

# **Safety of hydrophilic polymer-coated guide wires used for side-branch protection during bifurcation stenting and POT**

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# Disclosure Statement of Financial Interest

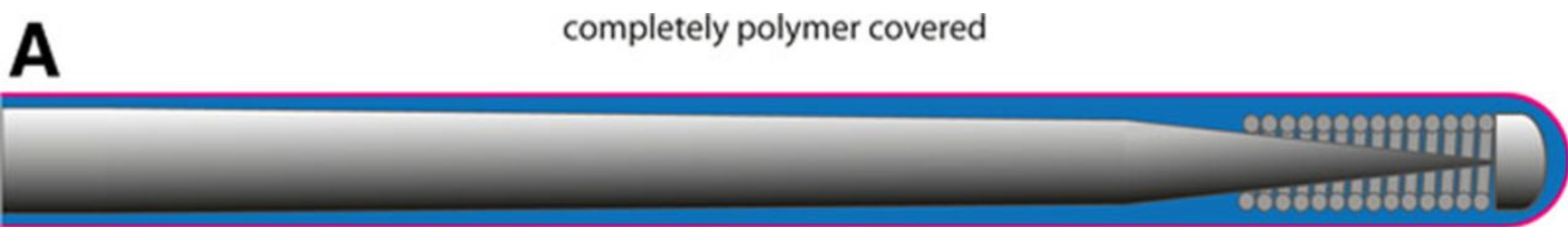
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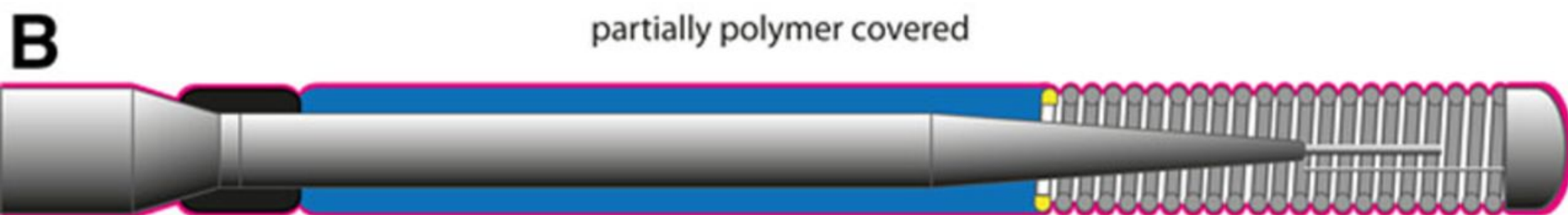
- Grant/Research Support
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- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
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## Company

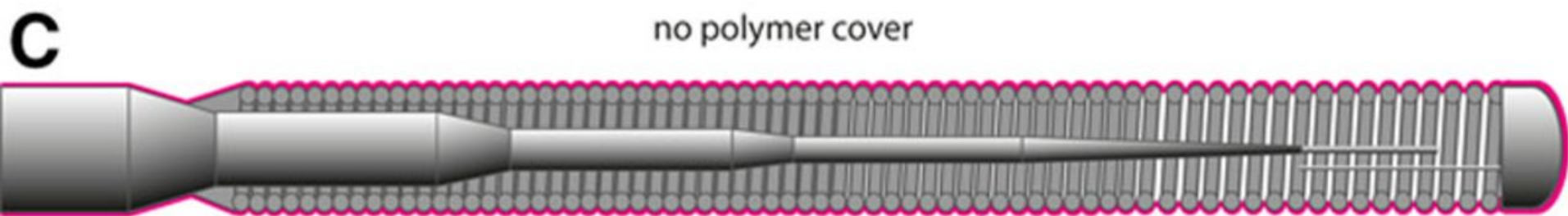
- NIH, AstraZeneca, ACIST
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HT Whisper

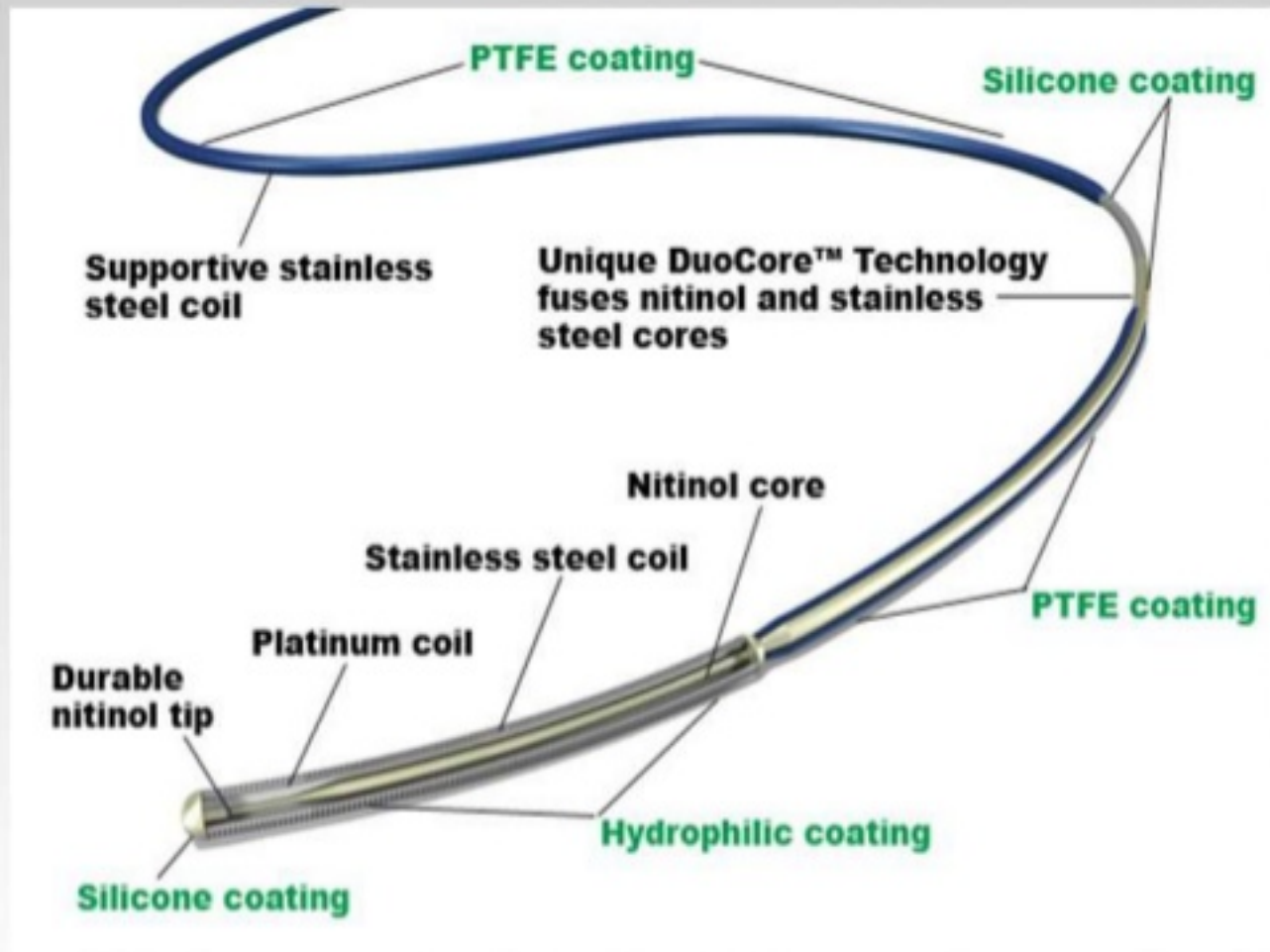


HT BMW Universal II



HT Floppy

# Runthrough NS: Terumo



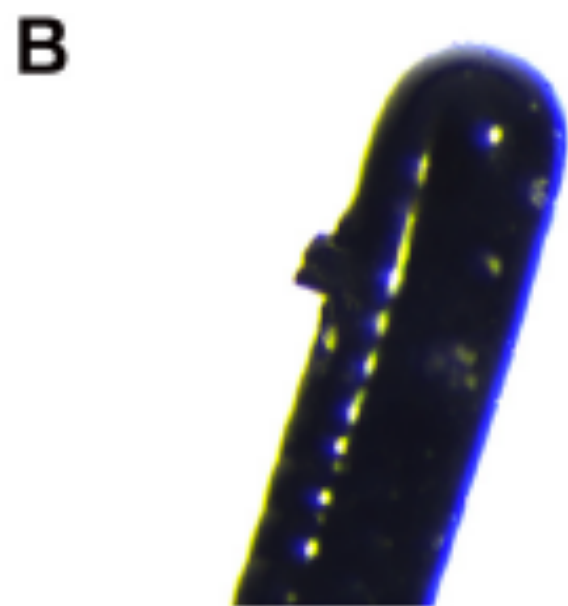
Runthrough™ NS Guidewire:

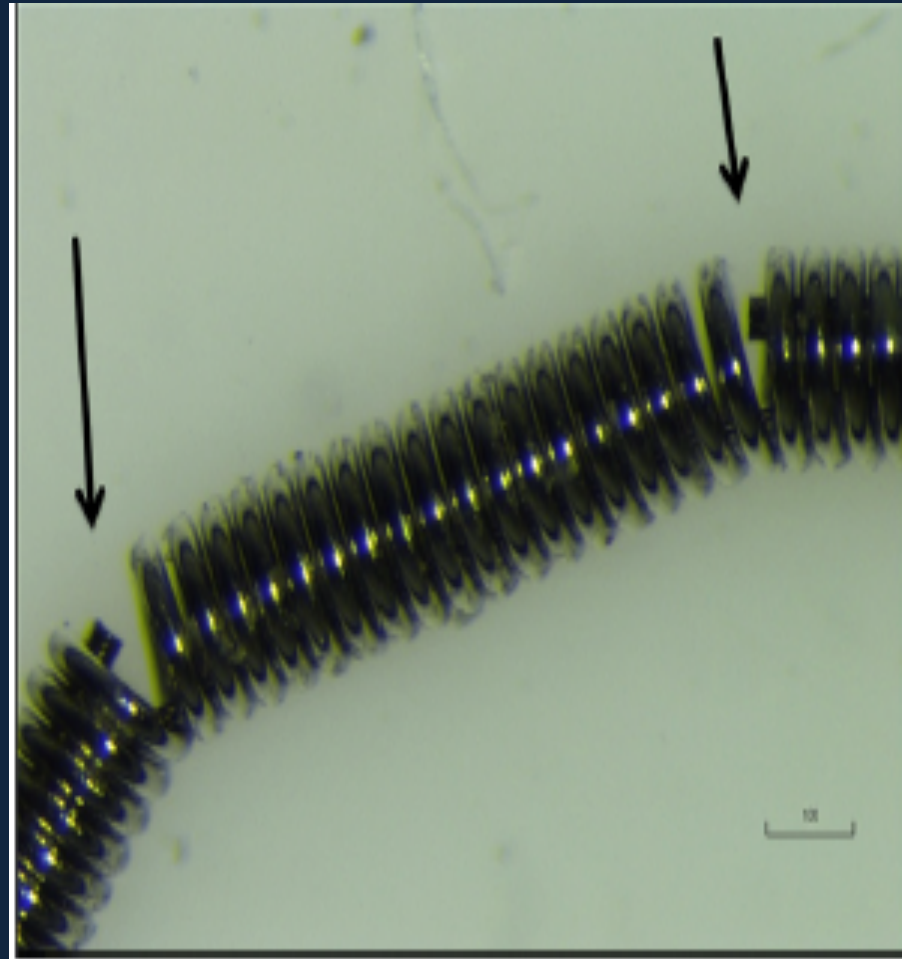
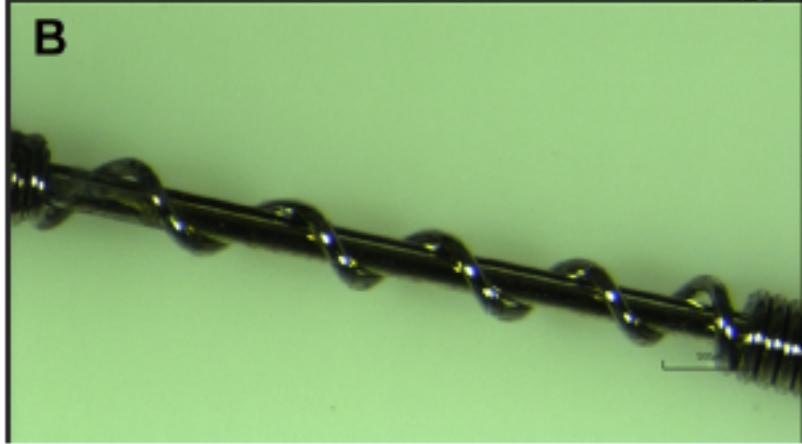
# Safety Concerns with polymer-coated wires

- Pan et al. showed that structural damage to the Jailed wire (i.e., wire Fracture, overstretching, or entrapment) is minimal

# Microscopic Damage

Microscopic damage	Polymer-coated (n=114)	Non-polymer coated (n=120)	P value
No damage	112 (97)	51 (45)	
Mild damage	2 (3)	37 (32)	
Severe Damage	0 (0)	24 (21)	0.001
Fracture	0 (0)	2 (2)	



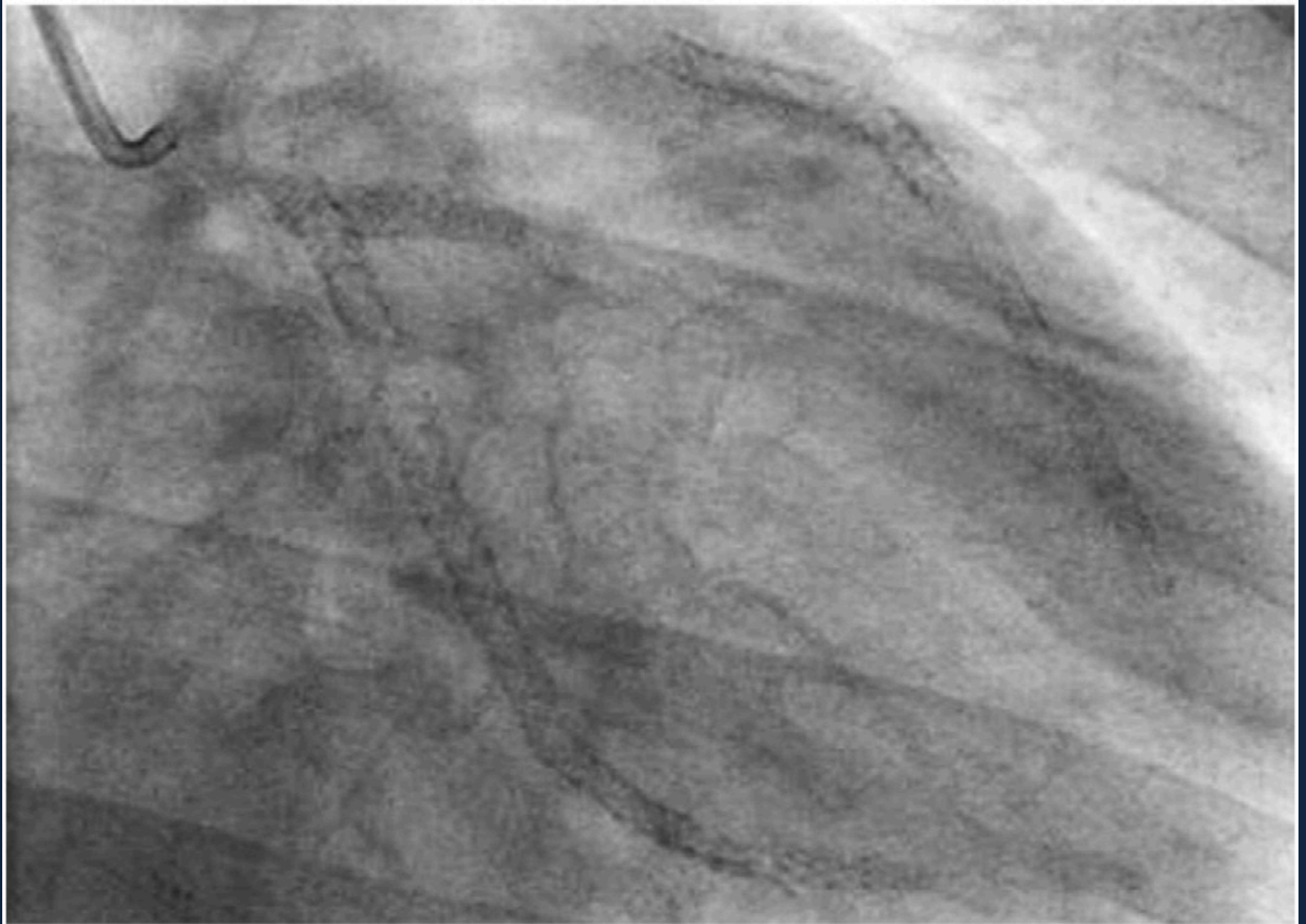




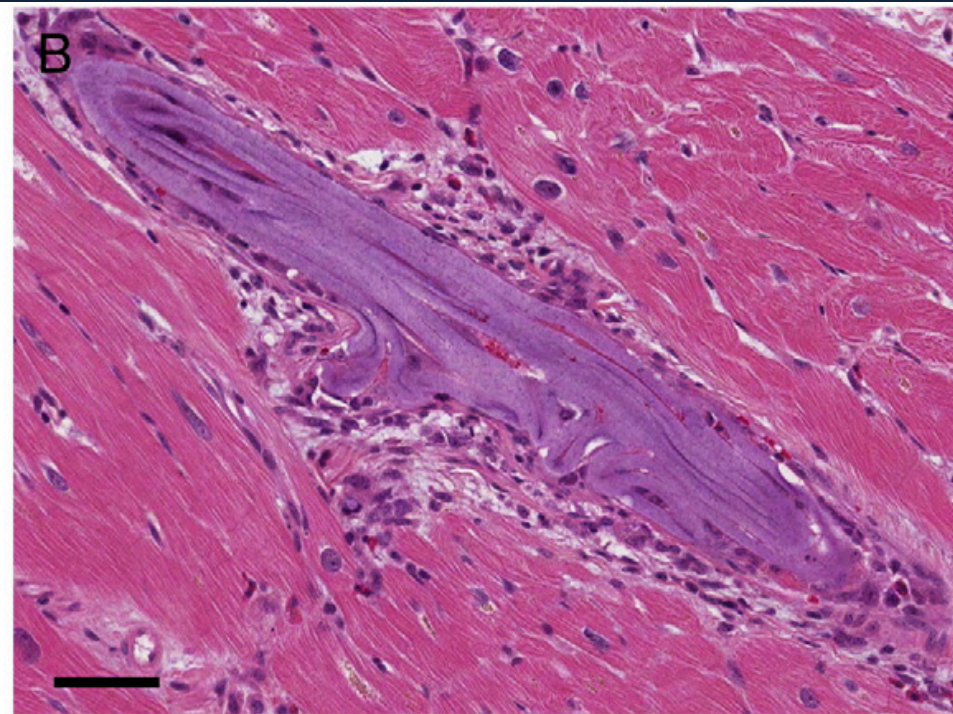
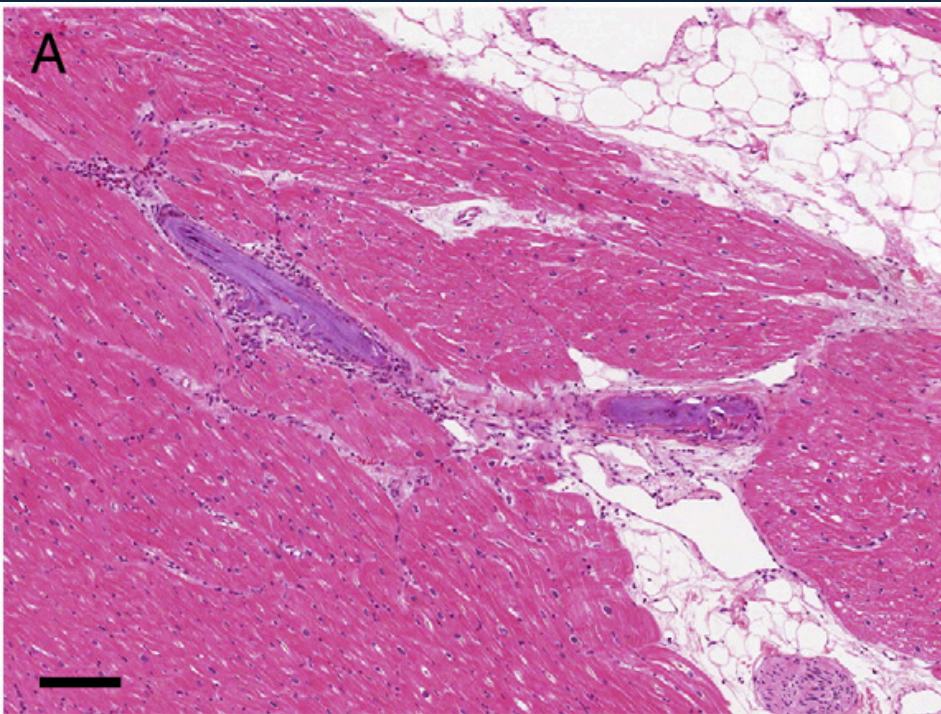
# Safety Concerns with polymer-coated wires

- **Polymer shearing and embolization**

# Polymer shearing and embolization

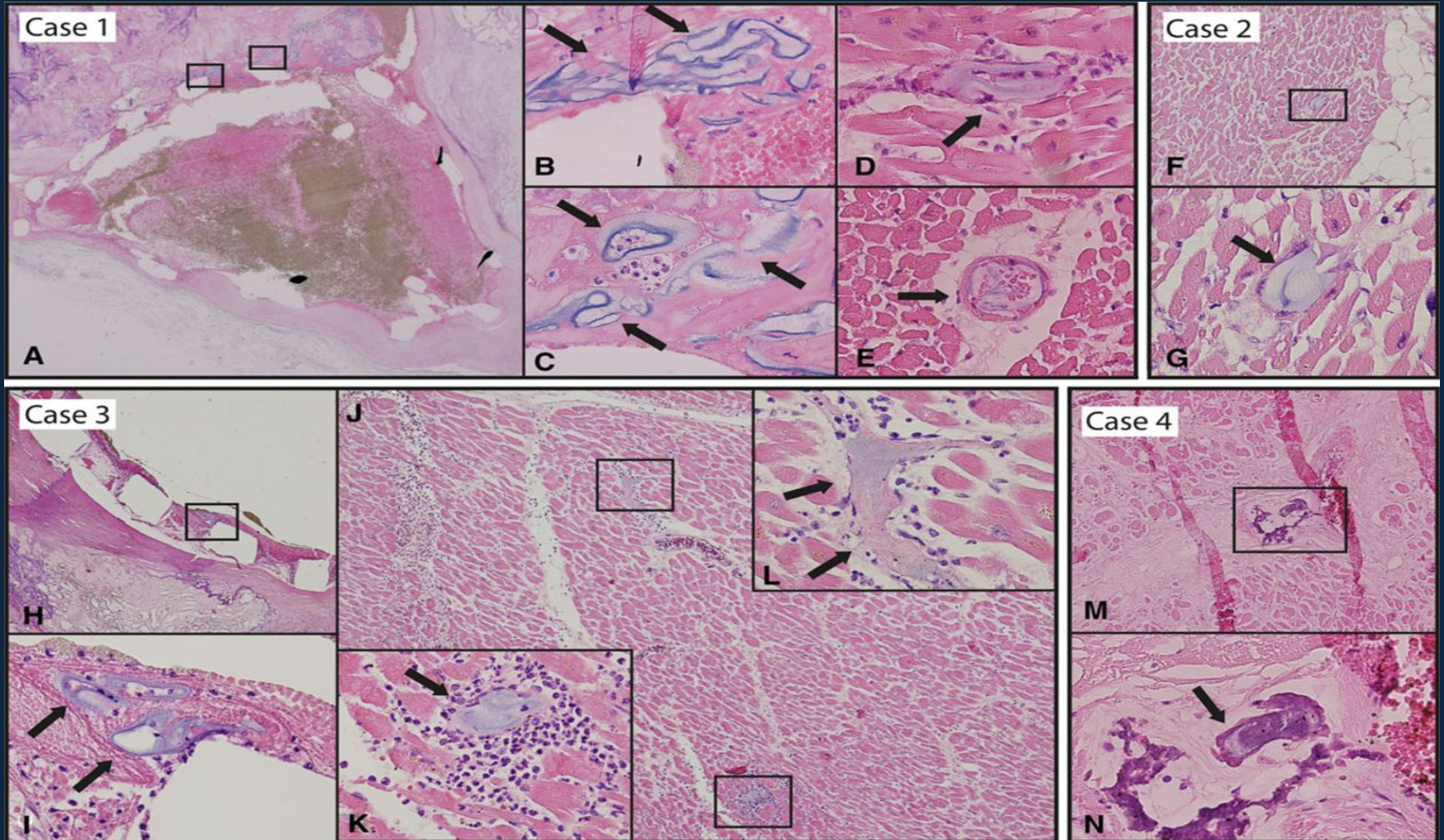


# Polymer shearing and embolization

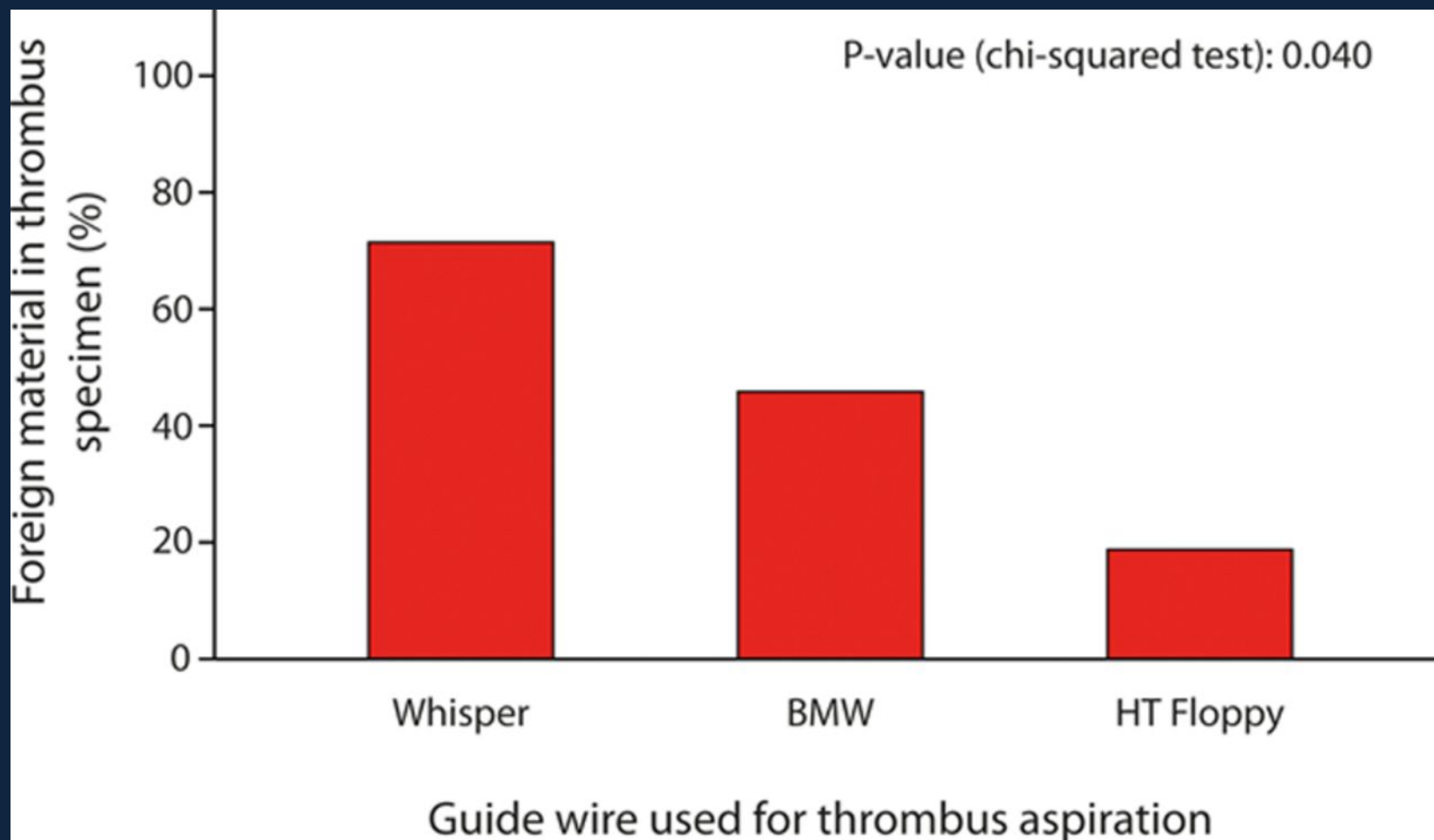


Schipper et al. I J Card;2012;155:e45-e46

# Polymer shearing and embolization



## Differences in the frequency of foreign material in thrombus specimen found between the 3 most used coronary guidewires.



Grundeken et al. *Circ Cardiovasc Interv.* 2015;8:e001816

# Polymer shearing and distal embolization with polymer-coated guidewires

- Autopsy studies have shown that polymer shearing and embolization was associated with the occlusion of small intramyocardial arterioles
- Although distal embolization during PCI is attributed to atheroemboli from the culprit lesion, it might be attributable to iatrogenic embolization of polymer coating in some cases
- Extent of polymer shearing and myocardial infarction with polymer-coated wires have not been investigated by scanning electron microscopic examination

# Patients with coronary bifurcation lesions

Whisper wire (full polymer cover) Jailed in SB, (n=15)

Stent the MV

POT (KBI if SB stenosis >70%)

Scanning electron microscopy of the jailed wire was performed

After magnification, fracture and defects on the wire were measured

Runthrough (partial polymer cover) wire jailed in SB (n=15)

Stent the MV

POT (KBI if SB stenosis >70%)

Scanning electron microscopy of the jailed wire was performed

After magnification, fracture and defects on the wire were measured

Periprocedural MI defined as CK MB > 3 times URL

# Demographic Characteristics of Patients

	Whisper wire (n=15)	Runthrough wire (n=15)	P value
Age (years)	65 ± 12	69 ± 9	0.11
Male sex (n)	11	11	1
Diabetes (n)	6	3	0.23
Hypertension (n)	10	8	0.46
Smoking (n)	12	13	0.62
Hyperlipidemia (n)	15	14	1
NSTEMI	2	1	1
Previous CABG (n)	3	5	0.41



## Angiographic and procedural characteristics

	Whisper Wire	Runthrough Wire	P value
Medina class			
1,1,1	11	10	1
1,1,0	3	3	1
1,01	0	2	0.48
0,1,0	1	0	1
True bifurcation lesions	11	12	1
Vessels involved			
Left main bifurcation	4	3	1
LAD/Diagonal	3	9	0.06
LCX/OM	6	3	0.43
RCA/RV branch	1	0	1
PDA/PLV	1	0	1
Calcification	8	6	0.26
Antithrombotic therapy			
Clopidogrel	13	11	0.65
Ticagrelor	2	4	0.65
Heparin	13	12	1
Bivalirudin	2	3	1
Eptifibatide	2	7	0.11
Stent length (mm)	25 ± 9	24 ± 13	0.62
Stent diameter (mm)	3.1 ± 0.5	3.2 ± 0.4	0.39
Balloon diameter for post-dilation (mm)	3.6 ± 0.6	3.6 ± 0.5	0.97
Balloon length for post-dilation (mm)	13 ± 4	14 ± 4	0.87
Maximum balloon inflation pressure (atm)	17 ± 4	19 ± 4	0.68
Kissing balloon inflation	2	4	0.36

**Area of polymer shearing (mm<sup>2</sup>)**

P<0.05



**Whisper Wire**

**Runthrough Wire**

**Length of polymer shearing (mm)**

P<0.05



**Whisper Wire**

**Runthrough Wire**

**Figure 4**

CK-MB (ng/mL)

**A**

r=0.61  
P<0.01

Total area of PS (mm<sup>2</sup>)

CK-MB (ng/mL)

**B**

r=0.60  
P<0.01

Total length of PS (mm)

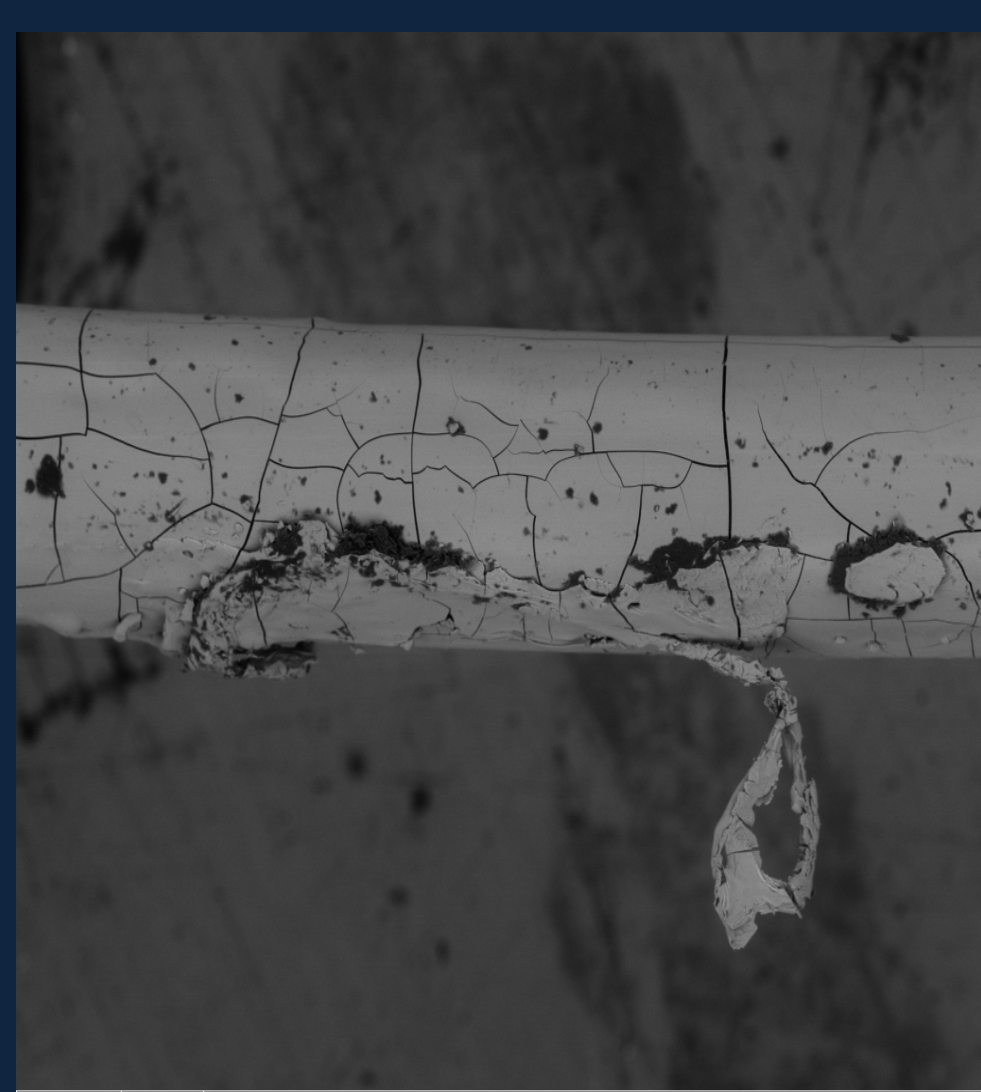
CK-MB (ng/mL)

**C**

r=0.63  
P<0.01

No of Defects>500 microns

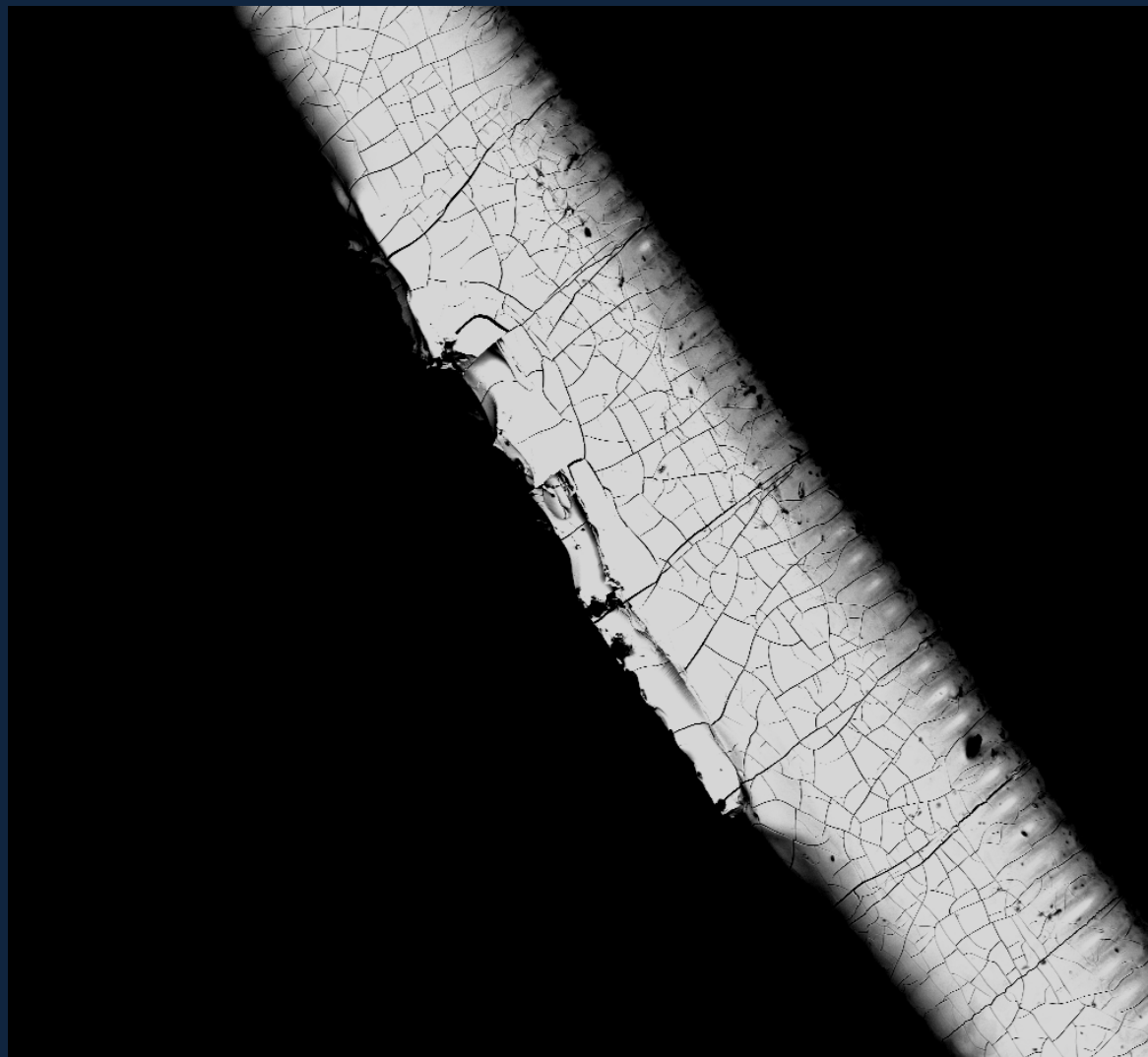
**Figure 5**



HV	mode	500 $\mu$ m
10.00 kV	Z Cont	
		UAB



HV	mode	500 $\mu$ m
5.00 kV	Z Cont	
		UAB



HV	mode
15.00 kV	Z Cont

←————— 1 mm —————→  
UAB

To further investigate the relationship  
between the use of polymer-coated  
guidewires and PMI

# Jailing polymer jacketed guide-wires during bifurcation coronary interventions is associated with procedural myocardial infarction

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**Author contributions:** Chatterjee A formulated the research question, designed the study, performed statistical analyses and wrote the manuscript; White JS and Hashim T were involved in individual chart reviews to extract data and verify accuracy; Leesar MA supervised the study as senior investigator.

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**Informed consent statement:** The institutional Review Board of the University of Alabama at Birmingham waived the need for informed consent since this was a retrospective study using de-identified data only.

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## Abstract

### *AIM*

To study the relationship of jailed polymer jacketed guide wires (PGW) with procedural myocardial infarction (PMI) after bifurcation coronary interventions.

### *METHODS*

Consecutive bifurcation interventions performed from January 2010 to October 2014 were included in the study. Chart review was performed to obtain demographic, clinical and procedural data. PMI was defined as Creatine Kinase MB  $> 3 \times$  upper reference limit of normal. Multivariate logistic regression was used to ascertain relationship of PGW use with PMI.

### *RESULTS*

Two hundred and ninety-three patients (age  $63.5 \pm 12.3$  years; 33.8% diabetic) were included in the study. Eighty point two percent ( $n = 235$ ) were true bifurcation lesions use of PGW was associated with PMI on univariate analysis (OR = 4.1;  $P = 0.002$ ). This association remained significant after adjusting for other possible risk factors (OR = 3.5;  $P = 0.02$ ).

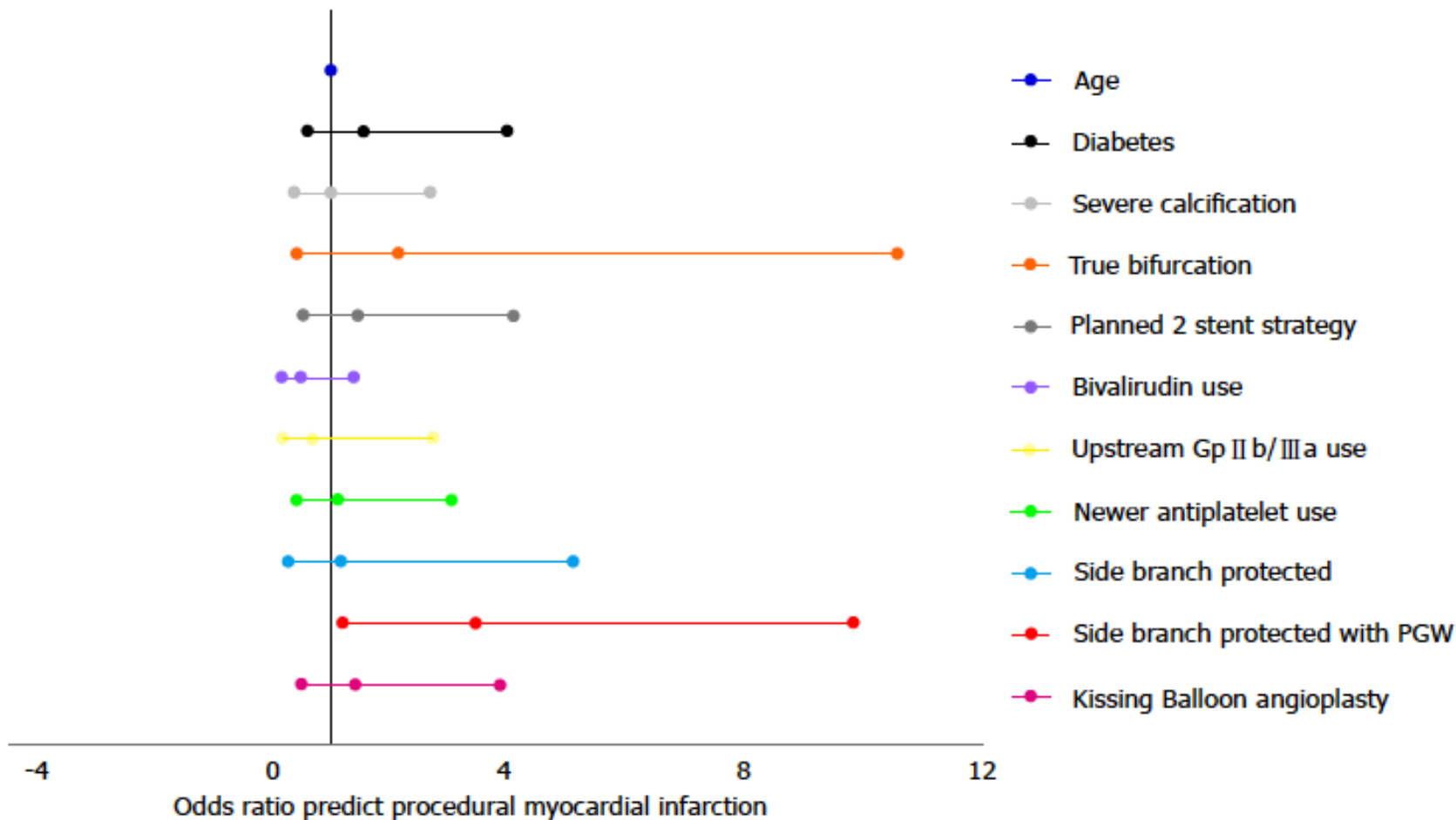
# Design of the study

- We reviewed the records of 293 patients who underwent PCI of bifurcation lesions from 2010-2014 at UAB
- Of these, 23 patients (8%) developed PMI



**Table 2** Angiographic and procedural characteristics

	No PMI ( <i>n</i> = 270)	PMI ( <i>n</i> = 23)	<i>P</i> value
Vessels involved			0.68
LM bifurcation	15.9%	21.7%	
LAD/Diagonal	40.0%	47.8%	
LCX/OM	34.8%	21.7%	
RPDA/RPLA	8.8%	4.3%	
RCA/RV marginal	0.003%	0%	
Severe calcification	57.4%	65.2%	0.52
True bifurcation (Medina 1,1,1; 1,0,1; 0,1,1)	79.3%	91.3%	0.27
Main vessel diameter (mm)	3.3 ± 0.5	3.3 ± 0.4	0.4
Side branch diameter (mm)	2.6 ± 0.5	2.6 ± 0.4	0.94
Antiplatelet therapy			0.97
Plavix	73.7%	69.6%	
Prasugrel	7.0%	8.7%	
Ticagrelor	19.3%	21.7%	
Anticoagulant			0.08
Heparin	45.2%	65.2%	
Bivalirudin	54.8%	34.8%	
Upstream GpIIb/IIIa use	11.5%	13.0%	0.74
Planned 2 stent approach	28.1%	39.1%	0.34
Final kissing balloon angioplasty	45.9%	56.5%	0.39
SB protected	73.3%	87%	0.21
PGW jailed	15.9%	43.4%	0.003



# Conclusions

- There was no wire fracture by jailing polymer-coated wires
- The extent of polymer shearing was significantly higher with Whisper wire than Runthrough wire probably as a result of complete polymer coverage
- The use of polymer-coated guide wires was associated with embolization of polymer to the myocardial microvasculature system and was an independent predictor of PMI
- The impact of polymer shearing on myocardial infarction warrants future studies

**Thank You!**

# Comparisons of parameters between Whisper wires vs. Runthrough wires

Quantitative analysis of wire damage by scanning electromicroscopic examination	Whisper wire (n = 15)	Runthrough Wire (n = 15)	P value
Total area of polymer shearing (mm <sup>2</sup> )	0.15 ± 0.04	0.026 ± 0.01	0.002
Largest defect (mm <sup>2</sup> )	0.04 ± 0.05	0.01 ± 0.01	0.016
Total length of polymer shearing (mm)	12.1 ± 14.5	2.7 ± 3.0	0.005
Longest defect (mm)	2.9 ± 4.2	1.0 ± 1.2	0.029
Number of defects (n)	21.4 ± 27.1	4.7 ± 5.5	0.008
Defects > 500 micron (n)	4.6 ± 4.4	1.7 ± 2.2	0.033
Fracture	0	0	