Evaluation of Clinical Outcome of 6 months Anti-TB therapy in Rifampicin sensitive Tubercular Cervical Lymphadenopathy in Tertiary Level Hospital, Dhaka, Bangladesh

Salahuddin Al Azad[1*], Kamrul Hasan Mollick[2], Rifat Hassan[3], Sajid Ahsan[4], Musfiqur Rahaman[5]

ARTICLE INFO

Received: 12 July 2026
Accepted: 18 July 2026
Published Online: 18 July 2026

DOI: 10.5281/zenodo.21773667

Volume: 10, Number: 1, Page: 15-21

e-ISSN: 2789-5912
ISSN: 2617-0817

*Corresponding author

ABSTRACT

Background: Tuberculous lymphadenitis (TBL) is the most common form of extrapulmonary tuberculosis and a major cause of lymph node enlargement in tuberculosis-endemic countries. It is characterized by chronic, painless lymphadenopathy with granulomatous inflammation and caseous necrosis. Although antitubercular therapy (ATT) is the standard treatment, clinical response is often slower than in pulmonary tuberculosis and treatment outcomes remain variable despite the recommended 6-month regimen in Bangladesh. **Objective:** To evaluate the clinical outcome of anti-tubercular therapy in rifampicin-sensitive tubercular cervical lymphadenopathy at a tertiary-level hospital. **Methods & Materials:** This prospective interventional study was conducted in the Department of Otolaryngology and Head-Neck Surgery, Dhaka Medical College Hospital, from October 2021 to September 2022. Patients with newly diagnosed, cytologically confirmed tubercular cervical lymphadenopathy were enrolled using purposive sampling. Detailed history, clinical examination and relevant investigations were performed. All patients received Category I ATT according to national guidelines. Data were recorded in structured case report forms and analyzed using SPSS version 22 and Microsoft Excel. **Results:** A total of 100 patients were included. The majority (44%) were aged 31–45 years, with a mean age of 39.05 ± 9.32 years. Females predominated (68%), with a male-to-female ratio of 1:2.1. Painless lymph node swelling was present in all patients. Common associated symptoms included weakness (35%), weight loss (26%), cough (15%), and night sweats (12%). Lymphadenopathy was unilateral in all cases, single in 87%, and most commonly measured 3–6 cm (65%). Solid lymph nodes were noted in 92% of patients. Successful treatment outcomes were observed in 92% of cases after 6 months of ATT. Treatment failure occurred in 8%, including 3 presumptive and 5 bacteriologically confirmed failures. Five percent of cases were microbiologically positive. Eight patients required surgical excision due to persistent lymphadenopathy despite clinical improvement. **Conclusion:** Six-month ATT for rifampicin-sensitive tubercular cervical lymphadenopathy demonstrated high efficacy with a 92% treatment success rate and an 8% failure rate supporting its effectiveness as standard therapy.

Keywords: *Tuberculous lymphadenitis; Cervical lymphadenopathy; Extrapulmonary tuberculosis; Anti-tubercular therapy; Rifampicin-sensitive tuberculosis; Treatment outcome.*

1. *Assistant Professor (ENT), National Institute of ENT, Tejgaon, Dhaka, Bangladesh (ORCID: 0009-0002-7745-9410)*
2. *Assistant Professor (ENT), National Institute of ENT, Tejgaon, Dhaka, Bangladesh (ORCID: 0009-0001-6839-9260)*
3. *Assistant Professor (ENT), National Institute of ENT, Tejgaon, Dhaka, Bangladesh (ORCID: 0009-0001-4600-8628)*
4. *Assistant Professor (ENT), National Institute of ENT, Tejgaon, Dhaka, Bangladesh (ORCID: 0009-0004-4376-9642)*
5. *Junior Consultant (ENT), National Institute of ENT, Tejgaon, Dhaka, Bangladesh (ORCID: 0009-0007-9757-8755)*

INTRODUCTION

Tuberculous lymphadenitis is the most common form of extrapulmonary tuberculosis (EPTB) and a leading cause of peripheral lymphadenopathy worldwide. Previously known as scrofula, peripheral tuberculous lymphadenopathy is caused by organisms belonging to the Mycobacterium tuberculosis complex. The disease most frequently affects individuals between 30 and 40 years of age and shows a female predominance. Patients typically present with a painless, slowly enlarging swelling of a single group of cervical lymph nodes persisting for one to two months. Although antimycobacterial therapy remains the cornerstone of treatment, response is often slower than pulmonary tuberculosis, with persistent lymph node swelling, pain and paradoxical reactions occurring in up to 20% of cases[1]. Retrospective case series have reported a median age of 38 years and a male-to-female ratio of 1:1.3. Cervical lymph node involvement was present in approximately 80% of cases, while systemic symptoms such as fever and weight loss were observed in 36%. Most patients (89%) reported lymphadenopathy lasting longer than one month. Diagnostic yields varied among investigations with tuberculin skin testing positive in 83%, chest radiography in 27%, fine-needle aspiration cytology (FNAC) in 46% and excisional lymph node biopsy in 97% of cases[2]. Lymph node tuberculosis (LNT) is characterized by chronic granulomatous inflammation, with cervical lymph nodes being the most frequently affected. Tubercular cervical lymphadenopathy accounts for approximately 63.8% of generalized cervical lymph node enlargement[3]. The most common presenting complaint is a palpable neck mass. Epidemiological studies show a higher prevalence among females and contact history with active tuberculosis or previous pulmonary tuberculosis is infrequently reported[4]. Following diagnostic confirmation, standard anti-tuberculous therapy (ATT) administered for at least six months has demonstrated favorable outcomes. Historically, Mycobacterium bovis was a common cause of tuberculous lymphadenitis, but pasteurization of milk and bovine tuberculosis control programs have largely eliminated this source in developed countries. Currently, M. tuberculosis is the predominant causative organism[5–6]. Differential diagnoses of chronic lymphadenitis include nontuberculous mycobacteria, toxoplasmosis, bartonellosis, fungal infections, malignancy, sarcoidosis, Castleman disease, drug reactions and nonspecific reactive hyperplasia. Clinically, tuberculous lymphadenitis

usually presents as a unilateral, painless lymph node enlargement involving one to three nodes. Symptom duration ranges from three weeks to eight months, with a mean duration of one to two months[7–9]. Median lymph node size is approximately 3 cm, though nodes may enlarge up to 8–10 cm. Tenderness is reported in only 10–35% of cases and draining sinuses occur in 4–11%. Cervical lymph nodes are involved in 45–70% of cases, with supraclavicular involvement in 12–26% and bilateral disease in about 20%[10–11]. Systemic symptoms vary by geographic region and immune status. Fever and weight loss are reported in 19–60% of HIV-negative patients and are significantly more common among HIV-positive individuals[10–12]. HIV-associated tuberculous lymphadenitis often presents with asymmetric, larger lymph nodes compared to HIV-related reactive lymphadenopathy. Definitive diagnosis requires culture or polymerase chain reaction (PCR) detection of M. tuberculosis from lymph node tissue. Although culture remains the gold standard, it may take several weeks for results. Acid-fast bacilli (AFB) staining has high specificity but limited sensitivity. Histopathological findings such as caseating granulomas and Langhans giant cells support the diagnosis in culture-negative cases[1]. Excisional biopsy offers the highest diagnostic yield and may provide symptomatic relief, particularly in patients with multiple lymph nodes involved[7]. The Infectious Diseases Society of America (IDSA) recommends a six-month regimen for drug-susceptible tuberculous lymphadenitis consisting of isoniazid, rifampicin, pyrazinamide and ethambutol for two months, followed by isoniazid and rifampicin for four months[13]. Studies have demonstrated comparable cure and relapse rates between six-and nine-month regimens[14–16]. WHO guidelines also support six months of ATT for rifampicin-sensitive disease, with no additional benefit observed from extended therapy[17–18]. Post-treatment lymph node enlargement is most commonly due to paradoxical reaction rather than relapse and typically does not require retreatment. However, microbiological relapse may occur and surgical excision can aid in diagnosis in such cases[19]. Therefore, this study aims to evaluate the clinical outcomes of six-month ATT in patients with rifampicin-sensitive tubercular cervical lymphadenopathy.

MATERIALS & METHODS

This was a prospective interventional study conducted in the Department of Otolaryngology and Head–Neck Surgery, Dhaka Medical College Hospital (DMCH), Dhaka. The study period extended over six months from October 2021 to September 2022. Purposive sampling technique was applied for selecting study participants.

The sample size was calculated using the formula:

$n = (Z^2pq) / d^2$, where Z = 1.96, p = 0.10 (peripheral tuberculous lymphadenitis constitutes approximately 10% of tuberculosis cases), q = 0.9, and d = 0.05. The calculated sample size was 138. Considering a 15–20% dropout rate, the adjusted sample size became 162. However, due to time constraints, a total of 100 patients were finally enrolled.

Selection Criteria

Inclusion criteria were newly diagnosed cases of tubercular cervical lymphadenopathy, cytologically or histopathologically confirmed, patients of both sexes and patients receiving a 6-month anti-tubercular therapy (ATT) regimen.

Exclusion criteria included presumptive TB cases, treatment failure, relapse or drug-resistant TB, cervical lymphadenopathy due to other causes (lymphoma, infective, inflammatory, or neoplastic), chronic lung disease, previous TB, alcohol or substance use disorder and immunocompromised patients.

Data Collection Procedure

After fulfilling the inclusion and exclusion criteria, 100 newly diagnosed cases of tubercular cervical lymphadenopathy were enrolled and assigned unique identification numbers. Written informed consent was obtained after explaining the study objectives, benefits, risks, and confidentiality issues. Detailed history taking and thorough general and local examinations were performed. Routine laboratory investigations were conducted, including complete blood count, ESR, chest X-ray and neck X-ray. Diagnostic confirmation was based on lymph node aspirate or tissue sampling for Acid-Fast Bacilli (AFB) smear, culture, histopathology and TB-PCR (Xpert MTB/RIF). AFB smears were stained using auramine-rhodamine fluorescence staining and confirmed by Ziehl-Neelsen staining. Mycobacterial cultures were performed on solid media in the pathology department of DMCH. A diagnosis of tuberculous cervical lymphadenitis was confirmed by positive MTB culture, positive AFB smear with TB-PCR, or histopathological features compatible with TB with positive TB-PCR. Patients were treated according to Category-I TB treatment protocol and followed up at two-month intervals until completion of therapy. Treatment outcomes were recorded using a pre-structured case record form (CRF).

Data Analysis

Socio-demographic and clinical data were collected through a pre-designed questionnaire. Data were checked, coded, entered and analyzed using SPSS version 23. Results were presented as tables and graphs using MS Excel. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval was obtained from the Ethical Review Committee (ERC), Dhaka Medical College, Dhaka, Bangladesh, before commencement of the study. Written informed consent was obtained from all participants prior to enrollment. Confidentiality and anonymity of all participants were maintained throughout the study and all data were used solely for research purposes.

RESULTS

Among the 100 study patients, the majority (44.0%) belonged to the 31–45 years age group, followed by 46–60 years (30.0%). The mean age was 39.05 ± 9.32 years. Females predominated (68.0%) with a female-to-male ratio of 2.1:1. Most patients were from urban areas (64.0%). Regarding occupation, housewives constituted the largest group (26.0%), followed by day labourers (24.0%) and farmers (20.0%). Nearly half of the patients (48.0%) belonged to the poor socioeconomic class (*Table I*).

Table I
Socio-demographic characteristics of the study patients (*n* = 100).

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18–30	16	16.0
	31–45	44	44.0
	46–60	30	30.0
	>60	10	10.0
	Mean ± SD	—	39.05 ± 9.32
Gender	Male	32	32.0
	Female	68	68.0
	Female: Male ratio	—	2.1: 1
Residence	Rural	36	36.0
	Urban	64	64.0
Occupation	Service holder	12	12.0
	Business	18	18.0
	Day labourer	24	24.0
	Housewife	26	26.0
	Farmer	20	20.0
Socioeconomic status	Poor	48	48.0
	Middle	34	34.0
	Upper	18	18.0

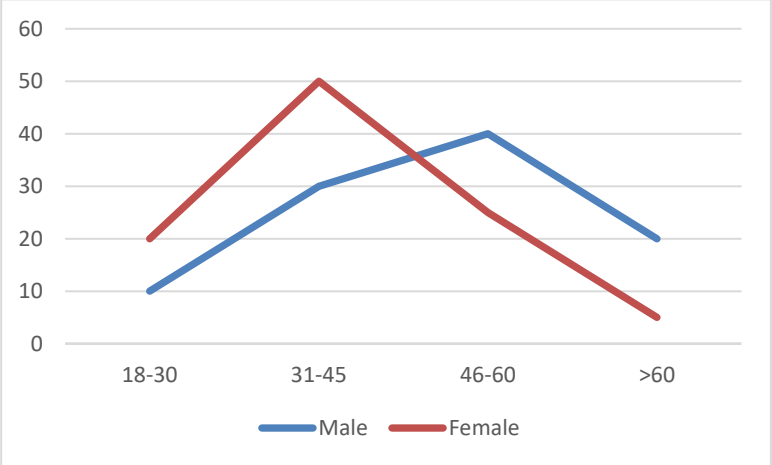


Figure 1 Frequency of tubercular cervical lymphadenopathy with age -gender variation (*n*=100).

Line chart shows the prevalence of tubercular cervical lymphadenopathy gradually increased with age. More male is affected in elderly age (*Figure 1*).

Table II
Distribution of respondents by clinical presentation's (*n*=100).

clinical presentation's	Frequency*	Percentage (%)
Indolent painless swelling	100	100.0
Systemic symptoms (n/%)	38	38.0
Coughing	15	15.0
Night Sweats	12	12.0
Weight loss	26	26.0
Weakness	35	35.0

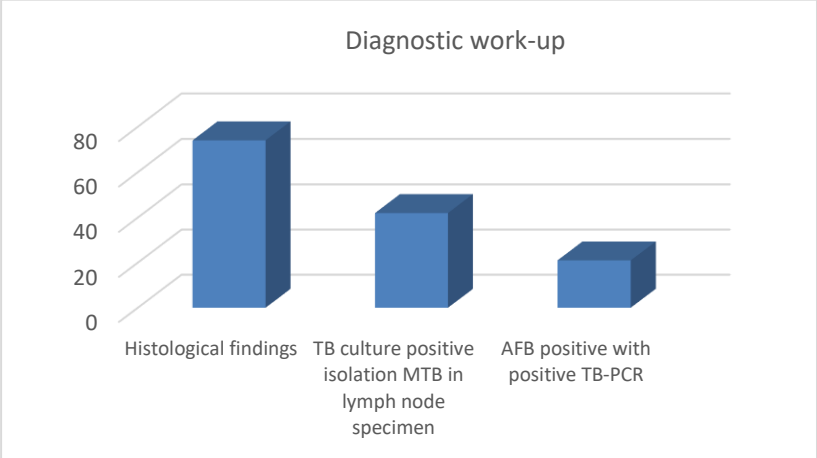
**Multiple responses.*

Above *Table II* shows that indolent painless swelling was detected in all cases. Most common symptom was coughing (15.0%), night sweats (12.0%), weight loss in 26.0% and weakness in 35.0% of patients.

Table III shows the lymph node examination findings. All cases were unilateral distribution. Number of enlarged lymph node revealed that single 87.0% cases and multiple 13.0% cases. The most common size (65.0%) of involved lymph node was 3-cm. Solid lymph nodes were most frequently involved in (92.0%) patients.

Table III
Lymph node examination findings (*n*=100).

Clinical characteristics of LN	Frequency	Percentage (%)
Distribution		
Unilateral	100	100%
Bilateral	0	0
Number of enlarge lymph node		
Single	87	87%
Multiple	13	13%
Number of involved Neck swelling		
<3 cm	5	5.0%
3-6 cm	65	65.0%
>6 cm	30	30.0%
Mode of presentation		
Solid mass	92	92.0%
Abscess	6	6.0%
Discharging sinus	2	2.0%



**Multiple responses.*

Figure 2 Intial diagnostic work-up.

Figure 2 shows the results of the intial diagnostic work-up. Histological findings compatible with TB and positive TB-PCR was detected in 74.0% cases, TB culture positive isolation of MTB in lymph node specimen was found in 42.0% patients and AFB positive with positive TB-PCR in 21 patients.

Table IV shows the evaluation of Ancillary Diagnostic Tests in Tuberculous Lymphadenitis. Associated chest lesions on radiography were evident in 22 cases: local pulmonary lesions in seven cases, hilar tuberculosis lymphadenopathy in 15 cases. The chest radiography was normal in other patients (78.0%). Tuberculin skin test was positive in 83.0% cases.

Table IV
Evaluation of Ancillary Diagnostic Tests in Tuberculous Lymphadenitis (*n*=100).

Ancillary skin test	Frequency	Percentage (%)
Tuber skin test		
Positive	83	83.0%
Negative	17	17.0%
CXR		
Normal	78	78.0%
Positive radiography evident	22	22.0%
Local pulmonary les/fibrosis	7	7.0%
Hilar/mediastinal/paratracheal nodes	15	15.0%

Table V shows the follow up after treatment completion. At 2nd follow-up (4th month later), indolent painless swelling, systemic symptoms and lymph node size was improved (35.0%, 17.0% & 23.0% respectively). At final follow-up (6th month later) significant improvement occurred. But indolent painless swelling present in 9.0% patients and lymph node size >3 cm found in 8 patients.

Table V
Assessment of major symptomatic improvement/ deterioration at different follow-up time (*n*=100).

Follow up time	Significant findings	Frequency	Percentage (%)
At 2nd month	Indolent painless swelling	100	100.0
	Systemic symptoms (n/%)	38	38.0
	LN (size >3)	95	95.0
At 4th month	Indolent painless swelling	35	35.0
	Systemic symptoms (n/%)	17	17.0
	LN (size >3)	23	23.0
At 6th month	Indolent painless swelling	9	9.0
	Systemic symptoms (n/%)	0	0
	LN (size >3)	8	8.0

Figure 3 shows the outcome of cases. Study revealed that successful treatment found in 92 patients. Presumptive treatment failure developed in 3 patients and Bacteriologically confirmed treatment failure in 5 patients.

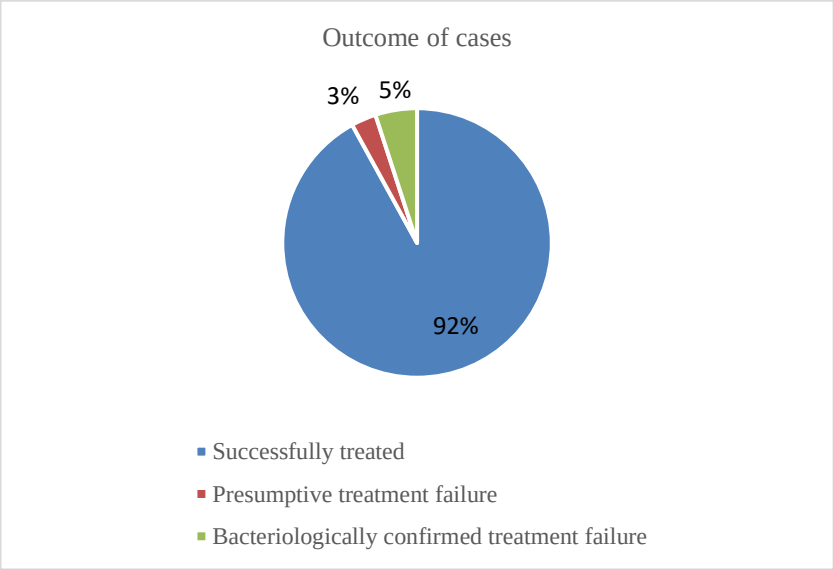


Figure 3 Overall outcome of cases (*n*=100).

DISCUSSION

This prospective interventional study was conducted in the Department of Otolaryngology & Head–Neck Surgery, Dhaka Medical College Hospital, Dhaka, to evaluate the clinical outcome of a 6-month anti-tubercular therapy (ATT) regimen in patients with rifampicin-sensitive tubercular cervical lymphadenopathy. Cervical tuberculous lymphadenitis (CTL) remains one of the most common forms of extrapulmonary tuberculosis (EPTB), particularly in endemic regions such as Bangladesh. In the present study, the majority of patients (44.0%) belonged to the 31–45-year age group with a mean age of 39.05 ± 9.32 years. This finding is consistent with previous studies reporting a peak incidence in the third to fifth decades of life. [4] Tuberculous lymphadenitis is commonly seen in young and middle-aged adults, likely reflecting higher exposure rates and active immune responses during these years. Female predominance was observed with females comprising 68.0% of cases and males 32.0%, yielding a male-to-female ratio of 1:2.1. Similar findings have been reported in earlier studies. One study involving 21 patients reported 61.9% females and 38.1% males with a mean age of 41 ± 21 years and a female-to-male ratio of 1.6:1.[4] In contrast, another study involving 140 patients found a more balanced distribution with a male-to-female ratio of 1:1.15 and a higher mean age of 59.55 ± 14.46 years. [20] Although pulmonary tuberculosis is traditionally more common in males, recent studies have reported a higher incidence of cervical lymph node tuberculosis among females, [21,22] supporting the findings of the present study. Several explanations have been proposed for this gender difference. Women may present earlier due to cosmetic concerns related to neck swelling, whereas men may delay seeking medical attention until the disease is advanced. [23–25] Biological differences in immune response, hormonal influences, nutritional status, and socioeconomic factors may also contribute.[25] Ramanathan et al. suggested that hormonal modulation of immunity may explain the higher susceptibility or different disease patterns in women. [25] Clinically, all patients in this study presented with indolent, painless cervical lymph node swelling, which is characteristic of tuberculous lymphadenitis. Constitutional symptoms were variably present, including weakness (35.0%), weight loss (26.0%), cough (15.0%) and night sweats (12.0%). These findings align with previous reports describing painless, slowly enlarging lymph nodes accompanied by systemic symptoms such as fever, malaise, weight loss and night sweats.[24] All cases in the present study had unilateral cervical lymphadenopathy, with single lymph node involvement in 87.0% of patients and multiple nodes in 13.0%. The most common lymph node size was 3–6 cm (65.0%) and most nodes were solid (92.0%). Similar observations were reported in a study of 140 patients, where 87.85% presented with solid lymph nodes, unilateral involvement was seen in 87.14%, and lymph node size ranged predominantly between 3 and 6 cm. [20] These consistent findings reinforce the typical clinical presentation of cervical tuberculous

lymphadenitis. Diagnostic evaluation in this study showed that 74.0% of cases had histopathological findings compatible with tuberculosis along with positive TB-PCR. Culture positivity for Mycobacterium tuberculosis was found in 42.0% of patients, while acid-fast bacilli positivity with TB-PCR was detected in 21 cases. These results highlight the diagnostic challenges of tuberculous lymphadenitis, where culture positivity rates are often low due to the paucibacillary nature of the disease.[1] Fine-needle aspiration biopsy (FNAB), histopathology, and molecular tests such as TB-PCR play complementary roles, especially in resource-limited settings. Ancillary investigations revealed associated chest lesions in 22.0% of patients, including local pulmonary lesions (7 cases) and hilar lymphadenopathy (15 cases). Chest radiography was normal in 78.0% of patients, similar to previous studies reporting normal chest X-rays in approximately 75–76% of cases. [4,20] Tuberculin skin test positivity was observed in 83.0% of patients, supporting its utility as an adjunctive diagnostic tool in endemic areas. Treatment outcomes in the present study were highly favorable. Successful treatment was achieved in 92.0% of patients following a standard 6-month Category I ATT regimen while treatment failure occurred in 8.0%. Among failures, 3 patients had presumptive treatment failure and 5 had bacteriologically confirmed failure. Although lymph node size did not regress in these cases, patients showed improvement in general health and weight gain. Surgical excision was performed, and microbiological positivity was confirmed in five cases. These findings are consistent with international guidelines and published literature. The Infectious Diseases Society of America (IDSA) recommends a 6-month regimen for drug-susceptible tuberculous lymphadenitis, consisting of isoniazid, rifampicin, pyrazinamide and ethambutol for 2 months, followed by isoniazid and rifampicin for 4 months. [13] Multiple studies have demonstrated no significant difference in cure or relapse rates between 6- and 9-month regimens. [14–16] WHO guidelines similarly endorse 6-month regimens for rifampicin-susceptible and even isoniazid-resistant lymph node tuberculosis. [17,18] Surgical intervention in tuberculous cervical lymphadenitis is generally reserved for diagnostic biopsy or for residual lymphadenopathy after adequate chemotherapy. Tuberculosis of cervical lymph nodes is primarily a medical disease, and surgery plays a limited, adjunctive role. [26,27,28] In the present study, surgical intervention was required only in a small proportion of patients, further supporting the effectiveness of short-course chemotherapy. In this study demonstrates that a 6-month ATT regimen is highly effective in the management of rifampicin-sensitive tubercular cervical lymphadenopathy. Early diagnosis using a combination of clinical evaluation, histopathology, and molecular methods, followed by timely initiation of standard therapy, results in excellent treatment outcomes with minimal need for surgical intervention.

CONCLUSIONS

This study suggests that lymph node tuberculosis is seen more frequently in female than male. In this study total 8 cases (8.0%) had TB treatment failure. The failure in all cases was diagnosed as clinical or presumptive failure and microbiological confirmed treatment failure was 5 patients. Six months anti tubercular therapy was effective in 95% cases of RIF sensitive tubercular cervical lymphadenopathy.

LIMITATIONS

This study was not without limitation. The limitations of the studies were as follows:

- It was a short follow up time. Only patients admitted in DMCH, were taken for the study. So this will not reflect the overall picture of the country. A large scale study needs to be conducted to reach to a definitive conclusion
- Study was conducted in tertiary care hospital which may not represent the real scenario of the country.
- Sample size is not adequate.

RECOMMENDATION

1. Study with larger sample size.
2. Sample should be representative the whole country by taking sample from all socio-cultural and geographical groups of the country.
3. A health care policy should be formulated with wide range publicity for developing awareness of TB for prevention, detection, accurate treatment.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article.

SOURCE OF FUNDING

This research received no external funding. The study was conducted using departmental and personal resources of the investigators.

ACKNOWLEDGEMENT

The authors express their sincere gratitude to the Department of Otolaryngology and Head–Neck Surgery, Dhaka Medical College Hospital, Dhaka, for providing the necessary facilities and institutional support to conduct this study. The authors are also grateful to all patients who willingly participated in the study and to the physicians, nursing staff, laboratory personnel and hospital authorities for their valuable cooperation during data collection and follow-up.

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