

SVG Stenting without Distal Protection Device: My Experience

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Lilavati Hospital

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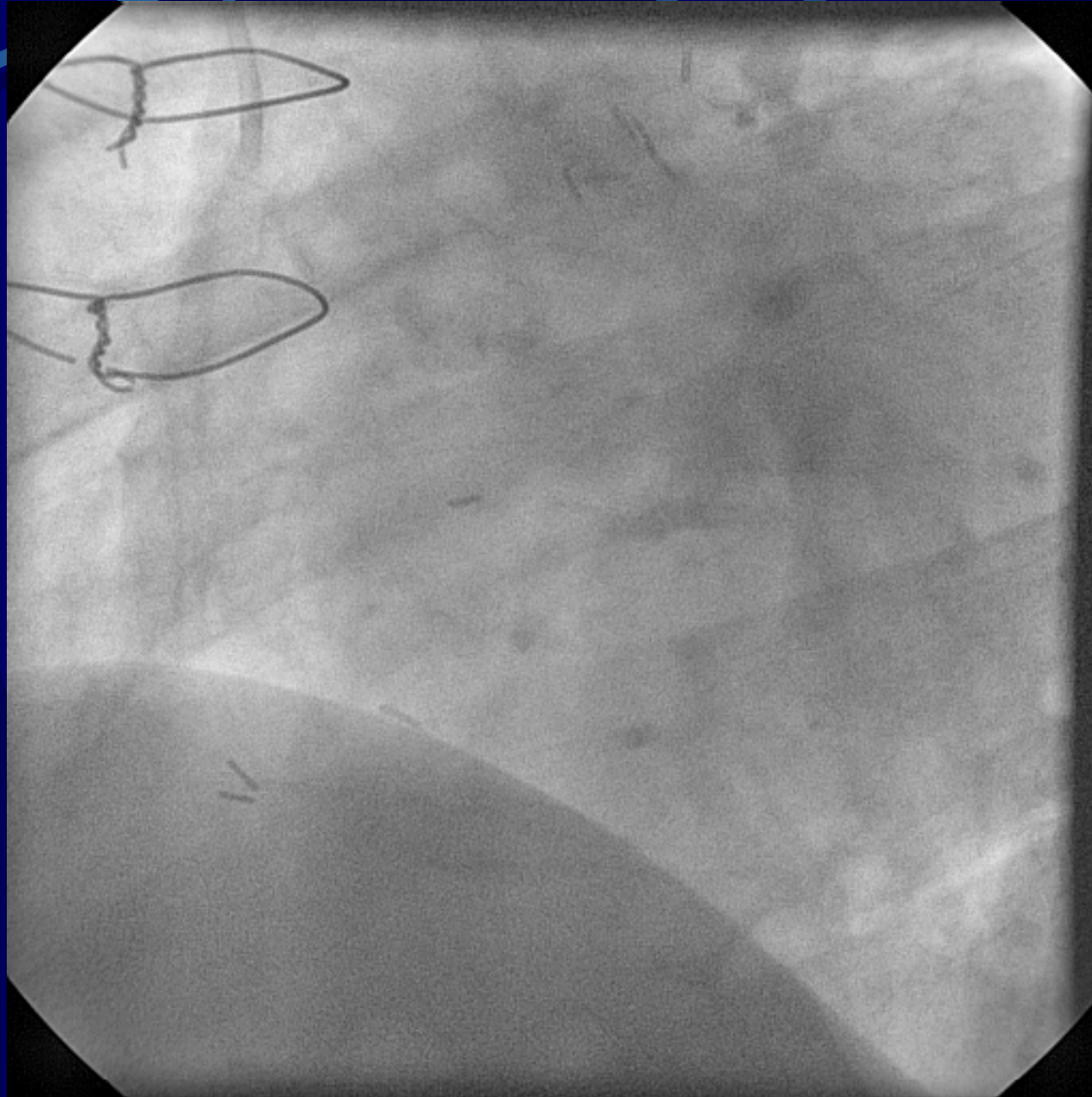
Zynova Heart Hospital

Heart Rhythm Clinic, Mumbai

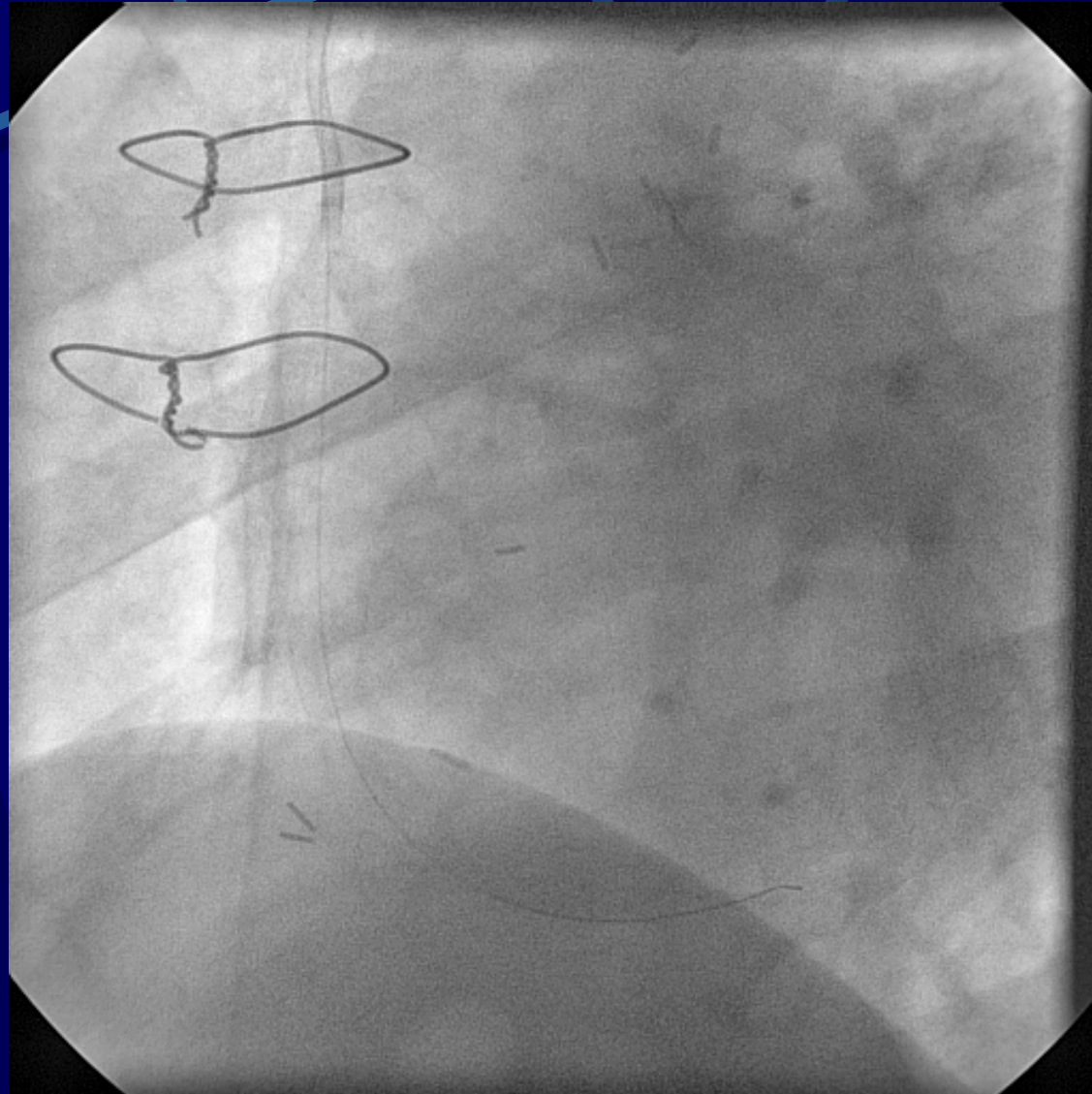


**70/M SVG to PDA 17 yrs ago now with
angina on exertion class III**

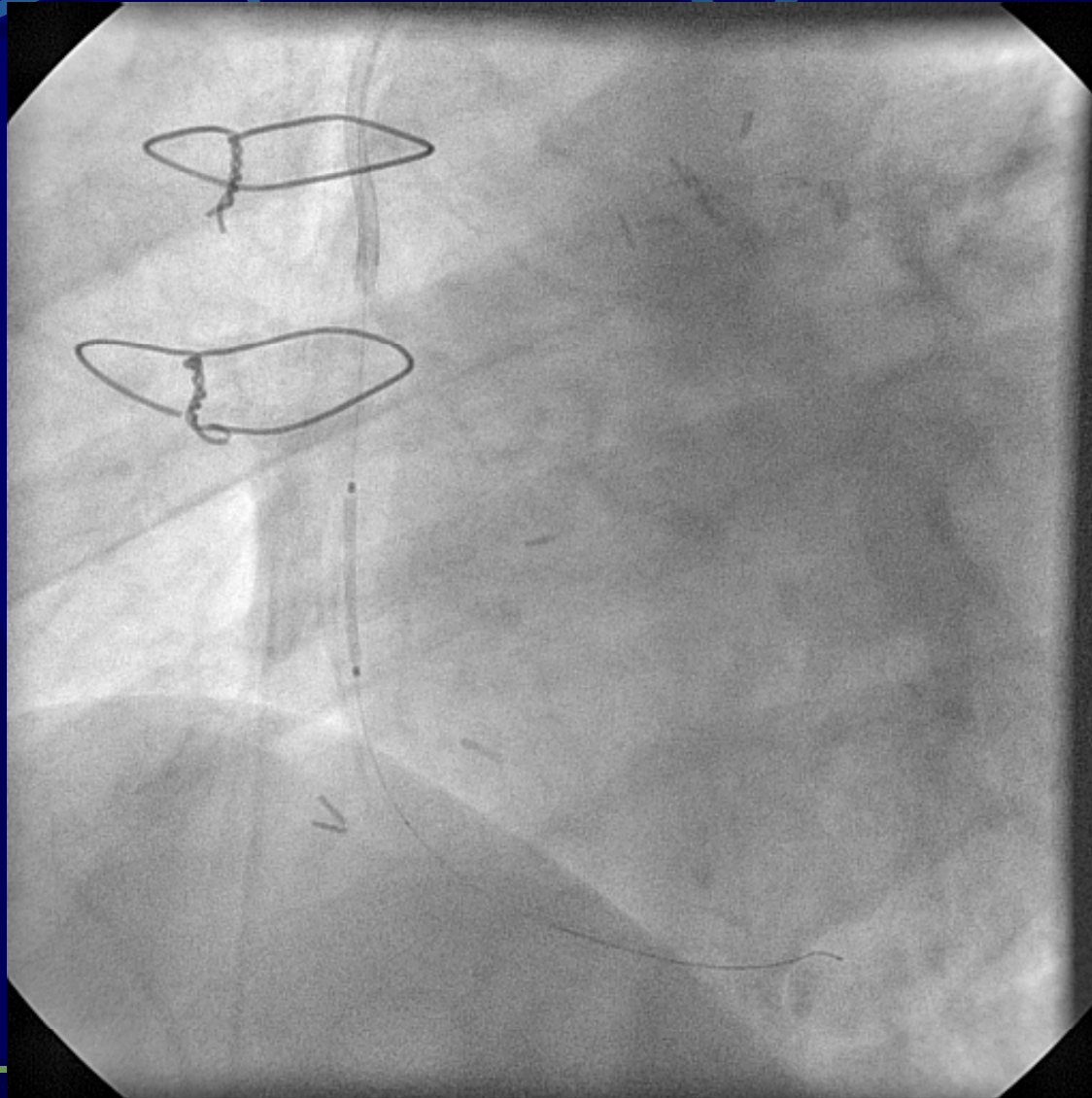
**SVG to PDA was cannulated with AR1
guiding catheter**

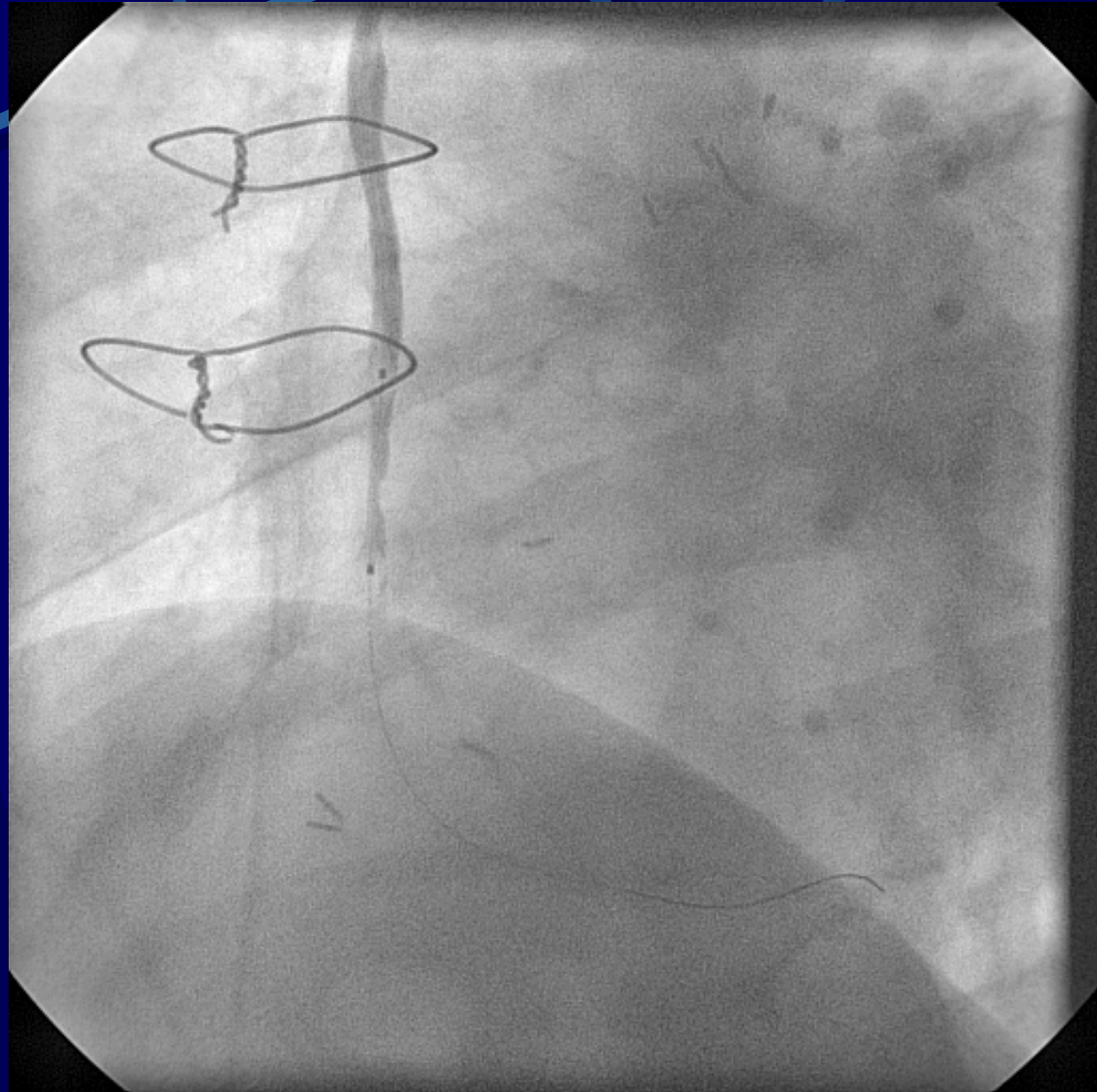


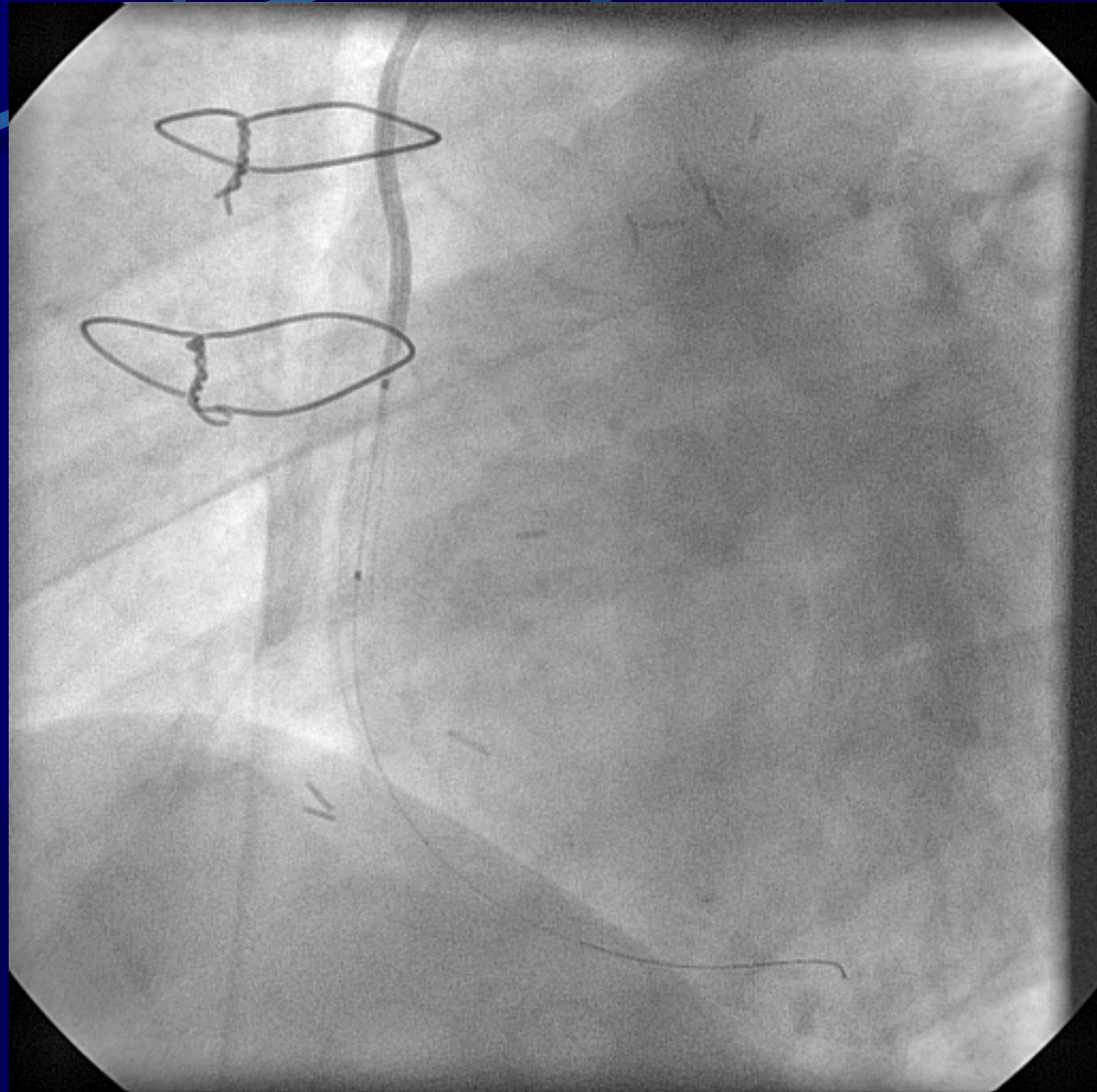
Lesion was crossed with Rinato guidewire

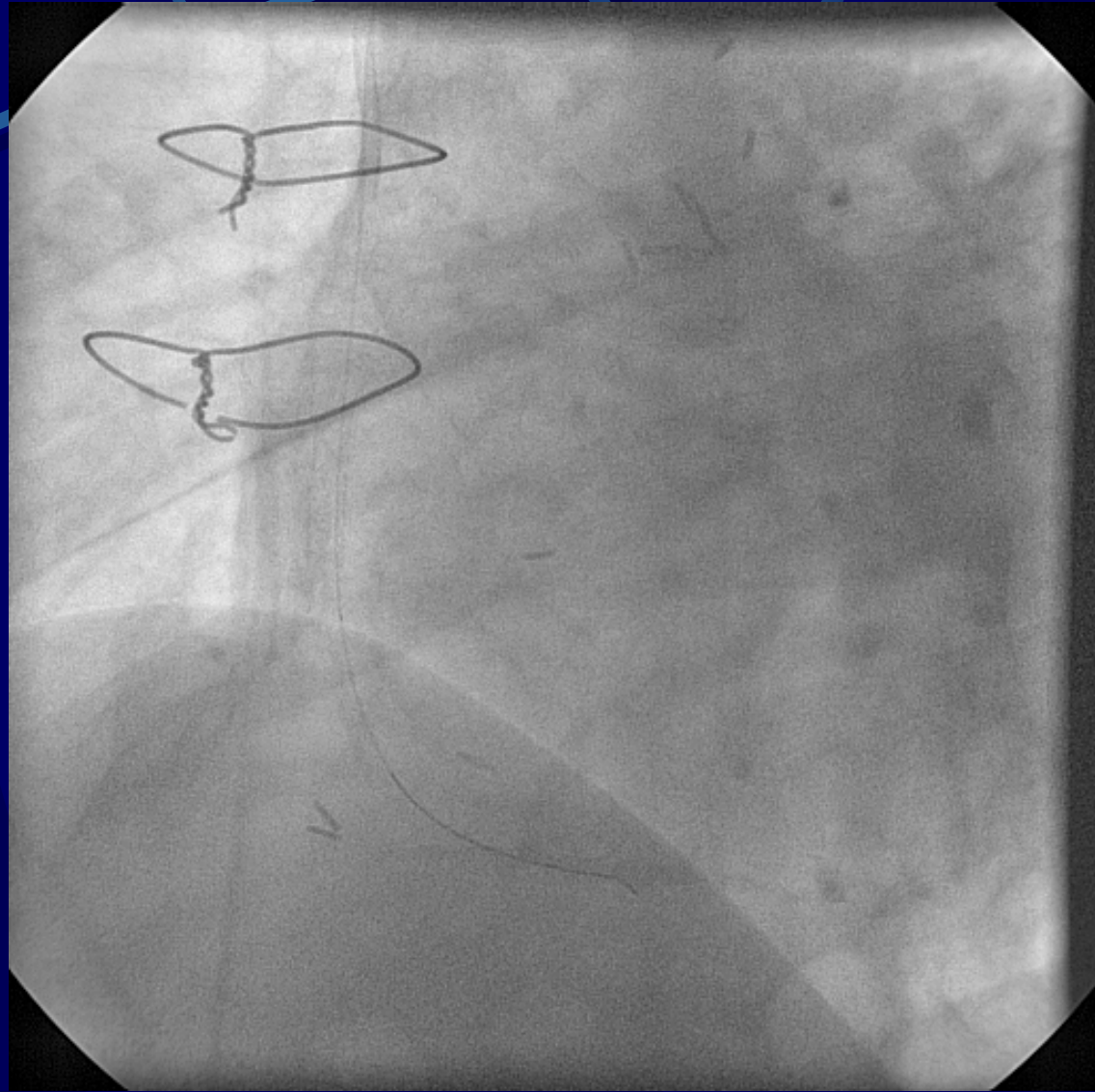


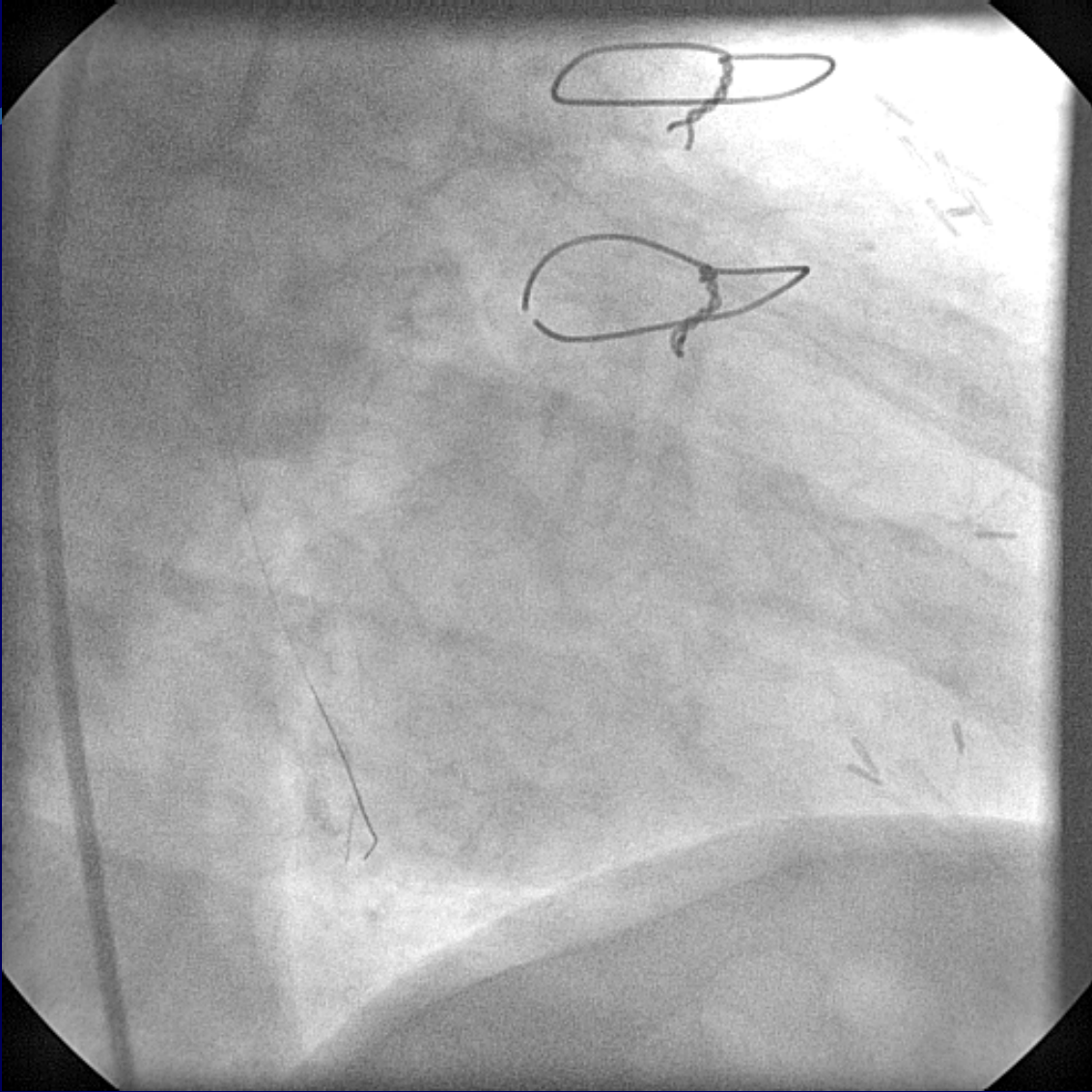
**Lesion was stented with 3x15 mm
Medtronic Endeavor sprint stent**

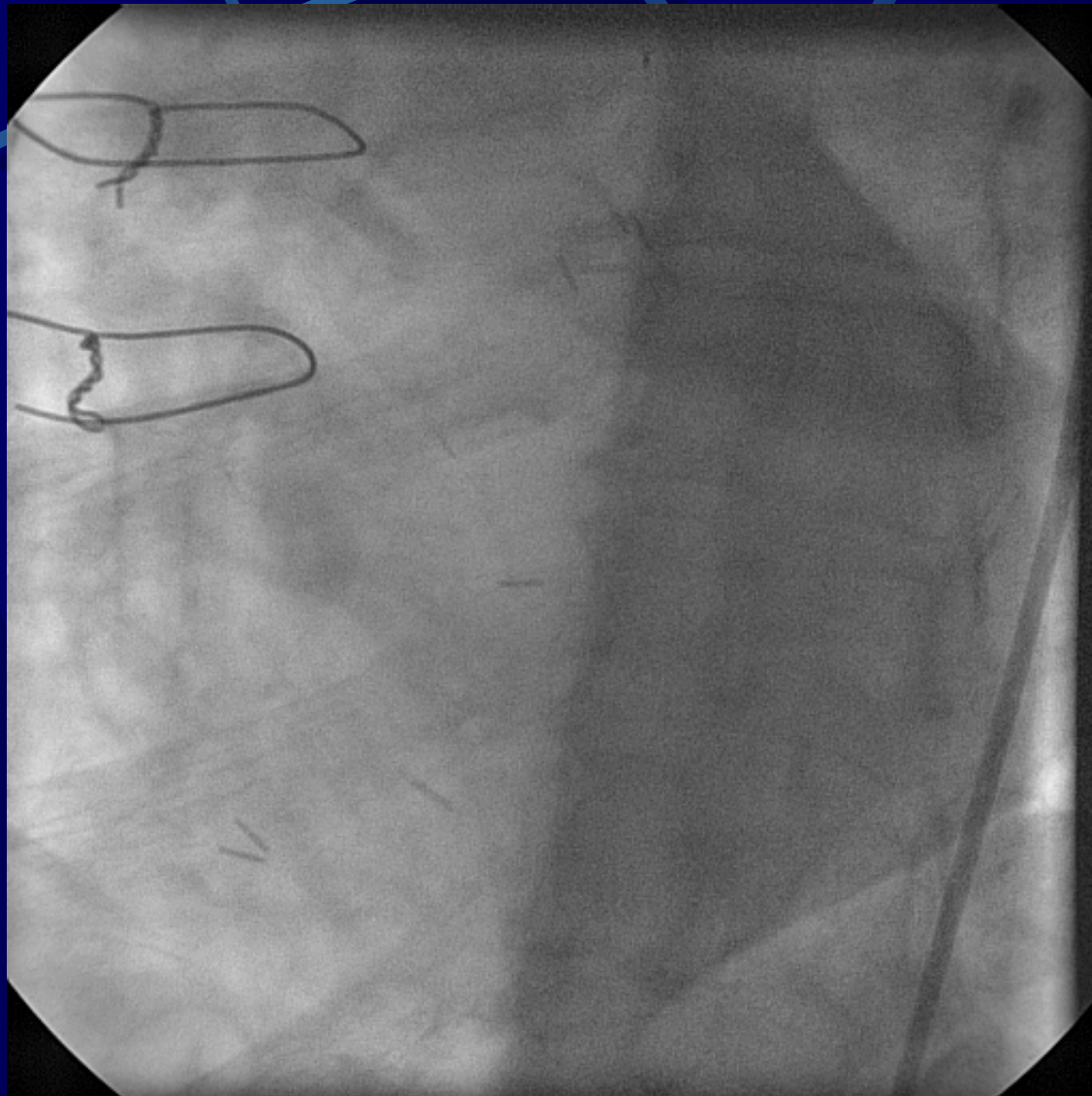


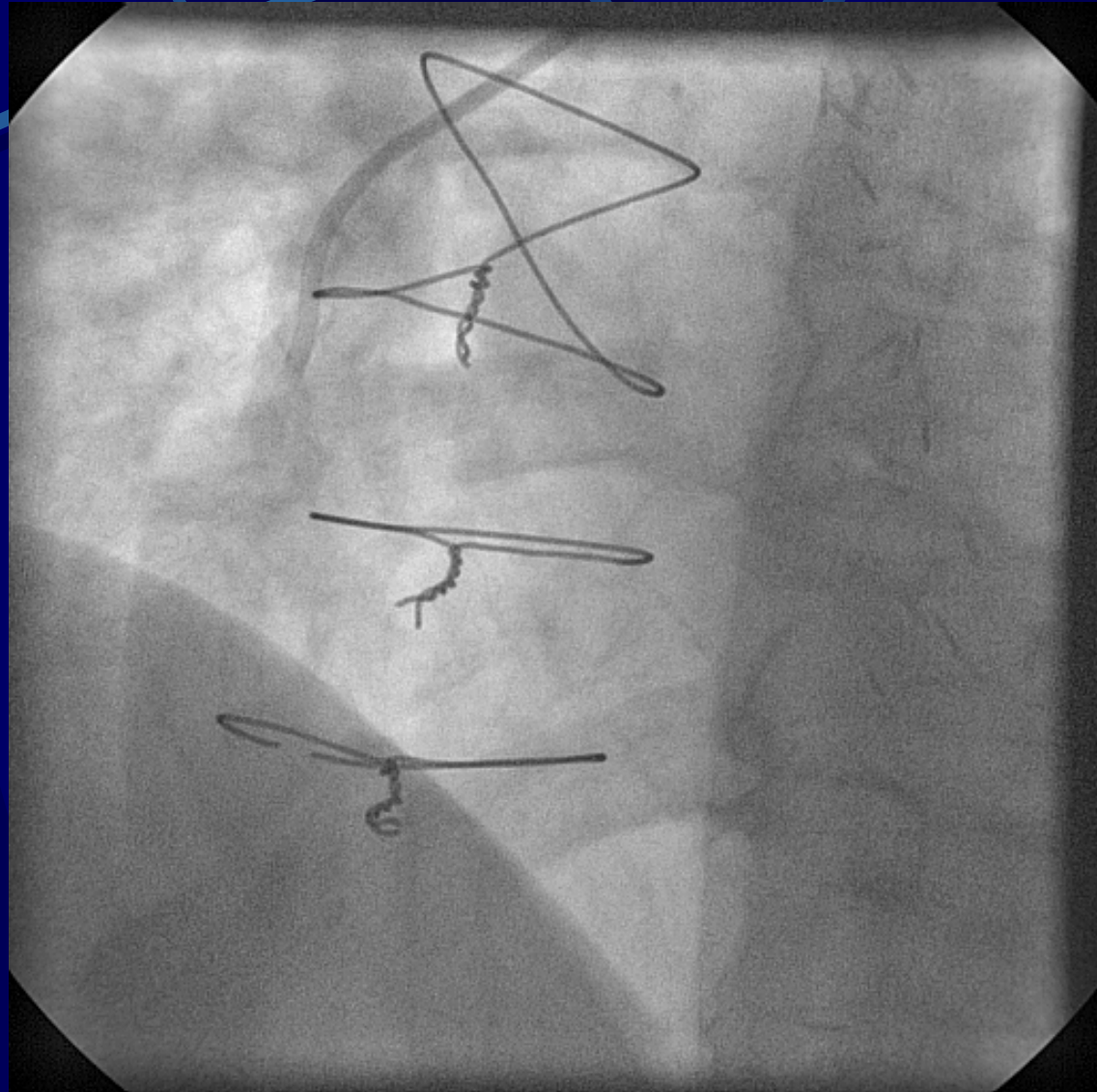






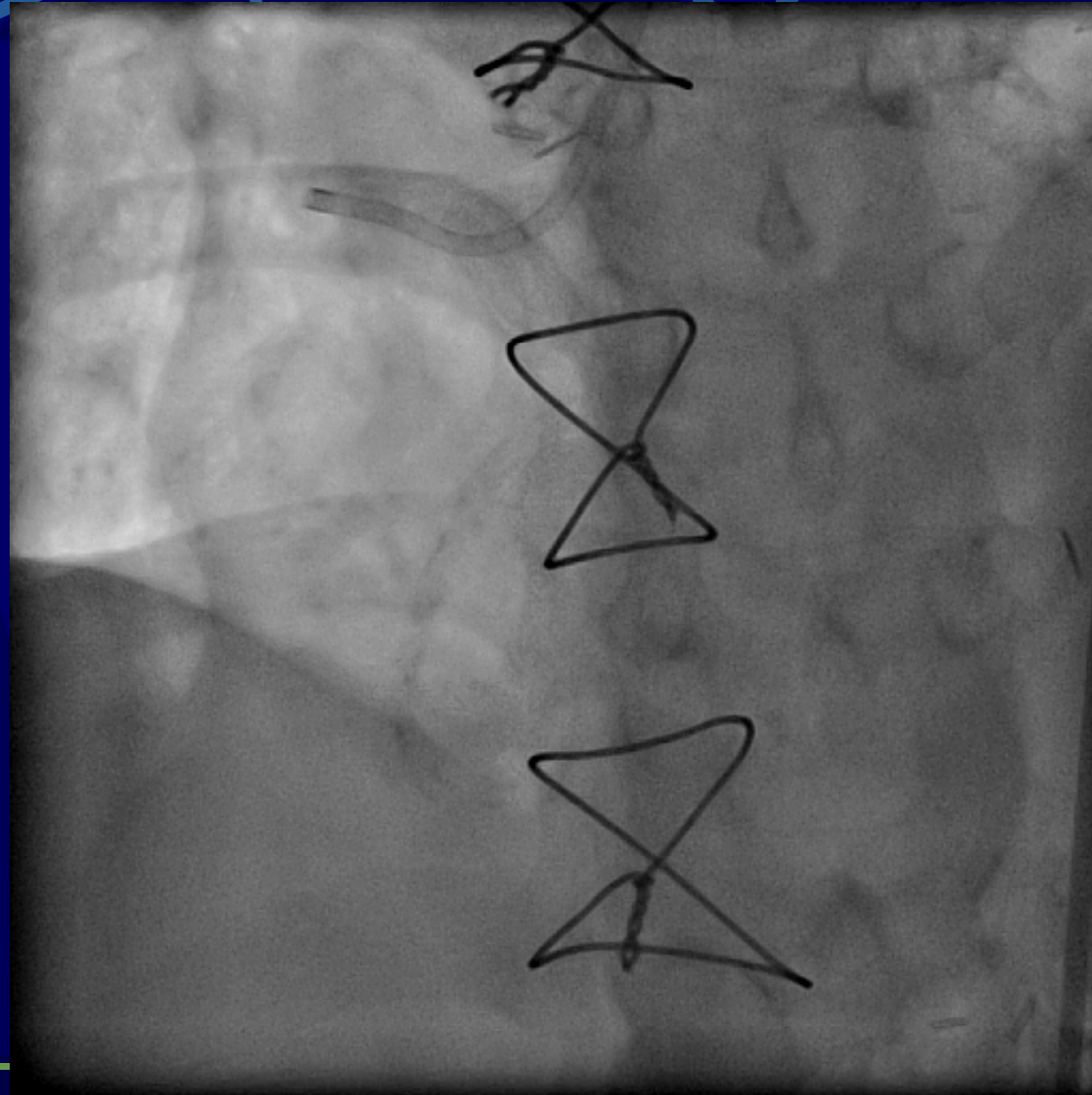




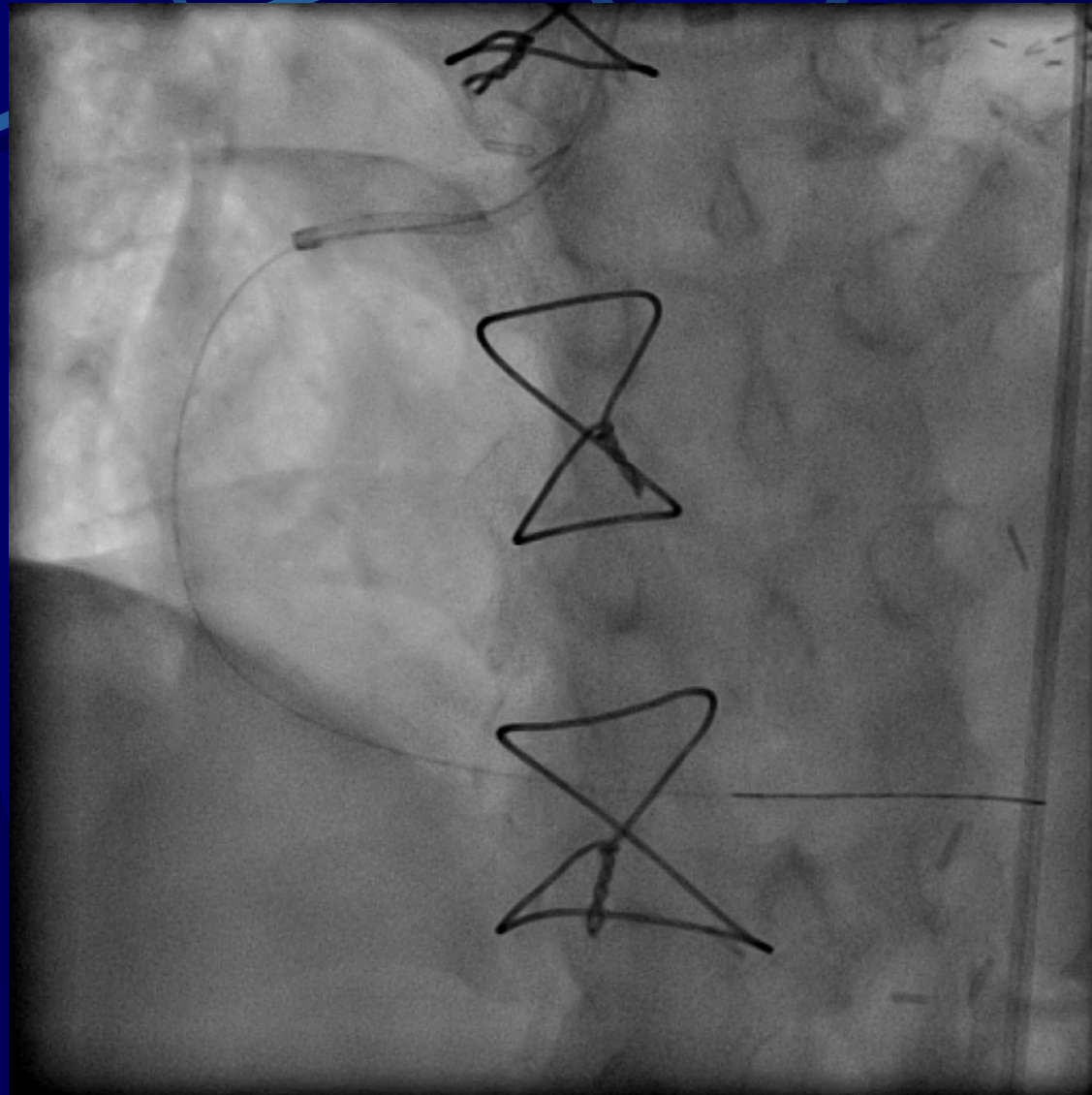


**67/M SVG to PDA 13 yrs ago now with
angina on exertion class III**

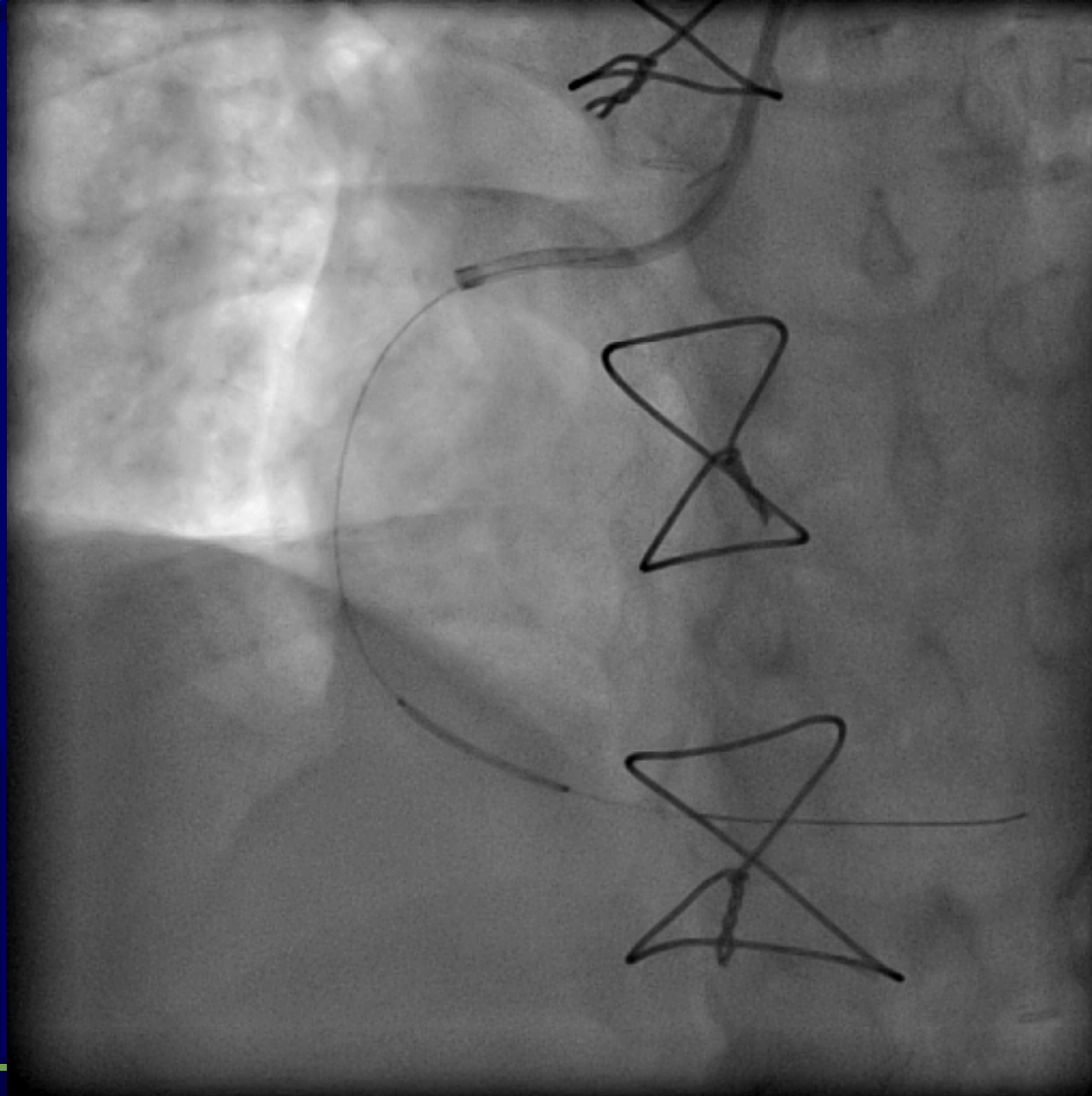
**SVG to PDA was cannulated with AR1
guiding catheter**

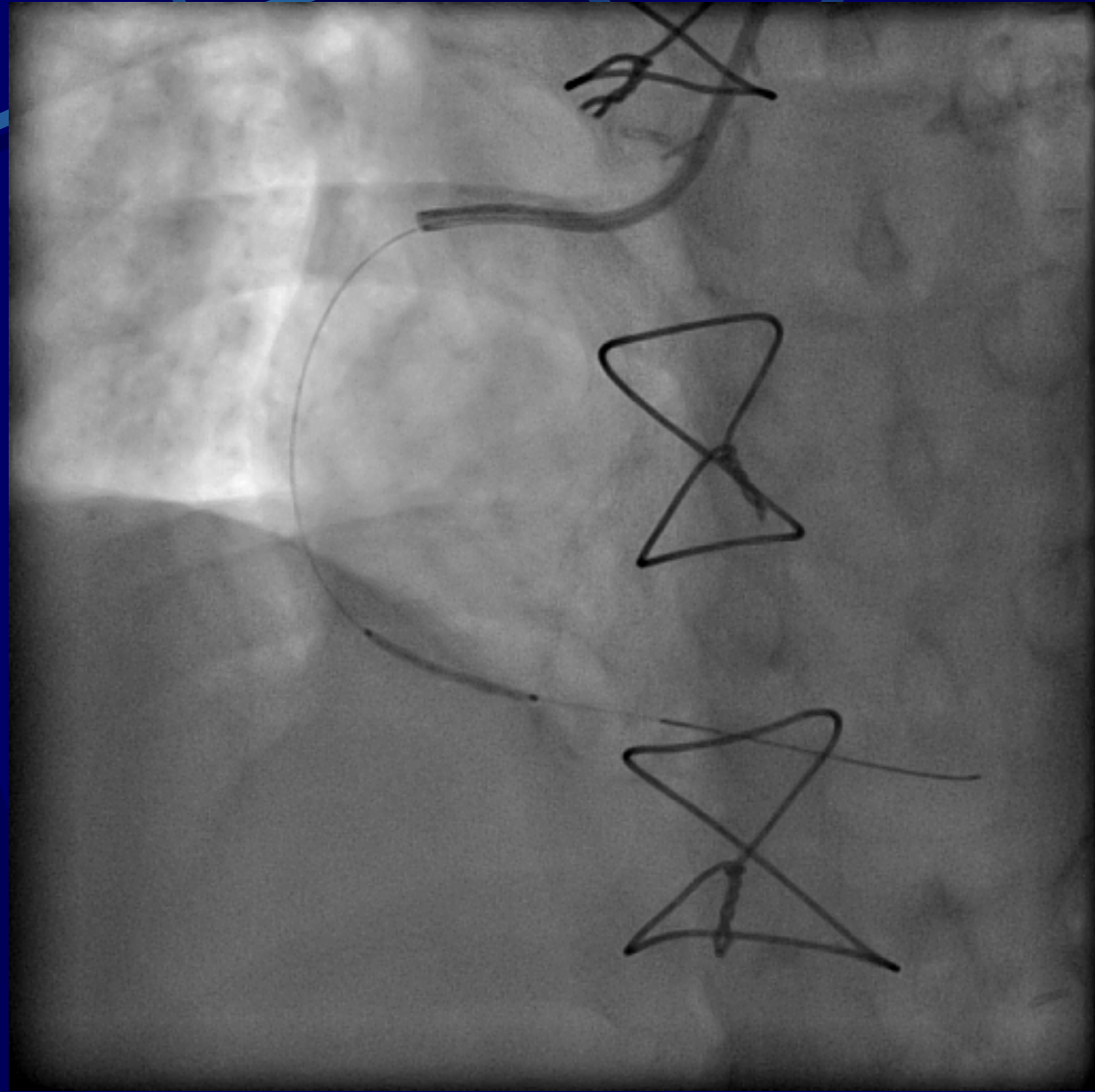


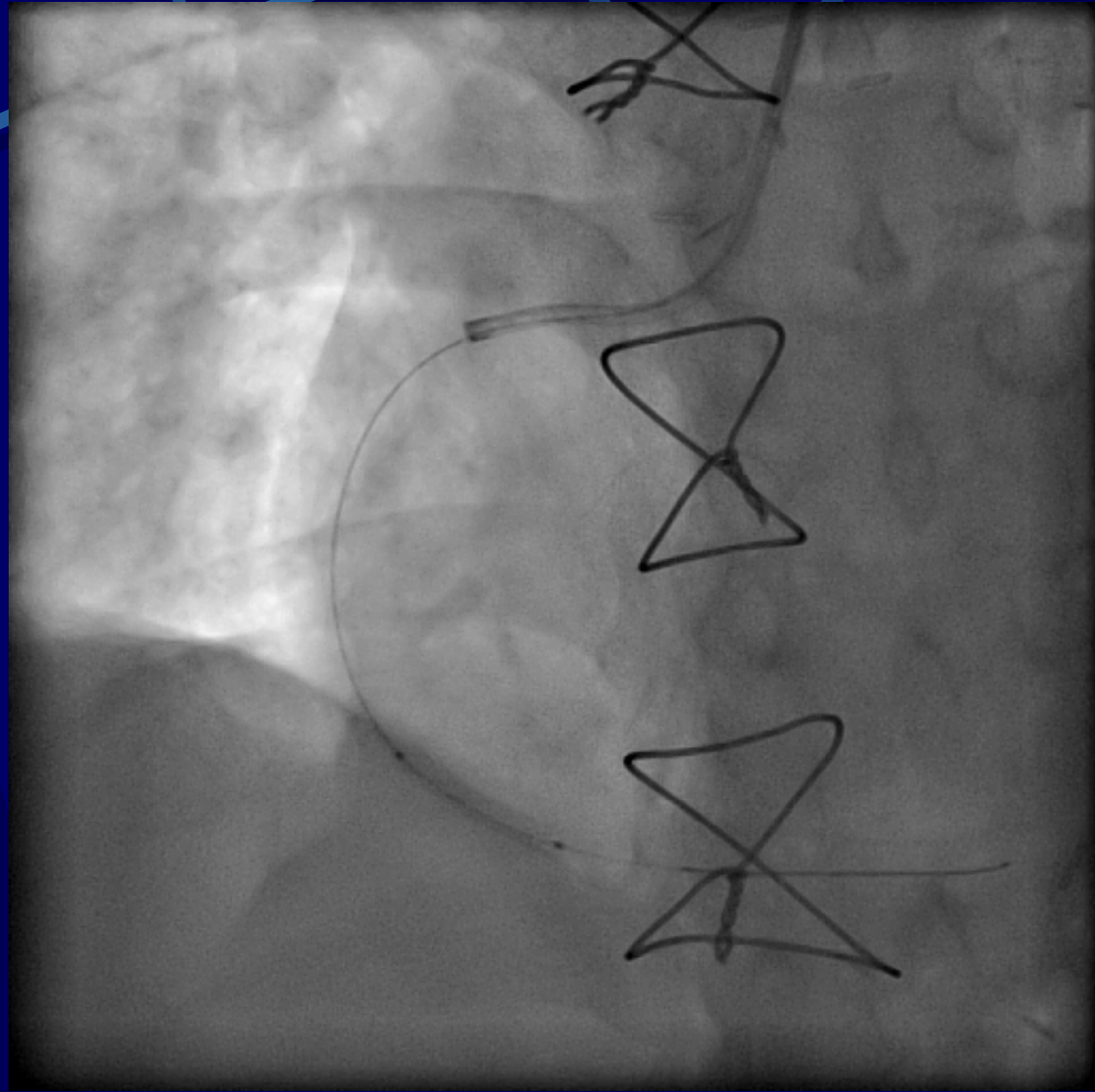
Lesion was crossed with Rinato guidewire

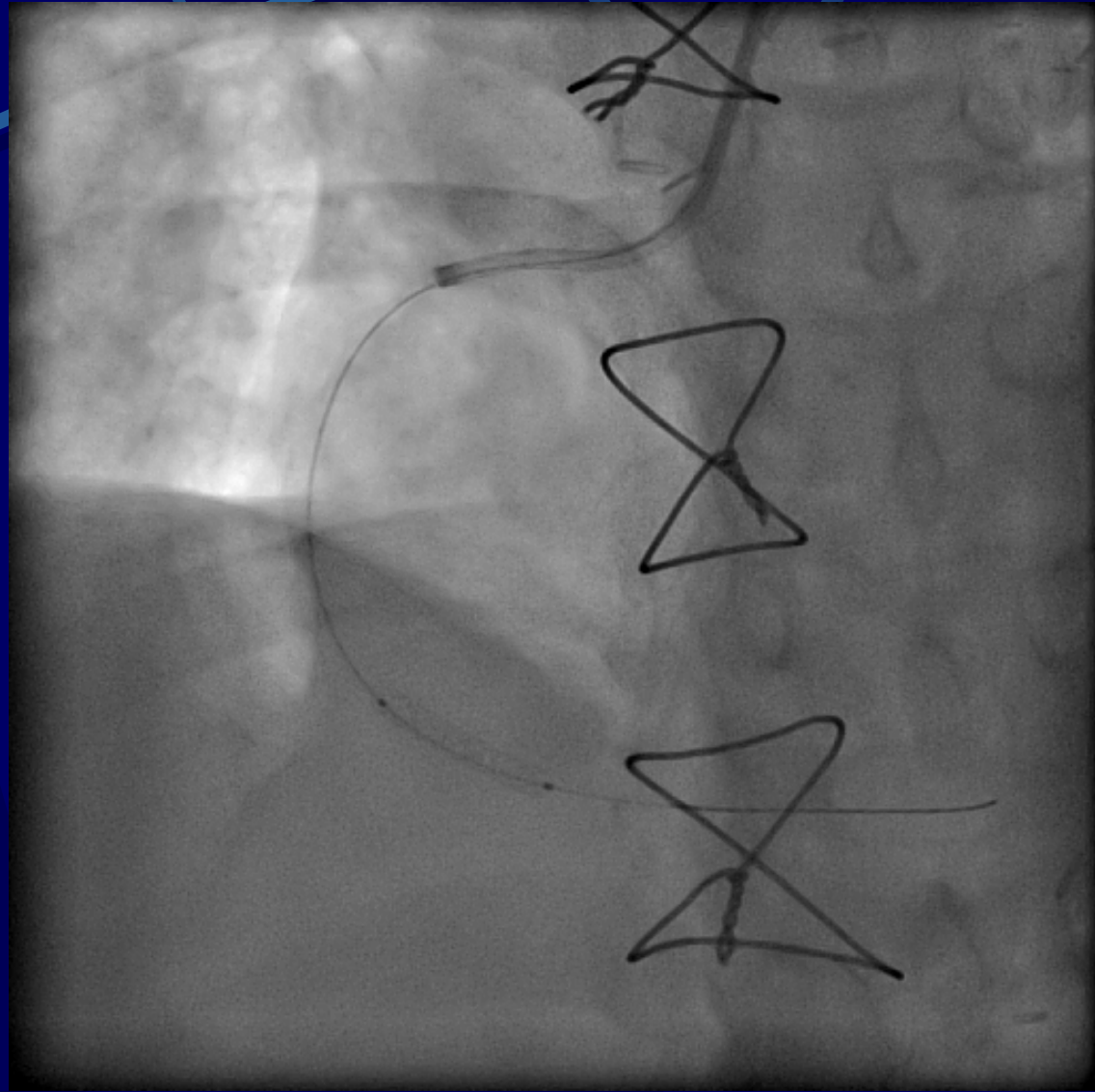


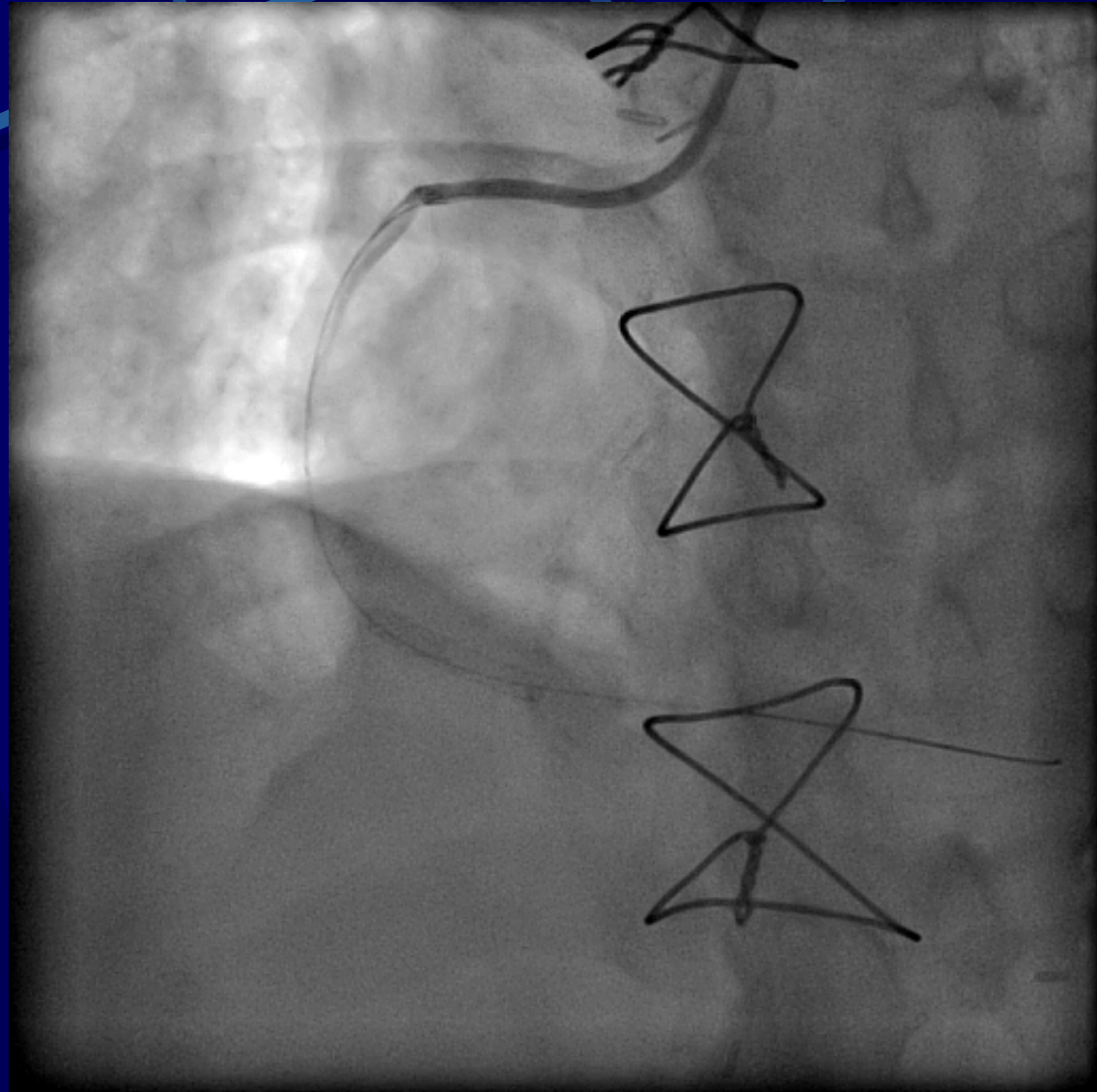
**Lesion was stented with 3x18 mm
Biomime stent**

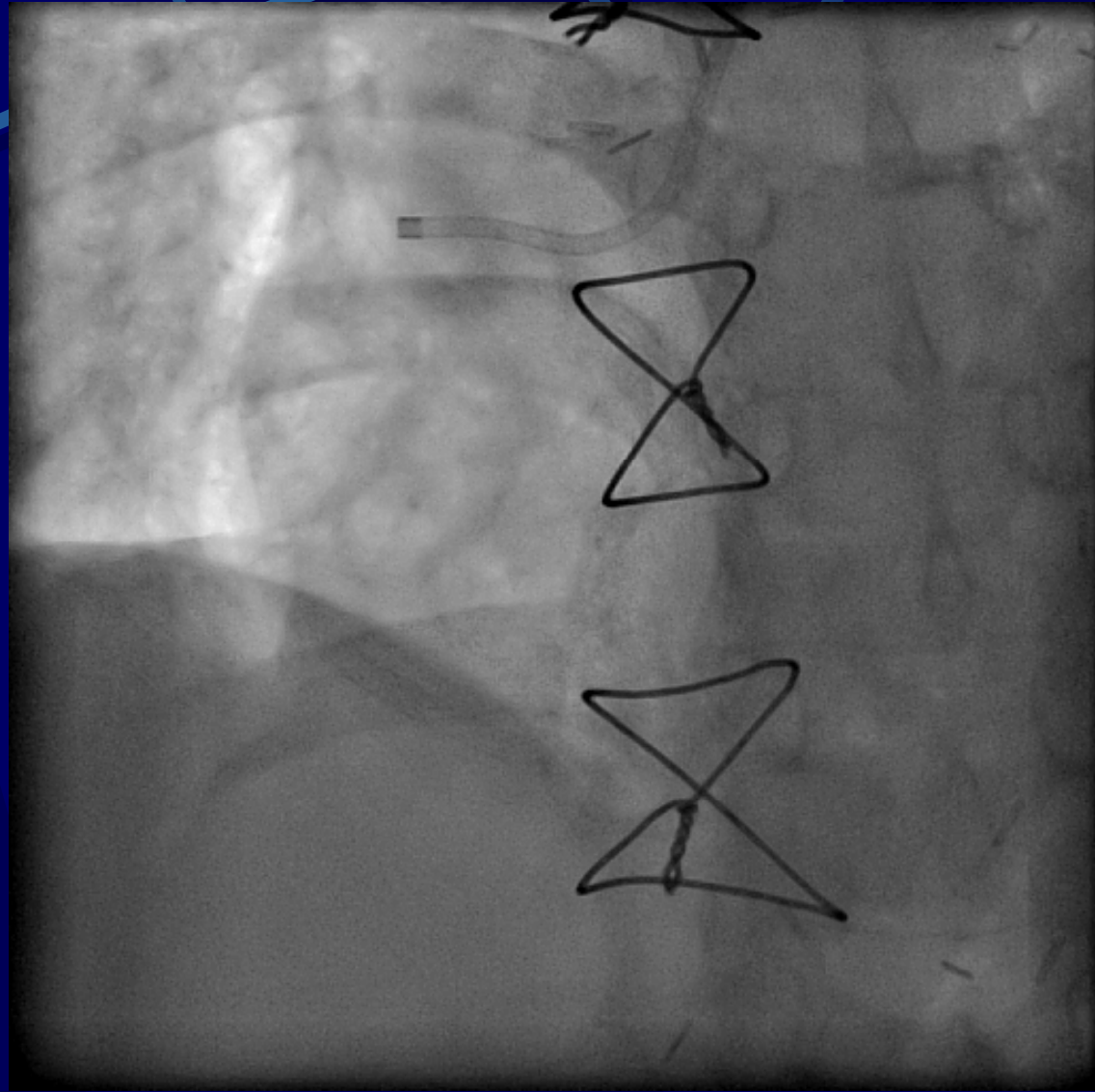


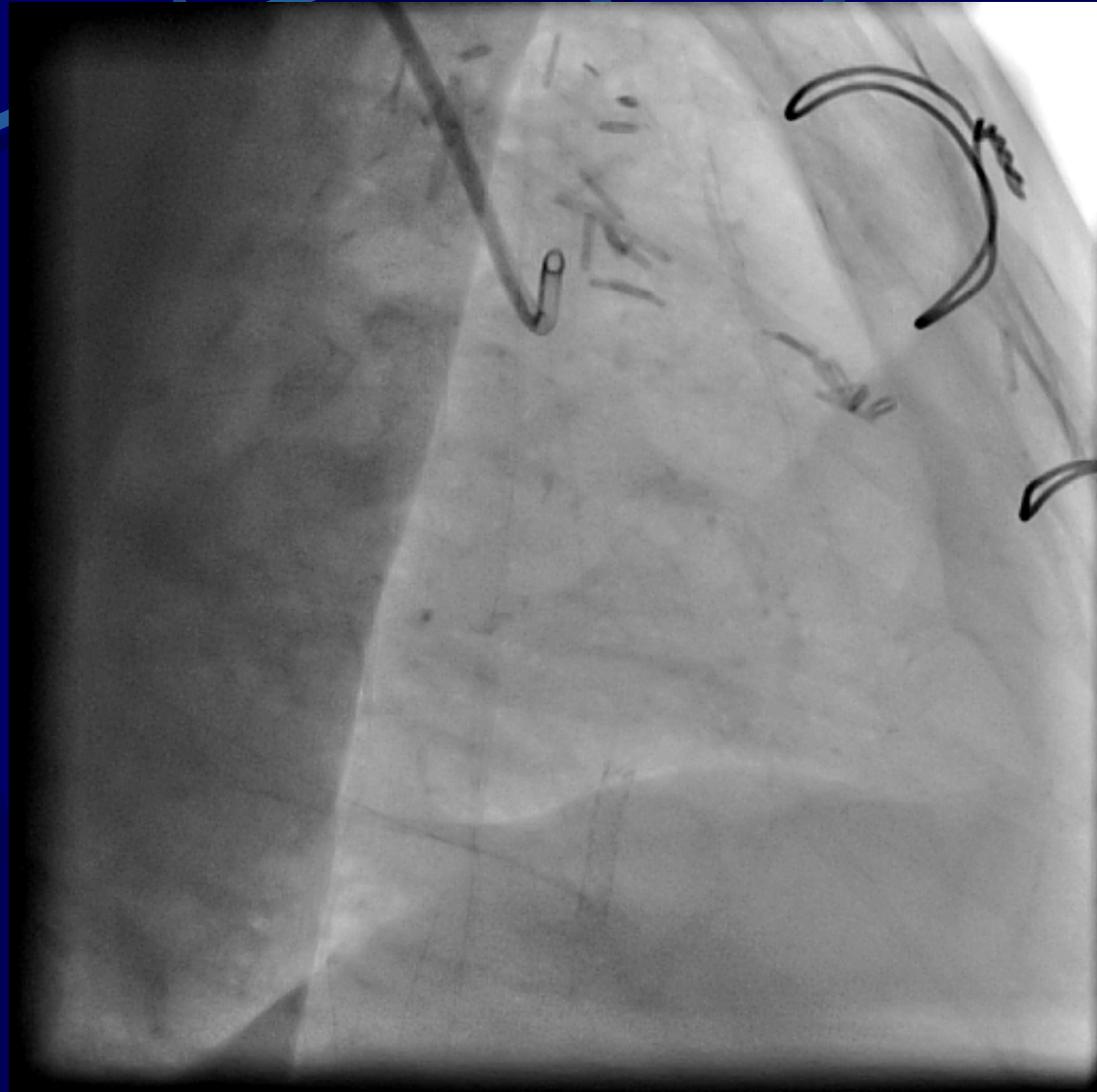




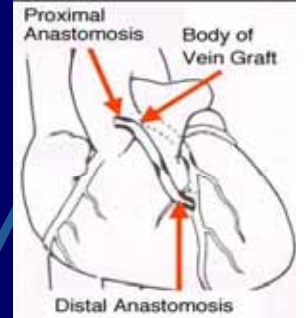








SVG Interventions



- Patients undergoing percutaneous coronary interventions (PCI) in SVGs may have slightly increased risk of adverse events (periprocedural MI) due to plaque embolization
- Distal embolization during SVG PCI is common, and embolic events cannot be accurately predicted by clinical or angiographic variables.
- Mechanical embolic protection devices are used to try to capture the atheroemboli that are liberated during the SVG intervention



Examples of Distal Embolic Protection Devices for SVG Interventions

- **Distal occlusion and aspiration**

- Example:
Medtronic GuardWire®
Temporary Occlusion and
Aspiration System (shown)



- **Distal filters**

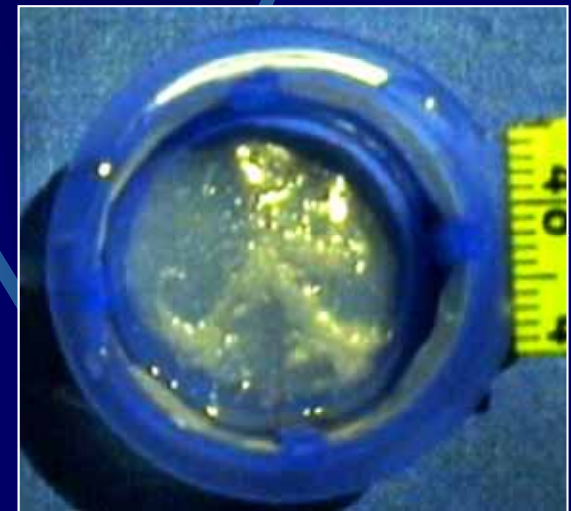
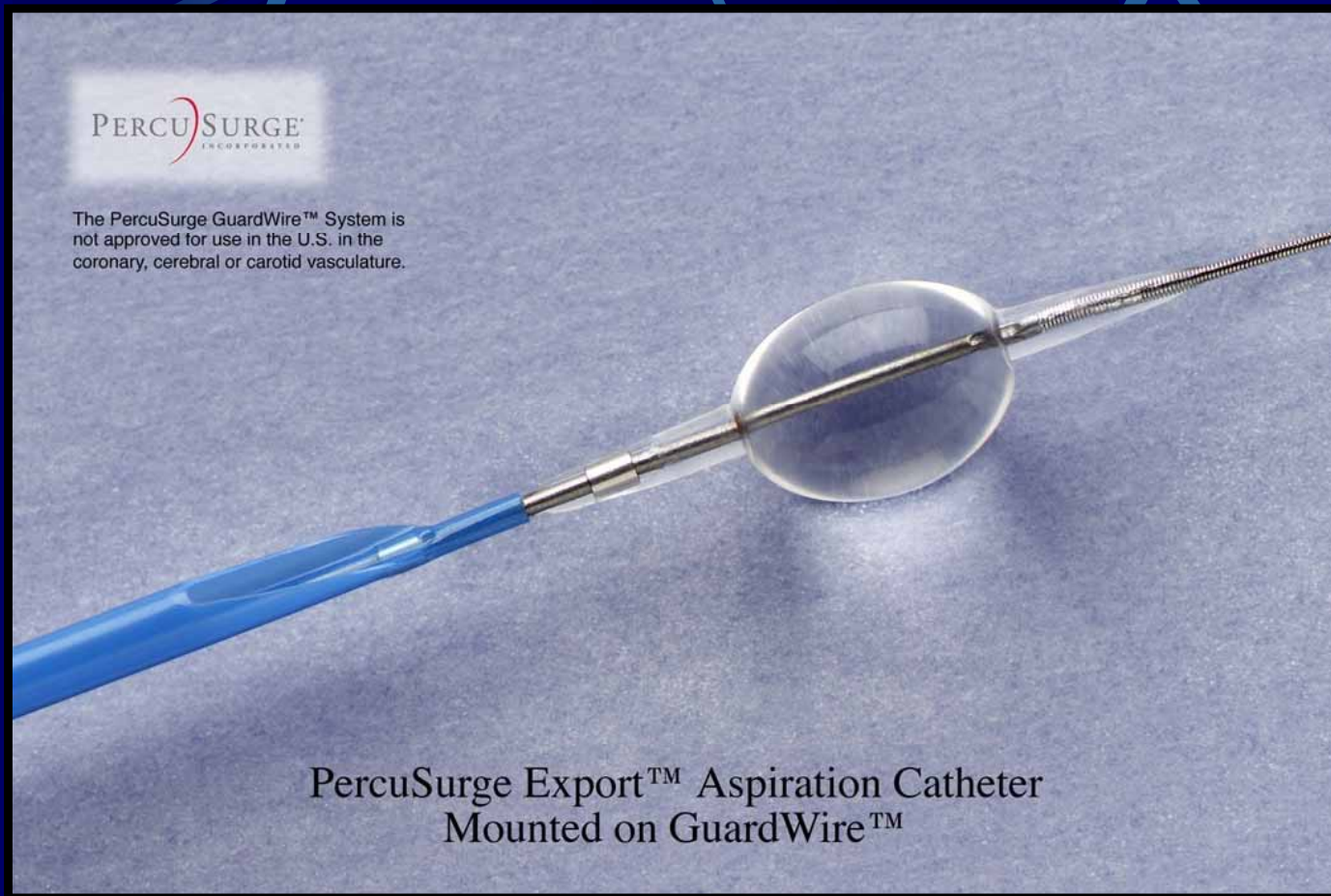
- Example:
Boston Scientific FilterWire
EZ™ Embolic Protection
System (shown)



- Example: ev3 SpiderFX® Embolic Protection Device

The SAFER Trial

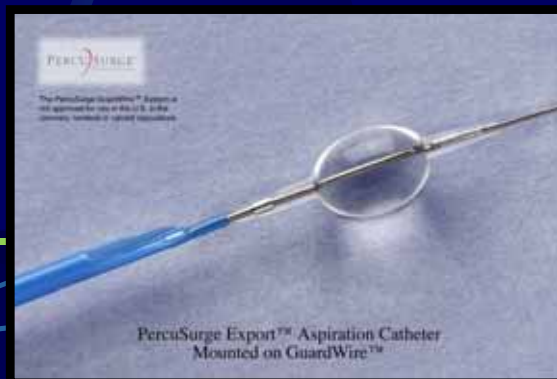
PercuSurge GuardWire System



Donald S. Baim, MD FACC
Harvard Medical School
Brigham and Women's Hospital

The SAFER Trial

- Saphenous Vein Graft Angioplasty Free of Emboli Randomized (SAFER)
- The SAFER Trial studied 801 patients at 47 sites receiving SVG PCI, 406 of these procedures were performed with embolic protection, and 395 were performed without embolic protection
- Defined endpoint: MACE rate at 30 days
 - MACE defined as the composite of death, myocardial infarction, emergency bypass, or target lesion revascularization
- The SAFER Trial showed 30-day MACE rates of 16% (65/395) for SVG patients who underwent PCI without embolic protection, and 10% (39/406) in patients who received embolic protection.

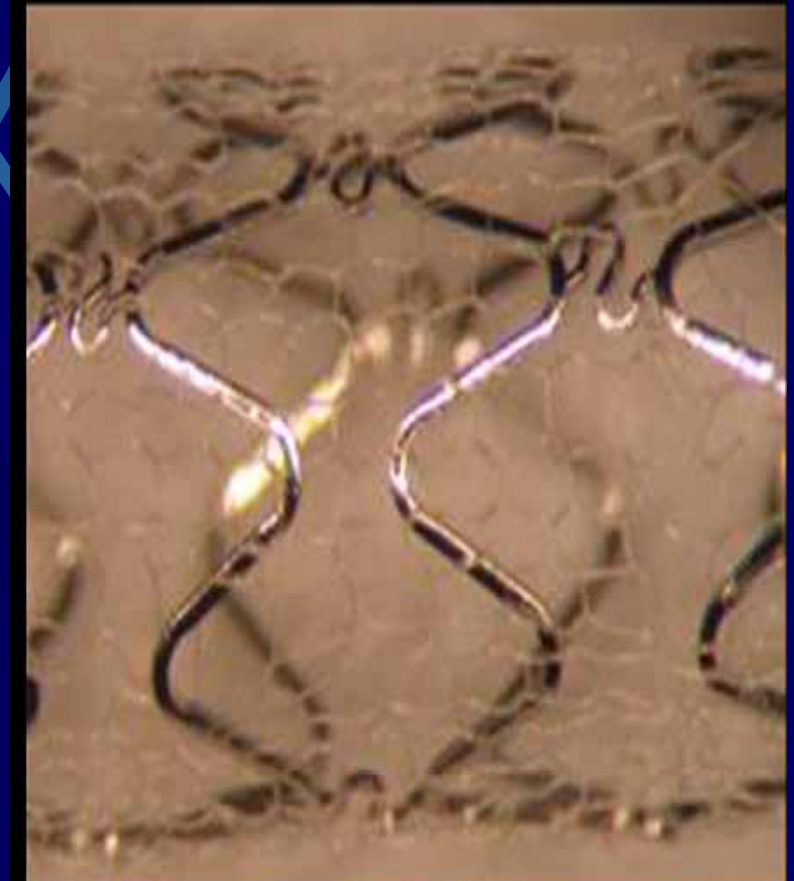
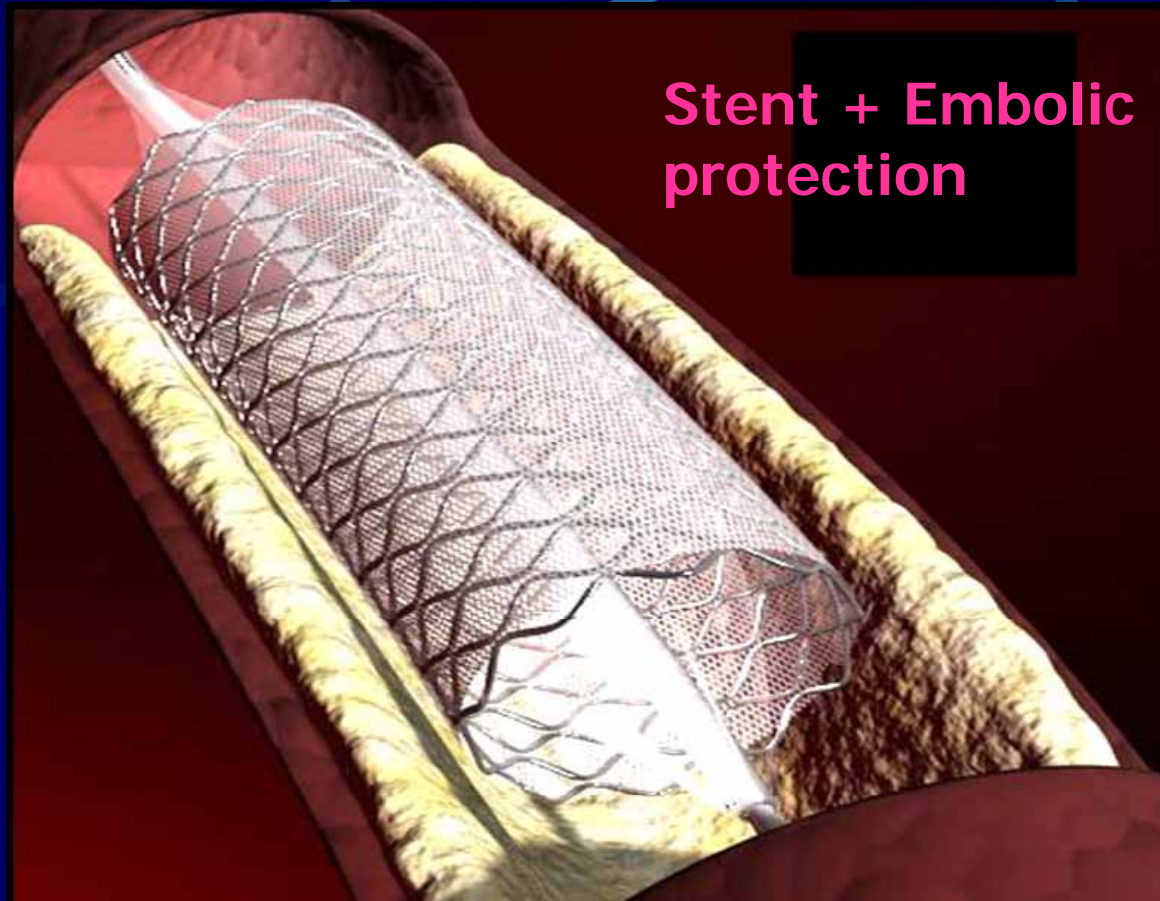


The FIRE Trial

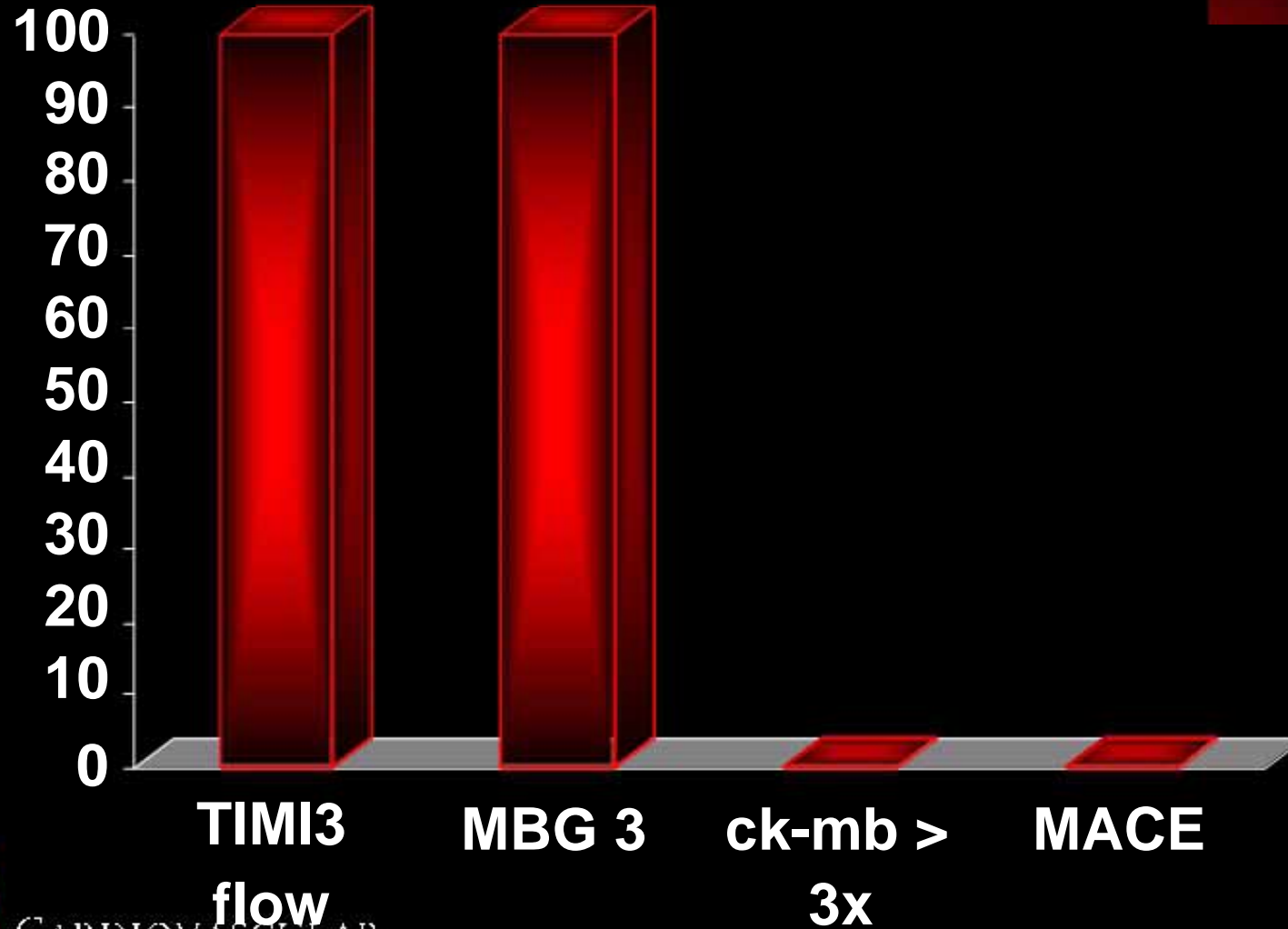
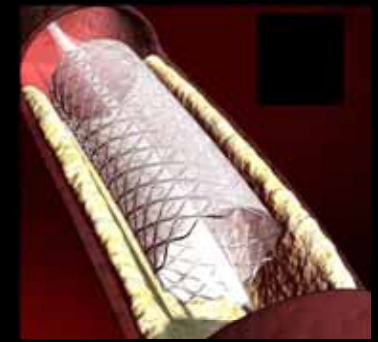


- **Objective:** To evaluate the safety and efficacy of treatment with the FilterWire EX System during angioplasty/stenting of saphenous vein grafts with vessel diameters between 3.5mm and 5.5mm
- **Design:** A prospective, multi-center, randomized, controlled trial; patients were randomized 1:1 to distal protection with either the FilterWire EX System or the GuardWire System
- 651 patients at 66 sites in the U.S. (59) and Canada (4)
- **Primary Endpoint:** MACE at 30 days post-procedure
 - MACE defined as the composite incidence of death, myocardial infarction (MI), or target vessel revascularization (TVR)
- **Determined that the 30-day MACE rate for the FilterWire EX® System 10% (33/332) was non-inferior from the GuardWire Plus System 12% (37/319) (P for non-inferiority=0.0008)**

Mguard Concept



INSPIRE Trial (SVG 16 patients) In-Hospital Results



CARDIOVASCULAR
RESEARCH CENTER

My experience in 19 patients in SVG-PTCA

18 transfemoral & 1 transradial approach.

AR1 guiding catheter in all patients.

Non-medicated stents for 15 pts & medicated stents for last 3 patients.

No distal protection device used in any of these patients.

Tirofiban infusion in all these patients.

In one patient, stent could not be passed despite good predilatation.

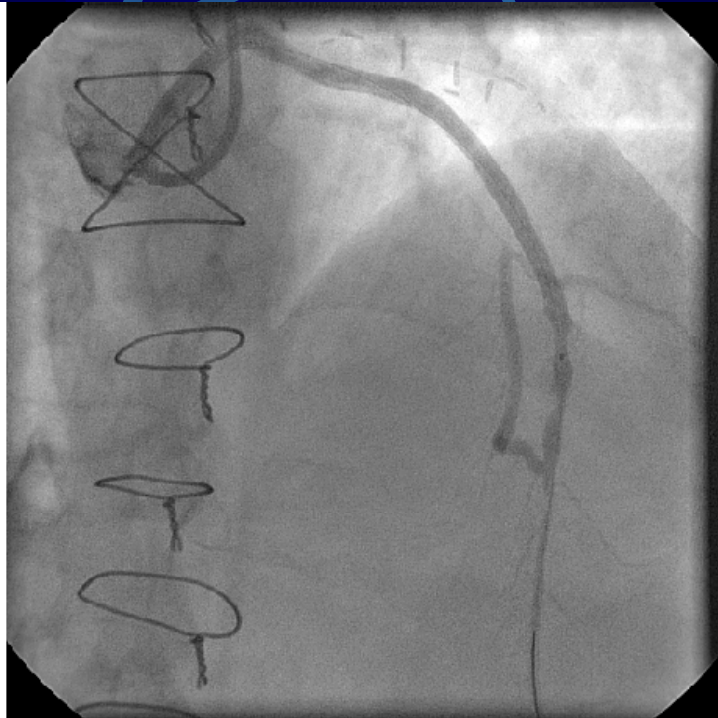
No immediate adverse event in any of the patients.

One death after 4 years due to non-cardiac cause (cancer).

Negative TMT in 11 patients at 6 months.

Name	Month/Yr	SVG to	Stent
Nanaji Tope	Feb 2006	OM1	BMS
Mahadev Sule	May 2006	LAD	BMS
Pradhan Bhanushali	Jan 2007	PDA	BMS
Akhtar Khan	April 2007	PDA	BMS
Ramesh Patel	Dec 2007	OM	BMS
Karsan Velani	Jan 2008	PDA	BMS
N S Thaker	Sept 2008	OM	BMS
Harindra Shah	Nov 2008	PDA	BMS
Tejinder Singh	Jan 2009	OM	BMS
Bharat Acharya	April 2009	LAD	BMS
Sumantrao Shinde	Aug 2009	OM	BMS
Waman Chipkar	Oct 2009	PDA	BMS
Rafique Shaikh	Jan 2010	PDA	BMS
Sarswati Krishnan	Sept 2010	OM	BMS
Valji Vedant	June 2011	LAD	DES
Kantilal Bakhda	June 2012	PDA	DES
Maruti Lohkare	Aug 2012	PDA	DES

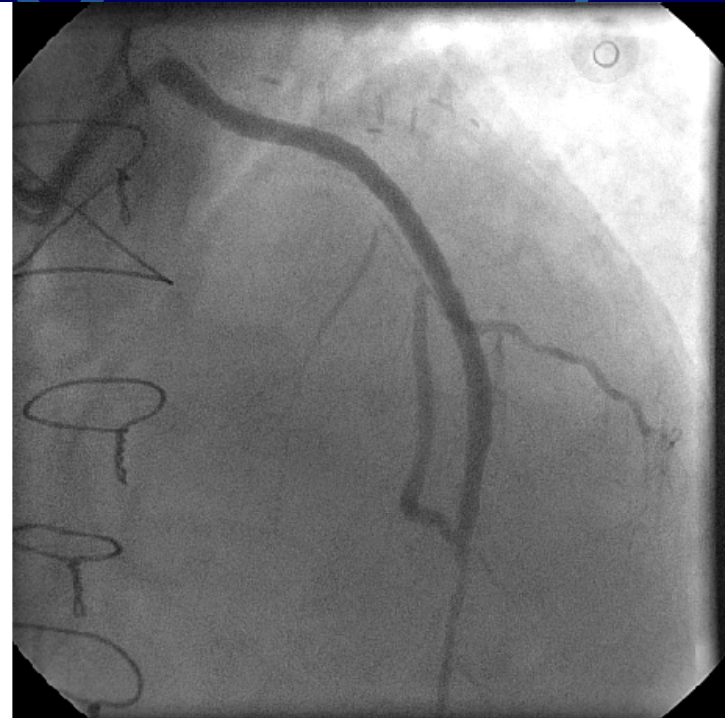
69/M SVG to LAD 20 yrs ago now with angina on exertion class III



AP 698 VEDANT VALJI M/69
AP 698 DR C SHAH
12/6/1942
M
12/6/2011 10:04:55 AM

12/6/2011 10:54:51 AM
A: RAO: 0.8, CRAN: 39.9
Scene: 1 of 34
Frame: 22 of 43

Zynova Heart Hospital

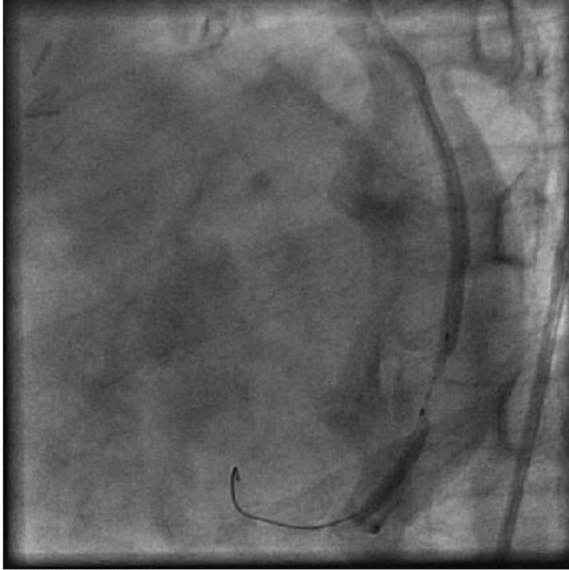


AP 698 VEDANT VALJI M/69
AP 698 DR C SHAH
12/6/1942
M
12/6/2011 10:04:55 AM

12/6/2011 11:27:08 AM
A: LAO: 0.7, CRAN: 46.3
Scene: 1 of 34
Frame: 23 of 67

Zynova Heart Hospital

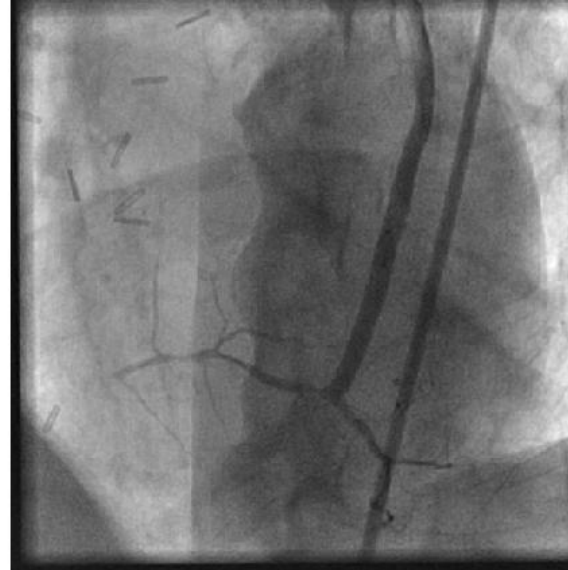
75/M SVG to PDA 5 yrs ago now with angina on exertion class III



1126 MR. N.S.THAKER. 75Y^{~~~~}
2893/AP

A: LAO: 45.7, CAUD: 7.9
Scene: 1 of 41
Frame: 59 of 76

M
9/25/2008 9:02:56 AM
DR CHETAN SHAH
S R Mehta Cardiac Institute, Mumbai.

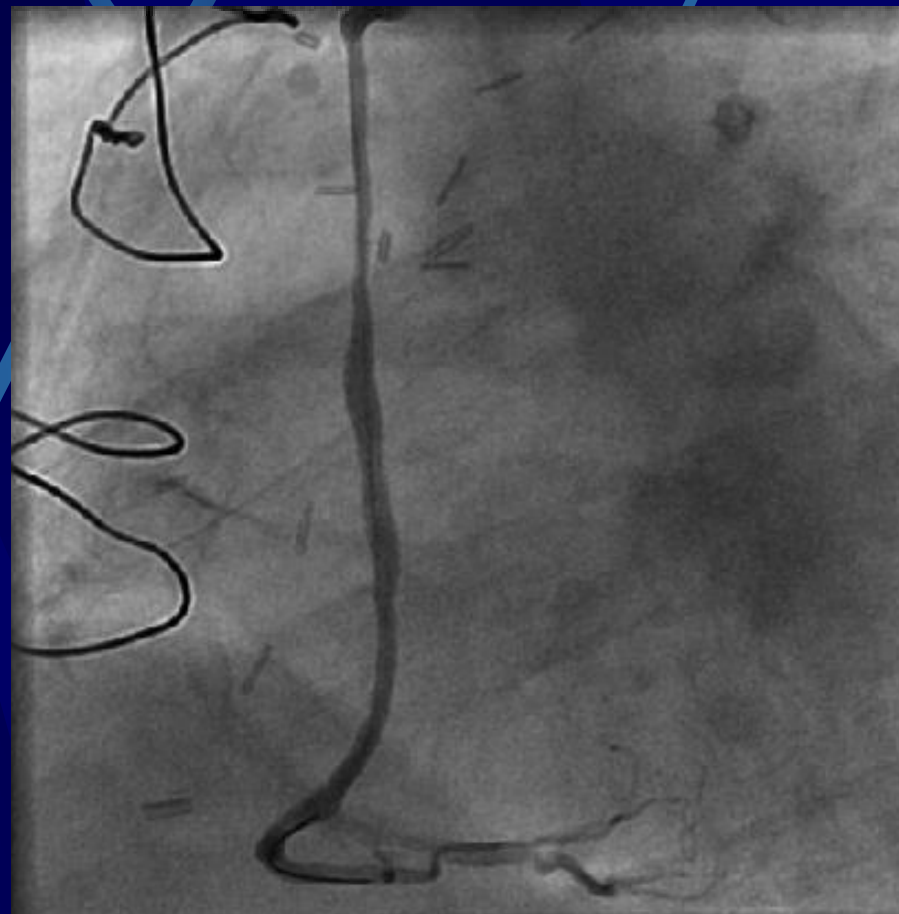
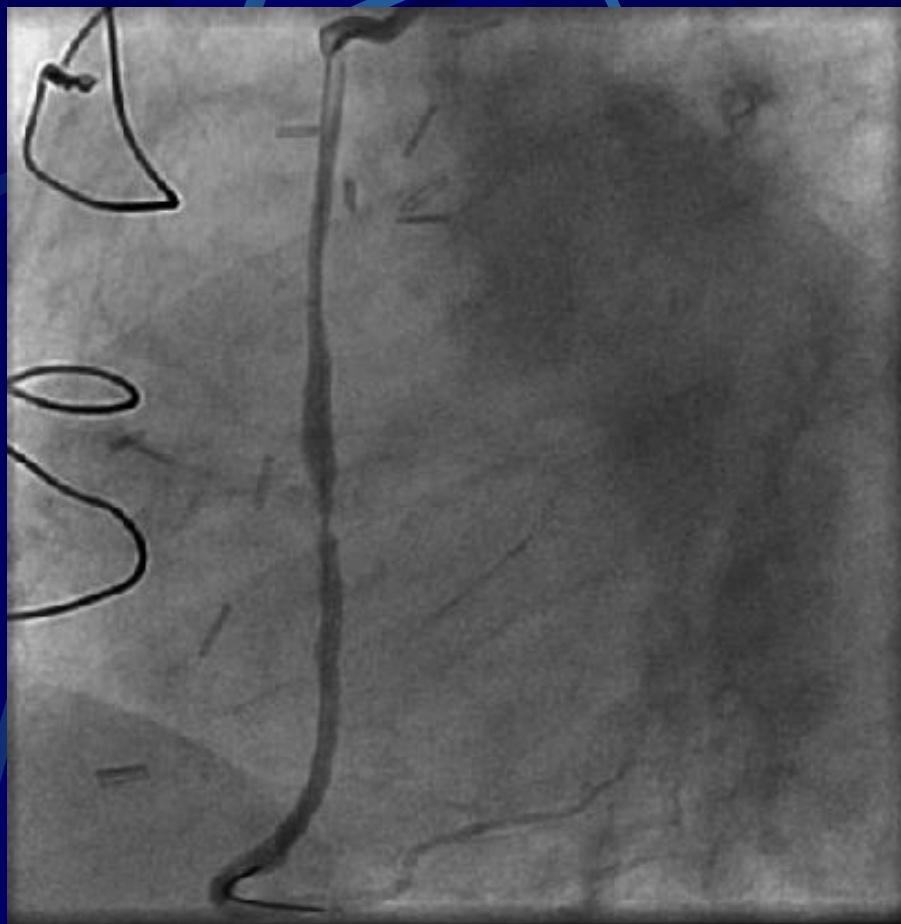


1126 MR. N.S.THAKER. 75Y^{~~~~}
2893/AP

A: LAO: 33.4, CRAN: 25.4
Scene: 1 of 41
Frame: 43 of 75

M
9/25/2008 9:02:56 AM
DR CHETAN SHAH
S R Mehta Cardiac Institute, Mumbai.

66/M SVG to PDA 10 yrs ago now with angina on exertion class III



Real World Embolic Protection Device Utilization

- **Utilization of Distal Embolic Protection in Saphenous Vein Graft Interventions¹**
 - **Analysis of data from the ACC-NCDR Registry** to determine frequency of embolic protection device (EPD) use and to identify the patient, anatomic, and institutional factors associated with EPD use
 - Primary outcome: EPD use
 - **Evaluation of 19,546 patients included in the ACC-NCDR Data Registry who underwent SVG PCI at 452 hospitals from January 1, 2004 through March 30, 2006**
 - **No EPD used, n=15,216**
 - **Yes EPD used, n=4,330**
 - **Study Population:**
 - **Twenty-two percent of patients who underwent SVG PCI (4,330 of 19,546) received an EPD**

¹ Mehta SK, et al., Utilization of Distal Embolic Protection in Saphenous Vein Graft Interventions (An analysis of 19,546 patients in the American College of Cardiology-National Cardiovascular Data Registry). Am J Cardiol. 2007 Oct 1;100(7):1114-8.

Real World Embolic Protection Device Utilization

• Utilization of Distal Embolic Protection in Saphenous Vein Graft Interventions

- Outcomes:

- EPD use was associated with a decreased incidence of postprocedural no-reflow (1.8% vs 1.0%)
Findings remained consistent after multivariable adjustments were applied (OR 0.68, 95% CI 0.48 to 0.97, $p=0.032$).
- In-hospital mortality was similar in patients who were and were not treated with an EPD (1.0% vs 0.9%, $p=NS$).
- Patients who received an EPD had greater procedural fluoroscopic times (17.2 vs 15.2 minutes, $p<0.001$).
- There was a trend toward more vessel dissection in the group of patients who received an EPD (1.5% vs 1.0%, $p=0.06$) and there was no significant difference in the incidence of graft perforation (0.5% vs 0.4%, $p=0.57$).



Embololic Protection Device Use and Outcomes in Patients Receiving Saphenous Vein Graft Interventions A Single-center Experience

Harsh Golwala, MD, Beau M. Hawkins, MD, Stavros Stavrakis, MD, PhD, Mazen S. Abu-Fadel, MD

J Invasive Cardiol. 2012;24(1):1-3.

Patient Characteristics:

A total of 164 consecutive vein graft interventions were identified. EPDs were used in 71 cases (43.4%).

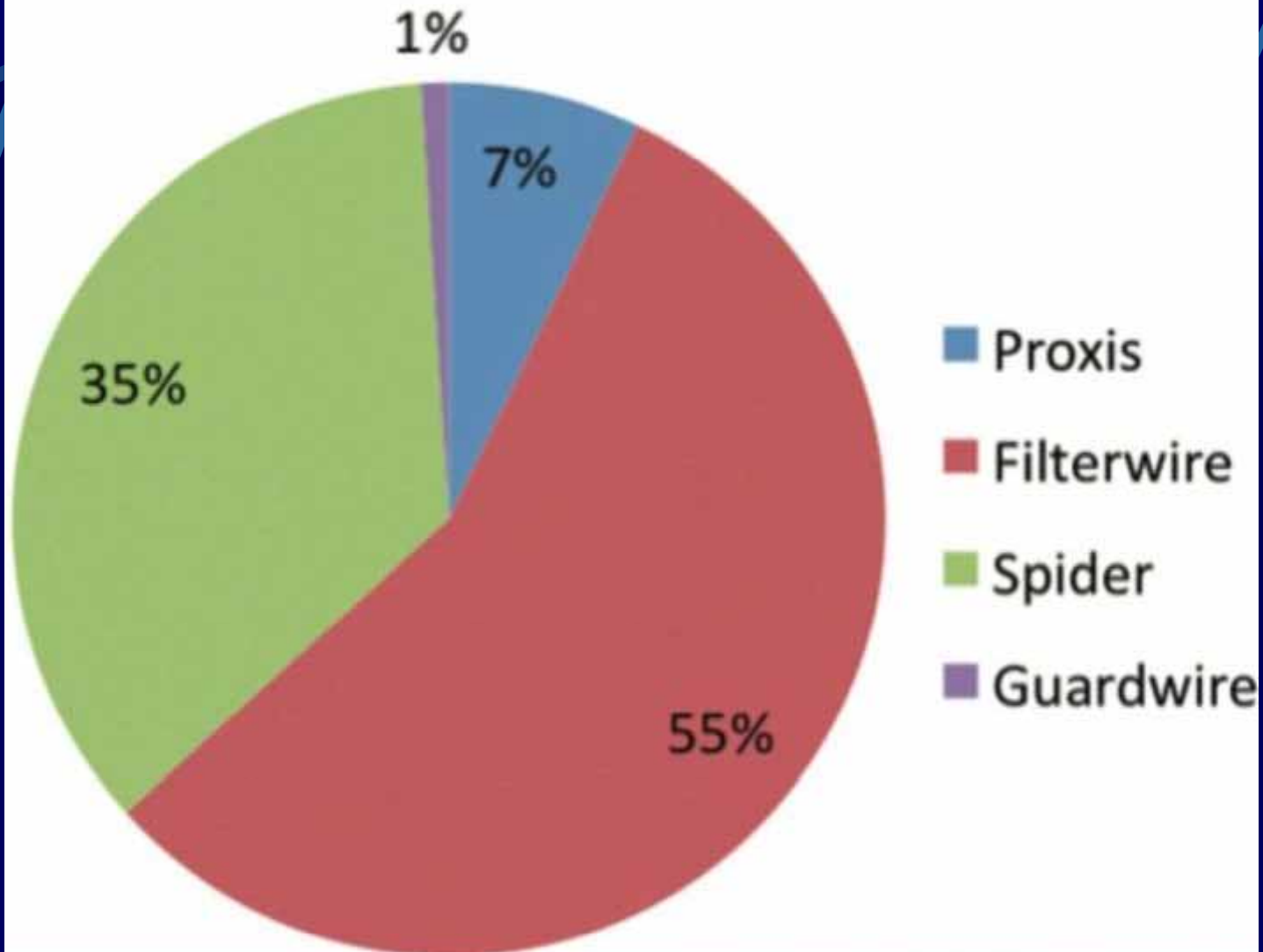
The EPD group had a higher prevalence of hypertension and diabetes.

Time since CABG was significantly longer in the EPD group as well. EPD was not used in any patient with ST-segment elevation MI.

EPD group had more patients on beta-blockers and ACE inhibitors as compared to the non-EPD group.

More importantly, however, the anticoagulation and antiplatelet strategies between the 2 groups (bivaliridin, heparin, and glycoprotein IIb/IIIa inhibitors) were similar.

Percentage



Outcomes:

The primary endpoint of the study, which was periprocedural MI as defined above, occurred in 22 cases — 12 in the non-EPD group and 10 in the EPD group (14.1 vs 12.9%; $P=.82$). In addition, when analysis was done using any troponin elevation as a marker for periprocedural MI, there was no statistical difference between the 2 groups.

The secondary endpoints of the study, which included the composite endpoint of death, MI, or TVR at 12 months, were significantly lower when EPDs were used (11.3 vs 25.8%; $P=.03$) .

Role of embolic protection devices in ostial saphenous vein graft lesions

Abdel-Karim, Abdul-Rahman R. MD et al

Catheterization & Cardiovascular Interventions. 80(7):1120-1126, December 1, 2012.

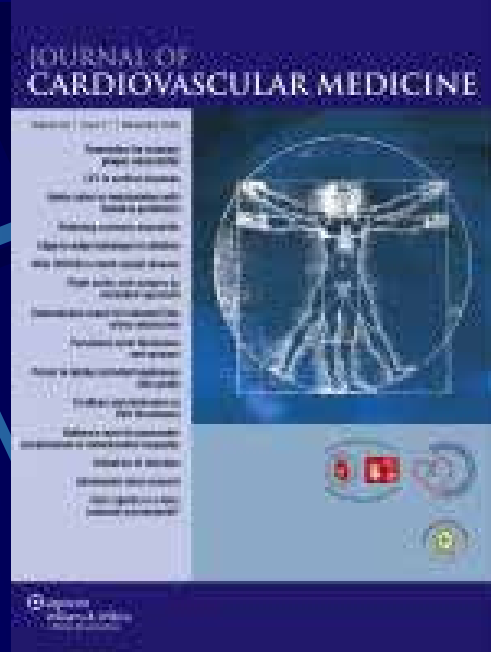
Background: Although embolic protection devices (EPDs) have been shown to be beneficial in saphenous vein graft (SVG) lesions, their role in the subgroup of ostial SVG lesions has received limited study.

Methods: The coronary angiograms and procedural outcomes of 109 patients undergoing stenting of 113 ostial SVG lesions were reviewed retrospectively to determine frequency of EPD use.

Results: Ninety-eight (87%) of the 113 lesions were suitable for EPD use, that was used in 70 lesions (71%). A Filterwire (Boston Scientific) or a SPIDER (ev3) filter were used in 54 (77%) and 16 (23%) of lesions, respectively. Difficulty retrieving the filter post stenting was encountered in eight lesions (11%) and led to stent thrombosis causing cardiac arrest in one patient (1%).

Angiographic success was achieved in 111 (98%) of 113 lesions.

Conclusions: EPDs can be utilized in the majority of ostial SVG lesions, but in 11% of cases filter retrieval can be challenging and may rarely (in approximately 1%) lead to a significant complication.



Tirofiban administration and percutaneous coronary intervention with stenting of saphenous vein graft thrombosis

D'Andrea, Claudia; Esposito, Giovanni; Piscione, Federico; Chiariello, Massimo

Journal of Cardiovascular Medicine

Issue: Volume 10(11), November 2009, p 875–878

Distal embolization during percutaneous coronary intervention (PCI) of saphenous vein graft (SVG) lesions is associated with a high risk of myonecrosis and myocardial infarction. PCI guidelines advocate the use of distal embolic protection devices, when technically feasible, in patients undergoing PCI for SVG disease. To date, alternative management strategies are not fully investigated.

Preprocedural tirofiban administration followed by PCI with stenting of an SVG thrombotic lesion without a distal protection device might be a well-tolerated and feasible option for patients with degenerated SVG disease. Further studies are needed to further expand our findings.



Distal protection devices appear seductively simple, elegant, and beneficial to both physicians and patients. Why would you not want to use something called “distal protection?” To not use “distal protection” during SVG angioplasty and stent placement sounds irresponsible, like not practicing “safe sex.” In a simple world, distal protection devices would do exactly what their name implies, that is, eliminate complications that are caused by distal emboli.



~~But we do not live in such a simple world.~~

Every medical device has both benefits and risks. To properly characterize the risk-benefit profile of a device, large controlled studies are needed, comparing patients treated with the device to patients not treated with the device. That sounds like simple, high school science. But no such study exists. Instead we have retrospective data comparing patients treated before and treated after the introduction of distal protection devices.