

# Stent implantation for the unprotected left main coronary artery. The long-term outcome of 62 patients

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## Abstract

**Introduction:** Stent implantation for the unprotected left main coronary artery (ULMCA) is regarded as controversial and coronary heart disease with LMCA stenosis still remains a basic indication for bypass surgery. Although there is no doubt that the risk of stent implantation for LMCA lesions is low, there are still limited data on long-term outcomes. There have been no reports so far answering the question whether ULMCA stenting ensures adequate coronary blood flow in the vessel.

**Aim:** Assessment of the effect of LMCA flow restoration with stenting on the coronary flow reserve assessed by an exercise test, as well as on left ventricular function and angina in patients followed for 12 months after the procedure.

**Methods:** The study population included 62 patients (17 women and 45 men) aged 61.4±11.1 (35-84 years) who underwent coronary angioplasty with elective ULMCA stenting. In all patients, serial echocardiography (before and 1, 3, 6, and 12 months after the procedure) and the exercise test according to the Bruce protocol (1, 3, 6, 12 months after the procedure) were carried out. Routine coronary angiography was performed 3 to 6 months after the procedure. Fifty-nine patients (95.2%) survived a 12-month period. In 24 (38.7%) patients major adverse cardiac events (MACE) occurred. In-stent restenosis was observed in 13 patients; in 11 of them repeated PCI was performed and 2 of them underwent CABG. One patient after repeated PCI required CABG.

**Results:** Severity of angina, evaluated according to the CCS scale, decreased significantly in the 12-month follow-up period as compared with the preprocedural period ( $p < 0.00001$ ). The mean baseline left ventricular ejection fraction was 51.6±12.5%. It increased to 53.8±12.8% ( $p < 0.02$ ) at 6 months and remained at this level at 12 months. The mean exercise test time was 7.0±3.4 minutes in the first month after ULMCA stenting, and in the sixth and the twelfth month of follow-up it increased to 7.6±3.4 minutes ( $p < 0.002$ ) and 7.8±3.2 minutes ( $p < 0.05$ ), respectively. The metabolic equivalent task (MET) value did not change significantly during the observation period.

**Conclusions:** Restoration of the physiological blood flow in the unprotected left main coronary artery with stent implantation is associated with a significant reduction of angina, significant improvement of the left ventricular systolic function and preservation of exercise capacity in long-term follow-up.

**Key words:** left main coronary artery stenting, ejection fraction

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## Introduction

In 3-5% of patients undergoing coronary angiography, left main coronary artery stenosis (LMCA) is found. Medical therapy is associated with

poor prognosis, and coronary artery bypass grafting (CABG) significantly prolongs the life of these patients [1-4]. However, over long-term follow-up, mortality increases in this group, approaching mortality in the

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**Table I.** Baseline characteristics of study population (n=62)

Age [years]	61.4±11.1
Men [%]	72.5
Cardiovascular risk factors [%]	
hypertension	71
diabetes mellitus	19
smoking	40
hypercholesterolaemia	60
unstable angina [%]	48.3
CABG not applicable [%]	37.1
Left main coronary stenosis; segment [%]	
proximal	37
medium	11
distal	52
Significant lesions [%]	
RCA	56
LAD	73
Cx	53
Previous PCI [%]	21
Low left ventricular ejection fraction (EF ≤35%)	11.3
PCI ULMCA and additional PCI [%]	
of one arteries	32.3
of two arteries	29
of three arteries	16.1

Abbreviations: CABG – coronary artery bypass grafting, LAD – left anterior descending coronary artery, RCA – right coronary artery, Cx – circumflex coronary artery, PCI – percutaneous coronary intervention, ULMCA – unprotected left main coronary artery, EF – left ventricular ejection fraction

conservative therapy group [3-5]. The reasons for this include natural atherosclerosis progression in native vessels, accelerated vein grafts degeneration, as well as embolic episodes in the peripheral segments of native vessels, supplied by grafts [6].

The advancement in percutaneous coronary interventions (PCI) and widespread availability of intracoronary stents enabled unprotected LMCA (ULMCA) stenting [7-14]. Despite early benefits, ULMCA stenting is regarded as controversial and coronary heart disease with LMCA stenosis is still thought to require bypass surgery. Although there is no doubt that the risk of stent implantation for LMCA lesions is low, there are still limited data on long-term outcomes. There have been no reports so far answering the question whether ULMCA stenting ensures adequate coronary blood flow in the vessel.

### Aim of the study

To assess the effect of LMCA flow restoration with stenting on the coronary flow reserve assessed by an exercise test, as well as on left ventricular (LV) function and angina in patients followed for 12 months after the procedure.

### Methods

Sixty-two patients (17 women and 45 men), aged 61.4±11.1 (35-84 years), who underwent PCI with elective ULMCA stenting from January 1997 to June 2003 were enrolled into the study. The study protocol was approved by the Silesian Medical Academy Ethics Committee. Demographic characteristics of the analysed group are given in Table I.

In all patients a successful ULMCA stenting procedure was performed.

Baseline echocardiography was performed 1-2 days before stent implantation and control assessment (exercise testing and echocardiography) was planned at 1, 3, 6 and 12 months. Control quantitative coronary angiography (QCA) analysis was planned at 3-6 months after stenting.

Two-dimensional echocardiography was performed using Hewlett-Packard Sonos 1000 in standard views to assess the global LV ejection fraction (LVEF) (measured from apical two- and four-chamber views using Simpson's rule). Treadmill tests were performed according to the Bruce protocol. Total exercise time and metabolic equivalent task (MET) values were taken into account.

### Statistical analysis

Values of parametric data are given as the mean value and standard deviation (±SD). Nonparametric data are given as absolute and percentage values. Comparison of the same variables at prespecified time-points was carried out with analysis of variance (ANOVA, Friedman's ANOVA).

### Results

Fifty-nine (95.2%) patients survived 12 months. In 24 (38.7%) patients major adverse cardiac events (MACE) occurred. In-stent restenosis in the ULMCA was observed in 13 patients. Repeated PCI (re-PCI) was performed in 11 patients. All patients after re-PCI underwent control angiography after 3-6 months. Due to recurrent restenosis in the ULMCA, three patients required another (third) PCI.

The CABG procedure due to restenosis in the ULMCA was performed in three patients. Two of these patients required surgery for first in-stent restenosis; in one patient who underwent two percutaneous revascularisation procedures (stent implantation and subsequent balloon angioplasty of the restenosis) the

**Table II.** Data from digital angiogram analysis in patients with ULMCA stenting

	mean	minimum	maximum	median	±SD	SE
REF. PROX [mm]	3.70	1.37	5.55	3.64	0.79	0.10
REF. DYST [mm]	3.46	2.01	5.54	3.44	0.78	0.10
ULMCA Length [mm]	12.64	4.25	21.50	12.35	3.94	0.51
Stenotic lesion length [mm]	5.74	1.71	17.04	5.27	2.78	0.37
MLD0 [mm]	1.56	0.40	2.88	1.64	0.60	0.08
MLD1 [mm]	3.27	2.01	4.78	3.19	0.70	0.10
MLD2 [mm]	2.32	0.40	3.56	2.41	0.81	0.12
DS0 [%]	60.32	40.00	84.24	58.6	11.70	1.59
DS1 [%]	11.85	0.00	40.00	8.17	8.99	1.27
DS2 [%]	28.00	3.59	85.00	19.2	23.13	3.34
AG [mm]	1.73	0.44	3.61	1.73	0.66	0.09
LL [mm]	1.02	-0.48	3.07	0.87	0.75	0.12
LLI	0.64	-0.31	1.42	0.64	0.44	0.07

Abbreviations: SD – standard deviation, SE – standard error, REFPROX. – proximal segment reference diameter, REF. DYST. – distal segment reference diameter, MLD0 – minimal lumen diameter before stenting, MLD1 – minimal lumen diameter immediately after stenting, MLD2 – minimal lumen diameter in control angiogram, AG – acute gain, LL – minimal diameter lumen loss, LLI – minimal diameter lumen loss index

decision to perform elective CABG was forced by the relapse of restenosis.

Three deaths (4.8%) were recorded during twelve months of follow-up. The causes included: myocardial infarction (two months after stent implantation, de novo LAD lesion), sudden cardiac death five months after the procedure (probably due to third-degree atrioventricular conduction block, which was periodically present before the stenting), and cholesterol embolisation syndrome six months after stenting.

Angiographic characteristics from the studies at follow-up are shown in Table II.

Severity of angina, evaluated according to the CCS scale, decreased significantly in the 12-month follow-up period as compared with the preprocedural period ( $p < 0.00001$ ). The changes in anginal symptoms during twelve months of observation are shown in Figure 1.

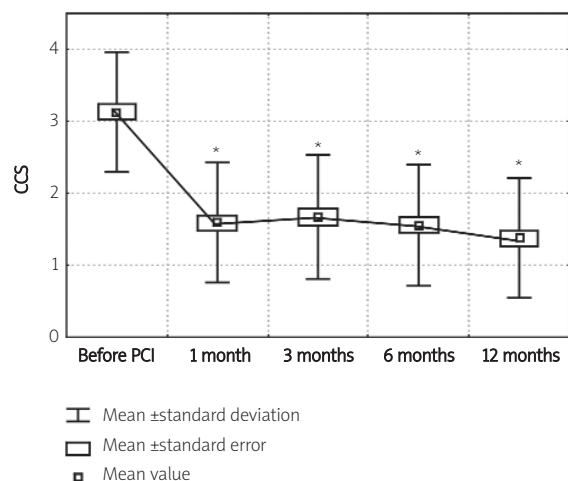
In long-term follow-up, the LVEF was found to be higher than at baseline. The mean LVEF at baseline was  $51.6 \pm 12.5\%$ , it increased to  $53.8 \pm 12.8\%$  ( $p < 0.02$ ) at six months and remained at this level at 12 months (Figure 2).

The mean exercise test duration was  $7.0 \pm 3.4$  minutes in the first month after ULMCA stenting, and  $7.6 \pm 3.4$  minutes ( $p < 0.002$ ) and  $7.8 \pm 3.2$  minutes ( $p < 0.05$ ) in the sixth and the twelfth month, respectively (Figure 3).

Benefits of the procedure were confirmed with serial treadmill tests using the standard Bruce protocol. The mean exercise duration and metabolic equivalent task (MET) evaluated with ANOVA test did not change significantly during the observation, but there was a significant increase of exercise duration with

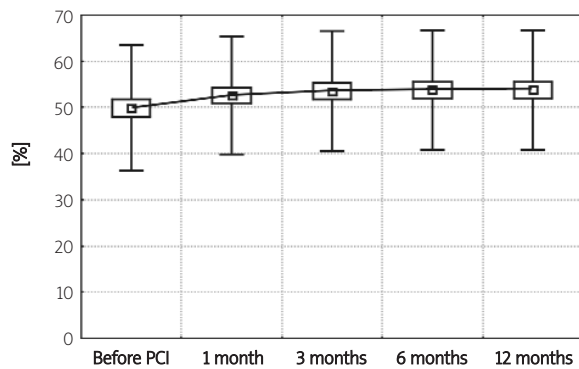
Student's t-test analysis at six ( $p < 0.002$ ) and twelve ( $p < 0.03$ ) months, as well as good exercise tolerance during the whole observation period.

At the first month of follow-up, the mean metabolic equivalent task value was estimated to be  $8.9 \pm 3.1$  MET, at the sixth month  $9.3 \pm 3.2$  MET ( $p = 0.08$ , NS) and at twelve months  $9.7 \pm 2.9$  MET ( $p = 0.35$ , NS) (Figure 4).



\* $p < 0.001$  vs baseline

**Figure 1.** Changes in anginal symptoms according to the CCS scale during twelve-month follow-up



$p < 0.023$  baseline vs follow-up results  
Abbreviations: as in Figure 1

**Figure 2.** Left ventricular ejection fraction (EF) during twelve-month follow-up

## Discussion

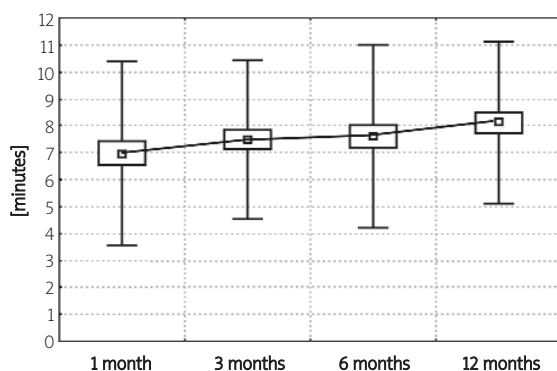
The present study is the first prospective clinical trial which aims to evaluate LV function and exercise capacity in patients with ULMCA stenosis, based on serial echocardiograms and exercise tests.

Constant, significant improvement of LV systolic function as compared to baseline was observed in our study. Available medical literature lacks data on LV function improvement in patients after ULMCA stenting. However, studies on other patient populations (with low LVEF, acute myocardial infarction, chronic vessel occlusion or after stenting of another coronary vessel) reported an improvement of LV function assessed by echocardiography after PCI [15, 16]. The LVEF increase after PCI should be attributed to the

restoration of normal blood flow and improved myocardial perfusion.

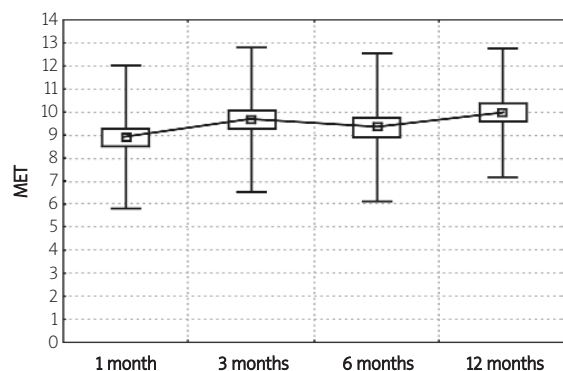
Wong et al. [12] and Silvestri et al. [14] applied exercise testing to evaluate patients after ULMCA stenting. In both studies the exercise test was performed at six months after stent implantation in order to detect possible restenosis in patients who did not undergo angiography. In the present study serial treadmill tests were performed not only to detect restenosis but also to indirectly assess myocardial perfusion. Good exercise capacity in patients at one month after ULMCA stenting, which is maintained over long-term follow-up, indicates that stent implantation improves myocardial perfusion.

Keeping in mind that surgical revascularisation has been so far a 'gold standard' of ULMCA stenosis revascularisation, data on short- and long-term results of such treatment are worth presenting. Ellis et al. [17] in his study estimated in-hospital mortality of patients with LMCA disease to be 2.3% and 23% in the high-risk group. In-hospital mortality of such patients was reported in UK data to remain within the range of 3.2 and 4.4% [18]. The APPROACH trial, a Canadian non-randomised study enrolling 11661 patients, evaluated the course of treatment and long-term survival of patients with multivessel coronary artery disease, who underwent PCI or CABG [19]. In the group with LMCA stenosis one-year survival after CABG and PCI was 92.7% and 86.9% respectively. In a retrospective study d'Allonnes et al. [20] evaluated short- and long-term results of the treatment of isolated LMCA stenosis in 106 patients after CABG. In-hospital mortality and total mortality were 4.7% and 13.3%, respectively (mean follow-up 57.8±42.4 months). Two patients from this population required repeated CABG surgery, and in another five PCI was performed. One-year survival was



Abbreviations: as in Figure 1

**Figure 3.** Exercise testing duration changes during twelve-month follow-up



Abbreviations: as in Figure 1

**Figure 4.** Metabolic equivalent test (MET) values during twelve-month follow-up

92.5% and MACE free survival 90%. Interesting results of surgical LMCA revascularisation were presented in a group of 10 patients in whom in long-term follow-up (mean 7 months) an improvement of LVEF from the baseline value of 56.4±11.3% to 61.9±9.9% (p=0.26) as well as good exercise capacity in the exercise test (159±18W) were observed [21].

## Conclusions

Restoration of normal blood flow in the unprotected left main coronary artery with stent implantation is associated with a significant reduction of angina, significant improvement of the left ventricular systolic function and maintenance of exercise capacity in long-term follow-up.

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## Implantacja stentu do niezabezpieczonego pomostem pnia lewej tętnicy wieńcowej. Wyniki obserwacji odległej u 62 chorych

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### Streszczenie

**Wstęp:** Stentowanie niezabezpieczonego pomostem pnia lewej tętnicy wieńcowej (ULMCA) uważane jest za kontrowersyjne i choroba wieńcowa z zajęciem pnia nadal stanowi podstawowe wskazanie do leczenia chirurgicznego. O ile panuje zgodność co do tego, że ryzyko zabiegu implantacji stentu do pnia lewej tętnicy wieńcowej jest niskie, to ciągle mało informacji mamy na temat wyników odległych. Jak do tej pory nie ma doniesień odpowiadających na pytanie, czy poszerzenie pnia lewej tętnicy wieńcowej za pomocą implantacji stentu zapewnia odpowiedni przepływ wieńcowy w jej zakresie.

**Cel:** Ocena wpływu odtworzenia naturalnego przepływu przez pień lewej tętnicy wieńcowej za pomocą przeskórnej implantacji stentu na rezerwę wieńcową ocenianą testem wysiłkowym, funkcję lewej komory serca oraz nasilenie dolegliwości dławicowych u chorych obserwowanych przez okres 12 miesięcy po zabiegu.

**Metoda:** Populacja badana obejmuje 62 chorych (17 kobiet, 45 mężczyzn), w wieku  $61,4 \pm 11,1$  lat (35–84 lata) poddanych zabiegowi angioplastyki wieńcowej z implantacją stentu (BMS) do ULMCA. U chorych wykonywano seryjne badania ECHO (przed zabiegiem oraz w 1., 3., 6. i 12. mies. po zabiegu) oraz próbę wysiłkową wg protokołu Bruce'a (1, 3, 6 i 12 mies. po zabiegu). Rutynowa angiografia przeprowadzana była w okresie 3–6 mies. po zabiegu. Okres 12 mies. przeżyło 59 chorych (95,2%). U 24 (38,7%) chorych zanotowano wystąpienie poważnych incydentów sercowo-naczyniowych (MACE). Restenoza w stencie implantowanym do ULMCA wystąpiła u 13 chorych, u 11 z nich przeprowadzono ponowny zabieg PCI, u 2 CABG. Jeden chory po zabiegu re-PCI wymagał pomostowania naczyń wieńcowych.

**Wyniki:** Nasilenie dolegliwości dławicowych, oceniane w oparciu o klasyfikację CCS, uległo znacznemu zmniejszeniu w ciągu 12 miesięcy w porównaniu do wartości zanotowanych przed zabiegiem ( $p < 0,00001$ ). Wyjściowa frakcja wyrzutowa wyrażona w procentach wynosiła średnio  $51,6 \pm 12,5\%$ . W obserwacji odległej wartość ta uległa zwiększeniu do  $53,8 \pm 12,8\%$  po sześciu miesiącach obserwacji ( $p < 0,02$ ) i utrzymywała się na tym poziomie przez kolejne sześć miesięcy. W pierwszym miesiącu po zabiegu implantacji stentu do ULMCA średni czas trwania próby wysiłkowej wynosił  $7,0 \pm 3,4$  min, w szóstym miesiącu obserwacji uległ zwiększeniu do  $7,6 \pm 3,4$  min ( $p < 0,002$ ) a w dwunastym miesiącu czas trwania wysiłku wynosił średnio  $7,8 \pm 3,2$  min ( $p < 0,05$ ). Wartość równoważnika metabolicznego wysiłku nie zmieniła się istotnie w trakcie obserwacji.

**Wnioski:** Przywrócenie fizjologicznego przepływu krwi dzięki implantacji stentu do pnia lewej tętnicy wieńcowej niezabezpieczonego pomostem wiąże się z istotnym zmniejszeniem nasilenia dolegliwości dławicowych, istotną poprawą funkcji skurczowej lewej komory oraz utrzymywaniem się dobrej wydolności fizycznej u chorych w okresie obserwacji odległej.

**Słowa kluczowe:** stentowanie pnia lewej tętnicy wieńcowej, frakcja wyrzutowa

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