Section: Community Medicine

Original Research Article

IMPACT OF COVID-19 PANDEMIC ON TUBERCULOSIS CONTROL IN HAPUR DISTRICT OF UP – A RETROSPECTIVE COHORT STUDY

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ABSTRACT

Background: Tuberculosis (TB) remains the world's leading cause of death from an infectious agent with approximately 10 million cases and 1.25 million deaths in 2023. The COVID-19 pandemic caused disruption and hampered TB care.

Objectives: This study aims to estimate the impact of the pandemic on TB enrolment, diagnosis, treatment adherence, and treatment outcomes in the Hapur district of India.

Material & Methods: This research is a retrospective cohort study based on secondary data from the 'Nikshay' portal. Patients enrolled in the second and third quarters of 2020 (Q2 & Q3) were classified as the "exposed cohort," while patients enrolled during the same quarters in 2018 were designated as the "non-exposed cohort." We compared the two groups in terms of enrolment, demographic variables, comorbidities, diagnostic methodologies, and treatment outcomes. Statistical significance was established at $p < 0.05$ for all analyses.

Results: We observed a significant drop in TB case enrolment initially, followed by an increase during the intra-COVID period. There was a marked increase in the reliance on radiological methods for diagnosis, and we noted a 10.5% rise in the number of patients who completed their treatment compared to those in the pre-COVID period of 2018. Additionally, there was a decrease in the number of patients lost to follow-up (LTFU) and those classified as "unevaluated," indicating better adherence to TB management strategies. We also found an increase in the percentage of the population opting for public healthcare facilities to access treatment.

Conclusion: Our findings indicate that the anti-tuberculosis campaign in the Hapur district has continued to perform adequately, demonstrating that it is feasible to maintain TB care even amid significant disruptions..

Key Words: Tuberculosis, Pre-COVID-19, Intra-COVID-19, Nikshay, NTEP, Treatment Outcomes.

INTRODUCTION

Tuberculosis (TB) remains the world's leading cause of death from an infectious agent, with approximately 10 million cases and 1.25 million deaths in 2023.[1,2] With the implementation of the End TB strategy, the incidence of TB began decreasing, however, this progress was disrupted by the unprecedented health emergency of the COVID-19 pandemic.[2,3] In response to this pandemic several measures were taken such as diversion of health resources and nationwide lockdown. During such lockdowns, TB care was hampered leading to decreased TB diagnoses and treatment initiation.[2-4] Many health systems were overwhelmed, and

resources were diverted to combat COVID-19 which increased unfavourable TB treatment outcomes.[5,6] Besides the diversion of resources, other factors that affected TB management outcomes included fear of visiting health facilities, the stigma attached to the disease, fear of contracting COVID from healthcare workers, and interruption in the medicine supply chain.[7]

In pursuance of the commitment to eliminate TB from India, the drive against the deadly disease tuberculosis is orchestrated through the National Tuberculosis Elimination Programme (NTEP).[8] All presumptive cases are registered on a web-enabled nationwide patient management system 'Nikshay' for monitoring and coordination among various government and private agencies. [8,9]

In India, the first case of COVID was spotted on 30th Jan 2020 marking the beginning of the first wave of the pandemic which continued till 15th Feb 2021. The nationwide lockdown was imposed in four phases beginning from 25th March 2020 and continued till 31st May 2020.[10] It was rigorous in the beginning but slightly relaxed in later phases. Lockdowns and social distancing measures resulted in reduced access to health facilities for TB care, leading to a significant drop of 59% in the number of people diagnosed and treated for TB.[10]

The present retrospective cohort study is conducted to estimate the impact of the COVID-19 pandemic on TB registrations and its influence on TB treatment outcomes among people registered before the pandemic (2018) and during the pandemic (2020) and to determine various factors affecting outcomes in the district of Hapur, located in western Uttar Pradesh, India.

MATERIALS AND METHODS

This study is a retrospective cohort study carried out on secondary data of the 'Nikshay' portal obtained from the District Tuberculosis Centre, Hapur. The population of Hapur district [11] formed the study population which was 13.38 lakh according to census 2011.

The two quarters of 2020 when most of the routine healthcare activities came to a halt and healthcare machinery was diverted into anti-COVID activities were Q2 (April to June) and Q3 (July to Sept). Patients registered on 'Nikshay' during Q2 & Q3 of 2020 termed as Intra-covid period were considered the "Exposed Cohort" and those registered during Q2 & Q3 in the year 2018 (pre-covid period) were considered "Non-Exposed" Cohort" in this study.

All presumptive cases (patients with symptoms and signs suggestive of TB) enrolled during Q2 and Q3 of 2018 and 2020 (3086) were included while duplicate entries (16) were removed from the analysis.

The research proposal was cleared by the Institutional Ethics Committee of GS Medical College & Hospital (IEC). Since this is a record-based study, the requirement of individual subject's consent was waived.

To estimate the impact of the pandemic, treatment outcome was categorised according to a reporting framework suggested by WHO in the year 2013.[12] Treatment was considered as follows:

Success: The sum of 'treatment completed' (who have completed treatment without evidence of failure) and cured (who are smear or culture negative after completing treatment)

Not success: Those who are lost to follow-up (LTFU), transferred, experienced treatment failure, or died without any other obvious cause of death while on anti-TB treatment.

Results were analysed using Statistical Package for Social Science (SPSS) version 26. Categorical data were compared using the chi-square test, while the t-test was applied to assess quantitative differences. In all analyses, statistical significance was set at $p < 0.05$.

RESULTS

All unique presumptive cases (3070) were subjected to clinical, radiological / laboratory evaluation and 288 were presumptively closed. The remaining 2782 were assigned the diagnosis of tuberculosis. Out of these, treatment outcome was assigned in only 2736. [Fig.1] Among the 46 who were diagnosed but not assigned outcomes, 13 refused to take treatment for reasons not mentioned in the database. Other reasons included death (7), not being evaluated (12) and untraceable (10). Four turned out to be wrongly diagnosed. In nineteen, the assigned outcome was not as per WHO categories. The difference between those who were diagnosed but not put on treatment was not significant between exposed and not exposed. Of patients who were presumptively closed (288), 59 were not suffering from tuberculosis while 229 abandoned treatment. Significantly more patients were wrongly suspected of suffering from tuberculosis during the intra-covid period than pre-covid period. There was no difference in the cases who abandoned treatment during the two periods.

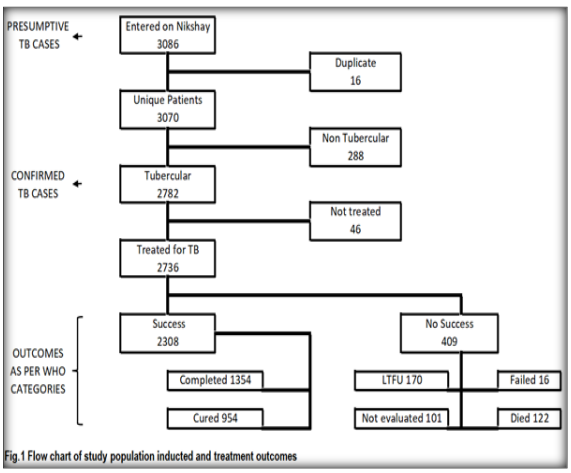

Fig.1 Flow chart of study population inducted and treatment outcomes

Males formed 52% of the cohort in the intra-covid period and 54.9% in the pre-covid period. The difference was not significant. There was no significant difference in age groups. The number of newly diagnosed cases and those presenting for retreatment decreased significantly during the intra-covid period ($p<0.001$). The decrease was significant also for both Pulmonary ($p<0.05$) and Extra Pulmonary TB ($p<0.001$). MDR-TB patients registered for PMDT (Programmatic Management of Drug-resistant Tuberculosis) did not show significant change. [Table -1]

Diabetic status was known in 1616 patients only. Being diabetic was found to be associated with more likelihood of suffering from tuberculosis in the intra-covid period than the pre-covid period ($p<0.05$). HIV status was known for 2477 patients. Only 15 were found positive. There was no significant difference between the two periods. [Table -1]

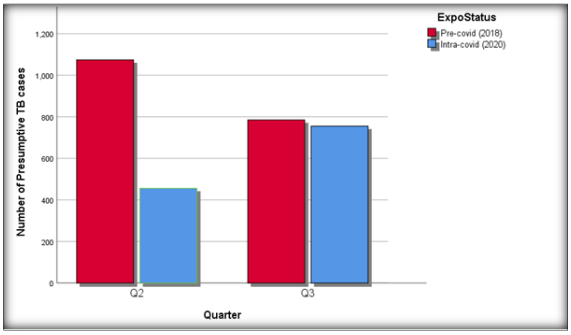

Figure 2: Bar diagram showing number of presumptive cases registered on Nikshay by quarters

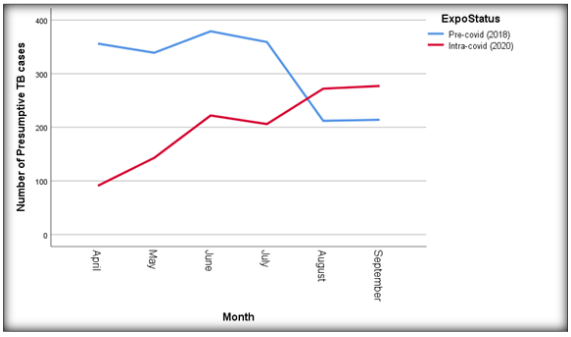

Figure 3: Line diagram showing number of cases registered on Nikshay by months

The number of patients who were registered during the second quarter of 2020 (lockdown period) was 57.5 % lower than the corresponding quarter of 2018. The difference was significant during 3rd quarter too ($p<0.001$). Analysis of month-wise difference showed an interesting pattern of sudden drop of 74.44% in the number of patients registered in April 2020 compared to April 2018. The difference began to narrow as the lockdown was relaxed in the subsequent months of May, June, and July (- 57.82%, - 41.42%, and - 42.62% respectively). In August and September, more cases were registered compared to the same months of 2018 (+ 28.30% and + 29.44% respectively). [Table 2, Fig. 2, Fig. 3]

Public sector facilities registered 2453(80%) TB cases, while private sector facilities contributed 617 (20%). The relative role of private health facilities as 'enrolling facility' increased during the pandemic compared to public health facilities ($p<0.05$). [Table -2] The public health facilities played a greater role as 'current health facility' during the intra-covid period however. Whereas 10.7% of patients switched from private to public health facilities during the pre-covid period, 17.0% switched during the intra-covid period. Government to private facility switch was negligible during the pre-covid period (0.2%) and none during the Intra-covid period.

The use of molecular and microbiological methods for the diagnosis of TB remained the same during both periods. The non-molecular and non-microbiological methods such as X-rays together played a higher role during the intra-covid period. Radiological diagnosis played a significantly greater role ($p<0.001$), while the use of clinical diagnosis decreased significantly ($p<0.001$). [Table -3]

Treatment outcome was assigned for 2717 patients as per WHO categorisation, 1728 in pre-covid and 989 in the intra-covid period. Proportionately more patients met treatment success as per WHO criteria.[(12)] during intra-covid period than during pre-covid-period ($p<0.05$). Most of this success was contributed by the cases belonging to the treatment completed category which went up from 46% to 56.5%. The percentage of patients classified as cured microbiologically however, decreased from 37.5% to 30.9%. [Table -4]

More patients were lost to follow-up during the pre-covid period than the intra-covid period ($p<0.05$). Similarly, more patients remained unevaluated (no treatment outcome assigned due to transfer out or outcome unknown to reporting unit) in the pre-covid period ($p<0.001$). The proportion of patients who died (TB patients who died of any reason before starting or during treatment) was higher during the intra-covid period ($p<0.05$). The proportion of patients whose treatment failed was not different during the two periods.

Table 1: Demographic and Clinical characteristics of Study Population

Characteristics	Notified TB Cases (N = 3070) (%)	Pre-COVID-19 (Apr–Sep 2018) (N = 1859) (%)	Intra-COVID-19 (Apr–Sep 2020) (N = 1211) (%)	p-Value
Gender				
Male	1651(53.8)	1021(54.9)	630(52.0)	p = 0.115
Female	1417(46.2)	838(45.1)	579(47.8)	p = 0.142

Transgender	2(0.1)	0(0.0)	2(0.2)	P = 0.054
Age in years				
≤ 15	170(5.5)	108(5.8)	62(5.1)	p = 0.407
15 24	870(28.3)	518(27.9)	352(29.1)	p = 0.471
25–34	707(23.0)	407(21.9)	300(24.8)	p = 0.062
35–44	407(13.3)	261(14.0)	146(12.1)	p = 0.129
45–54	386(12.6)	241(13.0)	145(12.0)	p = 0.415
55–64	322(10.5)	191(10.3)	131(10.8)	p = 0.658
≥ 65	208(6.8)	133(7.2)	75(6.2)	p = 0.282
HIV status				
Positive	15(0.5)	10(0.5)	5(0.4)	p = 0.689
Negative	2462(80.2)	1437(77.3)	1025(84.6)	**p < .001**
Unknown	593(19.3)	412(22.2)	181(14.9)	**p < .001**
Diabetic Status				
Diabetic	90(2.9)	44(2.4)	46(3.8)	**p < .05**
Non-Diabetic	1526(49.7)	678(36.5)	848(70.0)	**p < .001**
Unknown	1454(47.4)	1137(61.2)	317(26.2)	**p < .001**
Basis of diagnosis				
Microbiological + Molecular	1491(48.6)	913(49.1)	578(47.7)	p = 0.448
Radiological + Clinical.	1579(51.4)	946(50.9)	633(52.3)	p = 0.448
Patient type				
Newly diagnosed	2523(82.2)	1615(86.9)	908(75.0)	**p < .001**
Retreatment	245(8.0)	175(9.4)	70(5.8)	**p < .001**
PMDT	75(2.4)	40(2.2)	35(2.9)	p = 0.222
Information missing	227(7.4)	29(1.6)	198(16.4)	**p < .001**
Type of TB				
Pulmonary	1914(62.3)	1192(64.1)	722(59.6)	**p < .05**
Extrapulmonary	792(25.8)	518(27.9)	274(22.6)	**p < .001**
Information missing	364(11.9)	149(8.0)	215(17.8)	**p < .001**

PMDT: Programmatic Management of Drug Resistant Tuberculosis

Table 2: Study population by Quarter / month and health facility

Characteristics	Notified TB Cases (N = 3070) (%)	Pre-COVID-19 (Apr–Sep 2018) (N = 1859) (%)	Intra-COVID-19 (Apr–Sep 2020) (N = 1211) (%)	Percent change	p-Value
Quarter wise					
Q2 (April - June)	1530(49.8)	1074(57.8)	456(37.7)	- 57.54	**p < .001**
Q3 (July - Sept.)	1540(50.2)	785(42.2)	755(62.3)	- 3.82	**p < .001**
Month wise					
April	447(14.6)	356(19.2)	91(7.5)	-74.44	**p < .001**
May	482(15.7)	339(18.2)	143(11.8)	-57.82	**p < .001**
June	601(19.6)	379(20.4)	222(18.3)	-41.42	p = 0.151
July	565(18.4)	359(19.3)	206(17.0)	-42.62	p = 0.108
August	484(15.8)	212(11.4)	272(22.5)	+28.30	**p < .001**
September	491(16.0)	214(11.5)	277(22.9)	+29.44	**p < .001**
Enrolling Health Facility					
Public	2453(79.9)	1513(81.4)	940(77.6)	-37.87	**p < .05**
Private	617(20.1)	346(18.6)	271(22.4)	-21.68	**p < .05**
Diagnosing Health Facility					
Public Health Institution	2266(73.8)	1486(79.9)	780(64.4)	-47.51	**p < .001**
Private Health Facility	443(14.4)	271(14.6)	172(14.2)	-36.53	p = 0.758
Private Lab	154(5.0)	87(4.7)	67(5.5)	-22.99	p = 0.321
Information missing	207(6.7)	15(0.8)	192(15.9)		**p < .001**
Current Health Facility					
Public	2533(82.5)	1547(83.2)	986(81.4)	-36.26	p > .05
Private	537(17.5)	312(16.8)	225(18.6)	-27.88	p > .05

Table 3: Basis of Diagnosing TB during Pre-covid and Intra-covid period

Characteristics	Diagnosed TB Cases (N = 2782) (%)	Pre-COVID-19 (Apr–Sep 2018) (N = 1763) (%)	Intra-COVID-19 (Apr–Sep 2020) (N = 1019) (%)	p-Value
MOLECULAR				
CBNAAT	349(12.5)	228(12.9)	121(11.9)	p = 0.443
F Line LPA	7(0.7)	1(0.1)	6(0.6)	p = 0.017
S Line LPA	6(0.6)	0(0.0)	6(0.6)	p = 0.001
MICROBIOLOGY				
Microscopy	985(35.4)	629(35.7)	356(34.9)	p = 0.452
Culture	1(0.1)	0(0.0)	1(0.1)	p = 0.184
RADIOLOGICAL				
Chest X Ray	479(17.2)	171(9.7)	308(30.2)	**p < .001**
CLINICAL				

Other	877(31.5)	656(37.2)	221(21.7)	**p < .001**
Missing	78(7.7)	78((4.4)	0(0.0)	**P < 0.001**

CBNATT (Cartridge based nucleic acid amplification technique); **F Line LPA:** First line line probe assay **S Line LPA:** Second line line probe assay

Table 4: Comparison of TB treatment outcomes during the pre- and intra-COVID-19 periods

Characteristics	Notified TB Cases (N = 3070) (%)	Pre-COVID-19 Apr–Sep 18 (N = 1859) (%)	Intra-COVID-19 Apr–Sep 20 (N = 1211) (%)	p-Value
Treatment outcomes	**2717**	**1728**	**989**	
Cured	954(35.1)	648(37.5)	306(30.9)	**p < .001**
Completed	1354(49.8)	795(46.0)	559(56.5)	**p < .001**
Lost to follow up (LTFU)	170(6.3)	127(7.3)	43(4.3)	**p < .05**
Transferred/not evaluated)	101(3.7)	86(5.0)	15(1.5)	**p < .001**
Failed treatment	16(0.6)	10(0.6)	6(0.6)	p = 1.00
Died	122(4.5)	62(3.6)	60(6.1)	**p < .05**
Treatment success	**2717**	**1728**	**989**	
Yes	2308(84.9)	1443(83.5)	865(87.5)	**p < .05**
No	409(15.1)	285(16.5)	124(12.5)	**p < .05**

DISCUSSION

We conducted a retrospective cohort study to evaluate the impact of the COVID-19 pandemic on TB enrolment, treatment adherence, and associated factors during pre-covid and intra-covid periods in the population of Hapur district in India. We observed a sudden drop in the enrolment of TB cases followed by an increase in the registration of new cases during the intra-COVID period. There was significantly higher reliance on radiological modalities for diagnoses and an upturn was observed in the trend of cases who completed treatment (10.5% increase) as compared to cases recorded during pre-COVID (2018). Another indicator that showed positive change during the intra-COVID period was LTFU and cases classified as "unevaluated", implying higher adherence to TB management strategies. We also observed a higher percentage of the population who opted for public healthcare facilities to avail treatment.

The drop in the enrolment of presumptive TB cases was 57.5% during 2nd quarter of the intra-covid period. This is close to the drop of 59% reported for the whole of India during lockdown when compared with the previous year though this is significantly lower than 73% reported for the whole of Uttar Pradesh state in India.[10] A similar decline in TB cases detected is reported by authors from India and other low and middle-income countries (LMICs).[9,13-15] The drop seen in our study maybe a net result of less transmission owing to seasonal variation, divergence of available resources to combat ongoing pandemic, inability of the healthcare professionals to distinguish pulmonary TB from COVID-19, inaccessible healthcare services due to lockdown measures, and fear of the stigma of contagion among patients.[7]

Understandably when lockdown and travel restrictions were lifted during the third quarter of the intra-covid period a surge in TB enrolment was observed. Some researchers have considered the reduction in TB cases to be true due to the use of masks, decreased spitting in public spaces, and physical distancing.[15,16] The surge following the lifting of lockdown negates this explanation. A similar opinion has been expressed by Huang Fei et al.[17] This argument is also supported by a 19% increase witnessed all over India in the year 2021 from the previous year in notification rate for patients suffering from TB.[18] However, a significantly higher number of patients were 'wrongly suspected' of suffering from tuberculosis during the intra-covid period than the pre-covid period. The reason may have been due to more persons presenting with respiratory symptoms and the similarity of clinical presentation between COVID-19 and TB.

Overall decrease was seen in intra-covid period compared to pre-covid period for both newly diagnosed and retreatment cases of pulmonary ($p<0.05$) and extrapulmonary ($p<0.001$) tuberculosis. A similar pattern has been seen in many other countries.[19,20]

In contrast to findings reported by various authors,[21] utilisation of microbiological diagnostic methods, in the population of Hapur, remained similar to that of the pre-COVID phase. However, there was over-reliance on radiological methods for diagnosis which indicated a change social behaviour of the healthcare workers during the pandemic where physically distancing from patients mandated the use of X-Ray for diagnosis of TB.

A recent trend of increased utilisation of private healthcare facilities for TB management has been observed.[22] A similar finding we observed in this study as the private sector acted as the preferred enrolling facility during the intra-covid period. This was primarily due to restrictions on movements and the availability of private facilities in the vicinity for enrolment during the pandemic.[23] However, all patients who started therapy during the intra-covid period from public facilities continued doing so but 17.0% of patients who started therapy from private facilities switched to public health facilities. During the pre-covid period, this switch was only 10.7%. This can be attributed to economic reasons as

earnings dwindled during the pandemic reducing the capacity to bear Out-of-pocket (OOP) expenses.

Despite various predictions that the COVID-19 pandemic will hamper TB treatment exponentially, [7,24,25] the same was not observed in this study population where a majority of the enrolled patients completed their therapy during the intra-covid period than in the pre-covid period. Similar findings were reported by Lakoh et al.[13] However, most of the studies have reported the opposite observation.[9,21]

Some studies have found treatment success unaffected during the intra-covid period.[14,26,27] TB treatment remained unimpacted and even improved during the pandemic in a cohort investigated by Gandhi et al.[15] Similar findings were seen in Sierra Leone.[13] The continued availability of healthcare personnel despite the lockdown and political commitment to achieve targets of the End TB strategy explains the reduced impact of the pandemic on TB services in this study population, however, in-depth drivers of success need to be further explored.

A reduced proportion of patients classified as 'cured' i.e., microbiologically confirmed after treatment completion, could be explained as most of the laboratory services were primary diagnostic centres for COVID.[28]

Less patients were lost to follow-up (4%) and remained unevaluated 2% during the intra-covid period. This may be due to the fear factor associated with all respiratory symptoms during the intra-covid period. This contrasts with the findings from a hospital-based study from Italy, where despite keeping all anti-tuberculosis services intact, 10.8% lost to follow-up,[29] 11.7% were LTFU from India,[26] while in Haiti 8.8% were LTFU.[27]

Mortality due to TB has increased during the COVID phase and has been consistently reported from all over the world, with Haiti at 9.3%,[27] India at 4.4%,[26] Eswatini at 21.3%. [19] Even in Higher Middle-Income Countries (HMIC) such as Italy where the anti-TB cascade was not disturbed, mortality due to TB was 4.3% in the intra-covid period compared to none in the previous year.[29] This may be a result of TB-COVID coinfection which increases the fatality among the patient with TB. A meta-analysis conducted by Quan Wang et al. to estimate the effect of TB-COVID co-infection in 19 countries found a fatality rate of 6.5% in High-Income Countries (HICs) and 22.5% in Low- and Middle-Income Countries (LMIC),[30] which was higher than being affected with COVID-19 alone.

CONCLUSION

Our findings indicate that the anti-tuberculosis campaign in Hapur District has performed relatively well during the intra-COVID period. We assert that, given the local political commitment to maintaining the availability of primary healthcare services—including healthcare workers, laboratory services, and paramedical staff—it is possible to sustain a resilient TB care cascade under the National Tuberculosis Elimination Programme (NTEP), even amidst a pandemic. Therefore, with strong organization in place, patient dedication, and if this collaboration is effectively replicated at the national level, it is feasible to ensure continued TB care despite external disruptions.

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