Intravascular examination in patients with Very Late Stent Thrombosis

Protocol For Prestige Investigators

OCT pullback during emergency percutaneous coronary intervention (PCI) in patients presenting with ST-segment elevation myocardial infarction (STEMI) caused by DES LST.

Exclusion criteria for OCT pullback:

Cardiovascular History

1. Cardiogenic shock (BP < 80mm Hg for > 30 minutes).
2. Patient is post-resuscitation.

Angiographic exclusion criteria

1. Unprotected left main coronary artery disease with ≥ 50% stenosis.
2. Infarction lesions in bypass grafts.
3. No suitable anatomy for OCT:
    - extreme tortuousity,
    - very distal culprit lesion, and
    - large infarct vessel > 4 mm in diameter
    - thrombus aspiration unable to reestablish antegrade blood flow

OCT imaging

- Intracoronary nitroglycerin (200 mcg) shall be administered before any imaging procedures.
- Images are acquired with an automated pullback at a high speed rate of 20 mm/s, then digitally stored and submitted to the core laboratory for offline evaluation and subsequent analyses.
- OCT pullback are to be performed using C7XR OCT Imaging System, LightLab Imaging, Westford, Massachusetts.

- The OCT pulback performed in non-obstructive angiographic lesions with TIMI grade 2-3 flow.
- In patients with TIMI flow grade 0-1 or evidence of angiographic filling defect, the OCT assessment of the infarct-related is performed after thrombectomy using a manual thrombus aspiration catheter and following coronary flow restoration.
- Patients with no reflow phenomen (TIMI 0-1 flow grade) after thrombus aspiration will be excluded from the protocol.
- No predilation is allowed before OCT scan.
- Coronary occlusion at the ostium of the infarct related artery will be considered for the OCT analysis only if after the wire crossing the culprit lesion could be located distally to the ostium.

Guidelines for OCT Acquisition using the C7XR Imaging System and Dragonfly Catheter

- Before introduction in the coronary artery, the OCT image catheter (Dragonfly) should be inspected for proper functioning and the z-offset should be manually corrected if the automatic setting is considered inappropriate.

Recording

- The Dragonfly catheter should be positioned distally to the target segment in such a way that the tip is approximately 2 cm distally to the region of interest. The lenght of the OCT scan, normally 5.4 cm, has to be used to extend at maximum the vision of the infarct related artery, inlcuding the proximal segment. The position of the Dragonfly catheter should be documented by cine-angiography in an overlap-free, non-foreshortened view of the target vessel.
- An automatic injector (i.e. Medrad pump or Acist) filled preferentially with Visipaque (270 or 320) at 37 degrees C should be connected to the standard y-piece of the guiding catheter. After confirming correct position of the Dragonfly catheter and that the guiding catheter is selectively engaged into the ostium of the coronary artery by

fluoroscopy, the artery should be cleared from blood by automatic injection of Visipaque at a flow rate of 3-4 ml/sec and 350-450 psi, depending upon type of vessels, size of vessel, and lesion location. EKG should be continuously recorded during the injection

- After sufficient clearance of the artery, the automated pullback should be started at a speed of 20mm/sec. Injection flow rate and pressure should be adjusted according to the image quality if needed. The pullback should be stopped after visualization of the complete coronary segment or in case of arrhythmia, ST-elevation or severe chest pain.
- After completion of the OCT study, the OCT image the OCT catheter should be removed and guiding catheter disengaged for a complete and prompt clearance of the injected media.

Data Export

- The OCT images should be recorded on DVD as RAW files to allow an independent analysis by Core Labs.

OCT Measurements

OCT Quantitative measurements are performed off-line throughout the entire length of the stent, including distal and proximal reference segments at every 1 mm interval, using a dedicated automated contour-detection system (OCT system software B.0.1, LightLab).

All cross-sectional images (frames) were screened for quality and excluded from analysis if >25% of the image was out of the screen, if a sidebranch was present in the cross-section, or for poor image quality caused by residual blood.

Qualitative imaging assessment is performed in every frame to detect the presence of intra-luminal thrombus.

Intracoronary thrombus identified as any abnormal mass protruding beyond the stent struts into the lumen, with signal backscattering and various degrees of attenuation.

A ruptured plaque defined using validated criteria for plaque characterization.

Stent and lumen contours are semi-automatically delineated, and folowing parameters are assessed:

strut level neointimal hyperplasia (NIH) thickness,

strut coverage

strut wall apposition

Struts graded as covered (>10 μm neointimal thickness) or uncovered (<10μm neointimal thickness), based on the current axial resolution of the available OCT system.

The number and percentage of completely apposed vs. unopposed, and covered vs. uncovered struts are determined. The proportion of frames with >30% uncovered struts is calculated.

The maximum uncovered segment length defined as the number of consecutive frames at 1 mm intervals with uncovered struts.

Strut malapposition –synonymous with incomplete strut apposition (ISA) – defined as separation of the stent strut surface from the inner vessel wall by a distance greater than the width of the stent strut plus the polymer coating, according to the different manufacture specifications.

The maximum malapposition length - defined as the number of consecutive frames at 1 mm intervals with malapposed struts.

Table 1. Optical coherence tomography imaging parameters.

Cross-section level analysis
Number of analyzed cross-sections per patient
Number of struts analyzed per cross-section
Frequency of cross-sections with uncovered struts
Frequency of cross-sections with >30% uncovered struts
Maximum length of segments with uncovered struts, mm
Maximum length of segments with malapposed struts, mm
Minimum stent area, mm^2
Mean stent area, mm^2
Mean neointimal area, mm^2
Strut-level analysis
Number of struts analyzed per patient
Number of uncovered struts per patient
Frequency of uncovered struts per patient, %
Number of malapposed struts per patient
Frequency of malapposed struts per patient, %