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Dr. UT Kumbar
Department of Community
Medicine KIMS, Karad,
Maharashtra, India

SV Kakade
Department of Community
Medicine KIMS, Karad,
Maharashtra, India

Study of treatment outcomes and adverse reactions in patients treated under RNTCP in Karad Tuberculosis unit

UT Kumbar and SV Kakade

Abstract

Aim: document the effectiveness of RNTCP regimens under programme conditions. With this in view the present study was undertaken.

Material and Method: There are three Integrated Counseling and Testing Centres (ICTC) – KH, SDH and Undale. Delivery of TB activities is carried out by trained staff based in general health facility for their earmarked population.

Result: There was no significant association between Treatment of ADR and DOTS treatment. 147(21.4%) patients continued DOTS treatment after giving treatment for ADR, 240(34.9%) continued DOTS treatment even if they were not treated for their ADR, 301(43.8%) continued DOTS treatment after given reassurance for ADR.

Conclusion: Males 225 (27.9%) were more aware about the curability of tuberculosis than females 151 (18.7%). With community involvement and highly motivated staff and their attitude towards patients and close supervision of treatment we achieve high cure rate as well as completion rate.

Keywords: Adverse Reactions, Tuberculosis, Treatment Outcomes

Introduction

Tuberculosis is one of the man's oldest foes. India is one of the worst affected countries among the most feared. One of triumphs of modern medicine has been the development of vaccination and medication capable of combating this ancient disease. Yet tuberculosis remains our major concern [1].

Tuberculosis has been found in human society since time immemorial. From Egyptian mummies to Indian Ayurveda ample evidence testifies to formidable presence of tuberculosis [2]. This is a bacterial disease caused by Mycobacterium Tuberculosis, occasionally by Mycobacterium Bovis and Mycobacterium Africanam. Mycobacterium Tuberculosis organisms are also known as Tubercle bacilli because they cause lesions like tubercle. They are sometimes referred to an Acid fast bacilli (AFB). These organisms were discovered by Dr. Robert Koch on 24th march 1882 (The day celebrated as World TB Day). Hence they are also known as Koch's bacilli and disease as "Koch's"

To obtain satisfactory co-operation of stake holders of health care delivery it is necessary to document the effectiveness of RNTCP regimens under programme conditions. With this in view the present study was undertaken [3]. A Cohort of tuberculosis patient was followed up prospectively to evaluate their treatment outcomes supported with pre and post treatment bacteriological profile and to assess their bacteriological and clinical status 6 months after treatment initiation. In addition the associated socio-demographic and treatment related factors were also studied.

Material and Method

Population of Karad Taluka is 4, 76, 034. Under Karad Tuberculosis Unit there are nine PHCs, Sub District Hospital and Krishna Hospital. Nine PHC's were Kale, Undale, Yewati, Supane, Kole, Rethare Bk, Vadgaon Haveli, Sadashivgad and Masur. There are six Designated Microscopy Centres (DMC); Krishna Hospital (KH), SDH, Sadashivgad, Vadgaon Haveli, Kale, Undale.

Correspondence

Dr. SA Lomate
Department of Medicine
KIMS, Karad, Maharashtra,
India

There are three Integrated Counseling and Testing Centres (ICTC)–KH, SDH and Undale. Delivery of TB activities is carried out by trained staff based in general health facility for their earmarked population.

All patients registered in Karad Tuberculosis Unit selected from January 2008 to June 2009, from the cohort for two phases of community based cohort analysis. i.e. 806 patients formed the study cohort. Hence no sampling procedure was used. Before commencement of study permission of District Tuberculosis Officer (DTO) was taken.

During subsequent interviews details about treatment regularity, any adverse drug reactions and regularity of drug administration were obtained. Several attempts were made to contact the defaulted patients through frequent home visits. Defaulted patients were persuaded to approach the RNTCP treatment Centre for further treatment.

The cohort was further followed up for approximately six months. Information on persistence or reappearance of chest symptoms after stopping treatment was obtained, health centers were approached, and investigations were undertaken. The details regarding subsequent TB treatment if any (duration and regimen) was obtained through interviews. For patients reported dead, cause of death was obtained from close relatives through questionnaires based on interviews and scrutiny of available records including death certificate. Information regarding the presence of chest symptoms and subsequent anti-TB treatment during intervening period prior to death was also collected from a reliable responder. Information regarding any adverse drug reactions of the beneficiaries was also collected during initial and subsequent visits. Few suggestion were given and if needed they were referred to Krishna Hospital.

Data was summarized in number and in percentage. Chi-square test was applied to assess statistical significance between variables.

Results

In present study we tried to find out various adverse reaction in tuberculosis patients who were receiving DOTS and also there time of occurrence.

Table 1: Literacy wise awareness about curability of treatment outcomes

	illiterate	literate	Total
Correct	87 46.8%	289 46.6%	376 46.7%
Incorrect	6 3.2%	20 3.2%	26 3.2%
Do not Know	93 50.0%	311 50.2%	404 50.1%
Total	186 100.0%	620 100.0%	806 100.0%

$\chi^2 = 0.002, df = 2, p = 0.999$

It was observed that the most of the reaction were in intensive phase of treatment i.e. in the first 2 months. It was observed that out of 513 (63.64%) had adverse reactions while 293 (36.35%) did not have any adverse reaction. Thus the gastritis was being the most common adverse reaction.

There was no any single patient had jaundice as adverse reaction.

There was no significant association between Treatment of ADR and DOTS treatment. 147(21.4%) patients continued DOTS treatment after giving treatment for ADR, 240 (34.9%) continued DOTS treatment even if they were not treated for their ADR, 301 (43.8%) continued DOTS treatment after given reassurance foe ADR.

Discussion

The study has been undertaken to assess treatment outcomes, adverse reactions, causes of death, default, failure, and relapse in Karad T.U. The study has revealed perception of patients about duration & treatment, curability of Tuberculosis disease. Cohort has been patients registered for DOTS in Karad Tuberculosis unit from January 2008 to June 2009. The study was conducted on 806 patients. The present study findings have reflected that the prevalence of Tuberculosis disease has been higher in males than in females at all ages and difference has been more marked as the age increased. Higher concentration of cases occurred in higher age group. The proportion of less than 15 years population in India is 35.4% as compared to 3.8% amongst cases of tuberculosis. It indicates that there are significantly more cases of tuberculosis among population more than 15 years and above years of age [3].

The sex wise distribution showed that more males were affected with TB It is usual to find that males commonly avail the health facilities compared to females for various reasons The observation in the present study that majority of patients are from the economically productive age group (15-44yrs) [4, 5] has also been seen in various studies The studies conducted agree with the finding of present study that males are more affected than females. Age distribution of extra pulmonary Tuberculosis has indicated higher disease prevalence in young age [4]. Case distribution with regard to age as well as male: female ratio has demonstrated respectively similar annual trends. The study have found similar findings in their study [5].

However it is noteworthy that great upswing in cases has occurred in Hindu community. The proportion of Hindus is significantly more and that of Muslim is significantly less than expected numbers as per population proportions [7]. Thus it is difficult to elicit the relationship between religion and tuberculosis. However our study findings are comparable with studies conducted by Shailendra Bhatnagar [6] who have found that out of 1415 patients 723 (51.9%) to be Hindu while 692 (48%) present Muslim community.

The strength of our study is that this was a community based study in which information regarding socio-economic status of patients is collected [9]. The socio-economic status of patients indicates that more number of tuberculosis cases have occurred in economically deprived section of society [8]. The present study findings are more or less similar to the findings of study conducted by Mahesh Kumar *et al.* 32 who have found that out of 386 cases 25 (6.47%) are from two upper class 254 (65.80%) from middle class and 101 (27.72%) from lower class.

Low occupational levels and unemployment are common findings amongst tuberculosis patients [10]. This unemployment (29.6%) puts a heavy financial burden on other family members thereby having a detrimental effect of economic crisis for families with tuberculosis patients. The daily wages labourers, self-employed workers indulge in

outdoor activities they are highly mobile, they seldom have any health records and they usually don't have savings. All these concerns are supported by our study findings. In our study we have found that majority of patients are from economically productive age group. In the Indian context marriages 105 are universal^[11]. It is quiet possible that due to more number of patient above 15 years of age, higher proportion of 69.6% of married patients are seen.

Present study findings are well in accord with the findings have also found that out of 271 patients 161(59.40%) to be unmarried. In our study 186 (23%) out of 806 cases have been extra pulmonary cases and that lymph nodes to be the commonest extra pulmonary site involved in 83 (42.8%) patients. Tuberculosis can involve any organ system in the body while pulmonary tuberculosis is the most common presentation; extra pulmonary tuberculosis is also an important clinical problem. Studies show that extra pulmonary TB (EPTB) comprises about 10% to 15% & of all new TB cases in our country. Among than 75% have lymph node or pleural TB¹⁴

The present study is good evidence to support this fact. The pleural space is also common site. Sub pleural effusion usually presents as an acute illness and most of the patients due to its accompanying symptoms like chest pain and dyspnea avail health care facility earlier. The abdominal tuberculosis is also presenting as common disease^[12]. In developing world tuberculous meningitis is still a disease of childhood and present study also supports this fact. Female genital tuberculosis is secondary to tuberculosis infection elsewhere in the body and is an important cause of infertility^[13, 15]. The present study findings are more or less similar to findings of study conducted has found that lymph node involvement is 54%.

In present study we have found that common causes for delay in treatment initiation of DOTS is that patient did not avail the care of government health facility due to their job. It is therefore necessary to educate private health care providers for screening of cases and also to develop a good referral system. To cope up with problems like negligence, lack of awareness, alcoholism, information, education and communication activities should be intensified. The present study findings are consistent with following studies.

In present study out of enrolled 806 patients enrolled, 208 (25.8%) have been categorized as cured, 466 (58.4%) as treatment completed, 31 (3.8%) as defaulted, 71 (8.8%) as died, 16 (2%) as failure, 14 (1.7%) as lost for follow up i.e. transferred out. It is observed that our regimens produced decline in failure rate, default rate is near expected, death rate is little more. As cure rate was very close to RNTCP objectives, probable reason for good case holding is in study.

Conclusion

17 (2.1%) defaulted due to migration, 5 (0.6%) defaulted due to addiction of alcohol, 3 (0.4%) defaulted due to not relief from symptoms, 1 (0.1%) defaulted due to adverse reaction. 16 (2%) failed in due to initial heavy bacillary load. More than 50% of males and female patients were unaware about duration of treatment in this study. Males 225 (27.9%) were more aware about the curability of tuberculosis than females 151 (18.7%). With community involvement and highly motivated staff and their attitude towards patients and close supervision of treatment we achieve high cure rate as well as completion rate.

Conflict of Interest: No conflict of interest

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