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Table 1 Baseline patient characteristics

Characteristics	
Number of patients	313
Average follow-up time (years)	6.8±4.9
Age (years)	60.9±8.9
Male/female	263/50
Hypertension	157(50%)
Hyperlipidemia	164(52%)
Diabetes mellitus	139(44%)
LVEF(%)	52±13
Number of CABG	
CABG 2	93
CABG 3(including one RCA bypass)	220
Target branches without LAD	
Dx	43
LCX	270
Graft to Dx or LCX territory	
ITA	64
SVG	249

Table 2

Characteristics	BITA	ITA/SV	p value
Number of pts	64	249	
Age	59.8±8.7	61.2±8.9	ns
Male/female	59/5	204/45	.046
HT	40	117	.027
HL	38	126	ns
DM	30	109	ns
LVEF(%)	50.4±12.2	52.8±13.5	ns
Op procedure			
On pump	29	248	
Off pump	35	1	<.0001
Target branches without LAD			
Dx	6	37	
LCX	58	212	ns
Number of CABG			
CABG 2	45	48	
CABG 3	19	201	<.0001

Efficacy of angiographically confirmed complete revascularization and prevention of competitive flow in total arterial off-pump coronary artery bypass

short title: Total arterial complete revascularization

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Off-pump, CABG, CABG surgery, Arterial graft, Angiography

Abstract

Background: We sought to delineate the effect of completeness of revascularization to three-vessel disease in total arterial coronary bypass grafting and the strategy for graft arrangement aiming at prevention of competitive and reversal flow.

Methods and results: Since December 2000, 481 patients underwent totally arterial off-pump complete revascularization(CR) without aortic manipulation for three-vessel territories and following postoperative angiography. The graft configuration was designed aiming at avoidance of competitive flow in arterial grafts since March 2003. Current standard configuration consisted of the in-situ ITA to the anterior descending artery and the composite I-graft of the right ITA and radial artery to the left circumflex and right coronary arteries, sequentially. The number of distal anastomoses was 4.09±0.90, and the mean follow up period was 27.9±18.5 months. In early angiography, CR was confirmed in 460 patients (CR), while revascularization was incomplete in 21 patients (IR group). Distal anastomoses per patients were 4.10±0.91 in CR group and 3.76±0.90 in IR group, respectively ($p=0.04$). The graft patency rate in CR group was 99.6% (1881/1888), and was significantly higher ($p=0.02$) than that in IR groups (54/79; 68.4%) ($p<0.0001$). There were more moredately stenotic branches (44/79; 55.7%) in IR group than in CR group (859/1888; 45.5%) ($p=0.08$). The univariate and multivariate Cox-regression analysis demonstrated that the early period (HR=2.78; $p=0.02$) and IR (HR=4.81; $p=0.001$) were the significant predictors of cardiac events.

Conclusion: Moderately stenotic coronary branch could be a cause of IR, when the arterial grafts were exclusively used. Angiographically confirmed CR and the appropriate graft configurations, which maximize antegrade bypass flow, had beneficial effects on the intermediate term outcome of total arterial off-pump coronary bypass grafting.

Introduction

Fewer bypass grafts and more incomplete revascularization (IR) may explain the increased recurrence of angina and repeated coronary intervention associated with off-pump surgery. Currently, complete revascularization (CR) may be essential for rationale of coronary surgery without cardiopulmonary bypass (1,2,3), it was reported as the significant predictor of the lower incidence of adverse cardiac events in the follow-up period. However, in most previous studies which demonstrated the advantage of CR against IR, patients' selection bias would be a major concern.

All patients in the present study underwent CR for three-vessel disease without cardiopulmonary bypass and following early angiographic examination. The patients with CR or with IR were categorized by the findings of the early postoperative angiography, not by what the surgeon had performed. Therefore, there was no major bias in selection of the patients or decision of the operative procedure. In addition, arterial grafts were exclusively used. We have introduced bypass flow grading system since 2000 (4). Since characteristics of blood flow in the lumen determine the fate of the bypass graft, we have adjusted the graft design for each coronary artery branches to prevent competitive and reversal flow (4,5).

The purpose of the study is to delineate the effect of angiographically confirmed CR and the results of our strategy aiming at prevention of competitive flow on the intermediate-term outcome after total arterial off-pump coronary bypass.

Materials and methods

Between December 2000 and May 2006, 481 patients with three-vessel coronary artery disease underwent total arterial off-pump complete revascularization using internal thoracic artery (ITA) and radial artery without aortic manipulation. There were 397 men and 84 women with the mean age of 66 ± 9 years. Early postoperative coronary angiography was carried out in all 481 patients. These patients were consecutive after exclusion of those with the gastroepiploic artery, inferior epigastric artery, or saphenous vein graft, and those who did not undergo early postoperative coronary. All patients provided written informed consent after explanation of the potential risks.

Early coronary angiography was performed about 2 weeks after surgery. The native coronary artery stenosis and the patency of the bypass grafts were independently evaluated by cardiologists. A patent graft meant that the graft lumen had a complete continuity throughout from the subclavian artery to the target coronary branch, irrespective of the flow direction. Angiographically confirmed CR was defined as the situation that at least one bypass graft to each of the three major vascular regions was patent in angiography. In our evaluation, whenever the continuity of the graft lumen from the origin of the in-situ ITA to the anastomotis site was interrupted at any level, it was defined as occlusion (Grade O). Grade A was defined as a situation in which antegrade graft flow was found in most of the multi-plane ITA angiographs. Grade B (competitive) was defined as a situation in which the target vessel was slightly opacified from the ITA graft injection, and the bypass graft did fill by retrograde flow from the native coronary injection. Grade C (reverse flow) was defined as a situation in which the distal anastomotic site was not opacified from the ITA graft injection at all, but it did fill clearly by retrograde flow from the native coronary injection. Flow grade and the maximal severity of stenosis were recorded for each target coronary branch.

Graft selection and arrangement

CR, which meant bypass grafting to all three vascular regions, was performed using only arterial grafts without aortic manipulation in all 481 patients. The arrangement of the bypass conduits was primarily determined by the operative risk and positional relationship of the target sites. As shown in Table 1, 197 patients had a single in-situ ITA graft as the composite graft, while 284 patients had bilateral in-situ ITAs in various configurations. Based on the results of previous studies and clinical experience, our current standard strategy has been introduced in March 2003 aiming at prevention of reverse and competitive flow. In this technique, one in-situ ITA was anastomosed to the left anterior descending artery (LAD) and an I-graft of the contralateral ITA and the radial artery was connected the circumflex (LCX) and the right coronary artery (RCA) in a clockwise orientation, via a side-to-side anastomosis with the LCX branch and an end-to-side anastomosis with the RCA branch. When RCA had only 75% stenosis and LCX had severe stenosis, the counterclockwise orientation was chosen

(5,6). Before introduction of this strategy, the I-graft was used only in a counterclockwise orientation for the safety of redo operation.

The mean follow-up period was 27.9 ± 18.5 months.

Statistical analysis

The continuous variables are expressed as the mean values ± standard deviation and compared by unpaired Student t-test. The data of two independent groups were compared by Fisher's exact probability test. The actuarial survival and event-free rates were determined by Kaplan-Meier method, and compared by log rank method. Cox regression analysis was used to examine the significance of the clinical and angiographic variables in predicting the survival and event-free time. The differences in the outcomes were considered statistically significant when the p value was less than 0.05.

Results

By the early postoperative angiography, CR was confirmed in 460 (95.6%) patients, whereas IR due to graft occlusion was detected in 21 (4.4%) patients. The overall graft patency rate was 98.4% (1935/1967). The number of distal anastomoses in patients with CR was 4.10±0.91, and was significantly greater than that in patients with IR (3.76±0.70) (p=0.04) (Table 3). The graft patency rate in patients with CR was 99.6% (1881/1888), and was significantly higher than that in patients with IR (68.4%; 55/79) (p<0.0001). The rate of moderately stenotic coronary branches in patients with IR (55.7%) was relatively higher than that in patients with CR (45.5%) (p=0.08), while the rates of small coronary branches, which included 1.25mm or less in diameter, were similar in the two group (p=0.80).

During the follow-up period, 6 patients in CR group died (sudden cardiac death in 3, others in 3). Twenty seven patients in CR group and 6 in IR group underwent percutaneous coronary intervention for myocardial infarction or recurrent angina. The actuarial survival rates at 40 months were 98.4% in CR group and 100% in IR group. There was no significant difference (p=0.55). The actuarial cardiac event free rate at 40 months in CR group was 91.9%, and was significantly higher than that in IR group (58.9%) (p<0.0001). The

univariate and multivariate Cox regression analyses demonstrated that incomplete revascularization (p=0.001; HR=4.81) and the early period; December 2000 ~ March 2003 (p=0.02 HR=2.78) were the significant predictors of the cardiac events, which included cardiac death and repeated coronary intervention (Table 4).

Discussion

The superior patency and long-term results associated with the ITA has stimulated total arterial bypass grafting to overcome the limitations of vein grafting. It may be true that there is a concern for increased risk of early morbidity and mortality, which may be owing to the use of bilateral ITA and its associated risk for sternal complications. Legare and colleagues reported increased morbidity but not mortality with total arterial grafting (7). Baskett and colleagues, mentioned that total arterial revascularization did not increase the procedural risk of bypass graft surgery (8). Regarding the number of arterial grafts and postoperative complications, Guru and colleagues reported that the use of two or three arterial grafts was beneficial in the early and midterm follow-up period, as compared with one arterial graft, but there was no obvious advantage of the use of three arterial grafts versus two arterial grafts (9).

Previously, several large studies advocated the significance of CR as the predictive factor of the late survival and less adverse cardiac events. Completeness of the revascularization to all three major vascular regions is reported as one of the independent predictors of survival after coronary artery bypass grafting (10,11,12,13), including short (14) and long term survival (15). CR using multiple vein grafts in patients with three-vessel disease appeared to most benefit those with severe angina and left ventricular function in the 5-year follow up period (11). This could be more successfully achieved by surgical treatment as compared with catheter intervention, and may be an important factor supporting the clinical benefit of surgical revascularization.

The efficacy of traditional CR, which was defined as revascularization of all coronary vessels with significant stenosis, was remains controversial. Salm and colleagues reported that the MI-free survival rate of patients with multiple anastomoses to non-LAD system was

significantly lower than those with no more than one graft insertion to a non-LAD system, and construction of more than one graft to the LCX or RCA territory may be deleterious (16).

The most common reported reason for IR was too small vessel size (12). The next most frequently recorded reasons for IR were severely diseased vessel, nondominant RCA, prior myocardial infarction (13), and unavailability of proximal anastomosis to the ascending aorta (12). The predictors of IR were identified as off-pump, territories diseased, female sex, prior myocardial infarction, and ejection fraction (13). These reported reasons and predictors were for abandonment of anastomosis. Fewer bypass grafts and IR in off-pump coronary bypass grafting may be an explanation of increased recurrence of angina and repeated coronary intervention. CR may be essential for rationale of off-pump coronary bypass (13).

On the other hand, in recent some mid-term follow-up investigations, the negative effect of IR was unclear (17). No independent survival disadvantage existed for traditional or functional IR as compared with CR (16). There was no significant difference in event-free survival between surgically treated patients with CR using an ITA to the LAD and saphenous vein graft to other branches and those with IR (18). For octogenarians, the use of the ITA improved survival and functional class, while CR did not have similar impact (19). IR associated with off-pump surgery did not decrease survival or increase ischemic events at 4 years (17).

There may be several possible explanations for differences in the results regarding efficacy of CR. First, there were some obvious differences between the patients' profiles with CR and those with IR. There was significant selection bias in choosing the modality of therapy, which meant CR or IR, graft materials, on-pump or off-pump and so on (13). Second, as improvement of medical therapy and interventional coronary angioplasty and the frequent use of arterial grafts, longer follow-up may be necessitated for significant difference. Third, in patients with IR, there was the difference between the surgeon's intension during operation and what was actually done. Technical failure would be the most important bias. Occlusion of anastomotic site will be highly associated with the small branches in the RCA and LCX territories. Relatively ambiguous definition of completeness may be a possible reason.

In addition, there may be some issues specific for total arterial revascularization. In total arterial grafting, the ITA graft is commonly connected to two or more coronary branches as a composite or sequential graft to achieve complete revascularization, because the number and its length are limited. Various graft configurations were reported (8,9,20.21). The conduit design played a critical role in successful revascularization to three vessel territories (5). Since the number of grafts, the site of proximal anastomosis of the radial artery, and the graft design strategy (5) appear to influence the risk of operative complications (22,23), long-term patency of the grafts, and the durability of completeness of revascularization.

In present study, bypass grafting to three coronary territories was performed in all patients. All patients underwent off-pump coronary bypass with the ITA and the radial artery without aortic manipulation. Since completeness of revascularization was classified by the early postoperative angiography, selection bias for performing CR versus IR or for performing the early angiography or not is not present.

In our patients, the common reasons for IR, which was detected by postoperative angiography, were not only the less distal anastomoses and technical difficulty in small target branches but also moderate stenosis in the target coronary branches. This might be due to the facts that severity of the native coronary stenosis is reported as the significant predictor of graft occlusion in arterial grafts (24). In the results, angiographically confirmed CR and prevention of competitive and reverse flow inversely correlated with the occurrence of cardiac event, and the use of bilateral in-situ ITAs did not independently correlated with the less cardiac event. In previous report, the use of bilateral in-situ ITAs provided the higher rate of antegrade flow in the bypass graft (25). These results suggest that bilateral in-situ ITAs is advantageous, only when competitive and reverse flow do not occur.

The present study has some limitations. This study was retrospective and consisted of small number of patients, especially in IR group. In addition, the patients were hospital survivors. Therefore, operative mortality and morbidity were not concerned. Second, this study was focused on the arterial grafts and graft thinning associated with flow insufficiency. There was no significant disadvantage in the survival rate of the IR group as compared with the CR group. We believe that the early angiography is effective for improvement of late

results after CABG, because thinning and occlusion of the arterial graft can be not only detected and but also frequently predicted by the graft flow pattern. Third, luminal size of the grafts and anastomotic sites were not mostly measurable, because we utilized multiple sequential anastomoses in side-to-side fashion especially for moderately stenotic coronary branches, where contrast medium did not fill completely by mixture of the blood flows from native coronary and bypass graft. At last, this study is not randomized. However, these data were collected prospectively, and assigning CR or IR is considered unsuitable for randomization.

In conclusion, current graft arrangement, which provided increase of bypass grafts with antegrade flow, and angiographically confirmed CR associated with improvement of the clinical outcome after CABG. Adequate graft arrangement with consciousness of anticipated bypass flow may be necessary to enhance the advantage of arterial materials and durable completeness of revascularization.

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Figure Legends

Figure 1,

Comparison of the cumulative cardiac event free rates; complete versus incomplete revascularization.

Table 1

Patients' characteristics

	CR group	IR group	p value
Angiographically confirmed CR	Complete	Incomplete	
No. of patients	460	21	
Age (yrs)	66.4±9.0	65.1±7.6	0.23
Male/Female	383 / 77	14 / 7	0.07
Hypertension	251 (55%)	11 (52%)	>0.99
Hyperlipidemia	237 (52%)	11 (52%)	>0.99
Diabetes	192 (42%)	5 (24%)	0.12
End-diastolic volume index of LV (ml/m2)	84.6±29.1	89.3±19.7	0.26
Ejection fraction of LV (%)	47.2±11.7	47.8±10.1	0.42
< 40%	85 (18%)	4 (19.0%)	>0.99
Date of surgery Early period (~ Feb. 2003)	194 (42%)	10 (48%)	0.65
Late period (Mar. 2003~)	266 (58%)	11 (52%)	0.65
Total distal anastomoses per patient	4.10 ± 0.91	3.76 ± 0.70	0.04
Bilateral in-situ ITAs	271 (59%)	13 (62%)	0.82

ITA; internal thoracic artery LV; left ventricle EF; ejection fraction

Table 2

Characteristics of target coronary branches

		CR group	IR group	p value
No. of patients		460	21	
Total distal anastomoses		1888	79	
Sererity of stenosis in target branch	51-75%	859 (45.5%)	44 (55.7%)	0.08
	76-90%	522 (27.6%)	18 (22.8%)	-
	91-100%	507 (26.9%)	17 (21.5%)	-
Diameter of target branch	< 1.5mm	552 (29.2%)	24 (30.4%)	0.80
	≥ 1.5mm	1224 (64.8%)	48 (60.8%)	-
	not recorded	112 (5.9%)	7 (8.9%)	-

CR; complete revascularization. IR incomplete revascularization