Short communication

Percutaneous transradial artery approach for femoro-polpopliteal artery intervention in the current era in Japan

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ABSTRACT

The percutaneous transradial artery approach for coronary angiography and intervention has been recognized as a safe and effective method, however, it is limited for endovascular therapy (EVT) for femoro-polpopliteal artery because of lack of devices with longer shaft. Recently, some peripheral percutaneous transluminal angioplasty (PTA) balloons with longer shaft reached to the distal portion of superficial femoral artery (SFA) or popliteal artery are available in Japan. These devices enable us to treat the patients with peripheral artery disease (PAD) in these arteries via radial artery. Herein, we present our experience with RA approach for EVT procedure using long-shaft devices for femoro-polpopliteal artery disease.

1. Introduction

The percutaneous transradial artery approach for coronary angiography and intervention has been recognized as a safe and effective method.1–3 Radial artery (RA) approach is also one of the useful methods for endovascular therapy (EVT) procedure for subclavian, renal, or iliac artery disease,4 however, it is limited for EVT for femoro-polpopliteal artery because of lack of devices with longer shaft. Recently, some peripheral percutaneous transluminal angioplasty (PTA) balloon with longer shaft reached to the distal portion of superficial femoral artery (SFA) or popliteal artery are available in Japan. These devices enable us to treat the patients with peripheral artery disease (PAD) in these arteries via radial artery. Herein, we present our experience with RA approach for EVT procedure using long-shaft devices for femoro-polpopliteal artery disease.

2. Preliminary work

Initially, we measured the distance to the level of 1) the descending aortic bifurcation, 2) the distal epiphyseal line of the femur, 3) the mid portion of popliteal artery, and 4) the ostium of anterior tibial artery from the puncture site of the left RA using a 0.014-inch 300 cm-long Agosal XS wire (St. Jude Medical Japan Co., Ltd., Tokyo, Japan) in 54 patients (41 male, mean age 69.4 ± 10.3 years, mean height 164.7 ± 4.0 cm) with angina pectoris during the treatment by transradial coronary intervention (TRI). As shown in Fig. 1, we need devices with longer shaft more than 160 cm for EVT procedure in the distal lesion of SFA, and those more than 167 cm in the distal lesion of popliteal artery. To date, PTA stents reached to the distal portion of SFA are not available in the world, and only a few balloons with longer shaft are technically feasible by the RA approach. The measurement was conducted according to the principles expressed in the Declaration of Helsinki, and written informed consent was obtained from the patients.

1) Insertion of 6 Fr Glidesheath Slender® introducer sheath and 4 Fr peripheral guiding sheath

An insertion of the long guiding catheter or sheath is desirable in EVT procedure for femoro-polpopliteal artery with RA approach. It enables us to contrast the vessels during the procedure, and to improve the operability, stability or trackability of the devices such as the long-shaft balloons and long wires. To minimize the damage to RA during EVT procedure, a 6 Fr Glidesheath Slender® introducer sheath (Terumo Co., Ltd., Tokyo, Japan) is inserted into the left RA after successful left RA puncture as the initial step, and then we insert a 4 Fr sheathless PV® (large curve) 115 cm-long guiding sheath (Asahi Intec Co., Ltd., Nagoya, Japan) into the Glidesheath Slender® sheath (Terumo) (Fig. 2A).

Because the adequate inner size of the guiding catheter or sheath is 4 Fr size in transradial EVT without stent implantation, we usually select 4 Fr sheathless PV® sheath (large curve) 115 cm-long guiding sheath. This long sheath enables us potentially

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selection of right or left common iliac artery (Figs. 1, 2 B, C). Glidesheath Slender® sheath is a new style sheath only for RA approach and it has a thinner wall, with resulting the decrease of outer diameter. The outer size of 6 Fr Glidesheath Slender® sheath is compatible with that of a 5 Fr conventional sheath. Recently, the safety and feasibility of 6 Fr Glidesheath Slender® sheath are shown in TRI.9

2) Selection of long-shaft balloons and long wires
We need a PTA balloon with longer shaft length >160 cm to treat lesions in distal portion of SFA, and that ≥167 cm in length in popliteal artery. Several PTA balloon with longer shaft has been developed, and a PTA balloon with the longest shaft size available in Japan is Trytop Longbow® balloon (DVx CO., Ltd., Tokyo, Japan). The shaft length size of this balloon is 170 cm. A Trytop Longbow® balloon (DVx) is an over-the-wire type balloon and this necessitates a wire with longer size than conventional wire. That is, we need a long wire of at least two times length of the balloon shaft (≥340 cm in length) to exchange this balloon for other size balloon or device while keeping the wire position. A 400 cm-long wire such as a Plywire® wire (Optimed Global Care CO., Ltd., Ettingen, Germany)® is not available in Japan. We connect the proximal end of a 235 cm-long wire such as a 0.018-inch Halberd® or Gaia® PV wire (Asahi Intec CO., Ltd., Nagoya, Japan) with a 165 cm-long Extension® wire (Asahi Intec CO., Ltd., Nagoya, Japan), and it can be used as suitable substitutes for a commercially available 400 cm-long wire.

3. Case 1

In November 2014, a 79-year-old woman (height: 160 cm; weight: 65 kg) with hypertension and diabetes mellitus was referred to our hospital for effort related chest squeezing for 3 months. She obtained prompt relief with sublingual tablets of nitroglycerin. Physical examination revealed no abnormalities. Roentgenogram findings of the chest showed within normal limits, and cardiothoracic ratio was 49%. An electrocardiogram showed no specific ST-T segment changes. Transthoracic echocardiography revealed mild hypokinesis in anteroseptal wall. She also had a one-year history of progressive lateral calf Rutherford-Becker class 3 intermittent claudication (IC) despite medication optimization. The patient’s maximum walking distance was about 200 m, and the ankle-brachial index (ABI) at rest was 0.52 for the right leg with the monophasic wave form. Computed tomography (CT) angiogram of the coronary arteries and leg arteries was performed at the outpatient department and revealed severe stenosis of the left anterior descending artery (LAD) and the total occlusion of the distal SFA. We made a diagnosis of effort angina pectoris and PAD from clinical course, clinical examination, and CT angiogram.
After admission, coronary angiogram through left RA access showed severe stenosis at the mid-LAD (Segment 7) (Fig. 3A). We identified this stenosis as the culprit lesion causing this patient’s angina, and planned to treat this lesion by percutaneous coronary intervention (PCI) using 6 Fr guiding catheter via the left RA. A 5 Fr introducer sheath was exchanged with a 6 Fr Glidesheath Slender® introducer sheath (Terumo), and Heparin (total 7000IU) was administered intravenously before PCI. Through a 6 Fr JL 3.5 guiding catheter (Launcher, Medtronic, CO., Ltd., Tokyo, Japan) engaged into the left coronary artery, a SION blue® guide wire (Asahi Intec CO., Ltd., Nagoya, Japan) was advanced and the lesion was crossed successfully. After the intravascular ultrasound (IVUS) observation, a TREK® 3.0 × 15 mm balloon (Abbott Vascular, Abbott Park, IL, USA) was inserted to dilate the lesion in the LAD, and then a 3.0 × 24 mm Nobori stent (Terumo CO., Ltd., Tokyo, Japan) was implanted at 12 atmospheres (Fig. 3B). The final angiographic result showed successful dilation of the lesion (Fig. 3C).

Next, EVT for the total occlusion of the distal SFA was performed through left RA access. A 4 Fr sheathless PV® (large curve) 115 cm-long guiding sheath (Asahi Intec) inserted into the Glidesheath Slender® sheath (Terumo) was placed at the distal portion of the right external iliac artery. The initial angiography showed the peripheral chronic total occlusion (CTO) in the right distal SFA (Fig. 3D). A 0.018-inch Halberd® wire (Asahi Intec) with the support of a 5 × 40 mm Trytop Longbow® balloon (shaft length: ...
170 cm, (DVx) was advanced into the CTO lesion. After passage of this wire across the lesion, the CTO lesion was dilated with this balloon. However the angiography showed that the dilated vessel was insufficient in size. For an additional dilatation using a larger size balloon, we connected the proximal end of a 0.018-inch Halberd® wire (Asahi Intec) with a 165 cm-long Extension® wire (Asahi Intec). After removal of a Trytop Longbow® balloon (DVx), we exchanged the balloon for a 6 x 40 mm Trytop Longbow® balloon (shaft length: 170 cm, DVx) and dilated the lesion (Fig. 3E). A final angiography showed an excellent result (Fig. 3F). The wire and the sheath were retrieved, and manual arterial compression was performed for 10 min. TR Band radial artery compression device (Terumo CO., Ltd., Tokyo, Japan) was positioned and removed 6h later. The postprocedure course was uneventful, and no major complications, including ischemic heart or leg events, or RA access site complications, were observed. The patient was discharged next day after the PCI and EVT procedures. The patient did not complain any chest or leg symptoms. ABI at rest of the right leg improved from 0.52 to 0.87.

4. Case 2

In May 2013, a 73-year-old man (height: 162 cm; weight: 58 kg) with hypertension, dyslipidemia, and former tobacco use was underwent the EVT for the CTO lesion in the SFA on both sides with conventional techniques in our hospital. The PTA stents were implanted in the right SFA (6 x 100 mm, 6 x 100 mm, 6 x 100 mm S.M.A.R.T. Control® stents, Cordis, CO., Ltd., Warren, NJ, USA), and in the left SFA (6 x 100 mm, 6 x 100 mm S.M.A.R.T. Control stents, 6 x 120 mm E-Luminexx® stent, Bard Peripheral Vascular, CO., Ltd., Tempe, AZ, USA). After one year from the EVT, CT angiogram of the legs showed good vessel patency (Fig. 4), and ABI was 1.11 in right leg; 1.00 in left leg, respectively. However, in April 2015, the patient was readmitted in our hospital for a two-month history of progressive both calf Rutherford-Becker class 3 IC despite medication optimization. The patient’s maximal walking distance was about 150 m, and the values of ABI at rest revealed a decline to 0.59 in right leg and 0.57 in left leg. Angiography revealed the in-stent occlusion of the right SFA from its ostium, the occlusion of the left common femoral artery (CFA), and the in-stent occlusion of the left SFA (Fig. 5A). Subsequently, EVT for these lesions in both legs was started by placing a 6 Fr Glidesheath Slender® introducer sheath (Terumo) in the left RA. Through a 4 Fr sheathless PV® (large curve) 115 cm-long guiding sheath (Asahi Intec) placed at the proximal portion of the right external iliac artery, a 0.018 inch Gaia® PV wire (Asahi Intec., CO., Ltd., Nagoya, Japan) with a 6 x 40 mm Trytop Longbow® balloon (shaft length: 170 cm, DVx) was advanced and crossed successfully into the in-stent occlusion lesions in the right SFA. After balloon dilatation with several overlapping inflations (Fig. 5B; right), the angiography showed good vessel patency (Fig. 5C; right). Next, EVT for the occlusion lesions of the left CFA and SFA was performed. After the placement of the guiding sheath in the left external iliac artery, a 0.018 inch Gaia® PV wire (Asahi Intec) was crossed into the lesions and a 6 x 40 mm Trytop Longbow® balloon (DVx) was dilated (Fig. 5B; left). After exchanging the wire for a 400 cm-long wire, we further dilated the CFA lesion with another large balloon because of insufficient vessel expansion. The final angiography showed good
device (Terumo) for 6 h. The procedure was carried out without any minor or major events or complications. The patient was discharged next day after EVT procedure. He was completely free from quality of life-threatening claudication. ABI at rest improved from 0.59 to 0.89 in right leg; 0.57 to 0.93 in left leg.

5. Discussion

We present here our clinical experience for successful femoropopliteal artery intervention using a balloon with long shaft via the RA. Case 1 was a total occlusion case in the distal SFA immediately after PCI, and Case 2 was an in-stent occlusion case in both the right and left SFA which was treated simultaneously. In both cases, RA access was established for the insertion of a 6 Fr Glidesheath Slender™ introducer sheath (Terumo). After the placement of a 4 Fr sheathless PV™ 115 cm-long guiding sheath (Asahi Intec) in the iliac artery of the lesion side, wire crossing and subsequent inflation with long-shaft PTA balloon were performed through this route.

Thus far, the femoral artery has been regarded as the first choice access site for peripheral EVT, especially femoro-popliteal artery intervention. However, not all patients will be suitable for this artery access. The puncture of femoral artery is not necessarily an easy procedure in some patients with obesity, heavily calcified femoral artery, or femoral surgical history such as bypass surgery with prosthetic materials. In patients with previous kissing iliac stents or a bifurcated aortic graft who need for the crossover the aortoiliac bifurcation technique, the contralateral femoral artery does not serve a useful access site even if its puncture is technically feasible.

5.1. Advantages in RA approach for femoro-popliteal artery intervention

RA approach has also several advantages in peripheral EVT. First, as shown in Case 1, it enables us peripheral EVT immediately after transradial PCI. Nowadays, RA approach is gaining popularity for PCIs in not only Japan but also other countries due to the decrease in rates of puncture site-related complications such as bleeding.

Second, as shown in Case 2, it enables us the EVT treatment simultaneously in both right and left legs through one arterial access route. Third, the femoral artery access requires for patients to stay supine several hours after the EVT procedure, whereas RA access allows ambulation with totally normal walking activities immediately after the procedure. Patients in our cases discharged at the next day due to completion of the procedure in the evening. However, RA access may have the potential for the EVT procedure on an outpatient basis even if the patients are anticoagulated.

5.2. Disadvantages in RA approach for femoro-popliteal artery intervention

There are some disadvantages in performing RA approach for femoro-popliteal artery intervention, which are mainly ascribed to the lack of small enough diameter systems and adequate length systems. A 6 Fr Glidesheath Slender™ introducer sheath (Terumo) used in our cases possesses a thinner wall, with resulting reduction of the outer diameter by one French size as compared with a 6 Fr conventional sheath while the inner lumen diameter is not changed. Now that the technical progress in slender devices for RA approach such as the sheath has been remarkable, and the safety and feasibility of intervention using with these devices have been reported. Almost EVT devices compatible with 5 or 6 Fr conventional sheath can be inserted into this slender sheath, however, unfortunately, the current length limits the ability to

vessel patency (Fig. 5C; left). The guiding sheath into the left external iliac artery and the introducer sheath into the left RA were withdrawn, and the puncture site was managed by manual compression for 10 min and TR Band radial artery compression.
perform many femoro-popliteal procedures with RA access. As shown in Fig. 1, the distance to the distal portion of SFA, popliteal artery shows 160 ± 12, 167 ± 10 cm, respectively. The working length of PTA balloon available in the Japanese market is around 140–150 cm at the longest. Recently, a Trytop Longbow® balloon (DVx) is available and has a working length of 170 cm. To our knowledge, this is currently the longest PTA balloon available in Japan, and this can allow the treatment of proximal SFA and popliteal lesions. Trani et al. reported the experience with a 180 cm long shaft self-expanding Nitinol stent (The Sinus SuperFlex-518 Optimed, Ettlingen, Germany).15 The stent system with long shaft over 135 cm in working length is currently not available in our market. Thus, the balloon catheters enable us the treatment of in-stent restenotic and de novo lesions in femoro-popliteal artery, but if stent implantation is required, the current stent systems are not long enough. It is also impossible to observe the target lesions in the femoro-popliteal artery using invasive imaging modalities such as intravascular ultrasound. Technically, a long distance from RA access might make it difficult to control the wire because of the lack of axial force, especially when trying to cross the total occlusion lesion. Coscas R, et al. reported that percutaneous RA approach for femoro-popliteal artery intervention would be preferred for TransAtlantic Inter-Society Consensus (TASC) A and B lesions rather than occlusive lesions.5

5.3. Limitations of devices and technical issues

Despite femoro-popliteal artery intervention through RA access has several limits for available devices and technical issues, it is a very promising therapeutic approach for patients with absent femoral artery pulses, the crossover technique hampered by severe calcification, tortuousity, an acute angle at the aortoiliac bifurcation, or previously placed iliac stent. In patients with a need for preventing prolonged bed rest, it may particularly benefit. Although we need patient selection for radial EVT, this approach allows ambulation with totally normal walking activities immediately after the EVT procedures, and it may facilitate outpatient procedures and simplify postoperative surveillance.

6. Conclusion

Although RA approach has been safe and effective in PCI, it is not a recognized procedure for femoro-popliteal artery intervention. In planned femoro-popliteal EVT, brachial artery approach is preferred in case of non-availability of femoral artery access. However, development of devices with slender and longer size shaft will enable us ambulatory EVT procedure for femoro-popliteal artery lesions from RA.

Conflict of interest

None.

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