Drug Resistance Patterns & Treatment Outcomes among Patients Enrolled for MDR-TB Treatment under PMDT at a Tertiary Care Teaching Hospital in Swat.

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ABSTRACT:

Objective: To evaluate drug resistance patterns and treatment outcomes among patients with Multidrug-Resistant Tuberculosis (MDR-TB) enrolled in the Programme for Management of Drug-Resistant Tuberculosis (PMDT) at Saidu Teaching Hospital, Swat, Pakistan. A secondary objective was to identify determinants of poor treatment outcomes and to assess the impact of fluoroquinolone resistance.

Methodology: This retrospective cohort study included 166 MDR-TB patients enrolled between May 21, 2014, and February 6, 2020. Patient data were obtained from medical records, and drug resistance was determined using phenotypic drug susceptibility testing. Treatment outcomes were categorised as cure, failure, death, lost follow-up, or transfer out. Chi-square tests were performed to assess associations between drug resistance and treatment outcomes.

Results: Of the 166 patients, 130 (78.3%) were cured, 15 (9%) died, 13 (7.8%) were lost to follow-up, and 2 (1.2%) failed treatment. Rifampicin (n=50, 30.1%) and Isoniazid (n=52, 31.3%) showed the highest resistance rates. Fifteen percent of the patients (n=25) were found to be resistant to fluoroquinolones. The resistance to rifampicin had a significant impact on the treatment results ($p < 0.00001$), whereas the resistance to fluoroquinolone also had a strong effect ($p < 0.00001$).

Conclusion: This study highlights the critical issue of drug resistance among MDR-TB patients in Swat, particularly to rifampicin, isoniazid, and fluoroquinolones. The findings underscore the urgent need for improved diagnostic strategies, stronger medication adherence, and enhanced healthcare services, especially in rural areas. Larger multicentre investigations are warranted to validate these results and to strengthen local treatment approaches.

Keywords: Multidrug-resistant tuberculosis, drug resistance, treatment outcomes, fluoroquinolone resistance, Pakistan.

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Introduction:

Multidrug-Resistant Tuberculosis (MDR-TB) is a major global health issue, particularly in countries with a high TB burden like Pakistan. MDR-TB is caused by Mycobacterium Tuberculosis that is resistant to isoniazid and rifampicin.[1] The World Health Organization (WHO) estimates that about 500,000 new cases of rifampicin-resistant TB (MDR-TB) occur every year and that countries such as Pakistan have serious problems in the management and treatment of MDR-TB.[2] This is because of the increased incidence of drug-resistant strains, and more difficult treatment due to long course of treatment, costs and risk of death.[1] The situation is worse in Pakistan, where multiple issues like widespread improper usage of anti TB treatment, lack of proper diagnostic centres and poor educations of people on adherence to treatment make MDR-TB particularly worrisome.[3] The situation is made worse by inadequate health care facilities in many areas like Swat. In regions with a high burden of multidrug-resistant tuberculosis (MDR-TB), such as Swat, Pakistan, systematic assessment of drug resistance patterns and rigorous validation of treatment outcomes are imperative to optimize the clinical management of MDR-TB. Evidence suggests[4] that treatment outcomes for multidrug-resistant tuberculosis (MDR-TB) under Pakistan's Programmatic Management of Drug-Resistant TB (PMDT) remain suboptimal, largely due to delays in diagnosis, poor adherence to treatment regimens, and insufficient monitoring throughout the therapeutic course. Furthermore, the emergence of fluoroquinolone-resistant Mycobacterium tuberculosis strains has been documented[5], posing additional challenges to therapeutic efficacy and underscoring the urgent need for robust management strategies to address these resistant phenotypes.

One of the most significant issues in the management of MDR-TB is Extensively Drug-Resistant Tuberculosis (XDR-TB), which has resistance to both first- and second-line drugs, including Fluoroquinolones (FQ) and Injectable Agents (IA). Research indicates that the global burden of XDR-TB cases is on the rise, particularly in patients with history of previous treatment for MDR-TB.[6] The results indi-

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cate the possibility of fast detection of resistance in TB patients and personalised treatment strategies for preventing XDR-TB. Considering these facts, knowledge about the patterns of drug resistance and its effect on treatment outcomes is crucial[7], particularly in low-resource areas such as Swat, where newer drugs and diagnostic tests are not available.

MDR-TB treatment generally requires second line drugs, which are less effective, more toxic and more expensive than first line drugs. A study showed that although medical conditions such as diabetes are common in patients, there is a negative impact on treatment outcomes when diabetes coexists with other medical conditions.[8] The problem in Pakistan is aggravated due to lack of availability of second line drugs, inadequate treatment compliance and poor compliance of PMDT guidelines.[1] This underscores the need for study of treatment outcomes and the understanding of local factors and challenges that contribute to the difficulties of MDR-TB management in Pakistan.

Treatment outcomes for multidrug-resistant tuberculosis (MDR-TB) are increasingly shaped by patient demographics, comorbid conditions, and evolving drug resistance. The influence of these factors is particularly pronounced in Swat, where limited access to healthcare exacerbates the challenges of effective management. Evidence indicates that regional variations in drug resistance and treatment efficacy constitute critical determinants for national TB control programs.[9] Recognition of these regional disparities is therefore essential to improving MDR-TB treatment outcomes in Pakistan.

Although the incidence of multidrug-resistant tuberculosis (MDR-TB) is rising in Pakistan, localized patterns of drug resistance and treatment outcomes in smaller regions remain insufficiently characterized. The Department of Pulmonology at Saidu Teaching Hospital, Swat, represents a key setting to investigate these dynamics, as it serves as a tertiary care centre and manages a substantial number of MDR-TB cases under the Program Management of Drug-Resistant TB (PMDT). The data on specific resistance profiles in this region particularly concerning fluoroquinolones, which are an escalating global concern[10] are limited. Comprehensive knowledge of local resistance patterns is essential to guide optimal therapeutic decision-making and improve patient outcomes.

The need for this study is based on the alarming situation of local epidemiology of MDR-TB and its effect on the treatment outcome in Swat. Several studies [4],[5] have suggested that local resistance patterns and factors that affect treatment adherence and outcomes play a major role in the success or failure of the treatment of MDR-TB. This is particularly important in areas with scarce medical facilities such as Swat. The present study has aimed to address this gap in knowledge; by looking at the pattern of drug resistance and treatment outcomes of MDR-TB patients enrolled under the PMDT at Saidu Teaching Hospital, Swat. The results of the study will help inform the development of better treatment strategies, considering the unique challenges of this region, and help inform policy changes to address the management of MDR-TB in Pakistan.

Objective:

To evaluate drug resistance patterns and treatment outcomes among patients with Multidrug-Resistant Tuberculosis (MDR-TB) enrolled in the Programme for Management of Drug-Resistant Tuberculosis (PMDT) at Saidu Teaching Hospital, Swat, Pakistan. A secondary objective was to identify determinants of poor treatment outcomes and to assess the impact of fluoroquinolone resistance.

Methodology:

This retrospective study was conducted at the designated DR-TB treatment centre; Department of Pulmonology, Saidu Teaching General Hospital, Swat, from May 21, 2014, to February 6, 2020. The study included a total of 166 MDR-TB patients enrolled under the PMDT program during study period. The sample size was calculated using the WHO formula, based on a previously reported prevalence of MDR-TB of 3.5% in the general population[4] at a 95% confidence level and a 5% margin of error. The study included a total of 166 MDR-TB patients enrolled under the PMDT program during the specified study period. A purposive sampling technique was employed, whereby all eligible patients meeting the inclusion criteria were selected. Although the WHO formula is commonly used for probability-based sample size estimation, in this study the sample size was determined by the number of MDR-TB patients available during the study period, guided by a previously reported prevalence of 3.5% in the general population.[4] Patient aged 4 years or above with confirm diagnosis of DR-TB based on phenotype drug susceptibility testing (DST) were included. Exclusion criteria comprised patients with incomplete treatment records, those previously treated for drug-resistant TB at other facilities, and individuals diagnosed with comorbid conditions likely to confound the analysis of DR-TB treatment outcomes.

Data Collection Procedure:

Data collection was conducted through the retrieval of patient records from the treatment centre that included information on drug resistance, demographic and clinical characteristics (including age, gender, and treatment history), drug susceptibility test results, and treatment outcomes. All data were systematically reviewed, and missing values were addressed to ensure transparency. Categorical variables were coded as 'Not Tested,' while continuous variables were imputed using the median. The study was carried out in strict compliance with the ethical and research guidelines of the Institutional Ethical & Research Committee. The primary variables assessed in this study were categorized as

demographic variables that include age, gender, and previous history of TB treatment; clinical variables that includes phenotypic drug susceptibility test (DST) results for first-line and second-line drugs (e.g., rifampicin, isoniazid, ethambutol), type of drug-resistant TB (e.g., MDR-TB, XDR-TB), while treatment outcomes was categorized according to PMDT definitions as cured, treatment completed, treatment failed, died, lost to follow-up, not evaluated, transferred out, or still under treatment.

Data analysis was performed using descriptive and inferential statistical methods. Descriptive statistics were used to summarise the demographic and clinical characteristics of the patients. For comparison between treatment outcomes and other categorical variables, chi-square tests were applied. For continuous variables, t-tests or ANOVA were used to determine significant differences. All statistics tests were performed using a 5% significance level. Data: SPSS or other equivalent software was used.

Results:

A total of 166 patients with diagnosis of MDR-TB were included in this retrospective study. These patients were referred to Programmatic Management of Drug-Resistant Tuberculosis (PMDT) in a Swat tertiary care teaching hos-

pital. There were 88 females (53%) and 78 males (47%) with ages from 4 to 79 years. Patients' mean age was 31.08 ±14.7 years; median age was 27 years and the interquartile range 20-37 years Table 1 shows the demographic distributions and treatment outcomes. Results of treatment were varied, with majority of patients cured (130, 78.3%). Failure, death, loss to follow-up (LTFU) or transfer-out were experienced by the remaining patients.

Table No1: Demographic Details of MDR-TB Patients.

Demographic Factor	Frequency (n) (%)
Age	
Mean (± SD)	31.08±14.7
Gender	
Female	88 (53%)
Male	78 (47%)

The study assessed the drug resistance patterns among the MDR-TB patients using phenotypic drug susceptibility testing (DST). Rifampicin resistance was seen in 50 (30.1%) patients while 52 (31.3%) were resistant to Isoniazid. In 25 (15.1%) patients' resistance to fluoroquinolones, specifically Levofloxacin (Lfx) and Moxifloxacin (Mfx) was observed. The other drugs, Ethambutol (E) and Pyrazinamide (Z), were also tested. Overall resistance pattern to first line and second line drugs (according to WHO grouping) is mentioned in Table 3.

Table No 2: The treatment outcomes of the MDR-TB patients.

Drug Resistance	Frequency (n) (%)
Rifampicin (R)	50 (30.1%)
Isoniazid (H)	52 (31.3%)
Ethambutol (E)	23 (13.8%)
Pyrazinamide (Z)	28 (16.9%)
Levofloxacin (Lfx)	15 (9%)
Moxifloxacin (Mfx)	10 (6%)
Amikacin (Am)	3 (1.8%)
Kanamycin (Km)	4 (2.4%)

Table No 3: Treatment Outcomes of MDR-TB Patients

Treatment Outcome	Frequency (n) (%)
Cured	130 (78.3%)
Died	15 (9%)
Lost to follow up	13 (7.8%)
Transfer out	3 (1.8%)
Not Evaluated	2 (1.2%)
Failed	2 (1.2%)
Still under treatment	1 (0.6%)

The treatment outcomes of the MDR-TB patients were categorized as cure, failure, death, lost to follow-up (LTFU) and transfer out.

Majority of patients were cured (130, 78.3%), 15 (9%) patients died, 13 (7.8%) patients were lost to follow up and 3 (1.8%) patients were transferred out. 2 (1.2%) patients were not evaluated, 2 (1.2%) failed treatment, and 1 (0.6%) patient was still under treatment. These results are presented in Table 4.

We also assessed factors associated with poor outcomes; chi-square tests were performed to examine the relationship between gender, drug resistance (including Rifampicin), and treatment outcomes. The chi-square statistic for gender was 11.69 with a p-value of 0.069, indicating no significant association between gender and treatment outcomes. The effect of Rifampicin resistance (R) on treatment outcomes, however, was significant, with a chi-square statistic of 167.80 and a p-value of <0.00001, indicating a strong association of drug resistance with poor treatment outcomes, such as treatment failure, mortality and loss to follow-up. The results of the chi square test for gender, and Rifampicin resistance against the treatment outcome respectively are summarized in table no 5 and 6

Table No 4: Chi-Square Test for Gender and Treatment Outcome.

Treatment Outcome	Female (n = 88)	Male (n = 78)	Total (n = 166)
Cured	65 (73.9%)	65 (83.3%)	130 (78.3%)
Died	9 (10.2%)	6 (7.7%)	15 (9%)
Lost to follow up	7 (8%)	6 (7.7%)	13 (7.8%)
Transfer out	2 (2.3%)	1 (1.3%)	3 (1.8%)
Not Evaluated	1 (1.1%)	1 (1.3%)	2 (1.2%)
Failed	2 (2.3%)	0 (0%)	2 (1.2%)
Still under Tx	1 (1.1%)	0 (0%)	1 (0.6%)
Chi-Square (p-value) 11.69 (0.069)			

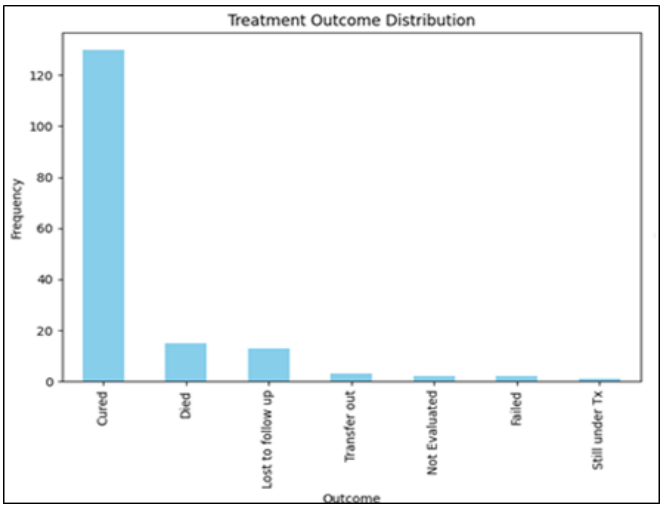
Table No 5: Chi-Square Test for Rifampicin Resistance and Treatment Outcome.

Rifampicin Resistance	Cured (n = 130)	Died (n = 15)	Lost to follow up (n = 13)	Transfer out (n = 3)	Not Evaluated (n = 2)	Failed (n = 2)	Still under Tx (n = 1)	Total (n = 166)
Sensitive	98 (75.4%)	8 (53.3%)	6 (46.2%)	1 (33.3%)	1 (50%)	2 (100%)	0 (0%)	116 (69.9%)
Resistant	32 (24.6%)	7 (46.7%)	7 (53.8%)	2 (66.7%)	1 (50%)	0 (0%)	1 (100%)	50 (30.1%)
Chi-Square (p-value) 167.80 (<0.00001)								

The study further examined the impact of fluoroquinolone resistance (specifically to levofloxacin [Lfx] and moxifloxacin [Mfx]) on treatment outcomes. A total of 25 patients (15.1%) were identified as resistant to fluoroquinolones. The chi-square test revealed a highly significant association between fluoroquinolone resistance and adverse treatment outcomes, with a chi-square statistic of 62.4 and a p-value <0.00001. This finding indicates that fluoroquinolone resistance was strongly linked to poor outcomes, including death, treatment failure, and loss to follow-up. The results are illustrated in bar charts: Figure 1 depicts the distribution

of treatment outcomes (cured, died, lost to follow-up, transferred out).

Figure No 1: Treatment Outcome Distribution.



Discussion:

The primary aim of this study was to assess the drug resistance patterns and treatment outcomes of MDR-TB patients enrolled in the PMDT. Among 166 patient's majority cured (78.3%), which reflects the effectiveness of the treatment regimens in place. The study identified high resistance to Rifampicin and Isoniazid, with resistance to Fluoroquinolones being observed in 15.1% of patients. These results are in line with previous study reporting high resistance rates in Pakistan.[7] The study also found a strong association between Rifampicin resistance and poor treatment outcomes, such as failure, death, and loss to follow-up. Additionally, fluoroquinolone resistance was found to significantly compromise treatment success, a finding consistent with global research reports.[6] This study makes an original contribution to understanding MDR-TB treatment outcomes in Pakistan, particularly in Swat, where research on local drug resistance patterns and PMDT effectiveness remains scarce. While numerous studies on MDR-TB have been conducted globally, few have explored regional variations in resistance patterns and treatment outcomes within Pakistan. Existing literature is largely confined to national level data or studies from major urban centres, leaving rural contexts underrepresented. By focusing on Swat, a region with limited healthcare infrastructure, this study addresses that gap and provides novel insights. The findings have important implications for local healthcare planning and the development of tailored treatment strategies in resource-constrained settings.

The resistance levels seen in this study were comparable to those found in other studies, both national and international, including the United States and Europe,[4,5] while the level of successful treatment outcome are seemingly lower in this study. This is probably because of the disparity in health system infrastructure, access to diagnostics and treatment in Pakistan as compared to the US and Europe. The results of this study emphasize the importance of a more personalized approach to MDR-TB treatment, especially in rural areas such as Swat, where patients are likely to encounter numerous challenges, including delayed diagnosis, access to newer drugs, and treatment adherence.[8] Globally, studies have shown that the most common resistances in MDR-TB cases are to Rifampicin and Isoniazid, which is consistent with the findings of this study. A research noted similar resistance patterns in countries like South Africa and India, where the MDR-TB burden is similarly high.[3,5] The resistance to Fluoroquinolones is also a growing concern globally, with studies such as study highlighting the role of fluoroquinolone resistance in treatment failure.[6] However, the prevalence of Fluoroquinolone resistance observed in this study (15.1%) is slightly lower than reported in other countries, which could be due to differences in treatment regimens and the emergence of newer drugs in the global market.[10]

The prevalence of drug-resistant TB in Pakistan is well documented in published studies. A study found that Rifampicin resistance was a significant predictor of poor treatment outcomes, which aligns with the findings of this study.[11] Similarly, a study reported similar resistance patterns in MDR-TB patients treated in urban centres.[12] But with more advanced healthcare facilities, which may contribute to better treatment outcomes compared to rural areas like Swat.

Research on drug resistance patterns and treatment outcomes in MDR-TB has been extensively reported in high-burden countries such as India, South Africa, and Brazil. For instance, a study conducted in South Africa demonstrated that fluoroquinolone resistance was a major predictor of poor treatment outcomes, including higher mortality rates and treatment failures.[5] This finding is consistent with the present study, which also identified fluoroquinolone resistance as strongly associated with adverse outcomes. Similarly, research from India reported high levels of resistance to rifampicin and isoniazid, with treatment success rates varying significantly depending on patient adherence to therapy.[4] A major distinction, however, is that while second-line drugs and newer treatment regimens are available in countries such as India, South Africa, and Brazil, they remain largely inaccessible in Pakistan. Agents such as Bedaquiline and Delamanid have demonstrated effectiveness in improving MDR-TB outcomes in high-income settings,[6] yet their use in resource-limited regions like Swat, Pakistan, has been constrained by unavailability and prohibitive costs.

Studies related to MDR-TB have been conducted in some urban centres in Pakistan like Karachi and Lahore, but there is limited research on the rural areas of Pakistan such as Swat. The majority of studies available are national or urban based, where access to health care is greater. This gap of the literature makes this study relevant because it offers a glimpse into the unique experience of MDR TB patients in rural Pakistan where health care access is often limited, and the treatment outcomes are often poorer.

In a study, the treatment outcomes of MDR-TB patients in Limpopo, South Africa, were analysed.[13] This study found that the success rates were lower in regions with inadequate diagnostic facilities and limited access to second-line drugs, which is a challenge faced by patients in rural Pakistan as well. There are several studies conducted in Pakistan that address MDR-TB, including the research, which highlights the increasing burden of drug-resistant TB in the country.[11,14] These studies have emphasised the need for improved treatment regimens, better diagnostic tools, and increased awareness among patients regarding adherence to their treatment schedules. However, these studies mainly focus on urban populations, and rural areas, such as Swat, have been largely under-represented in the literature.

MDR-TB has been well-documented in the local literature, especially in major cities like Karachi, Lahore, and Islamabad, where treatment facilities are more advanced. Studies such as those have provided detailed data on drug resistance patterns, including Rifampicin and Isoniazid resistance. [12,15] However, the lack of studies from rural areas makes this research highly significant, as it sheds light on the MDR-TB burden in less-developed regions of Pakistan, where treatment outcomes can vary due to multiple social, economic, and healthcare-related factors. The results of this study indicate that overall treatment outcomes in Swat are encouraging; however, several challenges remain. The high levels of resistance to rifampicin and isoniazid highlight the limited effectiveness of current first-line TB regimens for a substantial proportion of patients. The strong association between rifampicin resistance and poor outcomes mirrors findings from global studies, underscoring the urgent need for improved diagnostic tools and more effective treatment approaches. Furthermore, the observed impact of fluoroquinolone resistance emphasizes the necessity of exploring alternative therapeutic options, as resistance to existing second-line drugs continues to rise.

Study Limitations and Future Directions:

This study provides valuable insights into the MDR-TB situation in Swat; however, certain limitations must be acknowledged. Key data such as patient adherence and comorbidities were not comprehensively documented, which may have influenced treatment outcomes due to the retrospective design. In addition, the absence of follow-up information for patients lost to follow-up makes it difficult to fully assess the extent of treatment failure. Future research should adopt prospective designs to capture detailed patient histories, adherence patterns, and access to second-line drugs. Moreover, the evaluation of newer agents such as Bedaquiline in Pakistan is essential to determine their feasibility and effectiveness in resource-limited settings. Despite these limitations, this study bridges a crucial gap in knowledge regarding MDR-TB in rural Pakistan and offers evidence that can inform local treatment strategies and healthcare policies. The findings underscore the urgent need for improved diagnostic capacity, greater access to second-line drugs, and enhanced patient education to strengthen adherence and ultimately improve treatment success.

Conclusion:

This study highlights the critical issue of drug resistance among MDR-TB patients in Swat, particularly to rifampicin, isoniazid, and fluoroquinolones. The findings underscore the urgent need for improved diagnostic strategies, stronger medication adherence, and enhanced healthcare services, especially in rural areas. Larger multicentre investigations are warranted to validate these results and to strengthen local treatment approaches.

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Authors' Contribution	
Ajmal Khan	Study concept and design, patient enrollment, clinical data collection and interpretation, manuscript writing.
Hasnain Arif	Clinical assessment, data collection, literature review, critical revision of manuscript.
Akhtar Ali Khan	Study supervision, methodological guidance, interpretation of findings, critical review and final approval of manuscript.
Khalid Jamal	MDR-TB program coordination, patient follow-up, clinical data management, manuscript revision.
Atiq Ullah	Data organization, literature search, statistical support, manuscript editing and revision
Ashbala Khan	Data collection assistance, literature review, manuscript formatting.