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ORIGINAL ARTICLE
Ischemic Heart Disease

Prospective Identification of Stent Fracture by Enhanced Stent Visualization System During Percutaneous Coronary Intervention

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Background: No study has evaluated the clinical consequences of stent fracture (SF) detected during the index percutaneous coronary intervention (PCI). Thus, we sought to investigate the relationship between SF detected during PCI and clinical outcome.

Methods and Results: We consecutively enrolled 832 patients with SF-predisposing factors undergoing 2nd-generation drug-eluting stent implantation and enhanced stent visualization (ESV) system evaluation to detect SF at index PCI. The primary endpoint was a 9-month device-oriented endpoint (DOCE, including cardiac death, target vessel myocardial infarction, and target lesion revascularization). We observed 136 SF in 115 patients (14% of study population). SF I–II was present in 78 patients (68% of patients with SF), and SF III–IV occurred in 37 patients (32%). DOCE at 9 months occurred in 135 patients (16% of the overall population). There was a significant difference in DOCE occurrence between the 3 groups (P=0.006 at log-rank), driven by the SF III–IV group (P=0.001 vs. no SF group, and P=0.01 vs. SF I–II group). In 23 cases of SF III–IV (62%) a further stent was implanted. DOCE occurrence was significantly higher in patients with "untreated" type III–IV SF as compared with the "treated" ones (9% vs. 79%, P<0.01).

Conclusions: The ESV system is helpful in detecting SF during the index PCI. Type III–IV SFs are associated with a higher incidence of DOCE.

Key Words: Drug-eluting stent; Enhanced stent visualization system; Stent fracture

Nowadays, stent implantation in complex settings and lesions is common, and likely to increase. This has brought stent fracture (SF) occurrence to the attention of the scientific community because it has become more frequent in conjunction with the growth in procedural complexity. The reported incidence of SF is highly variable, ranging from 2% to 22%, according to the applied diagnostic tool and classification.[1–3] Most of the data refer to 1st- or 2nd-generation drug-eluting stents (DES),[1–3] and SF has been mainly diagnosed at the 9–12-month angiographic follow-up, based solely on angiography, with the likelihood of being underestimated. No study has evaluated the incidence and outcomes of SF occurring during the index percutaneous coronary intervention (PCI). This information could be clinically relevant as it may affect both the procedure (further stent implantation) and the therapeutic strategy (i.e., more aggressive antithrombotic regimen). In addition, previous studies were aimed at identifying the predisposing factors of SF (e.g., right coronary artery, long stents, overlap, tortuosity, balloon overexpansion),[1–4] rather than the actual clinical implications of SF.[5,6] We have taken a different approach, performing a prospective analysis of consecutive patients with SF-predisposing factors treated with a 2nd-generation DES, with the aim of: (1) testing the value of an enhanced stent visualization (ESV) system in SF detection during the index PCI and (2) identifying patients at high risk for adverse events during follow-up.

Methods

Study Population

In our center, clinical and procedural data from all patients undergoing PCI for ischemic heart disease are recorded and patients are prospectively followed up for at least 12 months.[7–9] According to our institutional protocol,[8,10,11] we systematically perform an ESV system evaluation after stent implantation in patients undergoing PCI. The present analysis was performed in those patients with both SF-predisposing factors[1–5] and available ESV images from during their index procedure (**Figure 1**). Predisposing factors for SF were: (1) overlapping stents, (2) vessel tortuosity (defined as ≥2 bends of ≥75°, 1 bend ≥90° or significant

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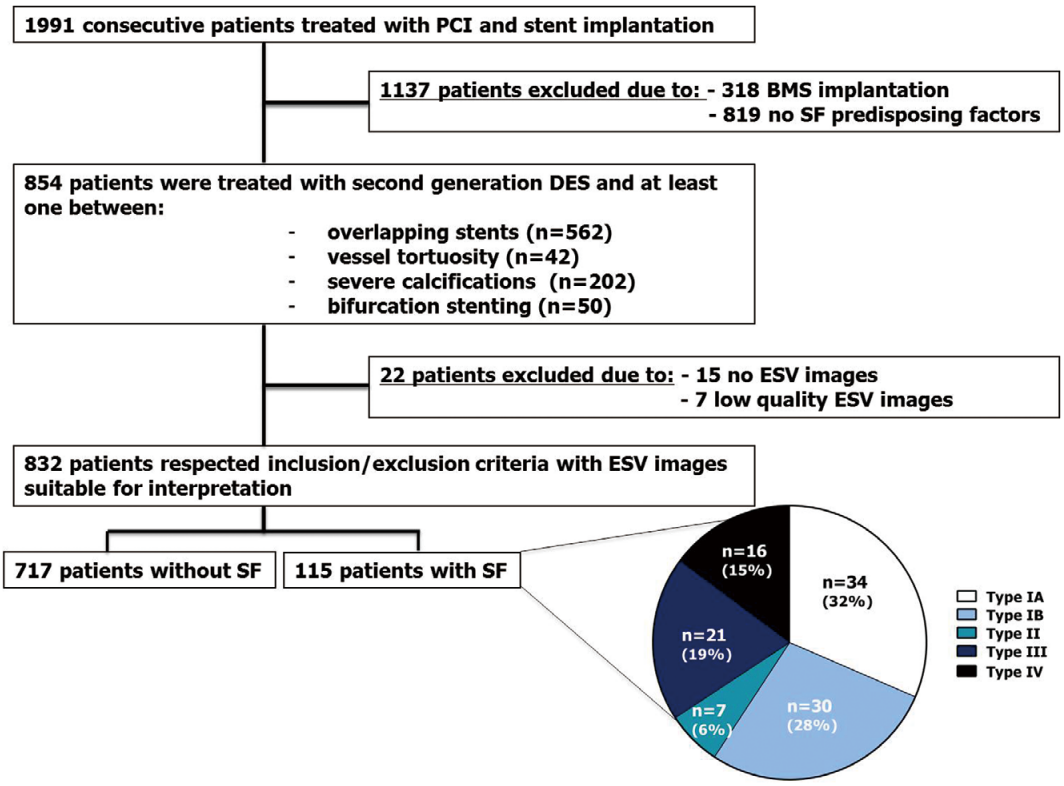

Figure 1. Study flow chart with patients' classifications according to stent fracture type. Type IA: single-strut fracture. Type IB: gap between struts >2 times the 2.5-mm expanded cell diameter. Type II: incomplete transverse stent fracture that resulted in V-shaped horizontal separation of stent struts without discontinuity at 1 edge of stent. Type III: complete transverse fracture of stent without displacement of 2 components of the fractured stent by >1 mm. Type IV: complete transverse fracture of stent with torsion during the cardiac cycle or displacement of 2 stent fragments >1 mm. BMS, bare metal stent; DES, drug-eluting stent; ESV, enhanced stent visualization; PCI, percutaneous coronary intervention; SF, stent fracture.

vessel curvature proximal to the lesion or a highly angulated vessel ≥45°), (3) severe calcification (highly visible diffuse calcification, >70% of the stented segment), and (4) bifurcation stenting with 2-stent technique. The analysis was based on current clinical practice, so the regulatory authorities required ordinary written informed consent to PCI, which was obtained from all patients. The protocol of the study was in accordance with the Declaration of Helsinki.

Procedural Protocol

All interventions were performed using standard techniques. Predilation, postdilation, and use of intracoronary imaging (intravascular ultrasound (IVUS) or optical coherence tomography (OCT)) were left to the operator's discretion, as well as the decision to implant a further stent in patients with ESV-confirmed SF. ESV system utilization was mandatory after stent implantation and after postdilation (if it was performed). The following DES were implanted: Xience V or Xience Prime or Xience PRO (Abbott Vascular, Santa Clara, CA, USA), Promus Element or Promus Premier (Boston Scientific, Natick, MA, USA), Biomatrix Flex (Biosensors Europe SA, Morges, Switzerland), and Cre8 (CID and Alvimedica. S.P.A., Saluggia, Italy). After the procedure, all patients were advised to continue dual antiplatelet therapy (DAPT) with aspirin and P2Y12 inhibitor (clopidogrel, prasugrel or ticagrelor according to current guidelines) for 12 months unless contraindicated.[12]

ClearStent Live Evaluation and SF Assessment and Classification

The module and software for the ESV images were built into the radiographic system (ClearStent Live system®, Siemens Healthcare, Munich, Germany). A balloon catheter with radiopaque markers is placed in the region of interest to allow registration and processing of all frames within the acquired sequence. Next, 45–60 frames of cine images were obtained at the rate of 30 frames/s, without contrast medium injection, with images immediately available on the screen.

SF was detected and recorded by the 1st operator during the index procedure (**Figure 2**). Two independent reviewers (F.G., G.S.) blinded to the adjudication of the 1st operator and to the clinical outcome, reviewed all angiograms to validate SF, which was classified as types I–IV according to Popma's classification[13] (**Table S1**, **Figures 2**,**S1**,**S2**). Patients with more than 1 SF were classified according to the worst type of SF (from type IV to type I).

Quantitative Coronary Analysis

Quantitative coronary angiography (QCA) was performed

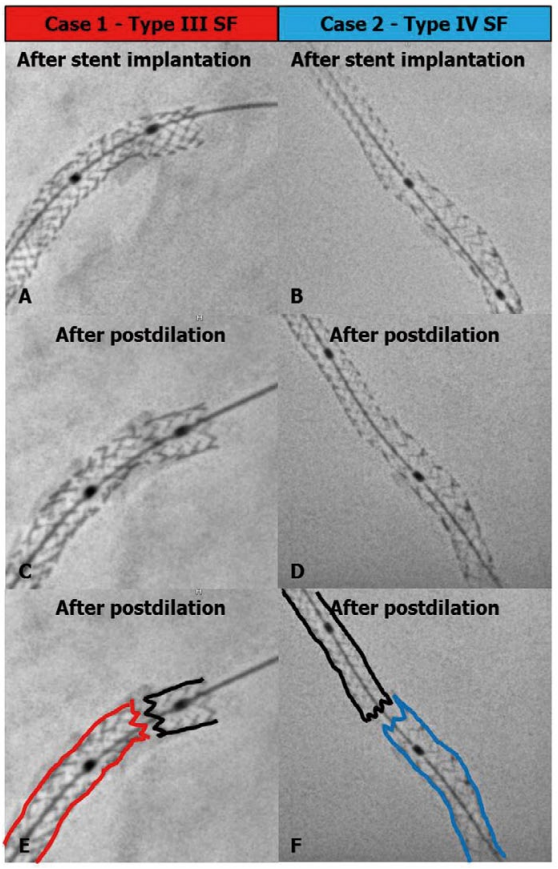

Figure 2. Paradigmatic cases of stent fracture (SF). Case 1 exemplifies a type III SF. (**A**) ESV image after stent deployment before optimization. It shows an underexpanded zone in the proximal portion of the stent. Therefore, the operator decided to perform postdilation with a non-compliant balloon. (**C**,**E**) ESV images showing a type III SF after postdilation. Case 2 exemplifies a type IV SF. (**B**) ESV image after stent deployment. The operator decided to perform postdilation with a non-compliant balloon. (**D**,**F**) ESV images showing a type IV SF also after postdilation. ESV, enhanced stent visualization.

by 2 independent, blinded operators (M.T., C.T.) using a computer-based QCA system (CAAS QCA-2D system, Pie Medical Imaging BV, Maastricht, the Netherlands) with a dye-filled catheter used for calibration. For each lesion, the following QCA parameters were measured: minimal lumen diameter (MLD) pre- and post-stenting, reference vessel diameter (RVD), percentage area stenosis, and length of coronary obstruction.

Follow-up and Endpoints

Patients returned for study visits at 30 days and 9 months after PCI. They were examined and assessed for adverse events, compliance with medical therapy, and 12-lead ECG recordings were obtained.

Endpoints were defined as per Academic Research Consortium recommendations.[14] The primary endpoint was a device-oriented composite endpoint (DOCE) of cardiac death, target vessel myocardial infarction (TVMI), and clinically-driven target lesion revascularization (TLR) at 9 months after 2nd-generation DES implantation in patients with SF-predisposing factors. Secondary endpoints were: (1) any component of the primary endpoint; (2) definite and probable stent thrombosis (ST), and (3) target vessel revascularization (TVR). Finally, as a preliminary analysis, we compared the occurrence of the primary endpoint in patients with SF III–IV stratified according to the implantation (or not) of a further stent. All endpoints were adjudicated by an independent reviewer (R.P.), who was unaware of any data.

Statistical Analysis

According to Peduzzi et al,[15] given a 9-month DOCE incidence of 12–15%,[16,17] at least 800 patients are needed to test at logistic regression if age, diabetes, body mass index (BMI), clinical presentation, ejection fraction, treated vessel, stent length, stent type, chronic renal disease, minimal stent diameter, P2Y12 inhibitor at discharge and SF are related to DOCE. This sample size was inflated to 830 patients to account for possible losses to follow-up. Continuous data were tested for normal distribution with the Kolmogorov-Smirnov test. Normally distributed variables are presented as mean±SD and were compared by t test. Otherwise, they are presented as median and interquartile range (IQR) and the Mann-Whitney U test was used. Categorical variables are summarized in terms of number and percentages and were compared by Chi-square test. Estimation of the cumulative primary endpoint rate was performed by Kaplan-Meier method, and events were compared by log-rank test. Hazard ratios with 95% confidence intervals (CIs) were calculated for SF III–IV vs. no SF/SF I–II with a proportional hazards model (all variables in **Tables 1** and **2** were included at univariate analysis, then those with a P-value <0.1 were entered in the multivariable analysis). A 2-sided value of $P<0.05$ was considered significant. All analyses were performed with STATISTICA 8 (Statsoft Inc., Tulsa, OK, USA).

Results

From September 2013 to May 2015, 1,991 consecutive patients underwent PCI in our center. Overall, 854 (43%) patients satisfied the inclusion criteria and underwent DES implantation. ESV imaging was performed and recorded in 832 (97%) patients, who represented the final study population (**Figure 1**). The most frequent inclusion criterion was overlap stenting (68%), followed by severe calcification (24%), tortuosity or bifurcation stenting (11%) (**Table 1**, **Figure 1**). The total number of implanted stents was 2091 (2.5±0.5 per patient).

Incidence and Type of SF

At the time of index PCI, the ESV system revealed at least 1 SF in 115 (14%) patients, and the 1st operator reported 136 SF overall (**Table 1**). A total of 78 (68%) patients were classified as SF I–II, and 37 (32%) as SF III–IV (**Table 1**, **Figure 2**). All SF III–IV patients were confirmed after blinded revision off-line, while a higher number of SF I–II was reported when compared with those reported by the 1st operator (124 vs. 99 SF in 97 vs. 78 patients, P=0.4 and P=0.12, respectively). Patients with and without SF were comparable for baseline clinical and procedural characteristics (**Tables 1**,**2**). SF occurrence did not differ between DES platforms (**Table 2**), although SF III–IV were numerically higher for Biomatrix stent if compared with other

Table 1. Baseline Characteristics of the Study Population of Patients Undergoing Index PCI

	No SF (n=717)	SF I–II (n=78)	SF III–IV (n=37)	P value
Age (years)	69±11	67±11	67±12	0.1
Men, n (%)	556 (78)	60 (77)	28 (76)	1
Cardiovascular risk factors, n (%)				
Hypertension	525 (73)	54 (69)	27 (73)	0.8
Dyslipidemia	412 (57)	43 (55)	21 (57)	0.9
Diabetes mellitus	208 (29)	26 (33)	10 (27)	0.7
Current or previous smoker	335 (47)	41 (53)	18 (49)	0.6
Family history of CAD	204 (28)	26 (33)	11 (30)	0.7
BMI (kg/m^2)	27±4	28±4	28±5	0.2
Medical history, n (%)				
MI	220 (31)	23 (29)	12 (32)	0.9
PCI	121 (17)	14 (18)	8 (22)	0.7
CABG	75 (10)	7 (9)	4 (11)	0.9
Clinical presentation, n (%)				0.4
STEMI	218 (30)	29 (37)	11 (30)	
NSTEMI	184 (25)	23 (30)	13 (35)	
UA	133 (19)	8 (10)	7 (19)	
SCAD	186 (26)	18 (23)	6 (16)	
Clinical data, n (%)				
LVEF (%)	50±11	49±11	50±9	0.2
CrCl (mL/min)	76±31	80±27	81±31	0.1
DAPT at discharge, n (%)				0.8
Clopidogrel	361 (50)	38 (49)	18 (49)	
Prasugrel	37 (5)	3 (4)	2 (5)	
Ticagrelor	319 (45)	37 (47)	17 (46)	
CV therapy at discharge, n (%)				
ACEI	543 (76)	62 (79)	29 (78)	0.9
β-blocker	584 (81)	64 (82)	32 (86)	0.7
Statin	640 (89)	69 (88)	31 (84)	0.6
Inclusion criteria				
Severe calcifications	174 (24)	18 (23)	10 (27)	0.9
Tortuosity	37 (5)	4 (5)	1 (3)	0.8
Bifurcation stenting	38 (5)	10 (13)	2 (5)	0.03
Overlap stenting	489 (68)	48 (62)	25 (68)	0.5

ACEI, angiotensin-converting enzyme inhibitor; BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; CrCl, creatinine clearance; CV, cardiovascular; DAPT, dual antiplatelet therapy; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NSTEMI, non-ST-segment elevation MI; PCI, percutaneous coronary intervention; SCAD, stable coronary artery disease; SF, stent fracture; STEMI, ST-elevated MI; UA, unstable angina.

platforms, without reaching statistical significance (**Table 2**). Patients undergoing bifurcation stenting were more prone to have type I or II SF (**Table 2**).

Primary Endpoint

DOCE at 9 months occurred in 135 patients (16%) (**Table 3**). As shown in **Figure 3**, there was a significant difference in the cumulative occurrence of DOCE between the 3 groups (P=0.006 at log-rank). DOCE occurrence did not differ between patients with no SF vs. those with SF I–II either according to 1st operator (P=0.7 at log-rank) or blinded reviewer evaluation (P=0.7). We observed a significant difference in the occurrence of the primary endpoint between patients with type III–IV SF vs. those without SF (P=0.001) or vs. those with SF I–II (P=0.01) (**Table 3**, **Figure 3**). In the univariate analysis, age, creatinine clearance, diabetes mellitus, ST-elevated myocardial infarction (STEMI), stent length, multivessel disease, and SF (III–IV vs. no SF/SF I–II) were predictors of the primary endpoint. After multivariable analysis, age, STEMI and SF III–IV emerged as independent predictors of the primary endpoint (**Table 4**).

Secondary Endpoints

We found no difference between the 3 groups regarding CV death. However, all other secondary endpoints differed significantly between groups (**Table 3**). This was totally driven by patients with SF III–IV, as the rate of secondary endpoints was similar between patients with no SF and those with SF I–II (**Table 3**). Accordingly, the secondary endpoints were significantly higher in patients with SF III–IV as compared with those with no SF (TVMI: 14% vs. 4%, P=0.003; TLR: 35% vs. 12%, P=0.00003; TVR: 35% vs. 13%, P=0.0001; definite ST: 5% vs. 1%, P=0.007; definite/probable ST: 14% vs. 1%, P<0.000001). Of note, ST was

Table 2. Procedural Characteristics of the Study Population of Patients Undergoing Index PCI

	No SF (n=717)	SF I–II (n=78)	SF III–IV (n=37)	P value
No. of diseased vessels, n (%)				0.8
1	121 (17)	14 (18)	9 (24)	
2	259 (36)	28 (36)	11 (30)	
3	337 (47)	36 (46)	17 (46)	
No. of treated lesions, n (%)				0.2
1	229 (32)	21 (27)	14 (38)	
2	328 (46)	41 (53)	14 (38)	
3	116 (16)	11 (14)	6 (16)	
>3	44 (6)	5 (6)	3 (8)	
No. of implanted stents, n (%)				0.7
1	66 (9)	12 (15)	3 (8)	
2	348 (49)	33 (43)	15 (41)	
3	175 (24)	19 (24)	11 (30)	
>3	128 (18)	14 (18)	8 (22)	
No. of treated vessels, n (%)				0.9
1	369 (51)	41 (53)	18 (49)	
2	280 (40)	32 (41)	15 (41)	
3	68 (9)	5 (6)	4 (10)	
Treated vessel				
LAD	410 (57)	53 (68)	25 (68)	0.1
LCX	316 (44)	28 (36)	18 (49)	0.3
RCA	314 (44)	33 (42)	15 (41)	0.9
LM	77 (11)	9 (12)	4 (11)	1
Stent				
Length (mm)	57±23	59±23	62±24	0.4
Diameter (mm)	7.8±2.7	7.9±2.7	8.3±2.2	0.1
Mean stent diameter (mm)	3±0.4	3±0.4	3±0.4	0.8
Promus	231 (32)	26 (33)	15 (41)	0.6
Xience	335 (47)	38 (49)	11 (30)	0.1
Biomatrix	125 (17)	14 (18)	9 (24)	0.6
Cre8	26 (4)	0 (0)	2 (5)	0.2
QCA analysis				
RVD proximal pre (mm)	2.7±0.5	2.6±0.5	2.6±0.6	0.1
MLD pre (mm)	0.6±0.4	0.5±0.4	0.6±0.4	0.2
Area stenosis pre (%)	78±13	80±12	79±15	0.7
Lesion length (mm)	14±9	13±9	15±8	0.2
MLD post (mm)	2.6±1.2	2.9±1.4	2.6±0.4	0.6
Area stenosis post (%)	10±7	10±8	10±7	1
Postdilatation, n (%)	502 (70)	55 (71)	26 (70)	0.8
Maximal postdilatation balloon diameter (mm)	3.55±0.5	3.6±0.5	3.6±0.5	0.3
Maximal postdilatation balloon pressure (atm)	16±2	16±3	16±3	0.8

LAD, left anterior descending; LCX, left circumflex; LM, left main; MLD, minimal lumen diameter; PCI, percutaneous coronary intervention; QCA, quantitative coronary angiography; RCA, right coronary artery; RVD, reference vessel diameter; SF, stent fracture.

responsible for the majority of TLR in patient with type IV SF (67% of TLR), while in-stent restenosis (ISR) was predominant in type III SF (86% of TLR). Among patients undergoing coronary artery angiography for TLR, the lesion was at the SF site in 92% of patients with SF III–IV (12 of 13), but in only 10% of patients with SF I–II (1 of 10) (**Table S1**, **Figures S1**,**S2**). During the index PCI, the 1st operator decided to implant a further DES in 14 cases (66%) of SF III and in 9 cases (56%) of SF IV (P=0.5). Interestingly, DOCE occurrence was significantly higher in patients with "untreated" type III–IV SF as compared with those in which operator decided to implant a further DES (9% vs. 79%, P<0.01).

Discussion

The results of our study can be summarized as follows: (1) DOCE occurred more frequently in patients with type III–IV SF than in those without SF or with SF I–II; (2) type IV SF was highly associated with ST, while type III was associated with ISR; and (3) "untreated" type III–IV SF was associated with a poor outcome. The implications

Table 3. Adverse Events in the Study Population of Patients Undergoing Index PCI

	No SF (n=717)	SF I–II (n=78)	SF III–IV (n=37)	P value
Primary endpoint				
DOCE, n (%)	111 (15)	11 (14)	13 (35)	0.003
Secondary endpoints				
CV death, n (%)	35 (5)	1 (2)	3 (8)	0.2
TVMI, n (%)	26 (4)	4 (5)	5 (14)	0.01
TLR, n (%)	86 (12)	10 (13)	13 (35)	0.0001
TVR, n (%)	95 (13)	11 (14)	13 (35)	0.0003
Definite ST, n (%)	6 (1)	2 (3)	2 (5)	0.02
Definite/probable ST, n (%)	9 (1)	2 (3)	5 (14)	0.000001

DOCE, device-oriented endpoint; ST, stent thrombosis; TLR, target lesion revascularization; TVMI, target vessel myocardial infarction; TVR, target vessel revascularization. Other abbreviations as in Table 1.

of these findings are clinically relevant. Our data suggest first that the systematic application of ESV during the index PCI stratifies the risk related to "iatrogenic" SF (occurring during the index PCI), and, second, that treatment of type III–IV SF with an additional stent could reduce adverse events. Of course, these suggestions need to be confirmed in proper multicenter studies.

The major strengths of the present study were: (1) novel timing of SF identification: during index PCI with a prespecified and standardized diagnostic method; (2) systematic use of an ESV system not as a "post-hoc" interpretation during follow-up, but "preventatively" at the time of the index procedure; (3) blinded, independent adjudication of adverse events; and (4) reproducibility of SF diagnosis, especially in SF III–IV (those linked to the worst outcome).

The weaknesses were: (1) single-center enrollment, even though consecutive and in a high-volume center; (2) exclusion of a consistent number of cases of SF from our analysis, namely those diagnosed at angiographic follow-up occurring as a result of chronic fatigue; (3) lack of power to assess the best strategy for SF; (4) intrinsic ESV system limits in the identification of the precise mechanism underlying SF (i.e., calcification, stent overexpansion); (5) absence of angiographic follow-up in the enrolled patients because it is not part of our daily clinical practice; and (6) possible selection bias regarding implantation of a further stent in SF because

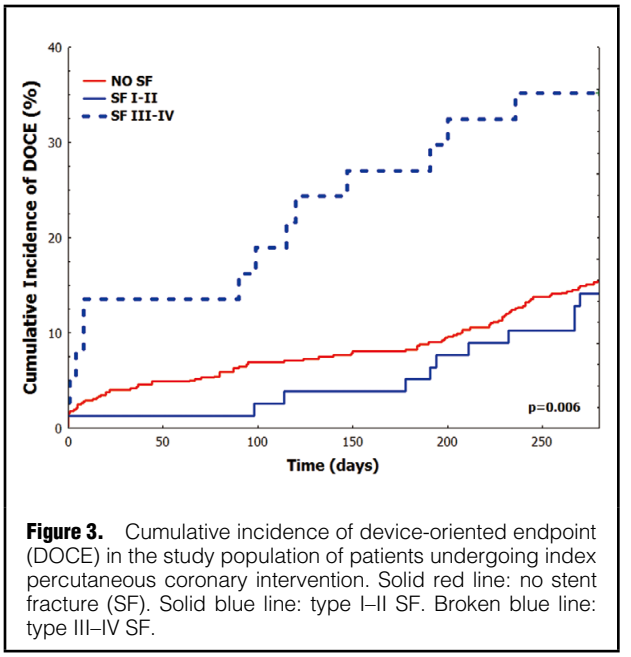

Figure 3. Cumulative incidence of device-oriented endpoint (DOCE) in the study population of patients undergoing index percutaneous coronary intervention. Solid red line: no stent fracture (SF). Solid blue line: type I–II SF. Broken blue line: type III–IV SF.

Table 4. Predictors of Primary Endpoint in the Study Population of Patients Undergoing Index PCI

Device-oriented endpoint	HR	95% CI	P value
Univariate analysis			
Age (×1 year increase)	1.1	1.05–1.5	0.02
CrCl (×1 mL/min increase)	0.9	0.8–0.98	0.04
Diabetes mellitus	1.3	0.99–1.6	0.055
STEMI	1.7	1.2–2.4	0.001
Stent length (×1 mm increase)	1.02	1.01–1.05	0.03
Multivessel disease	1.4	0.95–2	0.07
SF III–IV	2.7	1.5–4.8	0.0007
Multivariable analysis			
Age (×1 year increase)	1.05	1.01–1.08	0.04
STEMI	1.6	1.1–2.2	0.01
SF III–IV	2.6	1.4–4.7	0.001

CI, confidence interval; HR, hazard ratio; STEMI, ST-segment elevation MI as clinical presentation. Other abbreviations as in Table 1.

the decision was left to the operator.

We deliberately applied strict inclusion criteria that have been widely validated by previous studies[1–6] to select patients at high risk for SF because we were interested in the effect of SF detection during the index PCI on subsequent events, and in the consequences on the outcome of the eventual implantation of another stent. All previously published clinical studies have focused on SF detection at 9–12-month angiographic follow-up (i.e., "late" SF);[1–3,18] none has focused on SF detection at the time of the index procedure (i.e., "early" SF). We thought that gaining this information could be relevant for interventional cardiologists because, in everyday clinical practice, the vast majority of patients do not undergo control angiography. Knowledge of the clinical implications related to SF detected at angiography follow-up is useful as a comparison between different stent platforms, but has limited value in everyday decision-making. Appropriate detection and treatment of SF at the time of the index procedure can be of paramount importance, especially if its treatment may affect hard endpoints. Another relevant issue in the previous studies relates to the different diagnostic tools used for SF diagnosis. Angiography has limited sensitivity in the detection of SF, especially in new cobalt-chromium stents with thinner struts.[19] Systematic utilization of advanced coronary imaging techniques (i.e., IVUS or OCT) may help in SF diagnosis, especially given the recent developments in 3D-OCT. However, these techniques may have limited application in everyday clinical practice for organizational and economic reasons. We acknowledge that the ESV system has relevant limitations, mainly related to the 2D representation of a 3D structure. Another ESV system caveat could be the difficulty in distinguishing pseudofracture and stent deformation from types I and II SF. However, our results show that none of these was related to a worse outcome. Consequently, we think ESV systems could be an acceptable alternative, combining improved accuracy with time and cost saving. Our group has a wide experience in ESV systems utilization for PCI optimization,[8,10,11] so it seemed logical to explore this issue. Our main result was demonstration of higher DOCE occurrence in patients with types III and IV SF detected during the index PCI when compared with other patients.

In the 1st-generation DES, pathological analysis showed that while type I–III SF did not increase ST or restenosis rates, type IV SF was associated with adverse structural findings at the fracture site.[20,21] Our results confirmed that type IV SF detected during the index PCI are associated with adverse events, in particular ST. The pathophysiology relies on the presence of struts exposed to blood flow, acting as a thrombogenic factor, causing poor strut coverage, malapposition with excessive fibrin deposition, and delayed healing. We also found that type III SF are associated with DOCE, but mainly to TLR caused by ISR. As previously demonstrated, this could be caused by the gap between stents,[22] including hinge movement at the "gap" site, with subsequent inflammation and neointimal hyperplasia. Moreover, the fractured struts may act as additional source of inflammation and hyperplasia because of poor distribution or interruption of drug delivery, leading to neointimal overgrowth as a response to injury and subsequent stenosis.[5] Moreover, changes in local shear stress may cause focal differences in vascular compliance, thus enhancing extracellular matrix deposition.[5] With regard to stent platforms, we found a slightly higher percentage of SF III–IV in patients receiving a Biomatrix stent (6.1% vs. 4.1% of other platforms), without reaching statistical significance (P=0.3). Our results are in line with a recent study comparing contemporary stent platforms through a repetitive bend bench-test that showed a higher incidence of SF at the level of the "S"-shaped connectors between the 1st (largely fixed) hoop and the 2nd hoop.[23] However, it is important to underline that our study was not designed for this purpose and that, in the absence of statistical significance, we cannot infer an actual difference between different stent platforms.

There is still no consensus about the best treatment strategy for SF, because no ad hoc study has been designed to address this issue.[5] A recent analysis from the Food and Drug Administration Manufacturer and User Facility Device Experience Database reports that a further stent was implanted in most cases (68% of patients).[5] In our exploratory analysis, 62% of patients with SF III–IV was treated with further stent implantation, and we found significantly less occurrence of DOCE, as compared with those in whom the operator decided not to implant a further stent (9% vs. 79%, P<0.01). However, it is noteworthy that when SF is caused by non-modifiable factors such as excessive vessel tortuosity, complex bifurcation stenosis or heavy calcification, it is doubtful whether this strategy should be adopted because all these factors still persist and may even be worsened, because overlapped stents themselves predispose to SF. If secondary SF occurs, this may also lead to catastrophe and certainly another option would be coronary bypass surgery.

Conclusions

Our study suggested that an ESV system could be added to the armamentarium of the interventional cardiologist for the detection of SF during PCI. In our study, the DOCE incidence in patients with SF type III or IV was higher than in the other patients. Finally, we hypothesize that the best treatment strategy for type III–IV SF detected during the index PCI is further stent placement. It is important to note that our findings are exploratory and need to be confirmed in properly constructed trials.

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Conflict of Interest

The authors report no relationships that could be construed as conflicts of interest.

Disclosures

All authors have reported that they have no relationships relevant to the content of this paper to disclose.

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Supplementary Files

Supplementary File 1

Table S1. DOCE stratified according to inclusion criteria

Figure S1. Description of adverse events in the study group according to the presence and site of SF at index and/or follow-up angiography.

Figure S2. ESV-detected stent fracture according to Popma's classification.

Please find supplementary file(s);
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