Stent Graft Induced New Entery (SINE) after TEVAR: Predictor and Management

Young-Guk Ko, M.D.

Severance Cardiovascular Hospital, Yonsei University Health System, Seoul, Korea

Disclosure

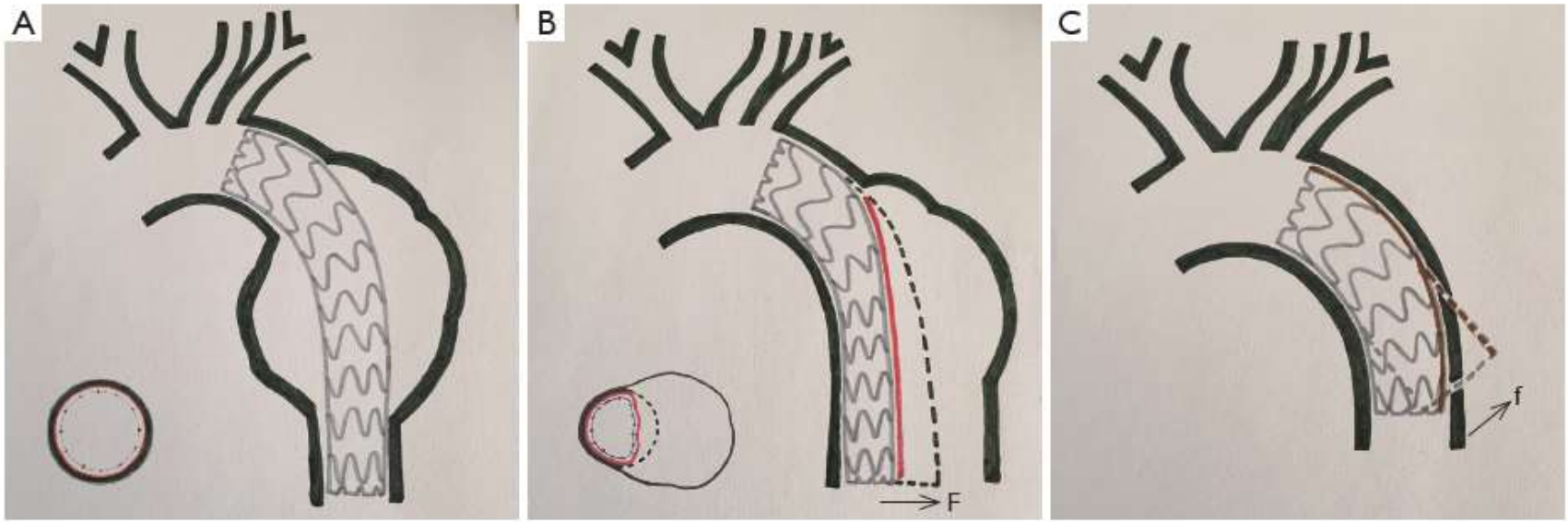
- Research funds
  - *Cook*
  - *Medtronic*
  - *Boston scientific*
  - *Cordis*
  - *Otsuka*
  - *Korea United Pharm*
  - *Dong-A Pharmaceutical*

- *Severance Cardiovascular Intervention (SCI) Workshops in cooperation with Medtronic, Cordis, Abbott, Cook, Boston Scientific*

Pathologic Mechanisms of SINE

Type B aortic dissection

At the curvature



F = radical force

f = spring-back force

Li Q, J Thorac Dis 2015;7:1907

Risk Factors for SG-induced New Entry

Incidence and risk factors for retrograde type A dissection and stent graft-induced new entry after thoracic endovascular aortic repair

Tao Ma, MD,[a] Zhi Hui Dong, MD,[a] Wei Guo Fu, MD,[a] Da Qiao Guo, MD,[a] Xin Xu, MD,[a] Bin Chen, MD,[a] Jun Hao Jiang, MD,[a] Jue Yang, MD,[a] Zhen Yu Shi, MD,[a] Ting Zhu, MD,[a] Yun Shi, MD,[a] Bao Hong Jiang, PhD,[b] and Xiao Yun Xu, MD,[a] *Shanghai, China and London, United Kingdom*

ABSTRACT

Objective: Stent graft (SG)-induced new entry (SINE) and retrograde type A dissection (RTAD) are serious device-related complications occurring after thoracic endovascular aortic repair (TEVAR) for Stanford type B aortic dissection (TBAD) and may lead to endograft-related complications including retrograde dissection and death. The purpose of this study was to investigate the incidence and risk factors for the development of RTAD and SINE after TEVAR for TBAD and to identify the complications associated with this.

Methods: From April 2005 to October 2013, there were 997 patients who underwent TEVAR for TBAD; 852 were followed up (0-6 years; mean, 2.6 years), and 59 SINEs developed in 53 patients. The oversizing ratio and incidence of RTAD and SINE were compared between proximal bare stent (PBS) and non-PBS groups and RTAD and SINE and non-RTAD and non-SINE groups. The baseline characteristics and SG configurational factors potentially affecting both RTAD and distal SINE were analyzed.

Results: There was no significant difference between PBS and non-PBS groups in the incidence of RTAD. A greater oversizing ratio was related to a higher distal SINE rate. SINE was seen more frequently in smokers and in patients with hypertension, Marfan syndrome, and TEVAR in the chronic phase and less frequently in complicated dissection cases. Device-related factors for SINE were SG with a connecting bar and SG length <165 mm. The SG length <165 mm increased the overall proximal and distal SINE incidence in multivariate analysis.

Conclusions: The presence of a PBS is not associated with a higher RTAD rate, whereas the use of an SG with a connecting bar and length <165 mm increases the risk of RTAD and SINE after TEVAR. (J Vasc Surg 2017;■:1-8.)

Variables	RTAD and SINE			RTAD			Distal SINE		
	OR	95% CI	*P* value	OR	95% CI	*P* value	OR	95% CI	*P* value
Male gender	–	–	–	–	–	–	–	–	–
Age >60 years	–	–	–	–	–	–	–	–	–
TEVAR in chronic phase	2.32	1.30-4.25	.01	–	–	–	2.63	1.22-5.68	.01
TEVAR for complicated dissection	0.55	0.31-1.00	.05	–	–	–	0.44	0.21-0.95	.03
Smoking	–	–	–	–	–	–	–	–	–
Hypertension	–	–	–	–	–	–	–	–	–
Marfan syndrome	3.72	1.09-12.75	.05	–	–	–	–	–	–
SG with connecting bar	2.51	1.38-4.54	<.01	–	–	–	3.28	1.54-7.00	<.01
SG <165 mm	4.17	2.31-7.53	<.01	2.99	1.35-6.64	.007	5.65	2.60-12.64	<.01
Two SGs implanted	–	–	–	–	–	–	–	–	–

CI, Confidence interval; *OR*, odds ratio; *TEVAR*, thoracic endovascular aortic repair.

Ma T, J Vasc Surg 2017

Distal Stent Graft-Induced New Reentry

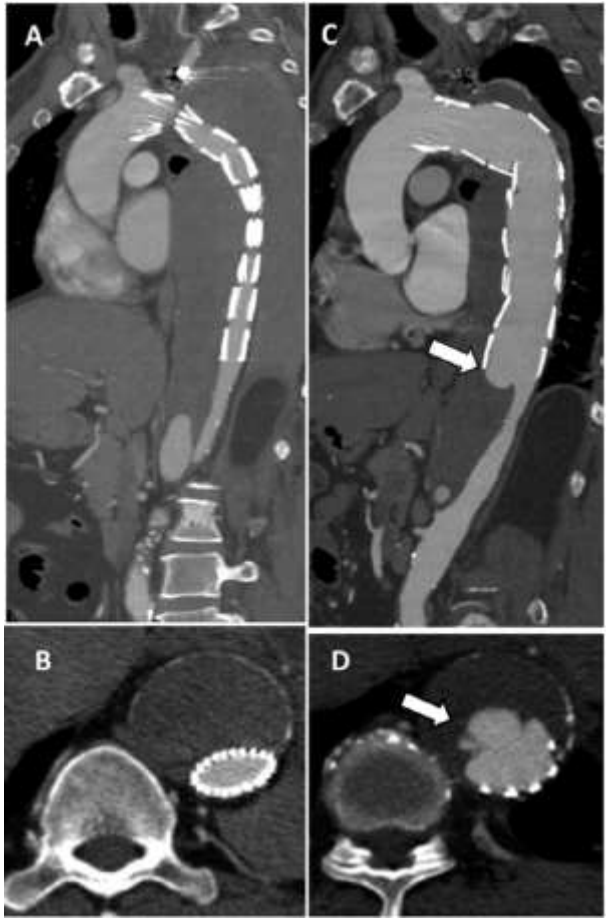


Table 3. Multivariate Analysis for Risk Factors of Stent-Induced New Entry Development

Characteristics	OR	95% CI	*p* Value
Female	3.140	0.893–9.524	0.076
Age	…	…	0.841
Body surface area	…	…	0.928
Systemic hypertension	…	…	0.783
Dyslipidemia	…	…	0.108
Diabetes mellitus	…	…	0.860
Chronic kidney injury	…	…	0.999
Marfan syndrome	…	…	0.969
Aortic kinking	…	…	0.236
Acute type B dissection	…	…	0.445
Residual type B dissection	…	…	0.325
Oversizing ratio maximum diameter	2.641	0.993–7.026	0.052
Oversizing rate A/B	…	…	0.631
Oversizing ratio area	1.843	1.109–3.064	0.018
Oversizing ratio mean diameter	0.034	0.001–0.802	0.036

CI = confidence interval; OR = odds ratio.

Ann Thorac Surg 2016;102:527

Stent Graft Induced New Entry (SINE)

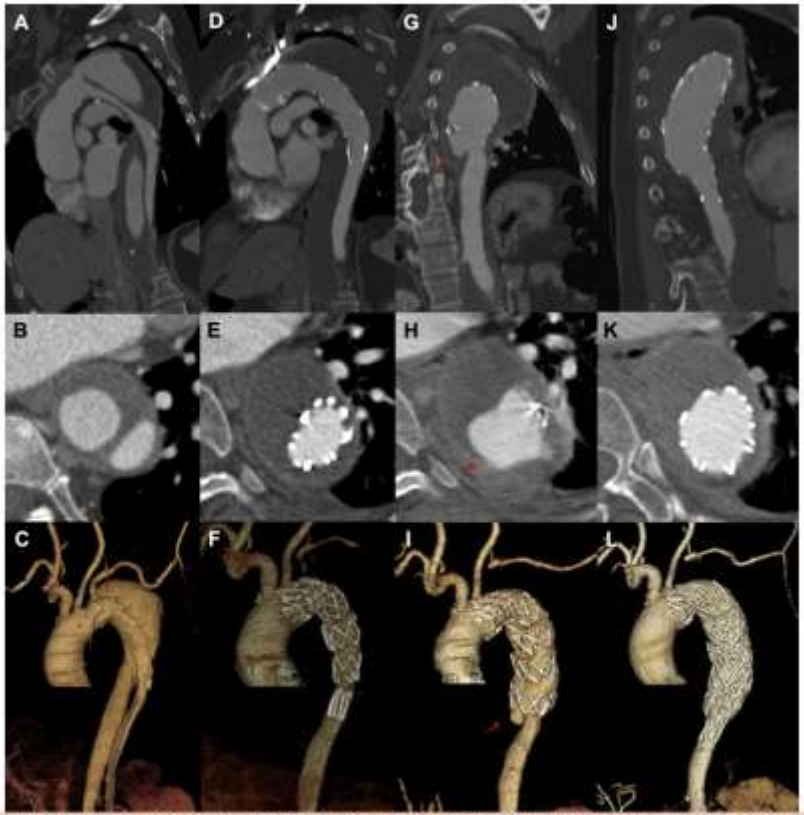
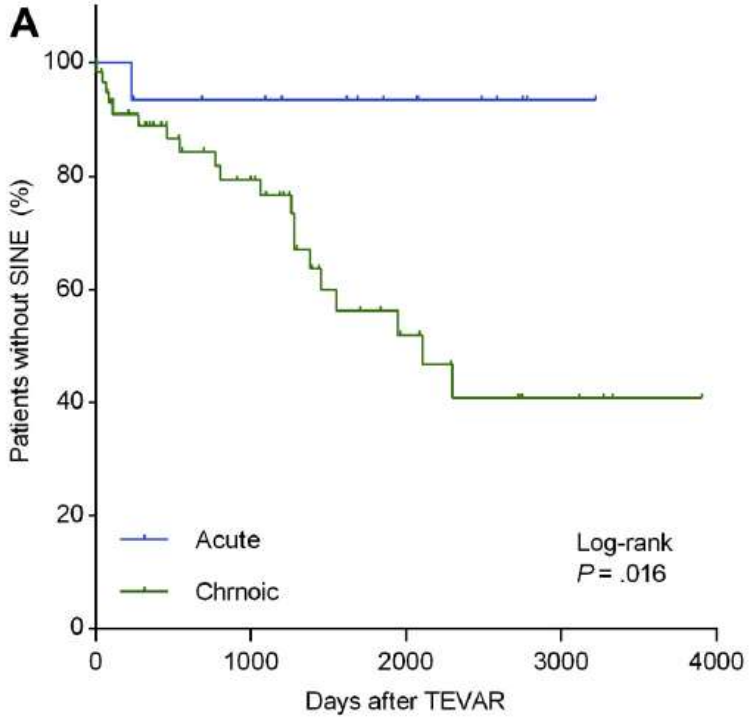


Fig 2. A, Multiplanar reconstruction image, **(B)** axial image, and **(C)** three-dimensional volume-rendered computed tomography (CT) image of a 53-year-old woman with a Stanford type B chronic descending thoracic aortic dissection. **D-F,** Thoracic endovascular aortic repair (TEVAR) is performed with a 38 × 150 SEAL stent graft (S&G Biotech Inc, Seongnam, Korea) and the false lumen is completely thrombosed. Distal oversizing ratios of the stent graft by maximal diameter, mean diameter, circumference, and area were 111%, 161%, 146%, and 580%, respectively. **G-I,** At follow-up 9 months later, small new intimal tear (*red arrow*) has developed at the distal margin of the stent graft. **J-L,** An additional 40 × 110 SEAL stent graft is inserted at the distal margin of the original stent graft, and the distal intimal tear is completely regressed.



Jang H, J Vasc Surg 2017;65:676

Taper & Oversizing Ratio

$$\text{Taper Ratio (\%)} = \left(1 - \frac{Xd}{Xp}\right) \times 100$$

$$\text{Oversizing Ratio (\%)} = \left(\frac{Xg}{Xd} - 1\right) \times 100$$

p: proximal aorta
d: distal aorta
G: stent graft

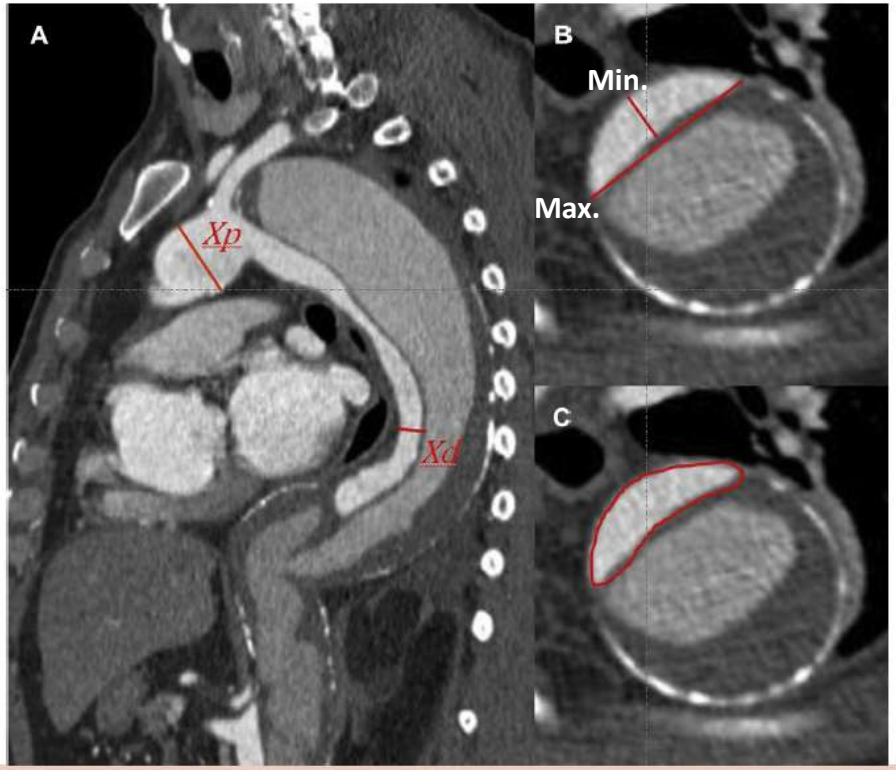


Fig 1. **A,** Saggital computed tomography (CT) view before thoracic endovascular aortic repair (TEVAR) shows the size of presumed proximal landing zone (*Xp*) and the size of the presumed distal landing zone (*Xd*). **B,** Maximal and minimal diameter and mean diameter of Xd. **C,** Area and circumference of Xd.

Predictors of SINE

Risk for SINE is increased, if SG diameter is ~40% larger than max. diameter of distal aorta TL

Variable[a]	Cutoff value	Sensitivity	Specificity	Predictive value	
				Positive	Negative
Taper ratio					
Maximal diameter	26.1	71	60	42	84
Mean diameter	48.0	71	66	45	85
Circumference	40.8	67	70	45	84
Area	72.9	71	66	45	85
Oversizing ratio					
Maximal diameter	43.8	55	85	58	83
Mean diameter	108.8	60	76	48	83
Circumference	87.0	50	89	63	82
Area	335.9	60	76	52	84

[a]Data are presented as percentages.

Jang H, J Vasc Surg 2017;65:676

Stent Graft Implantation

- Mismatch between the proximal and the distal landing zone diameters > 4 mm
  - **Tapered stent grafts**,
  - **Restrictive bare stent**
  - **Bottom-up technique** using two SGs of different diameters

  => The small endoprosthesis deployed distally first, and the larger device inserted proximally into the smaller to facilitate good sealing

Restrictive Bare Stent

Restrictive bare stent for prevention of stent graft-induced distal redissection after thoracic endovascular aortic repair for type B aortic dissection

Jiaxuan Feng, MD, Qingsheng Lu, MD, Zhiqing Zhao, MD, Junmin Bao, MD, Xiang Feng, MD, Lefeng Qu, MD, Jian Zhou, PhD, and Zaiping Jing, MD, *Shanghai, China*

Background: Stent graft-induced distal redissection (SIDR) is one of the major concerns in the durability of endovascular repair for complicated Stanford type B aortic dissection. The characteristics and means of prevention of this complication remain unknown.

Methods: From April 1997 to March 2010, 674 patients with type B aortic dissections were treated primarily by thoracic endovascular aortic repair (TEVAR) at our center. Criteria for inclusion in this study were treatment primarily with TEVAR and an estimated mismatch rate (ratio of distal diameter of stent graft to long diameter of true lumen) greater than 120%. By this protocol, 465 patients were included in this study and were retrospectively analyzed. Among them, 266 patients were treated in the acute phase, and 199 were treated in the chronic phase.

Results: A total of 311 patients were treated with standard TEVAR and 154 patients with TEVAR + restrictive bare stent (RBS). The preoperative mismatch rate (measured as the preoperative long diameter of the true lumen at the level of the intended distal end of the stent graft) of the SIDR was significantly higher than that of the non-SIDR (192.7 ± 54.9% vs 131.9 ± 10.4%; $P < .05$). The follow-up mismatch rate of the SIDR was significantly higher than that of the non-SIDR (145.4 ± 34.6 vs 120.3 ± 16.1; $P < .05$). Compared with the standard TEVAR, TEVAR + RBS was associated with a lower incidence of SIDR (0% vs 2.9%; $P = .033$) and less secondary intervention (3.9% vs 9.3%; $P = .040$). Placement of the RBS significantly expanded the true lumen at the level of the descending aorta with the narrowest true lumen and at the level of the distal end of the stent graft.

Conclusions: The mismatch between the distal diameter of the stent graft and the diameter of the compressed true lumen seems to be the major factor in the occurrence of SIDR. Placement of an RBS, as an adjunctive technique to TEVAR, could reduce the incidence of SIDR. On the basis of early- to midterm observations, RBSs may improve morphological remodeling of the dissected aorta at certain levels. (J Vasc Surg 2013;57:44S-52S.)

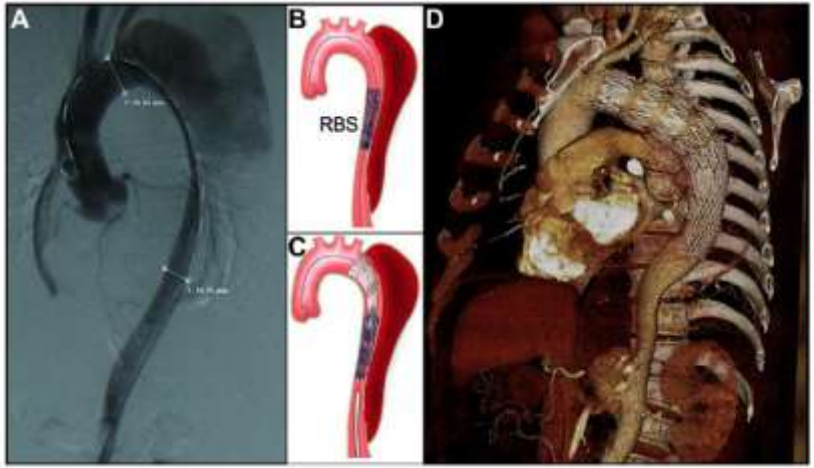


Table III. Comparison of patient outcomes between the TEVAR and the TEVAR + RBS groups

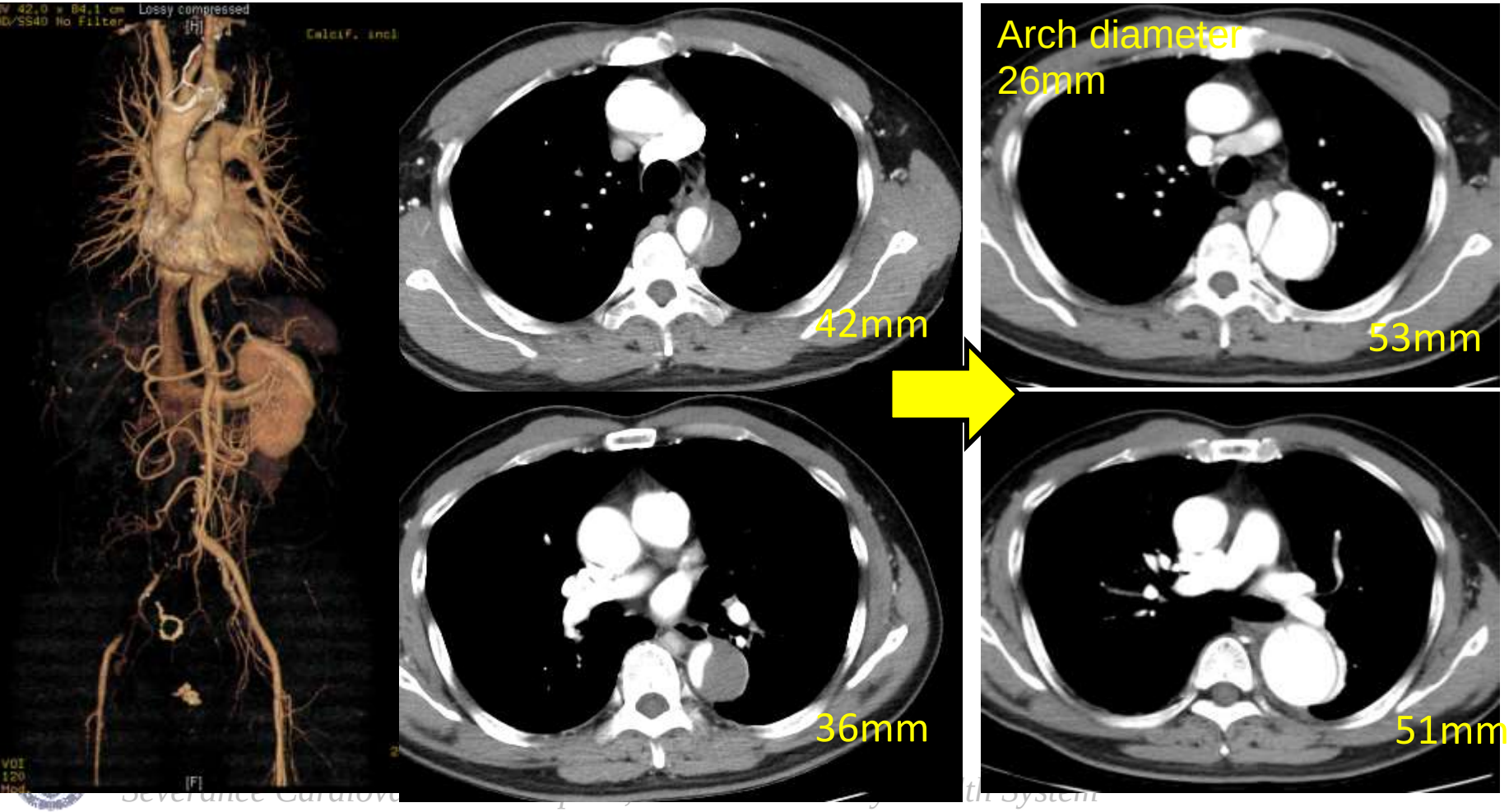
	TEVAR group (n = 311)	*TEVAR + RBS group (n = 154)*	P
Acute/chronic aortic dissection, n	180/131 (57.9%/42.1%)	86/68 (55.8%/44.2%)	.691
Preoperative mismatch rate, %	135.5 ± 13.6%	131.8 ± 10.7%	.172
Complications, n			
Access problem	6 (1.9%)	2 (1.3%)	.910
Paraparesis/paraplegia	3 (1.0%)	1 (0.6%)	.729
SIDR	9 (2.9%)	0	.033*
Secondary intervention for all causes	29 (9.3%)	6 (3.9%)	.040*
Conversion to surgery	2 (0.6%)	0	.807
Overall death	9 (2.9%)	2 (1.3%)	.352
Aorta-rated death	6 (1.9%)	1 (0.6%)	.434

RBS, Restrictive bare stent; *SIDR*, stent graft-induced distal redissection; *TEVAR*, thoracic endovascular aortic repair.
*Significant, $< .05$.

RBS dimeter = longest diameter of TL

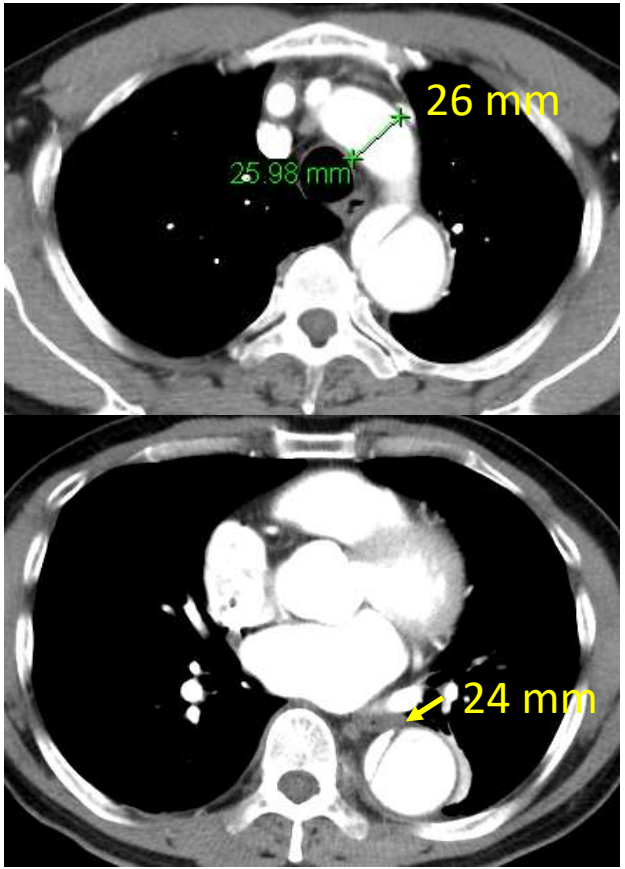
Feng J, J Vasc Surg 2013;57:44S

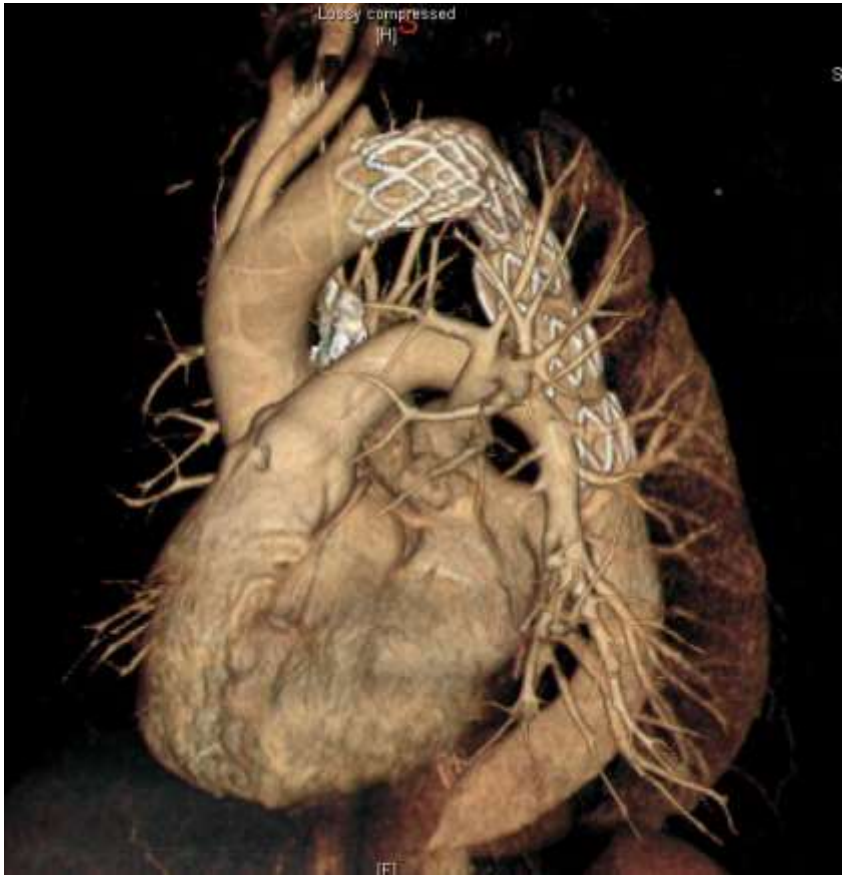
M/56, (AHK, #8159514) At 5 months after Acute TBAD



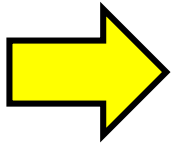
TEVAR

2014/6
TEVAR
S&G 30-130mm,



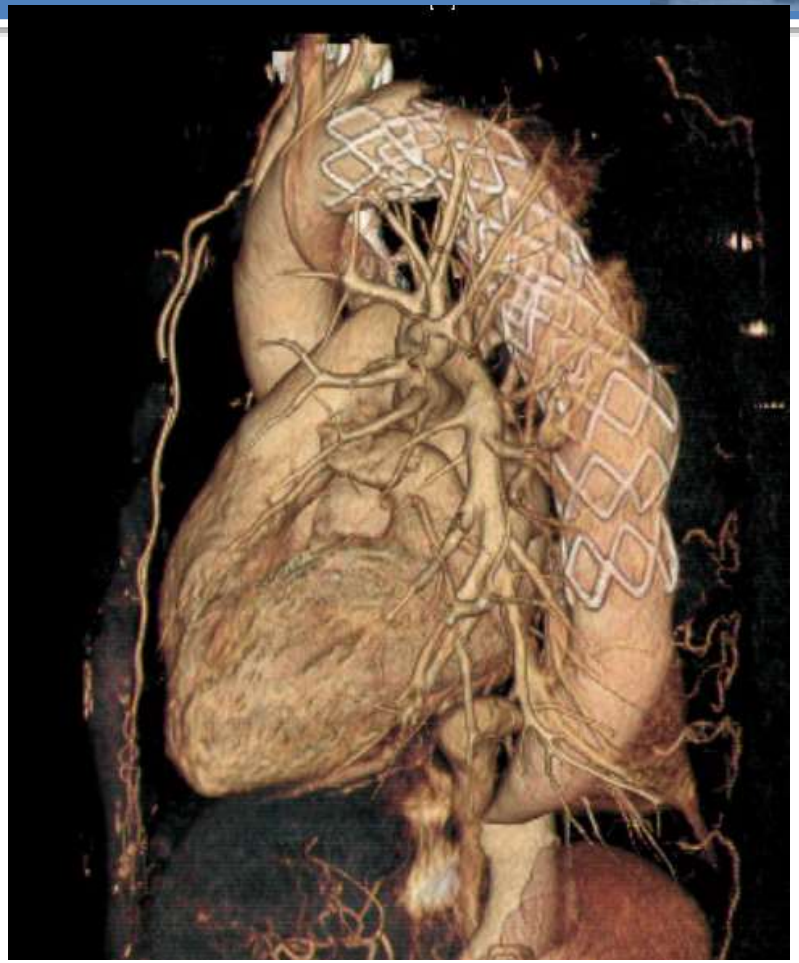


SINE occurred after 8 months

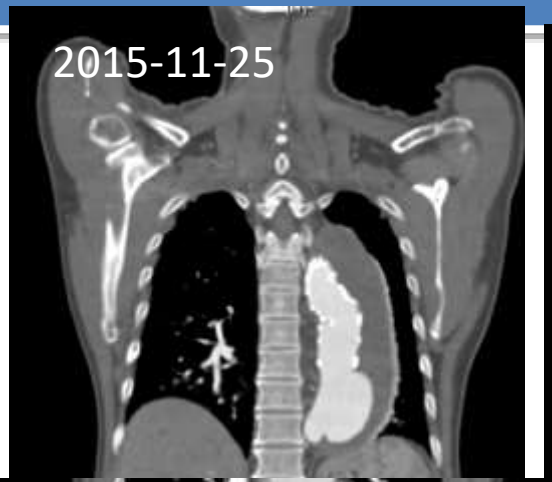


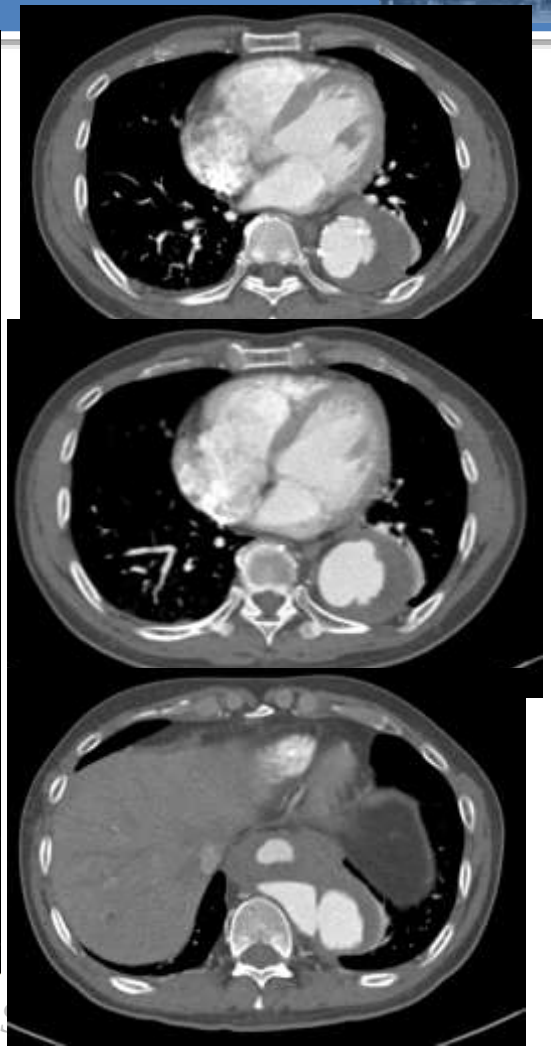
2nd TEVAR

2015/2
S&G 36-32-110 mm,
tapered type



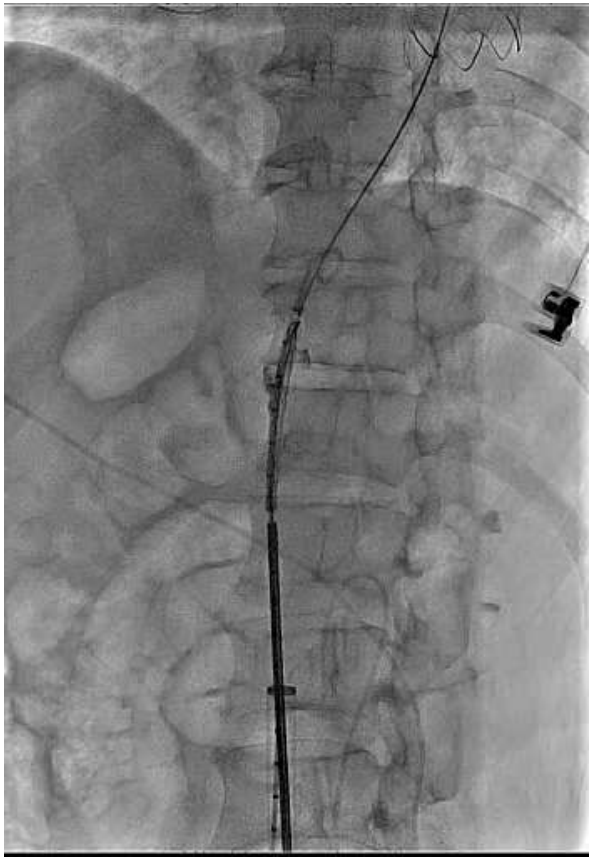
2nd SINE occurred after 8 months

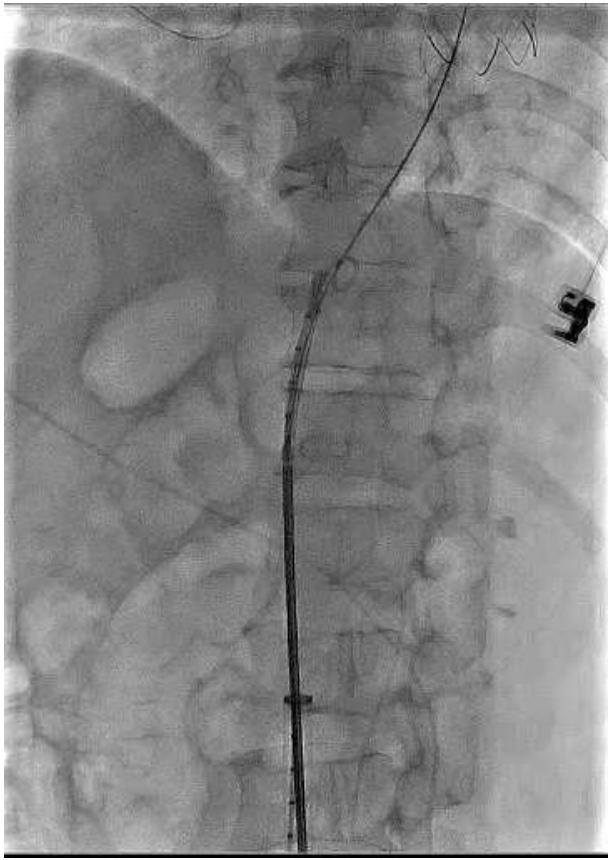




Restrictive Bare Stent

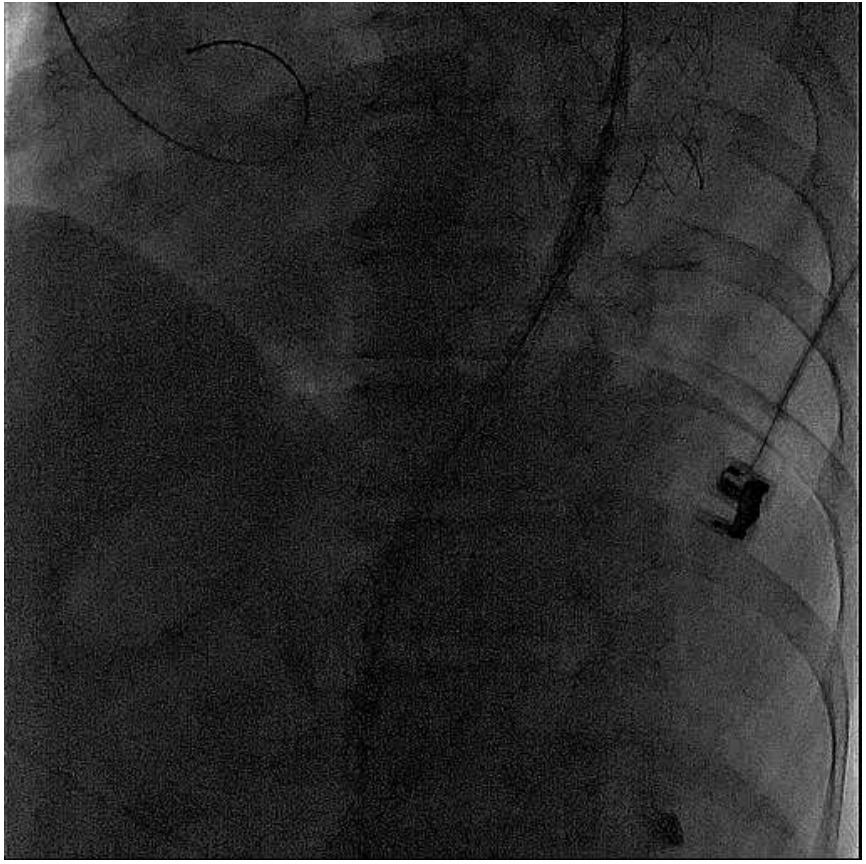
BMS 24X40 mm
Hercules Vascular



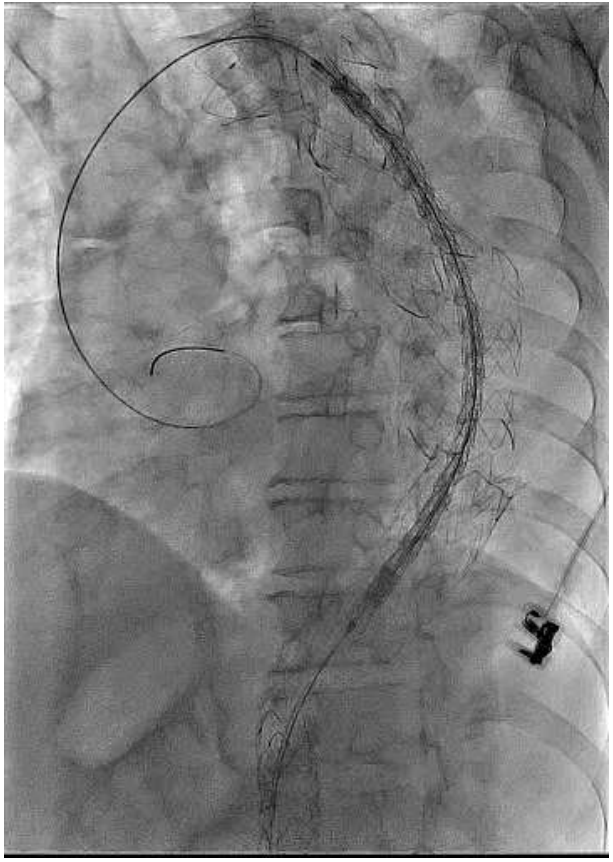


3rd TEVAR

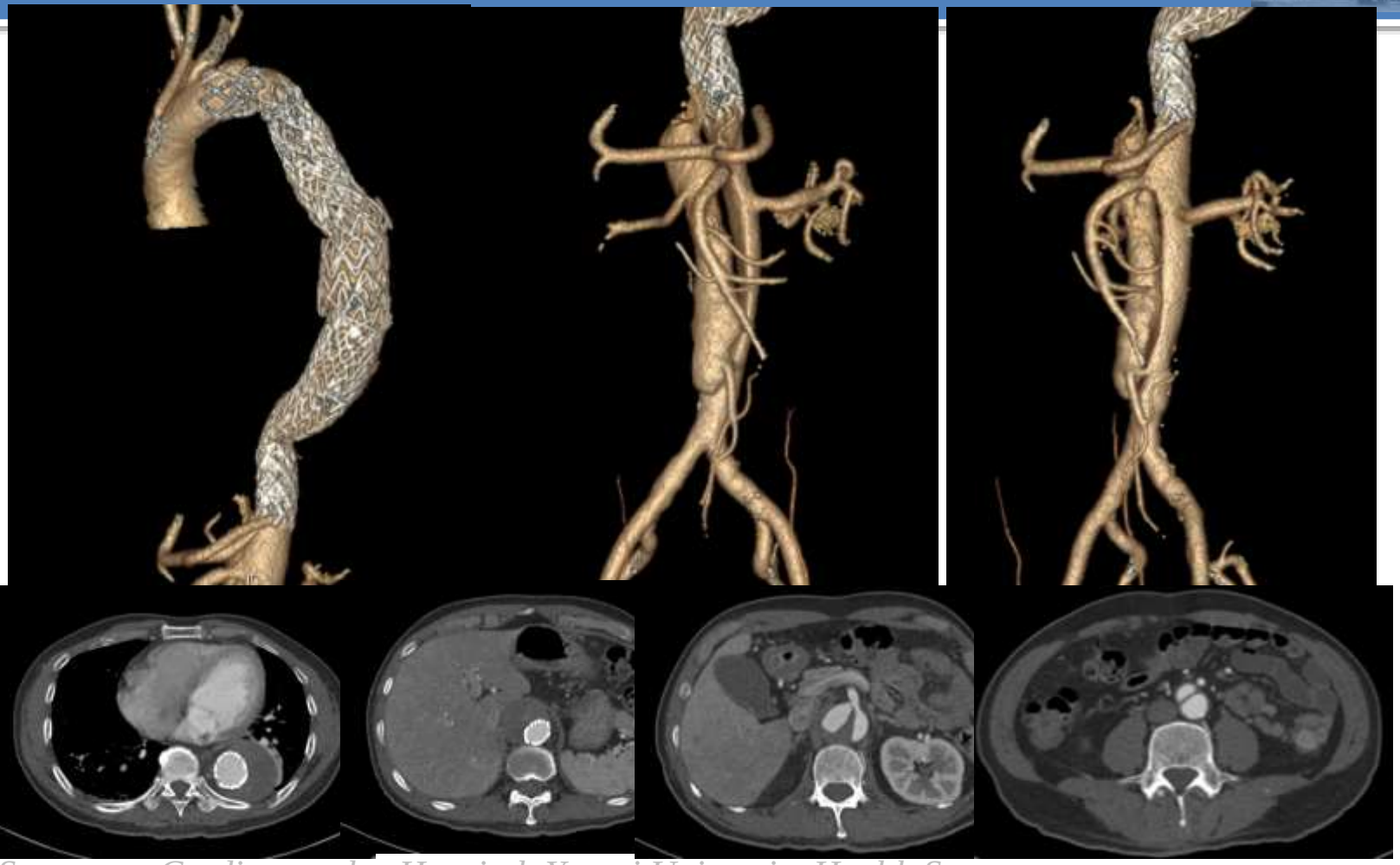
TAG 31 X 150 mm



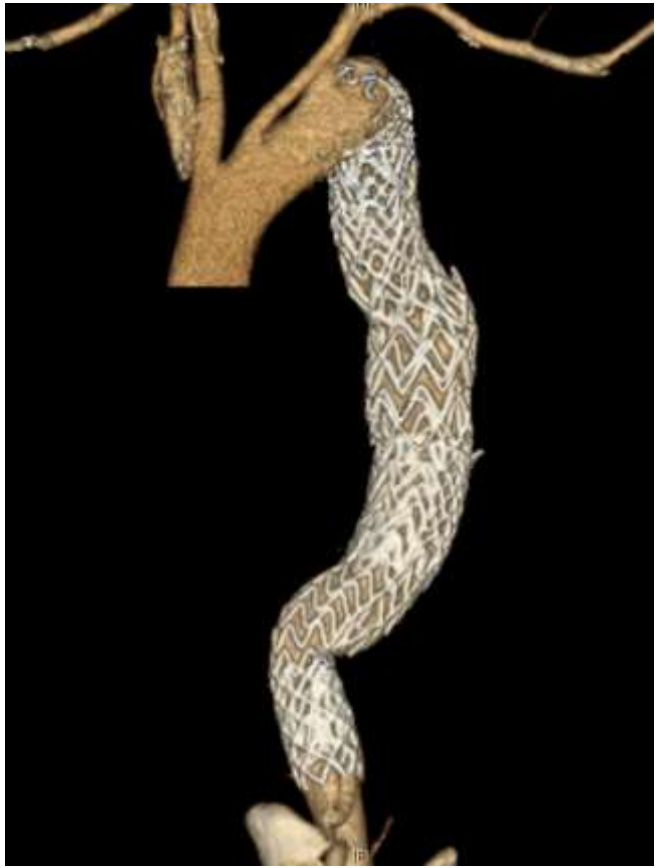
TAG 37X200mm



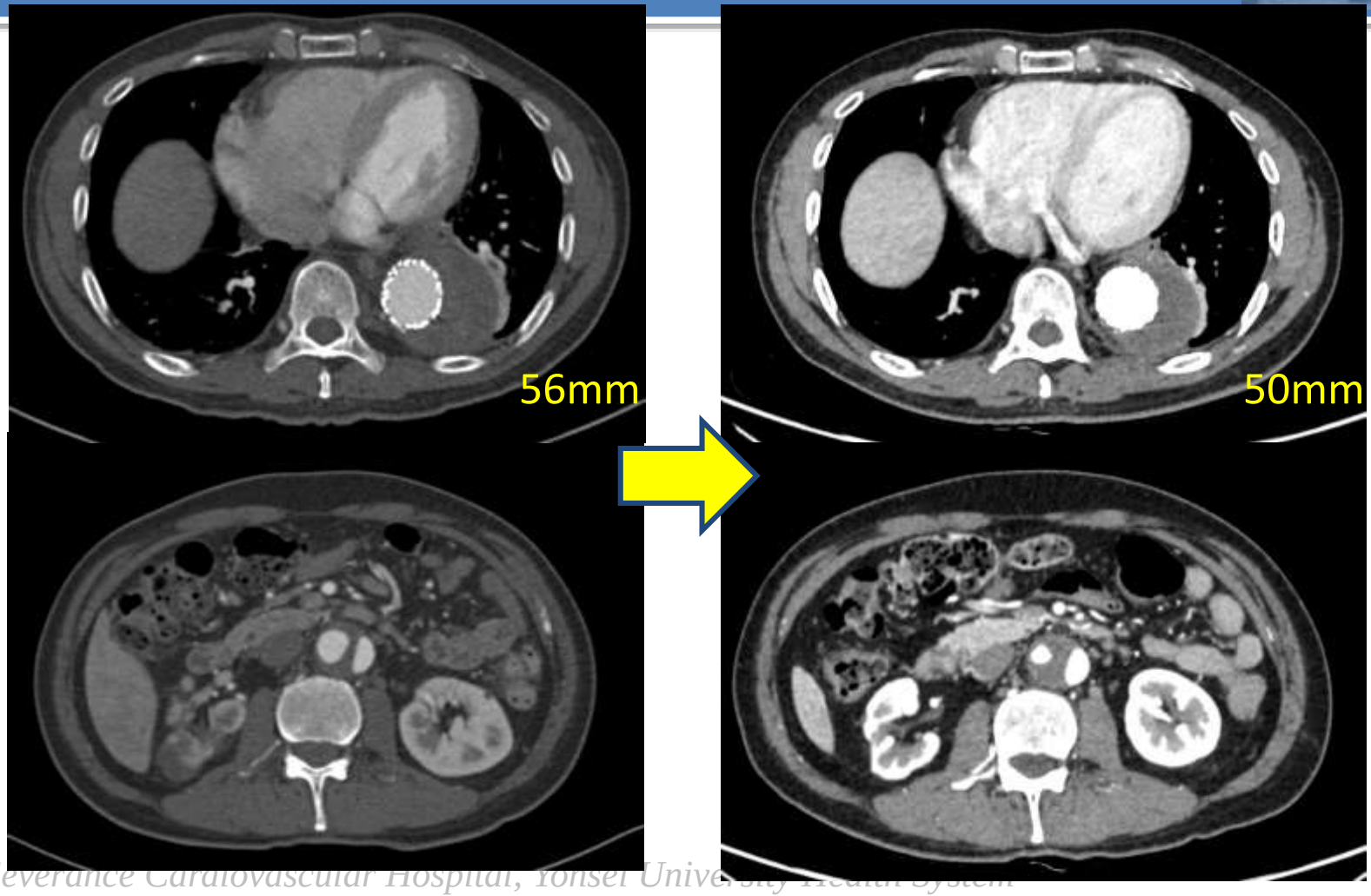
Post-procedural CT



Follow-up CT (6 months later)

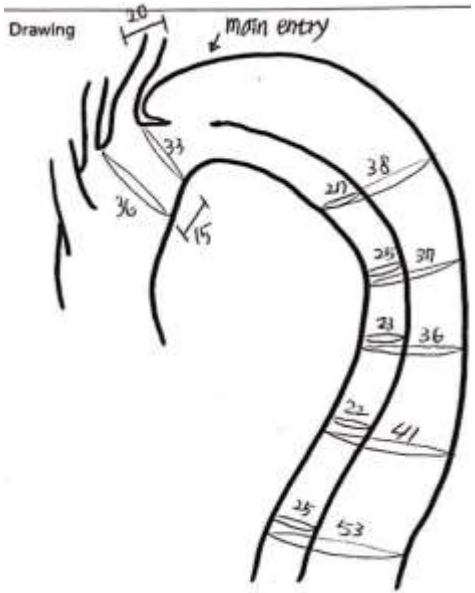


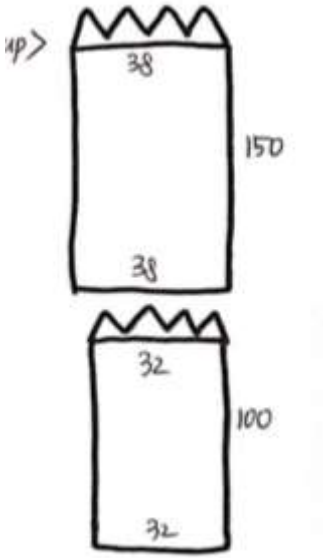
Follow-up CT (6 months later)

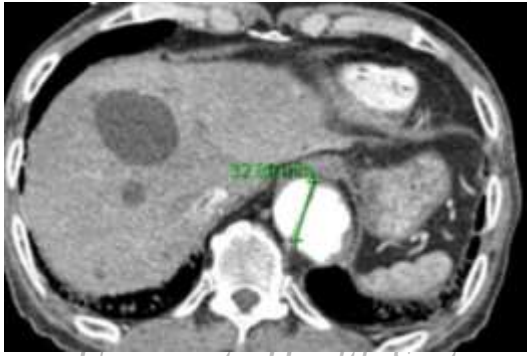


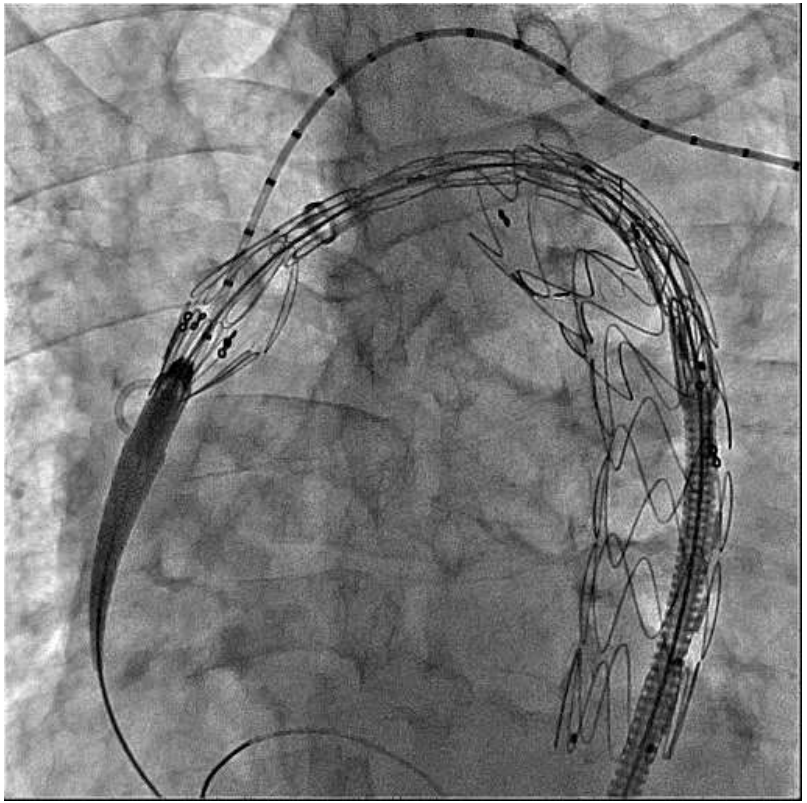
M/83, Chronic Type B AD

JCD #5917613



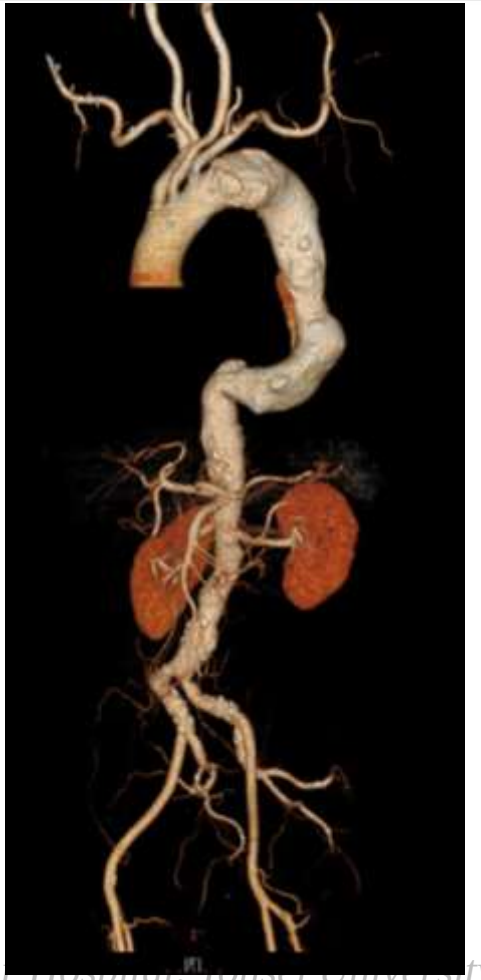




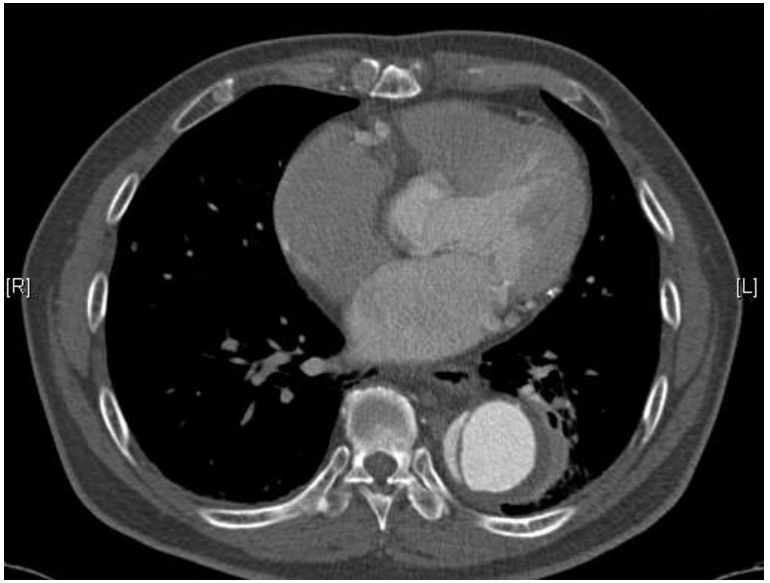


M/65, Dissecting TAA KWC #2516258

S/P CABG (1999)
Stroke



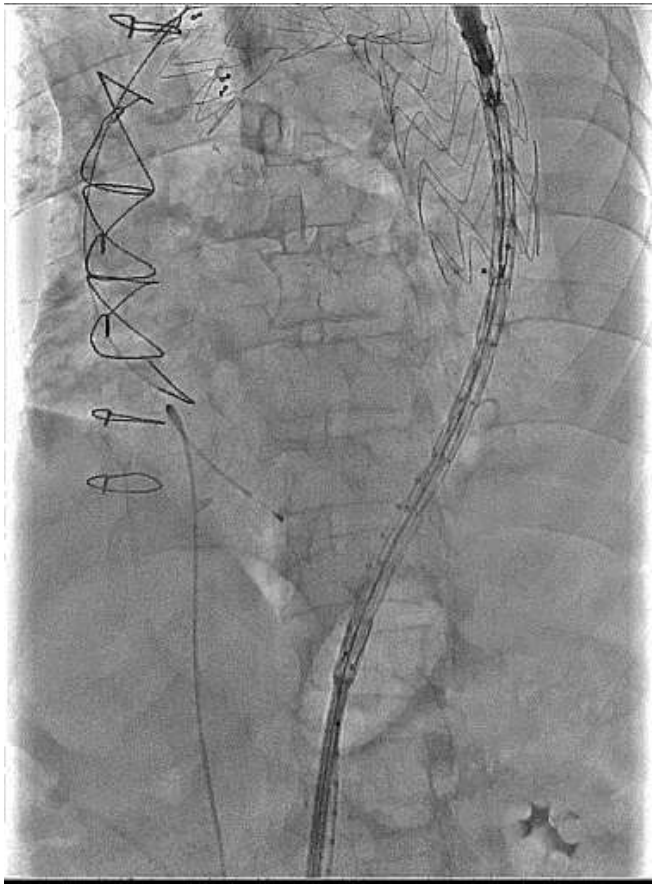
Max . Diameter 65 mm

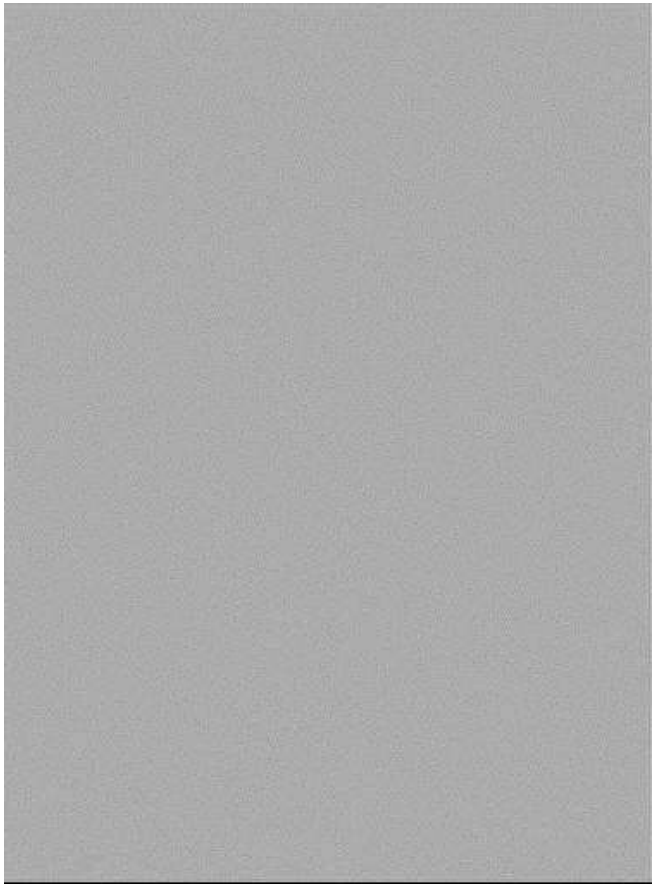


TEVAR

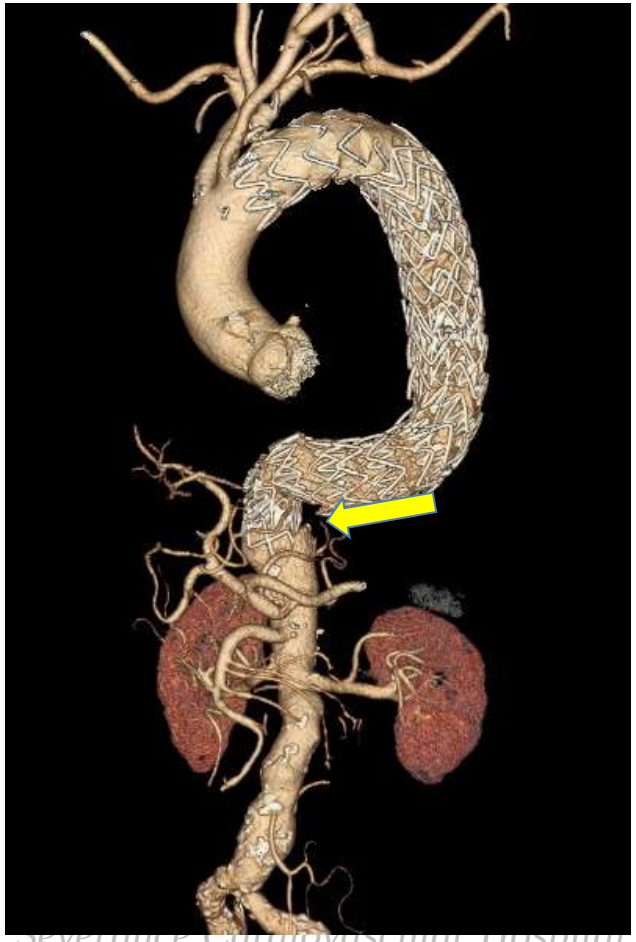
After
LCCA-LSCA
Bypass

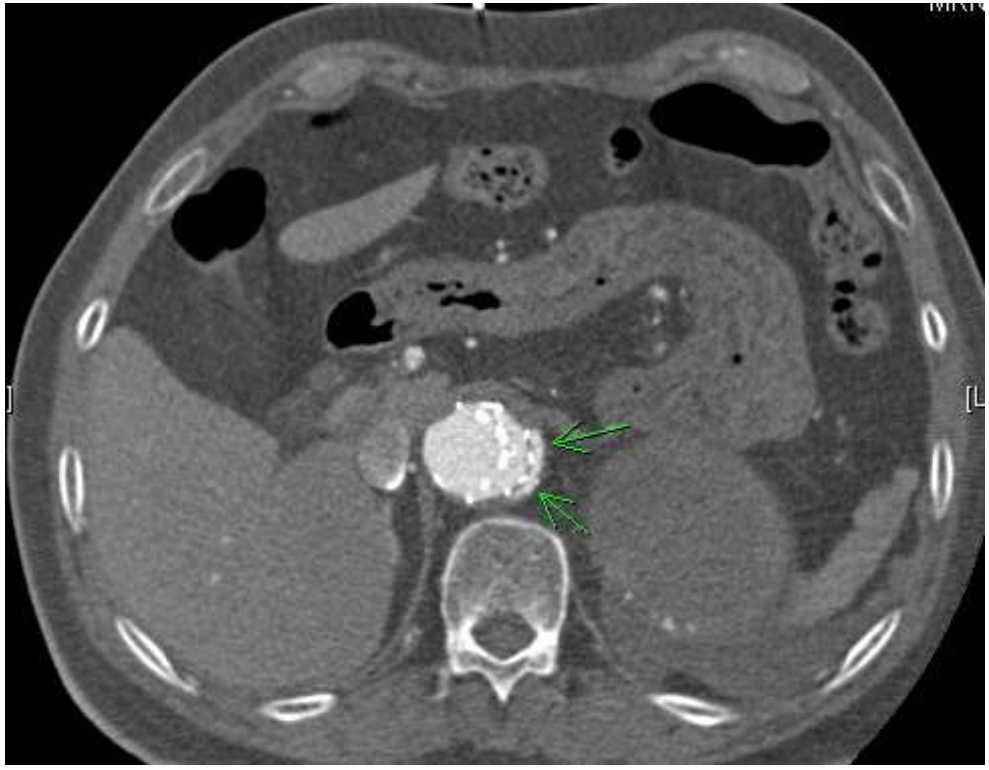
Valiant 40-40-212
x 2





Aneurysm Sac Enlargement during FU





Take Home Messages

To prevent SINE after TEVAR:

- Use a flexible SG
- Longer SG coverage
- Avoid oversizing distal SG by using
  - properly tapered SGs
  - a restrictive BMS
  - bottom up technique
- Avoid distal landing zone at a curvature