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Background. We assessed the clinical outcome and conducted an angiographic study of total arterial off-pump coronary artery bypass grafting for revascularization of the total coronary system.

Methods. Of 382 consecutive patients who underwent off-pump coronary artery bypass between April 2000 and December 2002, 235 patients (193 men and 42 women, mean age 66 ± 9 years) with three-vessel disease underwent off-pump coronary artery bypass with all arterial grafts. A total of 872 vessels were bypassed (average number of grafts 3.7 ± 0.8). The internal thoracic arteries, radial arteries, and gastroepiploic arteries were used for revascularization of 306, 542, and 24 coronary arteries, respectively. Two hundred twenty-five patients underwent revascularization with composite grafts that were connected to the in situ internal thoracic artery (Y configuration 181, I configuration 55, K configuration 27, X configuration 3, T configuration 1); 10 patients underwent revascularization with all in situ grafts.

Results. Three (1.3%) hospital deaths and 1 late death occurred. There were no occurrences of clinical underperfusion syndrome or new intraaortic balloon pump insertion. Cerebral infarction occurred in 2 patients (0.8%). Early postoperative angiography was performed on 833 grafts in 223 patients (95%); the overall patency rate was 98%. Stratified by coronary distribution, the patency rate was 99% (218/221) in the left anterior descending artery, 97% (84/87) in the diagonal artery, 99% (70/71) in the obtuse marginal artery, 98% (262/268) in the posterolateral artery, 98% (167/170) in the posterior descending artery, and 100% (16/16) in the right coronary artery.

Conclusions. Total arterial off-pump coronary artery bypass yielded good clinical results and an excellent patency rate of revascularization for the total coronary system.

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Recently, off-pump coronary artery bypass (OPCAB) operation has been widely used and adopted by many surgical groups due to the accumulation of experience and improvement of surgical techniques and stabilization devices [1-4]. However, a major concern still exists in the accuracy of the coronary anastomosis performed with arterial grafts on a beating heart. Another concern is the ability to perform a complete revascularization in patients with multiple-vessel disease using this technique. The aim of this study was to demonstrate the feasibility of performing total arterial revascularization for the total coronary system with this approach.

Material and Methods

Patient Selection

Between April 2000 and December 2002, OPCAB was performed in 451 patients, except for 2 patients who were converted from off-pump to on-pump coronary artery bypass grafting (CABG) because of hemodynamic instability during anastomosis of the left anterior descending artery (LAD). Three hundred thirty-two patients had three-vessel disease. Of these patients, 235 patients underwent revascularization with all arterial grafts. The preoperative characteristics of the patients are summarized in Table 1.

Conduit Selection

Basically, we used the radial artery (RA) composite graft in combination with one or both internal thoracic arteries (ITA) for revascularization of the total coronary system. In particular, single ITA and the RA as a composite graft were used for elder patients or patients with poor risks. The gastroepiploic artery (GEA) was harvested in pa-

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Abbreviations and Acronyms

- CABG = coronary artery bypass grafting
- CK-MB = creatine kinase-MB
- DG = diagonal branch
- ECG = electrocardiogram
- GEA = gastroepiploic artery
- ITA = internal thoracic artery
- LAD = left anterior descending artery
- LITA = left internal thoracic artery
- OM = obtuse marginal
- OPCAB = off-pump coronary artery bypass
- PD = posterior descending
- PL = posterolateral
- RA = radial artery
- RITA = right internal thoracic artery

tients whose RA was not available because of a positive Allen's test in the bilateral forearms or chronic renal failure (serum creatinine > 1.5 mg/dL).

Because possible stenosis of the subclavian artery and celiac artery may be a cause of concern, we routinely evaluate by preoperative imaging such as computed tomography, magnetic resonance angiography, or angiography.

Preparation of the Conduits

A conventional, semiskeletonized method was used for the dissection of the ITAs. The RA was harvested from the nondominant arm using an ultrasonic dissection technique [5]. All arterial conduits were wrapped in a sponge soaked with a solution of papaverine hydrochloride. After administration of heparin (1.5 mg/kg), the

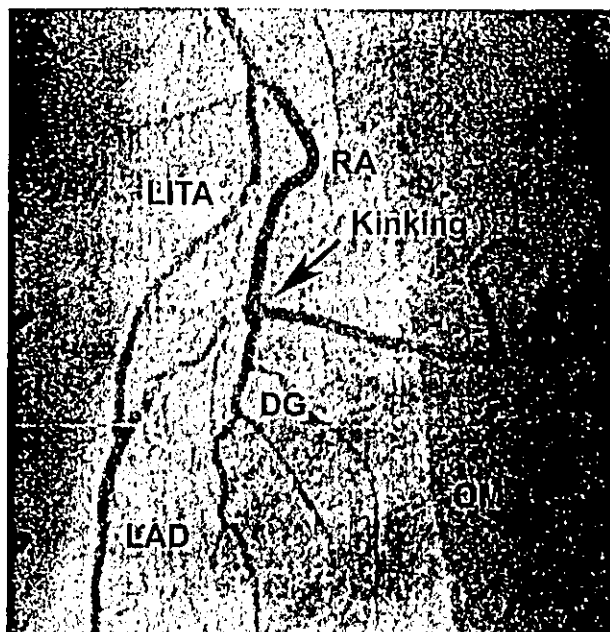


Fig 1. Y composite graft. The radial artery (RA) shows kinking when the RA as a Y composite graft is sewn on the diagonal (DG) that runs parallel to the left anterior descending artery (LAD) in a side-to-side fashion. (LITA = left internal thoracic artery; OM = obtuse marginal.)

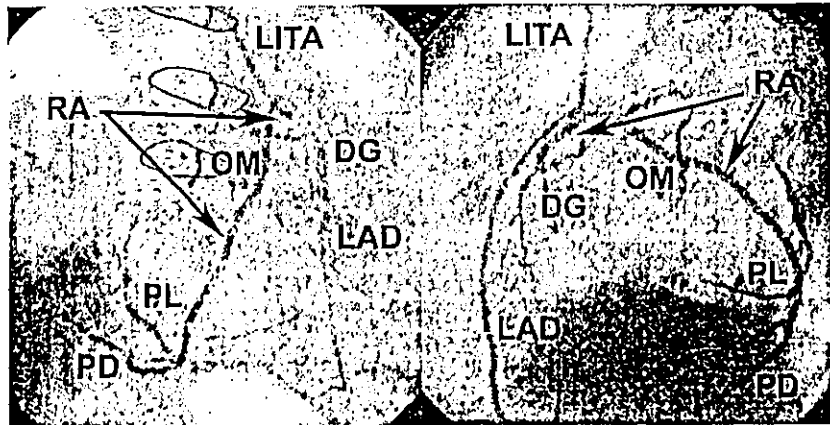
arterial grafts were divided. A mixture of blood and a solution of papaverine hydrochloride was gently injected into the lumen of the RA to prevent spasm. The left internal thoracic artery (LITA) was generally used for revascularization of the LAD, or blood source of the RA as various configurations of the composite graft. When the GEA was harvested, it was used as an in situ graft to the posterior descending (PD) or/and posterolateral (PL) artery. The right internal thoracic artery (RITA) was anastomosed to the LAD as an in situ graft or connected to the RA for extension as an I or Y graft. Y configuration was the most common composite graft for multivessel revascularization. A K configuration was used when the diagonal branch (DG) ran parallel to the LAD. The advantage of the K graft is that it spares the length of RA, because a long RA segment is required to avoid kinking when the RA is used as a Y composite graft sewn on the DG that runs parallel to the LAD in a side-to-side fashion (Fig 1). With this K graft, the other end of the RA extends to the PD with a few side-to-side anastomoses (Fig 2). Sequential bypass of the LITA to DG and the LAD was also performed in our series. However, side-to-side anastomosis between the LITA and the DG is technically demanding on the beating heart when the LITA is small. As for the X graft, the RA can extend fully around the heart from the DG to the right coronary artery (Fig 3). All composite grafts except the I configuration were arranged before the distal anastomoses. In the I configuration, the RA was connected to the RITA after the distal anastomoses to adjust the length of the RITA.

Table 1. Preoperative Characteristics (n = 235)

	Number	Percent
Age (y)		
Mean	66.2 ± 8.7 (range 42-84)	
≥65 y and ≤74 y	99	42
≥75 y	45	19
Male/Female	193/42	
LVEF < 0.35	40	17
Preoperative IABP	7	3
Acute MI	4	2
Emergency case	7	3
Reoperation	7	3
History of PCI	46	20
Diabetes mellitus	83	35
Cerebrovascular disease	51	22
Chronic renal failure	8	3
Hemodialysis	6	3
COPD	7	3
Higgins Score		
Mean	3.3 ± 2.8	
≥5	61	26

COPD = chronic obstructive pulmonary disease; IABP = intra-aortic balloon pumping; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention.

Fig 2. K composite graft. The advantage of the K graft is sparing the length of the radial artery (RA), when bypass is necessary for the diagonal (DG) that runs parallel to the left anterior descending artery (LAD). (LITA = left internal thoracic artery; OM = obtuse marginal; PD = posterior descending; PL = posterolateral.)



Surgical Procedure

A standard median sternotomy was used in all patients. The pericardium was opened and deep pericardial retraction sutures were made. Proper positioning and stabilization of the heart were achieved by pericardial sutures and suction stabilizers (Medtronic Octopus, Starfish, Medtronic, Inc, Minneapolis, MN) with rotation of the operative table. Transesophageal echocardiography and pulmonary artery pressure monitoring were performed to check mitral regurgitation due to extensive left ventricular geometric change and right ventricular outflow obstruction due to the right ventricular geometric change. Only transient proximal compression of the target vessel to control the coronary blood flow was accomplished with a silicone rubber loop. The heart rate and blood pressure control were obtained with diltiazem, landiolol hydrochloride, and norepinephrine. After coronary arteriotomy, an intraluminal shunt was inserted to maintain the coronary blood flow and bloodless operative field. A carbon dioxide saline-blower was also used to eliminate excessive blood from opened coronary vessel. The coronary artery was anastomosed in the order of LAD, DG, obtuse marginal (OM), and PL to the PD. The sequential anastomosis technique is a diamond-shaped (90° crossing) method with the RA, and usually a parallel method with in situ arterial grafts. To prevent arterial spasm, diltiazem (0.5 to 1.0 $\mu\text{g}/\text{kg}$) or nicardipine (0.1 to

0.2 $\mu\text{g}/\text{kg}$) was infused intraoperatively and during the first 16 hours after the operation. Diltiazem (100 to 200 mg/d) or amlodipine (2.5 to 5.0 mg/d) was then prescribed orally in conjunction with aspirin (162 mg/d) from the next morning.

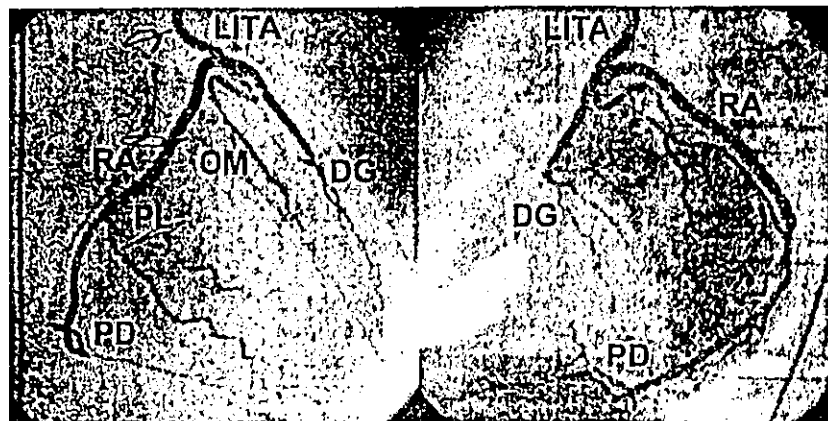
Angiographic Study

In 223 (94.9%) patients, informed consent was obtained and follow-up angiography was performed before hospital discharge by cardiologists. By means of the Cardiovascular Measurement System (QCA-CMS, version 4.1; Medical Imaging System, Leiden, The Netherlands), the stenotic percentage of anastomosis was calculated by comparing the diameter of anastomosis with that of the proximal portion of the graft at the view of the minimum lumen. A percentage stenosis of less than 50% was assessed to be patent [6, 7].

Data Collection and Follow-Up

We retrospectively reviewed the data from the operation notes, anesthesia records, clinical histories, laboratory investigations, and cardiac catheterization. This retrospective study was approved by the Internal Review Board of the National Cardiovascular Center. Follow-up data were collected from the medical records of outpatient visits and correspondence with referring physicians.

Fig 3. X composite graft. In an X graft, the radial artery (RA) can extend fully around the heart from the diagonal (DG) to the posterior descending (PD) artery. (LITA = left internal thoracic artery; OM = obtuse marginal; PL = posterolateral.)



All clinical characteristics were accumulated as a computerized database and analyzed.

Statistical Methods

All values are expressed as the mean ± standard deviation. The discrete variables were analyzed with the Fisher's exact test between two groups and Kruskal-Wallis rank test for more than three groups. Scheffé's test was performed when a significant difference was recognized in the results of the Kruskal-Wallis test. All statistical analyses were performed using the software package SPSS 10.0 for Windows (SPSS Inc, Chicago, IL). The differences were considered statistically significant when the *p* value was less than 0.05.

Results

Eight hundred seventy-two distal anastomoses were performed on 235 patients. The mean number of distal anastomoses was 3.71 ± 0.82 (range 3 to 7). Distal anastomosed sites were 233 LADs, 88 DGs, 73 OMs, 282 PLs, 180 PDs, and 17 right coronary arteries.

Unilateral ITA was used in 127 patients (54.0%) and bilateral ITA in 108 patients (46.0%). The RA was used as a composite graft in 232 patients (98.7%) and the GEA was used as an in situ graft in 16 patients (6.8%). Y, I, K, X, or T configuration was used for the RA composite graft in 181, 55, 27, 3, and 1 patients, respectively. Revascularization with all in situ grafts was performed in 10 patients for 40 distal anastomoses.

Angiographic Study

The patency rates according to coronary distribution, graft materials, and anastomotic fashions are shown in Table 2. The patency rates according to the configurations of the composite graft are also shown in Table 3. The overall patency rate was 98.1% (817/833). Stratified by coronary distribution, the patency rate was 98.6% in LAD, 96.6% in DG, 98.6% in OM, 97.8% in PL, 98.2% in PD, and 100% in the right coronary artery. The patency rate was 98.7% with the LITA, 95.9% with the RITA, 98.5% with the RA, and 88.0% with the GEA. The patency rate was 97.6% with the end-to-side fashion and 98.9% with the side-to-side fashion. The patency rate with GEA was significantly lower than that of the other graft materials (LITA versus GEA, *p* = 0.001; RA versus GEA, *p* < 0.001). However, no significant changes were noted in the patency rates between coronary distribution (*p* = 0.846), anastomotic fashion (*p* = 0.197), and the configuration of the composite graft (*p* = 0.779).

Five of 254 composite grafts (2.0%) showed kinking or stenosis of the LITA just proximal to the composite graft anastomosis site with the RA. Four of 303 ITAs (1.3%) showed stenosis in the middle of the vessel probably due to intraoperative injury.

Evident flow competition was observed in 36 patients. Of those, 24 RA composite grafts and 12 of the LITA distal from the anastomotic site of the composite graft to the target coronary artery were not opacified in angiography of the in situ graft, although the target coronary artery

Table 2. Patency for Bypass Distribution, Graft Material and Anastomotic Fashion

	Graft Material												Total			
	LITA				RITA				RA						GEA	
	E-S	S-S	E-S	S-S	E-S	S-S	E-S	S-S	E-S	S-S	E-S	S-S	E-S	S-S	E-S	S-S
LAD	199/201 (99.0%)	1*	16/17 (94.1%)	1*	1*	35/37 (94.6%)	1*	0	0	216/219 (98.6%)	2*	2	48/51 (94.1%)	0	36*	
DG	7*	12*	6/7 (85.7%)	1*	22*	86/88 (97.7%)	0	1*	0	32/33 (97.0%)	38*	38*	101/104 (97.1%)	0	161/164 (98.2%)	
OM	7/8 (87.5%)	0	2*	0	114/116 (98.3%)	0	35*	6/7 (85.7%)	1/2 (50.0%)	126/129 (97.7%)	41*	41*	538/551 (97.6%)	0	279/282 (98.9%)	
PL	6*	2*	3*	0	260/266 (97.7%)	3*	0	15/17 (88.2%)	7/8 (87.5%)	15/17 (88.2%)	1*	1*				
PD	0	0	4*	0												
RCA	0	0	13*	1*												
Total	219/222 (98.6%)	15*	44/46 (95.7%)	3*	260/266 (97.7%)	3*	254/256 (99.2%)	15/17 (88.2%)	7/8 (87.5%)	15/17 (88.2%)	7/8 (87.5%)	538/551 (97.6%)	279/282 (98.9%)			

* 100% of patency rate.

DC = diagonal; E-S = end-to-side anastomosis; GEA = gastroepiploic artery; LAD = left anterior descending artery; LITA = left internal thoracic artery; OM = obtuse marginal; PL = posterolateral; PD = posterior descending; RCA = right coronary artery; RITA = right internal thoracic artery; S-S = side-to-side anastomosis.

Table 3. Patency for Configurations of Composite Graft

	Configurations of Composite Graft					Total
	Y	I	K	X	T	
	171	53	26	3	1	254
DG	39/42 (92.9%)	0	28*	3*	0	70/73 (95.9%)
OM	54*	0	10*	0	0	64/64
PL	168/169 (99.4%)	45/47 (95.7%)	34*	3*	3*	253/256 (98.8%)
PD	100/102 (98.0%)	46*	12*	2*	1*	161/163 (98.8%)
RCA	3*	6*	0	1*	0	10*
Total	364/370 (98.4%)	97/99 (98.0%)	84*	9*	4*	558/566 (98.6%)

* 100% of patency rate

DG = diagonal; OM = obtuse marginal; PD = posterior descending; PL = posterolateral; RCA = right coronary artery.

and its anastomotic site were clearly opacified in the native coronary angiography.

Early and Late Mortalities and Morbidities

Table 4 lists the early and late complications. Early death occurred in 3 patients (1.3%) due to intracranial bleeding, aspiration pneumonia, and intestinal hemorrhage. Perioperative myocardial infarction (new Q waves in electrocardiogram [ECG], creatine kinase-MB [CK-MB] more than 50 with ECG change or CK-MB more than 70 without ECG change; normal value less than 11 IU/L in our institute) occurred in 6 patients (2.6%). Two patients had a stroke during rehabilitation, one of which occurred during the postoperative angiographic study. No clinical

underperfusion syndrome was noted and new intraaortic balloon pump insertion was not necessary.

Eleven patients underwent successful percutaneous catheter intervention (balloon angioplasty or coronary stenting), although they were asymptomatic. Balloon angioplasties were performed in the stenosis of the LITA just proximal to the connection of the Y composite graft (Fig 4) in 3 patients, in the stenosis of the middle of the LITA in 4 patients, and in the stenosis of the native coronary artery in 2 patients. Coronary stenting was performed in the stenosis of the RITA just proximal to the connection of the I composite graft (Fig 5) in 1 patient and the stenosis of the middle of the LITA in 1 patient. One patient underwent redo OPCAB before discharge due to occlusion of the LITA to the LAD.

One patient died suddenly 6 months after the operation because of unknown causes. Two patients whose predischarge angiography showed anastomotic stenosis

Table 4. Early and Late Results

Results	Number
Early Results	
Hospital mortality	3 (1.3%)
Morbidity	
Perioperative MI	6 (2.6%)
Postoperative IABP	0 (0%)
Early coronary intervention	12 (5.1%)
Reexploration for bleeding	2 (0.8%)
Sternal	
Dehiscence	6 (2.6%)
Infection	0 (0%)
Cerebral infarction	2 (0.8%)*
Renal failure with dialysis	2 (0.3%)
Forearm	
Circulatory injury	0 (0%)
Infection	1 (0.4%)
Paresthesia	0 (0%)
Late Results	
Late death	1 (0.4%)
Cardiovascular event	
Admission for angina or CHF	3 (1.3%)
Coronary intervention	2 (0.8%)
Cerebral infarction	4 (1.7%)

* One occurred during postoperative angiographic study

CHF = congestive heart failure; MI = myocardial infarction.

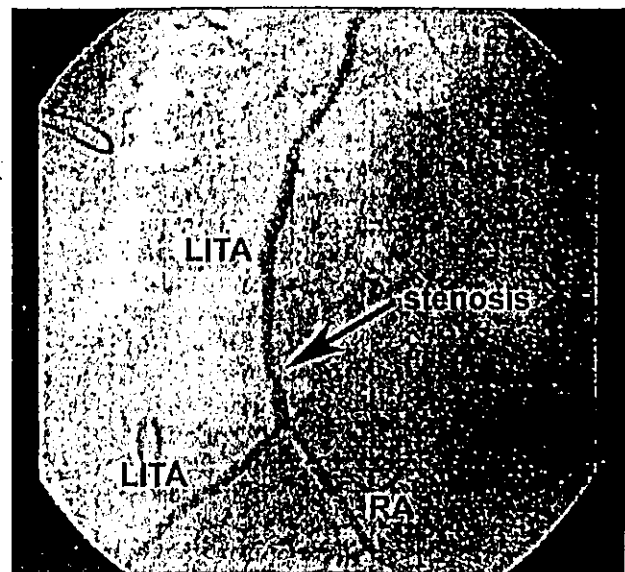


Fig 4. Stenosis of a Y composite graft. Three patients underwent balloon angioplasty, which was performed successfully in the stenosis of the left internal thoracic artery (LITA) just proximal to the connection of the Y composite graft. (RA = radial artery.)

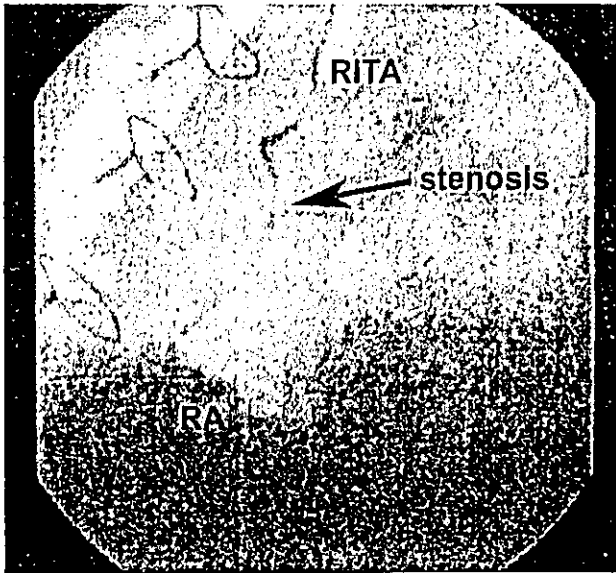


Fig 5. Stenosis of an I composite graft. Coronary stenting was performed in the stenosis of the right internal thoracic artery (RITA) just proximal to the connection of an I composite graft in 1 patient. (RA = radial artery.)

of the LAD returned to the hospital for recurrent angina and underwent successful percutaneous coronary intervention 5 months after the operation. One patient with poor left ventricular function was readmitted for congestive heart failure.

Comment

The OPCAB operation is currently considered to be a safe alternative to myocardial revascularization with cardiopulmonary bypass [1-4]. However, the ability of total arterial OPCAB for multivessel disease remains controversial. In our series, the total arterial OPCAB for the total coronary system achieved excellent patency in the early postoperative term and showed good clinical results. No significant changes were noted in the patency rates between coronary distributions ($p = 0.846$), anastomotic fashions ($p = 0.197$), and the configurations of the composite graft ($p = 0.779$), except the graft materials. The patency rate with GEA was significantly lower than that of the other graft materials (LITA versus GEA, $p = 0.001$; RA versus GEA, $p < 0.001$). The size of the GEA was variable and sometimes too small for multivessel revascularization. This finding may be the result of our performing the sequential bypass graft using small GEA. Recently, when the GEA was essential for revascularization, we have used skeletonized GEA using an ultrasonic scalpel to facilitate visual inspection [8].

Our standard technique to achieve total arterial revascularization for total coronary system is the RA composite graft in combination with one or both ITAs. The RA is used as a material for the free arterial graft because of its easier harvesting and handling. The distal sequential bypass to the coronary arteries, a thicker wall, and wider

lumen compared with ITA and GEA allow meticulous anastomosis on the beating heart.

The composite graft technique appears to have advantages over the free graft that is anastomosed to the ascending aorta. First, aorta no-touch OPCAB using a composite graft reduces the incidence of neurologic complications [9, 10]. Second, a composite graft makes more efficient use of the conduit by placing the inflow close to the target coronary arteries [10-12]. Finally, the inflow of the ITA does not expose the free arterial graft to high wall stress, which may cause the early development of intimal hyperplasia [13, 14].

The composite graft technique has the pitfall of total dependence of the coronary bypass flow on the flow of the proximal ITA. We routinely evaluate the subclavian artery and the ITA by preoperative angiography, magnetic resonance angiography, or three-dimensional computed tomographic angiography, because stenosis of the proximal ITA or subclavian artery may be a cause of global ischemia. However, the adaptability of the ITA as a blood source of the arterial composite graft is still a potential risk in this technique. Multiple clinical and experimental studies have examined the suitability of the ITA as a blood source of the arterial composite graft [15-21]. From the results of positron emission tomography, Sakaguchi and colleagues [18] documented that the composite Y graft was not as effective as independent grafts for improving the coronary flow reserve soon after bypass grafting. However, most investigations have reported that the flow reserve of the proximal ITA is sufficient for a blood source of composite graft for multiple coronary revascularizations. Indeed, in the present series, there was no hypoperfusion syndrome or need for new intraaortic balloon pump insertion even in the patients whose total coronary artery system was supplied by single ITA.

In general, hypoperfusion syndrome related to the conventional CABG occurs typically 30 to 40 minutes after discontinuation of a cardiopulmonary bypass [22]. It is conceivable that the reactive hyperemia of the myocardium that presents after removal of the aortic clamp [23-25] may require greater conduit flow while the oxygen debt is repaid. This situation might produce a drastic imbalance between graft flow and myocardial demand, resulting in the hypoperfusion syndrome [17, 26]. In our standard technique, the LAD is revascularized at first by the ITA because it is the most important coronary artery and exposure of the LAD has no major hemodynamic consequences [27]. After revascularization of the LAD, the coronary artery was anastomosed in the order of the diagonal, obtuse marginal, and posterolateral to posterior descending arterial branches with only local ischemia of the target vessel. We predicted that these techniques, which avoid intraoperative global myocardial ischemia, contributed at least partially to avoiding the hypoperfusion syndrome in our patients.

The competitive flow between the native coronary artery and bypass graft is another concern in any composite graft attached to the ITA [28]. This phenomenon was induced by graft-recipient artery mismatch. In 38

patients with composite grafts, the target coronary artery and its anastomotic site were clearly opacified in the native coronary angiography, although the bypass graft to the target coronary artery (ie, the composite graft or the distal ITA of the composite bifurcation) was not opacified in angiography of the in situ graft. Diffuse narrowing of the distal LITA, from the anastomotic site of the composite graft, was recognized in 13 patients who had competitive flow in the distal LITA to the LAD. No definite conclusion has been reached concerning the relationships between the competitive flow, diffuse narrowing, and true graft failure [29-33]. It still remains to be determined whether a particular coronary artery with a noncritical lesion should be grafted prophylactically using the arterial graft for future progression [34]. We prefer to graft to a coronary artery with moderate stenosis in a side-to-side fashion, and the termination of this conduit was to the coronary artery of severe stenosis. When the posterior descending coronary artery had only mild stenosis, we anastomosed the side of the composite graft to that branch and the end of the composite graft to the circumflex branches. In our study, no patient with competitive flow of bypass grafts was readmitted for angina or congestive heart failure. Although late follow-up angiography was performed in only 2 cases with competitive flow of the RA composite graft, the RA was patent at more than 1 year after the operation [10]. These results prompted us to conclude that the RA has potential as a physiologically functional arterial graft that can be recruited on demand with progression of the native coronary artery disease.

In conclusion, the total arterial OPCAB for the total coronary system achieved excellent patency in the early postoperative period and showed good clinical results. These results have prompted us to continue performing complete arterial revascularization, although long-term studies are required to provide evidence of the validity of our technique.

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DISCUSSION

DR CRAIG R. SMITH (New York, NY): One minor technical issue: you obviously carried out many side-to-side sequential anastomoses in this group. Based on your data, do you have any opinion as to whether the sequential anastomoses are better done in a diamond orientation, or in a parallel orientation, or do you do both depending on the circumstances?

DR TAGUSARI: I usually use a diamond anastomosis technique for the radial artery and a parallel fashion for the ITA and GEA.

DR HITOSHI HIROSE (Cleveland, OH): We performed a similar study for patients with three-vessel disease undergoing off-pump CABG and published the results in *Surgery* last year. Off-pump CABG provided excellent results compared with on-pump CABG and the angiographic results were competitive, as you reported today. I have several questions for the authors. First, what are the inclusion and exclusion criteria for total arterial off-pump CABG? Although the authors stated total arterial bypass is the goal for cardiac surgery, only 52% of the patients received total arterial bypass; what kind of bypass was performed in the rest of 48%? Were they received saphenous vein grafts? How do you select patients undergoing total arterial bypass? Second, only 3% of patients received a gastroepiploic artery graft. Why are the authors not using the gastroepiploic artery?

Thank you.

DR TAGUSARI: I did not include one- and two-vessel disease in this study. All the patients had three-vessel disease. The rate of complete revascularization is 100% in this series. And the next question. The size of the GEA varies; sometimes it was too small to use as a sequential bypass graft. However, recently we have used skeletonized GEA using an ultrasonic scalpel to facilitate visual inspection. We only used saphenous vein graft for the patients more than 80 years old or the patients whose radial artery was not adequate to use, such as chronic renal failure.

DR SMITH: To that question also, I think 52% was the number of patients who received OPCAB out of the total, not the percent that had total revascularization.

DR CHARLES BRIDGES (Philadelphia, PA): I have a couple of questions. One is how soon after surgery did you perform the

angiogram? I know you showed one slide where it was performed two days after the operation. Another question I had was how you manage your radial artery patients after the operation, are you using nitrates, calcium blockers, and for how long are you using them? Finally, I wanted to learn a little bit more about the patient characteristics. How sick were your patients? What kind of ejection fractions did they have and how much other comorbid disease did they have? I didn't hear that or see that in your abstract, to get an idea of what kind of results we should expect. And then can you help us with the theory behind composite grafting as opposed to taking, say, a radial artery off the aorta or off of a patch of vein, et cetera, from the aorta? What is the evidence that shows us that composite grafting is theoretically superior to the more routine way, even with arterial grafts? Obviously one reason is that with a composite graft you can graft more territory than you could with just taking things off the aorta. But I was wondering if you could comment on your feeling about that.

DR TAGUSARI: We usually perform postoperative Angiography ten to fourteen days after operation. To avoid spasm of the radial artery, we use intravenous diltiazem or nicardipine until the following morning. Since then, a calcium blocker such as amlodipine has been prescribed for a long time because most of the patients have hypertension. As I have showed on the slide. In 17% of the patients, ejection fraction was less than 35%. Long-term follow-up is waiting for evidence that the composite graft is superior to the coronary graft. But, when the radial artery is anastomosed directly to the aorta, it is exposed not only to high blood pressure but also to higher shear stress, which may cause the early development of the intimal hyperplasia. Additionally, we can perform aorta no-touch technique and spare the length of the radial artery and by using as a composite graft.

DR AYHAN OZDEMIR (Bursa, Turkey): The patients you had with low ventricular function, what happened after you did the coronary bypass surgery off-pump? Did their left ventricular function get better or stay the same or worse?

Thank you.

DR TAGUSARI: After the OPCAB, left ventricular function recovered significantly in most cases.

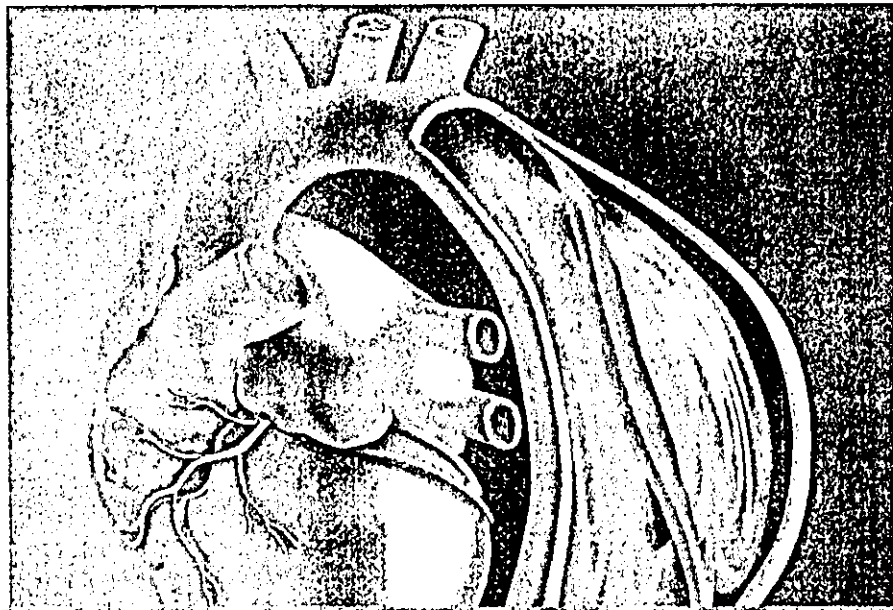
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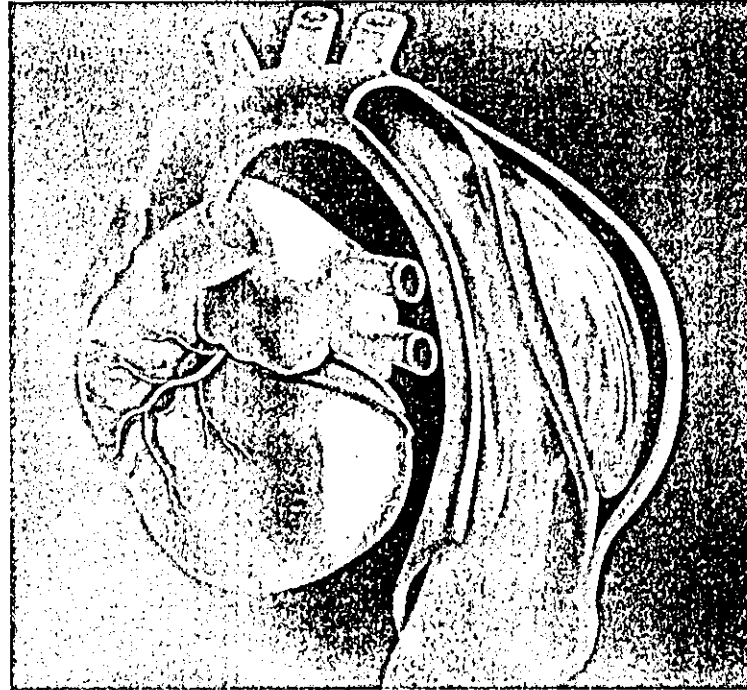
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移植コーディネーター

概論

監修 日本組織移植学会

編著

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巻 頭 言

この度、日本組織移植学会の田中秀治、篠崎尚史両理事の監修により立派な成書として『移植コーディネーター概論』が上梓された。両氏は東日本組織移植ネットワークの中心的存在であり、その設立にも深く関与されてきた専門家である。当学会の理事長としても誠に喜ばしく、かつ時期を得た重要な書であると感じている。臓器移植、組織移植、細胞移植など人からの善意の提供を受けて成り立つ、病める人への治療法には共通した基盤があり、広い領域の医療関係者の連携した努力を必要としている。その最も重要な点は、透明性の高い説明と同意(インフォームドコンセント)と公平な配分である。この基盤点を担っているのが移植コーディネーターといわれる人たちである。

臓器移植に携わるコーディネーターは脳死臓器移植法に則り、臓器移植ネットワークの本部・支部で活躍されている。一方、組織移植に関してはわが国には法的な取り決めはなく、日本組織移植学会のガイドライン(厚生労働省:医薬食品局『生物由来製品の取り扱い基準』を遵守)に則り行われているが、全国的に一律に行われているとは云い難い状況である。この状況を改善する目的で、日本組織移植学会は「組織移植コーディネーター育成規準」「組織移植バンク開設規準」などを作成しているところであるが、わが国での組織移植ネットワーク作りにおける一連の事業のなかでコーディネーターの育成は最も重要な課題であった。本書は、社会的にも経済的にも厳しい状況におかれているわが国の組織移植医療に、情熱をもって取り組んでこられた二人の専門家により完成したおそらく初めての書である。折しも、西日本でも東日本組織移植ネットワークを見本として西日本組織移植ネットワークを構築中であり、新たに組織移植コーディネーターを育成しているところであるが、日本組織移植学会の監修によりコーディネーターのための教科書となる本書が出版されたことは極めて重要である。

本書は移植医療に携わり、支えている広い領域の医師、看護師、臨床工学士、臨床検査技師、そして臓器・組織移植コーディネーターの座右の書として御推薦申し上げたく思っている。

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補助循環と心臓移植

中谷武嗣*

abstract

慢性心不全において心筋障害が高度な症例に対しては、機械的補助循環あるいは心臓移植を考慮すべきである。補助循環としては、長期補助が可能な補助人工心臓があり、体外設置型においても1年以上の補助が可能となってきた。また、心臓移植もわが国での施行例は17例と少数ではあるが全例生存し、その成績は良好である。慢性心不全に対する補助人工心臓あるいは心臓移植の適応を決定するには、心臓のみならず他臓器や長期にわたる治療が可能であるかなど十分な検討が必要であり、急性心不全への補助循環の適応検討とは異なることに注意が必要である。今後、心臓移植のわが国への定着に加え、補助人工心臓によるbridge to recoveryの可能性の拡大、また、新たな補助人工心臓の導入によるdestination therapyとしての補助人工心臓の役割拡大により、慢性心不全に対する治療戦略の選択の広がりが期待される。

I はじめに

心筋障害が高度な心不全に対しては、機械的な循環補助あるいは置換が必要となり、補助循環あるいは心臓移植が考慮される。本稿では、慢性心不全に対する治療戦略における補助循環と心臓移植についてわが国の現状を中心に概説する。

II 補助循環¹⁾

1) 短期的補助循環法

1～数週間程度までの補助が可能なシステムとして、大動脈内バルーンポンピング (intraaortic balloon pumping : IABP) と経皮的心肺補助法

(percutaneous cardiopulmonary support : PCPS) がある。

IABPは下行大動脈内に留置したバルーンによる圧補助法である。その補助能力は自己心拍出量の10～15%程度で、自己心機能に依存し不整脈時には有効な補助効果が得られない。

PCPSは経皮的に大腿部から送・脱血管を挿入し、膜型肺と遠心ポンプにより流量補助を行うもので、緊急時に全身循環の維持が可能である。その補助量は心拍出量の50～70%程度であるが、左心に対しては直接前負荷を軽減せず、補助量を増加させるに伴い自己左心への後負荷が増大し、肺水腫をきたす危険性がある。

2) 補助人工心臓 (ventricular assist system : VAS)²⁾

VASは、自己心を温存しその近傍に血液ポンプを設置し心臓ポンプ機能を100%代行する長期施行

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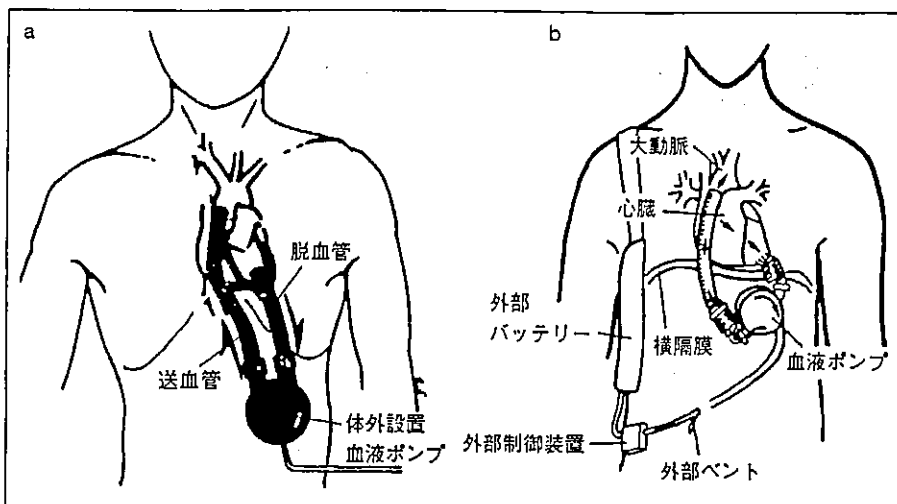


図1
VAS装着図
a: 体外設置型 (左室脱血方式)
b: 体内収納携帯型

可能な補助手段で、血液ポンプを体外に置くものと体内に収納するものがある (図1)。

①体外設置型VAS (図1a)

急性重症心不全に対し一時的に補助するシステムとして開発されたもので、わが国には世界で初めて健康保険で適用された2つのシステムがある。

a) 東洋紡製国立循環器病センター型 (国循型) VAS

血液ポンプは空気圧駆動ダイヤフラム型で、1回拍出量70mL、最大拍出量7L/minである。制御駆動装置は、固有レートおよび心電図同期駆動が選択でき、病棟や病院内の移動が可能である。装着は開胸体外循環下に行い、左心補助人工心臓 (LVAS) では従来右側左房へ心房カフを介して脱血管を挿入し、送血管の人工血管部を上行大動脈へ端側吻合して行われた (左房脱血方式)。最近ではカフを左室心尖に縫着し、このカフを介して脱血管を左室に挿入する左室脱血方式が用いられるようになった。左室脱血方式の採用により補助期間は著明に延長し、1年を超えた補助が行われるようになり、最長例では3年を超えて施行中である。右心補助人工心臓 (RVAS) では、脱血管はカフを介して右房に挿入し、送血管を主肺動脈に装着する。

体外設置型では、送・脱血管を上腹部で体外へ出し、右または左上腹部に設置した血液ポンプに接続し、この血液ポンプと制御駆動装置を駆動チューブで接続し駆動する。

b) 日本ゼオン/アイシン精機製東京大学型 (東大型) VAS

血液ポンプは、日本ゼオン製空気圧駆動塩化ビニル製サック型で、血液接触面をポリウレタン・シリコンゴム共重合体のCardiothane®で被覆し、1回拍出量は40mLと60mLのものがある。駆動装置はアイシン精機製で、固有レートおよび心電図同期駆動が可能である。

②体内収納携帯型LVAS (図1b)

2つのシステムがあり、Thoratec社製HeartMate® LVASは、プッシャープレート型血液ポンプで、粗面構造の血液接触面とすることで良好な抗血栓性が得られている。空気圧駆動装置によるもの [Implantable pneumatic type (IP)] とモータ駆動携帯型 [Vented Electric type (VE)] がある。また、携帯型の電磁力駆動プッシャープレート方式のNovacor® LVASがあり、耐久性に優れている。

両者とも左室心尖脱血方式で、駆動部を含む血液ポンプは左腹壁内か腹腔内に収納され、制御およびエネルギー供給用のチューブにより体外の装置と接続される。ともに70~80kg前後の成人男性を想定して開発されており、体表面積1.5m²未満の小さい体格の人への適応は困難である。

3) 補助循環の適応

慢性心不全患者への補助循環適応にあたっては、急性心不全への適応と異なり、心機能の回復は期待しがたいことを念頭に置き、さらにIABPやPCPSの補助能力に限界があり、当初からVASの適応を考

表1 慢性難治性重症心不全患者に対するVASの適応基準

1. 左心補助人工心臓 (LVAS)
 - 内科的治療および/あるいはIABPに反応しない心不全
 - 1) 血行動態
 - PCWP \geq 20mmHg
 - および
 - 収縮期血圧 \leq 80mmHgあるいは心係数 \leq 2.0
 - 2) 副徴
 - 1時間排尿 \leq 0.5mL/kg
 - Svo \leq 60%
 - 臨床経過
 - 急激な血行動態の変化
 - 進行する腎機能障害*
 - 進行する肝機能障害**
 2. 右心補助人工心臓 (RVAS)
 - 左心補助人工心臓駆動下において一酸化窒素(NO)吸入を含む内科的治療および三尖弁形成術(高度三尖弁逆流)に反応しない右心不全
 - CVP $<$ 18mmHgでは、収縮期血圧 \leq 80mmHgあるいは心係数 \leq 2.0
 3. 適用除外
 - 1) 回復不能な腎機能障害
 - 2) 回復不能な肝機能障害
 - 3) 呼吸不全(循環不全に伴うものは除く)
 - 4) 高度な血液障害(出血傾向など)
 - 5) 重症感染症
 - 6) インフォームド・コンセントがとれない場合
- * : 進行する腎機能障害の指標
 BUN \geq 40mg/dLおよび/あるいはクレアチニン \geq 2mg/dL
 1時間排尿 \leq 0.5mL/kg (利尿剤の使用下)
- ** : 進行する肝機能障害の指標
 総ビリルビン \geq 2.0mg/dLおよび/あるいはSGOT \geq 200IU/L

慮する。また、心臓移植の適応についても検討のうえ決定する必要があり、本人および家族への十分なインフォームド・コンセントが必須である。

慢性難治性重症心不全におけるVAS適応基準を表1に示すが、血行動態的指標に加え、重要臓器の機能障害の進行にも配慮が必要である。特に諸臓器機能障害の判定には注意が必要で、VASにより循環は良好に維持されるようになって、不可逆的な障害をきたした症例は救命できない。急激に循環不全が進行する症例において、VAS装着までのつなぎとしてIABPやPCPSが適応となる。

VASの選択は、体格が大きく右心不全を伴わない症例では体内収納携帯型LVASを考慮し、小さな体格の症例では体外設置型を選択する。両心補助人工心臓(BVAS)が必要な高度右心不全合併例では、体外設置型を選択する。

4) VAS施行中の管理および離脱

VAS装着後は、循環動態の安定を図り、全身状態が落ち着けば早期に抜管、経口摂取を開始し、種々のラインを抜去する。また、ベッド上や病室でのリハビリテーションを開始し、徐々に病棟内歩行や自転車こぎを行い、VAS装着下に可能な限り日常生活を行えるようにする。なお体外設置型VASの駆動法には、固有レートおよびカウンタパルゼーション法があるが、VAS装着例では不整脈頻発例が多いため、固有レートを選択する。

全身状態が安定し、リハビリテーションを開始した段階からACE阻害薬や β 遮断薬を含む内科的心不全治療を再開する。適宜心エコー法などにより自己心機能を評価し、自己心の回復がみられればVASからの離脱可能性を検討する。

VAS装着中に注意すべきこととして、抗凝固療法と感染対策がある。抗凝固療法は外科的出血がコントロールされてから開始し、ワーファリンによりPT-INRを3~4前後に維持し、抗血小板剤を併用する。なお、HeartMate[®]においては抗血小板療法のみで行う。感染対策として、体外にできるチューブの管理が重要である。さらに、精神状態への配慮も重要で、VAS装着にて長期待機を続けると精神的に不安定になりやすい。このため、精神神経科医によるサポートも含めた対応が必要となる。

5) 国立循環器病センターでの経験²⁾

当センターの心臓移植適応患者の生存率をみると、1年および3年生存率は84%および55%であった。しかし、死亡およびVAS適応回避率でみるとおのおの57%、38%であり、VAS適応により待機期間が長くなっていることが明らかになっている。

また、これまでに59例の慢性難治性重症心不全の急性増悪例にVASを適応してきたが、その補助期間は施行中を含め7~1,224(平均359)日である。うち12例が心臓移植されその補助期間は39~669(396)日と平均1年以上である。また、16例が施行中でその補助期間は14~1,224(498)日である。24例が7~1,005(309)日後に死亡したが17例は移植待機であった。VASは従来心臓移植へのブリッジ(bridge to transplant)と考えられてきたが、最近では長期待機により自己心機能が回復し、離脱できる症例

1. 適応となる疾患

心臓移植の適応となる疾患は従来の治療法では救命ないし延命の期待がもてない以下の重症心疾患とする。

- 1) 拡張型心筋症、および拡張相の肥大型心筋症
- 2) 虚血性心筋疾患
- 3) その他（日本循環器学会および日本小児循環器学会の心臓移植適応検討会で承認する心臓疾患）

2. 適応条件

1) 不治の末期の状態にあり、以下のいずれかの条件を満たす場合

- ① 長期間または繰り返し入院治療を必要とする心不全
- ② β 遮断薬およびACE阻害薬を含む従来の治療法ではNYHAⅢ度ないしⅣ度から改善しない心不全
- ③ 現存するいかなる治療法でも無効な致死的重症不整脈を有する症例

2) 年齢は60歳未満が望ましい

3) 本人および家族の心臓移植に対する十分な理解と協力が得られること

3. 除外条件

1) 絶対的除外条件

- ① 肝臓、腎臓の不可逆的機能障害
- ② 活動性感染症（サイトメガロウイルス感染症を含む）
- ③ 肺高血圧症（肺血管抵抗が血管拡張薬を使用しても6 wood単位以上）
- ④ 薬物依存症（アルコール性心筋疾患を含む）
- ⑤ 悪性腫瘍
- ⑥ HIV（human immunodeficiency virus）抗体陽性

2) 相対的除外条件

- ① 腎機能障害、肝機能障害
- ② 活動性消化性潰瘍
- ③ インスリン依存性糖尿病
- ④ 精神神経症（自分の病氣、病態に対する不安を取り除く努力をしても、なんら改善がみられない場合に除外条件となることがある）
- ⑤ 肺梗塞症の既往、肺血管閉塞病変
- ⑥ 膠原病などの全身性疾患

表2
心臓移植におけるレシピエント適応基準

(bridge to recovery) が報告されるようになり、当センターにおいても7例が90～310（147）日の補助後離脱している。特に計画的に離脱した6例は全例退院し現在外来で加療中であるが、最長9年を経過している。

III 心臓移植

1) 心臓移植の適応（表2）

① 適応疾患

対象疾患は、拡張型および拡張相肥大型心筋症および虚血性心筋疾患が主なもので、その他の疾患についてわが国では日本循環器学会の心臓移植適応検討会で検討される。

② 適応条件

現在の治療手段では心臓移植以外に有効なものがなく、表2に示す状態にあり、患者・家族が移植治

療を理解し、移植後免疫抑制療法などの治療を継続できることが条件となる。対象年齢は、現状では60歳以下が望ましいとされている。適応を考慮すべき状況においても、表2の除外条件に示されるような心臓以外の臓器や全身性疾患を有する場合は除外されるため、慎重な評価が必要である。特に一生涯続く治療を進めるうえで問題となるコンプライアンスに十分配慮しなければならない。

③ 適応決定・待機

わが国では当面心臓移植施設を限定することとなっており、当初は3施設でスタートし、最近4施設が追加された。適応決定は、各施設内検討会に加え日本循環器学会心臓移植適応検討会でも行う2段階審査を経ることとなっている。適応決定されれば、本人および家族へのインフォームド・コンセントおよび諸手続きを経て、日本臓器移植ネットワークの待機リストへ登録し、移植を待つこととなる。

登録後も心不全に対する治療を続けるが、待機中

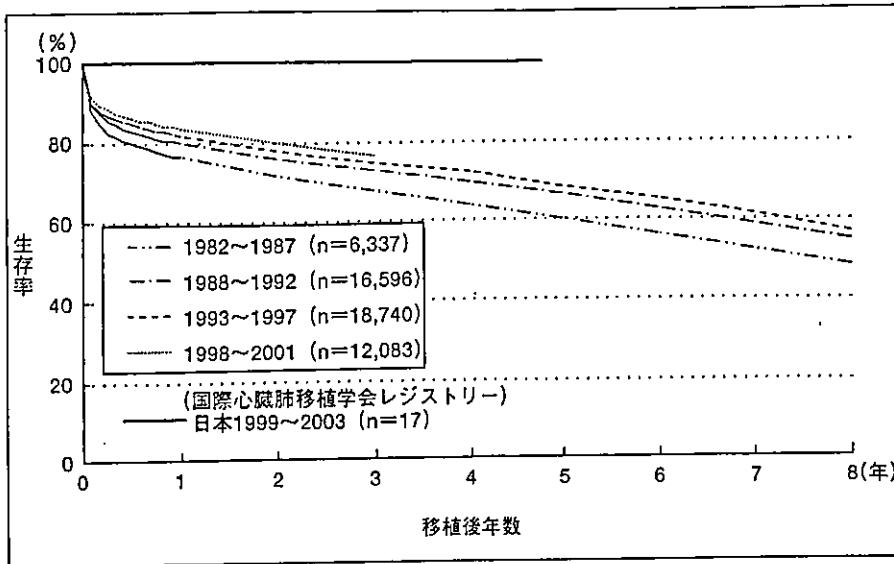


図2
心臓移植後の累積生存率
〔文献3〕より引用

に心機能改善例や適応外となる症例があるため、6カ月ごとに再検討する。また心不全が進行する場合、他臓器機能不全を引き起こす前にVASの適応を考慮する。

2) 世界における心臓移植の成績 (図2)

2003年の国際心肺移植学会の統計³⁾によると、1982年から2002年までに62,851例の心臓移植が行われている。1年生存率は80%で、50%の患者の生存期間は9.3年であった。生存率は1年以後年間約4%ずつほぼ直線的に低下し、移植後1年生存した症例における50%生存期間は12年であった。また、免疫抑制療法などの進歩により生存率は上昇し、1年生存率は1982~1987年の76%から1998~2001年の82%となった。免疫抑制療法としては、三者併用療法が行われており、最近ではシクロスポリン (あるいはタクロリムス)、ムコフェノール酸モフェチル、ステロイドが用いられている。死亡原因は、急性期は移植心不全、急性拒絶反応の頻度が高く、1年以後では移植後冠動脈病変や悪性腫瘍の頻度が増大する。また、移植後5年までの身体活動に関する調査では、90%以上が活動制限なしの生活を送っている。

3) わが国における心臓移植の現状 (図2, 表3)

1997年10月「臓器の移植に関する法律」の施行後、日本臓器移植ネットワークへ152人が登録され、17例の心臓移植が実施されたが、待機中に46名が死亡した。

移植17例における原疾患は、拡張型心筋症12例、

表3 わが国における心臓移植症例

移植症例数	17例
年齢	8~55 (平均35) 歳
性別	男性:13例, 女性:4例
原疾患	拡張型心筋症:12例, 拡張相肥大型心筋症:4例, 薬剤性心筋症:1例
待機状況	Status1:全例 (LVAS装着:11例)
LVAS	国循環型:7例 (LA:1, LV:6), Novacor [®] 型:2例, HeartMate [®] IP:2例
LVAS 補助期間	21~1,087 (平均428) 日 (1年以上:6例)
待機期間	29~977 (平均511) 日 (1年以上:12例)
実施施設	国立循環器病センター:8例, 大阪大学:7例, 東京女子医科大学:2例

〔文献4〕より引用

拡張相肥大型心筋症4例、薬剤性心筋症1例であった (表3)⁴⁾。待機状態は全例Status1と緊急度が高く、うち11例はLVAS装着例であった。移植待機日数は当初比較的短期だったが、その後長期化し、平均511日で1年以上待機は12例に及んだ。このためLVAS装着期間も長期化し、平均428日と1年を超え、6例が1年以上であった。

移植後全例が退院し、最長4年を経過しているが全例生存している。治療を要する拒絶反応を6例に、感染症を4例に認めたが、おのおの治療により軽快している。また15例が社会復帰し、良好な成績を示している。日常生活では、仕事や学業など特に大きな生活制限を認めず、旅行やスポーツを行っており、良好なQOLが得られている。