



A STUDY OF EFFECTIVENESS ON DOTS ON TUBERCULOSIS PATIENTS TREATED UNDER RNTCP

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ABSTRACT

Background: Tuberculosis is one of the top 10 causes of death and the leading cause from a single infectious agent. India accounts for one fourth of the global TB burden. NTP was introduced for TB control and this NTP was become RNTCP after review and performance of NTP with adaptation of DOTS strategy. The key to the success of the DOTS strategy is that it places the responsibility for curing TB patients on the health workers

Methods: Those patients of tuberculosis, who were registered from July 2010 to September 2010 at tuberculosis units of Jodhpur city. All informations were collected from tuberculosis register and by interview. These patients were followed up for sputum examination during three visits. The data collected was grouped into cured and non-cured group. The cured group includes cured and completed the treatment. The non-cured group includes treatment failures, defaulters, died and transferred out cases.

Results: Total 363 patients were registered with M/F ratio 1.47:1. 264, 81 and 36 patients registered in Category I, II and III respectively. Mostly patients (66.94%) were in 15-45 years age group. Among these, 72.18% (262) had pulmonary tuberculosis; of these 167 were new smear positive cases and remaining were retreatment cases. Treatment success (Cured/Treatment completed) among Category-I was 221/246 (89.84%), among Category-II was 56/81 (69.13%) and among Category-III was 31/36 (86.11%). 30 patients were defaulter, 15 were died, 6 were transferred out and 4 were failed treatment.

Conclusion: Higher cure and sputum conversion rates due to strict supervision and monitoring along with motivation of cases by health and non-health personnel. Experiences from the past also emphasized the importance of these factors.

KEYWORDS : TB, RNTCP, DOTS, NSP

INTRODUCTION

Tuberculosis (TB) is a disease of great antiquity. Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS). Globally, the best estimate is that 10 million people developed TB disease in 2017. There were a total of 16 lakhs TB related deaths.¹

The estimated incidence of TB in India was approximately 28,00,000 accounting for about a quarter of the world's TB cases and mortality due to TB (exclude HIV) was 4,23,000.²

To curb the menace of TB and to reduce the TB load, National Tuberculosis Control Programme (NTCP) was launched throughout the country in 1962. GOI with SIDA reviewed the NTCP and launches its revised strategy, i.e. Revised National Tuberculosis Control Programme (RNTCP) with the objectives of achieving at least 85% cure rate through DOTS (Directly Observed Treatment, Short course) and case finding 70% of the estimated cases.³ This revised programme was introduced in India as a pilot project since 1993 in a phased manner and proposed to be expanded throughout the country by the year 2005.⁴

During 2006-2011, in its second phase RNTCP improved the quality and reach of service and work to reach global case detection and cure targets.

Significant interventions and initiatives were taken during National Strategic Plan (NSP) 2012-2017 in terms of mandatory notification of all TB cases, integration of the programme with the general health services (National Health Mission), expansion of diagnostics services, programmatic management of drug resistant TB (PMDT) service expansion,

single window service for TB-HIV cases, national drug resistance surveillance and revision of partnership guidelines. RNTCP has released a National Strategic plan for TB 2017-2025 for control and elimination of TB in India by 2025. According to NSP, TB elimination have been integrated into four strategic pillars of "Detect-Treat-Prevent-Build" (DTPB).⁵

The essential principles of DOTS were first demonstrated in India. The key to the success of the DOTS strategy is that it places the responsibility for curing TB patients on the health workers-not the patients.¹² The one important component of the DOTS strategy is systemic monitoring and accountability. That means a systemic recording, reporting and evaluating the treatment outcome of every patient treated at different levels of the health systems.⁶

OBJECTIVE

To evaluate the effectiveness of DOTS regimen in term of cure rate, failure rate, defaulter rate and relapse rate in different categories of TB under RNTCP programme.

METHODOLOGY

The study was a retrospective type, carried out at 3 tuberculosis units of Jodhpur city (KN chest hospital, Satellite hospital Paota and DTC Jalori gate) under Department of Community Medicine, SN Medical College, Jodhpur, Rajasthan from July 2010 to September 2010. Patients registered under RNTCP in all 3 tuberculosis units during study period were study population. Information about the name, age, sex, socio-demographic profile, initial sputum smear result, during and at the end of their treatment, treatment category, date of start of treatment and outcome were collected from tuberculosis register maintained at

tuberculosis units. All the patients were interviewed, door to door, at their homes with the help of health visitor. These patients were followed up for sputum examination by smear microscopy during 3 visits carried out namely at the end of intensive period, mid-way of continuation phase and at the completion of treatment regimen. The final outcome was confirmed with the help of TB register. The data collected was grouped into cured and non-cured group and expressed in percentage. The cured group includes all those who were declared cured and completed the treatment. The non-cured group includes treatment failures, defaulters, died and transferred out cases. All collected data were transferred in a computer. Chi-square test was applied as a test of significance using SPSS 21. Tuberculosis patients were not on DOTS regime and not gave consent, excluded for the study. P value < 0.05 was considered as significant.

RESULT

During study period, a total of 363 patients were registered for treatment in all categories (Cat I: 264, Cat II: 81, Cat III: 36). Of

these, 216 (59.51%) were males and 147 (40.49%) were females, mostly patients 243 (66.94%) were in 15-45 years age group. (Table 1) 262 (72.18%) patients had pulmonary tuberculosis and 101 (27.82%) had extra-pulmonary tuberculosis. Among 262 pulmonary tuberculosis patients, New Smear Positive (NSP) patients were 167 (63.74%) and 95 (36.26%) were retreatment cases. (Table 3)

Table 1: Distribution of patients according to Age and Sex

| Age in years | Males | Females | Total |
|--------------|---------------------|---------------------|------------------|
| 0 – 15 | 07 (30.43%) | 16 (69.57%) | 23 (06.34) |
| 16 – 25 | 37 (49.33%) | 38 (50.67%) | 75 (20.66) |
| 26 – 35 | 44 (48.89%) | 46 (51.11%) | 90 (24.79) |
| 36 – 45 | 58 (74.36%) | 20 (25.64%) | 78 (21.49) |
| 46 – 55 | 39 (81.25%) | 09 (18.75%) | 48 (13.22) |
| 56 – 65 | 12 (54.54%) | 10 (45.46%) | 22 (06.06) |
| >65 | 19 (70.37%) | 08 (29.63%) | 27 (07.44) |
| Total | 216 (59.51%) | 147 (40.49%) | 363 (100) |

Table 2: Outcome of patients after completion of DOTS

| Category | Patient registered | Cured | Treatment Completed | Defaulter | Failure | Died | Transferred Out |
|--------------|--------------------|---------------------|---------------------|-------------------|-----------------|-------------------|------------------|
| I | 246 (67.77%) | 91 (36.99%) | 130 (52.84%) | 14 (5.69%) | 1 (0.41%) | 7 (2.84%) | 3 (1.22%) |
| II | 81 (22.31%) | 35 (43.21%) | 21 (25.92%) | 11 (13.58%) | 3 (3.7%) | 8 (9.88%) | 3 (3.7%) |
| III | 36 (9.92%) | 0 (0%) | 31 (86.11%) | 5 (13.89%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Total | 363 (100%) | 126 (34.71%) | 182 (50.14%) | 30 (8.26%) | 4 (1.1%) | 15 (4.13%) | 6 (1.65%) |

Overall treatment success (Cured/Treatment completed) in study group were 308/363 (84.84%). Treatment success among Category-I was 221/246 (89.84%), among Category-II was 56/81 (69.13%) and among Category-III was 31/36 (86.11%).

It is observed that in category-I patients, 91 (36.99%) cured, treatment complete 130 (52.84%), 14 (5.69%) defaulted, 1 (0.41%) failed treatment, 7 (2.84%) died, and 3 (1.22%) were transferred out.

It is observed that in category-II patient, 35 (43.21%) cured, treatment complete 21 (25.92%), 11 (13.58%) defaulted, 3 (3.7%) failed treatment, 8 (9.88%) died, and 3 (3.7%) were transferred out.

It is observed that in category-III patients, treatment completed 31 (86.11%) and 5 (13.87%) defaulted.

Table 3: Distribution of Patients according to Category and Sputum Status

| Category | Pulmonary Tuberculosis (n=262) | | Extra Pulmonary Tuberculosis (n=101) | | Total |
|--------------|--------------------------------|--------------------|--------------------------------------|-------------------|-------------------|
| | Sputum Positive | Sputum Negative | Seriously ill | Not seriously ill | |
| I | 107 (43.49%) | 72 (29.27%) | 67 (27.23%) | 0 (0%) | 246 (67.77%) |
| II | 60 (74.07%) | 14 (17.28%) | 7 (8.64%) | 0 (0%) | 81 (22.31%) |
| III | 0 (0%) | 9 (25%) | 0 (0%) | 27 (75%) | 36 (9.92%) |
| Total | 167 (46.01%) | 95 (26.17%) | 74 (20.38%) | 27 (7.44%) | 363 (100%) |

Majority of patients 262 (72.18%) had pulmonary tuberculosis whereas 101 (27.82%) had extra pulmonary tuberculosis. Among category I (246), 107 (43.49%) were sputum positive cases, 72 (29.27%) were sputum negative pulmonary TB (serious ill extension pulmonary involvement) and 67 (27.23%) were extra pulmonary seriously ill.

In category II (81) cases, 60 (74.07%) were sputum positive cases, 14 (17.28%) were sputum negative pulmonary TB and 7 (8.64%) were extra pulmonary seriously ill.

In category III (36) patients, 9 (25%) were sputum negative and

27 (75%) had EPTB which was not seriously ill.

DISCUSSION

TB mostly affects the lungs but it may affect other organs of the body. Our study had found that most common organ affected by tuberculosis is lung (72.18%), while extra-pulmonary TB accounted for about 27.82% of the disease. K.Jagarajamma et al (2007) also found that mostly patients 92.22% were having pulmonary manifestation of TB, while only 7.78% patients had extra pulmonary TB disease.⁷

The study had also found out that TB was more common in males (59.5%) compared to female (40.5%). Dipesh V. Parmar et al (2009) in Rajkot, Gujarat found that 68.08% were males and 31.92% were females.⁸

It is observed that maximum number patients 90 (24.79%) were in 25-34 years age group followed by 78 (21.49%) in 35-44 years age group and 75 (20.66%) in 15-24 year age group. The mean age of male patients being 36.7 years, while that of female patients is 30.5 years. Thejeshwari H.L. et al (2008) found that mean age of males was 40.36±14.34 years and 28.97±13.33 years in females.⁹

Rahul Saini et al (2004) found that 50.23% patients were in 16-30 years followed by 35.21% patients were 31-50 years and 11.97% patients were > 50 years. Only 2.58% patients were < 15 years.¹⁰

It is observed that majority of patients were in category-I; 246 (67.77%). About 81 (22.7%) had past history of TB and treated for the same, so they were classified as category-II. Only 36 (9.92%) patients were being treated as category-III. A. Mishra et al (2007) found that there were 46.47%, 27.88% and 32.05% belonged to category-I, II and III respectively.¹¹

It is observed that in category-I mostly patients were sputum positive 43.49% (107), whereas in category-II sputum positive were 74.07% (60) and in category-III 75% (27) were extra pulmonary cases. Mahadev B et al (2004) in Bangalore observed similar result that mostly patients 156 (87.6%) were pulmonary and 22(12.4%) extra pulmonary cases. Out of 69 smear positive, 50 (72.46%) were new sputum smear positive and 19 (27.54%) were re-treatment cases.¹²

It is observed that in category-I 36.99% (91) cured, treatment

complete 130 (52.84%), 5.69% (14) defaulted, 0.41% (1) failed treatment, 2.84% (7) died and 1.22% (3) were transferred out. Singh A et al (2005) also found that the treatment outcome of 388 NSP cases was; treatment success 310(80%), death 10(3%), failure 18(5%), defaulted 45(12%), and transferred out 6(2%).¹³

Among the 7 died, 1 (14.28%) are smear positive and 6 (85.71%) patients are smear negative in our study.

The other known risk factor for mortality in TB are advanced age, low literacy, alcoholism, HIV infection and delayed care-seeking.

It is observed that out of 14 defaulters, 50% were smear positive, 50% smear negative.

Chadha et al (2000) also found that default rate was 8.5% and failure rate was 1.6%.¹⁴

One patient failed treatment, even though regular in treatment. The failure rate of 0.41% is either due to wrong categorization or due to drug resistance in our study.

It is observed that overall cure rate is more among the EP seriously ill 100% (67) followed by smear positive 90.65% (97) and new smear negative 79.17% (57).

It is observed that in category-II, 50.62% (41) were relapsed, 6.17% (5) failure, 18.52% (15) treatment after default cases and 24.69% (20) others.

It is observed that in category-II patient, 35 (43.21%) cured, treatment complete 21 (25.92%), 11 (13.58%) defaulted, 3 (3.7%) failed treatment, 8 (9.88%) died, and 3 (3.7%) were transferred out.

Among 41 relapse cases, 25 (60.98%) achieved treatment success (23 cured+02 treatment completed), 5 (12.19%) died, 2 (4.88%) failed treatment 6 (14.63%) defaulted the regimen and 3 (7.32%) transferred out.

Out of the 5 failure cases (6.17%), 3 cured, 1 died and 1 defaulted.

Out of 15 TAD patients, 9 (60%) cured, 4 (26.67%) defaulted and 2 (13.33%) died. Out of 20 others patients, 19 (95%) completed treatment and 1 (5%) defaulted.

Quy H.T.W. et al (2003) in Vietnam found that the cure rate among 464 relapse and 119 failure cases was 82.5% and 47% respectively. The overall failure rate was 39% among Cat-II Patients. Quy H.T.W. says emergence of combined primary isoniazid and streptomycin resistance was a strong risk factor for the failure of relapse cases.¹⁵

It is observed that 86.11% (31) completed their treatment, 13.87% (5) defaulted in category III. Of the 9 pulmonary smear negative patients; 6 completed treatment and 3 defaulted under category III patients.

Out of 27 extra pulmonary patients, 92.59% (25) had completed treatment and 7.41% (2) were defaulted.

Akramal Islam et al (2002) found that in which of the 16 patients; 10 (62.5%) treatment completed, 3 (18.7%) died and 3(18.7%) defaulted.¹⁶

CURE RATE IN DIFFERENT CATEGORIES (Table-35)

In our study overall cure rate for Cat-I and Cat-II was only 36.99% and 43.21%. Only 86.11% cases could be labeled as treatment completed for Cat-III

It is observed that overall outcome for category-I, II and III were 87.2%, 59.77% and 83% respectively. The cure rate was higher than the rates reported by various investigators such as Bhat S et al (68%) and Pio et al (50%) in their respective studies.^{17,18}

CONCLUSION

Higher cure and sputum conversion rates due to concrete efforts in the form of strict supervision and monitoring along with motivation of cases by health and non-health personnel. Experiences from the past also emphasized the importance of these factors.

RECOMMENDATIONS

1. To discover new drugs, regimens and Vaccine so that the treatment of TB becomes more shorter duration to reduce relapse, failure and drug resistance. To achieve this research and funding have to be strengthened.
2. Collaboration of Government health services with other social welfare measures to improve the economic condition of patients.
3. Vacant posts in the RNTCP centers must be filled up with training of the health staffs of the public sector regarding RNTCP have to be undertaken.

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