Endurant : 2 years single center experience and results from clinical studies

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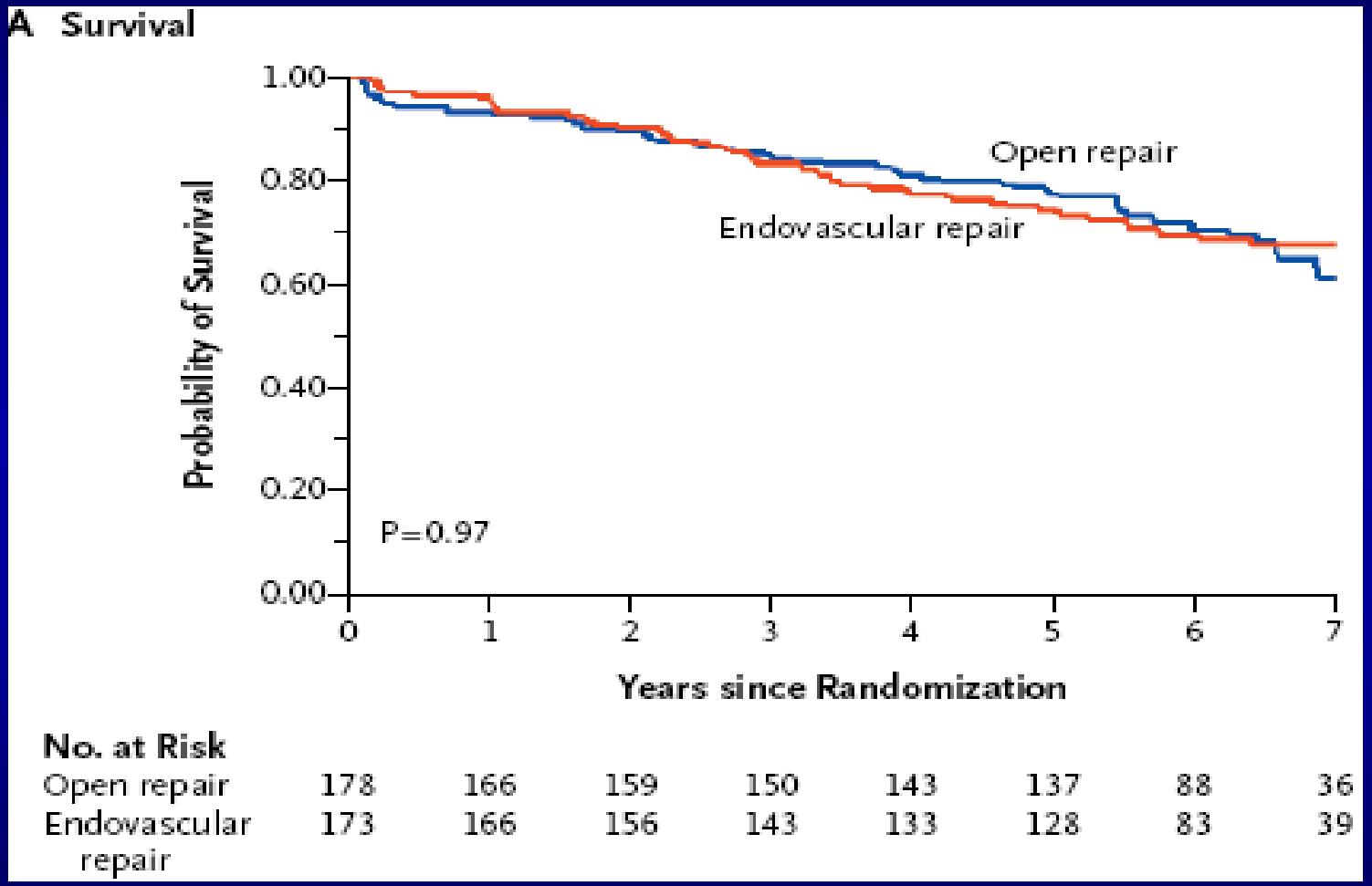
CATHARINA-ZIEKENHUIS

Why a new stentgraft???



N Engl J Med 2010 May 20;362(20):1881-9

Suitability for EVAR

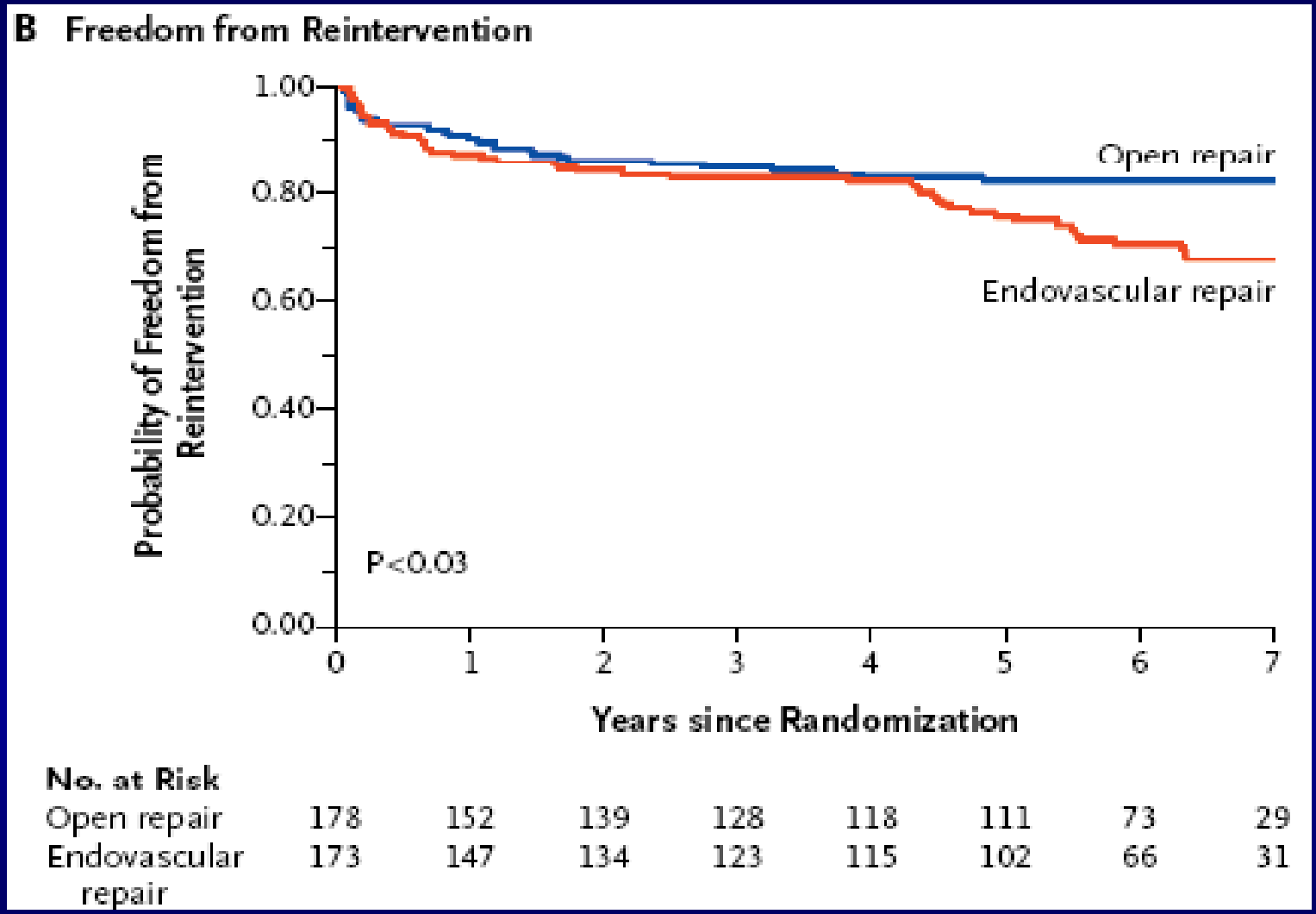
Ranges between 50% - 80%

Neck issues > acces issues

Arko, J Endovasc Ther 2004
Timaran, Ann Vasc Surg 2008

Unsuitability issues

- Room for improvement
- Technical versus longterm succes !



dream

2010 May 20;362(20):1881-9

New EVAR technology: challenge

- MORE patients can be treated
- MORE DURABLE in long term

Catharina Hospital experience

- Febr 2008 – March 2011
- 206 Endurant cases
- 175 elective - 31 acute
- 26 prox neck angulation > 60°
- Participation Endurant trial and Engage registry

Catharina Hospital experience

99 % deployment succes:

- 2 conversions to open surgery
- 1 conversion to AUI in ruptured case

Catharina Hospital experience

- 4 type I endoleaks

-1 distal type I in acute case, resolved with extension

-1 proximal type I resolved spontaneously

-2 proximal type I, resolved with CP stent

Catharina Hospital experience

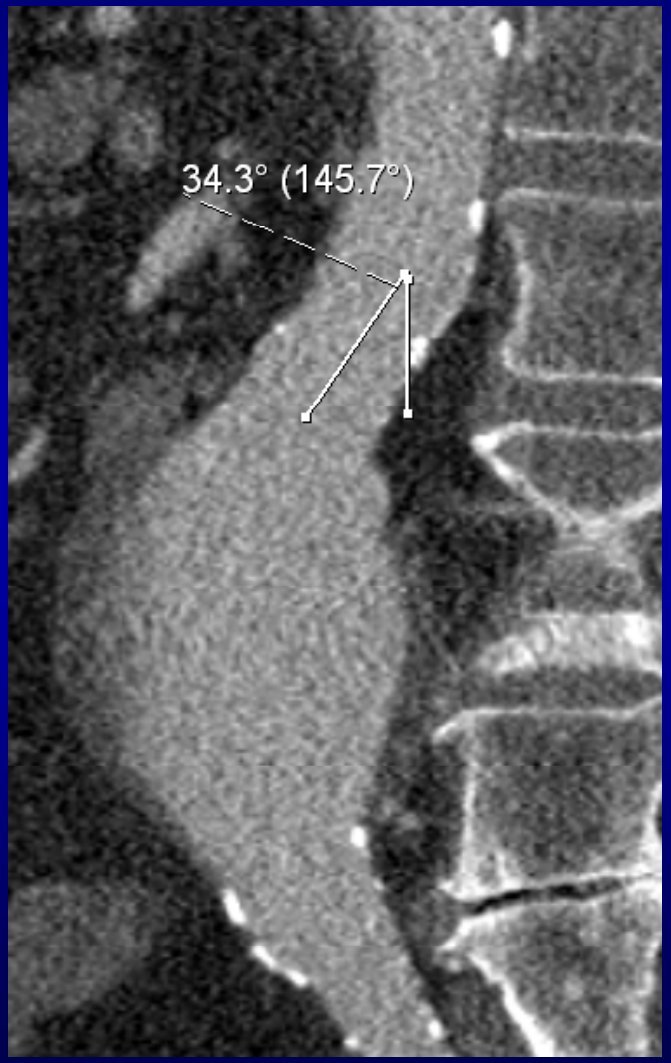
- No type III endoleak
- No migration
- 5 secondary procedures for limb thrombosis/stenosis

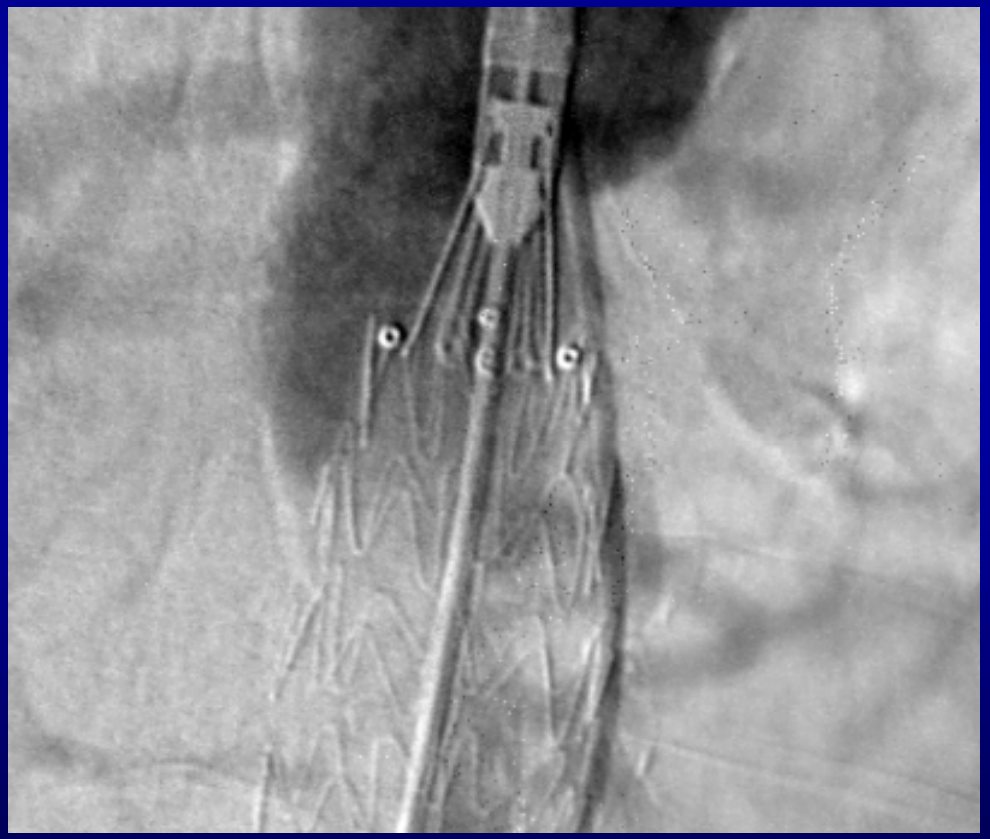
Endurant

Dealing with difficult proximal necks

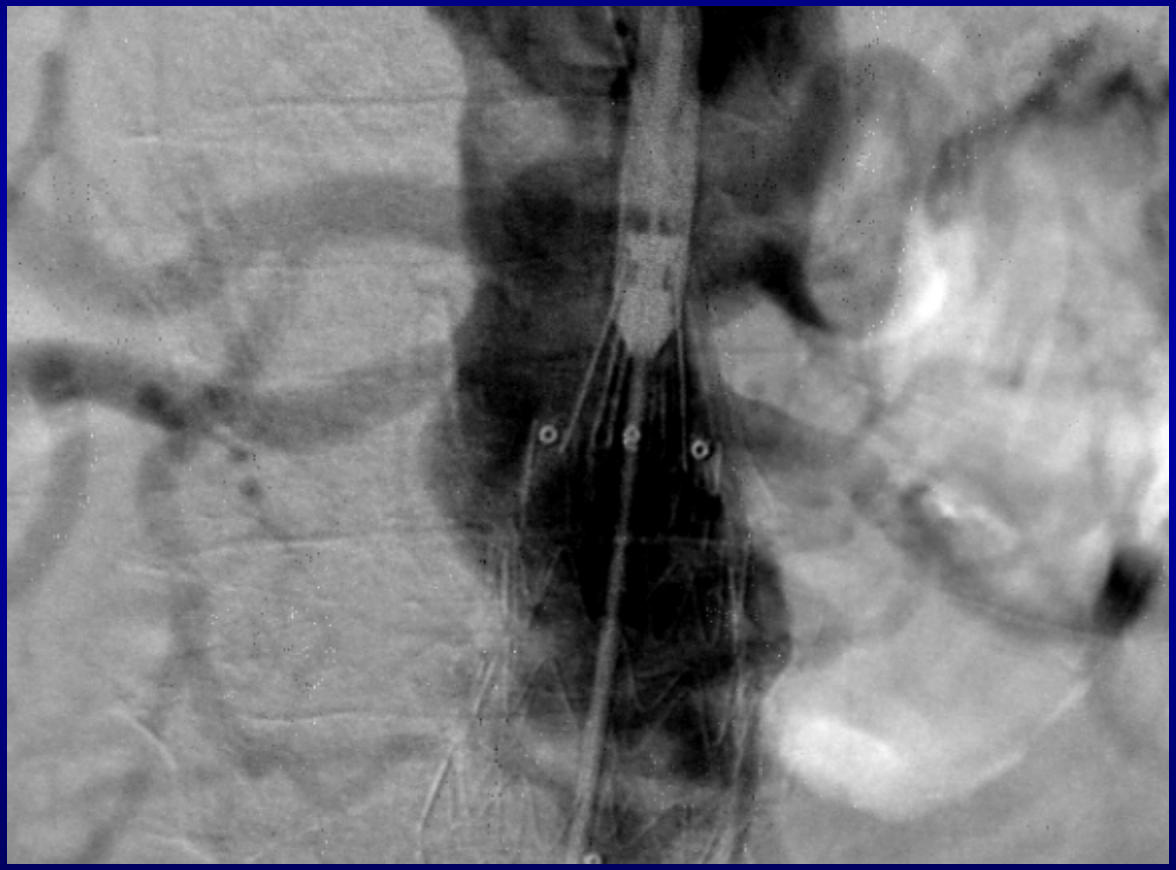
Carefull preop planning required

Angulated necks

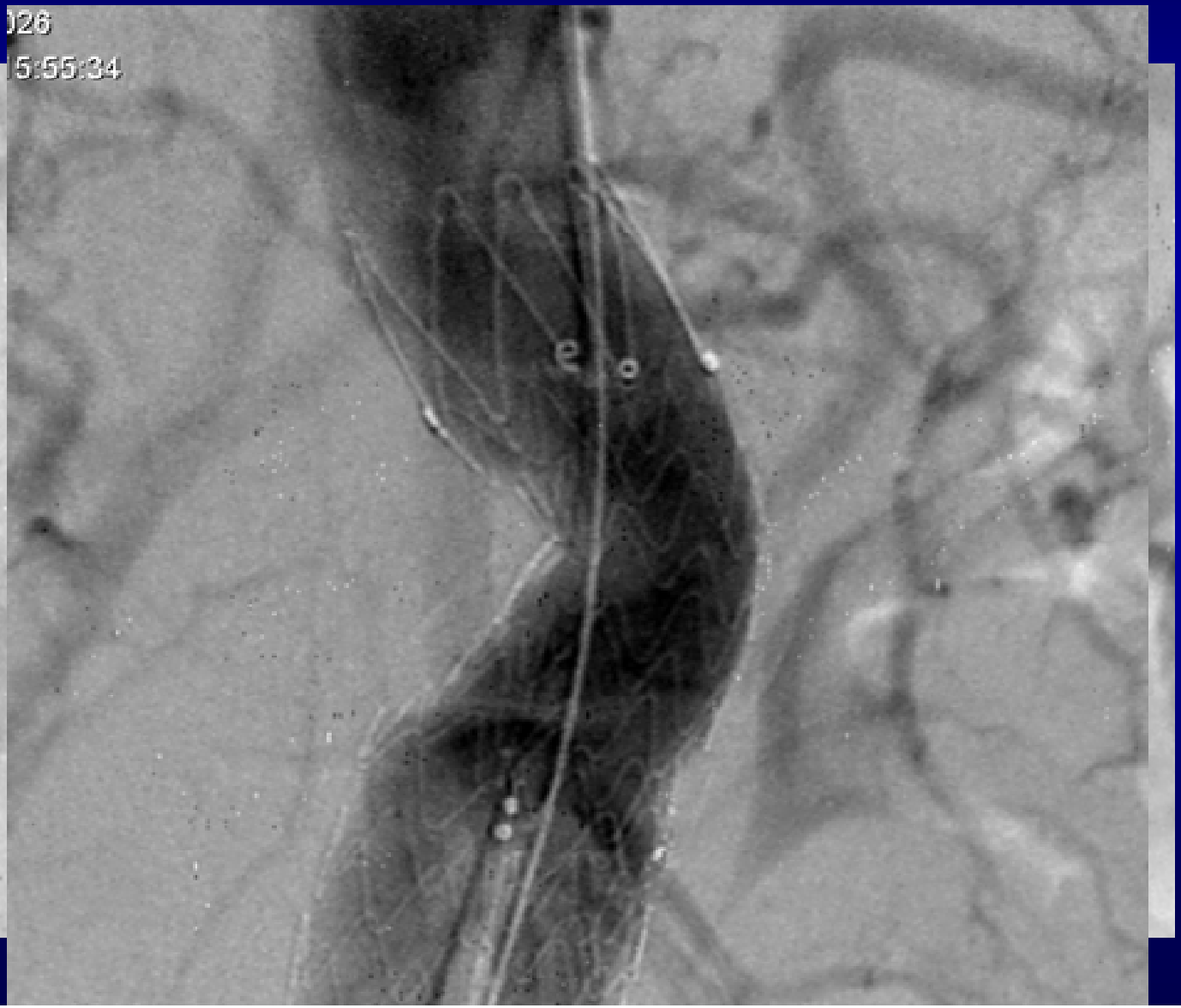




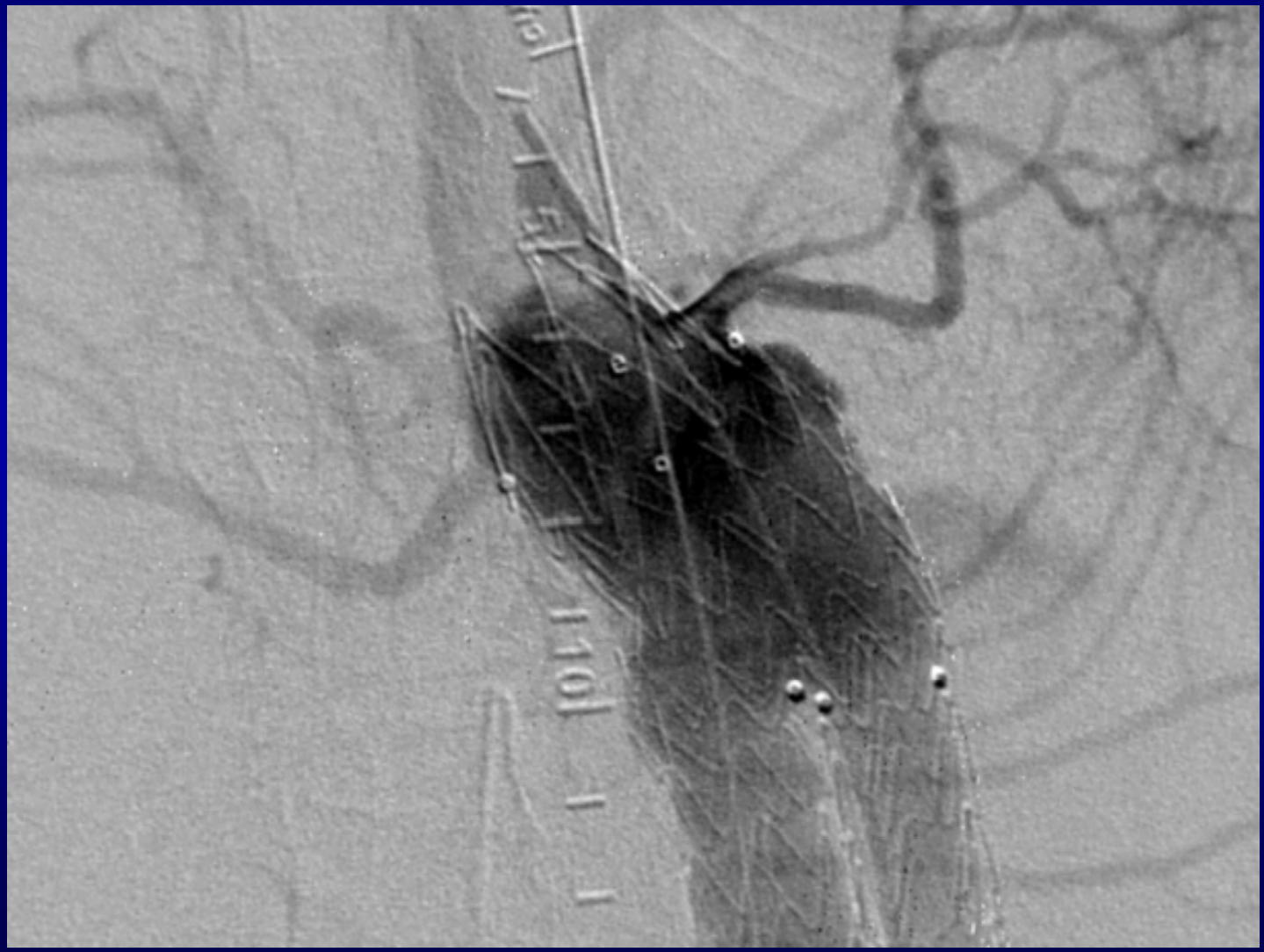
Angulated necks – C arm rotated



Angulated neck > 90°



Ruptured AAA – 6 mm, angulated neck

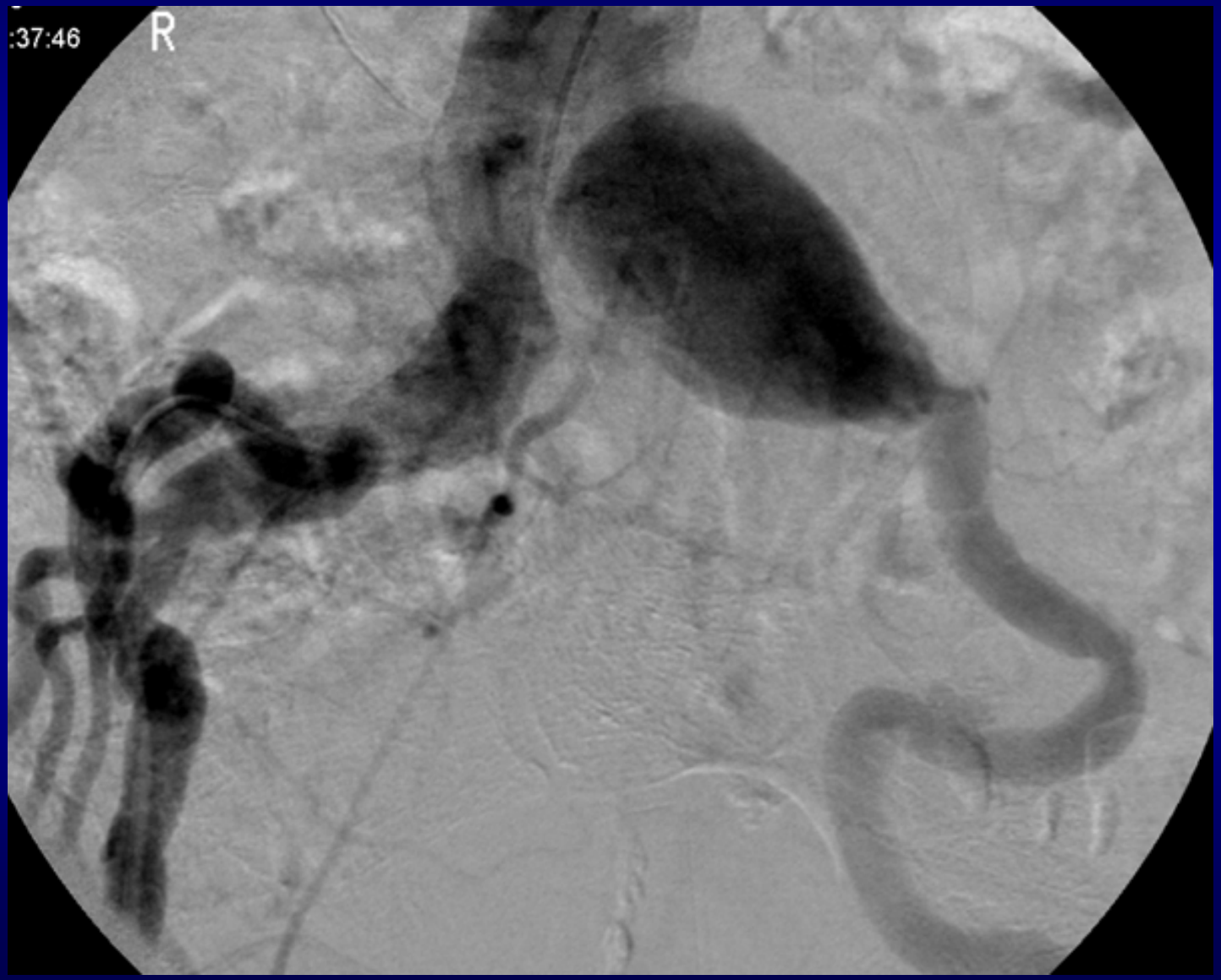


Endurant

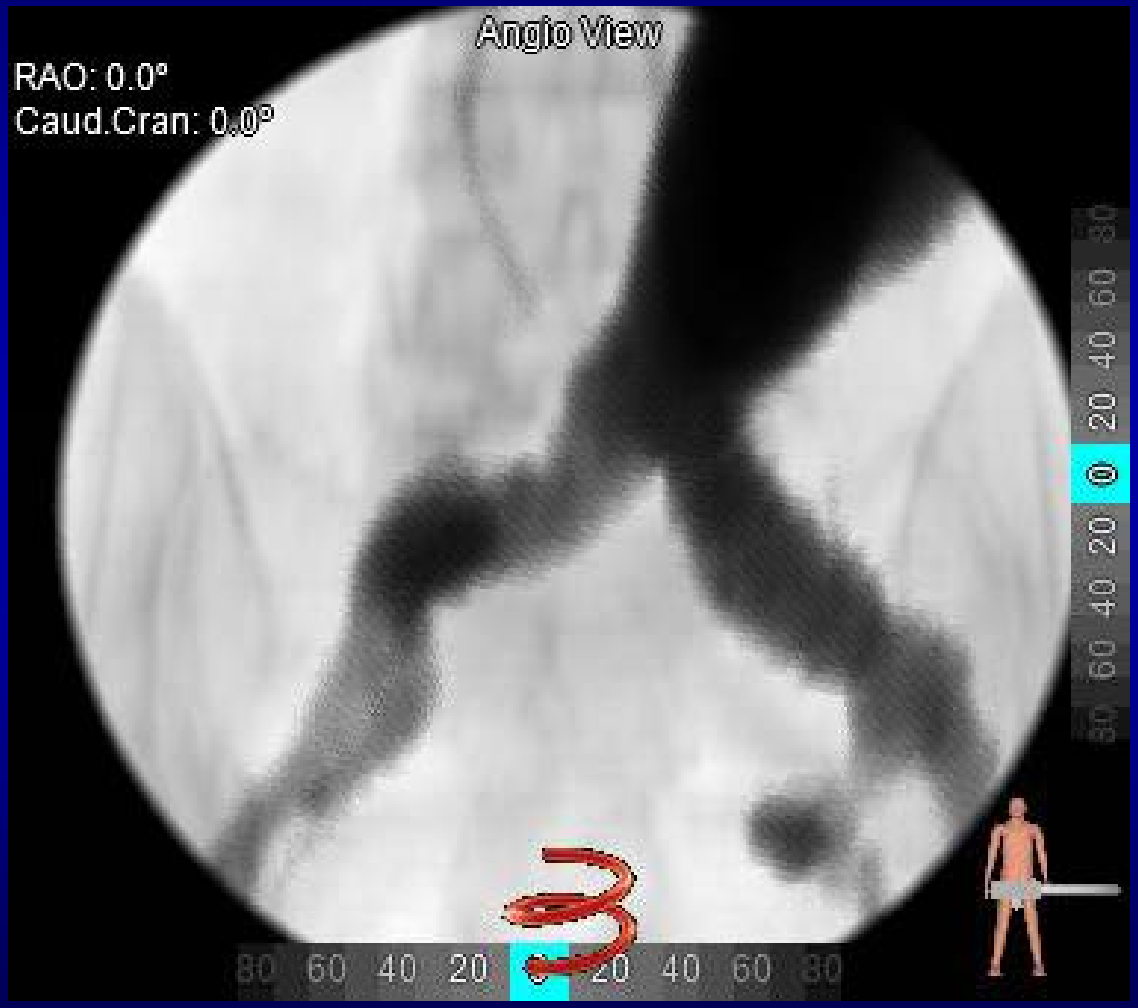
- Challenging access can be overcome
- Conformability good, but….

  -precise preop planning (terrarecon/ 3mensio)

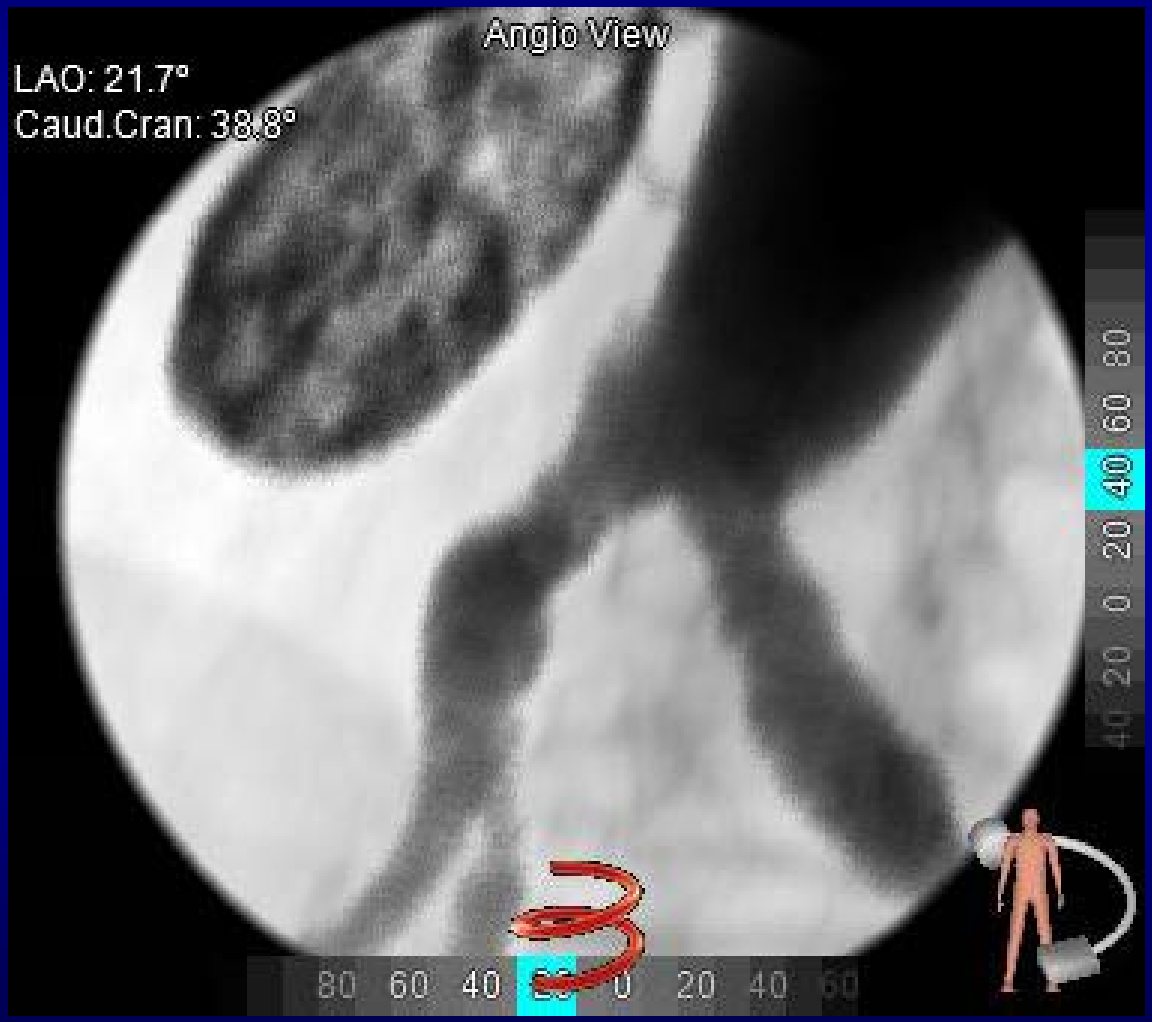
Challenging access



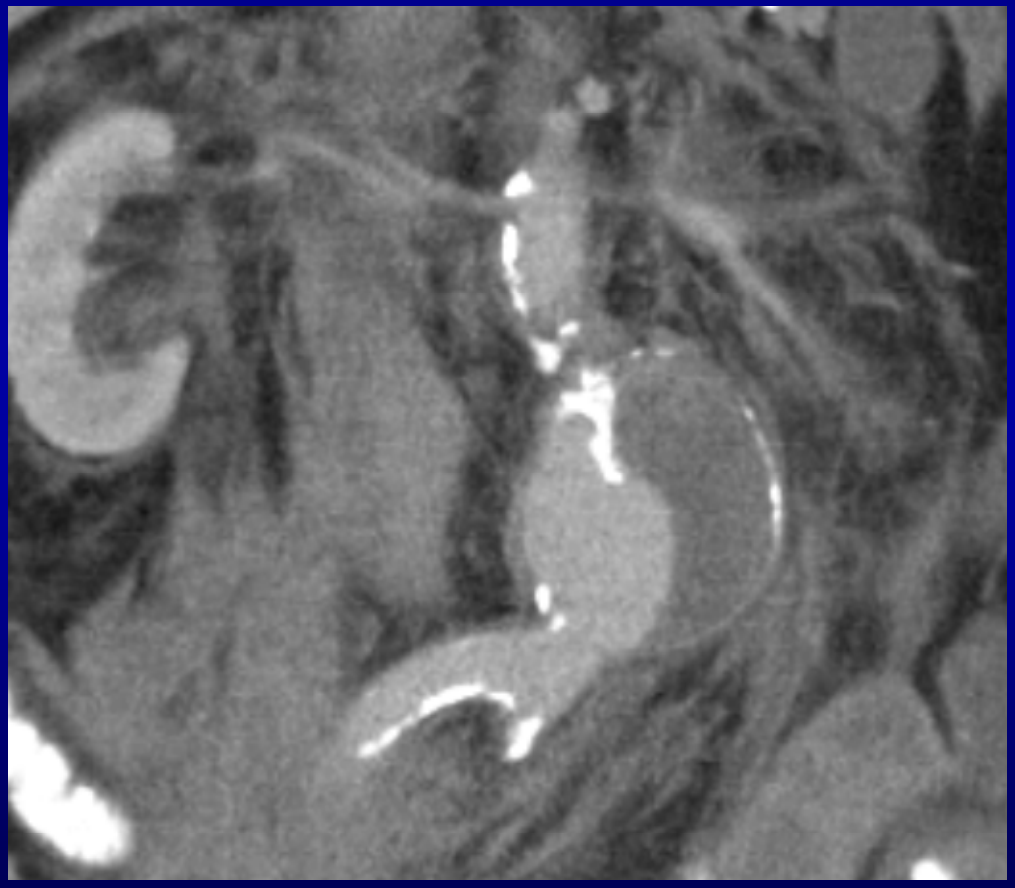
Preop planning orientation C-arm



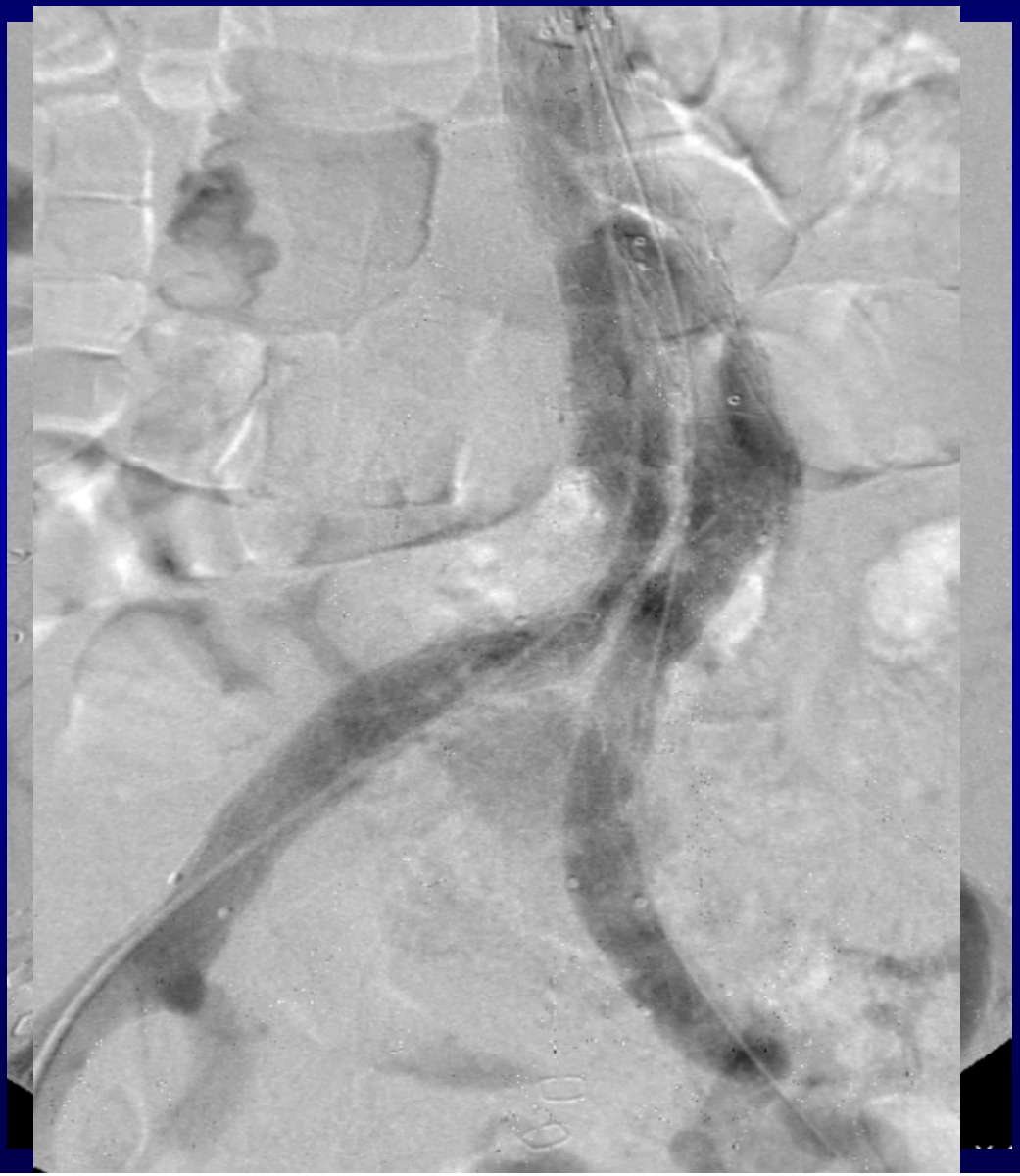
Preop planning orientation C-arm

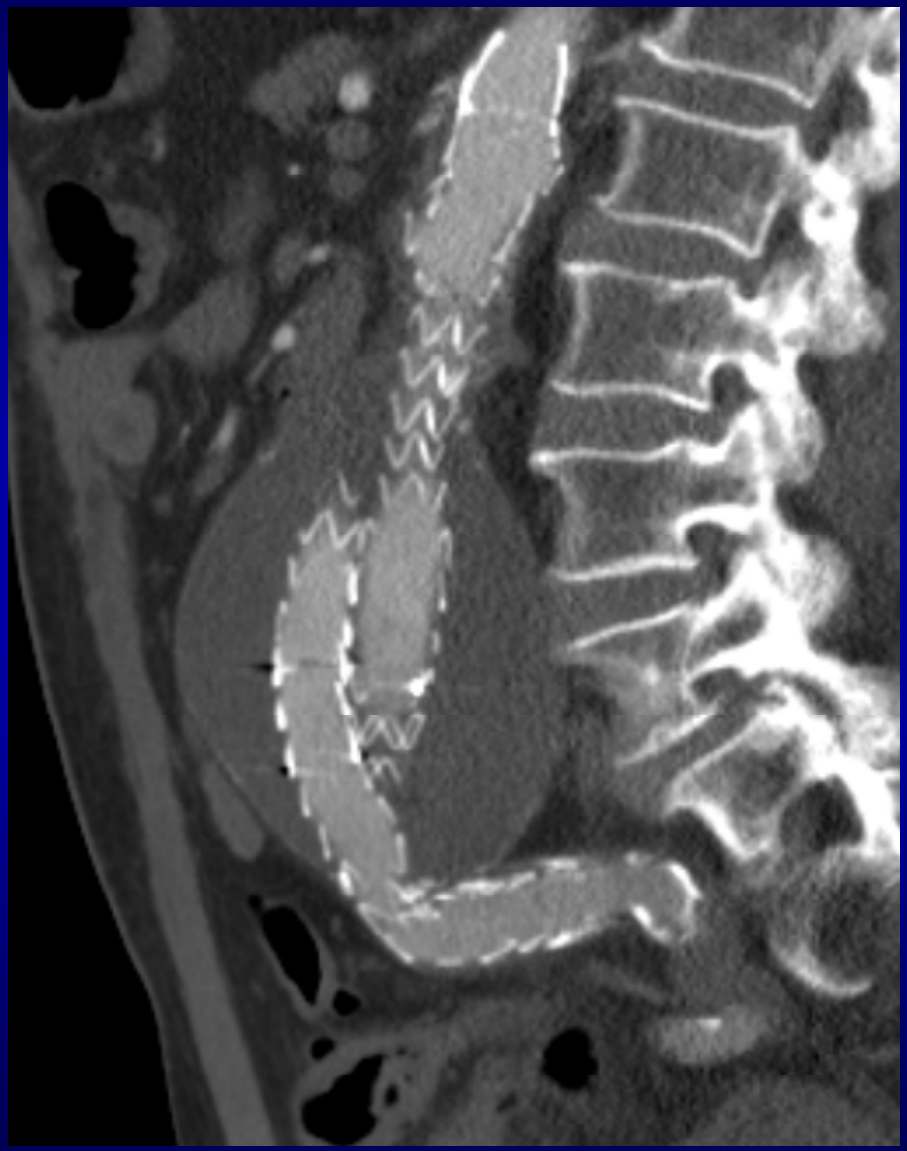


Ruptured AAA – difficult access (1)



Ruptured AAA – difficult access (2)





Update on the ENGAGE ENDURANT Global Registry:

Insights from 800 patients - with 30-day follow-up

Philippe W. M. Cuypers, MD, PhD

on behalf of the ENGAGE Investigators

ENGAGE

Endurant Stent Graft Natural Selection Global Post market Registry

Study Purpose

- To prospectively collect global ‘real life’ data on Endurant stent graft
  - Real world patients
    - Short list of in/exclusion criteria
  - Real-world practice
    - Absence of study procedures and tests
    - Documentation of physician’s preferred treatment choices
- To create a database that can be pooled/compared with other available stent graft data

Materials and Methods

- Study design
  - Prospective, Post-market, Multi-center
  - Non-randomized, Single-arm
  - > 1200 subjects consecutively enrolled
  - Follow-up Schedule: 30-days, annual visits through 5 years
  - Led by Executive Committee

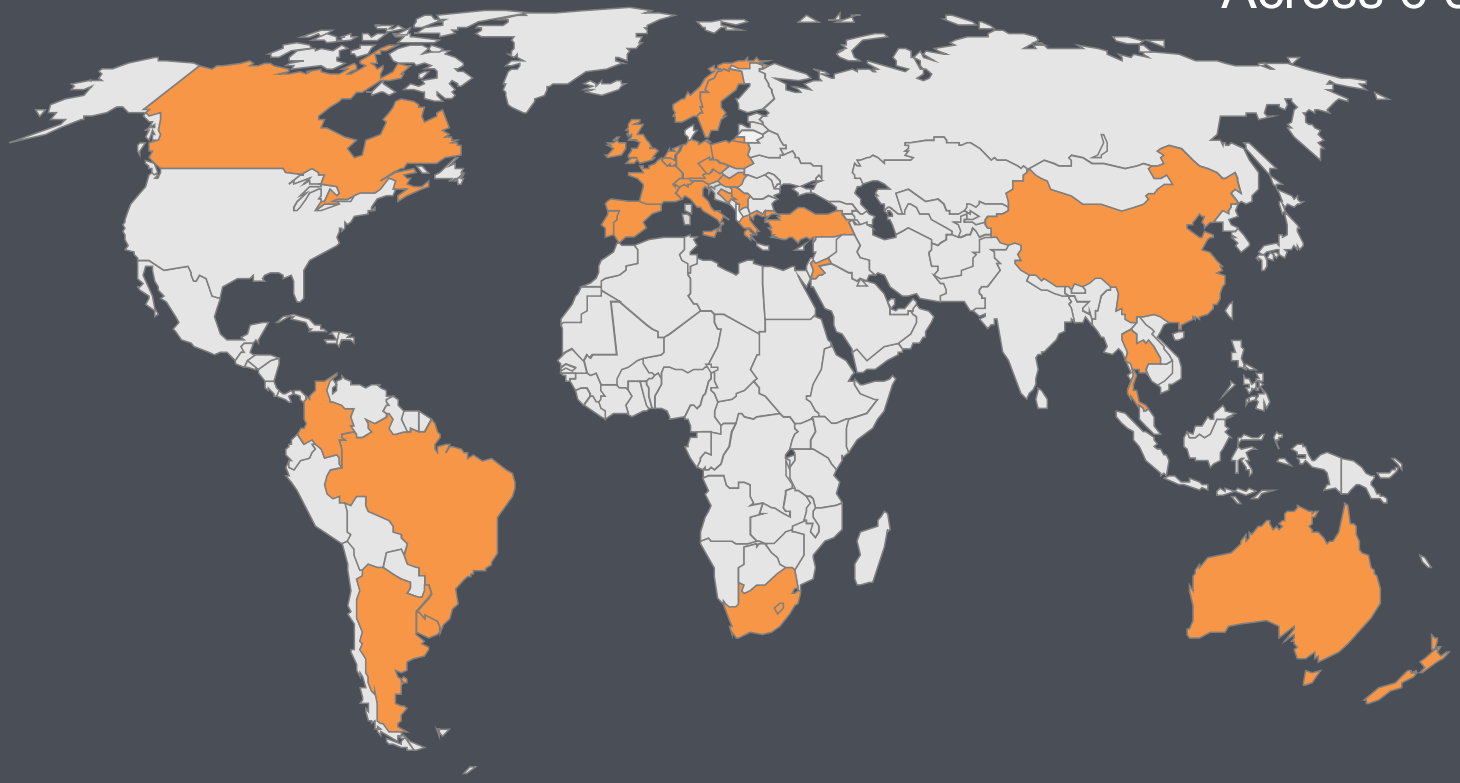
Current Study Status

1200 Patients Enrolled

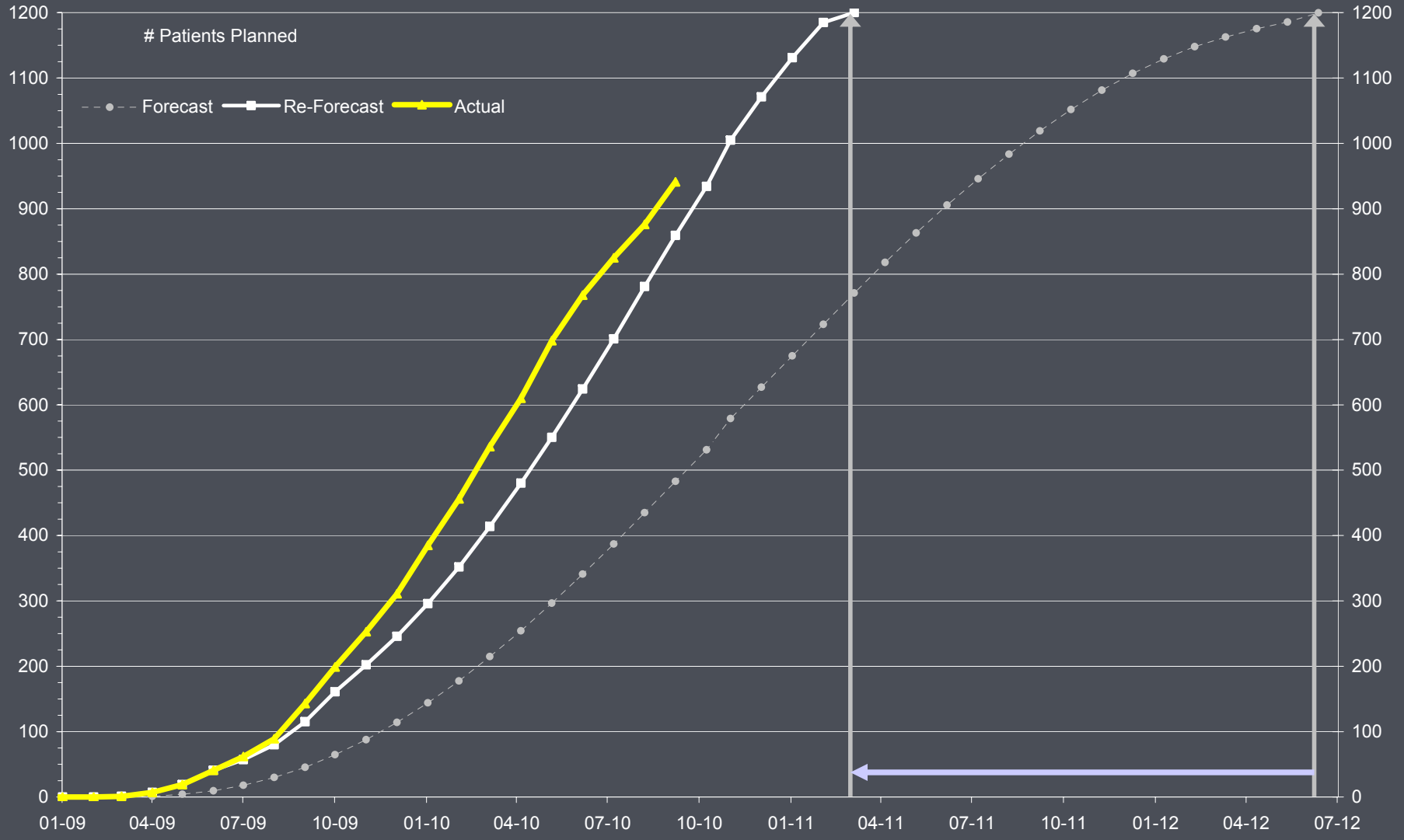
By 72 sites

From 28 countries

Across 6 continents



Enrollments: Actual versus Forecast



Materials and Methods

- Data Quality Methods
  - Experienced EVAR centres
  - Informed consent by patient prior to Implant
  - Patients are enrolled consecutively
  - Data Review - completeness and consistency
  - Data Correction – queries generated for data errors
  - Data Monitoring – source data verification at site

Interim analysis

- Interim analysis on 839 patients enrolled:
  - Baseline Characteristics
  - Procedural data
  - Implantation outcome
  - **Within 30-day results**

Baseline Characteristics

	N, %, Mean (±SD)
Total Number of Patients (N)	839
Primary Indication (AAA size)	
> 50 mm	88.2%
Gender (% males)	90.3%
Age (years)	73.0 (±8.0)
Aneurysm diameter (mm)	59.8 (±11.7)
Proximal Neck	
Length (mm)	27.8 (±13.4)
Length <15mm	18.1%
Infrarenal Angle >60˚	11.1%

Procedural Data

	%	(N/m)
Endurant implanted	99.6%	(826/829)
Delivery Success	99.6%	(826/829)
Deployment Success	99.6%	(825/828)

Procedural Data

	%, Median (Range)
Implant duration (min)	90 (20 – 300)
General Anesthesia:	63.3%
Blood Loss (cc)	200 (0 – 2000)
Contrast Volume (ml)	120 (9-400)
Fluoroscopic time (min)	18 (0 – 90)
Hospital Stay (days)	5 (0.5 – 217)

Mortality ≤30 days

	%	(N/m)
All Cause Mortality	0.8 %	(7/839)

One death was classified as Device Related*

- Ruptured thoracic aneurysm (1)
- Myocardial Infarction (2)
- Chest Pain followed by Loss of Consciousness (1)
- Perforated Gastric Ulcer (1)
- Pneumonia (1)
- Heart failure and intestinal ischemia* (1)

Technical Observations
Procedure and ≤30 days

	Procedure	≤30-days
Endoleaks		
Type I	0.8% (7/824)	0.2% (2/827)
Type II	11.7% (96/824)	4.0% (33/827)
Type III	0.4% (3/824)	0.0% (0/827)
Type IV	1.3% (11/824)	0.0% (0/827)
Loss of Stent Graft Integrity		0.0% (0/827)
Loss of Stent Graft Patency		0.2% (2/827)

Open Repairs & Secondary Procedures ≤30 days

	% (N/m)
Conversion to Open Repair	0.36% (3/827)
Secondary Endovascular Procedures	0.97% (8/827)

Secondary Endovascular Procedures to resolve:

- Stent Graft Limb Occlusion (2)
- Arterial/Branch vessel Occlusions (2)
- Stent Graft Limb Stenosis (2)
- Type I Endoleak (2)

Summary

- ENGAGE is a unique worldwide prospective ‘real life’ registry with a new generation device (Endurant)
- ENGAGE Data are reviewed & monitored > high data quality
- Enrollment was much faster than anticipated
- **Early Experience with 30 day FU is very promising (mortality, EI-Rate)**
- Longer Follow- up is needed and will be reported