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THE PHARMACOTHERAPY MANAGEMENT OF CARDIOVASCULAR DISEASES IN HOSPITALISED PATIENTS: CLINICAL PHARMACIST'S VIEW

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The aim. *To assess pharmacotherapy of hospitalised patients with coronary heart disease in Ukraine, identify the types of drug-related problems, and recommend interventions to improve the management of cardiac inpatients.*
Materials and methods. *The objects of the study were 25 medical records of inpatients with coronary heart disease complicated by heart failure and atherosclerotic cardiosclerosis. Methods applied: systematisation, generalisation, comparison, clinical and pharmaceutical approach. The statistical analyses were performed using the SPSS Trial.*
Results. *A comprehensive retrospective study was conducted to assess the management of cardiovascular diseases. In total, 25 patients were prescribed 62 drugs. It was established that 53.5 % of medicines were "Agents affecting the cardiovascular system"; out of them, 26.9 % were "other cardiac drugs" (C01E) used for enhancing cardiac energy metabolism. The study identified 597 drug-related problems (DRPs) (23.9±12.6 DRPs per patient) with the drug-drug interactions prevalence (62.6 %). Other common groups of DRPs were:*
1) no indications for drug administration (8.5 %);
2) despite indications, the drug was not prescribed (8.2 %). 99 DRPs (16.6 %; 95 % CI:13.7-19.8 %) were associated with "other cardiac drugs".
They included 4 types of DRPs:
1) no indications for drug administration (33.3 %);
2) insufficient duration of the treatment (31.3 %);
3) drug-drug interactions (22.3 %);
4) insufficient dosage or frequency of use (13.1 %).
Conclusion. *Our findings suggest that the treatment of cardiac inpatients is associated with numerous DRPs. Thus, we formed a list of recommendations to improve the management of cardiovascular diseases in hospitalised patients*
Keywords: *management, cardiovascular diseases, inpatients, drugs enhancing the cardiac metabolism, drug-related problems*

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1. Introduction

Cardiovascular diseases (CVD), especially coronary heart disease (CHD) and stroke, are among the main causes of death in the world. Approximately 18.6 million people die annually from these diseases [1, 2]. According to the World Heart Federation data, 1 out of 3 deaths from CVD occurs in people under 70 years of age; 85 % of deaths are associated with heart attack and stroke; more than 75 % of fatal events due to CVD occur predominantly in low- and middle-income countries [1]. In Ukraine, mortality from CVD has increased by almost 8 % over the past 3 decades. It amounted to 64.3 % of the total deaths in 2019 compared to 56.5 % in 1990 [3]. Moreover, Ukraine ranks the 1st in Europe in terms of mortality from CVD [4]. Ischemic heart disease is the leading cause of death in this country (633.4 deaths per 100,000 population), which is 5.5 times as high as in the world [5, 6].

The aim of cardiac inpatient treatment (in particular for those with CHD) is to reduce the symptoms of the disease, improve the prognosis, and prevent the development of cardiovascular complications [7, 8]. This could be achieved by lifestyle modification, controlling CHD risk factors, and reducing the rate of drug-related problems (DRPs) [9–11]. Different DRPs are common in CHD patients, with a worldwide prevalence of over 60 % [12]. Thus, the management of DRPs is crucial for enhancing the safety and effectiveness of drug therapy. However, there is limited data on DRPs in cardiac inpatients in Ukraine [13].

The aim of the study. To assess pharmacotherapy of hospitalised patients with CHD in Ukraine, identify the types of DRPs, and recommend interventions to improve the management of cardiac inpatients.

2. Research planning (methodology)

To reach the goal of this study, we developed a 7-step algorithm:

1. Literature search and analysis of current management of CVD.

2. Analysis of clinical and demographical characteristics of inpatients included in the study sample.

3. Calculate drug administration rate according to the Anatomical Therapeutic Chemical (ATC) classification system.

4. Identification and standardisation of DRPs.

5. Profound analysis of the following DRPs:

1) drug-drug interactions (DDIs);

2) no indications for drug administration;

3) despite indication, no drug prescribed.

6. Processing and critical analysis of the obtained results.

7. Defining the main interventions to improve the management of cardiac inpatients.

3. Materials and methods

A retrospective study was done in one of the inpatient facilities of the L'viv region, Ukraine, in 2021. The sample size included 25 medical records of hospitalised patients with CHD complicated by heart failure and atherosclerotic cardiosclerosis. The information sources for the analysis were: inpatients' medical records (for the second quarter of 2021); instructions for the medical use of drugs [14]; medical-technological documents on CVD management, approved by the Ministry of Health of Ukraine [15]; Drug Interaction Checker [16, 17]. The criterion for inclusion of medical records in the sample size was the presence of a diagnosis of "CHD" in the archived medical documentation.

The analysis of pharmacotherapy was carried out through the identification of DRPs, which were further grouped into the main headings of the adapted classification system of the Pharmaceutical Care Network Europe version 5.01 [18].

Statistical analysis was carried out in the environment of the SPSS Trial. The average value and standard deviation (SD) were determined for each of the studied parameters of descriptive statistics. A 95 % confidence interval (CI) was calculated for the proportions.

Ethics approval.

The study received ethical approval from the Human Research Ethics Committee of Danylo Halytsky Lviv National Medical University in December 2019 (Protocol N 10).

4. Results

According to our findings, CHD was diagnosed much more often in men than in women (72.0 % vs 28.0 %, respectively). The average age of the patients was 57.2±8.8 years, while the youngest patient at the time of hospitalisation was 41 years old; the oldest – 74 years old. Duration of hospitalisation varied from 7 to 17 days, on average 11.2 per 1 patient (Table 1).

Patients took 62 drugs (from 9 anatomical groups according to the 1st level of ATC classification), which were prescribed 248 times. The most common medicines were drugs from group «C» – "Agents affecting the cardiovascular system" and «B» – "Agents affecting the cardiovascular system the blood and haematopoiesis", accounted for 58.5 % and 23.0 % of all prescriptions, respectively (Table 2).

The detailed analysis of drugs affecting the cardiovascular system is shown in Fig. 1.

Table 1

Demographic and clinical characteristics of the sample size (*n*=25)

Characteristic	*n* (%)
Age, years	–
Range (min-max)	41–74
Mean±SD	57.2±8.8
Gender	–
Men	18 (72.0)
Woman	7 (28.0)
Administrated drugs, number	62
Range (min-max)	6–19
Mean±SD	9.8±3.1
Length of stay in hospital, days	–
Range (min-max)	7–17
Mean±SD	11.2±2.5
Detected DRPs, number	597
Range (min-max)	13–66
Mean±SD	23.9±12.6

Table 2

Distribution of drug prescription (*n*=248) according to the 1st level of ATC classification

No.	Code ATC	Groups name	Number of drugs according to the INN*	Number of prescriptions	
				abs.	%
1	C	Medicines affecting the cardiovascular system	28	145	58.5
2	B	Medicines affecting the blood and hematopoiesis	8	57	23.0
3	A	Medicines affecting the digestive system and metabolism	10	17	6.9
4	N	Medicines affecting the nervous system	8	16	6.5
5	R	Medicines affecting the respiratory system	3	8	3.2
6	M	Medicines affecting the musculoskeletal system	2	2	0.8
7	J	Antimicrobial agents for systemic use	1	1	0.4
8	H	Medicines of hormones for systemic use (except sex hormones and insulins)	1	1	0.4
9	V	Antidotes	1	1	0.4
Total			62	248	100.0

*Note: *INN – international nonproprietary name.*

The most common group of medicines affecting the cardiovascular system was "Other cardiac drugs" (C01E). This group included Meldonium (*n*=18), Tiazotic acid (*n*=13), Trimetazidine (*n*=5), Arginine, magnesium, potassium asparaginate (*n*=2) and Ivabradine (*n*=1) (Fig. 2). 23 of 25 medical records included at least one of these medicines (from 1 to 3 drugs per one medical record).

According to the study results, 597 DRPs were identified (an average of 23.9±12.6 DRPs per patient). They included 13 types of DRPs with the (1) potential DDIs predominance (*n*=374, 62.6 %), followed by (2) no indications for drug administration (*n*=51, 8.5 %),

and (3) despite indication, no drug prescribed (n=49, 8.2 %) (Fig. 3).

«Other cardiac drugs» (C01E) were associated with 99 DRPs (16.6 %; 95 % CI: 13.7–19.8 %), which were categorised into 4 subgroups:

1) no indications for drug administration (*n*=33, 33.3 %);

2) cases of insufficient duration of use (*n*=31, 31.3 %);

3) DDIs (*n*=22, 22.3 %); 4) insufficient dosage or frequency of drug use (*n*=13, 13.1 %). The proportion of these DRPs among the total number of the same DRPs is presented in Fig. 4.

Out of 374 DDIs, 311 (83.2 %) – were considered to be clinically significant, 46 (12.3 %) – minor and 17 (4.5 %) – serious. The list of drug combinations with possible serious consequences is presented in Table 3.

The subgroup of DRPs «No indications for drug administration» (*n*=51) amounted to 8.5 % of all problems. We have identified 12 drugs (51 cases), whose purpose has not been determined (Table 4).

Next, we analysed the subset of DRPs «Despite indication, no drug prescribed» with the rate of 8.2 % DRPs (*n*=49). We found that 10 drugs and/or their combinations were indicated for patients but not prescribed (Table 5).

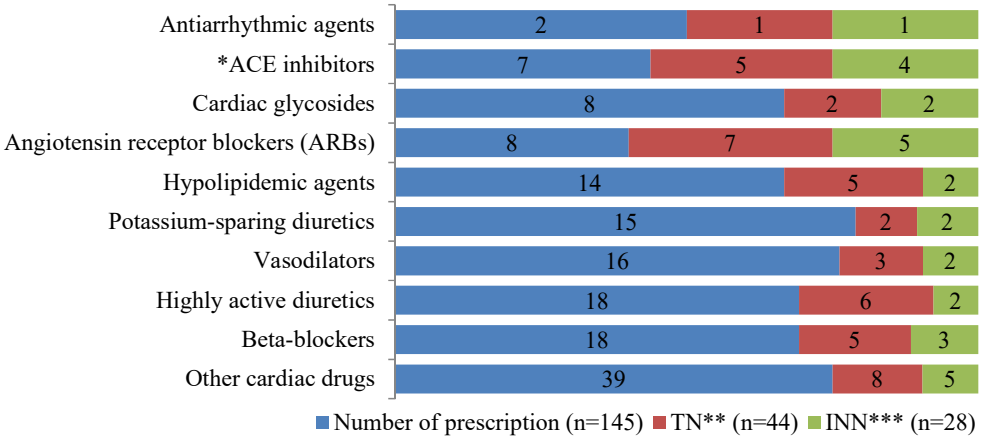

Fig. 1. Detailed distribution of the cardiological drug groups by the number of prescriptions, TN, and INN (*in abs.*): *ACE inhibitors – angiotensin-converting enzyme inhibitors (simple drugs and in combination with a diuretic); **TN – trade names, ***INN – international nonproprietary name

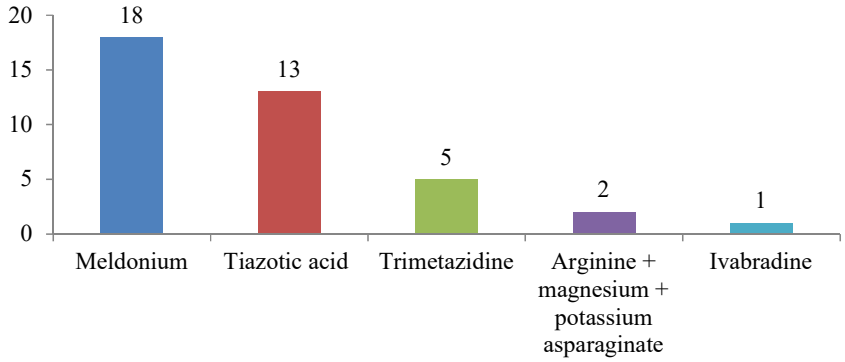

Fig. 2. Distribution of drugs enhancing cardiac energy metabolism *(in abs.)*

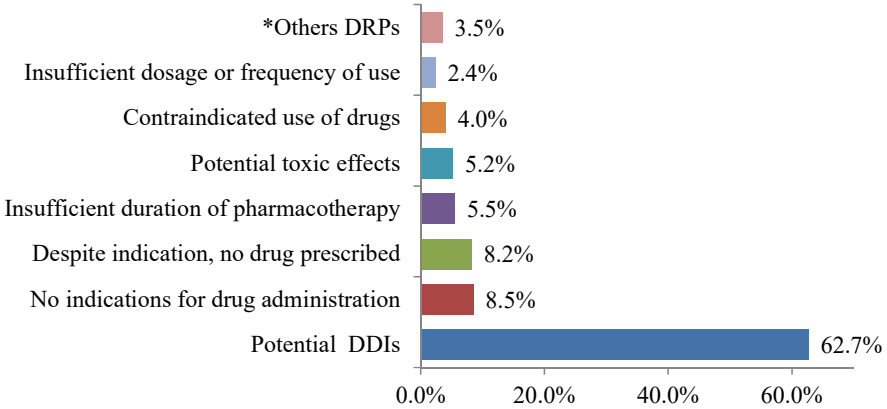

Fig. 3. The proportion of detected DRPs (*n*=597) in 25 medical records: *Others DRPs – technical DRPs (1.2 %); exceeded the duration of pharmacotherapy (0.9 %); incorrect route of administration (0.5 %); drugs which are not appropriate for the indication (0.3 %); excessive dosage (0.3 %); therapeutic duplication (0.3 %)

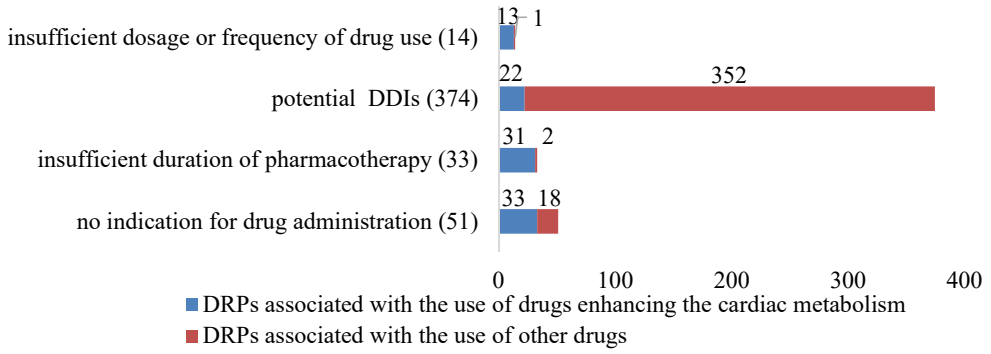

Fig. 4. Distribution of DRPs

Table 3

Serious DDIs (*n*=17)

Drug combinations	Result of interaction	*n*=17
Aspirin+ +Ramipril/Fosinopril/Lisinopril	Pharmacodynamic antagonism. Concurrent use may lead to a significant reduction in renal function	6
Digoxin+Bisoprolol/Nebivolol	Mutual reduction of toxicity through an unclear mechanism. Increased risk of bradycardia	3
Spironolactone+Potassium Chloride	Increased serum potassium levels, risk of hyperkalemia	2
Nicotinic acid+ +Atorvastatin/Rosuvastatin	Mutual enhancement of toxicity, pharmacodynamic synergy. Increased risk of rhabdomyolysis (with daily intake of over 1 g of nicotinic acid)	2
Bisoprolol+Carvedilol	Both drugs enhance the blockade of antihypertensive channels	2
Omeprazole+Clopidogrel	Omeprazole decreases the effects of clopidogrel by affecting hepatic enzyme CYP2C19 metabolism	1
Amiodarone+Amisulpride	Prolongation of QTc interval. Simultaneous use recommends electrocardiogram monitoring	1

Table 4

Distribution of medicines which were prescribed without indications

Medicines	Code ATC	Number of cases (*n*=51)
Meldonium	C01E	18
Tiazotic acid	C01E	13
Mexidol	N07X	6
Essential phospholipids	A05B	4
Arginine + magnesium + potassium asparaginate	C01E	2
Piracetam	N06B	2
Mebicar	N06B	1
Dexketoprofen	M01A	1
Silymarin	A05B	1
Metoclopramide	A03F	1
Thiosulfate	V03A	1
Infusion drug «cocktails» (Glucose+Magnesium {different salts in combination}+Digoxin)	–	1

Table 5

The subset of DRPs «Despite indication, no drug prescribed» with an indication of modern evidence-based medicine data

Drugs that are not prescribed	Comment	*n*=49 (100 %)
1	2	3
Statins	Statins are recommended for all patients with stable CHD (Grade A) [7, 10, 11]	9 (18.4)
ACE Inhibitors or angiotensin II receptor blockers	ACE inhibitors (or angiotensin II receptor blockers) are recommended for patients with CHD with concomitant pathologies (heart failure, hypertension, diabetes) (grade A) [7, 10, 11, 19]	8 (16.3)
Nitrates	Short-acting nitrates are recommended for patients with CHD. Fast-acting nitrates are used to eliminate angina pectoris attacks. (Grade B) [7, 10, 11, 19]	8 (16.3)
Beta-blockers and/or Calcium Channel Blockers (CCBs)	First-line therapy with beta-blockers and/or CCBs is prescribed for reducing angina/ischemia symptoms in patients with CHD to control heart rate and disease symptoms (Grade A) [7, 10, 11]	7 (14.3)
Proton pump inhibitors	Proton pump inhibitors are recommended for patients receiving monotherapy with aspirin, dual antiplatelet therapy, or monotherapy with low-molecular-weight oral anticoagulants and have a high risk of gastrointestinal bleeding (grade A) [10, 19, 20]	7 (14.3)
ACE Inhibitors	ACE inhibitors are recommended for all patients with reduced left ventricular ejection fraction, including asymptomatic patients, in the absence of contraindications or intolerance (grade A) [21]	5 (10.2)

Continuation of Table 5

1	2	3
Oral anti1coagulant	Anticoagulant therapy is recommended for patients with CHD and AF to reduce the risk of complications, especially ischemic stroke. Preference is given to modern drugs – new oral anticoagulants (apixaban, dabigatran, edoxaban, or rivaroxaban). In some cases, vitamin K antagonists, mostly warfarin, may be used [10, 11]	2 (4.1)
Aspirin	75–100 mg of Aspirin per day is recommended for patients with a history of myocardial infarction or after revascularisation (grade A) [7, 10, 11]	1 (2.0)
Spironolactone	It is recommended for patients with heart failure and reduced ejection fraction who receive ACE inhibitors and beta-blockers (grade A) [7, 11]	1 (2.0)
Beta-Blockers	Long-term treatment with beta-blockers can improve survival without decompensation in patients with compensated cirrhosis and clinically significant portal hypertension (grade B) [22]	1 (2.0)

5. Discussion

CHD is common in Ukraine. The management of this disorder requires pharmacotherapy, which could be associated with numerous DRPs. Thus, the appropriate prescription of medicines is essential in CHD management.

According to our results, the mean age of patients was 57.2±8.8, with men predominating. Our findings agree with the results of other studies [23, 24]. Notably, age is a significant risk factor associated with DRPs. Older patients (aged 65 years) are at four times the risk of DRPs as others [23, 25].

Current strategies to treat CHD aim to increase cardiac oxygen delivery (thrombolysis, revascularisation, ACE inhibitors, ARBs, and antiplatelet therapy) and decrease cardiac oxygen demand (beta-blockers and nitrates) [7–9, 11]. International experience shows that the most frequently prescribed groups of cardiac drugs in patients with CHD are diuretics (43.7–27.6 %), beta–blockers (34.4–14.5 %), angiotensin–converting enzyme inhibitors (27.5–24.8 %), statins (16.5–7.0 %), and antithrombotics (15.4–13.1 %) [23, 24, 26, 27]. Instead, in our study, the following groups prevailed: other cardiac drugs (15.7 %), beta-blockers (7.6 %), highly active diuretics (7.6 %), vasodilators (6.5 %), potassium-sparing diuretics (6.1 %) and hypolipidemic agents (5.7 %).

At the same time, our findings revealed that the most common group of medicines used to treat inpatients with CHD was “Other cardiac drugs” (Meldonium, Tiazotic acid, Trimetazidine, Arginine, magnesium, potassium asparaginate, and Ivabradine). Even though the violation of the energy supply of the heart muscle is a central factor in the pathology of CHD, therapeutic approaches that change the cardiac energy metabolism have not found significant clinical application [28]. Numerous reports of preclinical experiments have shown the efficacy of meldonium. However, clinical data is limited. In addition, this drug is unavailable in the USA and EU (except Latvia) [29]. Trimetazidine is not available in the USA but is used in Europe and over 80 countries worldwide. Clinical studies have shown that Trimetazidine works as an adjunctive therapy and improves symptoms of stable CHD, diabetic, and ischemic chronic heart failure. However, there is no clear evidence to support the routine use of trimetazidine as a second-line agent for patients with CVD [11, 30–32].

DRPs are very common in cardiac inpatients. They are associated with patients’ morbidity and mortality and financial burden [12, 33]. As described in scientific literature, the prevalence of DRPs varies from 52.7 % to 82.0 %, with the highest rate of 2.6±1.8 DRPs per patient [23, 24, 27, 33]. In this study, the estimated prevalence of DRPs was 100 %, with a mean of 23.9±12.6 DRPs per patient. Thus, our findings are considerably higher (in 9 times) compared to other studies. This difference might be explained, at least partially, by polypharmacy and comorbidity, which have a significant association with the number of DPRs in cardiac inpatients [23, 24, 33]. People enrolled in this sample size took 6 to 19 medicines simultaneously and had 2 to 4 comorbidities.

We found that DDIs were the most common DRPs, with a percentage of 62.6 %. This result is about twice as high as in other studies (up to 30 %) [33]. In different countries, such DRPs as «Despite indication, no drug prescribed» and «No indication for drug administration» prevailed, accounting for up to 32 % and 13 % of all DRPs, respectively [23, 24]. In Ukraine, the rates of these DRPs are much lower (8.2 % and 8.5 %, respectively). This difference could be associated with study designs, clinical and demographical features of patients, identification of DRPs, etc.

Summarising the obtained data, it was found that DRPs are a common phenomenon in patients with CVD and significantly contribute to the development of side effects and other complications of pharmacotherapy. Thus, the medical community strives to reduce the frequency and clinical consequences of DRPs by increasing the level of their identification and using effective methods for their prevention and resolution [24, 34, 35]. Detection, resolution, prevention, and characterisation of DRPs among hospitalised cardiological patients are extremely important to optimise pharmacotherapy, reducing the cost of treatment, morbidity, and mortality and improving quality of life [24, 34, 36]. Based on the study results, we formed a list of recommendations to improve the safety and effectiveness of CVD pharmacotherapy in hospitalised patients:

1. Avoid unjustified prescription of drugs, especially if they are not included in the current standards (clinical protocols).

2. Don’t prescribe medications in such situations:

1) there is no precise indication (taking into account the primary and concomitant diagnoses);

2) there is no evidence regarding their effectiveness in specific clinical cases;

3) there is a contraindication.

3. Consider both the possibility of DDIs (especially serious ones) and their negative influence on patients' conditions.

4. Prescribe drugs if there are precise indications (diagnoses) for their use, recommended by the standards approved by the Ministry of Health of Ukraine and evidence-based medicine data.

5. Control the duration of therapy, especially with injectable medicines. Avoid exceeding the length of pharmacotherapy.

At the final stage of the research, we developed a model of interventions to improve the management of cardiac inpatients (Fig. 5).

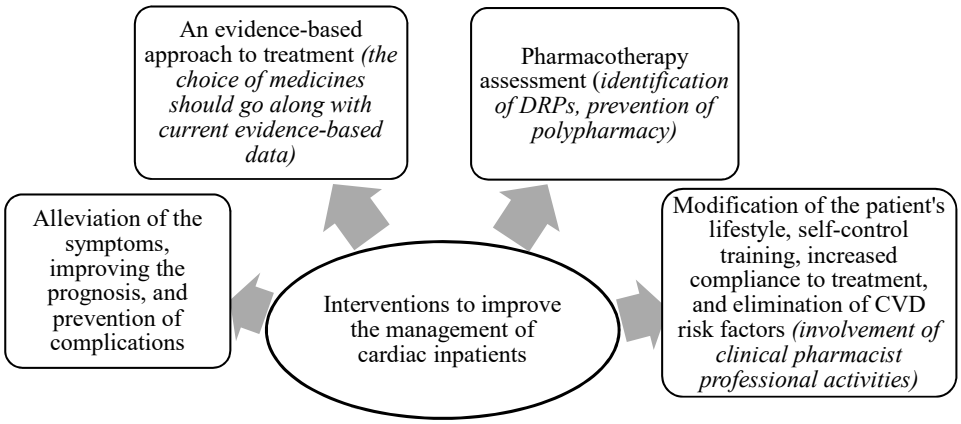

Fig. 5. Interventions to improve the management of cardiac inpatients

Thus, the developed model includes:

1) alleviation of the symptoms of both primary and concomitant diagnoses (heart failure, hypertension, diabetes, atherosclerosis, etc.); improvement of prognosis and prevention of complications;

2) the implementation of current evidence-based medicine data;

3) pharmacotherapy assessment, which includes identification of the most common subsets of DRPs and defining the key points on how to deal with DRPs;

4) clinical pharmacist participation in effective patient education, which might provide substantial benefits in self-control, lifestyle modification, increasing compliance with treatment, eliminating CVD risk factors (in particular, quitting smoking and drinking alcohol), correcting excess weight, and moderating physical activity.

Practical relevance. Our findings can help to improve the safety, effectiveness and outcomes of cardiac inpatient pharmacotherapy by raising the awareness of DRPs and implementation of suggested interventions.

Research limitations. Methodological limitations of this study include its retrospective design. DRPs can be considered as potential, as we did not monitor patients. Some DRPs may be assigned to another DRP rubric or to several rubrics at the same time. Thus, there is a subjective factor.

Another notable limitation is that the sample size included medical records from one hospital. Consequently, the results cannot be statistically generalised, so further research is needed.

Prospects for further research. Prospective studies are necessary to assess the efficacy of interventions for improving the management of cardiac inpatients.

6. Conclusions

The treatment of cardiovascular diseases includes different medicines, with drugs that enhance cardiac energy metabolism (C01E – "Other cardiac drugs") predominance. The management of cardiac inpatients is associated with numerous DRPs. Drug-drug interactions were the most common subset of DRPs, followed by «No indications for drug administration» and «Despite indication, no drug prescribed». Thus, we formed a list of recommendations to improve the management of cardiovascular diseases in hospitalised patients.

Conflict of interest

The authors declare that they have no conflict of interest in relation to this research, whether financial, personal, authorship or otherwise, that could affect the research and its results presented in this article.

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Data availability

Data will be made available at a reasonable request.

Use of artificial intelligence

The authors confirm they did not use artificial intelligence technologies to create the current work.

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