ORIGINAL ARTICLE

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July 2020 | Vol. 1 Issue.2
www.uijir.com

EFFECTIVENESS OF DIRECTLY OBSERVED THERAPY AND TO COMPARE WITH SELF ADMINISTERED THERAPY IN PATIENTS WITH TUBERCULOSIS

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Abstract *Tuberculosis (TB) remains the major cause of morbidity and mortality in India and affects largely the most productive members of the society. The major concern is increasing number of TB cases due to inadequate and improper treatment of primary and post primary TB cases.*
Extend of Awareness of Tuberculosis, Directly Observed Treatment (DOT) in Rural Community. A cross sectional study on 96 patients with stroke aged more than 25 years was carried out Village-Janakpur, Block & The.-Bharatpur, District-Korea, State-Chhattisgarh for a period of 4 months from (1st August 2018 to 30th November 2018) The statistical analysis were performed by using Microsoft Excel and SPSS version 22 respectively. Observe mean, standard deviation and mean percentage of knowledge interview were and respectively.
The score of patients there was significant difference seen in quality of life score according to sex, socioeconomic status, occupation, statistically significant difference in quality of life score was not seen with respect to age, locality, religion, marital status, type of family, educational status, occupation, alcohol intake, smoking, diet.In this study the aspects like knowledge of TB patients as well as their family members so that need based information can be provided and get them motivated to get their patient treated in the hospital. The findings of the study showed that majority of the samples had Inadequate, had moderate adequate and only had adequate knowledge.DOTS program will continue to be effective in treating TB, and with some improvements will allow more positive outcomes to occur. TB impacts whole communities, and its treatment. Patients treated by Directly Observed Therapy (DOT) have excellent cure rates with lesser default rates.

Keywords *Tuberculosis, DOT, HIV/AIDS*

INTRODUCTION

Tuberculosis (TB) is an infectious disease usually caused by Mycobacterium Tuberculosis (MTB) bacteria tuberculosis generally affects the lungs, but can also affect other parts of the body. Most infections do not have symptoms, in which case it is known as latent tuberculosis. About 10% of latent infections progress to active disease which, if left untreated, kills about half of those infected. The classic symptoms of active TB are a chronic cough with blood-containing sputum, fever, night sweats, and weight loss. It was historically called "consumption" due to the weight loss.Infection of other organs can cause a wide range of symptoms. Tuberculosis is spread through the air when people who have active TB in their lungs cough, spit, speak, or sneeze. People with latent TB do not spread the disease. Active infection occurs more often in people with HIV/AIDS and in those who smoke.

According to the World Health Organization (WHO), one–third of the world's population is currently infected with the tuberculosis bacillus (WHO Fact sheet No. 104 Revised March 2007). World Health Organization estimates that 9.27 million new cases of tuberculosis occurred in 2007 (139/100,000 population) compared with 9.24 million new cases (140/100,000 population) in 2006 (WHO/HTM/TB/2006.362). Of these 9.27 million new cases, 44% or 4.1 million (61/100,000 population) were smear-positive cases. India, China, Indonesia Nigeria and South Africa rank first to fifth in terms of the total number of incident cases. The report further states that of the 15 countries with the highest estimated tuberculosis incidence rates remains

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July 2020 | Vol. 1 Issue.2
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the most common opportunistic infection and leading cause of death in people living with Human Immunodeficiency Virus (HIV) in low and middle income countries (Joint United Nations Program on HIV/AIDS (UNAIDS). In 2007,

Presently, one-quarter of the world's population is thought to be infected with TB. New infections occur in about 1% of the population each year. In 2016, there were more than 10 million cases of active TB which resulted in 1.3 million deaths. This makes it the number one cause of death from an infectious disease. More than 95% of deaths occurred in developing countries and more than 50% in India, China, Indonesia, Pakistan, and the Philippines. The number of new cases each year has decreased since 2000. About 80% of people in many Asian and African countries test positive while 5–10% of people in the United States population test positive by the tuberculin test. Tuberculosis has been present in humans since ancient times.

AIMS & OBJECTIVES

Extend of Awareness of Tuberculosis, Directly Observed Treatment (DOT) in Rural Community.

REVIEW OF LITERATURE

Tuberculosis

Tuberculosis (TB) is caused by bacteria (Mycobacterium tuberculosis) that most often affect the lungs. Tuberculosis is curable and preventable. Tuberculosis (TB) is an infectious disease usually caused by bacteria tuberculosis generally affects the lungs, but can also affect other parts of the body. Most infections do not have symptoms, in which case it is known as latent tuberculosis. About 10% of latent infections progress to active disease which, if left untreated, kills about half of those infected. The classic symptoms of active TB are a chronic cough with blood-containing sputum, fever, night sweats, and weight loss. It was historically called "consumption" due to the weight loss. Infection of other organs can cause a wide range of symptoms. Tuberculosis is spread through the air when people who have active TB in their lungs cough, spit, speak, or sneeze. People with latent TB do not spread the disease. Active infection occurs more often in people with HIV/AIDS and in those who smoke.

Directly Observed Treatment (DOTS)

Directly Observed Treatment, short-course (**DOTS**, also known as **TB-DOTS**) is the name given to the tuberculosis (TB) control strategy recommended by the World Health Organization. According to World Health Organization "The most cost-effective way to stop the spread of TB in communities with a high incidence is by curing it. The best curative method for TB is known as DOTS."

DOTS HAVE FIVE MAIN COMPONENTS

1. Government commitment (including political will at all levels, and establishment of a centralized and prioritized system of TB monitoring, recording and training)
2. Case detection by sputum smears microscopy.
3. Standardized treatment regimen directly of six to nine months observed by a healthcare worker or community health worker for at least the first two months.
4. Drug supply
5. A standardized recording and reporting system that allows assessment of treatment results.

ROLE OF NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS IN TB CONTROL

The National Institute for Research in Tuberculosis (NIRT), Chennai, is a permanent institute of the Indian Council of Medical Research (ICMR). NIRT's research agenda has always been geared to the felt needs of the programme. Since its inception in 1956, NIRT undertook landmark research in several areas including the effectiveness of domiciliary treatment for TB, the need

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July 2020 | Vol. 1 Issue.2
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for supervising treatment, the efficacy of intermittent short-course chemotherapy regimens, and the protective efficacy of BCG vaccine. Over the years, NIRT has gained a wealth of experience in research and earned credibility for its scientific rigor. It has a well-trained and multidisciplinary team consisting of clinicians, epidemiologists, microbiologists, immunologists, statisticians, social scientists and other paramedical workers.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAM (RNTCP)

Revised National Tuberculosis Control Program (**RNTCP**) is the state-run tuberculosis (TB) control initiative of the Government of India. As per the National Strategic Plan 2012–17, the program has a vision of achieving a "TB free India", and aims to achieve Universal Access to TB control services. The program provides, various free of cost, quality tuberculosis diagnosis and treatment services across the country through the government health system. It seeks to employ the WHO recommended tuberculosis control strategy, DOTS(Directly Observed Treatment, Short Course), to the Indian scenario.

The Control of tuberculosis (TB) in India has come a long way since the initiation of the National TB Programme (NTP) in 1962. Despite the establishment of more than 440 District TB Centers, the NTP suffered from several serious drawbacks including managerial weaknesses, inadequate funding, over reliance on chest radiographs, lack of standardized treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes. The cure rate was dismally low-only 30% of all patients were diagnosed whom of only 30% were treated successfully. This prompted the Government of India, in collaboration with the World Health Organization (WHO) to evolve a revised strategy for the control of tuberculosis in India. The Revised National TB Control Programme (RNTCP), an application of the WHO recommended Directly Observed Treatment, Short Course (DOTS) strategy was launched in 1992 with the objective of detecting at least 70% of new sputum positive TB patients and curing at least 85% of such patients.

THE BASIC PRINCIPLES OF RNTCP

1. Political commitment for ensuring adequate funds, staff and other key inputs.
2. Establishment of diagnosis primarily by microscopic examination of specimens obtained from patients presenting to health care facilities.
3. Regular and uninterrupted supply of anti-TB drugs in the form of a patient-specific box that contains the medicines for the entire course of treatment so that no patient is subjected to interruption of treatment for lack of medicines.
4. Direct observation of every dose of treatment in the intensive phase and of at least the first dose in the continuation phase of treatment.
5. Systematic monitoring, supervision and cohort analysis-one Senior Treatment Laboratory Supervisor (STLS) is responsible for organization of uninterrupted treatment and one Senior Tuberculosis Laboratory Supervisor for ensuring quality laboratory service for every 5,00,000 population.

DIAGNOSIS OF PULMONARY TB UNDER RNTCP

Diagnosis is made primarily based on sputum smear examination. X-rays play a secondary role in the standard diagnostic algorithm for pulmonary tuberculosis

Sputum smear microscopy, using the Ziehl-Neelsen staining technique, is employed as the standard case-finding tool. Two sputum samples are collected over two days (as spot-morning/morning-spot) from chest symptomatic (patients with presenting with a history of cough for two weeks or more) to arrive at a diagnosis. In addition to the test's high specificity, the use of two samples ensures that the diagnostic procedure has a high (>99%)

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July 2020 | Vol. 1 Issue.2
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test sensitivity as well As a national health program, RNTCP pays more attention to the sputum-positive pulmonary tuberculosis patients (who are likely to spread the disease in the community) than people with other, non-pulmonary forms of the disease.

TREATMENT CATEGORIES AND DRUG REGIMENS

Based on results from a recent study, RNTCP has issued guidelines to states on daily treatment for tuberculosis. The daily regimen will replace the existing alternate day (thrice weekly) regimen from January - February 2016 in selected states. The daily regimen has shown to be effective in reducing relapse rates and drug-resistance. Standardized treatment regimens are one of the pillars of the DOTS strategy. **Isoniazid**, **Rifampicin**, **Pyrazinamide**, **Ethambutol**, and **Streptomycin** are the primary anti tubercular drugs used. Most DOTS regimens have thrice-weekly schedules and typically last for six to nine months, with an initial intensive phase and a continuation phase. Based on the nature/severity of the disease and the patient's exposure to previous anti-tubercular treatments, RNTCP classifies tuberculosis patients into two treatment categories.

MATERIALS AND METHODOLOGY

Material and methods will be discussed under following headings.-

1. Sampling Area
2. Type of Study
3. Study Period
4. Study Population
5. Sampling methods
6. Method of Collection of Data
7. Statistical Analysis
8. Study Variables

SAMPLING AREA

Village – Janakpur, Block &Teh. – Bharatpur, District – Korea, State – Chhattisgarh

- **Village** – Janakpur is not more developed area and here mostly many people are un-educated. Who are not aware about health and TB and Associated with HIV/AIDS.
- **Distance** – About 145KM away from the District Headquarters Baikunthpur, Korea, and about 100KM away from the City Manendragarh, Korea, Chhattisgarh.

TYPE OF STUDY

Community based cross sectional study.

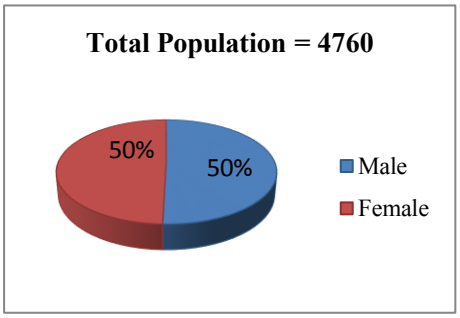
STUDY PERIOD

The total duration of research conduction is **Four Months (1st August 2018 to 30th November 2018)**

STUDY POPULATION

All Tuberculosis Patients who were registered at theCommunityHealth Centre (CHC),Janakpur, during the above mentioned study period.

Population of this area – Approximately, Male – 2401 & Female – 2359, Total = 4760



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July 2020 | Vol. 1 Issue.2
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SAMPLING METHODS

- **Inclusion Criteria**

1) Tuberculosis patients aged 25 years and above.
2) Duration of TB more than 2 months. (Time since diagnosis and initiation of treatment)

- **Exclusion criteria**

1) Patients with severely ill and not able to communicate. Who didn't participation in the study.

The total sample size is **96 peoples.**

(I can't mention the name of those who participates in this program)

- 73 peoples who have suffer from TB
- 19 peoples who have suffer from TB an Associated with HIV/AIDS
- 04 peoples who have suffer from HIV/AIDS

METHOD OF COLLECTION OF DATA

Prior informed written consent in the local language was taken from all the patients included in the study. For those who were illiterates, the consent was read out and explained to them in their language and consent was obtained by taking their signature in the consent form. All patients under the study were personally interviewed and administered the questionnaire.

The study tool consisted of following sections:-

A. **Socio-Demographic Profile** - this section consists of socio demographic characteristics and the variables that were included were age, sex, locality, religion, education, occupation, side of lesion, types of cases, marital status, types of family, blood pressure, alcoholism, smoking, diet and socio economic status scale.
B. **Quality of Life** - The facets were originally subsumed within one of six domains but factor analysis of the indicated that Domain 1 could be merged with Domain 3 (physical with independence), and Domain 2 with Domain 6 (psychological with spirituality, religion and personal beliefs) Similar results were found during the extraction of data for the currently scored in four Domains:- Physical health, Psychological, Social relations, Environment,

STATISTICAL ANALYSIS

Mean and standard deviation of the QOL scores are calculated for each of the socio-demographic variable and compared by Suitable statistical test like **t-test/ANOVA** are applied. Finally, the minimum, maximum and mean score are calculated as on overall domain score for the each four domain i.e. physical domain, psychological domain, social relationship domain and environment domain.

STUDY VARIABLES

a. Age:

We have arbitrarily classified age into <25 years, 25 to 65 years and more than 66 years.

b. Sex:

We have classified into Male and Female.

c. Educational Status

- **No Education:** The person who cannot read and write with understanding in any language.
- **Schooling:** The person who can read in any school level i.e.
  - **Primary School:** - A person who has studied in any class between 1st to 5th standard.
  - **Middle School:** - A person who has studied anywhere between 6th and 8th standard.

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July 2020 | Vol. 1 Issue.2
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- **High School:** - The person who has studied 9th and 10th passed.
- **Intermediate:** - The person who has studied 11th and 12th passed.
- **Graduate:** - The person who has done a degree or diploma course.
- **Post Graduate:** - The person who has done a post graduate degree course.

d. Type of Family:

- **Nuclear Family: -** Married couple and their children, while they are still regarded as dependents.
- **Joint Family:** - It consists of a number of married couples and their children who live together in the same household. All the men are related by blood and the women of the household are their wives, unmarried girls and widows of the family kinsmen.
- **Three Generation Family:** - It is a household where there are representatives of three generations, related to each other by direct descent. It occurs usually when young couples are unable to find separate housing accommodation and continue to live with their parents and have their own children.

OBSERVATION AND RESULTS

Calculation of percentage -

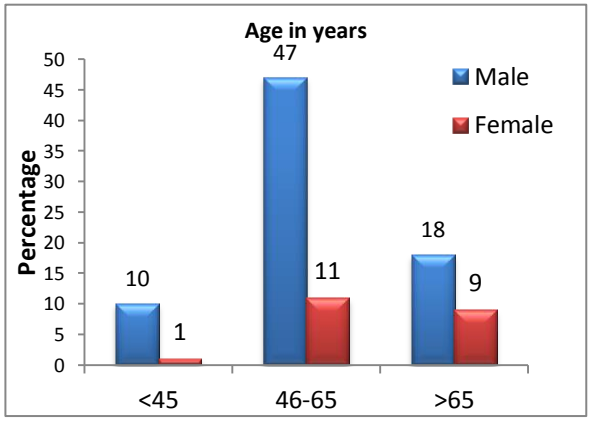
- Total percentage = No. of patients / total Sample Size X 100

SOCIO-DEMOGRAPHIC PROFILE OF STUDY SUBJECTS

Table – 1 Distribution of study subjects according to Age and Sex

Sex	Age in years			Total
	45 years or less	46 to 65 years	66 years or more	
Male	10 (10.41%)	47 (48.95%)	18 (18.75%)	75 (78.12%)
Female	1 (1.04%)	11 (11.45%)	9 (9.37%)	21(21.87%)
Total	11 (11.5%)	58 (60.4%)	27(28.1%)	96 (100%)

Figure – 1Distribution of study subjects according to Age and Sex



Religion	Number	Percentage
Hindu	83	86.5
Muslim	13	13.5
Total	96	100.0

It is observed that, 47 TB patients (48.95%) were in the age group of 46 to 65 years (males) and11 TB patients (11.45%) were females in the same age group.

Table - 2 Distribution of study subjects according to their Religion

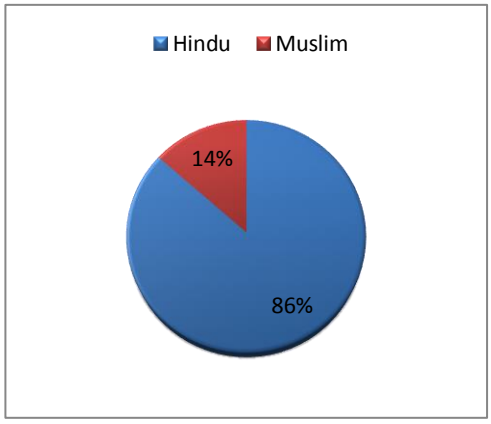


Figure - 2 Distribution of study subjects according to their Religion

It is observed that, majority of 83 (86.5%) TB Patients were Hindu by religion.

Table - 3 Distribution of study subjects according to their Marital Status

Marital status	Number	Percentage
Married	87	90.6
Unmarried	5	5.2
Widow	4	4.2
Total	96	100.0

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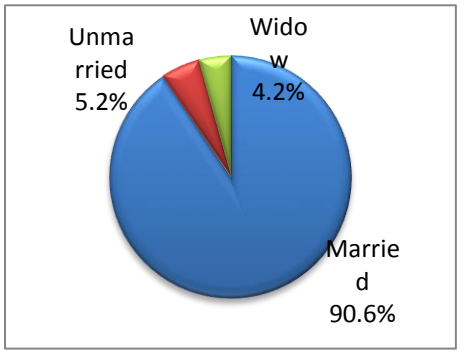
Figure - 3 Distribution of study subjects according to their marital status



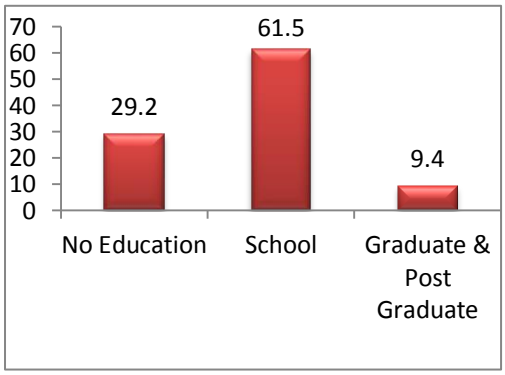
Education	Number	Percent
No Education	28	29.2
School	59	61.5
Graduate & Post graduate	9	9.4
Total	96	100

It is observed in the study subject majority 87(90.6%) of TB patients were married group.

Table 4: Distribution of study subjects according to their Educational Status.

Figure - 4 Distribution of study subjects according to their Educational status

It is observed that maximum no. of study subjects had been to school (i.e. primary, high school, secondary) 59(61.5%) and 9(9.4 %) of them were graduate and postgraduate degree.



Occupation	Number	Percentage (%)
Unemployed	23	23.00
Unskilled worker	5	5.00
Semi-Skilled	28	28.00
Skilled worker	1	1.00
Clerical/Shop/Farm owner	17	17.00
Semi professional	20	20.00
Professional	2	2.00
Total	100	100.0

Table: 5, Distribution of Study subjects according to their Occupation.

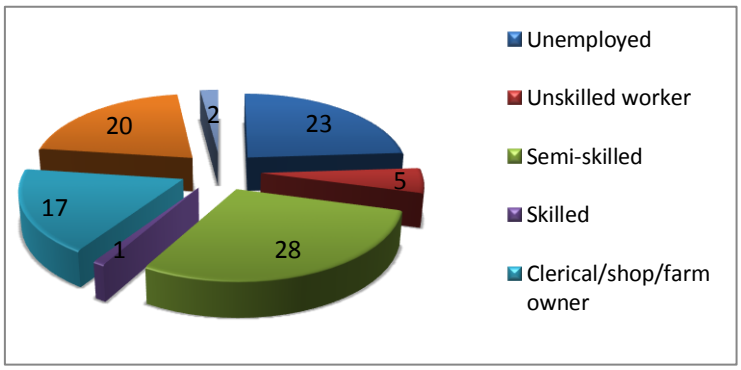


Figure - 5 Distribution of study subjects according to their Occupation

It is observed that majority of study subjects were semi-skilled (28%) and Unemployed groups (23%).

SES	Frequency	Percent
>5775	36	37.5
2887to2886	47	49.0
1733to2886	12	12.5
866to1732	1	1.0
Total	96	100.0

Distribution of study subjects according to their SES

Figure - 6 Distribution of study subjects according to their Socioeconomicstatus

In the present study, majority of study subjects were in class III & IV (49%) socio-economic status, class II were (37.5%), class I were (13.5%)

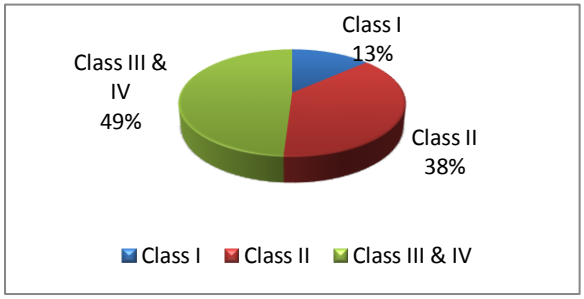


Table - 7 Distribution of study subjects according to the type of Family

Types of Family	Number	Percentage
Nuclear	28	29.2
Joint	64	66.7
Three Generation	4	4.2
Total	96	100.0

Figure - 7 Distribution of study subjects according to the type of family

It is observed in the present study majority of patients were from the Joint Family (66.7).

Locality	Number	Percentage
Urban Area	31	32.3
Rural Area	65	67.7
Total	96	100.0

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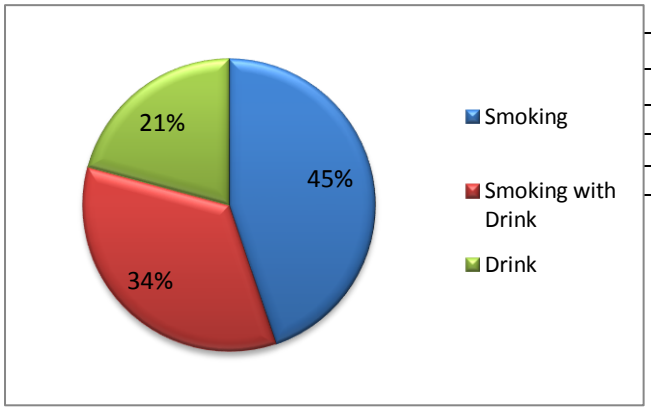
Table - 8 Distribution of study subjects according to their locality

It is observed in the present study, Patients from Rural locality (67.7%) are higher than urban locality (32.3%).

Table – 9 Distribution of study subjects according to personal habit

Figure - 9 Distribution of study subjects according to personal habit



Locality	Number	Percentage
Smoking	43	44.8
Smoking with Drink	33	34.4
Drink	20	20.8
Total	96	100.0

It is observed in the present study, Patients habit smoking (44.8%) Smoking with Drink (34.4%) and drink only (20.8%)

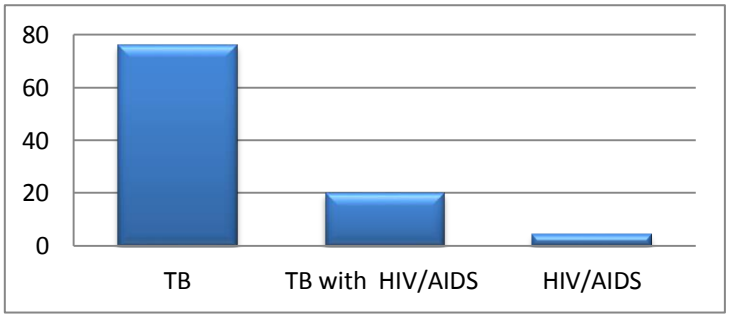
Table – 10 Distribution of study subjects according to TB, TB with HIV/AIDS & HIV/AIDS

Figure – 10 Distribution of study subjects according to TB, TB with HIV/AIDS & HIV/AIDS

Locality	Number	Percentage
TB	73	76
TB with HIV/AIDS	19	19.8
HIV/AIDS	04	4.2
Total	96	100

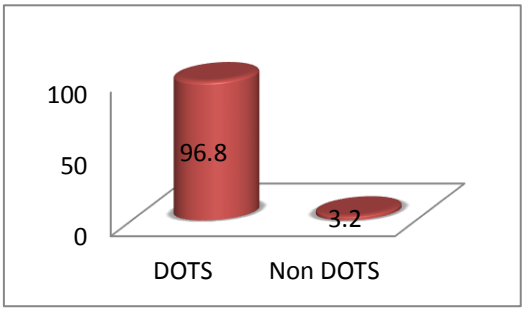
It is observed in the present study, TB Patients (79%) TB with HIV/AIDS (19.8%) and HIV/AIDS (4.2%)

Table – 11 Distribution of study subjects according to supply of DOTS



Locality	Number	Percentage
DOTS	93	96.8
Non DOTS	03	3.2
Total	96	100

Figure – 11 Distribution of study subjects according to supply of DOTS

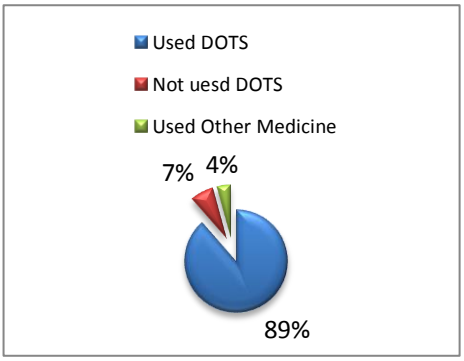


It is observed in the present study, TB Patients who taking DOTS (96.8%) and non-DOTS (3.2%)

Table – 12 Distribution of study subjects according to use of DOTS and other medicine.

Locality	Number	Percentage
Used DOTS	85	88.6
Not used DOTS	07	7.2
Used Other Medicine	04	4.2
Total	96	100

Figure – 12 Distribution of study subjects according to used of DOTS and other medicine



It is observed in the present study, TB Patients who used DOTS (88.6%), not used DOTS (7.2%) and other medicine (4.2%)

Table – 13 Distribution of study subjects according to effect of DOTS and other medicine

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July 2020 | Vol. 1 Issue.2
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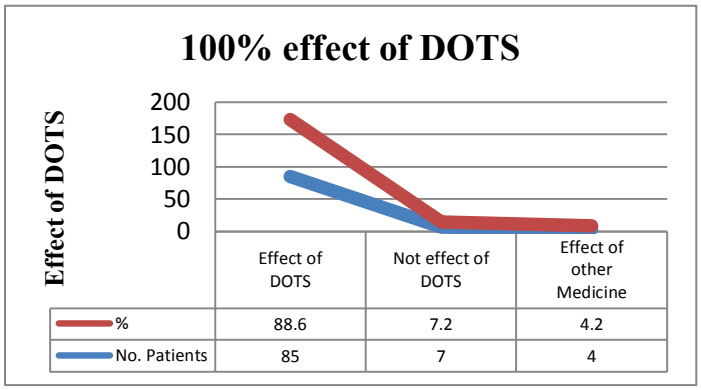

Locality	Number	(%)
Effect of DOTS	85	88.6
Not effect of DOTS	07	7.2
Effect of other Medicine	04	4.2
Total	96	100

Figure – 13 Distribution of study subjects according to effect of DOTS and other medicine

It is observed in the present study, TB Patients the effect of DOTS (88.6%), not effect of DOTS (7.2%) and effect of other medicine (4.2%)

CONCLUSION

In this study the aspects like knowledge of TB patients as well as their family members so that need based information can be provided and get them motivated to get their patient treated in the hospital. The findings of the study showed that majority of the samples had Inadequate, had moderate adequate and only had adequate knowledge.

DOTS program will continue to be effective in treating TB, and with some improvements will allow more positive outcomes to occur. TB impacts whole communities, and its treatment. Patients treated by Directly Observed Therapy (DOT) have excellent cure rates with lesser default rates.

Those who are already getting treatment can be educated regarding treatment compliance so that relapses can be prevented and moreover psychological problems can be reduced as tuberculosis patients living in the society may experience physical, psychological and social problems because people have many misconceptions and stigma is also attached to this disease.

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