

Progression to 100% Off-Pump Coronary Artery Bypass With the Octopus[®] 1 Dual Holder

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ABSTRACT

Background: Can off-pump coronary artery bypass grafting become the routine standard in all elective primary coronary artery bypass grafting (CABG) operations? This paper shows how this aim has been achieved during one year in 130 off-pump cases performed through a sternotomy. This strategy allows for full revascularization (up to six grafts) without the disadvantage of cardiopulmonary bypass. The study introduces a variant of the Octopus stabilizer, a single Octopus[®] 1 arm (Medtronic, Inc., Minneapolis, MN) with a dual holder.

Materials and Methods: From November 1998 through February 2000, 130 patients underwent coronary artery bypass grafting through a sternotomy off-pump utilizing a stabilizer and CO₂ blower. The stabilizer most frequently used to achieve this was a single Octopus[®] 1 arm equipped with a dual holder to accommodate two straight suction pods. The holder allowed increased flexibility and manipulation of the suction pods with an equivalent of seven degrees' freedom of motion at the dual holder junction. Techniques for carrying out total revascularization are discussed. The progress of proportion of elective primary CABG revascularization performed off-pump is shown and results are compared with published reviews of the literature for off-pump coronary revascularization.

Results: Patient demographics included: age range 32 to 87, mean 61.3; female sex: 17%; ejection fraction < 50%: 54%; presence of left main stem disease: 17%. Overall Parsonnet risk score ranged 0-31, with a mean of 8.8. Graft

numbers carried out were: 34 x 2, 34 x 3, 32 x 4, 25 x 5 and 5 x 6 anastomoses respectively. The mean number of distal anastomoses was 3.6 ± 1.0 . There was extensive coverage of the lateral aspect of the heart (153 circumflex territory grafts, 33%). Radial artery, left internal mammary artery or saphenous vein sequential (jump) grafts were used in 26 cases (20%). Apart from general experience, the use of the dual holder and wide opening of the right pleura were the two important factors allowing freedom for multi-vessel lateral and posterior wall grafting. Thirteen Genzyme[™] (Genzyme Surgical Products, Inc., Cambridge, MA) and ten Octopus[®] 2 (or 2+) stabilizers were used, mostly for two or three grafts. The remainder were carried out using the Octopus[®] 1 (dual holder: 83). In the first three-month period, 31% of cases were off-pump compared to the last three-month period, when 96% were off-pump. In the last two months we performed 100% of all 27 cases referred off-pump. There were no deaths, strokes or myocardial infarctions. Ventricular arrhythmia occurred in two cases. Conversions to bypass were undertaken twice. Two unexpected renal failures occurred, neither of which were from the 13 patients with preoperative incipient renal failure, of whom none suffered a rise in postoperative creatinine of greater than 30%. The results compare favorably with published results despite having a large mean number of grafts of 3.6.

Conclusion: Off-pump surgery with full revascularization has now become feasible for all primary elective coronary artery graft operations.

INTRODUCTION

Worldwide, more than 750,000 patients a year undergo coronary artery revascularization using cardiopulmonary bypass. However, the morbidity associated with extracorporeal circulation and oxygenation is well recognized [Edmunds 1997]. This has led to a resurgence of performing coronary artery bypass grafting (CABG) without the use

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Table 1. Beating heart stabilizer used

Single arm Octopus-1 with dual holder	83
Double arm Octopus-1	24
Octopus 2 & 2+	10
Genzyme stabilizer	13

of cardiopulmonary bypass (off-pump). This alternative has been greatly facilitated by the use of epicardial stabilization devices to allow construction of accurate anastomoses on the beating heart. Most of the early off-pump cases carried out worldwide have involved limited revascularization applying one to two grafts, typically to the anterior surface of the heart, and have tended to avoid the difficult circumflex coronary artery territory. Moreover, cases traditionally have been selected to be performed off-pump that avoid complex configurations of coronary disease on angiogram, including the presence of left main stem coronary disease, in favor of those with good left ventricular function.

Can off-pump coronary artery bypass become the routine standard in all elective primary CABG operations? This paper shows how this aim has been achieved during one year in 130 off-pump cases performed through a sternotomy. This strategy allows for full revascularization of up to six grafts without the disadvantage of cardiopulmonary bypass. The study introduces a variant of the Octopus® stabilizer, a single Octopus® 1 arm (Medtronic, Inc., Minneapolis, MN) with a dual holder.

MATERIALS AND METHODS

Materials

One hundred thirty patients underwent coronary artery bypass surgery by a single surgeon [RDLS] between November 1998 and February 2000 without the use of cardiopulmonary bypass. This was achieved with the use of beating heart stabilizers. Four such stabilizers were employed as described in Table 1 (●), employing either suction fixation (Octopus® 1, Octopus® 2, and Octopus® 2+ (Medtronic, Inc, Minneapolis, MN) or pressure fixation Genzyme™ (Genzyme Surgical Products, Inc., Cambridge, MA) to maintain the operative field.

The single-arm Octopus® 1 with dual holder was used in the majority of cases (64%). The dual holder was developed before the Octopus® 2 became commercially available. It allowed a single Octopus® 1 arm to hold two straight pods, thus removing the need for a second arm and allowing far greater accessibility to all regions of the heart. It is essentially comprised of a 'T'-bar with screw attachments for two suction pods, which are then attached to a single Octopus® 1 clamp. The holder allowed increased flexibility and manipulation of the suction pods with an equivalent of seven degrees' freedom of motion at the dual holder junction (see Figures 1 and 2, ●).

Methods

Informed consent was obtained from all patients to carry out off-pump CABG. Preoperative risk factors of age, sex, impaired left ventricular function, left main stem coronary artery disease, diabetes, elevated plasma creatinine, internal carotid artery stenosis and operative priority (emergency or elective) were recorded prospectively. Postoperative outcomes of mortality, CT-confirmed cerebrovascular accident, myocardial infarction, postoperative creatinine, time to extubation, stay in intensive care or fast track unit and postoperative day of discharge were recorded.

Operative Technique

Off-pump CABG presents specific problems, including:

- Difficulty in grafting the circumflex artery territory and inferior surface
- Maintenance of adequate blood pressure
- Development of myocardial ischemia
- Maintenance of a still, bloodless field in order to achieve optimal grafting conditions
- Drop in body temperature due to open chest and lack of active re-warming

These problems were overcome by adopting a defined surgical strategy. All cases were carried out with a perfusionist on standby, though the cardiopulmonary bypass circuit was not pre-primed. Patients were placed on a warming mattress on the operating table, and were covered with a warming blanket during the procedure. The theater temperature was set to 23°C. All operations were performed via routine sternotomy, with conduits harvested in routine fashion. Conduits employed were the left and right internal mammary arteries, the radial artery and the long saphenous vein. One-third of the dose of heparin required to achieve full anticoagulation was administered, aiming to sustain an activated clotting time of greater than 250s. On preparation of the mediastinum, several key steps were carried out to facilitate off-pump coronary artery surgery:

- The right pleura was opened widely (Figure 3, ●)
- All right pleuro-pericardial fat and thymic tissue was removed (Figure 3, ●)
- The right pericardium was incised 1 cm parallel to its diaphragmatic reflection down to the inferior vena cava (Figure 4, ●)
- Initially, deep pericardial stay sutures were placed to lift the heart ("LIMA stitch")
- The operating table was tilted according to the territory being grafted, to help balance the heart in optimum position.

These maneuvers allowed dislocation of the heart into the right hemi-thorax during the lifted and rotated position required for circumflex coronary artery territory grafting (Figure 5a, ●). This reduced the impingement on

Table 2. Preoperative risk factors

Risk Factor	No.	(%)
N	130	
Female	22	17
Ejection fraction < 50%	70	54
Left main stem stenosis	25	17
Emergency	4	3
Pre-operative creatinine > 150 mmol	13	10
Carotid stenosis	7	5
Diabetes	32	25
Parsonett score mean :	8.8 (0–31)	

venous return through the inferior vena in this position, allowing an adequate blood pressure to be generated under which distal coronary anastomoses could be carried out. The Trendelenburg position and the addition of volume were also employed to ensure adequate venous filling. Further still, methoxamine and, if required, low dose adrenaline were administered when needed to maintain blood pressure.

Myocardial ischemia was determined by ST segment changes on electrocardiogram, bradycardia, ventricular arrhythmia and hemodynamic instability. In order to prevent these changes, the order of anastomoses was guided by the coronary angiogram. Patients with left main stem disease and unstable angina had the left internal mammary artery anastomosed to the left anterior descending artery first, with minimal manipulation of the heart. If necessary, proximal anastomoses were performed immediately after completion of the corresponding distal anastomosis, in order to revascularize a critically ischemic territory. If signs of early myocardial ischemia ensued, intra-coronary shunts were placed while the anastomosis was completed to uphold coronary blood flow.

Anastomoses were carried out under nearly bloodless conditions by placing encircling proximal and, very occasionally, distal silastic snare sutures around the coronary artery. Aclan clips were also used in some instances. Visibility was further improved with the use of a humidified CO₂ blower.

RESULTS

Preoperative Risk Factors

Preoperative risk factors and patient demographics are shown in Table 2 (●). The presence of such risk factors did not exclude patients from off-pump CABG. Over half of the cases carried out had at least moderately impaired left ventricular function, with 21 of them (16%) having severely impaired ejection fractions of less than 30%. Off-pump CABG was successfully carried out in patients with left main stem coronary artery disease. In 17 cases (13%), a significant lesion in the right coronary artery accompanied the left main stem disease. Renal failure, carotid stenoses and emergency status did not prevent off-pump CABG from being undertaken. The mean age of patients was 61.3 years, although off-pump CABG was carried out on patients up to the age of 87 (Figure 6, ●), with 25 patients (19%) being over 70 years old.

Operative Data

Four hundred sixty-two distal anastomoses in total were constructed off-pump in 130 patients, giving an overall mean of 3.6 ± 1.0 gpp (grafts per patient). The range of number of grafts carried out per patient was from two to six (Figure 7, ●), with 74% of cases being triple bypasses or greater, and nearly half (47%) being quadruple bypasses or greater. During the early experience, when the technique was being developed, patients were selected who needed only two grafts (34 cases). Excluding these early cases, a mean number of 4.1 ± 0.9 gpp were performed, demonstrating that off-pump CABG is not confined to limited coronary artery revascularization. Complete revascularization was always achieved.

The number and type of distal anastomoses by target coronary vessel is given in Table 3 (●). The circumflex territory was initially thought a difficult area to graft. However, experience and the use of the Octopus® 1 dual holder allowed access to all areas of the heart, which could therefore be fully grafted (Figure 8, ●). No territory of the heart was ungraftable, with 153 (33%) of grafts being applied to the circumflex coronary territory. The use of the Octopus® 1 dual holder also facilitated the construction of side-to-side anastomoses as part of a sequential graft in 26 cases (20%), further enabling complete revascularization to be attained.

Table 3. Total number of grafts applied to each coronary artery, and target of sequential grafts

Target Coronary Artery (130 patients)	Total no. of distal anastomoses	No of side to side anastomoses (sequential graft)
Left anterior descending artery (LAD)	114	3
1st/2nd diagonal branch of LAD	77	
1st obtuse marginal branch of circumflex artery/ramus intermedius	101	13
Distal circumflex artery/2nd obtuse marginal branch	52	
Right coronary artery/posterior descending artery	98	10
Posterior-lateral branch of right coronary artery	20	
TOTAL	462	26

Table 4. Outcomes and results from 130 off-pump coronary artery bypass procedures

n	130
Mortality (30 day)	0
Cerebrovascular accident	0
Myocardial infarction	0
Doubling of pre-operative creatinine	2 (1.5%)
Re-operation for bleeding	0
Time to extubation time	6.9 ± 5.1 hrs
Time to ICU discharge	19 ± 6.7 hrs
Day of discharge	6.7 ± 1.5 days

Furthermore, the stability achieved off-pump allowed for easy arterial anastomoses: 50 radial arteries (38% of cases) were applied, most commonly in the circumflex region.

Electrocardiographical changes during off-pump CABG were infrequently seen. However, rhythm disturbances included two instances of ventricular fibrillation, two episodes of bradycardia, a single induction of transient heart block and a single bout of atrial fibrillation. Six cases showed a reversible rise of over 1.5 mm in the ST segment on their electrocardiogram, with only two of these being at the most 2 mm. Eighteen cases (14%) needed the placement of an intra-coronary shunt. These were most frequently needed during right coronary grafting, although they were used in all territories, with the following frequency: circumflex artery, 2; left anterior descending artery, 5; right coronary artery, 10. Thirty-seven cases (28%) required the use of low dose intra-operative adrenaline. Only two cases during the one-year experience required conversion to cardiopulmonary bypass due to difficulty in finding intra-myocardial arteries or hemodynamic instability.

The progression of off-pump CABG practice can be seen in Figure 9 (●). This represents the percentage of all cases referred to the same surgeon, which were carried out without cardiopulmonary bypass between November 1998 and February 2000. There was a steady rise in off-pump CABG usage, reflecting the learning curve of the new technique. In the first three-month period, 31% of cases were off-pump, compared to the last three months when 96% were off-pump. In the last two months, we achieved the target of performing 100% off-pump CABG on all 27 cases referred for coronary artery bypass.

Outcomes:

There were no deaths, strokes or myocardial infarctions resulting from the 130 cases performed off-pump (Table 4, ●). Two patients developed renal failure following off-pump CABG surgery. However, neither was one of the 13 patients with preoperative incipient renal failure. Of these patients, none of them suffered a rise in post-operative plasma creatinine of greater than 30%. Additionally, of the seven patients with pre-existing internal carotid artery disease, none experienced any strokes, transient ischemic attacks, or other neurological events.

DISCUSSION

Our results compare favorably with published data for off-pump CABG surgery. Two reviews of off-pump CABG [Tasdemir 1998, Stanbridge 1999], reviewing 2,052 and 3,060 cases respectively, quote an overall incidence of death of 1.9% and 2.2% respectively, and myocardial infarction rates of 2.9% and 1.45%. Our mean of 3.6 gpp also compares favorably with averages reported by Spooner [1999]: 1.9 gpp (456 cases), Pavie [1999]: 2.05 gpp (167 cases), Cartier [1999a]: 2.89 gpp (250 cases), and Baumgartner [1999]: 3.3 gpp (132 cases).

Complete revascularization is believed to be important in producing a re-intervention free result following off-pump CABG surgery. A seven-year follow-up comparing off-pump CABG surgery against a cohort of cases on-pump revealed that the re-intervention rate for symptomatic relief by means of percutaneous transluminal coronary angioplasty (PTCA) and redo-CABG was up to three times higher in the off-pump group (20%) than in the on-pump group (7%), although survival rate remained similar (80% compared to 79% respectively) [Gundry 1998]. This difference was attributed to the lack of complete revascularization in the off-pump group, which averaged 2.4 gpp in contrast to 3.2 gpp in the on-pump group. Furthermore, Tasdemir et al. [Tasdemir 1998] found that ungrafted circumflex coronary artery disease was an early mortality predictor and that non-bypassed circumflex disease was also associated with a high incidence of perioperative myocardial infarction and low cardiac output state. This emphasizes the importance of complete revascularization of all diseased coronary arteries, and the importance of employing techniques that allow safe and appropriate grafting of the circumflex coronary territory, as has been our practice.

Since December 1999, we have carried out off-pump CABG surgery on 100% of first-time coronary artery disease patients referred for surgery. Bypass surgery for high risk groups, including elderly patients as demonstrated by Boyd et al. [Boyd 1999], those with impaired left ventricular function [Kappert 1999], left main stem coronary disease [Cartier 1999b] and emergency cases [Hirose 1999], has been previously carried out successfully off-pump by the above investigators. The relative contraindications to total revascularization by off-pump CABG surgery are a large, bulky heart that cannot fit under the right sternum during the circumflex anastomoses, small intra-myocardial arteries, and profound preoperative hemodynamic instability.

Off-pump CABG surgery offers a low incidence of morbidity. Our rate of myocardial infarction and renal failure is consistent with the findings of Bouchard et al. [Bouchard 1998] who found that, in the setting of total revascularization, off-pump CABG caused less CK-MB release than CABG on-pump, along with a lesser rise in plasma creatinine. This is further demonstrated by the fact that plasma creatinine did not rise to greater than 30% in our 13 patients who had incipient renal failure preoperatively (creatinine >150 mmol). Hence, off-pump CABG is the preferable technique in patients with preoperative renal failure.

Low morbidity was also demonstrated in terms of neurological function. There were no cerebrovascular accidents in our series of 130 patients, which included 25 patients aged over 70 and seven patients with significant carotid artery stenosis. Though the data set is not large enough for meaningful stroke rate evaluation, it does support the notion that there is a reduced incidence of stroke with off-pump CABG. This would be consistent with the finding of reduced release of brain injury marker S100B in off-pump CABG surgery [Anderson 1999]. One effect of total revascularization by off-pump CABG is that the construction of multiple anastomoses increases the duration of the operation, which leads to substantial cooling through the open sternotomy. Paradoxically, this may play a beneficial cerebro-protective role by reducing cerebral metabolism during the procedure, and hence possibly lowering the likelihood of neurological complications.

The factors enabling us to achieve 100% off-pump application are a combination of increasing experience over the one-year period, the wide opening of the right pleura with incision of the right-side pericardium down to the inferior vena cava, and the use of the Octopus® 1 dual holder. Small and mounted on a single arm, the Octopus® 1 dual holder allowed easier access to all regions, especially the circumflex coronary artery territory, without compromising operator or assistant access to the surgical field.

Off-pump CABG is a safe method of carrying out CABG and can be used to provide total revascularization in multiple-vessel coronary artery disease. It can be performed on nearly all patients and appears to be associated with a reduction in the morbidity and mortality identified with on-pump CABG surgery. Now that the technique is established, it is appropriate to carry out a prospective, randomized trial to fully investigate any possible benefits of off-pump CABG surgery over traditional CABG with cardiopulmonary bypass.

REFERENCES

1. Anderson RE, Hansson LO, Vaage J. Release of S100B during coronary artery bypass grafting is reduced by off-pump surgery. *Ann Thorac Surg* 67(6):1721–5, 1999.
2. Baumgartner FJ, Gheissari A, Capouya ER, et al. Technical aspects of total revascularization in off-pump coronary bypass via sternotomy approach. *Ann Thorac Surg* 67(6):1653–8, 1999.
3. Bouchard D, Cartier R. Off-pump revascularization of multi-vessel coronary artery disease has a decreased myocardial infarction rate. *Eur J Cardiothorac Surg* 14 Suppl 1:S20–4, 1998.
4. Boyd WD, Desai ND, Del Rizzo DF, et al. Off-pump surgery decreases postoperative complications and resource utilization in the elderly. *Ann Thorac Surg* 68(4):1490–3, 1999.
5. Cartier R, Bouchard D, Martineau R, et al. Systemic coronary surgery in the beating heart. Experience in 250 cases. *Ann Chir* 53(8):693–700, 1999.
6. Cartier R, Brann S, Martineau R, et al. Left main coronary artery stenosis and revascularization in the beating heart. Short- and long-term experience. *Ann Chir* 53(8):701–5, 1999.
7. Edmunds LH, ed. *Extracorporeal Perfusion in Cardiac Surgery in the Adult*. McGraw Hill, 272–283, 1997.
8. Gundry SR, Romano MA, Shattuck OH, et al. Seven-year follow-up of coronary artery bypasses performed with and without cardiopulmonary bypass. *J Thorac Cardiovasc Surg* 115(6):1273–7; discussion 1277–8, 1998.
9. Hirose H, Amano A, Yoshida S, et al. Emergency off-pump coronary artery bypass grafting under a beating heart. *Ann Thorac Cardiovasc Surg* 5(5):304–9, 1999.
10. Kappert U, Guliemos V, Knaut M, et al. The application of the Octopus® stabilizing system for the treatment of high risk patients with coronary artery disease. *Eur J Cardiothorac Surg* 16 Suppl 2:S7–9, 1999.
11. Pavie A, Lima L, Bonnet N, et al. Perioperative management in minimally invasive coronary surgery. *Eur J Cardiothorac Surg* 16 Suppl 2:S53, 1999.
12. Spooner TH, Hart JC, Pym J. A two-year, three institution experience with the Medtronic Octopus®: systematic off-pump surgery. *Ann Thorac Surg* 68(4):1478–81, 1999.
13. Stanbridge RD, Hadjinikolaou LK. Technical adjuncts in beating heart surgery comparison of MIDCAB to off-pump sternotomy: a meta-analysis. *Eur J Cardiothorac Surg* 16 Suppl 2:S24–33, 1999.
14. Tasdemir O, Vural KM, Karagoz H, et al. Coronary artery bypass grafting on the beating heart without the use of extracorporeal circulation: review of 2052 cases. *J Thorac Cardiovasc Surg* 116(1):68–73, 1998.