

TCTAP Fellowship Course - Left Main & Bifurcation PCI II. Bifurcation PCI

Stent Thrombosis After BMS, DES and BRS for Bifurcations

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Disclosure of Financial Interest

Within the past 12 months, I, Davide Capodanno, have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Speakers' Honoraria
- Advisory Board

Company

- Eli-Lilly/Daiichi Sankyo, AstraZeneca, Bayer, Abbott Vascular
- Eli-Lilly/Daiichi Sankyo, AstraZeneca

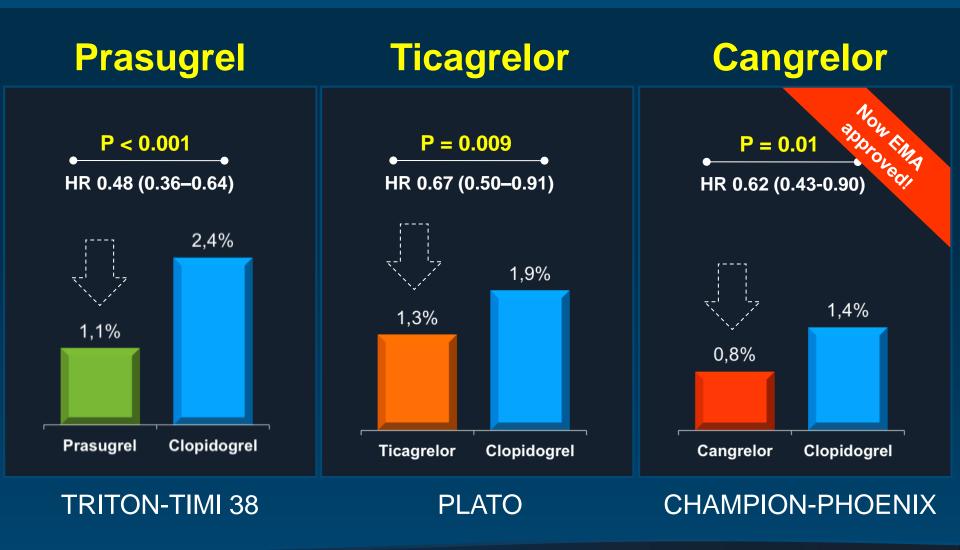


Stent Thrombosis in 2015: Impact of Stent Evolution

| | First ge | neration | Second generation | | | |
|---------------------------------|------------|---------------------------------------|---------------------|----------------------------------|--|--|
| Product | Cypher | Taxus | Resolute | Xience | | |
| Stent | CARRENT OF | C C C C C C C C C C C C C C C C C C C | A | | | |
| Polymer | | | J | | | |
| Drug | 2 Conto | A THE | | vý dintingingo dintingingo | | |
| Propensity for ST versus BMS | Greater | Greater | Similar or Iower | Similar or Iower | | |



Stent Thrombosis in 2015: Impact of New Antiplatelets

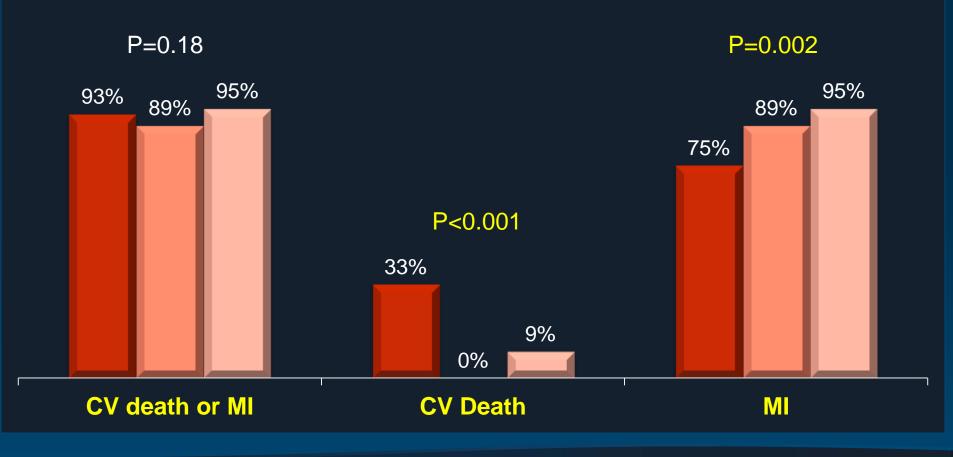




Cardiac Outcomes of Acute, Late and Very Late ST

184 stent thromboses in 8,709 patients with SES and PES from the PROTECT studies

Early ST Late ST Very late ST



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Secemsky EA et al. Am J Cardiol 2015 Epub Ahead of print



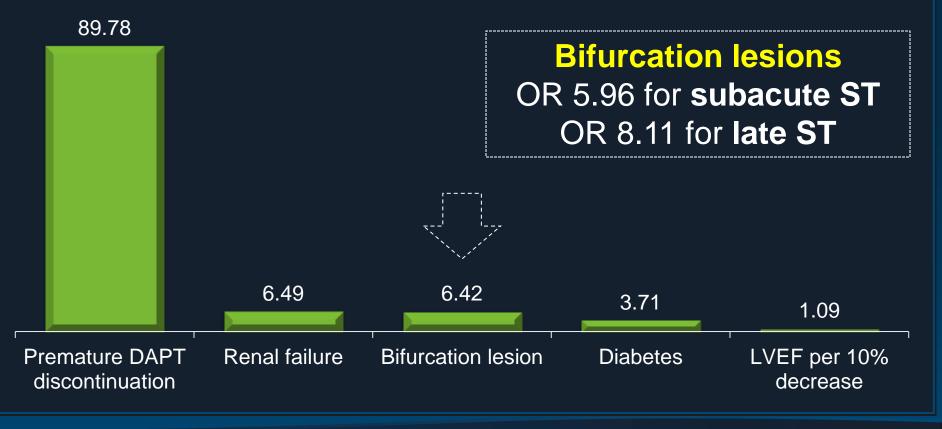
WHAT ABOUT **STENT THROMBOSIS** IN CORONARY BIFURCATION LESIONS?

degli STUDI di CATANIA

Predictors of ST with 1st Generation DES

2229 patients undergoing PCI with SES or PES between April 2002 and January 2004

Adjusted Odds Ratio for Cumulative ST



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Bifurcation ST and 2nd Generation DES

| EES+ZES-R | EES | EES+ZES-R | | |
|--|--|--|--|--|
| 2-Year def. or prob. ST | 2-Year def. or prob. ST | 2-Year def. or prob. ST | | |
| P = 0.66 | P = 0.72 | P = 0.62 | | |
| 1.8% 1.6% I I I I I I I I I I I I I I I I I I I | 2.3% 2.0% Bif. Non Bif. | 1.1% 0.5% Bif. Non Bif. | | |
| RESOLUTE AC | SPIRIT V | TWENTE | | |
| N=392 bif, 1-stent in 79.1% Diletti R, et al. Heart 2013;99:1267–1274 | N=492 bif, 1-stent in 92.5% Džavík V, et al. CCI 2013;82:163-72 | N=362 bif, 1-stent in 77.3% Lam MK, et al. AHJ 2015;169:69-77 | | |



In-Hospital Mortality of Coronary Bifurcation ST

173 cases of stent thrombosis from 5 US centers between 2005 and 2010

Bifurcations

20%

Non-Bifurcations

2%

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Armstrong EJ, et al. JACC Cardiovasc Interv. 2012;5:57-63



Impact of Bifurcation Strategy on ST

Meta-analysis of 6,961 patients from 5 RCTs and 7 Oss of single vs double stenting

| Study | Year | DDS | SDS | Double:Single | Weigth | RR (95% CI) |
|-----------------|-------------|-----------------------------|---------|---------------------------------------|---------|--------------------|
| Randomize | ed conti | rolled tria | als | | | |
| NORDIC | 2008 | 1/196 | 2/199 | | 5.37% | 0.50 (0.04-5.55) |
| Ferenc et al. | 2008 | 2/101 | 1/101 | | 5.40% | 2.00 (0.18-21.71) |
| CACTUS | 2009 | 3/177 | 2/173 | | 9.73% | 1.46 (0.24-8.66) |
| BBC-ONE | 2010 | 5/249 | 1/246 | | 6.71% | 4.97 (0.58-42.31) |
| DK-CRUSH II | 2011 | 4/185 | 1/185 | | 6.45% | 4.00 (0.45-35.44) |
| | | 15/908 | 7/906 | | | 2.01 (0.77-5.23) |
| Cochrane Q: 2.4 | 46 (P=0.651 | 1), I ² : 0% | | | | |
| Observatio | onal stu | dies | | | | |
| Ge et al. | 2007 | 3/57 | 0/117 | | — 3.54% | 14.24 (0.74 |
| Di Mario et al. | 2007 | 4/109 | 0/38 | | 3.66% | 3.19 (0.27-57.92) |
| ARTS II | 2007 | 1/61 | 4/263 | | 6.50% | 1.07 (0.12-9.47) |
| COBIS | 2010 | 2/292 | 9/1376 | | 13.17% | 1.04 (0.22-4.62) |
| J-CYPHER | 2011 | 3/263 | 10/1870 | | 18.64% | 2.13 (.59-7.70) |
| J-PMS | 2011 | 4/37 | 2/263 | | 11.12% | 14.21 (2.69-74.92) |
| Assan et al. | 2011 | 2/141 | 3/260 | | 9.72% | 1.23 (0.21-7.27) |
| | | 19/960 | 27/4167 | · · · · · · · · · · · · · · · · · · · | | 2.55 (1.13-5.78) |
| Cochrane Q: 8.3 | 36 (P=0.234 | 4), I ² : 25.57% | , D | | | |
| | | 34/1868 | 35/5093 | | 100% | 2.31 (1.33-4.03) |
| Cochrane Q: 10 | .65 (P=0.47 | 73), I ² : 0% | | | | |
| | | | | RR (Log Scale) | | |



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Zimarino M et al. J Am Coll Cardiol Intv 2013;6:687–95

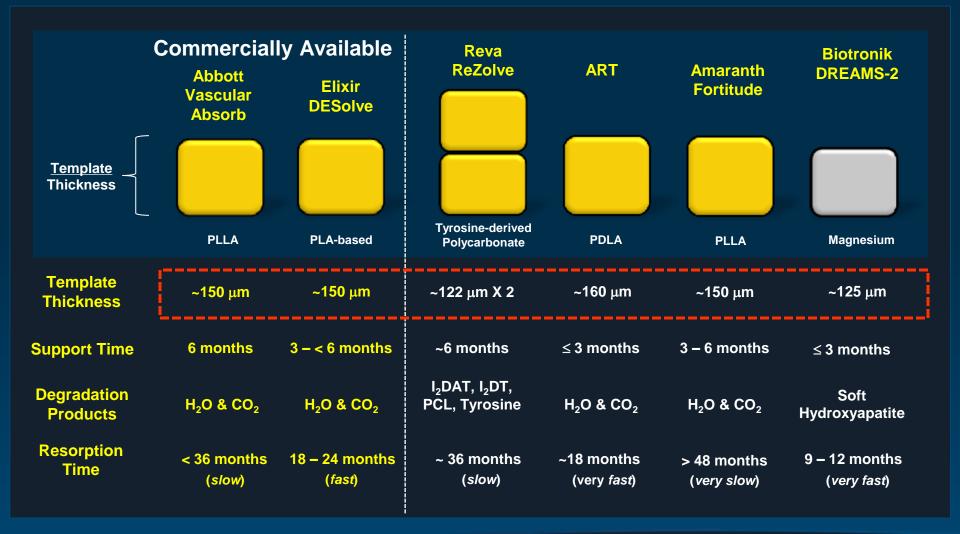
WHERE DO BIORESORBABLE SCAFFOLDS STAND IN THE CURRENT LANDSCAPE OF BIFURCATION PCI?

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Capodanno D, et al. Eurointervention 2015 Epub Ahead of Print



Strut Thickness of BRS Resembles 1st Gen DES

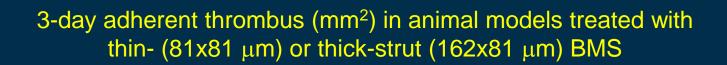


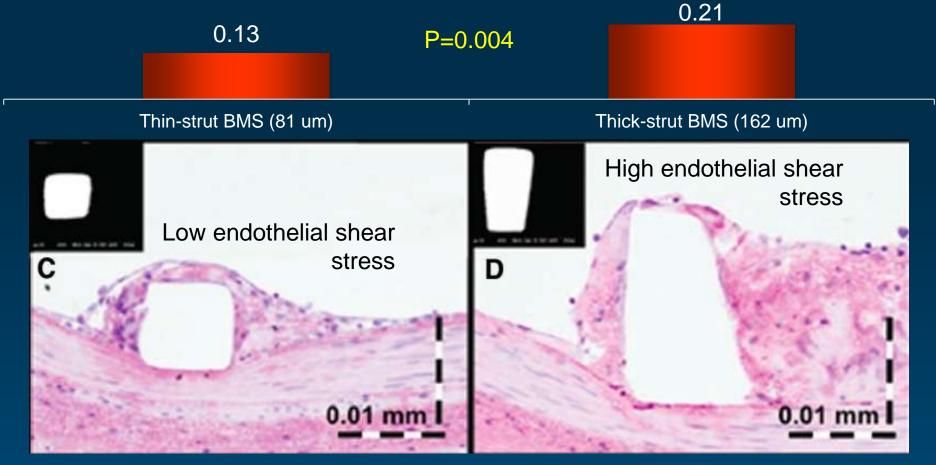
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cvPipeline and company presentations



Impact of Strut Geometry on Thrombogenicity



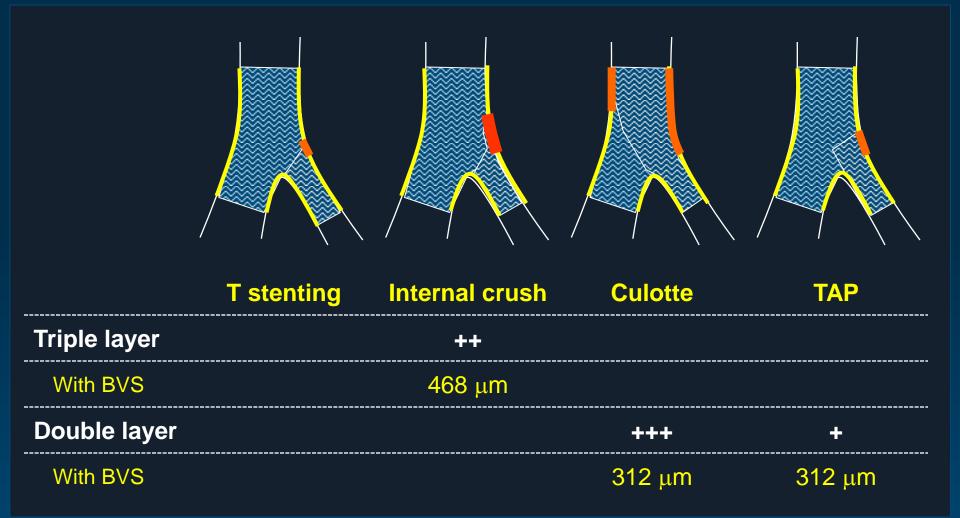


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Kolandaivelu K, et al. Circulation. 2011;123:1400-1409



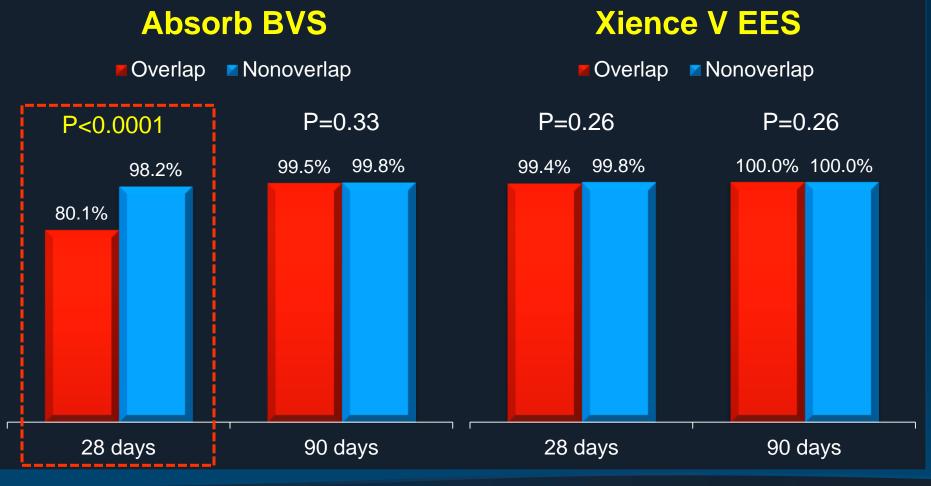
Strut Layering In BRS Double Stenting





Early Delay in Strut Coverage in Overlapping BVS

Serial OCT assessments in 41 swine at 28 and 90 days (1,407 cross-sections)



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AOU Policlinico-Vittorio Emanuele Catania, Italy Farooq V, et al. JACC Cardiovasc Interv. 2013;6:523-32



ABSORB II - Scaffold thrombosis

501 patients with coronary artery disease 2:1 randomized to BVS or EES

| | BVS (N=355) | EES (N=166) | Difference (95% CI) | P value |
|-------------------------|----------------|----------------|-----------------------|---------|
| 1-year definite ST | 2 (0.6%) | 0 | 0.61% (-1.72 to 2.19) | 1.00 |
| Acute (0-1 day) | 1 (0.3%) | 0 | 0.30% (-1.98 to 1.67) | 1.00 |
| Subacute (2-30 days) | 1 (0.3%) | 0 | 0.30% (-1.98 to 1.68) | 1.00 |
| Late (31-365 days) | 0 | 0 | 0.00% (NA) | 1.00 |
| Definite or probable ST | 3 (0.9%) | 0 | 0.91% (-1.45 to 2.65) | 0.55 |

"Two myocardial infarctions in the BVS group (one Q-wave and one non-Q-wave) were attributed to definite scaffold thrombosis, in one case involving overlapping scaffolds and in the other case involving bifurcation scaffolding (a protocol deviation)"

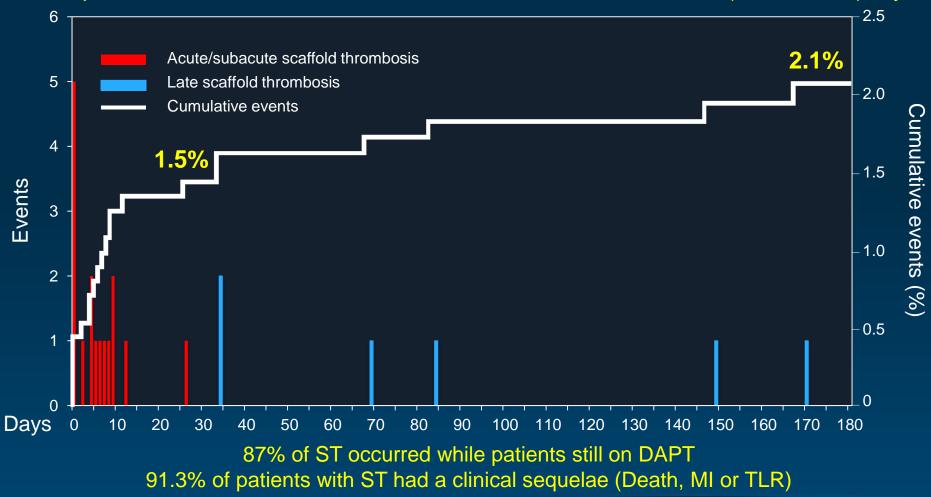
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Serruys PW et al, Lancet. 2015;385:43-54



GHOST-EU Absorb BVS in Daily Practice

1,189 patients, 1,440 lesions, 1,731 BVS from 10 centers. Median FU 189 (IQR 120-284) days



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GHOST-EU Absorb BVS in Bifurcations

289 patients, 302 bifurcation lesions from 10 centers (86% provisional)

Kaplan-Meier Estimates of Definite Stent Thrombosis



| Diabetes mellitus | 25% |
|-------------------------|-----|
| ACS at presentation | 34% |
| Prasugrel or ticagrelor | 19% |
| True bifurcation | 45% |
| Predilation of MB | 95% |
| Postdilation of MB | 61% |
| FKBI | 19% |
| IVUS | 22% |
| OCT | 21% |



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GHOST-EU Absorb BVS in Bifurcations

289 patients with 302 bifurcation lesions from 10 centers (86% provisional)

| Case | DM | ACS | Medina | Technique | Post- dilation on MB | KBI | OCT and/or IVUS | P2Y12 inhibitor | On DAPT |
|------|-----|-----|--------|-----------|----------------------------|-----|-----------------------|--------------------|---------|
| 1 | Yes | No | 1,1,1 | Single | Yes | No | Yes | Clop | No |
| 2 | No | No | 0,1,0 | Single | No | No | No | Clop | Yes |
| 3 | No | Yes | 1,0,0 | Single | No | No | Yes | Clop | Yes |
| 4 | No | Yes | 1,1,1 | Single | No | No | No | Ticlop | Yes |
| 5 | Yes | Yes | 1,1,0 | Single | No | No | No | Clop | Yes |
| 6 | No | Yes | 1,1,1 | Double* | Yes | No | No | Clop | No |
| 7 | No | Yes | 1,1,0 | Single | No | No | No | Clop | Yes |
| 8 | Yes | Yes | 1,1,0 | Single | No | No | No | Clop | Yes |
| 9 | Yes | Yes | 0,0,1 | Single | No | Yes | No | Pras | Yes |

*DES on SB. Favorable characteristics are shown in green. Unfavorable characteristics are shown in red.

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Naganuma T, Latib A, GHOST-EU Investigators. Submitted



Contemporary practice and technical aspects in coronary intervention with bioresorbable scaffolds: a European perspective

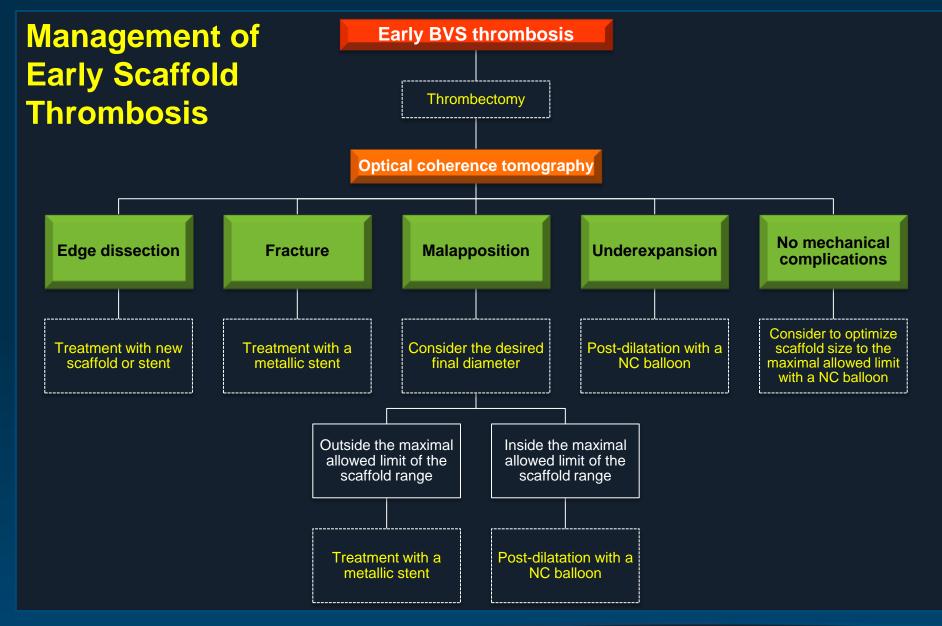
Corrado Tamburino¹, MD, PhD; Azeem Latib², MD; Robert-Jan van Geuns³, MD; Manel Sabate⁴, MD; Julinda Mehilli⁵, MD; Tommaso Gori⁶, MD, PhD; Stephan Achenbach⁷, MD; Manuel Pan Alvarez⁸, MD; Holger Nef⁹, MD; Maciej Lesiak¹⁰, MD; Carlo Di Mario¹¹, MD; Antonio Colombo², MD; Christoph K. Naber¹², MD; Giuseppe Caramanno¹³, MD; Piera Capranzano¹, MD; Salvatore Brugaletta⁴, MD; Salvatore Geraci¹³, MD; Aleksander Araszkiewicz¹⁰, MD; Alessio Mattesini¹¹, MD; Stylianos A. Pyxaras¹², MD; Lukasz Rzeszutko¹⁴, MD; Rafalo Depukat¹⁴, MD; Roberto Diletti³, MD; Els Boone¹⁵, MSc; Davide Capodanno^{1*}, MD, PhD; Dariusz Dudek¹⁴, MD

- 1. Provisional technique whenever possible
- 2. POT, SB fenestration and KBI (ie, undersized or snuggle) with caution
- **3.** For single stent techniques:
 - One BVS across the bifurcation and nothing else
 - SB dilatation and one BVS across the bifurcation
- 4. For double stent techniques:
 - For bailout SB DES or BRS stenting, prefer techniques with least strut layering (ie, T, TAP)
 - Avoid systematic double scaffolding whenever possible

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Closing Remarks

- Stent thrombosis in bifurcation lesions has decreased over time, reflecting ongoing progresses in DES platforms, antiplatelet drugs and procedural strategies.
- 2. The use of BRS in coronary bifurcations carries many limitations, including the uncertain outcome of procedural steps known to be important with DES but potentially hazardous with a breakable device.
- 3. Until more BRS data are available to provide guidance in this field, provisional DES strategies should be regarded as the standard of care for most (~70-90%) bifurcation lesions.

