Percutaneous Endovascular Aortic Aneurysm Repair: A Prospective Evaluation of Safety, Efficiency, and Risk Factors

Markus Eisenack1; Thomas Umscheid, MD2; Joerg Tessarek, MD1; Giovanni F. Torsello1; and Giovanni B. Torsello, MD1

1Department of Vascular Surgery, St. Franziskus-Hospital Münster, and Center for Vascular and Endovascular Surgery, University Hospital Münster, Germany.
2Department of Vascular Surgery, HELIOS William Harvey Klinik, Bad Nauheim, Germany.

Purpose: To evaluate the efficiency of totally percutaneous endovascular aortic aneurysm repair in a large cohort of patients and to define risk factors for failure with a 10-F vascular closure system.

Methods: A prospective study examined the feasibility and safety of percutaneous femoral artery closure with a single Prostar XL 10-F vascular closure device applied in conjunction with the preclose technique. Between January 2004 and December 2005, 535 consecutive patients were treated for aortic aneurysmal disease. Thirty-five patients were excluded, leaving 500 patients (417 men; mean age 72.6 years) treated for aortic aneurysms using the Talent or Zenith stent-graft delivered through sheaths measuring 14-F (191, 21.2%), 16-F (33, 3.7%), 18-F (179, 19.8%), 20-F (2, 0.2%), 22-F (228, 25.2%), and 24-F (271, 29.9%).

Primary clinical success was defined as the freedom from additional early or late procedures to treat any complication at the access site. Data were analyzed to reveal any correlation of access site complications or early/late repairs to operator experience or risk factors (obesity, extensive femoral artery calcification, and previous interventions/scars in the groin).

Results: Primary success was achieved in 96.1% of all percutaneous approaches. Twenty-three patients developed early (n=16) or late (n=7) complications at the access vessel; in 12 cases, hemostasis was achieved using pledgets with the Prostar sutures. No wound complications were recorded. The need for early conversion to an open access correlated with CFA calcification (OR 74.5, 95% CI 17.8 to 310.7; p<0.001) and operator experience (OR 43.2, 95% CI 9.8 to 189.0; p<0.001). The risk of late access site repairs was significantly higher in the presence of a groin scar (OR 48.8, 95% CI 9.2 to 259.0; p<0.001). Correlation of sheath size with early conversion to open access was weaker compared to all the other factors (OR 1.2, CI 95% 1.0 to 1.4; p<0.05). Obesity was not a risk factor for any complication.

Conclusion: Percutaneous EVAR using the Prostar XL is safe, with minimal early and late complications. Operator experience is one of the most significant predictors of success. Anterior wall calcification and severe fibrosis of the access vessel are also predictors of primary failure, whereas obesity and sheath size are not.

Key words: aortic aneurysm, endovascular aneurysm repair, percutaneous access, stent-graft, complications, outcome analysis
The most common access site for endovascular aneurysm repair (EVAR) of aortic aneurysms is through the common femoral artery (CFA) using either open or percutaneous techniques. Since the development of the percutaneous approach in the late nineties, many investigators have discussed the advantages of this technique.1–9 The convenience and shorter time to ambulation of the percutaneous method stand in contrast to the complications of an open cutdown, such as wound infection, lymphocele, and hematomas.6 In the past, obesity, calcification of the CFA, and scars in the groin were considered to be contraindications to a percutaneous procedure.1,4,7–9 The learning curve of the interventionist is also considered to be an important factor for success.1,6,9

Closure devices for percutaneous access sites are approved only for use with up to 10-F sheaths,10,11 but the introduction of the “pre-close” technique made it possible to close vessels in which larger bore sheaths were used.12,13 The aim of the present prospective study was to evaluate the safety and feasibility of percutaneous femoral artery closure with a single 10-F device in a large cohort of patients and identify the most important factors influencing the outcome.

METHODS

Study Design

In January 2004, a study was commenced to prospectively examine the feasibility and safety of percutaneous femoral artery closure with a single Prostar XL 10-F vascular closure device (Abbott Vascular, Abbott Park, IL, USA) applied in conjunction with the preclose technique. Patients being treated for abdominal aortic aneurysm (AAA) or thoracic aortic aneurysm (TAA) were candidates for the study; obesity [defined as a body mass index (BMI) >35 kg/m²], severe calcification of the CFA, and previous interventions or operations in the groin were not contraindications. Exclusion criteria were severe atherosclerosis of the access site requiring reconstruction, use of an aortomonoiliac endograft, CFA aneurysm, or existing femoropopliteal bypass grafts. Written consent was obtained from the patients before enrollment into the study.

Device Description and Preclose Technique

The design and application of the Prostar XL 10-F device has been described in detail elsewhere.2 The device consists of 4 components: a hydrophilic catheter for guiding the system into the aorta, a marker lumen for identification of correct device position in the vessel, a sheath containing 4 lance-like nitinol needles that are connected to 2 braided sutures, and a rotating barrel for dissection and needle capture. The device is advanced into the artery to guide the needle trajectory through the subcutaneous tissue, and the sutures are pulled out from the inside through the arterial wall.

Since the Prostar XL device is constructed to achieve hemostasis in procedures performed through 7-F to 10-F introducer sheaths, a preclose technique must be employed when larger introducers are used. After careful blunt dissection of the subcutaneous tissue down to the vessel wall with a mosquito clamp, the 10-F Prostar XL is advanced and deployed. The sutures are fixed loosely with a small clamp, and a 14-F sheath replaces the closure system. After deployment of the stent-graft, the sutures are tied to the vessel with a fisherman’s knot.2 To avoid major blood loss in case of a failure, a guidewire is left in place to maintain access to the vessel. Hemorrhage is controlled during dissection of the groin and exposure of the vessel. In case of oozing, the knots are held against the vessel wall with the knot pusher for awhile, manually compressing the artery above the puncture site. If compression is not effective, a polytetrafluoroethylene (PTFE) felt pledget patch can be sewn with the 4 vascular sutures of the Prostar device to achieve hemostasis.4

Patient Population

Between January 2004 and December 2005, 535 consecutive patients were treated for aortic aneurysmal disease. Thirty-five patients were excluded owing to access site atherosclerosis (n = 12), aortomonoiliac endo-
grafts (n=13), CFA aneurysm (n=3), or femoropopliteal bypass grafts (n=7), leaving 500 patients (417 men; mean age 72±6.6 years) treated with a percutaneous approach for 403 AAAs and 97 TAAAs. The majority of patients (450, 90%) were treated under spinal anesthesia, the remaining under general or local. Aortic repair was performed using the Talent stent-graft (Medtronic Vascular, Santa Rosa, CA, USA) in 273 (54.6%) cases and the Zenith stent-graft (Cook Inc, Bloomington, IN, USA) in 227 (45.4%) patients (403 bifurcated devices and 97 tube grafts). Sheath sizes were 14-F (191, 21.2%), 16-F (33, 3.7%), 18-F (179, 19.8%), 20-F (2, 0.2%), 22-F (228, 25.2%), and 24-F (271, 29.9%). The mean time of surgery was 76.0±15.3 minutes and the average stay in the intensive care unit was 3.6±1.2 hours.

Follow-up included duplex examination after the procedure and computed tomography (CT) within 3 months and at yearly intervals.

Definitions and Statistical Analysis

Primary clinical success was defined as the freedom from additional early (on table) or late procedures (vascular suture or reconstruction, including use of a pledge) to treat any complication at the access site. Logistic regression analysis was performed using the Hosmer-Lemeshow test to determine if there was an relationship between sheath sizes and complications. A Cox proportional hazards model was used to reveal any correlation of complications and early/late additional repair procedures to risk factors [obesity (BMI >35), extensive CFA calcification, and previous interventions/scars in the groin] or operator experience (cutpoint of >30 closures performed with the Prostar XL based on previous studies at our institution]. Data from the model are given as the odds ratio (OR) and 95% confidence intervals (CI). The threshold for significance was set at p <0.05. Statistical analysis was performed by means of SPSS 15.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Primary success was achieved in 96.1% (n=868) of all 903 percutaneous approaches. Secondary procedures were performed in 35 (3.9%) cases to treat insufficient hemostasis (n=28), false aneurysm (n=4), or arterial thrombosis (n=3). In 23 cases, the complications were treated by vessel exposure and suture; in the remaining 12 patients, the failure was corrected using a PTFE pledge with the Prostar sutures. The access complications were detected and treated exclusively during the first week after endovascular repair: 16 vascular repairs were performed at the end of the procedure, 4 after 24 hours, 2 after 2 days, and 1 after 4 days. No wound complications were recorded during the early or late period. During follow-up (mean 28.5±8.0 months), duplex and CT scan examinations showed no complications at the vascular site.

Complications were frequently found in patients with severe calcification of the CFA (37.8%), scar in the groin (23.8%), or those treated by inexperienced (<=30 cases) operators (14%). CFA calcification (OR 74.49, CI 95% 17.8 to 310.7; p<0.001) and operator experience (OR 43.2, CI 95% 9.8 to 189.0; p<0.001) were significantly correlated with early conversion to femoral cutdown (Table). Sheath size (OR 1.2, CI 95% 1.0 to 1.4; p<0.05) and scar in the groin (OR 8.2, 95% CI 1.1 to 61.0;
p<0.05) also correlated with early conversion but to a much lesser degree. The presence of a scar in the groin increased the likelihood of late repairs (OR 48.8, 95% CI 9.2 to 259.0; p<0.001). False aneurysms developed significantly more often (OR 14.6, 95% CI 1.4 to 147.3; p<0.05) in scarred groins, as did arterial thromboses (OR 81.2, 95% CI 6.8 to 971.0; p<0.001). Thromboses were also more frequent in patients with CFA calcification (OR 35.6, 95% CI 3.0 to 421.0; p<0.005). Obesity was not a risk factor for any complication.

**DISCUSSION**

Minimally invasive interventions are becoming commonplace in vascular surgery. Today, it is widely accepted that percutaneous arterial closure offers a wide range of advantages, so an increasing number of centers perform EVAR using a totally percutaneous approach. A prospective randomized study performed to evaluate results of the surgical cutdown versus the percutaneous technique indicated a lower complication rate at the access site in the percutaneous group. Avoiding surgical femoral artery exposure increases patient comfort and decreases the rate of wound infection and lymph fistula. Howell et al. recorded no in-hospital complications, such as infections, bleeding, or femoral neuropathy, in their cohort of 30 consecutive patients. These data were confirmed by other studies that also showed a significant decrease in costs compared to femoral cutdown.

Since the available closure systems are not approved for an access larger than 10-F, 2 Prostar XL devices have been used to suture the femoral artery after endovascular aortic repair. Over time, we learned by experience that deploying one Prostar XI device and performing the preclose technique are sufficient to achieve hemostasis. Our high technical success rate demonstrates the efficacy and feasibility of this strategy. Among the various percutaneous arterial closure devices, suture-mediated systems offer the advantages of a surgical vessel closure, but complications have been reported. The most frequent sequelae have been observed in obese patients and those with calcifications of the CFA, as well as in patients treated with bigger introducer sheaths.

In a single-institution retrospective review, Traul et al. demonstrated a significant association between morbid obesity and the incidence of conversion to open access or complications after percutaneous endovascular aneurysm repair. They also identified an increasing failure rate of the preclose technique with larger sheath sizes (≥22F); 5 (38.5%) of 13 patients treated with a large bore sheath were converted to open access.

In 2001, Teh et al. reported a remarkable incidence of bleeding (5 of their 12 failures) related to morbid obesity as a main risk factor for complications of a percutaneous closure. In our study performed in a larger cohort of patients, obesity was not a significant factor for technical failure. Percutaneous treatment of obese patients has the advantage of reducing wound complications, but requires an accurate dissection of the subcutaneous tissue to advance the closure device down to the vessel. Back-bleeding through the marker lumen of the Prostar device must be assessed to provide sufficient penetration of the catheter into the lumen. We recommend flushing the port and slightly rotate the device to exclude mechanical obstruction of the marker lumen.

In obese patients, the arterial puncture can also be demanding. If the arterial puncture is too low, cannulation of the profunda or superficial femoral artery causes vessel rupture or occlusion. These complications can be avoided by identification of the CFA using preoperative imaging (duplex, CT). Angiography or ultrasound-controlled puncture can also be helpful during the procedure.

It is notable that sheath size played a minor role as related to failure of hemostasis in our study. In logistic regression, we did not find differences between the various sizes related to complication rates, which confirms observations by Singh et al. These authors achieved a 100% success rate and recorded no complications in their 15 patients treated with large bore sheaths.

Other factors played a major role in complications among our patients. Scars in the groin and CFA calcification were primary causes of complications, necessitating sec-
ondary open repair of the access artery. Several other studies also considered scars and calcification to be unfavorable anatomy for successful percutaneous closure. In case of a scarred groin or calcification of the anterior vessel wall, the needles can be deflected while retracting the handle. In this case, the needle should be pushed back into the catheter.

The most remarkable result of our study was the relationship between failure and operator experience. On the basis of earlier experience, we defined an operator as experienced if he had performed >30 interventions using a Prostar device. As a consequence of this study, we strictly train our fellows for correct blunt dissection, careful handling of the sutures, and controlled tightening of the knot after the introducer sheath has been removed. To avoid disrupting the vessel wall if the fisherman’s knot slips, it is advisable to test the free run and irrigate the sutures, removing accumulated fibrin and debris before tying the knot. It is also important to pull the long end of the suture in the right direction while slipping the knot and to use the knot pusher appropriately for advancing the knot to the vessel wall.

In this study, the overall failure rate was low even in demanding cases. Therefore, we use percutaneous access in patients regardless of severe calcification or scarred groin, taking a small risk of open femoral cutdown in case of complications. During long-term follow-up, we did not see major complications such as late occlusion or stenosis or even wound infection.

Usually, synthetic graft material is regarded as a contraindication to the use of percutaneous closure devices due to a high risk of infection, as Pullen et al. highlighted. With increasing experience, we have now successfully used the Prostar system even in patients with Dacron material in the groin, but we avoid a percutaneous approach if there is a PTFE graft in place because the sutures may cut the graft material when fastening the knot.

Conclusion

The use of the Prostar XL 10-F system for vascular closure after EVAR is safe and efficient. Operator experience is one of the most significant predictors of success. Anterior wall calcification and fibrosis of the CFA are predictors of primary failure, whereas obesity and sheath size do not appear to influence outcome. Failure of hemostasis is usually not difficult to repair.

REFERENCES


