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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' technique⁷ 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 \pm 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 aneurysms⁹ 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

duplex US scan prompted us to perform a femoral artery cutdown on one side.

Endografts used were: Zenith (Cook): 21 (abdominal: 15, thoracic: six), Talent (Medtronic): eight (abdominal: four, thoracic: four), AneuRx (Medtronic): one (abdominal). Inner and outer diameters were, respectively, 20/23 F for Zenith abdominal and 22/25 for Zenith thoracic. Outer diameters were 18/21 F for AneuRx abdominal, 18/24 F for Talent abdominal and 20/25 F for Talent thoracic. Twenty-nine patients had 47 percutaneous closure and one femoral artery cutdown. We used 58 Prostar XL 8F (two 8F to close 22–24F access sites) and 18 Prostar XL 10F (to close 16F access sites).

Procedural success was achieved in 21 (72.4%) patients and at 39 (83%) access sites. Twenty-nine attempts at percutaneous closure of 22–24F arteriotomy with tandem 8F Prostar devices resulted in 23/29 (79.3%) successes. Eighteen attempted percutaneous closures of 16F arteriotomy with 10F Prostar device resulted in 16/18 (88.8%) successes.

There were seven periprocedural failures in seven patients which, respectively, occurred on the 3, 5, 7, 8, 11, 14, 19th cases. Reasons for failures were identified in four cases: difficult device introduction due to iliac tortuosity in one case, femoral calcifications underestimated by the duplex scan in one case and missing sutures in two cases. In one case, a needle was deflected through the skin by a calcified plaque. These failures resulted in three per-operative surgical exposures of the accessed artery for surgical repair, one pseudoaneurysm which occurred at day 3 and spontaneously healed, three bleeds which spontaneously healed following prolonged compression and one minor bleed occurred at day 2 requiring additional compression. One delayed bleed occurred at day 9 and was treated by a surgical intervention to repair the femoral artery.

Despite an access complication in four cases (one pseudoaneurysm and three bleeds which healed without surgical conversion), complete percutaneous repair was achieved. Thus, overall 25/29 (86.2%) patients had an entirely percutaneous repair.

No late complication was detected during the follow-up, median 17.5 months (IQR 9–26 months).

Discussion

The results of this prospective series are satisfactory and confirm the feasibility, safety and efficacy of percutaneous repair of aortic aneurysms. The percutaneous deployment of both abdominal aortic and thoracic endografts was successful in 72.4% of patients (21/29)

with no complications. Of the seven periprocedural access complications, four resolved spontaneously allowing a complete percutaneous repair in 86.2% of patients. Percutaneous closure of the main access site (22–24F) was successful in 79.3% of patients, while closure of the 16F access site was successful in 88.8%. (chi-square test: $p = 0.25$, Fischer's exact test: $p = 0.43$).

Arterial closure devices, such as plug mediated systems, originally were developed for use with small access sheaths and work relatively well up to 8F sheath, however, they cannot be used safely to close arterial punctures with 10F or larger sheaths. The suture-mediated Prostar XL device (8–10F) can be used «off-label» to percutaneously close large access sites up to 24 or 26F, required to place abdominal aortic endografts as well as thoracic endografts.^{1,2,4–7} The advantages are obvious: allowing placement of aortic endografts while avoiding femoral artery cutdowns, thus decreasing the invasiveness of these procedures. The percutaneous procedure also maintains, at least partially, perfusion of lower limbs. Aortic endografting can, therefore, be performed in high risk patients under regional or even local anaesthesia.

However, the 'off-label' use of this device is not free of risk and complications and requires special expertise.⁷ Clearly, there is a learning curve associated with the use of suture-mediated closure devices: in our series, most complications were due to technical problems, which occurred mainly at the beginning of the series. These complications could have been prevented by more experience with the Prostar device. All complications except two (delayed bleeding at day 9 and pseudoaneurysm at day 3) occurred during the procedure itself, requiring immediate treatment with surgical exposure of the accessed artery in three cases.

Despite the deleterious effect of the learning curve, our results compare favourably with those reported in the literature. Table 1 summarizes literature rates of successful percutaneous endograft insertions without conversion to an open groin incision. Success rates vary from 46.2⁶ to 93%.³ These results differ from success rates of unilateral percutaneous femoral artery closure as demonstrated in the series of Traul *et al.* where success rates in percutaneous deployment of

Table 1. Success rates of percutaneous endograft insertions

Author	Procedures (n)	Success rate (%)
Morasch ⁷	47	85.1
Torsello ⁸	15	86.6
Teh ⁵	42	73.8
Rachel ⁴	44	63
Traul ⁶	12	46.2
Howell ³	30	93
Personal series	30	86.2

the main body stent graft via a 22–24F sheath and of the contralateral limb via a 16F sheath were, respectively 61.5 and 64.7%, whereas the rate of complete percutaneous endograft repair was only 46.2%.⁶ Results also vary with sheath size (Table 2). It is postulated that results of percutaneous closure of 16F access sites are better than those of larger access sites (22–25F) required to implant abdominal and thoracic aortic endografts. In the study of Rachel *et al.*, introducer sheath size was the only predictor of successful percutaneous closure based on multivariate analysis.⁴ In our series, perhaps due to the small number of patients, the difference in the rate of success between closure of 16F and larger access sites (22–25F) was not statistically significant. We suggest that observed differences in the literature might reflect the learning curve of a technique, which is slightly more difficult to master using two Prostar devices instead of one.

We observed no cases of infection in our small series. Although the reported incidence of infection after placement of percutaneous suture-mediated devices is low (reported as 0.2% by Johanning *et al.*⁸), consequences of this complication may be potentially devastating. Prevention is best ensured by pre-procedural antibiotics, together with a sterile technique (sterile adhesive draping, etc.) and environment, optimally offered in the operating room.

Some technical points deserve discussion. For sheaths over 18F, most teams use tandem devices (8F or 10F), the second device being rotated 45° clockwise according to the manufacturer's recommendations.⁵ In contrast, Howell *et al.* recommended rotation of the second Prostar device by 90° instead of 45°, arguing that 'this rotation prevents the sutures of each device from being placed in the same location in the arterial wall'.³ However, by doing this the chances are that sutures of each device would have the exact same location in the arterial wall, thus potentially making the edges of the arteriotomy more fragile. Instead of using tandem devices, Torsello *et al.* used only one Prostar 10F for closure of all access sites, regardless of sheath size.⁹ These authors suggested that 'too many threads can cause catching on other sutures, disrupting the vessel wall during fastening of the knot'. This risk is minimal if a rigorous technique is observed with

sutures placed carefully and maintained in radial orientation. All loops of sutures should be kept taut and generously soaked with heparin saline, ensuring that sutures run freely by alternatively pulling on both ends gently and then tied in order of placement. Moreover, we observed that although haemostasis usually was obtained after tying the second knot, in some cases, the third and sometimes the fourth knot were necessary to achieve hemostasis, avoiding the need for additional compression.

To avoid that sutures may cut through the arterial wall when the 10F arteriotomy is later on dilated to 20F or more, similarly to Howell *et al.*,³ we dilated both the arteriotomy and iliac arteries with dilators of progressive size before inserting the endograft. This technique also has the advantage of facilitating the advancement of the endograft via iliac arteries. Major tortuosity may prevent the progression of the device and it accounted for one failure in our series. This problem can be overcome by using a rigid or a semi-rigid guide wire that facilitates the progression of the device by correcting the tortuosity. Inguinal scarring, presence of a femoral arterial prosthesis and calcifications can prevent the needles from being retrieved or can cause the deflection of a needle. In these situations, the operator can attempt to push back the needles into the hub by pushing the handle back into the device. Fluoroscopy can help to determine the position of the needles: if they are successfully returned to the hub, the Prostar device can be removed and replaced with a new one.¹ If this manoeuvre does not correct the problem, or if a needle deflected in subcutaneous tissue and cannot be retrieved, conversion to an open groin incision is necessary to remove the needles and repair the femoral artery. According to Traul *et al.*, the wire may be kept in place until the sutures are tied and the haemostasis achieved.⁶ In case of unsuccessful percutaneous closure, the wire maintained in place allows to reinsert a sheath to control the bleeding during the surgical exposure. However, leaving the wire in place could expose to tying the sutures on the wire as reported by Howell *et al.* in two cases.³ The use of a hydrophilic wire could minimise this risk.

There are several contraindications to percutaneous closure technique. First is a severely calcified femoral artery shown on duplex ultrasound scanning, especially if calcifications are anterior. However, in the prospective randomized study performed by Starnes *et al.*, percutaneous closures were successfully achieved in arteries with anterior calcification.¹⁰ Second is a heavily scarred groin or the presence of an inguinal arterial prosthesis.¹⁰ Third, morbid obesity is often cited as a cause of failure.^{5,6,9} Although percutaneous treatment may be more difficult in obese patients, it

Table 2. Success rates of percutaneous femoral artery closure according to sheath size

Author	Procedures (n)	Success rate (%)	Sheath size (F)
Traul ⁶	12	16	≥22
Rachel ⁴	44	64.7	61.5
Howell ¹	144	85	64
Howell ³	30	94.4	96
Personal series	30	88.8	79.3

is highly beneficial in this context when successful, avoiding the risks of an open arterial access.⁷

Conclusion

Percutaneous treatment of patients with AAA is almost always feasible with a very low risk of access-related complications. We recommend that percutaneous treatment of AAA be performed by experienced endovascular specialists who are familiar with the Prostar device. The procedure should be performed in an operating room, in cases where conversion to an open groin exposure is required.

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