Original Article

Descriptive study of the implementation and impact of the directly observed treatment, short-course strategy in the São José do Rio Preto municipal tuberculosis control program (1998-2003)*

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Abstract

Objective: To describe treatment outcomes (cure, noncompliance or death) after the implementation of the Directly Observed Treatment, Short-course (DOTS) strategy for tuberculosis control in the city of São José do Rio Preto, Brazil, between 1998 and 2003. **Methods:** A descriptive study, based on secondary data (National Case Registry database, Tuberculosis Epidemiology database, and the 'Black Book' Registry), was conducted using a specific instrument. The data were analyzed using descriptive statistics. **Results:** After the implementation of the DOTS strategy, there was a decrease in noncompliance and case detection rates as well as an increase in cure and death rates. The increase in the number of tuberculosis-related deaths might be attributable to three factors: the predominance of the disease in individuals over 50 years of age, tuberculosis/HIV co-infection, and the presence of accompanying diseases. **Conclusion:** The implementation of the DOTS strategy strengthened the decentralization of the tuberculosis control plans as well as the integration of the Basic Health Care Clinic teams with the Tuberculosis Control Program team. Political commitment of the administrator to tuberculosis control, in conjunction with the policy of benefits and incentives, is essential for the sustainability of the DOTS strategy.

Keywords: Tuberculosis; Epidemiology; Health services; Politics; Directly observed therapy.

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Introduction

Brazil ranks fifteenth among the twenty-two countries that are responsible for 80% of the total number of tuberculosis (TB) cases worldwide, with a prevalence of 58 cases per 100,000 inhabitants. Despite being a curable disease, TB still kills at least 6000 people/year in Brazil. The cure rate is 72.2%, and the treatment noncompliance rate is 11.7%, reaching, in some cities, 30 to 40%. It is estimated that 111,000 new cases occur annually. These data represent a great challenge for Brazil in terms of the goals established in conjunction with the World Health Organization (WHO), which has declared TB a global emergency and proposed that the directly observed treatment, short-course (DOTS) strategy be used, with the goals of achieving favorable outcomes in 85% of cases, identifying 70% of all new cases, and reducing treatment noncompliance by 5%.[1]

The DOTS strategy consists of five pillars: "Case detection through sputum smear microscopy among patients with respiratory symptoms who seek general health care; standardized, directly observed and monitored, short-course treatment; uninterrupted supply of anti-TB drugs; a system of registering data and information that ensures the evaluation of the treatment; and government commitment to make TB control a priority."[2]

The DOTS strategy proposes "the integration of primary health care as well as the implementation of continuous reform in the health sector."[3] In 1998, the DOTS strategy was proposed, incorporated into the National Tuberculosis Control Plan,[4] and gradually implemented in Brazilian cities as a strategy within the Unified Health System, encouraging the identification and treatment of new cases by granting benefits upon the signatories of a statement of compliance.[5]

The city of São José do Rio Preto (SJRP), with a population of 406,827 inhabitants,[6] is located in the northwest region of the state of São Paulo, which is characterized as a regional center, the headquarters of the 8th administrative region (comprising 96 municipalities), and an area of influence that reaches part of the states of Minas Gerais, Mato Grosso, and Mato Grosso do Sul.

According to the 2000 and 2002 editions of the Paulista (state of São Paulo) Social Responsibility Index, SJRP is classified as belonging to the state of São Paulo Group 1 (elite group) with high levels of wealth, longevity, and education. However, there is the official SJRP, which can be compared to cities in first world countries, and the real SJRP, which is characterized by illegal housing developments (in which 5% of the population resides), where there are no schools, squares or health services and whose inhabitants have no property deeds and drink water contaminated by sewage from cesspools.[7] The population structure of the city is similar to that of cities in developed countries, with a decrease in the population aged 0-4 years and a noticeable increase in the economically active population (14 to 49 years of age) as well as in the population aged 50 or older, especially in the population older than 75 years of age.[6,7]

In addition to the increased need for equipment and services available for use by the community, the construction of housing units for migrants, stimulated by the National Housing Bank through the Program for Mid-sized Cities (created in order to evaluate the demographic situation in large metropolitan areas), in conjunction with the changes in the health policy of the country, from the 1980s onward, led to the development and growth of public health services in SJRP.

The city became a referral center for health care, receiving patients from the region and from other states in Brazil. It has a mean of 4.4 doctors/1000 inhabitants, a rate double that of the state of São Paulo as a whole.[7]

In 2003, the risk of developing active TB among the SJRP inhabitants at the lower socioeconomic levels (Class C) was approximately three times higher than that among those at the higher levels (Class A).[8]

The implementation of the Unified Health System in 1988 promoted changes in the SJRP health system, and, in May of 1998, the city was certified for Full Management of Public Health Care.[9,10]

Prior to 1998, the treatment of patients with TB was coordinated by the State Department of Health and centralized in Health Center I. However, with the decentralization of the state health care services, execution of the *Programa de Controle da Tuberculose* (PCT, Tuberculosis Control Program) came to be the responsibility of the Specialty Outpatient Services and patients with TB began to receive treatment at Unit 60 of the Treatment Management Program, TB treatment being consid-

ered a secondary-care specialty in the referral standard of the region.

In 1998, SJRP was designated a priority city for TB control due to its high prevalence of TB/HIV co-infection (35% in 1998 and 51% in 2004).[8] At that time, the implementation of supervised treatment was aimed at patients co-infected with TB/HIV.

The objective of the present study was to describe treatment outcomes (cure, noncompliance or death) between 1998 and 2003, after the implementation of the DOTS strategy for TB control in SJRP.

Methods

This article is the result of a project entitled 'Status of the implementation of the DOTS strategy for TB control in some regions of Brazil: history and peculiarities according to regional characteristics in 2005'.

This was a descriptive study involving the review of operational and epidemiological data after the implementation of the DOTS strategy.

We used epidemiological and operational markers, such as diagnostic sputum smear microscopy and TB cases with positive sputum smear microscopy results, as well as rates of cure, treatment noncompliance, and death. This study, based on secondary data obtained from the Tuberculosis Epidemiology (Epi-TB) database, National Case Registry database, and the 'Black Book' Registry, among others, was conducted using a specific instrument.

For inclusion in the study, only new cases of pulmonary TB with positive sputum smear microscopy results at diagnosis were considered. The data were analyzed using descriptive statistics.

The present study was approved by the Ethics in Research Committee of the University of São Paulo at Ribeirão Preto School of Nursing.

Results

The year 2001 represented, for SJRP, the beginning of the restructuring and reorganization of its health system. The city was divided into health care districts, and the area served by each health care facility was defined. There was significant investment in the reformulation and expansion of the Epidemiological Surveillance Program, which is currently computerized. The use of geoprocessing technology[11] made it possible to instrumentalize, plan, and evaluate all of the interventions, especially those related to diseases for which reporting is compulsory, such as TB, thereby streamlining the services.

The current legislation, the support of the São Paulo State Department of Health, and interest in receiving the bonus were some of the reasons that administrators decided to implement the DOTS strategy. As of 2000, treatment of TB/HIV became the responsibility of the Sexually Transmitted Diseases/AIDS Program and began to be conducted at the Specialized Treatment Unit. An employee was hired, through an agreement with the Pan American Health Organization, in order to perform the supervised treatment in co-infected patients in the home.

Operational status

Initially, the supervised treatment (ingestion of the medication) was performed at the referral outpatient clinic under the supervision of a nurse. In 2001, with financial support from the Brazilian Ministry of Health via the São Paulo State Department of Health, the city hired a health agent in order to administer the supervised treatment in the outpatient clinic and, especially, at patient places of residence. In 2002, priority was still given to the treatment of patients at a higher risk of noncompliance, including drug addicts, alcoholics, vagrants, individuals excluded from their family circle, and co-infected patients.

At that time, the strategy used to start decentralizing the supervised treatment to the *unidades básicas de saúde* (UBSs, basic health clinics) was to integrate the PCT team and the UBS managers so that the UBS teams would care for their patients by supervising the intake of medicine.

In the years 2000 and 2001, the sensitization work regarding the decentralization of the supervised treatment was markedly influenced by the training offered to the technicians of public hospitals (physicians, nurses, and nursing assistants/technicians) as part of the Epidemiological Tuberculosis Surveillance Basic Training Program. Subsequently, some UBSs, embodied by the attending nurse, agreed to the proposal of initiating the supervised treatment of the patients living in their service area.

Various factors, such as the inconsistent availability of transport for daily supervised treatment activities and the lack of training of the drivers of

the transportation headquarters, have interfered with the availability of supervised treatment for all patients.

In 2001, the number of *Equipes de Saúde da Família* (ESF, Family Health Care Teams) increased, and the Epidemiological Tuberculosis Surveillance Basic Training Program implemented a continuing education program. As a consequence, the active search, diagnosis, treatment, and supervised treatment of TB were decentralized.

At the end of 2002, in the attempt to promote the supervised treatment, the practice of donating baskets of groceries, eggs, green vegetables, and transportation passes was adopted.

At the end of 2004, the municipal administrator increased the political commitment of to the DOTS strategy, and TB came to be considered one of the priorities in health surveillance. The goals of the PCT were set, and it was proposed that the functions of the program be decentralized by gradually transferring its functions to the UBS service areas. It was incumbent upon the PCT team to hire a medical professional, selecting the one with the most appropriate profile, to take responsibility for the management of patients, supervise the treatment administered in the UBSs, and monitor the decentralization process.

A study carried out in SJRP, using geoprocessing of information by municipal census sector, found that the risk of developing active TB among the inhabitants of areas in which the socioeconomic level was lower (Class C) was approximately three times higher than among the inhabitants of areas in which the socioeconomic level was higher (Class A).[9]

After having considered the historical course of the implementation of the DOTS strategy in the city, we will now analyze its repercussions on TB prevalence from 1998 onward.

Figure 1 shows the rates of cure, death, treatment noncompliance, and identification of new cases of pulmonary TB in SJRP between 1998 and 2003. The year 2004 was not considered in the study since, during the data collection period, many patients had not yet completed the treatment regimen.

The number of new cases of pulmonary TB with positive sputum smear microscopy results at diagnosis in relation to treatment noncompliance, cure, death, and detection, between 1998 and 2003, indicate a decrease in treatment noncompliance and case detection rates, as well as an increase in cure and death rates.

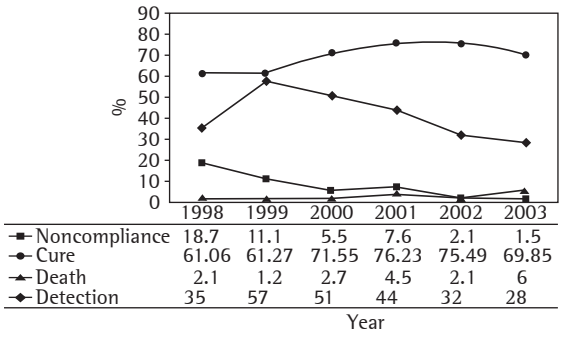

Figure 1 - Rates of cure, death, treatment noncompliance, and detection of new cases of pulmonary tuberculosis. São José do Rio Preto, 1998-2003.

The implementation of the DOTS strategy in the city had a positive impact on the rates of cure and treatment noncompliance during the period analyzed. There was increased political commitment to the implementation of the strategy, as evidenced by the hiring of health agents, specific training of health professionals, and the initiation of the decentralization process, in which supervised treatment was transferred to the UBSs and ESFs.

During the six years analyzed, the mortality rate presented a tendency toward growth. Results of an evaluation using data from the Municipal Department of Health and Surveillance Epi-TB database indicate that, of the deaths of individuals with TB and over 50 years of age, one-third were attributed to TB alone, one-third to TB/HIV co-infection, and one-third to TB accompanied by other diseases. In 1998, the overall mortality rate was 2.1%, increasing to 6% in 2003.[12,13]

In order to gain a better understanding of the case detection rates, two different periods (1996-1999 and 1999-2003) were analyzed independently (Figures 2 and 3, respectively).

In SJRP, between 1996 and 1999, there was a positive slope in the regression line, which ranged from 2.5 to 13.4% in case detection.

Case detection was 21% lower in the 1999-2003 period than in the 1996-1999 period.

Discussion

The political commitment of the municipal government, embodied by the health administrator, was one of the components that promoted

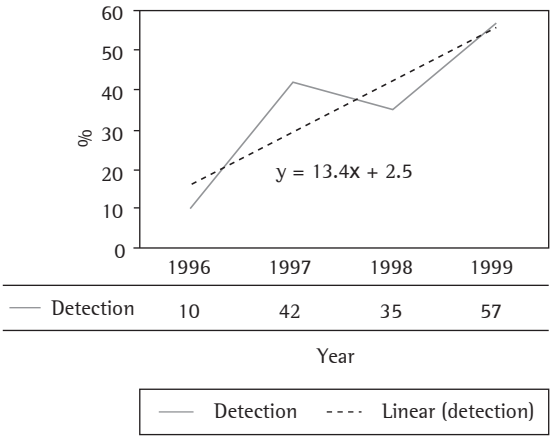

Figure 2 - Rate of detection of new cases of pulmonary tuberculosis in São José do Rio Preto, 1996-1999.

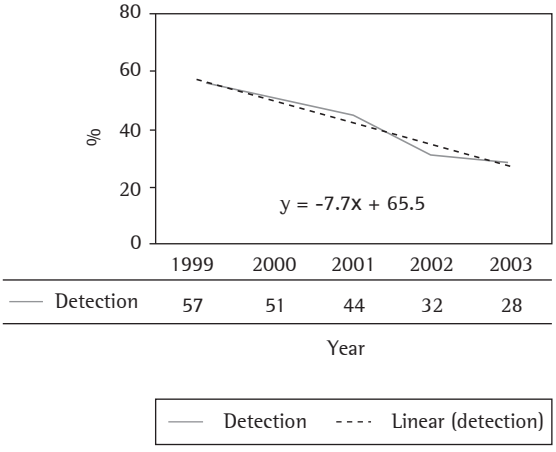

Figure 3 - Rate of detection of new cases of pulmonary tuberculosis in São José do Rio Preto, 1999-2003.

the implementation of the DOTS strategy in SJRP. This political commitment was evidenced by the hiring of health agents, specific training of the PCT professionals, and the decentralization (transfer to the UBSs and ESFs) of the supervised treatment.

It is noteworthy that one of the pillars of the DOTS strategy resides is political commitment to prioritize TB control.[2]

Implementation of the DOTS strategy in the city had a positive impact on the rates of cure and treatment noncompliance during the period analyzed. In 1998, the coverage of the strategy was 3.1%, increasing to 62% in 2004.[6] The number of new cases of pulmonary TB with positive sputum smear microscopy results at diagnosis in relation to treatment noncompliance, cure, death, and detection, between 1998 and 2003, indicate decreases in the rates of treatment noncompliance and case detection, as well as increases in cure rates and mortality rates (Figure 1).

The mortality rate presented a tendency toward growth during the six years analyzed. Several hypotheses could be put forward in order to explain this situation. The first is related to the aging of the population: many individuals who were initially infected in the first decades of the twentieth century could become susceptible in their old age. Since such individuals present atypical clinical profiles, they are not easily diagnosed, which increases mortality among the elderly.[14] Another hypothesis is that these trends result from the limited access to health services, despite the proposal for reorganizing the model of basic health services. We can also hypothesize that the composition of the population of health care workers plays a role, given the difficulty of the professionals at different levels of the health system in incorporating the search for patients with respiratory symptoms into their treatment routines. In addition, it is likely that late diagnosis and the consequent poor clinical status of patients at the initiation of treatment, is responsible for the increase in the number of deaths.[15]

Our results show that there was a negative slope in case detection, This suggests that, although the city took over full management of the system and initiated the process of decentralization of health services in 1998, the priority of the Department of Health was dengue prevention, putting the identification of patients with respiratory symptoms into a secondary role in the routine of health services.

In the past decade, this situation has also been reported in other countries in which the DOTS strategy was implemented. Worldwide, the supervised treatment coverage increased dramatically (by more than 10 million patients) from 1995 to 2000, whereas there was only a modest increase (from 35 to 40%) in the detection rates.[16]

The political commitment to implement the DOTS strategy at the end of the 1990s was met by the PCT team in the secondary referral outpatient clinic in a centralized way, achieving improvements in the rates of cure and treatment noncompliance, as well as increasing the supervised treatment coverage in recent years. Ironically, the success of these strat-

egies might have reinforced the idea that TB is a second-tier disease, thereby reducing the active search for TB, in its initial phase, in the UBSs.

This centralized approach to the management of TB control in this city is in accordance with the ideas proposed in a study of the global TB situation and of the situation of the new strategy that primarily focused on improving cure rates through supervised treatment, broadening availability of medication, and analyzing treatment outcomes, rather than on expanding case detection, which should be pursued after the improvement of the cure rates.[17]

Some operational factors, such as the inconsistent availability of transportation for the daily supervised treatment activities and the lack of training of the drivers of the transportation headquarters, act as barriers to increasing the availability of the supervised treatment for all patients. Key positive factors include the establishment of a rapport between the patient/families and the team of professionals, supported by incentives and benefits (foods, transportation passes, etc.), as well as general guidelines regarding sickness and unemployment benefit applications.

Another hypothesis to explain the increase in the number of deaths could be related to the ratio between the TB cases that were of the pulmonary form and those that were of the extrapulmonary form, since the pulmonary form maintains the chain of TB transmission. However, the extrapulmonary form of the disease indicates profiles of immunosuppression, which are mainly caused by the presence of the TB/HIV co-infection. The decrease in the pulmonary/extrapulmonary ratio might be due to an increase in the incidence of the extrapulmonary form, and this could indicate an increase in immunosuppressive diseases, although the pulmonary form is also sensitive to situations of immunosuppression.[18] This last hypothesis corroborates the data found in SJRP, which, from the year 2000 onward, presented a decrease in the pulmonary/extrapulmonary ratio as a result of the increase in the extrapulmonary form, probably due to the high rate of TB/HIV co-infection. Another possible explanation is the increased use of appropriate technology by the program in its diagnostic investigations, since, most of the TB cases in the city are diagnosed in the hospitals.[7]

Another factor, according to Epi-TB data,[7] is that the number of cases of pulmonary TB, diagnosed using sputum smear microscopy results (positivity for acid-fast bacilli), has decreased in the city. Epidemiologically, this suggests a decrease in transmission.

In SJRP, the DOTS strategy, in addition to contributing, in cooperation with the PCT, to the involvement and integration of the UBS teams with the PCT team, was especially useful for the reorganization of the PCT, which, from the implementation of the strategy onward, presented a significant improvement in the rates of cure and treatment noncompliance, as well as contributing to the process of decentralization of the plans for the management and follow-up of as many patients as possible.

In conjunction with the issues related to the political will of the administrator and to the reorganization of the service, the team responsible for the coordination of the PCT in the city considers that, in addition to monitoring the supervised dose, the supervised treatment includes a set of support activities for the team as well as the maintenance of incentives and benefits that allow health workers to come into closer contact with patients, favoring the results obtained in SJRP, allowing greater treatment compliance and increasing the number of cases cured.

The issues regarding TB control, being re-evaluated in macropolitical terms, undoubtedly require steady improvement of the living conditions of the population of the city and also indicate the need for the implementation of health policies aimed at the populations living in areas of SJRP in which the risk for the occurrence of TB is higher.

It is of utmost importance to adopt intersectoral measures that promote health and health surveillance. It is also crucial to deal with conditioning factors in a coordinated way, not only monitoring cases, outbreaks, and TB contacts but also supporting the DOTS strategy, principally in order to increase treatment compliance and avoid the emergence of drug-resistant strains.

The advancements seen in the reformulation of the Municipal Health Council, with the more effective participation of the segment of users mainly represented by less privileged groups of society, especially the segment of representatives of non-governmental organizations dealing with AIDS, favor not only the PCT but also other non-priority programs in the municipal health agenda.

This underscores the need for organized civil society to participate more actively through social movements.

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