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The New Prognostic-Therapeutic Index for Diabetic Foot Surgery - Extended Analysis

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Rezumat

Noul indice de prognostic-terapeutic pentru chirurgia piciorului diabetic – analiză extinsă

Introducere: Indicația chirurgicală disproporționată la pacienții cu picior diabetic, precum și numărul mare de amputații majore ale membrului pelvin au creat necesitatea de a concepe un indice prognostic-terapeutic pentru a ghida medicul în stabilirea indicației chirurgicale adecvate. Scopul acestei analize este de a extinde o cercetare realizată în anul 2014, în ceea ce privește noul indice de prognostic-terapeutic utilizat în patologia piciorului diabetic, care a inclus 929 de pacienți.
Material și metodă: Am analizat un număr de 1221 de pacienți, care au fost internați în Clinica de Chirurgie a Spitalului Cantacuzino, între ianuarie 2013 și iunie 2015 și care suferă de diabet zaharat și asociază leziuni ale piciorului diabetic.
Rezultate: Noul indice prognostic-terapeutic a fost calculat pentru lotul retrospectiv, rezultând o concordanță între intervenția chirurgicală propriu-zisă și indicele de prognostic de 79,4%; pentru pacienții evaluați prospectiv am regasit o confirmare a relației dintre intervenția chirurgicală efectuată și intervenția chirurgicală prognozată, de 86,8%.
Concluzii: Noul indice terapeutic-prognostic este de o utilitate majora in recomandarea unui comportament terapeutic adecvat corelat cu severitatea leziunii, în special în instituțiile în care patologia piciorului diabetic este mai puțin cunoscută.

Cuvinte cheie: diabet zaharat, picior diabetic, indice de prognostic-terapeutic

Abstract

Background: The disproportionate surgical indication in patients with diabetic foot, as well as the large number of major amputations of the pelvic limb have created the necessity of conceiving a therapeutic-prognostic index to guide the physician in establishing the adequate surgical indication. The aim of this analysis is to extend a former research published in 2014, regarding the new prognostic-therapeutic index used in the diabetic foot pathology, that included 929 patients.
Methods: We have analyzed a number of 1221 patients, that were admitted at the Surgery Clinic of the Cantacuzino Hospital, between January 2013 and June 2015, suffering from diabetes mellitus and associating diabetic foot lesions.
Results: The new therapeutic-prognostic index has been calculated for the retrospective lot, resulting into a concordance between the actual surgical intervention and the prognostic index of 79.4%; for the patients evaluated prospectively we have found a confirmation of the relation between the performed surgical intervention and the forecasted surgical intervention, of 86,8%.
Conclusions: The new therapeutic-prognostic index is of a major usefulness in recommending an adequate therapeutic conduct correlated to the severity of the lesion, especially in facilities where the pathology of the diabetic foot is less known.

Key words: diabetes mellitus, diabetic foot, prognostic-therapeutic index

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Introduction

The diabetic foot is a complex pathologic entity that includes all modifications (tegumental, vascular, osseous, muscular, nervous), which occur at the foot level during the course of the diabetic disease.

Starting from a previous research regarding 929 patients with diabetic foot lesions, on wich there were evaluated the results of applying the new prognostic-therapeutic index, the aim of the actual study is to extend the analysis on a larger number of patients (1,2).

As a less known pathology, the diabetic foot requires a multidisciplinary approach, therefore clinical and para-clinical parameters that quantify the condition of the vascular status, the loss of sensitivity, the patients' associated morbidities, the condition of the skeletal system and of skin are very important and must be studied, and last but not least, the compensation of the diabetic disease, that is an essential criteria on the balance of which depends the healing of these types of lesions (1,3,4,5).

The large number of invalidating surgical interventions in patients suffering from diabetic foot lesions, including major amputations, the tardy recognition of the lesions and at times the impercipient assessment of their severity created the necessity of a multi-parameter study of these types of patients and the elaboration of a therapeutic prognostic index, that can guide the physician in adopting the appropriate method of treatment (2,4,6). Beginning with the therapeutic-prognostic index developed by professor Traian Patrascu, we have elaborated a new therapeutic prognostic index, by adding two new parameters, with the purpose of facilitating the surgical indication, correlated with the type of diabetic foot lesion.

By increasing the number of analysed patients (1221 patients), the statistical analysis has gained an increased significance and brings about a new approach in the evaluation of the severity of the diabetic foot lesions and the appropriate therapeutic conduct.

The therapeutic-prognostic index includes a parameter scale, representing the main risk factors for the diabetic foot lesions to which given values are assigned, depending on the severity (1,2).

The results of applying the therapeutic-prognostic index are distributed on a scale of 1 to 10, the value thusly quantified being directly proportional to the severity of the lesions. Therefore, there are two categories of results: with a value of less than 5, the recommendation for such cases is minor surgical intervention (simple drainage incisions, amputation of phalanges, amputations of toes, trans-metatarsal amputations), and for values of over 5 of the index, the indication being major amputation (calf or thigh) (1,2).

Starting from both the retrospective and the prospective research of the patients lot, after analyzing clinical as well as para-clinical parameters, we have elaborated this new therapeutic prognostic index, for the purpose of improving the results of the diabetic foot surgery, thus avoiding repeated and disproportionate sugical interventions by comparison to the extent of the lesion, in an attempt not to transform this type of patient into a permanently socially dependent person.

The large variety of diabetic gangrene lesions that require different therapeutic decisions, represents the main reason for identifying an efficient method of evaluation and surgical treatment.

Material and methods

We have analyzed a total number of 1221 patients, divided in two groups: 450 patients that were evaluated retrospectively and 771 prospectively, studied separately. The patients were admitted at the Surgery Clinic of the Cantacuzino Hospital, between January 2013 and June 2015 and suffering from:

- Diabetes type I or type II;
- Diabetic foot lesions on a predominantly arteriopathic, neuropathic or mixed field;
- With or without associated co-morbidities: cardio-vascular, renal, ocular;
- With or without septic status or skeletal associated pathology;

and for which we have created a monitoring scheme, including the parameters for evaluating the diabetic foot, parameters which we have included in the evaluation chart for the diabetic foot patient (*Table 1*)(2)

We have extended the therapeutic-prognostic index by adding new parameters, after making a preliminary test of their statistical significance, one of them being correlative and by analyzing the extended therapeutic-prognostic index on a wider range of patients, to ensure an increase in the statistical significance of the study.

SPSS software, version 19, was used for the statistical analysis of the data collected in the two types of samples. The survey involved quantitative analysis, each database (retrospective/prospective) with a number of 450, respectively 771 medical records.

The research aimed to rebuild the prognostic-therapeutic index by adding new variables that influence the type of medical intervention: "surgical interventions for the diabetic foot in antecedentes" and "glycaemia+leukocytosis".

To identify the correlation between the proposed variables the "Hi square" test was used, that measures the degree of homogeneity between two variables. This statistical analysis was needed to determine the influence of each of the new parameters upon the medical prognosis. Also, for the reliability of the study, the degree of uniformity influenced the numerical value of each of the new proposed parameters added in the formula of the prognostic-therapeutic index.

The two parameters that were added to the therapeutic-prognostic index are: (2)

- Surgical interventions for the diabetic foot in antecedents, occupying position IX in the new index.
- Glycaemia + leukocytosis, being assigned the Position X.

The parameter: surgical interventions for the diabetic foot in antecedents

The analysis is done according to:

- No intervention;

Table 1. *Diabetic foot evaluation chart*

1. Identification Data
- Age
- Gender
- Background
- Social status
2. Environmental and individual factors
- Toxic emission – smoking
- Consumption of alcohol
- Consumption of drugs
- Body mass index
3. Co-morbidities
- Type
- Phase
- Treatment
4. Diabetes mellitus
- Type
- Debut
- Identification
- Treatment
- Diet
5. Complications of diabetes
- type (arteriopathy, neuropathy, nephropathy, etc.)
- diagnostic (clinical, para-clinical)
- Neuropathy: sensitivity tests in tactile, thermal, vibration, pain; ROT, electro-diagnostic test, abnormal testing of vegetative functions (sinus arrhythmia, decrease of sweating, increase of pupil latency), simple radiography of the foot
- Arteriopathy: - clinical tests; sensing the pulse, modifications in the skin coloring, presence of edema, temperature gradient, modifications of the tegument (atrophy and thinning of the tegument, absence of hairiness, onychodystrophy);- non-invasive testing: ankle-brachial index
6. Glycaemia, leukocytes at admission
7. Type of Surgical Intervention
- incisions, debridement
- minor amputations
- major amputations
8. Post-Surgery Evolution
9. Re-interventions
10. Re-admissions

- One intervention;
- Two interventions;
- More than two interventions.

- Surgical interventions in antecedents signify inadequate compensation of the diabetes, lack of compliance, precarious biologic terrain andit is statistically associated with an evolution towards major amputation.
- Assigned values:
  - No intervention =0p
  - One intervention = 0.2p
  - Two interventions = 0.4p
  - More than two interventions = 0.6p

The parameter: glycaemia + leukocytosis, has a statistical significance, resulting as a consequence of the method of analysis described above and represents an expression of the inter-relation between the two composing parameters (*Table 2*).

The devices necessary for calculating the new therapeutic-prognostic index are: the ankle-brachial index measurement device and the radiology equipment.

Table 2. *Parameter: Glycaemia + leukocytes*

Glycaemia (mg/dl)	Leukocytes(/mm^3)	Assigned Value (points)*
115-150	11,000-15,000	0.2
150-200	15,000-20,000	0.4
200-300	15,000-20,000	0.6
300-400	15,000-20,000	0.8
>400	>20,000	1

*All the values falling outside of these intervals are evaluated at 0p

The new therapeutic-prognostic index consists of the following parameters: (2)

I. Gender			Male = 0.4 points Female = 0.2p
II. Age of the patient			20-29 years old = 0.1p 30-39 years old = 0.2p 40-49 years old = 0.4p 50-59 years old = 0.6p 60-69 years old = 0.8p 70 + years old = 1 p
III. Diabetes debut			1 -5 years = 0.2p 6-10 years = 0.4p 11-15 years = 0.6p 16-20 years = 0.8p 20 + years = 1p
IV. Type of lesion			simple neuropathic ulceration = 0.2p deep neuropathic ulceration = 1p ulceration with extensive humid gangrene = 2.4p dry gangrene of the toes = 0.2p humid gangrene of the toes = 1.1p extensive humid gangrene = 2.4p deep abscess of the foot = 0.4p necrotizing cellulite = 0.6p necrotizing fasciitis = 0.4p phlegmon of the dorsal side of the foot = 0.4p abscess of the calf = 0.2p fistulizing osteitis = 1.1p deep phlegmon of the foot = 0.4p
V. Bone infection (Osteitis)			yes = 0.3p no = 0p
VI. Visceralization of diabetes			nephropathy = 0.3p retinopathy=0.3p cardiac disease = 0.3p
VII. Emergency (surgery during the first 24h)			yes = 1.1p no = 0p
VIII. Associated co-morbidities			compensated = 0.2p decompensated = 0.4p
IX. Surgical interventions for the diabetic foot in antecedents			no intervention =0p one intervention = 0.2p two interventions = 0.4p more than two interventions = 0.6p
X. Glycaemia + leukocytosis	Glycaemia (mg/dl)	Leukocytes (/mm^3)	Assigned Value (points)*
	115-150	11,000-15,000	0.2
	150-200	15,000-20,000	0.4
	200-300	15,000-20,000	0.6
	300-400	15,000-20,000	0.8
	>400	>20,000	1
XI. Circulatory condition(ankle-brachial index)			0-0.4 = 2.5-1.5p 0.41-0.9 = 1-0.5p 0.91-1.3 = 0p

The new reference values of the therapeutic-prognostic index are: (2)

- For values of less than 6 limited interventions, including minor amputations are recommended;
- For values of more than 6 major amputations (calf and thigh) will be performed

Results

Of the patients being analyzed retrospectively, most are of male gender (73.3%) and belong to the age category 60-69 years old, 2.4 % are patients with diabetes of type I and 97.6% are patients with diabetes of type II (*Table 3*).

As far as the method of compensation for the diabetes mellitus, 43.1 % have been following a treatment by insulin and 56.9% have been using oral antidiabetics, providing them with low metabolic balancing.

31.5% of the patients analyzed retrospectively were predominantly neuropathic and 68.5% were arteriopathic, 67.3 % have shown associated cardio-vascular antecedents (arterial hypertension, ischemic cardiac disease, congestive cardiac insufficiency, atrial fibrillation).

As far as the diagnosis upon admission is concerned, the distribution, within the respective sample is as in *Fig. 1*.

The analysis of the lot from the prospective point of view has yielded the following results:

- Highlights an approximately equal number of patients in the age categories 60-69 years (32.1%) and over 70 years (32.7%), the majority of male gender (76.7%);
- 98.2% are patients suffering from diabetes of the type II, the rest of 1.8%, suffer from diabetes type I;
- 34.5% of patients are neuropaths and 65.5% of patients are predominantly arteriopaths;
- The distribution of diagnostic upon admittance, on the age groups with the highest number of patients is shown in *Fig. 2* and *Fig. 3*.

The new therapeutic-prognostic index has been calculated for the retrospective lot, separately, resulting in a concordance between effective surgical intervention and the prognostic index of 79.4%; in patients that were evaluated prospectively we have found a confirmation of the relation between surgical intervention and the forecast by means of calculating the index at 86.6%.

Discussion

Most of the patients that were analyzed from the retrospective as well of prospective point of view are of a the male gender, predominantly arteriopathic, treated with oral antidiabetics, with associated cardio-vascular comorbidities and having as an diagnostic upon admission, for the most part, a gangrene of the toe.

The vascular and nervous complications, present in all cases of patients suffering from diabetic foot lesions, but in variable proportions (predominance of the arteriopathy or neuropathy), are associating lesions characteristic to each category but also a surgical therapeutic attitude correlated with

Table 3. *Distribution on gender and age groups, retrospective sample*

Age	Female	Male	TOTAL
20-29	1	1	2
30-39	0	1	1
40-49	6	28	34
50-59	23	99	122
60-69	34	128	162
70 and over	56	73	129
TOTAL	120	330	450

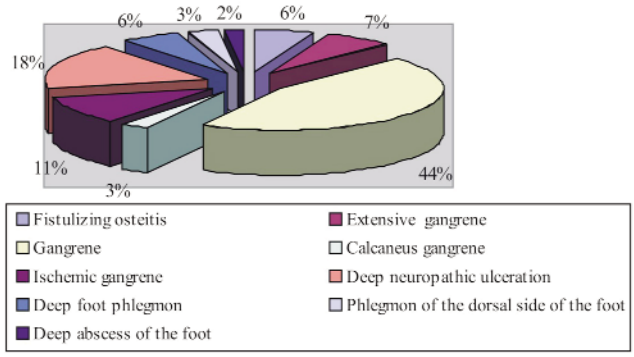

Figure 1. *Distribution of diagnosis upon admission Age category 60-69 years, retrospective sample*

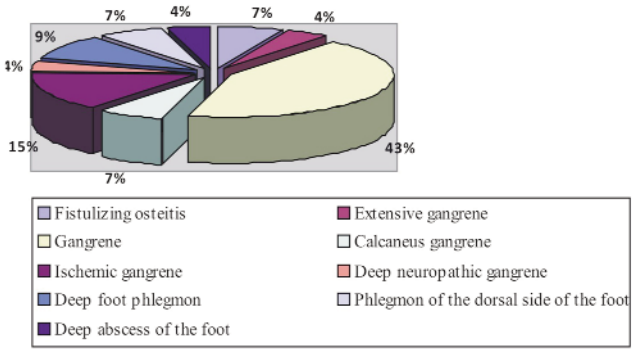

Figure 2. *Distribution of diagnosis upon admission Age category 60-69 years, prospective sample*

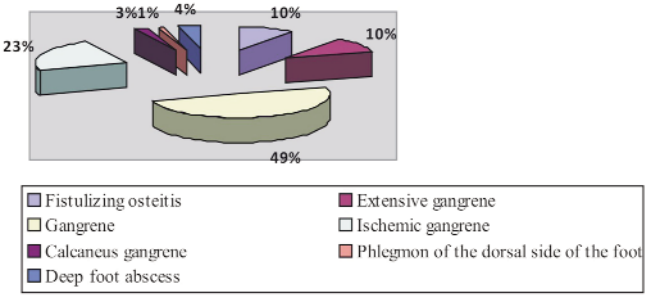

Figure 3. *Distribution of diagnostic upon admission Age category 70 years and over, prospective sample*

the type of lesion and the condition of the vascular status (7,8,9,10).

The surgical indication in the diabetic foot lesions vary depending on a series of factors, such as: the age of the patient, the type and number of associated cardio-vascular morbidities, the association of diabetes complications (diabetic nephropathy and retinopathy), the presence of a sepsis and anaemia, however, the most important parameters are the predominance of the diabetic arteriopathy or neuropathy; the predominance of the vascular status deficiency, in the absence of the possibility of re-vascularization, is signing, in most cases, the evolution towards a major amputation; the predominance of the neuropathy, by the presence of the vascularisation required for healing, is most frequently associated to a favourable evolution (12,13,14).

The calculation of the new therapeutic prognostic index on a larger lot(1221 patients) plays the role of confirming the importance of the new index in recommending the surgical intervention adapted to the type of lesion, by taking into consideration the above-mentioned parameters.

The main role of the new therapeutic prognostic index is to lead to the decrease of the number of major amputations (calf or thigh), by calculating it on a lot of patients as large as possible.

Conclusions

The importance of calculating the new therapeutic-prognostic index resides in the existence of a large number of amputations in patients with diabetic foot lesions, due to late recognition and disproportionate assessment of the severity of the lesions.

The new therapeutic-prognostic index finds its usefulness especially in such medical centers in which the surgical pathology of the diabetic foot is less known, thus avoiding repeated operations, on a ground which is already affected by the presence of diabetes, often found at a stage in which compensation is showing a deficit.

The new therapeutic-prognostic index is an effective method of establishing the surgical indication for the patient suffering from lesions of the diabetic foot, it can be easy to be calculated and the results are based upon the most important parameters that evaluate the conditions of the diabetic disease and of its complications.

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