

Comparison of Off-pump Coronary Artery Bypass Grafting With Percutaneous Coronary Intervention Versus Drug-Eluting Stents for Three-Vessel Coronary Artery Disease

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Background. Drug-eluting stents (DESs) have challenged coronary bypass grafting as the gold standard for 3-vessel coronary artery disease. This study compared the clinical results between percutaneous intervention with DESs vs off-pump coronary bypass surgery (OPCAB).

Methods. The study included 388 matched patients with 3-vessel coronary artery diseases who were treated either with DESs or OPCAB. We compared 30-day, 12-month, and cumulative major adverse cardiac and cerebrovascular events (MACCE) during the follow-up.

Results. The overall follow-up was 98.5%. Follow-up duration was 621.1 ± 259.9 days (range, 13 to 1117 days). The rates of MAACE in the DES and OPCAB group were, respectively, 1.5% at 30 days ($p = 0.315$) and 9.8% and 3.6% at 12 months ($p = 0.015$). During follow-up, five deaths occurred in the DES group and one in OPCAB

group ($p = 0.1$). Three-year survival rate was $95.1\% \pm 2.9\%$ in DES group and $99.5\% \pm 0.5\%$ in OPCAB group ($p = 0.075$). Survival free from MACCE at 3 years was $73.3\% \pm 5.3\%$ in DES group and $91.3\% \pm 2.9\%$ in OPCAB group ($p < 0.001$). The major event for the differences between the groups was target vessel revascularization ($p < 0.001$): 21 DES patients (10.8%) vs 6 OPCAB patients (3.1%).

Conclusions. OPCAB showed better clinical outcome in 12-month and cumulative MACCE rate in 3-vessel coronary artery diseases. The major factor for the difference was target vessel revascularization. Longer follow-up is needed to clarify the differences between the two groups.

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Drug-eluting stents (DESs) show a lower incidence of restenosis after percutaneous coronary interventions (PCI) compared with bare-metal stents [1, 2]. With its widespread use, PCI with DESs has challenged coronary artery bypass grafting (CABG) as the gold standard for 3-vessel and left main coronary artery diseases, only with little documented supportive data. Data from the run-in phase from Synergy between PCI with TAXUS Drug-Eluting Stent and Cardiac Surgery (SYNTAX) trial showed that 27% of patients with 3-vessel disease were referred for PCI, with a more prevalent incidence in Europe compared with North America [3].

In large series of randomized trials comparing PCI and CABG, the CABG groups showed a lower incidence of major adverse cardiac and cerebrovascular events (MACCE) and repeated revascularization procedures [4, 5]. But most of the patients enrolled in those trials underwent coronary intervention with bare-metal stents or conventional CABG, which is performed with cardio-

pulmonary bypass. Recently, off-pump coronary artery bypass grafting (OPCAB) has become the preferred surgical strategy due to avoidance of side effects from cardiopulmonary bypass, just as the DES is the preferred option in PCI for its advantage in the restenosis rate.

Currently ongoing randomized clinical trials comparing the clinical results between DESs and CABG (SYNTAX trial and Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease [FREEDOM] trial) will be helpful for choosing the best treatment option for 3-vessel disease patients, but surgical patients enrolled in those trials include the patients who underwent on-pump CABG. The purpose of this study was to compare the results of PCI with DESs and OPCAB by focusing on postoperative MACCE and to define the preferred treatment strategy in 3-vessel coronary artery disease.

Patients and Methods

The study included 508 patients with 3-vessel coronary artery disease treated between July 2003 and June 2005; of these, 267 patients underwent PCI with DESs (DES

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group) and 241 patients underwent OPCAB (OPCAB group). The baseline characteristics of the two groups were different in that the OPCAB patients were younger ($p < 0.05$) and had a higher incidence of diabetes mellitus ($p < 0.05$). Propensity score matching was used and the following factors were considered: age, sex, incidence of diabetes mellitus, hypertension, chronic renal failure, chronic obstructive pulmonary disease, peripheral artery occlusive disease, old myocardial infarction, and stroke history. After matching, each group contained 194 patients with similar demographics.

Patient data were prospectively collected and follow-up data were retrospectively reviewed. Because this study was not a randomized trial, there were preferences for OPCAB owing to following reasons: unsuitable lesions for PCI such as severe calcification, long-segment lesions, or total occlusions; and patient preference or patient economic considerations. Whether to use the off-pump technique was mainly decided by the surgeon's preference and not by the patient's underlying condition. Approval of the Institutional Review Board of Yongdong Severance Hospital was obtained for the data collection and follow-up.

In the OPCAB group, the left internal thoracic artery (LITA) was used in all patients (100%), and the bilateral internal thoracic artery was used in 96 (49.5%). The LITA was mainly anastomosed to left anterior descending artery, and the radial artery was usually anastomosed to LITA as a composite graft. For the right coronary system, right internal thoracic artery (RITA) or free vein grafts were mainly used.

The operation was performed under general endotracheal anesthesia with full sternotomy. The internal thoracic artery was harvested in a semiskeletonized method. Heparin mixed papaverine was used to avoid vasospasm. A calcium channel blocker was used during the operation and then afterward to avoid spasm of radial artery. Intravenous heparin was used (100 units/kg), and activated clotting time was maintained at more than 250 seconds during the operation.

For cardiac displacement, the Octopus system mechanical stabilizer (Medtronic Inc, Minneapolis, MN) was used. Total arterial grafting was performed in 92 patients (47.4%), and a mean of 3.36 distal anastomoses were done per patient.

All patients in the OPCAB group routinely underwent postoperative multislice computed tomography (CT) imaging before discharge unless the patient had renal failure or an economic hardship.

All DES patients received aspirin and clopidogrel before and after the procedure. Stenting was performed after balloon angioplasty dilatation. Aspirin (100 mg/d) and clopidogrel (Plavix; Sanofi, New York, NY; a loading dose of 300 mg the day before the procedure and 75 mg daily thereafter) were routinely maintained for 9 months after DES implantation. Every patient in DES group received one or more DESs during the procedures. Taxus (Boston Scientific Corp, Natick, MA) or Cypher (Johnson and Johnson, Miami, FL) stents were selected by randomization.

All patients in DES group were recommended to undergo follow-up angiography 9 months after DES implantation. Follow-up angiography was done in 116 patients (59.8%), and the rest were without follow-up angiography by patient refusal or physician decision.

Follow-Up and Definitions

Patient follow-up was done in an outpatient clinic and by telephone interview. Diabetic patients included patients receiving oral hypoglycemic agents or insulin. Chronic renal failure patients were those who required hemodialysis, peritoneal dialysis, or whose preprocedural serum creatinine level exceeded 2.0 mg/dL.

MACCEs were defined as the occurrence of nonfatal myocardial infarction, death of any cause, stroke, or need for target vessel revascularization (TVR). For analysis of the MACCE rate, the primary end point was any MACCE event during the follow-up period. Myocardial infarction was defined as creatine kinase (CK)-MB elevation with appearance of new Q-wave or S-T segment elevation of more than 2 mm on the electrocardiogram. TVR was defined as any revascularization performed on a treated vessel during the initial procedure with PCI or OPCAB. Complete revascularization was defined when the number of revascularized vessel was the same or greater than the number of diseased vessels.

Statistical Analysis

Continuous variables are expressed as mean \pm standard deviation. For comparison of two variables, the Student *t* test and χ^2 test were used. A significant level of 0.05 was used throughout the tests. For survival and event-free survival analysis, the Kaplan-Meier method was used, and differences were assessed with the log-rank test.

Table 1. Patient Demographics by Treatment Group

Variables	DES (n = 194), No. (%)	OPCAB (n = 194), No. (%)	<i>p</i> Value
Age, y ^a	63.3 \pm 10.3	61.9 \pm 9.2	0.159
Female gender	51 (26.3)	51 (26.3)	0.976
Hypertension	122 (62.9)	134 (69.1)	0.223
Diabetes	97 (50.0)	96 (49.5)	0.897
COPD	1 (0.5)	1 (0.5)	0.997
Chronic renal failure	16 (8.2)	15 (7.7)	0.864
MI			
Acute (< 14 d)	35 (18.0)	36 (18.6)	0.934
Old	32 (16.5)	23 (11.9)	0.183
Left main disease	20 (10.3)	55 (28.4)	< 0.001
PAOD	45 (23.2)	40 (20.6)	0.522
CVA history	21 (10.8)	18 (9.3)	0.601
LVEF < 0.35	8 (4.1)	18 (9.3)	0.042

^a Continuous data are mean \pm standard deviation.

COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; DES = drug-eluting stent; LVEF = left ventricular ejection fraction; MI = myocardial infarction; OPCAB = off-pump coronary artery bypass grafting; PAOD = peripheral artery occlusive disease.

Table 2. Revascularization Strategy by Treatment Group

Variables	DES (n = 194)	OPCAB (n = 194)	p Value
Revascularized vessels, mean ± SD, No.	1.50 ± 0.61	2.76 ± 0.42	< 0.001
Complete revascularization, No, (%)	16 (8.2)	140 (72.2)	< 0.001
Distal anastomoses, ^a mean ± SD (range)	...	3.36 ± 0.71 (2-5)	...
Total arterial grating, No. (%)	...	92 (47.4)	...
Bilateral ITA use, No. (%)	...	96 (49.5)	...
Stents inserted, ^b mean ± SD (range), No.	2.01 ± 0.94 (1-5)
DESs inserted, mean ± SD (range), No.	1.76 ± 0.83 (1-4)

^a OPCAB group. ^b Including bare metal stents.

DES = drug-eluting stent; ITA = internal thoracic artery; MACCE = major adverse cardiac and cerebrovascular events; OPCAB = off-pump coronary artery bypass grafting.

Statistical analyses were performed using SPSS 12.0 software (SPSS Inc, Chicago, IL).

Results

Patient Demographics

After propensity score matching for age, sex, incidence of diabetes mellitus, hypertension, chronic renal failure, chronic obstructive pulmonary disease, peripheral artery occlusive disease, old myocardial infarction, and stroke history, the two groups (194 patients each) showed similar patients demographics. However, incidences of left main disease and poor left ventricular ejection fraction (< 0.35) were more frequent in the OPCAB group (*p* < 0.001, *p* = 0.042, respectively; Table 1).

Revascularization Strategies

The OPCAB patients underwent a mean of 3.36 ± 0.71 distal anastomoses (range, 2 to 5). The DES patients received a mean of 2.01 ± 0.94 implanted stents (range, 1 to 5), including bare-metal stents, and the mean number of implanted DESs was 1.76 ± 0.83 (range, 1 to 4). The mean number of revascularization vessels was 2.76 ± 0.42 in the OPCAB group and 1.50 ± 0.61 in the DES group. Complete revascularization was performed in 140 patients in the OPCAB group (72.2%) and in 16 in the DES group (8.2%), which was a significant difference (*p* < 0.001; Table 2).

Table 3. Postprocedural Patency^a by Treatment Group

Variables	DES (n = 116), %	OPCAB (n = 174), %
Total patency rate	87.8	95.7
LAD territory	86.7	98.1
LCx territory	86.8	95.9
RCA territory	90.8	92.8
Left main	100	...

^a Patency rate was calculated as total number of patent stents (grafts)/total stents (grafts) evaluated × 100 (%).

DES = drug-eluting stent; LAD = left anterior descending artery; LCx = left circumflex artery; OPCAB = off-pump coronary artery bypass grafting; RCA = right coronary artery.

Postprocedural Patency Evaluation

A postoperative CT scan was done in 174 patients. Follow-up duration in the OPCAB group was 110.2 ± 232.8 days (range, 5 to 951 days) and the follow-up rate was 89.7%. The overall graft patency was 95.7% (25 of a total of 580 grafts evaluated were occluded). The LITA to left anterior descending artery graft showed 99.5% patency and grafts to the right coronary system showed 93.3% patency rate. In the DES group, 116 patients (59.8%) underwent postoperative angiography during the

Table 4. Major Adverse Cardiac and Cerebrovascular Events Rates by Treatment Group

Variables	DES (n = 194), No. (%)	OPCAB (n = 194), No. (%)	p Value
30-day MACCE	3 (1.5)	1 (0.5)	0.315
Death	0	0	
Myocardial infarction	1 (0.4)	1 (0.4)	1.0
TVR	1 (0.4)	0	0.317
PCI	1 (0.4)	0	0.317
CABG	0	0	
Cerebrovascular events	1 (0.4)	0	0.317
12-month MACCE	19 (9.8)	7 (3.6)	0.015
Death	3 (1.5)	1 (0.4)	0.315
Myocardial infarction	2 (1.0)	1 (0.4)	0.562
TVR	11 (5.7)	3 (1.5)	0.029
PCI	10 (5.2)	3 (1.5)	0.048
CABG	1 (0.4)	0	0.317
Cerebrovascular events	3 (1.5)	2 (1.0)	0.653
Cumulative MACCE	30 (15.5)	11 (5.7)	0.002
Death	5 (2.6)	1 (0.4)	0.100
Myocardial infarction	4 (2.1)	1 (0.4)	0.177
TVR	16 (8.2)	5 (2.6)	0.014
PCI	15 (7.7)	5 (2.6)	0.022
CABG	1 (0.4)	0	0.317
Cerebrovascular events	5 (2.6)	4 (2.1)	0.736

CABG = coronary artery bypass grafting; DES = drug-eluting stent; MACCE = major adverse cardiac and cerebrovascular events; OPCAB = off-pump coronary artery bypass grafting; PCI = percutaneous coronary intervention; TVR = target vessel revascularization.

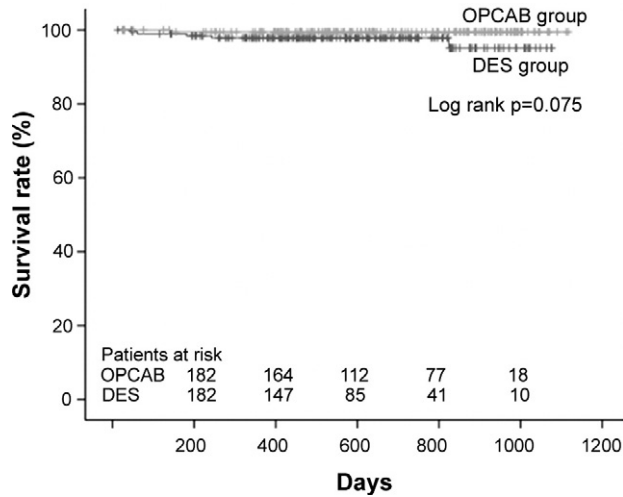


Fig 1. Survival curve comparing the drug-eluting stent (DES) group (bottom line) and off-pump coronary artery bypass grafting (OPCAB) group (top line) using the Kaplan-Meier method.

follow-up duration of 305.6 ± 167.1 days (range, 4 to 1060 days). In-stent restenosis (ISR) was found in 29 sites (12.2% of total stents evaluated) in 26 patients (22.0%). Patency rates of each procedure are summarized in Table 3.

Follow-Up and Events

The overall follow up rate was 98.5%. Three patients in OPCAB group and 3 patients in DES group were lost to follow-up, including 2 patients who went abroad. The overall follow-up duration was 621.1 ± 259.9 days (range, 13 to 1117 days) and was similar between the two groups. There was no 30-day mortality in either group. The 30-day MACCE rate was 1.5% in the DES group and 0.5% in the OPCAB group ($p = 0.315$). There were five late deaths in DES group and one late death in OPCAB group

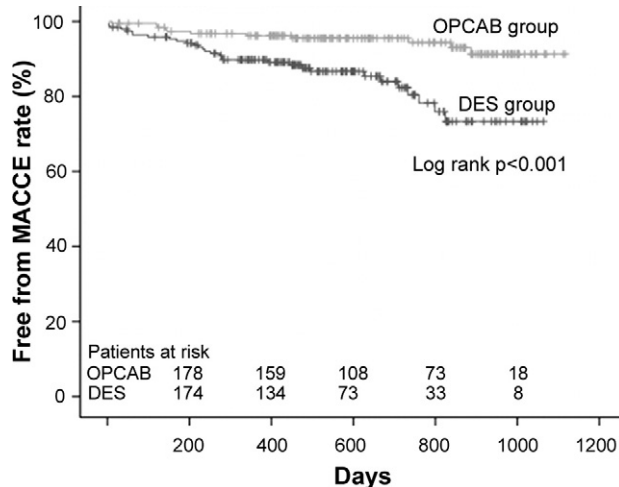


Fig 2. Kaplan-Meier curve shows freedom from major adverse cardiac and cerebrovascular events rate in the drug-eluting stent (DES) group (bottom line) compared with the off-pump coronary artery bypass grafting (OPCAB) group (top line).

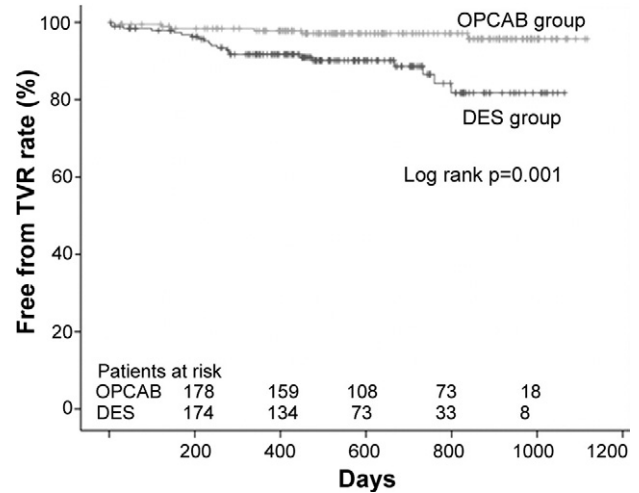


Fig 3. Kaplan-Meier curve shows freedom from target vessel revascularization rate in the drug-eluting stent (DES) group (bottom line) compared with the off-pump coronary artery bypass grafting (OPCAB) group (top line).

($p = 0.100$). In DES group, three deaths were cardiac related, and two deaths were noncardiac related, one of malignancy and the other of sepsis. No deaths in OPCAB group were cardiac-related death, and one patient died of malignancy. The two groups showed no significant differences ($p = 0.082$) in the incidence of cardiac death.

The 1-year MACCE rate was 9.8% in DES group and 3.6% in OPCAB group ($p = 0.015$). The overall MACCE rate was 15.5% in DES group and 5.7% in OPCAB group ($p = 0.002$). The detailed descriptions of MACCEs are summarized in Table 4. According to the Kaplan-Meier method, 3-year survival rate was $95.1\% \pm 2.9\%$ in the DES group and $99.5\% \pm 0.5\%$ in the OPCAB group ($p = 0.075$, Fig 1). The free-from-MACCE survival rate at 3 years was $73.3\% \pm 5.3\%$ in the DES group and $91.3\% \pm 2.9\%$ in the OPCAB group ($p < 0.001$, Fig 2).

During the entire follow-up period, 21 DES patients (10.8%) and 6 OPCAB patients (3.1%) underwent TVR ($p < 0.001$). A TVR procedure was required more than one time in 5 patients in the DES group (23.8% of TVR patients in DES group) and in no patients in OPCAB group. The 6 patients in OPCAB group underwent stent insertion due to graft failure or native disease progression. In DES group, 4 patients were referred to repeat surgical revascularization during the follow-up period. The free-from-*TVR* rate at 3 years was $81.7\% \pm 4.6\%$ in the DES group and $95.7\% \pm 1.9\%$ in OPCAB group, which also showed a significant difference ($p = 0.01$, Fig 3).

Comment

PCI and CABG are two major treatment methods for coronary artery diseases. Since its first introduction as a form of balloon angioplasty, PCI developed from inserting bare-metal stent to the DES. Recently, DESs have gained more popularity due to better clinical outcome compared with bare-metal stents in many randomized to

trials [6]. In the field of CABG, the off-pump technique is now applied in many institutions because of its advantage by avoiding side effects of cardiopulmonary bypass.

Several observational studies comparing the results of PCI and CABG showed better clinical outcome in the CABG patients [7–9], who had better survival and less need for reintervention in multivessel diseases compared with PCI patients. Also, in large series of clinical randomized trials, the CABG groups showed a lower incidence of repeat revascularization [4, 5]. In a meta-analysis of randomized controlled trials of PCI and CABG, CABG has been proven to have lower 5-year mortality, less angina, and fewer revascularization procedures compared with PCI, especially in multivessel disease [10].

In the Medicine, Angioplasty, or Surgery Study (MASS II) trial, which compared medicine, angioplasty, and CABG as therapeutic strategies for multivessel coronary artery disease, CABG was an independent predictor of lower rates of event-free survival [11]. But in real practice, many patients with multivessel disease are referred for PCI, especially after the development of DESs. According to the preliminary report of the SYNTAX trial, CABG still remained as the dominant revascularization strategy, but it is true that there are not enough supporting data for PCI in patients with 3-vessel disease.

Since the introduction of DESs, PCI with DESs is challenging the role of CABG in patients with 3-vessel disease. Determining the most appropriate treatment strategy with evidences in coronary artery diseases has been emphasized in many articles [12–14]. Few reports have compared the results of PCI with DESs vs OPCAB. Several authors reported better clinical outcome in the surgical group regardless of surgical technique (on-pump or off-pump), especially in diabetic patients [15–17]. In our study, we only included patients with 3-vessel disease and compared the results between DESs and OPCAB.

Most studies comparing DESs and OPCAB showed better clinical advantage of OPCAB in repeated revascularization procedures [18, 19], which is in concordance with our results. Although the 30-day MACCE rate was not significantly different between the two groups, differences were evident in the 1-year and cumulative MACCE rate and were mainly attributed to the differences in the mortality rate and TVR rate. An interesting point is that the only death in OPCAB group was caused by hepatocellular carcinoma, which was noncardiac related. In DES group, three deaths were cardiac related and two were noncardiac related. TVR was performed in 6 patients in the OPCAB group, which is comparable with the previous reports [18, 19]. This prognostic benefit of surgical intervention might be more clarified after a longer follow-up period. A larger cohort study with longer follow-up may clarify the benefit of either strategy.

One of the most prominent benefits in the CABG group is complete revascularization. The OPCAB group in our study showed significant differences in the complete revascularization rate. The complete revascularization was defined when the number of revascularized

vessel was same or more than the diseased vessels, which was discussed in the Bypass Angioplasty Revascularization Investigation (BARI) trial [20]. In early experiences of OPCAB, limited revascularization, which leads to a decreased number of distal anastomoses, was pointed out as the weak point of OPCAB compared with conventional CABG. In our data, the rate of complete revascularization was 73.8% and the mean number of distal anastomoses was 3.36. The result can be interpreted that there are no more limitations for revascularization owing to difficult anastomoses sites because of advances in surgical devices for surgeons who are skilled in the off-pump technique.

A direct comparison of postprocedural patency is impossible in this study because of different evaluation methods and follow-up duration between the DES group and the OPCAB group. Although most patients were followed up in the immediate postoperative period, grafts to the right coronary system in OPCAB group showed the worst patency. From this result, we are trying a multidisciplinary approach to multivessel coronary artery disease that involves revascularizing the right coronary artery system by PCI and bypass grafting to left coronary system in selected cases. To define the best treatment strategy for each coronary artery system, patency evaluation with same diagnostic tool for longer period is inevitable.

This is a nonrandomized comparison study. The data of 4 surgeons and 3 interventionists, each of whom might have had different revascularization strategies, were included in this study. Lack of consideration for the characteristics of each native coronary artery disease, such as degree of calcification, degree of stenosis, or length of lesion, adds to the confounding factors, possibly leading to altered postprocedural clinical results. The relatively short follow-up period is another limitation.

However, despite such limitations, this study is significant in that it is an initial experience of DESs since they became available in June 2003 in our institution. A longer follow-up period is essential in evaluation of both short-term and long-term patency of DESs and the incidence of late thrombosis, which has been pointed out in several other reports [21, 22]. The future results of currently ongoing randomized trials (SYNTAX trial, FREEDOM trial) will provide more evidence-based foundation to approach multivessel coronary patients.

In conclusion, the midterm clinical results in patients with 3-vessel disease was better after treatment with OPCAB compared with PCI with DESs. The 1-year MACCE rate and cardiac-related mortality was higher in patients with DESs. A randomized clinical trial comparing the PCI with DES vs OPCAB is needed to obtain the evidence of treatment strategy in patients with 3-vessel coronary artery disease.

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