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# A Randomized Comparison of Direct Stenting With Conventional Stent Implantation in Selected Patients With Acute Myocardial Infarction

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**OBJECTIVES** We sought to determine whether direct stenting might prevent the adverse events associated with stent implantation during primary angioplasty and to compare it with conventional stent implantation in patients with acute myocardial infarction (AMI).

**BACKGROUND** No trial has demonstrated that stents favorably influence mortality rate. Recent studies have even suggested a negative impact of stents on coronary blood flow and clinical outcome.

**METHODS** Of 409 patients treated by primary angioplasty with stent implantation in our center, 206 (50%) were enrolled in this randomized, single-center trial and allocated to direct stent implantation (n = 102) or stent implantation after balloon pre-dilation (n = 104). The study end points included angiographic results (final corrected Thrombolysis In Myocardial Infarction [TIMI] frame count and a composite end point of slow and no-reflow or distal embolization), an electrocardiogram marker of myocardial reperfusion assessment (ST-segment resolution) and in-hospital clinical outcome (death and recurrent infarction).

**RESULTS** Direct stent implantation failed in eight patients but succeeded after pre-dilation in all. A non-significant increase in TIMI flow grade 3 was achieved after direct stenting (95.1% vs. 93.3%, p = 0.74) without significant difference in the corrected TIMI frame count (31.5 ± 17 and 35.2 ± 20 frames after direct and conventional stent, respectively, p = 0.42). The composite angiographic end point was significantly reduced by direct stent implantation (11.7% vs. 26.9%, p = 0.01). ST-segment resolution was also significantly improved after direct stent (no ST-segment resolution in 20.2% vs. 38.1% after direct and conventional stent, respectively, p = 0.01). Death and/or recurrent infarction occurred in six patients after conventional stent implantation and in two patients after direct stenting (p = 0.28).

**CONCLUSIONS** In selected patients with AMI, direct stenting can be applied safely and effectively. This strategy may result in a significant reduction of microvascular injury, as suggested by improved ST-segment resolution after reperfusion with major potential clinical consequences. (J Am Coll Cardiol 2002;39:15–21) © 2002 by the American College of Cardiology

Several studies have evaluated the benefit of coronary stents during primary angioplasty. Coronary stent implantation has been shown to result in lower rates of recurrent ischemia and subsequent target vessel revascularization after primary angioplasty (1–4). However, no trials have demonstrated a significant impact of coronary stents on the survival rate after myocardial infarction (MI). The most representative randomized trials to date even suggest that coronary stent implantation may be associated with a slight, although nonsignificant, increase in the mortality rate compared with primary balloon angioplasty (5,6). Conflicting results have been reported on the primary success rate after stent implantation, and there is some concern as to possible coronary blood flow degradation, with a decrease in Thrombolysis in Myocardial Infarction (TIMI) grade flow compared with balloon angioplasty alone (1–7). Recent trials evaluating the benefit of glycoprotein (GP) IIb/IIIa inhibitors in the setting of acute coronary syndrome have suggested that microembolization may play a deleterious role and have highlighted a new target of acute MI (AMI) therapy with major implications in terms of prognosis (8–11). Preserved left ventricular (LV) function and improved outcome have been reported with the combined use of GP IIb/IIIa inhibitors and conventional stent implantation (12,13). We hypothesized that direct stent implantation could prevent embolization and no-reflow and also improve clinical outcome of primary angioplasty with stent implantation. Consequently, we conducted a prospective randomized trial comparing direct coronary stenting with conventional stent implantation in AMI.

## METHODS

**Patient selection.** Our institution policy is one of direct admission to the cath-lab for all suspected AMIs managed by pre-hospital emergency mobile units staffed by a trained physician (Service d'Aide Médicalisé d'Urgence). Conse-

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**Abbreviations and Acronyms**

| | |
|---|---|
| ADMIRAL | = Abciximab Before Direct Angioplasty and Stenting in Myocardial Infarction Regarding Acute and Long-term Follow-up |
| AMI | = acute myocardial infarction |
| CADILLAC | = Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complication trial |
| cTFC | = corrected Thrombolysis in Myocardial Infarction frame count |
| GP | = glycoprotein |
| MI | = myocardial infarction |
| PAMI | = Primary Angioplasty in Myocardial Infarction trial |
| PTCA | = percutaneous transluminal coronary angioplasty |
| STENTIM | = Stenting in Acute Myocardial Infarction study |
| TIMI | = Thrombolysis In Myocardial Infarction |

quently, patients were screened by the operator inside the cath lab. Inclusion criteria involved patients with AMI who presented within 12 h of symptom onset or between 12 h and 24 h if they had persistent symptoms with evidence of ongoing ischemia. Patients were considered for the trial if they had either ST-segment elevation of at least 1 mm in two contiguous electrocardiographic leads or a non-diagnostic electrocardiogram (ECG) (including left bundle-branch block, ST-segment depression or T-wave inversion) with prolonged chest pain (>30 min) and documentation of MI in the catheterization laboratory (with evidence of high-grade coronary stenosis and associated LV wall-motion abnormalities). Patients who received pre-hospital thrombolysis were included in the study, and patients in cardiogenic shock were excluded. The decision to include a patient was made after identification of the infarct-related vessel and after successful crossing of the lesion with a guide wire, when coronary stenting was deemed feasible. Angiographic exclusion criteria were unprotected left main disease, extensive thrombus throughout the infarct-related artery, heavy coronary calcification and target lesion located in a saphenous vein graft. Most patients with TIMI flow 0 were included only when partial or complete reperfusion was achieved, because sustained TIMI 0 perfusion precluded the assessment of the distal vessel bed as well as the selection of the appropriate stent. Patients with a target lesion located in a true bifurcation were excluded. After giving oral informed consent in the cath lab, patients were randomized to direct stenting or balloon angioplasty followed by stent implantation by means of a non-blinded allocation system.

**Procedure.** Percutaneous transluminal coronary angioplasty (PTCA) procedures were performed by six experienced operators (300 to 600 PTCAs per operator, per year). Pre-dilation was performed with a single low-pressure inflation followed by stent implantation with a pre-mounted stent. For direct stenting, an effort was made to use a single stent whenever possible, with a mean stent size compatible with both the proximal and distal reference diameter, delivered at low pressure in cases of poor distal vessel opacification and over-expanded when necessary if undersized. Pre-mounted tubular or multicellular stents were recommended. High-pressure inflation was not performed except in cases of non-optimal angiographic results. Intravascular ultrasound guidance was not used. Prior to the intervention, all patients received intravenous aspirin (250 mg to 500 mg) and heparin with an activated clotting time target of 250 s. The use of GP IIb/IIIa inhibitors was optional in the trial, except in instances such as distal embolization, no-reflow phenomenon and sub-optimal flow after coronary stenting. The use of intracoronary verapamil or adenosine was at the operator's discretion but was strongly recommended in cases of slow and no-reflow and when coronary blood flow was sub-optimal. After stent implantation, the arterial sheath (radial/femoral) was directly removed with immediate hemostasis at the femoral access site by means of a percutaneous suture device (Perclose Inc., Redwood City, California). A combination of aspirin and ticlopidine (250 mg to 500 mg/day for one month) was immediately initiated in all patients upon leaving the cath lab.

**Study end points.** Study end points included the final TIMI frame count for the number of frames required to opacify standardized angiographic landmarks and normalized for vessel length (14), a composite angiographic end point including angiographic events such as distal embolization, slow-flow (decrease in flow from TIMI 3 to TIMI 2) or no-reflow (decrease in flow from TIMI 2 or 3 to TIMI 0 or 1), a binary ECG criterion of microvascular reperfusion injury as defined by the presence of persistent (>50% of initial value) ST-segment elevation 30 to 60 min after completion of the procedure as previously described (15) and a composite clinical end point of in-hospital mortality and reinfarction. No core laboratory was used for the study, but all angiographic data were centralized and analyzed separately by a single operator. ST-segment data analysis was carried out separately and blinded to treatment allocation. All analyses were on an intention-to-treat basis.

**Statistical analysis.** Statistical analysis was performed using SAS 6.08 software (Dynamic Microsystem, Inc., London, United Kingdom). Data were summarized using the means ± SD for continuous variables and frequency for categorical variables. Univariate analysis was performed using Student *t* test or chi-square when appropriate.

## RESULTS

From June 1999 to November 2000, 409 patients with AMI were treated by PTCA with stent implantation in our institution: 206 patients were randomly assigned (two patients were excluded because of protocol violation) to either direct stenting (102 patients) or balloon angioplasty fol-

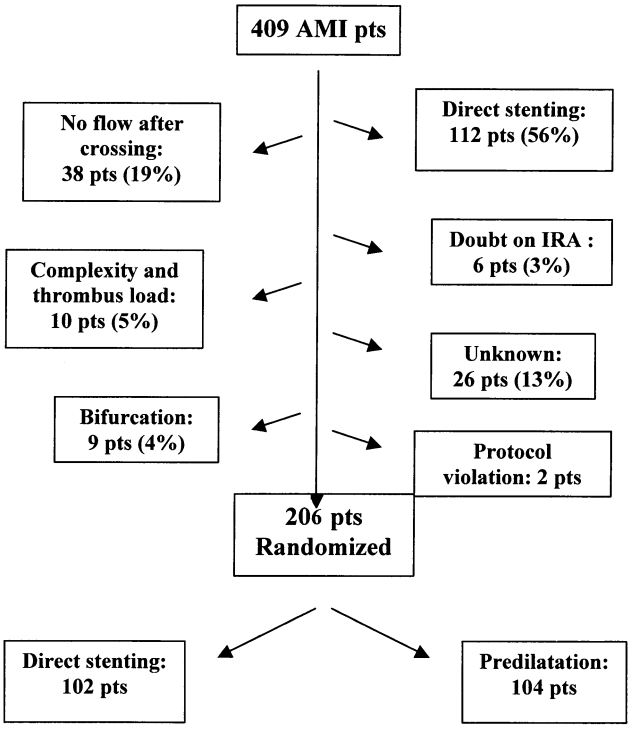


**Figure 1.** Selection of patients and reasons for exclusion. AMI = acute myocardial infarction; IRA = infarct-related artery; pts = patients.

lowed by stent (104 patients). The number of patients excluded and the reasons are shown in Figure 1. An analysis of these exclusions showed that despite potential eligibility many of these patients were treated by direct stenting (non-randomized). Sustained no-flow distal to the obstruction after crossing the lesion with a guide wire accounted for 19% of the exclusions.

**Procedural outcome.** The baseline characteristics of the two groups were well matched (Table 1) with an even AMI population distribution for most of the clinical and angiographic variables. Except for heparin, aspirin and ticlopidine, the use of adjunctive medications was limited and defined by protocol as rescue treatment, depending on the angiographic results (GP IIb/IIIa inhibitors in 11.6% of the global study population). Procedural data are listed in Table 2. All patients received a stent. Direct stent implantation failed in eight patients in whom pre-dilation was necessary before final and successful stenting could be achieved. The cumulative angiographic incidence of slow-flow, no reflow or distal embolization occurred in 12 patients in the direct stent group and in 28 patients in the conventional stent group ($p = 0.01$). Timing of these adverse events relative to the procedure are detailed in Table 2. Despite these differences, the final TIMI 3 flow grade rate was high in the two groups, with a non-significant increase in the direct stent arm (95.1 vs. 93.3%) and no significant difference in the corrected TIMI frame count (cTFC) (31.5 ± 17 vs. 35.2 ± 20 frames, $p = 0.42$). Electrocardiogram analysis after reperfusion showed no ST-segment resolution in 17 and 32 patients after direct and conventional stenting, respectively

**Table 1.** Baseline Characteristics of the 206 Study Patients

| | DS (n = 102) | CS (n = 104) | p Value |
|---|---|---|---|
| Age, yr | 59.9 ± 13 | 59.2 ± 14 | 0.85 |
| Men (%) | 81 (79.4) | 92 (88.4) | 0.94 |
| Risk factors | | | |
| Hypertension | 36 (35.3) | 32 (30.7) | 0.6 |
| Smoker (%) | 60 (58.8) | 64 (61.5) | 0.8 |
| Dyslipidemia (%) | 56 (54.9) | 33 (31.7) | 0.01 |
| Diabetes (%) | 16 (15.7) | 9 (8.6) | 0.18 |
| Family history (%) | 26 (25.5) | 24 (23.1) | 0.8 |
| Previous infarction (%) | 9 (8.8) | 2 (1.9) | 0.16 |
| Previous bypass surgery/angioplasty (%) | 10 (9.9) | 5 (4.8) | 0.22 |
| Anterior MI location (%) | 41 (40.2) | 47 (45.2) | 0.73 |
| Prehospital thrombolysis (%) | 17 (16.6) | 24 (23.1) | 0.20 |
| Symptom-onset time to admission, h* | 4.0 (3–24) | 4.0 (3–24) | 1 |
| Multivessel disease (%) | 42 (41.1) | 43 (41.3) | 0.90 |
| Ejection fraction (%) | 56.8 ± 13 | 56.0 ± 14 | 0.84 |
| Infarct-related vessel (%) | | | |
| Left anterior descending | 40 (39.2) | 47 (45.2) | 0.74 |
| Right coronary | 44 (43.1) | 38 (36.5) | 0.45 |
| Circumflex | 18 (17.6) | 19 (18.3) | 0.71 |
| TIMI grade flow (%) | | | |
| TIMI 0 | 46 (45.1) | 49 (47.1) | 0.96 |
| TIMI 1 | 8 (7.8) | 9 (8.6) | 0.83 |
| TIMI 2 | 21 (20.6) | 17 (16.3) | 0.36 |
| TIMI 3 | 27 (26.4) | 29 (27.9) | 0.70 |

CS = conventional stenting implantation; DS = direct coronary stenting; MI = myocardial infarction; TIMI = Thrombolysis In Myocardial Infarction.
*Median (range).

($p = 0.01$). An increase in ST-segment elevation occurred in four and nine patients ($p = 0.14$) after direct versus conventional stenting, respectively.

**In-hospital outcome.** Figure 2 shows in-hospital outcomes. Death occurred in four patients after conventional stenting and in one patient after direct stenting ($p = 0.36$). Three deaths occurred on Day 1, with suspected myocardial rupture in two cases and ventricular fibrillation in one; one octogenarian patient died after 12 days from progressive LV failure. In the direct stent group, the only death occurred in an octogenarian patient with three-vessel disease, non–Q-wave MI and irreversible cardiogenic shock after angioplasty. sub-acute stent occlusion occurred in three patients in each group (within 30 min to three days after percutaneous coronary intervention). Repeat angioplasty was performed in these six patients, and only two had recurrent MI (conventional stent group). Therefore, the combined clinical end point of death and recurrent MI was 5.7% in the conventional stent group and was not significantly higher than the 1.9% rate reported in the direct stent group ($p = 0.28$). Mean hospital stay was 6.9 days in the direct stent group and 7.4 days in the conventional stent group ($p = 0.89$).

## DISCUSSION

Patients with AMI benefit from primary angioplasty, as shown by lower rates of mortality, recurrent infarction and stroke compared with thrombolysis (16–18). Coronary stent

**Table 2.** Procedural Data and Results

| | DS (n = 102) | CS (n = 104) | p Value |
|---|---|---|---|
| Catheter balloon used, (%) | 24 (23.5) | 108 (107.3) | 0.0001 |
| Direct stent failure (%) | 8 (7.8) | — | — |
| Stent implantation | | | |
| Total number (n/patient) | 126 (1.23) | 120 (1.15) | 0.14 |
| Mean total length, mm | 16.6 ± 7 | 16.3 ± 5 | 0.35 |
| Mean diameter, mm | 3.25 ± 0.4 | 3.29 ± 0.3 | 0.42 |
| Mean balloon pressure, atm | 13.8 ± 2.8 | 12.5 ± 2.5 | 0.001 |
| Stent implanted | | | |
| Bx velocity (%) | 57 (45.6) | 52 (43.4) | 0.84 |
| ACS multilink (%) | 46 (36.8) | 37 (31.1) | 0.47 |
| AVE (%) | 10 (9.9) | 10 (8.4) | 0.89 |
| Others (%) | 13 (9.9) | 21 (17.1) | 0.19 |
| Post-stent inflations (%) | 52 (49.1) | 40 (38.4) | 0.11 |
| Mean inflations nb (%) | 2.1 ± 1.6 | 2.6 ± 1.1 | 0.01 |
| Slow flow | | | |
| Predilation (%) | 0 | 3 (2.8) | 0.50 |
| Stent (%) | 1 (1.9) | 8 (7.6) | 0.11 |
| Post-stent (%) | 2 (3.8) | 2 (5.0) | 0.8 |
| Total (%) | 3 (2.9) | 13 (12.5) | 0.02 |
| No reflow | | | |
| Predilation (%) | 0 | 4 (3.8) | 0.66 |
| Stent (%) | 2 (1.9) | 2 (1.9) | 0.61 |
| Post-stent (%) | 3 (5.7) | 2 (5.0) | 0.75 |
| Total (%) | 5 (4.9) | 8 (7.6) | 0.56 |
| Distal embolization | | | |
| Predilation (%) | 0 | 5 (4.8) | 0.79 |
| Stent (%) | 3 (2.9) | 2 (1.9) | 0.98 |
| Post-stent (%) | 1 (1.9) | 0 | 0.88 |
| Total (%) | 4 (3.9) | 7 (6.7) | 0.50 |
| Composite angiographic end point | 12 (11.7) | 28 (26.9) | 0.01 |
| Verapamil/adenosine (%) | 24 (23.5) | 33 (31.7) | 0.19 |
| Glycoprotein IIb/IIIa inhibitor (%) | 11 (10.7) | 13 (12.5) | 0.85 |
| Angiographic success (%) | 82 (98.8) | 82 (96.5) | 0.64 |
| Final TIMI flow grade 3 (%) | 97 (95.1) | 97 (93.3) | 0.74 |
| Mean cTFC, frames | 31.5 ± 17 | 35.2 ± 20 | 0.42 |
| No ST-segment resolution (%) | 17 (20.2) | 32 (38.1) | 0.01 |
| ST elevation majoration (%) | 4 (4.7) | 9 (8.6) | 0.14 |
| Peak creatine kinase, U/l | 1,577 ± 2,139 | 1,678 ± 1,393 | 0.49 |

Because of rounding, not all percentages total 100.
CS = conventional stenting implantation; cTFC = corrected TIMI frame count; DS = direct coronary stenting; TIMI = Thrombolysis In Myocardial Infarction.

implantation during primary angioplasty further reduces the six-month event rate and has a major effect on the target vessel revascularization rate (5,6). Compared with the previously reported reocclusion rates that can be as high as 15% after balloon angioplasty for AMI, all stenting trials of primary angioplasty have reported a lower reocclusion rate at six months. So far no trial has established the long-term beneficial influence of coronary stenting on mortality reduction. Even the most recent Primary Angioplasty in MI (PAMI) stent and Stenting in Acute MI (STENTIM)-2 trials suggested a possible (nonsignificant) deleterious effect of stent implantation after conventional balloon angioplasty (5,6). Nevertheless, considering the demonstrated impact of late reocclusion after balloon angioplasty on long-term mortality, one may assume that stents may have a significant impact on long-term survival (19). Therefore, although definite evidence is lacking, there are many arguments in favor of considering stent implantation on a systematic basis. In this setting, the role of direct coronary stenting is unknown and has never been evaluated.

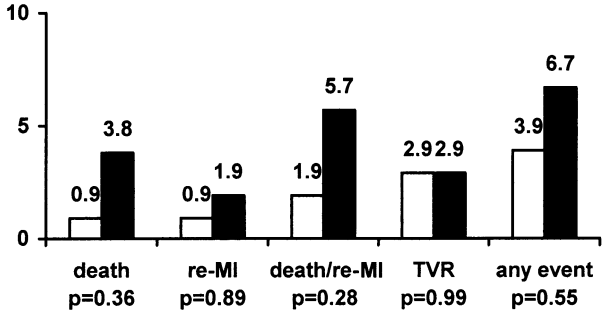


**Figure 2.** In-hospital clinical outcome (numbers indicate percent of events) in both study groups. **Open bar** = direct stent; **solid bar** = conventional. Re-MI = recurrent myocardial infarction; TVR = target-vessel revascularization.

**Direct stenting feasibility in AMI.** Improvement in stent profile flexibility and delivery systems with manufactor-crimped stents permit stent implantation without pre-dilation. Several groups have reported satisfactory results in consecutive series of patients who underwent direct stenting (20–23). Experimental data even suggest that direct stenting may favorably affect the restenosis process and decrease the restenosis rate (24). This study is the first clinical trial to date focusing on the role of direct stenting in AMI and showing that a direct stent strategy is feasible in patients with AMI treated by primary angioplasty. Although patients were selected, no age restriction was applied, and failure of direct stent implantation was observed in <8% of cases, without clinical consequences. In these cases, stent implantation was always successful after pre-dilation. Therefore, direct stenting in AMI seems feasible, without major limitations and safe, as was observed in our consecutive patients admitted for primary angioplasty. The first and direct consequence of this direct stent strategy is the reduction in procedure costs as demonstrated by the dramatic reduction in balloon-catheter use. Several reports have also stressed the reduction in radiation exposure time and procedural duration (22,23).

**Angiographic and clinical impact of direct stenting.** One important finding of this study is that direct stenting facilitates percutaneous revascularization and prevents periprocedural complications compared with conventional stent implantation with pre-dilation. The incidence of slow reflow or no reflow as well as direct visualization of distal embolus as possible angiographic evidence of thrombus and/or atheromatous embolization are all reduced by the direct approach. The composite angiographic end point is significantly reduced compared with the conventional stent strategy, which reflects the impact and preventive effect of direct stenting. The positive impact of direct stenting in reducing the no-reflow phenomenon and in preserving microcirculation was recently suggested in a retrospective and non-randomized comparison of direct stent implantation in AMI (25), and our results definitely confirm these data. However, even if direct stenting does reduce the incidence of no reflow, it must be stressed that this event still occurs in 5% of cases after direct stenting. Additional therapeutic measures are, therefore, necessary. Several mechanisms may explain the preventive effect of direct stenting. First of all, direct implantation allows a reduction in the number of inflations, decreasing the likelihood of thrombus and/or plaque content dislodgment and fragmentation. The absence of pre-dilation before stenting may prevent thrombus fragmentation and further plaque injury before stent insertion, with the stent acting primarily as a scaffold to trap the thrombus and plaque content before any manipulation. The impact of inflation pressure on the incidence of slow/no flow is another issue. Since distal embolization may occur more frequently after high-pressure stent deployment and because a higher deployment pressure was evident in the direct stent group, a negative effect could have been expected. Therefore, we can only speculate that a lower stent deployment pressure would have maximized differences in the two groups.

The final impact on epicardial reperfusion is more limited because only a slight and non-significant difference in the final TIMI flow grade 3 and in the cTFC was demonstrated. However, the very high TIMI flow grade 3 rate that we obtained in the control group only compares to the upper limit of 78% to 98% TIMI flow grade 3 after primary angioplasty or stenting published so far (1–7,26), which makes any further significant improvements in TIMI flow grade hard to achieve. The liberal use of verapamil and adenosine in cases of slow reflow or no-reflow allowed us to achieve a high TIMI 3 grade in both groups, which may have mitigated larger differences in the two study groups. We may also hypothesize that the major impact of a direct stent strategy may not lie in the TIMI flow grade 3, which coronary stent implantation has already achieved with better cTFC compared with primary balloon angioplasty (27), but in the capacity to decrease both macro- and micro-embolization with a final and significant effect at the microvascular level. The sensitivity of the TIMI frame count and TIMI grade may also be too low in this case. In contrast, ECG analysis proved to be of particular value. Analysis of ST-segment changes is a simple and validated technique for assessing myocardial integrity after reperfusion and can be correlated to the evaluation of myocardial perfusion defect (no-reflow) by myocardial contrast echography (28). Our results indicate a 50% absolute reduction in the incidence of persistent ST-segment elevation after direct stenting. These results are clinically relevant and have major implications given that the long-term prognosis of persistent ST-segment elevation after primary PTCA has been clearly demonstrated to be poor by Van't Hof and Claeys (15,29). These ST-segment course abnormalities have been reported by Claeys et al. (15) in 36% of cases after successful primary angioplasty with a 50% cutoff value. Matetzky et al. (30) report the same absence of early ST-segment elevation resolution after angiographically successful primary angioplasty (same cutoff value) in 24% of cases with similar unfavorable outcome (i.e., increased in-hospital and long-term mortality, congestive heart failure and long-term chronic heart failure indicative of microvascular damage and less myocardial salvage). Recently, a sub-analysis from the Hirulog Early Reperfusion Occlusion-1 trial study demonstrated an improved infarct zone wall motion at 48 h in patients with TIMI 2 or 3 infarct-related vessel post-thrombolysis and ST-segment recovery (31). The impact of direct stenting on the resolution of ST-segment elevation that we report suggests an improved microvascular reperfusion status and less myocardial damage with potential clinical implications. Consequently, in our study, the direct stent strategy seems to influence the early outcome favorably as demonstrated by a clear trend toward decreased reinfarction and mortality rates. The small study sample size together with the low event rate after primary angioplasty

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with stenting did not allow us to demonstrate any significant early clinical difference between the two strategies. Although non-significant, the reduction in the combined event rate of reinfarction and death that we observed after direct stenting is in accordance with the observed effect on ST resolution; this reduction can be compared with the clinical benefit demonstrated in the Abciximab Before Direct Angioplasty and Stenting in Myocardial Infarction Regarding Acute and Long-term Follow-up (ADMIRAL) study, a positive study evaluating the role of abciximab before direct angioplasty and stenting (13). Therefore, the results of the study reinforce the role of stents in primary angioplasty as reported in previous randomized stent trials (1–6) and give further insight into the positive impact of a stent-mediated strategy on the outcome of primary angioplasty. Furthermore, they give support to a strategy of routine stenting in AMI, offsetting recent concern about the possible deleterious role of stent—conventional implantation—in AMI. This new strategy, by preventing stent-associated micro-embolization, may have the potential to magnify the benefits of stent as compared with balloon angioplasty for primary angioplasty.

**Study limitations.** One major limitation of the study is the fact that the results were obtained from a single high-volume center involving only half of the patients screened. However, in the event of a selection bias and because most of the exclusion criteria were angiographic (excluding situations where direct stenting may have been necessary), the major impact of direct stenting may have been missed and the power of the study decreased. As a consequence, the results of the study may not be generalized to all patients with AMI. Further trials should address the issue of direct stenting in a larger AMI population, with a randomization process occurring before angiography. Several major issues have yet to be resolved. In particular, it is still not known whether a direct stent approach can be safely applied when the culprit artery remains totally occluded with no flow after wire passage. The latter situation may represent a major challenge for direct stenting in AMI. Recent technological advances may allow the use of specific thrombectomy devices before (direct) stenting; such a strategy could increase the impact of a direct stent strategy focused on the prevention of distal micro-embolization and improve tissue reperfusion. Another limitation of the study is the lack of LV assessment during follow-up. However, the early reduction in clinical events together with the substantial effect on ST-segment recovery suggests a favorable impact of the direct stent strategy. Long-term follow-up is pending, and confirmation is awaited.

Additional trials are warranted in order to test adjunctive therapies such as GP IIb/IIIa inhibitors combined with direct stenting. The TIMI 14 study showed that patients with a patent artery 60 min after abciximab and thrombolytic therapy had a higher frequency of >70% ST-segment resolution at 90 min (32). Conversely, the preliminary results of the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complication (CADILLAC) trial do not underline any benefit in combining abciximab with primary stenting in terms of in-hospital outcome in 1,961 randomized patients (7). However, pharmacologic agents, when given before intervention, may improve the outcome by opening arteries before intervention in a higher proportion of patients amenable to direct stenting (13,33,34).

**Conclusions.** Percutaneous coronary intervention for AMI benefits from the direct use of stents without pre-dilation. Such an approach is safe, feasible and reduces the incidence of no-reflow or distal embolization; moreover, it may favorably influence the outcome of primary angioplasty. A significant effect on early ST-segment elevation resolution after PTCA suggests that direct stenting prevents microvascular damage and may improve myocardial reperfusion.

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