Percutaneous Handling of Coronary Lesions >20mm Through Stents. Is There a First Choice Strategy?

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Objective – *This study compared the early and late results of the use of one single stent with those of the use of multiple stents in patients with lesions longer than 20mm.*

Methods – *Prospective assessment of patients electively treated with stents, with optimal stent deployment and followed-up for more than 3 months. From February '94 to January '98, 215 patients with lesions >20mm were treated. These patients were divided into 2 groups as follows: Group A - 105 patients (49%) with one stent implanted; Group B - 110 patients (51%) with multiple stents implanted.*

Results – *The mean length of the lesions was 26mm in group A (21-48mm) versus 29mm in group B (21–52mm) (p=0.01). Major complications occurred in one patient (0.9%) in group A (subacute thrombosis, myocardial infarction and death) and in 2 patients (1.8%) in group B (one emergency surgery and one myocardial infarction) (p=NS). The results of the late follow-up period (>6 months) were similar for both groups (group A = 82% vs group B = 76%; p=NS), and we observed an event-free survival in 89% of the patients in group A and in 91% of the patients in group B (p=NS). Angina (group A = 11% vs group B = 7%) and lesion revascularization (group A = 5% vs group B = 6%; p=NS) also occurred in a similar percentage. No infarction or death was observed in the late follow-up period; restenosis was identified in 33% and 29% of the patients in groups A and B, respectively (p=NS).*

Conclusion – *The results obtained using one stent and using multiple stents were similar; the greater cost-effectiveness of one stent implantation, however, seems to make this strategy the first choice.*

Until the appearance of coronary stenting, percutaneous treatment of lesions longer than 20 mm (considered type C, according to the American Task Forces of 1988 and 1993) was a challenge. Dilation with a balloon had some early (procedural successes and in-hospital complications) and late (coronary events and restenoses) results markedly inferior to those usually observed with focal stenosis, while rotational atherectomy and the laser, even though having better in-hospital results as compared with the balloon, showed clear weaknesses because of the high incidence of restenosis [1-4].

Since the mid '90s, especially after the introduction of a new generation of stents, the percutaneous treatment of this type of lesion has become routinely indicated, because the in-hospital and late results are very similar to those found in treatment of focal lesions [4,5]. In these stenoses, however, it has not yet been clearly demonstrated if the strategy of choice should be the implantation of one single long stent or of multiple stents. This study aimed to assess this question in detail.

Methods

We evaluated 215 patients electively and consecutively treated using the technique of optimal stent deployment, corresponding to the total number of patients with lesions >20mm treated with stent placement from February '94 to January '98 (13% of the 1,653 patients treated during this period of time). The cases were prospectively included in a database. Some patients were excluded from the analysis as follows: those treated in a nonelective manner, stent implantations performed through the original technique (which required oral anticoagulation for 30 days), and the lesions between 11 and 19 mm handled during this period of time. The patients were divided into 2 groups: group A – 105 patients (49%) treated with one single long stent; and group B – 110 patients (51%) treated with multiple stents.

The main definitions employed were the following: a)

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procedural success: residual lesion <50% without major complications during the in-hospital phase; b) restenosis: lesion >50% in a previously treated site assessed through objective quantification in an angiographic study perfor–med in the late follow-up; c) event-free survival (EFS): ab–sence of angina recidivation, of acute myocardial infarction, of target lesion revascularization and of death due to a car–diovascular cause in the late phase; d) acute Q wave myo–cardial infarction: elevation of CKMB higher than twice the normal value associated with the presence of new patholo–gical Q waves in the conventional electrocardiogram; e) stent implantation with optimal stent deployment: use of high pressures (>12 atm) for stent deployment, with a resi–dual lesion smaller than 10% at the end, TIMI 3 coronary flow, and absence of coronary thrombi or of dissections not covered by the stent, making possible the use of an an–tithrombotic scheme constituted only by platelet antiaggre–gating agents.

Patients were admitted to the hospital one day before the procedure or on the day of the procedure. The pharma–cological protocol employed recommended the use of aspi–rin (200mg/day) associated with ticlopidine (500mg/day), both initiated at least 24 hours before stent implantation. In addition, all patients received a coronary vasodilating drug, usually diltiazem, at the dosage of 180mg/day.

After hospital discharge, 24 hours to 48 hours follo–wing stent implantation, ticlopidine was continued for 30 days and aspirin for an indefinite time. The pharmacological protocol did not foresee the need for routine heparinization due to stent implantation. Abciximab was not routinely em–ployed, being reserved for more complex angiographic si–tuations, such as the presence of extensive intracoronary thrombi and degenerated saphenous bypasses.

All angiographic assessments were quantitatively performed through digital angiography or the CMS system. The length of the stent to be implanted was estimated according to the objective evaluation prior to the procedu–re, aiming to entirely cover the target lesion.

Late clinical follow-up was performed through clinical appointments, telephone and mailing contacts. Since the treated patients did not belong to any specific study protocol, a late angiographic study was not routinely recommended.

For statistical analysis, the Student t test was used for continuous variables, and the chi-square test was used for discontinuous variables. Values of $p<0.05$ were considered statistically significant.

Results

Table I shows the various clinical characteristics of the population evaluated. No significant differences occurred in the population assessed.

In regard to angiographic characteristics, a significan–tly higher number of interventions in venous grafts occurred in group B than in group A (22% versus 9%; p=0.01). The length of the lesions was also slightly but significantly hi–gher in group B than in group A (29.3 mm versus 26.1 mm;

Table I – Clinical characteristics of the 2 groups evaluated			
	One stent	Multiple stents	P
Male gender	77%	80%	NS
Female gender	23%	20%	NS
Age (years)	59.0	58.7	NS
Age >70	17%	14%	NS
Systemic hypertension	61%	61%	NS
Diabetes mellitus	25%	16%	NS
Dyslipidemia	20%	22%	NS
Smoking	61%	61%	NS
Previous infarction	19%	26%	NS

p=0.01). Treatment of proximal lesions (group A = 80% versus group B = 75%; p=NS), of restenotic lesions (group A = 4% versus group B = 5%; p=NS) and the diameter of reference (group A = 3.3 mm versus group B = 3.4 mm; p=NS) did not show any difference. Left ventricular function was also similar; we observed a global ejection fraction higher than 45% in 92% of the patients in group A and in 88% of the patients in group B (p=NS).

In regard to clinical findings, acute coronary syndro–mes (unstable angina and the in-hospital phase of acute myocardial infarction) predominated in both groups A and B, with no significant difference between the groups (group A = 57% versus group B = 65%; p=NS).

In group A (105 patients, 105 stents), the most fre–quently used stents were the following: AVE (lengths of 24, 30 and 39mm) in 38% of the patients; Multilink (lengths of 25 and 35 mm) in 28% of the patients; NIR (lengths of 25 and 32mm) in 15% of the patients; and Palmaz-Schatz Crown (lengths of 22 and 30mm) in 10% of the patients. In the remaining 9% of the patients, other types of stents were em–ployed. In group B (110 patients, 241 stents), the average of stents per patient was 2.2; most of the patients were treated through the implantation of 2 stents (78%), while 3 stents were placed in 17% of the patients and, in the remaining 5%, 4 or more intracoronary stents were used.

Stent implantation was successful in 100% of the pati–ents in group A and in 98% of the patients in group B (p=NS); procedural success occurred in 99% of the patients in group A and in 97% of the patients in group B (p=NS). All patients with procedural success also fulfilled the criteria for optimal stent deployment. In group A, only one patient (0.9%) had subacute thrombosis on the 4th day of implanta–tion, due to the incorrect use of the pharmacological proto–col, resulting in acute myocardial infarction and death. In group B, major complications occurred in 2 patients (1.8%): one patient had an acute myocardial infarction and another an emergency surgery.

In the late phase (table II), all patients with procedural success (104 patients in group A and 108 patients in group B) were assessed. The great majority was followed up for more than 6 months (group A = 82% versus group B = 76%; p=NS). Therefore, in an average follow-up of 9.5 months for group A and 11 months for group B (minimum of 3 months and maximum of 36 months), indices for angina recidivation (group A = 11% versus group B = 7%) and for revasculariza–

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Table II – Late outcome of patients successfully treated in the 2 groups

	One stent (N=104)	Multiple stents (N=108)	P
Time >6months	82%	76%	NS
Angina	11%	7%	NS
Silent ischemia	2%	3%	NS
Acute myocardial infarction	-	-	NS
PTCA/surgery *	5%	6%	NS
Death	-	-	NS

PTCA- percutaneous transluminal coronary angioplasty; * target lesion.

tion of the target lesion (group A = 5% versus group B = 6%) were low and similar for both groups. No acute myocardial infarction or late deaths occurred. No major coronary events occurred in 89% of the patients in group A or in 91% of the patients in group B (p=NS).

Late angiographic reevaluation was carried out in 40% of the patients in group A and in 48% of the patients in group B (p=NS), with a similar mean time interval (group A = 7 months versus group B = 8 months; p=NS). Angiographic restenosis indices were 33% and 29% (p=NS) for groups A and B, respectively.

Discussion

This study shows that in patients with lesions >20mm, implantation of one single long coronary stent had immediate and late results equivalent to those obtained with multiple stents. Therefore, procedural success, incidence of major complications in the in-hospital phase, subacute thrombosis, and restenosis and revascularization of the target lesion are not influenced by the strategy adopted.

These conclusions, if confirmed in future more comprehensive and possibly randomized studies, may represent 2 major advantages as follows: 1) higher accessibility to the method because of the clear reduction in hospital costs with equal effectiveness; 2) higher speed in revascularization because of the simplification of the procedure, resulting in a smaller time of X-ray exposure, which is beneficial for the patient and for the interventional cardiologist.

In the era prior to stent implantation, the mere presence of a lesion >20mm significantly reduced procedural success, while increasing the chance of major complications [1-5]. In addition, in successfully treated patients, the incidence of restenosis was high [4,6]. Due to this evidence, several patients with similar lesions were referred for surgical revascularization, especially if they had other unfavorable clinical (diabetes mellitus) and angiographic (significant calcification, stenoses in bifurcations) findings.

According to the literature, the usual management of stenoses >20mm is the implantation of multiple stents [7-13]. Results of some investigations reveal early and late results very similar to those observed in lesions of shorter lengths [7,8]. Recently, Kornowski et al [7], evaluating 117 patients treated with 3 or more stents (48% with lesions >20mm), as compared with 1,673 patients in whom one or 2 stents were implanted, repor-

ted similar indices of procedural success (97%), of Q wave infarction (0.9%), and of emergency surgery (3 stents = 1.7% versus 1 or 2 stents = 1.1%; p=NS). Only the incidence of non-Q wave infarctions was significantly higher in the group with long lesions (23% versus 13%; p=0.005). Late coronary events were also not influenced by the length of the target lesion, with an incidence of 25% for both groups [7]. The same happened with revascularization of the target lesion, equally similar (3 stents = 14% versus 1 or 2 stents = 13%). Management of very long lesions using multiple stents, as in this study, did not prove to be a predictor of late coronary events or of revascularization of the target lesion (the only angiographic predictor identified as of worse prognosis was the reduced vascular diameter of reference) [7].

Other smaller studies report an equal tendency in regard to procedural success, even though late restenosis was significantly higher [9-13]. Among these studies, that of Kobayashi et al [11] deserves special attention. In that study, 3 different lengths of segments treated with stents (<20mm, between 20 and 35mm, and >35mm) were evaluated. Only the extremely long lesions, i.e., those >35mm, significantly correlated with a lower procedural success and a higher incidence of late restenosis [11].

Reports on the placement of one single long stent are scarce. The only reference is that of the group led by Antonio Colombo, in which 185 patients (266 lesions) with stenoses >20mm were treated [11]. Even though these authors did not detail their in-hospital results, they observed that failure in stent deployment occurred in 9% of the patients, a much higher percentage than that observed in our series (no patient) [14]. The incidence of restenosis was 48%, with 75% of the lesions restudied, and also a higher index than that of the present study (restenosis of 33%, restudy of 40% of the patients) [14].

We should emphasize that the technique employed in this study aimed to entirely cover the segment impaired by the target lesion. Currently, this strategy is not unanimously accepted. For stenosis comprising excessively long segments, some groups have recommended that the coverage of the stent should be restricted to the most severely impaired portion of the vessel (spot-stenting). Future investigations will certainly clarify which of these 2 alternatives is the most adequate.

In regard to limitations, this study seems to present 2 main weaknesses as follows: 1) despite being prospective, the analysis was not randomized, which might have caused the discrepancies observed between the 2 groups in regard to some clinical and angiographic findings that might have interfered with the results observed; 2) the percentage of late angiographic reexamination was below 80%, preventing a more precise evaluation of coronary restenosis.

Finally, lesions >20mm may clearly be adequately managed through stent implantation in a large number of patients. In regard to the ideal strategy of revascularization for cases where the therapeutical choice is the percutaneous management through the use of coronary stents, the greater cost-effectiveness of the implantation of one single long stent, if this is actually confirmed, will possibly become the first choice option.

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