

Renal artery stenting: early results

Hesham N. Abdel Mooty^a, Engie T. Hefnawy^a, Heba S.H. Kareem^b
and Khaled El Kaffas^c

Departments of ^aSurgery, ^bInternal Medicine and
^cRadiology, Cairo University, Cairo, Egypt

Correspondence to Hesham N. Abdel Mooty, MD,
Department of Surgery, Faculty of Medicine,
Cairo University, 11211 Giza, Egypt
Tel: + 0020233364418;
e-mail: drheshamnabil@hotmail.com

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Background

Atherosclerotic renovascular disease (ARVD) is defined as renal artery stenosis with an occlusion of 60% or more. It is an established cause of resistant hypertension and renal insufficiency. ARVD is evaluated using renal artery duplex ultrasound, which measures the degree of renal artery stenosis and renal resistance index. Treatment with renal artery balloon angioplasty and stents has been shown to improve blood pressure and renal function in some patients.

Aim of the study

This was a prospective study evaluating the early effects of renal artery angioplasty and stenting in patients with ARVD as regards the blood pressure and renal function.

Methods

During March 2009 to September 2011, 37 patients (21 men and 16 women) with ARVD (unilateral or bilateral), resistant hypertension, and renal impairment were selected and divided into two groups: group A (25 patients) comprised patients who underwent renal artery balloon angioplasty and stenting (intervention group) and group B (12 patients) comprised those who were kept on medical treatment as controls and followed up without intervention.

Results

Two weeks after intervention, eight patients (32%) stopped one medication, seven patients (28%) stopped two medications (i.e. one antihypertensive medication only), and five patients (20%) stopped all medications, whereas the blood pressure did not change in five patients (20%). The average mean systolic blood pressure of group A was 140 mmHg and the average serum creatinine level was 2.1. As regards group B, the average mean systolic blood pressure was 170 mmHg for patients who were on three antihypertensive medications, and the average serum creatinine level was 2.4.

Conclusion

The main effect of renal artery revascularization in ARVD is on blood pressure control in patients with resistant hypertension, with minimal influence on the renal function.

Keywords:

angioplasty, atherosclerosis, hypertension, renal artery stenosis, renal impairment, stenting

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Introduction

Renovascular disease is commonly reported among patients with resistant hypertension and multiple risk factors. Atherosclerotic renovascular disease (ARVD) is defined as a diameter-reducing renal artery stenosis (RAS) or occlusion of 60% or more [1]. The stenotic lesions are largely secondary to atherosclerosis (90%), that is ARVD, and their prevalence increases with age [2]. Other causes of renovascular disease include fibromuscular dysplasia, which is present in ~10% of patients with RAS, more frequently in young women. Fibromuscular dysplasia is successfully treated using balloon angioplasty [3]. ARVD is a common disorder, and is an established cause of hypertension and renal insufficiency [4]. Patients with resistant hypertension and known atherosclerotic disease and declining kidney function should be evaluated using renal artery duplex

ultrasound to measure the degree of RAS and renal resistance index (RI) [5]. The renal RI is an indirect parameter that is determined by obtaining Doppler wave curves from the intrarenal segmental arteries. The RI is calculated using the formula [6]:

$$\text{Resistance index} = \frac{\text{peak systolic flow velocity} - \text{diastolic flow velocity}}{\text{peak systolic flow velocity}}$$

Power Doppler facilities have improved the diagnostic capabilities of vascular sonography, mainly because it is independent from the angle of insonation [7].

Although treatment with renal artery balloon angioplasty and stents has been shown to improve the blood pressure and renal function in some patients, the patient population most likely to benefit is unknown [8,9]. There is increasing evidence that in patients with ARVD and chronic renal dysfunction, the etiology of the latter is

more often due to long-standing intrarenal vascular disease and parenchymal injury compared with reversible ischemia [10]. This is reflected in the variability in the renal functional outcome after revascularization, with an improvement in the renal function being observed in only a minority of patients, the majority showing no apparent change or even a decline in the renal function [11,12].

The follow-up of the renal functional outcome was carried out using measurement of serum creatinine levels before and after revascularization [13]. The choice of treatment for atherosclerotic renal lesions is controversial because of the lack of strong evidence in favor of either medical treatment or revascularization for blood pressure control and preservation of kidney function [10,14]. The safety, efficacy, and long-term clinical benefits of renal artery revascularization by stenting are still a matter of debate [13].

Patient selection

During March 2009–September 2011, 50 patients (25 men and 25 women) were referred to the Internal Medicine and Nephrology Units at Cairo University Hospitals suffering from resistant hypertension (under treatment with three antihypertensive medications: β -blockers, vasodilators, and diuretics) and renal impairment, which is documented by high serum creatinine levels. Patients with established renal failure were not included in the study.

These patients ($n = 50$, 25 men and 25 women) were subjected to history taking and general examination; their clinical criteria (age, blood pressure, renal functions, hyperlipidemia, diabetes mellitus, smoking, and chronic lower limb ischemia) were recorded. These patients were submitted to duplex scanning of the renal arteries after proper bowel preparation using charcoal tablets and repeated cleansing enemas. The duplex machine used was HDI 5000 sono (Philips Healthcare, DA Best, The Netherlands), which is equipped with Power Doppler facilities. The patient undergoing renal sonography is kept recumbent in a lateral position: a left decubitus to explore the right renal artery and a right decubitus to explore the left renal artery. A short-axis scanning of the aorta was to be obtained in order to align as much as possible the ultrasonic beam to the axis of renal artery, resulting in a low angle of attack. Thus, our purpose was to obtain the highest signal intensity of the renal artery using an orthogonal variant of the 'banana peel'.

A total of 40 patients (23 men and 17 women) diagnosed with RAS with 60% or more diameter reduction, unilateral or bilateral and uncontrolled systolic blood pressure, that is above 140 mmHg (under treatment with three antihypertensive medications), and renal impairment with serum creatinine levels above 1.2 were offered endovascular intervention in the form of renal artery balloon angioplasty and stenting.

Before the procedure, a written informed consent form was signed by the patient after explaining the pros and cons and possible complications of the procedure.

A total of 12 patients (five men and seven women) refused intervention because they believed that it is risky and thought they were doing well on medical treatment.

Male patients with single unilateral complete renal artery occlusion were subjected to a dimercaptosuccinic acid renal scan that showed no residual renal function in their kidneys. Unilateral nephrectomy was offered, and these patients were excluded from the study (Fig. 1).

Patients and methods

This study included 37 patients (21 men and 16 women) diagnosed with ARVD with a reduction in the diameter of the renal artery of 60% or more unilaterally or bilaterally, resistant hypertension, and renal impairment.

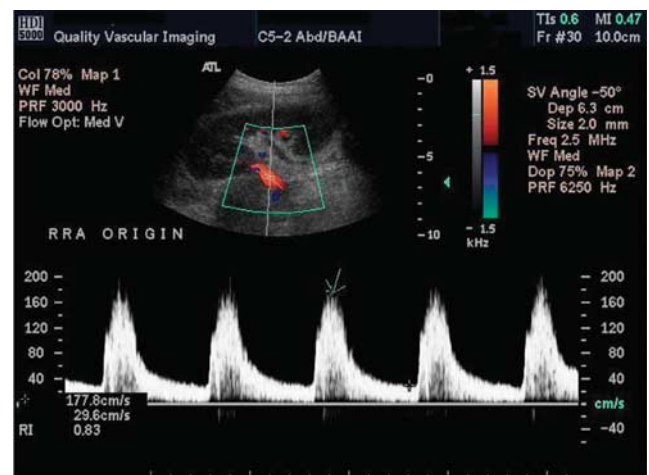
The studied patients were divided into two groups: group A included 25 patients (15 men and 10 women) who were subjected to renal artery balloon angioplasty and stenting (intervention group) and group B included 12 patients (five men and seven women) who were kept on medical treatment as controls and followed up without intervention.

All patients were subjected to thorough history taking and a clinical examination: a fundus examination was carried out for diabetic patients, along with investigations such as determination of blood sugar levels (both fasting and postprandial), kidney functions, and lipid profile, a urine analysis, determination of the albumin–creatinine ratio, an abdominal ultrasound, a duplex ultrasound for the renal arteries, and balloon angioplasty and stenting (for group A only). Before the procedure, renal protection was carried out using acetyl cysteine and intravenous hydration.

Procedure

Access to the renal artery for endovascular intervention was achieved through the percutaneous femoral artery approach in 19 patients and the percutaneous brachial artery approach in six patients with aortoiliac occlusive

Figure 1



A colored duplex ultrasonogram showing ostial renal artery stenosis.

disease. Once an introducer sheath was placed within the femoral or brachial artery, an anteroposterior aortogram was obtained with a pigtail catheter placed within the suprarenal aorta (to avoid missing a diseased accessory or duplicating the renal artery). Catheterization of the renal artery was performed using a selective angled catheter (Cobra-2, Cook Vascular Incorporated, Pennsylvania, USA). Systemic heparin (5000 IU) was administered intravenously. Selective renal angiography was then performed using a hand-injection technique with a ULTRAVIST contrast.

Thereafter, a 0.035-inch guidewire or a smaller 0.018–0.014-inch coronary guidewire was used to cross the stenotic lesion. Once the guidewire traversed the RAS, the catheter was carefully advanced over the guidewire across the lesion. A vasodilator (e.g. glycerol trinitrate, 150 µg) was administered into the renal artery through the catheter to minimize the possibility of renal artery spasms. The angioplasty balloon (less than 4 mm in diameter) was then advanced over the guidewire through the guiding sheath and positioned across the RAS and inflated to the stated nominal pressure for 30 s. A postangioplasty angiogram was performed to document the procedural result. Stenting was performed for all patients, either after a successful balloon angioplasty or after suboptimal angioplasty results such as residual stenosis or renal artery dissection. Atherosclerotic involvement of the renal artery involving the vessel orifice (ostial stenosis) required a balloon-expandable stent placement (PALMAZ, balloon-expandable stent for renal arteries).

Completion angiography was performed by hand-injecting a small volume of contrast through the guiding sheath. It is critical to maintain the guidewire access until a satisfactory completion angiogram is obtained. The sheath was then removed and compressive dressing was applied at the end of the procedure. Four tablets of clopidogrel (75 mg) were given initially and then the patients were continued on one tablet a day for 3 months. Patient monitoring included: assessment of hypertension and renal function responses before and after intervention, determination of blood pressure responses using serial blood pressure measurements, and assessment of medication requirements. All estimates were calculated using the mean of up to three measurements [15,16].

The renal function responses were assessed by measuring the serial serum creatinine levels at least three times, once before the intervention and twice or more thereafter (Figs 2 and 3).

Results

In this study, 37 patients with ARVD ($n = 37$) (21 men and 16 women) were divided into two groups: group A ($n = 25$) (15 men and 10 women) comprised patients who were subjected to intervention and group B ($n = 12$) (five men and seven women) comprised those who had not undergone intervention and only received medical treatment: β -blockers, vasodilators, and diuretics to control

Figure 2



A flush aortogram with the arrow pointing toward ostial stenosis within the right renal artery.

Figure 3



A selective renal angiogram postdilatation with the arrow pointing toward ostial stenosis within the right renal artery.

the blood pressure. The average age of the patients was 59 years. The atherosclerosis risk factors include: male sex (21 patients, 57%), diabetes mellitus (17 patients, 46%), smoking (16 patients, 43%), ischemic heart disease (14 patients, 38%), peripheral vascular disease (seven patients, 19%), cerebrovascular disease (four patients, 11%), and hyperlipidemia (16 patients, 43%).

In the intervention group (group A), the number of patients subjected to intervention was 25 (15 men and 10 women). Of the patients, 18 had bilateral lesions and

seven had unilateral lesions. The total number of lesions was reported to be 43.

Radiological results

According to the abdominal ultrasonograms, the kidney size was normal; the renal artery duplex ultrasound determined the degree of RAS, and the renal RI determined the total number of lesions ($n = 43$) in all patients. During angiography, these lesions were either ostial stenotic ($n = 24$) (56%) or nonostial stenotic ($n = 19$) (44%). There were no major complications during the interventions, but three patients with unilateral ARVD and diabetes mellitus, hypertension, hyperlipidemia, as well as smokers, had unsuccessful cannulation due to near-total ostial occlusion, and the procedures were aborted. Two patients needed hemodialysis for 2 weeks after the procedure and then regained their initial serum creatinine levels.

In the nonintervention group (group B), the number of patients was 12 (five men and seven women). They were maintained on medical treatment in the form of diuretic therapy, angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers. One patient had an attack of flash pulmonary edema, which complicated the hypertension; the patient was admitted to the intensive care unit with a systolic blood pressure of 190 mmHg and responded to an intravenous injection of furosemide and was saved.

The initial blood pressure and renal characteristics were as follows: the average mean systolic blood pressure of group A was 172 mmHg for patients who were on three antihypertensive medications before intervention, with the highest blood pressure being 200 mmHg (three patients) and the lowest was 150 (one patient). The average serum creatinine level was 2.3, with the highest serum creatinine level being 3.1 (one patient) and the lowest being 1.7 (one patient). The average mean systolic blood pressure of group B was 168 mmHg for patients who were on three antihypertensive medications, with the highest blood pressure being 200 mmHg (one patient) and the lowest being 150 (one patient). The average serum creatinine level was 2.4, with the highest serum creatinine level being 3.1 (two patients) and the lowest being 1.8 (one patient).

Postintervention blood pressure and renal characteristics were as follows: 2 weeks after intervention, eight patients (32%) stopped one medication (i.e. two antihypertensive medications only), seven patients (28%) stopped two medications (i.e. one antihypertensive medication only), and five patients (20%) stopped all medications, whereas the blood pressure did not change in five patients (20%). The average mean systolic blood pressure of group A was 140 mmHg.

After intervention, the average serum creatinine level was 2.1, with the highest level being 2.9 (one patient) and the lowest being 1.5 (one patient).

P value is greater than 0.5.

Discussion

The increase in the number of patients diagnosed with RAS led to an increase in the procedures aiming at improving renal perfusion. The assumption was that restoring renal blood flow will improve both blood pressure control and renal functions [17]. This hypothesis did not prove to be entirely correct [18,19]. Various prospective trials raised the question on whether percutaneous transluminal renal artery angioplasty should be performed and which patients would benefit most [20,21].

These trials focused on the clinical and radiological features of the candidates and/or on the clinical outcome of the procedure, that is the changes in the renal function and blood pressure control. Moreover, the safety, efficacy, and long-term clinical benefits of renal artery revascularization by angioplasty and stenting are still a matter of debate.

A Cochrane database systematic review comparing the effectiveness of balloon angioplasty (with and without stenting) with medical therapy for blood pressure control, renal function, frequency of renovascular complications, and side effects in hypertensive patients with atherosclerotic renal artery stenosis (ARAS) concluded that the available data are insufficient, and there is a need for randomized controlled trials comparing the effect of balloon angioplasty and medical therapy on the preservation of renal function on the long term [22].

In this study focusing on the early clinical outcome of the procedure and the effect on the renal function and blood pressure control, the screening of the patients was performed using a duplex ultrasound, which is a noninvasive tool, without using a dye so as not to jeopardize the residual renal function, but limiting factors were also present such as, patient obesity, bad preparation of the bowel, and the operator dependency of the procedure [23].

Before intervention, neither the initial blood pressure nor renal function (serum creatinine) was significantly different among the two groups; the renal affection in diabetic patients was due to both RAS and diabetic nephropathy (as evidenced by the presence of albuminuria and diabetic retinopathy on fundus examination).

In group A (intervention group), before the intervention, the mean average systolic blood pressure was 172 mmHg, whereas after the intervention, the mean average systolic blood pressure was 140 mmHg, that is, lowering of the mean average blood pressure of the patients by 30 mmHg. Antihypertensive medication needs were also reduced in eight patients (32%) who stopped one medication, in seven patients (28%) who stopped two medications, and in five patients (20%) who stopped all medications. Twenty patients (80%) responded after the procedure, whereas five patients (20%) did not respond, and their blood pressure did not change. In group B (nonintervention group), one patient had an attack of flash pulmonary edema, which complicated the hypertension; the patient was admitted to the intensive care unit with a systolic

Table 1 Group A data

Patient number	Age (years)	DM	Hyperlipidemia	Smoking	Serum creatinine before PTA	Serum creatinine after PTA	BP before	BP after
1	59	Yes	Yes	Yes	2.1	2.2	160	130
2	55	Yes	Yes	No	1.8	1.6	200	150
3	63	Yes	Yes	Yes	3.0	2.9	180	120
4	60	No	No	Yes	2.6	2.0	180	180
5	57	Yes	Yes	No	2.0	2.0	160	160
6	70	No	No	No	2.7	2.7	170	140
7	59	No	No	No	2.1	2.2	160	110
8	62	Yes	Yes	Yes	2.8	2.6	150	130
9	60	No	Yes	Yes	3.0	1.7	200	140
10	57	No	No	No	2.1	2.2	160	140
11	54	No	No	No	1.8	2.0	160	160
12	56	Yes	Yes	No	1.8	1.6	180	140
13	60	Yes	No	No	2.5	2.4	170	140
14	62	No	No	Yes	2.2	2.4	160	130
15	48	Yes	Yes	No	3.0	3.1	190	140
16	53	Yes	Yes	No	1.8	1.3	180	140
17	60	No	No	Yes	2.6	2.2	180	150
18	65	No	No	Yes	2.5	2.5	180	140
19	60	Yes	Yes	Yes	1.7	1.9	160	160
20	57	Yes	No	Yes	3.1	2.4	180	140
21	59	No	No	No	2.3	2.4	170	170
22	44	Yes	No	Yes	2.2	2.0	160	150
23	58	Yes	Yes	No	2.9	2.0	200	110
24	64	No	No	Yes	2.0	2.2	150	130
25	67	No	No	Yes	1.9	1.5	160	110
%		52%	44%	52%	Average 2.308	Average 2.16	Average 172	Average 140.4

BP, blood pressure; DM, diabetes mellitus; PTA, percutaneous transarterial angioplasty.

Table 2 Group B data

Patient number	Age (years)	DM	Hyperlipidemia	Smoking	Serum creatinine	Blood pressure
1	59	No	Yes	Yes	1.8	160
2	55	Yes	Yes	No	1.9	190
3	63	No	No	No	2.3	180
4	60	No	No	Yes	2.0	180
5	57	Yes	Yes	No	2.7	160
6	70	No	No	No	3.1	170
7	59	No	No	No	2.4	160
8	62	Yes	Yes	Yes	2.7	150
9	60	No	No	No	2.0	200
10	57	No	No	No	2.9	160
11	54	No	No	No	3.1	160
12	56	Yes	Yes	No	2.4	150
		33.3%	41.6%	25%	Average 2.44	Average 153.33

DM, diabetes mellitus.

blood pressure of 190 mmHg and responded to an intravenous injection of furosemide and was saved.

Before the intervention, the average serum creatinine level was 2.3, whereas after intervention, the average serum creatinine level was 2.1, which was an insignificant difference showing that the renal function was around the same values without marked improvement or deterioration.

Sapoval and colleagues carried out a prospective multi-center registry (ODORI) that enrolled 251 consecutive patients, (276 renal arteries) in 36 centers across Europe to study the periprocedural morbidity and early functional responses to primary renal artery angioplasty and stenting (RA-PTAS) in patients with ARVD. The study reported that the acute success rate was 100%. The systolic/diastolic blood pressure decreased from a mean of 171/89 mmHg at baseline to 142/78 mmHg at 6 months ($P < 0.0001$ vs. baseline) and 141/80 mmHg at

12 months ($P < 0.0001$ vs. baseline), whereas the mean serum creatinine concentration did not change significantly in the total population [13]. The results of our study are in agreement with these results.

In 2008, the American Society of Nephrology reported the results of the Angioplasty and Stenting for Renal Artery Lesions trial on patients with ARVD: there was no difference between the revascularization and medical treatment as regards renal events [24].

Corriere *et al.* [25] reported low periprocedural morbidity and mortality but only modest early improvement in the blood pressure and renal functions.

RAS is common in hypertensive type 2 diabetic patients. The presence of a femoral artery bruit is a useful predictive clinical marker. The captopril test was not useful in predicting the hemodynamic significance of RAS in this patient group [26].

A recent study in 2012 reported that percutaneous transluminal renal angioplasty with stent implantation (PTRAS) has become the treatment of choice for ARAS. The study evaluated the long-term effects of PTRAS on hypertension and renal function in elderly patients with ARAS during 2003–2010. Changes in the blood pressure, antihypertensive treatment, and estimated glomerular filtration rate were analyzed before and after PTRAS. A total of 86 stents were placed successfully in 81 elderly patients. The mean follow-up was 31.3 months (range 12–49 months). There was a significant decrease in both systolic and diastolic blood pressures at the third day after the PTRAS procedure, and the reduction in blood pressure was constant throughout the follow-up period until 36 months after PTRAS. However, there was no marked benefit to the renal function outcome during the follow-up period. The incidence of contrast-induced nephropathy was 9.9% in this study group. The rate of renal artery restenosis was 14.8%. The survival rate was 96.3% for 4 years after the procedure. Moreover, the study concluded that it is beneficial to control the blood pressure in patients with ARAS for up to 36 months after a PTRAS procedure [27]. However, their renal function improvement is limited.

As regards medical therapy alone or in combination with revascularization, renal angioplasty and stenting was followed by a better control of blood pressure and acceptable morbidity, as documented by many studies. In contrast, hypertensive encephalopathy, acute pulmonary edema, and intracerebral hemorrhage are all resistant hypertension complications that can be prevented by the procedure, with or without renal function improvement.

Conclusion

Taking into consideration the results of our study and those of previous studies, it appears that the main effect of renal artery revascularization in ARVD is on blood pressure control in patients with resistant hypertension, with minimal influence on the renal function. Further studies are needed to validate this observation (Tables 1 and 2).

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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