Procedural results, in-hospital course and six-month follow-up after rescue compared to primary stenting in acute myocardial infarction

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Acute myocardial infarction; Coronary angioplasty; Stenting.

Background. **Although many previous reports showed a worse outcome after rescue compared to primary coronary angioplasty, a direct comparison of these two strategies in the era of stenting is lacking.**

Methods. **Fifty patients treated with rescue stenting were retrospectively compared to 61 patients treated with primary stenting during acute myocardial infarction over a 4-year period in our Laboratory.**

Results. **Baseline demographic and angiographic parameters were not significantly different in the two groups. Despite a significantly longer time-to-reperfusion in rescue stenting (4.7 – 2.7 vs 2.8 – 2.1 hours, p < 0.0001), procedural success rate (98 vs 97%), in-hospital mortality (6 vs 11%) and target vessel revascularization at 6 months (8 vs 10%) were similar in rescue compared to primary stenting.**

Conclusions. **These data suggest that stenting may help improve results of rescue angioplasty, and support the concept that aggressive treatment after failed thrombolysis can be pursued with satisfactory results.**

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Introduction

Primary coronary angioplasty (PTCA) has been shown to be more effective than thrombolysis in restoring vessel patency[1,2] and can result in improved myocardial salvage and in a lower mortality rate during acute myocardial infarction (AMI)[1]. On the other hand, angioplasty performed after failed thrombolysis (rescue PTCA) has been associated with a lower success rate[3,4], a high incidence of reocclusion[5], and questionable effects on left ventricular function[5] and long-term prognosis[6]. Moreover, failed rescue PTCA is associated with a very high mortality[5,7,8].

In recent years, parallel to the development of these revascularization strategies, coronary stenting has become an established and effective procedure to treat complications, and optimize immediate and long-term results of PTCA[9]. Therefore, stents have been increasingly utilized in AMI and results of recent work strongly support their effectiveness in this setting[10,11]. However, most of the available data concerning the use of coronary stents in AMI were collected in primary procedures[10], while little information is presently available on rescue stenting. For this reason, we reviewed our series of urgent procedures performed in AMI and compared primary to rescue stenting, testing the hypothesis that stenting tends to decrease the gap observed in the procedural success and complication rate in these two situations.

Methods

Study patients. From January 1995 to January 1999, 145 patients were treated in our catheterization laboratory for AMI. Of these, 111 (77%) received one or more stents and constitute the object of the present report. The group consisted of 81 males and 30 females with a mean age of 63 years (range 37-95 years). The criteria utilized for the definition of AMI were: chest pain of > 30 min and ST segment elevation in at least 2 contiguous leads persistent after sublingual nitrates. The accepted time for intervention from the onset of chest pain was 12 hours. After admission to the coronary care unit, the physician on duty was responsible for the activation of the catheterization laboratory per-

sonnel, according to his/her evaluation of the severity of the clinical status, potential benefits of PTCA, and availability of the interventional cardiologist. These patients are therefore identified not on the basis of a predefined protocol but rather on the combination of severity and availability. For all patients treated with intravenous thrombolysis, the drug utilized was tissue-type plasminogen activator (t-PA), according to the GUSTO protocol[12].

Definitions. Primary angioplasty is defined as a percutaneous revascularization procedure performed in a patient with the above-mentioned clinical and electrocardiographic criteria. Rescue angioplasty refers to the same revascularization procedures performed after the administration of full-dose t-PA in the presence of persistent ST segment elevation with or without chest pain, or early recurrence of ST segment elevation after an initial improvement. Procedural success refers to the achievement of a TIMI 3 flow in the infarct-related artery and a residual stenosis < 20%. A suboptimal result is considered a residual stenosis > 20% or TIMI 2 flow. The indications for stenting are either bailout (reocclusion or critical flow reduction after initial successful re-opening with PTCA) or elective (stenting planned regardless of the result obtained with PTCA). Cardiogenic shock is identified in the presence of persistent hypotension (systolic blood pressure < 90 mmHg) secondary to extensive left ventricular myocardial infarction and/or right ventricular infarction, associated with evidence of target organ hypoperfusion. An acute ischemic event in the territory of the stented vessel with angiographic documentation of stent occlusion or critical flow reduction is defined as acute stent thrombosis if occurring < 24 hours after stent implantation and subacute stent thrombosis if occurring > 24 hours after implantation. Target vessel revascularization is the term used to define a new procedure (percutaneous or surgical) performed in the stented vessel deemed clinically indicated within 6 months of entering the study.

Stenting procedure. Most of the procedures were performed using a percutaneous femoral approach, a standard dose of 10 000 IU of heparin as an intravenous bolus before coronary instrumentation and conventional monorail balloon systems. In 3 cases, a percutaneous brachial approach was required because of severe peripheral vascular disease. In all the cases included in this analysis, no additional thrombolytic drug was administered either intravenously or intracoronarily as adjunctive treatment. Starting from 1998, GP IIb/IIIa receptor inhibitors became routinely available and were used in 21 cases (50% of the total population treated in that period). In these patients, the initial heparin bolus was halved. Bare and pre-mounted stents were utilized aiming at a stent-to-vessel ratio of 1.0-1.1. Intracoronary ultrasound and quantitative angiography were not available in our laboratory during the study period. Left ventricular ejection fraction was calculated either angiographically at the end of the procedure (30 right anterior oblique ventriculography) or by echocardiography in the coronary care unit within 24 hours of stenting. The combination of ticlopidine and aspirin was the routine medical treatment for the prevention of rethrombosis in all study patients.

Statistical analysis. Results are presented as mean – 1 SD. Continuous variables were compared using Student s t-test for unpaired data or non-parametric analysis (Mann-Whitney s U test), where appropriate. All tests are two-tailed. Discrete variables are presented as percentages and analyzed with the χ^2 likelihood ratio with Fisher s correction when indicated. A p value of < 0.05 was considered as statistically significant.

Results

Sixty-one patients (55%) were treated with primary stenting (Group P) and 50 (45%) with rescue stenting (Group R). Of the 34 patients treated in the same period with PTCA alone, 28 (82%) had a primary angioplasty, while 6 (18%) had a rescue angioplasty. Thus, stent implantation was significantly more frequent in rescue procedures compared to direct procedures (89 vs 69%, p = 0.008). In the years 1995-1996, rescue stenting represented one third of all cases of stenting in AMI, while it has increased to one half in the years 1997-1999 (Table I). Patients characteristics are illustrated in table II. Ten percent of patients in Group R and 18% in Group P were over age 75. Fifteen had evidence of cardiogenic shock upon admission, 7 in Group R and 8 in Group P. Vessel distribution was comparable in the two groups. Left ventricular ejection fraction was available in 44 patients (88%) in Group R and averaged 45 – 11%. This value was not statistically different from that obtained in Group P which was equal to 43 – 15%. Procedural data are summarized in table III. Angiographic evidence of post-balloon dissection was present in 14% of cases in Group R vs 16% in Group P. Bailout stenting was performed in a similar proportion of cases (14 vs 23%, respectively).

Different types of stents were used. In Group R, a total of 61 stents were implanted in 50 patients (1.2 stent/patients). They were: NIR (n = 23); Palmaz-Schatz (n = 14); Multilink (n = 9); Minicrown (n = 5); Wiktor

Table I. Frequency of primary and rescue stenting in the study period.

	1995-1996	1997-1999	Total
Rescue	11 (33%)	39 (51%)	50
Primary	23 (67%)	38 (49%)	61
Total	34	77	111

Table II. Baseline clinical characteristics of the study population.

	Group R (n=50)	Group P (n=61)	p
Age (years)	60 – 12	64 – 11	0.070
Males (%)	38 (76)	43 (70)	0.663
Hypertension (%)	12 (24)	16 (26)	0.961
Diabetes (%)	4 (8)	6 (10)	0.998
Multivessel disease (%)	22 (44)	29 (48)	0.856
Previous myocardial infarction (%)	7 (14)	19 (31)	0.068
Cardiogenic shock (%)	7 (14)	8 (13)	0.886
Infarct-related vessel			
LAD	25 (50)	28 (45)	
RCA	20 (40)	20 (31)	
LCX	4 (8)	10 (17)	0.555
SVG	1 (2)	2 (5)	
LMCA	—	1 (2)	

LAD = left anterior descending coronary artery; LCX = left circumflex artery; LMCA = left main coronary artery; RCA = right coronary artery; SVG = saphenous vein graft.

Table III. Clinical and procedural variables in the two study groups.

	Group R (n=50)		Group P (n=61)		p
	Mean – SD	Range	Mean – SD	Range	
Time to reperfusion (h)	4.7 – 2.7	2-13	2.8 – 2.1	0.5-11	< 0.0001
Stents/patient (n=)	1.2 – 0.5	1-3	1.4 – 0.7	1-5	0.093
Length of the stented segment (mm)	16.3 – 7	9-45	20.3 – 12	8-73	0.058
Size of largest balloon used (mm)	3.2 – 0.4	2.5-4.0	3.2 – 0.5	2.5-4.5	1.000
Inflations (n=)	4.8 – 2.9	1-13	5.7 – 3.3	2-17	0.134
Total time of inflation (s)	348 – 432	40-1980	435 – 392	30-1155	0.269
Maximal inflation pressure (atm)	13.3 – 2.4	7-18	13.6 – 2.5	8-20	0.523
Left ventricular ejection fraction (%)	45 – 11	20-68	43 – 15	20-70	0.434
Peak CK-MB mass (ng/ml)	347 – 256	7-1205	287 – 214	0-763	0.185

(n = 3); AVE (n = 3); Crossflex (n = 2); V-Flex (n = 2). The distribution of stent types did not differ significantly between the two groups (Fig. 1). However, there was a trend for a higher number of stents and a longer stented segment in Group P compared to Group R patients (1.4 – 0.7 vs 1.2 – 0.5, p = 0.093, and 20.3 – 12 vs 16.3 – 7 mm, p = 0.058, respectively) (Table III).

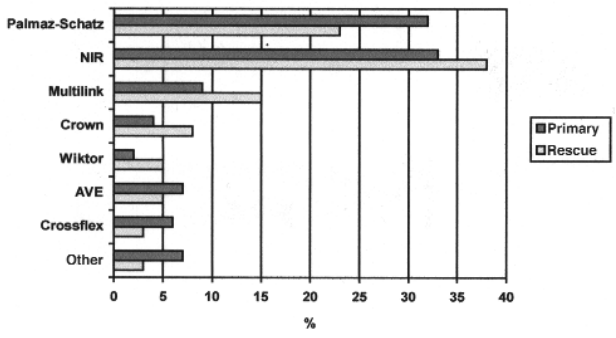

Figure 1. *Frequency of different stent types in the two study groups. The differences are not significant.*

Intra-aortic balloon counterpulsation was started either during or immediately after the procedure in 40% of patients in Group R vs 28% in Group P (p = 0.252) and was continued for at least 48 hours. None of the 21 patients treated with Reo-Pro experienced major bleeding (i.e. requiring transfusion).

The most relevant difference between the two groups reflects, as expected, a longer time-to-reperfusion in rescue stenting (4.7 – 2.7 vs 2.8 – 2.1 hours, p < 0.0001).

TIMI flow data are illustrated in table IV. Baseline distribution of TIMI grading shows no significant difference between the two groups. After the procedure, a final TIMI 3 flow was obtained in 88% of patients in Group R and in 94% of patients in Group P (p = 0.507).

Five cases of subacute stent thrombosis were recorded in the early phase (1995-1996), 1 in Group R and 4 in Group P. The stented vessel was the left anterior descending coronary artery in 4 cases and a saphenous vein graft to the left anterior descending coronary artery in 1. Two subacute thromboses were fatal, while 3 were treated with repeated PTCA and were uneventful. Details on subacute thrombosis in these patients have been de-

Table IV. TIMI flow at baseline and after the procedure in the two study groups.

TIMI flow	Group R (n=50)		Group P (n=61)	
	Initial	Final	Initial	Final
0	25 (50%)	1 (2%)	40 (65%)	2 (3%)
1	13 (26%)	0	9 (15%)	0
2	10 (20%)	5 (10%)	8 (13%)	2 (3%)
3	2 (4%)	44 (88%)	4 (7%)	57 (94%)

scribed elsewhere[13,14].

Table V provides analytic data regarding procedural results, in-hospital course and 6-month follow-up. Overall, 10 hospital deaths and no late deaths were observed. Of these, 3 occurred in Group R and 7 in Group P and were all but one due to cardiogenic shock. One death in Group P was secondary to massive retroperitoneal bleeding in a patient with aortic counterpulsation. The difference in mortality between the two groups was not significant (6 vs 11%, p = 0.503). The composite end point of death, reinfarction and target vessel revascularization at 6 months was also comparable in the two groups (14 vs 20%, p = 0.592).

Table V. Procedural results and follow-up data in the study population.

	Group R	Group P
In-lab	50 (100%)	61 (100%)
Procedural success	49 (98%)	59 (97%)
Uncomplicated failure	1 (2%)	0
Death	0	2 (3%)
In-hospital	50	59
Death	3 (6%)*	5 (8%)*
Re-infarction	0	0
Target vessel revascularization	0	1*
Total in-hospital mortality	3 (6%)	7 (11%)
Six-month follow-up	47	54
Death	0	0
Re-infarction	0	0
Target vessel revascularization	4 (8%)	4 (10%)*
Composite end points at 6 months	7 (14%)	12 (20%)

* including cases of subacute stent thrombosis: 2 in-hospital deaths (1 Group R and 1 Group P); 1 in-hospital and 2 late target vessel revascularizations.

Discussion

The activation of a timely and effective system for ensuring prompt percutaneous revascularization in AMI requires a high degree of commitment, training and practice. In fact, although coronary angioplasty has an established role in the treatment of AMI and is performed in many centers, very few teams are actively engaged in providing equal treatment for all patients with pre-defined criteria 24 hours a day, 7 days a week. For this reason, medical treatment will remain the first approach not only for patients admitted to peripheral hospitals without catheterization facilities, but also for some or most of those admitted to larger centers. Due to logistical limitations, the issue of referring patients for PTCA after failed thrombolysis has a major clinical impact and is expected to have an increasingly important role in the near future. Currently, the more severe the patient s condition, the more likely he or she will be offered rescue PTCA, with a higher rate of adverse events even in case of success.

Experimental data provide supporting evidence that PTCA after failed thrombolysis is a cumbersome procedure. It has been observed that after thrombolysis more thrombin is generated which then promotes massive platelet adhesion[15]. Evidence of a high complication rate in rescue angioplasty was historically of such a magnitude as to be observed even in small-sized studies[16,17], and has persisted in more recent trials[18]. Larger clinical database confirm that the efficacy of rescue PTCA is suboptimal. Results from the TIMI 4 trial report a 29% adverse in-hospital outcome after successful rescue PTCA and 83% after failed rescue PTCA, for a combined total of 35%. This equals the number of patients who did not undergo rescue PTCA at all[6]. More recent data gathered from the GUSTO I database report a 30% mortality after 1 month in patients with rescue failure[7]. These authors emphasize that patients who are offered a rescue procedure represent, by definition, a high-risk subgroup that already possesses the clinical predictors for a poor outcome (compared to patients with failed thrombolysis who are treated conservatively)[7].

Although rescue PTCA was reported to be successful in > 80% of the cases in this large series, only 68% of the procedures achieved a TIMI 3 flow, and the mean residual stenosis was close to 45%[7]. These angiographic results differ substantially from the accepted success criteria defined in more recent trials, in which a TIMI 2 flow at the end of the procedure as well as a diameter stenosis > 30% were considered as suboptimal[10]. Reocclusion after successful rescue PTCA is frequent, occurring in approximately 18-20% of patients treated with t-PA[5], while a lower percentage of patients was reported in the FRESCO trial[10]. Thus, suboptimal criteria for the definition of procedural success match well with the very different incidence of complications observed in these two studies.

Primary stenting is known to be effective in AMI[10,11] and has recently been demonstrated to be superior to PTCA in terms of death, reinfarction and target vessel revascularization at 1 (3.4 vs 12.5%)[11] and 6 months (9 vs 28%)[10]. Consistent data on rescue stenting, however, are lacking.

The aim of our report was to present and analyze results of rescue stenting in our laboratory. To do so, we

felt it necessary to provide data obtained in a reference group of patients treated with primary stenting in the same time period and carried out by the same operators.

Two closely related aspects that reflect our clinical setting and have an impact on the results presented need to be highlighted. First, rescue stenting in our laboratory represents > 40% of all procedures performed in AMI (Table I). Second, primary procedures are selected mainly for high-risk patients. Although there is a shortage of nationwide *ad hoc* registries, available data suggest that the proportion of rescue procedures performed in our laboratory is much higher compared to most other centers. For instance, Repetto et al.[19] have recently provided a contribution consisting of 49 rescue stenting procedures collected over a similar length of time. However, according to the recent national survey by GISE[20], the same group in 1998 performed 98 primary procedures compared to only 10 by us. Thus, in this unique situation, rescue and primary procedures are almost equally performed, not because we overtreat patients after thrombolysis, but because primary procedures are relatively underrepresented. As a consequence, patients treated with primary stenting are not representative of the more general population of AMI patients and the results obtained must take into account the high-risk profile of this subgroup (Table I). Mean age, prevalence of multivessel disease and frequency of shock appear to be consistently higher compared to previous studies on primary angioplasty[2] and to the PAMI stent study group[11]. These patients show a greater resemblance to those included in the non-randomized arm of the FRESCO study[10], in which a 10% mortality and 10% target vessel revascularization were observed.

Thus, the main conclusion of our report is that rescue stenting in our setting provides procedural and clinical results which are comparable and not worse to those of primary stenting, given a similar caseload experience of the operators in these two clinical situations. It is possible that centers which extensively perform primary procedures, including low-risk patients, and offer salvage procedures only to high-risk patients after failed thrombolysis may face a different scenario in terms of results and complications between the two groups.

We do realize that randomized trials are the only way to define whether one strategy is definitely better or worse than another. However, data substantiating the role of rescue stenting are scarce. Most of the available studies compare rescue procedures to conservative medical management after failed[21] or effective[22] thrombolysis, while others compare primary procedures with thrombolysis[2]. Thus, conclusions on this particular issue remain inferential.

Although our study has neither the sample size nor the design to answer the question as to whether rescue stenting is equally effective compared to primary stenting, our results suggest that rescue stenting is feasible and associated with an acceptable rate of clinical events. In fact, we observed a 6% mortality and a 14% incidence of combined end points at 6 months, in a population that does not seem to be at low risk (Table II). These appear to be intermediate results and lie between the data provided by Antoniucci et al.[10], describing a 1% mortality and 9% event rate at 6 months, and previous available data on rescue PTCA, in which the 30-day mortality alone was 11%[7].

The use of intra-aortic balloon counterpulsation in our patients was higher than usually reported, especially in the rescue group. Although an *ad hoc* randomized trial did not show any significant benefit for primary PTCA patients with the routine use of intra-aortic balloon counterpulsation[23], we felt that a liberal utilization of this device might help improve flow especially during and/or after rescue procedures, in which we were able to obtain a TIMI 3 flow in 88% of patients (compared to 94% in Group P). As a matter of fact, a previous study by Ohman et al.[24] reported a lower incidence of reocclusion and a higher incidence of TIMI 3 flow in patients randomized to intra-aortic balloon counterpulsation. Interestingly, a substantial proportion of rescue procedures was included in that particular study.

The availability of GP IIb/IIIa receptor antagonists opens new perspectives in the treatment of AMI, in combination with either thrombolysis[25] or percutaneous coronary interventions[26]. Data collected in the very last part of the study period do not allow us to draw any conclusions concerning efficacy. However, the lack of major bleeding in rescue procedures represents an encouraging element in favor of Reo-Pro use in carefully selected cases after failed thrombolysis.

Study limitations. The number of patients being studied is limited and the analysis was carried out retrospectively. In this context, differences that are not statistically significant may be clinically relevant. Although our results cannot be automatically translated into the conclusion that rescue and primary stenting are equally effective, this report may be given the credit for an improvement in the results of rescue procedures has occurred, and that it is most likely attributable to coronary stenting.

In conclusion, our experience suggests that rescue stenting is feasible and is associated with clinical results that are comparable to those obtained by primary stenting, despite a significantly longer time-to-reperfusion. We consider these data as supportive evidence in favor of an aggressive strategy of stenting in patients after failed thrombolysis.

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