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REVIEWER'S REPORT

Manuscript No.: IJAR-50552 Date: 08-03-2025

Title: Adverse Drug Reaction: A study with First- and Second-line Anti-TB Drugs at tertiary care with Nodal DRTB center.

Recommendation:
Accept as it is……**YES……**
Accept after minor revision……
Accept after major revision ……
Do not accept (*Reasons below*) ……

Rating	Excel.	Good	Fair	Poor
Originality	√			
Techn. Quality		√		
Clarity		√		
Significance			√	

Reviewer's Name: Dr Aamina

Reviewer's Decision about Paper: **Recommended for Publication.**

Comments (*Use additional pages, if required*)

Reviewer's Comment / Report

The study provides an in-depth exploration of adverse drug reactions (ADR) associated with first- and second-line anti-tuberculosis (TB) drugs. The research aims to analyze the occurrence, severity, and impact of ADRs in patients undergoing treatment at a nodal drug-resistant TB (DR-TB) center. The comprehensive discussion on ADR classification, their pharmacological basis, and their clinical manifestations establishes a strong foundation for the study.

The introduction effectively highlights the significance of ADRs in TB treatment and the need for continuous monitoring. The classification of ADRs into Type A and Type B reactions, along with their immunological and pharmacological underpinnings, enhances the understanding of their occurrence. The discussion on drug-induced hypersensitivity syndromes such as Stevens-Johnson Syndrome (SJS), Drug-Induced Hypersensitivity Syndrome (DiHS), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) provides a well-rounded view of potential severe ADRs.

The study acknowledges India's high TB burden and the emergence of multidrug-resistant (MDR), pre-extensively drug-resistant (pre-XDR), and extensively drug-resistant (XDR) TB cases. By presenting recent epidemiological data, the research contextualizes the scope of the problem and the necessity for rigorous ADR surveillance. The diagnostic methods and treatment regimens for rifampin-sensitive TB

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(RSTB) and rifampin-resistant TB (RRTB) are well explained, with a focus on newer drugs and repurposed antibiotics used in drug-resistant TB management.

The discussion on ADR incidence rates among first-line drugs (FLDs) and second-line drugs (SLDs) effectively highlights the higher toxicity and lower efficacy associated with SLDs. The research addresses ADR-related challenges, such as treatment interruptions and non-adherence, which could compromise TB control efforts. The study's methodology is appropriately structured, employing a prospective observational cohort design. The inclusion of pre-treatment investigations, monitoring of comorbid conditions, and follow-up assessments ensures comprehensive data collection.

The results section presents a clear breakdown of ADR incidence among TB patients, distinguishing between RSTB and DR-TB cases. The finding that ADRs predominantly occur within the first month of treatment aligns with existing literature. The identification of malnutrition and comorbidities as significant factors associated with ADRs further strengthens the study's findings. The discussion on common ADRs and their temporal onset provides valuable insights into the critical periods for monitoring.

Overall, the study successfully addresses the research objectives, providing meaningful contributions to the understanding of ADRs in TB treatment. The structured approach, robust methodology, and relevant epidemiological data make this study a valuable addition to the field of pharmacovigilance in TB management.

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