

# A Comparison Of Three-Drug Anti-Tuberculous Treatment And Directly Observed Treatment Short Course In The Treatment Of Tuberculous Lymphadenitis

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## Citation

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## Abstract

Setting: DOTS program implemented in the management of extra pulmonary T.B. cases under RNTCP. Objective: To study the efficacy of DOTS vs. conventional three-drug antituberculous treatment in the outpatient setting and to compare patient compliance and recurrence rates. Methods: Sputum-negative patients with tuberculous lymphadenitis cases identified at OPD level in Goa Medical College (GMC). Cases randomly allocated to three-drug and DOTS regimens. Three-drug regimen cases followed up on monthly basis at GMC OPD with monthly drug collection. DOTS cases assigned to nearby health centre for drug collection and supervised therapy and followed up at two and six months of therapy at GMC OPD. Cases assessed for decrease in lymph node size and total clearance. Results: A total of 50 outpatients were enlisted in the study and randomly assigned to DOTS and three-drug groups after clinical workup and a pretreatment interview. At two month follow-up, 100% DOTS cases showed decrease in lymph node size as compared to 0% of three-drug cases. At six months follow-up, both groups showed total lymph node clearance in 100% cases. DOTS group had three defaulters (12.5%) due to migration, and could not be followed up. No recurrences or treatment failures were observed. Conclusions: DOTS therapy is shown to be equally efficacious to the conventional three-drug regimen in management of tuberculous lymphadenitis, with early reduction in lymph node size. Default rate is still high, despite availability of drugs, due to migrant population.

## INTRODUCTION

One Fifth of the global T.B. incidence is in India, with 1.8 million new cases every year, 0.8 million of these being infective and smear positive cases. The disease incidence peaks in people belonging to the most economically productive age group of 15-60 years.

Peripheral lymph node involvement is the commonest form of extra pulmonary mycobacterial tuberculosis and the cervical region is the most commonly affected site.

Tuberculous cervical lymphadenitis tends to occur more often in females and presents in young adults. According to Raviglione et al, HIV is the single most important risk factor for the progression of dormant tuberculosis into clinical disease, the virus compromising the immune response.

The Revised National Tuberculosis Control program was introduced in India in 1993, and expanded to cover the entire population by June 2005. The RNTCP applied the WHO recommended DOTS strategy (Directly Observed Treatment

Short Course), thus shifting the responsibility for cure from the patient to the health system.

A study was carried out in the Goa Medical College (GMC) – Bambolim, Goa, comparing the standard Three-drug anti-tuberculous treatment regimen to DOTS in the management of Tuberculous Lymphadenitis on an outpatient basis.

## MATERIAL AND METHODS

### STUDY POPULATION

The study was conducted in the Out Patient Department of Surgery, Goa Medical College from August 2004 – August 2006. Study subjects had to fulfill the following:

### PRETREATMENT INVESTIGATIONS

#### A) CLINICAL WORKUP

#### B) PRETREATMENT INTERVIEW: AS PER CLINICAL PROFORMA

Treatment regimens:

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Patients were allocated to two groups by random sampling numbers.

Group A: Daily self administered AKT3

**2 MONTHS**

**4 MONTHS**

Group B: Category III DOTS-thrice weekly administration

**2 MONTHS**

**4 MONTHS**

Patients weighing > 60 kg received additional Rifampicin 150 mg. Patients weighing less than 30 kg received drugs as per body weight.

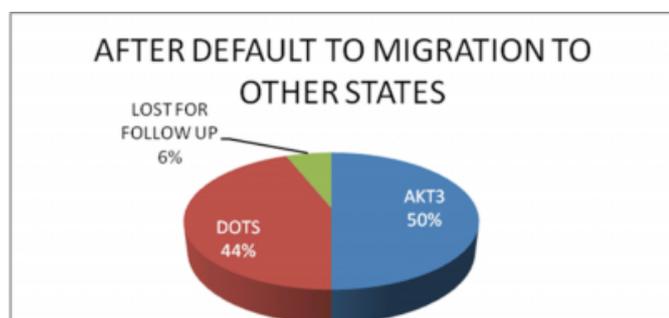
## LOGISTICS

Patients with self administered regimen were asked to visit the GMC OPD once a month to collect the drugs to be self administered at home. They also had to follow up at the end of two months and at completion of treatment.

Patients started on Category III DOTS were registered under the same and asked to follow up at the closest health centre for drug collection. For the first two months (24 doses), the patient visited the health centre thrice weekly and took anti-tuberculous treatment under direct supervision of the DOTS provider. For the next four months (54 doses), the patient visited the DOTS centre once weekly to collect the blister pack for the weekly treatment.

One separate box containing blister packed rugs was earmarked for the patient in the health centre from Day 1 of treatment to avoid treatment interruption due to drug shortage. The patient followed up in GMC OPD at two months and six months for assessment.

**Figure 1**



After Default to Migration to Other States

## RESULTS

**Patient Allocation:** Fifty patients fulfilling the criteria of eligibility were admitted to the study. By random allocation, twenty-five were prescribed AKT3 regimen and the remaining were prescribed DOTS regimen

**Response at two months:** All twenty-five patients in the DOTS group showed a favorable response (reduction in size of lymph node size) at the end of two months. No such reduction was seen in the AKT3 group (statistical difference  $p < 0.001$ )

**Response after six months:** Both groups showed a favorable response after six months of therapy. There were three defaulters in the DOTS group due to migration to other states, and could not be followed up

**Figure 2**

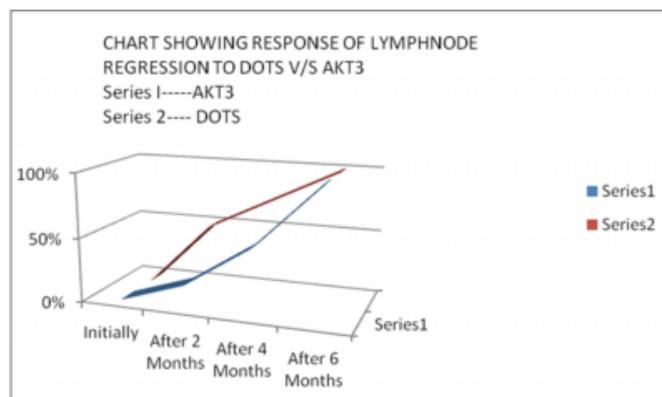


Chart Showing Response Of Lymphnode Regression To Dots V/S Akt3

## DISCUSSION

Chaube et al<sup>3</sup> in a study comparing THSH2/SH2, SH2 and TH showed that all three chemotherapeutic regimens were equally efficacious, acceptable and well tolerated. Our study compared daily administered 2HRZ/4HR to supervised intermittent 2HRZ/4HR and showed that while DOTS achieved better initial gland clearance, it was equally efficacious as AKT3 over six months.

Baily et al<sup>2</sup> in a concurrent comparison of unsupervised self administered daily regimen and a fully supervised twice weekly regimen of chemotherapy in routine OPD treatment program, showed that, in rural areas, due to distance and nature of employment, refusal for supervised regimen played a role in reducing drug collection for SHTW as compared to TH patients. In our study, defaults were recorded in the

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DOTS group, primarily due to migration to other states, during the course of the study.

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