Impact of risk minimisation measures on the use of strontium ranelate: A multinational cohort study in 5 EU countries by the EU-ADR Alliance

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Background

In May 2013 and March 2014 the European Commission issued two decisions restricting the use of strontium ranelate (SR). These risk minimisation measures (RMM) introduced new contraindications and limited the indications of SR therapy. At the 32nd and 33rd ICPE we presented the interim findings of our study evaluating the effectiveness of these measures; we here report the final studyresults.

Objectives

To assess the impact of RMMs on SR utilization in three periods: Reference (01JAN2004-31MAY2013), Transition (01JUN2013-31MAR2014) and Assessment (from 01APR2014).

Methods

Design: Multi-national, multi-database cohort study.

Setting: Routinely collected electronic health care databases: 1 hospital discharge registry (Denmark) and 4 primary care registries (Italy, Spain, the Netherlands, UK).

Exposure: In addition to the prior venous thromboembolism contraindication, RMMs included new contraindications (ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, uncontrolled hypertension) and restricted indications (initiation by experienced physician, not as first line anti-osteoporosis therapy, severe osteoporosis).

Outcomes and statistical analyses: We conducted population (average monthly prevalence rates per year and annual incidence rates of SR use), prescription (prevalence of contra/ indications) and treatment episode level analyses (1-year cessation probability).

Results

Follow-up time comprised more than 143 million personyears (PY) including 76 141 incident episodes of SR treatment. Average monthly prevalence rate of SR use dropped from 62.63/10 000 PY [95% CI: 62.37-62.89] in the Reference to 8.54 [8.45-8.62] in the Assessment period. Similarly, the incidence rate of SR use fell from 7.35/10 000 PY [7.35-7.35] to 0.22 [0.22-0.22] in the same two periods. The prevalence of any contraindication changed from 2.16% [2.06-2.27] to 1.75% [1.03-2.97] in incident SR prescriptions and decreased from 2.28% [2.24-2.31] to 1.61% [1.48-1.76] in prevalent SR prescriptions; the prevalence of restricted indications increased for both incident and prevalent SR prescriptions. The probability of therapy cessation after 1 year changed from 91.3% [91.0-91.5] to 93.6% [91.4-95.3].

Conclusions

These findings confirm a substantial impact of RMMs on SR utilization: SR use decreased overall, and the proportion of patients fulfilling the limited indications and lacking contraindications increased.