Evaluation of treatment outcome of tuberculosis patients in the urban field practice area of D. Y. Patil Medical College, Pimpri, Pune

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Abstract

Background: Tuberculosis (TB) bacilli have lived in symbiosis with mankind since time immemorial. RNTCP is the largest and the fastest expanding programme throughout the world as 1.29 million patients in 2005, 1.39 million patients in 2006 and 1.48 million patients in 2007 were enrolled for treatment. In 2008, 1.51 million patients have already been placed on treatment. Treatment success rates have tripled from 25% to 86% & TB death rates have been cut 7 fold from 29% to 4% in comparison to the pre-RNTCP (Revised National Tuberculosis Control Programme) era.[1] Objective: To study treatment outcome in the form of cure rate, treatment completion rate, failure rate, death rate in the study area. Method: An ambispective study was done in urban field practice area attached to Padamshree Dr. D.Y. Patil Medical College Pimpri, Pune. The study was carried out during 1st July 2011 - 30th September 2013. Results: A total 429 subjects were enrolled in the study of which, 224(52.24%) were successfully completed the treatment, followed by 110(25.54%) which were cured, 34(07.92%) were defaulted, 28(06.52%) were transferred out, 17(03.96%) died and 16(03.72%) underwent treatment failure during the study period. Conclusion: In spite, of many efforts by RNTCP to treat tuberculosis patients it was found only 50 % of the subjects successfully completed the treatment.

Key Words

RNTCP; Treatment; Tuberculosis

Introduction

Robert Koch (1843–1910), a pupil of Henle, a gifted microscopist produced irrefutable evidence in 1882 that a specific microbe is the fundamental cause of tuberculosis. Using special staining techniques he succeeded in visualizing slender rods – which he called tubercle bacilli, Mycobacterium tuberculosis.[2] In the practice of public health regarding tuberculosis prevention and control, the natural history of Mycobacterium tuberculosis infection and tuberculosis disease underpins our understanding of tuberculosis epidemiology and the principles of tuberculosis control though the bacilli was discovered more than a century back by Sir Robert Koch in 1882 and effective drugs for treatment were available for more than half a century, still TB is ranked 7th in the world accounting for 2.5 percent of all deaths as per the WHO global burden of disease estimates for the year 2004.[3,4] In India since 1993, under implementation of the Revised National Tuberculosis Control Programme (RNTCP), the diagnosis of Pulmonary Tuberculosis is also primarily sputum based in accordance with the WHO guidelines.[5] India has had an on-going National TB Program (NTP) since 1962, under this program main emphasis was given on diagnosis based upon X-ray and slightly on sputum examination. In 1992, a national wide review was conducted with the assistance of SIDA & WHO (GOI 1992) to address the reasons for the failure of (NTP) National Tuberculosis Program. Based on these finding WHO recommended DOTS strategy in 1997 with the support of World Bank. The target of DOTS program was successful treatment or cure rate of 85% of new smear positive cases and detection of...
70% of such cases.[6] While many claims have been made about the success of DOTS expansion in terms of numbers covered[7-14], there are only a few reports providing details about actual treatment success rates.[15-17]

**Aims & Objectives**

To study treatment outcome in the form of cure rate, treatment completion rate, failure rate, death rate in the study area.

**Material and Methods**

An Ambispective study was carried out during 1st July 2011 – 30th September 2013 in urban field practice area attached to Padamshree Dr. D.Y. Patil Medical College Pimpri, Pune. Patients from DOTS centers in urban field practice population were the study subjects. Field practice area is situated at Landewadi, Bhosari, Pune. Population of field practice area is 1,10,000. Field practice area include 8 slums viz. Landewadi, Shanti Nagar, Gawali Nagar, Gawalimatha, Gavane Vasti, Balaji Nagar, Maali ali and Ambedkar Nagar. It runs under TU Bhosari, hospital of PCMC. There is one designated Microscopic centre and 30 DOTS providers in the area and some of which are taken for the qualitative study based on conventional sampling. Patients of tuberculosis who were registered from 1st July 2011 and completing treatment before 31st March 2013 were taken for the prospective study with informed consent and for retrospective analysis, data from DOTS registers was taken from 1st July 2010 to 30th June 2011. Regular visits were made to DOTS center and to patient’s houses during prospective study attached to urban field practice area of Padamshree. Dr. D.Y.Patil Medical College, Pimpri, Pune. Interviews were taken using structured and pretested questionnaire for study with written informed consent from the patients. Statistical analysis: Data was entered in MS-EXCEL sheet, compiled and analyzed by Epi Info 6 version and SPSS 17 version by proper statistical tests (Percentage, Chi-square). P-value of < 0.05 was considered statistically significant. The study was approved by Institutional ethical committee.

**Results**

Out of 429 subjects, a total 266(62%) were male and 163(38%) were female, a total 121(28.20%) subjects were belonging to age category between 15-24 years (70-Male, 51-Female) followed closely by 118(27.50%) subjects were in age group between 25-34 years (Male-66, Female-52) while least subjects were in age group between 0-14 years i.e. 33(07.69%) (Male-19,Female-14), mean age of the patients came out to be 31.89,std dev of 15.70, median of 28.0, mode 25.0 (Table 1 & Figure 1)

Out of the total 429 subjects, 224(52.24%) were successfully completed the treatment, followed by 110(25.54%) which were cured, 34(07.92%) were defaulted, 28(06.52%) were transferred out, 17(03.96%) died and 16(03.72%) underwent treatment failure during the study period. (Table 2) A total of 429 subjects enrolled in the study, the results shows that, among total 429 subjects, treatment success rate was 78% and among new smear positive subjects cured rate was 78%. Among total 429 subjects, failure rate was 4% and defaulter rate was 8%, retreatment sputum positive cases had cure rate of 28.57%, retreatment cases had treatment completion rate of 77%, failure rate of nil in others and 20% in retreatment sputum positive cases, defaulter rate of 10% in others cases and 26% in retreatment sputum positive cases. Total number of deaths during the study period was 17(4%), new smear negative cases who had completed treatment were 83%, failure rate was nil , defaulter rate was 10% and 2(03.07%) died. (Figure 2) New extra pulmonary subjects were 141 of which 89% were in the category of treatment completed, failures were 0.07% and 0.70% were died. Overall it was found that out of the total 429 subjects recorded, 78% were cured, 7.92% were the defaulter and 4% died. (Table 3).

**Discussion**

In our study it was found that, out of 429 subjects, there were 62% male and 38% female further it was found that new smear positive subjects were 129 (30.06%) while in the retreatment category there were 94(21.91%) subjects of which 10 were in Relapse, treatment after default (TAD) were 18, Failure were 7, Others were 59 and in new smear negative category a total of 65(15.15%) subjects were present, while in the new extra pulmonary there were 141(32.86%) subjects. A study conducted in Ernakulum showed that Pulmonary Tuberculosis patients were 186(65.3%) out of these 90(31.6%) were smear positive and 96(33.6%) were smear negative patients. Extra pulmonary tuberculosis patients were 99(34.7%). In smear positive patients cured were 79(87.7%), failures were 2(2%), defaulter were 5(5%) and died were 4(5%). In smear negative pulmonary and extra pulmonary combined patients treatment completed
were 155(79.4%), defaulters were 25(12.8%), relapses were 4(2%) and died were 8(4%).

In our study outcome of 429 patients enrolled in the study, the results showed that new smear positive had cured / treatment completion rate of 78%, failure rate was 6% and defaulter rate 4%, retreatment cases had cure rate of 77%, failure rate nil, defaulter rate of 10% and total number of deaths during the study period was 17(4%), new smear negative who were cured were 83%, failure rate nil last defaulter rate was 9% and 2 among them have died. New extra pulmonary subjects were 141 of which 89% were treatment completed, failure 1 (0.70%) & 1(0.70%) died.

A study conducted in Delhi by Chadha S.L. and Bhagi R.P. showed following results for category 1 and category 2, the sputum conversion rate after 2 months of intensive phase treatment was 92.6% and 76.9% and cure rate was 97% and 73.3%. 49 out of 639 defaulted over all default rate was 7.7%, failure rate was 1.6%. [19]

A study conducted by Dholakia Yatin in Mumbai on Relapse following directly observed therapy short course revealed cure rate of 83.59% whereas treatment failure and defaulter rate was 1.08% and 9.45% respectively.[20]

Xiangi chen et al in China showed that, in smear positive new cases the cure rate was 95.3%, treatment completed rate was 1.2%, death rate was 1.3%, failure rate was 0.9%, default rate was 0.7% and transferred out was 0.2% and others were 0.3%. In smear positive relapse cases the cure rate was 90%, treatment completed rate was 2.3%, death rate was 2.4%. Failure rate was 0.3% and others were 0.6%. In smear positive re- treatment cases the cure rate was 90%, treatment completed rate 2.3%, death rate was 2.3%, failure rate was 3.3%, default rate was 1.3%, and transferred out rate was 0.2% and others were 0.7%.[21]

In our study slightly higher failure rate was observed as compared to the studies described, while 0% failure rate was observed in retreatment cases which are far better that study done in China by Xiangi Chen et al. Defaulter rate was found to be less as compared to studies conducted by Chadha SL and Dholakia in Delhi. Jethani S et al found that out of 362 subjects 44.8% had past history of pulmonary tuberculosis and 5% subjects had family history of tuberculosis but 50% were sputum positive. [22]

**Conclusion**

On the basis of outcome in this study it is concluded that, 78% successfully cured / completed treatment cases, failure rate was 4%, default rate was 8% and death rate was 4%.

**Recommendations**

Today, even after half century have passed since the introduction of chemotherapy for Tuberculosis, the burden of tuberculosis still remain on the peak and with emergence of drug resistance control of cases of tuberculosis still remain a challenging task.

Various recommendations can be made, the key is Patient Awareness - Patients should be made aware with health education regarding treatment duration, completion of treatment to avoid failure and proper sputum disposal to avoid transmission of disease. Proper and Frequent Training of DOTS provider and Health Worker. Strengthening of DOTS Treatment Centres and active participation and involvement of Private sector and NGOs.

**Limitation of the study**

A wide area could have been surveyed to get a better picture but the study was time bound.

**Relevance of the study**

As Tuberculosis have become a notifiable disease since 2012 and with increasing number of relapse and defaulter cases it have become mandatory not only to identify the cases but also keep a watch on the treatment outcome so as to prevent simple TB cases to convert into MDRs (Multi Drug Resistant) and XDRs (Extensively drug resistant).

**Authors Contribution**

All authors have contributed to the study.

**Acknowledgement**

We would like to express our thanks and gratitude to Dr V A Kakrani, Dr Harshal Pandav, Dr Megha Mamulwar, Dr Kajal Srivastava for helping and providing valuable inputs.

**References**


### Tables

#### TABLE 1 AGE WISE AND GENDER WISE DISTRIBUTION OF STUDY SUBJECTS

<table>
<thead>
<tr>
<th>Age groups (years)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14</td>
<td>19(57.57%)</td>
<td>14(42.43%)</td>
<td>33(67.69%)</td>
</tr>
<tr>
<td>15-24</td>
<td>70(57.85%)</td>
<td>51(42.15%)</td>
<td>121(28.20%)</td>
</tr>
<tr>
<td>25-34</td>
<td>66(55.93%)</td>
<td>52(44.07%)</td>
<td>118(27.50%)</td>
</tr>
<tr>
<td>35-44</td>
<td>45(75.00%)</td>
<td>15(25.00%)</td>
<td>60(13.88%)</td>
</tr>
<tr>
<td>45-54</td>
<td>33(67.34%)</td>
<td>16(32.66%)</td>
<td>49(11.42%)</td>
</tr>
<tr>
<td>55 above</td>
<td>33(68.75%)</td>
<td>15(31.25%)</td>
<td>48(11.31%)</td>
</tr>
<tr>
<td>Total</td>
<td>266(62.00%)</td>
<td>163(38.00%)</td>
<td>429(100%)</td>
</tr>
</tbody>
</table>

#### TABLE 2 DISTRIBUTION OF TUBERCULOSIS SUBJECTS AS PER OUTCOME

<table>
<thead>
<tr>
<th>Outcome as per DOTS</th>
<th>Number</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>110</td>
<td>25.54</td>
</tr>
<tr>
<td>Defaulted</td>
<td>34</td>
<td>07.92</td>
</tr>
<tr>
<td>Failure</td>
<td>16</td>
<td>03.72</td>
</tr>
<tr>
<td>Transferred out</td>
<td>28</td>
<td>06.62</td>
</tr>
<tr>
<td>Died</td>
<td>17</td>
<td>03.96</td>
</tr>
<tr>
<td>Treatment completed</td>
<td>224</td>
<td>52.24</td>
</tr>
<tr>
<td>Total</td>
<td>429</td>
<td>100</td>
</tr>
</tbody>
</table>
TABLE 3 CATEGORY VS TREATMENT OUTCOME DISTRIBUTION

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
<th>Cured/Treatment completed</th>
<th>Died</th>
<th>Failure</th>
<th>Defaulted</th>
<th>Transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>New smear +ve</td>
<td>129(100%)</td>
<td>100(77.58%)</td>
<td>06(04.69%)</td>
<td>08(06.36%)</td>
<td>05(03.58%)</td>
<td>10(07.79%)</td>
</tr>
<tr>
<td>Retreatment S.+ve</td>
<td>35(100%)</td>
<td>10(28.57%)</td>
<td>05(14.28%)</td>
<td>07(20.00%)</td>
<td>09(25.73%)</td>
<td>04(11.42%)</td>
</tr>
<tr>
<td>Other</td>
<td>59(100%)</td>
<td>45(76.27%)</td>
<td>03(05.10%)</td>
<td>00(00.00%)</td>
<td>06(10.16%)</td>
<td>05(08.47%)</td>
</tr>
<tr>
<td>New smear –ve</td>
<td>65(100%)</td>
<td>54(83.06%)</td>
<td>02(03.07%)</td>
<td>00(00.00%)</td>
<td>06(09.23%)</td>
<td>03(04.64%)</td>
</tr>
<tr>
<td>New Extra Pulmonary</td>
<td>141(100%)</td>
<td>125(88.65%)</td>
<td>01(00.70%)</td>
<td>01(00.70%)</td>
<td>08(05.67%)</td>
<td>06(04.25%)</td>
</tr>
<tr>
<td>Total</td>
<td>429(100%)</td>
<td>334(77.85%)</td>
<td>17(03.96%)</td>
<td>16(03.72%)</td>
<td>34(07.92%)</td>
<td>28(06.52%)</td>
</tr>
</tbody>
</table>

(S.+ve- sputum positive)

Figures

FIGURE 1 AGE WISE AND GENDER WISE DISTRIBUTION OF STUDY SUBJECTS

FIGURE 2 DISTRIBUTION OF TUBERCULOSIS SUBJECTS AS PER OUTCOME