Original Article

Compliance with tuberculosis treatment after the implementation of the directly observed treatment, short-course strategy in the city of Carapicuíba, Brazil*

Adesão ao tratamento da tuberculose após a instituição da estratégia de tratamento supervisionado no município de Carapicuíba, Grande São Paulo

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Abstract

Objective: To determine the compliance with tuberculosis treatment among patients enrolled the tuberculosis control program in the city of Carapicuíba, Brazil, before and after the implementation of the directly observed treatment, short-course (DOTS) strategy. **Methods:** A retrospective historical cohort study of operational aspects based on records of attendance and treatment evolution of patients in self-administered treatment (SAT) and of those submitted to DOTS. Monthly treatment outcome tables were created, and the probability of compliance with the treatment was calculated for both groups of patients. **Results:** A total of 360 patients with tuberculosis met the inclusion criteria: 173 (48.1%) in the SAT group; and 187 (51.9%) in the DOTS group. Treatment compliance was 6.1% higher in the DOTS group than in the SAT group. The proportion of patients completing the six months of treatment was 91.6% and 85.5% in the DOTS group and in the SAT group, respectively. **Conclusions:** The results of this study show that DOTS can be successfully implemented at primary health care clinics. In this population of patients, residents of a city with low incomes and a high burden of tuberculosis infection, DOTS was more effective than was SAT.

Keywords: Tuberculosis; Mycobacterium tuberculosis; Treatment outcome; Medication adherence.

Resumo

Objetivo: Verificar a adesão ao tratamento dos casos atendidos no programa de controle da tuberculose do município de Carapicuíba (SP), antes e após a implantação da estratégia *directly observed treatment, short-course* (DOTS, tratamento supervisionado). **Métodos:** Estudo operacional do tipo coorte histórica a partir dos registros de comparecimento e evolução do tratamento dos pacientes submetidos ao tratamento autoadministrado (TAA) e daqueles submetidos a DOTS. Tábuas de desfecho de tratamento mês a mês foram elaboradas, e a probabilidade de adesão foi calculada para cada grupo de pacientes. **Resultados:** Um total de 360 pacientes com tuberculose preencheu os critérios de elegibilidade: 173 (48,1%) no grupo TAA e 187 (51,9%) no grupo TS. A adesão ao tratamento foi 6,1% maior no grupo DOTS do que no grupo TAA. Ao final de seis meses, 91,6% dos pacientes sob TS completaram o tratamento padrão, enquanto 85,5% dos pacientes do grupo TAA completaram o tratamento. **Conclusões:** Este estudo mostrou que a estratégia DOTS pode ser realizada com sucesso em unidades básicas de saúde e que essa estratégia foi mais efetiva que o TAA nesta população de pacientes de uma cidade com população de baixa renda e alta carga de tuberculose.

Descritores: Tuberculose; Mycobacterium tuberculosis; Resultado de tratamento; Adesão ao medicamento.

Introduction

Tuberculosis (TB) remains a challenge and a major public health problem in the 21st century, although there are treatment regimens that have a greater than 95% efficacy in TB patients infected with *Mycobacterium tuberculosis* strains susceptible to first-line drugs. A large number of patients are noncompliant with treatment, especially in developing or underdeveloped countries, where the TB burden is much heavier, examples including Uganda (13.0%), Nigeria (10.0%), the Russian Federation (9.6%), South Africa (9.1%), and Brazil (8.3%).[1-3]

In an attempt to explain poor TB treatment compliance, many factors have been reported, such as the low level of investment in maintenance and in financing programs, as well as the low quality of health care services, the lack of motivation of professionals, TB/HIV co-infection, the impoverishment of marginalized populations, and limited access to health care services on the part of certain groups considered vulnerable, such as the unemployed, the homeless, chronic alcoholics, and drug users, especially in large urban areas.[4,5]

In 2000, the World Health Organization set targets for the Millennium Development Goals and for the control of certain diseases, such as TB, creating the initiative known as Stop TB, which aims to halve the incidence of TB and the number of deaths from TB by 2015 in relation to 1990. Consolidated data for 2008 provided by the *Programa Nacional de Controle da Tuberculose* (PNCT, Brazilian National Tuberculosis Control Program) showed that the incidence of TB infection was 37.1/100,000 population and that the incidence of active TB was 20.6/100,000 population.[6,7]

In 2003, TB was listed as one of the public policy priorities in Brazil, and the need for detection of at least 70% of the active TB cases, as well as the increase of the cure rate to at least 85%, was agreed upon by municipal and state managers. In order to achieve this goal, the PNCT strengthened and decentralized the directly observed therapy, short-course (DOTS) strategy. Previously, on the basis of epidemiological criteria and operational data, the PNCT had classified 230 cities as priority cities, because the majority of the TB cases in Brazil were concentrated in those cities.[3,7,8]

Carapicuíba, a bedroom community located in the greater metropolitan area of São Paulo, Brazil, is one of the most densely populated cities in the country (10,936 inhabitants/km²) and has been considered one of the priority cities since 1998 because it has one of the highest incidences of TB in the state of São Paulo (54.2/100,000 population infected; and 32.3/100,000 population with active TB—data for 2005).

The DOTS strategy rests on five pillars: political commitment; detection of active cases; supervised drug administration; regular supply of first-line antituberculosis drugs; and the implementation of a case reporting and surveillance system.[7-9]

In 2008, approximately 40% of the TB patients in Brazil were treated under the DOTS strategy. However, there have been only a few studies assessing the results of the DOTS strategy in health care facilities and in municipal programs, and those have been uncontrolled.[8,9]

The objective of the present study was to determine the compliance with TB treatment among patients enrolled in the *Programa de Controle da Tuberculose* (PCT, Tuberculosis Control Program) in Carapicuíba, before and after the implementation of the DOTS strategy.

Methods

This was a retrospective historical cohort study of operational aspects involving TB patients enrolled in the Carapicuíba PCT, before and after the implementation of the DOTS strategy: those under self-administered treatment (SAT), between January 1 and December 31, 2003; and those treated under the DOTS strategy, between July 1, 2004 and June 30, 2005.

For the TB patients treated under the DOTS strategy, drug administration was directly observed at the referral health care clinic or at the health care clinic closest to their home, at a predetermined time of day, at least three times a week in the attack phase and twice a week in the maintenance phase, on weekdays. On weekends, the drug was self-administered. For housebound patients, drug administration was supervised in the home.

A TB case was defined as follows[10]: an individual in whom the diagnosis of TB had been confirmed by sputum smear microscopy or culture; or an individual whose physician had

made a diagnosis of TB on the basis of clinical/ epidemiological data and complementary test results (e.g., X-ray, anatomopathological examination, determination of adenosine deaminase levels, etc.) and had prescribed one of the six-month treatment regimens that were standard at the time of data collection, either for new cases (treatment-naïve cases) or for retreatment after recurrence or noncompliance. An individual diagnosed with TB and meeting one of the following criteria was classified as a new TB case: having no history of TB treatment; having previously undergone TB treatment for less than 30 days; or having undergone TB treatment more than 5 years prior. Individuals who resumed treatment after being noncompliant with the basic regimen were classified as cases of retreatment, as were those who experienced recurrence after being treated and cured more than 5 years prior. Cases of tuberculous meningoencephalitis, drug-resistant TB, and multidrug-resistant TB were excluded from the study, as were confirmed cases of transfer and cases in residents of other cities.

We used the TB treatment outcome criteria established by the Brazilian National Ministry of Health[10]:

- Discharge after cure: Patients who initially tested positive for pulmonary TB will be discharged if, during treatment, they have two negative sputum smear microscopy results, one in the follow-up phase and one at the end of treatment.
- Discharge after treatment completion: Patients who were not submitted to sputum smear microscopy due to absence of expectoration will be discharged if the clinical data and complementary test results indicate that they are free of disease, as will those who initially tested negative for pulmonary TB and those with extrapulmonary TB.
- Discharge due to noncompliance: Patients who, after starting TB treatment, fail to appear for their scheduled follow-up appointments (for evaluation or for administration of the medication) for more than 30 consecutive days will be discharged.
- Discharge due to a change in the diagnosis: Patients who were initially misdiagnosed will be discharged.

- Discharge due to death: Patients who die during treatment will be removed from the rolls, regardless of the cause of death.
- Discharge due to unconfirmed transfer: Patients transferred to another health care facility will be discharged when there is no confirmation of their appearance at the other facility.

Because our groups were consecutive cohorts of patients enrolled in a local PCT, rather than a probability sample,[10] we used TB reporting forms and patient medical charts in order to compare the SAT and DOTS groups in terms of age, gender, level of education, occupation, HIV serology, localization of TB foci, sputum smear results (AFB detection), and history of TB treatment. The Epi Info 2000 statistical package, version 3.3, was used in order to create a database. We employed double data entry in order to check data consistency and eliminate typographical errors. To compare sociodemographic variables and clinical characteristics, we conducted bivariate analyses using the chi-square test or Fisher's exact test and the same statistical package. The level of significance was set at $p < 0.05$.

In order to assess treatment compliance in the two groups (SAT and DOTS), we used the actuarial method, better known as the survival analysis technique or a survival table.[11] Survival (the dependent variable) was represented by treatment compliance, defined as the time elapsed between the inclusion of a TB case (date of initiation of the Brazilian National Ministry of Health-approved standard treatment regimen) and the occurrence of the event of interest (date of discharge after cure). In this technique, cases lost to follow-up, except for cases of noncompliance, are designated incomplete observations or censored cases (w_x). This method calculates the probability of treatment compliance at pre-set intervals (monthly follow-up appointments), and the number of those at risk of noncompliance corresponds to the patients under treatment at the beginning of each x interval. The number of those at risk (l_x) is adjusted for the number of censored cases occurring in the period, assuming that the censored cases occurred uniformly during the x period. Therefore, in the presence of censored cases, the number of patients under treatment and at risk of noncompliance at the beginning

of the x period is adjusted (I_x^*) by subtracting half of the censored cases from the total number of those at risk at the beginning of the period, assuming that the censored cases were, on average, at risk of noncompliance for only half of the follow-up period. In this technique, time is also divided into fixed (monthly) intervals, and the probability of treatment compliance (p_x) or noncompliance (q_x) is calculated for each interval.[12,13] We therefore have the following:

$$(p_x = 1 - q_x), (q_x = d_x/I_x), \text{ and } I_x = I_x - (w_x/2)$$

where

- p_x is the conditional probability of treatment compliance in the x interval
- q_x is the conditional probability of treatment noncompliance in the x interval
- I_x is the number of those at risk of noncompliance, in the x interval, corrected for the censored cases occurring in the x interval
- I_x is the number of patients at risk of noncompliance at the beginning of the period
- d_x is the number of patients who were noncompliant with the treatment
- w_x is the number of censored cases in the x interval

We calculated 95% CIs for the probabilities of treatment compliance in percentage on the basis of the survival tables, which are presented in the form of charts showing the conditional probabilities of compliance by x interval (monthly interval) up to the last month of follow-up (month 6), which resulted in the overall rate of treatment compliance (discharge after cure). The study protocol was approved by the Research Ethics Committee of the Federal University of São Paulo.

Results

A total of 360 patients met the inclusion criteria, of whom 173 (48.1%) were in the SAT group and 187 (51.9%) were in the DOTS group. Thirty-nine patients were excluded: 23 (59.0%) because they had been transferred to another facility (confirmed transfer); 9 (23.1%) because they were infected with single drug-resistant or multidrug-resistant *M. tuberculosis* strains; 4 (10.2%) because they were residents of other cities; and 3 (7.7%) because they had tuberculous meningoencephalitis. The mean age of the patients was 37.3 years (range, 4-84 years), and males predominated (at 60.6%). Regarding level of education, 27.1% had had 3 or fewer years of schooling and only 36.3% had had more than 8 years of schooling. Regarding occupation, 26.9% were homemakers or students, 45.3% were officially employed, and 27.8% were unofficially employed or were unemployed. Of the 237 subjects tested for HIV, 119 (50.2%) were in the SAT group and 118 (49.8%) were in the DOTS group. Of all subjects tested, 18 (7.6%; 9 in each group) were HIV-positive.

Of the 360 patients studied, 301 (83.6%) had pulmonary TB, and 211 (70.1%) of those patients had active TB. Of the 59 patients diagnosed with extrapulmonary TB, 35 (59.3%) had pleural TB, 10 (16.9%) had peripheral lymph node TB, 3 (5.1%) had miliary TB, 2 (3.4%) had bone TB, and 9 (15.3%) had other forms of TB. Table 1 shows that there were no significant differences between the patients in the SAT group and those in the DOTS group in terms of sociodemographic variables, the variable "TB/HIV coinfection", or the variable "localization of TB foci", as previously described. For the variable "history of TB treatment", the SAT group had a higher proportion of retreatment cases than did the DOTS group, and this difference was significant.

Figures 1-4 were created on the basis of the information collected from the survival tables, with the conditional probabilities of compliance with the monthly treatment (intervals x_1 to x_6), in order to determine the percentage of discharges after cure among the TB patients enrolled in the Carapicuíba PCT, by treatment strategy (SAT or DOTS). Figure 1 shows that, at six months after treatment initiation, there was a significant difference in effectiveness between the SAT group and the DOTS group (6.09%). The probability of discharge after cure among the patients in the DOTS group was 91.61% (95% CI: 91.48-91.64), compared with 85.52% (95% CI: 85.30-85.73) among the patients in the SAT group.

By stratifying the TB patients in the DOTS group and those in the SAT group by type of case (new or retreatment), localization of TB foci (pulmonary or extrapulmonary), and pulmonary TB (active or latent), we found that treatment compliance was also significantly higher among the patients in the DOTS group (Figures 2-4).

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Table 1 – General characteristics of the tuberculosis patients under self-administered treatment and those
treated under the directly observed treatment, short-course strategy, Tuberculosis Control Program, Carapicuíba,
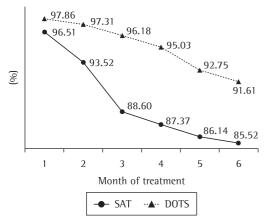Brazil, 2003-2005.

General characteristic	SAT		DOTS		p
	n	%	n	%	
Gender					NS
Male	106	61.27	112	59.89	
Female	67	38.73	75	40.11	
Age, years					NS
0-19	13	7.51	24	12.83	
20-39	80	46.24	84	44.92	
40-49	50	28.90	36	19.25	
≥ 50	30	17.34	43	22.99	
Educational level, years[a]					NS
0-3	56	32.94	39	21.67	
4-7	55	32.35	73	40.56	
≥ 8	59	34.71	68	37.78	
Occupation[b]					NS
Homemaker/student	43	25.15	52	28.57	
Officially employed	83	48.54	77	42.31	
Unofficially employed/unemployed	45	26.32	53	29.12	
HIV testing					NS
Positive	9	5.2	9	4.81	
Negative or not performed	164	94.8	178	95.19	
Type of tuberculosis					NS
Pulmonary	148	85.55	153	81.82	
Extrapulmonary	25	14.45	34	18.18	
Sputum smear microscopy					NS
Positive	110	74.32	101	66.01	
Negative or not performed	38	25.68	52	33.99	
History of TB treatment					0.017
Yes	34	19.65	19	10.16	
No	139	80.35	168	89.84	

SAT: self-administered treatment; DOTS: directly observed treatment, short course; and NS: not significant. [a]10 cases lost
to follow-up. [b]7 cases lost to follow-up.

The probability of cure of new TB cases was 2% higher in the DOTS group than in the SAT group (95% CI: 91.94-92.19 vs. 89.47-89.59; Figure 2a). For the retreatment cases, the cure rate was 80.33% and 68.65% in the DOTS group and in the SAT group, respectively (95% CI: 78.84-81.20 vs. 66.47-70.72; Figure 2b). In the DOTS group, treatment compliance among the patients with pulmonary TB was 91.13% (95% CI: 91.04-91.27), compared with 85.30% (95% CI: 85.15-85.44) in the SAT group (Figure 3a). The proportion of patients with extrapulmonary TB was 3.1% greater in the DOTS group than in the SAT group (Figure 3b), the respective cure rates being 90.09% (95% CI: 89.88-90.20) and 87.00% (95% CI: 86.73-87.26). Among the patients with active TB, the cure rate was 90.75% (95% CI: 90.64-90.80) for those in the DOTS group and 87.38% (95% CI: 85.51-87.24) for those in the SAT group (Figure 4a). Among the patients with latent TB, the cure rates were 90.95% (95% CI: 90.56-91.02) and 79.06% (95% CI: 78.23-79.87), respectively (Figure 4b).

Discussion

Although compliance with TB treatment is difficult to predict, previously noncompliant patients and patients with alcohol, drug abuse, or mental health problems, as well as homeless individuals and HIV-positive patients, are usually noncompliant.[4,14-17] Incorrect or incomplete treatment is a cause of acquired resistance.[4,18]
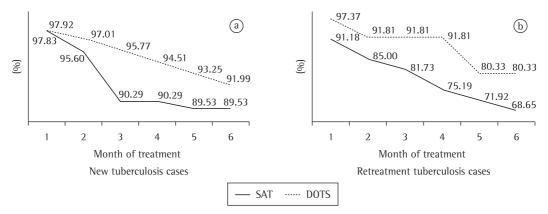
Figure 1 – Compliance with the six-month tuberculosis treatment, in percentage of cases, among the patients enrolled in the Tuberculosis Control Program, Carapicuíba, Brazil, 2003-2005, by treatment strategy. SAT: self-administered treatment; and DOTS: directly observed treatment, short-course.
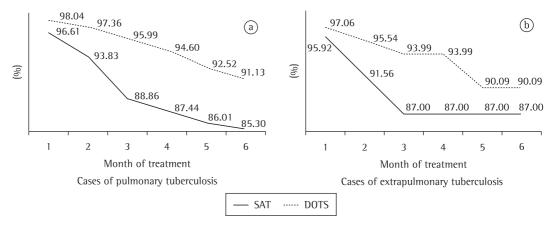
The World Health Organization recommends the use of the DOTS strategy for the treatment of TB, especially in developing countries. [2,5,7,14] One of the major lines of research on TB is assessing the efficacy of the therapeutic interventions and the effectiveness of the DOTS strategy in selected, randomized groups of patients. Operational studies help to assess the acceptability and applicability of new or innovative treatment modalities in different settings and everyday situations in health care facilities and health programs. In Brazil, epidemiological and operational data related to TB indicate that, in recent years, there have been

no significant decreases in the rates of incidence, mortality, noncompliance, or cure. In addition, in Brazil, there have been few studies like this one, involving the analysis of the effectiveness of DOTS under operational conditions. [8,11,14-19]

One of the limitations of this study was the comparison between the SAT group and the DOTS group. For ethical reasons, this comparison involved a historical series of patients treated in two different periods. However, the two groups were treated in consecutive years, which implies that were no significant changes in the major sociodemographic variables related to TB or in other important factors related to the various outcomes, except for the change in treatment strategy, from SAT to DOTS. The difference observed in the number of deaths, which was greater in the DOTS group, can be explained by the improved quality of the data in the case reporting and surveillance system databases. After the implementation of the DOTS strategy, it became possible to cross-reference the data in the Mortality Database with those in the São Paulo State Tuberculosis Patients Control System Database, which had not previously been a routine procedure.

Under operational conditions, the implementation of the DOTS strategy in Carapicuíba resulted in improved treatment compliance in comparison with SAT. These findings are consistent with those of studies conducted in the Brazilian cities of Rio de Janeiro, Ribeirão Preto, and Taboão da Serra, as well as with those of studies conducted in China. [8,9,11,16] Our data showed that the probability of
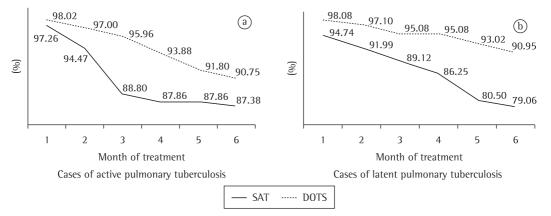
Figure 2 – Compliance with the six-month tuberculosis treatment, in percentage of new cases (2a) and retreatment cases (2b), among the patients enrolled in the Tuberculosis Control Program, Carapicuíba, Brazil, 2003-2005, by treatment strategy. SAT: self-administered treatment; and DOTS: directly observed treatment, short-course.

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Figure 3 – Compliance with the six-month tuberculosis treatment, in percentage of cases of pulmonary tuberculosis (3a) and extrapulmonary tuberculosis (3b), among the patients enrolled in the Tuberculosis Control Program, Carapicuíba, Brazil, 2003-2005, by treatment strategy. SAT: self-administered treatment; and DOTS: directly observed treatment, short-course.

discharge after cure/treatment completion was greater among the patients treated under the DOTS strategy than among those under SAT. At the end of the six-month treatment, the probability of discharge after cure/treatment completion was 91.6% among the patients treated under the DOTS strategy, compared with 85.5% among those under SAT. The results of this study show that the DOTS strategy can be successfully implemented at primary health care clinics, even in low-income populations residing in large urban areas with a high burden of tuberculosis infection, such as Carapicuíba and other PNCT priority cities in Brazil. Similar findings have been reported in other studies.[11,14-16)] Among the patients who reported a history of TB treatment, treatment compliance was better in the DOTS group than in the SAT group. In addition, the probability of discharge after cure was greater among the patients treated under the DOTS strategy, regardless of disease localization or sputum smear microscopy result.

Some studies have demonstrated that providing incentives to patients increases the rates of discharge after cure.[(4,20-23)] In the present study, the patients treated under the DOTS strategy were offered breakfast after each dose, as well as a monthly supply of nonperishable food items (a food basket) and public transportation passes. When necessary, the patients were

Figure 4 – Compliance with the six-month tuberculosis treatment, in percentage of cases of active pulmonary tuberculosis (3a) and latent pulmonary tuberculosis (3b), among the patients enrolled in the Tuberculosis Control Program, Carapicuíba, Brazil, 2003-2005, by treatment strategy. SAT: self-administered treatment; and DOTS: directly observed treatment, short-course.

offered amenities, such as drug administration at work or at home and extended hours at the health care clinics, in order to facilitate and individualize treatment, as has been done in other localities.[9,16-24]

The results of TB control programs are influenced by their managers and by the level of training/motivation of the health care professionals involved.[14,24-26] Greater treatment effectiveness and greater treatment compliance can be related to improvements in the relationships between patients/patient families and health care professionals.[13] The quality of the interaction between patients and health care professionals might be one of the main reasons for the excellent results of the DOTS strategy in different programs worldwide, including the PCT evaluated here.[10,11,14-17]

The relationship between directly observed treatment and cure rates is complex. In addition, the factors that might influence different outcomes are not totally predictable and cannot be objectively determined. However, direct observation of treatment is important for ensuring high rates of discharge after cure. In addition to directly observed treatment, systematic data monitoring and the political commitment to ensure prompt and appropriate access to diagnostic tests, with trained and motivated staff, are important measures, all of which are components of the DOTS strategy.[14,18]

Our results show that the DOTS strategy for TB control improved treatment compliance among the patients enrolled in the PCT under study, increasing the probability of cure after six months of standard treatment, under operational conditions.

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