

# Does stent design impact the outcome in bifurcation treatment?

**Scot Garg**  
**Thoraxcentre**  
**Rotterdam**

# Potential conflicts of interest

Speaker's name: Scot Garg

I have the following potential conflicts of interest to report:

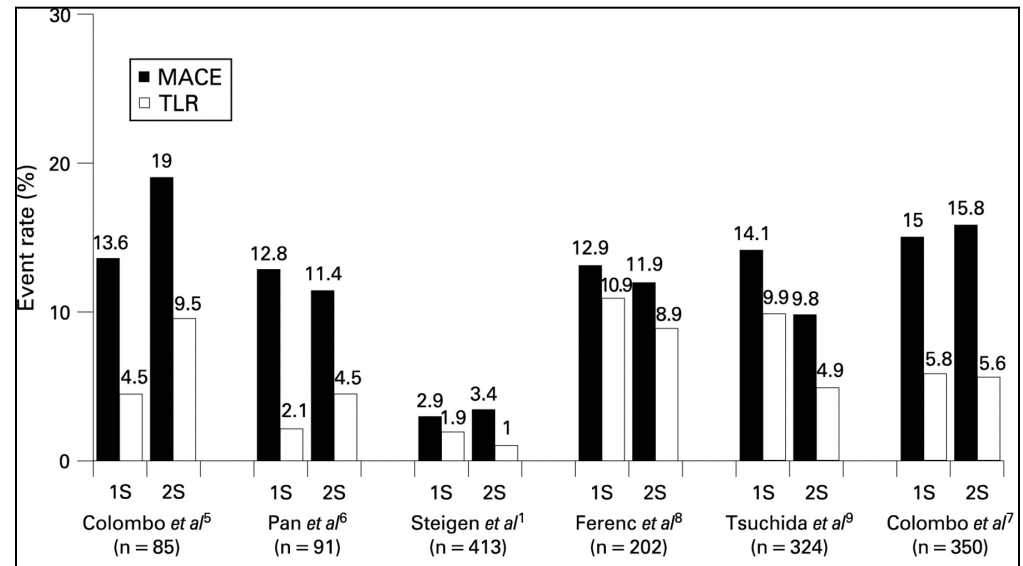
- Research contracts
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest

# Bifurcation Lesions

- Remain a challenge to today's interventionalist.

| Study         | No. of patients | % Bifurcations |
|---------------|-----------------|----------------|
| ARRIVE I & II | 7,592           | 8%             |
| e-CYPHER      | 15,157          | 9%             |
| RESEARCH      | 508             | 16%            |
| ARTS-II       | 607             | 22%            |
| LEADERS       | 1,707           | 29%            |
| SYNTAX        | 903             | 72%            |



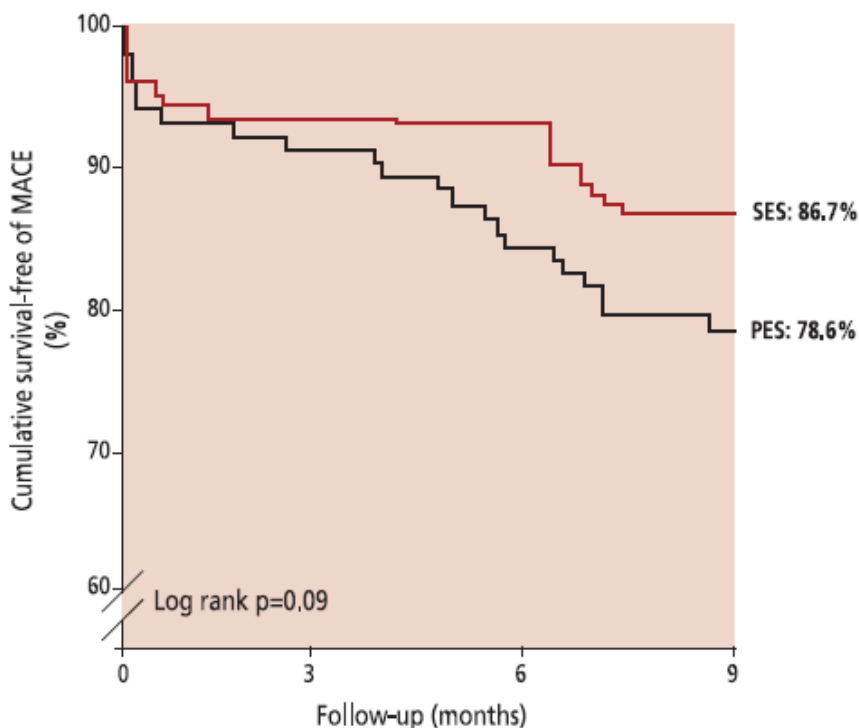
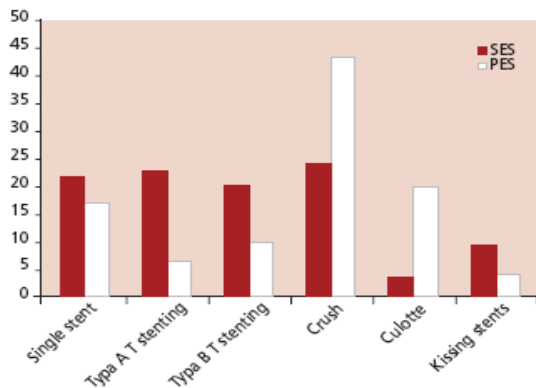
# Aims

- (1) Present evidence that suggests that stent design does impact on outcome of bifurcation lesions
- (2) Explore the potential reasons

# Registries

# Treatment of de novo bifurcation lesions: comparison of Sirolimus- and Paclitaxel-eluting stents

Hoye et al.



## Independent predictors of major adverse cardiac events and target lesion revascularization at 6 months

|   | Odds ratio | 95% confidence intervals |
|---|------------|--------------------------|
| <b>MACE</b>                                   |            |                          |
| Age   | 1.02       | 1.01 to 1.05             |
| Prior CABG                                    | 2.75       | 1.1 to 7.2               |
| Diabetes mellitus                             | 2.15       | 1.2 to 4.0               |
| Multivessel disease                           | 1.36       | 1.0 to 1.9               |
| Presentation with acute myocardial infarction | 2.35       | 1.1 to 5.0               |
| Therapy with Sirolimus-eluting stent          | 0.71       | 0.4 to 1.0               |
| <b>TLR</b>                                    |            |                          |
| Therapy with Sirolimus-eluting stent          | 0.45       | 0.19 to 0.95             |

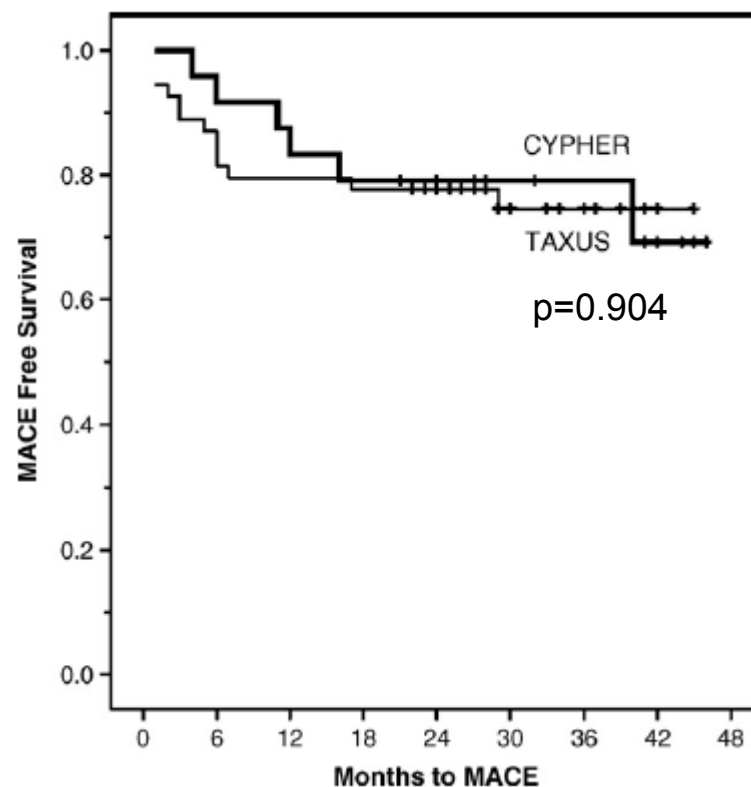
# CYPHER versus TAXUS stent for bifurcation lesions beyond 30 days—long-term follow-up results

Chi-Hang Lee\*, Adrian Low, Jimmy Lim, Hwee-Bee Wong,  
Yean-Teng Lim, Huay-Cheem Tan

## Baseline clinical characteristics

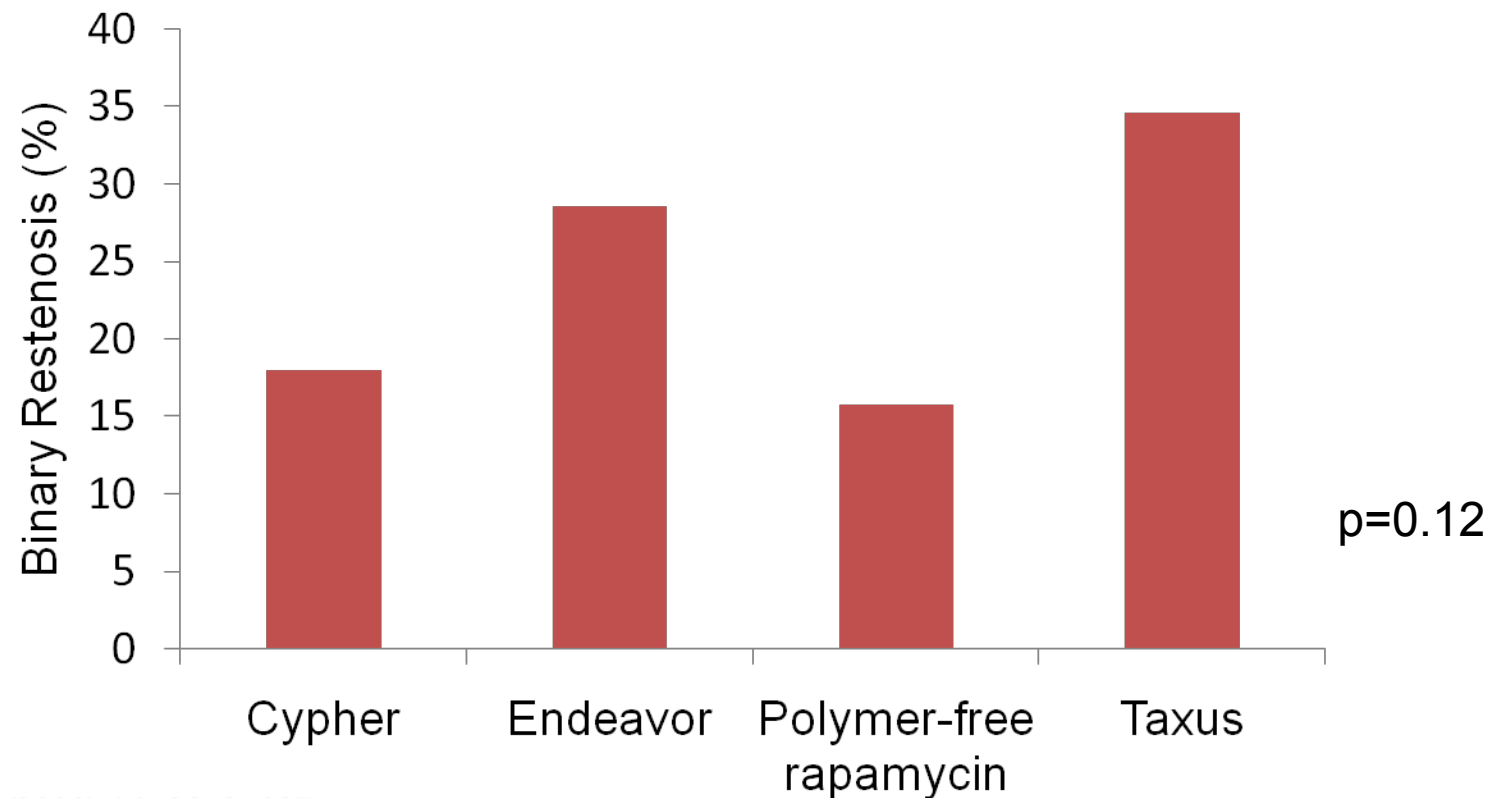
| Characteristics          | CYPHER (n=24) | TAXUS (n=54) | P value |
|--------------------------|---------------|--------------|---------|
| Age, mean ± S.D. (years) | 58.0 ± 10.0   | 58.3 ± 10.3  | 0.592   |
| Male                     | 18 (72%)      | 50 (86%)     | 0.061   |
| Risk factors             |               |              |         |
| Hypertension             | 15 (63%)      | 35 (65%)     | 1.000   |
| Diabetes mellitus        | 6 (25%)       | 22 (41%)     | 0.181   |
| Hyperlipidemia           | 18 (75%)      | 39 (72%)     | 0.799   |
| Family history           | 0 (0%)        | 2 (4%)       | 1.000   |
| Current smoker           | 4 (17%)       | 15 (28%)     | 0.291   |

| Characteristics                                     | CYPHER (n=24) | TAXUS (n=56) | P value |
|---|---------------|--------------|---------|
| Target vessel                                       |               |              | 0.579   |
| LAD <sup>a</sup> /diagonal                          | 15 (63%)      | 39 (70%)     |         |
| LCx <sup>b</sup> /obtuse marginal                   | 5 (21%)       | 9 (16%)      |         |
| RCA <sup>c</sup> /PDA <sup>d</sup> /PL <sup>e</sup> | 3 (13%)       | 3 (5%)       |         |
| Left main/LAD/LCx                                   | 1 (4%)        | 5 (9%)       |         |
| Side-branch intervention                            | 12 (50%)      | 26 (46%)     | 0.769   |
| Final kissing balloon angioplasty                   | 4 (17%)       | 13 (23%)     | 0.512   |



# Culotte stenting technique in coronary bifurcation disease: angiographic follow-up using dedicated quantitative coronary angiographic analysis and 12-month clinical outcomes

Tom Adriaenssens<sup>†\*</sup>, Robert A. Byrne, Alban Dibra, Raisuke Iijima, Julinda Mehilli, Olga Bruskina, Albert Schömig, and Adnan Kastrati





# Randomised Control Trials

# Drug-eluting stents for the treatment of bifurcation lesions: A randomized comparison between paclitaxel and sirolimus stents

Manuel Pan, MD,<sup>a</sup> José Suárez de Lezo, MD,<sup>a</sup> Alfonso Medina, MD,<sup>b</sup> Miguel Romero, MD,<sup>a</sup> Antonio Delgado, MD,<sup>b</sup> José Segura, MD,<sup>a</sup> Soledad Ojeda, MD,<sup>a</sup> Francisco Mazuelos, MD,<sup>a</sup> Enrique Hernandez, MD,<sup>b</sup> Francisco Melian, MD,<sup>b</sup> Djordje Pavlovic, MD,<sup>a</sup> Fátima Esteban, MD,<sup>a</sup> and Juan Herrador, MD<sup>a</sup>  
*Córdoba and Las Palmas de Gran Canaria, Spain*

**Table III.** Procedural data

|                                  | Sirolimus<br>(n = 103) | Paclitaxel<br>(n = 102) | P  |
|----------------------------------|------------------------|-------------------------|----|
| Main vessel stent diameter (mm)  | 3.0 ± 0.3              | 3.0 ± 0.3               | NS |
| Main vessel stent length (mm)    | 25.1 ± 10.4            | 26.9 ± 13.9             | NS |
| Inflation pressure (atm)         | 14 ± 0.9               | 14 ± 0.6                | NS |
| Remote site intervention         | 53 (51%)               | 61 (60%)                | NS |
| Proximal geographic miss         | 11 (11%)               | 10 (10%)                | NS |
| Distal geographic miss           | 15 (15%)               | 12 (12%)                | NS |
| Glycoprotein IIb/IIIa inhibitors | 35 (34%)               | 38 (37%)                | NS |
| Final kissing balloon            | 49 (47%)               | 46 (45%)                | NS |
| Stent at side branch             | 8 (8%)                 | 7 (7%)                  | NS |
| Femoral angioseal                | 94 (91%)               | 90 (88%)                | NS |

**Table IV.** Major adverse cardiac events and follow-up, angiographic results

|  | Sirolimus<br>(n = 103) | Paclitaxel<br>(n = 102) | P       |
|--|------------------------|-------------------------|---------|
| In-hospital and 1-m outcomes             |                        |                         |         |
| Non-Q MI                                 | 2 (2%)                 | 1 (1%)                  | NS      |
| Death                                    | 0                      | 0                       | NS      |
| CK after procedure (IU/L)                | 131 ± 222              | 154 ± 225               | NS      |
| Troponin I after procedure (IU/L)        | 11 ± 47                | 12 ± 46                 | NS      |
| Femoral hematomas                        | 2 (2%)                 | 1 (1%)                  | NS      |
| Surgical vascular repair                 | 1 (1%)                 | 0                       | NS      |
| Blood transfusions                       | 4 (4%)                 | 2 (2%)                  | NS      |
| 24-Month follow-up                       |                        |                         |         |
| Recurrent infarction                     | 0                      | 1                       | NS      |
| Death                                    | 2*                     | 3†                      | NS      |
| Need for target lesion revascularization | 4 (4%)                 | 13 (13%)                | .021‡ ← |
| Remote site revascularization            | 5 (5%)                 | 6 (6%)                  | NS      |
| Angiographic reevaluation                |                        |                         |         |
| Restenosis                               | 5 (9%)                 | 16 (29%)                | .011§ ← |
| Main vessel                              | 1                      | 6                       |         |
| Side branch                              | 2                      | 5                       |         |
| Both vessels                             | 2                      | 5                       |         |

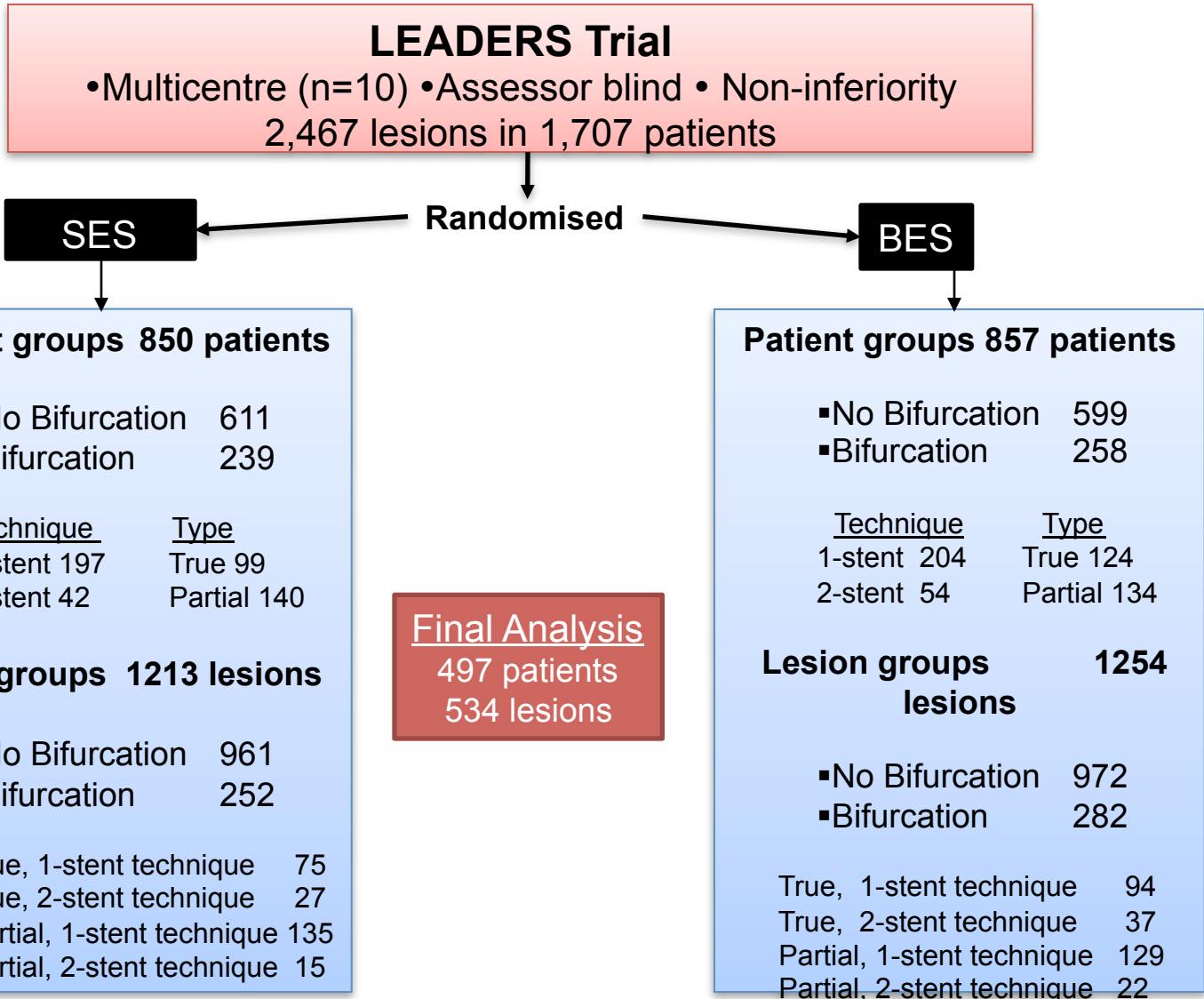
# Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomised non-inferiority trial

*Lancet* 2008; 372: 1163-73

*Stephan Windecker, Patrick W Serruys, Simon Wandel, Pawel Buszman, Stanislaw Trznadel, Axel Linke, Karsten Lenk, Thomas Ischinger, Volker Klaus, Franz Eberli, Roberto Corti, William Wijns, Marie-Claude Morice, Carlo di Mario, Simon Davies, Robert-Jan van Geuns, Pedro Eerdmans, Gerrit-Anne van Es, Bernhard Meier, Peter Juni*

A post hoc subgroup analysis was performed to:

- (1) To assess the outcomes of patients treated with BES and SES for the treatment of bifurcation lesions compared to non-bifurcation lesions in patients from the LEADERS trial without a pre-specified bifurcation strategy.
- (2) To compare the outcomes of patients with bifurcation lesions treated with a drug eluting stent with and without a biodegradable polymer.



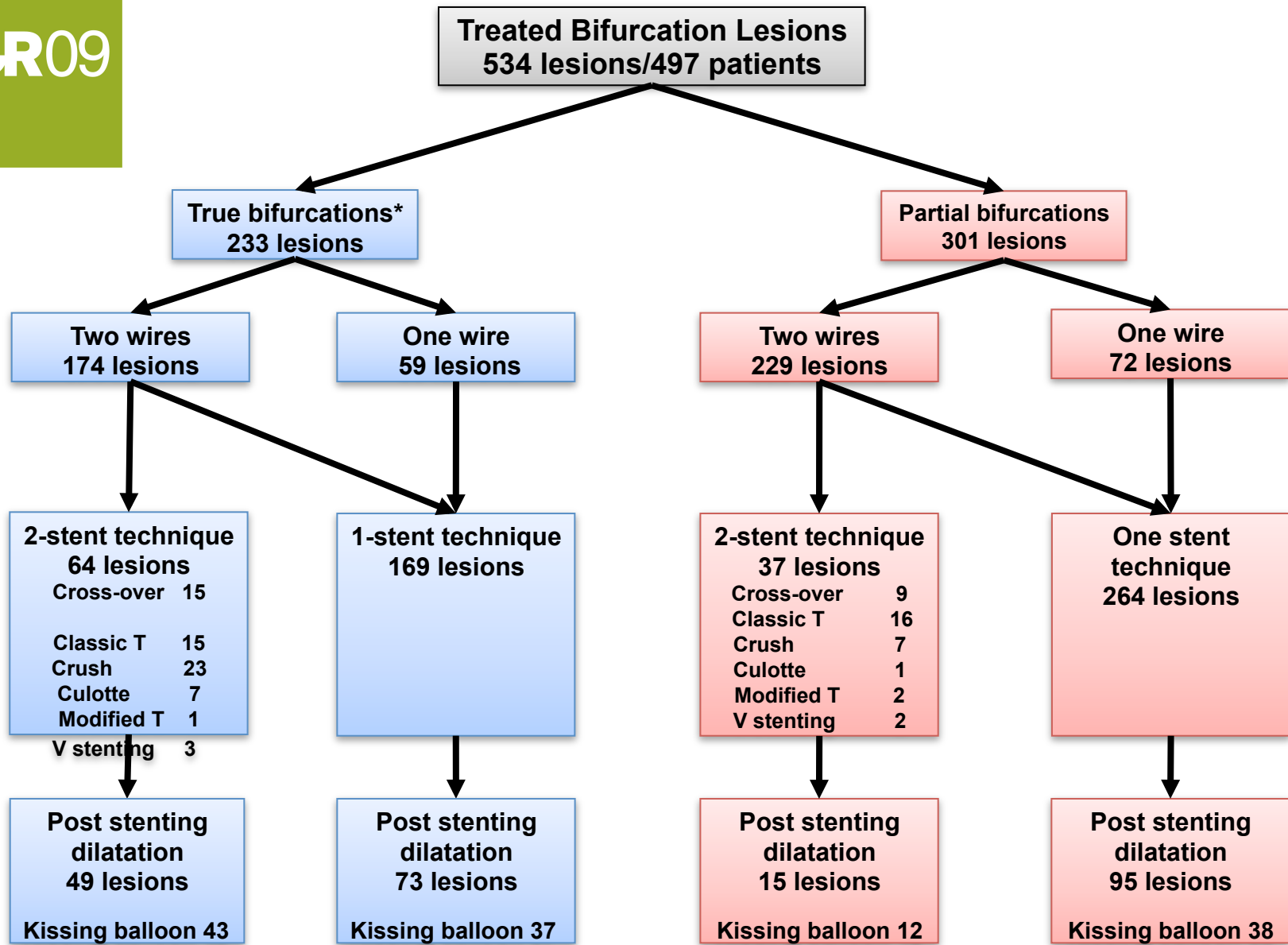
- Procedural data was collected on bifurcation technique by reviewing the angiogram of each bifurcation lesion.
- MACE, in terms of myocardial infarction, cardiac death and clinically driven target vessel revascularisation was assessed at 12 months.

True bifurcation: Medina 1,1,1; 1,0,1; 0,1,1    Partial bifurcation: Medina 1,0,0; 1,1,0; 0,1,0; 0,0,1

# Results

|                                 | Bifurcation<br>Lesion (n=497) | Non-bifurcation<br>lesion (n=1210) | P value |        |
|---------------------------------|-------------------------------|------------------------------------|---------|--------|
| Baseline<br>demographics        | Age (years)                   | 64.7                               | 64.6    | NS     |
|                                 | Male (%)                      | 72.6                               | 75.7    | NS     |
|                                 | Previous MI (%)               | 37.2                               | 30.4    | 0.007  |
|                                 | Diabetes (%)                  | 21.7                               | 25.3    | NS     |
|                                 | Current smoker (%)            | 20.5                               | 26.3    | 0.011  |
|                                 | Hypertension (%)              | 72.8                               | 73.2    | NS     |
|                                 | Hypercholesterolaemia (%)     | 68.0                               | 66.3    | NS     |
|                                 | ACS (%)                       | 53.9                               | 55.8    | NS     |
| Angiographic<br>Characteristics | SYNTAX Score                  | 16.8                               | 12.0    | <0.001 |
|                                 | LVEF (%)                      | 54.8                               | 56.0    | NS     |
|                                 | Number of lesions/patient     | 1.8                                | 1.3     | <0.001 |
|                                 | Number of stents              | 2.3                                | 1.8     | <0.001 |
|                                 | Total stent length (mm)       | 40.4                               | 32.4    | <0.001 |

**No significant difference between BES and SES**



\*Includes 8 trifurcation lesions

True bifurcation: Medina 1,1,1; 1,0,1; 0,1,1    Partial bifurcation: Medina 1,0,0; 1,1,0; 0,1,0; 0,0,1

# Bifurcation Results (1)

| Outcome (12 months)                                   | Bifurcation Group<br>(n=497) | Non-Bifurcation Group<br>(n=1210) | P Value |
|---|------------------------------|-----------------------------------|---------|
| Death (%)   | 3.2                          | 3.2                               | NS      |
| Cardiac Death (%)                                     | 2.8                          | 2.2                               | NS      |
| Myocardial Infarction (%)                             | 7.2                          | 4.3                               | <0.05   |
| All Target Lesion Revascularisation (TLR) (%)         | 8.2                          | 6.4                               | NS      |
| Clinically Justified TLR (%)                          | 6.4                          | 5.0                               | NS      |
| All Target Vessel Revascularisation (TVR)(%)          | 10.1                         | 8.3                               | NS      |
| Clinically Justified TVR(%)                           | 7.6                          | 6.0                               | NS      |
| MACE (%)<br>[cardiac death/MI/clinical justified TVR] | 14.5                         | 10.0                              | <0.05   |

# Bifurcation Results (2)

| Outcome (12 months)                                    | Bifurcation Group |                | P Value |
|--|-------------------|----------------|---------|
|  | BES<br>(n=258)    | SES<br>(n=239) |         |
| Death (%)  | 3.5               | 2.9            | NS      |
| Cardiac Death (%)                                      | 2.7               | 2.9            | NS      |
| Myocardial Infarction (%)                              | 8.9               | 5.4            | NS      |
| All TLR(%)   | 4.7               | 12.1           | <0.05   |
| Clinically Justified TLR (%)                           | 3.5               | 9.6            | <0.05   |
| All TVR(%)   | 6.2               | 14.2           | <0.05   |
| Clinically Justified TVR(%)                            | 4.3               | 11.3           | <0.05   |
| MACE (%)<br>[cardiac death/MI/ clinical justified TVR] | 12.8              | 16.3           | NS      |

Non-bifurcation group: BES vs. SES p=NS



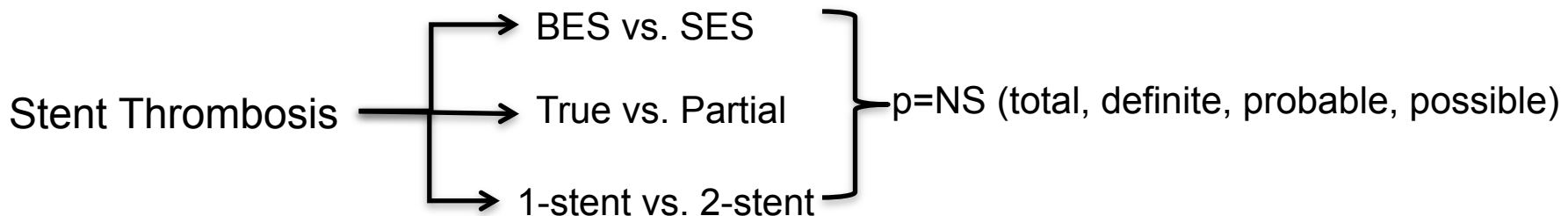
# Bifurcation Results (3)

| Outcome (12 months)                                    | One stent technique |                | P Value |
|--|---------------------|----------------|---------|
|  | BES<br>(n=204)      | SES<br>(n=197) |         |
| Death (%)  | 3.9                 | 2.5            | NS      |
| Cardiac Death (%)                                      | 3.4                 | 2.5            | NS      |
| Myocardial Infarction (%)                              | 7.8                 | 5.6            | NS      |
| All TLR(%)   | 4.9                 | 11.7           | <0.05   |
| Clinically Justified TLR (%)                           | 3.9                 | 9.1            | <0.05   |
| All TVR(%)   | 6.4                 | 13.7           | <0.05   |
| Clinically Justified TVR(%)                            | 4.4                 | 10.7           | <0.05   |
| MACE (%)<br>[cardiac death/MI/ clinical justified TVR] | 12.3                | 15.7           | NS      |

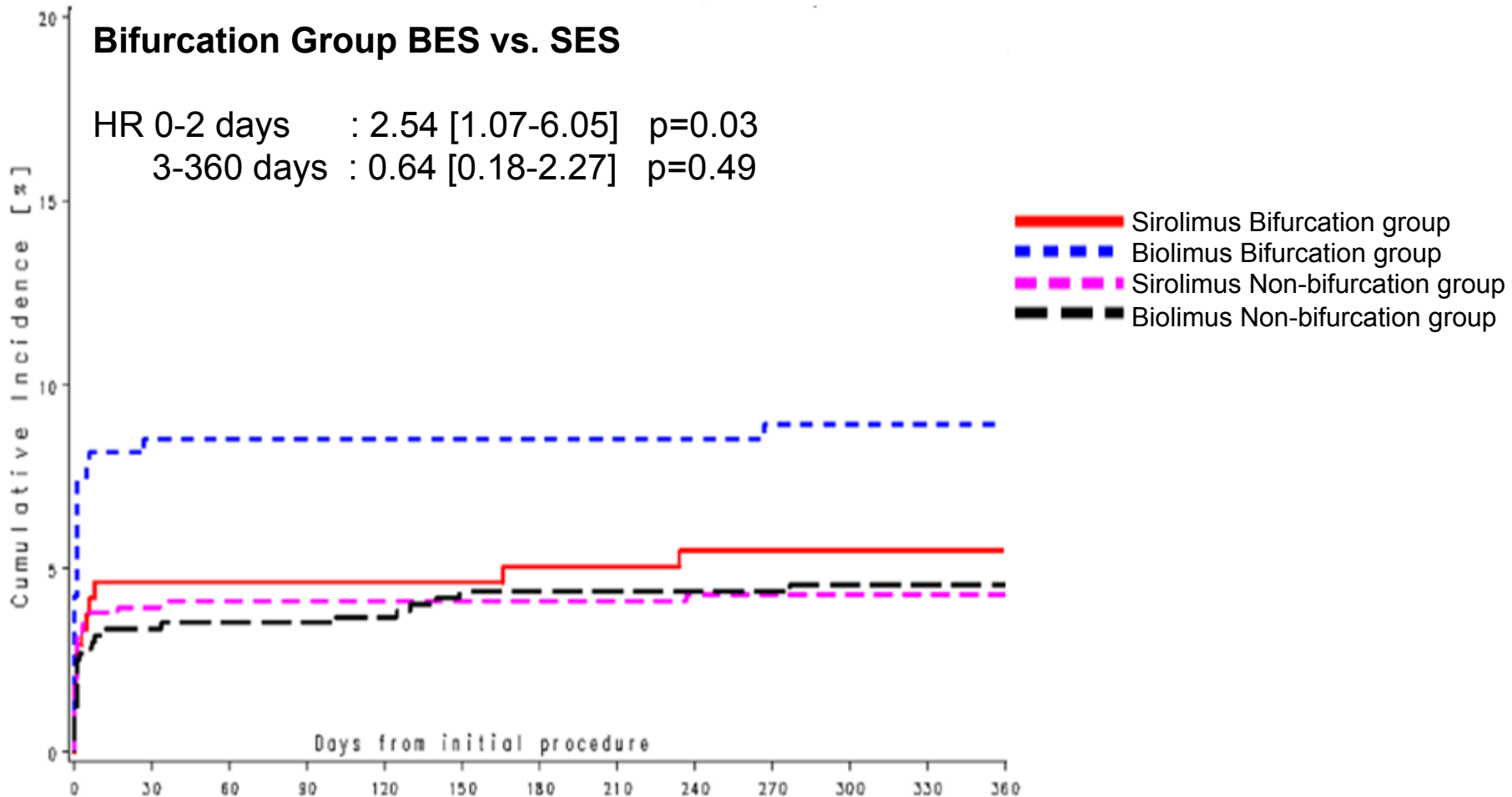
2-stent group: BES vs. SES p=NS

# Stent Thrombosis

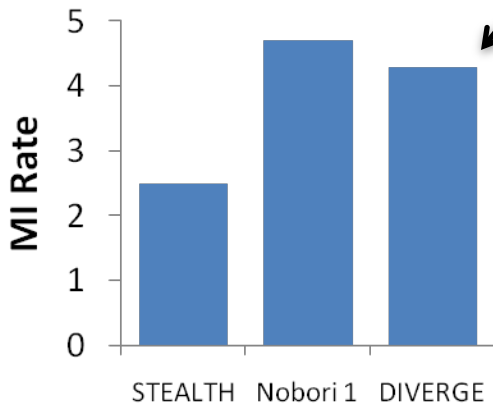
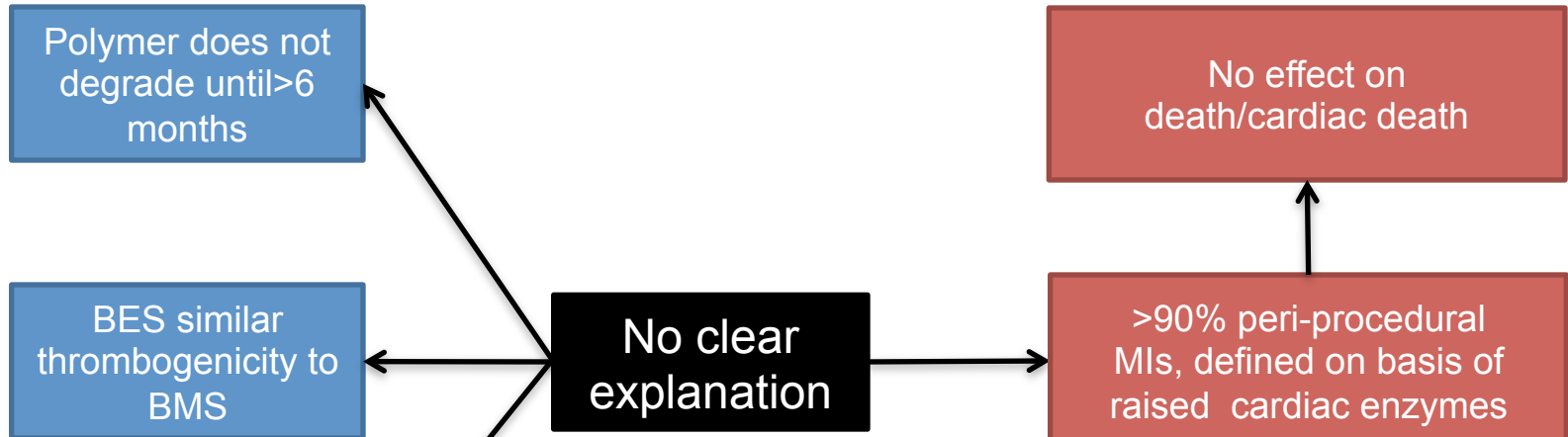
| Stent Thrombosis (%) | Bifurcation Group<br>(n=497) | Non-Bifurcation Group<br>(n=1210) | P Value |
|----------------------|------------------------------|-----------------------------------|---------|
| Stent thrombosis (%) | 4.0                          | 3.0                               | NS      |
| Definite             | 2.2                          | 1.9                               | NS      |
| Probable             | 0.6                          | 0.5                               | NS      |
| Possible             | 1.2                          | 0.8                               | NS      |



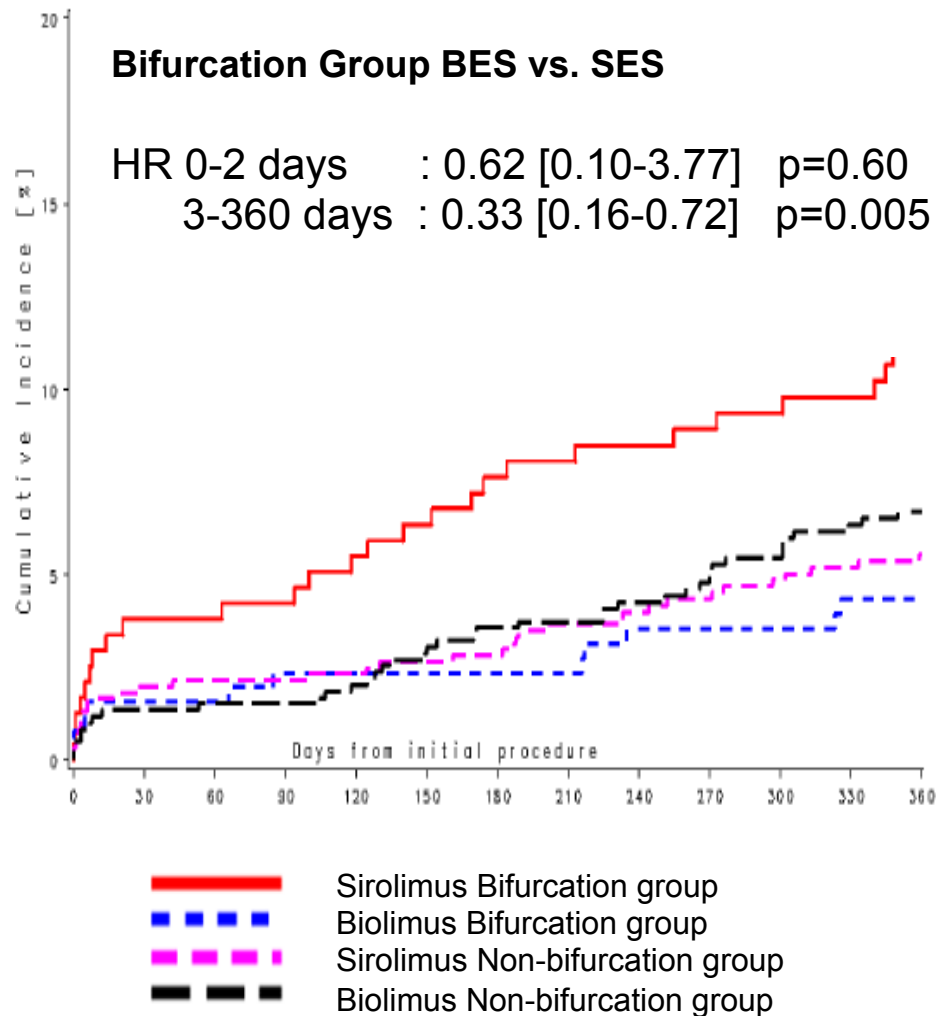
# Myocardial Infarction



# Myocardial Infarction



# Clinically Justified TVR



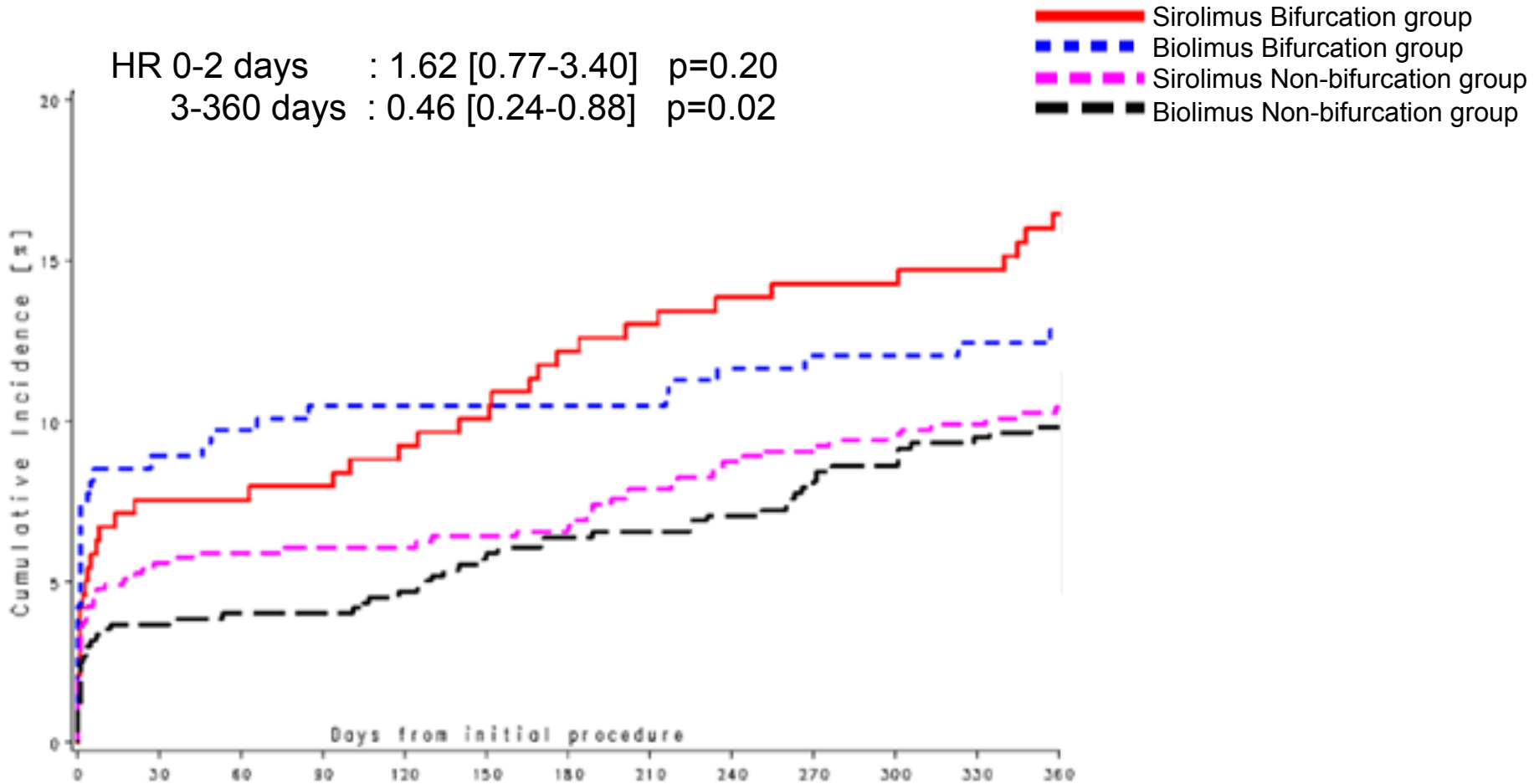
| Variable                     | BES vs. SES |
|------------------------------|-------------|
| Demographics                 | NS          |
| Angiographic characteristics | NS          |
| Lesion characteristics       | NS          |
| Post dilatation              | NS          |

# MACE\*

\*MI, cardiac death and clinically driven TVR

## Bifurcation Group BES vs. SES

HR 0-2 days : 1.62 [0.77-3.40] p=0.20  
 HR 3-360 days : 0.46 [0.24-0.88] p=0.02



# Summary

- Risk of MACE is higher amongst patients with bifurcation lesions
- A one stent strategy is the most prevalent stenting technique
- In patients with bifurcation lesions:
  - Observed trend for more MI with BES (p=NS)
  - Significantly greater TVR/TLR with SES (p<0.05)
  - Overall MACE at 12 months was similar between BES and SES (p=NS).
- Evidence exists from registries and randomised trials which suggests that stent design does impact on outcome in bifurcation lesions.

PCI procedure



Outcome



**Acute procedural outcome**  
i.e. ability to deploy the stent  
across the lesion



**Clinical outcome**  
(immediate, short & long term)



Cell Size  
Stent profile  
Stent strut thickness

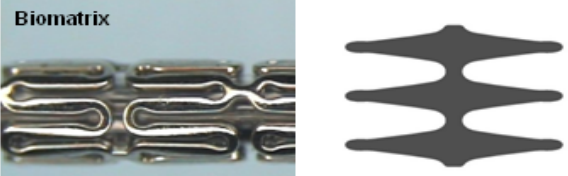

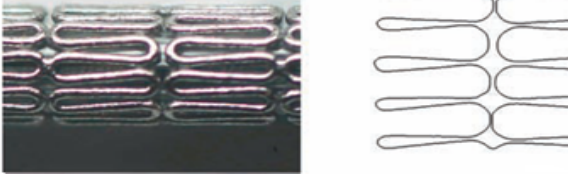
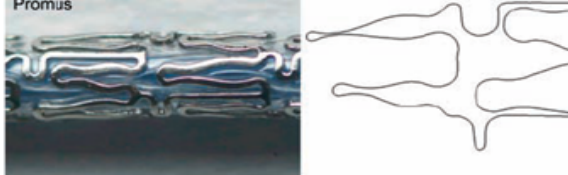

Stent  
properties



Stent coating  
Stent polymer  
Stent strut thickness



# Stent Cell Size

|                      |   | Maximum cell circumference*<br>(mm) | Maximum cell diameter*<br>(mm) |
|----------------------|---|-------------------------------------|--------------------------------|
| <b>Biomatrix</b>     |    | 10.8                                | 3.7                            |
| <b>Cypher</b>        |    | 9.5                                 | 3.0                            |
| <b>Endeavor</b>      |    | 19.8                                | 6.3                            |
| <b>Promus</b>        |  | 12.6                                | 4.0                            |
| <b>Taxus Liberté</b> |  | 12.6                                | 4.0                            |

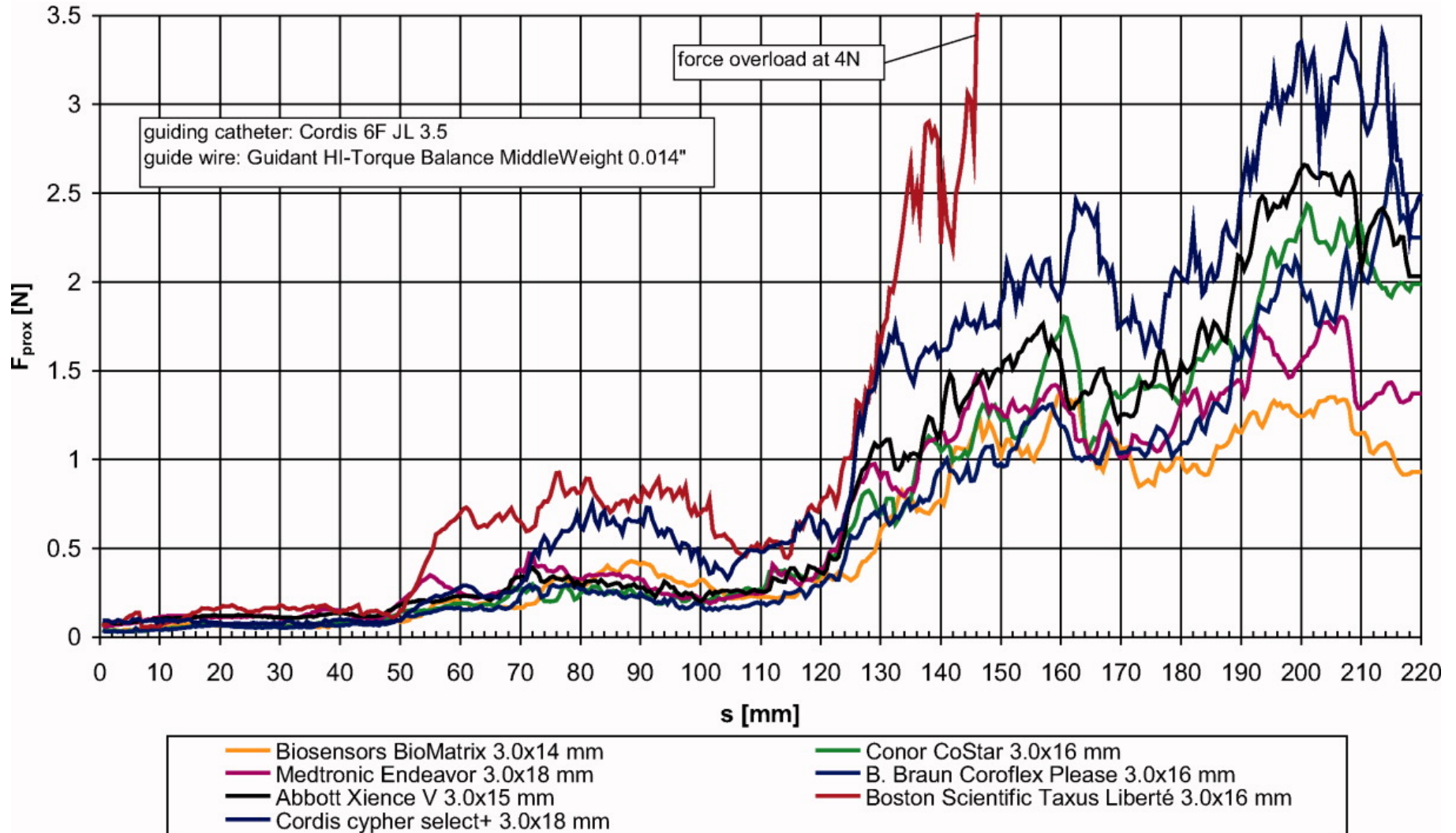
\*Based on 3mm stent

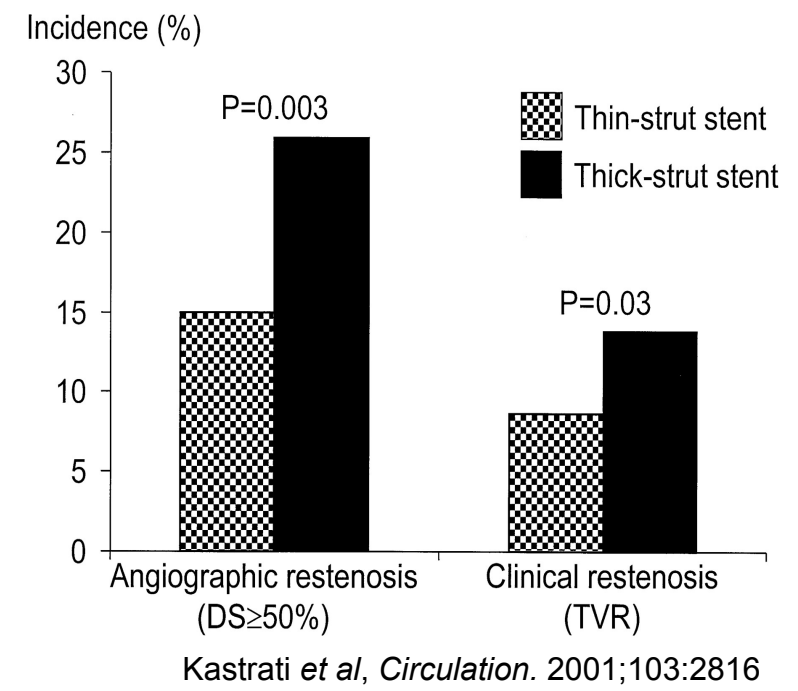
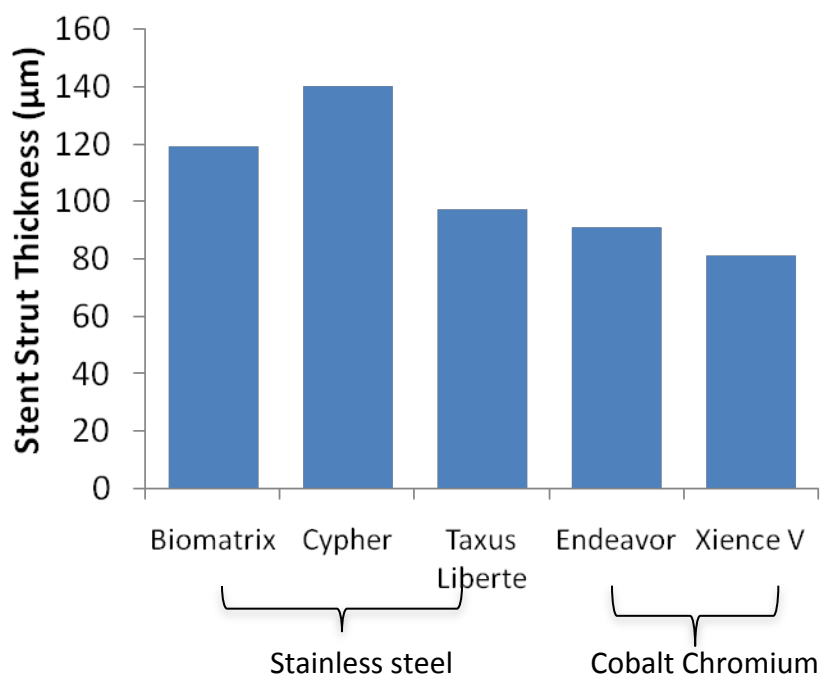
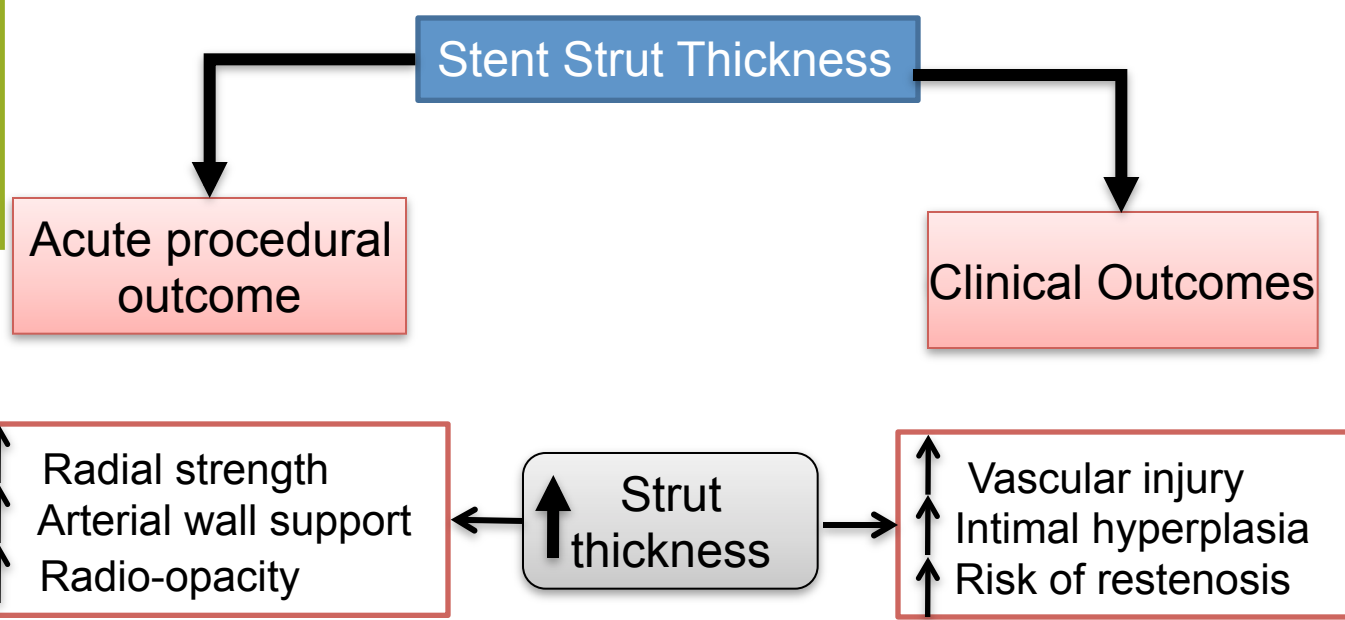
| Study                   | Technique                           | Failure rate (%) | Stent        |
|-------------------------|-------------------------------------|------------------|--------------|
| Columbo et al 2004      | Operator's discretion               | 2/43 (4.7)       | Cypher (SES) |
| Pan et al 2007          | Provisional T                       | 6/205 (2.4)      | 2 SES, 4 PES |
| Ferenc et al 2008       | T stenting                          | 3/101 (3.0)      | SES          |
| Adriaenssens et al 2008 | Culotte                             | 0/134 (0.0)      | Various DES  |
| Hoye et al 2006         | Kissing balloon post crush stenting | 6/128 (4.7)      | SES, PES     |

# Stent Properties

| 3mm stent system | Mean track force (N) | Mean cross force (N) | Crimped stent profile (mm) | Bending stiffness of crimped stent (Nmm <sup>2</sup> ) |
|------------------|----------------------|----------------------|----------------------------|--|
| Biomatrix        | 0.55                 | 0.09                 | 1.13                       | 30.06  |
| Cypher           | 1.14                 | 0.08                 | 1.20                       | 25.90  |
| Endeavor         | 0.69                 | n.a                  | 1.13                       | 47.20  |
| Taxus Liberte    | n.a                  | 0.09                 | 1.12                       | 17.24  |
| Xience V         | 0.87                 | 0.04                 | 1.06                       | 25.78  |

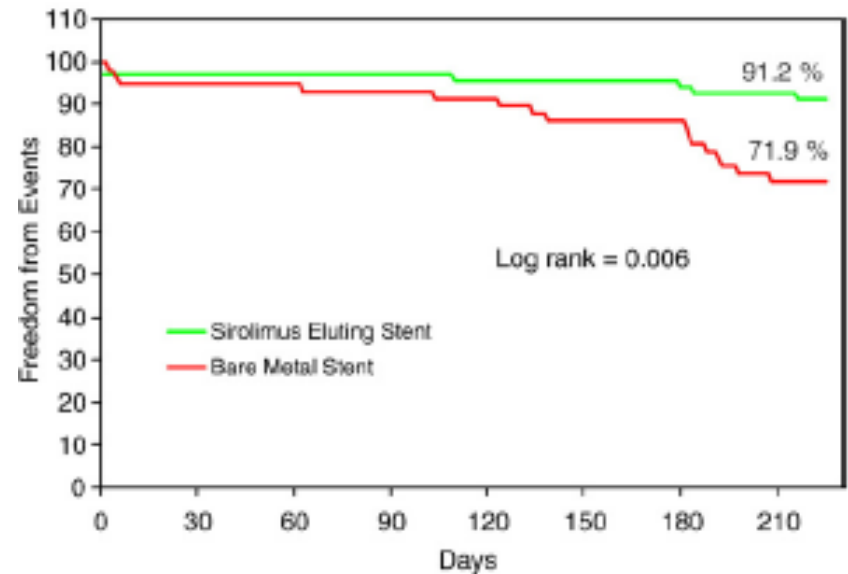
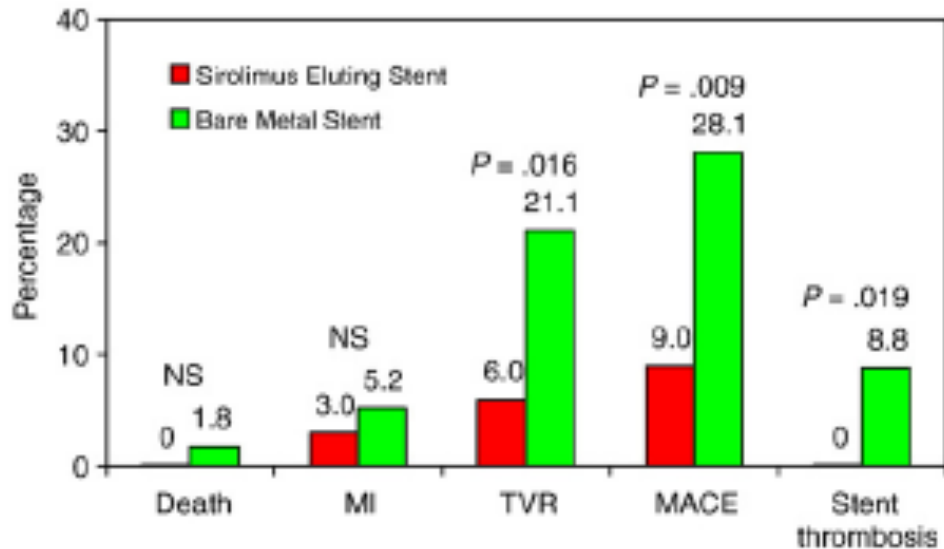
# Stent Profile-Trackability





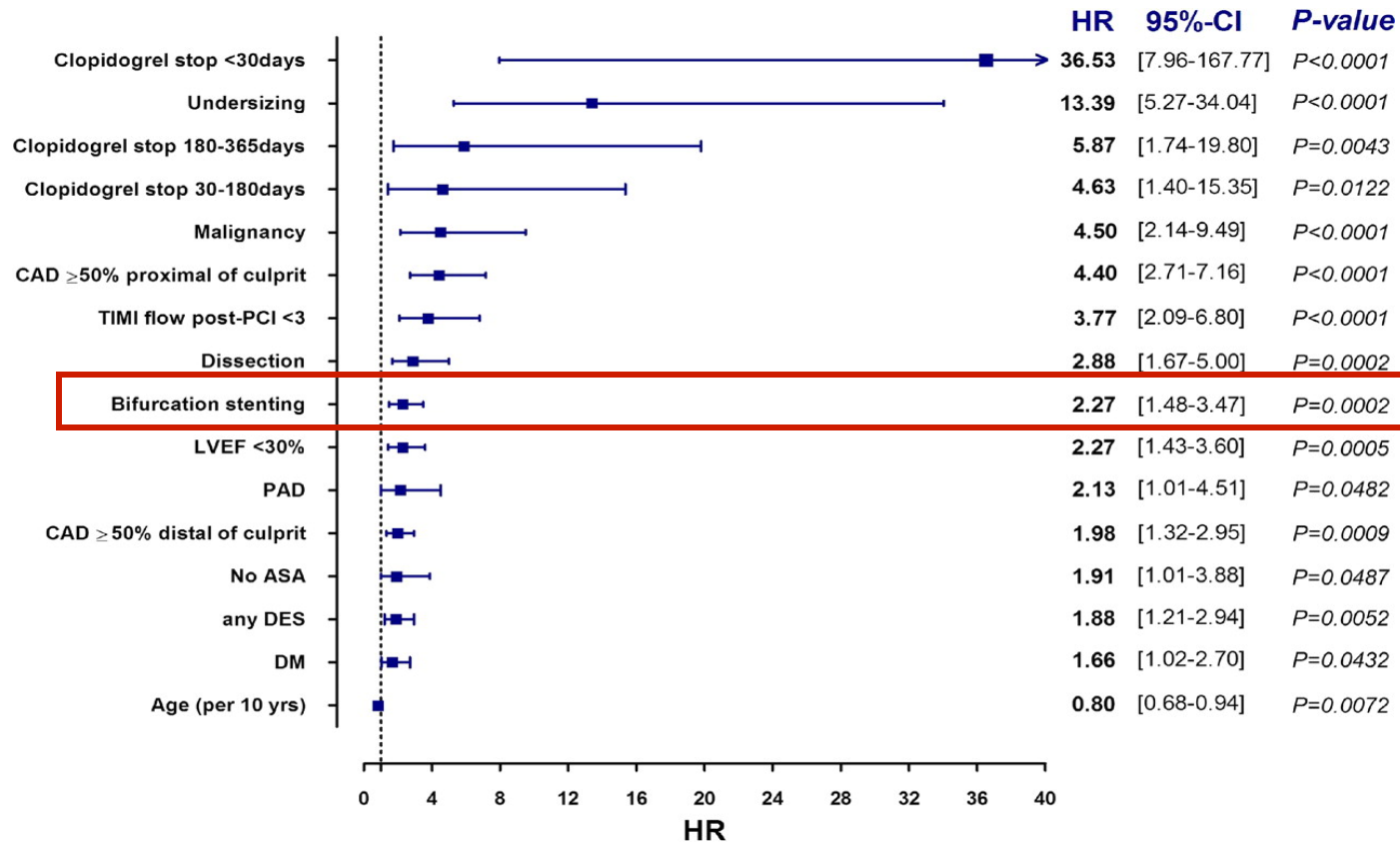
# Stent Coating

**Comparison of sirolimus-eluting and bare metal stents in coronary Bifurcation lesions: Subgroup analysis of the Stenting Coronary Arteries In Non-Stress/Benestent Disease Trial (SCANDSTENT)**



# Drug Polymer

- Suggested link between persistence of polymer and late stent thrombosis



# Conclusions

- A major limitation of comparing outcomes in bifurcation lesions is that anatomically no two bifurcation lesions are the same.
- Evidence exists, from non-dedicated trials, that stent design can influence outcomes.
- Acute procedural success can be influenced by the physical properties of a stent.
- Clinical outcomes are influenced by strut thickness, stent coating, and potentially the polymer.
- When dealing any lesion, especially a bifurcation lesion the choice of stent appears to have a role on subsequent outcome.