Safety, feasibility, and six-month outcomes of a systematic strategy of direct coronary stenting by a transradial approach in patients with single-vessel disease

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Key words:
Bleeding complications; Restenosis; Stents.

Background. **Strategies for percutaneous coronary intervention are continuously evolving, in order to reduce complications and to warrant better immediate and long-term outcomes. We sought to evaluate the safety, feasibility, and long-term outcomes of a systematic strategy of coronary stenting without predilation (direct stenting) via a transradial approach for single-vessel procedures.**

Methods. **Stenting was performed with Snapper® stent and wide inner-lumen, preformed, guiding catheters; 118 minimally-selected patients (59% of all single-vessel procedures performed at our center during the study period) were enrolled: among them 39% presented for acute coronary syndromes, 28% were under glycoprotein IIb/IIIa inhibitor treatment, and 10% had a poor left ventricular function; 130 lesions were treated (1.1 stents/lesion): 53% were type B2/C, 8% longer than 20 mm, and 16% on bifurcations.**

Results. **The transradial approach was successful in 96% of cases; 7% required predilation. The immediate angiographic and clinical success rates were 100 and 98% respectively. No bleeding complications occurred when the transradial approach was successful. At 6 months, the mortality, major adverse events, recurrent ischemia, and target lesion revascularization rates were 0, 14, 15, and 10% respectively.**

Conclusions. **A systematic strategy of direct stenting via a transradial approach for single-vessel procedures seems safe, feasible, and efficacious both immediately, and at 6 months of follow-up, even when treating complex lesions and/or high-risk patients.**

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Introduction

The use of stents during percutaneous coronary interventions (PCIs) warrants both a better immediate angiographic result, and a reduction in immediate and long-term complications when compared to balloon angioplasty[1,2]. For this reason, in daily practice, whether it was planned or not, a vast majority of PCIs ends up with stent positioning[3]. A strategy of stenting without predilation (direct stenting) may offer some advantages by reducing the procedure time and costs. Indeed, recent studies suggest that direct stenting may be also more effective than conventional stenting with predilation, in terms of the acute and long-term results[4]. Definitive data, however, are still lacking, and most studies investigating the feasibility and the efficacy of direct stenting have been performed in selected populations, with the exclusion of complex lesions and high-risk patients. To date, it is still not clear whether a systematic strategy of direct stenting is feasible in the majority of patients undergoing PCI.

Bleeding from the puncture site represents a major concern after coronary stenting: sometimes it may be life-threatening and usually it prolongs the in-hospital stay. To prevent bleeding complications from the puncture site, the radial artery has been increasingly chosen as the route of choice for PCI (transradial approach)[5,6]. A transradial approach also warrants better patient comfort and a shorter in-hospital stay[7]. Recent studies suggested that, in selected populations, not only conventional, but also direct stenting, is feasible via a transradial approach[8-10].

Nevertheless, it has not yet been proved whether, in the overall population, direct stenting can be systematically performed via a transradial approach.

The aim of our study was to evaluate the safety, feasibility, and long-term outcomes

of direct stenting and a transradial approach in a minimally-selected population undergoing single-vessel PCI.

Methods

Population and study design. This is a single-center, prospective observational study in which patients undergoing PCI via a transradial approach for single-vessel disease with one or more stenosis have been enrolled. With the aim of including the widest possible population, we did not consider as exclusion criteria for direct stenting: left main stenosis, bifurcation and ostial lesions, an angiographic finding of an intraluminal thrombus, lesions > 20 mm, congestive heart failure (left ventricular ejection fraction < 30%), older age. We excluded patients with: chronically-occluded (> 3 months) vessels, severe coronary calcifications, excessive vessel tortuosity, intrastent restenosis, vessels < 2.5 mm. The patients gave their written informed consent to the study.

The primary endpoints were: angiographic (residual stenosis < 20%) and procedural (freedom from major adverse cardiac events [MACE] during index hospitalization) success; recurrent ischemia and/or need for target lesion revascularization at 6 months; and MACE at 6 months.

The secondary endpoints were: total (door-to-door) procedure duration, length of in-hospital stay, and access-site bleeding complications.

Cannulation of the radial artery. The transradial approach represents the preferred route of catheterization, both for diagnostic and interventional procedures, at our center. Cardiogenic shock, atherectomy procedures, stenting of saphenous vein grafts and the inadequacy of both radial arteries and of both palmar collateral blood supplies are the sole pre-specified contraindications. All the procedures are performed after careful evaluation by palpation of the adequacy of the artery and of the ipsilateral ulnar artery (Allen's test). All the study procedures have been performed by three operators (GA, UL, ASP), with a wide (> 100 PCIs per year) experience in the transradial approach. We used an 11-cm long 6F sheath, a 21G needle and a 0.021" wire (Transradial kit, Cordis Co., Miami, FL, USA). Isosorbide dinitrate 1 mg, heparin 5000 IU, and verapamil 1 mg were injected through the arterial sheath immediately after cannulation.

Percutaneous coronary intervention. All procedures have been performed using the following wide-inner-lumen (0.070") 6F guiding catheters: Vista Brite Tip (Cordis) in the traditional curves (Judkins, Amplatz, XB, Multipurpose) and in preformed curves for the transradial approach (Fajadet and RB); Mach 1 (Boston Scientific/Scimed, Maple Grove, MN, USA) in preformed curves for the transradial approach (Muta Left, Radial and Kimny). Deep intubation was discouraged. The guidewire of first choice was the 0.014" Balance MiddleWeight (Guidant Co., Santa Clara, CA, USA).

The coronary stent used for this study was the Snapper® (CathNet Science, Paris Cedex, France), a device with EC approval for direct stenting, available in multiple lengths and diameters (8-28 × 2.0-5.0 mm) (Fig. 1). This slotted-tube, laser-cut and electro-polished, 316 LVM stainless-steel stent consists of five (2.0-3.0), six (3.5-4), or eight (4.5-5.0) cells, each of which is connected to the others by oblique bridges with an asymmetric and rotational configuration. The stent is pre-mounted on a semi-compliant balloon with concave shoulders, which exceeds each external margin of the stent by 1 mm. The profile of the device is 0.13 mm. Stent dimensions have always been chosen with the aid of quantitative coronary angiography. In case of failure when crossing the stenosis with the stent, or in case of inadequate distal visualization, predilation was allowed before stent positioning.

Patients received an additional bolus of 5000 IU heparin i.v. at the end of the procedure. The choice whether or not to administer glycoprotein IIb/IIIa inhibitors was left to the operator: in this case no additional heparin was given. At the end of the procedure every patient received clopidogrel 300 mg *per os*. Patients were subsequently treated with clopidogrel 75 mg daily *per os* for 1 month and acetylsalicylic acid 100 mg indefinitely.

Quantitative coronary angiography. Quantitative coronary angiography has been performed using the Quantocor Siemens System (Siemens AG, Erlangen, Germany) before the index procedure, in order to determine: reference lumen diameter (RLD), minimal lumen diameter (MLD), stenosis length, percent stenosis (RLD-MLD/RLD%); after the index procedure, in order to determine: MLD, residual stenosis, immediate

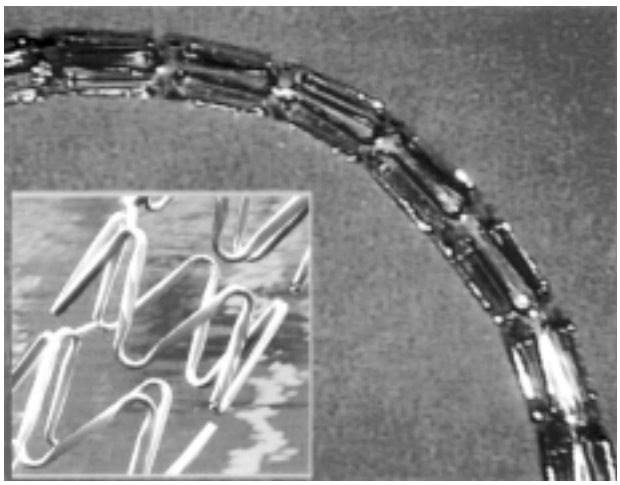

Figure 1. *The Snapper® stent (CathNet Science, Paris Cedex, France) and, in the frame, a detail of the stent struts.*

gain, side branch occlusion (ostial stenosis > 70%, TIMI < 3). Angiographic runs have been acquired after the intracoronary injection of nitrates (isosorbide dinitrate 500 μg), and, in patients presenting with acute myocardial infarction, after the positioning of the guidewire through the thrombotic occlusion.

Clinical events. The following events have been considered as MACE: death, due to cardiac reasons or for unknown reasons, when cardiac death could not be excluded; myocardial infarction, as the development of persistent ST-segment elevation, or new Q waves at the ECG, or an elevation in the creatine kinase-MB serum levels twice or more above the upper normal limit (in patients presenting with acute myocardial infarction this laboratory datum was not considered as indicative of this event during index hospitalization); stroke; necessity of any further revascularization (by means of PCI or coronary bypass); recurrent ischemia, as the recurrence of angina and/or a frankly positive test for myocardial ischemia; target lesion revascularization, as any revascularization on the index lesion; major bleedings, as those resulting in a drop in hemoglobin > 2 g/dl. Clinical events have been screened during the index hospitalization and a follow-up of 6 months.

Statistical analysis. Data are presented as absolute values and percentages of the total (patients, lesions, or stents, as indicated) in case of categorical variables, and mean values ± SD in case of continuous variables.

Results

Between September and December 2002, 349 PCIs have been performed at our center; 201 (58% of total) were single-vessel PCIs, and, among them, 118 patients (59%) satisfied the inclusion criteria and were enrolled in the study. The reasons for exclusion were: contraindications to the radial access (6%), in-stent restenosis (13%), heavily-calcified vessels (10%), small vessels (7%), chronic total occlusions (4%), and extremely-tortuous vessels (4%). The demographic characteristics and clinical presentation are summarized in table I. Briefly, patients were fairly old (mean 66.5 years), mostly male (70%), and hypercholesterolemic (70%).

Procedural outcomes. The procedural details are summarized in table II. We treated 1.1 lesions per patient, with 1.1 stents per lesion; 53% of the lesions were type B2/C. The transradial approach was successful in the majority of patients (96%) but 5, owing to an anomalous course of the artery (2 patients) or because of failure to properly engage the coronary ostium with the guiding catheter (3 patients) in the latter. In these cases, the procedures were successfully accomplished via a brachial or femoral approach. No spasm of the radial or brachial artery occurred during the transradial procedures. In 9 patients (9 lesions, 7%) predilation was necessary: in 5 cases due to failure in crossing the lesion with the stent, in 4 cases (acute myocardial infarction) due to insufficient visualization of the vessel. In 8 patients (9 bifurcation lesions) partial or complete (1 case) occlusion of a side branch occurred: in all these cases it was possible to cross the stent struts and dilate with the balloon (kissing-balloon technique). When necessary (1 case), subsequent stenting of the side branch was performed. In 8 patients (8 lesions, 6%), additional stenting was necessary: in 4 cases due to distal dissection after positioning of the first stent, in 4 cases due to incomplete coverage of the lesion (2 lesions > 20 mm). In all cases of distal dissection, the stents had been deployed at high pressures (> 12 atm). In no case did stent loss occur.

Table I. Demographics, risk factors and clinical presentation of the study population.

Demographics	
No. patients	118
Age (years)	66.5 ± 10.1
Males	83 (70%)
Risk factors	
Diabetes mellitus	21 (18%)
Hypercholesterolemia	83 (70%)
Smokers	35 (30%)
LVEF < 30%	12 (10%)
Clinical presentation	
Stable angina	72 (61%)
Unstable angina	29 (25%)
Acute myocardial infarction	17 (14%)
Treated vessel	
LAD	61 (52%)
Circumflex artery	23 (19%)
Right coronary artery	32 (27%)
Coronary bypass	1 (1%)
Left main trunk (not-protected)	1 (1%)

LAD = left anterior descending coronary artery; LVEF = left ventricular ejection fraction.

In-hospital outcomes. The in-hospital outcomes are summarized in table III. The angiographic and procedural success rates were 100 and 98% respectively. No new ST-elevation myocardial infarction was reported, but one patient, admitted for unstable angina, showed myocardial enzymatic release, in the absence of any symptoms or ECG changes. One patient suffered from an ischemic cerebrovascular attack which partially resolved within 48 hours. One patient presented with major bleeding from the site of puncture after sheath removal. He had been admitted for an acute myocardial infarction, was under treatment with glycoprotein IIb/IIIa inhibitors and had undergone the PCI via a femoral approach, due to failure of the transradial approach. Four patients presented with minor hematomas at the access site: 2 at the radial, and 2 at the brachial site.

Table II. Procedural details.

Type of lesion	
No. lesions treated (total)	130 (1.1 per patient)
Restenosis after POBA	4 (3%)
Bifurcation lesions	21 (16%)
Lesions > 20 mm	11 (8%)
Ostial lesions	7 (5%)
Thrombus-containing lesions	23 (18%)
Isolated calcifications	26 (20%)
Lesions on vessels < 3.0 mm	6 (5%)
B2/C type lesions (ACC/AHA)	69 (53%)
Minimal lumen diameter (mm)	0.7 ± 0.7
Stenosis diameter (%)	79 ± 20
Stent characteristics	
Stents implanted (total)	138 (1.2 per patient; 1.1 per lesion)
Patients with > 1 stent	15 (13%)
Stent diameter (mm)	3.3 ± 0.7
Stent length (per patient) (mm)	17.3 ± 8.0
Inflation pressure (atm)	13.5 ± 3
Procedural characteristics	
Successful transradial approach	113 (96%)
Ad hoc procedures*	109 (92%)
Need for predilation (lesions)	9 (7%)
Need for post-dilation (stents)	13 (9%)
By kissing balloon	9 (6%)
By bigger balloon	4 (3%)
High support guidewire (lesions)	25 (19%)
Y or T stenting (lesions)	4 (3%)
Need for additional stenting (lesions)	8 (6%)
Glycoprotein IIb/IIIa inhibitors	35 (28%)
Irradiation dose** (Gy)	5180 ± 1750
Contrast dye injection** (ml)	185 ± 92
Total (door-to-door) procedure time** (min)	57 ± 14

POBA = plain-old balloon angioplasty. * diagnostic and percutaneous coronary interventions performed during the same procedure; ** including diagnostic procedure.

Table III. Procedural outcomes and in-hospital events.

Angiographic outcomes	
Residual stenosis < 20% (lesions)	130 (100%)
Minimal lumen diameter (mm)	3.2 ± 0.8
Immediate gain (mm)	2.6 ± 0.8
Side branch occlusion (unsolved)	0
Major dissections (unsolved)	0
Clinical outcomes	
In-hospital death	0
Urgent coronary bypass	0
Re-PCI	0
Myocardial infarction*	1 (1%)
Cerebrovascular accident	1 (1%)
Major bleeding	1 (1%)
In-hospital stay (days)	
Stable patients (n=77)	2 ± 2
ACS patients (n=48)	5 ± 3

ACS = acute coronary syndromes (unstable angina + myocardial infarction); PCI = percutaneous coronary intervention. * excluding those presenting for acute myocardial infarction.

Six-month outcomes. All patients completed the 6-month follow-up. The results are summarized in table IV.

MACE occurred in 14% of the study population. No deaths were reported. Recurrent ischemia occurred in 15% of patients, and target lesion revascularization was performed in 10% of patients (11 patients had a re-PCI, and 1 underwent coronary bypass surgery).

Discussion

In our experience, a systematic strategy of direct coronary stenting via a transradial approach was safe and feasible in the majority of patients undergoing a single-vessel PCI, both on an elective and urgent basis, even when complex lesions and/or high-risk patients were treated. The transradial approach decreased vascular complications virtually to zero, and warranted short in-hospital stays. The 6-month outcomes of such a strategy were favorable too.

Direct coronary stenting. It has been proved since a long time that, under selected conditions, direct stenting can compete with conventional stenting with predilation, in terms of immediate outcomes[11,12]. Above its economical convenience, the potential advantages of direct stenting rely on lesser plaque or thrombus embolization, particularly in the setting of acute coronary syndromes[13-15], and on the reduction of vessel trauma induced by ballooning, with a lower rate of major dissections[16].

A recent meta-analysis of all randomized studies suggests that direct stenting, when compared to conventional stenting, is safe, optimizes resource usage, and may improve immediate results[4]. In our prospective, non-randomized observational study, the immediate angiographic and procedural success rates were 100 and 98% respectively. No deaths were reported. Predilation was necessary in 7% of patients. These results overlap those of the direct-stenting arms in many randomized studies. Of note, our study presented a high rate of enrolled/total single-vessel PCIs (59%), and only lesions in which we considered stenting itself hazardous or not indicated (ex-

Table IV. Six-month follow-up outcomes.

MACE (total)	16 (14%)
Death	0
Myocardial infarction	1 (1%)
Stroke	0
Revascularization*	15 (13%)
Recurrent ischemia	18 (15%)
TLR	12 (10%)
Ischemia-free patients	100 (85%)
Event-free patients	102 (86%)

MACE = major adverse cardiac events; TLR = target lesion revascularization (any revascularization, percutaneous coronary intervention or bypass, of the index lesion). * both TLR and non-TLR.

tensive calcifications, tortuous vessels, chronic occlusions, small vessels, in-stent restenosis) were excluded. In contrast to most other studies, we enrolled medium-to-high-risk subgroups (ostial, long, and bifurcation lesions, left main disease, chronic heart failure, acute coronary syndromes, etc.), with, on average, severely stenotic vessels (reflecting the high incidence of acutely occluded vessels). One might assume that a systematic strategy of direct stenting, for one or more vessels, might be safe and feasible in most PCIs, but more data are needed to extrapolate to the overall population, also including multivessel PCI, the immediate outcomes of our minimally-selected single-vessel population.

Coronary stenting via a transradial approach. Many authors[5,6,17] have already proven the usefulness of the transradial approach in almost nullifying bleeding complications after a PCI, with or without stenting, in elective and urgent cases. The transradial approach offers the adjunctive advantage of a faster mobilization and discharge of the patient, with favorable economic relapses[7]. Other authors[8-10] have recently demonstrated the feasibility of direct stenting via a transradial approach. However, only Hamon et al.[8] reported the rate of enrolled/total patients, which was, indeed, low (27%). Laarman et al.[10] adopted wide selection criteria, but they found that to treat circumflex arteries and complex lesions, or to implant long stents highly predicted the failure of direct stenting. Since a strategy of direct stenting via a transradial approach requires long-trained personnel, dedicated material, and a change in procedural work-flows, it can be significantly advantageous only when adopted on a large-scale basis. In our experience, a transradial approach may be the route of choice in most patients undergoing direct stenting (94%), and the cross-over rate to another arterial approach is very low (4%). Of note, most of the procedures (92%) were performed immediately after coronary angiography. A systematic transradial approach yielded virtually no bleeding complications and short procedural times and in-hospital stays, with no negative effects on the immediate outcomes. The safety and feasibility of the transradial approach for direct stenting is also highlighted by the fact that we treated complex lesions (type B2/C accounting for 53% of the total) and acute patients (39% of them with acute coronary syndromes), and that we liberally used aggressive antiplatelet regimens (glycoprotein IIb/IIIa inhibitors in 28% of cases).

A solid experience of the operators with the transradial approach, a careful pre-procedural evaluation at quantitative coronary angiography and the choice of proper material could all be reasons for our favorable results. In particular, the exclusive use of wide inner-lumen guiding catheters in preformed curves allowed us to perform stenting on bifurcations (16% of cases), with no preclusion for the contemporary use of multiple balloons and stents (kissing-balloon technique in 43% of bifurcation lesions) (Fig. 2). Moreover, such guiding catheters warranted a good vessel opacification and an adequate support during stent release, without the systematic need for high support wires or deep intubation, even when treating ostial (5% of cases), long (8%) or thrombus-containing (18%) lesions.

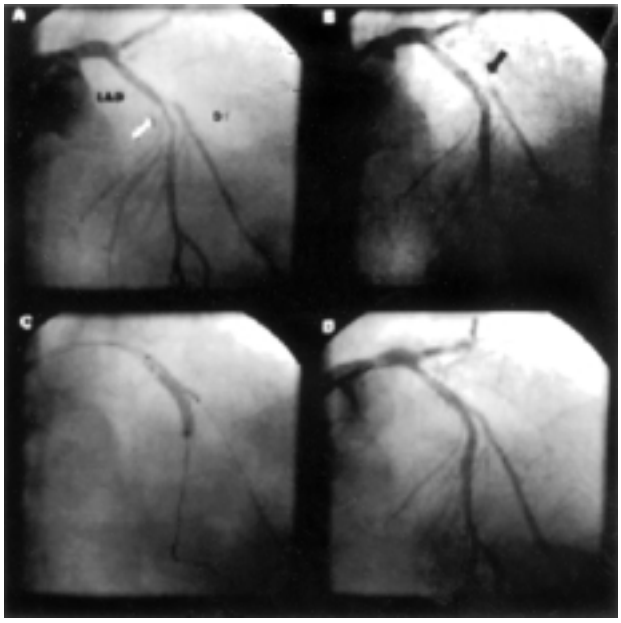

Figure 2. *Case example of direct stenting via a transradial approach on a bifurcation lesion* (panel A). *The* white arrow *indicates a significant stenosis on the mid left anterior descending coronary artery (LAD). A stent (Snapper 3.0/24) was directly positioned on the mid LAD (guiding catheter Radial 6F), with partial occlusion of the ostium of the first diagonal branch (D1)* (black arrow) (panel B). *The procedure was successfully completed with the kissing-balloon technique* (panel C) *and immediate angiographic success* (panel D).

When opting for a systematic strategy of direct stenting via a transradial approach, the choice of an adequate stent is of great importance. The ideal device should be characterized by a low profile, good flexibility and traceability and an adequate radiopacity. The device struts should also respect the ostia of side branches or, at least, allow easy re-crossing. The coronary stents available on the market may perform differently to each other in these particular settings[18]. To avoid possible confounding effects, we opted for a single-stent study: the new-generation stent we chose (Snapper) proved to perform very well, with only minor concerns for a tendency to distal dissections (4 cases) when the stent was deployed at high pressures.

Six-month outcomes of direct stenting via a transradial approach. On the basis of promising results in animal models, it has been hypothesized that direct stenting could have a favorable effect on long-term events and restenosis[19]. Direct stenting may induce less endothelial damage, and, by definition, no "geographical mismatch" between the segment injured by the balloon and that covered by the stent. Indeed, preliminary results from the E-SIRIUS trial suggest that geographical mismatch could be a critical issue after drug-eluting

stent implantation, and that direct stenting can be of advantage in further reducing restenosis rates in this setting (2.4 vs 7.2% of 9-month binary restenosis, respectively for direct stenting vs predilation with the sirolimus-eluting stent)[20].

The long-term results of direct stenting are somewhat discordant[4,21,22] among all randomized studies. However, when data are pooled together, it appears that direct stenting yields the same long-term outcomes as conventional stenting, with a trend toward reduced restenosis and long-term events. Nevertheless, it could be assumed that, due to its technical complexity, direct stenting via a transradial approach, even when successful, could achieve less-than-optimal results. This may translate in a higher rate of adverse events and restenosis at the medium-to-long-term follow-up. In our study the MACE rate at 6 months was 14%, mainly due to repeated revascularization. No deaths were reported. The recurrent ischemia and target lesion revascularization rates were 15 and 10% respectively. These data are in agreement with those of Laarman et al.[10], who found 6-month follow-up mortality, target lesion revascularization and MACE rates of 2, 5.2, and 20% respectively, and with those of Ijsselmuiden et al.[9], who reported 79% of angina-free and 89% of event-free patients at 7 ± 2.8 months. When taken cumulatively, all these non-randomized series of patients, including ours, suggest that the long-term outcomes of direct stenting performed via a transradial approach are more than satisfactory.

Limitations of the study. Our study was not randomized and so it is not possible to draw definitive conclusions about the advantages of direct vs conventional stenting, and of a transradial vs femoral approach. Historical control groups or other studies can offer a useful comparison, still taking into account the rapid evolution of methods and materials over the years, and the differences in approach among different operators.

Having included only patients with single-vessel disease, neither can we draw definitive conclusions on the safety and feasibility of direct stenting via a transradial approach in the ever-growing population with multivessel PCIs. Although dedicated studies are needed, we feel that the transradial approach does not prevent us from successfully performing stenting in patients with multivessel disease. Still, the feasibility of direct stenting in multivessel PCIs should be evaluated on a per-vessel basis.

In conclusion, a systematic strategy of direct stenting via a transradial approach can be successfully adopted in the majority of patients undergoing single-vessel PCI, both in elective and urgent cases, even when complex lesions and/or high-risk patients are treated. Indeed, both the immediate, in terms of angiographic success and in-hospital events, and 6-month outcomes, in terms of late events and clinical restenosis, are remarkably favorable. In addition, this strategy appears safe and virtually void of bleeding complications at the access site.

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