CONCLUSIONS

1. All the patients in the study group ranged from 2 years to 45 years. Age group 21-30 years contained the maximum number of patients. There was preponderance of the female patients in the study.

2. The most common clinical/systemic symptom in the patients was weight loss followed by fever, anorexia and night sweat.

3. 26 (26%) patients had the contact/family history of tuberculosis and 22 (22%) patients had the past history of tuberculosis.

4. Mantoux was found to be reactive (>10mm) in 81 patients. Non-reactive results of Mantoux cannot rule out disease in patients. The sensitivity of PCR when compared with Mantoux test was found to be 91.66% in the cases. The NPV were found to be 78%. The p value was significant (p value = 0.009). This result indicates that this test is useful in diagnosis of tuberculous lymphadenitis in suspected cases.

5. Chest X rays report with PCR results revealed that 24 patients were having pulmonary tuberculosis along with tuberculous lymphadenitis.

6. The average haemoglobin was found to be 10.056 ± 1.80gm/dl. Erythrocyte sedimentation rate (ESR) which is usually expected to be raised in a patients with tuberculosis, was < 30 mm in the first hour in about 21% and >30 mm in the first hour in about 78% cases.

7. Cervical region was the most common site of swelling in the patients. Followed by swelling of submandibular, supraclavicular, multiple lymph nodes, axillary and inguinal node swelling.

8. Out of the 100 patients, (i) 23 (23%) were suggestive of tuberculous lymphadenitis with AFB positivity and (ii) 77 (77%) were suggestive of tuberculous lymphadenitis and AFB negative by cytopathology.

9. 23 patients who were suggestive of tuberculous lymphadenitis and AFB positive by cytopathology among them 20 were found to be reactive (≥10 mm) of Mantoux test (20/23). 77 patients who were suggestive of tuberculous lymphadenitis and AFB negative by cytopathology among them 61 were found to be reactive (≥10 mm) of Mantoux test (61/77).
CONCLUSION

Mantoux test (61/77). This result indicates that this test is useful in screening of the patients and in diagnosis of tuberculous lymphadenitis in suspected cases.

10. The sensitivity and specificity of PCR when compared with presence and absence of systemic symptoms was found to be 46.06% and 36.4% respectively in these cases. The PPV were found to be 85.4% (p value = 0.09, 0.25, 0.16 and 0.38). This result clearly indicates that presence of lymphadenopathy along with clinical/systemic symptoms increases the suspicion rate of tuberculous lymphadenitis and the absence of constitutional symptoms does not make the diagnosis of tuberculous lymphadenitis less likely.

11. The sensitivity and specificity of PCR when compared with Chest X rays was found to be 100% and 68.74% respectively in these cases. The PPV and NPV were found to be 50% and 100%. The p value was significant (p value = 0.0001). The overall agreement between two assays was found to be 76%. The Kappa value (agreement between two assays beyond chance) was 49.88% (k value= 0.4888 i.e. fair). This result indicated that PCR had 100% sensitivity with Chest X rays hence, should be performed in all the suspected cases of tuberculous lymphadenitis.

12. Overall 48% cases were PCR positive for tuberculous lymphadenitis in the study population (48/100). All the patients, who were suggestive of tuberculous lymphadenitis and AFB positive, were positive by PCR for tuberculous lymphadenitis (23/23). The sensitivity and specificity of PCR was found to be 100% and 100% respectively in the patients, suggestive of tuberculous lymphadenitis with AFB positivity.

13. The sensitivity and specificity of PCR when compared with Cytopathology was found to be 66.67% and 80% respectively in these cases. The PPV and NPV were found to be 83.3% and 61.5%. The overall agreement between two assays was found to be 72%. The Kappa value (agreement between two assays beyond chance) was
CONCLUSION

14. The sensitivity and specificity of PCR when compared with culture (gold standard) was found to be 100% and 94.54% respectively in these cases. The PPV and NPV were found to be 93.75% and 100%. The overall agreement between two assays was found to be 97%. The Kappa value (agreement between two assays beyond chance) was 95% (k value= 0.95 i.e. excellent). The p value was observed to be highly significant (p value = 0.0001).

15. The sensitivity and specificity of different molecular markers, when compared with Cytopathology was found to be 60% to 66.67% and 80%. The PPV were found to be and NPV 81.8% to 83.3% and 57.14% to 61.5% respectively in these cases. The p value was observed to be highly significant (p value = 0.0001).

16. The sensitivity of PCR with five different primers namely Hsp 65, Hup B, MPB 64, 16S-23Sr RNA and rpo B when compared with BACTEC culture was found to be 100%, 100%, 100% and 95.55% respectively and the specificity was 94.45%, 96.36%, 98.18% and 100% respectively. The PPV were found to be 93.75%, 95.74%, 97.78% and 100% respectively and NPV 100%, 100%, 100% and 96.49% respectively. The p value was observed to be highly significant (p value = 0.0001).

17. The maximum PCR positive results was obtained in 48/100 samples by Hsp 65 gene followed by Hup B gene in 47/100, 45/100 by MPB 64 & 16S-23Sr RNA and 44/100 by rpoB gene.

18. PRA analysis of Hsp 65, rpoB and 16S-23SrRNA correlated well with each other. All these primers were found to be useful in identification of Mycobacteria up to species level.

19. The biochemical tests like niacin production, nitrate reduction, Catalase production test, Arylsulphatase test, Urease test, Pyrazinamidase test and Tween 80 hydrolysis test correlated well with the PRA analysis and sequencing results in the present study. Presence of Mycobacterium
tuberculosis was confirmed among the tuberculous lymphadenitis patients in our study.

20. The PRA analysis revealed the presence Mycobacterium tuberculosis, in cases of tuberculous lymphadenitis in our study. This was further confirmed by sequencing of the amplicons.

21. Sequencing results of amplicons confirmed the presence of Mycobacterium tuberculosis.

22. Blood based PCR was found to be positive in only 16% cases. The sensitivity and specificity of PCR when compared with cytopathology was found to be 23.33 % and 95 % respectively in these cases. The PPV and NPV were found to be 87.5% and 45.24% respectively. When blood PCR was compared to cytology results the p value was observed to be significant (p value = 0.014). The results indicates that the specificity and PPV of blood PCR was 95% and 87.5%, it may be said that, blood based PCR, may be used as an additional diagnostic technique in diagnosis of tuberculous lymphadenitis.

23. The sensitivity and specificity of PCR when compared with LJ culture was found to be 100% and 93.3% respectively in these cases. The PPV and NPV were found to be 62.5% and 94% . When blood PCR and LJ culture were compared the p value was observed to be highly significant (p value = 0.0001). The overall agreement between two assays was found to be 94 %. The Kappa value (agreement between two assays beyond chance) was 22.04% (k value= 0.2240 i.e. moderate).

24. The sensitivity and specificity of blood PCR when compared with BACTEC culture was found to be 63.15% and 95 % respectively in these cases. The PPV and NPV were found to be 75 % and 91.66%. The overall agreement between two assays was found to be 89 %. The Kappa value (agreement between two assays beyond chance) was 25.57% (k value= 0.2557 i.e. moderate). The p value was observed to be highly significant (p value = 0.001).
25. When Blood PCR was compared with FNA culture positive case the sensitivity and specificity of PCR was found to be 35.5% and 100% respectively in these cases. The PPV and NPV were found to be 100% and 65.47%, the p value was observed to be significant (p value = 0.001). The overall agreement between two assays was found to be 71%. The Kappa value (agreement between two assays beyond chance) was 33.58% (k value= 0.33587 i.e. moderate).

26. The p value of 0.001 and 0.0001 in our study indicates that the results are significant and highly significant.

27. Polymerase chain reaction was found to be useful in diagnosis of tuberculous lymphadenitis. Low amount of samples and paucibacillary nature of the specimens can be a cause of negative culture and PCR results in the patients.

28. The cytological and microbiological results of Fine needle aspirates in tuberculous lymphadenitis each give an exclusive diagnostic yield. When combining both modalities, the efficacy of FNA was observed to rise. The fine needle aspiration is a diagnostic efficacious, and when used in the context of suspicion of tuberculous lymphadenitis, samples should be provided for both cytological and microbiological examination to optimize the sensitivity of diagnostic yield.

29. In this study we observed that PCR proves to be highly sensitive and specific in diagnosis of tuberculous lymphadenitis against the culture. The sensitivity and specificity of PCR when compared with culture (gold standard) was found to be 100% and 94.54% respectively in these cases. The PPV and NPV were found to be 93.75% and 100%. The overall agreement between two assays was found to be 97%. The Kappa value (agreement between two assays beyond chance) was 95% (k value= 0.95 i.e. excellent). The p value was observed to be highly significant (p value = 0.0001). Presence of *Mycobacterium tuberculosis* was confirmed among the tuberculous lymphadenitis patients in our study. It may be said that, blood based PCR, might be used as an additional diagnostic technique in diagnosis of tuberculous
lymphadenitis, as the sensitivity and specificity of blood PCR when compared with BACTEC culture was found to be 63.15\% and 95 \% respectively in these cases. The PPV and NPV were found to be 75 \% and 91.66\%. The \( p \) value was observed to be highly significant (\( p \) value = 0.001). Along with that, when Blood PCR was compared with FNA culture positive case the sensitivity and specificity of PCR was found to be 35.5 \% and 100 \% respectively in these cases. The PPV and NPV were found to be 100\% and 65.47\%, the \( p \) value was observed to be significant (\( p \) value = 0.001).

30. The clinical and radiologic features of tuberculosis may mimic those of many pathologic processes. A positive culture, polymerase chain-reaction based assay for mycobacterial DNA on specimens obtained during fine needle aspiration cytology or biopsy for mass lesions are still required to reach a firm diagnosis. In the appropriate clinical setting, recognition of the spectrum of imaging features of tuberculosis may guide diagnostic work-up and may result in earlier and adequate treatment.

31. In our study we observed that FNA PCR was able to diagnose the cases, which were direct smear negative, culture negative and were suggestive of tuberculous lymphadenitis along with other cases that had no systemic symptoms. 100\% PCR positivity was observed in AFB smear and culture positive specimens’ proving itself again that PCR is rapid, sensitive, and useful technique in diagnosis of tuberculous lymphadenitis

32. When culture and blood PCR results were combined, diagnosis of tuberculous lymphadenitis was observed to increase.

33. There is a need of new and rapid methods for diagnosis of tuberculous lymphadenitis, especially in paucibacillary and low sample amount cases.