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Change in C-Reactive Protein Level with Anti-Tuberculosis Therapy in Patients with Pulmonary Tuberculosis

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ABSTRACT

Pulmonary tuberculosis is a widespread disease with high mortality and morbidity rates in developing countries, caused by Mycobacterium tuberculosis. However, there is limited information on how serum CRP levels relate to the severity of pulmonary tuberculosis. **Objective:** To determine the mean change in C-reactive protein with anti-tuberculosis therapy in patients with pulmonary tuberculosis. **Methods:** The quasi-experimental study was conducted at the Department of Pulmonology, Mayo Hospital, Lahore, from August 25, 2020, to February 25, 2021, enrolling 85 patients with pulmonary tuberculosis. A blood sample was obtained by using a 5cc disposable syringe under aseptic measures and stored in sterile vials for assessment of CRP level at baseline. Then all patients were given anti-tuberculosis therapy and followed up in OPD for 2 months. Change in CRP level was calculated. The data were analysed statistically by using SPSS version 25.0. A p-value ≤0.050 was taken as significant. **Results:** 60 (70.6%) were males, while 25 (29.4%) were females. Baseline levels of CPR were 60.15 mg/dl and 17.76mg/dl after 2 months; the mean change in CPR levels was 42.39mg/dl. The average change in CRP levels was 42.39 ± 21.52mg/dL (p-value<0.050). **Conclusions:** The results of the study showed a significant reduction in mean CRP levels before and after treatment with ATT. The patients with pulmonary tuberculosis had a high level of serum C-reactive protein (CRP), which implies that CRP can be used as an effective biomarker in the assessment of disease activity and treatment response.

INTRODUCTION

Tuberculosis (TB) remains a major global public health problem and is the second leading cause of death from infectious diseases worldwide after COVID-19. The World Health Organization (WHO) estimates that nearly two billion people have latent TB infection, and in 2021, TB caused approximately 1.6 million deaths globally, including 187,000 among people living with HIV [1, 2]. However, 22 countries with high burden carry more than 80% of the total number of cases, with Pakistan ranking 5th in the prevalence of TB and 4th in multi-drug-resistant TB (MDR-TB), and occurrence in the Eastern Mediterranean Region by the WHO [3]. A survey of the inventory of notified TB cases in Pakistan showed that out of all the diagnosed cases, only 32 percent were reported to the National Tuberculosis Control Program (NTP), and most of the cases were under-reported at 27 percent (Pakistan) [4]. National TB

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prevalence surveys are the most dependable way of estimating the disease burden and tracking epidemiological trends in most settings. Such surveys in Asia have shown that the prevalence of TB can be reduced significantly over a period of 10 years, with men being the most vulnerable and older age groups becoming the most affected in the disease burden [5]. Diagnostic biomarkers are a necessity in the treatment monitoring of TB. C-reactive protein (CRP), which is an acute-phase reactant and an element of innate immune response, has become a possible candidate [6]. It is crucial to measure treatment response among patients with pulmonary TB to determine the efficiency of therapy, detect resistance to the drug, and curb transmission of the disease. Traditional tests, namely sputum smear microscopy and culture, though informative, are time-consuming and time-lagging; therefore, there is a need to have dependable biomarkers that could offer rapid information on disease activity and treatment response [7]. A promising biomarker in the management of TB is C-reactive protein (CRP), an acute-phase reactant that is produced by the liver due to inflammation. The level of CRP has been very high in patients having active pulmonary TB and correlated with the severity of the disease and the degree of lung involvement [8]. Rapid CRP testing has also been found to be useful in the presumptive diagnosis of TB and the clinical progression of the disease in HIV-infected people during treatment [9]. Moreover, CRP concentrations are a measure of systemic immune reaction and have been utilized as a marker of airway inflammation in other respiratory diseases, including bronchial asthma [10]. Notably, research indicated that there is a marked decrease in the levels of CRP with the onset of anti-tuberculosis therapy, which is associated with clinical effect and the diminution of the total bacterial load [11]. This implies that serum CRP may be a simple, low-cost, and minimally invasive instrument to evaluate treatment response in pulmonary TB to be used in combination with microbiological and radiological tests. Nevertheless, the nature of CRP persists throughout the treatment, and its relationship with clinical and radiological patient outcomes is understudied in most groups, especially in high-burden, low-resource states [12].

C-reactive protein (CRP) is increasingly recognized as a useful biomarker for monitoring treatment response in pulmonary tuberculosis; however, evidence from Pakistan remains scarce. Given differences in disease burden, patient demographics, and healthcare infrastructure, locally generated data are essential to confirm its clinical utility. Establishing changes in CRP levels during anti-tuberculosis therapy may support timely disease monitoring, inform clinical decision-making, and improve patient outcomes. Therefore, this study aims to determine the mean change in serum CRP levels during anti-tuberculosis therapy in patients with pulmonary tuberculosis.

METHODS

This quasi-experimental research was performed at the Department of Pulmonology, Mayo Hospital, Lahore, from August 25, 2020, to February 25, 2021, after the ethical approval (Ref: CPSP/REU/PUL/-2019-062-522). A total of 85 patients were enrolled using non-probability consecutive sampling. The sample size was calculated with a 95% confidence level, absolute precision (d) of 1, and an expected mean change in CRP level of 38 ± 4.66 mg/dL, based on previous literature [13]. Patients aged 16 to 70 years of both genders presenting with pulmonary tuberculosis were included. C-reactive protein (CRP) was measured using a quantitative immunoturbidimetric assay on a Roche Cobas c311 automated chemistry analyzer (Roche Diagnostics, Mannheim, Germany) employing the CRP Latex reagent kit (Roche Diagnostics), according to the manufacturer's instructions. The normal reference range for CRP was <5 mg/L. Blood samples were obtained at two time points: at baseline before initiation of anti-tuberculosis therapy and after completion of the intensive phase of treatment (2 months). All patients received standard first-line anti-tuberculosis therapy, consisting of isoniazid, rifampicin, pyrazinamide, and ethambutol during the intensive phase, in accordance with national TB treatment guidelines. Pulmonary tuberculosis was defined by compatible clinical symptoms (cough >14 days, chest pain, shortness of breath, and fever ≥100°F) with microbiological confirmation by positive acid-fast bacilli (AFB) smear and GeneXpert detection of Mycobacterium tuberculosis. Patients were excluded if they were pregnant, had a Karnofsky Performance Status score <40 [14], tuberculous meningitis on CT scan, other infectious or inflammatory conditions, prior anti-tuberculosis treatment for ≥1 week, or antiretroviral therapy for <3 months, or fluoroquinolone use within the preceding 8 weeks. After obtaining informed consent, demographic and clinical information, including age, gender, BMI, history of diabetes mellitus (random blood sugar >186 mg/dL), smoking status (>5 pack-years), hypertension (BP ≥140/90 mmHg), and duration of symptoms, was recorded. A baseline blood sample was collected under aseptic conditions using a 5cc disposable syringe and sent to the hospital laboratory for CRP level measurement. All patients were started on standard anti-tuberculosis therapy and followed up after two months. A second blood sample was obtained and analyzed for CRP levels. The change in CRP was calculated as the difference between the baseline value (T0) and the value after two months of treatment (T2), i.e., CRP (T0) – CRP (T2). All data were recorded using a structured proforma.

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The analysis of data was done in SPSS version 25.0. The quantitative variables (age, BMI, symptom duration, CRP levels), whereas the categorical variables (gender, diabetes, smoking, hypertension) were presented as the mean ± SD and as frequencies, and percentages, respectively. Normality of data was assessed by Shapiro Wilk test, and then the changes in the level of CRP at the time of treatment and before the treatment were evaluated using a paired t-test (p≤0.050). They were stratified on the basis of age, gender, BMI, duration of the symptoms, diabetes, smoking, and high blood pressure. The independent t-test and one-way ANOVA were used to test CRP changes by stratification.

RESULTS

The study involved 85 patients with pulmonary tuberculosis, including 60 males (70.6%) and 25 females (29.4%) of the study population. The mean age was 46.34 ± 17.03 years. Most patients (56.5%) were aged above 45 years of age, then 24.7 aged 18-30 years, and 18.8 aged 31-45 years. In terms of comorbidity, 10 patients (11.8%) were hypertensive, and 10 (11.8%) patients had diabetes mellitus. Twenty-five (29.4%) patients indicated a history of smoking. According to body mass index (BMI), 51 patients (60.0%) were of normal body mass index, 33 patients (38.8%) were overweight, and one (1.2%) patient was obese. In terms of the duration of the symptoms, 33 (38.8%) patients said they lasted below one month, and 52 (61.2%) patients said they lasted above one month (Table 1).

Table 1: The Baseline and Demographic Characteristics of the Study Patients (n=85)

Variables	Category	Frequency (%)
Gender	Male	60 (70.6%)
	Female	25 (29.4%)
Age Group	18-30 Years	21 (24.7%)
	31-45 Years	16 (18.8%)
	>45 Years	48 (56.5%)
Hypertension	Yes	10 (11.8%)
	No	75 (88.2%)
Diabetes Mellitus	Yes	10 (11.8%)
	No	75 (88.2%)
Smoking Status	Yes	25 (29.4%)
	No	60 (70.6%)
Body Mass Index (BMI)	Normal	51 (60.0%)
	Overweight	33 (38.8%)
	Obese	1 (1.2%)
Duration of Symptoms	<1 Month	33 (38.8%)
	>1 Month	52 (61.2%)

The baseline CRP level was 60.15 ± 21.97mg/dl, which decreased to 17.76 + 4.05mg/dl after two months of anti-tuberculosis treatment. The average change in CRP levels was 42.39 ± 21.52mg/dL, which means that there is a significant decrease in systemic inflammation as a result of treatment (p-value<0.050) (Table 2).

Table 2: A comparison of C Reactive Protein (CRP) Levels Before and After Anti-Tuberculosis Therapy (n=85)

CRP Measurement	Baseline (mg/dL)	After 2 Months (mg/dL)	Mean Change (mg/dL)	p-value*
Mean ± SD	60.15 ± 21.97	17.76 ± 4.05	42.39 ± 21.52	<0.001

*p-value obtained with paired sample t-test. A p-value of less than 0.050 was found to be statistically significant

A stratification of change in levels of C-reactive protein (CRP) was conducted on different baseline characteristics to determine whether these were significantly affecting response to the treatment. The difference in the change of CRP level between males (43.36 ± 22.78 mg/dL) and females (40.04 ± 18.36 mg/dL) was not significantly different (p=0.520). The mean decrease in CRP levels was highest in the patients of age group 18-30 years (48.32 ± 24.76 mg/dl), then 31-45 years (41.06 ± 17.32 mg/dl), and over 45 years (40.23 ± 21.21 mg/dl), and the difference between age groups was not significant (p=0.347). The mean change in CRP of patients with hypertension was 43.18 + 26.02mg/dl, with no hypertension being 42.28 + 21.05mg/dl (p=0.902). Similarly, the difference in CRP reduction between diabetic (38.35 ± 18.47 mg/dL) and non-diabetic patients (42.92 ± 21.94 mg/dL) was not statistically significant (p=0.531). Smokers experienced a mean change of 41.58 ± 20.90 mg/dL compared to 42.72 ± 21.93 mg/dL in non-smokers, again with no significant difference (p=0.825). With respect to BMI, normal-weight individuals had a mean CRP reduction of 43.27 ± 21.97 mg/dL, overweight individuals 41.64 ± 21.12 mg/dL, and the single obese patient showed a reduction of 21.73 mg/dL; the overall comparison was not statistically significant (p=0.598). Finally, patients with symptom duration <1 month had a mean CRP change of 42.97 ± 19.45 mg/dL, while those with symptoms for >1 month showed a change of 42.01 ± 22.91 mg/dL (p=0.843). Overall, none of the baseline variables, including gender, age, hypertension, diabetes, smoking status, BMI, or symptom duration, showed a statistically significant effect on the change in CRP levels, indicating that the reduction in CRP following anti-tuberculosis therapy was consistent across these subgroups (Table 3).

Table 3: Stratification of Change in CRP Levels with Respect to Baseline Variables (n=85)

Variables	Category	Mean Change (mg/dL)	p-value*
Gender	Male	43.36 ± 22.78	0.520
	Female	40.04 ± 18.36	
Age Group	18-30 Years	48.32 ± 24.76	0.347
	31-45 Years	41.06 ± 17.32	
	>45 Years	40.23 ± 21.21	
Hypertension	Yes	43.18 ± 26.02	0.902
	No	42.28 ± 21.05	

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Diabetes Mellitus	Yes	38.35 ± 18.47	0.531
	No	42.92 ± 21.94	
Smoking	Yes	41.58 ± 20.90	0.825
	No	42.72 ± 21.93	
BMI	Normal	43.27 ± 21.97	0.598
	Overweight	41.64 ± 21.12	
	Obese	21.73 ± 18.91	
Duration of Symptoms	<1 Month	42.97 ± 19.45	0.843
	>1 Month	42.01 ± 22.91	

*p-values were obtained by an independent sample t-test or ANOVA. A p-value of less than 0.050 was taken as significant

DISCUSSION

The growing burden of multidrug-resistant (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) has drawn attention to tuberculosis, particularly in the context of antibiotic misuse [15-17]. These resistant forms significantly contribute to increased morbidity and mortality, highlighting the need for reliable, non-invasive biomarkers to monitor disease activity and treatment response. Moreover, TB-associated structural lung damage and reliance on invasive diagnostic and follow-up procedures increase the risk of secondary bacterial infections, further emphasizing the clinical value of C-reactive protein (CRP) as a simple inflammatory marker to assess treatment response and guide timely clinical decision-making [18]. Clinical symptoms of TB tend to be similar to those of other respiratory diseases, and hence, early diagnosis is not easy; thus, it usually takes too long to treat the disease before it becomes serious [19]. In the experiment, our results revealed that C-reactive protein (CRP) levels were significantly higher at the baseline among the patients with pulmonary tuberculosis (mean 60.15 ± 21.97 mg/dL). As an example, one study reported a significant reduction in CRP levels from a mean of 56.2 mg/dL to 8.6 mg/dL (p<0.001) [13], and another study showed a similar reduction of 60.71 ± 10.98 mg/dL to 22.71 ± 6.32mg/dL (p<0.001) [14]. This observation is in line with former studies reporting significantly elevated CRP levels in TB patients, particularly those who present with fever, dyspnea, tachypnea, hypotension, and respiratory distress [20]. Likewise, Kaminskaia et al. found that there is a close relationship between the extent of systemic intoxication and the CRP levels [21]. This study's data, however, did not find any significant correlation between CRP levels and the occurrence of hemoptysis, which agrees with the literature [22]. Notably, in current study, the study noted that there was a great improvement in CRP levels in two months of anti-tuberculosis therapy, whereby the baseline level of 60.15 ± 21.97mg/dL improved to 17.76 ± 4.05mg/dL after treatment. The statistical significance of the mean change in CRP was 42.39 ± 21.52mg/dl, which was significant (p<0.001). This trend of a progressive decline in CRP after treatment is similar to previous studies [23]. Furthermore, a study conducted by Githua *et al.* also indicated that CRP can be used as a reliable biomarker of treatment response in pulmonary tuberculosis [11].

No control, quasi-experimental design, small sample (n=85), short follow-up (2 months), no adjustment of confounding factors, two time points of CRP, no association with sputum conversion, non-probability sampling. Prospective cohorts with longer follow-ups, serial CRP measurements, and corruption of microbiological/radiological response, and validation of CRP as an inexpensive monitoring biomarker in Pakistani TB settings.

CONCLUSIONS

Our study revealed that patients with pulmonary tuberculosis have high serum CRP levels at baseline (mean 60.15 ± 21.97 mg/dL, p-value<0.001), which are likely to be normalized after successful treatment. This implies that CRP can be an effective biomarker to measure disease activity and treatment response.

Authors' Contribution

Conceptualization: SBK, HMFN, HKD, MZUA
Methodology: SBK, HMFN, MR, AH, MZUA
Formal analysis: SBK, HMFN, MR, HKD, AH, MZUA
Writing and Drafting: SBK, AH, MZUA
Review and Editing: SBK, HMFN, MR, HKD, AH, MZUA, SMF

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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