

# Percutaneous peripheral interventions in patients with multivessel coronary artery disease

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## Abstract

**Background:** Coronary artery disease (CAD) is often accompanied by peripheral artery disease. There are patients who are disqualified from surgical approach in the treatment of limb ischaemia due to many comorbidities including severe CAD.

**Aim:** To examine whether multilevel intervention (peripheral and coronary) in patients with multi-vessel CAD (MVD) carries a higher in-hospital and long-term risk in comparison to patients with a single vessel disease (SVD).

**Methods:** Data on consecutive patients with peripheral artery disease and CAD (acute coronary syndrome) were gathered in our department from January 2003 till June 2009. All patients included in the study had peripheral and coronary angioplasty performed during the same index hospital stay. Patients were divided into two groups: those with SVD and those with MVD in coronary angiography.

**Results:** There were 116 patients included in the study — 56 patients in the SVD group and 60 patients in the MVD group. The frequency of major adverse cerebrovascular and cardiac events during long-term follow up tended to be higher in patients with MVD, however the difference did not reach statistical significance (MVD vs SVD: 13.3% vs 3.6%,  $p = 0.061$ ). There were significantly more major adverse peripheral events such as repeat percutaneous transluminal angioplasty, stroke/transient ischaemic attack and lower limb amputation in the MVD group than in the SVD patients (20% vs 1.8%,  $p = 0.002$ ).

**Conclusions:** Percutaneous angioplasty of lower limb arteries in patients with MVD seems to be an effective and relatively safe method of treatment of patients with disseminated atherosclerosis and an alternative to surgical treatment.

**Key words:** atherosclerosis, percutaneous interventions, peripheral arteries, coronary heart disease

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## INTRODUCTION

The main cause of peripheral arterial disease (PAD) is occlusive atherosclerosis related to the development of atherosclerotic plaques. Risk factors include, among others, smoking, diabetes, dyslipidaemia, hypertension and homocysteinaemia [1–6]. These factors increase the risk of PAD, similarly to other parts of the vascular bed. The prevalence of co-morbid coronary and peripheral atherosclerosis increases with age [7, 8].

Rapid development of endovascular techniques has enabled the efficient treatment of more and more complex occlusions of coronary vascular bed and other vessels [9]. Owing to their growing experience, invasive cardiologists can also

more effectively treat occlusions of peripheral vessels of lower limbs [10]. These patients are often disqualified from peripheral revascularisation procedures, mainly surgical ones, due to many risk factors, such as multivessel coronary artery disease (MVD) [2, 11, 12].

The aim of the study was to assess long-term (12-month) safety and efficacy of peripheral endovascular procedures in MVD patients.

## METHODS

### Study population

Consecutive patients with ischaemic heart disease, undergoing peripheral interventions in the 2<sup>nd</sup> Department of Cardio-

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logy of the Institute of Cardiology, *Collegium Medicum* of the Medical University of Cracow, admitted between January 2003 and May 2009, were included in the study. Main cause of hospitalisation were symptoms of angina in the course of an acute coronary syndrome (ACS). Peripheral intervention was performed during the index hospitalisation. The interventions were performed only in patients with critical ischaemia of the lower extremity as confirmed by angiography or in patients with symptomatic atherosclerosis of the lower limbs (> 3 months of intermittent claudication).

Single-vessel coronary disease (SVD) was diagnosed when  $\geq 70\%$  stenosis in one of the native coronary arteries was present. The MVD was diagnosed when  $\geq 70\%$  stenoses were found in at least two native coronary arteries. Patients with significant stenosis of the left main were not included in the study.

### Clinical endpoints

Primary endpoint was defined as occurrence of a major adverse cardiovascular or cerebrovascular event (MACCE) during the long-term, 12-month follow-up. The MACCE were defined as occurrence of: death, non-fatal myocardial infarction, urgent coronary revascularisation (percutaneous coronary intervention [PCI] or coronary artery bypass grafting, or stroke/transient ischaemic attack [TIA]).

Myocardial infarction was defined as chest pain with concomitant elevation of cardiac creatine kinase (CK-MB) (> 3 times upper limit of normal values or  $\geq 50\%$  if the value was above normal at baseline) and/or new ECG changes (ST-segment elevation, left bundle branch block or new Q-waves).

Stroke was defined as new neurological deficit lasting for > 24 hours and diagnosed by a neurologist. The TIA was defined as transient, reversible neurological deficit.

Secondary end-point of the study was occurrence of a major adverse peripheral event (MAPE) during the long-term (12-month) follow-up. The MAPE in the long term follow-up were defined as occurrence of target lesion reintervention in the peripheral artery, stroke/TIA or lower limb amputation. Amputation was defined as partial or total removal of a lower limb due to ischaemia-related infection or necrosis.

### Procedures

**Coronary interventions.** Coronary angiography was performed according to the Seldinger technique, by femoral artery approach with use of 6 F haemostatic sheath. The PCI of significant atherosclerotic lesions was performed according to the current guidelines. Angiographic success was defined as restoration of TIMI 3 flow with residual stenosis of less than 30%.

**Peripheral interventions.** Occlusions were initially crossed with hydrophilic 0.035" guidewire (260 cm, stiff, J-shaped; Terumo, Tokyo, Japan). Stenoses were crossed with a soft 0.035" guidewire (260 cm stiff, J-shaped; Cook, USA) or a non-hydrophilic 0.018" guidewire (V18 Boston Scientific, USA).

Peripheral stents were implanted after restoration of flow or after dilation of the stenotic lesion, if the initial effect was suboptimal and/or flow-limiting dissection occurred. Angiographic success was defined as restoration of inflow and < 30% residual stenosis.

### Periprocedural treatment

Prior to intervention, the patients were receiving acetylsalicylic acid (ASA), clopidogrel for at least 2–3 days or a loading dose of 600 mg of clopidogrel immediately before the procedure. During the procedure patients were receiving 100 U/kg of unfractionated heparin intra-arterially, followed by boluses so as to maintain activated clotting time (ACT) at the level of 300–400 s. After the procedure patients were receiving clopidogrel (75 mg/d.) or ticlopidine (2 × 250 mg/d.; patients who were treated between 2003 and 2005) for at least a month and life-long ASA (75 mg/d.).

### Clinical follow-up

Clinical follow-up was designed as control visits at the outpatient facility (12-month follow-up) or — in rare instances — as telephone conversation carried out by a physician.

### Statistical analysis

Data were analysed by standard methods of descriptive statistics. Categorical variables were compared with use of  $\chi^2$  test or Fisher exact test. These data are presented as the percentage of patients in the groups. Continuous variables are presented as arithmetical means  $\pm$  1 SD. For comparisons of continuous variables two tailed Mann-Whitney U test was used. Survival curves for one year survival by subgroup are presented by Kaplan-Meier method and between-group differences were assessed by the log-rank test.

Statistical significance was defined as p value < 0.05. All the statistical calculations were carried out with Statistica 8.0 statistical package (Statsoft Inc., Tulsa, OK, USA).

## RESULTS

Procedural outcome was analysed in 116 consecutive patients with lower limb atherosclerosis and coronary atherosclerosis, treated by PCI and peripheral percutaneous transluminal angioplasty (PTA) during the same index hospital stay. All the patients had angiographically confirmed atherosclerosis of one (SVD group; 56 patients) or several arteries (MVD group; 60 patients).

The two groups did not differ significantly in terms of age, gender and body mass index. However, patients with MVD had higher cardio-vascular risk, with more frequent classical risk factors of coronary artery disease (CAD) and associated conditions. More patients in the MVD group had a history of myocardial infarction, stroke or TIA. These patients were also more frequently hypertensive, diabetic and more often had a history of at least one prior peripheral intervention. De-

**Table 1.** Demographic data and medical history of patients with multivessel disease (MVD) and single-vessel disease (SVD)

	MVD group (n = 60)	SVD group (n = 56)	P
Gender (males)	82%	80%	NS
Age [years]	62.6 ± 8.0	61.3 ± 10.3	NS
Body mass index [kg/m <sup>2</sup> ]	25.7 ± 3.1	27.1 ± 3.4	NS
History of myocardial infarction	70%	9%	< 0.001
Arterial hypertension	87%	25%	< 0.001
Dyslipidaemia	75%	21%	< 0.001
Diabetes	20%	7%	0.045
Smoking	43%	18%	0.003
Stroke/transient ischaemic attack	15%	3.6%	0.036
Previous percutaneous transluminal angioplasty	20%	5.4%	0.019

**Table 2.** Angiographic characteristics of atherosclerotic lesions and treatment of lower limbs

	MVD group	SVD group	P
Artery:			
Common iliac	28%	33%	NS
External iliac	14%	0%	0.04
Superficial femoral	55%	59%	NS
Deep femoral	1.5%	0%	NS
Femoral	1.5%	8%	NS
Stenting during PTA:	52%	37%	NS
Diameter [mm]	7.3 ± 1.5	7.4 ± 1.3	NS
Length [mm]	77 ± 52	72 ± 48	NS
Number of stents	1.3 ± 0.6	1.2 ± 0.5	NS
Good PTA effect	83%	85%	NS
Total occlusion at baseline	35%	21%	NS

MVD — multivessel disease; SVD — single-vessel disease; PTA — percutaneous transluminal angioplasty

**Table 3.** Angiographic characteristics of atherosclerotic lesions and the treatment of coronary artery disease

	MVD group	SVD group	P
Troponin + ACS (NSTEMI)	52%	52%	NS
Coronary stent implantation	89%	82%	NS
Culprit lesion in the LAD	45%	46%	NS
PCI effect — TIMI 3 flow, with no residual stenosis	93%	95%	NS

ACS — acute coronary syndrome; NSTEMI — non-ST-elevation myocardial infarction; LAD — left anterior descending coronary artery; PCI — percutaneous coronary intervention

mographic data are presented in Table 1. In Tables 2 and 3 complete angiographic and procedural data are displayed.

Average follow-up period was 36 months (range: 1–71 months). During a 12-month follow-up no significant between-group (MVD vs SVD) differences in mortality, myocardial infarction, stroke/TIA or lower limb amputation were recor-

ded. In the MVD patients during the 12-month follow-up target lesion reintervention or elective interventions in other peripheral arteries were performed more frequently. No significant differences in the MACCE frequency were noted however, these was a trend towards higher rate of MACCE in the MVD group (13.3% vs 3.6%;  $p = 0.061$ ). The MAPE were

**Table 4.** Long-term clinical follow-up of patients with coronary artery disease after percutaneous coronary intervention (PCI) and peripheral percutaneous transluminal angioplasty (PTA), stratified by disease severity (single-vessel [SVD] vs multi-vessel [MVD]) by coronary angiography

	MVD group (n = 60)	SVD group (n = 56)	P
Death	3.3%	3.6%	NS
MI (STEMI + NSTEMI)	3.3%	0%	NS
Stroke/TIA	5%	0%	NS
PCI	6.7%	0%	0.049
Re-PTA	15%	1.8%	0.012
Elective PTA of other vessels	8.3%	0%	0.027
Lower limb amputation	1.7%	0%	NS
Death + MI	6.7%	3.6%	NS
Death + MI + stroke/TIA + urgent coronary revascularisation (MACCE)	13.3%	3.6%	NS (0.061)
Re-PTA + stroke/TIA + amputation (MAPE)	20%	1.8%	0.002
In-hospital hemorrhagic complications	0%	0%	–

TIA — transient ischaemic attack; MACCE — major adverse cerebrovascular and cardiac events; MAPE — major adverse peripheral events

**Table 5.** In-hospital periprocedural complications

	MVD group (n = 60)	SVD group (n = 56)	P
Death	0%	0%	NS
Artery perforation	0%	0%	NS
Artery dissection	6.7%	5.4%	NS
Artery occlusion	0%	1.8%	NS
Lower limb amputation	0%	0%	NS
Retroperitoneal bleeding	0%	0%	NS
Access site hematoma	8.3%	8.9%	NS

significantly more frequent in MVD group. Full clinical data from follow-up are presented in Table 4. Peri-procedural complication rates did not differ in the studied groups (Table 5). The Kaplan-Meier curves showing the MACCE and MAPE occurrence during follow-up are presented in Figures 1 and 2.

## DISCUSSION

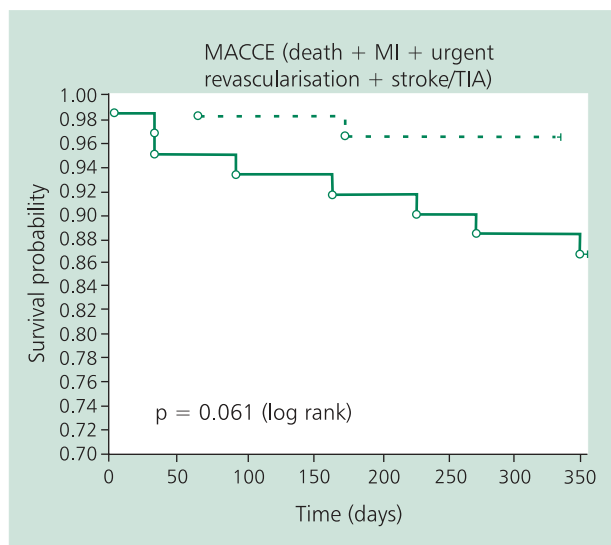
In our study MVD patients were by far more burdened with comorbid conditions and risk factors of atherosclerosis. More risk factors and, hence, more advanced atherosclerosis were the reason that these patients had to undergo reinterventions more frequently, either within coronaries or within peripheral arteries, due to restenosis. However, in these patients MACCE did not occur significantly more frequently than in the SVD group.

Mortality rates in both groups were comparable and did not exceed 4%. The MVD patients underwent repeat PCI significantly more frequently, but in our opinion this was due to severity of atherosclerosis and not to the fact of prior peripheral intervention.

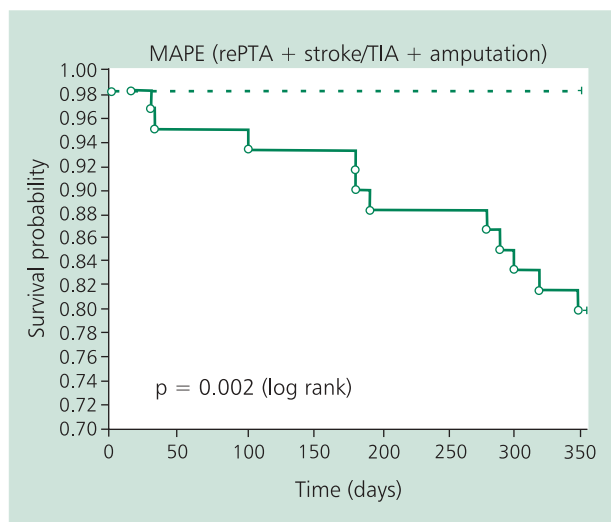
Atherosclerosis progresses with age. At the age of 75, total percentage of PAD patients is approximately 30% in the general population [11]. It is believed that in 1/3 of these patients, PAD is symptomatic. The natural history of the disease is such that 1/3 of these patients die within 5 years, and at 6 years mortality is close to 50% [11]. Atherosclerosis is a systemic, generalised disease. According to epidemiological data, among patients undergoing surgery of the peripheral arteries, only 10% did not have atherosclerotic lesions in the coronaries [1], and among patients undergoing PCI at least in 30% symptomatic atherosclerosis of lower limbs was diagnosed.

Multi-vessel CAD is diagnosed in a significant proportion of patients undergoing coronary angiography. The MVD is a risk factor of increased mortality, especially in the elderly, and its presence worsens prognosis as well as the long-term treatment outcome [12]. Concomitant kidney disease may also worsen prognosis of these patients [13].

American guidelines suggest vascular surgical interventions in patients with type B, C and D TASC changes [2].



**Figure 1.** Major adverse cerebrovascular and cardiac events (MACCE) occurrence in multivessel disease (MVD) and single-vessel disease (SVD) groups using Kaplan-Meier method at 1-year; MI — myocardial infarction; TIA — transient ischaemic attack; dotted line — SVD; solid line — MVD



**Figure 2.** Major adverse peripheral events (MAPE) occurrence in multivessel disease (MVD) and single-vessel disease (SVD) groups using Kaplan-Meier method at 1-year; rePTA — repeat percutaneous transluminal angioplasty; TIA — transient ischaemic attack; dotted line — SVD; solid line — MVD

However, patients selected for vascular surgery are low surgical risk patients [14]. High surgical risk patients are usually referred for medical treatment because of numerous comorbidities, including MVD and history of ACS. In a study by Boersma et al. [15], cardiovascular conditions were the main cause of death in 1/4 of the patients undergoing surgery. This

was particularly true for the vascular surgery subgroup. Authors underlined that peri-operative cardiovascular mortality was the major limitation of non-cardiac surgery [15]. Despite good long-term patency of the grafts, reaching as much as 80% at 5 years, such treatment is available only for a small group of low risk patients. The choice of medical management is itself a factor that increases the risk of death in these patients [11]. However, especially in case of critical lower limb ischaemia, for a patient disqualified from surgical treatment, endovascular procedure seems to represent the only option, as no effective pharmacotherapy has been introduced to date.

Multi-vessel disease, intermittent claudication, dyslipidaemia, hypertension, smoking and elevated serum creatinine (> 1.3 mg/dL) are all associated with increased risk of multi-level atherosclerosis [16]. Patients with ischaemic heart disease and PAD are at increased risk. Non-coronary atherosclerosis accompanying CAD increases the risk of in-hospital mortality as well as high complication rates after coronary interventions, irrespective of other comorbidities or classical risk factors [17–19], and their long-term prognosis is inferior to that in patients with less severe atherosclerosis [20–22]. Interventional cardiologists must be aware of the risk, but peripheral PTA in higher risk patients performed by interventional cardiologists putatively reduce the risk by providing direct cardiovascular peri-procedural backup.

Finally, it should be mentioned that in patients with CAD, after ACS, physical rehabilitation and exercise are crucial. Symptomatic lower limb obstructive atherosclerosis reduces the extent of such rehabilitation substantially, thus worsening prognosis. That is why full coronary and peripheral revascularisation is really important [23].

**Limitations of the study**

Our study has all the limitations inherent to single-centre registries. Clinical end-points were not assessed by independent observers, and part of the data from long-term follow-up were collected by telephone calls. In our registry, data concerning contrast-induced nephropathy were not analysed, because retrospective data were collected for slightly over 50% of the patients and due to lack of unequivocal management strategy and well defined method of testing they were not suitable for analysis.

**CONCLUSIONS**

Peripheral transluminal interventions in patients with MVD are safe. Despite more comorbidities and more numerous atherosclerosis risk factors in patients with MVD confirmed by coronary angiography, peripheral interventions of lower limbs during index hospitalisation do not significantly increase the risk of mortality as compared to SVD patients during the long-term follow-up. Our single-centre experience shows that peripheral interventions in the lower limb arteries are safe, and multi-level interventions in these patients bring satisfactory results.

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# Przezskórne interwencje obwodowe u pacjentów z wielonaczyniową chorobą niedokrwienną serca

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## Streszczenie

**Wstęp:** U osób z chorobą niedokrwienną serca bardzo często współistnieje także miażdżyca zarostowa tętnic kończyn dolnych. Część pacjentów jest dyskwalifikowana z chirurgicznych zabiegów w zakresie tętnic kończyn dolnych ze względu na obecność innych chorób przewlekłych, w tym wielonaczyniowej choroby niedokrwiennej serca (MVD). Potwierdzono skuteczność przezskórnych interwencji wieńcowych w leczeniu miażdżycy zarówno w zakresie tętnic wieńcowych, jak i obwodowych.

**Cel:** Celem badania było ustalenie, czy wielopoziomowe zabiegi przezskórne w zakresie tętnic wieńcowych i równocześnie obwodowych kończyn dolnych u osób z MVD wiążą się z większym ryzykiem odległym i powikłaniami niż u pacjentów z jednonaczyniową chorobą niedokrwienną serca (SVD).

**Metody:** Analizie poddano osoby ze współistniejącą chorobą niedokrwienną serca (pod postacią ostrego zespołu wieńcowego) oraz istotną miażdżycą zarostową tętnic kończyn dolnych. Pacjenci byli włączani do badania rejestrowego w okresie od stycznia 2003 do czerwca 2009 roku. U wszystkich chorych włączonych do badania wykonano zabieg przezskórnej angioplastyki wieńcowej i przezskórnej interwencji obwodowej podczas tej samej hospitalizacji. Stosowano standardową farmakoterapię. Pacjentów podzielono na dwie grupy: z SVD w koronarografii oraz z MVD.

**Wyniki:** Do badania włączono 116 kolejnych chorych, z których 56 znalazło się w grupie SVD (48%), a 60 kolejnych chorych w grupie MVD (52%). Występowanie złożonego pierwotnego punktu końcowego badania (zgon, zawał, pilna rewaskularyzacja wieńcowa, udar mózgu, TIA) oceniano w obserwacji 12-miesięcznej, a jego częstość w obu grupach była podobna i nie różniła się istotnie statystycznie (MVD vs SVD: 13,3% vs 3,6%;  $p = 0,061$ ). Niemniej jednak drugorzędowy złożony punkt końcowy (ponowna przezskórna rewaskularyzacja obwodowa w zakresie leczonej uprzednio zmiany, amputacja, udar mózgu, TIA) występował istotnie częściej u osób z MVD w 12-miesięcznej obserwacji (20% vs 1,8%;  $p = 0,002$ ).

**Wnioski:** Przezskórna angioplastyka obwodowa w zakresie tętnic kończyn dolnych u osób z wielonaczyniową chorobą wieńcową wydaje się bezpieczna i skuteczna w porównaniu z pacjentami z chorobą jednonaczyniową. Jest to być może alternatywa dla chorych, u których zabieg chirurgiczny jest przeciwwskazany.

**Słowa kluczowe:** miażdżyca, zabiegi przezskórne, tętnice obwodowe, choroba niedokrwienna serca

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