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Early and Midterm Results of Off-Pump Coronary Artery Bypass Grafting without Patient Selection

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ABSTRACT

Background: Many reports have addressed the technical feasibility and early clinical results of off-pump coronary artery bypass grafting (OPCABG). It is uncertain, however, whether OPCABG provides midterm results equivalent to those of conventional CABG.

Methods: At Shiga University of Medical Science Hospital from January 2002 to May 2007, 477 consecutive patients underwent isolated OPCABG myocardial revascularization performed by a single surgeon (T.A.). OPCABG surgery was performed on all patients, with no exclusion criteria. These 477 patients were followed up for time-related events, including death from all causes, cardiac death, myocardial infarction, percutaneous coronary intervention, reoperation, and the combined end-point of cardiac events. Follow-up was completed in 96.0% of the patients (458 of 477).

Results: The number of distal anastomoses per patient was 3.46 ± 0.9, and complete revascularization was achieved in 96.6% of patients. No patient required conversion from off-pump to on-pump surgery. The average operation time was 272 ± 63 minutes. Thirteen patients (2.9%) required reoperation for bleeding. Deep sternal infection occurred in 5 patients (1.1%). One patient (0.2%) had a stroke and 4 patients (0.9%) had perioperative myocardial infarction. Acute renal failure requiring hemodialysis occurred in 10 patients (2.2%). Overall 30-day mortality was 1.1% (5 of 477). Follow-up was completed in 96.0% of patients. Mean follow-up was 3.0 ± 1.3 years. Five-year freedom from death from any cause was 79.1%, freedom from cardiac death 93.4%, and freedom from the combined end-point of cardiac death, myocardial infarction, repeat coronary intervention, and heart failure was 75.8%.

Conclusions: Our results demonstrate the safety of performing OPCABG surgery in all patients, without the use of exclusion criteria. Early and midterm outcomes were acceptable and encouraged continued use of the OPCABG approach in all CABG patients.

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INTRODUCTION

Recently reported studies have demonstrated that complete revascularization can be achieved safely with off-pump coronary artery bypass grafting (OPCABG), and that this method provides better early clinical outcomes than conventional CABG with cardiopulmonary bypass (CPB). However, some exclusion criteria for the OPCABG approach are still used in cases involving technical difficulty, such as severe left ventricular dysfunction, cardiomegaly, acute myocardial infarction, and hemodynamic instability. Many studies have demonstrated excellent early clinical outcomes in OPCABG surgery [Arom 2000; Atsushi 2001; Calafiore 2001; Cleveland 2001; Suzuki 2003]. Some recent reports have addressed the midterm clinical outcomes of patients undergoing OPCABG surgery [Gundry 1998; Sabik 2004; Calafiore 2005; Fukui 2007; Hannan 2007]. In these reported studies, however, the selection of which surgical approach to apply was made based on clinical presentation, so their comparisons of off- and on-pump surgical approaches were nonrandomized. At our institution, OPCABG surgery was performed routinely in all isolated CABG patients with no exclusion criteria. Thus there is no patient selection bias in the present study and, because all patients were accrued into the study consecutively, the results offer a high degree of reliability.

MATERIALS AND METHODS

From January 2002 to May 2007, 519 consecutive patients underwent isolated myocardial revascularization via the OPCABG technique performed by a single surgeon (T.A.) at Shiga Medical University Hospital. The study did not include cases of single-vessel disease, acute myocardial infarction, or salvage procedures. We performed OPCABG surgery in all isolated CABG patients, with no exclusion criteria. A total of 477 patients formed the study patient group. The preoperative characteristics of the patients are shown in Table 1.

Postoperative renal failure was defined as the requirement for hemodialysis. Postoperative stroke was defined as a new neurologic event persisting for more than 24 hours after onset, and was confirmed by computed tomography. Atrial fibrillation was defined as sustained atrial arrhythmia requiring treatment.

Table 1. Preoperative Patient Characteristics*

Age, y	68.5 ± 10.1
Female sex	79 (17.7%)
New York Heart Association class III or IV	175 (39.1%)
Smoking history	247 (55.3%)
Diabetes mellitus	218 (48.8%)
Insulin-dependent	74 (16.6%)
Hypertension	323 (72.3%)
Hyperlipidemia	232 (51.9%)
Chronic obstructive pulmonary disease	78 (17.4%)
Peripheral arterial disease	57 (12.8%)
Previous stroke	59 (13.2%)
Chronic renal failure (serum creatinine >1.5)	88 (19.7%)
Congestive heart failure	72 (16.1%)
Left ventricular ejection fraction <40%	55 (12.3%)
Left main disease	165 (36.9%)
Triple-vessel disease	340 (76.1%)
Previous myocardial infarction	179 (40.0%)
Unstable angina	159 (35.6%)

*Data are mean ± SD or n (%).

Follow-up was achieved by direct communication with the patient, the patient's family, or the attending physician.

Anesthetic and Surgical Techniques

A standard anesthetic technique was used in all patients. The induction of anesthesia was achieved with fentanyl citrate (5 to 10 μg/kg), thiopental (3 to 5 mg/kg), propofol infusion (3 to 4 mg/kg per hour), or vecronium bromide (0.1 mg/kg). Anesthesia was maintained with fentanyl, propofol (2-3 mg/kg), or low concentrations of sevoflene as necessary. Anticoagulation was achieved with heparin (1 mg/kg) after the conduits were harvested. The activated clotting time was maintained at ≥250 seconds. Heparin was reversed with protamine after completion of the anastomosis. Standard intraoperative monitoring techniques were used. Pulmonary artery floatation catheters were used routinely and provided continuous evaluation of cardiac output. Transesophageal echocardiography was also used routinely.

All procedures were performed through a median sternotomy. The conduits (one or both internal thoracic arteries, the right gastroepiploic artery, and the saphenous vein) were harvested and skeletonized. We used a suction-type mechanical stabilizer (Octopus 4.3, Medtronic, Minneapolis, MN, USA) to immobilize the target coronary artery, but did not use a heart positioner. An intracoronary shunt tube and CO_2 blower were used routinely. The distal anastomosis was constructed using 7-0 polypropylene according to a standard technique. A red blood cell saving device was used in all cases.

Statistical Analysis

Data are presented as the mean ± SD. Categorical variables were analyzed using the χ^2 or Fishers exact test. Constant variables were examined using a *t* test or the Mann-Whitney U test. Actuarial survival and event-free survival curves were estimated using the Kaplan-Meier method. Calculated *P* values of less than .05 were considered significant. Data were analyzed using SPSS 11.5.1 (SPSS Inc, Chicago, IL, USA) for Windows (Microsoft Corp, Redmond, WA, USA).

RESULTS

Surgical Results

Outcomes after surgery are shown in Table 2. The number of distal anastomoses per patient was 3.46 ± 0.9, and complete revascularization was achieved in 96.6% of patients. No patient's surgical procedure was converted from off-pump to on-pump. Bilateral internal thoracic arteries were used in 288 patients (60.3%). The average operation time was 272 ± 63 minutes. Red blood cell transfusion was required in 202 patients (45.2%).

Early Results

Prolonged respiratory support (>24 hours) was required in 22 patients (4.9%), and prolonged intensive care unit stay (>48 hours) was required in 27 patients (6.0%). The mean duration of hospital stay after surgery was 15.7 ± 13.1 days. Thirteen patients (2.9%) required reoperation for bleeding. Deep sternal infection occurred in 5 patients (1.1%). One patient (0.2%) had a stroke and 4 patients (0.9%) had perioperative myocardial infarction. Acute renal failure requiring hemodialysis occurred in 10 patients (2.2%). Atrial fibrillation occurred in 102 patients (22.8%) after surgery, but was not persistent in any patients. Overall 30-day mortality

Table 2. Operative and Postoperative Data*

Conversion from off-pump to on-pump	0
Intraaoritc balloon pump use (intra-postoperative)	10 (2.2%)
No. of distal anastomoses	3.46 ± 0.9
Bilateral internal thoracic artery use	288 (64.4%)
Operative time, min	272 ± 63
Complete revascularization	432 (96.6%)
Transfusion	202 (45.2%)
Prolonged intubation time (>24 hours)	22 (4.9%)
Prolonged intensive care unit stay (>48 hours)	27 (6.0%)
Hospital stay (days, surgery to discharge)	15.7 ± 13.1
Reoperation for bleeding	13 (2.9%)
Deep sternal infection	5 (1.1%)
Permanent stroke	1 (0.2%)
Perioperative myocardial infarction	4 (0.9%)
Atrial fibrillation	102 (22.8%)
Renal failure requiring dialysis	10 (2.2%)
Motality (30 days)	5 (1.1%)

*Data are n, mean ± SD, or n (%).

was 1.1% (5 of 477). Two urgent high-risk patients died of low-output syndrome 5 and 8 days after surgery. One patient died 1 day after surgery because of rupture of an abdominal aortic aneurysm. One patient died of acute renal failure and sepsis 4 days after surgery. One patient died of pneumonia 4 days after surgery.

Midterm Results

Follow-up was completed in 96.0% of the patients (458 of 477). Mean follow-up was 3.0 ± 1.3 years. During the follow-up period, 55 patients died, 15 of them of cardiac causes. Five-year freedom from death from any cause was 79.1%. Freedom from cardiac death was 93.4%. One patient required repeat OPCABG 25 months after the first surgery. Twenty-four patients underwent percutaneous coronary intervention after surgery. Four patients experienced a new acute myocardial infarction, and 14 patients experienced congestive heart failure requiring treatment on admission. Freedom from the combined end point of cardiac death, myocardial infarction, repeat coronary intervention, and heart failure was 75.8%.

DISCUSSION

For patients with multiple coronary artery disease, the long-term benefits of CABG compared with medical therapy and percutaneous coronary intervention have been established [Hannan 2005]. OPCABG has been developed to eliminate problems associated with CPB and is expected to provide better early and long-term clinical outcomes than conventional CABG. There have been few reports on the midterm results of OPCABG surgery, however, and the information available is insufficient to evaluate the long-term benefits of OPCABG surgery.

Recently, numerous studies have demonstrated that OPCABG has excellent early clinical outcomes superior or equal to those of conventional CABG with CPB [Arom 2000; Atsushi 2001; Calafiore 2001; Cleveland 2001; Suzuki 2003]. There are, still some patients who cannot be treated with OPCABG, however, such as those with severe left ventricular dysfunction, cardiomegaly, acute myocardial infarction, or hemodynamic instability. A number of studies have indicated that OPCABG itself can be a reason for incomplete revascularization. Czerny and coworkers [2001] reported that the rate of complete revascularization is lower (65% vs 85%), with fewer bypass grafts (2.6 vs 3.1), in OPCABG patients than in patients undergoing conventional CABG. Shennib and coworkers [2002], who compared the clinical outcome of OPCABG and conventional CABG in patients with poor left ventricular function, reported that operative mortality was lower in the OPCABG group (3.2% vs 10.9%), but that the number of distal anastomoses per patient was also fewer (2.8 vs 3.9) in this group. We believe that complete revascularization improves long-term cardiac survival but we also emphasize that the OPCABG approach should not be selected if complete revascularization cannot be achieved. Kleisli and colleagues [2005] demonstrated that the 5-year survival rate with complete revascularization was superior to that with incomplete revascularization (82.4% vs 52.6%). In our OPCABG series, the number of distal anastomoses per patient was 3.46 ± 0.9, and complete revascularization was achieved in 96.6%. No patient's surgical procedure was converted from off-pump to on-pump, and operative mortality was 1.1% (5 of 477). The results of the present study, in which OPCABG was performed safely and with quality of outcome equal or superior to that of conventional CABG, indicated the feasibility and effectiveness of the OPCABG approach. We therefore believe that it is not unreasonable to apply the OPCABG technique to all CABG patients, with no exclusion criteria.

In our series, postoperative hospital stays were very long (15.7 days). One reason is that in Japan, postoperative bypass angiography is performed routinely during the hospital stay, and in most cases patients remain in the hospital until they can be discharged directly to their home.

Few reports in the literature address midterm outcomes after OPCABG [Gundry 1998; Sabik 2004; Calafiore 2005; Fukui 2007; Hannan 2007]. The clinical results of a 7-year follow-up of CABG with and without CPB [Gundry 1998] showed that off-pump patients had fewer distal anastomoses (2.4 vs 3.2 per patient) and that twice as many patients in the off-pump group required a second intervention (20% vs 7%), whereas Sabik and colleagues [2004] reported equal midterm outcomes after off-pump and on-pump coronary surgery, with 4-year survival rates of 87.5% after OPCABG and 91.2% after conventional CABG ($P = .2$), in spite of the high incidence of incomplete revascularization (31% vs 18%) and the small number of distal anastomoses (2.8 vs 3.5 per patient) in the off-pump group. Hannan and coworkers [2007] compared the 3-year follow-up clinical outcome of OPCABG and conventional CABG and reported that hospital mortality and complication rates were lower in the OPCABG group, but in the long-term period, the revascularization rate

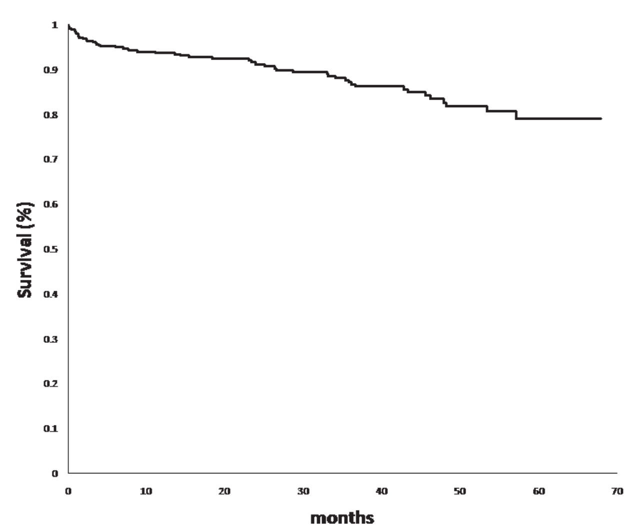

Figure 1. Five-year actuarial freedom from death of any cause after off-pump coronary surgery. Number of patients at risk after 1, 3, and 5 years was, respectively, 385, 227, and 48.

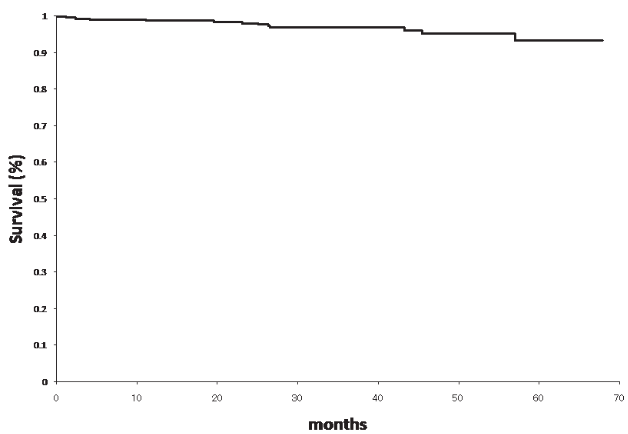

Figure 2. Five-year actuarial freedom from death of cardiac cause after off-pump coronary surgery.

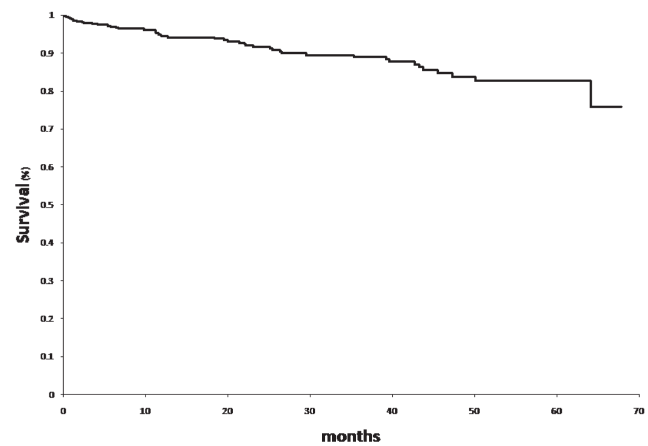

Figure 4. Five-year actuarial freedom from any cardiac event (cardiac death, myocardial infarction, coronary reintervention, and heart failure).

was higher in the OPCABG group. In their series, also, the number of distal anastomoses was fewer in the OPCABG group (2.96 vs 3.42).

Some studies have investigated mid- and long-term neurocognitive outcomes after CABG with and without CPB. Dijk and coworkers [2007] showed that avoiding the use of CPB had no effect on 5-year cognitive outcome in low-risk patients. Selnes and colleagues [2007] also reported that during a 3-year follow-up they observed no significant differences in the degree of late cognitive decline after on-pump compared with off-pump surgery.

Recently, a number of clinical studies of OPCABG performed by experienced surgeons have shown excellent early and midterm results. Calafiore and associates [2005], who studied the 6-year clinical outcome of CABG with and without CPB, found equal numbers of distal anastomoses and complete revascularization in the 2 groups. Their midterm findings in the off-pump group were equal to those of the on-pump group. Fukui and associates [2007], who investigated a series of 602 OPCABG patients, reported excellent midterm results, with 87.9% 5-year survival, 97.7% freedom from cardiac death, and 83.8% freedom from any cardiac event. The average number of distal anastomoses (3.6 per patient) and the complete revascularization rate (99.2%) were also very high. These results suggest that high-quality OPCABG may improve clinical outcomes not only in the early period but also in the long term. The studies cited above were nonrandomized in their comparison of the 2 different surgical approaches, however, because the selection of which surgical approach to apply was made based on the clinical presentation. The present study shows a 5-year survival rate from all causes of death of 79.1% (Figure 1) and a survival rate from cardiac death of 93.4% (Figure 2-4). Because the OPCABG series we studied included all CABG cases, with no patient selection bias, the results reflect a real world situation and indicate reliably what OPCABG can offer patients with coronary artery disease.

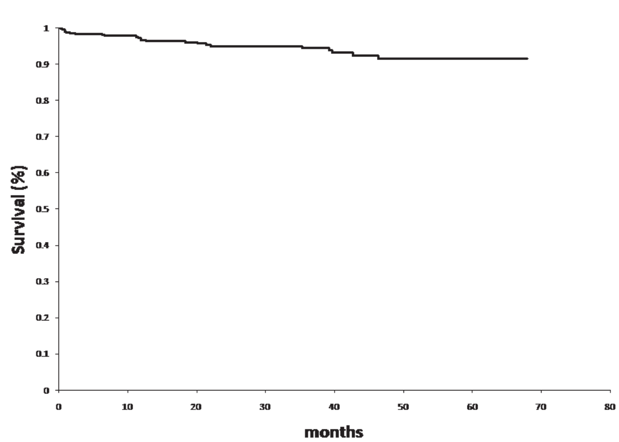

Figure 3. Five-year actuarial freedom from percutaneous coronary intervention after off-pump surgery.

OPCABG surgery continues to develop refinement of details, such as aortic nontouch technique, use of bilateral internal thoracic arteries, skeletonized arterial conduits, and arterial-only revascularization. More time is needed to reveal the effectiveness of these surgical techniques.

We studied early and midterm clinical outcomes in patients who underwent OPCABG surgery with no patient selection. Because the number of patients in the study was small and the follow-up period was only 5 years, more information is needed to ascertain the effectiveness of OPCABG surgery. We can conclude, however, that if complete revascularization can be achieved safely using OPCABG techniques without worsening early results, this technique can provide mid- and long-term outcomes equivalent to those of conventional CABG.

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