

Twelve-month patency with the PAS-port proximal connector device: a single center prospective randomized trial.

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Abstract

BACKGROUND:

The PAS-Port (Cardica Inc, Redwood City, CA) is an automated system that allows for the clampless anastomosis of vein grafts to the aorta. The intent of this study was to prospectively compare one year graft patency of this system with conventional hand-sewn anastomoses in a prospective, randomized trial.

METHODS:

A total of 99 patients undergoing elective off-pump coronary bypass surgery were randomized to receive their proximal anastomoses with either the hand-sewn conventional technique or with the PAS-Port system. Patient follow-up consisted of multislice computed tomographic scans performed at discharge and one year postoperatively.

RESULTS:

Three patients had to be converted to on-pump due to technical reasons. Fifty-one patients were randomly assigned to the PAS-Port group and 48 patients to the control group. In five patients in the control group severe atherosclerosis of the aorta required cross-over to the use of the PAS-Port device, and in one patient in the PAS-Port group conversion to a hand-sewn anastomosis. Sequential anastomoses were performed in 88% of the control group and 73% of PAS-Port group grafts. Time needed for completion of the proximal anastomosis including graft loading was 187 +/- 19 seconds for the PAS-Port group and 406 +/- 34 seconds for the control group ($p < 0.001$). One patient died unrelated to cardiac events due to septic multiorgan failure and one stroke was observed in the control group. There was a trend toward a lower rate of postoperative delirium in the PAS-Port group (11.7% vs 25%, $p = 0.088$). Patency at discharge (100% PAS-Port group vs 97.8% control group) and after one year (97.8% PAS-Port group vs 93.7% control group) were comparable. One patient of the PAS-Port group died during long-term follow-up as a result of a severe stroke due to cerebrovascular disease.

CONCLUSIONS:

This prospective randomized study demonstrated excellent short and midterm patency in both the hand-sewn and PAS-Port grafts. The PAS-Port system allowed for the rapid, safe, and effective creation of a proximal anastomosis without the need to clamp the aorta. Based on this study we consider this product a valid alternative for proximal anastomosis, especially in patients with severe aortic disease, to avoid side clamping of the aorta.