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IMPLANTATION OF THE ANDRASTENT XL FOR THERAPY OF HEAVY STENOSIS OF THE AORTA IN PATIETS WITH TAKAYASU AORTITIS

Introduction:

Stenosis in the area of larger peripheral vessels are currently treated successfully with Stentimplantation in most of the cases. The Palmaz-Schatz-Stents and also recently the CP-Stents are commonly used. Unfortunately both of these Stents require quiet a big access site as CSI Catheter Sheath Introducer. In this clinical review we want to report about a new peripheral Cobalt Chromium Stent Type Andramed GmbH Germany. This stent has been implanted in 3 Patients with heavy stenosis of the Aorta descendens in connection with Takayasu Ateriitis.

Material and Methods:

The AndraStent XL is manufactured out of a cobalt chromium alloy. Cobalt chromium has been proven with a very high biocompatibility and is already in use as medical implants. Its been found in pacemaker leads and as well in stents like the “Vision” stent by Guidant Inc. and the “Driver” stent by Medtronic Inc..
Stents made out of cobalt chromium alloy are more stabil and have a much higher radial force compared to stainless steel stents. The radiopacity is known to be good and the CT scan is showing less irritation compared to conventional steel stents.
The AndraStent XL has a multicellular hybrid cell structure with star type segments. 12 Zig-Zag-Elements are building the stent structure.
The braces of the AndraStent XL are 3.7 mm in length so the stent covers the vessel wall much better than eg. the CP-Stent which has a brace length of 5.4mm
The wallthickness of the AndraStent XL is 0.027mm. The stent minimum diameter is smaller than 3mm. The sheath compatibility should have a minimum of 10F. The AndraStent XL is available in 6 different lengths ranging from 17 to 48 mm. The AndraStent XL can be dilated to a diameter up to 25mm. The foreshortening of the AndraStent XL is 6% at a diameter of 18mm, 10% at a diameter of 20mm and 18% at a diameter of 25mm.

3 adult padients (2 male, 1 female) with a diagnosis of Takayasu Arteriitis had a longer clinical relevant partially multiple stenosis of the Aorta descendens.
In one patient (Pat. #3) the aorta descendens was distal to the renal arteries functional interrupted for about 30mm.

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Additionally the patient had a severe mitral valve insufficiency with rezidiv auricular fibrillation. In patient #2 a CP-Stent has been implanted previously 2 years earlier in a longer stenosis of the aorta abdominalis.
In all of the patients the femoral pulsation was very low or not palpable. The blood pressure measured in the upper extremities was hypertensive in Pat. #1 and Pat. #2 and normotensive in Pat. #3. All patients have gone through a heart catheterization under angiography of the aorta and followed stent implantation. In 2 of the patients the treatment was performed under local anesthesia, in the patient with the functional interrupted aorta descendens in intubation anesthesia. A 5F sheath has been placed in the right femoral artery under seldinger technique. Patient #3 additionally got a 5F sheath in the right brachial artery. After placement of the interventional sheath the patients were heparinized i.v. at a dosis 50 I.E. per kg bodyweight. Pressure measurement before and behind the stenosis has been performed and an arteriography has been performed in order to measure the location and legth of the stenosis. The selection for the pta balloon catheter (high pressure balloon Meditech, Watertown, MA, USA) was 60% to 100% of the diameter of the healthy aorta.
The length of the stents (Andramed GmbH, Germany) was selected appropriate to the length of the stenosis. In any case the selected stent was longer then the to be treated segment by 3mm. For stent implantation the 5F arterial sheath has been replaced by a 12F sheath (Cook Inc.) After successful stent implantation a pigtail catheter control angiography has been performed. Pressure measurement before and behind the stented segment was registered.
All patients received anticoagulation therapy for 3 months with 100mg ASS.

Results:
Stentimplantation with the AndraStent XL was successful in all patients and without any complications. While the implantation of the AndraStent XL in patient # 1,2 was relatively easy the implantation in patient #3 was highly difficult and complicated.
Apriori for a better orientation a simultaneously performed angiography was done in the aorta descendens before and behind the stenosis with the right brachial and the right femoral approach. A 0.014” guide wire was than used from the right brachial to pass the lumen of the aorta. After the guidewire has passed the stenosis a 10mm GooseNeck (Microvena Inc.) has been used to catch the wire from the right femoral and extracted through the sheath.
The 0.014“ guide wire was than used to dilate the stenosis with coronary ptca catheter dimensions 1.5mm to 4mm. After that manoeuvre it was possible to advance the 12F Mullins sheath (Cook Inc.) like in the previous 2 cases.
After the stent implantation of the severe and long stenosis another 2 stents needed to be implanted. In stenosis of the caudal part of the aorta. The other patients remained with 1 stent implanted. All the stents have been dilated to a diameter 10 and 12mm
The AndraStent XL could be mounted on the pta balloons without any complications.
At all time the AndraStent was stabile when passing through the Mullins sheath.
During the inflation of the balloon the AndraStent was expanding homogenously in all cases and suited well to the anatomy.
Stentdistorsionen, Stentfracture or missplacement of the AndraStent was not seen.

Furthermore even when the post angiography has been performed there was no vesselwall degeneration recorded as well as no dissection or aneurysmatic change. The systolic pressure gradient before and behind the stented aortic segment could be reduced in all the cases from 50 to 70 mmHg to under 15 mmHg.

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Tabel 1. Patient data

	age/sex	Number # of stenosis	Co-morbidities
Pat. 1	37 years; male	1	None
Pat. 2	27 years; female	1	post Stentimplantation en in Aorta abdominalis
Pat. 3	32 years; male	1	Severe Mitralinsufficiency. Auricullar fibrilation

Tabelle 2. Anatomical and technical findings:

	Localisation of Stenosis	Length of the Lesion	Relation Steno-sis/Aorta	Ballon-diameter	Amount of stents Stents/Length
Pat. 1	Distal the renal artery	7 mm	20%	12 mm	1 (21 mm)
Pat. 2	Aorta thoracalis	6 mm	40%	10 mm	1 (26 mm)
Pat. 3	Distal the renal artery	30 mm	<5%	10 mm	1 (39 mm)

Tabelle 3. Haemodynamic and angiographic results

	Pat. 1	Pat. 2	Pat. 3
Systolic pressure gra-dient before Sten-timplantation	50 mmHg	65 mmHg	70 mmHg
Systolic pressure gra-dient before Sten-timplantation	10 mmHg	10 mmHg	15 mmHg
Diameter Stenosis before Stentimplantation	2 mm	4 mm	0 mm
Diameter stenosis Steno-sis before Stentimplanta-tion	10 mm	12 mm	10 mm

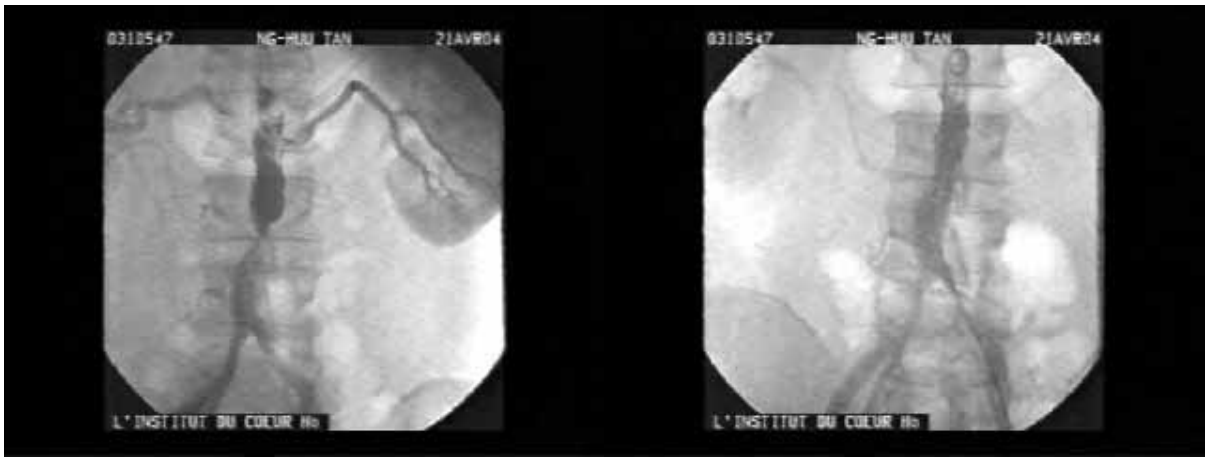

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Fig. 1: Angiographic findings in Patient # 1
The Stenosis is localized between the orifice of the renal artery and the Arteriae iliacae. Post interventional result after AndraStent XL placement the aorta could be dilated to its original vessel diameter.

Fig. 2: Angiographic findings in patient # 2
The left picture demonstrates the lesion in the area of the thoracic aorta and the previous implanted CP-Stent with a local fracture 1 year ago.
The right picture demonstrates a successful interventional result after the implantation of a 26mm AndraStent in the thoracic aorta.

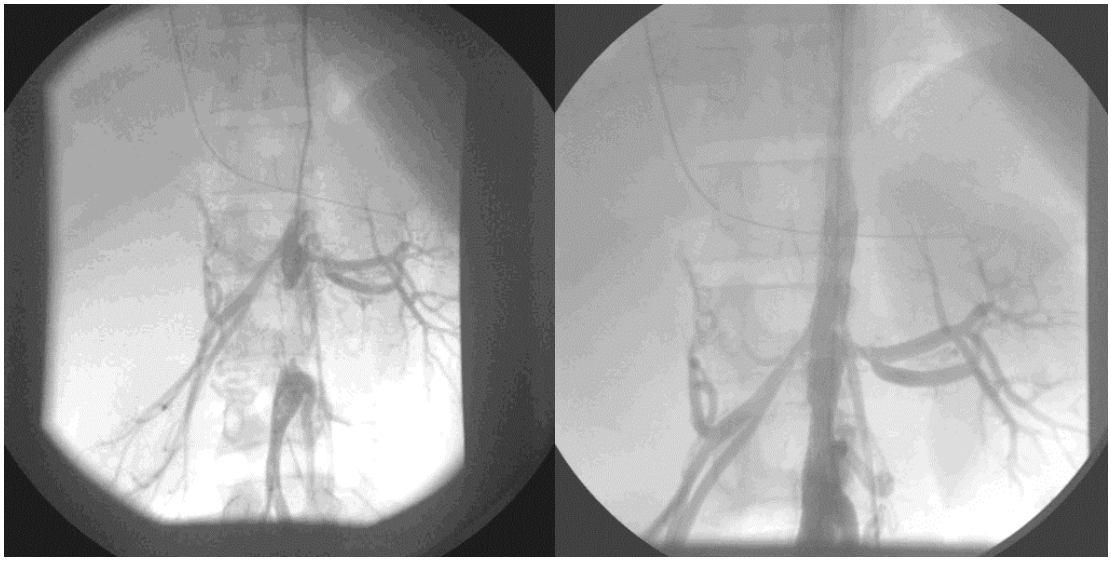

Fig. 3: Angiographic findings in patient # 3.
In the left picture it is demonstrated clearly the very long lesion in the aorta abdominalis distal the renal arteries under simultaneous angiography. Post recanalization of the rest lumen and continous dilatation with bigger pta balloons a 39mm AndraStent XL has been implanted to a size of 10mm in diameter. You can clearly see the recanalization and a very good post interventional result.

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Discussion:

Stent fracture is reported rarely in the literature but in clinical reality it happens more and more. If it is in coronary stents (Cypher, Cordis) (Sianos G, Hofma S, Ligthart J et al. Stent fracture and restenosis in the drug-eluting stent era. Cathet Cardiovasc Interv 61: 111-116, 2004) but also in peripheral implanted stents Palmaz-Stent, Cordis (Sacks B, Miller A, Gottlieb M: Frature of an iliac artery Palmaz stent. J Vasc Interv Radiol 7: 53-55,1996).
Or younger generation stents like the CP-stent made out of a platinum wire. (Ewert P, Abdul-Khaliq H, Peters B et al.: Transcatheter therapy of long extreme subatretic aortic coarctations with covered stents. Cathet Cardiovasc Interv 63: 236-239, 2004).
In these cases 2 out of 4 cases (50%) stent fractures could be found in the curriculum around the stent at the fusion points. An additional placed CP-stent could resolve this issue.
In the patient #2 the treated patient received a CP-stent prior to the AndraStent XL implantation. A stent fracture at the cranial end of the CP-Stent was observed and the AndraStent was successfully implanted over the destructed CP-stent in order to prevent further fractures of the CP stent. (Fig.2). A further gold plating are thought to prevent this issue.
Other reported complications are sharp stent edges. This has been found with the Palmaz Stent. It is reported in the literature that in one case were a Palmaz-Stent was implanted in the inferior vena cava lead to a perforation of the neighbouring aorta. (EvansJ, Saba Z, Rosenfeld H et al.: Aortic laceration secondary to Palmaz Stent Placement for treatment of superior vena cava syndrome. Cathet Cardiovasc Interv 49: 160-162, 2000)

That is the reason to have a stent design with more rounded ends and a good electropolishing to minimize the risk of vessel wall perforation.
These features have been specially taken care of during the design and manufacturing of the Andramed Stent XL & XXL.

In all of the patients the AndraStent XL could be implanted without any problems.
Especially in Pat. # 3 with a functional longer obstruction the aorta could be dilated and stented impressively and successfully.

Conclusion: The AndraStent XL & XXL has a very good radial force to dilate vessels like the aorta effectively. The radiopacity compared to the CP-Stent and the Palmaz Stent is a little lower but sufficient enough to visualize the stent. The criming process of the AndraStent on the balloon is very easy. The AndraStent need a 1F smaller delivery sheath compared to eg. the CP-Stent.

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