What Are the Limits of the Gore Excluder for Aortoiliac Aneurysms and Can these Limits be Extended?

NOTES

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The original Gore Excluder Bifurcated Endoprosthesis is being evaluated in a multicenter, concurrent-controlled trial: 334 subjects were treated with standard open repair (control, n = 99) or the endograft (test n = 235). The trial is planned for a total of 5 years; 2-year results have been published, and 4-year data has matured.

Compared with controls, test subjects had less blood loss, fewer transfusions, faster recovery, and a striking reduction in early major adverse events. Planned analysis included reinterventions as adverse events and complications occurring in any crossover subjects were included in the original cohort. Marked reduction in major adverse events persists at four years. Specifically, cumulative major adverse events per person-year were significantly greater for controls than for the test group (2.8 versus 1.9 by Nelson, $p < .0001$ by log rank). Overall all-cause mortality was similar ($p = .118$). These parallel results of recently published randomized trials which have demonstrated decreased aneurysm-related mortality with endovascular repair but no difference in all cause mortality. The 4-year endoleak rate is low, but the aneurysm growth (? 5 mm increase from baseline to 4 years) rate is 32%. There have been several open conversions after implantation and no aneurysm ruptures. Analysis of these conversions suggests that transgraft ultrafiltration occurs in many patients with sac enlargement. Graft material was modified to address the increased frequency of sac enlargement identified with the original endograft.

The pivotal trial illustrates device performance in a controlled situation reflecting labeled indications. Physicians commonly care for patients with complex problems and anatomy which require customized treatment plans. Additionally, as therapies evolve in widespread clinical practice, unusual applications and innovative solutions develop. Cases will be presented illustrating the extended limits and intrinsic advantages of this endograft system.

References

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