Percutaneous peripheral interventions in patients with non-ST elevation acute coronary syndromes performed by interventional cardiologists: rationale and results

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Abstract

Background: The coexistence of peripheral artery disease (PAD) and multilevel atherosclerosis increases death and stroke rates in patients with coronary artery disease (CAD). Due to many comorbidities these patients are often treated conservatively without revascularisation.

Aim: To investigate whether complex percutaneous cardiovascular interventions for CAD and PAD may improve prognosis and long-term outcome in this group of patients.

Methods: We studied consecutive patients treated for symptomatic CAD who also had chronic PAD. The primary cause of hospital admission for all our patients was non-ST elevation acute coronary syndrome (NSTE ACS). All percutaneous peripheral interventions were performed during one hospital stay (index hospitalisation). Major adverse cardio- and cerebrovascular events (MACCE) during follow-up were defined as follows: death (cardiac and non-cardiac), myocardial infarction (MI), urgent revascularisation (surgical or repeat PCI, peripheral percutaneous intervention), stroke/TIA or amputation.

Results: We performed 109 interventions in 78 consecutive patients with chronic peripheral artery stenoses and occlusions. The average age was 61.5±8.6 years and the majority were males (80%). Preinterventional angiography showed occlusions that involved the common iliac artery in 28 (36%) patients, the external iliac artery in 16 (21%) patients, internal iliac artery in 2 (3%) patients, and superficial femoral artery in 63 (81%) patients. Stenting was performed in half of the patients with a mean stent length of 69.6±50.3 mm. An average number of 1.24±0.55 stents was used for each lesion. During a mean follow-up of 18 months (range 4 to 42), there were 4 deaths, 3 MIs, 13 repeated percutaneous peripheral interventions due to restenosis in previously treated peripheral lesions, two urgent coronary interventions, two ischaemic strokes, two TIAs and one amputation. The combined follow-up MACCE end-point occurred in 32% of patients.

Conclusions: Patients with concomitant CAD and PAD could safely undergo percutaneous cardiovascular and peripheral interventions. Multilevel intervention is associated with a promising long-term follow-up.

Key words: peripheral percutaneous interventions, acute coronary syndrome, atherosclerosis

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Introduction

The rapid progression of aggressive endovascular techniques has led interventional cardiologists to treat more complex lesions and has allowed the treatment of patients with more advanced and disseminated atherosclerosis and concomitant diseases [1]. The coexistence of coronary artery disease (CAD) and peripheral artery disease (PAD) is well known; thus no endovascular procedures can be performed without taking into consideration the status of the coronary and peripheral arteries together [2-5]. However, there is still a lack of data on possible treatment options of these two disorders together by interventional techniques, e.g. performing multilevel interventions, clinical status and long-term outcome of these patients after such procedures. In this paper we summarise the experience of a single centre performing peripheral interventions for patients with CAD.

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Methods

Patients

The study group consisted of 78 consecutive patients treated between January 2003 and April 2007 for symptomatic CAD who also had chronic PAD. The primary cause of hospital admission for all our patients was non-ST elevation acute coronary syndrome (NSTE ACS). As many as 27% of patients had already undergone coronary angioplasty of at least one coronary artery before current hospitalisation for NSTE ACS. The average age was 61.5± 8.6 years and the patients were usually men (80%). Most of them had typical past medical history of CAD (Table I). Details of coronary interventions are presented in Table II. All percutaneous peripheral interventions were performed during one hospital stay hospitalisation). patients (index Only with angiographically proven critical stenoses and stable clinical symptoms of PAD of at least 3-month duration were included.

We did not perform preinterventional standardised treadmill tests (5 minutes at 2 miles per hour on a 12% incline) due to the fact that all of the patients had coronary-dependent limited walking capacity and symptoms of ACS.

Table I. Baseline characteristics of patients (n=78)

Parameter	Value
Age [years]	61.5±8.6
Male gender [%]	80
Body mass index [kg/m²]	26±3.2
Previous myocardial infarction [%]	64
Prior percutaneous coronary intervention [%]	27
Arterial hypertension [%]	83
Diabetes mellitus [%]	17
Dyslipidaemia [%]	72
Current smokers [%]	42
Prior stroke or transient ischaemic attack [%]	10
Fontaine grade ≥2b [%]	69
Claudication distance [m]	118±170

Table II. Coronary angiography and PCI details (n=78)

Parameter	Value
Troponin positive non-ST elevation acute coronary syndrome	39 (50%)
Multivessel disease	48 (62%)
Stent	66 (85%)
Multivessel percutaneous coronary interventions	10 (13%)
Left anterior descending culprit lesion	35 (45%)
Procedural success	76 (97%)

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Procedures

Coronary procedures. Coronary angiography was performed through femoral or radial access via a 6 F haemostatic sheath. Percutaneous coronary intervention (PCI) of the ischaemia-related artery was performed according to the contemporary standards. Angiographic success was defined as restoration of the coronary flow to TIMI grade 3 and residual stenosis of <30% at the site of the procedure.

Peripheral procedures. The occlusions were initially passed with a 0.035" hydrophilic guide wire (260 cm; stiff type, angled tip; Terumo, Tokyo, Japan). The stenoses were passed with a 0.0350" soft guide wire (260 cm; stiff type, angled tip; Cook, USA) or 0.018" nonhydrophilic wire (V18 Boston Scientific, USA).

Peripheral stents were implanted after restoring patency of the artery or dilatation if the result of balloon angioplasty was suboptimal and/or if a dissection compromised the blood flow. Angiographic success was defined as restoration of the blood flow and residual stenosis of <30% at the procedure site.

Definitions

Technical success was defined as patency of the vessel with an angiographic residual diameter stenosis of <30% and a residual translesion pressure gradient of <5 mmHg. Primary patency was defined as uninterrupted patency with no procedures performed on or at the margins of the treated segment. Secondary patency was defined as patency of the target vessel after reintervention.

Periprocedural treatment

Before the procedure patients received aspirin and clopidogrel for at least 2-3 days (or loading dose of clopidogrel of 600 mg), as they had had coronary interventions. During intervention, all patients received 100 U/kg of unfractionated heparin intra-arterially, followed by additional intravenous boluses of heparin to keep the ACT time at 300-400 seconds. After interventions patients received clopidogrel (75 mg daily) or ticlopidine (250 mg twice daily) for 4 weeks and aspirin (75 mg) lifelong.

Follow-up protocol

Follow-up examinations, performed during patient visits or if not possible by telephone call, with ABI measurement and colour-coded duplex ultrasonography, were performed at hospital discharge, at 1, 3, 6, and 12 months, and yearly thereafter.

Clinical endpoints

Major adverse cardio- and cerebrovascular events (MACCE) during follow-up were defined as follows: death (cardiac and non-cardiac), myocardial infarction (MI), urgent revascularisation (surgical or repeat PCI, repeat peripheral percutaneous intervention), stroke/transient ischemic attack (TIA), amputation.

Myocardial infarction was defined as chest pain with concomitant creatine kinase (CK) elevation (>3 times normal or \geq 50% if it had never returned to normal), and/or new ECG changes (ST segment elevation, left bundle branch block or appearance of new Q waves).

Stroke was defined as any new neurologic deficit lasting for >24 h and diagnosed by a neurologist.

Bleeding was classified as severe when it was associated with haemodynamic compromise and moderate when requiring transfusion without haemodynamic compromise.

Statistical analysis

Standard descriptive statistics were applied. Continuous variables are presented as mean \pm standard deviation (SD). Part of the data is presented as medians and inter-quartile range. Patency rates and event-free survival were calculated using the Kaplan-Meier life table method. All statistical analysis were performed using STATISTICA 7.1 Software (Statsoft Inc., Tusla, OK, USA).

Results

Altogether 109 lesions were treated in the group of 78 consecutive patients. Preinterventional angiography showed occlusions that involved the common iliac artery in 28 (36%) patients, the external iliac artery in 16 (21%), internal iliac artery in 2 (3%), and superficial femoral artery in 63 (81%) patients. Five (6%) patients had a contralateral ostial stenosis of the common iliac artery. Poor run-off with occlusion of the ipsilateral superficial femoral artery was observed in 6 (8%) patients. As for per lesion count: the common iliac artery accounted for 26%, the external iliac artery for 15% and the superficial femoral artery for 58% of lesions (Table III). Left-side occlusions occurred more rarely (left to right index at 0.62).

Forty total occlusions (37%) were treated and the mean diameter stenosis of non-occluded arteries was 82±9%. The mean length of the stenosis was 59.5±31.9 mm (range 20 to 160 mm). Stenting was performed in half of the patients (50%) with the mean stent length of 69.6±50.3 mm. An average number of 1.24±0.55 stents was used for each lesion. Treatment of more than one peripheral lesion during the index procedure was performed in 29% of cases. Four (5%) patients had concomitant one-stage coronary and peripheral procedure. The remaining patients (95%) had their peripheral procedures performed with a median time of delay of 4 days during the same hospitalisation for NSTE ACS. Five (6%) patients were diagnosed with internal carotid artery critical stenoses and elective carotid artery stenting was performed in these patients during another hospitalisation (within 3 months).

Mean follow-up time was 18 months (range 4 to 42). There were 4 deaths (3 cardiac and 1 non-cardiac caused by cancer), 3 MI, 13 repeated percutaneous transluminal **Table III.** Target lesions by artery (per lesion)(n=109)

Parameter	Value
Common iliac artery	28 (26%)
External iliac artery	16 (15%)
Internal iliac artery	2 (2%)
Superficial femoral artery	63 (58%)
Left to right ratio	0.62



Figure 1. Kaplan-Meier curve for event-free survival



Figure 2. Restenosis-free survival to clinical end--point defined as rePTA and no patency

angioplasty (PTA) due to restenosis in previously treated peripheral lesions, two urgent PCIs and additionally two ischaemic strokes and two TIAs and one amputation. No bleedings occurred. The combined follow-up MACCE end-point occurred in 32% of patients. Restenosis and rePTA in superficial femoral arteries occurred in 11 patients (17.5% of treated superficial femoral lesions) and rePTA of iliac arteries in 2 patients (4.5% of treated iliac lesions). Additionally, 31 elective peripheral percutaneous interventions in other arterial beds were performed within the follow-up period. The Kaplan-Meier curves for event--free survival, defined as absence of death+MI+urgent PCI/CABG+stroke/TIA, are depicted in Figure 1. The median time to MACCE occurrence was 90 days (inter-quartile range 30-180 days). Figure 2 shows restenosis-free survival to clinical end-point defined as rePTA and re-occlusion during the long-term follow-up.

In follow-up examinations ankle-brachial index (ABI) measurements and colour-coded duplex sonography was performed by one experienced doctor (T.R.) at 12 months after the procedure. We found that 8% of the lesions were occluded, 14% were tightly stenosed, whereas the rest of the lesions (78%) were patent without stenoses after one year. The average ABI at 12 months after the index PTA procedure was 0.95±0.13 at the right and 0.92±0.12 at the left side (NS).

Discussion

Peripheral arterial disease is an obstruction of arteries other than the coronary and intracranial vessels. The prevalence of PAD increases with age and reaches 54/100 000 in women and 61/ per 100 000 in men at age 65-75 [1]. According to epidemiological data, among patients undergoing elective peripheral vascular surgery, only 10% have normal coronary arteries [6] and among patients undergoing coronary interventions at least 30% have symptomatic PAD. It is estimated that the prevalence of advanced, angiographic CAD ranges from 37 to 78% in patients undergoing operations for PAD [2, 7].

Thirty percent of the population above age 75 has PAD; however, only 1/3 of them are symptomatic [1]. Mortality in the group of patients with symptomatic PAD and decreased ABI is relatively high - ten-year survival in the group of patients with ABI 0.45-0.5 is approximately 55-60% [2]. According to another registry [8], in a group of 16 440 patients with symptomatic PAD 5-year mortality was 33.4% [3]. This high mortality is a consequence of the following factors. First of all, in the group of patients with PAD over 60 years of age, only 3% do not have any other vascular disease, about 2/3 have CAD and the remaining 1/3 have already suffered from stroke [4]. Claudication is only an important sign of systemic atherosclerosis with considerable overlap of disease manifested in multiple vascular beds. It is a strong marker of cardiovascular disease; there exists a very strong association between PAD and other atherosclerotic disorders such as CAD and cerebrovascular disease [6]. A similar phenomenon was observed in our study, in which all patients had CAD and 27% had PCI already before index hospitalisation for NSTE ACS. The presence of concomitant diseases such as diabetes, hypercholesterolaemia, hypertension and smoking in this group of patients is comparable or even higher than in patients without PAD. In our group of patients, prior MI was observed in 64% of patients and males constituted the majority of cases (80%).

The annual mortality rate derived from epidemiological studies of patients with lower extremity PAD is 4-6%, and is the highest in those with the most severe disease [9-12]. More recent trials reported a lower annual mortality rate; the combined event rate for MI, stroke, and vascular death was approximately 4-5% per year and increased to 6% per year if revascularisation was included [13–15].

The consequence of coexisting coronary and cerebrovascular disease is an increased risk of MI, stroke, and cardiovascular death in patients with PAD. The risk of MI is increased by 20-60% and there is a 2- to 6-fold increased risk of death due to CAD-associated events [13, 16-18].

In our group of patients, the incidence of deaths was 5% during follow-up and the risk of MI was 4%. According to current knowledge, PCI procedures do not decrease the risk of death in stable patients. However, life-saving procedures in ACS significantly increase survival. In our group of patients, who were followed very strictly, we did not observe a higher rate of deaths. The number of patients after complete revascularisation (coronary and peripheral) is not high enough to draw the conclusion that it really can improve survival of the patients. However, in our opinion it is really important for this group of patients after coronary procedures to improve walking capacity and can be beneficial for this group.

Diabetes mellitus increases the risk of lower extremity PAD 2 to 4-fold [19-23] and is present in 12-20% of patients with lower extremity PAD [20, 23]. In the Framingham Heart Study, diabetes increased the risk of intermittent claudication by 3.5- and 8.6-fold in men and women, respectively [24]. The risk of developing lower extremity PAD is proportional to the severity and duration of diabetes [23, 25]. The risk of developing chronic limb ischaemia is also greater in diabetics than nondiabetics [26, 27]. Diabetes and hypertension grade 2 or higher were associated with more than 2-fold increase in intermittent claudication, whereas clinical evidence of CAD almost tripled the risk [20].

Large epidemiological studies have found that smoking increases the risk of lower extremity PAD by 2- to 6-fold and the risk of intermittent claudication by 3- to 10-fold [5, 20, 28, 29]. More than 80% of patients with lower extremity PAD are current or former smokers [20, 28].

Lipid abnormalities that are associated with lower extremity PAD include elevated total and low-density lipoprotein (LDL) cholesterol, decreased high-density lipoprotein (HDL) cholesterol, and hypertriglyceridaemia [5, 22, 30, 31]. The risk of developing lower extremity PAD increases by approximately 5-10% for each 10 mg/dl rise in total cholesterol [21, 32, 33]. In epidemiological studies, total cholesterol levels are generally higher in patients with intermittent claudication than in those without lower extremity PAD [7, 28, 34].

Hypertension is associated with lower extremity PAD, although the association is generally weaker than that

with cerebrovascular disease and CAD [33, 35]. Hypertension increased the risk of developing lower extremity PAD in some studies but not in others [5, 28, 33]. In the Framingham Heart Study, hypertension increased the risk of intermittent claudication 2.5 and 4-fold in men and women, respectively, and the risk was proportional to the severity of high blood pressure [24].

In our group, 72% of patients had hypercholesterolaemia All these patients received statin therapy and after discharge received optimal treatment including aspirin, thienopyridines, ACE inhibitors, beta-blockers and statins. All of them are carefully followed and treated for prevention of coronary adverse events. There is still a discussion regarding the efficacy of PCI in preventing deaths, but there is no doubt that optimal pharmacotherapy in this group of patients is crucial.

In everyday clinical practice, patients with PAD should be selected for endovascular or surgical treatment after index coronary intervention (PCI or CABG). However, in the literature there are no data demonstrating benefits of such treatment. According to the guidelines, patients should undergo the walking exercise programme first, together with optimal pharmacotherapy, and then can be selected for vascular surgery procedures. Unfortunately, the majority of these patients are at high risk of any procedure (not only vascular surgery) due to advanced age and atherosclerotic-dependent concomitant disorders (CAD, renal failure, heart failure, chronic obstructive pulmonary disease etc.). Thus, the majority of them are selected for conservative treatment of PAD.

Our approach was to treat lesions in the coronary bed and peripheral arteries, and optimise the treatment of this group of patients, in order to prevent vascular complications during procedures and during long-term follow-up.

According to the current guidelines, surgery has been the mainstay of revascularisation therapy for PAD. However, percutaneous vascular interventions offer a less invasive and more effective modality for the treatment of atheromatous disease. In our group of patients peripheral interventions were scheduled after coronary stenting to prevent perioperative MI, which is the main cardiac complication of vascular surgery.

Interventional cardiologists must take into consideration that patients with CAD and PAD are at higher risk of coronary and peripheral procedures, but these procedures can be performed in the coronary cathlab, which hypothetically can decrease the risk of perioperative mortality in case of MI.

Many patients with multilevel disease prefer to have a one-stage procedure to treat all lesions or all interventions to be performed during a single hospital stay. At the same time, interventional cardiologists have to treat all local complications, such as dissections or acute closures of iliac arteries, which may occur after peripheral procedures.

Conclusions

Patients with concomitant CAD and PAD could safely undergo percutaneous cardiovascular interventions. Multilevel intervention is associated with a promising long-term follow-up.

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Przezskórne interwencje obwodowe u chorych z ostrym zespołem wieńcowym bez uniesienia odcinka ST wykonywane przez kardiologów inwazyjnych – uzasadnienie i wyniki

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mózgu/przemijającego niedokrwienie mózgu (TIA), amputacji.

Streszczenie

Wstęp: Współistnienie miażdżycy tętnic obwodowych (PAD) i rozsianych wielopoziomowych zmian miażdżycowych zwiększa ryzyko zgonu i udaru mózgu u osób z chorobą niedokrwienną serca (CAD). Współwystępowanie miażdżycy w wielu łożyskach naczyniowych sprawia, że chorzy ci często są leczeni zachowawczo, bez zabiegów przezskórnej rewaskularyzacji.

Cel: Określenie rokowania odległego chorych z CAD i miażdżycą tętnic obwodowych kompleksowo leczonych inwazyjnie.
Metodyka: Do badania włączono kolejnych chorych leczonych z powodu ostrego zespołu wieńcowego bez uniesienia odcinka
ST (NSTE ACS), którzy mieli także miażdżycę tętnic kończyn dolnych. Wszystkie zabiegi rewaskularyzacji wieńcowej i obwodowej wykonano w trakcie jednej hospitalizacji. Duże niepożądane zdarzanie sercowo-naczyniowe (MACCE) w trakcie trwania obserwacji odległej zdefiniowano jako wystąpienie: zgonu (sercowego, pozasercowego), zawału serca (MI), pilnej rewaskularyzacji wieńcowej [chirurgicznej (CABG) lub przezskórnej (PCI)], ponownego zabiegu przezskórnej interwencji obwodowej (rePTA), udaru

Wyniki: Do badania włączono 78 kolejnych chorych, u których leczono 109 krytycznych zmian miażdżycowych w zakresie tętnic kończyn dolnych. Wszyscy chorzy mieli potwierdzoną CAD i byli hospitalizowani z powodu NSTE ACS. Średni wiek chorych to 61,5±8,6 roku. Większość stanowili mężczyźni (80%). Badanie angiograficzne wykazało krytyczne zwężenia w tętnicy biodrowej wspólnej u 28 (36%) chorych, tętnicy biodrowej zewnętrznej u 16 (21%), tętnicy biodrowej wewnętrznej u 2 (3%) oraz tętnicy udowej powierzchownej u 63 (81%) chorych. Implantację stentu wykonano u połowy (50%) chorych, średnia długość stentu to 69,6±50,3 mm. Implantowano przeciętnie 1,24±0,55 stentu na każdą leczoną zmianę miażdżycową. Średni czas obserwacji odległej chorych wyniósł 18 (4–42) mies. Zaobserwowano 4 zgony, 3 MI, 13 rePTA w uprzednio leczonych tętnicach, 2 pilne PCI, 2 udary mózgu oraz 2 TIA i jedną amputację. Złożony punkt końcowy (MACCE) wystąpił u 32% chorych.

Wnioski: Chorzy ze współistniejącą miażdżycą tętnic wieńcowych oraz tętnic kończyn dolnych mogą być bezpiecznie poddani zabiegom PCI i PTA. Interwencje wielopoziomowe zdają się zapewniać dobre wyniki i rokowanie.

Słowa kluczowe: przezskórne interwencje obwodowe, ostry zespół wieńcowy, miażdżyca

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