Ultrathin-strut versus thin-strut drug-eluting stents in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention
A subgroup analysis of the BIOSTEMI randomized trial

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Potential conflicts of interest

Speaker's name: Juan F. Iglesias

☑️ I have the following potential conflicts of interest to report:

- Consultant: BIOTRONIK, CARDINAL HEALTH, MEDTRONIC, TERUMO.

- Honoraria/speaker’s fee: ASTRA ZENECA, BIOTRONIK, CARDINAL HEALTH, MEDTRONIC, TERUMO, PHILIPS VOLCANO.

- Institutional grant/research support: ABBOTT VASCULAR, ASTRA ZENECA, BIOTRONIK, PHILIPS VOLCANO.

BIOSTEMI was an investigator-initiated trial supported by a dedicated research grant from Biotronik AG, Switzerland.
Why this study?

**BIOSTEMI TRIAL**


- **Target lesion failure (%):**
  - DP-EES: 5.5%
  - BP-SES: 3.9%

- **Difference:** -1.6 percentage points
- **Rate ratio:** 0.59
- **95% Bayesian CI:** 0.37-0.94

**Probability density plot:**
- **Bayesian posterior probability of superiority:** 98.6%
- **Superiority margin:** 3.5

**Number at risk:**
- DP-EES: 847 801 787 785 781 779 777 775 770 767 757 718
- BP-SES: 860 824 805 800 798 797 795 794 792 790 786 782 750

**Days since index procedure:**
- 0 30 60 90 120 150 180 210 240 270 300 330 365

**Rate ratio:** 0.59

**Bayesian 95% CI:** 0.37-0.94
# Why this study?

<table>
<thead>
<tr>
<th>PLATFORM</th>
<th>ORSIRO – BP-SES</th>
<th>XIENCE – DP-EES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobalt-Chromium, L-605</td>
<td>60 μm ≤3.0 mm</td>
<td>Cobalt-Chromium, L-605</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POLYMER</td>
<td>Silicon carbide passive coating</td>
<td>Biodegradable PLLA: poly-L-lactic acid</td>
</tr>
<tr>
<td>DRUG</td>
<td>Sirolimus (1.4 µg/mm²)</td>
<td>Everolimus (1.0 µg/mm²)</td>
</tr>
</tbody>
</table>

Juan F. IGLESIAS
What did we study?

- To assess the **1-year clinical outcomes** after treatment with biodegradable polymer sirolimus-eluting stents compared with durable polymer everolimus-eluting stent in patients with STEMI undergoing **primary PCI** with **small** (≤ 3.0 mm) versus **large** (>3.0 mm) **stent sizes**, as a surrogate to compare **ultrathin-strut BP-SES (60 μm)** versus **thin-strut DP-EES (81 μm)**.
How was the study executed?

Post-hoc subgroup analysis of the BIOSTEMI trial (NCT02579031)

Patients with acute STEMI undergoing primary PCI within 24 hours of symptom onset

1:1 randomization

*All stents with diameter >3.0 mm

1:1 randomization

# ≥1 stent with diameter ≤ 3.0 mm

ORSIRO BP-SES

Large stent sizes* BP-SES 80 µm

Small stent sizes# BP-SES 60 µm

XIENCE DP-EES

Small stent sizes# DP-EES 81 µm

Large stent sizes* DP-EES 81 µm

PRIMARY ENDPOINT:
Target lesion failure, a composite of cardiac death, target-vessel myocardial re-infarction, or clinically-indicated target lesion revascularization, at 1 year
What are the essential results?

1,707 patients included

407 STEMI patients in BIOSCIENCE

1,300 patients randomized in BIOSTEMI

860 patients allocated to BP-SES (1099 lesions)

847 patients allocated to DP-EES (1073 lesions)

7 excluded (no stent)

573 BP-SES patients with small stent sizes

280 BP-SES patients with large stent sizes

550 follow up information for clinical primary endpoint available up to 1 year

263 follow up information for clinical primary endpoint available up to 1 year

578 BP-SES patients with large stent sizes

269 BP-SES patients with large stent sizes

263 follow up information for clinical primary endpoint available up to 1 year

558 follow up information for clinical primary endpoint available up to 1 year

269 analysed for primary clinical endpoint

573 analysed for primary clinical endpoint

280 analysed for primary clinical endpoint

578 analysed for primary clinical endpoint

269 analysed for primary clinical endpoint

573 analysed for primary clinical endpoint

280 analysed for primary clinical endpoint

578 analysed for primary clinical endpoint

269 analysed for primary clinical endpoint

524 followed up and alive

26 followed up and died

260 followed up and alive

3 followed up and died

534 followed up and alive

24 followed up and died

252 followed up and alive

7 followed up and died

23 censored at time-point of refusal or loss to follow-up

17 censored at time-point of refusal or loss to follow-up

20 censored at time-point of refusal or loss to follow-up

10 censored at time-point of refusal or loss to follow-up
What are the essential results?

**BASELINE CLINICAL CHARACTERISTICS**

<table>
<thead>
<tr>
<th></th>
<th>SMALL STENT SIZES (n=1'151)</th>
<th>BP-SES</th>
<th>DP-EES</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients – no.</td>
<td></td>
<td>n = 573</td>
<td>n = 578</td>
<td></td>
</tr>
<tr>
<td>Age — years (SD)</td>
<td></td>
<td>62.8±11.9</td>
<td>63.6±12.0</td>
<td>0.26</td>
</tr>
<tr>
<td>Male gender — no. (%)</td>
<td></td>
<td>433 (75.6%)</td>
<td>412 (71.3%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Diabetes mellitus — no. (%)</td>
<td></td>
<td>73 (12.8%)</td>
<td>83 (14.4%)</td>
<td>0.44</td>
</tr>
<tr>
<td>Hypertension — no. (%)</td>
<td></td>
<td>268 (47.1%)</td>
<td>277 (48.2%)</td>
<td>0.72</td>
</tr>
<tr>
<td>Hypercholesterolaemia — no. (%)</td>
<td></td>
<td>280 (49.3%)</td>
<td>271 (47.4%)</td>
<td>0.55</td>
</tr>
<tr>
<td>Active smoker — n (%)</td>
<td></td>
<td>241 (43.0%)</td>
<td>212 (37.6%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Prior myocardial infarction — n (%)</td>
<td></td>
<td>26 (4.5%)</td>
<td>22 (3.8%)</td>
<td>0.56</td>
</tr>
<tr>
<td>Prior PCI — n (%)</td>
<td></td>
<td>28 (4.9%)</td>
<td>29 (5.0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Prior CABG — n (%)</td>
<td></td>
<td>4 (0.7%)</td>
<td>7 (1.2%)</td>
<td>0.55</td>
</tr>
<tr>
<td>Renal failure — no. (%)</td>
<td></td>
<td>67 (12.1%)</td>
<td>65 (11.7%)</td>
<td>0.85</td>
</tr>
<tr>
<td>Left ventricular EF (%) — mean ± SD</td>
<td></td>
<td>49.3±11.0</td>
<td>47.8±11.3</td>
<td>0.059</td>
</tr>
</tbody>
</table>
What are the essential results?

### Baseline Angiographic and Procedural Characteristics

#### Small Stent Sizes (n=1'151)

<table>
<thead>
<tr>
<th></th>
<th>BP-SES</th>
<th>DP-EES</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients – no.</td>
<td>n = 573</td>
<td>n = 578</td>
<td></td>
</tr>
<tr>
<td>Lesions – no.</td>
<td>N = 797</td>
<td>N = 780</td>
<td></td>
</tr>
</tbody>
</table>

**Target vessel location - per lesion no. (%)**

<table>
<thead>
<tr>
<th></th>
<th>BP-SES</th>
<th>DP-EES</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left main coronary artery</td>
<td>433 (75.6%)</td>
<td>412 (71.3%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Left anterior descending artery</td>
<td>259 (45.4%)</td>
<td>300 (52.0%)</td>
<td></td>
</tr>
<tr>
<td>Left circumflex artery</td>
<td>109 (19.1%)</td>
<td>111 (19.2%)</td>
<td></td>
</tr>
<tr>
<td>Right coronary artery</td>
<td>197 (34.5%)</td>
<td>163 (28.2%)</td>
<td></td>
</tr>
</tbody>
</table>

Number of lesions treated per patient — mean ± SD

<table>
<thead>
<tr>
<th></th>
<th>BP-SES</th>
<th>DP-EES</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombus aspiration — n (%)</td>
<td>191 (33.4%)</td>
<td>178 (30.8%)</td>
<td>0.36</td>
</tr>
</tbody>
</table>

Total number of stents implanted — mean ± SD

<table>
<thead>
<tr>
<th></th>
<th>BP-SES</th>
<th>DP-EES</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total stent length (mm) — mean ± SD</td>
<td>34.69±20.31</td>
<td>36.75±21.33</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Overlapping stents — n (%)

<table>
<thead>
<tr>
<th></th>
<th>BP-SES</th>
<th>DP-EES</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>193 (33.7%)</td>
<td>205 (35.5%)</td>
<td>0.84</td>
</tr>
</tbody>
</table>
What are the essential results?

TARGET LESION FAILURE @ 1 YEAR

SMALL STENT SIZES

RR 0.70; 95% CI 0.43-1.13; p=0.144
What are the essential results?

TARGET LESION FAILURE @ 1 YEAR

**LARGE STENT SIZES**

RR 0.14; 95% CI 0.03-0.64; p=0.011

<table>
<thead>
<tr>
<th>Number at risk</th>
<th>Small - BP SES</th>
<th>573</th>
<th>548</th>
<th>538</th>
<th>534</th>
<th>532</th>
<th>531</th>
<th>530</th>
<th>529</th>
<th>527</th>
<th>525</th>
<th>523</th>
<th>519</th>
<th>495</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small - DP EES</td>
<td>578</td>
<td>545</td>
<td>536</td>
<td>533</td>
<td>530</td>
<td>528</td>
<td>527</td>
<td>527</td>
<td>524</td>
<td>522</td>
<td>521</td>
<td>514</td>
<td>493</td>
</tr>
<tr>
<td></td>
<td>No Small - BP SES</td>
<td>260</td>
<td>272</td>
<td>267</td>
<td>267</td>
<td>267</td>
<td>267</td>
<td>266</td>
<td>266</td>
<td>266</td>
<td>266</td>
<td>264</td>
<td>264</td>
<td>256</td>
</tr>
<tr>
<td></td>
<td>No Small - DP EES</td>
<td>269</td>
<td>257</td>
<td>254</td>
<td>254</td>
<td>253</td>
<td>253</td>
<td>252</td>
<td>250</td>
<td>248</td>
<td>247</td>
<td>245</td>
<td>230</td>
<td></td>
</tr>
</tbody>
</table>
What are the essential results?

INDIVIDUAL COMPONENTS OF THE PRIMARY ENDPOINT @ 1 YEAR

- **CARDIAC DEATH**
- **TARGET VESSEL MI**
- **CLINICALLY-DRIVEN TLR**

Juan F. IGLESIAS

**NO SIGNIFICANT INTERACTION BETWEEN TREATMENT EFFECT AND STENT SIZE**

- $p$ for interaction = 0.13
- $p$ for interaction = 0.96
- $p$ for interaction = 0.29
What are the essential results?

**DEFINITE STENT THROMBOSIS @ 1 YEAR**

- Small stent sizes (≤ 3 mm)
  - BP-SES: 0.9
  - DP-EES: 1.4
  - p = 0.41

- Large stent sizes (>3 mm)
  - BP-SES: 0.4
  - DP-EES: 0.8
  - p = 0.54

- p for interaction = 0.84
Why is this important?

- In a post-hoc subgroup analysis of the BIOSTEMI trial, we found a **consistent treatment effect** between BP-SES and DP-EES with respect to TLF at one-year follow-up **across all stent sizes** in patients with STEMI undergoing primary PCI.

- We observed a **borderline significant treatment interaction** between **clinical outcomes** and **stent size** favoring BP-SES among patients treated with **large stent sizes**, in which **strut thickness** between BP-SES and DP-EES is **similar**.

- The **lower TLF risk** with BP-SES compared to DP-EES in STEMI patients in the BIOSTEMI trial might be explained by **differences in clinical outcomes** in patients treated with **large stent sizes**, rather than in those with **small stent sizes** with **between-stent differences in strut thickness**.
The essentials to remember

• **Why?** In the BIOSTEMI trial, BP-SES were found superior to DP-EES with respect to TLF at one year among patients with STEMI. It remains uncertain whether differential clinical outcomes between BP-SES and DP-EES might be explained by differences in strut thickness.

• **What?** 1-year clinical outcomes in patients with STEMI undergoing primary PCI with small versus large stent sizes, as a surrogate to compare ultrathin-strut BP-SES (60 μm) versus thin-strut DP-EES (81 μm).

• **How?** Post-hoc subgroup analysis of the BIOSTEMI trial.

• **What are the results?** Borderline significant interaction between treatment effect and stent size with greater benefit of BP-SES over DP-EES with regards to TLF at one-year follow-up in STEMI patients treated with large stent sizes.

• **Why is this important?** Differences in TLF rates between BP-SES and DP-EES among STEMI patients in the BIOSTEMI trial might be explained by differential clinical outcomes in patients treated with large stent sizes with comparable between-stent strut thickness.
Ultrathin-strut versus thin-strut drug-eluting stents in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention
A subgroup analysis of the BIOSTEMI randomized trial

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