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RESEARCH ARTICLE

CLINICO-EPIDEMIOLOGICAL PROFILE AND TREATMENT OUTCOMES OF TUBERCULOSIS PATIENTS DIAGNOSED AT 2 DESIGNATED MICROSCOPY CENTRES (DMCS) IN NEW DELHI, INDIA

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Abstract

Objective: To study the clinical-epidemiological profile and treatment outcomes of tuberculosis patients diagnosed at two designated microscopy centres (DMCs) in New Delhi, India.

Methods: Data was collected from the available treatment records as well as from the online notification platform Nikshay, for the patients diagnosed in the period 01 October 2021 to 30 June 2022 and analysed.

Results: This study involved 1181 patients in total, of which 536 (43.39%) were male, 644 (54.53%) were female, and 1 (0.08%) identified as transgender. 382 (32.34%) had pulmonary, 642 (54.36%) had extrapulmonary and 157 patients (13.29%) had both pulmonary and extrapulmonary TB. 1071 (90.68%) were newly diagnosed, the remaining 110 (9.31%) being re-treatment cases. Out of 116 patients that underwent testing for suspected drug resistance, rifampicin resistance (RR) was detected in 7 cases (6.86%) and multi-drug resistance (MDR-TB) was detected in 1 (0.98%). 2 additional patients were diagnosed clinically as MDR-TB and all 10 given the PMDT regimen. 133 (11.26%) were deemed cured, 806 (68.25%) successfully completed treatment, 79 (6.68%) were lost to follow-up, 45 (3.81%) died, 9 (0.76%) were failures and in 14 (1.18%) patients, treatment regimen was changed. Outcome was not reported for 24 (2.03%) and not evaluated for 71 (6.01%).

Conclusion: India has adopted a successful endeavour for case notification of TB patients through the web-based portal, Nikshay. Periodic training for the field staff on data quality and completeness can be implemented for better harmonization. Higher proportion of treatment success under programmatic conditions is encouraging for TB control efforts.

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Introduction:-

Tuberculosis (TB) is an infectious disease that mostly affects the lungs (known as pulmonary TB), but it can also affect other body parts such as the meninges, lymph nodes, abdominal organs, bones, and spine (extra-pulmonary TB) [1]. It is caused by mycobacterium tuberculosis (Mtb) which is its main causative agent and is a serious threat to community health. After COVID-19, TB was the second most common infectious agent-related cause of death worldwide in the year 2022, accounting for nearly twice as many fatalities as HIV/AIDS or 1.30 million deaths (including 167 000 with HIV co-infection) [2]. 87% of the world's TB cases in 2022 were in thirty high-burden countries, and eight countries accounted for two-thirds of the global total: India (27%), Indonesia (10%), China (7.1%), the Philippines (7.0%), Pakistan (5.7%), Nigeria (4.5%), Bangladesh (3.6%), and the Democratic Republic of the Congo (3.0%).[2] An estimated 3,42,000 people died in India from tuberculosis (3,31,000 among HIV-negative individuals and 11,000 among HIV-positive individuals).

The country's HIV epidemiology may have an impact on clinical presentation of tuberculosis cases. While the predicted prevalence of HIV in adults (15–49 years old) has decreased since the epidemic peaked in 2000—from 0.55% in 2000 to 0.32% in 2010 to 0.21% in 2021, this still corresponds to 24,01,284 infected cases, which is a high number, given the high population in India [3]. Controlling the TB burden is further challenging due to the rising prevalence of drug resistance. Periodic evaluation of the clinical and epidemiological factors is necessary due to its varied clinical profile, chemotherapeutic responses, and social implications. One of the main causes of lost disability-adjusted life years (DALY) and out-of-pocket expenses is tuberculosis [4].

The World Health Assembly endorsed the World Health Organization's (WHO) END TB Strategy in 2014 with the goal of putting an end to the global tuberculosis epidemic by 2030. The strategy lists its three sub-targets of lowering incidence of TB by 80% in 2030 as compared to 2015, tuberculosis deaths by 95%, and that no family experiences catastrophic expenses as a result of tuberculosis [5-7].

The Strategy must be modified for various national contexts in order to be successful; it is not a "one size fits all" approach. The India's National Strategic Plan’s (NSP 2017–25) has laid down an ambitious goal for eliminating TB by 2025, incorporating the methods and actions needed to do so, into four strategic pillars: detect, treat, prevent, and build [8].

In 1997, the Revised National TB Control Programme (RNTCP) which employs the DOTS (Directly Observed Treatment, Short-course Chemotherapy) method was launched in India, growing quickly and producing outstanding outcomes- and nationwide coverage achieved by 2006. Sputum smear microscopy of high diagnostic quality, a regular provision of superior quality medications and directly observed treatment were the essential elements of DOTS. In May 2012, the Government of India issued an additional directive requiring all healthcare practitioners to report to local authorities any cases of tuberculosis that are identified and/or treated. 2012 saw the nationwide implementation of the creative and ground-breaking RNTCP electronic recording and reporting system (Nikshay), with 98% of reporting units submitting case-based reports of TB patients, including notices from private practitioners. The program (now called as National Tuberculosis Elimination program or NTEP) has continuously advanced to meet international standards for successful case detection and treatment.

In order to determine what additional advancements are necessary to meet the target of eliminating tuberculosis, it is necessary to evaluate the effects of more recent NTEP activities and also increase the level of knowledge on the disease to enable us to make necessary course adjustments and maximize our efforts to realize the End T.B. strategy in India.

Materials and Methods:-

This case-series analysis was conducted at two designated microscopy centres (DMCs) in New Delhi area, one each from its South and Central Delhi districts. The capital of India, Delhi is divided into nine districts and has an increasing number of migrants living in the city, which is a result of its rapid expansion and development, which has created plenty of job opportunities for both skilled and unskilled workforce [9].

Data was retrospectively collected at periodic visits from treatment records or from the online notification platform, Nikshay for all patients diagnosed at the selected DMCs (Safdarjung hospital DMC and Lady Hardinge Medical

College DMC) in the period October 2021 to June 2022 (both months included). Sociodemographic data, sputum and other microbiological or molecular examination results, HIV and diabetes status, TB category (I or II) based on prior treatment history, type of disease (pulmonary, extrapulmonary, both), site of involvement (lymph node, pleural, TBM etc.), type of case (if it was new, relapse or retreatment), treatment outcomes etc., were all recorded in a pre-structured form designed to capture all the desired epidemiological data elements.

A validated data collection tool based on the paper form was also developed on Visual Basic for Applications (VBA) Excel MACROS software for entering and storing of the collected data and for analysing results from similar sentinel surveys repeated in future. No patient identifiable information (PII) like patient name, telephone or mobile number, social security like Aadhar card, full residential address, email ID, etc. by which the patient could be potentially identified was collected. Information bias was reduced as a single observer collected the data.

Final analysis was done by MedCalc statistical software. Approval was taken from the State Operational Research Committee and also the District TB Officers. Ethics approval was not required as no direct interaction was done with the patients.

Results:-

Data from a total of 1181 patients diagnosed at these 2 DMCs (102 in Safdarjung hospital DMC and 1079 in Lady Hardinge Medical College DMC) was available out of which all were included in the analysis.

Epidemiological profile

Of the total 1181 cases, 644 (54.53%) were female and 536 (45.39%) were male; there was only one transgender person. The patients ranged in age from 1 to 89 years, with a mean age of 25.64 years and a standard deviation of ± 16.51. The age range of the majority of patients (50.89%) was 20 to 60 years old. HIV status was reactive in 18 (1.52%), non-reactive in 1037 (88.81%), and was unknown in 126 (10.67%). 45 patients (3.81%) were diabetic, in 882 (74.68%) cases diabetes was absent, in 254 cases (21.51%) status was not known. Breakup on disease category and classification are as described in Table 1. A combination of clinical features and epidemiological suspicion, supported by the results of multiple investigations, were used to make the diagnosis (Table 1).

Table 1:- Epidemiological profile of TB patients in the two selected DMCs.

Variable	SHDMC (n=102)		LHMCDMC (n=1079)		Total (n=1181)	
	Frequency	**%**	**Frequency**	**%**	**Frequency**	**%**
Age						
0-9 years	5	4.9	148	13.72	153	12.96
10-19 years	25	24.5	343	31.79	368	31.16
20-60 years	70	68.62	531	49.21	601	50.89
>60 years	2	1.96	57	5.28	59	5.00
Gender						
M	57	55.88	479	44.39	536	45.39
F	45	44.11	599	55.51	644	54.53
Transgender	0	0	1	0.09	1	0.08
Category						
New	71	69.61	1000	92.67	1071	90.68
Prev. treated	31	30.39	79	7.32	110	9.31
HIV status						
Reactive	5	4.9	13	1.2	18	1.52
Non-reactive	90	88.23	947	87.77	1037	87.81
Unknown	7	6.86	119	11.03	126	10.67
Diabetes status						
Diabetic	3	2.94	42	3.89	45	3.81

Non-diabetic	97	95.09	785	72.75	882	74.68
Unknown	2	1.96	252	23.35	254	21.51
Classification						
P	44	43.14	337	31.23	381	32.26
P+EP	14	13.73	143	13.25	157	13.29
EP	43	42.126	599	55.55	642	54.36
Basis of Initial Diagnosis						
CBNAAT	17	16.66	4	0.37	21	1.78
Chest X Ray + Clinical	12	11.76	188	17.42	200	16.93
Microscopy- ZN/Fluorescent	24	23.53	282	26.13	306	25.91
Other (Clinical)	47	46.08	564	52.27	611	51.74
Trunat (MTB)	0	0	1	0.09	1	0.08
Cytopathology	2	1.96	27	2.5	29	2.46
F Line LPA	0	0	1	0.09	1	0.08
Histopathology	0	0	12	1.11	12	1.02

Drug resistance profile

A total of 116 patients underwent at least one type of molecular testing for suspected drug resistance(CBNAAT, Truenat MTB RIF, Line Probe Assay etc.). Rifampicin resistance (RR) was detected in 7 cases out of the 116 (6.86%) and multi-drug resistance (MDR-TB) was detected in 1 patient (0.98%). 2 additional patients were diagnosed clinically as MDR-TB and all 10 given the PMDT regimen. Of these 10 cases, 3 were having a previous history of treatment and 7 were newly diagnosed.

Extrapulmonary involvement

Extrapulmonary tuberculosis was seen in a total of 642 out of 1181 cases (43 out of the 102 cases (42.12%) in SHMC and in 599 out of the 1079 cases (46.9%) in LHMC DMC) and the breakdown of the cases is as mentioned below in Table 2.

Table 2:- EPTB site in the TB patients diagnosed at the two selected DMCs.

EPTB Site	SHDMC (n=43)		LHMCDMC (n=599)		Total (n=642)	
	Frequency	**%**	**Frequency**	**%**	**Frequency**	**%**
Abdominal	9	20.93	191	31.88	200	31.15
Bone (Excluding Spine)	0	0.00	15	2.50	15	2.34
Genitourinary	0	0.00	7	1.17	7	1.09
Lymph Node	20	46.51	72	12.20	92	14.33
Miliary	0	0.00	2	0.33	2	0.31
Pericardial	0	0.00	2	0.33	2	0.31
Pleural	3	6.98	107	17.86	110	17.13
Spinal	4	9.30	36	6.01	40	6.23
TBM	4	9.30	43	7.17	47	7.32
Other	3	6.98	31	5.17	34	5.30
Site not specified	0	0	93	15.52	93	14.49

The most common site for EPTB cases was abdominal (31.15%), lymph node (14.33%) and pleura (17.13%). The other 37.38% patients had involvement of other less commonly involved sites. These included genitourinary TB (1.09%), miliary TB (0.31%), pericardial TB (0.31%), spinal TB (6.23%), TBM (7.32%) and other rare site like cutaneous, pericardial TB etc. (5.30%). In 14.49% cases the EPTB site was not mentioned.

In addition to this, 14 pulmonary cases (13.73%) in the SHMC and 143 (13.25%) in LHMC DMC, showed extrapulmonary involvement and breakdown of the same is shown below in Table 3.

Table 3:- EPTB involvement in PTB cases.

EPTB involvement (Pulmonary cases)	SHDMC (n=14)		LHMCDMC (n=143)		Total (n=157)	
	Frequency	**%**	**Frequency**	**%**	**Frequency**	**%**
Abdominal	2	14.29	12	8.39	14	8.92
Lymph Node	4	28.57	114	79.72	118	75.16
Other	1	7.14	11	7.69	12	7.64
Pericardial	0	0.00	1	0.70	1	0.64
Pleural	7	50.00	5	3.50	12	7.64

Treatment outcomes

806 (68.25%) of the 1181 patients successfully completed their treatment, and 133 (11.26%) of the patients were declared as cured. There were 79 lost to follow ups (6.68%), 9 failures (0.76%), and 45 deaths (3.81%), as indicated in Table 4.

Table 4:- Treatment outcomes.

Outcomes	SHDMC (n=102)		LHMCDMC (n=1079)		Total (n=1181)	
	Frequency	**%**	**Frequency**	**%**	**Frequency**	**%**
Cured	20	19.61	113	10.47	133	11.26
Treatment Complete	72	70.59	734	68.03	806	68.25
Lost to Follow-up	6	5.88	73	6.76	79	6.68
Treatment Failure	2	1.96	7	0.64	9	0.76
Died	1	0.98	44	4.08	45	3.81
Treatment regimen changed	1	0.98	13	1.20	14	1.18
Not reported	0	0	24	2.22	24	2.03
Not evaluated	0	0	71	0.64	71	6.01

In 14 (1.18%) patients, treatment regimen was changed, outcome was not reported or missing for 24 (2.03%) patients while for 71 (6.01%) patients the outcome was not evaluated.

Discussion:-

The current study revealed patients between the ages of 20 and 60 had a larger caseload which is also consistent with what is already reported in other studies [10]. The greater number of female cases in one of the DMCs could point towards an improvement in the usually lower notification rates of TB among women [10,11]. Males had accounted for a higher proportion of cases at the Safdarjung DMC with 57 out of the total 102 (55.88%) whereas in Lady Hardinge DMC females were the higher proportion, with 599 out of 1079 or 55.51%, although the sex distribution between the two centres did not show a significant difference (p= 0.081). A larger study with sampling method that includes the linked chest clinics and referral centres, where a significant number of cases would also have been registered, should be undertaken to shed more light into the sex distribution of the registered patients.

According to another hospital-based study conducted in West Bengal between 2014 and 2018, 2% of study participants had HIV and 43% had diabetes as co-morbidities [12]. 35.2% of participants in a different study conducted in Southern India between 2014 and 2016 had diabetes mellitus [13]. In a hospital-based study conducted in northeast India in 2016–17, 53.17% of the patients had comorbidities, with diabetes mellitus (DM) accounting for 26.58% and hypertension for 17.34% of cases [14]. Comparing our analysis to the previous research, the percentage of comorbidities was quite low. This might be the case because, although previously conducted studies were based in hospitals, ours was conducted in patients diagnosed at the DMCs which were associated with the tertiary care hospitals, also catering to an abundant rural migratory population. The same study conducted in northeast India

between 2016 and 2017 showed 43.94% of patients had pulmonary tuberculosis (PTB), 52.02% had extra-pulmonary TB (EPTB), and 4.04% had disseminated TB. The most common sites of involvement were abdominal, lymph nodes, pleura, and bone [14].The higher number of extra-pulmonary cases in this study is comparable with these findings. According to recent research, the occurrence of type of TB may differ based on host variables, population groups, and geographic region [15].

Almost 30.39% of the patients in the South Delhi area DMC of Safdarjung hospital had a previous history of TB while only 7.32% patients in the Central Delhi DMC had a positive previous history and this difference was found to be statistically significant ($p < 0.05$). Similar studies have reported proportion of previously treated cases between 5.7% and 23.7% [16-18].

One of the five TB control criteria included in the DOTS plan is monitoring treatment outcomes, which is still a key element of the end-of-treatment approach. As a result, evaluating patient treatment outcomes and selecting pertinent components form the cornerstone of the TB control plan. Patients who completed the treatment or were cured were higher in Safdarjung DMC (90%) as compared to Lady Hardinge DMC (78.5%). In 2019, tuberculosis cases reported nationwide had a treatment success rate of 82%, a death rate of 3.9%, and a loss to follow-up rate of 3.5%. A change in regimen after the start of treatment and treatment failure accounted for about 1.8% of cases. Additionally, after notification, outcome of 9% of patients remained not evaluated [19].

Conclusion:-

All things considered; TB is a complicated illness that necessitates a multidisciplinary team effort to lower the disease's burden. There is a need to step up efforts to address the socioeconomic factors that contribute to TB, find cases that go undetected, and enhance treatment outcomes with highly efficient therapies [20].

This study showed a high percentage of successful treatment outcomes along with fewer failures and defaults. This could be related to the centre’s appropriately supervised treatment program. Policymakers can efficiently deploy resources and prioritize tailored actions to address the unique needs of vulnerable populations by identifying high-risk groups. Comprehensive data on all TB patients is crucial for ensuring accurate TB diagnosis and case management, preventing TB transmission, and addressing the issues surrounding the emergence and spread of drug-resistant TB while a gap in awareness among private health care providers and a lack of legislative measures at the policy level could make it more difficult to implement TB notification. While more TB cases are being reported at the state level thanks to active operation, it is crucial to quickly and effectively integrate the country's large private sector, that provides for treatment in at least 50% of TB cases. There is an urgent need to significantly change the way the public and private sectors of the health sector function [21]. Universal training on the online notification portal for healthcare workers, private doctors etc. can be considered to ensure full case notification. Ensuring that every TB patient receives adequate monitoring and follow-up is imperative. A variety of adherence techniques can be assessed in order to scale the program even further and increase its efficacy.

National incidence reporting of TB, also known as case notification, was started in the US in 1953 with aggregated case documentation and operational data being submitted from all reporting jurisdictions [22].Major changes were made to the US National Tuberculosis Surveillance System (NTSS) in 2009, that included adding new data fields to the reporting form and changing some of the already existing elements. State and local governments simultaneously switched from using the standalone Tuberculosis Information Management System (TIMS) to report tuberculosis case data to one of four electronic reporting schemes: state-built, commercial, or two schemes created by the Centers for Disease Control and Prevention [23].The majority of the data items in TB surveillance continued to be highly complete despite significant modifications [24].

Similar to this, criteria like completeness and consistency should be routinely assessed in India, and the risks of missing data in the Nikshay portal entered by program workers and other field staff should be explored.

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Competing interest
The authors declare no conflict of interest.

Ethical approval
Being a retrospective operational research study, approval was taken from Delhi State OR Committee, under the aeigis of the NTEP.

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