

DRAFT PROGRAM OF PREVENTION OF DIABETIC FOOT DEVELOPMENT AND LOWER EXTREMITY AMPUTATION IN PERSONS WITH DIABETES MELLITUS

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Key words: diabetes mellitus, diabetic foot, lower limb amputation, epidemiology, incidence, prevention

SUMMARY

Patients with diabetes mellitus have a twenty-fold risk of lower limb amputation recorded in the general population. In most countries, the incidence of leg amputation has been on a decrease over the last two decades as the result of organized preventive actions, improvement in surgical techniques, and a multidisciplinary approach to the issue. However, there are still examples of unchanged incidence despite specific measures undertaken. The objective of the planned program is to upgrade foot care in diabetes patients at Vuk Vrhovac University Clinic and to reduce the number of amputations in patients routinely examined at the Clinic by 50% by the year 2010 (during a 5-year period). The program will be carried out in three stages: analysis of the current situation; implementation of prevention program; and evaluation of results. The incidence of foot ulcers and amputations will be estimated by the analysis of records of all patients examined during September and October 2005. Patient education on foot care has so far been carried out at Outpatient Department as part of the general patient education, which has been evaluated as inadequate in both the quality and quantity. Feet have not been examined in all patients. The

program target population are all persons with diabetes mellitus examined during a year, i.e. 15,000 persons. The program consists of three substages: screening of feet at risk (case history, feet and footwear inspection, pulse test and test for neuropathy (monofilament, tuning fork or cotton wool)), education of patients (brief introductory and extended education carried out by a nurse using a structured questionnaire), and for those found to be at risk of amputation referral to additional work-up. Records of patients examined during September and October will be analyzed annually, and statistical analysis will include all patients who underwent the given program.

INTRODUCTION

Out of the total number of all lower limb amputations, 40%-60% are carried out in persons with diabetes mellitus, and more than 85% of them are the consequence of a diabetic foot affected by deep infection and gangrene (1). Persons with diabetes mellitus are at a twenty-fold risk of lower limb amputations recorded in the general population (2,3), amputations of lower extremities and diabetic foot being the main cause of morbidity and disability as well as of emotional and physical losses in persons with diabetes mellitus. Therefore, programs of prevention which would lead to a reduction in their incidence deserve particular consideration.

Reduction in the number of amputations associated with diabetes by at least a half within 5 years was one of the primary goals for Europe as declared by the St.

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Vincent Declaration from 1989 (4). This also points to the extent and recognition of the importance of the problem of amputations in diabetes by the public health and clinical communities.

PREVALENCE OF THE DISEASE

Data from the International Diabetes Federation (IDF) estimate the prevalence of lower extremity amputations in persons with diabetes as ranging from 0.2% (Mauritius; persons with undiagnosed diabetes mellitus included) to 4.8% (Sri Lanka; only persons with type 2 diabetes included) (5). The incidence rate in particular European countries ranges from 20 to 50/10,000 patients with diabetes *per year* (6,7,14). In most countries, e.g., The Netherlands, United Kingdom, U.S.A., Denmark, Sweden, Finland, Turkey etc., a decrease in the incidence of lower limb amputations has been recorded over the last two decades (7-13) as the result of organized preventive actions (1), improvement in surgical techniques, e.g., better revascularization techniques (10) and multidisciplinary approach to the problem (9), although the results from studies in certain countries indicate an unchanged incidence despite the specific measures undertaken, e.g., Germany (14).

ETIOPATHOGENESIS

The interaction between diabetic neuropathy and circulatory impairments occurring in persons with diabetes leads to functional and structural changes, which are preconditions for the development of neurotrophic and ischemic foot ulcers (15). The development of diabetic foot ulcer is shown in Fig. 1 (16).

PREVENTION

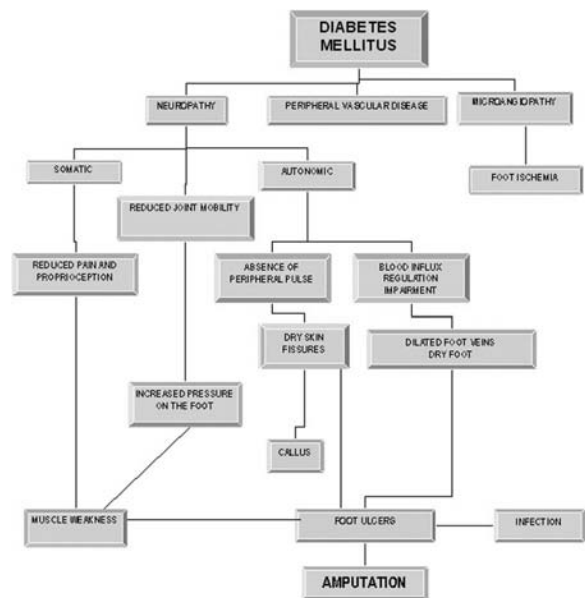
Early detection and treatment of independent risk factors may prevent or delay the onset of diabetic foot (17). The risk of ulcers and amputations is increased in persons with diabetes duration longer than 10 years, in men, and in those with poor glycemic control (18) and/or cardiovascular, retinal or renal complications (19). The following conditions are related to an increased risk of amputation (17):

- peripheral neuropathy with loss of protective sensation,

- altered biomechanics (in the presence of neuropathy),
- evidence of increased pressure (erythema, hemorrhage under a callus),
- bone deformity,
- peripheral vascular disease (decreased or absent pedal pulses),
- a history of ulcers or amputation, and
- severe nail pathology.

International studies report data on up to 50% efficiency of preventive programs (20), implementation of clinical guidelines in primary health care (11), patient education (13), foot care and wearing appropriate footwear (12), education of health professionals and multidisciplinary approach (1) to the reduction in the incidence rate of amputations in persons with diabetes (1). Until recently, the analysis of the economic effect of interventions in diabetes care could not establish clear economic influence of preventive programs of foot care because of the lack of studies, although presumptions have been made that a formal economic research will corroborate their undisputable cost-effective and even cost-saving effect (21). A recent study conducted in The Netherlands has confirmed an unambiguous cost-effective and cost-saving effect of the application of clinical guidelines in treatment (22), whereas thorough economic studies of other interventions are still lacking.

Figure 1. Development of ulcers on diabetic foot



CROATIA

Epidemiologic data on Croatia are very scarce. Estimates based on polls among diabetologists from the secondary and tertiary health care levels report on the prevalence of peripheral vascular disease and neuropathy in persons with diabetes mellitus of 11% and 28%, respectively, whereas exact data on amputations are lacking (23). Extrapolating current data from European countries (6,7,14) (20-50 amputations/10,000 persons with diabetes a year) to Croatia, with an estimate that approximately 250,000 persons in Croatia suffer from diabetes mellitus, it can be calculated that the number of amputations ranges from 400 to 1250 persons *per* year. The Working Group of the Croatian Model for the Prevention and Care of Foot Complications has adopted a national consensus in 1998, expressing the needs and defining the methods to implement prevention and treatment in this part of health care (24). This consensus has stressed the importance of all aspects of education as well as the team and multidisciplinary approach to the prevention and treatment of diabetic foot and reduction in lower extremity amputations (25). The document also describes a clinical protocol and a questionnaire for the early detection of diabetic neuropathy, clinical guidelines for the indication of arteriography, and the examination of a diabetic foot.

The International Working Group on the Diabetic Foot (IWDF) published the International Consensus on the Diabetic Foot in 1999, with the aim to provide guidelines for the prevention and treatment that would lead to a reduction in the incidence of diabetic foot and consequential amputations by means of high quality health care, taking into account the costs of care and the implementation of the principles of evidence-based medicine based on expert opinions (26). The Croatian National Consensus has also recognized all these problems and issued almost identical guidelines for diabetes foot care.

The basic principles of diabetes foot care are as follows:

- regular examination and inspection of a foot at risk,
- identification of a foot at risk,
- education of the patient, family and health professionals,
- appropriate footwear, and
- treatment of non-ulcerous pathology.

The planned preventive program will primarily comprise screening of a foot at risk and education of the patient and/or his/her family (efficient and efficacious measures that are relatively easy to implement in daily routine of the Vuk Vrhovac University Clinic outpatient clinic at a low cost, which have not yet been fully implemented in terms of quality).

THE AIM OF THE PROGRAM

The aim of the planned program is to improve the care of persons with diabetes in relation to diabetic foot and to reduce the number of lower limb amputations by 50% by 2010 (during the next 5 years) in the population of patients regularly followed at the Vuk Vrhovac University Clinic.

DRAFT PROGRAM AND PLAN OF FOOT AT RISK SCREENING WITH INTENSIVE PATIENT EDUCATION

The program should be carried out in 3 main stages:

- analysis of the current situation
- implementation of prevention program
- evaluation of results

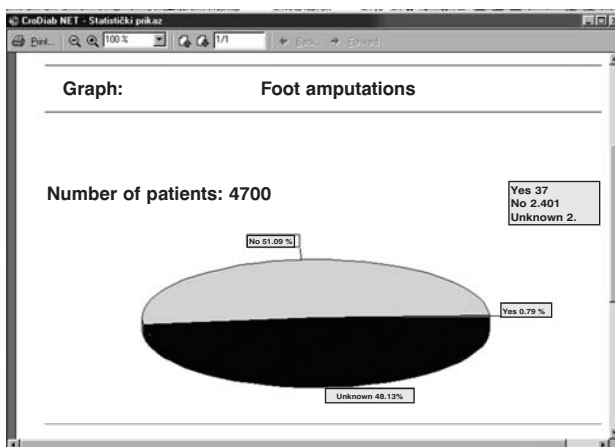
Analysis of the current situation

More than 50% of patient medical records do not contain data on lower limb amputations (Fig. 2). Records of all patients examined during September and October 2005 will be analyzed in parallel with intervention, thus to improve the quality of data from the National Registry of Patients with Diabetes Mellitus (Fig. 3). The data obtained will serve as a basis for the evaluation of the incidence of foot ulcers and lower limb amputations in the population of persons with diabetes treated at the Vuk Vrhovac University Clinic.

Patient education on foot care has so far been carried out at the Outpatient Department as part of the general patient education on diabetes and its complications at the patient's first visit to the Clinic. The education was carried out by registered nurses trained in diabetes care. Because of such an organization, the education has proved inadequate in both its quantity (patients were educated on several most important procedures of foot care considering a

large number of topics that should be covered) and quality (the quality of the data presented is good, yet considering a large number of facts presented over a short period of time, only a small number of patients could actually adopt them). Moreover, although recording of an appropriate foot examination has been anticipated in the application software (CroDiabNET) used in daily routine for documenting patient visits, examinations and analyses as well as forming a case history, such examination was not made in all outpatients (Fig. 2).

Figure 2. Number of patients expected to undergo examination at the Vuk Vrhovac University Clinic Outpatient Department over a 2-month period with actual availability of amputation data



Approximately 18,000 persons are examined at Outpatient Department *per* year, with only a small number of cases not being diagnosed with diabetes mellitus (the persons are found to have a good glycemic status or to suffer from impaired glucose tolerance). The target population of this preventive program are all persons with diabetes mellitus examined at the Vuk Vrhovac University Clinic Outpatient Department during a year (about 15,000 persons).

Implementation of prevention program

The program consists of the following substages:

- screening of feet at risk
- education of patients
- referral to additional work-up

Screening of feet at risk should be carried out in each patient who presented to the Clinic more than six months before, or more than four months before if

previous screening test contained at least 1 affirmative answer. The screening should include history data on the possible previous ulcers and/or amputations, foot inspection (deformities, bone prominence, callus, skin integrity, joint motility, and discoloration) and footwear, examination of pulse at dorsal arteries of the foot and posterior tibial artery, and neuropathy testing (monofilament, tuning fork or cotton wool) (Fig. 3). Predilection sites for foot ulcers as well as monofilament and tuning fork examinations are presented in Figures 4 and 5.

Figure 3. The form for screening patients at an increased risk of diabetic foot development during clinical examination

A FOOT IS AT RISK IF ANY OF THE ANSWERS IS AFFIRMATIVE

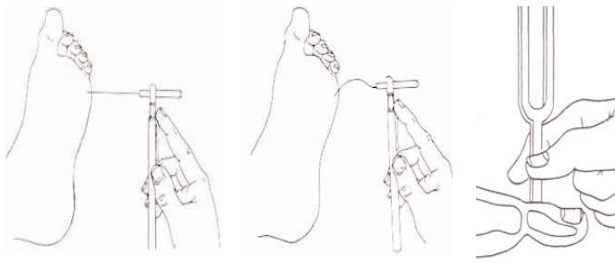
Deformities or bone prominence	YES/NO
Skin is not intact (ulcer)	YES/NO
Neuropathy	
- monofilament undetectable	YES/NO
- tuning fork undetectable	YES/NO
- cotton wool undetectable	YES/NO
Abnormal pressure, callus	YES/NO
Loss of joint mobility	YES/NO
Pulse	
- absent in posterior tibial artery	YES/NO
- absent in dorsal arteries of the feet	YES/NO
Discoloration	YES/NO
Other	
- previous ulcer	YES/NO
If yes, was it within the last year	YES/NO
- previous amputation	YES/NO
If yes, was it within the last year	YES/NO
Inappropriate footwear	YES/NO
Actions should be undertaken	
Actions recommended	YES/NO
Referred for additional work-up	YES/NO

Figure 4. Predilection sites for the onset of diabetic foot ulcers



Education of patients should be carried out in two forms. All patients who present to the Clinic for the first time and who have not been identified as having a

Figure 5. **Testing for the presence of diabetic neuropathy by monofilament and tuning fork**



foot at risk by the screening, should be educated in general in accordance with the practice performed so far. Extensive education should be provided to all other patients, according to the following recommendations: the patient should be given educational material containing all information presented within education. The aim of the education is to enhance the patient's motivation and to improve his/her skills in diabetic foot care. The patient should be educated on how to recognize the potential foot problems and undertake necessary measures in case these occur.

Extended education should be carried out on several occasions (the first part of education should be performed along with screening at program implementation on the day of the patient's visit to the Clinic and blood sampling; the second part should be performed at the patient's second visit a week later, when he/she comes to discuss the findings with the physician). The education should be performed by use of several methods, and it is important that the educator demonstrates particular skills (e.g., proper nail cutting) whenever possible. The patient's understanding, motivation and level of competence in foot care should be evaluated after the education. The following areas should be encompassed by the education of patients with high risk feet:

- daily foot inspection, including areas between the toes,
- if the patient cannot inspect the feet, someone else should do it,
- regular washing of the feet with careful drying, especially between the toes,
- temperature of the water should always be less than 37 °C,
- avoidance of barefoot walking in- or outdoors, and of wearing shoes without socks,

- chemical agents or plasters to remove corns and calluses should not be used,
- daily inspection and palpation of the inside of the shoes,
- in case of impaired vision, the patients should not try to treat the feet (e.g., nails) by themselves,
- lubricating oils or creams should be used for dry skin but not between the toes,
- daily change of stockings,
- wearing stockings with seams inside-out or preferably without any seams at all,
- cutting nails straight across,
- corns and calluses should not be cut by patients but by a health care provider,
- the patient must ensure that the feet are examined regularly by a health care provider, and
- the patient should notify the health care provider immediately if a blister, cut, scratch or sore has developed.

Each individual patient should be properly informed on the importance of quitting smoking and achieving good glycemic control as part of the prevention of diabetic foot development and consequential lower limb amputation. Education will be performed by a registered nurse trained in diabetes care.

Each patient who has given at least 1 affirmative answer should be additionally evaluated by a specialist diabetologist, who will decide whether the patient should be referred for additional work-up or examination by a specialist for diabetic foot care (an internist, a diabetologist or an angiologist at the Vuk Vrhovac University Clinic, or a surgeon at another institution).

Evaluation of results

Each year, as of 2005 until the end of the planned 5-year period, records of all patients examined during September and October of the current year will be analyzed (in case the quality of data from the registry at the time of analysis is satisfactory, it can also be used for the evaluation). Statistical analysis will include all patients having undergone the given program, and the groups will be standardized according to sex, age, disease duration, HbA_{1c} values, and presence of other chronic complications in case they differ in any of the above parameters.

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