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Primary Stenting for Renal Artery Stenosis

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= 국문초록 =

신동맥 협착증에서 풍선확장술 및 스텐트삽입술

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권 기 환

배 경 : 신동맥 협착증의 치료 방법으로 최근 경피적 경혈관 신동맥 확장술 및 스텐트삽입술(PTRA)이 도입되어 수술적 치료를 대체하고 있다. 그러나, PTRA의 문제점으로 내막박리나 이로 인한 급성 폐쇄 및 만족할 만한 결과를 얻지 못할 경우, 혹은 추적관찰에서의 높은 재협착률 등이 있다. 본 연구에서는 신동맥 스텐트 삽입술에 대한 유용성을 관찰하고 안정성, 효용성을 알아보고자 하였다.

방 법 : 동맥조영술 결과 신동맥 협착증(>50% diameter stenosis)이 발견되어 PTRA 및 신동맥 스텐트 삽입술을 시행 받은 55명의 환자(남자 : 34, 나이 : 56.8±15세)를 대상으로 하였다. 신동맥 협착 병변은 64병변(left : 34, right : 30)였으며 9명의 환자에서는 양측 신동맥에 병변이 있었다. 6명의 환자에서는 신기능 장애가 동반되었다. 병변의 위치는 86%(55/64병변)에서 대동맥으로부터 신동맥이 분지하는 개구부(ostial) 병변 이었다. 모든 환자에서 임상적 추적조사(mean duration : 14±11 months, range : 2~36 months)를 실시하여 신기능 변화, 혈압의 변화 및 고혈압 약제 요구량에 대하여 조사 하였다.

결 과 : 모든 환자에서 성공적으로 스텐트 삽입이 이루어 졌다. 협착부위 전후의 압력차이는 시술 후 현저히 감소하였으며(<5mmHg), 수축기 혈압도 현저히 감소하였다. 그러나, 시술 후 신기능의 통계적으로 유의한 변화는 관찰 할 수 없었다. 25명의 환자에서 신동맥 duplex scan으로 추적관찰 하였으며, 재협착률은 12%(3/25 병변)였다. 5명(9.1%)의 환자에서 혈압강하제를 중단 후에도 정상 혈압이 유지되고 있으며, 혈압조절을 위해 필요한 약제의 수가 감소한 경우가 72.7%였다. 사망이나 응급수술이 필요했던 경우, 신절제가 필요한 합병증의 발생은 없었다.

결 론 : 신동맥 협착병변에서 신동맥 스텐트 삽입술은 성공률이 높고 비교적 안전한 시술 방법으로 신기능 유지 및 혈압 조절에 효과적인 방법으로 사료된다.

중심 단어 : 신동맥협착 · 경피적 경혈관 신동맥 확장술 · 스텐트 · 고혈압 · 신기능.

Introduction

Atherosclerotic renal artery stenosis is the most common cause of secondary hypertension with a prevalence of about 1 percent in the general population of people with hypertension[1)2)]. Severe arterial stenosis may also lead to inadequate renal plasma flow and impair the excretory function of the kidney.

Despite antihypertensive therapy, atherosclerotic stenosis tends to progress, leading to renal ischemia and loss of renal mass[3)]. Ischemic nephropathy may be one of the most important causes of terminal renal failure in the elderly[4)]. Restoration of vessel patency reduces the

need for antihypertensive medication, and may slow the progression of renal failure[5-8]. Up till now, surgery has been the only treatment for renal artery stenoses, but the risks of surgical interventions are still high[9)10)]. Percutaneous transluminal renal angioplasty (PTRA) was first used in patients with renal artery stenosis in 1978 by Gruntzig et al[11)]. Since then percutaneous transluminal renal angioplasty has become widely used for renal artery stenosis treatment[6)] and has tended to replace surgical revascularization as the first line treatment in hypertensive patients with renal artery stenosis due to its low morbidity and mortality[12)].

There are two main etiologies of RAS i.e. atherosclerosis and fibromuscular dysplasia. The results of percutaneous transluminal renal angioplasty are excellent for fibromuscular dysplasia and successful for atherosclerotic stenosis located in the truncus of the renal artery[11)13)]. Ostial stenosis is less easy to treat ; although the rate of acute failure varies between 9% and 76%[10)14-16)] and rates of late restenosis vary between 25% and 40%[16)17)]. Angioplasty with balloon expandable stent placement is more successful with an acute failure rate of only 0−4% and secondary restenosis rate of 3−39%[7)18-20)]. It is less clear whether stent placement also has greater clinical benefit. The indications for treatment, technique, and the type of stents vary considerably. And there were large differences in the published results in terms of technical success, complication, and restenosis rates[7)18)19)21-23)]. The most of previous report for renal artery stenting, the indications of stenting were bailout procedure or suboptimal result by balloon angioplasty. But in randomized comparison trial, primary percutaneous transluminal angioplasty with stent placement and balloon angioplasty plus stent placement as rescue therapy had similar outcomes. However, the burden of reintervetion after balloon angioplasty outweighs the potential saving in stents, so primary stenting is a better approach to use.

The purpose of this study was to evaluate the safety, the efficacy and the long-term results with primary stenting for renal artery stenosis.

Patients and Methods

1. Patients

55 patients (male : 34, female : 21) underwent primary stenting for angiographic renal artery stenosis (RAS : >50% diameter stenosis) that was detected during coronary angiography. The mean age was 58±14 years. There was a high prevalence of coexisting vascular disease and bilateral angiographic renal artery stenosis exceeding 50% in 9 (16.4%) patients. Nine patients suffered from mild to severe renal dysfunction (Serum creatinine, SCr >1.5 mg/dl). Forty-five patients (81.9%) had hypertension that was resistant to intensive antihypertensive treatment. The causes of stenosis were atherosclerosis (83.6%), fibromuscular dysplasia (7.1%), Takayasus's arteritis (6.5%), and Bechet's disease (2.2%). Table 1 shows the characteristics of patients.

2. Lesions characteristics

The lesion sites were ostial in 55 (86%) lesions and non-ostial in 9 (14%) lesions. Ostial lesions were defined as stenoses of more than 50% of the diameter of the renal artery within 5mm of the aortic lumen, caused by atherosclerotic disease of the aorta. Table 2 shows the lesions characteristics of non-ostial and ostial lesions.

3. The indications for stent placement

The indications for stent placement were hemodynamically significant (>50% diametric narrowing) renal artery stenosis and mean transstenotic pressure gradient was greater than 20mmHg.

4. Methods

Multiplane abdominal aortograms were routinely per-

Table 1. Characteristics of 55 patients

Sex (M/F)	34/21
Mean age (years)	58±14
Clinical diagnosis	
Atherosclerosis	46
Fibromuscular dysplasia	5
Takayasus's arteritis	3
Bechet's disease	1
Associated disease	
Diabetes mellitus	6
Coronary artery disease	25
Peripheral artery obstructive disease	28
Carotid artery disease	3
Hypertension	45
Renal insufficiency	9

Table 2. Lesion characteristics (64 lesions)

Lesion sites	
Left	34
Right	30
Stenotic sites	
Ostium	55
Non-ostium	9
Total length of lesion	
<1cm	22
1-2cm	37
>2cm	5
Degree of occlusion (%)	65±8

formed before renal angioplasty. The diameter of the artery was calculated by a computer program with an edge-detecting algorithm (Siemens, Erlanger, Germany). The degree of stenosis was calculated as 1 minus the ratio of the diameter of the lumen at the stenosis to the diameter of the lumen of the uninvolved renal artery distal to the stenosis ; these values were expressed as percentages. The trans-stenotic pressure gradient was determined with use of a 5F multipurpose catheter before and after balloon angioplasty. In most of the cases, renal angioplasty was performed using the femoral access site (48/55, 87.3%). But 7 (12.7%) of 55 patients underwent renal artery stenting using the brachial access due to the very severe angle of the origin of the renal artery. We used an 8F guiding catheter in femoral approach and 6F guiding catheter in brachial approach, placed directly at the ostium of the renal artery, enabling placement of a guidewire into the renal artery, usually a 0.018" Roadrunner® guidewire (COOK). In the presence of ostial lesions, special care was given to the position of the stent, which should slightly protrude into the aorta (approximately 1-2mm). Angiogram was routinely performed at the end of the procedure in order to evaluate the result. Pressure gradient was measured and if the result was satisfactory, the guiding catheter was withdrawn. A bolus dose of 5,000 IU of Heparin was routinely administered during the procedure. Aspirin (100-300mg/d) and Ticlopidine hydrochloride (500 mg/d) had been given for a month, and just Aspirin (100mg/d) administered thereafter. Technical success was defined as residual stenosis of less than 20% of the reference diameter and peak transstenotic pressure gradient of less than 10mmHg. We measured the patients' blood pressure and plasma creatinine concentrations before clinical intervention. Follow-up angiography was performed when high blood pressure sustained, increased serum creatinine, and restenosis was suspected on the duplex scan.

All patients were followed up (mean duration : 14±11months, range : 2-36months) for the effects of the procedure on renal function (serum creatinine), blood pressure control, and the number of antihypertensive medications. Cure of hypertension was defined as diastolic blood pressure of 90mmHg or less without medication. Improvement in hypertension corresponded to a diastolic pressure of 91-109mmHg, with a decrease of at least 10% and withdrawl of at least one drug. A renal dysfunction was considered when seurm creatinine was greater than 1.4mg/dl. Improvement of renal function was defined as at least a 20% reduction in the level of serum creatinine.

5. Statistical analysis

All values are given as mean±S.D. or as numbers of patients or arteries and percentages. Statistical significance was considered when the p value was less than 0.05.

Results

1. Immediate results of procedure

A total of 64 stents were implanted in 64 arteries (55 patients). Three types of stents were used : the Palmaz biliary stents were implanted in 55 arteries (85.9%) - P104, P154, P204, P308, the Jo stents were implanted in 8 arteries (7.8%) and the Micro-II stents were implanted in 1 artery (Table 3).

Stents were implanted successfully in all lesions and immediate patency was achieved in all cases. After placement of a stent, mean percent stenosis was decreased from 64.6±8.3% to 1.47±10.7%. After stent placement, mean and peak trans-stenotic pressure gradient decreased from 33.0±12.4mmHg and 63.1±35.2mmHg to 1.1±1.7mmHg and 2.5±3.4mmHg respectively (Table 4). Mean reference vessel diameter was 6.74±1.1mm. After stent implantation, minimal luminal diameters was in-

Table 3. Stent characteristics

Stent length	
<1cm	19
1−2cm	39
>2cm	5
Stent types	
Palmaz biliary	55
P104	19
P154	18
P204	21
P308	5
Micro II	8
Jo	1

Table 4. Immediate results (stenosis)

	Mean % stenosis	Mean PG (mmHg)	Peak PG (mmHg)
Before stenting	64.6 ± 8.3	33.0±22.4	63.1±35.2
After stenting	1.47±10.7	1.1± 1.7	2.5± 3.4
p-value	<0.01	<0.01	<0.01

creased from 2.39±0.69mm to 6.6±1.04mm.

2. Complications

The procedural complications occurred in 4 patients : Blood loss requiring transfusion in 1 patient, stent migration requiring another stent implantation in 1 patient and transient renal failure due to contrast agent in 2 patients. But, there was no serious complication such as a death, emergency surgery or nephrectomy.

3. Clinical results during follow up

All patients were followed-up clinically and mean duration was 14±11 months, range : 2−36months. Follow-up renal artery duplex scan studies and angiograms were available for 25 patients, and the restenosis occurred in 3(12%) lesions. One of them was Takayasus's arteritis with incomplete stent dilatation and other two cases were ostial atherosclerotic lesions. Hypertension was cured in 5(9.1%) patients, improved in 40 (72.7%) patients, and unchanged in 10(18.2%) patients (Fig. 1). The mean systolic blood pressure reduced from 163±26mmHg before stent placement to 96±15mmHg after placement of stent(p<0.05). The mean diastolic blood pressure reduced from 138±19mmHg to 82±

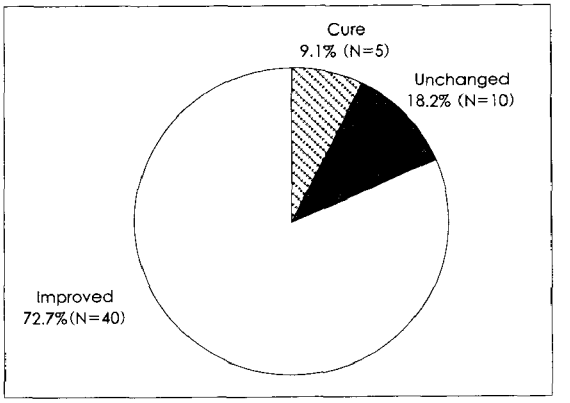

Fig. 1. Effects of renal artery stenting on hypertension : Cure of hypertension was defined as diastolic blood pressure of 90mmHg or less without medication. Improvement in hypertension corresponded to a diastolic pressure of 91−109mmHg, with a decrease of at least 10% and withdrawl of at least one drug.

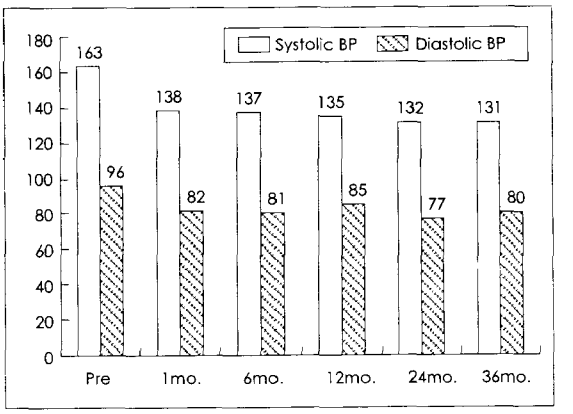

Fig. 2. The mean systolic and diastolic blood pressure reduced after placement of stent. But there was no statistically significant change of blood pressure during follow-up. p<0.05 paired comparison to pre stenting value.

11mmHg(p<0.05) (Fig. 2). There was no statistically significant change of blood pressure during follow-up. The average number of antihypertensive drugs administered per patient after stent placement was 1.5 in comparison to 2.2 before stent placement(p<0.05) (Table 5). The percentage of cases which decreased the requirement for antihypertensive drugs was 72.7%. Generally, the renal functions were not modified by the procedure. The mean serum creatinine level was 1.2±0.8mg/dl before stenting and 1.1±0.6mg/dl after stenting(p>0.05). Renal function was aggravated in 4(7%) patients, was

Table 5. Effects on antihypertensive medication

	Baseline	1 mo.	6 mo.	12 mo.	24 mo.	36 mo.
Drugs(N)	2.22±1.0	1.67±0.7	1.55±0.7	1.48±0.6	1.50±0.7	1.50±0.8

Table 6. Effects on renal function : serum creatinine

	Baseline	1 mo.	6 mo.	12 mo.	24 mo.	36 mo.
SCr(mg/dl)	1.2±0.8	1.35±0.6	1.68±1.9	1.1±0.2	1.1±0.4	1.6±0.6

p>0.05 paired comparison to pre value

improved in 3(5%), and remained unchanged in 48 (88%) (Table 6).

Discussion

Atherosclerotic renal artery stenosis is generally identified incidentally in asymptomatic patients. Most of them are elderly and have multivascular disease. It might be associated with mild to moderate hypertension, end stage renal disease, and diffuse atherosclerosis. Treatment modalities of renal arterial stenosis are still controversial. The selection criteria for patients who may need therapy vary considerably among different institutions. But there hasn't been any specific test that is accurate enough for predicting renovascular hypertension[24] and the final proof in most situations is the post-treatment evaluation of hypertension or the improvement of renal functions. Furthermore, this obstructive process is progressive and stenoses become occlusions in approximately 15% of cases, renal function deteriorates in 10-20% of cases[25][26] ; the more severe the initial stenosis, the more likely progression to occlusion[25] which correlated with a loss of renal mass[27]. These findings should prompt us to treat these patients earlier.

A medical treatment may be proposed to reduce blood pressure. However the lower the arterial pressure means the lower the perfusion and may subsequently worsen renal failure. The surgical treatment has demonstrated its superiority as compared to the medical treatment[28][29]. However, surgical revascularization is associated with a perioperative mortality of 2 to 7%, a morbidity of 17 to 31% and deterioration of renal function in 11 to 31% of the patients, which are sharply contrasted to those of stent revascularization[9][10][30][31]. Renal angioplasty is currently proposed as the first treatment to a patient presenting with a significant renal stenosis. The procedural results of renal artery stenting have been demonstrated superior to those of balloon angioplasty[32][33].

This study showed that interventional treatment of renal artery stenosis is a safe and effective treatment method, especially for ostial stenosis. The results of this study are comparable to those obtained by previous studies[18][32]. No significant residual stenosis or transstenotic pressure gradient persisted after stenting and this probably contributed to better long term results. It has been demonstrated that the larger the initial gain, the larger will be the luminal diameter at follow-up[34]. The immediate technical success rate was 100% in this study. It was similar to those published in the literature, ranging from 96 to 100%[7][8][18-20][22][23].

Several types of stents have been implanted in the renal artery. The wallstent is difficult to be visualized and has high risk of misplacement[21]. The balloon expandable Palmaz stent is the most widely used and happens to be the best documented stent for treating renal artery stneosis. We also used Palmaz stent in 55 (85.9%) patients.

Renal artery stent placement is theoretically assumed that it could lead to increase the number of complications in comparison to renal artery balloon angioplasty alone. However, the complications were low in this study. The percentage of complications in the different previous studies showed considerable variations ranging from 0%[35] to 66%[21]. Complications are more likely to occur in patients with severe atherosclerosis of the abdominal aorta and renal arteries, presenting with unilateral occlusions or bilateral stenoses as compared to patients with mild atherosclerosis and a unilateral stenosis[36].

The restenosis rate after stent implantation is low. In

our study, only 12% of our patients had restenosis. This rate of restenosis is similar to those published in the literature, ranging from 11 to 16%[8)19)22)]. Restenosis is usually caused by myointimal hyperplasia but in Blum's series[20)] subsequent angiography revealed thrombus formation rather than intimal hyperplasia in the majority of the cases. Restenosis caused by disturbed flow and shear stress is particularly likely to be in renal lesions because of the steep angle of origin of the aorta[7)].

The long term results in our patients, with cure of hypertension in 9.1% and an improvement in 72.7% are similar to the results reported in other studies[6)10)23)]. The number of antihypertensive medications is decreased from 2.2 to 1.5 ($p<0.05$). Importantly, after stent implantation blood pressure could be controlled adequately without deterioration of renal functions in most patients. But renal function was improved slightly or remained unchanged in the majority of our patients ($p>0.05$). This phenomenon is similar to those of other published studies[18)20)23)] which did not show a significant improvement in renal functions. One reason of this result is that in these patients renal stenosis is only one of many causes of renal failure in association with renal artery stenosis that is usually of progressive deterioration of renal function[14)]. In this setting even the stabilization of renal functions is considered as a positive effect, thereby, suggesting possible preservation of renal functions. Harden et al showed that after stent implantation the progression of renal failure was significantly slower[8)].

In conclusion, this study shows that the primary renal artery stent revascularization appears to be a safe and feasible treatment modality. The favorable early and long-term results suggest that primary stenting has a beneficial effect on blood pressure control without any deleterious effect on renal function.

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