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Clinical outcome of coronary angioplasty in patients with ischaemic cardiomyopathy

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Abstract

Objective: To assess the clinical outcome of successful percutaneous transluminal coronary angioplasty (PTCA) in patients with poor ventricular function. *Methods:* Analysis of angiographic, echocardiographic and clinical records of patients with severe LV dysfunction who underwent PTCA from January 1, 1995 to December 31, 1997 was undertaken. Forty-one patients aged 63±10 years, 36 men, all with significant coronary artery disease and impaired LV function (fractional shortening, FS≤20%) were identified. Patients' data before and after angioplasty were analyzed. *Results:* Post PTCA: angiographic success was 95.2%. Major complications occurred in 19.5% and hospital mortality was 2.7%. At 6 months after PTCA:LV fractional shortening (FS) increased from 15.9±3.4% to 19.6±6.6%, $P=0.02$ and consequently cardiac output from 4.28±0.98 to 5.34±1.77 l/min, $P<0.01$. Change in at least one class of angina and cardiac functional status was observed in 46% of patients, $P<0.001$, and this was maintained to the end of the year. After 12 months follow-up: restenosis occurred in 10.8%; mortality was 5.4%; event-free and actuarial survivals were 62.3% and 91.9%, respectively. *Conclusions:* In patients with severe LV dysfunction, continued symptomatic improvement can be achieved with successful coronary angioplasty. This is associated with significant recovery of LV systolic function and cardiac output. In order to minimize procedure-related complications, careful patient selection should be considered.

Keywords: Left ventricular dysfunction; Coronary angioplasty; Echocardiography

1. Introduction

Percutaneous transluminal coronary angioplasty (PTCA) is now being widely applied in patients with multi-vessel coronary artery disease (CAD) [1,2]. With recent advancement in technology, the indications for PTCA have broadened to include patients with severe left ventricular (LV) dysfunction. In spite of this, studies in the literature documenting beneficial effects in this subset of patients are very few [3–8]. Immediate and long-term outcomes, however, have been reported and consistently show procedural complications occurring more frequently than in patients with normal or near normal LV function [3–7]. In addition, long-term mortality assessed at 1 year is still high, ranging from 13 to 21% [7]. A comparison between recent studies, in the last decade, and earlier reports suggests that hospital outcomes have improved [7]. This may, perhaps, be a result of advances in the management of procedure-related complications.

This study retrospectively looks at data over a

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period of 3 years (1995–1997) of patients with severe LV dysfunction who had undergone PTCA for symptoms not responding to medical therapy. The objective was to assess immediate and long-term outcome after coronary angioplasty, especially changes in symptoms and LV systolic function.

2. Patients and methods

2.1. Study population

The study population was selected from all adult patients who had undergone PTCA at the Royal Brompton Hospital within a period of 3 years beginning January 1, 1995 to December 31, 1997. Patient data were obtained from the Angioplasty Register in the Cardiac Catheterization Laboratory. These data were cross-checked with the Echocardiography Register to confirm whether the patients had undergone a complete echo study before and after the procedure. Patients with previous revascularization procedures, coronary artery bypass (CABG) surgery and PTCA were included. None of the patients included had CABG surgery 36 months prior to PTCA. Other inclusion and exclusion criteria were as follows.

2.1.1. Inclusion criteria

1. Evidence of undergoing PTCA within the defined study period.
2. Significant impairment of LV function by echocardiography (fractional shortening (FS)≤20% or ejection fraction (EF)≤35%).
3. Complete echo study before and 3–6 months after the procedure.

2.1.2. Exclusion criteria

1. Acute myocardial infarction within the last 7 days.
2. Patients with prosthetic valves or valvular heart disease.
3. Patients who did not undergo post-operative echocardiographic studies.

2.2. Coronary angioplasty procedure and data

Coronary angioplasty was the preferred therapeutic option in these patients, and was performed for standard indications using conventional techniques. The procedure was attempted on all major coronary arteries that had >70% diameter narrowing with favorable anatomy. Similarly, significant stenoses affecting vein and arterial grafts were also dilated. Major arteries were defined as the left anterior descending and its large diagonal branches, the circumflex and its large obtuse marginal branches and the right coronary system. In most cases attempts were made to achieve complete revascularization including chronic occlusions with favorable characteristics. When hemodynamic conditions were unstable, an intra-aortic balloon pump (IABP) was inserted at the beginning or during the procedure. Surgical back up was available for all the patients.

Coronary stents were used electively and also following abrupt or threatened vessel closure. In the catheterization laboratory all patients were given 10,000 units of Heparin at the beginning of the procedure with an additional dose of 5000 units if the procedure was prolonged for more than 1 h. All patients who received intra-coronary stents were commenced on Ticlopidine 250 mg twice daily for 3 weeks. Prior to January 1997, patients were anticoagulated with Warfarin. Patients were also given Aspirin 75 mg daily to continue indefinitely.

Case notes were consulted to retrieve the following information: number of diseased major vessels, number of culprit lesions, native or graft vessel lesions, and number of total occlusions. The outcome of the procedure including number of lesions attempted/dilated, angiographic success, residual narrowings and types of stent/s deployed was extracted from the procedure notes. Immediate complications arising from PTCA were also noted and recorded.

2.2.1. Definitions

Angiographic success: a reduction of the luminal diameter stenosis to <40% as assessed visually in multiple projections.

Clinical success: an improvement in symptoms at hospital discharge without major complications, such as myocardial infarction, need for revascularization, or death, during hospitalization.

Complete revascularization: successful dilatation of all initial stenoses of >70%.

Incomplete revascularization: successful dilatation of one or more stenoses leaving one or more residual stenoses of >70%.

Unsatisfactory angiographic result: residual lumen narrowing of 50% or more after dilatation.

Abrupt vessel closure: thrombolysis in myocardial infarction (TIMI) 0–1 flow after successful dilatation.

Threatened vessel closure: the presence of at least one of the following criteria after successful dilatation:

- ≥50% residual stenosis
- dissection ≥10 mm and/or extraluminal contrast
- persistent ischemia (chest pain and/or electrocardiographic (ECG) changes).

2.3. Follow-up

Follow-up data were obtained in two ways. Initially all patients' case notes were reviewed. The following information was obtained: symptoms (angina or dyspnoea); cardiac events (history of myocardial infarction since the last PTCA, need for additional revascularization or cardiac transplant); death (cardiac or non-cardiac); hospitalizations since the last PTCA and any change in medications. These data were obtained at four points: (1) within the first week (at the time of discharge from hospital); (2) end of the first month (during the first post-procedure visit); (3) after 6 months, and at the end of the first year (coincided with the third out-patient visit). However, sick and unstable patients received more frequent reviews as dictated by their clinical condition.

A simple questionnaire was sent to General Practitioners (GPs) of 11 patients who had failed to attend hospital for their scheduled follow-up clinic or had failed to attend for a period longer than 6 months. Similar details as delineated above were included in the questionnaire. Only three patients had additional information obtained from their GPs by telephone interview. Data collection conformed to the guidelines of the local research ethics committee, which gave approval. Event-free survival is defined as the absence of myocardial infarction, repeat revascularization, cardiac transplant or death at follow-up.

2.4. Echocardiography

From the echocardiographic recordings of the left ventricle, fractional shortening was calculated as the percentage fall in LV dimensions in systole with respect to that in diastole [9]. Cardiac output was calculated as (stroke volume×heart rate); and stroke volume was derived from multiplying aortic flow time integral by outflow tract area.

2.5. Statistics

All baseline characteristics are presented as frequencies and percentages for discrete variables. Other values represent mean±S.D. Patients' data before and after angioplasties were compared using paired *t*-tests. A probability of 5% was taken as significant. Actuarial and event-free survival curves were generated using the Kaplan–Meier method.

3. Results

From January 1st, 1995 to December 31st 1997, inclusive, 1528 consecutive patients underwent percutaneous transluminal coronary angioplasty at the study institution. Forty-one adult patients (2.6%) fulfilled the inclusion criteria. The age range of the study population was 40 to 76 years with a mean of 63±10 years, and 36 (87.8%) were males.

3.1. Baseline clinical characteristics (Table 1)

This study population was elderly, predominantly men (87.8%) and 18 patients (43.9%) had comorbid systemic illnesses. A total of 34 (82.9%) patients, had at least one or more established risk factors for coronary artery disease—hypertension, 20 (48.8%); diabetes mellitus, nine (22.0%); hypercholesterolaemia, 20 (48.8%); current smokers, 12 (29.3%) and 19 (46.3%) had previously smoked. Thirty-one (75.6%) patients had a prior myocardial infarction and 27 (65.9%) had undergone previous revascularization procedures; 23 (56.1%) CABG surgery and 16 (39.0%) PTCA.

At the time of PTCA, 12 patients (29.3%) presented with unstable angina; 35 (85.4%) had Canadian Cardiovascular Society (CCS) Class III–IV

Table 1
Baseline clinical characteristics

Characteristic	Number	(%)
Total number of patients	41	–
Age range (years)	40–76	–
Mean age (S.D.) (years)	63 (10)	
Sex (men/women)	36/5	88/12
Diabetes mellitus	9	22
Hypertension	20	48.8
Current smoker	12	29.3
Previous history of smoking	19	46.3
Treatment for hypercholesterolaemia	20	48.8
Previous myocardial infarction	31	75.6
Previous coronary bypass surgery	23	56.1
Previous coronary angioplasty	16	39
Unstable angina	12	29.3
Angina pectoris CCS Class II	6	14.6
III	13	31.7
IV	22	53.7
Functional status–NYHA Class II	9	22
III	20	48.8
IV	12	29.2
Current major systemic illness	18	43.9
Treatment (ACE-I+BB) or BB, ACE-I alone	32	78

CCS, Canadian Cardiovascular Society; NYHA, New York Heart Association; ACE-I, angiotensin converting enzyme inhibitor; BB, β-blockers.

angina pectoris and 32 (78.0%) were in New York Heart Association (NYHA) class III–IV functional status. Thirty-two (78.0%) were taking angiotensin converting enzyme inhibitors (ACE-I) or beta-blockers alone or in combination.

3.2. Angiographic characteristics (Table 2)

Thirty-three (80.4%) patients had three-vessel disease as angiographically defined in the Coronary Artery Surgery Study (CASS) [10]. The remaining were divided equally in the one- and two-vessel disease groups. Significant coronary artery disease was present in LAD, 39 (95.1%); RCA, 37 (90.2%) and left circumflex (Cx), 34 (83.0%) patients, respectively. The graft vessels were also involved in patients with previous CABG surgery. Three patients (7.3%) had disease of the left internal mammary artery (LIMA) graft to LAD and seven (17.1%) had stenoses in saphenous vein grafts to the left circumflex. Similarly, 22 patients (53.6%), divided equally, had significant disease in the vein grafts to the RCA and the LAD.

Table 2
Angiographic characteristics of the 41 patients

Characteristic	Patients	(%)
Extent of CAD—one vessel	4	9.8
two vessels	4	9.8
three vessels	33	80.4
Native vessels involved—LAD	39	95.1
Cx	34	83.0
RCA	37	90.2
Grafted vessels involved—LIMA→LAD	3	7.3
VG→LAD	11	26.8
VG→Cx	7	17.1
VG→RCA	11	26.8

CAD, coronary artery disease; LAD, left anterior descending; Cx, left circumflex; RCA, right coronary artery; LIMA, left internal mammary artery; VG, vein graft.

A total of 112 lesions were identified in the entire study population with 13 (11.6%) being chronic total occlusions (Table 3). Native vessel lesions were distributed as follows: 21 (18.7%) in the LAD, 20 (17.8%) in the RCA and 19 (17.0%) in the Cx. The distribution of lesions in the graft vessels followed this pattern: LIMA and vein graft to LAD, four (3.6%) and 14 (12.5%) lesions, respectively, whereas saphenous vein grafts to RCA had 14 (12.5%) and to Cx seven (6.3%) lesions each.

3.3. Immediate results and complications of coronary angioplasty (Table 4)

Of the 76 lesions attempted, 63 (82.9%) were successfully dilated. Angiographic success was achieved in 60 lesions constituting 95.2%. Five patients (12.2%), all of whom had a single culprit lesion, achieved complete revascularization. The remaining 36 (87.8%) patients had incomplete revascularization. Endoluminal stents were implanted in 29 (70.1%) patients, a proportion similar to the applica-

Table 3
Angiographic distribution of coronary lesions

Characteristic	Number	(%)
Total number of lesions	112	–
Number of chronic total occlusions	13	11.6
Native vessel lesions—LAD	21	18.7
CX	19	17.0
RCA	20	17.8
Graft vessel lesions—LIMA→LAD	4	3.6
VG→LAD	14	12.5
VG→CX	7	6.3
VG→RCA	14	12.5

LAD, left anterior descending; CX, left circumflex; RCA, right coronary artery; LIMA, left internal mammary artery; VG, vein graft.

tion in the general population undergoing PTCA at the study center [11]. Two patients had unsuccessful procedures—one had emergency CABG surgery whereas the other was treated medically. The remainder with incomplete revascularization had multiple narrowings in other vessels despite good angiographic outcomes in the dilated vessels.

In general, complications were documented in 23 (56.1%) patients including one death (2.4%), which occurred 48 h after the procedure. Major complications occurred in eight (19.5%) patients; six (14.6%) Q-wave myocardial infarctions (Table 4), and one abrupt vessel closure immediately after the procedure, requiring stent insertion. Two others received emergency CABG surgery whereas the rest were treated conventionally. Overall, emergency CABG surgery was performed in three patients. Two had suffered acute myocardial infarctions secondary to stent occlusion. The third had circumflex vessel dissection with consequent myocardial infarction, pulmonary edema and cardiogenic shock requiring IABP insertion.

An intra-aortic balloon pump (IABP) was placed in a total of five patients, for hemodynamic support during the procedure in three patients and as an emergency in two. Other complications noted included angiographic evidence of dissection with TIMI-3 flow, arrhythmias, hypotension, infections, entry site hematoma and distal emboli from a saphenous vein graft. Minor vessel dissection complicated the procedure in 10 patients. On the other hand, infections though extremely rare following PTCA were reported in two patients; one at the peripheral cannula site and the other had lobar pneumonia. Both were successfully managed with antibiotics.

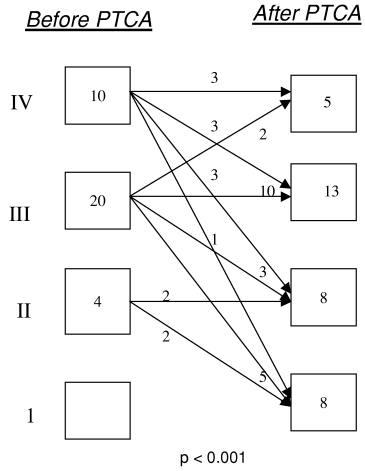
Table 4
Results of percutaneous transluminal coronary angioplasty

	Number	(%)
Total number of patients	41	–
Number of angioplastied vessels (1/2/3)	37/4/0	90.2/9.8/0
Number of lesions dilated/attempted	63/76	82.9
Patients with stent implantation	29	70.1
Angiographic success (lesions)	60	95.2
Clinical success (patients)	33	80.5
Complete revascularization	5	12.2
Incomplete revascularization	36	87.8
Complications	23	56.1
Major	8	19.5
Death	1	2.4
Q-wave myocardial infarction	6	14.6
Emergency CABG	3	7.3
Cardiogenic shock	3	7.3
Others	15	36.6
Minor coronary dissections	10	24.4
Arrhythmias (AF, VT/VF)	3	7.3
Hypotension	3	7.3
Infection (pneumonia, IE)	2	4.9
Entry-site hematoma	1	2.4
Emboli from vein graft	1	2.4

AF, atrial fibrillation; VT/VF, ventricular tachycardia and ventricular fibrillation; IE, infective endocarditis; CABG, coronary artery bypass graft surgery.

3.4. Follow-up results (Table 5)

Apart from the one death and three patients who underwent post-procedure CABG surgery, data of the remaining 37 patients were analyzed reflecting events only in the first 12 months. At 4 weeks post-procedure, 21 (56.8%) patients showed symptomatic improvement in their angina status. Six months later 17 (46%) patients showed a significant improvement in the NYHA functional class, $P<0.001$ (Fig. 1). A similar number of patients still showed evidence of sustained clinical improvement with a change in at least one class of angina or their cardiac functional status at 12 months (Table 5). At the same time, fractional shortening (FS) had increased from $15.9\pm3.4\%$ to $19.6\pm6.6\%$, $P=0.02$ and consequently cardiac output from 4.28 ± 0.98 to 5.34 ± 1.77 l/min,



PTCA and NYHA, as before

Fig. 1. Changes in NYHA functional class after PTCA ($n=34$).

Table 5
One-year follow-up data for 37 patients

	Follow-up time (months)		
	1	6	12
Number of patients	37	35 (94.6)	34 (91.9)
Improvement in angina class	21 (56.8)	18 (48.6)	17 (46)
Improvement in NYHA class	17 (46)	17 (46)	17 (46)
Clinical recurrence	0	2 (5.4)	8 (21.6)
Repeat angioplasty	0	0	4 (10.8)
Angioplasty for new disease	0	0	0
CABG surgery	3 (8.1)	5 (13.5)	7 (18.9)
Cardiac transplant	0	0	1 (2.7)
Hospitalization	6 (16.2)	14 (37.8)	22 (59.5)
Event-free survival	29 (78.4)	27 (73.0)	23 (62.3)
Non-fatal AMI	4 (10.8)	4 (10.8)	4 (10.8)
Death—cardiac	1 (2.7)	1 (2.7)	2 (5.4)
Non-cardiac	0	0	0
Lost to follow-up	0	1 (2.7)	1 (2.7)

CABG, coronary artery bypass surgery (emergency or elective); AMI, acute myocardial infarction; numbers in brackets refer to percentages.

$P<0.01$. One patient was lost to follow-up and two (5.4%) died of cardiac causes, namely, cardiogenic shock secondary to early stent occlusion and intractable heart failure, respectively. In general, patients who had shown improvement in their functional status by the end of the first month had maintained this improvement by the end of the year. Recurrence of symptoms necessitating a repeat angiographic study was noted in eight patients, four (10.8%) of whom required repeat angioplasty. There were no repeat procedures for new disease.

During the follow-up period, non-fatal Q-wave acute myocardial infarction occurred in four patients and CABG surgery was performed in seven others. One patient developed cardiogenic shock requiring LV assist device as a bridge to transplantation. The rate of hospitalization in this population tended to occur mid term post procedure. Twenty (54.1%) patients had been re-admitted at least once for worsening cardiac symptoms or for re-evaluation. No major change was observed in the types and dosages of the medications after angioplasty. Overall, event-free survival was 78.4% at 1 month and declined steadily to 62.3% by the end of the first year as depicted in the event-free survival curve (Fig. 2).

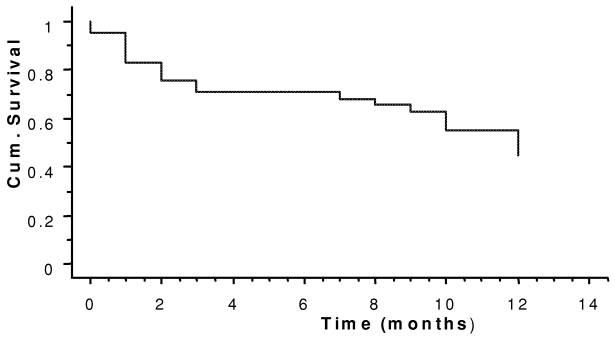


Fig. 2. Kaplan–Meier event-free survival curve.

4. Discussion

LV dysfunction constitutes an independent marker of poor prognosis in patients with coronary artery disease (CAD). In severe cases, revascularization procedures carry an additional significant risk of morbidity and mortality [3]. This study confirms that procedure-related major complications (death, emergency CABG, Q-wave myocardial infarction, or cardiogenic shock) are still high in this subset of patients. Previous studies noted rates ranging from 3.1 to 15.0% excluding cardiogenic shock [3–7]. Despite a 19.5% major complication rate in our series, there was only one procedure-related death over the entire period of 3 years. This low early mortality on a background of high major complications suggests an improvement in the management of potentially fatal complications. Indeed, in previous studies where mortality was 2–9%, this was attributed mainly to complications related to the procedure including, vessel dissections and abrupt closure. These complications can now be effectively managed by intracoronary stenting [12,13] thereby improving outcomes and preventing myocardial infarction and the need for emergency bypass surgery. A low mortality observed in our analysis may, therefore, be a result of the high application of endoluminal stents in our patient population. Similar observations were made recently by Lindsay et al. [7] in a study where 51.5% of patients received stents. These intracoronary devices, however, were not reported in all the previous studies except one in which they were used in only 10% of patients [6].

4.1. Changes in symptom profile and functional status

In general, the ultimate goals of any revascularization procedure are to treat the disease and improve

prognosis. Compared with medical treatment, coronary angioplasty in patients with angina and preserved LV function has been shown to improve quality of life assessed as physical functioning, vitality and overall general health [14]. In severe LV dysfunction, however, patients tend to be elderly, with history of previous myocardial infarction, previous revascularization procedures [3], heart failure and other comorbid conditions creating a formidable challenge in the assessment of symptomatic and functional improvement. It is therefore not surprising that these aspects were not investigated in previous studies. Nevertheless, Reynen et al. [15] have documented symptomatic improvement in patients with severe LV dysfunction who underwent coronary angioplasty. In our study, we have also shown that, even in patients with severely depressed LV function, improvement in symptom profile and functional status can be achieved and maintained for several months. Conversely, our results also show that, in about half the patients, there was no observable change in functional status at 1 month following coronary angioplasty. A similar proportion of patients showed no change in the angina symptoms in the mid-term, suggesting that the procedure may not be beneficial, at least in relieving symptoms, in a significant number of patients.

4.2. Changes in LV function after coronary angioplasty

Ejection fraction (EF), determined by echocardiography, is the most commonly assessed parameter of LV function after PTCA. In patients with poor LV function and segmental disturbances, however, this measure is poorly reproducible [16]. Other investigators have demonstrated improvement in angiographic LVEF in patients with CAD and maintained LV systolic function [17,18]. Only one study has previously shown angiographically an improvement in LV function in patients with poor ventricular function [15].

In the present study, we have shown an improvement at mid-term (3 to 6 months) in the LV function as assessed by fractional shortening and consequently cardiac output. This is brought about only by improvement in ventricular segmental function. Again this suggests the presence of significant amount of viable myocardium that recovers after improving its blood supply by opening the subtended artery.

4.3. Follow-up and late complications

Previous studies have shown high mortality rates ranging from 13 to 25% at 1 year in patients with severe LV disease undergoing PTCA [3–7,15,19]. Cardiac deaths and other complications related to coronary angioplasty in patients with severe LV dysfunction occurring months or years later are also well documented [8]. Restenosis plays a major role in these late outcomes. Yet, data regarding restenosis are limited due to small numbers of patients who undergo repeat angiography. Earlier, Vandormael et al. [20] reported that in 51% of cases, a second revascularization after a successful angioplasty procedure was due to restenosis. Others recognized it as a possible cause of morbidity and mortality but confirmatory investigations were not performed [6]. In our series, clinical recurrence occurred in 21.6% of patients, half of whom (10.8%) had repeat angioplasty for angiographically confirmed restenosis. This value was lower than 30% expected at 1 year in routine angioplasties [21], and also much lower than 41% reported in an earlier study with similar patient characteristics [15]. Furthermore, we documented a relatively lower mortality of 5.4% in comparison with previous studies. This also included both low early and late mortality outcomes. Again, this could be attributed to coronary stenting, which has been shown to reduce the likelihood of restenosis [22,23].

5. Study limitations

Our study has obvious limitations. Firstly, it is a retrospective non-randomized analysis and is likely to have the bias inherent in this type of study. Secondly, most patients have not had hibernation studies performed ultimately making comparative analysis of this data inconclusive. Thirdly, like previous studies the number of patients was small rendering it difficult to make specific conclusions. Patients, however, were not selected by any criteria apart from significantly depressed LV function. Moreover, they were a heterogeneous group including those with unstable angina, those with or without prior myocardial infarc-

tion, CABG surgery or both. Some of these baseline characteristics are recognized obstacles to outcomes analysis in percutaneous transluminal coronary revascularization [24].

6. Conclusions

Despite high procedure-related complications, symptomatic, functional and LV function improvement can be achieved in patients with severe LV dysfunction undergoing PTCA. Comparing with 'historical data' our results suggest that both early and late outcomes have improved. This new trend, perhaps, reflects a change in the angioplasty procedure in the last decade—the use of intracoronary stenting. However, whether PTCA, stenting, CABG surgery alone or in combination is the best therapeutic option in patients with severe LV dysfunction, only randomized clinical trials will provide appropriate answers.

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