

Trends in Statin Consumption and Cardiovascular Mortality in Croatia 2004–2012

Željko Vojvodić¹ and Danijela Štimac²

¹ Family Practice »Dr. Željko Vojvodić«, Bijelo Brdo, Croatia

² University Zagreb, School of Medicine, School of Public Health »Andrija Štampar«, Department for Social Medicine and Organization of Health Care, Zagreb, Croatia

ABSTRACT

Prescribing of statins showed an increasing trend in all developed countries, during the last two decades. The aim of this study was to research the trends in statin consumption in the period from 2004 to 2012 as well as trends of cardiovascular mortality during the 1990 to 2012 period, and to compare them between Croatia and several neighbouring countries. Data on statin expenditures and consumption expressed in defined daily doses per 1000 inhabitants per day (DDD/TID), were taken from annual reports of Croatian Agency for Medicinal Products and Medical Devices (HAL-MED). Data on crude mortality rates and standardized cardiovascular mortality rates, were taken from the Croatian Health Statistics Yearbooks. The utilization of statins increased by 196.7% during the observed period, with the highest consumption of atorvastatin and simvastatin. Financial expenditure of statins expanded at much faster rate in comparison with overall drug costs. Cardiovascular mortality rates decreased slightly, while maintaining higher level in comparison with some neighbouring countries.

Key words: drug consumption, statins, cardiovascular mortality

Introduction

A trend of reduction in overall cardiovascular mortality and mortality from coronary heart disease started in developed countries already in the 1950's, but with significant dissimilarities between countries, regions and ethnic or social groups. This phenomenon is explained primarily by improvement in socio-economic quality of life and by developments in health care, such as introduction of new drug classes and new procedures and techniques in interventional cardiology, in addition to improvement of organisational aspects of emergency care^{1–5}. Most of the interventions resulted in decrease of mortality among selected groups of patients (in controlled trials) or subjects with increased cardiovascular risks. However, as a rule, there was no definite conclusion regarding effect on the population, as the most relevant for public health planning and organisation of health care. In the last 15 years prescribing of statins showed an increasing trend in all developed countries, therefore also in Croatia, probably as a result of improved understanding of benefits of this therapeutic group in prevention of cardiovascular mortality. Numer-

ous well conducted clinical trials demonstrated their unquestionable efficacy in reduction of cardiovascular morbidity and mortality, since their introduction in clinical practice, in the beginning of 1990-ties, in thoroughly selected population groups. The rise of their utilization in the entire population has been taken for granted, therefore, as desirable and beneficial trend also in primary prevention, with the aim of controlling modifiable risk factors involved in pathogenesis of mainly coronary heart disease.

In Croatia, statins are introduced in the middle of 1990-ties. The Croatian Health Insurance Fund (CHIF) has, in the beginning, restricted their use to prescribing only after recommendation of cardiologist, because of their high price. The recommendations are later incorporated, as restricted indications, into the basic and supplementary lists of medicines. High costs of treatment and prevention were managed by prescribing restrictions, as well as lowering of drug prices in direct negotiations between the CHIF and pharmaceutical industry, and stimulation of generic prescribing^{6,7}.

In 2011, mandatory recommendation of cardiologist was abolished, but indication restrictions remained. In secondary prevention, indication guidelines enclosed patients after myocardial infarction, ischemic brain insult, transitory ischemic attack, carotide plaque or peripheral arterial occlusive disease verified by ultrasound, coronary heart disease verified by coronarography, or electrocardiography (ECG) stress test, and to diabetics with total cholesterol above 5 mmol/L. In primary prevention they ought to be prescribed to persons with total cholesterol above 7 mmol/L in two separate measurements, but only after at least three months of dietary and lifestyle change attempts, also in younger persons, and those above 50, if their Systematic Coronary Risk Evaluation (SCORE) result exceeds 10 percent⁸.

In Croatia, however, despite restrictions, there is a continuous rise of consumption^{9,10}. To what degree is that increase correlated with cardiovascular mortality, as the most important reason of their use, and to what degree is financial spending sustainable in the time of economic recession, remains to be understood. Hence, the aim of this study was to explore trends in statins consumption in the period 2004 and 2012 and trends of cardiovascular mortality in the period from 1990 to 2012, in Croatia and several neighbouring countries.

Materials and Methods

This population observational study was based on compiled data on drug utilization, as well as age standardized rates of cardiovascular mortality. Data on consumption of drugs for dyslipidemia (inhibitors of HMG CoA reductase, statins, C10AA), were taken from annual reports of Croatian Agency for Medicinal Products and Medical Devices (HALMED), from 2004–2012¹¹.

In the Agency reports, mainly outpatient and total utilization were traced, while hospital utilization was only roughly estimated between 2.98–3.7% of the total utilisation. The utilization was measured systematically from 2004, according to both ATC/DDD methodology and financial indicators, based on data from Croatian pharmacies. Financial spending was expressed in Croatian kunas (international abbreviation: HRK): 1 EUR = 7.625 HRK, 12.04.2014, and therapeutic consumption in number of defined daily doses per 1000 inhabitants per day (DDD/TID), as standardized measure on the population level, for both the statins in total and individual generic drugs, simvastatin (ATC C10AA01) and atorvastatin (ATC C10AA05), as the most frequently prescribed. Financial and therapeutic consumption of other drugs for dyslipidemia (fenofibrate, gemfibrozil, cholestiramine) registered in Croatia was not considered, due to their marginal (compared with statins) financial and therapeutic significance.

Data on overall mortality and age standardized cardiovascular mortality rates, coronary heart disease mortality and cerebrovascular disease mortality rates, for the age group 0–64, and per 100 000 inhabitants, were taken from the Croatian Health Statistics Yearbooks

(CHSY), for the period between 1980 and 2012¹². Except for Croatia, the same data were analysed for several neighbouring countries, Slovenia, Hungary, Czech Republic and Austria, as well as for group of 27 European Union countries before joining of Croatia in 2013 (EU27).

Results

Results are divided into two units: trends in statin consumption and trends in cardiovascular mortality.

Trends in statins consumption

Total drug utilization in Croatian population, in the last 10 years, expressed as DDD/TID was in constant rise. In 2004 consumption rate was 658.1 DDD/TID and in 2012 – 926.9 DDD/TID (increase of 40.7%). A generator of that increase was mainly outpatient statin prescriptions issued by family physicians. Hospital use was roughly between 2.98–3.7% of the total drug consumption from 2004 to 2007, and around 0.5 DDD/TID between 2008 and 2012.

From 2004 to 2012 the use of statins grew up, from 28.1 to 83.5 DDD/TID (increase by 196.7%), with sharp fall to 48.6 DDD/TID in 2011. Consumption of individual statins followed this trend. Simvastatin use increased at a rate of 64% until 2010, but fell in the last two years. From the eighth position on the rank list of most frequently prescribed drugs in 2004, simvastatin dropped to the seventeenth. Atorvastatin use grew sharply until 2010, from 8.9 in 2004 to 47.9 DDD/TID in 2010 (increase by 440%), followed by decrease to 26.9 DDD/TID in 2012. From the fourteenth position on the rank list, it shifted to the second in 2010. Fluvastatin was prescribed in greatly lesser proportion, but again, with a trend of slight growth, from 1.5 in 2004 to 6.5 DDD/TID in 2012. The use of newly registered rosuvastatin, available since 2010, increased for 20 times, from 0.4 to 7.0 DDD/TID in 2012 (Figure 1).

In 2004, the overall financial spending on drugs in Croatia was 3.82 billions of HRK (around 501 millions of EUR, according to exchange rate from 12.04.2014). Ap-

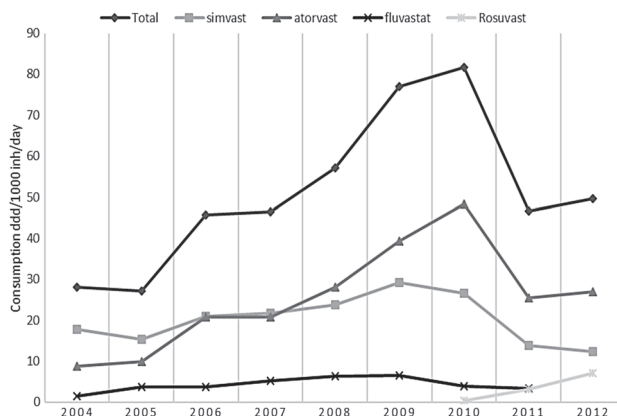


Fig. 1. Trends in overall statin consumption in Croatia from 2004–2012 (in DDD/TID).

proximately 90% of that amount were drugs on prescription regime, and therefore reimbursable by the CHIF. The overall costs were roughly equal from 2004 to 2007, while in the last few years increased by 32.7% – from 3.82 billions of HRK in 2004 to 5.07 billions in 2012 (Figure 2).

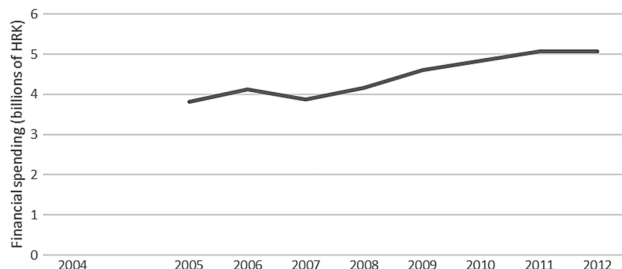


Fig. 2. Overall financial spending on drugs in Croatia from 2004–2012 (in billions of HRK).

Financial expenditure of statins expanded at much faster rate (at a rate of 53%), in comparison with the drug costs in total, from 161.76 millions of HRK in 2004 to 247.43 millions of HRK in 2012. Simvastatin and atorvastatin shared the greatest proportion in costs. Simvastatin expenditure decreased from 102.4 millions of HRK in 2004 to 50.36 millions of HRK in 2012, replacing its first position on the rank list of 25 top sales in 2004 with the fourteenth position in 2012. Atorvastatin sales, in the same period, advanced from 45.5 millions of HRK in 2004 to 114.05 millions in 2012 (increase by 150%), moving from the eleventh position on the rank list in 2004 to the first position in the year 2008 already (Figure 3). In the period of three years, rosuvastatin costs greatly advanced from negligible couple of thousands to significant 29.03 millions HRK, in 2012.

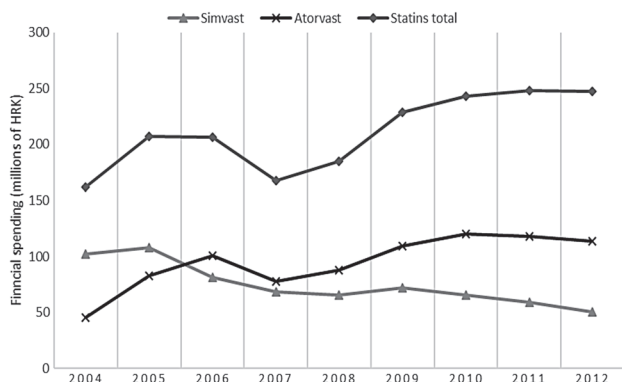


Fig. 3. Overall financial spending on statins in total, simvastatin and atorvastatin in Croatia from 2004–2012 (in millions of HRK).

Trends in cardiovascular mortality

The crude death rates in Croatia fluctuated between 10.9/1000 inhabitants in 1990 to 12.1/1000 inhabitants in 2012, or expressed in absolute numbers, from 50,100 to 52,400 deaths per year (Figure 4).

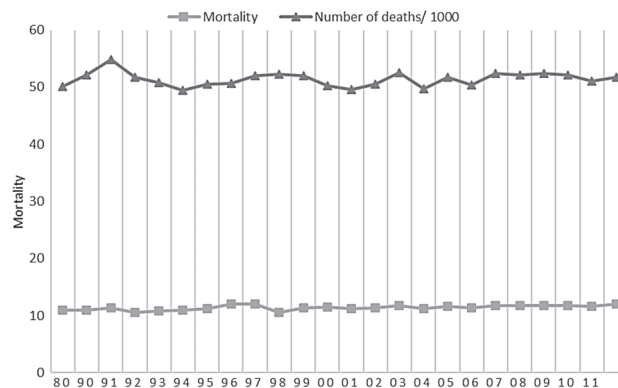


Fig. 4. Trends in crude death rates and absolute number of deaths in Croatia from 1980 to 2012.

Standardized cardiovascular mortality rates for the age 0 – 64 in all selected countries decreased continually. Only in Hungary, a slight increase from 1980 to 1993 was recorded, followed by a decline. Mortality rates, however, varied among countries for more than two times. In 2011 the highest rate was in Hungary (98.6/100,000), than in Czech Republic (59.9) and Croatia (59.8). The lowest rate was in Austria (29.8) (Figure 5). Similar trends existed with age standardized rates from ischemic heart disease and cerebrovascular disease (Figures 6 and 7).

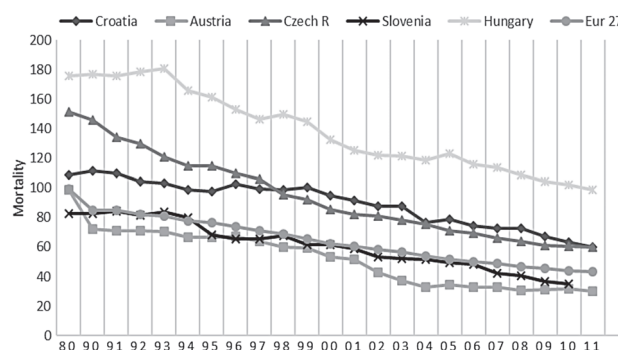


Fig. 5. Trends in standardized cardiovascular mortality rates (age 0–64, per 100,000 inhabitants) in Croatia, Austria, Czech Republic, Hungary, Slovenia and EU27, from 1980 to 2012.

Standardized mortality rates from ischemic heart diseases for the age 0–64 varied between the countries. In the EU27 group of countries, Austria and Slovenia, a trend of steady continuous decline was present, from levels, generally, two times lower than in Hungary and Czech Republic. The later showed a sharp decline, while mortality in Hungary, although decreasing, remained the highest during the entire period. In Croatia the rates slightly increased, from 38.9/100,000 in 1990 to 43.5/100,000 1998, and then declined to 30.5/100,000 in 2011. Despite that, in 2011, standardized mortality rate from ischemic heart diseases for the age 0–64, in our country was almost two times greater than in Slovenia, Austria and EU27 group (Figure 6).

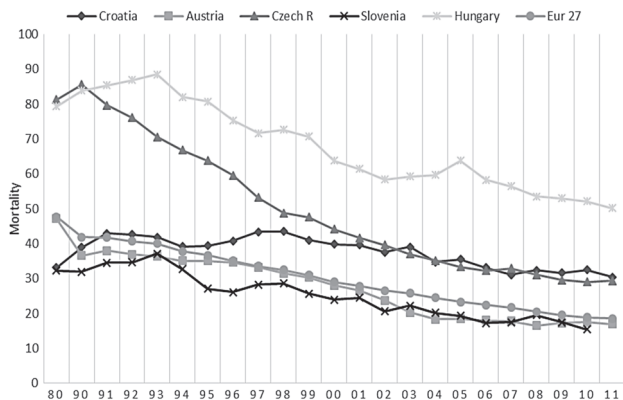


Fig. 6. Trends in standardized mortality rates from ischemic heart disease (age 0–64, per 100.000 inhabitants) in Croatia, Austria, Czech Republic, Hungary, Slovenia and EU27, from 1980 to 2012.

Trends in standardized mortality rates from cerebrovascular disease continually declined in all countries. Somewhat greater oscillations were noticeable only in Croatia, between 1995 and 2001. The highest rate was in 1996, 34.6/10,000, but than declined towards present time, remaining generally above average among the selected group of countries, except for Hungary. In comparison with Slovenia and the EU27 group, the rate was almost twice greater, while compared with Austria, it was more than three times (Figure 7).

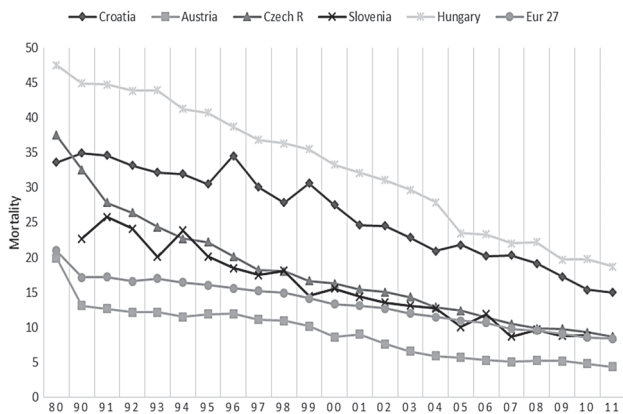


Fig. 7. Trends in standardized mortality rates from cerebrovascular disease (age 0–64, per 100.000 inhabitants) in Croatia, Austria, Czech Republic, Hungary, Slovenia and EU27, from 1980 to 2012.

Discussion

Concerning the proven efficacy of statins in the treatment of ischemic heart disease, as well as in secondary prevention, one would expect a significant decline in cardiovascular mortality after their introduction in clinical practice. However, the results of this investigation suggest that there is no, especially after 1995 (the registration of simvastatin in Croatia) any change in the trends.

While the use of statins almost doubled from 2004, cardiovascular mortality rates decreased in balanced linear mode since 1990-ties. Trends in ischemic heart disease mortality also declined continually in all selected countries, except in Croatia, where it was relatively stationary. Standardized rates for cerebrovascular mortality are also twice greater in Croatia, in comparison with neighbouring Slovenia, and the EU27 group, and three times higher than in Austria.

While in this study we selected mortality as the most important trend for comparison with the utilization of drugs for dyslipidemia, another research compared the use of hypolipemics in the City of Zagreb with the rate of hospital admissions due to acute complications of cardiovascular diseases^{10,13}. The rise of consumption from 31 DDD/TID in 2001 to 72.4 DDD/TID in 2006 was followed by a decline in hospital admissions by 18.5%. It was concluded that the declining trend was a result of improved secondary prevention, on a ground of positive impact of statins. The conclusion was probably correct from the aspect of secondary prevention and morbidity, but not sufficient enough for interpretation of considerably lesser effect on mortality.

Although the beneficial effect of statins on cardiovascular mortality is substantiated in numerous clinical trials, the question of their effect on the population level should be examined in a wider frame, having in mind the complexity of cardiovascular diseases. There is, in particular, a great influence of social gradient, a cluster of mixed social, cultural and economic factors, in their epidemiology^{14,15}. According to Marmont and al., social gradient could potentially be involved with more than a half of share¹⁶. Also classical risk factors can not be understood out of social context, including the employment status^{17,18}, important in Croatia nowadays. Interventions aiming at reduction of risks by modifying behavioural factors had, regrettably, limited achievements, and in Croatia being not carried out in systemic manner. If only hypertension and diabetes are considered as principal risk factors, then interventions aimed at their control again failed to reach any conclusive outcomes, because there are only 63% adequately controlled hypertensive patients and 22.3–34.7% diabetics^{12,19}. Because of that, only comprehensive intervention, including biological, social and behavioural factors, on both individual and population level, provides some chance for success²⁰.

If the utilization of statins is understood as one of many procedures, being a part of complex intervention, then our investigation demonstrates that their consumption, with the increase rate of 76% in the observed period, is overabundant. The use is even more excessive, if we compare regional differences. In the City of Zagreb only, the consumption was twice greater, than in our study: 72.4 DDD/TID in 2006 and 98.98 DDD/TID in 2008^{9,10,21}. However, both the overall drug consumption and the use of cardiovascular medicines in Zagreb are above the country’s average. The possible explanations are that there are situated 43% of all health resources as well as centres of clinical excellence, with greater flow of scientific information than in the country’s interior. Furthermore, near 50,000 employees commute daily in the

city, and at least part of them use city's health care facilities. But, it could also be understood as an additional example of health inequalities²¹.

It seems that administrative measures against over-spending of statins, such as prescribing after recommendation of cardiologist, restricted indications and price cutting in negotiations with pharmaceutical industry, failed to accomplish any measurable effect. On the contrary, when family physicians were authorized in 2011 to prescribe without prior recommendation, but within the framework of guidelines of the CHIF, there was a decline in prescriptions and the volume of consumption, in particular of simvastatin and atorvastatin. The only question is whether the trend is temporary or sustainable in the next period. Financial spending in HRK needs special attention, not only because of current economic recession in Croatia, but also because of their rapidly increasing proportion in healthcare costs, which rise in all developed countries due to their high price. The overall drug spending in Croatia approached about 25% of total healthcare costs, with 5% of that amount to statins alone (247.3 millions of HRK).

The structure of expenditure also reflects great influence of pharmaceutical industry. For example, in 2001, simvastatin costed between 70 and 176 HRK, depending on the size of package, and whether it was generic or brand, while atorvastatin cost, in that period available only as a brand product, was between 160 and 320 HRK, being from 2008 to 2012 on the first position of drug sales. The case of rosuvastatin, being on positive list since 2010, is exemplary, since its sales from a couple of thousands of HRK grew to impressive 29.03 millions of HRK in 2012 (3.93 millions of EUR)¹¹. In Croatia there is a scarcity of cost-benefit research, especially in this segment of healthcare spending, and therefore no information if such a great investments in this therapeutic group met expectations. It would, probably be more cost-effective to redirect a part of financial means to other, more certain interventions, for reducing a disease burden²¹.

Regarding the future trend of excessive statin consumption, there are two other questions that need to be addressed. The first is related to the changes in the newest clinical guidelines from the American College of Cardiology and American Heart Association, which provoked considerable concern among health professionals. In patients with already known cardiovascular risk, for example, statins are indicated irrespective of LDL values. They are recommended also for primary prevention in diabetics with LDL above 1.81 mmol/L or in persons with the overall 10-year SCORE cardiovascular risk above 7.5%²². According to Pencini and al. it means that the statin use will greatly increase, from approximately 30.4

to 87.4%, in the USA, among persons between 60 and 75, and with no known cardiovascular disease²⁴. Furthermore, near 12.8 millions of Americans, mostly elderly, but without heart disease, should take statin. »Take a statin, and your chance for cardiovascular event will be prolonged for a couple of days«, says Mascitelli²⁵.

The second question is related to the adverse effects. In our country, regrettably, there is a lack of precise data on the number of reports of adverse events to statins, but elsewhere there is abundance of such reports pointing out to potentially serious complications: statin myopathy, hepatic dysfunction, increased risk of developing diabetes, confusion, aggressive behaviour, cognitive disturbances, memory loss, immunoallergic skin reactions etc^{26–29}.

This study has, however, advantages and limitations. Advantages are in the use of data from the official national health statistics, which is commonly used in planning of health care, and in analyzing mortality trends on the population level during more than three decades. We could not, however, suggest any causality relation in this type of investigation, nor explore individual factors involved in the consumption of statins. How important is the role of clinical guidelines, pharmaceutical promotion, share of responsibilities between primary and secondary care, or prescribing habits and attitudes of family practitioners, as well as degree of patients' adherence, is also worth exploring.

Conclusions

The overall drug utilization in Croatian population was in constant rise. In that widespread increase in the use of medicines, outpatient statin prescribing increased more than in other therapeutic groups, with the greater rise of atorvastatin compared with simvastatin, and the greatest of rosuvastatin. Financial expenditure of statins expanded at much faster rate, in comparison with the drug costs in total, which is also an important fact in today's financial situation in Croatia. In the same time, standardized cardiovascular mortality rates and ischemic and cerebrovascular rates for the age 0–64 decreased in balanced linear mode since 1990-ties, while maintaining higher level in comparison with some neighbouring countries.

Acknowledgements

This study was supported by the Foundation for the Development of Family Medicine in Croatia and WHO Collaborating Centre for Primary Health Care, School of Public Health »Andrija Štampar«, School of Medicine, University of Zagreb.

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Ž. Vojvodić

Family Practice »Dr. Željko Vojvodić«, Nikole Tesle 67, 31 204 Bijelo Brdo, Croatia
e-mail: zeljko.vojvodic@os.t-com.hr

TREND OVI KRETANJA POTROŠNJE STATINA I SMRTNOST OD KARDIOVASKULARNIH BOLESTI U HRVATSKOJ OD 2004–2012

SAŽETAK

U zadnja dva desetljeća, potrošnja statina bilježi značajan rast u svim razvijenim zemljama. Cilj ovoga rada bio je istražiti trend potrošnje statina od 2004.–2012. godine u Hrvatskoj te istražiti trend kardiovaskularne smrtnosti u razdoblju od 1980.–2012. i usporediti ga sa susjednim zemljama. Podaci o financijskoj potrošnji statina te o potrošnji iskazanoj brojem DDD/1000/dan dobiveni su iz izvješća Hrvatske agencije za lijekove i medicinske proizvode (HALMED). Podaci o ukupnoj smrtnosti te standardiziranim stopama smrtnosti od kardiovaskularnih bolesti dobiveni su iz zdravstveno statističkih ljetopisa Hrvatskog zavoda za javno zdravstvo. Tijekom promatranog razdoblja, potrošnja statina porasla je 196,7%, a najveću potrošnju unutar te skupine, kroz promatrano razdoblje pokazuju simvastatin i atorvastatin. Prema finacijskim pokazateljima potrošnja statina je rasla značajno više od ukupne potrošnje lijekova. Iako stope smrtnosti od kardiovaskularnih bolesti tijekom promatranog razdoblja pokazuju blagi pad, one su tijekom čitavog razdoblja znatno više nego u nekim susjednim zemljama.