CASE SPOTLIGHT

JADE® Rx
PTA BALLOON CATHETER

Use of JADE PTA in Difficult Lesions after Guidewire Crossing

With the advancement in endovascular treatment (EVT) for peripheral artery disease, procedures have been performed more extensively on more complex and challenging lesions (including those which are long, occluded, severely calcified, and below-the-knee vessels) where balloon crossing can be difficult after successful guidewire crossing. Using the JADE PTA balloon, we were able to overcome the above-mentioned challenges and demonstrate the following successful case results.

Dr. Yoshimitsu Soga
General Manager
Cardiovascular Medicine, Kokura Memorial Hospital
Fukuoka, Japan

CASE STUDY 1

CASE DETAILS

- 64-year-old male patient with a severely calcified lesion in the SFA
- Previous history of hypertension, diabetes, maintenance dialysis and angina (after stent placement)
- Right intermittent claudication (Rutherford Stage 3) developed since a few months ago and a drop in the Ankle-Brachial Index (ABI) to 0.84 was recorded upon admission. As symptoms worsened despite medical treatment with a further drop in the ABI to 0.64, the patient was referred for EVT treatment.

PROCEDURE

ABI of 0.84 and 1.34 were measured respectively for the right and left systems [Fig.1a]. The target lesion via vascular echo was identified at the right SFA with severe calcification at the occluded site.

A 6F 45 cm guiding sheath was inserted into the right SFA from the left inguinal region via crossover approach and pre-operative imaging [Fig.1b] revealed calcific mass at distal SFA which appeared consistent with the initial echo findings. A 0.014" guidewire successfully crossed the lesion with the support of a microcatheter, although the microcatheter could not pass the lesion. A 2.0 × 40 mm rapid exchange (RX) balloon was used but it could not be advanced due to insufficient force transmission [Fig. 2a], and was then replaced with a 2.5 × 40 mm JADE balloon which successfully crossed the lesion without any shaft deflection [Fig. 2b] and was inflated [Fig. 2c]. As residual stenosis remained [Fig. 2d], an upsized 5.0 × 80 mm JADE [Fig. 3a] was selected to perform a long-duration balloon dilatation. Post angiogram showed severe recoiling and a straight dissection due to heavy calcification so a 6.0 × 40 mm self-expanding stent was deployed [Fig. 3b] followed by post-dilatation with the same 6.0 × 40 mm JADE balloon [Fig. 3c]. Excellent blood flow was obtained with an improved ABI from 0.84 to 1.18 and the procedure was completed [Fig. 4a and 4b].

Fig. 1a

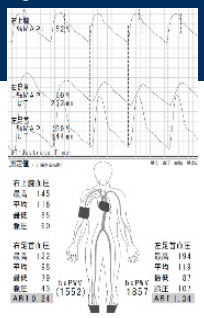


Fig. 1b

Fig. 2a

Fig. 2b

Fig. 2c

Fig. 2d

Fig. 3a

Fig. 3b

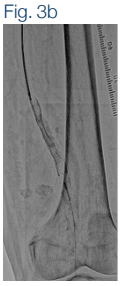


Fig. 3c

Fig. 4a

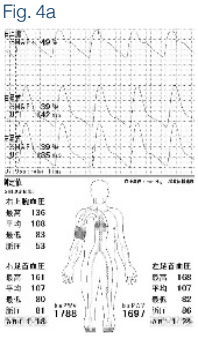
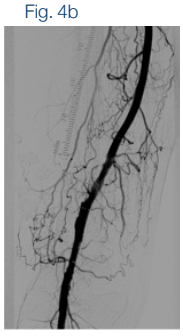


Fig. 4b



CASE SPOTLIGHT

JADE® RX
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CASE STUDY 2

CASE DETAILS

- 76-year-old female patient with occlusion at the peroneal artery
- Pain in the left limb during resting (Rutherford Stage 4)
- Previous history: Hypertension and maintenance dialysis
- Patient was admitted with numbness and cold sensation in the left toes developed from a few years ago. Pain was recently felt at rest during dialysis and cyanosis developed. The patient was referred to from another hospital with suspicion of decreased blood flow.

PROCEDURE

With an ABI of 0.77 in the left system with no stenosis detected in the iliac artery nor SFA via lower-limb vascular echo, the lesion was suspected to be below-the-knee. A 3.3F 55 cm guiding sheath was inserted into the popliteal artery via ipsilateral antegrade approach from the left inguinal region and pre-operative imaging revealed occlusion in all 3 below-the-knee arteries [Fig.1a and 1b]. The stenosed segments were long in the anterior tibial artery (ATA) and posterior tibial artery (PTA) but shorter around 3 cm at the peroneal artery which had diffused stenosis. ATA and PTA were the targeted lesions with ATA as the initial target. Unfortunately, the guidewire could not penetrate through the hard occlusion [Fig.2a] so attempt was made on the PTA. The guidewire successfully crossed but a 2.0 × 40 mm balloon failed to pass the lesion and was replaced with a 2.5 × 80 mm JADE balloon which did [Fig.2b and 2c] and was dilated with excellent re-perfusion to the toes [Fig.3].

Fig. 1a

Fig. 1b

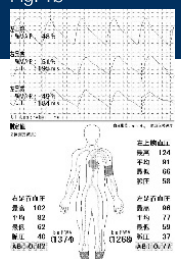

Fig. 2a

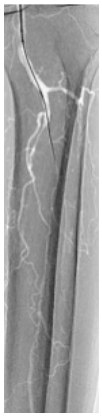

Fig. 2b

Fig. 2C

Fig. 3 Pre

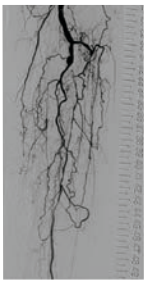

Fig. 3 Post

Fig. 3 Post

DISCUSSION

From the 2 successful EVT cases reported, the JADE balloon performed under the following circumstances where device crossability was anticipated to be difficult:

1. Inside an extremely narrow and calcified lesion where plaque modification would be required and desirable

2. Inside a distal lesion far from the guiding sheath where backup is expected to be weak if using conventional RX balloon system

In case 1, there were limited choices in Japan. In case 2, extended guiding catheter towards the lesion could help strengthen backup or also the consideration of performing distal puncture for shorter distance access to lesion site. In both cases, OTW balloon system with strong backup support could be useful except if the shaft is too long. On the other hand, a typical RX balloon system with a shorter guidewire lumen has weak backup support due to the location of the guidewire exit port being outside of the guiding sheath, resulting in shaft deflection.

In case 1, JADE's extended (RX) guidewire lumen (at 60 cm vs. 30 cm for conventional balloons), along with a fortified hypotube shaft construction, facilitated great trackability support without shaft deflection as well as provided excellent power transmission for extra pushability, creating a great overall balance to deliverability. JADE's non-compliant nature also allowed for effective and even balloon expansion as well as high pressure tolerance against rupture in calcified lesions, making it an ideal workhorse in complex lesions with difficult crossability. For EVT procedures, balloon expansion is a key element and the best choice of a first balloon is one that can cross and expand well.

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