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ORIGINAL ARTICLE

AN ANALYSIS OF TREATMENT OUTCOME AMONG TB PATIENTS PUT UNDER DOTS AT A TERTIARY LEVEL HEALTH FACILITY OF ORISSA

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Abstract

Introduction World Health Organization Report 2008 on Global Tuberculosis Control states that there were 9.2 million new tuberculosis cases and approximately 1.7 million tuberculosis deaths in 2006. 25% of global incidences of new TB cases occur in India and India tops the list of 22 High Burden Countries (HBC) in the world followed by China. In India adequate studies are yet to be conducted in medical colleges to know about performance of the program, case detection of tuberculosis, cure of the patients registered etc at medical colleges where RNTCP has already been launched. RNTCP was launched in Maharaja Krishna Chandra Gajapati Medical College, Brahmapur, Orissa in February, 2004.

Objectives (i) To evaluate the treatment outcome among cases registered for Directly Observed Treatment Short-course (DOTS) under DMC of MKCG Medical College Hospital (ii)To assess various indicators of RNTCP at MKCG Medical College Hospital.

Materials & Methods A hospital and community based longitudinal study which had both quantitative and qualitative components was carried out in the RNTCP-DMC of Department of Pulmonary Medicine and catchments areas of Brahmapur municipality under DMC of M.K.C.G. Medical college Hospital, Brahmapur.from 1st January,2007 to 31st December 2008. 58 Tuberculosis patients registered and put on DOTS under the DMC of M.K.C.G.Medical College were taken as study subjects and they were followed up during their course of treatment to observe their treatment outcome and data analysed using Chi-square test & proportion.

Observation A total of 58 patients had been registered in 4 quarters of 2007 for DOTS under DMC of MKCG Medical College. There were 29, 11 and 18 patients belonging to Cat-I,Cat-II and Cat-III respectively. Sputum Conversion Rate among new smear positive cases (NSP) was observed to be 82.6% at the end of Intensive Phase which needs further monitoring in motivating such cases for timely follow-up. Cure rate among new smear positives was calculated to be 78.2%. Treatment success rate was 86.9% among new smear positive cases in the study. Initial defaulter rate among new smear positives was observed to be 17.4%. Overall default rate was 3.4% and failure rate was 1.7% in this study. Death rate among cases was 6.8%.

Conclusion Low sputum conversion rate at the end of Intensive phase is mainly due to low motivation and low awareness among patients. Low cure rate is due to ignorance of patients who completed their DOTS in time but did not come
for final sputum examination. Alcoholism plays the most crucial role behind defaulting consequently leading to deaths recorded in present study.

Key Words:Tuberculosis, RNTCP, DOTS, DOTS Providers(DP**).**

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Introduction

World Health Organization Report 2008 on Global Tuberculosis Control states that there were 9.2 million new tuberculosis cases with approximately 1.7 million tuberculosis deaths in 2006. 25% of global incidences of new TB cases occur in India and India tops the list of 22 High Burden Countries (HBC) in the world followed by China. These High Burden Countries account for more than 80% of all new TB cases. [(1)]

The role of medical colleges in TB control as opinion leaders and role models for practicing physicians, in imparting knowledge and skills among medical and paramedical students, shaping their attitude in diagnosing and treating tuberculosis patients can not be underestimated. Besides benefiting the community directly through the provision of quality services for TB care, their participation can help in sustaining the program by training the future generations of physicians about the principles of DOTS and influencing practices both in the public and private sector. As such, there is a pressing need for all medical colleges to advocate DOTS strategy to provide the best opportunity for cure of the patients.

The involvement of Medical colleges in RNTCP is very important. Their activities primarily include: (i) Training and teaching of RNTCP,(ii) Service delivery of RNTCP through quality assurance net-work group,(iii) Advocacy of RNTCP by sensitization and training through Indian Medical Association,(iv) Operational research by improving DOTS services and managing childhood TB, extra-pulmonary TB and MDR- Tuberculosis.[(2)]

Use of X-Rays as primary method of diagnosis and use of non-RNTCP regimens for cure are still prevailing in these patients. There is no system of retrieval of irregular and treatment defaulting patients [(3)].

In India, adequate studies have not been conducted yet in medical colleges to know about performance of the program, case detection of tuberculosis, cure of the patients registered etc at medical colleges where RNTCP has already been launched. Correct information about staffing pattern, their performance, quality of program activities etc is not available.

RNTCP was launched in Maharaja Krushna Chandra Gajapati Medical College, Brahmapur, Orissa in February, 2004. Yet no studies have been conducted on the case detection, registration of patients for DOTS and quality of services provided at Designated Microscopy Centre (DMC) of MKCG Medical College in recent past. The current study has been designed and conducted to assess the performance of Revised National Tuberculosis Control Program at MKCG Medical College, Brahmapur and to what extent this premier medical college of Orissa has succeeded in case detection, treatment of tuberculosis patients and control of this killer disease in recent past.

Materials & Methods

The study was carried out in the RNTCP-DMC of Department of Pulmonary Medicine of M.K.C.G. Medical College Hospital which serves as one of the two DMCs of Brahmapur municipality catering to a population of about 1, 50,000. The study was carried out from 1st January, 2007 to 31st December 2008. This was a hospital and community based longitudinal study which had both quantitative and qualitative components. All of the 58 TB patients registered under this DMC put on DOTS during 4 quarters of 2007 were taken as study subjects. They were followed up during their course of treatment to assess treatment outcome using both qualitative and quantitative methods. Cat-I and Cat-III patients were followed up thrice and Cat-II patients were followed up 4 times after each follow-up sputum examination during their course of treatment. Primary data from each patient included the demographic profile, sputum smear

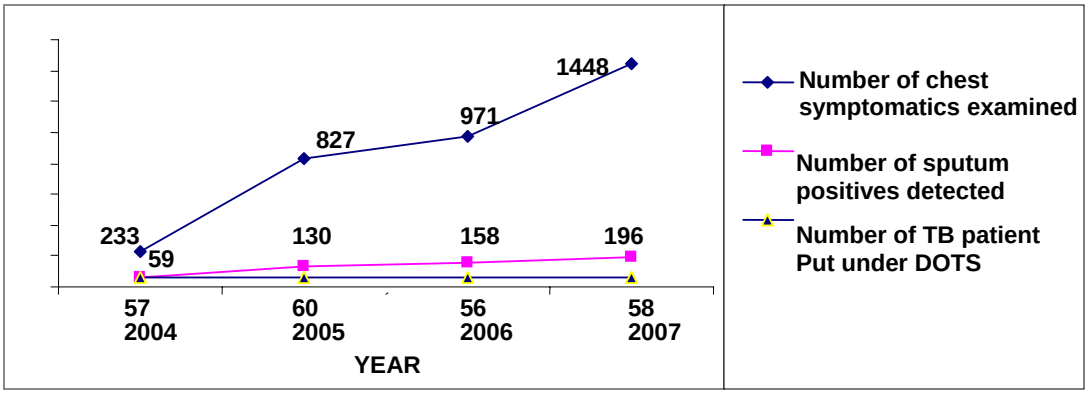
report, type of tuberculosis, category of treatment regimen and outcome .Secondary data were collected from OPD registers, various registers maintained under RNTCP and treatment cards of patients. Different technical and managerial indicators were calculated and analysis was done using appropriate statistical method ie. Proportions and chi-square test. The qualitative data were collected from patients, DPs, MO, STS and STLS through in-depth interviews and focus group discussions.

Observation

In the year 2007 a total number of 2,31,481 patients had attended different Out Patient Departments of MKCG Medical College Hospital. Out of them 1448(0.62%) were chest symptomatic who were referred to RNTCP-laboratory for sputum smear examination. 196 chest symptomatic were found to be positive for Acid-Fast Bacilli.

The number of chest symptomatic referred to RNTCP-laboratory from different OPDs of this medical college has increased many times since implementation of RNTCP in this medical college.1448 chest symptomatic were referred to RNTCP-laboratory for sputum examination in 2007 against 233 in 2004. In the year 2007, 1448 chest symptomatic were examined. 196 were found sputum positive. 18 out of 196 were put under DOTS at DMC of MKCG Medical College while rest 178 New Smear Positive cases were referred for DOTS at other TUs. These 18 cases along with other 40 cases of TB constitute the total study sample of 58 put under DOTS at medical college DMC (fig- **I**).

Figure-: Chest Symptomatics, Sputum Positives and TB Patients on DOTS under Medical College DMC.



65% of the patients were males. In present study paediatric cases contribute 1.7% of total study population. The study revealed that 53 (91.4%) cases belonged to economically productive age group (15-59 years). Majority of patients belonged to Backward Classes(OBC/SC/ST).

About 35% of the patients were illiterate or had a low level of education. During an interaction with patients and community members in the study area, it was found that higher the educational status of a person higher the awareness about the mode of the spread and prevention of Tuberculosis. Most of the persons in the community did not know that anti-TB treatment was available free of cost.

64% of patients had overcrowding in their household. Average Household size was calculated to be 4.6 and it was ≥ 5 in 60% of patients.

Table- I: Socio-demographic profile of study sample (n=58).

Characteristics	Variables	Number(%)
1.Sex	Male	38(65)
	Female	20(35)
2.Age Group(years)	0-14	1(2)
	15-44	44(76)
	45-59	9(15)
	≥ 60	4(7)
3. Caste	General	7(12)
	Other Backward Caste	32(55)
	SC	15(26)
	ST	4(7)
4. Literacy	Literate	38(65)

	Illiterate	20(35)
5.Overcrowding(Persons per living room>2)	Present	37(64)
	Absent	21(36)
6.Occupation	Laborers	27(46)
	Government Employee	7(12)
	Housekeeping	8(14)
	Small scale business	5(9)
	Dependent sons/daughters	11(19)
7.Socio-economic Status	Low	40(70)
	Medium	16(27)
	High	2(3)
8.Knowledge on TB	Present	16(28)
	Absent	42(72)
9.Addiction	Present	34(59)
	Absent	24(41)

27(46.6%) patients were daily laborers and lived in poor housing conditions with unsanitary ,polluted, urban slum environment. Their low socio-economic status, poor nutrition and lack of awareness about the disease made them vulnerable to Tuberculosis. 40% of total female cases were house wives. 19% of patients were dependent sons or daughters which included students, unemployed children etc.

Overall 58.7% had addiction to any form of tobacco which was observed more among illiterate labor class patients. Smoking which is an important risk factor behind development of Tuberculosis was prevalent among 19% of patients. 26.3% male patients and 5% female cases had history of smoking.

Addiction to alcohol was noted among 22.4% of the study population and it was found to be a major risk factor behind defaulting and death in this study.

18 NSP cases were administered Cat-I regimen. Out of 13 smear negative pulmonary cases 6 patients were given Cat-I regimen for their serious illness. The rest 7 smear negative cases were given Cat-III regimen. 11 patients who were not seriously ill and suffering from extra-pulmonary disease were put under Cat-III regimen. 47 were new cases while 11 cases were in re-treatment group. There were 29, 11 and 18 TB patients registered for Cat-I, Cat-II and Cat-III treatment regimen respectively.

Sputum conversion rate among NSP cases was 82.6% at the end of Intensive Phase.

Cure rate among new smear positives was calculated to be 78.2% (18 out of 23). Cure rate among relapse cases and treatment after default cases were 40% and 33% respectively.

Treatment completion rate among new smear positive cases in this study was 8.6% (2 out of 23) which is more than RNTCP norm i.e., ≤3%. But treatment completion rates among smear-negative and extra-pulmonary cases were 92.3% and 100% respectively which shows satisfactory field performance by DPs.

Both cure rate and treatment completion rate contribute towards the treatment success rate among new smear positive cases (86.9%:20 out of 23). Treatment success rate among relapse cases and 're-treatment after default cases' were 100% and 33% respectively.

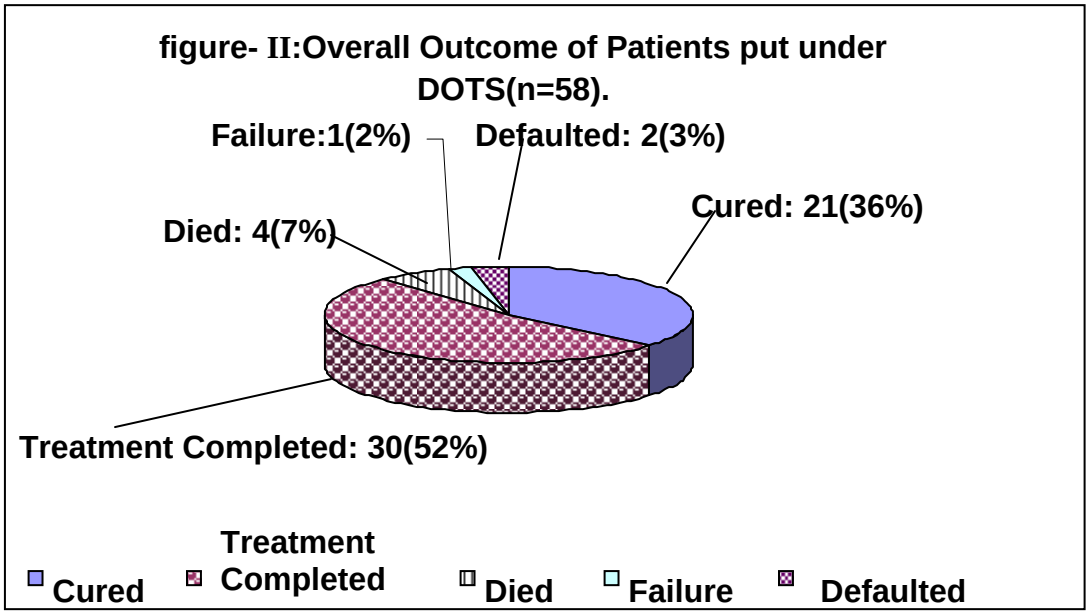
Initial defaulter rate among new smear positives was observed to be 17.4%. Overall default rate was 3.4% which is less than the RNTCP norm of 5%. Various factors as enumerated by DPs behind default were (i) early remission of symptoms which lead to false sense of cure among patients,(ii) early morning hang-over perceived as adverse drug effect of ATT in alcoholic patients,(iii) poor drug compliance due to nausea, vomiting, severe skin rash etc. But adverse drug effects leading to non-adherence to treatment and subsequently to defaulting were not properly and timely reported to corresponding Medical Officer at DMC.

Failure rate in this study was recorded to be 1.7% which is less than the RNTCP norm of <4% of patients put under DOTS. Not a single case of 'failure' was put in re-treatment.

Table- II: Distribution of TB patients according to their treatment outcome (n=58).

Type of TB Patients	Cured No. (%)	T/t completed No. (%)	Defaulted No. (%)	Failure No. (%)	Died No.(%)	Total No. (%)
A. New Cases						
Smear +ve: Pulmonary						
(Cat-I)	18	2	1	0	2	23
Smear –ve: Pulmonary						
Seriouslly ill (Cat-I)	0	5	0	1	0	6
Not seriously ill (Cat-III)	0	7	0	0	0	7
Ex-pulmonary						
Seriouslly ill (Cat-I)	0	0	0	0	0	0
Not seriously ill (Cat-III)	0	11	0	0	0	11
Sub-Total	**18**	**25**	**1**	**1**	**2**	**47(81)**
B. Re-treatment cases						
Smear +ve Relapse	2	3	0	0	0	5
Smear +ve Failure	0	0	0	0	0	0
Smear +ve Treatment After Default	1	0	1	0	1	3

Others treated With Cat-II	0	2	0	0	1	3
Sub-Total	**3**	**5**	**1**	**0**	**2**	**11(19)**
Grand Total(A+B)	**21 (36.2)**	**30 (51.7)**	**2 (6.8)**	**1 (1.7)**	**4 (3.4)**	**58 (100)**



Three of the four dead had discontinued the DOTS and two of them were alcoholic. Death rate in this study was 6.8% which is beyond RNTCP level of less than 2%. Among the deaths, 75% belonged to smear positive cases. 50% of deaths were in Cat-I and other 50% were in re-treatment group. Deaths in Cat-I were due to serious illness of cases, low body weight i.e.,<35kg and late diagnosis of the disease.

Discussion

The greatest burden of tuberculosis incidence and mortality in developing countries is in adults aged 15-60 years which includes the most socio-economically productive members of the society such as parents, workers, community leaders etc.Due to their age factor and socio-economic dependence of family they involve themselves in earning and get exposed to other cases in the community.[(5)]

In an urban area the disease is more related to socio-economic factor, nutritional status, other living conditions like overcrowding, environmental pollution, addiction to smoking etc rather than the caste of the person. TB India 2007, RNTCP Status Report shows that there are 2.88% and 18.57% of total population of Ganjam belonging to Scheduled Tribe and Scheduled

Cast respectively; hence the present study reveals the concentration of cases in these sections of community.

The study by Sahu SK et al showed that there is an increase in cure rate and decrease in CDR with an increase in the prevalence of literacy. Median literacy rate of Orissa was reported to be 63.41% and that of Ganjam 60.77%. They recommend to concentrate more on curing the literate TB patients and detecting literate TB cases to have a better figure of Cure rate and Case Detection Rate.[6]

In the present study it was also observed that patient with higher literacy had a better concept on disease, importance of treatment adherence & follow-up sputum examination. The cure rate among 'literates' is more than that of 'illiterates'($p<0.001$).

The addiction to alcohol noted to be 22.4% in present study was in concordance with the finding ie. 32% in a study carried out by Jaggarajamma et al. Alcoholism plays the most crucial role in defaulting and consequent deaths in present study.[7]

The sputum conversion rate among new smear positives registered in the 3rd quarter of 2007 in Orissa and India were reported to be 87% and 90% respectively. Low sputum conversion rate in this study(82.6%) at the end of IP is mainly due to low motivation and low awareness among patients.

Cure rate falls behind the desired RNTCP-norm of 85% as some of the New Smear Positive patients did not turn up for the end sputum examination.

The cure rate and treatment success rate among NSP cases in Orissa as reported in 1st quarter of 2007 was 82% and 87% respectively. The cure rate and treatment success rate among NSP patients registered in 4th quarter of 2006 in India were reported to be 84% and 86% respectively. Cure rate and treatment success rate among new smear positives in present study were calculated to be 78.2% and 86.9% respectively. However 85.3% of cured NSP cases had come for 'end of treatment-follow up sputum examination' within 7 days of last dose which is comparably more than the state and country figure of 72% and 82% respectively.

Cure rates among relapse cases in Orissa and India were 57.2% and 66.4% respectively which were more than that of the study area. Treatment success rate among relapse cases in Orissa and India were 68% and 73.2% respectively which were very less than the figure of study area ie.100%.

Treatment completion has a great role in reducing the chance of emergence of drug-resistant bacilli. Many studies have shown that patients who do not complete treatment have isolates which are resistant to the drugs they have taken and these patients infect other people with drug resistant bacilli. [8,9]

Higher rate of initial defaulting (17.4%) among NSP cases was due to lack of coordination between DMC and DPs as admitted by them in urban area. Defaulting was found in one third of cases registered as 're-treatment after default'. ,

Present study shows that default is due to side effects of drugs(50%), too many drugs(37.5%), early relief of symptoms(25%), non-willingness to come thrice weekly(25%) for DOTS in IP because of loss of daily earning, visit to relative's house(12.5%), etc.

This study shows that the risk factors behind death during treatment were male sex(100%), age >45 years(75%), smear positive(75%), alcoholism(50%), previous history of treatment(50%), body weight at initiation of treatment ie.<35kg(100%).

Death rate among re-treatment cases in study population was 18.18% (2 out of 11) which was 8.5% and 7.7% for the state and country respectively.

Conclusion

The case detection rate has increased since implementation of RNTCP in 2004.The case detection would have been more if all of the chest symptomatics from OPD and IPD of department of Paediatrics would have been referred to the RNTCP-DMC for sputum examination.

Irregular treatment, inadequate follow-up action and defaulting are found to be major problems in urban DMC. As alcoholism plays a major role behind drug interruption and deaths, smart and timely reporting on non-adherence to treatment along with proper counseling of these patients will certainly bring them back on DOTS.

MKCG Medical College Hospital being a tertiary health care center, the DMC is overburdened with the referral cases from adjacent districts and is not able to give systematic RNTCP services to the specified area as per the program norm which affects the treatment outcome. This needs strengthening with additional staff and reorientation of existing functionaries on RNTCP services.

Acknowledgement

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