Journal of Clinical Tuberculosis and Other Mycobacterial Diseases 29 (2022) 100332

Contents lists available at ScienceDirect

Journal of Clinical Tuberculosis and Other Mycobacterial Diseases

journal homepage: www.elsevier.com/locate/jctube

Pre-treatment chest X-ray stability duration and tuberculosis disease in San Diego, California, 2012–2017

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ARTICLE INFO

Keywords:
Tuberculosis
Screening
Public health
Immigrant health
Refugee health

ABSTRACT

Background: Overseas screening for tuberculosis (TB) has sought to reduce the burden of active TB in the United States. The duration of time between two unchanged, or stable, chest X-rays (CXRs) taken four to six months apart has been considered clinically useful in the evaluation of suspected pulmonary TB disease, but this relationship has not been previously quantified.
Objective: To investigate the association between pre-treatment CXR stability duration and future clinical or culture-confirmed (Class 3) diagnosis of pulmonary TB in San Diego, California, USA.
Methods: This retrospective record review included County of San Diego TB clinic patients with abnormal CXR results who were started on treatment between 2012 and 2017; multivariable logistic regression was used to analyze the clinical data.
Results: Pre-treatment CXR stability duration of at least four months was not significantly associated with a Class 3 pulmonary TB diagnosis (adjusted odds ratio [AOR], 0.83; 95 % confidence interval [CI], 0.20–3.48), nor was pre-treatment CXR stability duration of at least six months (AOR, 0.97; 95 % CI, 0.30–3.10). Similar results were obtained when four-to-six-month stability was considered (AOR, 0.78; 95 % CI, 0.16–3.89). Patients screened overseas (B1 notification) were less likely to develop Class 3 TB (unadjusted OR, 0.15; 95 % CI 0.05–0.44).
Conclusion: Pre-treatment chest X-ray stability duration was not associated with excluding Class 3 pulmonary TB in this setting, and CXR stability duration cut points may not be as clinically informative as previously understood, but overseas screening is likely an important step in reducing active TB disease burden in the U.S.

1. Introduction

Studies have shown chest X-rays (CXRs) to be valid, sensitive, and cost-efficient tools in the identification of abnormalities suggestive of tuberculosis (TB) disease [1–3], particularly while awaiting mycobacterial culture results. CXRs remain an integral step in ruling out TB disease in individuals who are undergoing diagnostic workup and, in some instances, for those who are being actively screened for disease.

In order to reduce the burden of active TB in the U.S., U.S. Citizenship and Immigration Services requires comprehensive screening for TB; prospective immigrants and refugees at least 15 years of age, or with symptoms of TB, undergo a CXR as part of this screening in their country of origin prior to departure. Acid-fast bacilli (AFB) smears and mycobacterial cultures are then performed for individuals with abnormal CXR results, and those who are AFB smear-negative and subsequently culture-negative after eight weeks are assigned a Class B1 TB, Pulmonary status for the purposes of immigration and given three months to relocate to the United States [4]. These Class B1 individuals then undergo a follow-up evaluation, including another CXR, by their local health jurisdiction upon their arrival in the U.S., which could be up to five months after their initial overseas screening CXR. Upon arrival to the U.S., Class B1 patients with suspect TB disease on CXR may still be

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https://doi.org/10.1016/j.jctube.2022.100332

Available online 11 September 2022

started on empiric TB treatment; if the repeat sputum cultures are negative, a final CXR would be repeated at two months of treatment to differentiate between Class 3 culture-negative TB and Class 4 inactive TB. These individuals thus would have a total of three CXRs as part of their TB screening process.

Patients outside of the Class B1 process may also have multiple CXRs taken during their clinical evaluation for TB. This can happen when (1) a previously taken CXR is not immediately available for review upon referral to a health department, (2) a patient is being monitored for TB off treatment, or (3) when a CXR is used to differentiate between culture-negative and inactive TB.

For all patients undergoing workup, including Class B1 individuals, those with "clinical, bacteriological, and/or radiographic evidence" of active tuberculosis disease upon evaluation of available results are assigned a Class 3 TB designation in the clinic under American Thoracic Society guidelines [5].

Comparison of two or more CXRs can be used to determine if findings have changed over time or if they are stable. Radiographic stability of six months or more has been described as indicative of inactive TB [6–8], but the magnitude and significance of this relationship have not been quantified. One review [9] suggests that even four months of radiographic stability is related to inactive disease. Previous studies [10,11], including multiple cohort analyses [12–15], have used logistic regression modeling to quantify the utility of various diagnostic results in predicting TB diagnoses, including CXR abnormality characteristics. However, neither radiographic stability, nor its duration, were previously considered.

To determine the relationship of pre-treatment CXR stability duration to a future clinical or culture-confirmed (Class 3) pulmonary TB diagnosis, data were analyzed from San Diego County Health & Human Services Agency TB Clinic records. It was hypothesized that having a CXR stability duration of four or six months or more would be negatively associated with a final Class 3 TB disease diagnosis as compared to shorter durations of CXR stability. Other patient characteristics were also collected to help characterize which patients were most likely to be diagnosed with Class 3 TB. The study ultimately intended to better inform future TB clinical decisions regarding empiric treatment for active TB, particularly for patients previously screened overseas. Elements of the current study could be considered to follow up on the work of LoBue and Moser [12], given the project occurred in a similar setting but after new overseas screening requirements were initiated.

2. Methods

2.1. Study design and population

This retrospective medical record review included clinic patients with abnormal CXRs and pending mycobacterial culture results who were empirically started on treatment for pulmonary TB based on suggestive CXR abnormalities using the standard four-drug regimen of rifampin, isoniazid, pyrazinamide, and ethambutol (RIPE) between May 2012 and March 2017 (N = 220). Clinic records included pre-treatment AFB smear results and CXR(s), along with one or more of the following: tuberculin skin test (Mantoux method), interferon-γ release assay (QuantiFERON), and/or nucleic acid amplification test (NAAT) results. All available CXRs were read by the same clinic radiologist; demographic and TB risk factors were obtained from a routine intake form completed by patients. Where applicable, TB screening information from an individual's country of origin was previously added to the charts from the Centers for Disease Control and Prevention's Electronic Disease Notification (EDN) system, a web-based notification platform for conditions of public health significance [16]. Although final TB disease diagnoses were available in the records at the time of data collection, all study variables were compiled in the records prior to the final diagnosis.

Individuals were excluded for having NAAT-positive, smear-positive, or culture-positive results prior to evaluation in the clinic, as they would be indicated for treatment regardless of further evaluation for TB disease. Those who had started TB treatment elsewhere or had an indeterminate TB diagnosis (i.e., lost to follow-up) were also excluded. Among the 193 individuals who were not excluded by these criteria, 47 individuals were excluded for either (A) having only one documented CXR prior to treatment initiation, thus lacking CXR stability duration documentation (N = 28), or (B) having their CXR worsen over time (N = 19), as a worsening CXR is similarly indicated for treatment. The final study population (N = 146) was then eligible for analysis of CXR stability duration (Fig. 1). These patients were followed by the clinic at least until their treatment completion and final diagnosis.

2.2. Variables and statistical analysis

Stability duration was defined as the period of time (in weeks and months) between two CXRs deemed radiologically stable, or unchanged, by the evaluating clinic radiologist's reports in patients' records. By this definition, worsening CXRs were deemed inherently unstable and were excluded. The outcome of interest was a final diagnosis of pulmonary TB disease (Class 3), determined by mycobacterial culture confirmation or clinical improvement in symptoms or CXR findings following TB treatment.

Age, Class B1 TB notification status, CXR abnormality type, and presence or absence of pulmonary TB disease symptoms (cough, night sweats, and weight loss) were considered as potential covariates based on previous studies [12–15]. Class B1 status was also considered as a potential effect modifier due to possible differences between those individuals classified as B1 and those who were not, given the required steps of the B1 screening process. Additional TB risk factor variables, including diabetes, patient's country of birth TB incidence rate (high vs. low), HIV status, and history of homelessness or incarceration, were collected from patient records, although HIV status and history of homelessness or incarceration outcomes were too sparse for reporting here.

Descriptive frequencies of all variables were obtained for the final study population. T-tests compared means across groups; Chi-square and Fisher's exact tests were used to evaluate differences for categorical variables. Univariate associations of all variables with the CXR stability

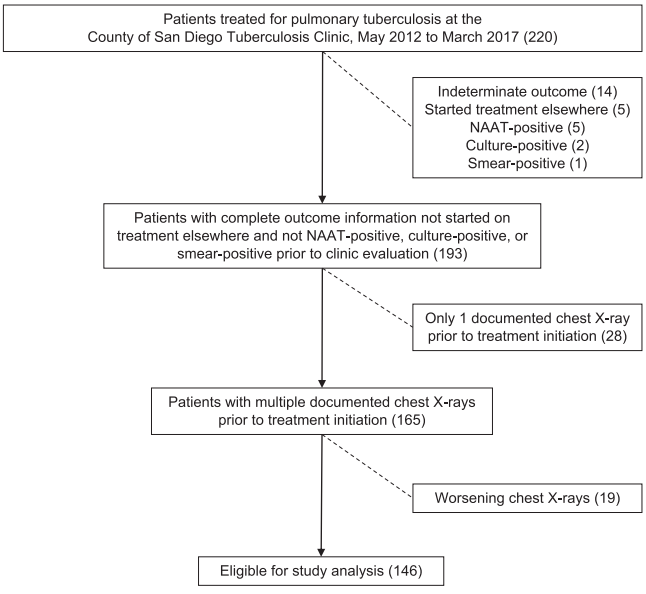

Fig. 1. Final study population selection flowchart.

duration cut-points and Class 3 TB diagnoses significant at $\alpha = 0.20$ identified potentially confounding variables for inclusion in the multivariable logistic regression model [12,14]. Forward-selection model building was used, with a 10 % change in the odds ratio identifying confounders. The association of CXR stability duration and Class 3 TB was modeled in three ways: (1) relative to a four-month cut-point, (2) relative to a six-month cut-point, and (3) relative to both four- and six-month cut-points. The models' goodness-of-fit statistics were evaluated with the Hosmer-Lemeshow test [12,13]. Possible effect modification by TB notification status was assessed using the likelihood ratio test. Analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

2.3. Institutional approval

This study was approved by the San Diego State University Human Research Protection Program and the County of San Diego Health & Human Services Agency's Office of Strategy and Innovation.

3. Results

Overall, patients were predominantly male (53 %), Class B1 TB, Pulmonary notification status (84 %), not diabetic (87 %), and from a high-TB-incidence country of birth (95 %). Distribution of TB risk factors and countries of birth mirrored that of TB disease cases reported in San Diego County [17], with a large proportion reporting the Philippines, Vietnam, or Mexico as their country of birth.

Having one or more infiltrates was the most commonly identified CXR abnormality (76 %), and most patients presented asymptomatically (86 %). Other CXR abnormalities identified included a cavity, nodule, pleural thickening, granuloma, and/or scarring. Seventeen individuals (12 %) were ultimately diagnosed with Class 3 TB, with five culture-positive cases and 12 clinical cases.

Demographic and clinical characteristics (main effects and possible covariates) for the study population (N = 146) are shown by diagnostic outcome in Table 1. Notably, CXR stability duration of four months or more or being Class B1 status were each significantly related to decreased odds of a Class 3 TB diagnosis ($p < 0.05$) in the unadjusted univariate analysis.

3.1. CXR stability duration

Mean CXR stability duration in weeks did not differ significantly between those ultimately diagnosed (19.29 weeks; standard deviation [SD], 17.42) and not diagnosed (28.62 weeks; SD, 25.66) with Class 3 pulmonary TB ($p = 0.15$). CXR stability durations ranged from less than one month to greater than ten months. Approximately 84 % of the study population had a CXR stability duration of four months or more, while only 43 % of the study population had CXR stability durations of six months or more. The final multivariable models are shown in Table 2. Hosmer-Lemeshow Goodness-of-Fit testing demonstrated no significant lack of fit for any of the three models ($p > 0.05$).

After adjusting for age and B1 status in Model 1, CXR stability duration of four months or more was not significantly associated with a Class 3 pulmonary TB disease diagnosis (adjusted odds ratio [AOR], 0.83; 95 % confidence interval [CI], 0.20–3.48) in the multivariable logistic regression. Model 2 results were similar to Model 1: after adjusting for age and B1 status, CXR stability duration of six months or more was not significantly related to a Class 3 pulmonary TB disease diagnosis (AOR, 0.97; 95 % CI, 0.30–3.10). In Model 3, neither a CXR stability duration of four to six months (AOR, 0.78; 95 % CI, 0.16–3.89) nor greater than six months (AOR, 0.88; 95 % CI, 0.19–4.10) was significantly associated with a Class 3 TB outcome.

Interaction terms for B1 status and CXR stability duration were not significant using the likelihood ratio test in Model 1 ($p = 0.09$), Model 2 ($p = 0.17$), or Model 3 ($p = 0.06$). Results were stratified to better understand possible differences occurring by Class B1 TB, Pulmonary status for Model 2 only, as small sample sizes prevented stratification for Models 1 and 3 (Table 3). The stratified adjusted odds ratios were not statistically significant but highlighted differences between B1 (AOR, 1.52; 95 % CI 0.39–6.02) and non-B1 patients' odds of a Class 3 TB diagnosis (AOR, 0.42; 95 % CI, 0.03–5.73).

Table 1
Univariate associations of main effects and possible covariates with Class 3 tuberculosis disease diagnosis among the study population.

Variable	Class 3 tuberculosis cases (N=17) Mean (SD) or N (%)	Non-Class 3 tuberculosis cases (N=129) Mean (SD) or N (%)	*p*-value*
Mean age in years	46 (17)	51 (16)	0.2
Mean CXR stability duration in weeks	19 (17)	29 (26)	0.15
Pre-treatment chest X-ray (CXR) stability duration: 4 months			0.04
≥4 months	11 (65)	111 (86)	
<4 months	6 (35)	18 (14)	
Pre-treatment chest X-ray (CXR) stability duration: 6 months			0.49
≥6 months	6 (35)	57 (44)	
<6 months	11 (65)	72 (56)	
Sex			0.29
Male	7 (41)	71 (55)	
Female	10 (59)	58 (45)	
B1 Classification			<0.01
Class B1 TB, Pulmonary	9 (53)	114 (88)	
Not Class B1 TB, Pulmonary	8 (47)	15 (12)	
Symptoms of TB disease			0.07
Symptomatic	5 (29)	16 (12)	
Asymptomatic	12 (71)	113 (88)	
Chest X-ray abnormality type			0.10
Infiltrate(s)	16 (94)	95 (74)	
Other	1 (6)	34 (26)	

SD = Standard deviation.
*Chi-square and Fisher's exact tests were performed for categorical variables; a *t*-test was performed for age and for CXR stability duration as continuous variables.

4. Discussion

This study was conducted to guide clinical decision-making about empirically treating for active pulmonary TB in patients with stable, abnormal CXRs from multiple time points in a low-TB-incidence public health clinic setting that serves a large number of recently arrived immigrants to the U.S. from high-TB-incidence countries. Our study demonstrated that, after adjusting for covariates, the duration of CXR stability relative to four- and six-month cut-points was not significantly associated with Class 3 TB disease diagnosis. From a clinical perspective, pre-treatment CXR stability duration was not associated with excluding pulmonary Class 3 TB in this patient population.

Despite the lack of statistical interaction by B1 status, there were notable differences in direction and magnitude of the AORs across the strata even though each AOR remained statistically insignificant. These results differ from previously published discussions of the clinical utility of these reference points [6–9], suggesting the four- and six-month stability duration thresholds may not be reliable, particularly among

Table 2
Multivariable logistic regression results showing the association of chest X-ray (CXR) stability duration with a future Class 3 tuberculosis disease diagnosis, after controlling for covariates, and Hosmer-Lemeshow Goodness-of-Fit test p-values.

Variable	Parameter estimate (β)	AOR	95% CI
Model 1 (Hosmer-Lemeshow p = 0.41)			
Pre-treatment CXR stability duration			
≥4 months	−0.19	0.83	0.20–3.48
<4 months		1.00	
Age (years)	−0.01	0.99	0.95–1.02
B1 Classification			
Class B1 TB, Pulmonary	−1.76	0.17	0.05–0.63
Non-Class B1 TB, Pulmonary		1.00	
Model 2 (Hosmer-Lemeshow p = 0.66)			
Pre-treatment CXR stability duration			
≥6 months	−0.03	0.97	0.30–3.10
<6 months		1.00	
Age (years)	−0.02	0.99	0.95–1.02
B1 Classification			
Class B1 TB, Pulmonary	−1.84	0.16	0.05–0.48
Non-Class B1 TB, Pulmonary		1.00	
Model 3 (Hosmer-Lemeshow p = 0.27)			
Pre-treatment CXR stability duration			
>6 months	−0.13	0.88	0.19–4.10
4–6 months	−0.25	0.78	0.16–3.89
<4 months		1.00	
Age (years)	−0.01	0.99	0.95–1.02
B1 Classification			
Class B1 TB, Pulmonary	−1.74	0.18	0.05–0.65
Non-Class B1 TB, Pulmonary		1.00	

AOR = Adjusted Odds Ratio.
CI = Confidence Interval.

Table 3
Stratified analysis of chest X-ray stability duration and Class 3 TB diagnosis by Class B1 TB, Pulmonary status for Model 2.

	Class B1 TB, Pulmonary (N = 123)	Not Class B1 TB, Pulmonary (N = 23)
Model and variable(s)	AOR (95 % CI)	AOR (95 % CI)
Model 2		
Chest X-ray (CXR) stability duration		
≥6 months	1.52 (0.39–6.02)	0.42 (0.03–5.73)
<6 months	1.00	1.00
Age (years)	1.00 (0.96–1.05)	0.96 (0.90–1.03)

AOR = Adjusted Odds Ratio.
CI = Confidence Interval.

high-risk populations. The duration of time between B1 patients' CXRs was likely affected by the overseas screening requirements of negative cultures at eight weeks, followed by the three-month window for travel to the U.S. This may help to explain why many (42 %) of included patients had a CXR stability duration of four to six months.

Further, it is notable that CXR abnormality type and TB symptoms, assessed as possible covariates based on previous studies [13,15], were not included in the final models based on lack of statistical significance in the data. The inclusion of age as a covariate in the model, however, was consistent with previous works [12–15]. LoBue and Moser [12] also found TB notification classification to be significantly related to active TB diagnoses.

4.1. Strengths

This was the first study to quantify the clinical utility of CXR stability duration thresholds among individuals treated for pulmonary TB disease. As the study variables reflect those often available to healthcare providers evaluating patients for TB disease, the results were intended to be generalizable to other clinics with higher burdens of TB relative to the U.S. overall, as well as to U.S. jurisdictions regularly evaluating Class B1 TB, Pulmonary individuals. This study did not compare CXR stability to improvement or instability.

Another notable finding of this study was that Class B1 clinic patients were less likely to ultimately be diagnosed with Class 3 TB as compared to non-B1 patients. This result emphasizes the important role of the overseas screening process with TB cultures in reducing the burden of active TB disease in the United States. This finding may be particularly relevant to clinics empirically starting patients on rifampin, isoniazid, pyrazinamide, and ethambutol (RIPE) treatment, which requires significant staff time, resources, and patient compliance under directly observed therapy. In times of limited public health resources, patients without prior screening may be considered a priority for empiric treatment based on these results.

4.2. Limitations

This study was, however, small, and results may not be widely generalizable to other populations. There were fewer TB cases available overall for inclusion in this study and that of LoBue and Moser [12] relative to the referenced studies conducted in higher-TB-burden countries like Peru [13] and Brazil [14]. It was also subject to selection bias, as patients were included in the convenience sample sequentially between May 2012 and March 2017 as they started RIPE treatment in the clinic. Patients not started on treatment were not considered, and information about prior history of TB was not collected here. The overseas screening of Class B1 TB, Pulmonary individuals resulted in greater availability of information about them at the time of their evaluation in the clinic as compared to non-Class B1 individuals presenting to the clinic for other reasons.

A small proportion (12 %) of the original dataset were excluded for lacking a determinate outcome (i.e., loss to follow-up) or presenting to the clinic with test results prompting immediate treatment initiation. Further, 38 individuals (17 % of the original sample) had only one documented CXR prior to treatment initiation; a high proportion of these individuals were (1) referred for evaluation due to symptoms (24 %), (2) not classified as B1 TB, Pulmonary (74 %), and (3) ultimately diagnosed with Class 3 TB (40 %). The study exclusion criteria may have removed those more likely to be classified as a Class 3 TB case, also contributing to the small number of Class 3 TB outcomes. Models 1 and 3, for example, were influenced by the absence of any individuals with fewer than four months of CXR stability duration who ultimately became a Class 3 case.

Data collection was retrospective in nature and thus limited to information previously documented in patient records, limiting the generalizability of results. The study also included self-reported variables, which may have been unreliable. Finally, the potential limitations to external validity of CXR interpretations resulting from reliance on only one evaluating radiologist should be acknowledged. Good overall inter-reader agreement for evaluating CXR abnormalities, however, has been reported elsewhere [1–3].

4.3. Potential for future research

Future study of CXR stability duration would benefit from a larger, multi-center sample, possibly focusing solely on Class B1 or non-Class-B1 individuals and further investigating of the specific types of CXR abnormalities. Clinicians, public health agencies, and future researchers alike would benefit from a more standardized definition and documentation of pre-treatment CXR stability duration. Subsequent research may be of particular interest as new technologies, such as computer-aided detection systems, become more widely available for evaluating patient CXRs for pulmonary TB disease.

5. Conclusion

In this study population, pre-treatment CXR stability durations of four or six months or more were not significantly related to excluding a diagnosis of Class 3 TB; however, Class B1 TB notification patients screened overseas were less likely to be diagnosed with Class 3 TB. These results were potentially influenced by the selection of the study population, data collection, and existing policies, such as the overseas screening cultures for those with suggestive CXRs, as well as the timing of these procedures and allocated travel time to the U.S. Further research is warranted to explore this topic in other populations.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Consent

This study was approved by the San Diego State University Human Research Protection Program and the County of San Diego Health & Human Services Agency's Office of Strategy and Innovation. Identifying details are not included in this article.

CRediT authorship contribution statement

Casey Barber: Methodology, Investigation, Writing – original draft. **Eyal Oren:** Methodology, Resources, Writing – review & editing, Supervision. **Madeline Slater:** Conceptualization, Methodology, Resources, Writing – review & editing. **Yi-Ning Cheng:** Conceptualization, Methodology, Resources, Writing – review & editing. **Susannah Graves:** Conceptualization, Methodology, Resources, Writing – review & editing, Project administration, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The authors would like to acknowledge Dr. Marisa Moore and the County of San Diego Tuberculosis Control and Refugee Health branch staff for facilitating data collection and analysis efforts.

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