ARTICLE IN PRESS

Cardiovascular Revascularization Medicine xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Safety of hydrophilic guidewires used for side-branch protection during stenting and proximal optimization technique in coronary bifurcation lesions

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ARTICLE INFO

Article history:
Received 11 December 2015
Received in revised form 7 April 2016
Accepted 19 April 2016
Available online xxxx

Keywords:
Coronary bifurcation lesions
Hydrophilic guidewire
Polymer shearing
Proximal optimization

ABSTRACT

Background and propose: In coronary bifurcation lesions (CBL), hydrophilic guidewires used for side-branch (SB) protection can be withdrawn from underneath the stent easier than other wires. However, the safety of which has not been investigated.

Methods/materials: We performed scanning electron microscopic (SEM) examination of hydrophilic wires – the Whisper and Runthrough wires – used for SB protection during stenting and proximal optimization technique (POT) in 30 patients with CBL. The distal 15 cm of the wire was examined every 1 mm by SEM and 4500 segments were analyzed to investigate for wire fracture, polymer shearing (PS), and its correlations with post-stenting creatine kinase (CK)-MB release.

Results: SEM examination showed no evidence for wire fracture. The total area of PS and the largest defect on the wire were significantly larger with the Whisper wire versus the Runthrough wire (0.15 ± 0.04 mm^2 vs. 0.026 ± 0.01 mm^2 and 0.04 ± 0.05 mm^2 vs. 0.01 ± 0.01 mm^2; $P < 0.05$, respectively). The total length of PS and the longest defect on the wire were significantly longer with the Whisper wire vs. the Runthrough wire (12.1 ± 14.5 mm vs. 2.7 ± 3.0 mm and 2.9 ± 4.2 mm vs. 1.0 ± 1.2 mm; $P < 0.05$, respectively), but there were weak correlations between the extents of PS with CK-MB release.

Conclusions: Hydrophilic guidewires may be safely used for SB protection during stenting and POT in CBLs. The extent of PS was significantly greater with the Whisper wire than with the Runthrough wire, but its correlation with post-stenting CK-MB release was weak.

1. Introduction

Coronary bifurcation lesions (CBL) are challenging and associated with a higher rate of adverse events than non-bifurcation lesions [1]. In the era of drug-eluting stents, 2 primary interventional strategies for treating CBL include the complex strategy – main vessel (MV) and side-branch (SB) stenting, and the simple strategy – MV stenting with provisional SB stenting. Since the complex strategy is associated with increased event rates, the simple strategy with provisional SB stenting is now the preferred approach [2–4].

In the simple strategy, a guidewire is frequently inserted into the side-branch (SB) to prevent acute SB occlusion during main vessel (MV) stenting. This is known as the "jailed wire technique". It has been shown that SB compromise is not inconsequential and is associated with a greater risk of myocardial infarction or cardiac death [5–7].

Hydrophilic guidewires can be withdrawn from underneath the stent struts easier than other wires. However, there are concerns that wire fracture or polymer shearing (PS) can occur during the withdrawal of hydrophilic wires, which may lead to myocardial infarction. However, data on the incidence of wire fracture with the jailed wire technique are scant. A number of case reports demonstrated the fracture of non-hydrophilic guidewires used as the jailed wire technique during MV stenting [8–11]. One case report showed evidence for polymer damage to a hydrophilic wire jailed in the SB [12]. The sheared and embolized polymers have been detected inside the small intramyocardial arteries in biopsy specimens, but the link between PS and myocardial infarction (MI) could not be ascertained [13].

Thus far, no study investigated the safety of hydrophilic wires used as the jailed wire during stenting and proximal optimization technique (POT) in CBLs. Therefore, we investigated the rate of wire fracture and

Abbreviations: CBL, coronary bifurcation lesions; MV, main vessel; POT, proximal optimization technique; SEM, scanning electron microscopic; SB, side-branch.

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http://dx.doi.org/10.1016/j.carrev.2016.04.006
1553-8389/

extent of PS with hydrophilic wires used as the jailed wire during stenting and POT by a sophisticated technique such as scanning electron microscopic (SEM) examination of jailed wires. We also investigated correlations between the extents of PS with post-stenting creatine kinase (CK)-MB levels.

2. Methods

2.1. Patient population

Between May 2013 and April 2014, 30 consecutive patients with CBL were enrolled into the study. All patients underwent the simple strategy — MV stenting with provisional SB stenting. Inclusion criteria were as follows: CBL requiring percutaneous coronary intervention (PCI); and the MV diameter > 2.5 mm, and the SB diameter ≥ 2.25 mm. Exclusion criteria were as follows: patients with chronic total occlusions; and the use of 2-stent strategy. The review board of the University of Alabama, Birmingham approved the study.

2.2. PCI procedure

A 6 F or 7 F guiding catheter was used for coronary intervention. All patients were pretreated with aspirin and either clopidogrel or ticagrelor. Heparin or Bivalirudin was used in all patients. Glycoprotein IIb/IIIa receptor inhibitors were used at the discretion of operators. We used 2 types of hydrophilic guidewires for the MV and SB protection: (1) Terumo Runthrough NS floppy guidewire (Terumo Medical Corporation, Somerset, NJ); and (2) Hi-Torque Whisper guidewire (Abbott Vascular, Santa Rosa, CA). The Whisper wire design consists of a stainless steel tapered core with a flexible tip. The wire is covered with hydrophilic coating on the distal portion and full polytetrafluoroethylene (PTFE) polymer jacket. The Runthrough wire design consists of DuoCore™ technology, which enables connection with two different metals to improve torque response. The wire is covered with durable hydrophilic coating (Terumo M Coat™) on the distal portion and PTFE polymer cover on the proximal portion.

The operators were permitted to use either of these wires for SB protection. If the operator used the Whisper wire in the SB, a Runthrough wire was advanced into the MV and vice versa. We used provisional stent strategy for the bifurcation lesions stenting and the stent diameter was chosen based on the distal reference vessel diameter. After stenting, the jailed guidewire was removed from underneath the stent struts and advanced into the SB. Subsequently, POT was performed using a large, short oversized non-compliant balloon for post-dilation. Kissing balloon inflation (KBI) of the MV and SB was performed if there was > 75% stenosis of the SB after POT [14]. Procedural success was defined as TIMI 3 flow in the MV and SB and a < 30% residual stenosis in the MV. SB occlusion was defined as TIMI flow grade < 3 immediately after the MV stenting. CK-MB levels were measured in all patients at baseline and every 8 h after PCI. Periprocedural myocardial infarction (MI) was defined as an elevation of CK-MB more than three times upper reference limit or new Q waves in 2 or more contiguous leads of the electrocardiogram [15].

2.3. Scanning electron microscopic examination

The jailed wires used for SB protection were analyzed at the Electron Optics Laboratory, Department of Material Science and Engineering, University of Alabama-Birmingham. The distal 15 cm of the wire was studied every 1 mm by SEM and 4500 segments (1 mm each) were analyzed to investigate for wire fracture and PS by the SEM (Model FEI FEG 650), as previously reported [16]. In addition, both secondary electron and backscatter electron imaging modes of SEM were used to study the detailed characterization of defects on the wires. Wires were first scanned at ×100 magnification to identify fractures or defects on the polymer surface and then imaged at incremental magnifications for optimal visualization and characterization. Recorded images were then imported onto the Image Pro Plus 7.0 software for quantitative analysis. After detailed assessment for the presence of fractures or defects, edges of defects were traced manually and the area and length of each defect were quantified using the Image Pro Plus 7.0 software. The following parameters were then calculated: the total area of polymer shearing; the largest defect on the wire; the total length of polymer shearing; the longest defect on the wire; the total number of defects; and the number of defects > 500 μm in length.

Table 1
Demographic characteristics of patients.

	Whisper Wire (n = 15)	Runthrough wire (n = 15)	P value
Age (years)	65 ± 12	69 ± 9	0.11
Male sex (n)	11	11	1.00
Diabetes (n)	6	3	0.23
Hypertension (n)	10	8	0.46
Smoking (n)	12	13	0.62
Hyperlipidemia (n)	15	14	1.0
NSTEMI	2	1	1.0
Previous CABG (n)	3	5	0.41

CABG, coronary artery bypass grafting; NSTEMI, non-ST-segment myocardial infarction.

2.4. Definitions of angiographic findings

Bifurcation lesions were classified according to the Medina classification [17] in which the proximal MV, distal MV, and SB components of the bifurcation were each assigned a score of 1 or 0 depending on the presence or absence of > 50% stenosis by angiography. Bifurcation lesions were also classified as true bifurcation lesions (Medina type 1,1,1, 1,0,1, or 0,1,1) vs. non-true bifurcation lesions (Medina type 1,0,0, 0,1,0, or 0,0,1).

2.5. Statistical analysis

Continuous variables were presented as the mean value ± SD and compared using Mann Whitney U test. Categorical variables were com-

Table 2
Angiographic and procedural characteristics.

	Whisper Wire (n = 15)	Runthrough Wire (n = 15)	P value
Medina class			
1,1,1	11	10	1.0
1,1,0	3	3	1.0
1,0,1	0	2	0.48
0,1,0	1	0	1.0
True bifurcation lesions	11	12	1.0
Vessels involved			
Left main bifurcation	4	3	1.0
LAD/Diagonal	3	9	0.06
LCX/OM	6	3	0.43
RCA/RV branch	1	0	1.0
PDA/PLV	1	0	1.0
Calcification	8	6	0.26
Antithrombotic therapy			
Clopidogrel	13	11	0.65
Ticagrelor	2	4	0.65
Heparin	13	12	1.0
Bivalirudin	2	3	1.0
Eptifibatide	2	7	0.11
Stent length (mm)	25 ± 9	24 ± 13	0.62
Stent diameter (mm)	3.1 ± 0.5	3.2 ± 0.4	0.39
Balloon diameter for post-dilation (mm)	3.6 ± 0.6	3.6 ± 0.5	0.97
Balloon length for post-dilation (mm)	13 ± 4	14 ± 4	0.87
Maximum balloon inflation pressure (atm)	17 ± 4	19 ± 4	0.68
Kissing balloon inflation	2	4	0.36

LAD: left anterior descending artery; LCX, Left circumflex coronary artery; OM, obtuse marginal coronary artery; RCA, right coronary artery; RV, right ventricular branch; PDA, posterior descending artery; PLV, posterior left ventricular branch.

Please cite this article as: Chatterjee A, et al, Safety of hydrophilic guidewires used for side-branch protection during stenting and proximal optimization technique in coronary b..., Cardiovasc Revasc Med (2016), http://dx.doi.org/10.1016/j.carrev.2016.04.006