INSTITUT JANTUNG NEGARA
National Heart Institute

DCB an Alternative in De Novo and Small Vessel Disease

Dr. Amin Ariff Nuruddin
National Heart Institute
Kuala Lumpur, Malaysia

IJN. caring BEYOND your HEART

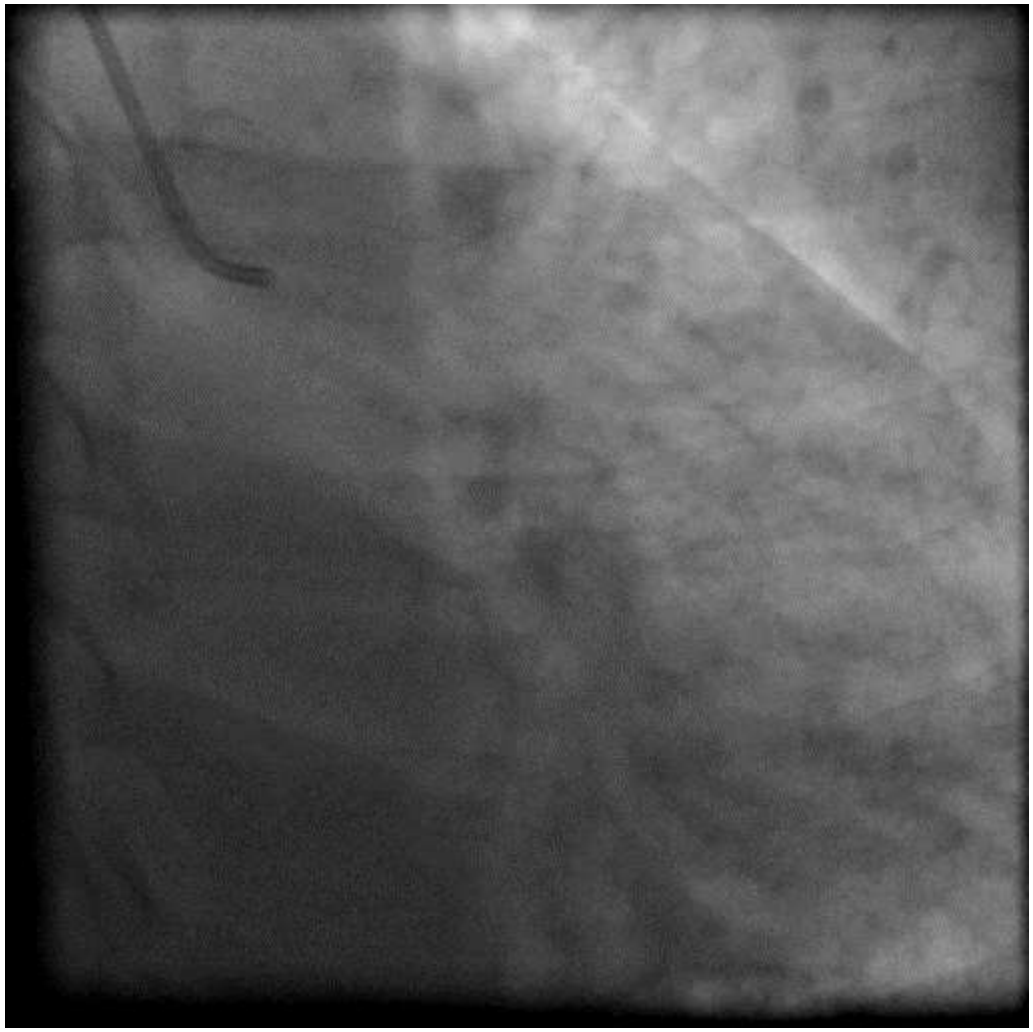
History

57 years old

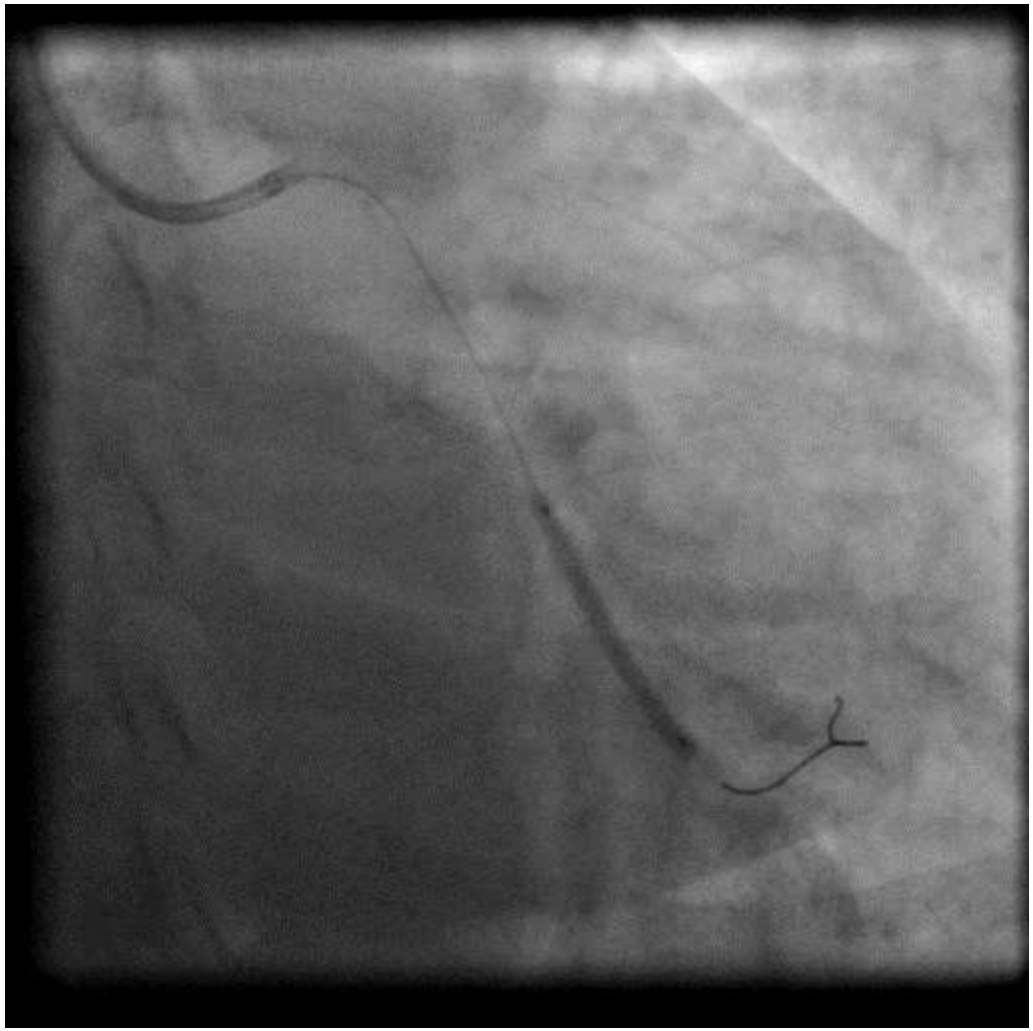
Presented with inferior myocardial infarction

Risk factors – Hypertension, diabetes mellitus

314331



314331

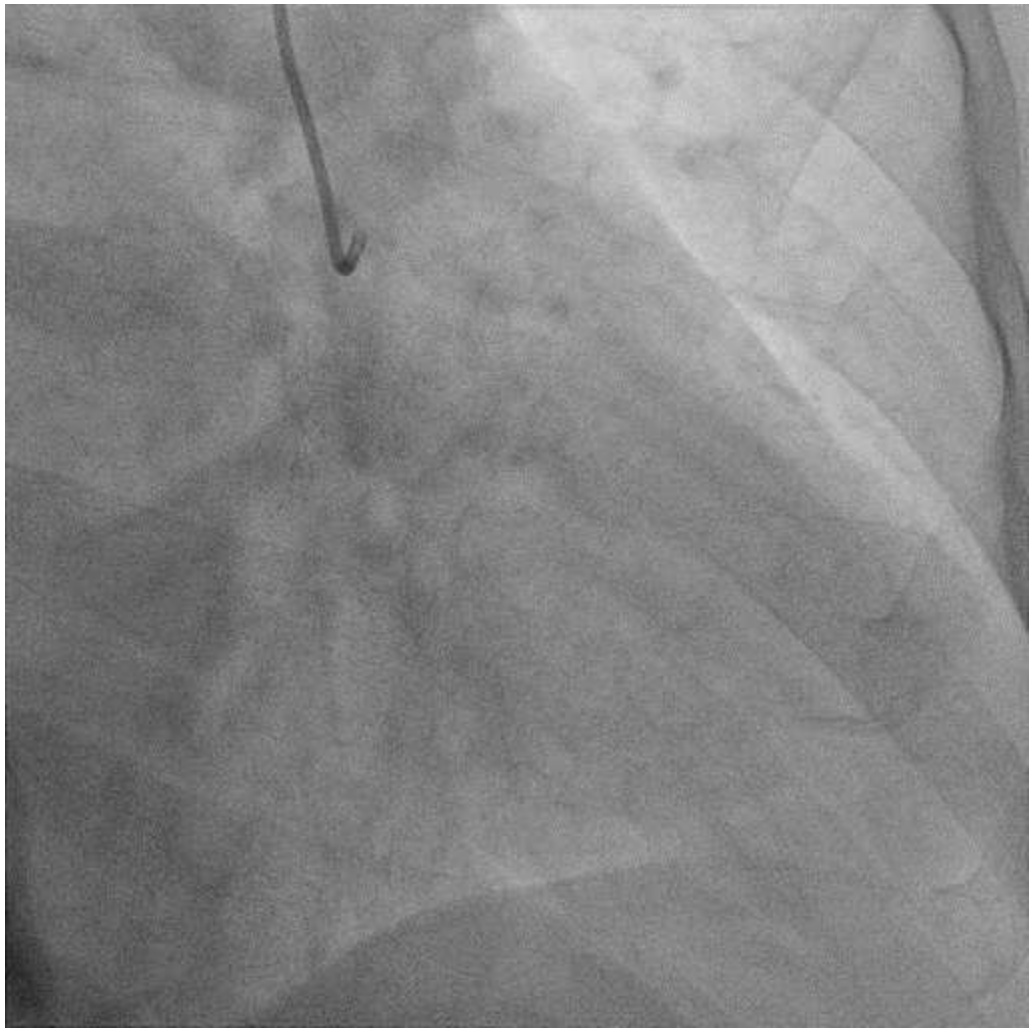


DEB Sequence 2.5 x 26 mm at 7 atm

314331

Restudied 2 years later when patient presented with acute coronary syndrome

314331



314331

History

58 years old

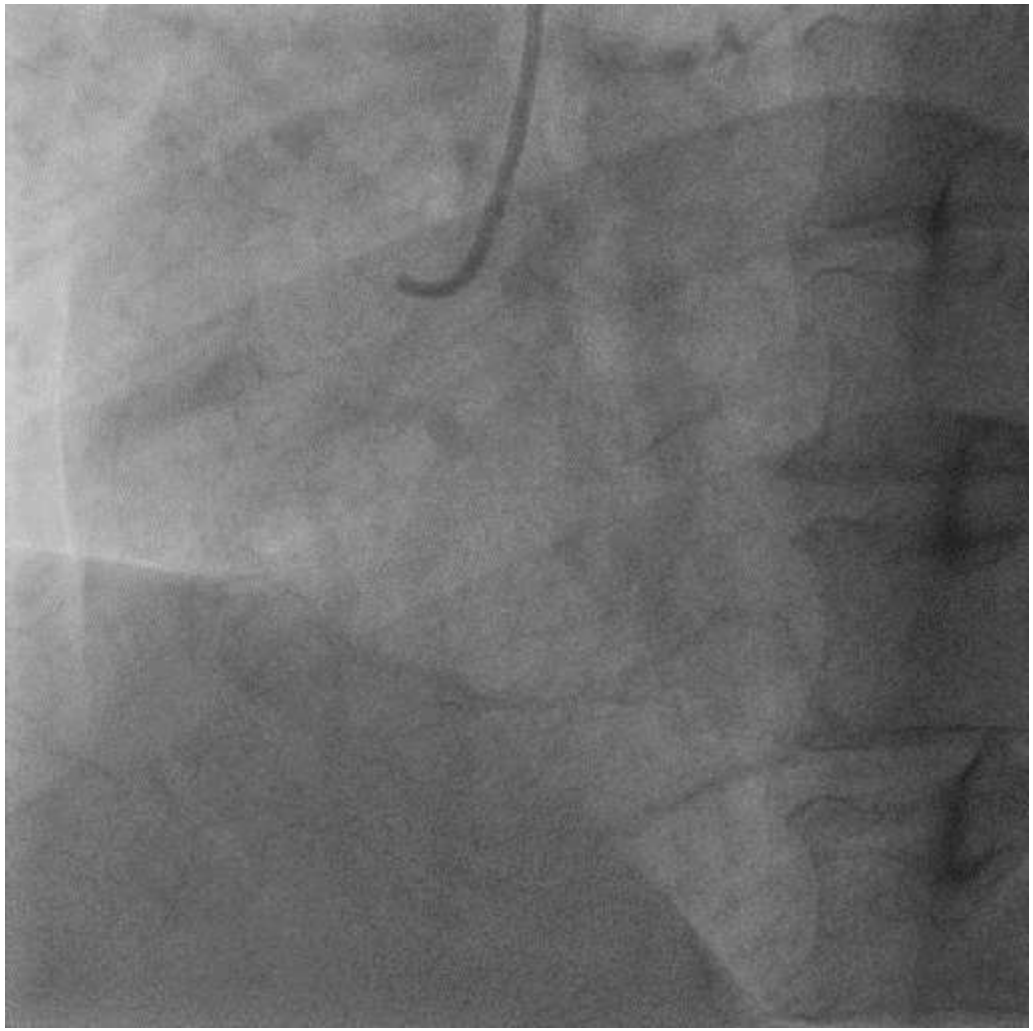
Male

Recent anterior myocardial infarction

Thrombolysed

Risk factors – Smoker, Dyslipidaemia

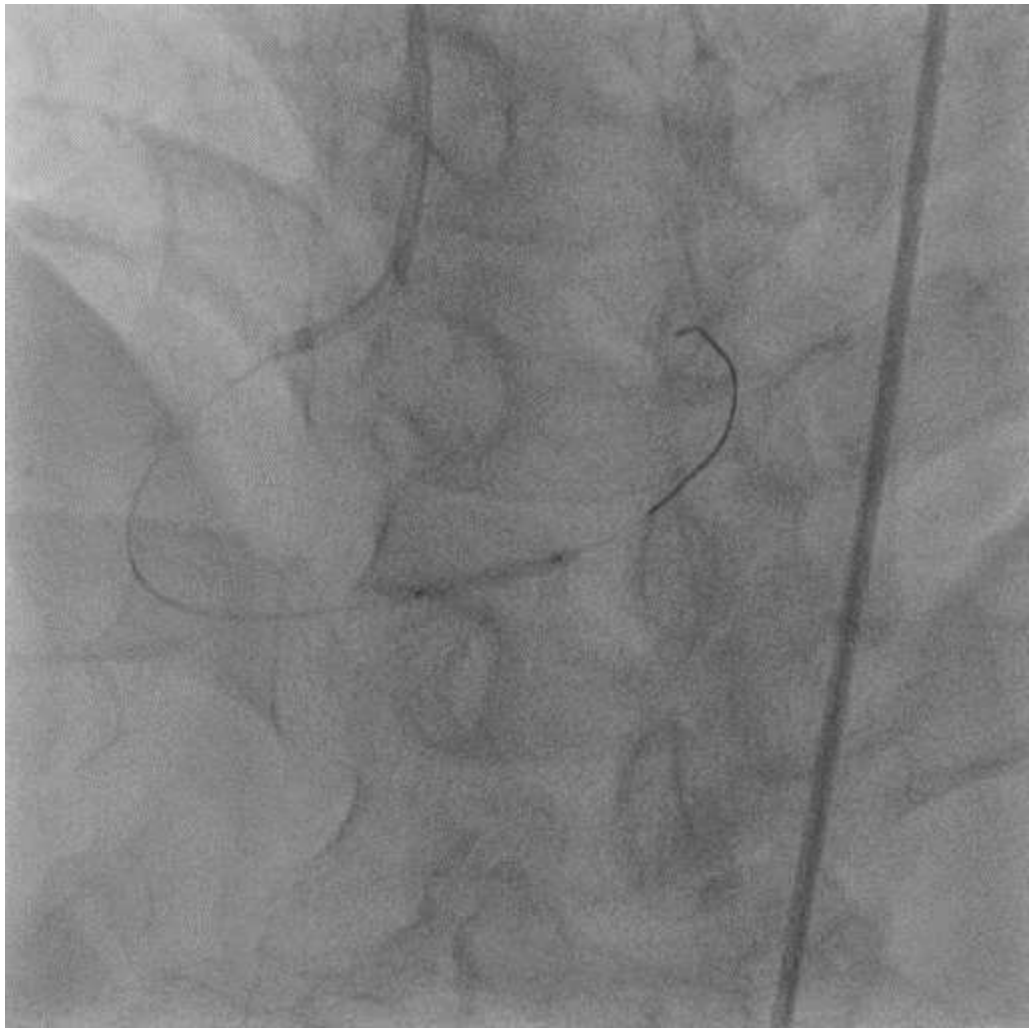
333118



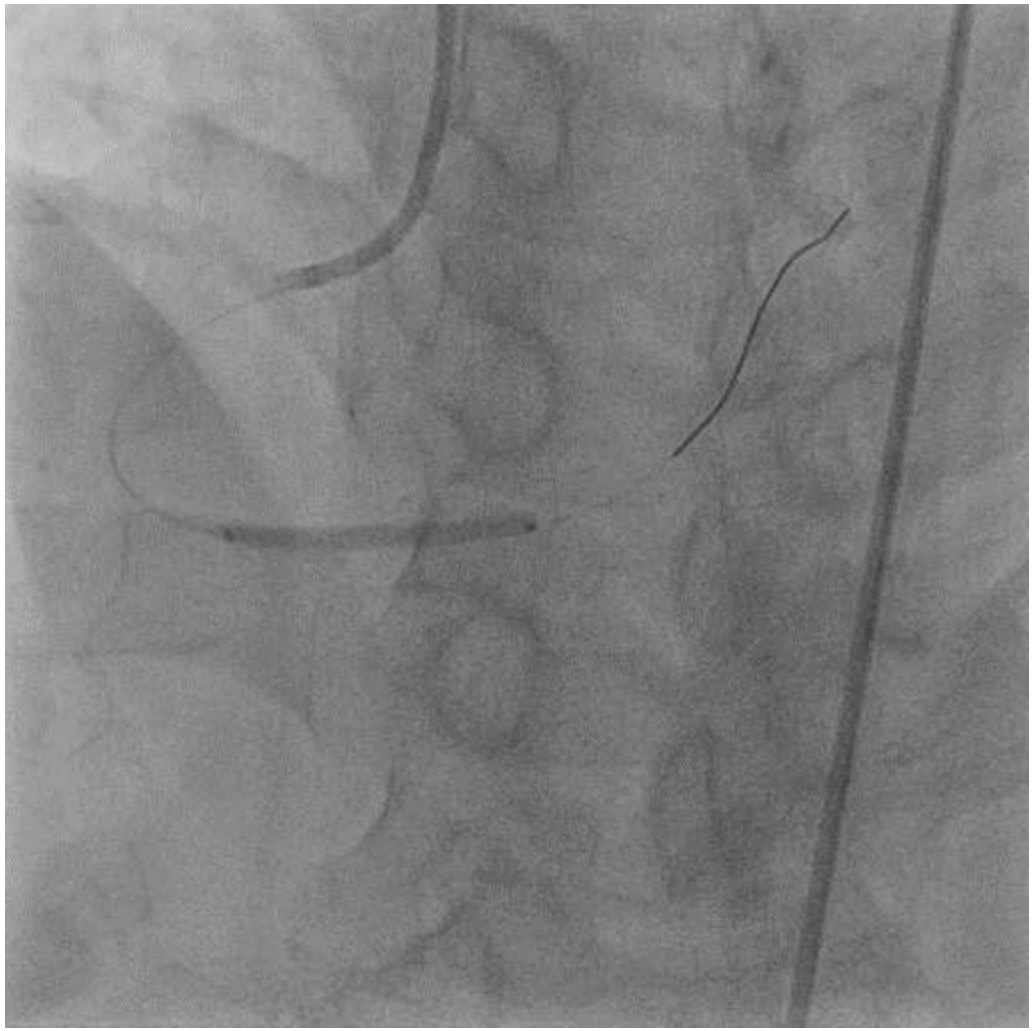
17th June 2015

333118

333118



333118

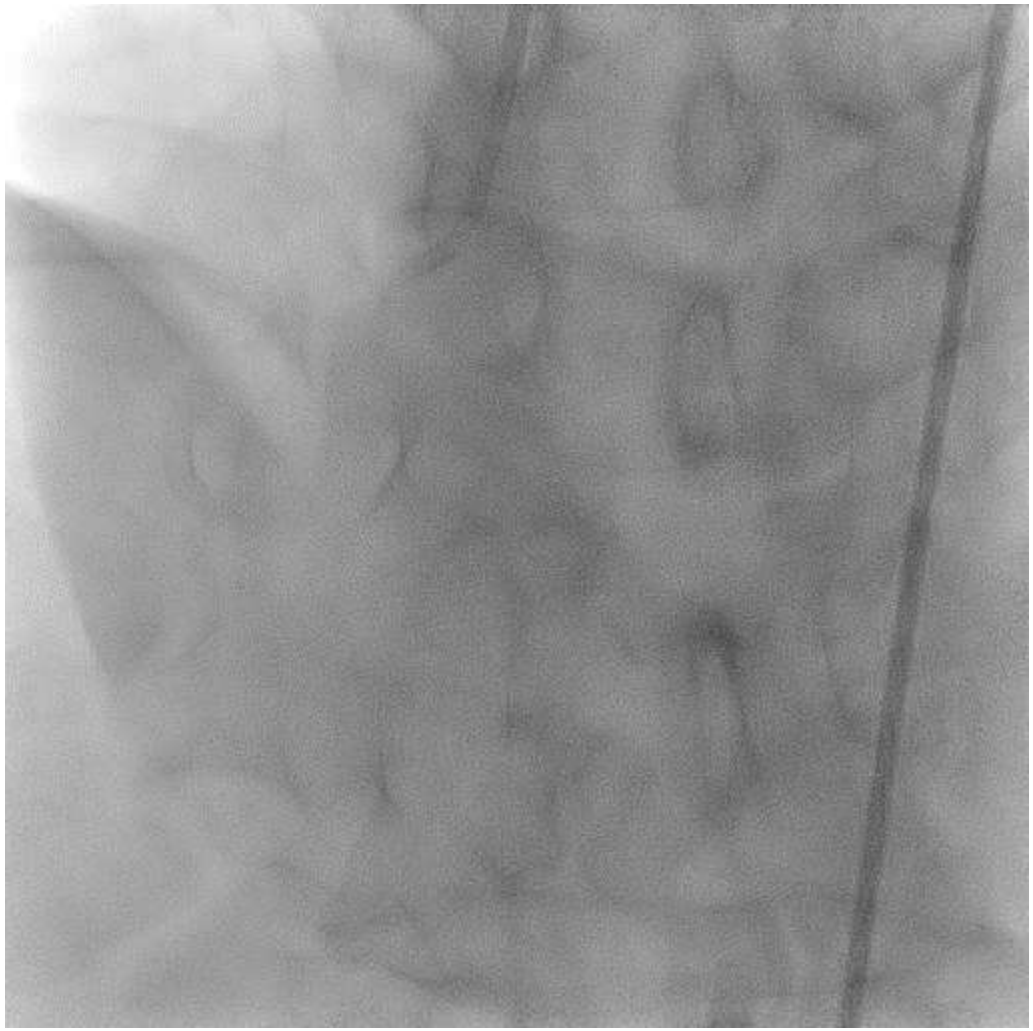


DCB Sequent Please 2.5 x 30 mm

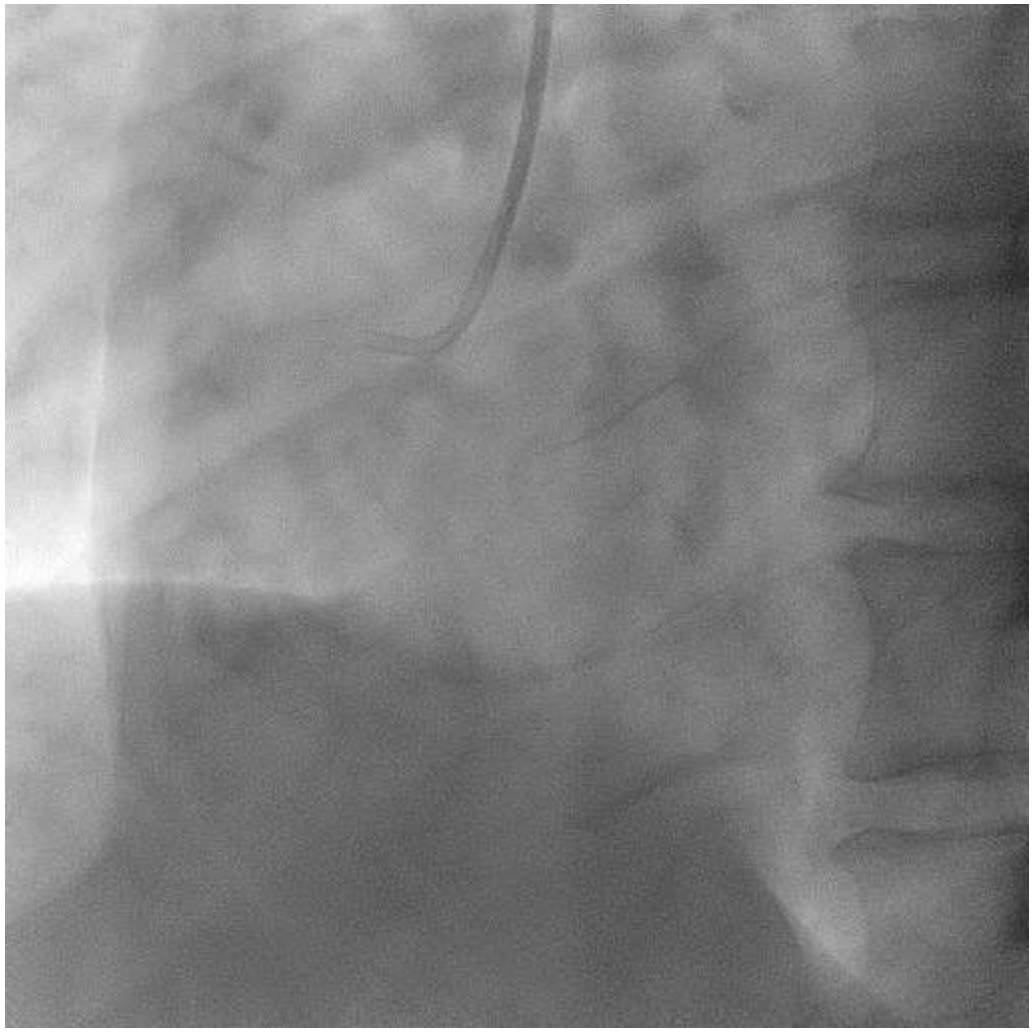
333118

Restudy 21st October 2015

333118



333118



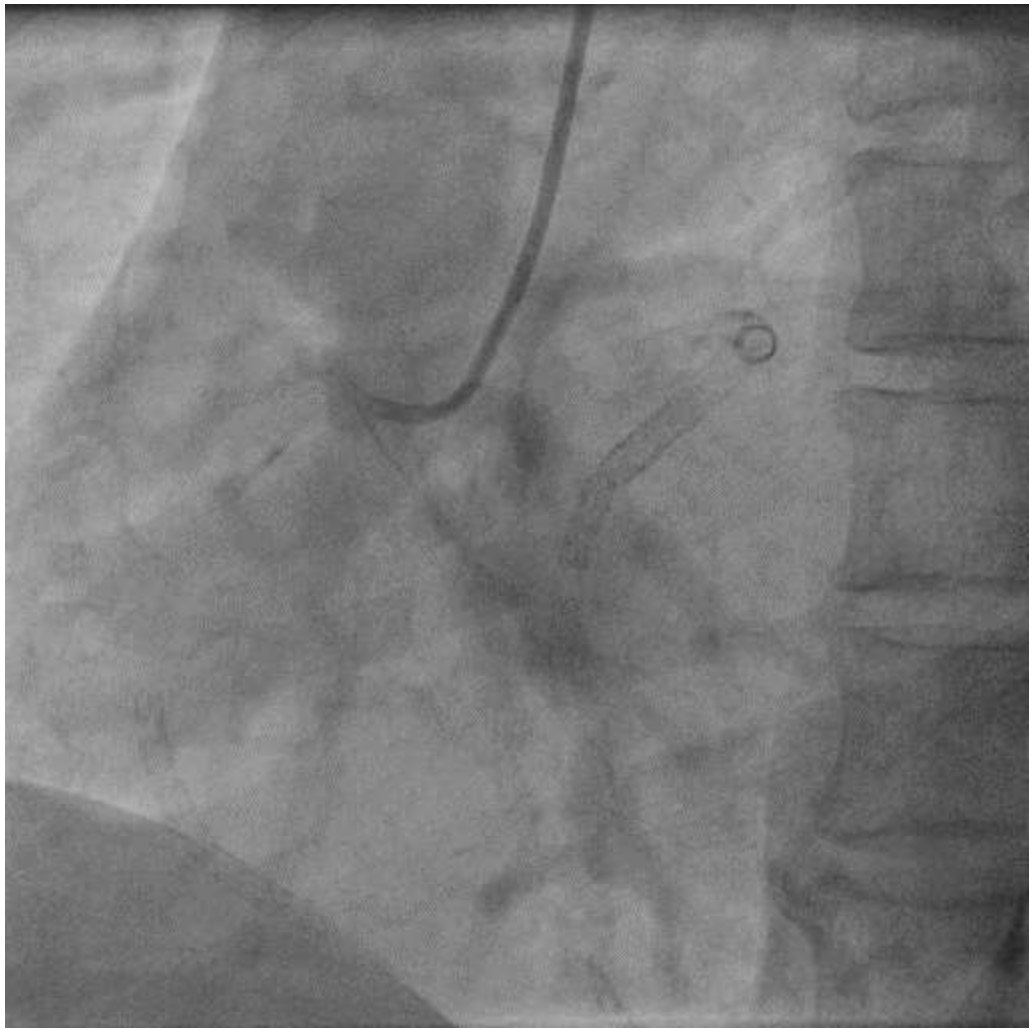
History

66 years old

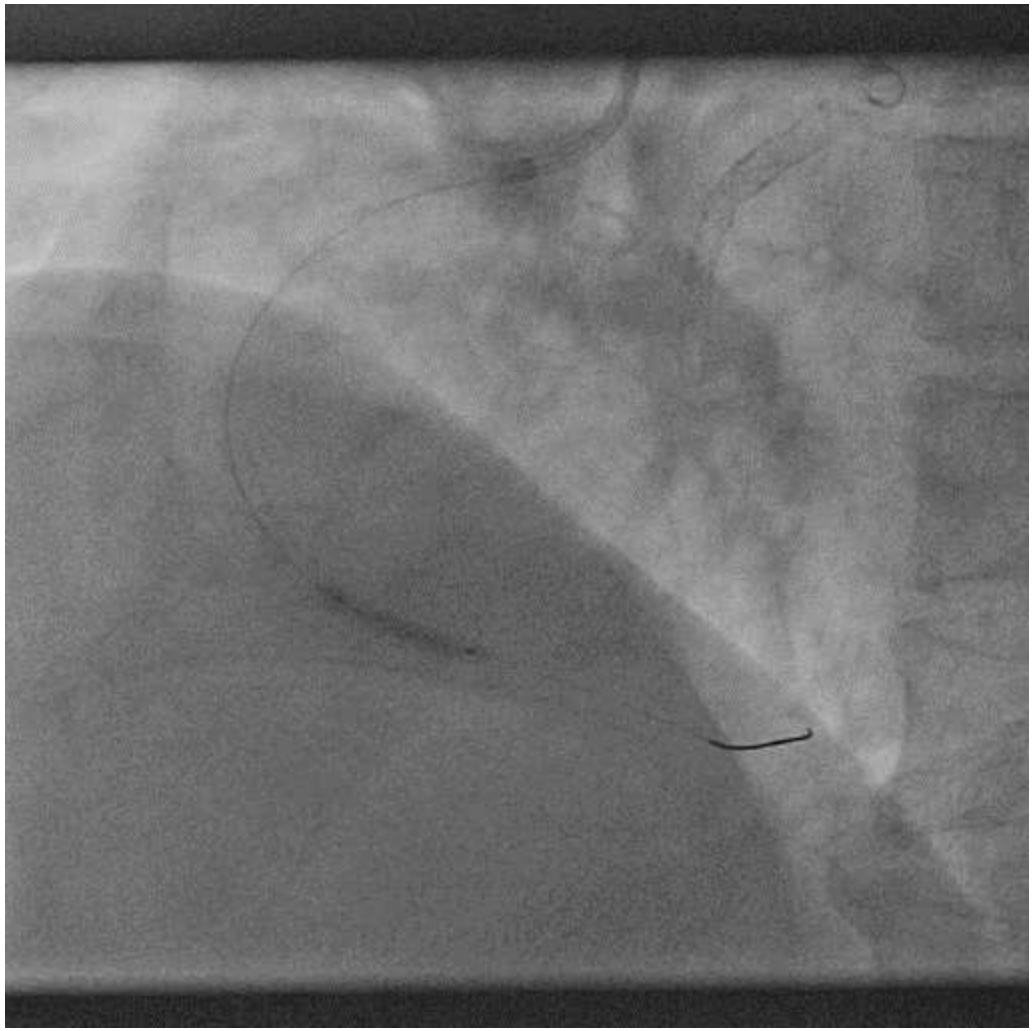
Male

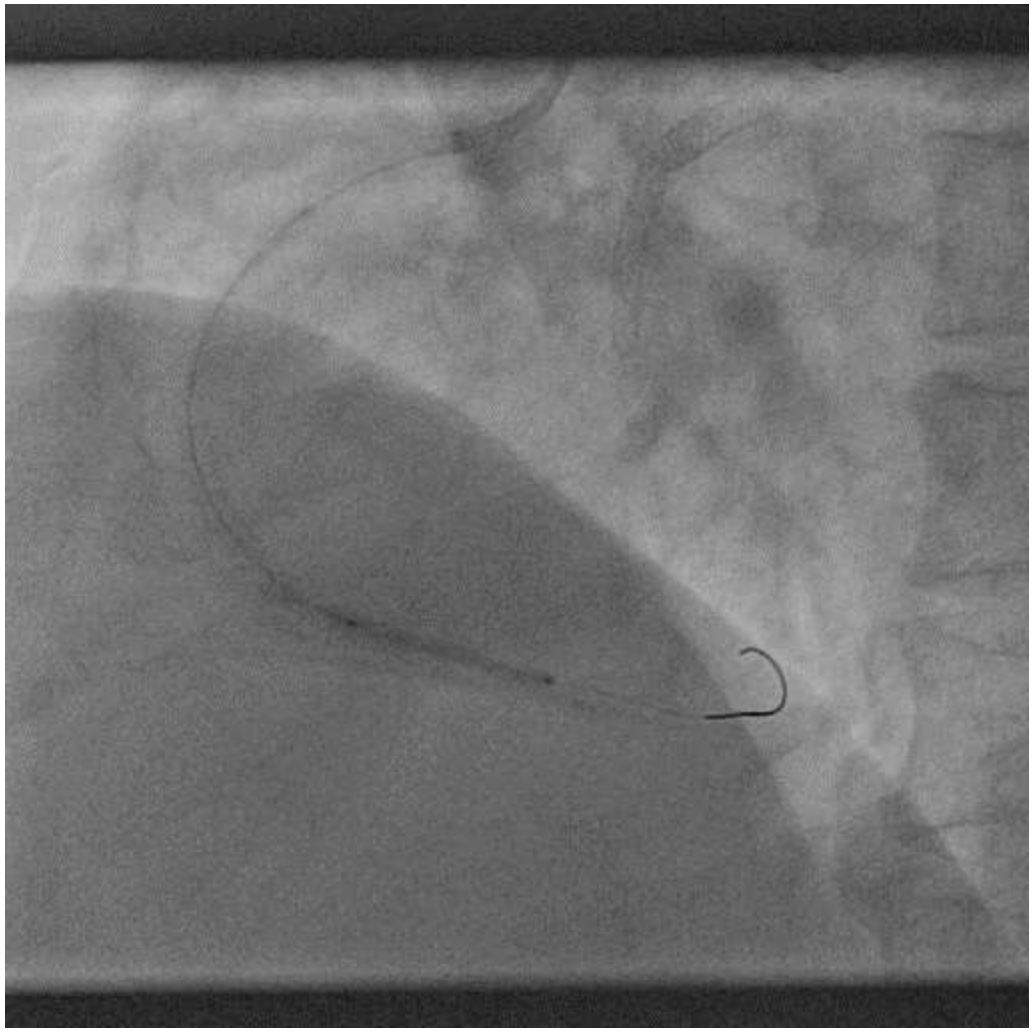
Recent angina

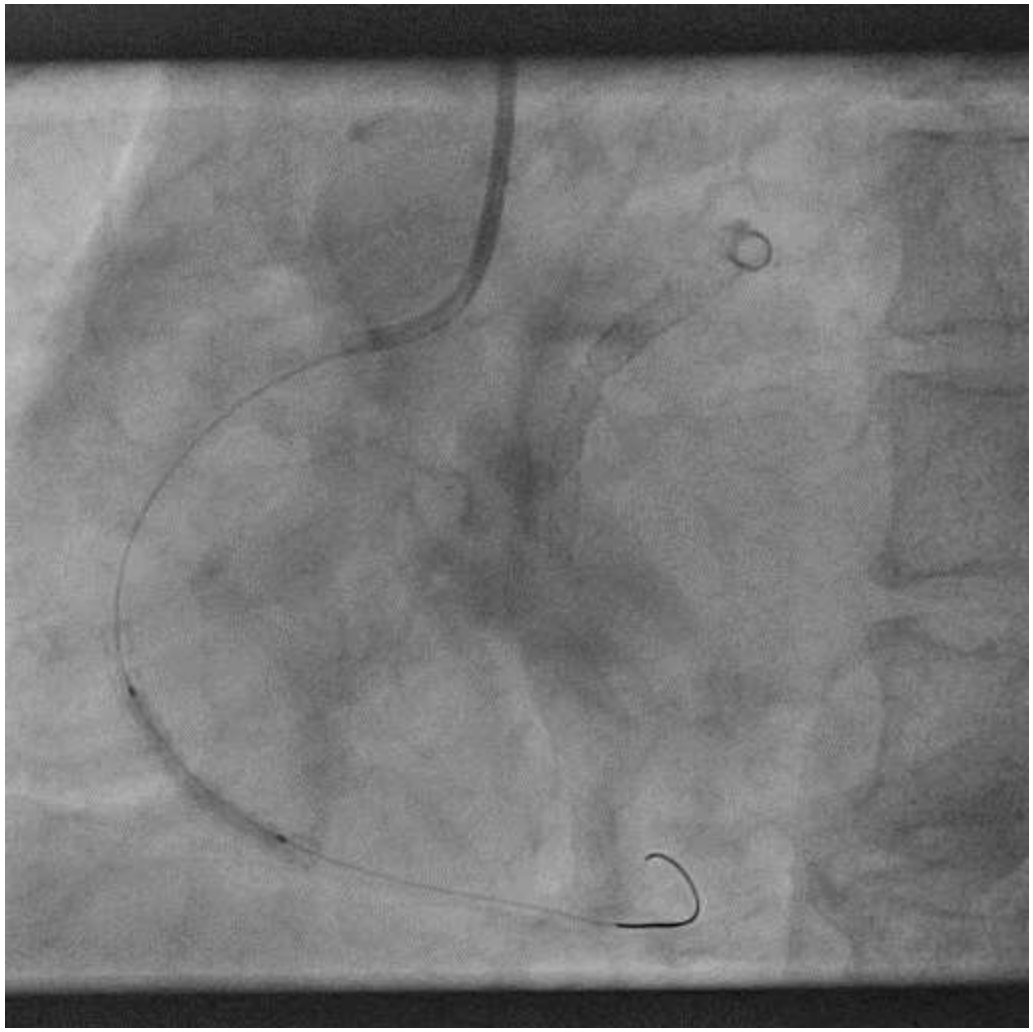
Risk factors – Diabetes mellitus and hypertension.

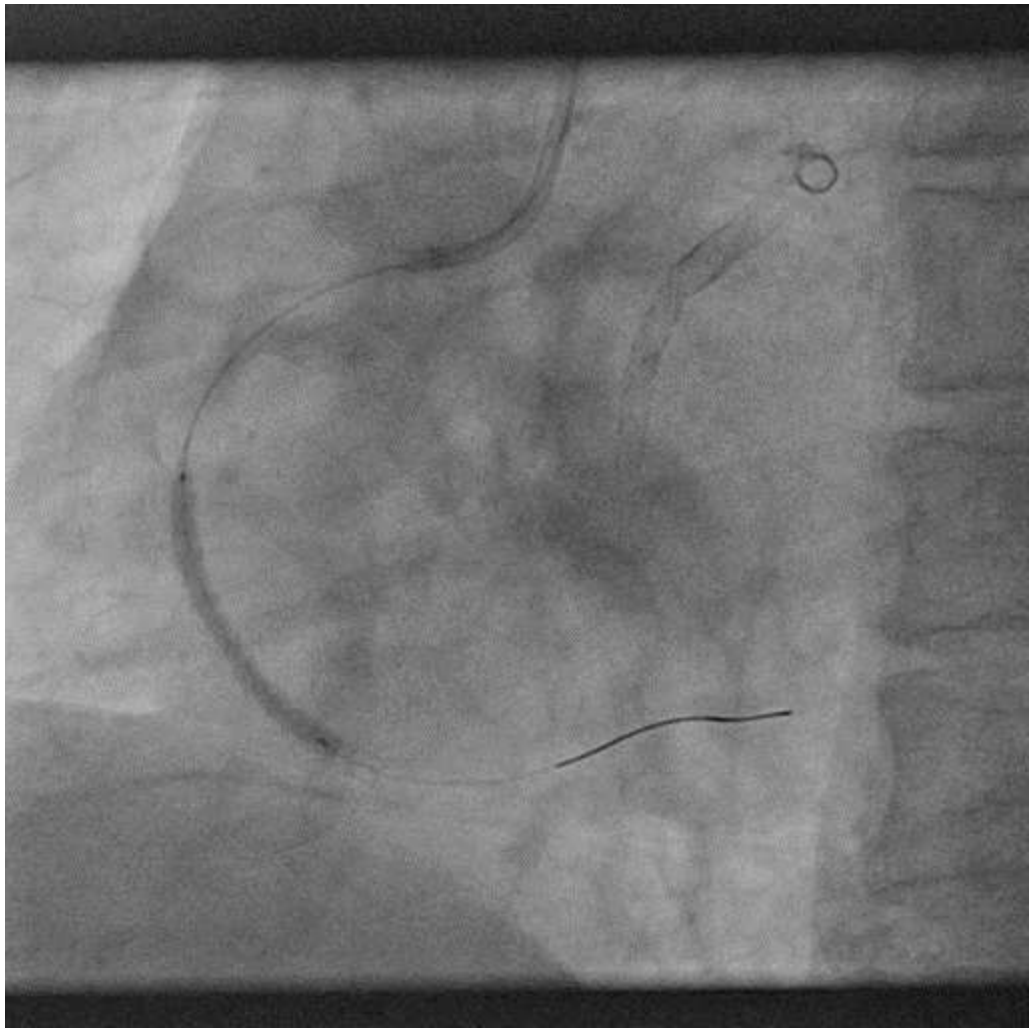


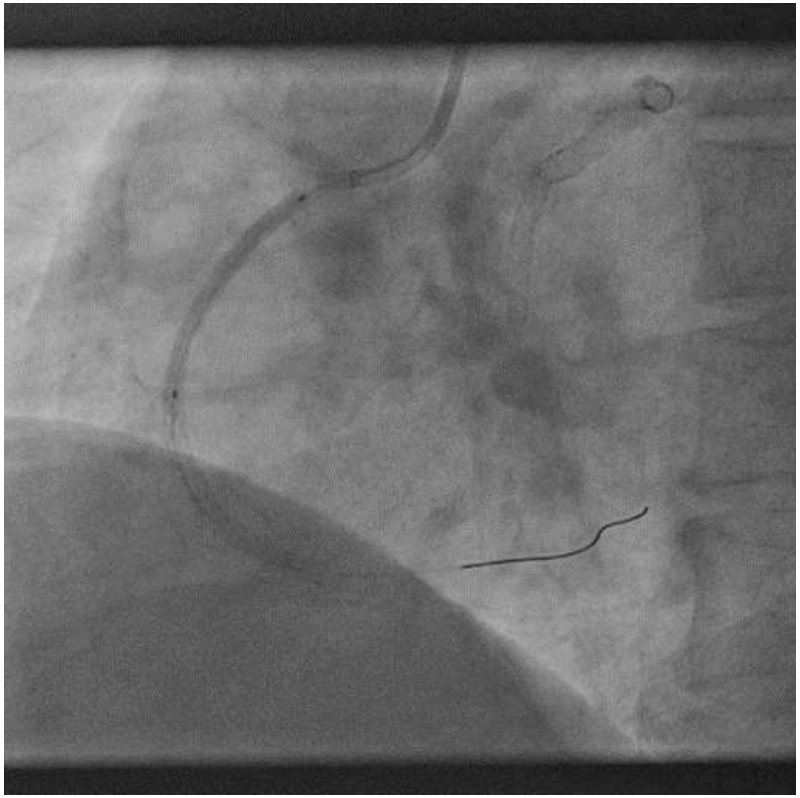
25th March 2015







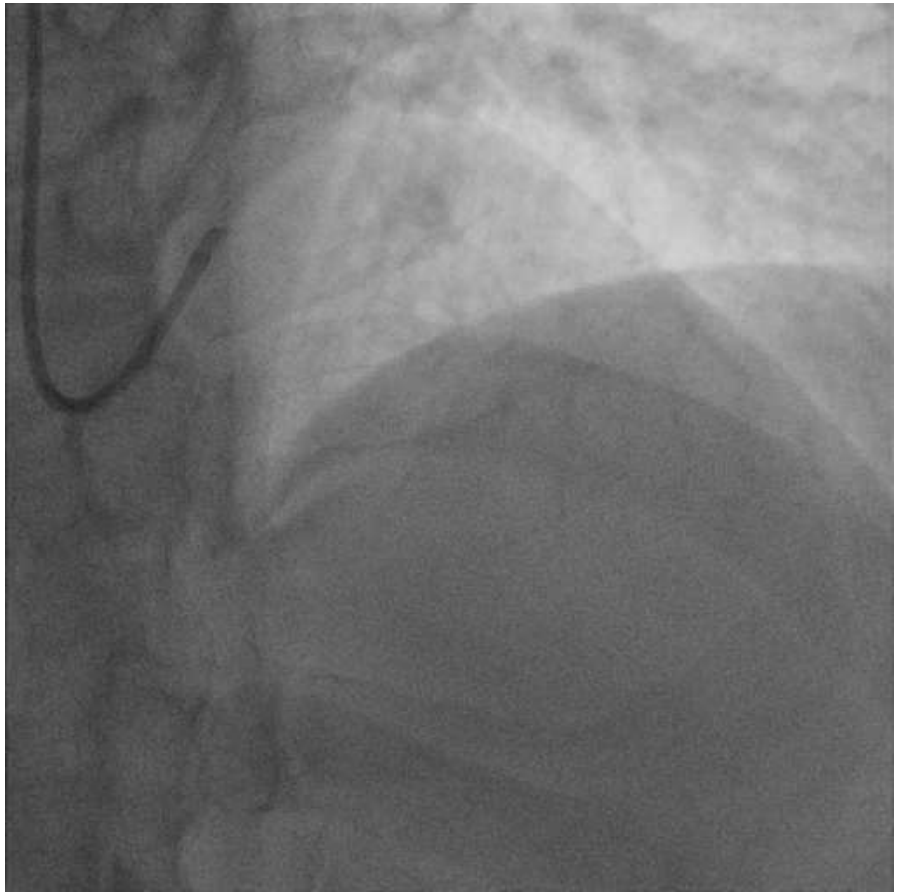




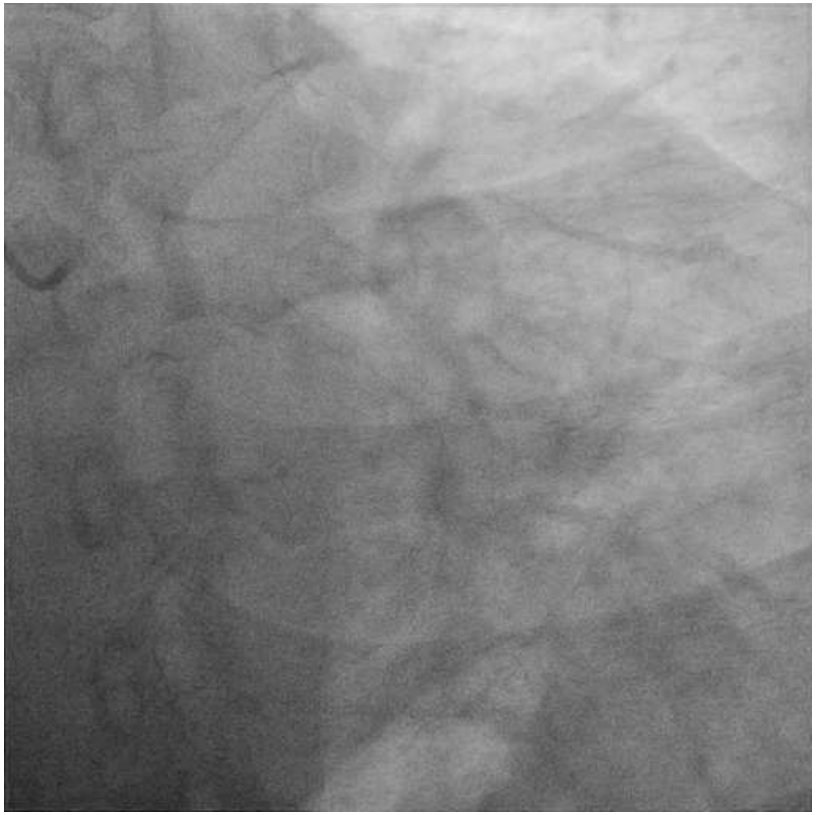
DCB Sequent Please 3.0 x 30 mm

Restudied 6th May 2015

59 Male
Diabetes, Hypertension
NSTEMI



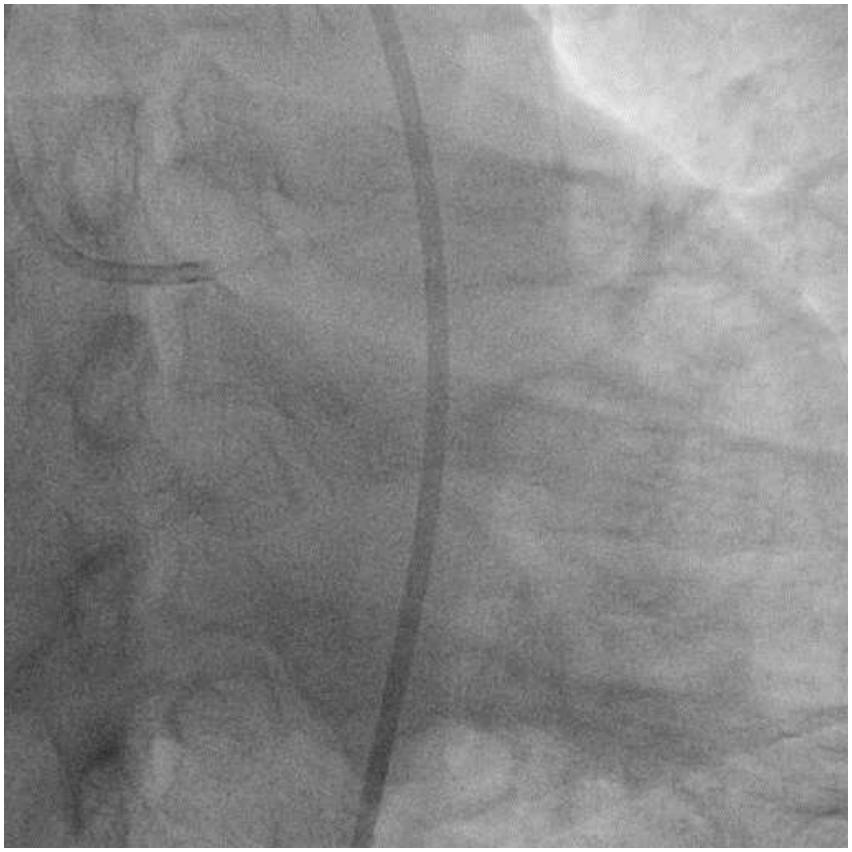
Post DCB mid, distal LAD and circumflex arteries

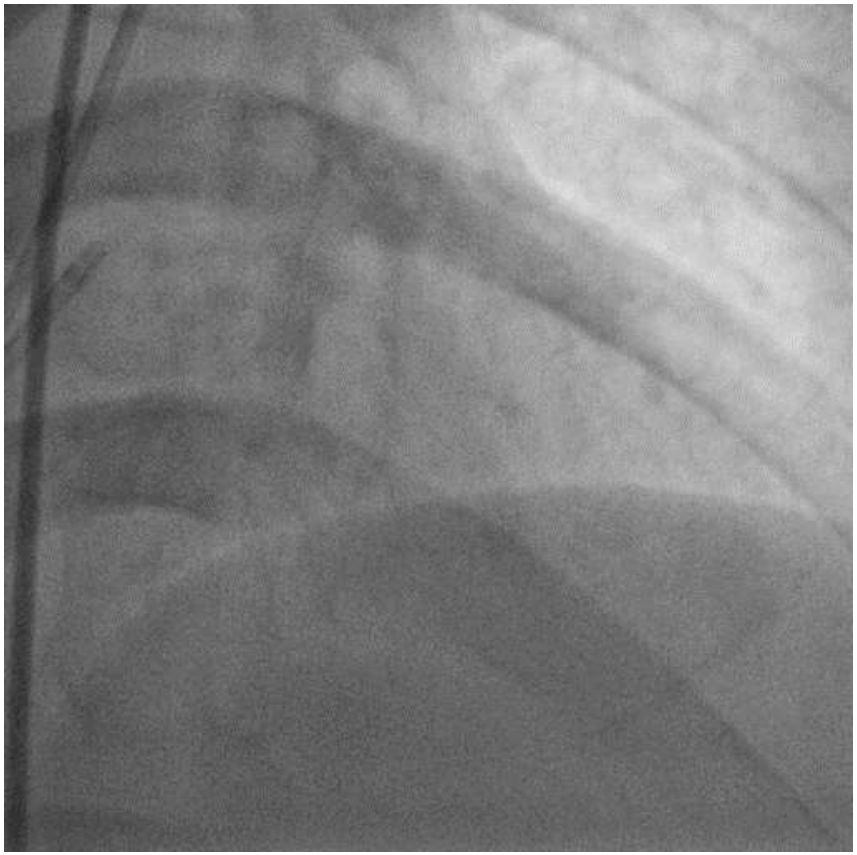


4 months follow up

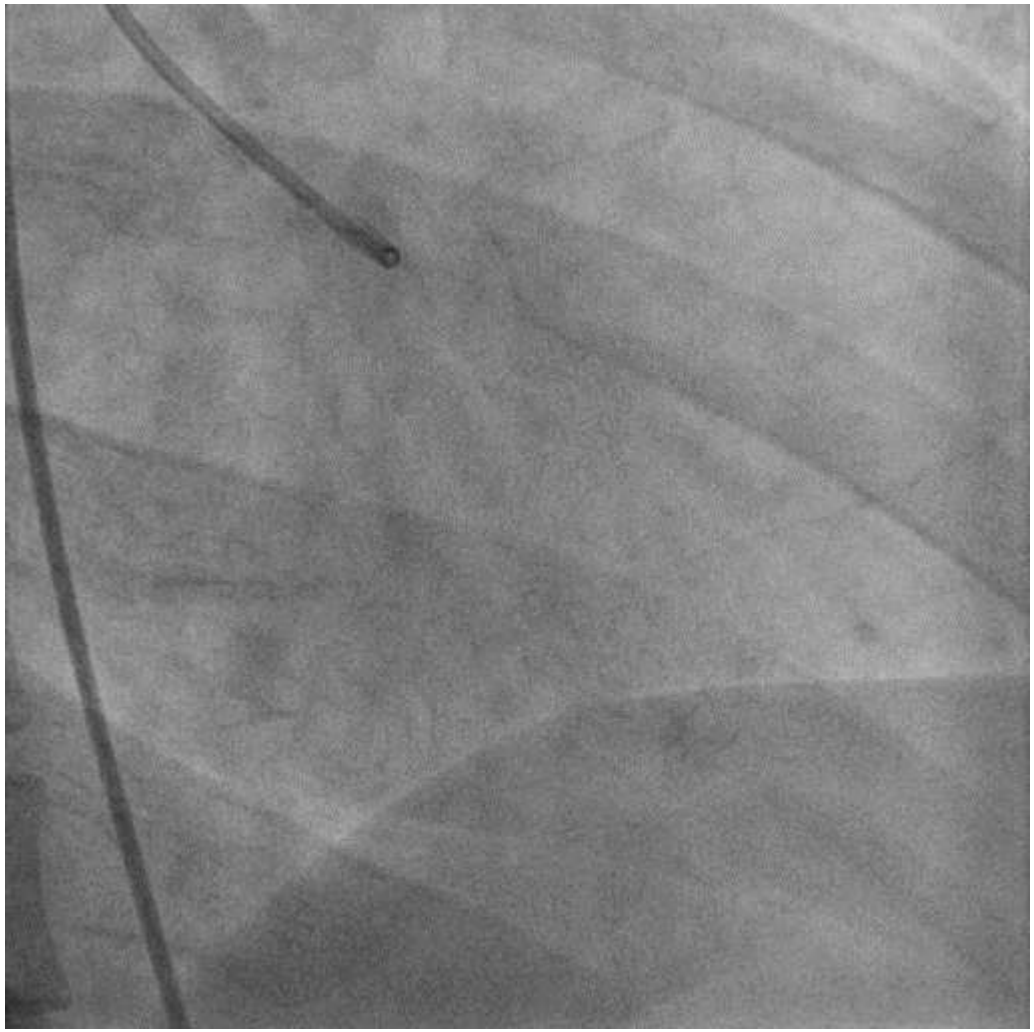
Restudy 4 months later

32 Male Soldier
Hypertension and Dyslipidaemia
NSTEMI

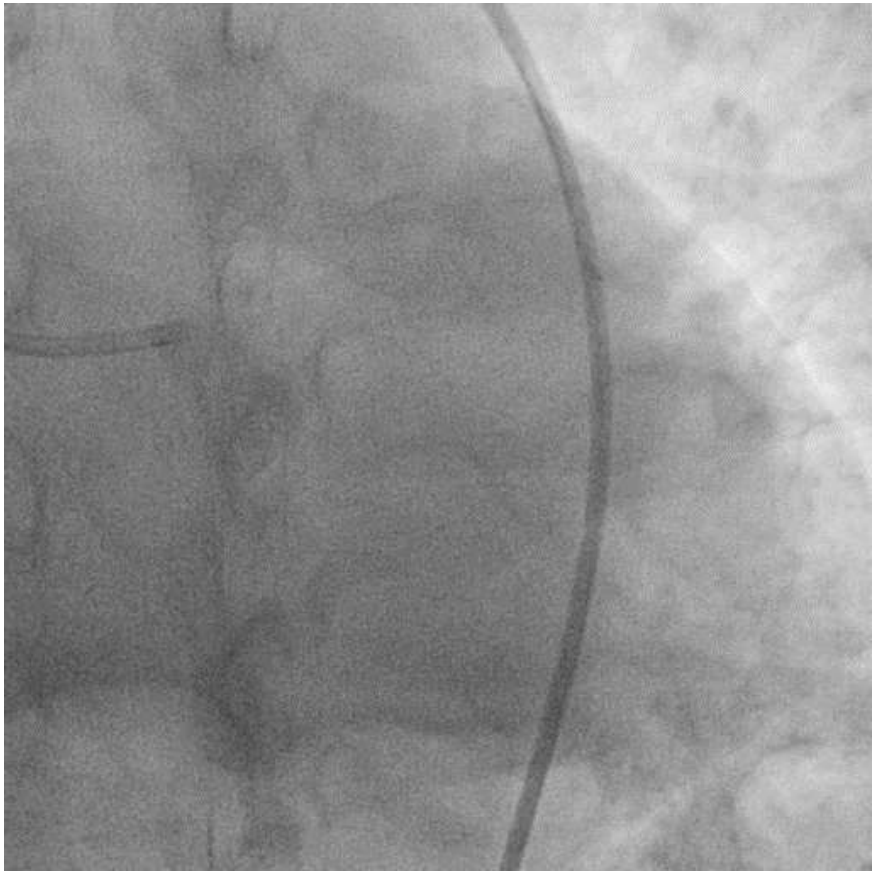


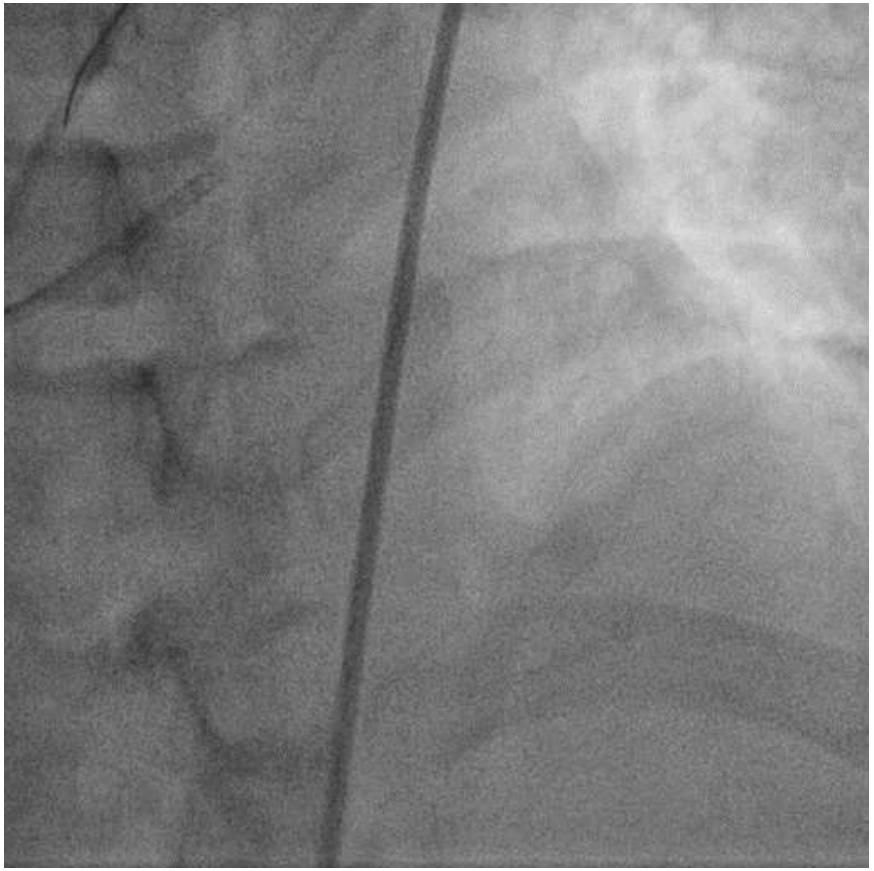


CTO proximal LAD

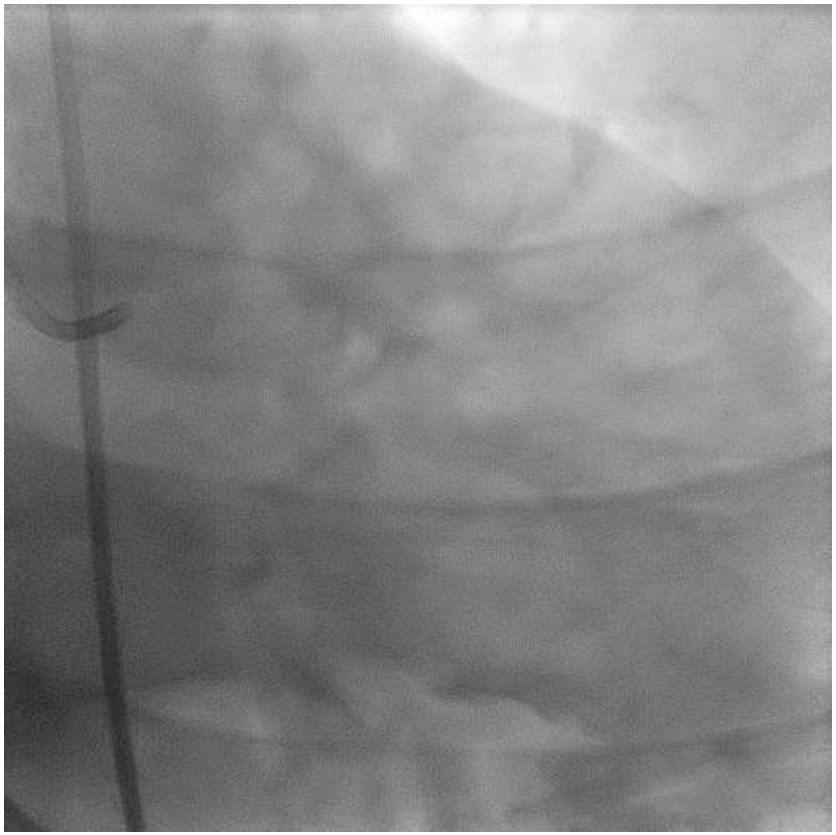


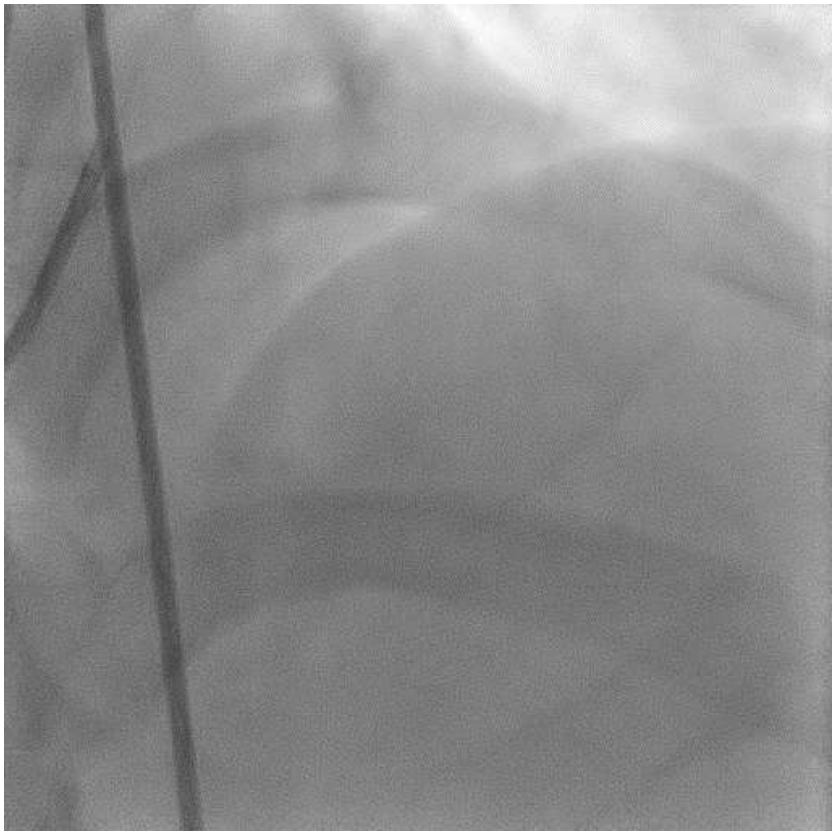
Post DCB





Sequent Please 2.0 x 35 mm - 17th August 2015
2.75 x 17 mm – 5th October 2015





Restudied 4 months later

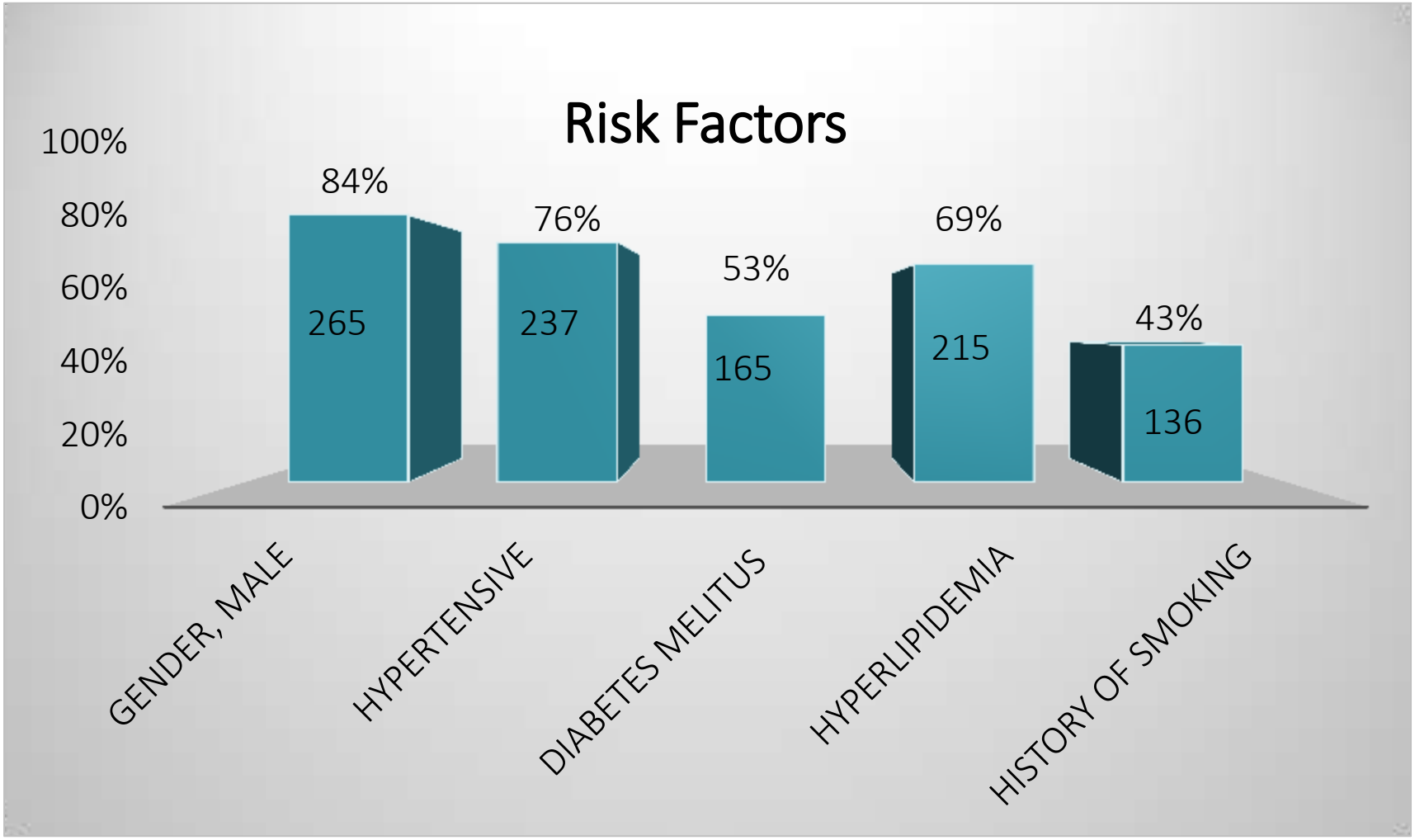
Last follow up 12th August 2016 – asymptomatic

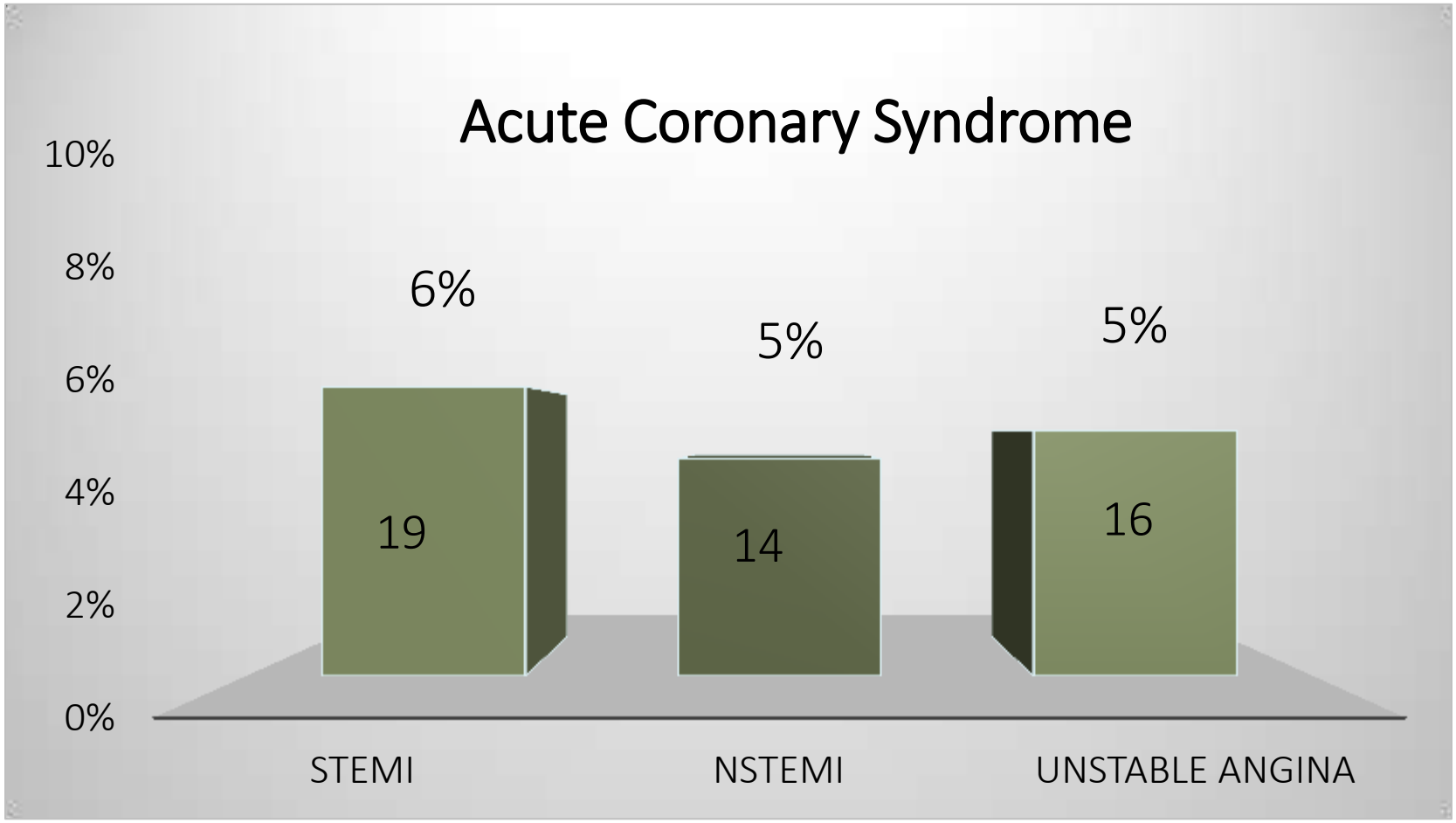
INSTITUT JANTUNG NEGARA
National Heart Institute

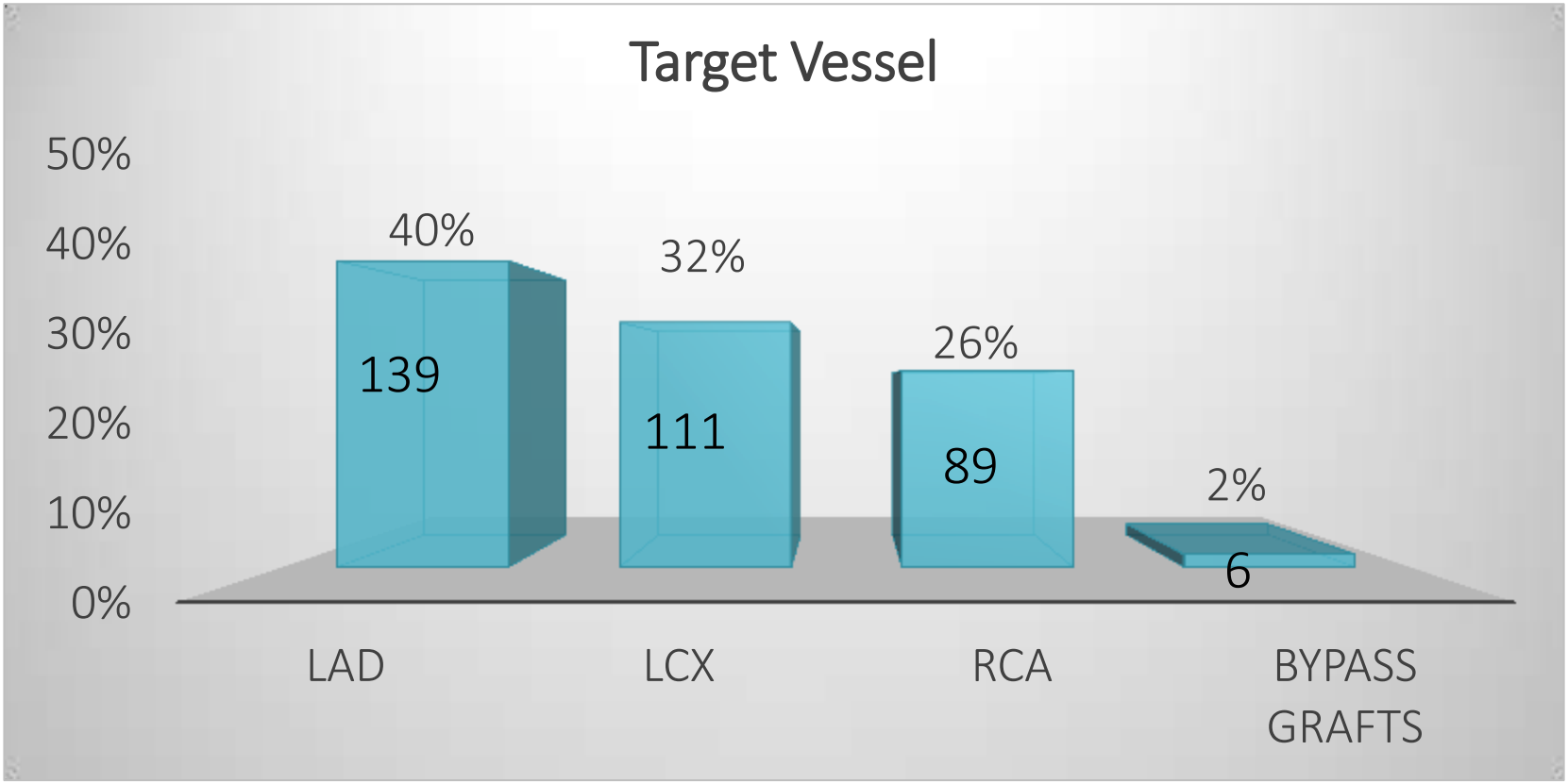
Experience with Paclitaxel-Drug Eluting Balloon (DEB) in treatment of De novo coronary artery lesions 2012-2015 at National Heart Institute, Kuala Lumpur, Malaysia

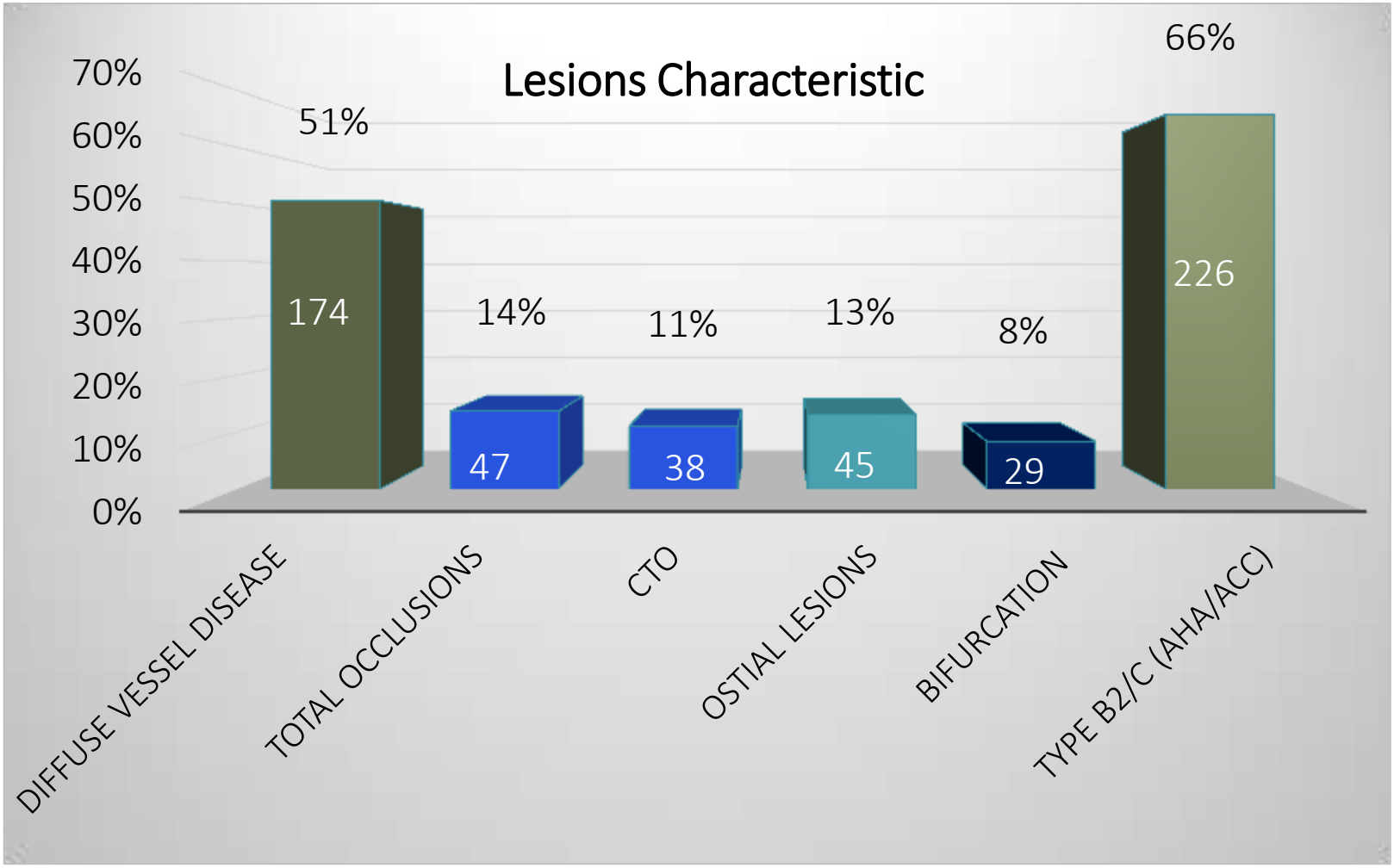
IJN. caring BEYOND your HEART

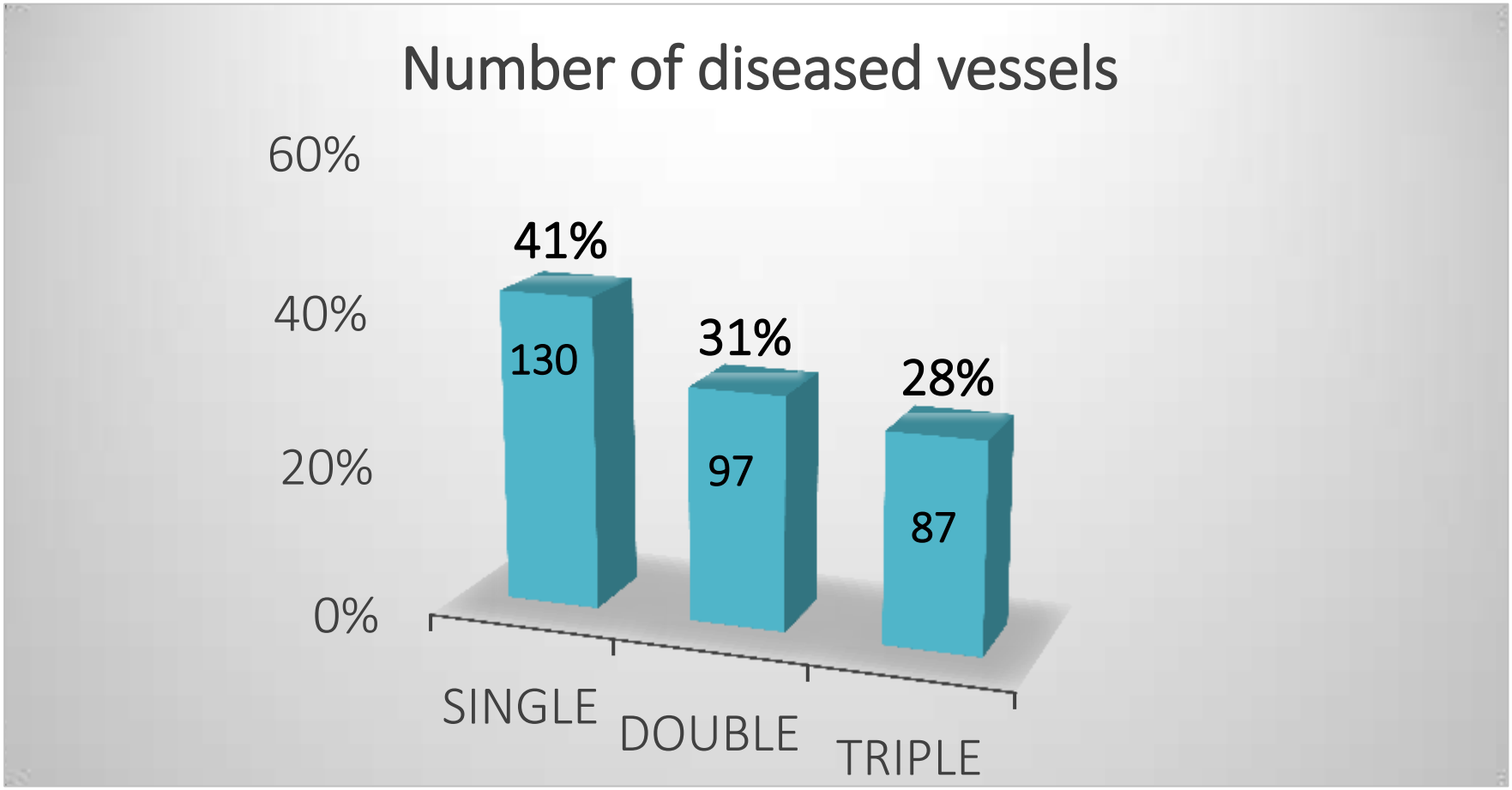
Jan 2012 to Dec 2015	Total (Percentage)
Total DCB cases	636
Total Lesions treated with DCB (Sequent Please)	715
Patients with Denovo lesions	314 (49%)
Total Denovo coronary artery lesions	344 (48%)


Risk Factors
100%
80%
60%
40%
20%
0%
84%
265
76%
237
53%
165
69%
215
43%
136
GENDER, MALE
HYPERTENSIVE
DIABETES MELITUS
HYPERLIPIDEMIA
HISTORY OF SMOKING


Acute Coronary Syndrome
10%
8%
6%
4%
2%
0%
6%
5%
5%
19
14
16
STEMI
NSTEMI
UNSTABLE ANGINA


Target Vessel
50%
40%
30%
20%
10%
0%
40%
139
32%
111
26%
89
2%
6
LAD
LCX
RCA
BYPASS GRAFTS

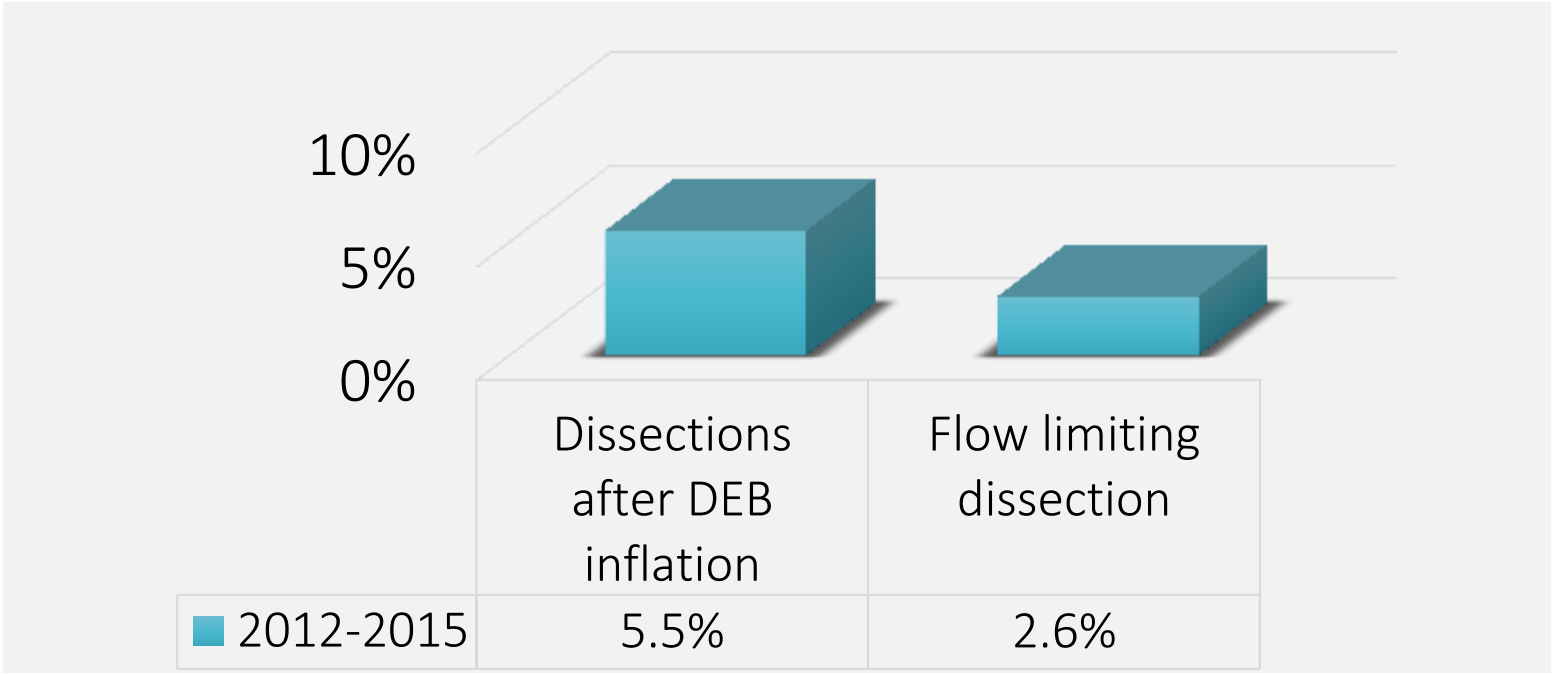

Lesions Characteristic
70%
60%
50%
40%
30%
20%
10%
0%
51%
14%
11%
13%
8%
66%
174
47
38
45
29
226
DIFFUSE VESSEL DISEASE
TOTAL OCCLUSIONS
CTO
OSTIAL LESIONS
BIFURCATION
TYPE B2/C (AHA/ACC)


Number of diseased vessels
60%
40%
20%
0%
41%
130
31%
97
28%
87
SINGLE
DOUBLE
TRIPLE

Lesion Description	2012- 2015
Vessel diameter, Mean ± SD	2.5 ± 0.4 mm
Lesion length, Mean ± SD	26 ± 18 mm

Lesion Description	2012- 2015
Percentage of stenosis Pre PCI, Mean ± SD	87 ± 12 %
Percentage of stenosis Post PCI, Mean ± SD	3 ± 8 %

Device characteristics	2012-2015
Total Predilation done, %	338 (98%)
Predilation diameter, Mean ± SD	2.1 ± 0.4 mm
Predilation length, Mean ± SD	14 ± 4 mm
Predilation pressure, Mean ± SD	11 ± 4 atm
Pre DEB percentage of stenosis, Mean ± SD	30 ± 16 %
DEB diameter, Mean ± SD	2.4 ± 0.4 mm
DEB length, Mean ± SD	22 ± 7 mm
Inflation pressure of DEB, Mean ± SD	9 ± 4 atm
Inflation time of DEB, Mean ± SD	59 ± 15 seconds



	2012 - 2015
Dissection, %	19 (5.5%)
Flow limiting dissection	9 (2.6%)

Patient Outcome	2012 - 2015
In hospital Mortality, %	**3 (1%)**
Total patients available for follow up, %	303 (97%)
Follow up duration, Mean ± SD	17 ± 11 months
Follow up duration, Median (Q1,Q3)	12 (12,24) months
Follow up MACE, %	8 (3%)
Death Event, %	8 (3%)
Cardiac Death, %	2 (1%)
TLR	6 (2%)

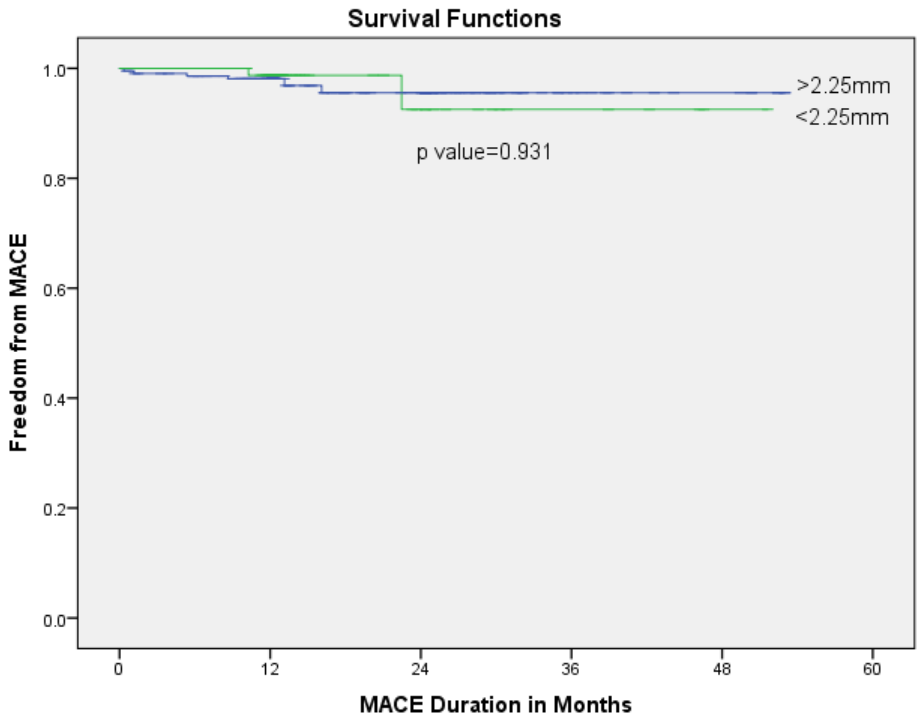
*MACE are TLR, MI and Cardiac Death

Small Vessel Diameter $\leq$ 2.25 mm

Baseline	≤2.25 mm Vessel	>2.25 mm Vessel	**p value**
Total Denovo coronary lesions,%	98 (28.5%)	246 (71.5%)	-
Total Denovo cases,%	92 (93.9%)	222 (90.2%)	0.281
Age, Mean ± SD years	58.0 ± 10.2	59.1± 10.1	0.974
Age, **(Min, Max) years**	(32.9,84.1)	(28.3,85.8)	-
Gender, Male %	76 (82.6%)	189 (85.1%)	0.574

Lesion Description	≤2.25mm Vessel	>2.25mm Vessel
Vessel diameter, Mean ± SD	2.0 ± 0.1 mm	2.7 ± 0.3 mm
Vessel diameter, **(Min, Max)**	**(2.0,2.25)mm**	**(2.5,3.5)mm**
Lesion length, Mean ± SD	24.5 ± 19.4 mm	26.8 ± 17.2 mm

	≤2.25mm Vessel	>2.25mm Vessel	**p value**
Dissection Post DEB,%	9(9.2%)	10 (4.1%)	0.061
Flow Limiting,%	6 (6.1%)	3 (1.2%)	**0.018**
Non Flow Limiting,%	3 (3.1%)	7 (2.8%)	>0.05



		1 year	2 years	3 years	4 years
Number at Risk	≤2.25mm vessel	70	12	4	1
	>2.25mm vessel	175	58	14	6
Probability, %	≤2.25mm vessel	98.7%	92.5%	92.5%	92.5%
	>2.25mm vessel	98.1%	95.5%	95.5%	95.5%

Single-centre experience with drug-coated balloon in the treatment of de novo small vessel coronary artery disease

AMIN A.N., *MOHAN R., TEOH C.K., JAYAKHANTHAN K., AL FAZIR O., AHMAD K.M.Y., SHAIFUL A.Y., FAIZAL M.R., INTAN S.S., ROSLI M.A.*
Institut Jantung Negara, KUALA LUMPUR, MALAYSIA

AIMS

To report the outcome of Paclitaxel-Drug Coated Balloon (DCB) angioplasty in the treatment of de novo small vessel coronary artery lesions.

METHODS AND RESULTS

A total of 636 patients with 715 coronary lesions treated with DCB (SeQuent Please) were reviewed between January 2012 – December 2015. Three hundred and twenty two (51%) patients with 371 (52%) lesions had in-stent restenosis (ISR). We evaluated the remaining 314 (49%) patients with 344 (48%) de novo coronary artery lesions. Mean age was 59±10 years with a predominance of males (n= 265, 84%). Majority were hypertensive (n=237, 76%) and diabetes mellitus accounted for 165 (53%) of cases. Sixteen percent presented with acute coronary syndrome (ACS), 6% had STEMI, 5% had NSTEMI and 5% unstable angina. Diffuse vessel disease were present in 174 cases (51%). Majority of the stenotic lesions were in the left coronary artery; left anterior descending artery, n=139, (40%) and left circumflex artery, n=111 (32%). Eighty nine (26%) lesions were in the right coronary artery and 6 were in the bypass grafts (2%). Total occlusions were found in 47 cases (14%). There were 45 (13%) ostial lesions and 29 (8%) bifurcation lesions. Majority of the lesions were type B2 and C lesions (n=226, 66%). The mean reference diameter of the lesion was 2.5±0.4 mm and mean lesion length treated was 26±18 mm. The mean lesion stenosis was 87±12%. Predilatation of the lesions were performed in majority of cases (n=338, 98%) with a pressure of 11±4 atmospheres. The mean DCB diameter and dilatation pressure were 2.4±0.4 mm and 9±4 atmospheres, respectively. The mean inflation time was 59±15 seconds. Lesions that were bailed out with stents were 9 (2.6%). Two hundred and fifty one (81%) patients received both Aspirin and Clopidogrel on discharge.

Clinical follow-up were available in 303 (97%) patients with a mean of 17±11 months. There were no complications of acute or subacute vessel thrombosis following treatment and all remained free of vessel thrombosis on follow-up. Major adverse cardiac events (MACE) were observed in 8 (3%) cases with 2 (1%) cardiac death and TLR occurred in 6 (2%) cases.

Out of 344 lesions, 98 (29%) cases treated with DCB had a diameter of ≤ 2.25 mm. Dissection in vessels ≤ 2.25 mm and > 2.25 mm were in 9 (9.2%) and 10 (4.1%) cases respectively (p=0.061). Flow limiting dissection was significant in vessels ≤ 2.25 mm as compared to vessels > 2.25 mm (p=0.018), which occurred in 6 (6.1%) and 3 (1.2%) cases respectively. TLR in vessels ≤ 2.25 mm were 1 (1.1%) and 5 (2.3%) in vessels > 2.25 mm, which was not significant. Overall freedom from MACE at 1, 2 and 3 years were 98%, 95% and 95%, respectively. Freedom from MACE at 1 and 2 years in vessels ≤ 2.25 mm was 99% and 93%, respectively and in vessels ≥ 2.25 mm was 98% and 96%, respectively (p=0.931).

CONCLUSIONS

PCI using DCB in the treatment of de novo coronary artery disease was favourable and safe with a low MACE rate at mid-term follow-up and offers an alternative treatment to stenting in de novo smaller vessel coronary artery disease.

Clinical follow-up were available in 303 (97%) patients with a mean of 17±11 months. There were no complications of acute or subacute vessel thrombosis following treatment and all remained free of vessel thrombosis on follow-up. Major adverse cardiac events (MACE) were observed in 8 (3%) cases with 2 (1%) cardiac death and TLR occurred in 6 (2%) cases.

Out of 344 lesions, 98 (29%) cases treated with DCB had a diameter of ≤ 2.25 mm. Dissection in vessels ≤ 2.25 mm and > 2.25 mm were in 9 (9.2%) and 10 (4.1%) cases respectively (p=0.061). Flow limiting dissection was significant in vessels ≤ 2.25 mm as compared to vessels > 2.25 mm (p=0.018), which occurred in 6 (6.1%) and 3 (1.2%) cases respectively. TLR in vessels ≤ 2.25 mm were 1 (1.1%) and 5 (2.3%) in vessels > 2.25 mm, which was not significant. Overall freedom from MACE at 1, 2 and 3 years were 98%, 95% and 95%, respectively. Freedom from MACE at 1 and 2 years in vessels ≤ 2.25 mm was 99% and 93%, respectively and in vessels ≥ 2.25 mm was 98% and 96%, respectively (p=0.931).

CONCLUSIONS

PCI using DCB in the treatment of de novo coronary artery disease was favourable and safe with a low MACE rate at mid-term follow-up and offers an alternative treatment to stenting in de novo smaller vessel coronary artery disease.

CONCLUSIONS

PCI using DCB in the treatment of de novo coronary artery disease was favourable and safe with a low MACE rate at mid-term follow-up and offers an alternative treatment to stenting in de novo smaller vessel coronary artery disease


Thank
you
INCHEON