Guidelines for the Clinical Application of Bypass Grafts and the Surgical Techniques (JCS 2011) Published in 2012

– Digest Version –

JCS Joint Working Group

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Abbreviations

AATS: American Association for Thoracic Surgery	HDL: high density lipoprotein
A-C: aortocoronary	Ho: Holmium
ACC(F): American College of Cardiology (Foundation)	ICU: intensive care unit
ACE: angiotensin converting enzyme	IEA: inferior epigastric artery
ACS: acute coronary syndrome	ITA: internal thoracic artery
AHA: American Heart Association	JACVSD: Japan Adult Cardiovascular Surgery Database
ARB: angiotensin II receptor blocker	JDS: Japan Diabetes Society
ASNC: American Society of Nuclear Cardiology	JSAP: Japanese Stable Angina Pectoris
BARI 2D: Bypass Angioplasty Revascularization Investigation 2 Diabetes	LAD: left anterior descending
BITA: bilateral internal thoracic artery	LDL: low density lipoprotein
BMI: body mass index	LITA: left internal thoracic artery
BMS: bare metal stent	LMT: left main trunk
CABG: coronary artery bypass grafting	MASS II: Medicine, Angioplasty, or Surgery Study
CAD: coronary artery disease	MIDCAB: minimally invasive direct coronary artery bypass
CAS: carotid artery stenting	NGSP: National Glycohemoglobin Standardization Program
CEA: carotid endarterectomy	NHI: National Health Insurance
CCAB: conventional coronary artery bypass grafting	OPCAB: off-pump coronary artery bypass grafting
COPD: chronic obstructive pulmonary disease	OPR: Ontario Province Risk
COURAGE: Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation	PCI: percutaneous coronary intervention
CREDO-Kyoto: Coronary REvascularization Demonstrating Outcome Study in Kyoto	POBA: percutaneous old balloon angioplasty
Cx: circumflex	PTCA: percutaneous transluminal coronary angioplasty
DES: drug eluting stent	QOL: quality of life
DPC: diagnosis procedure combination	RA: radial artery
DSWI: deep sternal wound infection	RCA: right coronary artery
Dx: diagonal	RITA: right internal thoracic artery
EACTS: European Association for Cardiothoracic Surgery	SCAI: Society for Cardiovascular Angiography and Interventions
ESC: European Society of Cardiology	SITA: single internal thoracic artery
EuroSCORE: European System for Cardiac Operative Risk Evaluation	STS: Society of Thoracic Surgeons
FITA: free internal thoracic artery	SVG: saphenous vein graft
GEA: gastroepiploic artery	SYNTAX: SYnergy between percutaneous coronary intervention with TAXus and cardiac surgery
Hb: hemoglobin	TEA: thoracic epidural anesthesia
	TMLR: transmyocardial laser revascularization

Introduction of the Revised Guidelines

Coronary artery bypass grafting (CABG), a procedure started in the 1960s using saphenous vein graft (SVG), has been established as one of the most commonly performed surgical revascularization for the treatment of ischemic heart disease. Since then there have been two major improvements in this procedure.

The first change is the development of arterial graft. After the use of the SVG was found to be associated with a low long-term patency rate due to the rapid progression of atherosclerotic lesions, the use of internal thoracic artery (ITA) grafts became prevalent. Especially, it has been demonstrated that anastomosis of the ITA to the left anterior descending (LAD) artery improves long-term prognosis after CABG. Following the ITA, the clinical use of the right gastroepiploic artery (GEA) and radial artery (RA) as coronary bypass grafts has become common. Total arterial revascularization, a CABG procedure using only arterial grafts, was established.

The second change is the introduction and rapid adoption of off-pump CABG (OPCAB), a form of CABG performed without cardiopulmonary bypass and cardioplegic arrest as an alternative to conventional CABG (CCAB) using cardiopulmonary bypass and cardioplegic arrest.

On the basis of ITA-LAD anastomosis, combining these two improvements resulted in a variety of grafting procedures including composite graft such as T- and Y-graft using the right and left ITA (RITA, LITA), GEA and RA grafts, and sequential graft, a technique to revascularize more than one coronary branch with the same graft, using off-pump techniques.

OPCAB has quickly become prevalent in Japan as it accounted for more than 60% of all CABG cases in an annual survey conducted by the Japanese Association for Thoracic Surgery in 2010. This survey also revealed that CABG using only arterial grafts accounted for 50 to 60% of all CABG cases. These results contrast sharply with the findings in Western countries in which OPCAB is used in about 15% of all CABG cases and the use of LITA-LAD anastomosis and SVG is prevalent.

On the other hand, arterial grafts are known to show typical biological responses that are not observed in vein grafts. When arterial grafts are anastomosed to coronary arteries with low-grade stenosis, the string phenomenon due to competitive flow from the native coronary arteries may develop and result in graft occlusion. The string phenomenon associated with the use of pedunculated ITA or GEA grafts is believed to be due

to insufficient flow capacities of grafts.

The use of RA grafts in CABG had been abandoned due to the frequent occurrence of spasm, but has resumed when calcium channel blockers can effectively prevent spasms of RA grafts.

It also has been known empirically that RA grafts used in aortocoronary (A-C) bypass grafting are often associated with graft occlusion when competitive flow from the native coro-

nary arteries with low-grade stenosis is present, and there is continuing debate on the use of RA grafts in this procedure.

The present guideline document is a partly revision of the “Guidelines for the Clinical Application of Bypass Grafts and the Surgical Techniques (JCS 2006)” prepared as a 2004–2005 JCS Joint Working Groups Report¹ after discussion of the evidence obtained in and outside Japan about patients “who receive which grafts using what procedures”.

Coronary Revascularization (PCI/CABG) for Stable Coronary Artery Disease: Statements and Indications Proposed by the Coronary Revascularization Council

I Statements

1. Purpose of Coronary Revascularization

In patients with stable coronary artery disease (CAD), coronary revascularization is performed to improve long-term prognosis, prevent myocardial infarction and unstable angina, and improve the quality of life (QOL) by reducing anginal symptoms.

2. Collaboration of Interventional Cardiologists and Cardiac Surgeons in Decision-Making Process for Coronary Revascularization

It is desirable that interventional cardiologists and cardiac surgeons discuss to decide how to perform coronary revascularization in patients with severe stable CAD (i.e., patients with left main disease, patients with multivessel disease involving the proximal LAD artery, especially patients with multivessel disease associated with cardiac dysfunction, and diabetic patients with multivessel disease) before proposing treatment options to the patients, and that the patients should decide their treatment options by themselves.

3. Treatment Outcomes of PCI

As compared with recent initial intensive medical therapy alone, percutaneous coronary intervention (PCI) plus medical therapy is effective in reducing anginal symptoms, but does not improve long-term prognosis or prevent myocardial infarction [Level of Evidence: A].

PCI plus medical therapy is not superior to recent initial intensive medical therapy in the prevention of unstable angina [Level of Evidence: B]. On the other hand, data available in Japan indicate the preventive effects of PCI plus medical therapy [Level of Evidence: B].

The incidence of repeat revascularization is lower in patients receiving drug eluting stent (DES) than those receiving percutaneous old balloon angioplasty (POBA) or bare metal stent (BMS) [Level of Evidence: A]. However, there is no conclusive evidence indicating that DES improves long-term prognosis and decreases the incidence of myocardial infarction.

4. Treatment Outcomes of CABG

CABG is effective in reducing anginal symptoms, prevents myocardial infarction, and improves long-term prognosis [Level of Evidence: A]. The use of ITA grafts increases and prolongs the beneficial effects of CABG on long-term prognosis [Level of Evidence: B].

5. PCI and CABG for Patients With Multivessel Disease

In randomized clinical studies in patients with multivessel dis-

ease without left main involvement before the DES era, the incidence of repeat revascularization was higher in patients receiving PCI than those receiving CABG, but these methods did not differ in terms of long-term prognosis and incidence of myocardial infarction [Level of Evidence: A].

In recent comparative studies in the DES era, the long-term prognosis of patients with three-vessel disease without left main involvement is poorer in patients receiving PCI than in those undergoing CABG, and the incidences of myocardial infarction and repeat revascularization are also high in patients receiving PCI [Level of Evidence: B].

6. PCI and CABG for the Treatment of Unprotected Left Main Disease

Basically, patients with unprotected left main disease should be treated with CABG. However, no high-level evidence is available regarding comparisons between CABG and PCI in this patient population. In recent comparative studies in the DES era, the incidence of repeat revascularization was higher in patients receiving PCI than CABG for the treatment of left main disease, but no differences were observed in long-term prognosis and the incidence of myocardial infarction.

II Descriptions

1. Introduction

In 2000, the first guidelines for interventional therapy of CAD in Japan were published.² The interventional therapy described in the guideline included CABG, and recommended indications of elective interventions were described. In 2006, the Guidelines for the Clinical Application of Bypass Grafts and the Surgical Techniques (JCS 2006) were published,¹ and many other guideline documents were published to promote comprehensive treatment of ischemic heart disease, including primary prevention, diagnosis and understanding pathophysiology, treatment strategies, and secondary prevention.

During the ten years since the publication of the “Guidelines on Indications of Elective Intervention (including CABG) in the Treatment of Coronary Artery Disease²”, techniques for coronary revascularization such as PCI and CABG have improved significantly. The Japanese Circulation Society started to revise the guideline documents to reflect the advancement of interventional techniques. During the revision process, a development of restructured guideline documents that systematically describe coronary revascularization and includes the “Guidelines for the Clinical Application of Bypass Grafts and the Surgical Techniques (JCS 2006)” was proposed.¹ A consensus was achieved that the new comprehensive guideline documents will consist of general statements including basic

principles of coronary revascularization such as the merits and demerits of different techniques, a multifaceted comparison between PCI and CABG, and the criteria for selecting between PCI and CABG, and specific guideline documents describing practical matters. The general statements will be consistent with the “Guidelines for Elective Percutaneous Coronary Intervention in Patients with Stable Coronary Disease (JCS 2011)”, which is a revision of the PCI guidelines published in 2000,² and the “Guidelines for the Clinical Application of Bypass Grafts and the Surgical Techniques (JCS 2011)”, which is a revision of the CABG guidelines published in 2006.¹ The present guideline documents discuss stable CAD, and do not include acute-phase CAD.

The joint guidelines on coronary revascularization prepared by the European Society of Cardiology (ESC) and the European Association for Cardiothoracic Surgery (EACTS) in 2010 emphasize the importance of the heart team including general practitioners, interventional cardiologists and cardiac surgeons in the treatment of CAD.³ It is expected that the heart team will play a central role in the treatment of CAD in Japan. To better describe the roles of the heart team, the statements, descriptions, and indications for coronary revascularization in the general statements chapter of the revised PCI and CABG guideline documents were prepared through extensive discussion by the “Coronary Revascularization Council” consisting of interventional cardiologists, cardiac surgeons and diabetes specialists who represent the Japanese Circulation Society, the Japanese College of Cardiology, the Japanese Coronary Association, the Japanese Association of Cardiovascular Intervention and Therapeutics, the Japanese Society for Cardiovascular Surgery, the Japanese Association for Thoracic Surgery, the Japanese Association for Coronary Artery Surgery, and the Japan Diabetes Society.

2. Criteria for Selection of Evidence, Levels of Evidence, Interpretation of Study Results, and Classification of Recommendations

Because these statements represent the basis of guidelines, the statements and descriptions were prepared on the basis only of high-level evidence (**Level A**, evidence demonstrated with more than one randomized clinical studies or meta-analyses, and **Level B**, demonstrated with a randomized clinical study or multicenter, large-scale registry studies). However, as the SYNTAX (SYnergy between percutaneous coronary intervention with TAXus and cardiac surgery) study (www.syntaxscore.com) is the only randomized clinical study that directly compared CABG vs. PCI using DES, the results of sub-analyses, which were **Level C** evidence, were also used. **Level C** evidence represents consensus opinion of experts, small-scale clinical studies, results of sub-analysis, and others.

Classification of Recommendations

- Class I:** There is evidence and/or general agreement that a given procedure/treatment is useful/effective.
- Class II:** There is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a given procedure/treatment.
- Class IIa:** Weight of evidence/opinion is in favor of usefulness/efficacy.
- Class IIb:** Usefulness/efficacy is less well established by evidence/opinion.
- Class III:** There is evidence and/or general agreement that the procedure/treatment is not useful/effective, and in some cases may be harmful.

Although the true treatment outcome can be assessed in randomized clinical studies, it is difficult to assess the validity of indications and treatment outcomes of PCI and CABG in the actual clinical practice by using the results of randomized clinical studies and meta-analyses only. We thus placed emphasis on the results of multicenter, large-scale registry studies. It has been widely known that the clinical characteristics, treatment strategies and outcomes of patients with stable CAD in Japan differ from those in Western countries, but much of high-level evidence available is on the Western patient populations. We should create patient database of PCI and CABG and assess the data to establish evidence in patients in Japan.

3. Purpose of Coronary Revascularization: Statement #1

The most important purpose of coronary revascularization for stable CAD is to improve long-term prognosis by preventing the incidence of myocardial infarction and unstable angina. Because stable CAD may often manifest as angina, management of angina to improve QOL is also an important purpose.

4. The Importance of Collaboration Between Interventional Cardiologists and Cardiac Surgeons in Decision-Making Process for Coronary Revascularization: Statement #2

PCI and CABG, two different approaches sharing a common goal of ensuring successful coronary revascularization, have different risks and benefits. When physicians consider whether PCI or CABG is better for a given patient, they should assess the expected outcomes of each technique on the patient as well as the risk of complications (e.g., stroke, infections, contrast-induced nephropathy, and radiation exposure), the safety and invasiveness of the technique used, expected duration of hospitalization, medical cost, and underlying diseases to determine the optimal treatment strategy for the patients.

Especially in patients of severe stable CAD (i.e., patients with left main disease, patients with multivessel disease involving the proximal LAD artery, especially patients with multivessel disease associated with cardiac dysfunction, and diabetic patients with multivessel disease), interventional cardiologists and cardiac surgeons should discuss to determine treatment options, and should fully inform patients about the expected short- and long-term treatment outcomes of PCI and CABG, the safety and invasiveness of these techniques, and the possibility of requiring further treatment before obtaining informed consent. When the heart team, a multidisciplinary team of healthcare professionals including interventional cardiologists and cardiac surgeons, is difficult to establish in the hospital due to the unavailability of cardiac surgeons, it is desirable to collaborate with nearby hospitals providing cardiac surgery services to ensure the safe treatment. Because the treatment outcomes of PCI and CABG may largely depend on the skill and expertise of interventionists/surgeons and medical team members, physicians should consider these factors carefully to determine what is the optimal treatment strategy for each patient. Data on the results in individual institutions such as the number of patients treated, severity of CAD, and short- and long-term outcomes should be accumulated and analyzed in a formal framework.

5. Treatment Outcomes of PCI: Statement #3

A meta-analysis of 11 randomized clinical studies of PCI in a total of 2,950 patients with stable CAD revealed that PCI does not improve long-term prognosis or prevent myocardial infarction as compared with patients receiving initial medical therapy.⁴ In the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation), a randomized

clinical study in 2,287 patients with stable angina (excluding patients with left main disease; proximal LAD disease was present in 31%, one-vessel disease in 31%, two-vessel disease in 39%, three-vessel disease in 30%, and diabetes in 32%), patients were randomized to receive PCI with optimal medical therapy (PCI plus medical therapy group) or to start optimal medical therapy and receive PCI whenever necessary (initial intensive medical therapy group).⁵ All patients received optimal medical therapy during the study (treatment targets were (1) smoking cessation, (2) low density lipoprotein [LDL] levels of 60 to 85 mg/dL, (3) high density lipoprotein [HDL] level of ≥ 40 mg/dL, (4) triglyceride of <150 mg/dL, 30 to 45 minutes of moderate exercise 5 times per week, body mass index [BMI] of <25 kg/m², blood pressure of $<130/85$ mmHg, and hemoglobin A1c [HbA1c] [National Glycohemoglobin Standardization Program; NGSP value]* of $<7.0\%$). During the follow-up period for 4.6 years, there were no differences between the two groups in the incidences of death, myocardial infarction and unstable angina. In the BARI 2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes), a randomized clinical study in 1,605 patients with type 2 diabetes (excluding patients with left main disease; proximal LAD disease was present in 10.3%, and three-vessel disease in 20.3%; the prevalences of one- and two-vessel disease were not reported), there were no significant differences in the incidences of death and myocardial infarction during the 5.3-year follow-up period between patients receiving PCI plus medical therapy and patients receiving initial intensive medical therapy and undergoing PCI whenever necessary.^{6,7} All patients received initial intensive medical therapy during the study (treatment targets were HbA1c [NGSP value] of $<7.0\%$, LDL level of <100 mg/dL, and blood pressure of $<130/80$ mmHg). The reasons why PCI plus medical therapy did not improve the incidences of death and myocardial infarction may include the following: (1) Because unstable plaques, a major cause of acute coronary syndrome (ACS), are often present in nonsignificant stenotic lesions, while significant stenoses causing anginal symptoms are often related to stable plaques, treatment of significant stenoses by PCI did not affect the incidences of myocardial infarction and death; (2) The incidence of cardiac accidents in patients receiving initial intensive medical therapy was lower than expected in both the COURAGE and BARI 2D studies, and these results are considered to reflect favorable efficacy of systemic treatment with aggressive risk management strategies. (3) Among patients receiving initial intensive medical therapy, patients with severe myocardial ischemia not responding to medical therapy, which accounted for 30 to 40%, underwent PCI for culprit lesions and showed an improvement in myocardial ischemia. As mentioned in the item (3) above, about one in three patients receiving initial intensive medical therapy underwent PCI. This means that these studies compared a group of patients undergoing PCI at the initiation of the study and a group of patients among whom PCI was conducted for selected patients whenever necessary. The absence of differences between the PCI plus medical therapy group and the initial intensive medical therapy group does not lead the conclusion that PCI does not improve long-term prognosis or prevent myocardial infarction. In order to demonstrate the effects of PCI on the incidences of death and myocardial infarction in clinical studies, patients not responding to medical therapy should be followed up for a long period of time without conducting PCI, but such studies are not allowed for ethical reasons.

*In Japan, HbA1c has been encouraged to report as the NGSP

value rather than the conventional JDS (Japan Diabetes Society) value from April 1, 2012, onward. The relationship between the NGSP and the conventional JDS is as follows: $\text{NGSP value (\%)} = 1.02 \times \text{JDS value (\%)} + 0.25\%$. Within the clinically relevant range between 5.0 to 9.9% (JDS), the relationship may be expressed as follows: $\text{HbA1c (NGSP)} = \text{HbA1c (JDS)} + 0.4\%$.

In the COURAGE study, patients in the PCI plus medical therapy group showed less anginal symptoms and better QOL as compared with those in the initial intensive medical therapy group, but these differences disappeared in the second to third year of the study.⁸ These findings may be explained by the study design where in the initial intensive medical therapy group patients not responding to medical therapy underwent PCI.

In the JSAP (Japanese Stable Angina Pectoris), a randomized clinical study in 384 low-risk patients with stable angina (one-vessel disease was present in 67.5%, two-vessel disease in 38.5%, and diabetes in 39.6%; patients with left main disease, those with three-vessel diseases, and those with proximal LAD disease were excluded), patients undergoing PCI plus medical therapy did not appear to be superior to patients with initial medical therapy (at the discretion of the treating physicians) in terms of the incidences of death and myocardial infarction during the 3.2-year follow-up period.⁹ In contrast to the COURAGE study, the JSAP study demonstrated that PCI plus medical therapy prevented the development of unstable angina and reduced anginal symptoms, and the differences were observed even in the third year of the study. Although the two studies cannot be compared directly as they are substantially different in terms of patient characteristics and drug treatment, the difference between the results of the COURAGE and JSAP studies may be explained with the following two facts. (1) While an aggressive intervention for multiple risk factors was made in the COURAGE study, in the JSAP study drug treatment such as statin therapy during the follow-up period was performed at the discretion of treating physicians. (2) The incidence of ACS developing as an acute complication of PCI may be lower among patients in Japan than among Western patients.

The results of meta-analyses revealed that the incidence of revascularization was significantly lower in patients receiving DES than BMS, indicating that DES is effective in the prevention of restenosis.^{10,11} However, although the restenosis rate has been decreasing as PCI devices become more advanced from POBA, BMS to DES, the incidences of death and myocardial infarction among patients receiving coronary revascularization have not improved.^{10,11} The absence of improvement is thought to be a result of the following facts: (1) Because repeat PCI for restenosis is easily and frequently performed, the advancement of stents used in PCI has little influence on the severity of myocardial ischemia after repeat PCI; and (2) PCI has been indicated for severer CAD as PCI devices become more advanced.

6. Treatment Outcomes of CABG: Statement #4

In a systematic overview using individual patient data from 7 randomized clinical studies in a total of 2,649 patients with stable CAD (among whom left main disease was present in 6.6%, proximal LAD disease in 59.4%, one-vessel disease in 10.2%, two-vessel disease in 32.4%, and three-vessel disease in 50.6%, and diabetes in 9.6%), Yusuf et al. reported in 1994 that the initial CABG group had significantly lower risk of death than the initial medical treatment group (37.4% of patients underwent CABG during the study period), and demon-

strated that CABG is effective in improving long-term prognosis.¹² The improvement in long-term prognosis became apparent at 5 years, and also observed at 10 years. A sub-analysis revealed that the risk reduction was greater in patients with proximal LAD disease, those with three-vessel disease, those with left main disease, and those with cardiac dysfunction, and the risk reduction was highest in patients with left main disease. Initial CABG was not effective in this regard for patients with one- or two-vessel diseases.

The ITAs are considered “the gold standard” of CABG grafts because of the favorable long-term graft patency. In a large multicenter registry in the United States, ITA grafts conferred a survival advantage as compared with vein grafts.¹³ The survival curves of the two groups showed separation over the years of follow-up, with a more marked downsloping after 8 years and thereafter during the follow-up period (mean, 16.8 years). In a meta-analysis of observational studies, Taggart et al. reported that bilateral ITA (BITA) grafts give better survival rates than single ITA grafts.¹⁴

Yusuf et al. analyzed the results of randomized clinical studies conducted in 1972 and 1984, which do not reflect the current surgical procedures and drug regimens.¹² The readers should be aware that (1) the 30-day mortality of patients undergoing CABG was 3.2%, which was higher than those in recent studies; (2) the use of ITA grafts, which are known to improve long-term prognosis, was limited to <10% of patients; and (3) patients did not receive statins, calcium channel blockers, angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs) that are commonly administered to patients undergoing CABG.

In the BARI 2D study recently conducted in 763 patients with type 2 diabetes (proximal LAD disease was present in 19.4%, and three-vessel disease in 52.4%; the prevalences of one- and two-vessel diseases were not reported), at 5-year follow-up, incidence of death did not differ significantly between the CABG and the initial intensive medical therapy group (39.7% of the patients underwent coronary revascularization during the study).⁶ In the MASS II (Medicine, Angioplasty, or Surgery Study), a randomized clinical study in 611 patients with multivessel disease (not including patients with left main disease and patients with cardiac dysfunction), the overall mortality and incidence of cardiac death at the 5-year follow-up did not differ significantly between the CABG group and the medical therapy group (39.4% of the patients underwent coronary revascularization during the study).¹⁵ However, the incidence of cardiac death at the 10-year follow-up was significantly lower in the CABG group than the medical therapy group, although the overall mortality did not differ between the two groups.¹⁶ At the present time when intensive medical therapy is available, the beneficial effect of CABG on long-term prognosis may have become smaller than before, or longer follow-up is required to demonstrate a significant difference between CABG and intensive medical therapy. Randomized clinical studies for at least 10 years should be performed to determine the true beneficial effects of CABG on long-term prognosis and how long such effect will continue.

The results of the BARI 2D study indicated that CABG was superior to initial intensive medical therapy in terms of the prevention of myocardial infarction⁷ and QOL including activity status.¹⁷ In the MASS II, the incidence of myocardial infarction at 10-year follow-up was lower in the CABG group than in the medical therapy group.¹⁶ The mechanism of the prevention of acute myocardial infarction in patients receiving CABG is thought to be “distal protection” in which bypass grafts may protect myocardium distal to a ruptured plaque when

a graft is connected to the distal part of the clogged artery.¹⁸ During the 10-year follow-up in the MASS II, patients in the CABG group showed a greater improvement in anginal symptoms than the initial medical therapy group.¹⁶

7. Important Points to Be Considered When Interpreting the Results of Randomized Clinical Studies Comparing PCI and CABG

A large number of randomized clinical studies have been conducted to compare PCI and CABG. Physicians should consider the following three points when interpreting the results of such studies. First, because patients with left main disease or three-vessel disease have been historically considered to require CABG, patients with left main disease have been excluded in the majority of randomized clinical studies, and the percentage of patients with three-vessel disease has been small. These studies have been conducted in patients with coronary stenosis treatable with PCI, and patients with complex lesions that require CABG rather than PCI have not been enrolled in these studies. Second, it is believed that 5 to 10 years of follow-up is required to confirm the treatment outcomes of CABG over PCI, but the observation period is often too short in many studies. Third, the importance of intensive medical therapy is widely acknowledged, but drug regimens during the follow-up period differ between the PCI and CABG groups.

The SYNTAX, the only randomized clinical study to date that directly compared between CABG and PCI with DES, was intended to show non-inferiority of PCI compared with CABG in 1,800 patients with left main disease or three-vessel disease (left main disease was present in 39%, three-vessel disease in 61%, and diabetes in 25%). For the primary endpoint, the 12-month rate of major adverse cardiac or cerebrovascular events (i.e., death, stroke, myocardial infarction, or repeat revascularization), were significantly higher in the PCI group, so the non-inferiority of PCI as compared with CABG was not demonstrated.¹⁹ At 3-year follow-up, the incidences of death (CABG 6.7% vs. PCI 8.6%) and stroke (CABG 3.4% vs. PCI 2.0%) were not significantly different between the treatment groups. However, the incidences of myocardial infarction (CABG 3.6% vs. PCI 7.1%) and repeat revascularization (CABG 10.7% vs. PCI 19.7%) were higher in PCI-treated patients.²⁰ It should be noted that among 3,075 patients registered in the SYNTAX study, 1,800 patients (59%) were considered to be indicated for both PCI and CABG and were randomly assigned to undergo CABG or PCI with DES, while the remaining 1,275 patients were enrolled in the registry study because 84% of them (1,077 patients) were indicated only for CABG, and 16% of them (198 patients) were indicated only for PCI. The most common reasons for the enrollment in the CABG registry were complex lesions inaccessible to PCI (70.9%) and chronic total occlusion (22.0%), while those in the PCI registry were underlying diseases (70.7%) and unavailability of suitable grafts (9.1%). Patients in the randomized cohort will continue to be followed for 5 years. Patients in the CABG cohort were less likely to receive antiplatelet drugs, statins, β -blockers, ARBs, and calcium channel blockers than those in PCI cohort.

8. PCI and CABG for Patients With Multivessel Disease: Statement #5

Hlatky et al. conducted a collaborative analysis of data from 10 randomized trials comparing between CABG and PCI not using DES which provided data on 7,812 patients (proximal LAD disease was present in 51%, two-vessel disease in 63%, three-vessel disease in 37%, and diabetes in 16%), and reported that the incidence of repeat revascularization during the 6-year

follow-up period was higher in patients receiving PCI than CABG, but the incidences of death and myocardial infarction did not differ significantly between the two groups.²¹ However, a sub-analysis of the SYNTAX study revealed incidences of death, myocardial infarction and repeat revascularization in patients with three-vessel disease were lower in patients undergoing CABG than those receiving PCI with DES. When patients with three-vessel disease were further classified into those with higher and lower SYNTAX scores, those with lower SYNTAX scores showed no significant differences in incidences of death, myocardial infarction and stroke between PCI and CABG, while those with higher SYNTAX scores showed superiority of CABG in these measures. According to these data, the ESC/EACTS Guidelines on Myocardial Revascularization published in August 2010,³ CABG is a **Class I** recommendation with **Level of Evidence: A** for patients with three-vessel disease, and PCI is a **Class IIa** recommendation for patients with three-vessel disease and a SYNTAX score of ≤ 22 , and a **Class III** recommendation for patients with complex three-vessel disease and a SYNTAX score of ≥ 23 .

Observational studies such as the CREDO-Kyoto (Coronary REvascularization Demonstrating Outcome Study in Kyoto) PCI/CABG registry in Japan²² and a registry study in New York State²³ have compared PCI and CABG in the treatment of multivessel disease without left main involvement in the clinical setting. In the CREDO-Kyoto registry in 5,420 patients (proximal LAD disease was present in 80%, two-vessel disease in 49%, three-vessel disease in 51%, diabetes in 46%, and total occlusion in 40%), the risk-adjusted mortality tended to be higher in PCI without DES than CABG, and significantly higher in PCI than CABG in diabetic patients and patients with cardiac dysfunction. However, there were no differences between PCI and CABG when compared in patients < 75 years of age. In the New York State registry study in 17,400 patients (proximal LAD disease was present in 52%, two-vessel disease in 56%, three-vessel disease in 41%, and diabetes in 38%), the incidence of repeat revascularization, risk-adjusted incidence of myocardial infarction, and mortality were lower in CABG than PCI with DES. The incidences of death and myocardial infarction were lower in CABG than PCI in patients with two- or three-vessel disease group, elderly patients ≥ 80 years of age, and patients with cardiac dysfunction. In an analysis of 6,327 patients with multivessel and/or left main disease in the CREDO-Kyoto registry, the risk-adjusted mortality and incidences of myocardial infarction and repeat revascularization during the 3.5-year follow-up period were higher in patients after PCI than those after CABG.²⁴ Mortality was also higher in PCI than CABG in patients with diabetes, patients with cardiac dysfunction, patients with proximal LAD disease, and elderly patients ≥ 75 years of age. The incidence of stroke was lower in PCI than CABG, but did not differ between PCI and OPCAB.

9. PCI and CABG for Patients With Left Main Disease: Statement #6

In a systemic overview of individual patient data from 7 randomized clinical studies, Yusuf et al. reported that the reduction in risk of death by CABG as compared with medical therapy was greatest in patients with left main disease.¹² Recent studies of stents vs. CABG for left main disease suggested that PCI might be an acceptable treatment option for patients with left main disease.²⁵ However, these studies included patients with stable CAD and patients with ACS. To date, there have been no well-conducted observational studies or randomized clinical studies that compared between PCI and

CABG for the treatment of unprotected left main lesions in patients with stable CAD. Accordingly, CABG rather than PCI has been selected in coronary revascularization for patients with left main disease.

In the ACCF/SCAI/STS/AATS/AHA/ASNC (American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions/Society of Thoracic Surgeons/American Association for Thoracic Surgery/American Heart Association/ American Society of Nuclear Cardiology) 2009 Appropriateness Criteria for Coronary Revascularization, CABG is considered as an appropriate procedure for unprotected left main disease, while PCI is considered inappropriate even for isolated left main lesions.²⁶ The 2009 Focused Updates of the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction and ACC/AHA/SCAI Guidelines on Percutaneous Coronary Intervention describe recommendations for PCI for unprotected left main disease as follows:²⁷ PCI of the left main coronary artery with stents as an alternative to CABG may be considered in patients with anatomic conditions that are associated with a low risk of PCI procedural complications (i.e., isolated left main lesions or left main plus one-vessel disease) and risk factors such as severe lung disease, prior thoracic surgery, or poor bypass graft targets that would make CABG a high-risk procedure or unlikely to be successful. Conversely, CABG for unprotected left main disease may be relatively more favorable for patients with left main plus multivessel disease, distal/bifurcation left main lesions, or low surgical risk with a good chance of technical success.²⁷ In the j-Cypher registry, a multicenter large-scale registry of patients undergoing sirolimus-eluting stent implantation in Japan, among patients with bifurcation lesions who underwent PCI for unprotected left main disease, patients with stenting of both the main and side branches using two-stent strategy had significantly higher incidences of cardiac death and revascularization than those with main-branch stenting alone using one-stent strategy.²⁸

The results of a sub-analysis of SYNTAX study after 3-year follow-up, the incidence of repeat revascularization was lower in patients undergoing CABG than those receiving PCI with DES, although the incidences of death and myocardial infarction did not differ between the two groups.²⁰ Among patients with left main disease and lower SYNTAX scores, there were no differences in incidences of death, myocardial infarction and stroke between the PCI with DES and CABG groups, while among those with higher SYNTAX scores, incidences of death and myocardial infarction tended to be lower in CABG than PCI with DES groups. However, we should be aware of the limitations of randomized clinical studies. In the SYNTAX study, 312 (29%) of the 1,085 patients with left main disease who were enrolled in the study were considered to be indicated only for CABG, and were enrolled in the registry study. In August 2010, the ESC and the EACTS published joint guidelines on myocardial revascularization. In the ESC/EACTS joint guidelines, CABG is a **Class I** recommendation with **Level of Evidence: A** for patients with left main disease on the basis of the results of the SYNTAX study.³ PCI is a **Class IIa** or **IIb** recommendation with **Level of Evidence: B** for patients with isolated ostial or shaft lesions of the left main coronary artery or patients with left main plus one-vessel disease, and is a **Class IIb** or **III** recommendation for the treatment of bifurcation lesions in patients with isolated left main coronary artery/left main plus one-vessel disease or the treatment of left main plus multivessel disease.

Table 1. Indications of PCI and CABG

Anatomical conditions	PCI	CABG
1- or 2-vessel disease		
No proximal LAD lesions	I A	IIb C
Proximal LAD lesions (without ostial LAD lesions)	I C	I A
Ostial LAD lesions	IIb C	I A
3-vessel disease		
No proximal LAD lesions	IIb B	I A
Proximal LAD lesions	III B	I A
Unprotected left main disease		
Isolated ostial or shaft lesions plus 1-vessel disease	IIb C	I A
Isolated bifurcation lesions or bifurcation lesions plus 1-vessel disease	III C / IIb C*	I A
Multivessel disease	III C	I A

*IIb recommendation for patients with no lesions involving the ostium of the circumflex artery for whom the use of PCI has been approved by the heart team including cardiac surgeons.

CABG, coronary artery bypass grafting; LAD, left anterior descending coronary artery; PCI, percutaneous coronary intervention.

III Indications for Coronary Revascularization (PCI/CABG) in Patients With Stable Coronary Artery Disease (Table 1)

1. Lifestyle intervention and drug treatment are essential components of the treatment of stable CAD. Coronary revascularization should be performed for patients in whom the improvement of physical conditions and long-term prognosis are expected.
2. Patients with one- or two-vessel disease without proximal LAD involvement are indicated for PCI. Both PCI and CABG should be considered for patients with one- or two-vessel disease with proximal LAD involvement. CABG should be considered for patients with ostial LAD lesions.
3. Patients with three-vessel disease should be treated with CABG, in principle, but may be treated with PCI when they have risk factors that would make CABG a high-risk procedure, or when PCI is considered to be a safe procedure because of the absence of proximal LAD lesions or other lesions.

4. Basically, patients with unprotected left main disease should be treated with CABG, but PCI may be alternative to CABG when they have risk factors that would make CABG a high-risk procedure, or when PCI is considered to be a safe procedure because of targeting ostial/shaft lesions of left main trunk (LMT) or other lesions. PCI must be conducted in a condition where emergency CABG can be performed without delay.

The above indications are provided as basic principles. Treatment strategies for individual patients should be determined on the basis of their clinical and anatomical characteristics, the results and systems available in each institution, the long-term treatment goals, and others. Especially for patients with severe CAD, interventional cardiologists and cardiac surgeons should discuss and decide optimal treatment options to be proposed to the patients.

A PCI/CABG registry must be established as soon as possible to prepare for the revision of the guideline documents on the basis of clinical evidence in Japan.

I Surgical Techniques

1. Conventional On-Pump and Off-Pump CABG

The characteristic features of CABG in Japan include: (1) a significantly higher prevalence of PCI than other countries; (2) the number of patients undergoing CABG per institution is small; (3) the elderly account for a large proportion of patients undergoing CABG; (4) OPCAB is prevalent; and (5) the use of arterial grafts is common.

With these differences, it is difficult to adopt CABG guidelines published in Western countries without modifications, and we should discuss matters to be considered to ensure wide use of OPCAB. In Japan, the Japanese Association for Thoracic Surgery has conducted academic research on CABG²⁹ and the Japanese Association for Coronary Artery Surgery has published annual reports on the results of national questionnaires on coronary surgery.³⁰ The Japan Cardiovascular Surgery Database Organization has published the data of the Japan Adult

Cardiovascular Surgery Database (JACVSD), and the results of risk assessment.^{31,32} We discussed the results of CABG in Japan reported as above and the results of large-scale studies of CABG in foreign countries to provide the following recommendations.

1. Indications of Conventional On-Pump CABG^{29,30,33–37}

- Patients who are hemodynamically unstable and are not suitable for OPCAB or those who are undergoing cardiopulmonary bypass. [Class I, Level of Evidence: B]
- Patients in whom a significant stenosis is present in a coronary artery which cannot be surgically exposed or safely accessed in an off-pump fashion due to anatomical or hemodynamic characteristics and complete revascularization can be achieved using cardiopulmonary bypass. [Class IIa, Level of Evidence: B]
- Patients in whom the target artery may not be sufficiently exposed or safely accessed in an off-pump fashion due to

anatomical or hemodynamic characteristics. [Class IIb, Level of Evidence: C]

- The following patients in whom the risk of complications during the acute phase of cardiopulmonary bypass such as cerebral infarction is high: [Class III, Level of Evidence: B]
 1. Patients with significant calcification or atherosclerosis in the ascending aorta, aortic arch, or carotid artery.
 2. Elderly patients.
 3. Diabetic patients with poor glycemic control.
 4. Patients with a history of cerebral infarction.

2. Comparison of Outcome of On-Pump vs. Off-Pump CABG^{30,34,35,38–42}

- In low-risk patients, there are no significant differences in surgical mortality (death within 30 days after surgery) and one- or two-year mortality between OPCAB and CCAB. [Class I, Level of Evidence: A]
- In high-risk patients, OPCAB decreases short-term mortality as compared with CCAB. [Class I, Level of Evidence: B]
- The incidence of perioperative complications is lower in patients undergoing OPCAB than those undergoing CCAB. [Class I, Level of Evidence: A]
- Patients undergoing OPCAB have shorter durations of mechanical ventilation, intensive care unit (ICU) stay, and hospitalization, significantly smaller amount of bleeding, and significantly less use of blood products as compared with patients undergoing CCAB. [Class I, Level of Evidence: A]

3. Short-Term Mortality^{30,31,40}

- In high-risk patients such as elderly patients and patients receiving hemodialysis, OPCAB decreases the risk of short-term mortality as compared with patients undergoing CCAB. [Class I, Level of Evidence: B]
- Conversion from OPCAB to CCAB increases the risk of short-term mortality. [Class IIa, Level of Evidence: B]

4. Brain Dysfunction^{43–55}

- Avoidance of surgical procedures involving the ascending aorta may decrease the risk of brain dysfunction. [Class I, Level of Evidence: A]
- The incidence of postoperative brain dysfunction is lower in

patients undergoing OPCAB than those undergoing CCAB. [Class IIa, Level of Evidence: A]

5. Deep Sternal Wound Infection and Mediastinitis^{43,56–69}

- OPCAB decreases the risk of deep sternal wound infection (DSWI). [Class IIa, Level of Evidence: B]
- Skeletonization of the ITA decreases the risk of DSWI. [Class IIa, Level of Evidence: B]
- In patients with diabetes, BITA grafting may impair sternal wound healing, and is a risk factor for DSWI. [Class IIa, Level of Evidence: B]
- Appropriate glycemic control decreases the risk of DSWI. [Class IIa, Level of Evidence: B]

6. Renal Failure^{70–76}

- In patients without renal dysfunction, OPCAB decreases the risk of postoperative renal dysfunction. [Class IIa, Level of Evidence: C]
- In patients with moderate or severe renal dysfunction, OPCAB is not superior to CCAB in terms of renal protective effect. [Class IIa, Level of Evidence: B]
- Renal function in the remote period after CABG is not affected by the type of CABG techniques. [Class IIa, Level of Evidence: B]

7. Long-Term Outcome^{42,77–87}

- Grafting of the ITA to LAD artery has a favorable long-term patency rate, and may thereby improve long-term survival and prevent cardiac accidents. [Class I, Level of Evidence: B]
- The long-term outcome is better in patients undergoing BITA grafting than those undergoing single ITA (SITA) grafting. [Class IIa, Level of Evidence: B]
- The long-term outcome is better in patients undergoing revascularization using arterial grafts only than those using arterial and vein grafts. [Class IIa, Level of Evidence: B]
- Achievement of complete revascularization is effective in improving mid- and long-term survival and preventing cardiac accidents. [Class IIa, Level of Evidence: B]
- Assessment of graft patency during CABG procedures improves the long-term patency rate. [Class IIa, Level of Evidence: C]

II Graft Vessels

1. Left Internal Thoracic Artery^{88–103}

- The LITA should be used preferentially to bypass the LAD artery. [Class I, Level of Evidence: B]
- The use of LITA to bypass the circumflex (Cx) artery is inferior to the use of LITA to bypass the LAD artery in terms of outcome. [Class IIa, Level of Evidence: B]
- Skeletonization of the LITA ensures a longer available length of the graft and higher blood flow. [Class IIa, Level of Evidence: B]

2. Right Internal Thoracic Artery^{60,80,91,96,104–137}

- BITA grafting decreases both long-term mortality and morbidity after CABG. [Class IIa, Level of Evidence: B]
- In-situ RITA grafting to the left coronary artery system should be prioritized over those to the right coronary artery (RCA)

system. [Class IIa, Level of Evidence: B]

3. Right Gastroepiploic Artery^{107,138–175}

- The right GEA grafting to the RCA system is comparable to the results of RCA grafting using other arterial grafts, and is beneficial. [Class IIa, Level of Evidence: B]
- Right GEA grafts and SVGs are comparable in terms of the long-term prognosis after CABG to the RCA system. [Class IIa, Level of Evidence: B]

4. Inferior Epigastric Artery

The inferior epigastric artery (IEA) is used as a composite or free graft. Because the IEA cannot be harvested concomitantly with the ipsilateral ITA, indications for IEA grafts are limited, and no sufficient evidence to support the use of IEA grafts has

been obtained.

5. Radial Artery^{159,176–194}

- When the RA is used to bypass non-LAD arteries, its graft patency rate is comparable with the patency rate of the ITA and other arterial grafts. [Class IIa, Level of Evidence: B]
- Patency rate of the RA graft does not differ significantly between when the proximal side of the RA graft is anastomosed to the in-situ ITA and when it is anastomosed to the aorta (A-C bypass). [Class IIa, Level of Evidence: B]
- Patency rate of the RA graft is superior to that of the SVG when it is used in A-C bypass. [Class IIa, Level of Evidence: B]
- Patency rate of the RA graft is unfavorable when it is used to bypass moderately stenosed coronary arteries. [Class IIa, Level of Evidence: B]

6. Saphenous Vein Grafts^{160,187–190,195–214}

Although SVG was used commonly in the earliest era of CABG,

the use of arterial grafts rather than SVG is preferred as long-term patency rate of SVG for CABG is not favorable. However, SVG is still commonly used in CABG. SVG is the grafts of choice for emergency rescue CABG because SVG can be harvested without disturbing the surgical field.

- The 10-year patency rate of SVG is about 60%. When it is used to graft the second target coronary artery in the presence of LITA grafted to the LAD, the patency rate and outcome of RA graft is superior to SVG. [Class IIb, Level of Evidence: B]
- Long-term patency rate of SVG is inferior to that of GEA grafts when used to graft the RCA. [Class IIb, Level of Evidence: B]
- Endoscopic harvesting may decrease the incidences of wound complications and infections without affecting the nature and short-term patency rate of SVG. [Class I, Level of Evidence: A]

III Graft Arrangement

1. In-Situ Graft^{77,88,89,91,96,100,102,108,113,114,119–121,123,124,134,149,153,167,215–223}

- The in-situ LITA is the graft of choice for the LAD. [Class I, Level of Evidence: B]
- The quality of in-situ RITA is expected to be high as that of LITA when used to graft the LAD. [Class I, Level of Evidence: B]
- The long-term outcome of BITA grafting to the left coronary artery system is expected to be more favorable than SITA grafting because it decreases mortality and morbidity after CABG. [Class IIa, Level of Evidence: B]
- Although the flow capacity of in-situ ITA is lower than the SVG anastomosed to the aorta, it responds to the flow demand of the recipient coronary arteries and increases flow volume and internal diameter. When used to graft native coronary arteries with low-grade stenosis, competitive flow may occur readily. [Class I, Level of Evidence: B]
- Ultrasonic complete skeletonization increases the length of in-situ ITA. Skeletonization may also decrease the risk of sternal wound infection after BITA grafting. [Class IIa, Level of Evidence: B]
- The in-situ GEA to graft the RCA system is beneficial when the graft size is considered carefully in each case. [Class IIa, Level of Evidence: B]

2. Free Grafts

1. Anastomosis to the Ascending Aorta^{159,160,179,180,187,188,190,195,197, 224–227}

- The 10-year patency rate of SVG anastomosed to the ascending aorta is about 50%. Patency rate of SVG anasto-

mosed to the LAD is higher than that of SVG anastomosed to non-LAD arteries. [Class IIa, Level of Evidence: B]

- Patency rate of RA grafts anastomosed to the ascending aorta in A-C bypass is superior to that of SVG. [Class IIa, Level of Evidence: B]
- When the RA is used to graft coronary arteries, competitive flow from the native coronary artery with low-grade stenosis can cause occlusion of the grafts even in cases of A-C bypass where graft blood flow is expected to be large. [Class IIa, Level of Evidence: B]
- When grafts are anastomosed during partial occlusion clamp of the ascending aorta, care should be taken to avoid the occurrence of atheromatous emboli from the aortic wall. [Class IIa, Level of Evidence: C]
- Anastomotic devices to avoid partial occlusion clamp of the ascending aorta during OPCAB have been developed. Further studies should be conducted to evaluate the efficacy and reliability of these devices. [Class III, Level of Evidence: C]

2. Composite Grafts^{159,173,179,187,228–242}

- When a LITA graft is connected to either a RITA or RA graft to make a Y-composite graft, the LITA may provide flow capacity that satisfies the demand of the recipient coronary arteries. [Class I, Level of Evidence: B]
- LITA-RITA or LITA-RA composite grafts enable revascularization using arterial grafts, and are expected to provide high long-term patency rate. [Class I, Level of Evidence: B]
- Competitive flow with the recipient coronary arteries may occur in composite grafts. Care should be taken when composite grafts are anastomosed to coronary arteries with low-grade stenosis. [Class IIa, Level of Evidence: B]
- Vein grafts should not be proximally anastomosed to the in-situ ITA to be used as branches of Y-composite grafts. [Class IIa, Level of Evidence: C]

IV Selection of Graft Vessels Suitable for the Target Vessels

Graft selection should be based on the need for target vessel revascularization, available grafts (Table 2), long-term graft patency rates (Table 3)^{96,124,156,158,160,205} and other factors. In terms of the need for target vessel revascularization, the LAD is believed to be the most important coronary vessel due to the large size of myocardium perfused by the LAD. Table 2 lists graft vessels that can be used to bypass for each coronary artery. Physicians should select the most suitable graft for each target coronary artery from the available options.

1. Left Anterior Descending Artery^{96,124,156,158,160,205,243}

- Expected long-term patency rate after CABG is highest in the LAD artery. [Class IIa, Level of Evidence: B]
- The use of the ITA to bypass the LAD artery is expected to result in better long-term survival and lower incidence of cardiac accidents as compared with the use of the SVG. [Class I, Level of Evidence: B]
- When the RITA is used to bypass the LAD artery, the long-term patency rate is expected to be similar to the use of LITA. [Class I, Level of Evidence: B]

2. Non-Left Anterior Descending Arteries^{160,187,190,225,235,244,245}

The ITA is usually used to bypass the LAD artery. When bypass of non-LAD arteries (e.g., Cx artery or RCA) is indicated, appropriate procedures should be selected. The ITA, RA and SVG may be used to bypass non-LAD arteries.

- When the ITA is used to bypass the LAD artery, the other ITA should be used to graft the Cx artery rather than the RCA. [Class IIa, Level of Evidence: B]
- Long-term outcomes after CABG using the ITA to bypass non-LAD arteries are almost comparable to that using the RA. [Class IIa, Level of Evidence: B]
- Ten year results after CABG are better when ITA grafts were used to bypass non-LAD arteries than when SVGs were used to bypass non-LAD arteries. [Class IIa, Level of Evidence: B]
- No differences have been demonstrated between the long-term outcomes of RA grafts and SVGs to bypass non-LAD arteries. [Class IIb, Level of Evidence: C]

1. Circumflex Arteries²⁴⁴

- When the ITA is used to bypass the LAD artery, the other ITA should be used to graft the Cx artery rather than the RCA. [Class IIa, Level of Evidence: B]

	General use	Special use
LAD artery	LITA, RITA, RA, SVG	
Dx artery	LITA, RITA, RA, SVG	Composite RA, FITA
Cx artery	LITA, RITA, RA, SVG	Composite RA, FITA
RCA (#1–3)	RITA, GEA, RA, SVG	Composite RA, FITA
RCA (#4)	GEA, RA, SVG	Composite RA, FITA

Cx, circumflex; Dx, diagonal; FITA, free internal thoracic artery; GEA, gastroepiploic artery; LAD, left anterior descending; LITA, left internal thoracic artery; RA, radial artery; RCA, right coronary artery; RITA, right internal thoracic artery; SVG, saphenous vein graft.

Reference/ Year	Mean follow-up period after CABG	No. of patients	Patency rate (%) or risk of occlusion (odds ratio)				
			Graft	LAD artery	Dx artery	Cx artery	RCA (#1–3) RCA (#4)
124/2000	5.6	962	RITA [¶]	1	2.0	2.8	4.0 2.6
158/2002	2.3	109	Composite RA	83.3%*		75.2%	70.0% [§]
205/2003	8.3	1,607	SVG	1	1.29	1.39	1.63 1.34
96/2004	6.6	1,434	LITA	97.2%	96.4%	91.0%	
			RITA [¶]	96%	93%	90%	79% 87%
160/2004	10	369	ITA	85%			
			SVG	69%*		58%	56% [§]
156/2004	6.4	1,408	LITA	97.1%*		91.7%	
			RITA	94.6%*		84.9%	79.5% [§]
			Free RITA	96.2%*		91.9%	88.8% [§]
			RA	87.1%*		91.6%	88.2% [§]
			SVG	60.2%*		61.2%	61.6% [§]

*LAD+Dx, [§]RCA (#1–4), [¶]including free RITA.

CABG, coronary artery bypass grafting; Cx, circumflex; Dx, diagonal; ITA, internal thoracic artery; LAD, left anterior descending; LITA, left internal thoracic artery; RA, radial artery; RCA, right coronary artery; RITA, right internal thoracic artery; SVG, saphenous vein graft.

2. Right Coronary Artery^{96,161,205}

- Among the all coronary arteries, long-term graft patency rate is the lowest in the RCA (#1–3). Long-term patency rate is expected to be high when the graft is anastomosed to the distal segment of the RCA (#4), rather than to the proximal

segments of the RCA (#1–3). [Class IIa, Level of Evidence: B]

- The superiority of GEA graft to SVG has not clearly been demonstrated in terms of long-term outcome of CABG to the RCA. [Class IIb, Level of Evidence: B]

V Issues After CABG

1. Antiplatelet Therapy to Prolong the Patency of the Saphenous Vein Grafts^{246–255}

- Aspirin should be used to prevent early-phase occlusion of vein grafts. Aspirin is a standard treatment for patients with vein grafts, and should be continued to prevent postoperative events. [Class I, Level of Evidence: A]

2. Treatment With Calcium Channel Blockers After CABG Using Radial Artery Grafts

Carpentier et al. first reported the use of the RA in CABG.²⁵⁶ However, no clinical studies have been conducted to date to evaluate the effect of calcium channel blockers on RA patency.¹⁸⁷

3. PCI to Treat Graft Lesions

1. Vein Grafts^{88,257–269}

- The use of coronary stents and embolic protection devices for peripheral applications may be considered for the treatment of vein graft lesions. [Class IIa, Level of Evidence: B]

2. Arterial Grafts

The initial success rate of stenting in ITA grafts is high, although the long-term restenosis rate is higher in ITA graft lesions treated with stenting than those with balloon angioplasty.²⁷⁰

4. Drug Treatment for Hyperlipidemia^{253,271–273}

- All patients undergoing CABG should receive statin therapy, unless contraindicated. [Class I, Level of Evidence: A]

5. Antihypertensive Treatment After CABG

In the treatment of hypertension associated with angina, calcium channel blockers and β -blockers that exert antianginal effects are the drugs of choice. Although patients before CABG should be carefully monitored not to lead excessive antihypertensive treatment because it may induce anginal attacks, sufficient antihypertensive treatment using appropriate combinations of drugs should be performed after CABG to achieve secondary prevention of cardiovascular events.

However, because these findings have been obtained from studies in hypertensive patients with ischemic heart disease including a limited number of patients undergoing CABG, no sufficient evidence has been obtained regarding antihypertensive treatment after CABG.

6. Hormone Therapy^{274,275}

- Hormone replacement therapy is not recommended for female patients after CABG. [Class III, Level of Evidence: B]

7. Smoking Cessation^{276–281}

- All smokers should receive educational counseling and be offered smoking cessation therapy postoperatively. [Class I, Level of Evidence: B]
- Drug treatment such as nicotine replacement therapy and varenicline should only be administered to patients who are willing to stop smoking. [Class I, Level of Evidence: B]

8. Cardiac Rehabilitation^{282–297}

- Cardiac rehabilitation is recommended for all eligible patients after CABG. [Class I, Level of Evidence: B]

VI Selection of CABG Procedures and Grafts for Specific Patient Populations

1. Very Elderly Patients ≥ 80 Years of Age^{298–304}

- The use of unilateral ITA to revascularize the LAD artery improves the prognosis of very elderly patients ≥ 80 years of age. [Class IIa, Level of Evidence: B]
- OPCAB reduces the risk associated with surgery in very elderly patients ≥ 80 years of age. [Class IIa, Level of Evidence: C]

2. Women^{305–352}

- Whenever possible, at least one ITA graft should be obtained and used to bypass the anterior descending artery. [Class I, Level of Evidence: B]
- Consideration on whether OPCAB is indicated should be made equally for both men and women, regardless of sex. [Class IIa, Level of Evidence: B]

3. Diabetes^{6,21,60,66–69,77,134,217,348,353–384}

- CABG is the procedure of choice for diabetic patients with multivessel disease. [Class I, Level of Evidence: B]
- It is desirable that postoperative plasma glucose should target <180 mg/dL. [Class I, Level of Evidence: B]

4. Respiratory Dysfunction^{385–391}

- Avoidance of the use of cardiopulmonary bypass may reduce the risk associated with surgery in patients with chronic obstructive pulmonary disease (COPD). [Class IIa, Level of Evidence: B]
- Minimally invasive direct coronary artery bypass (MIDCAB) is useful in maintaining postoperative respiratory function in patients with COPD. [Class IIb, Level of Evidence: C]

5. Renal Failure^{392–405}

- Avoidance of the use of cardiopulmonary bypass may reduce the risk of perioperative complications in patients with chronic renal failure. [Class IIb, Level of Evidence: C]

6. Cerebrovascular Disorders^{39,44,47,48,51,336,406–484}

Postoperative neurologic outcome is classified into type I outcome (e.g., cranial nerve disorders due to focal injury, or stupor or coma at discharge) and type II outcome (e.g., deterioration in intellectual function and memory deficit).^{47,336}

- A prior history of cerebral infarction and advanced age are risk factors for perioperative cerebral events. These patients should be treated with CABG procedures that may prevent atheroembolism from the ascending aorta. [Class IIa, Level of Evidence: B]
- When severe atherosclerosis in the ascending aorta is observed during intraoperative echocardiography for the measurement of the ascending aorta, transesophageal echocardiography or palpation, switching to CABG procedures including OPCAB that do not clamp the ascending aorta may prevent the development of postoperative cerebrovascular disorders. [Class I, Level of Evidence: C]
- Four-week anticoagulation therapy using warfarin is indicated for patients with recurrent or long-lasting (≥24 hours) atrial fibrillation after CABG. [Class IIb, Level of Evidence: C]
- Long-term (3 to 6 month) anticoagulation therapy may be required for patients who recently experienced apical anterior myocardial infarction and show persistent asynergy after CABG. [Class IIa, Level of Evidence: C]
- Because the presence/absence of left ventricular thrombosis may affect how and when CABG is performed, patients with a recent history of anterior myocardial infarction should be considered for echocardiography to screen for the presence of left ventricular thrombosis. [Class IIb, Level of Evidence: C]
- Carotid artery screening is probably indicated for the following patients: Patients ≥65 years of age, those with left main disease, those with peripheral vascular disease, those with a history of smoking, those with a history of transient cerebral ischemia or cerebral infarction, and those with ca-

rotid artery murmur. [Class IIa, Level of Evidence: C]

- Carotid endarterectomy (CEA) or carotid artery stenting (CAS) is recommended prior to or concomitantly with CABG in patients with symptomatic carotid artery disease and asymptomatic patients with ≥80% stenosis in either or both carotid arteries. [Class IIa, Level of Evidence: C]
- CEA and CAS should be performed by teams that have performed the procedures with an incidence of death and cerebral infarction at 30 days of ≤3% and ≤6% for patients with asymptomatic and symptomatic carotid artery disease, respectively. [Class I, Level of Evidence: A]
- A multidisciplinary team including neurologist should discuss and determine the indications for carotid angioplasty in individual patients. [Class I, Level of Evidence: C]
- Although even today CEA is a standard procedure to revascularize the carotid artery, a multidisciplinary team should discuss whether CEA or CAS should be selected for individual patients. [Class I, Level of Evidence: B]

7. Porcelain Aorta^{485,486}

- OPCAB without proximal anastomosis to the ascending aorta. [Class IIa, Level of Evidence: B]
- On-pump beating-heart CABG without involving the ascending aorta. [Class IIa, Level of Evidence: C]
- Use of an automatic anastomosis device for proximal anastomosis to the ascending aorta. [Class IIb, Level of Evidence: C]
- Conventional procedures involving the ascending aorta. [Class III, Level of Evidence: B]

8. Open-Heart Surgery in Patients With Cirrhosis^{487–495}

In patients with irreversible hepatic dysfunction especially cirrhosis, surgery is a high-risk procedure that often causes surgical complications such as excessive bleeding, infection, hepatic failure, renal failure and prolonged intubation, and may cause death when the indication is inappropriate.⁴⁸⁷

- OPCAB reduces the risk associated with surgery in patients with Child-Pugh classification B or C. [Class IIb, Level of Evidence: C]

9. Valvular Disease

1. Aortic Stenosis^{496–510}

- Patients with severe aortic stenosis undergoing CABG should have concomitant aortic valve replacement. [Class I, Level of Evidence: B]
- Aortic valve replacement may be indicated for patients with moderate aortic stenosis undergoing CABG and in whom concomitant aortic valve replacement is not considered to increase the risk associated with surgery. [Class IIa, Level of Evidence: C]
- Aortic valve replacement can be indicated for patients with mild aortic stenosis undergoing CABG and in whom concomitant aortic valve replacement is not considered to increase the risk associated with surgery. [Class IIb, Level of Evidence: C]

2. Indications of Mitral Valve Surgery in Patients With Ischemic Mitral Valve Regurgitation^{511–530}

- In patients undergoing CABG who have severe mitral valve regurgitation, concomitant mitral valve surgery should be performed. [Class IIa, Level of Evidence: B]
- In patients undergoing CABG who have moderate mitral valve regurgitation, concomitant mitral valve surgery is desirable. [Class IIb, Level of Evidence: C]

10. Left Ventricular Aneurysm^{531–535}

- CABG concomitant with left ventricular aneurysm resection and reconstruction. [Class I, Level of Evidence: B]
- Endoventricular patch plasty for the treatment of left ventricular aneurysm. [Class IIa, Level of Evidence: B]
- Aneurysm resection and plain suture. [Class IIb, Level of Evidence: B]

11. Aortic Aneurysm

1. Thoracic Aortic Aneurysm Associated With Ischemic Heart Disease

As the population ages, the number of patients with thoracic aortic aneurysm associated with ischemic heart disease has increased. They account for 16 to 30% of patients with thoracic aortic aneurysm,⁵³⁶ and 15 to 30% of patients undergoing aortic arch replacement concomitantly receive CABG.^{537,538}

2. Abdominal Aortic Aneurysm Associated With Ischemic Heart Disease

In a clinical study in patients under consideration for elective peripheral vascular reconstruction (e.g., abdominal aortic aneurysm, carotid artery diseases, and lower extremity atherosclerosis), coronary angiography revealed that 34% of them had CAD, and 25% of them required coronary angioplasty (CABG or percutaneous transluminal coronary angioplasty [PTCA]).⁵³⁹

12. Repeat CABG^{496,540–544}

- Repeat CABG is indicated for patients after CABG who have chest pain not responding to conservative treatment or PCI. When chest pain is atypical, myocardial ischemia must be demonstrated with stress testing and others. [Class I, Level of Evidence: B]
- Repeat CABG is indicated for patients after CABG when graft occlusion and native CAD requiring CABG (e.g., left main disease, and left main and three-vessel disease) are present. [Class I, Level of Evidence: B]
- Repeat CABG is recommended for patients after CABG when ischemia is present in a large myocardial territory supplied by an anastomosis peripheral vessel. [Class IIa, Level of Evidence: B]
- Repeat CABG should also be considered for patients after CABG when $\geq 50\%$ stenosis due to atherosclerosis is present in the SVG supplying the LAD artery or a large myocardial territory. [Class IIa, Level of Evidence B]

13. Peripheral Vascular Disease^{539,545–549}

It is well known that CAD and peripheral vascular disease are

often present concurrently. It has been reported that 37 to 78% of patients undergoing surgical treatment of peripheral vascular disease have CAD.⁵⁴⁵

- In patients with peripheral vascular disease undergoing CABG, the incidence of cerebral complications is lower in those not using cardiopulmonary bypass than those using it during CABG. [Class IIa, Level of Evidence: B]

14. Left Ventricular Dysfunction^{532,535,550–556}

- CABG for patients with severe multivessel disease associated with left ventricular dysfunction and documented severe myocardial ischemia. [Class I, Level of Evidence: B]
- CABG and left ventricular plasty for patients with left ventricular dysfunction due to left ventricular remodeling after myocardial infarction. [Class IIa, Level of Evidence: B]
- CABG and left ventricular plasty for patients with severe left ventricular dysfunction due to myocardial infarction affecting multiple segments. [Class IIb, Level of Evidence: C]

15. Malignant Tumor

There are many issues to be solved when patients with malignant tumor undergo CABG. However, no evidence has been established regarding CABG in this patient population.

16. Acute Coronary Syndromes^{370,557–577}

- In patients with myocardial infarction not associated with unstable angina or ST-elevation, CABG should be performed according to the indications for CABG in stable angina. [Class I, Level of Evidence: B]
- In patients with hemodynamically stable ST-elevation myocardial infarction, CABG should be performed according to the indications for CABG in stable angina. [Class I, Level of Evidence: B]
- In patients with hemodynamically unstable ST-elevation myocardial infarction, CABG should be performed when ischemia persists after PCI or when mechanical complications (e.g., ventricular septal perforation, free wall rupture, and mitral papillary muscle rupture) are present. [Class I, Level of Evidence: B]

17. Fatal Ventricular Arrhythmias^{578–583}

- CABG for patients with severe multivessel disease who have adverse events such as cardiopulmonary resuscitation due to fatal ventricular arrhythmias. [Class I, Level of Evidence: B]
- CABG for patients with severe multivessel disease who have fatal ventricular arrhythmias and documented myocardial ischemia. [Class IIa, Level of Evidence: B]
- Left ventricular plasty for patients with ventricular tachycardia with scarred myocardium after myocardial infarction. [Class IIb, Level of Evidence: C]

Table 4. Risk Assessment Methods

	Parsonnet score⁵⁸⁴	Higgins score⁵⁹⁰	French score⁵⁹⁴	OPR score⁵⁹⁵	Pons score⁵⁹⁹	EuroSCORE⁶⁰⁰	STS risk algorithm⁵⁹³
Year of publication	1989	1992	1995	1995	1997	1999	1994
No. of institutions	Single center	Single center	42 centers	9 centers	7 centers	128 centers	Single center
Country	USA	USA	France	Canada	Spain	8 European States	USA
No. of patients	3,500	5,051	7,181	13,098	1,309*	19,030	728
Preoperative factors	14	13	8	6	11	23	10
Procedure	Heart surgery	For CABG	Heart surgery	Heart surgery	Heart surgery	Heart surgery	For CABG
Outcome measure	Mortality	Mortality, Morbidity	Mortality, Morbidity	Mortality	Mortality	Mortality	Mortality, Morbidity
Statistics	Univariate and logistic regression analysis	Univariate and logistic regression analysis	Multivariate and logistic regression analysis	Multivariate and logistic regression analysis	Univariate and logistic regression analysis	Univariate and logistic regression analysis	Univariate and logistic regression analysis
How to use	Calculate the score using a score table based past data	Calculate the score using a score table based past data	Calculate the score using a score table based past data	Calculate the score using a score table based past data	Calculate the score using a score table based past data	Use a web page to calculate mortality and morbidity	Use a web page to calculate mortality and morbidity

*Procedures.

CABG, coronary artery bypass grafting; EuroSCORE, European System for Cardiac Operative Risk Evaluation; OPR, Ontario Province Risk; STS, Society of Thoracic Surgeons.

VII Methods of Patient Risk Assessment

1. Conventional Methods of Patient Risk Assessment

A lot of reports have described patient risk assessment in heart surgery,^{39,187,189,423,584–618} and these reports have greatly contributed to the risk assessment of individual patients planned to undergo heart surgery and the improvement in hospital revenue and expenses through cost reduction, and have encouraged institutions to improve outcomes. **Table 4** lists typical risk assessment methods reported to date.^{584,590,593,594,595,599,600}

2. Points to Consider for Patient Risk Assessment

In patient risk assessment, users should be aware of (1) the results depends on the types of variables used, (2) variables may depend on patient characteristics and factors of health-care providers, and (3) variables may change over time and as medical technology advances. The STS database and the EuroSCORE (European System for Cardiac Operative Risk Evaluation) are considered to be the international standards, and many surgeons have benefited from these methods. However, it is important and ideal to establish risk assessment methods considering the characteristic features in Japan and other areas.

3. Selection of Patient Risk Assessment Methods

Because there are no established databases and no methods of

patient risk assessment have been validated in Japan, physicians are selecting suitable methods from currently available international assessment methods on the basis of the characteristics in each institution. The STS risk algorithm and the EuroSCORE, which are used as standards in many countries, are frequently selected.

4. Risk Assessment Regarding Graft Selection

In order to assess risk factors affecting graft patency rate after CABG, mid- and long-term large-scale prospective studies must be conducted to follow-up patients after CABG with coronary angiography. Although the use of different grafts has been reported, risk factors affecting the outcome of CABG have not been precisely identified due to limited research funds.

5. Current Recommendations in This Guideline Document

In Japan, the JACVSD was established, and data of Japanese patients are being accumulated. It is realistic to use the STS database and the EuroSCORE to assess the risk of Japanese patients at this time. However, we recommend that risk assessment including morbidity assessment in Japan be based on factors characteristic of Japanese patients.

VIII Economic Efficiency of CABG

CABG is a medical procedure in natural science, and is also a treatment option provided as a part of the health care system. It is thus appropriate to describe measures for economic assessment of CABG in this guideline document. However, there are many challenges in establishing guidelines regarding the economic efficiency of CABG. The present guideline document summarizes standard economic efficiency of CABG mainly based on public data to provide issues to be considered in the future.

1. Challenges in Establishing Guidelines Regarding the Economic Efficiency of CABG

1. Differences Among Countries

Published reports that offer the highest level of evidence (such as multicenter randomized clinical studies comparing CABG and PCI in Western countries) are limited in terms of comparison of economic efficiency of the two procedures in Japan, because there are substantial differences between Western countries and Japan in health insurance system, prices of medical services, drugs and devices, and presence/absence of doctor's fee (surgeon's fee), among other factors.

2. Two Systems in One Country

As of 2005, there are two healthcare fee systems, i.e., the diagnosis procedure combination (DPC) system and the fee-for-service system in Japan. The DPC system is used in 82 advanced treatment hospitals and a small number of hospitals using the system as a trial. Because the economic efficiency of CABG differs between the two systems and cannot be described uniformly, this guideline document mainly describes the data of CABG conducted using the DPC system.

3. Rapid Cycle Change

In Japan, the National Health Insurance (NHI) prices are revised every other year. It is highly likely that the data described in this document will be significantly affected by the revision in 2006. As in the rapid advancement of devices used in PCI, the type, price and positioning of devices used for cardiac interventional procedures change in a very short period of time. On the other hand, the techniques of CABG have changed relatively slowly as compared with those of PCI, and cases of OPCAB account for more than 60% of all CABG cases in 2004. Currently available data are suitable for comparing economic efficiency of CCAB and OPCAB.

4. Limited Data

Unfortunately, data on the effects of DES (introduced in September 2004), which are essential in the discussion of the economic efficiency of CABG as compared with PCI, have not been published as formal data in Japan. Also, there are no sufficient data comparing economic efficiency of CABG and PCI between advance treatment hospitals and other hospitals. In this document, data accumulated and analyzed by a private research institute are partly provided.

2. Health Economic Analysis of CABG in Japan: National Data on DPC

In 2003, a study group on the use of the DPC combination

system in acute-phase hospital treatment analyzed data on CABG throughout Japan. The mean total duration of hospitalization was 35.2 ± 19.9 days (median 29 days; coefficient of variance 0.56), and consisted of 11.2 ± 11.2 days (median 7 days) before CABG and 23.2 ± 14.7 days (median 19 days) after CABG. The duration of hospitalization before CABG varied widely.

The average fee for hospital services, which was converted to the price based on the fee-for-service system, was $3,494,900 \pm 1,592,000$ yen (median 3,310,000 yen; coefficient of variance 0.46).

1. Comparison Between Conventional On-Pump and Off-Pump CABG

1) Duration of Hospitalization

The mean total duration of hospitalization was 34.2 ± 20.1 days and 36.7 ± 19.6 days for OPCAB and CCAB, respectively ($P=0.01$). The mean durations of hospitalization before CABG in the corresponding groups were 11.1 ± 11.3 days and 10.9 ± 11.1 days (non-significant), and those after CABG were 22.0 ± 14.8 days and 25.0 ± 14.5 days ($P<0.001$). The duration of hospitalization after CABG was significantly shorter in OPCAB.

2) Total Billing Amount

The mean total billing amount was $3,100,000 \pm 1,140,000$ yen for OPCAB and $4,100,000 \pm 1,960,000$ yen for CCAB ($P<0.001$). The fee for OPCAB was significantly lower than that of CCAB, and the difference was about 1,000,000 yen.

Although this finding represents the superior economic efficiency of OPCAB, the fee for services by physicians and hospitals, which is listed as the fee "surgery and others (technical fee)" in the NHI price listing, is set with an addition of 30% for OPCAB, but is unreasonably lower than CCAB by $\geq 200,000$ yen.

2. Problems in Technical Fees

The technical fee for CCAB is 487,000 yen for a single-graft procedure, and 813,000 yen for a multiple-graft procedure, while the technical fee listed as the "30% addition" in OPCAB is 146,100 yen and 243,900 yen for a single- and multiple-graft procedures, respectively.

When OPCAB is conducted instead of CCAB, the total billing fee does not include 255,000 yen for the technical fee for the use of cardiopulmonary bypass, and a 200% addition for cardiac anesthesia using cardiopulmonary bypass and hypothermia. The technical fee for the use of cardiopulmonary bypass is larger than the 30% addition for OPCAB.

3. Problems on the Use of Medical Materials

Although OPCAB, a technique not using expensive devices for cardiopulmonary bypass devices, greatly contributes to the reduction of healthcare cost, hospitals have almost no incentive to conduct OPCAB even in the DPC system era because devices for cardiopulmonary bypass used in on-pump techniques are classified as "special treatment materials" and may be added to the bill on the fee-for-service basis. Hospitals gain additional income from the difference between the NHI price and the purchase (market) price of such devices to supplement insufficient technical fees. CCAB in the era of OPCAB may be performed for financial reasons.

It has been suggested that single-use-devices for OPCAB are often reused.

IX Technical Innovations

1. Automatic Anastomotic Devices^{619–621}

[Class IIb (Class III for Some Recommendations),
Level of Evidence: C]

Automatic anastomotic devices currently available in Japan are limited to devices for proximal anastomosis of the SVG, and are classified into fully-automatic and semi-automatic anastomotic devices.

1. Automatic Proximal Anastomotic Devices

Automatic proximal anastomotic devices have been developed to ensure reliable anastomosis in a short period of time and decrease the incidence of cerebral infarction caused by clamping such as partial occlusion of the ascending aorta.

2. Automatic Distal Anastomotic Devices

Regarding automatic distal anastomotic devices, the MVP system and the St. Jude Medical ATG coronary connector system (St. Jude Medical, Inc., St. Paul, MN) are currently under clinical investigation. Only small-scale clinical studies have been conducted at this time.

2. Robotic Surgery^{622–626}

[Class III, Level of Evidence: C]

Surgery-assisting robots are classified into two types: One is endoscopic surgical robots such as AESOP (Intuitive Surgical, Inc., Sunnyvale, CA), and another one is surgical robots with a master-slave system such as da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA).

1. Introduction of Robotically-Assisted Internal Thoracic Artery Harvesting

There have been reports on robotic ITA harvesting during off-pump procedures using conventional endoscopic devices and endoscopic surgical robots or using robotic forceps controlled with a master-slave surgical robot system.

2. Introduction of Robotically-Assisted Anastomosis

There have been reports on the use of a master-slave surgical robot system in anastomosis during on-pump and off-pump procedures.

Robotically-assisted CABG is still under development due to the difficulty in robotically-assisted anastomosis. Stabilizers and other devices to facilitate anastomosis have been developed. The indications for robotically-assisted CABG (e.g., one-vessel vs. multivessel disease, or on-pump vs. off-pump procedure) have not been defined yet. It is expected that further innovations will define the indications and increase the use of these techniques.

3. Awake Off-Pump CABG

[Class III, Level of Evidence C]

The first case of awake OPCAB in the awake spontaneously breathing patient under high thoracic epidural anesthesia (TEA)

was reported in 2000.⁶²⁷ It is believed that awake OPCAB helps ensure early ambulation and discharge, and that it provides an environment suitable for anastomosis in off-pump procedures because TEA decreases heart rate and ensures sufficient coronary blood flow, which helps prevent arrhythmias.

1. Indications for Awake Off-Pump CABG

When awake OPCAB was first reported, the technique was used only for the treatment of one-vessel disease involving the LAD artery or two-vessel disease involving the RCA.

The usefulness of awake OPCAB remains established due to the limited number of cases reported to date. However, this technique is expected to be beneficial because TEA may dilate coronary arteries and prevent arrhythmias, and intubation and general anesthesia may be avoided. When further studies are conducted and safer and more reliable awake OPCAB techniques are established, physicians will be able to perform less invasive CABG.

4. Transmyocardial Laser Revascularization

[Class IIa, Level of Evidence: A]

Transmyocardial laser revascularization (TMLR) using CO₂ laser is a technique to establish blood flow to ischemic myocardium by irradiating high-energy laser from the epicardium to the endocardium to create new channels between the left ventricular cavity and ischemic myocardium. It is believed that TMLR promotes angiogenesis as a result of a mechanism of repair.

1. Indications

TMLR is best indicated for patients with drug-resistant angina in whom revascularization procedures such as PCI and CABG are not feasible.^{628–634}

2. Lasers Used for TMLR

Currently, TMLR is performed using a CO₂ laser system (Heart Laser™ kit, PLC Medical Systems, Inc., Milford, MA) and a Holmium (Ho:) YAG laser (Eclipse™, CardioGenesis Corporation, Sunnyvale, CA). The use and effects differ between the two lasers that differ in wavelength and energy characteristics. CO₂ laser, which has energy per pulse larger than Ho: YAG laser, can penetrate into the target myocardium in one pulse. On the other hand, Ho: YAG laser has a photoacoustic effect more potent than CO₂ laser, and can block the afferent network of sympathetic fibers more effectively than CO₂ laser.⁶³⁵

3. Risk Factors for Poor Outcome After TMLR

Outcome after TMLR depends on the presence/absence of (1) unstable angina, (2) global myocardial ischemia, and (3) left ventricular dysfunction.

The benefits of TMLR have been demonstrated in many prospective randomized clinical studies, and guidelines for the use of TMLR have been published. It is expected that the use of TMLR in combination with less invasive surgery such as OPCAB, cell transplantation therapy and neovascularization therapy will be proven to be effective in the future.

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Appendix 1. JCS Joint Working Group

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- Satoshi Ogawa, International University of Health and Welfare, Mita Hospital
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 - Kanji Kawachi, Ehime University
 - Nobuya Koyama, Division of Cardiovascular Surgery, Department of Surgery, School of Medicine, Faculty of Medicine, Toho University
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Appendix 2. Coronary Revascularization Council

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