

FREQUENCY AND SERIOUSNESS OF ADVERSE REACTIONS INDUCED BY CARDIOVASCULAR DRUGS AND CARDIOVASCULAR REACTIONS INDUCED BY ALL GROUPS OF DRUGS : A 10-YEAR NATIONAL SURVEILLANCE IN THE REAL-WORLD

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Introduction

Cardiovascular (CV) disorders are a leading cause of death¹. Adverse drug reactions (ADRs) are an important cause of morbidity and mortality². Drugs for the treatment of CV disorders and antithrombotic drugs (AT) are commonly prescribed and a cause of serious ADR (SAR)³. CV system is also a target for non-CV and CV prescribed drugs.

Objectives

In a national registry data, we aimed to identify the most reported ADR associated with CV and AT drugs and the non-CV and CV drugs more prone to affect CV system.

Methods

We conducted an observational retrospective study, of reports of ADRs submitted to the Portuguese Competent Authority (Infarmed, I.P) between January 2006 and December 2015. We performed a descriptive analysis to assess the ADRs and drugs related.

Results

ADRs related with CV and AT drugs

The ADR reports related with CV and AT drugs were 10% (n= 2724) of all ADR reports submitted to the Infarmed, I.P., of which 51% of occurred in patients ≥65 years, and 55.6% occurred in women. 73.9% of these episodes were Serious ADRs. Generally, CV drugs affected more the gastrointestinal system (24.6%), the skin (22.4%) and the nervous system (20.7%). AT drugs were the class most frequently associated with ADRs, 35.1% (mainly hemorrhages), followed by modulators of Renin-Angiotensin System, 20% (ACEI) (cough and dizziness), and by lipid modifying agents, 19.6% (musculoskeletal disorders). AT drug related reports/year increased in 7.7 2006-2013 to 88.5 in 2013 to 2015.

During the study period, there were, on average, 45 reports per million of packages prescribed of antiarrhythmics, while AT, lipid agents and renin-angiotensin drugs had a much lower proportion of reports.

Figure 1. Annual trend of ADR reports associated with different subgroups of CV and AT drugs (ATC: C01-10; B01)

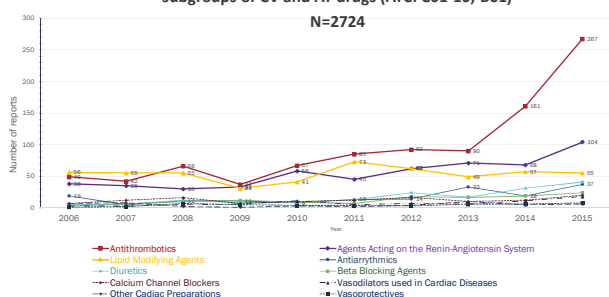
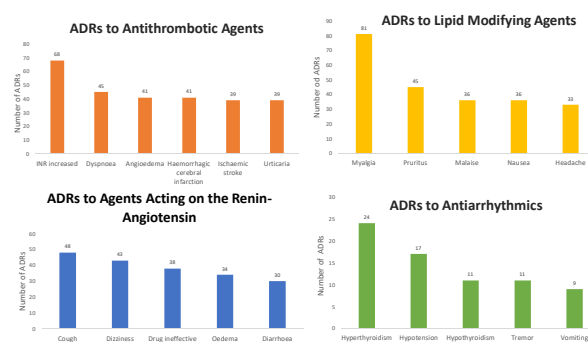


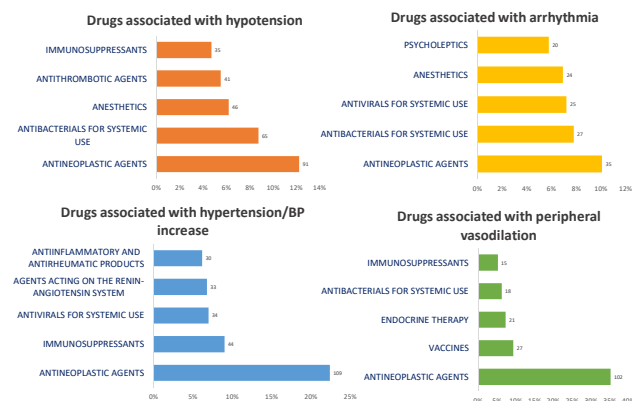
Figure 2. ADRs (Pt MedDra) to most reported CV and AT drugs



CV ADRs related with both non-CV and CV drugs

The reports of CV ADRs were 6% (n=1706) of all submitted to the Infarmed, I.P., of which 38% occurred in patients ≥ 65 years, and 59.4% occurred in women. 87% were Serious ADRs. The most common CV ADRs associated with non-CV and CV drugs were hypotension (24.4%), hypertension (16.5%), peripheral vasodilatation (11.6%), and Arrhythmia (11.1%). Antineoplastic agents were the drugs most involved in CV ADRs (17.4%), followed by immunosuppressants (7.4%) and antithrombotics (7.1%).

Figure 3. Most frequently reported CV ADRs and drugs associated



Conclusions

Drugs for treatment of CV disorders are a common cause of serious ADRs. ADRs involving the CV system by non-CV drugs are also frequent, specially by antineoplastic drugs. Further research is needed to understand the determinants (age, sex, comorbidities) of these serious ADRs.

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