AN ALTERNATIVE METHOD OF PROVIDING SUPERVISED SHORT COURSE CHEMOTHERAPY IN DISTRICT TUBERCULOSIS PROGRAMME*

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Summary: The feasibility of involving ‘Dais’ in supervised administration of an oral 6 month’ SCC regimen in DTP was studied in 2 districts. A concurrent comparison was made between the Dai Method and the present DTP procedure, called the PHI Method, in terms of treatment completion and cure rates at the end of treatment period. A total of 617 patients were observed; 332 in Dai method and 285 in PHI method. About 68% of patients in the Dai method and 33% in the PHI method took more than 75% of treatment in both intensive and continuation phases. The outcome in terms of smear negativity at the end of treatment period was 86.9% and 72.2% respectively. There were 17 (5.72%) deaths in the Dai method and 16 (8.5%) in the PHI method. Treatment completion and cure rates were significantly higher in the Dai method. It is concluded that Dais can be used for supervised drug administration in DTP for increasing the cure rates.

INTRODUCTION

Non-adherence to prescribed anti-tuberculosis treatment is a major obstacle in tuberculosis control. The District Tuberculosis Programme (DTP) performance in terms of SCC treatment completion rate has been observed in several operational studies such as the one conducted by National Tuberculosis Institute (NTI), Bangalore1 and the other by Tuberculosis Research Centre (TRC), Madras2. Treatment completion rates observed in the two studies and from DTP monitoring report3 were 33%, 54.6% and 55% respectively. Thus, poor treatment adherence remains a problem despite having SCC regimens of high efficacy. Directly Observed Therapy-Short Course (DOTS) has been adopted under the Revised National Tuberculosis Control Programme4 (RNTCP). At present, DOTS implementation is mostly at established centres. Extension of drug administration to patients near their homes through health workers, health functionaries, neighbours, close relatives, etc, although recommended has as yet not been carried out. It was felt necessary to find an alternative drug distribution method applicable nearer to patients’ residence, at suitable and acceptable timings for supervised SCC administration. The traditional birth attendant (Dai) is invariably available in each village. Hence, a study was conducted by the NTI to assess the utility of Dais for supervised administration of anti-tuberculosis drugs to patients.

Objectives

i. To compare the treatment completion pattern and cure rate, as assessed by sputum microscopy, when drug distribution is undertaken by Dais with similar data for the usual DTP procedure.

ii. Operational efficiency of drug supply from the PHI under the two methods.

MATERIAL AND METHODS

Study Design and Area

The study was conducted in Kolar and Tumkur districts of Karnataka state because of comparability in their health administration. A total of 47 PHIs from 8 taluks in the Dai Method and 59 PHIs from 7 taluks in the PHI Method were selected. The selection of PHIs was based on 60% of the X-ray (XC) and Microscopy (MC) centres by probability proportion to size with replacement (PPSWR), size being the case finding activity. The remaining PHIs were used as

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basal group for comparison.

Criteria for Admission

Smear positive pulmonary tuberculosis patients diagnosed at the PHIs with no history of previous treatment with anti-tuberculosis drugs and residing within the study area were eligible for intake.

Regimen: 2 EHRZ/4H$_2$R$_2$

An SCC regimen containing 4 drugs in the intensive phase, i.e. Ethambutol 800 mg, Isoniazid 300 mg, Rifampicin 450 mg and Pyrazinamide 1.5g daily for the initial two months followed by Isoniazid 600 mg and Rifampicin 600 mg twice weekly for 4 months was given to the study patients. In the PHI method, drugs were issued on fortnightly basis for self-administration at home.

Fig. 1 and Table 2 show the distribution of patients treated under the Dai method. Of the 332 patients, 187 patients were initiated to treatment by Dais and 145 by other health workers. Of the 187 patients, 125 were treated by Dais throughout while 62 continued their treatment with PHI/DTC, hospital, HW and other staff.

Training of Dais

Dais were trained in two stages: In the I stage, they were called to the PHCs in batches for one-day training on characteristics of anti-tuberculosis drugs, mode of administration, method of issue, motivation, side effects and maintenance of treatment cards. In the second stage, retraining was given at their homes, as and when a patient belonging to their village was diagnosed and allotted for treatment through them. The supervisory staff administered the first dose of drugs in her presence, for demonstration. The Dai then administered the drugs to the patient at her home and recorded the same on treatment card kept with her. For this purpose, the monthly drug supply, packed as daily doses, along with patient’s treatment card and a pencil were put in a plastic bag and handed over to her by a health worker.

Patients were carefully advised to go to Dai’s home and consume the drugs in front of her. Entries were to be made in the treatment card as soon as the drugs were consumed. Subsequently, the Health worker (HW) replenished drug supply and supervised the Dai every fortnight. A research worker from NTI visited each patient and concerned Dai’s homes to verify initiation of treatment by Dai. After that, no visit was made till the end of treatment to avoid any interference by the research team. In the PHI method (Control group), the patients collected their drugs as per routine procedure. Management of drug default and adverse reactions was done as per the DTP procedure.

Incentives to Dais

No incentives were given to Dais for administration of drugs. However, they were not barred from receiving any benefit in cash or kind from the patients. During the one-day training a sum of Rs. 25 was given to each Dai as travelling allowance.

Study Period

The intake of patients lasted from September 1994 to March 1995 and a total of 617 patients were inducted into the study, 305 in Kolar district and 312 in Tumkur district. Of them, 332 were placed in Dai method and 285 in PHI method, as given in Table 1.

Drug Supply and Followup

Drug supply was provided by NTI for both the methods. In the Dai method, patients were issued drugs for 10 days from the PHI and sent to the Dai through the Health Worker (HW). In the PHI
method, the drugs were issued to patients on fortnightly basis as per DTP procedure. The NTI Research workers were not allowed to interfere in the day to day management of patients except for the initial home visit done to verify initiation of treatment and subsequent visit at the end of treatment period.

Follow-up examinations were done by sputum smear examination at the end of 3rd and 5th/6th months of treatment. The PHI staff were supposed to do these routine examinations but NTI research workers collected sputum specimens while collecting the treatment cards from Dais at the end of treatment period. No attempt was made by them to collect the 3rd month specimens.

**RESULTS**

Fig. 1 and Table 2 show the distribution of patients treated under Dai method according to various drug distributors. Of the 332 patients, 187 (56.3%) were initiated on treatment by Dais, of whom 125 continued to be treated by them, 41 went back to PHI and 21 were treated by others who could be considered equivalent to Dai. 44 patients were treated by other drug distributors, most of them were considered to be equivalent to Dai by the HW. So of the 332, 190 (187 + 2 + 1) were treated through Dai at some point of time.

Table 3, shows the coverage for follow up examinations at the end of treatment. About 89.5% of patients in Dai method and 65.6% in PHI method were followed up. The coverage for Dai method was higher perhaps because NTI research team could collect sputum also at the end of 3rd month in Dai method.

Table 3. Coverage for follow up examination at the end of treatment

<table>
<thead>
<tr>
<th>Method</th>
<th>Total patients</th>
<th>Follow up done</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No.</td>
</tr>
<tr>
<td>Dai</td>
<td>332</td>
<td>297</td>
</tr>
<tr>
<td>PHI</td>
<td>285</td>
<td>187</td>
</tr>
</tbody>
</table>

Table 4. Treatment compliance according to amount Of drugs taken

<table>
<thead>
<tr>
<th>Level</th>
<th>Intensive phase</th>
<th>Continuation phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>&lt;75%</td>
<td>&lt;75%</td>
</tr>
<tr>
<td>b</td>
<td>≥75%</td>
<td>&lt;75%</td>
</tr>
<tr>
<td>c*</td>
<td>≥75%</td>
<td>≥75%</td>
</tr>
</tbody>
</table>

* Completed optimum treatment in DTP
compliance levels. The level ‘c’ is equivalent to completed treatment group under DTP.

Table 5 shows the distribution of patients according to 3 compliance levels for both the drug distribution methods. A total of 68.1% patients in Dai method and 33.3% in PHI method completed level ‘c’ of treatment compliance. The difference between the two methods is significant (P < 0.01). However, in PHI method, 43.2% of patients took level ‘b’ treatment indicating that 76% of the patients completed 2 months of intensive phase of treatment. Compliance levels in the two sub-groups of Dai method i.e. by Dai and others were not significantly different.

Table 6 presents the result of treatment at the end of chemotherapy. In the Dai method, 297 of 332 patients were followed up, of whom 258 (86.9%) became smear negative, 22 (7.4%) remained smear positive and 17 (5.7%) were dead. In the PHI method, of the 187 patients whose sputum was examined during follow up 135 (72.2%) became smear negative, 36 (19.3%) were positive and 16 (8.5%) were dead. The difference in the outcome in the Dai method is significantly higher (P < 0.01). In Dai method, 97.2% compared with PHI method (91.3%) became smear negative with level c treatment compliance. The favourable response to treatment is directly related to level of compliance.

**DISCUSSION**

In the RNTCP, a major thrust has been given to DOTS to achieve 85% cure rate. DOTS can be extended to majority of the patients in DTP by offering an alternative method of drug administration, through various health functionaries, i.e., Dai, Anganwadi worker, Health Worker and others, after doing proper operational studies.

This study presents the feasibility of offering an oral SCC regimen through Dais to improve treatment adherence and achieving better response to treatment. The findings represent the performance in an average DTP, if treatment is brought nearer to the patients’ homes, and regular drug supply is maintained at PHIs. The operational aspects involved such as default pattern, drug supply from PHI, etc. will be reported separately. It is seen that about 68% of patients in Dai method and 33% in PHI method completed optimum treatment (≥ 75% of drug intake in both the phases). Bacteriological negativity by direct smear examination under respective methods was around 87% and 72%, the difference being significant. However, given the very poor compliance of 33% in PHI method and attaining 72% sputum negativity needs explanation. It could be attributed
to two factors i.e., robustness of the regimen used and about 43% of patients completing level b of treatment compliance implying that if patients take 4 drugs in the initial intensive phase the chances of favourable response are better. Similar observations were made in a study with SHTW regimen of 12 months’ duration wherein 68% of patients became culture negative with 31% of treatment completion rate\(^5\). These results also show the importance of regimen and supervised administration of drugs.

**CONCLUSION**

It appears possible to utilise the services of Dais for distribution of drugs to tuberculosis patients with a suitable SCC regimen. Both levels of compliance and favourable response to treatment were significantly higher in the Dai method in comparison to PHI method. The patients who were treated by other drug distributors than the Dai, also achieved better results in comparison to the PHI method. Deaths among the two groups were low and similar.

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