Suboptimal stent deployment is associated with subacute stent thrombosis: Optical coherence tomography insights from a multicenter matched study. From the CLI Foundation investigators: the CLI-THRO study

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Background Acute or subacute stent thrombosis (ST) is a well-described complication usually causing acute coronary syndromes and, in the worst case scenario, sudden cardiac death. In this study, we aimed at exploring the potential role of optical coherence tomography (OCT) in the understanding of the mechanism of ST.

Methods Twenty-one consecutive patients, after acute coronary syndromes due to a definite subacute ST, were assessed with OCT and matched 1:2 with 42 patients undergoing OCT for scheduled follow-up. Optical coherence tomography assessment was focused on features indicative of nonoptimal stent deployment: underexpansion, malapposition, edge dissection, and reference lumen narrowing.

Results Optical coherence tomography revealed a minimum stent area sensibly smaller in the ST group (5.6 ± 2.6 vs 6.8 ± 1.7 mm^2; $P = .03$) with a higher incidence of stent underexpansion when compared with the control group (42.8% vs 16.7%; $P = .05$). Dissection at stent edges was more commonly detected in ST group (52.4% vs 9.5%; $P < .01$). No significant differences between the 2 groups were observed for malapposition (52.4% vs 38.1%; $P = .651$) and reference lumen narrowing (19.0% vs 4.8%; $P = .172$). At least 1 OCT finding indicative of suboptimal stent deployment was detectable in 95.2% of patients experiencing ST versus 42.9% of the control group ($P < .01$).

Conclusions Optical coherence tomography assessment in patients experiencing subacute ST revealed nonoptimal stent deployment in almost all cases with higher incidence of stent underexpansion and edge dissection, potentially explaining the cause of this adverse event. The adoption of an OCT-guided percutaneous coronary intervention protocol could have a potential for the prevention of ST in complex cases. (Am Heart J 2015;169:249-256.)

Despite the substantial improvement in interventional procedures due to the use of new materials and the adoption of novel therapeutic strategies, acute or subacute stent thrombosis (ST) remains a critical issue both with metal or drug-eluting stents (DES).[1-3]

Clinical manifestations of ST are often dramatic, presenting as acute coronary syndrome (ACS) or sudden unexplained death. Thus, ST contributes to major morbidity and mortality after percutaneous coronary intervention (PCI), with an incidence of 0.5% to 3% and a mortality rate of >45%.[1-3]

The mechanism at the base of subacute ST is likely multifactorial;[4] however, procedural factors and particularly the adequacy of stent deployment exert an important role.[5,6] For these reasons, the adoption of intravascular imaging assessment to fine tune the procedural results is a possible solution to tackle abrupt ST and ameliorate the patient outcome.[7]

It was recently shown that PCI result assessment by means of optical coherence tomography (OCT) can improve the patient outcome in comparison with standard pure

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angiographic-guided approach.[8] This clinical benefit is the direct consequence of the OCT ability to identify all procedural defects acting as a potential cause of ST.

Surprisingly, information on OCT findings in patients with subacute ST is scarce and limited to anecdotal cases; indeed, most of the studies available focused on OCT findings in patients with late and very late ST.[9-11]

Thus, to better understand the mechanism of subacute ST and the potential impact of high-resolution OCT assessment in its prevention, we compared the OCT features of stented segments sustaining subacute ST with matched uneventful stented segment undergoing scheduled OCT evaluation within 1-month after implantation.

Methods

Study design and patient population

The present study was conceived as a prospective investigation in which all the study centers agreed to perform manual thrombus-aspiration followed by OCT evaluation in every patient presenting with suspected ST.

We retrospectively collected 25 consecutive patients with subacute ST in 5 independent centers between January 2010 and January 2012. All patients presented with ACS related to a definite ST occurring between 24 hours and 30 days after implantation of either bare-metal stents (BMS) or DES.[12] Patients with ostial left main and ostial right coronary artery were excluded from the study.

All enrolled patients were then screened at the Rome Heart Research core laboratory to verify the diagnosis and appropriateness of OCT assessment. Four patients were excluded for either suboptimal images (2 cases) according to validated quality standards[13] or incorrect diagnosis (late instead of subacute thrombosis) (2 cases). Twenty-one patients (ST group) entered the study and were compared with a case-matched control cohort of 42 patients without ST (control group). The control arm was selected from the Rome Heart Research OCT core laboratory database that included patients enrolled in research studies requiring the OCT assessment at 1-month follow-up and was matched for main clinical (eg, risk factor) and procedural (eg, stent size) variables with the ST group. In all patients features indicative of nonoptimal OCT stent deployment as previously described in the CLI-OPCI study[8] were accurately evaluated.

Procedural details and definitions

All ST patients were treated with thrombectomy using manual or mechanical systems at ST site. Thrombectomy is a widespread technical solution in the management of patients with ST[14] and is a prerequisite for OCT assessment, as thrombotic formations can hamper visualization of struts and vessel walls.[15,16]

The pharmacologic treatment was given according to standard clinical practice. Most of patients received dual antiplatelet drugs with loading dose when required (clopidogrel bolus of 600 mg plus 75 mg/d or prasugrel bolus of 60 mg plus 10 mg/d) and aspirin 100 mg/d (Table I), whereas glycoprotein IIb/IIIa inhibitors were given at physician's discretion.

After thrombus aspiration, stents were assessed by OCT to address the features indicative of suboptimal stent deployment applied in the CLI-OPCI study.[8] Significant *edge dissection* was defined as the presence of a linear rim of tissue, with a width of ≥200 μm, a length of ≥600 μm, and a clear separation from the vessel wall or plaque that was adjacent (<5 mm) to a stent edge. Stent edge dissection arc degree was measured as the maximal angle comprised between the 2 boundaries of the flap at the cross-sectional level.[17]

Reference lumen narrowing was defined as a lumen area <4.0 mm^2 in presence of a significant plaque burden. *Malapposition* was identified when the stent lumen distance was greater than the sum of strut thickness plus abluminal polymer thickness, according to each stent manufacturer's specifications, plus a compensation factor of 20 μm to correct for strut blooming and was considered significant if the stent lumen distance was >200 μm.[16,18] Stent underexpansion was defined as in-stent minimal area ≥90% of the average reference lumen area or ≥100% of lumen area of the reference segment with the lowest lumen area. As stents were evaluated after acute events and some thrombotic remnants were present despite thrombus aspiration, we relied on the measurements of stent area instead of the measurements of lumen area to address underexpansion.

Because of the nature of patients selected, it was not possible to evaluate the presence of intrastent thrombus defined in the CLI-OPCI study. Indeed, in presence of subacute ST, it is not possible to identify remnants of intrastent thrombus that occurred immediately after stent positioning from thrombus burden acutely generated during the abrupt stent occlusion.

Acquisition

Both the time domain (TD) and frequency domain (FD) OCT C7 system were allowed to study the target stented segment. Optical coherence tomography images using TD-OCT were obtained with a nonocclusive technique. Full details on this methodology are described elsewhere.[13] Briefly, the OCT system used in this study consisted of an interface unit (Model M2 Cardiology Interface System; LightLab Imaging, Inc, Westford, MA) providing images at a longitudinal resolution of 15 μm and a 0.019 inches wire-type imaging catheter (ImageWire; LightLab Imaging, Inc), which contains a 0.006-in fiber-optic imaging core and a distal radiopaque tip, like any other conventional guidewires. A motorized pull-back system at 2.0 mm/s was used, and OCT images were acquired at 15.6 frames/s.[13]

The FD-OCT system (LightLab Imaging, Inc) is equipped with a tunable laser light source with sweep range of 1,250 to 1,370 nm. The optical fiber is

Table I. Baseline clinical features

Patients	Controls (42)	Cases (21)	P
Time from PCI (d)	14 ± 10	13 ± 9	.701
Age (y)	60 ± 12	63 ± 12	.353
Male gender	25 (59.5%)	12 (57.1%)	.928
Indication for the index procedure			
ST-elevation myocardial infarction	16 (38.1%)	8 (38.1%)	.783
Non–ST-elevation myocardial infarction/unstable angina	15 (35.7%)	7 (33.3%)	.926
Stable coronary artery disease	11 (26.2%)	6 (28.6%)	.920
Left ventricular ejection fraction (%)	48 ± 10	47 ± 13	.737
Diabetes mellitus	9 (21.4%)	5 (23.8%)	.915
Dyslipidemia	31 (73.8%)	10 (47.6%)	.076
Hypertension	33 (78.6 %)	14 (66.7%)	.474
Family history of coronary artery disease	10 (23.8%)	1 (4.8%)	.127
Smoking status			
Never	26 (61.9%)	10 (47.6%)	.418
Former	4 (9.5%)	2 (9.5%)	.649
Current	12 (28.6%)	9 (42.9%)	.395
Chronic renal failure	1 (2.4%)	2 (9.5%)	.530
Medical therapy			
Angiotensin-converting enzyme inhibitor/angiotensin II antagonist	26 (61.9%)	11 (52.4%)	.651
Aspirin	40 (95.2%)	20 (95.2%)	.530
β-blocker	22 (52.4%)	10 (47.6%)	.929
Calcium-channel antagonist	4 (9.5%)	3 (14.3%)	.887
Clopidogrel	35 (83.3%)	16 (76.2%)	.734
Prasugrel	3 (7.1%)	2 (9.5%)	.869
Statin	35 (83.3%)	17 (80.9%)	.907

Values are given as number of patients (%) or mean ± SD.

encapsulated within a rotating torque wire built in a rapid exchange 2.6F catheter. The FD-OCT imaging catheters were delivered over a 0.014-in guidewire through a 6F or larger guiding catheters. Images were obtained at a pullback speed of 20 mm/s.[16,18]

Core laboratory assessment

Quantitative coronary angiography and OCT. Analyses were performed in a validated centralized core laboratory.[15-19] Quantitative coronary angiography analysis was performed off-line with a computer-assisted system using an automated edge detection algorithm (Cardiovascular angiography Analysis System II; MEDIS, Maastricht, The Netherlands). Quantitative coronary angiography analyses were performed by observers who were unaware of the group allocation. The treated segment was analyzed preintervention and postintervention using 2 orthogonal views.

Frequency domain-OCT images were calibrated adjusting the Z offset. This critical step was done before image acquisition to obtain accurate measurements. All OCT frames were digitally stored and independently analyzed using an off-line software (LightLab Consolle, St. Jude Medical, St. Paul, MN) by personnel blinded to procedural data and clinical outcome. For the TD-OCT images, analyses were done at 0.16-mm intervals, whereas for the FD-OCT images, 0.20-mm intervals were adopted.

Statistical analysis

Continuous data were expressed as mean ± SD and categorical data as count and proportions (%). Comparisons were performed by the χ^2 tests and unpaired *t* test as appropriate. All tests were 2 sided, and an α level of .05 was considered statistically significant.

To compare the OCT findings in patients with subacute ST included in the present study, a case-matched control (1:2) group of patients without ST, undergoing OCT for follow-up assessment of previously deployed stent, was selected from the Rome Heart Research OCT core laboratory database. Matching process was performed through an automatic query on the database, blinded to OCT findings. For each ST patient, the first patient in the database satisfying the matching parameters and fulfilling inclusion/exclusion criteria was chosen. The matching parameters in order of sequential selection were as follows: (1) stent type (BMS vs DES); (2) days from stent implantation to OCT assessment (from 2 to 30 days after the index procedure); (3) ACS presentation; (4) stent size and length; and (5) clinical and demographic characteristics, including a previous history of ACS and age.

Multivariate logistic regression was performed to assess the impact of OCT findings on ST (dependent variable) including in the final model all variables nominally significant ($P < .05$) at bivariate association.

Table II. Procedural details

	Controls (42)	Cases (21)	*P*
Vessel treated			1.000
Distal left main	3 (7%)	1 (5%)	.801
Left anterior descending	18 (43%)	10 (48%)	.929
Left circumflex	6 (14%)	3 (14%)	.703
Right coronary artery	15 (36)	7 (33%)	.926
Reference lumen diameter (mm)	2.87 ± 0.5	2.79 ± 0.6	.578
No. of stent implanted	1.14 ± 0.35	1.09 ± 0.30	.578
1	36 (85.7%)	19 (90.5%)	.894
2	6 (14.3 %)	2 (9.5%)	.894
Stent type			
BMS	32 (76.2%)	16 (76.2%)	.754
DES	10 (23.8%)	5 (23.8%)	.754
Everolimus-eluting stent	5 (11.9%)	3 (14.2%)	.894
Paclitaxel-eluting stent	2 (4.7%)	1 (4.7%)	.530
Sirolimus-eluting stent	3 (7.1%)	1 (4.7%)	.855
Nominal stent diameter (mm)	3.0 ± 0.3	3.0 ± 0.3	1.000
Nominal stent length (mm)	17.9 ± 4.1	18.3 ± 5.6	.748

Values are given as number of patients (%) or mean ± SD.

Cox and Snell R^2 and Nagelkerke R^2 were used to identify the amount of variation in the dependent variable explained by the model.

Ethical and legal considerations

The respect for the rights of the patients was guaranteed in each phase of the study in accordance with the Declaration of Helsinki and its current revision. Ethical approval was waived in the light of the observational retrospective design.

No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses and drafting and editing of the paper.

Results

The demographic and procedural characteristics of the patients are depicted in the Tables I and II. There were no significant differences regarding the main demographic variables that may impact on the subacute ST risk. In particular, the percentage of ST-elevation miocardial infarction as initial clinical presentation, DES/BMS ratio, stent length, and diameter were comparable in the 2 groups. The percentage of patients receiving dual antiplatelet regimen with thienopirydine and aspirine was similar in the 2 groups.

Quantitative coronary angiography and OCT data

Baseline angiography of patients with ST revealed a total occlusion in 14 (67%), subocclusive intrastent lesion in 5 (24%), and stenosis comprised between 60% and 80% with the angiographic appearance of acute thrombosis in 2 (9%) cases.

Preintervention reference vessel diameter was comparable at the quantitative coronary angiography evaluation (2.79 ± 0.6 vs 2.87 ± 0.5; $P = .578$).

The OCT readers analyzed 1,936 cross sections in the group with ST and 3,843 in the control group. Good image quality was obtained in 94% and 97% of cross section, respectively, in line with validated quality standard.[13] In 18 of 21 patients of the ST group, readers were able to address all 4 criteria of suboptimal stent deployment. Images of distal reference segments and proximal reference segments were of insufficient quality in 2 patients and in 1 patient, respectively. In the control arm, readers could evaluate all 4 criteria in all patients with the exception of 1 case due to a suboptimal quality of the proximal reference segment.

Optical coherence tomography findings revealed a minimum lumen area (4.1 ± 2.7 vs 6.2 ± 1.5 mm^2; $P < .01$) and stent minimum area (5.6 ± 2.6 vs 6.8 ± 1.7 mm^2; $P = .03$) sensibly smaller in the ST group (Table III). Stent underexpansion and edge dissections imaged both at proximal and distal edges were significantly more frequent in ST group in comparison with the control group (42.8% vs 16.7%; $P = .05$) and (52.4% vs 9.5%; $P < .01$), respectively (Figure 1). In particular, edge dissection length and width were significantly greater in ST group, especially at the distal stent edge (Table III). In the ST group, we also observed a trend toward a higher incidence of stent malapposition (52.4% vs 38.1%; $P = .651$) and reference lumen narrowing (19.0 vs 4.8%; $P = .172$) (Figure 2).

Globally, features indicative of suboptimal stent deployment occurred in 20 (95.2%) of 21 patients with ST versus 18 (42.9%) of 42 in control group ($P = .0003$) (Figure 3).

The calcific components, in the reference segments and having an arc degree >90°, were detected by OCT in 23.8% of patients in the ST group and in the 26.1% of patients in the control, group ($P = .918$).

The logistic regression analysis included the following variables in the final model: stent underexpansion, minimum stent area, edge dissection, reference lumen narrowing, and malapposition. The final model was explained between 41% (Cox and Snell R^2) and 56% (Nagelkerke R^2) of the variance of ST and correctly classified in 85.7% of cases. Stent underexpansion (odds ratio 17.5; 95% CI 1.6-182; $P = .01$) and edge dissection (odds ratio 90.6; 95% CI 5.7-250; $P < .01$) were the 2 independent predictors of subacute ST.

Discussion

The major findings of the present study are the following: (1) OCT definition of nonoptimal stent deployment is strictly associated with an increased risk of ST and (2) stent underexpansion and dissection at stent edges seem to be the main determinants of thrombosis in the early phases after implantation.

Table III. Optical coherence tomography findings

	Controls (42)	Cases (21)	*P*	95% CI
Stent underexpansion	16.7%	42.8%	.050	−0.48 to −0.03
Minimum stent area (mm^2)	6.8 ± 1.7	5.6 ± 2.6	.031	0.11 to 2.29
Stent area at proximal edge (mm^2)	8.7 ± 2.2	7.7 ± 3.0	.138	−0.33 to 2.33
Stent area at distal edge (mm^2)	7.9 ± 2.2	7.0 ± 2.4	.143	−0.31 to 2.11
Minimum lumen area (mm^2)	6.2 ± 1.5	4.1 ± 2.7	<.001	1.04 to 3.16
Lumen area at proximal edge (mm^2)	8.3 ± 2.0	7.5 ± 2.4	.167	−0.34 to 1.94
Lumen area at the distal edge (mm^2)	7.5 ± 2.2	6.2 ± 2.4	.036	0.09 to 2.51
Edge dissection	9.5 (%)	52.4 (%)	.007	−0.63 to −0.19
Proximal edge dissection length (mm)	1.5 ± 0.7	2.5 ± 1.5	<.001	−1.55 to −0.45
Proximal edge dissection width (mm)	0.48 ± 0.61	0.47 ± 0.19	.942	−0.26 to 0.28
Proximal edge dissection max arc (°)	90 ± 10	82 ± 34	.162	−3.29 to 19.29
Distal edge dissection length (mm)	3.1 ± 1.6	5.3 ± 5.8	.025	−4.11 to −0.29
Distal edge dissection width (mm)	0.43 ± 0.14	0.74 ± 0.30	<.001	−0.42 to −0.20
Distal edge dissection maximum arc (°)	113 ± 63	190 ± 69	<.001	−111.80 to −42.25
Stent malapposition (%)	38.1%	52.4%	.651	−0.38 to 0.11
Malapposed struts (n)	27 ± 56	26 ± 33	.940	−25.53 to 27.53
Cross sections with ≥1 malapposed strut	9.2 ± 15.0	9.2 ± 10.0	1.000	−7.25 to 7.25
Cross sections with ≥3 malapposed strut	3.5 ± 8.8	4.6 ± 6.7	.616	−5.47 to 3.27
Maximum malapposition distance (μm)	521.4 ± 227.4	548.5 ± 352.0	.713	−173.80 to 119.60
Reference lumen narrowing	4.8%	19.0%	.172	−0.35 to 1.60

Values are given as number of patients (%) or mean ± SD.

Most of the studies with intravascular imaging modalities that addressed the pathophysiology of ST were focused on the occurrence of late-occurring events.

Based on previous intravascular ultrasound (IVUS) studies findings with BMS, stents sustaining thrombosis had a smaller minimum stent area, a less complete expansion, and showed more often edge dissections.[10] Fujii et al[20] compared, in an IVUS study, 15 patients who developed acute/subacute DES thrombosis after successful implantation with a control group who had no evidence of ST. Stents with thrombosis were significantly smaller and less well expanded. Multivariate logistic regression analysis showed that independent predictors of ST were stent underexpansion ($P = .03$) and a significant residual reference segment stenosis ($P = .02$) that was diagnosed in presence of a reference plaque burden >70% and an minimum lumen area <4 mm^2. Importantly, there was no significant difference in the rate of DES malapposition between the groups. Furthermore, dissection and plaque protrusion were not observed in the ST group.[20]

Recently, Guagliumi et al[9] studied the role of uncovered stent struts on late ST after DES implantation with OCT. Patients with late ST compared with control subjects had a significantly higher percentage of uncovered and malapposed struts.

The identification of procedural problems after stenting by using intravascular imaging modalities offers precious information to improve the clinical outcome. This is in the search of an optimal intravascular strategy to perform coronary interventions.[21,22]

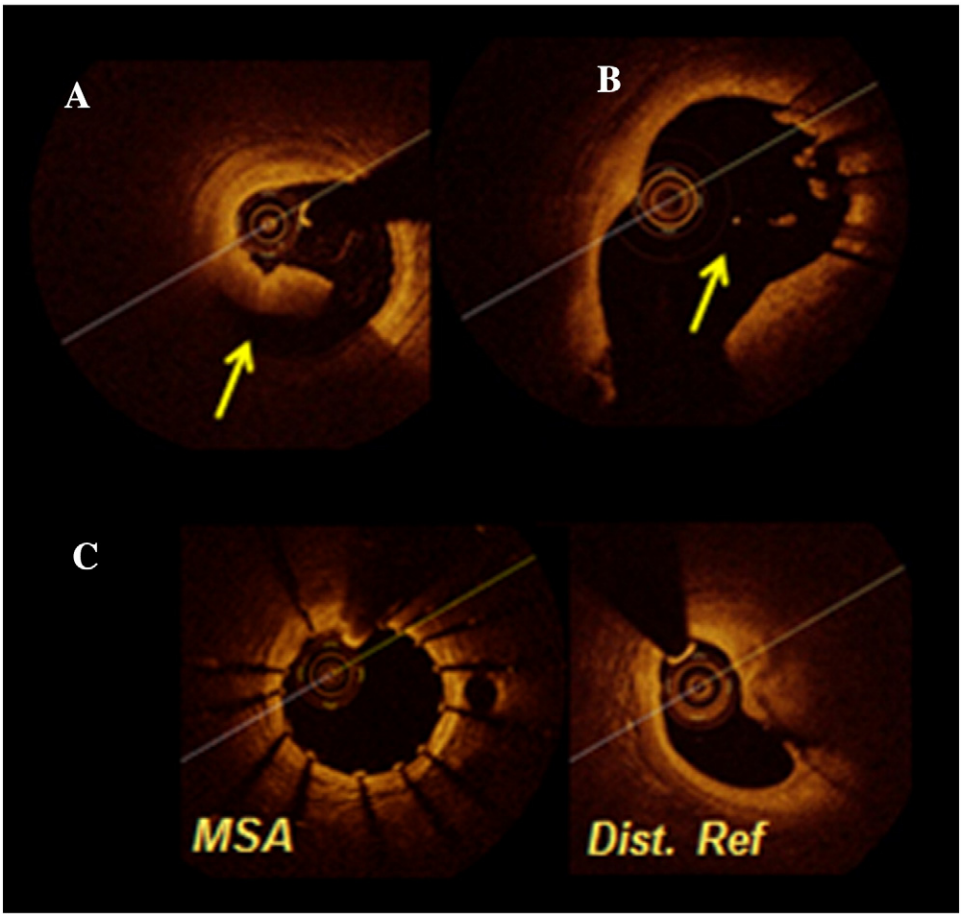
Intravascular ultrasound studies–guided studies focused on the reduction of ST and consequently on major acute coronary events after DES implantation. The contributions by Roy et al[23] and Park et al[24] suggested that IVUS can reduce, respectively, ST after DES implantation and mortality after PCI for unprotected left main disease. One of the potential reasons for the not fully convincing results shown by IVUS study may be the limited spatial resolution of IVUS as compared with OCT, which provides a higher resolution, in the range of 10 to 15 μm, at the expenses of a limited penetration. Therefore, IVUS-accepted criteria that require assessment of vessel architecture, particularly measurement of the external elastic membrane and plaque burden, cannot be obtained with OCT. However, OCT can identify details such as stent underexpansion, malapposition, uneven stent strut distribution, intrastent thrombotic formations, and dissections at the edges and inside the stents, with a level of accuracy unmatched by IVUS.

The first demonstration of the potential of OCT to improve clinical outcome during OCT-guided interventional procedures was offered by the CLI-OPCI study.[8] More than 300 patients undergoing OCT-guided interventions were compared with matched patients undergoing procedures guided by plain angiography. Optical coherence tomography disclosed adverse features requiring further interventions in 34.7% and led to a lower 1-year risk of cardiac death or myocardial infarction (6.6% vs 13.0%; $P = .006$).

Importantly, the CLI-OPCI study applied quantitative thresholds criteria of suboptimal stent deployment, following the concept that mild problems are easily detected by an imaging modality with a resolution in the range of 20 μm.

The present article was designed to further test the efficacy of the quantitative criteria that have been applied in the CLI-OPCI. Indeed, all OCT criteria adopted

Figure 1



Examples of suboptimal OCT results in patients with subacute thrombosis. **A**, A rime of dissections with a width of 300 μ and located at the distal edge of the stent. **B**, A marked underexpansion and malapposition of the proximal portion of a stent positioned in a large vessel. **C**, A small elliptical distal reference cross section with a lumen area of 2.5 mm^2.

in the CLI-OPCI study to define nonoptimal stent implantation were sensibly more frequent in patients experiencing ST (95.2% vs 42.9%; $P < .001$). In particular, edge dissection (with a width >200 μm) and underexpansion of stent are confirmed as main predictors of ST in the early phases after implantation.

This finding brings fuel to the concept that lumen reduction either inside or just outside the stent and the edge irregularities such as dissections are all features that can cause flow impairment. Following the concept that prevention of thrombosis rests mainly on the ability of imaging techniques to depict luminal problems, FD-OCT with its high resolution is likely to exert a key role in this regard.

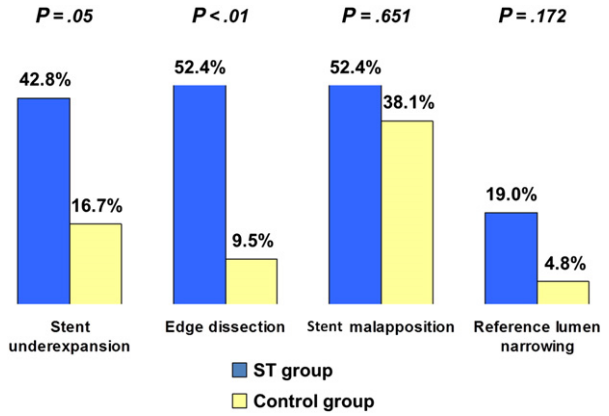
Limitations

The article has some limitations. The studied population is small and nonrandomized due to the complexity of the study design. In fact, subacute ST remains exceedingly rare, and it was not simple to recruit a sufficient number of patients experiencing ST and interrogated with FD-OCT after thrombus aspiration. Although limited in size, this study remains a unique effort to obtain OCT information. Furthermore, the high incidence of suboptimal results in the ST group made possible to convey a clinically relevant message even with a limited number of observations.

It was not possible to recruit the coronary angiograms of the patients, and we could not verify whether operators achieved an optimal angiographic result despite the OCT findings of suboptimal stent deployment. Based on previous data even in presence of optimal angiographic results, approximately one-third of patients have suboptimal results at OCT.

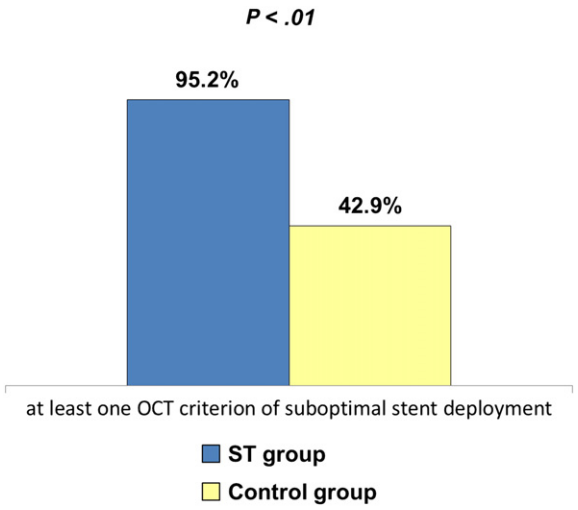
Moreover, OCT interrogation was obtained in the subacute phase and not postintervention. However, we

Figure 2



Percentage of patients with underexpansion, edge dissection, malapposition, and reference lumen narrowing in both ST group and control group.

Figure 3



Percentage of patients presenting ≥1 CLIO-PCI criteria of stent nonoptimal deployment in both ST group and control group.

can reasonably assume that OCT findings obtained within the first month would have been revealed also in the immediate postintervention. For instance, the presence of dissection tend to disappear after approximately 3 months,[25] and in the presence of stent malapposition >300 μm, the gap tend not to be filled even after 1 year since positioning.[26]

Because strut malapposition may be obscured by the presence of thrombus, it is possible that the rate of malapposition was underestimated in the group with ST.

Luminal measurements, either inside the stent or at the references, might get smaller during a short <1-month follow-up. However, this can occur in both groups (ST and controls) and should not generate bias.

Conclusions

Optical coherence tomography is able to reveal nonoptimal stent deployment in most patients who experience subacute ST. Stent underexpansion and edge dissection are confirmed as main determinants of ST in the early phase after implantation. The potential impact of OCT guidance to optimize PCI outcome seems promising and requires further investigations.

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