WHEN SECONDS COUNT: BEVAR FOR RUPTURED TAAA

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20TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
in aortic endografting 2016
May 20 & 21 - LILLE - FRANCE

Disclosures

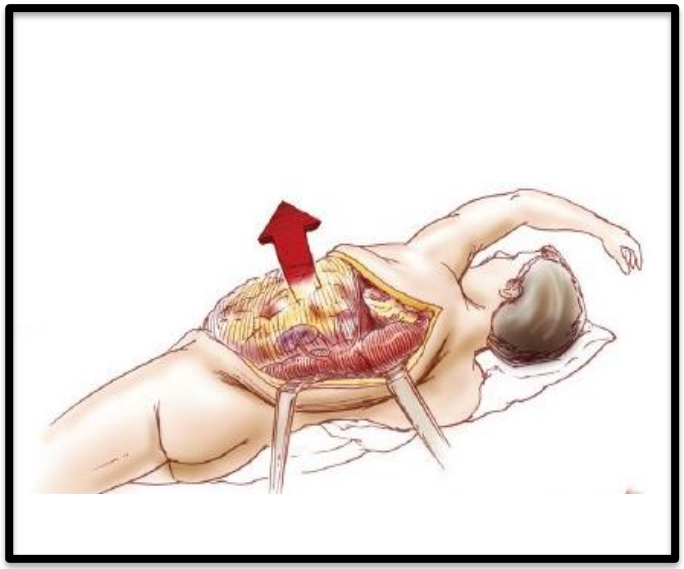
Proctoring/speakers fees

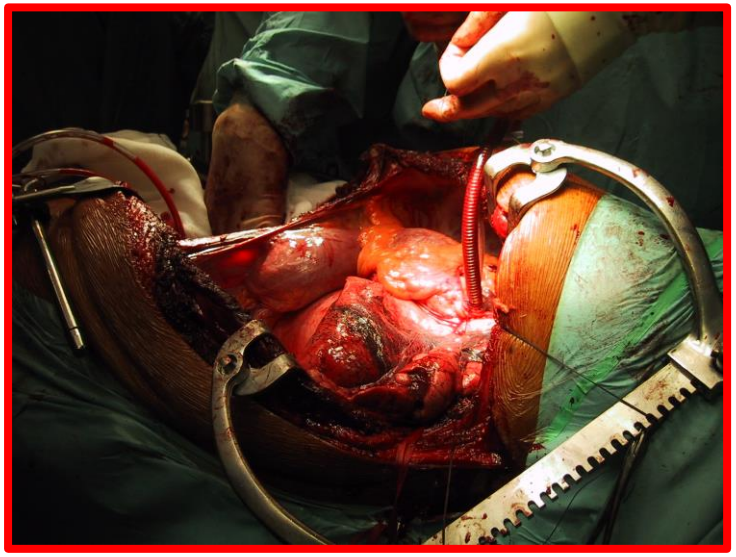
- **Cook Medical**
- **WL Gore**
- **Maquet**

Grant Support

- **Cook Medical**
- **Medtronic**

Ruptured TAAA: Open Repair



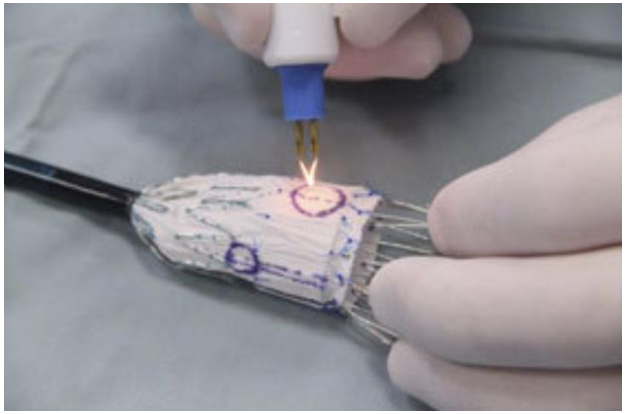


	Overall	*50-59 years*	*60-69 years*	*70-79 years*	*80-89 years*
Elective					
Patients (n)	797	77	273	392	55
30 day (%)	19.2	10.4	17.2	21.2	27.3
31-365 (%)	11.7	7.8	9.9	13.5	12.7
365 day (%)	30.9	18.2	27.1	34.7	40.0
Ruptured					
Patients (n)	213	9	63	109	32
30 day (%)	48.4	33.3	47.6	50.5	46.9
31-365 (%)	13.1	22.3	9.5	11.9	21.9
365 day (%)	61.5	55.6	57.1	62.4	68.8

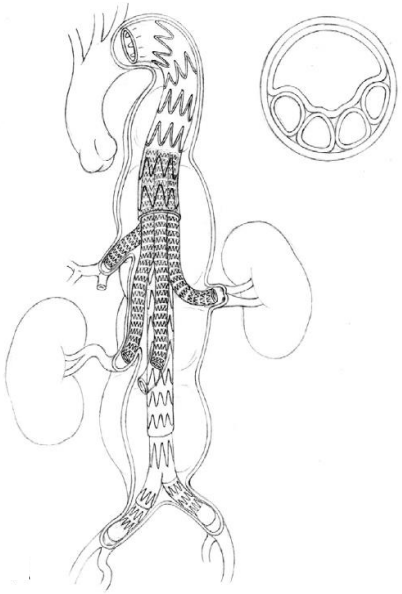
Rigberg et al. JVS 2006

Endovascular Solutions for Ruptured TAAA

SURGEON MODIFIED GRAFTS



SANDWICH



BEVAR

Off the Shelf Solutions

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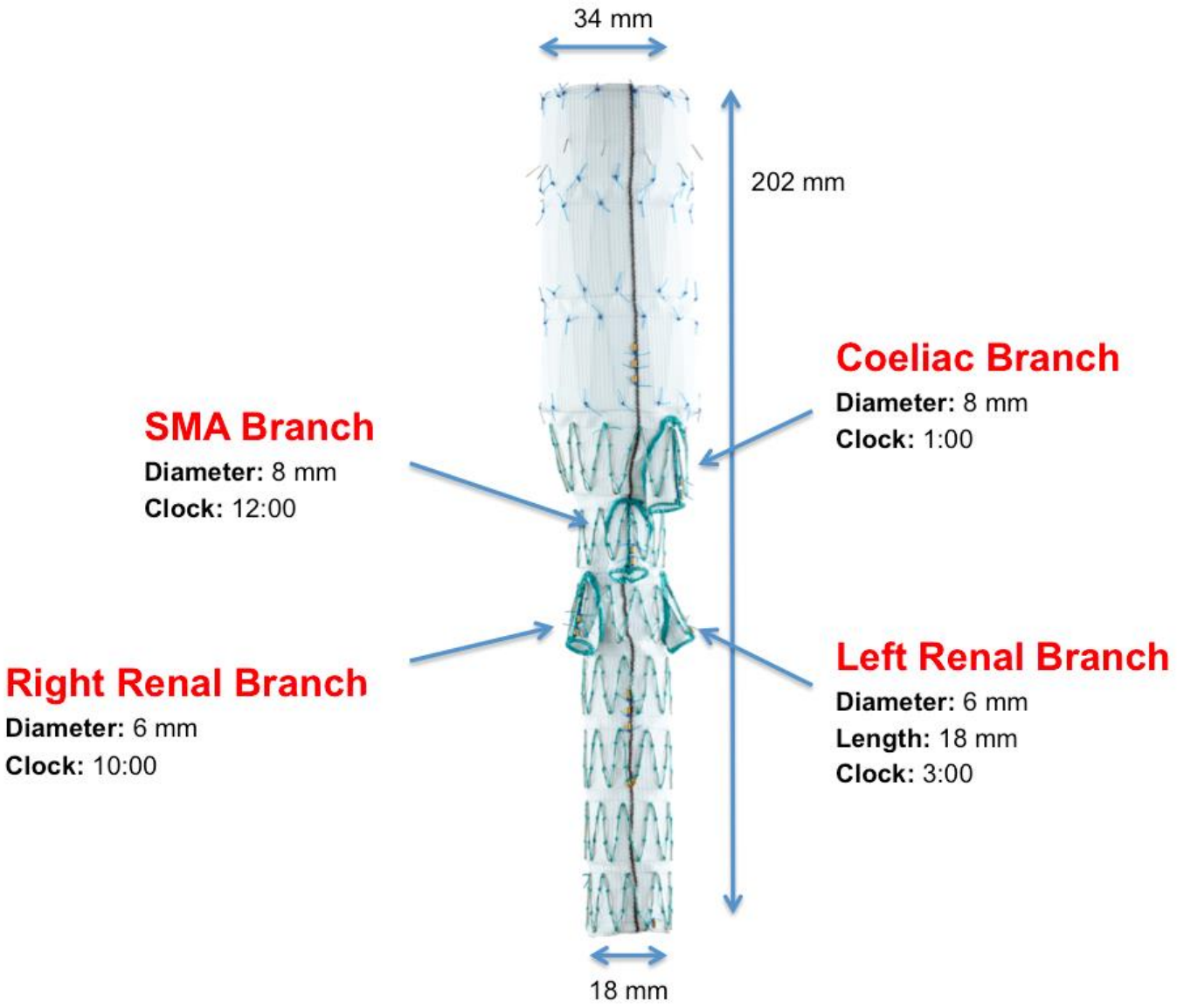
Starnes et al. Endovascular Today 2015



22F

Prox 22 mm
81-132mm length

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J ENDOVASC THER.
2009;16:359–364

◆ ISES ENDOVASCULAR RESEARCH COMPETITION, SECOND PLACE ◆

A Standardized Multi-Branched Thoracoabdominal Stent-Graft for Endovascular Aneurysm Repair

Matthew P. Sweet, MD, MS[1]; Jade S. Hiramoto, MD[1]; Ki-Hyuk Park, MD, PhD[2]; Linda M. Reilly, MD[1]; and Timothy A.M. Chuter, DM[1]

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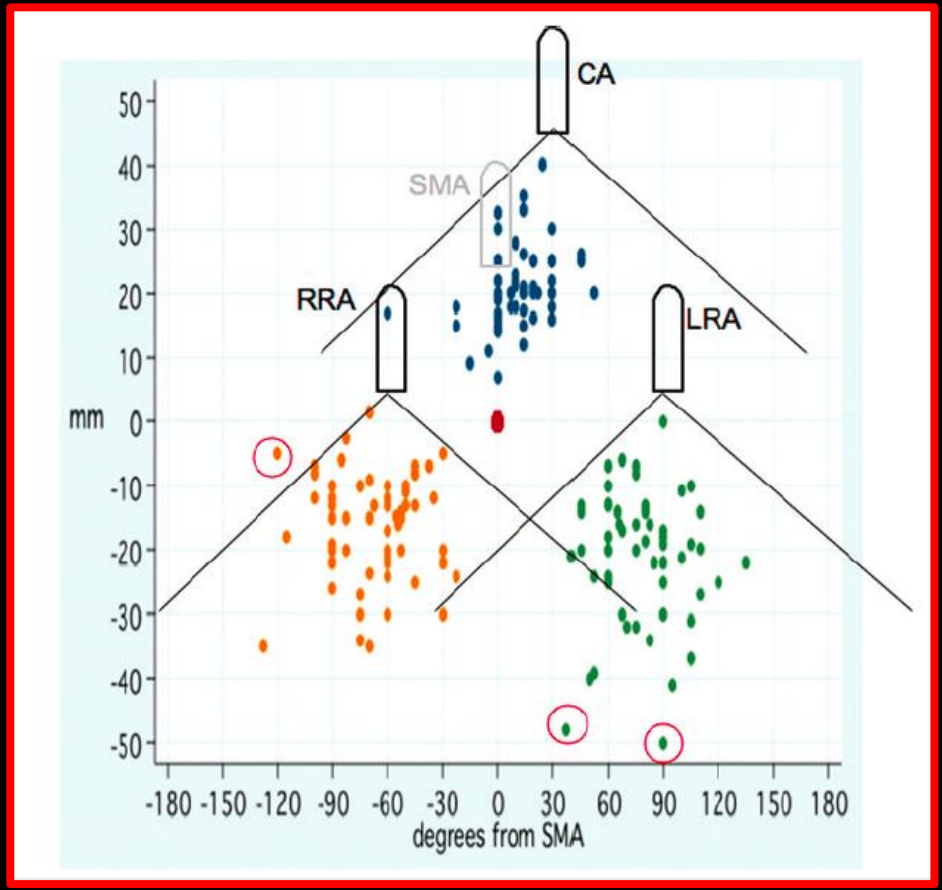

From the Vascular and Endovascular Surgery Society

Standard off-the-shelf versus custom-made multibranched thoracoabdominal aortic stent grafts

Charlene C. Fernandez, BS, Julia D. Sobel, BS, Warren J. Gasper, MD, Shant M. Vartanian, MD, Linda M. Reilly, MD, Timothy A. M. Chuter, MD, and Jade S. Hiramoto, MD, *San Francisco, Calif*

Objective: The complex aortic branch anatomy in thoracoabdominal aortic aneurysms (TAAAs) and pararenal aortic aneurysms (PRAAs) presents a challenge for endovascular repair. The multibranched endovascular device has durable midterm results with use of a custom branch stent graft (CSG) configuration. The midterm results with use of the standard branch stent graft (SSG) configuration are unknown, but it has the advantage of off-the-shelf technology. The goal of this study was to compare the midterm outcomes of CSG and SSG multibranched endovascular repair of TAAA and PRAA in a prospective trial. Beginning in December 2008, SSGs were used in those with suitable anatomy.

Methods: From July 2005 to September 2014, 133 patients underwent elective endovascular repair of TAAA and PRAA in 74 ± 9 years; 22 women [26.5%]) underwent repair using CSGs. The SSG and CSG groups were similar with regard to aneurysm size, aneurysm extent, and medical comorbidities, with the sole exception of lung disease, which was more common in the SSG group. All stent grafts were deployed as intended, with no conversions to open repair. Mean ± standard deviation follow-up (days) was 694 ± 525 for the SSG group and 942 ± 764 for the CSG group ($P = .045$). There were no significant differences in aneurysm-related death, renal failure requiring dialysis, stroke, endoleak, visceral or renal branch occlusion, lower extremity weakness, or reintervention ($P > .05$ for each). The volume of contrast material was significantly lower in those with SSGs compared with CSGs ($P = .016$), but there were no significant differences in operative or fluoroscopy times. Time to treatment (days from consent to surgery) was significantly lower in SSG patients compared with CSG patients ($P = .01$).

Conclusions: For patients with suitable anatomy, the use of SSGs for TAAA and PRAA repair results in significantly shorter wait times to surgery and is as safe, effective, and durable in the midterm compared with CSGs. (J Vasc Surg 2016;63:1208-15.)

Open repair of thoracoabdominal aortic aneurysm (TAAA) is associated with significant morbidity and mortality, even in contemporary series at centers of excellence. Multibranched endovascular aneurysm repair (MBEVAR) avoids extensive aortic exposure, aortic cross-clamp, and visceral ischemia.[1] However, these potential advantages apply only to those patients with the appropriate anatomic substrate.

The early experience with MBEVAR employed custom-made stent grafts (CSGs) in which the distribution of branch attachment sites (cuffs) reflected the distribution of branch arterial orifices in patients with TAAAs and pararenal aortic aneurysms (PRAAs). This approach proved to be safe, effective, and durable,[2] despite considerable variation in the relative positions of the cuffs and their corresponding arterial orifices.[3] Variation in the length and orientation of the stent graft's axially oriented modular branches accommodated errors in stent graft manufacture or implantation.

The urgent treatment of symptomatic patients who could not wait for individualized manufacture of a CSG suggested that this form of intraoperative customization would also permit successful MBEVAR using a premade standard stent graft (SSG). Retrospective analysis of branch distribution in cases of TAAA and PRAA[3] formed the basis for the design of a single-design SSG for use in combination with standard proximal and distal extensions in a wide range of patients.

The first case of MBEVAR using an off-the-shelf SSG took place in December 2008. Since then, SSGs have been used in more than half of all MBEVAR cases at University of California, San Francisco (UCSF)[3] without any apparent effect on short-term results. Meanwhile, refinements in stent graft design have continued to expand the potential application of this technique.[4] The current study was undertaken to compare SSG and CSG in a larger number of patients with longer follow-up.

From the Division of Vascular and Endovascular Surgery, University of California, San Francisco.

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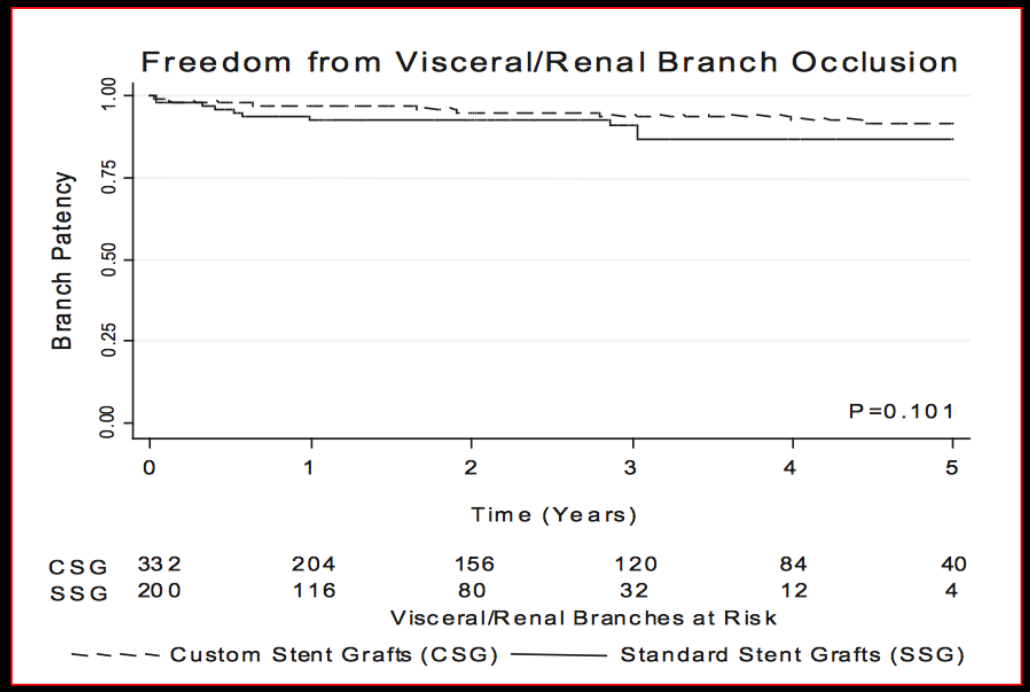

From the Society for Vascular Surgery

Custom-made versus off-the-shelf multibranched endografts for endovascular repair of thoracoabdominal aortic aneurysms

Theodosios Bisdas, MD, Konstantinos P. Donas, MD, Michel J. Bosiers, MD, Giovanni Torsello, MD, and Martin Austermann, MD, *Muenster, Germany*

Objective: This study compared early outcomes between the custom-made and the new off-the-shelf multibranched endograft (mbEVAR, t-branch; Cook Medical, Bloomington, Ind) for the endovascular repair of thoracoabdominal aortic aneurysms (TAAAs).

Methods: Between January 2010 and January 2013, 46 consecutive patients with TAAAs underwent endovascular aortic repair with mbEVARs. A custom-made device was used in 24 patients (group A, 52%), with Crawford classification type I, 2 (8%); type II, 4 (17%); type III, 9 (38%); and type IV/V, 9 (38%), and the a t-branch endograft was used in 22 patients (group B, 47%), with type II, 9 (41%); type III, 12 (55%); and type IV/V, 1 (4%). The main outcome measure was technical success, defined as successful target revascularization without occlusion of the bridging endografts or type I or III endoleak at the completion angiography. Secondary end points were mortality, unplanned reinterventions, branch occlusion, paraplegia, and persistent (after discharge) paraparesis.

Results: Technical success was 100% in both groups. The 30-day mortality was 8% in group A ($n = 2$) and 0% in group B ($P = .51$). Survival rates at 6 months were 71% in group A (mean follow up, 13 ± 11 months) and 94% in group B (mean follow-up, 6 ± 3 months; ($P = .04$). There was only one procedure-related death caused by cerebral bleeding and herniation in group A. The freedom from reintervention rate at 6 months was 100% in group A (mean follow up, 12 ± 11.5 months) and 90% in group B (mean follow-up, 6 ± 3.9 months; $P = .07$). No branch occlusions were observed in group A, whereas a branch occlusion occurred in three patients in group B (in all cases the bridging endograft for the renal artery). In two patients, the possible reason for branch occlusion was a thrombophilic disorder, whereas in one patient, the reason remains unknown. Paraplegia was observed in one patient in each group (group A: 4%; group B: 5%; $P = .51$) and persistent paraparesis in two patients in group A (8%) and in one patient (5%) in group B ($P = .94$).

Conclusions: The t-branch device, with the unique advantage of direct implantation without any delay for manufacturing, showed 100% technical success and comparable clinical outcomes to the traditional custom-made mbEVARs. Further long-term evaluation remains mandatory. (J Vasc Surg 2014;60:1186-95.)

The first clinical evaluation of the custom-made multibranched endograft used for endovascular aneurysm repair (mbEVAR) showed very promising outcomes in elective cases and may be the approach of choice in multimorbid patients due to the minimally invasive character (no aortic clamping, no visceral ischemia).[1-3] However, the custom-made design has two considerable limitations: Firstly, it has no standard branch configuration applicable to all types of aortic anatomy, and secondly, the manufacturing time extends up to 8 to 10 weeks.[4,5] The latter excludes symptomatic and ruptured thoracoabdominal aortic aneurysms (TAAAs), which still have to be repaired through conventional surgery or off-the-shelf techniques.[2] This delay also poses the risk of aortic rupture in asymptomatic patients waiting for the device.[5,6]

To overcome these limitations, a new off-the-shelf mbEVAR (t-branch; Cook Medical, Bloomington, Ind)[3] has been manufactured and is now available for use in Europe. The main characteristics are the standard design and the fixed position of the branches, suitable for at least in 50% of TAAAs treated with a custom-made mbEVAR.[4,7] The first clinical evaluation of technical success and perioperative outcomes confirmed the safety and effectiveness of the device.[3]

However, whether the new standard design with the fixed branches configuration is as equally effective as the traditional custom-made version remains questionable. We conducted this study to compare the efficacy of the t-branch with the standard custom-made mbEVAR in the framework of a single-center experience.

METHODS

Between January 2010 and January 2013, mbEVARs with four branches were implanted in 46 consecutive

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Author conflict of interest: none.

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Off shelf vs custom made

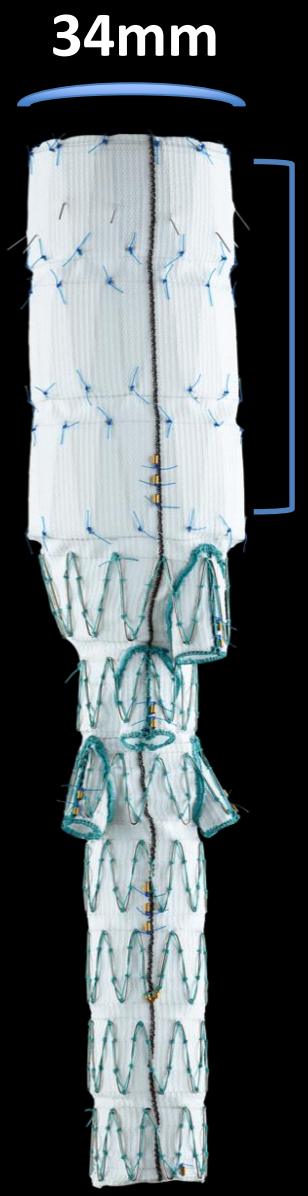
Survival: 94% vs 71%

Paraplegia: 5% vs 4%

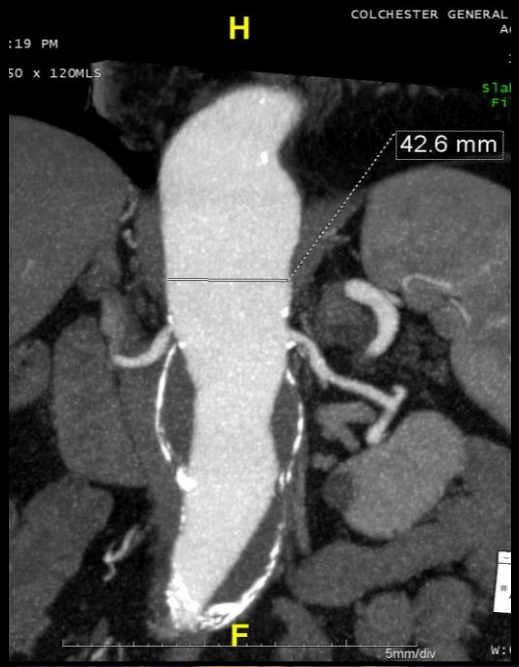
Re-intervention: 10% vs 0%

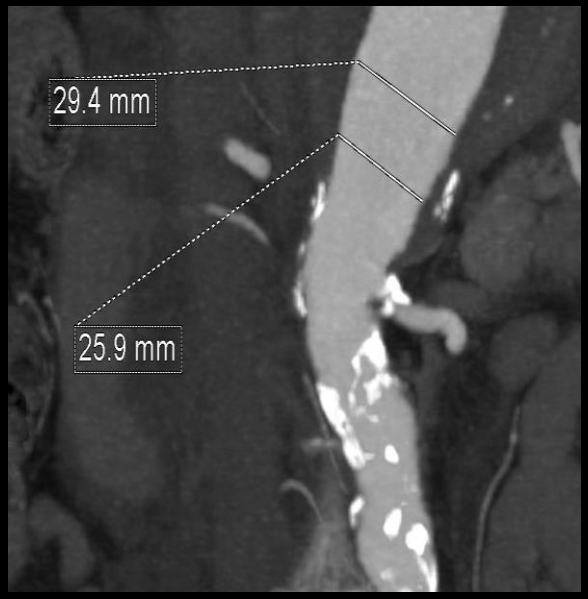
Anatomical Considerations

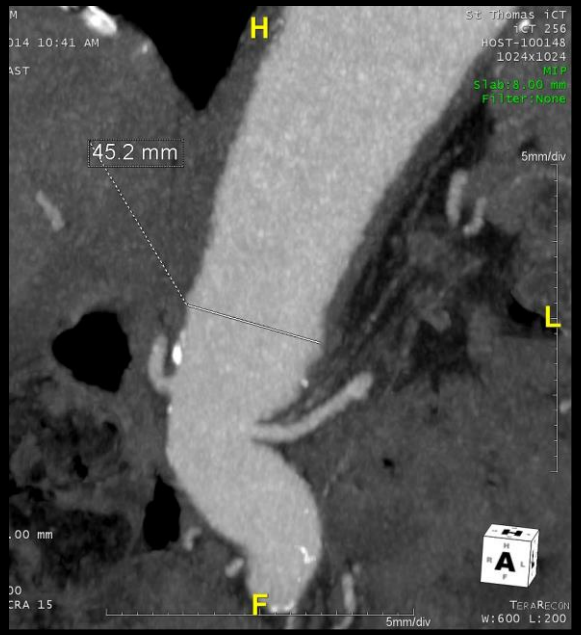
- Luminal diameter
- Orientation and trajectory of target vessels
- Proximal seal
- Distance coeliac → caudal renal
- Aortic angulation
- Access

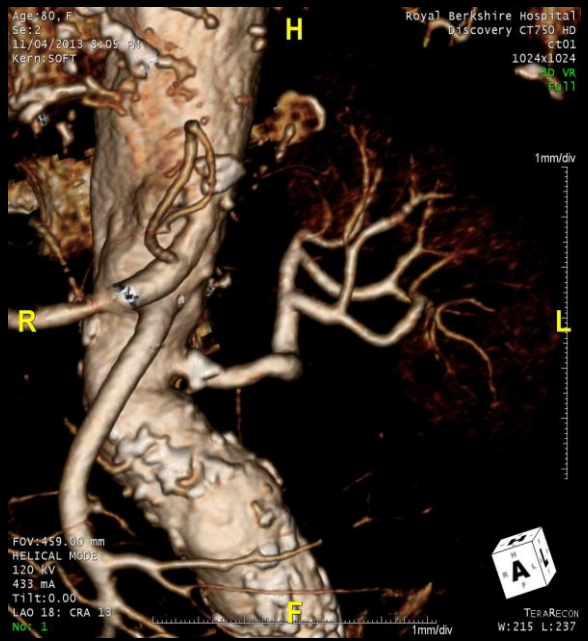


Renal vessels……the good, the bad, the ugly

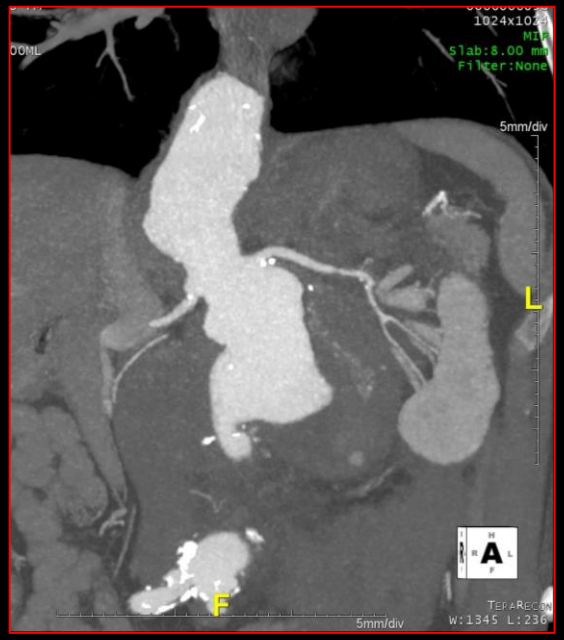








72 male
COPD
Previous MI



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CTA
C:NIOPAM 300 100ML

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1024x1024
MPR
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5mm/div
L

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LAO 0: CAU 90
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5mm/div

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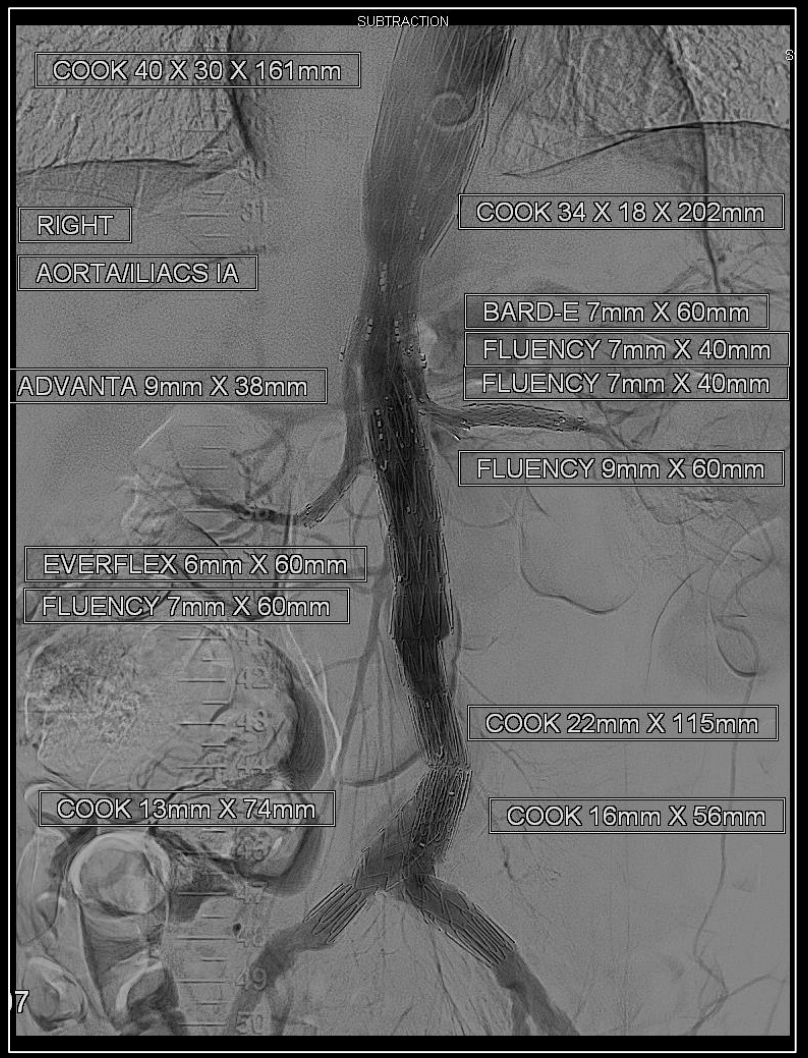

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C:CONTRAST

MPR
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L

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RAO 90: CAU 90
No: 1

P

5mm/div

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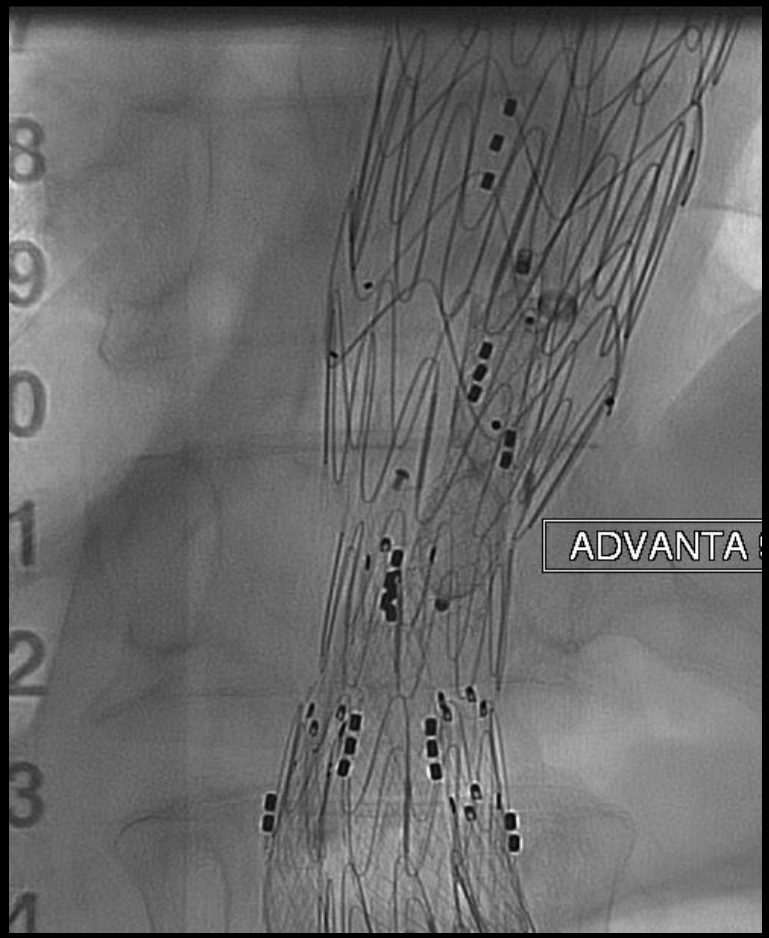
Every second counts……



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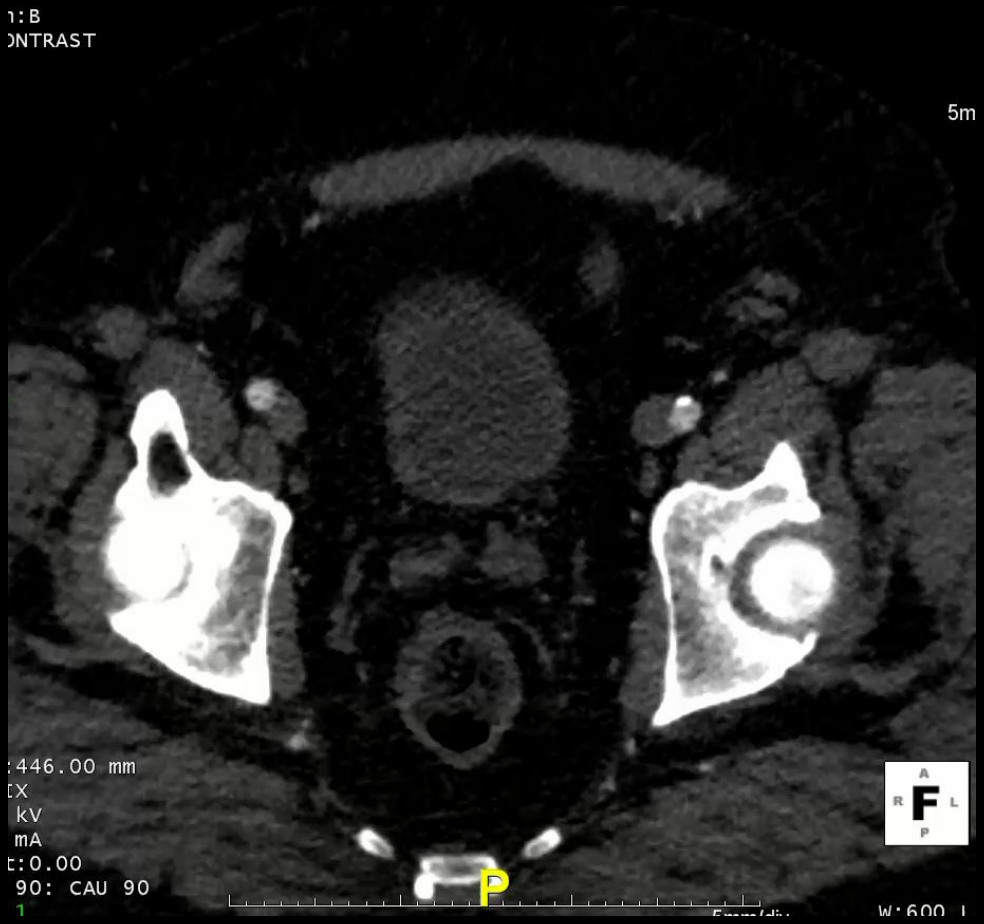
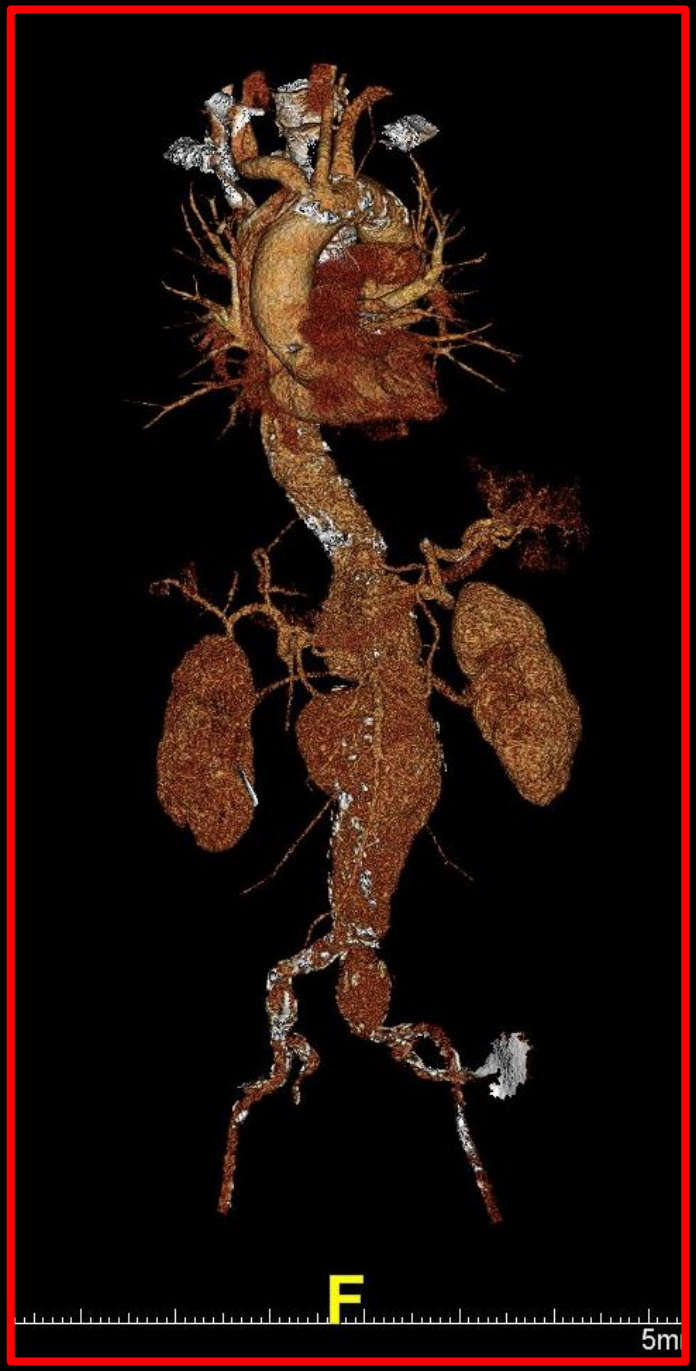
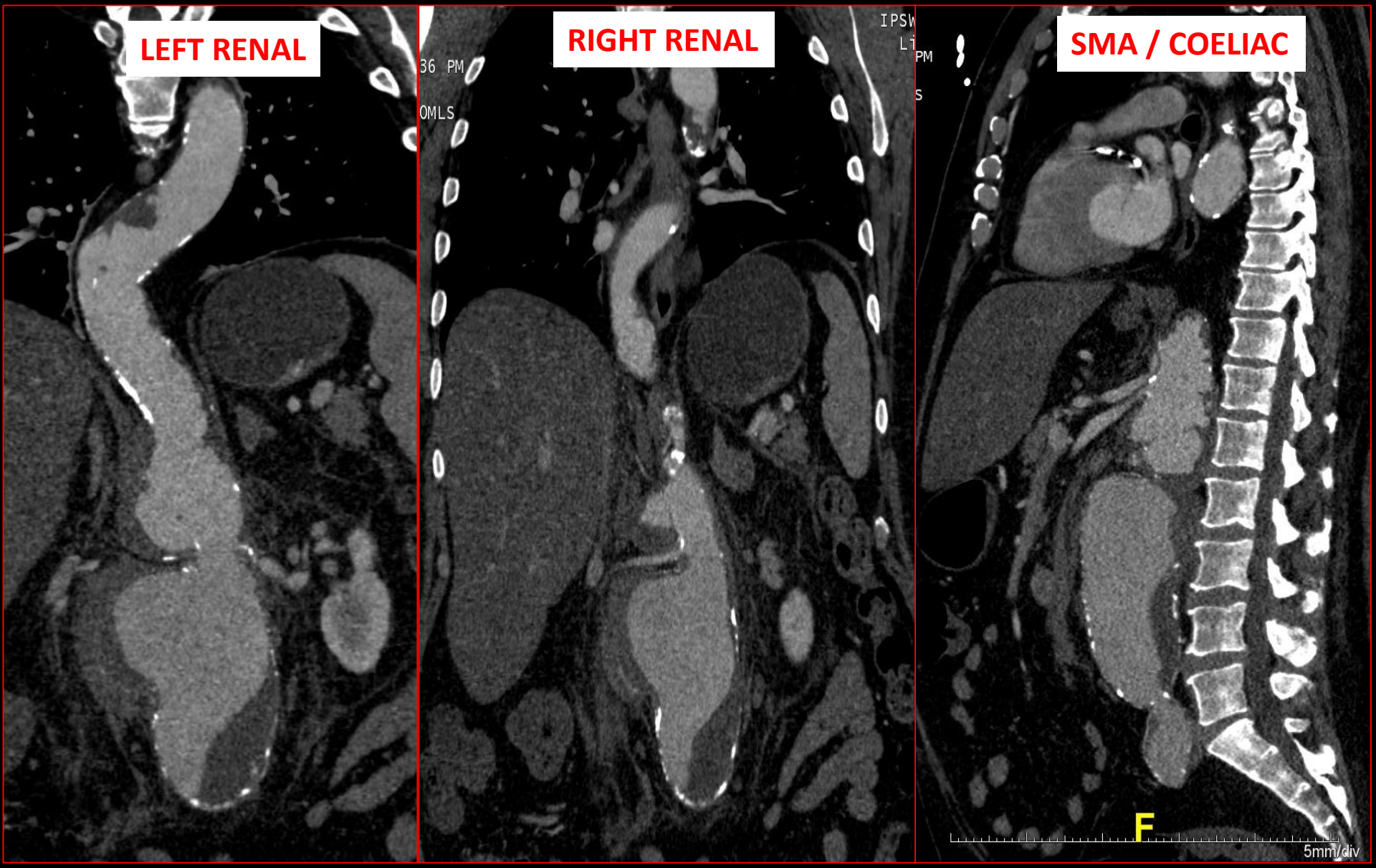
67 male
Type 2 DM
COPD
Osteoarthritis
High BMI



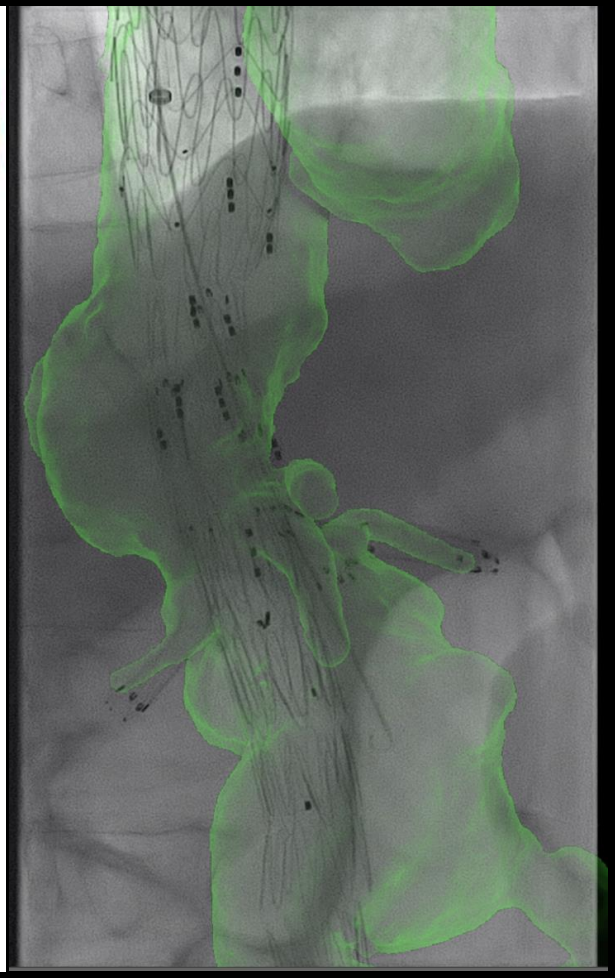



LEFT RENAL
RIGHT RENAL
SMA / COELIAC
5mm/div


SUBTRACTION
HT
RTA IA
OK THORACIC 40X30
MM X 165MM
COOK T-BRANCH
34/18MM X 20
FLUENCY 9X60
LUMINEXX 9X60
ENCY 9X60
INEXX 9X60
ENCY 7X80
INEXX 7X80
OK UNIBODY 22X132
LUMINEXX 7X8
FLUENCY 7X8
FLUENCY 7X4

Post-operative day 4

Every second counts……



KEEP
CALM
AND
Teamwork
ON

Guy's and St Thomas' NHS
NHS Foundation Trust

- Skåne University Hospital, Malmö
- Uppsala University Hospital, Uppsala
- St Thomas' Hospital, London

BEVAR for Ruptured TAAA: 2008-2016

Total number of patients	21
Age	76 (34-82)
Crawford classification	
Type 1 (n=2)	
Type 2 (n=10)	
Type 3 (n=5)	
Type 4 (n=4)	
Previous aortic surgery	9
Shock	4

Aneurysm exclusion	19/21
Target vessels stented	72 / 79
Branches Plugged	7
SCI	6 (Permanent: 1)
Endoleak	2
Mortality (30 day)	5

Summary

- Management of ruptured TAAA remains challenging
- BEVAR extends treatment options
- Planning and patient specific approach is key
- Some flexibility in anatomical criteria
- Adjuncts /ancillary tools / experience required
- True utility more apparent as experience grows