

Effectiveness of tuberculosis treatment*

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Abstract

Objective: To analyze the treatment strategies that influence the effectiveness of tuberculosis treatment at primary care clinics (PCCs) in Brazil. **Methods:** This was a descriptive, retrospective epidemiological survey based on the medical records of 588 tuberculosis patients enrolled in the tuberculosis control programs at two PCCs located in the city of Belém, Brazil: *Centro de Saúde Escola do Marco* (CSEM) and *Unidade Básica de Saúde da Pedreira* (UBSP). The survey was limited to patients enrolled between January of 2004 and December of 2008. We included only patients between 18 and 59 years of age, and we excluded those who were transferred or were found to have been misdiagnosed. We collected data regarding age, gender, type of treatment (self-administered or supervised), co-infection with HIV, and treatment outcome. The health professionals involved in the tuberculosis control program at the two PCCs were interviewed regarding the strategies used for tuberculosis control and regarding routine clinical care for tuberculosis patients. **Results:** There were no significant differences between the CSEM and UBSP patients regarding age, gender, or co-infection with HIV. Supervised treatment was used significantly more frequently and the rate of cure was higher at the CSEM than at the UBSP, whereas the rate of treatment noncompliance was higher at the UBSP than at the CSEM. **Conclusions:** For patients enrolled in tuberculosis control programs at PCCs in Brazil, supervised treatment appears to be an extremely important strategy for reducing the rate of treatment noncompliance.

Keywords: Tuberculosis; Patient dropouts; Patient care planning; Treatment outcome.

Resumo

Objetivo: Analisar as estratégias que influenciam a efetividade do tratamento da tuberculose em Unidades Básicas de Saúde (UBS). **Métodos:** Levantamento epidemiológico, descritivo, retrospectivo, envolvendo os prontuários médicos de 588 pacientes com tuberculose cadastrados no programa de controle da tuberculose, entre janeiro de 2004 e dezembro de 2008, em duas UBS – Centro de Saúde Escola do Marco (CSEM) e UBS da Pedreira (UBSP) – localizadas na cidade de Belém (PA). Os critérios de exclusão foram ter idade < 18 anos ou > 59 anos e ter alta por transferência ou mudança de diagnóstico. Os dados coletados foram idade, sexo, tipo de tratamento (autoadministrado ou supervisionado), coinfeção por HIV e desfecho do tratamento. Os profissionais de saúde envolvidos no programa da tuberculose das duas UBS foram entrevistados quanto às estratégias utilizadas no controle da doença e à rotina de atendimento. **Resultados:** Não houve diferenças significativas quanto a idade, sexo e coinfeção com HIV nas duas UBS. A utilização de tratamento supervisionado foi significativamente maior no CSEM que na UBSP, assim como a taxa de cura, enquanto a taxa de abandono foi maior na UBSP que no CSEM. **Conclusões:** Para pacientes cadastrados em programas de controle da tuberculose em UBS no Brasil, o tratamento supervisionado provavelmente é uma estratégia de extrema importância para se alcançar uma menor taxa de abandono.

Descritores: Tuberculose; Pacientes desistentes do tratamento; Planejamento de assistência ao paciente; Resultado de tratamento.

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Introduction

Tuberculosis is considered the leading cause of death from infectious diseases in adults,⁽¹⁾ and, despite being an ancient disease, it remains a serious public health problem worldwide, primarily affecting developing countries.⁽²⁾ Early diagnosis and prompt pharmacological treatment initiation are essential for effective disease control.⁽³⁾

In Brazil, it is estimated that there are 50 million infected individuals and that 85,000 new cases occur each year, 6,000 tuberculosis-related deaths occurring annually.⁽⁴⁾ Among the 22 countries that collectively account for 80% of all cases of tuberculosis worldwide, Brazil ranks 19th.⁽³⁾

In our country, the problem of tuberculosis treatment lies in the high rate of treatment noncompliance, which, in some capitals, can be as high as 25% of treated patients. The great concern about the effectiveness of treatment is due to the fact that noncompliance (or irregular treatment), in addition to not producing cure, can give rise to bacteria that are resistant to standard drugs.⁽⁵⁾ This has been a challenge in the individual treatment of patients.^(6,7)

In view of this situation, the objective of the present study was to analyze the treatment strategies that influence the effectiveness of tuberculosis treatment at two primary care clinics (PCCs) in the city of Belém, Brazil, in order to identify strategies that can improve adherence to tuberculosis treatment and be used by other PCCs in an attempt to increase the effectiveness of disease control.

Methods

This was a descriptive, retrospective epidemiological survey of male and female tuberculosis patients in the 18-59 year age bracket enrolled in the tuberculosis control programs at one of two PCCs: *Centro de Saúde Escola do Marco* (CSEM) or *Unidade Básica de Saúde da Pedreira* (UBSP). The survey was limited to patients who were enrolled between January of 2004 and December of 2008 and who completed the treatment (satisfactorily or not). We excluded all of the patients who did not meet the pre-established inclusion criteria, as well as those for whom there were missing data in the databases searched. In addition, we excluded those who were transferred (because

they no longer constituted cases treated at the PCCs studied) and those who were found to have been misdiagnosed (because they no longer constituted cases of tuberculosis).

In the study period, 638 and 464 patients, respectively, were diagnosed with tuberculosis at the CSEM and at the UBSP. After applying the inclusion and exclusion criteria to the medical records, we selected a total of 588 patients. Of those, 249 were enrolled in the CSEM tuberculosis control program and 339 were enrolled in the UBSP tuberculosis control program.

The study was performed in two phases. In the first phase, we analyzed the medical records of the CSEM and UBSP patients, as well as the tuberculosis registries of the Brazilian National Tuberculosis Control Program, together with databases containing all of the available information (including test results and the clinical course of the disease) on those patients. In the second phase, we interviewed the health professionals (physicians, nurses, and nursing technicians) who had been working at the CSEM or UBSP since at least January of 2004 and who were involved in providing care for tuberculosis patients. The interviews were aimed at gathering information regarding the tuberculosis control strategies used at the two PCCs.

In the first phase of the survey, we analyzed possible treatment outcomes (discharge after cure, treatment noncompliance, and death from tuberculosis) and the type of treatment (self-administered or supervised). In addition, we profiled the treated patients, the profile variables including gender, age, and co-infection with HIV. In the second phase, the tuberculosis control strategies used at the PCCs were analyzed, as was routine clinical care for tuberculosis patients.

The results obtained were statistically analyzed by the chi-square test or Fisher's exact test (depending on the type of variable) with the program BioEstat, version 5.0. The level of significance was set at $p < 0.05$ (5%).

All of the patients included in the present study were studied in accordance with the principles of the Declaration of Helsinki, and the study project was approved by the Research Ethics Committee of the *Hospital de Clínicas Gaspar Viana* (Protocol nº. 069/09).

Results

Of the 588 selected patients, 249 and 339, respectively, were treated at the CSEM and

at the UBSP. Regarding treatment outcomes (Table 1), we found a higher rate of cure among the CSEM patients than among the UBSP patients ($p = 0.0016$). We also found that the rate of treatment noncompliance at the CSEM was within the goal range established by the Brazilian National Ministry of Health (i.e., $< 5\%$). In addition, self-administered treatment prevailed at both PCCs (57.43% at the CSEM and 98.23% at the UBSP; Table 2).

There were no statistically significant differences between the CSEM and UBSP patients regarding gender, age, or co-infection with HIV (Tables 3-5). There was a predominance of males at the two PCCs (Table 3), a finding that is in agreement with the literature.^(9,10) As can be seen in Table 4, most of the CSEM patients were in the 18-23 year age bracket, whereas most of the UBSP patients were in the 24-29 year age bracket, with no significant differences between the groups in terms of age. Most of the patients

who underwent HIV testing were found to be HIV negative (Table 5).

Discussion

Treatment noncompliance among tuberculosis patients has been seen as a major problem in tuberculosis control, because in addition to causing individual damage, it endangers public health, leading to treatment failure and the emergence of resistant strains.^(5,7,8)

Several factors determine or influence adherence to tuberculosis treatment. Therefore, in addition to investigating the dynamics of care and the strategies used at the PCCs studied, we evaluated some of the characteristics of the population profile. In general, there were no significant differences between the CSEM and UBSP patients regarding gender, age, or co-infection with HIV. Males and patients in the 18-29 year age bracket predominated, and there was a low rate of co-infection with HIV.

Regarding the factors that are important in assessing the effectiveness of treatment, it is essential to remember that AIDS is chief among the diseases that can accompany tuberculosis.⁽¹¹⁾ We found that most of the CSEM and UBSP patients who underwent HIV testing were HIV negative, which is at odds with some studies,^(12,13) in which most patients were found to have tuberculosis/HIV co-infection. This might have been due to the difference between the location in which our study was conducted and those in which those studies were conducted in terms of the incidence of HIV. In Brazil, according to official data,⁽¹⁴⁾ the incidence of HIV is much lower in the northern region than in the southeastern and southern regions, where the aforementioned studies were conducted. In addition, the rate of tuberculosis infection is higher in the northern

Table 1 – Distribution, by treatment outcome, of tuberculosis patients treated at the *Centro de Saúde Escola do Marco* and at the *Unidade Básica de Saúde da Pedreira*, both located in the city of Belém, Brazil, 2004-2008.

Treatment outcome	Place of treatment	
	CSEM	UBSP ^a
	n (%)	n (%)
Cure	229 (91.97)	302 (89.09)*
Noncompliance	11 (4.42)	27 (7.96)*
Failure	2 (0.80)	0 (0.00)
Death	7 (2.81)	4 (1.18)
Total	249 (100.00)	333 (98.23)

CSEM: *Centro de Saúde Escola do Marco*; and UBSP: *Unidade Básica de Saúde da Pedreira*. ^aThe 6 patients who underwent supervised treatment were excluded. * $p = 0.0016$.

Table 2 – Distribution, by type of treatment, of tuberculosis patients treated at the *Centro de Saúde Escola do Marco* and at the *Unidade Básica de Saúde da Pedreira*, both located in the city of Belém, Brazil, 2004-2008.

Type of treatment	Place of treatment	
	CSEM	UBSP
	n (%)	n (%)
Self-administered	143 (57.43)	333 (98.23)
Supervised	106 (42.57)	6 (1.77)
Total	249 (100.00)	339 (100.00)

CSEM: *Centro de Saúde Escola do Marco*; and UBSP: *Unidade Básica de Saúde da Pedreira*.

Table 3 – Distribution, by gender, of tuberculosis patients treated at the *Centro de Saúde Escola do Marco* and at the *Unidade Básica de Saúde da Pedreira*, both located in the city of Belém, Brazil, 2004-2008.

Gender	Place of treatment	
	CSEM	UBSP
	n (%)	n (%)
Male	126 (50.60)	189 (55.75)*
Female	123 (49.40)	150 (44.25)
Total	249 (100.00)	339 (100.00)

CSEM: *Centro de Saúde Escola do Marco*; and UBSP: *Unidade Básica de Saúde da Pedreira*. * $p = 0.2487$.

Table 4 – Distribution, by age bracket, of tuberculosis patients treated at the *Centro de Saúde Escola do Marco* and at the *Unidade Básica de Saúde da Pedreira*, both located in the city of Belém, Brazil, 2004–2008.

Age bracket, years	Place of treatment	
	CSEM	UBSP
	n (%)	n (%)
18-23	57 (22.89)	68 (20.06)
24-29	50 (20.08)	71 (20.94)
30-35	37 (14.86)	42 (12.39)
36-41	25 (10.04)	46 (13.57)
42-47	28 (11.24)	56 (16.52)
48-53	33 (13.25)	31 (9.14)
54-59	19 (7.63)	25 (7.37)
Total	249 (100.00)	339 (100.00)

CSEM: *Centro de Saúde Escola do Marco*; and UBSP: *Unidade Básica de Saúde da Pedreira*.

Table 5 – Tuberculosis/HIV co-infection in tuberculosis patients treated at the *Centro de Saúde Escola do Marco* and at the *Unidade Básica de Saúde da Pedreira*, both located in the city of Belém, Brazil, 2004–2008.

Tuberculosis/HIV co-infection	Place of treatment	
	CSEM	UBSP
	n (%)	n (%)
Present	9 (5.03)	8 (5.75)*
Absent	170 (94.97)	131 (94.25)
Total	179 (100.00)	139 (100.00)

CSEM: *Centro de Saúde Escola do Marco*; and UBSP: *Unidade Básica de Saúde da Pedreira*. *p = 0.9588.

region than in the southern and southeastern regions.⁽¹⁴⁾

Regarding the type of treatment (Table 2), the CSEM is set apart by one peculiarity: the use of directly observed treatment, short-course (DOTS). In Brazil, the DOTS strategy was implemented in 1998 and increased the rate of detection by 18%, as well as significantly increasing tuberculosis treatment success rates.⁽⁴⁾ The DOTS strategy is recommended by the World Health Organization and is based on direct supervision of antituberculosis drug intake (at least three weekly observations in the first two months and one weekly observation for the duration of the treatment). In addition, the DOTS strategy plays an essential role in improving treatment adherence and, consequently, in increasing cure and discharge rates. The implementation of supervised treatment in countries such as Peru has been shown to

be an effective strategy, reducing the rates of treatment noncompliance.⁽¹⁵⁾

In Brazil, the DOTS strategy has been implemented at various facilities in recent years. However, because of problems that are inherent to the current public health system, such as limited human and financial resources, there are operational difficulties in the use of DOTS for most patients undergoing tuberculosis treatment.⁽¹⁶⁾ Therefore, although DOTS was implemented at the CSEM in 2002, most patients still undergo self-administered treatment.

Unlike what occurred at the CSEM, supervised treatment was not used at the UBSP during most of the study period, having been implemented in the second half of 2008.

When analyzing the mechanisms of care delivery at the two PCCs between January of 2004 and December of 2008, we observed the differences between the use of DOTS and the use of self-administered treatment, as well as the strategies used for improving treatment success.

In this context, the CSEM provides two lines of care for the diagnosis and treatment of tuberculosis: primary health care, accounting for 80% of cases; and specialty care referral.

Primary health care is related to patients who seek medical attention on their own initiative. Patients with symptoms of tuberculosis are first referred to the nursing ward, where they are interviewed regarding epidemiological links, risk factors, and the possible presence of another medical condition, two sputum samples being collected for sputum smear microscopy. Typically, the first sample is collected on the same day and the second sample is collected on the following day. Sputum smear microscopy is performed in the CSEM laboratory. In addition, for all patients, vulnerable contacts, such as children, are traced and notified. Therefore, as is recommended by the Brazilian National Ministry of Health,⁽⁴⁾ the patients treated at the CSEM receive instructions regarding their treatment before starting chemotherapy. In the initial interview, they receive information, in accessible language, regarding the characteristics of the disease and the treatment regimen to be used, including drugs, treatment duration, benefits of regular medication use, consequences of treatment noncompliance, and possible adverse drug effects. However, only patients who have clinical complications during the course of the treatment or who are referred for specialist care

consult with the CSEM physicians. This is due to the fact that the CSEM has no team providing care exclusively for tuberculosis patients. In addition, the CSEM is a referral center for tuberculosis and therefore receives a larger number of patients.

At the CSEM, in contrast to the World Health Organization recommendation, DOTS is not used in all cases of active tuberculosis, priority being given to the following cases: smear-positive cases; cases of treatment noncompliance; cases of recurrence; cases of treatment failure; and patients facing social risks (such as alcoholism, poor nutrition, and living alone).⁽¹⁶⁾ According to Morrone et al.,⁽¹⁷⁾ one way to overcome the difficulties in adopting supervised treatment is to restrict it to patients who really need it, preventing noncompliance with the assigned treatment.

Patients receiving DOTS are therefore selected on the basis of the aforementioned priorities and undergo two phases of treatment: the first phase, in which the patient has to report to the clinic Monday through Friday for follow-up and medication intake; and the second phase, in which the patient reports to the clinic twice a week.

Regarding the strategies employed at the CSEM, it is of note that the number of visits to the clinic for medication intake in the two treatment phases is higher than that recommended by the Brazilian National Ministry of Health.

This peculiarity of the CSEM is essential for the effectiveness of tuberculosis treatment, given that the first two to three months of treatment is when noncompliance is most likely to occur, which underscores the importance of adopting measures to reduce noncompliance as soon as the treatment begins. Therefore, the strategy of frequent follow-up visits is an intervention designed to be implemented at the beginning of treatment and has been shown to have favorable results.⁽¹⁸⁾

Other strategies that have been used at the CSEM since the implementation of DOTS on September 16, 2002, in order to increase treatment effectiveness include material incentives, such as transportation passes and meals (breakfast or porridge), and non-material incentives, such as caring for patients and providing clarification to families. This caring refers to improved access to treatment—given that one of the reasons that can lead to noncompliance is the distance between the place of residence and the hospital or health

care facility⁽¹¹⁾—and to giving weight to patient complaints. Osterberg & Blaschke⁽¹⁹⁾ found that providing little or no information regarding the possible side effects of the medication is one of the major obstacles to treatment compliance. In contrast, reaching out to patients and family members fosters mutual understanding of views on the disease and its treatment, promotes clarification, and attempts to establish a bond that will promote trust in scientific knowledge.⁽¹¹⁾ This clarification is essential, given that families play a role in providing support to tuberculosis patients, although in some cases families are unable to provide the support required in order to achieve favorable results. Providing information to and raising awareness of families are essential so that families do not negatively affect treatment compliance.

Still on the topic of supervised treatment, a group strategy is adopted at the CSEM. Therefore, patients receive the medication at the same time of day, which facilitates rapport and stimulates the exchange of information. This strategy allows patients not to feel isolated and helpless.

Self-administered treatment, which is another form of treatment at the CSEM, is also given appropriate attention. According to the professionals interviewed, the priorities include “treating patients well and listening carefully to them” and “giving weight to their complaints”, as well as “ensuring the quality of sputum smear microscopy”. Patients undergoing self-administered treatment receive sufficient medication for 30 days of treatment during a six-month period.

In cases of failure to attend a routine visit, either for self-administered treatment or for DOTS, the CSEM immediately contacts the patient or family members. First, whenever possible, telephone contact is attempted in order to clarify the reason for the absence. Subsequently, if the first contact attempt fails, a representative of the clinic goes to the place of residence of the patient in a final attempt to bring the patient back to treatment.

Secondary care referral, which is also available at the CSEM, corresponds to scheduled demand. This type of care allows clarification of difficult cases, such as complicated cases that do not progress as expected, as well as diagnostic elucidation of smear-negative cases suspected of treatment failure, multidrug resistance, and adverse effects.

At the CSEM, the care provided to tuberculosis patients includes HIV serology, and, since 2008, rapid HIV testing has been performed at the clinic itself. If the test result is positive, the patient is referred to the AIDS referral center, which is prepared to treat the two infections, given that immunocompromised patients should receive twice as much attention because they are at a higher risk of developing the disease and its complications.⁽⁴⁾ In addition, co-infection with HIV/AIDS is an important factor for the unfavorable outcome of tuberculosis treatment.⁽²⁰⁾ Therefore, early diagnosis of co-infection allows health care providers to adjust the treatment to the actual needs of the patient and reduces the weaknesses resulting from HIV infection, guaranteeing integrated health care and increasing treatment effectiveness.

A similar analysis of the mechanism of care provision for tuberculosis patients at the UBSP revealed that the organizational structure is as follows: completion of a general care form; first medical visit, in which clinical examination is performed; referral for laboratory tests (two sputum smear microscopy tests); and second medical visit or a nursing visit. Patients with a positive sputum smear are enrolled in the program, and notification, investigation, and treatment control forms are completed. At this point, patients receive counseling about the disease and the treatment, undergo a thorough history taking, are prescribed the medications, and are referred for HIV testing at the clinic itself, where rapid HIV testing began to be performed in 2008 (as it did at the CSEM).

It is of note that the rate of tuberculosis/HIV co-infection was lower at the UBSP than at the CSEM. This is an important difference between the two PCCs, given that measures for prevention and control of HIV and tuberculosis cannot be considered separately. Tuberculosis/HIV co-infection should be identified at the beginning of treatment so that individualized follow-up procedures can be implemented.⁽²⁰⁾

We found that most of the patients treated at the UBSP received self-administered treatment. This type of treatment requires that patients return to the clinic once a month for a routine visit and to receive medications, the clinical and etiological status being monitored.

The UBSP team consists of a general practitioner, a nurse, and a nursing technician, and

this team provides care exclusively for tuberculosis patients, who can also be monitored by a dentist and a psychologist as needed. In cases of failure to attend a routine visit, the health care team telephones the patient or family members in an attempt to prevent treatment noncompliance.

As occurs at the CSEM, the UBSP health care team reaches out to patients and their family members, providing information regarding the disease and the treatment to be followed, in order to establish a bond that will promote trust in the team.

It is of note that, until the second half of 2008, tuberculosis control at the UBSP was based exclusively on self-administered treatment. However, after the implementation of DOTS, only a few special cases received supervised treatment during the study period, including patients with a low level of education and without adequate family support.

Although DOTS was officially implemented in the second half of 2008 at the UBSP, the clinic still has no structure for the program, because there is no adequate space to welcome patients and there are no financial resources for providing breakfast or other incentives, such as transportation passes.

Analysis of the types of care provided to tuberculosis patients and the strategies used at each PCC investigated in the present study revealed different values in terms of treatment outcomes. Although the cure rates at both PCCs were higher than that set by the Brazilian National Ministry of Health,⁽⁴⁾ i.e., 85% of the estimated number of cases of tuberculosis, the rate of cure was statistically higher at the CSEM than at the UBSP.

With regard to treatment noncompliance (Table 1), only the CSEM achieved the national goal set by the Brazilian National Ministry of Health (rate of noncompliance < 5%),⁽⁴⁾ with two or three cases of noncompliance per year. In comparison with the literature, the rate of noncompliance observed at the CSEM was relatively lower than were those found at other health care clinics in Brazil^(9,10) providing supervised treatment.

In view of this, we can infer that the use of supervised treatment with additional strategies (i.e., scheduling a higher number of visits to the clinic than that recommended by the Brazilian National Ministry of Health and administering the

treatment in a collective fashion) contributes to a lower rate of noncompliance at the CSEM and should be adopted by other health care clinics in an attempt to improve the effectiveness of tuberculosis treatment.

On the basis of these results and considering that there were no statistically significant differences between the CSEM and UBSP patients in terms of age, gender, or co-infection with HIV, we can state that the influence of these factors, although present, as discussed earlier, does not explain the better outcome at the CSEM.

In conclusion, DOTS has proven to be an effective strategy to reduce the rates of noncompliance with tuberculosis treatment,⁽²¹⁾ reducing the risk of disease transmission in the community and resulting in major changes in the epidemiological indicators of tuberculosis. In addition, for better results in terms of treatment effectiveness, a higher number of visits to the PCCs can be scheduled in the first two to three months of treatment and the strategy of administering the medication in a collective fashion can be used.

It should be noted that the results obtained and discussed in the present study confirm the need for further studies focusing on obtaining data that are more precise and accurate for the development of strategies to improve the effectiveness of tuberculosis treatment and reduce noncompliance.

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