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

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Authors: R. Gandini, E. Pampana, D. Morosetti, G. Loreni, A. Chiaravalloti, G. Simonetti; Rome/IT  
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Purpose

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 fibromuscolar 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

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+1=151±2.7 mEq/dl), a potassium decrease (K+1=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 imagines 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 of informed consent for our retrospective study and approved our treatment protocol. Written patient 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 anesthesia 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, which 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: (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) Postprocedural 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.
Fig. 2: (A) 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.

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Table I

<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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<td>4.2</td>
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<td>2</td>
<td>170/110</td>
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<td>68</td>
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<td>2.7 e 3.4</td>
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<td>39</td>
<td>5.5</td>
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<td>60</td>
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<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>
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Table I: Blood pressure values, anti-hypertension drug Defined Daily Doses, pre-procedural GFR values and RAA diameters.

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Table II

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<td>3 months</td>
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<td>135/85</td>
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<td>130/80</td>
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<tr>
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<td>130/75</td>
<td>140/80</td>
<td>2.0</td>
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<tr>
<td>Mean</td>
<td>103.9 ± 26.6*</td>
<td>106.4 ± 27.1*</td>
<td>0.9 ± 0.8*</td>
</tr>
</tbody>
</table>

*Statistically significant change from baseline (Student t test P <.05)

Table 2: 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.

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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 ± 2 mm, 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 hematoma, 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).

The traditional treatment of renal artery aneurysm is represented by surgery, especially aneuvysmorrhaphy, aortorenal bypass, renorenal interposition, patch angioplasty, ex vivo repair and reinplantation, and nephrectomy (02,04,16), with a mortality and morbidity
rate estimated in about 10% in excellent center (23). Potential complications include death, need for nephrectomy, branch occlusion, ureteral stricture, or postoperative graft occlusion (04). The percutaneous endovascular treatment involves the exclusion of the aneurysm with covered stent or metallic microcoil deployment (02,11,12,19,21-27). Coils can be placed within the aneurysm to develop thrombosis of the lesion and to maintain the blood flow in the renal artery or, in aneurysm difficult to reach, they can be placed in the feeding artery with subsequent parenchyma ischemia. Some authors, like Rao Gutta et Al and Klein et Al, showed good results obtained with microcoils (16,19), but the distal embolization risk may reach high percentage, up to 21%, with the subsequent end-organ infarct (06,08,12-14,20,21). Moreover other coil-related complications are described, as continuous transmission of blood pressure inside the sac with high rupture risk exposure (12,13,20) and the occurrence of recanalization, between 9 and 42.9%, which can cause enlargement of the aneurismatic sac, due to the underfilling following the presence of mural thrombus (06, 10, 28). However, coils placement should be considered as primary treatment in patients with aneurysms positioned in the distal branches and with complex anatomy.

The graft stent deployment allows the exclusion of the aneurysm with a low rupture and dissection risk, and a low peri- and post-procedure complications rate with a high technical success rate (02,11-13,21-27).

In accordance to the classification of RAAs reported by Rundback et al. (11,13,26), in our opinion, saccular aneurysms arising from the main branch with a small neck (type 1) have to be treated percutaneously using covered stent. The type 1 aneurysm, following Rundback classification, is characterized by a sacciform anatomy, a narrow and wide neck, with a juxtarenal position, remote from bifurcation of the main branch and outside the kidney. Furthermore, in these aneurysms, a sufficient requested sealing zone for stent placement was present (10,15).

In this fashion, it is possible to preserve renal perfusion and, at the same time, to treat stenosis and RAA (7). Stent-grafts have the advantage of excluding the aneurysm from systemic blood flow. This technique allow to maintain the flow to the target organ and to exclude completely the aneurismatic sac; in fact incomplete embolization could cause aneurysm reperfusion, with a new needed procedure, and altered arterial flow with subsequent renal ischemic suffering and arterial hypertension (05-07). Some limitations about stent deployment are present in literature, especially in vessel with a diameter lower than 6 mm and tortuous anatomy due to covered stents bulky and stiff structure (05,06,09,10,28). However no studies with long term follow up are available for covered stent placement in renal arteries. Sprouse et Al. followed up to 2 years a case of covered stent placed in a renal artery for a venous fistula with good results and longer term studies of covered stents in coronary arteries have shown excellent outcome with late restenosis rate of 28% at 10 years (29) . In our case history with long-term follow-up, no cases of restenosis occurred. About the bulky and stiff structure of the placed devices, we facilitated the advancement of the covered stent in complex anatomy vessels with
two guidewires in renal artery and a transbrachial approach in order to achieve a stable carrier system, a sufficient pushability and a better control over the shaft. Rossi et al and Laganà et al. reported a stiff guidewire placement to obviate to these drawbacks (10,14). The graft stent choice depends on vessel anatomy, technical characteristics of the devices and experience of the author. In our experience we used self- and balloon-expandable graft-stent, in particular Symbiot, Jostent peripheral stent-graft, Advanta V12 and Direct-stent. The Jostent peripheral stent-graft, Advanta V12 and Direct-stent stent-graft are balloon expandable stents which should be used in vessels with simple anatomy and large diameter. The advantages involve a precise deployment on the site of lesion with an high radial strength that allows a total exclusion of the aneurysm and, moreover, in patient with renal stenosis, allows the physiologic vessel patency restore. A disadvantage in balloon expandable stent placement is the high profile of the device, compared to the self-expandable device, which requires a protection sheath and a guide catheter with larger size (02). The high profile, about 7 Fr or more, except Advanta V12 device, represents a limitation in patients with vasculopathy, because the device can determine a trauma in the passage through its endovascular route, especially at the level of renal artery ostium where a possible trauma can evolve in dissection and, afterwards, in occlusion (26). We have tried to limit this complication by the use of Destination sheath reducing the sizes of the guiding catheter. The vessel occlusion can also be a result of a dislodgement or migration of the stent, when the stent is placed on the ostium of a segmental artery, or when the stent remains undeployed inside the vessel 02.

In our experience we used in two cases Jostent peripheral stent-graft, in two cases Direct-stent stent-graft, in one case the Advanta V12. In medical literature some authors used Jostent peripheral stent-graft with good results in term of precise placement, exclusion of aneurismatic sac and clinical improvement (04,11,14,21-24). In particular Jostent placement was reported by Tan et al. and Pershad et al. in case reports in which the deployment has been performed in distal renal bifurcation, resulting in the sacrifice of a distal branch vessel with subsequent partial renal parenchyma ischemia with poor patient discomfort (04,21). In the cited studies complications during Jostent deployment are not underlined. To the best of our knowledge any Advanta V12 and Direct-stent weren't placed in patients with primary renal artery aneurysm.

Concerning the self expandable stent, Symbiot stent is deployed in renal artery with a complex anatomy, because it is simpler than other devices to advance in tortuous vessels for the lower dimension and major flexibility, excellent especially in vasculopathic patients. However, due to its structure, it is characterized by a low tensile strength body and, consequently, a weaker adhesion to vessel wall, which require some dilatations after placement. Moreover the disadvantages are determined by a difficult deployment, due to possible foreshortening and dislodgment of the stent which can determine, ultimately, occlusion. In our experience we used the Symbiot stent in three patients. Two stents were placed in one patient in both renal arteries because the presence of bilateral aneurysms.
In medical literature a Fluency device deployment was described by Klonaris et al, even if this self-expandable stent-graft has a higher caliber and requests a simpler vessel anatomy to be advanced and deployed (02).

The presence of clinical symptoms and the position of lesions on middle segment of the renal artery represent not common features in this pathology, reflecting a lack of power of our sample size. In this setting it is difficult to apply our results on general population, however we obtained about the long term follow up of covered stent placement in renal arteries.
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 resulted, even if a wider patients number and a randomized trial are required in order to demonstrate the feasibility and effectiveness of the endovascular approach.
References

