Abdominal Aortic Aneurysm

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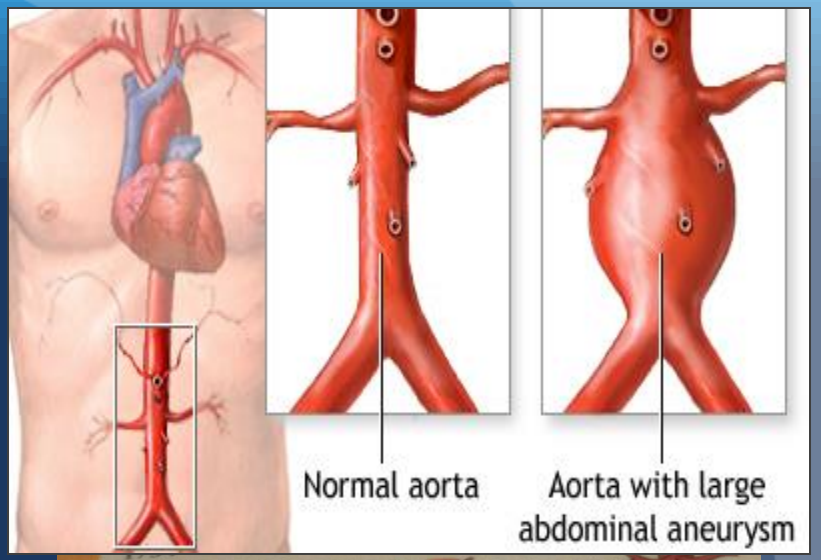
Overview:

- AAA Defined
- Pathogenesis & Epidemiology
- Risk Factors
- Presentation
- Diagnosis & Management
- Treatment Options

AAA Defined

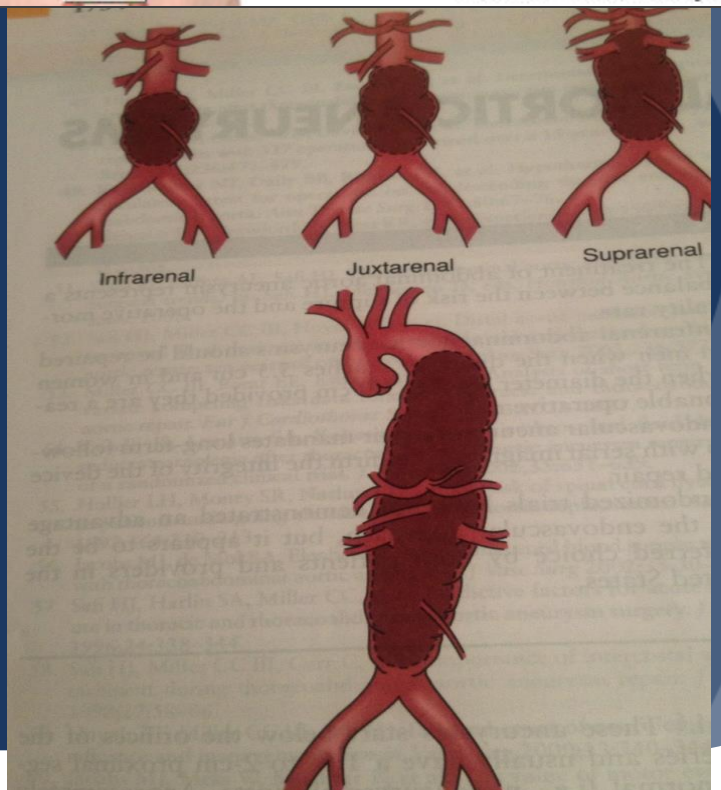
- **AAAs are located below the level of the diaphragm**
  - May be infra-, juxta-, para-, or supra-renal
  - Account for 90% of all aortic aneurysms



- **Weakening of the blood vessel wall architecture causing dilation**
  - Defined as absoulte diameter ≥ 3.0cm; or diameter 2x adjacent normal aorta

  Normal adult aorta measures approximately 2cm (1.4 – 3cm)

- **Progressive disease**
  - Small AAAs tend to grow over time
  - Rates of growth vary individually



AAA and other Aneurysms

- Multiple aneurysms occur in 3.5-15% of patients with AAA
- 72% synchronous; 28% metachronous
- 12% AAA have thoracic aneurysm
- Likelihood of detecting AAA in men with
  - Common femoral aneurysm: 92%
  - Popliteal Aneurysm: 64%
  - < 50% of detected AAA are palpable

Pathogenesis of AAA

Pathogenesis of Abdominal Aortic Aneurysm remains unresolved…

What we know…

- Medial and adventitia walls in AAA patients demonstrate inflammatory infiltrates
- Unclear what causes the acute inflammatory reaction
- Increase expression of matrix metalloproteinases(MMP)
- Chronic inflammation of aortic wall results in progressive degradation of the extracellular matrix, and leads to increasing dilation over time

Pathogenesis of AAA

Proposed Initial Events:

- Chronic Inflammation
- Oxidative stress
- Stimulation of MMP release by medial smooth muscle cells

Pathogenesis of AAA

Current Concepts:

Aneurysm Formation

- Elastin
  - Not synthesized in adult aorta after age 40
  - Fragmentation is the beginning of aneurysm formation
  - Aneurysm Growth and Rupture

- Collagen
  - Deposition
  - Remodeling
  - Degradation

Pathogenesis of AAA

- Two types of aortic pathology
  - Atherosclerotic Occlusive Disease
  - Aneurysmal Degeneration

- It is likely that multiple factors including inflammation, smoking and genetic predisposition act to shift the equilibrium between elastase and collagenase activity and inhibition in favor of elastin and collagen destruction or weakening

Pathogenesis of AAA

- Experimental and clinical investigation points to potential causes including:
  - Atherosclerosis
  - Aging
  - Cigarette Smoking
  - Pulmonary Emphysema/Inguinal Hernia
  - Hypertension
  - Family History

- Genetic and environmental components determine onset and progression

Epidemiology of AAA

What is the magnitude of problem in the U.S.???

- 1.7 million people have AAA
- 190,000 New AAA Diagnosed annually
- 15,000 deaths per year from ruptured AAA
- AAA rupture is the 13th leading cause of death; 10th in men over 55
- 50,000 AAA repairs annually

Epidemiology of AAA

Demographic Factors

- Incidence:1-3% (Autopsy); variable
- Male/Female ratio: 4:1
- Age: 7^{th}-8^{th} decades
- Race: 90% caucasian; 5% Black/Asians
- Location: 95% infrarenal
- Coronary Heart Disease – 25% symptomatic
- Hypertension: 40%
- Peripheral Arterial Disease: 20-30%

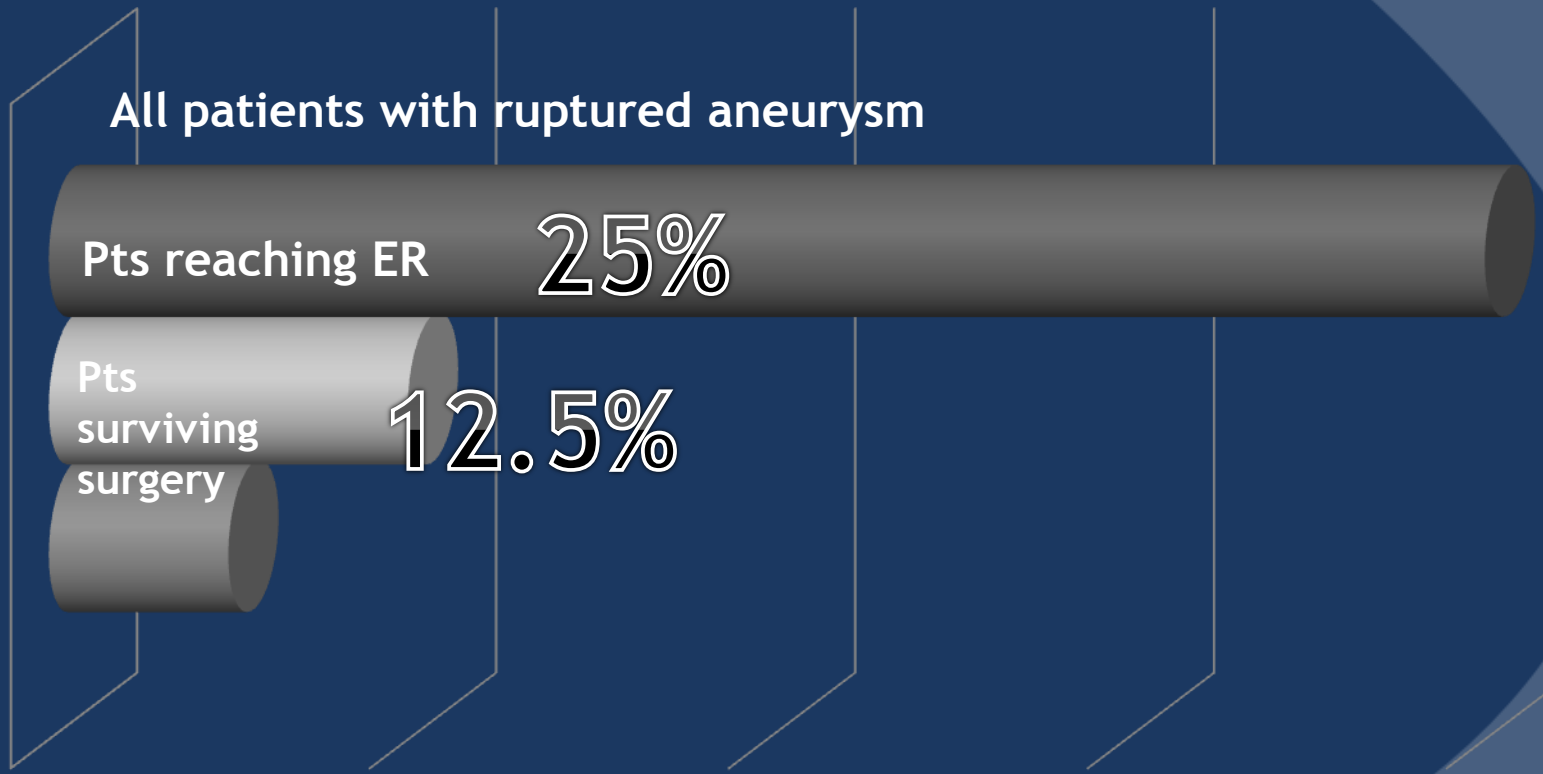
AAA is a public health concern!

- Increasing incidence
- Aging population at risk
- High Morbidity and Mortality from rupture
- Increasing incidence of rupture
- No known medical therapy

AAA Rupture Deaths:

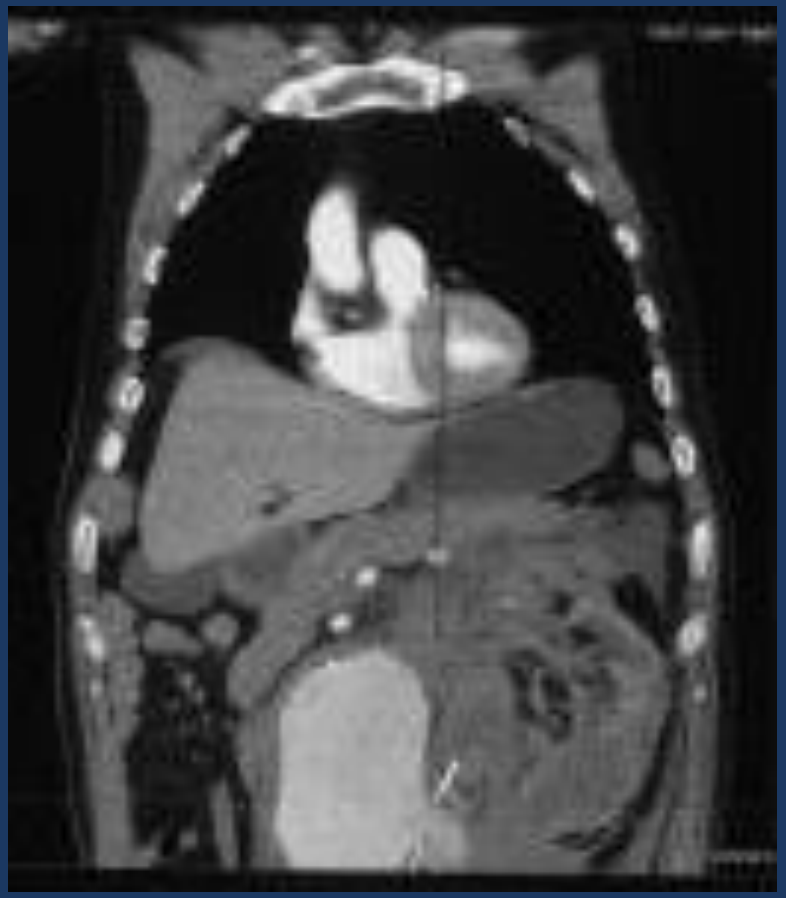
- Rupture is most likely Fatal
- 2 out of 3 patients that rupture die before they reach the ER
- Rupture claims more than 15,000 lives annually in the USA
- Rupture is the 16th leading cause of Death in the USA

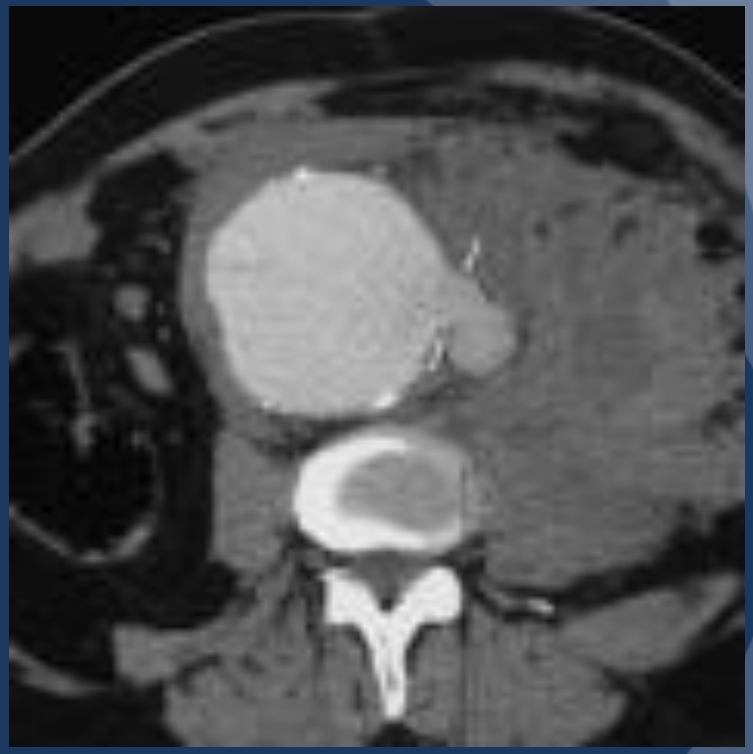
AAA rupture carries as much as 90% mortality



Source: Al—Omran M, et al. "Clinical Decision Making for Endovascular Repair of Abdominal Aortic Aneurysm". Circulation. 2004; 110: e517-e523

Ruptured Aorta



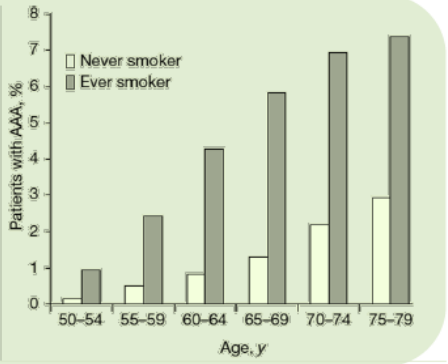


Risk Factors:

- Older Age
- Male Sex
- Tobacco
- Family History of AAA
- Hypertension
- Manifest Atherosclerotic Disease (peripheral & coronary vascular disease)
- Other collagen vascular disease (Marfan's Syndrome, Ehlers-Danlos)
- AAA appears to be lower in women*, African Americans, and diabetics
  - *Women are 2 – 4 times more likely to experience rupture than men

Prevalence of AAAs greater than 3 cm by age and smoking history

Smoking is associated with a 3- to 5-fold increase in the prevalence of abdominal aortic aneurysms.[8]

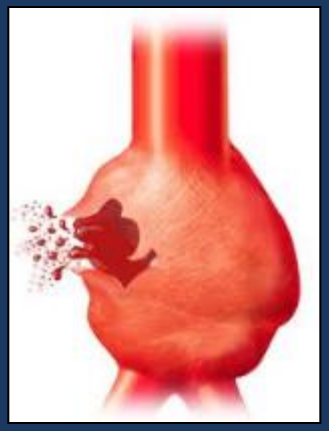


Source: Fleming C, Whitlock EP, Bell TL, Lederle FA. Screening for abdominal aortic aneurysm: A best-evidence systematic review for the U.S. Preventive Services Task Force. AHRQ Pub. No. 05-0569-B. 2005

Source: Lloyd-Jones, Adams, Brown, et al. Circulation "Heart Disease and Stroke Statistics - 2010 Update: A report from the American Heart Association". 2010; 121:e46-e215

AAA Presentation:

- AAA rarely presents with symptoms and is most often an incidental diagnosis
- Only 30-40% are noted on physical exam*; detection dependent on size
- Rarely, patients can present with
  - Abdominal pain
  - Back pain
  - Pulsating, peri-umbilical mass



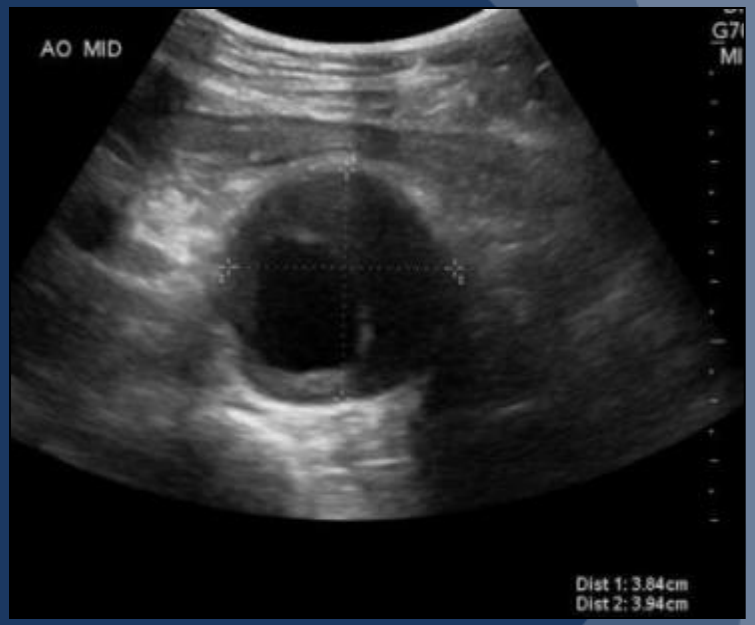
- A ruptured aneurysm can present with:
  - Abdominal or back pain
    - May be sudden, persistent, or constant
    - May radiate to groin, buttocks, or leg – severe, sudden, persistent, or constant
  - Diaphoresis, pre-syncope, nausea and vomiting
  - Tachycardia, shock

**Source: Chaikof EL, Brewster DC, Dalman RL, et al. "The care of patients with an abdominal aortic aneurysm: The Society for Vascular Surgery practice Guidelines." J Vasc Surg 2009 50 (8S): 2-42S*

Screening – SAAAVE Act

Screening Abdominal Aortic Aneurysms Very Efficiently

- Legislation introduced in 2007 to provide AAA screening for all newly eligible MediCare beneficiaries as part of "Welcome to Medicare"*
  - Includes all existing male MediCare beneficiaries with a history of smoking, and females with a family history of AAA
  - No co-pay for the patient; performing facility is reimbursed (HCPCS code G0389, CPT 76700)
- ONE-TIME SCREENING FOR
  - MEN > 65 YEARS
    - Smoking History
  - MEN OR WOMEN
    - Family History of AAA



** Legislation applies to all male "ever-smokers" (≥100 cigarettes in their lifetime), and male and female patients with a family history of AAA*

Diagnostic Evaluation:

- PMH:
  - Smoking
  - Atherosclerosis (CAD, PAD)
  - Hypertension
  - Collagen vascular disease: Marfan's Syndrome, Ehlers-Danlos, etc.
- FMH
  - History of AAA

- For patients with established risk factors, abdominal ultrasound exam *(sensitivity & specificity approach 100%; may be limited by body habitus)*
  - SAAAVE Act CPT G0389
  - Co-insurance and deductible are waived (Jan, 2011)
- Ultrasound is extremely effective for screening; but may be imprecise for measuring aneurysm size

In patients receiving diagnostic workup for other abdominal pain, follow-up is important*:

- In a study of ~80,000 abdominal images (CT, US, MRI), 1% showed a AAA with mean diameter of 4.0 cm
- Only 15% of these were communicated to the referring MD

**Source: Walraven C, Wong J, Morant K, et al. "Incidence, follow-up, and outcomes of incidental abdominal aortic aneurysms." J Vasc Surg. 2010;52(2):282.*

Screening for AAA

- Method: ULTRASOUND
- Results:
  - Identifies anuerysms
  - Reduces AAA-related death by 50%
  - Can be cost-effective

ULTRASOUND

ADVANTAGES

- Widely available
- No radiation
- Multiple views
- Physiologic Data
- Painless
- No side effects
- Least expensive

DISADVANTAGES

- Can be technician dependent

CAT Scan for AAA

Advantages

- Not Technician Dependent
- Rapid
- Precise Anatomic Definition
- Shows non-vascular areas
- 3-D Reconstructin (CTA)

Disadvantages

- Ionizing Radiation
- Nephrotoxic Contrast

Initial Considerations:

- ✓ All patients should be counseled to stop smoking
- ✓ Treatment for underlying hypertension, hyperlipidemia, diabetes, and other atherosclerotic risk factors should be initiated
- ✓ Family members should be screened
- ✓ Surveillance schedule initiated
- ✓ Aneurysms ≥ 5.5 cm are indicated for repair

Source: Chaikof EL, Brewster DC, Dalman RL, et al. "The care of patients with an abdominal aortic aneurysm: The Society for Vascular Surgery practice Guidelines." **J Vasc Surg 2009 50 (8S): 2-42S*

Size Matters

Maximum AAA Diameter	5 year Rupture Rate
<4.0cm	2%
4.0-4.9cm	3-12%
5.0-5.9cm	25%
6.0-6.9cm	35%
>7.0	75%

AAA Screening: Beyond SAAVE

- Society for Vascular Surgery also recommends screening of men ≥ 55y who have a positive family history
- ALL patients diagnosed with an aneurysm will require continued surveillance due to progressive nature of the condition

AAA Size	Recommended Follow-Up
≥ 5.5 cm	REPAIR (Endovascular or Open)
4.5 – 5.4 cm	6 month interval imaging* (may be indicated for repair based on presentation)
3.5 – 4.4 cm	12 month interval imaging
3.0 – 3.4 cm	3 year interval imaging
2.6 – 2.9 cm	5 year interval imaging

Source: Chaikof EL, Brewster DC, Dalman RL, et al. "The care of patients with an abdominal aortic aneurysm: The Society for Vascular Surgery practice Guidelines." **J Vasc Surg 50 (8S): 2-42S.*

Indications for AAA repair

- Rupture
- Symptomatic
- Asymptomatic
  - >5.4cm in good risk men
  - >4.5cm in good risk women
  - Rapid enlargement
  - Saccular shape regardless of size
  - Blebs

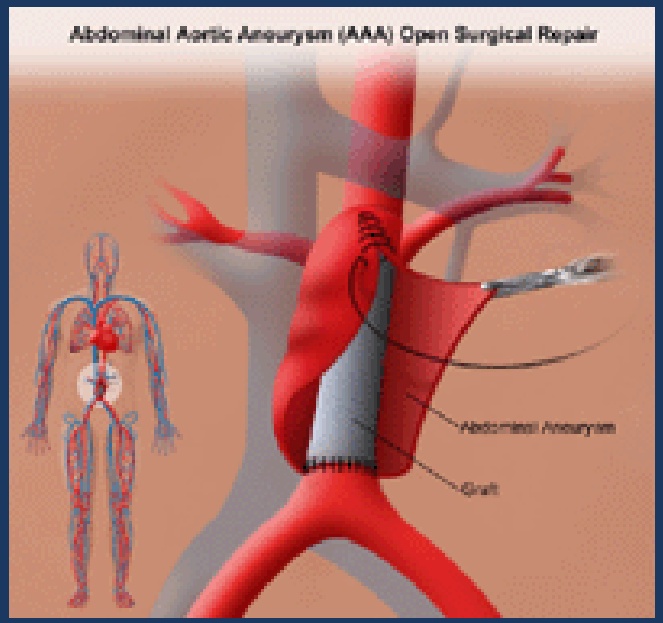
Repair of Aortic Aneurysms

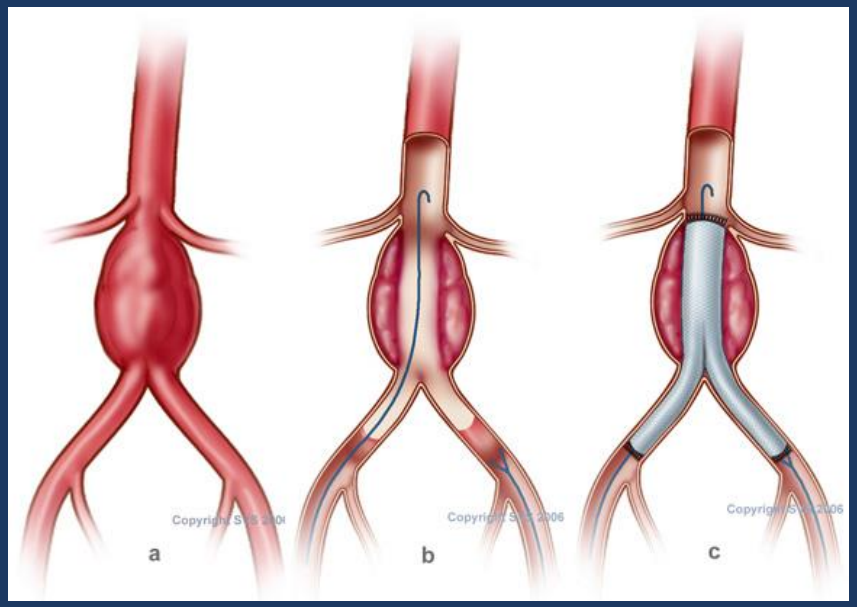
Decision to Operate…

- AAA Rupture Risk (risk increases with age)
- Elective Operative Risk
- Life Expectancy

✔ **Treatment goals for patients with AAA are to relieve symptoms, prolong life, and prevent rupture**

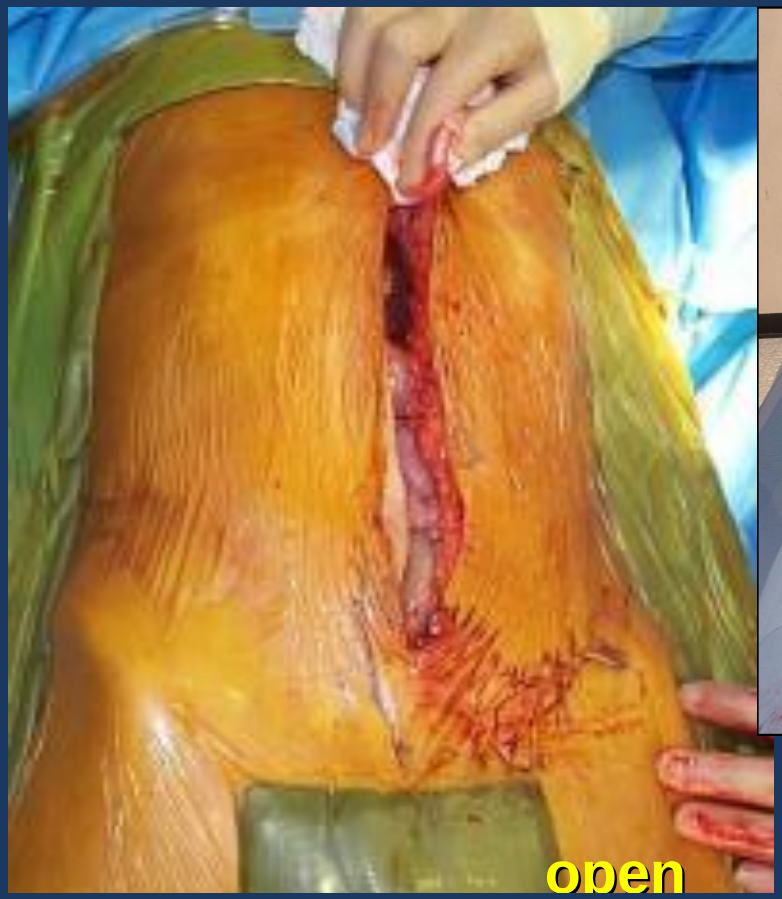
Which Therapy to Choose?

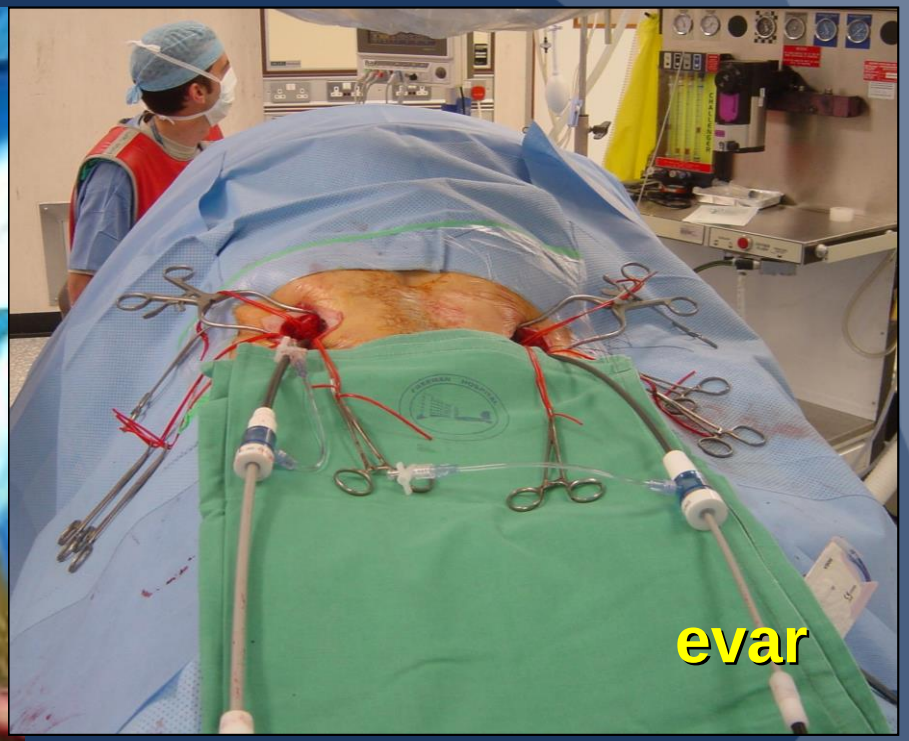




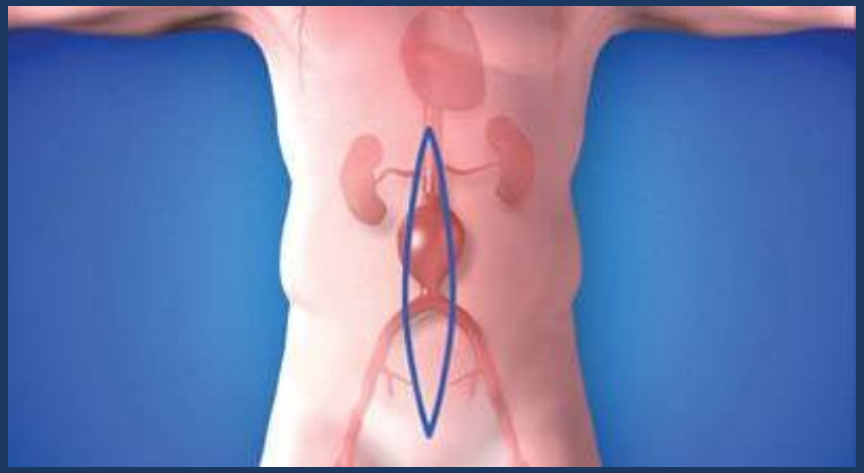
Open vs. Endovascular Repair

How Do You Choose?





Is there a Formula?



Age + Anatomical Requirements

+ Under Lying Medical Conditions

x Medical Follow Up

= Treatment

AAA Repair Options

Open Surgical Repair

- First performed in 1951 using homograft (DuBost)
- Aneurysm is accessed via laparotomy or retroperitoneal approach
- Aneurysm is divided
- Homograft is sewn into the distal and proximal portions of healthy aorta
- Aneurysmal tissue is used to oversew the homograft

Endovascular Repair

- Introduced in 1991 (Juan Parodi)
- Stent endograft is implanted via a bilateral femoral access approach
- Graft is fixed proximally and distally to healthy aortic tissue
- Graft excludes the aneurysm
- Initially intended for patients seen as high risk for operative approach
  - Cardiovascular disease
  - COPD
  - Advanced Age

Overview: Open repair vs. EVAR

TRIAL	Centers (N)	Patients (N)	Study Period	Max (Avg) Follow Up (y)	Conclusion
DREAM (EU)	25	351	2000-2009	8.2 (6.4)	• Survival rates ~69% for EVAR & Open • Higher secondary interventions
EVAR-1 (UK)	37	1252	1999-2009	10 (6)	• 30 d op mortality 1.8% (EVAR) vs. 4.3% (open) • Equivalent mortality long term
OVER (US)	42	881	2002-2008	9 (5.2)*	• Perioperative mortality 0.5% (EVAR) vs. 3.0% (open) • No difference in morbidity or secondary procedures

- Meta analysis of prospective, RCTs show early and intermediate benefit for peri-operative and AAA-related mortality with EVAR vs. Open
- EVAR patients have higher re-intervention rates
- Long term survival rates between the two groups are equal

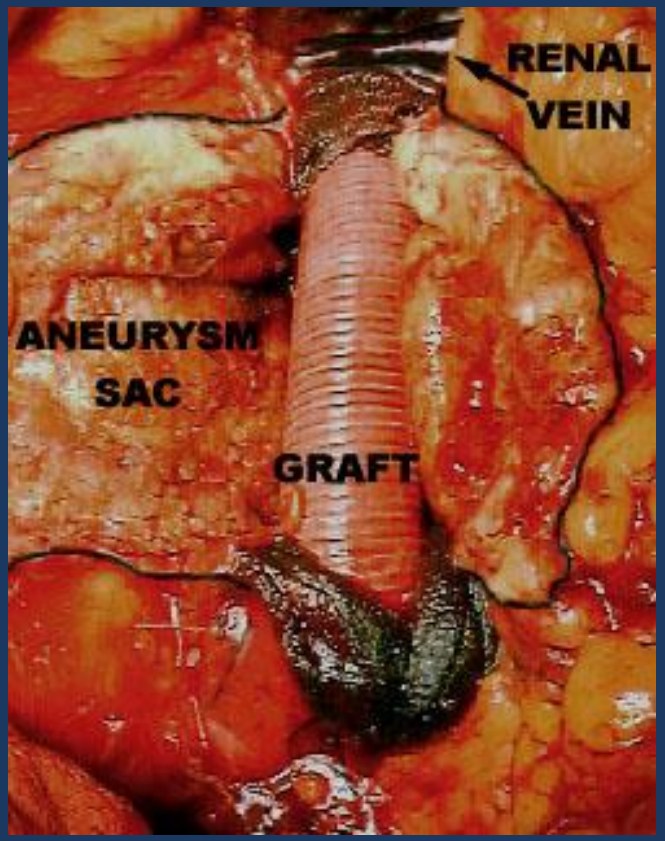
Source: Dangas G, et al. "Open Versus Endovascular Stent Graft Repair of Abdominal Aortic Aneurysms: A Meta Analysis of Randomized Trials" J Am Coll Cardiol Intv 2012; 5:1071-80
** Lederle FA, et al. "Long Term Comparison of Endovascular and Open Repair of Abdominal Aortic Aneurysm". N*

Choosing Open Repair vs. EVAR

	ADVANTAGES	DISADVANTAGES
Open	• Definitive repair for patients at low risk • Shorter follow-up required • No need for subsequent reinterventions	• Highly invasive • Higher short- and intermediate term AAA mortality • Long in-hospital recovery (7-10 days) • Long at-home recovery • Not suitable in high risk patients
EVAR	• Minimally invasive • Lower mortality • Shorter LOS (2-3 days) • Quicker recovery • Safer for high risk patients	• Need for lifelong surveillance • May require subsequent re-intervention

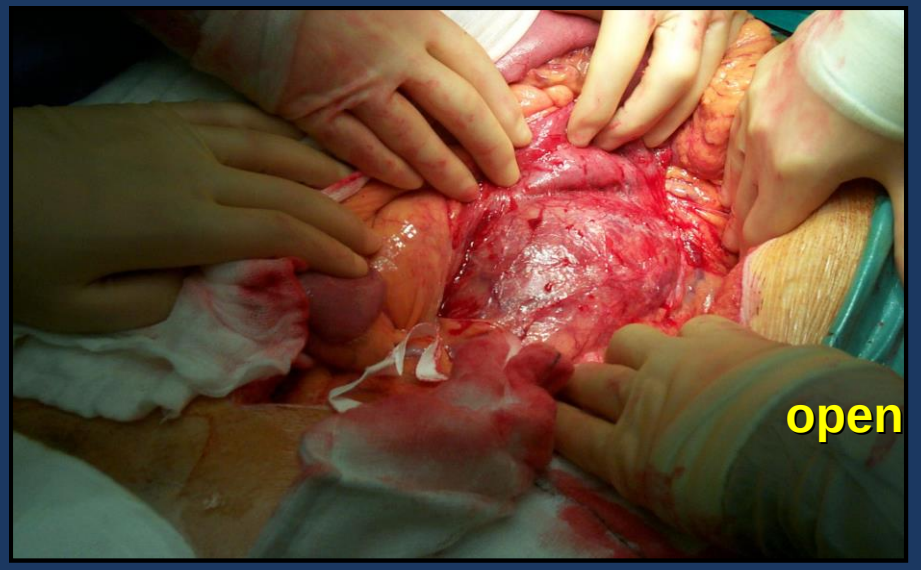
Advantages of Open Repair

- Traditional Open Repair Has been around longer than EVAR
- Over 40,000 Procedure done Annually in the USA
- Limited Medical Follow-up



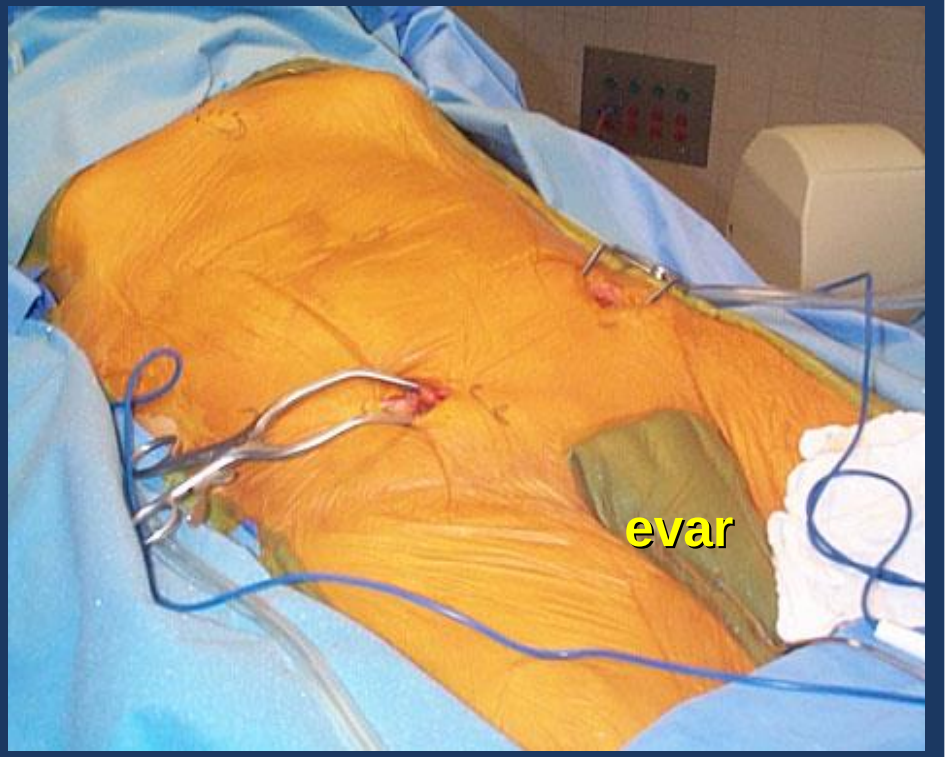
Limitations of Open Repair

- Complication rates are Higher
- OR time is Longer
- Hospital stay is Longer
- High Mortality and Morbidity Rates
- Recovery Time is Longer



Advantages of EVAR

- Minimally Invasive Procedure
- Local Anesthesia
- Small Punctures or Cut Downs in the Groins
- Lower Complication Rates
- Shorter Hospital stay and Recovery



EVAR Endograft Options:

- Several FDA approved devices exist
  - Address range of anatomies
  - Each have specific attributes
- Vary in profile
- Each with established, published data

FDA Approved AAA Endografts

Medtronic Endurant™

Gore Excluder™

Endologix AFX™

Trivascular Ovation™

Cook Zenith™

Limitations of EVAR repair:

- Long Term Durability Unknown
- Higher Potential for Endoleaks or Late Rupture
- Possibility for Secondary Surgical Procedures
- Long Term Medical Follow up

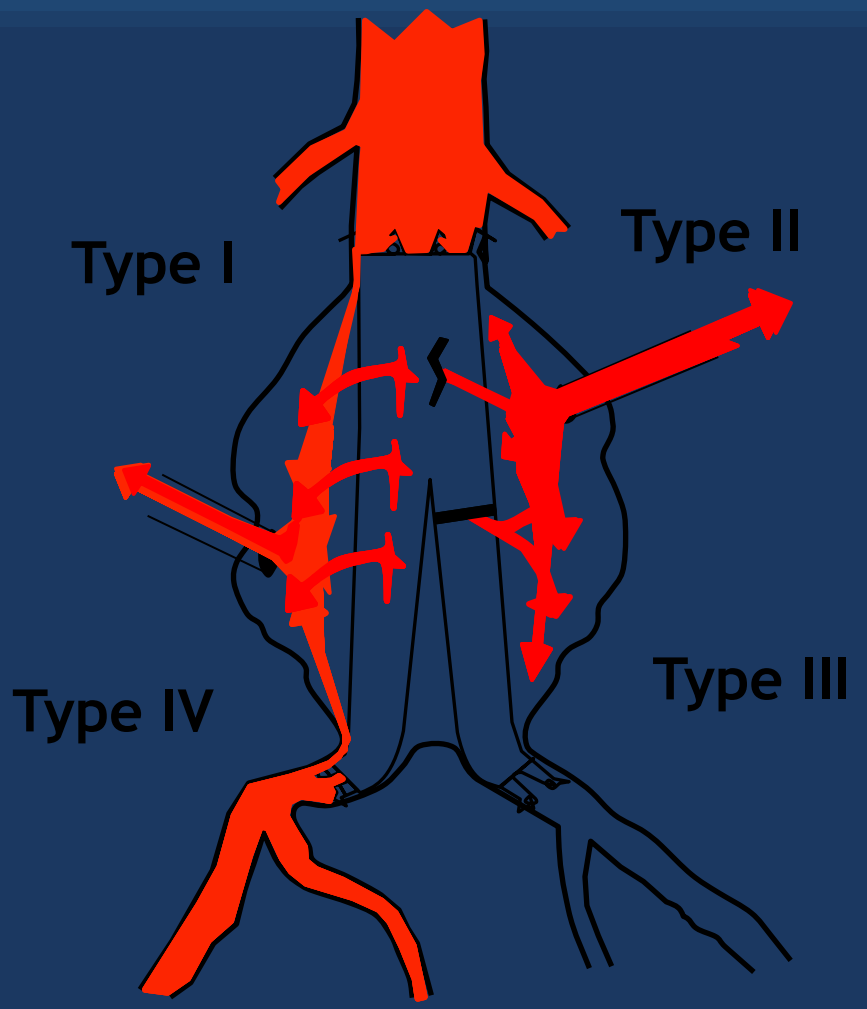
Endoleaks Definitions

Type I
Attachment Leak

Type II
Branch Flow

Type III
Defect in graft or
Modular disconnection

Type IV
Fabric porosity



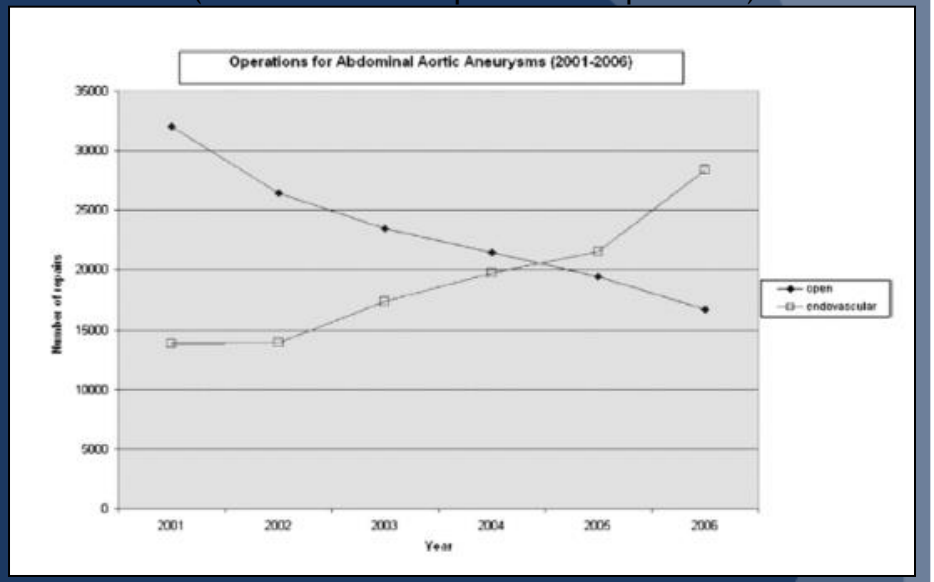
White et.al., Endoleak Classification, Journal of Endovascular Surgery, 1998;5:305-309

Trend and Distribution of Treatment

- Rate of EVAR has grown in the past decade
- Rates of EVAR surpassed open cases between 2004 and 2005 (US data)
- Today, 65% of AAA are repaired using an endovascular approach

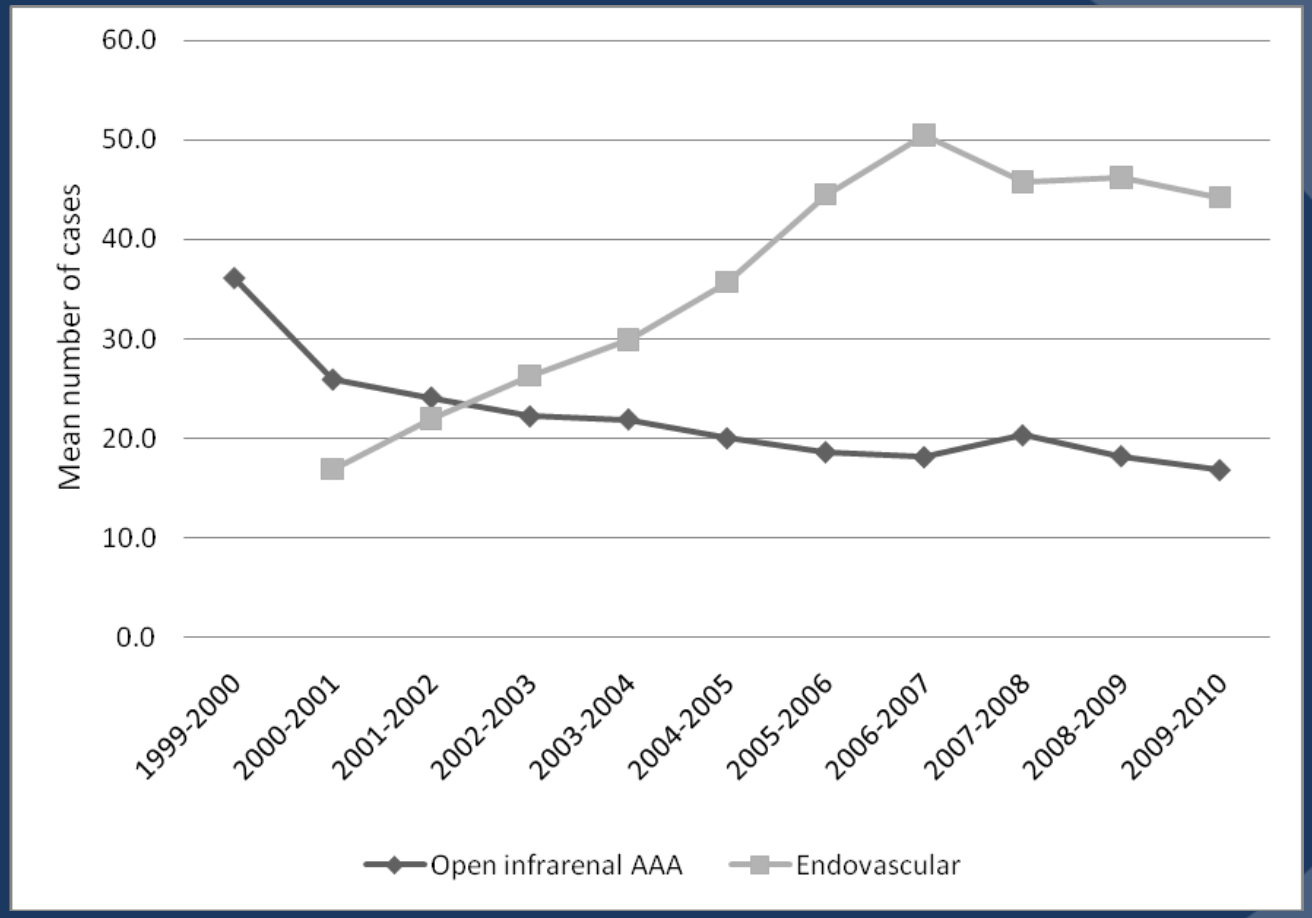
Volume of EVAR vs. Open Procedures: US 2001-2006

(HCUP/National Inpatient Sample Data)



Source: Ng T, et al. "Variations in the utilization of endovascular aneurysm repair reflect population risk factors and disease prevalence" J Vasc Surg 2010; 51:801-809

Trends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Mean number of cases
1999-2000
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2005-2006
2006-2007
2007-2008
2008-2009
2009-2010
Open infrarenal AAA
Endovascular

Several factors may contribute to success

Patient-specific Attributes[1]	Physician-specific Attributes[2]	Device-specific Attributes[3]
✓ Gender	✓ Presence of multispecialty team	✓ AAA Endograft
✓ Vessel Diameter	✓ Experience with EVAR	✓ Sheath-based
✓ Vessel Calcification		✓ Delivery Profile
✓ Vessel Tortuosity		
✓ Body Mass Index		
✓ Presence of PAD		

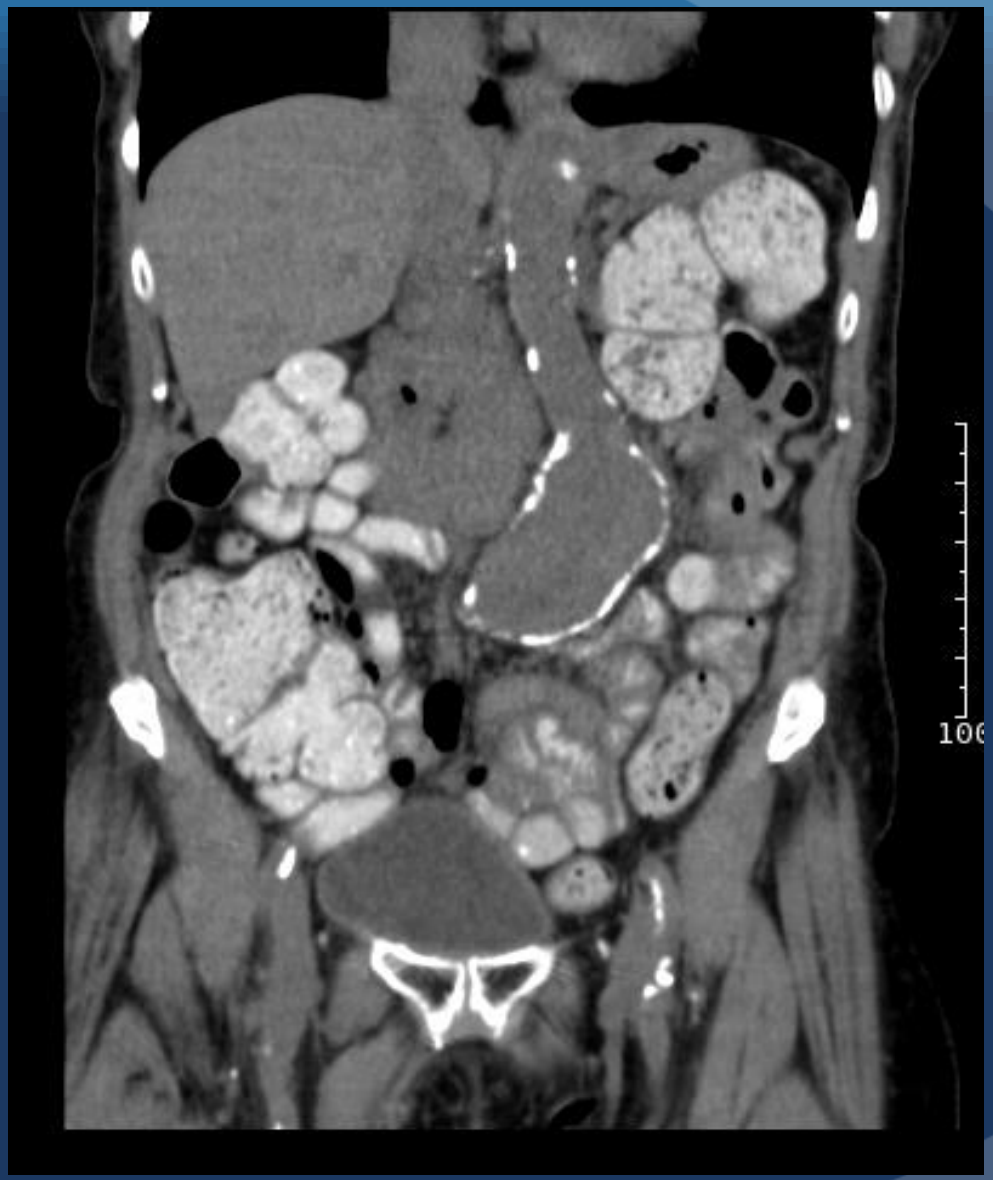
- Need for appropriate patient selection
- By an experienced EVAR physician
- Using devices optimally suited for a EVAR approach

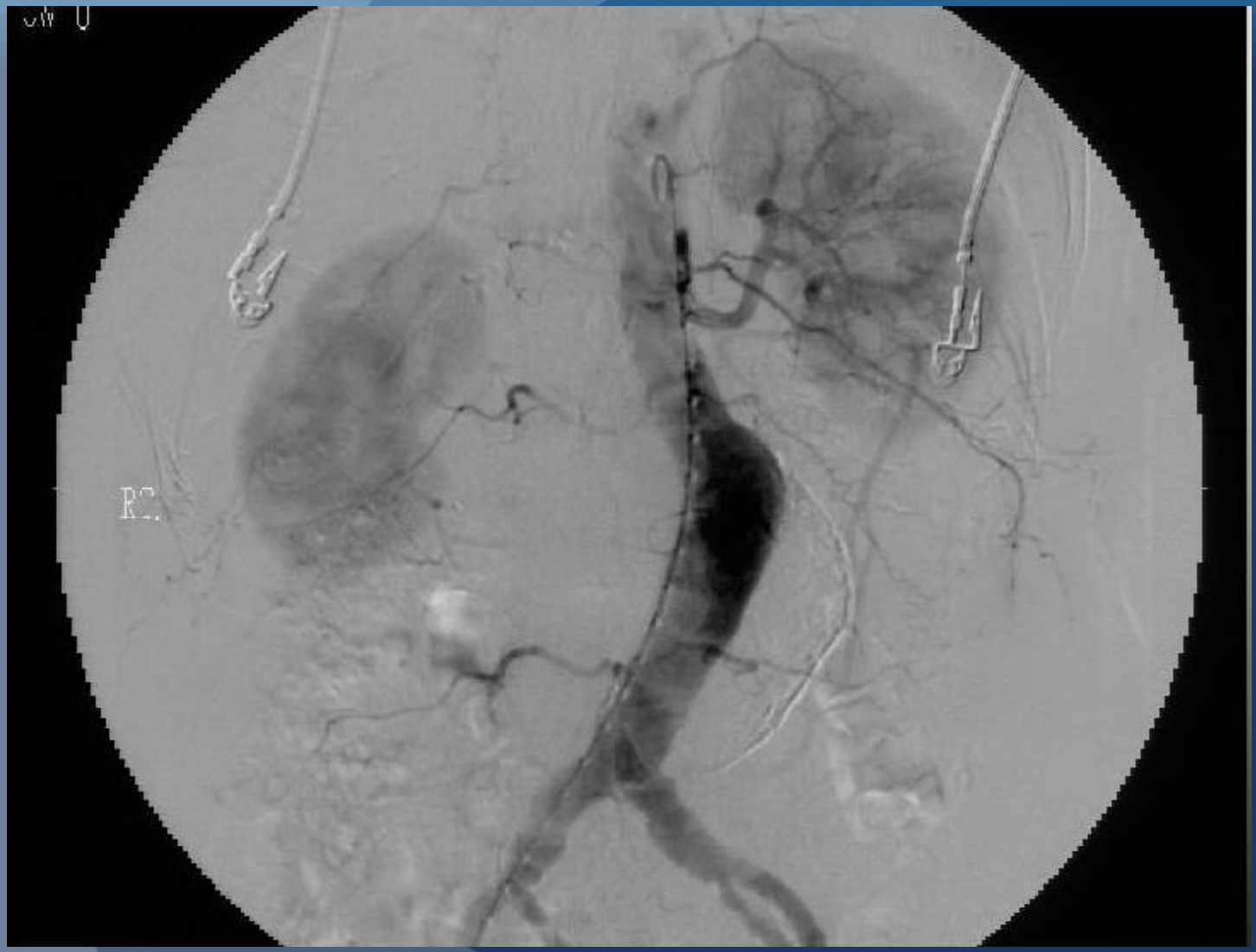
[1]Lee et al. *J Vasc Surg* 2008; 47:919-23; Al-Khatib et al. *Ann Vasc Surg* 2012; 26: 276-82
[2]Bechara et al. *J Vasc Surg* 2013 Jan;57(1):72-6
[3]Georgiades et al. *J Endovasc Ther* 2011;18:445-459

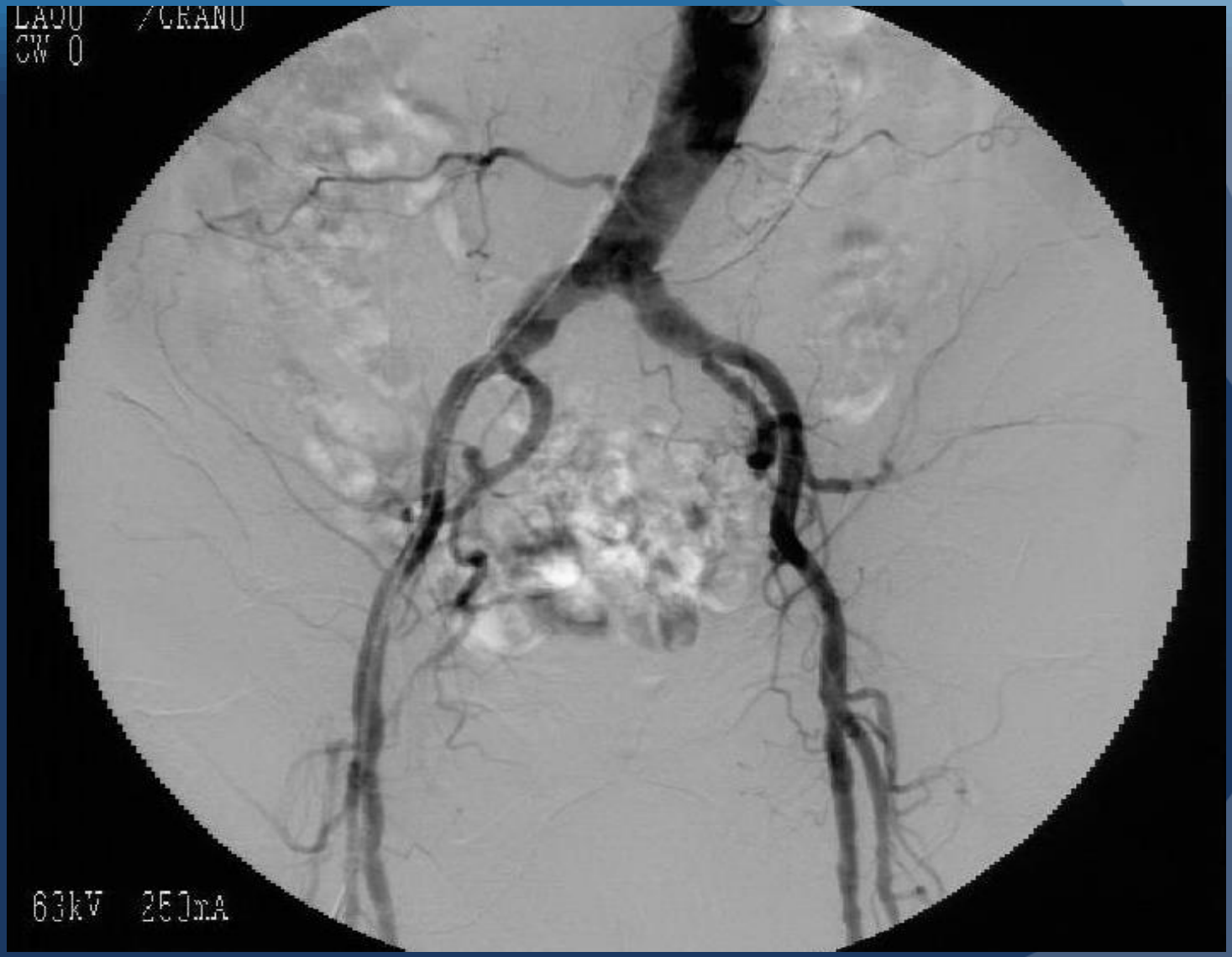
82y Female with history of an infrarenal AAA. Patient was first diagnosed with a 3.0cm AAA at age 71, and had since been followed up with yearly U/S and/or CAT scans for the past 11 years. Her most recent CAT-scan showed a 4.8cm infrarenal AAA.

Patient complains of generalized weakness, abdominal tenderness, and bilateral lower extremity pain

PMH: HTN, CAD, DM-II, Hyperlipidemia, PVD



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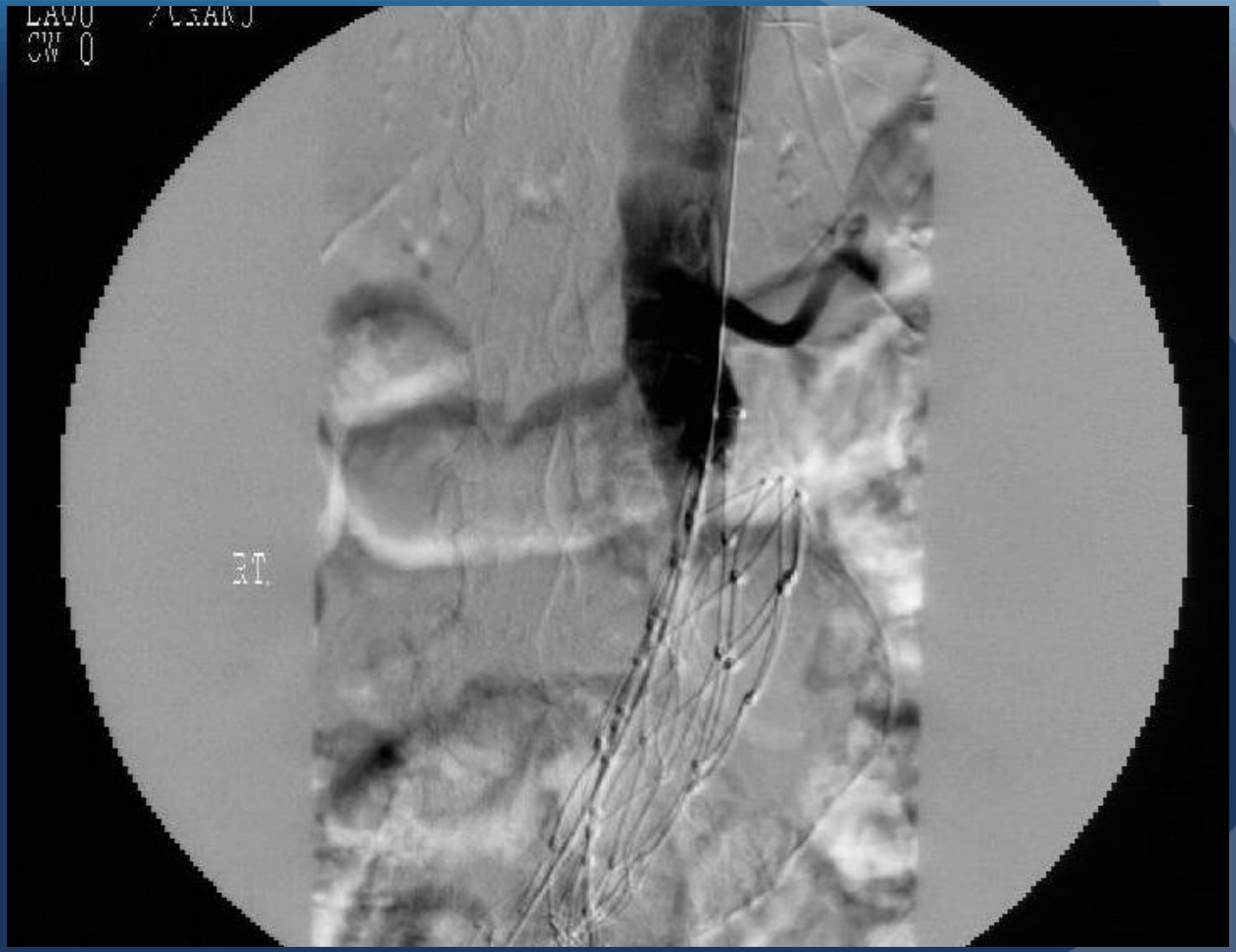

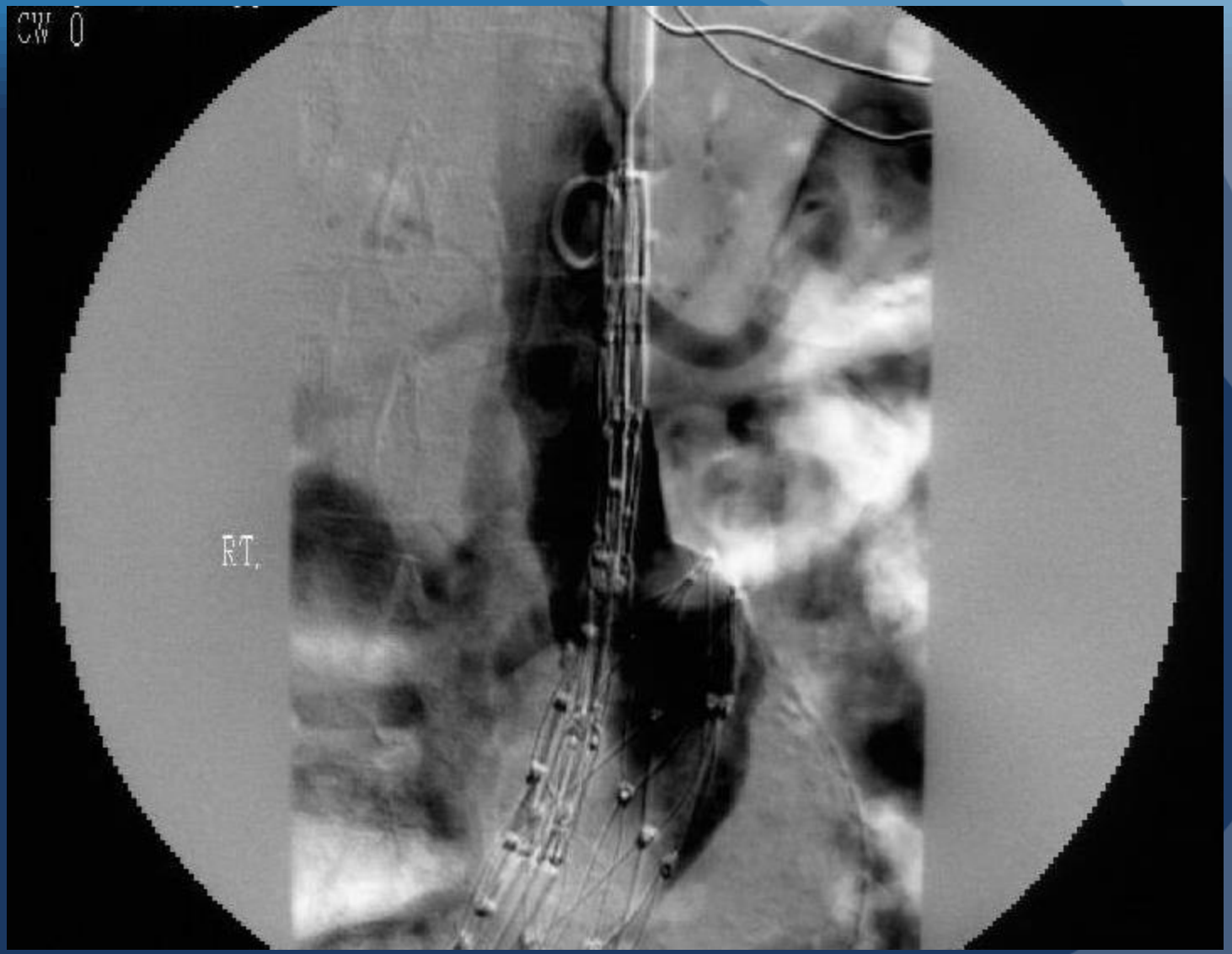
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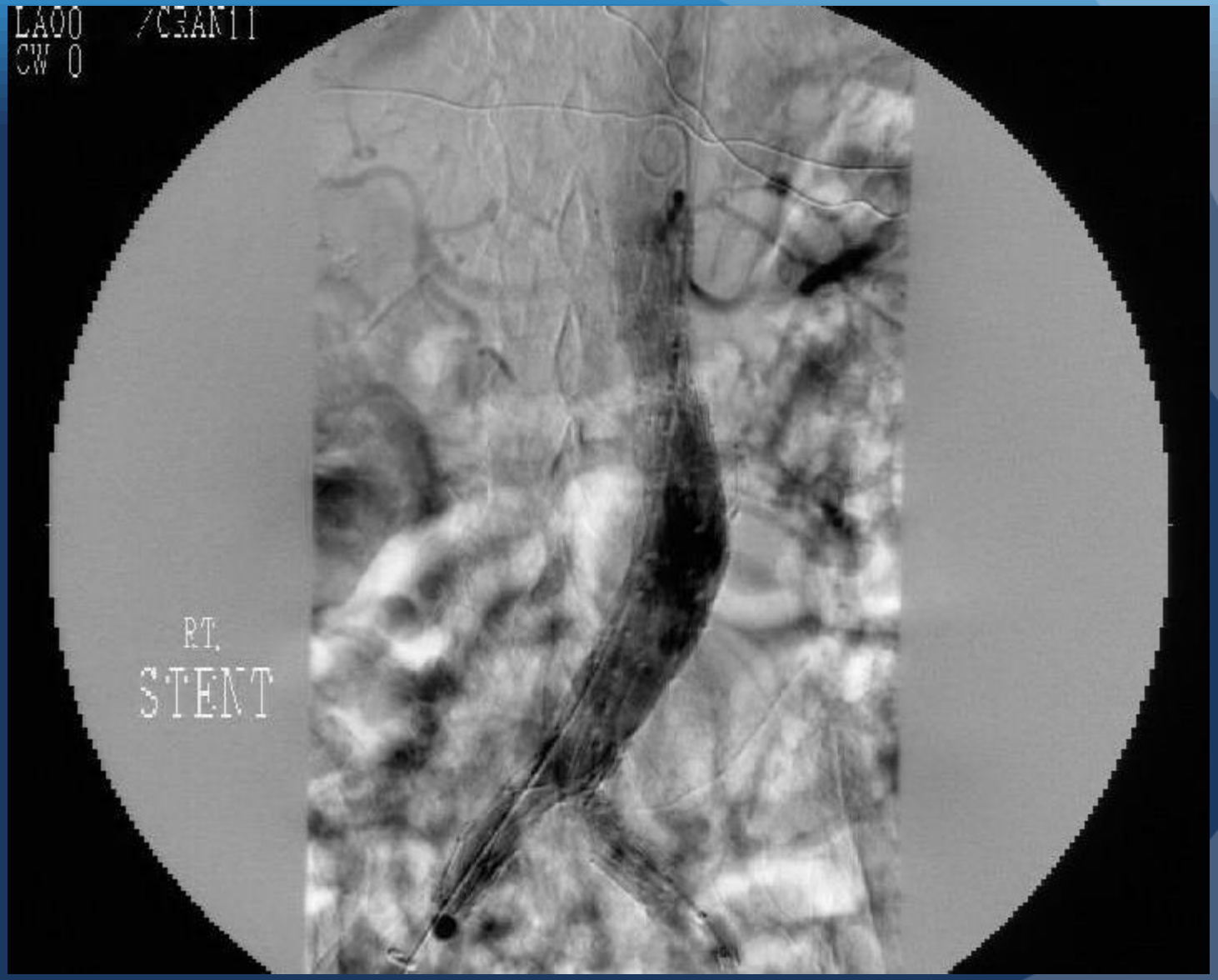
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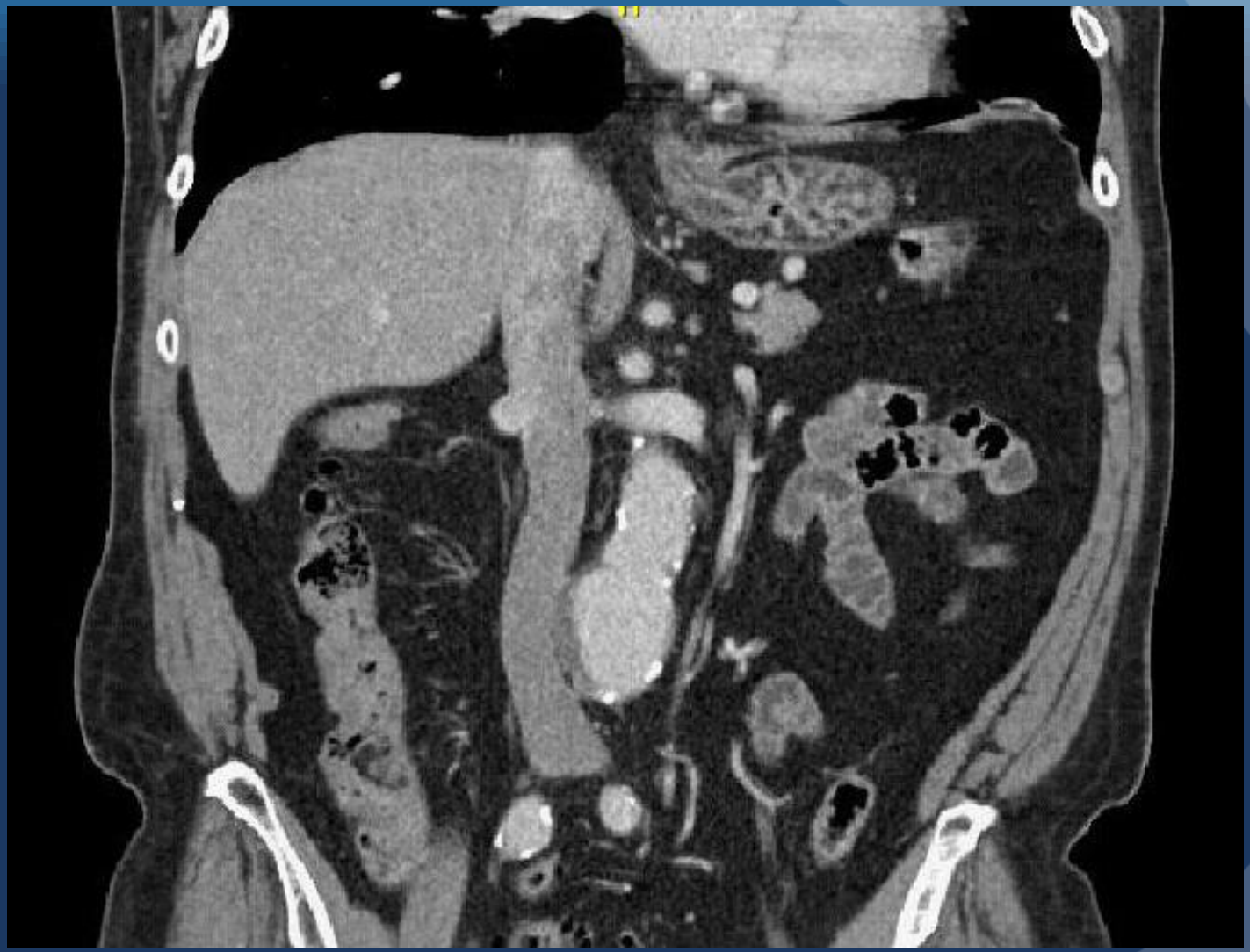
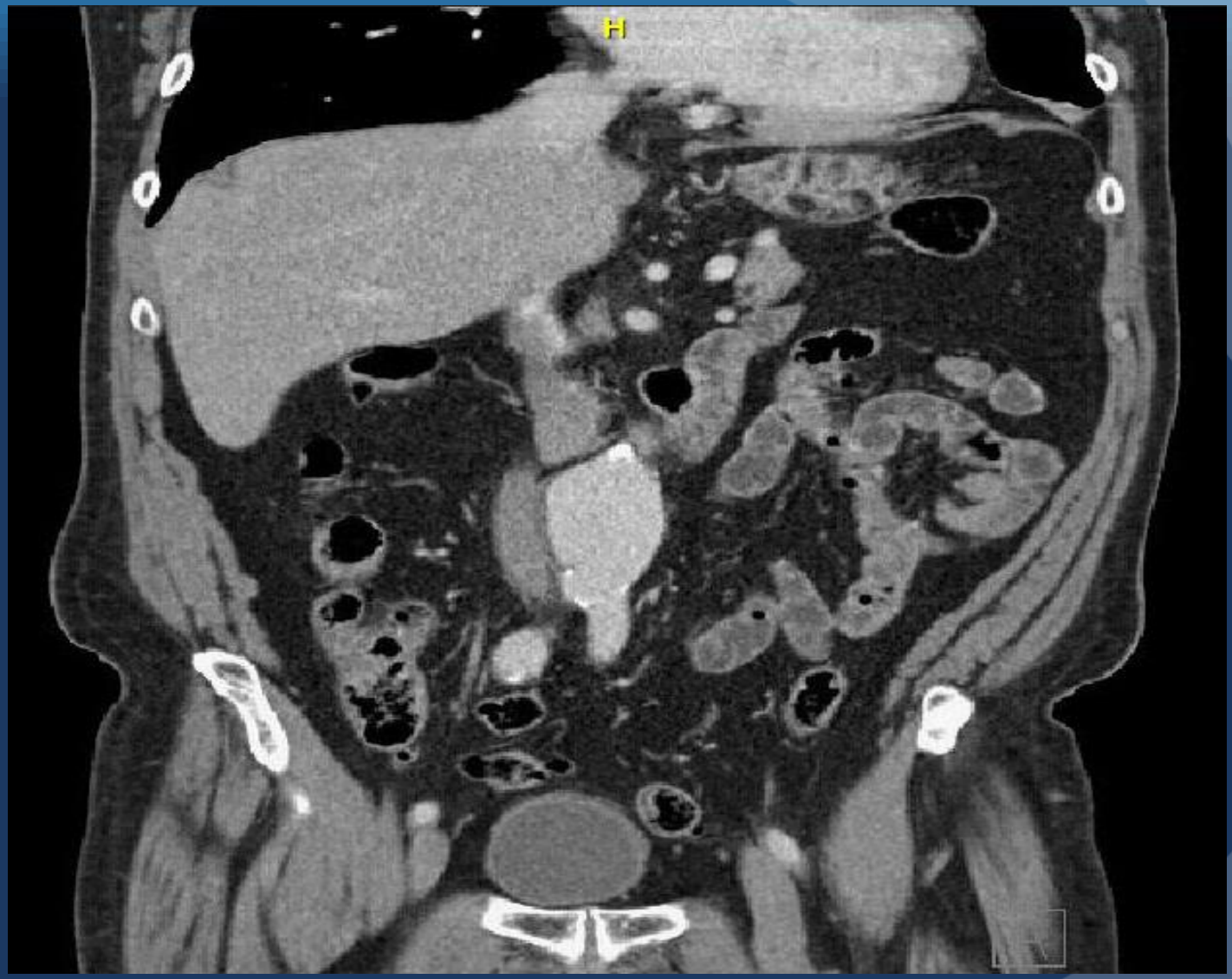
STENT

80 y Male who went into the ER for evaluation of acute abdominal pan. Patient had a CAT scan which showed acute cholecystitis with an incidental finding of a 4.4cm infrarenal AAA. One month later, patient was involved in an MVA. Repeat CT-scan now showed a 4.8cm AAA. (0.4cm increase in size within 1 month)

Patient is very anxious with complains of epigastric pain and vague abdominal pain.

PMH: HTN, Hyperlipidemia, Arthritis

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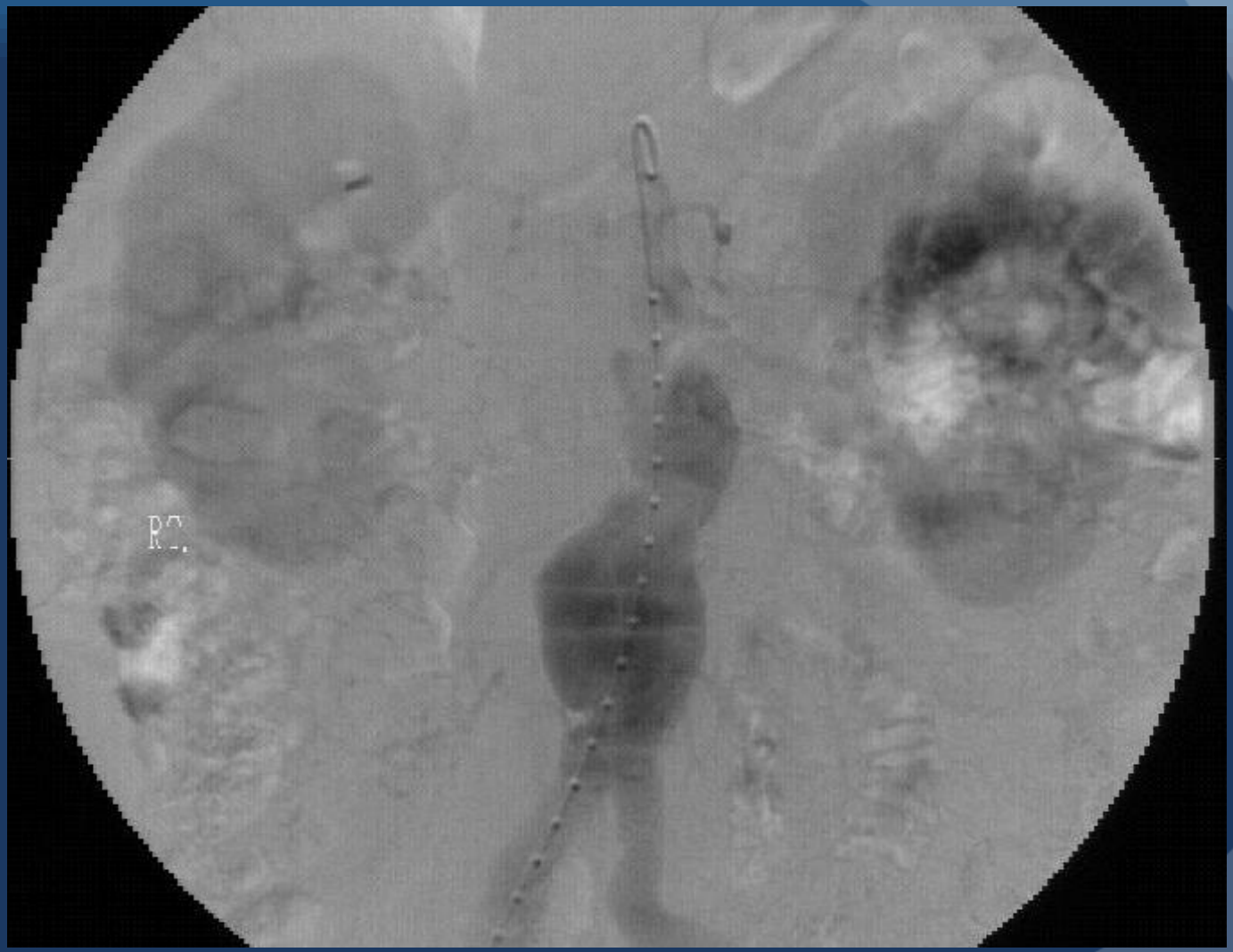
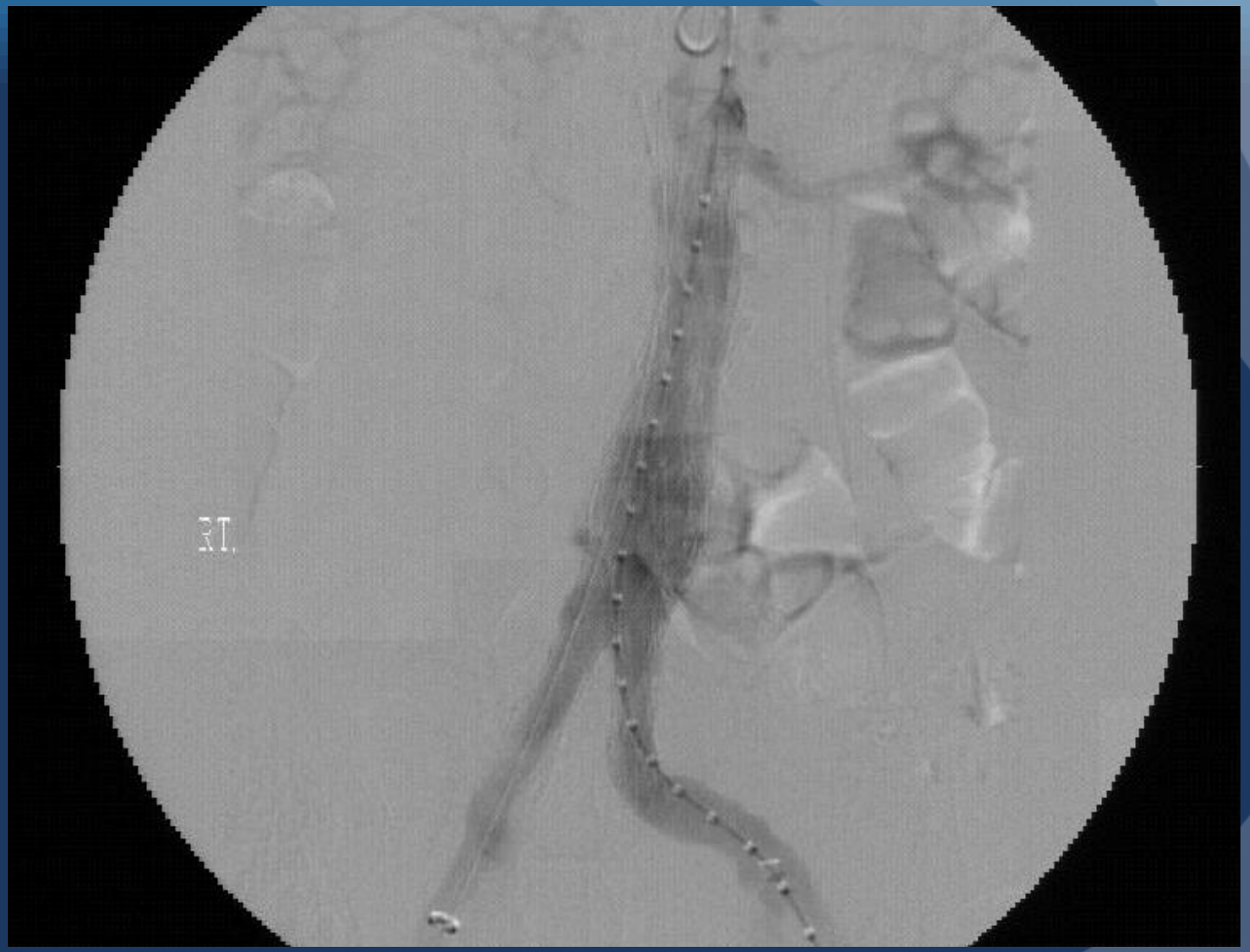
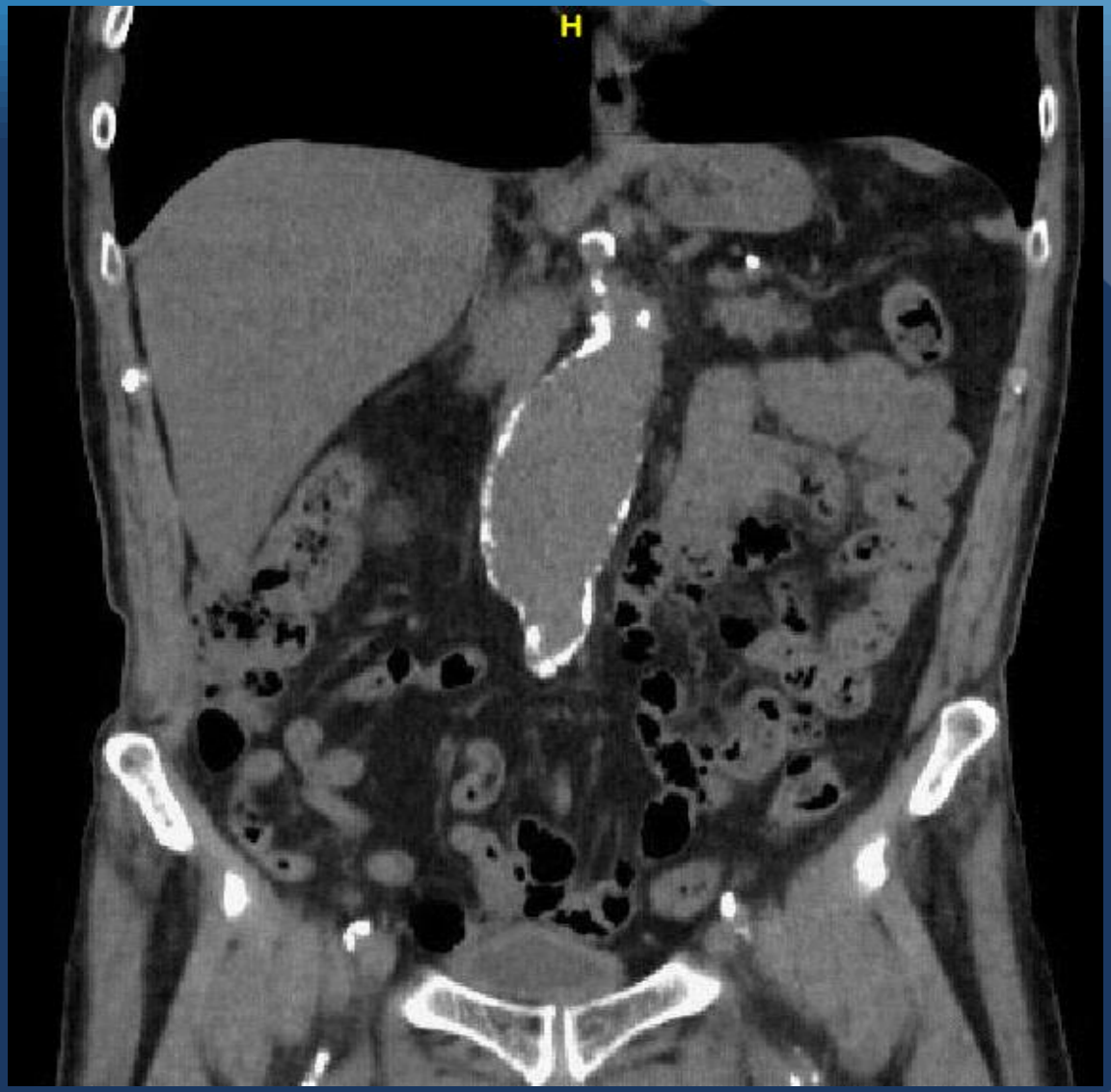



RT

79 y Male with known history of a 3.2cm infrarenal AAA that was diagnosed during screening test at age 71. We have been following him yearly for 8 years with yearly U/S and CT. His recent CAT scan showed a 5.5cm infrarenal AAA.

Patient had been asymptomatic.

PMH: HTN, CAD, Aortoiliac Dz, PVD, Chronic Back Pain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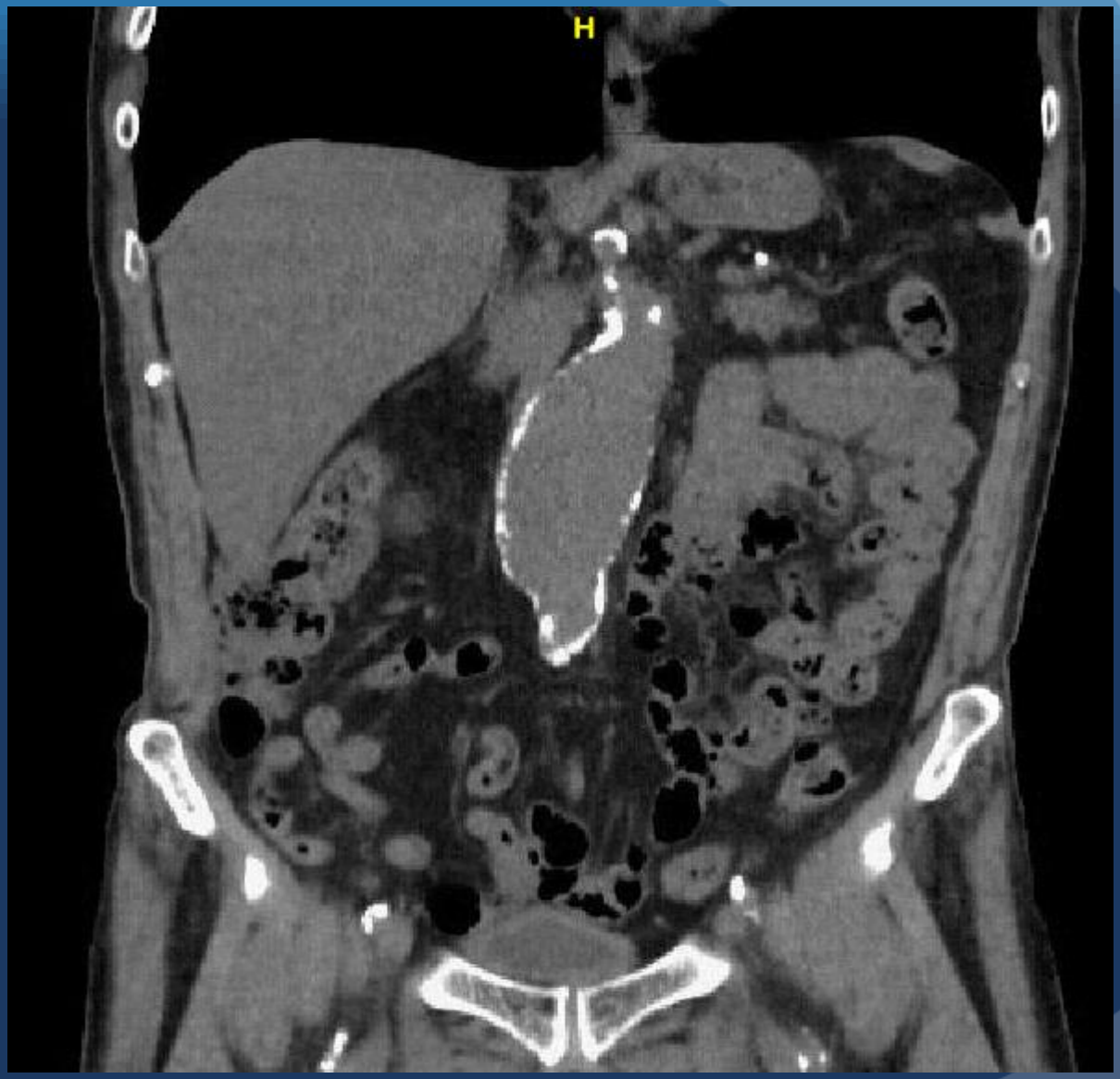
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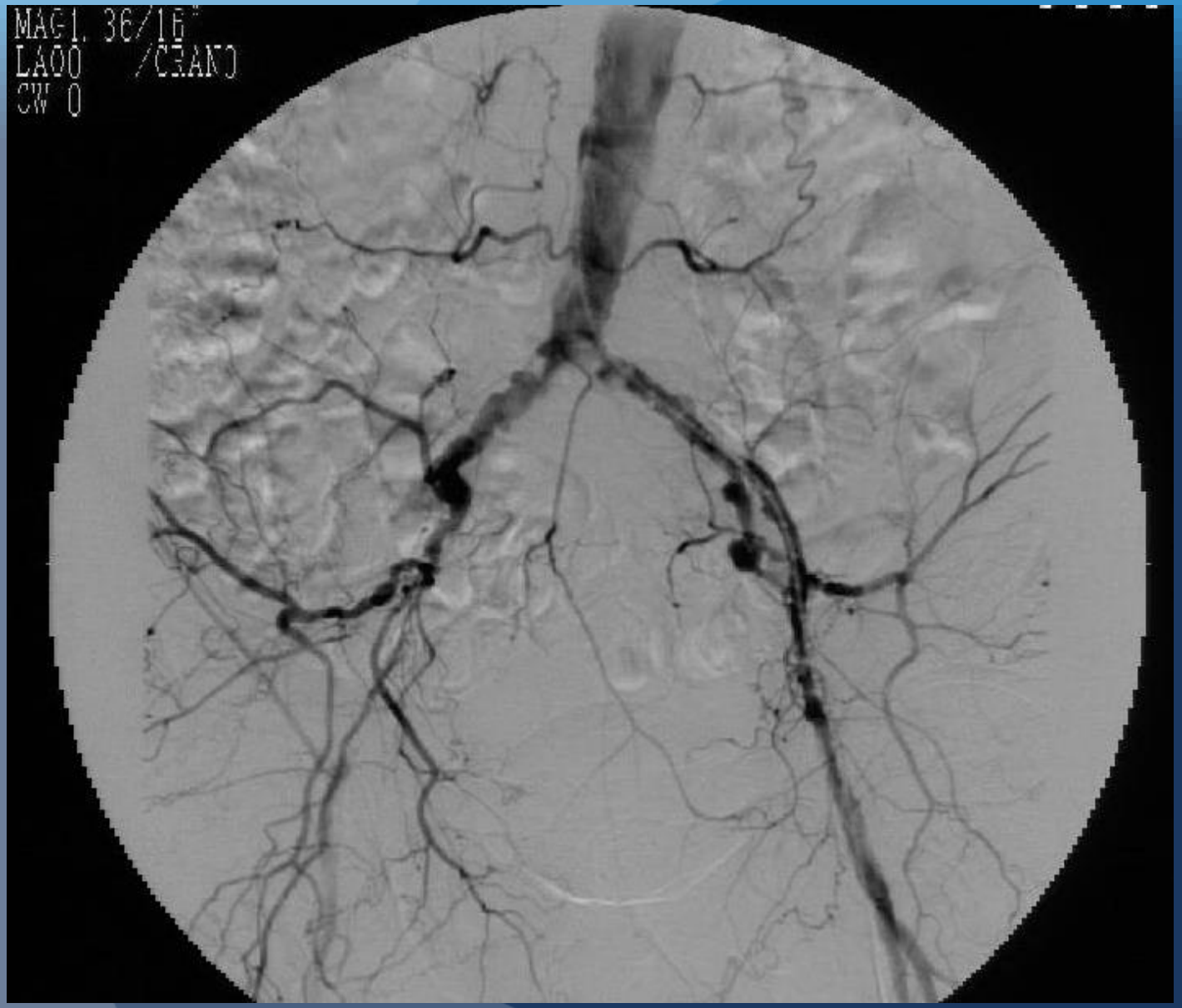
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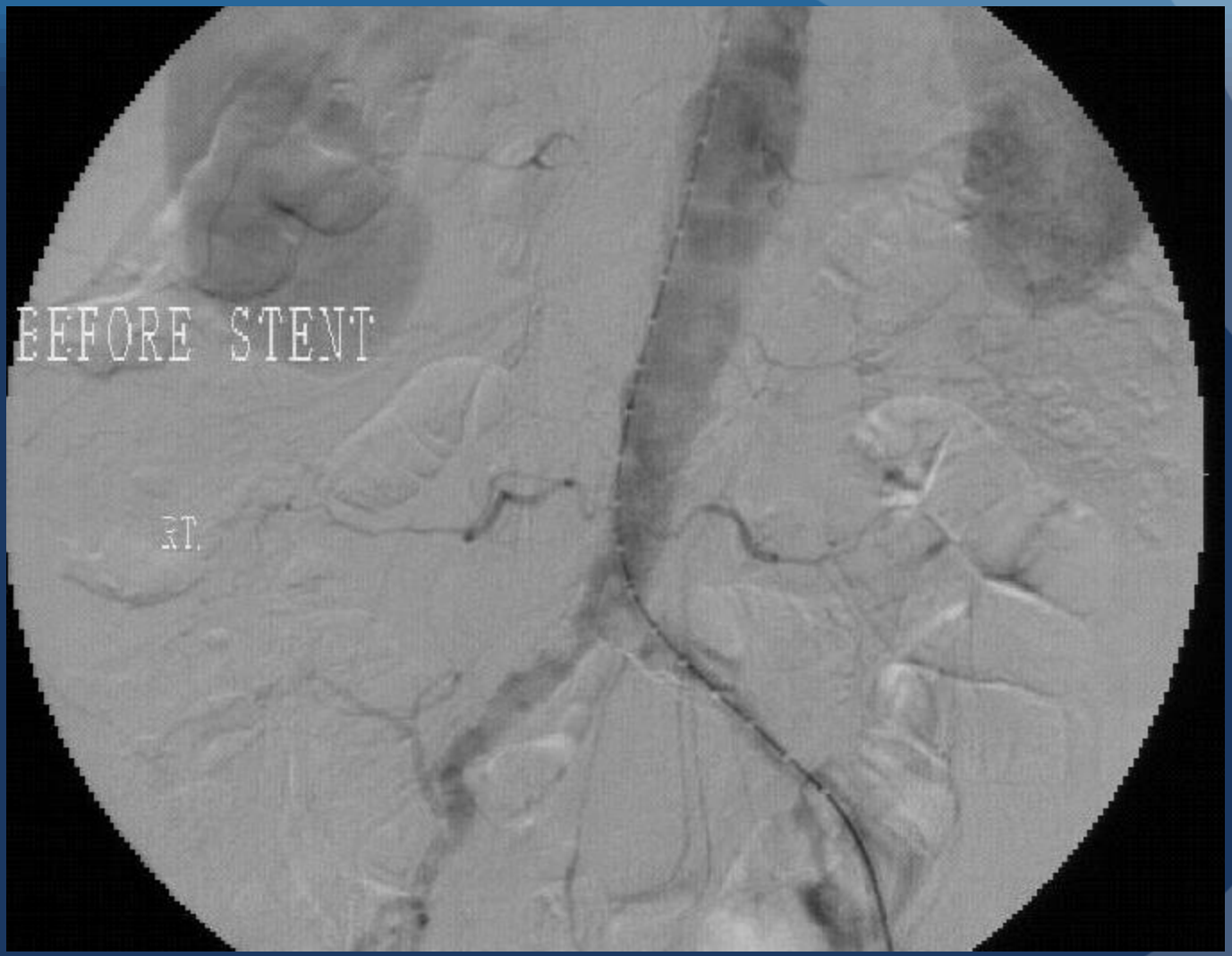
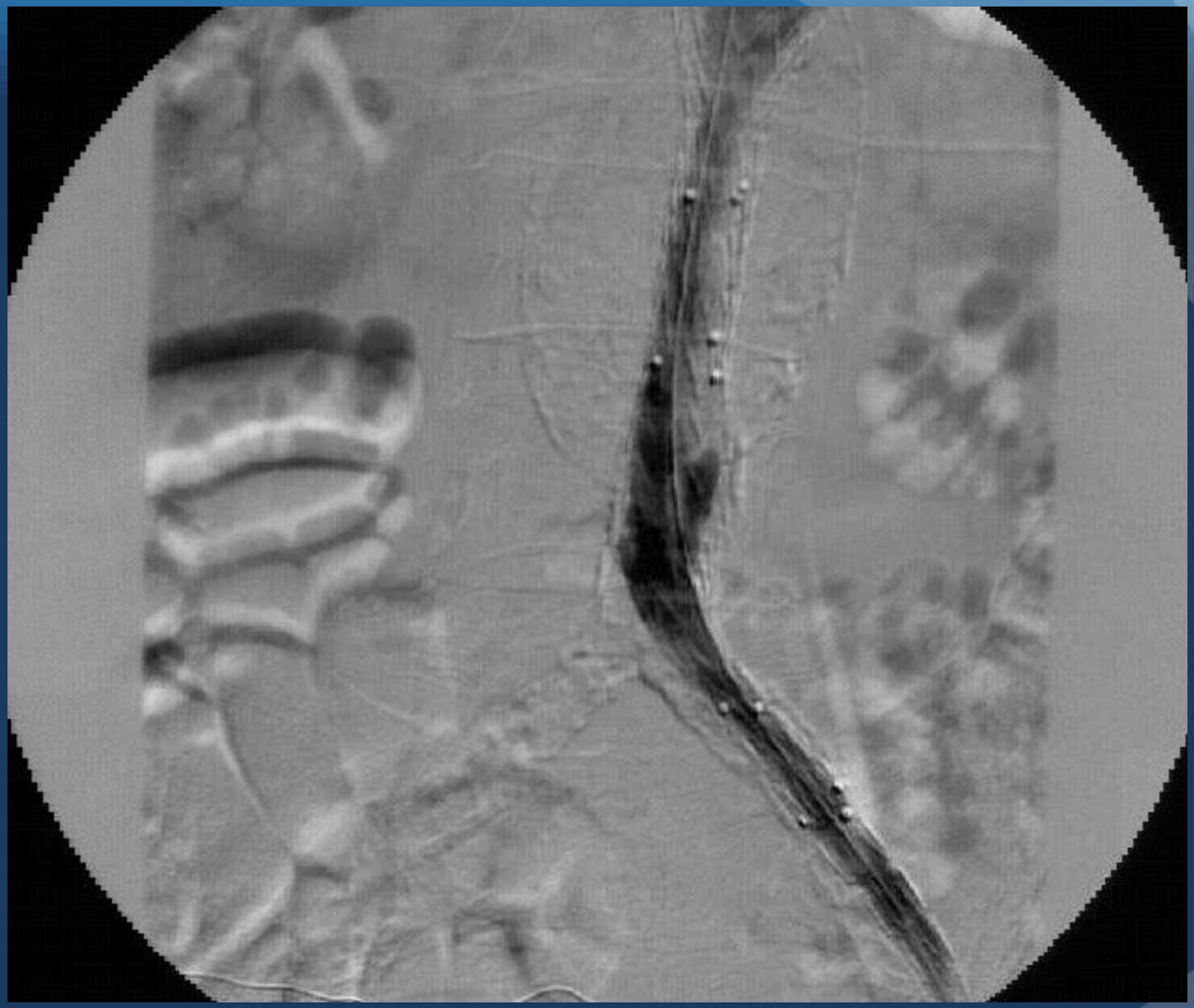
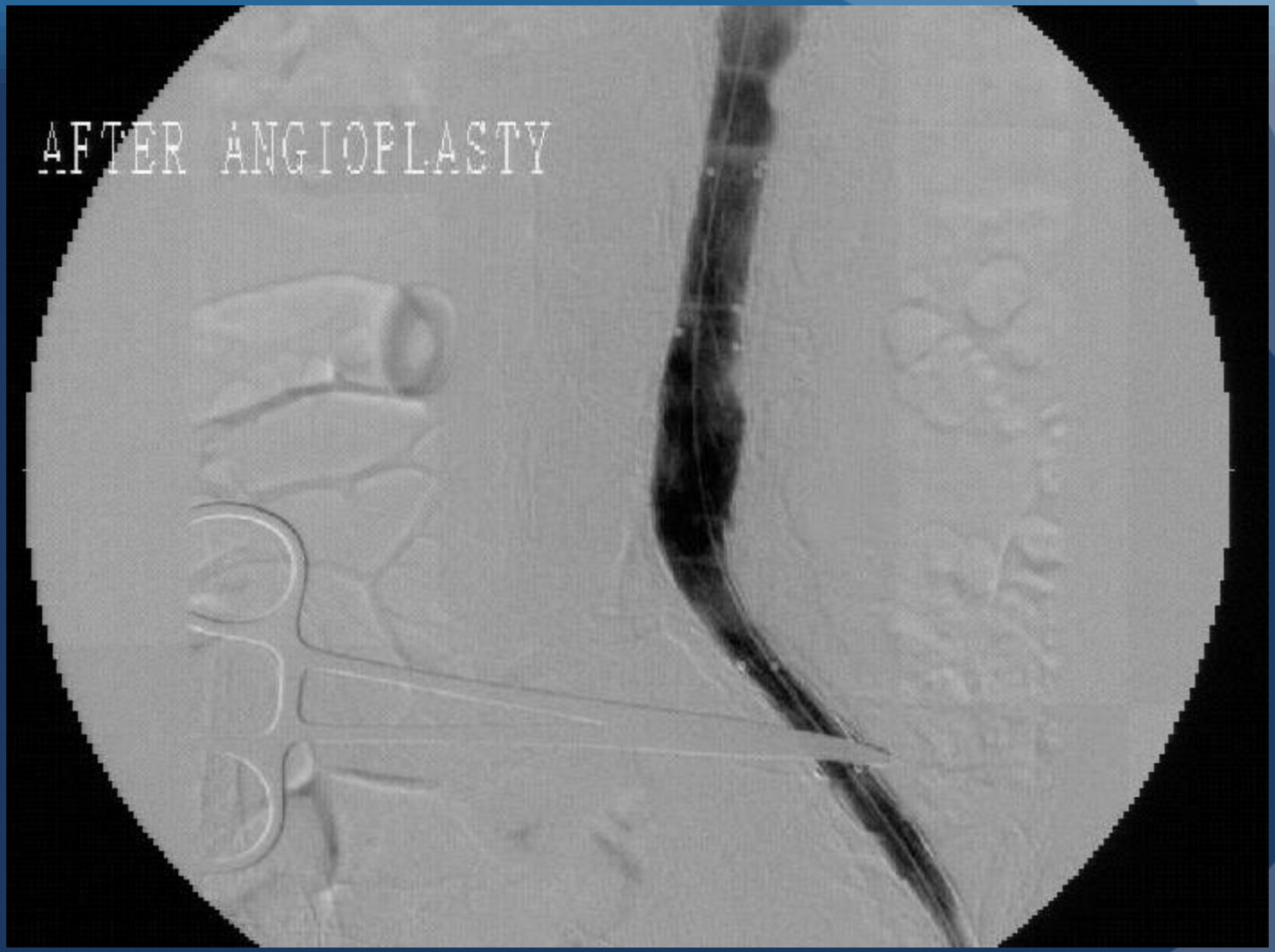

BEFORE STENT
RT.

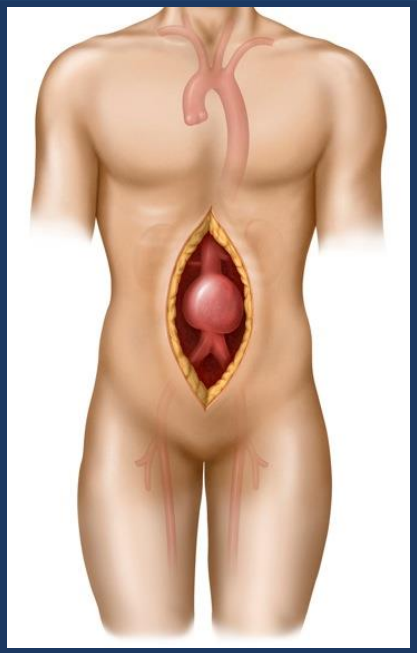



AFTER ANGIOPLASTY

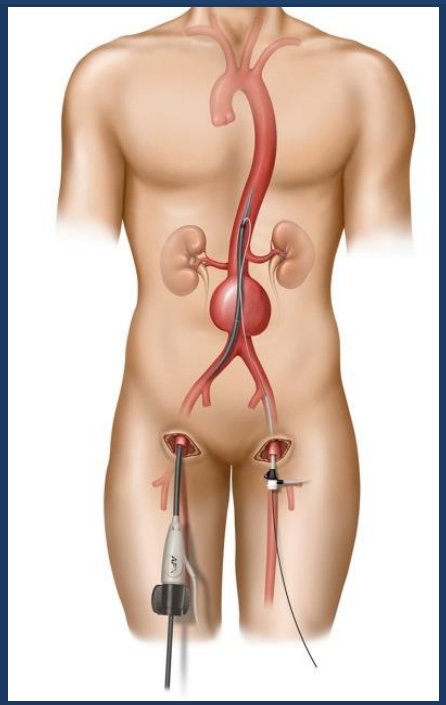
SUMMARY:

- AAA is a silent and deadly condition that is most often an incidental finding
  - Screening has been demonstrated to improve detection and outcomes over time
- Approach to repair must consider patient-specific risk factors and aneurysm characteristics
- Open surgical repair and EVAR offer good acute and long term outcomes
  - Many patients will be candidates for an endovascular approach
  - Some patients are considered high risk for open surgery and will therefore be better EVAR candidates
- For EVAR candidates, a percutaneous-EVAR offers potential advantages
  - Shorter procedure time, lower risk for groin complications, decreased need for post-operative pain medication
  - Contributes to shorter length of stay, enabling ever better patient outcomes

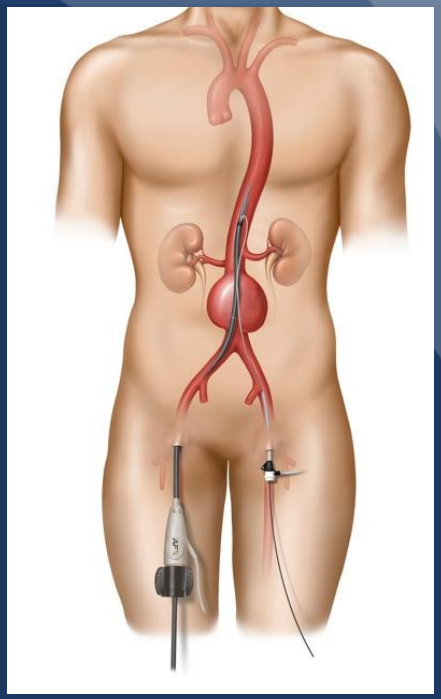
Percutaneous EVAR (PEVAR) is an option for many patients



Open Surgical Aortic Aneurysm Repair

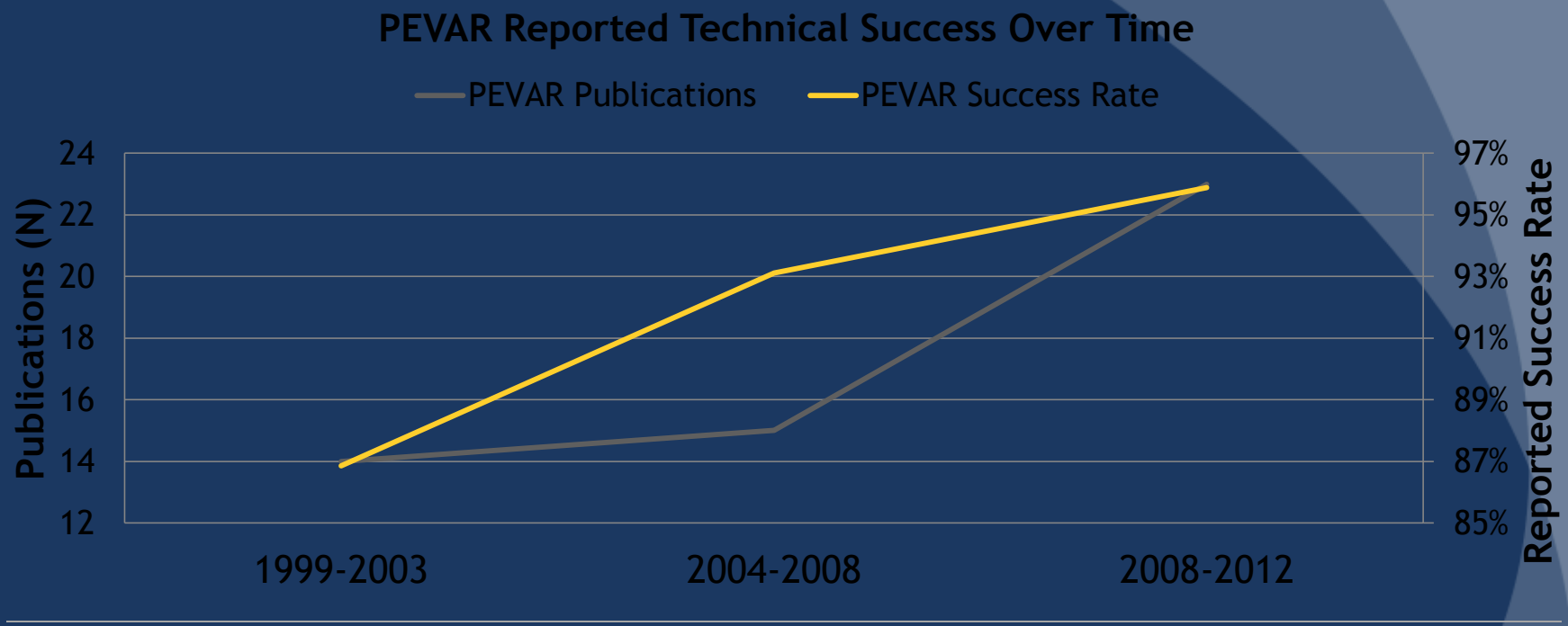


Endovascular Aortic Aneurysm Repair (EVAR)



Percutaneous Endovascular Aortic Aneurysm Repair (PEVAR)

Experience and technical success rates have improved over time to >95%



- Increasing number of publications demonstrating feasibility and technical success
- Success and experience have improved with improvements in technology (lower delivery profiles, etc.)