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Key Studies Supporting Beating Heart Bypass Surgery

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A growing body of studies and publications are examining the patient impact of different approaches to bypass surgery. Following is a list of some of the top study publications regarding Beating Heart bypass surgery.

1. Diegler A, et al. Neuromonitoring and neurocognitive outcome in off-pump vs. conventional coronary bypass operation. *Ann Thorac Surg.* 2000;69:1162-1166.
2. BaskerRao B, et al. Evidence for improved cerebral function after minimally invasive bypass surgery. *J Card Surg.* 1998;13:27-31.
3. Ascione R, et al. Beating heart versus arrested heart revascularization: evaluation of myocardial function in a prospective randomized study. *Eur J Cardiothorac Surg.* 1999;15:685-690.
4. Boyd WD, et al. Off-pump surgery decreases post-operative complications and resource utilization in the elderly. *Ann Thorac Surg.* 1999;68:1490-1493.
5. Puskas J, et al. Clinical outcomes and angiographic patency in 125 consecutive off-pump coronary bypass patients. *Heart Surgery Forum.* 1999;12(3):216-221.
6. Yokoyama T, et al. Off-pump versus on-pump coronary bypass in high-risk subgroups. *Ann Thorac Surg.* 2000;70:1546-1550.
7. . Ascione R, et al. Economic outcome of off-pump coronary artery bypass surgery: a prospective randomized study. *Ann Thorac Surg.* 1999;68:2237-2242.
8. Newman M, et al. Longitudinal assessment of neurocognitive function after coronary artery bypass surgery. *NEJM.* 2001;344(6):395-402.

In addition to the studies noted above, Medtronic is collaborating with leading research centers in the US and in the Netherlands to determine the clinical outcomes and cost effectiveness of beating heart surgery as it compares to traditional alternative forms of revascularization.

The "Octopus Study" being conducted at the University of Utrecht consists of two multicenter randomized clinical trials in which coronary artery bypass grafting (CABG) on the beating heart (off-pump CABG) is compared to intracoronary stent implantation and conventional CABG utilizing the heart lung machine. The primary endpoint in the comparison of off-pump CABG versus stent implantation is medical effectiveness (i.e., absence of reintervention and major adverse cardiac and cerebrovascular events at 1 year after treatment). The primary endpoint in the comparison of off-pump CABG versus conventional CABG is cerebral function (i.e., absence of neurologic injury and cerebrovascular events at 3 months after treatment). Secondary endpoints in both trials include presence and severity of angina, quality-of-life, exercise capacity and

cost-effectiveness. A total of 560 patients have been enrolled.

The *SMART* Study (aka *Surgical Management - Arterial Revascularization Treatments*) is a 200 patient, randomized trial being conducted by a single surgeon - Dr. John Puskas - at Emory University. Patients eligible for CABG surgery are randomized to one of two groups - those undergoing CABG with CPB (control) and those patient patients undergoing surgery without CPB (experimental or off-pump). Outcome analysis will focus on several categories of variables: a) graft patency, b) neurologic and neuropsychological function, c) pulmonary function, d) indices of inflammation, e) routines measures of postoperative morbidity and mortality and f) cost analysis. Graft patency will be assessed by cardiac cauterization prior to discharge and again at one year following surgery.

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