

Detection of a Potential Pericarditis Safety Signal Associated with Azithromycin: Evidence from FAERS Disproportionality Analysis

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INTRODUCTION

Azithromycin is a widely used macrolide antibiotic indicated for the treatment of various bacterial infections including respiratory tract infections, sexually transmitted infections, and certain enteric infections. Pericarditis, an inflammation of the pericardium, is a rare but potentially serious cardiac adverse event that has not been extensively reported in association with azithromycin use.

OBJECTIVE

This study aims to detect and evaluate a potential pharmacovigilance signal linking azithromycin to pericarditis, using disproportionality analysis of the FDA Adverse Event Reporting System (FAERS) database. The analysis further aims to assess the strength, consistency, and clinical relevance of the identified signal to support early risk identification and patient safety.

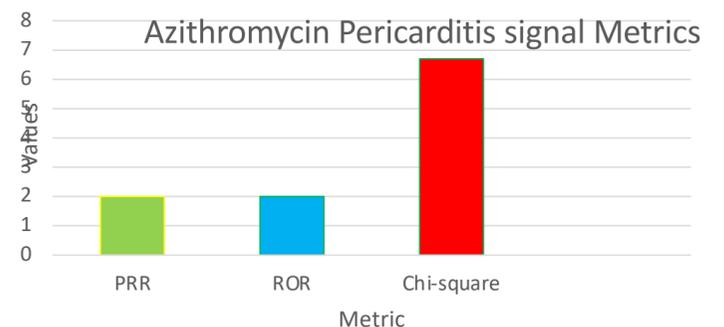
METHOD

A retrospective disproportionality analysis was conducted using the FAERS database. Reports mentioning azithromycin and the adverse event of pericarditis were extracted. Data mining was performed using Open Vigil and PubMed for literature corroboration. The analysis included calculation of Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), and chi-square statistics to evaluate the disproportionality signal. Positive signal criteria were defined as $PRR \geq 2$, $ROR - 1.96SE > 1$ and $\chi^2 > 4$. Additionally, the study seeks to quantify the strength of the association through established signal detection metrics and identify whether it is supported by published literature.

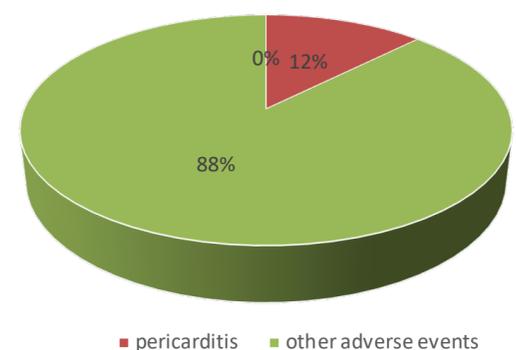
RESULTS

The disproportionality analysis revealed a strong signal between azithromycin and pericarditis in the FAERS database. The PRR of 2.071 and ROR of 2.069 with a highly significant chi-square value 6.709 and drug event is 14 support the association beyond random chance. Literature review via PubMed showed limited case reports corroborating this association, suggesting that pericarditis may be an under recognized adverse event related to azithromycin therapy.

Parameters	Observed Value
Number of reports (n)	14
Proportional Reporting Ratio (PRR)	2.071
Reporting Odds Ratio (ROR)	2.069
Chi-square (X^2)	6.709



azithromycin adverse event in (FAERS)



CONCLUSIONS

This analysis identified a statistically significant signal linking azithromycin to pericarditis in FAERS data.

Although causality cannot be established, the findings highlight a potential under-recognized cardiac risk.

Further epidemiological and mechanistic studies are recommended to validate this association and ensure patient safety during azithromycin therapy.

REFERENCES

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