Endovascular Repair of Abdominal Aortic Aneurysms in Women after FDA Approval: Results, Complications, and Limitations

Luis A. Sanchez, MD,1 Brian G. Rubin, MD,1 Christine A. Keller, RN,1 Eric T. Choi, MD,1 Patrick J. Geraghty, MD,1 Suresh Vedantham, MD,2 David Hovsepian, MD,2 Daniel Picus, MD,2 and Gregorio A. Sicard, MD,1 St. Louis, Missouri

Women account for approximately 25% of patients with AAAs, but unfortunately, only 8-10% of patients considered candidates for endovascular treatment during prospective trials were women. We reviewed our experience with open surgical and endovascular techniques before and after the FDA approval of the Ancure and AneuRx devices to evaluate our results and the role of endovascular treatment of AAAs in women. From January 1999 to August 2000, 269 patients underwent elective repair of their AAAs at our institution. The 20-month period was divided into the 10 months before and after the FDA approval of the endovascular devices for comparison. In the initial time period, 75 patients (62 men and 13 women) underwent repair with 40% undergoing endovascular repair. In the 10 months after FDA approval, 194 patients (160 men and 34 women) underwent repair with 87% undergoing endovascular treatment. Ninety-two percent (155) of the patients undergoing endovascular repair in this period were treated with the AneuRx device. These 155 patients were divided into two groups based on gender to compare their early treatment results. The FDA approval of endovascular grafts has profoundly affected the treatment of infrarenal AAAs in the United States. Women continue to account for a small, but complex, proportion of patients treated with available endovascular devices and the results in these patients is worse than their male counterparts. Careful patient selection and meticulous operative techniques are needed to reliably treat women with available endovascular devices. Further developments are necessary to improve the current results and increase the proportion of women being safely and effectively treated with endovascular devices.

INTRODUCTION

The treatment of infrarenal abdominal aortic aneurysms (AAAs) has evolved and improved over the last four decades since its inception in the 1950s, but the results in women continue to lag behind those in men. Women account for approximately 25% of patients with AAAs being treated in the United States.1,2 Open surgical repair of an AAA is associated with higher perioperative morbidity and mortality rates in women than in their male counterparts. This is true for elective as well as emergent surgical repair.3,4 Over the past decade, endovascular grafts have rapidly evolved as
a potentially less invasive option for the treatment of AAAs. This technique, initially described by Parodi et al. in 1991, was conceived as a less invasive alternative that could potentially reduce the morbidity and mortality associated with open surgical repair. In June 1999, the Food and Drug Administration (FDA) evaluated the data accumulated from the EVT/Ancure and AneuRx trials6,7 and used it to approve the use of these devices for the treatment of AAAs in the United States. These devices had good short-term results in a carefully selected group of patients with perioperative mortality rates that were similar to those of patients undergoing standard open surgical repair. The morbidity rates were lower in the AneuRx trial and most complications in both studies were associated with the approach used to deliver the endovascular grafts and were not major systemic complications.6,7 Unfortunately, a limited number of women (8% in the EVT/Ancure trial and 10% in the AneuRx trial) were included in these prospective trials, making it very difficult to assess the effect of endovascular therapy in such a small subgroup of patients. In addition, many institutions have had great difficulty in treating women with AAAs because of their “unsuitable anatomy.” Velazquez et al.8 published that, in their experience, 63% of women being considered for endovascular treatment with the Ancure or Talent devices had “unsuitable anatomy” for these arterial reconstructions. But most of these patients, if not all, were still being considered for participation in prospective trials. As endovascular devices become more readily available, the percentage of women being treated may be higher than in prospective trials, since the use of the device will be decided by an experienced endovascular surgeon.

To evaluate the effect of FDA approval of the Ancure and AneuRx devices on the endovascular treatment of AAAs in women, we reviewed our experience with the elective treatment of AAAs 10 months before FDA approval of these endovascular devices and 10 months after.

PATIENTS AND METHODS

Patient Selection

From January 1999 to August 2000, 269 patients underwent elective repair of infrarenal aortic aneurysms at Barnes-Jewish Hospital. This period of 20 months was divided into the a 10-month period before the initial availability of FDA approved endovascular devices in October 1999 and the 10-month period after the Ancure and AneuRx devices were available for general use. Over these two time periods, all the patients who underwent elective repair of aortoiliac aneurysms with standard open surgical techniques and endovascular devices were entered in a database for careful long-term follow-up and comparison of their outcomes.

Open Surgical Reconstructions

Seventy-one patients underwent elective open surgical repair of their infrarenal AAAs over the 20-month period. These patients underwent surgical reconstructions because their anatomy was not suitable for endovascular repair or because this was the patient’s and their vascular surgeon’s preference after a detailed discussion of the available options for treatment. These patients were considered reasonably good candidates for open surgical repair and were free of major comorbid complicating factors. In the initial period of 10 months, 45 patients (33 men and 12 women) underwent open surgical repair, while 26 patients (17 men and 9 women) underwent open repair during the subsequent 10-month period.

Endovascular Graft Devices

One hundred and ninety-four patients underwent endovascular repair of their infrarenal AAAs over the 20-month period. These patients underwent endovascular reconstructions because their anatomy was considered suitable for this type of repair and the patients agreed to the treatment after a detailed discussion of the risk and benefits of this evolving technique for aortoiliac reconstruction with their vascular surgeon. In the initial 10-month period, 30 patients (29 men and 1 woman) underwent endovascular repair under FDA-approved protocols, which included 17 patients treated with the EVT/Ancure endovascular graft (Guidant Corporation, Menlo Park, CA) and 13 patients with the Excluder endovascular graft (W.L. Gore and Associates, Flagstaff, AZ). All patients were considered to be good anatomical candidates for endovascular repair and reasonable candidates for open surgical repair, with only mild to moderate medical comorbidities. During the subsequent period of 10 months, 168 patients (143 men and 25 women) underwent endovascular repair of their infrarenal AAAs. These included 7 patients (5 men and 2 women) treated with the Excluder endovascular graft under FDA-approved protocols, 6 patients (5 men and 1 woman) treated with the FDA-approved Ancure device, and 155 patients (133 men and 22 women) treated with the AneuRx endovascular graft (Medtronic/AVE, Santa Rosa, CA). The