Review

Recent Update on Peripheral Arterial Endovascular Therapy for Peripheral Arterial Occlusive Disease

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Abstract

Endovascular treatment is effective for symptomatic peripheral arterial disease (PAD). Following recent device improvements, favorable long-term outcomes have been achieved in iliac arteries as well as small arteries such as the femoral and popliteal arteries.

This paper outlines the history and recent advances in endovascular treatment of peripheral vascular diseases as well as the characteristics and usage of devices. The history and the advances in endovascular treatment of peripheral vascular disease have been parallel, with the development of devices such as catheters and stents. Accordingly, endovascular treatment is now recommended in guidelines as the first-line for PAD.

Key words: peripheral arterial occlusive disease, angioplasty, stent, intervention

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Introduction

Peripheral arterial occlusive disease (PAD) causes organ ischemia by arterial luminal stenosis typically due to arterio- or atherosclerosis.

Although PAD occurs in all arteries, it is most commonly targeted for peripheral endovascular therapy when it occurs in the lower extremity.

Recent advances in interventional devices have allowed active adoption of endovascular treatment for PAD. However, appropriate techniques and strategies should be identified.

This review describes the evolutionary history of endovascular therapy and current advances in its strategies and devices.

History and basic endovascular techniques

Since the 1920s, angiography by direct exposure or puncture of blood vessels has been experimentally performed [1, 2], and angiography for the cerebral arteries [3], the aorta [4], and the lower limb arteries [2] has been reported. However, after the development of the Seldinger technique [5], a percutaneous intravascular catheterization method presented in 1953, the clinical use of angiography became widespread.

After the announcement of the Seldinger technique, various techniques that used catheters were developed. The Dotter method was the first and the most important in angioplasty. The Dotter method is a bougie technique for dilating the stenosis of vessels [6]. After its introduction, the balloon catheter for angioplasty was developed, and peripheral vascular angioplasty became a common procedure (the first successful iliac balloon angioplasty was performed by Grüntzig in 1974) [7, 8].

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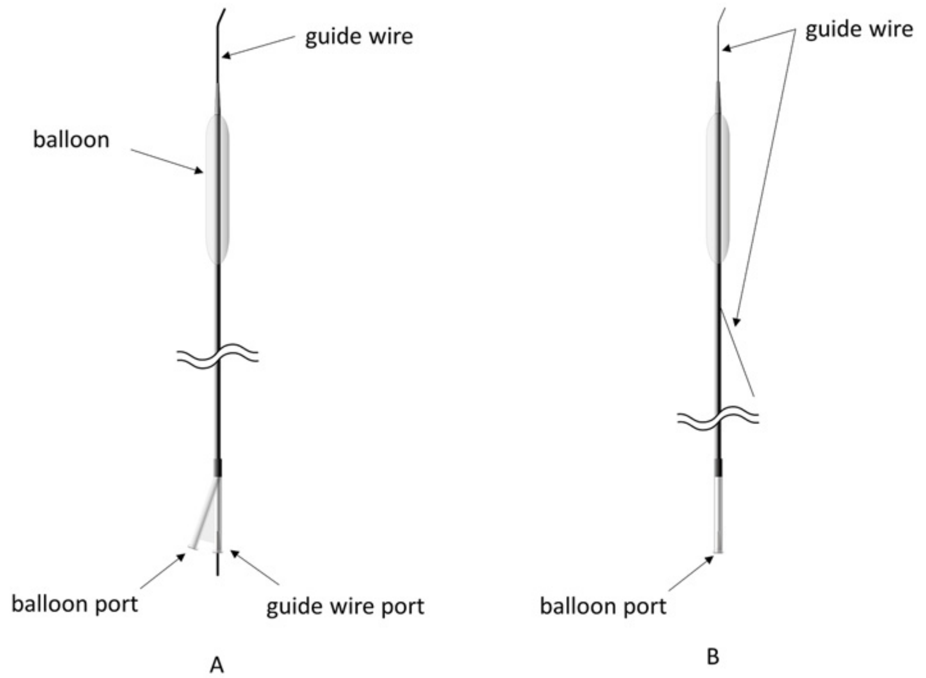

Figure 1. The structure of balloon catheter. Over-the-wire balloon catheter is double lumen catheter that have guide wire port and balloon port at the proximal end of the catheter (A). Rapid exchange balloon catheter is also called as monorail type that the guide wire lumen locates at the distal part of the catheter. At the proximal end of the catheter, there is one port that is connected to balloon lumen (B).

Balloon angioplasty was effective, but it was complicated by elastic recoil or early restenosis, and this was a major problem. In the late 1980s, Palmaz developed the balloon-expandable metallic stent [9, 10]. The use of the Palmaz stent in iliac or renal angioplasty improved primary patency [11]. However, in the femoropopliteal artery, its effectiveness was limited to short segmental stenosis [12], and the nitinol self-expandable metallic stent was developed.

Peripheral arterial (occlusive) disease (PAD)

1) Epidemiology, etiology, and inclusion criteria

The major cause of PAD is atherosclerosis [13]. Atherosclerosis is an expression of severe arteriosclerosis, which includes a lipid-rich necrotic core in the plaque, which is called atheroma. The common major risk factors for atherosclerosis are smoking, hypertension, dyslipidemia, and diabetes [14, 15]. As a result of atherosclerosis, coronary, carotid, and renal artery diseases are often associated with lower extremity artery diseases. Therefore, a multidisciplinary approach is recommended.

For patients with lifestyle-limiting claudication and hemodynamically significant aortoiliac occlusive disease, endovascular revascularization is strongly recommended. For femoropopliteal lesions, endovascular revascularization is also considered as a reasonable option [16].

For critical limb ischemia, endovascular revascularization can be justified for minimizing tissue loss by establishing in-line blood flow to the foot [16].

Recent updates to guidelines recommend the use of statins for improving walking distance, with reference to the possible advantage of using clopidogrel over aspirin; however, antiplatelet therapy is limited to asymptomatic lower extremity artery disease. The guidelines also recommend primary endovascular therapy for “TASC-D” aorto-iliac lesions and as first-line for infrapopliteal lesions [17].

2) Interventions

(1) Balloon angioplasty
I. conventional balloon angioplasty

Conventional balloon angioplasty is the most traditional procedure for PAD. Balloon catheters have double lumina; one is connected to the end hole as a guidewire lumen and the other is connected to the balloon lumen (**Figure 1**). The material of a balloon defines the mechanical performance of a catheter. Typically, non-compliant and semi-compliant balloon catheters exist (**Figure 2**). Non-compliant balloon catheters have relatively stiffer material than their semi-compliant counterparts; generally, they have higher nominal and rated burst pressures and their working diameters are stable irrespective of the pressure (**Figure 2A**).

Semi-compliant balloon catheters can be used through smaller diameter sheaths, and they can be controlled with less pressure. If a semi-compliant balloon catheter is used for dilating a hard lesion, an expansion of the balloon may cause intimal injury following over-dilatation of both of its edges, which results in the so-called "dog-bone" shape (**Figure 2B**).

(2) Drug-coated balloon

Balloon dilatation of stenotic lesions is usually accompanied by injury of the arterial intima and media, which may lead to intimal hyperplasia and restenosis. Drug-coated balloons were developed to prevent restenosis; embedded paclitaxel crystalline particles on the balloon surfaces are rapidly absorbed into the deep layers of arterial walls. Paclitaxel terminates the cell cycle during the G2 period [18]. The excessive regrowth of smooth muscle cells is suppressed and restenosis is prevented [19]. However, a recent review showed that drug-coated balloons and drug-eluting stents may increase mortality rates within the remote period [20]. Therefore, careful patient selection is required.

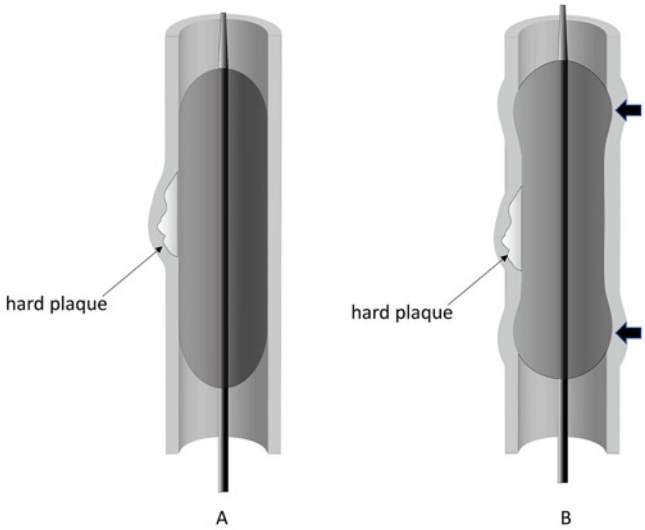

Figure 2. The compliance of balloon catheter. Since the non-compliant balloon expands evenly, there is almost no deformation of the balloon even with hard plaque (A). On the other hand, since the material of the semi-compliant balloon is softer than that of the non-compliant balloon, when the lesion with hard plaque is expanded at a high pressure, both ends of the balloon are expanded like a dog bone shape (black arrows, B).

(3) Stents

I. Bare-metal stent

A bare-metal stent is a non-drug-coated traditional metallic stent. Initial metallic stents were balloon-expandable, and they were made of stainless steel (SUS 316L)(**Figure 3A**) [21, 22]; cobalt-chromium alloys are alternative materials [23, 24]. For self-expandable stents, nitinol (nickel-titanium), a shape-memory alloy, is the major material [25-36]. With these metallic implants, metal allergy [37] is thought to be related to in-stent restenosis or stent thrombosis [38-40].

i. Balloon-expandable metallic stent

The dilatation of balloon-expandable metallic stents relies on the expansion of the balloon catheter. Balloon-expandable metallic stents have excellent radial forces, but they are not self-expanding. When they are compressed, they remain deformed and stenosis occurs. Balloon-expandable metallic stents should be selected in target arteries where no external forces are applied.

ii. Self-expandable stent

Self-expanding metallic stents (**Figure 3B**) are used to treat deformities of the superficial femoral artery, which include axial shortening and elongation, bending, twisting, and pinching [41-43]. The primary patency of the first-generation self-expanding stents in the superficial femoral

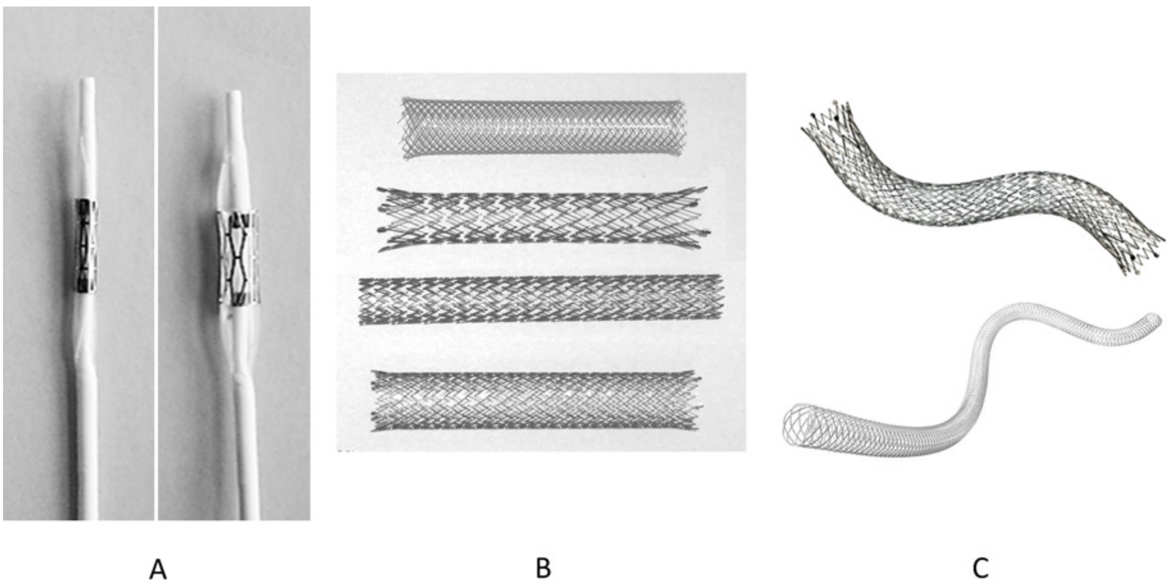

Figure 3. Metallic stents. Balloon expandable stent which is a metallic stent mainly made of stainless steel is dilated by PTA balloon catheter (A). There are many strut designs in self-expandable stents (B). Selfexpandable stents are mainly used and designed to have flexibility for adapting tortuous arteries (C, images are used under the permission of Medicon Co., Ltd. and Century Medical, Inc.).

Figure 4. Covered stents. Flexible self-expandable covered stent is a vascular stent for superficial femoral artery. Restenosis due to plaque protrusion or neointimal overgrowth is prevented because of the coverage by the graft (A). Balloon expandable covered stent is used mainly for iliac artery. Because stent struts are independently fixed on the graft material, this covered stent can be aligned along the bend of the artery. And its radial force is stronger than self-expandable type because of the nature of balloon expandable stent (B). (Images are used under the permission of W. L. Gore & Associates, Inc.)

artery was not so good [32, 44-48], but improvements in stent design have yielded better outcomes [49-52].

II. Covered stent

Covered stents are alternative devices for improving the late outcomes of treatment for femoropopliteal lesions. Viabahn (W. L. Gore & Associates, Inc., Tokyo)(**Figure 4A**) is a self-expanding stent covered by heparin-bonded polytetrafluoroethylene and fluorinated ethylene propylene [53]. Viabahn is used to control arterial bleeding and treat chronic total occlusion or long-segment lesions of the superficial femoral artery.

Recently, Viabahn VBX (W. L. Gore & Associates, Inc., Tokyo), which is a balloon-expandable covered stent (**Figure 4B**), was approved for treating lesions in the iliac arteries of symptomatic PAD patients.

Because of its heparin-bonded material, Viabahn is contraindicated in heparin-induced thrombocytopenia.

III. Drug-eluting stents

Drug-eluting stents achieved favorable long-term patency [54-57] with the suppression of neointimal progression by paclitaxel. The delay of vascular-wall healing after the implantation of drug-eluting stents has been reported and the prolonged use of dual antiplatelet drugs may be considered [58]. The increase in mortality rates by paclitaxel is the same as that of the drug-coated balloon [20].

(4) Other devices

I. Re-entry catheter

The initial step of the endovascular process is to cross the lesion using a guidewire, and although passing through the true lumen is the principle, subintimal angioplasty [59, 60] is an alternative option. Re-entry devices such as OUTBACK (Cardinal Health Japan G.K., Tokyo) (**Figure 5**) are used for navigating guidewire tips through subintimal spaces to distal true lumina [61-69].

II. High-frequency mechanical vibration

The Crosser CTO recanalization device (Medicon Co., Ltd., Tokyo) (**Figure 6**) is another alternative for chronic total occusion [70, 71]. This system can be used to initiate entry into the fibrous cap of the plaque or calcified plaque. A micro guidewire can be advanced through the crosser system after recanalization of a plaque.

Tip vibration that is activated over wires without polymer-jackets and aimed at atherectomy of calcium plaques after the failure of simple balloon angioplasty may be useful [72]; however, this is not documented in the latest package insert information. Careful use is required to avoid guidewire or vessel injury. The slow flow complication after the debulking of plaque should be noted [73].

Drug therapy

Drug therapies are used to improve the outcomes of endovascular therapy. Antiplatelet drugs and anticoagulants are commonly used concomitantly with drugs such as vasodilators, antihyperlipidemics, and antihypertensives.

Heparin, which is an anticoagulant, is used because various devices are used inside the body during the procedure. There are controversies regarding the postoperative heparin combinations [74]. If antiplatelet therapy is not used before endovascular therapy and an implant such as a stent is placed, the use of heparin may be considered until the effect of the combination antiplatelet drug is fully expressed.

Antiplatelet drugs are also used for endovascular therapy. The characteristics of the effect and the time it takes for the effect to manifest depend on the type of drug.

Cilostazol and clopidogrel are commonly used to control platelet aggregation, vasodilation, and intimal hyperproliferation. They are used to prevent early thrombotic re-occlusion and restenosis due to intimal overgrowth at the edge of the stent. Dual antiplatelet therapy is a standard for endovascular therapy [75-78].

Outcomes

Arteriosclerosis is a systemic disease, and PAD is only a part of it. The prognosis of PAD is affected by cerebrovas-

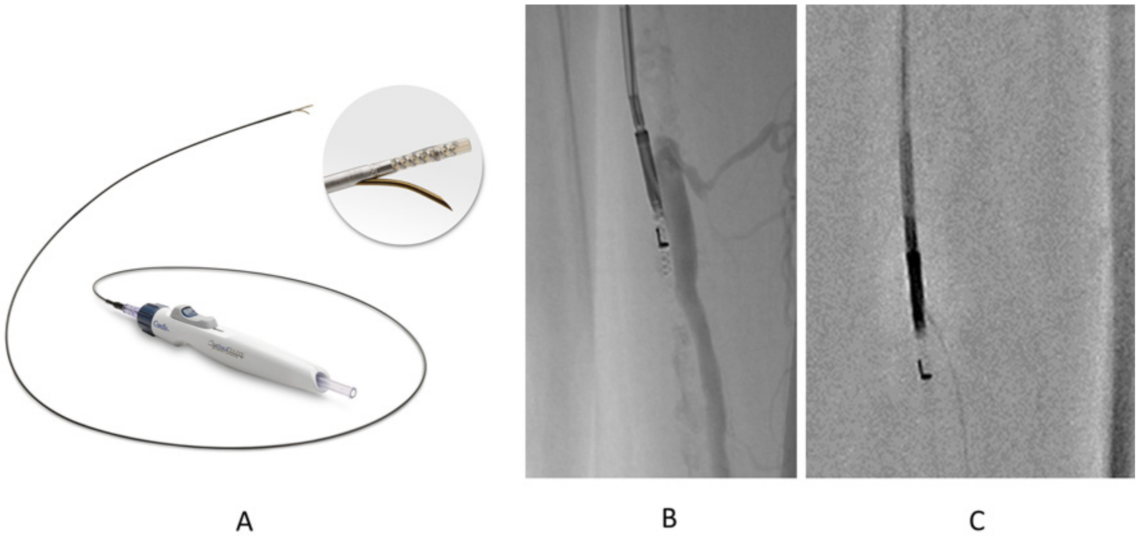

Figure 5. Re-entry device. The reentry device has a retractable needle near the tip of the catheter and is used to navigate a guidewire into the true lumen distal to the occlusion (A). Since the needle exit direction is determined, adjust the needle so that it exits toward the lumen of the blood vessel by referring to the marker at the distal end of the catheter (B). When the tip of the needle enters the lumen of the blood vessel, a guide wire is inserted into the true lumen of the blood vessel through the needle (C). (Images are used under the permission of Cardinal Health Japan GK)

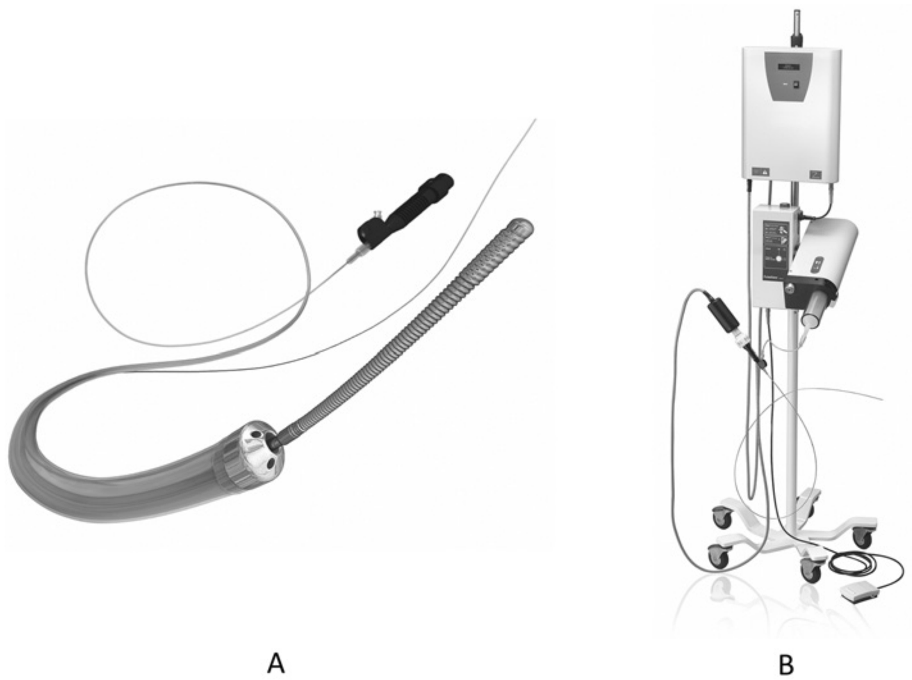

Figure 6. High frequency mechanical vibration device for crossing chronic total occlusion. With hard plaque, such as calcification, the balloon catheter or stent delivery system may not always be able to cross the lesion. In order to pass through such a hard plaque, high frequency mechanical vibration device is used. The metallic tip of the catheter vibrates and crushes hard plaques (A). Dedicated drive is required to vibrate the catheter tip (B). (Images are used under the permission of Medicon Co., Ltd.)

cular and cardiovascular diseases, and the 5-year survival rate is worse in patients with critical limb ischemia than in those with breast or colon cancers [79]. Endovascular treatment for PAD is aimed at alleviating symptoms or improving function rather than extending life.

The long-term primary patency rates of endovascular treatment in the iliac artery are between 80 and 90%. In addition, the primary patency rates in the femoral and popliteal arteries have improved to approximately 70% within 3 to 5 years due to improvements in stents [49, 51, 80-82]. Endovascular treatment has also been recognized as a standard treatment for these regions.

Conclusion

Endovascular treatment is currently a standard treatment for PAD. Improvements in devices and materials are still ongoing, and there are concerns about the use of paclitaxel; however, endovascular therapy is a promising treatment for PAD.

Conflict of interest: The authors declare that they have no conflict of interest.

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