

Early Outcomes of the Conformable Stent Graft for Acute Complicated and Uncomplicated Type B Aortic Dissection from China

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Disclosure

Speaker name: Weiguo FU

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- I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest



Background

➤ VIRTUE study

– For *complicated ATBAD*: Earlier TEVAR allows better remodeling of aorta

– For *uncomplicated ATBAD*: currently medical treatment is recommended; Late intervention: >25% *u-ATBAD* due to delayed aortic-related complications

The VIRTUE Registry. *Eur J Vasc Endovasc Surg.* 2014;48:363–71



CHALLENGE & OPPOTUNITY

It is important to explore whether *u-ATBAD* can be managed by TEVAR in the early stage.



Study Design: Prospective and Single-Arm study

➤ Aim: evaluate

- initial performance
- short-term clinical outcomes of CTAG
- assessment of the conformability of the CTAG device

➤ Primary endpoints:

- early mortality
- conversion to open surgery
- complications related to CTAG



Patient eligibility

➤ Included criteria:

- complicated or uncomplicated ATBAD
- complicated: TEVAR within 48 hours
- uncomplicated: TEVAR within 7 days

➤ Excluded criteria:

- subacute and chronic aortic dissection
- pregnant women
- patients with tortuous or stenotic iliac or femoral arteries
- patients allergic to the contrast



Primary Outcomes:

- 2016.2–2017.2: 5 complicated and 47 uncomplicated were treated
- Mean follow-up was 8.2 ± 3.5 months (range, 4–12 months)
- 5 Complicated: 1 SMA ischemia; 2 LRA ischemia; 2 RIA ischemia
- *No difference of baseline between complicated an uncomplicated*

Variables	No.(%)		p
	Complicated(5)	Uncomplicated(47)	
Median age, years	53	61	0.592
Male sex	4	43	0.271
ASA 3 or 4	5	35	0.182
Hypertension	4	27	0.347
Coronary artery disease	0	2	0.282
Previous myocardial revascularization	0	0	NA
Previous stroke	0	2	0.282
Renal insufficiency	0	1	0.465
Smoke	1	7	0.871
COPD	0	1	0.465
Diabetes	0	1	0.465



TEVAR Procedure and conformability measurement

- **Standard procedure of TEVAR**
- ***Oversizing Rate:***
 - — **Complicated: 10%**
 - — **Uncomplicated: 20%**
- ***(Past: 0~10%)***
- **Chimney or periscope technique:**
 - — **landing zone was less than 20mm**



Primary Outcomes:

- *TEVAR time (Door to table):*
 - — Complicated: **0.5 d**
 - — Uncomplicated: **6 d**

- *SG length*
 - — 150 mm **9.6%** (5/52)
 - — 200 mm **90.4 %** (47/52)



Primary Outcomes:

- **Total 11 chimney/periscope (Uncomplicated)**
- **10 double-chimney (LCA and LSA)**
- **1 double-chimney (innominate artery, left carotid artery) plus 1 single periscope LSA**
- **All chimney/periscope grafts: Viabahn**
- **No auxiliary stenting in visceral or lower extremity**



Primary Outcomes:

➤ *Major Complications:*

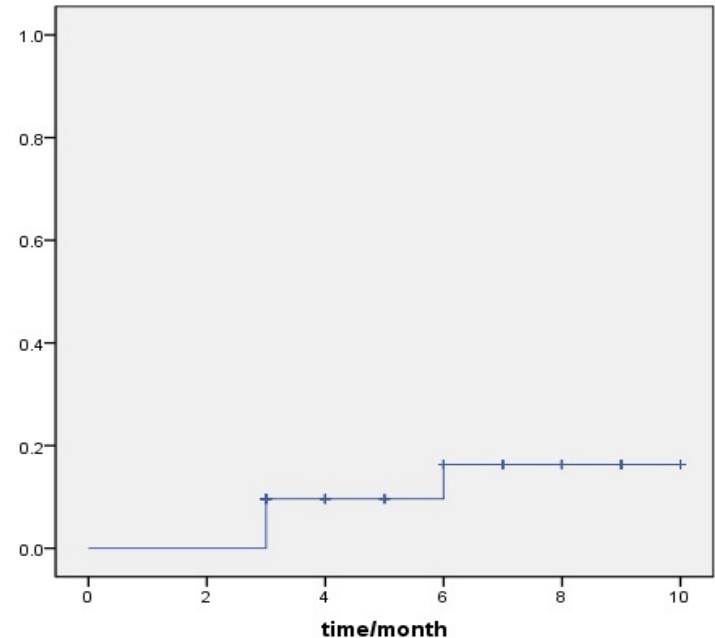
- 30d hospital mortality: 0 %
- Bird-beak: (7/52) 13.5 %
- Ia endoleak: 0 %
- RTAD: 0 %

➤ *Minor Complications:*

- minor wound hematomas 3.8% (2/52)

➤ *Bird-beak configuration*

- 5 cases in 3mths;
2 in 6mths



	0m	3m	6m	12m
Bird-Beak cases	0	5	2	0
Total numbers	0	5	7	7



Bird-beak configuration

- *Max bird-beak angel*: 29.74; *Min bird-beak angel*: 6.12
- *Possible related factors to bird-beak*: ① *arch type*, ② *PLZ* and ③ *chimney/periscope* et al.
- *Chimney/Periscope*: associated with BB ($P < 0.05$)

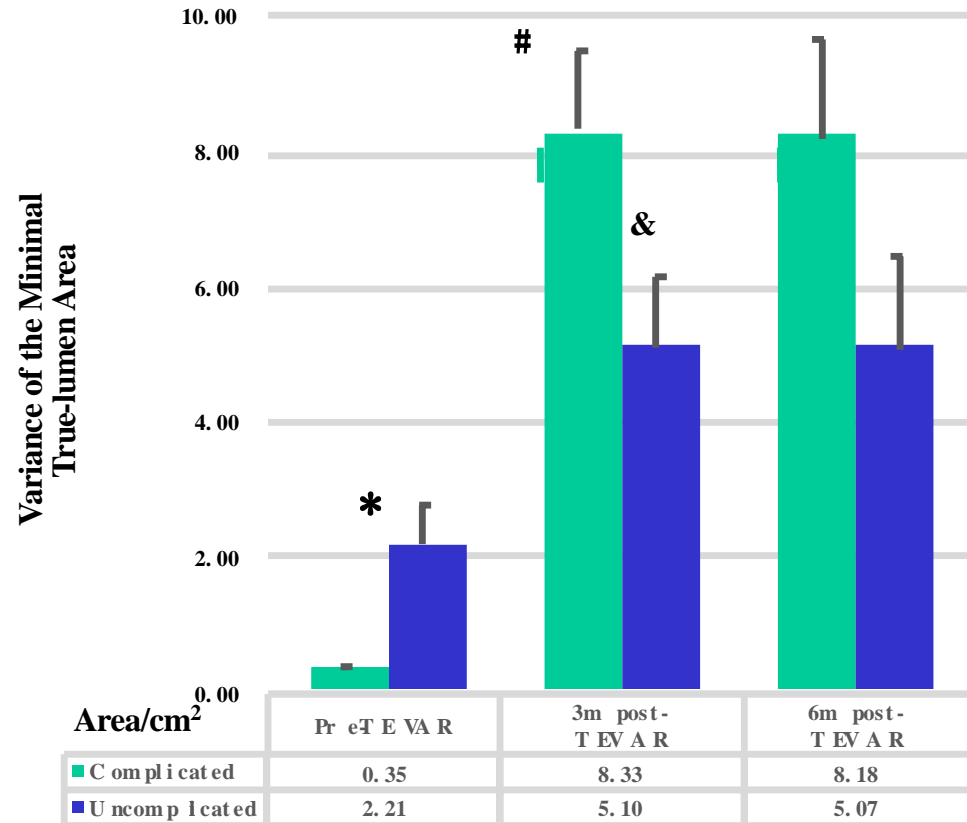
Patient No.	Arch type	PLZ	DS (mm)	HBB (mm)	LBB (mm)	BBA (°)	RSV	Univariate		Multivariate		
								OR(95%CI)	p	OR(95%CI)	p	
03	3	2	37	2	12	9.46	N					
12	1	0	37	3	12	14.04	Y	Chimney/Periscope	0.051(2.551-103.494)	0.000	29.950(1.194-751.403)	0.039
15	3	2	37	3	7	23.2	Y					
16	1	2	40	3	28	6.12	Y	Arch type II	0.066(0.005-0.864)	0.038	0.228(0.011-4.844)	0.343
22	3	2	37	3	6	26.57	Y					
26	2	2	34 37	4	7	29.74	N	PLZ 2	0.357(0.051-2.500)	0.300	2.990(0.087-103.124)	0.544
039	3	0	45	4	18	12.53	Y					

PLZ: proximal landing zone, DS: device size (mm), HBB: heighth of bird-beak
LBB: length of bird-beak, BBA: bird-beak angle, RSV: revascularization



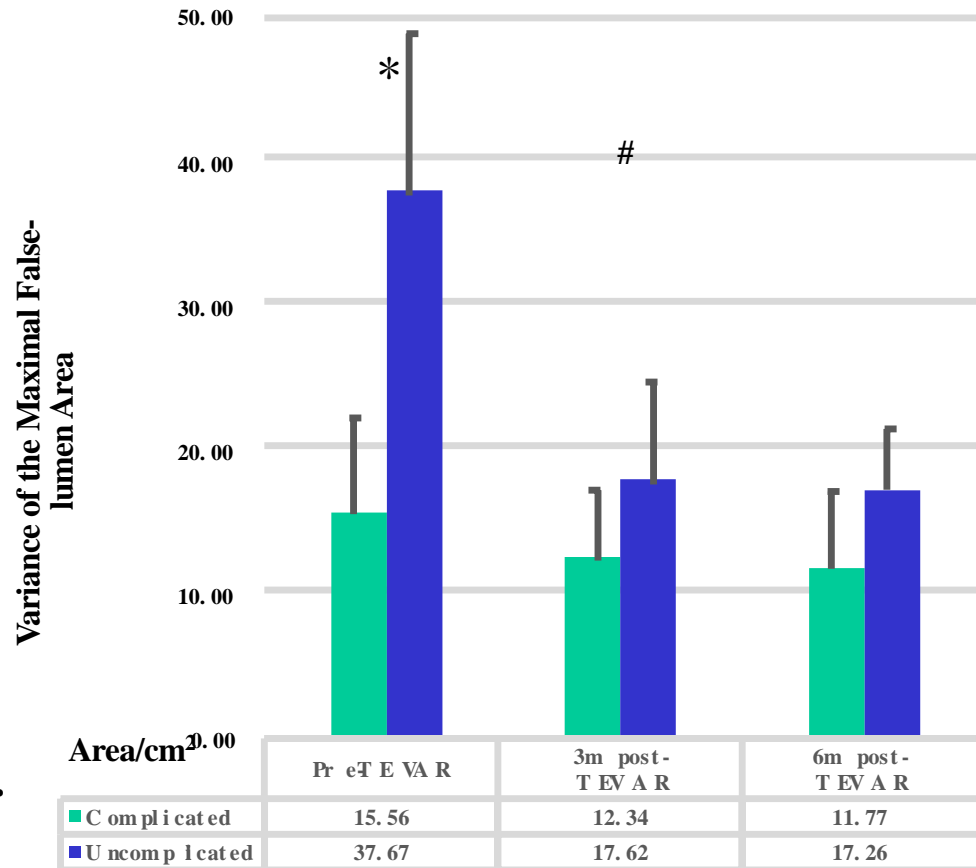
Aortic morphology

- Minimal true lumen area in the complicated group was significantly smaller than that in the uncomplicated group before TEVAR, and no difference after TEVAR.
- True lumen increased significantly in both groups after TEVAR, with no differences between 3-month and 6-month follow-up.



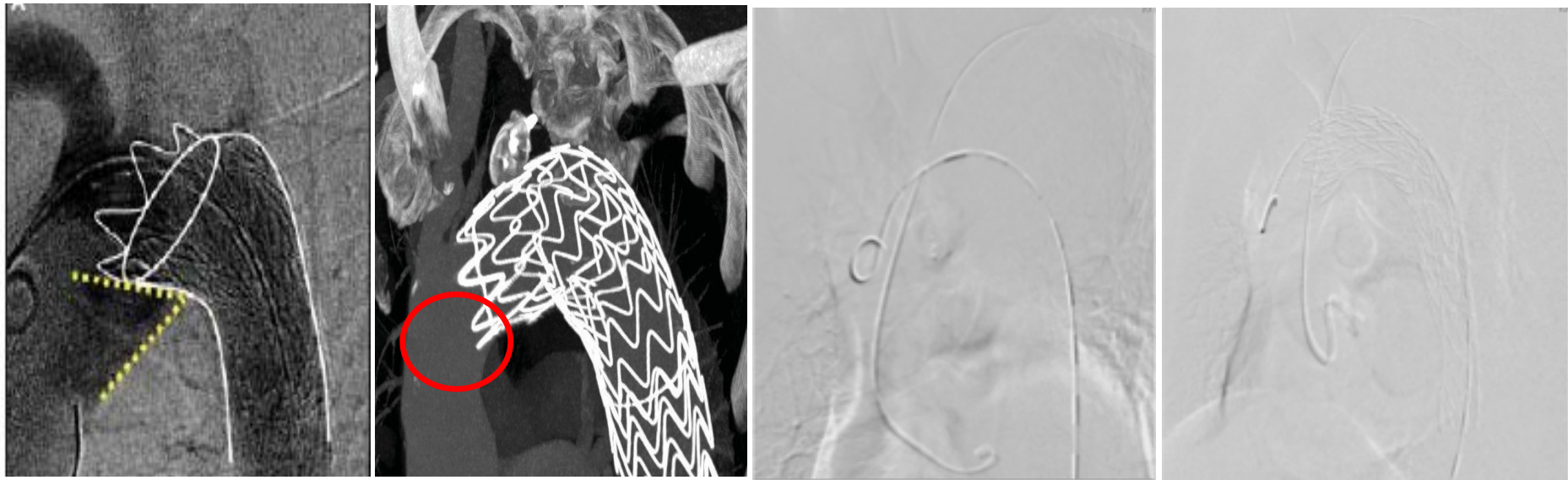
Aortic morphology

- Maximal false lumen in the complicated group was significantly smaller than that in the uncomplicated group before TEVAR, and no difference after TEVAR.
- False lumen remarkably decreased in uncomplicated dissection, but no significant change was detected in complicated dissection.
- **Partial false lumen thrombosis was observed in the device sections** while the persistent blood flow was still visible distal to the non-device section.



Typical cases:

Hostile arch: CTAG could conform to the vessel configuration to avoid bird-beak and then to prevent type I endoleak. Thus it is appropriate to hostile arch or lesions in lesser curvature of arch.



Typical cases:

- **Small true lumen**
- **Huge false lumen**
- **Oversizing rate (20%)**

Our findings also suggest that besides CTAG device can excellently conform to the steep aortic arch and decrease the risk of type I endoleak, the increased oversizing rate could benefit aortic remodeling by expanding the flattened true lumen.



Conclusions

Early outcomes indicate that the cTAG provides reliable clinical effectiveness

- Low spring back force
- Excellent conformability
- 10%~20% oversizing

**Safe
feasibility**
➔

*Complicated &
Uncomplicated
ATBAD*

Limitation:

Studies with larger sample sizes and longer follow-up periods are required to evaluate longer term outcomes





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THANK YOU!



→ English