Long-term follow-up of endovascular treatment of renal artery aneurysms with covered stent deployment.

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Aims and objectives

Renal artery aneurysms (RAA) are uncommon conditions, with a reported prevalence of 0.01% and 1.0% (01-09). They correspond to the 22% of visceral aneurysms and most are due to fibromuscular dysplasia and atherosclerosis. However, these aneurysms can also arise from congenital disorders (i.e., Ehlers-Danlos syndrome and neurofibromatosis), trauma, dissection, infectious sources, and inflammatory causes, such as polyarteritis nodosa (02,06-13). The risk of rupture seems to increase as the diameter exceeds 1.5 cm, with a 20-100% rupture-related mortality rate (03,07,10,14,15). Often, before the rupture, this pathology is asymptomatic and the diagnosis is accidental, but, in some patients, it can be associated with hypertension and, in advanced stages, chronic renal insufficiency (03,04,13,16). Up to 80% of the aneurysms have saccular shape and can be treated either with coil embolization or with stent deployment (04,16). The aim of the study is to examine feasibility, effectiveness and results of treatment of the renal artery aneurysms positioned in the main artery using covered stents.
Methods and materials

MATERIALS AND METHOD

We retrospectively analyzed seven consecutive patients with eight renal artery aneurysms who underwent endovascular treatment from 2004 to 2009 using stent grafts in our institution. These patients were referred from Nephrology to Diagnostic Imaging Department to be examined due to arterial hypertension (137.9±35.0 mmHg) refractory to pharmacological treatment (Table I).

Patients did not have a family history of hypertension, and they suffered from headache and dizziness (2 patients), macroscopic hematuria and backache (1 patient), and abdominal bruits (3 patients). In all patients have been previously examined the following laboratory indexes: glomerular filtration rate (GFR), creatinine, nitrogen urea blood, sodium, potassium, calcium, phosphorus, magnesium, aldosterone, renine, angiotensin II, ACTH, cortisol, adrenalin. The GFR was calculated using the formula of the Modification of Diet in Renal Disease Study Group (17) while the drug therapy was quantified in Defined Daily Doses (Defined Daily Doses: DDD) (18). Patients showed a GFR decrease (56.6±15.7 mL/min/1.73m2) (table I) associated with creatinine (4.6±3.1 mg/dl) and nitrogen urea blood (60±4.5 mg/dl) increase, a slight increase of sodium (NA =151±2.7 mEq/dl), a potassium decrease (K =2±2.3 mEq/dl); the other blood parameters were within the normal range.

The diagnostic step involved Duplex UltraSound evaluation which has diagnosed the presence of the aneurismatic lesion on renal artery in six patients (86 %), in three cases a hemodynamically significant stenosis was found, in one (14 %) there were two bilateral aneurysms. In one patient because the abdominal fat and meteorism, ultrasound was not exhaustive and only morphologic and flowmeter parameters were evaluated. Parameters showed a slight renal dimension decrease (maximum longitudinal length range between 7.5 and 9 cm) with a thinner cortical area. The Duplex evaluation demonstrated in all patients a blood flow turbulence inside the lesion, and, moreover, in three patients pathological resistance index (RI= 0.9±0.1) and systolic velocity pick (svp=270±16 cm/s) were detected.

The following diagnostic step has been a Computed Tomography-Angiography (CTA), to obtain morphologic images in order to plan a correct procedure. Patients with low GFR level (GFR<59 mL/min/1.73m2) were studied with an Magnetic Resonance-Angiography (MRA). In both examinations we evaluated the side and the precise dimensions of the aneurysm, presence of stenosis, shape of the aneurysmatic sac, length of the artery before and after the aneurysm neck, length and diameter of the neck, components of
the wall as fibrous or calcified tissue, presence of thrombosis within the sac and signs of active or recent bleedings.

Indications for treatment were: symptomatic lesions, diameters of the aneurysm >1.5 cm, rupture or dissection, growth or increasing size with serial observations, asymptomatic lesions in high risk patient (e.g. pregnancy, one only kidney) (03, 04). All treated aneurysms were type 1 following Rundback classification, namely aneurysms arisen from the middle segment of the renal artery.

Fusiform RAAs (type 2) located near a bifurcation of the main trunk and distal or intralobar RAAs (type 3) were excluded from the study (12).

The institutional review board at our institution gave full approval and waiver for our retrospective study and approved our treatment protocol. Written patient informed consent of informed consent was obtained from each patient prior to intervention.

The procedures were performed in the angiographic room with the control of patient's parameters. After a local anestesia using lidocaine 2%, a right transfemoral approach was obtained and a 6 Fr 10 cm long introducer sheath (Radiofocus Terumo, Tokyo, Japan) was positioned. In only one patient the transbrachial approach was preferred due to an acute angled of renal artery origin and the Shuttle introducer sheath (Cook Medical, Bloomington, US) was used. In two cases we used a 7 Fr Pinnacle Destination guiding sheath (Terumo, Tokyo, Japan), with a renal curve, in order to achieve a good stability and to avoid a high diameter shaft in femoral access. In one patient a 7 Fr 10 cm long introducer sheath was placed. 5000 IU heparin were administered to the patients. In one patient two 0.014 inches guidewires were used, one in order to catheterize the artery and to give support in the complex anatomy vessel, the other one to advance and deploy the device. In two patients there were severe stenosis and, in one case, we used a monorail balloon catheter for a predilatation as Gazzelle 5 x 20 mm (Boston Scientific, Natwick, US) while in the other patient an Advanta balloon expandable covered stent was placed (Fig. 2). Once obtained a stable access to the aneurysm, the device was advanced until the neck of the aneurysm and was deployed in the vessel to exclude the lesion from the blood flow. The deployed stents had several sizes, diameter size between 4 and 6 mm and length size ranged from 25 to 48 mm. We deployed two Jostent peripheral stent-graft, four Symbiot, one AdvantaV12, and two Direct-stent stent-graft. In one case we used two Symbiot (Boston Scientific, Natick, US) in overlapping in order to cover completely the large neck of the aneurysm and to improve the strength of the stent structure, while in one patient two Symbiot stents 5 x 45 mm were placed in both renal arteries due to the presence of bilateral aneurysms. Two Jostent peripheral stent-grafts (Abbott, Illinois, US) were placed in two patients, whose dimensions were respectively 4-9 x 28 mm and 4-9 x 48 mm (Fig. 1), respectively mounted on a 5 x 30 mm and 5 x 60 mm monorail balloon Ultrasoft (Boston Scientific, Natick, US). An Advanta V12 (Atrium, Hudson, US) was deployed in one patient and it was 6 x 38 mm as measurement (Fig. 2). We deployed
two Direct-stent stent-graft (Minneapolis, Minnesota, USA) in two patients; they were 5 x 13 mm and 6 x 19 mm as measurement.

The pre-procedural drug therapy has been based on double anti-aggregation treatment with aspirin (100 mg/die) and ticlopidin (500 mg/day) or clopidogrel (75 mg/day) for three days. This therapy was administered to patients also in the after-procedural period for 6 weeks promoting re-endothelization; at the end of the period a life-long assumption of aspirin was kept. Moreover a broad-spectrum antibiotic therapy was included, based on penicillin (2g/day) per os for one day, as prophylactic for infection to stent-graft or to necrotic tissue in the case of embolic infarcts.

The day after, a Duplex ultrasound was performed to demonstrate patency of renal artery and exclusion of RAA and 2 days after procedure patients were discharged.

Our follow-up consisted on clinical and instrumental examination which involved: laboratories indexes, especially the GFR and blood pressure, the administered pharmacological therapy before treatment and during follow-up period, and CTA at 1-6-12 months and once a year after the last examination, and Duplex US evaluation at 3-9 months after the procedure.

The treatment was considered successful when aneurysmatic sac exclusion, patency of the placed stent-grafts and absence of complications related to device deployment can be observed on the CTA or MRA examination. It represents the primary endpoint of our study.

Secondary endpoint was represented by clinical and laboratory parameters improvement during the follow-up period evaluated by an expertise clinician.

All data are expressed as mean ± standard deviation (SD). The categorical data are expressed in percentages. Statistical significance of differences between the data pre- and post-treatment was defined as P value <0.05. We used the Student t test for continuous variables. All statistical analysis were performed using the software Epi Info 3.5.1 (CDC, Atlanta USA).
Fig. 1: Fig.1: (A) Preliminary angiography after trans-brachial puncture and right selective renal artery catheterization confirmed the presence of renal artery aneurysm, shown on previous Angio-CT examination (B). The images was reformatted with volume rendering algorithms. (C) Post-procedural angiography reported covered stent placement, type "Jostent peripheral stent-graft", with the subsequent complete aneurysm exclusion and stenosis resolution. (D) Angio-CT control at 12 months follow-up, showed the correct stent placement with regular vessel diameter and thrombosis within the aneurysm.

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**Fig. 2:** Preliminary angiography showed the presence of aneurysm at the III medium of the right renal artery associated with a stenosis proximal to the lesion. (B) Covered stent, type "Advanta V12", advanced over a 0.014 guidewire. (C-D) In relation to non-passage of the stent, selective renal artery catheterization with Simmons I catheter and another 0.014 guidewire was performed to give support in advancement of the device. (E) Stent-graft deployment and (F) post-procedural angiography.
**Results**

Patients were aged between 63 and 78 years and presented, as risk factors, hypertension (n:7, 100%), smoke habit (n:1, 14%) and dislypidemia (n:1, 14%). Five of the eight aneurysms were placed on left renal artery (63%), three on right side (37%) and all lesions presented the following characteristics: diameter of the sac between 29 and 55 mm (mean = 32.5 +/- 5 mm) (Table I) characterized by a saccular shape (100%), presence of an associated stenosis in two of the eight lesions (25%), average length of the renal artery behind and forward the neck of the aneurysm of 9 ± 3 mm, average length of the neck of 5 ± 2 mm and average diameters of 3 ± 2mm, thrombosis was present in two lesions while calcifications on aneurysm wall in one patient. No patients showed direct or indirect signs of active or recent bleeding.

Technical success was obtained in all patients (100%) and no specific complications related to the procedure, as device dislodgement, renal parenchyma ischemia, type II endoleak and aneurysm reperfusion, and no complications related to the endovascular procedure, as haematoma, haemorrhage and infections occurred. All lesions were placed in the middle part of renal artery and no renal branches were sacrificed during stent deployment. Mean follow up time was 28±5 months, although two patients were lost after two years follow-up. At follow up the instrumental exams have shown covered stents patency, absence of endoleaks, no re-stenosis inside the vessels and a decrease of the aneurysm diameters (10% at 6 month, 15% at 12 month follow up). In only one patient (14%), where the Advanta covered stent was deployed, a restricted area on superior pole of the right kidney characterized by an absent contrast enhancement was observed in CTA at six months follow-up and unchanged in the following CTA examinations. This lesion was not present in the CTA at 1 month follow-up and was probably caused by suspension of the after-procedural double anti-aggregation therapy, due to surgical removal of bladder polyp at 4 weeks since endovascular procedure. However the stent-graft remain patent at long-term follow-up and a slight increase of blood pressure as unique clinical sign was observed (patient 2).

Clinical improvement was achieved in all patients, especially headache and dizziness which were not observed in follow-up period, and backache which disappeared in approximately 2 weeks. All patients didn't show any micro- or macro-haematuria episode immediately after procedure. We achieved a decrease of blood pressure (103.9±26.6 mmHg at 3 months, 106.4±27 mmHg at 12 months follow-up) and drug therapy adaptation with an improvement of drugs posology (0.9±0.8 at 3 months, 0.4±0.5 at 12 months follow-up) (Table II). The GFR significantly increased in all patients at 6 months after the procedure, and it slightly increased after 12 and 24 months (table II).
### Table 1: Results

<table>
<thead>
<tr>
<th>N Patients</th>
<th>Blood pressure (mmHg)</th>
<th>DDD</th>
<th>GFR (mL/min/1.73 m²)</th>
<th>RAA diameters (mm)</th>
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<tbody>
<tr>
<td>1</td>
<td>190/115</td>
<td>3.3</td>
<td>49</td>
<td>4.2</td>
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<tr>
<td>2</td>
<td>170/110</td>
<td>2.8</td>
<td>72</td>
<td>3.3</td>
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<td>3</td>
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<td>68</td>
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<tr>
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<td>190/120</td>
<td>3.4</td>
<td>32</td>
<td>2.7 e 3.4</td>
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<td>2.9</td>
<td>60</td>
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<tr>
<td>Mean</td>
<td>137.9 ± 35.0</td>
<td>3.0 ± 0.3</td>
<td>56.6 ± 15.7</td>
<td>3.25 ± 1.0</td>
</tr>
</tbody>
</table>

Table 1: Blood pressure values, anti-hypertension drug Defined Daily Doses, pre-procedural GFR values and RAA diameters.
Table II

| N Patients | Blood Pressure (mmHg) | | DDD | | GFR |
|---|---|---|---|---|---|---|
| | 3 months | 12 months | 3 months | 12 months | 6 months | 12 months | 24 months |
| 1 | 130/85 | 135/80 | 0 | 0 | 58 | 63 | 61 |
| 2 | 135/80 | 140/85 | 1.3 | 0.8 | 91 | 89 | 90 |
| 3 | 120/70 | 125/80 | 1.1 | 1.1 | 83 | 85 | 88 |
| 4 | 140/80 | 135/85 | 0 | 0 | 85 | 92 | 89 |
| 5 | 125/75 | 120/70 | 0 | 0 | 96 | 99 | 95 |
| 6 | 130/80 | 135/80 | 1.6 | 1.2 | 83 | 87 | 88 |
| 7 | 130/75 | 140/80 | 2.0 | 1.8 | 94 | 98 | 95 |
| Mean | 103.9 ± 26.6* | 106.4 ± 27.1* | 0.9 ± 0.8* | 0.4 ± 0.5* | 84.3 ± 11.8* | 87.6 ± 11.2* | 86.6 ± 10.8* |

Table II: Blood Pressure values and DDD at 3 e 12 months follow-up, and GFR values at 6, 12 and 24 months follow-up. *Statistically significant change from baseline (Student t test P <.05)

Table 2: results

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Conclusion

At our knowledge, this is the largest case history in which covered stent deployment on renal artery aneurysm limited to the main renal artery is considered. The procedure was shown to be safe for kidney function, feasible to exclude the aneurismatic sac and to restore vessel patency. At long-term follow-up high technical success rate and good clinical outcome are confirmed, even if a wider effectiveness of the endovascular approach.
References


