

Figure 1. The implant is constructed of a nitinol frame and an implant occlusion membrane consisting of a laminated ePTFE. Small anchors along the frame and passing through the occlusive membrane assist with device anchoring.



Left Atria Appendage Closure/Occlusion

Early-bird experience and Worst Cases

From Shanghai Tenth People's Hospital

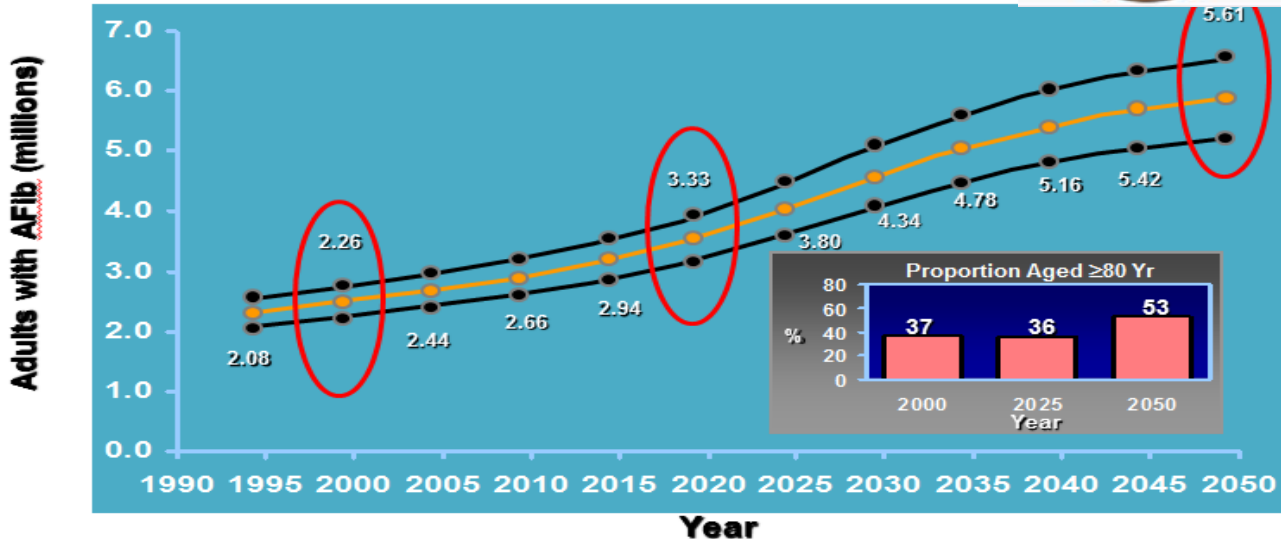
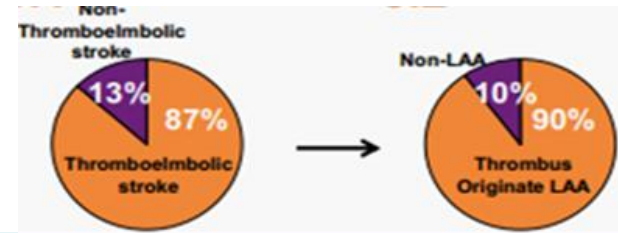
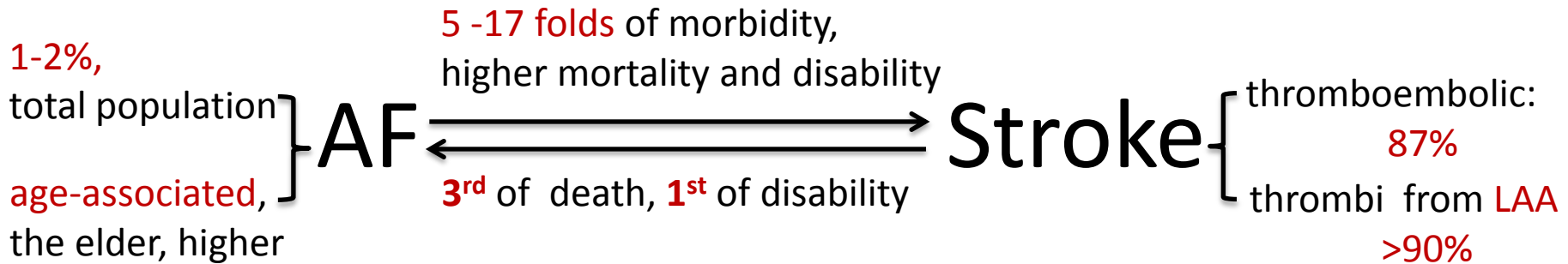
Yawei Xu, Wei Chen, Kai Tang, Weiming Li, Mengyun Zhu, Dachun Xu, **Shuang Li**



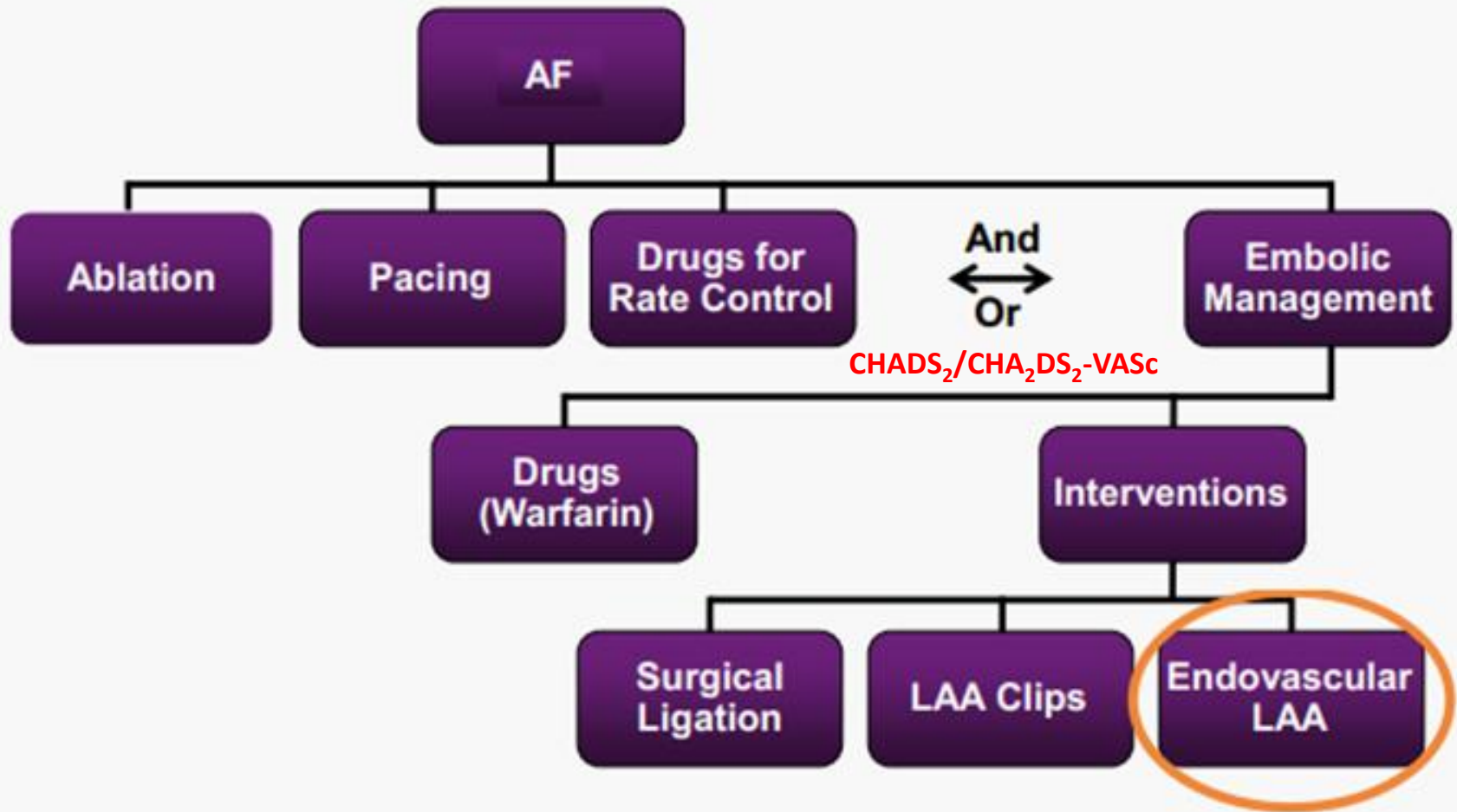
上海市第十人民医院
 同济大学附属第十人民医院
 SHANGHAI TENTH PEOPLE'S HOSPITAL
 TENTH PEOPLE'S HOSPITAL OF TONGJI UNIVERSITY



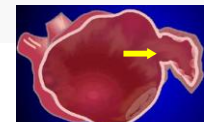
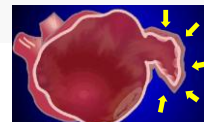
Stop the stroke where it starts !



Clinical strategies for AF



LAA: left atrium appendage
AF: atrial fibrillation



Left Atrial Appendage, “Devil” of Stroke

- Formed in the 3th of pregnancy, Functioned as the LAA in the fetal period
 - Size: thumb
 - Oriface diameter: 10 - 40mm

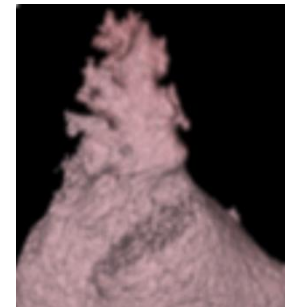
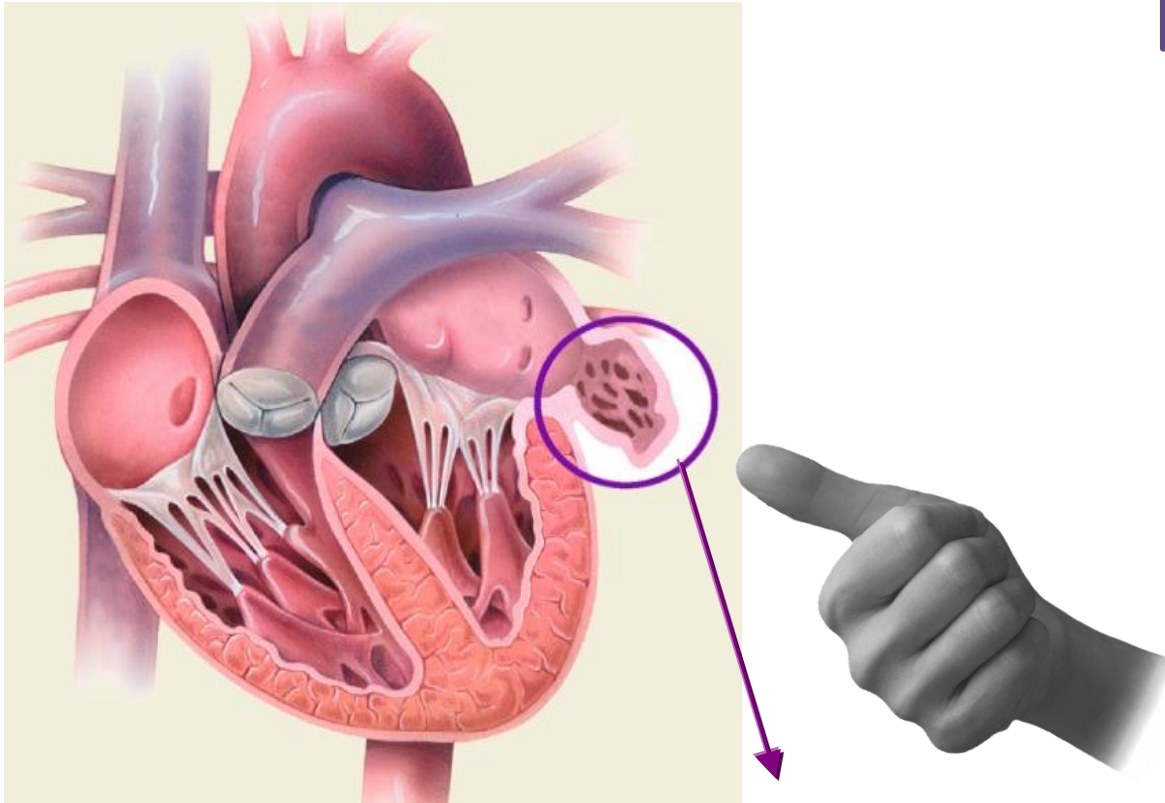
Thromboembolic Stroke **87%**:

Non-valvular AF

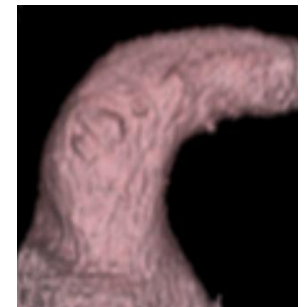
>90% thrombi from LAA

Valvular AF

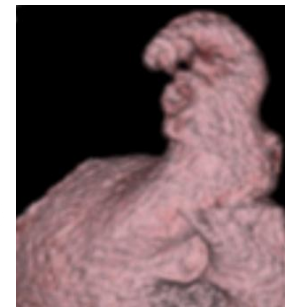
>60% thrombi from LAA



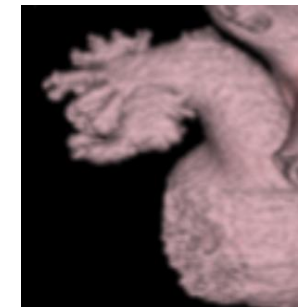
Cactus (30%)



Chicken wing (30%)



windsock (19%)



cauliflower (3%)

➔ Percutaneous closure of the left atrial appendage versus

Circulation



CLINICAL RESEARCH
Arrhythmia/electrophysiology



European Heart Journal (2012) **33**, 2700–2708
doi:10.1093/eurheartj/ehs292

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<http://dx.doi.org/10.1016/j.jacc.2013.02.089>

Lancet 2009; 374: 534

**Percuta
Atrial I
Append
Vivek Y.**

**Percut
for str
fibrilla**

**Sandeep R.
and Vivek Y**

CLINICAL RESEARCH

Mini-Focus: Left Atrial Closure in Atrial Fibrillation

**Percut
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Contra**

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<http://dx.doi.org/10.1016/j.jacc.2013.01.061>

Heart Rhythm Disorders

**Quality of Life Assessment in the Randomized PROTECT AF
(Percutaneous Closure of the Left Atrial Appendage
Versus Warfarin Therapy for Prevention of Stroke
in Patients With Atrial Fibrillation) Trial of Patients
at Risk for Stroke With Nonvalvular Atrial Fibrillation**

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"

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22 studies found for: Left Atrial Appendage Occlusion

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20 studies found for: Left Atrial Appendage closure

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Guideline for LAAC-IIb level



European Heart Journal
doi:10.1093/eurheartj/ehs253

ESC GUIDELINES

2012 focused update of the ESC Guidelines for the management of atrial fibrillation

An update of the 2010 ESC Guidelines for the management of atrial fibrillation

Developed with the special contribution of the European Heart Rhythm Association

Authors/Task Force Members: A. John Camm (Chairperson) (UK)*, Gregory Y.H. Lip (UK), Raffaele De Caterina (Italy), Irene Savelieva (UK), Dan Atar (Norway), Stefan H. Hohnloser (Germany), Gerhard Hindricks (Germany), Paulus Kirchhof (UK)

Recommendations for LAA closure/occlusion/excision

Recommendations	Class	Level
Interventional, percutaneous LAA closure may be considered in patients with a high stroke risk and contraindications for long-term oral anticoagulation.	IIb	B

Single-center data

- **LAmbre (Lifetech)**

NCT02029014, Phase 3, Multi-center

154 should be recruited

Shanghai Tenth People's Hospital: **53 cases**, 2014.4-2014.8

- **WATCHMAN (Boston Scientific)**

we finished 2 case in 2014.7.2

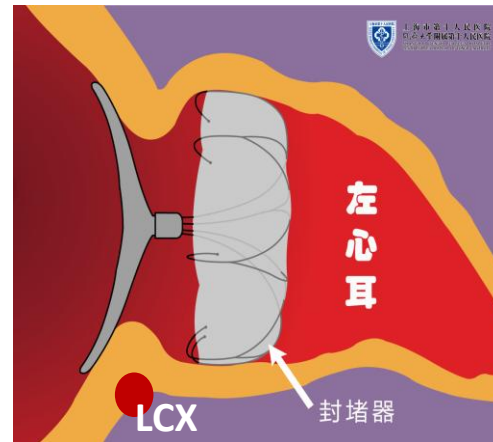
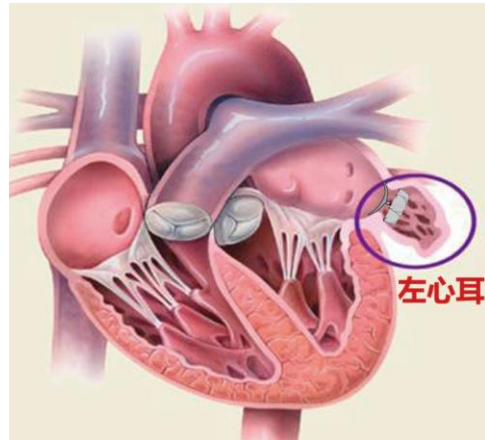
- **Lefort (LEPU Medical)**

First-in-man study, Multi-center

100 should be recruited,

we have finished the **first case** in this week 2014.10.8

LAmbre: LA+umbrella, LAm+umbrella



LAmbre

Implanter



Hook



Cover

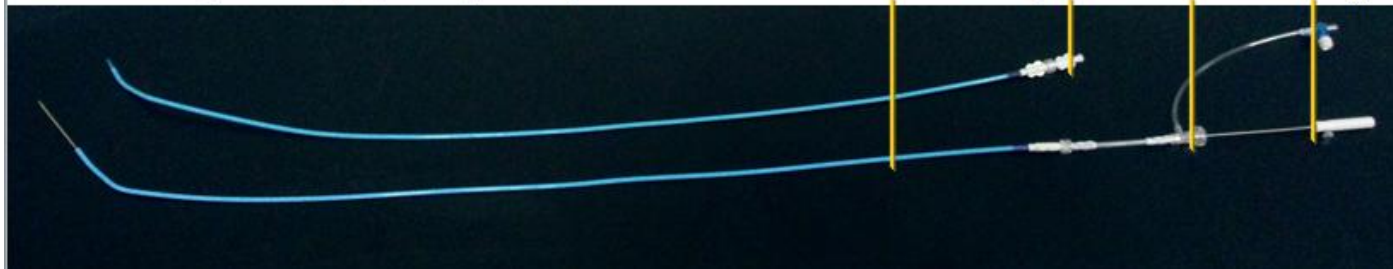


Umbrella

Delivery system (8-10 F)

Sheath

Expander Loader Guiding



Baseline characteristics of LAmbre trials

- Included 54 cases (**53 with AF**, 2014.4.14-8.18) :

Permanent AF n=35 、 Persistent AF n=11、 Paroxysmal AF n=7 , **LA atrial flutter n=1**

- Age **72.7 ± 9.14** (52-86) , ≥ 75 **n=25** , ≥ 65 **n=44**

- Male n=28, Female n=26

- CHADS₂: **2.9 ± 1.14** , CHA₂DS₂-VASC: **4.2 ± 1.39** , HAS-BLED : **3.3 ± 1.01**

CHF n=4, HTN n=44, DM n=7 , Previous Stroke/TIA **n=40**

- INR 1.3 ± 0.67 , **INR (2-3) n=6**

- Pre-procedural TTE:

LVEF **$62 \pm 8.2\%$** , no severe valvular regurgitation

- Pre-procedural TEE:

LA Φ **48.8 ± 6.63 mm**,

LAA lobes **2.1 ± 0.7** , ostium Φ : **20.2 ± 3.55 mm**

Summary of the Procedure

- **Post-operative evaluation: TEE** peri-device flow jet ≤ 3 mm
no leak **n=47**, slight (<1 mm) n=4, mild(≤ 3 mm) n=2, **moderate (4mm) n=1**
- **LAAC performance:**
- **Release time** **2.2 ± 1.51**
One: **n=26**, Two: n=9, Three: n=8, Four: n=7, Five: n=3, **Eight: n=1**
- **Replacement** **10 devices (n=6)**
- **Cover Φ : 32.7 ± 3.63 mm, Umbrella Φ : 26.6 ± 4.03 mm**
- **Delivery Sheath: 10 F (n=43), 9 F (n=11)**
- **Total time-cost: 67.1 ± 18 min , In-out Sheath: 42.6 ± 16.61 min.**
- **Contrast(iodixanol/visipaque): 85 ± 29 ml**

Follow-up visiting (to 10/8/2014)

- The day from operation to discharge: **3.8±1.47 (2-30)**
 - Numbers of discharge: **54/54**
 - One-month follow-up: **54/54 (EKG、 TTE)**
 - Three-month follow-up: **31 (EKG、 TTE、 TEE)、 33 (EKG、 TTE) / 36 in the window**
- Primary Outcomes:
 - **Ischemic stroke (n=0)**
 - **LAA closure (53/54 98.1%, 3-month 30/31) TEE criteria peri-device flow jet ≤ 3 mm**
 - Device migration/device-associated embolization/regurgitation (n=0)
- Severe Adverse Events :
 - **All-cause re-hospitalization (12 events, n=11)**
 - Partly thrombogenesis at Puncture site (n=1)
 - Femoral A-V fistula (n=1)
 - Transfusion as bleeding from the puncture's site (4 events, n=2)
- Adverse Events :
 - **Asymptomatic increase of cardiac biomarkers (n=18)**
 - New onset of mild pericardial effusion/elevated pericardial effusion (n=7)
 - Post-procedural increase of liver enzymes (n=6)

LAmbre vs. Watchman

	LAmbre ^a	WATCHMAN ^b
Patients Numbers	54	463
Successful Implantation	54/54 (100%)	408/449 (91%)
Successful sealing		
TEE criteria: LAmbre peri-device flow jet ≤ 3 mm, WATCHMAN < 5 mm		
Post-operatively	53/54 (98.1%) 54/54 (100%)	
Follow-up	3 months 30/31 (96.8%)	45 days 349/408 (86%) 6 months 355/385 (92%)

a single-center data from shanghai tenth people's hospital

b PROTECT-AF. *Lancet* 2009; 374: 534–42

Worst Case presentation

NO.18 Unexpected air thrombi

CC:

80 yrs, female, Refractory palpitation for 1 ms and chest tightness for 5 ds

PMHx:

AF for 1 month, no Warfarin received

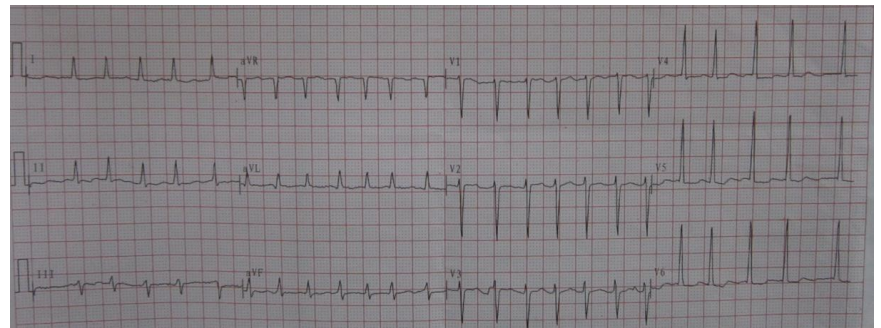
no history of HTN, stroke, DM, CHF

PE: mild edema of lower extremities

Lab: cTnT, ng/ml 0.017 (<0.014 Ref), INR 1.15

EKG: AF, ventricular rate 150 bpm, ST depression in the anterior leads

Chest X-film: larger heart



NO.18 Unexpected air thrombi

TTE

- LA Φ 38mm, LVEF=50% ,
- slight MR , moderate AR

TEE

- LA (Φ 38mm)
- **Three lobes of LAA**
 - Ostium Φ 28mm , length 27mm
- mild MR, mild AR

Diagnosis

- AF persistent

CHADS₂ : 1

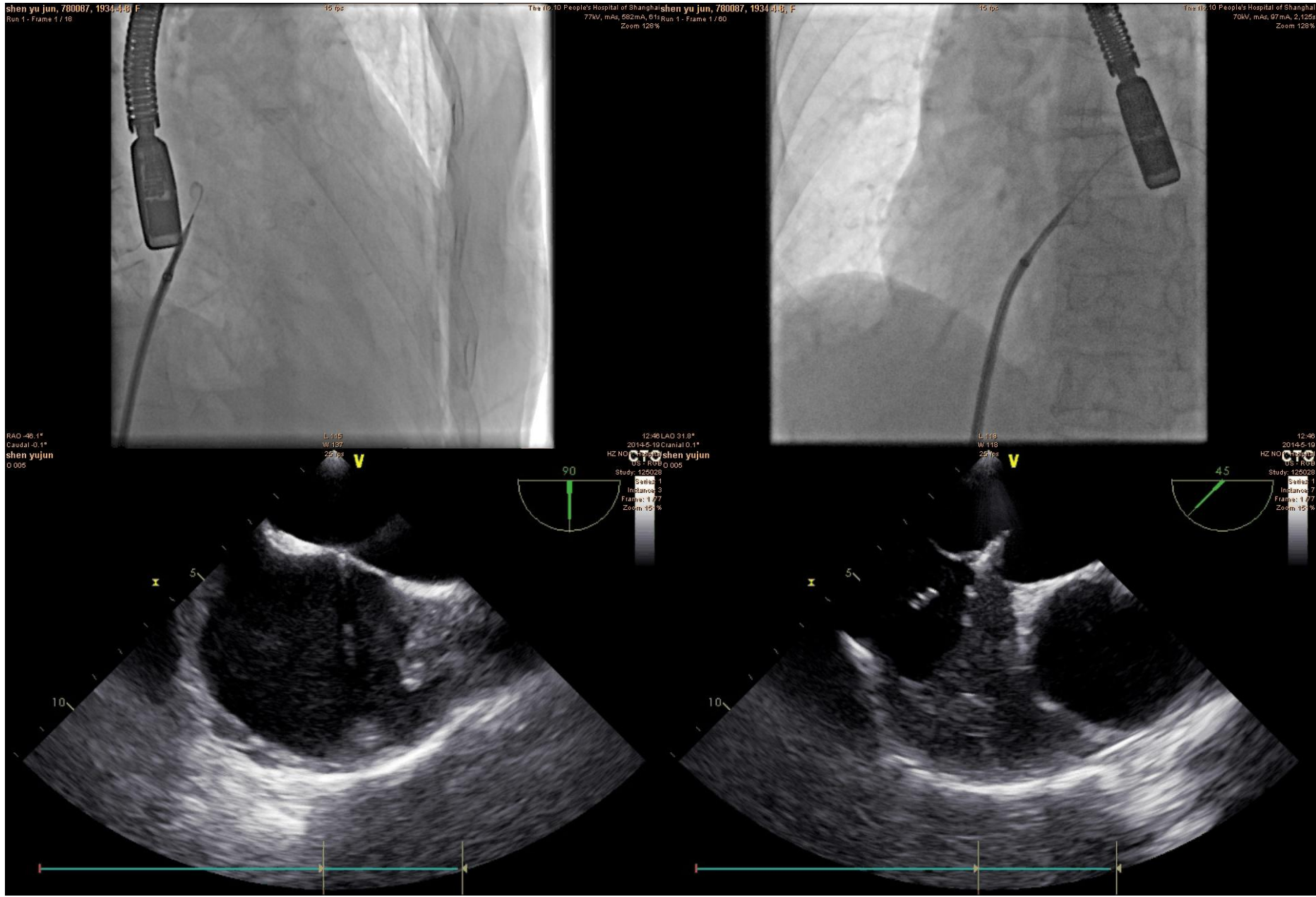
CHA₂-DS₂-VASc: 3

Therapy:

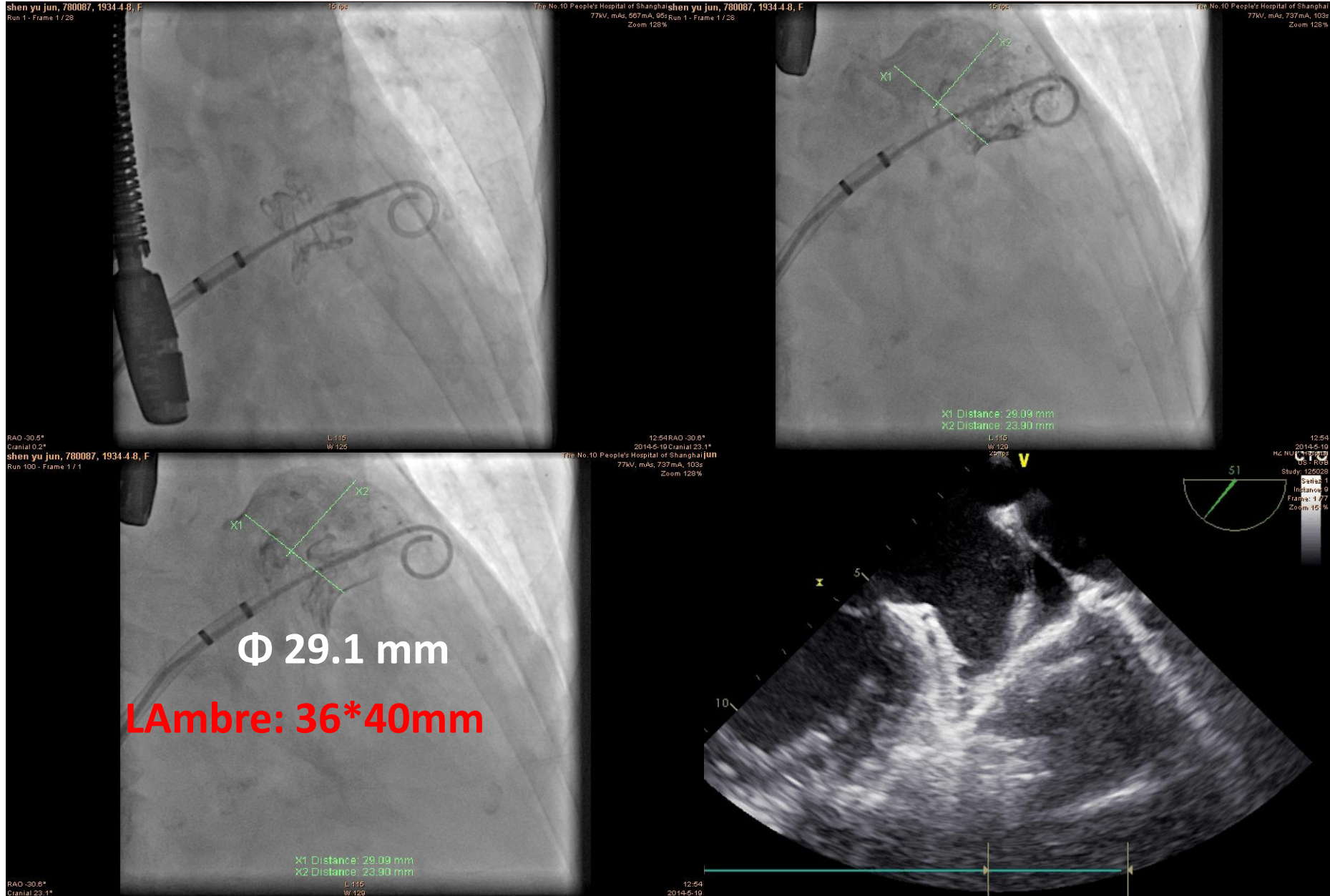
LAAC

he refused to Ablation or warfarin therapy

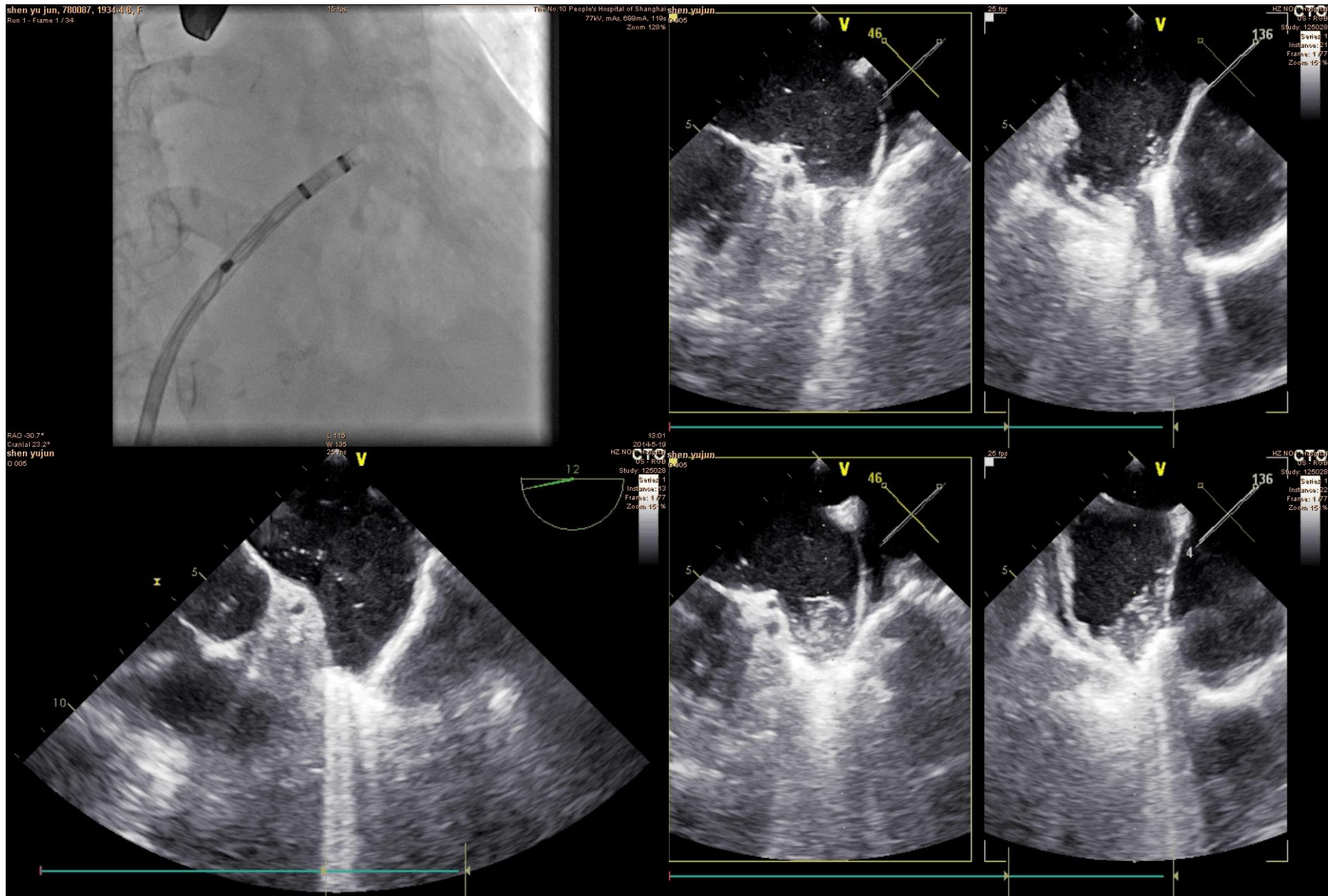
NO.18 Unexpected air thrombi



NO.18 Unexpected air thrombi



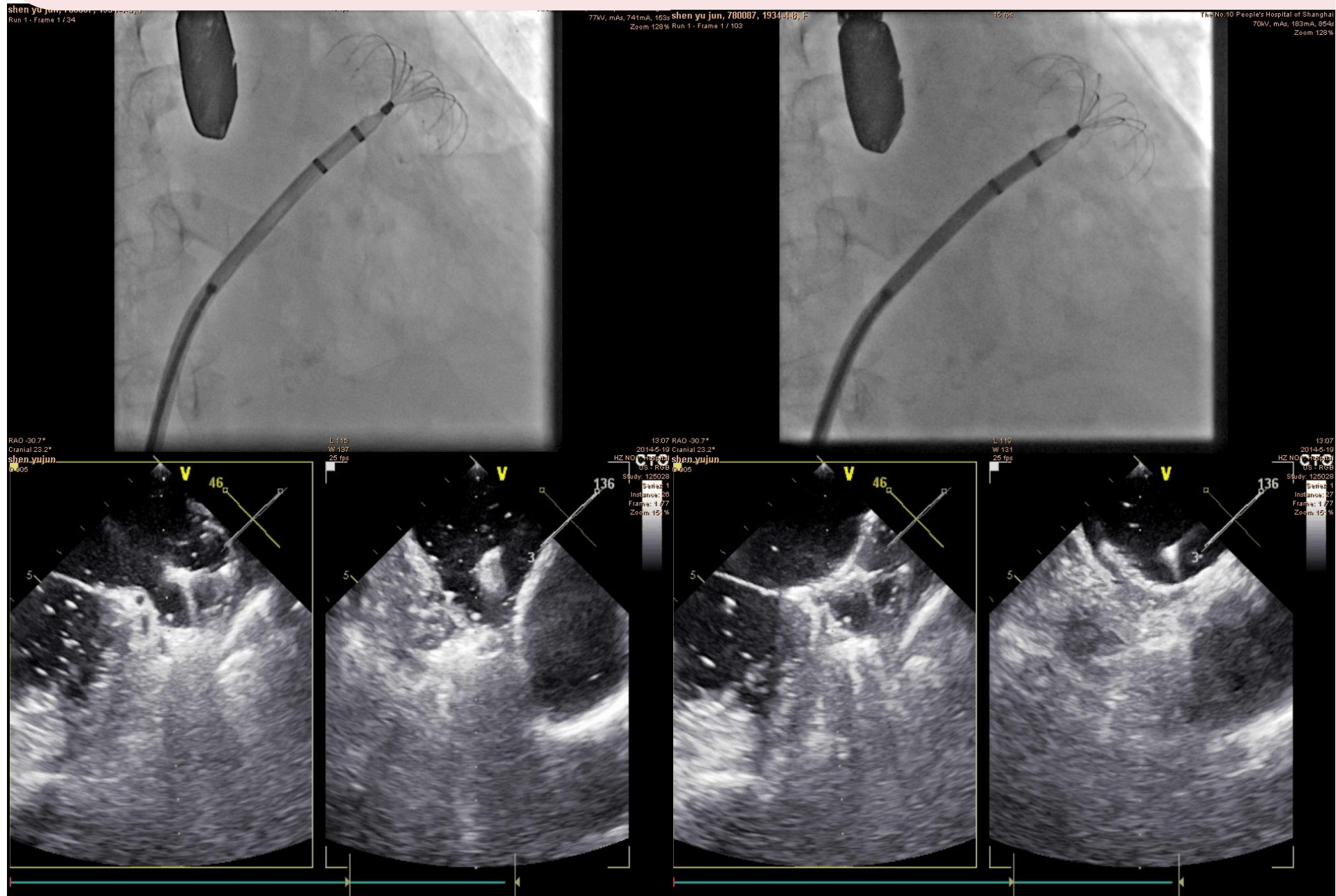
NO.18 Unexpected air thrombi



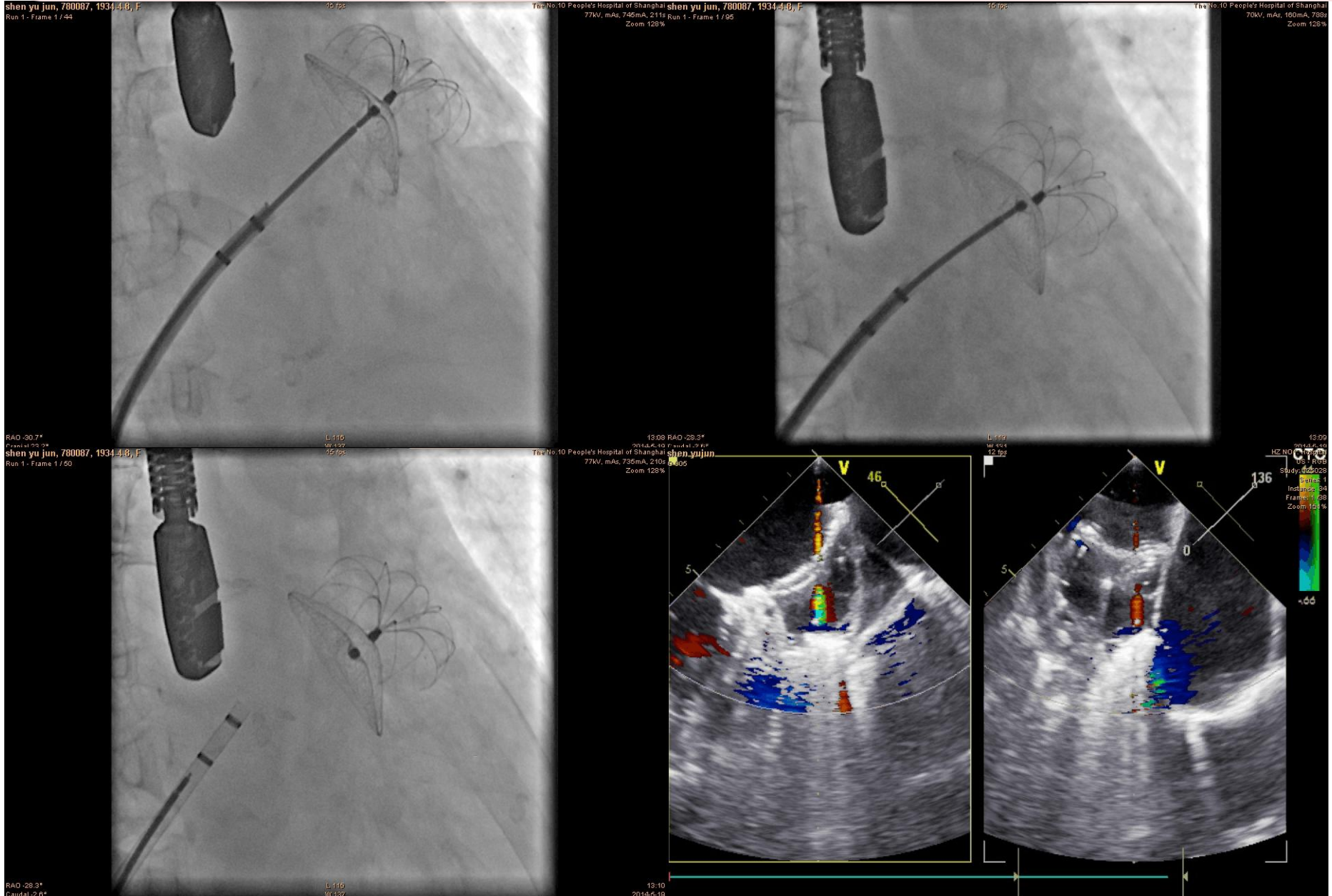
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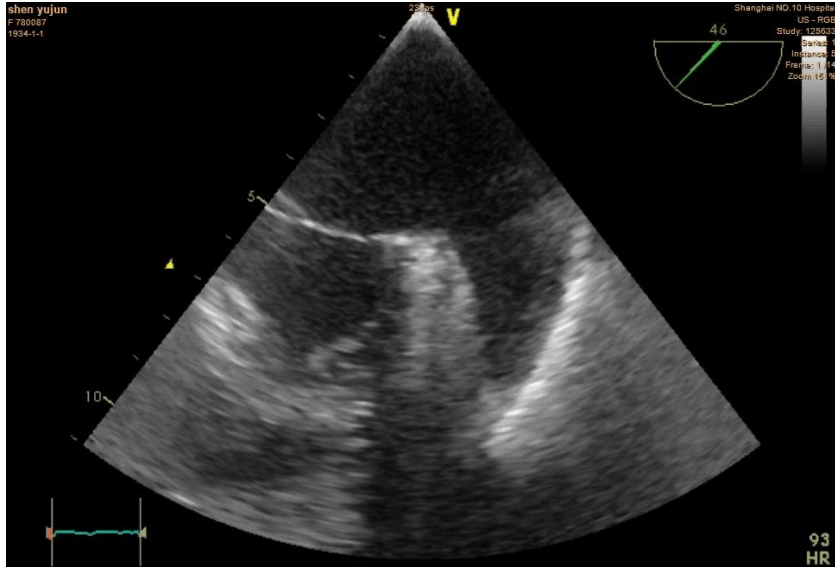
NO.18 Unexpected air thrombi



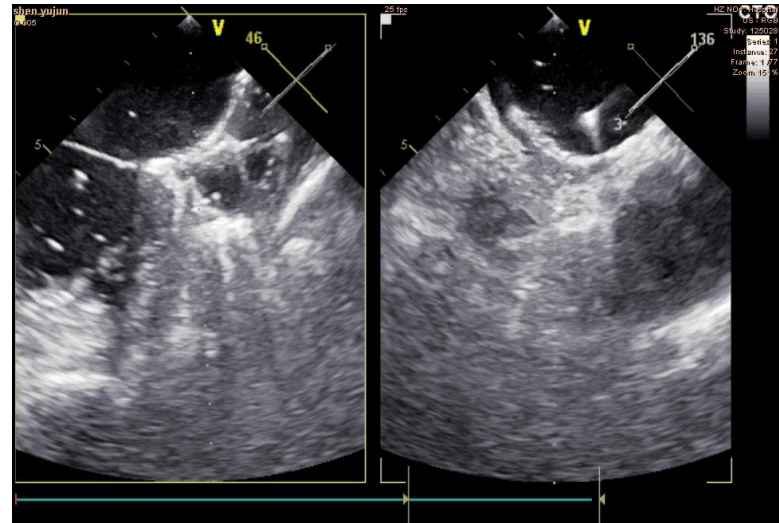
NO.18 Unexpected air thrombi



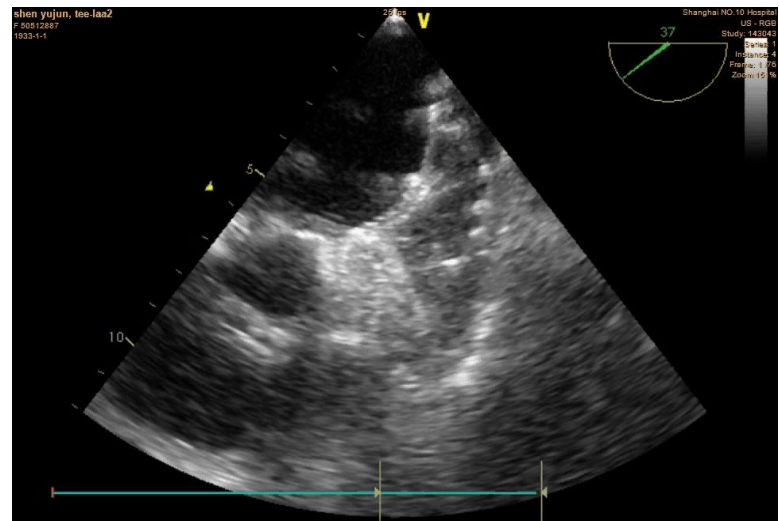
NO.18 Unexpected air thrombi



Pre-procedural TEE

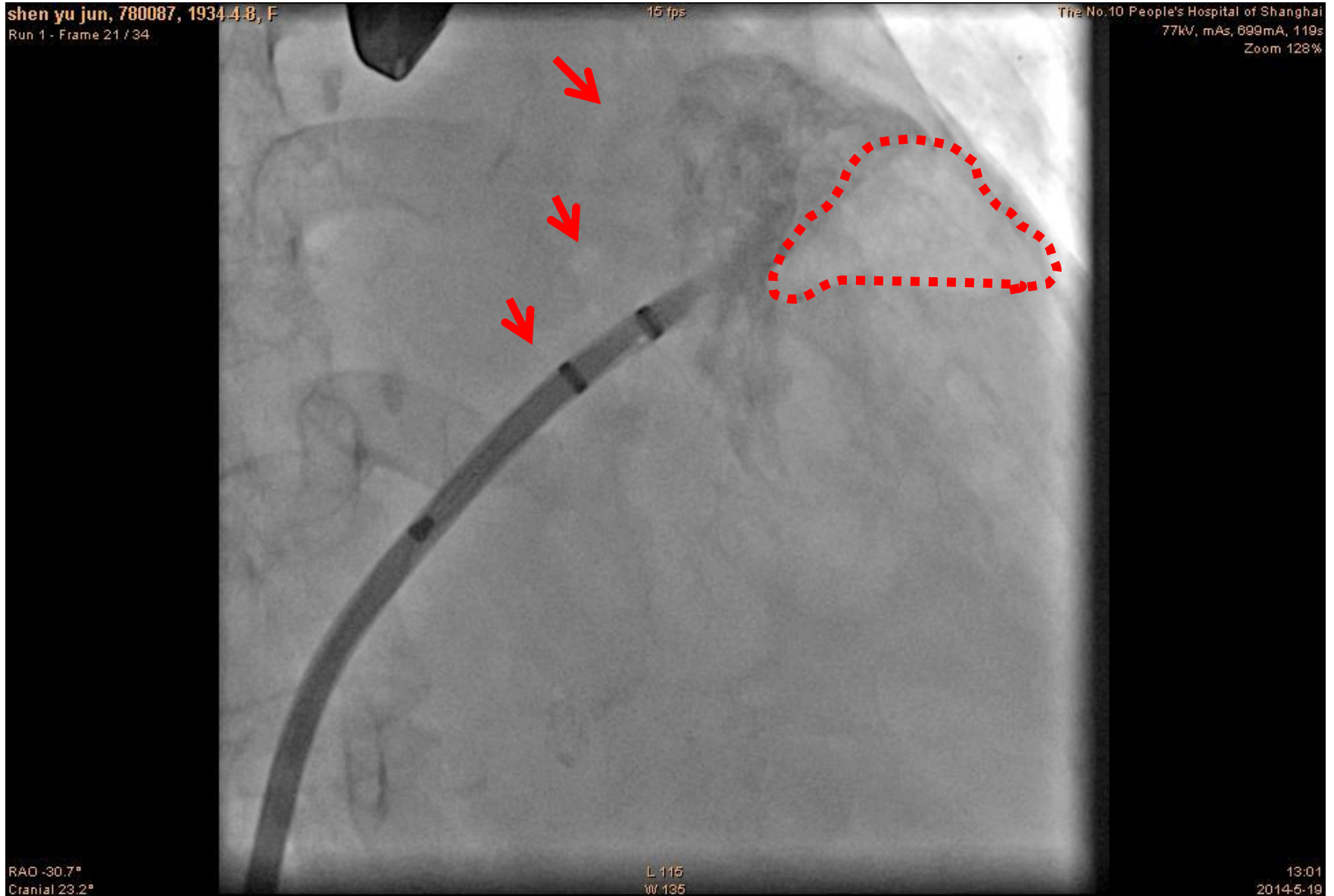


Post-procedural TEE



3-month follow-up TEE

NO.18 Unexpected air thrombi



NO.18 Unexpected air thrombi



Tips :

Saline

1,000ml per bag

Release the LAMBERT quickly

Thank you for your patience

