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PHARMACOTHERAPY OF SYSTEMIC AUTOIMMUNE DISEASES IN CONDITIONS OF THE COVID-19 PANDEMIC: INNOVATIVE EXPERIMENTAL STUDY

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ABSTRACT

The article presents the results of an innovative experimental study of pharmacotherapy of systemic autoimmune diseases in a pandemic of coronavirus infection is a timely and socially oriented way. The methodology of conducting a content analysis based on the theoretical principles of pharmaceutical and medical law and its components. Author used the method of drug selection developed by the Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy of the Kharkiv Medical Academy of Postgraduate Education. Content analysis performed by dosage forms by grouping them using the Sturgess formula, followed by construction of discrete series of variations and distribution polygon. Received data made possible to state, that in some circumstances, doctors have a choice of both drugs and dosage forms. However, the data obtained show a lack of balance between supply and demand for patients and physicians. The analysis allows to obtain a complete description of the balance of "supply and demand" between the range and types of dosage forms of drugs INN Silymarin ATC code A05BA03, that approved for use.

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Introduction. In the current context of the spread of the coronavirus pandemic, the role of innovative methods in the study of pharmacotherapy of systemic diseases among patients with dual health disorders is growing. Despite numerous publications on COVID-19, conceptual thinking of the mentioned problem is currently in its first steps. Pharmacotherapy of patients with systemic autoimmune diseases during the COVID-19 pandemic is a topical issue. Further analysis of COVID-19 among patients with systemic autoimmune diseases is important [1, 2, 3].

Among the systemic autoimmune diseases are systemic lupus erythematosus, systemic vasculitis, psoriasis, rheumatoid arthritis. The introduction of innovative approaches to pharmacotherapy to determine the balance of "supply and demand" for drugs of different clinical and pharmacological, classification and legal, nomenclature and legal groups is timely in a pandemic COVID-19. Medicines for privileged categories of patients with systemic autoimmune diseases purchased at the expense of the budget and are subject to release on a free basis or 50.0% discount from their price. Today it is important to use modern, effective and safe drugs for pharmacotherapy of systemic autoimmune diseases, which are selected on the principles of evidence-based medicine, forensic pharmacy, evidence-based pharmacy, medical and pharmaceutical law [4, 5, 6, 7, 8, 9].

The use of innovative experimental methods in the study of pharmacotherapy of systemic autoimmune diseases in a pandemic of coronavirus infection is a timely and socially oriented scientific task. The social focus of pharmacotherapy of systemic autoimmune diseases needs to be personalized.

At the same time, a fair balance between the supply and demand of drugs needs its implementation. Patients with systemic autoimmune diseases form demand for drugs. Domestic and foreign drug manufacturers form the offer. It is hard to achieve a fair balance if patients do not receive the pharmacotherapy prescribed by doctors on time [10].

Pharmacoeconomic studies in the pharmacotherapy among patients with systemic vasculitis using antiviral drugs described in study [11].

In continuation of studies, the purpose of the research was to conduct an innovative experimental study of pharmacotherapy of systemic autoimmune diseases using content analysis on the example of drugs by the International nonproprietary name (INN) Silymarin ATC code A05BA03 in healthcare facilities (hospitals, clinics, pharmacies).

Materials and methods. The methodology of conducting a content analysis of drugs according to INN Silymarin ATC code A05BA03 was based on the theoretical principles of pharmaceutical and medical law and its components: pharmaceutical and medical legislation; forensic pharmacy in the framework of forensic and pharmaceutical practice; evidence-based medicine and evidence-based pharmacy; clinical pharmacology and pharmacotherapy [12, 13, 14, 15, 16].

To conduct content analysis, the method of drug selection developed by the Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy of the Kharkiv Medical Academy of Postgraduate Education (Head of the Department – Prof. Viktoriya Shapovalova) was used, which included seven criteria [17, 18, 19].

Criteria for selection of drugs for INN Silymarin ATC code A05BA03 shown on the Fig. 1.

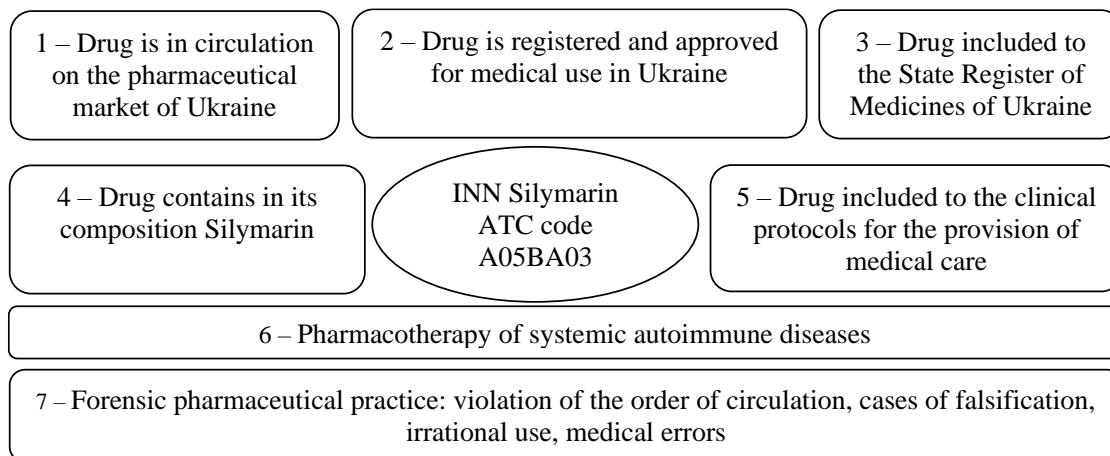


Fig. 1. Criteria for selection of drugs according to the INN Silymarin ATC code A05BA03 of innovative experimental study

Study material were drugs by the INN Silymarin ATC code A05BA03. All drugs meet six criteria, forensic and pharmaceutical practice (the 7th criteria Fig. 1) is absent as of June 2021. Names of drugs were systematized by the INN Silymarin ATC code A05BA03, trade names, range and types of dosage forms.

Content analysis of INN Silymarin ATC code A05BA03 was performed by dosage forms by grouping them using the Sturges formula, followed by construction of discrete series of variations and distribution polygon: $n=1+3,322\lg N$, where n – is the number of groups; N – is the number of drugs. The boundaries of the step of certain groups of drugs were determined by the formula:

$$h = \frac{X_{\max} - X_{\min}}{n}$$

where h – is the step size of the group; X_{\max} – is the maximum value of the number of dosage forms; X_{\min} – is the minimum value of the number of dosage forms [17, 18, 19].

The information base of the study consisted of scientific works of foreign and domestic scientists on the topic of the article. The review of scientific sources of literature was carried out taking into account the recommendations of the Cochrane Society for PICO: P (population) – the population suffering from systemic autoimmune diseases; I (intervention) – pharmacotherapy, drugs by the INN Silymarin ATC code A05BA03; C (comparison) – comparison in research technology, innovative experimental study; O (outcomes) – research results [20, 21, 22, 23, 24].

Among the additional research methods, used regulatory, documentary, clinical and pharmacological, marketing, forensic and pharmaceutical and graphic. Microsoft Excel 2010 (descriptive characteristics: minimum and maximum value, average value) was used to process the results and determine the consistency between the studied parameters.

The research of the article is a fragment of research works of Lviv Medical Institute LLC on the topic of "Improvement of the drug circulation system during pharmacotherapy on the basis of evidence-based pharmacy and forensic pharmacy, organization, technology, biopharmacy and pharmaceutical law" (state registration number 0120U105348, terms 2021-2026), Kharkiv Medical Academy of Postgraduate Education on "Improving the organizational and legal procedure for providing patients with drugs from the standpoint of forensic pharmacy, organization and management of pharmacy" (state registration number 0116U003137, terms 2016-2020) and "Pharmaceutical and medical law: integrated approaches to the system of drug circulation from the standpoint of forensic pharmacy and organization of pharmaceutical business" (state registration number D/21U000031, terms 2021-2026) [25, 26, 27].

Research results. At the first stage author conducted of the innovative experimental study, a marketing analysis of the INN Silymarin ATC code A05BA03 drug range. During the marketing analysis of the range of drugs on the national market, an information array of marketing information about drugs was initially formed using the content analysis of official reference publications. Primary data for content analysis: drugs, which according to the regulatory and documentary analysis as of June 2021 were registered, allowed for circulation in Ukraine, allowed for inclusion into the pharmacotherapy of systemic autoimmune diseases. After summarizing the processed data, a marketing list of drugs was compiled according to the INN Silymarin ATC code A05BA03, which has ten names of drugs (Table 1).

Table 1. Marketing list of drugs according to the INN Silymarin ATC code A05BA03 for pharmacotherapy of patients with systemic autoimmune diseases

No.	Trade name	Dosage form, strength, amount per unit
1	2	3
1.	Triosil	Tablets 22.5 mg N.30
		Tablets 22.5 mg N.50
		Tablets 22.5 mg N.100
2.	Legalon	Capsules 140 mg N. 20
		Capsules 140 mg N. 30
		Capsules 140 mg N. 60
		Capsules 70 mg N. 20
		Capsules 70 mg N. 30
		Capsules 70 mg N. 60
3.	Silibor forte	Capsules 70 mg N. 20
		Capsules 70 mg N. 40
4.	Silibor max	Capsules 140 mg N. 20
		Capsules 140 mg N. 40
5.	Silibor 35	Coated tablets 35 mg N. 20
		Coated tablets 35 mg N. 25
		Coated tablets 35 mg N. 30
		Coated tablets 35 mg N. 80
6.	Fumart	Capsules 50 mg N. 20
		Capsules 50 mg N. 30
7.	Carsil forte	Hard capsules 90 mg N. 30
8.	Darsil	Coated tablets 22,5 mg N. 30
		Coated tablets 22,5 mg N. 50
		Coated tablets 22,5 mg N. 100
9.	Carsil	Coated tablets 22,5 mg N. 80
10	Hepabene	Hard capsules N. 30

For the next stage of the content analysis of drugs according to INN Silymarin by dosage forms, primary data on the types of dosage forms and the range of drugs of INN Silymarin ATC from the marketing list (Table 2) were selected and processed.

Table 2. Primary data for content analysis drugs of the INN Silymarin ATC code A05BA03 from the list of dosage forms

No.	Dosage form	Assortment
1	Hard capsules	2
2	Tablets	3
3	Coated tablets	8
4	Capsules	12
	Total	25

In the pharmacotherapy of systemic autoimmune diseases, doctors use four dosage forms of the drug INN Silymarin ATC code A05BA03.

Subsequently, the number of groups (three) and the step of group (two) for drug formulations for INN Silymarin were determined. The distribution of groups according to the initial and final values of the step (Table 3) showed that the dosage forms of drugs for INN Silymarin formed three groups.

Table 3. Determination of the boundary of the step groups of drugs INN Silymarin ATC code A05BA03 when summarizing the dosage forms

Group No.	Initial step value	Final step value
1 st group	1	4
2 nd group	5	8
3 rd group	9	12

Next, the distribution of drugs by the INN Silymarin ATC code A05BA03 conducted according to the range and type of dosage forms, which presented in Table 4.

Table 4. Distribution of drugs of the INN Silymarin ATC code A05BA03 by range and type of dosage forms

No.	Dosage form	Drugs assortment
The first group		
1.	Hard capsules	2
2.	Tablets	3
	Total	5
The second group		
1.	Coated tablets	8
	Total	8
The third group		
1.	Capsules	12
	Total	12

Based on the content analysis of drugs by dosage forms and range, statistical processing of research results performed by constructing discrete variation series and polygons of distribution of the obtained data. Discrete variation series of drug distribution shown in Table 5.

Table 5. Discrete variation series by the INN Silymarin ATC code A05BA03

Group No.	Group range	Frequency, f_i
1	1-4	5
2	5-8	8
3	9-12	12

Discussion. Content analysis is a widely used innovative method of analysis of pharmacotherapy schemes for systemic connective tissue diseases. There are three approaches to conduct content analysis: conventional, directed, and summative. All three approaches used to interpret meaning from the content of text data and, hence, adhere to the naturalistic paradigm. The major differences among the approaches are coding schemes, origins of codes, and threats to trustworthiness. In conventional content analysis, coding categories derived directly from the text data. With a directed approach, analysis starts with a theory or relevant research findings as guidance for initial codes. A summative content analysis involves counting and comparisons, usually of keywords or content, followed by the interpretation of the underlying context. An innovative experimental study is that the content analysis based on the creation of a neutral framework for the classification of efficacy descriptions drugs of the INN Silymarin ATC code A05BA03. The use of innovative experimental methods for personalized drug selection for patients with systemic autoimmune diseases in a pandemic of coronavirus infection is promising and socially justified [28, 29, 30, 31].

Received data of an innovative experimental study on dosage forms of drugs of the INN Silymarin ATC code A05BA03 given in the Table 4. The first group included five drugs of the INN Silymarin in double dosage forms (hard capsules and tablets). When prescribing pharmacotherapy, doctors have a choice of both drugs and dosage forms. The range of drugs in the second group consists of eight names of drugs of the INN Silymarin ATC code A05BA03, which doctors have to prescribe only in one dosage form – coated tablets. The data obtained show a lack of balance between supply and demand for patients and physicians. The picture is similar in the third group: twelve drugs have one dosage form – capsules. Unfortunately, in last group there is also no balance in dosage forms.

However, the obtained discrete variation series (Table 6) indicates that in the third group the studied quantitative indicator has the highest frequency ($f_i = 12$). It is possible to assume that the capsules are more widely used in the pharmacotherapy of systemic autoimmune diseases.

Graphically discrete variation series of the studied drugs INN Silymarin ATC code A05BA03 presented on Fig. 2 in the form of a distribution polygon.

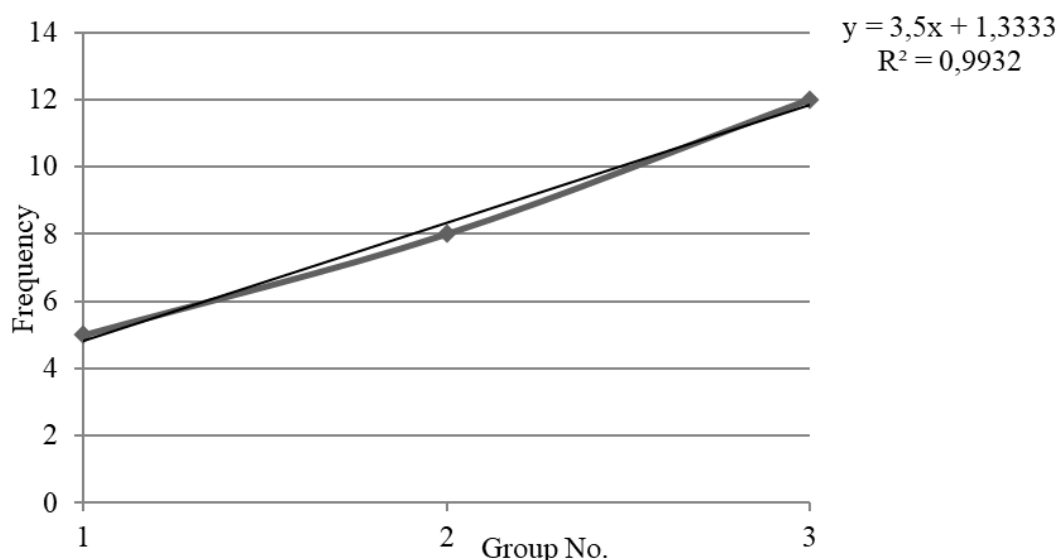


Fig. 2. Distribution polygon of drugs of the INN Silymarin ATC code A05BA03 by dosage forms from innovative experimental study.

In doctors' arsenal during pharmacotherapy of systemic autoimmune diseases, there are three groups of drugs with INN Silymarin ATC code A05BA03 (Fig. 2). In the first group, there are five drugs in two dosage forms. The second group – eight drugs in one dosage form (coated tablets). The third group – twelve names of drugs with INN Silymarin ATC code A05BA03 in one dosage form (capsules).

Conclusions. Conducted an innovative experimental study of pharmacotherapy of systemic autoimmune diseases using content analysis on the example of drug of the INN Silymarin ATC code A05BA03 in healthcare facilities (hospitals, clinics, pharmacies). The analysis allows to obtain a complete description of the balance of "supply and demand" between the range and types of dosage forms of drugs INN Silymarin ATC code A05BA03, that approved for use. Doctor has a choice of the appropriate drug

and dosage form that corresponds to social personalized pharmacotherapy. Content analysis is a widely used innovative method of analysis of pharmacotherapy schemes for systemic connective tissue diseases. We hope it serves to orient and encourage a more creative use of methods in future studies.

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Conflict of interests. There is no conflict of interest to disclose for author.

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