Latent Tuberculosis Infection Treatment Completion with Self-administered, Once Weekly Isoniazid-Rifapentine under Programmatic Conditions

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Background

- Short-course regimens for latent TB infection (LTBI) have higher completion rates
- 12 doses of once-weekly isoniazid and rifapentine (3HP) by self-administered (SAT) was non-inferior to directly observed therapy (DOT) in the U.S.
- The Denver Metro TB clinic (DMTBC) provides care for patients with latent and active TB in the Denver Metro area

Objectives

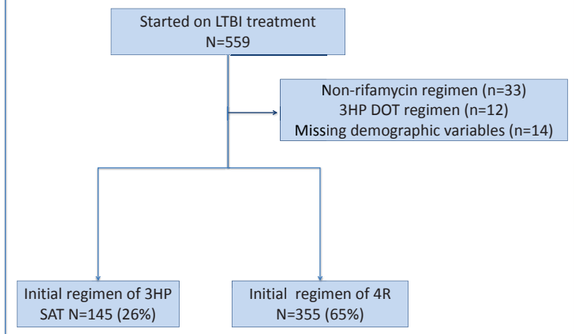
1) Compare completion of once weekly isoniazid-rifapentine (3HP-SAT) to rifampin for 4 months (4R)
2) Describe adverse events among patients receiving 3HP

Methods

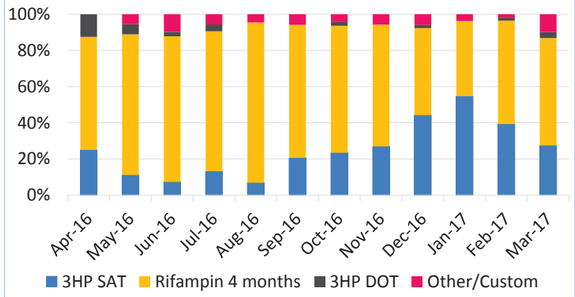
- **Study Design**: Retrospective cohort study
- **Study Population**: Patients started on an initial short-course rifamycin latent therapy plan at DMTBC from 4/11/2016– 3/31/2017. Patients were presented with options to take 4R, 3HP-SAT, or 9 months of INH (9H) unless there were contraindications to a particular regimen.
- **Exclusion Criteria:** Treatment with non–standard LTBI regimen (fluoroquinolone, rifamate); treatment with 9H; active TB diagnosed at any time.
- **Data Collection:** Data was obtained from the electronic medical record; reasons for non-completion were chart reviewed for 3HP-SAT. Patients received 1 month of medications with refills dispensed at follow-up visits. Treatment completion was determined by the pharmacy dispensing data.
- **Statistical Analysis**:
  - Bivariate analyses to compare differences in demographic data for those starting on 3HP-SAT vs. 4R and our primary outcome of treatment completion (t-tests for continuous variables and Chi-Square for categorical)
  - Log-binomial multivariable regression

Results

Figure 1: Enrollment of participants



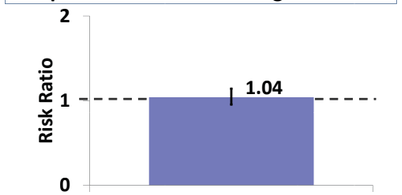
Trends in LTBI regimen starts over time, DMTBC Apr 2016- Mar 2017



Summary of patients started on short-course LTBI treatment 4/2016- 4/2017

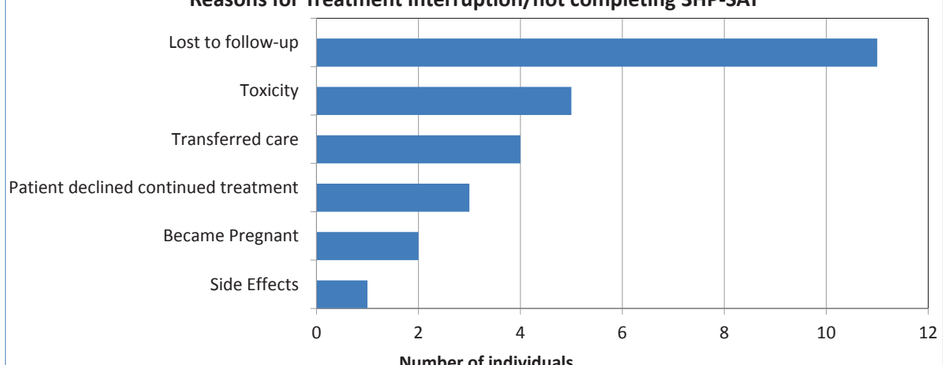
Demographic Characteristics	Overall (N=500)		3HP (N=145)		4R (N=355)		p-value
	n	%	n	%	n	%	
Age, median (IQR)	35 (25-45)		34 (26-45)		32 (23-45)		0.10
Female	277	55%	81	56%	196	55%	0.89
Race/Ethnicity							0.01
Asian/Pacific islander, non-Hispanic	154	31%	31	21%	123	35%	
Black, non-Hispanic	161	32%	47	32%	114	32%	
Hispanic	127	25%	45	31%	82	23%	
Other	20	4%	5	3%	15	4%	
White, non-Hispanic	38	8%	17	12%	21	6%	
Foreign-born	449	90%	128	88%	321	90%	0.47
Primary Language							<0.01
English	158	32%	60	41%	98	28%	
Other	256	51%	59	41%	197	55%	
Spanish	86	17%	26	18%	60	17%	
Insurance at first visit							0.61
Private Insurance	41	8%	14	10%	27	8%	
Medicaid	271	54%	73	50%	198	56%	
Medicare	10	2%	4	3%	6	2%	
Self-pay/Uninsured	178	36%	54	37%	124	35%	
Completed Treatment	**400**	**80%**	**119**	**82%**	**281**	**79%**	**0.46**

Association of LTBI treatment completion with 3HP-SAT regimen vs. 4R



*Adjusted for foreign-born

Reasons for Treatment Interruption/not completing 3HP-SAT



- During the study period there were no hospitalizations and no deaths. One patient had an ALT >4 times upper limit of normal with symptoms after one month of 3HP. This patient eventually completed treatment with rifampin without any recurrence of hepatotoxicity.
- Adverse events were the cause for discontinuation in 6/145 or 4% of all patients

Conclusions

- LTBI treatment completion with 3HP-SAT was similar to 4R under programmatic conditions
- Lost to follow-up was the leading factor associated with not completing
- Adverse events overall were low in 3HP-SAT

Limitations

- Single site, non-randomized retrospective study
- Possible selection bias on the part of providers with regard to offering 3HP-SAT vs. 4R.
- No data on why patients chose 3HP over 4R

Implications

- Additional options for self-administered short course LTBI regimens may increase patient acceptance and completion of treatment.

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