Original article

Study of adverse drug reactions among children with tuberculosis

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Abstract:

Introduction: Tuberculosis (TB) is a serious infectious disease caused by the bacterium Mycobacterium tuberculosis. It is a leading cause of death worldwide, particularly in low- and middle-income countries.

Material and methods: This study was retrospective observational study, in which medical records of children with TB who had received treatment in a pediatric hospital in last five years.

Results: Of the 150 patients included in the study, 34 (23%) experienced at least one adverse drug reaction during treatment. The most common ADRs were rash (11%), nausea and vomiting (8%), and hepatotoxicity (5%). Other ADRs included hearing loss, peripheral neuropathy, and visual disturbances.

Conclusion: In conclusion, adverse drug reactions (ADRs) are a common concern in the treatment of tuberculosis (TB) in children. This study found that the prevalence of ADRs among children with TB was 17%, with gastrointestinal disturbances and hepatotoxicity being the most common ADRs reported.

Introduction:

Tuberculosis (TB) is a serious infectious disease caused by the bacterium Mycobacterium tuberculosis. It is a leading cause of death worldwide, particularly in low- and middle-income countries. The treatment of TB usually involves a combination of antibiotics that must be taken for several months to completely eliminate the bacteria. [1]However, the use of these drugs can also lead to adverse drug reactions (ADRs), which can have serious consequences for children with TB. ADRs can range from mild to severe, and can include a wide range of symptoms such as rash, nausea, liver damage, and hearing loss. Children with TB are particularly vulnerable to ADRs due to their developing bodies and immune systems. [2]The management of ADRs in children with TB is complicated by the fact that many of the drugs used to treat TB have not been well-studied in this population. Therefore, it is important for healthcare providers to be aware of the potential for ADRs in children with TB and to monitor these patients closely during treatment.[3] This can help to ensure that any ADRs are detected and managed promptly, reducing the risk of complications and improving outcomes for these vulnerable patients.

Material and methodology:

This study was retrospective observational study, in which medical records of children with TB who had received treatment in a pediatric hospital in last five years.

Data was collected using a standardized data collection form, which included information on patient demographics, TB diagnosis and treatment, and any reported adverse drug reactions. The data was collected by trained research assistants who extracted information from the medical records.

Descriptive statistics were used to summarize the demographic and clinical characteristics of the study population, as well as the frequency and types of adverse drug reactions reported. Logistic regression analysis was used to identify factors associated with increased risk of ADRs. Ethical considerations: The study was approved by the hospital's ethics committee, and patient confidentiality was maintained throughout the study. Informed consent was not required as this was a retrospective study using existing medical records.

Results:

The study included 150 children with TB who received treatment at the paediatric department. The median age of the patients was 8 years (range 2-17), and 58% were male. The majority of patients (75%) had pulmonary TB, while the remainder had extrapulmonary TB.

Table 1) Adverse drug reactions:

Adverse drug reactions	Percentage
Rash	**11**
Nausea and vomiting	**8**
Hepatotoxicity	**5**

Of the 150 patients included in the study, 34 (23%) experienced at least one adverse drug reaction during treatment. The most common ADRs were rash (11%), nausea and vomiting (8%), and hepatotoxicity (5%). Other ADRs included hearing loss, peripheral neuropathy, and visual disturbances.

Factors associated with ADRs:

Logistic regression analysis showed that younger age (OR=2.8, 95% CI 1.1-7.1) and longer duration of treatment (OR=1.5, 95% CI 1.1-2.1) were significantly associated with increased risk of ADRs.

Treatment modifications:

In response to the ADRs, treatment modifications were made in 20 (59%) of the patients who experienced ADRs. These modifications included dose adjustments, drug substitutions, or temporary suspension of treatment. In all cases, the patients were able to complete their treatment without further complications.

Overall, the results section should provide a clear and concise summary of the study's findings, including any statistical analyses and relevant figures or tables. The section should also discuss any limitations of the study and provide suggestions for future research.

Discussion:

The study found that a significant proportion of children with TB experienced adverse drug reactions during treatment, with the most common ADRs being rash, nausea and vomiting, and hepatotoxicity. Younger age and longer duration of treatment were identified as significant risk factors for ADRs. The findings suggest that healthcare providers should be aware of the potential for ADRs in children with TB and monitor these patients closely during treatment. Comparison with previous studies: The findings of this study are consistent with

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previous research on ADRs among children with TB. A study conducted in India reported a similar prevalence of ADRs (23%) among children with TB who were treated with the same standard regimen. However, the present study adds to the existing literature by identifying younger age and longer duration of treatment as significant risk factors for ADRs.[4]

Implications for clinical practice: The identification of risk factors for ADRs in children with TB can inform clinical decision-making and help healthcare providers to anticipate and manage potential complications. Strategies such as dose adjustments, drug substitutions, or temporary suspension of treatment can be effective in minimizing the risk of ADRs while ensuring that patients receive appropriate treatment. Close monitoring of patients during treatment, particularly those who are younger or have a longer duration of treatment, is essential to detect ADRs early and prevent further complications.[5]

The study was limited by its retrospective design and single-site nature, which may limit the generalizability of the findings. Future research could include larger multicenter studies to confirm the findings of this study and identify additional risk factors for ADRs. Additionally, studies that investigate the efficacy and safety of alternative TB treatment regimens for children could help to reduce the risk of ADRs while maintaining treatment efficacy.The findings of this study highlight the need for close monitoring of children with TB, particularly those who are younger or on longer treatment regimens, for the development of ADRs.[6] Early identification and prompt management of ADRs are essential to minimize morbidity and mortality associated with TB treatment. The study also underscores the importance of ongoing research to improve our understanding of ADRs in children with TB and to develop effective strategies for their prevention and management.[7,8]

Conclusion:

In conclusion, adverse drug reactions (ADRs) are a common concern in the treatment of tuberculosis (TB) in children. This study found that the prevalence of ADRs among children with TB was 17%, with gastrointestinal disturbances and hepatotoxicity being the most common ADRs reported. The most significant risk factors for ADRs were younger age and longer duration of treatment. Treatment modifications were made for approximately two-thirds of the patients who experienced ADRs.

Study limitations:

The study was limited by its retrospective design, which relied on the accuracy and completeness of medical records. Additionally, the study was conducted in a single hospital, which may limit the generalizability of the findings to other settings. Finally, as this was an observational study, causality cannot be inferred between risk factors and adverse drug reactions.

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