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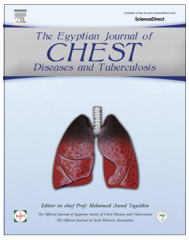

ORIGINAL ARTICLE

HIV and HBV co-infections among patients with active TB disease attending a primary health care centre in a rural area of north India

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KEYWORDS

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Abstract This prospective cross-sectional hospital based study was carried out in order to assess the prevalence of HIV and HBV co-infections among patients with active TB disease attending an OPD at the Model Rural Health Research Unit (MRHRU) in Ghatampur, a rural village in Kanpur district of UP. This is a field unit of National JALMA Institute for Leprosy & other Mycobacterial Diseases at Agra. The socio-demographic features and clinical profile of the TB patients were analysed in the context of symptoms at the time of testing. The HIV and HBV status were determined and correlated with clinical features at the time of testing. In our study, seroprevalence of HIV infection among TB patients is 1.48% (18/1215) and that of HBsAg reactivity was found to be 2.96% (36/1215). During 2007–2010, the HIV-positivity varied between 1.5% and 1.45% whereas HBV reactivity ranged between 2.4% and 3.63%. A substantial percentage of the TB patients attending the OPD in Ghatampur harbour HIV and HBV co-infections, which otherwise would remain undiagnosed without serological screening. There is an urgent need to perform population based surveys of HIV and Hepatitis infections among TB patients to assess the true extent of the problem.

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Introduction

Human immunodeficiency virus (HIV) and hepatitis B virus (HBV) co-infections have emerged as a leading cause of morbidity due to liver disease throughout the world in the last two decades [1,2].

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Among the HIV infected patients, HBV co-infection is more prevalent due to overlapping transmission routes. The introduction of highly-active antiretroviral therapy (HAART) has led to a marked reduction in the morbidity and mortality and has resulted in increased survival in HIV infected patients [3,4]. Consequently, the importance of co-morbidities such as chronic liver disease due to HBV infection is being recognized as a significant problem. In co-infection, the presence of one virus impacts the natural history of the other virus. HIV accelerates the natural course of HBV infection and facilitates faster progression of liver disease to cirrhosis and hepatocellular carcinoma. Disease progression to cirrhosis in HIV positive patients is almost three-times faster as compared to HIV negative patients. Most of the studies in HIV-HBV co-infected patients have been conducted among western patient populations [5]. Understanding HBV co-infection with HIV is particularly important in Asian countries due to high background prevalence of HBV.

The present study was undertaken to estimate the prevalence of HIV (Human Immunodeficiency Virus) and HBV (Hepatitis B Virus) co-infections among patients with active TB (Tuberculosis) disease attending an OPD at the Model Rural Health Research Unit (MRHRU) in Ghatampur, a rural village in Kanpur district of Uttarpradesh. MRHRU in Ghatampur is an ICMR Research field unit of the National JALMA Institute for Leprosy and Other Mycobacterial Diseases, Agra for research in Tuberculosis and Leprosy and serves the population of adjoining rural areas of Kanpur district. The socio-demographic features and clinical profile of the TB patients were analysed in the context of symptoms at the time of testing. Many risk behaviours as well as the routes of transmission for HIV and HBV are identical. This was precisely the reason for which the TB and HIV-infected sera samples were tested for HBV. This is the first report of the HIV and HBV screening among TB patients in a rural area in this region of the country.

Materials and methods

The detailed plan of study was submitted to the Ethics Committee as well as the Scientific Advisory Committee (SAC) of the Institute, which approved the assumptions for human research.

Study design

This was a prospective cross-sectional hospital based study.

Study period

The present study was carried over a period of 4 years, from 2007 to 2010.

Inclusion criteria

Adult TB patients, between the age group of 15 and 65 years, with active TB disease attending an OPD (Out patient's Department) of Model Rural Health Research Unit (MRHRU) at Ghatampur, Kanpur were included in the study. The diagnosis of active TB disease was confirmed based on the signs, symptoms, clinical, radiological and bacteriological findings. Children and old patients were excluded from the study assuming they were not likely to be sexually active. In order to ensure that the patients were not screened, over and over again, their OPD cards were marked, "HIV-HBV screened". This helped in excluding the repeat testing of the patients.

The socio-demographic data namely, age, gender, marital status, residential background, education, occupation/profession, symptoms at the time of testing, type of disease, status of initial infection/disease and history of earlier treatment etc., were recorded and patients were given pre-test counselling. They were interviewed using a standard questionnaire of the NACO (National AIDS Control Organization). The Counsellors elicited the detailed information regarding their complaints during pre-test counselling session and as well as after handing over the test result (post-test counselling session).

Methodology

Blood samples, 3 ml were collected aseptically by ante-cubital venipuncture from Clients, after obtaining pre-informed written consent. The sera samples collected after centrifugation at 2500 g were stored at -20 °C until the assays were performed. Sera samples of these TB patients were screened for HIV-1/2 and HBV antibodies by 2 ERS (ELISA, rapid and simple assays as is the strategy of NACO. ELISA was done using MICROLISA kit (J. Mitra & Co. Pvt. Ltd., A 180-181, Okhla Ind. Area, Ph-1, New Delhi). Those found positive were confirmed by rapid and simple assays, namely Capillus HIV-1/HIV-2 latex aggregation assay (Trinity Biotech PLC, Ireland) and/or Instachk HIV 1 + 2 (One Step Anti-HIV (1 & 2) Tri-Line Test (Intec Products, Inc. P.R.C., Transasia Bio-Medicals Ltd., Mumbai) and/or, Diagnos HIV Bi-dot (J. Mitra & Co. Pvt. Ltd., A 180-181, Okhla Indl. Area, Ph-1, New Delhi) and immunochromatography [ACON HBsAg] – One step HBsAg test device (Serum/Plasma) marketed by Rapid Diagnostics Pvt. Ltd., India – manufactured by Acon Biotech (Hangzhou) Co. Ltd., China).

TB patients, irrespective of their HIV status were referred to the nearest DOTS centre, Kanpur. HIV-positive TB patients were referred to ART (Anti-Retroviral treatment) Centre, G.S. V.M. Medical College, Kanpur after post-test counselling, for further treatment, care and management.

Statistical analysis

The demographic and clinical data were statistically analysed using the SPSS software-15.0 version – and Chi-square and Fisher's exact test with 5% level of significance was used to measure the association between the variables and infection rates. Normal *t*-test was applied to test the equality of proportion.

Results

In this study, which was carried over a period of 4 years, from 2007 to 2010, 1215 TB patients were screened for HIV-1/2 antibodies and HBV. Out of 1215 patients, 18 were found to be HIV-positive. Thus, seroprevalence of HIV infection among

Table 1 Depicts the trend of HIV and HBV positivity among TB patients from year 2007 to 2010.

Year	No. of TB patients screened ($n = 1215$)	HIV positive [$n = 18$ (1.48%)]	HBV reactive [$n = 36$ (2.96%)]	Chi square, p value
2007–08	665 (54.73%)	10 (1.5%)	16 (2.4%)	0.01, $p < 0.944$
2009–10	550 (45.26%)	8 (1.45%)	20 (3.63%)	

TB patients in Ghatampur is 1.48% (18/1215). HBV reactivity was found to be 2.96% (36/1215). Table 1 depicts the trend of HIV-positivity and HBV reactivity among the TB patients. During 2007–2010, the HIV-positivity varied between 1.5% and 1.45% whereas HBV reactivity ranged between 2.4% and 3.63%.

Table 2 shows the socio-demographic profile of the HIV-positive/HIV-negative and HBV-reactive/non-reactive TB patients. There is gender bias in TB patients attending the OPD, i.e., 77.71% males attended the OPD compared to 22.28% females. 1.5% of the males and 1.1% females were HIV-positive whereas 2.7% males and 3.7% females were reactive for HBV. There is statistically no significant difference in gender in HIV-positive clients. Among the age groups, which were divided into >20, 21–30, 31–40, 41–50 and 51–60 years, HIV-positivity of 2% was observed in the age group, 21–30 years and 1.2% in the age group, 31–40 years. HBV reactivity was high among the 3 age groups, 2.2% in 21–30, 2.4% in 31–40 and 5.2% in 41–50 years. This shows that it is prevalent among the most productive years of the life.

With regard to marital status, among 59% of married clients, 38% of unmarried and 3% of single clients, maximum HIV-positivity of 1.3% and HBV reactivity of 2.6% was observed among the clients who were married. This emphasizes the fact that being sexually active could be one of the factors for acquiring the infections. The observed difference in HIV-positivity among the married as well as the bereaved clients when compared with unmarried clients is statistically significant ($p < 0.0001$).

62% of the TB patients were illiterate and 33.3% had studied upto primary school but 1.1% and 2.6% of the illiterate patients were HIV-positive and HBV reactive, respectively. Literacy status had a statistically significant ($p < 0.001$) impact on HIV and HBV-positivity. About 78% of the TB patients were labourers, i.e., migrant workers (who have stayed away from their families, for sometime due to work, or other responsibilities). Of these, 1.2% of the labourers and 8.5% having no specific job were HIV-positive whereas 2.5% of the labourers and 5.7% having no specific job were HBV reactive. Occupation of the TB patients had a statistically significant ($p < 0.001$) impact on HIV-positivity.

Table 3 shows the clinical profile, viz., type of TB, category of TB, Mantoux test, Sputum Examination and history of contact of the HIV-positive/HIV-negative and HBV-reactive/non-reactive TB patients. Among HIV-positive TB patients, 72.2% (13/18) were of pulmonary and 27.7% were of extra-pulmonary type. 1.2% of pulmonary TB patients and 3.2% of extra-pulmonary type TB patients were HIV-positive. This appeared to be marginally significant [$p < 0.056$)]. 50% each were Cat-I and Cat-II type of TB patients. Further, 1.2% of Cat-I and 1.7% of Cat-II patients were HIV-positive. 2.2% of HIV-positive TB patients were PPD positive and 1.1% were PPD negative. The bacillary examination from sputum revealed that bacillary positivity was 2.3% and bacillary negativity was 0.38% among the HIV-positive TB patients. Bacillary positive status was statistically significant factor of HIV positivity ($p < 0.005$). 1% of TB patients had a history of positive contact, i.e., spouse or one of the family members was HIV-infected. 4% of the TB patients had no contact with HIV-positive individuals. History of positive contact played a significant role in HIV-positivity ($p < 0.003$).

2.2% of pulmonary TB patients and 7.6% of extra-pulmonary type of TB patients were HBV reactive. This appeared to be significant ($p < 0.001$). Further, 2.7% of Cat-I and 3.3% of Cat-II patients were HBV reactive. 3.5% of HBV reactive TB patients were PPD positive and 2.7% were PPD negative. The bacillary examination from sputum revealed that bacillary positivity was 3.0% and bacillary negativity was 2.8% among the HBV reactive TB patients. 1% of TB patients had a history of positive contact, i.e., spouse or one of the family members was HBV reactive. 9% of the TB patients had no contact with HBV-reactive individuals. History of positive contact played a significant role in HBV-reactivity ($p < 0.001$). Statistical analysis showed that age group, category (Cat-I and Cat-II), mantoux test, and bacillary index were not significantly different among the groups.

The major signs and symptoms among these TB patients were fever, cough, anorexia, loss of weight, lethargy, diarrhoea, pallor, lymphadenitis, and hepatosplenomegaly along with correlative positive chest radiography and respiratory findings. Among the HIV-positive TB patients, fever, loss of weight, cough, anorexia, lethargy, pallor and positive chest radiography were more common than those patients having TB only. The difference in the above symptoms among the HIV-positive and HIV-negative TB patients was found to be statistically significant as analysed by the Chi-square test, p value is <0.0001 for all the 5 parameters. HIV-positive patients are more likely to suffer from fever and weight loss while HIV-negative are more likely to suffer from cough. Therefore, HIV-positive TB patients are less infectious. In this study, only 25% (9) of the patients presented with features of hepatitis i.e., jaundice. The others presented with other HIV related co-morbidities such as diarrhoea and weight loss. This shows that most of these infections (HBV) are clinically asymptomatic and likely to be chronic. They might be missed unless actively sought for. Pulmonary TB may be a risk factor for clinical expression of chronic HBV infection because of the hepatotoxic effects of potent anti-tuberculosis drugs used in its treatment.

The mode of transmission of HIV and HBV infections among TB patients was heterosexual as revealed during the post-test counselling session. None of the HIV-positive and HBV-reactive cases admitted of having a homosexual relationship.

Discussion

Tuberculosis which is a major public health problem in most of the developing world, is posing a big threat with the worldwide epidemic of Human Immunodeficiency virus (HIV) infection.

Table 2 Depicts the socio-demographic profile of HIV-positive/HIV-negative TB patients & HBV-reactive/non-reactive TB patients.

Parameters		No. of TB patients (n = 1215)	HIV-positive (n = 18, %)	HIV-negative (n = 1197, %)	Chi square, p value	HBV-reactive (n = 36, %)	HBV-non-reactive (n = 1179, %)	Chi square, p value
Gender	Male	945	15 (1.59%)	930 (98.41%)	0.34,	26 (2.75%)	919 (97.25%)	0.66,
	Female	270	3 (1.11%)	267 (98.89%)	$p < 0.56$	10 (3.70%)	260 (96.30%)	$p < 0.415$
Age (in years)	< =20	182	0 (0.0)	182 (100%)	4.38,	6 (3.30%)	176 (96.70%)	4.65,
	21–30	450	9 (2%)	441 (98%)	$p < 0.358$	10 (2.22%)	440 (97.78%)	$p < 0.325$
	31–40	332	4 (1.20%)	328 (98.80%)		8 (2.41%)	324 (97.59%)	
	41–50	170	3 (1.76%)	167 (98.24%)		9 (5.29%)	161 (94.71%)	
	51–60	81	2 (2.47%)	79 (97.53%)		3 (3.70%)	78 (96.30%)	
Marital status	Married	717	10 (1.39%)	707 (98.61%)	0.46,	19 (2.65%)	698 (97.35%)	1.25,
	Unmarried	462	7 (1.52%)	455 (98.48%)	$p < 0.796$	15 (3.25%)	447 (96.75%)	$p < 0.545$
	Divorcee	36	1 (2.78%)	35 (97.22%)		2 (5.56%)	34 (94.44%)	
Educational qualifications	Illiterate	754	9 (1.19%)	745 (98.81%)	14.23,	20 (2.65%)	734 (97.35%)	9.61,
	Primary school	405	6 (1.48%)	399 (98.52%)	$p < 0.003$	11 (2.72%)	394 (97.28%)	$p < 0.022$
	Secondary school	51	2 (3.92%)	49 (96.08%)		4 (7.84%)	47 (92.16%)	
	College & above	5	1 (20.00%)	4 (80%)		1 (20.00%)	4 (80%)	
Occupation	Daily wages Labourer	949	12 (1.26%)	937 (98.74%)	12.41, $p < 0.002$	24 (2.53%)	925 (97.47%)	3.04, $p < 0.218$
	Salary	231	3 (1.30%)	228 (98.70%)		10 (4.33%)	221 (95.67%)	
	No specific job	35	3 (8.57%)	32 (91.43%)		2 (5.71%)	33 (94.29%)	

Table 3 Depicts the clinical profile of HIV-positive and HIV-negative TB patients & HBV-reactive and non-reactive TB patients.

Tuberculosis patients		No. of TB patients (n = 1215)	HIV–positive (n = 18, %)	HIV-negative (n = 1197, %)	Chi square, p value	HBV-reactive (n = 36, %)	HBV-non-reactive (n = 1179, %)	Chi square, p value
Type	Pulmonary TB	1059	13 (1.23%)	1046 (98.77%)	3.64, $p < 0.056$	24 (2.27%)	1035 (97.73%)	13.92, $p < 0.0001$
	Extra-pulmonary TB	156	5 (3.21%)	151 (96.79%)		12 (7.69%)	144 (92.31%)	
Mantoux test	Mantoux-positive	399	9 (2.26%)	390 (97.74%)	2.44,	14 (3.51%)	385 (96.49%)	0.62,
	Mantoux-negative	816	9 (1.10%)	807 (98.90%)	$p < 0.118$	22 (2.70%)	794 (97.30%)	$p < 0.431$
History of contact	Positive contact	1042	11 (1.06%)	1031 (98.94%)	9.09, $p < 0.003$-	20 (1.92%)	1022 (98.08%)	27.72, $p < 0.001$
	Negative contact	173	7 (4.05%)	166 (95.95%)	S	16 (9.25%)	157 (90.75%)	
Sputum Examination	Bacillary-positive	688	16 (2.33%)	672 (97.67%)	7.74,	21 (3.05%)	667 (96.95%)	0.44,
	Bacillary-negative	527	2 (0.38%)	525 (99.62%)	$p < 0.005$	15 (2.85%)	512 (97.15%)	$p < 0.834$
Category of TB	Category-1	701	9 (1.28%)	692 (98.72%)	0.44,	19 (2.71%)	682 (97.29%)	0.37,
	Category-2	514	9 (1.75%)	505 (98.25%)	$p < 0.506$	17 (3.31%)	497 (96.69%)	$p < 0.544$

Globally, there are more than 14 million persons dually infected with TB and HIV [6–8] and India accounts for more than 1 million of them [9–11].

HIV-TB co-infections have been reported from other parts of India by several authors. Although these periodic studies indicated that the rates of HIV-positivity are rapidly increasing among these patients [12–30], India continues to be in the category of low prevalence countries with overall prevalence rates ranging from 0.5% to 20%. Awareness about HIV/AIDS and HBV infections among these TB patients is lower despite various IEC programmes with a wide coverage in print and electronic media.

In our study, seroprevalence rate of HIV infection among TB patients is 1.48% (18/1215) and HBV reactivity was found to be 2.96% (36/1215). A substantial percentage of the TB patients attending the OPD in Ghatampur harbour HIV and viral hepatitis infections, mainly HBV which otherwise would remain undiagnosed without serological screening. Co-infection with hepatitis B viruses among TB patients potentiates the risk of anti-tuberculous therapy induced

hepatotoxicity, therefore, exercising caution and carefully monitoring the patients for drugs associated hepatotoxicity is essential [31]. Hepatitis B infections among TB patients have been reported in different studies [32–37]. These studies found a stronger association ($p < 0.001$) between the presence of HBsAg and TB suggesting that HBV carriers might be at a higher risk of contracting TB. There are only a few reports from our country on the prevalence of HBV/HCV in HIV patients and the observations have been highly variable. Co-infection observed in these studies was 30.4% from Nagpur, 2.25% from Lucknow, 7.7% from Chennai and 3.5% from Mumbai [38–42]. In India, HIV testing and counselling services are offered free of cost to all the clients attending the ICTCs (Integrated Counselling & Testing Centre). Mushrooming of ICTCs in every district of the states of India has helped in early detection of the infection but still a lot needs to be done.

Conclusion

A low seroprevalence of HBV is associated with HIV infection in Ghatampur, north India. Interventions to prevent HIV and HBV transmission among TB patients include counselling for patients and preventive intervention programs that attempt to change high-risk behaviour. Cost-effective drug treatment and HIV prevention programs for TB patients are needed in all areas of the country in order to reduce morbidities and mortalities from liver diseases among HIV positive patients. HIV infection may predispose to many infections like TB and HBV. There is, however, serious implication of co-infection with both organisms especially in resource poor rural centres like the one in which our study was done. Efforts should be made to make physicians aware of the peculiarities and manage these patients effectively.

Co-infections in HIV-positive patients are of great importance, both as a public health concern and in the provision of appropriate antiviral and antibacterial treatments.

There is an urgent need to perform population based surveys of HIV and Hepatitis infections among TB patients in India to assess the true extent of the problem.

We, therefore, feel that screening the patients with active tuberculosis disease, irrespective of the pulmonary or extra-pulmonary involvement, for HIV and HBV infections would go a long way in early detection of co-infections. An early treatment, if initiated, would help in further spread of both the infections. There is a need, therefore, to support an approach of targetted screening, integrate HIV testing, counselling and referral services into the existing system for HIV/Hepatistis/TB prevention and/or treatment services.

Limitations

HBV DNA by polymerase chain reaction was not done due to unavailability of the technology. This may have increased the prevalence of HBV in our study as it would allow early diagnosis of these infections before surface antigen of HBV were detectable in serum. Limited availability of funds prevented viral load studies as well as measurement of other serologic viral markers among the co infected patients.

Conflict of interest

None.

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