1. ABSTRACT

Title

Drug utilisation study, in five European countries, using cross sectional analysis, to assess the extent of prescriptions of trimetazidine for its withdrawn ophthalmological and/or ENT indications among general practitioners, ophthalmologists and ENT specialists.
Date: December 10, 2015
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Keywords

Trimetazidine, Drug Utilisation Study, withdrawal of ENT and ophthalmological indications, risk minimization effectiveness.

Rationale and background

The indication of trimetazidine was restricted to cardiology (stable angina pectoris) in September 2012.
In this context, Les Laboratoires Servier sent a DHPC letter as part of their risk minimisation measures (RMM) to inform prescribers or potential prescribers of the discontinuation of ophthalmological and ENT indications.

Research question and objectives

The aim of the study was to verify the effectiveness of RMMs in terms of compliance of prescribers with the trimetazidine withdrawn indications. The primary objective was to assess, per country, the proportion of prescriptions of trimetazidine for ophthalmological or ENT diagnoses (within the scope of its past indications) among the total prescriptions of trimetazidine after the restriction of its indications.

Study design

Pre-post cross-sectional study using prescription/delivery databases in five European countries: France, Greece, Poland, Romania and Spain.
Two periods were studied:

- A reference period before the restriction of trimetazidine to cardiology from July 2011 to June 2012.
- An assessment period beginning six months after DHPC sending from April 2013 to March 2014.

Setting

All prescriptions of trimetazidine (brand and generic names) made by GPs, ophthalmologists and ENT specialists in outpatient settings.

Subjects and study size, including dropouts

All prescriptions of trimetazidine (brand and generic names) made by GPs, ophthalmologists and ENT specialists in outpatient settings.

Variables and data sources

All prescriptions of trimetazidine prescriber's characteristics (brand and generic names) made by GPs, ophthalmologists and ENT specialists in outpatient settings.
Data sources were:

- IMS Prescribing Insights™, collecting the physicians' prescriptions for a random stratified sample in France, Greece, Poland and Spain.
- National Diagnostic Index™, covering 90% of pharmacy deliveries in Romania.

Results

The overall absolute number of trimetazidine prescriptions in the databases decreased between the reference and assessment periods in France (657 to 182, -72%), Greece (288 to 113, -61% only assessable in GPs), Spain (313 to 240, -23%), and Poland (802 to 623, -22%) but not in Romania (2,548,291 to 5,289,182, +108%). The vast majority of trimetazidine prescriptions were issued by GPs.
In Poland and Romania, the proportion of trimetazidine prescriptions for its withdrawn indications was very low during both periods (respectively 1.6% and 2.2% in Poland, and 0.07% and 0.06% in Romania). In France and Greece, this proportion was similar between the two periods, while the decrease in absolute numbers was substantial, ranging from -61% among ENT specialists to -76% among GPs in France, and -67% among GPs in Greece. In Spain, this proportion decreased significantly in GPs, together with a decrease in absolute number of prescriptions in withdrawn indications (-26% in GPs, -57% in ENT specialists).

Discussion

The results provide evidence of the RMMs effectiveness, although this is reflected in various ways across countries. For the two most contributing countries to trimetazidine use (Poland and Romania), this is supported by very low proportions of trimetazidine prescriptions in withdrawn indications. In the other countries (France, Greece and Spain), the decrease in the volume of trimetazidine prescriptions overall and in withdrawn indications was very substantial after the indication restrictions.

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