A Comparative Analysis of Primary Stenting and Optimal Balloon Coronary Angioplasty in Acute Myocardial Infarction. Six Month Results from the STENT PAMI Trial

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Objective *– To compare the outcome of balloon PTCA with final coronary stenosis diameter (SD) £30%, with elective coronary stenting.*

Methods - *We performed a comparative analysis of the 6 month outcomes in patients treated with primary stenting and those who obtained an optimal balloon PTCA result treated during the first 12 hours of AMI onset included in the STENT PAMI randomized trial.*

Results - *The results were analysed into 3 groups: primary stenting (441 patients, SD=22±6%), optimal PTCA (245 patients), and nonoptimal PTCA (182 patients, SD= 37±5%). At the end of the 6 months primary stent group presented with the lowest restenosis(23 vs. 31 vs. 45%, p=0.001, respectively). Ischemia-driven target vessel revascularization rate (TVR) (7 vs. 15.5 vs. 19%, p=0.001, respectively).*

Conclusion - *At the 6 month follow-up, primary stenting offered the lowest restenosis and ischemia-driven TVR rates. Compared to optimal balloon PTCA. Nonoptimal primary balloon PTCA pts (SD=31-50%), had the worst late angiographic outcomes and should be treated more actively with coronary stent implantation.*

Keywords: stent, angioplasty, restenosis

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A series of randomized trials were performed to obtain a comparative analysis between two percutaneous revascularization methods, primary coronary stent implantation and primary balloon PTCA [1-3], available for the treatment of acute myocardial infarction (AMI) in the first 12 hours of its onset. The STENT PAMI trial randomized a greater number of AMI patients than did the previous trials (900) in 62 centers worldwide, concluding that primary heparin-coated Palmaz-Schatz stent implantation offered greater final luminal diameter, a lower restenosis rate and fewer ischemia-driven target vessel revascularization (TVR) procedures at the end of the first 180 days when compared with balloon PTCA [4].

The BENESTENT I trial [5] compared the elective coronary stent implantation strategy with balloon PTCA in non-AMI patients showing that 36% of patients randomized to the balloon obtained a final procedural stenosis diameter lower than 30%, and with reduced restenosis rates with fewer occurrences of major coronary events at the long-term follow-up, benefits similar to those obtained with routine stenting. Serruys et al referred to these optimal balloon PTCA results as a *stent-like* procedure [6,7]. The clinical and cost-effectiveness implications of these findings have stimulated the specific design of trials capable of proving or disproving this conclusions.

In the first 12 hours of AMI onset, this comparison was not yet realized. The objective of this study was to perform the comparative analysis of the clinical and angiographic results at the end of the first 6 months after AMI of patients who had been submmited to a routine coronary stent implantation and those who obtained an optimal primary balloon PTCA angiographic result, and were included in the STENT PAMI trial.

Methods

This analysis follows the protocol determined for the

main STENT PAMI trial. We included patients of both sexes, above 18 years of age, within the first 12h of AMI (symptions and ST-T segment elevation ≥1mm in more than 2 contiguous ECG leads). Clinical exclusion criteria included prior administration of thrombolytics for the index infarction, current use of warfarin, stroke within one month, renal failure, cardiogenic shock, expected survival of <1 year, women of childbearing potential unless a recent pregnancy test was negative, or known contraindications to aspirin, heparin, or ticlopidine.

The patients were medicated at the emergency room with aspirin (325mg/PO), ticlopidine (500mg/PO, for 30 days), heparin (5,000 to 10,000IU/IV), beta blockers (IV) in the absence of contraindications.

The coronary arteriography and left ventriculography were performed with the Judkins technique with low osmolar ionic contrast medium. Only the infarct-related artery was treated. Once flow was established (either spontaneously or after initial balloon inflations), the operator determined whether the infarct lesion(s) qualified for randomization. The randomization process was conducted with a central computerized system (Amsterdam, The Netherlands).

The technicians selected only native arteries, 3.0-4.5 mm reference segment diameter (visual), and lesion(s) that could be covered with one or two stents (15 mm length). Vessels were also excluded if the stent would protrude into the left main artery (ostial LAD or circumflex lesions), if large branches (≥3.0mm in diameter) would be constricted by the stent, or if tortuosity and calcification made it unlikely that the stent could be delivered and expanded.

Patients randomized for routine coronary stent implantation and received a 15-mm Palmaz-Schatz heparin-coated stent mounted on a balloon that incorporated a sleeved stent delivery system. After stent deployment at 8 atm, a separate high pressure inflation of ≥16 atm was recommended. The objective was the achievement of an optimal stent implantation, with an SD ≤10% (visual assessment), without edge dissections or severe adjacent nontreated stenosis.

In patients randomized to ballon PTCA, the technique already tested was used, with the goal of a final stenosis as low as possible. At the operators discretion, coronary stents could be implanted in the presence of suboptimal results (stenosis diameter ≥50% or flow threatening dissections), using other commercially available stent.

All the procedures were performed with full intravenous heparinization (ACT≥350 seconds). Administration of thrombolytics or abciximab was discouraged. Intracoronary ultrasound was not mandatory, being performed at the technician's discretion.

Clinical and angiographic analysis - The cumulative occurrence of all major clinical events was monitored throughout the index hospitalization, and at 1 and 6 months. Prior to performance of the protocol follow-up angiography at 6.5 months, investigators documented the angina class or evidence of ischemia at stress testing.

Detailed case report forms were completed by clinical coordinators at each site. Independent monitors traveled to the sites to verify source documentation on all patients. All acute and follow-up cineangiograms were obtained using standard acquisition guidelines and submitted to independent Angiographic Core Laboratories (Washington Hospital Center, Washington D.C. and Cardialysis, Rotterdam, The Netherlands). The quantitative coronary angiographic (QCA) analysis was performed using the CAAS II system (Pie Medical, The Netherlands). Myocardial perfusion was graded using the Thrombolysis in Myocardial Infarction (TIMI) classification. The mean reference diameter and the minimal lumen diameter were used to calculate the percent SD. An MLD = 0.0 was assumed in the presence of a total occlusion at baseline or follow-up.

The primary objective was to assess the combined cumulative occurrence of death, reinfarction, stroke, or ischemia-driven TVR procedures at the end of the first 6 months after the index AMI. Each component of the primary endpoint was adjudicated by an independent clinical events committee.

Secondary endpoints were the 6-month minimal lumen diameter and SD, restenosis rate (≥50% SD), and reocclusion (TIMI 0-1 flow in a vessel that was previously patent) [8].

In this current analysis, the randomized patients were divided into 3 different groups according to the final procedural SD, after QCA analysis: routine stenting, optimal PTCA (SD ≤30%), and nonoptimal PTCA (SD= 31-50%).

Statistical analysis - Categorical variables were presented as frequency and percentual, and continuous variables as mean an standard deviation.

Categorial variables were analysed with Bi-caudal Chi-Saqure Test or Exact Fischer test, whichever fitted better. Continuous variables were analysed by linear regression model taking the subset (stent, optimal PTCA and non-optimal PTCA) as independent variable. A later analyse was done to compare pairs of subsets.

Results

Between December 1996 and December 1997, 900 patients were randomized. From these, the cinefilms of 868 (96%) were analyzed by the Central Angiographic core labs, with the calculation of the final procedural stenosis diameter by QCA.

According to the prespecified criteria, patients were divided into 3 groups: routine stenting, 441 (51%) patients; optimal balloon PTCA, 245 (28%); and nonoptimal balloon PTCA, 182 (21%) patients.

The clinical profile of these groups are displayed in table I. The clinical variables were well balanced among all 3 groups, without any statistical significance. The mean age was 60 years, more than 70% of participants were men and 15% had diabetes. The mean time between pain onset and emergency room admission was 160 minutes.

The angiographic profile is shown in table II, also without any major differences among the 3 groups. The majority of the patients had anterior myocardial infarction related to LAD occlusions, and more than 45% of the group

Table I - Clinical characteristics of the 3 groups analyzed

% of patients	Routine stenting N=441	Optimal PTCA N=245	Nonoptimal PTCA N=182
Mean age (years)	61±12	59±12	60±13
Men	75	74	77
Diabetics	15	16	14
Hypertensives	42	41	43
Previous events			
AMI	10	13	9
CABG	1	2	2

p= NS.

exhibited multivessel coronary heart disease. The mean global ejection fraction prior to the intervention was greater than 45%.

The optimal balloon PTCA patients required bail-out stent implantation in 23% of the group. On the contrary, only 3% ($p<0.05$) of nonoptimal PTCA patients received nonplanned stents. Regarding the number of stents required per artery, the average was similar between the routine stenting group and the optimal PTCA (1.4) group, but we observed a trend toward a higher number of stents per artery in the nonoptimal PTCA group (2.2).

The acute procedural results are demonstrated in table III. The coronary TIMI flow grade 3 was re-established in 90% of routine stent patients, 93.5% of the optimal PTCA group, and 92% of the nonoptimal PTCA patients (p= NS), assessed by core lab analysis.

The acute procedural QCA results revealed differences among the groups. The mean reference artery diameter was lower for the optimal balloon PTCA group. The greater MLD was obtained in the routine stent group and follows a lower progressive sequence, for the optimal and nonoptimal PTCA groups (2.6±0.4 vs. 2.3±0.4 vs. 1.9±0.4 mm, respectively, $p< 0.05$). The higher acute gain with the lower stenosis diameter followed that same sequence for the 3 different groups, all statistical differences favoring the routine stent patients (table III).

At the end of the first 6 months after AMI, 669 (77%) of the patients underwent a new protocol cineangiography, with a similar percentage for all groups (77, 78, and 75%, respectively, p= NS). The greater MLD at the follow-up was

Table II - Angiographic profile of the 3 groups

% of patients	Routine stenting N=441	Optimal PTCA N=245	Nonoptimal PTCA N=182
Vessel treated			
Left anterior descending	40	45	42
Left circumflex	14	12	16
Right coronary	45	43	42
Multivessel disease	46	43	46
Mean ejection fraction	49±12	48±11	48±11
# stents/vessel	1.4±0.6	1.4±0.6	2.2±0.8

p= NS.

Table III - Acute procedural results and quantitative angiographic analysis of the 3 groups

% of patients	Routine stenting N=441	Optimal PTCA N=245	Nonoptimal PTCA N=182	p
TIMI flow - 1	0.4	0.4	0	
- 2	9.6	6.1	8.2	
- 3	90	93.5	92	0.6
Nonplanned stents	-	23	3	0.0001
Residual dissection	6	18	28	0.0001
Final pressure (ATM)	15±4	9±4	9±3	0.001
Balloon/artery ratio	1.1±0.2	1.2±0.1	1.1±0,2	0.7
Final coronary DS (mm)	18±6	22±6	37±5	0.0001
Reference diameter	3.2±0.4	2.9±0.4	3.1±0.5	0.001
MLD preprocedure	0.4±0.5	0.4±0.5	0.4±0.5	0.7
Postprocedure	2.6±0.4	2.3±0.4	1.9±0.4	0.001
Acute gain	2.2±0.6	1.9±0.7	1.5±0.6	0.001

MLD- minimal lumen diameter; DS- diameter stenosis.

observed in the routine stenting group, becoming lower for the optimal and nonoptimal balloon PTCA groups (1.8±0.7 vs. 1.7±0.7 vs. 1.5±0.8mm, respectively, $p<0.05$). Lower stenosis was also observed in the same sequence of groups (40 vs. 44 vs. 53%, respectively, $p<0.05$).

The restenosis rate was lower for the patients included in the routine stenting group (table IV), even including the comparison with the optimal balloon PTCA group (23 vs. 31 vs. 45%, respectively, p= 0.001). In relation to the occurrence of the reocclusion phenomenon, patients included in the routine stenting group or with optimal PTCA results did not demonstrate significant differences (5 vs. 6%, p = NS), showing a benefit when compared with to nonoptimal PTCA patients who had twice that number (6 vs. 13%, p= 0.0008).

The primary endpoint events was observed significantly less often in the routine stenting strategy group (table V). The occurrence of combined clinical events was 12% (routine stenting), 17.5% (optimal PTCA), and 22.5% (nonoptimal PTCA), respectively. The clinical benefit was only detected in the comparison of routine stenting patients with optimal balloon PTCA patients (p = 0.001). In the side-by-

Table IV- Quantitative coronary angiographic results at the end of the first 6 months after percutaneous revascularization procedures during AMI

(mm)	Routine Stenting N=441	Optimal PTCA N=245	Nonoptimal PTCA N=182	p
Reference diameter	3.0±0.4	2.9±0.6	3.0±0.3	0.001
MLD	1.8±0.7	1.7±0.7	1.5±0.8	0.001
Late loss	0.8±0.6	0.6±0.6	0.5±0.7	0.001
Follow-up coronary SD	40±20%	44±21%	53±22%	0.001
Restenosis	23%	31%	45%	0.001
Reocclusion	5%	6%	13%	0.008*

* p = 0.008 only for routine stent and optimal balloon PTCA groups vs. nonoptimal PTCA group. MLD- minimal lumen diameter; DS- diameter stenosis.

Table V - Clinical combined events at the end of the first 6 months after AMI of the 3 different procedural results

% of patients	Routine Stenting N=441	Optimal PTCA N=245	Nonoptimal PTCA N=182	p
Death	4	1.2	3.3	0.2
Reinfarction	2.4	2	2.7	0.9
Stroke	0.2	0.4	0	0.8
Ischemia-driven TVR	7	15.5	19	0.001*
Combined events	12	17.5	22.5	0.003*

p<0.05 only for routine stenting group vs. optimal and nonoptimal balloon PTCA groups. TVR- target vessel revascularization.

side comparison of the occurrence of the primary endpoint between optimal balloon and nonoptimal PTCA groups, we did not find significant differences.

The reduction in the ischemia-driven TVR rate (routine stenting, 7 vs. optimal PTCA, 15.5%, p= 0.001) was the only clinical variable analyzed that exhibited an expressive benefit when patients participated in a routine stenting strategy. However, this benefit was not observed in the comparison of optimal and non-optimal balloon PTCA groups (15.5 vs. 19%, respectively, p= NS). The significant reduction observed in this clinical variable had a major contribution for a lower rate of clinical combined events.

The major complications related to AMI occurrence (death, reinfarction, and stoke) were not different among the 3 groups. A routine stenting strategy did not modify their occurrence.

Discussion

In the current analysis, we compared the acute (30 days) and follow-up (6 months) of more than 800 patients randomized in the STENT PAMI trial [4], during the first 12 hours of AMI onset, according to the final procedural stenosis diameter, assessed by QCA analysis. The group of patients originally randomized to the balloon PTCA strategy were divided according to the achievement of an optimal result (stent-like), with an stenosis diameter ≤30%, and compared with those randomized to the routine stenting strategy.

The clinical and angiographic results were obtained in a cumulative fashion at the end of the first and sixth months after AMI. The acute results did not reveal significant differences in the success rate, the re-establishment of TIMI 3 flow rate, and the occurrence of major complications. We only observed that patients who underwent a routine stenting strategy had a significantly lower procedural stenosis diameter, greater lumen gain and, as a consequence, a higher MLD, when compared with other groups. The marked differences in the results were observed in the clinical and angiographic analyses at the end of the first 6 months. So, the group of patients who had routine stenting exhibited a significantly lower restenosis rate (23%) and, as a consequence, a lower need for new TVR ischemia-driven procedures, reduced in more than 50% of patients. The group classified as having an optimal balloon PTCA result, despite being favored by 23% over coronary stent implantation, did not obtain similar clinical and angiographic benefits as compared with those who participated in the routine stenting strategy.

The late reocclusion rate was similar for routine stenting and optimal balloon PTCA groups, however 23% of patients in the optimal ballon PTCA group had stent implant that may have protected them from this hazardous complication, compared with the nonoptimal balloon PTCA patients (5-6% vs. 13%, p<0.05).

Optimal Balloon PTCA or Routine Stenting Strategy in AMI? - Since the subanalysis from the elective randomized trial BENESTENT I (balloon PTCA vs. coronary stenting), Serruys et al [5-7] have made the interesting observation that a range of 30 to 40% of patients who undergo only balloon PTCA who had achieved a final procedural stenosis diameter ≤30%, had a favorable long-term outcome similar to that observed in patients randomized to stenting. Because of this, the concept of a stent-like result was created [6].

The ability of coronary stents to improve balloon PTCA suboptimal results either by sealing dissection planes or reducing the restenosis rate are unquestionable and very well proven [5,7]. However, the multiple morphological presentations of coronary heart disease may draw into question routine stent application, which may not be suitable for all patients for example, those with long and tandem coronary stenosis, small vessels, bifurcations, and the present and possible scenario of in-stent restenosis [8].

In non-AMI patients, recent studies questioned the concept of optimal balloon PTCA with a stent-like result [6]. All of the studies discussed in their methods sections adjunct assisted devices capable of monitoring on-line the coronary stent implantation procedure. These devices can verify anatomical (IVUS or QCA) or physiological (coronary flow reserve by Doppler catheters) variables [9,10]. The results of the studies DEBATE I [11], DESTINI [12] and DEBATE II [13] were all very similar. When balloon catheters were able to obtain a lower stenosis diameter (<35% by QCA) associated with a normalization of coronary flow reserve (>2.0), the long-term clinical and angiographic results became very similar to those observed with routine stent application. However, a very wide range of patients were able to achieve that optimal result, from 25 to 50%. Additionally, in the DEBATE II trial, 25% of the patients required bail-out coronary stent implantation, and a surprising finding was that patients who, after obtaining optimal results received a stent by protocol decision, showed even lower rates of new late major clinical events (1%). These findings associated with the additional costs and longer procedures do not recommend these methods for all patients treated in daily practice.

The report of the most recent trial (OPUS [14]), applying a more friendly technology available in all major invasive cardiac laboratories (visual assessment with assisted QCA) has been released. Elective non-AMI patients (n= 500) with reference vessels ≥3.0mm and stenosis length <20mm were randomized into either the routine stenting strategy or to the achievement of an optimal balloon PTCA (SD≤30%). At

the end of the first 6 months after the index procedure, patients included in the stent arm showed a significant reduction in major combined clinical events (6 vs. 15%, p<0.003) and in the ischemia-driven TVR rates (4 vs. 11%, p<0.001). These results obtained in non-AMI patients were quite similar to those observed in our patients treated during the first hours of AMI onset.

The application of optimal balloon PTCA during AMI - Until now, no randomized sub-analysis of these two strategies in the setting of AMI has been performed. We proved that patients who underwent routine stenting during AMI exhibited better late clinical and angiographic results. The mechanisms of the restenosis process are complex and multifactorial, involving elastic recoil and excessive intimal hyperplasia [13]. The benefit of coronary stent implantation in the reduction of clinical and angiographic restenosis rates are strongly related to the acute procedural result (lower stenosis diameter) mixed with the positive effect of the chronic elastic recoil phenomenon. These facts were also observed in this AMI analysis.

Patients included in the optimal balloon PTCA group did not achieve the same clinical and angiographic results obtained in patients treated with the routine stenting strategy. Despite a 23% cross-over rate of stenting in this group, the only significant benefit was the avoidance of late infarct-related vessel reocclusion.

However, the percutaneous strategy of routine stenting during the first 12 hours of AMI did not modify the rates of major complications (death, reinfarction, and stroke) [10]. The achievement of a final procedural stenosis diameter ≤50%, classified as nonoptimal balloon PTCA, was enough to equalize the occurrence of these major clinical complications among all 3 groups.

Should we Perform Routine Stenting during AMI? - If our goal during the AMI mechanical reperfusion treatment is a reduction in the rates of major clinical complications (death and reinfarction), routine stenting will not provide us with these achievements [15]. The fast re-acquisition of normal TIMI 3 coronary flow in the infarct-related artery still persists as the main endpoint in the AMI setting, and that is achieved even with an stenosis diameter ≤50%, either with stent implantation or balloon PTCA [4,10].

However, if we want to prevent late restenosis occurrence, even after an optimal balloon PTCA result (SD ≤30%), we should implant coronary stents. It is important to mention that these findings were observed in patients with total native coronary stenosis, in vessels≤3.0mm (visual) and with a lesion length ≤30mm, with good distal run-off, without major bifurcations into large side branches. Until new evidence is available, we cannot promote this recommendation for other angiographic scenarios.

We also demonstrated that the categorization of a primary PTCA procedure as nonoptimal (stenosis diameter= 31-50%) implies that in 50% of patients a greater chance exists of suffering a late vessel reocclusion. This undesirable phenomenon occurred in 13% of these patients. The negative impact on the recovery of left ventricular function has already been well-documented [14,15], justifying a more liberal stent approach in this situation.

Study Limitations - The patients randomized to balloon PTCA only received stents in the face of a suboptimal angiographic result (stenosis diameter >50% with or without severe dissections) as a rescue or bail-out procedure, but not as a provisional stenting strategy.

The IIb/IIIa inhibitors were not widely used in this trial (<5%), according to the protocol requirement. Recent randomized studies [16,17] have demonstrated an optimization of the acute and late follow-up results, with the association of these new pharmacological agents, either when balloon or stent were applied. New ongoing trials [18-21] may clarify this issue.

Conclusions - In a selected group of AMI patients who underwent mechanical reperfusion techniques, the routine stenting strategy promoted a significant reduction in the final procedural stenosis diameter, with a 50% reduction in the 6 month restenosis and ischemia-driven TVR rates, when compared with patients who achieved an optimal balloon PTCA result (stenosis diameter ≤30% by QCA).

The group of patients classified as having nonoptimal balloon PTCA results (stenosis diameter = 331-50%) obtained the worst clinical and angiographic results with twice the late reocclusion rate, as compared with the other 2 groups. Coronary stent implantation was used in few patients (3%), justifying in the face of a final stenosis diameter >30%, a more liberal stent approach.

Appendix

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