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# Paclitaxel-Coated Balloon Angioplasty Versus Drug-Eluting Stent in Acute Myocardial Infarction

## The REVELATION Randomized Trial

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**ABSTRACT**

**OBJECTIVES** This study sought to assess the efficacy and safety of a drug-coated balloon (DCB) strategy versus drug-eluting stent (DES) in primary percutaneous coronary intervention for ST-segment elevation myocardial infarction (STEMI).

**BACKGROUND** In primary percutaneous coronary intervention for STEMI, stenting has proved to be beneficial with regard to repeat revascularization, but not recurrent myocardial infarction or death, compared with balloon angioplasty alone. A strategy of DCB angioplasty without stenting might abolish the potential disadvantages of stent implantation while reducing the probability of restenosis observed in plain old balloon angioplasty.

**METHODS** In the prospective, randomized, single-center REVELATION trial, we compared DCB with DES in patients presenting with STEMI. Patients with a new, nonseverely calcified culprit lesion in a native coronary artery and a residual stenosis of <50% after pre-dilatation were randomized to treatment with a DCB or DES. The primary endpoint was fractional flow reserve at 9 months, allowing for a functional measurement of the infarct-related lesion.

**RESULTS** A total of 120 patients were included. At 9 months after enrolment, the mean fractional flow reserve value was 0.92 ± 0.05 in the DCB group (n = 35) and 0.91 ± 0.06 in the DES group (n = 38) (p = 0.27). One abrupt vessel closure requiring treatment occurred after treatment with DCB. Up to 9-months follow-up, 2 patients required nonurgent target lesion revascularization (1 in each group).

**CONCLUSIONS** In the setting of STEMI, the DCB strategy was noninferior to DES in terms of fractional flow reserve assessed at 9 months. Furthermore, it seemed to be a safe and feasible strategy. (Revascularization With Paclitaxel-Coated Balloon Angioplasty Versus Drug-Eluting Stenting in Acute Myocardial Infarction [REVELATION]; NCT02219802) (J Am Coll Cardiol Intv 2019;■:■-■) © 2019 by the American College of Cardiology Foundation.

Primary percutaneous coronary intervention (PPCI) is the preferred reperfusion strategy for ST-segment elevation myocardial infarction (STEMI) (1). Stenting has proved to reduce the need for repeat revascularization compared with plain old balloon angioplasty (POBA) alone (2). However, routine stenting did not imply a reduction in the incidence of cardiac death or recurrent myocardial infarction (MI) (2). Additionally, permanent vascular implants lead to an increased risk of (late) stent thrombosis and impaired vasomotor function of the culprit coronary artery (3-5). Especially in the subset of STEMI, such factors as incomplete stent apposition and delayed tissue coverage are more frequently observed thereby increasing the long-term risk of stent-related events (6-8).

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**ABBREVIATIONS AND ACRONYMS**

**DAPT** = dual antiplatelet therapy

**DCB** = drug-coated balloon

**DES** = drug-eluting stent

**FFR** = fractional flow reserve

**LLL** = late luminal loss

**MI** = myocardial infarction

**POBA** = plain old balloon angioplasty

**PPCI** = primary percutaneous coronary intervention

**QCA** = quantitative coronary analysis

**STEMI** = ST-segment elevation myocardial infarction

**TLR** = target lesion revascularization

Considering the absence of superiority with regard to hard clinical endpoints and the potential short- and long-term disadvantages of stent implantation, angioplasty with a drug-coated balloon (DCB) may well serve as a therapeutic strategy of choice in STEMI if coronary flow is restored and no significant stenosis persists after balloon dilatation. A DCB strategy may be favorable because it provides a homogeneous distribution of the antiproliferative drug and a subsequent reduction in endothelial inflammation while it maintains the coronary vasomotor response and vessel geometry with proven positive remodeling (9-12).

The need for prolonged dual antiplatelet therapy (DAPT) after drug-eluting stent (DES) implantation for specific patient subsets (e.g., high bleeding risk, STEMI) is discussed extensively nowadays (13,14). Additionally, a strategy of genuinely leaving no implant behind might abate the need for prolonged DAPT even further.

A DCB strategy has already been shown to be safe and efficacious as treatment for in-stent restenosis and small vessel disease (15-17). Only a few, predominantly nonrandomized studies have evaluated a DCB strategy in the setting of STEMI (18-21). Our aim in the REVascularization With PaclitaxEL-Coated Balloon Angioplasty Versus Drug-Eluting Stenting in Acute Myocardial InfarcTION (REVELATION) trial was to assess the efficacy and safety of DCB versus DES in STEMI in a prospective, randomized fashion including angiographic and long-term clinical follow-up.

## METHODS

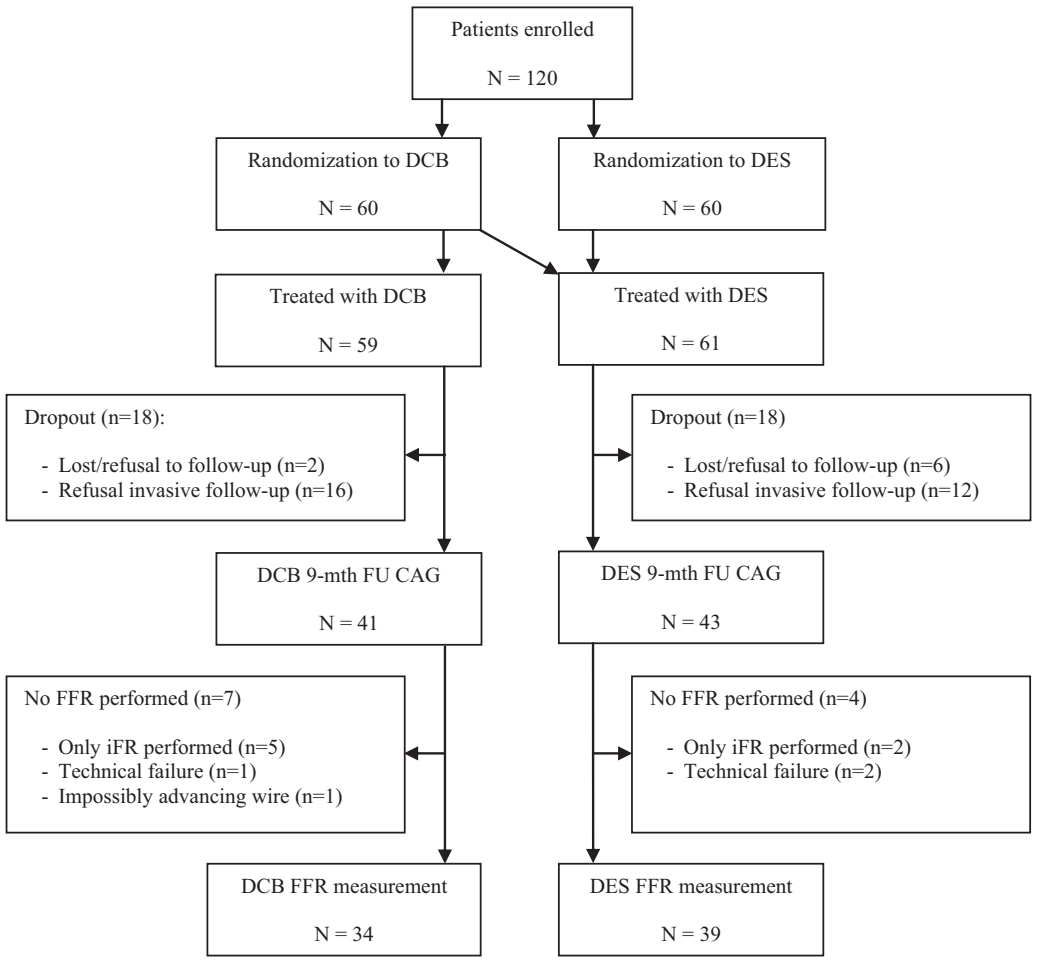
**STUDY DESIGN.** The design and methods of the REVELATION trial have been published previously (22). Briefly, it is a prospective, randomized controlled trial performed in the Onze Lieve Vrouwe Gasthuis in Amsterdam in which we assess the safety and efficacy of DCB angioplasty in STEMI. All patients gave written informed consent. The study is approved by the medical ethics committee "Verenigde commissies mensgebonden onderzoek" (Nieuwegein, the Netherlands) and the institutional review board of the Onze Lieve Vrouwe Gasthuis, and is registered at ClinicalTrials.gov (NCT02219802).

**STUDY POPULATION.** Patients presenting with a STEMI intended for PPCI were screened. A new culprit lesion in a native coronary artery was suitable for randomization in the absence of severe calcification and if residual stenosis was ≤50% (by visual assessment) after thrombus aspiration (in case of visible thrombus) and mandatory pre-dilatation. Although in large trials the use of routine thrombus aspiration did not affect mortality (23), this may be more valuable in a DCB strategy because of the importance of optimal lesion preparation before DCB usage and the need for homogeneous delivery of paclitaxel. Patients with a history of MI, stent implantation <1 month, contraindications for DAPT or anticoagulation therapy, and cardiogenic shock or intubation before randomization were excluded.

**STUDY PROCEDURE.** Allocation to treatment was done in a 1:1 fashion to either treatment with DCB (Pantera Lux, Biotronik, Berlin, Germany) or DES (Orsiro, Biotronik; or Xience, Abbott, Abbott Park, Illinois). Bailout stenting with a bare-metal stent was advised only in case of residual stenosis of the treated lesion >50% (by visual assessment) after balloon dilatations with sufficiently large balloons, or coronary dissection greater than or equal to type C leading to (threatening) vessel closure. All patients were treated according to current STEMI guidelines of the European Society of Cardiology (24). They received 1-year DAPT because of STEMI, and periprocedural bivalirudin. Coronary revascularization was performed according to the European Society of Cardiology guidelines "Myocardial revascularization" (25). A successful PPCI was defined as a diameter stenosis <30% (by visual estimation) and TIMI flow grade ≥2 for DCB angioplasty, and a diameter stenosis <20% and TIMI flow grade ≥2 for stent use.

**ENDPOINTS.** The primary endpoint of the study is the functional assessment of the infarct-related lesion by fractional flow reserve (FFR) at 9-months follow-up. It is difficult to identify lesions causing myocardial ischemia solely by coronary angiography and off-line quantitative coronary analysis (QCA) (26,27). FFR, an index of the functional severity of a lesion, is an independent and powerful predictor of the risk of future cardiac events (28-33). An immediate post-stent FFR value of ≥0.90 has been associated with low adverse event rates at follow-up, whereas an FFR value <0.85 has shown to result in increased event rates (32,33). Therefore, we accepted an FFR margin of ≤0.05 for DCB compared with DES at follow-up as noninferior. Unfortunately, this endpoint description in the design article is somewhat unclear. The angiographic secondary endpoint is late luminal loss (LLL) measured by QCA. Clinical secondary endpoints contain major adverse cardiac events, the occurrence of stent thrombosis, and major bleeding.

**FIGURE 1** Flow Chart Primary Endpoint




Flow chart of included patients who underwent fractional flow reserve measurement at 9-months follow-up. CAG = coronary angiogram; DCB = drug-coated balloon; DES = drug-eluting stent; FFR = fractional flow reserve; iFR = instantaneous wave-free ratio.

**FOLLOW-UP.** Besides clinical follow-up during the index hospitalization and at 9 months, patients were contacted by telephone at 1 month, and yearly up to 5 years after randomization.

**STATISTICAL ANALYSIS.** The study was designed to assess noninferiority of the primary endpoint at 9-months follow-up. The sample size calculation and power analysis were published before (22). The primary endpoint was evaluated using a 2-sample Student's *t*-test with a 1-sided p value <0.025. The margin of noninferiority was ≤0.05. A 2-sided $p < 0.05$ was considered to be significant for all other studied variables. Continuous variables are presented as mean ± SD in case of normal distribution or as median values with interquartile range if not normally distributed. Categorical variables are presented as proportions and percentages. Categorical outcomes were compared with chi-square or Fisher exact test. Continuous variables were compared by the independent *t* test or Mann-Whitney *U* test. All analyses were performed according to the intention-to-treat principle. The as-treated analysis is added in Online Tables 1 to 3. Data processing and statistical analysis were performed using the SPSS Statistics version 22.0 (IBM Corp., Armonk, New York).

## RESULTS

Between October 2014 and November 2017, a total of 120 eligible patients were assigned to receive a DCB (n = 60) or a DES (n = 60) (**Figure 1**). There was crossover of 1 patient from DCB to DES because of

**TABLE 1 Baseline Characteristics**

| | DCB (n = 60) | DES (n = 60) | p Value |
|---|---|---|---|
| Age, yrs | 57.4 ± 9.2 | 57.3 ± 8.3 | 0.92 |
| Male | 52 (87) | 52 (87) | 1.00 |
| Hypertension | 18 (30) | 19 (32) | 0.84 |
| Diabetes mellitus | 8 (13) | 4 (7) | 0.22 |
| Hypercholesterolemia | 10 (17) | 8 (13) | 0.61 |
| Body mass index, kg/m$^2$ | 26.7 ± 3.5 | 27.4 ± 4.4 | 0.37 |
| Cigarette smoking | | | 0.53 |
| Current smoker | 28 (47) | 24 (40) | |
| History of smoking | 8 (13) | 6 (10) | |
| Peripheral arterial disease | 1 (2) | 0 (0) | 1.00* |
| Family history CVD | 19 (32) | 25 (42) | 0.26 |
| Previous PCI | 2 (3) | 0 (0) | 0.50* |
| Previous CABG | 0 (0) | 0 (0) | 1.00 |
| History of angina pectoris | 8 (13) | 7 (12) | 0.87 |

Values are mean ± SD or n (%). *Fisher exact test.

CABG = coronary artery bypass graft; CVD = cardiovascular disease; DCB = drug-coated balloon; DES = drug-eluting stent; PCI = percutaneous coronary intervention.

**TABLE 2 Procedural Characteristics**

| | DCB (n = 60) | DES (n = 60) | p Value |
|---|---|---|---|
| DAPT loading dose | 60 (100) | 60 (100) | 1.00 |
| P2Y12 inhibitor | | | 0.70 |
| Prasugrel | 4 (7) | 3 (5) | |
| Ticagrelor | 56 (93) | 57 (95) | |
| Radial approach | 59 (98) | 60 (100) | 0.32 |
| Amount of diseased vessels | | | 0.91 |
| 1-VD | 44 (73) | 42 (70) | |
| 2-VD | 12 (20) | 14 (23) | |
| 3-VD | 4 (6.7) | 4 (6.7) | |
| Infarct-related artery | | | 0.50 |
| RCA | 29 (48) | 28 (47) | |
| LAD | 19 (32) | 24 (40) | |
| RCx | 12 (20) | 8 (13) | |
| TIMI flow grade pre-procedure | | | 0.53 |
| 0 | 30 (50) | 30 (50) | |
| 1 | 5 (8) | 3 (5) | |
| 2 | 6 (10) | 11 (18) | |
| 3 | 19 (32) | 16 (27) | |
| Thrombosuction performed | 47 (78) | 50 (83) | 0.49 |
| Predilatation performed | 60 (100) | 57 (95) | 0.08 |
| Pressure predilatation, atm | 13.2 ± 3.0 | 12.6 ± 2.5 | 0.28 |
| DCB | | – | – |
| Only | 49 (82) | | |
| Additional stenting | 11 (18) | | |
| DCB | | – | – |
| Average pressure, atm | 10.2 ± 2.7 | | |
| Inflation time, s | 64 ± 15 | | |
| Postdilatation performed | 11 (18) | 15 (25) | 0.14 |
| Pressure postdilatation, atm | 12.6 ± 2.8 | 15.1 ± 5.2 | 0.24 |
| TIMI flow grade post-procedure | | | |
| 0 | 0 (0) | 0 (0) | 0.32 |
| 1 | 0 (0) | 0 (0) | |
| 2 | 1 (2) | 0 (0) | |
| 3 | 59 (98) | 60 (100) | |
| Time to first medical contact, min | 60 (26–120) | 60 (30–120) | 0.54 |
| Time to balloon, min | 125 (90–210) | 128 (90–210) | 0.90 |
| ST-segment resolution (90–120 min), % | | | 0.20 |
| <30 | 3 (5) | 0 (0) | |
| 30–70 | 16 (27) | 15 (25) | |
| >70 | 41 (68) | 45 (75) | |

Values are n (%) or mean ± SD.

DAPT = dual antiplatelet therapy; LAD = left anterior descending artery; RCA = right coronary artery; RCx = ramus circumflexus artery; TIMI = thrombolysis in myocardial infarction; VD = vessel disease; other abbreviations as in Table 1.

unavailability (in stock) of an appropriately sized DCB.

**BASELINE AND PROCEDURAL CHARACTERISTICS.** The baseline characteristics of the study participants did not significantly differ between the 2 groups (Table 1). The mean age was 57.4 years and 87% of the patients were men. There were no differences in angiographic features and procedural data between the studied groups (Table 2). Most patients had 1-vessel disease (72%). The infarct-related vessel was the right coronary artery in 48% of the patients. The radial approach was used in 119 patients (99%). A loading dose of DAPT was administered in all patients before immediate coronary angiogram. In all patients treated with a DCB pre-dilatation was performed. Bailout stenting was necessary in 11 out of 60 DCB patients (18%) because of residual stenosis of >50% (2 cases), coronary artery dissection greater than or equal to type C (8 cases), and crossover to DES treatment (1 case). Procedural success was achieved in all patients. No periprocedural serious adverse events were reported.

**PHYSIOLOGIC AND ANGIOGRAPHIC FOLLOW-UP AT 9 MONTHS.** A control coronary angiogram was performed in 84 patients (Figure 1). Unfortunately, FFR was not measured in 11 patients. As shown in Table 3 and in the Central Illustration, the mean FFR at 9-months follow-up of patients assigned to treatment with a DCB (n = 35) was 0.92 ± 0.05, and in patients treated with DES (n = 38) 0.91 ± 0.06. The mean difference was 0.008, with a standard error difference of 0.012 (95% confidence interval: −0.018 to 0.032; 1-sided p = 0.27) (Figure 2). The FFR was normally distributed. Consequently, noninferiority of DCB compared with DES was established.

The results of QCA are presented in Table 3. In contrast to the reference vessel diameter and minimum lumen diameters, the LLL was not normally distributed. As shown in Table 3 and Figure 3, the LLL at 9-months follow-up was 0.05 mm (interquartile range: −0.40 to 0.20) in the DCB group, whereas in

the DES group it was 0.00 mm (interquartile range: −0.16 to 0.10) (p = 0.51).

**CLINICAL FOLLOW-UP AT 9 MONTHS.** At 9-months follow-up, no deaths were reported. Clinical follow-up regarding recurrent MI and target lesion revascularization (TLR) was available for 112 out of 120 patients (Table 3). One patient initially treated with DCB had an abrupt vessel closure within 2 h after the index procedure and was treated with a DES. One patient initially treated with DCB had a coronary dissection type D after the index procedure; however, bailout stenting was not performed. Because of anginal complaints and persisting dissection, he underwent a TLR at 9-months follow-up coronary angiogram. One patient initially treated with a DES underwent TLR because of in-stent restenosis 4 months after the index procedure. No major bleedings were reported. The mean left ventricular ejection fraction at 9 months was 57.1 ± 6.2% in the DCB group and 58.4 ± 7.1% in the DES group (p = 0.38). Medication compliance was high in both groups (Table 3). All patients were on DAPT and/or combined with oral anticoagulation.

**TABLE 3 Physiologic, Angiographic, and Clinical Follow-Up at 9 Months**

| | DCB | DES | p Value |
|---|---|---|---|
| Physiologic endpoint | (n = 35) | (n = 38) | |
| Fractional flow reserve | 0.92 ± 0.05 | 0.91 ± 0.06 | 0.27 |
| Angiographic endpoint | (n = 42) | (n = 42) | |
| Late luminal loss, mm | 0.05 (−0.40 to 0.20) | 0.00 (−0.16 to 0.10) | 0.51 |
| Reference vessel diameter, mm | 3.28 ± 0.52 | 3.20 ± 0.48 | 0.35 |
| Minimum lumen diameter post index procedure, mm | 2.64 ± 0.42 | 2.88 ± 0.41 | <0.01 |
| Minimum lumen diameter at 9-months follow-up, mm | 2.67 ± 0.68 | 2.86 ± 0.44 | 0.12 |
| Clinical endpoints | | | |
| MACE | | | 1.00* |
| Cardiac death | 0/60 (0) | 0/60 (0) | |
| Recurrent MI | 0/58 (0) | 0/54 (0) | |
| TLR | 2/58 (3) | 1/54 (2) | |
| LVEF, %† | 57.1 ± 6.2 | 58.4 ± 7.1 | 0.38 |
| Medication use | N = 58 | N = 54 | |
| DAPT and/or OAC | 58 (100) | 54 (100) | 1.00 |
| Beta-blocker | 46 (79) | 37 (69) | 0.19 |
| Statin | 56 (97) | 49 (91) | 0.20 |
| ACE inhibitor or ARB | 50 (86) | 45 (83) | 0.67 |

Values are mean ± SD, median (interquartile range), or n (%). *Fisher exact test. †DCB, n = 45; DES, n = 46.
ACE = angiotensin-converting enzyme inhibitor; ARB = angiotensin II receptor blocker; LVEF = left ventricular ejection fraction; MACE = major adverse cardiac event; MI = myocardial infarction; OAC = oral anticoagulant therapy; TLR = target lesion revascularization; other abbreviations as in Tables 1 and 2.

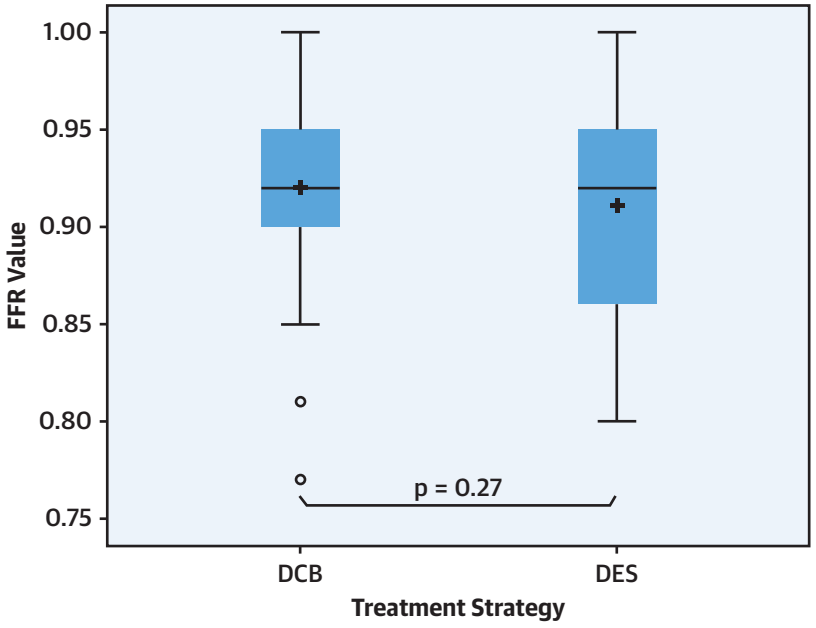
## DISCUSSION

To our knowledge this is the first prospective, randomized controlled trial comparing a DCB strategy with stenting in STEMI using a physiologic endpoint. The REVELATION trial showed noninferiority of DCB compared with DES regarding the primary endpoint of FFR at 9-months follow-up. In addition, there was no significant difference in LLL, and although adverse event rates were low, both treatment groups had comparable clinical outcomes at 9-months follow-up. Bailout stenting was performed in 18% of DCB patients. It is important to emphasize these results were achieved in a highly selected study population, because inclusion was largely determined by successful culprit lesion preparation.

The use of POBA in STEMI was abandoned because it was associated with recurrent ischemia, restenosis, and reocclusion of the target lesion (3,34). Treatment with stents significantly reduced the amount of TLR. However, this advantage was not seen in terms of mortality and recurrent MI, mainly because of stent-related complications, such as (very late) stent thrombosis (3–8). A DCB strategy has the potential to prevent the drawbacks of POBA without the disadvantages of stent implantation. To benefit the most from DCB, adequate lesion preparation is essential to maximize the balloon contact area to vessel wall (11,12). In our study, thrombus aspiration in case of visible thrombus and pre-dilatation were performed in all patients treated with a DCB. Sufficient application of a DCB allows a homogeneous and rapid distribution of highly lipophilic paclitaxel into the vessel wall to sustain an antiproliferative effect. In our study, mean inflation time of DCB was 64 ± 15 s as recommended in published data (35).

So far, a DCB strategy in STEMI was only evaluated in terms of clinical outcomes and angiographic results by visual assessment and/or QCA (18–21). The question arises whether angiographic assessment of the infarct-related lesion is the correct endpoint when comparing a balloon with stent strategy (36). Studies about POBA versus bare-metal stent already showed beneficial angiographic effects of stent implantation with greater increase in luminal diameter immediately after the procedure, and better minimum lumen diameter during follow-up (37,38). As with POBA, DCB does not counteract acute passive elastic vessel recoil, resulting in less optimal (initial) angiographic results. In addition, there is a growing awareness of the poor accuracy of coronary angiography and QCA for identifying lesions responsible for myocardial ischemia, in new and post-interventional lesions. Importantly, only ischemia-causing lesions are associated with poorer functional status and worse clinical outcomes (39,40). FFR is an invasively determined index of the functional severity of a coronary stenosis during hyperemia, irrespective of local previous treatments. A reduced FFR is an

**CENTRAL ILLUSTRATION** **Primary Endpoint: FFR Value at 9-Months Follow-Up**

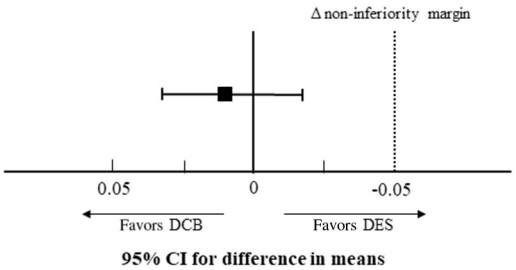



**Vos, N.S. et al. J Am Coll Cardiol Intv. 2019;■(■):■–■.**

Boxplot of fractional flow reserve value for drug-coated balloon versus drug-eluting stent strategy in ST-segment elevation myocardial infarction. The distribution of data is displayed by 5 lines (bottom to top: minimum, first quartile, median, third quartile, and maximum), **cross** (mean), and **circle** (outlier). DCB = drug-coated balloon; DES = drug-eluting stent; FFR = fractional flow reserve.

independent and powerful predictor of future cardiac event risk (32,33). However, because FFR measurement requires maximal hyperemia, it is dependent of microvascular resistance. In case of scar tissue, this resistance is increased. Therefore, in a given stenosis the FFR is dependent on the amount of viable myocardium (41). Although we did not quantify the amount of scar, the left ventricular ejection fraction was normal at 9-months follow-up, indicating little scar. Therefore, we believe that in our study the use of FFR for efficacy is accurate. At 9-months follow-up, we found a comparable FFR value in both groups. These values are associated with low adverse event rates and good prognosis (29-33).

**FIGURE 2** **Mean Difference of FFR Between DCB and DES Groups at 9-Months Follow-Up**




Mean difference of fractional flow reserve between drug-coated balloon and drug-eluting stent groups at 9-months follow-up with corresponding 95% confidence interval and margin of noninferiority. CI = confidence interval; other abbreviations as in Figure 1.

In acute MI, the coronary vasodilator response is severely impaired with deviating vessel geometry, resulting in high risks of incomplete stent apposition (42). Several studies have shown positive coronary remodeling after DCB, confirming the advantage of DCB in terms of maintenance of coronary vasomotor response and vessel geometry (9,10,43). Our study did not confirm these results. LLL calculated at 9-months follow-up was 0.05 mm (interquartile range: −0.40 to 0.20) in the DCB group versus 0.00 mm (interquartile range: −0.16 to 0.10) in the DES group (p = 0.51). Although these results do not show signs of positive remodeling in the DCB group, the LLL in both groups is extremely low compared with other compatible studies (20,21). Despite a nonsignificant higher reference vessel diameter in the DCB group, the minimum lumen diameter after PPCI is significantly lower in patients treated with DCB

versus DES, as could be determined by the treatment allocation itself (38).

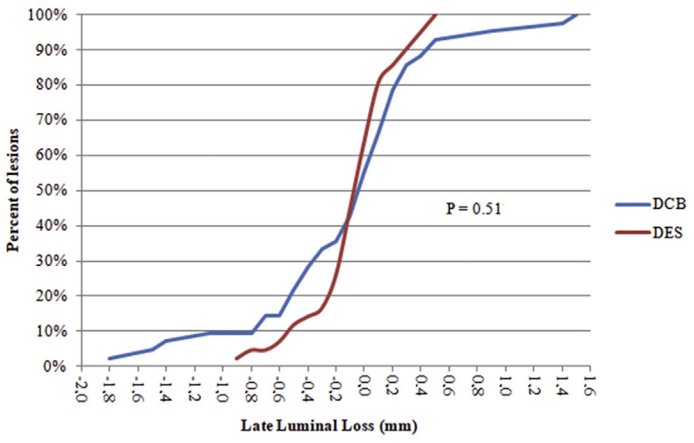
The incidence of bailout stenting in our study was 18%, mainly because of coronary artery dissection type greater than or equal to C. Iatrogenic coronary dissection occurs inevitably as a result of balloon angioplasty, especially in case of a balloon-to-artery ratio >1:1 (44,45). It is possible that the relatively high rate of coronary dissections, and related bailout stenting, was the consequence of slightly oversizing the balloons both for pre-dilatation (13.2 ± 3.0 atm) and drug delivery (10.2 ± 2.7 atm) in the DCB group.

Although our study was not powered to detect differences in the occurrence of clinical endpoints, our results showed no differences in major adverse cardiac events up to 9-months follow-up. Additionally, just 1 thrombotic event occurred in the DCB group and no major bleedings were reported.

A strategy of "truly leaving nothing behind" by DCB angioplasty may allow the restoration of normal coronary physiology and enable positive remodeling of the vessel, while leaving all percutaneous and surgical treatment options open. The bioresorbable vascular scaffolds were designed to provide transient mechanical support and drug delivery similar to DES, followed by complete resorption over several years to prevent long-term problems associated with polymers and metallic scaffolds. First-generation bioresorbable vascular scaffolds failed in terms of occurrence of stent thrombosis and restenosis, and still there is doubt about the real vessel functionality restoration and bioresorbability at long-term observation (46-48). Recently published short-term results of the ISAR-Absorb MI and TROFI-II trial are encouraging. However, long-term results are needed to draw definite conclusions (49,50). Therefore, a strategy of DCB remains of great interest. Especially in lesions underlying STEMI, which are mostly focal, soft, noncalcified lesions with occlusion caused by erosion or rupture of a nonsignificant plaque in large vessel segments. On average, STEMI patients are younger than patients with stable coronary artery disease, in which the absence of a permanent implant could be of particular interest. Additionally, it might be beneficial for those who are at increased risk of bleeding and in case of intolerance for DAPT, because the absence of a permanent implant might abate the need for prolonged DAPT. Further investigation is needed to evaluate the long-term safety and efficacy of a DCB strategy in STEMI, and to identify specific patient groups that benefit the most.

**STUDY LIMITATIONS.** First, the number of patients included is relatively small and our study was a single-center study. Although there was a fairly high dropout rate during follow-up, the study was adequately powered to assess noninferiority of DCB versus DES with regard to the primary endpoint. Second, all patients received a Pantera Lux DCB, thereby our results cannot be extrapolated to patients who receive another DCB. Third, the selection of eligible lesions was based on the operator's visual interpretation of the coronary angiogram. However, this did not induce bias because randomization was performed after the lesion had been interpreted as eligible. Fourth, QCA analyses were not performed by an independent core laboratory.

**FIGURE 3** Late Luminal Loss at 9-Months Follow-Up




Line graph of distribution of late luminal loss of drug-coated balloon versus drug-eluting stent strategy. Abbreviations as in Figure 1.

## CONCLUSIONS

In this prospective, randomized controlled trial in patients presenting with STEMI, a DCB strategy was noninferior to DES in terms of FFR assessed at 9 months after PPCI. Furthermore, it seemed to be a safe and feasible strategy. Therefore, this may represent a valuable alternative strategy by which the purpose of truly leaving nothing behind can be accomplished without compromising results. Strict patient selection and sufficient culprit lesion preparation are mandatory to optimize results and prevent bailout stenting.

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## PERSPECTIVES

**WHAT IS KNOWN?** Stenting has proved to reduce the need for repeat revascularization compared with balloon angioplasty alone after primary PPCI for STEMI. However, the incidence of cardiac death or recurrent myocardial infarction is not reduced by stenting, partly because of stent-related complications.

**WHAT IS NEW?** We found that a DCB strategy in STEMI was noninferior to drug-eluting stent in terms of fractional flow reserve assessed at 9 months after PPCI. Furthermore, it seemed to be a safe and feasible strategy.

**WHAT IS NEXT?** A DCB may represent a valuable alternative strategy in PPCI for STEMI by which the purpose of truly leaving nothing behind can be accomplished without compromising results. Further investigation is needed to evaluate the long-term results and to identify specific patient groups that benefit the most.

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**KEY WORDS** drug-coated balloon, fractional flow reserve, primary percutaneous coronary intervention, ST-segment elevation myocardial infarction

**APPENDIX** For supplemental tables, please see the online version of this paper.