Procedural Results of Coronary Angioplasty but Not Late Mortality Have Improved in Patients with Depressed Left Ventricular Function

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Summary

Background: Published experience with coronary angioplasty in patients with severely depressed left ventricular (LV) ejection fraction indicates that procedural complications are more frequent in such patients than in those with normal or near normal LV function. Although the immediate outcomes of transcatheter revascularization in unselected populations have improved substantially since the procedures upon which these reports were based were performed, outcomes with this subset of patients has not been recently reviewed.

Hypothesis: This study was undertaken to document the results of the application of current transcatheter technology to this patient subset.

Methods: We analyzed data from 194 consecutive patients with a visually estimated LV ejection fraction <30%, who underwent coronary angioplasty in this institution between January 1, 1995, and April 30, 1996, and compared their outcomes with those of 1,390 patients with normal LV function treated concurrently.

Results: Angiographic success in the two groups was similar. The hospital mortality of the patients with low ejection fraction was higher (2.6 vs. 0.6%, $p=0.02$) than in concurrently treated patients with normal LV function. Other procedural complications were no more frequent than in such patients.

Late mortality in patients with low ejection fraction was 16%, a similar value to that in older reports.

Conclusion: Compared with older reports, current hospital outcomes of coronary angioplasty are improved in patients with severely depressed LV function. Unfortunately, late outcomes are not demonstrably better.

Key words: coronary angioplasty, depressed left ventricular function

Introduction

Published experience with coronary angioplasty in patients with severely depressed left ventricular ejection fraction (LVEF) indicates that procedural complications are more frequent in such patients than in those with normal or near normal LV function treated contemporaneously. Moreover, even after successful dilatation of the target lesions, the late mortality rate in such patients is high.^{1–7} The immediate outcomes of transcatheter revascularization in unselected populations have improved substantially since the procedures upon which these reports were based were performed,⁸ but outcomes with this subset of patients have not been reviewed.

Interventional cardiologists now have greater experience and are equipped with improved guiding catheters, wires, and balloons, as well as with atherectomy devices, laser catheters, and endoluminal stents. In response to these advances, operators now more frequently attempt to treat patients with severely depressed LV function. Thus, it seems timely to document the results of the application of current transcatheter technology to this patient subset.

Methods

Patients

Between January 1, 1995, and April 30, 1996, 4,327 patients underwent a transcatheter revascularization procedure in our laboratory. The operating cardiologist visually estimated the LVEF and assigned each patient to one of five EF

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categories (≥ 50 , 40–49, 30–39, 20–29, and $< 20\%$). Ejection fraction was estimated to be $< 30\%$ in 200 patients. The six patients with an acute myocardial infarction within the 48 h preceding the index procedure were excluded. The remaining 194 constitute the study population of patients with low EF.

From the same data base, the 1,390 patients with an EF estimated to be at least 50% and who were treated during the same time period were analyzed for comparison. As with patients with low EF, those who had an acute myocardial infarction in the 48 h preceding the procedure were excluded.

Procedures

Transcatheter procedures were carried out by standard techniques. One or more new devices (i.e., directional, extracatheter, and rotational atherectomy; excimer laser angioplasty; or endoluminal stents) were employed for at least one target lesion in 128 (66.0%) of patients in the low EF group and in 912 (65.6%) of patients with normal EF. The devices employed were similar in both groups (Table I). Each operator chose the treatment modality based on the size of the artery containing the target lesion as well as its location and characteristics, so called "lesion specific" device choice. In keeping with the concept of "facilitated angioplasty,"⁹ adjunct balloon angioplasty was employed in nearly all instances in which a debulking device was used. Endoluminal stents were placed at the discretion of the operator either as a planned procedure or as a "bail out" for abrupt closure, threatened closure, or other unsatisfactory angiographic outcome.

TABLE I Baseline characteristics

	LVEF <0.30	LVEF ≥ 0.50	p Value
Number	194	1390	
Age (years)	67.5 $\pm$ 9.5	62.7 $\pm$ 11.3	<0.001
Male (%)	154 (79.4)	953 (68.6)	0.003
Diabetes (%)	39 (20.1)	219 (15.8)	0.15
Creatinine ≥ 2.0 (%)	12 (6.2)	20 (1.4)	<0.001
Shock (%)	4 (2.1)	6 (0.4)	0.03
Prior CABG (%)	86 (44.3)	265 (19.0)	<0.001
Prior PTCA (%)	66 (34.0)	392 (28.2)	0.11
Prior MI (%)	86 (44.3)	332 (23.9)	<0.001
Unstable angina (%)	139 (71.6)	827 (59.4)	<0.001
ACC/AHA Type-C (%) ^a	152 (79.6)	857 (63.1)	<0.001
Saphenous vein graft (%)	49 (25.3)	112 (8.1)	<0.001
≥ 2 Lesions targeted (%)	98 (50.5)	663 (47.7)	0.51
Balloon angioplasty (%)	66 (34.0)	478 (34.4)	0.98
Stent (%)	100 (51.5)	636 (45.7)	0.15
Debulking device (%)	54 (23.8)	428 (30.8)	0.45

^a In three patients with low EF and 32 patients with normal EF, the complexity of the lesions was not described.

Abbreviations: CABG = coronary artery bypass grafting, PTCA = percutaneous transluminal coronary angioplasty, MI = myocardial infarction, LVEF = left ventricular ejection fraction, ACC/AHA = American College of Cardiology/American Heart Association.

Data Collection

As is routine in this laboratory, the operating cardiologist or an assistant completed a report form describing the baseline clinical characteristics of each patient. The angiographic characteristics of the target lesions, the transcatheter devices employed, and the immediate outcome were added to the report at the conclusion of the procedure. To facilitate the analysis of patient-based outcomes, in any instance of attempted multilesion treatment, each patient was assigned an American College of Cardiology/American Heart Association (ACC/AHA) complexity category¹⁰ based on the most complex lesion targeted. Similarly, if one of the target lesions was a saphenous vein graft, the patient was assigned to that group.

To collect information regarding the subsequent hospital course, independent chart review was conducted by specially trained quality assurance nurses to identify the following complications: death, coronary bypass surgery (CABG), myocardial infarction, and repeat angioplasty of the same lesion.

Late follow-up information was sought in patients with low EF beginning no sooner than 7 months following the index procedure. Information was obtained by research nurses through telephone contact with 188 (96.9%) patients or their physicians. Available medical records of any reported events were reviewed.

Statistical Analysis

All data were entered into a computerized data base. Demographic, baseline clinical, procedural, and outcome variables were analyzed using standard statistical methods. Continuous variables are presented as the mean $\pm$ standard deviation, and comparisons were made by means of analysis of variance. Discrete variables are presented as percentages and were compared by means of contingency tables and chi-square analysis with Yates correction. Fisher's exact test was employed when appropriate. A p value of < 0.05 was taken as significant. Survival of patients with low EF is presented as a Kaplan-Meier curve.

Results

Baseline Clinical and Procedural Characteristics

Baseline and procedural variables are listed in Table I. Compared with the contemporaneously treated patients with a normal EF, those with an EF $< 30\%$ were older and more often male. Furthermore, they substantially more often had previous CABG and/or prior myocardial infarction and were more often treated for unstable angina. A greater proportion of the low EF group was treated during cardiogenic shock and/or with renal failure (serum creatinine > 2 mg/100 dl). Moreover, lesions treated were more complex in patients in the low EF group. They more often had a type-C lesion or a saphenous vein graft targeted.

TABLE II Hospital outcomes

	LVEF <0.30	LVEF ≥0.50	p Value
Number	194	1,390	
Success (%)	180 (92.8)	1,302 (93.7)	0.75
Clinical success (%)	174 (89.7)	1,283 (92.3)	0.27
Death (%)	5 (2.6)	9 (0.6)	0.02
Emergency CABG (%)	1 (0.5)	17 (1.2)	0.71
Q-wave MI (%)	2 (1.0)	6 (0.4)	0.26
Major complications (%) ^a	6 (3.1)	26 (1.9)	0.27
Elective CABG (%)	3 (1.5)	6 (0.4)	0.09
Repeat PTCA (%)	5 (2.6)	27 (1.9)	0.58
Non-Q-wave MI (%)	8 (4.1)	41 (2.9)	0.51
Any adverse event (%) ^b	19 (9.8)	84 (6.0)	0.07

^a Death, Q-wave MI, or emergency CABG.^b Death, any MI, any CABG, repeat PTCA of same vessel.

Abbreviations as in Table I.

Hospital Outcomes

Hospital outcomes are detailed in Table II. Angiographic success (defined as reduction of the luminal narrowing to <50% diameter stenosis in all target lesions) was accomplished in about 93% of both patient groups. Clinical success (defined as angiographic success and no mortality, emergency CABG, or Q-wave myocardial infarction prior to discharge) was achieved in 89.7% of patients with low EF, a value not significantly lower than the 93.7% rate achieved in those with normal EF ($p = 0.27$).

In-hospital mortality was higher in the low EF group. Five (2.6%) patients died before hospital discharge, a rate four times higher than that in those with normal EF ($p = 0.02$). The differences in need for emergency CABG and in the occurrence of nonfatal myocardial infarction (postprocedural chest pain and an increase in cardiac enzymes) were the same between the two groups. Three (1.5%) patients with low EF underwent elective CABG, a rate higher than the 0.4% encountered in those with normal EF, but the difference fell short of significance.

Late Outcomes

Of the 189 patients with low EF discharged alive, 6 (3.1%) were lost to follow-up. Thus, late follow-up information was available for 183. Mean length of follow-up on these was 12.6 ± 5.9 months. Twenty-eight (15.3%) died after hospital discharge, and 31 (16.9%) had an additional revascularization procedure. Additional transcatheter procedures were performed in 25 (13.7%) and CABG in 7 (3.8%) (1 had both). Eight (4.2%) patients reported a heart attack prior to the follow-up contact. Sixty-five (35.5%) patients were known to have one or more of these major adverse cardiac events.

Figure 1 depicts the actuarial survival and event-free survival for the low EF cohort. The actuarial survival at 1 year was

84%, and for 18 months it was 79%. Event-free survival was 71% at 12 and 56% at 18 months.

Discussion

Our data demonstrate that the overall improvement in the immediate outcomes of coronary angioplasty is shared by patients with severely depressed LVEF. In fact, current procedural success is similar to that of patients with normal EF. This is true despite the fact that those with low EF as a group are older and more severely ill and require treatment of more complex lesions (Table I). It must, however, be recognized that, almost certainly because of the greater severity of illness in these patients, hospital mortality is substantially greater than in those with normal EF. In view of the severity of illness of the patients with low EF, the mortality of 2.6% seems acceptable.

Comparison of the outcomes in the current study with "historical controls" from previous reports¹⁻⁷ must be made with caution. However, in so far as the patient populations and methods of data collection and analysis are comparable, the clinical success and complication rates in this series of patients treated in 1995 and 1996 are superior to those in seven previous reports,¹⁻⁷ covering procedures performed from 1979 to 1992 (Table III). In the current series, the frequency of major complications (death, emergency CABG, or Q-wave myocardial infarction) was 3.1%. In prior reports, this rate varied between 4.8 and 15%.¹⁻⁷ In only one small ($n = 42$) series⁵ was this rate < 6.0%. In the current series, clinical success (successful reduction of all target lesions to a percent diameter stenosis of <50% with no major complications) was 89.7%. In the previous reviews,¹⁻⁷ this or a similarly defined outcome ranged between 75 and 85% with one exception. In a study of 61 patients, Kohli *et al.*³ reported clinical success in 90%. Thus, the major complication rate appears to be about half that previously reported and the procedural success rate considerably improved.

In contrast to the improved hospital outcomes for transcatheter therapy in patients with a depressed LVEF, a favor-

FIG. 1 Actuarial survival is depicted by the solid line and event-free survival by the dotted line.

TABLE III Outcomes of coronary angioplasty in patients with low left ventricular ejection fraction (LVEF)

Reference No.	Dates	LVEF	No. of patients	Hospital mortality (%)	Major complication (%)	Clinical success (%)	1-Year mortality (%)
1	1985–86	≤35	51	2.0	11.8		
2	1983–89	≤40	73	5.5	6.8	82	21
3	1985–87	≤35	61	3.2	8.2	90	13
4	1979–88	≤35	98	4.1	9.1	85	215
5	1980–89	≤40	845	5.0	6.3	81	13
6	1987–91	≤35	100	9.0	15.0	75	16
7	1987–92	≤35	42	2.4	4.8	83	14
Present	1995–96	<30	194	2.6	3.1	90	16

able impact of current techniques was not maintained with longer follow-up. We encountered a 16% 12-month and a 21% 18-month mortality. These numbers do not appear to be an improvement over the previous reports^{1–7} which cited a 1-year mortality of 13 to 21% and a 2-year mortality of 20 to 26% (Table III). Thus, any expectation that improvement in immediate success with modern transcatheter modalities translates into improved long-term outcomes is not supported by these data.

One can only speculate as to the reason for the failure of the improved immediate outcomes of coronary angioplasty in the current era to translate into improved late outcomes. At least two possibilities can be suggested. First, the design of this analysis may have obscured a real benefit from transcatheter revascularization; that is, the sample size may be too small to show a difference or the patients may not be entirely comparable with those in the previously published series. Second, there may be an irreducible mortality inherent in patients with severely reduced LV function that cannot be lowered by revascularization with current angioplasty technology.

Conclusion

Compared with older reports, current hospital outcomes of coronary angioplasty are improved in patients with severely depressed left ventricular function in this analysis. Unfortunately, late outcomes are not demonstrably better.

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