Characteristics of Peripheral Microembolization During Iliac Stenting: Doppler Ultrasound Monitoring

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Objective. To evaluate the characteristics of distal microembolic signals (MES) during iliac stenting using Doppler ultrasound monitoring.

Design. Prospective clinical study.

Methods. A 2-MHz probe was used to monitor continuously at the ipsilateral tibioperoneal trunks during technically and hemodynamically successful iliac stenting in 10 patients without infrainguinal occlusive lesion. MESs at guide-wire, balloon, or stent crossing (phase 1), predilatation (phase 2), stent deployment (phase 3), postdilatation (phase 4), and contrast medium or heparinized saline injection (at injection) were analyzed. Differentiation of gaseous emboli from particulate emboli was achieved by calculation of the sample volume length.

Results. No distal embolic complications were observed. Five hundred and forty-one MESs were detected. The MES incidence and intensity in phase 3 were significantly higher than those in phase 1, phase 2, and phase 4 (p<0.05). The MES intensity at injection was significantly higher than that in each of four phases (p<0.0001).

Conclusions. Both the MES incidence and intensity were highest at stent deployment. Further study is required of microembolism during endovascular procedures in the lower extremities.

Keywords: Microembolization; Iliac artery; Stent; Angioplasty; Doppler ultrasound.

Introduction

Embolization to the distal arteries can complicate percutaneous transluminal angioplasty (PTA) and stent placement for the treatment of stenotic peripheral arterial lesions.1,2 However, there have been few reports regarding microembolic detection using Doppler ultrasound in the peripheral arteries.3–6 Furthermore, to our knowledge, no documentation has been reported regarding profiles of distal microemboli (ME) during endovascular procedures in the peripheral circulation.

The purpose of this study is to evaluate the characteristics of distal ME during stent placement in patients with iliac occlusive disease using Doppler ultrasound monitoring.

Material and Methods

Patients

Ten patients (eight men and two women) with the mean age of 67 (range 56–81) were included in this study. Indication for iliac stenting was intermittent claudication in nine patients and an ischemic foot ulcer in one. The preoperative median ankle brachial pressure index (ABI) was 0.60 (range 0.45–0.85). Each patient had a solitary iliac stenotic lesion (seven common iliac arteries [CIA] and three external iliac arteries) with the median degree of 70% (range 65–99%) and the median length of 20 mm (range 8–37 mm). Angiography revealed no significant occlusive lesion in the ipsilateral infrainguinal vascular trees. In seven patients with CIA lesions, five had occluded ipsilateral internal iliac arteries (IIA) and two had high-grade stenosis at the IIA orifice. All patients were treated with antiplatelet drugs including aspirin and cilostazol, which were ceased 5 days before the procedure, resumed after the procedure and continued thereafter. Patients, who had cardiac arrhythmia
or prosthetic valves, or who received anticoagulation therapy, were excluded from this study. All patients gave signed informed consent.

Stent placement

Iliac stent placement with pre- and post-dilatation was performed via the ipsilateral common femoral artery (CFA) route under local anesthesia. A 5-Fr sheath was placed in the CFA through which a 5-Fr catheter was passed into the abdominal aorta. Angiography was performed to confirm the degree and the length of stenosis and the luminal diameter of the artery immediately proximal to the lesion. A balloon (Synergy®, Boston Scientific Co., Natick, MA, USA) 1-mm larger in diameter was selected, and the length of the balloon was determined to just exceed the length of the lesion. A self-expandable stent (Easy Wallstent®, Boston Scientific Co., Natick, MA, USA) was used in all patients. The diameter of the stent was the same size as the balloon. The balloon was dilated for 30 s at pre- and post-dilatation. Pressure was 4 to 8 atmospheres. The contrast medium used was iohexol (Omnipaque®, Nylomed, Birmingham, UK), a non-ionic contrast medium with concentration of 300 mg iodine per milli liter. An intra-arterial bolus dose of 50 IU/kg of heparin was administered before the procedure, and the completion angiography was performed immediately after the procedure. The femoral arterial sheath was removed with compression of the puncture site.

Doppler ultrasound monitoring

In the current study, a commercially available Doppler ultrasound machine (EME Companion, Nicolet Biomedical, Madison, WI, USA) was used with a 2-MHz transducer. A single operator performed monitoring in all patients. The settings of the Doppler apparatus were determined as follows: the intensity threshold was 3 dB; a 128-point fast Fourier transform with a time-window overlap of 67% was used; scale setting was $-50$ to $100$ cm/s; a high-pass filter was set at 106 Hz; the sample volume was 10 mm; the amplitude was 44% (the minimum); and the gain was reduced to 2–6. The probe was fixed with specially designed holder at the anteromedial aspect of the calf and adjusted to an insonation angle of 60° to detect the tibioperoneal trunk. Depth was determined to obtain optimal Doppler flow wave of the artery (median 42 mm; range 38–48 mm). The recording was made continuously from the placement of the sheath at the CFA to the completion of stent placement and the removal of the sheath.

Data analysis

All Doppler audio signals were recorded onto hard disc of the same Doppler ultrasound machine for offline analysis. The SoundTrak software and a fine resolution mode were supplied with this machine (Nicolet Biomedical, Madison, WI, USA). The following identification criteria as microembolic signals (MES) was used for off-line analysis: intensity increase 3 dB above background, short duration (<300 ms), unidirectional, random appearance in the cardiac cycle, and with characteristic sound on the audible output according to a recent consensus.

Statistical analysis

Continuous variables were described as median and range. Statistics for between-group differences were calculated with the Mann–Whitney U-test (M–W). Variables were considered significant if the $p$ value was less than 0.05.

Results

In all patients, the stent placement was technically and hemodynamically successful defined by following criteria: completion angiography demonstrating less than 30% residual stenosis; the ABI was ameliorated more than 0.1; and the symptoms improved. No patient showed distal embolic complications after the procedure. Balloons’ sizes used ranged from 6 to 10 mm in diameter and from 1.8 to 4 cm in length, and stents’ sizes from 7 to 10 mm in diameter and from 2.7 to 6 cm in length. Predilatation was performed once in eight patients, twice in three, and three times in one, while two had no predilatation. One stent was placed in each patient. Postdilatation was performed once in two patients, twice in five, three times in two, four times in one. Doppler ultrasound monitoring was possible, and the study protocol was completed in all subjects.

A total of 541 MES were detected: 56 at passage of guide-wire, balloon, and stent (phase 1), 59 immediately after predilatation with balloon (phase 2), 119 during and immediately after stent deployment (phase 3), 44 immediately after postdilatation with balloon (phase 4), and 263 at injection of contrast medium or heparinized saline (at injection). In phase 1, the median incidence (range) and intensity (range) of
MES detected at each manipulation were 1 (0–7) and 25 dB (7–35 dB) at guide-wire crossing (*n* = 17), 2 (1–12) and 28 dB (13–39 dB) at balloon passage for predilatation (*n* = 27), 0 (0–3) and 27.5 dB (7–34 dB) at stent passage (*n* = 8), and 0 (0–2) and 21 dB (15–32 dB) at balloon passage for postdilatation (*n* = 4).

The sample volume length (= emboli velocity × duration; SVL)³⁸ of each MES in phase 1, phase 2, and phase 4, was calculated with the finest resolution mode. The SVLs of 159 MESs were analyzed and they had a median of 0.63 cm ranging from 0.12 to 1.31 cm. Based on this observation, the SVL threshold for determining embolic composition was assumed at 1.32 cm, with emboli producing SVLs less than 1.32 cm being classified as particulate and all those with SVLs greater than 1.32 cm, being classified as gaseous. According to this criterion, 100 (84.0%) MESs in phase 1 were defined as particulate, and 249 (94.7%) MESs at injection as gaseous. MESs with SVLs more than 1.32 cm in phase 3 and less than 1.32 cm at injection was excluded from the following statistical analysis.

In analysis of the MES incidence, MESs at the second or further balloon dilatation in phase 2 (*n* = 11) and phase 4 (*n* = 15) were excluded. The MES incidence in phase 3 (median 9, range 4–18) was significantly higher than that in phase 1 (median 3.5, range 1–15) (M–W, *p* = 0.048), phase 2 (median 3.5, range 1–21) (M–W, *p* = 0.037), and in phase 4 (median 1.5, range 1–9) (M–W, *p* = 0.0017) (Fig. 1). There was no significant difference of the MES incidence between phase 1 and phase 2 (M–W, *p* = 0.89), phase 2 and phase 4 (M–W, *p* = 0.14), and phase 2 and phase 4 (M–W, *p* = 0.12). In phase 1, the MES incidence at postdilatation balloon passage was significantly lower than that at guide-wire crossing (M–W, *p* = 0.041) and predilatation balloon passage (M–W, *p* = 0.0045).

The MES intensity in phase 3 (median 29 dB, range 9–43 dB) was significantly higher than that in phase 1 (median 26.5 dB, range, 7–37 dB) (M–W, *p* = 0.033), phase 2 (median 24 dB, range 7–43 dB) (M–W, *p* = 0.002), and phase 4 (median 19 dB, range 8–40 dB) (M–W, *p* < 0.0001) (Fig. 2). The MES intensity in phase 1 was significantly higher than that in phase 4 (M–W, *p* = 0.0082). The MES intensity at injection (median 33 dB, range 10–45 dB) was significantly higher than that in each of four phases (M–W, *p* < 0.0001). There was no significant difference of the MES intensity between phase 1 and phase 2 (M–W, *p* = 0.28), and phase 2 and phase 4 (M–W, *p* = 0.21). In phase 1, the MES intensity at predilatation balloon passage was significantly higher than that at guide-wire crossing (M–W, *p* = 0.049).

**Discussion**

In the current study, it was considered that endovascular procedures in each phase were associated with multiple embolic particles generated from plaques as described in the previous reports.⁹–¹² Our result agreed with one previous report which documented that self-expandable stent deployment was associated with higher embolic risk than pre- and post-dilatation.¹¹ The author described that it was possible that...
the sheer forces of the self-expanding stent, which was usually oversized to the artery, were responsible for the increased embolic release. In addition, mechanical factors, as trauma on the plaque surface with sharp end and hard material of stents compared with balloon surface, might act to dislodge higher number and larger size of emboli during their deployment. On the other hand, two previous documentations reported that carotid stent deployment was associated with low embolic risk due to the scaffolding effect of the stent, which traps atherosclerotic debris against the arterial wall.\(^9,10\) However, a major difference should be considered between the carotid procedures and the iliac procedures. Manninen et al.\(^12\) suggested that a self-expandable stent had the ability to expand during placement, beginning from the distal end and trapping the embolic fragments in place in the carotid artery. In contrast, such entrapment function might not be available in the current study because stent placement was approached from the ipsilateral femoral artery and stent deployment began from the proximal end in all cases. Self-expandable stent placement with a retrograde approach might contribute to higher potential embolic risk.

Orlandi et al.\(^10\) reported no substantial difference of the MES intensity between angioplasty group and stenting group in their series of carotid stenosis. The author described that the MES intensity seemed to have no clear significance since it might depend both on the volume and on the nature of ME. However, Manninen et al.\(^12\) investigated the histological nature of ME in an experimental model and reported that there was no difference between PTA alone group and stenting group. Thus, although the histological nature of ME in four phases (guide-wire, balloon, and stent manipulation, predilatation, stent deployment, and postdilatation) was not assessed in the current study, the MES intensity could represent the volume of ME rather than the nature of ME during endovascular procedures. A higher intensity of MES could represent a larger size of ME.\(^5,13\)

The higher MES intensity as measured by dB in phase 3 may reflect gaseous embolization from within the self-expandable stent even though we characterized emboli using the criterion with SVL.\(^3,8\) However, to our knowledge, there is no ‘gold standard’ for discrimination between gaseous and solid emboli. Even human experts, currently considered as the ‘gold standard’ for embolus detection, cannot reliably decide on the gaseous or solid nature of Doppler signals.\(^14\)

Our results using the Doppler MES profile during stenting in the iliac artery demonstrate four critical phases responsible for increased MESs, with the highest incidence and intensity of MESs observed at stent deployment. Further investigation of microembolization during endovascular procedures in the peripheral circulation is indicated.

References


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