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CLINICAL RESEARCH

Clinical and angiographic results of angioplasty with a paclitaxel-eluting stent for unprotected left main coronary artery disease (a study of 101 consecutive patients)

Résultats cliniques et angiographiques de l'angioplastie avec stent au paclitaxel des sténoses du tronc commun coronaire gauche (à propos de 101 patients consécutifs)

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KEYWORDS
Left main;
Angioplasty;
Drug-eluting stent;
Re-stenosis.

Summary
Background. — After coronary stenting with drug eluting stents, long-term clinical outcome of unprotected left main coronary artery disease is unknown, even large scale registries or randomised trials with coronary artery bypass graft are ongoing.
Aims. — To report clinical and angiographic results of paclitaxel-eluting stent implantation for left main coronary artery stenosis (a series of 101 consecutive patients).
Methods. — This report is a prospective study performed to evaluate the immediate and mid-term clinical and angiographic outcomes of patients undergoing paclitaxel-eluting stent (PES) implantation for unprotected left main coronary artery (LMCA) stenosis.
From January 2004 to December 2005, 101 consecutive patients were stented with paclitaxel-eluting stents (the provisional T stenting technique followed by Kissing balloon for distal left main vessel disease).
Results. — Mean age was 68.9±11.07 years. 73.3% of patients were male. Acute coronary syndrome was present in 65% of patients, of whom 22.8% had ST elevation. Distal left main trunk lesions were present in 87.1% of cases. Three-vessel disease represented 7% of cases. Angiographic success was obtained in 97.03% of patients with an acute gain of 2.18±0.53mm. GPIIbIIIa inhibitors were used in only 8.9% of cases. Hospital stay was 7.6 ± 3.7 days. In-hospital complications were present in 7.9%, with a hospital mortality rate of 2%.
At six month follow-up, the rate of target lesion revascularization (TLR) was 3%, and the rate for major adverse cardiac events (MACE) was 8.9%. Angiographic control was performed in 88.1% and a late loss of 0.1mm (0.04-0.2mm) was noted. Re-stenosis occurred in 4 patients (4.5% of cases). 4 patients (4%) died, including 2 from cardiac causes.

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Conclusion. — Paclitaxel-eluting stent implantation for unprotected left main coronary disease appears to be safe with high procedural success rate and a low re-stenosis rate at six month-follow-up.
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MOTS CLÉS
Tronc coronaire gauche;
Angioplastie;
Stent actif;
resténose.

Résumé
Justification. — L'histoire naturelle des dilatations avec stents des lésions du tronc commun de la coronaire gauche reste mal connue, en l'absence d'étude à large échelle et de comparaison randomisée à la chirurgie.
Objectifs. — Cette étude prospective rapporte les résultats immédiats et à moyen terme de l'angioplastie avec stent au Paclitaxel du tronc commun coronaire gauche (TCG).
Méthodes. — De Janvier 2004 à Décembre 2005, 101 patients consécutifs ont eu une dilatation suivi de stenting du TCG avec stent actif au paclitaxel (la technique du T provisional stenting a été utilisée pour les lésions distales).
Résultats. — L'âge moyen est de 68.9 ± 11.07 ans avec une prédominance masculine (73.3%). Un tableau de syndrome coronarien aigu est présent dans 65% des cas dont 22.8% avec élévation du segment ST. Les lésions de bifurcation du TCG distal sont présentes dans 87.1% des cas. L'atteinte tritronculaire représente 7% des cas. Le succès angiographique est obtenu dans 97% des cas avec un gain précoce de 2.18±0.53mm. Le recours aux anti-Gp IIb-IIIa a été nécessaire dans 8.9% des cas. La durée d'hospitalisation est de 7.6±3.7 jours. Les complications hospitalières sont présentes dans 7.9% dont 4% d'origine cardio-vasculaire. Le taux de mortalité hospitalière est de 2%. A 6 mois, le taux de revascularisation de la lésion cible est de 3% et celui des évènements cardio-vasculaires majeurs est de 8.9%. Le contrôle angiographique (88.1%) retrouve une perte tardive de 0.1 (0.04-0.2) mm avec 4 cas de resténose soit 4.5%. 4 décès (4%) surviennent dont 2 d'origine cardiaque.
Conclusion. — L'angioplastie avec stent actif au paclitaxel du TCG paraît une technique fiable avec un taux de succès initial important et un faible taux de resténose à 6 mois.
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Abbreviations	
ACS	Acute coronary syndrome
ACT	Activated cephalin time
AG	Acute gain
AVK	Antivitamin K (oral anticoagulant)
CABG	Coronary artery bypass graft
CK-MB	Creatinine phosphokinase MB fraction
CX	Circumflex artery
CXO	Circumflex artery ostium
DB	Daughter branch
HIV	Human immunodeficiency virus
LAD	Left anterior descending
LADO	Left anterior descending ostium
LL	Late loss
LMCA	Left main coronary artery
MACE	Major adverse cardiac events
MB	Mother branch
MI	Myocardial infarction
MLD	Minimal luminal diameter
OBTO	Obtuse-diagonal artery ostium
PCA	Percutaneous coronary angioplasty
PES	Paclitaxel-eluting stent
RVD	Reference vessel diameter
SD%	Stenosis diameter percentage
SL	Stenosis length
TIMI	Thrombolysis In Myocardial Infarction
TLR	Target lesion revascularization
UFH	Unfractionated heparin

Significant stenoses of the left main coronary artery (LMCA) are revealed in 5 to 7% of patients undergoing coronary angiography (1, 2, 3). Medical treatment alone is associated with a 3 year mortality of 50% (4, 5). Several studies have demonstrated the benefits of surgical treatment with coronary artery bypass graft (CABG) compared to medical treatment (6, 7). The results of angioplasty in the early series showed an increased rate of re-stenosis and acute thrombotic occlusion. This led various respected bodies (American College of Cardiology and American Heart Association) to favour surgery for unprotected LMCA revascularization (3, 8). However, since these recommendations were made, several technological developments and new drugs have appeared.

With this in mind, a re-evaluation of optimal treatment for unprotected lesions of the LMCA would seem essential, especially in the light of recent data from observational studies suggesting that dilatation of unprotected LMCA with drug-eluting stents based on sirolimus (Cypher) or paclitaxel (Taxus) are safe and effective in reducing the re-stenosis rate compared to bare-metal stents (3, 9,10, 11, 12).

Throughout our study, we attempted to corroborate these data and to show the feasibility, safety, and immediate and mid-term results of treating unprotected LMCA stenoses by systematic implantation of a paclitaxel-eluting stent.

Materials and methods

Patients

From January 2004 to December 2005, 101 consecutive patients with unprotected LMCA stenosis underwent percu-

taneous dilatation with implantation of a paclitaxel-eluting stent, representing 2.5% of overall activity. The LMCA was considered to be unprotected when there was no coronary bypass supplying the LAD or circumflex artery (CX).

The inclusion criteria were symptomatic lesions or angiographic stenoses > 50% with documented myocardial ischemia. The decision to perform percutaneous angioplasty was taken if the coronary anatomy was favourable and the patient or referring physician requested it, in the absence of surgical contraindications or significant comorbidity. Patients with a contraindication to platelet anti-aggregant treatment were excluded. In keeping with the Helsinki principles, this study was approved by the local ethics committee, and clear written consent was obtained for each patient.

Procedure

All of the patients received 160mg aspirin daily for life, and a loading dose of clopidogrel 300mg 12 hours before the procedure if they had not already received it, followed by 75mg a day for 6 months in the absence of any instability. In cases of acute coronary syndrome this double anti-aggregation therapy was continued for a year. Anticoagulation with a bolus of 55 U/kg of unfractionated heparin was administered during the procedure, keeping the ACT > 250 seconds. The use of GPIIbIIIa inhibitors was left to the discretion of the individual operators.

The various angioplasty techniques used were carefully noted (pre-dilatation of the stenosis with a balloon, or rotablator, followed by stenting; direct stenting; provisional T stenting with kissing balloon). In the case of LMCA bifurcation angioplasty, provisional T stenting was performed as follows: angioplasty with positioning of the stent in the distal LMCA and the ostium of one of the two coronaries (*LAD*O or CXO), known as the mother branch (MB); the ostium of the other coronary or daughter branch (DB) was then dilated with a kissing balloon across the stent mesh after having changed the guides between the two arteries. In cases where the result was incomplete, a second endoprosthesis was positioned, either at the distal LMCA and the ostium of the second branch (Y stent), or solely at the ostium of the second branch (T stent); the procedure was finished with a final kissing balloon, with the balloons of both stents being inflated simultaneously.

Quantitative coronary angiography

The coronary angiography acquisition and analysis was performed using a digital system (MEDICAL QCA/CMS MEDIS Imaging System). After administration of 1mg of molsidomine, the images were recorded and then transferred to CD-ROM. The stented coronary segment was then analysed. For angioplasty of the LMCA-LADO-CXO bifurcation, the stented segment of the MB (LMCA-LADO or LMCA-CXO) was analysed as well as the ostium of the non-stented daughter branch.

Quantification of the segments in two orthogonal projections was performed whenever possible, before and after angioplasty, and also during angiographic control at 6 months. The measurements taken were the minimum luminal diameter (MLD), reference vessel diameter (RVD), stenosis diameter percentage (SD%), and stenosis length (SL). After angioplasty, quantification was carried out for the residual stenosis percentage (post-dilatation SD%), post-dilatation MLD, and the acute gain (AG), defined as post-dilatation MLD less pre-dilatation MLD. A stenosis percentage less than 30% following dilatation was used to define primary success. At 6 months, quantification was carried out for SD%, MLD and late loss (LL), defined as the difference between post-dilatation MLD at month 0 and month 6. A reduction in luminal diameter greater than or equal to 50% (including complete obstruction) at six months was considered as significant re-stenosis.

Modes of follow-up

All of the patients were evaluated clinically at 1 and 3 month consultations, and again in hospital at 6 months, or by telephone for the patients who were followed up for more than 8 months. A check angiography was carried out systematically during hospitalisation or earlier in the presence of clinical symptoms or evidence of myocardial ischemia.

Definitions

Angiographic success was defined as grade 3 TIMI flow, a degree of residual stenosis determined by quantitative angiographic analysis < 30% and the absence of major adverse cardiac events (MACE). Myocardial infarction was defined as an elevation of creatinine kinase more than twice normal with elevation of the CK-MB fraction. Angiographic re-stenosis was defined as more than 50% stenosis in the mother or daughter branch at angiographic control after 6 months.

Statistical analysis

The results are presented as a mean and standard deviation of the mean for quantitative variables. Qualitative variables are expressed as a percentage. For continuous variables the data are presented as mean deviation and interquartile range. Statistical analysis was performed using SAS statistical software (SAS/STAT user's guide, release 6.12; SAS Institute Inc).

Results

Patients' clinical characteristics

The baseline clinical and angiographic data are summarized in Table 1. A total of 101 patients, predominantly male (73.3%) underwent LMCA dilatation. The mean age was 68.92 ± 11.07 years, ranging from 34 to 87 years. Diabetes was present in 23.8% of our patients. 20% had already had a revascularization procedure, either CABG or angioplasty. 65% underwent an emergency procedure in the context of acute coronary syndrome (ACS), of whom 22.8% had ACS with ST elevation. 73.7% of our patients had a medium or increased Euroscore risk. The left ventricular ejection fraction was reduced (<40%) in 28.2% of cases. The mean hospital stay was 7.6 ± 3.7 days. In-hospital complications occurred in 7.9%, including 4% which were of cardiovascular origin. The hospital mortality rate was 2%.

Patients' angiographic characteristics : Table 2

A radial approach was used in 9.9% of cases, and a femoral approach in 88.1%. The LMCA lesions were mostly distal at the bifurcation (87.1%). Ostial lesions represented only

Table 1 Clinical characteristics

	n	%
Number of patients	101	100
Male	74	73.27
Female	27	26.73
Age (years)	68.92 ± 11.07 (range 34 - 87)	
Cardiovascular risk factors		
Hypertension	60	59.41
Active smoking	56	55.44
Dyslipidemia	60	59.41
Diabetes	24	23.76
Family history	12	11.88
Body mass index (kg/m²)	26.65 ± 4.16	
Previous revascularization	20	20
Angioplasty	16	16
Coronary artery bypass graft	3	3
Mixed	1	1
None	80	80
Ejection fraction (%)	54.4 ± 18.25	
< 40%	22	28.20
Reason for angioplasty		
Silent ischemia	9	8.91
Stable angina	18	17.80
Unstable angina	39	38.61
Non Q wave MI	6	5.94
Q wave MI	23	22.77
Heart failure	6	5.94
Euroscore		
Low risk (1-2)	20	26.31
Moderate risk (3-5)	38	49.99
High risk (6 and +)	18	23.70
Pre-PCA troponin (ng/ml)	23.27 ± 64.70	
Creatinine (µmol)	100.47 ± 26.70	

MI : Myocardial infarction
PCA : Percutaneous coronry angioplasty

11.9% and median lesions 1% of cases. The distal lesions usually encompassed the ostium of the left anterior descending artery (LADO) either alone (57.3%) or in conjunction with the ostium of the circumflex artery (CXO) (19.1%). In 2.3% of cases the stenosis involved the trifurcation of the distal LMCA. Coronary involvement was diffuse in 25% of cases (two-vessel disease: 18%, three-vessel disease: 7%).

Procedural results

The procedural characteristics are summarized in Table 3. In 79.2% of cases dilatation was performed by direct sten-

Table 2 Angiographic characteristics

	n	%
Approach		
Femoral	89	88.12
Radial	10	9.90
Humeral	2	1.98
LMCA stenosis site		
Non-distal LMCA	13	12.87
Distal LMCA	88	87.13
LMCA stenosis combinations		
LMCA-LADO	51	57.30
LMCA-CXO	14	15.30
LMCA-LADO-CXO	17	19.10
LMCA-CXO-OBTO	3	3.37
LMCA-CXO-LADO-OBTO	2	2.25
Coronary status		
Single vessel	34	34
Two vessel	18	18
Three vessel	7	7

LMCA : Left main coronary artery
LADO : Ostial left anterior descending artery
CXO : Ostial circumflex artery
OBTO : Ostial obtuse diagonal artery

Table 3 Procedure characteristics

	n	%
Procedure		
Pre-dilatation	21	20.79
Direct stenting	80	79.21
LAD stent	70	
Secondary branch stent	19	
Kissing balloon	81	
Simultaneous double kissing balloon	6	
Provisional T stenting (1 stent)	83	
T stenting (2 stents)	16	
Other technique (Y)	2	
Mean inflation pressure (atm)	14.97	
Mean stent diameter (mm)	3.45 ± 0.44	
Mean stent length (mm)	14.79 ± 1.21	
Successful procedure	98	
Associated treatment		
GPIIbIIIa inhibitor	9	8.91
Aortic counterpulsion	1	0.99
AVK + two antiplatelet agents	5	5

LAD : *left anterior descending* artery
AVK : Antivitamin K (oral anticoagulant)

ting. Pre-dilatation for tight stenoses or a very calcified angiographic appearance was only necessary in 20.8% of cases. The endoprosthesis was positioned on the LADO in 78.6% of patients. Among the patients with bifurcation lesions, a final kissing balloon was carried out in 83.5% and a double kissing balloon (simultaneous inflation of 3 balloons) was necessary in 5.9% of patients. The angioplasty procedure involved provisional T stenting (single stent implanted) or 2 stents in the form of a T in 15.8% of patients. The technique of 2 stents implanted in the form of a Y was carried out in 2% of cases. The mean diameter of the stents was 3.45 ± 0.44mm and the mean inflation pressure was 15 atm. GPIIbIIIa inhibitors were only required in 9% of cases.

The overall success rate was 97%. Three failed angioplasties (3%) were recorded (1 stent thrombosis, 1 dissection, 1 no-reflow). Two in-hospital deaths occurred (1 stent thrombosis, and 1 retroperitoneal hematoma). The results of quantitative angiographic analysis are presented in Table 4. The reference vessel diameter was 3.39 ± 0.42mm. The minimal luminal diameter increased after angioplasty from 1.2 ± 0.48 to 3.37 ± 0.45mm ; and the stenosis percentage decreased from 62.4 ± 8.2 to 11 ± 10.2%. The acute gain was 2.18 ± 0.53mm.

Table 4 Baseline and post-procedure angiographic data

Reference vessel diameter (mm)	
MB	3.39 ± 0.42
DB	3.10 ± 0.54
Lesion length	
MB	7.4 ± 2.8
DB	6.8 ± 2.14
Minimum luminal diameter (mm)	
MB	
Basal	1.2 ± 0.48
Final	3.37 ± 0.45
DB	
Basal	2.33 ± 0.39
Final	3.05 ± 0.57
Degree of stenosis (%)	
MB	
Basal	62.4 ± 8.2
Final	11.05 ± 10.2
DB	
Basal	24.73 ± 23.8
Final	7.4 ± 8.5
Acute gain (mm)	
MB	2.18 ± 0.53
DB	0.72 ± 0.79

MB : mother branch
DB : daughter branch

Six-month results

Angiographic control at 6-months was performed in 89 patients (88.1%). 12 patients were not checked (4 deaths, 1 lost to follow-up, 7 due to refusal or co-morbidity). Quantitative angiographic analysis is presented in Table 5. The degree of stenosis was 14.3 ± 8.5% and the late loss was 0.1mm (0.04 - 0.2mm). 4 cases of re-stenosis occurred in the daughter branches in 3 patients, and was diffuse in a fourth.

9-month results

The mean duration of follow-up was 12.15 ± 3.18 months, and the clinical follow-up rate was 99.0% (1 patient lost to follow-up). A total of four patients died (two from cardiac causes): in addition to the two in-hospital deaths, there was one sudden death at 6 months, and one death from septic shock associated with HIV infection at 5 months. The cumulative rate of major adverse cardiac events (Table 6), including death from all causes, myocardial infarction, heart failure, target lesion revascularization was 8.9%, with a revascularization rate of 3%. The overall mortality rate was 4%.

Characteristics of patients with re-stenosis

Among the four patients with re-stenosis, three were asymptomatic. The LMCA lesion was distal in all four cases, with three-vessel disease in two cases. A T-stenting angioplasty had been performed in three cases, with direct stenting in all three. Three patients underwent revascularization (1 CABG and 2 angioplasties).

Table 5 9-month follow-up

	To	T>6 months(cumul)
Deaths	2	4
Cardiac	1	2
Non-cardiac	1	2
Myocardial infarction	1	1
Heart failure	0	1
Target lesion revascularization	0	3
Others		
Stent thrombosis	1	1
Stroke	1	1
Acute renal failure	2	2
Major hemorrhage	1	1
Rhythm disorder	2	2
Major cardiovascular adverse events	4 (4.0 %)	9 (8.9%)
Total mortality	2 (1.98%)	4 (3.96%)

Table 6 Angiographic data at 6 months (n=89; 88.1%)	
Minimum luminal diameter (mm)	
MB	3.16 ± 0.54
DB	2.85 ± 0.77
Degree of stenosis (%)	
MB	14.34 ± 8.5
DB	10 ± 12.5
Late loss (mm)	
MB	0.1 (0.04-0.2)
DB	0.03 (0-0.16)
Angiographic re-stenosis	4.49%
MB	1
DB	3

MB : mother branch
DB : daughter branch

Discussion

The first studies concerning angioplasty of the left main coronary artery disease without stent implantation often reported unsatisfactory mid- and long-term results (13, 14), restricting this procedure to inoperable patients, those with protected left main trunks (15) and cases of myocardial infarction with acute occlusion of the left main trunk (16, 17).

The recent development of coronary endoprostheses together with advances in implantation techniques and peri-procedural anti-thrombotics have spectacularly reduced thrombotic and hemorrhagic complications following endoprosthesis implantation. However, intra-stent re-stenosis is the principal factor limiting long term efficacy (12) and is probably associated with an surplus of late mortality for LMCA angioplasties (12, 20, 21).

In a recent series reported by the authors (12), 57 patients underwent coronary dilatation with implantation of bare-metal stents for unprotected LMCA stenoses. At 8 month follow-up, the rate for myocardial infarction was 5.1% and 22.8% for revascularization. The rate of angiographic re-stenosis was 29.8%.

The advent of drug-eluting stents has resulted in a reduction in re-stenosis in several series (21, 22, 23). A recent report from the T-SEARCH registry suggested that implantation of a paclitaxel-eluting stent for LMCA stenoses has a favourable effect on reducing re-stenosis (11). Despite these encouraging results, angioplasty of the main trunk remains a complicated procedure with very high risks. Angioplasty of the bifurcation of the distal LMCA is an additional problem in the treatment of LMCA lesions, because it combines the risks of LMCA dilatation with the technical difficulties inherent at the bifurcation. Several techniques have been described for treating bifurcation lesions (provisional T stenting, Crush stenting…) with the recent introduction of bifurcation-dedicated stents (data insufficient at present).

Very few studies have evaluated the results of LMCA angioplasty using drug-eluting stents. Valgimigli et al in the RESEARCH and T-SEARCH study of 110 patients undergoing LMCA angioplasty with a drug-eluting stent (sirolimus and paclitaxel), reported a lower distal stenosis rate (76%) than in our series. Their dilatation procedure included a higher pre-dilatation rate (60%) and a kissing balloon technique in only 20%. The acute gain was lower with a higher late loss. Re-stenosis in the paclitaxel group was 13% and the rate of major adverse cardiac events was 29% (11). In another study, Chieffo et al revealed a MACE rate of 20% and a mortality of 3.5% (10). In a comparison with coronary artery bypass surgery, a recent study on 123 patients showed a higher MACE rate in the CABGs group (3).

Our series is distinguished by the patients' elevated mean age (68. 92 ± 11.07 years), the inclusion of high-risk individuals (increased Euroscore risk in 23.7%), and a significant rate of left ventricular dysfunction (28.2%). However, we recorded a MACE rate of just 8.9%, a mortality rate of 4%, and a re-stenosis rate of 4.5%, all of which are relatively low compared to the rates reported in the literature.

In the various reported studies, mortality varies between 0% and 12%. In our work it was only 4%, despite the presence of high-risk patients and a surplus of LMCA bifurcation lesions. Although our rate of angiographic control was not totally exhaustive, we recommend systematic coronary angiographic control between 6 and 12 months, in view of the serious and complex nature of main trunk lesions. This would seem to be more specific and more sensitive than a stress test or coronary CT. In our study we have attempted to determine the predictive factors for major adverse cardiac events. However, no significant relationship was shown between the different parameters due to our low complication rate.

Table 7 Characteristics of patients with re-stenosis					
Age and sex	Dilatation strategy	LMCA stenosis site	Clinical state	Re-stenosis site	TLR
M, 54 years	Provisional T stenting	Distal	Asymptomatic	DB	None
M, 84 years	T stenting	Distal	Asymptomatic	DB	PCA
M, 58 years	T stenting	Distal	Angina	Diffuse	CABG
M, 73 years	T stenting	Distal	Asymptomatic	DB	PCA

TLR : target lesion revascularization
MB : mother branch
DB : daughter branch
PCA : Percutaneous coronary angioplasty
CABG : Coronary artery bypass graft

Limits of this study

Our work concerns a limited number of patients and our results cannot be generalised to all LMCA lesions. In addition, the angiographic data were not analysed by a central laboratory, and the evaluation of the procedure's final result was not confirmed by endocoronary echography. Lastly, the data could have been biased by the individual experience of the different LMCA angioplasty operators, and should not be generalised to all interventional centres.

Conclusion

Coronary artery bypass remains the treatment of reference for lesions of the unprotected left main coronary artery. However, data from recent studies showing that drug-eluting stents reduce mortality and intra-stent re-stenosis will probably improve the therapeutic management of these lesions. Multicenter and randomised trials are required to compare surgery with drug-eluting stent angioplasty in the management of these complex left main trunk lesions.

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