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Original Article

Stent Implantation With or Without Pre-Dilation in Non-ST-Segment-Elevation Acute Coronary Syndrome Patients

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ABSTRACT

Background: The benefits of direct stenting in non-ST-segment-elevation acute coronary syndromes (NSTE ACS) are not clearly established. We compared stenting with or without pre-dilation (direct stenting) of the target lesion in this population. **Methods:** Single center, retrospective registry including NSTE ACS patients treated from 2009 to 2010. Stenting for bifurcations, saphenous vein grafts, and in-stent restenosis were excluded. The primary endpoint was the comparison of in-hospital and late major adverse cardiac events (MACE). **Results:** Of a total of 182 patients, 42.3% were treated by direct stenting. Mean age was 61.1 ± 11.0 years, 67% were male and 33.5% were diabetics. Patients in the pre-dilation group had more type C lesions (37.1% vs. 18.2%; P = 0.01), smaller reference vessel diameter (2.3 [2.0-2.7] mm vs. 2.7 [2.2-3.1] mm; P = 0.01) and smaller preintervention minimal luminal diameter (0.5 [0.1-0.7] mm vs.0.6 [0.4-1.0] mm; P < 0.01). Moderate/severe calcification was observed in 13.2% of the cases, and was equally distributed in both groups. There were no differences in the occurrence of periprocedural angiographic complications (3.9% vs. 4.8%; P = 0.99). In-hospital MACE was not different between groups, although patients submitted to direct stenting have shown half of the events (2.6% vs. 5.7%; P = 0.47). At the end of 1 year, the MACE rate was similar for the two groups (6.5% vs. 5.7%; P > 0.99). **Conclusions:** In this series of NSTE ACS patients, direct stenting was not associated with better angiographic or clinical outcomes. However, lesion complexity remains a

RESUMO

Implante de Stents Com ou Sem Pré-Dilatação em Pacientes com Síndrome Coronária Aguda Sem Supradesnivelamento do Segmento ST

Introdução: O benefício do implante direto de stent não está bem estabelecido na síndrome coronária aguda sem supradesnivelamento do segmento ST (SCASST). Comparamos aqui o implante de stent, como usem pré-dilatação (stent direto) da lesão-alvo nessa população. **Métodos:** Registro unicêntrico, retrospectivo, que incluiu pacientes com SCASST tratados entre 2009 a 2010. Foram excluídas lesões reestenóticas, lesões em enxertos de safena ou em bifurcações. O desfecho primário foi a comparação de eventos cardíacos adversos maiores (ECAM) hospitalares e tardios. **Resultados:** Do total de 182 pacientes avaliados, 42,3% foram tratados com stent direto. A idade da população foi de 61,1 ± 11,0 anos, sendo 67% do sexo masculino e 33,5% diabéticos. Os pacientes do grupo pré-dilatação apresentaram mais lesões do tipo C (37,1% vs. 18,2%; P < 0,01), menor diâmetro de referência do vaso (2,3 [2,0-2,7] mm vs. 2,7 [2,2-3,1] mm; P < 0,01) e menor diâmetro luminal mínimo pré-intervenção (0,5 [0,1-0,7] mm vs. 0,6 [0,4-1,0] mm; P < 0,01). Calcificação moderada/grave foi evidenciada em 13,2% dos casos, igualmente distribuídos entre os grupos. Não foram observadas diferenças na ocorrência de complicações angiográficas periprocedimento (3,9% vs. 4,8%; P > 0,99). As taxas de ECAM hospitalar não diferiram entre os grupos, embora os pacientes submetidos ao implante direto tenham apresentado metade dos eventos (2,6%

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determinant factor in the choice of the pre-dilation strategy in daily practice.

DESCRIPTORS: Acute coronary syndrome. Percutaneous coronary intervention. Stents.

vs. 5,7%; P = 0,47). Ao final de 1 ano, os ECAM foram semelhantes entre os grupos (6,5% vs. 5,7%; P > 0,99). **Conclusões:** Nesta série de pacientes com SCASST, o implante direto de stent não esteve associado a melhores resultados angiográficos ou clínicos. Contudo, a complexidade da lesão permanece como fator determinante na escolha da estratégia de pré-dilatação na prática diária.

DESCRITORES: Síndrome coronariana aguda. Intervenção coronária percutânea. Stents.

Previous trials have demonstrated that the technique of direct stenting is superior to pre-dilation with balloon catheter, regarding the reduction in the occurrence of disorders in coronary flow during the procedure (slow flow/no-reflow), resulting in a lower incidence of periprocedural myocardial infarction, particularly in patients with acute coronary syndrome (ACS), with or without ST-segment elevation.[1] Other potential advantages of this technique include less time of exposure to radiation, a reduction in the duration of the procedure, the use of less constrast, and lower costs.[2-8]

However, a major limitation of the direct implantation relates to the capacity of stents of crossing lesions that are often severe and complex (e.g. with tortuosity and calcification). With the advent of new, thinner, and more flexible metal platforms and the use of new metal alloys (cobalt-chromium, platinum-chromium, among others), it has become easier to perform direct stenting.

The present analysis aims to compare the immediate outcomes and those at one year of a cohort of patients with non-ST-segment elevation acute coronary syndrome (NSTE-ACS) treated with stenting, with or without pre-dilation (direct stenting) of the target lesion.

METHODS

Study design and population evaluated

This was a single-center, retrospective, and nonrandomized registry, which included patients with NSTE-ACS undergoing percutaneous coronary intervention, divided according to stent implantation strategy (pre-dilation vs. direct stenting).

This study included patients with a single *de novo* lesion in native coronary arteries. Patients with restenotic lesions, lesions located in vein grafts, true bifurcation lesions (lateral branches > 2.0 mm and with > 50% stenosis), with lesion in the left main coronary artery, and patients who did not return for follow-up at this institution were excluded.

The trial protocol was approved by the Research Ethics Committee of this institution, and all patients signed an informed consent for the performance of the percutaneous coronary intervention.

Percutaneous coronary intervention

Previously, all patients had received acetylsalicylic acid (loading dose of 300 mg and maintenance with 100 mg/day), clopidogrel (loading dose of 300/600 mg and 75 mg for maintance/day), and low molecular weight heparin (1 mg/kg every 12 hours). The use of glycoprotein IIb/IIIa as an adjuvant to the procedure was at the discretion of the operator.

Percutaneous coronary intervention was performed via femoral or radial approach, as decided by the operator. All procedures were performed according to the recommendations of the current guidelines.[9] During the intervention, unfractionated heparin (UFH) was administered at a dose of 70 to 100 IU/kg in patients who had not received low molecular weight heparin (LMWH) 12 hours before the procedure.

The choice of implant technique (i.e. pre-dilation or direct stenting) was at the discretion of the operator. After the procedure, patients continued to receive dual antiplatelet therapy with acetylsalicylic acid 100 mg/day indefinitely and clopidogrel 75 mg/day for at least one month in case of bare-metal stents, and for one year if the device was a drug-eluting stent.

Qualitative and quantitative coronary angiography

Quantitative coronary angiography (QCA) was obtained in multiple projections and similar incidences before and after stenting. The QCA offline analysis included the measurement of the following parameters: vessel reference diameter, minimal luminal diameter, lesion length, pre- and postprocedural percentage of stenosis diameter (reference diameter – minimum lumen diameter/reference diameter × 100), and acute gain. The lesions were classified according to the American Heart Association/American College of Cardiology criteria. The morphological characteristics of the lesion (eccentricity, tortuosity, angulation > 45°, thrombus, occlusion, calcification, etc.) were evaluated. The degree of antegrade blood flow was measured in accordance with the Thrombolysis in Myocardial Infarction (TIMI) classification.

Primary outcome

The primary goal of this study was to compare the clinical outcomes, with inclusion of periprocedural

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angiographic complications (flux disturbance: slow flow/no-reflow, thrombus, and occlusion of lateral branch) and major adverse cardiac events (MACE), such as target-vessel revascularization, acute myocardial infarction, and death, that occurred in hospital and within one year.

Definitions

NSTE-ACS was defined as a typical chest pain at rest or with minimal exertion, with or without T-wave inversion and/or ST-segment depression > 0.5 mm in the electrocardiogram, with or without elevation of serum markers of myocardial injury.

All deaths were considered of cardiac origin unless another cause was identified. The diagnosis of periprocedural myocardial infarction was defined as an elevation > 3 times the normal value of CK-MB. Target-vessel revascularization was defined as a new revascularization (new percutaneous coronary intervention or coronary artery bypass graft [CABG] surgery) in the previously treated target vessel, due to restenosis or disease progression.

Angiographic success was defined as TIMI 3 distal flow or a residual lesion after stent implantation < 20%.

Statistical analysis

Categorical variables were expressed as absolute (n) and relative (%) frequency. To assess the association between categorical variables, the chi-squared or Fisher's exact test were used. Continuous variables were expressed as median (interquartile range). To compare groups, the Mann-Whitney test was used for nonparametric variables. P values < 0.05 were considered significant.

All analyses were performed by the Department of Research, Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil, using SPSS version 18.0.

RESULTS

From January 2009 to March 2010, 605 patients with NSTE-ACS were treated in this hospital, of whom 182 (30.1%) met the trial criteria. These patients were divided according to the strategy used for stenting (pre-dilation – n = 105, or direct stenting – n = 77). Figure 1 shows the flow chart of the trial.

The clinical, angiographic, and procedural characteristics are shown in Tables 1 and 2. The mean age was 61.1 ± 11 years, 67% were male, and 33.5% were diabetic. None of the clinical characteristics differed between the groups, except for clinical presentation, which showed a higher frequency of myocardial infarction without ST-segment elevation in the pre-dilation group.

182 lesions were treated, and the target vessel more frequently addressed was the left anterior descending artery (39%). Of all lesions treated, 78.0% had a moderate to high degree of anatomical complexity (B2/C). Patients from pre-dilation group had a higher frequency of type-C injuries. Lesions with moderate/severe calcification were present in 13.2% of cases, a feature equally distributed between groups (15.2% vs. 10.4% P = 0.38).

198 stents (1.08 stent/patient) were used, and 2 stents with overlapping rods needed to be implanted in 8.7% of cases. Drug-eluting stents were used in 14.8% of patients who had a stent implanted, and 31.2% of patients had two stents implanted. In the pre-dilation group, the stents showed smaller diameter (3.0 mm [2.5-3.0] vs. 3.0 mm [3.0-3.5]; P < 0.01), and a greater length (18 mm [14.5 to 24.0] vs. 18 mm [12.0 to 20.0]; P < 0.01). The incidence of patients with distal TIMI flow < 3 before the procedure was higher in pre-dilatation group, while distal TIMI 3 flow after the procedure was similar between the groups (97.1% vs. 98.7%). No

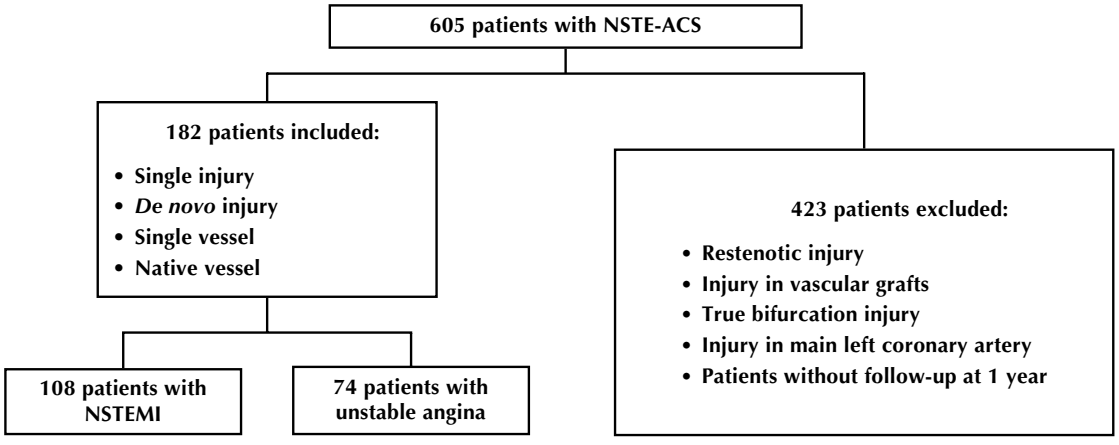

Figure – Selection of patients, with inclusion and exclusion criteria. NSTE-ACS = non-ST-segment elevation acute coronary syndrome; NSTEMI = Non-ST-segment elevation myocardial infarction.

TABLE 1
Baseline clinical characteristics

Characteristics	Pre-dilation (n = 105)	Direct stenting (n = 77)	P value
Age, years	61 (53-70.5)	59 (50-68)	0.12
Male, n (%)	68 (64.8)	54 (70.1)	0.52
Hypertension, n (%)	91 (86.7)	63 (81.8)	0.41
Diabetes *mellitus*, n (%)	34 (32.4)	27 (35.1)	0.75
Dyslipidemia, n (%)	62 (59.0)	45 (58.4)	> 0.99
Currently smoking (%)	25 (23.8)	24 (31.6)	0.30
Family history of CAD, n (%)	15 (14.3)	17 (22.1)	0.23
Prior AMI, n (%)	20 (19.0)	17 (22.1)	0.71
Prior PCI, n (%)	15 (14.3)	14 (18.4)	0.53
Previous CABG, n (%)	16 (15.2)	4 (5.2)	0.05
Clinical status, n (%)			
STEMI	70 (66.7)	38 (49.4)	
Unstable angina	35 (33.3)	39 (50,6)	

CAD = coronary artery disease; AMI = acute myocardial infarction; PCI = percutaneous coronary intervention; CABG = coronary artery bypass grafting; NSTEMI = Non-ST-segment elevation myocardial infarction.

TABLE 2
Angiographic and procedural characteristics

Characteristics	Pre-dilation (n = 105)	Direct stenting (n = 77)	P value
Target vessel, n (%)			0.10
Left anterior descending circumflex	36 (34.3)	35 (45.5)	
Right coronary	40 (38.1)	18 (23.4)	
Type of lesion	29 (27.6)	24 (31.2)	
(AHA/ACC), n (%)			0.03
A	1 (1.0)	3 (3.9)	
B1	19 (18.1)	18 (23.4)	
B2	47 (44.8)	42 (54.5)	
C	39 (37.1)	14 (18.2)	
Lesion morphology, n (%)			
Eccentricity	72 (68.6)	52 (67.5)	> 0.99
Tortuosity	19 (18.1)	14 (18.2)	> 0.99
Angle < 45°	6 (5.7)	2 (2.6)	0.47
Thrombus	7 (6.7)	5 (6.5)	> 0.99
Calcification	16 (15.2)	8 (10.4)	0.38
Lateral branch involvement	19 (18.1)	8 (10.4)	0.20
Ulcer	1 (1.0)	2 (2.6)	0.57
TIMI flow Pre-procedure, n (%)			0.02
3	78 (74.3)	68 (88.3)	
< 3	27 (25.7)	9 (11.7)	
TIMI flow post-procedure, n (%)			0.63
3	102 (97.1)	76 (98.7)	
< 3	3 (2.9)	1 (1.3)	
Stent diameter, mm	3.0 [2.5-3.0]	3.0 [3.0-3.5]	< 0.01
Stent length, mm	18 [14.5-24.0]	18 [12.0-20.0]	< 0.01
Drug-eluting stent, n (%)	19 (18.1)	8 (10.4)	0.20
Implantation of two stents with overlapping of their rods, n (%)	12 (11.4)	4 (5.2)	0.18
GP IIb/IIIa, n (%) inhibitor, n (%)	7 (6.7)	4 (5.2)	0.76

AHA/ACC = American Heart Association/American College of Cardiology; TIMI = Thrombolysis in Myocardial Infarction; GP = glycoprotein.

differences were observed between the groups in the occurrence of periprocedural angiographic complications: slow flow/no-reflow (2.9% vs. 3.9%; P = 0.29), thrombus (1.0% vs. 1.3%; P > 0.99), or occlusion of lateral branches (1.9% vs. 0; P = 0.50).

The results of QCA are shown in Table 3. Patients from pre-dilation group had smaller reference vessel diameter (2.3 mm [2.0-2.7] vs. 2.7 mm [2.2-3.1]; P < 0.01) and smaller minimal lumen diameter (0.5 mm [0.1-0.7] vs. 0.6 mm [0.4-1.0]; P < 0.01). After stent implantation, the minimal luminal diameter was smaller in the pre-dilation group (2.2 mm [1.8-2.6] vs. 2.7 mm [2.3-2.9]; P < 0.01), but the acute luminal gain did not differ between groups (1.7 mm [1.3-2.0] vs. 1.8 mm [1.4-2.3]; P = 0.15).

The incidence of MACE, although numerically greater in the in-hospital phase ofpatients in the pre-dilation group, was not statistically significant (5.7% vs. 2.6%; P = 0.47). At one year of follow-up, the occurrence of MACE was also comparable (5.7% vs. 6.5%; P > 0.99) (Table 4).

DISCUSSION

The main finding of this study was the fact that, in selected patients with a clinical picture of NSTE-ACS, direct coronary stenting is feasible without compromising the efficacy of the procedure. However, no angiographic or clinical benefit related to this strategy of stenting was observed, either in the immediate phase (in-hospital) or in the medium term (one year of clinical follow-up).

In theory, the lesions associated with SCA would be ideal for a direct stenting, since in over 50% of these patients, the culprit lesion is localized at a site of moderate stenosis (< 50%) by angiography.[3-5,10] In the present population, the direct stenting procedure was performed in 42.3% of patients, at the discretion of the operator. This result is comparable with other international series, such as that of Süselbeck et al.,[3] in which direct stenting was performed in 43% of patients.

TABLE 3
Quantitative coronary angiography

	Pre-dilation (n = 105)	Direct stenting (n = 77)	P value
Pre-procedure			
Reference diameter, mm	2.3 [2.0-2.7]	2.7 [2.2-3.1]	< 0.01
Minimal luminal diameter, mm	0.5 [0.1-0.7]	0.6 [0.4-1.0]	< 0.01
Stenosis diameter,%	80.4 [73.4-95.7]	76.9 [66.9-87.4]	< 0.01
Lesion length, mm	14.1 [10.0-20.7]	13.2 [10.4-17.3]	0.93
Post-procedure			
Reference diameter, mm	2.7 [2.4-3.0]	2.9 [2.7-3.4]	< 0.01
Minimal luminal diameter, mm	2.2 [1.8-2.6]	2.7 [2.3-2.9]	< 0.01
Stenosis diameter,%	16.3 [9.9-25.4]	12.2 [8.1-19.6]	< 0.01
Acute gain, mm	1.7 [1.3-2.0]	1.8 [1.4-2.3]	0.15

TABLE 4
In-hospital clinical results and after one year and after one year

	Pre-dilation (n = 105)	Direct stenting (n = 77)	P value
In-hospital results, n (%)			
TVR	1 (1.0)	0 (0)	> 0.99
AMI	6 (5.7)	1 (1.3)	0.24
Death	1 (1.0)	2 (2.6)	0.57
MACE	6 (5.7)	2 (2.6)	0.47
Results after one year*, n (%)			
TVR	4 (3.8)	5 (6.5)	0.49
AMI	5 (4.8)	3 (3.9)	> 0.99
Death	1 (1.0)	0 (0)	> 0.99
MACE	6 (5.7)	5 (6.5)	> 0.99

* Events not cumulative.
TVR = target vessel revascularization; AMI = acute myocardial infarction; MACE = major adverse cardiac events.

The mechanisms behind the occurrence of changes in coronary flow (slow flow/no-reflow) are complex and not yet fully understood. Mechanisms inherent to percutaneous coronary intervention itself, due to the effect of crushing and fragmentation of the atherosclerotic lesion, have emerged as the main cause of this phenomenon. The risk of microembolization during a percutaneous coronary intervention depends on the atherothrombotic load of the culprit lesion and on the degree of vascular aggression of the procedure. Other mechanisms described are: microvascular spasm, myocardial stunning, oxidative stress, endothelial dysfunction, and inflammation and thromboxane production.[11,12]

Trials such as PAMI and STENTIM-2 have suggested a promoting effect of the no-reflow phenomenon after pre-dilation with balloon in patients with ACS.[6,7] Likewise, Loubeyre et al.[13] evaluated both techniques in 409 patients with ST-segment elevation acute myocardial infarction (STEMI), and found a lower incidence of no-reflow in the group of direct stenting. Contrary to these results, the present study showed no significant difference in the incidence of coronary flow disturbance by both techniques of stenting. Similar results were obtained in the trial of Süselbecket al.,[3] in which the incidence of no-reflow was not significantly different between the groups.

With regard to the impact on clinical outcomes, Süselbecket al.[3] compared both techniques in 194 patients with ACS (STEMI 66%, NSTEMI 18%, and unstable angina 16%), finding no significant differences between groups for in-hospital major adverse cardiac events (death, myocardial infarction, and CABG) (direct stenting 4.1% vs. pre-dilation 11.5%; P = 0.11). In the same line, Atmaca et al.[10] evaluated the two techniques in a population of 145 ACS patients, and no significant differences were found with regard to the occurrence of death, AMI, or neorevascularization of the target lesion.

It is notable that the present population had greater complexity, representing a sample more compatible with the real clinical practice. This study included patients with lesions generally excluded from several controlled trials, such as calcified lesions, long stents, and those with overlapping.

In the past, the techniques of stenting (direct or pre-dilation stenting) were tested in mixed or selected populations, including patients with stable coronary artery disease, patients with NSTE-ACS and STEMI, or only with STEMI. This analysis represents the only review of a select population of NSTE-ACS (NSTEMI

and unstable angina) with late evolution. The results of this trial increase the knowledge available in this field.

Limitations of the trial

This is a retrospective observational trial, with all the limitations inherent to this type of trial, in which the choice of stenting technique was left to the operator, and was based on experience. Other limitations of trial include the differences in angiographic baseline characteristics between the two groups, and the relatively small number of patients analyzed in both groups.

CONCLUSIONS

In this series of patients with acute coronary syndrome without ST-segment elevation, the decision in favor of direct stenting was not associated with better clinical and angiographic outcomes, neither during hospitalization nor within one year.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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