2018 euroPCR

Comparing the efficacy and safety of two types of DEB (RESTORE and SeQuent® Please) in Chinese with coronary in-stent restenosis: a multicenter, randomized, controlled clinical trial

- RESTORE ISR CHINA -

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EAPCI EUROPEAN SOCIETY OF CARDIOLOGY PCR

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Potential conflicts of interest

Speaker's name : Yundai, Chen, Beijing

☑ I do not have any potential conflict of interest

RESTORE® DEB

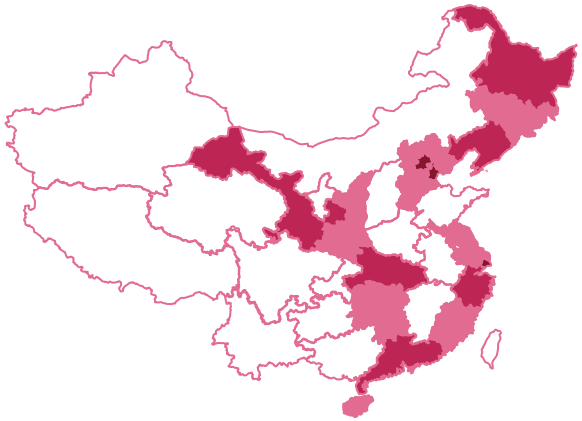
THE NEW GENERATION OF PACLITAXEL COATED CORONARY BALLOON DILATATION CATHETER.

- SAFEPAX® – The Revolutionary Excipient **Based on Ammonium Salt** – Lower wash-off rate **More effective PTX**
-  – The Nanocrystals **0.1µm particles** – Homogeneous coating **Less microembolization**
-  – The New coating technology **Homogenous crystal clear deposition** – Elastic, Smooth, Bendable **Excellent lesion crossing**

IS

PLAGH Chinese PLA General Hospital

Series Clinical Trials in China



Largest Scale, Full Indication Coverage

3 Products,

5 Indications,

64 Clinical Centers around China

Study title	Indication	Control Device	Status
RESTORE ISR CHINA	**Coronary in-stent restenosis**	**SeQuent Please DEB**	**Follow up**
RESTORE SVD CHINA	**Small vessel coronary artery disease**	**RESOLUTE DES**	**Follow up**
APERTO AVF CHINA	Arteriovenous Fistulae Stenosis	High Pressure PTCA Catheter	Follow up
LEGFLOW ATK CHINA	Stenosis or occlusions in femoral popliteal artery	Admiral Xtreme PTCA	Recruiting
LEGFLOW BTK CHINA	Stenosis or occlusion in below the knee artery	AMPHIRION DEEP PTCA	Recruiting

Sponsored by Cardionovum Medical Device GmbH.

PLAGH Chinese PLA General Hospital

Study Design

Objective

- **Safety** and **efficacy** of the **RESTORE DEB** in inhibiting restenosis

Design

- **Prospective**, **multi-center**, **randomized**, **controlled**

Principal Investigator

- **Prof. Yundai Chen** (Chinese PLA General Hospital, Beijing, China)

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

12 Participating Sites

Hospitals	Site Investigators
Chinese PLA General Hospital*	**Yudai Chen**
Tianjin Chest Hospital	Qin Qin
Nanjing First Hospital	Shaoliang Chen
Cangzhou Central Hospital	Jun Zhang
Beijing Friendship Hospital, Capital Medical University	Hui Chen
Beijing Anzhen Hospital, Capital Medical University	Zening Jin
Beijing chaoyang Hospital, Capital Medical University	Lefeng Wang
The First Hospital of Jilin University	Yang Zheng
The First Hospital of Lanzhou University	Zheng Zhang
Daqing Oilfield General Hospital	Hui Li
Tangdu Hospital, China Air Force Military Medical University	Xue Li
Sir Run Run Shaw, Zhejiang University School of Medicine Affiliated	Guosheng Fu

* The lead institution

Study Endpoints

- **Primary efficacy endpoint**
  - In-segment **LLL*** of the **target lesion** at **9 months**

- **Secondary endpoint**
  - The success rate of intervention treatment: device success, lesion success and clinical success
  - Restenosis in the target lesions
  - Target lesion revascularization (TLR)
  - Target vessel revascularization (TVR)
  - Target lesion failure (TLF)
  - Major adverse cardiovascular events
  - All adverse events and severe adverse events

*LLL: late lumen loss

Key In and Ex-Criteria

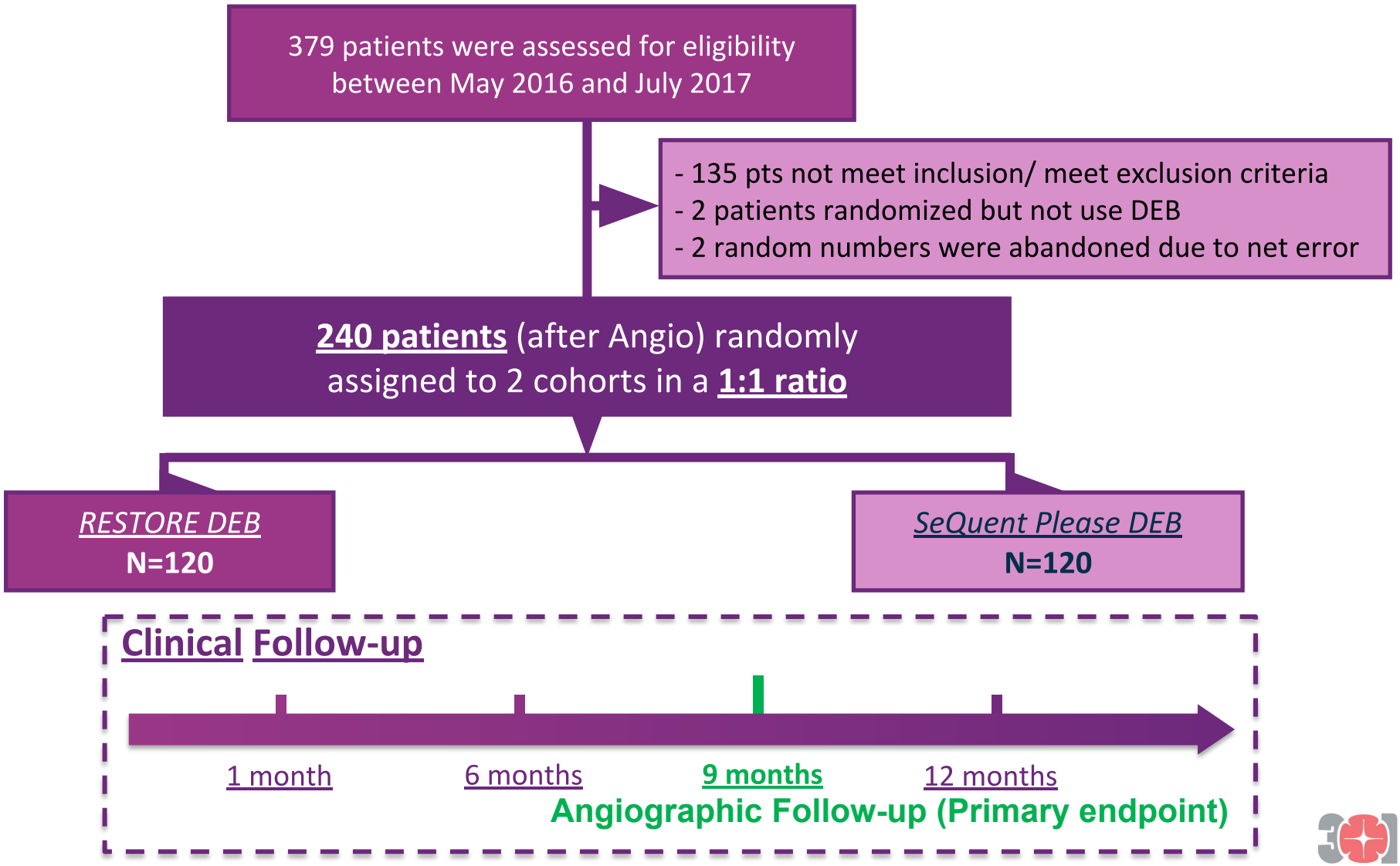
Inclusion criteria

- Angina or ischemia and showing ISR (**≥ 70%** diameter stenosis, **or ≥ 50%** diameter stenosis **and with ischemic symptoms**) on CAG
- ISR patterns are Mehran type Ⅰ-Ⅲ and the stent diameter of ISR is **2.5-4.0** mm.
- Patients with **≤ 2 episode of ISR** and those with **≤ 2 balloons** at the target lesion.

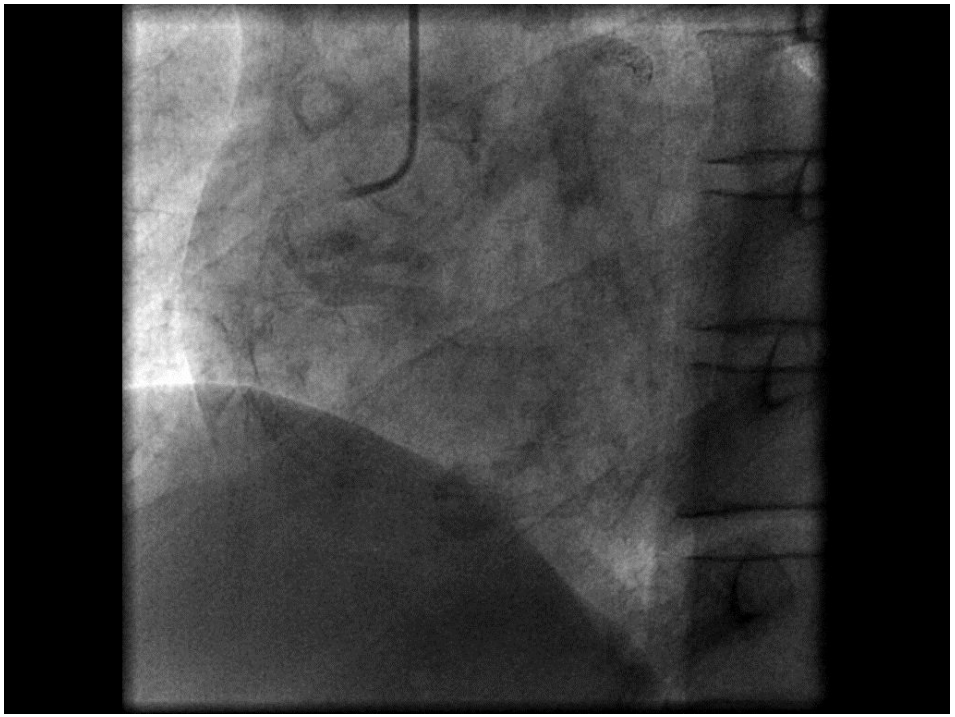
Exclusion criteria

- Patients with not only 2 target lesions (less than 10 mm) and the distant lesions, but also multiple lesions (≥ 3) requiring PCI treatment in the same artery;
- Lesions requiring intervention treatment in 3 vessels and branch lesions diameter more than 2.5 mm in the target lesion;
- Extensive thrombosis in the target vessel
- Unable to coordinate with angiographic follow-up

Patient Flow Diagram



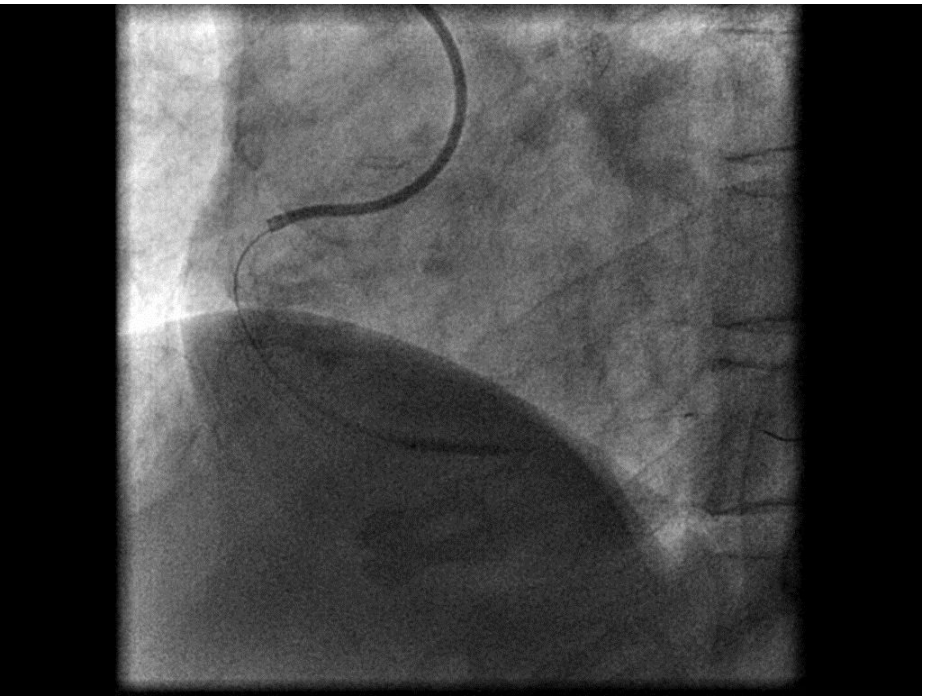
Case

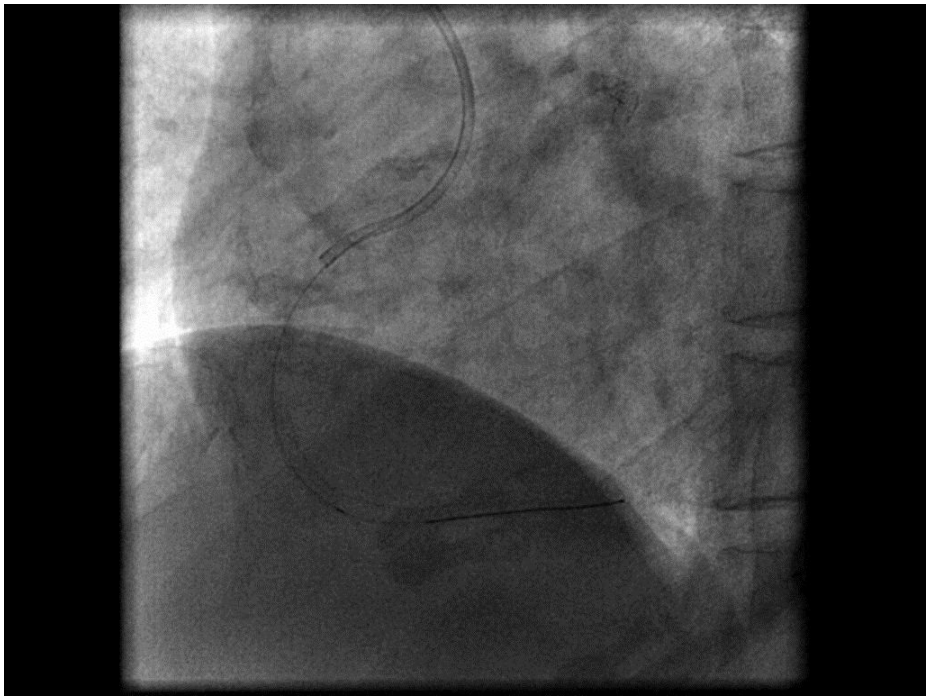


- Male, 69 years
- 2016 Recurrent chest pain, a sirolimus eluting stent was implanted in RCA mid-distal region
- 2017 Chest pain attack frequently
- CAG: In-stent distal region stenosis >95%

Pre-dilation

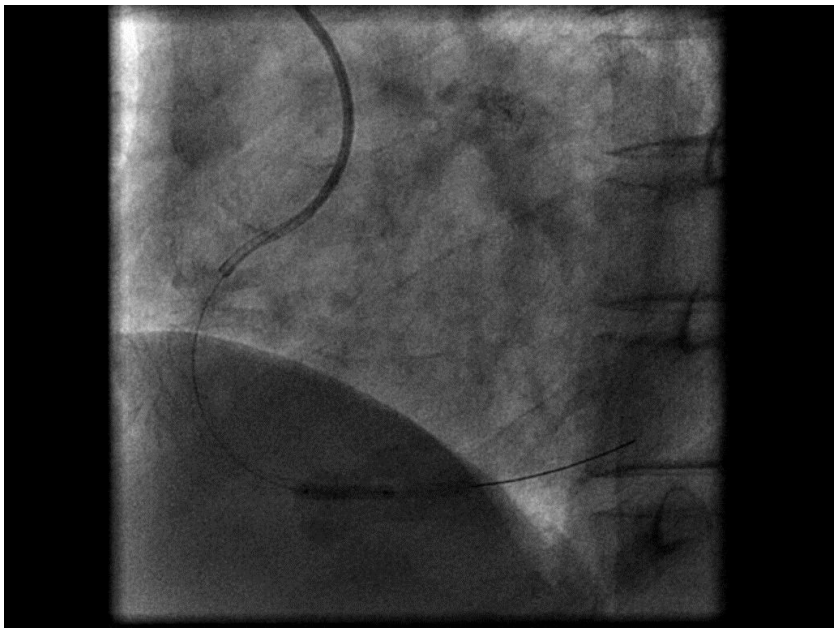
Pre-dilation with a high-pressure balloon 16 atm, 30 s



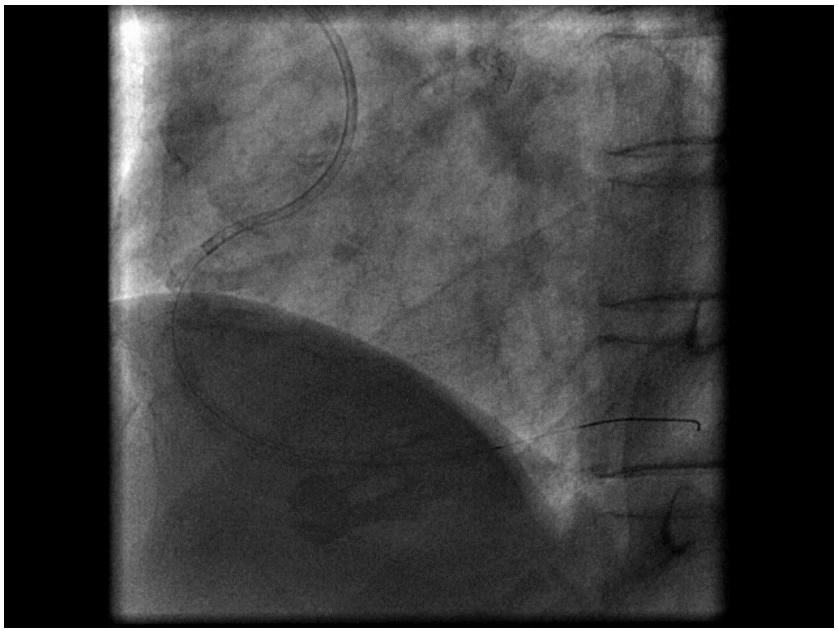


DEB dilation

A 2.5mm * 15mm DEB, 12 atm, 40s



Post-DEB dilation



The 9th month follow up

2018-02 Angiographic follow-up, no more chest pain

Conclusion

RESTORE ISR CHINA is a

Multicenter, Randomized, Controlled clinical trial

- RESTORE DEB is a novel & new generation paclitaxel-coated balloon
- Head-to-head comparison of RESTORE DEB vs. SeQuent Please® DEB in efficacy and safety for Chinese patients with coronary ISR
- The final results will be exposed in the end of 2018.

THANKS FOR ATTENTION