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EVALUATING THE CORRELATION AND DIAGNOSTIC VALUE OF CLINICO-RADIOLOGICAL DIAGNOSIS AND COLONOSCOPY-GUIDED TISSUE BIOPSY TB PCR IN INTESTINAL TUBERCULOSIS

Medicine

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ABSTRACT

Introduction: Tuberculosis (TB), caused by Mycobacterium tuberculosis, remains a significant global health challenge, particularly in regions like South-East Asia. While pulmonary TB is most common, intestinal TB poses unique diagnostic challenges due to its overlap with other gastrointestinal diseases. Accurate diagnosis is crucial for effective treatment, and combining clinico-radiological assessments with colonoscopy-guided tissue biopsy and TB Polymerase Chain Reaction (PCR) can enhance diagnostic precision. **Objective:** The purpose of the study was to evaluate the correlation between clinico-radiological diagnosis and colonoscopy-guided tissue biopsy TB PCR results in patients suspected of having intestinal TB. **Materials & Methods:** A prospective cross-sectional study was conducted over two years at the Department of General Medicine, Subharti Medical College, Meerut. 60 patients diagnosed with intestinal TB based on clinico-radiological criteria were included. Following initial assessment, colonoscopy-guided tissue biopsies were performed, and samples were analyzed using TB PCR to detect *Mycobacterium tuberculosis* DNA. The correlation between clinico-radiological findings and TB PCR results was analyzed using statistical methods. **Result:** The study found that the majority of the study population was aged 21-30 years, with a nearly equal gender distribution. Chest X-rays were normal in 80.0% of participants, with a small percentage showing pleural effusion or other opacities. Significant positive correlations were identified between creatinine and urea levels ($r = 0.827$, $p < 0.001$), and moderate correlations between hemoglobin and creatinine ($r = 0.404$, $p = 0.001$) and between WBC count and urea ($r = 0.368$, $p = 0.004$), indicating interrelated changes in these parameters. **Conclusion:** The study concluded that combining clinico-radiological methods with colonoscopy-guided tissue biopsy and TB PCR significantly improves the accuracy of intestinal TB diagnosis. The correlations observed between various blood parameters and kidney function tests suggest interrelated physiological changes in TB patients, highlighting the importance of comprehensive diagnostic approaches for timely and effective treatment.

KEYWORDS

Intestinal tuberculosis; Clinico-radiological diagnosis; TB PCR; Colonoscopy-guided biopsy.

INTRODUCTION

Tuberculosis (TB), caused by Mycobacterium tuberculosis, is a leading global health concern, with a significant impact in regions like South-East Asia, where the burden of the disease is particularly high.[1] While pulmonary TB is the most common form, intestinal TB presents a unique diagnostic challenge due to its varied clinical manifestations that often mimic other gastrointestinal diseases.[2] This overlap in symptoms and imaging findings with conditions such as Crohn's disease and malignancies complicates the diagnostic process, making accurate detection critical for effective treatment.[3]

Clinico-radiological methods are traditionally used to assess suspected cases of intestinal TB, with imaging techniques providing vital information about the extent and nature of abdominal involvement.[4] However, these methods often fall short of providing a definitive diagnosis due to the nonspecific nature of the radiological signs associated with intestinal TB. Therefore, there is a pressing need to explore and validate more precise diagnostic tools that can reliably confirm the presence of the disease.[5,6]

Colonoscopy-guided tissue biopsy has emerged as a valuable technique in this context, offering direct visualization of the intestinal mucosa and enabling targeted sampling of suspicious areas.[7,8] When combined with TB Polymerase Chain Reaction (PCR), which detects the genetic material of Mycobacterium tuberculosis, this approach enhances diagnostic accuracy by confirming the presence of TB at a molecular level.[9,10] This combination of methods has the potential to significantly improve the detection and diagnosis of intestinal TB, providing a clearer correlation between clinical presentations, radiological findings, and definitive molecular evidence of infection.[11]

This study sought to evaluate the correlation between clinico-radiological diagnosis and the results of colonoscopy-guided tissue biopsy TB PCR in patients suspected of having intestinal TB. By examining the diagnostic performance of these combined modalities, the research aimed to determine their effectiveness in accurately diagnosing the disease, thereby improving clinical decision-making and patient outcomes. The findings from this study led to more refined diagnostic protocols, ensuring timely and accurate treatment for those affected by this challenging form of TB.

MATERIALS & METHODS

The study was designed as a prospective cross-sectional analysis conducted over two years, from September 2022 to August 2024, at the Department of General Medicine, Subharti Medical College, Meerut (U.P.). The study population comprised 60 patients diagnosed with intestinal tuberculosis based on clinico-radiological criteria. Patients included in the study were over 18 years of age and provided informed consent to participate. Those diagnosed with other forms of tuberculosis, pregnant individuals, and patients under 18 years of age were excluded from the study. Consecutive sampling was employed to recruit participants who presented with symptoms indicative of intestinal tuberculosis and met the inclusion criteria.

The study involved a comprehensive clinical evaluation and radiological imaging to establish a preliminary diagnosis of intestinal tuberculosis. Patients underwent detailed assessments, including medical history, physical examination, and radiological imaging, such as CT scans. Following the initial clinico-radiological diagnosis, a colonoscopy was performed to obtain tissue biopsy specimens from the intestinal mucosa. These biopsy samples were subjected to TB PCR analysis to detect the presence of Mycobacterium tuberculosis DNA, providing a definitive molecular diagnosis.

Data were collected and analyzed to evaluate the correlation between the initial clinico-radiological findings and the TB PCR results obtained from the tissue biopsies. The primary outcome of the study was the strength and nature of the correlation between these two diagnostic modalities, with secondary outcomes including the distribution of the disease and the diagnostic value of each method. Statistical analyses were performed using the SYSTAT 2 software, and all patient information was handled with strict confidentiality to ensure

privacy. The findings from this study aimed to enhance the understanding of the diagnostic process for intestinal tuberculosis and improve clinical outcomes through more accurate and timely diagnosis.

RESULTS

Table 1 summarizes the demographic characteristics of the study population, with the 21-30 years age group having the highest representation at 21.7%. The gender distribution is nearly balanced, with 51.7% males and 48.3% females. Age data was unavailable for 15.0% of the participants, contributing to a total sample size of 60 individuals.

Characteristic	Category	Frequency (N)	% of Total
Age (in years)	<=20	9	15.0%
	21-30	13	21.7%
	31-40	8	13.3%
	41-50	6	10.0%
	51-60	6	10.0%
	>60	9	15.0%
	NA	9	15.0%
Gender	Male	31	51.7%
	Female	29	48.3%
Total		60	100%

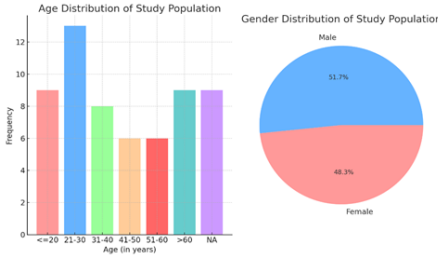


Table 2 illustrates that 80.0% of the study participants had normal chest X-ray findings, while bilateral pleural effusion was present in 8.3%. Various other findings, such as mild pleural effusion and different opacities, were observed in smaller proportions. Regarding tissue TB PCR results, only 5.8% of the participants tested positive, with 94.2% showing no detection of TB.

Findings	Category	Frequency (N)	% of Total
Chest X-Ray Findings	Normal	48	80.0%
	Homogenous	1	1.7%
	Bilateral pleural effusion	5	8.3%
	Inhomogeneous opacity in LU zone	1	1.7%
	Reticular opacities	1	1.7%
	Diffuse opacities	1	1.7%
	Cardiomegaly	1	1.7%
	Mild pleural effusion	2	3.4%
Tissue TB PCR Results	Detected	3	5.8%
	Not Detected	49	94.2%
Total Participants		60	100%

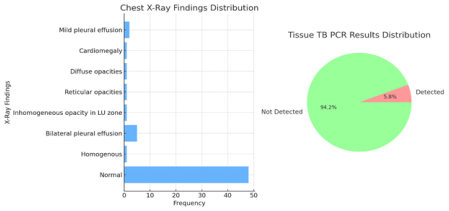


Table 3 summarizes the mean values and standard deviations (SD) for both blood parameters and kidney function tests among the study participants. Hemoglobin had a mean of 11.05 gm/dL with an SD of 2.29, while platelet count showed higher variability with a mean of 211.5 × 1000/ml and an SD of 83.19. Kidney function tests like creatinine had a mean of 0.765 mg/dL with low variability (SD of 0.353), whereas urea levels displayed significant variability with a mean of 30.023 mg/dL and an SD of 41.812.

Parameter	N	Mean	Lower CI	Upper CI	SD
Blood Parameters					
Hemoglobin (gm/dL)	60	11.05	10.45	11.64	2.29
MCH (Pg)	60	28.11	27.18	29.04	3.6
Lymphocytes (%)	60	26.48	23.24	29.72	12.54
Neutrophils (%)	60	69.35	65.84	72.86	13.57
Platelet count (×1000/ml)	60	211.5	190.01	232.99	83.19
MCV (fL)	60	86.88	84.52	89.25	9.16
WBC count (×1000/ml)	60	7.53	6.64	8.43	3.47
Hematocrit (%)	60	34.17	32.39	35.95	6.89
Kidney Function Tests (KFT)					
Creatinine (mg/dL)	60	0.765	0.674	0.856	0.353
Sodium (mmol/L)	60	139.283	138.299	140.267	3.809
Uric acid (mg/dL)	60	4.515	4.086	4.944	1.661
Urea (mg/dL)	60	30.023	19.222	40.824	41.812
Potassium (mmol/L)	60	3.892	3.747	4.037	0.561
Phosphorous (mg/dL)	60	3.33	3.158	3.502	0.666
Calcium (mg/dL)	60	8.287	8.066	8.507	0.855
Chloride (mmol/L)	60	102.7	101.394	104.006	5.057

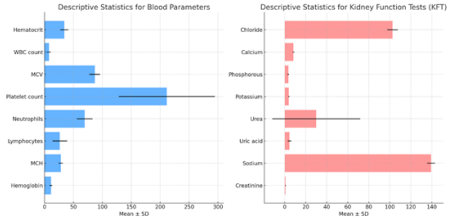
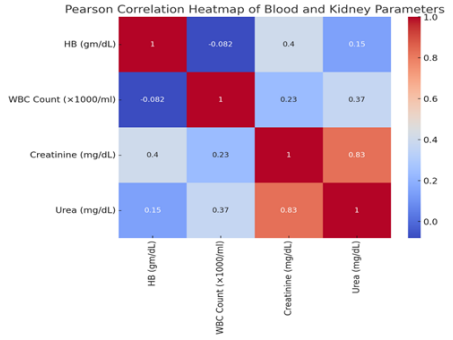


Table 4 displays the Pearson correlation coefficients (r) along with the corresponding degrees of freedom (df) and p-values for the relationships between hemoglobin (HB), WBC count, creatinine, and urea levels. Significant positive correlations were found between creatinine and urea ($r = 0.827$, $p < 0.001$) as well as between HB and creatinine ($r = 0.404$, $p = 0.001$). The correlation between WBC count and urea was also significant ($r = 0.368$, $p = 0.004$), indicating moderate relationships between these variables.

Parameters	HB (gm/dL)	WBC Count (×1000/ml)	Creatinine (mg/dL)	Urea (mg/dL)
HB (gm/dL)	-	-0.082	0.404	0.146
WBC Count (×1000/ml)	df = 58	-	0.231	0.368
	p = 0.534	-	p = 0.075	p = 0.004
Creatinine (mg/dL)	df = 58	df = 58	-	0.827
	p = 0.001	p = 0.075	-	p < 0.001
Urea (mg/dL)	df = 58	df = 58	df = 58	-
	p = 0.265	p = 0.004	p < 0.001	-



DISCUSSION

The study found that the demographic characteristics of the study population were diverse, with the 21-30 years age group representing the highest proportion of participants at 21.7%. The gender distribution was nearly equal, with 51.7% males and 48.3% females. It was noted that age data was unavailable for 15.0% of the participants, leading to a total sample size of 60 individuals.

Regarding chest X-ray findings, the majority of the participants (80.0%) had normal results. Bilateral pleural effusion was observed in 8.3% of the cases, while other findings, such as mild pleural effusion and various opacities (homogenous, inhomogeneous, reticular, and diffuse), each accounted for smaller percentages, ranging from 1.7% to 3.4%. Additionally, cardiomegaly was observed in 1.7% of the participants. For tissue TB PCR results, only 5.8% of the participants

tested positive for tuberculosis, while the vast majority, 94.2%, showed no detection of TB. **Haddad et al.[13] (1987)** also reported a high prevalence of normal chest X-ray findings among patients with abdominal tuberculosis, with 75% of their subjects showing no significant radiological abnormalities, which is slightly lower than the 80.0% observed in the current study. This study also identified bilateral pleural effusion in 9% of their patients, which is comparable to the 8.3% observed in the present study, indicating a consistent pattern of pleural involvement in abdominal TB cases.

In another study by **Sinan et al.[14] (2002),** the distribution of chest X-ray findings showed a higher prevalence of abnormal results, with 65% of patients presenting with some form of pleural or parenchymal abnormality. The difference could be attributed to variations in the study populations or the stage of the disease at the time of diagnosis. Sinan et al. also reported that 7% of their participants had bilateral pleural effusion, which closely aligns with the 8.3% found in this study.

Regarding tissue TB PCR results, the current study's detection rate of 5.8% is relatively low compared to the study by **Gulati et al.[12] (1999),** where a higher detection rate of 12% was observed among patients with abdominal TB. The difference in detection rates could be due to variations in the sensitivity of the diagnostic methods used or differences in the study populations' disease burden. Gulati et al. used a combination of PCR and culture techniques, which may have contributed to their higher detection rate.

The study found that the mean hemoglobin level among participants was 11.05 gm/dL, with a standard deviation (SD) of 2.29, indicating moderate variability. The mean platelet count was 211.5 × 1000/ml, with higher variability reflected by an SD of 83.19. Creatinine levels had a mean of 0.765 mg/dL, showing low variability (SD of 0.353), while urea levels exhibited significant variability with a mean of 30.023 mg/dL and an SD of 41.812. Other blood parameters, such as MCH, lymphocytes, and neutrophils, showed moderate to significant variability, with respective SDs of 3.6, 12.54, and 13.57.

Gulati et al.[12] (1999) reported hemoglobin levels in patients with abdominal tuberculosis, finding a mean value similar to the 11.05 gm/dL observed in the current study, although exact figures were not provided in their study. This suggests a consistent pattern of moderate anemia among tuberculosis patients, aligning with the current study's findings. In contrast, the study **by Sinan et al.[14] (2002**) examined various blood parameters, including platelet count, in patients with abdominal tuberculosis. They reported a mean platelet count of approximately 220 × 1000/ml, which is slightly higher but comparable to the current study's mean of 211.5 × 1000/ml. The variability in platelet counts observed in the current study, with an SD of 83.19, might reflect a broader spectrum of disease severity or differences in patient populations.

Similarly, kidney function markers like sodium, potassium, uric acid, phosphorous, calcium, and chloride were within expected ranges, with varying degrees of variability. **Haddad et al.[13] (1987)** found that creatinine levels in their study population were slightly higher than those in the present study, with a mean of around 0.8 mg/dL, compared to the current study's 0.765 mg/dL. The lower variability in the current study's creatinine levels (SD of 0.353) compared to urea levels suggests a relatively stable renal function in most participants, although the significant variability in urea levels (SD of 41.812) indicates potential fluctuations in renal function or hydration status.

The study found that there were significant positive correlations between certain blood parameters and kidney function tests among the study participants. Specifically, creatinine and urea levels were strongly correlated ($r = 0.827$, $p < 0.001$), indicating that as creatinine levels increased, urea levels also tended to rise significantly. Additionally, a moderate positive correlation was observed between hemoglobin (HB) and creatinine levels ($r = 0.404$, $p = 0.001$), suggesting a relationship between these two parameters. The study also found a significant correlation between WBC count and urea levels ($r = 0.368$, $p = 0.004$), indicating that higher WBC counts were associated with elevated urea levels. However, the correlation between hemoglobin and WBC count was not significant ($r = -0.082$, $p = 0.534$), nor was the correlation between hemoglobin and urea ($r = 0.146$, $p = 0.265$).

Haddad et al.[13] (1987) reported a significant correlation between creatinine and urea levels in patients with abdominal tuberculosis, with a correlation coefficient similar to the $r = 0.827$ observed in the present study. This strong correlation underscores the close relationship between renal function and nitrogen waste products in tuberculosis patients.

In contrast, **Sinan et al.[14] (2002)** examined correlations between various blood parameters and found a weaker correlation between hemoglobin and creatinine ($r = 0.350$) compared to the $r = 0.404$ found in the current study. This difference might be attributed to variations in the study populations or differences in the severity of renal impairment among participants. Sinan et al. also noted a significant correlation between WBC count and urea levels, similar to the $r = 0.368$ found in the present study, further supporting the association between inflammation and renal function.

Additionally, **Gulati et al.[12] (1999)** explored correlations between blood parameters in tuberculosis patients and reported no significant correlation between hemoglobin and WBC count, aligning with the findings of the current study ($r = -0.082$, $p = 0.534$). The lack of correlation suggests that these parameters may be influenced by different pathological processes or that the variability in these measures is too great to establish a significant relationship.

CONCLUSION

The study revealed that the study population was predominantly aged 21-30 years, with a nearly equal gender distribution. Chest X-ray results were normal in the majority of cases (80.0%), while a small percentage showed pleural effusion or other opacities. Blood parameters indicated moderate variability in hemoglobin levels (mean 11.05 gm/dL, SD 2.29), and significant variability in platelet counts and urea levels, with kidney function tests showing generally low variability except for urea. Pearson correlation analysis identified strong positive correlations between creatinine and urea levels, and moderate positive correlations between hemoglobin and creatinine, as well as between WBC count and urea, indicating interrelated changes in these parameters among the participants.

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