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Category: (A) Clinical Research

Title: Skin and Subcutaneous Adverse Events due to Abacavir Sulfate/Lamivudine/Zidovudine: An Analysis of the FAERS Database

Background:
Since the detection of the Human Immunodeficiency Virus (HIV) in the early 1980s, significant advancements have been made in managing and treating the virus. A standard treatment regimen typically includes a combination of three drugs, namely Abacavir Sulfate, Lamivudine, and Zidovudine. While this trio of antiretroviral agents has proven effective in managing HIV infection, it is important to note that some individuals may experience adverse skin reactions as a potential side effect. This study uses the Food and Drug Administration Adverse Event Reporting System (FAERS) to examine skin and subcutaneous adverse events associated with Abacavir Sulfate, Lamivudine, and Zidovudine.

Methods:
The FAERS database was used for a thorough retrospective analysis of skin and subcutaneous adverse events associated with the combined use of the antiretroviral medications Abacavir Sulfate, Lamivudine, and Zidovudine. After data collection, the results were systematically organized by key demographic factors, including reaction type, gender, age, and severity of the reported adverse events, and analyzed for trends.

Results:
The analysis identified 300 reported instances of adverse reactions documented in the FAERS database, specifically classified as "Skin and Subcutaneous Tissue Disorders." The majority of cases, accounting for 76%, involved individuals aged 18 to 64. The data indicated that adverse events were more common in males, with 155 cases compared to 72 in females. Among the 300 recorded cutaneous adverse events, hypersensitivity reactions were the most frequently reported, representing 35% of cases and correlating with the established Abacavir Hypersensitivity Syndrome (AHS). Additionally, maculopapular exanthema was observed in 20% of cases, urticaria/angioedema occurred in 15% of cases, and the delayed systemic hypersensitivity reaction known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome was noted in 8% of cases. Furthermore, photosensitivity and pigmentary changes were recorded in 12% of instances. Hospitalization was required in 30.1% of cases, with 7% classified as life-threatening and 6% resulting in death.

Conclusion:

The combination of Abacavir Sulfate, Lamivudine, and Zidovudine is linked to various skin and subcutaneous adverse effects, emphasizing the need for thorough discussions about these potential complications with patients before initiating treatment. However, there is an urgent requirement for improved pharmacovigilance studies to better clarify the profiles of adverse events, as the current database is limited in scope and subject to reporting bias. Clinicians should remain particularly cautious regarding drug-induced hypersensitivity syndromes, especially among high-risk populations. Future studies should focus on real-world patient cohorts to establish stronger causal relationships between combination antiretroviral therapy regimens and dermatological outcomes.

References:

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