Frequency and determinants of direct stenting in routine percutaneous coronary interventions: data on 835 consecutive procedures in a single center

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Percutaneous coronary intervention; Stents.

Background. **Recent studies evaluated the technique of direct coronary stenting as compared to stenting-after-predilation in selected anatomic and clinical settings. However, the impact of direct stenting in routine interventional practice remains poorly elucidated.**

Methods. **From April 1999 to March 2001, all percutaneous coronary interventions performed at our Center were prospectively analyzed to determine the frequency of direct stenting, the success rate and the variables associated with its utilization.**

Results. **1151 lesions were treated in 835 procedures. Stenting was attempted in 835/1151 lesions (72.5%), 309 (37%) with direct stenting and 526 (63%) with stenting-after-predilation. Direct stenting was successful in 300/309 (97%) and stenting-after-predilation in 515/526 (98%). The success rate of direct stenting was significantly lower in small vessels (≤ 2.75 mm) (89.2 vs 98.5%, p = 0.005). Patients treated with direct stenting were younger (63 ± 11 vs 65 ± 11 years, p = 0.024). Direct stenting was preferentially used in saphenous vein grafts and at the ostium of the left anterior descending coronary artery, while it was avoided in bifurcation lesions and with increasing calcium burden. Operators with a caseload > 140 interventions per year were significantly more likely to perform direct stenting than less experienced operators (p = 0.017). In direct stenting, the total contrast medium and the fluoroscopy and procedural times were all significantly (p < 0.0001) lower than those observed in case of stenting-after-predilation.**

Conclusions. **Direct coronary stenting is currently performed in about one third of the overall caseload. Variables pertaining to the operator's experience, lesion morphology and length, vessel size, and the clinical presentation are all important factors determining the selection of candidates suitable for direct stenting.**

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Introduction

In recent years, coronary stent use has grown tremendously. Consistent data collected in several clinical series supporting the benefits of coronary stents in reducing the acute complications and improving the long-term results of percutaneous coronary intervention (PCI) are responsible for this exponential increase[1,2]. At present, the improvement in stent design, structure and technology allow the interventionalist to treat most coronary lesions with a high degree of confidence[3]. Therefore, the strategy of PCI often consists of balloon dilation as a preparation for stenting. The direct coronary stenting (DCS) technique has become popular, as a simplified approach to the treatment of lesions that are deemed suitable for elective stenting[4,5]. Randomized trials have consistently shown that when applied for selected lesions, this technique significantly reduces procedural costs and radiation exposure without increasing the risk[6-10]. However, the applicability of this approach in routine practice is unclear and it is therefore difficult to determine the real impact of DCS in everyday activity. Although some high-volume centers report that over 30% of lesions are suitable for DCS[5] with a success rate exceeding 95%[5,11], centers and operators with lower caseloads may obtain different results. For this reason, we analyzed prospectively collected data on routine PCIs performed at our Center, trying to identify which selection criteria are employed in choosing patients/lesions for DCS, what are the procedural advantages, if any, of this approach, and what is the general impact of DCS on current treatment strategies of patients undergoing percutaneous revascularization.

Methods

Study population. All consecutive interventional procedures performed at our Center between April 1999 and March 2001 were entered in a database in which the variables regarding the DCS technique were pre-defined and included. This population had no exclusion criteria and therefore represents the real world of PCI in our laboratory.

Setting. In the study period our catheterization laboratory had an average caseload of 800-1000 diagnostic procedures and 400-550 interventional procedures per year. Four interventional cardiologists provided full time coverage for emergencies. All revascularization procedures were performed in either elective or urgent situations by an expert interventionalist who was left free to decide whether or not to perform DCS, taking into account the clinical setting, the patient's characteristics, the lesion morphology, and all other clinical variables felt to be relevant for the revascularization strategy. The operator was also free to decode on what type of stent to use, whether or not to post-dilate after deployment, and on the need or otherwise for IIb/IIIa receptor antagonists. A revascularization procedure was defined *ad hoc* when at least one lesion was treated in the same session of diagnostic catheterization. Coronary calcifications were semiquantitatively classified by the operator as: absent, mild, moderate, and severe.

Procedural data. The interventional procedure was carried out according to standard techniques. A femoral or radial approach was used and 6F guiding catheters were routinely employed. A variety of premounted coronary stents available in the cath lab were chosen according to the availability and operator's preference (Fig. 1). Procedural success was defined as successful stent deployment and lesion dilation with a residual stenosis < 50%. DCS failure was defined as the inability to reach or cross the attempted lesion and effectively deliver the stent. Dissections were classified according to the system proposed by the National Heart, Lung, and Blood Institute. Postdilation was performed at the operator's discretion using semicompliant or non-compliant balloons shorter than the stented segment, whenever possible. The total fluoroscopy time, total procedural time, and contrast medium use were recorded in the catheterization laboratory chart. Quantitative angiography as well as intravascular ultrasound were not routinely used for the decision-making process during PCI. The vessel size was assessed by visual estimation. The subgroup of patients treated with small vessel stenting was subsequently identified by means of off-line quantitative angiography, aimed at defining two subgroups with a reference vessel size above or below 3 mm; in these patients, given a stent-to-vessel ratio of 1.1-to-1.0 for the whole series, stents of a nominal diameter ≤ 2.75 mm were implanted. Moreover, in order to assess the potential role of the operator's experience in performing DCS, operators were divided into those performing > 140 PCIs per year vs those performing < 140 PCIs per year[12].

Statistical analysis. Data are presented as mean ± SD for continuous variables and as frequencies for categorical variables. The comparison of data between groups was performed using the two-tailed unpaired Student's t-test or χ^2 statistics with Fisher's correction as appropriate. Multivariate logistic regression analysis was performed in order to identify independent predictors of DCS in the studied population. A p value of < 0.05 was considered statistically significant. All data were analyzed using the SPSS statistical software package (version 10.0).

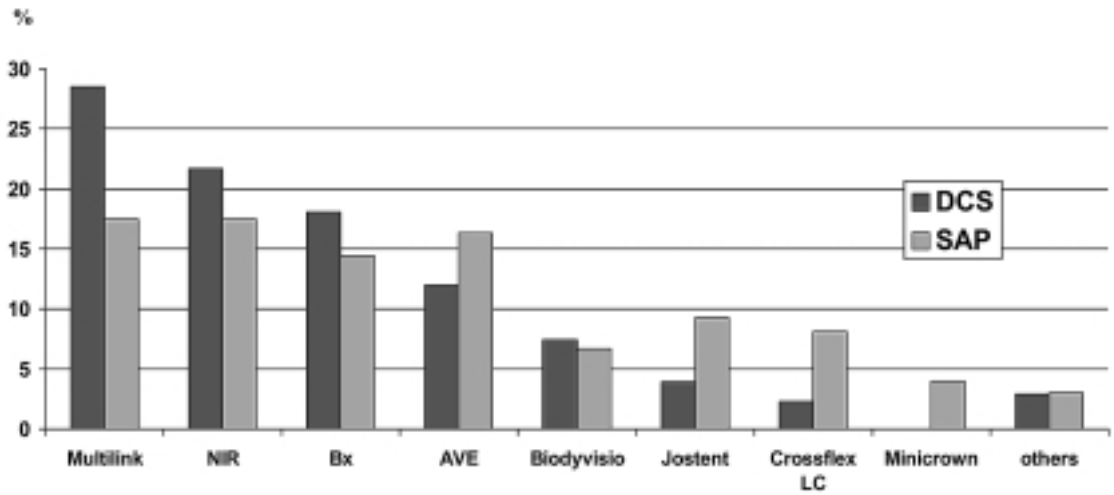

Figure 1. *Distribution of the different types of stents in the two groups. DCS = direct coronary stenting; SAP = stenting-after-predilation.*

Results

Figure 2 illustrates the treatment strategies in the study population. In the examined period, 1151 lesions were attempted in 835 consecutive PCI procedures. The patient population consisted of 77% males, with a mean age of 64 ± 11 years. The mean left ventricular ejection fraction was 57 ± 14%. A previous myocardial infarction was present in 35% and previous bypass surgery in 8%. A multivessel procedure was performed in 13% of patients, with a mean of 1.38 treated lesions per procedure. A total occlusion (TIMI flow 0-1), either acute or chronic, was present in 26% of cases and 10% of lesions were restenotic. About one half of interventions were performed in the same session of diagnostic catheterization (*ad hoc* procedures). Stenting was planned electively in 835 lesions. DCS was attempted in 309 lesions (37%) while stenting-after-predilation (SAP) was attempted in 526 lesions (63%); the success rate was 97% in DCS (300/309) and 98% in SAP (515/526). DCS failures were due to inability to reach (3 cases) or cross (6 cases) the lesion. All failures of DCS were successfully converted to SAP. In neither group did stent loss or embolization occur.

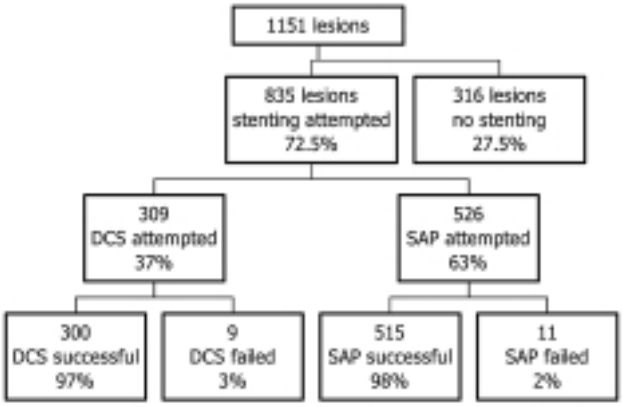

Figure 2. *Flow chart of the treatment and success rate in the treated lesions. DCS = direct coronary stenting; SAP = stenting-after-predilation.*

The clinical, angiographic and procedural data of the DCS and SAP groups are compared in tables I to III. DCS was preferred for unstable patients (48 vs 36%, p = 0.033) of a younger age (63 ± 11 vs 65 ± 11 years, p = 0.024). Lesion selection was in favor of DCS when located in the body of saphenous vein grafts (71 vs 29%, p < 0.0001) and at the ostium of the left anterior descending coronary artery (60 vs 40%, p = 0.055), while it was against DCS in acute myocardial infarction (12.3 vs 22.4%, p = 0.002), in bifurcation lesions (18 vs 82%, p = 0.027), in total occlusions (1.6 vs 28%, p < 0.0001) and in lesions located in the left circumflex coronary artery (14 vs 28%, p < 0.0001). Operators with a caseload > 140 PCIs per year were significantly more likely to perform DCS compared to SAP procedures (84 vs 75%, p = 0.007). DCS was associated with a lower frequency of dissection (3.2 vs 12.7%, p < 0.0001) and with a trend toward a higher frequency of postdilation (26 vs 20%, p = 0.061). The fluoroscopy time, procedural time and volume of contrast medium were all significantly lower in DCS than in SAP (Table IV).

At multivariate analysis, the severity of stenosis – after exclusion of total occlusions (odds ratio 0.92, 95% confidence interval 0.90-0.95, p < 0.0001), presence of calcium (odds ratio 0.31, 95% confidence interval 0.20-0.48, p < 0.0001) and a nominal stent size < 3 mm (odds ratio 0.13, 95% confidence interval 0.024-0.72, p = 0.019) were all independent negative predictors of DCS, while a lesion location in the body of a saphenous vein graft was a positive independent predictor of DCS (odds ratio 3.5, 95% confidence interval 1.06-11.58, p = 0.039).

Small vessel stenting. Coronary stents of a nominal size ≤ 2.75 mm were used to treat 162 lesions (21%), while larger vessels received a stent in 661 lesions (79%). DCS was attempted in 37 of such lesions (12% of all DCS) vs 272 in larger vessels (88% of DCS). Thus, DCS represented 41% of all stenting procedures in larger vessels (272/661) as opposed to only 22% of all stenting procedures in small vessels (37/162, p < 0.0001). The failure rate of DCS was significantly

Table I. Demographic and clinical characteristics of the study population.

	All patients (n=705)	DCS (n=260)	SAP (n=445)	p
Age	64 ± 11	63 ± 11	65 ± 11	0.024
Ejection fraction	57 ± 14	58 ± 14	56 ± 14	NS
Acute myocardial infarction	130 (18.4%)	30 (11.5%)	100 (22.4%)	< 0.0001
Unstable angina	277 (39.3%)	116 (44.6%)	161 (36.2%)	0.033
Stable angina	151 (21.4%)	52 (20%)	99 (22.2%)	NS
Previous myocardial infarction	82 (11.6%)	36 (13.8%)	46 (10.3%)	NS
Silent ischemia	59 (8%)	25 (9.6%)	34 (7.6%)	NS
Other	6 (0.9%)	1 (0.4%)	5 (1.1%)	NS
Ad hoc procedures	350 (51%)	116 (48%)	234 (52%)	NS

DCS = direct coronary stenting; SAP = stenting-after-predilation.

Table II. Angiographic characteristics of the treated lesions.

	All lesions (n=835)	DCS (n=309)	SAP (n=526)	p
Vessel location				
Left anterior descending artery	348 (41.7%)	137 (44.3%)	211 (40.1%)	NS
Left circumflex artery	189 (22.6%)	44 (14.2%)	145 (27.6%)	< 0.0001
Right coronary artery	264 (31.6%)	106 (34.3%)	158 (30%)	NS
Saphenous vein graft	32 (3.8%)	21 (6.8%)	11 (2.1%)	0.001
Left main stem	2 (0.3%)	1 (0.3%)	1 (0.2%)	NS
Anatomic subgroups				
Body of saphenous vein graft	28 (3.4%)	20 (6.5%)	8 (1.5%)	< 0.0001
Bifurcation lesion	34 (4.1%)	6 (1.9%)	28 (5.3%)	0.027
Ostial lesion of the left anterior descending artery	20 (2.4%)	12 (4%)	8 (1.5%)	0.055
Total occlusion	152 (18.2%)	5 (1.6%)	147 (28%)	< 0.0001
AHA/ACC classification				
Type A	95 (11.4%)	61 (20%)	34 (6.5%)	
B1	355 (42.5%)	178 (58%)	177 (33.7%)	< 0.0001
B2	214 (25.6%)	54 (17%)	160 (30.4%)	
C	171 (20.5%)	16 (5%)	155 (29.5%)	
Calcifications				
None	506 (60.6%)	232 (75%)	274 (52%)	
Mild	247 (29.6%)	68 (22%)	179 (34%)	< 0.0001
Moderate	55 (6.7%)	9 (3%)	46 (9%)	
Severe	27 (6.7%)	0	27 (5%)	

DCS = direct coronary stenting; SAP = stenting-after-predilation.

Table III. Procedural characteristics in the two groups.

	All lesions (n=835)	DCS (n=309)	SAP (n=526)	p
Stent size	3.2 ± 0.4	3.3 ± 0.4	3.1 ± 0.4	< 0.0001
Stent length	15.0 ± 5.5	14.4 ± 4.9	15.6 ± 5.8	0.002
Inflation pressure	12.9 ± 2.1	13.3 ± 2.1	12.6 ± 2.1	< 0.0001
Dissection	77 (9.2%)	10 (3.2%)	67 (12.7%)	< 0.0001
Postdilation	188 (22.5%)	81 (26.2%)	107 (20.3%)	0.061
IIb/IIIa use	201 (29%)	65 (27%)	136 (30.5%)	NS

DCS = direct coronary stenting; SAP = stenting-after-predilation.

Table IV. Comparison of procedural data.

	All procedures (n=690)	DCS (n=244)	SAP (n=446)	p
Fluoroscopy time (min)	16 ± 10	11 ± 6	19 ± 9	< 0.0001
Total procedural time (min)	69 ± 32	54 ± 26	77 ± 29	< 0.0001
Volume of contrast medium (ml)	255 ± 109	207 ± 78	293 ± 117	< 0.0001

DCS = direct coronary stenting; SAP = stenting-after-predilation.

higher in this subgroup (10.8 vs 1.5%, p = 0.005). In small vessels, shorter stents were implanted (12.5 ± 2.2 vs 14.4 ± 4.9 mm, p = 0.021), but the inflation pressure was similar to that used in larger vessels (13.1 ± 1.7 vs 13.3 ± 2.1 atm, p = NS).

Comparison with current practice. In order to put all these data in perspective, we analyzed our cath lab activity over the first 2 months of this year, so that the changes in the practice of DCS as a consequence of the continuous improvement in materials and new technologies could be appreciated. In this period, 128 PCIs were performed and 144 stents were implanted. These data correspond to an 80% increase in the laboratory caseload per year compared to the study period. Drug-eluting stents represented 31% of the total, cobalt-chro-

mium stents 25%, and conventional bare metal stents 44%. The proportion of *ad hoc* procedures increased to 75%. DCS was performed in 46% (+9%) of all elective stenting, with a proportion of 55% (+18%) for both bare metal stents and cobalt-chromium stents, and 24% (-13%) for drug-eluting stents.

Discussion

Most available data on DCS were collected in studies where this approach was compared to SAP in selected coronary lesions[8,13,14]. In these studies, it has been demonstrated that DCS has a high success rate, reduces costs and radiation exposure, and does not adversely affect the main clinical outcome measures. However, the authors of these studies do not report what percentage of their routine patients were eligible for DCS. Therefore, the applicability of DCS in routine cases is hard to assess. Current experience suggests that complex lesions in complex patients are increasingly requiring percutaneous revascularization. Thus, the setting of a randomized study may fail to appreciate the real impact of DCS in routine practice. The aim of our study was 2-fold: 1) to define the feasibility of DCS in unselected, consecutive patients presenting with any type of coronary syndrome; 2) to identify the clinical and angiographic variables associated with DCS.

In our population, 37% of all stented lesions (309 out of 835) were approached with a DCS technique. A large series from the Mayo Clinic reports a 20% use of DCS (777 out of 3953 stenting procedures), but refers to a period (1995-1999) in which the stent design was less adequate for DCS[15]. In the original report by Briguori et al.[5], 32% of patients were retrospectively considered eligible for DCS while only 21% were actually treated with this technique, suggesting that variables pertaining to the operator's confidence significantly impact on its utilization. Other authors report a much higher frequency of DCS, reaching 43% of all stented lesions[11]. As compared to the series presented by Herz et al.[11], however, our procedures were performed in older patients (mean age 63 vs 60 yeras) with a higher prevalence of acute myocardial infarction (12.3 vs 5%). Both these conditions were associated with the need for predilation.

DCS has been studied in different clinical settings, including stable angina pectoris[14], acute coronary syndromes[16,17], and acute myocardial infarction[18,19]. In unstable coronary syndromes, culprit lesions often have a significant amount of thrombus, are soft and friable and tend to embolize[20]. In these situations, a potential role of DCS might consist in less trauma to the lesion to be treated[6,15]. Previous observations report that DCS induces less arterial denudation than SAP[21]. It has been hypothesized that this approach may reduce the incidence of the no-reflow phenomenon, which has been consistently associated with deleterious consequences in terms of tissue perfusion, myocardial salvage and ventricular function[22]. Moreover, DCS has been demonstrated to have a favorable effect on plaque redistribution and axial stent centering in a study with intravascular ultrasound[23]. In addition, our data also suggest that DCS is associated with a lower frequency of coronary dissection. Taken together, all these findings support the concept that DCS may represent a less traumatic approach to the lesion to be treated than SAP. In our series, we observed a high frequency of DCS in unstable angina and a significant preference in favor of this procedure for lesions located in the body of saphenous vein grafts, where a similar thrombogenic medium and embolic risk are present. In acute myocardial infarction, however, the DCS technique is less likely to be feasible, due to poor distal vessel visualization before intervention. We were able to perform DCS in 23% of acute myocardial infarction patients, a proportion that roughly corresponds to the 26% reported by previous authors in observational studies[19]. A possible future development of DCS in acute myocardial infarction may occur in the setting of facilitated PCI[24], where a patent infarct-related vessel prior to PCI seems to predispose to a more favorable procedural result.

A combination of less risk of dissection and increased stability of the stent to facilitate positioning represent the reason for the prevalence of DCS in the proximal left anterior descending coronary artery.

Direct coronary stenting and small vessel stenting. In our series, one of the most relevant independent predictors of DCS was the use of stents ≥ 3.0 mm in diameter. Our study confirms that: 1) stenting is less often considered as an elective treatment for small vessels; 2) DCS is performed less often in small vessels; 3) DCS in small vessels has a significantly higher failure rate compared to larger vessels. The reasons for this are mainly related to anatomic factors (more distal location and tortuosity) which render DCS more complicated in small vessels.

Direct coronary stenting and procedural data. The total fluoroscopy time and contrast medium use were much higher in our series compared to those of randomized trials on DCS[6-8], reflecting the more complex case mix, the treatment of multiple lesions, and the burden of diagnostic catheterization, performed in the same session in 51% of procedures. Despite all these confounding factors, the fluoroscopy time and contrast medium use remain significantly lower in DCS, suggesting that the DCS technique provides a beneficial effect throughout the spectrum of procedures.

Current perspectives. The study population refers to the period 1999-2001. Since then, major advances in stent technology have occurred, thanks to the development of drug-eluting and cobalt-chromium stents. The low strut thickness and extreme flexibility of cobalt-

chromium stents favors a strategy of DCS; on the other hand, the current recommendations are to implant drug-eluting stents only after predilation. Thus, the net effect of these new technologies on DCS may vary according to the relative proportion of each type of stent in the cath lab armamentarium. We observed a 9% increase in DCS in our laboratory compared to 3 years before, which reaches 18% if we exclude drug-eluting stents. This updated analysis confirms the increasing feasibility of DCS in current practice.

Study limitations. The data collected in our center reflect the policy and attitude of each individual operator and the selection criteria; therefore, the DCS success rate appears to be very high. These data may not be applicable to different settings, especially if more challenging lesions are attempted. Regular follow-up data are not available for the whole series. Current evidence does not suggest better outcomes for DCS compared to SAP. It is unlikely that in an unselected population including patients with acute myocardial infarction such as the one presented here, potential differences in outcomes secondary to a strategy of DCS may be appreciated.

Conclusions. DCS may safely and effectively be performed in about 30 to 40% of unselected PCI procedures. Variables relative to the lesion (such as the presence of calcium, the size, and the severity of stenosis), the patient (unstable coronary syndromes and younger age), and the operator (high caseload) contribute to determine the use of DCS in routine practice. This approach is associated with a significant reduction in X-ray exposure and dye consumption evident across the whole spectrum of procedures.

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