# Direct Renal Stenting

Direct renal stenting has the potential to be as effective as stenting conducted by previous lesion dilatation.

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Stenting in symptomatic patients (untreatable systemic hypertension, acute left heart failure with flash pulmonary edema and renal insufficiency) with renal artery stenosis can be considered a reliable and effective procedure.[1-11]

Selection of the stenting procedure with or without predilatation depends on the renal lesion anatomy and complexity, the availability of specific low-profile materials, and the choice of the interventional team. The selection of renal direct stenting is based on two issues: anatomical lesion characteristics and angioplasty technical considerations.

A renal artery stenosis that is ideal for treatment by direct stenting technique should match the following characteristics: (1) critical stenosis (≥75%), monolateral or bilateral; (2) quantitative angiography (minimum lumen diameter at lesion site, ≥1.3 mm); (3) echo-Doppler and angiographic absence of diffuse/massive parietal calcifications at the renal lesion site; (4) angiographic absence of fresh thrombus at the renal lesion site; and (5) angiographic absence of chronic total occlusion or long preocclusive lesion (string sign lesion).

When dealing with a tight and complex renal artery stenosis by using bulky devices (guiding catheters, long introducers, .035-inch wires, peripheral balloons, and stents), the likelihood of plaque disruption, spiral dissection, material detachment, and distal embolization ranges from 0.9% to 1.7%.[3,8,9,12] Renal embolization or acute occlusion of the main renal artery can lead to severe deterioration of renal function, requiring hemodialysis.[2-4]

To reduce procedural complications in high-risk patients, we address complex lesions by making the procedure strategy as minimally invasive as possible. First, we use dedicated renal guiding catheters (6-8 F), low-profile wires (.014-inch), and low-profile and flexible premounted stents. Second, we engage the guiding catheter tip in the renal ostium by using the "no-touch technique" for reducing aortic wall trauma.[13] Cholesterol embolism, a serious but infrequent compli-

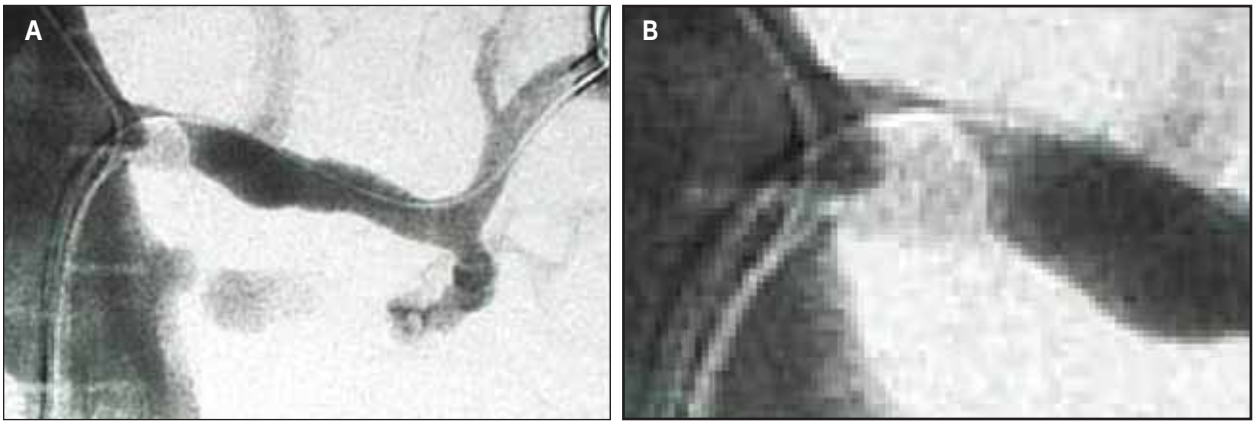


**Figure 1. Left renal artery severe eccentric stenosis treatment: "no-touch technique" for reducing aortic wall trauma and lesion crossing. A Terumo (Somerset, NJ) .035-inch, J wire is placed in the aorta within the guide catheter during cannulation of the renal artery to prevent the tip of the guide from rubbing the aortic wall. A second .014-inch coronary wire crosses the tight ostial lesion and is parked in a segmental branch (A). Left renal artery severe eccentric stenosis treatment: magnified image detail demonstrates that the tip of guiding catheter is not engaged deeply in the stenotic plaque. Intimal disruption and cholesterol embolization can be reduced (B).**

cation of renal artery stenting, may be avoided by minimizing contact between the guide catheter and the atherosclerotic aorta. By placing a Terumo (Somerset, NJ) .035-inch, J-wire within the guide catheter during cannulation of the renal artery to prevent the tip of the guide from rubbing the aortic wall, contact between the guiding catheter and atherosclerotic plaques can be minimized and the potential for intimal disruption and cholesterol embolization can be reduced. Finally, we cross the renal lesion with a very low-profile, premounted stent and we deploy the stent with progressive balloon inflations (direct stenting technique), avoiding any balloon predilatation (Figure 1-4).

## BACKGROUND

The primary endpoint of this study was to evaluate the procedural success rate and early complications (during the procedure and hospital stay) in 99 consecutive patients enrolled to undergo direct stenting for critical renal stenosis. The secondary aim was to evaluate the impact of direct stenting strategy on clinical outcome, analyzing the differences between direct stenting procedures and standard procedures, in which stent implantation was preceded by balloon predilatation.

## METHODS

Ninety-nine patients (103 renal artery stenoses) were admitted to undergo direct renal artery stenting for the treatment of symptomatic critical renal stenosis. The inclusion criteria were (1) renal critical stenosis (>75% carotid lesion), monolateral or bilateral, (2) patients symptomatic for untreatable systemic hypertension, acute left heart failure with flash pulmonary edema or renal insufficiency, and (3) renal stenosis characteristics (minimum lumen diameter, >1.3 mm at quantitative angiography). The exclusion criteria were (1) patients with thrombocytopenia, leukopenia, neutropenia, and gastrointestinal bleeding in the previous 3 months, (2) patients with an objective intolerance to the treatment regimen of ASA-ticlopidine, (3) echo-Doppler and angiographic evidence of diffuse parietal calcifications at the renal lesion site, (4) angiographic appearance of fresh thrombus at the renal lesion site, and (5) angiographic appearance of renal chronic total occlusion or long preocclusive lesion (string sign lesion). Clinical data, cardiovascular risk factors, and comorbidity of the study patients are summarized in Table 1.

In 99% of cases atherosclerotic lesions were treated. In one case (0.97%), the indication for renal stenting was a tight postangioplasty restenosis in a patient with fibromuscular dysplasia. In 71% of cases, the location of renal severe stenosis was ostial, in 29% the location was paraostial (Table 2).

Baseline renal function was moderately impaired in 66% of patients, and severely impaired in 17% of patients. An assessment of renal function revealed that 17 patients were normal (serum creatinine [Crea], <1.2 mg%), 65 were moderately impaired (Crea, 1.2-3 mg%), and 17 were severely impaired (Crea, >3 mg%).

## MATERIALS

Guiding catheter technique via femoral access was routinely used (initially 8 F, currently 6 F). The radial approach (6 F) was used in two patients. In all cases, we

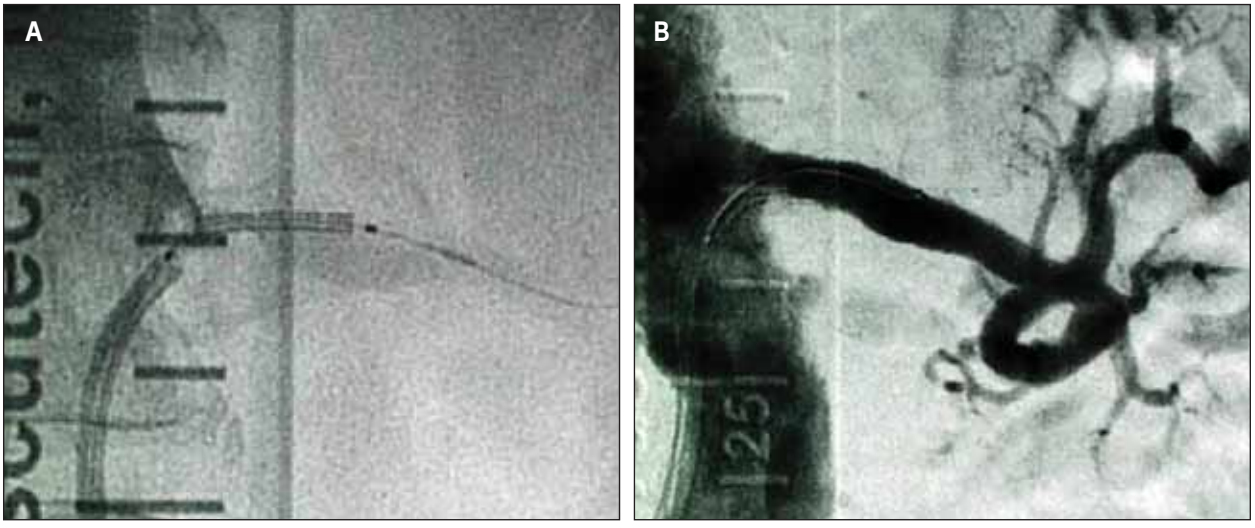


**Figure 2. Left renal artery severe eccentric stenosis treatment: direct renal stenting with Corinthian M3 6/15 mm (Cordis Corporation, a Johnson & Johnson corporation, Miami, FL) (A). Left renal artery severe eccentric stenosis treatment: final result after stent implantation (B).**

**TABLE 1. CLINICAL DATA, RISK FACTORS, AND COMORBIDITY**

| Clinical Data | No. | % |
|---|---|---|
| Population Study | 99 | 100 |
| Male | 60 | 56 |
| Female | 39 | 44. |
| Age | 67 | S.D.= 15 |

| Cardiovascular Risk Factors | No. | % |
|---|---|---|
| Family History | 63 | 64 |
| Hypertension | 99 | 100 |
| Dislipidemia | 67 | 68 |
| Diabetes | 55 | 56 |
| Obesity | 27 | 27 |
| Smokers | 98 | 99 |

| Comorbidity | No. | % |
|---|---|---|
| Coronary Artery Disease | 35 | 35 |
| Prior MI | 26 | 26 |
| Prior PTCA | 23 | 23 |
| Prior CABG | 18 | 18 |
| Peripheral Occlusive Disease | 21 | 21 |
| Cerebral Occlusive Disease | 23 | 23 |
| Abdominal Aneurysm | 11 | 11 |

engaged the guiding catheter tip in the renal ostium by using the "no-touch" technique to reduce aortic wall trauma.[13] In this series, three different types of stents were used (RX Herculink Plus, Guidant Corporation, Indianapolis, IN [80 lesions]; Corinthian M3 [18 lesions]; Antares, Inflow Dynamics Corporation, Munich, Germany [5 lesions]). The average renal vessel diameter was 5.8 mm (range, 4.5 mm to 7 mm).

## RESULTS

Renal direct stenting was effective in all treated lesions (success 100%). In 11 lesions (11%), the final result was optimized by an adjunctive balloon angioplasty after direct stenting. In two lesions (2%), placement of a second stent was necessary because of intimal renal dissection at the distal edge of first stent.

### Procedural Complications

No periprocedural death occurred in this group. The overall procedural complication rate was 2%. There were two reported procedural adverse events: one (1%) renal artery intimal dissection that was successfully treated by adjunctive stent placement and one (1%) retrograde aortic dissection that was localized and unchanged at angiographic and CT serial evaluations. Of interest, both occurred without distal embolization and deterioration of renal function (both transient and permanent) (Table 3).

### Follow-Up

All patients were followed-up at 9 months by clinical and echo-Doppler evaluation to determine either the restenosis rate and/or the late outcome of renal function (serum creatinine). In-stent restenosis recurrence was defined as peak blood flow velocity ≥1.7 m/sec at echo-Doppler, either symptomatic or asymptomatic. The outcome of serum creatinine evaluation was defined comparing baseline values to 9-month follow-up values: decreased >10%, unchanged ±10%, and increased >10%.

At 9-month follow-up, seven cases (7%) of in-stent restenosis were found at echo-Doppler evaluation; all were clinically symptomatic for recurrent unstable systemic hypertension resistant to medical therapy. There were no *de novo* lesions. Renal function was improved in 61 patients (62%), remained unchanged in 32 patients (32%), and worsened in 6 patients (6%).

### Direct Renal Stenting Versus Standard Technique

The direct renal stenting subset (99 patients/103 renal artery lesions) was compared to a standard technique (116 patients/123 renal artery lesions) that was homogeneous in terms of inclusion criteria, exclusion criteria, and materials and methods, and in which the stent delivery was always preceded by lesion predilatation

**TABLE 2. RENAL LESION CHARACTERISTICS**

| | No. | % |
|---|---|---|
| Atherosclerotic Lesions | 102 | 99 |
| Fibromuscular Dysplasia | 1 | 1 |
| Arteritis | 0 | 0 |
| Right RA | 57 | 55 |
| Left RA | 46 | 45 |
| Ostial Lesions | 73 | 71 |
| Paraostial Lesions | 30 | 29 |

**TABLE 3. PROCEDURAL COMPLICATIONS**

| | No. | % |
|---|---|---|
| Death | 0 | 0 |
| RA Dissection | 1 | 1 |
| Renal Artery Rupture/Perforation | 0 | 0 |
| Retrograde Aortic Dissection | 1 | 1 |
| Distal Embolization | 0 | 0 |
| Deterioration of Renal Function | 0 | 0 |

with a suitable balloon.

Procedural data, complications, and 9-month follow-up in the two subgroups (direct stenting, predilatation) are reported in Tables 4 and 5.

The major differences demonstrated between the two study groups are (1) balloon angioplasty after stenting (11% in the direct stenting group vs 40% in standard technique group), (2) adjunct stent placement (2% in the direct stenting group vs 6% in the standard technique group), (3) renal artery dissection (1% in the direct stenting group vs 6% in standard technique group), (4) in-hospital deterioration of renal function (absent in the direct stenting group vs 3% in the standard technique group), and (5) 9-month in-stent restenosis (7% in the direct stenting group vs 15% in the standard technique group).

## DISCUSSION

A review of published studies on renal artery stenting reveals some homogeneous outcome results, yet there are still some unanswered questions regarding indications and treatment strategy. In most studies, stent revascularization of ostial/proximal atherosclerotic renal artery stenosis is considered feasible in the majority of cases,[1-11] with a low procedural complication rate.[14] Most reports on endovascular stent revascularization of renal artery stenosis resulted in improved blood pressure control.[16-19] Survival after successful stenting for severe ostial renal artery stenosis depends on baseline serum creatinine and left ventricle function. Efforts must be made to avoid the development of advanced ischemic nephropathy and congestive heart failure.[20]

Discrepant results on the effect of stent angioplasty of renal artery stenosis on renal function have been published.[16-19] Transient renal dysfunction after renal artery angiography or PTRA/stenting occurs in approximately 15% of patients, but persistent renal failure is uncommon. Pre-existing renal impairment and amount of contrast agent are independent risk factors. Endovascular treatment of renal artery stenosis is not associated with a higher risk of renal deterioration compared to selective renal angiography.[6]

An acceptable renal in-stent restenosis rate is roughly 13% to 17%. Target vessel diameter is considered to be the only independent predictor for restenosis in the multivariate analysis: the smaller the diameter the high-

**TABLE 4. PROCEDURAL DATA AND COMPLICATIONS OF DIRECT STENTING AND PREDILATATION**

| Procedural Data | Direct Stenting | | Predilatation | |
|---|---|---|---|---|
| | No. | % | No. | % |
| Success | 103 | 100 | 121 | 98 |
| Balloon Angioplasty After Stenting | 11 | 11 | 49 | 40 |
| Adjunct Stent Placement | 2 | 2 | 7 | 6 |

| Procedural Complications | Direct Stenting | | Predilatation | |
|---|---|---|---|---|
| | No. | % | No. | % |
| Death | 0 | 0 | 0 | 0 |
| RA Dissection | 1 | 1 | 7 | 6 |
| Renal Artery Rupture/Perforation | 0 | 0 | 2 | 2 |
| Retrograde Aortic Dissection` | 1 | 1 | 0 | 0 |
| Distal Embolization | 0 | 0 | 0 | 0 |
| Deterioration of Renal Function | 0 | 0 | 4 | 3 |

**TABLE 5. 9-MONTH FOLLOW-UP OF DIRECT STENTING AND PREDILATATION**

| 9-Month Follow-Up | Direct Stenting | | Predilatation | |
|---|---|---|---|---|
| | No. | % | No. | % |
| In-Stent Restenosis | 7 | 7 | 17 | 15 |
| *De Novo* Lesion | 0 | 0 | 3 | 3 |

| Outcome of Creatinine at 9-Month Follow-Up | Direct Stenting | | Predilatation | |
|---|---|---|---|---|
| | No. | % | No. | % |
| Decreased >10% | 61 | 63 | 70 | 60 |
| Unchanged (±10%) | 32 | 32 | 36 | 31 |
| Increased >10% | 6 | 6 | 10 | 9 |

er the restenosis rate.[20,21]

A definite consensus on renal artery stenting still has not been reached because of a lack of level 1 scientific evidence regarding improvement of renal function after renal artery stenting. The results of ongoing studies may identify subgroups of patients with renal artery stenosis who gain a clear benefit from revascularization. In the meantime, it seems reasonable to attempt revascularization in severe hypertension resistant to medical therapy, rapidly progressive renal failure with no obvious cause other than renal artery stenosis, and recurrent flash pulmonary edema.[8]

New low-profile devices (dedicated guiding catheters, .014-inch wires, premounted stents with a very low crossing profiles) are more frequently accepted as standard technical equipment for dealing with renal artery stenting, with or without predilatation. Outcome results seem encouraging.[1,9-11]

Our initial experience with renal direct stenting shows a positive trend in terms of procedural success, complication rate, and in-hospital outcome, as well as 9-month clinical and echo-Doppler follow-up.

Our data are even more encouraging if compared to the results on renal stenting related to a "standard technique subset" homogeneous in terms of inclusion criteria, exclusion criteria, and materials and methods, and in which the stent delivery was always preceded by balloon lesion predilatation.

Even if no significant statistical difference can be demonstrated between the two study groups, the comparison pointed out some remarkable findings. Similar data have been reported by other groups,[1,4-7] but only a few experiences specifically report data on indication, technical management, and outcome results of direct renal stenting. The likely explanation of the good results we report in the subset of renal direct stenting probably lies in patient selection and procedure management.

The technical key points of direct renal stenting are (1) patient selection, (2) atraumatic engagement of dedicated guiding catheter of the renal artery ostium, (3) precise positioning of the low-profile premounted stent, (4) speed and minimum use of devices across the lesion, and (5) reduced need of contrast media.

Despite the encouraging data we report, we do not think renal direct stenting can be applied to all lesions and anatomies. In our study, we only admitted patients and renal lesions to direct renal stenting that complied with the specific inclusion and exclusion criteria.

Any time we determined that direct renal stenting was the strategy of choice, we put into practice an individual treatment strategy based on matching the specific lesion morphology and complexity to the technical features of renal stenting dedicated devices. Echo-Doppler and/or angiographic evidence of diffuse parietal calcifications at the renal lesion site were considered a contraindication to renal direct stenting. In such cases, it could be dangerous to directly implant a balloon-expandable endoprosthesis because the lesion could not be dilated at the balloon delivery burst pressure. If the delivery balloon blows up before achieving

the optimal stent expansion, it may be difficult or dangerous to remove the balloon, and the probability of stent migration and loss is not negligible. In cases of very diffuse lesion calcifications, we always try to remodel the calcified plaque before stent implantation with progressive inflations of standard noncompliant balloons or, better, by performing cutting balloon angioplasty.

Long preocclusive lesions (string sign lesion), as well as the appearance of fresh thrombus at the renal lesion site, have to be considered another contraindication to renal direct stenting. In these cases, even if the target lesion can be easily crossed by a .014-inch hydrophilic wire, stent insertion without predilatation could detach soft material and provoke distal embolization.

## CONCLUSIONS

In our experience, direct renal artery stenting, when performed in a selected population by using dedicated premounted, low-profile, and flexible stents, proved to be as safe and effective as renal stenting conducted by previous lesion dilatation. Direct renal stenting can significantly reduce the need for adjunctive balloon angioplasty after stenting. By using this strategy, we significantly reduced the occurrence of renal artery dissection and the need of adjunctive stents. ■

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