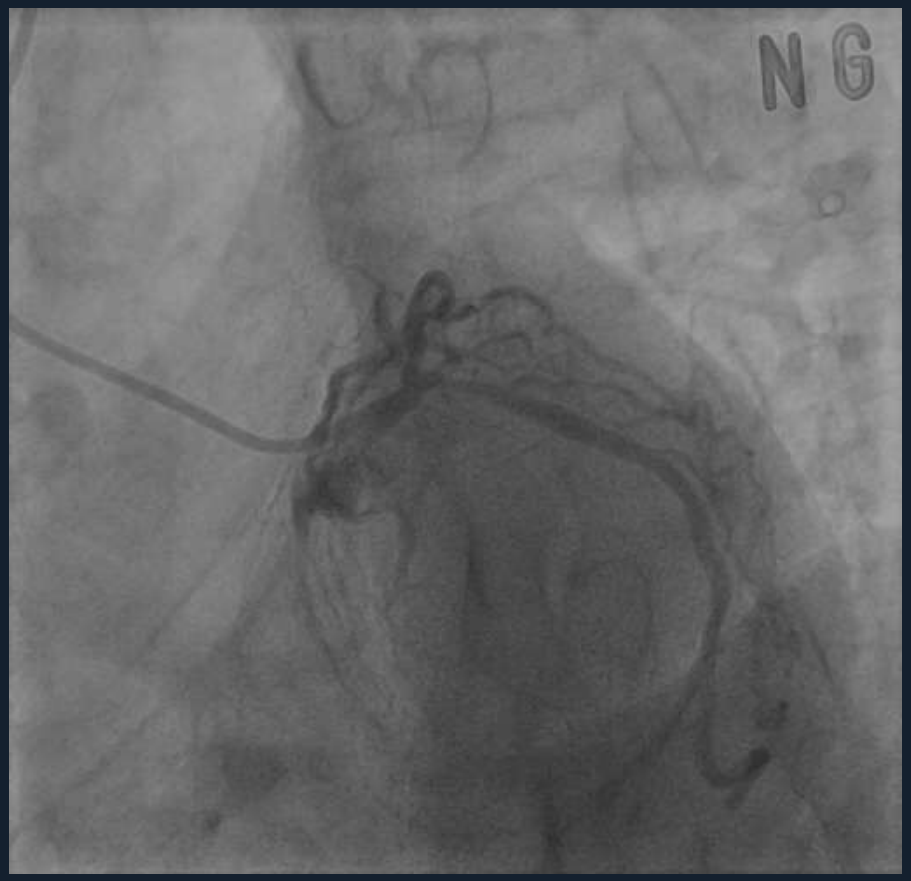
Treatment of Drug-Eluting Stent *RE*stenosis Using Drug-Eluting *ST*ents vs. Drug-C*O*ated Balloon for Preventing *RE*current In-Stent Restenosis

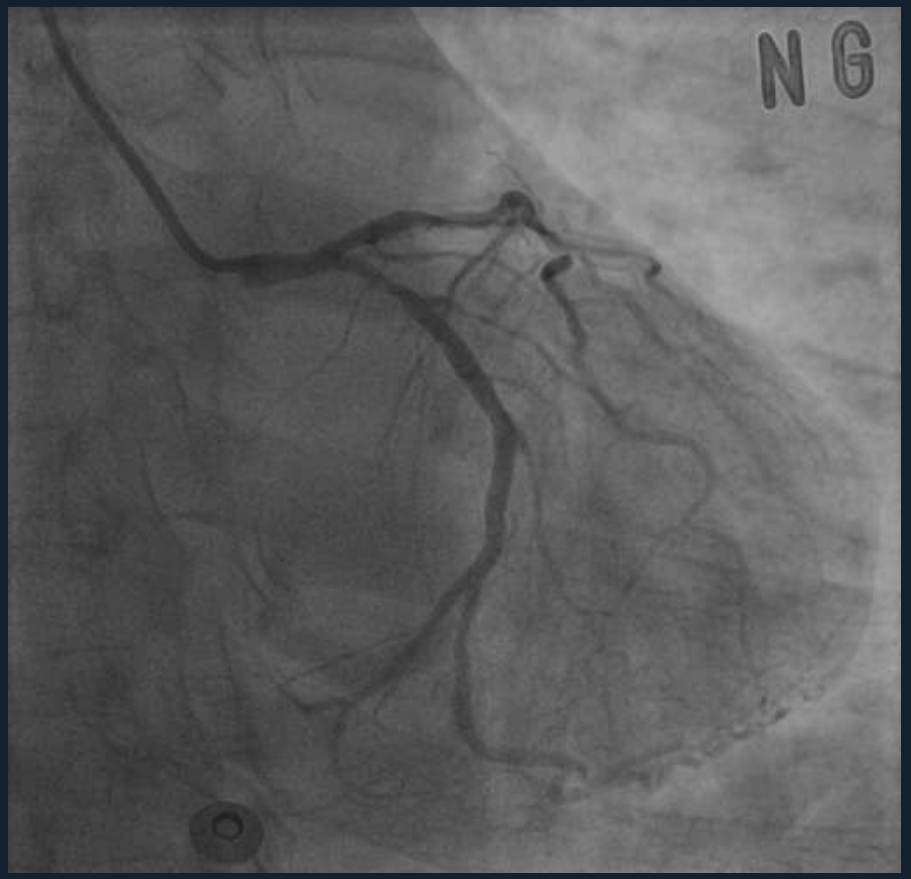
Final Answer "RESTORE"

Jung-Min Ahn, MD.

Asan Medical Center, Seoul, Korea
On the behalf of the RESTORE Trial

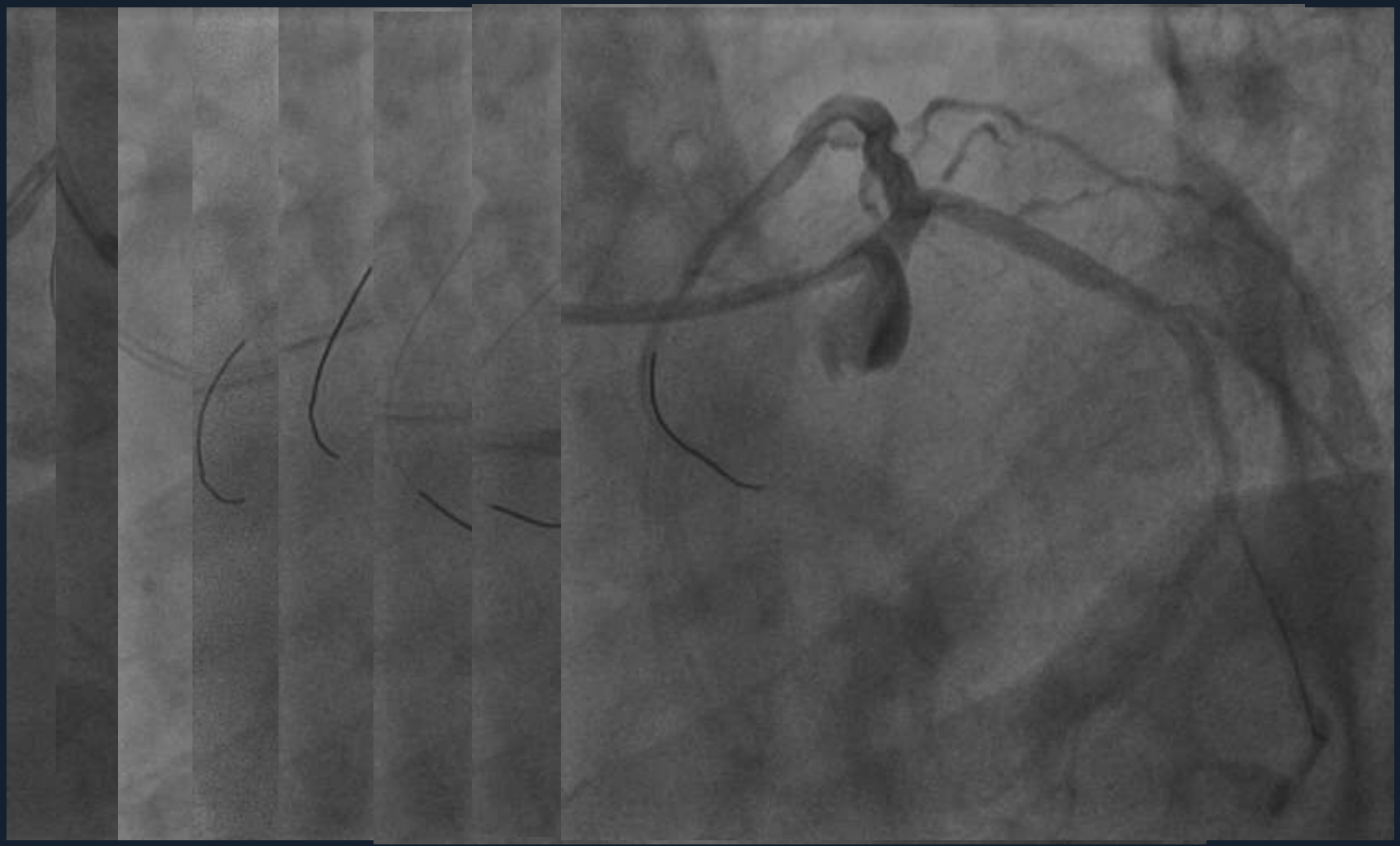
Initial CAG (2011-5-24)



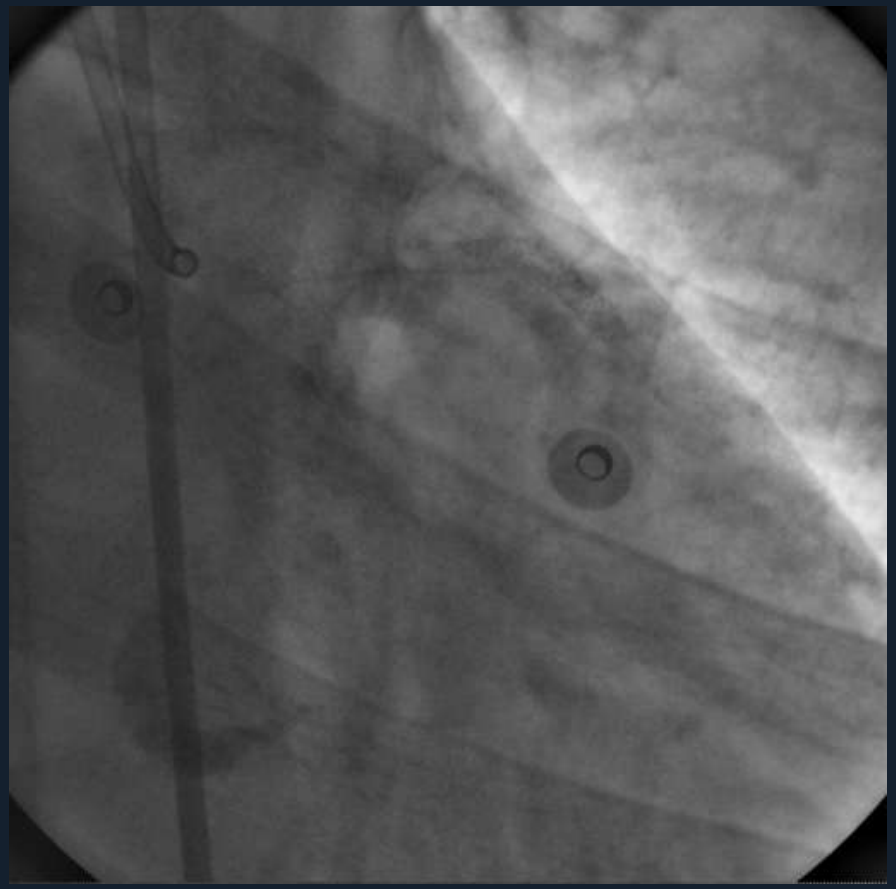


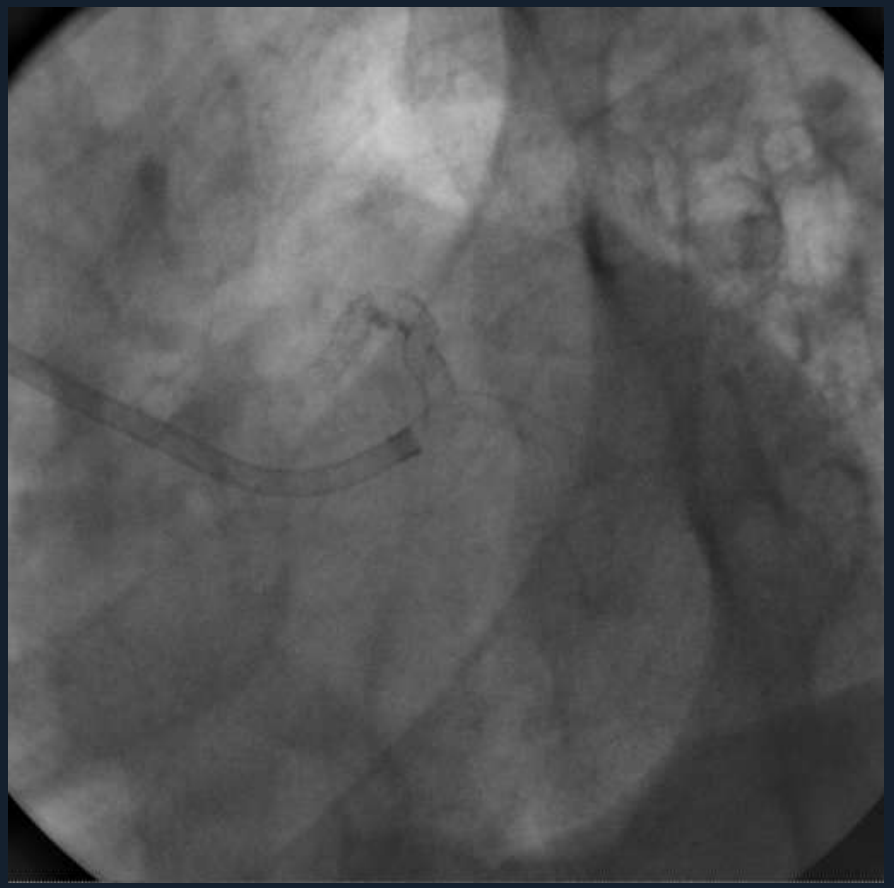
Distal Left Main Bifurcation Stenosis

Initial PCI Procedure (2011-5-24)



CAG (2012-4-30)





How to Treat DES-ISR
RCT from Asan Medical Center

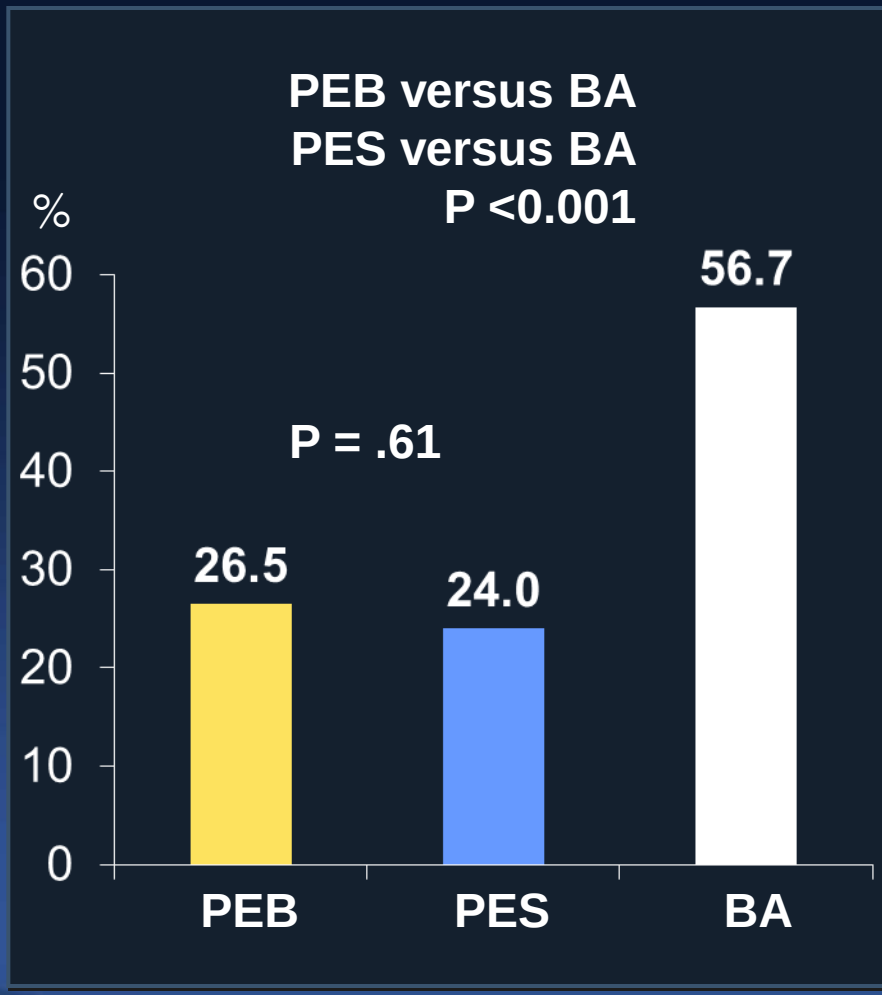
In-segment Late Loss at 9 months Follow up

J Am Coll Cardiol. 2012 Mar 20;59(12):1093-100

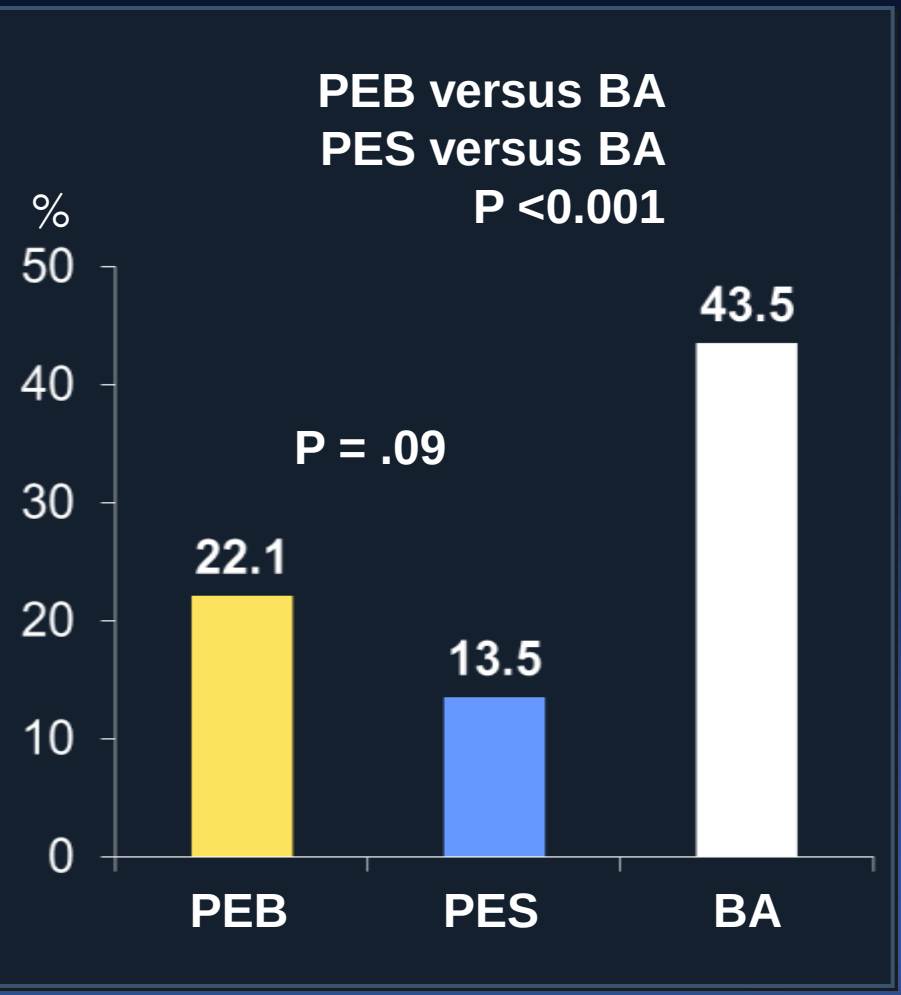
CardioVascular Research Foundation
UNIVERSITY OF ULSAN COLLEGE MEDICINE
ASAN Medical Center

ISAR-DESIRE III (DEB vs. PES)

Binary Restenosis



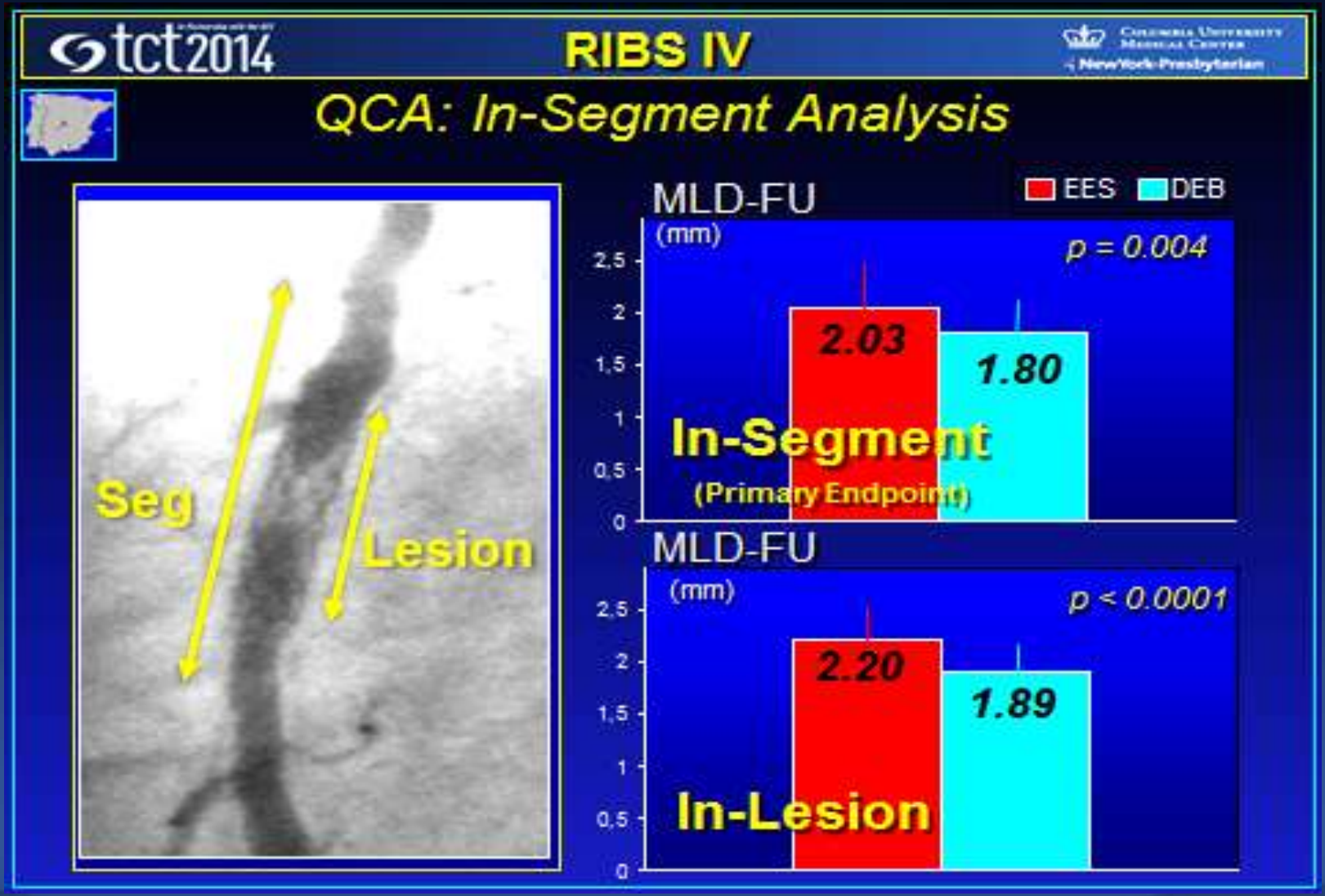
Target Lesion Revascularization



ISAR-DESIRE 3: Intracoronary Stenting and Angiographic Results: Drug Eluting Stents for In-Stent Restenosis: 3 Treatment Approaches

CardioVascular Research Foundation
University of Ulsan College Medicine
Asan Medical Center

RIB IV (DEB vs. EES)



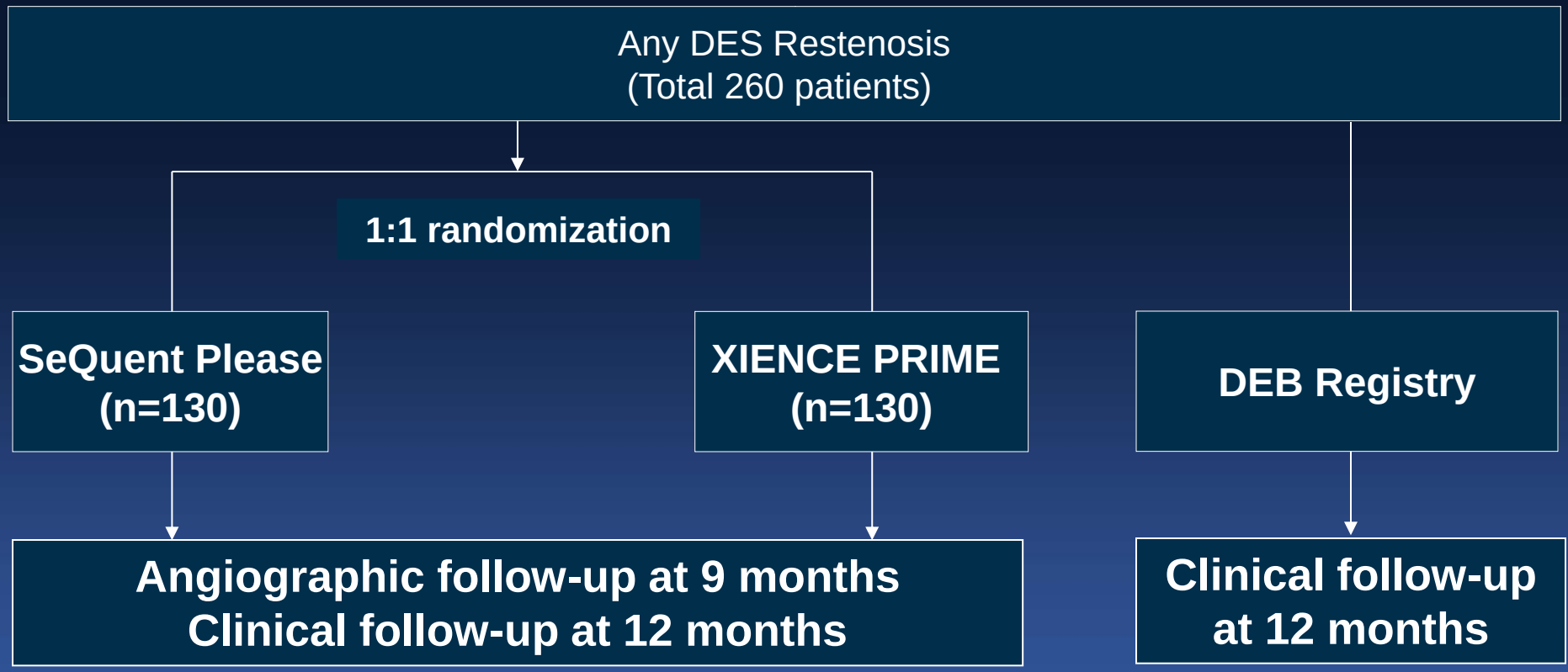
The RESTORE Trial

The trial has the following **primary objective**:

To establish the safety and effectiveness of paclitaxel-eluting balloon (**SeQuent Please**) as compared to coronary stenting with the Everolimus-eluting balloon expandable stent (**Xience PRIME**) in the treatment of **DES Restenosis**.

Treatment of Drug-Eluting Stent ***RE***stenosis Using Drug-Eluting ***ST***ents vs. Drug-C***O***ated Balloon for Preventing ***RE***current In-Stent Restenosis

RESTORE Trial



Primary end point: (1) Angiographic late loss at 9 months

Sample Size

- On the basis of results from previous report, we assumed late luminal loss of 0.35±0.5mm in the Xience PRIME group, 0.15±0.4 mm in the SeQuent Please group.
- Type I error; Set at 0.05
- Type II error; Set at 0.1, Statistical power = 90%
- Sampling ratio is 1:1 = Xience PRIME : SeQuent Please

  ➔ 109 patients per group.
- Adjustments; 15% drop out rate of angiographic follow-up predicted

  ➔ 130 patients per group (Total 260 patients).

END POINTS

The Primary End Points

- Late luminal loss at 9 months angiographic follow-up.

The Principal Secondary End Points

- Death.
- Myocardial infarction.
- Target-vessel revascularization.
- Target-lesion revascularization.
- Stent thrombosis (ARC definition).
- In-segment or In-stent restenosis.
- Procedural success.

Enrollment Criteria

Inclusion Criteria

1. The patient must be at least 18 years of age.
2. Restenosis after drug-eluting stents (>50% by visual estimate)
   Including edge-ISR.
3. ***Any Lesion length including focal ISR or diffuse ISR***
4. Patients with stable or ACS (unstable angina/NSTEMI) or silent ischemia with documentation of myocardial ischemia
5. The patient agrees to the study protocol and the schedule of clinical and angiographic follow-up, and provides informed, written consent.

Enrollment Criteria

Exclusion Criteria

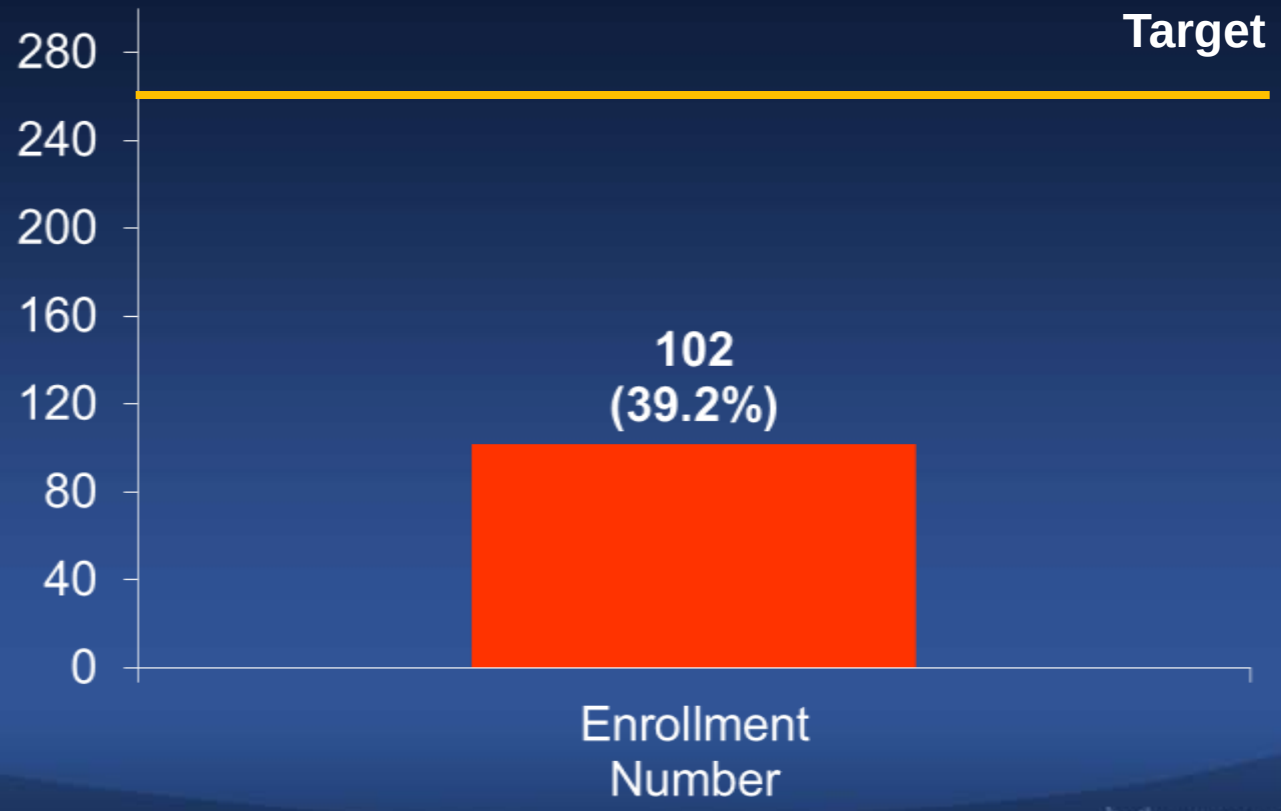
1. The patient has a known hypersensitivity or contraindication to any of the following medications: antiplatelet drugs, coated drugs, stainless steel and/or contrast media cannot be controlled with medications.
2. Systemic (intravenous) Paclitaxel or Everolimus use within 12 months.
3. STEMI.
4. Non-cardiac co-morbid conditions are present with life expectancy <1 year or that may result in protocol non-compliance (per site investigator's medical judgment).

Procedures

- After random assignment, PCI must be carried out in 7 days.
- Any lesion preparation (pre-balloon, cutting, safe-cut, or high-pressure balloon) is possible.
- The recommended inflation time for the drug-balloon was ≥30 seconds (optimally 60 seconds).
- Post-PCI IVUS is not recommended.
- In case with inadequate final results in the drug-balloon group due to severe dissection or residual stenosis, the bail-out stenting with only use of Xience V stent is allowed. However, this case is regarded as the protocol violation and the final analysis will be performed by the intention-to-treat and the per-protocol manner.

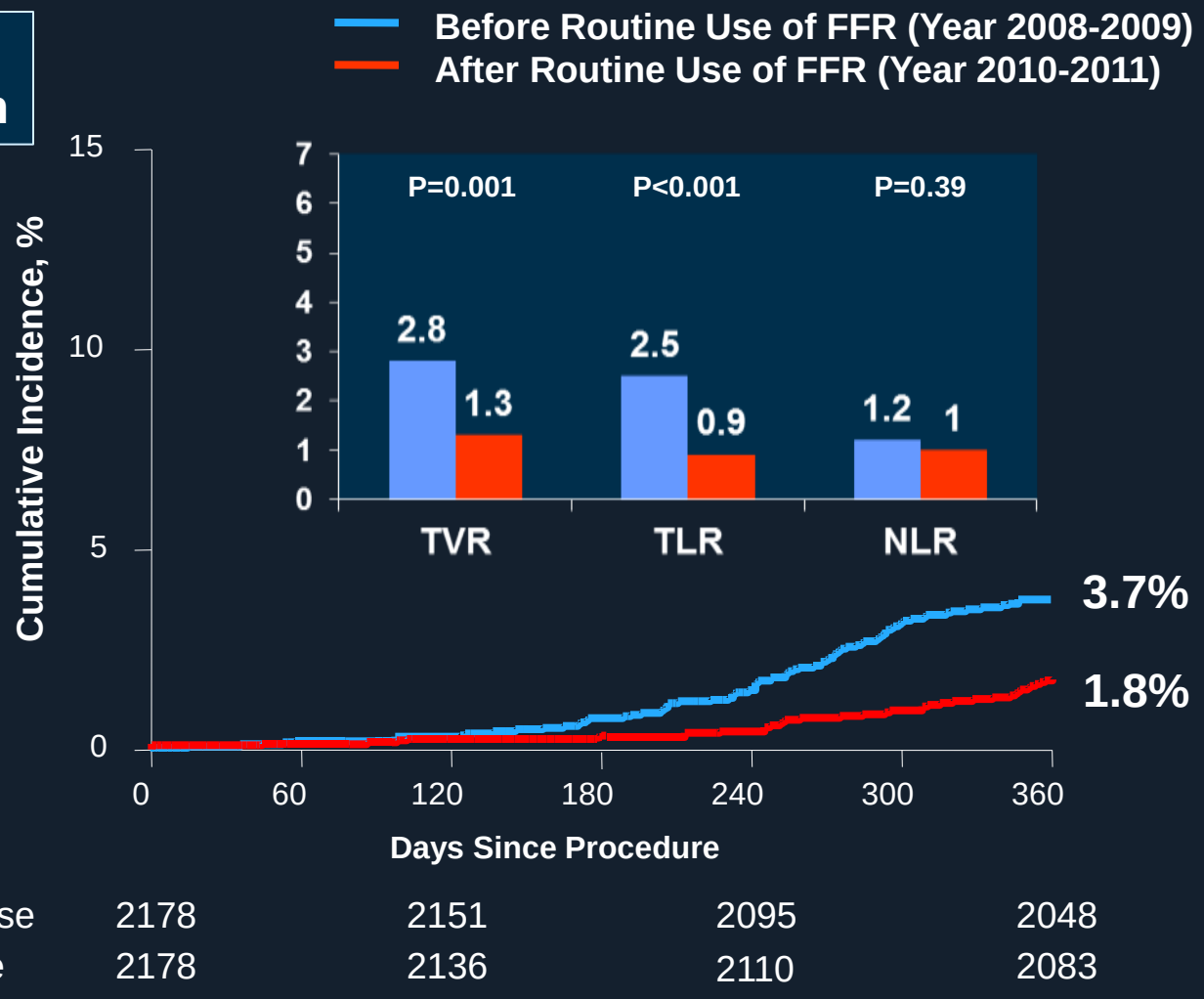
“Final Answer” Should be waited

Current Status: 2013.4.1 ~



ISR is Rare, Nowadays

Repeat Revascularization

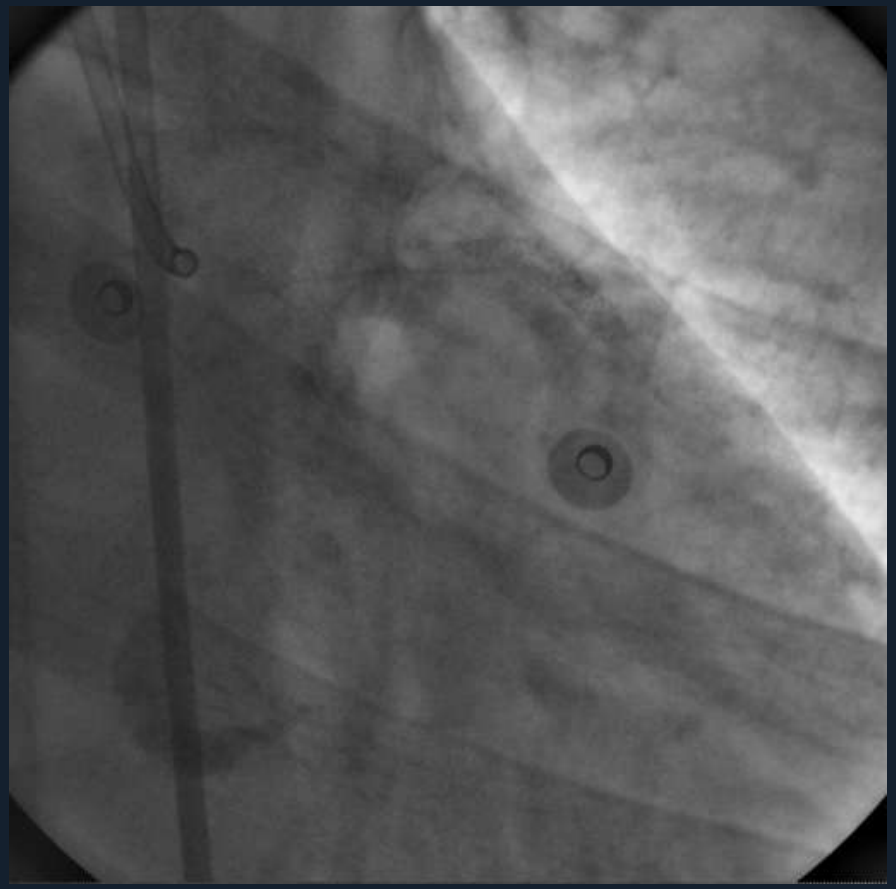


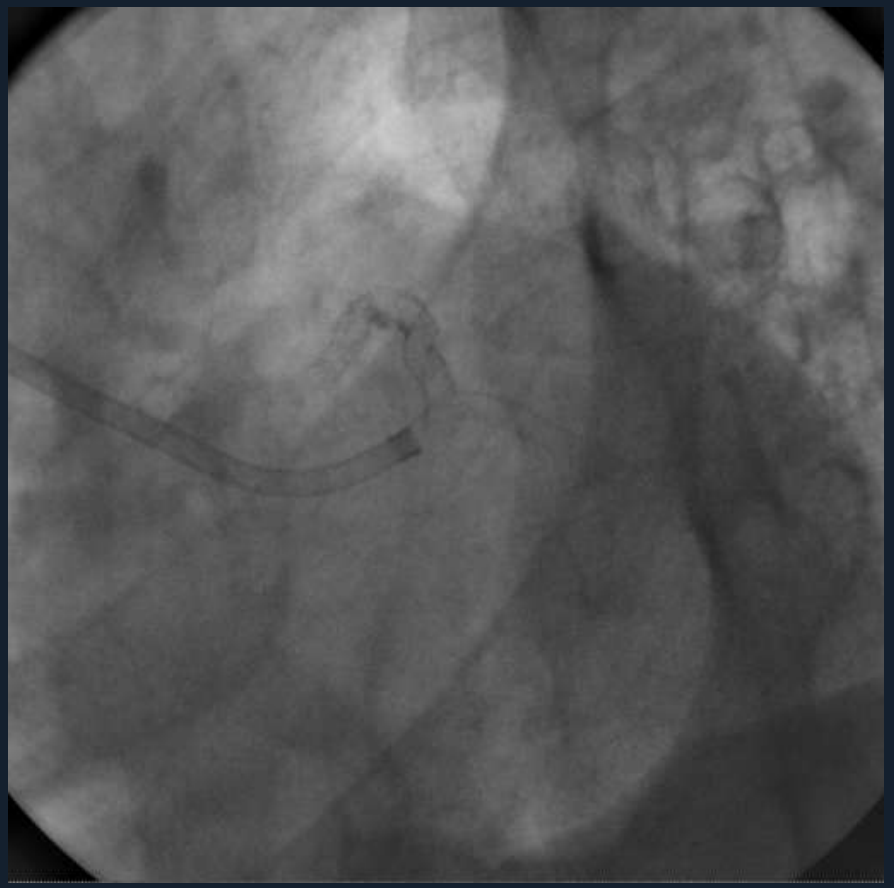
No. at Risk

Before Routine Use	2178	2151	2095	2048
After Routine Use	2178	2136	2110	2083

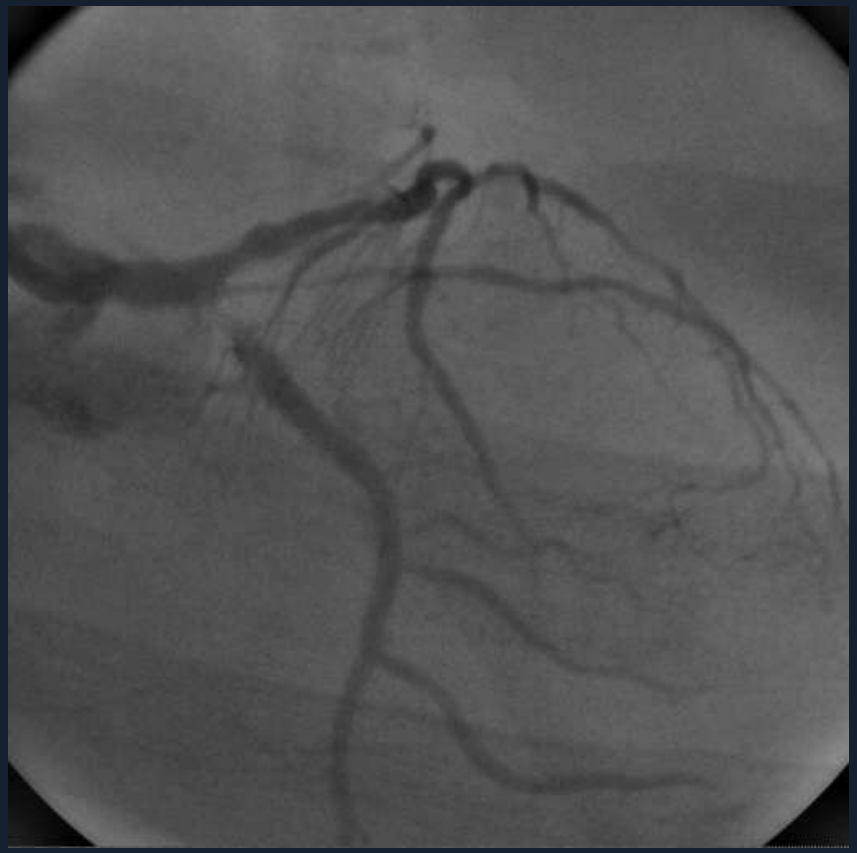
Park SJ, Ahn JM et al. Eur Heart J. 2013 Nov;34(43):3353-61

How to Treat ?



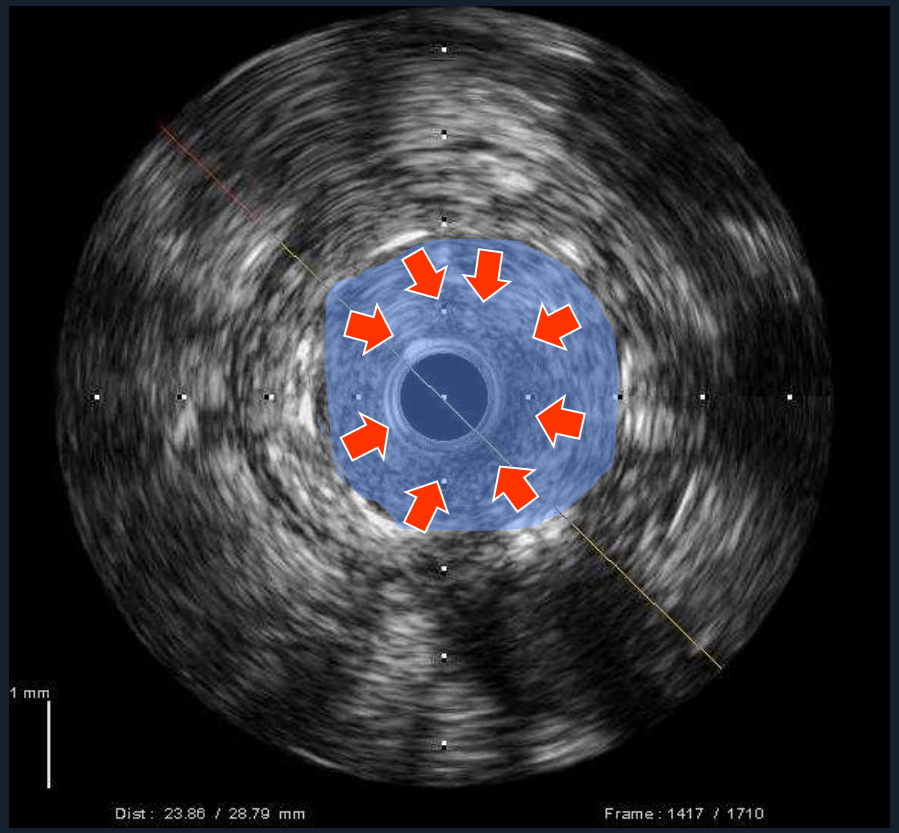


Mechanism of LM ISR



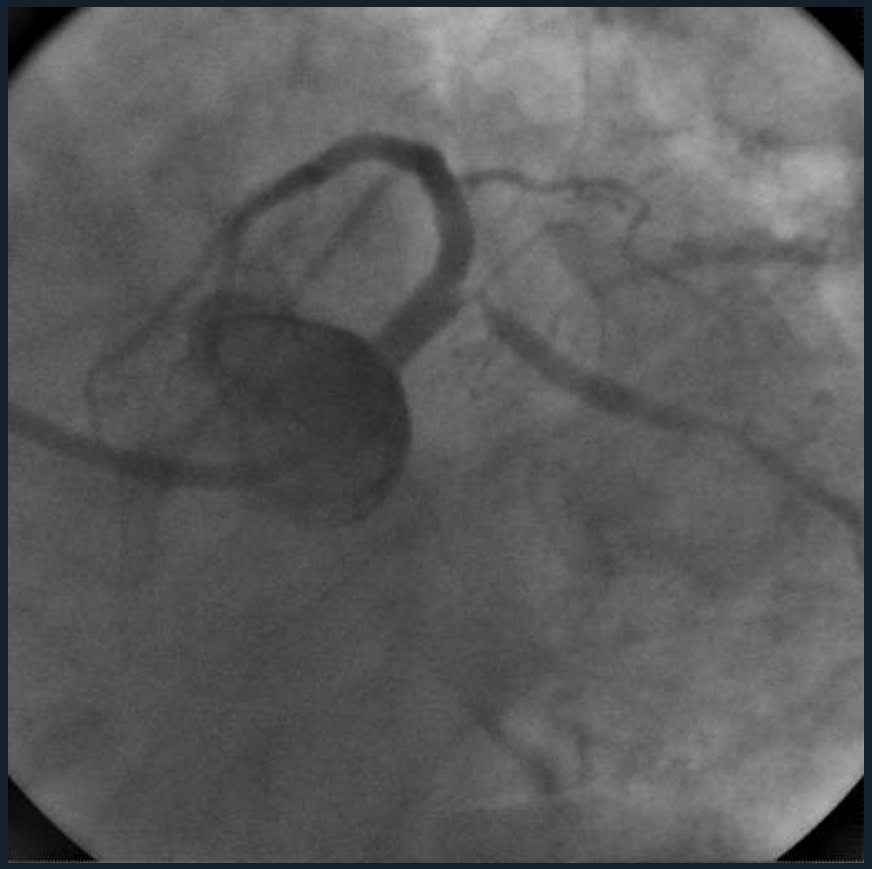
dLM bifurcation

LCX os



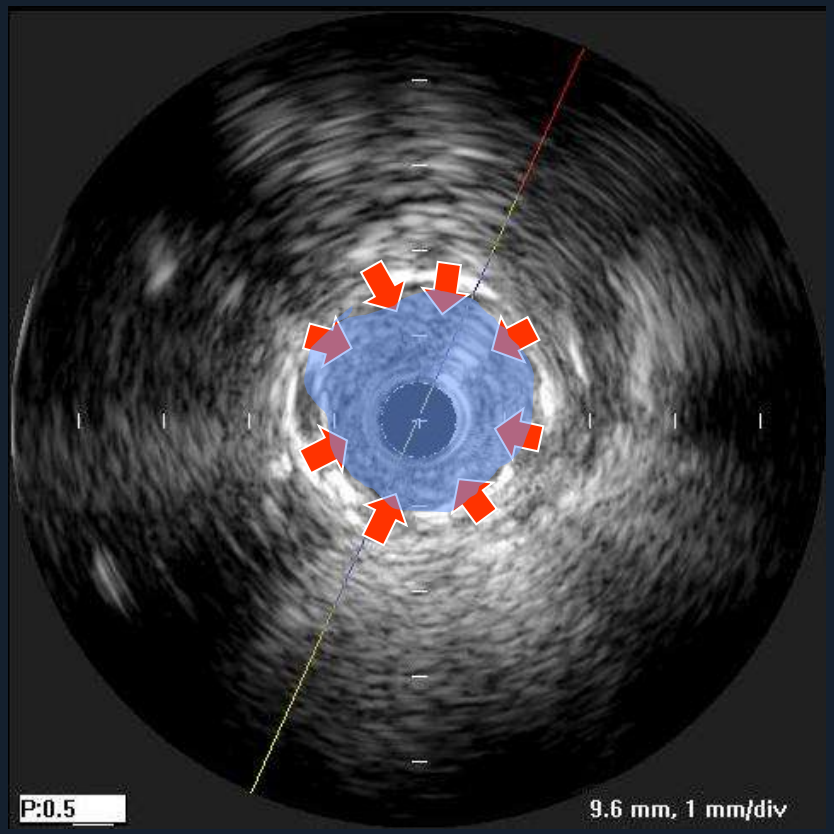
MSA: 9.8mm^2

Mechanism of LM ISR



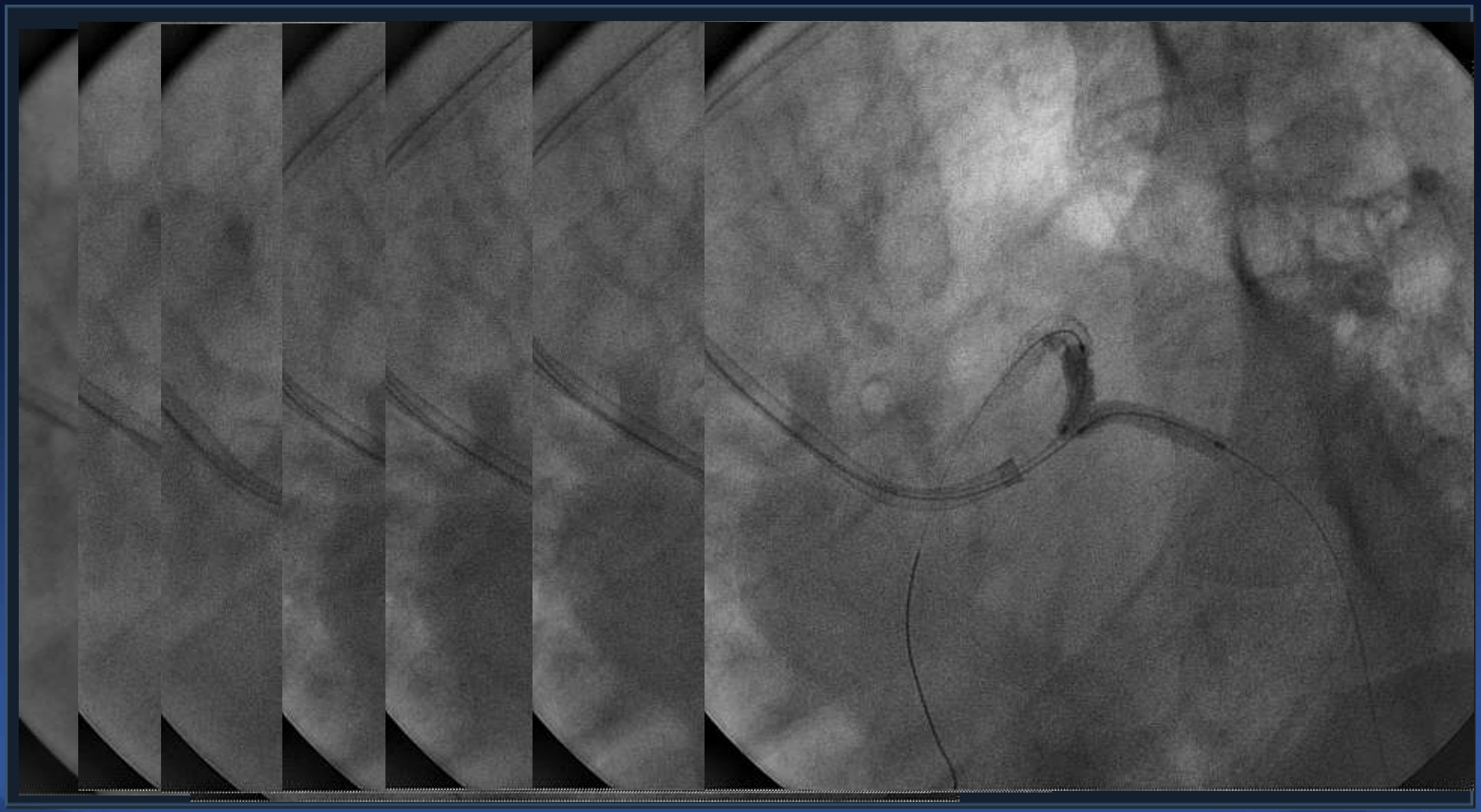
dLM bifurcation

LCX os



MSA: 4.6mm^2

My Solution:
PCI using Drug-Eluting Balloon



SeQuent Please 3.0(20)/3.5(20)

BMW wire IKAZUCHI 2.5(20) Dura Star 3.0(20)/3.5(20)

Final CAG