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"*

08-09-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Sertraline and the Risk of Cardiac arrest

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

Introduction

Sertraline is a medication used to manage and treat the major depressive disorder, obsessive-compulsive disorder, panic disorder, post-traumatic stress disorder, premenstrual dysphoric disorder, and social anxiety disorder. It is in the SSRI class of medications. [1] As defined by the American Heart Association and the American College of Cardiology, "(sudden) cardiac arrest is the sudden cessation of cardiac activity so that the subject becomes unresponsive, with no normal breathing and no signs of circulation". [2] The aim of this review is to evaluate the risk of Cardiac arrest associated with the use of Sertraline 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 causality between Cardiac arrest and Sertraline use. The search conducted on July 2025.

Results

Cases 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 421 global case-reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSRs with completeness score 0.7 and above (13 cases). [4] Among them, eight cases were possibly linked to Sertraline, while the remaining five cases assessed as unlikely.

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 (1.1) for this drug/ADR combination which reflects positive statistical association. [4]

Literature: A review of the published evidence was conducted to explore a potential association between sertraline and the reported adverse drug reaction (ADR). The literature search identified two publications describing cases of cardiac arrest occurring with the use of sertraline. [5,6]

Conclusion

The weighted cumulative evidence identified from assessed cases, disproportionality analysis and literature are suggestive for causal association between Sertraline and Cardiac arrest. 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. Singh HK, Saadabadi A. Sertraline. [Updated 2023 Feb 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK547689/
2. Patel K, Hipskind JE. Cardiac Arrest. [Updated 2023 Apr 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK534866/
3. Vigilyze.who-umc.org. 2025. [Online] Available at: https://vigilyze.who-umc.org/
4. World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at https://www.who.int/publications/m/item/WHO-causalityassessment
5. Aakjær, M., De Bruin, M. L., Kulahci, M., & Andersen, M. (2021). Surveillance of antidepressant safety (SADS): active signal detection of serious medical events following SSRI and SNRI initiation using big healthcare data. *Drug Safety*, *44*, 1215-1230.
6. Atmaca, M., & Mermi, O. (2014). A case of Ventricular Tachycardia and Cardiac Arrest Associated with Sertraline and Mirtazapine Combination. *Iranian journal of psychiatry*, *9*(1), 45–46.