

**Bioresorbable Scaffold  
in  
VERY LATE STENT THROMBOSIS**

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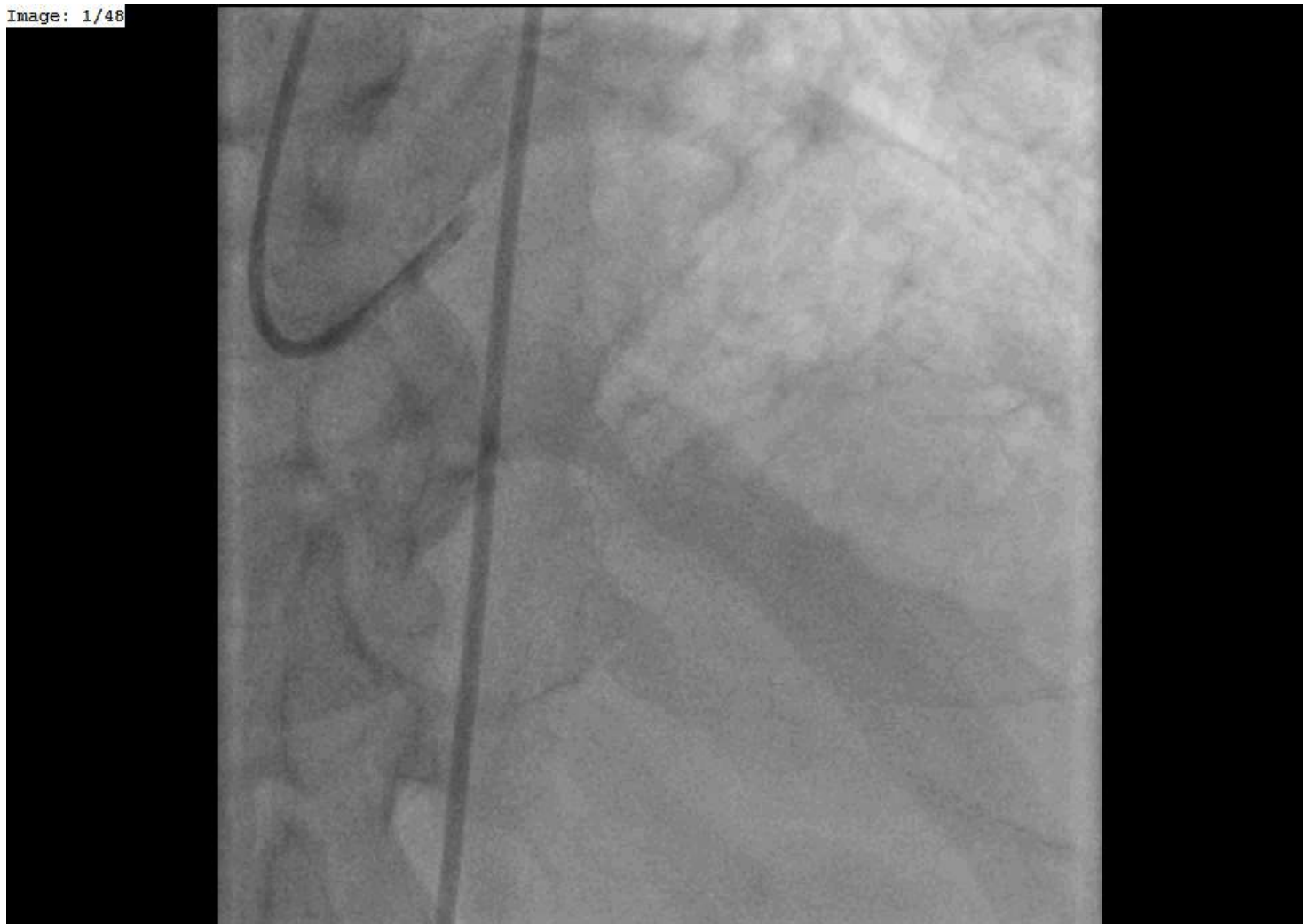
**Apollo Gleneagles Heart Hospitals, Kolkata**

**INDIA**

# Case history

- PR, 68 Yrs Male, Diabetic, hypertensive, ex-smoker, COPD had PTCA to RCA with Cypher was done in 2004
- Remained on follow up. Clopidogrel and Aspirin was given for 2 yrs. Diabetes was inadequately controlled (HbA1C -7.8), Cr – 1.3), Got admitted in Dec 2015 with acute Inferior Wall MI. Echo – EF – 45%, had initial thrombolysis within 4 hours of chest pain at Peripheral hospital. Angiography was done on the second day
- Before PCI was pretreated with IV abciximab

Image: 1/48



# FFR to LAD

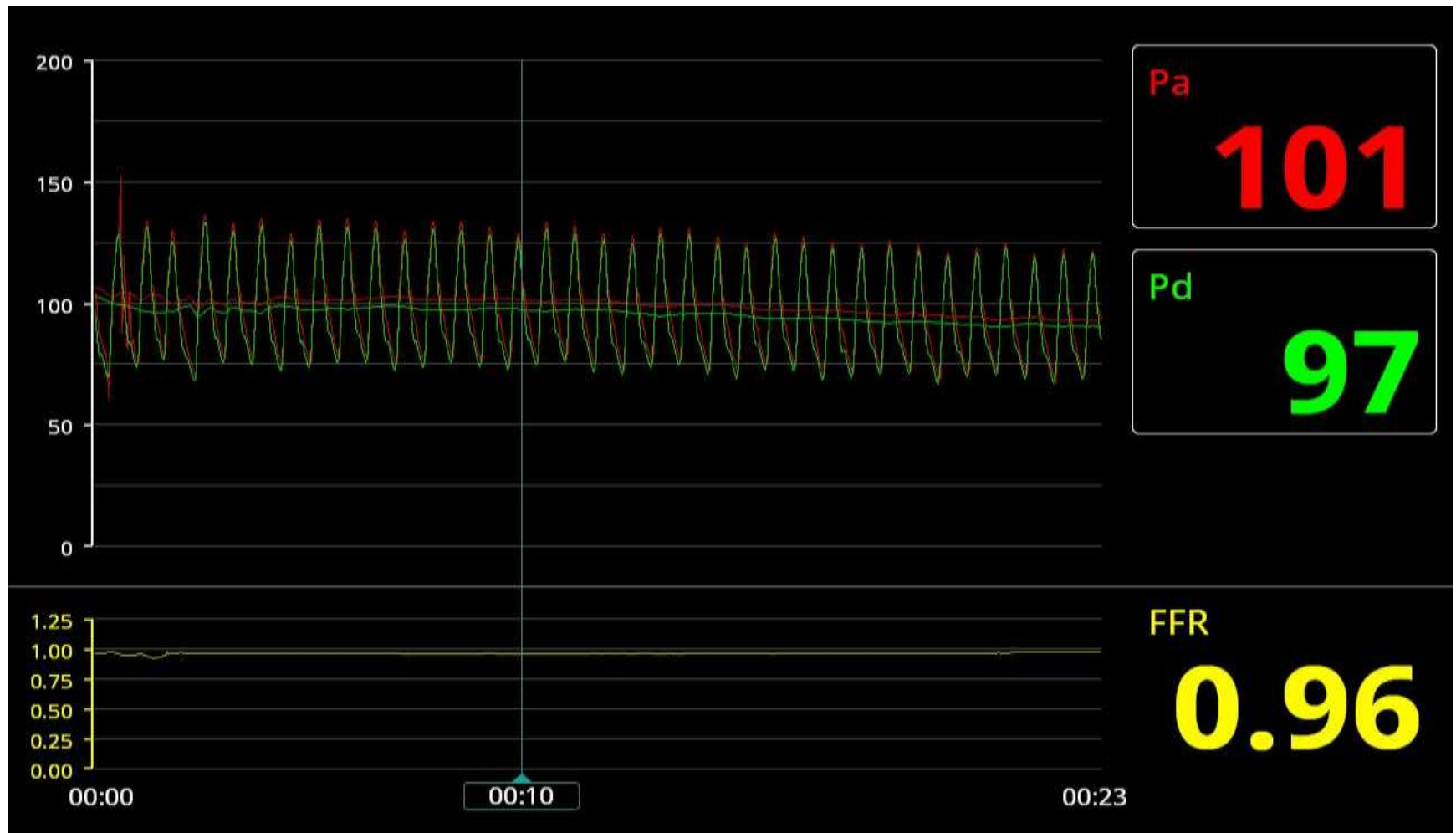


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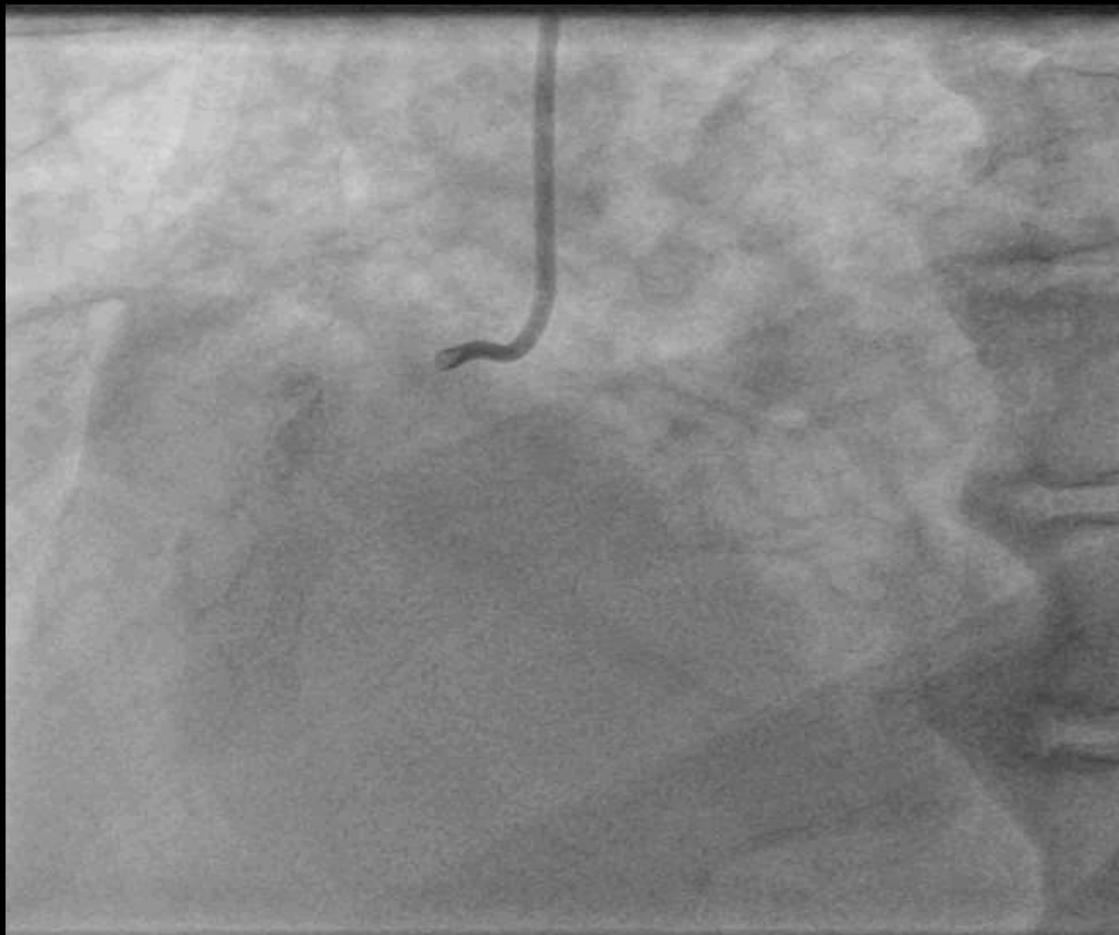


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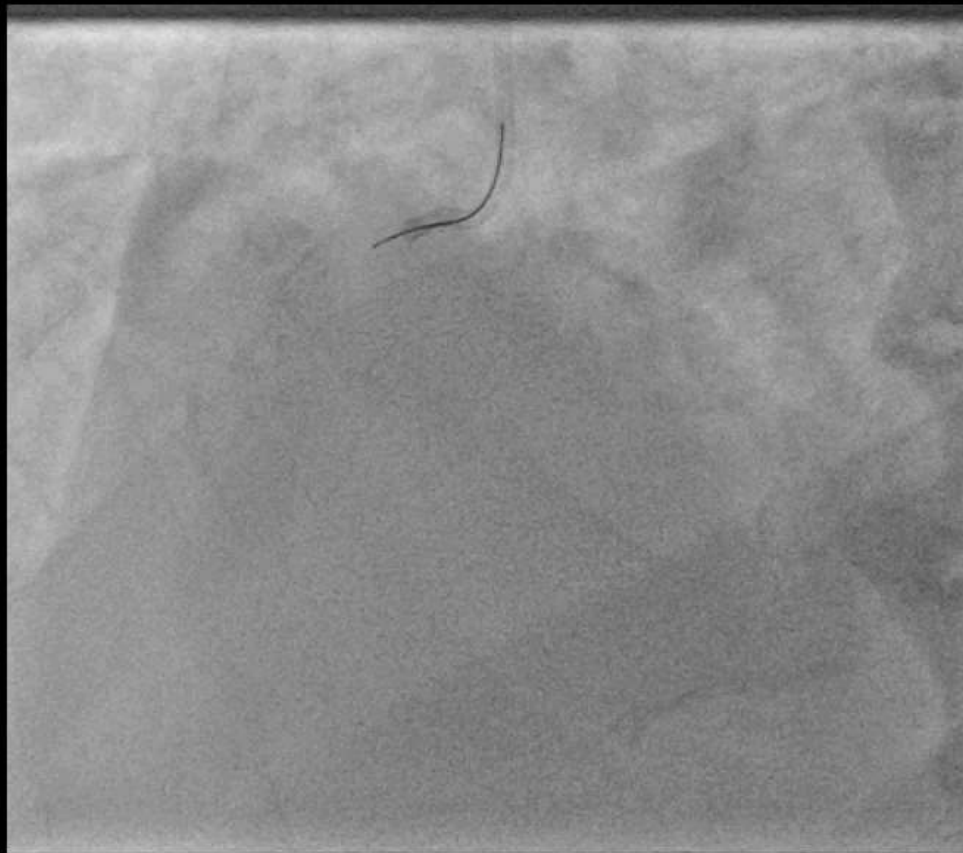


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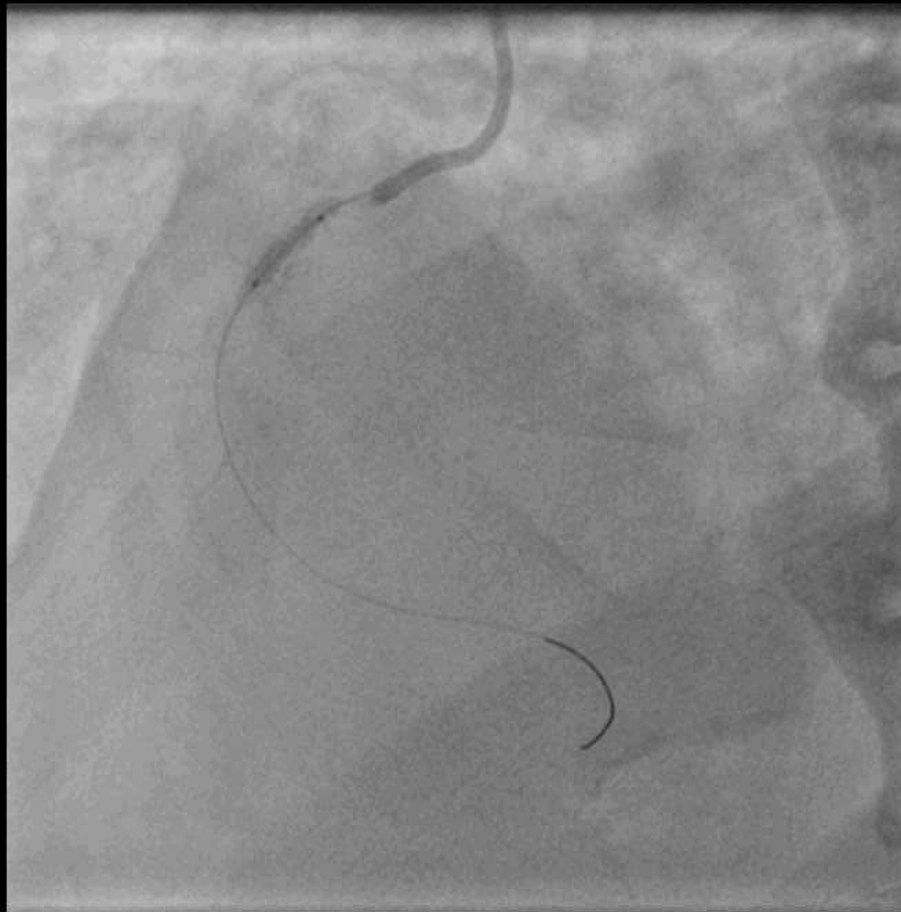
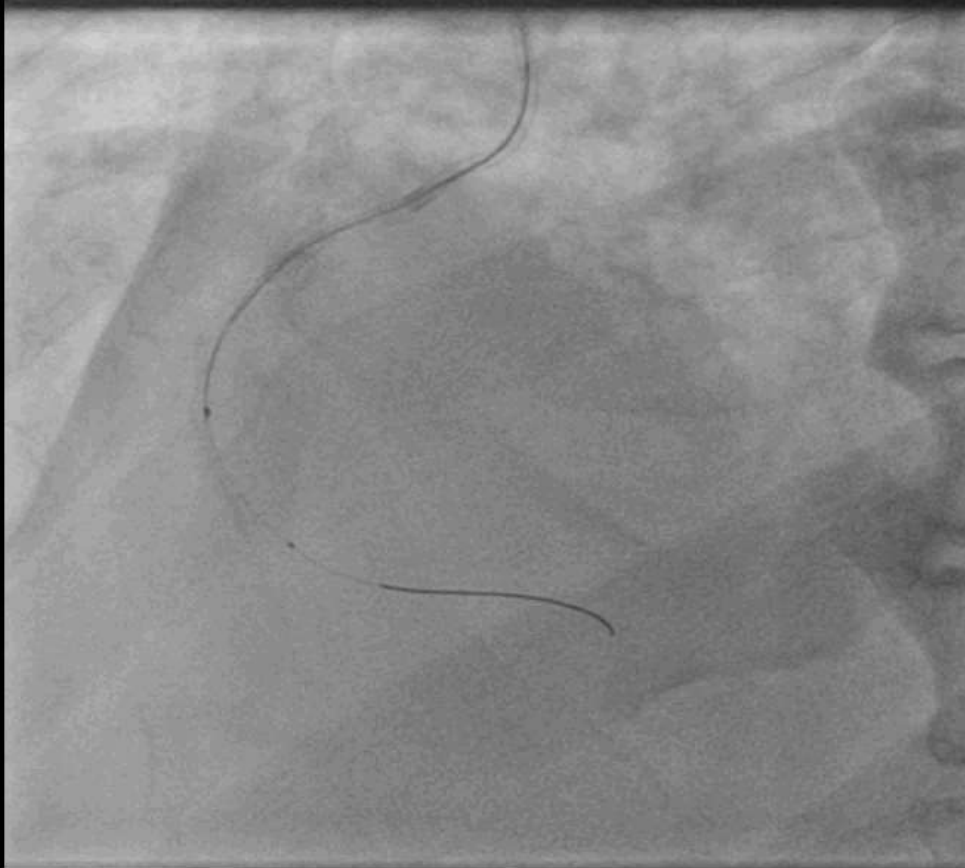


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Image: 1/9



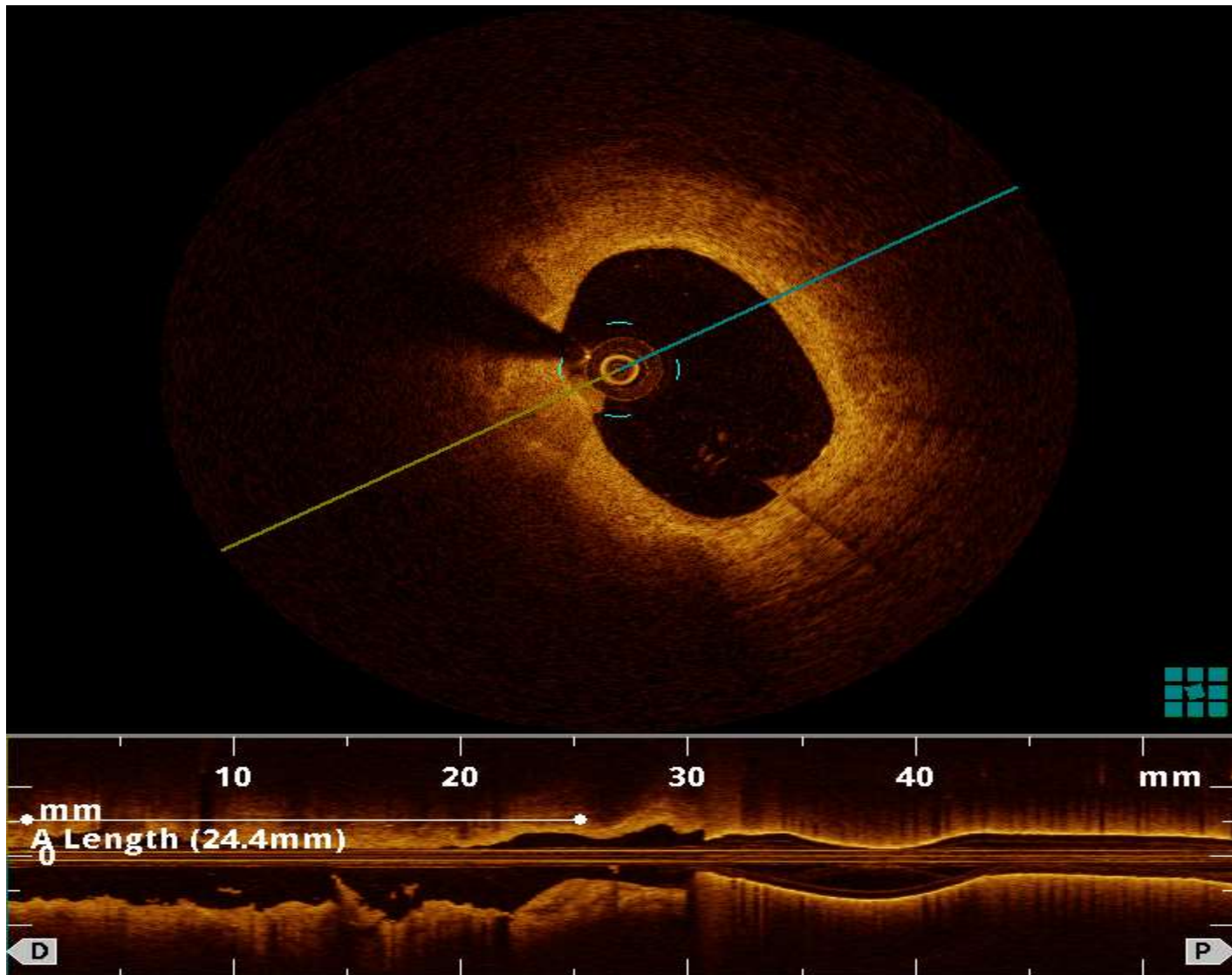
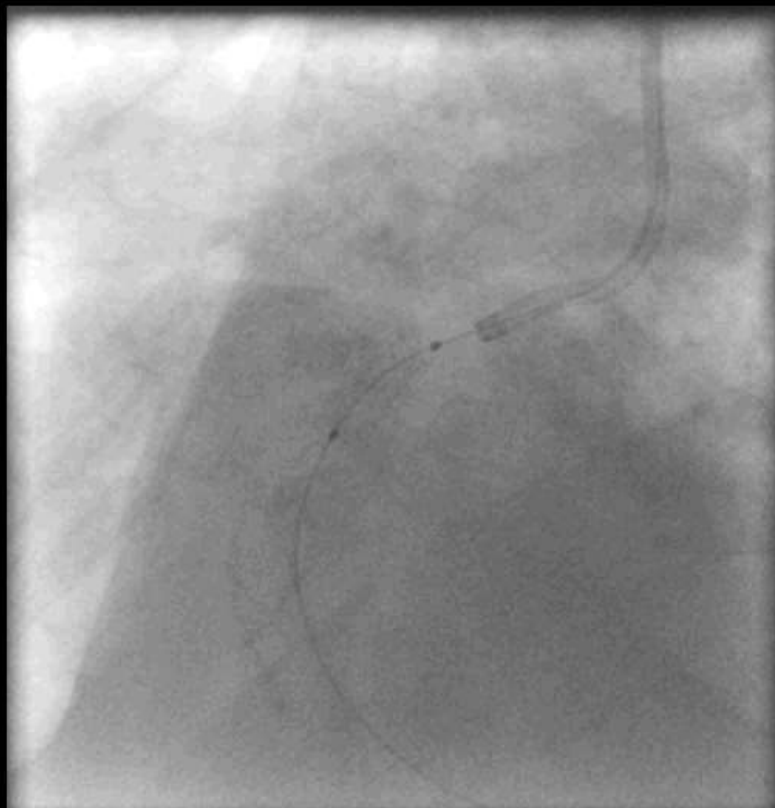


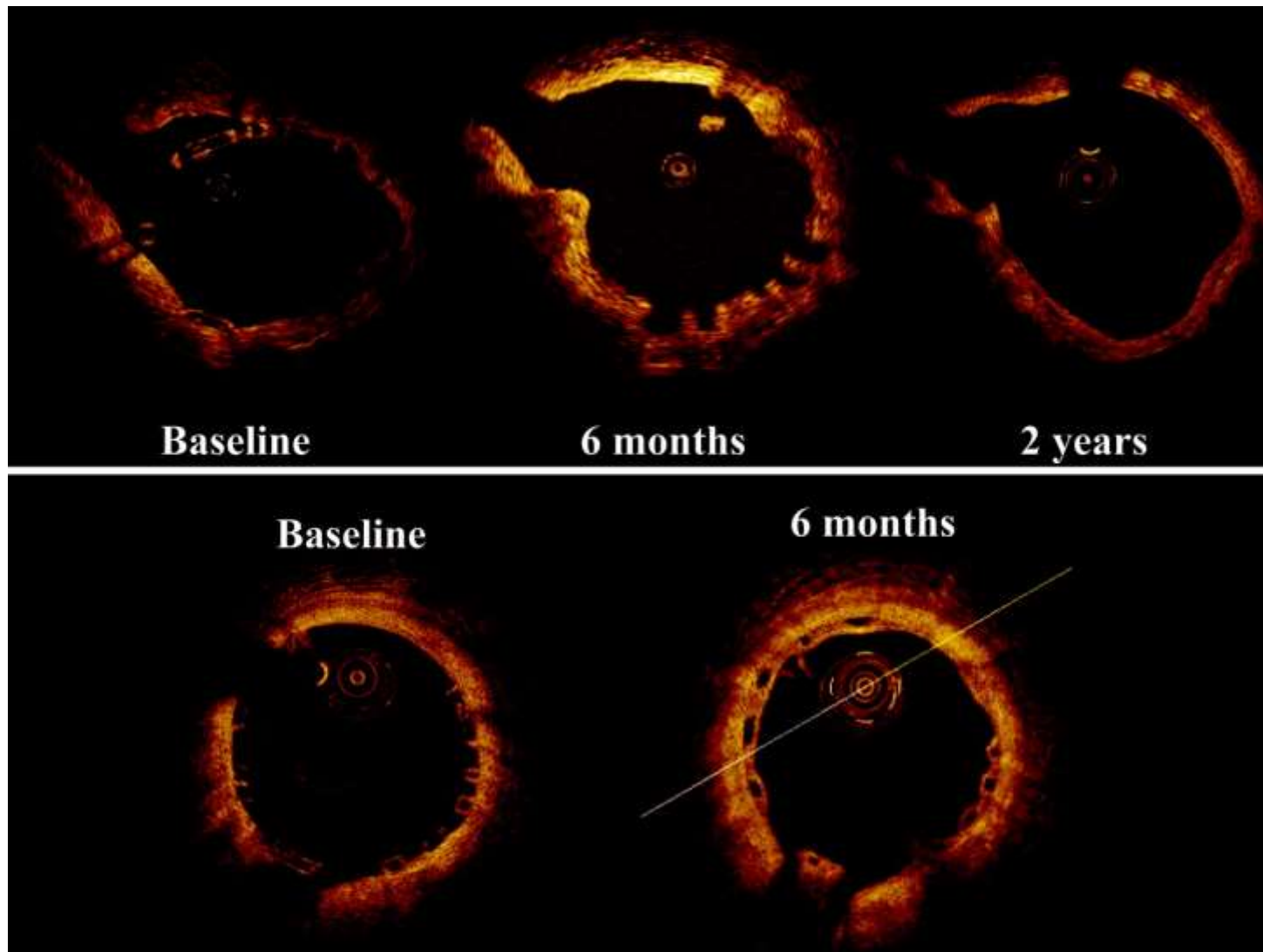
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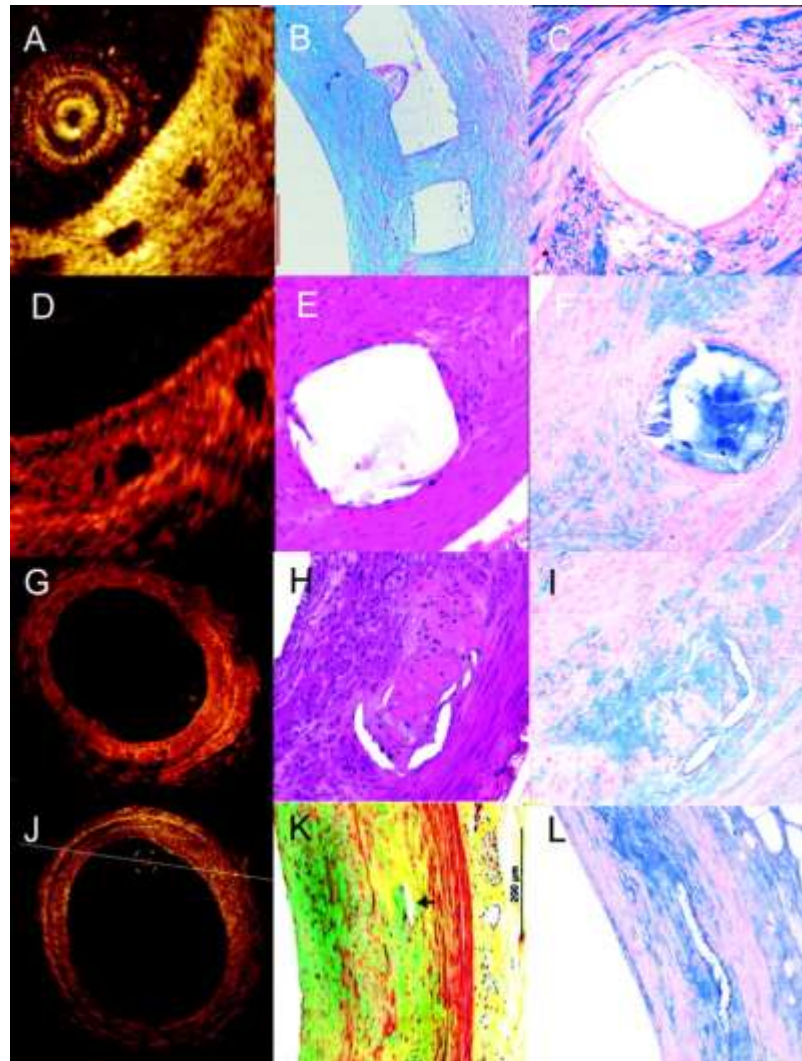
Image: 1/25



## Top, Serial changes in OCT images after implantation of BVS 1.0.



# OCT and histology at 28 days and 2, 3, and 4 years after stent implantation.



Yosinobu Onuma, and Patrick W. Serruys *Circulation*. 2011;123:779-797



Image: 1/48

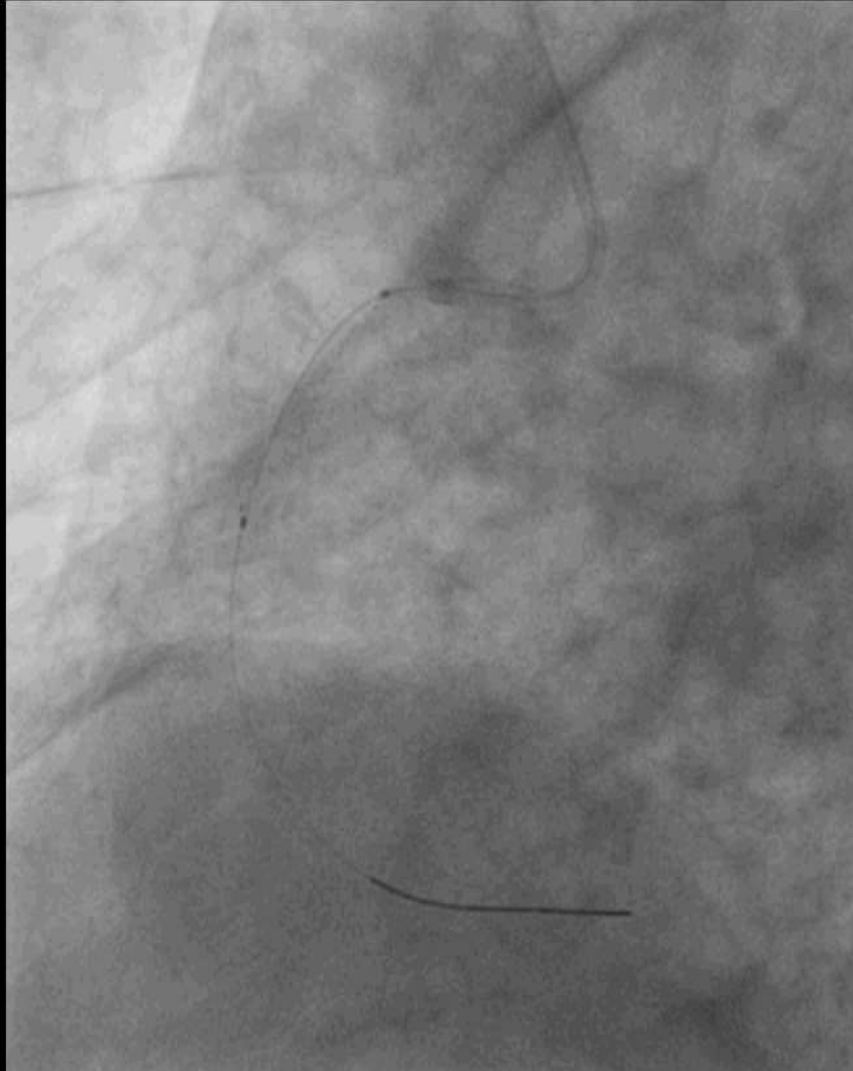


Image: 1/50



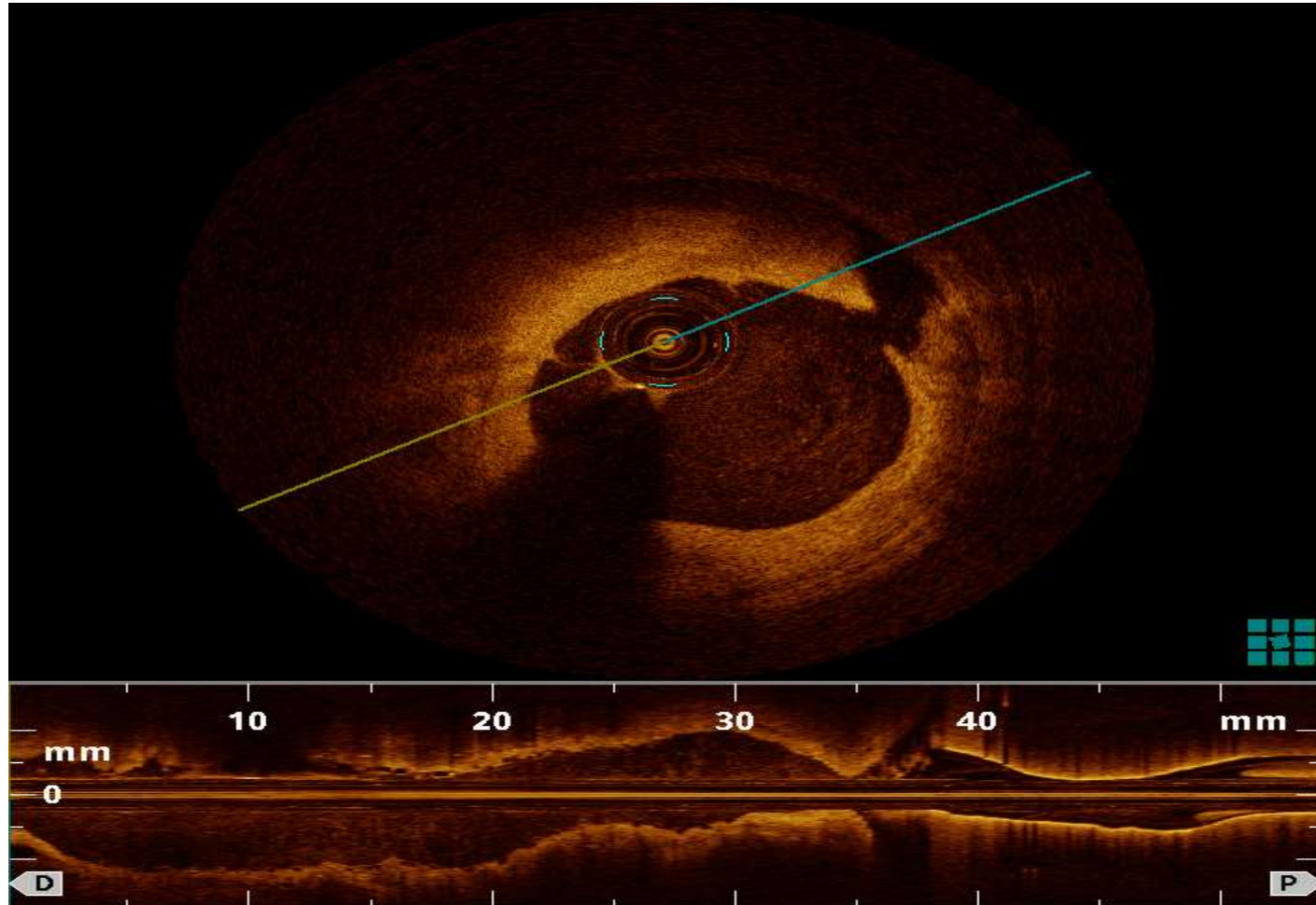


# High pressure NC Balloon dilatation

Image: 1/67

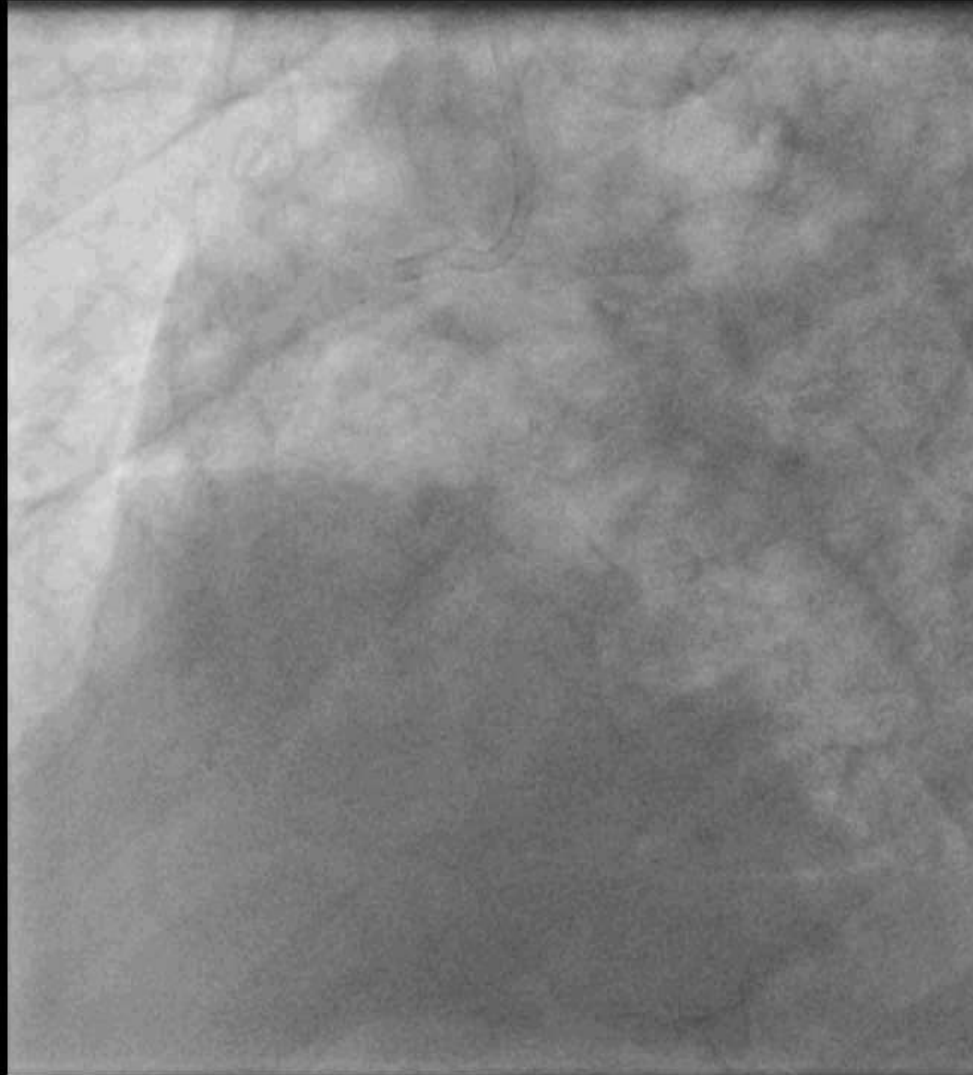


# OCT - Post Stent deployment and after high pressure balloon dilatation



# Final Angiogram

Image: 1/47



# Increased Incidence of Stent Thrombosis with BRS

In the *Lancet* paper, Salvatore Cassese, MD, of Deutsches Herzzentrum (Munich, Germany), conducted a meta-analysis of 6 clinical trials, including [ABSORB China](#), [ABSORB Japan](#), [ABSORB II](#) and [III](#), [EVERBIO II](#) and [TROFI II](#), and found that the rate of definite or probable stent thrombosis after a median of 12 months was significantly increased among patients who received the Absorb bioresorbable scaffold compared with those who received an everolimus-eluting metallic stent (OR 1.99; 95% CI 1.00-3.98). Stents included Xience V, Prime, and Expedition (Abbott Vascular).

Specifically, among 2309 patients with the bioresorbable stent, the rate of definite or probable stent thrombosis was 1.3% compared with 0.5% in the 1382 patients who received a Xience stent. There was also a trend toward more MI—5.2% with the Absorb device vs 3.5% with the everolimus-eluting stent—but the difference was not statistically significant. Rates of target lesion revascularization, target lesion failure, and all-cause mortality were all similar at one year.

The *JACC: Cardiovascular Interventions* report, by Michael Lipinski, MD, and Ron Waksman, MD, of the MedStar Cardiovascular Research Network (Washington, DC), included an expanded meta-analysis of trials testing the Absorb stent as well as data from other registries, such as [GHOST-EU](#). In all, this included data on 8,351 patients treated with the Absorb scaffold and 2,159 patients receiving a metallic DES. Overall, the rate of definite/probable stent thrombosis, at 1.2%, was twice as high for the Absorb-treated patients compared with DES-treated patients (OR 2.06; 95% CI 1.07-3.98). Moreover, this analysis showed a statistically significant doubling of MI risk with the bioresorbable stent (OR 2.06; 95% CI 1.31-3.22), but no differences in revascularizations.

And lastly, the analysis of patients treated with the Absorb stent at 2 high-volume centers **in Munich, Germany, published in *Catheterization and Cardiovascular Interventions*, showed that definite stent** thrombosis at 12 months occurred in 2.6% of patients who received the bioresorbable vascular

## Expert Reaction

According to investigators who conducted the German analysis, dubbed “ISAR-ABSORB,” the rate of definite stent thrombosis is “not insignificant” and needs further study. More patients with longer follow-up are required “before we can be sure of the role of these devices in clinical practice,” said senior investigator Robert Byrne, MD, and colleagues.

Gregg W. Stone, MD, Columbia University Medical Center (New York, NY), said the stent thrombosis signal was observed in the registry data, although it has declined over time, and was also seen again in the randomized trials, including ABSORB III, for which Stone was the study chairman. “On an absolute level, it’s a relatively small increase, but it does seem to be there,” Stone said in an interview. Still, the hazard needs to be put in perspective, particularly given the learning curve with this technology, he argued. “Physicians were using this device for the first time in the setting of these studies.

It may be that the increased risk of thrombosis might be the result of inadequately matching the scaffold to the vessel or being placed in small vessels, Waksman said. For example, in ABSORB III, the overall rate of stent thrombosis was 1.5% for patients treated with the Absorb stent and 0.7% in patients treated with the everolimus-eluting metallic stent, a nonsignificant difference.

**Routine Post Implant high pressuredilatation, newer Antiplatelets, Prasugrel therapy are important to be considered.**

# Take home message

- **Very late stent thrombosis is a different pathology**  
**Optimum DAPT therapy for optimum duration is important**
- **Intervention in Stent thrombosis patients should be done with Intravascular imaging**
- **BRS may be considered in these patients but needs more data for recommendation as acute stent thrombosis is a concern. IC imaging may obviate this problem**
- **BRS implantation must have high pressure post-implant balloon dilation to ensure adequate stent apposition**