A FOLLOW UP STUDY ON NEWLY DETECTED SPUTUM POSITIVE PULMONARY TUBERCULOSIS CASES ON ANTI TUBERCULAR TREATMENT IN BIJAPUR TALUK

By

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LIST OF ABBREVIATIONS USED

TB   : Tuberculosis

HIV   : Human Immunodeficiency Virus

AIDS   : Acquired Immunodeficiency Syndrome

MDR- TB : Multi Drug Resistant Tuberculosis.

XDR- TB : Extensively Drug Resistant Tuberculosis

WHO   : World Health Organization

ARTI   : Annual Risk of Tuberculosis Infection

PHC   : Primary Health Center

DOTS   : Directly Observed Treatment Short course

RNTCP : Revised National Tuberculosis Control Program

AFB   : Acid Fast Bacilli

ZN   : Ziehl Neelsen

LJ   : Lowenstein Jensen

LPA   : Line Probe Assay

CBNAAT : Cartridge Based Nucleic Acid Amplification test

PAS   : Para-aminosalicylic acid

IP   : Intensive Phase

CP   : Continuation Phase

NTCP   : National Tuberculosis Control Program

BCG   : Bacillus Calmette Guerin

S   : Streptomycin

H or INH : Isoniazid

T   : Thioacetazone

R   : Rifampicin

Z   : Pyrazinamide

E   : Ethambutol

GOI   : Government of India

SCC   : Short Course Chemotherapy

LED   : Light Emitting Diode

ASHA   : Accredited Social Health Activist

DLHS   : District Level Health Survey

CPI   : Consumer Price Index

X2   : Chi-square test

df   : Degree of freedom

ABSTRACT

Background:

TB remains a challenge and major public health problem in 21st century, although there are treatment regimens that have a greater than 95% cure rate. India is the highest TB burden country accounting for 1/5 th (21%) of the global incidence. According to 2011 census, incidence of tuberculosis in world was 9 million and in India it was 185/ 10000 population. Besides the disease burden, TB also causes an enormous socio- economic burden to India. Even though RNTCP has established good network throughout India, some states are still poor in their performance. Sputum conversion rate is <85% in >25% districts of Assam, Bihar, Karnataka, Kerala, and Meghalaya. Large number of district of Bihar(50%), Chattishgarh(50%), Karnataka(32%) and Uttrakand (38%) have reported cure rate of less than 80% of new sputum positive patients.

Objective:

To study the socio demographic profile of newly detected sputum positive pulmonary tuberculosis cases and to document its role in completing the schedule of treatment.

Materials and Methods:

A follow up study was conducted on 248 newly detected sputum positive tuberculosis cases. Each patient was visited 4 times during their treatment course-at the end of 1st month, 3rd month, 6th and 8th month. After obtaining oral consent, information was collected using a pre-tested questionnaire. Data was analyzed using SPSS v.16 and presented in the form of percentages and figures. Statistical test such as chi-square test was used to test for significance.

Results:

In our study majority of the patients belonged to economically productive age group of 21-50 years (67.34%). Majority were male (66.5%) and were illiterate (47.5%). Cure rate was 81.85%, default rate was 5.64%, failure rate was 4.83% and death rate was 7.66%. Main reasons for default were side effects of the drug and change of residence (28.57% each). Majority of defaulters were aged more than 50 years, unskilled workers, illiterate and belonged to class IV socio- economic class.

Sputum conversion at the end of 2 months was 81.78% , 88.75% at the end of 3 months, 94.53% at the end of 5 months and 94.39% after completion of treatment. There was no statistical association between socio- demographic factors and cure rate.

Conclusion:

Even though accessibility to DOT center was better in our study cure rate was less than the RNTCP norm of 85%. This can be attributed to high default rate. The main reasons for default were change of residence and side effect of the drug. These problems can be tackled by better health education to patients and better communication in case of transfer out and transfer in of patients.

High failure rate in our study may be due to resistance to the drugs. In depth research is needed to identify reasons for high failure rate.

Key words: Pulmonary Tuberculosis, sputum, follow up, treatment.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

INTRODUCTION

The germ that ancient mummies had,

And caused the deaths of many men,

is growing resistant with time

To drugs that killed it earlier, fast!

'Tis lurking still in various ways,

And causing mortality still,

Which can be prevented if we

Detect and treat all cases well.

This ain't the time to relax then,

For multi-drug resistant strains

Could rise to epidemic size,

And threaten poorer countries' folks.

The war against the TB germ

Must continue with increased verve,

Until the bacillus is gone

From face of earth, and all mankind!

To zero deaths from TB then

Means detecting all cases fast,

And treating them in proper ways,

Without one turning ev'r default!

World TB Day this year heralds

Concerted efforts to wipe out

The growing Tuberculous menace,

And save the mortal human race.

Dr. John Celes

(World TB day 2013 celebrations at Perundurai)

"I have no business to live this life if I cannot eradicate this horrible scourge from the mankind."

-Robert Koch (1882) delivering a lecture at Berlin university on his discovery of tuberculosis bacilli.

It has been 130 years since Robert Koch first discovered the tuberculosis bacilli and the world is still fighting hard to control this deadly but curable disease.

Tuberculosis (TB) is a specific infectious disease caused by Mycobacterium tuberculosis. The disease primarily affects lungs and causes pulmonary tuberculosis. It can also affect intestine, meninges, bones and joints, lymph glands, skin and other tissue of the body. The disease is usually chronic with varying clinical manifestations.[1]

Tuberculosis continues to be one of the most devastating and widespread infections in the world. It is estimated that one third of the world's population is infected with mycobacterium tuberculosis. In 2011, there were an estimated 9 million new cases of TB and 1.4 million people died from TB. Over 95% of TB deaths occur in low- and middle-income countries. Poor communities and vulnerable groups are most affected. TB is among the top three causes of death for women aged 15 to 44. There were an estimated 0.5 million cases and 64 000 deaths among children in 2011. Though TB is a global disease its prevalence is not uniformly distributed. Prevalence of TB is very less in developed countries than in developing and underdeveloped countries.[2]

Five countries which rank highest in global incidence of TB are India, China, South-Africa, Nigeria and Indonesia. Spread of HIV/AIDS globally has further

confounded the already existing problem.[3] Studies have shown that illiteracy, ignorance and poverty are some of the main reasons for improper, irrational and incomplete treatment.[4,5,6] This has lead to emergence of Multi-drug Resistant Tuberculosis (MDR-TB) and Extensively Drug Resistant Tuberculosis (XDR- TB) cases.

INDIAN SCENARIO

India accounts for 1/5 th (21%) of global incidence and has the dubious distinction of highest TB burden country in the world. As per 2011 census, the burden of disease is as follows,

Incidence- 185/ 1,00,000 population.

Prevalence- 256/ 1,00,000 population.

Mortality- 26/ 1,00,000 population.

Incidence of new smear positive TB- 75/ 1,00,000 population.

Annual Risk of Tuberculosis Infection (ARTI) – 1.5%.

Prevalence of MDR-TB - 2.1% in new TB cases and 15% in previously treated cases.

Prevalence of XDR TB among retreatment cases- 0.5%.[1]

It is estimated that about 40% of Indian population is infected with TB bacillus on national scale. TB accounts for 17.6% of deaths from communicable disease and for 3.5% of all causes of mortality.[7]

Besides the disease burden, TB also causes an enormous socio- economic burden to India. TB primarily affects people in their most productive years of life. Almost 80% of TB patients are between 15 and 45 years of age. TB kills more people in India than HIV, STD, malaria, leprosy combined. The direct and indirect cost of TB to the country amount to Rs 13,000 crore/ year.[1]

The social burden of TB is also immense. More than 1,00,000 women are stigmatized and rejected by their families each year due to TB. About 3,00,000 children are forced to leave school on account of their parents suffering from tuberculosis. TB kills more women in reproductive age group than all causes of maternal mortality combined and it may create more orphans than any other infectious disease. Nearly 1/3rd of female infertility in India is caused by TB.[8]

HIV infection has a close relationship with TB. Tuberculosis of the lungs is the commonest opportunistic infection among HIV positives. The HIV infection not only acts as a powerful risk factor for the acceleration of TB, but also results in rapid progression and spread of disease. Thus the situation is becoming worse with the emergence of HIV pandemic. An HIV positive person is six times more likely to develop TB disease once infected with TB bacilli, as compared to an HIV negative person. India has witnessed an increase in TB cases since 1983 mainly due to emergence of HIV infection. Emergence of MDR-TB and spread of HIV/AIDS are the principal reasons for the World Health Organization (WHO) in 1993 to declare TB as "Global Emergency".[9]

To control this dangerous communicable disease, Government of India launched National Tuberculosis Control Program in the year 1962 as per guidelines of National Institute of Tuberculosis, Bangalore. District TB center is the backbone of

this program. Through the existing network of PHCs, subcenter and health workers, new cases were detected, registered and drugs were distributed to patients. When program was evaluated in late 80's it was found that the objectives to be achieved were nowhere near the criteria set. The main reason was found to be non adherence to treatment schedule because of its long duration (12- 18 months).[1]

With the introduction of newer powerful anti- tubercular drugs like rifampicin, pyrazinamide etc, the duration of the course was reduced to a greater extent from 12-18months to 6- 8 months. The program was renamed as Revised National Tuberculosis Control Program (RNTCP) in the year 1992 with the following objectives,

1. Augmentation of the case finding activities by quality microscopic sputum examination to detect 70% of estimated cases.
2. To achieve cure rate of at least 85% through administration of supervised short course chemotherapy.
3. Involvement of The non-governmental organizations (NGO's).[1]

Under this program,

a. Algorithm of case detection was made so as to detect 70% of estimated cases.
b. To motivate and encourage the patients to adhere to the regimens strictly, Directly Observed treatment short course (DOTS) strategy was implemented.

One important component of DOTS strategy is SYSTEMATIC MONITORING and ACCOUNTABILITY. That means a systematic recording, reporting and evaluating the treatment outcome of every patient treated at different

levels of the health system. The NGO's are also included under this program. These organizations will help in creating awareness regarding the disease and importance of adherence to treatment by means of conducting health education camps, street plays and by becoming DOT agents etc.[10]

In spite of these efforts the incidence of TB in India is still high. The incidence of multi drug resistant tuberculosis is also increasing.[11,12,13] Under such scenario it becomes necessary to study and understand the factors which are hampering the success of RNTCP. Thus this study will help the planners to understand the problems and to take appropriate actions.

OBJECTIVES OF STUDY

8

To study the socio demographic profile of newly detected sputum positive pulmonary tuberculosis cases and to document its role in completing the schedule of treatment.

REVIEW OF LITERATURE

HISTORY:

Tuberculosis is one of the oldest diseases known to affect humans. It is known to man as "Raj Yakshma", King of diseases, in RigVeda.[14] This most ancient diseases finds a place in the works of Ancient Ayurvedic System practiced by Sushrutha, Charaka and others around 2500BC. It has also been documented in the Vedas and Ayurvedic Samhitas as the'Kshaya Rog' early as 2000 BC. There are archaeological evidences of spinal TB in the Egyptian mummies dating back to 1000 BC.[15] The Greeks called the disease phthisis ("consumption"), emphasizing the dramatic aspect of general wasting associated with chronic untreated disease.[9]

Modern era:

From the time of Hippocrates (c.460-377BC) to the nineteenth century, the infectious nature of the disease was not even acknowledged. The infectious aetiology was debated until Robert Koch's discovery of the bacillus in 1882.Tuberculosis reached epidemic proportion in Europe and North America during the 18th and 19th centuries.[16] It earned the sobriquet "Captain Among these Men of Death" which was given by John Bunyan.[17]

Understanding of the pathogenesis of tuberculosis began with the work of Theophele Laennec at the beginning of the19th century. The term tubercle was coined by Francius Sylvus (1614-1672) while the term tuberculosis was introduced by Laurent Bayle (1774-1816). In 1865, the French military doctor, Jean- Antoine Villemin, demonstrated that Phthisis could be passed from humans to cattle and from

cattle to rabbits. On the basis of this revolutionary evidence, he postulated a specific microorganism as the cause of disease, finally laying to rest the centuries old belief that pthisis arose spontaneously in each affected organism. The identification of the tubercle bacillus as the etiologic agent by Robert Koch in 1882 was a major milestone in the history of TB.[18] Clemens von Pirquet developed the tuberculin skin test in 1907 and 3 years later used it to demonstrate latent tuberculous infection in asymptomatic children.[19]

A further significant advance came in 1895 when Wilhelm Konrad Von Rontgen discovered the electromagnetic radiation in a wavelength range today known as X-ray.[20]

In 1906, French bacteriologist Calmette and Guerin began attenuating avirulent strain of M. Bovis, with a view to develop a vaccine against TB. After 230 subcultures over a period of 13 years, they evolved a strain known as Bacilli Camette Guerin or BCG.[1]

Different species have emerged in the course of history, and environmental pressures have conditioned changes in their evolution. "M. tuberculosis complex" includes M.tuberculosis, M.bovis, M.africanum, and M.microti. M.bovis is considered to be the oldest component of the complex.[21]

Epidemiology of Tuberculosis:

Tuberculosis (TB) is primarily due to infection with communicable Mycobacterium tuberculosis and infrequently by other Mycobacteria belonging to the Mycobacteria tuberculosis complex. Its principal reservoir is man. The route of transmission is mainly by inhalation of infected droplet nuclei that are released in to

the environment by coughing or sneezing of sputum positive cases. An individual's risk of infection depends on the extent of exposure to droplet nuclei and his susceptibility to infection. Once infected with M.tuberculosis, only a small proportion of individuals (about 10-12%) will develop the disease. The incubation period of tuberculosis is highly variable and ranges from few weeks to many decades. In the absence of treatment, tuberculosis has a high case fatality rate, ranging from 60 to 70 percent for smear-positive pulmonary tuberculosis and 40 to 50 percent for other forms of tuberculosis, depending on the site of the disease.[22]

Certain risk factors which enhance infection, reactivation and/ or progression to disease are as follows.

- HIV infection.

- Diabetes.

- Malnutrition.

- Silicosis.

- Malignancy.

- Indoor air pollution.

- Addiction to tobacco.

- Overcrowding, urbanization, poverty.

Tuberculosis is diagnosed more often in men than in women in most countries. This may result from differences in exposure due to varying socio-cultural factors.[23]

CLINICAL FEATURES:

Pulmonary tuberculosis patients presents with one or more of the following symptoms,

- Persistent cough of 3 or 4 weeks duration.

- Continuous fever.

- Chest pain.

- Haemoptysis.

Other nonspecific symptoms are anorexia, malaise and weight loss.[1]

INVESTIGATIONS:[24]

- Sputum smear microscopy

- Chest X-ray

- Sputum culture

- Newer diagnosis ,including Molecular diagnosis, GeneXpert etc

- Tuberculin test in children.

SPUTUM SMEAR MICROSCOPY-

Sputum smear microscopy is the primary tool for diagnosing TB under RNTCP as it is easy to perform at the peripheral laboratories, not expensive and specific with low inter and intra reader variation. Initially 3 sputum samples were collected for confirmation. According to new guidelines of RNTCP which is applicable from 1st April 2009, two samples are enough for confirmation. Among these two samples one should be early morning sputum. It is simple and requires

minimum training and can be used for diagnosis, monitoring and defining cure. With quality microscopic examination at least 50% of the new sputum smear positive pulmonary TB patients can be detected.

Interpretation:

Examination Finding	Results Recorded	Grading	No of fields examined
> 10 AFB per oil immersion field	Positive	3 +	20
1-10 AFB per oil immersion filed	Positive	2 +	50
10-99 AFB per 100 oil immersion field	Positive	1 +	100
1-9 AFB per 100 oil immersion field	Positive	Scanty	100
No AFB 100 oil immersion fields	Negative	Negative	100

Diagnostic algorithm for pulmonary tuberculosis
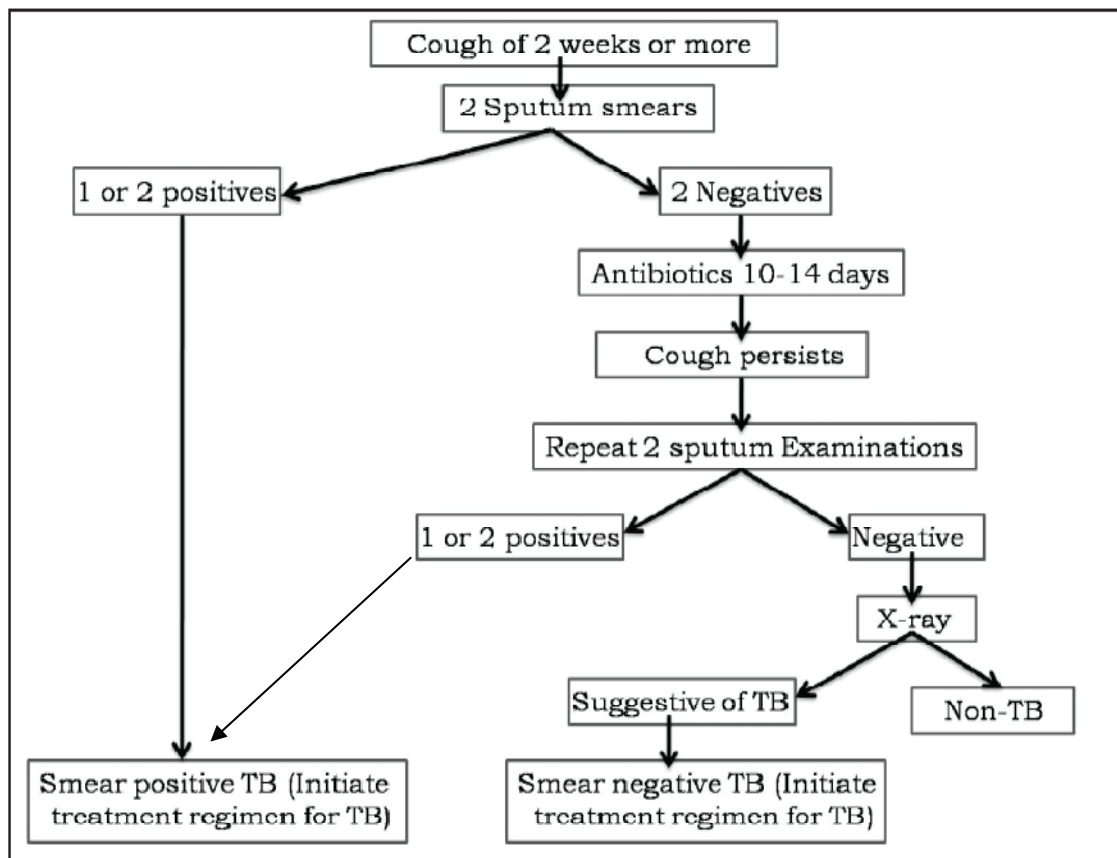
A study done by Niladri Sekhar Das, DC Thamke states that Positivity by Ziehl Neelsen (ZN) method was 33% and 34% with FL staining. The sensitivity of ZN microscopy was 82.9% and specificity was 93.8%, similar to that observed with FL microscopy and 94.3% correlation was found between ZN and Lowenstein Jensen (LJ) positive cases.[25]

A study done by Selvakumar N, Rahman F, Rajasekaran S, Narayanan PR, Frieden TR concludes that The sensitivity (72%; 101 of 140) of the modified-ZN staining method, which uses 0.3% carbol fuchsin, was significantly lower than that of the standard-ZN staining method.[26]

Chest X - Ray :

X - ray as a diagnostic tool is sensitive but less specific with large inter and intra reader variations. No shadow is typical of TB. 10 - 15% culture - positive cases remain undiagnosed and 40% patients diagnosed as having TB by X - ray alone may not have active TB disease. It is supportive to microscopy.

Culture :

Culture of bacilli Mycobacterium tuberculosis is very sensitive and specific but is expensive as it requires a specialized laboratory set – up. It takes atleast 6 weeks for the result. Culture and sensitivity testing is valuable for diagnosis and management of drug resistant tuberculosis, besides epidemiological surveillance and planning.

Media used: LJ based solid and liquid culture methods are used for diagnosis. Solid culture methods are less expensive than liquid culture, but the results are invariably delayed because of slow growth of mycobacteria. Liquid culture increases the case yield by 10% over solid media.

Tuberculin Test :

It is an intradermal hypersensitivity test discovered by Von Pirquet in 1907.[20] This may be useful as an additional tool for diagnosing paediatric TB, in whom a positive test is more likely to reflect recent infection with TB and indicates a much higher risk of developing disease. Children vaccinated previously with BCG show positive reaction during infancy.[27] However, the tuberculin test has no role in diagnosing adult pulmonary TB disease in India.

Diagnostic tools for MDR-TB are

Culture and drug sensitivity by

- Solid culture

- Liquid culture

Newer diagnostics tools- Line Probe Assay (LPA), Cartridge Based Nucleic Acid amplification Test – (CBNAAT-Gene Xpert).[28]

EVOLUTION OF ANTI- TB TREATMENT:

The evolution of treatment started off with the recommendations of dietary regimen proposed by Hippocrates and Galen. The other primitive approaches included building of sanatoriums at high altitudes following awareness of the infectious nature of TB, bleeding with the leeches, various surgical procedures to achieve lung collapse presuming that the disease heals earlier by this maneuver.

The therapy changed dramatically with the introduction of antibiotics for the management of infectious diseases. Number of antibiotics, both bactericidal and bacteriostatic against TB bacilli were developed. In 1944, streptomycin- an antibiotic newly isolated by Waksman from the soil organism streptomyces Griseus, showed a striking therapeutic effect on experimental TB in guinea pigs. Soon after it was used for the first time in human patients. In 1949, it was discovered that para-aminosalicylic acid (PAS) prevents the emergence of drug resistance if given in combination with streptomycin. Since then the administration of two or more drugs in combination has been recognized to be essential for adequate TB treatment. The discovery in 1952 of the anti- TB activity of Isoniazid (INH) has remained an

important component of all primary drug regimens because it is highly effective having low toxicity and inexpensive. The discovery in the late 1960's of Rifampicin is perhaps the most effective anti- TB medication. The discovery of ethambutol in 1961, and Pyrazinamide during early 1970's has changed the strategies in chemotherapy of tuberculosis.

The startling results in 1956 of trials in Chennai, demonstrating that ambulatory, domiciliary treatment was highly effective without increasing the risk of infection for family contacts prompted a radical departure from the traditional sanatorium treatment and opened new prospects for nationwide treatment programs in developing countries. Conventional chemotherapy with streptomycin, INH, PAS, thioacetazone and ethambutol for 18-24 months was practiced till 1972. In 1972, monumental work done by the British Medical Research Council and partners around the world led to the development of standard short-course chemotherapeutic regimens. These studies established a number of key points which provided the framework for the development of modern treatment. [29,30]

TREATMENT:

Treatment of tuberculosis under RNTCP is based on Direct observation of treatment (DOT) ensures the best possible result. Here an observer watches and assists the patient in swallowing the tablets, thereby ensuring that the patient receives the medication. Many patients who do not receive directly observed treatment stop taking drugs after two months because they feel better. Studies in India and many other countries consistently shows that at least one third of patients do not take medicines regularly.

The duration of treatment is usually 6 to 9 months. There are two phases in the treatment of tuberculosis: the intensive phase (IP) of 2-4 months and the continuation phase (CP) of 4-5 months, depending upon the category of treatment. During IP, all doses are given under direct observation, three times a week on alternate days for 2-4months. Thereafter, sputum is examined, and if found negative, the CP is started. During CP, the first dose of every week must be administered under direct observation. The patient collects the rest of the drugs for that week from the DOT Provider and consumes them at home. The following week, the patient comes with the empty blister pack, hands it over to the DOT Provider, takes the first dose under direct observation and collects drugs for the rest of the week to be consumed at home.[28]

Treatment groups	Type of patient	Intensive phase	Continuation phase
Cat I	New Sputum smear-positive New Sputum smear-negative New extra-pulmonary	$2(HRZE)_3$	$4(HR)_3$
Cat II	Smear- positive relapse Smear- positive failure Smear- positive treatment after default Others*	$2(HRZES)_3$ $1 (HRZE)_3$	$5 (HRE)_3$

*Those patients who are sputum smear negative and have recurrence or non response, diagnosis being based on culture or histological evidence.[20]

18

Evolution of tuberculosis control program in India:

1962   National Tuberculosis Control Programme was launched.

1992   Programme was reviewed.

1993   RNTCP pilot project was started in 5 states (Delhi, Kerala, West Bengal, Maharashtra, and Gujarat)

1998   Encouraged by the results of pilot project, RNTCP was implemented in a phased manner to cover 18 million population.

By 2001   450 million population was covered under RNTCP.

By 2004   >80% of population was covered.

By 2006   Entire country was covered under RNTCP.[31]

National tuberculosis control program (NTCP):

Launched in the year 1962. Aim was to detect cases at the earliest and treat them. District TB programme was the backbone of NTCP.

Objectives:

1. Long term objectives-

   a) one case infects less than one new person annually.

   b) prevalence of infection in age group 14 years - < 1%.

2. Short term objectives-

   a) to detect maximum number of cases among outpatients.

   b) to vaccinate newborn and infants with BCG.

   c) integration with all other health institutions.[1]

Strategies followed under District Tuberculosis Center were,

- Recording and reporting.

- Case finding through Laboratory and X – ray facility.

- Domiciliary treatment with INH, thioacetazone and streptomycin for one year to one and half year.

- BCG vaccination.

- Supervision.

The treatment regimen followed under National Tuberculosis Control Program was

1. 2 SHT + 10 HT

2. 2 SH + 10 $H_2 S_2$

3. 18 HT.[32]

In the year 1992, nationwide review of NTCP was done with the assistance of SIDA and WHO. Results showed no improvement in the disease burden of the country.

Some of the reasons for failure of NTCP were,

- Completion rate of treatment was 30% only.

- Inadequate budgetary outlay.

- Irregular supply of anti TB drugs.

- Poor quality of sputum microscopy.

- More emphasis on case detection rather than cure.

- Poor organization.

- Poor integration with other health facility.

- Poor awareness of TB patients about the disease.

- Non availability of trained staff.

To tackle these bottlenecks, certain strategic changes were made in the program and was renamed as Revised National Tuberculosis Control Program.

Major differences between NTCP and RNTCP are,[31]

	NTCP	RNTCP
Objectives	Early diagnosis and treatment	Breaking the chain of transmission
Target	Not defined.	Case finding- 70%. Cure rate- 85%.
Strategy	SCC	DOTS
Diagnosis	More emphasis on X-ray	Mainly sputum microscopy.

Important working definitions under RNTCP:

New case - A patient with sputum positive pulmonarv tuberculosis who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than 4 weeks.

Relapse - A patient who returns smear positive having previously been treated for tuberculosis and declared cured after the completion of his treatment.

Failure case - A patient who was initially smear positive. who began treatment and who remained or became smear positive again at five months or later during the course of treatment.

Return after default - A patient who returns sputum smear positive, after having left treatment for at least two months.

Transfer in - A patient recorded in another administrative area register and transferred into another area to continue treatment (treatment results should be reported to the district where the patient was initially registered).

Transfer out - A patient who has been transferred to another area register and treatment results are not known.

Cured - Initially smear positive patient who completed treatment and had negative smear result on at least two occasions (one at treatment completion).

Treatment completed - Initially smear negative patient who received full course of treatment, or smear positive who completed treatment, with negative smear at the end of initial phase, but no or only one negative smear during continuation and none at treatment end.[24]

DOTS strategy:

DOTS is promoted by WHO as the TB control strategy to reach the global targets of detecting at least 70% of all new infectious cases and curing 85% of those detected. WHO estimates that when the global targets are achieved, the prevalence of TB infection and the number of contacts infected will be reduced by 40%. It is estimated that, due to the implementation of DOTS, the global prevalence of TB fell from 309 to 245 per 100000 between 1990 and 2003 and by 5% between 2002 and 2003.

DOTS has been adopted by many countries as a TB control strategy to reach the global targets. By the end of 2004, about 80% of all the world population had access to DOTS in 183 countries. Although DOTS coverage has resulted in high treatment success rate of about 82%, case detection has remained low at 42%. Case detection under DOTS has progressed linearly over the years.[33]

The success of RNTCP depends on following 5 elements:

- o Political and administrative commitment.
- o Good quality diagnosis through sputum microscopy.
- o Uninterrupted supply of good quality drugs.
- o Directly observed treatment.
- o Systematic monitoring and accountability.

Political and administrative commitment-

Since TB can be cured and the epidemic reversed, it warrants the topmost priority which it has been accorded by the Government of India. This priority should be continued and expanded at the state, district and local levels. One of major initiative from the Government of India (GOI) in 2010 was the frequent review of the RNTCP by the Honorable Union Minister of Health and Family Welfare and Joint Secretary. These frequent reviews helped in ensuring sustained political commitment from the Individual States. More over this political commitment channeled resources in the states to sustain the program success.

Good quality diagnosis through sputum microscopy-

Sputum microscopy continues to be the primary tool for detection of infection. However in line with the stop TB strategy the programme is exploring all possible avenues with newer and innovative technologies for early detection of TB including use of LED microscopes.

Uninterrupted supply of good quality drugs-

RNTCP uses intermittent short-course chemotherapy (SCC) regimens to facilitate the direct observation of treatment. RNTCP ensures that there is no interruption in treatment due to shortage of drugs. Sufficient anti-TB drugs in patient-wise boxes are made available at all the appropriate levels. The uninterrupted supply of drugs to each patient is made possible through the "patient-wise box. Patient-wise drug boxes are an innovation of RNTCP wherein a box of medications for the entire duration of the treatment is earmarked for every patient registered. This ensures the availability of the full course of medication to the patient the moment s/he is registered for treatment.

Directly observed treatment-

Directly observed treatment (DOT) is one of the key elements of the DOTS strategy. In DOT, an observer (health worker or trained community volunteer who is not a family member) watches and supports the patient in taking drugs. The DOT provider ensures that the patient takes the right drugs, in the right doses, at the right intervals, for the right duration. DOT thus facilitate release free cure for TB and also helps to reduce development of drug resistance, because direct observation ensures adherence.

Systematic monitoring and accountability-

RNTCP has a systematic monitoring mechanism which accounts for/tracks the outcome of every patient put on treatment. There is a standardized recording and reporting structure in place. The cure rate and other key indicators are monitored regularly at every level of the health system and regular supervision ensures quality of

the programme. RNTCP shifts the responsibility for cure from the patient to the health system.[34]

Recent initiatives:

1. DOTS-Plus:

    This refers to a DOTS program that adds components for diagnosis, management and treatment of MDR-TB patients. This was launched by WHO during the year 2000 and by RNTCP in India during 2007. This strategy differs from DOTS by following characteristics

    a. Treatment is by daily regimen with second line of drugs.

    b. Patients are admitted and treated in the RNTCP designated sites only.

    c. Entire course of the treatment is given by DOTS providers.

    d. Total duration of treatment is minimum 2 years.[20]

2. TB notification order 7th May 2012

    According to this order all health care providers should notify every TB case to local authorities each month in a given format.

3. The gazette of India notification on 7th June 2012-

    Ban on serological test kits for TB in India (manufacture, sale, distribution, import).

    This step was taken by the government because serological test kits were giving imprecise results.

4. Introduction of NIKSHAY- which is case based web based recording and reporting system. So RNTCP can keep a track on all registered tuberculosis cases.[35]

National strategic plan under RNTCP (2012-2017)

Vision: "TB-free India" by 2050

Goal : 'To decrease mortality and morbidity due to Tuberculosis and stop transmission of infection until Tuberculosis ceases to be a major public health problem in India'.

Objectives:

- To reduce the incidence of and mortality due to TB

- To prevent further emergence of drug resistance and effectively manage drug-resistant TB cases.

- To improve outcomes among HIV-infected TB patients

- To involve private sector on a scale commensurate with their dominant presence in health care services.

- To further decentralize and align basic RNTCP management units with National Rural Health Mission block level units within general health system for effective supervision and monitoring.[1]

RELATED STUDIES

SOCIODEMOGRAPHIC PROFILE:

A study conducted by Vasantha M et al (1999-2004) at a rural TB Unit (TU) in Thiruvallurdistrict showed that of the 1,557 TB patients registered under DOTS programme, 1,175 (75%) were males, 690 (44%) were aged 45 years or more, 623 (40%) were illiterate and 478 (31%) were unemployed.[36]

In a study done by N. Pandit, S.K. Choudhary (2002) in Gujrat showed following results. Majority of study population (85%) was in age group of 15- 55 years, which is the productive age. The mean age was 36.6 (SD 14.1). Almost 63% were male, who is usually earning member of family. 51% had education up to primary school.[37]

The study done by S Bawri et al (2006) in Guwahati showed following findings, majority of the patients (74%) belonged to 2nd, 3rd and 4 th decades with mean age of 34 years and standard deviation of 16 years & 75% were males and 25% were female with male to female ratio 3:1 respectively.[38]

An observational study carried out by A Mishra et al (2006) in Gwalior city showed that, majority of patients were in 20-30 years of age group. 27.5% were belonging to class-IV socioeconomic status. Majority had education up to 8th standard.[39]

A study done by Moharana PR et al (2008) in Orissa showed that 65% of the patients were males. 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. 27(46.6%) patients were daily laborers and lived in poor housing conditions with unsanitary, polluted, urban slum environment.[40]

Socio-demographic profile of 104 participants in a study done by Mweemba P et al (2008) in Lusaka, Zambia is as follows, all the participants were aged between 18-66 years. Forty-nine percent were female, 51.9% were married and 42.3% had primary education only. About half of the respondents (49%) had no monthly income

and majority of those with no income were female. Two thirds of the respondents (76%) lived in high-density areas.[41]

Another study carried out by Ahmed J et al (2008) in Sandur TU (Tuberculosis Unit) of Bellary District, Karnataka showed that male to female ratio as 2.5:1. About two thirds of the cases were in the peak productive age group of 25-54 years. About two thirds of the cases among males were aged 35 years and above while 60% the female cases were below 35 years. The peak age group was 35-44 years in males and 25-34 years in females with mean age being 40 years and 34 years respectively.[42]

A study done by Srivastav Shalini et al (2009) in Jhansi showed that maximum number of tuberculosis cases (43.18%) in both the sexes were found in age group 26-45 years. 63% cases were from Urban areas as compared to 37.27% who belonged to Rural areas .TB cases were found to be more common in SC/ST population and in poor socio-economic group.[43]

A study done by Donald Christian et al (2009) in Anand District, Gujrat involving 100 patients consisted 68 males and 32 females, 75% of the subjects had an education below 9th standard. 46% of subjects were labourer.[44]

As per reports of the study done by Aryal S et al (2010) on DOTS clinics of Dharan Municipality, Nepal among 60 cases 39 were males and 21 females. 50% of cases were belonging to < 30 years of age. Twenty four were married and 45 of were literate.[45]

STUDIES ON NONCOMPLIANCE TO TREATMENT:

In a study done by Jasmin Johnson et al (2000) in Puna, the main reasons for default found to be travel to a different place (42.2%), relieved from symptoms (26.6%), adverse effects of drugs (26.6%) and cost of treatment (4.6%).[46]

In a study conducted by O'Boyle SJ et al (2000) in Malaysia, a total of 63 compliant and 23 non-compliant patients were interviewed. For non-compliant patients, reaching the treatment centre entailed greater cost ($P < 0.005$) and travel time ($P < 0.005$) compared to compliant patients. Cost of transport was the reason most frequently given for non-attendance.[47]

In a study done by Jaggarajamma K et al (2001) in Tiruvallur district, the main reasons given by patients and their DOT providers for noncompliance were: drug related problems (42%, 34%), migration (29%, 31%), relief from symptoms (20%, 16%), work related (15%, 10%), alcohol consumption (15%, 21%), treatment from other centers (13%, 4%), respectively.[4]

A study done by N. Pandit, S.K. Choudhary (2002) in Anand District, Gujrat ,it was observed that majority (12/19, 63.2%) of patients on DOT stopped treatment because of toxicity of drugs. The other reasons were feeling better during treatment (3/19, 15.8%) and lack of knowledge about various aspects of TB and its treatment (10.5%).[37]

According to study carried out by Mohanarani Suhadev et.al (2004) in rural Tamil Nadu found that 54% percent of working patients did not lose workdays on account of illness. He observed that 26% of patients lost less than 30 days of work, costs for transportation (range Rs 0-372) during treatment.[48]

Another study done by V.Chandrasekaran et al (2005) in Tamilnadu showed that the reasons for default were drug related problems (84%), work related problems (32%), alcoholism (23%), being symptom free(23%) followed by domestic problems and taking treatment from outside.[6]

In a study done by Chhaya Mittal and SC Gupta (2007) in Agra city found that the main reasons of default were side effects following medication (43.2%), improvement in symptoms (14.4%), and lack of time(13.5%). No relief in symptoms and lack of awareness were other important reasons.[5]

Sweta Gupta et al (2007) in their study in Delhi found that, main reasons for interruption in treatment were early improvement (30.05%), high cost of treatment (16.39%), side effects of drugs (12.84%), unaware about long duration of treatment (9.02%), no improvement (7.10%), alcoholism (4.37%).[49]

A study done by Moharana PR et al (2008) in Orissa 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%).[40]

A prospective nested case control study conducted by Mohamed Saif Anaam et al (2008) in Yemen showed the non-compliance rate of 16.3%. In the multivariate logistic regression analysis, factors that remained independently associated with non-compliance were: place of residence, literacy, travelling time, waiting time, employment, living status, family support, stigma and patients' knowledge of TB.[50]

A study by Weiguo Xu et al (2009) in China concluded that the main reasons for non-adherence listed by patients were adverse reactions to anti-tuberculosis drugs

(37.8%), relieved symptoms (26.8%), long course regimen and large dose of drugs (15.9%), worry about dangers of drugs (15.9%), other disorders (15.9%), financial burden and medical expenditures (15.9%).[51]

A study done by Srivastav Shalini et al (2009) in Jhansi showed that Majority of patients (48.18%) had to cover almost 2-3 Km to avail the treatment facilities and 15.45% patients had to cover >3kms to reach the centre. For 43.63% cases the DOTS Centre was approachable, without bearing any travel expenditure but 56.37% patients were bearing the indirect costs of travelling for availing the DOTS treatment and the money spent for this travel ranged from less than Rs10 for 25% cases to more than Rs. 30 for almost 8% patients.[43]

A cross- sectional study done by Suparna Bagchi (2010) in Mumbai showed following results. Among the newly-diagnosed patients smoking and cost-related travel factor (concerns of long distance to DOTS center and loss of time from work) were positively associated with non-adherence to the treatment. Among the residual group, alcohol consumption during treatment and non-availability of drugs at the health center were significantly associated with non-adherence to the treatment.[52]

A hospital based study was conducted by Sardar P et al (2010) in Kolkata fond that, the prevalence of non-compliance to ATT (anti-tubercular treatment) in HIV-TB co-infection patients was 40.5%. Multivariate logistic regression analysis showed that absence of proper counseling, lack of knowledge about correct route of TB transmission, visiting quacks during ATT and the urge to leave treatment once patient started feeling better were the significant determinants of non-compliance.[53]

A study in Sub Saharan Africa by B Castelnuovo (2010) found that risk factors for defaulting treatment were: distance from the hospital, not being on the first

course of TB medications, lack of repeated smears, unit transfer after the intensive phase, experiencing side effects, having no family support, poor knowledge about TB treatment, being more than 25 years old.[54]

STUDIES ON ATTITUDE:

A Study by N. Pandit, S.K. Choudhary (2002) in Gujrat revealed that the compliance to DOT was significantly high among those who have good knowledge about various aspects of disease like effectiveness of DOTS, knowledge about toxicity of drugs and importance of completion of therapy. Lack of knowledge about various aspects of TB and its treatment led to noncompliance in 10.5%.[37]

A descriptive study in Lusaka, Zambia by Mweemba P et al (2008) showed that half of the respondents (49%) had average knowledge of TB treatment. Majority of the respondents (89.4%) had positive attitude towards TB treatment. Most of the respondents (80.8%) reported complying with TB treatment regimens. There was a positive relationship between compliance and attitude, indicating that as the level of attitude increases, compliance level also increases ($r = 0.59$, $p < 0.001$). The results further showed that there was a significant positive correlation between knowledge and attitude ($r = 0.25$, $p = 0.005$). However, there was no relationship between knowledge and compliance ($r = 0.12$, $p = 0.12$) indicating that knowledge did not have an influence on compliance.[41]

A study by Saria Tasnim et al (2008) in Bangladesh showed that about 46.8% get information about TB from television, next was doctors chamber (18.2%). About mode of transmission of disease 22.9% were ignorant, 56% thought sneezing and cough, smoking 5.4%, and 2.2% mentioned TB is a familial disease. Most of them knew that TB can be cured completely. Ninety percent of them can mention the

duration of treatment should be 6–8 months. Regarding attitude towards other TB patients 65.7% felt compassionate and desire to help, 28.6% indifferent, and 4.9% would prefer to stay away. About self-perception of being TB patient 95.4% got family support, 59.3% are anxious for reduction of family income, 21.9% felt socially neglected, 46.6% expressed that utensils for food/drink are separated for them, and 11.2% felt isolated within family.[55]

A case control study done in a Moroccan region by Nabil Tachfouti et al (2010) concerning attitude, 82.4% of respondents said that TB patient can stop the treatment if he feels better; More than half of patients (57.9%) said TB patient can stop DOTS it if he can't support medication, and 76.5% said there are many treatment to take. 64.2% believes that if you have TB people do not respect you. Ninety one percent of respondents were satisfied with health facilities, the proportion was significantly higher among adherent patients: 94.1 versus 84.5 among non-adherent patients (p<0.01).[56]

STUDIES ON IMPORTANCE OF IMPLEMENTING DOTS:

In a study conducted at Institute of TB and Allied Diseases New Delhi between Oct. 95 to Sep 97 by Sunil Bhat et al, the cure rate of all new smear positive and retreatment cases was 80% and 65% respectively. The study demonstrated that under RNTCP not only case finding has improved but an excellent treatment outcome is also observed due to the treatment effectiveness of DOTS and it clearly indicated the technical soundness and Operational feasibility of DOTS under RNTCP in urban settings.[57]

A study by Khatri GR et al (2000) in Delhi showed that, the treatment success rate of smear-positive cases doubled (40% before and 80% after DOTS) and the death

rate became one-seventh (29% before and 4% after DOTS) after introduction of supervised treatment.[58]

A study by Olle-Golg et al (2001) at Artibonite Valley, a rural area in Haiti reported that, of 281 patients, 19% were treated by DOTS and 51% were treated without observation. Default rates were four times higher and death was three times higher in the group that was not observed (29% Vs 7% default, 12% Vs 4% death). The authors were able to demonstrate that by involving the community, directly observed treatment can be successful even in a scattered rural population with scarce economic resources, high HIV infection, high illiteracy rates, difficult access to transport, and unstable political conditions.[59]

In a study done at palamu district of Jharkhand by Mathew et al (2001), it was found that cure rate was 64% in unsupervised areas and was 89.2% in RNTCP-DOTS area. The findings of the study indicated that a hospital supervised directly observed treatment (DOT) programme can exceed WHO target for cure rate even in the poorest rural setting.[60]

A study done by Venugopal K (2002) in Alappuzha District, Kerala concluded that DOTS regime is effective for Neuro tuberculosis. Default rate is negligible with the supervised regime.[61]

A study done by Murali Madhav et al (2003) in Mangalore showed that 91% of the DOTS and 53% of the non- DOTS group were observed to be smear negative after 6 months of chemotherapy. This difference was statistically significant. The study findings confirm that DOTS is significantly superior health intervention compared to self administered regimen in the prognosis of tuberculosis patients.[62]

Balasubramanian et al (2005) in their study at Kerala showed DOT increased treatment success from 55% to more than 95%. Of the patients whose treatment was not directly observed, 45% had relapse or failure compared with 3% of those who were on DOTS.[63]

A study done by Nirupa C et al (2005) in Delhi, showed success rates among patients treated by different DOT provider, such as Anganawadi worker (80%), community volunteers, and PHC staff (76%). Authors conclude that patients who received drugs for self administration had a significantly higher risk of treatment failure or death compared to patient who received treatment from a DOT provider.[64]

An observational study done by A Mishra et al (2006) in Gwalior City showed that, higher cure rate and sputum conversion rate were observed after introduction of supervised treatment (DOTS) for tuberculosis. The study had calculated a cure rate of 85.04% for cat I. This was higher than the rates reported in TB status report 2007 for Gwalior District (79%) and for Madhya Pradesh (79%).[39]

A longitudinal study done by Subramani R et al (2006) in Tiruvallur area reported that during a 30-year period prior to DOTS , the annual decline in the prevalence of culture-positive and smear-positive cases were 2.3% and 2.5% respectively. During a 2.5 year DOTS period, the rates increased in both categories to 11.9% and 5.6% respectively.[65]

STUDIES RELATED TO MDR-TB:

In a study done by Jasmin Johnson et al (2000) in puna found that main risk factor for development of MDR-TB is default in the treatment caused by side effect of the drug, cost of treatment, symptom relief and change of residence.[46]

A study by Deepak Almeida et al (2003) in Mumbai showed that an alarmingly high percentage of multidrug-resistant M. tuberculosis isolates in Mumbai (51%) as compared with that at the rural center (2%). The major reasons found to be e erratic and highly variable treatment prescribed by doctors in Mumbai's private sector, overcrowding, HIV infection, inadequate public health TB control measures, and a lack of suitable treatment or containment of MDR-TB cases.[11]

A case control study done by Sharma SK et al (2003) in Delhi showed that Past history of disease, higher severity of illness, inadequacy of drug treatment and presence of HLA-DRB1*14, DQB1*0503 and DQB1*0502 alleles were found to be significant risk factors for MDR-TB. Multivariate analysis identified poor past compliance to treatment (odds ratio, OR=6.6; 95% confidence interval, CI [2.0-21.5]), higher number of cavities (OR=6; 95% CI [2.1-17.3]) in chest radiographs and the presence of the HLA-DRB1*14 allele (OR=8.2; 95% CI [2.1-31.3]) as independent predictors of MDR-TB.[66]

A review article by C.N. Paramasivan & P. Venkataraman (2003) Tuberculosis Research Centre (ICMR),Chennai, India told that the main reasons for MDR-TB are [i] deficient or deteriorating TB control programmes resulting in inadequate administration of effective treatment; (ii) poor case holding, administration of sub-standard drugs, inadequate or irregular drug supply and lack of supervision; (iii) ignorance of health care workers in epidemiology, treatment and control; (iv) improper prescription of regimens; (v) interruption of chemotherapy due to side effects; (vi) non-adherence of patients to the prescribed drug therapy; (vii) availability of anti-TB drugs across the counter, without prescription; (viii) massive bacillary load; (ix) illiteracy and low socio-economic status of the patients; (x) the epidemic of HIV infection; (xi) laboratory delays in identification and susceptibility testing of M.

tuberculosis isolates; (xii) use of nonstandardized laboratory techniques, poor quality drug and lack of quality control measures; and (xiii) use of anti-TB drugs for indications other than tuberculosis.[67]

A study done by Agrawal, D et al (2005) in Mumbai, showed that flouroquinolone resistance has increased exponentially from 3% in 1996 to 35% in 2004. The incidence of multidrug-resistant tuberculosis has also increased during the same period, from 33% in 1995 to 56% in 2004.[68]

A study done by Sunil Sethi et al (2006) in Chandigarh showed that the prevalence of MDR TB was found to be 9% in newly diagnosed cases, which is 3-5 % globally. There were 121 newly-diagnosed and 98 previously treated patients, of which MDR TB was found to be associated with 9.9% and 27.6% cases respectively.[12]

A study done in Lucknow by AK Maurya et al (2007) found that, the overall prevalence rate of MDR-TB to be 38.8%, increasing from 36.4% in 2007 to 40.8% in 2010. The prevalence of MDR-TB in new and previously treated cases was 29.1% and 43.3% ($P < 0.05$; CI 95%). The increasing trend of MDR-TB was more likely in pulmonary TB when compared with extra-pulmonary TB ($P < 0.05$; CI 95%).[13]

Surendra K. Sharma et al (2008) did a study in New Delhi showed that out of 177 cases, two cases of MDR-TB were detected. Thus, the prevalence of MDR-TB among newly diagnosed pulmonary tuberculosis patients was 1.1%.[69]

MATERIALS AND METHODS

Study area   : Bijapur Taluk.

Study design   : Longitudinal study.

Study technique: Interview technique.

Study period   : 2 years

October 1st 2011- October 31st 2011: Pilot study.

November 1st 2011– June 30th 2013: Data collection.

July 2013- September 2013: Analysis and documentation.

SAMPLE SIZE:

All newly detected sputum positive TB cases from Bijapur Taluk registered between November 1st 2011 to October 31st 2012 at DTC, Bijapur were included.

During this study period 248 new sputum positive cases were registered at District Tuberculosis Center.

ETHICAL CLEARANCE

The study protocol was submitted to the ethical committee of Shri B.M. Patil Medical College and clearance was obtained before commencement of study.

DATA COLLECTION:

Prior permission was procured from District Health Officer, District Health and Family Welfare office, Bijapur and District Tuberculosis Officer, District Tuberculosis Center, Bijapur for the study. Name and address of newly detected

sputum positive tuberculosis patients was obtained as and when cases were registered in DTC during the study period by personal visit.

Each patient was visited 4 times during their treatment course-at the end of 1st month, 3rd month, 6th and 8th month.

During first visit, the purpose of the study was explained to the patients. After obtaining their oral consent, information about socio- demographic profile and treatment was collected in a pretested proforma. The contact number of either the patient or the health worker was taken to inform about the next visit.

During next visits information about regularity of the treatment, results of the repeat sputum examination, treatment schedule and side effects of the drugs was collected.

STATISTICAL ANALYSIS

SPSS v.16 (Statistical Package for Social Sciences) was used to analyze data. Data was presented in the form percentages, graphs and figures. Chi square test, Chi square test for trend was applied to the data. A p value of < 0.05 was considered to be significant.

INCLUSION CRITERIA

All newly detected pulmonary TB cases during November 1st 2011- October 31st 2012 registered from Bijapur Taluk at DTC, Bijapur who gave consent to participate in the study.

EXCLUSION CRITERIA

1) Patients who are not willing to cooperate.
2) Patients who could not be contacted even after 3 visits.

RESULTS

The study was conducted on 248 new sputum positive pulmonary tuberculosis cases.

A. Socio-demographic profile:

Table 1: Age and sex wise distribution of patients(n=248)

Age group	SEX		Total
	Male	**Female**	
<20 yeays	12(7.27%)	1(1.2%)	13(5.2%)
21-30 years	30(18.18%)	24(28.91%)	54(21.7%)
31-40 years	38(23.03%)	27(32.53%)	65(26.2%)
41-50 years	29(17.57%)	19(22.89%)	48(19.3%)
51-60 years	26(15.75%)	7(8.43%)	33(13.3%)
> 60 years	30(18.18%)	5(6.02%)	35(14.1%)
Total	165(100%)	83(100%)	248(100%)

In our study majority of the patients belonged to economically productive age group i.e 21-50 years (67.34%).

Graph1: Distribution of patients based on age group.
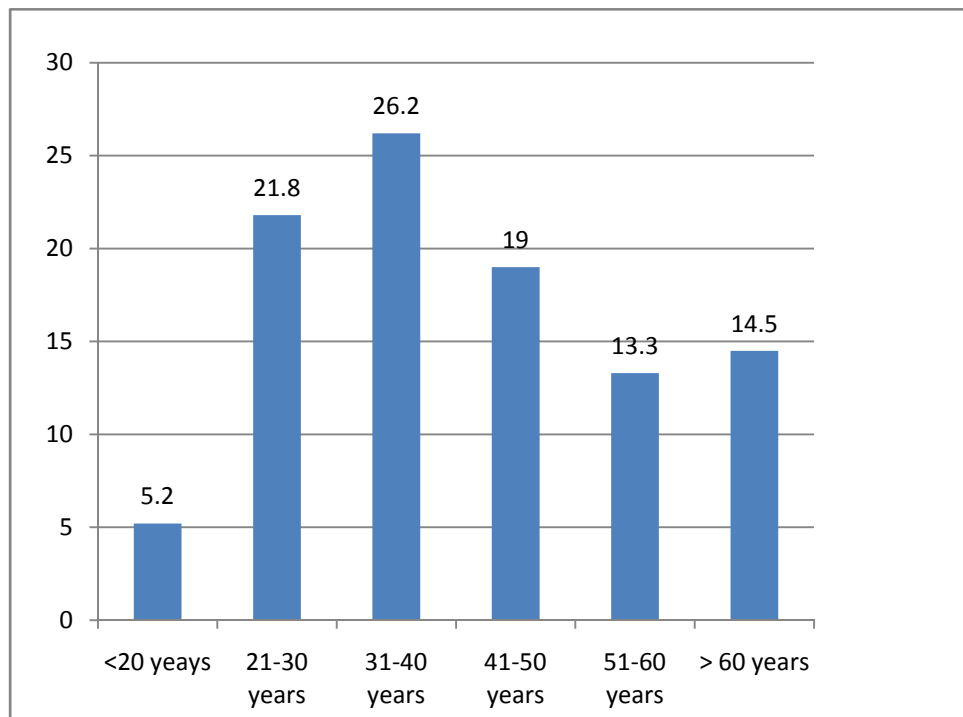
Graph 2 : Sex wise distribution of patients
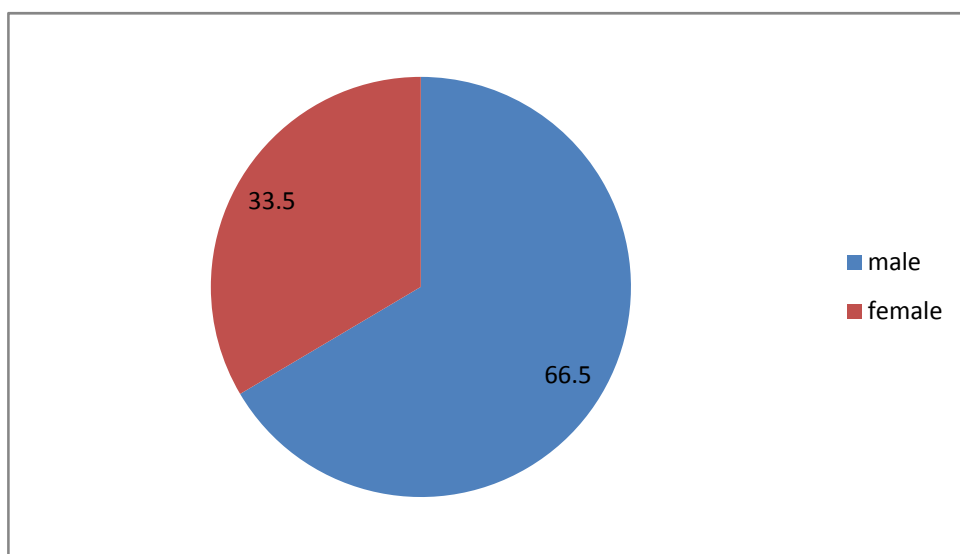
In our study majority of the patients were male 165 (66.5%) and 83 (33.5%) were female.

Table 2 : Distribution of patients based on education (n=248).

Education	SEX		Total
	Male	**Female**	
Illiterate	82(49.69%)	36(43.37%)	118(47.5%)
Primary School	68(41.21%)	39(46.98%)	107(43.1%)
Secondary School	12(7.27%)	8(9.63%)	20(8.06%)
College	3(1.81%)	0	3(1.2%)
Total	165(100%)	83(100%)	248(100%)

In our study majority of the patients were illiterate 118 (47.5%). 107 (43.1%) had education up to primary school.

Table 3: Distribution of patients based on other socio- demographic factors. (n= 248)

SOCIO-DEMOGRAPHIC FACTORS		FREQUENCY	PERCENT
RELIGION	HINDU	211	85.1
	MUSLIM	37	14.9
OCCUPATION	Unskilled worker	136	54.8
	Skilled worker	88	35.48
	Unemployed	24	9.67
TYPE OF FAMILY	Nuclear	104	41.9
	Joint	82	33.1
	three generation	62	25

211(85.1%) patients belong to Hindu religion and 37 (14.9 %) patients follow Muslim religion. This may be because majority of the population belong to Hindu religion in this area.

In our study majority were unskilled workers (54.8%). 24 (9.67%) were unemployed.

In the present study 104 (41.9%) patients were from nuclear family followed by joint family 82 (33.1%).

Table 4: Distribution of patients based on socio- economic status.

(Economic status as per Prasad's updated criteria[24]- Annexure III)

SOCIO-ECONOMIC STATUS	FREQUENCY (n=248)	PERCENT
Class II	10	4.03
Class III	98	39.5
Class IV	140	56.4
Total	248	100

(* none of the respondents were from class I and class V socio-economic status.)

Majority of the patients belonged to class IV socio- economic status (56.4%), 39.5% to class III and 4.03% to class II socio- economic status.

Graph 3: Distribution of the patients based on socio- economic status
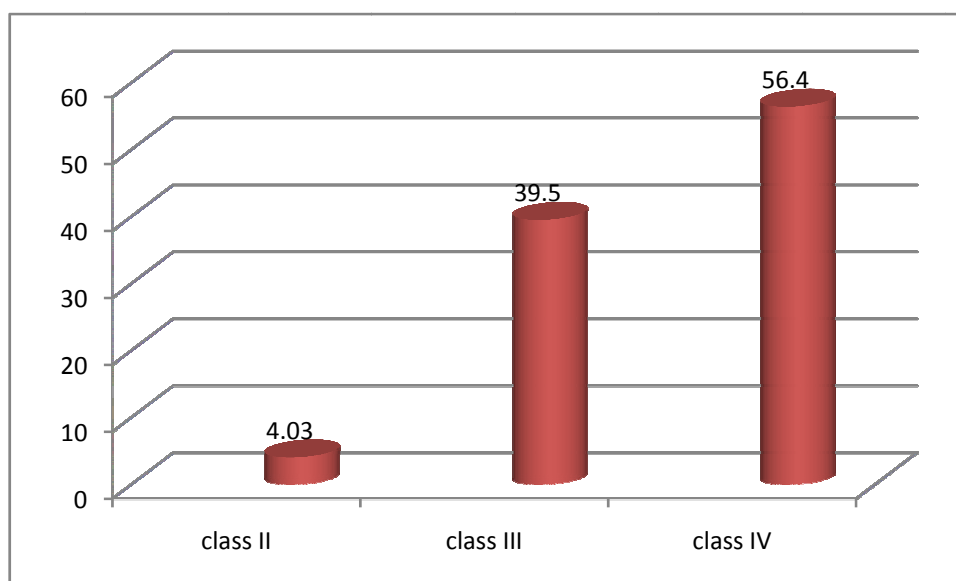
Table 5: Distribution of patients based on housing condition.

HOUSING CONDITION	FREQUENCY(n=248)	PERCENT
1. Type of the house		
Continuous	82	33.06
Separate	166	66.93
2. Nature of house		
Kutcha	17	6.85
Pucca	20	8.06
Kutcha-pucca	211	85.08
3. Cross ventilation		
Present	25	10.1
Absent	223	89.9
4. Kitchen		
Separate	76	30.64
Not-separate	172	69.35
5. Fuel used *		
LPG	92	37.09
Kerosene	3	1.2
Firewood	233	93.95
Biogas	0	0
6. Smoke vent		
Present	221	89.11
Absent	27	10.88

(* multiple answers were given)

85.08% of patients were living in kutcha- pucca house. Cross ventilation is absent in 89.9% of the families. Majority use firewood for cooking purpose (93.95%) and most of the family had smoke vent in their kitchen (89.11%).

B. Details regarding treatment:

Table 6: Distribution of patients based on time taken to approach the health care facility.

Duration	Frequency (n=248)	Percent
< 15 days	114	46.0
15-30 days	131	52.8
> 30 days	3	1.2
Total	248	100.0

Majority of the patients approached to the health facility after 2 weeks of appearance of symptoms like cough and fever 131(52.8%). 114 (46%) approached the health facility within 15 days of appearance of symptoms.

Table 7: Distribution of patients based on type of health care facility approached for initial treatment.

Health care facility	Frequency (n= 248)	Percent
Government	113	45.6
Private	135	54.4
Total	248	100.0

135 (54.4%) patients approached private health facility for initial treatment, where as 113 (45.6%) patients approached government set up for initial treatment. Those who approached private hospital had taken treatment for about 3-5 days. Because the symptoms did not subsided by the treatment, they were either sent or approached nearby government health facility (PHC or district tuberculosis center).

All the patients underwent 2 sputum examination before confirmation of diagnosis. All of them were receiving treatment according to RNTCP guidelines.

Table 8: Distribution of patients based on DOT agent.

DOT agent	Frequency (n=248)	Percent
Doctor	48	19.4
ASHA	142	57.3
Health Worker	32	12.9
Pharmacist	17	6.9
Relative	9	3.6
Total	248	100.0

In our study majority of the DOT agents were ASHA workers 142 (57.3%), followed by doctors 48 (19.4%), 32 (12.9%) health workers, 17 (6.9%) pharmacist and 9(3.6%) relatives.

Table 9: Distribution of patients based on the distance to DOT center.

Distance	Frequency (n=248)	Percent
≤1 km	217	87.5
1-3 km	31	12.5
Total	248	100.0

Among 248 patients, 217(87.5%) patients had their DOT center within the distance of 1 km. 31(12.5%) patients had to travel 1-3 km for collecting their medication. None of the patients had spent money for collecting drugs. 213 (85.88%) patients opined that their disease is 100% curable.

Table 10: Outcome during the treatment.

Outcome	Number (n=248)	Percent
Cured	203	81.85%
Deaths	19	7.66%
Treatment failure	12	4.83%
Default	14	5.64%

Cure rate in our study was 81.85%.19(7.66%) patients died during the course of treatment. 14(5.64%) patients defaulted from the treatment. 12 (4.83%) were treatment failure cases.

Graph 4: Outcome during the treatment.
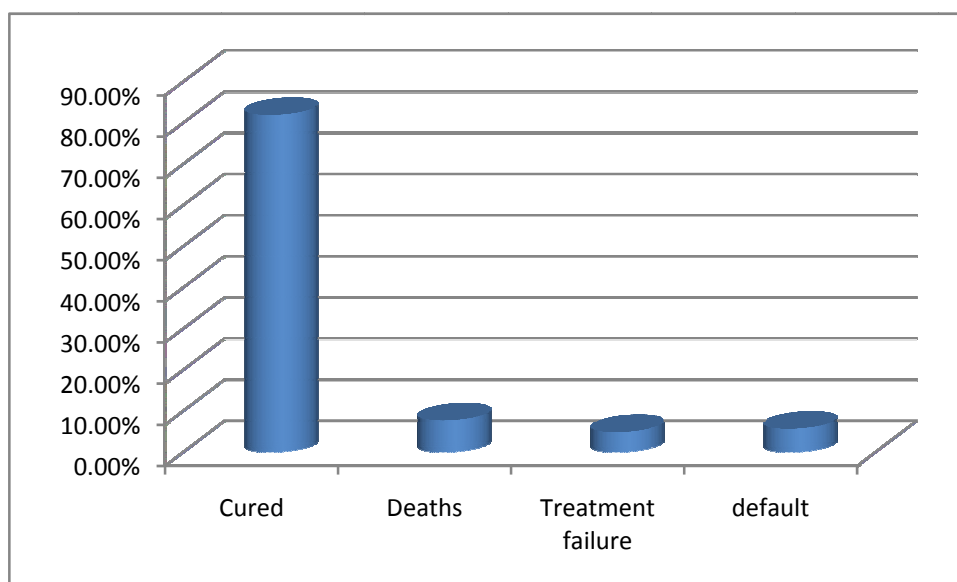
Table 11: Default rate according to gender

Sex	Male	Female
Default rate	10(71.42%)	4(28.58%)

Among the 14 defaulters 10 (71.42%) were male and 4 (28.58%) were female.

Graph 5: Sex- wise distribution of the defaulters.
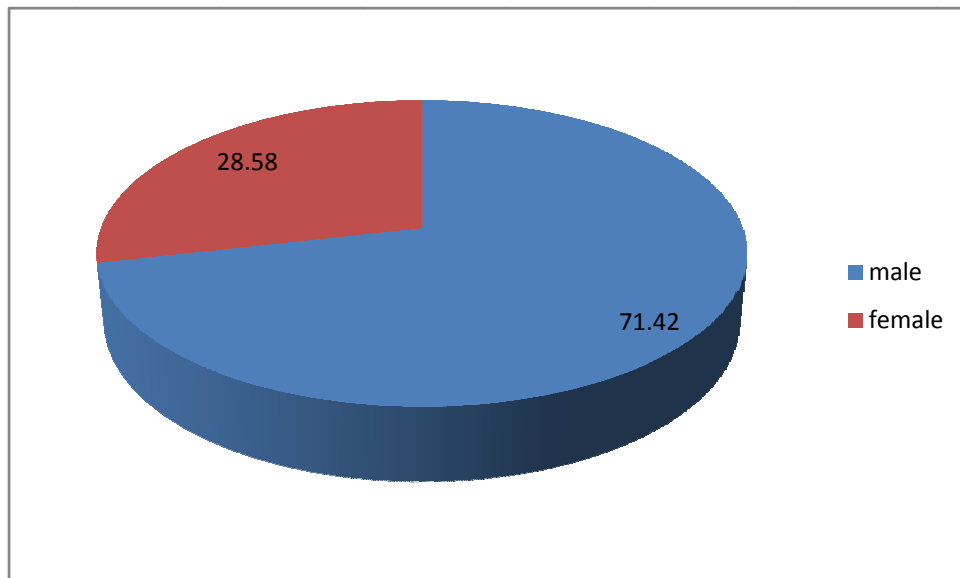
Table 12: Reasons for default.

Reason for default	Frequency (n=14)	Percentage
Relief from the symptoms	3	21.4%
Side effect of the drug	4	28.57%
Long duration of treatment	3	21.4%
Change of residence	4	28.57%

In our study following 4 reasons were given by the cases for default from the treatment. Those were mainly side effects of the drug and change of residence (28.57% each) followed by long duration of treatment and relief from symptoms (21.4% each).

Graph 6: Reasons for default
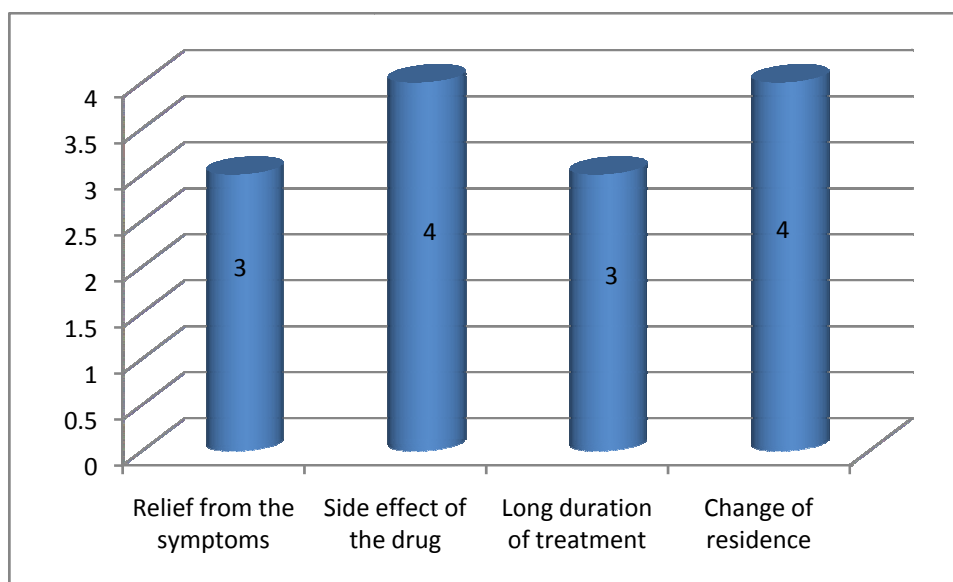
Table 13: Distribution of defaulters based on age group

Age group	Frequency(n=14)	Percentage
21-30 years	1	7.14%
31-40 years	3	21.42%
41-50 years	2	14.28%
51-60 years	4	28.57%
> 60 years	4	28.57%
Total	14	100%

In our study majority i.e 8 (57.14%) defaulters were aged more than 50 years. 5 (35.7%) were between the age group of 31-50 years.

Graph 7 : Distribution of defaulters based on age group
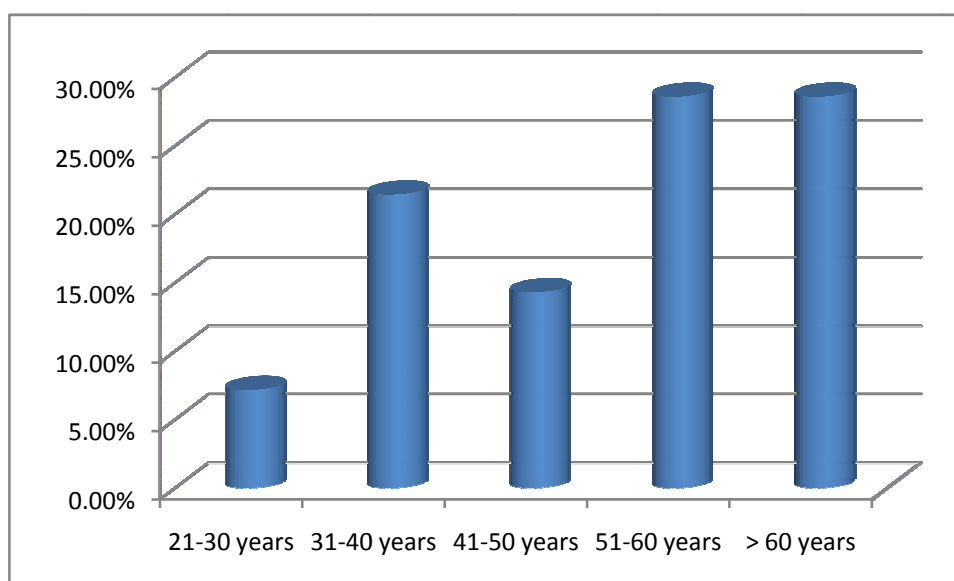
Table 14: Distribution of defaulters based on their occupation

Occupation	Frequency(n=14)	Percentage
Unskilled worker	7	50
Skilled worker	3	21.42
Unemployed	4	28.57

In our study maximum numbers of defaulters were unskilled workers (50%).

Graph 8 : Distribution of defaulters based on their occupation
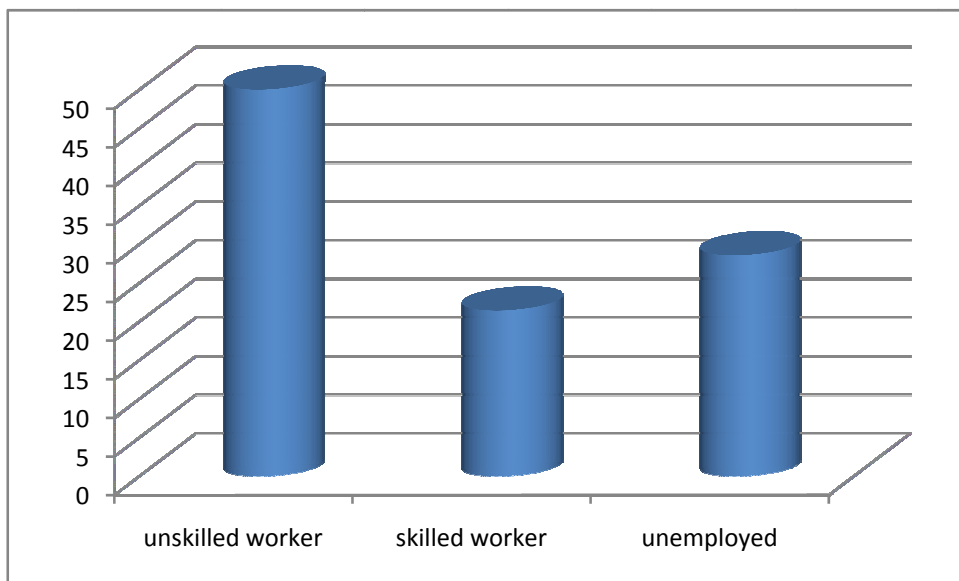
Table 15: Distribution of defaulters based on their education.

Education	Frequency(n= 14)	Percent
Illiterate	9	64.28
Primary school	4	28.57
Secondary school	1	7.14

In our study maximum numbers of defaulters were illiterate (64.28%).

Graph 9: Distribution of defaulters based on their education status
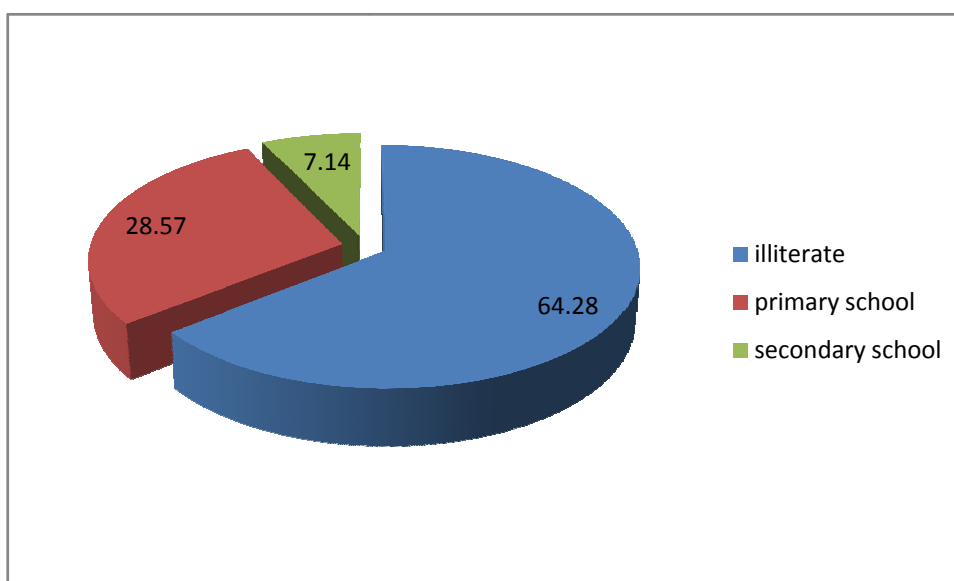
Table 16: Distribution of defaulters based on their socio- economic status

Socio-economic status	Frequency (n=14)	Percent
Class II	1	7.14
Class III	5	35.71
Class IV	8	57.14

In our study majority of defaulters 8 (57.14%) were belonging to class IV socio- economic class.

Graph 10: Distribution of defaulters based on their socio- economic status
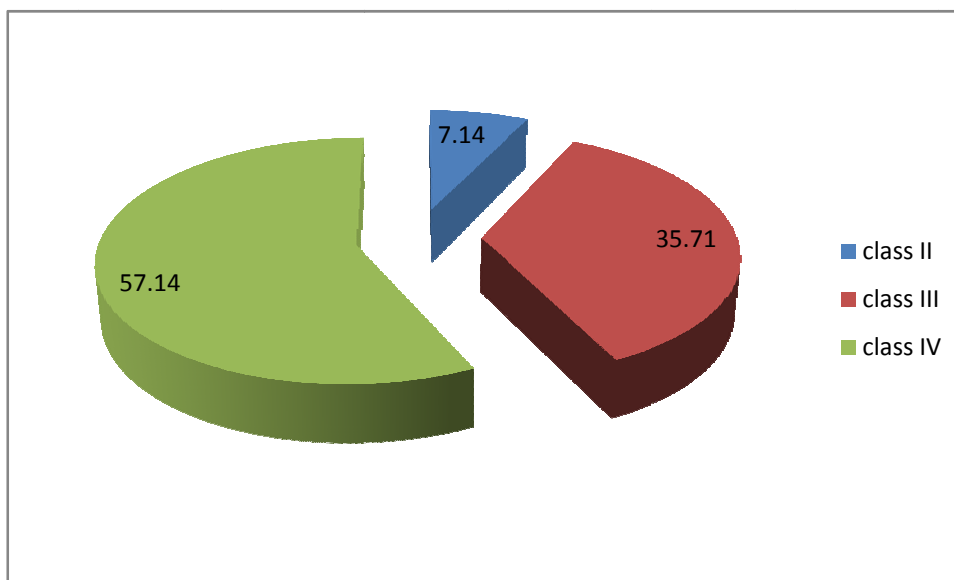
Table 17: Distribution of study group based on sputum conversion rate.

Sputum	After 2 months (n=236*)	After 3 months (n=231*)	After 5 months (n=219*)	After completion (n=215*)
Positive	43(18.22%)	26(11.25%)	12(5.47%)	12(5.6%)
Negative	193(81.78%)	205(88.75%)	207(94.53%)	203(94.39%)

(* number of study subjects was decreased over time either because of default or death.)

In our study sputum conversion rate at the end of 2 months was 81.78%, at the end of 3 months 88.75%, after 5 months it was 94.53% and after completion of treatment 94.39%. After completion of treatment 12(5.6%) patients were still sputum positive. These 12 were defined as failure cases and started on category II treatment.

Table 18: Relationship between cure rate and age group.

Age group	Frequency (n=248)	Cured	Percentage
<20 yeays	13	12	92.3
21-30 years	54	44	81.48
31-40 years	65	56	86.15
41-50 years	48	38	79.16
51-60 years	33	25	75.75
> 60 years	35	28	80
Total	248	203	81.85
χ^2 test for trend = 0.732 ; df = 1 ; p= 0.3922			

Cure rate was more among the patients < 20 years (92.3%) and it decreases as the age advances. This trend is found to be statistically insignificant.

Table 19: Relationship between education and cure rate.

Education	Frequency (n=248)	Cured	Percentage
Illiterate	118	93	78.81
Primary School	107	89	83.17
Secondary School	20	18	90
College	3	3	100
Total	248	203	81.85
χ^2 test for trend = 2.311; df = 1 ; p= 0.1285			

Cure rate was 100% among the patients who had education up to college level and it decreases as the education level decreases. However, there was no significant relationship found between education and cure rate.

Table 20: Relationship between occupation and cure rate.

Occupation	Frequency (n=248)	Cured	Percentage
Unskilled worker	136	114	83.82
Skilled worker	88	72	81.81
Unemployed	24	17	70.83
Total	248	203	81.85
$\chi 2 = 2.32$; df = 2; p=0.314			

Cure rate was highest among unskilled workers (82.94%) followed by skilled workers (78.94%). However, there was no significant relationship found between occupation and cure rate.

Table 21: Relationship between socio-economic status and cure rate.

SOCIO-ECONOMIC STATUS	FREQUENCY (n=248)	Cured	Percentage
Class II	10	8	80
Class III	98	77	78.57
Class IV	140	118	84.28
Total	248	203	81.85
$\chi 2 = 1.29$; df = 2; p=0.524			

Cure rate was more among the patients who belonged to class IV socio-economic status. But this association was not statistically significant.

DISCUSSION

A follow up study was conducted in Bijapur taluk from November 1st 2011-June 30th 2013. A total of 248 new sputum positive pulmonary tuberculosis cases were included in the study. Each case was examined and interviewed after 1st month, 3rd month, 6th month and 8th month of the treatment. The objective was to study the socio- demographic profile of newly detected sputum positive pulmonary tuberculosis cases and to document its role in completing the schedule of treatment.

A. Socio- demographic profile:

1. **Age**

   In our study majority of the patients belonged to economically productive age group of 21- 50 years (67.34%). This is comparable to study done by S Bawri et al (74%)[38] and is more compared to study done by Srivastav Shalini et al (43.18%)[43] and a study by KasiSrinivas et al (60%).[70]

2. **Gender**

   In our study majority of the patients were male (66.5%) and females were 33.5%.This finding is similar to studies done by Moharana PR et al in Orisssa where 65% were male [40], by Donald Christian et al in Gujrat where 68% were male[44] and a study done by tuberculosis research unit in Thiruvallur district where 75% were male.[36]

3. **Literacy**

   In our study majority of the patients were illiterate (47.5%). Illiteracy level is higher compared to national average as per 2011 census (25.96%)[71],

DLHS- 3 data for Karnataka state (27.8%)[72] and 2011census statistics for Bijapur District (32.85%).[71] Illiteracy level is high as compared to study done in Orissa by Moharana et al (35%)[40] and a study done by tuberculosis research center (40%).[36]

4. **Religion**

In our study 85.1% of patients belong to Hindu religion and 14.9 % of patients follow Muslim religion. This is comparable to study by Yadav et al where 70.7% were Hindus and 29.3% were other than Hindus.[73]

5. **Occupation**

In our study majority were unskilled workers (54.8%). 9.67% were unemployed. Proportion of unemployment in our study is less compared to studies done by M. Muniyandi et al (21%)[74] and Bawankule S et al (18.9%)[75], where as it is higher compared to study done by N. Pandit (2.7%).[37]

6. **Type of the family**

In the present study 41.9% were from nuclear family followed by joint family (58.1%). Similar results were seen in the study by Bawankule S et al wherein 58.5% belonged to nuclear family and 41.5% belonged to joint family.[75]

7. **Socio- economic status**

In our study majority of the patients belonged to class IV socio- economic status (56.4%), 39.5% to class III and 4.03% to class II socio- economic status. This is similar to study done by Bhattacharya Krishnadas et al. where 49.2% of the patients were from class IV SES followed by 25%

from class III and 10.8% from class II.[76] A study done in Gwalior showed 27.5% were belonging to class IV socioeconomic status.[39]

In this study none of the respondents were from class V socio-economic status. This may be due to the fact that unskilled laborers are paid more than Rs 200 a day.

B. Treatment :

1. Approach to health care facility

52.8% patients approached health facility after 2 weeks of appearance of symptoms. This reflects the indifferent attitude of patients towards their own health.

2. Distance to DOT center

Among 248 patients, 217(87.5%) patients had their DOT center within the distance of 1 km. 12.5% had to travel 1-3 km for collecting their medication. Accessibility to treatment was better in our study as compared to study done by Shalini Srivastav where 48.18% had to cover almost 2-3 km to avail the treatment facility and 15.45% patients had to cover > 3 km to reach the center.[43] Another study done by Sophia Vijay et al in Bangalore also showed that the patients had to travel a distance ranging from 1 km to 19 kms to reach the treatment centre.[77]

3. Outcome of the treatment

Cure rate in our study was 81.85% which is less as compared to RNTCP norms which is > 85%.[1] Cure rate is less compared to a study done by KasiSrinivas et al (91.11%)[70] and a study done by R. Prasad et al (89.5%).[78]

Default rate in our study was 5.83% which is slightly higher than what is expected under RNTCP i.e. < 5%.[79] Default rate is less compared to study done by Chhayya Mittal et al (15.1%)[5], a study by N. Pandit et al (6.93%)[37] and a study by V. Chandrasekaran et al (15%).[6]

The failure rate in our study was 4.83% which exceeds the expected rate under RNTCP i.e. 4%.[79] The failure rate is higher as compared to study done by SL Chadha et al (1.6%)[80], Study by RKS Chaudhari et al (3.3%)[81] and less compared to a study by Sanjay Rajpal et al (8.8%).[82] (Failure rate was calculated by considering total number of cases at the beginning of the study and not at the end of study.)

Crude death rate in our study was 7.66% which is higher compared to a study done by KasiSrinivas et al (4.4%)[70] and a study by Chhayya Mittal et al (5.9%).[5]

4. Reasons for default

The 4 main reasons given by the defaulters in our study were side effects of the drug and change of residence (28.57% each) followed by long duration of treatment and relief from symptoms (21.4% each). In a study done by N. Pandit et al main reasons for default were toxicity of drugs (63.2%) and feeling better during treatment (15.8%).[37] A study by moharana et al shows that default was due to side effects of drugs (37.5%), early relief of symptoms (25%).[40] Reasons found in study done by Jaggarajamma et al were side effects of drugs (42%), migration (29%), relief from symptoms (20%).[4] Another study done by Jasmin Johnson showed main reasons for default were travel to

a different place (42.2%), relieved from symptoms (26.6%) and adverse effects of drugs (26.6%).[46]

5. Characteristics of the defaulters

In our study majority of defaulters were aged more than 50 years (57.14%). 35.7% were between the age group of 31-50 years. According to Sweta Gupta et al 57% of treatment interrupts were in the age group of 25-44 years.[49] Kumar et al observed maximum defaulters in 35-44 year age group (25.4%), followed by patients aged above 45 years (18.1%) in their study.[83]

Among the 14 defaulters 10 (71.42%) were male and 4 (28.58%) were female. Reports by Chandrashekaran et al also showed higher incidence of default in males (13.8%) in comparison to females (5%).[6]

It was found that majority of defaulters were illiterate (64.28%). In the study conducted by Chandrashekaran et al the default rate among illiterate is more (12.7%) when compared to the literate (7.9%).

We observed that majority of defaulters belonged to class IV socio- economic class (57.14%). This may be because for them other responsibilities like earning bread, solving family problems, social problems become more important once their symptoms are relieved or lack of knowledge about the importance of completion of treatment.

6. Sputum conversion

In our study sputum conversion at the end of 2 months was 81.78%. This finding is higher as compared to the study by RKS Chaudhari et al (64.4%).[81]

It is comparable to findings in a study done by Ruohonen et al (82.8%)[84] and study by Kumaresan et al (85%).[83]

Sputum conversion at the end of 3 months was 88.75% which is comparable to studies done by Sanjay Rajpal et al (91.2%)[82] and a study by Ruohonen et al (91.1%).[84]

And sputum conversion at the end of 5 months was 94.53% which is higher as compared to the study by RKS Chaudhuri et al (86.44%).[81]

7. Characteristics of cured patients

In our study cure rate was more among the patients <20 years (92.3%). This may be because of the better supervision by their parents.

Cure rate was 100% among the patients who had education up to college level and it decreases as the education level decreases. This may be because of the better knowledge and positive attitude towards treatment among literate patients.

However we did not find any statistical association between age, education, occupation, socio-economic status with cure rate.

CONCLUSION

From our study we can conclude that tuberculosis is a social disease which mainly affects the economically productive age group and lower socio- economic status people.

Even though accessibility to DOT center was better in our study cure rate was less than the RNTCP norm of 85%. This can be attributed to high default rate. The main reasons for default were change of residence and side effect of the drug. These problems can be tackled by better health education to patients and better communication in case of transfer out and transfer in of the patients.

High failure rate in our study may be due to resistance to the drugs. In depth research is needed to identify reasons for high failure rate.

SUMMARY

The study was conducted in Bijapur Taluk, Karnataka state from 1st December 2011- 30th June 2013. A total of 248 new sputum smear positive tuberculosis cases were interviewed regarding their soci-demographic profile and treatment. The highlights of this study are as follows.

SOCIO- DEMOGRAPHIC PROFILE:

- Majority of the patients belonged to economically productive age group of 21-50 years (67.34%).

- Majority of the patients were male (66.5%).

- Majority of the patients were illiterate (47.5%).

- 85.1% of patients belong to Hindu religion.

- Majority (54.8%) were unskilled worker.

- Majority of the patients belonged to class IV socio- economic status (56.4%).

DETAILS ABOUT ANTI- TUBERCULAR TREATMENT:

- Majority (52.8%) of patients approached health facility after 2 weeks of appearance of symptoms.

- Majority (54.4%) approached private health facility for initial treatment.

- Majority (57.3%) of the DOT agents were ASHA workers.

- Majority (87.5%) had their DOT center within the distance of 1 km.

- Cure rate was 81.85%, default rate was 5.64%, failure rate was 4.83% and death rate was 7.66%.

- Main reasons for default were side effects of the drug and change of residence (28.57%).

- Majority of defaulters were aged more than 50 years, unskilled workers, illiterate and belonged to class IV socio- economic class.

- Sputum conversion at the end of 2 months was 81.78% , 88.75% at the end of 3 months, 94.53% at the end of 5 months and 94.39% after completion of treatment.

- None of the patient had spent money to collect drugs.

- Cure rate decreases as the age advances and as the level of education decreases. However this association was not statistically significant.

LIMITATIONS OF THE STUDY

A. Details about the various side effects of the drugs should have been collected from the each patient.

B. Details about the health education to patients regarding the importance of adherence to the treatment schedule and steps taken by DOT agents whenever cases have defaulted to collect drugs or complained of side effects due to drugs should have been collected.

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PROFORMA

A FOLLOW UP STUDY ON NEWLY DETECTED SPUTUM POSITIVE PULMONARY TUBERCULOSIS CASES ON ANTI TUBERCULAR TREATMENT IN BIJAPUR TALUK

GENERAL INFORMATION

1) NAME –

2) AGE-

3) SEX- male/ female

4) OCCUPATION-

5) RELIGION-

6) ADDRESS

7) EDUCATION-

8) TYPE OF FAMILY - nuclear/ joint/ three generation.

9) NUMBER OF FAMILY MEMBERS-

Children

Adult

10) ANNUAL INCOME-   PER CAPITA INCOME-

11) SOCIO-ECONOMIC CLASS

HOUSING -

12) Kutcha/ Pucca/ Kutcha-Pucca.

13) Continuous/ Separate

14) NO. OF LIVING ROOMS-

15) CROSS VENTILATION- present/ absent.

16) KITCHEN- separate/ not- separate.

17) FUEL USED- LPG/ Kerosene/ Firewood/ Biogas

18) SMOKE VENT-present/ absent.

1. History of chief complaints-

2. Time interval between onset of symptom and procuring health care advice-

3. Source of health care delivery- govt/ private

4. Investigations done-

   a. Blood-

   b. Urine-

   c. Sputum- Y/N

5. Treatment received

   a. Drug-

   b. Dose-

   c. Duration-

6. Expenses incurred-

7. Outcome of treatment- improved/ not improved

8. Time interval between onset of symptoms and registering in DTC-

9. Date of registration at DTC-

10. Investigations done in DTC

    a. Blood-

    b. Sputum-

    c. X-ray- Y/N

11. Sputum

    a. Number of samples collected-

    b. Time of collection-

12. Treatment given

    • Drug-

    • Dose-

    • Duration-

13. Who is your DOT agent?-

14. What are his functions-

15. From where you collect the drugs?-

16. What is the distance between your place and source of availability of drug-

17. How often you collect drugs in a month?-

18. What difficulty you have experienced in procuring the drug?-

19. On an average how much money you spend to go and collect the drug?-

20. Are you taking treatment regularly- Y/N

21. If no reasons-

    a. Side effect of drugs.

    b. Relief from symptoms

    c. Drug centre is too far.

    d. Travel is expensive.

    e. Non-availability of drugs when visited.

    f. No faith in treatment.

    g. Change of residence.

    h. Long duration of treatment.

22. What is your opinion about prognosis- 100% curable/ non curable

2nd visit:

    1. Are you taking treatment regularly- Y/N

    2. If no reasons-

- Side effect of drugs.

- Relief from symptoms

- Drug centre is too far.

- Travel is expensive.

- Non-availability of drugs when visited.

- No faith in treatment.

- Change of residence.

- Long duration of treatment.

    3. How many times sputum examination repeated-

    In which month of treatment-

4. Treatment given

- Drug-

- Dose-

- Duration-

3rd visit:

1. Have you completed the treatment?- Y/N.

2. When sputum examination is repeated?

4rth visit

Any problem related to disease or treatment?

ANNEXURE - II

ETHICAL CLEARANCE CERTIFICATE

B.L.D.E. UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103
INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on ___20-10-2011___ at ___10-30 am___ to scrutinize the Synopsis/Research projects of postgraduate/undergraduate student/Faculty members of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis/Research project has been accorded Ethical Clearance.

Title ___A follow up study on newly detected sputum positive pulmonary tuberculosis cases on anti tuberculas treatment in Bijapur taluk___

Name of P.G./U.G. student/Faculty member ___Dr Sowmya Bhat___
___Dept of community medicine___

Name of Guide/Co-investigator Dr. ___M.M.Angadi, prost & HoD. Com-Medicine___

DR.M.S.BIRADAR,
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEU'S, SHRI.B.M.PATIL
MEDICAL COLLEGE, BIJAPUR.
Chairman
Ethical Committee
BLDEA'S Shri. B.M. Patil
Madical College
Bijapur-586103

<u>Following documents were placed before E.C. for Scrutinization</u>
1) Copy of Synopsis/Research project.
2) Copy of informed consent form
3) Any other relevant documents.

83

ANNEXURE - III

SOCIO-ECONOMIC CLASSIFICATION

Updated B.G.Prasad's socio-economic classification 2012.

Consumer price index for the year 2012 was 969.

Multiplication factor = $\dfrac{\text{Mean CPI for 2012 x 4.93}}{100}$

$$= \frac{969 \times 4.93}{100} = 47.77$$

SOCIO-ECONOMIC CLASS	B.G.Prasad's classification 1961	Updated B.G.Prasad's classification 2012
Class I	>100	>4800
Class II	50-99	2400- 4799
Class III	30-49	1440-2399
Class IV	15-29	720- 1399
Class V	<15	<720

ANNEXURE – IV

MAP OF SELECTED PHC's

PHC's which reported <10 cases/year

PHC's which reported10-20 cases/year

PHC's which reported >20 cases/year
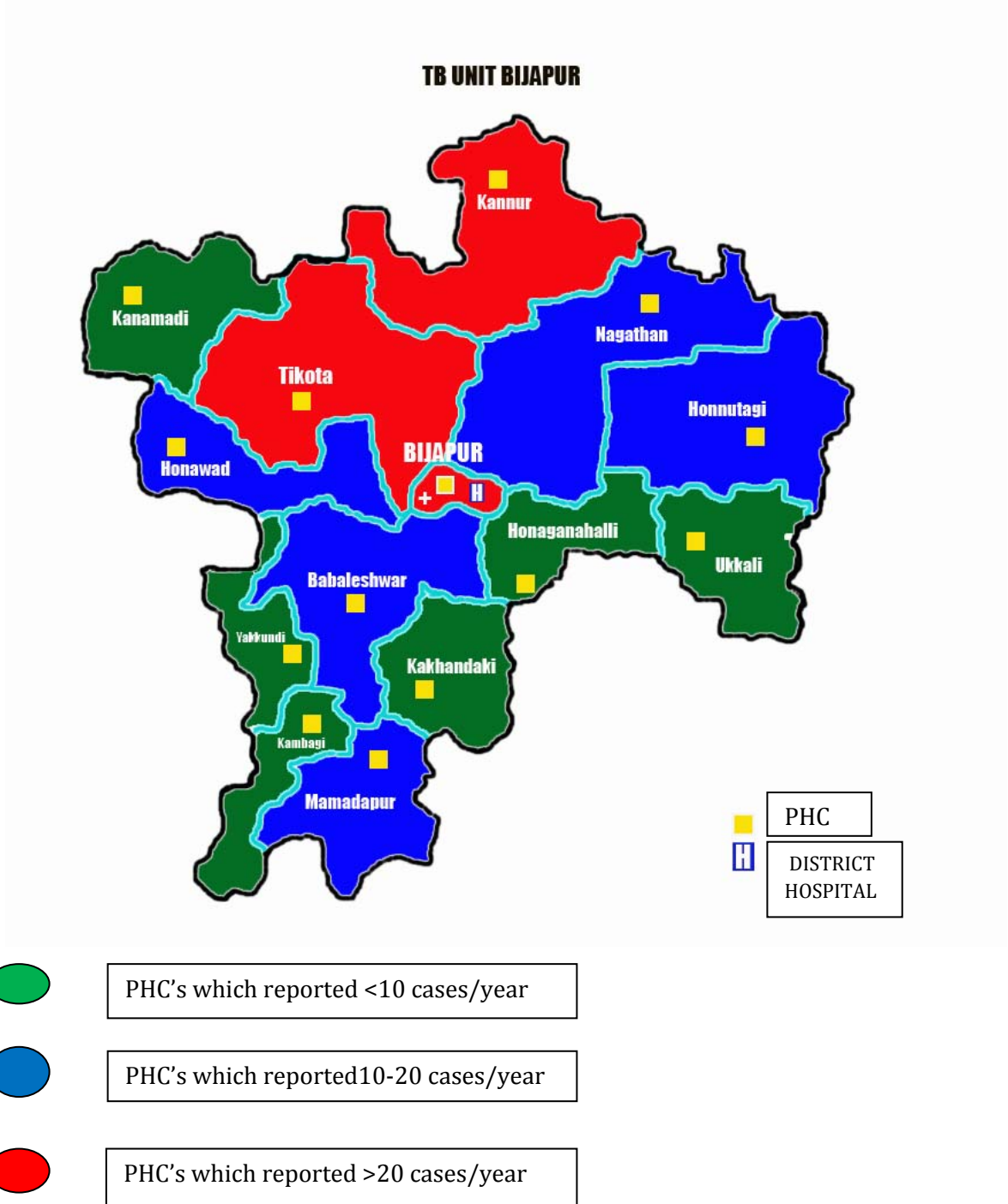
ANNEXURE - V

GANTT CHART - TIMELINE OF ACTIVITIES

ACTIVITY	2011							2012												2013								
	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
TOPIC SELECTION	■	■																										
SYNOPSIS PREPARATION & SUBMISSION			■	■																								
REVIEW OF LITERATURE					■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
PREPARATION OF PROFORMA					■																							
PILOT STUDY					■																							
ANALYSIS & INSTRUMENT MODIFICATION					■																							
DATA COLLECTION						■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■			
DATA ANALYSIS																										■	■	
DISSERTATION WRITING AND SUBMISSION																											■	■

ANNEXURE-VI

Photo graph showing interview with the patient

Photo graph showing the housing condition