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ORIGINAL ARTICLE

Slender transradial iliac artery stenting using a 4.5 French guiding sheath

Norihiko Shinozaki[1] · Takashi Minowa[2] · Tsutomu Murakami[1] · Yohei Ohno[1] · Masataka Nakano[1] · Toshiharu Fujii[1] · Gaku Nakazawa[1] · Fuminobu Yoshimachi[1] · Yuji Ikari[1]

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Abstract
We previously reported safety and usefulness of transradial iliac artery stenting using 6 Fr guiding sheath. However, radial artery occlusion was a major limitation of this procedure. We analyzed the safety and utility of slender transradial iliac artery stenting using a 4.5 Fr guiding sheath to prevent radial artery occlusion. We performed transradial iliac artery stenting in left radial artery, using a 4.5 Fr sheath incorporating a shaft length of 110 cm, for 34 lesions in 29 patients. Transradial intervention was attempted at the discretion of the operator. Clinical data were analyzed retrospectively. Cases with scheduled multiple sheath insertions for a bidirectional approach were excluded. Twenty-three (79.3%) patients were male. Diabetes mellitus, hypertension, dyslipidemia, and smoking habit were present in 11 (37.9%), 27 (93.1%), 19 (65.5%), and 24 (82.8%) patients, respectively. Nine lesions (26.5%) were diagnosed as chronic total occlusion. All lesions were successfully treated using a total of 40 stents incorporating a 4.5 Fr radial access system. Ankle-brachial index (ABI) significantly improved from 0.68 ± 0.15 to 0.99 ± 0.17 ($p < 0.0001$) after the procedure. No patients had procedural or access site-related complications such as hematoma, major bleeding, blood transfusion, stroke, cholesterol embolism, aortic dissection, or arterial perforation. Radial artery occlusion was absent in all cases. ABI value was well maintained at 0.98 ± 0.13 at 1 year, and no target lesion revascularizations were reported. Slender transradial iliac artery stenting using a 4.5 Fr guiding sheath is safe, feasible, and less invasive, and shows no incidence of radial artery occlusion, in carefully selected patient populations.

Keywords Transradial intervention · Iliac artery · Stent · Peripheral arterial disease · Endovascular treatment

Abbreviations

ABI	Ankle-brachial index
EVT	Endovascular treatment
CAG	Coronary angiography
PCI	Percutaneous coronary intervention

Introduction

There are three important points to consider in evaluating data obtained from endovascular treatment (EVT). Of primary importance is the achievement of an initial high success rate. Second, it is important to maintain a high patency rate in the long term. Finally, in addition to these two points, a low degree of invasiveness of the procedure is important. The initial and long-term results are particularly important, and consideration of these should be given priority. However, it is also important to select a less invasive treatment strategy when equivalent initial and long-term results are obtained. To achieve less invasive treatment, selection of the radial artery approach is important.

Based on earlier favorable outcomes of iliac artery stenting [1], we previously reported the initial results of transradial iliac artery stenting as a less invasive treatment strategy [2]. Stent placement was performed safely in all patients and there were no serious complications related to the procedure. On the other hand, we experienced several cases of radial artery occlusion after the procedure, although these were all asymptomatic. We used a 6 or 6.5 Fr guiding sheath, whose diameter may have been too large for use in radial artery of Japanese patients. In the previous reports showing favorable outcomes of transradial iliac artery stenting using a 6 Fr guiding sheath, the rate of radial artery occlusion has been

✉ Norihiko Shinozaki
shinori3@tokai-u.jp

1 Department of Cardiology, Tokai University School of Medicine, 143 Shimokasuya, Isehara, Kanagawa, Japan

2 Department of Vascular Surgery, Asama General Hospital, Saku, Japan

reported as ~ 16% [2–6]. This suggested that downsizing of sheath diameter is very important in preventing radial artery occlusion when we choose radial artery access. Therefore, we have used a 4.5 Fr sheath instead of a 6 Fr sheath for stent placement via the radial artery. In this manuscript, we report the first retrospective analysis of patients treated with slender iliac artery stenting using a 4.5 Fr guiding sheath.

Methods

Study population

We performed transradial iliac artery stenting using a 4.5 Fr sheath for 34 lesions in 29 patients between November 2014 and March 2017. Decision in favor of the radial artery approach was made at the discretion of the operator. Cases with scheduled multiple sheath insertions for the bidirectional approach were excluded. All patients gave informed consent for the procedure. Patients were prescribed the standard dosage of dual antiplatelet therapy (aspirin 100 mg/day plus clopidogrel 75 mg/day) in all cases for at least 1 week before the procedure. After the procedure, all patients were prescribed lifelong aspirin (100 mg/day), and prolonged (at least 1 month) clopidogrel (75 mg/day) was recommended.

The procedure of transradial iliac artery stenting

A 4 Fr sheath 16 cm in length (Terumo, Tokyo, Japan) was first inserted into the radial artery in the usual way and 2000 units of unfractionated heparin were injected. The left radial artery was selected as the access site in all patients. We initially performed coronary angiography if deemed necessary. We next performed angiography from the distal abdominal aorta to the artery below the knee with a 130 cm long pig-tail catheter (Asahi Intecc, Nagoya, Japan) placed in the abdominal aorta. Using a stiff type 260 cm length radifocus® guidewire (Terumo, Tokyo, Japan) we inserted a 4.5 Fr parent plus® guiding sheath with a shaft length of 110 cm (Medikitt, Tokyo, Japan) into the abdominal aorta or the common iliac artery, and additional 3000 units of unfractionated heparin were administered. After selective angiography of the target lesion, we implanted the stent in the usual way. We used a 0.014 inch guidewire and intravascular ultrasound in all cases. Finally, we performed angiography.

Clinical analysis

Clinical, lesion, and procedural characteristics were collected retrospectively from our database and analyzed retrospectively.

Table 1 Baseline patient characteristics

Number of cases, *n*	29
Number of lesions, *n*	34
Age, mean ± SD, years	71.3 ± 9.2
Male, *n* (%)	23 (79.3)
Height, mean ± SD, cm	161.7 ± 8.0
Body weight, mean ± SD, kg	58.9 ± 9.5
Fontaine I/IIa/IIb/III/IV, *n* (%)	0 (0)/17 (50)/15 (44)/1 (3)/1 (3)
TASC-II class A/B/C/D, *n* (%)	24 (71)/5(15)/5(15)/0(0)
Ankle-brachial index, mean ± SD	0.68 ± 0.15
Diabetes mellitus, *n* (%)	11 (37.9)
Hypertension, *n* (%)	27 (93.1)
Dyslipidemia, *n* (%)	19 (65.5)
Smoking history, *n* (%)	24 (82.8)
Hemodialysis, *n* (%)	0 (0)

Table 2 Procedural characteristics

Procedure success, *n* (%)	34 (100)
Necessity of another puncture, *n* (%)	0 (0)
Procedure time, mean ± SD, min	69.8 ± 23.3
Fluoroscopic time, mean ± SD, min	20.8 ± 8.9
Contrast medium volume, mean ± SD, ml	120.5 ± 50.8

Procedural success was defined as successful completion with achievement of less than 30% angiographic residual stenosis.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation, whereas discrete variables are given as absolute values, percentages, or both. Continuous variables were compared using the Wilcoxon signed-rank test. Results were considered statistically significant at $p \leq 0.05$.

Results

Table 1 shows baseline patient characteristics. Average age was 71.3 ± 9.2 years. Fontaine stage III or IV patients constituted 6% of the total, while TASC-II C or D lesions constituted 15%. Most patients did not exhibit severe status. Average ABI was 0.68 ± 0.15.

Table 2 shows procedural characteristics. All patients underwent successful revascularization. No patients required a change in the access site, e.g., to other sites such as the brachial artery or the femoral artery, during the procedure. Procedure time was 69.8 ± 23.3 min. Fluoroscopic time was 20.8 ± 8.9 min. Contrast medium volume was

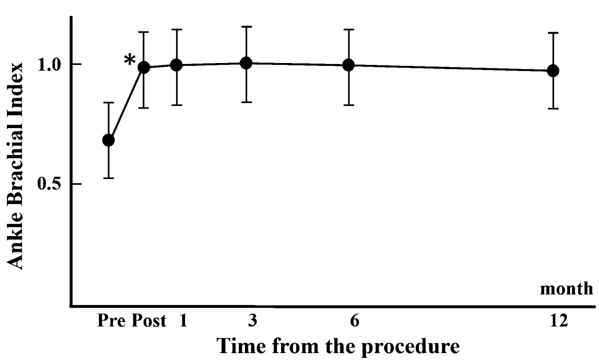
120.5 ± 50.8 ml. In addition to EVT, simultaneous diagnostic coronary angiography (CAG) was performed in 17 cases (58.6%). For these patients, the above amount of contrast medium, fluoroscopy time, and procedure time were calculated by subtracting the volume or time required for CAG. For 5 cases, we treated iliac lesions on both sides simultaneously in the same session. Stents were implanted directly in 8 lesions because of moderate stenosis, and another 26 lesions were implanted after pre-dilatation. We performed post-dilatation in all cases. Fifteen stents were implanted in 12 lesions of 10 patients at Asama General Hospital, while 25 stents were implanted in 22 lesions of 19 patients at Tokai University Hospital. All patients were discharged on the day after the procedure.

The Zilver 518® stent (Cook Medical, Bloomington, IN) was implanted in all cases, because this is the only stent which is compatible with the 4.5 Fr sheath. We selected the left radial approach, because the Zilver 518® stent system has a shaft length of 125 cm; thus, a shorter distance from access site to treatment site was desirable and there was a possibility that the stent system would not be long enough to allow use of the right radial artery approach.

ABI significantly increased from 0.68 ± 0.15 to 0.99 ± 0.17 post-procedure ($p < 0.0001$, Fig. 1).

No patients had procedural or access site-related complications such as hematoma, major bleeding, blood transfusion, stroke, cholesterol embolism, aortic dissection, or arterial perforation. On the day following the procedure and at the time of outpatient visit, radial artery patency was assessed by palpation of the radial artery pulse. Patency was confirmed in all patients by the presence of a palpable pulse.

Average follow-up period was 14.0 ± 7.8 months (3–31 months). ABI value was maintained at 0.98 ± 0.13



	Pre	Post	1	3	6	12
Mean ABI	0.68	0.99	1.00	1.01	1.00	0.98
SD	0.15	0.17	0.16	0.14	0.15	0.13
Number	34	34	30	27	24	14

Fig. 1 Changes in ankle brachial index. ABI significantly improved from 0.68 ± 0.15 to 0.99 ± 0.17 (*$p < 0.0001$) after transradial iliac artery stenting, and was well maintained at 0.98 ± 0.13, 12 months later

at 1 year (Fig. 1). There was no case of target lesion revascularization.

Discussion

This study reports the results of iliac artery stenting via the left radial artery using a 4.5 Fr sheath. Stent placement was successfully performed in all patients and no patients required a change in approach site during the procedure. In addition, there were no complications related to the radial artery approach, or occurrence of postoperative radial artery occlusion. Calculated amounts of contrast medium, fluoroscopy time, and procedure time were all satisfactory.

Femoral artery has been the gold standard as the access site for EVT. However, access site complications such as giant hematoma around the puncture site, retroperitoneal hematoma, pseudoaneurysm, and arteriovenous fistula are well known. In addition, bleeding complications have been reported to increase mortality [7]. Several studies in patients undergoing percutaneous coronary intervention (PCI) have reported that the radial approach was associated with significantly fewer complications [8–12]. The MATRIX trial [13], in which patients with acute coronary syndrome undergoing PCI were randomly assigned to either femoral artery approach or radial artery approach groups, found that the latter was associated with significantly decreased all-cause mortality and bleeding complication rate. These results again support the less invasive nature of the radial artery approach.

The initial and long-term results of stent placement in the iliac artery are reported to be favorable, irrespective of the type of stent, as far as nitinol stents are used. Therefore, if stent placement is feasible, it is reasonable to select the less invasive radial artery approach to make the overall procedure safe and minimally invasive. As we previously reported [2], transradial iliac artery stenting constituted a less invasive procedure with no serious complications at the puncture site. We were able to apply this approach, not only to simple lesions, but also to complex chronic total occlusion [14]. However, we experienced some degree of radial artery occlusion after the procedure. The rate of radial artery occlusion has been reported to be ~ 16% after transradial iliac artery stenting using a 6 Fr sheath [2–6]. Even if radial artery occlusion occurs, this does not lead to serious clinical problems as long as blood flow from the ulnar artery is preserved. However, if possible, the preservation of blood flow is desirable to maintain the access route for subsequent intervention and measurement of arterial pressure. Saito et al. reported that the insertion of a sheath with an outer diameter larger than the inner diameter of the radial artery led to an increase in the frequency of postoperative severe flow reduction [15]. According to the Saito data, the 6 and

6.5 Fr guiding sheaths with a diameter of 2.7–2.8 mm used in our previous study would carry a risk of severe blood flow reduction in nearly 30 and 50% of Japanese males and females, respectively. The 4.5 Fr sheath used in the present study had an outer diameter of only 2.17 mm, allowing the postoperative risk of severe blood flow reduction to be lowered to several percent. In fact, no patient in the present study developed radial artery occlusion. We can conclude that the use of a 4.5 Fr sheath further reduced the complication of radial artery occlusion, allowing less invasive stent placement in the iliac artery.

To the best of our knowledge, this is the first report showing the results of transradial iliac artery stenting using a 4.5 Fr sheath. However, there is a limitation in that the Zilver 518® is currently the only stent with a 4.5 Fr sheath available for placement in iliac artery. This stent is compatible with a 0.018 inch guidewire and has a shaft length of 125 cm. In our experience, stent placement in the iliac artery via the left radial artery was possible for patients with a height less than 176 cm, the tallest patients participating in this study. Therefore, this method is not applicable to all patients. Development of a stent system for iliac artery stenting with a longer shaft length and a smaller shaft diameter is awaited.

The ABI value in this study was well maintained by 1 year, and no target lesion revascularization was required. Stent placement with the Zilver 518® poses no problems in most lesions. However, the stent diameter is 6–10 mm and stent length is 40–80 mm; this is, therefore, a limitation when we wish to use a stent with a diameter > 10 mm, or length > 80 mm. This is also a limitation when we wish to use stents with a smaller free cell area for resolution of thrombotic or soft plaque lesions.

The radial artery approach appears to be associated with a risk of stroke because of the passage through the subclavian artery and the aortic arch. However, we have not experienced such a case of stroke thus far. An Italian multicenter study also reported that no patients developed stroke in a study of iliac artery stenting using a radial approach [5]. The rate of stroke has been reported to be ~ 4% after transradial iliac artery stenting [2–6]. We assume that selection of the left radial artery approach may have been related to the absence of stroke in our study, since the system did not pass into the right subclavian artery or brachiocephalic artery, and the length of the device passing through the aortic arch was smaller. We consider that we can prevent stroke using the left radial arterial approach with careful catheter manipulation.

Similar to the results obtained in our previous study using a 6 Fr sheath [2], we were able to safely perform iliac artery stenting with a 4.5 Fr sheath using the radial artery approach without any complications. This method should be considered for obese patients in whom puncture of the femoral artery is difficult and risks of bleeding complications are higher, those with a lesion in the common femoral artery, and those who are not able to remain on bed rest over a long period due to lumbago, etc. However, the radial artery approach would be expected to pose much higher risks for patients who have abundant plaques in vessels from the left subclavian artery to the descending aorta, those with aneurysm in the descending aorta, and those with tortuous vessels. For patients with these conditions, we should choose femoral artery access.

A limitation in the present study was that patency of the radial artery after the procedure was assessed only by manual palpation without the use of ultrasonography. Therefore, we were not able to assess the possibility of slight stenosis that could have caused blood flow impairment. However, the radial pulse was palpable in all patients, at least indicating the absence of occlusions, which is sufficient to establish clinical safety following the procedure.

Conclusions

This study has shown that iliac artery stenting with a 4.5 Fr guiding sheath could be safely performed using the radial artery approach without complications at the puncture site or other related complications; thus, there was no need to change the puncture site. We consider that this is a very useful technique that can dramatically decrease the risk of radial artery occlusion. In summary, slender transradial iliac artery stenting using a 4.5 Fr guiding sheath is feasible, safe, and less invasive, and shows no evidence of radial artery occlusion in carefully selected patient populations.

Compliance with ethical standards

Conflict of interest All authors have no conflict of interests.

Ethical statement The authors complied with human studies guidelines of Tokai University, and obtained informed consents from the patients.

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