

COVER PAGE**Title:**

Intensive Management of Dyslipidemia in Patients with Peripheral Artery Disease Including Their Families in Primary Care

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2. Abstract:

The main goal of this project is to improve effectiveness of the preventive care for patients with peripheral artery disease (PAD) through introducing intensive and individualized management of cardiovascular risk factors including family members. This will be accomplished at the level of primary health providers in cooperation with three professional societies: Czech Atherosclerosis Society, Czech Society of Angiology and Forum for Healthy Nutrition. Czech Atherosclerosis Society will be responsible for organization of the project and for education of management of dyslipidemias. Czech Society of Angiology will be responsible for special care regarding patients with PAD and will address primary care physicians from previous projects. In addition, patients and their families will be educated by nutritionist. To reach the latter goal the Forum of Healthy Nutrition and its specialists, namely nutritionists will develop comprehensive educational materials. The team including lipidologists, angiologists and nutritionists will collaborate with 30 primary care physicians. A total of approximately 300 patients will be included together with approximately 600 their family members. Because of educational character of this project and ethical reasons, control group will not be established. The main evaluated factor will be change of lipid parameters. Information about the study will be presented at meetings of professional societies operating in this area, and through established web sites including web sites of all three societies for professionals and lay public.

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MAIN SECTION

1. Overall Goal & Objectives:

The particular goals of the project are as follows:

1. To increase the awareness and effectiveness of treatment of dyslipidemia in patients with peripheral artery disease (PAD) while also including patients' relatives.
2. To establish a system of detection and care of these high-risk patients on a long term basis at the level of primary health care with the support of teams of specialists.
3. Motto: Do not only tell people what to do, but do it with them.

The overall outcomes of this activity should be the increased skills of primary care providers to detect and treat dyslipidemias, to improve cardiovascular risk profiles, mainly plasma lipids in patients with PAD.

2. Technical Approach:

Most patients with PAD are dying of ischemic heart disease and other vascular complications different from PAD. PAD is therefore also a marker of extremely high risk for all atherosclerotic cardiovascular events. However, not even physicians are aware of this and as a consequence the treatment of traditional risk factors is often neglected in this group, including hypolipemic therapy/statins. Our initiative should contribute to closing this gap in medical care in accord with RFPs: Reducing Cardiovascular Risk Globally. In this particular project a family approach will also be utilized for the timely detection and management of inborn patterns of cardiovascular risk factors and to increase compliance of patients.

a. Current Assessment of Need in Target Area

One of the most endangered and, at the same time, almost neglected patient groups at high risk for cardiovascular events is that which includes those with PAD. In almost all patients with PAD, mixed dyslipidemia is present. This kind of dyslipidemia is manageable with lifestyle intervention and statin treatment. If successful, it protects patients mainly from coronary events. The effectiveness in the care for patients with PAD could be substantially enhanced by an interdisciplinary approach supported by cooperation among three professional societies including intensive participation of lipidologists. A pre-established network of lipid centers organized by the Czech Atherosclerosis Society covering all districts throughout the Czech Republic is to be utilized for the purposes of this project. Another participating society – the Czech Society of Angiology – has already past experience in organizing comprehensive care for patients with PAD showing quite impressive results in the study entitled “Monitoring of Effective Therapy in PAD” (MOET study). In this study more than 200 primary care physicians were provided with introductory training in the detection of PAD and dyslipidemia as well as in the treatment of these conditions. This study led to an important decrease in total cholesterol, LDL-cholesterol, triacylglycerol levels after 12 months. However, no further data after this period are available. Baseline data are shown in the table below, which indicate a low prevalence of statin treatment in this high risk group of patients and mean levels of LDL cholesterol far above recommended and safe values. In addition, the mean level of triglycerides is by far not optimal and much higher than in the

general Czech population, which ranks among those at the highest risk in Europe. In Table below there are shown data from the Monica study (2007/2008). In contrast to data of patients with PAD, Monica data were collected by standardized protocol and lipids levels were established in one central laboratory of Institute of Clinical and Experimental medicine which is under continuous external quality control of the Center for Disease Control, Atlanta, USA. Therefore, this is really just for demonstration of the present status not for scientific analyses/comparisons.

Table: Data from the study on patients with peripheral artery disease (MOET study).

	Patients with peripheral artery disease	Czech population (Monica study)
Men/women (n)	2,455/1,466	1,229/1,392
Mean age \pm SD (years)	65.8 \pm 9.9	49 \pm 11
Current smokers x nonsmokers (%)	34.7 x 43.8	33.8 x 66.1
Diabetes mellitus (%)	36.5	13.8
Hypertension (%)	78.9	37.5
Stage PAD 1-3 (Fontain) (%)	90	-
Mean body mass index \pm SD (kg*m ⁻²)	28.6 \pm 4.5	28.4 \pm 4.5
Mean LDL cholesterol \pm SD (mmol/L)	3.63 \pm 1.05	3.70 \pm 1.1
Mean triglycerides \pm SD (mmol/L)	2.30 \pm 1.24	1.70 \pm 1.1
Mean HDL cholesterol \pm SD (mmol/L)	1.34 \pm 0.51	1.37 \pm 1.24
Treatment with statins (%)	21 %	6 %

Also based on these data, we would like to expand the care for patients with PAD by a more intensive and individualized approach focused on lipid disorders. To reach this goal the third society involved – the Forum of Healthy Nutrition – is able to provide effective lifestyle interventions approved by professional nutritionists and, most importantly, develop comprehensive educational materials both for the education of health care professionals as well as patients. All of the above mentioned organizations/societies have already been closely cooperating for several years in organizing interdisciplinary educational meetings and also in preparing educational materials for primary care providers. In summary, the team including lipidologists, angiologists and nutritionists will collaborate with 30 selected primary care physicians in detecting and treating dyslipidemias. A total of approximately 300 patients will be included together with approximately 600 family members.

Anticipated Challenges and Solutions:

The first challenge is the willingness of primary care physicians to participate. It could be encouraged using several steps. First, by persuading primary care physicians that this project will broaden their area of expertise together with increasing their esteem among colleagues and patients and easing their cooperation with specialists. Second, by stressing the importance of the fact that if the project is successful, it will be a powerful tool for negotiations with health care authorities and payers to include these activities into the

regular and insurance-covered areas of primary care. Third, by implementing a small initial motivation fee (ten USD per patient) that could increase cooperation (based on experience from MOET study).

The second main challenge is the compliance of patients with PAD, mainly that of smokers and type 2 diabetics who are less adherent to lifestyle changes and medication. The family approach is of critical importance here. Motivating the whole family, especially spouses and siblings, could improve the adherence to lifestyle changes and increase compliance to medical therapy. Another step towards increasing adherence to recommended management is an interdisciplinary approach offering particular patients and their families consultations with specialists in dyslipidemia.

Expected Outcome and Its Evaluation:

At the end of the project primary care physicians should be able to order appropriate tests for the detection of dyslipidemia, exclude its potential secondary causes and appropriately administer lipid lowering drugs. In complicated cases a team of specialists will be available for consultation and more specialized care for the patients. The outreach of the program will be enhanced by the training of primary care physicians so that they will be able to continue the education of their peers in the next planned phase of the program (train the trainers principle). The target outcome is to spread this project to every district of the Czech Republic. Results/experience obtained could also be used for negotiation with health care authorities and payers to support this approach on a long term and systematic basis. In addition, international cooperation is expected with neighboring countries and other countries in Eastern Europe. Evaluation will be done by analyzing risk profile, mainly lipid parameters of patients and their relatives before and after the project. Because of educational character of the study and ethical reasons (patients with PAD are at the highest risk if not treated) no control group will be used for comparison and outcomes will be assessed by the changes of cardiovascular risk profile inside the intervention group.

ii. Describe the primary audience(s) targeted for this intervention. Also describe who will directly benefit from the project outcomes.

The primary audience will be general practitioners, who will be continuously educated in management of dyslipidemia with the possibility of immediate consultation with appropriate specialists from the fields of lipidology, angiology and nutritional counseling. From the project outcomes the net benefit is expected in patients at the highest risk for cardiovascular events. We expect additional benefits to be delivered to family members of this group of patients, further expanding the impact of preventive measures.

b. Intervention Design and Methods:

This intervention will start with the selection of 30 primary care physicians; first contact was in fact already made and there has been very positive preliminary feedback indicating that most addressed primary care physicians will cooperate. The first step will be a one-day meeting of the 30 selected primary care physicians, followed by 3 additional one-day meetings. The approach to the patients will be as follows:

1. First contact with patient with PAD – explaining the purpose of the project (including reasoning why to involve family members). After patient approval, assessing the

global cardiovascular risk, assessing current treatment including hypolipemics and scheduling visit for him/her together with family members in one month.

2. Second visit: measuring fasting plasma lipids, glycaemia, other appropriate biochemical factors (creatinine, liver tests, plasma creatinine, ...), and if indicated thyroid stimulating hormone (TSH). At this visit, lifestyle intervention by nutritionists including delivery of prepared printed materials – brochures, leaflet to the patient and his family, filling up EPAT questionnaire. According to plasma lipid spectrum – treatment with statins with scheduled control in 6-8 weeks. If plasma/serum LDL cholesterol will be more than 5 mmol/l, triglycerides more than 5 mmol/l or HDL cholesterol less than 0,7 mmol/l, or other problems (intolerance of statins, ...) – contact with/referral to lipidologist. If problem with PAD (progression of disease) – contact or referral to angiologist. This visit will be documented in database as the **Visit 1**.
3. Third visit in 6-8 weeks to check the effect of nutritional intervention/ hypolipemic treatment. According to status/responsiveness next visit scheduled for 2-6 months.
4. Follow-up visits according to status/responsiveness including counseling/referral with/to lipidologist, angiologist, and nutritionist. Obligatory **Visits 2, 3 and 4** at **3rd, 9th and 20th** month after recruitment, at which data according to simple protocol are to be obtained, recorded.

The content of the first meeting before starting patient recruitment will be as follows:

- 1) Introduction of the project – why it is being implemented
- 2) Angiology basics, management of lipid disorders and nutritional counseling
- 3) Short test – evaluation of the basics in angiology, lipid disorders and nutritional counseling – optionally anonymous
- 4) Presentation of basic materials with instructions on how to use them: questionnaire/database, Eating Pattern Assessment Tool (EPAT)
- 5) Introducing main coordinator/co-workers, specialists and providing contacts
- 6) Presentation and distribution of materials needed for the project (Syllabus containing extraction of educational materials for physicians, education materials for patients, protocols)
- 7) Evaluation of the test

The content of the second meeting 3 months after the start of recruitment will be as follows:

- 1) Challenges of the project and their solutions
- 2) Repeating the basics in angiology, management of lipid disorders and nutritional counseling
- 3) Short test – on a similar level as at the first meeting
- 4) Presentation of first data
- 5) Presentation of challenging patient cases by coordinators
- 6) Evaluation of the test

The content of the third meeting approximately 12 months after the start of recruitment (approximately 10 months after the second meeting) will be as follows:

- 1) Challenges of the project and their solutions

- 2) A more advanced test based on cases
- 3) Presentation of data obtained in the project
- 4) Presentation of cases by coordinators and general practitioners
- 5) Evaluation of the test

The content of the fourth/final meeting 18 months after the start of recruitment (12 months after the third meeting) will be as follows:

- 1) A more advanced final test
- 2) Presentation of final data of the project
- 3) Discussion of strategy on how to disseminate outcomes of the study among the professional and lay public
- 4) Creation of a final document – will be used for future negotiations with health care authorities
- 5) Evaluation of the test

All coordinators and responsible specialists will be in personal/on-line contact with all participating physicians throughout the study regarding counseling and other organizational matters.

c. Evaluation Design

The impact of activities in the project will be determined at several levels:

- 1) By changes in the score of the tests for primary care physicians
- 2) By the number of patients and their family members recruited at particular periods (critical time points – 3rd and 6th months of the study)
- 3) By the number of patients treated by statins
- 4) By the risk profile of the patients determined by changes in smoking habits, EPAT score, weight, waist circumference, blood pressure and lipid parameters – compared with the historical control group

Sources of data to assess the impact of the project:

- 1) Test results
- 2) Database created for this project regarding basic data of patients included

Data regarding patients will be obtained in a single sheet protocol for each patient and his/her family members. Data will be collected in a simple database at the coordinating centre (Czech Atherosclerosis Society). Please see the content of the protocol below.

VISIT 1 (0 months)

Name: Gender: Date of birth: Peripheral artery disease diagnosed since:

Other cardiovascular diseases diagnosed since:

Family members available for intervention:

Smoking: Non-smoker Quit smoking in: Current smoker

Diabetes mellitus diagnosed since: Hypertension treated since:

Dyslipidemia treated since: E.P.A.T. score 1: E.P.A.T. score 2: Statins:

Height: Weight: Waist circumference: Blood pressure:

LDL cholesterol: Triglycerides: HDL cholesterol:

Fasting glycemia: TSH:

VISIT 2 (3 months – including family members)

Name: Gender: Date of birth:

Other cardiovascular diseases diagnosed since:

Smoking: Non-smoker Quit smoking in: Current smoker

Diabetes mellitus diagnosed since: Hypertension treated since:

Dyslipidemia treated since: E.P.A.T. score 1: E.P.A.T. score 2: Statins:

Weight: Waist circumference: Blood pressure:

LDL cholesterol: Triglycerides: HDL cholesterol: Fasting glycemia:

VISIT 3 (9 months – including family members)

Name: Gender: Date of birth:

Other cardiovascular diseases diagnosed since:

Smoking: Non-smoker Quit smoking in: Current smoker

Diabetes mellitus diagnosed since: Hypertension treated since:

Dyslipidemia treated since: E.P.A.T. score 1: E.P.A.T. score 2: Statins:

Weight: Waist circumference: Blood pressure:

VISIT 4 (FINAL – 20-22 months – including family member)

Name: Gender: Date of birth:

Other cardiovascular diseases diagnosed since:

Smoking: Non-smoker Quit smoking in: Current smoker

Diabetes mellitus diagnosed since: Hypertension treated since:

Dyslipidemia treated since: E.P.A.T. score 1: E.P.A.T. score 2: Statins:

Weight: Waist circumference: Blood pressure:

LDL cholesterol: Triglycerides: HDL cholesterol: Fasting glycemia:

These are visits to be stored in the database – other visits to manage risk factors are expected according to the status of particular patient.

Method used to control for other factors outside this intervention (e.g., use of a control group)

Because this program is focused on educational activities and also for ethical reasons no control group is to be used – only changes inside the intervention group will be evaluated. At the end of the study available records of patients with examined in 1-2 year interval before this project will be used for comparison.

Expected outcomes are as follows:

1. Quitting smoking (at least 30 % patients – original active smokers)
2. Decrease of waist circumference (at least 3 cm men/women)
3. Reaching recommended values of LDL cholesterol (bellow 2,0 mmol/l) in at least 75 % of patients
4. Reaching recommended values of triglycerides (bellow 1,7 mmol/l) in at least 50 % of patients

Engagement of primary care physicians is to be assessed as follows:

1. By attendance at the meetings
2. By results of the tests
3. By number of patients recruited (in 3 months intervals)
4. By number of patients treated with statins (in 3 months intervals)
5. By number of patients reaching the treatment goals (in 6 months intervals)

Dissemination of the outcomes will be as follows:

1. By presenting data at national meetings of professional societies – priority will be given to the professional meetings of general practitioners, but also to local meetings of the Czech Atherosclerosis Society and the Czech Society for Angiology
2. By presenting the data at smaller local meeting of general practitioners
3. By publishing information on web pages: general practitioners, Czech Atherosclerosis Society – www.athero.cz , Czech Society of Angiology – www.angiology.cz, Forum of Healthy Nutrition – www.fzv.cz; the latter focused rather on the lay public
4. By publishing an introductory paper in local Czech journals focused on general practitioners (“Praktický lékař”), and publishing the final results of the study in the same journal

Detailed Workplan and Deliverables Schedule:**Time schedule:**

Activity	Period
Preparation of protocols, questionnaires, educational materials, database incl. service, recruitment of general practitioners, preparation of web pages	April 2014 – June 2014
First introductory meeting	September 2014
Recruitment of patients and their families	September 2014 – February 2015
Second meeting	November/December 2014
3 month visits of patients/intervention	January 2015 – June 2015
Third meeting	September 2015
9 month visits	May 2015 – December 2015
24 month visits	January 2016 – March/April 2016
Final meeting	April 2016
Sharing the information at congresses, in the media, on websites, ...	Throughout the whole project