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Structural Damage of Jailed Guidewire During the Treatment of Coronary Bifurcation Lesions

A Microscopic Randomized Trial

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ABSTRACT

OBJECTIVES The study sought to compare the safety (resistance to damage) and efficacy (ability to cross the side branch) of polymer-coated and non-polymer-coated guidewires in the jailed wire technique used during the percutaneous treatment of bifurcation lesions.

BACKGROUND The jailed wire technique is a useful strategy in the treatment of bifurcation lesions by provisional stenting. However, these wires can be damaged or even be broken during their removal.

METHODS We performed a randomized study in patients with bifurcation lesions treated by provisional stenting. The jailed wire technique was mandatory, and the types of guidewires, polymer-coated ($n = 115$) and non-polymer-coated ($n = 120$), were randomized. After the procedures, the wires were evaluated by stereoscopic microscopy. The induced damage in the wires was classified as follows: no damage, mild, moderate, or severe.

RESULTS The clinical characteristics were similar between patients treated with polymer-coated or non-polymer-coated wires. Polymer-coated wires were significantly ($p < 0.001$) more resistant to retrieval damage (only 2 wires showed mild damage) than were non-polymer-coated wires. However, 63 (55%) of the non-polymer-coated wires were damaged; 37 (32%), 24 (21%), and 2 (2%) had mild, moderate, and severe damage, respectively. Additionally, the jailed length of the wire was a factor contributing to the degree of wire damage. The time of side branch wiring was shorter in the polymer-coated wire group (19 ± 40 s vs. 42 ± 72 s; $p < 0.05$).

CONCLUSIONS Jailed wires during interventional procedures of bifurcation lesions commonly showed microscopic damage. Polymer-coated wires were more resistant to retrieval damage and were more efficient in crossing the side branch ostium than non-polymer-coated wires. (Jailed Wire Technique in the Treatment of Coronary Bifurcations Lesions With Stent: Stereoscopic Microscopy Study; NCT02516891) (J Am Coll Cardiol Intv 2016;9:1917–24)

The jailed wire technique is a useful strategy in the treatment of bifurcation lesions by provisional stenting. However, these wires can be damaged or even broken during their removal (1–10). Clinical guidelines recommend the use of provisional stenting (11); however, the jailed wire technique is not recognized. Additionally, in the technical specifications, the manufacturing companies do not admit this indication. As such, in cases of wire rupture, the operator is held responsible. On the basis of a previous microscopy observational study (12), we postulate that jailed polymeric wires are more

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ABBREVIATIONS AND ACRONYMS

AMI = acute myocardial infarction

cTn = cardiac troponin

MV = main vessel

SB = side branch

resistant to retrieval damage than are non-polymeric wires during the removal of the wires. The objectives of the current study were to identify the guidewire type that is more resistant to the retrieval maneuvers after jailing, determine anatomical and technical factors influencing induced damages on the guidewires, and evaluate the ability for different guidewires to cross the side branch (SB).

METHODS

STUDY DESIGN AND POPULATION. This trial was a prospective, randomized, single-blind study conducted in our center between 2012 and 2015 (NCT02516891). The study protocol was approved by the ethics committees of our center and was conducted according to the principles of the Declaration of Helsinki, revised in Seoul 2008, regarding investigations in humans. All patients provided written, informed consent for participation in the trial. Patients flowchart and study design are presented in the Figure 1.

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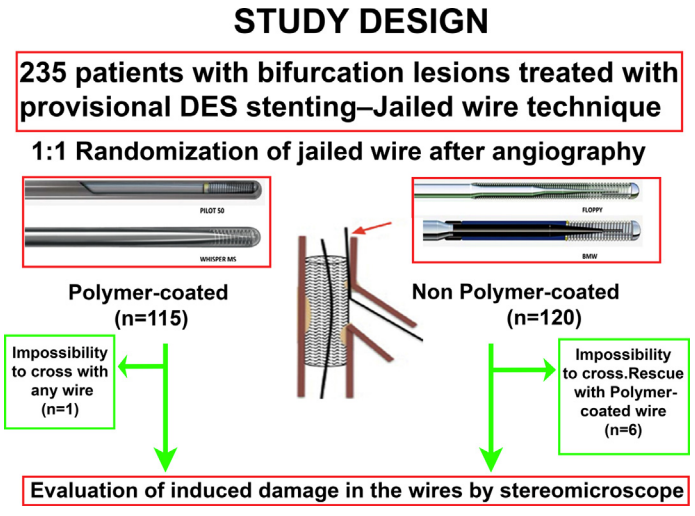
All included patients met the following inclusion criteria: 1) patients with stable angina, acute coronary syndrome or inducible ischemia, who had a lesion located at major bifurcation point, regardless of morphology and angulation; 2) main vessel (MV) diameter ≥2.5 mm; 3) SB diameter ≥2.25 mm by visual estimation; and 4) any type of Medina classification. The following exclusion criteria were used: 1) patients with contraindications to 1-year antiplatelet therapy; 2) cardiogenic shock; and 3) coexisting severe comorbidities.

FIGURE 1 Study Design and Patients Flow Chart



Polymer-coated wires (n = 115) and non-polymer-coated wires (n = 120).
DES = drug-eluting stent(s).

STUDY ENDPOINTS. The primary endpoint was the evaluation of induced damage in the wires by stereomicroscope. The secondary endpoints were the following: 1) to determine anatomical and technical factors influencing the induced damages in the guidewire; 2) to evaluate the ability of different guidewires to cross the SB in terms of time in SB wiring and incidence of SB wiring failure; and 3) to compare the incidence of in-hospital events in each group.

PROCEDURE. After angiographies patients were randomized by telephone calls to an external office where a random allocation sequence was generated and the participants were assigned, via sealed opaque envelopes, to polymer-coated (Pilot 50 or Whisper MS models, Abbott Vascular, Abbott Park, Illinois) or non-polymer-coated wires (Balance Middle Weight or Floppy II models; Abbot Vascular) (Figure 1). The wiring of the MV was performed according to the preference of the operator. The wiring of the SB was always attempted according to the randomization process and the time required for this maneuver was recorded. Times exceeding 5 min were considered an SB wiring failure. Subsequently, the other wire type was used to accomplish the SB wiring. After MV stenting, the jailed wire was then removed, cleaned and sent to be analyzed. The technique for stent implantation has been previously described as a stepwise strategy (13). A final kissing balloon or sequential balloon post-dilation technique was performed according to the preference of the operator (14). For SB post-dilation or kissing balloon inflation, the jailed wire was removed before these maneuvers. Stenting of the SB origin was considered when a severe acute recoil or flow-limiting dissection occurred (coronary Thrombolysis In Myocardial Infarction flow grade <3). The patients were pre-treated with dual antiplatelet medication. In the hemodynamic laboratory, patients received a bolus of 100 IU/kg of intravenous unfractionated heparin. The administration of glycoprotein IIb/IIIa inhibitors was performed at the discretion of the operator. After the procedure, all patients received 100 mg/day of aspirin indefinitely, and standard doses of clopidogrel, prasugrel, or ticagrelor for at least 12 months. The baseline bifurcation anatomy was assessed according to the Medina classification (15). Quantitative coronary angiography measurements were performed using an offline computerized quantitative coronary angiographic