First placement of a COVERA™ Vascular Covered Stent in a reference center for dialysis fistulas

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The terminal arch of the cephalic vein is the most frequent site of stenosis in autogenous brachial-cephalic fistulas for hemodialysis. Results after PTA or bare stents are usually disappointing, with poor reported 1-year primary patency rates ranging from 0 to 23% \(^\text{1-3}\). The first generation of covered stents offered barely improved results with a 1-year Primary Patency rate of 23% versus 0% \(^\text{2-3}\). For this reason some teams suggested to ignore PTA and to turn down surgically the cephalic vein into the axillary vein in order to exclude the stenosed terminal arch from the arteriovenous circuit \(^\text{4-5}\). Unfortunately, invasive surgery has drawbacks, mainly to impede the creation of future arteriovenous accesses on the same limb as stenosis will eventually develop at the new vein-to-vein anastomosis, thus in the outflow of any other ipsilateral peripheral arteriovenous access.

The COVERA™ Vascular Covered Stent is a novel ePTFE covered stent designed for the treatment of stenosis in the venous outflow of AV Fistulae. We report here the case of our first COVERA™ Vascular Covered Stent placed in the terminal arch of the cephalic vein.

This 60-year old male patient was dialysed via a right radial-cephalic fistula created in fall 2011 and first referred to the interventional radiology department for non-maturation 2 months later. The fistula underwent a successful declot procedure. Early on, all stenoses were located in the forearm and the upper arm cephalic vein was strictly normal. The fistula could be used uneventfully for 31 months until it was referred for venous hypertension due to an entirely newly developed stenosis in the convexity of the terminal arch of the cephalic vein [Fig 1].

The stenosis was dilated to 8 mm with a non perfect but acceptable result that did not warrant stent placement for the first ever PTA in this location [Fig 2].
Unfortunately, within 3 months recurring venous hypertension associated with intermittent hand edema led to new angiography early 2016: the rapidly recurring stenosis of the terminal arch was re-dilated to 8 mm with a CONQUEST™ High Pressure Balloon and covered with the new COVERA™ Vascular Covered Stent with the intention to delay any restenosis [Figs 3-6]. The associated subclavian vein stenosis had previously been dilated to 12 mm.

COVERA™
Vascular Covered Stent

Indication for Use
The COVERA™ Vascular Covered Stent is indicated for the treatment of stenoses in the upper extremity venous outflow of patients dialyzing with an arterio-venous (AV) access graft or fistula.

Contraindications
There are no known contraindications for the COVERA™ Vascular Covered Stent.

Warnings
Do NOT use in patients whose AV access grafts have been implanted less than 30 days or in an immature fistula. Do NOT use the device in patients where full expansion of an appropriately sized PTA balloon catheter could not be achieved during pre-dilatation with an angioplasty balloon. Placing a covered stent across a vessel side branch may impede blood flow and hinder or prevent future procedures. Covered stent placement beyond the ostium of the cephalic vein into the axillary/subclavian vein may hinder or prevent future access. Do NOT place a flared covered stent with the flared end in a straight vessel segment since this may lead to flow turbulences. The device has not been tested for tracking and deployment around an AV loop graft.

Precautions
Prior to covered stent implantation refer to the sizing table and read the Instructions for Use. The covered stent cannot be repositioned after total or partial deployment. Once partially or fully deployed, the covered stent cannot be retracted or remounted onto the delivery system. If unusual resistance is met during covered stent system introduction, the system should be removed and another covered stent system should be used. Do NOT introduce or manipulate the delivery system without an appropriately sized guidewire and without fluoroscopic guidance. Do NOT use a kinked delivery system. During covered stent release, do NOT hold the 30 cm long distal catheter assembly segment as it must be free to move and slide into the white stability sheath. Careful attention by the operator is warranted to mitigate the potential for distal migration of the covered stent during deployment. The covered stent cannot be post-dilated beyond its labelled diameter. The safety and effectiveness of the device when placed across an aneurysm or a pseudo-aneurysm has not been evaluated. The safety and effectiveness of the device when used in central veins has not been evaluated. The safety and effectiveness of the device when placed across the antecubital fossa has not been evaluated. The effects of direct cannulation of the covered stent have not been evaluated. Notify the patient that the covered stent should not be directly cannulated for hemodialysis and that applying pressure to the implant area should be avoided. Higher deployment force maybe encountered with longer length covered stents.

Potential Complications and Adverse Events
Complications and Adverse Events associated with the use of the COVERA™ Vascular Covered Stent may include the usual complications associated with endovascular stent and covered stent placement and dialysis catheter revisions. Please consult package insert for more detailed safety information and instructions for use.

The patient was referred late April for low flow and difficulties in cannulation. Stenoses in the forearm vein were dilated successfully. The good news was that there was not a single preliminary sign of restenosis or new stenosis in contact with the COVERA™ Vascular Covered Stent placed 10 weeks earlier [Fig.7].

No conclusion can be drawn from a single case with a 3 months’ follow-up. However, our first case of a COVERA™ Vascular Covered Stent in the terminal arch of the cephalic vein looks encouraging.

6. The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. The physician has been compensated by Angiomed GmbH & Co. Medizintechnik KG for the time and effort in preparing the above case study for Bard’s further use and distribution. Not for sale or distribution in the U.S.