Treatment of iliac artery bifurcation aneurysms with the second-generation straight iliac bifurcated device

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Background: **There are few long term studies to show the safety and efficacy of iliac artery aneurysm exclusion, especially in regards to the straight iliac branched device. The objective of our study was to add our data with a mean follow-up of 32 months to the existing data available.**

Methods: **Patients undergoing iliac bifurcation procedure either as standalone or in combination with abdominal aortic aneurysm exclusion at two vascular centers had data prospectively gathered between 2004 and 2014. Collected data was analyzed for baseline characteristics, procedural events, and clinical follow-up; variables included endoleaks, reinterventions, and internal iliac artery (IIA) closure.**

Results: **A total of 45 iliac vessels in 41 patients (36 male) with a mean age of 70.4 years were treated with the iliac branched device. Procedural success was achieved in 85% (35/41) of patients and 87% (39/45) vessels with no intraoperative death. Of the six technical failures, three occurred due to failure to place the straight iliac branched device or stent properly. Two occurred because of endoleaks at the end of the procedure, and one occurred because the IIA sidebranch occluded and could not be reopened. The mean patient follow-up was 32.0 ± 27.3 months (range, 0-109 months). During this time period, the IIA patency rate on an intention-to-treat basis was 81%, and the freedom from endoleak rate on an intention-to-treat basis was 76% per patient. The freedom from reintervention per patient was 75%. No patient reported symptoms of pelvic ischemia and permanent buttock claudication.**

Conclusions: **In this study with mean follow-up of 32 months, treatment with iliac bifurcated devices is a safe and durable option in a carefully selected population of patients with iliac artery bifurcation aneurysms. (J Vasc Surg 2015;62:1168-75.)**

More than two decades ago, Volodos et al and Parodi et al established the feasibility of endografting for abdominal aortic aneurysm (AAA) repair.[1,2] Since then, grafts and techniques have constantly evolved, including branched devices for the iliac artery. These were designed to treat patients with common iliac artery aneurysms (CIAAs), which coincide with an AAA in up to 20% of AAA patients.[3,4]

Optimal distal fixation of the endograft is crucial to prevent graft migration.[5,6] To achieve the needed distal fixation in patients with CIAAs, the operator can choose between techniques that close the internal iliac artery (IIA) and techniques that preserve flow. Techniques for closure of the IIA include embolization with coils or plugs or simple occlusion by overstenting.[7-9] Closure of the IIA can be associated with risks that range from mild (eg, intermittent buttock claudication) to severe (eg, pelvic ischemia).[10-14] Lin et al reported that the incidence of buttock claudication ranged from 13% to 55% in literature.[13] To preserve the perfusion of the IIA, one can use the bellbottom technique, complex combined endovascular and surgical procedures (eg, transposition or bypass) of the IIA, or iliac artery branched devices (IBDs).[15,16]

Currently, there are three types of IBD devices manufactured by Cook (W. Cook Inc, Brisbane, Australia) commercially or available for study purposes: a straight-branch iliac bifurcation device (S-IBD), the helical iliac bifurcation device (H-IBD), and the bifurcated-bifurcated iliac bifurcation device (BIF-IBD).[17] The S-IBD differs from the H-IBD in length of overlap with the stent landing in the IIA, in the way in which flow is directed into the IIA, and often in which type stent (self-expendable vs balloon-expandable) is used.[17] In addition, the S-IBD

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and H-IBD have both a first- and second-generation device. The first-generation S-IBD is no longer available. The main difference between these two grafts is that the first-generation device is a unibody graft, whereas the second-generation device is a modular two-component device.[18] The second-generation H-IBD has longer overlapping in the side branch.[17] The BIF-IBD was developed to address the problem of short CIAs, which can be treated by neither S-IBD nor H-IBD.[17]

Results for safety and efficacy with a median follow-up ranging from 6 to 24 months have been published for these IBDs.[17-31] However, most studies include several of the above described devices as well as the first-generation unibody (ie, non-modular) S-IBDs, which are no longer available. To our knowledge, studies focusing only on the second-generation S-IBD do not exceed a median follow-up of 17 months or a mean follow-up of 19 months.[28,31] The objective of this paper is to add data for the second-generation S-IBD device exceeding this follow-up period.

METHODS

Consecutive cases of second generation S-IBD of the Surgical Department Klinikum Frankfurt Höchst and the CardioVascular Center Frankfurt (CVC) between 2004 and 2012 were collected and followed up until 2014. Data were prospectively gathered in a database and retrospectively analyzed.

Protocol and informed consent were approved by the institutional review board. All subjects gave written informed consent for the procedure and to participate in this study prior to implantation. All patients fulfilled standard indications for endovascular aneurysm repair (EVAR). Patients were referred for endografting procedure by their primary physician or cardiologist. Indication for treatment with a second-generation S-IBD device was a CIA diameter of more than 25 mm. All patients had a contrast-enhanced spiral computed tomography (CT) performed prior to implantation. Patients in the CVC also had a pre-implant quantitative angiography performed. This was done to check measurements in vivo with a graduated pigtail catheter and to give the operator further insight on the anatomy at hand.

Device characteristics and implantation procedure. Device characteristics and procedure details have been described in length elsewhere.[18,19,21] The second generation Cook S-IBD (W. Cook Inc) is modular and consists of a bifurcated device with one part intended to land in the CIA (12 mm diameter; length 45 or 61 mm), one part for the external iliac artery (10 or 12 mm diameter; length 41 or 58 mm), and a short stump to be connected to the IIA (7 mm diameter; length 13 mm). The graft is delivered preloaded onto an introducer sheath. Additional to the graft is an indwelling catheter, which enters the S-IBD through the distal opening of the internal iliac segment (ie, the iliac "stump") and exits the S-IBD through the proximal end of the common iliac segment. The purpose of this indwelling catheter is to facilitate access to the side branch from the contralateral side.

Treatment of the CIAA could occur either in addition to AAA exclusion or as stand-alone therapy. The second-generation S-IBD device is delivered ipsilateral to the CIAA; a wire is brought up through the indwelling catheter and snared via a catheter from the opposite femoral artery; this creates a through-and-through access that cannulates the S-IBD stump. This through-and-through access is now used to introduce a large crossover sheath in the opposite femoral artery. A bridging covered stent (Advanta; Atrium Medical, Hudson NH; Viabahn; W. L. Gore & Associates, Inc, Flagstaff, Ariz; Fluency; C.R. Bard Peripheral Vascular Inc, Murray Hill, NJ) is delivered to extend the IIA stump. Finally, in cases when AAA exclusion is also simultaneously performed, the AAA endograft is delivered through the opposite limb. For patients with solo CIAA, the CIAA was addressed as previously described. Steps are shown in Fig 1.

In patients with bilateral IBD implantation, the procedure depends on the access used. If only femoral access is desired, both IBDs are placed before the implantation of the AAA graft in a manner which is similar to the unilateral placement. If an additional proximal access (eg, subclavian cut-down or brachial access) can be used, the operator chooses whether the IBD or the AAA endograft is placed first. The operator may use the proximal access to snare the wire from the indwelling catheter, thereby making a crossover maneuver unnecessary. In patients without a suitable proximal neck of the CIA or with abdominal aortic diameter more than 35 mm, this is followed by deployment of the main bifurcated Cook graft body from the opposite side and bridging of the gap into the second-generation S-IBD with an iliac limb. A final angiogram is performed to evaluate deployment position, vessel patency, aneurysm exclusion, and possible endoleak.

Follow-up. Follow-up was identical in both centers. Patients received a duplex ultrasound prior to discharge and a spiral CT within the first 6 months of the procedure. Routine CT angiography after 3 months was not performed, as in our experience many irregularities that were seen at 3 months were not clinically relevant nor seen at 6 months, which pushed us to change our protocol to 6-month CT angiography. Subsequently, CTs were performed at 12 months and annually thereafter. After 5 years, patients were followed with CT every other year if there were no pathological findings. In patients who could not be given contrast media due to allergy or renal insufficiency, a color duplex was performed. Follow-up imaging was assessed for device integrity, endoleaks, and patency into the IIA. Patients were asked about symptoms of claudication, procedure-related hospital stays, and reinterventions. Additionally, most patients had x-rays in two planes to detect configuration changes, stent fractures, and disconnections.

Primary endpoints and secondary endpoints. Primary endpoints were the absence of symptoms for pelvic ischemia (buttock claudication or necrosis, bowel or spinal ischemia, impotence) and patency of flow into the IIA on follow-up imaging. Symptoms of pelvic ischemia were determined by obtaining a focused patient history. In both