Influence of Balloon Pressure Inflation in Patients Undergoing Primary Coronary Stent Implantation during Acute Myocardial Infarction. A Quantitative Coronary Angiography Analysis

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Objective - *To verify the influence of moderate- or high-pressure balloon inflation during primary coronary stent implantation for acute myocardial infarction.*

Methods - *After successful coronary stent implantation, 82 patients were divided into 2 groups according to the last balloon inflation pressure: group 1 (³12 to <16 atm) and group 2 (³16 to 20 atm), each with 41 cases. All patients underwent late coronary angiography.*

Results - *In group 1, the mean stent deployment pressure was 13.58±0.92 atm, and in the group 2 it was 18.15±1.66 atm. Stents implanted with moderate pressures (≥12 to <16 atm) had a significantly smaller post-procedural minimal lumen diameter, compared to with those with higher pressure, with lesser acute gain (2.7± 0.4 mm vs 2.9±04 mm; p=0.004), but the late lumen loss (0,9±0,8 mm vs 0,9±0,6 mm) and the restenosis (22% vs. 17.1%) and target-vessel revascularization rates (9.8% vs 7.3%) were similar between the groups.*

Conclusion - *During AMI stenting, the use of high pressures (≥16 atm) did not cause a measurable improvement in late outcome, either in the late loss, its index, and the net gain, or in clinical and angiographic restenosis rates.*

Key-words: acute myocardial infarction, stents, restenosis

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Many clinical, angiographical, and procedural variables are related to the occurrence of in-stent restenosis. Among them, there is the influence of balloon pressure inflation, especially when high pressures were used (≥16 atm) [1-6]. High-pressure balloon inflations (>12 atm) are necessary to promote optimal stent implantation, but they can cause excessive tissue growth repair, with consequent higher rates of restenosis and new target-vessel revascularization [7-11]. Animal studies have already demonstrated the occurrence of this phenomenon, and this was also observed in clinical investigations with intravascular ultrasound monitoring [9,12-14].

In primary percutaneous coronary intervention, during acute myocardial infarction (AMI), the use of high-pressure balloon inflations (≥16 atm) has been recommended [15-17]. However, in the Stent Primary Angioplasty in Myocardial Infarction (PAMI) trial, this routine was one the reasons used to justify the degradation of epicardial coronary flow [15,17,18]. Otherwise, in the same trial, the authors demonstrated that primary coronary stent implantation with low-pressure inflation (<11 atm) was an unsafe strategy, resulting in higher death rates [19].

Comparative studies between different ranges of balloon-pressure inflations used for coronary stenting, are sparse, without homogenous data, and with controversial results, and are rare regarding AMI patients [20-26].

The objective of this analysis was to verify whether moderate pressure inflations (12 to 15 atm) promote similar acute lumen gain to that in high-pressure (16 to 20 atm), without significant modification in the clinical and angiographic restenosis rates.

Methods

The patients were included in a consecutive and prospective way (07/1998 to 01/2001). The inclusion criteria

were the diagnosis of acute myocardial infarction (≤12 hours of chest pain with ST segment elevation ≥1mm in contiguous EKG leads), with primary (without previous fibrinolytic therapy) coronary stent implantation, in patients of both sexes, with ages ranging from 18 to 80 years old. Patients were excluded if they were pregnant, had renal failure (creatinine ≥2.0 mg/dL), or a previous history of neutropenia, thrombocytopenia, hepatic failure, percutaneous coronary intervention (<30 days), a culprit vessel with a reference diameter less than <2.5 mm or target-lesion length greater than 35 mm (with more than 2 stents). Patients were also excluded if they had a coil or a self-expanding stent. All patients or their legal representative read and signed the inform consent of the study.

In table I, we describe the adjunctive pharmacology regimen. Abciximab was administered only in the catheterization laboratory according to the following criteria: persistent TIMI-2 flow in the culprit vessel or a great amount of intracoronary thrombus after balloon predilation or procedures performed in high-risk patients (Killip class IV).

The coronary angiography used the Judkins technique, with catheter size ranging from 6 to 8 F and ionic contrast. The coronary arteries were visualized in at least 2 orthogonal projections. Significant coronary heart disease was considered present when diameter stenosis was =50%, determined by quantitative coronary angiography analysis. The left ventricular angiogram was performed in a right anterior oblique projection. All stents were implanted with previous balloon predilation (6 to 10 atm). Only the infarct-related artery was treated with coronary stenting [27].

All the implanted stents were premounted. The final balloon-pressure inflation was performed with the same balloon used for delivering the stent, or at operator discretion, an additional balloon was used, following a balloon/artery ratio ≥1. The final pressure used in the procedure was noted and used to divide the patients into 2 groups (12 to 20 atm). The final goal was the obtainment of optimal stent implantation defined by a residual stenosis ≤10%, without edge dissections or the persistent presence of intracoronary thrombus in the target vessel.

After hospital discharge, patients were followed according to a routine: clinical on-site visit after 180 days from the index procedure for symptom evaluation, and performance of a new electrocardiogram and functional tests, if they were necessary. A new coronary angiography was performed in all patients independently from the presence of anginal symptoms, in a period of ≥6 to ≤12 months. A coronary angiography performed before this period was considered valid for the study if an in-stent restenosis was confirmed (%E ≥50%). A new target-vessel revascularization was performed only if it was ischemia-driven and associated with the presence of severe in-stent restenosis. All new percutaneous and surgical procedures were counted, either for target and nontarget vessels.

All the changes in lumen size were measured by off-line quantitative coronary angiography [CMS-Medis® (Cardiovascular Measurement System) da Medical Imaging Systems®] [28,29]. The frames were analyzed either on cine films or compact discs. The automatic edge detection method was used for that purpose, according to the reference size of the guiding catheter used in the procedure (user-defined). The measurements were performed pre- and post-stent implantation and at the late follow-up. The reference diameter was the average between the proximal and distal size of the vessel, when the target vessel was completely occluded. In the event of an occlusion, only the proximal measurement was used. The luminal changes measured were ÷acute gain [minimal luminal diameter (MLD post-MLD pre)], late loss (MLD post-MLD follow-up), net gain (acute gain - late loss) and late loss index (late loss acute gain). All these luminal changes were corrected by the reference diameter (relative value), either poststent (acute gain) or at the follow-up (late loss) [11,30]. The measurements were performed in a blinded manner. An experienced physician, aware of the purpose of the study, performed the measurements.

A comparative analysis was performed dividing the pa-

Table I - Adjunctive pharmacotherapy used in the Invasive Cardiology Section of the Instituto Dante Pazzanese de Cardiologia, for the patients who underwent primary coronary stent implantation during acute myocardial infarction

Place Drug	Emergency Room	Cath Lab	Intensive Coronary Care Unit	At Discharge
Aspirin	200 mg; chewable	No	200 mg/PO/day	200 mg/PO/day; indefinitely
Ticlopidine	250 mg/PO; 12/12 h	No	250 mg/PO; 12/12 h	250 mg/PO; 12/12h / 30 days
Metropolol *	15 mg IV	No	No	No
Atenolol	No	No	25 -100 mg/PO/day	25 - 100 mg/PO/day
Unfractionated heparin	No	10.000 IU/IV **	1.000 IU/h / 48 h (ACT 200 to 300 s)	No
Abciximab	No	IV bolus 0,25 mg/kg	0,125 mcg/kg/min/ 12 h, IV, without IV heparin	No
Nitroglycerin	No	0,2 mg intracoronary	No	No
Nitrates	5 mg SL	No	No	No
Captopril ***	No	No	50 - 150 mg/PO/day	50 - 150 mg/PO/day

* Total dose; it was not administered in patients with the formal contraindications like asthma, bradycardia (<60 bpm) or congestive heart failure; ** The ACT was monitored every 30 minutes during the procedure. The recommended value was between 300 and 350 seconds. Additional doses (2.500 UI) of intravenous unfractionated heparin were administered when necessary; *** It was administered for patients with left ventricular ejection fraction below 40%.

tients into 2 groups, according to the final stent pressure used: [group 1 (≥12 to <16 atm) and group 2 (≥16 to 20 atm)]. The primary end-point was the measurement of the acute gain, late loss, and the loss index. The secondary objectives were the infarct-related artery patency, classification of the epicardial coronary flow (TIMI classification) [31], in-stent restenosis, reocclusion, and target-vessel revascularization rates.

The sample size was estimated according to previous findings obtained from the elective coronary stent implantation study [25]. It was confirmed that a late loss index of 0.5 was expected when high pressures were used (≥16 to ≤20 atm). A 30% reduction in the late loss index was estimated (80% power) if lower pressure was used (≥12 to <16 atm). Forty-one patients were necessary in each group. Assuming that at least 85% of patients would return for a new coronary angiography, 95 patients would be necessary. The continuous variables were shown by averages with their standard deviation. The differences between them were analyzed with the Student *t* test. The continuous variables were displayed in absolute numbers with their respective percentage (%), and their differences verified with the chi-square or Fisher exact tests, when necessary. The software used was SPSS® for Windows® (Microsoft®) version 9.0. Statistical significance was considered as $p \leq 0.05$.

Results

Nighty-five patients were included for this analysis. Thirteen (13.7%) did not undergo a new coronary angiography and were excluded from the analysis. The reasons were absence of a clinical follow-up visit or request for rescheduling of the coronary angiography for a period longer than that stipulated by the protocol (6 patient), refusal to undergo a new coronary angiography (2), stroke during the follow-up period (1), pregnancy (1), progressive renal failure (1), severe ostio-articular disease (1), and diagnosis of malignancy (1). Table II displays the demographics of patients included and excluded from the study. No statistical differences existed between them. Eighty-two patients were then included, 41 in each group. Figure 1 displays the recruitment of patients during this period. Patients were allocated more frequently into the group 2 in the first 6 months and into group 1 more frequently in the last 13 months.

The clinical profile is provided in table III. The clinical profiles between groups were similar. The majority were males, 15% had diabetes, and both groups had similar rates of anterior and inferior wall myocardial infarction.

The angiographic characteristics are demonstrated in table IV. The left ventricular ejection fraction was significantly reduced in group 1 compared with that in group 2 patients (42.9±11.1% vs 49.1±11.4%; p=0.02). The presence of multivessel coronary heart disease was common (63.4%), and 17.1% of patients exhibited triple-vessel disease.

Table V provides an analysis of the procedural profile of the patients. All the stent types were similar between the groups (p=0.37). Six physicians performed the procedures. An analysis of the results according to the different operators was not performed.

The mean stent pressure inflation was 15.9±2.6 atm. In group 1, the average was 13.6±0.9 atm and in the group 2, 18.1±1.7 atm. In patients included in group 2, more stents were implanted per vessel treated (1.2±0.4 vs 1.1± 0.2; p=0.04). Two stents were implanted in 10 patients (12.2%). Of these, 2 were in group 1, and 8 were in group 2 (4.9% vs 19.5%; p=0.04). The patients in group 2 had larger reference diameters of the target vessel (3.3±0.3 mm vs 3.2±0.3 mm; p=0.047), and the balloon achieved bigger diameters (3.5±0.4 mm vs 3.3±0.3 mm; p=0.007), when compared with those in group 1. Otherwise, patients in group 1 received abciximab infusion more frequently than did those in group 2 (39% vs 17.1%; p=0.048) (tab. V).

Epicardial coronary flow was verified according to TIMI classification (tab. VI). No statistical differences existed between groups.

All 82 patients underwent a new coronary angiography at a similar follow-up time (214.4±72.7 days vs 199.1± 49.9 days; p=0.27) (tab. VII). The number of asymptomatic patients were the same for both groups (75.6%), as was that of patients with unstable angina (2.4%; p=0.25). No reinfarctions occurred during follow-up. A new target-vessel revascularization procedure were necessary in 8.5% of the 82 patients, but without a statistical difference between groups (9.8% vs 7.2%; p=0.17). Regarding nontarget-vessel revascularization, no differences occurred between the groups (19.5% vs 17.1%; p=0.77). The total new revascularizations procedures performed in all these patients was 26.8% (group 1, 29.3% vs group 2, 24.4%; p=0.62) (tab. VII).

The quantitative coronary angiography analysis showed (tab. VIII) that the balloon to artery ratio was similar in both groups (1.1±0.1 vs 1.1±0.1; p=0.65). In group 1, smaller arteries were treated, according to the reference diameter after stent implantation, when compared with arteries in group 2 (3.1±0.3 mm vs 3.3±0.4 mm; p=0.02). However, the reference diameter measurement showed only

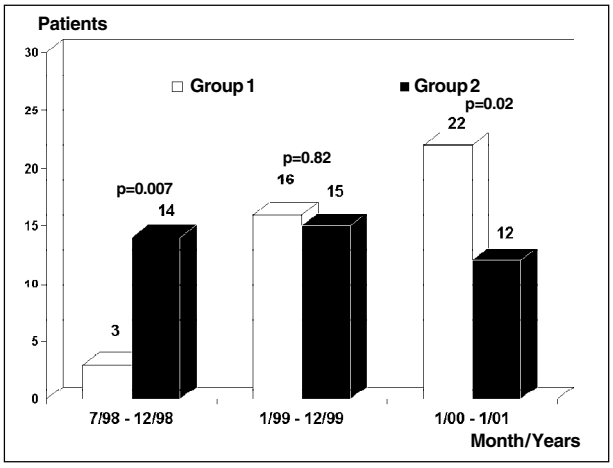

Fig. 1 - Temporal recruitment of patients for the investigation. divided according to the coronary stent implantation pressure [group 1 (≥12 a <16 atm) and group 2 (≥16 a ≤20 atm)]

Table II - Comparative analysis of the demographics from patients included and excluded from the study, regarding the lack of performing the follow-up coronary angiography

Variables		Included (82P)	Excluded (13P)	P
Age (years)		57.8±10.6	60±8	0.39
Male gender		65(79.3%)	11(84.6%)	0.49
Diabetics		13(15.9%)	3(23.1%)	0.38
Previous myocardial infarction		17(20.7%)	1(7.7%)	0.24
myocardial revascularization		11(13.4%)	2(15.4%)	0.56
Present MI:	anterior	36(43.9%)	6(46.1%)	0.88
	inferior	34(41.5%)	6(46.1%)	
	lateral or posterior	12(14.6%)	1(7.7%)	
Functional Class (Killip):	1	71(86.6%)	11(84.6%)	0.56
	2	6 (7.3%)	0	
	3	1 (1.2%)	1(7.7%)	
	4	4 (4.9%)	1(7.7%)	
Delay: pain-balloon dilatation (hrs)		4.4 ± 2.5	3.5 ± 1.6	0.12
CK-MB peak (UI)		79.4 ±44.8	70 ±40.6	0.45
Hospital discharge (days)		6.3 ± 3	5.7 ± 2.3	0.44
Infarct related artery:	left main	3 (3.7%)	0	0.95
	anterior descending	35 (42.7%)	6 (46.1%)	
	right coronary	33 (40.2%)	6 (46.1%)	
	left circumflex	11 (13.4%)	1 (7.7%)	
Number of vessels >50%:	1	30 (36.6%)	7 (53.8%)	0.38
	2	38 (46.3%)	4 (30.8%)	
	3	14 (17.1%)	2 (15.4%)	
Left ventricular ejection fraction (%)		45.9 ±11.6	47.2 ±11.8	0.72
Pressure of pre-dilation (atm)		8.2 ± 1.2	8.3 ± 1.1	0.81
Pressure of stent implantation (atm)		15.9 ± 2.6	15.6 ± 2.1	0.98
Number of stents		1.1 ± 0.3	1.1 ± 0.4	0.79
Stent diameter (mm)		3.2 ± 0.4	3.3 ± 0.3	0.77
Stent length (mm)		19.5 ± 6.5	17.1 ± 6	0.22
Maximum balloon diameter (mm)		3.4 ± 0.3	3.4 ± 0.1	0.48
Maximum inflation time (s)		47.6 ±18.4	48.5 ±20.5	0.88
Abciximab		23 (28%)	5 (38.5%)	0.66
Balloon/artery ratio		1.1 ± 0.1	1.1 ± 0.1	0.07
Reference diameter:	pre (mm)	3.1 ± 0.4	3.2 ± 0.2	0.14
	post (mm)	3.2 ± 0.4	3.3 ± 0.2	0.38
Minimal luminal diameter:	pre (mm)	0.1 ± 0.2	0.1 ± 0.2	0.68
	post (mm)	2.9 ± 0.4	3 ± 0.2	0.36
Acute gain (mm)		2.8 ± 0.4	2.9 ± 0.3	0.34
TIMI flow 0+1 (pre)		68 (83%)	12 (92.3%)	0.35
	2 (pre)	7 (8.5%)	1 (7.7%)	
	3 (pre)	7 (8.5%)	0	
	TIMI-2 (post)	8 (9.8%)	2 (15.3%)	0.41
	3 (post)	74 (90.2%)	11 (84.7%)	

a tendency toward this, when we analyzed the prestent values and at follow-up (pre: 3±0.3 mm vs 3.1±0.4 mm; p=0.06, and follow-up: 3.1±0.3 mm vs 3.2±0.4 mm; p=0.07, group 1 and 2, respectively). The patients in group 1 had a significantly smaller MLD poststent when compared with group 2 (2.8±0.3 mm vs 3±0.4 mm; p=0.001), but in the follow-up, no statistical differences existed between them (1.9±0.9 mm vs 2.1±0.8 mm; p=0.26). The percentage of the diameter stenosis in the target vessel followed the findings according to the MLD changes [prestent (96.6±7.9% vs 96.8±7.4%; p=0.90); poststent (11.6±5.3% vs 8.7±5.4%; p=0.02) and follow-up (38.7± 26% vs 35.4±21.1%; p=0.53)], group 1 vs group 2.

In group 1, the acute luminal gain was significantly less compared with that in group 2 (2.7±0.4 mm vs 2.9± 0.4 mm; p=0.004), but the late loss was similar (0.9±0.8 mm vs 0.9±0.6 mm; p=0.73), as was the net gain (1.8±0.9 mm vs 2±0.8 mm; p=0.24) and the late loss index (0.3± 0.3 vs 0.3±0.2; p=0.93). The relative values were not significantly different when both groups where compared (tab. VIII and fig. 2). The in-stent restenosis rate was 22% (group 1) and 17.1% (group 2; p=0.69), respectively.

The late angiographic analysis of the global ejection fraction demonstrated a significant recovery in both groups. The mean percentage gain was 6.8±2.9% for group 1 patients (49.1±11.4% vs 55.9±11.9%; p=0.01), and of 5.7±3.1%, for group 2 patients (42.9±11.1% vs 48.6±13.7%; p=0.047).

Discussion

The late follow-up results of the 82 patients who underwent primary coronary stenting during AMI, either clinical or angiographic, were similar independently of the different ranges of stent pressure inflation (≥12 to <16 and ≥16 to ≤20 atm).

The group 2 patients, who underwent stent implantation with high-pressure balloon inflation, obtained a significantly higher acute lumen gain (2.9±0.4 vs 2.7±0.4 mm; p=0.004). However, after the correction for the index value

Table III - Clinical profile from the 82 patients who underwent primary coronary stent implantation, divided according to the coronary stent implantation pressure

Variables	Group 1 (41P)	Group 2 (41P)	p
Age (years)	58.9+11.3	56.7+10.1	0.36
Range	28 to 79	37 to 77	-
Male gender	30(73.2%)	35(85.4%)	0.28
Diabetics	5(12.2%)	8(19.5%)	0.55
Hypertension	23(56.1%)	24(58.5%)	1
Smokers	31(75.6%)	28(68.3%)	0.62
Previous events			
Myocardial infarction	10(24.4%)	7(17.1%)	0.59
Percutaneous intervention	3(7.3%)	2(4.9%)	1
Surgical revascularization	4(9.8%)	2(4.9%)	0.67
Present myocardial infarction			0.41
Anterior	16(39%)	20(48.8%)	
Inferior	17(41.5%)	17(41.5%)	
Lateral or posterior	8(19.5%)	4(9.8%)	
Functional class (Killip)			0.20
1	36(87.8%)	35(85.4%)	
2	1(2.4%)	5(12.2%)	
3	1(2.4%)	0	
4	3(7.3%)	1(2.4%)	
Delay: pain-balloon dilatation (hrs)	4.4 ± 2.4	4.4± 2.5	0.96
CK-MB peak (UI)	86.1 ±42.9	73.7 ±46.3	0.28
Hospital discharge (days)	6.4± 3.2	6.1± 2.9	0.75

Normal value of the MB fraction of the creatine phosphokinase = 10 UI.

(reference diameter), the acute gain became similar between groups (group 1: 0.8±0.1 vs group 2: 0.9±0.1; p=0.13). The other quantitative angiographic variables also did not differ when the comparison was performed, either in the follow-up MLD (1.9±0.9 mm vs 2.1±0.8 mm; p=0.26), the late loss (0.9±0.8 mm vs 0.9±0.6 mm; p=0.73), the net gain (1.8±0.9 mm vs 2±0.8 mm; p=0.24) and their relative value (0.6±0.3 versus 0.6±0.2; p=0.50). The same finding was observed regarding the late loss index of the target vessel (0.3±0.3 vs 0.3±0.2; p=0.93).

The secondary end points were similar between the different strategies of primary coronary stent implantation

Table IV - Angiographic profile from the 82 patients who underwent primary coronary stent implantation, divided according to the coronary stent implantation pressure

Variables	Group 1 (41P)	Group 2 (41P)	p
Infarct related artery			0.14
Left main	3(7.3%)	0	
Anterior descending	15(36.6%)	20(48.8%)	
Right coronary	16(39.1%)	17(41.4%)	
Left circumflex	7 (17%)	4(9.8%)	
Total	41(100%)	41(100%)	
Number of vessels with ≥50%			0.62
1	13(31.7%)	17(41.5%)	
2	21(51.2%)	17(41.5%)	
3	7(17.1%)	7(17.1%)	
Coronary calcification	11(26.8%)	9(21.9%)	0.61
Left ventricular ejection fraction (%)	49.1+11.4 *	42.9+11.1**	0.02

* n = 37 p; ** n = 39 p.

(reestablishment of TIMI-3 flow, in-stent restenosis, reocclusion and target-vessel revascularization rates).

Some variables might influence the results of a primary coronary stent procedure. Four of these deserve comments: use of abciximab, the stent type, diabetes, and treatment of restenotic and long lesions.

The patients in group 1 received intravenous infusion of abciximab, a potent inhibitor of IIb/IIIa surface receptors of platelets more frequently, which caused a profound antiplatelet effect. We do not believe that this difference influenced the late angiographic results. Five former studies already demonstrated that abciximab did not cause a significant reduction in stent restenosis rates [16,33-35]. Their advantages are related much more to acute procedural improvements, either in coronary flow (epicardial and in the microcirculation) or in a better recovery of left ventricular function, especially, when it is administered before the procedure begins [35].

Other procedural differences were observed when both groups were compared. The group 2 patients received more stents per vessel compared with group 1, but the total stent length was similar between groups. This finding is because of the more recent availability of customized sizes for stents (fig. 1)[27]. This fact was strictly related to a temporal trend in stent availability, rather than the occurrence of stent implantation failure in the patients randomized to group 2 (edge dissections). Regarding stent type, no patients received coil or self-expanding stents. All the stent types implanted in this series already had similar clinical and angiographic results in previous head-to-head trials [36,37].

The fact that more patients in group 2 underwent multiple stent implantation might cause disagreement about its influence in the late angiographic results. Tanajura et al [38] demonstrated that the implantation of multiple stents per se does not directly influence the follow-up of patients (in-stent restenosis of multiple stents, 29% versus single stent, 33%; p=NS). Similar to these study, in our study only 2 stents were used. However, a word of caution is necessary, especially about patients who undergo very long stent length implantation (>35 mm): this is an angiographic situation that has a higher expectation of in-stent restenosis [38-39].

Regarding the implantation of long stents in AMI (>20 mm), the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) study [16] also determined that the upper limit of stent length should be 35 mm. In the procedural analysis, the mean stent length [12] was 23 mm in 1,037 patients treated, with an average of 1.3 stents per vessel. The 6-month target vessel revascularization rates were 7.4% and 5.0%, considering both randomized groups of stents, with or without abciximab, respectively. In the present investigation, the findings were similar. So, probably the difference in the number of stents used in both groups might not have influenced the final analysis.

The presence of diabetes [1,3], restenotic lesions [1], or lesion length also may cause an adverse late result after coronary stenting [2,39]. Neither of these variables was different in either group. The lesion length measurement during AMI

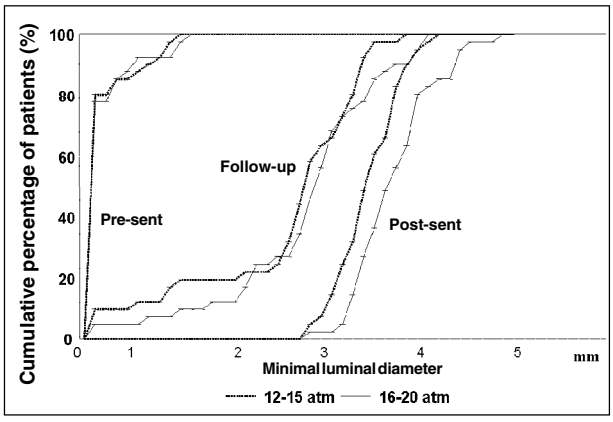

Fig. 2 - Cumulative analysis of the minimal luminal diameter of the 82 patients who underwent primary coronary stent implantation. divided according to the coronary stent implantation pressure.

percutaneous procedures may not be accurate [28-30]. More than 80% of the infarct-related vessels were initially found to be occluded. All vessels underwent balloon predilation, reestablishing the coronary epicardial flow. After that, a precise measurement of the lesion length is missed, in part, reduced by the balloon effect.

Quantitative coronary angiography with automatic edge detection was used to analyze the luminal changes [28-30]. Since 1994, all randomized series that tested the efficacy of stenting in AMI used the same technique, confirming its accuracy and reproducibility [2,15-18,40-43].

In 1995, Colombo et al [10] introduced the concept of optimal coronary stent implantation, with high-pressure assisted balloon inflation (≥12 atm). The former studies [9,20,21,26] that investigated the influence of balloon pressure on late angiographic results after stent implantation used mixed techniques (low and high pressure inflations), and also systematic exclusion of AMI patients from their data. The comparison of this series with these former ones had to be done with caution because of the different strategies used to perform coronary stenting.

The Optimal Stent Implantation Investigators (OSTI) registry very clearly demonstrates the acute mechanism of lumen enlargement related to progressive high-pressure inflations. Seventy-nine patients underwent progressive high-pressure balloon inflations during coronary stenting (12, 15, and 18 atm). The authors verified that the higher the pressure, the bigger the lumen gain achieved. They suggested that stents should be implanted with very high pressures (≥18 atm), in a systematic manner. However, this registry did not perform late coronary angiography in these patients to verify the possible influence of this strategy in late lumen loss. Probably, they said, smaller vessels should not accommodate the excess of mio-intimal hyperplasia [44].

Dirschinger et al [25] examined a randomized series of 933 patients, but again AMI cases were excluded. The patients were divided in a randomized way into 2 groups: one designated as lower pressure, from 8 to 13 atm (mean = 11.1±2.1 atm) and the other one as higher pressure, from 15 to 20 atm (mean = 16.9±2 atm). They did not find any significant difference in the clinical or angiographical results between these groups of patients (stent thrombosis, AMI, new PTCA, urgent surgery, or death), either in the acute phase [3% vs 2.8%; OR=0.92(CI=0.4-2.1)], or at 1-year [24.5% vs 21.2%; OR=0.85(CI=0.6-1.1)]. At 6-months, the in-stent restenosis rate was similar in both groups (31.4% vs 30.4%; NS), as was the late loss index (0.6±0.5 mm vs 0.5± 0.4 mm;NS). Only the CK-MB measurement was different in both groups, higher (>3x) in patients who underwent high-pressure inflations [3.4% vs 6.4%; OR=1.87(CI=1.02-3.42)] [25].

Uretsky et al [22] reported the results of a nonrandomized clinical series comparing very high-pressure stent implantation (20 atm) with moderate pressures [12 to 19 atm (mean = 14.3±2.6 atm)]. In 136 patients included, again AMI was an exclusion criterion. The acute procedural result was similar between both strategies, but at the 1-year follow-up,

Table V - Procedural data from the 82 patients who underwent primary coronary stent implantation, divided according to the coronary stent implantation pressure

Variables	Group 1 (41P)	Group 2 (41P)	P
Pressure of balloon predilation (atm)	8.1 ± 1.2	8.3 ± 1.2	0.52
Range	6 to 10	6 to 10	-
Pressure of stent implantation (atm)	13.6 ± 0.9	18.1 ± 1.7	<0.001
Number of stents	1.1 ± 0.2	1.2 ± 0.4	0.04
Stent diameter (mm)	3.2 ± 0.3	3.3 ± 0.3	0.047
Stent length * (mm)	19.3 ± 6.4	19.6 ± 6.6	0.81
Range	8 até 35	15 até 33	-
Stent type **			0.37
Coris/Johnson&Johnson®	10 (24.4%)	15 (36.6%)	
Guidant/ACS®	16 (39%)	13 (31.7%)	
Medtronic®	8 (19.5%)	10 (24.4%)	
Boston Scientific/*Scimed*®	7 (17.1%)	3 (7.3%)	
Maximum balloon diameter (mm)	3.3 ± 0.3	3.6 ± 0.4	0.007
Maximum inflation time (seconds)	45 ±18.1	50.1 ±18.6	0.21
Abciximab	16 (39%)	7 (17.1%)	0.048

* measured by quantitative coronary angiography; ** Cordis/J&J® (Palmaz-Schatz® Espiralado, Crown and BX Velocity®), Guidant® (Multi-link® Duet and Tri-star), Medtronic® (BeStent®, GFX® and S670®) and Boston Scientific® (NIR®).

Table VI - Epicardial coronary flow, according to the TIMI classification, from the 82 patients who underwent primary coronary stent implantation, divided according to the coronary stent implantation pressure

Variables	Group 1 (41P)	Group 2 (41P)	P
Pre-procedure			0.058
TIMI-0	32 (78%)	33(80.5%)	
1	2(4.9%)	1(2.4%)	
2	6(14.6%)	1(2.4%)	
3	1(2.4%)	6(14.6%)	
Post-stent			0.71
TIMI-0	0	0	
1	0	0	
2	5(12.2%)	3(7.3%)	
3	36(87.8%)	38(92.7%)	
Follow-up			0.24
TIMI-0	4(9.8%)	1(2.4%)	
1	0	1(2.4%)	
2	0	0	
3	37(90.2%)	39(95.1%)	

patients in whom the 20 atm was used had a higher rate of clinical composite adverse events (9.5% vs 28.8%; p=0.005), related to a higher rate of new target-vessel revascularization (5% vs 20%; p=0.009) [22].

These findings should be replicated in the AMI scenario [15,16]. The subanalysis from the STENT PAMI trial [19] gathered 508 patients divided into 6 groups according to the final pressure used for stent implantation (from 8 to 20 atm). The authors demonstrated that in 90 patients (17.7% of the total) that finalized the procedure with lower pressures (8 to 11 atm), the 30-day mortality rate was significantly higher (10.1% vs 2.1%; p<0.02) compared with that with high-pressure inflations (>11 atm). Using lower pressures constituted an independent predictor of higher mortality [p=0.002; RC=5.07(IC=1.90-14.3)]. Our series had similar late angiographic results when compared with those of STENT PAMI, regarding the late loss index in the target vessel (0.3 and 0.4, respectively). The conclusion was the same: coronary stent implantation with balloon-pressure >11 atm promotes similar late clinical and angiographical results, if an optimal stent implantation is obtained.

Table VII - Clinical follow-up of the 82 patients who underwent primary coronary stent implantation. divided according to the coronary stent implantation pressure

Variables	Group 1 (41P)	Group 2 (41P)	p
New coronary angiography (days)	214.4±72.7	199.1±49.9	0.27
Range (days)	104 to 370	100 to 350	-
Symptom			0.25
Asymptomatic	31(75.6%)	31(75.6%)	
Stable angina	9 (22%)	9(22%)	
Unstable angina	1(2.4%)	1(2.4%)	
Reinfarction	0	0	
Target-vessel revascularization			0.17
Balloon or new stent	2(4.9%)	2(4.9%)	
Surgery	2(4.9%)	1(2.4%)	
Total	4(9.8%)	3(7.3%)	
Non target-vessel revascularization			0.77
Balloon or new stent	5(12.1%)	6(14.7%)	
Surgery	3(7.3%)	1(2.4%)	
Total	8(19.5%)	7(17.1%)	

Table VIII - Quantitative coronary angiography analysis of the 82 patients who underwent primary coronary stent implantation. divided according to the coronary stent implantation pressure

Variables	Group 1 (41P)	Group 2 (41P)	p
Balloon/artery ratio	1.1 ± 0.1	1.1 ±0.1	0.65
Reference diameter (mm)			
Pre	3 ± 0.3	3.1 ±0.4	0.06
Post	3.1 ± 0.3	3.3 ±0.4	0.02
Follow-up	3.1 ± 0.3	3.2 ±0.4	0.07
Minimal luminal diameter (mm)			
Pre	0.1 ± 0.2	0.1 ±0.2	0.96
Post	2.8 ± 0.3	3 ±0.4	0.001
Follow-up	1.9 ± 0.9	2.1 ±0.8	0.26
Diameter stenosis (%)			
Pre	96.6 ± 7.9	96.8 ±7.4	0.90
Post	11.6 ± 5	8.7 ±5.4	0.02
Follow-up	38.7 ± 26	35.4 ±21.1	0.53
Luminal changes			
Acute gain (mm)	2.7 ± 0.4	2.9 ±0.4	0.004
Relative acute gain	0.8 ± 0.1	0.9 ±0.1	0.13
Late loss (mm)	0.9 ± 0.8	0.9 ±0.6	0.73
Relative late loss	0.3 ± 0.3	0.3 ±0.2	0.88
Loss index	0.3 ± 0.3	0.3 ±0.2	0.93
Net gain (mm)	1.8 ± 0.9	2 ±0.77	0.24
Relative net gain	0.6 ± 0.3	0.6 ±0.2	0.50
Restenosis	5(12.2%)	5 (12.2%)	1
Reocclusion	4 (9.8%)	2 (4.9%)	0.34

It is interesting to compare the late loss index results between AMI and non-AMI stenting cases (non-AMI, 0.4 ± 0.6 and AMI, 0.3 ± 0.4). This difference is justified by the way the late loss index is obtained. Its result is the division of the acute gain with the late lumen loss. In AMI cases, the majority of the vessels were found to be occluded (MLD = 0.1±0.2 mm), so the acute gain in the MLD is higher than that in non-AMI patients (>1 mm). At the follow-up, late loss is around 1 mm for both situations, but with a greater acute lumen gain; in AMI stenting, the late loss index is diminished.

The study had some limitations. The sample size may be understimated. The reason for this was the absence, in 1998, of AMI stenting experience reporting the effects of the balloon-pressure inflation in the late loss index [25]. The results of the larger STENT PAMI trial were only published in 1999 [19]. At the end of this investigation, the late loss index was smaller than expected. Future research analyzing this variable may require more rigorous criteria regarding the sample size calculation. The patients were included in a non-randomized fashion, also related to temporal trends regarding primary coronary stenting in AMI. Two major international randomized series recommend the systematic use of high pressure for coronary stent implantation in AMI (STENT PAMI, >16 atm and CADILLAC, >15 atm), to avoid subacute stent thrombosis. So, we left that decision to the operator at the time of the index procedure, leaving him free to obtain the best acute results achievable. The progressive change in procedural technique is clearly seen as the recruitment evolved (fig. 1) After the STENT PAMI subana-

lysis and this series, future studies may r ecruit patients in a randomized way, seeing that the safety limits now are more clearly determined.

These results allowed the conclusion that the systematic use of high-pressure balloon inflation (>16 atm) during primary coronary stent implantation is not necessary. A strong recommendation is the obtainment of an optimal angiographic result (%E ≤10%), guided by an objective method of analysis, such as the quantitative coronary angiography.

The 2 different stent implantation strategies achieved similar rates of reestablishment of TIMI-3 flow. Patients in whom high-pressures were used (≥16 to ≤20 atm) had significant acute lumen gain when compared with those who received moderate balloon pressure inflations (≥12 to <16 atm). However, high pressures for primary coronary stent implantation (≥16 atm) did not result in significantly better late clinical and angiographic results, either in the target-vessel revascularization, in-stent restenosis rates, or nor in the late loss index and in the net lumen gain.

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