

Six-Month Angiographic Follow-Up of the PAS-Port II Clinical Trial

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Abstract:

Background. The PAS-Port device (Cardica, Redwood City, CA) allows the rapid deployment of a clampless proximal anastomosis between a vein graft and the aorta.

Methods. Fifty-four patients awaiting elective coronary artery bypass graft surgery were enrolled. Outcome variables were intraoperative device performance, early and 6-month angiographic graft patency, and 12-month clinical follow-up.

Results. Sixty-three PAS-Port devices were deployed in 54 patients. Two deployments were unsuccessful. There were no reoperations for bleeding. Two patients died of causes unrelated to the device. Patency evaluation at discharge was performed by angiogram on 49 implants and computed tomography in 2 implants (86% follow-up). At discharge, all evaluated grafts were patent (100%) and rated Fitzgibbon A. At 6-month follow-up, there was no additional mortality; 47 implants (88% follow-up) were evaluated by angiography (Fitzgibbon O [n = 1], Fitzgibbon B [n = 1], and Fitzgibbon A [n = 45]) and 5 by computed tomography. All grafts but 1 were patent (98.1%). At 12 months, 2 additional patients died of causes unrelated to the PAS-Port implant. Forty-six of 50 alive patients (95.8%) were followed up without any reports of device-related major adverse cardiac events.

Conclusions. Discharge (100%) and 6-month patency (98%) are excellent; patency and 12 months' clinical follow-up compares favorably with data from historical hand-sewn controls. The PAS-Port system safely allows the clampless creation of a proximal anastomosis.

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