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High Completion Rate for 12 Weekly Doses of Isoniazid and Rifapentine as Treatment for Latent *Mycobacterium tuberculosis* Infection in the Federal Bureau of Prisons

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Abstract

Context: Correctional facilities provide unique opportunities to diagnose and treat persons with latent tuberculosis infection (LTBI). Studies have shown that 12 weekly doses of isoniazid and rifapentine (INH-RPT) to treat LTBI resulted in high completion rates with good tolerability.

Objective: To evaluate completion rates and clinical signs or reported symptoms associated with discontinuation of 12 weekly doses of INH-RPT for LTBI treatment.

Setting/Participants: During July 2012 to February 2015, 7 Federal Bureau of Prisons facilities participated in an assessment of 12 weekly doses of INH-RPT for LTBI treatment among 463 inmates.

Main Outcome Measures: Fisher exact test was used to assess the associations between patient sociodemographic characteristics and clinical signs or symptoms with discontinuation of treatment.

Results: Of 463 inmates treated with INH-RPT, 424 (92%) completed treatment. Reasons for discontinuation of treatment for 39 (8%) inmates included the following: 17 (44%) signs/symptoms, 9 (23%) transfer or release, 8 (21%) treatment refusal, and 5 (13%) provider error. A total of 229 (49.5%) inmates reported experiencing at least 1 sign or symptom during treatment; most frequently reported were fatigue (16%), nausea (13%), and abdominal pain (7%). Among

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these 229 inmates, signs/symptoms significantly associated with discontinuation of treatment included abdominal pain ($P < .001$), appetite loss ($P = .02$), fever/chills ($P = .01$), nausea ($P = .03$), sore muscles ($P = .002$), and elevation of liver transaminases $5\times$ upper limits of normal or greater ($P = .03$).

Conclusions: The LTBI completion rates were high for the INH-RPT regimen, with few inmates discontinuing because of signs or symptoms related to treatment. This regimen also has practical advantages to aid in treatment completion in the correctional setting and can be considered a viable alternative to standard LTBI regimens.

Keywords

latent infection; prisons; treatment; tuberculosis

The rates of tuberculosis (TB) disease in correctional facilities significantly exceed those of the total US population. Tuberculosis case rates in 2002 to 2013 were 2 to 7 times lower for the general population (4.4 per 100 000) than for the state prisons (8 per 100 000), federal prisons (25 per 100 000), and local jails (29 per 100 000).¹ Overall, up to 13 million people in the United States are infected with *Mycobacterium tuberculosis* and are considered to have latent tuberculosis infection (LTBI).^{2,3} Without treatment, 5% to 10% of infected persons will develop TB disease at some time in their lives.⁴

Testing and treatment of LTBI to prevent further TB transmission are core strategies for the elimination of TB.⁵ The Centers for Disease Control and Prevention recommends TB testing for individuals who are most at risk for developing TB disease, including both those at increased risk for exposure to persons with contagious TB disease and individuals with medical conditions that increase risk of progression from LTBI to TB disease. These recommendations include testing individuals who work or reside in correctional facilities.⁴

Historically, the primary option for treatment of LTBI was 6 to 12 months of isoniazid (INH) self-administered daily or administered twice weekly by directly observed therapy (DOT).⁴ The effectiveness of using INH for LTBI treatment has been limited by poor compliance with completion rates in correctional facilities ranging from 31% to 56%.^{6,7} Completion of treatment is deterred by frequent transfer or release of inmates before completion of treatment, with completion rates as low as 3% to 6% after release.^{6–10}

In 2011, Sterling et al¹¹ published results of a large study evaluating the efficacy of 12 weekly doses of INH and rifapentine (RPT), a long-acting rifamycin, administered to persons at high risk for developing TB disease. The authors concluded that the INH-RPT regimen administered by DOT was as efficacious as 9 months of self-administered INH in preventing TB disease and that the regimen was associated with higher treatment completion rates.¹¹ Guidelines were issued in December 2011 for the use of the new 12-dose INH-RPT regimen for the treatment of LTBI.¹² The guidelines suggested that the regimen should be used in situations in which INH-RPT offers practical advantages, such as correctional settings.

The recent availability of the 12 weekly doses of INH-RPT by DOT for treating LTBI provided an opportunity for the Federal Bureau of Prisons (BOP) to evaluate the use of the regimen in their facilities. The objectives of this pilot assessment of the INH-RPT regimen in the BOP were to assess treatment completion, tolerability, and rates of discontinuation of treatment due to clinical signs (provider recorded) or symptoms (patient-reported) associated with treatment. Ultimately, the BOP planned to use the results of this assessment to determine whether the use of this regimen should be expanded to all 122 BOP facilities.

Methods

Seven federal corrections facilities participated in this prospective pilot assessment. One facility that had demonstrated the capacity to implement the evaluation was chosen from each administrative region and one facility volunteered to participate after numerous infected contacts were identified in a large TB contact investigation.

The primary end point for the pilot assessment of INH-RPT was treatment completion defined as receiving at least 11 weekly doses within 16 weeks. The secondary end point was discontinuation of INH-RPT regimen, especially due to signs or symptoms associated with treatment. Participant information was collected during July 2012 to February 2015 and included demographic information, medical and social risk factors, weekly dose and symptom review, adverse events, laboratory monitoring, and final treatment disposition.

Candidates eligible to participate in the pilot assessment included any inmate with a positive result from a tuberculin skin test or an interferon-gamma release assay and no previous treatment of LTBI or TB. Exclusion criteria included inmates living with human immunodeficiency virus (HIV) infection on antiretroviral therapy (due to contraindications for INH-RPT use in combination with antiretroviral therapy); having confirmed or suspected TB disease; being a contact to an index case known to have TB resistant to rifampin or INH, pregnancy; being on warfarin, or on antiepileptic drug therapy; or having hypersensitivity to any of the rifamycins (eg, rifampin, rifabutin). To be included in the assessment, participants needed to have a projected release date beyond the anticipated treatment completion date. The protocol included placing participants on “medical hold” (to defer transfer the inmate to another facility during treatment).

All eligible participants were offered the option of once weekly INH-RPT by DOT for 3 months for treatment of LTBI or 9 months of biweekly INH; only those accepting INH-RPT were enrolled in the pilot assessment. Before starting treatment with INH-RPT, participants underwent a medical assessment including a complete history and a targeted physical examination, laboratory evaluation for hepatitis B virus surface antigen, anti-hepatitis C virus antibody, HIV antibody, liver transaminases, complete blood count with platelets, and a chest radiography unless there was documentation of a negative chest radiograph within the prior 3 months for non-HIV-infected participants and within 1 month for HIV-infected participants.

The INH-RPT regimen was administered weekly by DOT. Monthly liver transaminases were obtained on all participants throughout the treatment phase and once additionally at the

completion of treatment. Treatment was discontinued if liver transaminases exceed 3 times the upper limit of normal if associated with symptoms of hepatitis (eg, nausea, vomiting) and 5 times the upper limit of normal if the participant was asymptomatic. Treatment was also discontinued if the participant experienced severe adverse events that may have been a drug hypersensitivity reaction (eg, hypotension).

Statistical analyses were conducted using SAS 9.3 (SAS Institute Inc, Cary, North Carolina). Fisher exact test was used to assess the associations between patient sociodemographic characteristics and symptoms or clinical signs with discontinuation of treatment. A *P* value of less than .05 was considered statistically significant.

The BOP Research Review Board determined that this was an evaluation project using a recommended LTBI treatment regimen and did not require a full review and approval. The Centers for Disease Control and Prevention determined that the assessment was standard public health practice.

Results

A total of 463 participants started treatment with INH-RPT. The median age was 36 years (range: 20-71 years); 70% were male. The population treated was 12% white, non-Hispanic, 8% black, non-Hispanic, 2% Asian, 1% American Indian, and 77% Hispanic. Two-thirds of participants were foreign-born and 19.9% were contacts to a known TB case (see Supplemental Digital Content Table, available at <http://links.lww.com/JPHMP/A481>).

Of the 463 inmates treated, 424 (92%) successfully completed treatment. Reasons for discontinuation for 39 (8%) inmates included the following: 17 (44%) signs/symptoms associated with treatment, 9 (23%) transfer or release, 8 (21%) treatment refusal, and 5 (13%) provider error. Five patients who stopped INH-RPT because of symptoms subsequently completed treatment using either INH or rifampin. Asian race was the only characteristic significantly associated with discontinuation of treatment due to an adverse event signs/symptoms related to treatment (Table 1).

Half of the inmates treated reported signs/symptoms while on treatment and 42% of those reported 2 or more signs/symptoms. Overall, the most frequently reported signs/symptoms included fatigue (16%), nausea (13%), and abdominal pain (7%) (Table 2). For those inmates who discontinued treatment because of signs/symptoms, 94% reported experiencing at least 1 sign or symptom, and 71% reported experiencing 2 or more signs/symptoms. The most common signs or symptoms reported among those who discontinued treatment because of an adverse event were nausea (47%), abdominal pain (47%), fever/chills (24%), and sore muscles (24%). Signs/symptoms significantly associated with discontinuation of treatment included abdominal pain ($P < .001$), appetite loss ($P = .02$), fever/chills ($P = .01$), nausea ($P = .03$), sore muscles ($P = .002$), and liver transaminases exceeding 5 times the upper limits of normal ($P = .03$) (Table 3). There was no evidence of cluster effect based on site.

Discussion

In this pilot assessment of inmates in federal corrections facilities receiving the INH-RPT regimen for LTBI given by DOT, the treatment completion rate was 92%. This completion rate was slightly higher than but comparable with those seen in other studies of the INH-RPT regimen including a community INH-RPT clinical trial (82%), a study in a jail setting (85%), and a large postmarketing nationwide survey (87%).^{11,13,14}

Although not assessed here, primary factors contributing to the high treatment completion rate for INH-RPT were thought to include the shorter duration of the regimen and reduced number of doses (76 doses for biweekly 9-month INH vs 12 doses for INH-RPT). In addition, the regimen was generally well tolerated with few patients discontinuing therapy because of signs/symptoms associated with treatment. Recent studies have shown fewer adverse events, including hepatotoxicity, in patients treated with the INH-RPT regimen compared with INH.^{13,15} In this pilot assessment, approximately half of the inmates reported experiencing signs/symptoms, but only a small number of these inmates subsequently discontinued treatment indicating overall good tolerability of the INH-RPT regimen.

An additional contributing factor to the high completion rate was thought to be implementation of procedures to prevent treatment discontinuation due to transfer or release. Past studies have shown that completion is negatively affected by transfer within or between correctional facilities and release prior to completion.^{6–10} In addition, treatment with INH-RPT was not initiated for inmates with projected release dates before the anticipated treatment completion date. The protocol also included placing inmates on “medical hold” during treatment to prevent transfers to other facilities during the treatment. Only 9 inmates in the pilot who discontinued treatment did so because of transfer to another facility or release before completing treatment.

Finally, another factor that may have supported the high treatment completion rate for INH-RPT was a change in the method of medication administration during the pilot assessment that may have improved compliance with treatment. LTBI treatment using INH had traditionally been administered via “pill-line” in which inmates wait in sometimes lengthy lines to obtain treatment. During the pilot, INH-RPT was administered via a special weekly clinic in which participants saw the same health care provider and were placed on a weekly “callout” to keep their appointment. This change in procedure reduced waiting times to receive medication, increased one-on-one interaction between inmates and their health care provider, and included reminders of their appointment using the “callout” system.

Correctional facility populations are potential reservoirs of infection with *M tuberculosis* that, if left untreated, can lead to TB outbreaks and transmission to communities.^{10,16–20} However, jails and prisons are also highly structured environments that provide strategic public health opportunities for containment of infectious diseases, including TB. Screening for TB upon entry into the facility can detect both LTBI and TB disease effectively in incarcerated populations.²¹ Newly incarcerated inmates diagnosed with LTBI can be treated using DOT, an optimal strategy that may be challenging in community-based clinics. The INH-RPT regimen, evaluated in this pilot, offers a very promising alternative to the standard

INH treatment regimens for LTBI with its high completion rates and relatively good tolerability. Broader implementation of the INH-RPT regimen for LTBI in US jails and prisons could substantively enhance national TB control efforts.

This assessment had a few limitations. One important limitation was that relatively small numbers of persons did not complete treatment which limited our ability to assess associations. Also, information on behavioral risk factors (eg, drug use) for LTBI was obtained by self-report, which might have resulted in underestimation of the actual prevalence of these behaviors. Another limitation was the difficulty in tracking outcomes for inmates who were transferred to alternate facilities or released from incarceration; this may have led to an underestimation of treatment completion. Finally, facilities were chosen to participate in the assessment on the basis of a demonstrated capacity to implement the protocol and may not be reflective of facilities throughout the federal prison system; this may have resulted in higher completion rates in these facilities than would be seen among other facilities in the system.

We found in the prison setting that the treatment completion rate for LTBI using the INH-RPT regimen was high and, despite the majority of treated participants reporting 1 or more signs/symptoms during treatment, tolerability of the regimen was good. In addition, the regimen has practical advantages to aid in treatment completion including reduced number of DOT doses and a shorter duration of treatment. The INH-RPT regimen is a viable alternative to standard LTBI regimens in the correctional setting.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Implications for Policy & Practice

- Correctional facilities offer a unique opportunity to provide LTBI treatment to high-risk populations.
- In the past, effectiveness of INH-based regimens for LTBI in correctional settings has been limited by poor treatment completion rates.
- A newer regimen consisting of 12 weekly doses of INH-RPT for the treatment of LTBI can offer practical advantages by reducing the treatment duration and the number of directly observed doses compared with INH monotherapy.
- In this pilot assessment, the treatment completion rate for LTBI was high and tolerability of the regimen was good.
- Based upon the high completion rates and practical advantages associated with 12-week INH-RPT, in 2015 the Federal Bureau of Prisons adopted the regimen as the standard LTBI treatment in its 122 facilities.
- The INH-RPT regimen presents an opportunity to optimize LTBI treatment programs in correctional facilities and enhance the importance of their role in TB elimination efforts.

Characteristics of Participants Receiving 12Weekly Doses of Isoniazid and Rifapentine by Completion Status^a

TABLE 1

Participant Characteristics (n = 463)	Patients Who Completed Treatment (n = 424), n (%)	Patients Who Did Not Complete Treatment Due to Signs/Symptoms Associated With Treatment (n = 17), n (%)	<i>P</i> ^b
Gender			
Male	300 (70.8)	11 (64.7)	.59
Age categories, y			
20-29	95 (22.4)	5 (29.4)	.55
30-39	179 (42.2)	6 (35.3)	.63
40-49	100 (23.6)	4 (23.5)	1.00
50+	50 (11.8)	2 (11.8)	1.00
Race/ethnicity			
American Indian/Alaska Native	6 (1.4)	1 (5.9)	.24
Asian	7 (1.7)	2 (11.8)	.04
Black/African American, non-Hispanic	32 (7.6)	1 (5.9)	1.00
White, non-Hispanic	51 (12.0)	3 (17.7)	.45
Hispanic	328 (77.4)	10 (58.8)	.08
Medical conditions			
Diabetes	27 (6.4)	1 (5.9)	1.00
Mental health disorder ^c	68 (16.0)	5 (29.4)	.18
Renal disease	6 (1.4)	0 (0)	1.00
Hepatitis B	2 (0.5)	0 (0)	1.00
Hepatitis C	30 (7.1)	3 (17.7)	.13
HIV ^d	2 (0.5)	0 (0)	1.00
Risk factors			
Foreign-born	281 (66.3)	13 (76.5)	.44
Contact to TB case	82 (19.3)	4 (23.5)	.75

Abbreviation: HIV, human immunodeficiency virus.

^aValue in boldface indicates statistical significance ($P < .05$).

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Fisher exact test P value.
 p
Not related to substance abuse.
 p
Not on antiretroviral therapy.
 p

Signs and Symptoms Reported Among Participants Receiving 12 Weekly Doses of Isoniazid and Rifapentine

TABLE 2

Reported Signs or Symptoms	All Patients (n = 463), n (%)	Patients Who Completed Treatment (n = 424), n (%)	Patients Who Did Not Complete Treatment Due to Signs/Symptoms Associated With Treatment (n = 17), n (%)	Patients Who Did Not Complete Treatment Due to Other Reason (n = 22), n (%)
Any symptom	240 (51.8)	213 (50.2)	17 (100.0)	11 (50.0)
Two or more symptoms ^a	101 (21.8)	82 (19.3)	12 (70.6)	7 (31.8)
Abdominal pain	31 (6.7)	20 (4.7)	8 (47.1)	3 (13.6)
Appetite loss	10 (2.2)	6 (1.4)	3 (17.7)	1 (4.6)
Diarrhea	9 (1.9)	8 (1.9)	1 (5.9)	0 (0)
Dizziness	17 (3.7)	16 (3.8)	1 (5.9)	0 (0)
Fatigue	72 (15.6)	65 (15.3)	3 (17.7)	4 (18.2)
Fever/chills	13 (2.8)	9 (2.1)	4 (23.5)	0 (0)
Nausea	58 (12.5)	46 (10.9)	8 (47.1)	4 (18.2)
Numbness	16 (3.5)	15 (3.5)	0 (0)	1 (4.6)
Rash/hives	10 (2.2)	7 (1.7)	2 (11.8)	1 (4.6)
Sore muscles	11 (2.4)	6 (1.4)	4 (23.5)	1 (4.6)
Elevated LFTs (3× ULN)	13 (2.8)	11 (2.6)	2 (11.8)	0 (0)
Elevated LFTs (5× ULN)	6 (1.3)	4 (0.9)	2 (11.8)	0 (0)

Abbreviations: LFTs, liver transaminases; ULN, upper limits of normal.

^a Among those who reported at least 1 symptom.

TABLE 3

Signs and Symptoms Reported Among Participants Receiving 12Weekly Doses of Isoniazid and Rifapentine by Completion Status^a

Participants With Reported Signs/Symptoms (Total n = 229)	Patients Who Completed Treatment (n = 213), n (%)	Patients who Did Not Complete Treatment Due to Signs/Symptoms Associated With Treatment (n = 17), n (%)	P ^b
Two or more symptoms ^c	82 (38.5)	12 (75.0)	.01
Abdominal pain	20 (9.4)	8 (50.0)	<.001
Appetite loss	6 (2.8)	3 (33.3)	.02
Diarrhea	8 (3.8)	1 (6.3)	.49
Dizziness	16 (7.5)	1 (6.3)	1.00
Fatigue	65 (30.5)	3 (18.8)	.41
Fever/chills	9 (4.2)	4 (25.0)	.01
Nausea	46 (85.2)	8 (14.8)	.03
Numbness	15 (7.0)	0 (0)	.61
Rash/hives	7 (3.3)	2 (12.5)	.12
Sore muscles	6 (2.8)	4 (25.0)	.002
Elevated LFTs (3× ULN)	5 (2.4)	2 (12.5)	.08
Elevated LFTs (5× ULN)	2 (0.9)	2 (12.5)	.03

Abbreviations: LFTs, liver transaminases; ULN, upper limits of normal.

^aValues in boldface indicate statistical significance (P < .05).

^bFisher exact test P value.

^cAmong those who reported at least 1 symptom.