

Transradial Approach for Renal Artery Angioplasty and Stenting in Chinese Patients: Single Center Experience

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Background: Conventional renal artery angioplasty is performed through femoral artery access. Femoral artery access requires several hours of bed rest to ensure hemostasis, and combined vascular complications are frequently encountered. It has been proven that the transradial approach for coronary artery intervention is technically safe and feasible. In this study, we used this alternative approach for percutaneous transluminal renal angioplasty (PTRA) and stenting (PTRS).

Methods: Twenty patients with 21 renal artery stenotic lesions were treated via the left radial artery approach. The intervention was carried out using a 6 French (Fr) system for PTRA and PTRS.

Result: The immediate procedural success was 100% (three PTRAs and eighteen PTRSs). Direct stenting was performed in 8/21 stenoses; predilatation was necessary in 10/21. The only major complication was one renal artery perforation with perirenal hematoma requiring transfusion. There was no procedure-related death or cerebrovascular event. One patient with severe coronary artery disease suffered from sudden death 1 month after the intervention. Angiographic follow-up was obtained in 7 patients with 8 renal arteries treated (38.1%) after a mean 11.0 ± 7.8 months. There was one angiographic in-stent restenosis (12.5%), which required a repeat balloon angioplasty. Clinical follow-up at a mean of 14.3 ± 14.5 months revealed that renal function had improved in 4 (21.0%), had remained stable in 9 (47.4%), and had worsened in 6 (31.6%). Hypertension was found to have reversed in 1 (5.3%), to have improved in 5 (26.3%), and to have remained unchanged in 13 (68.4%).

Conclusions: Transradial renal artery intervention is technically feasible and safe. An additional advantage is the ease with which hemostasis is achieved and the elimination of bleeding complications that allow immediate ambulation after the procedure. Therefore, transradial approach can be considered as an alternative to traditional transfemoral approach for renal artery intervention.

Key Words: Transradial • Renal artery stenoses • Angioplasty • Stenting

INTRODUCTION

Atherosclerotic renal artery stenosis is the most

common cause of secondary hypertension and/or renal insufficiency. percutaneous transluminal renal angioplasty (PTRA) and stenting (PTRS) have gained increasing acceptance in the treatment of renovascular hypertension based on historic results of renal angioplasty.¹⁻⁵ The technique has evolved from initial 8-Fr systems utilizing guiding catheters with the femoral approach. Recent equipment allows for stenting of renal arteries with the use of 6 Fr guiding catheters. However, markedly inferior angulation of the renal artery, particularly in patients with calcified vessels, may complicate the femoral approach. In some patients with renal arterial disease

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combined with severe aortoiliac occlusion disease, femoral access is impossible. The transradial approach for coronary artery intervention has been proven to be a safe method in Western countries and Asian countries as well as in Chinese people.⁶⁻⁹ In this study, we investigated use of transradial approach for renal artery intervention in our patients; moreover, the procedural and clinical results were retrospectively reviewed.

MATERIALS AND METHODS

Patients

This retrospective study included patients undergoing PTRAs or PTRSs for hemodynamically significant renal artery stenosis plus hypertension (World Health Organization grade 1 or higher irrespective of concomitant therapy) and/or impaired renal function (serum creatinine concentration ≥ 1.5 mg/dL). Twenty patients with 21 renal artery stenoses were treated with PTRAs or PTRSs from the left radial artery. The lesions on which angioplasty was performed included 14 right renal artery stenoses and 7 left renal artery stenoses. Baseline clinical demographics are given in Table 1.

Definitions

Patients who had renal artery stenosis were diagnosed by a contrast medium abdominal angiogram or selective renal arteriography. Renal artery reference diameter stenosis of $\geq 70\%$ of one or both major renal arteries or renal artery luminal stenosis of $\geq 50\%$ and a peak-to-peak translesional pressure gradient of ≥ 20 mmHg were indications for performing angioplasty. Impaired renal function was defined as serum creatinine of

≥ 1.5 mg/dL according to our hospital standards. Acute renal failure (ARF) was defined as an increase in the serum creatinine of 0.5 mg/dL or $\geq 25\%$ of the baseline level (within 24 hrs before procedure) after contrast exposure within 48 hours. Success of the procedure was defined as residual stenosis of $< 20\%$ and a translesional peak-to-peak pressure gradient of ≤ 5 mmHg. Major complications included death, perirenal hematoma, arterial thrombosis, and a blood transfusion related to the procedure. Improved blood pressure was defined as a diastolic pressure of < 90 mmHg and a systolic pressure of < 140 mmHg on the same or a reduced number of medications. Renal function was considered to have improved if the serum creatinine level decreased by 20% or more of the baseline, to be stable if it remained within 20% of the baseline, and to have worsened if it increased by 20% or more of the baseline value. Angiographic restenosis was defined as renal arteriogram stenosis of $\geq 50\%$.

Interventional Procedure

After local anesthesia was administered, the left radial artery was punctured and a long 6-Fr introducer sheath (Terumo Corporation, Tokyo, Japan) was inserted. In order to prevent radial artery spasm, 200 μ g nitroglycerine, 2.5 mg verapamil, and 5000 IU heparin were administered through the sheath. A 6-Fr Kimmy Mini-radio ForceTM guiding catheter (Boston Scientific SciMed, Maple Grove, MN, USA) or a Mach1TM Judkins Right 4 guiding catheter (Boston Scientific SciMed) was used to engage the renal artery ostium. A 0.014-in Hi-Torque Floppy IITM (Guidant, Santa Clara, CA, USA) or an 0.018-in V-18 Control WireTM (Boston Scientific Corporation, Miami, FL, USA) guidewire was used to pass the stenotic lesion. Pre-dilated balloon angioplasty followed by stent implantation was performed on 10 renal arterial lesions and provisional stent placement was performed for angioplasty failure. As a result of ExpressTM balloon-expandable stents ($n = 10$) were used with a renal artery reference diameter of < 5.5 mm, and ExpressTM Vascular LD premounted stents (Boston Scientific Corporation, Natick, MA, USA) ($n = 8$) were used with a renal artery reference diameter of ≥ 5.5 mm. Implantation pressures ranged from 8 to 12 atm [give in CGS units first; 1 atm = 101.325 kPa] for 30 s (Figures 1 and 2). Balloon angioplasty utilized a monorail balloon

Table 1. Baseline demographic and clinical characteristics

Characteristic	Value (%)
Age (yr)	63.6 \pm 15.3 (22~82)
Gender (M/F)	7/13
Coronary artery disease (≥ 1 vessel)	16/20 (80%)
Smoking	3/20 (15%)
Diabetes mellitus	6/20 (30%)
Hypertension	20/20 (100%)
Hyperlipidemia (cholesterol ≥ 200 mg/dL)	8/20 (40%)
Serum creatinine (mg/dL)	2.38 \pm 1.24 (0.7~4.2)
Antihypertension drugs (n)	2.3 \pm 1.0

catheter (Gazella™, Boston Scientific Corporation, Medi-Tech, Natick, MA, USA) in 3 patients without

stent placement. Two of the 3 patients had non-ostial lesions, and the other patient was young. Additional

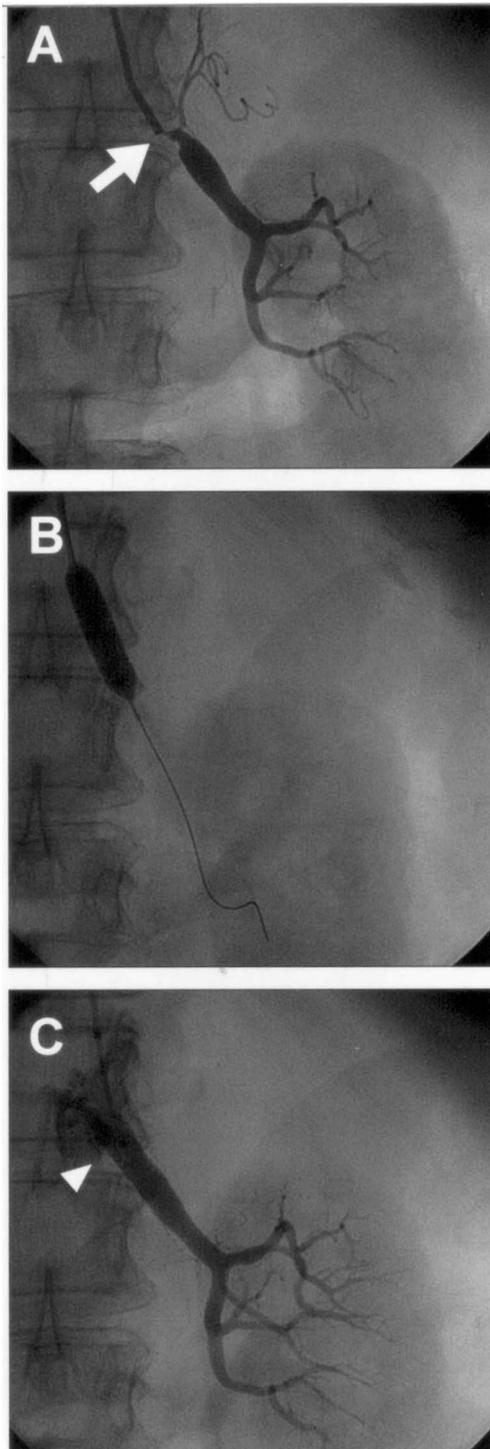


Figure 1. A: High-grade stenosis of the left renal artery. B: Implantation of a Boston Express LD stent (7 × 17 mm). C: Final renal artery angiogram result.

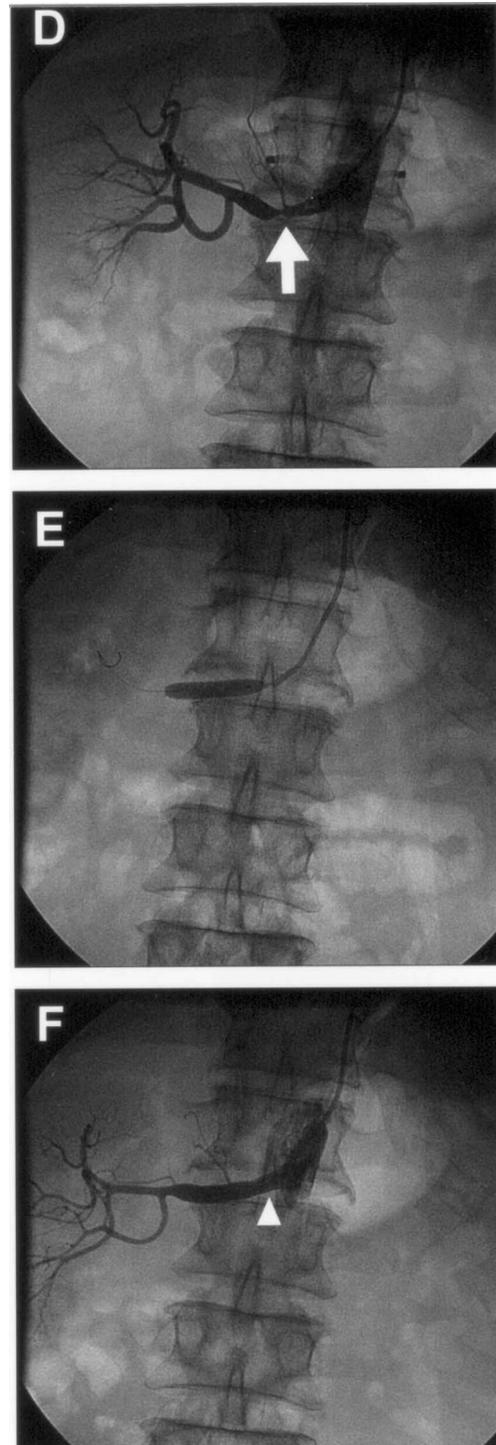


Figure 2. D: High-grade stenosis of the right renal artery. E: Implantation of a Boston Express stent (5 × 20 mm). F: Final renal artery angiogram result.

post-dilatations were performed on 8 renal arteries in order to achieve optimal expansion of the stent. The Guardwire embolic protection device had no used in our patients.

The sheath was immediately removed after the procedure. Hemostasis was achieved using figure-8 cross-bandage compression on the puncture site for 30 min. Post-intervention, 300 mg loading and 75 mg qd clopidogrel plus 100 mg qd aspirin were given for 4 weeks, then 100 mg aspirin was given alone. Hydration was performed with half-saline 12 hours before and 6 hours after the procedure. The serum creatinine was measured within 48 hours after the intervention and at each outpatient clinic visit.

Statistical Analysis

Data are expressed as mean values \pm SD or number of patients. Chi-square or independent-sample t-test was used to determine differences in categorical data or continuous variables between before and after procedure. A probability value of less than 0.05 was considered statistically significant. All analyses were performed with SPSS computer software, version 11.0.

RESULTS

Technical Results

There were 20 patients with 21 renal artery stenoses in this study. The patients' baseline characteristics are given in Table 1. The procedural success rate was 100% (18 stent implantation and 3 balloon angioplasties). The mean diameter stenosis decreased from $72.9\% \pm 13.4\%$ to $10.2\% \pm 12.3\%$ ($p < 0.001$), and the minimal lumen diameter (MLD) increased from 1.36 ± 0.68 to 5.25 ± 1.42 mm after stenting or balloon angioplasty ($p < 0.001$). Systemic complications were not observed, but one patient developed perirenal hematoma due to guide-

wire perforation. This was detected by CT scan after the patient complained of flank pain after the intervention. The patient received blood transfusion and was discharged one week later without further event. There was no vascular complication at the radial access site.

Clinical Results

ARF developed in 3 patients within 48 hours post-intervention. The renal function in one patient improved before discharge. One patient with a baseline serum creatinine level of 4.2 mg/dL progressed to end-stage renal failure, that regular hemodialysis was required during the follow-up period. Mean serum creatinine negligibly increased from 2.38 ± 1.25 to 2.40 ± 1.26 mg/dL ($p = 0.95$) (Table 2). After the procedure, 1 patient with severe triple-vessel coronary artery disease suffered from sudden death 1 month later. Angiographic follow-up was performed on 8 renal arteries in 7 patients over a mean of 11.0 ± 7.8 (range, 5~26) months. One (12.5%) renal artery in-stent restenosis occurred. During the mean 14.3 months of follow-up, the number of anti-hypertension drugs was reduced from 2.3 ± 1.0 to 1.9 ± 1.1 ($p = 0.02$), and serum creatinine changed from 2.38 ± 1.25 to 2.65 ± 2.12 mg/dL ($p = 0.29$).

DISCUSSION

PTRA or PTRS has become a standard procedure for people who have renal artery obstruction disease, in order to reduce renal insufficiency, blood pressure and/or medication requirement. It is the preferred revascularization technique for the treatment of renal artery stenosis.¹⁻⁵ The femoral artery is the traditional access site for coronary artery and peripheral artery interventions because of the ease of catheter manipulation. However femoral artery complications occur in 1.2%~6% of patients who undergo coronary artery or renal artery an-

Table 2. Pre- and post-interventional clinical data

	Before the procedure	After the procedure	Follow-up (14.3 mo)
Serum creatinine ≥ 1.5 mg/dl	14/20 (70%)	15/20 (75%)	13/19 (68.4%)
Serum creatinine (mg/dl)	2.38 ± 1.25 (0.7~4.2)	2.40 ± 1.26^a (0.9~5.9)	2.65 ± 1.35^b (0.9~9.9)
Antihypertension drugs (<i>n</i>)	2.3 ± 1.0 (1~4)		1.9 ± 1.1^c (0~4)

**p* value vs. the respective baseline value

^a*p* = 0.95; ^b*p* = 0.29; ^c*p* = 0.02.

gioplasty.^{4,5,10-12} Radial artery access for coronary angioplasty has been proven feasible and safe in Chinese patients,⁷⁻⁹ and hemostasis is easily achieved by simple application of a pressure bandage over the puncture site. There are fewer vascular complications with radial access than with femoral access even when using a vascular suture device.^{10,13} The femoral artery approach has limitations, such as a markedly inferior angulation of the renal artery, particularly in calcified vessels. The precise placement of the guiding catheter at the ostium is difficult. This causes poor back-up of the guiding catheter and easy misplacement of the stent. The precise placement of the stent is critical in order to minimize the rates of restenosis. Improvements in angioplasty peripheral equipment with low-profile balloon catheters and highly flexible, premounted stents have enabled the use of smaller lumen sheaths and guiding catheters. We used the transradial artery as an alternative entry method for angioplasty and/or stenting in renal artery interventions. This approach leads to an ideal coaxial alignment of the guiding catheter in selected patients.

Renal artery interventions have a high technical success rate. Some reports have described rates of 95%~100%.^{4,5,14-16} Our study also revealed a 100% procedural success rate using the transradial method. The experience with PTRA and PTRS has indicated a variable incidence of major complications, including renal artery ruptures, perforations, thrombosis, renal and systemic atheroembolisms, infections, major hemorrhage, and death, ranging from 1.9% to 66%.^{4,5,17-19} In our series, 1 patient (5.0%) had a major complication: a perirenal hematoma owing to guidewire perforation which necessitated a blood transfusion. He experienced no further sequelae after discharge. Also, there were no in-hospital deaths or cardiovascular events. One patient (5.0%) died during the clinical follow-up of 14.3 months. He had severe coronary artery disease but he refused bypass surgery and suffered from sudden death 1 month after the intervention.

Renal insufficiency commonly occurred in our clinical patients. Renal function impairment was found in 14 (70%) patients at the baseline. ARF was discovered in 3 patients, and 2 of them had baseline renal function impaired. One patient improved, while the others improved but still had higher than baseline levels before being discharged. With a mean clinical follow-up of 14.3 ± 14.5

months, renal function was found to have improved in 4 (21.0%), to be stable in 9 (47.4%), and to have worsened in 6 (31.6%) patients. Deterioration of renal function resulting in end-stage renal failure was found in one patient who was baseline serum creatinine 4.2 mg/dL four months post-intervention, and he required regular hemodialysis. The mean serum creatinine level increased from 2.38 ± 1.25 to 2.65 ± 2.12 mg/dL ($p = 0.29$). In Lederman et al's study,¹⁶ the investigators found that post-procedure azotemia was more common in patients with baseline renal insufficiency than without baseline renal insufficiency (22.5% vs. 4.2%), and they reported that serum creatinine increased from 2.22 ± 0.90 to 2.34 ± 1.21 mg/dL ($p < 0.001$).¹⁶ It is unclear whether the deterioration in renal function is related to renal atheroembolism, contrast-induced nephrotoxicity, progression of nephrosclerosis, or restenosis. It needs large, prospective and controlled study to be determined. Kay et al.²⁰ indicated that the use of hydration and oral N-acetylcystein before and after contrast exposure in renal insufficiency patients reduced the incidence of contrast-induced nephropathy from 12% to 4% ($p = 0.03$). Despite adequate hydration but no oral N-acetylcystein before and after contrast exposure in our patients, 3 patients (15%) experienced ARF. This may have been due to the large contrast volume used during the simultaneous coronary angiographic and renal artery intervention, and/or to an atheroembolism. So minimizing the amount of contrast and use of distal embolic protection device are important. Henry et al. reported the feasibility and safety of embolic protection in a series of 32 renal artery interventions.²¹

All patients in our study had hypertension and were taking at least 1 (range, 1-4; mean, 2.3 ± 1.0) anti-hypertension medication at the time of enrollment. After a mean 14.3 months of follow-up, the number of anti-hypertension medications decreased to 1.9 ± 1.1 ($p = 0.02$). Hypertension was found to have been reversed in 1 (5.3%), to have improved in 5 (26.3%), and to have remained unchanged in 13 (68.4%) patients. In previous studies, the reverse rates of hypertension in patients undergoing renal artery intervention were 4%~18%.^{14,22,23} This figure is similar to that of our study, which had a smaller number of patients. A reduction in blood pressure can reduce the probability of the occurrence of strokes and coronary events.²⁴ Therefore, the benefits of PTRA and PTRS are that they are easier for anti-hypertensive

treatment and for reducing cardiovascular disease.

Follow-up angiography was obtained in 8 renal arteries (40%) of 7 patients after a mean of 11.0 ± 7.8 months. There was 1 angiographic restenosis which required a repeat balloon angioplasty. Other investigators reported restenosis rates of 7.7%~21% when using stents.^{4,5,16,22,23} Lederman et al. described how the marker of a large vessel diameter was associated with a lower incidence of restenosis. The restenosis rate was 36% for a vessel diameter of < 4.5 mm compared with 15.8% for a vessel diameter of 4.5~6 mm ($p = 0.068$) and 6.5% for a vessel diameter of > 6 mm ($p < 0.01$).¹⁶ Shammas et al.²⁵ also demonstrated a 40% restenosis rate in renal arteries with a reference diameter of ≤ 4 mm versus 18.4% in those with a reference diameter of > 4 mm ($p < 0.05$). In this study, among 8 renal arteries in 7 patients, 6 had a renal artery vessel diameter of > 5 mm and 2 had a renal artery vessel diameter of < 5 mm. The patient who experienced in-stent restenosis belonged to the latter group. These results are similar to those of previous studies.

Although radial artery access for renal artery intervention can use either the left or right radial artery, we prefer the left radial approach in our catheterization laboratory. With the left radial approach, there is a shorter distance to the descending thoracic aorta. On the other hand, the right radial approach might make the procedure more difficult, particularly in elderly hypertensive patients with severe tortuosity and angulation of the innominate artery and/or subclavian artery.

Study Limitations

The major limitation of this study is that it is a retrospective, non-randomized analysis of the experience in a single center with a small number of patients. It is possible that selection bias may have existed for patients who underwent the intervention. Also, comparison with femoral and brachial arterial access routes is beyond the scope of this paper. The lower rate of angiographic follow-up may have underestimated the restenosis rates. Contrast medium is one of important factors in acute renal failure. The contrast volume was not calculated in this study.

CONCLUSIONS

Transradial renal artery intervention performed by

an experienced operator has a high technical and procedural success with a relatively low risk of vascular complications in those patients with renal artery stenosis as compared with that of traditional methods reported in the literature. Our patient population was too small to reach definitive conclusions, however, we think that it is clear that the transradial approach is an alternative method for treating renal artery obstruction disease with low incidence of complication.

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中國人經橈動脈執行腎動脈氣球擴張及支架術之經驗

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背景 傳統治療腎動脈狹窄的方法是經由股動脈執行腎動脈氣球擴張術和支架術，股動脈直接加壓止血後需臥床休息數小時，而且易有血管併發症；經橈動脈冠狀動脈介入性治療已經證實是安全且可行，在此回溯性報告中我們評估使用這種方法執行腎動脈狹窄介入性治療之可行性。

方法 在 20 位病人中，共 21 條腎動脈狹窄，我們使用 6Fr 導引導管經左橈動脈施行氣球擴張術和支架術之介入性治療。

結果 21 條腎動脈狹窄中，18 條腎動脈施行支架術，3 條腎動脈作氣球擴張術；18 條施行支架術的腎動脈中有 10 條腎動脈須先行氣球擴張，成功率 100%。住院中沒有病患死亡，只有一位病患發生腎臟周圍血腫需要輸血；一位病患有嚴重冠心病于術後一個月猝死。七位病患共 8 條腎動脈施行血管攝影追蹤平均 11.0 ± 7.8 個月，一位發生再狹窄 (12.5%)。臨床追蹤平均 14.3 ± 14.5 個月，4 位腎功能改善 (21%)，9 位穩定 (47.4%)，6 位變壞 (31.6%)；高血壓治療：1 位恢復 (5.3%)，5 位改善 (26.3%)，13 位不變 (68.4%)。

結論 經橈動脈執行腎動脈介入性治療是安全且可行的，容易止血且降低血管併發症，病患也可提早下床活動，值得考慮成為替代傳統股動脈途徑施行腎動脈介入性治療。

關鍵詞：經橈動脈、腎動脈狹窄、血管擴張術、支架術。