Side Branch Protection with Hydrophilic Polymer Coated Guide Wire During Cutting Balloon Angioplasty of a Bifurcated Lesion

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SUMMARY

Cutting balloon angioplasty (CBA) was performed in a patient with in-stent restenosis (ISR) which had an important side branch. We used a hydrophilic polymer-coated guide wire for side branch protection during CBA. After CBA was successfully performed, the cutting balloon and guide wire were microscopically examined and proven to have suffered minor damage which, in itself, did not disturb the procedure. Hydrophilic polymer-coated wire might be an effective and safe choice for ISR which needs to be treated by CBA while protecting an important side branch. (Jpn Heart J 2003; 44: 565-573)

Key words: Cutting balloon, Polymer-coated guide wire, Side branch protection

With the expanded application of coronary stenting, in-stent restenosis (ISR) has emerged as a new and significant problem.1) Recent reports suggested that cutting balloon angioplasty (CBA) might be of benefit in the treatment of ISR, decreasing the need for repeat revascularization procedures.2-5) However, the efficacy and feasibility of side branch protection during CBA have not been well established so far. In this report, we propose a novel use of a hydrophilic polymer-coated guide wire for side branch protection during CBA.

In vitro experiments: This experiment was done in order to clarify the feasibility and safety of using a hydrophilic polymer-coated guide wire for side branch protection during CBA. We deployed a 3.5 × 15 mm Palmaz-Schatz stent (Cordis Corporation, Piscataway, NJ) within a polyethylene tube with a 3.5 mm inner diameter. A 0.014" Hi-Torque Whisper guide wire (Guidant Corporation, Santa Clara, CA) was passed through a small side hole made at the middle of the stenting segment as a protective wire. We inflated a 3.75 × 15 mm Barath cutting balloon (Interventional Technologies, San Diego, CA) to 10 atmospheres at the stent
site three times for 15 seconds each (Figure 1). After removal of all devices, microscopic analysis was performed.

Microscopic analysis revealed damage to the surface polymer layer of the wire (Figure 2A) and minor damage to the blade of the cutting balloon (Figure 2B). Following the same procedure, another experiment using a 0.014" Hi-Torque Balance guide wire (Guidant Corporation), which was a conventional non-coated guide wire, revealed no damage to the guide wire itself (Figure 3A), but more profound damage to the cutting blades was observed by microscopic analysis (Figure 3B).

The polymer layer may act as a buffer zone against the blade, and effectively protect against damage to / by the blade and the guide wire itself. Based on these results obtained in in vitro experiments, we concluded that a hydrophilic polymer-coated wire is a feasible and safe device for side branch protection during CBA.

**Case Report**

A 71-year-old Japanese male had a 1-year history of effort angina pectoris. Coronary angiography (CAG) revealed a 90% stenosis at the mid portion of the left anterior descending coronary artery (LAD), 99% stenosis of the second diag-
ontal branch ($D_2$), and minor stenoses of the left circumflex coronary artery and right coronary artery. The bifurcated lesion was treated with directional coronary atherectomy followed by implantation of a $3.5 \times 16$ mm Multi-Link Tristar stent (Guidant Corporation). Follow-up CAG at 6 months showed 90% stenosis at the

Figure 2A. Microscopic analysis revealed damage to the surface polymer layer of the wire (black arrow).

Figure 2B. Microscopic analysis revealed minor damage to the blade of the cutting balloon (white arrow).
proximal edge of the stent, and 90% stenosis of D2 which had an ostium in the middle of the stent (Figure 4). To deal with this bifurcated ISR lesion, CBA with side branch protection was attempted.

Figure 3A. Microscopic analysis revealed no damage to the guidewire.

Figure 3B. More profound damage to the cutting blades was observed by microscopic analysis (white arrow).
With the patient under local anesthesia, a 7-French femoral sheath was placed in position. The patient systemically received 10,000 U of heparin intravenously to obtain an activated clotting time of 300 seconds. A 7-French Zuma guiding catheter JL 3.5 (Medtronic AVE, Danvers, MA) was engaged to the left coronary artery. We succeeded in crossing a 0.014" Hi-Torque Balance Middle Weight guide wire (Guidant Corporation) to the LAD and a 0.014" Hi-Torque Whisper guide wire to D2 for side branch protection. The Hi-Torque Whisper guide wire has a polymer cover with a hydrophilic coating which might reduce the possibility of injury caused by CBA. We advanced a 3.75 × 15 mm Barath cutting balloon to the target lesion and inflated it three times (Figure 5). Maximum balloon inflation pressure was 10 atmospheres. After removal of the cutting balloon, we performed a simultaneous kissing balloon inflation to achieve an optimal result, using a 3.5 × 20 mm Maestro (JOMED GmbH, Rangendingen, Germany) for the LAD and a 2.5 × 20 mm CrossSail (Guidant Corporation) for D2. Postprocedural CAG revealed no stenoses of LAD or D2 (Figure 6). The patient was treated without any complications, suggesting this CBA system might constitute a safe form of coronary intervention.

After the procedure, we inspected the cutting balloon and the guide wire for the side branch with a microscope. Microscopic analysis revealed minor damage
Figure 5. A 3.75 × 15 mm Barath cutting balloon was advanced to the target lesion and inflated three times. Maximum balloon inflation pressure was 10 atmospheres.

Figure 6. Postprocedural CAG revealed no stenoses of LAD or D2.
on the blade (Figure 7A), and a scratch on the polymer covering (Figure 7B). The damage to the blade was slight, suggesting that it was unlikely to have been caused by the guide wire. The scratch on the guide wire was found 9.5 cm from
the tip. The scratch was superficial and did not penetrate to the inner layer of the polymer cover.

**DISCUSSION**

Cutting balloon was introduced by Barath, *et al* in 1991 for transcatheter treatment of native coronary artery stenosis. The unique feature of this device is the presence of four 0.007" microblades bonded longitudinally on the balloon surface. These blades cut the atherosclerotic plaque during initial balloon inflation, making plaque dilatation easier when the balloon is fully inflated. CBA causes less histological damage outside of the incised area than conventional balloon angioplasty. CBA procedures can be performed with high initial success rates and low rates of major in-hospital events. Moreover, CBA significantly decreases the rate of repeat revascularization procedures at follow-up compared to other commonly used techniques, such as conventional balloon angioplasty, additional stent implantation, and rotational atherectomy for management of ISR.

Side branch occlusion is one of the major complications of intracoronary stenting. Although the occlusion of small side branches is well-tolerated, occlusion of large side branches may result in significant adverse clinical events. The presence of ostial narrowing that arises from within or just beyond the diseased portion is a powerful predictor of side branch occlusion. As ostial narrowing was present in our case, we sought to protect D2 with protective wire in order to avoid side branch injury.

To reduce friction against the cutting balloon, we chose a Hi-Torque Whisper guide wire that was covered by a polymer sleeve. Compared with conventional guide wires, Hi-Torque Whisper may reduce the risk of injury caused by the guide wires and blades of the cutting balloon. An inherent feature of conventional guide wires, which consist of spring coils, is the potential to cause two major adverse events during CBA. Namely damage to the blades due to the extreme stiffness of their surface, and damage to the spring coils of the guide wire by microblades; the 0.0025 inch diameter spring coils can be amputated by the 0.007 inch microblade. Our *in vitro* experiments indicated the possibility of adverse events occurring due to the use of the nonpolymer-coated guide wire, and highlighted the apparent safety of the polymer-coated guide wire. Although these experiments are supported by only one clinical case, we can extrapolate from the above that the polymer coated guide wire offers a safe form of coronary intervention through its function as a buffer zone.

Microscopic analysis revealed minor injury within the polymer covering and no damage to the core of the guidewire, and also no damage to the micro-
blade. The damage that did exist on the cutting blades was minor, and thought to have been caused by the contact with other devices used for angioplasty.

**CONCLUSION**

Our findings suggested that the use of a hydrophilic polymer-coated guide wire can be considered as a feasible and safe approach for side branch protection during CBA.

**REFERENCES**