



Possibilities of non-invasive diagnosis of diabetic peripheral polyneuropathy in children with type 1 diabetes

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Abstract. Background. Most diagnostic tests for diabetic peripheral polyneuropathy (DPNP) are not suitable for use in childhood, resulting in low diagnostic accuracy of this complication. Therefore, it is necessary to identify reliable and simple markers for early detection and monitoring of diabetic polyneuropathy progression in children. The purpose was to investigate the diagnostic value of the Clinical Neurological Examination (CNE), the pediatric-modified Total Neuropathy Score (ped-mTNS), and the Pediatric Balance Scale (PBS) in the non-invasive diagnosis of diabetic peripheral polyneuropathy in children with type 1 diabetes. **Materials and methods.** Ninety-one children with type 1 diabetes aged 10 to 17 years were examined. Group 1 included 57 patients with a duration of type 1 diabetes of up to 5 years, while group 2 consisted of 34 children with a disease duration of more than 5 years. To diagnose DPNP, a comprehensive neurological examination was conducted using the CNE, the ped-mTNS, and the PBS followed by determination of the diagnostic significance of each scale using ROC analysis. **Results.** It has been proven that two scales have diagnostic significance for identifying DPNP, the CNE and the ped-mTNS; based on the results of using both, DPNP was diagnosed in 50.5 % of patients. The clinical picture of DPNP was dominated by motor and sensory disorders, which are one of the first manifestations of this condition in children. The first signs of DPNP were registered already on the first years of illness. The frequency of development and stage of neurological disorders increased along with disease progression and the deterioration of glycemic control. **Conclusions.** Diabetic peripheral polyneuropathy is a common complication of diabetes in children, which is registered in 50.5 % of cases. The CNE and the ped-mTNS allows to expand diagnostic capabilities regarding the detection of DPNP in children without the use of invasive diagnostic methods.

Keywords: diabetes mellitus; neurological condition; diabetic neuropathies; medical screening; ROC analysis; children

Introduction

According to the International Diabetes Federation, 425 million people worldwide suffer from diabetes mellitus, making it the largest global epidemic of the 21st century [1]. Between 1 and 35 new cases of type 1 diabetes mellitus per 100,000 children population (under 14 years of age) are diagnosed annually. In different countries, its incidence has at least doubled over the past two decades [2]. Among the complications leading to a decrease in the quality of life and disability, the most common group of clinical syndromes, commonly referred to as various forms of diabetic neuropathy, is caused by diffuse and focal damage to the peripheral and autonomic nervous system and occur in approxi-

mately half of all individuals with diabetes [3, 4]. Diabetic peripheral polyneuropathy (DPNP) is the most common form of diabetic neuropathy, affecting approximately 30 % of patients, with an annual incidence of approximately 2 % [5]. Some researchers believe that the prevalence of diabetic neuropathy is much higher if asymptomatic neuropathy is included and is 45 % in type 2 and 54 % in type 1 diabetes. According to experts, without successful intervention, of the expected 9.7 billion people living in 2050, one third will have diabetes, and half of them will have neuropathy [5]. Therefore, there is no doubt that early diagnosis and timely intervention are important to prevent the development of diabetic neuropathy. However, the diagnosis of dia-

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betic neuropathy, determining its prevalence and incidence remain difficult, despite the constant search for methods for the early diagnosis of this complication of diabetes. Unlike adults whose clinical symptoms are easily recognized, children do not report early symptoms and early signs are less specific [6]. Diagnostic tests for diabetic peripheral polyneuropathy may include nerve conduction studies, punch biopsy, quantitative sudomotor axon reflex test, corneal confocal microscopy, but they are time-consuming, poorly available, and not suitable as clinical screening tools. As a result, this complication is underdiagnosed in children with type 1 diabetes [7]. Thus, there is a need to identify reliable and simple markers for early detection and monitoring of diabetic polyneuropathy progression in children.

Purpose: to investigate the diagnostic value of the Clinical Neurological Examination (CNE), the pediatric-modified Total Neuropathy Score (ped-mTNS), and the Pediatric Balance Scale (PBS) in the non-invasive diagnosis of diabetic peripheral polyneuropathy in children with type 1 diabetes.

Materials and methods

We examined 91 children with type 1 diabetes, 53 boys and 38 girls aged 10 to 17 (average of 13.52 ± 0.26) years. Depending on the duration of disease, participants were divided into 2 groups: group 1 included 57 patients with an average age of 13.24 ± 0.37 years and a duration of type 1 diabetes of up to 5 (average of 2.11 ± 0.17) years; group 2 consisted of 34 children with an average age of 14.19 ± 0.35 years and a disease duration of more than 5 (average of 7.56 ± 0.44) years.

Diagnosis and verification of the clinical diagnosis of type 1 diabetes mellitus was carried out in accordance with the Standards of Medical Care “Diabetes Mellitus in Children” (Order of the Ministry of Health of Ukraine No. 413 dated February 28, 2023) [8].

All patients received basal-bolus insulin therapy that meets modern requirements for the management of type 1 diabetes mellitus [8].

The children who participated in this study underwent a comprehensive examination in accordance with the specified standard. The presence and degree of diabetic peripheral polyneuropathy was assessed by the severity of symptom manifestations on the CNE [9], which was used to clinically test sensory sensitivity (pinprick, light touch, vibration, and position sense) of the feet; the anatomical level below which the sense of light touch is impaired; strength of the extensor hallucis longus and gastrocnemius muscles; ankle reflexes. A total score of the neurophysiological examination of 0 was graded as no polyneuropathy, 1–8 as mild, 9–15 as moderate, and 16–20 as severe polyneuropathy [9].

Additionally, all children were examined using the ped-mTNS [10]. According to it, sensation (tactile, pain, temperature and vibration) was tested on the forearm and then on the distal parts of the limbs (palmar pads and plantar pads of the toes) in patients with closed eyes. The strength of the extensors of the big toe, dorsiflexors of the ankle, abductors of the fingers and extensors of the wrist were evaluated according to the recommendations [10].

Deep tendon reflexes were assessed by eliciting the Achilles reflex and the knee reflex when the subject was sitting on a chair with free movement of the lower limbs. Upper limb reflexes were not tested because the distal reflex is not standard for the upper limbs.

To determine motor impairment in children with type 1 diabetes, the PBS was used [11], which included timed measurements of a static seat, tandem tests at rest, and modified Romberg tests: simple upright postures with different foot placement options (with open and closed eyes), and an evaluation of overall motor function. Each test was scored from 0 to 4 points with a total score calculated. The maximum score a patient could receive was 72 [11].

All tests were conducted in a quiet room with a stable temperature ($20\text{--}22\text{ }^{\circ}\text{C}$).

The results of the study were processed using the statistical licensed software package Statistica for Windows 13.0, serial number JPZ804I382130ARCN10-J, and SPSS 23.0 for Windows with the definition of the arithmetic mean (M), standard deviation (σ) and average errors (m) for indicators whose distribution met the criteria of normality. Normality was checked using the Shapiro-Wilk asymmetry test. The relationship between the indicators was estimated using the methods for calculating the Pearson correlation coefficient.

The diagnostic significance of each scale was determined using the receiver operating characteristic (ROC) analysis with calculation of the area under the ROC curve (AUC). The area value from 0.9 to 1 corresponds to excellent model quality, from 0.8–0.9 — very good, 0.7–0.8 — good, 0.6–0.7 — average, 0.5–0.6 — unsatisfactory. The cut-off point was calculated by determining the threshold criteria with maximum sensitivity and specificity. To select the optimal cut-off point, the Youden J criterion was used, determined by the formula: $J_{\max} = \{\text{sensitivity}(c) + \text{specificity}(c) - 1\}$ [12].

To assess the differences in the indicators in the compared groups, the Student's t-test and the ϕ criterion (Fisher's angular transformation) were used. The assessment of differences for small samples was carried out using the nonparametric Mann-Whitney U-test. Differences were considered reliable at $p < 0.05$.

Results

Subjective data analysis showed that 82 (90.1 %) of 91 patients reported neurological symptoms, predominantly sensory (periodic aching or tingling in the limbs, a feeling of cramps in the muscles of the shins) and asthenovegetative (general weakness, rapid fatigue, emotional lability, dizziness) (Table 1).

Functional complaints (difficulty climbing up or down the stairs, pain in the limbs when walking and frequent stumbling) ranked third — 34.1 %. In 31.9 % of children, complaints of a cerebral nature were observed (headaches, psychoemotional disorders) and 27.5 % of patients complained of impaired thermoregulation. It was noteworthy that such complaints as headaches, general weakness, periodic muscle cramps were significantly more common in children of group 2 ($p < 0.05$), while the frequency of other complaints did not have a statistical difference between the monitoring groups.

Further, we assessed the initial indicators of the neurological status in children with type 1 diabetes depending on its duration using the CNE. The analysis of the obtained results showed that 41 (45.0 %) children had some deviations, including 21 (36.8 %) patients of group 1 and 20 (58.8 %) of group 2. At the same time, the maximum score on the CNE in both groups did not exceed 8 points, which corresponded to the initial stage of peripheral diabetic polyneuropathy. The analysis showed that 14 (24.6 %) children of group 1 had a decrease in sensory sensitivity, and in 8 (14.0 %) cases, these changes occurred already in the first year of the disease. A decrease in reflexes of the lower limbs was found in 10 (17.5 %) patients of group 1, including in the first year of the disease — in 6 (10.5 %) cases. With an increase in the duration of diabetes mellitus, the percentage of patients with the above-mentioned types of neurological disorders in group 2 increased and amounted to 41.2 % (14 children) and 52.9 % (18 children), respectively ($p < 0.05$). Other types of neurological disorders according to the CNE were detected in isolated cases. Thus, a decrease in tactile sensitivity was observed only in 5 (14.7 %) patients of group 2 and was not found in group 1. A reduction in the strength of the calf muscles was also recorded in 4 (11.8 %) children of group 2 and in 2 (3.5 %) of group 1. There were no cases of a decrease in the strength of the finger muscles. The results of our study showed that it is the impairment of sensory sensitivity and decreased reflexes of the lower limbs that can be considered one of the first manifestations of diabetic peripheral polyneuropathy in children with type 1 diabetes. The correlation analysis conducted in them showed the presence of a positive relationship ($r = +0.33$, $p < 0.05$) between the CNE score and the level of glycated hemoglobin. That is, the degree of neurological disorders increased with deterioration of glycemic control.

In order to identify additional symptoms of diabetic polyneuropathy, we assessed neurological manifestations in children with type 1 diabetes using the ped-mTNS. The

study found that the average score on this scale in group 1 was 3.68 ± 0.46 points, and in group 2, it was 4.20 ± 0.97 points ($p > 0.05$). The total score in 45 (49.4 %) children was 0–2 points, in 25 (27.5 %) — 3–5 points, in 16 (17.6 %) — 6–9 points, and in 5 (5.5 %) patients — 10–12 points. As with the CNE, the analysis on the ped-mTNS confirmed the dominance of sensory disorders and decreased deep tendon reflexes of the lower limbs (ankle and/or Achilles and/or patellar) in both study groups.

To identify kinetic disorders in children with type 1 diabetes depending on its duration, we assessed their mobility and functional capabilities using the PBS. The results of the study showed no statistically significant differences between groups 1 and 2: the average score was 70.32 ± 0.25 points and 70.27 ± 0.34 points, respectively ($p > 0.05$). It should be noted that the maximum score (72 points) was reported by 22.8 % of children in group 1 and only 11.8 % of children in group 2, i.e. 81.3 % of children with type 1 diabetes, regardless of the duration of the disease, have mild kinetic disorders, namely, impaired balance function.

To compare the prognostic significance of the scales used in the study to diagnose diabetic peripheral polyneuropathy, we compared the ROC curves constructed for the Clinical Neurological Examination, the pediatric-modified Total Neuropathy Score, and the Pediatric Balance Scale (Fig. 1, Table 2).

As evidenced by the data in Fig. 1 and Table 2, two scales had the largest AUC and higher sensitivity and specificity, the ped-mTNS and the CNE. Pairwise comparison of ROC curves showed the absence of statistical significance between the above scales (Table 2).

Comparisons confirmed the presence of a close direct relationship between the CNE and the ped-mTNS ($r = +0.89$, $p < 0.01$) (Fig. 2).

At the same time, we did not obtain a correlation between the CNE and the PBS ($r = +0.10$; $p > 0.05$), as well as between the ped-mTNS and the PBS ($r = +0.20$; 0.05).

Table 1. The frequency of neurological symptoms in children with type 1 diabetes

Complaints	Total (n = 91)		Group 1 (n = 57)		Group 2 (n = 34)	
	n	%	n	%	n	%
Headache	22	24.2	11	19.3	11	32.4*
Psychoemotional disorders	7	7.7	5	8.8	2	5.9
Weakness	6	6.6	1	1.7	5	14.7*
Dizziness	31	34.1	20	35.1	11	32.4
Rapid fatigue	14	15.4	9	15.8	5	14.7
Emotional lability	7	7.7	5	8.8	2	5.9
Periodic aching in the limbs	6	6.6	4	7.0	2	5.9
Tingling in the extremities	25	27.5	16	28.1	9	26.5
Shin cramps	40	44.0	20	35.1	20	58.8*
Difficulty climbing up or down the stairs	14	15.4	9	15.8	5	14.7
Pain in the limbs while walking	3	3.3	1	1.7	2	5.9
Frequent stumbling when walking	14	15.4	9	15.8	5	14.7
Thermoregulation disorders	25	27.5	14	24.6	11	32.4

Note: * — $p < 0.05$ — compared to the indicators of group 1.

Thus, correlation analysis, as well as the low AUC and the low sensitivity of the PBS don't allow using it as a screening tool in the diagnosis of DPNP in children.

Given the lack of clear criteria for the score necessary to diagnose diabetic peripheral polyneuropathy in children according to the ped-mTNS, in the future, with the help of ROC curve analysis, we calculated the cut-off point for the number of points during the examination of the child. The following ROC curve was obtained when assessing the

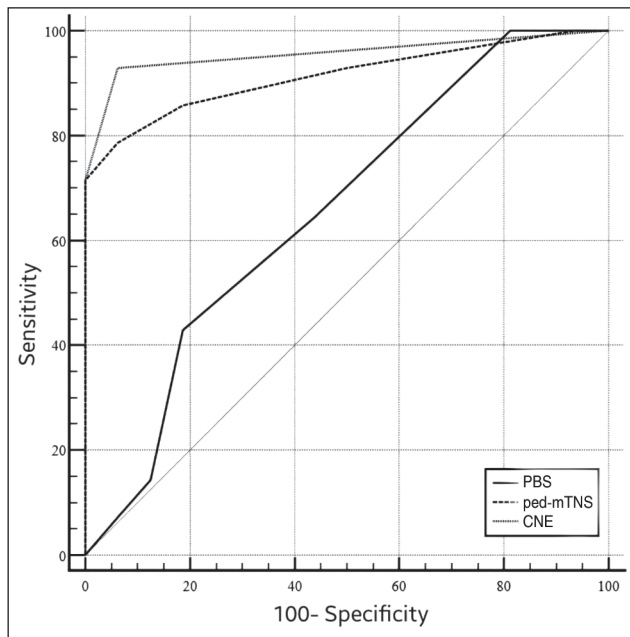


Figure 1. The ROC curves of the impulse scales (PBS, ped-mTNS, CNE)

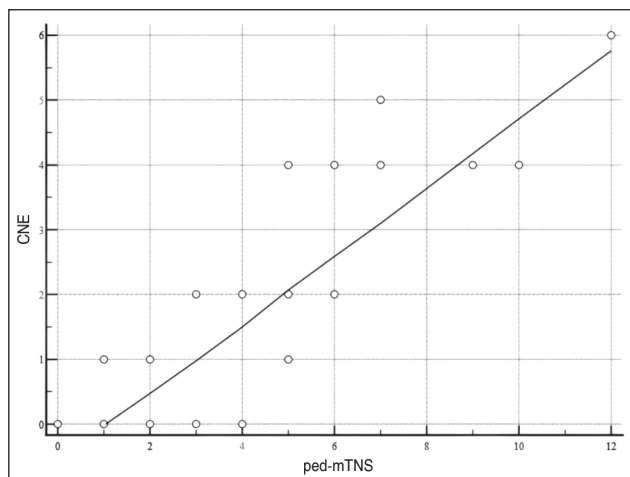


Figure 2. Correlation between the Clinical Neurological Examination and the pediatric-modified Total Neuropathy Score

probability of the development of DPNP depending on the obtained score (Fig. 3).

The AUC was 0.928 ± 0.044 with a 95% confidence interval of 0.787–0.988. The resulting model was statistically significant ($p < 0.001$). The score at the cut-off point, which corresponded to the highest value of the Youden index (0.727), was 3 points. That is, if, according to the results of the ped-mTNS, the score is 3 points or more, then the child is diagnosed with diabetic peripheral polyneuropathy. The sensitivity and specificity of the model were 78.95 and 93.75 %, respectively. Given the obtained cut-off point, the score on this scale of 3 points or more was received by 50.5 % of children with type 1 diabetes, including 5 (10.0 %) patients whose score on the CNE was 0.

Thus, according to the results of using the CNE and the ped-mTNS, diabetic peripheral polyneuropathy was diagnosed in 46 (50.5 %) children with type 1 diabetes mellitus, including 20 (35.1 %) patients in group 1 and 26 (76.5 %) in group 2 ($p < 0.05$).

Analysis of clinical manifestations of DPNP depending on the duration of diabetes mellitus showed that in the first 5 years of the disease, manifestations of polyneuropathy were limited to one type of disorder in 10 (50 %) patients, two types of disorders were observed in 9 (45 %) patients, and only in 1 case (5.0 %), there was a combination of all three types of disorders (Fig. 4A).

At the same time, the clinical picture of DPNP was dominated by motor (reduced deep tendon reflexes in the

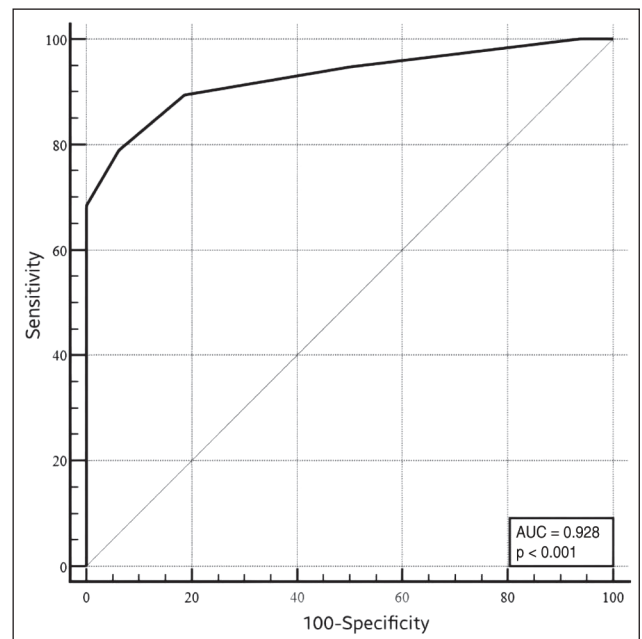


Figure 3. ROC curve of diagnosis of diabetic peripheral polyneuropathy in children with type 1 diabetes using the ped-mTNS

Table 2. AUC of level scales and their 95% confidence interval

Scale	AUC	Standard error	95% confidence interval	Sensitivity, %	Specificity, %
PBS	0.656	0.0984	0.461–0.819	42.86	81.25
ped-mTNS	0.928	0.0443	0.752–0.984	78.95	93.75
CNE	0.955	0.0386	0.811–0.997	92.86	93.75

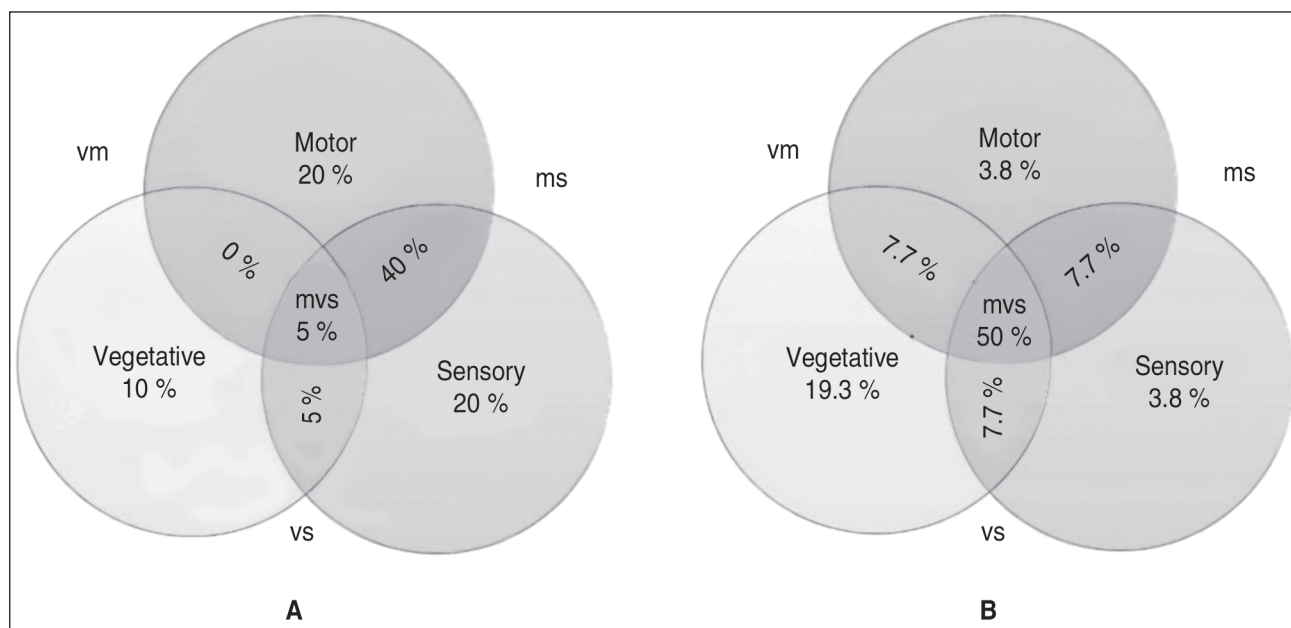


Figure 4. Venn diagram showing the main clinical manifestations of diabetic peripheral polyneuropathy in groups 1 (A) and 2 (B)

Notes: *vm* – a combination of vegetative and motor manifestations; *ms* – a combination of motor and sensory manifestations; *vs* – a combination of vegetative and sensory manifestations; *mvs* – a combination of motor, vegetative and sensory manifestations.

lower limbs and the presence of functional symptoms) and sensory disorders (various types of impaired sensitivity and complaints of pain, hyperesthesia or cramps in the lower or upper extremities), as well as their combination with other manifestations of polyneuropathy. In contrast to the first observation group, in the group 2, only 7 (26.9 %) children had manifestations of polyneuropathy limited to one type of disorder, two types of disorders were diagnosed in 6 (23.1 %) cases, while simultaneous motor and sensory deficit and autonomic dysfunction were present in 13 (50.0 %) patients ($p < 0.05$), that is, there was a combination of all three types of disorders (Fig. 4B). It should be noted that most children diagnosed with DPNP (69.6 %, 32 patients) had poor glycemic control, with a high risk to life, in 8 (17.4 %) patients, glycemic control was suboptimal and only 6 (13.0 %) children had optimal glycemic control. With the presence of all three types of disorders in the clinical picture of DPNP, glycemic control was poor in 85.7 % of cases. At the same time, in the group of children without signs of polyneuropathy, glycemic control with a high risk to life was 1.74 times less often (40.0 %, 18 people) than in the presence of DPNP ($p < 0.05$). Eighteen (40.0 %) children in this group had ideal (15.6 %) or optimal (24.4 %), another 9 (20.0 %) patients had suboptimal glycemic control.

Discussion

Currently, studies on the prevalence of diabetic peripheral polyneuropathy in children are limited due to the variability of tests used to diagnose this complication. In addition, many children have subclinical neuropathy, which is difficult to diagnose without sensitive tests and/or a detailed neurological examination [13, 14]. According to various authors, the prevalence of DPNP in children with type 1 diabetes ranges from 3 to 62 % [6, 14, 15]. As a rule, low

rates of DPNP in these patients were associated with the use of a minimal number of criteria for diagnosing neuropathy symptoms [14–16]. The American Diabetes Association suggests screening for DPNP five years after the initial diagnosis in children with type 1 diabetes, and then annually performing simple clinical tests with 10-g monofilaments [17]. However, our study using several scales, namely the Clinical Neurological Examination and the pediatric-modified Total Neuropathy Score, revealed signs of DPNP in 50.5 % of children with type 1 diabetes, and its manifestations in 35.1 %. Children were registered already in the first 5 years of diabetes, which requires screening for this complication from the first year of the disease. This study, as others [18, 19], demonstrated that the duration of diabetes was the most frequently registered risk factor for the development of DPNP. To date, there is a discrepancy regarding the significance of strict glycemic control in preventing late complications of diabetes, including diabetic neuropathy [20]. Our data indicate an increase in the symptoms of neurological disorders with deterioration of glycemic control, which is in line with the results of other studies that demonstrated the effectiveness of glycemic control in preventing the development of DPNP in type 1 diabetes mellitus [18, 21]. DPNP in children was characterized by the dominance of motor (67.4 %) and sensory (69.6 %) disorders, which were among the first manifestations of polyneuropathy. The clinical picture of DPNP indicates a greater involvement of large nerve fibers compared to small ones. This aligns with data from other researchers, suggesting that damage to large nerve fibers plays a dominant role in the clinical picture of diabetic polyneuropathy associated with type 1 diabetes mellitus [22]. It should be noted that among children with type 1 diabetes mellitus, a painless course predominates in the clinical picture of DPNP.

Conclusions

1. Diabetic peripheral polyneuropathy is a common complication (50.5 %) of diabetes mellitus in children.

2. The use of the Clinical Neurological Examination scale and the pediatric-modified Total Neuropathy Score allows us to expand the diagnostic capabilities of detecting diabetic peripheral polyneuropathy in children without using invasive diagnostic methods.

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Conflicts of interests. Authors declare the absence of any conflicts of interests and own financial interest that might be construed to influence the results or interpretation of the manuscript.

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Можливості неінвазивної діагностики діабетичної периферичної полінейропатії в дітей, хворих на цукровий діабет 1-го типу

Резюме. Актуальність. Більшість діагностичних тестів на діабетичну периферичну полінейропатію (ДПП) непридатні для використання в дитячому віці, наслідком чого є низька діагностика цього ускладнення. Тому існує потреба у визначенні надійних і простих маркерів для ранньої діагностики й моніторингу прогресування діабетичної полінейропатії в дітей. **Мета:** вивчити діагностичну цінність шкали клінічного неврологічного обстеження (CNE), модифікованої педіатричної загальної шкали нейропатії (ped-mTNS) та педіатричної шкали оцінки рівноваги (PBS) у неінвазивній діагностиці діабетичної периферичної полінейропатії в дітей, хворих на цукровий діабет 1-го типу. **Матеріали та методи.** Обстежено 91 дитину з цукровим діабетом 1-го типу віком від 10 до 17 років. У першу групу увійшли 57 пацієнтів із тривалістю хвороби до 5 років, у другу — 34 дитини з тривалістю діабету більше 5 років. Для діагностики ДПП проводилося комплексне неврологічне обстеження з використанням шкал CNE, ped-mTNS та PBS і подальшим визначенням діагно-

стичної значущості кожної з них за допомогою ROC-аналізу. **Результати.** Доведено, що діагностичну цінність у виявленні ДПП мали дві шкали — CNE та ped-mTNS, за результатами використання яких ДПП встановлено в 50,5 % пацієнтів. У клінічній картині ДПП домінували моторні й сенсорні розлади, що є одними з перших проявів цього ускладнення в дітей. Перші ознаки ДПП реєстрували вже на першому році захворювання. Частота розвитку та ступінь неврологічних порушень зростали в динаміці захворювання та при погіршенні глікемічного контролю. **Висновки.** Діабетична периферична полінейропатія є частим ускладненням цукрового діабету в дітей, яке реєструють у 50,5 % випадків. Застосування шкал CNE та ped-mTNS дозволяє розширити діагностичні можливості щодо виявлення ДПП у дітей без використання інвазивних методів діагностики.

Ключові слова: цукровий діабет; неврологічний стан; діабетична нейропатія; медичний скринінг; ROC-аналіз; діти