Original Article

DOI: 10.5582/bst.2013.v7.3.122

Factors affecting patient delay of diagnosis and completion of Direct Observation Therapy, Short-course (DOTS) among the migrant population in Shandong, China

Ruoyan Gai Tobe[1], Lingzhong Xu[1,*], Chengchao Zhou[1], Qing Yuan[1], Hong Geng[2], Xingzhou Wang[1]

[1] *Department of Health Management and Maternal and Child Healthcare, School of Public Health, Shandong University, Ji'nan, China;*
[2] *Shandong Province Tuberculosis Prevention and Control Center, Ji'nan, China.*

Summary **In China, the epidemiological and socioeconomic status of the migrant population suggests that the vulnerable population should be prioritized for tuberculosis (TB) control. A face-to-face interview using a structured questionnaire was performed on a total of 314 smear-positive pulmonary TB patients among the migrant population of 12 randomly selected counties in Shandong Province, China. From the results, the cases of patient delay of diagnosis accounted for 40.8%, and the completion rate of Direct Observation Therapy, Short-course (DOTS) was as low as 67.2%. There were 47.1% missed cases in the first diagnosis. Factors affecting detection and treatment were present in their socioeconomic status, working style, and the accessibility to related TB care. The findings indicated that migrant TB patients suffer delayed diagnosis, a low case detection rate and a low completion DOTS rate. Improvement of migrants' working conditions and accessibility to specialized TB care is essential and is expected to lead to better case detection and treatment completion.**

Keywords: Migrant population, tuberculosis, direct observation therapy, short-course (DOTS), China

1. Introduction

China has the world's second largest tuberculosis (TB) disease burden. The Chinese government has a political commitment for TB control, with an increased financing investment during the past ten years. As the results show, from 2000 to 2009, the prevalence of TB has declined from 466 per 100,000 to 459 per 100,000, and active cases decreased from 169 per 100,000 to 66 per 100,000 (*1*). Direct Observation Therapy, Short-course (DOTS) strategy has universally covered TB patients and the cure rate of active TB cases by DOTS reached over 90% at the county level, the global target for TB control (*2*).

**Address correspondence to:*
Dr. Lingzhong Xu, Department of Health Services Management & Maternal and Child Healthcare, School of Public Health, Shandong University, Wen-hua-xi Road No.44, Ji'nan City, Shandong Province, 250012, China.
E-mail: lzxu@sdu.edu.cn

In China, case management for the migrant population remains as one of the major challenges. With rapid economic growth and urbanization, the number of the rural-to-urban migrant population is estimated to reach to 211 million in 2010, and it will be continuously increasing in the up-coming several decades (*3*). After moving to the urban area, most of the rural-to-urban migrant population tends to be engaged in work with the poor environment, heavy loads, high risks, but low payment. They are exposed to a higher risk of TB infection due to the poor living and working environment, bad nutritional status and the characteristics of frequent migration. To the contrary, their accessibility to healthcare is often seriously restricted by their citizenship and their poor financial conditions (*4*). So far, due to civil registration status and temporary employment, most of the migrant population are not eligible for urban citizen medical insurance and has to pay out-of-pocket for healthcare services. The medical costs in the urban area are

much higher than those in the rural area, restricting their access to medical care when they become ill (*5*). Compared to urban residents they face longer delays in obtaining a TB diagnosis (*6*). Because the vulnerable population has brought a significant influence on the epidemiological status of TB control in the immigrated regions, particularly metropolitan areas, this suggests an urgent necessity for TB control strategies targeting them in the urban area (*7-9*).

China has recently implemented a free TB treatment policy that now covers the migrant population as well. The free service package includes diagnostic and treatment services, such as a free sputum smear test, a free X-ray examination upon one's initial visit, and free anti-TB drugs in accordance with the standard protocol (6 months for new patients and 8 months for re-treated patients). Nevertheless, barriers to TB detection, management and treatment among the migrant population continue to have both financial and non-financial aspects including poor health literature and social stigma in the working place, based on the review of previous qualitative studies (*10*). Due to their frequent moving, migrant TB cases are difficult to be managed and provided related healthcare services. Our previous study suggested a relevant number of rural-to-urban migrant workers defaulted or failed DOTS, leading to the actual gap between the surprisingly low success rate of DOTS in the rural field and that officially reported (*11*). Once the migrant workers default or fail treatment but leave for work, it potentially causes the spread of the disease and leads to a huge risk to public health. Moreover, deficient case management and irregular treatment leads to high-risk development and spread of drug-resistant tuberculosis (*12*), which is now another serious problem in TB control in China, paralleling the high burden among the migrant population. Once drug resistance occurs, it brings severe difficulties for treatment and case control, as current anti-TB drugs are limited in number (*13*). A study in eastern China also indicated that previously treated migrant patients were more likely to harbor drug-resistant TB and MDR-TB than new migrant cases (*14*). It is necessary to investigate case detection in patients and completion of DOTS among the migrant population, in order to find an effective way of case detection, management and treatment. Therefore, the objective of this study is to assess factors affecting delay of patient diagnosis and completion of TB treatment by DOTS among the migrant population.

2. Materials and Methods

2.1. *Study design*

This was a cross-sectional study conducted during the period from September to October 2009 in Shandong Province, the second largest province in China with a population of 96.7 million. The amount of the migrant population in Shandong Province has increased, and in 2008 it reached 6,910,000 (*15*). A huge amount of funds from the national government and international organizations has been injected into the TB control program (*16*). In 2008, there were 38,885 newly-enrolled cases and 4,320 re-enrolled cases reported for the treatment regimen in total, and 76.55% of the cases were rural residents (*17*).

The study subject is smear-positive pulmonary TB patients in the migrant population registered in the local County TB dispensary (CTD). The inclusive criteria were *i*) non-permanent residents in the study sites, *ii*) continuously working or living in the study sites for more than 3 months, and *iii*) registered in the CTD of the study sites and closed DOTS during the period from September 2008 to August 2009. A multi-stage random sampling was performed to recruit participants. First, a total of 141 counties in the province were grouped into 12 clusters based on socioeconomic and demographical status, which indicators included GDP per capita in 2008, population number, population density, amount of migrant population, work status, maternal & infant mortality, and compulsory education receiving rate. One county from each cluster was randomly selected, and the total number of the study sites came to 12 counties. Then, all patients meeting the inclusive criteria were recruited. In total, there were 314 migrant TB patients enrolled in the study.

2.2. *Data collection and quality control*

Migrant TB patients were face-to-face interviewed in the local CTD using a structured questionnaire, which included demographic and socioeconomic characteristics of participants, working, living conditions and life style, accessibility to health services, seeking healthcare services including severity of onset symptoms and the time interval from the first onset of symptoms to visiting a formal health care facility, and implementation, compliance and results of treatment course by DOTS. For those who could not return to the study sites during the period, we implemented a telephone interviewusing the same questionnaire. For quality control, a pilot study was implemented at non-study sites in 2008, to check the technical and logistical aspects of the investigation, including deficiencies in study design, the questionnaire and guideline for investigators and potential bias in the field survey. The investigators consisted of researchers in the School of Public Health, experts in Shandong University, Shandong Province Tuberculosis Prevention Center, and staffs from CTD of the study sites.

2.3. *Definitions*

- The migrant population refers to those non-

registered residents currently living in the study sites for more than 3 months or expected to live there for more than 3 months.

- Patient delay of diagnosis refers to more than two weeks time interval from the first onset of tuberculosis symptoms until visiting a formal health care facility (health centers, CTD, hospitals).
- According to the national guideline, "completion of treatment" refers to patients that completed the concentrated course of six months and were recorded as having at least one negative smear specimen result; "default" is defined as a patient who definitely stopped medicine for more than two months before completion of the concentrated course; "failure" is a smear-positive patient that had a positive result at the end of the fifth month.
- Regarding types of registration, a new patient refers to those who were newly diagnosed and registered in a CTD; while a re-enrolled patient was one who was recorded as treatment default or failure and was re-registered for DOTS.
- Consulting with clinical experts, severities of the onset symptoms were categorized in three levels: mild symptoms such as coughing up of sputum, night sweats; moderate symptoms such as chest pain, low weight and low fewer; and severe symptoms such as high fever and hemoptysis.

2.4. *Data analysis*

The data were entered and analyzed using SPSS 18.0 for Windows (SPSS, Inc., Chicago, USA). Descriptive and inferential analyses were performed as appropriate. χ^2 test was employed for univariate analysis. Moreover, a Multi-logistic regression model was developed to further assess the impact of variables on treatment outcomes.

2.5. *Ethical consideration*

The Ethical Committee of Shandong University approved this study. This investigation was conducted after the informed consent of all participants were obtained.

3. Results

3.1. *Demographic and socioeconomic characteristics*

Major demographic and socioeconomic characteristics of the surveyed patients are summarized in Table 1. There were 57.3% migrant patients working more than five days per week and 34.1% whose working time was over 8 hours. Regarding household economic status, 290 surveyed TB patients reported poor or moderate level in the study sites and 28.7% of their household bears debt. There were 64.6% of the surveyed TB patients not covered by any medical insurance. Regarding their enrollment into DOTS, 94.6% were registered as new patients in CTD and the rest were re-enrolled patients. For the distance to the closest community healthcare centers, 31.5% spent less than five minutes from living or working place to the destination, 31.2% spent 5 to 10 minutes, 24.5% spent 10 to 30 minutes, and 12.7% spent more than 30 minutes.

Table 1. Demographic and socioeconomic characteristics

Items	Frequency (%)
Gender	
Male	199 (63.4)
Female	115 (36.6)
Marital status	
Single	140 (44.6)
Married	163 (51.9)
Divorced/Widowed	11 (3.5)
Education	
Illiteracy and primary education	59 (18.8)
Middle school	126 (40.1)
High school and above	129 (41.1)
Type of householeld	
Rural residency	277 (88.2)
Urban residency	37 (11.8)
Household economic status in the study sites	
Good	24 (7.6)
Moderate	222 (70.7)
Poor	68 (21.7)
Household debt	
Yes	224 (71.3)
No	90 (28.7)
Working days per week	
≤ 5 days	134 (42.7)
> 5 days	180 (57.3)
Whether a welfare household	
Yes	17 (5.4)
No	297 (94.6)
Medical insurance	
Yes	111 (35.4)
No	203 (64.6)
Time spending on visiting the nearest health facilities	
less than 5 minutes	99 (31.5)
5 to 10 minutes	98 (31.2)
10 to 30 minutes	77 (24.5)
30 minutes or more	40 (12.7)
Severity of onset symptom	
Mild	120 (38.2)
Moderate	131 (41.7)
Severe	63 (20.1)

3.2. *Patient delay of diagnosis*

The average and median time interval from the first onset of tuberculosis symptoms until visiting a formal health care facility were 18.8 days and 10 days, respectively. Among the surveyed TB patients, the cases of patient delay of diagnosis accounted for 40.8%. As shown in Figure 1, 59.2% of the TB patients had a time interval less than two weeks, 16.3% had a time interval between two to four weeks, and 24.5% had a time interval more than four weeks. Regarding the health care facility the TB patients first

visited, 31.8% went to village or community health centers and 40.8% selected county general hospitals. In their first visit to health care facilities, only 52.9% of the cases were initially diagnosed as TB while the rest were missed. Less than half of the participants knew about the national free TB treatment policy (41.7%).

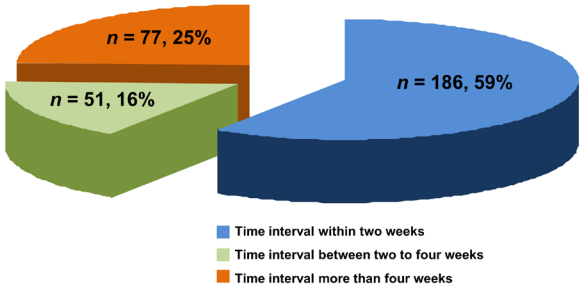

Figure 1. Proportion of patient delay of diagnosis.

We performed univariate and multivariate analysis for factors contributable to patient delay of diagnosis. Chi-square test, Fisher's exact test and Kruskal Wallis H test were employed for univariate analysis. As shown in Table 2, working days per week ($p < 0.001$), status of medical insurance ($p < 0.05$), time spent on visiting the closest health facilities ($p < 0.05$), status of a welfare household ($p < 0.05$), annual income ($p < 0.05$), and severity of onset symptoms ($p < 0.05$) significantly affected patient delay diagnosis. Variables associated with patient delay where $p < 0.05$ in the univariate analysis was subsequently included in the multivariate logistic regression model. As for the results, TB patients working more than five days every week, those that don't have any medical insurance, those spending more than 30 minutes on visiting the closest health facilities, those with a poorer annual income, those coming from a welfare household, and those with mild onset symptoms, were much more likely to have a delay of patient diagnosis.

Table 2. Multivariate analysis of factors affecting patient delay of TB diagnosis

Items	Not delayed % (n = 186)	Delayed% (n = 128)	p (univariate analysis)	OR (95% CI)	p (logistic regression model)
Gender					
Male	60.8	39.2	0.457		
Female	56.5	43.5			
Marital status					
Single	59.3	40.7	0.953		
Married	58.9	41.1			
Divorced/Widowed	63.6	36.4			
Education					
Illiteracy and primary education	57.6	40.1	0.924		
Middle school	58.7	41.3			
High school and above	60.5	36.5			
Type of household					
Rural residency	58.5	41.5	0.458		
Urban residency	64.9	35.1			
Household economic status in the study sites					
Good	62.5	37.5	0.127		
Moderate	62.2	37.8			
Poor	48.5	51.5			
Household debt					
Yes	60.0	40.0	0.861		
No	58.9	41.1			
Working days per week					
≤ 5 days	75.4	24.6	<0.001	1	
> 5 days	47.2	52.8		3.39 (1.98-5.79)	<0.001
Whether a welfare household					
Yes	35.3	64.7	0.039	1	
No	60.6	39.4		0.30 (0.10-0.94)	0.039
Medical insurance					
Yes	68.5	31.5	0.014	1	
No	54.2	45.8		1.97 (1.14-3.43)	0.016
Time spending on visiting the nearest health facilities					
less than 5 minutes	63.6	36.4	0.007	1	
5 to 10 minutes	59.2	40.8		1.36 (0.71-2.57)	0.354
10 to 30 minutes	66.2	33.8		0.80 (0.40-1.57)	0.511
30 minutes or more	35.0	65.0		2.52 (1.07-5.95)	0.035
Severity of onset symptom					
Severe	53.3	46.7	0.034	1	
Moderate	58.0	42.0		0.87 (0.49-1.52)	0.618
Mild	73.0	27.0		0.35 (0.16-0.75)	0.007

Table 3. Multivariate analysis of factors affecting DOTS completion

Items	Completed % (n = 211)	Not completed % (n = 103)	p (univariate analysis)	OR (95% CI)	p (logistic regression model)
Gender					
Male	65.4	34.6	0.587		
Female	70.0	30.0			
Marital status					
Single	68.5	31.5	0.919		
Married	66.7	33.3			
Divorced/Widowed	60.0	40.0			
Education					
Illiteracy and primary education	62.5	37.5	0.859		
Middle school	67.9	32.1			
High school and above	68.8	31.2			
Type of household					
Rural residency	65.5	34.5	0.402		
Urban residency	80.0	20.0			
Individual annual incom					
Forth quartile	86.7	13.3		1	
Third quartile	78.3	21.7		2.03 (0.91-2.69)	0.067
Second quartile	70.8	29.2		4.25 (2.61-6.86)	0.034
First quartile	50.0	50.0	0.021	6.22 (3.33-9.36)	0.022
Household debt					
No	71.1	28.9	0.031	1	
≤ 10,000 RMB	68.4	31.6		0.28 (0.03-2.67)	0.267
> 10,000 RMB	433.3	66.7		33.01 (1.17-93.21)	0.04
Proportion of medical expenditure for TB treatment in the annual income					
< 30%	76.6	23.4	0.005	1	
≥ 30%	52.9	47.1		0.77 (0.07-8.97)	0.835
Working days per week					
≤ 5 days	61.0	39.0	0.169		
> 5 days	72.5	27.5			
Status of medical insurance					
No	60.7	39.3	0.018	1	
Yes	82.1	17.9		0.06 (0.004-0.69)	0.024
Severity of onset symptom					
Severe	46.2	53.8	0.014	1	
Moderate	66.7	33.3		1.21 (0.14-10.82)	0.864
Mild	80.0	20.0		0.14 (0.01-2.69)	0.193
Adherence to drug intake and health check					
Yes (n = 299)	69.7	30.3	0.024	1	
No (n = 15)	16.7	83.3		6.14 (4.29-9.17)	0.011
Full-course supervision by community health staffs					
Yes (n = 211)	75.6	24.4	0.011	1	
No (n = 103)	51.2	48.8		12.79 (3.21-51.01)	0.019

3.3. *Completion of DOTS*

Among the 314 cases, the completion rate was 67.2% (211/314). During the duration of treatment, patients self-reported good adherence to daily drug intake and regular health checks accounted for 95.2% (299/314) and the proportion of participants that received full-course supervision by community health staffs was 59.2% (211/314).

Besides univariate analysis, we performed a multivariate logistic regression to control possible confounding of the influence on treatment outcomes. Individual annual income, household debt, status of medical insurance, proportion of medical expenditure for TB treatment in the annual income, adherence to drug intake and health checks, and full-course supervision by community health staffs were identified as independent factors affecting completion of DOTS (Table 3).

4. Discussion

Among migrant TB patients registered in twelve counties of Shandong Province, our study identified a relevant amount of migrant TB patients with delayed diagnosis (40.8%) and who did not complete DOTS (32.8%). Delayed TB diagnosis and treatment outcomes of migrant TB patients were reported poor elsewhere in urban China as well. The cure rate of smear-positive TB patients was 55% in migrants in Shanghai (*18*). Similar results were reported in Beijing that the cure rate among the smear-positive migrant population was 49% (*19*). The delayed diagnosis in our study was lower

than in a previous study, reporting that 68% of migrants delayed for more than two weeks before seeking care for symptoms suggestive of TB, in Chongqing (*6*).

The study results confirmed there is an economic barrier to accessing TB diagnosis, even though recently the free TB treatment policy has been widely provided to those registered migrant patients as well in TB dispensaries. Poor financial and insured status is closely related to the migrant population's seeking diagnosis and completion of DOTS, as indicated in several previous studies (*6,20-21*). The free treatment covered drug use, healthcare and medical tests during DOTS; but not additional treatment for side effects such as liver protection drugs. On the other hand, the costs of seeking health care and referral from general hospitals still represented a heavy financial burden. Our survey suggests the limited impact of such a free treatment policy on their financial burden, finding that medical expenditure for TB treatment still accounted for a relevant proportion of their annual income. Therefore, substantially, besides the basic package of TB treatment, the range of reimbursement should be extended and cover those additional but necessary costs in the process of case detection and treatment. Improvement in medical insurance and social security for migrants is crucial for the effective control of TB in China (*22-23*).

Moreover, we found the initial case detection rate among the participants was 52.9%, which did not meet the goal of 70% case detection made by the World Health Organization (WHO) (*24*). Delayed case detection leads to not only potential risk to public health, but also an increased financial burden for the patients due to the prolonged treatment process. Our study found that a relevant number of participants sought diagnosis at community health centers and general hospitals, rather than TB dispensaries, which provide a free TB treatment course and are recommended as the best one compared to other healthcare facilities such as community health centers and general hospitals. Community health centers tend to respond to basic healthcare and public health services, and the technical capacity for case detection is limited; while general hospitals provide advanced healthcare services and has less specialization for TB. The costs attending general hospitals are much more expensive than that in TB dispensaries, leading to the heavy financial burden for the patients (*25*). Deficient knowledge about the free treatment provided by TB dispensaries among migrant patients contributes to the low initial case detection rate and needs to be addressed.

We found that those working more than five days per week tended to have a higher proportion of patient delay. Recently in China, most migrant populations are working in a poor environment, such as prolonged working hours and lack of vacation. Relevant workers are working overtime forcibly or for economic incentives. Therefore, working conditions profoundly affect health care seeking behavior and TB detection. Moreover, the fact indicated in this study that knowledge of TB and the current free treatment policy are deficient among the migrant population and may further make the barrier difficult to seek diagnosis. Delay of TB diagnosis has not only a negative impact on treatment outcomes, but also potential to spread the disease in the working place. Strategies need to focus on strengthening their labor, medical security and health education (*23*).

Full-course supervision by health workers with regular follow-up and patient's adherence significantly improved DOTS completion, as it has been reported significant among other populations as well (*11,26*). On the other hand, due to various reasons, for example, long working times and irregular living places on the patient's side and lack of human resources and budgets on the health worker's side, recently it is often difficult to implement full-course supervision for migrant TB patients. Therefore, measures to ensure full-course supervision for migrant patients remains an important issue in the local health system.

We admitted that there have been some limitations in this study. First, we targeted those TB patients registered in CTD, which was the only feasible way to access the population. Because a relevant proportion of migrant patients were unable to be accessed due to the characteristics of migration and the potential social stigma to such a vulnerable population, the sample may have a constrained representativeness. Moreover, due to a retrospective study design, migrant TB patients may have a recall bias as their answer. Nevertheless, the questionnaire focused on what happened during the year prior to the study, in order to reduce the bias.

In conclusion, the results of this study indicated that problems remain in the surveyed migrant TB patients such as delayed diagnosis, low case detection rate, lack of knowledge on the national free treatment policy and a low completion rate of DOTS. Factors affecting detection and treatment were present in their financial conditions, working condition, and accessibility of related TB care. Due to additional costs, the free treatment policy has a limited impact on reduction of their financial burden. Improvement of migrants' working conditions and accessibility of specialized TB careis essential and is expected to lead to better case detection and treatment completion.

Acknowledgements

This study is granted by Chinese Tuberculosis Control Program of the Global Fund to Fight AIDS, Tuberculosis and Malaria and China Center for Disease Control and Prevention (Fund ID: TB08-004) and Shandong Excellent Young Scientist Research Award

Fund (Fund ID: BS2012SF010). We wish to express our sincere thanks to the officers of local health agencies and all participants and staffs at the study sites for their cooperation.

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(Received February 11, 2013; Revised April 1, 2013; Re-revised June 5, 2013; Accepted June 10, 2013)