

Incidence of Tuberculosis in Patients with Diabetes Mellitus: A Retrospective Study in a Tertiary Care Teaching Hospital Situated in Suburban and Rural Telangana State

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ABSTRACT

Background and Objectives: Diabetes mellitus (DM) is one of the risk factors of Tuberculosis (TB). The objective of this study was to determine the incidence of tuberculosis and TB patients co-existing with DM in the department of pulmonology and medicine.

Materials and Methods: Pulmonology and General medicine department registers were verified and extracted the data of number of TB patients, TB with DM and total DM patients respectively. The study consisted of patients from January2015 to December 2019. The number of DM, TB and TB with DM patients were expressed for 100000.

Results: 169658 DM patients were identified out of 664656 total patients attending Medical department and out of 143565 patients attending the TB clinic in the pulmonology between the years 2015-2019 a total of 814 TB patients out of which 34 patients had TB co-existing with DM. Below 20 years of age group 132 females developed TB and males were only 24. 21-30 age group was also showing similar incidence of TB. Above 30 years age groups increased incidences of TB in males were noted. There was higher incidence of tuberculosis without DM among females, but TB co-existing with DM was more among males.

INTRODUCTION

Tuberculosis (TB) is one of the most common infectious diseases worldwide. For several decades, the research community has been working for an effective preventive strategy namely mass screening programmes, newer diagnostic methods, identification of various risk factors and newer treatment modalities for TB. Although the current preventive efforts against the spread of TB have lowered its incidence, the problem is far from over. Therefore, the focus of research has now shifted to the previously untargeted risk factors involved in the spread of TB. One such **Conclusion:** In summary TB alone were more in younger females and TB co-existing with DM was more common in higher age groups of males. Mechanisms have to be initiated to capture these TB cases that are accessing treatment 'outside RNTCP' by expanding the scope of the current TB notification system in India.

Keywords: Diabetes Mellitus, Pulmonary Tuberculosis, Tuberculosis Co-existing with Diabetes.

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factor is diabetes mellitus (DM). It is well known that DM impairs the immunity of patients and therefore is an independent risk factor for infections such as TB. In 2007 and 2008, two systematic reviews of the medical literature alerted the scientific community to the important association between DM and TB.^{1,2} The studies demonstrated that the relative risk of TB in cohorts of DM patients compared with normal subjects was 3.1 (95% confidence interval 2.3–4.3), and that the odds ratios of TB occurring in persons with DM in case control studies varied from 1.2 to 7.8.^{1,2}

Further reviews have confirmed these findings and suggest that the overall risk of TB in persons with DM is two to three times higher than in the general population.^{3,4} Both type 1 and type 2 DM can increase the risk of TB, but as type 2 disease accounts for >=90% of DM cases worldwide, the public health burden of comorbid disease from type 2 DM is much greater.⁵ Although the link between the two diseases has been known for years from anecdotal reports, case studies and clinical experience, the implications of this interaction for public health were thought until recently to be insignificant, as TB is relatively rare in high-income countries where DM is prevalent, and DM is perceived as being a minor problem in low and middle-income countries (LMICs) where TB is epidemic. This perception has changed radically in the last decade with the recognition of the huge, unfolding epidemic of DM in LMICs, the slower decline in global TB incidence than would be expected from epidemiological modelling and a better understanding of how DM and TB interact. It is not clear why DM patients, particularly those with poorly controlled disease, are at increased risk of TB, although changes have been found in both their innate and their adaptive immune responses.^{1,6} The exact mechanisms underlying this susceptibility to TB are still relatively undefined and are in need of detailed evaluation. In 2012, the population attributable fraction of DM among adult TB cases was estimated at 15%, with the number of adult TB cases associated with DM being 1042000, only slightly less than observed for human immunodeficiency virus (HIV) associated TB.7 Out of the top 10 countries with the highest incidence of TB associated with DM, the first place is occupied by India followed by China.

Tuberculosis remains a major global health problem, with an estimated 8.6 million people developing TB and 1.3 million dying from the disease in 2012. Status of the TB epidemic globally, an estimated 10.0 million (range, 9.0–11.1 million) people fell ill with TB in 2018, a number that has been relatively stable in recent years. The burden of disease varies enormously among countries, from fewer than five to more than 500 new cases per 100 000 population per year, with the global average being around 130. There were an estimated 1.2 million (range, 1.1–1.3 million) TB deaths among HIV-negative people in 2018 (a 27% reduction from 1.7 million in the year in the year 2000), and an additional 251 000 deaths (range, 223 000–281 000) among HIV- positive people (a 60% reduction from 620 000 in the year 2000).

In addition to the increased risk for TB, persons with dual disease (DM & TB) have worse anti-tuberculosis treatment outcomes with longer times to sputum culture conversion, increased risk of death or treatment failure, and increased risk of recurrent TB after successful completion of treatment.^{8,9} Conversely, TB, like other infections, can worsen glycaemic control and complicate the clinical management of DM. Bidirectional screening and integrated management should help to improve early diagnosis, treatment and health outcomes of both conditions. In the light of this situation, the World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease (The Union) launched the Collaborative Framework for Care and Control of Tuberculosis and Diabetes in August 2011 to guide policy makers and implementers in combatting the TB-DM epidemic, with emphasis on operational (and other) research so that the evidence base for action can be built and strengthened.¹⁰ This has had the desired effect, with a multitude of studies being conducted in the last few years, as a result of which several programmatic issues and challenges have been and are continuing to be identified.

Keeping the above facts in mind we have planned to study the incidence of tuberculosis in individuals with diabetes mellitus diagnosed in the department of pulmonology and medicine, in the Shadan Institute of Medical Sciences (SIMS) Teaching Hospital & Research Centre, A Post Graduate Institute, Hyderabad during the early January 2015 to December 2019. The study is approved by the institutional ethical committee.

MATERIALS AND METHODS

From the TB centre of Pulmonology department and the General medicine department, Shadan Institute of Medical Sciences (SIMS) Teaching Hospital & Research Centre, A Post Graduate Institute, Hyderabad, registers were verified and extracted the data of number of TB patients, TB with DM and total DM patients were noted from the records, respectively. Diagnostic criteria for DM have taken the reference from American Diabetes Association. Diagnostic criteria for TB have taken from the criteria of national control of tuberculosis in India in addition to sputum examination, skin test (MANTOUX), CBNAAT test, etc. The study population consisted of diagnosed type2 DM patients aged 30-80 years between January 2015 and December 2019. The number of DM, TB and TB with DM patients were expressed for 100000.

RESULTS

As per the hospital records, (Table 1) newly diagnosed and already on anti-DM medication a total number of 169658 DM patients were identified out of 664656 total patients attending during the period 2015-2019. In a total of 169658 DM patients screened, 34 had DM co-existing with pulmonary TB. TB patients co-existing with DM was 23.68 per 100000 and were treated with anti-DM medication and anti-TB drugs. Newly diagnosed and earlier treated type 2 DM patients from out-patient and in-patient were taken from the records of Shadan Institute of Medical Sciences (SIMS) Teaching Hospital & Research Centre, A Post Graduate Institute, Hyderabad. Out of the total number of 143565 patients attending the TB clinic in the pulmonology department between 2015-2019 a total of 814 were treated in outpatient and in-patient out of which 34 patients had TB co-existing with DM of 4.2%. There were more males among TB patients and also more males suffering from TB with DM out of which one patient died during this period in spite of anti-DM medication and DOTS treatment may be due to age factor, delay in diagnosing, advanced DM status with requirement of insulin in attaining oral anti-DM medication and brief period of discontinuation of anti-TB drugs, etc. Table 1 representing various age groups of 814 TB patients. Under 20 years of age group 132 females developed TB which when compared with males is only 24. There is marked increase in the number of females developing pulmonary tuberculosis even 21-30 age group also showing similar incidence of suffering with TB noted. Above 30 years age groups increased incidences in males were noted.

There was higher incidence of tuberculosis without DM among females as its is mentioned in Table 2 but as we compared the data in Table 3 it was clear that TB co-existing with DM is appearing more among males. In summary TB alone is more in younger females and TB co-existing with DM was more common in higher age groups of males.

Table. 1. Distribution of DM, 1B and 1B with DM Patients attending the hospital				
Category	Number of cases	Per 100,000		
Total OP and inpatient	664656			
Total pulmonology OP	143565			
All DM patients	169658	25526		
All TB patients	814	566.99		
TB with DM cases	34	23.68		

Table: 1: Distribution of DM, TB and TB with DM Patients attending the hospital

Table 2: Distribution of different age groups of male and females of TB patients

AGE GROUPS (YEARS)	MALE	PER 100,000	FEMALE	PER 100,000	TOTAL	PER 100,000
<20	24	16.71	132	91.94	156	108.66
21-30	97	67.56	116	80.79	213	148.36
31-40	68	47.36	53	36.91	121	84.28
41-50	40	27.86	76	52.93	116	80.79
51-60	73	50.84	44	30.64	117	81.49
61-70	63	43.88	16	11.14	79	55.02
71-80	5	3.48	2	1.39	7	4.87
81-90	5	3.48	0	0	5	3.48
TOTAL	375	261.2	436	303.99	814	566.99

Table 3: Distribution of different age groups of male and females of TB co-existing with DM patients

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AGE GROUPS (YEARS)	MALE	PER 100,000	FEMALE	PER 100,000	TOTAL	PER 100,000
<30	0	0	0	0	0	0
31-40	6	4.17	3	2.08	9	6.26
41-50	7	4.87	4	2.78	11	7.66
51-60	6	4.17	3	2.08	9	6.26
61-70	2	1.39	1	0.69	3	2.08
71-80	2	1.39	0	0	2	1.39
TOTAL	23	16.02	11	7.66	34	23.68

DISCUSSION

TB remains a major source of morbidity and mortality throughout the world; one-third of the world's population is estimated to be infected with *Mycobacterium tuberculosis* (MTB), whereby approximately nine million people develop the disease each year, and almost two million die annually as a result.¹¹ Epidemiological analyses have elucidated an association between DM and the development of TB.¹²

There is a high burden of both DM and TB, and as DM increases the risk of TB and adversely affects TB treatment outcomes, there is a need for bidirectional screening of the two diseases.

DM and TB co-infection is associated with poor glycaemic control in DM patients. Reactive hyperglycaemia often accompanies chronic infections due to the associated pro-inflammatory state and release of counter-regulatory stress hormones such as epinephrine, cortisol and glucagon, all insulin antagonists.

The RNTCP reported more than 250 patients were newly diagnosed or identified with TB during the study period, giving TB case rates for patients with DM attending the clinics that were several orders higher than that nationally. TB case notification rate per 100 000 for all types of TB in 2011 was 107 by World Health Organization 2012.¹³ It is important to note, though, that more formal direct comparisons of TB case rates in patients with DM

with these national figures are not appropriate because denominators, time periods and ways of screening are different.

As HIV and tuberculosis (TB) screening services have developed mechanisms for collaboration, in the same way these need to be developed for diabetes mellitus (DM) and TB. Coordinated, integrated and patient centred services facilitate the concept of "one patient – one health care worker – one health system – two (or more) diseases". The key step is to set up joint coordinating DM and TB bodies, especially at the national level, that take responsibility for the development of a national plan, its implementation and monitoring. The national plan includes the development of national guidelines and tools, resource mobilization, monitoring and evaluation and operational research, pre-service and in-service training and advocacy, communication and social mobilization.

The overall goal of the collaborative TB and DM services is to reduce the burden of TB among persons with DM and the burden of DM among patients with active TB. Specific objectives of these services are:

- To address issues of primary prevention of both diseases by tackling underlying risk factors and social determinants.
- To ensure early diagnosis of DM among TB patients and the diagnosis of TB among persons with DM.

- To improve treatment outcomes of both diseases through initiating anti-TB treatment and DM treatment for persons with both diseases.
- To strengthen TB and DM surveillance, including cohort analysis of treatment outcomes.
- To make health services 'safer' by implementing effective infection prevention and control measures for TB (and other airborne pathogens).
- To strengthen health systems through training; supportive supervision; the collection, analysis and use of routine TB-DM data at all levels; good supply chain management for essential consumables and drugs; and operational research.

TB case finding in the community and is in contrast to the experience in China, where a relatively higher proportion of TB patients were detected as a result of referral from the diabetes clinics. So, the high proportion of these previously diagnosed patients with TB identified in the screening programme also reflects the wide coverage and population access of TB diagnostic services at the community level in India, either from the RNTCP or from the private sector.¹⁴

A cross sectional community-based survey in 30 districts out of 374 districts from all over India, with 371,174 household members, 761 TB patients were identified (~ 205 cases per 100,000 populations).¹⁴ Our records were showing ~ 567 cases per 100,000 population of pulmonary TB cases, when we screened 143565 patients in our out-patient and in-patients of which 814 pulmonary TB cases were identified.

Data from the 3rd National Health and Family Survey (NHFS) had shown that prevalence of medically treated TB was 418 per 100,000 usual household residents, with higher prevalence in men. Although the national programme in India is designed to benefit poor and vulnerable communities in the country but large proportions of patients who are accessing treatment 'outside DOTS/RNTCP' are illiterate, live in very low-income households, in rural areas and have to pay for their treatment. The current levels of income in households of patients who are on treatment are likely to be lower than their past and regular incomes, because of inability to work, or return to full work. This has important implications for TB control and the alleviation (or exacerbation) of poverty in the country. Reasons for patients seeking care from outside the national programme are many and include poor knowledge about the disease and the services available through the national programme.^{15,16} TB patients who were diagnosed in the nongovernment health facilities are more likely to be treated outside the programme setting, and this may not be in accordance with the patient management outlined in International Standards of TB care (ISTC).17,18

A study on care seeking behaviour in South India showed that the RNTCP has had an impact in the community with regard to the availability and accessibility of TB services in government health facilities. However relatively large numbers of the chest symptomatic patients had subsequently shifted to the non-Government health facilities prompting the authors to recommend urgent measures to make government facilities more patient friendly.¹⁹

RNTCP during the 12th Five Year Plan (2012-2017) aims to achieve 'Universal access' to quality assured TB diagnosis and treatment and elaborate plans are being made. This requires

broad and concerted efforts and support from all stakeholders with substantial enhancement of commitment and financing at all levels.

RNTCP programme has initiated over 13.8 million patients on treatment, thus saving more than 2.5 million additional lives in comparison to earlier programme.²⁰ The Programme has consistently maintained the treatment success rate >85 per cent since inception and new sputum positive (NSP) case detection of 70 per cent since 2007 after whole country coverage. In 2011, the NSP case detection rate was 71 per cent and treatment success rate 87 per cent.

'DOTS' model for TB control had much success in the last 20 years in reducing the burden of TB, the disease is still a considerable problem. A network of more than 4 lakh (0.4 million) DOT providers are available to provide quality assured directly observed treatment short-course (DOT) services. All States are implementing the 'Supervision and monitoring strategy'²¹ – detailing guidelines, tools and indicators for monitoring the performance from the peripheral health institutions level to the national level.

It is estimated that 4.85 per cent of the TB patients are HIV infection positive.²² NACP (National AIDS Control Programme) and RNTCP have jointly developed "National framework of joint TB/HIV collaborative activities"²³ and these are being implemented in the country.

In 2011, around 6,91,658 TB suspects were referred from Integrated Counselling and Testing Centers (ICTC) to RNTCP and of them, about 83,887 were diagnosed as having TB and initiated on DOTS. In the same period about 6,00,000 TB patients (67% of registered TB patients in State implementing intensified TB-HIV package) were tested for HIV, and of them about 44,000 were diagnosed as HIV positive and offered access to HIV care including co-trimoxazole preventive therapy (CPT) and antiretroviral therapy (ART).

India is one of highest MDR-TB burden countries in the world with an estimated 99,000 incident MDR-TB cases.²⁴

In our study representing various age groups of 814 TB patients, under 20 years of age group 132 females developed TB and males were only 24. Indicating there was a marked increase in the number of females developing pulmonary tuberculosis in this age group. Even 21-30 age group also shows similar high incidence of females suffering with TB. Above 30 years age group male incidence of TB was more. Provably the pulmonary TB in young females below 30 years of age group due to the factors like under nourishment, low socio-economic status, nutritional differences, low educational status in female population. Patients attending this hospital were mainly from rural and semi-urban areas.

There was a higher incidence of tuberculosis without DM among females as it was mentioned earlier but as we compare with data in Table 2 it was clear that TB co-existing with DM was more among males. TB alone is more in younger females and TB co-existing with DM was more common in higher age groups of males.

The researchers found that an estimated 1.5 million 14-20 years old, 535,000 15-19-year-olds, and 192,000 10-14-year olds developed active TB in 2012, totalling 1.8 million new TB cases among all young people. However, researchers point out this is just an estimate and the real figure across all 10-24-year-olds could be as high as three million globally.²⁵

Women of reproductive age have higher rates of progression to disease than men in this age group. Gender differentials exist in reporting and diagnosing TB, and passive case finding likely leads to failure to diagnose TB in women. The socioeconomic consequences of TB in women are exacerbated by later presentation, which leads to a poor prognosis. The stigma associated with TB causes women to be divorced or to be unlikely to become married. A study in India found that male patients with TB expected their wives to care for them but infected wives rarely received care. Thus, married women may try to hide their symptoms instead of seeking help. TB in women has an adverse effect on child survival and family welfare. Socioeconomic factors also have an impact on TB control efforts, especially for women who suffer from disproportionate poverty, low social status, less education (which impedes seeking diagnosis), and barriers to health care. Women may find it more difficult to comply with treatment once symptoms subside. Thus, TB control programs should be gender sensitive.26

CONCLUSION

In this scenario, one of the key pieces of information required for the indirect estimation is an answer to the question "What fraction of cases was missed in TB notification data"? This study, by providing information that 46% (95% CI 34–57%) of TB patients may not be notified under the programme, provides data for estimating the burden of TB by this indirect method as outlined by the WHO Task Force on TB Impact Measurement. In order to make the TB notification system in India complete, mechanisms have to be initiated in India to capture these TB cases that are accessing treatment 'outside RNTCP' by expanding the scope of the current TB notification system.

A growing body of evidence shows that women's health is a good indicator of economic development in a country: when women are healthy, economies tend to be healthy. If businesses want the economy around them to thrive, they should invest in women's health and support prevention and treatment programs for diseases and conditions that impact women adversely.

Achieving 'Universal access' is possible and necessary for controlling TB in the country.

LIMITATIONS

The number of TB patients (814) reporting to our centre is a small number as a tip of iceberg phenomenon even many outpatients are seen in the records of the hospital, semi-urban area surrounded by around 50 villages, etc.

It was our retrospective study of a small five-year period made from January 2015 to the end of December 2019.

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