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Endovascular anatomic reconstruction of the iliac bifurcation with covered stentgrafts in sandwich-technique for the treatment of complex aorto-iliac aneurysms☆

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ABSTRACT

Objective: Endovascular anatomic reconstruction of iliac artery bifurcation in aorto-iliac aneurysms using commercial stentgrafts in sandwich-technique by bilateral transfemoral approach.
Methods: 24 patients (mean 73.8 ± standard deviation 6.8 years) with complex aorto-iliac aneurysms (AAA): n = 17; diameter 64 ± 15 [48–100] mm; common-iliac-artery (CIA): n = 27; 43 ± 15 [30–87] mm; internal-iliac-artery (IIA): n = 14; 28 ± 8 [15–43] mm) were prospectively enrolled for EVAR with preservation of the IIA (n = 31; bi-lateral n = 7).
Maintenance of antegrade flow to IIA by iliac reconstruction was performed in sandwich-technique prior to EVAR.
Follow-up of 15.0 ± 10.8 [1–40] months included contrast-enhanced ultrasound and computed-tomography after 1 week, 3, 6 and every 12 months.
Results: Initial technical success for anatomic reconstruction of the iliac arteries in 31 instances was 100%. Primary patency of iliac neo-bifurcations was 90.9% (20/22) at 6 months and 84.2% (16/19) at 1 year. Postprocedural gutter-endoleaks type 1b were obvious in 6.5% (2/31) of cases, which disappeared 3 months later. Aortic/iliac aneurysm-size after 1 year decreased (>5 mm) in 61.5% of patients. No aneurysm-size increase or late rupture occurred.
Conclusions: Endovascular reconstruction of the iliac bifurcation with commercial standard stentgrafts is safe and effective. Transfemoral approach allows extension of distal landing zone for EVAR while preserving the internal iliac artery blood-flow, even in unfavorable iliac anatomy.

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1. Introduction

Abdominal aortic aneurysms (AAA) are associated with iliac artery aneurysms in up to 40% of patients [1,2]. Proximal and distal fixation and sealing is crucial for successful endovascular aortic repair (EVAR). The common iliac artery (CIA) typically serves as the distal landing zone for the iliac limb extension for aorto-iliac stentgrafts. If the diameter of available limb extensions is inappropriate for distal sealing, alternative landing zones in the external iliac artery (EIA), or alternative techniques are required [3]. Limb extension into the EIA typically requires occlusion of at least the proximal part of the internal iliac artery to avoid endoleakage. Unfortunately, embolization of the IIA may lead to significant (gluteal) claudication, erectile dysfunction or seldom colonic/sigmoid ischemia. The risk is significantly increased in the presence of disease or occlusion of the deep femoral artery with or without concurrent femoral-popliteal segment disease. Furthermore, colonic ischemia will be more likely in the presence of superior mesenteric artery and celiac trunk disease, as well as peripheral small vessel disease in the IIA-territory, which will compromise collaterals [4–6].

An option for IIA-preservation is the use of an iliac side-branch device (ISBD). However, unfavorable conditions including dimension of the CIA, access vessels or tortuosity may constitute technical

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contraindications [3,7,8]. Alternatively, implantation of standard stentgrafts through a trans-brachial or subclavian access has been successfully used to overcome these technical drawbacks. Experience with these innovative techniques is still limited making further evaluation necessary [9–12].

The purpose of our study was to prospectively evaluate the results of a standardized transfemoral approach to preserve antegrade pelvic perfusion via the hypogastric artery. Primary objectives included technical feasibility and mid-term results using regular commercially available "off-the-shelf" materials in complex aorto-iliac aneurysms. Instead of three access sites, a bi-lateral transfemoral approach was used without an additional transbrachial or subclavian access.

2. Methods

During 2010–2015, 24 consecutive male Caucasian patients with complex aorto-iliac aneurysms unsuitable for open or endovascular repair with ISBD were prospectively enrolled at two experienced tertiary centers for endovascular iliac artery bifurcation reconstruction. Demographic data, aneurysm characteristics and co-morbidities are presented in Table 1. Inclusion criteria consisted of uni- or bilateral aneurysms of CIA ≥30 mm, or IIA aneurysms defined as diameter more than twice of the IIA. In *all* patients, tortuous kinking and calcified atherosclerosis of iliac arteries, extreme infrarenal angulation or stenotic access, diameter of the CIA <18 mm at the level of iliac bifurcation and wide-angle branching or stenosis of IIA, which are unfavorable for ISBD, were present (Fig. 1A). Computed tomography angiography was obtained in all patients for pre-interventional planning on a dedicated workstation (TeraRecon Aquarius Workstation, TeraRecon, USA). Cerebro-, cardio-vascular and -pulmonary function was evaluated. Local ethics committee agreement was available and all patients underwent written informed consent including off-label use of stent-grafts.

2.1. The sandwich-technique

Endovascular anatomic reconstruction of an iliac "neo-bifurcation" to preserve antegrade flow to the pelvic arteries (Fig. 1A) was combined with EVAR in all patients (Fig. 1B). Iliac stentgraft-implantation was performed following EVAR in a percutaneous approach.

In the first step, a covered balloon-expandable, or self-expanding "mother"-stentgraft was deployed into the CIA just above the origin of the IIA via an ipsilateral transfemoral access. Afterwards, the mother-stentgraft and the IIA were cannulated from cross-over via a contralateral transfemoral access. With support of a cross-over sheath, embolization was reserved for smaller vessels branching off an IIA-aneurysm (ileolumbal, obturator or pudendal arteries) to avoid distal endoleak type 2. (Video 1) The superior gluteal artery was always preserved. Subsequently, covered stents were introduced via the contralateral cross-over access from of the mother-stentgraft into the distal part of the IIA common trunk, and via the ipsilateral access from the mother-stentgraft into the EIA. (Fig. 2B) Finally, both stentgrafts were simultaneously deployed in a so-called kissing-stent position (Video 2), which results in a kind of flow-diverter simulating an iliac neo-bifurcation. (Fig. 2C; Video 3) Post-procedural hemostasis was achieved by vascular closure device.

Table 1
Demographical data.

		n = number, mean ± standard deviation, [range: minimum–maximum]
Demographics		
Patients		n = 24
Male sex		100%
Age		74.8 ± 6.9 [58–85] years
Caucasians		100%
Pre-interventional aneurysm characterization		
AAA		n = 17; 64 ± 15 [48–100] mm
CIA aneurysm n = 27	Right	n = 12; 41 ± 15 [30–87] mm
	Left	n = 15; 46 ± 15 [31–81] mm
bilateral CIA aneurysm		n = 7
IIA aneurysm n = 14	Right	n = 6; 30 ± 8 [15–36] mm
	Left	n = 8; 27 ± 9 [15–43] mm
bilateral IIA aneurysm		n = 4
Medical history		
Hypertension		18 (75%)
Chronic obstructive pulmonary disease COPD		12 (50%)
Peripheral artery disease PAD		4 (17%)
Diabetes		5 (21%)
Transitory ischemic attack TIA/stroke		4 (17%)
Smoking		8 (33%)
Ischemic heart disease		13 (54%)
Dyslipidemia		16 (67%)
Chronic renal failure		1 (4%)
Creatinin [mg/dl]		1.02 ± 0.19 [0.69–1.51] 1 patient with chronic renal failure excluded
Estimated glomerular filtration rate eGFR [ml/min/1.73 m^2 body-surface]		74 ± 14 [45–94]
Drug history		
Antiplatelet therapy		18 (75%)
Statins		17 (71%)
Beta-blocker		13 (54%)

2.2. Stentgraft sizing

Stent-diameters for the IIA and EIA were adapted to the vessel diameter according to manufacturer's recommendation. The total cross-sectional area of the stents in the IIA and EIA was used to determine the appropriate diameter of the mother-stent in the CIA. In order to achieve sufficient sealing of the IIA and EIA stents within the mother-stent of the CIA, an undersizing of 10% according to the calculated CIA stent-diameter was used. (Formula 1; Fig. 2D).

$$\text{stent}-\text{diameter CIA} = 0.9 \times 2 \times \text{squareroot}((A_{IIA} + A_{EIA})/\pi) \quad (1)$$

The stent-length of the mother-stent in the CIA was always at least 5 cm to allow a sufficient overlap of the stents in the IIA, EIA and bridging stent of 2.5 cm. The stent length for the IIA and EIA was selected to achieve sufficient coverage from the mother-stent into the non-aneurysmal IIA and EIA.

According to the described strategy, a balloon-expandable Advanta-V12 (Atrium Maquet) stentgraft with a diameter of 12 mm and nominal length of 61 mm (physical stent-length 55.8 mm, nominal pressure 8 bar) was typically used for the mother-stent in the CIA. A stentgraft of 8 mm in diameter was inserted into the IIA and a stentgraft of 10 mm in diameter was inserted into the EIA. Typical stent-dimensions are given in Table 2. In case of severe tortuous angulation, stenosis or calcification Advanta stentgrafts were preferred for the IIA. Otherwise, Viabahn (W.L. Gore) stentgrafts were used. Stentgraft selection was at the operator's discretion. In one patient appropriate Advanta or Viabahn stentgrafts were unavailable. Alternatively, Endurant- (Medtronic) and Ovation-limb (Trivascular Technologies Inc.) stentgrafts were used for bilateral iliac neo-bifurcation reconstruction.

EVAR was completed after reconstruction of the iliac neo-bifurcation. Bridging-stent dimension for connection of the bifurcated aortic main-body with the mother-stent in the CIA were chosen similar to ISBD-procedures. Distal overlap into the iliac neo-bifurcation was 2.5 cm. The distal diameter of the bridging-stentgraft was 2 mm oversized related to the nominal diameter of the mother-stent in the CIA. Ballooning of the bridging-stentgraft must be performed very carefully (Fig. 3A) in order not to compromise the flow-divider of the iliac neo-bifurcation (Fig. 3B).

If the stentgraft in the IIA was too short, an additional covered stent was used for appropriate extension. Final angiography of the iliac neo-bifurcation and EVAR in at least two angulated projections was routinely assessed to confirm accurate deployment, patency and aneurysm exclusion. (Fig. 3A, Fig. 3B; Video 4).

Peri-interventional medication consisted of 5000 international units of heparin; post-interventional therapeutic heparinization for 48 h, clopidogrel 75 mg/day for 4 weeks and acetylsalicylic acid 100 mg/day lifelong.

Follow-up after aorto-iliac aneurysm repair included contrast-enhanced ultrasound and computed tomography in all patients, baseline after 1 week and afterwards in 3, 6 and 12 months of intervals.

Primary objectives included technical success defined as successful implantation of the iliac stentgrafts for anatomic reconstruction of the iliac artery bifurcation with preservation of antegrade flow to the internal iliac arteries. Secondary objectives were presence of pelvic ischemia (gluteal, thigh claudication or necrosis; bowel, spinal cord or nerve ischemia; erectile dysfunction), procedure-associated mortality, failure of iliac aneurysm exclusion (growth > 5 mm, or rupture).

2.3. Statistical analysis

Measured values are reported as percentages and mean ± standard deviation. Nominal data was evaluated using Chi^2-test and continuous data using Student's *t*-test. A value of $p < 0.05$ was considered statistically significant. All analyses were performed using GraphPad Prism 6 for MacOSX.

3. Results

Overall, 24 patients underwent percutaneous transfemoral reconstruction of an iliac neo-bifurcation for preservation of the hypogastric artery. A total of 31 anatomic reconstructions of iliac neo-bifurcations were performed; unilateral in 17 and bilateral in 7 patients. Initial

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