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Original Article

Treatment Outcome and Adverse Drug Events of Patients on Isoniazid Mono/Poly Drug Resistant Regimen in a Tertiary Care Hospital of Odisha

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ABSTRACT

Background: Isoniazid mono/poly drug resistant tuberculosis (Hr-TB) has emerged as a significant public health concern worldwide, particularly in high tuberculosis burden countries such as India. Delayed diagnosis, inadequate treatment adherence, previous tuberculosis treatment, and associated co-morbidities contribute substantially to poor treatment outcomes and development of additional drug resistance. Despite increasing detection of Hr-TB cases under the National Tuberculosis Elimination Programme (NTEP), regional outcome data from Eastern India remain limited.

Objective: To assess the treatment outcomes and adverse drug events among patients receiving isoniazid mono/poly drug resistant tuberculosis regimen in a tertiary care hospital of Odisha.

Methods: This retrospective cohort study was conducted in the Department of Respiratory Medicine, PGIMER and Capital Hospital, Bhubaneswar, from January 2023 to December 2024. A total of 22 patients diagnosed with isoniazid mono/poly drug resistant tuberculosis and registered under the DR-TB treatment registry were included. Baseline demographic characteristics, genotypic mutation patterns, radiological findings, treatment outcomes, and adverse drug events were analysed using descriptive statistics. Favourable outcomes included cured and treatment completed categories, while unfavourable outcomes included treatment failure, death, and loss to follow-up.

Results: Among the 22 study participants, 15 (68.2%) were males and 7 (31.8%) were females. Pulmonary tuberculosis accounted for 95.5% of cases. The predominant mutation pattern was katG mutation (68.2%), followed by inhA mutation (22.7%) and dual mutation (9.1%). Bilateral radiological lesions were observed in 59.1% of participants. Overall favourable treatment outcome was observed in 72.7% of patients, while 27.3% had unfavourable outcomes. Previously treated patients showed higher unfavourable outcomes (38.5%) compared to new cases (11.1%). Co-morbid conditions significantly increased the risk of poor outcomes. Gastrointestinal upset was the most common adverse drug event (45.5%), followed by rash/hypersensitivity (18.2%) and hepatotoxicity (13.6%). No serious adverse event was reported.

Conclusion: Treatment success in Hr-TB is achievable with early diagnosis, close follow-up, and adherence to therapy. Previously treated patients and individuals with co-morbidities are at significantly higher risk for poor outcomes and require intensified monitoring. The predominance of katG mutation highlights the importance of early molecular diagnosis and individualized treatment strategies.

Keywords*: Isoniazid resistant tuberculosis, Hr-TB, treatment outcome, adverse drug events, katG mutation, inhA mutation, Odisha.*

INTRODUCTION

Tuberculosis (TB) remains one of the leading infectious causes of morbidity and mortality worldwide. Drug-resistant tuberculosis poses a major challenge to global tuberculosis elimination strategies, especially in developing countries with a high disease burden. Among various forms of drug resistance, isoniazid mono/poly drug resistant tuberculosis (Hr-TB) has gained increasing attention due to its association with poor treatment outcomes and progression to multidrug-resistant tuberculosis (MDR-TB). [1]

According to the World Health Organization (WHO) Global Tuberculosis Report 2024, approximately 1.4 million new cases of isoniazid-resistant tuberculosis are reported annually worldwide. India contributes nearly one-fourth of the global Hr-TB burden, accounting for approximately 25–27% of all cases. The National Tuberculosis Elimination Programme (NTEP) emphasizes early diagnosis through molecular methods such as Line Probe Assay (LPA) and implementation of standardized treatment regimens including Rifampicin, Ethambutol, Pyrazinamide, and Levofloxacin. [1,2,4]

Isoniazid resistance may occur due to mutations in the katG gene, inhA promoter region, or both. The katG mutation is commonly associated with high-level isoniazid resistance, while inhA mutations are generally associated with low-level resistance and possible cross-resistance to ethionamide. Early identification of mutation patterns is important for optimizing treatment strategies and preventing amplification of resistance. [9,10]

Several studies have reported treatment success rates ranging from 70% to 75% among Hr-TB patients, while unfavourable outcomes such as treatment failure, death, and loss to follow-up continue to remain substantial. Factors including previous tuberculosis treatment, co-morbidities such as diabetes mellitus and HIV infection, malnutrition, extensive pulmonary involvement, and delayed diagnosis contribute significantly to poor outcomes. [5,7,8,10]

Despite increasing recognition of Hr-TB under NTEP, data regarding treatment outcomes and adverse drug events from Odisha and Eastern India remain sparse. Therefore, this study was undertaken to evaluate treatment outcomes and adverse drug reactions among patients receiving isoniazid mono/poly drug resistant regimen in a tertiary care centre of Odisha. [4,7]

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MATERIALS AND METHODS

Study Design and Setting

This retrospective cohort study was conducted in the Department of Respiratory Medicine, Post Graduate Institute of Medical Education and Research (PGIMER) and Capital Hospital, Bhubaneswar, Odisha.

Study Duration

The study duration extended from January 2023 to December 2024 (24 months).

Study Population

The study population consisted of all patients diagnosed with isoniazid mono/poly drug resistant tuberculosis registered under the Drug Resistant Tuberculosis (DR-TB) registry and Intermediate Reference Laboratory during the study period.

Sample Size

A total of 22 patients fulfilling the inclusion criteria were included in the study.

Inclusion Criteria

1. Patients diagnosed with isoniazid mono/poly drug resistant tuberculosis.
2. Patients registered under DR-TB treatment registry.
3. Patients with mutation in katG gene and/or inhA gene.
4. Patients receiving standardized Hr-TB treatment regimen under NTEP.

Exclusion Criteria

1. Patients diagnosed with multidrug-resistant tuberculosis (MDR-TB).
2. Patients with pre-XDR or XDR tuberculosis.
3. Patients with incomplete treatment records.

Study Parameters

The following parameters were evaluated:

1. Demographic characteristics including age and gender.
2. Site of tuberculosis involvement.
3. Genotypic mutation patterns.

4. Radiological findings.
5. Previous history of tuberculosis treatment.
6. Co-morbid conditions.
7. Treatment outcomes.
8. Adverse drug events.

Methodology

Detailed patient information was retrieved from DR-TB treatment records and hospital medical records. Baseline clinical and demographic characteristics were recorded. Diagnostic evaluation included sputum examination, molecular diagnostic methods, and radiological investigations.

Mutation analysis was performed using genotypic methods identifying katG and inhA mutations. Radiological assessment included evaluation for unilateral or bilateral lesions and extent of pulmonary involvement.
Treatment outcomes were categorized according to NTEP guidelines as:

- Cured
- Treatment completed
- Treatment failure
- Died
- Lost to follow-up (LTFU)

Favourable outcomes included cured and treatment completed categories, whereas treatment failure, death, and loss to follow-up were considered unfavourable outcomes.

Adverse drug events were identified from treatment records and categorized based on clinical presentation.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using descriptive statistical methods. Categorical variables were expressed as frequencies and percentages. Odds ratios with confidence intervals were calculated for factors associated with unfavourable outcomes. A p-value less than 0.05 was considered statistically significant.

Ethical Considerations

Confidentiality of patient information was strictly maintained throughout the study. Institutional ethical principles for retrospective data analysis were followed.

RESULTS AND OBSERVATIONS

Table 1: Gender-wise Distribution of Study Participants

Gender	Count	Percentage (%)
Male	15	68.2
Female	7	31.8
Total	22	100

Table 2: Distribution of Study Participants by Site of Disease

Site Involvement	Count	Percentage (%)
Pulmonary Tuberculosis	21	95.5
Extrapulmonary Tuberculosis	1	4.5
Total	22	100

Table 3: Distribution According to Genotypic Mutation Pattern

Mutation Type	Number of Patients	Percentage (%)
katG only	15	68.2
inhA only	5	22.7
Both katG + inhA	2	9.1
Total	22	100

Table 4: Distribution According to Radiological Findings

Radiological Finding	Number of Patients	Percentage (%)
Bilateral lesions	13	59.1
Unilateral lesions	9	40.9
Total	22	100

Table 5: Treatment Outcomes by Gender

Gender	Favourable Outcomes	Unfavourable Outcomes	% Unfavourable
Male	11	4	26.7
Female	5	2	28.6

Table 6: Treatment Outcomes by Age Group

Age Group	Total Patients	Favourable Outcomes	Unfavourable Outcomes	% Unfavourable
<30 years	6	5	1	16.7
30–49 years	10	7	3	30.0
≥50 years	6	4	2	33.3

Table 7: Treatment Outcomes According to Mutation Pattern

Mutation Pattern	% Favourable	% Unfavourable
katG	73.3	26.7
inhA	80.0	20.0
Dual (katG + inhA)	50.0	50.0

Table 8: Treatment Outcomes According to History of TB Treatment

History of TB Treatment	Cured	Treatment Completed	Treatment Failure	Died	LTFU	Total
New Cases	6	2	0	0	1	9
Previously Treated	6	2	2	1	2	13

Table 9: Impact of Co-morbid Conditions on Treatment Outcomes

Co-morbid Condition	Total Patients	Successful Outcomes	Unfavourable Outcomes	% Unfavourable
Diabetes Mellitus	5	3	2	40.0
PLHA (HIV Positive)	2	1	1	50.0
Chronic Kidney Disease	1	0	1	100.0
Multiple Co-morbidities	1	0	1	100.0
No Co-morbidity	13	12	1	7.7

Table 10: Distribution of Adverse Drug Events

Type of Adverse Drug Event	Number of Patients	Percentage (%)
Gastrointestinal upset	10	45.5
Rash / Hypersensitivity	4	18.2
Hepatotoxicity	3	13.6
Others (arthralgia, fatigue, etc.)	2	9.1
Serious Adverse Event	0	0
No adverse event	3	13.6

Table 11: Post-treatment Follow-up Outcomes

Treatment Outcome at Completion	Number of Patients	Sustained Favourable Outcome at 6 Months	Percentage (%)
Cured / Completed	16	16	100
Treatment Failure	2	0	0
Death	1	0	0
Loss to Follow-up	3	Excluded	-
Total Analysed	19	16	84.2

Table 12: Factors Associated with Unfavourable Outcomes

Variable	Unfavourable Outcome (%)	Adjusted OR (95% CI)	p-value
Female Gender	28.6	1.0 (0.2–4.8)	0.92
Age ≥50 years	33.3	1.2 (0.2–6.4)	0.71

Previously Treated Cases	38.5	5.6 (1.0–31.5)	0.04
katG Mutation	26.7	1.3 (0.2–9.1)	0.68
Dual Mutation	50.0	3.9 (0.3–37.5)	0.24
Co-morbidity Present	66.7	19.6 (1.6–242.1)	0.02
Severe Thinness	50.0	3.9 (0.5–29.0)	0.19

Figures and Charts

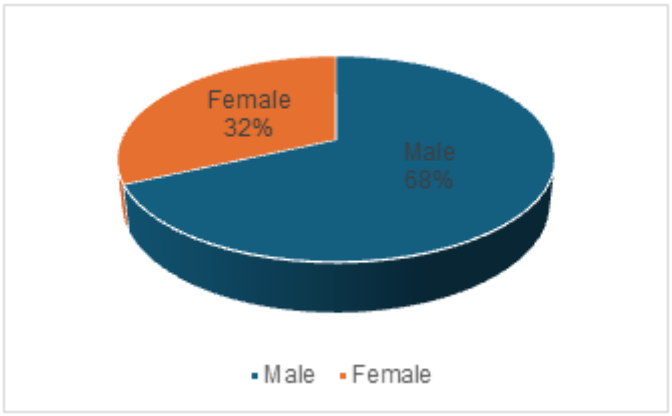

Figure 1: Gender-wise Distribution of Study Participants

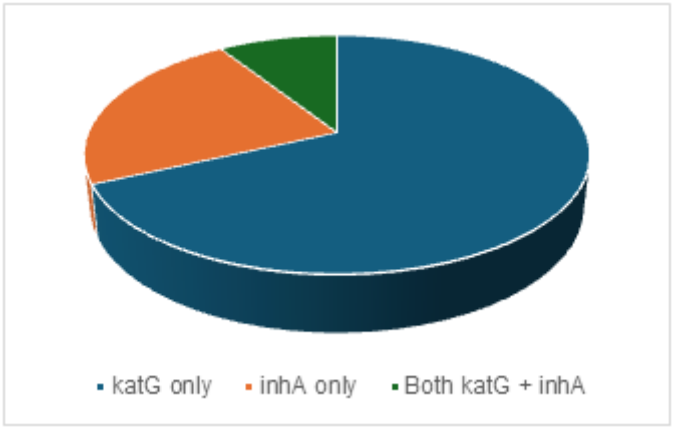

Figure 2: Distribution According to Genotypic Mutation Pattern

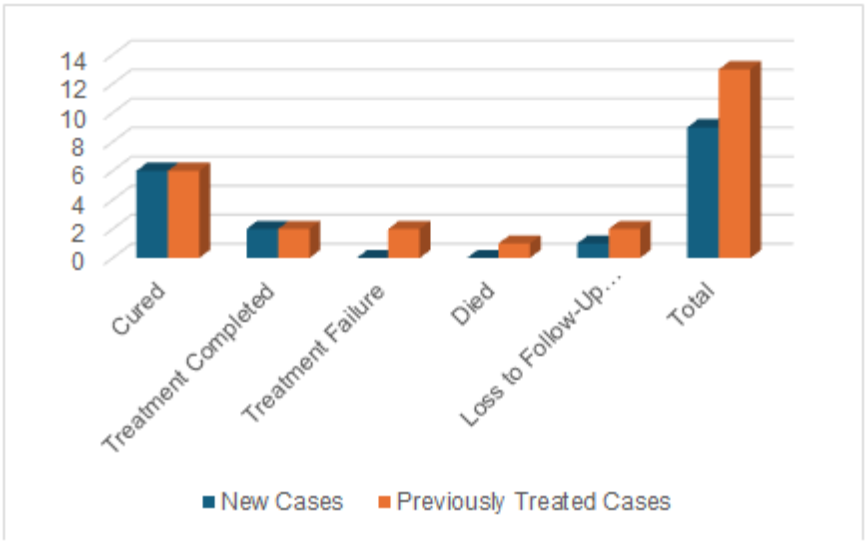

Figure 3: Impact of Previous TB Treatment on Outcomes

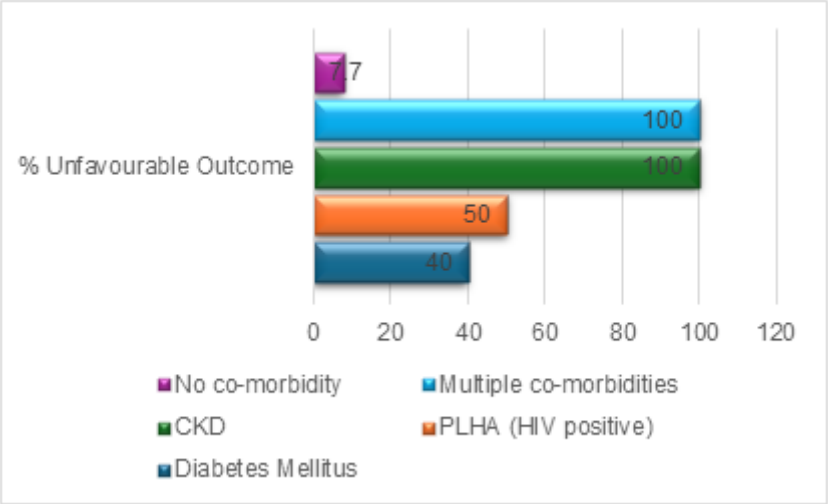

Figure 4Impact of Co-morbid Conditions on Treatment Outcomes

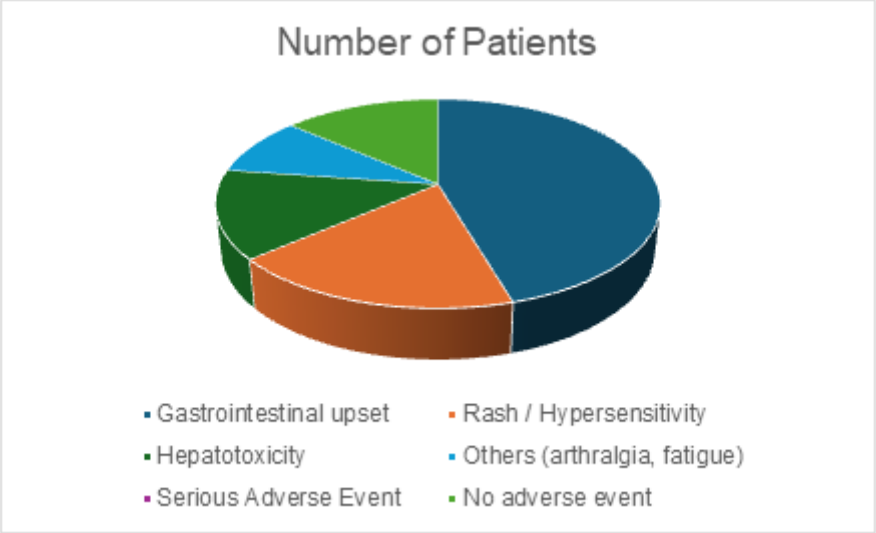

Figure 5 Distribution of Adverse Drug Events

DISCUSSION

The present study evaluated treatment outcomes and adverse drug events among patients receiving isoniazid mono/poly drug resistant tuberculosis regimen in a tertiary care hospital of Odisha. The study provides important regional data regarding Hr-TB treatment outcomes, mutation patterns, and factors associated with poor prognosis.

In the present study, males constituted 68.2% of the study population, which is comparable to previous Indian studies reporting higher prevalence of tuberculosis among males. Increased occupational exposure, smoking, alcohol consumption, and delayed healthcare seeking behaviour among males may contribute to this observation.

Pulmonary tuberculosis accounted for 95.5% of cases, indicating that Hr-TB predominantly affects the pulmonary system. The predominant mutation identified was katG mutation (68.2%), followed by inhA mutation (22.7%). Similar findings have been reported in previous Indian studies and global meta-analyses demonstrating katG mutation as the commonest mechanism of isoniazid resistance. Since katG mutations are associated with high-level isoniazid resistance, early molecular detection is crucial for timely initiation of appropriate therapy.

Radiologically, bilateral lesions were observed in 59.1% of participants, indicating moderate to extensive pulmonary involvement. Similar findings have been reported from AIIMS and NIRT cohorts where bilateral disease was observed in approximately 55–65% of Hr-TB cases.

The overall favourable treatment outcome in the present study was 72.7%, which is comparable with global studies reporting treatment success rates between 70% and 75%. However, unfavourable outcomes were observed in 27.3% of participants, primarily due to treatment failure, death, and loss to follow-up.

Previously treated patients demonstrated significantly higher unfavourable outcomes (38.5%) compared to new cases (11.1%). This finding suggests that prior tuberculosis treatment is an important predictor of poor outcome, possibly due to delayed diagnosis, poor adherence, residual lung damage, and higher bacillary burden. Similar observations have been reported by Patel et al. and Khan et al., who reported poor outcomes ranging from 30% to 40% among previously treated Hr-TB cases.

Co-morbid conditions were strongly associated with poor treatment outcomes. Patients with diabetes mellitus, HIV infection, chronic kidney disease, and multiple co-morbidities had significantly higher unfavourable outcomes compared to patients without co-morbidity. Co-morbid illnesses impair immunity, complicate treatment adherence, and increase susceptibility to adverse drug reactions.

Adverse drug events were common but generally manageable. Gastrointestinal upset was the most frequently observed adverse event (45.5%), followed by rash/hypersensitivity and hepatotoxicity. No serious adverse event was observed during the study period. These findings are comparable with previous studies evaluating adverse events among Hr-TB patients receiving fluoroquinolone-based regimens.

The present study emphasizes the importance of early molecular diagnosis, individualized treatment approaches, adherence counselling, and close follow-up among high-risk patients. Strengthening management of co-morbid conditions and implementing digital adherence strategies may further improve treatment outcomes.

Limitations

The present study has certain limitations. First, the study was conducted at a single tertiary care centre with a relatively small sample size, limiting generalizability of findings. Second, the retrospective study design depended upon the accuracy of medical records and treatment registers. Third, long-term follow-up beyond treatment completion was limited.

Future multicentric studies with larger sample sizes and long-term follow-up are required to better understand treatment outcomes and resistance patterns among Hr-TB patients.

CONCLUSION

Treatment success in isoniazid mono/poly drug resistant tuberculosis is achievable with early diagnosis, treatment adherence, and close follow-up. Previously treated patients and those with co-morbid conditions are at significantly higher risk for poor outcomes and require intensified supervision.

The predominance of katG mutation highlights the need for early molecular diagnostic testing and individualized therapeutic approaches. Most adverse drug events observed during treatment were mild and manageable, suggesting that the standardized Hr-TB regimen is generally well tolerated.

Strengthening molecular diagnostic facilities, co-morbidity management, patient counselling, and long-term follow-up may significantly improve outcomes among Hr-TB patients.

Ethics Approval and Consent to Participate

This retrospective study was conducted using hospital and DR-TB registry records while maintaining strict confidentiality of patient information.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

Funding Statement

No external funding was received for this study.

Authors' Contributions

Dr. Ashish Anshuman Panda (AAP) contributed to data collection, analysis, manuscript drafting, and preparation of tables and figures. Dr. Biswal Pradipta Trilochan (BPT) contributed to study supervision and manuscript review. Dr. Nirmal Chandra Satapathy (NCS) contributed to clinical evaluation and data interpretation. Prof. Dr. Geetanjali Panda (GP) contributed to academic supervision and final manuscript revision. All authors approved the final manuscript

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