The Tryton® Side Branch System in Distal Left Main PCI

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❒ **I have the following potential conflicts of interest to report:**

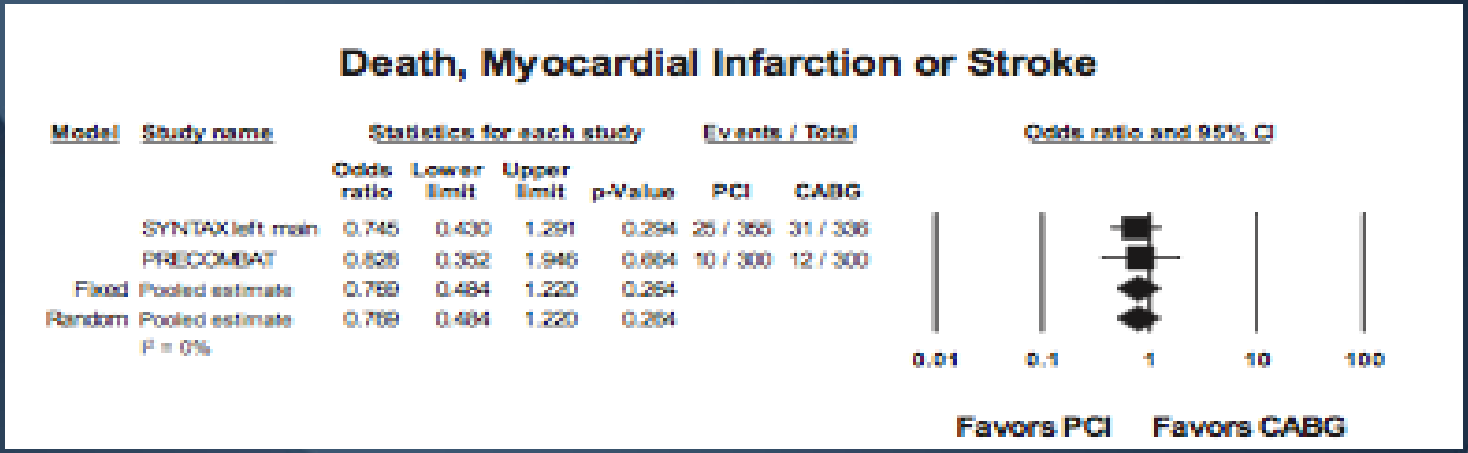
- ❒ Consulting
- ❒ Employment in industry
- ❒ Stockholder of a healthcare company
- ❒ Owner of a healthcare company
- ❒ Other(s)

☑ **I do not have any potential conflict of interest**

Left Main Bifurcation PCI

Table 3 1-Year Outcomes in Left Main Patients Revascularized by PCI or CABG

Endpoint	PCI (n = 809)	CABG (n = 802)	Absolute Difference (95% CI)	Number Needed to Treat	Number Needed to Harm	p Value
MACCE	14.5 (117/807)	11.8 (93/790)	2.7 (−0.6 to 6.0)	—	37	0.11
Death/MI/CVA	5.3 (35/655)	6.8 (43/636)	−1.5 (−4.1 to 1.2)	67	—	0.26
Death	3.0 (24/807)	4.1 (32/790)	−1.1 (−3.0 to 0.8)	91	—	0.29
MI	2.8 (23/807)	2.9 (23/790)	−0.1 (−1.8 to 1.6)	1,000	—	0.95
CVA	0.1 (1/707)	1.7 (12/689)	−1.6 (−2.9 to −0.6)	63	—	0.013
TVR	11.4 (92/807)	5.4 (43/790)	6.0 (3.3 to 8.7)	—	17	<0.001



Capodano et al, JACC Vol. 58, No. 14, 2011 September 27, 2011:1426–32

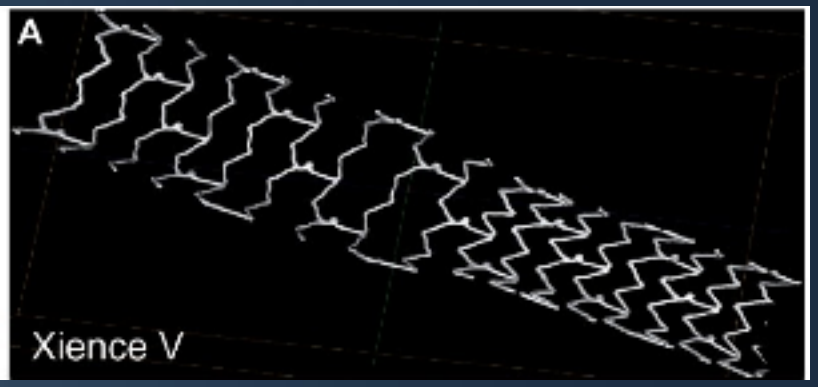
Provisional vs. Elective 2 Stent

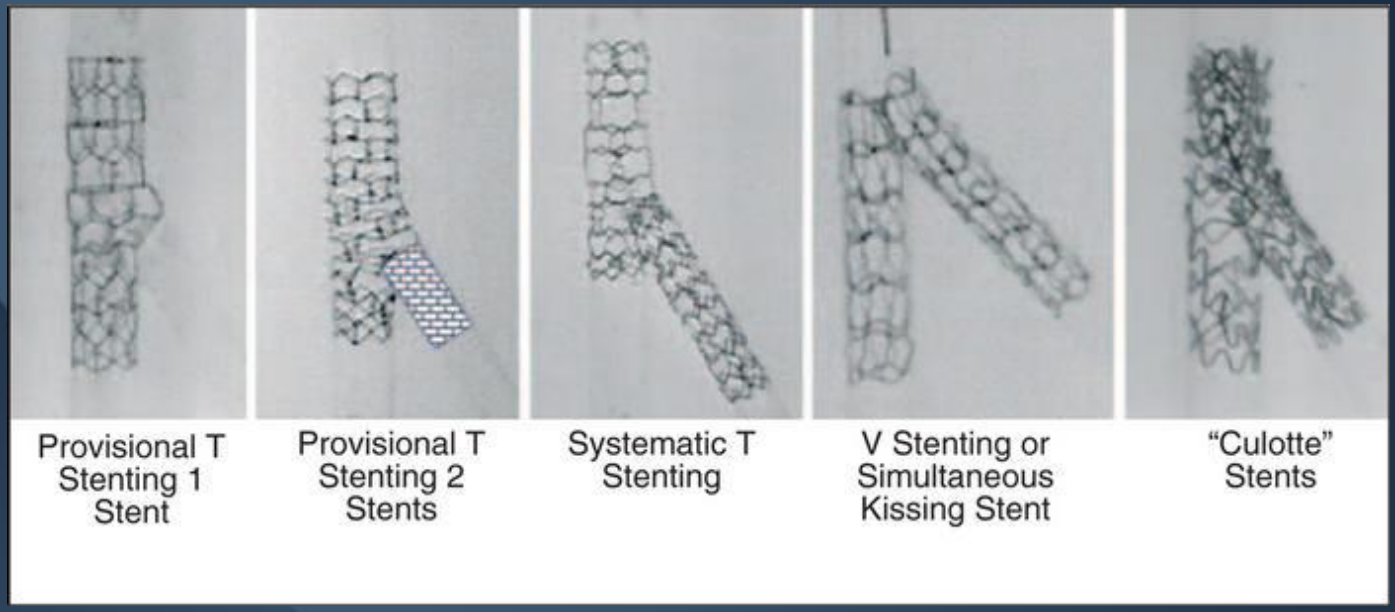
- True bifurcation / side branch involvement
- Large myocardial areas perfused in LMCA disease
- Distal LMCA: Cx is frequently considered to be the “side branch”
- Will POBA do ? ?

Elective 2 Stent Techniques

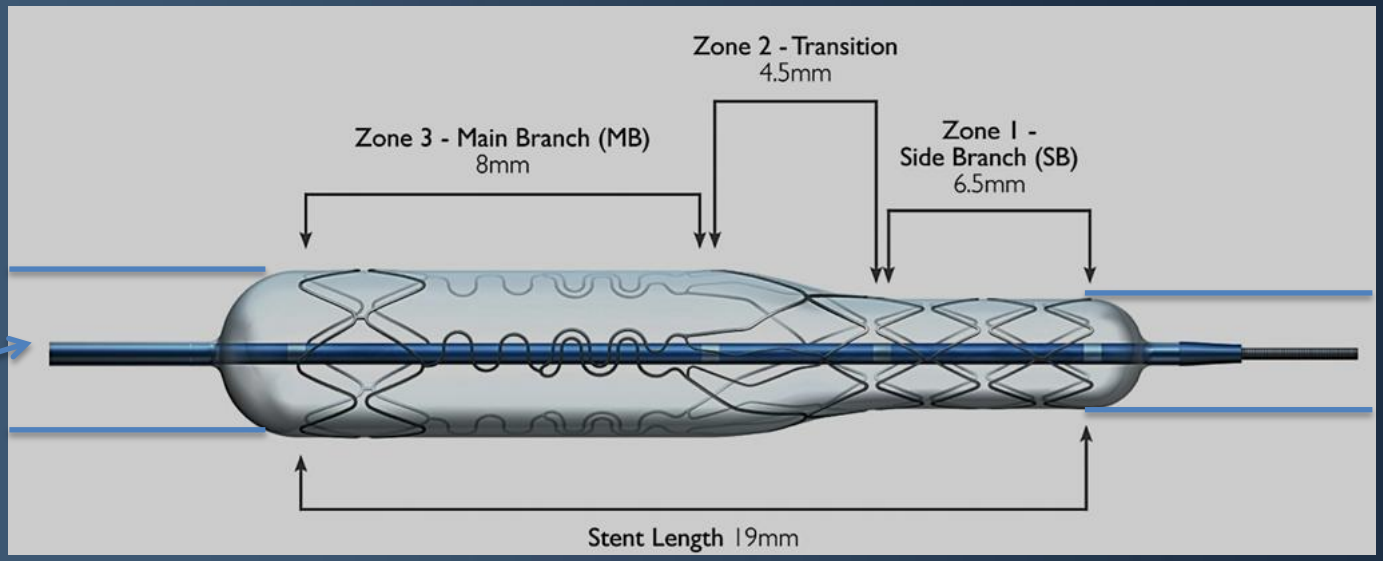
	PRO	CON
Modified T Stenting	- Provide immediate patency of both branches. - Provide good coverage of SB ostium with limited deformity.	- Not optimal technique for Y bifurcations. - Requires wire/balloon re crossing of one branch.
Mini Crush Stenting	-Provide immediate patency of both branches -- Can be used in a wide variety of bifurcation morphology.	- Not optimal technique for T bifurcations. - Potential for stent deformity at the SB ostium. - Requires wire / balloon re crossing of one branch which can be challenging due to metal multilayer.
Culotte Stenting	- Provides the best coverage and the least strut deformity at the SB ostium.	- Not optimal in patients with: • Large mismatch between LM and LCX • Critical disease involving the LAD and LCX - One branch is unprotected during the procedure. - Requires rewiring of both branches. - limited utility with closed cell design stents.
V Stenting	-Preservation of patency and wire access to both branches at all stages.	- Best when LM disease is limited to the carina or the LAD/LCX ostia. - Potential for asymmetric stent expansion.
SKS	- Preservation of patency	- Creation of permanent new metal carina.

Stent Deformation





Tryton® Side Branch System



Side Branch Diameter (mm)	Main Branch Diameter (mm)
2.5	2.5
2.5	3.0
2.5	3.5
3.0	3.5
3.5	4.0

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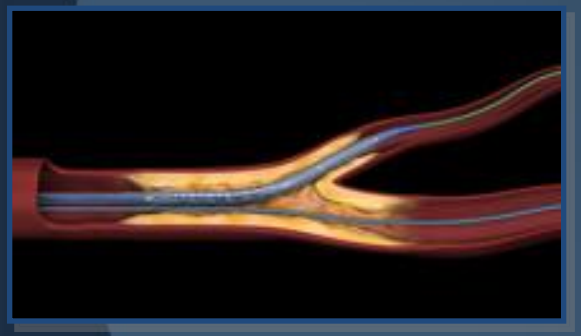
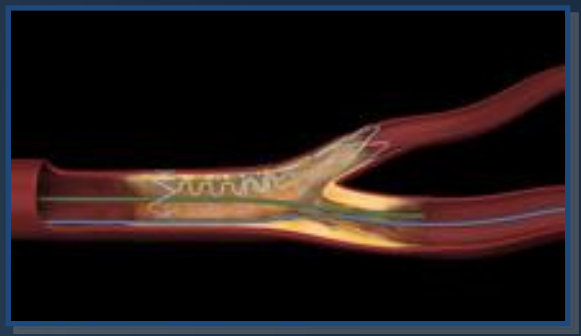
Deployment: "Culotte" Sequence



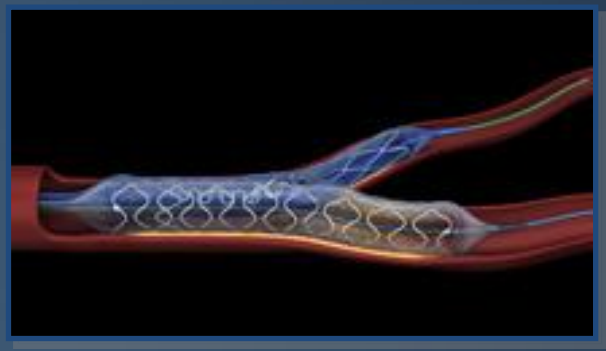
Position Side Branch Stent

Deploy Side Branch Stent

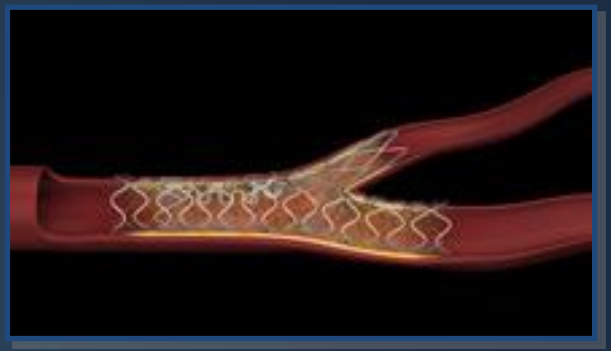


Advance Wire into Main Branch

Position Main Vessel Stent



Kissing Post-Dilatation of Bifurcation



Procedure Complete

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Acute procedural and six-month clinical outcome in patients treated with a dedicated bifurcation stent for left main stem disease: the TRYTON LM multicentre registry

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KEYWORDS

- 3-D quantitative coronary angiography
- dedicated bifurcation stents
- left main stem bifurcation
- procedural success
- six-month MACE

Abstract

Aims: Tryton side branch (SB) reverse culotte stenting has been employed for the treatment of left main (LM) stem bifurcations in patients at high risk for bypass surgery. The aim of this study was to assess acute angiographic results and six-month clinical outcome after implantation of the Tryton stent in the LM.

Methods and results: We studied 52 consecutive patients with LM disease treated in nine European centres. Angiographic and clinical data analysis was performed centrally. Fifty-one of 52 patients (age 68±11 yrs, 75% male, 42% unstable angina, SYNTAX score 20±8) were successfully treated with the Tryton stent. Medina class was 1,1,1 in 33 (63%), 1,0,1 in 7 (13%), 1,1,0 in 3 (6%), 0,1,1 in 8 (4%) and 0,0,1 in 1 (2%). The Tryton stent on a stepped balloon (diameter 3.5-2.5 mm) was used in 41/51 (80%) of cases. The mean main vessel stent diameter was 3.4±0.4 mm with an everolimus-eluting stent employed in 30/51 (59%) of cases. Final kissing balloon dilatation was performed in 48/51 (94%). Acute gain was 1.52±0.86 mm in the LM and 0.92±0.47 mm in the SB. The angiographic success rate was 100%; the procedural success rate reached 94%. Periprocedural MI occurred in three patients. At six-month follow-up, the TLR rate was 12%, MI 10% and cardiac death 2%. The hierarchical MACE rate at six months was 22%. No cases of definite stent thrombosis occurred.

Conclusions: The use of the Tryton stent for treatment of LM bifurcation disease in combination with a conventional drug-eluting stent is feasible and achieves an optimal angiographic result. Safety of the procedure and six-month outcome are acceptable in this high-risk lesion PCI. Further safety and efficacy studies with long-term outcome assessment of this strategy are warranted.

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	Center	Patients included
1	*Thoraxcenter, Erasmus MC, Rotterdam, the Netherlands	10 (1 failure of delivery)
2	Centro Cardiologico Monzino, Milano, Italy	7
3	†Padova University Hospital, Padova, Italy	8
4	‡ Ospedale Sant' Anna, Como, Italy	6
5	#University Hospital Son Espases, Palma de Mallorca, Spain	4
6	¤Hospital de Santa Cruz, Lisboa, Portugal	3
7	Universitair Ziekenhuis Brussel, Brussels, Belgium	10
8	University of Lord's Transfiguration Poznan, Poland	3
9	Beaumont Hospital, Dublin, Ireland	1
	Total	52

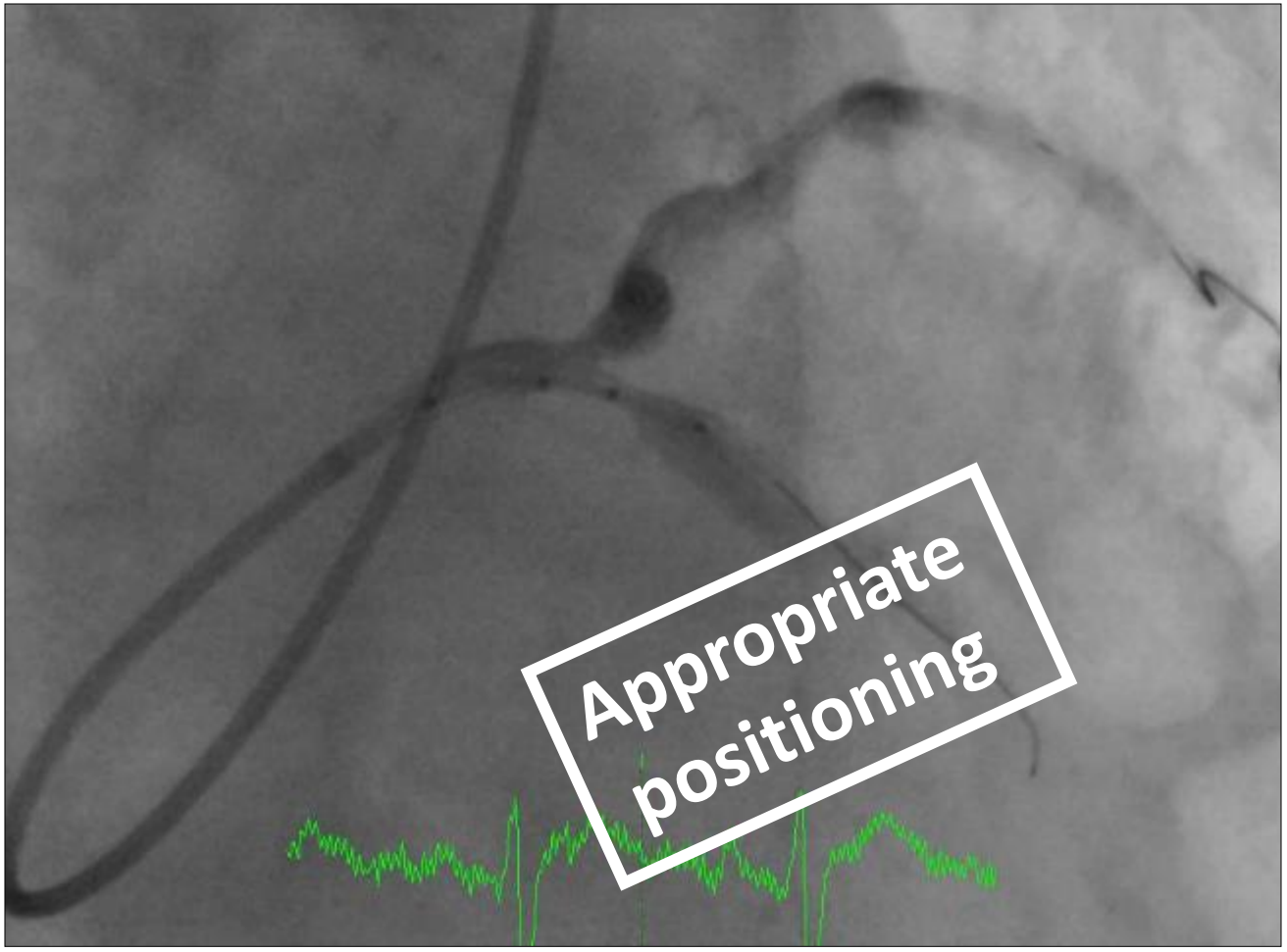
Baseline Characteristics

	N (%)
Age, yrs	68.7 ± 10.9
Sex, male %	39/49 (80%)
Hypertension	30/49 (61%)
Diabetes	20/49 (41%)
Hypercholesterolaemia	30/49 (61%)
Smoker	8/49 (16%)
Family History of CAD	15/39 (39%)
Previous PCI	18/49 (37%)
Previous CABG	8/49 (16%)
History of MI	14/49 (29%)

Acute and 6 month Clinical Outcome

Peri-Procedural MI In-hospital MACE	3/50 3/50	6% 6%
30 day MI 30 day MACE	3/50 3/50	6% 6%
6 month MI	5/50	10%
6 month TVR TVR –SB TVR - MB	6/50 6/50 1/50	12% 12% 2%
6 month MACE (Hierarchical)	10/50	20%

Depth of implantation of Tryton SideBranch Stent



Our Tryton LM Experience

Jerusalem

- 16 in distal LM bifurcation lesions (1 protected, 15 unprotected)
- Occluded/protected branch or infarct in 4
- Radial access used in 2, femoral in 14, Final kissing balloon in 15/16 cases

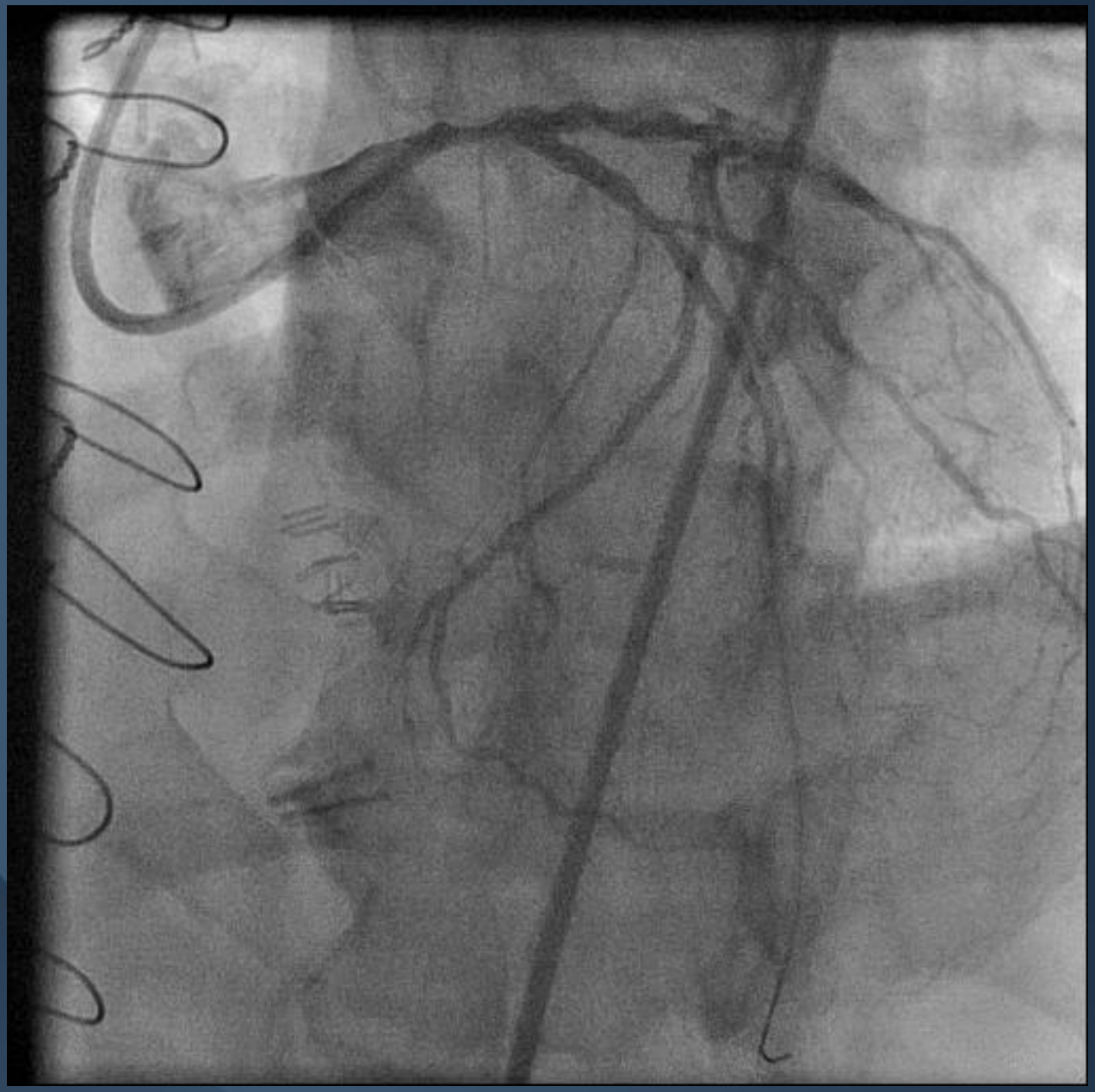
Outcome

- Technical success in all
- Avg. clinical follow-up of 9 months (range 5-21)
- MACCE occured in 2/16: Ischaemia-driven TLR 13 months in 2 PT one in MB and one in SB

- No cases of MI or stent thrombosis

Patient Characteristics

- Male , 72 y
- S/P CABG 2009
- Occluded Grafts
- Unstable AP
- 90% Distal LM
- Mid LAD 99%
- Medina 1:1:1



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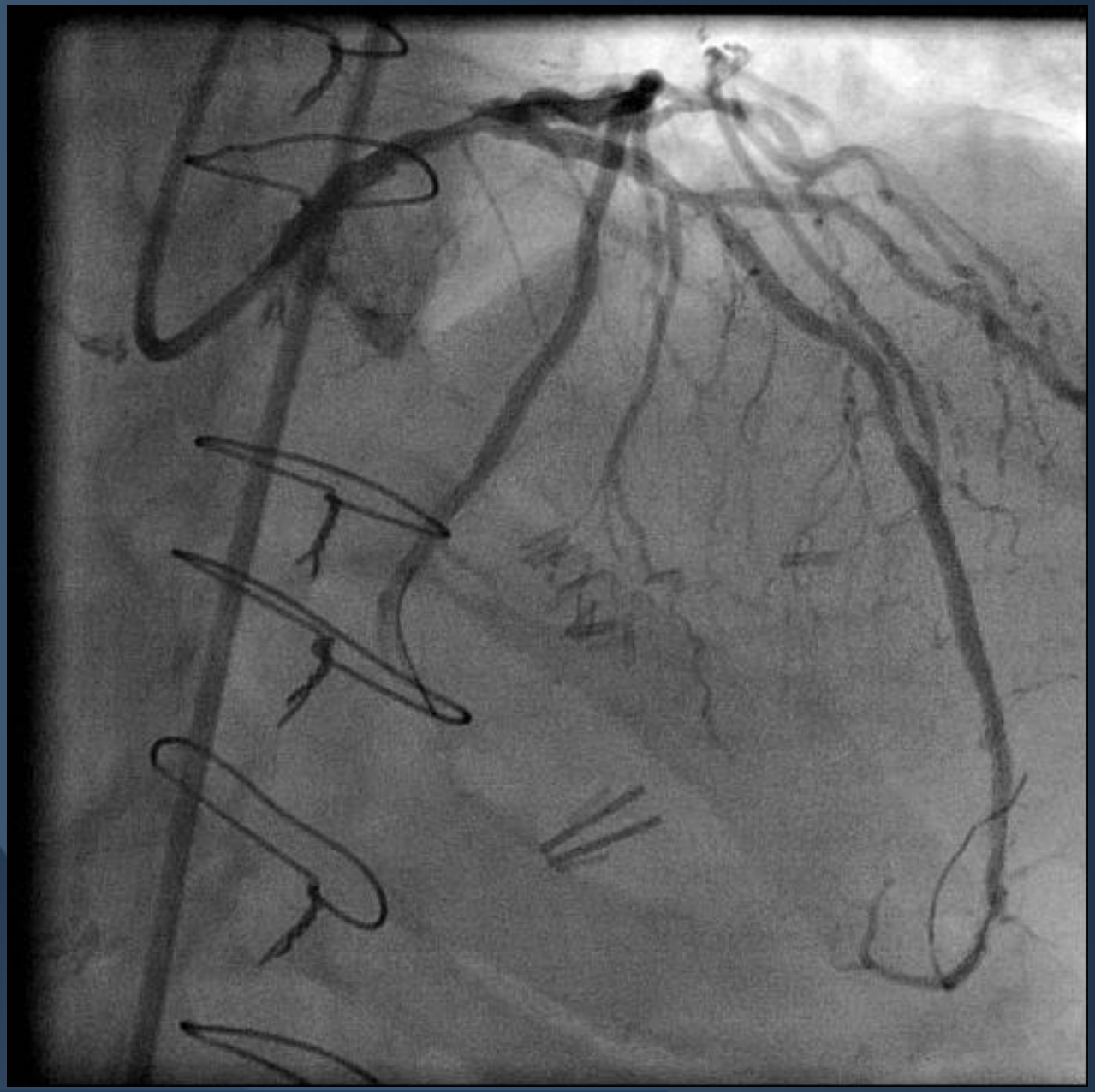

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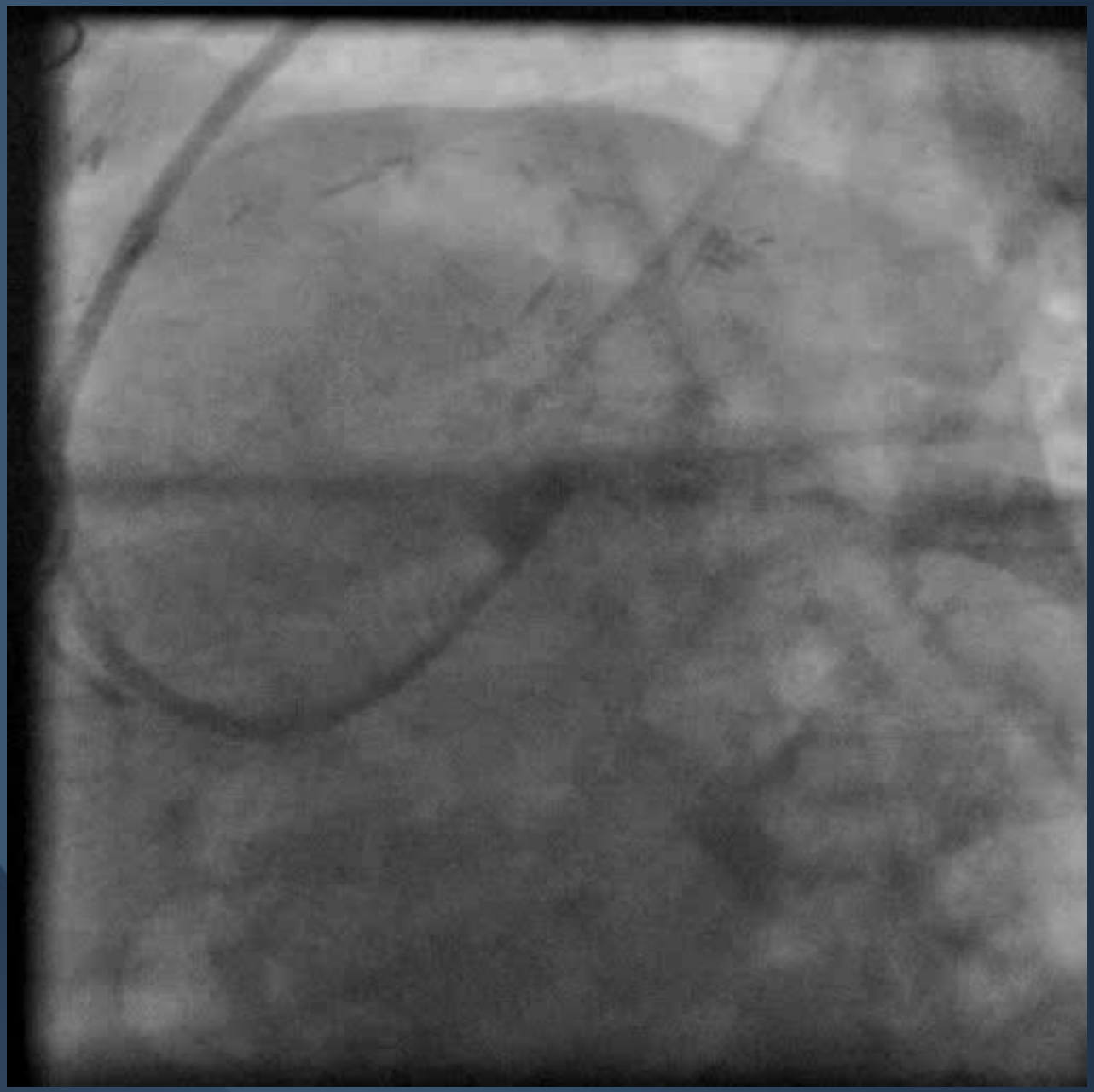

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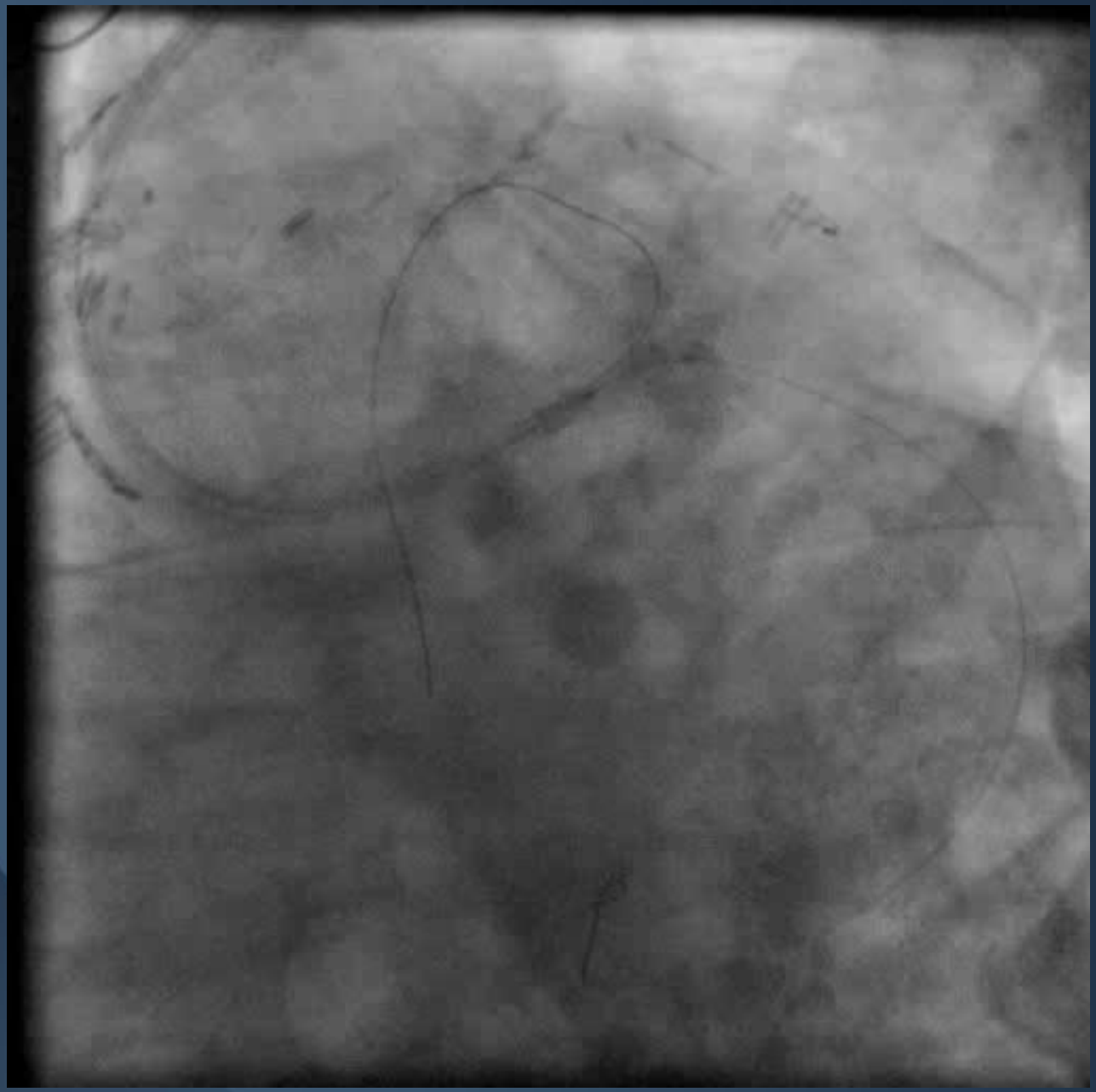

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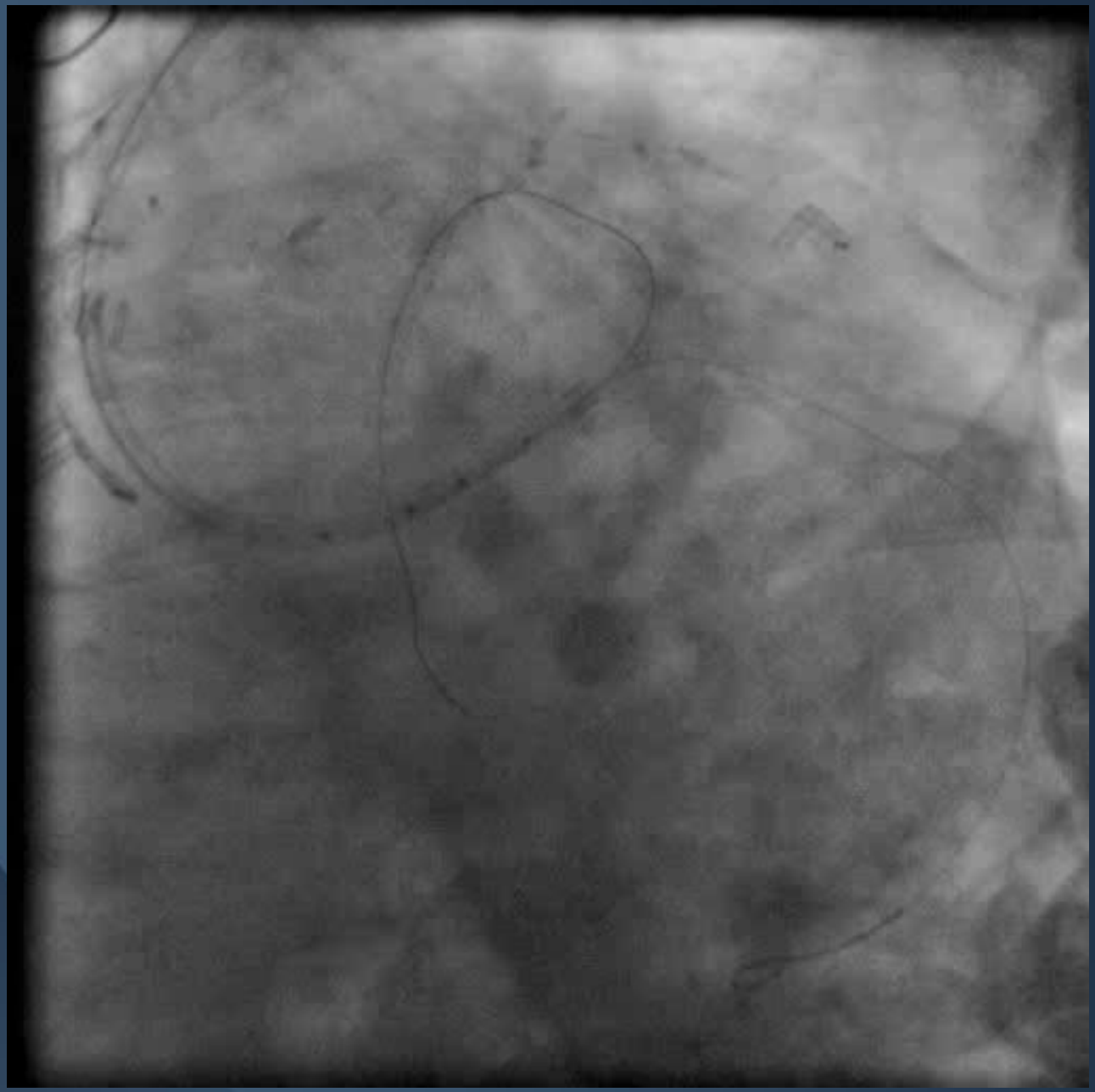

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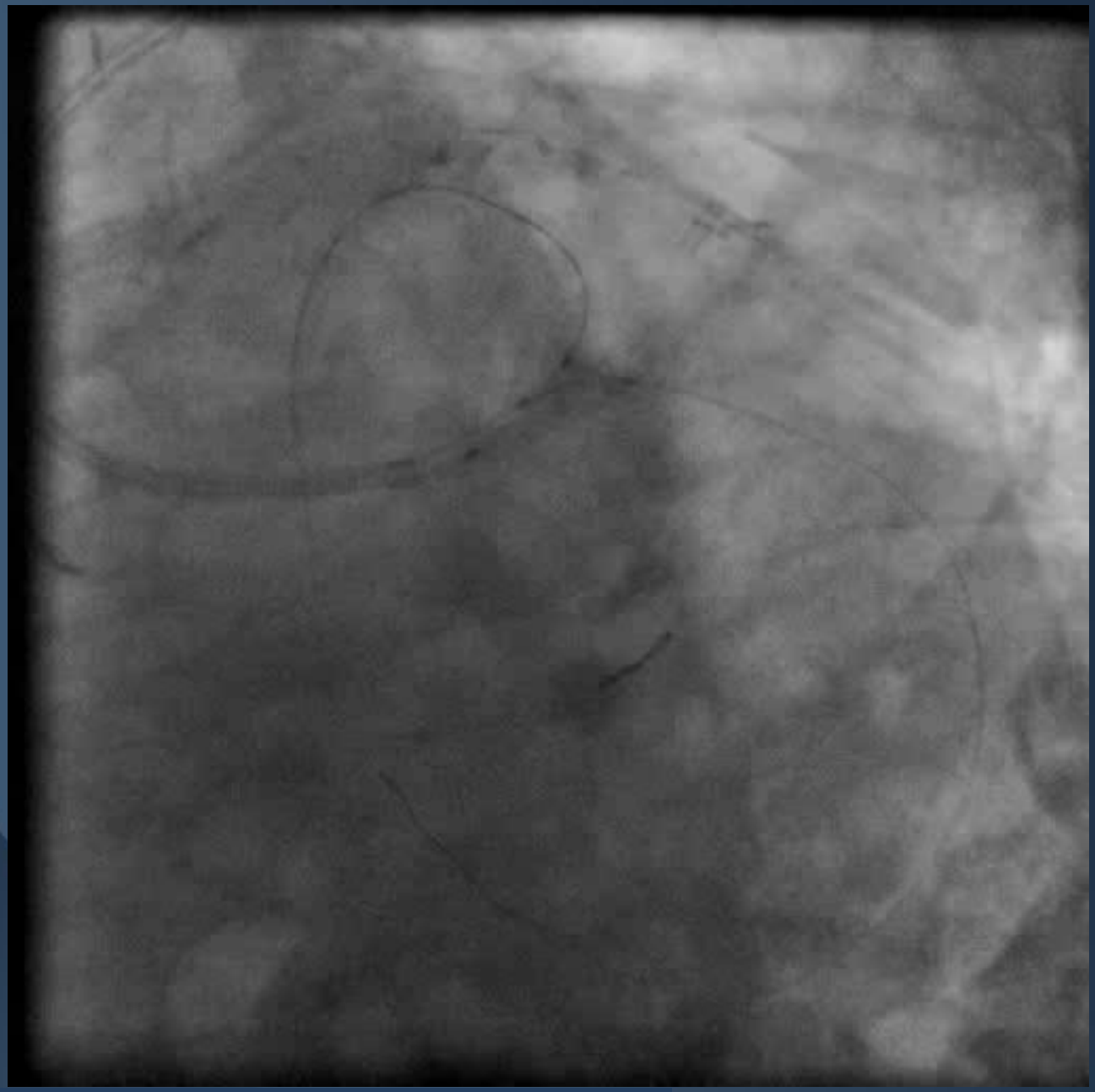

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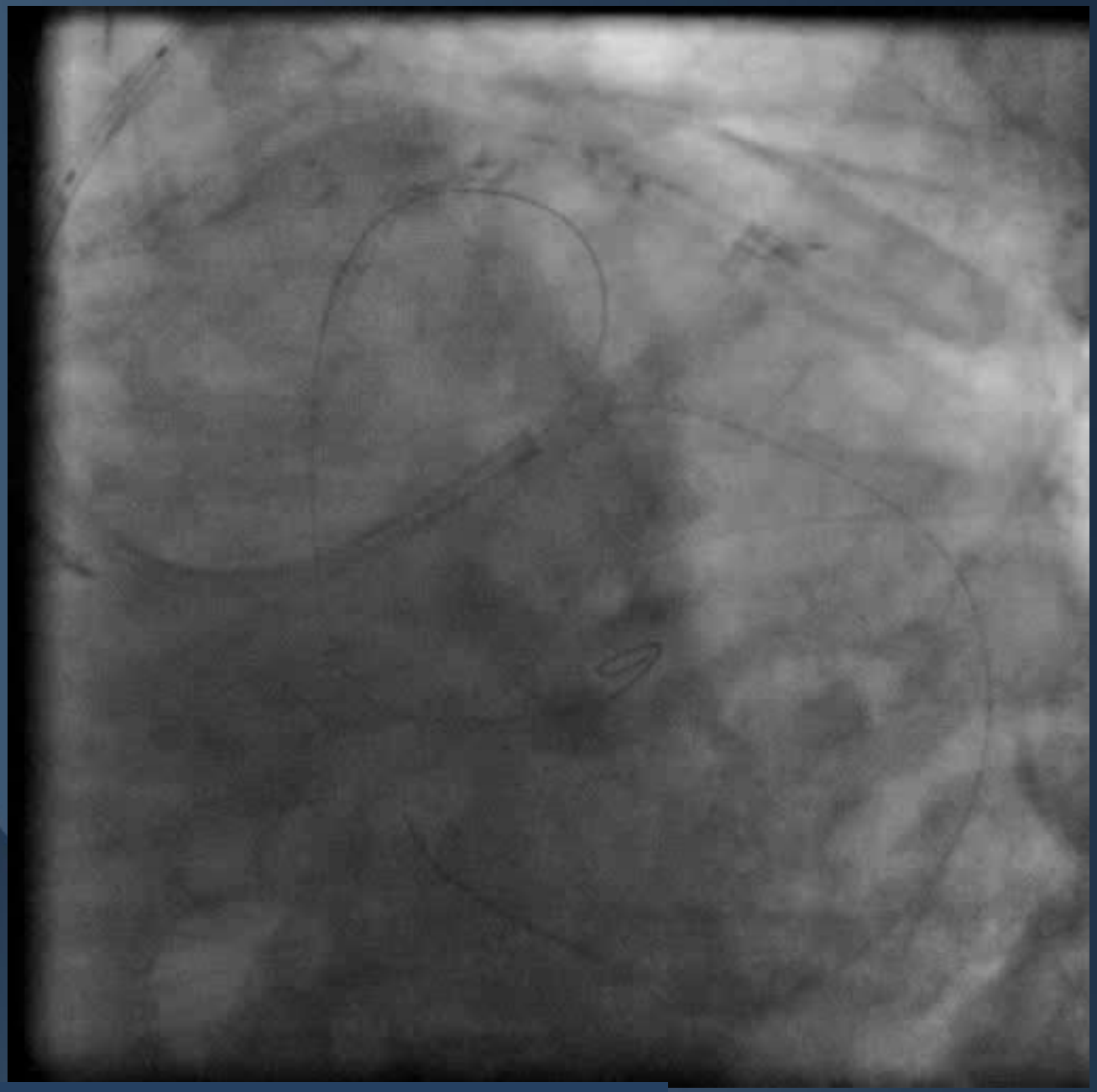

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Live Case TCT 2012

Left Main

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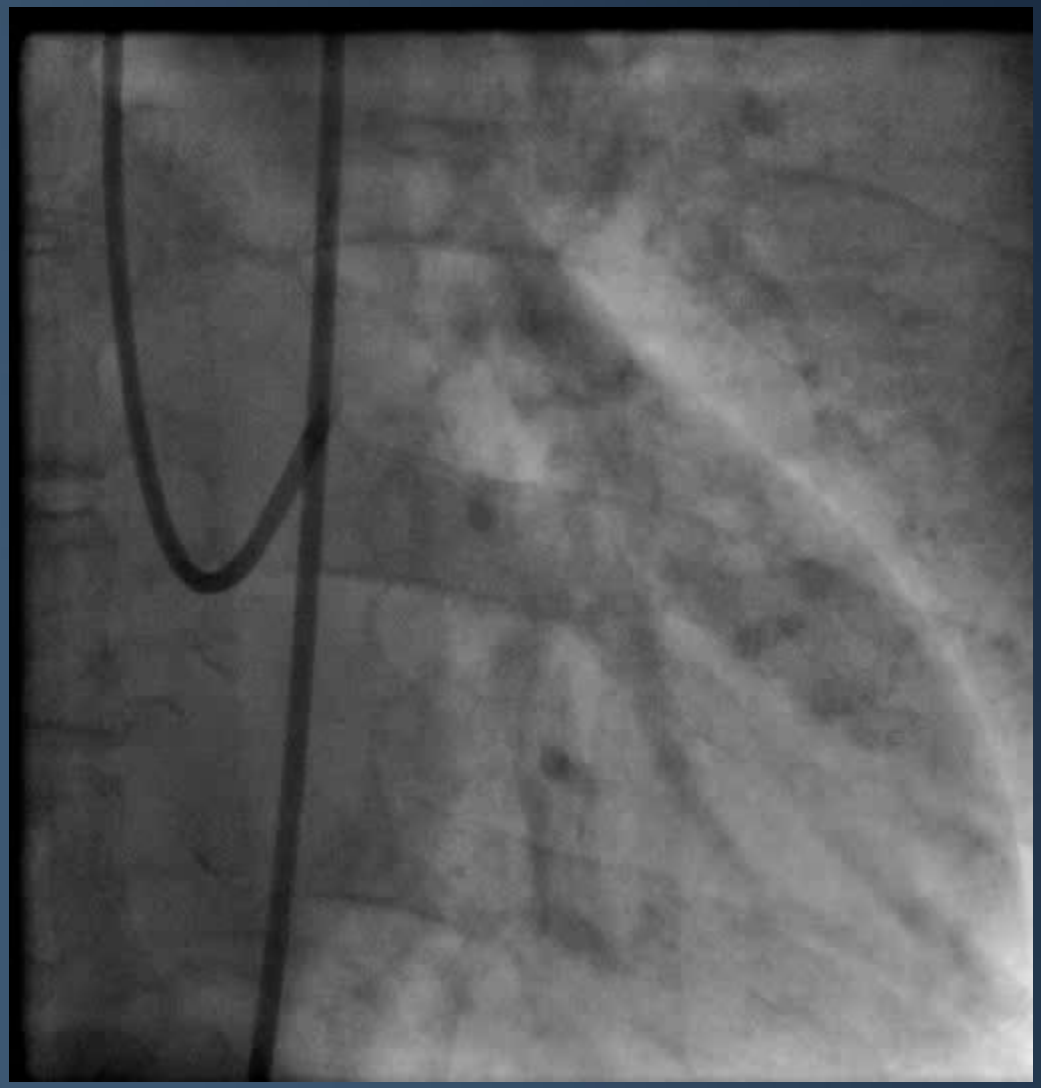

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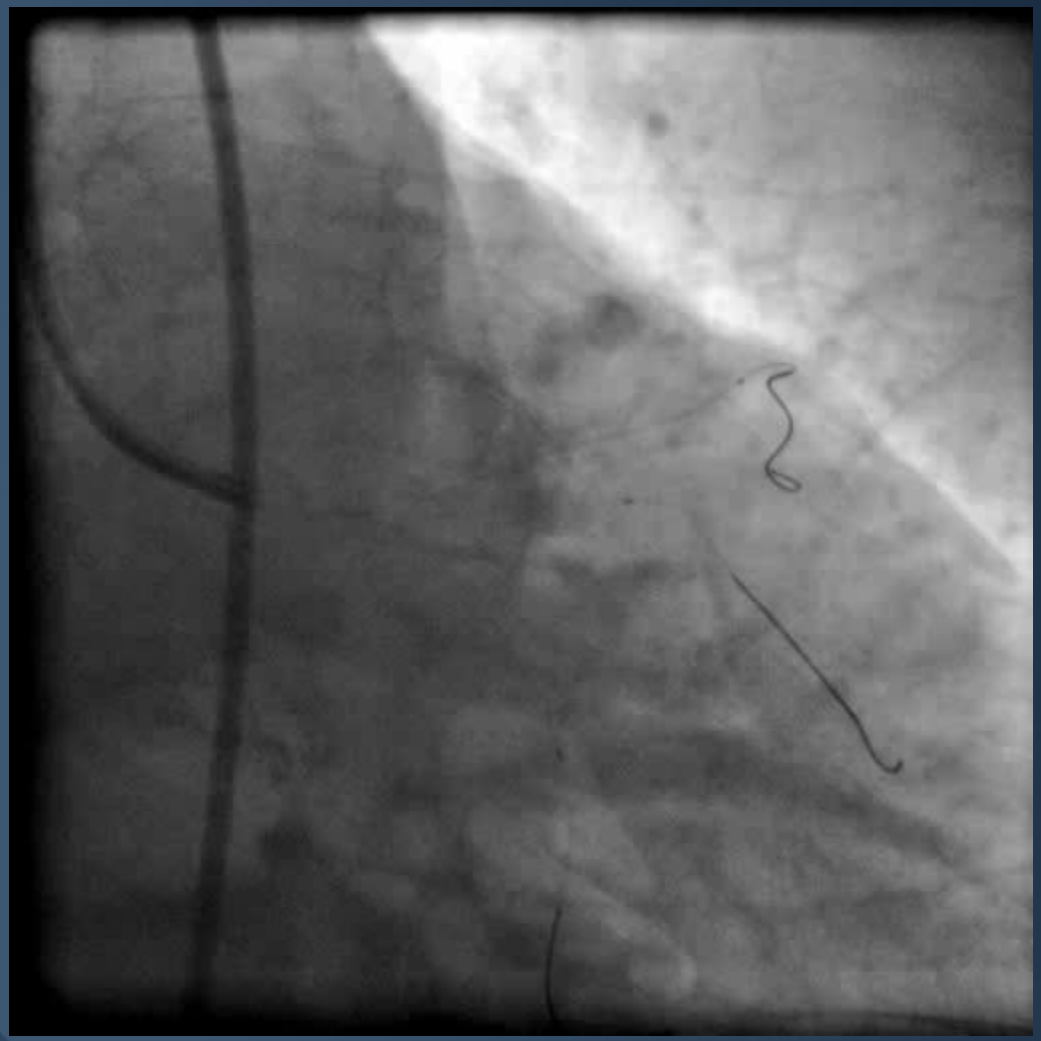

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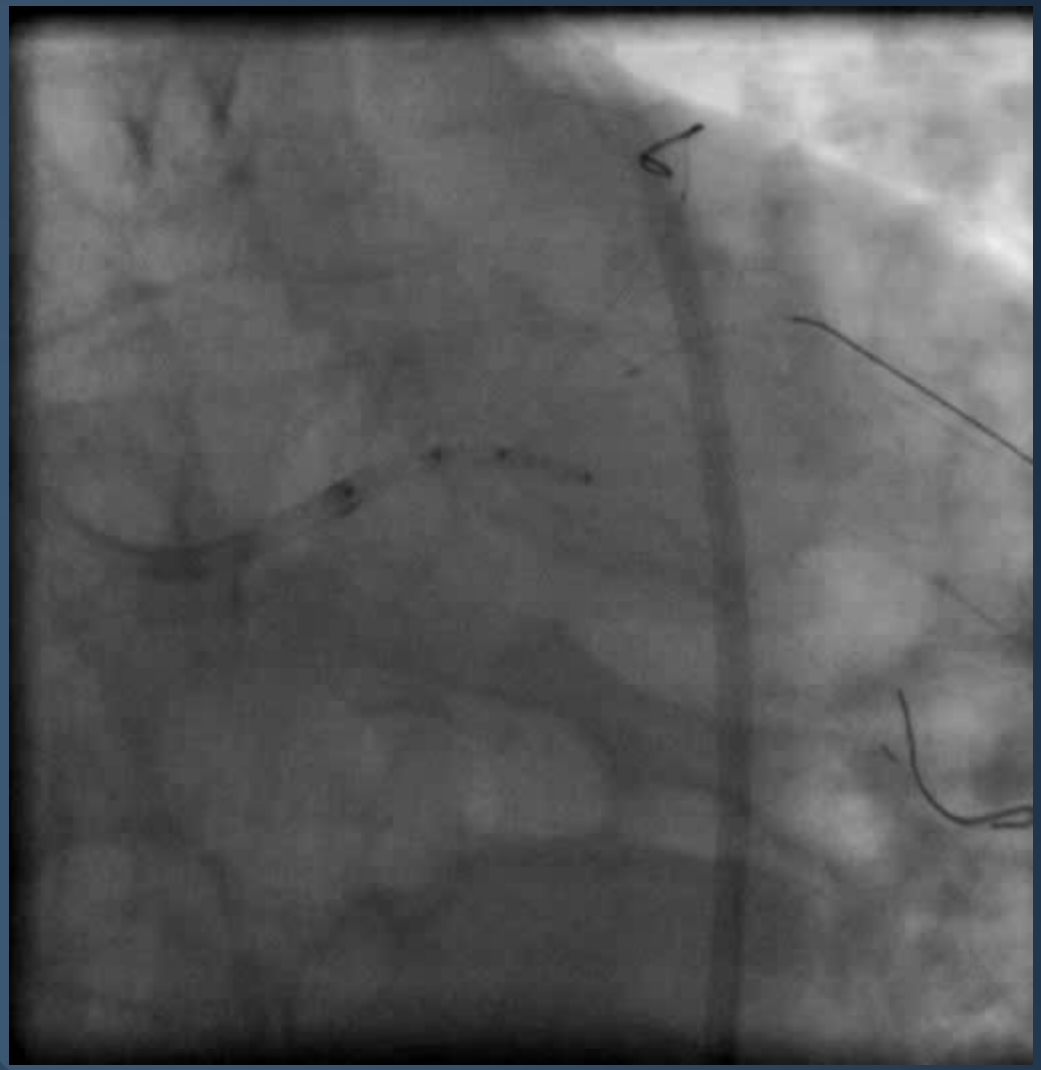

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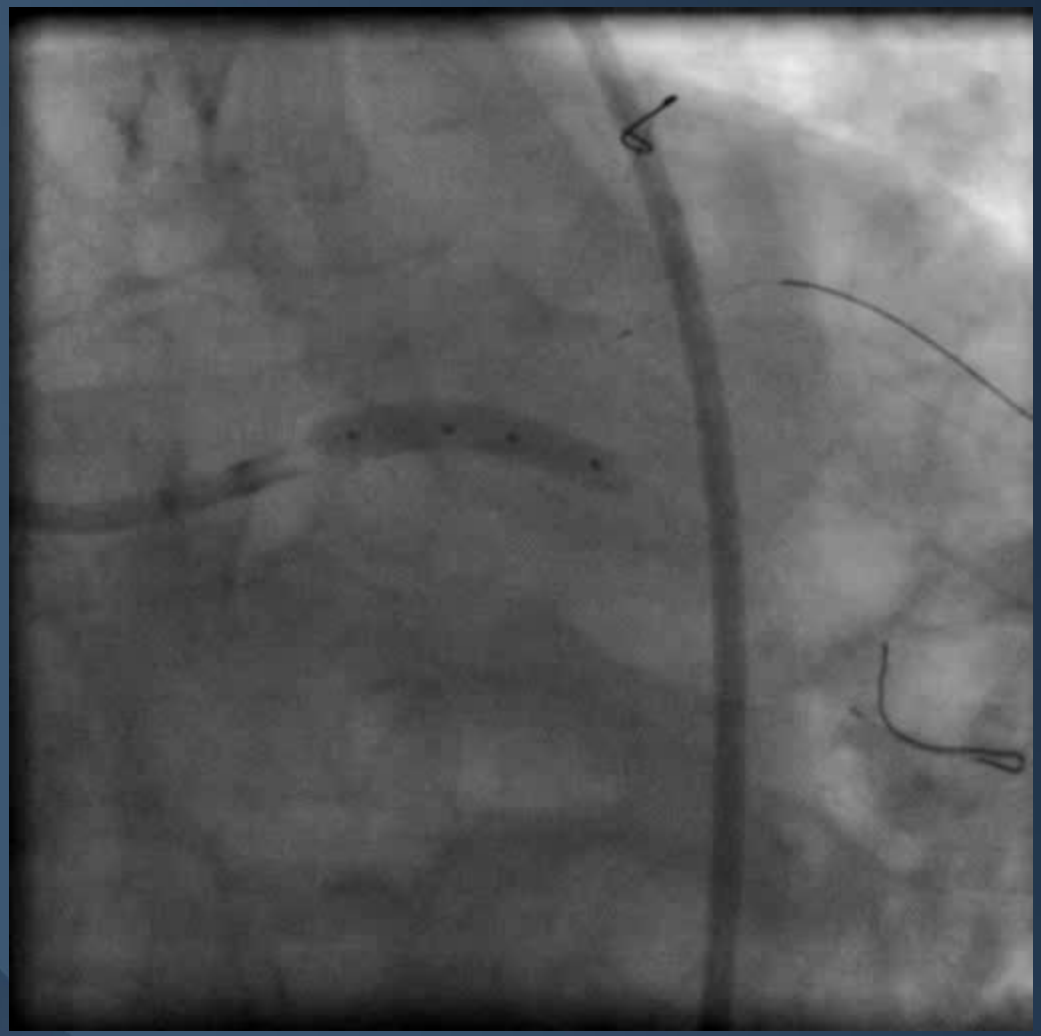

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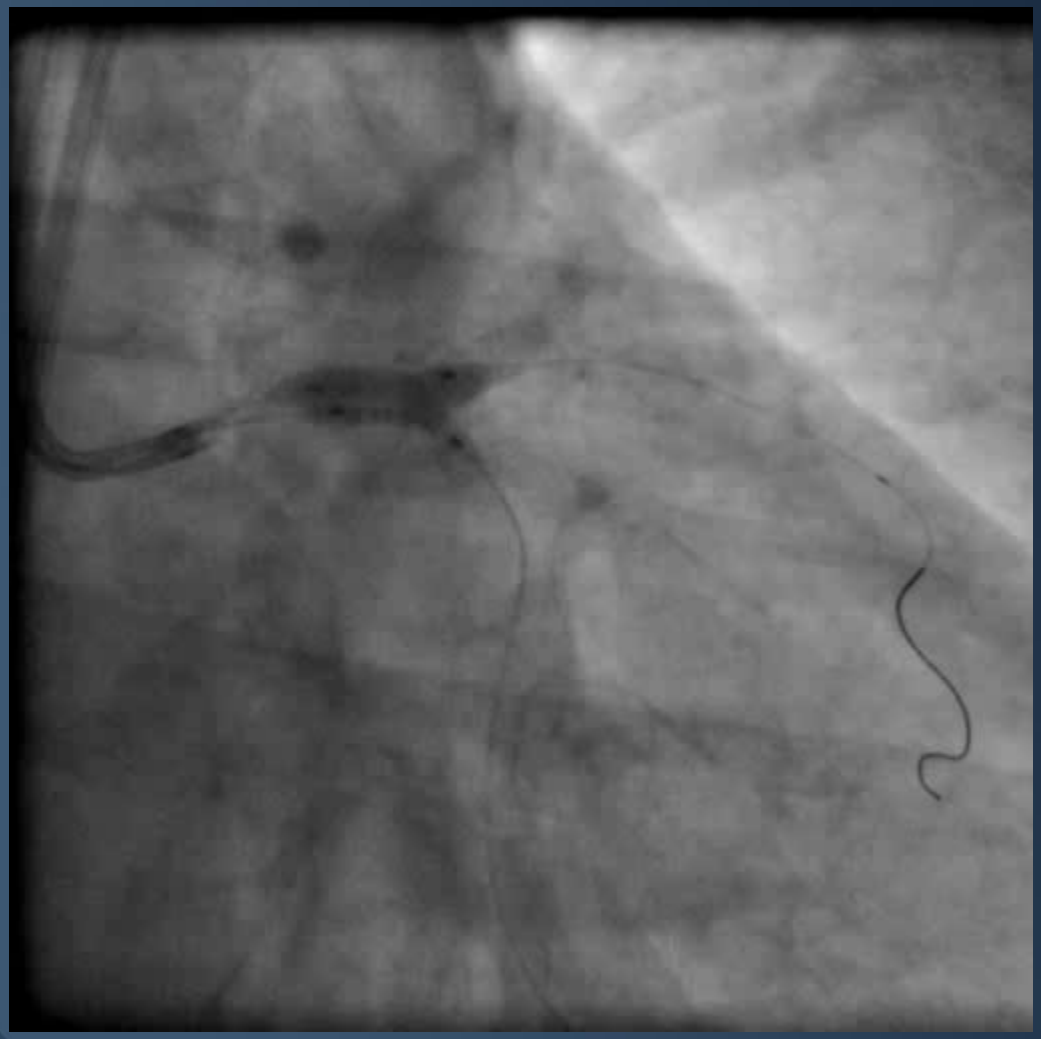

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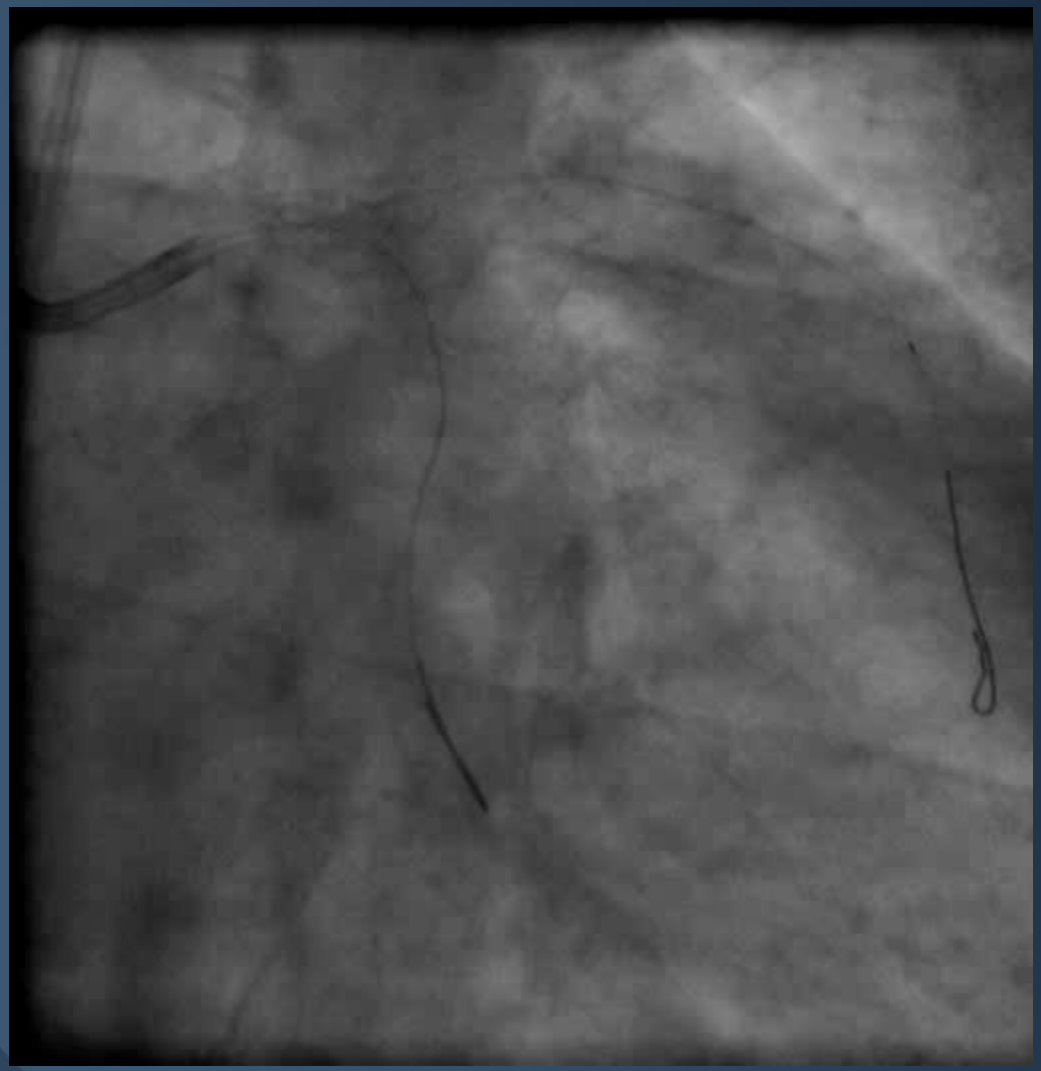

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Conclusion

- The Tryton Side Branch System is a feasible and comfortable solution for distal LM bifurcation PCI cases where 2-stent technique is desired
- Indications will broaden with larger sizes being available and shorter versions in the pipeline
- No long-term conclusions can be drawn from our small series
- Tryton IDE trial in non-LM bifurcations is ongoing, as well as Tryton-large vessel registry

Tryton IDE Study: *Schematic*