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# Clinical Recovery and Well-Being in Tuberculosis with Traditional Unani Adjuvant Therapy

**Azhar Jabin**

Associate Professor, Department of Moalajat, School of Unani Medical Education and Research (SUMER), Jamia Hamdard, New Delhi

## ABSTRACT

**Background:** Tuberculosis (TB) continues to pose a significant global health challenge despite the availability of effective chemotherapy. Prolonged treatment duration, drug-related adverse effects, delayed recovery, and the emergence of multidrug-resistant tuberculosis (MDR-TB) necessitate exploration of safe adjuvant therapies that enhance clinical recovery and improve patient well-being.

**Objective:** To evaluate the efficacy and safety of a traditional Unani formulation used as an adjuvant to standard anti-tubercular therapy (ATT) in patients with pulmonary tuberculosis.

**Methods:** A randomised, double-blind, placebo-controlled clinical study was conducted on pulmonary TB patients attending Majeedia Unani Hospital, New Delhi. Patients were allocated into two groups: the test group receiving ATT with Unani adjuvant formulation and the control group receiving ATT with a placebo. Clinical symptoms, microbial conversion, radiological changes, haematological indices, and biochemical safety parameters were assessed at baseline and during follow-up. Analysis of data was done as per statistical guidelines..

**Results:** Both groups demonstrated significant clinical improvement with ATT. However, the test group showed faster improvement in appetite and well-being, greater weight gain, improved haemoglobin levels, and more favourable trends in inflammatory markers at three months. Liver and renal function parameters remained within acceptable limits, indicating good tolerance of the Unani adjuvant.

**Conclusion:** The Unani formulation was found to be safe and showed potential benefits as an adjuvant to ATT by enhancing clinical recovery and patient well-being. Larger, multicentric trials are warranted to confirm these findings and explore their role in MDR-TB and high-risk populations.

**Keywords:** Tuberculosis, Unani medicine, adjuvant therapy, integrative health, clinical recovery

## 1. INTRODUCTION

Tuberculosis remains one of the most important infectious diseases worldwide and continues to be a major cause of morbidity and mortality, particularly in developing countries. Despite the availability of effective anti-tubercular chemotherapy, tuberculosis control is challenged by prolonged treatment regimens, adverse drug reactions, poor treatment compliance, relapse, and the rising burden of multidrug-resistant tuberculosis (MDR-TB) (1,2).. Multidrug-resistant tuberculosis, defined as resistance to at least isoniazid and rifampicin, requires

 

longer treatment durations with more toxic and expensive drugs and is associated with poorer clinical outcomes and higher mortality rates (3,4).

In addition to microbial eradication, tuberculosis is characterised by systemic manifestations such as fever, weight loss, anorexia, fatigue, anaemia, and generalised weakness, collectively described as tubercular toxaemia(5,6). These systemic effects significantly impair quality of life and delay return to normal social and occupational functioning. Even after microbiological cure, many patients experience prolonged convalescence due to persistent inflammation, immune dysregulation, and metabolic derangements (7–9).In recent years, there has been increasing interest in host-directed therapies that complement standard antimicrobial treatment by enhancing host immunity, reducing excessive inflammation, improving tolerance to chemotherapy, and accelerating clinical recovery (10,11). Traditional systems of medicine, including Unani medicine, have long emphasised holistic management of chronic diseases by strengthening the host, correcting systemic imbalance, and supporting functional recovery rather than focusing solely on pathogen elimination(12,13).

Unani medicine conceptualises chronic wasting diseases under entities characterised by derangement of temperament (Mizaj), accumulation of morbid humours, and loss of innate vitality (Quwwat)(14,15). Therapeutic strategies in Unani medicine focus not only on disease eradication but also on improving digestion, appetite, strength, and overall well-being. Several Unani formulations have been traditionally used as tonics, immunomodulators, and restorative agents in chronic debilitating illnesses (13).

Given the need for safe, affordable, and effective adjuncts to modern anti-tubercular therapy, the present study was undertaken to evaluate a traditional Unani formulation as an adjuvant to standard anti-tubercular treatment in patients with pulmonary tuberculosis, with special emphasis on clinical recovery, well-being, and safety.

## 2. MATERIALS AND METHODS

The present study was designed as a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of a Unani adjuvant formulation in patients with pulmonary tuberculosis. The study was conducted in the Department of Moalijat, Faculty of Medicine (Unani), Jamia Hamdard, in collaboration with MajeediaHospital, New Delhi. Patients diagnosed with pulmonary tuberculosis on the basis of sputum smear and/or culture positivity were screened for eligibility. Prior to enrollment, written informed consent was obtained from all participants. Newly diagnosed sputum-positive pulmonary tuberculosis patients aged between 18 and 60 years, who were willing to comply with the study protocol and follow-up schedule, were included in the study. Patients with known multidrug-resistant tuberculosis at baseline, severe hepatic or renal impairment, pregnancy or lactation, or severe comorbid illnesses requiring intensive medical care were excluded from the study.A total of 60 patients were initially enrolled in the study, of whom 44 completed the follow-up period. Forty patients, comprising 20 patients in each group, were included in the final analysis. Eligible patients were randomly allocated into two parallel groups using a simple randomization method. The test group (Group A) received standard anti-tubercular therapy as per World Health Organization guidelines along with a Unani adjuvant formulation

 

administered orally at a dose of 800 mg per day for a duration of up to three months. The control group (Group B) received standard anti-tubercular therapy along with a placebo identical in appearance and taste to the test formulation. The rest of the antitubercular drugs were continued to complete at least 6 - 8 months of therapy.Outcome measures included assessment of clinical, microbiological, radiological, haematological, and biochemical parameters. Clinical parameters such as fever, cough, appetite, body weight, and lethargy or sense of well-being were evaluated using standardised grading scales and visual analogue scores. Microbiological assessment was performed by sputum smear examination for acid-fast bacilli at baseline and at predefined follow-up intervals. Radiological evaluation was carried out using chest X-ray grading and assessment of lesion resolution.Haematological investigations included estimation of haemoglobin levels, total leukocyte count, differential leukocyte count, and erythrocyte sedimentation rate. Biochemical assessments comprised liver function tests, including serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, and serum bilirubin, as well as renal function tests such as blood urea and serum creatinine.Safety assessment was conducted through regular clinical monitoring and periodic laboratory investigations to detect any adverse drug reactions. Any adverse events observed or reported during the study period were documented and managed according to standard clinical practice.Statistical analysis of data was performed as per statistical guidelines.

## 3. RESULTS

The demographic characteristics of the study participants showed that both the test and control groups were comparable with respect to age, sex distribution, socioeconomic status, addiction history, and baseline disease severity. No statistically significant difference was observed between the groups at baseline, thereby ensuring homogeneity of the study population. Fever was a common presenting symptom in both groups at the time of enrollment, and a progressive reduction in mean body temperature was observed during the course of treatment in both groups. The pattern of defervescence was similar in the two groups, and no statistically significant intergroup difference was noted, indicating an expected response to standard anti-tubercular therapy. Severity of cough decreased progressively in both groups over the duration of therapy; although some patients in the test group appeared to show earlier symptomatic relief, the difference between the groups was not statistically significant.

Improvement in appetite was observed in both groups; however, the test group demonstrated significantly earlier recovery of appetite compared to the control group, particularly at the two and three month follow-up, suggesting faster resolution of systemic tubercular toxaemia. Both groups exhibited gradual weight gain during treatment, reflecting clinical recovery, with the test group showing a greater mean increase in body weight, indicative of improved metabolic recovery, although this difference did not attain statistical significance. A consistent improvement in subjective sense of well-being and reduction in lethargy was observed in both groups during follow-up, and the majority of patients achieved near-complete resolution of lethargy by the end of the study period.

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Sputum smear conversion occurred earlier in the test group, with a statistically significant difference observed at the three-month follow-up compared to the control group. By the end of treatment, sputum smear negativity was achieved in both groups, except in a few patients who exhibited delayed response. Radiological assessment revealed progressive resolution of pulmonary lesions in both groups, with a higher proportion of patients in the test group achieving marked or complete radiological clearance, indicating a favourable trend toward faster healing, although the difference was not statistically significant.

Hematological evaluation showed improvement in hemoglobin levels in both groups, with a significantly greater increase observed in the test group at three months. Erythrocyte sedimentation rate demonstrated a more pronounced decline in the test group, reflecting faster resolution of inflammatory activity, while total leukocyte count declined progressively in both groups and remained within normal physiological limits throughout the study. Biochemical safety assessment revealed mild elevations in liver enzymes in both groups during therapy, as expected with anti-tubercular treatment; however, values remained within acceptable limits. The test group showed a declining trend in serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, and serum bilirubin levels, whereas the control group demonstrated mild increases, particularly in serum bilirubin. Renal function parameters remained stable in both groups throughout the study period. The Figures A–Kprovide a comprehensive visual summary of the clinical, haematological, and biochemical trends observed in the study, clearly demonstrating a favourable recovery pattern and acceptable safety profile in the test group.

The trends in clinical parameters during treatment are illustrated in Fig. A–E. Improvement in lethargy and overall sense of well-being during follow-up is shown in Fig. A. Changes in body temperature observed during follow-up are shown in Fig. B, demonstrating a comparable progressive reduction in both the test and control groups. Improvement in cough severity over the treatment period is depicted in Fig. C, showing gradual symptomatic relief in both groups. Appetite scores over time are presented in Fig. D, highlighting earlier improvement in the test group. Progressive weight gain observed during therapy is illustrated in Fig. E, with a greater mean increase noted in the test group.

Haematological and biochemical changes observed during the study period are illustrated in Fig. F–K. Changes in haemoglobin levels during treatment are shown in Fig. F, demonstrating greater haematological recovery in the test group. The decline in erythrocyte sedimentation rate, reflecting resolution of inflammatory activity, is depicted in Fig. G. Trends in total leukocyte count during therapy are presented in Fig. H, showing progressive normalisation in both groups. Changes in serum bilirubin levels are illustrated in Fig. I, demonstrating a declining trend in the test group and a mild increase in the control group. Hepatic enzyme trends during treatment are shown in Fig. J and Fig. K, depicting changes in SGOT and SGPT levels, respectively, and indicating acceptable hepatic safety in both groups with favourable trends in the test group.

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### 3.1 Clinical Parameters Graphs

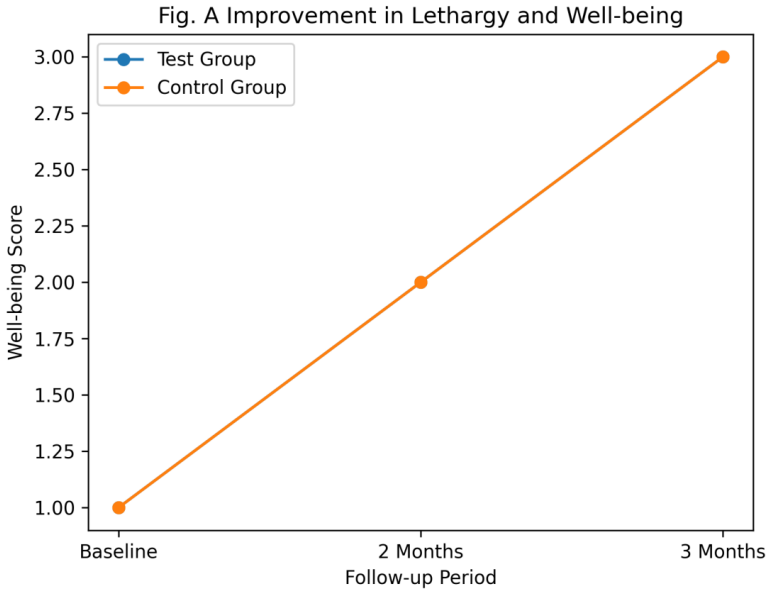


Fig. A. Improvement in Lethargy and Well-being

Mean well-being scores at baseline, 2 months, and 3 months in the Test Group (ATT + Unani adjuvant) and Control Group (ATT + placebo).

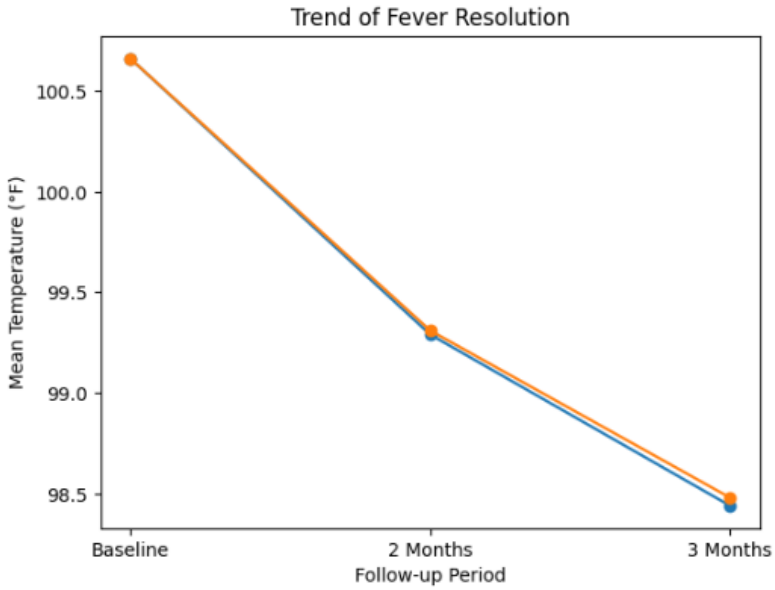


Fig. B. Change in Fever.

Mean body temperature during follow-up in both groups showing progressive reduction.

Fig. C. Change in Cough Severity:

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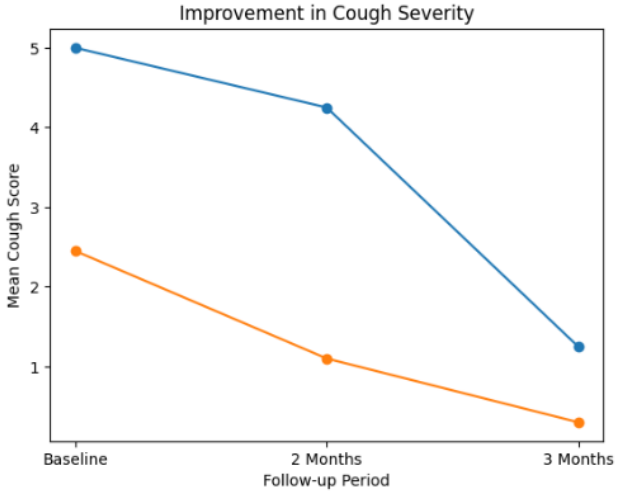
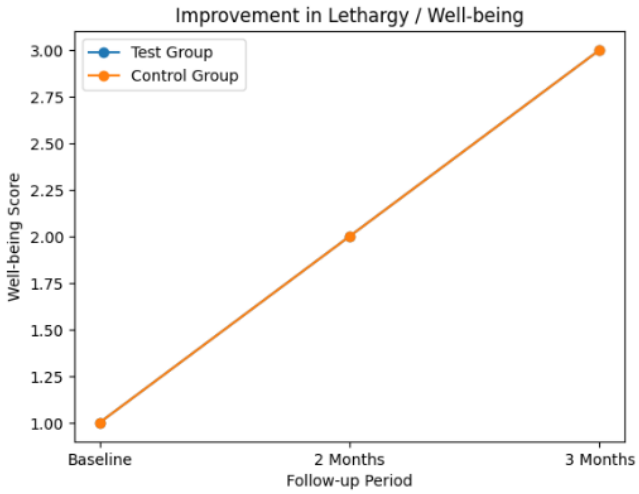
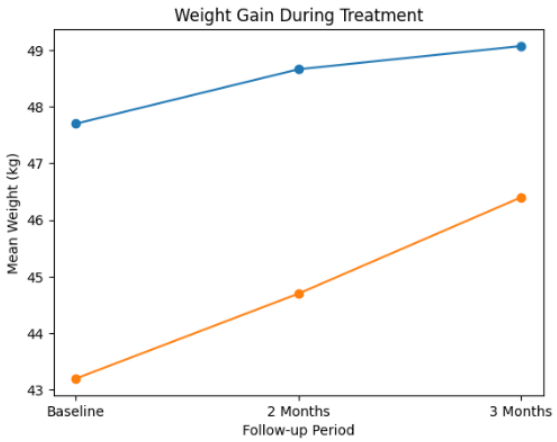



Mean cough severity scores during treatment in the Test and Control groups.







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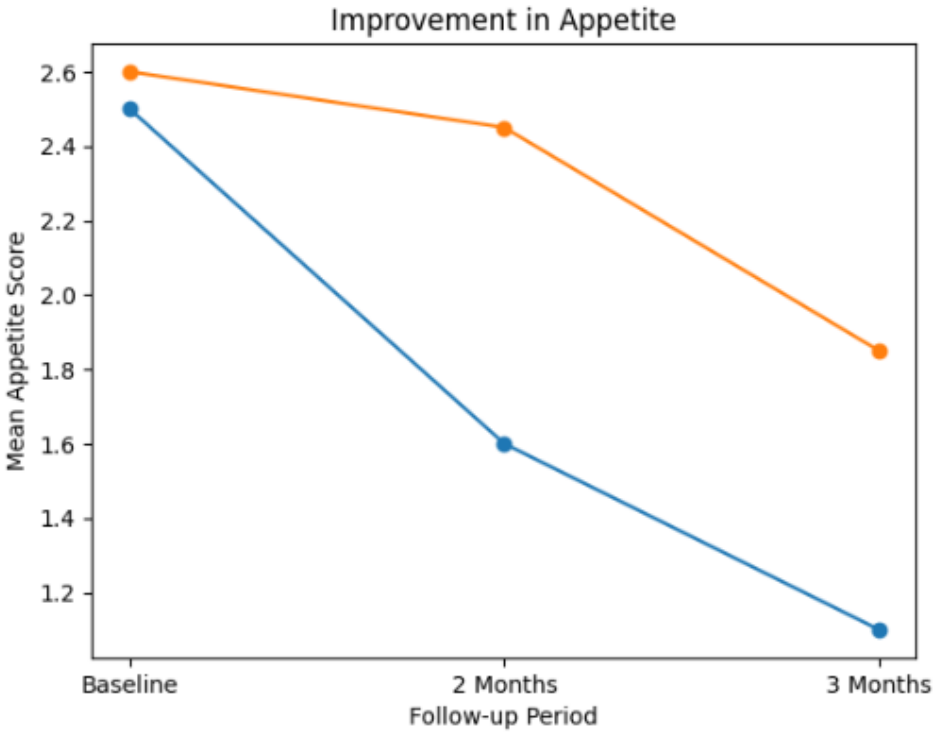
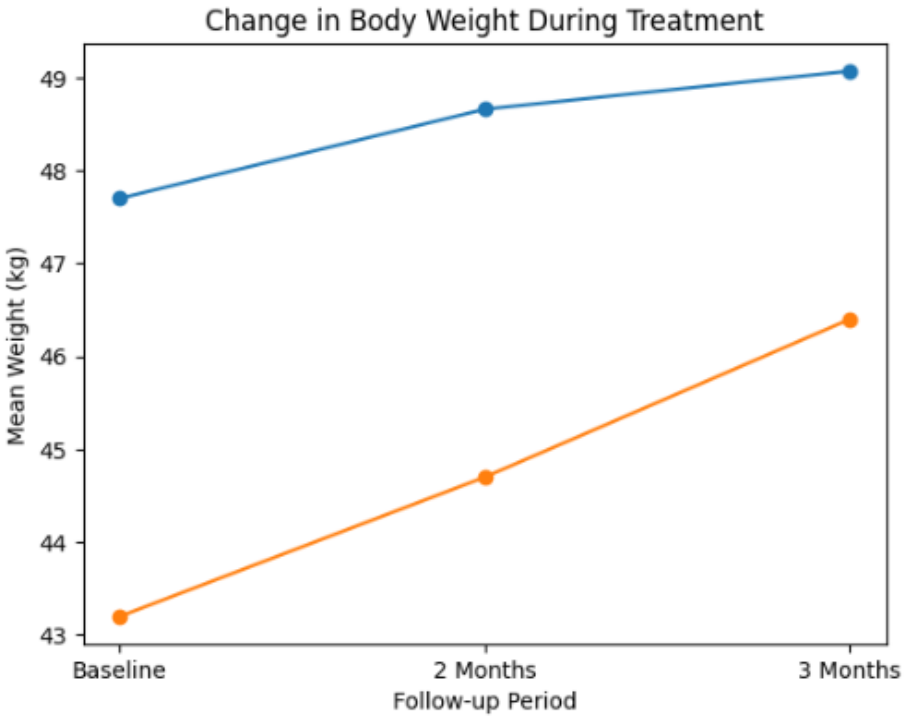



Fig. D. Change in Appetite.




.Fig. E. Change in Body Weight.

Mean body weight changes demonstrating progressive weight gain.

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### 3.2 Hematological & Biochemical Parameters Graphs

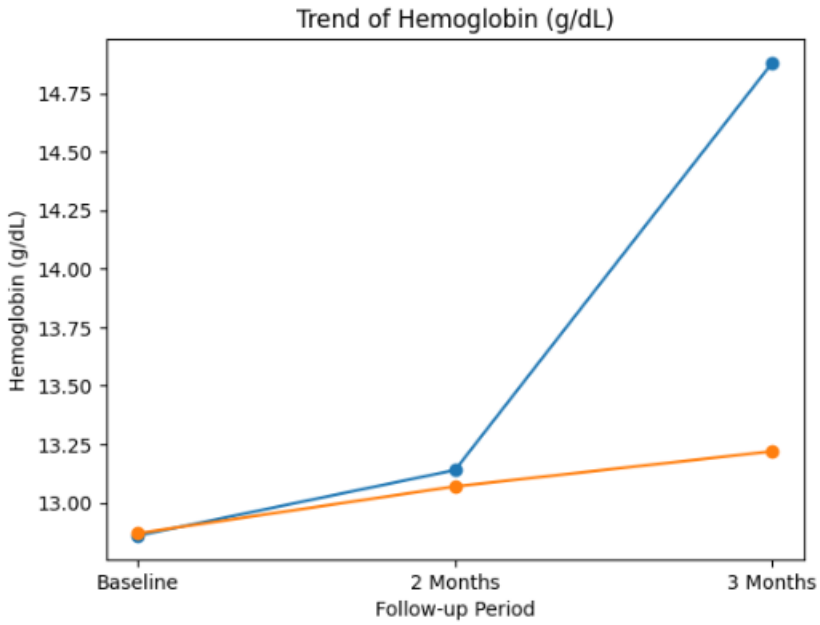


Fig. F. Change in Haemoglobin: Mean haemoglobin levels during follow-up in both groups.

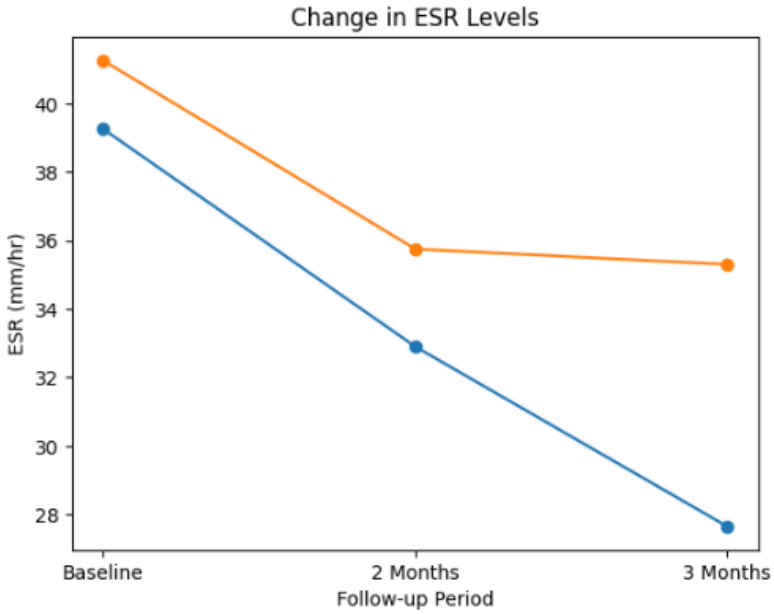


Fig. G. Change in ESR.: Mean erythrocyte sedimentation rate values showing decline in inflammation.

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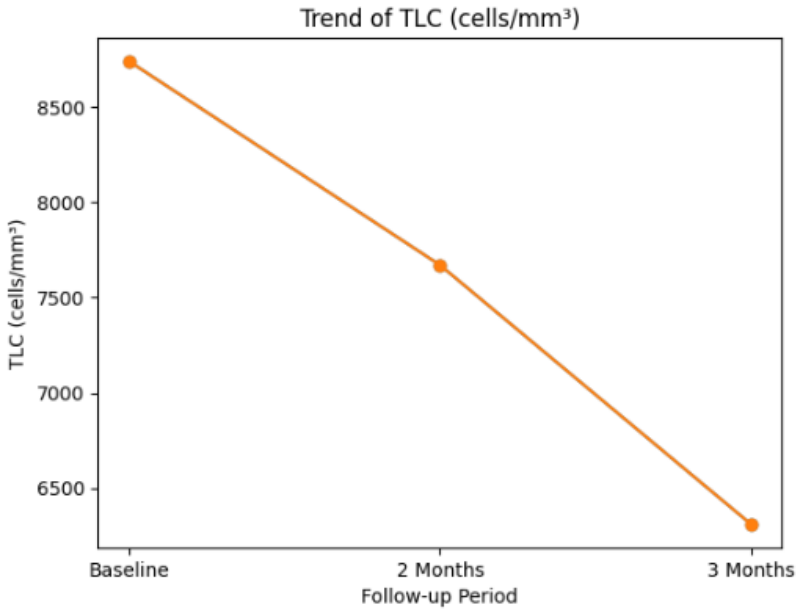


Fig. H. Change in Total Leukocyte Count: Mean total leukocyte count during treatment.

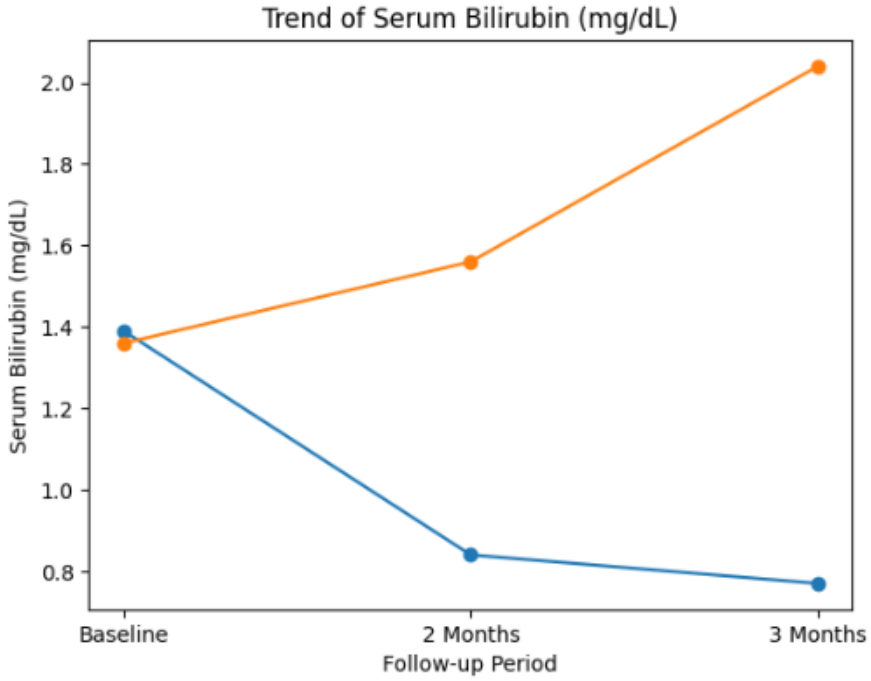


Fig. I. Change in Serum Bilirubin: Mean serum bilirubin levels demonstrating hepatic safety.

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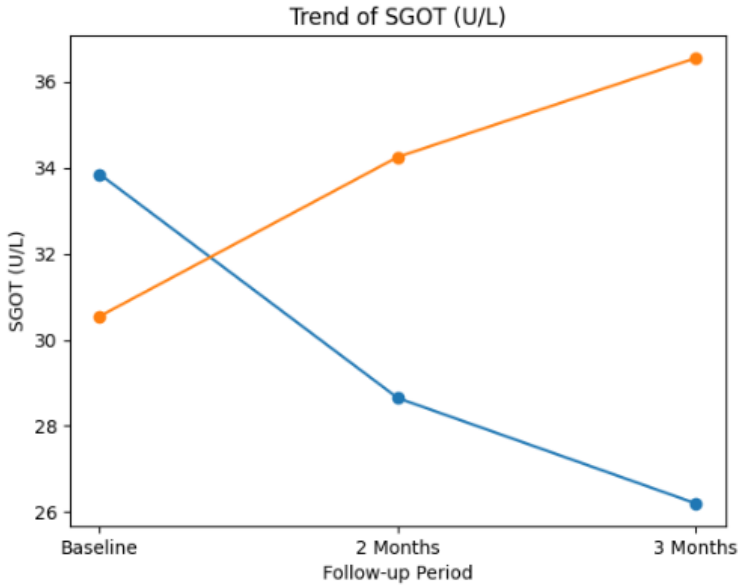


Fig. J. Change in SGOT: Mean SGOT levels during treatment in both groups.

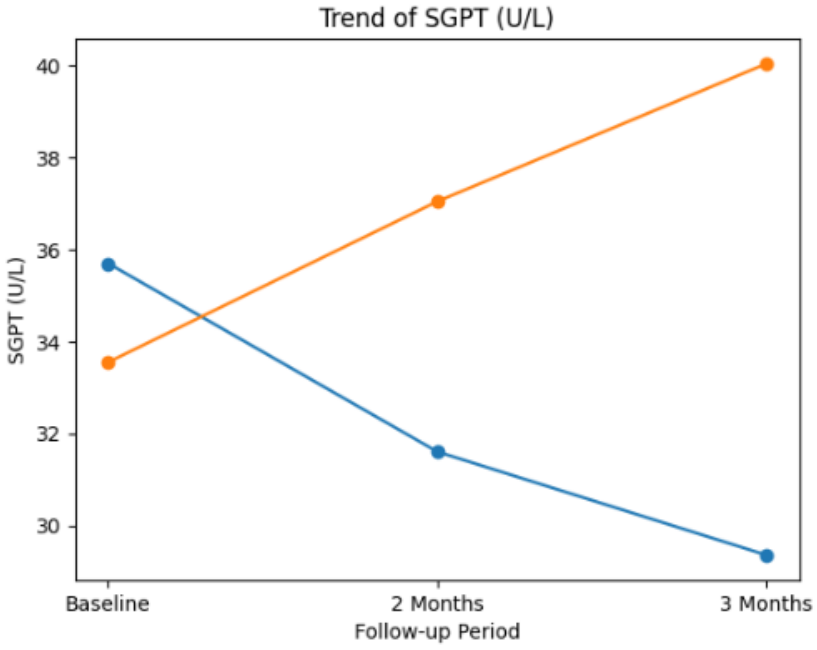


Fig. K. Change in SGPT: Mean SGPT levels during treatment in both groups.

## 4. DISCUSSION

The present study evaluated a traditional Unani formulation as an adjuvant to standard anti-tubercular therapy and demonstrated that its use was safe and associated with favourable trends in clinical recovery and patient well-being. Although anti-tubercular therapy remains the cornerstone of tuberculosis management, systemic symptoms related to tubercular

 

toxaemia and treatment-related adverse effects frequently prolong convalescence and adversely affect quality of life (16–19).

The earlier improvement in appetite, greater weight gain, and enhanced haemoglobin recovery observed in the test group suggest that the Unani formulation may support metabolic and haematological restoration during tuberculosis treatment. The faster decline in erythrocyte sedimentation rate further indicates a possible anti-inflammatory or immunomodulatory effect (20). Of particular importance is the observation of earlier sputum smear conversion in the test group, as early sputum negativity has significant clinical and public health implications, including reduced infectivity, decreased transmission risk, and earlier return to normal social and occupational activities(21–23).

Hepatic safety remains a major concern during anti-tubercular therapy because first-line drugs are known to cause hepatotoxicity in a proportion of patients. The favourable trends observed in liver function parameters in the test group suggest a possible protective or stabilising effect of the Unani formulation, although definitive conclusions cannot be drawn without larger studies specifically powered to evaluate hepatoprotection(18,24–26).

The holistic approach of Unani medicine, which emphasises strengthening of the host, correction of systemic imbalance, and restoration of functional vitality, aligns well with the modern concept of host-directed therapy in tuberculosis (27,28). The findings of the present study support the growing body of evidence advocating the integration of traditional medicine as a complementary approach to conventional anti-tubercular treatment, particularly for improving tolerance, recovery, and overall well-being (12,29).

The present study had certain limitations that should be acknowledged. The relatively small sample size may have limited the statistical power to detect significant intergroup differences for some outcome measures. As the study was conducted at a single center, the generalizability of the findings to broader populations may be restricted. In addition, the relatively short duration of administration of the Unani adjuvant therapy may not have been sufficient to fully assess its long-term effects and sustained benefits.

In conclusion, the Unani formulation evaluated in this study was found to be safe and demonstrated potential benefits as an adjuvant to standard anti-tubercular therapy by enhancing clinical recovery, improving patient well-being, and supporting hematological and biochemical stability. Although most outcomes showed favorable trends rather than definitive statistical superiority, the findings provide a scientific rationale for the adjunctive use of Unani medicine in tuberculosis management and justify further investigation through larger and methodologically robust clinical studies, particularly in multidrug-resistant tuberculosis and other vulnerable patient populations.

Future research should aim to further elucidate the role of Unani adjuvant therapy in tuberculosis management through larger randomised controlled trials with adequate statistical power. Emphasis should be placed on the standardisation and characterisation of the active constituents of the formulation, as well as on evaluating its efficacy and safety in multidrug-resistant tuberculosis and immunocompromised patients. Long-term studies assessing

 

sustained clinical outcomes, relapse rates, and quality-of-life parameters would also be valuable in establishing the broader applicability of this therapeutic approach(30,31).

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