**Treatment Outcome of Tuberculosis Patients Under Directly Observed Treatment Short Course and its Determinants in Shangla, Khyber-Pakhtunkhwa, Pakistan: A Retrospective Study**

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**Abstract**

**Background:** Tuberculosis (TB) is one of the leading causes of morbidity and mortality in Pakistan. Assessment of TB treatment outcomes, monitoring and evaluation of its risk factors in Directly Observed Treatment Short Course (DOTS) are among the major indicators of the performance of a national TB control program. Even though Pakistan ranks 5th among the 22 high-TB burden countries, there are no available data in this regard. **Methods:** Institution-based retrospective study was conducted to determine the treatment outcome of TB patients and investigate associated risk factors at District Head Quarter Hospital Shangla, Khyber-Pakhtunkhwa, Pakistan. Two-year record (January 2011 to December 2012) of TB clinic of the hospital was reviewed. A total of 493 patients’ complete information was reviewed in the study period. **Results:** Of these, 42.19% were smear-positive pulmonary TB (PTB), 35.09% were smear-negative PTB, and 22.72% were extra-PTB (EPTB). The overall prevalence of smear-positive PTB was 42.19% (95% confidence interval [CI]: 37.9–46.2). Records of the treatment outcome showed that 192 (38.94%) were cured, 276 (55.98%) completed treatment, 13 (2.6%) defaulted, 9 (1.8%) died, 1 (0.2%) treatment failure, and 1 (0.2%) had transferred to other facilities. The overall mean treatment success rate of the TB patients was 94.93%. TB age and TB form or baseline smear were significantly associated with unsuccessful treatment outcome. The risk of unsuccessful outcome was significantly lower among TB patients age <14 years (Adjusted odds ratio [AOR] = 0.118, 95% CI: 0.022–0.644), and PTB (smear positive: AOR = 0.125, 95% CI: 0.023–0.669; Smear negative: AOR = 0.024, 95% CI: 0.003–0.205) compared to their counterpart. **Conclusion:** The treatment success rate was high and match the World Health Organization criteria. To sustain the effective implementation of DOTS in the area, effective management, and diagnosis should be given for EPTB.

**Keywords:** Directly observed treatment short course, Pakistan, treatment outcome, tuberculosis

**INTRODUCTION**

Tuberculosis (TB) is considered a disease of poverty. The prevalence of TB is high in low-income countries than developed nations. According to the global report from the World Health Organization (WHO); among the 22 high TB-burden countries in the world, Pakistan ranks fifth. Majority of the new cases (60%) of TB in the world are attributable to India, Indonesia, China, Nigeria, Pakistan, and South Africa. The global progress of TB prevention depends on major advances in TB prevention and care in these countries. The incidence of TB (includes HIV + TB) in
Pakistan was 270 (175–386) per 100,000 population according to 2016 WHO report.[2] Pakistan is also facing a challenge of growing number of multidrug-resistance TB (MDR-TB) annually.[3] The incidence of MDR/RR-TB in the country was 14 (8.5–19) per 100,000 populations according to the latest WHO report.[3] However, low case registration is also observed. According to statistic of the National TB control programme, in the year 2013, approximately 12,997 drug-resistant TB cases were reported, of the total registered cases only 1570 (13%) cases were enrolled for the treatment. This low number of enrollment for treatment is a major factor to spread the disease more frequently in the country and is considered a serious threat for the control and elimination of TB.[4,5] In Pakistan, the rate of MDR-TB varies from 2.3% in untreated individuals and 17.9% in individuals who have been previously treated for TB, which is an alarming signal for the country.[6]

Pakistan is listed among countries with high prevalence of TB; the availability of Directly Observed Treatment Short Course (DOTS) services provides a good foundation for the initiation and expansion of TB control strategies in Pakistan.[7] However, there is a dearth of epidemiological data regarding TB in the country, especially in the province of Khyber-Pakhtunkhwa. Literature search revealed that no such study was carried out in district Shangla of Khyber-Pakhtunkhwa. Accordingly, the current study was designed to determine treatment outcome and factors affecting treatment outcome of TB.

**METHODS**

**Study participants**

Included all suspected TB patients, registered at DHQ hospital, Shangla, from January 2011 to December 2012.

**Study design**

A hospital-based retrospective study was designed.

**Inclusion and exclusion criteria**

Suspected individuals of TB who were enrolled at DHQ hospital, Shangla, from January 2011 to December 2012 were included in the study, whereas patients of TB who enrolled in private or other government health centers of the entire district were excluded from the study.

**Main outcome**

In the present study, main outcome of interest was treatment success rate of all types of TB patients.

**Data collection**

For data collection, data collection tool was designed based on the variables including both dependent and independent. Data were collected from the secondary source of TB patients registration record. Variables of interest were gender, age, type of TB (i.e., the record showed that the patients was either smear-positive pulmonary TB [PTB], smear-negative PTB, and extra-PTB [EPTB]) as independent variables, whereas outcome variables were treatment outcome (i.e., the record showed that the patient was either cured, treatment completed, died, treatment failure, treatment after default, transfer out, and no record) and treatment success (i.e., the record showed that the patient was either cured and treatment completed).

**Data processing and statistical analysis**

After collecting the data, data were organized and arranged categorically. The data were presented in the form of tables. The data were entered in Microsoft Excel sheet, cleaned, and analyzed using statistical package for the social sciences (SPSS) software (IBM SPSS Statistics Version 20, IBM, USA, 2011) for Windows. Descriptive statistics was determined including frequencies and percentage. To check the significant association between dependent and independent variables odds ratio with 95% confidence interval (CI) was used using binary and multivariate logistic regression model. $P < 0.05$ was considered as statistically significant.

**Ethical consideration**

The study protocol was reviewed and approved by the Institution Ethical Review Board of Department of Microbiology, Hazara University Mansehra, Pakistan. A formal letter was written from Department to the Medical Superintendent of DHQ hospital, Shangla, for conducting the study.

**RESULTS**

In the current study, a total of 493 cases of registered TB patients were included, of which (52.5%) were males and (47.5%) were females. The sex distribution of patients, age distribution of patients, and distribution of patients according to form of TB are shown in Table 1.

| Variable          | Frequency (%) |
|-------------------|---------------|
| Sex               |               |
| Male              | 259 (52.5)    |
| Female            | 234 (47.5)    |
| Age               |               |
| 0-14              | 178 (36.1)    |
| 15-30             | 122 (24.7)    |
| 31-45             | 93 (18.9)     |
| 46-60             | 67 (13.6)     |
| >60               | 33 (6.7)      |
| Form of TB        |               |
| Smear-positive PTB| 208 (42.2)    |
| Smear-negative PTB| 173 (35.1)    |
| EPTB              | 112 (22.7)    |
| Patient category  |               |
| New               | 461 (93.5)    |
| Relapse           | 20 (4.1)      |
| Failure           | 1 (0.2)       |
| Default           | 2 (0.4)       |
| Transfer in       | 9 (1.8)       |
| Treatment year    |               |
| 2011              | 238 (48.3)    |
| 2012              | 255 (51.7)    |

Table 1: Characteristics of the study participants attending directly observed treatment short course services at District Head Quarter Hospital, Shangla (2011-2012)
Ahmad, et al.: Treatment outcome of tuberculosis at Shangla, Pakistan

International Journal of Mycobacteriology | Volume 6 | Issue 4 | October-December 2017

**Table 2: Treatment outcomes of tuberculosis patients attending directly observed treatment short course services at District Head Quarter Hospital, Shangla (2011-2012), n (%)**

| Variables                          | Cured | Treatment completed | Died | Treatment failure | Treatment default | Transfer out | No record | Total |
|------------------------------------|-------|---------------------|------|-------------------|-------------------|--------------|-----------|-------|
| **TB patients category**           |       |                     |      |                   |                   |              |           |       |
| New                                | 174 (37.74) | 265 (57.48) | 7 (1.52) | 1 (0.22) | 12 (2.6) | 1 (0.22) | 1 (0.22) | 461   |
| Relapse                            | 15 (75)  | 2 (10)              | 2 (10) | 0                 | 1 (5)             | 0            | 0         | 20    |
| Failure                            | 1 (100) | 0                   | 0     | 0                 | 0                 | 0            | 0         | 1     |
| Default                            | 0       | 2 (100)             | 0     | 0                 | 0                 | 0            | 0         | 2     |
| Transfer in                        | 2 (22.22) | 7 (77.78) | 0     | 0                 | 0                 | 0            | 0         | 9     |
| **Types of TB**                    |       |                     |      |                   |                   |              |           |       |
| PTB positive                       | 191 (91.83) | 6 (2.88) | 4 (1.92) | 0                 | 5 (2.4) | 1 (0.48) | 1 (0.48) | 208   |
| PTB negative                       | 0       | 172 (99.42) | 0     | 0                 | 1 (0.58) | 0            | 0         | 173   |
| EPTB                               | 1 (0.89) | 98 (87.5) | 5 (4.46) | 1 (0.89) | 7 (6.25) | 0            | 0         | 112   |
| **Age (years)**                    |       |                     |      |                   |                   |              |           |       |
| 0-14                               | 22 (12.36) | 149 (83.71) | 2 (1.12) | 1 (0.56) | 4 (2.25) | 0            | 0         | 178   |
| 15-30                              | 63 (51.64) | 57 (46.72) | 0     | 0                 | 2 (1.64) | 0            | 0         | 122   |
| 31-45                              | 48 (51.61) | 39 (41.94) | 2 (2.15) | 0                 | 3 (3.23) | 0            | 1 (1.08) | 93    |
| 46-60                              | 40 (59.7)  | 20 (29.85) | 4 (5.97) | 0                 | 3 (4.48) | 0            | 0         | 67    |
| >60                                | 19 (57.58) | 11 (33.33) | 1 (3.03) | 0                 | 1 (3.03) | 1 (3.03) | 0         | 33    |
| **Gender**                         |       |                     |      |                   |                   |              |           |       |
| Male                               | 100 (38.61) | 141 (54.44) | 6 (2.32) | 1 (0.39) | 9 (3.47) | 1 (0.39) | 1 (0.39) | 259   |
| Female                             | 92 (39.31) | 135 (57.69) | 3 (1.280) | 0            | 4 (1.71) | 0            | 0         | 234   |
| **Baseline smear results**         |       |                     |      |                   |                   |              |           |       |
| Positive PTB                       | 208 (42.2) | 197 (94.7) | 197 (94.7) | 0.425 (0.184-0.983)* | 0.125 (0.023-0.669)* | 0.125 (0.023-0.669)* | 1       |
| Negative PTB                       | 173 (35.1) | 172 (99.4) | 172 (99.4) | 0.044 (0.006-0.344)* | 0.024 (0.003-0.205)* | 0.024 (0.003-0.205)* | 1       |
| EPTB                               | 112 (22.7) | 99 (88.4)  | 99 (88.4) | 1                 | 1                 | 1             | 1         | 1     |
| **Year**                           |       |                     |      |                   |                   |              |           |       |
| 2011                               | 97 (40.75) | 130 (54.62) | 6 (2.52) | 1 (0.42) | 4 (1.68) | 0            | 0         | 238   |
| 2012                               | 95 (37.25) | 146 (57.25) | 3 (1.18) | 0                 | 9 (3.53) | 1 (0.39) | 1 (0.39) | 255   |

**Table 3: Factor associated with treatment success rate of tuberculosis in DHQ Hospital, Shangla, (2011-2012)**

| Characteristics                  | Total number of cases (%) | Number (%) with successful outcome | COR (95% CI) | AOR (95% CI) |
|----------------------------------|---------------------------|------------------------------------|--------------|--------------|
| **Age (years)**                  |                           |                                     |              |              |
| 0-14                             | 178 (36.1)                | 171 (96.1)                          | 0.409 (0.100-1.672) | 0.118 (0.022-0.644)* |
| 15-30                            | 122 (24.7)                | 120 (98.4)                          | 0.167 (0.027-1.042) | 0.183 (0.027-1.257) |
| 31-45                            | 93 (18.9)                 | 87 (93.5)                           | 0.690 (0.162-2.930) | 0.611 (0.131-2.845) |
| 46-60                            | 67 (13.6)                 | 60 (89.6)                           | 1.167 (0.282-4.835) | 1.190 (0.267-5.304) |
| >60                              | 33 (6.7)                  | 30 (90.9)                           | 1             | 1            |
| **Gender**                       |                           |                                     |              |              |
| Male                             | 259 (52.5)                | 241 (93.1)                          | 2.422 (0.993-5.908) | 1.897 (0.73-4.901) |
| Female                           | 234 (47.5)                | 227 (97.0)                          | 1             | 1            |
| **Baseline smear results**       |                           |                                     |              |              |
| Positive PTB                     | 208 (42.2)                | 197 (94.7)                          | 0.425 (0.184-0.983)* | 0.125 (0.023-0.669)* |
| Negative PTB                     | 173 (35.1)                | 172 (99.4)                          | 0.044 (0.006-0.344)* | 0.024 (0.003-0.205)* |
| EPTB                             | 112 (22.7)                | 99 (88.4)                           | 1             | 1            |
| **Year**                         |                           |                                     |              |              |
| 2011                             | 238 (48.3)                | 227 (95.4)                          | 0.834 (0.371-1.876) | 1             |
| 2012                             | 255 (51.7)                | 241 (94.5)                          | 1             | 1            |
| **Patients category**            |                           |                                     |              |              |
| New                              | 461 (93.5)                | 439 (95.2)                          | 0.484 (0.137-1.714) | 1             |
| Other                            | 32 (6.5)                  | 29 (90.6)                           | 1             | 1            |

*Significantly associated. COR: Conditional odds ratio, AOR: Adjusted odds ratio, CI: Confidence interval, TB: Tuberculosis, EPTB: Extrapulmonary TB, PTB: Pulmonary TB, 1: Reference

females, at DHQ Hospital, Shangla, Khyber-Pakhtunkhwa, Pakistan, during the 2-year period from 2011 to 2012. Of the total cases, 42.2% were smear-positive PTB, 35.1% smear-negative PTB, and 22.7% EPTB. In total, 36.11% of TB cases were reported in ages 15–30 years. In terms of patient’s recruitment, 93.5% patients were identified as new cases.
and 4.1% were relapse. Higher number of cases 51.7% were reported in 2012 than 2011 [Table 1].

In terms of treatment outcome, 192 (39.0%) were cured, 276 (56.0%) treatment completed, 9 (1.8%) died, 1 (0.2%) had treatment failure, 13 (2.6%) defaulted, and 1 (0.2%) transferred out. The death rate declined slightly from 2011 to 2012. On the other side, default rate increased in 2012 from 2011. The treatment success in all type of TB cases was slightly decreased in 2012 than 2011 [Table 2].

After adjusting for potential predating factors for unsuccessful treatment outcome, the result reveals a lower treatment unsuccessful among 0–14-year-old study participants (Adjusted odds ratio [AOR] 0.118, [95% CI, 0.022–0.644]) comparing to > 60 years old. Furthermore, there is lower treatment unsuccessful among patients with smear-positive PTB AOR 0.125, (95% CI, 0.023–0.669) and smear-negative PTB (AOR 0.024, [95% CI, 0.003–0.205]) compared to EPTB [Table 3].

**Discussion**

The current study provides information about treatment outcomes of TB and associated risk factors during 2011–2012 at DHQ Hospital, Shangla. In the present study, a total of 493 TB patients were registered, of which 52.5% were male and 47.5% were female. High number of cases of all the forms of TB were recorded in males, though there was no statistically significant difference when compared to cases recorded in female participants of the study. The 2016 global TB report indicates that TB incidence is equally distributed between males and females Pakistan-wide. Our results agree with the previous studies; Sunday et al.[9] reported a high number of cases in males (60.0%), likewise in a study conducted by Ahmad et al.[9] at Chakdara Town, Dir (Lower), Pakistan, reported high number of cases of TB in males. Likewise, from other regions similar reports have been documented; the studies conducted in South Ethiopia and Gambella Regional Hospital, Western Ethiopia, notified high number of cases in male patients 55.8% and 54.5%, respectively.[9,10] Similarly, Adejumo et al.[11] and Ahmad et al.[12] reported a higher proportion of males 59.9% and 50%, respectively, among identified cases of TB in Lagos, Nigeria, and Karachi, Pakistan, respectively. The present study finding is in contrast with some other studies.[13-16]

In the current study, overall prevalence of smear-positive PTB was reported as 42.19% (95% CI: 37.9–46.2), which is similar to other studies. The previous studies conducted in nearby areas of the study area i.e District Dir (lower),[13] Dargai, District Malakand,[14] and Barikot Swat, Pakistan,[15] reported 44.41%, 40.08%, and 40.28% cases of smear-positive PTB, respectively.[13-15] In addition, a study conducted in Ethiopia reported the prevalence of smear-positive PTB as 40.9%.[17] The overall mean treatment success rate of the TB patients was 94.93%. Patient age and TB form or baseline smear were significantly associated with unsuccessful treatment outcome. The risk of unsuccessful outcome was significantly lower among TB patients age <14 years (AOR = 0.118, 95% CI: 0.022–0.644), and PTB (Smear positive: AOR = 0.125, 95% CI: 0.023–0.669; Smear negative: AOR = 0.024, 95% CI: 0.003–0.205) comparing to EPTB.

Similarly, high treatment success rate was recorded in the previous studies.[15-18] On the other hand, in contrast to our study lower treatment success rate was reported in previously published international studies.[10,13,17,19-32]

According to our finding, the overall death rate was (1.83%), which decreased in the year 2012; this is in contrast to the report of Sisay et al.[17] that recorded a higher death rate of 3.9%. Overall default rate was 2.64%; over the study period an increase in the default rate was seen; this finding is in agreement with the earlier studies.[17] but highly contrasts with the findings reported by Ahmad et al.[12] that reported a default incidence of 42%. This may be due to weak smear follow-up, tracing mechanism, and low level of knowledge and awareness about infectious diseases among the local inhabitant of the study area. It is important to address defaulting and drop-out as it is one of the preventable factors responsible for DOTS failure.[33] Moreover, defaulters are usually at higher risk of increased morbidity and mortality and they also pose potential threats to the community as a whole.[33] In the present study, information about housing, occupation, education, and other sociocultural was not determined which may also affect the treatment outcome of TB patients.

**Conclusion**

The high treatment success rate was recorded and meets the WHO criteria. To sustain the effective implementation of DOTS in the area, effective management, and diagnosis should be stressed for EPTB.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

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