

Serial optical frequency domain imaging in STEMI patients: the follow-up report of TROFI study

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Aims

To investigate the incidence of incomplete stent apposition and to explore the impact of the presence of thrombus and protruding plaque after stent implantation on neointima formation at follow-up in ST-segment elevation myocardial infarction (STEMI) patients with serial optical frequency domain imaging (OFDI) investigations.

Methods and results

In a multi-centre study, 141 patients with ST elevation myocardial infarction < 12 h from onset were randomized to either PPCI with thrombectomy (TB) using an Eliminate catheter (TB: $n = 71$) or without TB (non-TB: $n = 70$). OFDI after drug-eluting stenting was performed using TERUMO OFDI system. Per protocol, at follow-up 49 patients segments were reimaged. At post-procedure and follow-up, there were no differences in stent and lumen areas between the two groups. At follow-up, per strut-level analysis, percentage of incompletely apposed struts was 0.42 ± 0.94 vs. $0.38 \pm 0.77\%$ ($P = 0.76$), and percentage of covered struts was 92.7 ± 7.2 vs. $94.4 \pm 9.2\%$ ($P = 0.47$) in the TB and non-TB groups, respectively. There was a positive correlation between intra-stent structure (ISS) volume at post-procedure and the neointima volume at 6-month follow-up (Pearson's $r = 0.409$, $P = 0.04$). Up to 12 months, there have been two and four patients having target vessel failure in the TB and in the non-TB groups, respectively.

Conclusions

In patients with STEMI, there were no significant differences in OFDI parameters between TB and non-TB groups at both post-procedure and 6-month follow-up. However, ISS volume at post-procedure was positively associated with neointimal volume at 6-month follow-up.

Keywords

optical coherence tomography • coronary artery disease • acute myocardial infarction • coronary thrombosis • prolapse

Introduction

Primary percutaneous coronary intervention (PCI) has been recommended for the treatment of patients with ST-segment elevation myocardial infarction (STEMI).¹ In this highly thrombotic milieu, thrombus aspiration has been advocated.^{2,3} Nevertheless, the remnant of thrombus and protruding plaque following stent implantation has been not sufficiently studied.⁴ More importantly, little is known about the fate of residual thrombotic/protruding material existing around the struts.

Intravascular optical coherence tomography (OCT) is a light-based imaging modality that provides a high-resolution image of

coronary arteries and enables quantification of the remaining intra-stent structures (ISS) such as tissue prolapse and thrombus after stenting.^{5,6} At follow-up, evaluation of intra-stent neointima formation can be also achieved in a precise manner using OCT. The recently developed optical frequency domain imaging (OFDI) technique, an analogue of the Fourier-domain OCT, is the state of the art of this technology and commonly used in the current clinical setting.

The aim of this study is to investigate the incidence of incomplete stent apposition (ISA) and to explore the impact of the presence of thrombus and protruding plaque after stent implantation on neointima formation at follow-up in STEMI patients with serial OFDI investigations.

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Methods

Study population

We investigated the patients enrolled in the TROFI trial. This is a prospective, randomized controlled, single blinded, multicenter clinical study enrolling 141 STEMI patients at five European sites.⁷ Briefly, STEMI patients having an angiographically visible stenosis (>30%) or TIMI ≤ 2 in a single *de novo*, native, previously unstented vessel were considered for enrolment. Patients were randomized in a 1:1 ratio to receiving primary PCI either with TB (*n* = 71) or without TB (*n* = 70) prior to biolimus-A9 eluting metallic stent (Nobori[®]; Terumo Europe, Leuven, Belgium) implantation. The primary endpoint was defined as minimal flow area which was measured by OFDI after stenting during the baseline procedure. Per protocol, 49 patients underwent angiography and OFDI follow-up in three predefined enrolling centres.

This study protocol was approved by the Ethics Review Committee in each participating site, and written informed consent was obtained from each enrolled patient.

Treatment procedure

In the TB arm, multiple pullbacks with the TB catheter (Eliminate[®], Terumo, Tokyo, Japan) were recommended until no further decrease of the intraluminal mass on angiography could be obtained. At least two thrombus aspirations had to be done and the TB procedure could be stopped only when there was no more thrombotic material in the aspirate for at least two consecutive aspirations. In case of angiographic luminal defect after stenting, an additional aspiration could be performed. Per protocol, the operator was blinded to the OFDI results during the procedure.

The Nobori DES was implanted either after pre-dilatation or in a direct stenting manner. If pre-dilatation was performed, the use of a commercially available balloon with a length not exceeding the length of the stent to be implanted was recommended. Full lesion coverage had to be ensured by implantation of one or multiple stents. Post-dilatation after stenting could be performed at the discretion of the investigator in either treatment arm.

Image acquisition

As long as patient's haemodynamics was stable, intracoronary administration of 0.2 mg nitroglycerin was given before the OFDI imaging procedure. This imaging procedure was performed with a TERUMO OFDI system (LUNAWAVE[®], FastView[®]; Terumo Europe, Leuven, Belgium). The images were acquired using a non-occlusive technique at a rate of 160 frames/s during an automated pullback of the catheter at a speed of 20 mm/s. The pullback was performed during continuous intracoronary injection of contrast medium through the guiding catheter using an injection pump at a flow rate of 3–4 mL/s for a maximum of 4 s (300 psi). The imaging data once saved in the console were converted into AVI files and then transferred for the off-line analyses.

Off-line imaging analyses and definition

Off-line imaging analyses were performed at an independent imaging corelab (Cardialysis, Rotterdam, The Netherlands). A quantitative analysis software (QIVUS, MEDIS, Leiden University, Leiden, The Netherlands) was used for the OFDI analyses.

Region of interest (ROI) was selected as the stented segment, which was defined as the segment between the most distal and proximal frame where metallic stent struts were visible around the whole vessel circumference.⁸ The stent and lumen areas were semi-automatically traced at every 1 mm. Neointima area was defined as the difference between stent and lumen areas (in absence of ISA). Definitions of ISA

and coverage have been consistently described and reported in the literature.⁹ In addition, we analyzed all individual masses within the stent area which were defined as ISS. ISS was categorized into ISS attached to vessel wall (i.e. thrombus or prolapse) and non-attached ISS.⁶ These definitions were based on the following concepts: plaque prolapse has been defined as a convex-shaped protrusion of tissue between adjacent stent struts toward the lumen without disruption of the continuity of the luminal vessel surface.¹⁰ At variance with this definition, plaque prolapse as seen in acute myocardial infarction may have a disrupted and irregular surface, and adjacent struts may be embedded or even buried in the prolapsing masses. Consequently, plaque prolapse is frequently indistinguishable from an intraluminal mass attached to the vessel wall, which is presumably thrombus. Therefore, in this study, plaque prolapse and thrombus attached to the vessel wall were categorized as a single variable, attached ISS.⁷

In order to achieve a more accurate estimation for ISS volume, the cross-sectional ISS analysis was performed in every frame along the whole stented region. When more than two attached or non-attached ISS were detected in an analyzed cross-section, the ISS area was calculated by cumulating all individual ISS areas. If there is no ISS in an analyzed cross-section, ISS area was regarded as zero. ISS volume was calculated by numerical integration based on the disk summation method, which formula is shown as follows:

$$\text{ISS volume (mm}^3\text{)} = \sum_{i=1}^n \{\text{ISSarea}(i)\} \times h$$

where *n* indicates the number of analyzed frames in ROI and *h* indicates the width of sampling distance (0.125 mm).

The OCT healing score is a weighted index that combines the following parameters:

- (i) presence of ISS is assigned weight of '4';
- (ii) presence of both malapposed and uncovered struts (%MU) is assigned a weight of '3';
- (iii) presence of uncovered struts alone (%U) is assigned a weight of '2'; and finally,
- (iv) presence of malapposition alone (%M) is assigned a weight of '1'.

$$\text{Neointimal healing score} = (\%ISS \times '4') + (\%MU \times '3') + (\%U \times '2') + (\%M \times '1')$$

Data monitoring

The monitoring for this study was conducted by sponsor or sponsor designee in all centres. One hundred percent source data verification were performed including device malfunctions and serious events. The independent clinical events committee (CEC), which comprised interventional and/or non-interventional cardiologists, adjudicated all clinical events and clinical endpoints based on protocol. The CEC members were not participants in the study and were blind to OFDI imaging results of the study.

Clinical outcomes

The main clinical endpoint was target vessel failure (TVF) defined as cardiac death, reinfarction in the territory of infarction-related vessel (Q wave and non-Q wave), or clinically driven target vessel revascularization. Stent thrombosis was adjudicated according to academic research consortium definition.¹¹

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD), and categorical variables as percentages. Comparison was performed by unpaired *t*-test between the randomized groups and by paired *t*-test

between post-procedure and follow-up if continuous variable was normally distributed. In case of skewed distribution, the same approach was used after logarithmic transformation. Categorical variables were tested by Fisher's exact test. Correlations were tested by Pearson's correlation coefficient (r). All statistics were performed using PASW statistics 18 software (SPSS Inc., Chicago, IL, USA). $P < 0.05$ was considered statistically significant.

Results

Between 24 November 2010 and 11 October 2011, 141 patients (71 patients in the TB arm and 70 patients in the non-TB arm) were enrolled at five European sites. In three predefined centres, the enrolled patients were followed up angiographically and with OFDI at 6 months (26 patients in the TB arm and 25 patients in the non-TB arm) (Figure 1). Paired (post-procedure and follow-up) OFDI recordings were available in 25 and 24 patients in the TB and the non-TB arms, respectively. Baseline characteristics of the patients were well matched between the two groups (Table 1). The TB device reached and crossed the lesion in all cases. The number of aspirations

was 1.81 ± 0.40 . The number of stent per lesion, total stent length, and diameter are comparable between the two groups.

In the pre- and post-procedural angiographic assessments and TIMI flow grade were comparable in both groups Table 2.

OFDI results

At post-procedure, there were no differences in stent and lumen areas between the two groups. ISA area was 0.12 ± 0.20 vs. 0.07 ± 0.11 mm² in the TB and non-TB groups, respectively ($P = 0.75$). Similarly, the OCT healing score did not differ between the two groups (202 ± 45 vs. 196 ± 17 , $P = 0.49$) Table 3.

At 6 months follow-up, there were also no differences in lumen, ISA or neointima areas between the two groups. Per strut-level analysis, percentage of ISA struts was 0.42 ± 0.94 vs. $0.38 \pm 0.77\%$ ($P = 0.76$), and percentage of covered struts was 92.7 ± 7.2 vs. $94.4 \pm 9.2\%$ ($P = 0.47$) in the TB and non-TB groups, respectively. The OCT healing score considerably decreased from baseline in both groups, but was not significantly different between the two groups (17 ± 16 in the TB and 13 ± 20 in non-TB group, $P = 0.49$) Table 3.

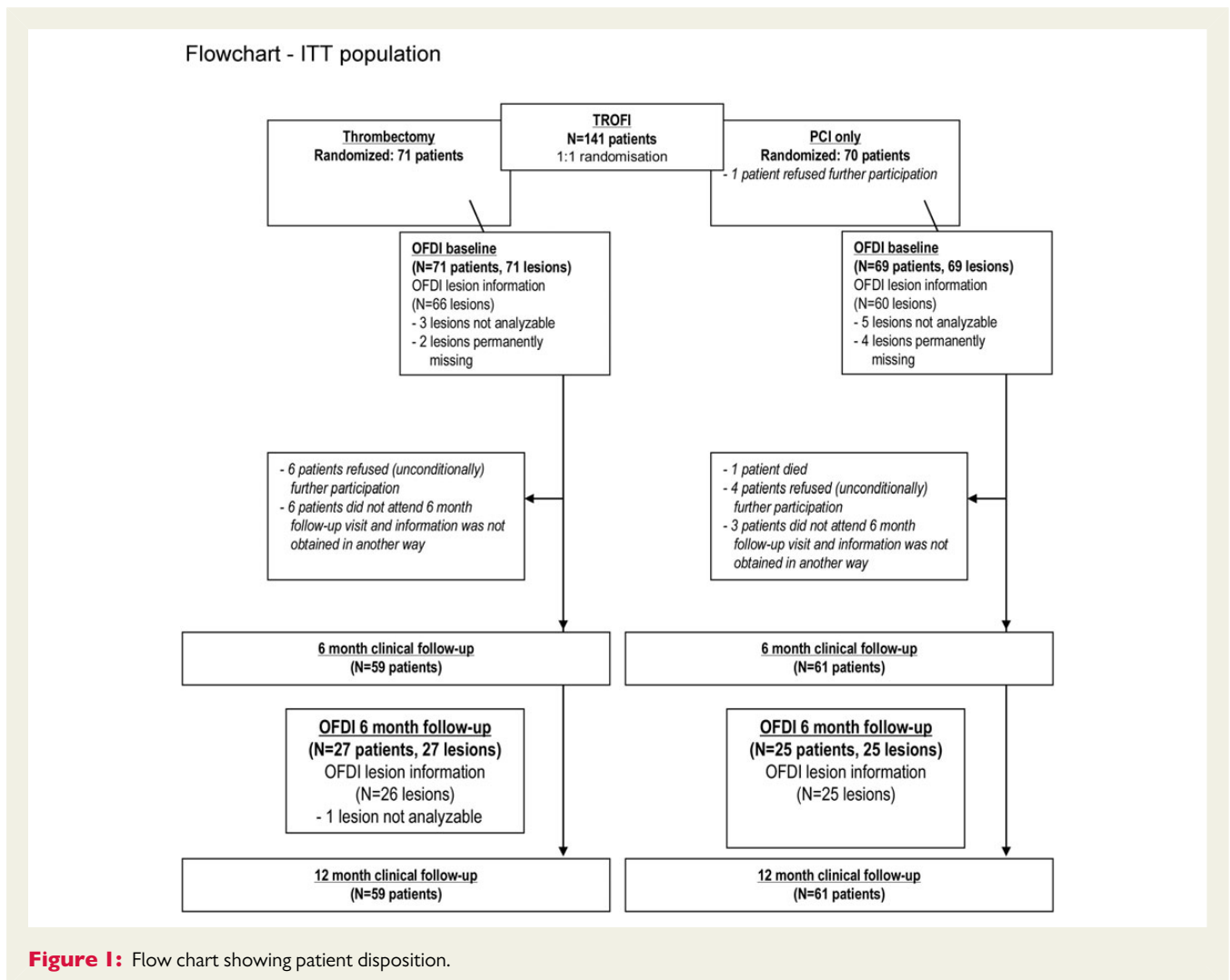


Table 1 Baseline and procedure characteristics

Demographics	Thrombectomy (N = 26)	Non-Thrombectomy (N = 25)	P
Age	59 ± 10	57 ± 13	0.42
Male (%)	77	76	0.94
Heart rate	73.77 ± 21.59	71.76 ± 14.68	0.7
Risk factors (%)			
Diabetes mellitus	7.7	8.0	0.97
Insulin	0.0	0.0	
Current smoking	58	52	0.49
Hypercholesterolemia	42	20	0.08
Hypertension	38	28	0.43
Family history of CAD	50	56	0.66
Procedural details			
Stents implanted per lesion	1.23 ± 0.6	1.36 ± 0.8	0.5
Mean total stent length/lesion (mm)	23.2 ± 10.5	25.4 ± 13.1	0.52
Mean stent diameter (mm, nominal)	3.1 ± 0.39	3.1 ± 0.37	0.64
Number of aspiration/lesion	1.81 ± 0.40		
Device successfully reached (%)	100		
Device successfully crossed (%)	100		
Thrombus successfully removed (%)	100		

Table 2 Quantitative coronary angiography pre- and post-PCI

	Thrombectomy (26 lesions)	Non-Thrombectomy (25 lesion)	P
Preprocedure			
TIMI flow (%)			0.38
0	36.0	29.2	
1	4.0	12.5	
2	32.0	16.7	
3	28.0	41.7	
Thrombus burden index before wiring (%)			0.81
0	4.0	4.2	
1	8.0	12.5	
2	4.0	8.3	
3	44.0	33.3	
4	4.0	12.5	
5	36.0	29.2	
Lesion length (mm)	15.3 ± 7.9	14.0 ± 4.9	0.64
RVD (mm)	2.8 ± 0.45	2.7 ± 0.52	0.27
Minimal lumen diameter (mm)	0.48 ± 0.45	0.56 ± 0.60	0.61
% Diameter stenosis (mm)	82.4 ± 15.8	79.4 ± 21.6	0.59
Post-procedure			
TIMI flow (%)			
3	100	100	1.0
Stent length (mm)	21.1 ± 10.5	20.2 ± 8.4	0.75
RVD post (mm)	2.9 ± 0.45	2.8 ± 0.50	0.61
Minimal lumen diameter post (mm)	2.5 ± 0.44	2.5 ± 0.52	0.88
% Diameter stenosis	12.9 ± 7.7	10.1 ± 7.3	0.20

Patient N=49 ITT population with 6M FUP

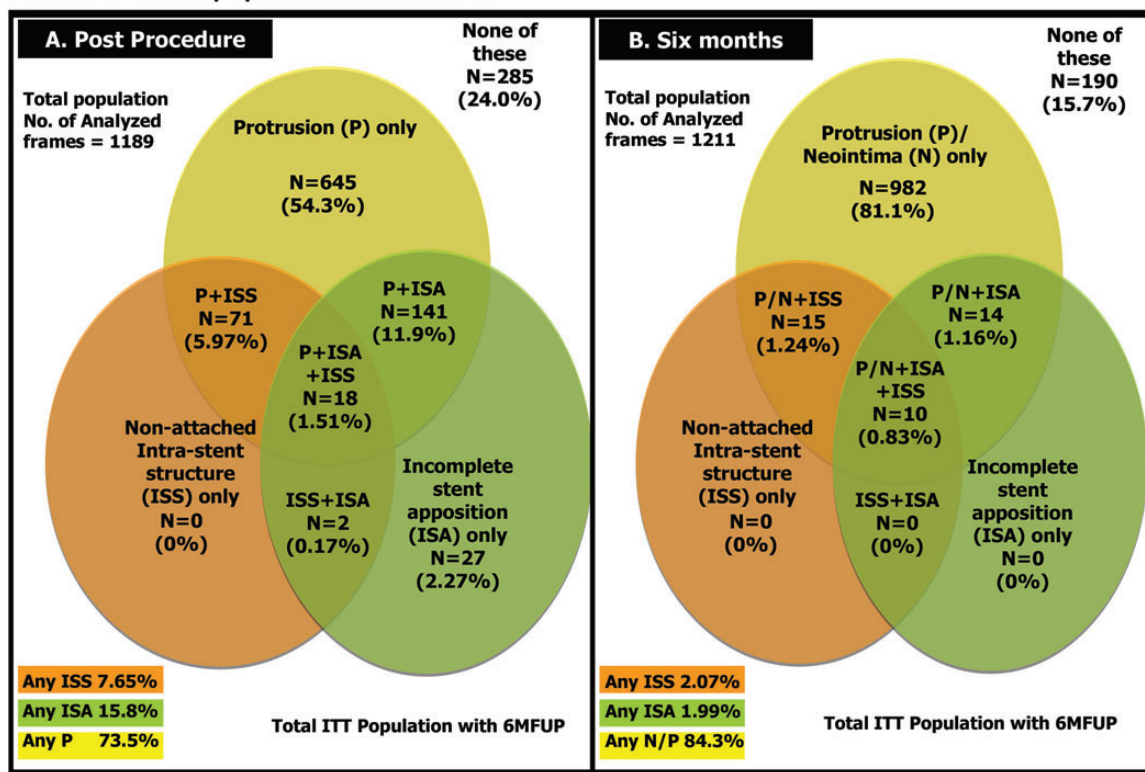


Figure 2: The Venn diagram shows the relationship of the three components that determine the flow area. This means the area where the blood flows, these are: intra-stent structure (ISS) either attached (i.e. prolapse at pos-PCT and neointima at follow-up) or non-attached (i.e. intraluminal mass); and incomplete stent apposition (ISA); in panel A, it appears that the most common isolated observation was prolapse of the material into the lumen (54.3%). The non-attached ISS consistently co-existed with prolapse (5.97%), with malapposition (0.17%), or with both (1.51%). In the same cross-section, prolapse and malapposition (11.9%) could co-exist. Malapposition alone was a quite rare phenomenon (2.27%). (B) At 6 months follow-up, most of frames showed only neointima (81.1%), or in combination with either with non-attached ISS (1.24%) or with ISA (1.16%). Only 0.83% of the frames showed neointima, non-attached ISS, and ISA. More importantly, there were 15.7% of the frames without any neointima which showed the clustering of the uncovered struts.

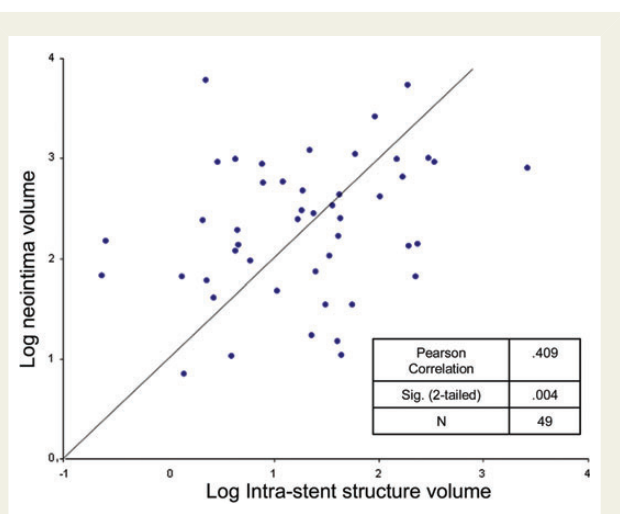


Figure 3: Correlation between ISS and neointima volumes.

finding, does not exist neither at baseline nor at follow-up; and (v) despite all patients had STEMI and were treated with DES, both factors associated with ISA, there was an important reduction in ISA from post-procedure to follow-up (15.8–1.99% of frames).

DES in a thrombotic lesion is associated with less strut coverage

Newer drug-eluting stents have demonstrated a reduction in incidence of adverse cardiac events when compared with bare-metal stents for the treatment of STEMI at 1 year.¹² Despite this, there are still concerns about a potentially higher risk of stent thrombosis (ST) after DES implantation during primary PCI at a later time follow-up. The two most common findings associated with ST are lack of endothelium coverage and presence of ISA. Morphometric analysis showed that ruptured plaque had significantly less neointimal thickness, greater fibrin deposition and inflammation, and higher prevalence of uncovered struts than stable plaque (49 [16, 96] vs. 9 [0, 39%], $P = 0.01$).¹³ One plausible explanation is the fact that these necrotic core rich lesions, which are more avascular and less

Table 4 Non-hierarchical clinical outcomes up to 12 months follow-up

N (%)	TB (N = 71)				Non-TB (N = 70)			
	Discharge	<1 month	<6 months	Total 12 months	Disch	<1 month	<6 months	Total 12 months
TVF	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.8)	1 (1.4)	1 (1.4)	3 (4.3)	4 (5.7)
All-cause mortality	0	0	0	0	0	0	1 (1.4)	1 (1.4)
Cardiac death	0	0	0	0	0	0	1 (1.4)	1 (1.4)
Non-cardiovascular death	0	0	0	0	0	0	0	0
Vascular death	0	0	0	0	0	0	0	0
Any myocardial (re) infarction	0	0	0	1 (1.4)	0	0	0	0
Target vessel revascularization	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.8)	1 (1.4)	1 (1.4)	2 (2.8)	3 (4.3)
Stent thrombosis	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)	0	0	0	0

Target vessel failure (TVF), defined as cardiac death, reinfarction in the territory of infarction-related vessel (Q wave and non-Q wave), or clinically driven target vessel revascularization.

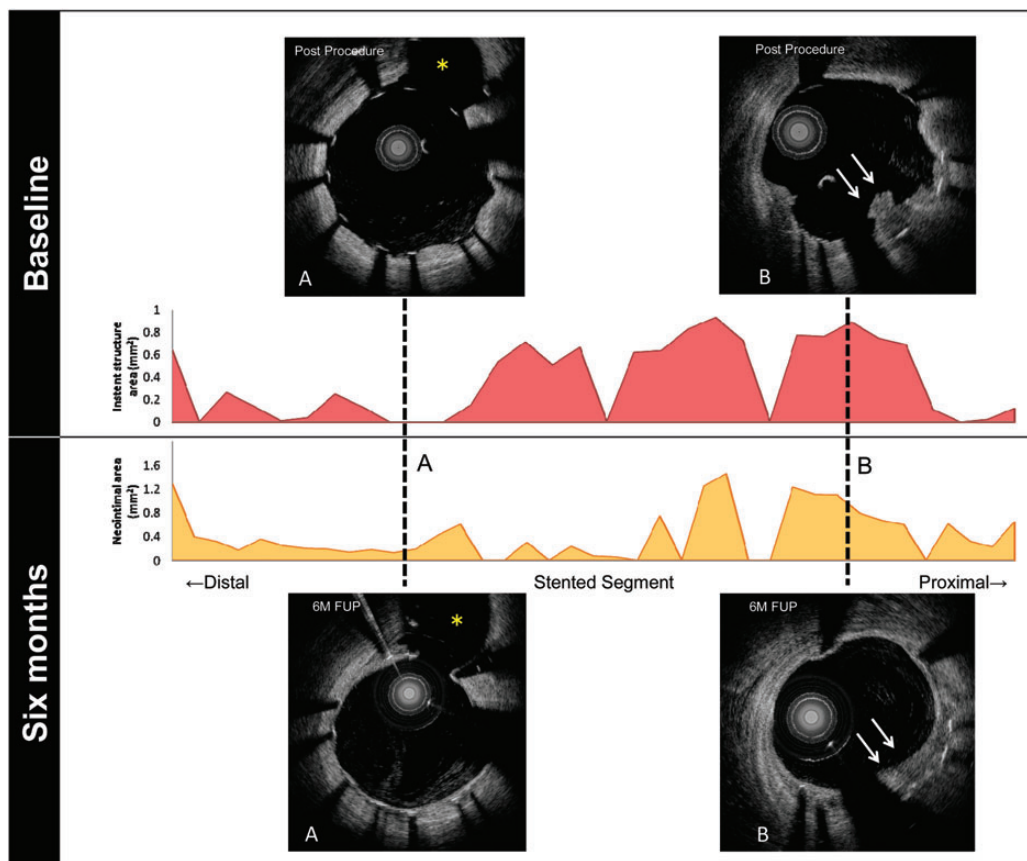


Figure 4: Case examples showing the relationship between ISS and neointima. In the upper panel (baseline), the area graph shows the trend of the ISS over the frames from distal to proximal. In the bottom panel, the area graph shows the distribution of neointima area. In general, it can be observed that the neointima formation occurs in regions where at post-PCI the ISS was present (red regions correspond to yellow regions). The corresponding cross-sections from baseline and follow-up (A and B) exemplified this further. (A) At baseline, there was no ISS and the corresponding cross-section at follow-up shows minimal neointima. In contrast, in (B) at baseline, ISS was present (white arrows) and the same angular sector shows neointima at follow-up.

cellular, are less prone to be covered by migrating cells.¹⁴ In addition, the biolimus-A9 is highly lipophilic (10 times more lipophilic than sirolimus) and thereby has great affinity for necrotic core which may result in higher concentration of the drug locally. Further, the superimposed thrombus will increase the drug uptake.¹⁴ Taken all together, it means that the tissue growth inhibition will be marked in these lesions. In the present study, however, the percentages of covered struts were observed in $92.7 \pm 7.2\%$ in TB group and $94.4 \pm 9.2\%$ in non-TB group at 6 months follow-up ($P = 0.47$), similarly to that reported for all-comer populations— 93.9% —in a pooled data from the LEADERS and the RESOLUTE OCT sub-studies, including stable and STEMI patients.¹⁵ This is a fair comparison, since all these data have been analyzed in the same imaging corelab, using exactly the same methodology and definitions.

We found a moderate positive relationship between the post-procedural ISS volume and neointima formation at 6 months follow-up. It has been described that the thrombus can nest and promote the growth of smooth muscle cells. This may be due to the presence of chemoattractants and growth factors in the thrombotic milieu.¹⁶

The exquisite analysis of prolapse and thrombus can only be achieved by OCT/OFDI. It has been reported that prolapse and thrombus can be detected in 100 and 54% of the cases by OFDI and only in 3 and 40% by IVUS.⁸ This may explain why IVUS has failed to show any relationship between prolapse and restenosis.¹⁷ Interestingly, an example case demonstrated that the location of ISS at post-procedure well matched that of neointima at follow-up (Figure 4).

Incomplete strut apposition

In both groups, the prevalence of ISA was very low at 6 months follow-up (0.42 vs. 0.38% for TB and non-TB groups, respectively). On the contrary to our assumption of the dissolution of thrombus existing between stent struts and vessel wall together with the profound neointima inhibition due to high concentration of the antiproliferative drug, the incidence of late ISA in STEMI patients was very low in the present study. Actually, the incidence (0.6%) is similar, if not smaller, to another report in which only one third of patients had STEMI.¹⁸ Needless to say, the observed percentage of malapposed struts in this study at 6 months might increase over time. Even in more stable populations, the percentage of malapposed struts (at >5 years), is higher (1.2% for SES and 0.7% for PES) than the one reported here.¹⁹ The reason for this cannot be only attributed to the longer term follow-up but also to the stent type. For example, it has been shown that the underlying mechanism(s) of ST is due to localized strut hypersensitivity in SES, whereas malapposition secondary to excessive fibrin deposition is mainly in PES at very long-term follow-up.²⁰

Clinical implications

It has been observed that thrombus aspiration improves ST segment resolution and myocardial blush scores, and a reduction in cardiac mortality was observed in the TAPAS study.²¹ In our study, adjunctive TB was not associated with any significant benefit in terms of flow area at post-procedure or ISA at 6 months follow-up.

Study limitations

First of all, the intraluminal mass outside the stent area was not taken into account in this study. In STEMI patients, the stent struts might be buried in thrombotic mass and potentially some amount of thrombus existed in the space between the struts and vessel wall. It was also challenging to depict the precise boundary between the vessel wall and thrombus behind the stent struts because of acoustic shadow and light-intensity attenuation by red thrombus. Secondly, as per protocol, only patients from selected centres have come back for follow-up imaging, which resulted in only 49 patients with repeated OFDI.

Conclusions

In patients with STEMI, there were no significant differences in OFDI parameters between TB and non-TB groups at both post-procedure and 6 months follow-up. However, ISS volume at post-procedure was positively associated with neointimal volume at 6 months follow-up. DES with biodegradable polymer showed to be safe with very low adverse events rate up to 1 year.

Conflict of interest: V.B. and D.P. are Terumo employees. The rest of authors have no conflict of interest to declare.

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IMAGE FOCUS

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Delayed presentation of a traumatic bilobed pseudoaneurysm of the left ventricular outflow tract

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A 37-year-old man presented with chest pain and shortness of breath following a high-velocity motorbike accident with blunt injury to the chest 10 months earlier. Thoracic computed tomography (CT) scan showed a communicating bilobed left ventricular (LV) pseudoaneurysm with a 6 cm (Panel A, black arrow) and 3 cm (Panel A, white arrow) aneurysm sack, respectively. Pre-operative transoesophageal echocardiography (TOE) provided a full depiction of the LV and the adjoining pseudoaneurysm, enhancing the pre-operative evaluation of the extent of the defect. It demonstrated an enlargement of the LV with two dyskinetic cavities (Panel B, black arrow, small aneurysm; white arrow, large aneurysm) localized in the diaphragmatic region.

Emergency surgery was done, and revealed the communication between the smaller anterior and the larger posterior aneurysm (Panel C, asterisk).

The smaller aneurysm sack was opened and retracted to visualize the LV wall defect. Repair of the defect was accomplished using a Dacron patch. Mattress sutures around the patch edges with Teflon pledgets achieved haemostasis (Panel D). Post-operative CT scan (Panel E) and TOE revealed no paraprosthetic leakage. Patient's post-operative recovery and follow-up were uneventful.

LV pseudoaneurysms occur through cardiac rupture limited by surrounding pericardium. As most cases are related to myocardial infarction or cardiac surgery, traumatic LV pseudoaneurysms are rare and difficult to diagnose. Besides signs of heart failure and dyspnoea, chest pain is a common symptom. Mortality rate is high, especially in patients not undergoing surgery.

