Preclose Percutaneous Endurant™ Endografting with the Proglide™ Device : a Safe and Feasible Combination

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Abstract. *Background :* Endovascular repair of abdominal aortic aneurysms has been revolutionized over the last two decades. Opening the doors for a percutaneous approach by avoiding surgical exposure of the vascular access site. The goal of this report is to analyze the feasibility and efficacy of using Perclose Proglide™ through a preclose technique in a percutaneous approach to Endurant™ endografting for Asymptomatic infrarenal aortic aneurysms in an elective setting. *Methods :* Between April 2011 and April 2014, 45 consecutive patients underwent percutaneous endovascular aortic aneurysm repair (PEVAR) for an asymptomatic infrarenal aortic aneurysm. Closure of percutaneous access sites was ensured with Perclose Proglide in a “preclose” technique. Data were collected in a prospective maintained database with a follow-up period of one month. Patient demographics, aneurysmal characteristics, procedural details and complications were recorded.

Results : A total of 170 Proglide devices were used to close 85 access sites. Adequate hemostasis was obtained in 96.5 percent (82 of 85 access sites). Conversion to a femoral cutdown was necessary in 2.4% (2 of 85 access sites). The mean hospitalization was 2.6 days and 86.7 percent of patients were discharged within 2 days. The incidence of post-procedural access-related complications was 2.2%.

Conclusions : PEVAR using the Perclose Proglide in preclosing 14Fr to 20Fr access sites for Endurant endografting in the treatment of asymptomatic infrarenal aortic aneurysms is feasible and effective. Moreover, the percutaneous approach allows for procedures to be performed under local anesthesia, while providing a low risk for access-related complications and a relatively short hospitalization.

Abbreviations

AUI, aortouni-iliac ; CFA, common femoral artery ; CT, computed tomography ; EVAR, endovascular aortic aneurysm repair ; PEVAR, percutaneous endovascular aortic aneurysm repair.

Introduction

Several landmark studies have made the endovascular repair of abdominal aortic aneurysms a widely accepted modality (1-3). The safety and efficacy of an endovascular repair has been thoroughly described, however these procedures require the closure of large bore vascular access sites at the common femoral artery (CFA). Routinely a surgical cutdown is used, thereby limiting the minimally invasiveness of this procedure.

Suture-mediated closure devices have revolutionized the approach, especially by means of the “preclose technique” (4). Perclose Proglide™ and Prostar XL™ (Abbott Vascular, Redwood City, CA, USA) can be obtained for single or tandem deployment and have been validated in their respective studies (5, 6). Hereby, opening the doors for a very appealing percutaneous approach in the endovascular exclusion of an aortic aneurysm.

Endograft delivery and deployment by these vascular access sites, will allow for the formation of a seal between

the endoprosthesis and the nonaneurysmal aorta. With the increasing popularity of endovascular aortic repair there has been an increase in the number of commercially available stent graft designs on the market (7). We have gained extensive experience with the Endurant endograft™ (Medtronic Vascular, Santa Rosa, CA, USA). Literature has proven superiority of the Endurant II over other available stent graft designs (8), while yielding satisfactory results in challenging aortic anatomies (9).

The goal of this report is to analyze the feasibility and efficacy of using Perclose Proglide™ through a preclose technique in a percutaneous approach to Endurant endografting for asymptomatic infrarenal aortic aneurysms in an elective setting.

Methods

Patient selection

We performed a prospective analysis during a period of three years, between April 2011 and April 2014, on all patients who underwent an elective endovascular repair for an asymptomatic infrarenal aortic aneurysm. Patient demographics, aneurysmal characteristics, procedural details and complications were recorded.

Preoperatively, patients received a computed tomography (CT) angiography for the evaluation of the

configuration and anatomy of the aneurysm and access sites. A number of anatomical criteria were used to assess patient suitability for EVAR including the morphology of the access vessels. However, during the inclusion period not a single patient was scheduled for elective open repair. All aneurysms fulfilled the national healthcare required criteria for endovascular treatment of an infrarenal aortic aneurysm. These are criteria regarding aneurysm diameter, iliac diameter and tortuosity, infrarenal neck angulation, neck length, and the distal landing zone. Symptomatic or ruptured aortic aneurysms, aneurysms that not fulfilled the national requirements or aortoenteric fistulae were excluded from analysis.

Procedures were performed using the Endurant endo-graft and vascular access was attained under ultrasound guidance with the preclose technique using a single or tandem ProGlide device. The type of anesthesia, local or general, was entirely based on the patient's preference. Previous groin surgery, obesity and calcifications of the CFA were not considered as exclusion criteria for a percutaneous approach. Patients requiring a concomitant iliofemoral endarterectomy were excluded. One single operator at the Antwerp University Hospital performed all procedures.

Follow-up / data collection

Each puncture site was assessed by clinical examination in the immediate postoperative period. At one month postoperatively patients were seen on ambulatory base for clinical assessment and duplex ultrasonography of the groin. Patients also received a CT angiography of the abdominal aorta, including the access sites. In patients with an impaired kidney function, we opted of a non-

contrast-enhanced CT. Documentation and grading of complications is in accordance with literature (10), and was performed during a period of one month. Thereafter, follow-up was performed in accordance with Belgian healthcare requirements.

Preclose technique

A preclose technique of each large bore vascular access site was used after ultrasound-guided retrograde puncture of the CFA. Two 6Fr ProGlide devices were inserted and deployed in a standard manner after 30–45° rotation. The sutures were left extracorporeally for closure at the end of the procedure. Upon completion of the procedure heparin is fully reversed and the preformed knots are lubricated with saline and tightened (Fig. 1). A detailed description of the preclose technique has been thoroughly described (4).

Figure 1. Deployment of the Perclose ProGlide™ through a preclose technique.

Table 1. Baseline characteristics of the patients.

Age – yr	71.7 ± 8.5
Male sex – no. (%)	38 (84.4%)
Aneurysm	
Fusiform	40 (88.9%)
Saccular	5 (11.1%)
Maximal diameter of fusiform aneurysm (mm)	
Mean	61.8 ± 13.1
Median	56.5
Range	55.0 to 120.0
Eurostar aneurysm morphology class – no. (%) *	
A (confined to aorta, distal aortic neck available)	11 (24.4%)
B (involves aortic bifurcation, normal iliac arteries)	22 (48.9%)
C (involves both proximal common iliac arteries)	2 (4.4%)
D (extends into one iliac bifurcation)	2 (4.4%)
E (extends into both iliac bifurcations)	3 (6.7%)

Plus-minus values are means ± SD.

**The Eurostar classification of aneurysm morphology has been described in detail by HARRIS *et al.* (11).

Results

From April 2011 through April 2014 45 endovascular repairs for asymptomatic infrarenal aortic aneurysms by a totally percutaneous approach in an elective setting were performed. The same vascular surgeon performed all procedures. The baseline characteristics of the patient population as well as the characteristics of the aortic aneurysms are summarized in Table 1. The mean ($\pm$ SD) age was 71.7 ± 8.5 years, and 38 patients (84%) were men. The mean aneurysm diameter was 61.8 ± 13.1 mm. Patients were followed for a period of one month, to adequately document all access related complications. All patients completed the follow-up period.

Endovascular exclusion of the aortic aneurysm was performed with the Endurant endoprosthesis (Table 2). Different configurations of the Endurant endoprosthesis are available, including a bifurcated endograft, aortouni-iliac (AUI) stent-graft and a tube graft. A bifurcated endograft ($n = 40$) requires two large bore vascular accesses, however the tube and AUI stent-graft require only one large bore access. Independent delivery and deployment of the Endurant endoprosthesis is possible without the need for a vascular access sheath. The main body has an outer diameter of 18Fr or 20Fr and a contralateral limb will have an outer diameter of 14Fr or 16Fr. The distribution of delivery device size (outer diameter) was 14Fr (31.8%), 16Fr (15.3%), 18Fr (29.4%) and 20Fr (23.5%).

Insertion of the Proglide was performed through the preclose technique after ultrasound-guided vascular

access was obtained. A total of 170 Proglides were used for preclosure of 85 access sites. In accordance with the Proglide guidelines, we deployed two Proglides per 14Fr-20Fr access site. However, with experience it became clear that adequate hemostasis could be obtained with one Proglide for the 14Fr and 16Fr access sites. All 18Fr and 20Fr access sites were preclosed using tandem Proglide deployment.

A total of 26 Proglide devices (15.3%) failed on deployment and an extra Proglide was needed to achieve an adequate preclosure. Successful hemostasis was seen in 96.5 percent of access sites (82 of 85). Two access sites required conversion to a limited femoral cutdown under local anesthesia due to wire breakage during knotting. One failure to obtain adequate hemostasis with two knotted Proglides was solved with the deployment of an extra closure device on top of the Proglides.

Due to our percutaneous approach, we presented all patients the option for treatment under local anesthesia. We believe that local anesthesia can be of added value during the procedure, while reducing the invasiveness of the procedure. Ultrasound-guided local anesthesia will procure adequate patient comfort. Forty-two percent of procedures were performed under local anesthesia.

The postprocedural outcome and complications are summarized in Table 3. No mortality was seen. In two cases a major adverse event occurred. One acute myocardial infarction was seen, requiring surgical revascularization. This patient stayed hospitalized for 47 days. One case of transient renal failure occurred. Two technical adverse events occurred. During one procedure

Table 2. Procedural characteristics and outcome.

Type of anesthesia	
Local	19 (42.2%)
General	26 (57.8%)
Configuration of endograft	
Bifurcated graft	40 (88.9%)
Aorto uni-iliac graft	3 (6.7%)
Tube graft	2 (4.4%)
Type of endograft	
Endurant I	14 (31.1%)
Endurant II	31 (68.9%)
Outer diameter of endograft	
14Fr	27 (31.8%)
16Fr	13 (15.3%)
18Fr	25 (29.4%)
20Fr	20 (23.5%)
Preclose Proglide deployment	
Success	144 (84.7%)
Failure	26 (15.5%)
Hemostasis	
Success	82 (96.5%)
Inadequate	3 (6.7%)
Extra closure device	1 (1.2%)
Femoral cutdown	2 (2.4%)

Table 3. Postprocedural data and complications.

Duration of hospitalization – days	
Mean	2.6 ± 7.1
Median	1.0
Interquartile range	1.0 to 2.0
Mortality	0 (0.0%)
Major adverse events – no. (%)	
Bowel ischemia	0 (0.0%)
Myocardial infarction	1 (2.2%)
Major blood loss	0 (0.0%)
Renal failure	1 (2.2%)
Stroke	0 (0.0%)
Technical complications – no. (%)	
Delivery / deployment failure	0 (0.0%)
Limb occlusion	1 (2.2%)
Endoleak	
Type I / III	0 (0.0%)
Type II	4 (8.9%)
Aneurysm rupture	0 (0.0%)
Endograft fracture / migration	0 (0.0%)
Vascular perforation	1 (2.2%)
Secondary interventions	0 (0.0%)
Conversion to open aneurysm repair	0 (0.0%)

stretching of a tortuous and calcified iliac artery by a rigid guidewire led to a limited perforation, for which a covered stent was placed. At last, sheath thrombosis complicated one procedure, which was successfully treated with systemic thrombolysis. This patient developed a hematoma with temporary compressional neuropathy. During examination of all postprocedural access-related complications, no other adverse events were identified. Table 4 shows the rate of postprocedural access-related complications. We experienced no incidence of wound infection or impaired wound healing. Clinical and duplex ultrasonography evaluation revealed no pseudoaneurysm or occlusion at the entry site.

The mean hospitalization was 2.6 ± 7.1 days with an interquartile range of 1.0 to 2.0 days. Overall, 69 percent of patients were discharged the next day and 87 percent of patients within two days. When excluding the patient who experienced a myocardial infarction, the mean hospitalization was 1.5 ± 1.1 days.

Discussion

We have gained experience with the Proglide since January 2011 and use the Proglide in a preclose technique for all endovascular aortic repair procedures since April 2011, including thoracic and abdominal aortic aneurysms, Stanford type B aortic dissections, traumatic aortic ruptures, ruptured aortic aneurysms and aortoenteric fistulae. However, in this article we have focused on the percutaneous treatment of asymptomatic infrarenal aortic aneurysms that fulfill the national healthcare required criteria.

We opted for a follow-up period of one month to adequately assess and objectify the vascular access related complications. A retrospective analysis by STARNES *et al* during six months revealed that the great majority of complications occur during the procedure and some events happen within 30 days (12). Postprocedural access-related complications were however relatively limited, especially compared to our previous experience with access by bilateral femoral cutdown. As has been shown by literature (13), ultrasound-guided vascular access will allow for fewer access-related complications, therefore all accesses were obtained with the aid of this technique. Moreover, ultrasonography allows us to obtain single puncture vascular access, while avoiding

anteriorly located calcifications of the CFA. The puncture can be meticulously placed centrally on the CFA, thereby reducing deployment failure of the Proglide device. At the same time, providing detailed visualization for infiltration of the local anesthesia in all penetrating layers and around the CFA. We observed no incidences of femoral nerve injury or arteriovenous fistulae on duplex ultrasonography evaluation.

We believe that the future for endografting will be the evolution towards leaner delivery devices. The Endurant II endoprosthesis can be delivered and deployed independently, without the need for a vascular sheath. Also, the outer diameter of the delivery device is relatively narrow in comparison to other stent grafts, with a maximum outer diameter of 20Fr, thereby facilitating a totally percutaneous approach. During the study period, Medtronic upgraded the Endurant stent graft to the Endurant II, thereby allowing for improved handling of the delivery device and reduced outer diameter of the bifurcated main body.

Due to research by HAAS *et al.* (6) in demonstrating the tandem preclose deployment of suture-mediated closure devices, Abbott guidelines recommend single Proglide deployment for 5Fr-8Fr access sites and to preclose sheath sizes greater than 8Fr with two Proglide devices. Our research and experience has changed this mindset, we have obtained adequate hemostasis for the insertion of the contralateral limb with one Proglide. Thorough analysis of our database revealed that when preclosing 14Fr and 16Fr access sites with a single Proglide device, adequate hemostasis was obtained in 100 percent of the access sites (25 of 25).

A valid alternative for the Perclose Proglide is the Prostar XL, which has four braided nonabsorbable polyester sutures instead of two monofilament polypropylene sutures, requires tying a handmade knot instead of a premounted knot and needles pass inside out instead of outside in. Both suture-mediated closure devices are capable of preclosing large bore vascular access sites. The maximal closure diameter of the access using the 6Fr Proglide and 10Fr Prostar XL is still up for debate, however a single Prostar XL is able to close larger diameter access sites than a single Proglide. The Proglide has the advantage over the Prostar XL of being less costly and placement is applicable in case of failure. Also, the monofilament sutures make it less prone to infections in comparison to the braided sutures (5).

We had a relatively short mean hospitalization of 2.6 days and 86.7 percent of patients were discharged within 2 days. Due to the low incidence of complications and the rapid postoperative recovery, patients are nowadays admitted to a short stay unit. Lastly, we would like to state that specialist team experience has an important influence on achieving optimal results, fewer adverse events and lower mortality. This has been

Table 4. Postprocedural access-related complications.

Hematoma	1 (1.1%)
Wound infection	0 (0.0%)
Pseudoaneurysm	0 (0.0%)
Sensibility disorder	1 (1.1%)
Impaired woundhealing	0 (0.0%)
Prolonged pain	0 (0.0%)

properly documented in an analysis on the EUROSTAR database including over 2800 patients (14).

Conclusion

PEVAR using the Perclose ProGlide in preclosing 14Fr to 20Fr for Endurant endografting in the treatment of asymptomatic infrarenal aortic aneurysms is feasible and effective. Moreover, the percutaneous approach allows for procedures to be performed under local anesthesia, while providing a low risk for access-related complications and a relatively short hospitalization.

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