Prospective, Randomized Study on the Use of the Cardica PAS-Port Aortic Connector System in Off-Pump Coronary Artery Bypass Surgery

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ABSTRACT

Background. The use of aortic connector devices for proximal vein graft anastomosis has been shown to be associated with a relevant rate of early graft complications. Cardica PAS-Port is a new aortic connector whose preliminary clinical results seem promising. The safety and efficacy of this aortic connector device have been evaluated in this prospective, randomized study.

Material and Methods. Twenty-four patients were randomized to receive proximal aorta-vein graft anastomosis with either the Cardica PAS-port aortic connector or by the hand-sewn technique. Twenty-three patients underwent multidetector computed tomographic scan (MDCT) of the chest 6 months after surgery to evaluate graft patency.

Results. All aortic connector devices (18) were successfully deployed and 31 proximal anastomoses were performed by the hand-sewn technique. MDCT showed that 6-month freedom from vein graft complication was 22.2% in the PAS-Port group and 58.1% in the hand-sewn group ($P = .04$). Four vein grafts (22.2%) anastomosed with the PAS-Port and 2 hand-sewn vein grafts (6.5%) were occluded ($P = .10$). The use of the PAS-Port aortic connector was also predictive of any vein graft complication when adjusted for vein graft flow ($P = .01$; OR 8.64, 95% CI 1.66-45.00) and for peripheral resistance units ($P = .02$; OR 6.14, 95% CI 1.33-28.43).

Conclusions. The results of this prematurely stopped, prospective, randomized study suggest that the use of PAS-Port aortic connector device is associated with a higher rate of early vein graft complications than the hand-sewn technique.