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ANALYSIS OF MEDICATIONS FOR SYMPTOMATIC TREATMENT OF THE PAINFUL DIABETIC POLYNEUROPATHY IN UKRAINE

Diabetic polyneuropathy (DPN) is the most common chronic complication of diabetes mellitus (DM). Neuropathic pain, which is one of the symptoms of DPN, requires pharmacological methods of treatment. Effective treatment according to the standards and the availability of the necessary medications is of crucial importance for improving the outcomes.

***The purpose** of this study is to analyze the pharmaceutical component of domestic and international recommendations for the treatment of pain syndrome DPN and the availability of medications on the pharmaceutical market of Ukraine for the treatment of this pathology.*

***Materials and methods.** National and international guidelines for treatment of DM and DPN, the State Register of Medicines of Ukraine were studied. Bibliosemantic, marketing, analytical analyzes were used.*

***The results.** Taking into account the new medications and modern research, it is advisable to update the Ukrainian clinical protocol for T2D with regard to DPN therapy. Based on the analysis of the guidelines, medications for the treatment of the painful form of DPN have been determined. Medications containing 4 INN names are registered on the pharmaceutical market of Ukraine: pregabalin (100 TN), gabapentin (14 TN), duloxetine (26 TN), and amitriptyline (5 TN). Tapentadol is not registered in Ukraine, capsaicin is not registered as a monopreparation, but combined medications for external use based on it are available on the market (4 TN). The largest part of the range of specified medications registered in Ukraine supplied by foreign manufacturers, the leaders of which are India, Slovenia, Turkey, and Poland. Part of the registered medications for the symptomatic therapy of DPN is absent in pharmacies.*

***Conclusions.** The study showed that in Ukraine there are medications for the treatment of painful DPN (excluding tapentadol) are registered and presented with a sufficient dosage line, which is important for minimizing the pharmacological burden on the patient.*

***Key words:** diabetes mellitus, diabetic polyneuropathy, pain syndrome, assortment, medicines.*

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АНАЛІЗ АСОРТИМЕНТУ ПРЕПАРАТІВ ДЛЯ СИМПТОМАТИЧНОГО ЛІКУВАННЯ БОЛЬОВОЇ ФОРМИ ДІАБЕТИЧНОЇ ПОЛІНЕЙРОПАТІЇ В УКРАЇНІ

Діабетична полінейропатія (ДПН) є поширеним хронічним ускладненням цукрового діабету (ЦД). Невропатичний біль, що є одним із симптомів ДПН, потребує фармакологічних методів лікування. Ефективна терапія згідно зі стандартами та доступність необхідного арсеналу лікарських засобів (ЛЗ) має вирішальне значення для покращення результатів.

***Мета роботи** – проаналізувати фармацевтичний складник вітчизняних і міжнародних рекомендацій для лікування больового синдрому ДПН та наявність ЛЗ на фармацевтичному ринку України для терапії такої патології.*

***Матеріали та методи дослідження.** Об'єктами дослідження слугували рекомендації та нормативні документи щодо лікування ЦД та ДПН, Державний реєстр лікарських засобів. Застосовували бібліосемантичний, маркетинговий, аналітичний аналізи.*

***Результат.** З огляду на нові досягнення в розробці ЛЗ та результати сучасних досліджень український клінічний протокол ЦД 2 типу доцільно оновити щодо терапії ДПН. На підставі аналізу настанов визначено препарати для лікування больової форми ДПН. На фармацевтичному ринку України зареєстровано препарати, що містять 4 МНН найменувань: прегабалін (100 ТН), габапентин (14 ТН), дулоксетин (26 ТН) та амітриптилін (5 ТН). Тапентадол в Україні не зареєстровано, капсаїцин не зареєстрований як монопрепарат, але комбіновані ЛЗ для зовнішнього застосування на його основі є на ринку (4 ТН). Більшу частину зареєстрованого в Україні асортименту визначених препаратів представлено іноземного виробництва. Частина зареєстрованого асортименту для симптоматичної терапії ДПН в аптеках фактично відсутня.*

***Висновки.** Дослідження показало, що в Україні зареєстровано препарати для лікування больової форми, окрім тапентадолу, і представлено достатньою лінійкою дозування, що важливо для мінімізації фармакологічного навантаження на пацієнта.*

***Ключові слова:** діабетична полінейропатія, цукровий діабет, больовий синдром, асоримент, лікарські засоби.*

Diabetes mellitus (DM) is big burden on health care due to the complexity and cost of treatment of the disease and its complications. Complications of diabetes significantly worsen the quality of life of people with diabetes (PwD) (daCosta DiBonaventura, 2011). Diabetic neuropathy is the most common chronic complication of diabetes, and its estimated prevalence exceeds 50% of PwD (Pop-Busui, 2017). Among the various forms of neuropathy, diabetic polyneuropathy (DPN) is the most common form and has the most evidence-based therapeutic approaches.

DPN is a symmetric, sensory-motor, distal polyneuropathy caused by metabolic and microvascular disorders due to the influence of chronic hyperglycemia and cardiovascular risk factors (Mankovsky, 2020). DPN is a complex of clinical and subclinical syndromes which characterized by damage to peripheral and/or autonomic nerve fibers as a result of DM. DPN is one of the early clinical manifestations of neurological disorders and is found in 13.0% of cases among patients with impaired glucose tolerance and in 11.3% of individuals with impaired fasting glycemia. In patients with type 2

diabetes (T2D), DPN develops at the beginning of the disease, but is diagnosed much later (Ziegler, 2021).

DPN is characterized by a pain syndrome and progressive damage to nerve fibers, which leads to loss of sensitivity and early disability of patients. Neuropathic pain, which is one of the symptoms of DPN, affects up to 30% of all people with DPN and is difficult to treat. This leads to among other problems: sleep disturbances, reduced quality of life, polypharmacy, socio-economic consequences (high costs of health care; reduction of patients' working capacity and their ability to self-care) (Pop-Busui, 2017; Vileikyte, 2017).

DPN with a painful symptoms' can occur in all age groups, but is more common in elderly patients. In addition, there are specific differences in pain. For example, in young people with poorly controlled diabetes type 1 (T1D), pain may be absent or very slight and accompanied by some other clinical signs (Abbott, 2011). Elderly people can have a significant dysfunction of muscle fibers, which leads to instability and gait disorders, which negatively affect the patient's life (Vinik, 2008). Since the majority of patients with T2Dare older people, the treatment of DPN with painful symptoms in the elderly requires special attention.

A low prevalence of DPN is characteristic for patients with T1D for less than 10 years. Over time, 25 years after the diagnosis, the prevalence of DPN increases to 34% (Martin, 2014). In addition to the traditional risk factors for the development of DPN for T1D (glycemic control, age and duration of diabetes), cardiovascular risk factors (obesity, hyperlipidemia, hypertension, smoking) and socioeconomic factors influence on the development of DPN negatively (Mizokami-Stout, 2020). More than half of all patients with T2D develop signs and symptoms of DPN during their lifetime. In fact, the prevalence of DPN is quite high, even in newly diagnosed patients with T2D (20–30%) (Andersen, 2018).

Painful symptoms require pharmacological and other methods of treatment. Considering the "pandemic" of DM worldwide (Boulton, 2004) the high prevalence of its complications, clinical and socioeconomic consequences, effective therapeutic and preventive measures for DPN are of critical importance.

Effective treatment according to the standards and the availability of the necessary medications is of crucial importance for improving the outcomes.

Therefore, the study of national and international standards regarding the therapy of DPN pain syndrome in patients with DM and the analysis of the range of medications for treatment are relevant.

The purpose of this study is to analyze the pharmaceutical component of domestic and international recommendations for the treatment of pain syndrome DPN and the availability of medications on the pharmaceutical market of Ukraine for the treatment of this pathology.

Research materials and methods. The objects of the study were national and international guidelines for treatment of diabetes and DPN (orders of the Ministry of Health of Ukraine, national and international clinical guidelines, protocols, recommendations), the State Register of Medicines of Ukraine (http:// www.drlz.com.ua) and information about the presence at the pharmacies in Ukraine (www.tabletki.ua, www.liki24.com) on data January 10, 2023. The Anatomical Therapeutic Chemical (ATC) classification was used. Bibliosemantic, marketing, analytical, graphic, generalizing analyzes were used.

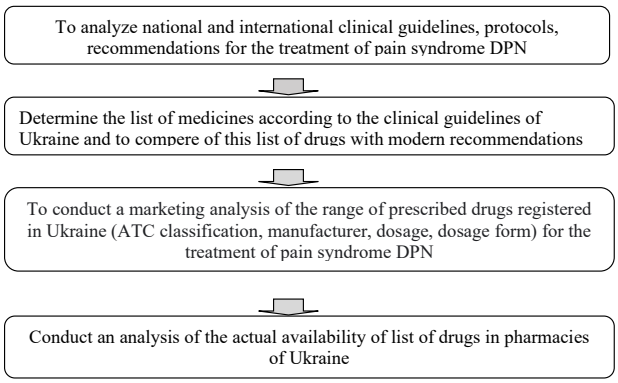

Fig. 1. Research algorithm

Result. At the first stage of the study, national and international clinical guidelines and recommendations for DPN therapy were analyzed and the range of medications specified in these guidelines was determined.

In 2023 "Diabetes Melitus. Evidence-based clinical guideline", which is a version of the clinical guideline (Releases Standards of Medical Care in Diabetes, 2021, USA) of the American Diabetes Association (ADA) adapted for the health care system of Ukraine. This guideline was selected by the working group as an example of the best practice of medical care to patients with DM and is based on evidence-based medicine data regarding the effectiveness and safety of medical interventions, pharmacotherapy and organizational principles of its provision.

Also, at the beginning of 2023, the updated Unified clinical protocol of primary, emergency and specialized medical care "Type 1 Diabetes in Adults" was approved. And for the treatment of T2D, the Unified clinical protocol of primary and secondary (specialized) medical care

"Type 2 diabetes" of 2012, which provides recommendations for the treatment of DPN, remains valid.

According to the current legislation in Ukraine the use of international clinical guidelines of professional or national medical organizations of member states of the European Union, the United States of America, Canada and the Australian Union also allowed.

List of a clinical guidelines for the treatment of polyneuropathy pain syndrome for PwD, which have been analyzed and medications (by *International Nonproprietary Names* (INN) and ATC groups) have been indicated:

– "Diabetes Melitus". Evidence-based clinical guideline, 2023;

– Unified clinical protocol of primary, emergency and specialized medical care "Type 1 Diabetes in Adults", 2023;

– Unified clinical protocol of primary and secondary (specialized) medical care "Type 2 Diabetes", 2012;

– Diabetes Canada Clinical Practice Guidelines;

– The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic: RACGP, 2020;

– National Institute for Health and Care Excellence (Great Britain) Treatment-Peripheral neuropathy;

– International Diabetes Federation. Global Guideline for Type 2 diabetes.

In addition to the guidelines, the analysis also includes specific therapeutic approaches to the diagnosis and treatment of DPN with pain syndrome (Diagnosis and Treatment of Painful Diabetic Peripheral Neuropathy) of 2022 of the American Diabetes Association (Pop-Busui, 2017).

The study of clinical Guidelines and recommendations for the treatment of DPN for PWD showed that most guidelines offer symptomatic therapy for the treatment of pain using anticonvulsants (pregabalin, gabapentin) and antidepressants (amitriptyline, duloxetine). Tapentadol and topical medicines with capsaicin are also recommended in the national "Diabetes Melitus" Guidelines. In Unified clinical protocol of primary, emergency and specialized medical care "Type 1 Diabetes in Adults" treatment of DPN is not specified, only the mechanism of development of this pathology is given. In the national Unified Clinical Protocol of Type 2 Diabetes (2012), pathogenetic therapy with the use of thioctic acid and actovegin is also added. In international recommendations, it is indicated about the expediency of using also benfotiamine and vitamin B12 as pathogenetic therapy. Recommendations regarding the use of pathogenetic pharmacological therapy are not indicated in most international guidelines. Taking into account the new medications and modern researches, it is advisable to update the Ukrainian clinical protocol for type 2 diabetes with regard to DPN therapy.

Pregabalin and duloxetine have high analgesic activity and are effective against pain which DPN induced. Pregabalin modulates calcium channels both at the level of the spinal cord and in the brain and has analgesic and anti-anxiety effects. Theare are the medications for first line for the treatment of pain associated with DPN (Oros, 2018). Pregabalin in doses of 150, 300 and 600 mg/day effectively restrains neuropathic pain. Pregabalin therapy was better tolerated and less frequently discontinued due to the development of side effects. It is important to note that pregabalin does not cause a withdrawal syndrome and is characterized by a low risk of addiction. Duloxetine works more like a sedative by increasing levels of serotonin and norepinephrine, which are involved in pain control.

Based on the analysis of national and international recommendations, a list of medications (according to INN and ATC groups) for the treatment of the painful form of DPN has been established.

The marketing analysis of the range of identified medications showed that 4 INN medications are registered on the pharmaceutical market of Ukraine for the treatment of the painful form of DPN. Tapentadol is not registered in Ukraine. Capsaicin is not registered as a monopreparation in Ukraine, but combined medications for external use based on it are registered.

The results of the analysis of drugs for the symptomatic treatment of the painful form of DPN, registered in Ukraine (2023) presents in the table 1.

Table 1

Medications for the symptomatic treatment of the painful form of DPN

Code ATC	International Nonproprietary Names of medications	The number of registered medications by trade name (TN) (unit)		
		Foreign	Ukrainian	In total
N03A X16	Pregabalin	24	76	**100**
N03A X12	Gabapentin	6	8	**14**
N06A X21	Duloxetine	2	24	**26**
N06A A09	Amitriptyline	4	1	**5**
M02AB	Capsaicin and preparations based on it	4	0	4

Almost all identified drugs for the pain syndrome of DNP belong to group – *Medications acting on the nervous system (N), – antiepileptic drugs (N03).* Pregabalin and Gabapentin are included in the group *Antiepileptics* (N03A) and in the subgroup *Other antiepileptics*

(N03A X), and Amitriptyline is included in the group *Psychoanaleptics (N06)*, in the subgroup *Antidepressants (N06A)*, while Amitriptyline belongs to the subgroup *Nonselective reuptake inhibitors monoamines (N06A)*, and duloxetine to *Other antidepressants (N06A X)*.

Combined capsaicin preparations according to the ATC classification belong to group X-group: *Capsaicin and preparations based on it (M02AB)*.

A detailed analysis found that pregabalin medications represented the largest group in terms of the number of medications, and taking into account the dosage, it is 100 TN, of which 76% is foreign production (Fig. 2). The leader in the supply of pregabalin medications from foreign companies, the number of which exceeds even domestic production, is India – 28 TN. Slovenia provides 10 TN, Turkey – 6 TN, Poland – 5 TN, others supply several medications.

Fig. 2. Segmentation of medications of pregabalin by country of manufacture in the pharmaceutical market of Ukraine (2023)

Pregabalin medications are produced mainly in the form of capsules with different amounts of the active pharmaceutical ingredient. It has been established that a wide range of pregabalin dosages is available on the Ukrainian market, but mainly these are medications with a pregabalin content of 75 mg, 150 mg, and 300 mg. That is medications with different dosages of pregabalin are registered, which is important considering the side effects of the medication for the possibility of minimizing the dose of the medication.

Two Ukrainian manufacturers (PJSC "Darnitsa", LTD "Zdorovye Narody") have registered pregabalin in the oral solution form, 20 mg/ml in 100 ml or 200 ml bottles, but in fact they are not available in pharmacies.

14 TN Gabapentin are registered. Gabapentin produced in the capsules of 400 mg, 300 mg and 100 mg of different packaging (No. 10 – No. 100). Ukrainian manufacturers: JSC "Farmak" produces 3 TN and 1 TN each are being produced by PJSC "Technolog", GC "Pharma Start" and GC "Kusum Pharm", which carries out secondary packaging, quality control and release of a series of Indian products in bulk. Three foreign manufacturers supply gabapentin to the Ukrainian pharmaceutical market from India (4 TN), Canada (3 TN) and Hungary (1 TN).

Duloxetine medications (26 TN) on the market of Ukraine are mainly of foreign production, with India (8 TN) being the leader in supply, Bulgaria and Turkey supplying 4 TN each, and other countries (Poland, Slovenia, Spain, Cyprus) presenting to the market 2 TN each. The domestic enterprise JSC ""Farmak" carries out packaging from the bulk manufacturer Laboratorios Normon, S.A., (Spain). Duloxetine is produced in the form of gastro-resistant capsules, enteric-dissolving tablets/capsules, and modified-release capsules with a dosage of 30 mg or 60 mg in various packaging.

Amitriptyline medications (5 TN) in the form of coated tablets of 25 mg, No. 25; No. 50; No. 100 is produced by two domestic enterprises (PJSC "Technolog", LTD "Zdorovye Narody") and one pharmaceutical enterprise in Denmark. Production of injection solution, 10 mg/ml, 2 ml in ampoule No. 10 is duplicated by LTD "Zdorovye Narody" and LLC Pharmaceutical company "Zdorovye" (Ukraine).

Capsaicin as a monopreparation is not registered in Ukraine, but there are combined medications for external use based on it, only domestically produced. In addition, pharmaceutical enterprises duplicate two medications. Thus, Espol ointment of 30 g in tubes is produced by JSC "Lubnypharm" and PJSC "Chervona Zirka" Chemical & Pharmaceutical plant", and tincture of capsicum in bottles of 50 ml is produced by PJSC "FITOFARM" and PJSC Pharmaceutical Factory "Viola".

In order to establish the actual availability of the specified medications, we checked the actual availability of these medications in Ukrainian pharmacies (according to information on www.tabletki.ua and www.liki24.com). It was established that a significant part of the registered range of medications is missing. Domestic medications are available in a higher percentage (86.7%) than foreign ones (46.7%), which implies ensuring the stability of treatment with appropriate medications. There is also a line of medications with different dosages, which is important for this group of medications.

Conclusions.

1. The current legislation of Ukraine allows doctors to use modern international clinical guidelines for the treatment of diabetes. Moreover, in 2023, the Guidelines "Diabetes Melitus" were adopted and the Unified clinical protocol for T1D was updated. At the same time, the Unified Clinical Protocol for T2D approved in 2012 continues to operate. In this Protocol

the pharmacotherapy of the painful form of DPN was specified, in addition to symptomatic therapy, pathogenetic therapy is recommended. Taking into account the new medications and modern research, it is advisable to update the Ukrainian clinical protocol for T2D with regard to DPN therapy.

2. Based on the analysis of the guidelines, medications for the treatment of the painful form of DPN have been determined. Medications containing 4 INN names are registered on the pharmaceutical market of Ukraine: pregabalin (100 TN), gabapentin (14 TN), duloxetine (26 TN), and amitriptyline (5 TN). Almost all identified medications belong to group N – Medications acting on the nervous system, N03 – antiepileptic medications. Tapentadol is not registered in Ukraine, capsaicin is not registered as a monopreparation, but combined medications for external use based on it are available on the market (4 TN).

3. The largest part of the range of specified medications registered in Ukraine supplied by foreign manufacturers, the leaders of which are India, Slovenia, Turkey, and Poland.

4. Part of the registered medications for the symptomatic therapy of DPN is absented in pharmacies. Comperative analisis has shown that significantly higher percentage Ukrainian producers' medications (86.7%) than foreign medications (48.7%), which implies ensuring the stability of treatment with appropriate medications.

5. The study showed that in Ukraine there are medications for the treatment of painful DPN (excluding tapentadol) are registered and presented with a sufficient dosage line, which is important for minimizing the pharmacological burden on the patient.

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