Adverse Drug Reactions to *β*-Lactam Antibiotics: A Portuguese Pharmacovigilance Database Analysis

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Background: The β-lactam antibiotics are one of the most relevant drug classes globally. They accounted for the largest share of systemic antibiotics consumption in Portugal across both community and hospital settings. Due to their significance, continuous monitoring of adverse drug reactions (ADR) associated with β-lactams is fundamental.

Aim: To analyse and characterise cases related to β-lactam antibiotics received by the Portuguese National Pharmacovigilance System.

Methods: Retrospective analysis of cases containing at least one medicinal product classified as suspect under the Anatomical Therapeutic Chemical (ATC) code J01C or J01D, reported to the Portuguese Pharmacovigilance System between 2014 and 2023. Characterisation of cases considered patient demographics, reported suspected medicines, MedDRA Preferred Term (PT), seriousness and type of reporter.

Results: A total of 3557 cases were identified (54.0% females; median age = 42.0 years; interquartile range = 52.2), with 95.9% originating from spontaneous reporting and 93.5% being reported by healthcare professionals. The most frequently reported medicines were those belonging to ATC J01CR. Around 70% of cases were classified as serious, with 38.7% being related to situations of disability or other criteria of greater seriousness. Most frequently reported PTs were related to skin disorders. Anaphylactic reaction was the most reported Designated Medical Event term. The PTs "Drug ineffective" and "Off label use" were reported in 5.2% and 2.4% of the cases, respectively.

Conclusions: Despite the majority of cases are serious, most of the ADR identified are related to already known hypersensitivity reactions. To improve the knowledge regarding these medicines and to generate evidence to address emerging public health issues it is of paramount importance to strength the Portuguese Pharmacovigilance System. This can be achieved through enhancing spontaneous reporting and implementing active pharmacovigilance programs.

Key messages:
- Monitoring the efficacy and safety profile of β-lactams in a real-world context is crucial to mitigate the impact in public health and associated economic burden.

- Enhancing the surveillance systems improves data collection and evidence generation, supporting tailoring treatment approaches and implementation of public health policies.