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PHARMACOECONOMIC ANALYSIS OF COSMOFER (IRON III - HYDROXIDE DEXTRAN) IN THE TREATMENT OF IRON DEFICIENCY ANEMIA FOR CHRONIC KIDNEY DISEASE PATIENTS

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Abstract: *Iron-deficiency anemia occupies the first place among the most common diseases. Approximately 700 million people worldwide suffer from iron deficiency anemia. In Russia, iron deficiency anemia is diagnosed in 6-30% of the population.*
The objective of this study was the comparative pharmacoeconomic analysis Cosmofer (Iron III - hydroxide dextran) compared with Venofer (Iron III - hydroxide sucrose complex) in the treatment of iron deficiency anemia for patients with chronic kidney disease.
An analysis of the value of the direct costs of patient treatment for 6 months amounted to 17,077 rubles for the treatment of Iron III - hydroxide dextran and 17,792 rubles for the treatment of Iron III - hydroxide sucrose complex.
Result of budget impact analysis revealed that the use of the treatment of Iron III - hydroxide dextran as compared with Iron III - hydroxide sucrose complex for one patient, leads to budget savings for 715 rubles.
The sensitivity analysis shows that a simultaneous increase the cost of Iron III - hydroxide dextran and decrease the cost of Iron III - hydroxide sucrose complex at 5%, will require additional funding in the amount of 157 rubles.
Conclusion: *Treatment with Iron III - hydroxide dextran as compared with Iron III - hydroxide sucrose complex in the treatment of iron deficiency anemia has clinical and economic advantage due to lower treatment costs and economy of money resources.*

Keywords: *efficacy analysis, cost analysis, budget impact analysis, iron deficiency anemia, chronic kidney disease, pharmacoeconomics, pharmacoeconomic analysis*

Introduction

Anemia - is a decrease in hemoglobin concentration per unit of blood volume, which is often accompanied by decrease in the concentration of red blood cells per unit blood volume. As a result, income discrepancies and iron intake, iron deficiency occurs and as a result the weakening of erythropoiesis, which is a sign of iron deficiency anemia while reducing the iron content of hemoglobin, followed by a decrease in hemoglobin in the red blood cell [4].

Development of anemia in chronic kidney disease (CKD) due to violation of production of erythropoietin (EPO) by the kidneys. The severity of anemia is correlated with the degree of renal dysfunction. Iron deficiency and elevated levels of inflammatory cytokines in the pathogenesis of anemia play an important role [11].

Currently there are several drugs of parenteral iron on the market. The most widespread are iron dextran and iron sucrose.

Iron dextran is available in two types: low molecular weight and high molecular weight. In their comparison, many studies have found a decrease in the number of adverse reactions in the application of low-molecular weight iron dextran.

Cosmofer (Iron III - hydroxide dextran) - low-molecular weight iron dextran. An important advantage of the drug is that the iron in the complex is presented in the form of a nonionic water-soluble and has very low toxicity. Iron (III) hydroxide dextran in their chemical structure is a complex physiological ferritin analogue with Iron (III) hydroxide. In the body ferritin, linking hydroxide Fe (III), provides neutralization of toxic iron ions.

Purpose of the study

The aim of this study was to perform the pharmacoeconomic analysis Cosmofer (Iron III - hydroxide dextran) compared with Venofer (Iron III - hydroxide sucrose complex) in the treatment of iron deficiency anemia for patients with chronic kidney disease.

To achieve this goal successively were completed the following tasks:

1. Information search in the databases of Medline database, Cochrane, Scientific Electronic Library eLIBRARY.RU, on the site http://www.pharmacosmos.com/ and other sources on the Internet.
2. Search and selection trials for comparative pharmacoeconomic analysis of the two treatment regimens (Iron III - hydroxide dextran; Iron III - hydroxide sucrose complex) in patients with iron deficiency anemia.
3. Determination of effectiveness parameters for the two treatment regimens based on the published data of clinical studies.
4. Cost analysis for two therapy schemes.
5. Budget impact analysis.
6. Sensitivity Analysis.

Results

Effectiveness Analysis

Analysis of effectiveness was the first phase of the cost-effectiveness analysis undertaken in our study. Such analysis involves collection of necessary data on drug effectiveness and selection of the effectiveness measure that satisfies conditions of the study.

The effectiveness data used in our study were derived from the from the appropriate prospective, crossover clinical study, Khalid A. Moniem et al, published in the «Transfusion Alternatives in Transfusion Medicine» Journal [1].

The study included 39 stable patients on hemodialysis. The average age of the patients was 60,5 ± 2,6 years (from 25 to 78 years). From the study were excluded patients with aluminum intoxication or significant hyperparathyroidism.

This study demonstrated that both drugs are equally effective in maintaining the level of ferritin and hemoglobin in patients with equivalent doses of EPO.

Based on the results of the present study, we can conclude that the efficacy and safety of Iron III - hydroxide dextran and Iron III - hydroxide sucrose

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complex comparable. However, the pharmacokinetics of Iron III - hydroxide dextran allows the injection of large doses as a total dose infusion, which is an advantage for patients with low glomerular filtration and peritoneal dialysis. These patients may receive the infusion of a total dose and does not be in need of frequent visits to day hospitals for the iron preparation.

Significant differences in adverse reactions when administered iron supplements were not revealed. Anaphylactic reactions were not marked.

Cost Analysis

Cost analysis was the next phase of our pharmacoeconomic analysis. The following costs associated with medical care have been considered in calculating the direct medical costs:

1. The cost of medical services (MS) has been calculated on the basis of the Order of the Health Ministry of the Russian Federation "On approval of the standard of care to patients with iron deficiency anemia" [7].
2. The cost of drugs [3].
3. The cost of administration of drugs according to tariff agreement under the Moscow territorial program of compulsory health insurance for 2016 [9].

The study of Iron III - hydroxide dextran and Iron III - hydroxide sucrose complex included patients on hemodialysis, the mean age was 60,5 ± 2,6 years (from 25 to 78 years). Therefore, as the average age of the patients reached the retirement, the indirect costs in this pharmacoeconomic studies were not considered.

Costs of MS were calculated considering the data on destination frequency and frequency of use of MS for the diagnosis and treatment of the patient in accordance with the Order of the Health Ministry of the Russian Federation of 28.02.2005 №169 "On approval of the standard of care to patients with iron deficiency anemia." Costs of MS amounted to 1,141 rubles for the treatment of one patient. Costs of MS amounted the same sum for both treatment regimens, as these services are provided to every patient with iron deficiency anemia.

According to the study Khalid. A. Moniem et al, patients received Iron III - hydroxide dextran and Iron III - hydroxide sucrose complex in the same manner: every 2 weeks by intravenous 100 mg during 6 months. Before application of Iron III - hydroxide sucrose complex, according to the instructions, it is necessary to introduce a test dose, namely 20 mg of iron enter for 15 minutes. In the absence of adverse effects the rest of the solution should be administered at the recommended rate.

Therefore, the cost of pharmacotherapy of Iron III - hydroxide dextran was 8,400 rubles, of Iron III - hydroxide sucrose complex – 9,038 rubles. (Table. 1).

According rates FFOMS of Moscow for 2016, it was found that the cost of the intravenous administration of 77 rubles, and the average cost of being in day care is 551 rubles. Therefore, the introduction of each of the compared products is accompanied by additional costs for administration of drugs and outpatient. Iron III - hydroxide dextran is injected 12 times and the cost of its administration amount to 7,536 rubles for 6 months, while the iron III - hydroxide sucrose complex is entered 13 times (12 injections + 1 test dose) and the cost is 7,613 rubles.

Thus, the costs for 6 months amount to 17,077 rubles for Iron III - hydroxide dextran and 17,792 rubles for Iron III - hydroxide sucrose complex (Table 2).

Table 2. Total treatment costs per patient, rubles.

MHH	Cost of drugs	Medical services	Administration	Total costs
Iron III - hydroxide dextran	8,400	1,141	7,536	17,077
Iron III - hydroxide sucrose complex	9,038	1,141	7,613	17,792

Budget Impact Analysis

Budget impact analysis (BIA), is fundamental to the modern system of pharmacoeconomic evaluation. Budget impact analysis (BIA), is fundamental to the modern system of pharmacoeconomic evaluation [14]. This analysis allows to predict the impact on the health care budget and to determine the economic impact, which is expressed in a cash economy, or require additional costs during the transition from the comparison therapy to evaluated therapy. To complete the analysis it is required to consider all types of costs.

Thus, the budget impact analysis in this study took into account the cost of medical services, the cost of drugs and the cost of administration. The results of the analysis are shown in Table 3.

Table 3. The results of budget impact analysis, RUR

	Iron III - hydroxide dextran	Iron III - hydroxide sucrose complex	Budget impact
Costs per patient	17,077	17,792	715
			Savings

According to the budget impact analysis it can be concluded that the transition of patients with iron deficiency anemia from Iron III - hydroxide sucrose complex therapy to Iron III - hydroxide dextran occurs budget savings in the amount of 715 rubles for the treatment of one patient, which allows reduce the cost of 4%.

Cost-Minimization Analysis

As a result, cost minimization analysis determined that in comparison with the use of Iron III - hydroxide sucrose complex, use Iron III - hydroxide dextran accompanied budget savings. Calculated that therapy Iron III - dextran hydroxide RUB 638 saves during 6 months of therapy, a decrease of 7% of the costs. [10]

Analysis of Missed Opportunities

The economic effect of the transfer patients from therapy with Iron III - hydroxide sucrose complex to therapy with the use of Iron III - hydroxide dextran can be estimated by analysis of missed opportunities. This analysis shows how many additional patients possible to treat with a less costly therapy, in this case, the therapy of Iron III - hydroxide dextran.

Analysis showed the possibility of additional treatment of 4 patients on the condition that 100 patients will be transferred to the therapy of Iron III - hydroxide dextran.

Sensitivity Analysis

The sensitivity analysis is used to determine the most significant indicator/measure, which when changed may significantly affect the final result of the study. This research assessed the variability of the total costs and cost-effectiveness ratios, depending on changes in the prices of different components.

As a result of the sensitivity analysis, it was found that the results of the budget impact analysis sustainability with an unchanged cost of therapy Iron III - hydroxide dextran and reducing the cost Iron III - hydroxide sucrose complex at 5%, as changing of values in this range indicators budget impact analysis for iron III - hydroxide dextran are less in relation to the indicators for Iron III - hydroxide sucrose complex. However, while simultaneously increasing the cost of treatment of Iron III - hydroxide dextran and reducing the cost of treatment of Iron III - hydroxide sucrose complex at 5% it would require additional funding in the amount of 157 rubles. (Tab. 4).

Table 1. Calculation of course cost of Iron III - hydroxide dextran and Iron III - hydroxide sucrose complex

INN	Dose, mg	Course, days	Test dose, mg	Dose, mg	Cost, RUR	
					Daily	Course
Iron III - hydroxide dextran	100	12	-	12,000	700	8,400
Iron III - hydroxide sucrose complex	100	12	20	12,000	753	9,038

Table 4. The results of the sensitivity analysis with simultaneous variations of the prices for background medicinal treatment in two study groups

Variations of the prices	Iron III - hydroxide dextran	Iron III - hydroxide sucrose complex
+5%	17,497	18,244
0	17,077	17,792
-5%	16,657	17,340

Results

An analysis of the value of the direct costs of patient treatment for 6 months amounted to 17,077 rubles for the treatment of Iron III - hydroxide dextran and 17,792 rubles for the treatment of Iron III - hydroxide sucrose complex.

Result of budget impact analysis revealed that the use of the treatment of Iron III - hydroxide dextran as compared with Iron III - hydroxide sucrose complex for one patient, leads to budget savings for 715 rubles. Therefore in the treatment of a group of 100 patients in a fixed budget can additionally treat four patients.

The sensitivity analysis shows that a simultaneous increase the cost of Iron III - hydroxide dextran and decrease the cost of Iron III - hydroxide sucrose complex at 5%, will require additional funding in the amount of 157 rubles.

Conclusion

On the basis of pharmacoeconomic analysis it can be concluded that therapy with Iron III - hydroxide dextran as compared with Iron III - hydroxide sucrose complex in the treatment of iron deficiency anemia has clinical and economic advantage by lower treatment costs and save funds.

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