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Diabetic retinopathy risk factors in patients with diabetic foot

Aristomenis Kossioris,[1] Efstratios Kossioris,[2] Dimitrios Koukoularis,[3] Eleni Kyritsi,[4] Ioannis Koutelekos,[5] Angeliki Stamou,[6] Eftychia Evangelidou[7]

Αμφιβληστροειδοπάθεια σε ασθενείς με διαβητικό πόδι

Περίληψη στο τέλος του άρθρου

[1]RN, MSc, PhD, Ophthalmology Outpatient Clinics, General Hospital of Athens "G. Gennimatas"
[2]RN, Estia Dionysou, Dionysos, Greece
[3]Biopathologist, MSc, PhD (c), Greece
[4]Em. Professor Department of Nursing, University of West Attica, Greece
[5]Assistant Professor, Department of Nursing, University of West Attica, Greece
[6]Lekturer, Department of Nursing, University of West Attica, Greece
[7]RN, MSc, MHSc, PhD, PostDoc ©, Subdirector of Nursing Management, G.H.N.I. "Konstantopouleio – Patission", Greece

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Corresponding Author:
Aristomenis Kossioris
RN, MSc, PhD
43 Avgis, Iraklio Attikis
Athens, p.o.: 14121
Mob: (+30) 6980801671
e-mail: akossioris@gmail.com

Introduction: Diabetic retinopathy is the result of the microvascular manifestations of retinal blood vessels due to diabetes and is the main visual impairment cause in the working-age population in developed countries having high prevalence in people at risk for diabetic ulceration or with diabetic ulceration. **Aim:** The aim of the present study was the exploration of the DR clinical and biochemical risk factors in patients at risk for diabetic ulceration or with diabetic ulceration. **Materials and Methods:** A cross-sectional research was conducted from October 2005 to November 2016. One-hundred-thirty-four persons with type 1 and 2 diabetes, at risk for foot ulceration or with active foot ulcer/s participated. **Results:** Ninety-two-point-three percent of the research subjects had type 2 diabetes, 57.9% peripheral neuropathy, 40.0% PAD, 44.8% active foot ulceration, 37.5% history of cataract, while 40.4% history of retinopathy. The univariate logistic regression analysis was significant (P≤.05) for somatic sensorimotor peripheral neuropathy (OR 3.94, 95% CI 1.51-10.27, P=.005), nephropathy (OR 6.22, 95% CI 1.69-22.87, P=.006), tablets and insulin (OR 5.54, 95% CI 1.61-19.07, P=.007), and insulin (OR 3.45, 95% CI 1.15-10.38, P=.028). As for the multivariate logistic regression analysis, only the tablets and insulin combination was significant (OR 10.47, 95% CI 1.25-87.78, P=.030) **Conclusions:** Diabetic retinopathy has a high prevalence in people at risk for diabetic ulceration or with diabetic ulceration. For the better prevention of diabetic retinopathy, healthcare professionals should be aware of the high likelihood of persons with persistent hyperglycemia and long-term diabetes to have diabetic retinopathy.

Key-words: *Diabetic retinopathy; diabetic foot ulceration; risk factors*

Introduction

Diabetes Mellitus and its complications, globally, constitutes a current major public health issue with the number of people being diagnosed to be constantly increasing.[1,2] The people affected by diabetes in 2013 it was calculated by the International Diabetes Federation (IDF) to be 381.3 million and by further estimates it will be projected to 519.9 million (55% increase) by 2035.[1] If blood glucose in patients with diabetes is poorly controlled, microvascular complications such as peripheral neuropathy (somatic and autonomic), nephropathy and retinopathy will be presented.[3] The microvascular manifestations of the retinal blood vessels due to diabetes comprise the nosological entity that is called "diabetic retinopathy", which its worldwide prevalence in type 2 persons with diabetes is 30-40% being considered to be one of the main partially visual loss causes and the primary cause of blindness of working-age population (20-60 years old) in the developed countries (DR currently represents the 4.8% of the total blindness cases).[4,5] Depending on the type of retinal blood vessels damages, DR can be classified to the below categories:[2,6]

- *Non-proliferative diabetic retinopathy (NPDR)*: characterized by the presence of microaneurysms, hard and soft exudates, spotted hemorrhages in the cornea, disturbances in the width and course of the veins as well as the formation of arteriovenous anastomoses in the retina (Intra Retinal Microvascular Abnormalities -IMRA-)
- *Proliferative diabetic retinopathy (PDR)*: characterized by neovascularization in the optic nerve and retinal periphery that it may lead to recurrent intravitreal hemorrhage as well as to fibrous tissue development with consequent retinal detachment, which ultimately leads to blindness and
- *Macular degeneration*: characterized by focal or diffuse macular edema, resulting in a visual acuity significant reduction.

Determining the DR risk factors, is a key step for the appropriate DR preventive interventions application by the clinicians, with more focus in persons with diabetes complications such as diabetic foot disease,[2] and for the generally better management of DR patients.

Aim

The aim of the present study was the exploration of the DR clinical and biochemical risk factors in patients at risk for diabetic ulceration or with diabetic ulceration.

Research questions

1. What are the frequencies of the clinical-biochemical characteristics (diabetes type, disease duration, therapy type, HbA1c value (%), peripheral arterial disease, peripheral neuropathy, nephropathy) and the presence of retinopathy history in patients at risk for diabetic ulceration or with diabetic ulceration?
2. Is there a linear relationship between the log odds of diabetes type, disease duration, therapy type, HbA1c value (%), peripheral arterial disease, peripheral neuropathy, nephropathy, and the presence of retinopathy history in patients at risk for diabetic ulceration or with diabetic ulceration?

Materials and Methods

Study design

The study was a cross-sectional research.

Setting

The research was conducted in three diabetic foot clinics of general hospitals and one wound unit of a special hospital in a large capital city. Ethics approvals were provided by the hospitals' scientific committees.

Research subjects

The study participants were persons with type 1 and 2 diabetes, at risk for foot ulceration or with active foot ulcer/s. Patients that did not provide written consent were excluded from the study.

Recruitment

This study was based on the data of Kossioris et al.[7,8] studies concerning diabetic foot ulceration and its connection to risk and preventive factors, since was compatible with their research questions.[9] Diabetes microvascular complications, such as retinopathy, comprise diabetic foot ulceration risk factors and are developed more commonly and before the macrovascular ones.[2,3] One hundred and thirty-four patients were conveniently approached by study team during their scheduled first or subsequent visit to the healthcare facilities, from October 2005 to November 2016. The sample size was estimated implementing the Hosmer & Lemeshow, of 1989, recommendation in Garson[10] that there should be at least 10 cases per independent variable. All participants were enrolled after providing written informed consent.

Data collection

For the data collection, a structured quantitative interview guide with closed-ended questions was utilized. The principal investigators interviewed one-on-one each patient gathering and recording demographic, clinical, and

biochemical data.

Measurements

The parameters that were measured were relevant to:

- *Sociodemographic characteristics:* Sex, age (years), residence, lonely living status, marital status, education level and labor market status, and
- *Clinical-biochemical characteristics:* Diabetes type, disease duration, therapy type, HbA1c value (%), and presence or absence of peripheral arterial disease (PAD), peripheral neuropathy, nephropathy, retinopathy, cataract, and active foot ulceration.

Instrumentation – procedures

For measuring the sociodemographic characteristics, appropriate interview guide items were used. The items were made by a panel of experts, asking primarily objective information, and thus they were subjected only to validity investigation. Considering that the items/questionnaire developing panel members had high expertise in the field of diabetes/diabetic foot, the validity method that was applied was the face validity one.

In terms of the clinical and biochemical characteristics of diabetes type, disease duration, therapy type, HbA1c value (%), and presence or absence of peripheral arterial disease (PAD), peripheral neuropathy, nephropathy, retinopathy, cataract, and active foot ulceration, at first, appropriate interview guide items were utilized, and afterwards the study team confirmed the data's validity by checking the medical records of the participants. Diabetic foot ulceration was defined as a full thickness break of the skin, at least of Wagner stage "1",[11] infected or not and being developed distal to the malleoli.

With reference to the loss of protective sensation due to peripheral neuropathy, it was diagnosed by applying the 10-g monofilament and the vibration perception threshold tests.[12]

In relation to PAD, the diagnosis was based on duplex ultrasonography with vessel stenosis >50% being indicative.[13,14]

As for the DR diagnosis, it was founded on the fundus examination. In the data/statistical analysis step of the current investigation, diabetic retinopathy was not classified as proliferative or non-proliferative.[6]

Statistical analysis

Descriptive and inferential statistical analysis took place by using the IBM SPSS 28 software package.

In the context of descriptive analysis, the frequencies of the sociodemographic, clinical, and biochemical characteristics were calculated.

Respecting the inferential statistical analysis, univariate logistic regression analysis for the diabetic retinopathy risk factors was performed.

In terms of the multivariate regression analyses, the "enter" variable selection method was utilized and 5% probability criterion was set for the variables to enter the model.

Results

Descriptive

Regarding the sociodemographic characteristics, 67.9% of the participants were men and the total sample's mean age was 64.9±12.2. Ninety-two per cent were living with others, 47.9% had primary and secondary education only and the 80.9% were outside of the labor market.

With respect to the clinical and biochemical characteristics, 92.3% of the research subjects had type 2 diabetes, 57.9% peripheral neuropathy, 40.0% PAD, 44.8% active foot ulceration, 37.5% history of cataract, while 40.4% history of retinopathy.

All the descriptive results are shown in detail in table 1.

Table 1. *Demographics and clinical-biochemical characteristics of the at risk for diabetic ulceration and DFU patients*

Characteristics	**N**	**Results***
Sociodemographic		
Sex	(134)	Men=67.9%; Women=32.1%
Age (years)	(129)	64.9±12.2
Residence	(41)	Attica basin=85.4; Prefecture capital=7.3%; County=7.3%
Lonely living	(75)	No=92.0%; Yes=8.0%
Marital status	(41)	Married=56.1%; Single=22.0%; Divorced=12.2%; Widower=9.8%
Education level	(71)	Secondary education=47.9%
		Tertiary education= 35.2%; Primary education=16.9%
Labor market status	(94)	Outside=80.9%; Inside=19.1%
Clinical-biochemical		
Diabetes type	(130)	Type 2=92.3%; Type 1=7.7%
Disease duration	(129)	17(9.5-24.0)
Therapy type	(121)	Insulin=41.3%; Tablets=34.7%
		Insulin and tablets=22.3%
HbA1c value (%)	(88)	6.8(6.2-7.8)
Peripheral Arterial Disease	(110)	No=60.0%; Yes=40.0%
Peripheral Neuropathy	(114)	Yes=57.9%; No=42.1%
Nephropathy	(81)	No=81.5%; Yes=18.5%
Retinopathy	(94)	No=59.6%; Yes=40.4%
Cataract	(40)	No=62.5%; Yes=37.5%
Active foot ulceration	(134)	No=55.2%; Yes=44.8%

**Results are %, Mean ± Standard deviation, Median (Interquartile range)*

Inferential

The univariate logistic regression analysis, in relation to the variables that were involved in the predictive model was significant ($P \leq .05$) for somatic sensorimotor peripheral neuropathy (OR 3.94, 95% CI 1.51-10.27, $P=.005$), nephropathy (OR 6.22, 95% CI 1.69-22.87, $P=.006$), tablets and insulin (OR 5.54, 95% CI 1.61-19.07, $P=.007$), and insulin (OR 3.45, 95% CI 1.15-10.38, $P=.028$) (Table 2).

As for the multivariate logistic regression analysis, only the combination of tablets and insulin was significant (OR 10.47, 95% CI 1.25-87.78, $P=.030$) (Table 2).

Table 2. *Univariate and multivariate logistic regression analysis for the presence of retinopathy determining factors and a two categories retinopathy absence or presence variable*

	Univariate analysis		**Multivariate analysis**	
Variable	**OR (95% CI)**	***P***	**OR (95% CI)**	***P***
Diabetes type (type 2)	6.67 (0.16-2.85)	0.58		
Disease duration	1.02 (0.98-1.06)	0.27		
Therapy type				
None/Tablets	Reference category			
Insulin	3.45 (1.15-10.38)	.028		
Tablets and insulin	5.54 (1.61-19.07)	.007	10.47 (1.25-87.78)	.030
Peripheral arterial disease (presence)	1.24 (0.49-3.14)	0.65		
Nephropathy (presence)	6.22 (1.69-22.87)	.006		
HbA1c value (%)	0.89 (0.63-1.26)	0.51		
Peripheral Neuropathy (presence)	3.94 (1.51-10.27)	.005		

Discussion

Even though this was a small-sized study based on preliminary data by Kossioris et al.,[7,8] considering that coping with a problem as common as diabetic retinopathy requires a larger sample, it brought in substantial results.

The most important finding of the current study was the fact that the combination of tablets and insulin, as antidiabetic therapeutic approach, it was found that is a predictive factor of retinopathy presence in patients at risk for diabetic ulceration or with diabetic ulceration (OR 10.47, 95% CI 1.25-87.78, *P*=.030). This detection is similar with that of Ejigu and Tsegaw[15] study, in which oral hypoglycemic agents in combination with insulin were significantly associated with the presence of DR in patients with Type 1 or 2 diabetes (*P*=.025), of Peng et al.[16] who detected that the medication mode of taking hypoglycemic tablet along with insulin was risk factor of DR in people with diabetes (*P*=.001), and of the one of Kvani[17] who found that the retinopathy prevalence was significantly more in Type 2 diabetes patients treated with insulin (71.8%, *P*=.031). According to the literature,[6] the antidiabetic therapy starts with tables, usually of metformin, and later in situations that tablets are no longer effective insulin is added to the therapeutic scheme. Considering the above, it could be said that the present study finding in question corresponds to patients with severe glycemia or more years diabetes, and therefore with more relevant complications such as the microvascular ones.

The percentage of retinopathy, treated or untreated, in patients at risk for diabetic ulceration or with diabetic ulceration was second most valuable detection of the present research being 40.4%. By a simple calculation, bearing in mind the relevant literature,[2,18-24] the percentage of DR presence, proliferative and non-proliferative, in patients with diabetic foot ulceration is 68.87%, while 17.02% in patients with diabetes without foot ulceration.

By the univariate logistic regression analysis, the parameters of somatic sensorimotor peripheral neuropathy, nephropathy/retinopathy, and insulin, in agreement with the literature[16,25-28] were found to be significantly associated with the presence of treated or untreated DR.

Conclusions

Diabetic retinopathy comprises the main visual impairment cause in the working-age population in developed countries and has a high prevalence in people at risk for diabetic ulceration or with diabetic ulceration (in the present study it was found to be 40.4%), facts that appoint its prevention of critical importance. Additionally, in the current study it was detected that the persons at risk for diabetic ulceration or with diabetic ulceration treated with the combination of tablets and insulin had a higher likelihood of having retinopathy history. Therefore, for the better prevention of diabetic retinopathy in patients at risk for diabetic ulceration or with diabetic ulceration, healthcare professionals should be aware of the high possibility of patients with persistent hypoglycemia and long-term diabetes to have diabetic retinopathy for consulting them regarding undergoing regular fundus examinations.

ABSTRACT

Αμφιβληστροειδοπάθεια σε ασθενείς με διαβητικό πόδι

Αριστομένης Κοσσιώρης,[1] Ευστράτιος Κοσσιώρης,[2] Δημήτριος Κουκουλάρης,[3] Ελένη Κυρίτση,[4]

Ιωάννης Κουτελέκος,[5] Αγγελική Στάμου,[6] Ευτυχία Ευαγγελίδου[7]

[1]RN, MSc, PhD, Γενικό Νοσοκομείο Αθηνών «Γ. ΓΕΝΝΗΜΑΤΑΣ», Αθήνα, Ελλάδα
[2]RN, Εστία Διονύσου, Διόνυσος, Ελλάδα
[3]Βιοπαθολόγος, MSc, PhD (c), Ελλάδα
[4]Ομ. Καθηγήτρια, Τμήμα Νοσηλευτικής, Πανεπιστήμιο Δυτικής Αττικής, Ελλάδα
[5]Επίκουρος Καθηγητής, Τμήμα Νοσηλευτικής, Πανεπιστήμιο Δυτικής Αττικής, Ελλάδα
[6]Λέκτορας εφαρμογών, Τμήμα Νοσηλευτικής, Πανεπιστήμιο Δυτικής Αττικής, Ελλάδα
[7]RN, MSc, MHSc, PhD, PostDoc ©,Υποδιευθύντρια Νοσηλευτικής Υπηρεσίας, Γ.Ν.Ν.Ι. «Κωνσταντοπούλειο – Πατησίων», Ελλάδα

Εισαγωγή: Η διαβητική αμφιβληστροειδοπάθεια είναι το αποτέλεσμα των μικροαγγειακών εκδηλώσεων των αιμοφόρων αγγείων του αμφιβληστροειδούς λόγω διαβήτη και αποτελεί την κύρια αιτία εξασθένησης της όρασης στον πληθυσμό εργάσιμης ηλικίας στις ανεπτυγμένες χώρες με υψηλό επιπολασμό στα άτομα που διατρέχουν κίνδυνο διαβητικής εξέλκωσης ή έχουν διαβητική εξέλκωση.

Σκοπός: Σκοπός της παρούσας μελέτης ήταν η διερεύνηση των κλινικών και βιοχημικών παραγόντων κινδύνου της διαβητικής αμφιβληστροειδοπάθειας σε ασθενείς που διατρέχουν κίνδυνο για διαβητικό έλκος ή με διαβητικό έλκος

Υλικό και Μέθοδος: Διεξήχθη συγχρονική έρευνα από τον Οκτώβριο του 2005 έως τον Νοέμβριο του 2016. Συμμετείχαν 134 άτομα με διαβήτη τύπου 1 και 2 σε κίνδυνο για ποδική εξέλκωση ή με ενεργή ποδική εξέλκωση.

Αποτελέσματα: Το 92,3% των υποκειμένων της έρευνας είχαν διαβήτη τύπου 2, το 57,9% περιφερική νευροπάθεια, το 40,0% περιφερική αρτηριακή νόσο, το 44,8% ενεργή ποδική εξέλκωση, το 37,5% ιστορικό καταρράκτη, ενώ το 40,4% ιστορικό αμφιβληστροειδοπάθειας. Η μονομεταβλητή ανάλυση λογιστικής παλινδρόμησης ήταν σημαντική (P≤,05) για τη σωματική αισθητικοκινητική περιφερική νευροπάθεια (OR 3,94, 95% CI 1,51-10,27, P=,005), τη νεφροπάθεια (OR 6,22, 95% CI 1,69-22,87, P=,006), τα δισκία και την ινσουλίνη (OR 5,54, 95% CI 1,61-19,07, P=,007), την ινσουλίνη (OR 3,45, 95% CI 1,15-10,38, P=,028),.Όσον αφορά την πολυμεταβλητή ανάλυση λογιστικής παλινδρόμησης, μόνο ο συνδυασμός δισκίων και ινσουλίνης ήταν σημαντικός (OR 10,47, 95% CI 1,25-87,78, P=,030).

Συμπεράσματα: Η διαβητική αμφιβληστροειδοπάθεια έχει υψηλό επιπολασμό στα άτομα που διατρέχουν κίνδυνο διαβητικής εξέλκωσης ή έχουν διαβητική εξέλκωση. Για την καλύτερη πρόληψη της διαβητικής αμφιβληστροειδοπάθειας, οι επαγγελματίες υγείας θα πρέπει να γνωρίζουν την υψηλή πιθανότητα άτομα με εμμένουσα υπεργλυκαιμία και μακροχρόνιο διαβήτη να έχουν διαβητική αμφιβληστροειδοπάθεια.

Λέξεις-ευρετηρίου: *Διαβητική αμφιβληστροειδοπάθεια, διαβητική ποδική εξέλκωση, παράγοντες κινδύνου.*

✉ **Υπεύθυνος αλληλογραφίας:** Αριστομένης Κοσσιώρης, RN, MSc, PhD, Διεύθυνση: Αυγής 43

ΤΚ: 14121, Πόλη: Ηράκλειο Αττικής, Αθήνα, Χώρα: Ελλάδα, Τηλέφωνο & Fax: 2102820895

Κινητό: 6980801671, E-mail: akossioris@gmail.com,

ResearchGate: https://www.researchgate.net/profile/Aristomenis_Kossioris

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