Early Neointimal Coverage and Vasodilator Response Following Biodegradable Polymer Sirolimus-Eluting vs. Durable Polymer Zotarolimus-Eluting Stents in Patients With Acute Coronary Syndrome – HATTRICK-OCT Trial –

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Background: Patients at high bleeding risk would benefit from a shorter dual antiplatelet therapy after PCI. Compared to first-generation devices, the design of newer generation drug-eluting stents may facilitate more rapid anatomical and functional healing of stented vessel based on thinner stent platforms, biodegradable/biocompatible polymers and rapid drug elution.

Methods and Results: Forty-four non-diabetic patients with acute coronary syndrome (ACS) and culprit lesion in the LAD were randomized to receive either biodegradable polymer sirolimus-eluting stent (BP-SES) or durable polymer zotarolimus-eluting stent (DP-ZES). Neointimal strut coverage was examined using optical coherence tomography, and vasodilator response on invasive thermodilution-derived coronary flow reserve (CFR) at 3-month follow-up. The primary endpoints were percent uncovered struts and CFR. A total of 425 cross-sections (4,897 struts) were analyzed in the BP-SES group, and 425 cross-sections (5,467 struts) in the DP-ZES group. The percent uncovered struts was lower in the BP-SES group compared with the DP-ZES group, both at strut level (3.9% vs. 8.9%, respectively, \( P<0.001 \)), and stent level (3.9±3.2% vs. 8.9±6.9%, respectively, \( P=0.019 \)). No significant difference was found between the 2 groups regarding CFR (3.0±1.3 vs. 3.2±1.0, respectively, \( P>0.05 \)).

Conclusions: In non-diabetic patients with ACS, BP-SES provided slightly better stent strut coverage at 3 months compared with DP-ZES, but neither stent was fully covered. No difference in vasodilator response was seen. (Circ J 2015; 79: 360–367)

Key Words: Biodegradable polymer; Coronary flow reserve; Optical coherence tomography; Sirolimus-eluting stent; Zotarolimus-eluting stent

Recent reports suggest a paradigm shift in the occurrence of stent thrombosis (ST) as evidenced by lower event rates in patients treated with newer generation drug-eluting stents (DES) compared to bare metal stents (BMS) or first-generation DES. Incomplete neointimal coverage over stent struts has been suggested as a potential substrate for late ST in histopathological studies, as well as in an observational case-control setting using optical coherence tomography (OCT) in vivo. Durable polymer is a possible stimulus for vessel wall inflammatory and hypersensitivity reaction leading to incomplete endothelialization following DES implantation. Localized hypersensitivity reaction has been demonstrated in the vessel wall at autopsy, and in thrombus aspirates, from patients with very late ST following first-generation DES.

Newer generation DES have thinner stent platforms, biodegradable/biocompatible polymers and rapid drug elution compared to first-generation devices. The frequency of uncovered struts was reported lower with biodegradable polymer biolim-
Usual-stent compared with durable polymer sirolimus-eluting stents (SES), as demonstrated on OCT at 9-month follow-up, but not compared with durable polymer everolimus-eluting stents (DP-EES). In a bench-top study, the biocompatible BioLinx polymer did not induce activated monocyte adhesion. BioLinx polymer-coated zotarolimus-eluting stent (ZES) was associated with low rates of uncovered and malaposed struts on OCT at 13 months. Earlier reports have also raised concerns about local epicardial vasomotor dysfunction associated with DES 6 months or later after implantation.

In this prospective randomized trial, we combined the anatomical and functional healing assessment by exploring neointimal strut coverage and vasodilator response 3 months following biodegradable polymer SES (BP-SES) vs. BioLinx durable polymer ZES (DP-ZES) implantation in non-diabetic patients presenting with acute coronary syndrome (ACS).

**Methods**

**Patient Selection and Study Design**

The Healing AT Three months after percutaneous coronary Intervention for ACS (HATTRICK-OCT) trial was a prospective multicenter single-blinded randomized controlled trial, with the chief aim of comparing neointimal coverage and vasodilator response 3 months following the implantation of BP-SES vs. DP-ZES in non-diabetic patients presenting with ACS. From June 2011 to July 2012, we enrolled 46 patients aged >18 years, presenting with ACS, with a significant (≥50% diameter stenosis) de novo lesion in the left anterior descending coronary artery. Consort flow chart is presented in Figure 1. The main exclusion criteria were diabetes mellitus (presumed microcirculatory dysfunction), unprotected left main disease, ostial or bifurcation lesion, multi-vessel disease, a second de novo stenosis ≥50% in the stented vessel, intolerance to the study medications, planned surgery within 12 months of the index procedure, and life expectancy <12 months. The HATTRICK-OCT trial was conducted in 4 referral centers. Patients were randomly assigned (1:1) to receive either BP-SES or DP-ZES. Computer-generated randomization was implemented using a closed-envelope system stratified by center. Study investigators were by necessity aware of treatment allocation, but patients and those who performed data management and analysis were blinded.

**Devices**

The BP-SES (Orsiro; Biotronik, Bülach, Switzerland) has a stent platform based on the Pro-Kinetic Energy BMS with a helicoidal design coated with passive and active coating layers. It is a tubular thin-strut balloon-expandable stent, made of L-605 cobalt-chromium alloy. The stent surface is completely coated with a layer of silicon carbide (PROBIO®) that acts as a diffusion barrier reducing ion release. The active coating layer (BIOlute) consists of high-molecular-weight poly-L-lactic acid that completely disintegrates into carbon dioxide and water. It covers the whole stent surface with an abluminal thickness of 7.5 µm, and a luminal thickness of 3.5 µm. The sirolimus
The thickness of the coated strut is 71 \( \mu m \) for stents with a nominal diameter \( \leq 3 \) mm, and 91 \( \mu m \) for larger sizes. DP-ZES (Resolute Integrity; Medtronic Cardiovascular, Santa Rosa, CA, USA) is a DES that contains zotarolimus at a dose of 1.6 \( \mu g/mm^2 \) of stent surface area; 85% of the drug is eluted in the first 60 days; the drug is completely eluted at 180 days. It is coated with BioLinx polymer, composed of 3 different polymers: the hydrophobic C10 acts as a drug reservoir for slow and sustained release; the hydrophilic polyvinyl-pyrrolidinone serves biocompatibility; and C19 contains both hydrophilic and hydrophobic components. The thickness of the coated strut is 97 \( \mu m \).

Pharmacological Interventions

Patients already maintained on aspirin received no additional aspirin loading. Aspirin-naive patients received a loading dose of 250 mg orally or 250–500 mg i.v., and continued at a daily dose of 75–150 mg indefinitely. Oral clopidogrel was initiated at a loading dose of at least 300 mg before or immediately after the procedure, and continued at a daily dose of 75 mg. As per protocol, patients in either group were prescribed oral clopidogrel for a minimum of 6 months, and thereafter, for extended periods (maximum 12 months) at the operator’s discretion. During the procedure, low-molecular-weight heparin or unfractionated heparin was administered i.v. in the standard dosage. Use of peri-procedural glycoprotein IIb/IIIa inhibitors or bivalirudin was at the operator’s discretion.

Ethics

This study is part of a wider protocol in progress to assess thrombotic and bleeding complications of cardiac procedures in Finland. The study was initiated and designed by the investigators and conducted according to the ethics guidelines of the 1964 Declaration of Helsinki, as revised in 2002. No industry representatives were involved in the study execution, analysis or reporting. Informed written consent was obtained from every patient after explanation of the study protocol. The protocol was approved by the Ethics Committees of the coordinating center, Turku University Hospital, and the other participating hospitals. The HATTRICK-OCT trial is registered with ClinicalTrials.gov, number NCT01391871.

OCT

Image Acquisition

OCT images were obtained 3 months after the index procedure, immediately after follow-up angiography, with the C7Xr frequency-domain system (LightLab Imaging, Westford, MA, USA), using the non-occlusive technique via radial or femoral approach. A 0.014-inch guidewire was introduced into the vessel using a 6-F guiding catheter. An imaging catheter (Dragonfly; LightLab Imaging) was positioned distal to the stent, and automated motorized pullback was performed at 20 mm/s during flush of 4–6 ml/s iso-osmolar contrast. A segment length of 54 mm was visualized, and images were stored digitally for subsequent analysis.

Image Analysis

Offline OCT analysis was performed independently by 2 investigators blinded to patient characteristics and to the stent used. Proprietary software (LightLab Imaging) was used to analyze cross-sections at 1-mm intervals (every 5 frames) within the stented segment. In each cross-section, the number of struts was counted. Struts were classified as uncovered if any part of the strut was visibly exposed to the lumen, or covered if a layer of tissue was visible all over the reflecting surfaces. The percent uncovered struts was calculated as the number of uncovered struts as a percentage of all analyzed struts. In covered struts, neointimal hyperplasia (NIH) thickness was measured from the strut marker to the endoluminal edge of the tissue coverage, following a straight line connecting the strut marker with the center of gravity of the vessel. Stent cross-sectional area (CSA) and lumen CSA were traced semi-automatically. NIH area was calculated by subtracting lumen CSA from stent CSA. Percent NIH area was calculated by dividing the NIH area by the stent CSA, multiplied by 100. Apposition was assessed by measuring the distance between the strut marker and the lumen contour following a straight line connecting this marker with the center of gravity of the vessel. A margin of 18 \( \mu m \) was added as a correction for half the blooming.

Struts with distance to lumen contour greater than the sum of strut thickness+polymer thickness+18 \( \mu m \) were considered malapposed. Given a coated strut thickness of 71 \( \mu m \), we adopted a malapposition threshold of 90 \( \mu m \) for the BP-SES (110 \( \mu m \) for stents \( >3.0 \) mm in diameter). Similarly, given a coated strut thickness of 97 \( \mu m \) for the DP-ZES, we adopted a threshold of 115 \( \mu m \). Struts located at the ostium of a side branch were excluded from the analysis. Thrombus was defined as an irregular high- or low-backscattering (red or white thrombus) mass protruding into the lumen discontinuous from the surface.

Hemodynamic Measurements

Patients were instructed to avoid heavy meals, caffeine, alcohol and tobacco for 12 h before the study. Coronary flow reserve (CFR), fractional flow reserve (FFR) and index of microcirculatory resistance (IMR) were measured as follows. A bolus of i.e. nitroglycerin (0.2 mg) was administered at the onset of the procedure, and repeated before baseline and hyperemia assessments. A coronary 0.014-inch pressure wire (Curtiss2; St. Jude Medical, MN, USA) was used. After calibration, the pressure wire was advanced to the tip of the guiding catheter for equalization of pressure and temperature signals, and then positioned distal to the stent approximately at two-thirds of the length of the artery. Care was taken to maintain the guiding catheter and sensor in position throughout all measurements. The sensor was used to obtain thermodilution curves and distal coronary pressure. The resting mean transit time was determined by 3 injections of 3 ml room-temperature saline. Hyperemia was induced by i.v. infusion of adenosine (140 \( \mu g \cdot kg^{-1} \cdot min^{-1} \)). After calibration, the pressure wire was advanced to the tip of the guiding catheter for equalization of pressure and temperature signals, and then positioned distal to the stent approximately at two-thirds of the length of the artery. Care was taken to maintain the guiding catheter and sensor in position throughout all measurements. The sensor was used to obtain thermodilution curves and distal coronary pressure. The resting mean transit time was determined by 3 injections of 3 ml room-temperature saline. Hyperemia was induced by i.v. infusion of adenosine (140 \( \mu g \cdot kg^{-1} \cdot min^{-1} \)). Steady-state maximum hyperemia was confirmed by minor drop of the aortic pressure and subjective sensation of adenosine effects. Measurements were obtained after at least 1 min from the onset of infusion. The hyperemic mean transit time was assessed using 3 injections of 3 ml room-temperature saline. In the case of large fluctuation (>20% variation) of hyperemic or basal coronary pressure, measurement was repeated. CFR was calculated as a ratio of baseline to hyperemic mean transit time. Simultaneous measurement of the mean aortic pressure (Pa) and the mean distal coronary pressure (Pd) were also performed at maximum hyperemia to calculate FFR. IMR was calculated as the distal coronary pressure at maximum hyperemia divided by the inverse of the hyperemic mean transit time.

Statistical Analysis

The primary endpoint was the percent of uncovered struts in BP-SES compared with DP-ZES at 3-month follow-up. Sample size was calculated using 2 methods. We assumed that an average of 150 struts per patient would be analyzed, and therefore we estimated that inclusion of 22 patients in each group would show 5% difference in the percent uncovered struts between BP-SES and DP-ZES (power of 80%, 2-sided type I error of 0.05). We also calculated a sample size of 22 patients/
formed using a random effects model (DerSimonian-Laird). Meta-regression was used to estimate the difference between the study groups. All statistical analysis was 2-sided at the 5% significance level using SPSS v. 16.0.1 (SPSS, Chicago, IL, USA) and Open Meta-analyst (http://www.cebm.brown.edu/open_meta).

**Results**

**Baseline Characteristics**

Forty-six non-diabetic patients with ACS were enrolled: 23 received BP-SES, and 23 received DP-ZES. Two patients withdrew consent (1 in each group), thus 22 patients in either group were available for analysis. Angiography was performed at median follow-up of 93 days (IQR, 23 days) following the index procedure in the BP-SES group, vs. 98 days (IQR, 20 days) in
Table 2. Optical Coherence Tomography

<table>
<thead>
<tr>
<th>Variable</th>
<th>BP-SES group (n=22)</th>
<th>DP-ZES group (n=22)</th>
<th>P-value</th>
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<tr>
<td>Cross-sectional analysis</td>
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<td></td>
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<td>No. cross-sections analyzed</td>
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<td>425</td>
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<td>Struts per cross-section</td>
<td>11.5±0.66</td>
<td>12.9±1.2</td>
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<td>Stent area (mm²)</td>
<td>6.8±1.6</td>
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<td>Lumen area (mm²)</td>
<td>6.5 [2.2]</td>
<td>7.1 [2.6]</td>
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<td>NIH area (μm²)</td>
<td>380 [410]</td>
<td>460 [550]</td>
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<tr>
<td>% NIH area</td>
<td>5.7 [5.9]</td>
<td>5.7 [7.6]</td>
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<tr>
<td>Strut-level analysis</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Total no. struts analyzed</td>
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<td>5,467</td>
<td>0.13</td>
</tr>
<tr>
<td>NIH thickness (μm)</td>
<td>69.1±58.2</td>
<td>76.5±82.9</td>
<td>0.15</td>
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<tr>
<td>Uncovered struts</td>
<td>189 (3.9)</td>
<td>495 (8.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Malapposed struts</td>
<td>101 (2.1)</td>
<td>292 (5.3)</td>
<td>&lt;0.001</td>
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<td>Stent-level analysis</td>
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<tr>
<td>% Uncovered struts</td>
<td>3.9±3.2</td>
<td>8.9±6.9</td>
<td>0.019</td>
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<tr>
<td>Stents with &gt;5% uncovered struts</td>
<td>7 (31.8)</td>
<td>14 (63.6)</td>
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<tr>
<td>% Malapposed struts</td>
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<tr>
<td>Intra-stent thrombus</td>
<td>2 (9.1)</td>
<td>1 (4.5)</td>
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</table>

Data given as mean±SD, median [IQR], or n (%). NIH, neointimal hyperplasia. Other abbreviations as in Table 1.

Figure 2. Evaluation of the study stents on optical coherence tomography at 3-month follow-up. (A,B) stent struts well covered with neointima (arrows). (C,D) uncovered struts.
the DP-ZES group (P=0.65). Clinical and procedural characteristics (Table 1) were balanced between the 2 groups (P<0.05 for all), apart from occurrence of post-dilation: 9 (40.9%) vs. 18 (78.3%) in BP-SES and DP-ZES, respectively (P=0.016). Culprit lesion-related thrombus was seen initially in 12 (54.5%) vs. 6 (27.3%), in the BP-SES vs. DP-ZES groups, respectively (P=0.11).

**OCT Measurements**

OCT image acquisition was successful in all patients, and no OCT procedure-related complications were observed. We analyzed 4,897 struts in 425 cross-sections of BP-SES and 5,467 struts in 425 cross-sections of DP-ZES (Table 2). The percent of uncovered struts was significantly lower in the BP-SES compared with the DP-ZES group, both at strut level (3.9% vs. 8.9%, respectively, P<0.001), and at stent level (3.9±2.3% vs. 8.9±6.9%, respectively, P=0.019; Figure 2). Moreover, the frequency of malapposed struts was significantly lower in the BP-SES group at strut level (2.1% vs. 5.3%, respectively, P<0.001), but not at stent level (2.2±3.7% vs. 4.3±9.5%, respectively, P=0.33). Mean NIH thickness, NIH area, and percent NIH area, however, were similar between the 2 groups (P>0.05 for all). Thrombi were detected in 2 stents in the BP-SES group vs. 1 stent in the DP-ZES group (P=1.0). Inter-observer variability for measurement of NIH thickness was 6±9 μm. In addition, the measurements of strut apposition and coverage were highly reproducible.

Pooled analysis showed that the proportion of uncovered struts in the overall series was 5.6% (95% CI: 4.6–6.6%), with significant heterogeneity between the evaluated struts (I²=93%). The pooled proportion of uncovered struts was 3.3% (95% CI: 2.3–4.2%, I²=82%) for BP-SES, and 8.2% (95% CI: 6.4–9.9%, I²=95%) for DP-ZES (P<0.001). The pooled proportion of malapposed struts was 1.5% (95% CI: 0.9–2.0%, I²=82%) for BP-SES, and 2.5% (95% CI: 1.7–3.3%, I²=95%) for DP-ZES, (P=0.479). The pooled mean NIH thickness was 68.2 μm (95% CI: 59.6–76.9, I²=98%) for BP-SES, and 74.2 μm (95% CI: 62.7–85.7, I²=98%) for DP-ZES, (P=0.465).

**Discussion**

The current HATTRICK-OCT trial has shown that in non-diabetic patients presenting with ACS, the percent of uncovered stent struts on OCT was slightly lower for BP-SES compared with DP-ZES at 3-month follow-up. Neither of the stents, however, was fully covered at 3 month follow-up. Vasodilator response assessed using CFR, FFR and IMR was similar between the 2 groups.

This is the first study to use a combination of OCT-derived anatomical as well as pressure wire-based functional healing assessment after stent implantation. Rationale for the early 3-month time frame was to gather up-to-date information on newer generation DES healing properties in patients treated for ACS; a condition often associated with delayed healing pattern. This information is important especially when shorter dual antiplatelet therapy (DAPT) needs to be considered for patients at high risk for bleeding complications. HATTRICK-OCT provides evidence that vascular healing was not complete at 3 months follow-up with these new-generation stent devices, as evidenced by the minor proportion of uncovered stent struts and abnormal vasodilator function in some patients. It is currently not known what would be the sufficient OCT-derived level of strut coverage (and lack of malapposition) to be able to safely discontinue DAPT without risk of ST. Nevertheless, recent clinical data suggest that patients who interrupt or discontinue DAPT medication between 1 and 12 months after DP-ZES implantation are considered at low risk and showed no increased risk for ST compared with those on continuous DAPT until 12 months. On this basis, it seems that BP-SES could have at least as low or lower ST risk compared with DP-ZES, but this needs to be verified in prospective clinical trial.

**BP-SES: Clinical Perspective**

Previously, SES demonstrated evidence of greater efficacy for reduction of restenosis and late lumen loss (LLL), compared with other first-generation DES. In one of the early attempts to use BP-SES, TIVOLI stent (Essen Technology, Beijing, China) was compared with a DP-ZES (Endeavor Medtronic Cardiovascular, USA) in a non-randomized fashion. In-stent LLL and binary restenosis at 8-month follow-up were significantly lower with the BP-SES compared with the DP-ZES; at 2-year follow-up, target lesion revascularization was significantly lower with the BP-SES. Another non-randomized study showed similar in-stent LLL in patients who received BP-SES (EXCELL M; JW Medical, Shandong, China) and DP-SES (0.14 vs. 0.12 mm, respectively, P=0.629) at 9-month follow-up. An angioscopy study on DP-ZES reported struts fully embedded in neointima at 4 months. A first-in-man report of a novel BP-SES with L-605 cobalt-chromium stent platform (FIREFAWK; MicroPort Medical, Shanghai, China) implanted in single de novo coronary lesions demonstrated an in-stent LLL of 0.13 mm at 4-month follow-up. And, similar to the present study, on OCT at 4 months, a frequency of uncovered struts of 3.8% was noted (3.9% in the present study), but the prevalence of malapposed struts was much lower (0.1% vs. 2.6% in the present study). The exclusive enrolment of patients with ACS in the present study may partly explain the...
higher prevalence of malapposed struts at a similar time point. The frequent use of balloon post-dilation in that study (52.4%) does not account for the difference in malapposition, because the rates of post-dilation in the present study were 40.9% and 78.3% between BP-SES and DP-ZES, respectively. Interestingly, malapposition was more frequent in DP-ZES, despite a higher rate of post-dilation. The malapposition at 3 months might be explained by positive remodelling of the vessel wall as a response to the drug polymer in DP-ZES, which is also supported by the statistically insignificant trend towards larger lumen CSA in DP-ZES despite equal baseline lumen diameters. Unfortunately, the absence of baseline OCT assessment limits the discrimination between persistent acute malapposition and late acquired malapposition. Finally, the BIOFLOW-I was a first-in-man study evaluating the efficacy and safety of the Orsiro BP-SES in 30 patients with single de novo native coronary lesions.26 Angiographic in-stent LLL was 0.05±0.22 mm at 9-month follow-up; at 12 months, the cumulative incidence of device-oriented major adverse cardiovascular events was 10%; no ST was observed. The current study in non-diabetic patients with ACS demonstrated better OCT-detected neointimal strut coverage associated with the Orsiro BP-SES compared with DP-ZES at 3 months.

Vasodilator Function

Impaired vasodilator response has been reported after DES implantation using i.e. acetylcholine infusion, rapid atrial pacing, physical exercise, and adenosine, as vasodilator stimuli.8,27 CFR was adopted as an indicator of functional healing because it was recently shown to predict outcome when added to standard evaluation, in unselected patient populations, as well as in patients with ACS.14,28,29 We used a coronary pressure wire (Curtus®) for the functional healing assessment because it allows simultaneous measurement of CFR, IMR and FFR. Where as FFR measures the pressure drop across an epicardial vessel and IMR the vasodilator capacity of the microcirculation, CFR reflects coronary flow through both the epicardial arteries and the microcirculation. Reduced CFR can be due to either stenosis in epicardial arteries or combined dysfunction of the coronary microcirculation and vascular endothelium.30 Previously, lower CFR was detected in patients with DP-SES compared with titanium-nitride-oxide-coated stents at 10-month follow-up, indicating persistent vasodilator dysfunction after DES implantation.14 In the HATTRICK-OCT study, we found no differences between the 2 stent groups regarding CFR, IMR and FFR. Nevertheless, the proportion of patients with abnormal CFR <2.5 was 44.4% vs. 12.5% for the BP-SES vs. DP-ZES groups, respectively (P<0.06). The high rates may imply that the vasodilator function had not recovered completely with either stent, although significant difference between the stent groups was not seen. The higher occurrence of culprit lesion thrombus and aspiration thrombectomy in BP-SES as a factor predisposing to distal embolization is another possible cause of impaired CFR at 3 months. Whether this translates into adverse clinical outcome remains to be addressed in larger prospective studies.

Study Limitations

The current trial had a relatively small sample size, and therefore its results should be interpreted with caution. Moreover, the current OCT technology cannot detect tissue coverage <10 μm and thus, cannot identify very thin layers of endothelial coverage. Additionally, the absence of baseline OCT and vasodilator response data immediately after the index procedure prevents comprehensive interpretation of data. It cannot be confirmed whether malapposed struts are due to persistent acute or late acquired malaposition. The fact that no independent core lab was involved in data analysis is another potential limitation.

Finally, the trial was underpowered to correlate clinical endpoints with OCT findings, and decision on the length of DAPT cannot be made based on these OCT results only. Therefore, larger prospective studies are needed.

Conclusions

In non-diabetic patients with ACS, neither of these newer generation stent devices was fully covered at 3 months follow-up. The percent of uncovered stent struts on OCT was lower for BP-SES compared with DP-ZES at 3-month follow-up, but CFR and IMR were similar between the groups.

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Disclosures

Conflicts of Interest: This study was supported by a scholarship for research within the area of ACS from the Finnish Cardiac Society (T.K.); by grants from the Finnish Fishman Foundation for Cardiovascular Research, Helsinki, Finland (T.K., J.K.E.A.); and by Turku University Hospital Research Foundation. The authors report no other relationships that could be construed as a conflict of interest.

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