Prevalence of and Factors Influencing Anti-Tuberculosis Treatment Non-Adherence Among Patients with Pulmonary Tuberculosis: A Cross-Sectional Study in Anhui Province, Eastern China

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Background: To assess the non-adherence rate among pulmonary tuberculosis (TB) patients in Anhui Province, eastern China and to explore the influential factors, so as to identify targets for intervention.

Material/Methods: A total of 339 TB patients were recruited from TB dispensaries in 8 counties of Anhui Province, eastern China using a stratified sampling method. All study subjects were surveyed using a structured questionnaire. Differences between groups involving categorical data were analyzed using the chi-square test.

Results: Overall, of the 339 patients, 33.63% missed medication. Divorced and widowed patients were more likely to miss medication compared with those who were married or unmarried (P < 0.01). Regarding the knowledge related to topics such as transmission route, preventive measures, and suspicious symptoms, the awareness rate in the group with good medication compliance was higher than in the group with poor compliance (P < 0.05). We found that compliance was not significantly associated with seeking medical treatment in professional institutions, the national free TB treatment policy, or discrimination (P > 0.05). The rate of non-compliance under supervision (26.10%) was lower than that without supervision (64.18%) (P < 0.001).

Conclusions: The anti-TB treatment non-adherence rate in TB patients is relatively high in Anhui Province, eastern China, and is associated with marital status, annual income, TB knowledge, and medical staff visits.

MeSH Keywords: Factor Analysis, Statistical • Patient Compliance • Tuberculosis

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Background

Tuberculosis (TB) remains a major public health problem globally despite the fact that the causative organism has been known for more than 100 years, and highly effective drugs and vaccines have been available for decades [1]. China has one of the highest burdens of TB worldwide and it ranks second among the 22 high-burden countries in the world [2]. In order to control the TB epidemic, China has implemented the Directly Observed Treatment Short Course (DOTS) strategy, which has been promoted vigorously by the World Health Organization (WHO) since 1991 and has provided universal coverage for patients with TB. Furthermore, all diagnosed TB cases (including new and relapsed patients) are required to be registered at the local TB dispensaries (LTD) and reported to upper-level health authorities in China. As a result, the cure rate of active TB cases has reached over 90% [3].

However, with the emergence of pulmonary TB multidrug-resistant (MDR) or extensively drug-resistant strains (XDR), treatment outcome of the disease is getting increasingly worse, contributing to prolonged duration of infectiousness and continued transmission [4–7]. Hence, it is of great importance to determine the risk factors leading to the emergence of MDR-TB strains to improve its overall management. As a consequence of global concerns about this problem, many studies have found that poor patient adherence to anti-TB treatment is the main risk factor [8]. Many TB patients do not complete their 6-month course of anti-TB medications and are not aware of the importance of sputum re-examinations, thereby putting themselves at risk of developing multidrug-resistant and extensively drug-resistant forms of tuberculosis and relapse [9]. According to the WHO, adherence to TB treatment is the extent to which a patient’s medication-taking coincides with the prescribed treatment. Those who have completed treatment (directly observed therapy strategy, DOTS) or are cured correspond to adherents, and the patients who do not complete treatment correspond to non-adherents [10]. Non-adherence to TB treatment threatens the success of treatment, increases the risk of TB spread, causes drug resistance, and increases morbidity and mortality [4,11–13]. Many quantitative studies have investigated risk factors associated with poor adherence to anti-TB treatment [9,14,15]. However, few studies have examined the relationship between socio-economic determinants and treatment adherence. Thus, the aim of this study was to assess the adherence rate among pulmonary TB patients in Anhui Province, eastern China and to explore the factors affecting adherence to anti-TB treatment.

Material and Methods

Sample size and sampling technique

The study used the stratified cluster sampling method. Data on pulmonary TB patients were collected from LTDs, and all patients were diagnosed and registered between January 1, 2015 and December 30, 2015. With DOTS treatment management, patients get their medicine at the outpatient clinic and are regularly checked. Community doctors or family supervisors are responsible for overseeing patients. After stochastically selecting 8 counties from the whole province, 45 eligible pulmonary TB patients over 15 years old were randomly selected from each county. In this study, the diagnosis of pulmonary TB was established according to the Tuberculosis Diagnosis Standard issued by the Ministries of Health of the People’s Republic of China. The diagnosis of active TB was confirmed by experienced clinicians according to sputum smear examination, chest X-ray examination for exudative lesions, cavities, and lesion size, and anti-tuberculosis treatment. Second, Smear-positive or smear-negative patients who were newly treated were included and the treatment regimens were all 2HRZ/4HR. We distributed 360 copies of the questionnaire, and 339 copies of the valid questionnaire were returned, with an effective rate of 94.17%.

Study design

This study was conducted in Anhui province, which consists of 106 counties (districts) with a total population of 62,548 million at the end of 2015. A total of 8 counties/districts (including Yuexi county, Taihu county, Jinzhai county, Shou county, Feixi county, Huoju county, Shushan district, and Tongcheng city) were selected as study sites. Based on relevant literature and expert consultation, the questionnaire was developed and administered by trained doctors and health workers. The questionnaire is composed of 4 parts: general information, status, annual income, annual income, medication adherence, and presence of chronic diseases). The second section consists of 23 questions, including questions on missed medication and reasons why, completion of treatment course, whether visited by the medical staff and levels of the staff, and distance from residence to the nearest clinic or hospital. The section on TB knowledge is composed of 12 questions covering items such as tuberculosis transmission, suspicious symptoms of tuberculosis, and BCG. The access to information on TB section is made up of 5 clear multiple-choice questions. For the respondents who were unable to respond themselves, the questionnaire was completed with the help of trained LTD nurses.
**Definition**

We used the frequency of missing taking medication to define adherence to TB treatment. In the course of treatment, if the patient had not missed any dose of medication or if the frequency of missing taking medication is 0, it was judged as adherent. If the frequency of missing taking medication is greater than or equal to 1, it was judged as non-adherent.

**Statistical analysis**

Statistical analysis was conducted with SPSS version 23.0 and Epi Info version 7.0. All data are presented as mean ±SD if normally distributed. The chi-square test or Fisher's exact test was used to assess differences in categorical data between 2 groups. Two-tailed \( P \leq 0.05 \) was considered statistically significant.

**Table 1. The Socio-demographic and clinical characteristics of the study participants.**

| Variables                  | Frequency | Percent (%) |
|----------------------------|-----------|-------------|
| Gender                     |           |             |
| Male                       | 259       | 76.4        |
| Female                     | 80        | 23.6        |
| Occupation                 |           |             |
| Farmer                     | 261       | 77.0        |
| Worker                     | 40        | 11.8        |
| Others                     | 38        | 11.2        |
| Educational level          |           |             |
| Primary and illiterate     | 170       | 50.2        |
| Junior and senior high schools or technical secondary schools | 142 | 41.9 |
| Junior college or above    | 27        | 7.9         |
| Marital status             |           |             |
| Unmarried                  | 74        | 21.8        |
| Married                    | 234       | 69.0        |
| Divorced or widowed        | 31        | 9.2         |
| Annual income              |           |             |
| <5000                      | 124       | 36.6        |
| 5000–9999                  | 78        | 23.0        |
| 10000–19999                | 60        | 17.7        |
| $\geq$20000                | 77        | 22.7        |
| Sputum smear status        |           |             |
| Positive                   | 81        | 23.9        |
| Negative                   | 258       | 76.1        |
| Suffering from chronic diseases |     |             |
| Yes                        | 85        | 25.1        |
| No                         | 254       | 74.9        |
| Medication adherence       |           |             |
| Adherent                   | 114       | 33.6        |
| Non-adherent               | 225       | 66.4        |

**Ethical approval**

All participants were fully informed before written consents were taken. Then, written informed consent was obtained from each participant who was willing to take part in this study. The participants were assured about the confidentiality of the data.

**Results**

**Characteristics of the Study Participants**

A total of 339 pulmonary TB patients were included in the study, with a mean age of 49.17±15.55 years; 259 (76.4%) were males and 80 (23.6%) were females. Most of them were farmers (77.0%). In terms of education level, 50.15% were primary level and illiterate, 41.89% were junior and senior high school or technical secondary school level, and only 7.96% were junior
More than half of the patients (234; 69%) were married. Most patients had a low annual income (less than 10,000 yuan). Furthermore, smear-positive adult PTB patients accounted for 23.9% and smear-negative 76.1%. Overall, 25.1% had chronic diseases and 33.6% of patients missed doses of medication. The results are shown in Table 1.

**Knowledge of TB**

We found that 92.0% of patients knew that pulmonary TB was transmitted through droplets. Regarding prevention, 89.7% believed that frequent hand washing, good ventilation, and physical exercise could effectively prevent pulmonary TB. Results showed that 84.1% of patients were aware that TB should be suspected when coughing and spitting last for more than 2 weeks or when there is blood in the sputum. As for treatment, 96.8% of the patients understood that TB patients should be treated by professional prevention and treatment institutions; 95.6% believed that TB could be cured through formal treatment, while 95.9% knew that the country had free TB medication policies. About half of the patients believed that Bacillus Calmette Guerin (BCG) vaccination can prevent TB. Most of them thought TB patients should be given adequate care and should not be discriminated against. The results are displayed in Table 2.

**The relationship between patient adherence and demographic factors**

Most demographic factors, including gender, occupation, and educational level, were not related with TB patient’s adherence to treatment ($P>0.05$). Notably, the ordinal logistic regression model showed that marital status ($\chi^2=36.32, P<0.001$) and annual income ($\chi^2=25.08, P<0.001$) were independent influencing factors. With regard to annual income, patients whose annual income was less than 5000 yuan had the highest frequency of missing doses of medication (54.65%), while patients whose annual income was greater than or equal to 20,000 yuan had the lowest rate of non-compliance (22.97%) (Table 3).

**The relationship between patient adherence and knowledge of TB**

Those patients who understood the symptoms of tuberculosis ($\chi^2=13.84, P<0.001$), who knew how to prevent TB
Having medical staff visits ($\chi^2=34.92, P<0.001$) and the level of the visiting personnel ($\chi^2=23.93, P<0.001$) were confirmed to be associated factors. The proportion of non-adherent patients who were visited by medical staff was only 26.10%, while the group who were not visited by medical staff was 64.18%, and this difference was significant ($P<0.001$). In addition, when visiting personnel were at the county level and above, the proportion of non-adherent patients was only 10.34%, while when the visiting personnel was a village doctor, the rate was 40.00%. Also, there was no significant difference between the distance from residence to the nearest clinic or hospital and treatment adherence ($P=0.096$). The results are displayed in Table 5.

### Association between adherence to treatment and the rate of successful treatment

This study included both smear-positive and smear-negative TB patients. The treatment outcome of smear-positive patients is indicated by cure rate, while the treatment outcome of smear-negative patients is described as the completion rate of treatment rather than cure rate. Therefore, in our study, we combined these together as the rate of successful treatment.

| Variables                      | Adherent | Non-adherent | $\chi^2$ | P       |
|-------------------------------|----------|--------------|----------|---------|
| Sex                           |          |              |          |         |
| Male                          | 168      | 64.86        | 1.12     | 0.291   |
| Female                        | 57       | 71.25        |          |         |
| Occupation                    |          |              |          |         |
| Farmer                        | 170      | 65.13        | 1.90     | 0.387   |
| Worker                        | 26       | 65.00        |          |         |
| Others                        | 29       | 76.32        |          |         |
| Educational status            |          |              |          |         |
| Primary and illiterate        | 105      | 61.76        | 3.25     | 0.197   |
| Junior and senior high schools or technical secondary schools | 101 | 71.13 | 41 | 28.87 |
| Junior college or above       | 19       | 70.37        |          |         |
| Marital status                |          |              |          |         |
| Unmarried                     | 43       | 58.11        | 36.32    | <0.001  |
| Married                       | 175      | 74.79        | 25.21    |         |
| Divorced or widowed           | 7        | 22.58        | 77.42    |         |
| Annual income                 |          |              |          |         |
| <5000                         | 39       | 45.35        | 54.65    | 0.001   |
| 5000–9999                     | 50       | 66.67        | 33.33    |         |
| 10000–19999                   | 79       | 75.96        | 24.04    |         |
| ≥20000                        | 57       | 77.03        | 22.97    |         |

($\chi^2=14.94, P<0.001$), who had knowledge of BCG ($\chi^2=31.96, P<0.001$), and who were not worried that they would miss work ($\chi^2=30.33, P<0.001$) were more likely to adhere to TB treatment. Among TB patients who were adherent, 79.44% considered TB to be a very serious problem. However, only 20.56% of patients who missed doses of medication thought that TB was very serious, revealing that the understanding of these people needs to be improved. As for related knowledge about TB, the awareness rate of the group who had not missed doses of medication was clearly higher than that of the non-adherent treatment group ($P<0.05$). On the other hand, as far as whether TB patients should be given professional diagnosis and treatment in formal medical institutions, the national policy and stigma, no significant differences were found between the 2 groups ($P>0.05$). The results are shown in Table 4.

## The relationship between treatment adherence and other related factors

Having medical staff visits ($\chi^2=34.92, P<0.001$) and the level of the visiting personnel ($\chi^2=23.93, P<0.001$) were confirmed to be associated factors. The proportion of non-adherent patients who were visited by medical staff was only 26.10%, while the group who were not visited by medical staff was 64.18%, and this difference was significant ($P<0.001$). In addition, when visiting personnel were at the county level and above, the proportion of non-adherent patients was only 10.34%, while when the visiting personnel was a village doctor, the rate was 40.00%. Also, there was no significant difference between the distance from residence to the nearest clinic or hospital and treatment adherence ($P=0.096$). The results are displayed in Table 5.
Overall, the treatment adherence among pulmonary TB patients in Anhui province was not good. Only 66.4% of the patients were considered adherent. The proportion of patients who had missed one or more doses of medication during treatment was 33.6%. In our study, a total of 114 people had missed taking medication. Among them, 101 people missed <10 doses of medication (88.6%) and 74 people missed <5 doses of medication (64.9%). Although the proportion of patients who missed taking medication was high, those who missed <5 doses accounted for the majority; therefore, the rate of successful treatment was relatively high. However, compared with the adherent group (96.00%), the rate of successful treatment was significantly lower in the non-adherent group (P<0.001). Some previous studies in China also indicated low treatment adherence among TB patients [16,17]. Zhou et al. reported that 16% of migrant TB patients were not adherent to TB therapy [16]. The proportion of non-adherence in our study was higher than those reported in previous studies, and the difference may be due to differences in study design and definition of non-adherence to anti-TB treatment. No criterion standard definition of adherence to anti-TB treatment is currently available, although consideration of quantity and timing of missed medication or

Discussion

Table 4. Comparison of medication adherence in patients with different knowledge of TB.

| Variables                                                                 | Adherent N (%) | Non-adherent N (%) | χ²       | P      |
|---------------------------------------------------------------------------|----------------|-------------------|-----------|--------|
| Do you think TB is serious                                                | Very serious  | 85 (79.44)        | 22 (20.56) | 13.73  | 0.001 |
|                                                                            | Serious       | 104 (58.10)       | 75 (41.90) |        |       |
|                                                                            | Not too serious| 36 (67.92)        | 17 (32.08) |        |       |
| Tuberculosis is spread by droplets                                        | Know          | 215 (68.91)       | 97 (31.09) | 11.31  | 0.001 |
|                                                                            | Unknown       | 10 (37.04)        | 17 (62.96) |        |       |
| Cough sputum more than two weeks or spumtum with blood, suspected TB     | Know          | 201 (70.53)       | 84 (29.47) | 13.84  | <0.001|
|                                                                            | Unknown       | 24 (44.44)        | 30 (55.56) |        |       |
| Hand washing, ventilation, and exercise can prevent TB                    | Know          | 212 (69.74)       | 92 (30.26) | 14.94  | <0.001|
|                                                                            | Unknown       | 13 (37.14)        | 22 (62.86) |        |       |
| Patients should go to professional TB prevention and treatment institutions| Know          | 219 (66.77)       | 109 (33.23) | –      | 0.518*|
|                                                                            | Unknown       | 6 (45.55)         | 5 (54.45)  |        |       |
| TB can be cured by sticking to regular treatment                          | Know          | 219 (67.59)       | 105 (32.41) | –      | 0.046*|
|                                                                            | Unknown       | 6 (40.00)         | 9 (60.00)  |        |       |
| The free policy                                                           | Know          | 216 (66.46)       | 100 (33.54) | –      | 0.536*|
|                                                                            | Unknown       | 9 (32.08)         | 15 (67.92) |        |       |
| Can BCG prevent TB                                                        | Yes           | 130 (76.47)       | 40 (23.53)  | 31.96  | <0.001|
|                                                                            | Uncertain     | 51 (73.91)        | 18 (26.09)  |        |       |
|                                                                            | No            | 24 (43.64)        | 31 (56.36)  |        |       |
|                                                                            | Unknown       | 20 (44.44)        | 25 (55.56)  |        |       |
| TB patients should be given enough care instead of discrimination         | Yes           | 195 (67.47)       | 94 (32.53)  | 4.07   | 0.131 |
|                                                                            | No            | 11 (78.57)        | 3 (21.43)   |        |       |
|                                                                            | Unknown       | 19 (52.78)        | 17 (47.22)  |        |       |
| If Leaders knew whether it affected your work                             | Yes           | 39 (51.32)        | 37 (48.68)  | 30.33  | <0.001|
|                                                                            | No            | 128 (81.53)       | 29 (18.47)  |        |       |
|                                                                            | Unknown       | 58 (54.72)        | 48 (45.28)  |        |       |
| If symptoms disappear, whether continue taking the medication             | Yes           | 219 (70.65)       | 91 (29.35)  | 0.14   | 0.712 |
|                                                                            | No            | 6 (20.69)         | 23 (79.31)  |        |       |

* Means that the theoretical number is too small and adopt the exact probability method.
hospital appointments was recommended by the WHO [18]. For example, a frequently used definition of non-adherence is the WHO-recommended measure, which defines a TB treatment defaulter as a patient who interrupted treatment for 2 consecutive months or more, but some studies considered a patient who had missed 10% or more of the total prescribed doses of TB drugs as non-adherent [16,19].

Adherence to long-term treatment is a complex phenomenon, influenced by various factors. Our study showed that TB knowledge in our subjects was fairly good: 92.0% of the patients knew that pulmonary TB was transmitted by droplets, 95.6% believed that TB could be cured through formal treatment, and 95.9% knew that the country had a free TB treatment policy. The relationship between presence of social support and cooperation with the treatment procedure was confirmed. Previous studies in India indicated that social support was important in treatment supervision [20]. We found that married patients had better treatment adherence than unmarried and divorced patients, which is consistent with studies that indicated family members played a positive role in treatment supervision [16,21].

Additionally, in accordance with the findings of other studies, this study also illustrated that the socio-economic status of TB patients was an important factor influencing TB treatment adherence [22–24]. In a study in Ghana, default from treatment was significantly associated with income, ability to afford supplementary drugs, availability of social support, and problems relating with others while on treatment [25]. Our study found that patients whose annual income was well below the average for the country had the highest frequency of missing doses of medication. China has implemented the DOTS at the county level from 2005, which provides free and standard short-course chemotherapy, but patients still have other costs, such as transportation and opportunity cost during treatment. Hence, when a strong economic guarantee is provided, patients are more likely to receive regular treatment and to have good treatment adherence.

Our study also indicated that TB disease knowledge is a vital factor associated with TB treatment adherence, showing that greater TB knowledge is associated with better adherence to treatment, which agrees with previous studies [2,16,20,26]. Moreover, supervision by medical staff during the treatment was an important indicator affecting patient compliance. Interestingly, there was a positive effect of medical personnel visiting on improving treatment adherence, which was similar to findings in Nepal and India [27,28], in which visits from higher-level visiting personnel were associated with better patient adherence. During the process of visiting patients, the medical staff teach patients about TB knowledge and made them more aware of the importance of treatment adherence. Undoubtedly, the higher the level of medical staff, the higher the level of health education. On the other hand, patients also thought that medical staff paid more attention to them and had more confidence to be cured. Furthermore, our study revealed an association between adherence to treatment and the rate of successful treatment, suggesting that patients with good adherence have a better prognosis.

Several limitations of this study need to be considered. Firstly, the treatment adherence levels were based on self-reported information from patients, so recall bias was unavoidable. Secondly, the occurrence of adverse drug reactions of taking anti-TB medications, which was a determinant of non-adherence, was not taken into consideration in our analysis. Despite these limitations, the present study has several merits. First, the questionnaire was developed using a range of scientific methodologies including literature reviews, focus groups, and pilot testing. Second, some key variables were measured in...
this study setting, such as individual or household income and marital status. Finally, we found that social support from family members or medical staff visiting could improve adherence.

Conclusions

Our study indicates that treatment adherence among pulmonary TB patients in Anhui province is not high. Moreover, marital status, annual income, medical personnel supervision, and patient knowledge about anti-TB treatment is crucial to improving pulmonary TB patients' treatment adherence. Understanding the risk factors affecting adherence to anti-tuberculosis treatment may help make more effective policies targeting the most at-risk patients and provide a scientific basis for making effective policies and measures in the future.

Conflict of interests

None.

References:

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