# Percutaneous Transluminal Angioplasty of Renal Artery Fibromuscular Dysplasia: Mid-term Results

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**Objective:** To evaluate mid-term imaging, clinical follow-up, and restenosis rates from patients that had undergone percutaneous transluminal renal artery angioplasty (PTRA) for symptomatic renal artery fibromuscular dysplasia (FMD).

**Materials and Methods:** Between March 1999 and July 2006, 16 consecutive renal artery FMD patients underwent PTRA for poorly controlled hypertension. The patients were enrolled into this retrospective study after receiving 19 primary and four secondary PTRAs in 19 renal artery segments. Follow-up monitoring of blood pressure, use of antihypertensive medication, and the serum creatinine level after PTRA were assessed at 1, 3, 6, 9, 12 months, and each following year. The degree of restenosis was evaluated with computed tomographic angiography (CTA) after PTRA at 6, 12 months, and every year if possible. Technical and clinical success rates for the treatment of FMD, and restenosis rates for the renal artery were evaluated.

**Results:** The technical success rate for primary PTRA was 79% (15/19) and the complication rate was 16% (3/19). Hypertension improved in 80% (12/15) of the patients after four weeks follow-up, and was finally cured or improved in 93% (14/15) during the mean follow-up period of 23.6 months. There was a cumulative 22% (4/18) restenosis rate during the follow-up period. All of the patients were treated with a second PTRA without complications and all of the patients were cured of hypertension after the second PTRA.

**Conclusion:** Percutaneous transluminal renal artery angioplasty for clinically symptomatic renal FMD is technically and clinically successful and safe to perform. For all patients with restenosis, there was a good response after undergoing a second PTRA.

Fibromuscular dysplasia (FMD) accounts for 10% of all cases of renal artery stenosis (1). FMD is usually seen in young women and can progress to uncontrolled hypertension, but it only rarely progresses to complete occlusion of the renal artery (2). Renovascular hypertension caused by FMD is one of the most common curable forms of hypertension (3–5).

Surgical reconstruction has been the accepted standard of therapy for renal artery FMD (6). Recently, percutaneous transluminal renal artery angioplasty (PTRA), with or without stent placement, has become the preferred choice for correcting symptomatic renal FMD as it is less invasive than surgical reconstruction (7, 8).

Several reports have described the short-term technical and clinical success of PTRA for renal artery FMD (9–11). However, few reports have described mid- to long-term durability and clinical success of PTRA. The purpose of this retrospective study was to evaluate the mid-term imaging and clinical follow-up of blood pressure responses and

restenosis rates from patients that had previously undergone PTRA for symptomatic renal artery FMD.

## MATERIALS AND METHODS

### *Patients*

We obtained approval from the institutional review board of our hospital for a retrospective review of patient medical and imaging records, but the institutional review board did not require informed consent. Written consent for the procedure from all patients was obtained after a discussion about the advantages and risks of the procedure (12).

From March 1999 through July 2006, 16 consecutive renal artery FMD patients underwent PTRA for poorly controlled hypertension (a systolic blood pressure of 140 mmHg or above and/or a diastolic blood pressure of 90 mmHg or above on antihypertensive medication with more than two drugs) (13). The patients consisted of eight men and eight women between the ages of seven and 61 years (mean age 32.5 years). The patients underwent 19 primary and four secondary PTRA operations for 19 renal artery segments. Five patients had decreased kidney size and one patient had a history of acute renal failure and diabetes mellitus.

The diagnosis of renal artery stenosis due to FMD was based on angiographic appearance as proposed by McCormack et al. (14) and clinical aspects. There was no intimal thickening or calcification in the aorta, but angiography revealed a non-ostial localization of stenosis with serum ESR and CRP values within the normal range through the entire follow-up period (15). Patients were

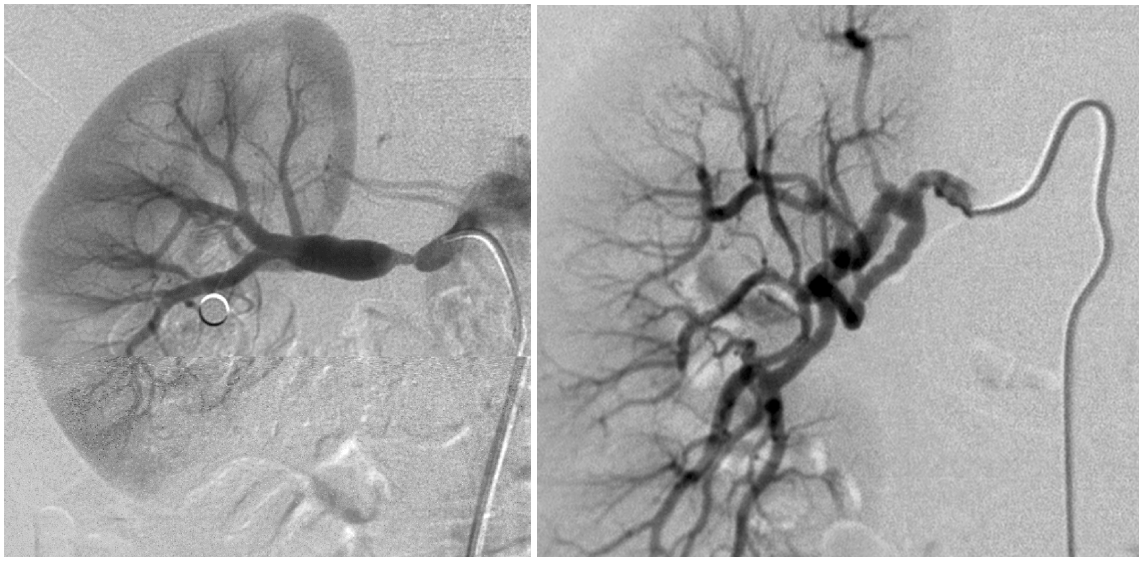

**Fig. 1.** Stenosis shapes of renal artery fibromuscular dysplasia.
**A.** focal stenosis
**B.** beaded-multifocal stenosis
**C.** diffuse segmental stenosis.

evaluated by computed tomographic angiography (CTA) or MRI to confirm the diagnosis of renal artery stenosis.

### *Follow-up Assessment and Definition*

After PTRA, patients stayed in the hospital for at least three days for blood pressure and renal function monitoring. During this time, antihypertensive treatment was adjusted according to the clinical needs of each patient. Patients were then discharged and began a follow-up period that included blood pressure monitoring, physical examinations, and if necessary, CTA follow-up.

Follow-up monitoring of blood pressure, antihypertensive medication, and the serum creatinine level were assessed at 1, 3, 6, 9, 12 months, and every year after PTRA. The degree of restenosis was evaluated with CTA after PTRA at 6, 12 months, and every year, if possible. Clinical follow-up ranged from one to 60 months (mean, 23.6 months) and imaging follow-up with CTA ranged from three to 40 months (mean, 18.3 months). The technical and clinical success rate, and the restenosis rates for the renal artery were evaluated. One of the 16 patients included in this study was unavailable for follow-up. CTA follow-up data was available from 12 patients; this information was not available from the three most recent patients.

After PTRA, blood pressure response was described according to the American Heart Association (AHA) guidelines (16). Hypertension was defined as a systolic blood pressure greater than 140 mmHg or a diastolic blood pressure greater than 90 mmHg. A cure was defined as a

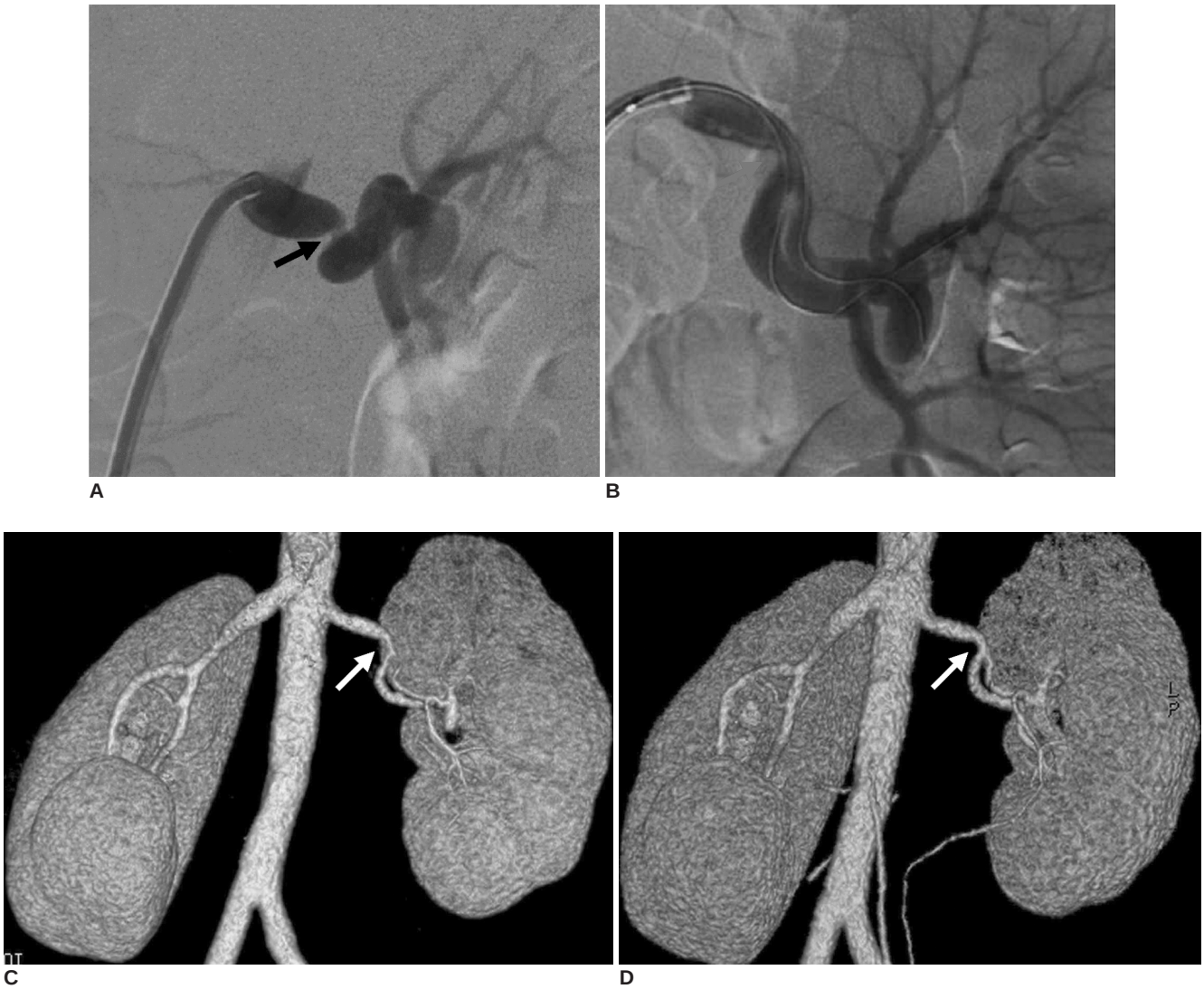


**Fig. 2.** A 29-year-old woman with a focal stenosis in the midportion of the left renal artery.
**A.** Angiography shows a focal stenosis (arrow).
**B.** There is an approximate 40% residual stenosis (arrow) after percutaneous transluminal renal artery angioplasty.
**C.** Six months later, CT angiography shows no interval change in the residual stenosis (arrow).
**D.** Twenty-six months later, CT angiography shows no interval change in the residual stenosis (arrow).

systolic blood pressure less than 140 mmHg and a diastolic blood pressure less than 90 mmHg without the use of antihypertensive medication. Improved status was defined as a diastolic blood pressure less than 90 mmHg and/or a systolic blood pressure less than 140 mmHg without an increase in the dosage of medication. Improvement could also be defined as a reduction in diastolic blood pressure by at least 15 mmHg without increased use of medication. No change was defined as no change or the inability to meet the above criteria for cure and improvement. Patients were seen to have a benefit or cure if improvement in the blood pressure status was observed. An elevated serum creatinine level was defined as > 1.5 mg/dL.

By analyzing the angiographic findings for the renal artery, focal stenosis was defined as focal, concentric lesions within 0.5 cm in length. Beaded type stenosis was defined as multifocal stenosis resembling a string of beads. Diffuse segmental type stenosis was defined as a long, smooth narrowing lesion. Ostial lesions were defined as lesions within 0.5 cm of the renal artery orifice. Proximal lesions were defined as lesions within 1 cm of the renal artery orifice. Middle lesions were defined as lesions not ostial or proximal, but appearing before any branching of the main renal artery. Distal lesions involved the branching renal artery.

Technical success was defined as a residual stenosis of less than 30%. Failure was defined as a residual stenosis of greater than 30% or lesion that could not be crossed or dilated. Restenosis was defined as a stenosis greater than 50%, as demonstrated by CTA or angiography during follow-up.

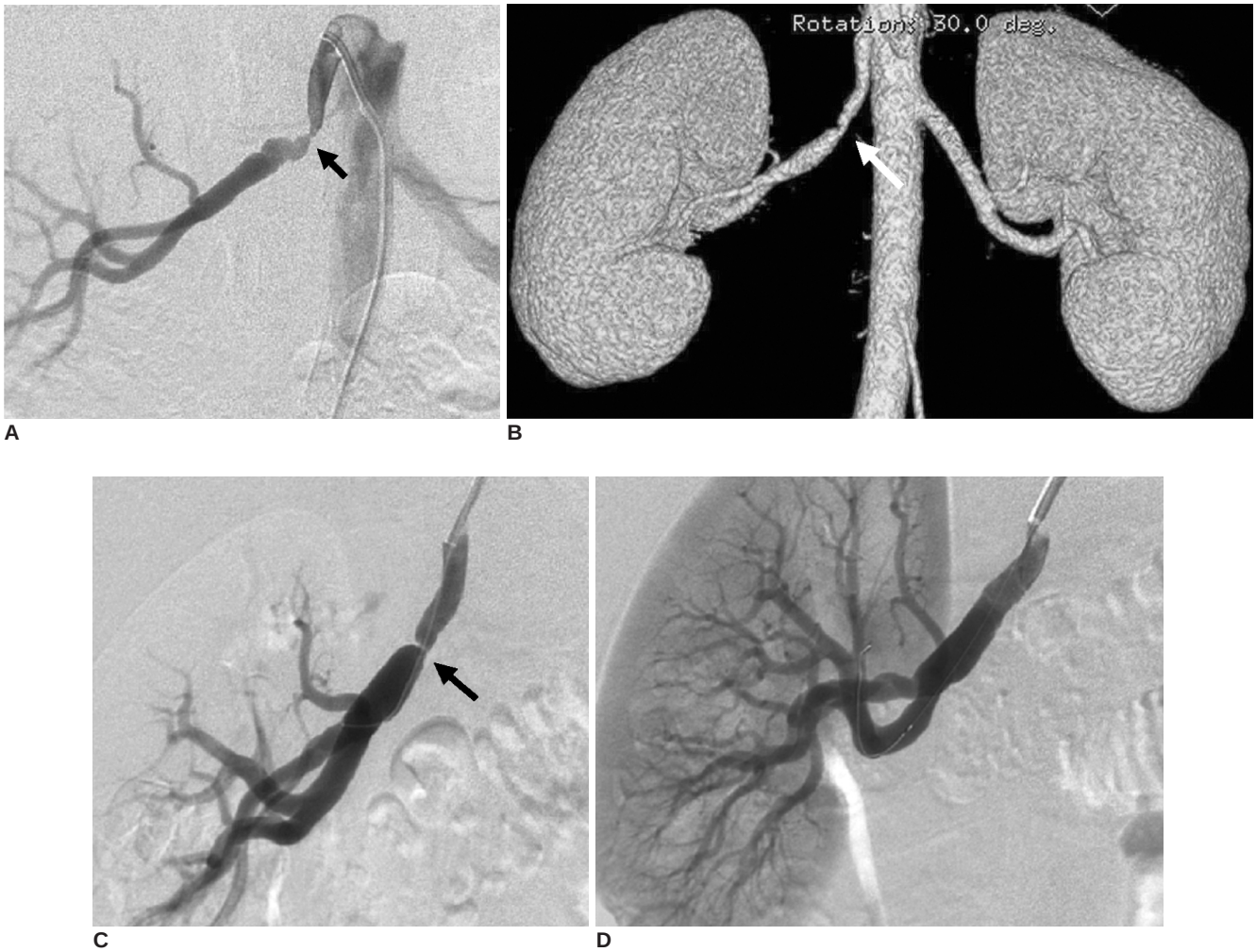


**Fig. 3.** A 26-year-old-man with a beaded stenosis in the midportion of the right renal artery.
**A.** Angiography shows a beaded stenosis of a renal artery (arrow).
**B**, **C.** Follow-up CT angiography and angiography show restenosis (arrows) of the renal artery after 28 months. At that time, there was a sudden elevation of blood pressure.
**D.** After a second percutaneous transluminal renal artery angioplasty, selective right renal angiography shows a successfully dilated renal artery. Clinical cure was achieved after performing a successful second percutaneous transluminal renal artery angioplasty.

*Angioplasty*

In general, angiographic analysis was performed via a femoral approach. Balloon angioplasty was performed with systemic heparinization (80 U/kg IV), a 0.035 inch guidewire (Terumo Medical Corporation, Tokyo, Japan) or an 180/350 cm microwire (SV-5, Cordis Endovascular, Miami Lakes, FL), guding catheter (RDC, Cordis Endovascular), 3–6 mm balloon expandible catheter (Genesis, Cordis Endovascular) and Genesis stent (Cordis Endovascular). A cutting balloon was used in one renal artery for residual stenosis after conventional angioplasty. The balloon diameter was selected to be equal to or slightly larger than the diameter of the renal artery that was estimated on an angiogram. Stents were inserted in three patients that had complications and one patient with residual stenosis after primary PTRA.

## RESULTS

Out of 16 patients, three patients that had bilateral renal artery stenosis underwent bilateral PTRA procedures in the same setting. Lesion distribution in the renal artery was proximal for four cases, middle for 12 cases, and distal for one case. Two lesions involved middle and distal vessels simultaneously. Nine lesions had focal stenosis, five lesions had beaded stenosis, four lesions had diffuse segmental stenosis, and one lesion had focal and segmental stenosis as seen by selective angiography (Fig. 1). Technical success was seen for 79% (15/19) of the PTRAs. One patient had a residual stenosis after a primary PTRA with no clinical change during the 26 months of follow-up (Fig. 2), and three other patients had complications (3/19, 16%) associ-

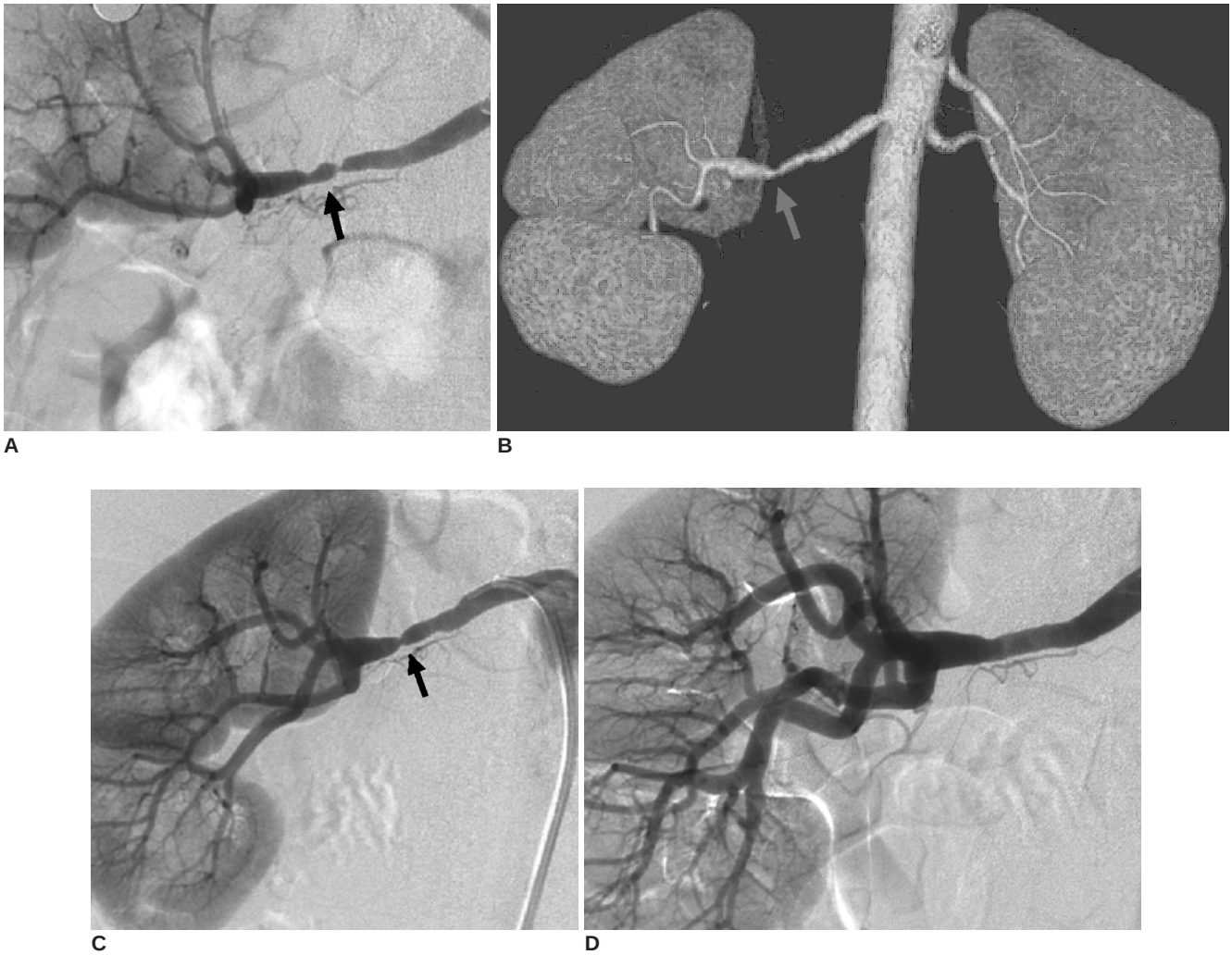


**Fig. 4.** A 29 year-old-woman with a beaded stenosis in the midportion of the right renal artery.
**A.** Angiography shows a beaded stenosis (arrow).
**B**, **C.** Restenosis (arrows) of the renal artery was noted on CT angiography and angiography without clinical change after 12 months.
**D.** After a second percutaneous transluminal renal artery angioplasty, selective right renal angiography shows successfully dilated renal artery. Clinical cure was achieved after performing a successful second percutaneous transluminal renal artery angioplasty.

ated with the primary PTRA: one patient suffered rupture of the renal artery, and two patients had flow-compromising dissection. A stent was inserted for each case of arterial rupture and dissection without complication. In one patient, a cutting balloon was used for residual renal artery stenosis after PTRA. The cutting balloon ruptured a renal artery. We inserted a balloon and inflated it with low pressure for 5 minutes. This caused near total occlusion of the renal artery. We inserted a self-expandable stent. Fortunately, final angiography and follow-up CT showed that the renal artery to have no leakage of contrast medium. One patient already had a flow-compromising dissection associated with renal artery FMD before the procedure. A stent was also inserted without complications. There were no serious adverse events associated with the interventions and no periprocedural mortalities.

### *Clinical Success and Restenosis Rates*

In this study, improvement was seen for 12 of 15 patients (80%), and no change of blood pressure control was observed for three of 15 patients (20%) after four weeks clinical follow-up (one patient was unavailable for follow-up). One of the improved patients seen to be cured of high blood pressure after 12 months as seen by clinical follow-up. There were four patients (4/18, 22%) with restenosis as confirmed by follow-up CTA, each at 6, 7, 14 and 28 months later. Two of the patients showed aggravation of blood pressure control during clinical follow-up (Fig. 3). All four restenotic lesions were treated with a second PTRA operation without complications and all of these patients were subsequently cured of hypertension (Fig. 4).

During the mean clinical follow-up period of 23.6 months (range, 1 to 60 months), six of 15 patients were finally cured of arterial hypertension and eight patients had improved blood pressure control. Clinical benefit (improved or cured hypertension) was seen for 14/15 (93%) patients overall.

There were two patients with impaired renal function (a serum creatinine level > 1.5 mg/dL) before PTRA. The serum creatinine level decreased with no further deterioration in these patients after PTRA.

## DISCUSSION

This study evaluated outcomes for PTRA in hypertensive patients with renal artery FMD. Technical success for PTRA was seen in 79% (15/19) of all patients studied. Clinical success with improvement/cure of arterial hypertension was 80% (12/15) through the first one month, and 93% (14/15) through the second year of the follow-up period. There were four patients (4/18, 22%) with restenosis, as confirmed by follow-up CTA (Fig. 3). All four restenotic lesions were treated with a second PTRA procedure without complications and all of these patients were cured of hypertension after the second PTRA. Few studies have focused solely on patients with FMD (8, 17). A study by Bonelli et al., the largest subset analysis described to date, reported on 105 patients treated with PTRA for renal artery FMD over a 14-year period (18). Of these patients, 63% had improved blood pressure levels and about 50% maintained the same blood pressure for eight years (18). Even though the number of patients was small and the follow-up period was short, our study had a better outcome with a 93% clinical benefit through the mean follow-up period of almost two years.

PTRA is often misunderstood to be a cure for renal artery FMD. However, this study shows clinical improvement is more common than clinical cure. Thus following PTRA, it is much more likely that one is able to reduce the number of medications needed than to replace them completely. In our study, a 40% (6/15) cure rate and a 53% (8/15) of improvement rate was recorded during the follow-up period. Klinge et al. reported a cure rate of 38% (18/47), and improved blood pressure control in 55% (26/47) of patients after six months (19). Mounier-Vehier et al. used CTA to evaluate renal length, cortical thickness, cortical area, and medullary length in 20 patients with unilateral FMD (15). These investigators reported a cure rate of 25% (5/20), and improvement in other patients. In this study, despite successful revascularization and stabilization, there was no recovery from renal atrophy. This could partially explain the persistence of hypertension in 15 of 20 patients (15).

Fewer studies have documented the effects of PTRA on renal function in patients with FMD (13). Our data on renal function in patients with FMD is limited. In our study, there were two patients with serum creatinine levels above 1.5 mg/dL before PTRA. The level of serum creatinine decreased or stabilized in these patients after PTRA. Birrer et al. reported on five patients with elevated serum creatinine levels, and all improved after PTRA. These five patients began with impaired renal function, but none progressed to end-stage renal failure over the 12-month follow-up period (17).

One patient in our study was a 20-year-old man that had a rupture of the renal artery after cutting balloon angioplasty. A stent was deployed soon afterwards. After one month, there was improvement in his blood pressure. Oguzkurt et al. reported a case of arterial rupture with cutting balloon PTA in renal artery FMD. These investigators stated that arterial involvement in FMD causes

thinning of the arterial wall, probably making it susceptible to rupture with cutting balloon PTA (20).

There were four patients with restenosis during follow-up. All of the patients underwent a successful secondary PTRA without complications, and the patients were cured of renal artery hypertension. We found that performing a secondary PTRA for recurring stenosis of renal arteries shows good technical and clinical outcomes.

There are some limitations to be considered in this study. First, as this study was a retrospective study, we had variable imaging and clinical follow-up periods for each patient. Therefore, the statistical analysis was not shown to be significant by the Kaplan-Meier method. Second, due to the small sample size, it was difficult to calculate primary and secondary renal artery patency rates after PTRA. Third, due to the relatively short mean follow-up period, we could not evaluate the long-term effects of PTRA in these symptomatic FMD patients.

In conclusion, PTRA for clinically symptomatic renal FMD is technically and clinically successful and safe to perform. For all patients with restenosis, there was a good response to a secondary PTRA in this study. However, a longer follow-up period is necessary for the evaluation of the long-term effects of PTRA.

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