SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually m ore than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature"

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Saudi Food and Drug Authority (SFDA) – Safety Signal of Amiodarone and the Risk of Acute kidney injury

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Acute kidney injury** associated with the use of **Amiodarone**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Amiodarone is generally considered a class III antiarrhythmic drug, but it possesses electrophysiologic characteristics of all four Vaughan Williams classes. Like class I drugs, Amiodarone blocks sodium channels at rapid pacing frequencies, and like class II drugs, Amiodarone exerts a noncompetitive antisympathetic action. Is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patient's refractory to other therapy. Amiodarone also can be used to treat patients with VT/VF for whom oral Amiodarone is indicated, but who are unable to take oral medication. [1] Acute kidney injury (AKI) is a clinical syndrome manifested by a rapid or abrupt decline in kidney function and subsequent dysregulation of the body electrolytes and volume, and abnormal retention of nitrogenous waste. AKI is a complex condition with a wide range of causes, including ischemic injury and exposure to nephrotoxic agents. [2] The aim of this review is to evaluate the risk of Acute kidney injury associated with the use of Amiodarone and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the potential link between Acute kidney injury and Amiodarone use.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 582 global case reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases.[3] The author applied WHO Causality assessment tool on the top 30 extracted cases. [3] Among them, sixteen cases were probably linked to Amiodarone, ten cases resulted in possible association, three cases resulted in unlikely association, while the remaining one case lacked sufficient information for a proper assessment.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (1.4) for this drug/ADR combination which reflects positive statistical association. [3]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Amiodarone. The search identified one published study suggesting a possible association between the drug and this potential risk. [4]

Conclusion

The weighted cumulative evidence identified from assessed cases, disproportionality analysis and literature are suggestive for causal association between Amiodarone and Acute kidney injury. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References

1- Nih.gov. (2021). DailyMed - AMIODARONE HYDROCHLORIDE injection, solution. [online] Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6cd870d7-6381-421a-89bc-bce5c9518219.

2- Workeneh, B.T. (2019). Acute Kidney Injury: Practice Essentials, Background, Pathophysiology. [online] Medscape.com. Available at: https://emedicine.medscape.com/article/243492-overview.

3- Vigilyze.who-umc.org. 2026. [online] Available at: https://vigilyze.who-umc.org/

4- Mohamed M, Al-Hillan A, Flores M, Kaunzinger C, Mushtaq A, Asif A, Hossain M. Concomitant Acute Hepatic Failure and Renal Failure Induced by Intravenous Amiodarone: A Case Report and Literature Review. Gastroenterology Res. 2020 Feb;13(1):40-43. doi: 10.14740/gr1254. Epub 2020 Feb 1. PMID: 32095172; PMCID: PMC7011916.