

**THERAPEUTIC PRINCIPLES IN DIABETES- RELATED FOOT
PROBLEMS WITH COMPLICATIONS OF VASCULAR LESIONS AND
SOFT TISSUE**

- SUMMARY-

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INTRODUCTION

The treatment of the diabetic foot requires a multidisciplinary approach by the specialists, for the classification and the management of the lesions. Efficient care of diabetic foot wound assumes elaborating a therapeutic program adapted to local human and material resources. The screening and diagnostic of diabetic foot must identify etiopathology factors, concomitant diseases, ulceration and clinical aspects.

Diabetes patients may develop many types of foot wounds, many of which can become infected. Foot infections at patients with diabetes cause substantial morbidity and frequent visits to health care professionals. Limb salvage requires early prevention therapy, knowledgeable use of wound care technology and active approach management of the diabetic foot complication.

The association of several pathological conditions in the notion of “diabetic foot” was imposed by the necessity of a unitary management of multiple apparent manifestations: neurological, vascular, orthopedic or infectious. [1]The complications of the diabetic foot represent the most important long term issue of diabetes mellitus with considerable medical, social and economical implications. It is also the most invalidating complication. Lower limb amputation, a devastating consequence of diabetes, remains a common outcome of diabetic foot complication. Amputation is not only a costly outcome for the patient but also expensive for the health care system.

Although diabetic foot affections were known and described since Middle Age in Avicenna's articles (980-1037) then in Falopius studies (XVIth century), or in antiquity in EBERS writings (1500 BC), the presence of molds and antique statues with the aspect of arterial lesion limbs, complication treatment suffered alterations during time. Current knowledge about diabetes and vascular pathology impose correlation of surgical treatment with endocrinology as well as a therapeutic educational program for diabetic patients.

MANAGEMENT OF COMPLEX DIABETIC FOOT CARE

Various classifications for evaluating the diabetic foot lesions (diabetic neuropathy stage formulated by Mayo Clinic, mentioned by Tanenberg, evaluation of diabetic foot ulcer by Wagner- Meggit, Edmond and Foster staging) in order to improve therapeutic approach of the complicated diabetic foot and the results of the past two decades in specialised centers in Europe (Holland, Sweden) managed to lower amputation rate to 49- 85%.

Diabetic foot care in pre- lesion stage

The management of diabetic foot care in this stage aims to maintain employment in this stage, by holding mechanical, metabolic and educational control. Mechanic control addresses to adequate shoe use and rigorous monitoring of minor foot problems. Metabolic factors treatment that predispose to neuropathy and ischemia aims to hyperglycemia, arterial hypertension, hyperlipemia control and giving up smoking. Educational control is extremely important for preventing complications and needs full cooperation from the patient. Auto-examination and daily care of the feet as well as annual medical examination of the feet must be a part of the diabetic patient care program

Diabetic foot care in high risk stage

Employing the diabetic foot in this stage assumes the existence of one or more risk factors for ulcer appearance: neuropathy, ischemia, foot deformities, callus and transpiration. Care management of the foot consists in dry skin care using hydration creams, staging the physiopathologic form : neuropathic or neuro ischemic. After confirmation of peripheral vascular affection antithrombotic treatment starts. Physical exercises, metabolic and educational control may help slowing down vascular and soft tissue deterioration processes. General inadequate individual approaches must be avoided. Education must be intensive, individualized and continuous and medical evaluations must be biannual or even every four months.

Diabetic foot care with ulcerative lesions

Diabetic foot ulcerations, neuropathic as well as neuro ischemic, may aggravate rapidly, skin lesions representing a bacterial way in thus every ulceration must be controlled and

individually evaluated. Treatment strategy assumes transformation of ulcerations in "acute" lesions which retake physiological cycle towards healing and aims to ulcer cure in 6 weeks. It aims avoiding local pressure points, inflammatory response monitoring and microbiological effects evaluating antibiotic use possibility, improving wound self care techniques. The absence of a favorable response in six weeks may be due to ischemia and the possibility of a vascular intervention must be quantified and taken in consideration. Surgical treatment of the wound means debridement adequate dressing, exudate drainage and removal of devitalized tissue. In case of reduced exudative wounds are indicated hydrogel, semi-permeable film, hydrocolloid products and in case of abundant exudate are indicated alginate calcium or hydrophobic products covered with secondary dressing. Hydrogel products contain insoluble polymers which increase their volume, up to saturation, facilitating epithelization by maintaining a humid medium at the surface of the wound. It is not used in case of suspicion of anaerobic infection.

Diabetic foot care in cellulitic stage

Clinical signs of cellulitic leg may be undercover by the presence of neuropathy and/or ischemia, infection of diabetic foot being aggravated by the existence of immune system deficiencies. A multidisciplinary approach and a rapid evaluation of the lesions is imposed in order to prevent tissue loss. Infection features are: lower temperature of the feet than needed for development of most pathogenic bacteria, fat acid excess and low pH of plantar and dorsal surfaces and corneum thickness in the plant. Care management assumes introducing cavitory dressings and use of large spectrum antibiotics, surgical debridement of the wound and surgical re-vascularization interventions (angioplasty or by- pass). Protection against bed sores is important. Metabolic and educational control must monitor risk factors and help the patient to protect his/ hers health.

Foot care in necrotic stage

Wet necrosis is the most frequent necrosis of diabetic foot and appears when there is an uncontrolled infection of the foot which determines septic vasculitis. Dry necrosis, acute or chronic is caused due to poor tissue perfusion. Lesion approach assumes surgical debridement and vascular control: neuropathic foot which presents palpable arterial pulse does not necessitate surgical intervention and neuro ischemic foot needs investigations that confirm ischemia (echo Doppler, angiography). Percutaneous angioplasty and by-pass may optimize

perfusion and increases chances of tissue salvage. Debridement methods include humid gauze with physiologic serum, bio- surgery (sterile larvae), surgical debridement as well as non-mechanic debridement: polysaccharides powders and pastes (Dextranomer, cedexamer iodine) enzymatic agents (trypsin, streptokinase), hydrogel applied directly on wound bed and held with nonadherent dressing.

Apart from amorphous gels, hydrogel- plaques are available. Debridement is a critical component in preparing the wound bed in order to heal. Non- mechanical debridement techniques increased amongst wound cleaning methods and include: enzymes, hydrogel and chemical specific components. The patients with dry necrosis need fast intravenous treatment with a large spectrum antibiotic. The antibiotic treatment is also perscribed for those with humid contaminated necrosis. The methabolic control can appeal to the use of insuline. The mechanical and educational control must underlina the importance of resting in bed and avoiding applying pressure on the affcted areas.

Foot care in major amputation stage

Patients who suffered major leg amputation despite interventions for infection treatment or leg reperfusion, necessitate longer period for rehabilitation. Non-amputated part presents a high risk of amputation in the absence of an adequate treatment. Plastic reconstructive surgery is necessary sometimes in repairing important tegument defects. As methods can be used autologous skin grafting or skin flaps mobilization. Unfortunately amputations currently represent a frequent resolution of diabetic foot complications, especially diabetic gangrene.

THE PRACTICAL SECTION

MATERIALS AND METHODS

Diabetic foot complications are leading cause of lower extremity amputation and also represent a challenge to the health care centers. The aim of this study is to develop therapeutic principles that can be used in current practice.

We made the retrospective analysis of the treatment on 106 patients which presented various foot lesions secondary to diabetes mellitus complications during January 2002 - October 2007 (control group) and the prospective analysis of therapeutic efficiency applied on a number of 78 patients with diabetic foot complications during November 2007 - January 2011 (study group), hospitalized in the Surgery Clinic I in Sibiu.

Different risk factors of the diabetic foot have been estimated within the prospective study as well as the special features of each individual among patients such as: environment, age, gender, duration of the diabetes mellitus, smoking, previous surgical interventions, body mass index, associated pathology. We have followed up the use of the new products, the latest on the market and their efficiency regardless of the manufacturer in order to establish the function of the different types of wound dressings in modern therapy of the diabetic ulcers.

Physical-kinetic treatment applied off and on to patients of the case-control group was included in a well supervised program addressed to patients with amputations of lower limbs and it was directed to the immediate post surgical phase as well as after the recovery period of the surgical blunt. While treating the patients of the control group, there were used traditional methods to care for the wound: sterile gauze dressings, used in the epitalisation stage but also as a secondary, absorbent wrapping and non stick dressings, or with small adhesion, used in the case of less exudative wounds. The patients in the study group benefitted of a more modern treatment by using modern dressings of the wounds: alginate, dressings with silver, polyurethanes, hydrocolloids, hydro gels, and films as well as processing outbreak of necrotic purulent surgery in successive stages and the help of plastic and reconstructive surgery in successive stages and the help of plastic and reconstructive surgery.

The clinical data, introduced in the case-control study, was selected based on the existing records of the registry of the Surgery Clinic I of Sibiu, operative protocols and the observation sheets, while the lab analysis and the types of wound dressings used on the patients of the prospective study, were synthesised based on the annotations of the research charts written at the patients' hospital admission and diagnostic.

The statistical analysis was feasible by written records on the research sheet filled in regularly for each individual patient. The obtained parameters were noted in tables, statistically processed and graphical rendered. The results were compared through t Student test or the analysis of variance (ANOVA). Only the values $p \leq 0,05$ were considered statistically significant. The standard linear regression analysis and the r Pearson's correlation coefficient were used to determine the relationship between the variables.

In order to establish a therapeutic program for improving the medical assistance of the patients' diabetic foot with complications of vascular lesions and soft tissue, different synthesised data from this study was corroborated with the recent research described in the specialized literature (2011) and the results of my personal study carried out as a member of the surgical team performing vascular surgeries at the Cardio-vascular Surgery and Transplant

Clinic of Targu-Mures during January 2009- October 2011 as well as the experience in the vascular and endovascular surgery techniques acquired at the Service of Vascular and Thoracic Surgery of Avignon, France starting with November 2011.

I've considered useful the analysis of data collected from the patients of a single medical service in order to access the information gathered in a unitary manner thus eliminating the relative codifications of the studied variables which could have appear on the charts or files of different wards.

ANALYSIS OF THE VARIOUS RESULTS, DISCUSSIONS

The analysis of the results was carried out through keeping track of some aspects of the individual features of the diabetes mellitus as well as the complications occurred in the diabetic foot.

Main diagnosis for patients with diabetic foot complication at hospitalization shows an increased number of gangrene (wet and dry) on towels and foot, distributed on both groups. (Table I)

Table I: Diagnosis for patients with diabetic foot complication

DIAGNOSIS	Control group- frequency	Control group- percentage	Study group- frequency	Study group- percentage
wet gangrene towes	14	13,20%	11	14,10%
wet gangrene foot	16	15,09%	9	11,53%
dry gangrene towes	9	8,49%	7	8,97%
dry gangrene foot	8	7,54%	6	7,69%
osteitis/ osteoarthritis	9	8,49%	7	8,97%
foot cellulite	11	10,37%	8	10,25%
trophic ulceration	18	16,98%	15	19,23%
necrotizing fasceiitis	2	1,88%	3	3,84%
phlegmon in the back of the leg	6	5,66%	3	3,84%
deep abcess of the foot	13	12,26%	9	11,53%

The patients were distributed by the forms of clinic manifestation in two subgroups: first subgroup: neuropathic form and the second subgroup: neuroischemic form. (Table II)

Table II: The distribution of patients according to clinical form

Clinical forms	Control group		Study group		Total number
neuropathic form	54	50,94%	42	53,84%	96
neuroischemic form	52	49,06%	36	46,16%	88

We analyzed the type of treatment of diabetic foot complication for patients included in the two groups. Our analysis found that disarticulation of the fingers was made at 74 cases with wet or dry gangrene of the fingers and those with infected neuropathic ulcers. The frequency of minor amputations and disarticulation of the fingers in both groups were distributed as follows: 46, 2% in the control group and 44, 8% in the study group.



Figure number 1. Aspects after disarticulation of the 2th finger.

High amputations were done on 35, 8% of cases in the control group versus 21, 7% cases in the study group, identifying a big statistic difference between the two groups ($p = 0.05$). The efficient caring of the wounds of the diabetic foot, involves the implementation of a therapeutic schedule adapted to the local human and material resources.

Table III: Types of interventions for diabetic foot complications

	control group frequency(percentage)	study group frequency(percentage)
necrectomy	9 (8,49%)	16(20,51%)
finger disarticulation	43(40,56%)	31(39,74%)
thigh amputation	38(35,84%)	17(21,8%)
leg amputation	6(5,66%)	4(5,13%)
exhaust phlegmon incision	2(1,88%)	4(5,13%)
tarso- metatarsal disarticulation	4(3,77%)	3(3,85%)
lobar sympathectomy	3(2,83%)	1(1,28%)
periarterial sympathectomy	1(0,95%)	2(2,56%)

There was no significant difference between the groups with regard to age and co morbidities. In the control group were 69 men and 37 women and in the study group were 52 men and 26 women with an average age of 62, 4 years.

The analysis of patients evolutions from the study group has attached a high impact of the surgical debridement of wound (removal of necrotic cellular material, foreign bodies and atonal tissue) and of the role of the hydro active dressing in wound healing.

While facing the patients' necrotic- purulent lesions of the diabetic foot with complications, we took into account the following:

- optimizing the vascularisation of the tissue in the area to be operated
- the tissue abscissions of the necrotic and suspected areas including the pusses, exudations or bone sequestra
- the large dissection and draining of the suppurating focus with the possibility of forming well vascularised flaps used for the subsequent plastic surgery of the wounds and defects

Surgical treatment of the purulent necrotic outbreak at the patients from the study group took place in several surgical stages. 78 numbers of patients have undergone 165surgeries with an

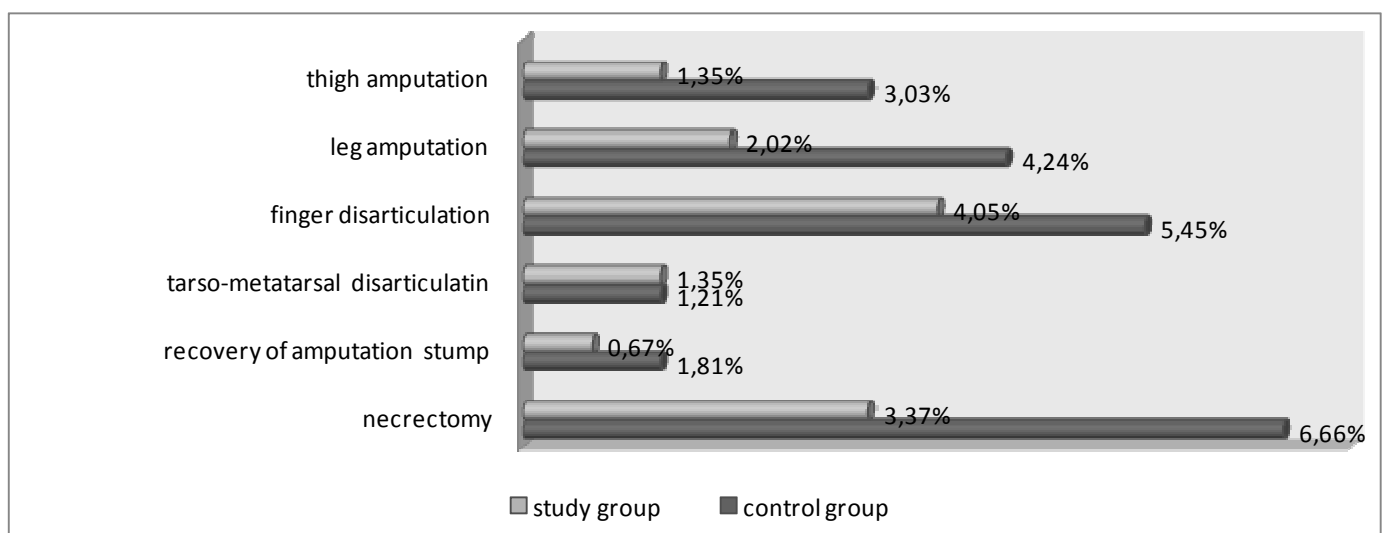
average of 2, 1 intervention per patient. In the control group there were 148 surgeries with an average of 1, 4 interventions per patient.



Figure number 2. Processing necrotic- purulent source, intraoperative aspects.

The hydro active treatment helps healing the wound by preventing infection and necrosis and by reducing the number of bacteria. The proportion of reinterventions for the post operative complications in the control group were 34.9%, and for the study group 24.3%. Most common causes of reintervention are: infection or suppurative wound (21 cases in control group versus 3 cases in study group), amputation stump necrosis (9 cases versus 4 cases in study group), post operative atonal wound (17 cases versus 7 cases). (Figure 3)

Figure 3: The distribution of cases according to reinterventions types



The impact of new kinds of dressings used in the local management of the diabetic wounds helps lowering the number of hospitalization days of the patients with complicated diabetic foot and the return to physical activities in a shorter time.

Calcium or sodium alginate dressings, derived from brown seaweed, should be used with a secondary cover dressing. These are indicated for wounds having moderate to heavy exudates (21 cases) as well as in case of cavity wounds (7 cases).

Polyurethane dressings have been used mainly for wounds having heavy exudates (12 cases) with granulation tissue and less for infected wounds (3 cases). Recommended especially for patients having a sensitivity to dressing adhesive or with a very sensitive skin.

Hydrocolloid dressings can be semi-occlusive which allow the vapour's transfer or occlusive, considered to be real interactive dressings. The vapour's transfer rate is controlled in proportion with the exudate, therefore I chose to apply them in wounds with light to moderate exudate (19 cases).

Hydrofibre dressings were used on necrotic wounds (12 cases) and for wounds with heavy exudate (14 cases).

Hydrogel dressings are biologically inactive, water based (around 70%) debridement agents. They were applied directly on the wound beds and maintained by a non-adherent dressing combined most of the times with an absorbent bandage. This type of dressing is recommended for wounds needing additional moisture and it facilitates the autolysis.

These types of dressings were used to remove fibrinous or necrotic tissue from the wound beds in case of granulating minor or light exudating wounds (11 cases).

Treatment of patients in the study group also included diabetes therapy, antibiotics, treatment of associated pathology, correction of ischemic phenomena and therapy of diabetic neuropathy and plantar pressure reduction in the affected limb by using different kinds of planting sustainers.

Lately, **wound dressings containing silver** are increasing in importance. White's studies from 2001 showed the successful use of silver sulfadiazine in different stages of the infected wounds. The silver containing dressings were indicated for wounds with signs of infections (11 cases).

The diabetic foot with solution of continuity of the skin represents a high risk for infections. There are no guides that would ensure the use of prophylactic antibiotics in case of uninfected

ulcerous lesions although some authors recommend them in the treatment of these types of lesions. The infection of the diabetic wound is frequently related to the cause of the lower limb amputations. In 30-60 % of the cases, the diabetic lower limb amputations are caused by infections.



Figure number 4. Wet necrosis.

The ATB treatment depends on the type of neuropathic ulcer / neuroischemic, the stages of cellulite, the presence or absence of osteomyelitis. The neuropathic ulcerous infections are the most common infections of the diabetic foot.

An empiric antibiotic therapy should be started while waiting for the results of the samples. There have been numerous studies to argue the use of amoxicillin combined to clavulanic acid. This combination is active on the most frequent germs met in the diabetic wounds: staphylococci, streptococci or enterococci.

The physical kinetic procedures were applied off and on to patients with amputations from the case control group (21 cases) and to all the patients with lower limb amputations of the clinical trial, although these procedures were complicated by specific individual situations such as edema and local infections or the patient's disinterest.

Our observations led to an obvious underestimation of the patient's physical efforts and controlled movements as well as the lack of enthusiasm of the family and friends' circle regarding the doctor's recommendations. The physical kinetic measures applied were the following: passive and active kinetherapy, isometric contractions, massages and the use of the orthopaedic/prosthetic devices.

The previous surgical interventions may lead to a change of the leg's architecture with changes of the body position and the plantar pressure points thus forming ulcerations. Within the clinical group these complications occurred in most of the cases of necrectomy as of 23,91 % of the previous interventions. The statistical analysis applied to patients of the clinical trials ($P \leq 0,05$) proves that previous surgical interventions represent a statistically significant risk factor.

The presence of traumas, the correction of deformations, the treatment of inter-digital mycosis represent the base of the prevention treatment in case of gangrene while in case of the mal perforans, avoiding the pressure areas and the septic purulence discharge and the ablation of keratosis through a constant care, represent a therapeutically efficient strategy.

CONCLUSIONS

1. The modern wound management with hydro active dressings is very well tolerated by the patients, with no prolonged hospitalization, needing only an ambulatory care under optimal medical conditions.
2. Surgical treatment of the necrotic-purulent focus in the diabetic foot with neuropathic complications should be conducted as early as the first stages thus definitely stabilizing the focus while in the neuro-ischemic complications we should take into account the revascularization of the limb.
3. The physical kinetic therapies facilitate the sustenance of the joints, the maintain of a good muscular trophicity and represent therapeutic options to improve the quality of life of diabetic patients with lower limb amputations.
4. The treatment of the diabetic foot ulcers may lead to successful results by combining the surgical therapy within the specialized services with the self-care of the lesions by the instructed patients.
5. Suppressing the pressure areas is a key component in managing the therapeutic strategy on patients with neuropathic plantar ulcer but it may be used successfully in other lesions as well regardless of its stage.
6. The optimal care measures depend on the individual features and the ambient environment. An unilateral direction of the therapy cannot be valid for all the patients. The patient and the medical team must select the benefits and the limitations of each strategic plan and decide together the appropriate approach.
7. Patients must be instructed and informed of the diabetes' fatal consequences. Any limb lesion or change even insignificant of the body position must be reported to the attending physician as soon as possible.
8. Modern dressings as an alternative to the conventional ones, represent a fine choice in the local therapy of the diabetic foot but they account only for a stage in the intricate treatment of the diabetic complications. They are recommended to use by the less-acquainted personnel with this type of lesions especially because of the easy way of applying the dressings and the efficient control of the wound. Their efficiency is evinced in a rigorous and systematic treatment of the diabetic wounds.

9. The limitations of the revascularization are underlined in the extension of the necrotic lesions and the distal infection as well as in the condition of the arterial areas. The ischemic necrotic lesion towards the foot leads in most of the times to the amputation of the leg.

10. The early draining of the abscesses and the exclusion of the infected areas of the diabetic foot represents a priority in the surgical debridement as it reduces the duration of the administration of the antibiotic treatment and the large amputations while in case of dry bedsores, these procedures must be carried out taking into account the revascularization of the limb.

11. When the foot amputations cannot be avoided, the most important procedure is to save the knee joints through transtibial amputations that would ensure the best proximal level at which the possibility of walk using a prosthesis, may be achieved almost as normal.

12. Revascularization of the lower limb is a crucial component in saving the limb but the responsibility of the medical surgical treatment of the diabetic foot with complications must be assumed by the multidisciplinary teams of doctors and surgeons that would cater for the needs of the patients at different stages of their recovery process.

13. The surgical treatment of the wound as well as choosing the appropriate type of wound dressing are essential factors in the local healing process.

14. Short plantar amputations, serial surgical interventions and a modern care of the wounds may help the patient to maintain the proper body position and the support of the lower limbs compared with high disabling amputation by first intention.

15. Noncompliant diabetic patients (to metabolic control and lower extremity lesions) have unfavourable results despite the medical efforts of the attending physicians.

16. Preventing the diabetic gangrene may be an achievable objective through a periodically control plan of the diabetic patients, metabolic balance and appropriate arteriopathy and neuropathy treatment as well as by instructing the patients on how to care for their legs and using proper footwear.

6. PRACTICAL ADVICE

Ambulatory medical chart of the patient with a diabetic foot

Date: year/month/day

<p>Surname....Forename..... SSN..... Telephone no..... Personal health self-evaluation</p> <p><input type="checkbox"/> excellent <input type="checkbox"/> good <input type="checkbox"/> satisfactory <input type="checkbox"/> poor <input type="checkbox"/> severely impaired</p>	<p>Physical examination: -inspection: ulcers, nails, callus, trophic changes - pulse/ level - cold/warm - motility/ sensibility</p>
<p>Description </p>	<p>Changes occurred since the last medical exam </p>
<p>Living conditions: -place of work..... - profession..... -place of residence.....</p>	<p>Recommendations (for example: ophthalmological exam, type of dressing used, etc.) : -</p>
<p>Antecedents:</p> <ul style="list-style-type: none"> • known diseases..... • surgical interventions..... <ul style="list-style-type: none"> a) other surgical interventions..... b) the clinic of the intervention..... c) date of the intervention d) postsurgical evolution 	<p>Doctor's name (preferably the same previous physician)..... </p> <p>Telephone no:</p>
<p>The treatment followed:</p> <p>Recent change of the treatment/ dosages +/- insulin, type + daily insulin dose</p>	<p>Date of the following examination </p>
<p>Risk factors: - smoking - obesity - dyslipidemia - HTN - blood sugar level/ glycated haemoglobin</p>	<p>Health centre:</p> <p>Physician:</p>

Therapeutic principles in the management of the diabetic foot ulcers

