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Clinicohistopathological Correlation of Hansen's Disease: A Retrospective Study from a Tertiary Care Centre of Central India

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ABSTRACT

Background: Hansen's disease is a chronic granulomatous infectious disease caused by *Mycobacterium leprae*, affecting mainly skin and peripheral nerves. The disease shows a broad clinicopathological spectrum depending on host immunity. This study aimed to evaluate clinicohistopathological correlation of Hansen's disease using the Ridley–Jopling classification.

Methods: A retrospective observational study was conducted on 90 clinically diagnosed Hansen's disease cases undergoing skin biopsy at a tertiary care centre of Central India. Clinical data were retrieved from records. H&E-stained sections were evaluated and classified according to Ridley–Jopling classification. Agreement between clinical and histopathological diagnosis was assessed using Cohen's kappa statistics.

Results: Among 90 cases, 54 (60%) were males and 36 (40%) females. Most patients belonged to 21–40 years age group (55.5%). Hypopigmented hypoesthetic patches were the commonest presentation (83.3%). Highest agreement was observed in lepromatous leprosy (95.2%). Overall clinicohistopathological agreement was 88.9%, with Cohen's kappa coefficient (κ=0.855), indicating almost perfect agreement.

Conclusion: Histopathological examination is an important tool for accurate classification of Hansen's disease, particularly borderline forms. Combined clinical and histopathological evaluation improves diagnostic accuracy and supports timely management.

Key-words: Hansen's disease; Leprosy; Clinicohistopathological correlation; Ridley–Jopling classification; Histopathology; Cohen's kappa

INTRODUCTION

Leprosy, also known as Hansen's disease, is a chronic granulomatous infectious disease caused by *Mycobacterium leprae*, an obligate intracellular acid-fast bacillus with a predilection for the skin and peripheral nerves. The disease has been recognized since ancient times and continues to be an important public health concern, particularly in developing countries including India [1]. Although the introduction of multidrug therapy (MDT) has significantly reduced the global burden of leprosy, new cases continue to occur, indicating ongoing transmission and the need for early diagnosis and effective management [2,3].

The clinical presentation of Hansen's disease is highly variable and is primarily determined by the host's cell-mediated immune response against *M. leprae*. Patients may present with a wide spectrum of manifestations ranging from localized tuberculoid disease, characterized by strong cellular immunity and low bacillary load, to disseminated lepromatous disease associated with impaired cellular immunity and abundant bacilli [4].

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Ridley and Jopling proposed a widely accepted classification system based on clinical, immunological, bacteriological, and histopathological parameters. According to this classification, Hansen's disease is categorized into five major groups: tuberculoid leprosy (TT), borderline tuberculoid leprosy (BT), mid-borderline leprosy (BB), borderline lepromatous leprosy (BL), and lepromatous leprosy (LL). This classification helps in understanding the disease spectrum, prognosis, and therapeutic approach [5-7].

Although clinical examination remains the primary method for diagnosing Hansen's disease, accurate classification based only on clinical features may be challenging because of overlapping presentations, particularly among borderline forms. Histopathological examination of skin biopsy plays a crucial role by demonstrating characteristic features such as granulomatous inflammation, cellular infiltrate pattern, involvement of dermal nerves, and bacillary load, thereby improving diagnostic accuracy [8-10].

Previous studies have reported variable levels of agreement between clinical and histopathological diagnosis of leprosy. Polar forms such as TT and LL generally show higher concordance due to their characteristic features, whereas borderline forms frequently demonstrate diagnostic discrepancies because of their immunologically unstable nature [11,12].

Clinicohistopathological correlation is therefore essential for accurate classification, appropriate treatment selection, and prevention of complications. Early diagnosis and proper categorization of Hansen's disease can help prevent progressive nerve damage, deformities, disability, and further transmission within the community [7].

Hence, the present study was undertaken to evaluate the clinicohistopathological correlation among diagnosed cases of Hansen's disease at a tertiary care centre of Central India and to classify them according to the Ridley–Jopling classification system.

MATERIALS AND METHODS

Study Design and Study Setting- The present study was a retrospective observational study conducted in the Department of Pathology at a tertiary care centre of Central India. The study included clinically diagnosed cases of Hansen's disease who underwent skin biopsy for histopathological evaluation.The study was carried out over a period of six months**.**

Study Population and Sample Size- A total of 90 clinically diagnosed cases of Hansen's disease with available skin biopsy specimens were included in the study. As this was a retrospective record-based study, all eligible cases fulfilling the selection criteria during the study period were included using the complete enumeration method**.**

Data Collection- Relevant demographic and clinical details including age, gender, clinical presentation, site of lesion, peripheral nerve involvement, deformities, and clinical diagnosis were obtained from patient case records and the Medical Record Department.

Inclusion Criteria

- ✓ Clinically diagnosed cases of Hansen's disease who underwent skin biopsy.
- ✓ Biopsy specimens with adequate tissue for histopathological evaluation.
- ✓ Cases with complete clinical and demographic records.

Exclusion Criteria

- ✓ Cases with incomplete clinical information.
- ✓ Inadequate or poorly preserved biopsy specimens.
- ✓ Previously treated cases with insufficient diagnostic details.

Histopathological Examination- Skin biopsy specimens were fixed in 10% neutral buffered formalin, processed routinely, embedded in paraffin blocks, and stained with Hematoxylin and Eosin (H&E) stain**.** Microscopic examination was performed to evaluate epidermal and dermal changes, granulomatous inflammation, cellular infiltrate pattern, and peripheral nerve involvement. Cases were categorized according to the Ridley–Jopling classification system **.**

- Tuberculoid leprosy (TT)
- Borderline tuberculoid leprosy (BT)
- Mid-borderline leprosy (BB)
- Borderline lepromatous leprosy (BL)
- Lepromatous leprosy (LL)

Clinical diagnosis was compared with histopathological diagnosis to determine the degree of correlation.

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Statistical Analysis- Data were entered into Microsoft Excel 2021 and analyzed using Epi Info version 7.2.6.0**.** Descriptive statistics were used to summarize the data. Quantitative variables were expressed as mean and standard deviation, while categorical variables were presented as frequency and percentages. The agreement between clinical and histopathological diagnosis was assessed using Cohen's kappa (κ) statistics**.** The strength of agreement was interpreted according to the Landis and Koch criteria. A kappa value of >0.80 was considered as almost perfect agreement.

Ethical Consideration- The study was conducted after obtaining approval from the Institutional Ethics Committee (IEC), Gandhi Medical College, Bhopal (IEC No. 6702/MC/IEC/2022). Written informed consent was obtained from all participants prior to enrolment. Patient confidentiality, anonymity, and privacy were strictly maintained throughout the study in accordance with ethical guidelines.

RESULTS

A total of 90 clinically diagnosed cases of Hansen's disease were included in the study. The demographic characteristics, clinical presentation, histopathological spectrum, and clinicohistopathological correlation were analyzed. Among the study participants, 54 (60%) were males and 36 (40%) were females, with a male-to-female ratio of 1.5:1. The majority of patients belonged to the 21–40 years age group (55.5%) (Table 1).

Table 1: Distribution of cases according to demographic characteristics (n=90)

Variables	Category	Number of cases (n)	Percentage (%)
Gender	Male	54	60.0
	Female	36	40.0
Age group (years)	0–20	14	15.5
	21–40	50	55.5
	41–60	20	22.2
	>60	6	6.6

Values are expressed as frequency (n) and percentage (%).
n = total number of study participants.

Hypopigmented hypoesthetic patches were the most common clinical manifestation, observed in 75 (83.3%) patients, followed by peripheral nerve involvement in 58 (64.4%) patients. A positive contact history was reported in 11 (12.2%) patients, while limb deformities were present in 6 (6.6%) patients. The distribution of the clinical features of Hansen's disease among the study participants is presented in Table 2.

Table 2: Distribution of cases according to clinical features (n=90)

Clinical features	Number of cases (n)	Percentage (%)
Hypopigmented hypoesthetic patches	75	83.3
Peripheral nerve involvement	58	64.4
Positive contact history	11	12.2
Limb deformities	6	6.6

Histopathological evaluation was performed according to the Ridley–Jopling classification system. Tuberculoid leprosy (TT) was the most frequently observed histopathological subtype, accounting for 29 (32.2%) cases, followed by lepromatous leprosy (LL) in 21 (23.3%) cases and mid-borderline leprosy (BB) in 20 (22.2%) cases. Borderline tuberculoid (BT) and borderline lepromatous (BL) leprosy were identified in 11 (12.2%) and 9 (10.0%) cases, respectively. The distribution of histopathological subtypes among the study participants is presented in Table 3.

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Table 3: Distribution according to histopathological subtype (n=90)

Histopathological subtype	Number of cases (n)	Percentage (%)
Tuberculoid leprosy (TT)	29	32.2
Borderline tuberculoid leprosy (BT)	11	12.2
Mid-borderline leprosy (BB)	20	22.2
Borderline lepromatous leprosy (BL)	9	10.0
Lepromatous leprosy (LL)	21	23.3
Total	90	100

TT: Tuberculoid leprosy; BT: Borderline tuberculoid; BB: Mid-borderline; BL: Borderline lepromatous; LL: Lepromatous leprosy.

Clinicohistopathological correlation demonstrated the highest agreement in lepromatous leprosy (LL) (95.2%), followed by mid-borderline leprosy (BB) (90.0%) and borderline lepromatous leprosy (BL) (88.9%). Tuberculoid leprosy (TT) showed an agreement of 86.2%, while borderline tuberculoid leprosy (BT) demonstrated the lowest agreement (81.8%), reflecting the overlapping clinicopathological features of borderline lesions. The detailed clinicohistopathological correlation between clinical and histopathological diagnoses is presented in Table 4.

Table 4: Correlation between clinical and histopathological diagnosis of Hansen's disease (n=90)

Histopathological diagnosis	TT Clinical	BT Clinical	BB Clinical	BL Clinical	LL Clinical	Total histopathological cases	Agreement (%)
Tuberculoid leprosy (TT)	25	4	0	0	0	29	86.2
Borderline tuberculoid leprosy (BT)	2	9	0	0	0	11	81.8
Mid-borderline leprosy (BB)	0	1	18	1	0	20	90.0
Borderline lepromatous leprosy (BL)	0	0	0	8	1	9	88.9
Lepromatous leprosy (LL)	0	0	0	1	20	21	95.2
Total clinical cases	27	14	18	10	21	90	-

TT = Tuberculoid leprosy; BT = Borderline tuberculoid; BB = Mid-borderline; BL = Borderline lepromatous; LL = Lepromatous leprosy.

Cohen's kappa analysis demonstrated a high level of agreement between the clinical and histopathological diagnoses beyond chance. Among the 90 study participants, concordance between the clinical and histopathological diagnosis was observed in 80 cases, resulting in an overall observed agreement of 88.9%. The calculated Cohen's kappa coefficient (κ) was 0.855, indicating almost perfect agreement according to the Landis and Koch classification. This finding confirms a strong level of consistency between clinical assessment and histopathological examination for the classification of Hansen's disease. The agreement was statistically significant ($p < 0.001$), highlighting the reliability of clinicohistopathological correlation in establishing an accurate diagnosis (Table 5).

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Table 5: Cohen's Kappa analysis for clinicohistopathological agreement

Parameter	Result
Total cases	90
Cases with agreement between clinical and histopathological diagnosis	80
Observed agreement	88.9%
Cohen's kappa coefficient (κ)	0.855
p-value	<0.001
Interpretation	Almost perfect agreement

Cohen's kappa statistics were used to assess agreement beyond chance.
Interpretation was based on Landis and Koch criteria: κ >0.80 indicates almost perfect agreement.

DISCUSSION

Hansen's disease is a chronic granulomatous infectious disease with diverse clinical and histopathological manifestations. The clinical spectrum is mainly influenced by the host immune response against *M. leprae*. Although clinical examination is important for diagnosis, histopathological evaluation remains essential for confirmation, classification, and assessment of disease activity [4,8].

In the present study, a total of 90 clinically diagnosed cases of Hansen's disease were evaluated to determine the correlation between clinical and histopathological diagnosis. A male predominance was observed, with 54 (60%) males and 36 (40%) females and a male-to-female ratio of 1.5:1. Similar male predominance has been reported by Semwal *et al*. and Atram *et al*., which may be attributed to greater outdoor exposure, occupational risk, and healthcare-seeking differences among males [6,11].

The majority of cases in the present study were observed in the 21–40 years age group (55.5%). Similar findings were reported by Atram *et al*., where maximum cases were seen among young adults. This age distribution may be explained by the long incubation period of leprosy and increased social and occupational exposure during the productive age group [11].

The most common clinical presentation in our study was hypopigmented hypoesthetic patches (83.3%), followed by peripheral nerve involvement (64.4%). Classical cutaneous lesions along with sensory impairment remain important clinical indicators of Hansen's disease.

However, variation in clinical presentation, especially in borderline cases, may result in diagnostic difficulty and highlights the importance of histopathological confirmation [5,7].

Histopathological classification according to the Ridley–Jopling system showed that tuberculoid leprosy (TT) was the most common subtype (32.2%), followed by lepromatous leprosy (LL) (23.3%) and mid-borderline leprosy (BB) (22.2%). Variation in predominant histological types among different studies may occur due to differences in geographical distribution, immune status of patients, and selection criteria [9,10].

In the present study, maximum clinicohistopathological agreement was observed in lepromatous leprosy (LL) cases (95.2%). This high concordance may be due to the characteristic clinical features and well-defined histopathological findings of LL, such as Grenz zone formation, foamy macrophages, and diffuse dermal infiltration. Atram *et al*. also reported the highest agreement in LL cases, supporting better diagnostic accuracy in polar forms of leprosy [11].

Borderline forms of Hansen's disease demonstrated relatively lower agreement compared with polar forms. In the present study, agreement was 81.8% in borderline tuberculoid (BT), 90.0% in mid-borderline (BB), and 88.9% in borderline lepromatous (BL) cases. The reduced concordance in borderline forms can be explained by their immunological instability and overlapping clinical and microscopic features. Similar difficulties in classification of borderline lesions were also reported by Bijjaragi *et al*. [12].

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The overall clinicohistopathological agreement in the present study was 88.9%, with a Cohen's kappa coefficient (κ) of 0.855**,** indicating almost perfect agreement. These findings emphasize that combining clinical assessment with histopathological examination improves diagnostic accuracy and helps in appropriate classification of Hansen's disease.

Table 6: Comparison of clinicohistopathological correlation with previous studies

Study	Year	Sample size	Major findings
Semwal *et al*. [6]	2018	372 cases	Significant clinicohistological correlation; discrepancies mainly in borderline cases
Atram *et al*. [11]	2020	210 cases	Highest correlation observed in lepromatous leprosy
Bijjaragi *et al*. [12]	2012	60 cases	Diagnostic difficulty mainly observed in borderline spectrum
Present study	2026	90 cases	Highest agreement in LL (95.2%); κ=0.855 showing almost perfect agreement

LL: Lepromatous leprosy; κ: Cohen's kappa coefficient.

Thus, histopathology remains a valuable diagnostic tool, particularly for borderline and clinically uncertain cases. A combined clinicohistopathological approach is necessary for accurate classification, timely initiation of treatment, prevention of nerve damage, and reduction of disability associated with Hansen's disease [5,12].

LIMITATIONS

The present study has certain limitations. Being a retrospective, single-centre study**,** the findings may have limited generalizability, and larger multicentric studies are required for better evaluation of different histopathological subtypes of Hansen's disease. The study focused mainly on clinicohistopathological correlation using routine H&E staining. Additional investigations such as Modified Fite-Faraco staining, bacillary index assessment, and molecular techniques were not performed**,** which could have enhanced diagnostic accuracy. Interobserver variability in histopathological interpretation was also not assessed.

CONCLUSIONS

The present study demonstrated substantial clinicohistopathological concordance in Hansen's disease, highlighting the complementary role of histopathology alongside clinical evaluation for accurate diagnosis and classification. Borderline forms (BT, BB, and BL) showed relatively lower concordance because of their immunologically unstable nature and overlapping clinicopathological features, emphasizing the importance of histopathological confirmation in clinically equivocal cases. The high overall agreement between clinical and histopathological diagnosis, supported by Cohen's kappa analysis, indicates that an integrated clinicopathological approach enhances diagnostic accuracy, facilitates appropriate classification and treatment, and contributes to the prevention of disease progression, nerve damage, deformities, and disability. Future multicentric studies involving larger sample sizes and incorporating histopathological, bacteriological, and molecular diagnostic techniques are warranted to further improve the diagnostic accuracy and classification of Hansen's disease. Such an integrated approach may strengthen early diagnosis, optimize patient management, and reduce long-term disease-related complications and disabilities.

CONTRIBUTION OF AUTHORS

Research concept- Rashmi Meena, Ramgopal Baghel
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Supervision- Jiwan Singh Meena
Materials- Rashmi Meena, Ramgopal Baghel
Data collection- Rashmi Meena, Ramgopal Baghel
Data analysis and interpretation- Rashmi Meena, Jiwan Singh Meena
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