Extended Abstract

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Pharmacology 2018: Availability and affordability of novel biological therapy in Serbia for patients with metastatic colorectal cancer - Aleksandra Kovacevic - Military Medical Academy

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Abstract

Colorectal cancer has been a health burden for many years . Although it's considered to be a disease of the developed world, the incidence rate of CRC has been on the increase in developing countries also (Favoriti et al., 2016; Douaiher et al., 2017). consistent with the planet Health Organization GLOBOCAN database (Bray et al., 2018), is that the third most ordinarily diagnosed cancer and therefore the fourth main explanation for cancer death within the world, accounting for 881,000 deaths in 2018. Colorectal cancer also causes substantial morbidity and mortality in Serbia. consistent with an equivalent database, the amount of latest cases of in 2018 was 6,049 (12.6% of any sort of cancer), while the amount of the deaths caused by was 3,187 (2.9% of all cancer-related deaths) (The Global Cancer Observatory, 2018).

The Serbian health system is facing an additional challenge due to a steep rise in the number of people diagnosed with CRC. From 1997 to 2007, the incidence of CRC increased by 24.6% (Knezevic, 2009). Since this trend will, without doubt, stress the National Health Insurance Fund (NHIF) of Serbia, the objectives of this study were to identify different types of medical services provided to CRC patients and therefore the associated expenditures so as to estimate the entire medical cost at the national level between 2104 and 2017. This information is expected to assist healthcare decision planners and policymakers on how to allocate resources optimally

Patients with metastatic colorectal cancer (mCRC) have typically overall survival (OS) of approximately 30 months, if multi disciplinary team approach was applied. The first-line treatment comprises cytotoxic agents, a fluoropyrimidines in various protocols, combined with irinotecan or oxaliplatin. Additional benefit, in the terms of clinical outcome for such patients, is shown by adding the monoclonal antibodies (bevacizumab, as anti-VEGF and cetuximab and panitumumab as anti-EGFR). Second-line treatment comprehends adding the anti-angiogenic fusion protein aflibercept or anti-VEGFR2 antibody ramucirumab to the firstline protocols. The third line treatment is multi-targeted kinase inhibitor regorafenib. In Serbia, all cytotoxic drugs and monoclonal antibodies bevacizumab and cetuximab, are reimbursed for mCRC patients. Aflibercept, ramucirumab and regorafenib are not on the National Health Insurance Fund (NHIF) reimbursement list. Therefore, we conducted a retrospective randomized case series study, in the large tertiary health care hospital in Serbia. It was concluded that patients with added reimbursed monoclonal antibodies, had 6-month longer OS in five-year period, associated with significantly higher direct medical costs and ICER that was three-fold higher than informal willingness to pay threshold of Serbia. Costs could be significantly decreased only when bevacizumab biosimilars would be available on the Serbian market, but not prior than in 2022, when European Avastin patent expires. European patent on Erbitux expired in 2014; there aren't any biosimilar competitors in Europe approaching the horizon. Aflibercept is the only third-line treatment option that is registered but not reimbursed in Serbia, and ramucirumab and regorafenib are not registered. As a conclusion, it could be said that novel third-line biological treatment is neither available nor reimbursed for the Serbian patients with mCRC. New patent expiration of the monoclonal antibodies is expecting to allow biosimilar market entry and generate significant savings to the NHIF, which is expected to increase the affordability for mCRC treatment.

Data Report Method

This is a retrospective, observational, descriptive study of various medical expenditures accrued by the patients with CRC in Serbia during the 4-year period. Included within the study were records of all patients with CRC who received medical aid at any Serbian hospital no matter the stage of CRC at the time of diagnosis or treatment.

The main source of data for this study was the registry maintained by the NHIF, which is that the government-run insurance program (https://www.eng.rfzo.rs/index.php). The authors were provided with the data limited to patients with CRC (personal health identifiers removed), which contained information on demographics, medical services provided and the associated expenses (archived at https://figshare.com/account/articles/7660853). The medical services were split into the procedures and expenditures associated with diagnosis, therapy, inpatient/outpatient care, physician examination, preparation and administration of drugs, nursing care, and other related medical services. Note that in Serbia, chemotherapy and radiotherapy can be administered only in the public hospitals and are fully covered by the NHIF, ensuring the validity of our data. The out-of-pocket expenses (OTC preparation, dietary supplements,

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vitamins, minerals, etc.), loss of productivity-related cost and cost associated with premature death were not available and are beyond the scope of this report.

The use and cost of chemotherapy (including conventional cytotoxic drugs and mAbs) were derived from the publication "Marketing and Consumption of Medical Products for Human Use," published annually by the Drugs and Medicines and Medical Devices Agency of Serbia (2015–2017 editions). The annual financial reports for the years 2014-2016 were also available therein (accessed at https://www.alims.gov.rs/latin/o-agenciji/publikacije/). The data on the realized market consumption of medication were divided according to the Anatomical Therapeutic Chemical (ATC) Classification System and the international non-proprietary name (INN). The information included within the analysis was pharmaceutical formulations, medication doses and packaging, and defined daily dose (DDD) of drug per 1,000 inhabitants per day. Finally, the consumed drug quantities (packages or DDD) were multiplied by the respective unit prices and summed into total national drug consumption.

The principles of ICH Good Clinical Practice were strictly followed and the approval from the Ethics Committee was obtained (Approval No 26/04/17 for the study protocol No MFVMA/12/17-19, entitled: Cost-effectiveness and cost-utility analysis of CRC treatment and budget impact analysis from the perspective of the patient, hospital and third-party payer).

The Cost of Colorectal Cancer in Serbia

The number of patients with CRC in Serbia between 2014 and 2017 ranged from about 20 thousand to 21 thousand (Table 1). More specifically, we found a gentle increase from 2014 to 2017, with 803 cases more in 2017 than in 2014 (4% increase). Based on the NHIF data for the period 2014–2018, the 5-year prevalence rate of CRC in Serbia was estimated at 17.82/10,000 inhabitants (15,611 cases among 8,762,022 inhabitants). Based on the recently published estimates of CRC incidence and mortality patterns across Europe (Ferlay et al., 2018), the annual number of new cases in Serbia is projected at about 3,700 for men and 2,300 for women. These figures are largely in agreement with the estimates of the World Health Organization GLOBOCAN database (Bray et al., 2018).

Biography

Aleksandra Kovacevic has completed her PhD in clinical and experimental pharmacology in 2016. She is a pharmacist, specialist for pharmaceutical technology and pharmacoeconomy. She is an assistant professor of pharmacology and clinical pharmacology at the Military Medical Academy Medical Faculty, University of Defence, Belgrade. She has published more than 35 papers in reputed journals and has been serving as an editorial board member of repute.

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