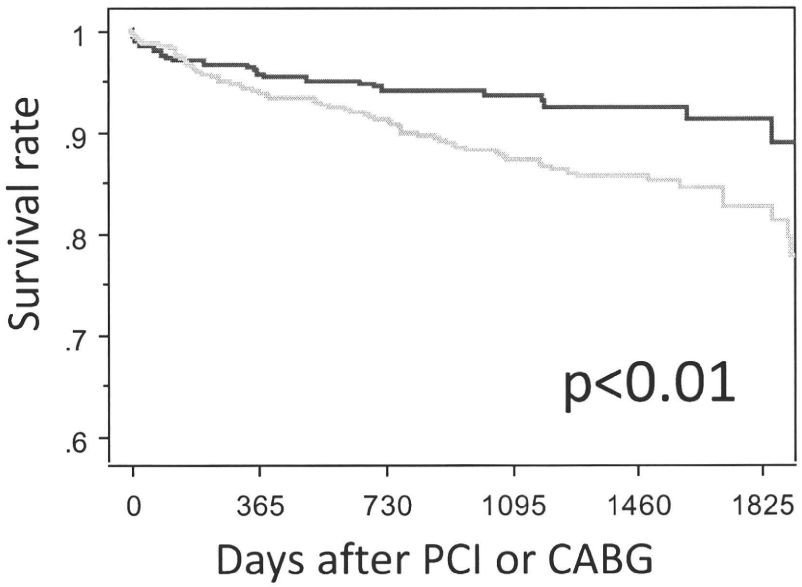
Figure 2A, 2B (Poor control group)

CABG
PCI

A. All-cause death

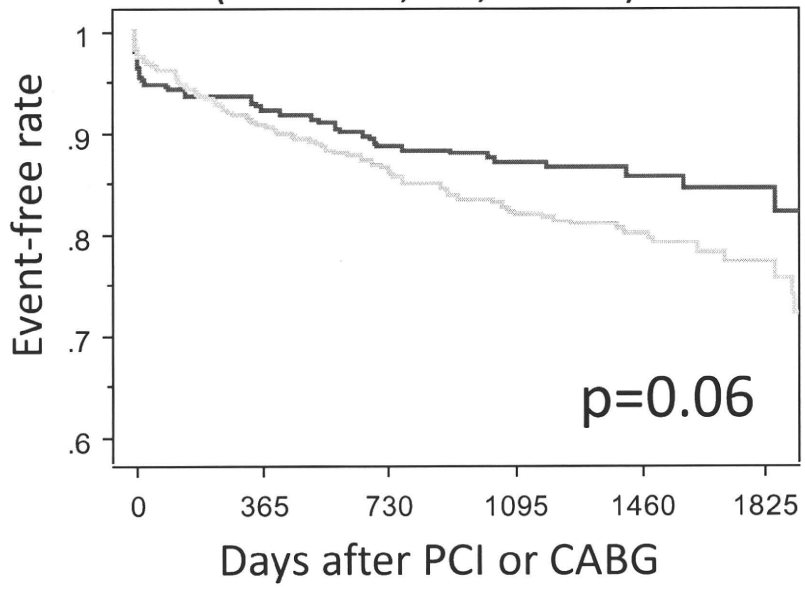


No. at Risk

	0	1yr	2yrs	3yrs	4yrs	5yrs
PCI	562	514	481	349	186	60
CABG	323	299	286	193	110	43

B. Composite event

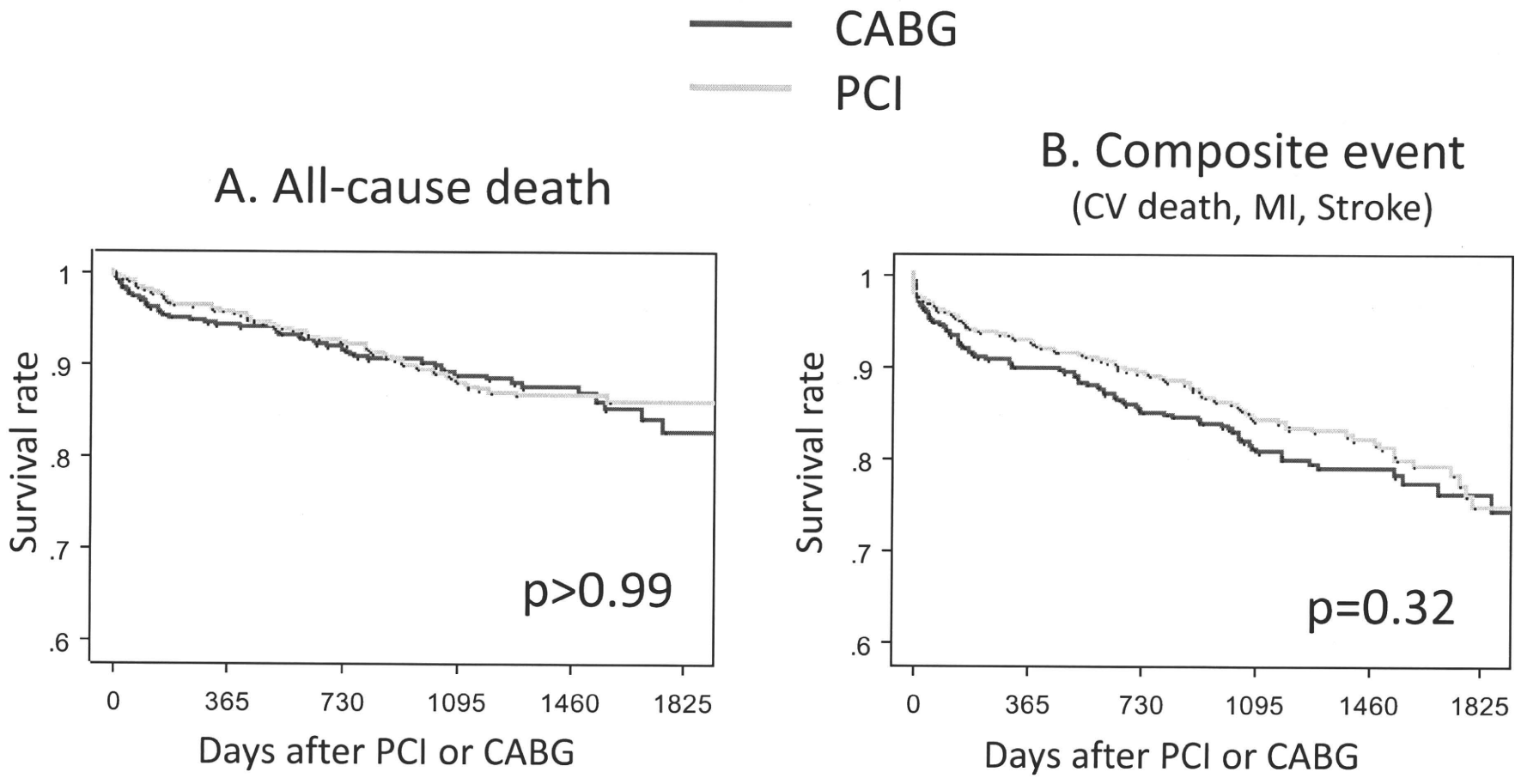
(CV death, MI, Stroke)



No. at Risk

	0	1yr	2yrs	3yrs	4yrs	5yrs
PCI	562	491	446	315	166	53
CABG	323	286	266	180	102	40

Figure 3A, 3B (Good control group)



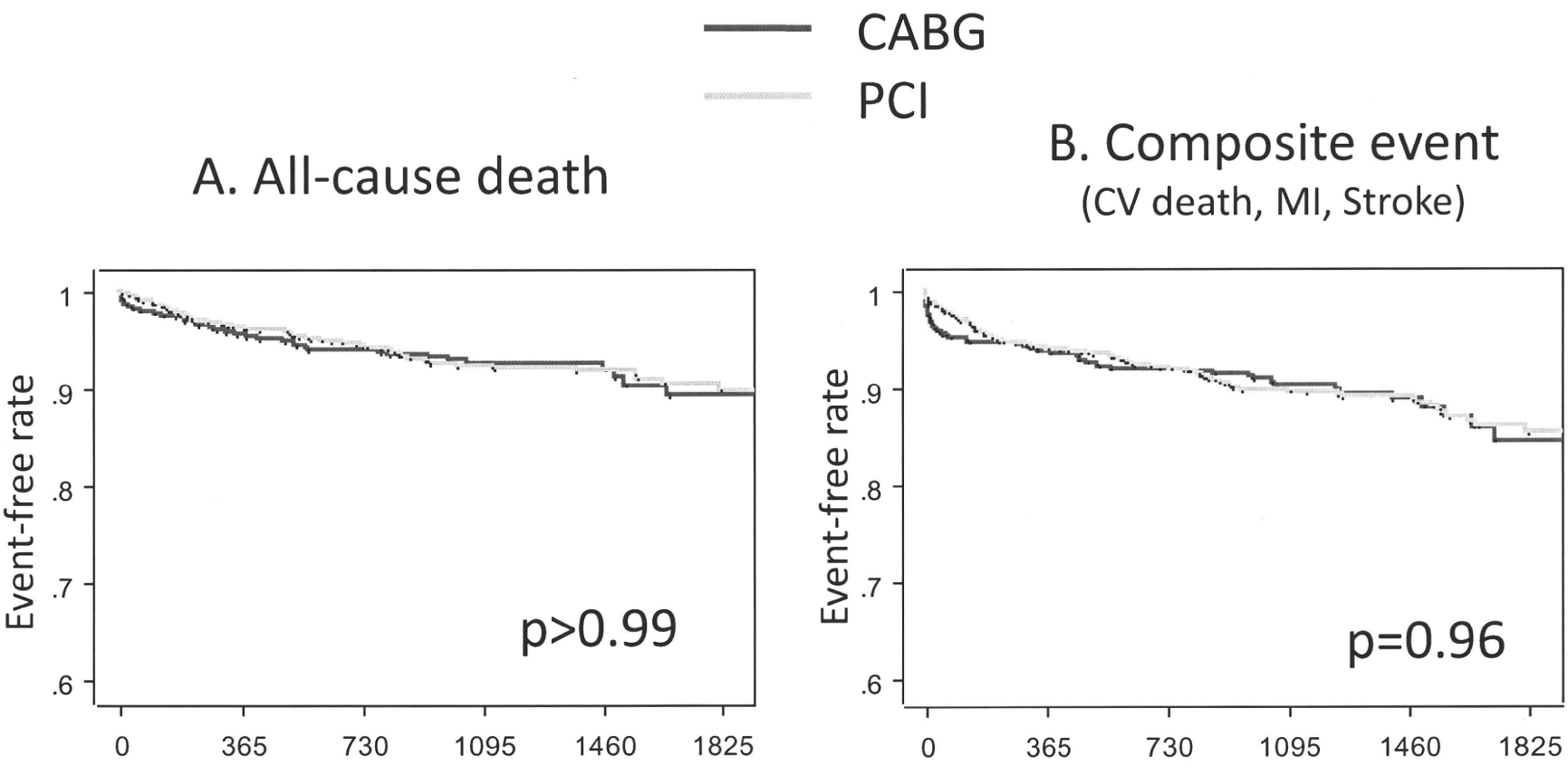
No. at Risk

	0	1yr	2yrs	3yrs	4yrs	5yrs
PCI	555	518	486	357	190	67
CABG	399	366	344	247	138	50

No. at Risk

	0	1yr	2yrs	3yrs	4yrs	5yrs
PCI	555	502	462	329	174	59
CABG	398	346	316	222	126	47

Figure 4A, 4B (Normal group)



No. at Risk

	0	1yr	2yrs	3yrs	4yrs	5yrs
PCI	858	812	805	595	331	125
CABG	453	426	403	283	133	39

No. at Risk

	0	1yr	2yrs	3yrs	4yrs	5yrs
PCI	858	787	742	571	313	117
CABG	453	413	387	238	124	41

Impact of Proximal Anastomosis Procedures on Stroke in Off-Pump Coronary Artery Bypass Grafting

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ABSTRACT ***Background:*** **There are many options for proximal anastomosis during off-pump coronary artery bypass grafting (CABG), but the efficacies of these procedures have not been well clarified. Therefore, we examined the clinical impact of our strategy to modify the proximal anastomosis procedure for aortic atherosclerosis.** ***Methods:*** **We retrospectively reviewed 535 consecutive patients undergoing off-pump CABG between 2004 and 2007. The patients were divided into three groups depending upon the type of proximal anastomosis procedure: 241 patients with normal or mild atherosclerosis underwent partial clamping (clamp group), 81 patients with moderate atherosclerosis underwent the procedure with Heartstring (Guidant Corporation, Santa Clara, CA, USA), 28 patients underwent with Enclose II (Novare Surgical Systems, Inc., Cupertino, CA, USA) (device group), and 185 patients underwent the procedure without clamping, including six with severe atherosclerosis (no-touch group).** ***Results:*** **There were seven in-hospital mortalities (1.3%) and five strokes (0.9%). There was no difference in the mortality rate (clamp, 1.2%; device, 1.8%; no-touch, 1.1%; $p = 0.42$) or stroke rate (clamp, 0.8%; device, 2.8%; no-touch, 0.5%; $p = 0.09$) among the three groups. Graft patency was similar regardless of the method (clamp, 94.7%; Heartstring, 96.7%; Enclosed II, 96.0%; $p = 0.80$).** ***Conclusions:*** **Our strategy to modify the proximal anastomosis procedure resulted in a low stroke rate. Aortic clamping could be performed safely in patients with normal or mild atherosclerotic aorta. In patients with moderate atherosclerosis, the result of an anastomotic device may need a further investigation.** doi: 10.1111/j.1540-8191.2009.00911.x *(J Card Surg 2009;24:644-649)*

Stroke after coronary artery bypass grafting (CABG) is a devastating complication. It occurs for various reasons, but the liberation of atheromatous debris from a diseased ascending aorta is the most significant mechanism.[1,2] Therefore, a careful assessment of the ascending aorta and a judicious selection of operative procedure are essential for stroke prevention. Epiaortic ultrasonographic scanning is a widely established method to detect atherosclerotic changes in the aorta.[2-5] We have modified the aortic anastomosis procedure using epiaortic ultrasonographic scanning. There are many options for proximal anastomosis during off-pump CABG, but the efficacies of these procedures have not been well clarified. The objective of this study was to retrospectively review our experience and investigate the impact of this procedural modification on clinical outcome.

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MATERIALS AND METHODS

We retrospectively analyzed 535 consecutive patients, from a single institution, who underwent off-pump CABG between September 2004 and June 2007. Patients who underwent any associated procedures were excluded from the analysis. During this period, all isolated CABGs were scheduled to be performed off-pump. Six patients who were converted to an on-pump CABG were excluded from the study. We routinely performed coronary angiograms before discharge for patients who underwent off-pump CABG, regardless of the patient's symptoms. Patients who died, refused angiographic evaluation, were older than 75 years old, or had renal dysfunction (serum creatinine >1.2 mg/dL) were excluded from the angiographic study. Postoperative angiographic study was performed in 432 patients (80.7%). Our Institutional Ethics Committee waived the need for patient consent and provided approval before publication of the data.

Epiaortic ultrasonography

Epiaortic ultrasonographic scanning was conducted when the revascularization strategy included proximal

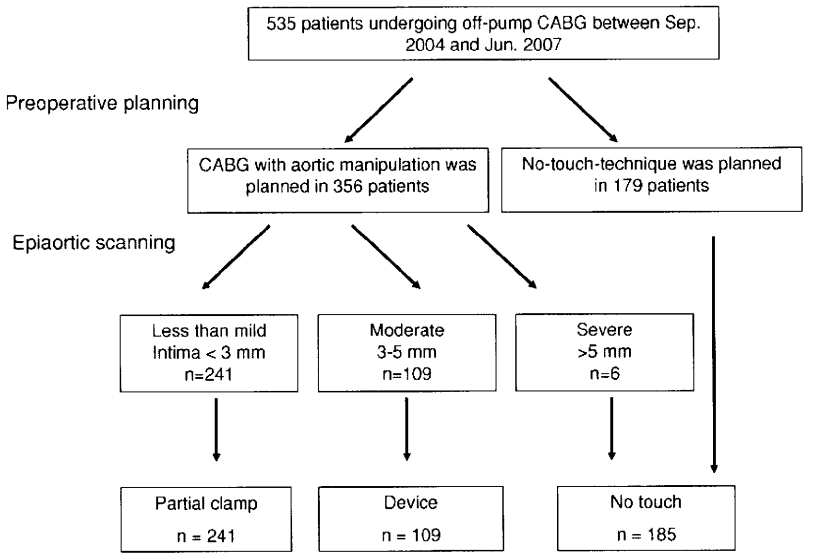

Figure 1. *Schematic of our strategy to modify the proximal anastomosis procedure using epiaortic ultrasonography.*

anastomosis to the aorta. There were 179 patients who did not receive aortic scanning, because aortic no-touch technique had been planned preoperatively. The scanning was performed with a 7.5-MHz linear ultrasonic probe (Sonos 7500; Philips Medical Systems, Andover, MA, USA), coated with ultrasonic gel as an acoustic medium, and packed in a sterile plastic sleeve. Ascending aortic atherosclerotic disease was defined as normal/mild (intimal thickness <3 mm), moderate (intimal thickness 3 mm to 5 mm), and severe (intimal thickness >5 mm; or the presence of marked calcification, protruding mobile intraluminal atheromatous portions, and ulcerated plaques).

Strategy of proximal anastomosis

The proximal anastomosis procedure was modified according to the results of epiaortic scanning (Fig. 1). Aortic scanning was performed on 356 patients who were to receive proximal anastomosis to the aorta. Partial clamping was performed in 241 patients who had normal or mild aortic atherosclerosis. A less invasive anastomotic device was selected for 109 patients who had moderate aortic atherosclerosis. Heartstring (Guidant Corporation, Santa Clara, CA, USA) was selected for 81 patients and Enclose II (Novare Surgical Systems, Inc., Cupertino, CA, USA) was selected for 28 patients. The selection of the two anastomotic devices depended on the preference of each surgeon. In six patients who had severe aortic atherosclerosis, the operative procedure was modified to an aortic no-touch technique.

Operative technique

Heparin (3.0 mg/kg) was administered intravenously after sternotomy to maintain an activated clotting time of more than 400 seconds, and it was neutralized at the end of the procedure with protamine sulfate (3.0 mg/kg). After hemostasis was achieved, patients who underwent CABG with a saphenous vein graft received a continuous heparin infusion to maintain an activated clotting time of 160 to 180 seconds until warfarin control was achieved. Aspirin was given to all patients.

Diagnosis of brain infarction

Stroke was suspected from any new global or focal neurological deficit and was confirmed by computed tomography or magnetic resonance imaging (MRI). It was diagnosed definitively by an attending neurologist. Reversible cerebral ischemic events were not considered as stroke. Stroke etiologies were identified and divided into thromboembolism and hypoperfusion. Thromboembolism was further divided into embolic, lacunar, and thrombotic.

Statistical analysis

Continuous variables are reported as mean ± standard deviation (SD). The chi-square test was used to analyze between group differences in the categorical variables. The Kruskal-Wallis test was used to analyze differences in continuous variables. Statistical significance was accepted at $p < 0.05$ and was performed with SPSS statistical software (SPSS version 11.0; SPSS Japan, Tokyo, Japan).

RESULTS

There were significant differences in age, gender, history of stroke, ischemic MRI findings, carotid artery stenosis, three-vessel disease, number of distal anastomoses, anticoagulant use, and new-onset atrial fibrillation (Table 1). Patients in the device group were older, more likely to have a history of stroke, show ischemia on MRI, and have carotid artery stenosis. Moreover, these patients were more likely to have a new-onset of atrial fibrillation and anticoagulant therapy. Those patients in the no-touch group had a lower prevalence of three-vessel disease and a lower number of distal anastomoses.

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TABLE 1
Patient Characteristics

Characteristics	Clamp n = 241	Device n = 109	No-Touch n = 185	p Value
Preoperative				
Age (years)	68.1 ± 9.1	70.9 ± 8.4	68.4 ± 8.8	0.01
Male	73.0% (176)	83.5% (91)	90.3% (167)	≤0.01
Coronary risk factor				
Hypertension	75.5% (182)	75.2% (82)	71.9% (133)	0.67
Diabetes	42.7% (103)	38.5% (42)	38.4% (71)	0.60
Insulin dependent	10.0% (24)	8.3% (9)	9.2% (17)	0.14
Hyperlipidemia	63.9% (154)	57.8% (63)	54.6% (101)	0.88
History of stroke	9.1% (22)	20.2% (22)	10.8% (20)	0.01
Ischemic finding in MRI	49.5% (106)	56.9% (62)	43.8% (81)	0.05
Carotid artery stenosis	7.1% (17)	16.5% (18)	8.1% (15)	0.01
Three-vessel disease	80.9% (195)	79.8% (87)	40.0% (74)	≤0.01
Operative				
Emergent surgery	12.4% (30)	13.8% (15)	13.5% (25)	0.92
Results of aortic scanning	Normal or mild	Moderate	Severe 6 unknown 179	
No. of distal anastomosis	4.4 ± 1.2	4.2 ± 1.2	3.6 ± 1.3	≤0.01
Postoperative				
Anticoagulant use	84.2% (203)	92.7% (101)	29.7% (55)	≤0.01
New onset of atrial fibrillation	28.2% (68)	44.0% (48)	31.4% (58)	0.01

Parentheses represent the actual number of patients in each group.
MRI = magnetic resonance imaging.

There were seven in-hospital mortalities (1.3%), and five strokes (0.9%) (Table 2). The stoke rate in patients who received aortic scanning was 1.1% (four of 356). There was no difference in the mortality rate among the three groups. Patients in the device group had a slightly higher stroke rate than those who underwent clamp or no-touch procedures but the difference was not statistically significant. All strokes occurred postoperatively and the profile of each stroke patient is shown in Table 3. Patients who developed postoperative atrial fibrillation were more likely to have a stroke than those who did not, but there was no difference in the stroke rate for patients that did or did not undergo aortic manipulation (Table 4).

The operative procedures were compared among patients with three-vessel disease to determine whether the proximal anastomosis method affected the choice of a graft (Table 5). The number of distal anastomoses was similar among the three groups. The operative procedures were similar between those in the clamp and the device groups. Composite grafting and use of the gastroepiploic artery were more frequently chosen for the no-touch procedures, whereas the saphenous vein was chosen less frequently. Graft patency was similar regardless of the method (Table 6).

DISCUSSION

Our strategy to modify the proximal anastomosis procedure following epiaortic ultrasonographic scanning resulted in a low stroke rate. Aortic clamping could be performed safely in patients with a normal or mild atherosclerotic aorta. In patients with moderate atherosclerosis, the use of less invasive devices may need a further investigation. Each proximal anastomosis procedure resulted in a similar patency rate.

In conventional on-pump CABG, stroke occurs at a rate of 0.8% to 5.2%.[6] The presence of atherosclerosis in the ascending aorta, a leading risk factor for stroke, is associated with a fourfold increase in stroke.[1,2] Transcranial Doppler ultrasonography has shown that surgical manipulation of the ascending aorta with atherosclerosis may liberate atheromatous debris and cause brain embolism.[7] Therefore, the detection of atherosclerosis in the ascending aorta and a procedural modification to minimize aortic manipulation are essential to reduce the risk of stroke after CABG. Epiaortic ultrasonographic scanning is a widely established method to detect atherosclerosis in the aorta.[2-4] A low stroke rate (2.3%) has been achieved using epiaortic scanning with on-pump CABG followed by a procedural modification.[5]

TABLE 2
Clinical Results

	Overall n = 535	Clamp n = 241	Device n = 109	No-Touch n = 185	p Value
In-hospital mortality	1.3% (7)	1.2% (3)	1.8% (2)	1.1% (2)	0.42
Stroke	0.9% (5)	0.8% (1)	2.8% (3)	0.5% (1)	0.09

Parentheses represent the actual number of patients in each group.

TABLE 3
Profile of Stroke Patients

No.	Group	Age/Sex	Cause of Stroke	Timing of Onset	CT/MRI Findings	Carotid Lesion	Stroke History	AF	Anticoagulant	Coronary Risk Factor
1.	Clamp	68/male	Embolic	5	Left corona radiata	Not screened	No	Yes	Yes	HT, HLP DM (insulin)
	Stroke occurred just after cessation of postoperative atrial fibrillation. The INR value at the time of stroke onset was 2.51									
2.	Device (Heartstring)	81/male	Embolic	2	Multiple	Not screened	No	Yes	No	DM, smoking
	Stroke occurred just after cessation of postoperative atrial fibrillation. The INR value at the time of stroke onset was 1.62									
3.	Device (Heartstring)	76/female	Hypoperfusion	1	Right corona radiata	No	Yes	Yes	No	HT, DM, HD
	Stroke occurred after recovery from hypovolemic shock during postoperative hemodialysis									
4.	Device (Heartstring)	88/female	Embolic	1	Bilateral cerebellum	Unilateral	Yes	Yes	Yes	HT
	She had symptomatic severe unilateral carotid artery occlusion. Stroke occurred after the recovery from anesthesia									
5.	No-Touch	80/male	Thrombotic	6	Multiple	No	No	No	No	HT, HLP
	Stroke occurred after weight loss due to polyuria. He had an almost normal ascending aorta									

CT = computed tomography; MRI = magnetic resonance imaging; INR = international normalized ratio; AF = atrial fibrillation; HT = hypertension; HLP = hyperlipidemia; DM = diabetes mellitus; HD = chronic hemodialysis.

Although the efficacy of off-pump CABG to reduce stroke remains controversial,[8-10] it has been effective for reducing stroke in patients with aortic atherosclerosis.[11,12] Off-pump CABG does not require aortic manipulation, except when performing a proximal anastomosis to the aorta, and there are a wide variety of proximal anastomosis procedures that minimize aortic manipulation. The strategy for managing aortic atherosclerosis in off-pump CABG is drawing interest, but has not yet been established.

There is no consensus as to whether avoiding aortic manipulation actually reduces stroke even in patients undergoing off-pump CABG. According to Calafiore et al., the use of side-clamping during off-pump CABG results in a similar stroke rate as patients undergoing conventional on-pump CABG.[13] However, epiaortic ultrasonography can aid in the selection of good candidates for aortic clamping and reduce their stroke risk. We found a low stroke rate (0.8%) in patients of the clamp group who had a normal or mild atherosclerotic aorta. These results suggest that aortic clamping is safe in patients with normal or mild atherosclerotic aorta.

The efficacy of using a less invasive device to reduce stroke, especially in patients with atherosclerotic aorta, has not been determined. One small study (n = 19) found a relatively high stroke rate (5.2%) following the use of the Heartstring device in patients with a diseased aorta.[14] In patients with a moderately atherosclerotic aorta, we used Heartstring and Enclose II and the stroke rate (2.8%) was slightly higher than in patients who underwent clamps or no-touch procedures. Due to differences in patient background, it may be simplistic to compare stroke rates among these groups. However, our study is too small to determine the efficacy of anastomotic devices for patients with an atherosclerotic aorta, further investigation is considered necessary.

The aortic no-touch technique is an effective method to reduce stroke.[13,15,16] Our study also confirmed a low stroke incidence (0.5%) in no-touch group including six patients with a severe atherosclerotic aorta. However, use of the aortic no-touch technique may limit the revascularization strategy. In most studies, the number of distal anastomoses is lower in those undergoing an aortic no-touch procedure (Lev-Ran et al.; 2.30 vs. 2.54, $p = 0.003$,[16] Bolontin et al.; 2.27 vs. 3.11, $p < 0.001$).[16,17] The in-flow source was limited to only three in situ grafts. Revascularization for the lateral wall usually requires composite grafting, whereas revascularization for the right coronary artery usually requires the use of the gastroepiploic artery. The consequence of this special strategy has not been completely clarified, but Gaudino et al. suggested that using the radial artery as a composite graft is more vulnerable to the detrimental effect of flow competition.[18] We usually performed the no-touch technique only in patients whose target right coronary artery is severely stenosed and suitable for grafting with gastroepiploic artery. And currently, the no-touch technique is our first-choice treatment only for patients with severe atherosclerosis.

TABLE 4
Predictors of Stroke

Characteristics	Stroke Rate (%)		p Value
	With Characteristics	Without Characteristics	
Age >70 years	1.47	0.38	0.37
History of stroke	3.13	0.64	0.11
Carotid artery stenosis	2.00	0.48	0.29
Ischemic finding in MRI	0.82	0.51	1.00
Aortic manipulation	1.14	0.54	0.66
Postoperative atrial fibrillation	2.27	0.28	0.04

MRI = magnetic resonance imaging.

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TABLE 5
Impact of the Proximal Anastomosis Procedure on Graft Choice

Characteristics	Clamp n = 195	Device n = 87	No-Touch n = 74	p Value
Number of distal anastomosis	4.6 ± 1.1	4.5 ± 1.1	4.5 ± 1.0	0.40
Frequency of use of composite graft	52.8% (103)	60.0% (52)	85.1% (63)	≤0.01
Frequency of use of each graft				
LITA	100% (195)	97.7% (85)	98.6% (73)	0.13
RITA	90.8% (177)	95.4% (83)	93.2% (69)	0.38
RA	60.5% (118)	48.3% (42)	55.4% (41)	0.16
SV	93.3% (182)	94.3% (82)	14.9% (11)	≤0.01
GEA	9.2% (18)	3.4% (3)	60.8% (45)	≤0.01

Parentheses represent the actual number of patients in each group. The number of distal anastomoses represents the mean ± standard deviation.
LITA = left internal thoracic artery; RITA = right internal thoracic artery; RA = radial artery; SV = saphenous vein; GEA = gastroepiploic artery.

TABLE 6
Angiographic Patency

	Clamp	Heartstring	Enclose II	p Value
Saphenous vein	94.5% (156/165)	96.4% (53/55)	94.7% (18/19)	0.87
Radial artery	95.0% (57/60)	100% (5/5)	100% (6/6)	0.75

Parentheses represent the actual number of patients with patent grafts/the total number of patients studied.

Study limitation

The limitations of the study include those inherent to all retrospective, nonrandomized studies. The number of study patients was relatively small, which did not allow us to make strong conclusions regarding the effect of an off-pump procedure on a rare complication such as stroke. Graft patency was only assessed in the immediate postoperative period. Therefore we can not determine the effects of this strategy on long-term graft patency or the recurrence of angina symptom based on our study design.

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Influence of carotid artery stenosis on stroke in patients undergoing off-pump coronary artery bypass grafting

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Abstract

Objective: It is well known that the presence of carotid artery stenosis increases the risk of perioperative stroke in patients undergoing cardiac surgery with cardiopulmonary bypass. Although off-pump coronary artery bypass grafting (CABG) can avoid the adverse effects of cardiopulmonary bypass, the influence of carotid artery stenosis on the incidence of stroke in patients undergoing off-pump CABG has not been well clarified. **Methods:** We conducted a retrospective study of 461 patients who underwent elective off-pump CABG after screening for carotid artery stenosis at our institute between September 2004 and May 2007. The incidence and etiologies of stroke were identified. Preoperative screening revealed significant carotid artery stenosis in 49 patients. Clinical results were compared between patients with and without carotid artery stenosis. **Results:** Postoperative stroke occurred in two (0.43%) of the 462 study patients, and in-hospital mortality occurred in three (0.65%). Stroke was due to decreased perfusion resulting from hypovolemic shock in one and thrombosis in the other. There was neither stroke nor in-hospital mortality in patients with carotid artery stenosis, although there were two strokes (0.49%) and three in-hospital mortalities (0.73%) in patients without carotid artery stenosis. **Conclusions:** The influence of carotid artery stenosis on the incidence of perioperative stroke may be little in off-pump CABG, especially in patients with moderate carotid artery stenosis.

Keywords: CABG; Off-pump; Carotid arteries; Cerebral complications

1. Introduction

Carotid artery stenosis (CAS) is present in 10–20% of patients undergoing coronary artery bypass grafting (CABG) and accounts for 30% of strokes associated with CABG [1]. Current ACC/AHA guidelines recommend prophylactic carotid endarterectomy (CE) to reduce the risk of perioperative stroke in patients with CAS who are scheduled for CABG. This recommendation is based mainly on results of several randomized studies [2–4] of general CAS patients that compared carotid endarterectomy (CE) with medical treatment for stroke prevention. However, in patients with CAS who undergo CABG evidence of a protective effect of prophylactic CE against coronary bypass stroke is lacking, and some researchers have doubted whether there is such an effect on risk reduction [5,6].

The etiology of stroke associated with CABG in patients with CAS may be multifactorial. A recent report by Schoof et al. emphasized the importance of impaired cerebral autoregulation distal to CAS as a main cause of stroke [6]. A typical mechanism is intra-operative hypoperfusion of the brain downstream of significant CAS, which may be due to the adverse effects of extracorporeal circulation. Although off-pump CABG can avoid the adverse effects of extracorporeal circulation, the influence of CAS on stroke in patients undergoing off-pump CABG has not been well clarified. Thus, we conducted a study to evaluate the clinical results of off-pump CABG in patients with unprotected CAS.

2. Materials and methods

The study was a retrospective single institutional analysis of 461 consecutive patients who underwent elective off-pump CABG after screening for CAS between September 2004 and May 2007. No patient who underwent any other associated procedure was included in the analysis. Seventy-three patients who did not undergo screening for CAS before surgery and 71 patients who underwent emergent operation were excluded from this study. During this period, all isolated CABGs were scheduled to be performed off-pump, and six patients in whom the procedure was converted to on-pump CABG were excluded from the study. Our institutional ethics committee waived the need for patient consent for this

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study, and approval was provided before publication of the data.

2.1. Screening for CAS

Magnetic resonance angiography (MRA) was performed in all patients who were scheduled for elective CABG. In patients with suspected CAS, carotid artery duplex scanning was conducted to determine the severity of CAS. CAS was classified according to laterality and severity of the stenosis. The severity of CAS was quantified according to the method used in the European Carotid Surgery Trial and was categorized as none/mild (<50%), moderate (50–70%), severe (80–99%), or total occlusion. Significant CAS was found in 49 patients (10.6%). The decision to treat CAS was determined by an attending neurologist. Treatment for CAS before CABG was considered in patients with a symptomatic carotid stenosis or in asymptomatic patients with internal carotid stenosis of 80% or more, if the condition of the patient was stable and surgery on the carotid artery could be performed safely before CABG. In one patient, whose cardiac condition was considered stable, carotid artery stenting proceeded CABG. This patient was excluded from the CAS group.

2.2. Operative techniques

Heparin (3.0 mg/kg) was administered intravenously after sternotomy to maintain an activated clotting time of more than 400 s, and it was neutralized at the end of the procedure with the use of protamine sulfate (3.0 mg/kg). In patients who underwent CABG with a saphenous vein graft, continuous heparin infusion was started after hemostasis was achieved to maintain an activated clotting time of 160–180 s until warfarin control was achieved. In patients who suffered new atrial fibrillation postoperatively, continuous heparin infusion was also started in the same manner. Aspirin was given to all patients.

In patients with a proximal anastomosis, epiaortic ultrasonography was performed to identify any atherosclerotic lesion of the ascending aorta. In patients with a diseased ascending aorta, a heartstring anastomotic device (Guidant, Indianapolis, IN) was used. During manipulation of the heart systolic arterial pressure was maintained above 80 mmHg.

2.3. Diagnosis of brain infarction

Stroke was suspected from any new global or focal neurological deficit and was confirmed by computed tomography or magnetic resonance imaging. Stroke was diagnosed definitively by an attending neurologist. Reversible cerebral ischemic events were not included. Stroke etiologies were identified and divided into two categories: thromboembolism and hypoperfusion. Thromboembolism was further divided into three types: embolic, lacunar, and thrombotic.

2.4. Statistical analysis

Continuous variables are reported as mean ± SD. Fisher's exact test was used to analyze between group differences in categorical variables. The Mann–Whitney test was used to analyze differences in continuous variables. Statistical significance was accepted at $p < 0.05$. Statistical analysis was performed with SPSS statistical software (SPSS version 11.0; SPSS Japan, Tokyo, Japan).

3. Results

3.1. Stroke associated with off-pump CABG

Patient characteristics and clinical outcomes are shown in Table 1. The incidence of perioperative stroke was 0.43% (2/461), and operative mortality was 0.65% (3/461). Character-

Table 1
Patient characteristics and clinical results

	Total $n = 461$	CAS $n = 49$	non-CAS $n = 412$	p-value CAS vs non-CAS
Age	68.1 ± 9.0	72.9 ± 6.7	67.6 ± 9.1	<0.001
Age > 70	222 (48.2%)	35 (71.4%)	187(45.4%)	0.001
Age > 80	33(7.2%)	7 (14.3%)	26 (6.3%)	0.07
Male sex	379 (82.2%)	38 (77.6%)	341 (82.7%)	0.428
Risk factors				
Hypertension	347 (75.3%)	37 (75.5%)	310 (75.2%)	1.000
Diabetes	189 (41.0%)	25 (51.0%)	164(39.8%)	0.166
(Insulin use)	43 (9.32%)	6 (12.2%)	37 (9.0%)	0.433
Hyperlipidemia	277 (60.1%)	30 (61.2%)	247 (60.0%)	1.000
Smoking history	218 (47.3%)	31 (63.3%)	225 (54.6%)	0.288
Peripheral vascular disease	42(9.1%)	14(28.6%)	28(6.8%)	<0.001
Prior stroke	57 (12.4%)	8(16.3%)	49 (11.9%)	0.361
Number of grafts	4.1 ± 1.3	4.1 ± 1.1	4.1 ± 1.3	0.977
Proximal anastomosis	300 (65.1%)	34(69.4%)	266 (64.6%)	0.531
Use of heartstring	81 (17.6%)	10 (20.4%)	71 (17.2%)	0.297
Postoperative atrial fibrillation	150 (32.5%)	16 (32.7%)	134 (32.5%)	1.000
Postoperative anticoagulant	311 (67.5%)	37 (75.5%)	274 (66.5%)	0.259
Death	3(0.65%)	0 (0%)	3 (0.73%)	
Stroke	2 (0.43%)	0 (0%)	2 (0.49%)	
Death or stroke	5(1.1%)	0(0%)	5 (1.2%)	

CAS: carotid artery stenosis.

Table 2
Profile of stroke patients

No.	Age/sex	Cause of stroke	Timing of onset	Location of stroke	Carotid lesion	Stroke history	Aortic clamp	AF	Anti-coagulant	Coronary risk factor
1.	80/male	Thrombotic	6	Multiple	No	No	No	No	No	HT, HLP
2.	76/female	Hypoperfusion due to shock	1	Right corona radiata	No	Yes	Yes	Yes	No	HT, DM, HD

AF: atrial fibrillation; HT: hypertension; HLP: hyperlipidemia; DM: diabetes mellitus.

istics of the stroke patients are listed in Table 2. All strokes occurred during the postoperative period, and there was no intraoperative stroke. Stroke was due to thrombosis in one, and decreased perfusion resulting from hypovolemic shock in the other.

3.2. CAS

Results of carotid artery screening are shown in Table 3. CAS was found in 49 patients (10.6%). Unilateral stenosis was found in 39 patients with moderate stenosis in 26, severe stenosis in 6, and total occlusion in 7. Bilateral stenosis was xfound in 10 patients with moderate bilateral stenosis in 8, and severe bilateral stenosis in 2. All patients were asymptomatic.

Patients in the CAS group were significantly older than patients in the non-CAS group and the prevalence of peripheral vascular disease was significantly higher in the CAS group than in the non-CAS group. Among patients with CAS there was no mortality (0%) or stroke (0%). Among patients without CAS, there were 2 strokes (2/412, 0.49%) and 3 in-hospital mortalities (3/412, 0.65%).

4. Discussion

The incidence of stroke associated with conventional on-pump CABG with cardiopulmonary bypass is around 0.8% and 5.2% [7]. Whether off-pump CABG reduces the incidence of stroke remains controversial. According to two meta-analyses, the benefit of off-pump coronary artery bypass surgery in reducing the incidence of stroke is marginal [8,9]. However, according to a large retrospective analysis ($n = 16,184$), the incidence of stroke is significantly lower with off-pump CABG (2.5%) than with conventional CABG (3.9%) [10].

The characteristics of stroke may differ between on- and off-pump CABG. With regard to the timing of stroke, less than half of the strokes (35–46%) occurred intraoperatively in patients undergoing conventional on-pump CABG [11–14]. In our patients undergoing off-pump CABG no stroke occurred intraoperatively. Our results are in agreement with results of the Peel et al. study in which on-pump surgery was associated with early stroke (2 days), whereas off-pump surgery was associated with later stroke (4 days) [15]. With regard to the reported etiology of stroke, most strokes in patients undergoing conventional on-pump CABG were of two major causes: embolism (40.9–54.3%) and hypoperfusion (35.6–45.7%) [11,13,14,16]. In off-pump CABG, the number of strokes due to low perfusion has decreased dramatically, which suggests an advantage of off-pump CABG in eliminating the adverse effects of cardiopulmonary bypass.

Table 3
Results of carotid artery screening

Laterality	Severity	Number of patients
Unilateral	Moderate	26
	Severe	6
	Occluded	7
Bilateral	Moderate and moderate	8
	Moderate and severe	0
	Severe and severe	2
	Both occluded	0

CAS is considered to play an important role in the mechanism of stroke associated with coronary bypass. In the general CABG population, the prevalence of significant CAS is relatively high. The reported prevalence of moderate CAS (more than 50% stenosis) is 22% [17] and results in a 3.8% stroke rate [18], and the prevalence of severe CAS (more than 80% stenosis) is 8.5% [17], which results in a 14% stroke rate [19]. Therefore, CAS is considered to account for 30% of strokes associated with coronary bypass [1]. The typical characteristic of stroke caused by CAS is intraoperative hypoperfusion ipsilateral to the location of the CAS [6,20]. Stamou et al. reported that among 21 CAS patients who suffered stroke, 16 strokes were ipsilateral [21]. Mickleborough et al. reported that among 7 CAS patients who suffered strokes, 4 strokes were ipsilateral and 6 strokes occurred intraoperatively [20]. Recently, Schoof et al. reported that typical strokes in CAS patients undergoing on-pump CABG were caused by decreased cerebral perfusion pressure and impaired cerebral autoregulation to compensate for the additional blood pressure decrease [6]. Our result is very interesting because there were no strokes in the 49 CAS patients who underwent elective off-pump CABG. This suggests that such low perfusion status might have a detrimental effect on the brain only under extracorporeal circulation. Unfortunately, one patient with CAS who underwent emergent CABG suffered a stroke in this study period. This patient was excluded from this study because the operation was emergent. The stroke occurred in a female patient who had suffered a transient ischemic attack and was diagnosed with unilateral carotid artery occlusion (symptomatic CAS) before the onset of ischemic heart disease. She suffered unstable angina due to severe stenosis of the left main trunk and emergent CABG was performed immediately after diagnosis. The stroke occurred on postoperative day 2 after she had recovered from anesthesia without any neurologic deficit. Computed tomography revealed multiple small strokes in both hemispheres, which suggested an embolic cause.

The current ACC/AHA guidelines recommend prophylactic CE to reduce the incidence of perioperative stroke in patients with moderate symptomatic CAS or severe asymptomatic CAS. However, some authors have doubted the effectiveness of prophylactic endarterectomy for reducing coronary bypass stroke [22]. Gaudino et al. reported similar in-hospital results between patients with and without prophylactic CAS treatment, although a significant difference was observed in cerebral events at mid-term follow-up [5]. Schoof et al. reported that among 113 patients with severe CAS who were candidates for prophylactic CAS treatment, stroke occurred in only two patients (1.8% stroke incidence). Thus, it seems prophylactic CAS treatment would not have been beneficial because the incidence of stroke, even with prophylactic treatment, was similar [6] (2–3% stroke incidence). The findings of our study were similar; the only stroke occurred in a patient with an occluded carotid artery.

4.1. Study limitations

Limitations of the present study include those inherent to retrospective, nonrandomized data collection. The number of study patients is relatively small which does not allow discussion of the effect of an off-pump procedure on rare complications like stroke. Our results would not override the need for carotid artery screening in patients undergoing off-pump CABG because our study did not include the highest risk group, patients with an occluded artery and severe contralateral stenosis. In addition, the possibility of intraoperative conversion to on-pump CABG cannot be avoided.

5. Conclusion

There may be little influence of carotid artery stenosis on the incidence of perioperative stroke in off-pump CABG especially in patients with moderate carotid artery stenosis.

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Remodeling of Reconstructed Left Anterior Descending Coronary Arteries With Internal Thoracic Artery Grafts

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Background. The internal thoracic artery (ITA) remodels its diameter in response to flow requirements. The objective of this study was to elucidate the remodeling capacity of the reconstructed coronary artery using the ITA.

Methods. We evaluated coronary angiograms in 63 patients who had left anterior descending artery (LAD) segmental reconstruction with or without endarterectomy after off-pump coronary artery bypass graft surgery. The diameters of the ITA and reconstructed coronary artery were measured early and at 1 year after surgery.

Results. The mean diameter of the reconstructed LAD was significantly larger than that of the ITA, but significantly decreased 1 year after surgery (2.69 ± 0.53 mm versus 1.87 ± 0.39 mm; $p > 0.0001$). The proximal ratio, the ratio of the ITA to proximal reconstructed coronary artery, and the distal ratio, the ratio of the distal LAD to distal reconstructed coronary artery, increased to a value of almost 1.0 (0.77 ± 0.11 versus 1.05 ± 0.18, $p < 0.0001$, and 0.77 ± 0.14 versus 0.92 ± 0.12, $p < 0.0001$, respectively). Based on the mean diameter of the reconstructed coronary artery, there were no relationships between the use of endarterectomy and the degree of native coronary stenosis. The proximal ratio in the group with severe stenosis was significantly greater than that in the group with mild stenosis (1.08 ± 0.18 versus 0.95 ± 0.16; $p = 0.036$), although the distal ratio was not different between the two groups.

Conclusions. Vascular remodeling of the coronary artery reconstructed with the ITA is observed within 1 year after surgery.

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Coronary artery bypass graft surgery (CABG) using the internal thoracic artery (ITA) has been clearly recognized to provide an excellent long-term patency rate and survival benefit [1]; however, extensive and calcified atheromatous lesions cannot be treated by conventional CABG. The incidence of diffuse coronary artery disease is likely to increase because of increasing age, associated comorbidities, and the increased use of percutaneous interventions. Therefore, we have developed a technique of left anterior descending artery (LAD) reconstruction using the ITA in which atheromatous plaques are excluded or removed outside the lumen of the reconstructed vessel [2, 3].

Although there is abundant evidence that arterial conduits will adjust their caliber and wall structure by vascular remodeling to adjust to the flow requirements of the distal vasculature [4], changes of the LAD reconstructed with the ITA have not been reported. The objective of this study was to elucidate the remodeling capacity of the reconstructed LAD using the ITA by angiography early and at 1 year after surgery.

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Material and Methods

Patient Population

Between September 2004 and December 2006, isolated off-pump CABG was performed in 477 patients. Of these patients, 133 patients had segmental reconstruction (> 3 cm) of the LAD using the ITA. To evaluate the patency of the graft and anastomosis, 84 (63.2%) of 133 patients had postoperative coronary angiography before discharge and at 1 year of follow-up. Early angiography was not performed in 9 patients because of being elderly or having impaired renal function, and 40 patients declined 1-year follow-up angiography. For the purpose of this study, 17 patients with ITA-composite or sequential grafts and 4 patients with complications of the graft or segmental reconstruction were excluded. Finally, both the early (11.4 ± 7.2 days) and 1-year (373.3 ± 57.6 days) coronary angiograms in 63 patients were reviewed in this study. All angiograms were reviewed by a Board-certified cardiologist, and the patients were divided into two groups according to the degree of stenosis of the proximal native coronary artery: (1) a mild stenosis group with less than 90% stenosis, and (2) a severe stenosis group with 90% or greater stenosis. All patients signed informed consent forms before the operation and each angiography. The protocol of this study was approved by

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Table 1. Preoperative Patient Characteristics

Variable	Value	Percent
Age, years	66.5 ± 7.8	—
Male	58	92.1
CVA/TIA	7	11.1
Diabetes mellitus	35	55.5
Hypercholesterolemia	47	74.6
Hypertension	43	68.3
Current smoker	20	31.7
Unstable angina	19	30.2
Previous myocardial infarction	34	54.0
Three-vessel disease	45	71.4
Left main disease	13	20.6
Ejection fraction (%)	56.5 ± 12.4	—

CVA/TIA = cerebrovascular accident/transient ischemic attack.

the Institutional Review Board, and the necessity for patient consent regarding this study was waived.

The preoperative characteristics and operative data of the patients are shown in Tables 1 and 2. All patients had low-dose aspirin (81 mg/day) from the first postoperative day. Patients with extended segmental reconstruction (≥4 cm) were additionally given ticlopidine (200 mg/day) for 1 month and coumadin (maintained with a target international normalized ratio of 2.0 to 2.5) for 6 months after surgery.

Surgical Technique

Details of the surgical indication and technique of the segmental reconstruction were previously reported [2, 3]. The method of segmental reconstruction consisted of either coronary artery reconstruction with plaque exclusion or with endarterectomy. Coronary artery reconstruction without endarterectomy was performed by covering the arteriotomy with an ITA onlay graft to exclude atheromatous plaques from the lumen of the coronary artery. The ITA wall made up 75% of the reconstructed vessel, and the native artery formed the posterior wall that gave rise to septal and diagonal branch arteries. In case the needle could not be passed through calcified plaques, an endarterectomy was performed with distal intimal suture fixation. The majority of the reconstructed lumen consisted of intact intima of the ITA.

Angiographic Measurement

Coronary angiograms were analyzed at an institutional QCA core laboratory by means of the Clinical Measurements Solutions System (QCA-CMS, version 5.1; MEDIS Imaging Systems, Leiden, Netherlands) by experienced technicians. For serial measurement of the graft and reconstructed coronary artery, great care was taken to obtain similar projections for the measurements early and at 1 year of follow-up, and to use the projection that best visualized both the ITA and LAD. An automatic edge detection program determined the vessel contours by assessing brightness along scan lines perpendicular to the vessel center. Five coronary dimensions were measured referenced to catheter sizes, as shown in Figure 1. All measurements were carried out separately by two different observers blinded to each other's assessments. The proximal matching ratio was defined as the diameter ratio of the ITA to proximal reconstructed LAD, and the distal matching ratio was defined as the diameter ratio of the distal LAD to distal reconstructed LAD.

Table 2. Operative Data of Left Anterior Descending Artery Segmental Reconstruction

Variable	Value	Percent
Without endarterectomy	40	63.5
Length (cm)	4.3 ± 1.1 (3.0–7.0)	
With endarterectomy	23	36.5
Length (cm)	5.8 ± 1.1 (4.5–9.0)	

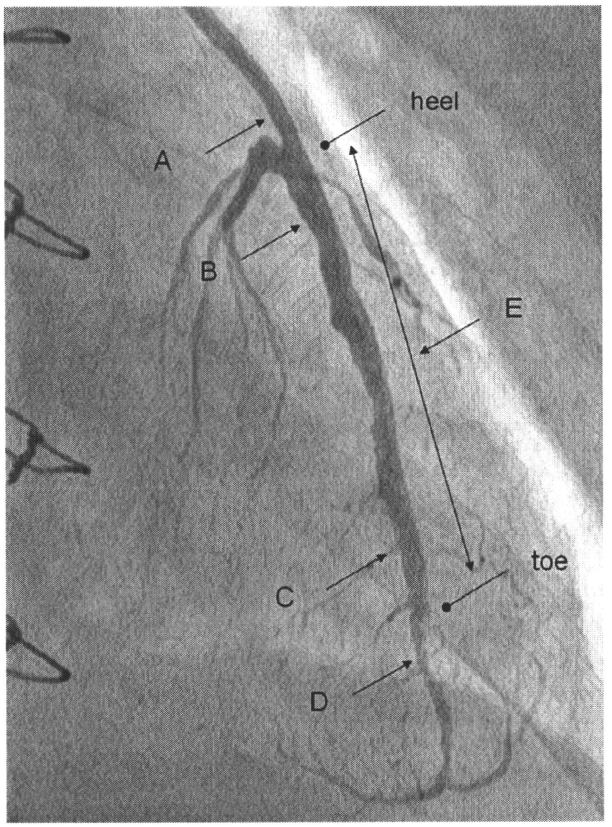

Fig 1. Five coronary dimensions were measured by the quantification system: A, the diameter of the internal thoracic artery about 5 mm proximal to the anastomosis; B, the diameter of the proximal reconstructed left anterior descending artery (LAD) approximately 5 mm from the heel; C, the diameter of the distal reconstructed LAD approximately 5 mm from the toe; D, the diameter of the distal LAD approximately 5 mm from the toe; and E, the mean diameter of the reconstructed LAD. (MRd = distal matching ratio [dashed line]; MRp = proximal matching ratio [solid line].)

Intraobserver and Interobserver Variability

Intraobserver and interobserver variability were assessed for the mean diameter of the reconstructed LAD. The

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Table 3. Findings of Early and One-Year Angiography

	Early	One Year	*p* Value
Vessel diameter, mm			
Internal thoracic artery	2.36 ± 0.36	2.14 ± 0.35	0.001
Proximal reconstructed LAD	3.16 ± 0.71	2.09 ± 0.47	<0.0001
Distal reconstructed LAD	2.18 ± 0.50	1.66 ± 0.38	<0.0001
Distal LAD	1.66 ± 0.37	1.52 ± 0.38	0.037
Mean vessel diameter, mm			
Reconstructed LAD	2.69 ± 0.53	1.87 ± 0.39	<0.0001
Proximal ratio	0.77 ± 0.11	1.05 ± 0.18	<0.0001
Distal ratio	0.77 ± 0.14	0.92 ± 0.12	<0.0001

LAD = left anterior descending artery.

measurement of the mean diameter of the reconstructed LAD showed a high degree of intraobserver reproducibility (2.68 ± 0.53 mm versus 2.69 ± 0.55 mm, $r = 0.98$; $p < 0.0001$) and interobserver reproducibility (2.68 ± 0.53 mm versus 2.70 ± 0.54 mm, $r = 0.92$; $p < 0.0001$).

Statistical Analysis

Statistical analyses were performed using SPSS software (SPSS Inc, Chicago, IL). All data were expressed as the mean ± SD. Differences in the variables between early postoperative and 1-year angiography were determined by using a Wilcoxon test. Differences in the variables within a group or between two groups were determined by using a Mann-Whitney *U* test or Fisher's exact test for categorical variables. All *p* values were two-tailed, and values less than 0.05 were taken as significant.

Results

Early and 1-Year Angiography

In 63 patients, the diameter of the ITA and the mean diameter of reconstructed LAD were 2.36 ± 0.36 mm and 2.69 ± 0.53 mm, respectively. There were no significant differences in the diameters and ratios between the groups with mild and severe stenosis. At 1 year after surgery, the diameter of the ITA and the mean diameter of the reconstructed LAD were significantly decreased (2.36 ± 0.36 mm versus 2.14 ± 0.35 mm, $p < 0.0001$, and 2.69 ± 0.53 mm versus 1.87 ± 0.39 mm, $p < 0.0001$, respectively). The diameter of the ITA in the severe stenosis group was significantly larger than that in the mild stenosis group (2.21 ± 0.33 mm [n = 49], versus 1.88 ± 0.31 mm [n = 14], $p < 0.005$). However, the two groups showed no significant difference in the mean diameter of the reconstructed LAD (1.85 ± 0.33 mm versus 1.88 ± 0.41 mm, $p = 0.779$). Early and 1-year angiographic measurements are shown in Table 3.

The diameter of the ITA and reconstructed LAD showed no relationship with the application of endarterectomy, although the diameter of the proximal reconstructed LAD was significantly greater in patients with endarterectomy (3.40 ± 0.61 mm [n = 23] versus 3.02 ± 0.73 mm [n = 40], $p = 0.039$) at early angiography.

Change in Matching Ratio

During the 1-year follow-up, proximal and distal matching ratio significantly increased (0.77 ± 0.11 versus 1.05 ± 0.18, $p < 0.0001$, and 0.77 ± 0.14 versus 0.92 ± 0.12, $p < 0.0001$, respectively), as shown in Figure 2. At early angiography, there were no significant differences in either proximal or distal ratio between the two groups. However, proximal ratio of the severe stenosis group was significantly greater than that of the mild stenosis group at the 1-year follow-up angiography (1.08 ± 0.18 versus 0.95 ± 0.16, $p = 0.036$), although distal ratio was not different between the two groups (1.11 ± 0.17 versus 1.15 ± 0.20, $p = 0.667$).

Comment

The present study demonstrated following main findings: The diameter of the reconstructed LAD decreased to become equivalent to the diameters of the ITA and distal LAD at 1 year after surgery. Furthermore, the ratio of the ITA and proximal reconstructed LAD depended on the stenosis of the native coronary artery. These results suggest that the LAD reconstructed with the ITA remodels physiologically over time, in a manner similar to the ITA graft. This is a novel study demonstrating the remodeling capacity of the reconstructed LAD using the ITA.

Wall shear stress is the force induced by blood flow acting on the endothelium. This force modulates the levels of two potent endothelium-derived vasoactive mediators, the vasodilator nitric oxide [5] and the vasoconstrictor endothelin-1 [6]. Vascular remodeling of the arterial wall in response to changes in flow occurs over weeks to months and includes both cellular and noncellular elements. The end result of vascular remodeling is

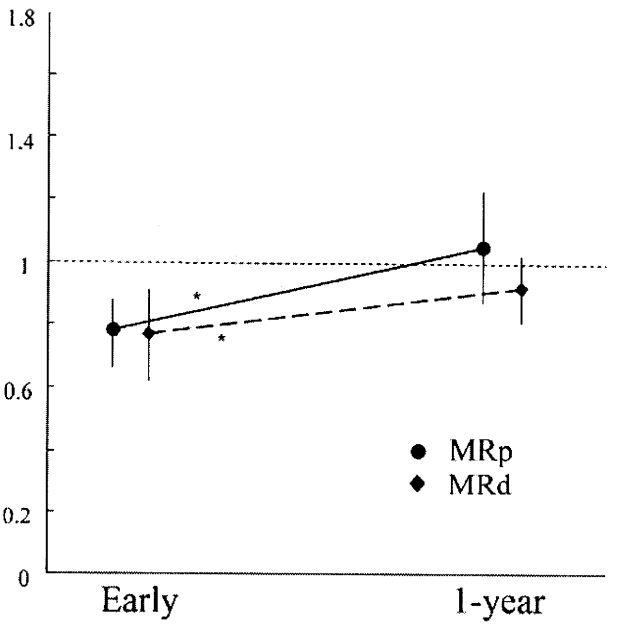

Fig 2. Changes in the matching ratio. The proximal ratio and distal ratio increased during the 1-year follow-up.

normalization of wall shear stress as detected by the endothelium. However, although healthy smooth muscle is highly responsive to dilators and constrictors, atherosclerotic vessels may not only have impaired endothelial responses but the smooth muscle can be destroyed or impaired by transmural sclerosis.

In this study, LAD reconstruction with endarterectomy was performed in 36.5% of the patients. Adaptive vascular remodeling after endarterectomy may be prevent by removal of the coronary endothelium and most of the smooth muscle, and is also influenced by inflammatory mediators, surface deposition of platelets and fibrin, occasional thrombosis, fibrosis, intimal hyperplasia, and endothelialization during the healing process. Moreover, nitric oxide, which has secondary effects on noncellular elements of the vessel wall, inhibits smooth muscle proliferation and neointimal hyperplasia. Despite of these situations, the diameter changes of the reconstructed LAD with endarterectomy were similar to those without endarterectomy. These responses must principally depend on the wall of the onlay grafting ITA. However, we guess that because the majority of the endarterectomized coronary arterial wall was excluded from the reconstructed coronary lumen in our technique, complete endothelial covering may be achieved rapidly and, thus, possibly decrease the risk of myofibrointimal proliferation.

Previous reports showed the ITA diameter had a particularly strong correlation with the degree of LAD stenosis within 1 month of CABG [7, 8]. In the present study, the stenosis of the native coronary artery significantly affected the proximal ratio but not affected the distal ratio. Moreover, the proximal ratio was larger at 1 year. There is substantial evidence that the reconstructed LAD dilate or narrow when flow dictates this response, although the posterior wall remains severely disease coronary artery. These findings suggest that shear stress in the entire reconstructed artery normalizes, and this may provide the best long-term patency, because lower shear stress is associated with the development of atherosclerosis.

There are a few limitations of this study that must be recognized. First, in our analysis, no data on flow velocity with a Doppler wire or intimal thickness measurements with an intravascular ultrasonography catheter were included. We only elucidated the anatomic change in the reconstructed LAD using the ITA early and at 1 year after surgery, and this anatomic change was defined as vascular remodeling. Second, long-term patency of the reconstructed LAD using the ITA has not been evaluated. There is some evidence that the patency rate ranged from 56% to 90% at 1 year using the vein graft with endarterectomy [9, 10]. Moreover, the patency rate was 92.5% using the ITA anastomosed to the vein patch [11], and ranged from 94.6% to 98.6% using the ITA in LAD reconstruction with or without endarterectomy [3, 12]. Third, the percent diameter stenosis is not always the best predictor of native coronary flow. Fourth, the number of patients enrolled was relatively small because the complexity of the study protocol made it difficult to recruit patients, especially the need for angiography at 1 year.

In conclusion, vascular remodeling of the reconstructed LAD is obtained angiographically within 1 year after segmental reconstruction using the ITA. Endarterectomy does not affect the remodeling. These results suggest that the LAD that has been reconstructed with the ITA over a long segment remodels over time, and that may provide the high long-term patency rate in the severely diseased coronary artery.

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INVITED COMMENTARY

Shimokawa and colleagues [1] present a follow-up study of a technique for left anterior descending coronary artery (LAD) reconstruction using the internal thoracic artery (ITA). In this article, the diameter changes in

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Intermediate-Term Patency of Saphenous Vein Graft With a Clampless Hand-Sewn Proximal Anastomosis Device After Off-pump Coronary Bypass Grafting

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Background. To avoid complications related to aortic manipulation, devices were developed to perform clampless anastomosis. However, there are few studies concerning the late patency of the graft. The aims of this study were to investigate the patency rate of saphenous vein (SV) graft after off-pump coronary artery bypass grafting (OPCAB) and to evaluate the influence of a clampless hand-sewn proximal anastomosis on late graft patency.

Methods. Patients (n = 232) were enrolled who underwent OPCAB with SV grafts from 2004 to 2007 and had follow-up angiography. For proximal anastomoses, a clampless device was used in 73 (group A; HEARTSTRING [Guidant Corporation, Santa Clara, CA] in 54, Enclose II [Novare Surgical Systems, Inc, Cupertino, CA] in 19), and partial clamping was used in 159 (group B). The proximal anastomosis procedure was modified according to the results of epiaortic ultrasonography. Coronary angiography was performed early (11.8 ± 10.4 days) and one-year postoperatively (n = 180, 371.5 ± 102.6 days).

Results. There were no significant differences in patient characteristics between the two groups except for a higher reoperation rate in group A. The overall SV patency rate at the early and one-year postoperative angiography was 95.7% and 83.0%, respectively. The patency rates were similar between the two groups (early: 97.3% vs 98.1%, $p = 0.729$; 1 year: 87.0% vs 81.3%, $p = 0.316$). There was also no significant difference in the target vessel revascularization rate during follow-up (6.8% vs 10.1%, $p = 0.623$).

Conclusions. Intermediate-term angiographic follow-up demonstrate an acceptable SV patency rate after OPCAB. The SV patency rate with a clampless device for proximal anastomosis is comparable with that with partial clamping during the first postoperative year.

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Off-pump coronary artery bypass (OPCAB) has been suggested to reduce postoperative neurologic events. However, manipulation of the ascending aorta during construction of proximal aortocoronary bypass anastomosis may produce particulate cerebral emboli with adverse neurologic outcome [1]. To avoid this problem, devices were developed to perform clampless anastomoses. Recently, new proximal seal devices, the HEARTSTRING (Guidant Corporation, Santa Clara, CA) and Enclose II (Novare Surgical Systems, Inc, Cupertino, CA), were introduced to facilitate the creation of a clampless hand-sewn coronary artery bypass-to-ascending aorta anastomosis. The use of these devices yielded encouraging results in terms of neurologic complications and early patency [2, 3]. Nevertheless, there is concern about the late patency rate because the first-generation automatic anastomotic device provided unacceptable patency within 6 months [4, 5]. The aims of this study were to investigate the patency rate of saphenous vein (SV) graft after OPCAB and to demonstrate the influence of a clampless hand-sewn proximal anastomosis on late graft patency.

Material and Methods

This study enrolled 232 consecutive patients with postoperative early angiography after isolated OPCAB surgery using SV grafts from September 2004 to March 2007. We compared the angiographic results with two techniques for creating anastomoses: a clampless device in 73 patients with 74 SV grafts (group A; HEARTSTRING device in 54, Enclose II device in 19), and partial clamping in 159 patients with 161 SV grafts (group B). During the same period, 288 patients underwent OPCAB with aortocoronary SV bypass. The patient exclusion criteria for postoperative angiography were age greater than 80 years in 38 patients, impaired renal function in 11, chronic obstructive pulmonary disease that required tracheostomy in 3, severe peripheral vascular disease in 2, and postoperative severe conditions in 2 (mediastinitis

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Table 1. Patient Characteristics

Characteristics	All (n = 232)	Group A (n = 73)	Group B (n = 159)	*p* Value
Age (years)	66.9±7.7	68.0±7.9	66.4±7.7	0.076
Male	180 (77.6%)	61 (83.6%)	119 (74.8%)	0.139
Weight (kg)	62.4±10.4	61.6±9.9	62.7±10.8	0.811
Smoking	75 (32.3%)	30 (41.1%)	45 (28.3%)	0.053
History of stroke	28 (12.1%)	12 (16.4%)	16 (10.1%)	0.166
Hypertension	176 (75.9%)	55 (75.3%)	121 (76.1%)	0.900
Diabetes	103 (44.4%)	28 (38.4%)	75 (47.2%)	0.210
Hyperlipidemia	151 (65.1%)	45 (61.6%)	106 (66.7%)	0.456
Creatinine (mg/dL)	0.89±0.26	0.93±0.32	0.88±0.22	0.666
Number of diseased vessels	2.8±0.4	2.9±0.4	2.8±0.2	0.097
Left main trunk	70 (30.2%)	19 (26.0%)	51 (32.1%)	0.351
Emergent or urgent surgery	25 (8.6%)	8 (11.0%)	17 (10.7%)	0.951
Reoperation	6 (2.5%)	5 (6.8%)	1 (0.6%)	0.013
Ejection fraction (%)	57.3±12.4	57.4±12.8	57.2±12.6	0.750
Operative time (minutes)	287.9±55.9	298.8±66.5	284.4±51.9	0.348
Number of distal anastomosis	4.5±1.2	4.5±1.2	4.6±1.2	0.133
SV graft				
Number of distal anastomosis	1.4±0.6	1.4±0.7	1.4±0.6	0.440
RCA territory	219/235 (93.2%)	66/74 (89.2%)	153/161 (95.0%)	0.160

RCA = right coronary artery; SV = saphenous vein.

and gastrointestinal bleeding). For all study patients early angiography was performed before discharge (11.8 ± 10.4 days) to evaluate the patency of the graft and anastomosis, and a follow-up study was planned for 1 year after surgery regardless of symptoms. A board-certified cardiologist reviewed all angiography results and graded the degree of stenosis. All patients signed informed consent forms before the operation and each angiography. The study protocol was approved by the Institutional Review Board and the necessity for patient consent regarding this study was waived.

The preoperative characteristics of the patients are shown in Table 1. Risk factors included diabetes mellitus (diet controlled, oral agent-treated, or insulin-treated), hyperlipidemia (total cholesterol ≥ 240 mg/dL or oral agent-treated), and hypertension (systolic blood pressure ≥ 140 mm Hg, diastolic blood pressure ≥ 90 mm Hg, or oral agent-treated). Every patient was given an intravenous heparin injection 6 hours after surgery to prevent perioperative stroke and myocardial infarction. Most patients had low-dose aspirin (81 mg/day) from the first postoperative day. Coumadin was prescribed for at least 6 months and was maintained at a target international normalized ratio of 2.0 to 2.5. Target vessel revascularization was defined as repeat revascularization of the initial grafted vessel. The SV graft-related vessel revascularization was defined as repeat revascularization of the initial SV graft.

Surgical Technique

The technique of OPCAB has been described previously [6]. The SV graft was our first choice for revascularization of the right coronary artery territory, and bilateral internal thoracic artery (ITA) and radial artery (RA) grafting for the left coronary territory was the standard method. We used SV graft for the left coronary territory when arterial conduits were in poor preoperative condition on angiography and ultrasonography, arterial conduits had already been used in previous operations, or an emergency operation was necessary.

Full anticoagulation was achieved with heparin (3.0 mg/kg). We bypassed all significantly diseased coronary vessels with a diameter greater than 1 mm. After completion of the distal anastomoses, the proximal RA or SV graft anastomoses were performed on a disease-free segment of the aorta as assessed by epiaortic ultrasonography (Sonos 7500; Philips Medical Systems, Andover, MA). The proximal anastomosis procedure was modified according to the results of epiaortic scanning [7]. An anterior segment of normal or mildly diseased aorta entirely was required for the partial clamping technique, and a segment partially free of disease for the clampless device. The selection of the two anastomotic devices depended on the preference of each surgeon. In patients with severe aortic atherosclerosis, the operative procedure was modified to an aortic-no-touch technique. All proximal anastomoses were constructed manually with continuous 6-0 polypropylene using a blower-mister device to enhance visualization.

Statistical Analysis

Statistical analyses were performed with SPSS software (SPSS Inc, Chicago, IL). All data were expressed as means ± standard deviation. Univariate analysis was determined by a Mann-Whitney test for continuous variables or the Fisher 2-tailed exact test for categoric vari-

Table 2. Early Patency Rate

Variable	Group A (n = 73)	Group B (n = 159)	*p* Value
SV			
FG-A	95.9% (71/74)	95.0% (153/161)	
FG-B	1.4% (1/74)	0%	0.729
FG-O	2.7% (2/74)	5.0% (8/161)	
LITA	100% (73/73)	98.7% (155/157)	1.000
RITA	100% (65/65)	100% (132/132)	-
RA	96.7% (29/30)	98.9% (87/88)	0.445

FG = FitzGibbon grade; LITA = left internal thoracic artery; RITA = right internal thoracic artery; RA = radial artery; SV = saphenous vein.

ables. Multivariate analysis was performed using the logistic regression method. All p values less than 0.05 were taken as significant.

Results

There were no significant differences in patient characteristics between the two groups except for a higher rate of reoperation in group A than in group B (6.8% vs 0.6%, respectively, $p = 0.013$). The number of distal anastomoses and SV graft distal anastomoses were similar in both groups (4.4 ± 1.2 vs 4.6 ± 1.2, $p = 0.133$; 1.4 ± 0.7 vs 1.4 ± 0.6, $p = 0.440$, respectively). No patients had postoperative neurologic complications in this study. The incidence of postoperative heparin administration, aspirin intake, and Coumadin (DuPont, Wilmington, DE) intake were also similar in both groups (95.9% vs 95.6%, $p = 1.00$; 100% vs 99.4%, $p = 1.00$, 97.3% vs 96.2%, $p = 1.00$, respectively). Postoperative early angiography demonstrated a 97.3% graft patency rate of the SV (FitzGibbon grade A+B) in group A and 98.1% in group B ($p = 0.729$), as shown in Table 2. The ITA graft showed an excellent patency rate in both groups A and B, even though most of the LITA (left internal thoracic artery) grafts were anastomosed to the left anterior descending coronary artery. There was no significant difference between the two groups in the patency rate of the LITA (100% vs 98.7%), RITA (right internal thoracic artery; 100% vs 100%), and RA (96.7% vs 98.9%).

Among all enrolled patients, 53 patients declined one-year follow-up angiography because of noncardiac death in 2, cerebral infarction in 3, and no symptoms in 48 within one year after the operation. As a result, one-year angiography was performed in 180 patients with 182 SV grafts (group A, n = 53; group B, n = 127; 371.5 ± 102.6 days). The incidence of aspirin and Coumadin intake at one-year angiography were similar in both groups (100% vs 98.4%, $p = 0.100$; 39.6% vs 47.2%, $p = 0.412$, respectively). The overall SV graft patency rate decreased significantly during the first postoperative year (early 95.7% vs one-year 83.0%, $p < 0.0001$). Postoperative one-year angiography demonstrated an 87.0% patency rate of the SV graft (FitzGibbon grade A+B) in group A and an 81.3% rate in group B ($p = 0.316$), as shown in Table 3. There was also no significant difference between the two groups in the patency rate of the LITA (100% vs 97.6%), RITA (91.1% vs 91.6%), and RA (65.2% vs 83.1%). Univariate analysis demonstrated a higher incidence of hyperlipidemia (27 of 33, 81.8% vs 124 of 199, 62.3%, $p = 0.029$) and less Coumadin use (3/33, 9.1% vs 5/199, 2.5%, $p = 0.089$) in the occluded SV-graft group than in the patent SV-graft group. Multivariate logistic regression analysis showed hyperlipidemia (odds ratio [OR] 2.59, 95% confidence interval [CI] 1.02 to 6.6, $p = 0.046$) to be an independent predictor of SV-graft failure during the first postoperative year after OPCAB.

Twenty-one of 230 survivors underwent target vessel revascularization during the follow-up period at 21.7 ± 10.0 months. In group A, 2 of 7 target vessel revascularizations were related to vein graft occlusion, whereas 9 of 16 were related to occlusion in group B. There were no significant differences in the rate of target vessel revascularization and SV-related vessel revascularization rates between the two groups (6.8% vs 10.1%, $p = 0.623$; 2.7% vs 5.7%, $p = 0.510$, as shown in Table 4).

Comment

The present study demonstrated the following main findings. First, the overall SV graft patency rate decreased significantly during the first postoperative year. Second, the early and one-year patency rates were similar between patients with device and partial clamping. The use of a proximal hand-sewn device was not an independent predictor of graft failure during the first year after OPCAB. Third, there were also no significant differences in rate of all target vessel and SV graft-related target vessel revascularizations. To our knowledge, this is the novel study in OPCAB comparing the effect of a clampless hand-sewn proximal anastomosis device and partial clamping on intermediate-term SV graft patency rate.

Although the SV is still the most widely used graft because of its accessibility and ease of use, the surgical results of coronary artery bypass grafting (CABG) have demonstrated that SV long-term patency is lower than that of the ITA [8, 9]. Long-term angiographic studies of CABG grafts show occlusion rates of 15% to 20% at one

Table 3. One-year Patency Rate

Variable	Group A (n = 53, 74.0%)	Group B (n = 128, 80.5%)	*p* Value
SV			
FG-A	85.2% (46/54)	75.8% (97/128)	
FG-B	1.9% (1/54)	5.5% (7/128)	0.316
FG-O	13.0% (7/54)	18.8% (24/128)	
LITA	100% (52/52)	97.6% (123/126)	0.557
RITA	91.1% (41/45)	91.6% (98/107)	1.000
RA	65.2% (15/23)	83.1% (59/71)	0.083

FG = FitzGibbon grade; LITA = left internal thoracic artery; RITA = right internal thoracic artery; RA = radial artery; SV = saphenous vein.