UDC 615.036.8

THE QUALITY ANALYSIS OF PHARMACOTHERAPY OF PATIENTS WITH SCIATICA

L.V.Iakovlieva, O.Ya.Mishchenko, I.V.Konuschynska

National University of Pharmacy

Key words: back pain; sciatica; pharmacotherapy; retrospective analysis of drug prescriptions; VEN analysis; frequency analysis

The article presents the results of the rationality assessment for pharmacotherapy of patients with sciatica on the basis of pooled VEN/ frequency analysis. A retrospective analysis of medication administration records of 112 patients diagnosed with sciatica has been conducted. A total of 61 TNs (46 INN) were prescribed to patients with sciatica. The total number of prescriptions was 964, the number of prescriptions per a patient – 8.6, indicating polypharmacy. The main directions of pharmacotherapy of patients with sciatica have been determined. They are anti-inflammatory and analgesic (non-opioid analgesics, NSAIDs, local anesthetics), antispasmodic (muscle relaxants), perfusion therapy to improve microcirculation and hemodynamics; they comply with the requirements of the current regulations – Clinical Protocol of medical care for patients with dorsalgia (2007). Comparison of the results of VEN and frequency analysis indicates that there are non-essential drugs with the metabolic action in the doctor's prescriptions, such as deproteinized blood derivative (actovegin), L-lysine aescinat, etc. In case of prescribing a significant number of non-essential drugs with the metabolic action leading to polypharmacy the use of antisecretory drugs, in particular proton pump inhibitors, to prevent complications in the gastrointestinal tract, which may be caused by NSAIDs, is insufficient. A possible way to increase the rationality of pharmacotherapy of patients with sciatica is to reduce the number of prescriptions of non-essential drugs that will reduce the number of prescriptions to a patient.

Back pain takes a leading place among painful musculoskeletal syndromes in terms of the number of disability days of the working population [1, 2, 8, 10]. Over the lifetime, about 70-80% of people experience at least one episode of back pain. In 15-20% of patients, acute back pain is transformed into chronic one. Back pain is one of the most common causes of disability among persons of different age, disability occurs in 10-20% of patients. Due to the fact that the peak incidence occurs in people of the working age, the problem of back pain has also the economic value. The economic damage of the state includes not only the direct costs of medical care, but also indirect costs – in the form of social benefits because of temporary or permanent disability, and damage caused by the backlog of work, as well as reduced efficiency [1, 2, 8, 10]. In the USA the annual direct costs associated with the treatment of back pain are estimated in 26.3 billion USD [11], and indirect costs caused by the lost working days due to the illness make up about 2% of the annual compensation for this reason [7].

Sciatica is a pathological condition characterized by appearance of pain along the sciatic nerve and in the lumbosacral region. This syndrome occurs in the case of pathological changes in the spine, hip joint, muscles and fasciae, as well as diseases of internal organs. Sciatica can lead to permanent performance degradation without timely and effective treatment [1, 2]. Medical and socio-economic importance of sciatica is caused by increase in disease incidence of people of the working age due to the spread of risk factors for the disease development, such as the lack of exercise, hard physical labour, poor posture, stress, pathological lordosis and kyphosis, increased body weight, pregnancy, etc. [1, 2, 6, 8, 9]. The above sciatica effects and development conditions necessitate its timely and effective treatment.

In case of the limited funds for healthcare the issue of the rational use of available resources and reduction of the cost for treatment of common diseases, such as sciatica, is urgent. One solution to this problem is an effective treatment of patients by means of the rational prescription of drugs selected on the basis of assessment of efficiency, safety and cost of the treatment. This goal is achieved by using the results of clinical and economic studies [5].

The aim of this study is to evaluate the rationality of prescriptions to patients with sciatica based on the results of VEN/ frequency analysis.

To achieve this goal, the following tasks were performed: a retrospective analysis of medication administration records of patients with sciatica was conducted; the main directions of pharmacotherapy were determined as a result of frequency analysis of drug prescriptions for patients with sciatica; compliance of pharmacotherapy with the current regulations was assessed based on the results of formal VEN analysis of drug prescriptions.

Materials and Methods

The assessment of the rationality level for pharmacotherapy of patients with sciatica was per-

L.V.Iakovlieva – Doctor of Pharmacy, professor, head of the Department of Pharmacoeconomics of the National University of Pharmacy (Kharkiv)

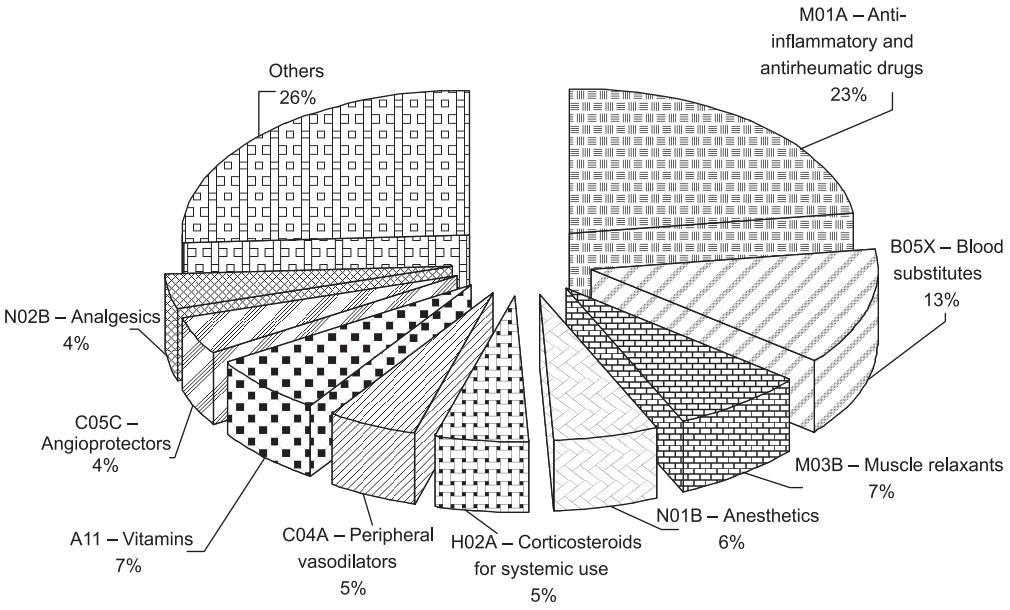

Fig. 1. Distribution of various pharmacotherapeutic groups of drugs by the frequency of prescriptions

formed using pooled VEN/frequency analysis. Frequency analysis is an assessment of the frequency of using a drug for the treatment of patients with a particular disease in a healthcare institution [5]. In this study, the frequency analysis of prescriptions was conducted according to the International Nonproprietary Names (INN), drug trade names (TNs), pharmacological groups, and the proportion of patients who received drugs of particular pharmacological groups. The formal VEN analysis involved the distribution of drugs by their significance into two categories: V – vital, and N – non-essential [5]. The drug was referred to category V by the presence of INN in the current Clinical Protocol (CP) of medical care for patients with sciatica [4] and in the National Drug Formulary (NDF, the Vth edition 2013) [3], and to category N – in case of its absence.

Results and Discussion

The analysis of regulations has indicated that pharmacotherapy of sciatica is determined by the current CP for patients with dorsalgia (Order of the Ministry of Health of Ukraine No. 275 dated 03.08.2007). According to this document the drug treatment of sciatica involves the use of the main groups of drugs. They are nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, muscle relaxants, anticonvulsants, anxiolytics, antidepressants, drugs with the chondroprotective action, drugs that improve microcirculation, regional and central hemodynamics, reduce venous congestion and tissue hydration; drugs with the metabolic action, as well as drug blockades (epidural sacral, selective radicular, etc.) with long-acting glucocorticoids (GCs) and a local anesthetic. Physio-, reflex and manual therapy, as well as exercise therapy are recommended for patients.

The rationality of drug prescriptions to patients with sciatica was assessed based on the results of frequency and VEN analysis. A retrospective analysis of medication administration records of 112 patients diagnosed with sciatica and treated at the Therapeutic Department of the district healthcare institution in the Poltava region in 2013 was conducted. A large proportion of patients were male patients – 64 patients, a smaller proportion – female – 50 patients, respectively. The average age of the patients was 56 ± 8.6 years old.

A total of 61 TNs (46 INN) were prescribed to patients with sciatica. The total number of prescriptions was 964, the number of prescriptions per a patient – 8.6, indicating polypharmacy. The average cost for the course of treatment per a patient was UAH 368.51. The average time for an inpatient in the hospital was 6 days.

Frequency analysis was conducted at the first stage of the study. It characterizes the frequency of prescriptions of a specific drug and its rating and proportion in the total number of prescriptions. Frequency analysis by pharmacological groups makes it possible to get an idea of the prevailing areas of pharmacotherapy. Comparison of the results of frequency analysis by pharmaceutical groups according to the current CP of treatment provides the opportunity to assess the degree of compliance of pharmacotherapy with the existing regulations of the Ministry of Health of Ukraine [5].

The results of frequency analysis summarized by pharmaceutical groups are shown in Fig. 1.

Drugs from 25 pharmacotherapeutic groups were used for the pharmacotherapy of patients with sciatica. It was found that anti-inflammatory and analgesic therapies were the prevailing areas of treating patients with sciatica. The following pharmacotherapeutic groups of drugs were used:

Table

Leading drugs (TOP-10) by the frequency of prescriptions among trade names

Drugs	Dosage form	Manufacturer	Frequency of prescriptions	Prescriptions, %	Patients, %
Saline solution	Solution for injection, 0.9%, 200 ml	Niko LLC (Ukraine, Makiivka)	60	6.22	53.57
Dexamethasone	Solution for injection, 4 mg, 1 ml amp., No. 10	DZ DNTSLZ LLC (Ukraine, Kharkiv)	52	5.39	46.43
Novocaine	Solution for injection, 20 mg/ml, 2 ml amp., No. 10	Darnytsia PJSC (Ukraine, Kyiv)	52	5.39	46.43
Tolperil	Solution for injection, 1 ml amp., No. 5	Zdorovya LLC (Ukraine, Kharkiv)	52	5.39	46.43
Euphyllin	Solution for injection, 20 ml, 5 ml amp., No. 10	Niko LLC (Ukraine, Makiivka)	48	4.98	42.86
Saline solution	Solution for injection, 0.9%, 100 ml vial	Niko LLC (Ukraine, Makiivka)	48	4.98	42.86
Vitamin B_{12}	Solution for injection, 0.05%, 1 ml amp., No. 10	Galychpharm PC (Ukraine, Lviv)	44	4.56	39.29
L-lysine aescinat	Solution for injection, 1 ml, 5 ml amp., No. 10	Galychpharm PC (Ukraine, Lviv)	40	4.15	35.71
Reumoxicam	Tabl., 7.5 mg, No. 20	Farmak LLC (Ukraine, Kyiv)	40	4.15	35.71
Analgin	Solution for injection, 500 mg/ml, 2 ml amp., No. 10	Lekhim-Kharkiv CJSC	36	3.73	32.14

M01A – Anti-inflammatory and antirheumatic drugs, they were 22.7% of the total cost of prescriptions, one patient was prescribed two drugs from this group; N01B – Anesthetics – 5.7% of the total number of prescriptions, they were received by 50% patients; H02A – Corticosteroids for systemic use – 5.3% of the total number of prescriptions, 46.4% of patients received them; A11D – Vitamins (mainly vitamins with the neurotrophic action: B_1, B_6, B_{12} and their complex preparations) – 6.6% of the total number of prescriptions, they were prescribed to 57.1% of patients. Therapy to relieve spasms of skeletal muscles and reduce pain included prescription of muscle relaxants (M03B) – 7.4% of the total number of prescriptions, 64.2% of patients received these drugs.

Reperfusion therapy used to improve microcirculation and hemodynamics was 13% prescriptions, some patients received simultaneously two drugs from this group.

Peripheral vasodilators (papaverine hydrochloride, dibazol) that were 5% of the total number of prescriptions were taken by 43% of patients, probably to improve hemodynamics of the nerve and muscle tissue [5].

Prescription of drugs from other pharmacotherapeutic groups was 25.7%, i.e. it was less. It is worth noting that antisecretory drugs, preferably omeprazole (24 prescriptions) and ranitidine (4 prescriptions), which were prescribed for prevention of gastrointestinal complications against the background of anti-inflammatory therapy with the use of NSAIDs and corticosteroids, were taken only by 25% of patients although two anti-inflammatory drugs were prescribed to almost everyone of them, parenterally and orally. Despite the significant risk of gastrointestinal complications when combining two NSAIDs [12, 13] prescription of antisecretory drugs is insufficient.

Thus, comparison of these main directions of pharmacotherapy with those defined by the current CP for patients with sciatica (Order of the Ministry of Health of Ukraine No. 275 dated 03.08.2007) shows that they are the same in general. These are such areas as anti-inflammatory and analgesic therapy included prescription of NSAIDs, analgesics, anesthetics, corticosteroids, muscle relaxants and preparations of neurotrophic vitamins (B_1, B_6, B_{12} and their complexes). All patients were treated with parenteral dosage forms, including NSAIDs, vitamins, and they also received perfusion therapy with metabolic drugs to improve microcirculation and hemodynamics.

Leading drugs (TOP-10) by the frequency of prescriptions (FP) among INN were saline solution (FP – 108), NSAID diclofenac sodium (FP – 84), muscle relaxant of the central action tolperisone hydrochloride (FP – 72), local anesthetic procaine (FP – 56), corticosteroid of the systemic action dexamethasone (FP – 52), NSAID ketorolac (FP – 48) and meloxicam (FP – 48), vasodilator theophylline (FP – 48), vitamin with the neurotrophic effect cyanocobalamin (FP – 44), metabolic drug L-lysine aescinat (FP – 40).

Leading drugs (TOP-10) among TNs are given in Table. Comparison of the results of frequency ana-

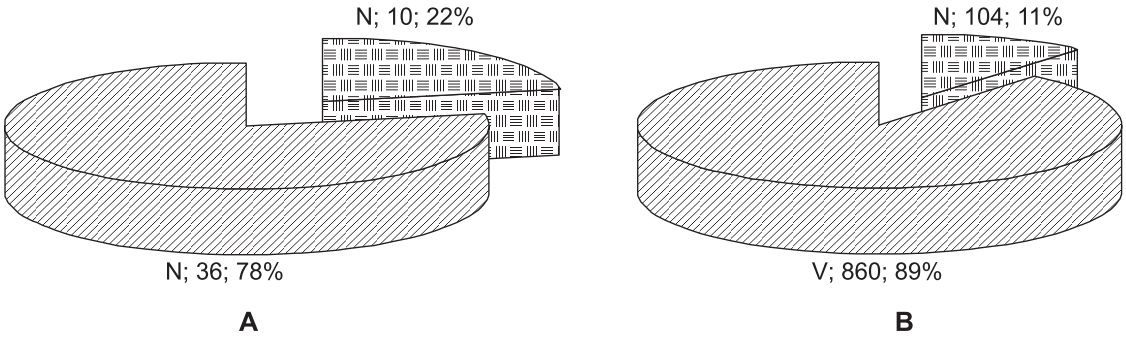

Fig. 2. A – distribution of the prescribed drugs by INN for categories V – vital and N – non-essential;
B – proportion of the drugs of categories V (vital) and N (non-essential) in the total number of prescriptions

lysis by INN and TNs has shown that the leaders by the frequency of prescriptions are drugs used to provide the main areas of pharmacotherapy of sciatica determined by the current CP. In general, the group of leading drugs included generic drugs that were more economically affordable for a Ukrainian patient.

At the next stage VEN analysis was conducted, and this allowed evaluating the compliance of pharmacotherapy of patients with a specific pathology with the current treatment protocols. The formal VEN analysis conducted has shown that out of 46 INN prescribed for the treatment of patients with sciatica 36 (78%) belong to category V – vital, 10 (22%) drugs – to category N – non-essential (Fig. 2A). The group of drugs of category N included drugs of the metabolic action: L-lysine aescinat, deproteinized hemoderivative (actovegin), citicoline, meldonium dihydrate, propionate dihydrate, enzyme preparation serratiopeptidase, etc.

Comparison of the results of frequency and VEN analysis (Fig. 2B) shows that drugs of category V (vital) make up 89% of all prescriptions, and drugs of category N (non-essential) – 11%. These are the drugs with the low level of evidence-based efficiency.

Therefore, vital drugs make up 89% of prescriptions of doctors for patients with sciatica. This demonstrates a sufficiently high degree of compliance of drug prescriptions with the current treatment protocol and NDF, the Vth ed., 2013, existing at the time of study, which is a standard of the pharmaceutical component of medical care.

CONCLUSIONS

1. In general, the main areas of the therapy of patients with sciatica comply with the requirements of the current clinical protocol. Leaders by the frequency of prescriptions are drugs used to provide the main directions of pharmacotherapy of sciatica.

2. The results of the formal VEN analysis show a certain level of compliance of pharmacotherapy with the current regulations – the most INN prescribed belong to the category of vital drugs: 78% of the number of INN prescribed, and 89% of the total number of prescriptions, respectively. A possible way to increase the rationality of pharmacotherapy of patients with sciatica is to reduce the number of prescriptions of non-essential drugs that will reduce the number of prescriptions to a patient.

3. In case of prescribing a significant number of non-essential drugs with the metabolic action leading to polypharmacy the use of antisecretory drugs to prevent complications in the gastrointestinal tract, which may be caused by NSAIDs, is insufficient.

REFERENCES

1. *Амелин А.В. // РМЖ. – 2013. – Специальный выпуск. Болевой синдром. Режим доступу: http://www.rmj.ru/numbers_662.htm*
2. *Баринов А.Н. // РМЖ. – 2013. – Специальный выпуск. Болевой синдром. – Режим доступу: http://www.rmj.ru/numbers_662.htm*
3. *Державний формуляр лікарських засобів / МОЗ України Держ. фармакол. центр; за ред. В.Т.Чумака. – К.: МОРІОН, 2013. – Вип. 5. – 1308 с.*
4. *Наказ МОЗ України №275 від 03.08.2007 р. Клінічний протокол надання медичної допомоги хворим на дорсалгії. – Режим доступу: http://www.dec.gov.ua/mtd/index.html*
5. *Морозов А.М., Яковлєва Л.В., Бездітко Н.В. та ін. Оцінка клінічної та економічної доцільності використання лікарських засобів у лікувально-профілактичному закладі (супровід формулярної системи): Метод. рекоменд. – Х.: Стиль-Издат, 2013. – 35 с.*
6. *Chen S.M., Liu M.F., Cook J. et al. // Int. Arch. Occup. Environ. Health. – 2009. – Vol. 82, №7. – P. 797-806.*

7. *Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society / Roger Chou, Vincenza Snow, J. Thomas Cross Jr. et al. // Clinical Guidelines. – Режим доступу : http://annals.org/ on 07/15/2015.*
8. *Hand L. Low back pain top cause of disability worldwide // Medscape Medical News from WebMD. March 24. – 2014. – Режим доступу: http://www.medscape.com/viewarticle/822492.*
9. *Heuch I., Hagen K., Heuch I. et al. // Spine (Phila Pa 1976). – 2010. – Vol. 35, №7. – P. 764-768.*
10. *Hoy D., March L., Brooks P. et al. // Ann. Rheum. Dis. – 2014. – Vol. 73, №6. – P. 968-974.*
11. *Luo X., Pietrobon R., Sun S.X. et al. // Spine. – 2004. – Vol. 29, №1. – P. 79-86.*
12. *Roelofs P.D., Deyo R.A., Koes B.W. et al. // Spine (Phila Pa 1976). – 2008. – Vol. 33, №16. – P. 1766-1774.*
13. *United States Preventative Task Force, 2012. Health care guideline: Adult acute and subacute low back pain. Institute for Clinical System Improvement. – Режим доступу: https://www.icsi.org/_asset/bjvqrj/LBP.pdf*

АНАЛІЗ ЯКОСТІ ФАРМАКОТЕРАПІЇ ХВОРИХ НА ЛЮМБОІШІАЛГІЮ

Л.В.Яковлєва, О.Я.Міщенко, І.В.Конющинська

Національний фармацевтичний університет

Ключові слова: біль у спині; люмбоішіалгія; фармакотерапія; ретроспективний аналіз призначень лікарських засобів; VEN-аналіз; частотний аналіз

Наведені результати оцінки раціональності фармакотерапії хворих на люмбоішіалгію на основі сукупного VEN/частотного аналізу. Був проведений ретроспективний аналіз листків призначень 112 пацієнтів з діагнозом люмбоішіалгія. Усього хворим на люмбоішіалгію було призначено 61 ТН (46 МНН). Загальна кількість призначень склала 964, кількість призначень на одного хворого – 8,6, що свідчить про поліпрагмазію. Встановлені основні напрямки фармакотерапії хворих на люмбоішіалгію: протизапальна і аналгетична (неопіоїдні аналгетики, НПЗЗ, місцеві анестетики), антиспастична (міорелаксанти), перфузійна терапія для поліпшення мікроциркуляції і гемодинаміки, які відповідають вимогам чинних нормативних документів: клінічному протоколу медичної допомоги хворим на дорсалгії (2007 р.). Співставлення результатів VEN- і частотного аналізу свідчить, що в призначеннях лікарів присутні другорядні лікарські засоби метаболічної дії: актовегін, L-лізину есцинат та ін. На тлі призначення значної кількості другорядних препаратів, що призводило до поліпрагмазії, недостатнім є застосування антисекреторних засобів, зокрема інгібіторів протонної помпи, з метою профілактики ускладнень з боку шлунково-кишкового тракту, що можуть бути спричинені застосуванням НПЗЗ. Можливим шляхом підвищення раціональності фармакотерапії хворих на люмбоішіалгію є зменшення кількості призначень другорядних ЛЗ, що дозволить зменшити кількість призначень одному хворому.

АНАЛИЗ КАЧЕСТВА ФАРМАКОТЕРАПИИ БОЛЬНЫХ ЛЮМБОИШИАЛГИЕЙ

Л.В.Яковлева, О.Я.Мищенко, И.В.Конющинская

Национальный фармацевтический университет

Ключевые слова: боль в спине; люмбоишиалгия; фармакотерапия; ретроперспективный анализ назначений лекарственных средств; VEN-анализ; частотный анализ

Приведены результаты оценки рациональности фармакотерапии больных с люмбоишиалгией на основе совокупного VEN/частотного анализа. Был проведен ретроспективный анализ листков назначений 112 пациентов с диагнозом люмбоишиалгия. Всего больным было назначено 61 ТН (46 МНН). Общее количество назначений составило 964, количество назначений на одного больного – 8,6, что свидетельствует о полипрагмазии. Установлены основные направления фармакотерапии больных с люмбоишиалгией: противовоспалительная и анальгетическая (неопиоидные анальгетики, НПВС, местные анестетики), антиспастическая (миорелаксанты), перфузионная терапия для улучшения микроциркуляции и гемодинамики, которые соответствуют требованиям действующих нормативных документов: клинического протокола медицинской помощи больным с дорсалгиями (2007 г.). Сопоставление результатов VEN- и частотного анализа свидетельствует, что в назначениях врачей присутствуют второстепенные лекарственные средства метаболического действия: актовегин, L-лизина эсцинат и др. На фоне назначения значительного количества второстепенных препаратов, что приводило к полипрагмазии, недостаточным является применение антисекреторных средств, в частности ингибиторов протонной помпы, с целью профилактики осложнений со стороны желудочно-кишечного тракта, которые могут вызываться применением НПВС. Возможным путем повышения рациональности фармакотерапии больных с люмбоишиалгией является уменьшение количества назначений второстепенных ЛС, что позволит уменьшить количество назначений одному больному.

Address for correspondence:
4, Valentynivska str., Kharkiv, 61168, Ukraine.
Tel. (572) 65-88-95. E-mail: ph-econom@nuph.edu.ua.
National University of Pharmacy

Received in 06.04.2016