Original Article

The intention to receive tuberculosis preventive therapy in adult household contacts of pulmonary TB patients in Delhi, India

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Abstract

Introduction: The integration of newer tuberculosis preventive therapy regimens, which have shorter treatment duration, simpler dosing requirements, and improved safety profile, is being considered within India's national tuberculosis elimination program. However, a potential operational challenge in the successful rollout of the expanded TPT plan is the extent of its acceptability in adult household contacts of pulmonary tuberculosis patients due to possibility of lower risk perception and suboptimal perceived benefit. This study was conducted to determine the intention to accept Tuberculosis Preventive Therapy among adult household contacts of pulmonary tuberculosis patients in Delhi, India.

Methodology: This cross-sectional study was conducted from June-November 2020 in Delhi, India. Data were collected through face to-face interviews by trained field investigations from the high-risk adult household contacts of PTB patients.

Results: A total of 536 household contacts including 237 (44.2%) men and 299 (55.8%) women were recruited with median (IQR) age 40 (22-52) years. Risk factors for incident tuberculosis observed in the HHCs were undernourishment (32.3%), overweight (47.8%), and diabetes comorbidity (10.6%). Most of the participants had not heard of latent TB infection (97.3%) The intention to accept tuberculosis preventive therapy was reported by 394 (73.5%) participants with an absence of symptoms (33.1%), feeling completely healthy (42.9%), and drug adverse effects (27.5%) (n=142) being primary drivers of non-intention.

Conclusions: Nearly three in four HHCs without TB disease expressed willingness to accept TPT if prescribed with caveat for the social desirability bias.

Key words: Tuberculosis; tuberculosis infections; latent tuberculosis; chemoprophylaxis.

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Introduction

Latent tuberculosis infection (LTBI) is the persistent immune response generated through stimulation by Mycobacterium tuberculosis (MTb) infection [1]. Close household contacts (HHCs) of pulmonary tuberculosis (PTB) patients on acquiring MTb infection have higher susceptibility of developing incident TB disease (TBD) especially if they are immunodeficient or undernourished [2,3]. TB preventive therapy (TPT) refers to the treatment of LTBI infection in these high-risk individuals to prevent TBD and is effective in reducing the risk of incident TBD in the HHCs of PTB patients by ~90% [1,4]. TPT regimens with proven efficacy include Isoniazid (INH) monotherapy for 6 months, combination therapy using a weekly INH-Rifapentine (3HP) regime for 3 months, daily INH-Rifapentine regime (1HP) for 1 month, and a daily INH-Rifampicin (3RH) regime for 12 weeks [1]. However, the use of TPT is maximized in low burden countries and paradoxically restricted in most of the high-burden lower-middle income countries (LMICs) [4].

India has the highest global burden of TB with an estimated 2.4 million TB cases and 79,144 related deaths in 2019 [5]. The national TB elimination program (NTEP) prescribes TPT only for HHCs below 6 years of age and the people living with HIV (PLHIV) although evidence for expansion of its use in other groups is mounting [6-8].

The World Health Organization (WHO) (2018, 2020) made a conditional recommendation for advancing TPT to all HHCs of PTB patients including older children, adolescents, and adults after excluding TBD [1,9]. Paradkar et al. (2020) observed a high incidence of TBD in a cohort of HHCs of PTB patients [10]. Furthermore, early initiation of TPT in HHCs is

desirable since the excess risk of developing TBD is the highest within 18-24 months of contracting the infection [11-13]. Nevertheless, several operational challenges are recognized in the programmatic management of TPT including reliable screening of the TB contacts for TBD, additional training needs and workload of the associated workers, and potential challenges related to drug adverse effects, adherence and resistance [1].

The government of India plans to expand TPT to other HHCs of PTB patients for achieving TB elimination by breaking the chain of disease transmission. A significant operational challenge in the successful rollout of the expanded TPT plan is the extent of acceptability of the proposed intervention among the beneficiaries. It is well-established that the initiation and adherence to treatment depends on the individual's perceptions in terms of the benefits and barriers arising from the real or imagined adverse effects of the drugs [14,15]. Nonadherence to antitubercular medication is already a persistent public health challenge for several decades [16]. Moreover, HHCs infected with MTb may be asymptomatic with an otherwise low (~ 10%) lifetime risk of progression to TB disease, factors that can possibly inhibit the intention to accept TPT as per the conceptual framework of the health belief model [17]. A study in Delhi among medical doctors exposed to patients with TB found suboptimal acceptability of TPT due to the perception that the benefits did not outweigh the risk [18]. Consequently, the identification of the extent of intention to receive TPT and the factors associated with non-intention is necessary for developing suitable health communication packages accompanying the intervention.

This study was conducted with the objective of determining the intention to accept TPT among adult household contacts of pulmonary TB patients in Delhi, India.

Methodology

Operational definitions for index TB case and close household contacts were identical to the standard WHO definitions applicable in the context of TB infection in high-transmission settings [1].

Study design, setting, and participants

This cross-sectional study was conducted from June-November, 2020. The index microbiologically confirmed pulmonary TB (PTB) patients on Directly Observed Treatment (DOTS) with fixed dose daily regimen at conveniently selected chest/DOTS-TB clinics in three districts (Central New Delhi and North-East) of Delhi were contacted consecutively, either inperson or telephonically. The index-TB patients diagnosed as Multidrug Resistant TB (MDR-TB)/Extensively Drug Resistant (XDR-TB)/extrapulmonary-TB/PLHIV were excluded. Furthermore, those index TB patients lacking any close household contacts (HHCs), and those with concerns suggestive of TB related stigma were also excluded.

After obtaining consent from the index TB patients, a team of trained field investigators (FI), one male, and one female, visited the household of the index TBpatients. Within each household, the adult close HHCs present were assessed for active TB using the foursymptom screening method [19] and those with any TB related symptom were referred to the nearest chest clinic or the government hospital for further management. The weight and height of all the adult HHCs were measured to calculate the body mass index (BMI). Moreover, any adult HHC with a past history of TB or those currently on DOTS were excluded. Subsequently, the FI screened the HHCs for the following risk factors that can increase their risk of progression to active TB including: (i) age \geq 70; (ii) BMI < 18.5; (iii) BMI \ge 25; (iv) Diabetes; (v) Chronic Kidney Disease; (vi) Silica industry worker. From each household, a minimum of 1 and a maximum of 2 eligible HHCs having any of these risk factors were recruited in this study. The age-order procedure was used to select the study participants by first enlisting all eligible adult HHCs living in the household in their ascending age order and the required number of selections were achieved through the lottery method [20].

Primary outcome

The intention of the acceptance of TB preventive therapy in adult HHCs of microbiologically confirmed PTB patients on DOTS.

Sample Size

At 95% confidence levels, 5% absolute precision, expecting the proportion of adult HHCs willing to receive TB preventive therapy as 50%, and 20% nonresponse, the net sample size was calculated as 480.

Study instruments

1. Pretested patient interview schedule

2. Perceived TB severity score was measured through a single-item 'How serious an illness is Tuberculosis in your view' (Ordinal scale 1: Least serious; 10: Most serious) 3. TB excess risk perception in HHC-TB score (How much is the excess risk of developing TB disease among household contacts of existing TB patients? (Ordinal scale 1: Low risk; 10: Highest risk). The Cronbach's alpha of the 2-item scale was 0.768 indicating acceptable reliability.

Study Procedure

The HHCs were interviewed face to face by the FI in the following steps:

(i) Assess knowledge of Latent TB infection (ever heard of LTBI, symptoms of the condition, factors, which increased the risk of TB disease, and the treatment options).

(ii) The FI briefly explained the HHC on 'what is latent TB', and it being 'an asymptomatic and

noncontagious' condition. The contacts were further informed of the high prevalence of LTBI among close household contacts of index TB cases, the lifetime risk of conversion of LTBI to TB disease with the maximum risk concentrated in the first 18-24 months after the acquisition of infection. Moreover, they were explained which sociodemographic and clinical factors were known to accentuate the risk of progression of LTBI to incident TB disease.

(iii) Assess the perceived TB disease severity score, and the LTBI risk perception score.

(iv) The FI informed the HHC on the TPT regimen options that were likely to be available under the programme run by the government, and the known adverse effect profile of the drugs [21].

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Table 1.	Characteristics of the	ie adult household	contacts of drug	sensitive TB ca	ses (N = 536).

Characteristic	n (%)	95% CI
Age (in Years)		
18-40	287 (53.4)	49.1-57.6
\geq 41	250 (46.6)	42.4-50.9
Gender		
Male	237 (44.2)	40.1-48.5
Female	299 (55.8)	51.5-60.1
Education		
Illiterate	183 (34.1)	30.2-38.3
Primary	58 (10.8)	8.5-13.8
Middle	105 (19.6)	16.4-23.2
Secondary	129 (24.1)	20.6-27.9
Graduate and above	61 (11.4)	9.0-14.4
Clinical susceptibility		
Low BMI (< 18.5)	173 (32.3)	28.4-36.4
$BMI \ge 25$	256 (47.8)	43.6-52.0
Diabetes	57 (10.6)	8.3-13.6
CKD	3 (0.6)	0.2-1.7
Age (\geq 70 years)	47 (8.8)	6.7-11.5
Awareness of LTBI		
Ever heard of LTBI		
Yes	14 (2.6)	1.6-4.4
No	522 (97.4)	95.6-98.5
Symptoms of LTBI		
Asymptomatic	29 (5.4)	3.8-7.7
Fever	74 (13.8)	11.1-17.0
Cough	14 (2.6)	1.6-4.4
Don't know	419 (78.2)	74.5-81.5
LTBI is contagious		
Yes	69 (12.7)	10.1-15.8
No	21 (3.9)	2.6-5.9
Don't know	447 (83.4)	80.0-86.3
Increased risk of TB		
Children	308 (57.5)	53.2-61.6
Undernourished	310 (57.8)	53.6-62.0
Diabetes	137 (25.6)	22.0-29.4
Elderly	306 (57.1)	52.8-61.2
Obese	73 (13.6)	11.0-16.8
TB Preventive Therapy		
Anti-TB medication	92 (17.2)	14.2-20.6
No medication available	17 (3.2)	2.0-5.0
Don't know	427 (80)	76.0-82.9

(v) Assess the intention to accept TPT, and the reasons for the lack of intention.

Statistical analysis

The data were entered in EpiData v.3.1 [22] with single-entry and exported and cleaned in MS-EXCEL 2013. The data were analysed with IBM SPSS Version 25 for Windows (IBM Corp., Armonk, NY). The categorical results were expressed as frequency and proportions, and the continuous variables as mean and standard deviation for normal, and median and interquartile range for non-normally distributed data. The chi-square test was applied to assess for the association between categorical variables. The variables which were associated with the lack of intention to receive TPT (p < 0.2) were included in a multivariate logistic regression model. A *p*-value < 0.05 was considered statistically significant.

Ethics

Written and informed consent was obtained from all the study participants. The study was approved by the Institutional Ethics Committee, F.1/IEC/MAMC/(66/01/2019/No116).

Results

The net response rate of the survey was 81% with most of the nonresponse attributable to issues of TB related stigma further accentuated during the ongoing COVID-19 pandemic.

We contacted 306 adult (index) patients with microbiologically confirmed drug-sensitive pulmonary tuberculosis including 174 (56.9%) men and 132 (43.1%) women with median (IQR) age of 28 (20-45)

years. Educationally, a total of 152 (49.7%) of the PTB patients were educated up-to middle school but below high-school pass. The median (IQR) duration of DOTS therapy received by the index TB cases was 5 (3-6) months. Past family history of TB was reported in 122 (39.9%) households. The average household size was 5 (4-7).

A total of 536 adult household contacts (HHCs) including 237 (44.2%) males and 299 (55.8%) females were recruited in the study from the 306 households, with 2 HHCs each enrolled from 230 households, and only 1 HHC from 76 households. The median (IQR) age of the HHCs was 40 (22-52) years. Risk factors for TB disease observed in the HHCs included undernourishment (32.3%), overweight (47.8%), diabetes comorbidity (10.8%), and older people age \geq 70 years (8.8%).

Most HHCs had not heard of LTBI (97.3%) and lacked knowledge regarding the availability of TPT (100%). A majority of the HHCs perceived higher risk of TB disease in children, elderly, and the undernourished (Table 1The median (IQR) perceived TB severity score amongst the HHCs was 7 (3-8). However, the median (IQR) perceived excess risk of TB score was only 5 (4-7). Nevertheless, most of the adult HHCs perceived TPT as a highly beneficial intervention for preventing TB disease in the child contacts (median score 9 IQR 8-10)

The intention to accept TPT if prescribed by a government physician was affirmed by 73.5% of the HHCs with most declining the preference for any specific regimen (88.3%). The reasons for lack of intention were absence of symptoms (33.1), feeling completely healthy (42.9%), and the concern over

Table 2. Acceptability of TB preventive therapy in adult household contacts of drug sensitive TB cases (N=536).

Variable	Median (IQR)	95% CI
Perceived severity of TB disease	7 (3, 8)	-
Perceived excess risk of TB in household contacts	5 (4, 7)	-
Perceived benefit of TPT in child contacts	9 (8, 10)	-
Intention to accept TPT		
Yes	394 (73.5)	69.6-77.1
No	117 (21.2)	18.5-25.5
Undecided	25 (4.8)	3.2-6.8
Willing to accept TPT post testing and diagnosis (n = 142)		
Yes	13 (9.2)	5.4-15.2
No/Undecided	129 (90.8)	84.8-94.6
Reason for lack of intention to accept TPT (No/undecided)		
Asymptomatic condition	47 (33.1)	25.8-41.3
Feel completely healthy	56 (39.4)	31.7-47.8
Drug related adverse effects	39 (27.5)	20.7-35.4
Preference for drug regimen (in willing participants)		
Specific regimen	32 (8.1)	5.8-11.3
Any regimen	14 (3.6)	2.1-6.0
As instructed by the physician	348 (88.3)	84.7-91.1

adverse effects of drugs (27.5%) (n =142) (Table 2). On bivariate analysis, HHCs of female gender, lower economic status, and those with family history of TB showed statistically significant higher odds of intention to accept TPT. However, on adjusted analysis, only lower economic status and the rating of TB as a highly serious illness were statistically significant predictors of intention to accept TPT (Table 3).

Discussion

The findings from our study have important implications for the NTEP for planning the implementation of TPT among adult HHCs of PTB patients in India. This study found that most HHCs of PTB patients had never heard of LTBI and lacked awareness on how to differentiate it from TB disease. However, following brief didactic communication from a trained investigator, nearly three in four HHCs without TB disease expressed willingness to accept TPT if prescribed. In this study, age, gender and educational level of the HHCs was not independently associated with the intention to accept TPT. However, an increased perceived risk of TB disease predicted higher acceptability of TPT although the excess risk of incident TB disease among HHCs of PTB patients was perceived to be low-moderate by most participants.

The strengths of the study are that it was conducted in the real-world as opposed to controlled settings socioeconomically disadvantaged amongst populations' representative of India's urban highburden and TB transmission hotspots. A study limitation was that most HHCs lacked any awareness of LTBI, which necessitated the provision of information regarding TPT to these participants. Consequently, the responses of the HHCs may have lacked adequate contemplation [23]. Furthermore, we excluded adolescents and older children in our study because the decision to initiate TPT in them was in high likelihood determined by their adult caregivers. The findings may also lack generalizability in the non-respondent profile

Table 3 Distribution of factors associate	d with lack of intention to acce	nt TR preventive therapy an	ong adult household contacts
Table 5. Distribution of factors associate	a with lack of intention to acce	pi i b preventive therapy an	iong adunt nousenoid contacts

Variable	Total (N = 536)	Unwilling for TPT (n = 142)	Unadjusted odds (95% CI)	Adjusted odds (95% CI)
Age (in Years)			/	/
< 60	449 (83.8)	113 (25.2)	1	1
≥ 60	87 (16.2)	29 (33.3)	1.4 (0.9, 2.4)	2.0 (0.8-5.5)
p-value			0.116	0.4
Gender				
Male	237 (44.2)	73 (30.8)	1.4 (1.0, 2.1)	1.3 (0.7-2.2)
Female	299 (55.8)	69 (23.1)	1	1
<i>p</i> -value			0.045	0.402
Education				
Illiterate	241 (45.0)	67 (27.8)	1.0 (0.7, 1.5)	-
Literate	295 (55.0)	75 (25.4)	1	
<i>p</i> -value			0.921	
Family history of TB				
Yes	248 (47.4)	51 (20.6)	1	1
No	275 (53.6)	87 (31.6)	1.4 (0.9, 2.2)	1.3 (0.7-2.4)
<i>p</i> -value			0.137	0.322
Per-capita income (INR)				
≤ 30,000	300 (57.3)	42 (14.0)	1	1
> 30,000	224 (42.8)	89 (40.0)	4.0 (2.6, 6.1)	1.9 (1.0-3.4)
<i>p</i> -value			< 0.001	0.034
BMI				
< 18.5	173 (37.2)	42 (24.8)	1.4 (0.9, 2.2)	0.9 (0.5-1.6)
≥ 18.5	292 (62.8)	54 (18.5)	1	1
<i>p</i> -value			0.137	0.827
DM				
Present	57 (11.2)	24 (42.1)	2 (1.1, 3.7)	1.8 (0.2-19.3)
Absent	479 (88.8)	118 (24.6)	1	1
p-value			0.014	0.599
Perceived TB Severity score				
≤ 6	267 (49.8)	136 (50.9)	45.5 (19.5, 105.8)	41.1 (14.3-118.1)
≥ 7	269 (50.2)	6 (2.2)	1	1
<i>p</i> -value			< 0.001	< 0.001

characterized by higher TB related stigma with associated nondisclosure, guilt, and social isolation [24].

Conclusions

In conclusion, more than one in four household contacts of pulmonary Tuberculosis (TB) patients expressed a lack of intention to accept TB preventive therapy either because of perceived lack of benefit, and some concern over possible adverse effects. These findings reflect the need for development of a comprehensive information, education, and communication (IEC) package on LTBI and its management with local validation before the initiation of rollout of the proposed TPT expansion plan among HHCs of PTB patients. Sensitization of the stakeholders with regard to the benefits and also the potential adverse effects of the drugs comprising the TPT regimen to enable informed decision-making based on an individualized risk-benefit assessment is necessary to enhance the acceptability of this pivotal intervention toward eliminating TB in LMICs.

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