ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 04 | April - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

PREVALENCE OF DRUG-RESISTANT TUBERCULOSIS IN PATIENTS RECEIVING DRUG SENSITIVE ANTI-TUBERCULAR MEDICATIONS WITHIN AND OUTSIDE THE DOTS AT NODAL DRTB CENTER, SNMC, AGRA.

Pulmonary Medicine

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ABSTRACT

Introduction: India accounts for 27%of global TB burden. Private sector plays an important role in providing health care services to a large proportion of tubercular patients. Need for innovative measures to increase participation of private sector in national TB elimination program as Usage of inappropriate TB management strategies documented among private practitioners, potentially contributing development of resistance. **Objectives:** To estimate and compare Prevalence of Drug-Resistant Tuberculosis among those receiving DSTB regimen within and outside DOTS. **Materials And Methods:** Hospital-based, prospective observational study, performed at SNMC, Agra on sputum smear positive pulmonary tubercular patients receiving DSTB medications in both categories. Sputum specimens subjected to Rapid molecular drug-resistance and drug-susceptibility testing (DST). **Results:** Prevalence of DRTB Within the DOTS category 8.16% and outside the DOTS category 10.88%. **Conclusions:** Prevalence rates of DRTB are more outside the DOTS category with high statistical significance.

KEYWORDS

Drug-resistant tuberculosis; Within DOTS, Outside DOTS.

INTRODUCTION:

Drug-resistant TB (DR-TB) continues to be a public health threat. Resistance to Rifampicin, the most effective first-line drug – is of greatest concern. In 2022, the estimated proportion of people with TB who had MDR/RR-TB was 3.6% among new cases and 17% among those previously treated. [1]

Private providers play an important role in providing health care services to a large proportion of patients with tuberculosis. There is a need for innovative measures to increase the participation of the private sector in the national TB elimination program and to improve the quality of services in government facilities. Dissatisfaction with services in government facilities was cited as the main reason for preferring private facilities. [3,4,5].

Although the Government of India's National TB Elimination Program (NTEP) provides free TB healthcare services, TB-related symptoms in urban Indian settings first seek healthcare from private practitioners and about 50% ultimately get TB treatment outside the NTEP [2].

However, usage of inappropriate TB diagnostic and treatment practices and lack of adherence to ISTC continue to be documented among private practitioners, potentially contributing to delays in TB diagnosis, development of drug resistance, and ongoing TB transmission.

To achieve the targeted goal of TB elimination from India by 2025, 5 years ahead of global elimination plan further research, as well as an up-to-date assessment of the TB epidemic at all levels required [6].

Our study to determine the prevalence of Drug-Resistant Tuberculosis (DRTB) among those receiving DSTB regimen within and outside DOTS and Compare the prevalence in both populations, was an attempt to suggest the betterment of existing elimination strategies.

MATERIAL AND METHODS:

A hospital-based, observational prospective study, conducted from January 2021 to June 2022 at nodal DRTB center, department of TB & Respiratory Diseases S. N. Medical College Agra.

Inclusion And Exclusion Criteria:

Newly diagnosed smear-positive pulmonary Tuberculosis patients on DSTB regimen within and outside DOTS with informed consent and those with extrapulmonary TB, Previous treatment of MDR or XDR and not given informed consent are excluded.

Participants have been subjected to clinical history, examination, and information obtained about demographic features and Previous history of TB or anti-TB Drug intake, or any preventive therapy and if present the drugs used, etc., and subjected to investigations like CBNAAT, Line Probe Assay. Drug Susceptibility Testing (DST) etc.

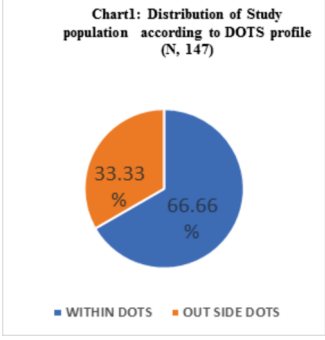
The STTDC, Agra, is a Central TB division-certified Culture and drug-susceptibility test IRL laboratory and is well-equipped with molecular diagnostics like CBNAAT and LPA. Results of the CBNAAT were available as (I) MTB-detected/not detected and (II) rifampicin resistance-detected/not detected/ indeterminate. Rifampicin resistance detected (by CBNAAT) sputum specimens were subjected to a first line-line and second line-line probe assay, and liquid culture-drug susceptibility testing (LC- DST).

R-R not detected by CBNAAT subjected to FL-LPA, and if H (isoniazid) resistance was detected by FL-LPA, then subjected to SL-LPA LC-DST.

Statistical Analysis Of Data:

Statistical analysis was conducted with SPSS 20 software. P value <0.05 was considered statistically significant for the tests applied like Chai square, Fisher exact, and regression models.

RESULTS:



The study was done on a cohort of 147 patients and approximately half were males and half females, with mean age of 31.6 years with majority of patients being in the younger age group. 32.65% were severely undernourished with the body mass index below 16. 68.69% study population had personal habits such as tobacco and alcohol consumption. 42.85% were categorized in class IV (Upper lower) of kuppuswamy scale. 33.33% originated from the private and 66.66% belong to the Government sector.

Among 147 smear-positive pulmonary tuberculosis on DSTB regimen subjected to CBNAAT, 21 (14.28%) were diagnosed as rifampicin-resistant (RR), whereas 126 (85.71%) were rifampicin-sensitive (RS). All 21 rifampicin-resistant tuberculosis patients subjected to FL-LPA, SL-LPA, and LC-DST.

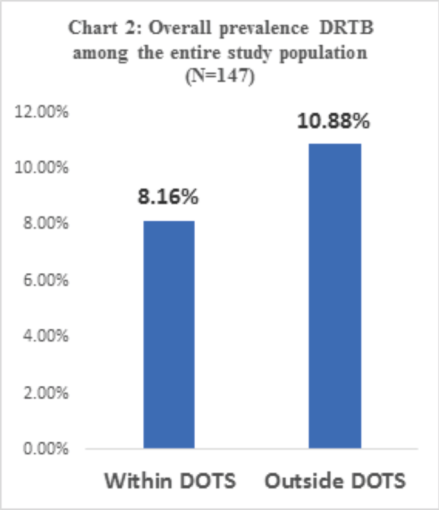
MDR/RR-TB was detected in 19 patients and XDR-TB was detected in 2 patients. Among the MDR/RR patients, 11 had no additional resistance to the fluoroquinolone (FQ) or second-line injectable-drug (SLID); while 10 patients had additional resistance to the FQ/SLID (8 MDR/RR-TB had additional resistance to the FQ and 2 MDR/RR-TB with additional resistance to the SLID). 126 rifampicin-sensitive patients subjected to first-line-line probe assay. 7 of whom H-mono/poly-drug-resistance detected were subjected to a second line-line probe assay and liquid culture–drug susceptibility testing, out of these, 5 patients had no additional resistance to the fluoroquinolone (FQ) or second-line injectable-drug (SLID) class, while 2 had additional resistance to the fluoroquinolone (FQ).

The prevalence of DRTB Within DOTS category is 8.16% and outside DOTS category is 10.88% (chai-square statistic is 5.711. The p-value is .016859 and the result is significant at $p < .05$)

DISCUSSION:

In our study, 53.57% of the patients were in the age group of 18-25 years. The mean age was 30.6 years; similar to studies conducted in the public sector [7,8,9]. The high prevalence of DR-TB in the young population is alarming as this would result in considerable health and financial burden. [10]

8.16% within DOTS category and results of the study match with study conducted by Dawit Asmamaw et al in Addis Ababa, Ethiopia obtaining the prevalence of 10.4% for newly diagnosed DRTB in smear-positive patients in the public sector[11] and that of the study conducted by Jain A et al at Lucknow Uttar Pradesh obtaining Overall Prevalence of 19.8%[11].



We have not come across any specific study of estimation of prevalence in the private sector in the country or abroad and our finding that patients outside DOTS have more prevalence is supported by various studies carried out in the private sector concerning prescription practices and some of the documents of National importance in the field of Tuberculosis [13]. The data outside DOTS from the private sector is higher than that of the public sector 10.88% may be due to delayed diagnosis, suboptimal quality of care, incorrect diagnostic & and treatment protocols, lack of systems for treatment adherence, and a high drop-out rate due to illiteracy, ignorance, and financial constraints, raising risk of drug resistance to first-line or second-line drugs [14]. Inappropriate prescribing patterns related to active TB disease in the private health sector and easy/over-the-counter access to fluoroquinolones both contribute to the pool of DRTB patients. Findings are the same in a study conducted by Alpa Dalal et al in Mumbai [7] Among 28 patients 12 (42.84%) were within DOTS and 16 (57.16%) were outside DOTS. Among them, the drug resistant profiles are as follows H MONO/POLY 7 (25%), RR 5 (17.85%), MDR 6 (21.42%), PRE XDR 8 (28.57%), and XDR 2 (7.14%). Results are in concordance with study conducted by Vishal Prakash Giri et al in eastern parts of India.[65] and Yuanping Pan et al in Dalian, China[14]. The monoresistance to rifampicin was detected in 7.14%. This is higher than the Studies conducted in Ethiopia quoting the ranges from 0% to 1.9% and other parts of India (1.1%) Myanmar (2%) and Cameroon (2.1%). HIV seropositivity, Diabetes and Low BMI also act as risk factors for rapid progression from DSTB to DRTB as reflected by various other studies.[12,13,14]

Limitations:

An extensive search online and manually at various standard academic institutions we could not get a study where a specific estimation of prevalence in the private sector and that limit us to compare and obtain inference to the category of outside DOTS population.

CONCLUSIONS:

Prevalence of DRTB more in private sector (outside the DOTS), need special emphasis in the management of Tuberculosis in private sector as per the national guidelines to achieve the ambitious goal of TB elimination.

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