

The role of aortouniiliac devices in the treatment of aneurysmal disease

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Abstract. – **PURPOSE,** Many studies have shown that aortouniiliac (AUI) devices have comparable outcome in high risk patients as the treatment with bifurcated devices. The purpose of this article is to review the relevant literature and discuss the outcomes.

METHODS, A systematic search from 1991 until 2010 was performed on PubMed and Medline databases for studies evaluating the role of AUI devices accompanied with occlusion of one iliac artery and crossover femoral-femoral or iliac-femoral bypass, for the treatment of abdominal aortic aneurysmal disease. Keywords used were abdominal aortic aneurysms (AAA), endovascular aortic aneurysm repair (EVAR), aortouniiliac, aortomonoiliac, stent graft, outcome analysis, in various combinations. The reference lists of the gathered reports were also manually searched. Only articles with series of more than twenty (20) patients were included in this review.

RESULTS, Seven articles were found referring to the results of endovascular aortic aneurysm repair with AUI stent grafts, three are comparing AUI, tube, bifurcated devices or between them or /and with open surgery repair, four are referring to the patency of the femoral-femoral bypass that couples the AUI stent graft deployment, and two are referring to the treatment of r-AAA with the AUI stent grafts.

CONCLUSIONS, There is increasing evidence in the literature that the AUI configuration endoprosthesis placement is a safe procedure over the mid- and long-term period and compares well with the results of AAA endovascular repair with bifurcated endoprostheses that have been published.

Key Words:

Aorto-uni-iliac endoprosthesis, Cross-over by pass, EVAR.

crossover femoral-femoral or iliac-femoral bypass, have comparable outcome in selected patients as the treatment with bifurcated devices. Although the use of this strategy is limited in daily practice for the treatment of abdominal aortic aneurysms (AAA) in fit patients, this may not be the case for the treatment of high risk patients with complex iliac anatomy, in the treatment of r-AAA, or in the treatment of complications of previous applied endovascular bifurcated devices for the treatment of AAA. The purpose of this article is to review the relevant literature and discuss the outcomes on the use of AUI stentgrafts.

The Devices: Aorto-Uni-iliac Stent-Grafts

The first endovascular repairs for AAA were performed using simple tubular aorto-aortic stent-grafts⁷. Soon it was clear that only a few patients have the necessary anatomy for deployment of an aorto-aortic stent-graft⁸. In most cases secure implantation can be achieved by tapered bifurcated (aortobiiliac) or aortouniiliac stent-graft coupled with occlusion of the contralateral common iliac artery and an iliac-femoral or femoral-femoral crossover bypass, to ensure perfusion of the contralateral limb. The bifurcated approach became the industry standard soon after its introduction in 1993⁹. However, aortouniiliac stent-graft was also adopted early by the vascular community due to its simplicity (ability to load the stent graft to a smaller sheath which was manufactured more easily than the bifurcated one) in treating abdominal or abdominal-iliac aneurysms, where hostile iliac anatomy complicates the operation. Since 1993 May et al¹⁰ and afterwards Parodi et al¹¹, Marin et al¹² described the use of a transluminally placed aortofemoral graft in combination with a femorofemoral crossover graft. In addition, the technique involves either ligation or balloon occlusion of the contralateral common iliac and internal iliac arteries in such a manner that excludes the AAA from the circulation.

Introduction

The endovascular aortic aneurysm repair (EVAR) is a relative new weapon of the vascular surgeon's armamentarium¹⁻⁶ and studies have shown that aortouniiliac (AUI) devices coupled with occlusion of contralateral iliac artery and

Many surgeons, however, debate the disadvantages of the method due to the extra-anatomic bypass and express doubts concerning the long term results, claiming mainly poor femoral-femoral bypass outcome, which varies on different reports from 35% to 92%, for 5-year patency rates¹³⁻²³.

Despite this potential drawback of using an extra-anatomic bypass, deployment of an AUI stent graft device is still being used for the treatment of abdominal aortic aneurysms in different and complicated circumstances, such as presence of narrow terminal aorta, small diameter, tortuous, kinked, calcified or even occluded contralateral iliac artery, presence of common iliac aneurysm, treatment of rAAA, management of endoleaks of previous implanted endoprosthesis.

Today, several AUI devices are approved for use in the USA and in Europe. They can be custom made or manufactured devices. It can be made of stainless steel Z stents (Zenith, Cook) or nitinol self expanding stents (Talent and Endurant devices by Medtronic, Endofit by LeMaitre Vascular). They come in tapered configurations (proximal diameter larger than the distal diameter) and may have or not proximal bare stent. They feature woven polyester fabric (Zenith, Cook), multifilament polyester (PET) graft fabric (Talent and Endurant devices by Medtronic), polytetrafluoroethylene (Endofit, LeMaitre Vascular), uncrimped polyester fabric (Ella-CS, Hradec Kralove).

Custom Made Devices

Custom made aortouniiliac devices were the first which were used for the treatment of complex abdominal aortic aneurysms already from 1993¹⁰. Some of them are still made and used in big reference hospitals like the Veith/Montefiore device, Gianturco device, Chuter device, Nottingham-Malmö device, Ivancev-Malmö device, that were used mainly at the beginning of the endovascular era and the more recent SX- ELLA stent-graft (Ella-CS, Hradec Kralove, Czech Republic) which is a conical stainless steel, fully supported stent-graft covered by thin-walled Dacron. This endograft has 2 rows of barbs on the proximal end and one on the distal iliac end. The delivery system varied from 18 to 24F²⁴.

Manufactured Devices

Manufactured devices are also used since 1994. EVT-Guidant aortouniiliac system was one of the first devices to be deployed, but no longer in use. Currently in the market are available several aortouniiliac stent graft devices in different diameters and different lengths.

Endofit (LeMaitre Vascular) stent-graft is a self-expanding device, made of nitinol. It has conical shape. The first covered stent is double to increase radial force and sealing. Fabric is made from ePTFE in 2 layers that encapsulates the stent skeleton with a thermal process to avoid the need for fixation sutures (no interface of metallic stent with either, the blood, the aortic wall or the incoming wires). A nitinol bare proximal stent situated on top of the endograft enhances proximal fixation. The graft is inserted through a flexible 18F or 22F hydrophilic sheath for maximal trackability. The proximal diameter varies from 20 to 36 mm, and the distal diameter from 12 to 26 mm, with available lengths of 10 to 20 cm

AneuRx (Medtronic) stent-graft features an exterior nitinol skeleton (exoskeleton), which provides a structure for tissue ingrowth and friction, over woven polyester fabric, without bards or hooks for infra-renal deployment. Dual tapered sheath facilitates insertion and retraction.

Talent (Medtronic) stent-graft is a self-expanding device, made of nitinol and coupled to a polyester fabric. The graft at the proximal end has a bare spring (called freeflow for a proximal diameter >22 mm) that allows placement across the renal arteries. It has hydrophilic coating and it is tapered. Available sizes from 22 mm to 36 mm for the proximal diameter and 14 mm or 16 mm for the distal diameter. The AUI system can be of one piece or of two pieces. Delivery system of 22F or 24F.

Endurant (Medtronic) stent-graft is a self-expanding device, made of nitinol. It has M-shaped proximal stent to enhance wall apposition. The suprarenal stent has anchoring pins for secure fixation while back-end thumb wheel provides slow and controlled release of the stent. It features shorter stents to the body and limbs for higher conformability. It has low crossing profile and hydrophilic coating. Fabric is made of high density multi-filament polyester providing low porosity. It is tapered with proximal diameter 23, 25, 28, 32, 36 mm and distal diameter of 14 mm. Graft's covered length is 105 mm. Delivery system has inner nitinol tube for more flexibility, kink resistance and trackability while outer diameter is 18F or 20F.

Zenith (Cook) stent-graft is a full-thickness woven polyester fabric self expanding stainless

steel and nitinol Cook Z-stents with braided polyester and monofilament polypropylene suture. It has a suprarenal stent with barbs. Barbs are located on the outside of the top uncovered stent. Nitinol rings are positioned at the proximal end of the graft. The delivery system is 20F. The aortouniiliac graft may be either custom made, or commercial with proximal diameters of 24, 28, 32, 36 mm and distal diameter of 12 mm. Exists also the possibility of converting a bifurcated main body graft with a converter (ancillary graft) to an aortouniiliac stent-graft. Proximal diameters vary from 22 mm to 36 mm and 12 mm for the distal diameter.

Aorfix (Lombard Medical, Oxfordshire, UK) stent-graft is a two-part modular implant, comprising a bifurcated main body section and a straight contralateral limb section. It is self expanding made from nitinol, while fabric is woven polyester. It has a fishmouth configuration at the proximal section for infra-renal fixation, while⁸ hooks provide secure fixation. The skeleton has a concentric ring design made of polished nitinol rings. It does not have an AUI device but the bifurcated device can be converted if needed by the use of a converter. Proximal diameter varies from 24 mm to 31 mm, and distal diameter from 10 mm to 20 mm. The largest delivery catheter is 7.6 mm and the smaller 6.6 mm. It is the only stent graft device approved for 90° proximal neck angulation.

Methods

A systematic search from 1991 was performed to PubMed /Medline databases for studies evaluating the role of AUI devices coupled with occlusion of contralateral iliac artery and crossover femoral-femoral or iliac-femoral bypass, for the treatment of abdominal aortic aneurysmal disease. Keywords used were AAA, EVAR, aortouniiliac, aortomonoiliac, stent graft, outcome analysis, in various combinations. The reference lists of the gathered reports were also manually searched. Only articles with series of more than 20 patients were included in this review. 7 articles are referring to the results of endovascular aortic aneurysm repair with aortouniiliac stent grafts, 3 are comparing aortouniiliac, tube, bifurcated devices or between them or /and with open surgery repair, 4 are referring to the patency of the femoral-femoral bypass that couples the AUI stent graft deployment, 2 are referring to the treatment of r-AAA with the AUI stent grafts.

Use of Aortouniiliac Device for the Treatment of Abdominal Aortic Aneurysm-Elective Cases

Several studies outlining the efficacy of the AUI devices for the treatment of abdominal aortic disease were indentified (Table I). The majority of these studies showed that for treatment of high risk patients with complex iliac anatomy deployment of AUI devices had acceptable short and midterm results.

One of the first reports for the use of AUI stent graft for the treatment of patients with abdominal aortic aneurysm in high risk patients is made by Yusuf et al²⁵ in 1997 from the UK. Thirty, high risk for open surgery patients with aorto-iliac aneurysms, were treated from August 1994 to August 1995. Median age 72 years (year range 52 to 86 years) and median aneurysm diameter 6.0 cm (range, 4.0 to 9.0 cm). They used a custom made endoprosthesis made of Dacron graft coupled to a modified Gianturco (self expanding) stent. The graft was preloaded in the Chuter delivery system (18F) in 5 cases and in Ivancev delivery system (20F) in 25 cases. Contralateral limb was occluded by an occluding device or coils and a femoral-femoral crossover graft bypass was performed, under general anesthesia. Endovascular repair was successfully carried out in 25 of 30 patients (83.3%). Of these 28 procedures were elective and 2 were on emergency base. The 30-day mortality was 1/28 (3.5%) for the elective cases, while overall mortality rate was 2/30 (6.6%), and morbidity rate was 4/30 (13.3%). At a median follow up of 4 months 22 of 25 (88%) patients were free from migration, limb occlusion or endoleak. The Authors concluded that “endovascular aortouniiliac repair of abdominal aortic aneurysm with Gianturco stent is feasible in both elective and emergency situations. The majority of patients at high risk for open surgery can safely undergo endovascular repair. However, longer follow-up is required to determine its role in the management of abdominal aortic aneurysm”.

In the same year Thompson et al²⁶ reported the a series of 25 patients treated with a custom-made tapered endoprosthesis, made of PTFE and Palmaz stent loaded in a 21F packing sheath. They confirmed the short term efficacy of the method and concluded that technical changes made in response to early learning curve problems have led to a safer, more reliable procedure.

The third report also in 1997 was made by Ivancev et al²⁷. They reported a series of 45 patients (from November 1993 to October 1996) with median AAA diameter of 60 mm involving the

Table II. Use of aortouniliac device for the treatment of AAA in high risk patients.

Study (year)	Study details	Study outcome
Yusuf et al. (1997) 25	33 high risk pts for OR Custom made AUI device Occluding device for contralateral iliac artery/coils/ligation via extraperitoneal approach Crossover Femoral-Femoral Bypass – Dacron graft General anesthesia	Successful endovascular repair: 25/30 (83.3%) 30-day mortality: 2 (6.6%) Conversion: 2 (6.6%) Endoleaks: 2 (6.6%) Morbidity: 6 (20%) CFBG failure: 0 Conclusion: AUI repair feasible in both elective and emergency cases. Safe procedure for majority of high risk pts. Longer follow up data are needed
Thompson et al. (1997) 26	25 high risk pts for OR (AAAs involving the iliac arteries) Custom made AUI device Occluding device for contralateral iliac artery Crossover Femoral-Femoral Bypass – ePTFE graft General anesthesia	Successful endovascular repair: 20/25 30-day mortality: 2 pts Conversion: 5 pts Endoleaks: 2 pts Morbidity: 5/25 CFBG failure: 0 Conclusion: AUI is effective in pts involving the iliac arteries. Short-term results are acceptable, acceptable, long-term efficacy still to be addressed
Ivancev et al. (1997) 27	45 high risk pts / 8 nonsurgical candidates Custom made AUI device (Ivancev-Malmö device) Occluding device for contralateral iliac artery Crossover Femoral-Femoral Bypass Regional/General anesthesia	Successful endovascular repair: 32/45 (71%) 30-day mortality: 5 (11%) Conversion: 8 (18%) Endoleaks: 9 (20%) Morbidity: 6 (13%) CFBG failure: 0 Conclusion: large AAAs exclusion with AUI is feasible. Early complications due to learning curve. Strict inclusion criteria in order to improve mortality, minimize risk for late migration”
Rehring et al. (2000) 28	51 pts Custom made AUI (28) and commercial device EVT-Guidant (22) Crossover Femoral-Femoral Bypass – Dacron graft (22)/ ePTFE graft (28) Confirmation by intraoperative angiography Epidural/General anesthesia	Successful endovascular repair: 88% 30-day mortality: 2 pts Conversion: 2 cases. (1 due to persistent leak + symptomatic aneurysm, 1 due to persistent type II endoleak + sac enlargement) Endoleaks: 11 (22%), Type Ia: 3, Type Ib: 2, Type II: 6 Secondary intervention: 7 (14%) Complications: 38% mainly remote/wound related Clinical failures: 6 (12%), persistent endoleak > 6 months or sac enlargement CFBG failure: 1 (external iliac dissection) Conclusion: treatment with AUI device is reliable and extends the capability of an endoluminal approach to patients with complex iliac anatomy
Pereira et al. (2002) 24	57 high risk pts Custom made AUI device (SX-ELLA) External iliac artery as insertion site for delivery system via extraperitoneal approach Iliac-femoral crossover graft through a prevesical tunnel Crossover Femoral-Femoral Bypass- Dacron graft Epidural/General anesthesia	Successful endovascular repair: 56/57 (98.2%) Mid- term clinical success: 94.7% 30-day mortality: 2 (3.5%), overall mortality: 5 Conversion: 1 Endoleaks: 9 (14%) Postoperative complications: – Vascular/local: 18 – Systemic: 12 CFBG failure: 0 Conclusion: simple and safe technique alternative to bifurcated systems for high risk pts. By extraperitoneal approach, the crossover bypass remains in a retropubic space not exposed

Table continued

Table II (Continued). Use of aortouniiliac device for the treatment of AAA in high risk patients.

Study (year)	Study details	Study outcome
Saratzis et al. (2005) 29	39 high risk pts Commercial device (Endofit, LeMaitre Vasculaire) Occluding device for contralateral iliac artery Crossover Femoral-Femoral Bypass – ePTFE graft Regional/General anesthesia	Successful endovascular repair: 39/39 (100%) 30-day mortality: 0 Conversion: 0 Endoleaks: 3 (7.7%) Type I: 1, Type II: 2 Postoperative complications: – Vascular/local: 6 – Systemic: 4 CFBG failure: 1 graft (insufficient inflow due to residual stenosis of the endograft) Conclusions: In high surgical risk pts with complex iliac anatomy AUI endograft is feasible and efficacious. Mid-term patency of the CFBG appears satisfactory
Lazaridis et al. (2009) 30	106 pts Commercial device (Endofit, LeMaitre Vasculaire) Occluding device for contralateral iliac artery Crossover Femoral-Femoral Bypass – ePTFE graft Regional/General anesthesia	Successful endovascular repair: 106/106 (100%) 30-day mortality: 3/106 (2.83%) Conversion: 0 Early Follow up: Endoleaks: 18 – Type I: 3 (2.87%), Type II: 15 (14.15%) Postoperative complications: – Vascular/local: 18 (7.54%) – 10 hematomas, 8 superficial infection, lymphorrhea – Systemic: 1 (0.94%) – Postimplantation syndrome: 14 CFBG failure: 1 graft thrombosis (insufficient inflow due to residual stenosis of the endograft) Late Follow up: – Deaths: 8 (7.54%) – AMI: 4 (3.77%) – Endoleaks: 16 – Type I: 2 (1.88%), Type II: 14 (13.2%) – Aortoenteric fistula: 1 (0.94%) – CFBG failure: 2 grafts (1.88%) – 1 graft thrombosis and 1 graft with stenosis Conclusions: the AUI configuration for elective AAA repair is safe and efficacious. Mid-term and long term follow up results are comparable with those reported for AAA endografting with bifurcated devices

AAA: abdominal aortic aneurysm; AUI: aortouniiliac; pts: patients; AMI: acute myocardial infarction; CFBG: crossover femorofemoral bypass grafting; OR: open surgery.

common iliac arteries, using unilimb stent grafts deployed with the Ivancev-Malmö system. The Authors outlined that early complications were associated with the learning curve, while exclusion of large AAAs using unilimb stent-grafts is feasible. Thus, strict inclusion criteria are necessary in order to improve mortality among nonsurgical candidates and minimize the risk for later migration.

Rehring et al²⁸ in 2000 reported the reliability of the method; clinical success was achieved in 88% of 51 patients, using both custom made and commercial AUI devices, commenting that this strategy “extends the capability of an endoluminal approach to patients with complex iliac anatomy”.

Pereira et al²⁴, in 2002 proposed a new approach for the introduction of the aortomonoiliac stent-grafts, through the external iliac artery and an iliac-femoral crossover graft through a prevesical tunnel. Using the custom made SX-ELLA device, successful deployment was achieved in 56/57 patients (98.2%). The Authors emerged this technique, as simple and safe alternative to bifurcated systems for high-risk patients, while the crossover graft remains in a retropubic space and consequently does not have all the disadvantages of a subcutaneously placed prosthesis.

Saratzis et al²⁹ in 2005 reported a study with 39 high-risk patients treated with the AUI com-

mercial device Endofit (LeMaitre Vasculaire) stent-graft. None of the aneurysms has ruptured or been converted to an open procedure. Graft migration, serious infection, paraplegia, distal embolization, or any other serious complication has not been observed. The Authors pointed out that midterm patency of the method appear to be quite satisfactory.

The same group in 2009, Lazaridis et al³⁰, in one of the biggest series till now, with 106 patients and mean follow up of 34.9 months reported comparable mid- and long-term results of endovascular grafting for abdominal aortic aneurysms with the AUI configurations to the reported for bifurcated ones. These series demonstrates that AUI endografts are more simply, more rapidly placed and permits treatment of more patients who need EVAR due to associated comorbidities because of fewer restrictions according to the morphological criteria of feasibility, such as narrow terminal aorta and tortuous, narrow, calcified or occluded iliac axis.

Outcome of Aortouniliac and Bifurcated Devices

Outcome between the endovascular modalities, AUI and bifurcated configurations, to open surgery repair for the treatment of patients with aneurysmal disease, troubled vascular surgeons from the beginning of the endovascular era. The first report trying to highlight this issue is published by Moore et al representing the results of the first multicenter EVT/Guidant aorto-uni-iliac trial³¹. The trial compared the AUI stent-graft with the tube, the bifurcated graft, and open control series in regard to patient demographics, medical comorbidity, 30-day morbidity/mortality, and outcome at 1 year. The trial enrolled one hundred twenty-one (121) patients not eligible for tube or bifurcated endografts (A-I) group. These were compared with 153 patients in a tube (T) group, 268 patients in a bifurcated endograft (BI) group, and 111 patients in an open control (C) group. Peripheral arterial occlusion was present more frequently in the A-I group. However, no differences were found in mean age, incidence of coronary artery disease, and American Society of Anesthesiologists III/IV classification. Implantation was achieved in 94.2% of the A-I group, 90.3% of the BI group, and 92% of the T group. No significant difference was seen in the operative mortality rate. Postoperative cardiac complications were similar for the A-I (22%) and C (20.7%) groups but significantly less for the other groups, whereas pul-

monary problems were significantly reduced in all endograft groups. Median blood loss, intensive care unit use, and hospital stays were markedly and significantly reduced in all endograft groups compared with the control group. The incidences of type I endoleak at 1 year were 2.4% A-I, 2.3% BI, and 3.8% T, and no ruptures occurred in any of the patients treated with endografts. No femoral-femoral graft thromboses occurred in the A-I group. The trials results showed that the aortouniliac configurations outcomes are competitive with the results by tube or bifurcated graft systems and are associated with a lower morbidity than open surgery repair.

Mid-Term Results

Concerning the mid-term results between the AUI and the bifurcated deployed devices, 2 recent articles, provide important information. These reports are comparing the two configurations between them only, with very interesting results.

Dalainas et al³² in 2007, compares the outcome between a bifurcated and an AUI stent-graft, in the short- and mid-term period, for the treatment of aneurysmal aortic disease. Eight-seven patients were treated with the Talent (Medtronic) bifurcated endograft (group A), 98.8% technical success (86 in 87), and 21/21 with the Endofit (LeMaitre Vasculaire) aorto-uni-iliac endograft (group B), 100% technical success, in the same institute by the same surgical team. There was no significant difference in outcome between the patients treated with the Talent device and those treated with the Endofit endoprosthesis, in Kaplan-Meier analysis. The results showed that treating abdominal aortic aneurysms with aorto-uni-iliac endoprosthesis is as safe and effective as treating them with bifurcated endografts.

The second and biggest series was published Jean-Baptisteab³³, in 2009. He reported the mid-term results following the use of bifurcated and AUI endovascular devices in the treatment of abdominal aortic aneurysms in a population of patients deemed to be at high risk for open surgery. 447 patients underwent elective endovascular aneurysm repair using Zenith® stent-grafts. The results in this study demonstrates that bifurcated devices were associated with better results than AUI ones. Iliac artery occlusive disease was significantly associated with a higher risk of complications, while the crossover graft itself was not. Nevertheless, the outcomes for both groups are encouraging in the high risk population.

Use of Aortouniiliac Device for the Treatment of Ruptured Abdominal Aortic Aneurysms

The first ruptured AAA was treated by Veith in 1994, and in the same year Yusuf et al, published the first case³⁴. Since then several Authors³⁵⁻³⁷ published their experience with endovascular repair of ruptured abdominal aortic aneurysms (rAAA). Despite encouraging results, the proportion of patients with rAAA being treated by EVAR remains low³⁸. This may be because of logistical problems including the availability of an experienced endovascular team and a sufficient stock of suitable grafts. To enable EVAR for rAAA, it has been suggested that endovascular stent-grafts must be immediately available in a wide range of sizes. This would require a large stock of bifurcated stent-grafts and may not, for financial and storage reasons be possible in most vascular units. The modular AUI stent-graft system comprising 16 components could replace a total of 750 unitary bifurcated systems³⁹.

Two recent large studies are referring to this particular field, presenting the results of the AUI devices, in the treatment of rAAA. Peppelenbosch et al³⁶ in 2006 reported the results of an international multicenter study for the treatment of ruptured abdominal aortic aneurysms using the Talent AUI system. Between February 2003 and September 2004, 10 participating institutions enrolled a representative sample of 100 consecutive patients in whom EVAR was considered. The study included patients who were treated by stent-graft technique or by open surgery in the case of adverse anatomy for endoluminal stent-grafting or severe hemodynamic instability, or both. The work was performed with a Talent AUI system in all endovascular treated patients. Stent-graft repair was performed in 49 patients and open surgery in 51. No significant differences were observed between these treatment groups with regard to comorbidity at presentation, hemodynamic instability, and the proportion of patients who could be assessed by preoperative computed tomography (CT) scanning. Patients with EVAR more frequently demonstrated a suitable infrarenal neck for endovascular repair, a longer infrarenal neck, and suitable iliac arteries for access than patients with open repair. The primary reason to perform open aneurysm repair was an unfavorable configuration of the neck in 80% of the patients. In patients undergoing EVAR, operative blood loss was less, intensive care admission time was shorter, and the duration of mechanical ventila-

tion was shorter ($p < .02$, all comparisons). The 30-day or in-hospital mortality was 35% in the EVAR category, 39% in patients with open repair, and 37% overall. There was no statistically significant difference between the treatment groups with regard to crude mortality rates or rates adjusted for age, gender, hemodynamic shock, and pre-existent pulmonary disease. The cumulative 3-months, all-cause mortality was 40% in the EVAR group and 42% in the open repair group. The 3-month primary complication rate in the two treatment groups was similar at 59%. The overall first-month mortality did not differ across treatment groups yet was somewhat lower than observed in a recent meta-analysis reporting on open repair. Authors in this international multicenter report concluded that in approximately half the rAAA patients, EVAR appeared viable. An unsuitable infrarenal neck was the most frequent cause to select open repair. In experienced centers using an aortouniiliac system, EVAR appeared to be a feasible method for treatment of a rAAA.

The second study by Hinchliffe et al⁴⁰ in 2007, reported the one-year results of another prospective European multicentre investigation of a modular AUI stent-graft. Seven centers, with elective EVAR experience, participated in the study. Sixty-five patients were enrolled from September 2002 to April 2005. Some 45 patients had rAAA and 20 were acutely symptomatic. Using the Zenith stent-graft and from a choice of 4 body and 4 limb sizes, stent-grafts were deployed under local or general anesthesia. The endovascular delivery system was introduced and the aneurysm excluded from the circulation in a median of 40 (30-60) minutes from the first incision. The median operative duration was 150 (120-190) min, blood loss 300 ml (200-800). Thirty-three (51%), operations were performed by a vascular surgeon alone. There were a total of 4 (6%) peri-operative re-interventions, endovascular ($n = 1$), open ($n = 2$) and thrombectomy ($n = 1$). The peri-operative mortality in the rupture group was 40% and 10% in the symptomatic group. Authors outlined that AUI stent-grafts provide rapid exclusion of r-AAA but still the mortality rate from rAAA treated with EVAR remains high.

The advantages of endovascular repair are mainly related to the avoidance of an abdominal incision, reduction in aortic occlusion and the absence of any intraperitoneal manipulation, factors that reduce the overall mortality of AAA. However, the mortality of r-AAA is high and it is in this field that endovascular means and particularly AUI devices may offer the greatest potential to reduce mortality.

Durability of the Crossover Femoral-Femoral Bypass Graft

One of the largest drawbacks to the use of AUI procedures is the reliance on extra-anatomic bypass grafts to revascularize the contralateral limb. The patency of crossover iliac-femoral or femoral-femoral bypass is acceptable when used for occlusive disease. But these procedures are often complicated by the development of graft infection, graft occlusion, false aneurysm formation, seromas in the groin. Previous reports on crossover femoral-femoral bypass graft patency have been related to patients with occlusive arterial disease. Patency rates for femoral-femoral bypass grafts vary in the literature. Ng et al⁴¹ reported a cumulative patency rate at 6 years of 92% for femoral-femoral crossover procedures and a low early mortality rate of 1.3%, whereas Lamerton et al⁴² showed a cumulative patency rate of 60% at 5 years. The durability and complication rate of CFBG in a high risk patient population undergoing EVAR with an AUI is evaluated by the following studies.

Walker et al⁴³ in 1998 published one of the first reports regarding the outcome of crossover femoral-femoral bypass grafts in patients treated with AUI devices for aneurysmal disease. The study analyzed 136 patients of which 109 had Dacron graft as conduit and 27 ePTFE graft. 2 patients had bypass graft infection, which were removed, 4 superficial wound infections, seven groin hematomas, 1 scrotal hematoma, 1 perigraft hematoma, 1/136 (0.75) femoral-femoral bypass occlusion, complications required intervention 4/136 (3%), 1 death could be related to bypass graft. High incidence rate of groin hematomas is probably related to the technique used in the study. The Authors concluded that patency rates in this group of patients may be higher than in those with occlusive disease because both the inflow and the run-off are good.

Hinchliffe et al⁴⁴ in 2003, reported a large series of 231 patients underwent EVAR with an AUI endovascular stent-graft over 8 years, at a single institution. Median follow-up was 22 months. Localized wound complications were observed in 25 patients (11%). Cumulative 3-year patency rate for the femoral-femoral bypass graft was 91%. At the end of 5 years 83% of grafts remained patent. Authors outlined that femoral-femoral bypass graft used during EVAR with aortouniliac stent grafts offers encouraging medium and long-term patency. When graft occlusion occurs, it is usually directly attributable

to inadequate inflow from the endovascular stent graft itself or to endoluminal damage of the external iliac artery. Early detection of stent-graft distortion or complications in the external iliac artery may result in improved patency rates. Also in 2003 were published 2 more important studies from Yilmaz et al⁴⁵, and Lipsitz et al⁴⁶, respectively.

In the first one 148 patients were enrolled. During follow-up averaging 23.6 ± 16.2 months, nine crossover femorofemoral bypass grafting (CFBG) complications developed in 8 patients (5.4%), including disruption ($n = 2$), infection ($n = 3$), thrombosis ($n = 2$), and pseudoaneurysm ($n = 3$). Four patients with CFBG complications died, of consequences of infection ($n = 2$), intracranial hemorrhage during attempted CFBG thrombolysis ($n = 1$), and intracranial hemorrhage during anticoagulation ($n = 1$). There were no amputations. At life table analysis, freedom from CFBG complication was $96.3\% \pm 1.6\%$ at 12 months, $94.1\% \pm 2.2\%$ at 24, 36, and 48 months, and $86.2\% \pm 7.8\%$ at 60 months. Overall survival for this high-risk patient group was $83.4\% \pm 3.1\%$ at 12 months, $70.4\% \pm 4.1\%$ at 24 months, $56.5\% \pm 5.3\%$ at 36 months, and $44.8\% \pm 6.4\%$ at 48 months. Yilmaz et al⁴³ advocated that CFBG is durable, with a low rate of complications in patients undergoing aortomonoiliac EVAR.

Lipsitz et al⁴⁶, enrolled 110 patients. Mean follow-up data 2.3 years. There were 2 early (<7 days) acute myocardial infarction (AMI/F) endograft thromboses with secondary femoral-femoral graft occlusion. Three late (4, 5, and 10 months) AMI/F endograft thromboses led to femoral-femoral graft failure. No femoral-femoral bypass failed in the absence of AMI/F endograft thrombosis. There were no femoral-femoral graft infections. Four-year lifetable primary and secondary patency rates were 95% and 99%, respectively. Same conclusion for this article Authors who outlined that femoral-femoral bypasses with AUI endografts for aneurysmal disease are durable procedures and have better patency than femoral-femoral grafts used to treat occlusive disease. Femoral-femoral bypass patency rates alone are not a disadvantage of AUI endografts.

All the studies highlighted the superior patency rates of cross-over bypass when are performed along with AUI configurations for the treatment of aneurysmal disease. The need for CFBG should not discourage the use of AUI devices in patients with anatomy unfavorable for other endovascular approaches.

Discussion

Role and Indications

In the early 1990s, the pioneering work of Parodi et al⁷ introduced minimally invasive techniques to the treatment of aortic aneurysmal disease. At the beginning, the devices were simple tubular balloon-expandable aorto-aortic stent-grafts. Soon it was clear that only a few patients had the necessary anatomy for deployment of an aorto-aortic stent-graft. In most cases secure implantation can be achieved by tapered bifurcated (aortobiiliac) or aortouniiliac stent-graft coupled with occlusion of the contralateral common iliac artery and an iliofemoral or femorofemoral crossover bypass, to ensure perfusion of the contralateral limb. The question is how many patients can benefit from the use of the endovascular means for the treatment of aneurysmal disease, as the relative advantages of aortouniiliac and bifurcated stent-grafts depend on the patient's anatomy and clinical status. Therefore, eligibility of patients for endovascular treatment of AAA is a controversial subject. Some of the difficulties are related to endograft technology, but other limitations are imposed by vascular anatomy and the protocol. The reported eligibility varies from 10% up to 55%, depending on the criteria and the source of the study (referral centers versus population studies)^{37,39}, while some Authors believe that <50% of patients are eligible for endovascular treatment⁴⁷. Short proximal aortic neck length and aortic neck diameter, neck angulation, wide neck diameter, presence of neck thrombus, are generally thought to be main contraindications for EVAR. However, access is another cause of exclusion, hostile iliac anatomy being present in about 50% of patients. The presence of narrow aortic bifurcation, iliac tortuosity, unilateral iliac occlusive disease, extensive aneurysmal disease extending to both common iliac arteries also are contraindications for EVAR with a bifurcated device. In many of these cases the use of AUI endoprosthesis in combination with femoral-femoral crossover graft would permit the application of the method to a wider range of patients.

The primary indications today for the treatment of AAA by EVAR with the AUI configuration as they were proposed in the reviewed studies are the following:

1. Distance to lower renal artery to aortic bifurcation < 70 mm;
2. Narrow terminal aorta < 15 mm (transverse diameter);

3. Contralateral common iliac artery angle > 90° from the longitudinal axis of the aneurysm;
4. Obstructed contralateral common iliac artery;
5. Isolated infrarenal abdominal aortic dissections;
6. Combination of the previous indications;
7. Conversion to the AUI configuration while deploying a bifurcated endograft due to impossible contralateral limb catheterization;
8. Ruptured AAA;
9. Concomitant ecstatic or frankly aneurysmal bilateral common iliac arteries, unless the patient has indispensable internal iliac arteries (relative indication);
10. Heavily calcified contralateral external iliac artery (relative indication);
11. Narrow contralateral common iliac artery (diameter < 5 mm), with or without previous transluminal angioplasty (relative indication);
12. Previous stents to the iliac arteries (relative indication).

Advantages of Aortouniiliac Stent-Grafts

The delivery system is usually simple either in custom made or commercial devices. No stent-graft orientation is needed; no limb cannulation required thus less intraortic manipulations in 3-dimensional space under 2-dimensional fluoroscopic guidance and decreased risk of embolization. Less contrast agent is needed. Home-made systems have several advantages even comparing to commercial ones; it can be customized, pre- or intraoperatively, to deal with any unusual circumstances and can incorporate quickly lessons learned intraoperatively. The presence of a separate occluder for the contralateral iliac artery occlusion is an advantage of the method. Common iliac occluder is independent from the primary stent-graft in both size and position. The two parts are separate, so that occluders diameter can vary widely regardless of the diameter of the primary stent-graft. It can also be placed exactly where it is needed regardless of the position of the primary stent-graft.

Disadvantages of Aortouniiliac Stent-Grafts

Of course, the simplicity of AUI stent-graft deployment comes at a price. An occlusion of the contralateral iliac artery is required so as to seal the aneurysm associated with a femoral-femoral bypass in order to reestablish perfusion to the contralateral limb. This fact may put the patient at risk, as AUI stent-graft channels all the blood flow into one iliac artery and from there to pelvic

circulation and both legs. Even widely patent AUI stent-grafts can limit flow enough to cause claudication, if external iliac artery is small and the patient active. The patency of crossover iliofemoral or femorofemoral bypass is very high as demonstrated in this review. But these procedures are often complicated by the development of graft infection, graft occlusion, false aneurysm formation, seromas in the groin.

Conclusions

This review regroups evidence that the AUI configuration is a safe procedure over the mid- and long-term period which compares well with the results of the bifurcated endoprostheses. In patients with anatomical limitations for the use of a bifurcated endograft, the deployment of an AUI stent graft followed by a femoral-femoral crossover bypass can exclude the aortic pathology with similar immediate and mid-to-long-term results, avoiding therefore an open surgery procedure. The main advantages of the AUI endograft are its simplicity and versatility.

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