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*

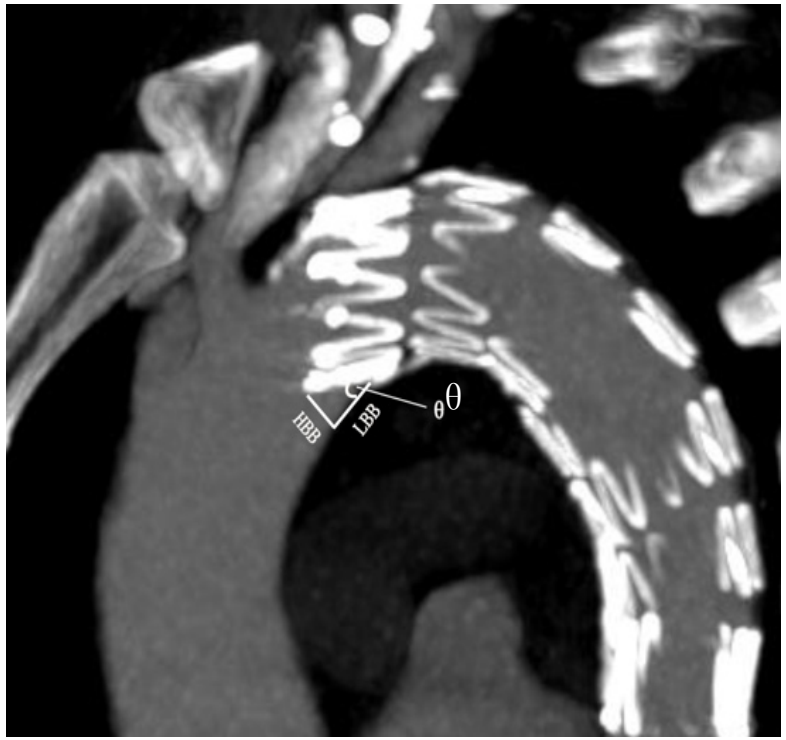
Variables	No.(%)		*p*
	Complicated(5)	Uncomplicated(47)	
Median age, years	53	61	0.592
Male sex	4	43	0.271
ASA 3 or 4	5	35	0.182
Hypertension	4	27	0.347
Coronary artery disease	0	2	0.282
Previous myocardial revascularization	0	0	NA
Previous stroke	0	2	0.282
Renal insufficiency	0	1	0.465
Smoke	1	7	0.871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

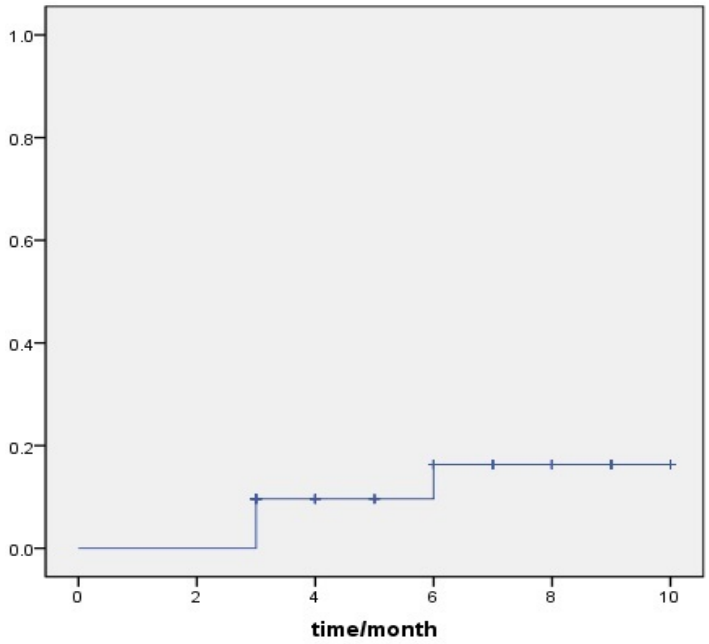
Primary Outcomes:

- **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)*

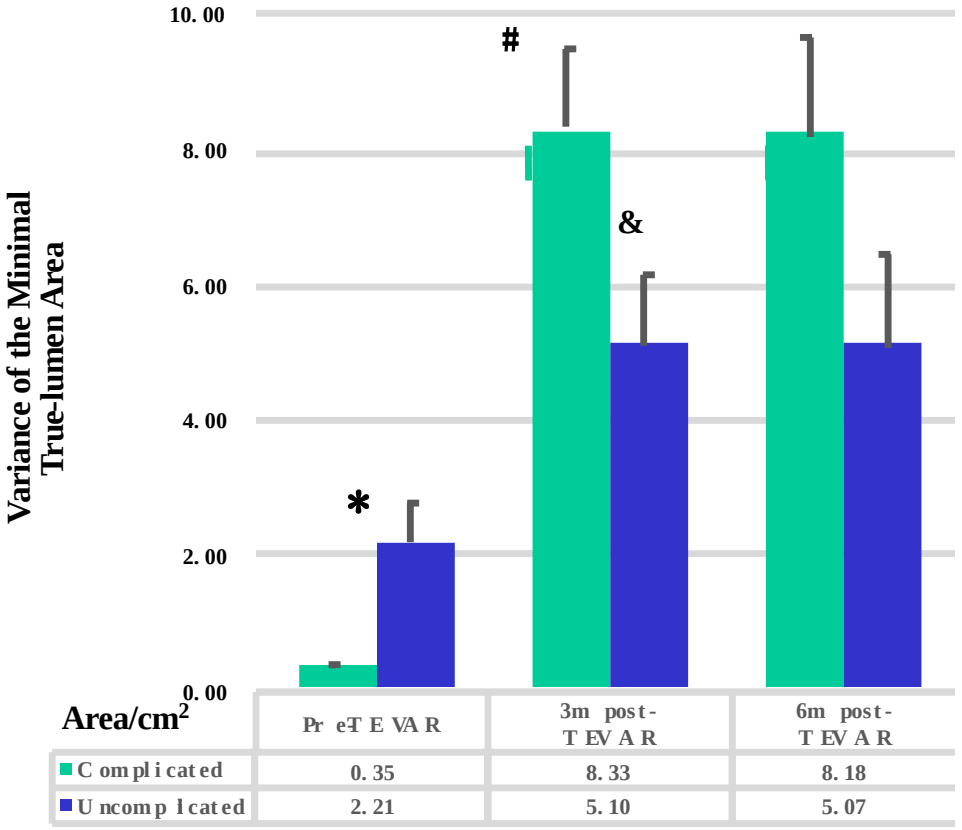
Patient No.	Arch type	PLZ	DS (mm)	HBB (mm)	LBB (mm)	BBA (°)	RSV
03	3	2	37	2	12	9.46	N
12	1	0	37	3	12	14.04	Y
15	3	2	37	3	7	23.2	Y
16	1	2	40	3	28	6.12	Y
22	3	2	37	3	6	26.57	Y
26	2	2	34 37	4	7	29.74	N
039	3	0	45	4	18	12.53	Y

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

	Univariate		Multivariate	
	OR(95%CI)	*p*	OR(95%CI)	*p*
Chimney/ Periscope	0.051(2.551-103.494)	0.000	29.950(1.194-751.403)	0.039
Arch type II	0.066(0.005-0.864)	0.038	0.228(0.011-4.844)	0.343
PLZ 2	0.357(0.051-2.500)	0.300	2.990(0.087-103.124)	0.544

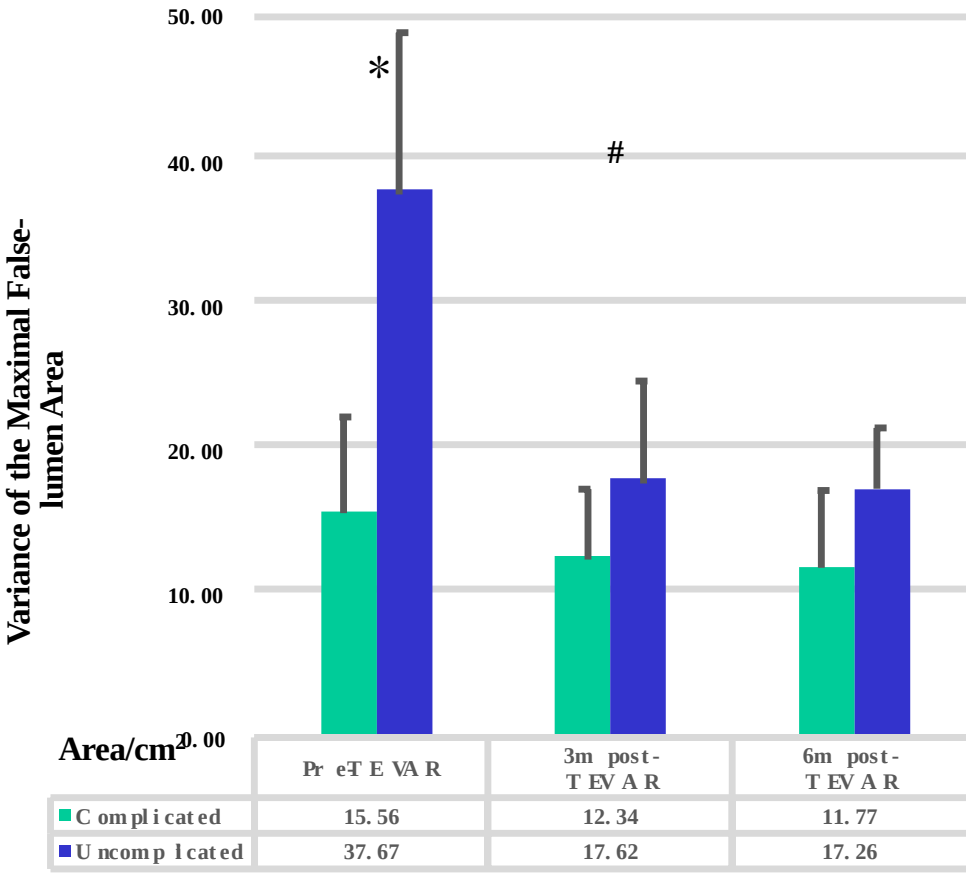
Aortic morphology

- **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.**



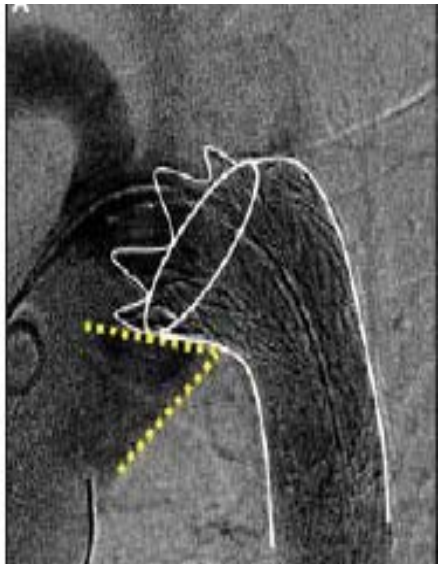
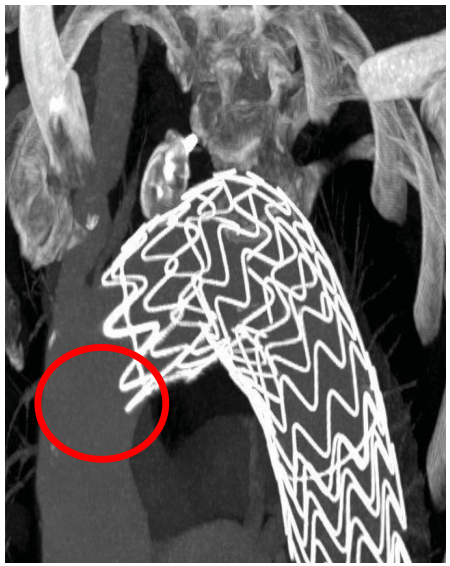
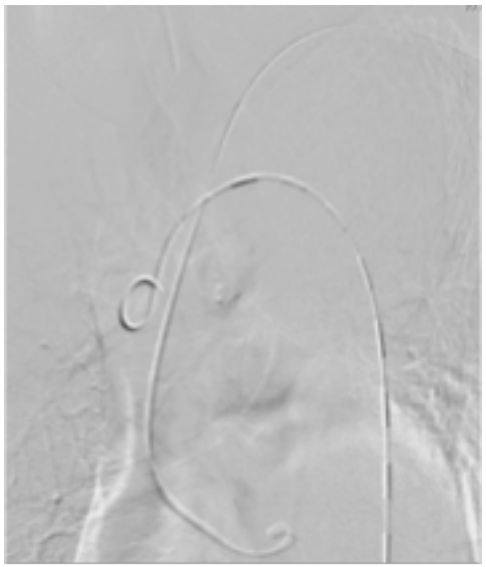
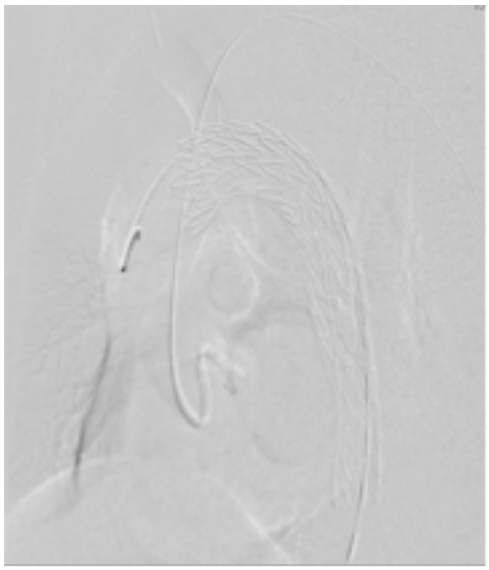
Aortic morphology

- 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:

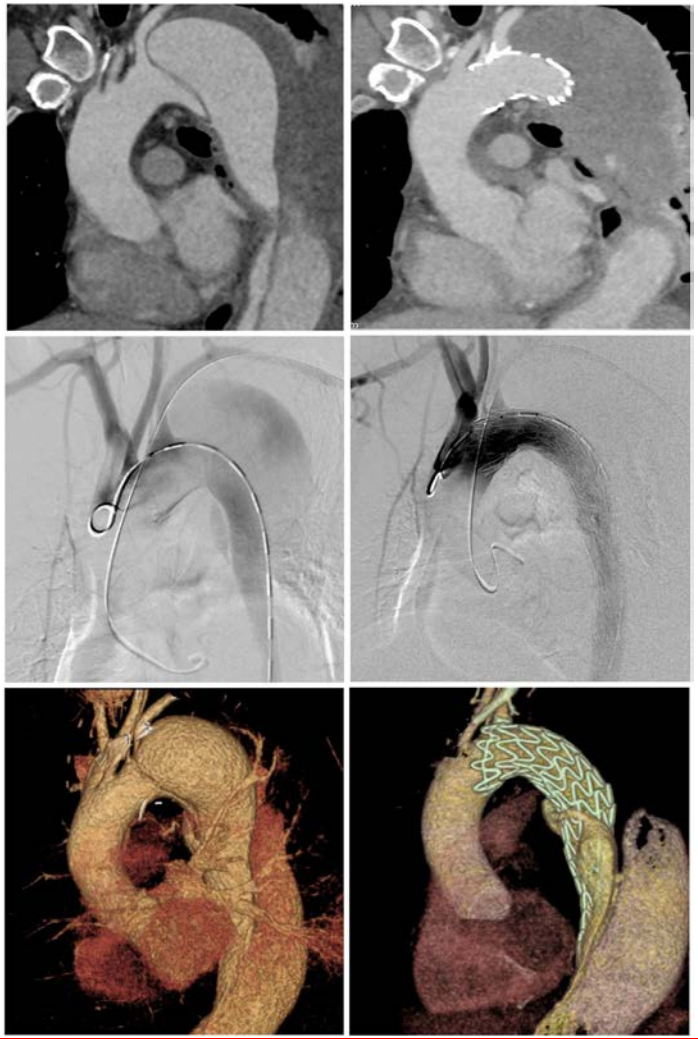
Hostile arch: CTAG could conform to the vessel configuration to avoid bird-beak and then to prevent type I endoleak. Thus it is appropriate to hostile arch or lesions in lesser curvature of arch.

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