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The impact of changes in national prescribing conditions for statins on their public expenditure and utilization in the Czech Republic 1997–2013

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ABSTRACT

Objectives: In the Czech Republic (CZ) extensive price regulation and prescribing conditions are common instruments often employed with new drugs. Since the introduction of statins onto the market in 1990s the originally strict conditions gradually relaxed while the prescription rates and public costs were rising. The aim was to analyze long-term utilization trends of statins, changes in their reimbursement prices and prescribing conditions, and the evolution of the market.
Methods: From January 1997 to December 2013 statin use was measured in terms of defined daily doses per 1000 insured per day (DDD/TID). The prescription-based database of the General Health Insurance Company of the Czech Republic in 1997 covering 7825,216 inhabitants, i.e. 76% of CZ population, was used as the administrative data source. Also the overall expenditure, unit prices, and reimbursement criteria were analyzed.
Results: Between 1997 and 2013 the utilization of statins rose from 2 to 96 DDD/TID while the expenditure rose 5.5-fold. The rise of prescription for each molecule was always observed after the liberation of the prescribing criteria. In the study period reimbursement prices of simvastatin and atorvastatin gradually decreased to just 5% of their initial values.
Conclusions: The rising consumption of statins in CZ clearly corresponds in time with the liberation of prescribing conditions allowing for prescription by general practitioners and with the introduction of generics accompanied by a swift and repeated reimbursement price cuts.

1. Introduction

HMG-CoA reductase inhibitors (statins) are among the most commonly prescribed drugs worldwide in the prevention of cardiovascular diseases and their effectiveness is largely acknowledged. Their beneficial effects as lipid-lowering agents were demonstrated in patients with coronary heart disease, other atherosclerotic cardiovascular diseases, diabetes, and also in the primary prevention [1,2]. Such evidence has had major implications for dyslipidemia management and prevention. Evolving clinical guidelines and recommendations naturally result in the still higher number of patients eligible for statin therapy which further increases the size of the already enormous market [3–5].

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In order to control increasing public health care spending, namely in pharmaceuticals, European countries develop and employ various cost containment policies, namely in pricing and reimbursement regulation [6,7]. Limitation regarding reimbursement from the public sources, and thus also the utilization of a drug, via specific rules and conditions is an instrument used in various countries, e.g. Baltic states, Slovakia, Ireland, United Kingdom, Italy, and others [8–10]. The practical obligatory effects and ways of determination vary but such conditions are usually connected with the national process of health technology assessment and appraisal. In the Czech Republic (CZ) many drugs, or drug clusters, are attributed specific obligatory prescribing conditions (by whom, i.e. by what health care providers, e.g. specialists, it may be prescribed to be reimbursed, and/or for whom, i.e. for what subpopulation of patients or disease states, it may be prescribed to be reimbursed). Currently 56% of the nearly 9500 publicly reimbursed drugs in CZ have either prescription or indication conditions or both [11]. These prescribing conditions are always decided together with (and published inseparably from) the decision on the reimbursement price by the Czech pricing and reimbursement authority (formerly Ministry of Health and Ministry of Finance, nowadays State Institute for Drug Control).

Since their first appearance in 1990s the reimbursement of all statins in CZ was limited to prescribing solely by specialized physicians. Later those prescribing conditions were gradually liberated to allow for prescribing by general practitioners (GPs). Also the indication criterion has evolved to be less strict concerning the reimbursed indications, especially the primary prevention. At the same time, the statin market was undergoing a swift and marked evolution in terms of its overall volume, number of presentations available, and price decrease due to generification and consequent high competition.

Therefore the aim of this long-term retrospective study was to evaluate the overall changes in statin utilization and expenditure with particular regards to the changing prescribing conditions.

2. Methods

2.1. Data source and collection

A retrospective study using the prescription claims-based database of the General Health Insurance Company of the Czech Republic (GHIC CZ) as the administrative data source was performed.

The data of GHIC CZ on all prescriptions with drugs containing simvastatin, lovastatin, pravastatin, fluvastatin, atorvastatin, and rosuvastatin were collected. An insured person with a recorded prescription for any of statins in the period of interest was defined as a patient. The quarterly data on utilization measured in terms of defined daily doses per 1000 insured per day (DDD/TID) from January 1997 to December 2013. The costs to GHIC CZ in local currency (Czech Koruna, CZK) from 1997 to 2013 were also collected. The exchange rate between CZK and one unit of the common European currency (ECU/EUR) was 36.882 CZK in 1999 and 25.974 CZK in 2013.

The pricing and reimbursement information were (until 2007) collected from decrees of Ministry of Health and pricing catalogues of GHIC CZ and since 2008 from administrative proceedings of State Institute for Drug Control. The unit prices were calculated per defined daily doses (DDD) according to WHO Collaborating Centre for Drug Statistics Methodology [12], which are 30 mg for simvastatin, 45 mg for lovastatin, 30 mg for pravastatin, 60 mg for fluvastatin, 20 mg for atorvastatin, and 10 mg for rosuvastatin. Additional information regarding the numbers of insured individuals and the contractual network of providers between 1997 and 2013 were obtained either on request from internal databases or from published annual reports of GHIC CZ [13], and also from Yearbooks published by the Institute of Health Information and Statistics of the Czech Republic [14].

2.2. Statistical analysis

Segmented regression analysis using interrupted time series data was conducted to examine the effects of the major changes in prescribing conditions on the utilization of individual molecules, namely simvastatin, atorvastatin, and rosuvastatin [15]. Also to evaluate the influence of the individual molecules on the overall consumption of these three drugs, another separate scenario was performed.

The effect was assessed by two parameters, level (β_2) and trend (β_3), according to the following linear regression model:

$$Y_t = \beta_0 + \beta_1 \times \text{time}_t + \beta_2 \times \text{intervention1}_t + \beta_3 \times \text{time after intervention1}_t + \cdots + e_t$$

where Y_t is the DDD/TID at time t; intervention is a dichotomous variable for pre-intervention and post-intervention period; time after intervention is a continuous variable indicating time from the intervention; β_0 and β_1 represent the intercept and trend over time (slope) during the pre-intervention period; β_2 represents the change in the level at the time of the intervention no. 1 and β_3 represents the trend change in the slope after the intervention no. 1, both compared to those in the pre-intervention period. In case of simvastatin, effects of three interventions were assessed (with the respective coefficients β_4–β_7): (1) releasing prescription to GPs of simvastatin itself, (2) releasing prescription of atorvastatin and (3) releasing prescription of rosuvastatin. For atorvastatin, effect of two interventions was studied: (1) releasing prescription of atorvastatin itself and (2) that of rosuvastatin. Finally, for rosuvastatin, only the effect of rosuvastatin itself (1 intervention) was studied.

In the regression analysis all the data points available were used, except for rosuvastatin, where 2 data points of 1Q and 2Q 2010 were omitted due to high temporary co-payment as described below which influenced significantly the consumption of rosuvastatin within this period.

The Durbin–Watson test was used to examine presence of autocorrelation. No autocorrelation was detected. Statistical analyses were performed in R Statistical Software (Foundation for Statistical Computing, Vienna, Austria), and statistical significance was set at $P < 0.05$.