

Evaluation of the PAS-Port Proximal Anastomosis System in coronary artery bypass surgery (the EPIC trial)

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Objective: During coronary surgery, proximal vein graft anastomoses have been performed by using an aortic partial occlusion clamp to allow for a hand-sewn anastomosis. The purpose of this multicenter, prospective, randomized trial was to evaluate the efficacy of the PAS-Port device (Cardica, Inc, Redwood City, Calif), which allows an automated proximal anastomosis to be performed without aortic clamping.

Methods: Between June 22, 2006, and March 22, 2007, 220 patients requiring coronary artery bypass grafting with at least 2 vein grafts were enrolled. Within each patient, 1 graft was randomly assigned to receive a PAS-Port device, and the other was assigned to receive a hand-sewn anastomosis to the ascending aorta. The primary end point was angiographic patency (<50% stenosis) 9 months after surgical intervention. Secondary end points included average time to complete each anastomosis and 9-month freedom from major adverse cardiac events.

Results: One hundred eighty-three patients received matched grafts that were angiographically assessed at 9 months. The 9-month graft patency was 82.0% (150/183) for hand-sewn and 80.3% (147/183) for PAS-Port grafts. The patency rate of PAS-Port anastomoses was statistically noninferior to that of hand-sewn anastomoses (95% lower confidence limit for difference, -7.95%). The freedom from major adverse cardiac events at 9 months was 97.7% for PAS-Port (95% confidence interval, 94.5%–99.0%) and 98.2% for hand-sewn (95% confidence interval, 95.1%–99.3%) grafts. The PAS-port device was associated with a 4.6 ± 3.9-minute reduction in anastomotic time compared with that seen with a hand-sewn anastomosis (P<.001).

Conclusions: The PAS-Port proximal anastomotic device produces an effective anastomosis with a 9-month patency rate that is comparable with that of a hand-sewn anastomosis. It allows for construction of a proximal anastomosis without aortic clamping and requires less time than a hand-sewn anastomosis.