Budget Impact Analysis on the intranasal form of Interferon-Gamma in the Complex Therapy of Influenza in the Russian Federation

S.L. PLAVINSKIY¹, P.I. SHABALKIN², J.A. ISAKOVA³
¹North-western State Medical University named after I.I. Mechnikov, Russia, 195067, Saint Petersburg, Piskarevskyprospekt, 47;
²Federal State Budgetary Institution “N.N. Blokhin Medical Research Center of Oncology”, Russia, 115478, Moscow, Kashirskoe sh. (Rd), b.24;
³Non-State Healthcare Organization “Scientific Clinical Centre of the “Russian Railways”, Russia, 125315, MoscowChasovoyast., 20.,

ABSTRACT

To estimate the budget impact on the intranasal form of interferon-gamma for the health care system of the Russian Federation, data was used from the research work by Sologub T.V. et al. on the evaluation of clinical and economic efficiency and the profitability of using recombinant interferon-gamma (Ingaron) in complex therapy of influenza patients. The conducted calculations using the cost-effectiveness indicator for recombinant interferon-gamma showed a positive budget impact for the health care system: in the form of a total budget savings of 1331568 thousand rubles with the subsequent reduction of the estimated indicator of the economic burden of influenza on 43% that will be reflected in the budget savings of 1018909 thousand rubles with current incidence.

Keywords: influenza, interferon-gamma, budget impact analysis, acute infections of the upper respiratory tract.

INTRODUCTION

Influenza causes significant socioeconomic burden for the health system and is one of the most common infectious diseases. According to the official data of the Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, the economic burden of the 35 most widespread infectious diseases in 2016 was 604,352,789.9 thousand rubles. This indicator increased by 10.1% compared to the previous year [1]. In general, the calculated indicator of the economic burden due to acute infections of the upper respiratory tract of multiple and unspecified localization was 499 550 050.5 thousand rubles. The estimated indicator of the economic burden for influenza is 2 350 478.2 thousand rubles [1]. The incidence of influenza in 2016 was 60.5 per 100 thousand of population that is almost twice higher than in 2015 (34.01 per 100 thousand). The incidence of influenza in recent years has ranged from indicators - 17.23 (2012) and 9.04 (2014) per 100 thousand population to the maximum values 70.28 (2013) and 60.50 (2016) per 100 thousand population [1]. The amount of the economic burden of infectious diseases consists of direct and indirect economic losses. The economic burden of influenza depends on the coverage of the population with vaccination, as well as the specific features of the epidemiological process. Influenza vaccination against is an effective anti-epidemic activity [2,3]. The actions taken to increase vaccination coverage significantly influenced on the decrease of the intensity of the epidemiological process in the 2016-2017 epidemic season but even this level of vaccination cannot completely stop the circulating of pathogen among the population [1]. Influenza vaccination does not completely exclude the possibility of infection in vaccinated. Economic losses caused by influenza also depend on the duration of temporary incapacity for work and hospitalization (for a complicated course of influenza).

Materials And Methods

The purpose of this work is to assess the budget impact on the intranasal form of interferon gamma (Ingaron) in the Russian Federation. The role of interferon gamma in the immune response to the influenza infection has been proven in several preclinical studies and the clinical efficacy of the drug has been studied in a range of controlled clinical trials [4-6]. To assess the efficacy and tolerability of Ingaron in the intranasal administration for the prevention of influenza and other ARVI in adults, a randomized, placebo-controlled study was conducted in the Ministry of Health of the Russian Federation FSBI “Research Institute of Influenza” [6]. The course of prevention included two 10-days cycles with an interval of one week. During a 10-days cycle, Ingaron was intranasally administered alternate days with 2-3 drops in each nasal passage, in total 10 times for 2 cycles. The results of the study showed that the preventive course of using of Ingaron provided a reliable reduction of the incidence of ARVI
in the main group. In addition, among those who received Ingaron for prophylactic purposes, there was an easier course of developed ARVI and a 1.9 decrease in the number of complicated forms, and the duration of uncomplicated ARVI was 1.5 days shorter than in the control group [6]. Further study of the clinical efficacy of Ingaron was aimed at studying its efficacy in the complex treatment of influenza and ARVI with the intranasal administration. Also, an open randomized controlled study was conducted on the basis of FSBI “Research Institute of Influenza” of the Ministry of Health of the Russian Federation. The study included 155 adult patients with a clinically established diagnosis of "influenza" or "ARVI". Patients of the main group (n = 90) received Ingaron 2 drops in each nasal passage 5 times a day for 5 days. Treatment of patients in the control group (n = 65) was performed with baseline therapy medications that did not contain interferons. The results of the study showed that the tolerability of the study drug was good, adverse events and allergic reactions were not registered. The therapeutic course with the use of Ingaron for 5 days provided a reduction of the duration of the disease main syndromes: fever - 1.7 times, and intoxication - 2 times (p <0.05) [7]. A background for this analysis was the result of a randomized multicentral comparative clinical study (Sologub, T., et al., 2017) of the clinical and economic efficacy of Ingaron for the treatment of influenza as a part of complex therapy. It should be noted that in this study the standard recommended regimen of influenza therapy was used, in accordance with the current clinical guidelines [8,9] and official recorded indications for the studied medications. In the study of Sologub T.V. et al. 88 patients with a laboratory-confirmed diagnosis of influenza A (H1N1) pdm09 were included [8]. Patients of the main group (n = 46) received complex therapy with the use of antiviral (oseltamivir) and immunomodulating (interferon-gamma) agents. Patients of the control group (n = 40) received only antiviral therapy (oseltamivir). To assess the efficacy and economic profitability of the two different treatment regimens, the outcome of the disease was analyzed: an extract from the hospital up to the 10th day of the illness and absence of symptoms of the disease to 3rd-6th days of treatment. It has been established that the inclusion of recombinant interferon-gamma in the treatment regimen of patients with influenza A (H1N1) pdm09 helps faster reverse of catarrhal and respiratory symptoms of the disease: absence of dry cough by 3-6 days of treatment (RR = 1.43, 95% CI 0.86 - 2.38), rhinitis (RR 1.21, 95% CI 1.05-1.40), and dyspnea (RR 1.28, 95% CI 1.06 - 1.54). Besides, the inclusion of recombinant interferon-gamma in the treatment regimen of patients with influenza A (H1N1) pdm09 helped to a significant reduction in the timing of recovery and discharge from the hospital (RR = 1.39, 95% CI 0.97 - 2.00). Clinical and economic analysis of the use of two alternative treatment regimens has showed that the inclusion of recombinant interferon gamma in the treatment of patients with influenza A (H1N1) pdm09 is economically profitable [9]. During the budget impact analysis, official data on the incidence of influenza for the period of 2016 were used and were transformed into absolute values. The incidence indicator of influenza in 2016 was 60.5 people per 100 thousand people, or 87120 people in absolute values, the maximum number of hospitalized patients was 26 thousand people per week in the epidemic season of 2016-2017 [1]. To assess the budget impact on Ingaron as a part of complex influenza therapy as a result of reduction of the disease duration from work of Sologub T.V. et al. [10] the cost-effectiveness indicator was used for the regimen of complex therapy of influenza with inclusion of Ingaron in the intranasal form - 1,528.43 rubles per unit. [7]. To estimate the overall impact on the economic burden of influenza, the estimated economic burden for influenza for 2016 was estimated 2 350 478.2 thousand rubles [1].

Results

Table 1 presents the results of the budget impact analysis on the inclusion of interferon-gamma in the intranasal form to the complex therapy of influenza in the Russian Federation.

<table>
<thead>
<tr>
<th>Treatment regimen</th>
<th>Cost-effectiveness indicator rubles per unit</th>
<th>Total savings per year, thousands rubles</th>
<th>Savings, estimated indicator of economic burden Δ, thousands rubles</th>
<th>Reduction of expenses, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingaron + complex therapy</td>
<td>1528,43</td>
<td>1331568,21</td>
<td>1018909,984</td>
<td>43,34</td>
</tr>
</tbody>
</table>

Table 1. Budget impact analysis and estimated indicator of economic burden of influenza complex therapy with Ingaron (2016).
Table 1 Shows That The Regimen Of Treatment Of Influenza With The Inclusion Of Ingaron Is Cost-Effective. Budget Impact Analysis Showed A Decrease In Budget Expenditures From Use Of Ingaron By More Than 1331568 Thousand Rubles Per Year. Inclusion Of Ingaron In Complex Influenza Treatment Regimens Reduces The Economic Burden Of Influenza By More Than 43%, Which Will Be Accompanied By The Reduction In Direct And Indirect Economic Losses Of 1018910 Thousand Rubles Per Year With The Current Incidence Of Influenza In The Russian Federation.

Conclusion
Budget Impact Analysis On The Intranasal Form Of Recombinant Interferon-Gamma (Ingaron) In The Complex Therapy Of Influenza Demonstrated Its Clinical And Economic Efficacy For The Health Care System Of The Russian Federation. The Use Of Ingaron In The Intranasal Form In The Complex Therapy Of Influenza Is Justified From The Position Of Evidence-Based Medicine And Health Economics.

References
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