

2018 | euro  
**PCR**

The Effectiveness and Safety of the RESTORE<sup>®</sup> Drug-eluting Balloon  
versus a Drug-eluting Stent for Small Coronary Vessel Disease:  
Study Protocol for A Multi-center, Randomized, Controlled Trial

# — RESTORE SVD CHINA —

**Yida Tang**

**Fu Wai Hospital, Beijing, China**

Shubin Qiao, Jian Tian, Jue Chen, Yongjian Wu, Hongbing Yan, Yuejin Yang, Runlin Gao, Bo Xu



NCT02946307

**Speaker's name : Yi-da Tang, Beijing**

I do not have any potential conflict of interest

# RESTORE<sup>®</sup> DEB

THE NEW GENERATION OF PACLITAXEL COATED  
CORONARY BALLOON DILATATION CATHETER.



The Revolutionary Excipient  
Based on Ammonium Salt

Lower wash-off rate  
More effective PTX



The Nanocrystals  
0.1µm particles

Homogeneous coating  
Less microembolization

SVD



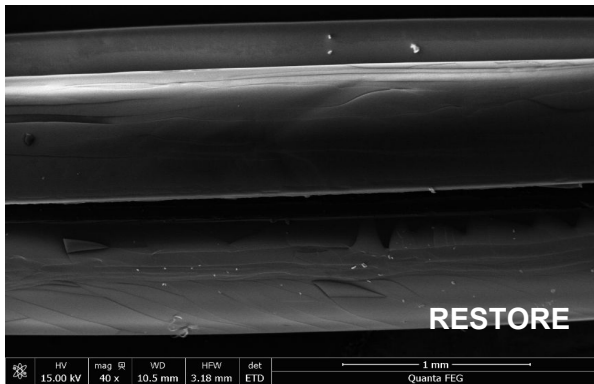
The New coating technology  
Homogenous crystal clear deposition

Elastic, Smooth, Bendable  
Excellent lesion crossing

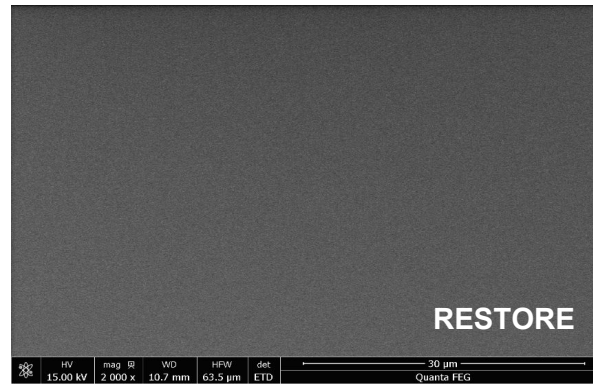
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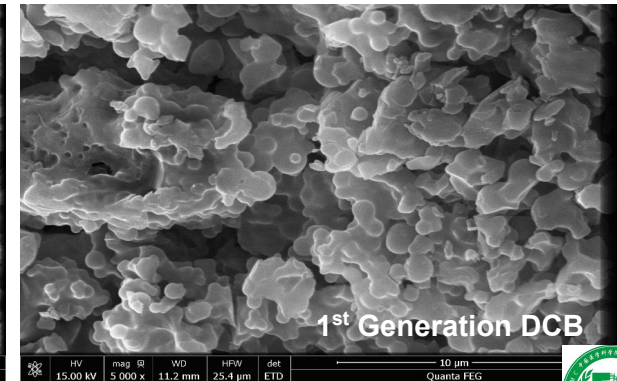
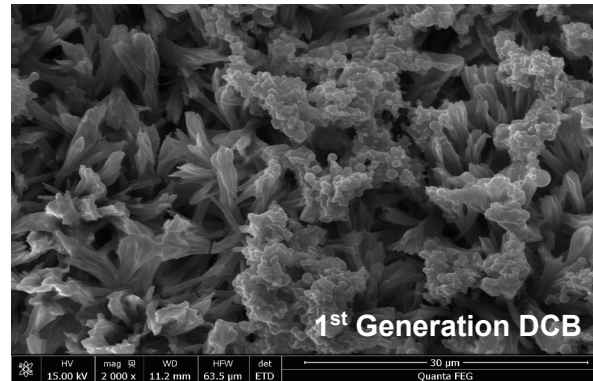
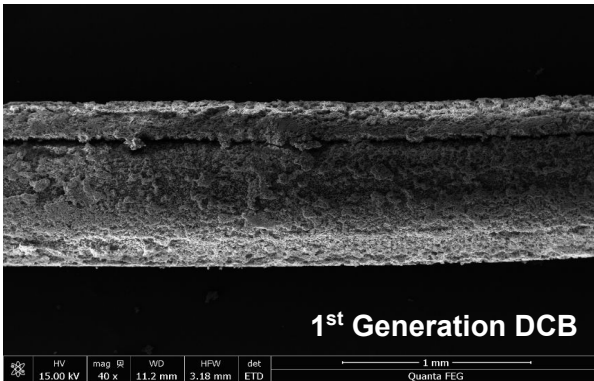
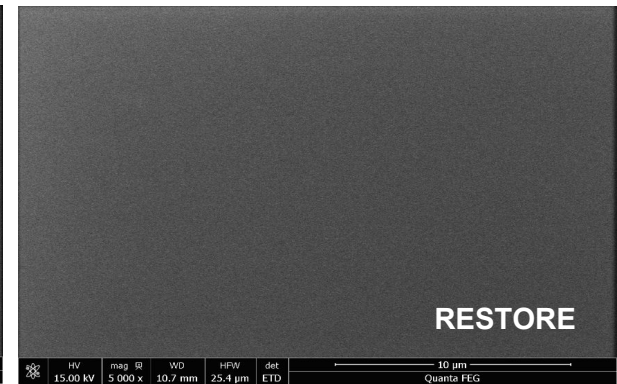
40X



2000X



5000X



## Clinical Trials of RESTORE DEB for Coronary Vessel Disease in Chinese Patients

### RESTORE SVD CHINA

- DEB only vs. Zotarolimus-eluting stent in small vessel de novo stenosis
- High-quality in 12 top hospitals
- The largest study comparing the angiographic endpoint

### RESTORE ISR CHINA

- Head to head comparing RESTORE DEB vs. SeQuet Please DEB
- Following the rules of both CFDA and ICH-GCP strictly

- Small coronary vessel disease is commonly addressed with PCI more than **30%**
- The **smaller** vessel diameter was, the **higher** incidence of restenosis occurred
- DEB have been proved to be **safe** and **effective** in ISR treatment
- The role of DEB in treating small coronary vessels when compared with that of next-generation DES needs further exploration



## Objective:

- Safety and efficacy of the RESTORE DEB in small ( $\leq 2.75$  mm) vessel and very small ( $\approx 2$  mm) vessel de novo stenosis

## Design

- Prospective, multi-center, randomized, controlled

- - Independent monitoring with 100% source data verification
- - Independent core lab for angiography and QCA
- - Clinical events committee

Hospitals	Site Investigators
<b><u>Fuwai Hospital</u></b>	<b><u>Runlin Gao, Shubin Qiao</u></b>
Chinese PLA General Hospital	Yundai Chen
Beijing Anzhen Hospital, Capital Medical University	Zening Jin
Beijing Friendship Hospital, Capital Medical University	Hui Chen
Wuhan Asia Heart Hospital	Xi Su
Daqing Oilfield General Hospital	Hui Li
Shengjing Hospital of China Medical University	Wenyue Pang
Nanjing Drum Tower Hospital	Biao Xu
Xiangya Hospital Central South University	Zaixin Yu
Tangdu Hospital	Xue Li
Tianjin 4th Centre Hospital	Yong Liu
Jiangsu Province Hospital	Xiangqing Kong





## Inclusion

- One lesion in the target small vessel with **a visual stenosis of  $\geq 70\%$  or  $\geq 50\%$  complicated by evidence of ischemia** according to visual inspection before PCI;
- Lesion length limited to  $\leq 26$  mm;
- Visual diameters of the target lesions limited **to  $\geq 2.25$  mm and  $\leq 2.75$  mm in the small vessel cohort and  $\geq 2.00$  mm and  $< 2.25$  mm in the tiny vessel cohort.**

## Exclusion

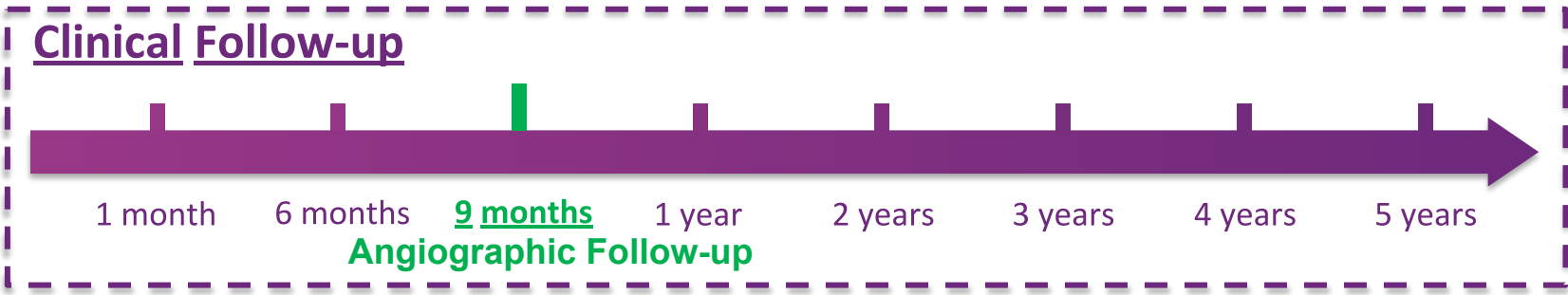
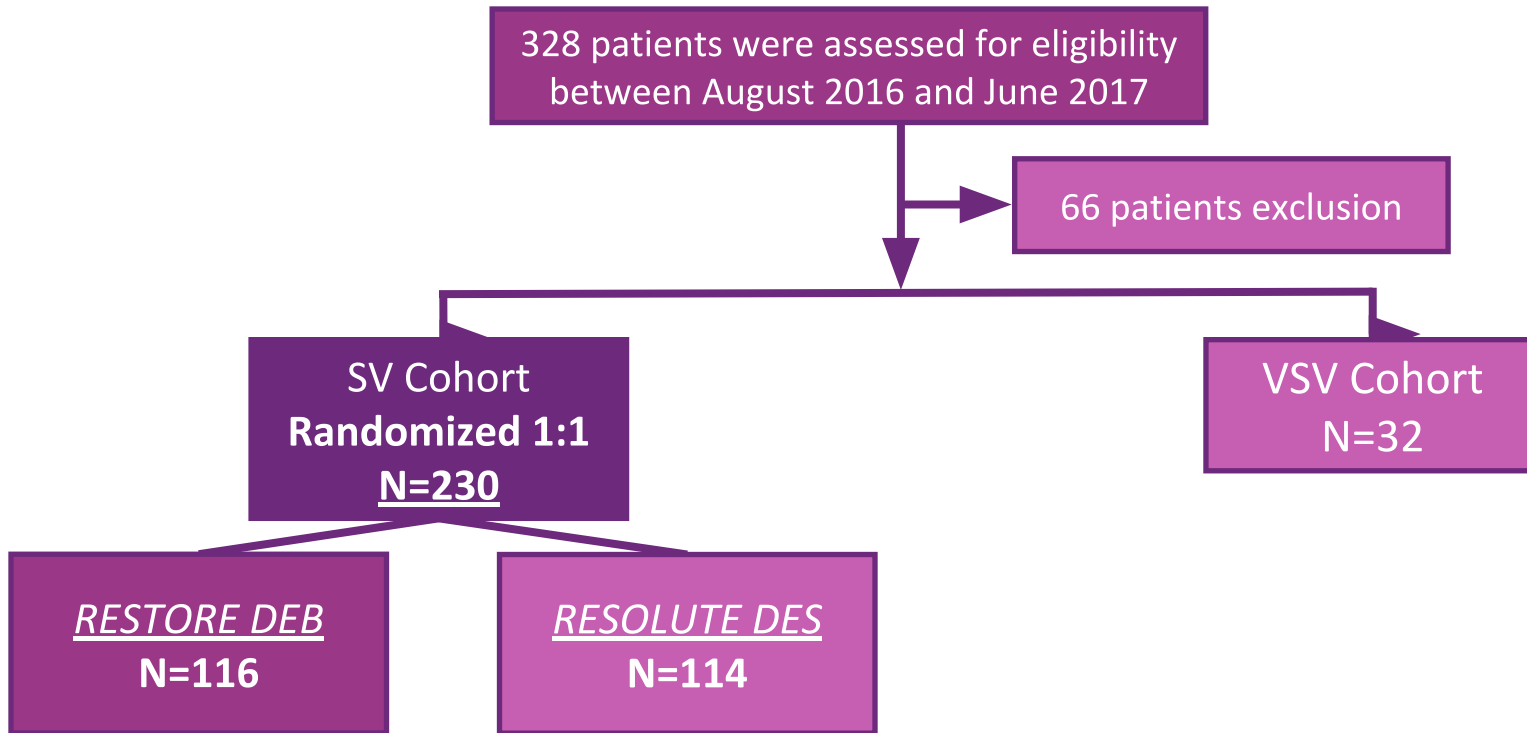
- Acute myocardial infarction within 1 week of the study;
- Left ventricular ejection fraction of  $< 35\%$ ;
- Total occlusion, bifurcation and left main lesions
- Patients with more than two non-target lesions requiring treatment

## Primary Endpoint

- In-segment diameter stenosis (%) at **9 months** after the index procedure

## Secondary Endpoints

- Acute success
- In-device diameter stenosis
- All-cause death
- Myocardial infarction
- Target vessel revascularization
- Target lesion revascularization
- Device related thrombosis



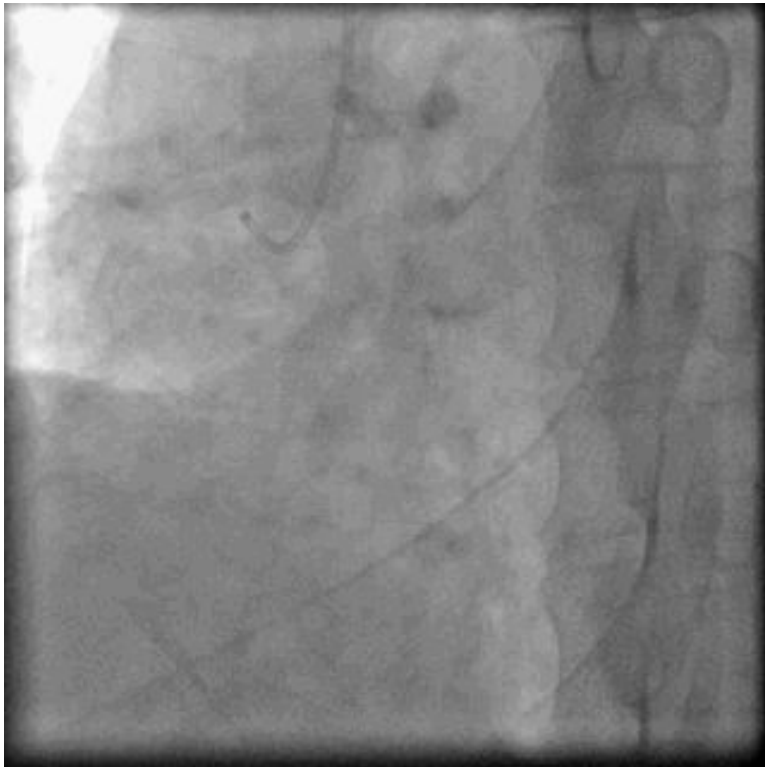
Primary endpoint: In-segment diameter stenosis (%) at 9 months



- Male, 46 yrs
- 2015 Recurrent chest pain, 2 stents implanted at RCA
- 2016 Chest pain attack frequently
- Treadmill test showed a positive result: I avL V5-6 ST segment depression at the recovery stage

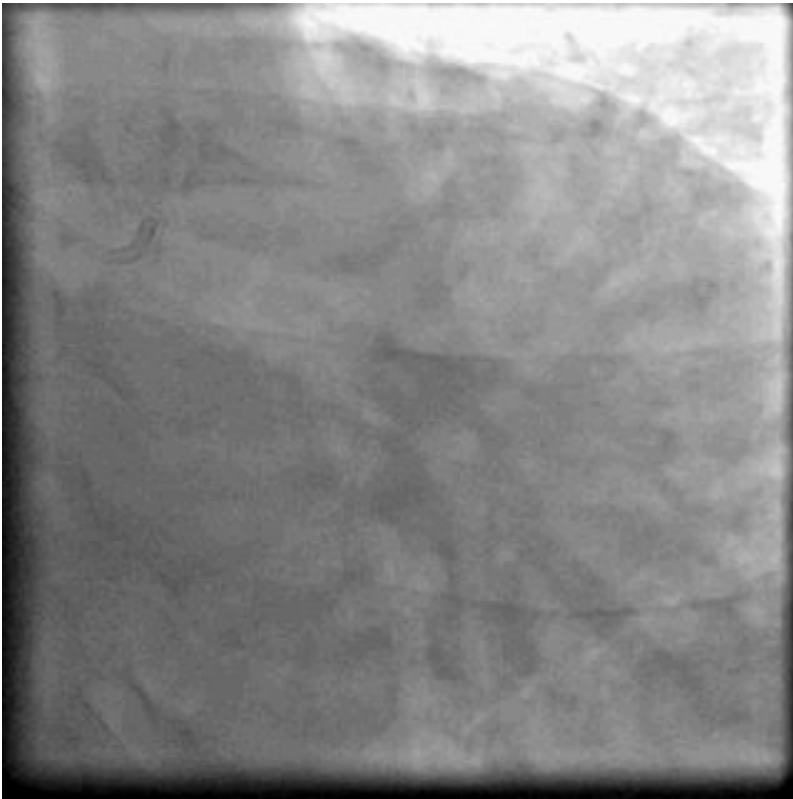
**2016-11-29 CAG**

**LAD 70% stenosis, 1<sup>st</sup> Dia. 70% stenosis; LCX 90% stenosis;  
RCA 60% stenosis**

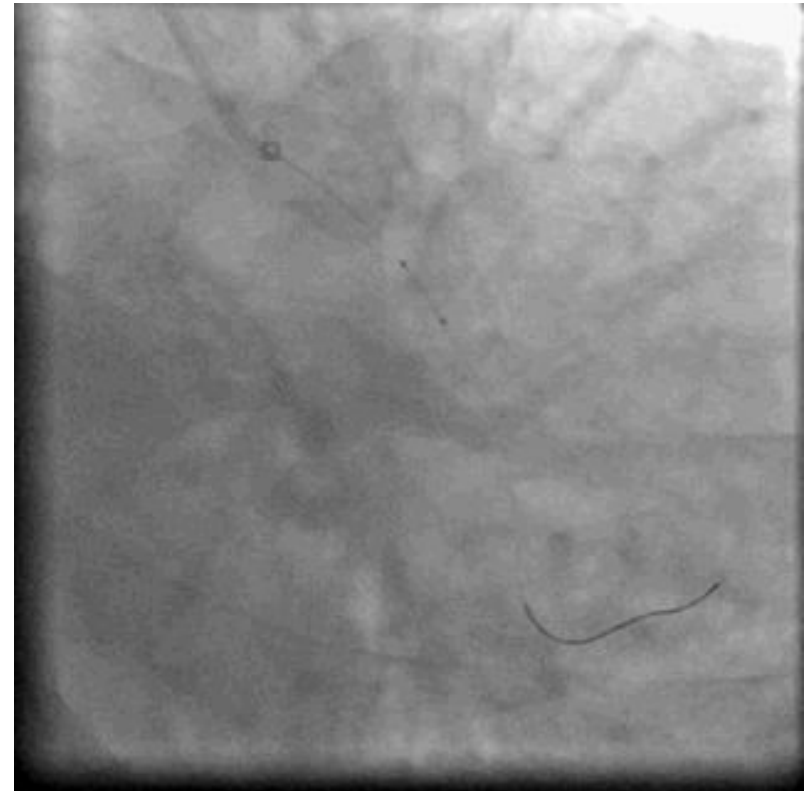


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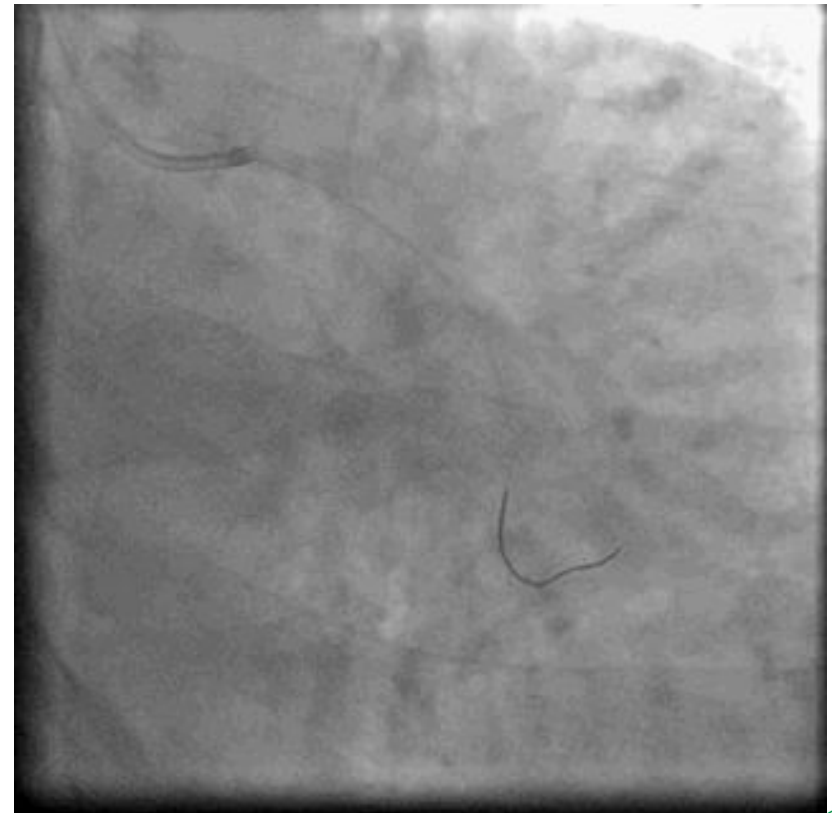
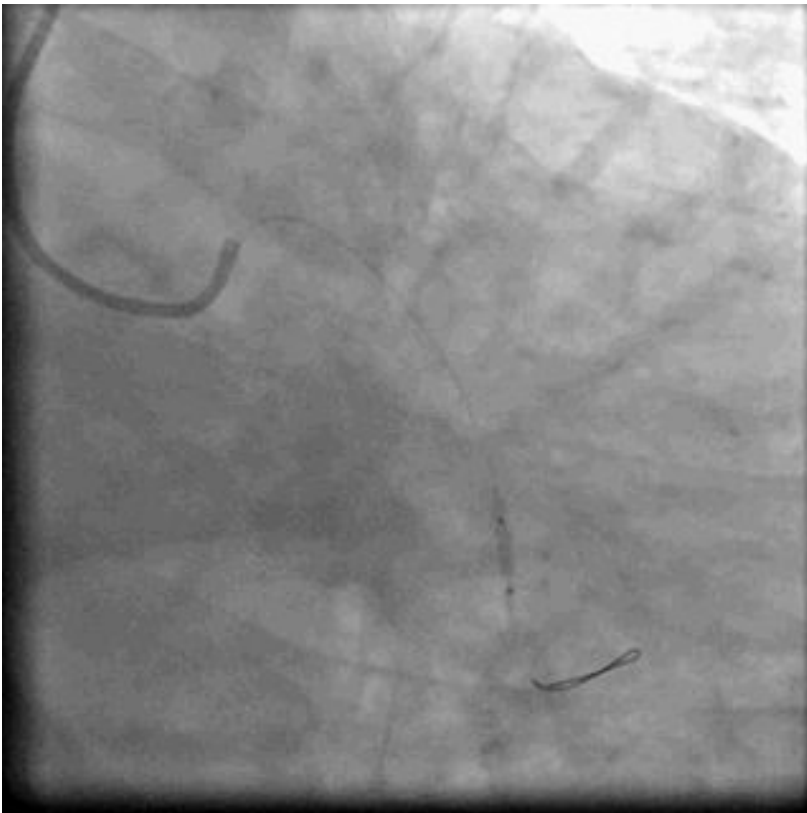


## Balloon 2.0\*10mm 12atm at LCX



DEB 2.25\*15 mm 7 atm\*70s at LCX

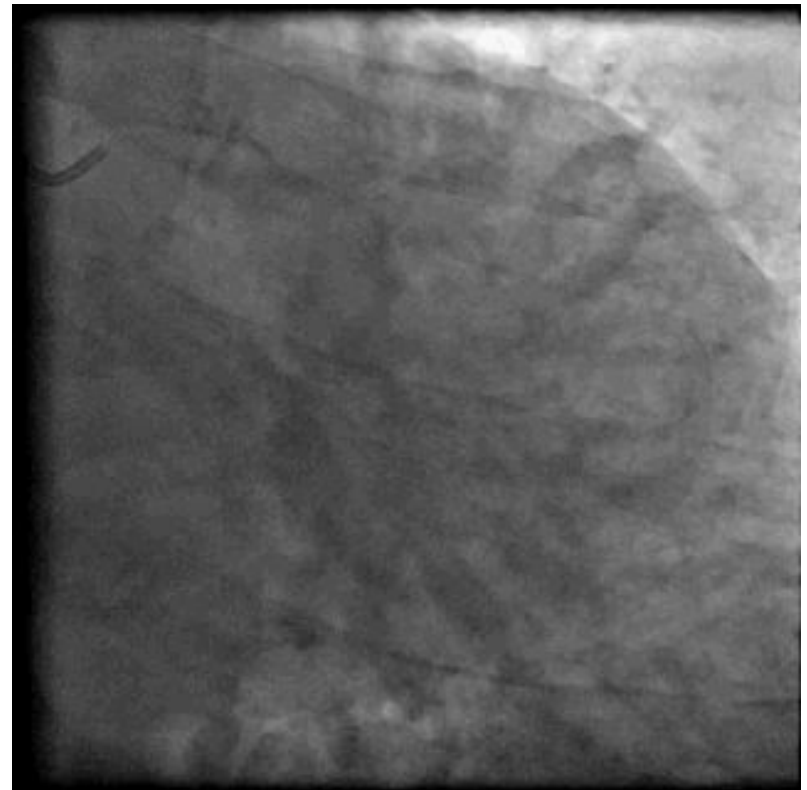
2016-11-29 Final





**2017-10-19 Angiographic follow-up**

**No more chest pain, UCG: LVEF 64%, no wall motion abnormality**



**RESTORE SVD CHINA** is a**Multicenter, Randomized, Controlled clinical trial**

- - So far as we know, this is the largest study comparing the angiographic endpoints in subjects undergoing interventional treatment in small coronary artery with drug-coated balloons vs. drug-eluting stents.
- - The recruitment of the 30 patients in the very small vessel cohort also provides important experience in treating vessels with reference vessel diameter  $\geq 2.00$  mm and  $\leq 2.25$  mm, which is still a scarcity so far.
- - The primary results will come out in the end of 2018, and the follow-up results will expose at 2022

When the **New Generation DEB ( RESTORE )** comes up



- Pre-dilation is required?
- bifurcation lesion?
- De novo lesion?

We should explore more  
in “intervention with no implantation”

Thanks  
For  
Attention

