

## Original Research Article

# Treatment outcome of tubercular lymphadenopathy cases treated under dots: a five year follow up study

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## ABSTRACT

**Background:** Treatment of tubercular lymphadenopathy consists of at least 6 months of therapy with antitubercular drugs as DOTS in India. Some studies recommend that extension of therapy for some time may lead to lesser recurrence and relapse. This study was planned to assess the outcome of DOTS therapy in lymph node tuberculosis (TB) cases treated under RNTCP and to find out the prevalence of relapse in these patients in southern Rajasthan.

**Methods:** This was a retrospective analysis of 275 cases of lymph node tuberculosis treated with DOTS under RNTCP. An immediate outcome of these cases was recorded and further traceable 81 patients were interviewed for long term outcome.

**Results:** In our study population, treatment completion rate was 93.09%, defaulter rate was 4% and death reported in 3.7% (3/81) cases. We observed relapse rate of 9.1% after treatment completion. A total of 7.04% patients received extended treatment and none of them had relapsed during our follow up.

**Conclusions:** Our study confirms that the efficacy of DOTS treatment is quite good in cases of tubercular lymphadenopathy but still requires review of programmatic strategy. An extension of antitubercular therapy is recommended because patients treated with DOTS had a little higher relapse rate in comparison to whom the treatment extended who had no recurrence and relapse.

**Keywords:** Antitubercular therapy, Directly observed therapy, Tubercular lymphadenopathy

## INTRODUCTION

Extrapulmonary tuberculosis (EPTB) constitute about 15-20% of all TB cases in immunocompetent patients, but often more than half of all TB cases in immune-suppressed individuals. The most common sites of involvement in EPTB are lymph nodes (LN) followed by pleura (occurring in approximately 35% and 20% of all EPTB cases). Treatment of EPTB consists of standard 6 months anti-tubercular therapy (ATT) with 4 first line drugs, namely Rifampicin (R), Isoniazid (H),

Pyrazinamide (Z) and Ethambutol (E). Few of EPTB sites are difficult to treat and some authors and scientific societies recommend extending the duration of treatment to 9 months in meningeal, osteoarticular and lymphatic TB, but there is no firm evidence supporting this recommendation as treatment trials conducted for EPTB have not been as thorough as those for PTB.

Under revised national tuberculosis control program of India (RNTCP) there is no difference in treatment of EPTB and PTB.<sup>1</sup>

Management of tuberculous lymphadenitis also involves appropriate use of anti-tuberculous chemotherapy with the judicious use of surgical excision in a minority of patients and generally, no modifications or prolongation in anti-tuberculous treatment regimen is indicated.<sup>2,3</sup> India has been implementing Revised National Tuberculosis Control Program, WHO recommended Directly Observed Treatment Short Course (DOTS) to control TB. Some of the authors have raised doubts about the efficacy of DOTS treatment in lymph node TB.<sup>4,5</sup> Therefore the present retrospective study was undertaken to follow up the cases of lymph node TB treated under the RNTCP DOTS regimen with the aim to observe the efficacy of DOTS for TB lymphadenitis in the form of immediate outcome as well as relapse rate in such patients in a tertiary referral center at Udaipur (Rajasthan).

**METHODS**

The present study was conducted in Department of Tuberculosis and Chest Diseases, RNT Medical College, Udaipur (Raj.). The patients registered under RNTCP during January 2001 to December 2006 at the District Tuberculosis Centre, Udaipur and treated at DOTS Centers in the vicinity of DTC, Udaipur were included in the study.

**Present study consists of two phases**

*Phase-I: Treatment outcome*

A retrospective analysis of records of lymph node TB patients was done to assess various immediate outcomes of DOTS and recorded as cured, defaulted, transferred out, treatment completed, treatment failure and death.

*Phase-II: Follow up*

The addresses of cured patients residing in vicinity of DTC, Udaipur (a total of 141) were collected from DTC records and then sorted out according to Gali, Mohalla and Colony. Home visits were made to all traceable cases (81) who completed the treatment and interviewed to record further extension of treatment, failure or NON-DOTS intake if any.

For the patients reported 'DEAD', the cause of death was ascertained from the close relatives through interview and scrutiny of available records including death certificate, if any. Data were entered and analyzed using SPSS version 20 and Microsoft excel.

**RESULTS**

Retrospective analysis of records of 275 cases of lymph node tuberculosis treated under DOTS category III or I, revealed that a total of 256 patients (93.09%) completed the treatment, 11 patients defaulted the treatment followed by 4 patients declared as treatment failure (Table 1).

**Table 1: Various immediate outcomes of patients registered under DOTS.**

Outcomes	No. of patients	%
Treatment completed	256	93.09
Treatment defaulted	11	4.00
Treatment failure	4	1.45
Died	1	0.36
Transfer out	3	1.09
Total	275	100

Out of 281 patients 81 cases residing nearby area could be traced out by their address and rest were either distantly located from the study centre or shifted to other-place. These 81 patients were further interviewed for follow up (Table 2).

**Table 2: The treatment outcome of further followed-up, 81 patients.**

Outcome	No. of patients	%
Fully responded to Treatment	61	75.30
Treatment defaulted	06	7.40
Relapse	05	6.17
Treatment extension with DOTS/Non-DOTS	05	6.17
Diagnosed as MDR TB	01	1.23
Died	03	3.70
Total	81	100

Out of total 81 patients 11 (13.6%) received further treatment after completion of DOTS treatment. 5 out of total 81 patients (6.17%) received an extension of treatment by DOT/non-DOTS ATT. Three were registered under DOTS Cat (II) (3.73%) as relapse while one patient stated treatment for MDR TB by 2nd line drugs (1.2%). Two of the patients switched to Non-DOTS treatment after relapse of the disease (Table 3).

**Table 3: History of further treatment after completing DOTS in followed up 81 patients.**

History of treatment	No. of patients	%
Extension with non-DOTS (for 3-6 months)	05	6.17%
DOTS Cat (II)	03	3.73%
MDR (on 2 <sup>nd</sup> line)	01	1.2%
Non-DOTS ATT (after reappearing or relapse)	02	2.4%
Total	11/81	13.6%

When patients were assessed in term of long term outcome, we observed that none of the patients relapsed in five years follow up period, who received extended duration treatment. While 9.1% (6/66) patients relapsed in this follow up period who received the conventional 6 months DOTD therapy (Table 4).

**Table 4: Comparison of 71 patients who completed the treatment.**

Treatment Received	No of patients	No. of relapse	%
Patients with extended duration treatment	5	None	00%
Patients with usual duration treatment	66	6	9.1%

## DISCUSSION

The present study was a two-phase retrospective study of 275 patients of lymph node TB registered under DOTS in RNTCP during year 2001-2006 at the DTC, Udaipur, Rajasthan. Various immediate outcomes of primary treatment were recorded in 275 cases by careful screening of all available documents. A cohort of 141 treatment completed cases living in the vicinity of DTC, Udaipur was also identified to find out current status/ late outcome of these patients by visiting them at their address provided during treatment and interviewed personally. Only 81 out of these 141 patients (57.44%) with treatment completed status could be traced out despite our extensive efforts and rest were either distantly located from the study centre or shifted to other places. Similarly, Verma SK et al were also able to trace out only 38.14% of patients from their study cohort.<sup>6</sup> The low percentage of traced out cases in our study is probably due to the territorial margin of the area and a gap of more than 5 years for follow-up studies. The time gap may be responsible for lot of migration. Some cases could not be traced out due to incomplete addresses.

Of the 81 traced cases, 78 were alive at time of visit and 3 were dead. Detailed history and verbal autopsy was done to ascertain the cause of death from relatives wherever possible, it reflected that 2 out of 3 dead patients were suffering from simultaneous respiratory diseases.

A total of 93.09% of our study patients completed the DOTS treatment. This finding is in consonance with the study done by Jain NK et al who reported treatment completion rate of 96.7% and Sharma et al reported treatment completion rate of 94.9% in their study population.<sup>7,8</sup> The similar adherence rate was also observed by other authors.<sup>9</sup>

In our study, default of treatment was observed in 4% of the patients similar to Jain NK, et al who reported a default rate of 3.26%.<sup>7</sup> Other authors have observed similar default rates.<sup>9</sup> While Sharma et al reported slightly lower default rate (2.2%) probably due to better educational status of their patient population.<sup>8</sup>

We observed treatment failure in 4 (1.45%) cases, while 1 (0.36%) patient died during the treatment similar to findings of Sharma S, et al who also found a failure rate of 2.5% and the death rate of 0.3%.<sup>8</sup>

Further analysis of 81 patients traced by their address, revealed that 75.3% patients fully responded to the treatment similar to study by Jain NK, et al who found success rate of 71.9%.<sup>7</sup>

Some authors have observed slightly higher cure rates ranging from 82.7 % to 96%, with the primary regimen assigned to them at the beginning of treatment, while other authors have reported much lower success rate (63%) in such cases.<sup>10-12</sup>

Out of total 81 patients 11 (13.6%) did not show response at the end of treatment and received further treatment after completion of DOTS treatment, while 28.14% patients in a study by Jain N K et al, did not respond to treatment.<sup>7</sup> 6.17% of (81) patients received an extension of treatment for at least 3-6 months either through DOTS or Non DOTS, the rest were either switched to DOTS CAT II or 2<sup>nd</sup> line ATT similar to previous studies.<sup>7</sup> Kabra SK, et al reported that 14.8 % required extension of treatment for three months and 2.5 % patients required a change in the treatment regimen in their study patients.<sup>10</sup> Some other authors also have advocated the extension of anti-tubercular therapy in non-responding cases of lymph node TB.<sup>13,14</sup>

None of the patients relapsed in five years follow up period, who received extended duration treatment, while 9.1% (6/66) patients relapsed in this follow up period who received the conventional 6 months DOTD therapy, that is slightly more than reported by Jain NK et al (5.18%), Verma SK et al. (5%) and Dhingra et al (2.5%) whereas a study from van Loenhout-Rooyackers et al reported the relapse rate as 3.3% out of 422 cases even though they used daily regimen instead of DOTS therapy.<sup>6,15,16</sup> Surprisingly a study from India have reported that there were no relapse cases in their study after the end of 6 months DOTS therapy treatment and the cases were followed up for 22 months.<sup>11</sup> Probable explanation for this increased relapse rate in our study, may be due to less duration of follow up period in other studies in comparison to ours.

## CONCLUSION

To conclude, DOTS therapy for 6-month is effective modality in the treatment of tuberculous cervical lymphadenopathy with good compliance and low default rate, but the relapse rate is higher and an extension of ATT may reduce the relapse rate. This fact requires a larger multicentric study involving a large number of patients to prove adequacy of this regimen. The limitations of our study include its retrospective nature, single DOTS centre and a small number of patients traced out and interviewed for long term follow up.

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