Pulmonary tuberculosis treatment regimen recommended by the Brazilian National Ministry of Health: predictors of treatment noncompliance in the city of Porto Alegre, Brazil*

Fatores preditores para o abandono do tratamento da tuberculose pulmonar preconizado pelo Ministério da Saúde do Brasil na cidade de Porto Alegre (RS)

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Abstract

Objective: To determine the predictors of noncompliance with the pulmonary tuberculosis treatment regimen recommended by the Brazilian National Ministry of Health, in previously treatment-naïve patients with active tuberculosis treated in the city of Porto Alegre, Brazil. **Methods:** This was a case-control study involving six referral primary health care clinics for tuberculosis in Porto Alegre. We reviewed the medical charts of all previously treatment-naïve patients with active pulmonary tuberculosis who were noncompliant with the treatment between 2004 and 2006. Those were paired with other patients having similar characteristics and having been cured. We conducted univariate and multivariate analyses. **Results:** Of the 2,098 patients included, 218 (10.4%) became noncompliant with the treatment. In the multivariate analysis, the factors most strongly associated with treatment noncompliance were being an alcoholic (with or without concomitant use of illicit drugs), being HIV-infected, not residing with family members, and having a low level of education. In the univariate analysis, treatment noncompliance was also significantly associated with being younger and with being non-White. Gender was not significantly associated with treatment noncompliance; nor was the occurrence of adverse effects of the drugs included in the regimen. **Conclusions:** In the population studied, being an alcoholic, being HIV-infected, and not residing with family members were the major predictors of noncompliance with treatment for pulmonary tuberculosis among previously treatment-naïve patients.

Keywords: Tuberculosis; Patient dropouts; Primary health care; Patient compliance; Medication adherence.

Resumo

Objetivo: Determinar os fatores preditores de abandono do tratamento da tuberculose pulmonar, preconizado pelo Ministério da Saúde do Brasil, em pacientes bacilíferos virgens de tratamento atendidos na cidade de Porto Alegre (RS). **Métodos:** Estudo de caso-controle envolvendo seis unidades básicas de saúde de referência para o tratamento da tuberculose em Porto Alegre, com a revisão dos prontuários de todos os casos de abandono do tratamento por parte de pacientes com tuberculose pulmonar bacilíferos e virgens de tratamento entre 2004 e 2006. Os pacientes incluídos no estudo foram pareados com pacientes com características semelhantes e cujo desfecho foi de cura. Foram realizadas análises univariada e multivariada. **Resultados:** Dos 2.098 pacientes incluídos no estudo, 218 (10,4%) abandonaram o tratamento. De acordo com a modelo da análise multivariada utilizado, as associações mais significantes para o abandono do tratamento foram o etilismo (com ou sem a concomitância de uso de drogas ilícitas), a infecção por HIV, o fato de o paciente não residir com familiares e o baixo nível de escolaridade. Na análise univariada, indivíduos mais jovens e de etnia não branca também se revelaram significativos para o abandono do tratamento. Gênero e ocorrência de efeitos adversos da medicação não mostraram associação com o abandono. **Conclusões:** Na população estudada, alcoolismo, infecção por HIV e o fato de o paciente não residir com familiares foram os fatores preditores mais importantes para o abandono do primeiro tratamento da tuberculose pulmonar.

Descritores: Tuberculose; Pacientes desistentes do tratamento; Atenção primária à saúde; Cooperação do paciente; Adesão à medicação.

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Introduction

Success in the treatment of tuberculosis is largely dependent on patient compliance with the regimen chosen. The currently used treatment regimen is highly effective, is provided free of charge, and can cure almost any case. However, in a significant proportion of affected individuals, the expected success does not occur, principally because of irregular medication use and treatment noncompliance.[1,2]

Treatment compliance is considered the major obstacle to disease control in public health practice, representing a challenge and significantly contributing to the onset of drug resistance.[3,4] Studies on the causes of irregularities in the treatment of tuberculosis have been conducted in various locations around the world, and the understanding of these causes can certainly help reduce the problem, with obvious benefits to the general population.

In 1993, tuberculosis was declared a global emergency by the World Health Organization.[5] That decision was prompted by the significant increase in the number of cases of the disease, mostly due to the advent of HIV infection, as occurred in Brazil as well.[6,7]

According to the World Health Organization reports for 2009,[8] Brazil ranks 18th among the 22 countries that, together, account for most (80%) of all tuberculosis cases worldwide, improving its situation in relation to previous years, when it ranked 16th.[9]

According to the *Sistema de Informação de Agravos de Notificação* (SINAN, Brazilian Case Registry Database), between 1999 and 2008, the incidence rate of tuberculosis dropped from 51.54/100,000 population to 37.12/100,000 population, and the absolute number of new cases decreased from 82,934 to 70,379.

In the state of Rio Grande do Sul, 5,344 new cases were registered in 2006, with an incidence rate of 43.0/100,000 population, a cure rate of 68.9%, and a noncompliance rate of 7.5%. In that state, tuberculosis had been considered a serious problem since 1971, when the global action plan of the tuberculosis control program was developed and then gradually implemented.[10]

Currently, the city of Porto Alegre, Brazil, holds a prominent place among the other Brazilian cities in terms of the number of cases of tuberculosis/HIV co-infection, with the incidence of both conditions increasing in parallel.[7,11]

Noncompliance with treatment for pulmonary tuberculosis in smear-positive patients favors the persistence of the transmission chain, as well as the increase in bacterial populations that are resistant to first-line chemotherapy.[12,13] This situation is a cause for concern, because it requires strategic measures to motivate patients to be more compliant with the treatment regimen.

Nearly 100% of new cases of tuberculosis are curable, provided that correct chemotherapy principles are obeyed. The most significant recent changes in the natural history of tuberculosis are associated with the HIV epidemic and the emergence of antituberculosis drug resistance.

Infection with HIV exacerbates the tuberculosis epidemic, whether by increasing susceptibility to infection with *Mycobacterium tuberculosis* or by converting cases from latent to active tuberculosis.[7,14]

From the beginning of the 1980s to the end of 2009, Brazil used a regimen consisting of three drugs—rifampin, isoniazid, and pyrazinamide—known in Brazil as regimen 1 or the RHZ regimen. This regimen was employed in the initial phase of treatment of previously treatment-naïve patients, because resistance to isoniazid was low in Brazil,[15] unlike in other countries, where ethambutol was added as a fourth drug. Various studies had already indicated that treatment regimens containing rifampin should form the backbone of antituberculosis chemotherapy, because they are effective. It also became clear that the minimum duration of therapy should be six months for smear-positive or culture-positive cases.[16,17]

Psychosocial problems, such as being an alcoholic, having a mental disorder, being homeless, and being HIV-infected, have been implicated as affecting tuberculosis treatment success. According to two groups of authors,[18,19] most cases of noncompliance usually occur in the first months of tuberculosis treatment, which underscores the importance of adopting measures to reduce noncompliance.

In the city of Porto Alegre, the treatment regimen used is self-administered, the medication being provided by the primary health care (PHC) clinic at doses intended for daily administration over a 30-day period. At each patient visit, the

next visit is scheduled, so that the patient can be reassessed and can continue to receive the medication for the next period, and this occurs consecutively for the duration of the treatment.

The main objective of the present study was to identify the true predictors of noncompliance with pulmonary tuberculosis treatment in previously treatment-naïve patients with active tuberculosis treated in Porto Alegre, determining the profile of those patients. In addition, we sought to elucidate in which treatment period noncompliance occurred, as well as to determine the rate of noncompliance, intending thereby to provide support for adopting measures that can improve treatment compliance.

Methods

This was a case-control study involving the six referral PHC clinics for tuberculosis in Porto Alegre. We reviewed the medical charts and the SINAN reporting forms of all previously treatment-naïve patients with active pulmonary tuberculosis who were noncompliant with the treatment between 2004 and 2006.

The inclusion criteria were as follows: being an adult; having a microbiologically confirmed (sputum smear microscopy or culture) diagnosis of pulmonary tuberculosis; being treatment-naïve; having been treated with the RHZ regimen; residing in Porto Alegre; having been treated in that city; and having been cured or being noncompliant. Patients with extrapulmonary tuberculosis were excluded from the study, as were those for whom there was no microscopy or initial culture confirmation, those for whom the treatment regimen was changed, those experiencing recurrence, those requiring retreatment, and those who did not reside in Porto Alegre.

For the groups formed at each PHC clinic—noncompliance group and control group—treatment equity was the criterion used for the 1:1 pairing.[20] We studied 436 treatment-naïve patients who received the RHZ regimen for the treatment of microbiologically confirmed pulmonary tuberculosis. Of those, 218 were included in the noncompliance group (outcome category "noncompliant") and paired with 218 patients included in the control group (outcome category "cured"). The outcome category "noncompliant" was defined as failing to report to one of the PHC clinics for more than 60 days after the last visit and, thereby, remaining off medication for at least 30 days. The outcome category "cured" was defined as completing the six months of treatment and showing a satisfactory bacteriological response, i.e., converting to a negative sputum culture by the end of the fourth month and maintaining that status until the sixth month.

The control group was composed of patients who had been cured. Those patients were selected by random sampling, at each PHC clinic, among those whose date of initial treatment immediately preceded or immediately followed that of the noncompliant patient.

Continuous variables (age) were compared with the Student's t-test, and categorical variables were analyzed with the chi-square test. Finally, we performed a multivariate analysis of the risk factors on the likelihood of noncompliance (odds ratio). The level of significance was set at 5%. To calculate the sample size, we used a study by Bergel & Gouveia,[21] which involved a total of 224 patients, as a parameter. For a level of significance of 0.05 and a power of 80%, we estimated that at least 148 patients per group were required.

Results

Between 2004 and 2006, the total number of new cases of active pulmonary tuberculosis reported in Rio Grande do Sul was 16,935. The incidence rate of the disease in that state was 42.7/100,000 population, with a rate of noncompliance of 8.4%, according to the SINAN data.[22] Of those new cases, 2,098 were concentrated in Porto Alegre, being reported in the SINAN cohorts and being confirmed in the registries of each PHC clinic included in the study. The population consisted mostly of working-age adults of legal age (95.4%).

The frequency of patients with active pulmonary tuberculosis who became noncompliant with the treatment, by PHC clinic, is shown in Table 1. The mean rate of noncompliance was 10.4%, and there were no significant differences among the PHC clinics studied.

On average, noncompliance occurred at 3.7 ± 2.3 months. Examination of the standard deviation value reveals that there were cases in which the patients missed their first return visit, scheduled to take place within 30 days following

Table 1 - Frequency of patients with active pulmonary tuberculosis included in the study, as well as of patients who became noncompliant with the treatment, by primary health care clinic, Porto Alegre, 2004-2006.

PHC clinic	Patients with active pulmonary tuberculosis	Patients who became noncompliant with the treatment	Noncompliance rate
	n	n	%
1	388	67	17.3
2	557	52	9.3
3	326	26	8.0
4	411	33	8.0
5	216	23	10.6
6	200	17	8.5
Total	2,098	218	10.4

PHC: primary health care.

their first medical visit. Table 2 shows the results of the comparison between the patients in the noncompliance group and those in the control group.

The mean age of the patients in the noncompliance group was significantly lower than was that of the patients in the control group (33.3 years vs. 38.0 years; $p < 0.001$), indicating that noncompliance was most common among the younger patients. Males predominated in both groups, although no significant association was found between treatment noncompliance and this variable. There was a significantly higher frequency of non-White individuals in the noncompliance group ($p = 0.008$), although White patients predominated in both groups. The level of education was lower in the noncompliance group than in the control group ($p < 0.001$), and most cases of noncompliance occurred among individuals with a low level of education (7 or fewer years of schooling). Patients who did not reside with family members had a higher rate of noncompliance ($p < 0.001$). At PHC clinic 2 (Table 1), this group of patients included convicts who became noncompliant with the treatment because they escaped from prison.

Treatment noncompliance was associated with alcohol and illicit drug abuse ($p < 0.001$ for both). In general, illicit drug dependence was found to be associated with alcoholism, suggesting overlapping of variables. In addition, there was a significantly greater number of HIV-infected individuals among the cases of noncompliance ($p < 0.001$). There was no significant difference between the two groups in terms of the occurrence of adverse effects of the drugs included in the regimen ($p = 0.229$).

In the multiple logistic regression analysis, being an alcoholic (OR = 5.4; 95% CI: 2.5-11.2; $p < 0.001$), being HIV-infected (OR = 5.1; 95% CI: 2.7-9.7; $p < 0.001$), not residing with family members (OR = 5.0; 95% CI: 1.5-16.9; $p = 0.05$), and having a low level of education (OR = 2.0; 95% CI: 1.1-3.6; $p < 0.01$) were found to be independent risk factors for treatment noncompliance (Table 3).

Discussion

The results of the present study show that being an alcoholic, being co-infected with HIV, not residing with family members, and having a low level of education were predictors of noncompliance in previously treatment-naïve patients with active pulmonary tuberculosis residing in Porto Alegre, which is in agreement with the findings of other national and international studies in this area. Alcoholism has repeatedly been reported as one such predictor.[11,23-25] Illicit drug dependence, regardless of the type of drug used, was found to be associated with alcoholism in nearly all cases, which suggests overlapping of the two variables, both of which play a significant role in patient noncompliance.[11] Studies conducted in the Brazilian cities of Carapicuíba and Pelotas have also shown that being an alcoholic is a predisposing factor for noncompliance with self-administered treatment regimens.[4,25]

Tuberculosis/HIV co-infection was also found to be significantly important as a predictor of noncompliance, which is in agreement with the findings of another study.[11] In the city of Ribeirão Preto, Brazil, better therapeutic results were reported among HIV-negative individuals.[26]

Table 2 - Comparison of the paired groups in terms of the variables studied.[a]

Variable	Group		p
	Noncompliance	Control	
	(n = 218)	(n = 218)	
Age, years[b]	33.4 ± 11.2	38.0 ± 15.1	< 0.001*
Gender			> 0.05*
Male	151 (69.3)	140 (64.2)	
Female	67 (30.7)	78 (35.8)	
Race			0.006**
White	131 (60.1)	158 (72.5)	
Non-White	87 (39.9)	60 (27.5)	
Level of education			< 0.001**
< 7 years	164 (75.9)	116 (54.5)	
≥ 7 years	52 (24.1)	97 (45.5)	
Residing with family members			< 0.001**
Yes	184 (85.6)	211 (97.2)	
No	31 (14.4)	6 (2.8)	
Being an alcoholic			< 0.001**
Yes	67 (30.7)	33 (15.1)	
No	151 (69.3)	185 (84.9)	
Being dependent on illicit drugs			< 0.001**
Yes	41 (18.8)	9 (4.1)	
No	177 (81.2)	209 (95.9)	
Being HIV-positive			< 0.001**
Yes	61 (41.5)	21 (13.2)	
No	86 (58.5)	138 (86.8)	
Occurrence of adverse effects			0.229**
Yes	22 (10.1)	15 (6.9)	
No	196 (89.9)	203 (93.1)	

[a]Values expressed as n (%), except where otherwise indicated. [b]Values expressed as mean ± SD. *Student's t-test. **Chi-square test.

Most of the patients in the present study had a fixed address. However, being homeless, living in a shelter, and being in prison were significantly associated with noncompliance, which defines "not having a fixed address" as a predictor. In a study of the profile of tuberculosis patients with AIDS, imprisonment was reported to be a risk factor for noncompliance, as were illicit drug use and alcoholism.[6]

The patients in the present study were young working-age adults, and there were more cases of noncompliance among the youngest individuals. Similar results in terms of age group have been described in other studies.[4,11,21,27]

Most patients in both groups were male and White, which is in agreement with the results of another study conducted in Porto Alegre. However, in reviewing the literature,[27,28] we found that the number of cases of noncompliance was higher among non-White individuals.

The highest rate of noncompliance was found among patients with a lower level of education, although the strength of the association was weaker than was that of the association with being HIV-infected, being an alcoholic, and not residing with family members. Other studies have shown a higher level of education to be predictive of a lower noncompliance rate.[21,29]

Adverse drug effects, requiring no changes to the treatment regimen and showing no statistical significance, occurred most commonly among the cases of noncompliance, although similar percentages were found in both groups. Studies conducted in the Brazilian states of Rio Grande do Sul and São Paulo showed that, in less than 4.0% of the cases treated with the RHZ regimen, the treatment regimen had to be changed.[4,12] In the present study, noncompliance was most common within the first three months of treatment, corroborating the findings of other

Table 3 - Multivariate analysis of the predictors of noncompliance.

Predictor	OR	95% CI	p
Being an alcoholic	5.4	2.5-11.2	< 0.001
Being HIV-positive	5.1	2.7-9.7	< 0.001
Not residing with family members	5.0	1.5-16.9	0.012
Having had fewer than 7 years of schooling	2.0	1.1-3.6	< 0.01

studies conducted in Brazil,[29,30] and the mean rate of noncompliance in the general population of patients with active tuberculosis was 10.7%.

We found that the factors most strongly associated with noncompliance with the treatment for active pulmonary tuberculosis with a first-line regimen among patients residing in Porto Alegre were being an alcoholic (with or without concomitant illicit drug use), being HIV-infected, not residing with family members, and having a low level of education (the last showing a weaker association). Males and Whites predominated in both groups. However, the number of non-White individuals was found to be significantly higher in the noncompliance group. The rate of noncompliance in the general population of patients with active tuberculosis was 8-17%. Noncompliance was most common within the first three months of treatment.

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