Simple classification and clinical outcomes of angiographic dissection after balloon angioplasty for femoropopliteal disease

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ABSTRACT

Objective: Angiographic dissection is considered to be associated with restenosis. However, little is known about the impact of the severity of angiographic dissection on future restenosis.

Methods: A total of 319 consecutive de novo femoropopliteal lesions were treated by balloon angioplasty alone. All of these lesions were divided into three groups: group A, no angiographic dissection; group B, mild dissection, the width of the dissection was less than one-third of the lumen; and group C, severe dissection, the width of the dissection was more than one-third of the lumen. Kaplan-Meier analysis estimated the primary patency rate at 3 years between the groups.

Results: The primary patency rates at 3 years were 66.0% in group A, 63.8% in group B, and 32.5% in group C (log-rank, $P < .001$). Cox proportional hazards analysis revealed that a lesion length >100 mm (hazard ratio, 1.734; 95% confidence interval, 1.099-2.735; $P = .018$) and severe angiographic dissection (hazard ratio, 1.956; 95% confidence interval, 1.276-2.997; $P = .002$) were predictors of primary patency loss at 3 years. When the lesions were divided into two groups according to the lesion length >100 mm or not, angiographic dissection had a larger impact on restenosis in a long lesion >100 mm (≤100 mm: 65.5% in group A, 75.6% in group B, and 48.0% in group C [log-rank, $P = .015$]; >100 mm: 68.8% in group A, 42.5% in group B, and 24.2% in group C [log-rank, $P = .017$]).

Conclusions: Severe angiographic dissection was associated with future restenosis after balloon angioplasty for femoropopliteal lesions, but mild angiographic dissection was not. Angiographic dissection had more impact on future restenosis particularly in treated long lesions. Stents might not be necessary in short lesions with mild dissection. (J Vasc Surg 2018;67:1151-8.)

The use of bare-metal stents and drug-eluting stents has resulted in an increase in the primary patency rate compared with conventional balloon angioplasty for femoropopliteal lesions.[1,2] However, their long-term durability remains limited because of restenosis, stent thrombosis, and stent fracture.[3,4] The stentless strategy for femoropopliteal lesions has been progressively focused on, and the importance of lesion modification using atherectomy devices[5] and the clinical impact of drug-coated balloons (DCBs)[6,7] have recently been demonstrated.

Balloon angioplasty continues to be a main option of endovascular therapy (EVT) for femoropopliteal lesions; however, dissection after balloon angioplasty is one of the concerns of this strategy. In coronary artery disease, the severity of angiographic dissection is classified and shown to be associated with worse clinical outcomes.[8,9] On the other hand, classification of angiographic dissection for femoropopliteal lesions is still not advocated. Moreover, it is difficult to fit the classification of coronary artery disease as it is for femoropopliteal lesions because there are numerous types of angiographic dissection after balloon angioplasty for femoropopliteal lesions. Therefore, we classified the severity of angiographic dissection for femoropopliteal lesions more conveniently and evaluated its clinical impact on future restenosis.

METHODS

Study population. This study was performed as a single-center, prospectively maintained database, retrospective analysis. A total of 830 femoropopliteal lesions (646 patients) underwent EVT for femoropopliteal lesions at our institution from April 2007 to December 2014. Of these, 479 femoropopliteal lesions underwent nitinol stent implantation and were excluded from the study. The remaining 351 femoropopliteal lesions were treated by balloon angioplasty alone. However, 14 were excluded because of carbon dioxide angiography; 2 were excluded because of flow-limiting dissection at final angiography; and 16 were procedural failures, which consisted of 10 failures in which the wire could not cross the lesion and 6 failures in which the balloon could not cross the lesion after successful wire crossing.

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Finally, a total of 319 femoropopliteal lesions (283 patients) that underwent balloon angioplasty alone were evaluated. All lesions were divided into three groups according to the severity of angiographic dissection caused by balloon angioplasty, and their outcomes were investigated. The study protocol was in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of our hospital. Written informed consent to participate in this study was obtained from all the patients.

Interventional procedure. Before the procedure, the patients were receiving dual antiplatelet therapy consisting of aspirin (100 mg/d) and either ticlopidine (200 mg/d) or clopidogrel (75 mg/d). Dual antiplatelet therapy was continued for at least 1 month, after which the antiplatelet regimen depended on the discretion of each operator. Heparin (5000 units) was administered after sheath insertion, and additional heparin was given to maintain an active clotting time of >200 seconds. Our strategy for femoropopliteal disease was to obtain a true lumen using a 0.014-inch wire as much as possible under body surface echography or intravascular ultrasound. An antegrade approach was performed first, but if it was difficult to cross the lesion by this approach alone, we also used the retrograde approach through a popliteal artery. Whether to perform balloon angioplasty alone or stenting for lesions with subintimal recanalization depended on the operator's discretion. However, we tended to avoid stenting for heavily calcified lesions with subintimal recanalization because it was expected that the stent would not fully expand. After a 0.014-inch guidewire crossed the lesions, we decided on the optimal balloon size using intravascular ultrasound. We selected undersized balloons, that is, 1.0 to 2.0 mm smaller than the reference lumen diameter. We usually use balloons that are longer than the lesion length when treating one continuous lesion. However, superficial femoral artery lesions often have a tandem lesion, and there is a healthy vessel between the lesions. In such cases, we usually use a short balloon that does not cover all the lesions to avoid injury to the healthy vessel. The types of balloon, balloon inflation time, and balloon pressure depended on the operator's discretion.

In Japan, DCBs are not yet available; thus, all of the lesions evaluated were treated by conventional balloon angioplasty. In case of flow-limiting dissection or residual stenosis >30%, prolonged balloon dilation that was 1 to 2 minutes longer than the initial dilation was performed, and if necessary, a slightly larger balloon was used according to the operator's discretion. Bailout nitinol stent implantation was performed when flow-limiting dissection and recoil could not be resolved even after prolonged balloon dilation by angiographic assessment according to the operator's discretion. However, if stenting was finally performed, these lesions were excluded from the study.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective, single-center, cohort study
- **Take Home Message:** After 319 superficial femoral artery balloon angioplasties, more severe dissections had worse 3-year primary patencies than less severe or no dissections (32.5% vs 63.8% and 66.0%; $P < .001$). Severity of dissection had a larger impact on restenosis in longer lesions (>100 mm).
- **Recommendation:** This study suggests that more severe dissections have an impact on restenosis and primary patency after superficial femoral artery balloon angioplasty, whereas mild dissections of short lesions may not require stenting.

Simple classification of angiographic dissection. We defined the severity of angiographic dissection after balloon angioplasty for femoropopliteal disease as follows: group A, no angiographic dissection; group B, mild dissection, the width of the dissection was less than one-third of the lumen; and group C, severe dissection, the width of the dissection was more than one-third of the lumen (Fig 1). Spiral dissection was included in group C.

When angiographic dissection occurred in several sites of the treated femoropopliteal lesion, we selected the most severe site of dissection as a representative type of dissection. Severity of angiographic dissection was evaluated on final angiography of one or two different angles. The severity of angiographic dissection was analyzed by two independent observers who had no knowledge of the baseline characteristics, lesion background, or clinical outcomes.

Follow-up. Clinical follow-up was performed every 3 months after the initial procedure. Vessel patency was evaluated using ankle-brachial pressure and duplex ultrasound.

Study end points. The primary outcome measure was primary patency rate at 3 years, defined as freedom from >50% stenosis as evaluated by angiography or restenosis as indicated by a duplex ultrasound-derived peak systolic velocity ratio of >2.4.[10]

Definitions. The severity of femoropopliteal lesions was evaluated using the TransAtlantic Inter-Society Consensus (TASC) II classification.[11] Flow-limiting dissection was defined as dissection with deterioration of the distal antegrade flow. Calcified lesion was defined as obvious densities on the vessel wall by angiography. Poor runoff was defined as one or fewer below-the-knee tibial