Фармакоэкономика

теория и практика

www.pharmacoeconom.com

- ❑ ФАРМАКОЭКОНОМИКА ТУБЕРКУЛЕЗА:
МЕТОДОЛОГИЧЕСКИЕ ОСОБЕННОСТИ
ПРОВЕДЕНИЯ ИССЛЕДОВАНИЙ
- ❑ ФИНАНСИРОВАНИЕ СИСТЕМЫ ЗДРАВООХРАНЕНИЯ
НА РЕГИОНАЛЬНОМ УРОВНЕ. ВЗАИМОСВЯЗЬ КАЧЕСТВЕННЫХ
И КОЛИЧЕСТВЕННЫХ ПОКАЗАТЕЛЕЙ С ВЕЛИЧИНОЙ
ФИНАНСИРОВАНИЯ ЗДРАВООХРАНЕНИЯ

№4 ^{Том 2}
2014

PHARMACOECONOMIC STUDY OF HERCEPTIN® (TRASTUZUMAB) SC FOR BREAST CANCER PATIENTS

Kulikov A. Yu., Rybchenko Yu. V.

Department of Organization of Medicinal Provision and Pharmacoeconomics, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation

Summary: Breast cancer is a global problem due to its wide prevalence which is increasing every year. The comparative pharmacoeconomic study of Herceptin in subcutaneous and intravenous formulations was conducted for optimization of drug supply for this nosology. Direct medical expenses without taking into account the drug price were compared. As a result of pharmacoeconomic evaluation of the alternative treatment options, it was established that subcutaneous Herceptin saves 39,806 roubles per patient during one treatment year due to the cost differences related to administration, medical staff, as well as hospitalization. Moreover, when IV formulation is used for one treatment year per patient, the medicinal substance is lost due to «throwing out» the remaining part of the drug in the vial, which may not be used in connection with breach of sterile dosage forms. The loss is as high as 166,208 roubles; this translates into 11% monetary loss from the whole treatment cycle.

Keywords: breast cancer, innovation, Herceptin, subcutaneous administration, intravenous administration, HER2-positive profile, medical staff, hospitalization/day-time staying, costs, time savings.

Introduction

Breast cancer is an actual problem of modern society due to its wide prevalence which is increasing every year. In 2013, 57,307 Russian patients with newly-diagnosed breast cancer were registered, 7,947 of them have HER2-positive profile (Figure No.1 and 2) [3,10].

In the Russian Federation, the pharmacoeconomic studies are currently becoming more and more important; on their basis, the most cost-effective therapy can be determined.

As mentioned above, the objective of this study was the pharmacoeconomic evaluation of innovative therapy using subcutaneous (SC) Herceptin compared to intravenous (IV) in HER2-positive BC patients.

A new Herceptin formulation has a number of advantages in comparison with

Herceptin IV. For example, the drug dosage does not depend on the patient's body weight and a standard fixed dose of 600 mg/5 mL is used for each SC administration that is much easier compared to IV formulation. When Herceptin IV is used, the dosage is calculated based on the patient's body weight leading to loss of medicinal substance, at least in 15% of cases. This loss is due to "disposal" of the drug remained in the vial, which may not be used as drug is compromised [9,13].

The next important advantage of Herceptin SC compared to IV formulation is time saving which has been defined for Russia in the study "Time&Motion" [16]. This saving was considered from the point of view of both patients and medical staff. Due to detailed description of time spent on each procedure performed with the patient in the hospital, it was possible to express time saving in monetary units, which clearly demonstrated the benefit of Herceptin SC.

Study methodology

The study compared pharmacoeconomics of Herceptin in a new formulation for subcutaneous administration versus intravenous formulation for Breast cancer patients in conditions of the equal prices of these drugs. These alternative regimens were used for one year. Herceptin IV dosages depended on the patient's body weight and were 8 mg/kg (single loading dose) and 6 mg/kg (maintenance dose) (17 infusions). Herceptin SC regimen consisted of 18 injections at a standard dose independent of the patient's body weight.

Then, based on the costs associated with diagnosis, treatment and pharmacotherapy, the expenses were analysed to determine the total cost of the therapies compared. The expenses analysis also took into account the costs related to patient's hospitalization, services provided by the medical personnel and mandatory testing for HER2- expression [6].

Figure No.1. Breast cancer prevalence in Russia over 2003-2013 (Number of patients per 100,000 population).

Figure No2. Number of HER2-positive patients

Expenses analysis

This study analyzed the direct medical costs including the following expenditure items:

- medical services;
- pharmacotherapy;
- HER2-testing;
- drug administration;
- hospitalization/day-time staying;
- services provided by the medical staff.

Prior to the therapy start, all female patients in both arms under study had HER2-testing to determine the treatment feasibility [1, 9].

Further, when the expenses related to diagnosis, treatment and pharmacotherapy were calculated, the standard of medical care for breast cancer patients was used (Order No. 612H dated November 07, 2012), from where the information on the frequency of medical services and drug prescription was taken [4, 14]. Data sources on medication prices were the State Register of Approved Limit Prices of the Medicinal Products contained in the List of Vital and Essential Medicines (as of November 23, 2014) and open electronic resource aptechka.ru [7, 8]. The expenses for diagnostic and therapeutic procedures were calculated based on the prices provided in the tariffs of the Federal Mandatory Medical Insurance Fund (FOMS) of Moscow [4, 11]. The result of this calculation has the similar monetary value for patients using both Herceptin IV and SC, and is 4,000 roubles for medical services and 51,431 roubles for pharmacotherapy. The equal value of these expenses for both formulations is explained by the standard of medical care for Breast cancer patients, which lists medical services and medicinal products which any Breast cancer patient receives [15].

After that, the expenses for drug administration were calculated, and according to the Moscow FOMS tariffs, they were 76.98 roubles for IV and 30.84 roubles for SC administration. Accordingly, one Herceptin IV/SC treatment cycle will cost 1,386 / 555 roubles per patient, respectively; this allows 831 roubles to be saved with the latter regimen. Given the HER2-positive Breast cancer prevalence in Moscow

(926 patients), the savings related to SC formulation will about 769,506 roubles. The following expenses calculated in this study were associated with the time spent by medical staff for services provided to the patient [14]. Given less time needed for subcutaneous administration, the savings related to this formulation amount, on average, to 1,570 roubles per for one year. What is more, the benefit of Herceptin SC compared to Herceptin IV for whole Moscow population will be 1,453,820 roubles for the entire treatment cycle.

In addition to the abovementioned savings, counting the expenses for hospitalization or day-time staying, it was found that the benefit of Herceptin SC compared to Herceptin IV is on average 37,405 roubles per patient and 34,637,030 roubles for whole population of the identified HER2+ patients.

The expenses analysis determined that Herceptin SC saves money on drug administration, hospitalization/day-time staying, as well as services provided by the medical staff which translates into about 39,806 roubles per patient and 36,860,356 roubles per for one year (Figure No.3) [2,11].

Medicinal Product Loss

Along with dominating money saving when Herceptin SC is used, there is a loss of funds related to use of Herceptin IV. Despite possibility of shared utilisation in case of IV formulation, the medicinal substance is lost in at least 15% of the medicinal substance loss due to “disposal” of the drug remained in the vial was taken into account, as assumption in this study.

Thus, the loss of money is 166,208 roubles per patient and 23,086,345 roubles in a year in total, given the number of Moscow patients.

Time Saving

Additionally, one of the advantages of SC formulation is time saving for injection compared to infusion. As it is stated in the «Time&Motion» study the IV infusion takes 67.1 min, and SC injection takes 7.6 min. In terms of treatment cycle, the time saving related to Herceptin SC is 1,071 min. (17.85 hours) [16]. Taking into account the difference in the procedures' duration it was defined that during Herceptin IV treatment time it is possible to have 8 Herceptin SC treatment courses.

Figure No3. Money saving related to SC formulation

Discussion

During the following study the cost analysis was performed for one-year Herceptin IV and SC treatment of patients with breast cancer with HER+ profile. The same cost of drugs and loss of substance while intravenous usage in not less than 15% of cases due to "disposal" of the drug remained in the vial, which may not be used as drug is compromised.

Conclusions

The transfer from intravenous to subcutaneous form:

1. Leads to the saving of 39,806 roubles per patient 36,860,356 roubles for whole population for one year;
2. allows to prevent 166,208 roubles per patient loss for one year due to "disposal" of the drug remained in the vial, which may not be used as drug is compromised;
3. leads to time saving from the point of view of both patients and medical staff which results in about 1,453,820 rubles for whole population for one year.

References

1. Herceptin (440 mg) Prescribing Information dated October 20, 2014.
2. Kulikov A.Yu., Litvinenko M.M. Methodological basics of modeling in the pharmacoeconomic studies: different levels of complexity and different value of the results obtained // Pharmacoeconomics: theory and practice. - 2014. - Vol.2, №2. - P.16-22
3. Status of oncology care for Russian population in 2013. Edited by A.D. Kaprin, V.V. Starinskiy, G.V. Petrova. Moscow: FGBU "P.A. Gerzen MNIIOI", Minzdrav Rossii, 2014. -235 pp.
4. The standard of medical care for primary generalized and recurrent forms of stage IV malignant breast neoplasms – initially; stages I-IV – progression (systemic medicinal including chemotherapy treatment) dated November 07, 2012 г. No 612H.
5. The tariffs of the Federal Mandatory Medical Insurance Fund, 2014.
6. Khabriev R.U., A.Yu. Kulikov, E.E. Arinina Methodological basis of pharmacoeconomic analysis. Moscow.: Meditsina. – 2011. 128 pp.
7. Electronic resource: aptechka.ru
8. Electronic resource: www.grls.rosminzdrav.ru
9. Electronic resource: www.roche.ru
10. Epidemiology program of HER2-screening in breast cancer patients: results of 2013/G.A. Frank [et al.]// Sovremennaya Oncologia. – 2014. – No2. - P. 3-11.
11. Yagudina R.I., I.Yu. Zinchuk, M. M. Litvinenko «Disease cost» analysis: types, methodology, and features in the Russian Federation // Pharmacoeconomics. – 2012. – V.5, No. 1. – P. 4 - 9.
12. Yagudina R.I., A.Yu. Kulikov. Theoretic basis of pharmacoeconomics method: «Budget influence» analysis// Pharmacoeconomics. – 2011. – V.4, No. 2. – P. 9 - 12.
13. Yagudina R.I., A.Yu. Kulikov, E.E. Arinina. Pharmacoeconomics in oncology. Moscow: Praktika. – 2011. 424 pp.
14. Yagudina R.I., A.Yu. Kulikov, I.A. Komarov. Methodology of the "costs" analysis for pharmacoeconomic studies // Pharmacoeconomics. – 2011. – V.4, No.3. – P. 3 - 6.
15. Yagudina R.I., Serpik V.G. On the possibilities of combining budget impact analysis and cost-effectiveness analysis - development of «3D» pharmacoeconomic model // Pharmacoeconomics: theory and practice. - 2014. - Vol.2, №3. - P.9-13
16. E De Cock, MSc; I Pan, MSc; S Tao, MSc; P Baidin, DEGREE. Time Savings with Trastuzumab Subcutaneous (SC) Injection vs. Trastuzumab Intravenous (IV) Infusion: a Time and Motion Study in 3 Russian Centers Presented at the ISPOR 7th Annual European Congress; November 8–12, 2014; Amsterdam, The Netherlands

www.pharmacoeconom.com