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ORIGINAL ARTICLE

Short-term outcome and mid-term access site complications of the percutaneous approach to endovascular abdominal aortic aneurysm repair (PEVAR) after introduction in a vascular teaching hospital

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Abstract
The objective is to evaluate our center's experience with the safety and efficacy of the percutaneous approach to endovascular abdominal aortic aneurysm repair (PEVAR) with use of the Perclose Proglide device, in the first period after introduction in our center in 2014. We retrospectively identified all patients that underwent PEVAR or endograft extension with percutaneous approach in our center in the urgent and elective setting. Included were all procedures performed between the introduction of the technique in January 2014 and February 2016 when PEVAR had become the predominant technique in our center. Exclusion progressed from expected difficulty of the procedure as estimated by the operator to total calcification of the ventral wall of the CFA towards the end of the study period. Surgical and clinical reports were used to analyze patient characteristics, procedural success, and short-term outcome after 30 days. Follow-up imaging was used to assess mid-term access site complications at 1 and 2 years postoperatively. A univariate regression analysis was conducted to determine significant predictors of access-related complications with the Perlcose Proglide system. Of all 78 patients (mean age 74, SD: 7 years, 70 men), 68 (87.2%) underwent PEVAR and 10 (12.8%) underwent endograft extension procedures with percutaneous approach. Sixty-seven (85.9%) patients underwent an elective procedure and 11 (14.1%) patients underwent urgent PEVAR. The total number of vessels that was percutaneously accessed was 142. Direct technical success of the procedure as analyzed per vessel was 98.6% (140/142), with two cases of conversion to the femoral cut-down approach. A total of 274 Perclose Proglide devices were placed. Device failure of the Perclose device occurred in 5.8% (16/274) and was reason for conversion to cut-down procedure in one case. Mean duration of the procedure and median time of hospitalization were 100 (SD: 34) min and 2 (IQR 1, 3) days, respectively. Event-free survival per vessel after 30 days was 91.0%, with two minor access-related complication. Fifty-five individual patients (105 vessels) were eligible for inclusion in the 1-year follow-up analysis. Of these patients, 19 (34 vessels) could be included in the 2-year follow-up analysis. No additional access site complications occurred at mid-term follow-up. No significant predictors of device failure were found. The percutaneous approach to EVAR appears to be a safe and effective option with high success rate and low complication rate in a real-world setting. Based on our findings, we conclude that the technique can safely be introduced in a vascular center.

Keywords Abdominal aortic aneurysm · Endovascular aneurysm repair · Vascular closure devices

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Introduction

Since its introduction, endovascular abdominal aortic repair (EVAR) with the traditional bilateral femoral cut-down method has steadily become the preferred method of treatment for abdominal aortic aneurysms (AAA), in both the elective and the urgent setting [1]. The safety and efficacy of this technique have been demonstrated in many studies throughout the world [2]. Nevertheless, short- and long-term local complications of femoral cut-down are not rare and secondary interventions are fairly common [3, 4]. The introduction of suture-mediated closure devices has made a completely percutaneous approach of EVAR (PEVAR) possible. Although long-term outcome studies are still scarce, there is evidence that a percutaneous approach with use of an endovascular closure device is safe and effective, with minimal access-related complications [5]. Studies that suggest an increased safety for PEVAR are often conducted in a controlled setting with extensive exclusion criteria for patients entering the PEVAR group. Although this is a trusted research method, it is perhaps less successful in offering a realistic impression of the feasibility, safety, and efficacy of the introduction of PEVAR in a vascular center, with all its real-world complexities. The present study aims to analyze our center's experience with PEVAR with use of the Perclose Proglide device (Abbott Vascular, Santa Clara, California USA) for the treatment of AAAs since the introduction of the technique in our center in 2014.

This study aims to provide insight on device performance, procedural and short-term outcome as well as mid-term clinical outcome after PEVAR during the introduction period of the technique in a real-world setting.

Materials and methods

Data compilation

We retrospectively identified all patients who underwent EVAR between the introduction of the PEVAR technique January 2014 and February 2016 in urgent or elective setting. February 2016 was chosen as the end date for inclusion as it was estimated that by that time the learning curve had stabilized as PEVAR had become the predominantly used technique in our center (Fig. 1). Identification of patients was done using the hospital's records of the Dutch medical classification system (the DBC registry), in which all patients undergoing abdominal aortic aneurysm surgery are registered per protocol.

Based on surgical reports, all patients were selected who underwent vascular closure using the Perclose

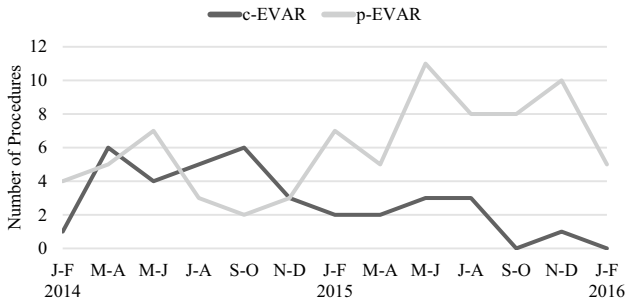

Fig. 1 Number of EVAR surgeries performed with percutaneous approach (PEVAR) ($n=78$) vs. cut-down approach (c-EVAR) ($n=35$) over 2-month intervals during the 2-year study period

Proglide device for PEVAR procedures or endograft extension after previous (P)EVAR (rePEVAR). No additional exclusion criteria were set. Patients who underwent multiple surgeries that met the inclusion criteria during the study period, were analyzed per procedure for procedural outcome and per individual for mid-term follow-up duration. All the second surgeries were classified as rePEVAR. Only follow-up time, since the second surgery was used. Data for demographics, diagnosis, and surgical procedures were retrospectively analyzed using patient records, preoperative imaging, and surgical reports.

Anatomical information of the common femoral artery was determined using the axial cut of the pre-operative computed tomography (CT) scan (vessel diameter (1 cm proximal femoral bifurcation), degree of access vessel calcification (mild < 33% of circumference, moderate 33–50% circumference, and extensive > 50% circumference), location of the calcification (medial, anterior, and posterior wall), and presence plaque at the puncture site).

Short-term outcomes were analyzed using 30-day imaging and the Dutch Surgical Aneurysm Audit (DSAA) of the Dutch Institute for Clinical Auditing (DICA) that are filled in per protocol 30 days postoperatively for all abdominal aneurysm surgery patients.

Mid-term outcome was based on follow-up imaging performed between January 2014 and June 2017. Mid-term follow-up analysis was done based on 1-year and 2-year follow-up imaging. Patients were included gradually during the study period and follow-up analysis was done cross-sectionally at the end date of our study. This meant that not every individual had undergone their 1-year, respectively, 2-year follow-up imaging at the time of analysis. Therefore, not every patient could be included in the mid-term follow-up analysis, even if follow-up was done per protocol (Fig. 2). To clarify timing of follow-up on an individual level during the study period and to differentiate between incomplete follow-up per protocol and loss-to-follow-up, Fig. 3 was added.

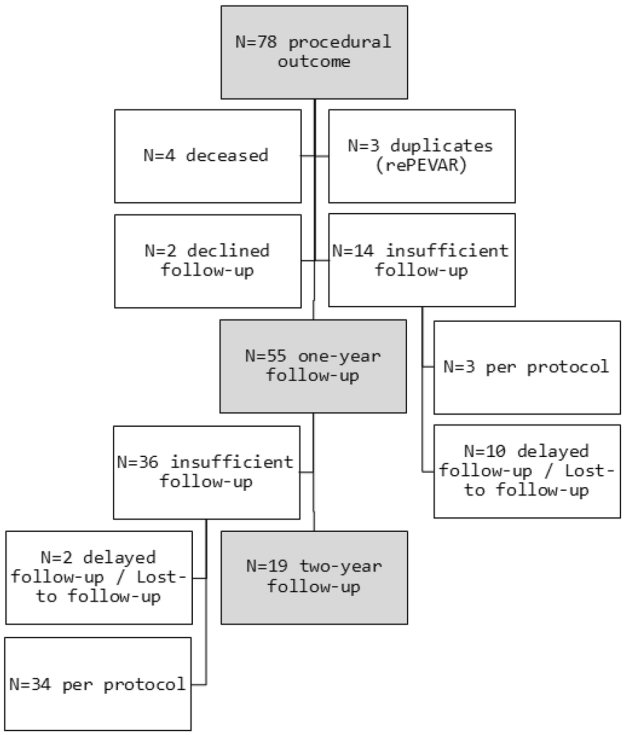

Fig. 2 Inclusion in mid-term follow-up

Procedure and patient selection

All procedures took place at our vascular center and were performed by or under direct supervision of vascular surgeons. All vascular surgeons were trained using a model provided by the device company prior to clinical introduction of the technique.

Introduction was done gradually and the first cases were proctored. Initially, patients were selected for percutaneous approach based on expected difficulty of the procedure as estimated by the operator, based on vessel diameter and calcification. As experience progressed, the only exclusion criterion used was total calcification of the ventral wall of the CFA.

Interventions

All patients underwent computed tomography angiography (CTA) preoperatively to assess vascular anatomy and CFA calcification. All elective patients were preoperatively screened by an anesthesiologist, where method of anesthesia was determined. Percutaneous access was obtained with use of ultrasound guidance in all cases. In PEVAR procedures access was usually gained bilaterally, whereas unilateral access was preferred in endograft extension procedures. Once access was obtained with a 7F sheath, two Perclose Proglide devices were advanced over the guidewire. Sutures were preloaded at 10 and 2 o'clock positions according to the Perclose technique protocol, before insertion of larger caliber devices. Heparin was administered intravenously after introduction of the Perclose system. At the end of the procedure, vascular closure was obtained by advancing the Perclose Proglide sutures using the knot pusher and locking the sutures. Postoperatively, patients wear compression bandages for a period of 12 h, of which 6 h constitute of bedrest with a hip flexion limitation of 30°.

Procedural outcome definitions

The direct technical success of the percutaneous approach was defined as CFA haemostasis without perioperative vascular complications or conversion to the femoral cut-down approach and was analyzed accessed per vessel. Vascular complications or any kind of device failure was noted. Duration of the procedure was measured between first puncture and vascular closure. Duration of hospitalization was defined as the total of nights spent in hospital. Short-term outcome was limited to 30 days postoperatively. Short-term complications were analyzed per vessel. 30-Day event-free survival was analyzed per patient. Results are shown as absolute numbers and absolute percentages.

Follow-up

All patients underwent follow-up imaging per protocol with CTA at 30 days and 6 months postoperatively. Hereafter, follow-up was done yearly with CTA or duplex ultrasound. Only in case of reported claudication, magnetic resonance angiography (MRA) was used. Patients with chronic kidney disease (CKD) with a glomeral filtration rate (GFR) < 30 ml/min received follow-up CTA with 45 ml of contrast agent at 3 months postoperatively and only duplex ultrasound or plain CT thereafter, with an additional CTA only performed in case of suspected endoleak. Patients with a GFR between 30 ml/min and 60 ml/min received follow-up without modifications.

Mid-term follow-up analysis was performed retrospectively on all patients with at least 1 year and 2 years of follow-up, respectively. All imaging was screened by a radiologist and a vascular surgeon for mid-term access site complications related to the percutaneous approach, including stenosis and pseudoaneurysm. Results are shown as absolute numbers and absolute percentages.

Statistical analysis

A univariate regression analysis is performed using SPSS version 22.0 (SPSS Inc. Chicago, Ill.) to predict the Perlcose Proglide-related complications. The following variables are analyzed: vessel diameter (≤ 10 mm or > 10 mm and 1 cm

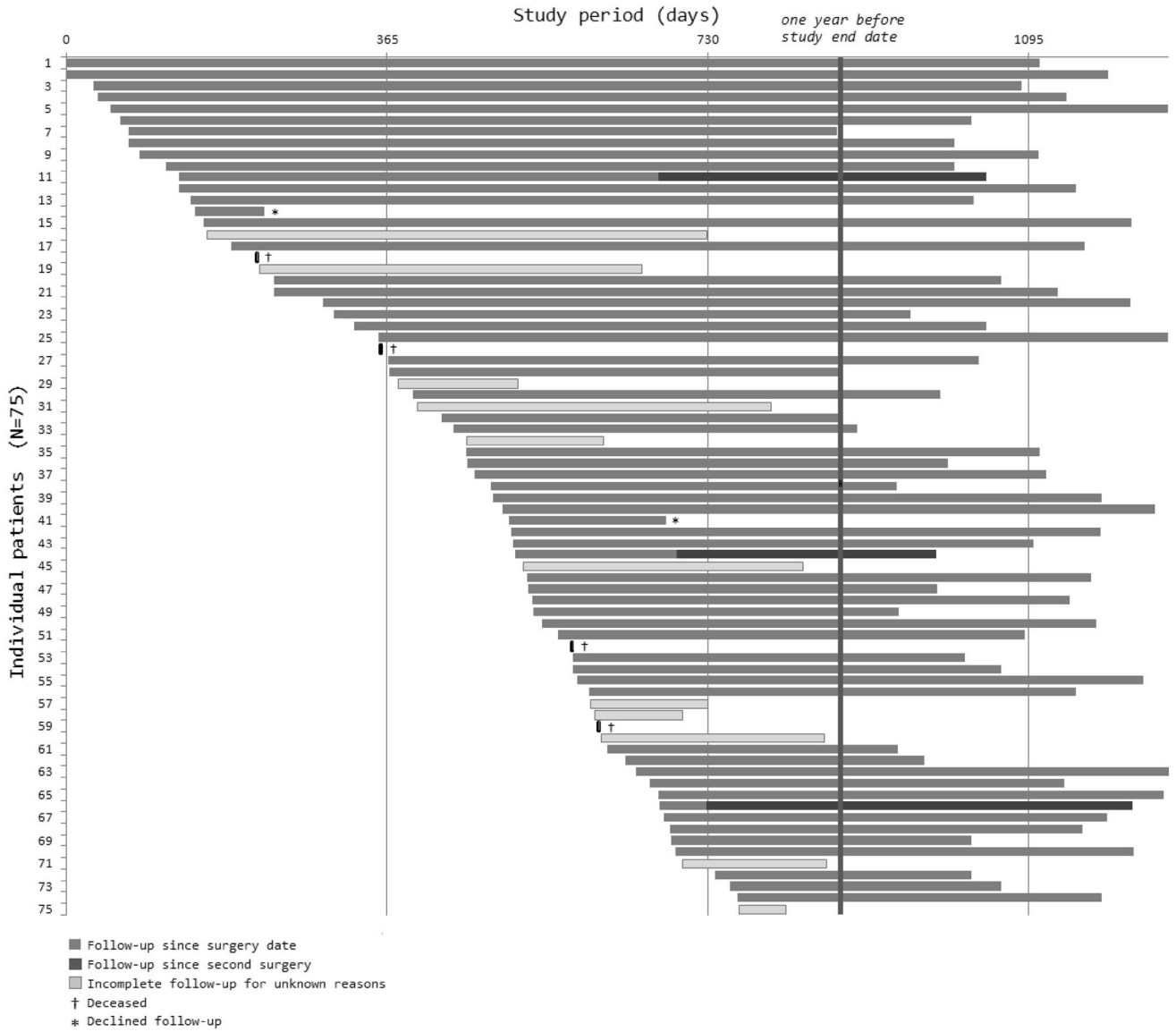

Fig. 3 Clarification of follow-up of individual patients during study period

proximal to femoral bifurcation), degree of access vessel calcification (mild < 33% of circumference, moderate 33–50% circumference, and extensive > 50% circumference), location of the calcification (medial, anterior, and posterior wall), presence of plaque at the puncture site, French size (14F, 16F, 18F, and 20F), and previous groin surgery. A *P* value of 0.05 or less was considered significant.

Consent

Publishing authors are members of the treatment team of the patients included in this research. The treating medical specialists retrieved the research data from the medical records of their own patients. All data were collected in an anonymized database for analyses by the researchers. Privacy of the patients was always protected. Under these conditions, there was no legal obligation under Dutch law to obtain informed consent from the patient. In addition, the Medical Research Involving Human Subjects Act does not apply to retrospective data analysis. Therefore, this study was not assessed by the Medical ethical committee.

Results

Procedural outcome

During the study period, a total of 78 procedures was performed.

The patients (70 men, 8 women) had a mean age of 74 (SD: 7) years. Of all patients, 83.3% had known cardiovascular risk factors. Table 1 summarizes the characteristics of the patients included in the study.

Of all 78 procedures, 68 (87.2%) were PEVAR and 10 (12.8%) were endograft extension procedures with percutaneous approach (rePEVAR). Sixty-seven (85.9%) patients underwent an elective procedure, and 11 (14.1%) patients underwent urgent PEVAR.

Bilateral percutaneous access was initially gained in 62 (91.2%) of all PEVAR procedures and in 2 (20%) of endograft extension procedures. In the vast majority of cases an Endurant (Medtronic, Minneapolis, Minnesota USA), endograft device was used (72/77, 93.5%). The total number of percutaneously accessed vessels was 142. Details of the procedures are displayed in Table 2. Direct technical success of the procedure was 98.6%. In two vessels, the procedure had to be converted to the femoral cut-down approach. In one case, dissection of the CFA due to graft size led to perioperative limb ischemia. This was not noted as failure of the Perclose Proglide. In the other case, severe tortuosity of the iliac artery prevented advancement of the Perclose Proglide device, which was recorded as device failure.

In 142 vessels, a total of 274 Perclose Proglide devices were placed initially. Device failure occurred in 16 devices (5.8%) throughout the study period, with failure of deployment being the largest contributor to failure rates. No vascular complications of the use of Perclose Proglide were observed perioperatively. Perclose Proglide failures and their treatment are summarized in Table 3. In 14 cases, the operator diverted from the Perclose technique protocol and initially used either one or three closure devices per vessel. In none of these cases, failure of haemostasis was observed.

Mean duration of procedure was 100 (SD: 34) minutes.

Table 1 Patient characteristics

Variables	*N* (78)[a]	(%)
Age (years) (mean ± SD)	74 ± 7	
Gender		
Men	70	89.7
Women	8	10.2
Cardiovascular risk factors	65	83.3
Hypertension	48	61.5
Diabetes mellitus	8	10.2
Myocardial infarction	22	28.2
Peripheral artery disease	14	17.9
Heart failure	8	10.2
Cardiomyopathy	1	1.3
Cerebrovascular disease[b]	16	20.5
Smoking		
Current	28 (*N* = 73)	38.3
Previous[c]	21 (*N* = 73)	28.8
Chronic kidney disease	9	11.5
COPD	18	23.0
Malignancy[d]	16	20.5
Previous groin surgery	17	21.7
AAA diameter (mean ± SD)	62 ± 11 (*N* = 71)	
Morphology		
AAA	67	85.9
Iliac aneurysm	1	1.3
Insufficient sealing[e]	6	7.7
Endoleak[e]	4	5.1
ASA score[f]		
I	2	2.6
II	49	62.8
III	24	30.7
IV	4	5.1

Summary statistics are given as absolute numbers and percentages

SD standard deviation, *COPD* chronic obstructive pulmonary disease, *AAA* abdominal aortic aneurysm, *ASA-score* American Society of Anesthesiologists

[a]Unless mentioned otherwise due to insufficient data

[b]Including transient ischemic attack

[c]> 1-year ago

[d]Including cured

[e]After previous (p)EVAR

[f]At time of procedure

Table 2 Procedure characteristics

Variables	*N* (78)[a]	(%)
Type of surgery		
PEVAR	68	87.1
rePEVAR	10	12.8
Urgency		
Elective	67	85.9
Emergency	11	14.1
Type of access		
PEVAR (*n* = 68)		
Unilateral percutaneous	6	8.8
Bilateral percutaneous	62	91.2
rePEVAR (*n* = 10)		
Unilateral percutaneous	8	80.0
Bilateral percutaneous	2	20.0
Type of endograft device (*n* = 77)[b]		
Endurant (Medtronic)	72	93.5
Excluder (Gore)	2	2.6
AFX (Endologix)	2	2.6
Anaconda (Vascutek)	1	1.3

Summary statistics are given as absolute numbers and percentages

[a]Unless otherwise mentioned

[b]In one case of rePEVAR, no endograft device was used

Table 3 Proglide-related complications and treatments during percutaneous procedure

Complications of Perclose Proglide	*N* (274)	(%)	Treatments		
			Cut-down	Additional device	Compression
Device failure	16	5.8			
Positioning failure	2	0.7	1	2	
Deploy failure	8	2.9		6	4
Suture rupture/dislocation	3	1.1			2
Haemostasis failure	3	1.1		3	2
Vascular complications	0	0.0			

Results are given as absolute numbers and percentages

Short-term outcomes

The median time of hospitalization was 2 (IQR 1, 3) days. Of all patients, 71.8% left the hospital within 2 days. Few patients had a markedly longer time of hospitalization. Their prolonged stay was unrelated to the percutaneous approach; indications were urinary tract infection in a patient with pre-existing kidney failure, pneumonia, and prolonged recovery from hemorrhagic shock. Event-free survival was 91.0% after 30 days. In one case (1.3%), a significant femoral hematoma was observed postoperatively that did not require treatment. In another patient (1.3%), and 30-day CTA imaging showed a small pseudoaneurysm of the CFA that did not require treatment. Other access site complications, including wound infection, did not occur. Two patients (2.6%) died within 30 days of surgery. Neither of these deaths could be related to the percutaneous approach. Three patients were readmitted within 30 days. Indications were abdominal pain of unknown cause, constipation, and ileus. Re-intervention within 30 days related to the percutaneous approach did not occur.

Mid-term complications

Of all patients, 55 (105 vessels) had undergone follow-up of at least 1 year at the end date of this study (Fig. 2). Two additional patients died before 1-year follow-up could be completed, due to causes that were not related to the percutaneous approach. Two patients declined further follow-up due to terminal morbidity unrelated to the procedure. The remaining patients received adequate follow-up, but had not had at least 1 year of follow-up at the end date of this study (Fig. 3). At 1-year follow-up, none of the access sites showed new access site complications related to the percutaneous approach. The pseudoaneurysm that was reported at 30 days was still visible.

Nineteen patients (34 vessels) could also be included in the 2-year follow-up analysis. An additional two patients were lost to follow-up for reasons unknown. The remaining 36 patients had not reached the 2-year mark per protocol (Fig. 3). No new access site complications related to the percutaneous approach were found.

Discussion

This study shows that the totally, percutaneous approach of EVAR with the Perclose Proglide device can be safely introduced in a vascular center by physicians who are already familiar with endovascular techniques. The introduction of this technique is an attractive alternative to the more traditional femoral cut-down method.

The use of PEVAR in our vascular center increased steadily after the introduction of the technique, as shown before in Fig. 1. Initially, patient selection was at the operator discretion, only including patients most suitable for the percutaneous approach. Due to the retrospective nature of our analysis, we had no recorded data on specific selection criteria in this initial period. As the experience of our staff and their enthusiasm for the technique grew, exclusion criteria were only limited to total calcification of the ventral wall of the CFA. However, this phenomenon is very rare. We found that a small gap in the calcified CFA can usually be identified with ultrasound. Hence, placement of a Perclose Proglide suture is possible, even in a severely calcified femoral artery. Presently, the percutaneous approach has almost completely replaced femoral cut-down in our daily practice.

Studies reporting mid- and long-term complication rates are still scarce. Furthermore, few studies have managed to provide a realistic impression of the learning curve of the technique after its introduction in a vascular center. In this study, we aimed to do both. We included all patients who underwent PEVAR in both the urgent and the elective setting and did not set any additional exclusion criteria. We believe that this will provide the most realistic impression of the introduction of PEVAR in a vascular center.

During the inclusion period for our analysis, a total of three patients underwent multiple surgeries that met the inclusion criteria. In two cases, stent elongation was required to treat endoleak persisting after the initial PEVAR; in one

case, the second procedure addressed an aneurysm of the internal iliac artery, previously left untreated. We chose to include these patients per procedure in the procedural analysis. For mid-term outcome, patients were analyzed as individuals. Only follow-up time, since the second surgery was used.

We found a procedural success of 98.6% and a device failure rate of 5.8% for the Perclose Proglide. Studies have shown a technical success of 93–99.1% [6, 7] and a reduced short-term complication rate [8]. The PEVAR trial by Nelson et al. [5] that was published in 2013 found similar results with a procedural success of 94% (47/50) for PEVAR with use of Perclose Proglide. In their study, they did not report device failure without need for conversion and, therefore, found a device failure rate of 6% (3/50) when analyzed per vessel. The procedural failures entailed three cases of conversion to femoral cut-down to resolve stenosis, excessive bleeding, and stenosis. In our study, we found comparable device failure rates, but we analyzed failure per device and device failure usually let to placement of an additional device or no treatment at all. We reported two cases of conversion (2/78; 2.6%) to address perioperative limb ischemia resulting from dissection of the CFA due to graft size and failure to advance the Perclose device due to severe tortuosity of the CFA. Only one case of conversion could be related to failure of the Perclose system and was, therefore, included in the device failure rate.

A univariate regression analysis did not show any significant predictor of Perclose Proglide failure (Table 4). The sample size of this study may be too small to determine significant predictors. On the other hand, this analysis shows that possible predictors of failure are not a strong contraindication to the use of the percutaneous technique during EVAR.

Mean duration of the procedure and median time of hospitalization were 100 (SD: 34) min and 2 (IQR 1, 3) days, respectively. A study by Buck et al. published in 2015 [7] in which PEVAR was compared to the femoral cut-down approach to EVAR in elective patients, found significant reduction of operative time (mean 135 vs. 152 min; $P < 0.1$) and hospitalization (median, 1 day vs. 2 days; $P < 0.1$). Although we did not compare efficacy between PEVAR and EVAR in our center, our results are similar to those found by Buck et al. and would suggest non-inferiority of the percutaneous approach. The larger median time of hospitalization as found in our study could not directly be related to the percutaneous approach and might be the logical result of the inclusion of urgent procedures in hemodynamically unstable patients. We expect that with better patient information provision, it should be possible to achieve a median hospitalization time of 1 day in elective patients.

Our short-term analysis based on findings 30 days after surgery showed an event-free survival of 91.0%. In two cases, a minor access site complication was observed, but did not require additional surgery. Two patients died within 30 days of surgery, and three were readmitted. In one case, the patient died perioperatively after arriving to the hospital in deep state of shock due to a ruptured AAA. Another patient with severe cardiovascular, nephrogenic, and malignant co-morbidities was operated on in septic state of unknown focus and died postoperatively of acute-on-chronic kidney failure. These cases could not be related to the percutaneous approach.

Mid-term follow-up analysis was done cross-sectionally at the end date of our study period based on 1-year and 2-year follow-up imaging. This meant that not all patients were eligible for one or both mid-term analyses at the end point of our studies, even though follow-up was done according to protocol. Prolonged follow-up of these patients in the future could solidify our results.

Overall loss-to-follow-up was 11. Due to the nature of our follow-up protocol, loss-to-follow-up could not be determined until more than 1 year had passed since the last follow-up recording. As shown in Fig. 3, 11 patients had

Table 4 Prevalence and significance of predictors of Perclose Proglide failure

Predictors	*P* value
Vessel diameter[a]	0.417
≤ 10 mm ($n=41$)	
> 10 mm ($n=101$)	
Degree of calcification	0.221
Mild (< 33%) ($n=96$)	
Moderate (33–50%) ($n=37$)	
Extensive (> 50%) ($n=10$)	
Location of calcification	0.488
Medial ($n=34$)	
Anterior ($n=2$)	
Posterior ($n=59$)	
Medial posterior ($n=33$)	
Medial posterior anterior ($n=11$)	
None ($n=4$)	
Presence of plaque at puncture site	0.465
Yes ($n=22$)	
No ($n=121$)	
French size	0.554
14F ($n=24$)	
16F ($n=55$)	
18F ($n=48$)	
20F ($n=16$)	
Previous groin surgery ($n=18$)	[b]

[a]1 cm proximal to femoral bifurcation

[b]Device failure did not occur in any patients with the previous groin surgery

not had a check-up in the 12 months prior to the end of our studies for reason unknown and could, therefore, truly be considered lost to follow-up. Nevertheless, we deem it unlikely that any major complications were missed because of this, as incidence is very low and no patients reached out because of symptoms, potentially related to complications.

No access site complications were found at 1-year and 2-year follow-up. The high success rate and low rate of complications of PEVAR in our studies make it an attractive alternative to more traditional methods. This is strengthened by the fact that prior groin surgery and even prior PEVAR is no contraindication for the percutaneous technique. However, relatively high cost of the closure device has in the past been raised as a potential counter argument, especially when compared to the less expensive fascial closure technique. Although in our experience, cost is significantly reduced by frequent use of a single distributor, a cost–effect analysis is beyond the scope of our present study. Because of its use of a small incision, we feel that it stands to reason that the fascial closure technique is more prone to seroma and wound infection than the completely percutaneous approach, but future research is needed to objectify this argument.

Conclusion

This study of the PEVAR technique with Perclose Proglide device explicates not only procedural outcome, but both short- and mid-term complications of the technique after introduction in a real-world setting. The introduction of the percutaneous approach to EVAR appears to be a safe and effective option. In this study, the procedural success rate is high and both short- and mid-term complication rates are remarkably low. Based on our findings, we conclude that it is a safe option to introduce this technique in a vascular center.

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