, reinterventions, and resource use until the end of 2009. Logistic regression and Cox regression were used to compare outcomes in the two groups.

RESULTS

The 30-day operative mortality was 1.8% in the endovascular-repair group and 4.3% in the open-repair group (adjusted odds ratio for endovascular repair as compared with open repair, 0.39; 95% confidence interval [CI], 0.18 to 0.87; P=0.02). The endovascular-repair group had an early benefit with respect to aneurysm-related mortality, but the benefit was lost by the end of the study, at least partially because of fatal endograft ruptures (adjusted hazard ratio, 0.92; 95% CI, 0.57 to 1.49; P=0.73). By the end of follow-up, there was no significant difference between the two groups in the rate of death from any cause (adjusted hazard ratio, 1.03; 95% CI, 0.86 to 1.23; P=0.72). The rates of graft-related complications and reinterventions were higher with endovascular repair, and new complications occurred up to 8 years after randomization, contributing to higher overall costs.

CONCLUSIONS

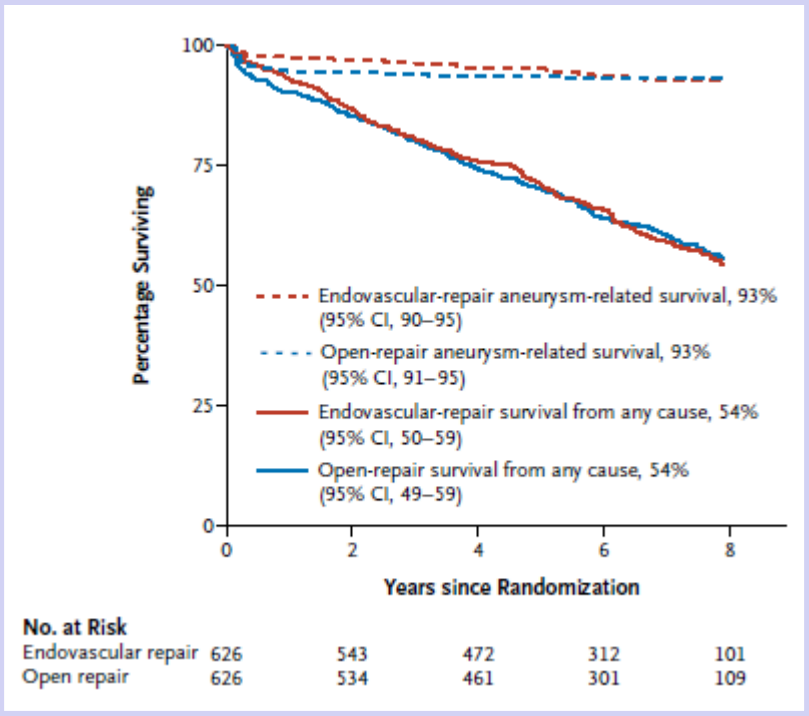
In this large, randomized trial, endovascular repair of abdominal aortic aneurysm was associated with a significantly lower operative mortality than open surgical repair. However, no differences were seen in total mortality or aneurysm-related mortality in the long term. Endovascular repair was associated with increased rates of graft-related complications and reinterventions and was more costly. (Current Controlled Trials number, ISRCTN55703451.)

The members of the Writing Committee — Roger M. Greenhalgh, M.D., Louise C. Brown, Ph.D., and Janet T. Powell, M.D., Ph.D., Imperial College, London; Simon G. Thompson, D.Sc., Medical Research Council Biostatistics Unit, Cambridge; David Epstein, M.Sc., and Mark J. Sculpher, Ph.D., University of York, York (all in the United Kingdom) — assume responsibility for the content of the article. Address reprint requests to Dr. Greenhalgh at the Imperial College Vascular Surgery Research Group, Charing Cross Hospital, Fulham Palace Rd., London W6 8RF, United Kingdom, or at r.greenhalgh@imperial.ac.uk.

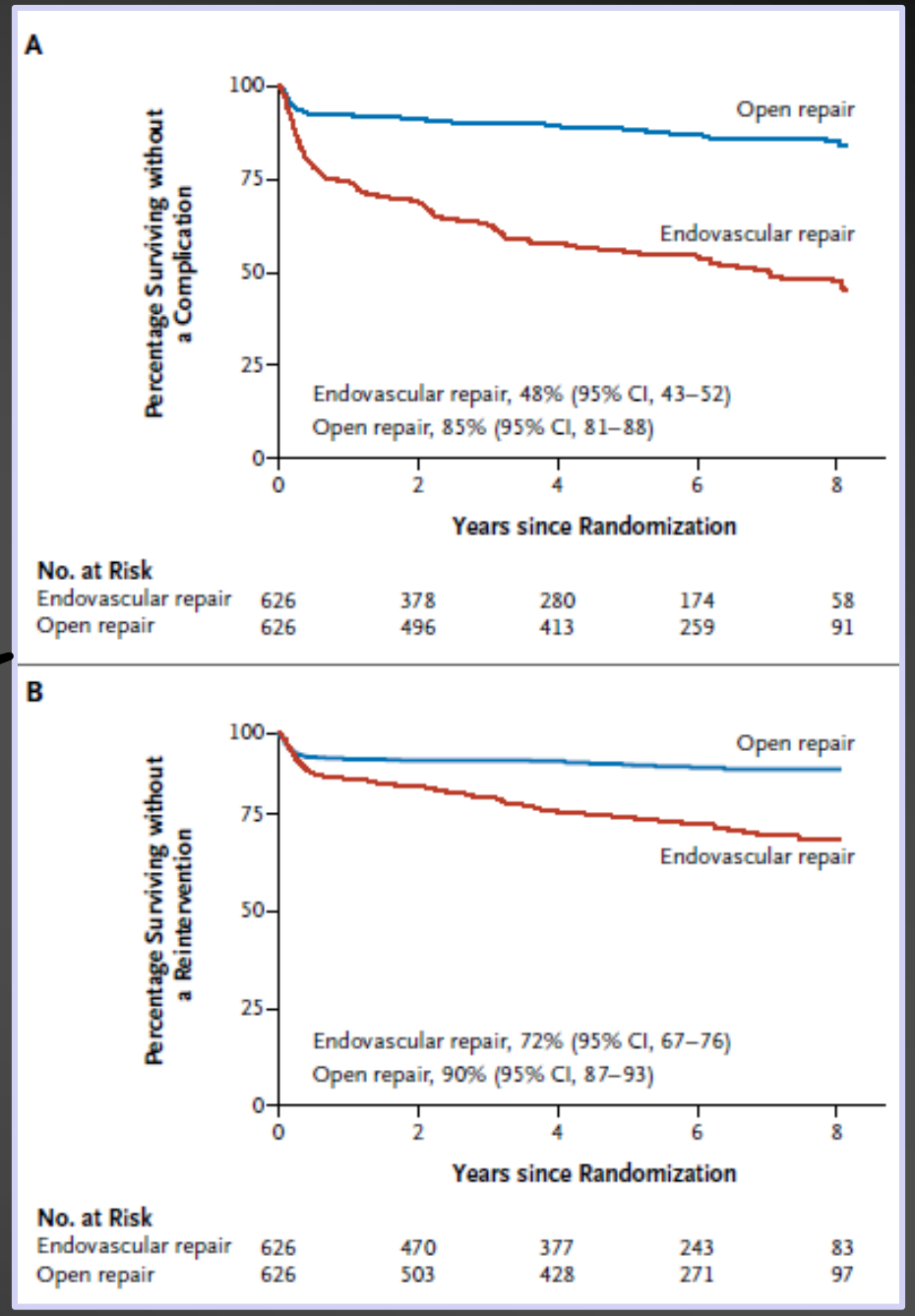
*The investigators in the United Kingdom Endovascular Aneurysm Repair (EVAR) trial are listed in the Appendix.

This article (10.1056/NEJMoa0909305) was published on April 11, 2010, and was updated on April 30, 2010, at NEJM.org.

N Engl J Med 2010.



"…equivalent long-term survival…increased complications, increased reinterventions…"



Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial inves

Lancet 2016; 388: 2366–74

Published Online October 12, 2016 http://dx.doi.org/10.1016/S0140-6736(16)31135-7

See Comment page 2326

*The EVAR trial investigators are listed in the appendix

Vascular Surgery Research Group, Imperial College London, London, UK (R Patel PhD, Prof J T Powell MD, Prof R M Greenhalgh MD); and Cardiovascular Epidemiology Unit, Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK (M J Sweeting PhD)

Correspondence to: Prof Roger M Greenhalgh, Vascular Surgery Research Group, Imperial College London, London W6 8RP, UK r.greenhalgh@imperial.ac.uk

See Online for appendix

Summary

Background Short-term survival benefits of endovascular aneurysm re… abdominal aortic aneurysms have been shown in randomised trials, but … years. We investigated whether EVAR had a long-term survival benefit co…

Methods We used data from the EVAR randomised controlled trial (EVA… 37 centres in the UK between Sept 1, 1999, and Aug 31, 2004. Patients had … of at least 5·5 cm in diameter, and deemed suitable and fit for either E… randomly assigned (1:1) using computer-generated sequences of randon… receive either EVAR (n=626) or open repair (n=626). Patients and treating … no masking was used. The primary analysis compared total and aneurys… the intention-to-treat population. This trial is registered at ISRCTN (I…

Findings We recruited 1252 patients between Sept 1, 1999, and Au… were lost to follow-up by June 30, 2015. Over a mean of 12·7 y… recorded 9·3 deaths per 100 person-years in the EVAR group … group (adjusted hazard ratio [HR] 1·11, 95% CI 0·97–1·27, …4). At 0… the EVAR group had a lower mortality (adjusted HR 0·61, …% CI 0·37–1·0… for aneurysm-related mortality, p=0·031), but beyond 8 years of follow-up … mortality (adjusted HR 1·25, 95% CI 1·00–1·56, p=0·048 for total mortality; and 5·82, 1·64–20·65, p=0·0064 for aneurysm-related mortality). The increased aneurysm-related mortality in the EVAR group after 8 years was mainly attributable to secondary aneurysm sac rupture (13 deaths [7%] in EVAR *vs* two [1%] in open repair), with increased cancer mortality also observed in the EVAR group.

"…beyond 8 years of follow-up open-repair had a significantly lower mortality..increased aneurysm-related mortality in the EVAR group after 8 years was mainly attributable to secondary aneurysm sac rupture…."

Long-Term Comparison of Endovascular and Open Repair of Abdominal Aortic Aneurysm

Frank A. Lederle, M.D., Julie A. Freischlag, M.D., Tassos C. Kyriakides, Ph.D., Jon S. Matsumura, M.D., Frank T. Padberg, Jr., M.D., Ted R. Kohler, M.D., Panagiotis Kougias, M.D., Jessie M. Jean-Claude, M.D., Dolores F. Cikrit, M.D., and Kathleen M. Swanson, M.S., R.Ph., for the OVER Veterans Affairs Cooperative Study Group*

From the Veterans Affairs Medical Centers in Minneapolis (F.A.L.), Baltimore (J.A.F.), West Haven, CT (T.C.K.), Madison, WI (J.S.M.), East Orange, NJ (F.T.P.), Seattle (T.R.K.), Houston (P.K.), Cleveland (J.M.J.-C.), Indianapolis (D.F.C.), and Albuquerque, NM (K.M.S.). Address reprint requests to Dr. Lederle at the Department of Medicine (III-0), Veterans Affairs Medical Center, 1 Veterans Dr., Minneapolis, MN 55417, or at frank.lederle@va.gov.

*The members of the Open versus Endovascular Repair Trial (OVER) study group are listed in the Supplementary Appendix, available at NEJM.org.

N Engl J Med 2012;367:1988-97.
DOI: 10.1056/NEJMoa1207481

ABSTRACT

BACKGROUND

Whether elective endovascular repair of abdominal aortic aneurysm reduces long-term morbidity and mortality, as compared with traditional open repair, remains uncertain.

METHODS

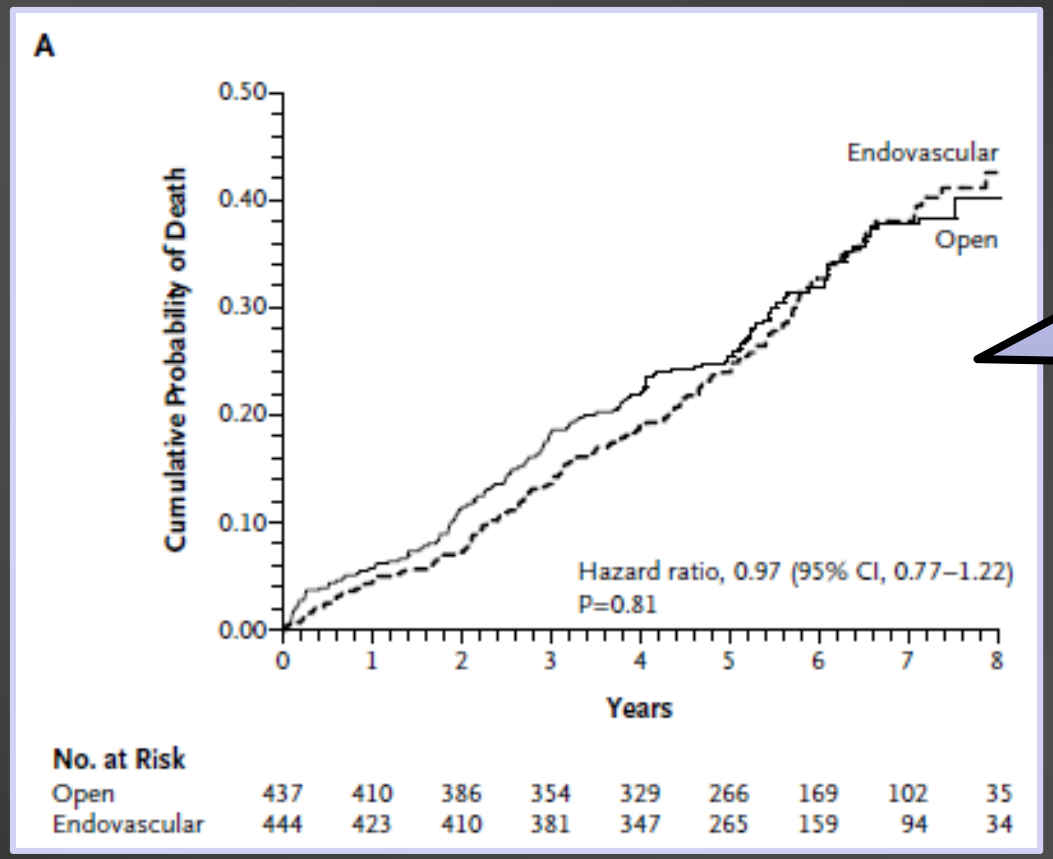
We randomly assigned 881 patients with asymptomatic abdominal aortic aneurysms who were candidates for both procedures to either endovascular repair (444) or open repair (437) and followed them for up to 9 years (mean, 5.2). Patients were selected from 42 Veterans Affairs medical centers and were 49 years of age or older at the time of registration.

RESULTS

More than 95% of the patients underwent the assigned repair. For the primary outcome of all-cause mortality, 146 deaths occurred in each group (hazard ratio with endovascular repair versus open repair, 0.97; 95% confidence interval [CI], 0.77 to 1.22; P=0.81). The previously reported reduction in perioperative mortality with endovascular repair was sustained at 2 years (hazard ratio, 0.63; 95% CI, 0.40 to 0.98; P=0.04) and at 3 years (hazard ratio, 0.72; 95% CI, 0.51 to 1.00; P=0.05) but not thereafter. There were 10 aneurysm-related deaths in the endovascular-repair group (2.3%) versus 16 in the open-repair group (3.7%) (P=0.22). Six aneurysm ruptures were confirmed in the endovascular-repair group versus none in the open-repair group (P=0.03). A significant interaction was observed between age and type of treatment (P=0.006); survival was increased among patients under 70 years of age in the endovascular-repair group but tended to be better among those 70 years of age or older in the open-repair group.

CONCLUSIONS

Endovascular repair and open repair resulted in similar long-term survival. The perioperative survival advantage with endovascular repair was sustained for several years, but rupture after repair remained a concern. Endovascular repair led to increased long-term survival among younger patients but not among older patients, for whom a greater benefit from the endovascular approach had been expected. (Funded by the Department of Veterans Affairs Office of Research and Development; OVER ClinicalTrials.gov number, NCT00094575.)



"…similar rates of survival…"

"…our results also indicate that late rupture remains a concern and that endovascular repair does not yet offer a long-term advantage over open repair…"

Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population

Marc L. Schermerhorn, M.D., Dominique B. Buck, M.D., A. James O'Malley, Ph.D., Thomas Curran, M.D., John C. McCallum, M.D., Jeremy Darling, B.A., and Bruce E. Landon, M.D., M.B.A.

ABSTRACT

BACKGROUND

Randomized trials and observational studies have shown that perioperative morbidity and mortality are lower with endovascular repair of abdominal aortic aneurysm than with open repair, but the survival benefit is not sustained. In addition, concerns have been raised about the long-term risk of aneurysm rupture or the need for reintervention after endovascular repair.

METHODS

We assessed perioperative and long-term survival, reinterventions, and complications after endovascular repair as compared with open repair of abdominal aortic aneurysm in propensity-score–matched cohorts of Medicare beneficiaries who underwent repair during the period from 2001 through 2008 and were followed through 2009.

RESULTS

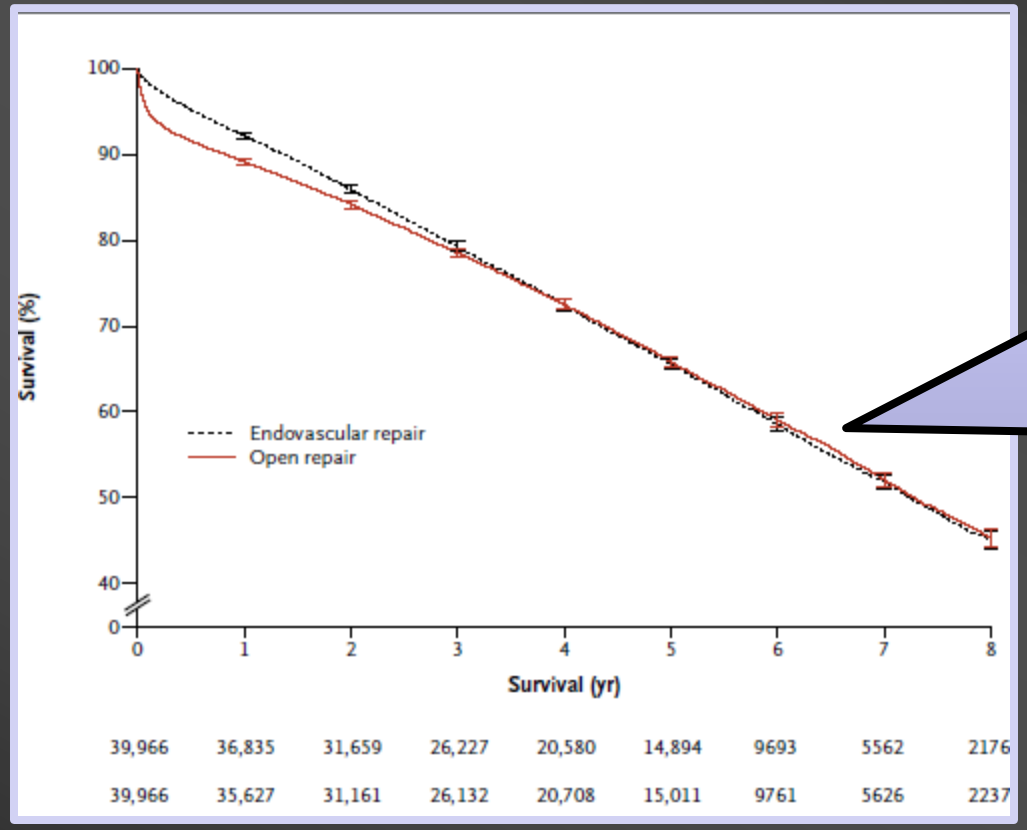
We identified 39,966 matched pairs of patients who had undergone either open repair or endovascular repair. The overall perioperative mortality was 1.6% with endovascular repair versus 5.2% with open repair ($P<0.001$). From 2001 through 2008, perioperative mortality decreased by 0.8 percentage points among patients who underwent endovascular repair ($P=0.001$) and by 0.6 percentage points among patients who underwent open repair ($P=0.01$). The rate of conversion from endovascular to open repair decreased from 2.2% in 2001 to 0.3% in 2008 ($P<0.001$). The rate of survival was significantly higher after endovascular repair than after open repair through the first 3 years of follow-up, after which time the rates of survival were similar. Through 8 years of follow-up, interventions related to the management of the aneurysm or its complications were more common after endovascular repair, whereas interventions for complications related to laparotomy were more common after open repair. Aneurysm rupture occurred in 5.4% of patients after endovascular repair versus 1.4% of patients after open repair through 8 years of follow-up ($P<0.001$). The rate of total reinterventions at 2 years after endovascular repair decreased over time (from 10.4% among patients who underwent procedures in 2001 to 9.1% among patients who underwent procedures in 2007).

CONCLUSIONS

Endovascular repair, as compared with open repair, of abdominal aortic aneurysm was associated with a substantial early survival advantage that gradually decreased over time. The rate of late rupture was significantly higher after endovascular repair than after open repair. The outcomes of endovascular repair have been improving over time. (Funded by the National Institutes of Health.)

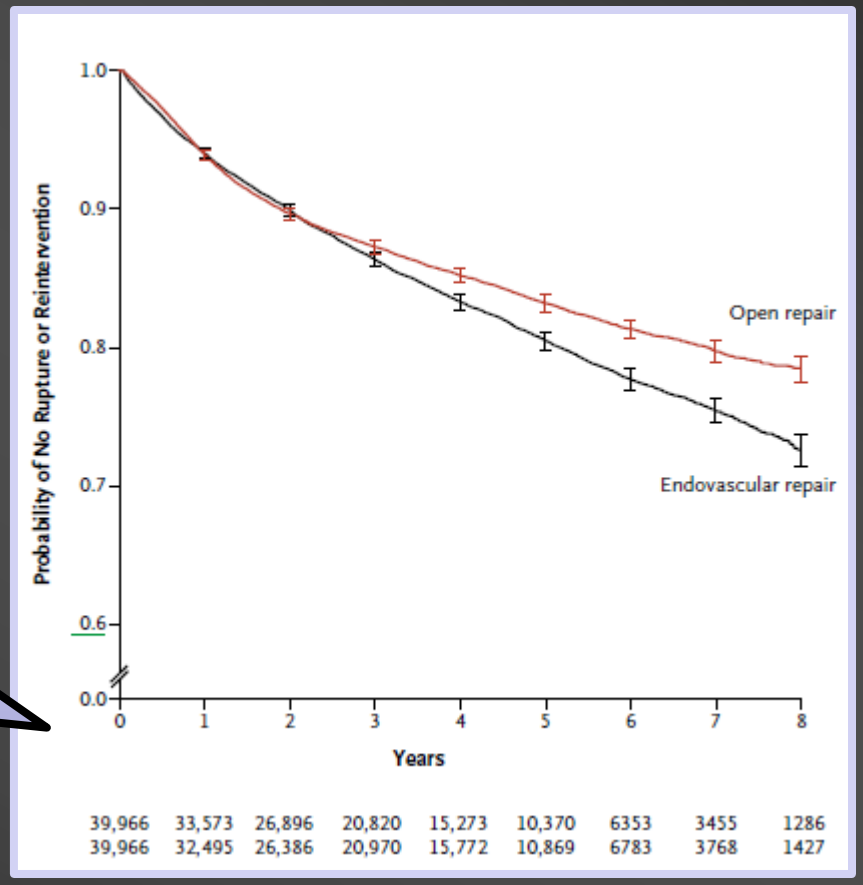
From the Departments of Surgery (M.L.S., D.B.B., T.C., J.C.M., J.D.) and Medicine (B.E.L.), Beth Israel Deaconess Medical Center, and the Department of Health Care Policy, Harvard Medical School (B.E.L.) — both in Boston; and the Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth, Lebanon, NH (A.J.O.). Address reprint requests to Dr. Schermerhorn at the Division of Vascular Surgery, Beth Israel Deaconess Medical Center, 110 Francis St., Boston, MA 02215, or at mscherm@bidmc.harvard.edu.

N Engl J Med 2015;373:328-38.
DOI: 10.1056/NEJMoa1405778



"…substantial early survival advantage that gradually decreased over time…"

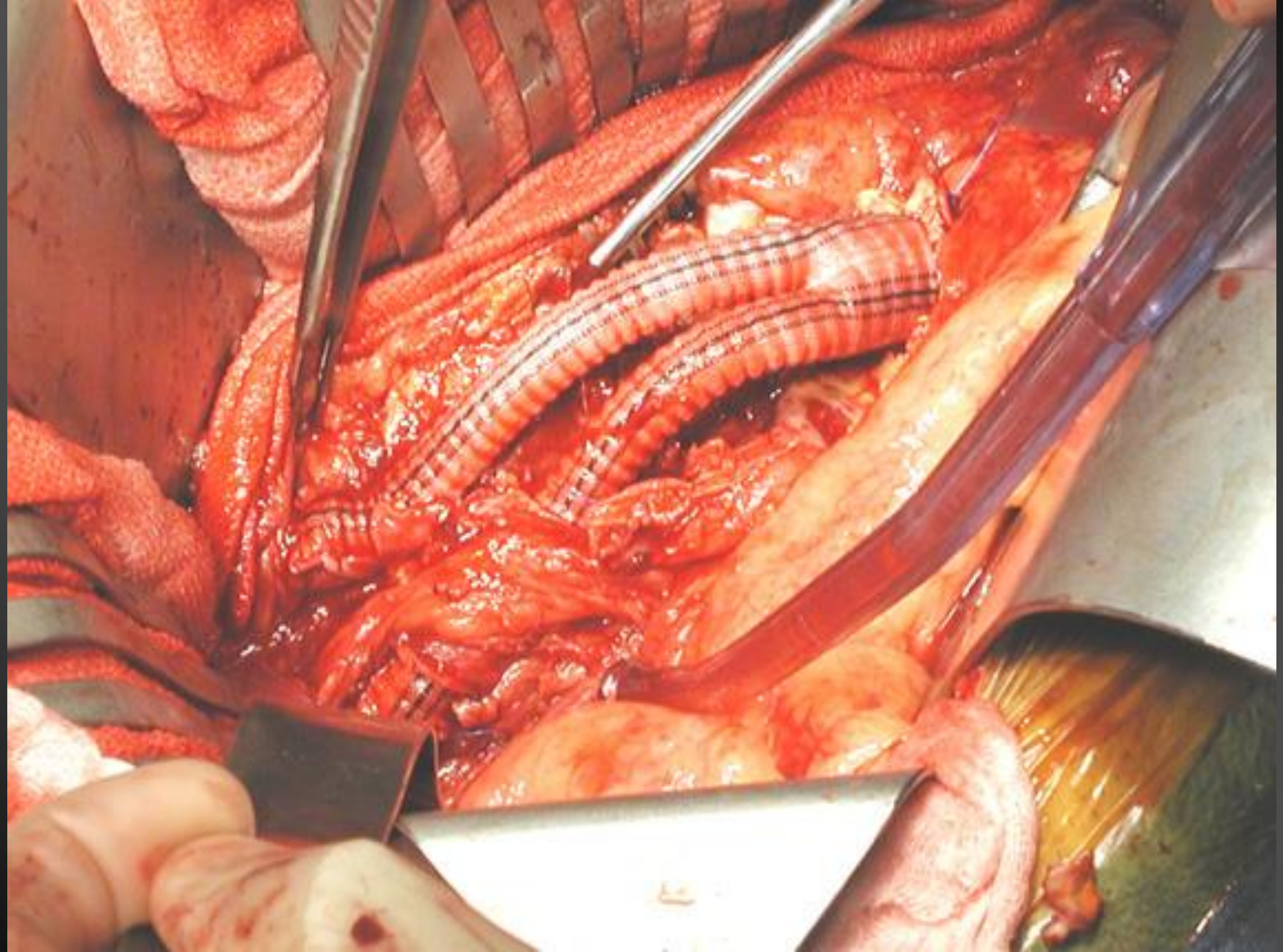
"…late rupture was significantly higher after endovascular repair than after open repair…"



Fundamental Difference

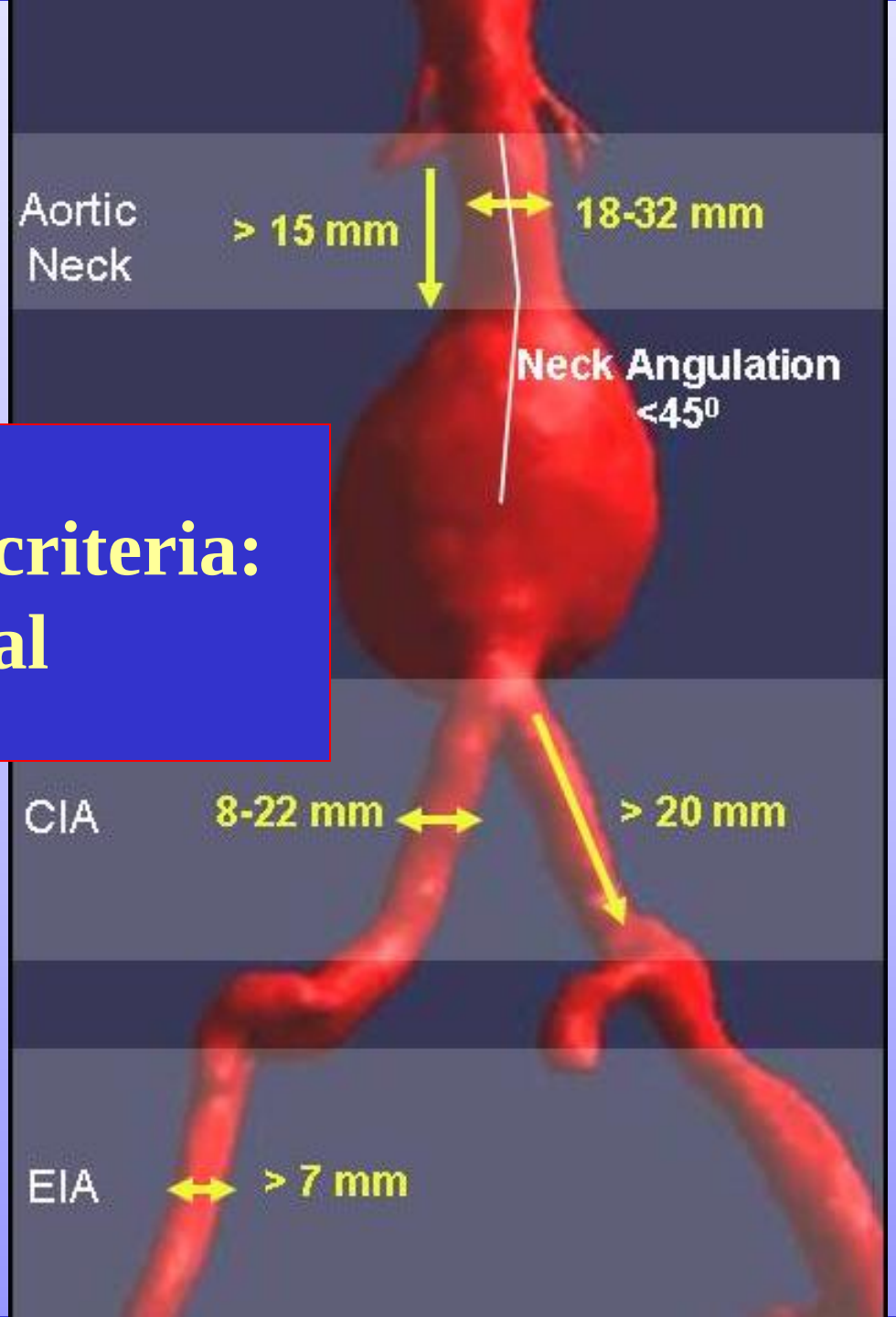
- **Open**:
  - Can effectively deal with any AAA morphology

- **Endovascular**:
  - Favorable anatomy is essential



The DREAM: Paris on a Summer Night

Anatomic criteria: Ideal



*Schanzer et al, Circulation, 2011.

The REALITY: Worcester on a Summer Night

Anatomic Criteria:
deviations from ideal
= ↑↑↑ chances for failure

*Schanzer et al, Circulation, 2011.

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION
American Heart Association®
Learn and Live℠

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background—The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection for endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance with anatomic guidelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR AAA sac enlargement.

Methods and Results—Patients with pre-EVAR and at least 1 post-EVAR computed tomography scan were identified from the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore, morphological measurements were compared with the most liberal and the most conservative published anatomic guidelines as stated in each manufacturer's instructions for use. The primary study outcome was post-EVAR AAA sac enlargement (>5-mm diameter increase). In 10 228 patients undergoing EVAR, 59% had a maximum AAA diameter below the 55-mm threshold at which intervention is recommended over surveillance. Only 42% of patients had anatomy that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age ≥80 years, aortic neck diameter ≥28 mm, aortic neck angle >60°, and common iliac artery diameter >20 mm.

Conclusion—In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture. (*Circulation.* **2011;123:2848-2855.**)

Key Words: abdominal aortic aneurysm ■ endovascular procedures ■ graft

Goals:

To analyze a large, multicenter, prospectively acquired dataset, representative of "real world" EVAR practice, containing extensive baseline and postoperative anatomic imaging data.

Schanzer et al, Circulation, 2011.

Instructions for Use (IFU)

	Guidant Ancure	Medtronic AneuRX	Gore Excluder	Cook Zenith	Gore Excluder Low Permeability	Endologix Powerlink	Cook Zenith Enlarged Neck	Medtronic Talent	Endologix Enlarged Neck	Gore Excluder Enlarged Neck
Year of Release	1999	1999	2002	2003	2004	2004	2006	2008	2009	2009
Neck Diameter (mm	18-26	18-25	19-26	18-28	19-26	18-26	18-32	18-32	18-32	19-29
Neck Length (mm)	≥15	≥10*	≥15	≥15	≥15	≥15	≥15	≥10	≥15	≥15
Neck Angle (degrees	NS	≤45	≤60	≤45	≤60	≤60	≤60	≤60	≤60	≤60
Iliac Fixation Length	≥20	NS	≥10	≥15	≥10	≥15	≥15	≥15	≥15	≥10
Iliac Diameter (mm)	<13.5	NS	10 to 18.5	10 to 20	10 to 18.5	8 to 18	10 to 20	8 to 22	10 to 23	10 to 18.5

*changed to ≥15 mm in 2003 IFU revision; NS, not specified

Does compliance with IFU predict outcomes?

Schanzer et al, Circulation, 2011.

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION
American Heart Association®
Learn and Live℠

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background—The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with ular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance idelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR A

Methods and Results at least 1 post-EVAR computed tomography scan were identified from

"…31% of patients treated outside the most liberal Instructions For Use (IFU) parameters."

Co

sac enlargement was high, raising concern for long-term risk of aneurysm rupture. (*Circulation.* 2011;123:2848-2855.)

Key Words: abdominal aortic aneurysm ■ endovascular procedures ■ graft

UMassMemorial CENTER FOR COMPLEX AORTIC DISEASE

UMASS

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION
American Heart Association®
Learn and Live℠

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background— of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascul aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection fo pair (EVAR) and key determinants of long-term success. We evaluated compliance with anatom the relationship between baseline aortoiliac arterial anatomy and post-EV

Methods the M2 for eac morph guideli enlarge below th that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age ≥80 years, aortic neck diameter ≥28 mm, aortic neck angle >60°, and common iliac artery diameter >20 mm.

Conclusion—In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture. (*Circulation.* **2011;123:2848-2855.**)

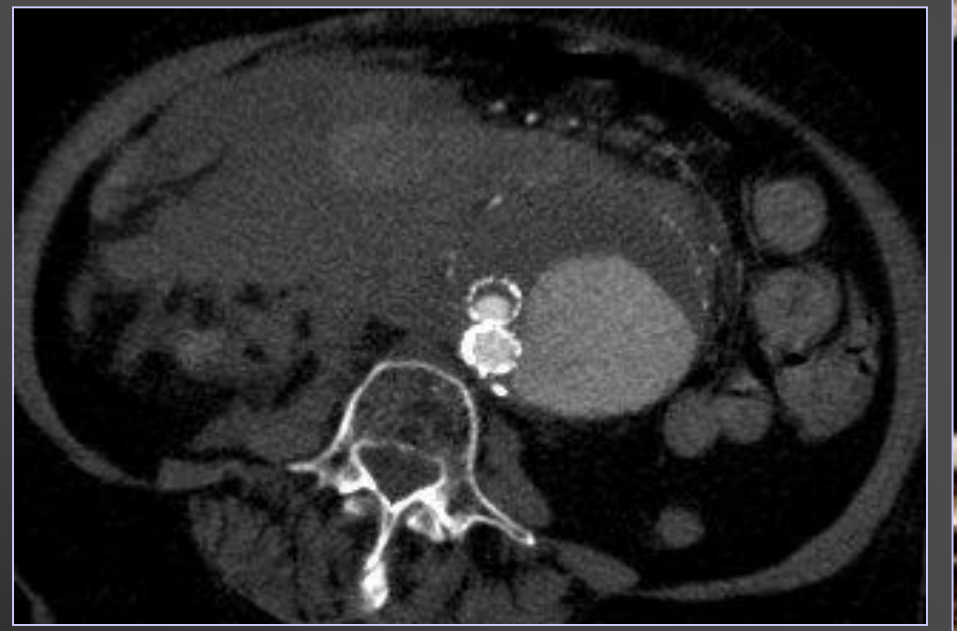
Key Words: abdominal aortic aneurysm ■ endovascular procedures ■ graft

"5-year post-EVAR rate of sac enlargement was 41%."

Baseline aortic anatomy is a key determinant of EVAR appropriateness and long term clinical success.

EVAR in 2004

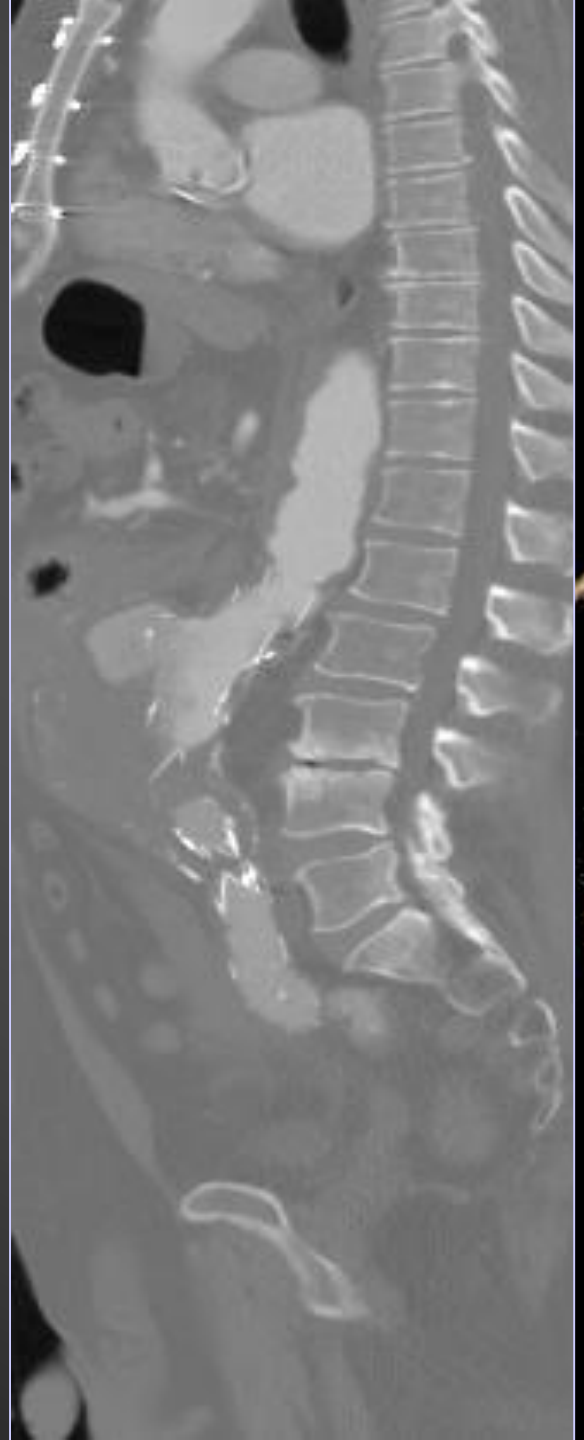
Rupture 2/10/2012

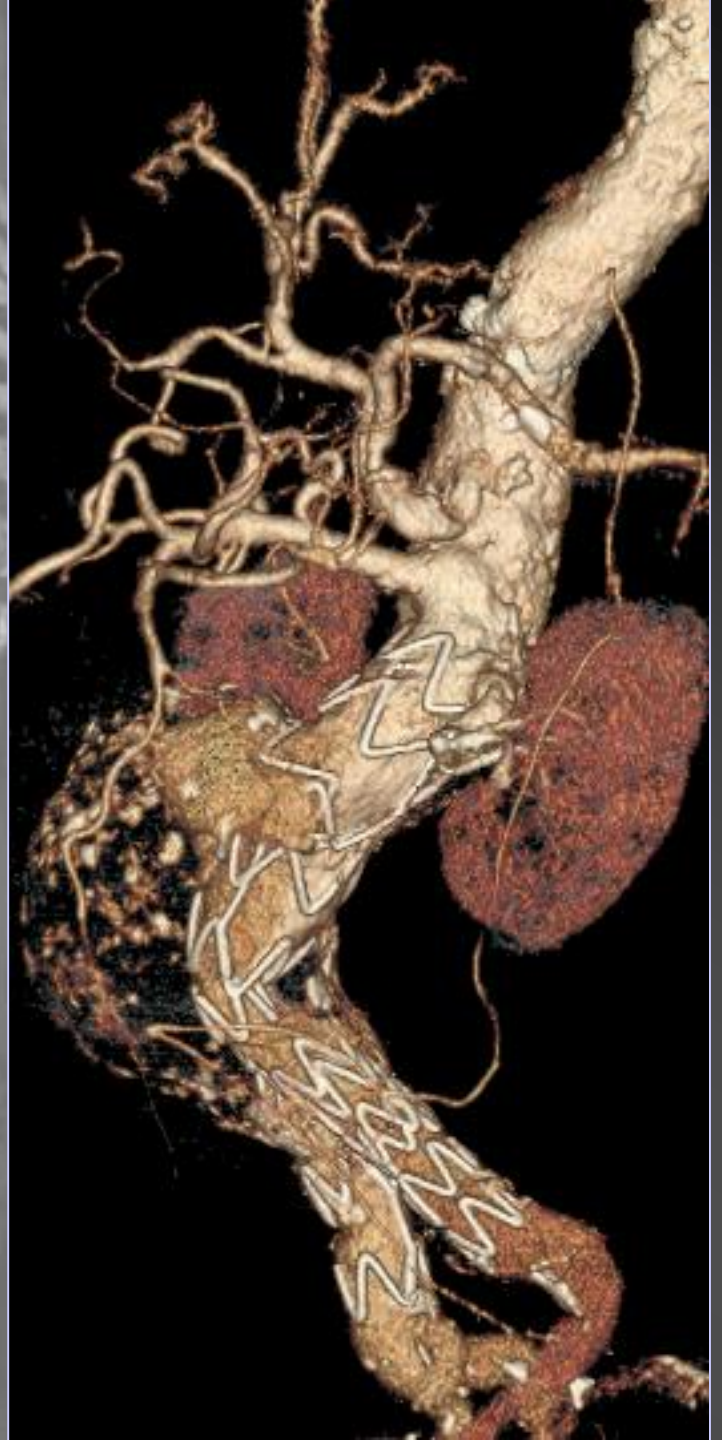


Aortic neck angle 90 degrees

EVAR in 2007

Rupture 2/11/2012

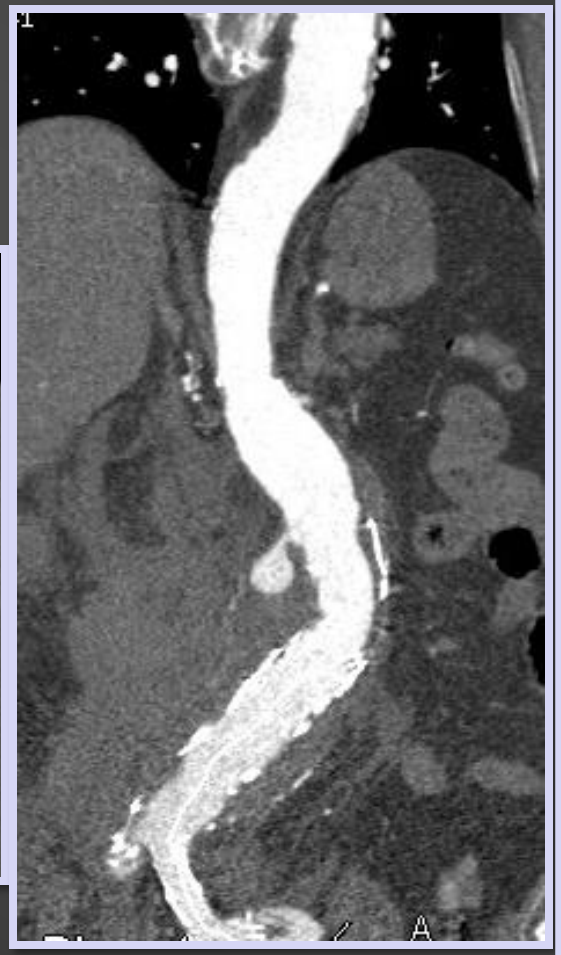




Aortic neck 38 mm

EVAR in 2007

Rupture 12/26/2012



Aortic neck 32 mm

Highly angulated

ORIGINAL ARTICLE

Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population

Marc L. Schermerhorn, M.D., Dominique B. Buck, M.D., A. James O'Malley, Ph.D., Thomas Curran, M.D., John C. McCallum, M.D., Jeremy Darling, B.A., and Bruce E. Landon, M.D., M.B.A.

ABSTRACT

BACKGROUND

Randomized trials and observational studies have shown that perioperative morbidity and mortality are lower with endovascular repair of abdominal aortic aneurysm than with open repair, but the survival benefit is not sustained. In addition, concerns have been raised about the long-term risk of aneurysm ru
need for reintervention after endovascular repair.

METHODS

We assessed perioperative and long-term survival, reinterventions,
tions after endovascular repair as compared with open repair of ab
aneurysm in propensity-score–matched cohorts of Medicare ben
underwent repair during the period from 2001 through 2008 and
through 2009.

RESULTS

We identified 39,966 matched pairs of patients who had undergo
repair or endovascular repair. The overall perioperative mortality
endovascular repair versus 5.2% with open repair (P<0.001). From
2008, perioperative mortality decreased by 0.8 percentage points a
who underwent endovascular repair (P=0.001) and by 0.6 perce
among patients who underwent open repair (P=0.01). The rate of conversion from endovascular to open repair decreased from 2.2% in 2001 to 0.3% in 2008 (P<0.001). The rate of survival was significantly higher after endovascular repair than after open repair through the first 3 years of follow-up, after which time the rates of survival were similar. Through 8 years of follow-up, interventions related to the management of the aneurysm or its complications were more common aft
endovascular repair, whereas interventions for complications related to laparot
were more common after open repair. Aneurysm rupture occurred in 5.4% o
tients after endovascular repair versus 1.4% of patients after open repair th
8 years of follow-up (P<0.001). The rate of total reinterventions at 2 years aft
vascular repair decreased over time (from 10.4% among patients who u
procedures in 2001 to 9.1% among patients who underwent procedures i
).

CONCLUSIONS

Endovascular repair, as compared with open repair, of abdominal aortic aneurysm was associated with a substantial early survival advantage that gradually decreased over time. The rate of late rupture was significantly higher after endovascular repair than after open repair. The outcomes of endovascular repair have been improving over time. (Funded by the National Institutes of Health.)

39,996 EVAR patients.

"Aneurysm rupture occurred in 5.4% of patients after EVAR…."

From the New England Society for Vascular Surgery

Follow-up compliance after endovascular abdominal aortic aneurysm repair in Medicare beneficiaries

Andres Schanzer, MD,[a] Louis M. Messina, MD,[a] Kaushik Ghosh, PhD,[b] Jessica P. Simons, MD, MPH,[a] William P. Robinson III, MD,[a] Francesco A. Aiello, MD,[a] Robert J. Goldberg, PhD,[a] and Allison B. Rosen, MD, MPH, ScD,[a,b] *Worcester and Cambridge, Mass*

Objective: Lifelong imaging follow-up is essential to the safe and appropriate management of patients who undergo endovascular abdominal aortic aneurysm repair (EVAR). We sought to evaluate the rate of compliance with imaging follow-up after EVAR and to identify factors associated with being lost to imaging follow-up.

Methods: We identified a 20% sample of continuously enrolled Medicare beneficiaries who underwent EVAR between 2001 and 2008. Using data through 2010 from Medicare Inpatient, Outpatient, and Carrier files, we identified all abdominal imaging studies that may have been performed for EVAR follow-up. Patients were considered lost to annual imaging follow-up if they did not undergo any abdominal imaging study within their last 2 years of follow-up. Multivariable models were constructed to identify independent factors associated with being lost to annual imaging follow-up.

Results: Among 19,962 patients who underwent EVAR, the incidence of loss to annual imaging follow-up at 5 years after EVAR was 50%. Primary factors associated with being lost to annual imaging follow-up were advanced age (age 65-69 years, reference; age 75-79 years: hazard ratio [HR], 1.23; 95% confidence interval [CI], 1.15-1.32; age 80-85 years: HR, 1.45; 95% CI, 1.35-1.55; age >85 years: HR, 2.03; 95% CI, 1.88-2.20) and presentation with an urgent/emergent intact aneurysm (HR, 1.27; 95% CI, 1.20-1.35) or ruptured aneurysm (HR, 1.84; 95% CI, 1.63-2.08). Additional independent factors included several previously diagnosed chronic diseases and South and West regions of the United States.

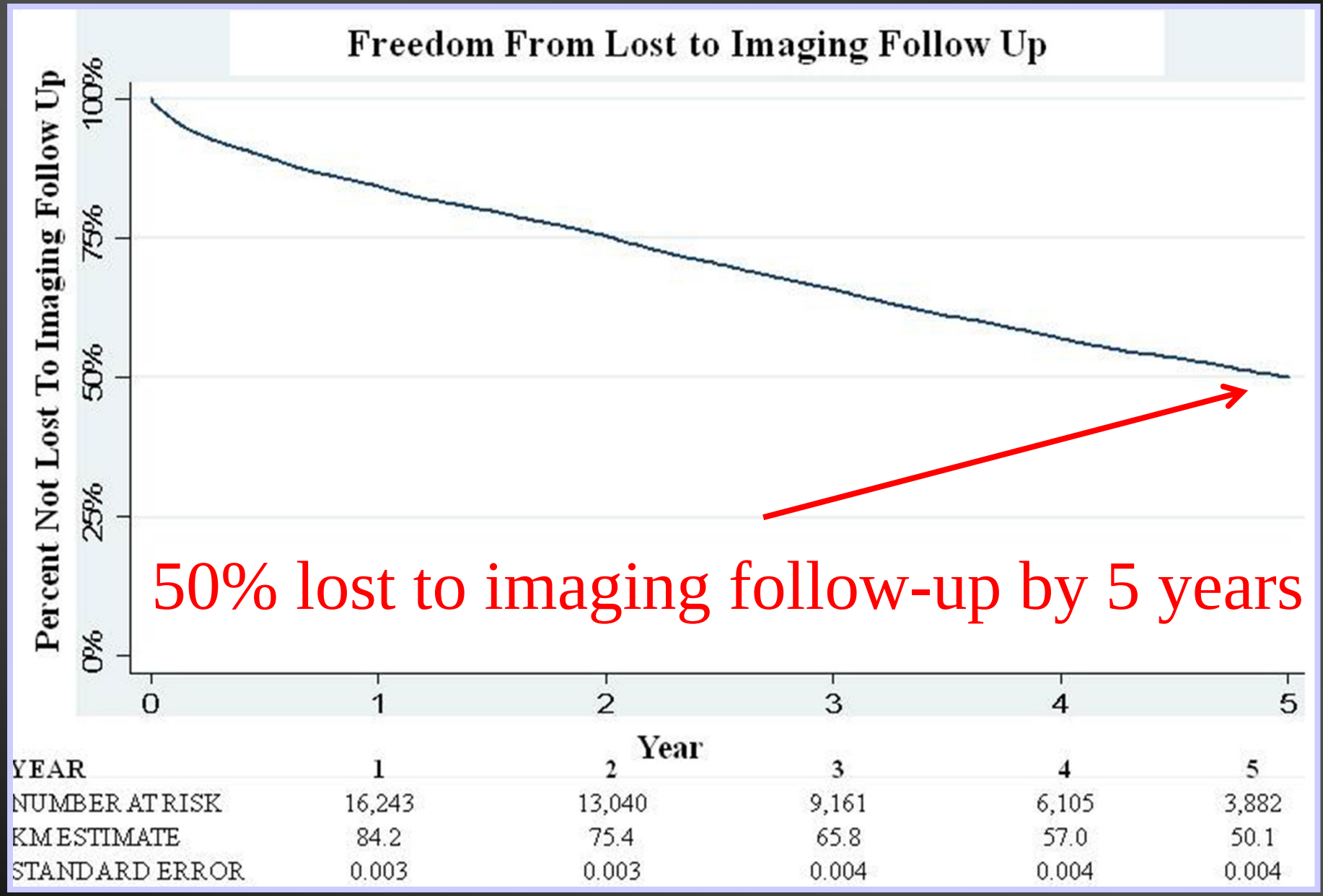
Conclusions: Annual imaging follow-up compliance after EVAR in the United States is significantly below recommended levels. Quality improvement efforts to encourage improved compliance with imaging follow-up, especially in older patients with multiple comorbidities and in those who underwent EVAR urgently or for rupture, are necessary. (J Vasc Surg 2015;61:16-22.)

Goals:

To evaluate the rate of compliance with imaging follow-up post EVAR and to identify factors associated with being lost to imaging follow-up.

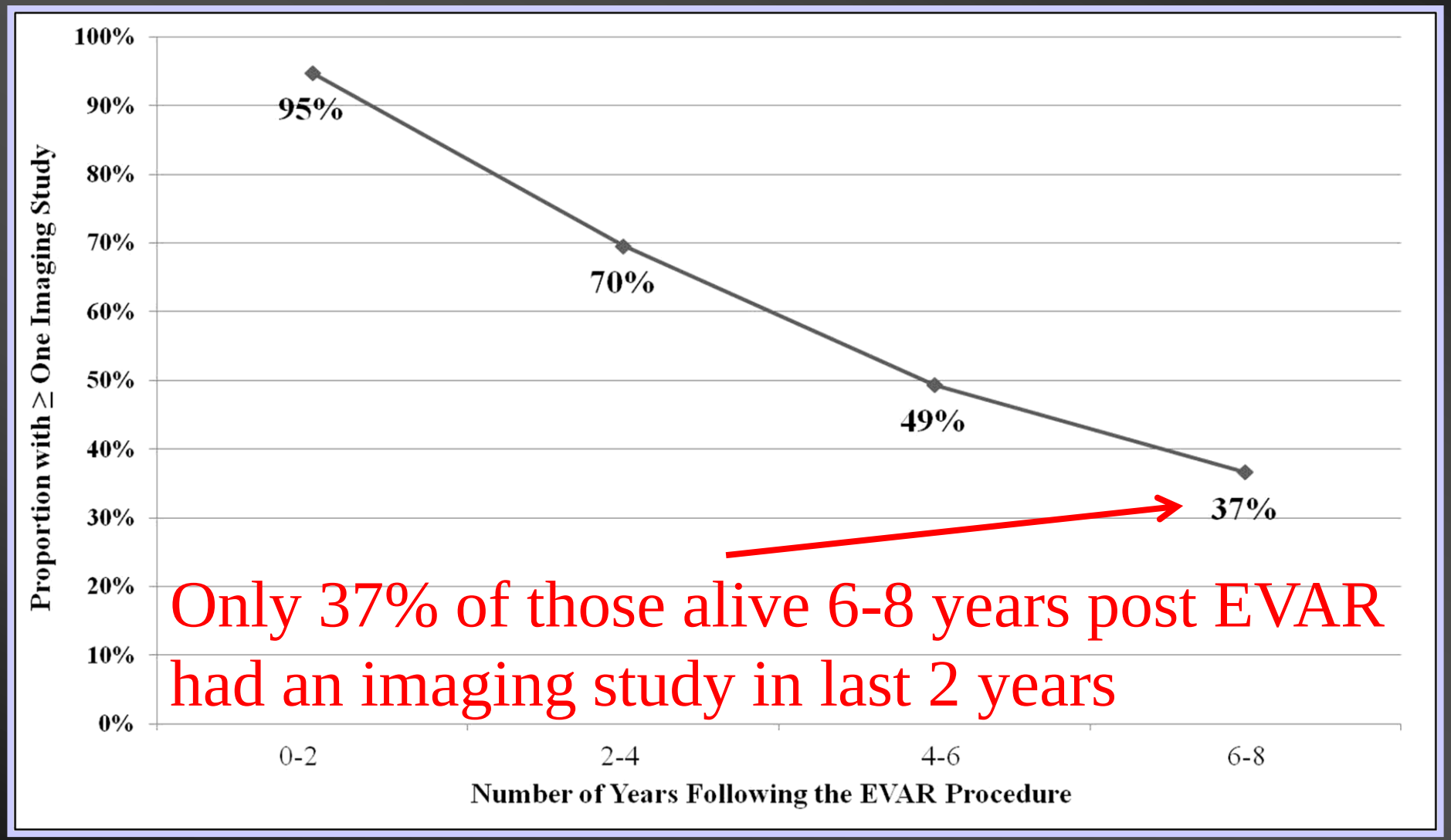
Research Design and Methods

- Data Sources
  - Linked data through 2010 from Medicare Inpatient, Outpatient, and Carrier files, to identify all abdominal imaging studies that may have been performed for EVAR follow-up.
  - N=19,962



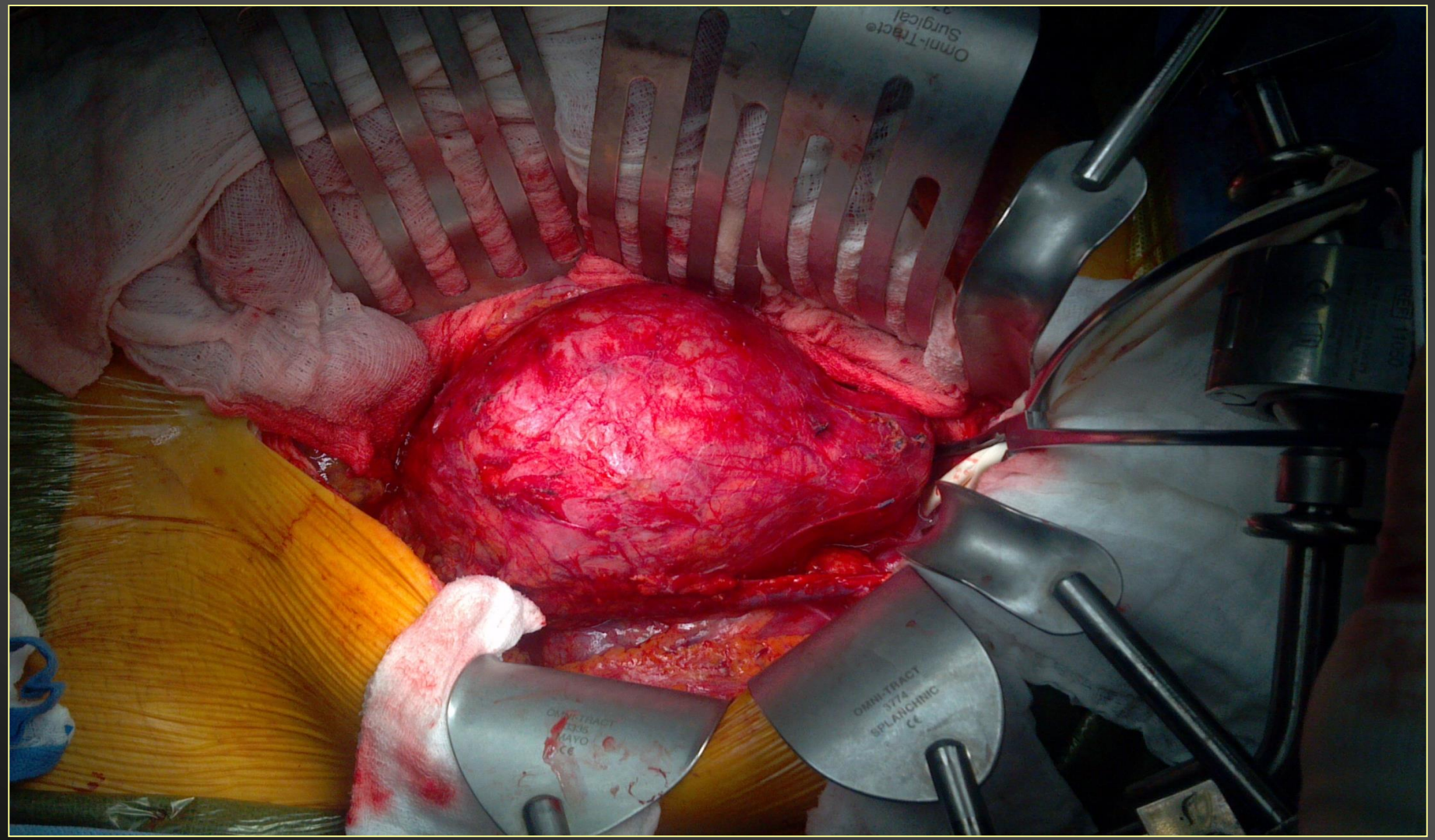
YEAR	1	2	3	4	5
NUMBER AT RISK	16,243	13,040	9,161	6,105	3,882
KM ESTIMATE	84.2	75.4	65.8	57.0	50.1
STANDARD ERROR	0.003	0.003	0.004	0.004	0.004

Imaging Follow-Up Compliance



Compliance with imaging follow-up recommendations after EVAR in the United States is well below the recommended rate.

Lesson from the Past:
Open Repair Has a Role, but it is Second line Treatment



EVAS
The game
solution f
aneurysm

RETHINK THE NECK
The Ovation Prime System is
does not have a conventional

INDICATED FOR
NECKS
<10mm
DOWN TO 4mm
LENGTH

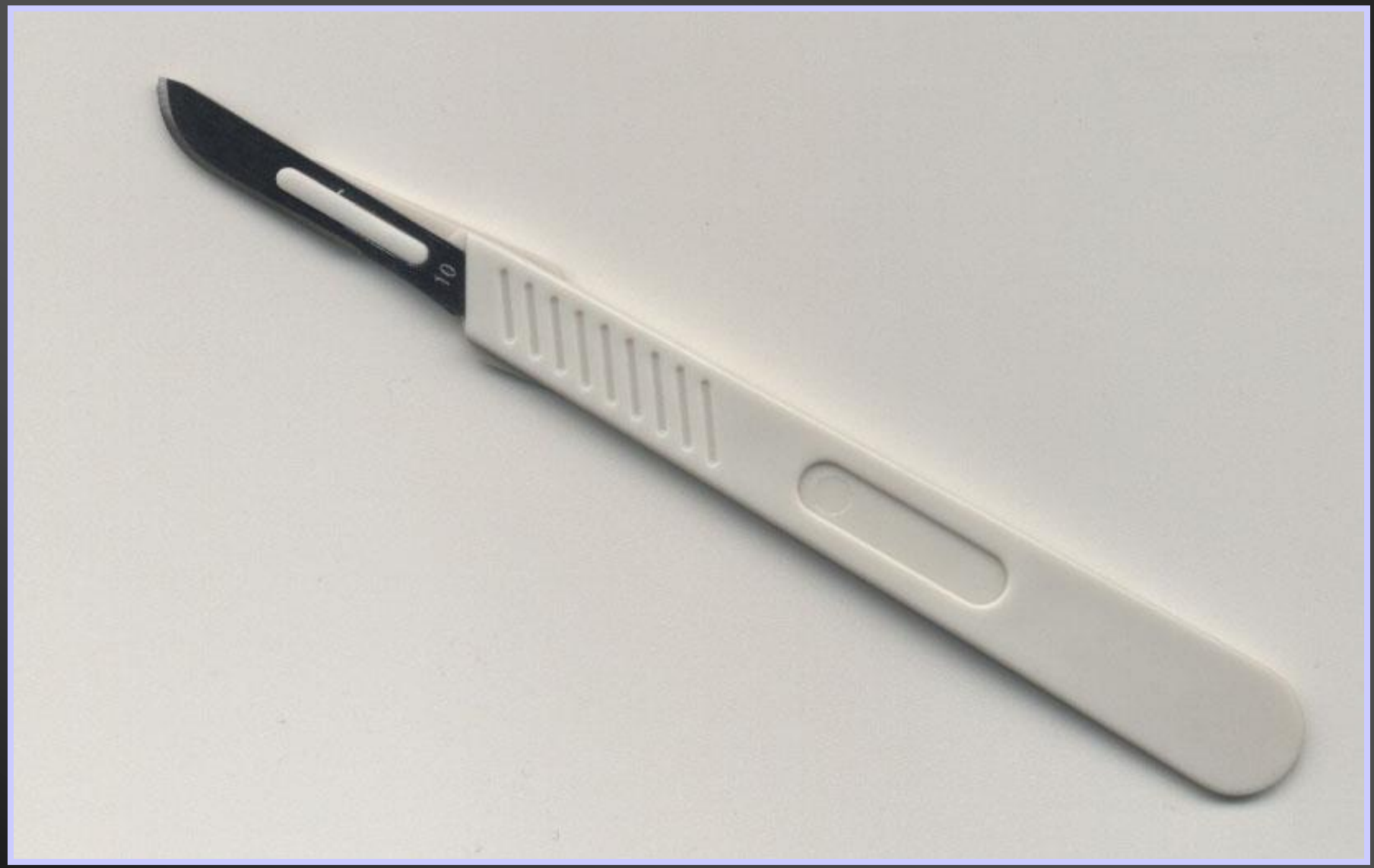
Endurant™II/IIs
AAA Stent Graft System

Heli-FX™
EndoAnchor™

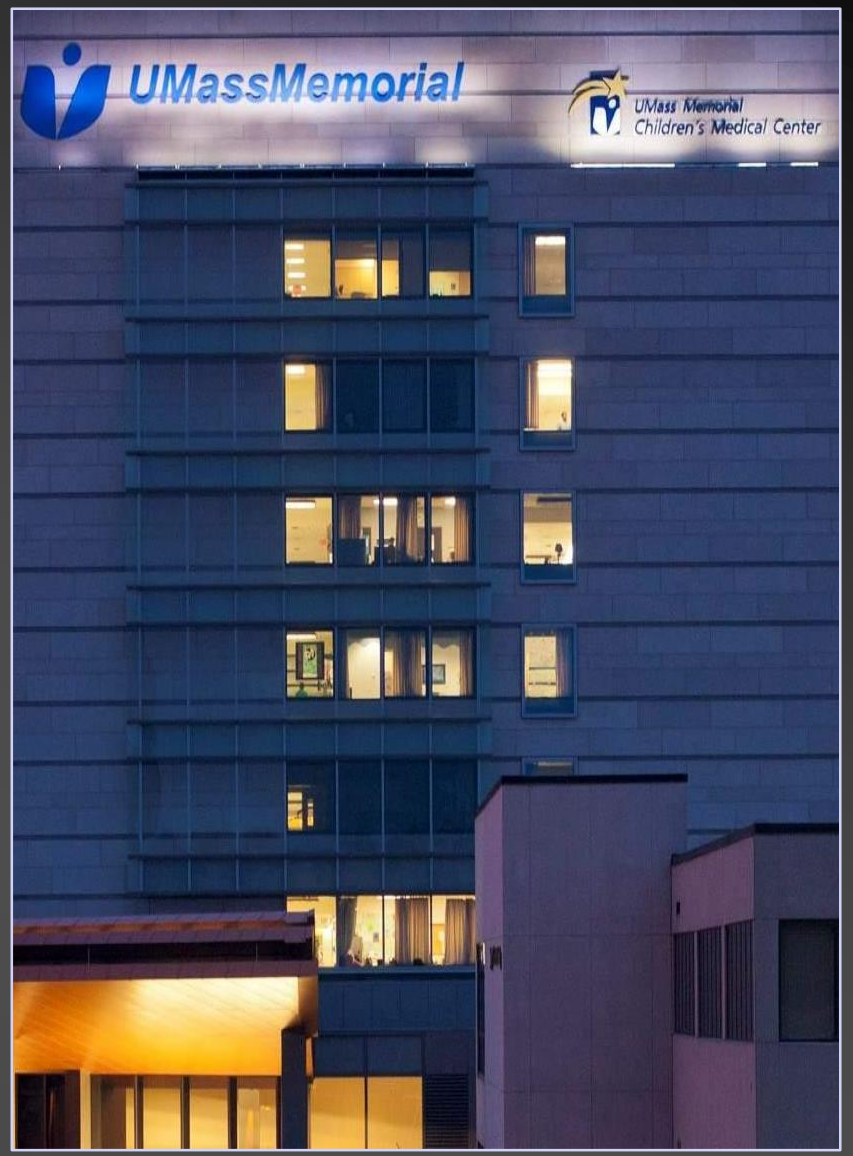
UMassMemorial
CENTER FOR COMPLEX AORTIC DISEASE

NORMAL ARTERY

NORMAL ARTERY


10

Lesson from the Past:
Open Repair Has a Role, but it is Second Line Treatment



Thank You.