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Improved treatment completion with shorter treatment regimens for latent tuberculous infection

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Abstract

SETTING: Four New York City (NYC) Health Department tuberculosis (TB) clinics.

OBJECTIVE: To assess the effectiveness of preferentially offering two shorter treatment regimens—4 months of daily rifampin (4R) and 3 months of once-weekly isoniazid and rifapentine (3HP)—as an alternative to 9 months of daily isoniazid (9H) for the treatment of latent tuberculous infection (LTBI).

DESIGN: Retrospective analysis of patients treated for LTBI from January to June 2015. Poisson regression with robust standard error was used to examine the factors associated with treatment completion.

RESULTS: Of the patients on 9H, 49% (27/55) completed treatment compared with 70% (187/269) of patients on 4R (P=0.003) and 79% (99/125) of patients on 3HP (P < 0.001). When adjusting for age, sex, and TB risk factors, patients on 4R (adjusted risk ratio [aRR] 1.39, 95%CI 1.07–1.81) and 3HP (aRR 1.67, 95%CI 1.27–2.19) were more likely to complete treatment than patients on 9H. Treatment was discontinued due to side effects in 1% (3/269) of patients on 4R, 2% (2/125) of patients on 3HP, and 4% (2/55) of patients on 9H.

CONCLUSIONS: Most patients were placed on shorter regimens for LTBI treatment, and higher treatment completion was observed. Encouraging community providers to use shorter regimens for LTBI treatment would reduce the TB disease burden in NYC.

Abstract

Quatre centres de tuberculose (TB) du service de santé à New York (NYC)

Evaluer l’efficacité de l’offre de préférence de deux protocoles de traitement plus courts, 4 mois de rifampicine quotidienne (4R) et 3 mois d’isoniazide et de rifapentine (3HP) hebdomadaires, comme alternative à l’isoniazide quotidien pendant 9 mois (9H) pour le traitement de l’infection tuberculeuse latente (LTBI).

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Analyse rétrospective de patients traités pour LTBI de janvier à juin 2015. La régression de Poisson avec erreur-type robuste a été utilisée afin d'examiner les facteurs associés à l'achèvement du traitement.

Quarante-neuf pour cent (27/55) des patients sous 9H ont achevé le traitement comparés à 70% (187/269) des patients sous 4R (*P*=0,003) et 79% (99/125) des patients sous 3HP (*P* < 0,001). Après ajustement sur l'âge, le sexe et les facteurs de risque de TB, les patients sous 4R (ratio de risque ajusté [RRa] 1,39 ; IC95% 1,07–1,81) et sous 3HP (RRa 1,67 ; IC95% 1,27–2,19) ont été plus susceptibles d'achever le traitement que les patients sous 9H. Le traitement a été suspendu à cause d'effets secondaires chez 1% (3/269) des patients sous 4R, 2% (2/125) des patients sous 3HP et 4% (2/55) des patients sous 9H.

La majorité des patients a été mise sous protocoles plus courts pour le traitement de LTBI et le taux d'achèvement du traitement a été plus élevé que sous 9H. Encourager les prestataires de soins communautaires à utiliser des protocoles plus courts pour le traitement de la LTBI réiduirait le poids de la TB à NYC.

Abstract

Cuatro consultorios de tuberculosis (TB) del Departamento de Salud de la Ciudad de Nueva York (NYC).

Evaluar la eficacia práctica del hecho de dar preferencia a una oferta de dos pautas de tratamiento acortado de la infección tuberculosa latente (LTBI), a saber: 4 meses con rifampicina diaria (4R) y 3 meses con isoniazida y rifapentina una vez a la semana (3HP), como una opción a la pauta de 9 meses con isoniazida diaria (9H).

Fue este un análisis retrospectivo de los pacientes tratados por LTBI de enero a junio del 2015. Mediante un modelo de regresión de Poisson con un error estándar consistente se examinaron los factores asociados con la compleción del tratamiento.

Cuarenta y nueve por ciento (27/55) de los pacientes que recibían la pauta 9H completó el tratamiento, en comparación con 70% (187/269) de los pacientes que recibían 4R (*P*=0,003) y 79% (99/125) de los pacientes tratados con 3HP (*P* < 0,001). Tras corregir con respecto a la edad, el sexo y los riesgos de contraer la TB, la probabilidad de completar el tratamiento fue mayor en los pacientes que recibían la pauta 4R (razón de riesgos ajustados [aRR] 1,39; IC95% 1,07–1,81) y la pauta 3HP (aRR 1,67; IC95% 1,27–2,19), que en los pacientes tratados con 9H. El tratamiento se suspendió debido a reacciones adversas en el 1% de pacientes (3/269) que recibían 4R, el 2% (2/125) de los que recibían 3HP y en el 4% (2/55) de los pacientes tratados con 9H.

En la mayoría de pacientes se indicaron las pautas más cortas para el tratamiento de la LTBI y se observaron tasas de compleción más altas que con la pauta 9H. Motivar a los trabajadores de salud comunitarios a utilizar pautas más cortas de tratamiento de la LTBI reduciría la carga de morbilidad por TB en la NYC.

Keywords

LTBI; 4R; 3HP; adherence

TREATMENT OF LATENT TUBERCULOUS infection (LTBI) in high-risk populations can reduce the burden of active tuberculosis (TB).[1,2] In the United States, a component of the Centers for Disease Control and Prevention's (CDC's) TB elimination strategy is to expand treatment of individuals diagnosed with LTBI to prevent the development of active TB disease.[3] The most widely used treatment regimen for LTBI is isoniazid (INH) taken daily for 6–9 months (9H) because it is effective, inexpensive, and easy to administer.[1] However, while 9H is considered 90% efficacious, only 34–53% of patients complete treatment under routine programmatic conditions.[1,4–7] Furthermore, serious adverse events, such as drug-induced hepatitis, have been associated with INH.[8–11]

Shorter treatment regimens for LTBI have been shown to increase treatment completion and are being used increasingly across the United States.[12] In 2011, a clinical trial by Sterling et al. showed that 3 months of once-weekly INH and rifapentine (RPT) (3HP) was not inferior to 9H for the prevention of TB disease and resulted in higher treatment completion (82% vs. 69%).[13] Use of 3HP was also associated with lower hepatotoxicity than 9H, although potential complications with drug-drug interactions limited the use of RPT in some patients.[13,14] In the clinical trial, the 3HP regimen was taken by patients under directly observed therapy (DOT) and, as such, the current CDC recommendation is that 3HP be administered using DOT.[15] Another regimen comprising 4 months of rifampin (RMP) (4R) has been available for nearly two decades,[1] but has generally been reserved for patients who cannot tolerate INH or have been exposed to someone with INH-resistant TB. Lardizabal et al. showed that 81% of patients on 4R completed treatment compared with 53% of patients on 9H.[4] Furthermore, patients on 4R experienced fewer adverse effects, particularly hepatotoxicity.[1,5]

At four New York City (NYC) Health Department TB clinics, treatment is offered to persons who have recently been exposed to an infectious TB patient (contacts), who come from or have had a prolonged stay in a country with a high TB burden, who are immunosuppressed, and/or who are living in congregate settings such as hospitals, homeless shelters, correctional facilities, or nursing homes if diagnosed with LTBI.[5,6] Historically, the standard regimen for LTBI at the NYC TB clinics was 9H. The 4R regimen was used minimally.[6] In 2013, the Health Department introduced 3HP at two clinics.[5] TB clinic data on patients on treatment for LTBI showed higher treatment completion with 4R and 3HP than among patients on 9H.[5,6] The 3HP regimen was expanded to all four NYC TB clinics in 2014.

In an effort to increase treatment completion for LTBI in Health Department TB clinics, in January 2015 the TB clinics instituted a policy to preferentially offer 4R and 3HP for treatment of LTBI to eligible patients. We evaluated the policy change and examined treatment outcomes with the shorter regimens.

METHODS

A retrospective study was conducted among all patients who initiated treatment for LTBI from 1 January to 30 June 2015 at all four NYC Health Department TB clinics. Patient demographics, TB risk factors, treatment type, and treatment outcomes were obtained from the TB clinics' medical records.

All clinic providers were familiar with the use of 4R and 3HP, and therefore additional training was not necessary for the policy to take effect. However, 2 weeks before the policy change, clinic providers met to discuss tracking and follow-up of treatment side effects from 4R and 3HP. Updates on the progress of the policy change was provided to clinic providers and other staff during follow-up meetings.

As part of routine care, all patients in the TB clinics with a positive test for tuberculous infection underwent medical evaluation and chest radiography to rule out active TB disease. Once diagnosed with LTBI, information on pre-existing liver disease and concomitant hepatotoxic medication was obtained from patients to determine eligibility for the study and the tolerability of medications. Patients were educated by the physician about treatment regimens for LTBI and potential side effects. The physicians prescribed the shorter treatment regimens, 3HP with DOT or 4R under self-administration, in discussion with the patient and as clinically indicated. Patients were offered 9H if they were contacts of an infectious TB patient with resistance to a rifamycin, if they declined the shorter treatment regimens, or based on clinical judgement, such as concerns about interactions with other drugs taken by the patient. Evaluation for LTBI and offering of treatment to patients generally occurred at the initial visit. Patients who refused treatment could return to the clinic at any time if they decided to undergo treatment later. Patients who accepted were prescribed 1 month of medication and were required to return to the clinic for monthly follow-up visits and medication refills. Patients prescribed 3HP had to make DOT arrangements with clinic staff. Physicians discontinued treatment due to medication side effects or other clinical reasons such as contraindication with other medications. If patients missed their monthly clinic appointment, three telephone calls were attempted to bring them back to the clinic. If there was no success or if patients stated they no longer wanted to return to the clinic, they were discharged from care as refusing to continue treatment.

According to the American Thoracic Society, the Infectious Diseases Society of America, and CDC clinical practice guidelines, the recommended dose in adults for daily 9H is 5 mg/kg body weight, rounded to the nearest 50 mg or 100 mg, with a maximum dose of 300 mg.[1] For the 4R regimen, treatment consists of 120 doses of daily RMP at 10 mg/kg up to 600 mg.[1] For 3HP, it is recommended that medication be administered under DOT, and consists of 12 doses of INH and RPT, where INH is prescribed at 15 mg/kg with a maximum dose of 900 mg and RPT at 300–900 mg based on weight.[15]

Patients received monthly clinical examinations. Liver function tests and other blood tests (i.e., complete blood count and comprehensive metabolic panel) were performed as needed. Patients were advised to inform the Health Department if either symptoms of TB disease or possible side effects to medications occurred. Patients on treatment for LTBI were followed up until treatment completion or the patient was no longer in care.

The primary outcome of the present study was treatment completion. Patients were considered to have completed treatment if they completed 270 doses of treatment within 12 months on 9H, 120 doses of treatment within 6 months on 4R, and 12 doses within 16 weeks on 3HP.

Risk factors for TB were grouped into four categories: medical, population, contact with a TB case, and other. Medical risk factors included having a recent conversion of tuberculous infection, diabetes mellitus, and immunosuppression caused by a medical condition or treatment. Population risk factors included homelessness, birth in a high TB burden country, and using drugs or alcohol. Pearson's χ^2 test was used for categorical variables to examine differences in characteristics between patients on short-course treatment and patients on 9H. Poisson regression with robust standard error was used to estimate unadjusted and adjusted risk ratios (RRs) and 95% confidence intervals (95%CIs).[16] Variables with estimates that were statistically significant on bivariate analysis or known to be confounders based on previous studies were retained in the model. All tests were performed using a 5% level of significance. Analyses were performed using SAS v9.4 (Statistical Analysis System, Cary, NC, USA).

Ethics

As this study was considered to be a public health program evaluation that was not research, it was not submitted to the NYC Department of Health and Mental Hygiene Institutional Review Board for review. Furthermore, the CDC determined that this project was non-human subject research.

RESULTS

From January to June 2015, 649 patients were diagnosed with LTBI and eligible for treatment at the four NYC Health Department TB clinics. Of these, 449 (69%) initiated treatment for LTBI: 394 (88%) were placed on one of the shorter treatment regimens (3HP or 4R) and 55 (12%) on 9H (Figure). With the exception of sex and ethnicity, the characteristics of patients on a shorter treatment regimen were similar to those of patients on 9H (Table 1). The remaining 200 (31%) patients refused to initiate treatment.

Among the 449 patients who initiated treatment, 313 (70%) completed treatment: 49% (n = 27) of patients on 9H completed treatment compared with 70% (n = 187) of patients on 4R (P = 0.003) and 79% (n = 99) of patients on 3HP (P < 0.001). When adjusting for age, sex, and TB risk factors, the 4R (aRR 1.39, 95%CI 1.07–1.81) and 3HP (aRR 1.67, 95%CI 1.27–2.19) regimens were significantly associated with treatment completion. In addition, contacts were more likely to complete treatment than patients in the population risk category (aRR 1.18, 95%CI 1.05–1.34) (Table 2).

The most common reason for not completing treatment was refusal to continue treatment (28%) (Figure). These patients received at least two doses of medication before being lost to follow-up. Three (1%) patients on 4R and one (2%) on 9H discontinued treatment due to clinical reasons not related to TB (i.e., pregnancy and kidney disease). These patients received at least 1 month's supply of medication before discontinuing treatment. Across all treatment types, few patients experienced side effects leading to treatment discontinuation: 2 (2%) patients on 3HP, 3 (1%) on 4R, and 2 (4%) on 9H. Reported side effects for those who discontinued treatment were skin rash (n = 2), increased levels of liver enzymes (n = 3), dizziness (n = 1), and vaginitis (n = 1). Patients experiencing side effects did so early in their

treatment course. One patient on 4R discontinued treatment and was transferred to another provider; the patient received 16 doses before being transferred.

DISCUSSION

The change in the NYC Health Department's policy to preferentially offer shorter treatment regimens at its four TB clinics was successfully implemented, with 88% of the patients started on one of the shorter treatment regimens. Treatment completion was 73% with the shorter regimens compared with 49% with 9H. Side effects were generally mild, and relatively few people experienced them. Placing the majority of patients on the shorter regimens increased overall treatment completion in the clinics to 73%, higher than was reported previously (45–65%) in those clinics.[5,6]

Our findings that treatment completion with the shorter regimen was higher than 9H is consistent with existing studies.[4,5,12,13] However, we also found that under program conditions, treatment completion with 3HP was higher than with 4R (79% vs. 70%). Treatment monitoring with DOT for patients on 3HP may have played a part in the difference observed in treatment completion between the two regimens. This observation is supported by a recent study by McClintock et al.[17] They found patients on 4R benefited from weekly monitoring via telephone calls or webcam, and treatment completion was just as high as that for patients on 3HP administered with DOT (85%). In contrast, a recent clinical trial by Belknap et al. found that in the United States, 3HP under self administration was not inferior to 3HP under DOT.[18] Further evaluation of self-administered 3HP under program settings is needed.

Before taking effect, providers in the TB clinics were informed of the policy change and were provided information about the shorter treatment regimens. Some providers expressed concerns that patients could experience more side effects with the shorter regimens. A concerted effort was made by senior physicians to engage the TB clinic providers in the development and implementation of the policy and provide opportunities to ask questions and share successes during regularly scheduled meetings. These efforts likely played a role in encouraging providers, and may have contributed to the high proportion (88%) of patients being placed on the shorter regimens. Concerns about increased rifamycin-resistant TB resulting from incomplete treatment of the shorter regimens were also raised, but this has not been observed.

Our study had limitations. First, use of shorter treatment regimens was limited to patients being treated for LTBI at the NYC Health Department TB clinics. Results may therefore not be generalizable to patients receiving treatment from other community providers. Second, as this was a retrospective evaluation, we were not able to ask important questions related to the reasons for non-completion of treatment or provider preference in offering 4R or 3HP. We also could not examine whether changing the policy impacted treatment acceptance, as data were not available for analyses. However, studies have shown that offering shorter treatment regimens does not impact treatment initiation and that treatment acceptance is influenced by a patient's attitudes and beliefs about his/her risk of developing active TB.[5,6] There are no existing data that support the view that offering a shorter treatment regimen

impacts patients' acceptance of treatment. Finally, we did not examine the costs associated with the change in policy. In NYC, the cost of RMP and RPT is higher than that of INH. Furthermore, while 3HP requires fewer patient follow-up visits to the clinic than 9H and 4R, the DOT requirement is an added cost. In an era of funding reductions for TB control efforts, cost-benefit analyses may be needed to help sustain these treatment options.

A large proportion of patients in our study (31%) did not initiate treatment. These were missed opportunities, as benefits in starting patients on LTBI treatment regardless of their ability to complete have been observed. A study by Anger et al. showed that contacts with LTBI partially treated with INH are at lower risk from progressing to active TB than those who did not start treatment.[19] The challenge with treating LTBI is persuading patients to start treatment in the absence of signs and symptoms.[20] TB programs should enhance efforts to initiate patients on LTBI treatment regardless of the type of treatment.

The findings of our study demonstrate the effectiveness of shorter regimens for LTBI treatment in a high-volume public health setting. A robust data set of patient populations representing different TB risk groups enabled us to compare treatment completion among three treatment types and assess the effect of the policy change. The policy was successfully implemented in that the majority of patients were placed on one of the shorter treatment regimens, and both 4R and 3HP were significantly associated with treatment completion. Side effects were generally mild, and few led to treatment discontinuation. The Health Department plans to share the success of using shorter treatment regimens for LTBI in the TB clinics with our community providers to increase their use in the community and reduce the overall burden of TB in NYC.

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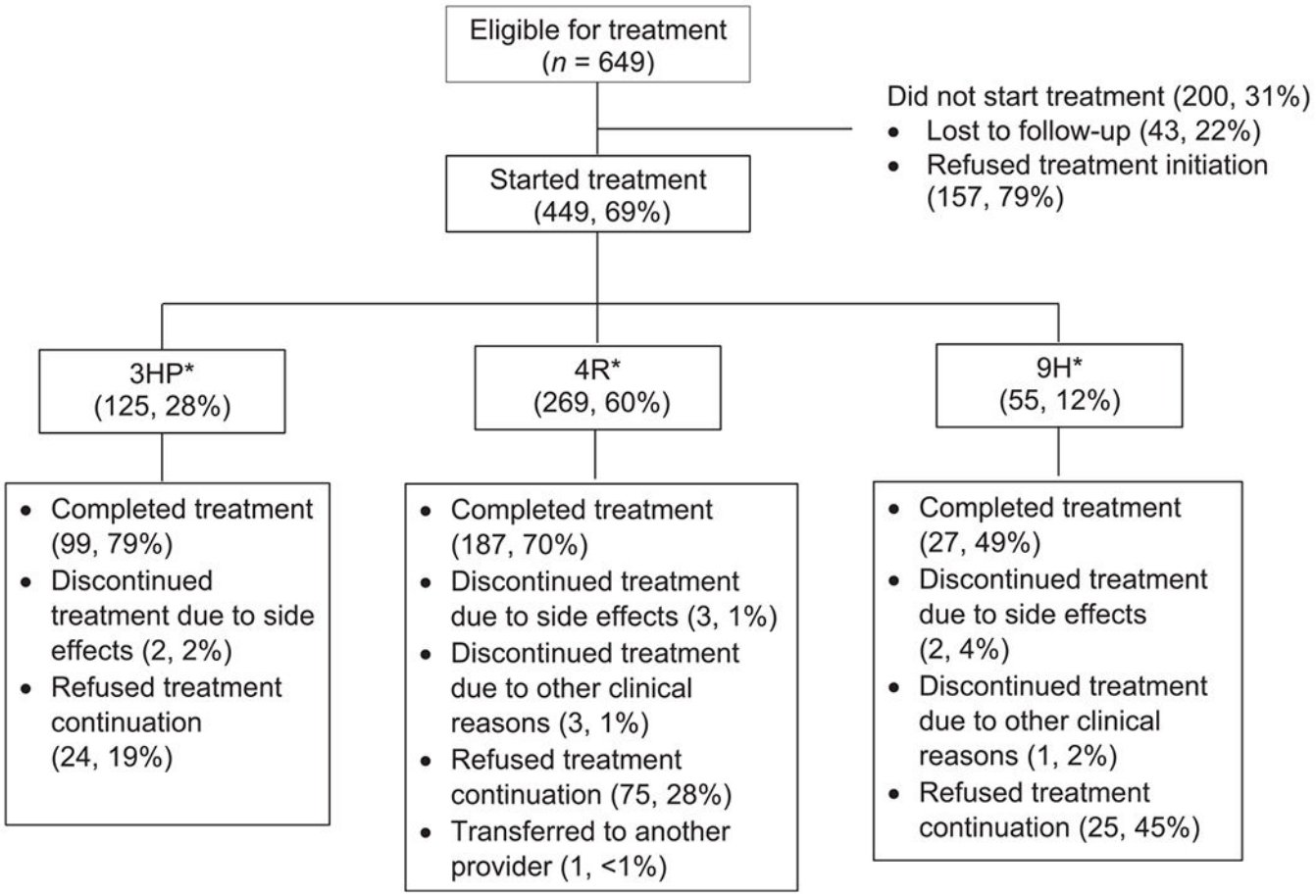

Figure.

Eligibility and treatment initiation for LTBI in New York City Health Department TB clinics, January–June 2015. *3HP = 3 months of once-weekly isoniazid and rifapentine with directly observed therapy; 4R=4 months of rifampin self-administered daily; 9H = 9 months of isoniazid self-administered daily. LTBI = latent tuberculous infection.

Table 1

Characteristics and outcomes of patients treated for LTBI in New York City Health Department TB clinics by treatment type, January–June 2015

	4R* *n* (%)	3HP* *n* (%)	4R and 3HP *n* (%)	9H *n* (%)	4R and 3HP vs. 9H *P* value
Total	269	125	394	55	
Age groups, years					
<18	56 (21)	12 (10)	68 (17)	17 (30)	0.18
18–24	36 (14)	22 (18)	58 (15)	8 (15)	
25–44	103 (38)	60 (48)	163 (41)	19 (35)	
45–64	63 (23)	28 (22)	91 (23)	9 (16)	
≥65	11 (4)	3 (2)	14 (4)	2 (4)	
Sex					
Male	121 (45)	63 (50)	184 (47)	19 (35)	0.09
Female	148 (55)	62 (50)	210 (53)	36 (65)	
Race					
Asian	65 (24)	23 (19)	88 (23)	9 (17)	0.17
Black	94 (35)	53 (42)	147 (37)	15 (27)	
Caucasian	16 (6)	5 (4)	21 (5)	4 (7)	
Other	94 (35)	44 (35)	138 (35)	27 (49)	
Ethnicity					
Hispanic	87 (32)	39 (31)	126 (32)	28 (51)	0.01
Non-Hispanic	182 (68)	86 (69)	268 (68)	27 (49)	
English as primary language					
Yes	86 (32)	49 (39)	135 (34)	18 (33)	0.82
No	183 (68)	76 (61)	259 (66)	37 (67)	
Place of birth					
US-born	41 (15)	18 (14)	59 (15)	13 (24)	0.10
Non-US-born	228 (85)	107 (86)	335 (85)	42 (76)	
Risk factor					
Medical†	32 (12)	15 (12)	47 (12)	10 (18)	0.38
Population‡	153 (57)	85 (68)	238 (60)	30 (55)	

	4R* *n* (%)	3HP* *n* (%)	4R and 3HP *n* (%)	9H *n* (%)	4R and 3HP vs. 9H *P* value
Contact	77 (29)	21 (17)	98 (25)	12 (22)	
Other	7 (2)	4 (3)	11 (3)	3 (5)	
Treatment outcomes					
Completed treatment	187 (70)	99 (79)	286 (73)	27 (49)	<0.01
Did not complete treatment	82 (30)	26 (21)	108 (27)	28 (51)	

*3HP = 3 months of once-weekly isoniazid and rifapentine with directly observed therapy; 4R = 4 months of rifampin self-administered daily; 9H = 9 months of isoniazid self-administered daily.

†Includes individuals at increased risk of LTBI due to recent conversion of a test for tuberculous infection, diabetes mellitus, immunosuppressive conditions, or treatment with immunosuppressive drugs.

‡Includes individuals at increased risk of LTBI due to demographic and social risk factors, including birth outside of the United States, homelessness, and drug or alcohol use.

LTBI = latent tuberculous infection.

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Table 2

Factors associated with completion of treatment for LTBI

	Total *n*	Completed (*n* = 313) *n* (%)	RR (95%CI)	aRR (95%CI)
Treatment				
4R *	269	187 (70)	1.42 (1.07–1.88)	1.39 (1.07–1.81) †
3HP *	125	99 (79)	1.61 (1.22–2.14)	1.67 (1.27–2.19) †
9H *	55	27 (49)	Reference	Reference
Age group, years				
<18	85	67 (79)	1.68 (1.21–2.06)	1.62 (1.24–2.10) †
18–24	66	33 (50)	1.34 (1.03–1.74)	1.30 (1.01–1.68) †
25–44	182	122 (67)	Reference	Reference
45–64	100	80 (80)	1.60 (1.23–2.08)	1.55 (1.20–2.01) †
≥65	16	11 (69)	1.38 (0.91–2.07)	1.29 (0.87–1.90)
Female	246	159 (65)	0.85 (0.76–0.96)	0.88 (0.79–0.99) †
Hispanic	154	103 (67)	0.94 (0.82–1.07)	
Non-US-born	377	263 (70)	1.01 (0.85–1.19)	
Risk factor				
Medical ‡	57	34 (60)	0.89 (0.71–1.12)	0.91 (0.73–1.14)
Population §	268	180 (67)	Reference	Reference
Contact	110	90 (82)	1.22 (1.08–1.38)	1.18 (1.05–1.34) †
Other	14	9 (64)	0.96 (0.64–1.43)	1.02 (0.66–1.58)

* 3HP = 3 months of once-weekly isoniazid and rifapentine with directly observed therapy; 4R = 4 months of rifampin self-administered daily; 9H = 9 months of isoniazid self-administered daily.

† Statistically significant.

‡ Includes individuals at increased risk of LTBI due to recent conversion of a test for tuberculous infection, diabetes mellitus, immunosuppressive conditions, or treatment with immunosuppressive drugs.

§ Includes individuals at increased risk of LTBI due to demographic and social risk factors, including birth outside of the United States, homelessness, and drug or alcohol use.

LTBI = latent tuberculous infection; RR = risk ratio; CI = confidence interval; aRR = adjusted RR.