

Burden of latent tuberculosis infection among People living with HIV in Shanghai, China: A 4-year cohort study

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Abstract

Background

Mycobacterium tuberculosis/ human immunodeficiency virus (TB/HIV) co-infection remains a significant global public health challenge. In areas with a lower incidence of TB and HIV, how to elevate screening efficiency while maintaining cost-effectiveness worth further exploration. This study aimed to provide a suitable algorithm for TB prevention and intervention among people who live with HIV (PLHIV) in Shanghai based on a cohort study.

Methods

A 4-year cohort study was conducted from May 2019 to December 2024, enrolling PLHIV from two districts in Shanghai. Participants underwent baseline and annual follow-up assessments using interferon-gamma release assays (IGRA) and questionnaires. Demographic, clinical, and laboratory data were collected.

Results

Among 963 enrolled participants, 857 completed baseline assessments. The baseline TBI prevalence was 6.8% (58/857). Older age and higher CD4 + T-cell count were associated with TBI. During a mean follow-up of 788 days among 615 participants, the IGRA conversion rate was 1.75% per person-year. One case of active TB was diagnosed (incidence rate: 84.33 per 100,000 person-years), occurring in a participant with an indeterminate baseline IGRA result. Participants with indeterminate baseline results had a significantly higher risk of subsequent IGRA conversion or active TB compared to those with negative results.

Conclusion

Given the low prevalence of latent TB infection and active TB among PLHIV in Shanghai, universal preventive treatment is not optimally efficient. The high rate of indeterminate IGRA results at baseline requires focused clinical assessment. A targeted screening and preventive treatment strategy based on local epidemiology and resources should be developed to enhance TB prevention in this population.

Background

Tuberculosis (TB) and acquired immune deficiency syndrome (AIDS) are both chronic infectious diseases caused respectively by *Mycobacterium tuberculosis* (MTB) and human immunodeficiency virus (HIV), whose correlation becomes a growing global public health concern. MTB is a typical opportunistic pathogen which usually under the control of human immune system presenting as tuberculosis infection (TBI) instead of active TB. Owing to impaired immune function, HIV-positive individuals are more susceptible of TBI and are at a constant risk of progressing to active TB through reactivation of TBI[1]. Co-infection of MTB/HIV will accelerate process of both diseases and increase the risk of severe case

and death. According to World Health Organization (WHO)'s Global Tuberculosis Report, 5.8% of the TB patients and 12.2% of the TB death are HIV-related in 2024[2]. Meanwhile, TB is accounted for nearly one-fourth of AIDS-related death in 2023[3]. The severe situation of MTB/HIV co-infection hinders the achievement of "End TB" goal in 2035[2, 4].

Globally speaking, the prevalence of TB/HIV co-infection varies depending on the very different distributions of two diseases. A meta-analysis estimates the prevalence of TB/HIV co-infection ranged from 2.93% to 72.34% in countries except China. [5] Compared to other countries, China has significantly lower burden of co-infection 0.9% (95% CI: 0.6%-1.4%) of TB patients co-infected with HIV[6], and the pooled prevalence of TB is 6.0% (95% CI: 4.0%-7.0%) among people who live with HIV (PLHIV) [7]. However, the burden of TB and HIV are still serious and the uneven distribution of both diseased increases the difficulty of prevention and control especially in low-HIV burden and medium-TB burden regions such as Shanghai. Following WHO's recommendation, Shanghai has started to screen for HIV antigen among TB patients and to systematically screen for active TB PLHIV annually among all patients since 2012[8]. After more than ten years of practice, the inspection rate has significantly improved. However, the current measures seem to reach its limit on finding more active cases. In our previous study, only 0.08% TB patients are newly confirmed with HIV, and 0.21% of PLHIV under management are diagnosed with active TB in 2020[9].

As screening for active patient has decreasing yield, we have moved our focus forward on screening for infectious individuals and provide early intervention. The question in front of us now is how to enhance the screening efficiency while also taking cost-effectiveness into account. In this study, we try to acquire the prevalence of TBI among PLHIV in Shanghai and to build up a cohort to follow-up on the changes of TBI status and the development to TB disease, in order to explore a better algorithm to identify and prevent TBI and active TB cases.

Methods

Study design

This is a cohort study design, including PLHIV under management in two districts of Shanghai, namely Jing'an and Baoshan district, from 2019.5.1 to 2024.12.31. These two districts were selected based on their relatively higher incidence of HIV case report. All patients were examined and treated at Shanghai Public Health Clinical Center (SPHCC), which is the only designated hospital for PLHIV in Shanghai.

All participants were enrolled on the premise of fully understanding of the purpose and procedure of this study. Individuals with a previous history of TB (whether pulmonary tuberculosis, tuberculous pleurisy, or extrapulmonary tuberculosis) within five years or had been underwent tuberculosis preventive treatment (TPT) within five years were excluded.

We provided a standardized questionnaire and an interferon-gamma release assay (IGRA) for every participant at baseline and every follow-up visit unless the former IGRA test was positive. The

questionnaires were developed specifically for this study (see supplementary file 1 and 2). Both baseline and follow-up questionnaires were recorded by trained interviewers including exposure history of active TB patients, susceptible symptoms of TB (cough, hemoptysis, fever, night sweat, and weight loss), weight and height and relative test results. QuantiFERON-TB Gold In-Tube (QFT-GIT; Cellestis, Carnegie, Australia) was used for IGRA. At least 5 ml of blood is needed for QFT-GIT. All tests were performed by qualified technicians in laboratory of SPHCC. Participant with a positive IGRA test excluding clinical evidence of active TB disease is deemed as TBI. All screening and diagnose processes followed the local standard of protocol. Other tests results, such as CD4 + lymphocyte count, HIV virus load, as well as other contagious disease which includes Hepatitis B, Hepatitis C, syphilis and pneumocystis pneumonia as well as tuberculosis diagnosis records were collected from hospital information system of SPHCC.

Data collection and Statistical Analysis

Professionals from Jingan and Baoshan district center for disease control and prevention (CDC) are responsible for the collection and quality control of baseline and follow-up questionnaires. Data were collected by Epidata (Version 3.1) and pre-processed by Microsoft Excel (Version 2010). Statistical analysis was performed by IBM SPSS Statistics (version 20.0) and R (version 4.5.2). A P-value less than 0.05 (two-tailed) was regarded as the level of significance. Logistic regression models were used to evaluate the association between MTB infection status and socio-demographic, clinical and laboratory characteristics. All factors were included into the multivariate linear regression using an enter procedure. Multiple categorical variables were included in the model as dummy variables. Paired T-test, Chi-square, Odds ratio (OR) and 95% confidence interval (CI) were calculated. Due to different enroll and ended follow-up time, we used person day and person year to evaluate follow-up period. And a sankey diagram was plotted to demonstrate the changes in the TB infection status of the study population.

Ethnics approval

The study protocol was approved by the Ethical Review Committee of Shanghai Municipal Center for Disease and Prevention (Approval number: 2019-12). All participants have provided signed informed consent prior to the investigation.

Results

In this study, a total of 963 HIV-positive participants were enrolled. A pilot trial was performed at May 2019 and the formal enrollment initiated at September 2019. The enrollment ceased at December 2021 and the follow-up continued till December 2024. Among those participants, 560 individuals (58.2%) were from Jinan district and 403 (41.8%) were from Baoshan district. After cross-checking with previous TB patients database, one participant was found to have been diagnosed with active TB in 2018, thus was excluded from this study according to the exclusion criteria. The inclusion diagram is displayed in Fig. 1.

Demographic and epidemiological characteristics of the participants at baseline

Among participants enrolled, 857 completed all the required steps at baseline thus was included in further analysis. The median age of the participants was 42.2 years old, and 92.5% of them were male. Most of the participants are previous patients with an average diagnosis time of 4.5 years. A total of 58 individuals tested positive for IGRAs, accounting for 6.8% of the whole cohort. All participants underwent systematic screening for active TB and none was diagnosed. Indeterminate (15, 1.8%) and negative (784, 91.5%) results are counted as TBI negative.

Baseline demographic clinical and epidemiological characteristics are displayed in Table 1. Age and CD4 + lymphocyte count are statistically significant factors in the logistic regression.

Table 1
Logistic regression of demographic, clinical and epidemiological characteristics for the participants at baseline

Variables	All patients (n = 857)	TBI at baseline (n = 58)	P value	Adjusted OR (95% CI)
Gender			0.269	1.989 (0.588–6.722)
male	793(92.5)	55(94.8)		
female	64(7.5)	3(5.2)		
Age Group			0.048	1.237 (1.002–1.528)
17–30	171(20.5)	8(12.5)		
31–40	296(34.8)	17(30.4)		
41–50	152(17.6)	11(19.6)		
51–60	139(15.5)	16(26.8)		
≥ 61	99(11.6)	6(10.7)		
Newly Diagnosed HIV-Positive(within 1 year)			0.169	0.346 (0.076–1.569)
Yes	95(11.1)	2(3.4)		
No	762(88.9)	56(96.6)		
Body Mass Index				
< 18(underweight)	31(3.6)	2(3.5)	0.216	0.705 (0.406–1.226)
18–24(normal)	576(67.2)	42(72.4)		
> 24(overweight)	250(29.2)	14(24.1)		
Suspicious Symptoms			0.971	0.986 (0.466–2.086)
Positive	130(15.2)	9(15.5)		
Negative	727(84.8)	49(84.5)		
CD4 + lymphocyte count			0.018	0.453 (0.235–0.873)
< 400 /μl	314(36.6)	13(22.4)		
≥ 400/μl	543(63.4)	45(77.6)		
HIV virus load			0.418	1.365 (0.642–2.903)
< 20 copies	170(19.8)	10(17.2)		
≥ 20 copies	687(80.2)	48(82.8)		

Variables	All patients (n = 857)	TBI at baseline (n = 58)	P value	Adjusted OR (95% CI)
HBV			0.168	2.497 (0.680–9.171)
Positive	20(2.3)	3(5.2)		
Negative	837(97.7)	55(94.8)		
HCV			0.950	1.068 (0.133–8.567)
Positive	19(2.2)	1(1.7)		
Negative	838(97.8)	57(98.3)		
Syphilis			0.129	0.282 (0.055–1.446)
Positive	75(8.8)	2(3.4)		
Negative	782(91.2)	56(96.6)		
Other infectious diseases			0.471	1.567 (0.462–5.315)
Positive	66(7.7)	4(6.9)		
Negative	791(92.3)	54(93.1)		

Changes of TBI status and immune function during the follow-up period

By the end of the follow-up (December 31, 2024), a total of 615 individuals had completed at least one follow-up, with an average follow-up period of 788 days and a follow-up rate of 71.8%. According to the protocol, 554 of the 799 baseline IGRA negative participants have accepted annually IGRA test. There are 117 (21.1%) and 46 (8.3%) participants underwent the second and the third follow-up IGRA test respectively. Among all the participants, 21 turned positive. Most conversion was detected at the first follow-up test (17, 81.0%) and none positive conversion was detected at the third follow-up period. The average time interval is 466 days for the individuals who converted at first follow-up, 975 for those at second follow-up period, and 646 days for all converted participants. The follow-up positive conversion rate for IGRA was 1.75% per person year. Follow-up indeterminate result is not regarded as a positive outcome in this study.

None of the baseline TBI individual developed to active TB, while one participant has been diagnosed with pulmonary TB, whose baseline IGRA result was indeterminate. It took 505 days from the first test of IGRA to the diagnosis of active TB, with an annualized adjusted incidence density of 84.33 per 100,000. And 3 participants died before the second IGRA test was taken. The change of TBI status is shown in Fig. 2.

Statistical significance of the changes of CD4 cell count, virus load and BMI between baseline and last follow-up test were detected (Table 2). The overall immune related status for all participants is improved, though the degree of improvement in the positive conversion group was only slightly lower than the non-positive conversion group and the difference was not statistically significant.

Table 2
Changes of CD4 count, virus load and BMI between baseline and last follow-up

Pair		means	standard deviation	T	P value
CD4 count	Baseline	501.67	172.96	-6.54	< 0.001
	Last follow-up	548.65			
Virus load	Baseline	8760.4	8554.51	2.66	0.008
	Last follow-up	206.17			
BMI	Baseline	22.58	1.55	-4.95	< 0.001
	Last follow-up	22.92			

Notably, the indeterminate result of IGRA at baseline alerts worse follow-up outcome, which included the only TB patient found in this study and 6.7% positive conversion rate, which is significantly higher than those with baseline negative results at baseline (3.7%, $\chi^2 = 3.20$).

There are 245 participants who haven't accepted a second IGRA test due to various reasons. Although their TBI status couldn't be directly observed by this study, we managed to obtain the information whether they were diagnosed with active TB from annual screening for PLHIV and none of them has active TB diagnose until the end of follow-up.

Discussion

The global challenge of managing TBI in PLHIV necessitates intensified screening and prevention, in alignment with the United Nation's 2030 targets to end TB and HIV/AIDS. This study is designed to answer the question that, what is the most suitable strategy to screening and prevent TBI among PLHIV in Shanghai, China. A total of 963 eligible participants were enrolled from Jing'an and Baoshan District. At baseline, 857 participants completed both IGRA and questionnaire. The demographic characteristics of the included participants are in line with the profile of PLHIV in Shanghai. Taking QFT positive as the TBI criterion, 58 (6.8%) TBI were identified at baseline. By multivariate analysis, we found it's hard to separate between TBI and not infected individuals by most factors, except for age group and CD4 T lymphocyte count.

Similar studies have been taken place in various regions with different demographic and epidemic background with the prevalence of TBI ranged from 4.8% to 25.2%[10–13], thus it is hard to compare the absolute value of the prevalence of TBI due to high heterogeneity between studies concerning local TB

and HIV burden, ART coverage and immune status of sampled subjects. Still, all those studies have reached a consensus that CD4 T lymphocyte count, virus load, ART use, and age are strongly related to tuberculosis infection, which is also agreed with our findings. Especially among individuals with low level of CD4 count, their risk of TBI or active TB is doubtlessly higher but the TBI status may not be detected due to impaired immune function[12, 14]. Thus the subgroup of low CD4 count would be facing a double risk of higher TB infection and false negative of either IGRA or TST. This should be taken into account during policy making process.

In the follow-up period, 615 participants had completed at least one follow-up visit. By the end of December 31, 2024, the average follow-up period were 788 days. At the start of the follow-up, the immune levels of the participants were already higher than individuals in other regions in similar studies. However, it is encouraging to see after more than two years of follow-up, the overall immune levels of the participants have increased, proving that continuous ART has a sustained effect on the control of viral load and the improvement of CD4 lymphocyte level.

There were 1 (0.2%) pulmonary TB patient and 21 (3.8%) participants turned positive among 554 baseline TBI negative or indeterminate participants during follow-up period. No active TB patient was found among IGRA positive individuals and no ex-pulmonary TB patient was found. The prevalence of active TB is 84.33 per 100,000 person year and TBI conversion rate by year is 1.75%. It should also be noted that the conversion rate could not be simply equaled to recent infection, as the special immune status of PLHIV may lead to false negative results at baseline.

Another issue worth to discuss is how to treat individuals with indeterminate result. A meta-analysis shows that the pooled proportion of indeterminate results in IGRA is 3.9% (95% CI: 3.5%-4.2%) in all populations and 5.7% (95% CI: 4.8%-6.6%) in the immune compromised subgroup[15] indicating that indeterminate results are more common in PLHIV. Other than immune status, indeterminate result is also related to factors such as personal condition, co-morbid, interaction of other co-infection and laboratorial operation.[16] In our study, 11.1% of the indeterminate individuals turned to positive during follow-up, the difference is statistically significant comparing to baseline negative participants. It is suggested that long-term follow-up and comprehensive evaluation of the detection results is a strategy to deal with the indeterminate results of IGRA. In some resource limited regions with high TB/HIV co-infection prevalence, the algorithm of defining both positive and indeterminate results as TBI could be adapted to avoid more test.[17] However, considering the characteristics of the epidemic situation in Shanghai and the conditions of health resources comprehensively, it is not recommended to handle the indeterminate result as IGRA positive.

Overall speaking, the baseline TBI prevalence, the follow-up positive conversion rate of TBI and the incidence of active TB obtained in this study were quite different comparing to similar studies in some high TB burden areas such as Brazil[13], Mexico[18] or Ghana[19]. Even in China, the distribution of TB and HIV epidemic varies greatly. A multicentered prospective study in rural China acquired 0.87 per 100 person year after 2 years follow-up among QFT positive population[20] which indicates that even in

China, a fixed policy is not an effective method of controlling TB/HIV. In the latest recommendations from WHO consolidated guidelines, it is recommended to provide universal TPT for PLHIV irrespective of the degree of immunosuppression and even if TBI testing is unavailable. [21] According to our study, this approach may not be directly applicable to China, to be more particularly, to Shanghai, where the proportion of TB patients co-infected with HIV is significantly lower (1.8% nationally, 0.35% in Shanghai) than in regions that informed the WHO guidance (12.8%–56.7%)[22–25]. After integrated consideration, we believe that conducting TPT on the bases of TBI status is a more suitable prevention and control strategy for Shanghai.

There are certain limits of this study. First of all, a large proportion of enrolled individuals are previous diagnosed PLHIV who have been on ART for years. Most of them have already re-established a stable immune function with a relatively high CD4 T-cell level. Secondly, interpreting the results of IGRA can always be troublesome among PLHIV because the false negative rate in this population is not ignorable. Thirdly, it is also hard to differentiate recent or previous infection of MTB if participants are IGRA positive at baseline.

In conclusion, in light of the low prevalence of TBI and the low incidence of active TB among PLHIV in Shanghai, the implementation of universal TPT for all PLHIV may not represent the most efficient prevention strategy in this setting. The occurrence of indeterminate IGRA results warrants intensified attention, underscoring the need for enhanced interdisciplinary interpretation during the screening process. It is therefore recommended that tailored algorithms for TBI screening and risk-stratified management be developed, taking into account local epidemiological patterns and resource availability, in order to implement a targeted TPT approach and optimize the overall effectiveness of TB prevention and care among PLHIV in Shanghai.

Abbreviations

TB: Tuberculosis

AIDS: acquired immune deficiency syndrome

MTB: *Mycobacterium tuberculosis*

HIV: human immunodeficiency virus

TBI: tuberculosis infection

WHO: World Health Organization

PLHIV: people who live with HIV

TPT: tuberculosis preventive treatment

IGRA: interferon-gamma release assays

SPHCC: Shanghai Public Health Clinical Center

OR: odds ratio

CI: confidence interval

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Ethical Review Committee of Shanghai Municipal Center for Disease and Prevention (Approval number: 2019-12). All participants have provided signed informed consent prior to the investigation.

Clinical trial

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The data in this study were collected by questionnaires and the hospital information system of SPHCC. We would like to share statistical results of this study. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors state that they do not have any conflicts of interest.

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Author contributions

Rao designed the questionnaire and the survey process, performed the statistical analysis and wrote the article. Gu was in charge of implementing the on-site survey in Jing'an District, including cohort establishment, cohort management, and follow-up retention. Yang was in charge of implementing the

on-site survey in Jing'an District, including cohort management, questionnaire collection and quality control for data entry. Le was responsible for implementing the on-site survey in Baoshan District, including cohort establishment, cohort management, and follow-up retention. Zhang was responsible for implementing the on-site survey in Baoshan District, including cohort management, questionnaire collection and quality control for data entry. Chen provided technical support, including coordination of medical institutions and public health institutions. Ning provided technical support, including coordination of medical institutions, statistical analysis suggestions and quality control. Yue provided technical support, including coordination of medical institutions, statistical analysis suggestions and quality control. Zhu was responsible for coordinating laboratory testing. Shen was responsible for overall coordination and review of the paper for finalization.

All authors read and approved the final version of the paper.

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Figures

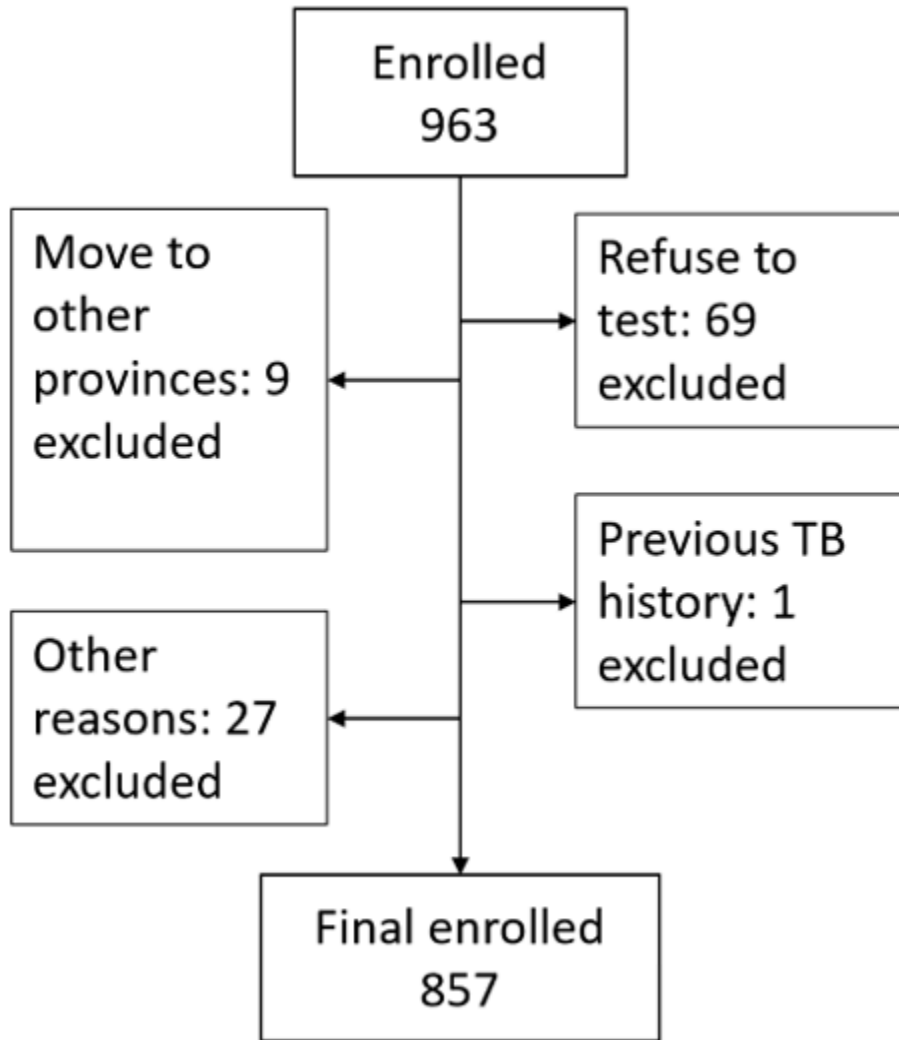


Figure 1

Flowchart of enrollment

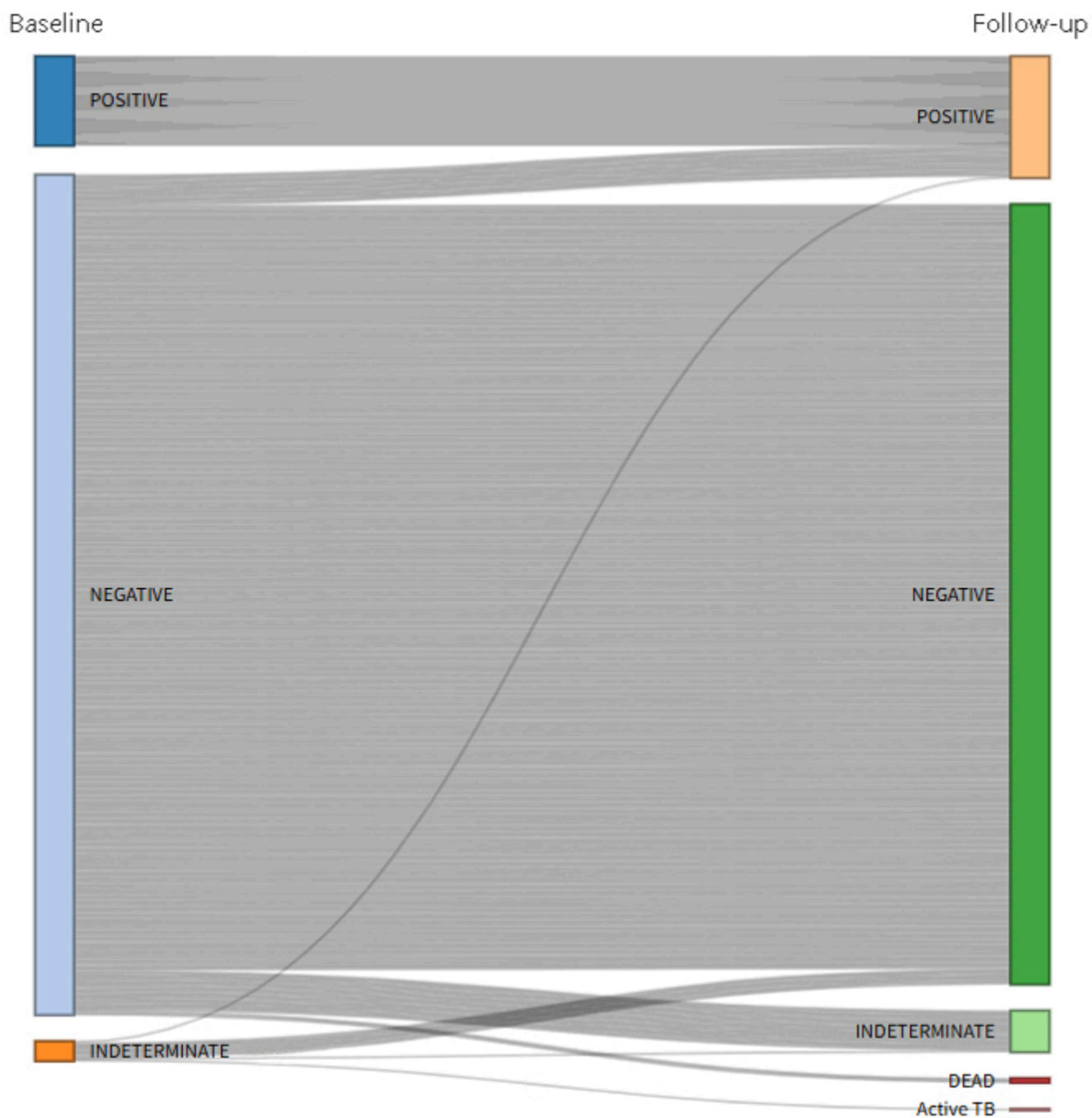


Figure 2

Sankey diagram on the change of TBI state during follow-up period

Supplementary Files

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- [Questionnaires.pdf](#)