CLINICAL STUDY

Predictive Factors for Additional ProGlide Deployment in Percutaneous Endovascular Aortic Repair

Shen-Yen Lin, MD, Sin-Yi Lyu, MD, Ta-Wei Su, MD, Sung-Yu Chu, MD, Chien-Ming Chen, MD, Chien-Fu Hung, MD, Chee-Jen Chang, PhD, and Po-Jen Ko, MD

ABSTRACT

Purpose: To evaluate outcomes and predictive factors for additional ProGlide device deployment in percutaneous endovascular aortic repair (PEVAR) with the preclose technique.

Materials and Methods: Clinical data of patients who underwent PEVAR with the preclose technique from February 2012 to January 2015 were retrospectively reviewed. A total of 268 patients (229 men, 39 women) who underwent PEVAR (thoracic endovascular aortic repair [TEVAR], n = 113; endovascular abdominal aortic repair [EVAR], n = 152; simultaneous TEVAR and EVAR, n = 3) with 418 femoral access sites were enrolled. The mean age of the patients was 69 years ± 14. Univariate and multivariate analyses were performed to identify predictive factors associated with additional ProGlide device deployment.

Results: Primary technical success with adequate hemostasis and two ProGlide devices was 87.6%, and 48 femoral arterial access sites (11.5%) required additional ProGlide device deployment. The secondary technical success rate was 99.0%. Four femoral access sites (1.0%) needed surgical repair. Anterior wall calcification near the arteriotomy increased the risk of additional ProGlide device deployment (adjusted odds ratio, 6.19; 95% confidence interval, 2.81–13.64; $P < .001$), whereas larger sheath size, common femoral artery (CFA) diameter, and depth from the skin to the arteriotomy did not.

Conclusions: Additional ProGlide device deployment reduces the rate of surgical repair after primary hemostasis failure in PEVAR. Anterior CFA wall calcification is a significant predictor for additional ProGlide device deployment.

ABBREVIATIONS

BMI = body mass index, CFA = common femoral artery, CI = confidence interval, EVAR = endovascular abdominal aortic repair, OR = odds ratio, PEVAR = percutaneous endovascular aortic repair, TEVAR = thoracic endovascular aortic repair, VCD = vascular closure device

Percutaneous endovascular aortic repair (PEVAR) typically involves sheaths and delivery systems with 14–24-F profiles. The preclose technique involves the deployment of two vascular closure devices (VCDs) before insertion of a large sheath to achieve hemostasis at the end of the procedure (1–3). This technique, success rates of which range from 62% to 100% (4–10), provides a safe and effective method of percutaneous arteriotomy closure for PEVAR. Greater access vessel depth, large sheath size, and calcified femoral arteries have been reported as the main risk factors for preclose technique failure and need for surgical repair (1,11–13). Some studies have reported that additional VCD deployment (ie, more than the planned two devices) could increase the success rate of hemostasis after PEVAR and reduce the rate of surgical repair (10,13,14). However, there is limited literature exploring the predictive factors affecting additional VCD deployment.

From the Department of Medical Imaging and Intervention (S.-Y.Lin, S.-Y.Lyu, S.-Y.C., C.-M.C., C.-F.H.), and Division of Thoracic and Cardiovascular Surgery, Department of Surgery (T.-W.S., P.-J.K.), Chang Gung Memorial Hospital, Linkou, and Chang Gung University, Taoyuan, Taiwan; Graduate Institute of Clinical Medicine, Research Services Center for Health Information, and Clinical Informatics and Medical Statistics Research Center (C.-J.C.), Chang Gung University, Taoyuan, Taiwan and Department of Cardiovascular Medicine (C.-J.C.), Chang Gung Memorial Hospital, Taoyuan, Taiwan, ROC. Received July 12, 2016; final revision received December 6, 2016; accepted December 19, 2016. **Address correspondence to** P.-J.K., Division of Thoracic and Cardiovascular Surgery, Department of Surgery, Chang Gung Memorial Hospital, Linkou, and Chang Gung University, No. 5, Fu-Hsing St., Kuei-Shan Hsiang, Taoyuan Hsien, 333 Taiwan, ROC; E-mail: pojenko@gmail.com

S.-Y.Lin and S.-Y.Lyu contributed equally to this work and share first authorship.

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The purpose of the present retrospective study is to evaluate outcomes and predictive factors for the deployment of additional ProGlide devices (Abbott Vascular, Santa Clara, California) in PEVAR with the preclose technique.

MATERIALS AND METHODS

Patient Population

From February 2012 to January 2015, 437 patients underwent endovascular aortic repair at a single institution. Of these, 344 underwent percutaneous thoracic endovascular aortic repair (TEVAR) or endovascular abdominal aortic repair (EVAR) with one or both femoral arterial access sites being closed with the preclose technique. The endovascular procedures consisted of percutaneous access requiring 12–24-F sheaths. The clinical data of these patients were reviewed. Patients with complete preoperative and postoperative ($\leq$ 1 mo) computed tomography (CT) studies were included. The exclusion criteria were incomplete CT study (n = 71) and prosthetic hip–induced metallic artifacts on CT angiography (n = 5). The study was approved by the institutional review board, and the need for informed consent from the patients was waived because of the retrospective and anonymous nature of the analysis.

The study included 268 patients (229 men and 39 women) and 418 femoral access sites. Patient demographic data and procedural details are summarized in Table 1. Obesity, defined as a body mass index (BMI) $\geq$ 30 kg/m^2 (15), was present in 26 patients (9.7%). There were 17 access sites with previous femoral artery catheterization for coronary angioplasty (n = 13), carotid angioplasty (n = 1), hepatic artery embolization (n = 1), and endovascular aortic repair (n = 2).

Table 1. Demographic Data and Device-Specific Parameters of the Study Cohort (N = 268)

Characteristic	Value
Mean age (y) ± SD	69 ± 14
Sex	
Male	229 (85.4)
Female	39 (14.6)
Mean BMI (kg/m^2) ± SD	24.5 ± 3.9
Diagnosis	
TAA	35 (13.1)
AAA	125 (46.6)
Aortic dissection, type B	51 (19.0)
Mycotic aneurysm	16 (6.0)
Penetrating aortic ulcer	13 (4.9)
Iliac artery aneurysm	8 (3.0)
Traumatic aortic injury	8 (3.0)
Others*	12 (4.5)
Procedure type	
TEVAR	113 (42.2)
EVAR	152 (56.7)
TEVAR and EVAR	3 (1.1)
Type of access	
Bilateral percutaneous	150 (56)
Unilateral percutaneous	118 (44)
Sheath size (N = 418)	
12–18 F	253 (60.5)
20–24 F	165 (39.5)
Prior femoral artery catheterization	17 (4.1)

Note–Values in parentheses are percentages.
AAA = abdominal aortic aneurysm; BMI = body mass index; EVAR = endovascular abdominal aortic repair; SD = standard deviation; TAA = thoracic aortic aneurysm; TEVAR = thoracic endovascular aortic repair.
*Endoleak, tumor invasion of the aorta, innominate artery pseudoaneurysm.

Preclose Technique

All PEVAR procedures for each arterial access site were performed with a suture-mediated closure system (Perclose ProGlide; Abbott Vascular). Real-time ultrasound (US)–guided common femoral artery (CFA) access along its anterior aspect was performed in all cases (Site-Rite 6 Ultrasound System; Bard Access Systems, Salt Lake City, Utah; or Aplio XG; Toshiba Medical Systems, Otawara, Japan) with the use of an 18-gauge puncture needle (AMC/4 Arterial Access Needle; Argon, Plano, Texas). This allowed the puncture site to be at least 1 cm proximal to the origin of the profunda femoris artery and distal to the inguinal ligament. The incision above the CFA access site was widened with a scalpel to 1 cm. A 6-F sheath was then inserted to dilate the subcutaneous tract. Two ProGlide devices were deployed before introducer sheath insertion, and the devices were rotated medially and laterally from the entrance axis approximately 30° each direction (ie, a 60° separation between the devices). Details of the preclose technique have been previously published (1–3). After PEVAR, a soft or stiff wire was placed before sheath removal. The wire was not removed until appropriate hemostasis was achieved. If hemostasis could not be established, a third (or fourth) ProGlide device was placed.

Experience with the preclose technique among the six interventional radiologists and three cardiovascular surgeons in the present study ranged from 1 to 3 years (each operator had deployed > 30 ProGlide devices). The study occurred within the learning curve of one interventional radiologist and two cardiovascular surgeons (3).

Data Collection and Definition

The CT imaging studies were performed on a 320-row CT system (Aquilion ONE; Toshiba Medical Systems) from the level of the clavicle to the ischium (16). The depth from the puncture site to the arteriotomy and