A comparison of direct versus conventional stenting in patients undergoing primary angioplasty for ST-elevation myocardial infarction

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Objective **The aim of our study was to determine the impact of direct stenting (DS) on procedural success and the in-hospital outcome among patients with ST-elevation myocardial infarction (STEMI) treated with a primary percutaneous coronary intervention (PCI).**

Background **With improvements in stent designs, DS has become more widespread. The theoretical advantages of DS include a shorter procedural time, a lower contrast dose, and reduced spiral dissections, along with reduced radiation exposure and procedural costs.**

Methods **A total of 1992 consecutive STEMI patients were reviewed; 621 patients (31.2%) were included in the DS group and 1371 (68.8%) in the conventional stenting (CS) group. The clinical and angiographic characteristics, in-hospital outcomes, and predictors of unsuccessful primary angioplasty were analyzed.**

Results **The incidence of in-hospital major adverse cardiac events (MACE) was 6.1% in the CS group and 4.3% in the DS group. The difference between the two patient groups was not statistically significant for myocardial reinfarction (re-MI), target-vessel revascularization, and MACE. Nonetheless, the rates of in-hospital mortality and advanced heart failure were significantly lower in the DS group. CS [odds ratio (OR) 3.49, 95% confidence interval (CI) 1.65–7.37, $P=0.001$], Killip class 2/3 (OR 2.5, 95% CI 1.2–5.23, $P=0.01$), glomerular filtration rate less than 60 ml/min/1.73 m^2 (OR 2.2, 95% CI 1.22–3.94, $P=0.008$), and anterior MI (OR 1.61, 95% CI 1.01–2.56, $P=0.04$) were found to be independent predictors of unsuccessful procedures.**

Conclusion **DS improves the in-hospital outcomes of STEMI patients treated with primary PCI, particularly by reducing the rates of in-hospital mortality and advanced heart failure. CS was an independent predictor of unsuccessful PCI.** *Coron Artery Dis* **23:348–353 © 2012 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

In a standard coronary intervention, predilatation is required for the stent to pass through the lesion easily and the lesion site to achieve complete expansion. However, a number of subsequent trials showing the negative effects of percutaneous transluminal coronary angioplasty on the microvascular bed and coronary flow and the recent advances in stent technology (lower crossing profiles, greater flexibility, trackability, and pushability) have raised questions about preferring direct stenting (DS) over conventional stenting (CS) [1,2]. The major factor preventing the application of DS in a primary percutaneous coronary intervention (PCI) is the generation of inadequate flow [thrombolysis in myocardial infarction (TIMI) flow grade 1–0] after advancement of the guide through the lesion and the difficulty in adjusting the stent length. Moreover, despite the development of low-profile and more flexible stents, the DS method still fails in bifurcating, calcified, and tortuous lesions, and requires predilatation [2]. Although it is claimed that DS has some disadvantages such as an increase in the in-stent restenosis [3], it has been shown to be as feasible and safe as CS, while having some additional advantages (e.g. decreased radiation exposure, amount of contrast agent, cost, and procedure time) [4,5].

This study aimed to determine the real-world percentage of patients treated by DS, the difference between the DS and the CS groups in the procedural success and the in-hospital outcome, and the factors involved in unsuccessful procedures (in our institution), while testing whether CS is an independent predictor of unsuccessful procedures.

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Methods

Study population

In this study, 2825 consecutive patients with ST-elevation myocardial infarction (STEMI) (who were admitted to the Emergency Department of our institution and underwent emergency cardiac catheterization between October 2003 and March 2008) were evaluated retrospectively. The patients fulfilling the following inclusion criteria were enrolled in the study: (a) presenting within 12 h (18 h for cardiogenic shock) of the onset of symptoms (typical chest pain lasting for >30 min), (b) ST-segment elevation 1 mm or more in at least two contiguous ECG leads or new onset of complete left bundle branch block. In total, 833 patients who had received percutaneous balloon angioplasty ($n = 398$), were scheduled for coronary by-pass or medical therapy ($n = 181$), had failure of guidewire insertion through the occlusive lesion ($n = 110$), presented with cardiogenic shock ($n = 67$), had a saphenous lesion ($n = 13$), or had a history of drug evaluating stent (DES) ($n = 64$) were excluded from the study. Therefore, the final study population consisted of 1992 primary PCI patients. All primary PCI procedures were carried out in the same high-volume (> 3000 PCIs/year) tertiary healthcare center by experienced experts performing more than 75 PCIs/year.

The study protocol was approved by the Local Ethics Committee.

Data analysis

The entire demographic information, cardiovascular history, and risk factors [age, sex, smoking, hypercholesterolemia, hypertension, diabetes mellitus (DM), family history of coronary artery disease and history of MI, PCI, or by-pass] of the patients were obtained from the medical records. Blood values measured upon hospital admission, and daily until discharge, were collected from the medical records. A 12-lead ECG was obtained in each case, just after the hospital admission, to confirm the diagnosis of the MI.

Before discharge, a transthoracic echocardiography was performed using a system V (Vingmed GE, Horten, Norway) with a 2.5 MHz phased-array transducer. Transthoracic echocardiography was performed with patients positioned in the left lateral decubitus position. The left ventricular (LV) ejection fraction was measured using the modified Simpson's rule [6].

Coronary angiography, primary angioplasty, and stenting

All patients received 300 mg chewable aspirin and clopidogrel (300 mg loading dose) before coronary angiography. Angiographic data of the patients were evaluated from catheterization records. Emergency coronary angiography and angioplasty were performed using the percutaneous femoral approach. Heparin (10 000 IU) was administered after securing the arterial access. Once the left and right coronary arteries were visualized, 2.5 mg of nitrate was selectively injected into the infarct-related artery (IRA) to rule out a possible coronary spasm.

Primary angioplasty, including DS or CS, was performed only on the IRA, on the basis of the lesion type. Optimal angiographic success was defined as the achievement of TIMI grade 3 flow and less than 20% stenosis in the IRA at the end of the procedure [7]. After angioplasty, all patients were admitted to the Coronary Care Unit and treated with intravenous heparin (500 U/h) or subcutaneous low molecular weight heparin (1 mg/kg/day). All patients received a combination antiplatelet regimen of aspirin (100 mg) and clopidogrel (75 mg). The use of glycoprotein IIb/IIIa inhibitors was left to the discretion of the physician. Concomitant medical therapy with β-blockers, angiotensin-converting enzyme inhibitors, and statins was started according to the guidelines of the American College of Cardiology/American Heart Association.

Definitions

Time to reperfusion was measured as the duration from the onset of symptoms to the coronary reperfusion obtained with balloon inflation. The door-to-balloon time was defined as the interval between hospital admission and balloon inflation. Patients were also evaluated according to the Killip classification [8]. Cardiogenic shock was defined as prolonged hypotension (systolic blood pressure < 85 mmHg) along with evidence of reduced organ perfusion caused by severe LV dysfunction, right ventricular infarction, or mechanical complications of infarction. Renal failure was defined as a glomerular filtration rate (GFR) less than 60 ml/min/1.73 m^2, which was estimated using the simplified Modification of Diet in Renal Disease equation [9]. Contrast-induced nephropathy was identified as an increase in serum creatinine level at least 0.5 mg/dl or 25% or more from baseline (admission value) within 72 h of administration of radiocontrast [10]. DM was defined as having a documented DM, while using either oral hypoglycemic agents or insulin treatment at the time of admission. Hypercholesterolemia was defined as a total cholesterol level 200 mg/dl or more or the use of cholesterol-lowering agents. Anemia on admission was defined as a baseline hemoglobin concentration less than 13 mg/dl in men and less than 12 mg/dl in women, according to the WHO criteria. Three-vessel disease was defined as the presence of more than 50% stenosis in three major epicardial coronary arteries.

Cardiovascular mortality was identified as unexplained sudden death and mortality associated with acute MI, heart failure, or arrhythmia. Myocardial reinfarction (re-MI) was defined as an increase in creatine kinase (CK) of more than twice the last value associated with CK-MB 10% or more of the total CK and ST-segment re-elevations. Target-vessel revascularization (TVR) was

defined as the presence of a need for PCI or coronary surgery because of restenosis or reocclusion of the IRA. Advanced heart failure was described as a heart failure of at least class III severity on the basis of the New York Heart Association functional classification system. Major adverse cardiac events (MACE) were defined as cardiovascular death, re-MI, and repeat TVR (percutaneous or surgical). Only cardiovascular mortality was recorded.

Statistical analysis

Quantitative variables were expressed as the mean ± SD and qualitative variables were expressed as percentages (%). Comparison of parametric values of two groups was performed using a two-tailed Student's *t*-test. Categorical variables were compared using the likelihood-ratio χ^2-test or Fisher's exact test. Multivariate logistic regression analysis was carried out to identify the independent predictors of unsuccessful procedures. All variables with a significance value less than 0.1 on univariate analysis (Killip class 2/3, CS, GFR < 60 ml/min/1.73 m^2, pre-TIMI grade 0–1, anterior MI, age ≥ 75 years, stent length > 20 mm, hypertension, three-vessel disease, PCI history, DM) were included in the model. *P* value less than 0.05 was considered statistically significant. All statistical analyses were carried out using the SPSS statistical software package (version 15.0; SPSS Inc., Chicago, Illinois, USA).

Results

The patients [1992 patients treated with primary angioplasty (mean age 56.2 ± 11.7 years, 15.6% women and 84.4% men)] were divided into two groups: DS and CS. The DS group included 621 (31.2%) patients and the CS group included 1371 (68.8%) patients. The baseline characteristics and the laboratory findings of the study patients are presented in Tables 1 and 2. The DS and CS groups were similar in terms of cardiovascular risk factors. Killip class 2/3, anterior MI, and long reperfusion duration were more common in the CS group. Moreover, peak CK-MB, admission blood glucose, and white blood count values were higher and hemoglobin levels were lower in the CS group. There was no difference between the groups in the presence of anemia on admission.

The angiographic and procedural characteristics are presented in Table 3. Patients with CS were more likely to have left anterior descending coronary artery lesions, preprocedural grade 0–1 TIMI, stent length 20 mm or more, and increased average stent length. Patients with DS were more likely to have lesions in arteries other than the left anterior descending coronary artery, a successful procedure, and higher postprocedural LV ejection fraction values.

The data on the clinical outcomes are presented in Table 4. The incidence of in-hospital MACE, including death, re-MI, and TVR, was 6.1% (84 patients) in the CS group and 4.3% (27 patients) in the DS group. The difference between the two patient groups was not statistically significant for re-MI, TVR, or MACE. However, the rates of in-hospital mortality and advanced heart failure were significantly lower in the DS group than in the CS group (1.4 vs. 2.9%, $P = 0.05$ and 7.4 vs. 11.5%, $P = 0.004$).

The assessment of independent determinants of unsuccessful procedures was carried out by stepwise multiple logistic regression models. CS [odds ratio (OR) 3.49, 95% confidence interval (CI) 1.65–7.37, $P = 0.001$], Killip class 2/3 (OR 2.5, 95% CI 1.2–5.23, $P = 0.01$), GFR less than 60 ml/min/1.73m^2 (OR 2.2, 95% CI 1.22–3.94, $P = 0.008$), and anterior MI (OR 1.61, 95% CI 1.01–2.56, $P = 0.04$) were found to be the independent predictors of unsuccessful procedures (Table 5).

Table 1 Baseline characteristics of the study patients

Variable	Conventional stenting (*n* = 1371)	Direct stenting (*n* = 621)	*P* value
Age [years (SD)]	56.4±11.9	55.5±11.2	0.14
Age ≥ 75 years [*n* (%)]	112 (8.2)	38 (6.1)	0.10
Female [*n* (%)]	222 (16.2)	89 (14.3)	0.28
DM [*n* (%)]	327 (23.8)	132 (21.2)	0.19
Current smoker [*n* (%)]	862 (62.8)	382 (61.5)	0.59
Hypertension [*n* (%)]	558 (40.7)	231 (37.2)	0.14
Hypercholesterolemia [*n* (%)]	485 (35.3)	243 (39.1)	0.12
PCI history [*n* (%)]	83 (6.1)	26 (4.2)	0.09
By-pass history [*n* (%)]	21 (1.5)	16 (2.6)	0.11
MI history [*n* (%)]	129 (9.4)	56 (9)	0.74
Killip class 2/3 [*n* (%)]	92 (6.7)	10 (1.6)	<0.001
Anterior MI [*n* (%)]	722 (52.7)	239 (38.4)	<0.001
Reperfusion time [h (SD)]	3.36±2.46	2.90±1.99	<0.001
Door-to-balloon time [min (SD)]	33±21	32±18	0.76

Mean values (SD) and % (*n*) are reported for continuous and categorical variables, respectively.
DM, diabetes mellitus; MI, myocardial infarction; PCI, percutaneous coronary intervention.

Table 2 Laboratory findings of the study patients

Variable	Conventional stenting (*n* = 1371)	Direct stenting (*n* = 621)	*P* value
Peak CK-MB [U/l (SD)]	229±174	178±149	<0.001
Creatinine concentration at admission [mg/dl (SD)]	0.97±0.34	0.96±0.46	0.41
Admission GFR < 60 ml/min/1.73 m^2 [*n* (%)]	150 (10.9)	58 (9.3)	0.25
Admission blood glucose [mg/dl (SD)]	155±71	147±69	0.01
Hemoglobin [g/dl (SD)]	13.6±1.6	13.7±1.5	0.05
Anemia at admission [*n* (%)]	343 (25)	140 (22.5)	0.23
Contrast-induced nephropathy [*n* (%)]	350 (25.5)	143 (23)	0.4
Total cholesterol [mg/dl (SD)]	188±41	189±42	0.62
LDL-cholesterol [mg/dl (SD)]	117±35	117±32	0.8
HDL-cholesterol [mg/dl (SD)]	40±9	41±9	0.8
White blood count [10^3/Ul (SD)]	12.7±3.9	11.9±3.5	<0.001

Mean values (SD) and % (*n*) are reported for continuous and categorical variables, respectively.
GFR, glomerular filtration rate; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Table 3 Angiographic and procedural characteristics of the patients

Variable	Conventional stenting ($n=1371$)	Direct stenting ($n=621$)	*P* value
Culprit lesion [*n* (%)]			
LMCA	2 (0.1)	0 (0)	0.8
LAD	725 (52.8)	240 (38.6)	<0.001
CX	153 (11.2)	96 (15.4)	0.007
RCA	488 (35.5)	284 (45.7)	0.001
Intermediate artery	0 (0)	3 (0.41)	0.75
Pre-TIMI grade 0–1 [*n* (%)]	1287 (93.8)	431 (69.4.4)	0.01
Successful procedure [*n* (%)]	1263 (92)	612 (98.5)	<0.001
Stent length, average [mm (SD)]	19.8±6.8	17.5.9±5.4	<0.001
≥ 20 mm [*n* (%)]	489 (35.6)	124 (19.9)	<0.001
Stent diameter, average [mm (SD)]	3.1±0.3	3.1±0.2	0.39
≤ 3 mm [*n* (%)]	915 (6.7)	409 (65.8)	0.68
Three-vessel disease [*n* (%)]	321 (23.4)	149 (23.9)	0.75
Postprocedural LVEF [(%) (SD)]	47±11	51±9	<0.001

Mean values (SD) and % (*n*) are reported for continuous and categorical variables, respectively.
CX, circumflex coronary artery; LAD, left anterior descending coronary artery; LMCA, left main coronary artery; LVEF, left ventricular ejection fraction; RCA, right coronary artery; TIMI, thrombolysis in myocardial infarction.

Table 4 In-hospital cardiac events

In-hospital cardiac events and complications	Conventional stenting ($n=1371$)	Direct stenting ($n=621$)	*P* value
In-hospital mortality [*n* (%)]	40 (2.9)	9 (1.4)	0.05
Reinfarction [*n* (%)]	31 (2.2)	11 (1.7)	0.4
Target-vessel revascularization [*n* (%)]	51 (3.7)	19 (3.1)	0.45
MACE [*n* (%)]	84 (6.1)	27 (4.3)	0.1
Advanced heart failure [*n* (%)]	159 (11.5)	46 (7.4)	0.004

% (*n*) are reported for continuous and categorical variables.
MACE, major adverse cardiac events (cardiovascular death, reinfarction, target-vessel revascularization).

Table 5 Clinical and angiographic predictors of unsuccessful procedure

	Odds ratio	95% confidence interval	*P* value
Univariate predictors			
Killip class 2/3	6.04	3.39–10.76	<0.001
Conventional stenting	5.81	2.92–11.55	<0.001
GFR < 60 ml/min/1.73 m^2	2.61	1.61–4.21	<0.001
Pre-TIMI grade 0–1	2.59	1.19–5.63	0.01
Anterior MI	2.07	1.4–3.06	<0.001
Age ≥ 75 years	2.05	1.18–2.58	0.01
Stent length > 20 mm	1.57	1.07–2.31	0.02
Hypertension	1.56	1.05–2.31	0.02
Three-vessel disease	1.47	0.98–2.21	0.06
Diabetes mellitus	1.44	0.94–2.2	0.08
Independent predictors			
Conventional stenting	3.49	1.65–7.37	0.001
Killip class 2/3	2.5	1.2–5.23	0.01
GFR < 60 ml/min/1.73 m^2	2.2	1.22–3.94	0.008
Anterior MI	1.61	1.01–2.56	0.04

GFR, glomerular filtration rate; MI, myocardial infarction; TIMI, thrombolysis in myocardial infarction.

Discussion

This study showed that DS improves the in-hospital outcomes of STEMI patients treated by primary PCI, particularly by reducing in-hospital mortality and advanced heart failure rates. CS was an independent predictor of unsuccessful PCI.

To our knowledge, this is the largest study comparing the outcomes of DS and CS in patients treated by primary PCI. In this study, the real-world DS implantation rate among the STEMI patients was observed to be 31.2%. The same rate was found to be 43% in the study of Süselbeck *et al.* [11] and 31.2% in the study of Antoniucci *et al.* [12]. Despite the varying rates obtained in different studies, the most important factor favoring CS is the presence of preprocedural grade 0–1 TIMI, which makes it impossible to clearly identify the infarct-related lesion [2]. Similarly, in the current study, the presence of a higher rate of preprocedural grade 0–1 TIMI in the CS group supports this conclusion.

Previous studies have determined the variables that play a role in unsuccessful PCI and the following have been found to be independent predictors for unsuccessful PCI: advanced age, prolonged perfusion time, increased heart rate, angiographic evidence of thrombus, low LV ejection fraction, and GFR [13,14]. In this study, CS, GFR less than 60 ml/min/1.73m^2, anterior MI, and Killip class 2/3 were found to be the independent predictors of unsuccessful primary PCI.

Unsuccessful procedure and impaired coronary flow are known to be strong independent predictors of high mortality [15]. Similar to this study, Cuellas and colleagues [2,16] showed that CS was an independent predictor of an unsuccessful procedure. As in many previous studies, in this study it was found that procedural success was significantly lower in the CS group than in the DS group [2,16,17]. However, there are studies in the literature that show there is no significant difference between the CS and DS groups in procedural success [3]. The different results obtained can be attributed to methodological differences and varying definitions of procedural success. The effects of predilatation on myocardial perfusion are contentious. The higher number of inflations and microvascular injuries generated by CS increases the likelihood of thrombus and/or plaque dislodgement and fragmentation. In short, CS yields significantly lower final grade 3 TIMI flow, TMPG 2/3, and ST-segment resolution [2,12,17]. Moreover, elevated troponin I values, known to be an indicator of poor prognosis after PCI, were significantly more common in the CS group [18,19]. However, studies in the literature have indicated the absence of a statistically significant difference between the groups in terms of the final grade 3 TIMI flow, no-reflow frequency, TMPG 2/3, and ST-segment resolution [3,11,20].

Lesion morphology is a very important factor in PCI success. Patients with renal insufficiency are known to have more complex lesion morphology and a higher level of vascular involvement [21–23]. Therefore, the difference in the severity of atherosclerosis may have resulted in the reduced procedural success rate in this patient group, particularly in patients scheduled for emergency PCI. Investigators of Heart Institute of Japan Acute Myocardial Infarction (HIJAMI) analyzed the impact of GFR on the procedural success of 1706 patients who had received primary PCI, and similar to this study they showed that decreased GFR was associated with a risk of an unsuccessful primary PCI [23].

The anterior region affected in patients presenting with acute MI is a major indicator of myocardial damage and high mortality [24]. However, the pathophysiology of this poor prognosis caused by anterior MI is considerably complex. Similar to this study, Kandzari and colleagues [25,26] showed that the procedural success of primary PCI against anterior MI was low. Kandzari *et al.* [25] reported that anterior MI patients had a lower LV ejection fraction, less frequent collateral flow, and a higher likelihood for Killip class 2 or greater. Reduced anterograde flow and tissue perfusion in anterior MI cases can be attributed to a greater propensity for distal embolization, decreased ventricular contractility, and higher filling pressures [14,27–30]. In patients presenting with anterior MI and a high Killip class, an elevated filling pressure leads to increased capillary resistance and no reflow in tissues [31].

The prognostic value of DS during primary angioplasty is contentious. In this study, the DS group had a higher procedural success rate compared with the CS group, and the in-hospital mortality and advanced heart failure rates were lower in the DS group compared with the CS group. In a meta-analysis of 24 studies and 6803 patients, mortality or MI was significantly reduced in DS patients when compared with the CS patients within a follow-up time of 6 months. This reduction was primarily driven by a lower MI occurrence [32]. Similar to this study, Antoninucci *et al.* [12] reported a significantly lower mortality rate in patients who underwent DS. Ly *et al.* [16] showed that DS was associated with a lower mortality rate, MI, or congestive heart failure during hospitalization and at the 30-day follow-up among patients treated with fibrinolytic therapy. However, Cuellas and colleagues found no significant difference in adverse clinical events during the in-hospital period and at 6-month follow-ups despite improved myocardial perfusion in DS patients. In the study of Süselbeck *et al.* [11], the incidence of in-hospital MACE was 4.1% after DS and 11.5% after CS. This did not show a statistically significant difference as in earlier studies [20,33,34]. Previous studies have not allowed the confirmation of significant clinical differences because of the small study samples and low cardiac event rates in the DS groups despite the presence of a clear trend toward reduced adverse outcomes.

Another remarkable result of this study was the same mean stent diameter found in the CS group and the DS group, and a significantly shorter mean stent length in the DS group than in the CS group. This difference has previously been shown in patients who have received a stent for stable angina pectoris or acute coronary syndrome, and it can be attributed to a possible vessel injury occurring after predilatation of the culprit lesion [11,35].

Study limitations

Several limitations need to be kept in mind when interpreting the results of this study. First, this study has a retrospective design, which *per se* is a well-known limitation. Second, these results represent a single-center experience; however, as data obtained from a high-volume single-center study are considered more reliable than data obtained from low-volume multicenter studies, it should not be considered as a disadvantage in our study. Third, microvascular perfusion, the main target of myocardial reperfusion, was not assessed in this study. Fourth, we could not analyze why the interventional cardiologists chose DS or CS, as it was a retrospective nonrandomized study in which the interventional cardiologist had the sole discretion over the choice of the stenting method. Fifth, we used bare metal stents. The results of this study may not be valid for DES. Moreover, there is a concern for damage to the polymer coating and nonuniform drug elution when using the DS technique. Nonetheless, recent studies have shown the feasibility and effectiveness of DS with DES, which possibly reduces angiographic restenosis and TVR [36,37].

Conclusion

DS is not only a feasible technique but it also improves the in-hospital outcome in STEMI patients treated with primary PCI by reducing in-hospital mortality and advanced heart failure. CS was an independent predictor of unsuccessful PCI.

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The authors are the only responsible bodies for the design and conduct, analyses, drafting and editing, and final contents of the study.

Conflicts of interest

There are no conflicts of interest.

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