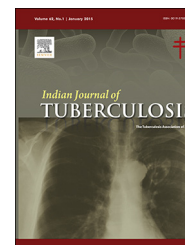


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Original Article

Add-on prednisolone in the management of cervical lymph node tuberculosis

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ABSTRACT

Studies defining role of systemic steroids in routine management of cervical lymph node tuberculosis (CLNTB) are too few and inconclusive. The present study was carried out to define the role of add-on prednisolone in the management of CLNTB. Patients of CLNTB were randomized into two groups. Group I patients received DOTS Category I treatment along with prednisolone 1 mg/kg for first 4 weeks and then tapered down. Group II patients received DOTS Category I treatment along with placebo. Patients were kept under close follow up for 6 months. Response to therapy and adverse drug reactions, if any, were recorded.

A total of 120 patients completed the study protocol. The two groups were similar with respect to age, sex, smoking, alcoholism, and clinical profile ($p > 0.5$). At 2 months, 54 out of 60 patients in Group I showed symptom relief when compared with 44 out of 60 patients in Group II ($p < 0.001$). Abscess, sinus, and/or appearance of new lymph node/s were noted in 3 and 13 patients in Group I and Group II, respectively ($p < 0.001$). Complete resolution was seen in 57 patients in Group I when compared with only 40 patients of Group II and sequel in form of residual LN was noted in three patients of Group I when compared with 20 in Group II ($p < 0.001$). Gastrointestinal side effects were reported by higher number of patients in Group I but skin rashes and joint pain were fewer when compared with Group II ($p > 0.05$). All the adverse reactions were transient and amenable to symptomatic treatment.

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1. Introduction

The commonest form of extra pulmonary tuberculosis (EPTB) in humans is peripheral lymph node tuberculosis (PLNTB). The

reported prevalence of the disease is 5% and 30–55% of all the TB and EPTB cases, respectively.^{1,2} Like all other forms of TB, PLNTB is also managed with standard anti-tubercular (ATT) drugs/directly observed treatment strategy (DOTS) Category I under RNTCP,³ but some of these patients often show up with

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appearance of new nodes, increase in the size of existing nodes and/or sinus formation while on ATT and require surgical intervention.⁴

Add-on steroids to ATT have led to better outcomes in many forms of EPTB including pleural effusion,⁵ pericardial effusion,⁶ and tubercular meningitis. Anecdotal reports are also available; they show that add-on steroids are useful in the management of mediastinal lymphadenitis as well,⁷ but studies defining the role of add-on steroids in routine management of PLNTB are too few and inconclusive.⁸

Since cervical lymph node tuberculosis (CLNTB) is the most common form of PLNTB,⁹ and it is also the most cosmopolitan form of the disease, the present study was carried out to define the role of add-on prednisolone in its management.

2. Materials and methods

All the patients presenting with cervical lymphadenopathy between 1st April 2011 to 30th April 2013 at the Institute of Respiratory Diseases, Sawai Man Singh Medical College, Jaipur, Rajasthan, were recruited for the study. Permission of the ethical committee was obtained vide No. 453/MC/EC/17/12/2012. The trial was registered with clinical trial registry vide No. CTRI/2014/12005299. After giving full information regarding the nature of the study, a written consent was obtained from all the patients.

These patients were then re-evaluated with detailed clinical history, thorough physical examination and investigations including skiagram chest PA view, complete blood counts, complete urine examination, random blood sugar, HIV serology, sputum smear for acid fast bacillus, and Mantoux skin test. Ultrasound abdomen and contrast enhanced computerized tomography of thorax/abdomen/head were also done, as and when required.

A thorough examination of the enlarged lymph node/s (LN/s) was undertaken that included the site, size, number, tenderness, consistency, and mobility. Patients with diabetes mellitus, hypertension, acid peptic disease, and those with poor response to treatment in the past and/or pre-formed LN abscess were excluded from the study. Pregnant women, alcoholics, HIV seropositives, and those refusing consent for the study were also excluded.

Fine needle aspiration of the largest LN was aseptically done in the remaining patients. The material so obtained was subjected to cyto-pathological and bacteriological examination to find out evidence of TB. Whenever the material was shown as insufficient, an excisional biopsy was also done and processed as above. Only those, who were found positive for TB on cyto/histo-pathology and/or bacteriology, were eligible for final inclusion in the study.

The study patients were randomized into two groups. **Group I** patients were put on DOTS Category I treatment along with prednisolone 1 mg/kg body weight for first 4 weeks, subsequently tapered to 0.5 mg/kg body weight for another 4 weeks and then tapered down by 5 mg every week to zero dose. **Group II** patients were put on DOTS Category I treatment along with placebo.

Patients were kept under close follow-up during the course of treatment and response to therapy as well as adverse drug

reactions, if any reported by the patients, were recorded. Adverse reactions were first managed symptomatically and if persisting, then by transient withdrawal of drugs. Complications in the form of abscess, sinus formation or appearance of new LN were also recorded. An abscess was managed by repeated aspirations as advocated by Jha et al.⁹ A sinus was managed surgically and new LN/s, by prolongation of ATT.

The data so collected were analyzed for statistical significance using Student's *t* tests for continuous variables and χ^2 tests for non-continuous variables.

3. Results

After exclusions, 120 patients completed the study protocol, 60 in each group. The demographic profile of the patients is shown in Table 1. The two groups were similar with respect to

Table 1 – Pretreatment profile of the study patients.

Parameter	Group I	Group II	<i>p</i> -Value
Mean age in years	27.5 ± 12.9	26.3 ± 11.7	≥0.5
Sex			
Male	24	22	≥0.5
Female	36	38	
Smoker	2	2	≥0.5
	58	58	
Alcoholic	10	6	≥0.5
	50	54	
Symptoms ^a			
Swelling	44	46	≥0.5
Fever	25	28	
Loss of appetite	20	18	
Loss of weight	19	14	
Fatigue	28	15	
LN examination			
Number			
1	28	35	≥0.5
2	14	10	
±3	18	15	
Local tenderness			
Yes	24	18	≥0.5
No	36	42	
Mobility			
Yes	58	58	≥0.5
No	2	2	
Location			
U/L	53	57	≥0.5
B/L	7	3	
Mantoux test			
≤10 mm	2	2	≥0.5
≥10 mm	58	58	
Lesion in skiagram chest			
Yes	4	2	≥0.5
No	56	58	
Cyto/histopathology			
Positive	54	53	≥0.5
Negative	6	7	
AFB in LN smear			
Positive	8	12	≥0.5
Negative	52	48	

AFB, acid fast bacillus; LN, lymph node.

^a Some patients had more than one symptoms.

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