Long-Term Results of the Multicenter Trial of the Powerlink Bifurcated System for Endovascular Aortic Aneurysm Repair

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Purpose

The purpose of this study was to assess the first report of the long-term results of abdominal aortic aneurysm (AAA) repair with the Powerlink bifurcated endovascular stent graft (Endologix, Inc., Irvine, CA) compared with open AAA repair. (Current analysis includes 76 patients at 36-month follow-up. Approximately 50 patients with 48-month follow-up will be available for analysis by November 2005.)

Methods

Between July 2000 and March 2003, 258 patients (192 test patients, 66 control patients) were prospectively enrolled in a controlled multicenter trial of the Powerlink system for endovascular aneurysm repair. Fifteen sites participated in the pivotal US Food and Drug Administration trial. Stent grafts were oversized by 10 to 20% relative to computed tomography (CT)-based diameter measurements. _All repairs were performed in the operating room through one _surgically exposed femoral artery and a contralateral percutaneously placed 9F sheath. Results were assessed with contrast-enhanced _CT scans, plain abdominal x-ray studies, and three-dimensional reconstructions produced by the core lab, MMS (Medical Metrx Solutions, West Lebanon, NH), at 1, 6, and 12 months, and annually postoperatively.

Results

Technical success was achieved in 97.9% of patients, with 4 failed insertions (3 early conversions because of deployment issues, and 1 access failure). There was an early mortality benefit (< 30 days) in the Powerlink arm, but no statistical difference in mortality at 1 year between Powerlink and control patients. Only 1 death was procedure related. Blood loss, operative time, intensive care unit stay, and hospital length of stay were significantly less in the Powerlink cohort compared with those in the control group. There were significantly fewer adverse events in the perioperative period in the Powerlink cohort compared with the control group. Overall endoleak rate at _30 days was 22.5% with device-related endoleaks being very low (only one type I endoleak and no type III or IV endoleaks). There were no type I, III, or IV endoleaks at 36 months.

Secondary procedures were performed in 19 patients (9.9%) for the treatment of endoleak (n = 10), limb obstruction (n = 7), and other causes (n = 2). There were 3 graft migrations (2.2%) of greater than 10 mm; _1 led to a secondary procedure (< 1%). There have been no ruptures, graft fabric defects, or wire fractures in the follow-up of all patients. Follow-up compliance in this trial is high at over 85% having core lab CT scans. Significant reduction in mean AAA diameter and volume has been noted at every follow-up interval to date. Seventy-seven percent of patients experienced decrease in volume by 36 months. Increase in AAA diameter has been noted in 6 patients. Retrospective review of sac morphology has revealed that 82.8% of patients have experienced some degree of straightening of sac angulation in the 36 months post implant.

Conclusions

The Powerlink system appears safe, and based on initial results of the long-term data, appears to effectively protect patients from AAA rupture. The ePTFE graft material and cobalt chromium alloy stent has been free from failure and fatigue in contradistinction to published reports of other commercially available AAA stent graft systems. The requirement for only one surgically exposed femoral artery with percutaneous contralateral limb access can facilitate graft placement in patients with compromised access routes. The Powerlink patients have experienced significantly fewer early major adverse events than open surgical control patients. Further long-term follow-up will be conducted to ensure the maintenance of these promisingly durable results.