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Percutaneous Repair of Aortic Aneurysms: A Prospective Study of Suture-Mediated Closure Devices

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Purpose. *To evaluate prospectively the safety and efficacy of totally percutaneous placement of abdominal and thoracic aortic endografts using the Prostar XL suture-mediated closure system.*
Methods. *From January 2002 to January 2005, we attempted to insert percutaneously all bifurcated abdominal aortic and thoracic endografts. Consecutive patients (25 men, four women), with mean age 74.9 years (range 44–84), underwent endovascular repair for 20 abdominal aortic aneurysms (AAA) and nine thoracic aortic aneurysms (repeat operation in one case).*
Endografts used included 21 Zenith (Cook), eight Talent (Medtronic), one AneuRx (Medtronic). For the «pre-close» technique, two Prostar XL 8F were used to close 22–24F access sites and one Prostar XL 10F to close 16F access sites.
Results. *Procedural success was achieved in 21/29 (72.4%) patients and in 39/47 access sites (83%). Closure of 22–24F access sites with tandem 8F Prostar devices was successful in 23/29 (79.3%) cases. Closure of 16F access sites with 10F Prostar device was successful in 16/18 (88.8%) cases. There were seven peri-procedural failures requiring surgery to repair the femoral artery in three cases. Four access complications healed without intervention. Overall 25/29 (86.2%) patients had complete percutaneous repair. No late complications were detected during follow-up (median 17.5 months).*
Conclusions. *Percutaneous treatment of patients with AAA and thoracic aneurysms is feasible in most cases, with a very low risk of access-related complication, providing that the operator has sufficient practical experience of this technique.*

Keywords: Aortic aneurysm; Abdominal; Endovascular procedures.

Introduction

Endovascular repair of abdominal aortic aneurysms and thoracic aortic aneurysms have progressively gained widespread acceptance. Devices currently used are placed through relatively large sheaths (16F–26F), usually requiring open femoral artery cut-down. This type of access, although limited, is associated with local groin complications such as infection, haematoma, seroma in up to 14% of patients.[1] Furthermore, open femoral artery exposure usually requires general or spinal anaesthesia, produces patient discomfort and prolongs hospital stay. Therefore, it has been tempting to decrease the invasiveness of these procedures by performing them percutaneously. Haas *et al*.[2] first described closure of 16F percutaneous access sites using a suture-mediated closure device (Prostar XL—Abbott vascular devices, Redwood City, CA) which appeared, in comparison to other available closure devices, able to seal access sites as large as 16F. Later, some authors reported successful percutaneous endovascular aneurysm repairs.[3–6]

The objective of this study was to assess prospectively the feasibility, safety and efficacy of complete percutaneous endograft deployment for AAA, as well as for thoracic aneurysms.

Methods

Between January 02 and January 05, we attempted to insert percutaneously all infrarenal aortic endografts as well as thoracic endografts. Data were collected prospectively including demographics, duplex ultrasound (US) scan of accessed femoral arteries and device failures. Device failure was recorded and we analyzed the reasons for our access complications with a product specialist from the device manufacturer.

All patients had a duplex US scan of accessed femoral arteries prior to the procedure to determine the

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presence or absence of calcified plaque. The anterior or posterior localization of a calcified plaque also was recorded. During follow-up, the surveillance of access sites was based on duplex US scan, post operatively and at 3 months searching for any access related complication as haematoma, arteriovenous fistula, pseudoaneurysm, stenosis and occlusion.

Exclusion criteria were implantation of an aorto-uni-iliac endograft, heavily scarred groin, presence of an inguinal arterial prosthesis and severely calcified femoral arteries with anterior calcifications revealed by duplex ultrasound scan. This resulted in the exclusion of eight patients due to seven cases of aorto-uni-iliac endografts, combined with a femoro femoral bypass and one case with previous aorto-bi-femoral bypass graft, where femoral artery cut-down was used to insert a thoracic aortic endograft. The procedures were performed by the vascular surgical team in the operating room under general anaesthesia. All percutaneous access with the Prostar XL device according to the 'pre-close' technique[7] was performed by the same surgeon (JW).

Technique

The Prostar XL is a suture-mediated closure device used to close femoral arterial access sites of 8–10F sheaths. The device consists of two components: a sheath that holds two pairs of needles connected with a suture loop and a rotating barrel, used to accurately position the device prior to needle deployment and to guide the needles through the subcutaneous tract. The 8F and 10F devices deliver two pairs of needles and two sutures. The 8F and 10F Prostar XL devices are used to close access sites after interventional procedures performed through 7F–10F sheaths. Larger sheaths require a different technique ('pre-close' technique), where a percutaneous closure device is deployed at the start of the procedure, before the arteriotomy is enlarged by introduction of sheaths larger than 10F. A 10F Prostar XL is used to close access sites up to 16–18F. When sheaths over 16–18F are used, two 8F Prostar are routinely used, the second closure device (8F) being inserted in a similar manner except that the needles are deployed at 45 degrees clockwise in relation to the first device. The 'pre-close' technique has been described previously.[2,5,7]

Once the endograft is inserted and before removing the sheath, sutures are generously soaked with heparin saline and tested to ensure that they run freely. The sheath and the guide wire are then removed while proximal pressure is maintained, and sutures are fastened individually with a sliding knot. A knot pusher is used to ensure approximation of the knot to the surface of the vessel wall. Manual pressure is then released. Suture ends are cut well beneath the surface of the skin. Incisions are closed with a single suture or with adhesive steri strips. Concerning the guide wire, it can be either removed before tying sutures, or maintained in place. In cases where haemostasis is not obtained, if the wire access has been maintained, a sheath can be readvanced over the wire to control the haemorrhage and a femoral cutdown is then performed. All patients received a single intravenous regimen of antibiotics at the beginning of the procedure.

Postoperatively all patients underwent a physical examination, a duplex ultrasound scan and determination of ankle-brachial index. Outpatient follow-up was performed at 1, 6, 12 months and yearly thereafter.

The primary end point was access-related complications, including infection, bleeding, arterial stenosis, occlusion and pseudoaneurysm. Procedural success was defined as the completion of percutaneous placement of the endograft, without any complication at the access sites.

Data are expressed as mean ± SEM. The chi-square test or Fisher exact test was used to compare nominal variables. Statistical significance was assumed at $p < .05$.

Results

Twenty-nine consecutive patients 25 men, four women, mean age: 74.9 years (range: 44–84) who underwent endovascular repair of an AAA (20) and thoracic aortic aneurysms[9] were assessed for evidence of access related complications. One woman with a thoracic aortic aneurysm had a secondary endovascular procedure at 7 months for a distal type I endoleak. The additional endograft was inserted percutaneously via the same femoral artery previously accessed. The number of patients recruited during this period of time was curtailed by the strict limitations imposed in France by health authorities since October 2001, restricting indications for endovascular treatment of AAA to high-risk patients. Thus, in this study, all patients with AAA were classified as high risk according to the AFSSAPS classification (Agence Française pour la Sécurité Sanitaire des Produits de Santé). The 29 patients described in this report represented approximately one tenth of patients operated on for AAA in our unit. There were 18 bifurcated abdominal aortic endografts, two abdominal aortic tubes and 10 thoracic aortic endografts. In one patient (with bifurcated endograft), a heavily calcified femoral artery on the