

Totally Percutaneous Endovascular Abdominal Aortic Aneurysm Repair

30-Day Results from the Independent Access-Site
Closure Study of the PEVAR Trial

Zvonimir Krajcer, MD
Jesus M. Matos, MD

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Joseph S. Coselli, MD

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From: Department of Cardiology (Dr. Krajcer), Texas Heart Institute and St. Luke's Hospital; and Division of Vascular Surgery (Dr. Matos), Michael E. DeBakey Department of Surgery, Baylor College of Medicine; Houston, Texas 77030

Address for reprints:

Zvonimir Krajcer, MD,
Department of Cardiology,
St. Luke's Hospital and
Texas Heart Institute,
6624 Fannin St., Suite 2780,
Houston, TX 77030

E-mail: zvonkomd@aol.com

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The endovascular abdominal aortic aneurysm repair (EVAR) has been successfully used for more than 2 decades. Single-center reports for more than a decade have shown promising results with percutaneous EVAR (PEVAR).^{1,2} Increased numbers of publications have reported greater technical success over time.^{1,2} However, a randomized and controlled clinical trial was needed to show the safety and benefits of the PEVAR technique versus surgical femoral artery cutdown and repair during EVAR (SEVAR). The PEVAR trial¹ was designed as a prospective, multicenter randomized and controlled trial to compare with SEVAR the safety and effectiveness of PEVAR's "pre-close" technique. The primary endpoint of the independent access-site closure study was the major ipsilateral access-site vascular sequelae rate at 30 days. The study took place at over 20 U.S. investigational centers. A total of 192 patients were enrolled. Forty-one patients were included in the roll-in phase to evaluate the safety and proficiency of each enrollment site, and 151 patients were then randomized to PEVAR or SEVAR. The pre-closure devices used were the Perclose ProGlide® 6F Suture-Mediated Closure (SMC) System and the Prostar® XL 10F Percutaneous Vascular Surgical System (both from Abbott Vascular, a unit of Abbott Laboratories; Redwood City, Calif). The ProGlide is a 6F SMC device approved for percutaneous closure of femoral artery access sites for 6F to 8F sheaths. The Prostar XL is also an SMC device approved for closure of femoral artery access sites for sheath sizes up to 10F. The results from the Prostar XL arm of the trial are still being evaluated and are not available for publication at this time. The endovascular device used was the AFX™ Endovascular AAA System (bifurcated stent-graft model) (Endologix, Inc.; Irvine, Calif). The pre-close technique consisted of deployment of 2 ProGlide devices in the common femoral artery before the insertion of the AFX stent-graft system.

Every patient met strict inclusion and exclusion criteria that included computed tomography with 3D reconstruction and detailed physical examination. The computed tomograms were reviewed by an independent core laboratory to evaluate the anatomic suitability of the common femoral artery (CFA) for percutaneous access. Patients were included if 1) the abdominal aortic aneurysm (AAA) had a maximal diameter of greater than 5 cm, 2) the CFA was suitable for percutaneous access by means of the pre-close technique, and 3) the AAA was anatomically eligible for the AFX stent-graft. Patients were excluded if they had 1) extensive CFA calcifications, 2) femoral artery aneurysms, or 3) excessive scarring from previous surgery or closure devices. A major ipsilateral access complication was defined as 1) an access-site vascular injury necessitating repair, 2) new onset of lower-extremity ischemia necessitating surgical or percutaneous intervention, 3) access site-related bleeding necessitating transfusion, 4) access site-related infection necessitating intravenous antibiotics or prolonged hospitalization, or 5) access site-related nerve injury that was permanent or necessitated surgery. A secondary endpoint of minor ipsilateral access-site vascular sequelae was also evaluated. Minor sequelae included 1) pseudoaneurysm/arteriovenous fistula, 2) hematomas >6 cm, 3) post-discharge bleeding necessitating >30 minutes to achieve hemostasis, and 4) deep vein thrombosis.

In terms of patient characteristics, the independent variables were similar in both groups except for the PEVAR group's having younger patients and a higher propor-

tion of American Society of Anesthesiologists Physical Status 3 or 4 patients. The characteristics of the aneurysm were similar in most variables measured except for the PEVAR group's having a smaller proximal neck diameter (22 mm vs 24 mm, $P=0.031$) and longer renal to bifurcation length (121 vs 110 mm, $P=0.01$).

The primary endpoint was achieved with the following results. Major ipsilateral access-site vascular sequelae at 30 days were encountered in 6% of the PEVAR group (3/50) and in 10% of the SEVAR group (5/50) ($P=0.0048$). Minor ipsilateral access-site vascular sequelae were similar in the PEVAR (4%; 2/50) and SEVAR (8%; 4/50) groups ($P=0.6777$). Other independent variables revealed the closure devices to be 96% successful at achieving hemostasis. The total procedural time was significantly shorter for the PEVAR than the SEVAR group (106.5 vs 141.1 min, $P=0.0056$). Time to hemostasis on the ipsilateral-access side was significantly shorter for the PEVAR than the SEVAR group (9.8 vs 22.7 min, $P=0.023$).

In conclusion, the PEVAR trial supports the safety and effectiveness of the Perclose ProGlide SMC system in closing femoral artery access sites effectively. The 30-

day ipsilateral access-site vascular complication rate was 6% for the PEVAR group and 10% for the SEVAR. There was no early (30-day) death. On the basis of the results of the arm of the PEVAR trial that made use of the Endologix AFX stent-graft system and the Perclose ProGlide SMC device from Abbott Vascular, these devices received U.S. Food and Drug Administration approval and specific labeling for bilateral percutaneous EVAR. The ProGlide also received an indication for closure of large-bore arterial punctures for EVAR access with use of the pre-close technique. Training and operator experience with the closure device and the pre-close technique are important in ensuring successful outcomes.

References

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