Original Studies

Transradial and Transulnar Access for Iliac Artery Interventions Using Sheathless Guiding Systems:
A Feasibility Study

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Purpose: Our aim was to evaluate the acute success and complication rates of the transradial and transulnar access for iliac artery stenting using sheathless guiding systems. Methods: Clinical and angiographic data from 156 consecutive patients with symptomatic iliac artery stenosis who were treated with transradial or transulnar access were evaluated. All patients underwent Duplex ultrasound before and after the intervention. The primary endpoints were the procedural success rate, major adverse events, and access site complication rates. The secondary endpoints were the angiographic result of the iliac artery intervention, fluoroscopy time, X-ray dose, procedure length, crossover rate to another puncture site and hospitalization duration. The impact of the learning curve was also investigated, along with right or left radial access. Results: The indication for the intervention was intermittent claudication in 109 patients (69.9%), critical limb ischemia in 44 (28.2%) subjects and acute limb ischemia in three individuals (1.9%). Technical success was achieved in 155 patients (99.4%), with a crossover rate of 3.8%. Radial and ulnar artery access was used in 151 (96.8%) and 7 (4.5%) patients, respectively. The Ankle-brachial index increased from 0.69 [0.65–0.72] to 0.91 [0.88–0.95] as a result of the procedures (P < 0.001). The cumulative incidence of major adverse events was 3.8% at the 2-month follow-up (0% in patients with intermittent claudication and 13.8% in patients with critical limb ischemia). Radial artery access site complications were encountered in eight patients (5.1%). We documented decreased X-ray doses (1742.0 [783.9–2701] vs. 1435 [991.1–1879] vs. 692.8 [275.3–1110] Gy cm⁻² P < 0.05) over time; however, the fluoroscopy time, procedure time, and contrast consumption were not significantly different. Left hand access was not associated with significantly better results than right radial artery access. Conclusions: Iliac artery stenting can be safely and effectively performed using radial or ulnar artery access and sheathless guiding catheters, with acceptable complication rates and high levels of technical success. The physician learning curve plays an important role in decreasing the X-ray dose.

Key words: iliac artery stenosis; iliac artery stenting; radial approach; ulnar approach

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INTRODUCTION

The radial artery (RA) is the preferred access site for percutaneous coronary interventions (PCI), and it is also gaining popularity for peripheral interventions [1–3]. Percutaneous iliac artery interventions (PIAI) are usually performed using the femoral [4,5] or brachial artery (BA) [6], but limited data exists for iliac artery (IA) angioplasty performed through transradial (TR) approaches [7–9]. In large prospective studies of PCI, the TR access was associated with low vascular complication rates, improved patient comfort due to swift mobilization, and lower procedural costs compared to traditional transfemoral (TF) options [1–3]. Contrary to the TR access, thus far, the ulnar artery (UA) approach has received little attention as a potential interventional access site. For PIAI, the common anatomic limitations of the arteries in the upper extremity are the narrower lumen and the distance between the puncture site and target lesion, while the main advantage is that atherosclerotic involvement is rare. The SheathLess Eaucath (Asahi Intec, Japan) is a new hydrophilic sheathless guiding catheter (SG) system available in 6–8.5 F sizes, which does not require the use of an introducer sheath. The internal lumen size of the system is similar or even higher than ordinary catheters, despite its lower external diameter, which makes it more effective for PIAI, without increasing the risk of RA complications [10,11]. The purpose of our prospective pilot study was to evaluate the acute success and complication rates of the TR and TU access for iliac artery stenting using the SG catheters.

METHODS

Clinical and angiographic data from 156 consecutive patients with symptomatic IA stenosis were evaluated in a prospective pilot study. Between 2013 and 2014, the patients were treated utilizing RA and UA access and 6F peripheral and 8.5F coronary SGs. Right (RH) and left hand ( LH) access procedural data were analyzed, but crossover and dual access cases were excluded from the statistical analysis. The impact of the learning curve was analyzed each year and after 50 transradial cases. Our Institutional Review Committee approved the study, and all patients provided written informed consent prior to study inclusion.

Inclusion Criteria

We included patients with significant iliac artery stenosis and intermittent claudication (IC) (Fontaine IIa–b, III, Fontaine IIa–b, III); or critical limb ischemia (CLI) (crural ulcer, pedal gangrene, ischemic rest pain) with proven limb viability.

Exclusion Criteria

Patients with negative bilateral Allen tests were not included. Subjects with small diameter upper extremity arteries that posed a contraindication to the use of 8.5 F catheters, as well as severe stenosis or calcification of these vessels, were all excluded. We also excluded individuals in whom the 125 cm diagnostic catheter did not reach the site of the iliac stenosis.

Duplex US Protocol

Before and after the intervention, all patients underwent Duplex ultrasound, which was performed by trained a physician. The RA, UA diameter, and peak systolic velocity were measured at the wrist level. On the first postoperative day, the patency of the UA and RA was evaluated, and the artery sizes were recorded.

Access Site Selection

Two skilled operators trained in bilateral TR access and PIAI performed all cases. The preferred access site was the right RA. The alternative access site was the right UA, which was used when the RA was smaller than 1.5 mm, according to Doppler ultrasound. Contra lateral access was used in cases of right RA occlusion.

Antithrombotic Regimen

After a loading dose of 325 mg aspirin and 300 mg clopidogrel, the patients underwent dual antiplatelet therapy for 2 months (aspirin 100 mg and clopidogrel 75 mg). In addition, 2.5 mg verapamil, 5,000 IU heparin sodium, and 250 mcg nitroglycerine was administered directly to the radial artery through the sheath. Additional Na-Heparin was given until reaching 100 IU kg⁻¹. Routine ACT was not measured during the intervention.

Angioplasty Technique: Puncture

After local anesthesia, the radial or ulnar artery was punctured with a dedicated transradial needle and sheath (Terumo, Japan, 5F). Advancement the guide wire in the descending aorta was performed using a pigtail catheter and J tip guidewire (GW) in a lateral 40-degree view (Fig. 1A–C). In the case of complex aortic arch the loop technique was used (Fig. 1D and E).
Diagnostic Angiography

The aortoiliac anatomy was identified in an anteroposterior view with aortography, using a 5F 125-cm-long pigtail catheter, which proved to be helpful in estimating the distance between the puncture site and the lesion.

Cannulation

The diagnostic catheter and introducer sheath were exchanged for a dedicated transradial SG system (Asahi, Japan, 8.5F 100 cm or 6F 120 cm) over a long 260 cm 0.035 GW (Starter or Jindo, Cordis, USA). A short hemostasis valve (Terumo) was used to decrease the length of the delivery system. After angiography, the common iliac artery (CIA) was selectively cannulated with a 125-cm-long MP diagnostic catheter (telescopic method), and the GW was advanced through the lesion (Fig. 2A).

Angioplasty

The procedure was performed under road map imaging (Fig. 2B). The lesion was stented directly or after balloon predilation. Direct stenting was chosen when the lesion was not critical (Fig. 2C and D). Balloon expandable (BE) (Omnilink Elite, Abbot, USA) and self-expandable stents (SE) (Absolute, Abbot, USA) with long shafts (135 and 120 cm) were used for stenting. All SE stents were post dilated.

Postoperative treatment

After the procedure, the sheath was immediately removed, and hemostasis was achieved with a tourniquet for 6 hr. We did not use a dedicated hemostatic device, but the radial artery pulse was always checked distally. All patients were immediately mobilized after the procedure.

Quantitative angiography and measurements were performed, according to standard clinical practice. The

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Fig. 1. Crossing the aortic arch (A–C): The pig tail catheter must rotate clockwise without the GW (white arrow) (A) and then the 0.035-in. GW must be advanced in the descending aorta (B). Finally the pig tail can be pushed in the descending aorta (C). In difficult aortic arch the pig tail must be pushed against the aortic valve (white arrow) without the GW (D) and after creating a loop, we can advance the GW in the descending aorta (E). By pulling back the pig tail (white arrow) together with the wire, the loop can be straightened (F).
vessels and lesions were analyzed using a computerized quantification system (General Electric, Innova 3100).

Postprocedural Follow-up

After the procedure, Duplex ultrasound was used to investigate the access arteries after the procedure, along with a physical examination. All patients underwent a detailed clinical follow-up examination 2 months after the procedure. Furthermore, patients with CLI and non-healing wounds returned for the treatment of outflow disease.

Definitions

Our primary endpoints were technical success, major adverse events (MAE), and the access site complication rate. The secondary endpoints were angiographic outcomes of the iliac artery interventions, fluoroscopy time and X-ray dose, procedural time, crossover rate to another puncture site, and hospitalization duration (in days).

Major Adverse Events (MAE)

MAE was assessed as the composite of death, major amputation, and repeated revascularization of the target vessel by PTA or artery bypass graft operation during the hospital stay and at the 2-month follow-up.

Definition of Vascular Complications

Major vascular complication was defined as diminished or lost arterial pulse or the presence of any pseudo-aneurysm or arteriovenous fistula during the clinical follow-up. Minor complications were defined as hematomas requiring no further treatment, measuring ≥2 cm in diameter over the radial or ulnar
puncture area or measuring ≥5 cm in diameter over the femoral puncture site. Major bleeding was defined as a drop in the hemoglobin level of >3 g dL⁻¹, as well as any bleeding requiring blood transfusions.

Technical success was defined as PTA resulting in <30% residual stenosis with sufficient anterograde flow; a “suboptimal result” was characterized by sluggish flow and/or a residual stenosis between 30 and 50% after repeated dilatation.

Clinical Success

Primary clinical success was defined as an improvement of at least one clinical category in the Rutherford–Becker classification [12]. Primary patency was defined as persistent patency without any reintervention (angioplasty, surgical procedures, or amputation) or on at the margins of the treated lesion. Limb salvage was defined as the prevention of major amputation. An amputation at or distal from the trans-metatarsal level was classified as being minor while, while any amputation above that level was considered to be major.

Statistical Analysis

Statistical analysis was performed using the commercially available Graph Pad Prism 6.0 software (USA). Continuous variables were expressed as the mean ± standard deviation or as the median with inter-quartile range. Categorical variables were tabulated as percentages. The different patient cohorts were compared using either the Mann–Whitney U test or the Kruskal–Wallis test. Probability values <0.05 were considered to be significant.

RESULTS

PIAI was performed in 143 patients with angiographically significant IA stenosis, using the RA (n = 151, 96.8%) or UA (n = 7, 4.5%) access. In five patients, FA access (n = 5, 3.2%) was used, and in one patient, BA access (n = 1, 0.6%) was used due to cross over requirements. The indication for the intervention was intermittent claudication in 109 patients (69.9%), critical limb ischemia in 44 (28.2%) patients and acute limb ischemia in three patients (1.9%). Demographic and clinical data are summarized in Table I. Procedural data are summarized in Tables II and III.
salvage was achieved in 109 IC patients (100%), including 43 CLI subjects (97.6%) and three acute limb ischemia patients (100%). Major amputation was performed in one case (0.6%), and minor amputation was necessary in five cases (3.2%). Planned common femoral artery endarterectomy was performed in two patients on the first postoperative day, without any complications.

Chronic total occlusion recanalization was performed in 28 patients, with a 96.5% success rate; however, dual arterial access (femoral and radial) was necessary in three individuals due to unsuccessful re-entry (10.7%). Kissing PIAI was performed in two cases using bilateral RA access (Fig. 3).

The crossover rate was 3.8% (one failed puncture, three failed re-entry issues with iliac artery chronic total occlusions, two due to a short delivery system). All crossover patients were successfully treated using the alternative FA or BA access. The crossover patients were not associated with significantly prolonged hospitalization rates (2.08 vs. 2.04 [1.57–3.25], \( P = \text{ns} \)). There were no significant differences in the fluoroscopy time, X-ray dose, procedure time and contrast consumption, whether right or left hand access was chosen (see Table IV).

To analyze the effect of the learning curve, we compared the procedural data obtained in the first, second and third years of our study, and we compared the first

| Equipments and devices | n (%) |
|------------------------|-------|
| Sheath                 |       |
| - 8.5 F coronary sheathless guiding | 26 (16.7) |
| - 6F peripheral sheathless guiding | 130 (83.3) |
| Diagnostic catheter    | 163 (104.5) |
| Guidewire 0.035 and 0.018 | 300 (192.3) |
| Balloon                | 81 (51.9) |
| Stent                  | 148 (94.9) |
| - Balloon expandable   | 126 (80.8) |
| - Self expandable      | 22 (14.1) |
| Mean radiation dose (Gycm2) | 1295 [963.6-1626] |
| Mean fluoroscopy time (sec) | 452.0 [386.3-517.7] |
| Mean procedure time (min) | 25.8 [22.3-29.3] |
| Mean contrast volume (ml) | 98.25 [87.5-109.1] |
| Hospitalisation (day)  | 2.0 [1.6-2.5] |

Fig. 3. (A) High-grade right and left common iliac stenosis (white arrow) and left iliac external occlusion (black arrow). (B) Selective cannulation of the left common iliac artery, with a long 125 cm multipurpose catheter and recanalization with a hydrophilic Terumo wire. (C) Balloon angioplasty in the left iliac artery. (D) Simultaneous kissing stent implantation (white arrows) and the result after dual stent implantation. (E) The final post-dilatation result.
50 patients with the remaining patients. We did not find any significant differences in the procedure times (30.15 [18.5–41.8], 22.4 [19.1–25.7], 26.0 [22.1–30.0], and 30.2 [18.6–41.8] vs. 22.8 [19.4–26.2] vs. 25.2 [20.7–29.8] min, \( P = \text{ns} \), fluoroscopy times (444.9 [316.3–565.5], 387.4 [308.1–466.7], 482.8 [378.1–587.6], and 444.4 [320.4–568.6] vs. 430.8 [314.1–547.4] vs. 427.7 [330.2–525.2] sec, \( P = \text{ns} \), or contrast consumption (110.3 [80.9–139.7], 81.2 [68.7–93.6]) * (106.4 [89.1–123.8] 110.8 [81.5–129.6] ml, \( P < 0.001 \)) decreased significantly over time (see Table V). A significant decrease was observed in the X-ray dose 1651 [927.5–2374] vs. 1436 [991.1–1879], and 692.8 [275.3–1110] ** (1678.0 [965.5–2390] vs. 1436 [999.4–1873] vs. 799.9 [283.3–1316] Gy cm\(^{-2} \) P < 0.001) decreased significantly over time (see Table V). A significant decrease was observed in the X-ray dose 1651 [927.5–2374] vs. 1436 [999.4–1873] vs. 799.9 [283.3–1316] Gy cm\(^{-2} \) P < 0.001) decreased significantly over time (see Table V).

Major procedural complications were detected in two patients (1%) (one distal embolization requiring surgical embolectomy of the common femoral artery and one hydrophilic guidewire induced psosas hematoma in a patient with iliac artery CTO recanalization treated with protamine administration). Both patients had uneventful post-procedural courses. RA access site complications were encountered in eight patients (5.1%) (eight asymptomatic occlusions including one radial artery perforation treated with a coronary stent graft). The cumulative incidence of MAE months was 3.8%, with a 0% occurrence of MAE in patients with intermittent claudication and a 12.7% occurrence in patients with critical limb ischemia (one major amputation, two cardiac deaths, one myocardial infarction, one rePTA due to stent thrombosis, and one surgical embolectomy).

**DISCUSSION**

Our study is the first publication describing the feasibility of TR and TU interventions in treating iliac artery disease in a large cohort of consecutive patients using sheathless guiding catheters, with good procedural outcomes and a contrast and radiation exposure comparable to a previously published TF series [4].

TF access is the traditionally used approach for PIAI because the puncture is effortless, provides good backup support for the intervention, and allows the use of large femoral sheaths (6–8 F). However, when the puncture site is compromised by scar tissue, or if the lesion itself involves the CFA, a crossover to the contralateral access becomes mandatory, which is not always possible in cases of calcified, tortuous or angled iliac arteries. The main disadvantage of the femoral technique is the high number of bleeding complications and the prolonged immobilization due to the fairly low applicability of the closure devices. Iida O et al. [5] have retrospectively analyzed the POC in 2012 patients undergoing IA intervention, and they reported that older age (older than 80 years of age), CLI, TASC C/D lesions and associated femoral artery stenosis were all independent predictors of complications following IA stenting. The most frequent access site complications were hematomas (1.6%) and pseudo-aneurysm formations (0.3%); freedom from MAE and major amputation were naturally higher in the patients without POC. With the introduction of new, alternative access sites (brachial, radial), there has been a movement towards decreasing the incidence of access site complications during PIAI through the routine use of closure systems [5–9], and low profile 6F compatible devices.

BA access could provide an alternative puncture site for PIAI; however, it is associated with a high risk of vascular and nerve complications [7]. Despite its disadvantages, BA access is still considered to be the second access site for many interventionists because it is easy to puncture, less prone to spasm and the diameter of the artery together with the relatively shorter distance...
of the lesion from the puncture site usually allow the application of most devices used for PIAI through the femoral approach.

TR access has been used as an alternative access site for PIAI in some case report and pilot studies [7–9]. The main advantage of RA access is the low rate of bleeding complications, improved patient comfort due to its fast mobilization, and decreased procedure costs [[1–3], 23]. Despite these excellent results, this method has not gained widespread acceptance due to its technical and anatomical limitations. In the past, the main technical reason for the infrequent utilization of TR access for PIAI was the large diameter and inflexible and short delivery shafts of the first-generation catheters. However, due to recent advances in technology, the new iliac artery stents are now mainly 6F sheath compatible, and their shafts are often 120–135 cm in length. Another important technical improvement was the development of the hydrophilic, flexible, kink-resistant long sheath and SG. In contemporary peripheral interventional practice, the use of TR access for PIAI has become much more feasible. Note that some anatomical limitations still remain for the RA. The artery is more difficult to puncture, it is more prone to spasm, and sometimes the passage of the sheath in the tortuous and calcified subclavian artery and aortic type II–III descending aorta can prove to be difficult. It is also important to consider the previously reported complications (e.g., spasm, radial artery occlusion, perforation, brachial artery dissection, and pseudo-aneurysm formation) [13–16]. In our study, group radial and ulnar artery occlusion occurred in only eight cases (5.1%), despite the use of large bore SG, and all patients remained asymptomatic. The hydrophilic coating and the distal conical tip of the SG may have played important roles in the avoidance of symptomatic RA spasm in our study. We had one procedure-related psoas artery hematoma in CTO recanalization, which was related to the use of hydrophilic guidewire, and note that we must be careful with hydrophilic guidewires because they can easily pass in the external iliac artery due to its inferior origin.

UA access studies have not been previously published for PIAI, but there are many publications describing its use in coronary interventions [[17,18],20]. In the SWITCH register, Pierfrancesco Agostoni et al. have reported that in cases of failed radial sheath insertion, switching directly to the ipsilateral ulnar artery in percutaneous coronary procedures does not cause symptomatic hand ischemia [17]. In the randomized PCVI-CUBA trial, consecutive unselected patients were randomized to the ulnar or radial approach before the Allen’s test and the palpation of the forearm pulses. Successful access was obtained in 93.1% of the patients in the ulnar group and in 95.5% of patients in the radial group \((P = 0.82)\), and the artery diameters did not differ significantly, according to US. [18] In our study group, UA access was chosen only in those cases when the RA was small, to prevent occlusion and/or perforation. We observed UA occlusion in only one patient, who remained asymptomatic despite the concomitant low RA diameter. The disadvantages of UA access over the RA are that it is a more difficult puncture due to limited palpability, as well as the seemingly more difficult compression, but the latter factor does not translate into a higher complication rate, according to the literature.

### Technical Aspects

Puncturing and traversing the radial and brachial artery are the same compared to coronary procedures, and it is important for the operator to be aware of the RA anomalies, particularly the loops, to avoid complications. The catheter advancement in the descending aorta is sometimes difficult, particularly from the right RA, but by advancing a pigtail catheter oriented in the posterior position of the aortic arch, a hydrophilic GW can easily be placed in the descending aorta. Knowing the compatibility of the devices is a crucial factor in achieving good angiographic results using the radial approach. An important rule is that the 8.5 F 100 cm long coronary SG has a 2.80 mm inner diameter, and it requires a minimum balloon and stent length of 120 cm, while the 120 cm long peripheral SG has a narrower (2.21 mm) internal diameter and a longer minimum balloon and stent length of 135 cm. For short lesions, we preferred the 6F 120 cm SG and BE stents, with the 135-cm-long delivery shaft; however, for long

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**TABLE VI. Periperal Complications**

| Complications          | n (%) |
|------------------------|-------|
| **Procedural complications** |       |
| Distal embolisation    | 1 (0.6) |
| Psoas haematoma        | 1 (0.6) |
| **Summary**            | 2 (1.3) |
| **Access site complications** |       |
| RAO                    | 7 (4.5) |
| UAO                    | 1 (0.6) |
| Compartment syndrome   | 0 (0)  |
| Spasm                  | 0 (0)  |
| **Summary**            | 8 (5.1) |
| **MAE at two month FU** |       |
| Death                  | 2 (1.3) |
| Major amputation       | 2 (1.3) |
| Urgent operation or PTA| 1 (0.6) |
| Myocardial infarction  | 1 (0.6) |
| **Summary**            | 6 (3.85) |
iliac artery lesions, the short 100 cm 8.5F SG was used with SE stents with the 120 cm shaft. Note that cross-over access occurred in two tall patients (>180 cm). Therefore, the patient height should also be considered; furthermore, the 120 cm pig tail catheter may help to measure the distance between the lesion and the puncture site.

Study Limitations

The primary limitation of the study is the lack of direct comparison with the femoral approach, and a separate randomized analysis of left and right radial access would be worthwhile in future studies.

CONCLUSIONS

Iliac artery stenting can be safely and effectively performed through radial and ulnar artery access using sheathless guiding systems with acceptable complication rates and high technical success. The learning curve plays an important role in decreasing the radiation dose.

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