

RESEARCH ARTICLE (ORIGINAL) 

Directly observed therapy in the tuberculosis control strategy in Portugal

O tratamento diretamente observado na estratégia de controlo da tuberculose em Portugal
El tratamiento observado directamente en la estrategia de control de la tuberculosis en Portugal

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Abstract

Background: Tuberculosis is a global health problem that requires effective treatment. The World Health Organization (WHO) recommends that treatment should be tailored and supervised. Portugal has adhered to this strategy, but no studies on this issue were identified.

Objective: To describe the implications of Directly Observed Therapy (DOT) for tuberculosis control in Portugal.

Methodology: Exploratory and descriptive study with a sample of 303 people suffering from pulmonary tuberculosis, in Pulmonary Diagnostic Centers, in Northern Portugal, between March 2019 and January 2020.

Results: DOT was the treatment modality used in 88.1% of the sample. Most participants (75.9% of women and 66.3% of men) received treatment under the supervision of a nurse in the health care units. Patients' expectations do not seem to be a priority. Decision-making regarding the adopted strategy is left to the health professionals and does not seem to prioritize the patient's participation.

Conclusion: The DOT modality is a source of dissatisfaction, aggravates patients' financial burden, and promotes social stigma.

Keywords: tuberculosis; treatment; primary health care; nursing

Resumo

Enquadramento: A tuberculose, como problema de saúde à escala global, requer um tratamento eficaz. A World Health Organization recomenda a toma da medicação de forma supervisionada e personalizada. Portugal aderiu a esta estratégia, não se tendo identificado estudos desta problemática.

Objetivo: descrever as implicações do tratamento diretamente observado (TDO) no controlo da tuberculose, em Portugal.

Metodologia: Estudo exploratório e descritivo, numa amostra de 303 pessoas com tuberculose pulmonar, em centros de diagnóstico pneumológico da região Norte de Portugal, entre março de 2019 e janeiro de 2020.

Resultados: A TDO é a modalidade de tratamento em 88,1% da amostra. A maioria dos participantes (75,9% das mulheres e 66,3% dos homens) fazem o tratamento sob supervisão do enfermeiro, nas unidades de saúde. As suas expectativas individuais não parecem ser priorizadas. A tomada de decisão sobre a estratégia aplicada surge centrada nos profissionais de saúde e não aparenta privilegiar a participação da pessoa doente.

Conclusão: A modalidade TDO, apresenta-se como fonte de insatisfação, potencia o agravamento dos recursos económicos da pessoa doente e do estigma social.

Palavras-chave: tuberculose; tratamento; cuidados de saúde primários; enfermagem

Resumen

Marco contextual: La tuberculosis, como problema de salud mundial, requiere un tratamiento eficaz. La Organización Mundial de la Salud recomienda tomar la medicación de forma supervisada y personalizada. Portugal se ha adherido a esta estrategia, aunque no se ha identificado ningún estudio al respecto.

Objetivo: Describir las implicaciones del tratamiento observado directamente (TDO) para el control de la tuberculosis en Portugal.

Metodología: Estudio exploratorio y descriptivo, en una muestra de 303 personas con tuberculosis pulmonar, en centros de diagnóstico neumológico de la región norte de Portugal, entre marzo de 2019 y enero de 2020.

Resultados: El TDO es la modalidad de tratamiento en el 88,1% de la muestra. La mayoría de los participantes (el 75,9% de las mujeres y el 66,3% de los hombres) realizan el tratamiento con la supervisión del enfermero, en las unidades sanitarias. No parece que se prioricen sus expectativas individuales. La toma de decisiones sobre la estrategia aplicada parece centrada en los profesionales sanitarios y no parece priorizar la participación de la persona enferma.

Conclusión: La modalidad de TDO se presenta como una fuente de insatisfacción, potencia el empeoramiento de los recursos económicos de la persona enferma y el estigma social.

Palabras clave: tuberculosis; tratamiento; atención primaria de salud; enfermería

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Introduction

Tuberculosis is an infectious disease that can be contagious if pulmonary, causing high mortality and morbidity rates worldwide. Despite being a global public health issue, it is curable and preventable. In 2019, there were an estimated 10 million new cases, and around 1.2 million people died from tuberculosis worldwide. Therefore, it is urgent to break its cycle of transmission, namely through the patient's adherence to treatment (World Health Organization [WHO], 2020). Although there is a positive evolution in Portugal, the targets set for 2030 do not seem to be achieved (Serviço Nacional de Saúde [SNS], 2019).

Tuberculosis control cannot merely focus on economic aspects and treatment and cure rates. It is important to identify and consider patient-related aspects that may interfere with treatment (WHO, 2020).

No studies were found that addressed the problem of tuberculosis in Portugal from the perspective of the treatment modality and the patients' perceptions. Thus, it is relevant to investigate this area. Knowledge of these factors will help assess and guide interventions for the organization, planning, and operationalization of nursing care. A comprehensive and holistic understanding of patient- and treatment-related issues can contribute to the development of an individualized treatment plan. This study aimed to describe the implications of directly observed therapy (DOT) for tuberculosis control in Portugal.

Background

WHO has declared tuberculosis a global public health emergency (WHO, 2020).

The Directly Observed Therapy, Short-Course (DOTS) strategy is effective in combating this epidemic, and it has been recommended to all countries. It consists of five key components: sustained political commitment; systematic case detection; standardized short-course chemotherapy, including DOT; uninterrupted drug supply; and a standardized recording and reporting system that assesses disease evolution and treatment results (WHO, 1999).

As an infectious disease, it can be contagious. It is spread when a patient infected with tuberculosis expels the bacteria, and their contacts inhale them, starting the chain of transmission (Direção-Geral da Saúde [DGS], Programa Nacional para a Tuberculose, 2016). To help break this chain of transmission, patients must adhere to treatment. There is strong evidence that many individuals undergoing prolonged treatment (as in tuberculosis) have difficulty adhering to the recommended therapeutic regimens, which leads to poor management and control of the disease. Concerning tuberculosis, drugs are only effective if taken correctly (O'Boyle et al., 2002), and research suggests problems of adherence to treatment in all situations where self-administration of treatment is necessary. Taking the medication under supervision is essential to ensure that drugs are taken in the right combinations and for the appropriate duration (DGS, Programa Nacional para a Tuberculose, 2016). Depending on individual specificities, treatment

observers should be accessible, acceptable to the patient, and accountable to the health services (WHO, 1999).

Despite its wide dissemination as a recommended treatment strategy, scientific evidence is not consistent regarding its superiority in terms of effectiveness and efficiency. There are several studies on DOT and the factors contributing to non-adherence to treatment. Since 1993, several questions have been raised about DOTS and one of its components - DOT - as a WHO-recommended method (Frieden & Sbarbaro, 2007).

Studies focused on human rights from the perspective of current tuberculosis control activities were also found. These studies have analyzed several concepts, such as stigma, treatment, adherence to treatment, limitations to freedom, and living conditions, among others (Balasubramanian et al., 2000; Chakrabarty et al., 2019; Pronyk & Porter, 1996) Portugal also implemented WHO recommendations and strengthened tuberculosis control by creating the National Tuberculosis Program and adopting the DOTS strategy. The provision of care and the planning of health policies focused mainly on primary health care, with the pulmonary diagnostic centers (PDCs) as their pillars (DGS, 2016).

Tuberculosis programs were updated and adjusted to WHO guidelines to achieve the goals and meet new challenges. New guidelines were disseminated, reinforcing previous ones. Concerning standardized short-course chemotherapy, it should be administered under appropriate management conditions, including DOT, with solid technical and social support (Magalhães et al., 2013). According to the guidelines, nurses play a key role in this strategy for combating the disease. Therefore, for the *Ordem dos Enfermeiros* (OE, the Portuguese nursing and midwifery regulator), "nurses are at the front line of the implementation of a treatment . . . always considering a patient-centered approach" (OE, 2013, p.12).

In Portugal, the notification rate has been decreasing since 2015, and, in 2018, the incidence rate was below 20 cases per 100,000 inhabitants. The districts of Porto and Lisbon had the highest notification rates, remaining above 20 cases per 100,000 inhabitants, which is a profile associated with large urban centers (DGS, 2018).

Despite having adhered to the DOTS strategy since 1995 and presenting a positive evolution, Portugal is at risk of not meeting WHO 2030 targets (SNS, 2019). In this context, no studies were found on the results related to this area in Portugal.

Research question

What are the implications of DOT for tuberculosis control in Portugal?

Methodology

As part of a broader study, an exploratory and descriptive study was conducted in PDCs in the northern region of Portugal between March 2019 and January 2020.



The sample consisted of 303 participants and was selected through a nonprobability accidental or convenience sampling method. Participants met the following inclusion criteria: having pulmonary tuberculosis, undergoing treatment for at least a month or being followed up, and being 18 years of age or older.

Nurses of the PDCs collected data through a self-completed form consisting of 32 multiple-choice questions and three open-ended questions. The form was pre-tested in a sample of 33 participants, including nurses and physicians with experience in tuberculosis treatment and people who had already undergone tuberculosis treatment. The areas in the form originated from areas mentioned in the national and international literature (referred to as factors associated with pulmonary tuberculosis) and suggestions resulting from the pre-test.

This study analyzed the answers related to the treatment modality, the patient's involvement in the modality, the reasons why (and if) the modality corresponds to the patient's expectations, and the reasons for abandoning treatment.

Quantitative data were treated using IBM SPSS Statistics for Windows, version 26.0. Descriptive statistics were used for data analysis and presentation, particularly measures of central tendency. Qualitative data were analyzed using the thematic content analysis technique (Bardin, 2016). Data were collected after approval from the Health Ethics Committee of the Regional Health Administration - North, I.P., Porto (No. 021/2019). All participants signed an informed consent form.

The researchers committed to respecting the privacy, confidentiality, and anonymity of the participants, the institutions, and the collected data. Collected data were exclusively used for this study.

Results

The sample consisted of 303 patients with pulmonary tuberculosis. Men were more affected (61.7%; $n = 187$) than women (38.3%; $n = 116$). The 30-49 age group was more frequent among women ($n = 58$; 50%), while the 50-69 age group was more frequent among men ($n = 97$; 51.9%). Considering each group as a whole, the mean age among men was 46.8 years ($SD = 16.21$; Min = 18; Max = 87) and among women was 51.2 years ($SD = 13.47$; Min = 18; Max = 82).

Of the total universe of participants (men and women), 51.8% were married, and 60.4% were professionally active. Concerning each participant's phase of treatment at data collection, women had been undergoing treatment between two and four months and men for 6 or more months, including follow-up.

Table 1 shows that the vast majority of participants (90.1%) reported being the first time they had tuberculosis.

In 88.1% ($n = 267$) of the patients, the nurse supervised the treatment. The majority of women (75.9%) and men (66.3%) took their medication in the health unit during the entire treatment period. Moreover, 12.1% of women and 21.9% of men took their medication at home under the supervision of a nurse during the first two months of treatment. The remaining treatment was done at the health unit. In this study, 76.7% ($n = 89$) of women and 72.7% ($n = 136$) of men did not negotiate the modality and site where they took their medication. Most women (69.8%; $n = 81$) and men (68.4%; $n = 128$) were not given the opportunity to choose where to take their medication. Only 33.6% ($n = 39$) of women and 38% ($n = 71$) of men reported that the treatment modality corresponded to their expectations. Moreover, 19% of women and 9.6% of men had thought about abandoning treatment.

Table 1*Distribution of answers related to medication intake, according to gender*

	Women		Men	
	<i>n</i>	%	<i>n</i>	%
+ Place of Medication Intake				
Health unit throughout the treatment period.	88	75.9	124	66.3
Home, first two months, by a nurse. In the health unit for the remaining period.	14	12.1	41	21.9
Others	14	12.0	22	11.8
Total	116	100%	187	100%
+ Negotiation of modality and place of medication intake				
Negotiated	21	18.1	38	20.3
Not negotiated	89	76.7	136	72.7
Does not know	6	5.2	13	7.0
Total	116	100%	187	100%
+ Possibility of choosing where to take the medication				
Yes	31	26.7	52	27.8
No	81	69.9	128	68.5
Does not know	4	3.4	7	3.7
Total	116	100%	187	100%
+ The treatment modality corresponds to your expectations				
Yes	39	33.6	71	38.0
No	25	21.5	26	13.9
Does not know	52	44.9	90	48.1
Total	116	100%	187	100%
+ Have you ever thought about abandoning treatment?				
Yes	22	19.0	18	9.6
No	90	77.6	157	84.0
Does not know	4	3.4	12	6.4
Total	116	100%	187	100%

Three categories emerged from the answers to the open-ended question about the reasons why the treatment modality does not correspond to the participants' expectations (Table 2): Dissatisfaction with institutional guidelines related to the medication intake modality;

Economic factors aggravated by the period of absence from work and the direct expenses with treatment; and Promotes social stigma as a result of the patient's public exposure, which is aggravated due to wearing a mask, isolation, shame, and psychological changes.

Table 2*Implications of the treatment modality for the sample*

Category	Subcategory	Recording Unit
Dissatisfaction with institutional guidelines	Treatment modality	"I could take it at home, as I take other medications" (Q32); "I don't understand this way of forcing people to take their medication at the health care center" (Q41); "I didn't expect the nurse do the whole treatment" (Q76); "I don't understand why it's only in this disease that nurses give the medications" (Q91); "Why can't I take it?" (Q94); "Having to go every day to the Center to take the medication, I consider myself responsible" (Q103); "I haven't missed, and I don't intend to miss a dose, . . . why do I have to go to the Health Unit every day?" (Q109); "I don't agree with having to go to the Nurse every day to take the medication" (Q163); "Why the rule that I can't take it a home?" (Q210).
Aggravated economic factors	Period of absence from work	"I need to work, the medical leave is not well-paid" (Q32); "They could let me take it myself . . . I could go to work, we need the money" (Q99).
	Direct treatment expenses	"I spend a lot of money because I have to go every day there to take the medication" (Q196); "I have to spend a lot of money to go there" (Q199); "Because of going every day to the health care center" (Q254); "Time spent" (268).
Promotes social stigma	Reveals one's condition	"Why do they make me go to the center where everyone knows me because of my work? It shouldn't be that way" (Q96); "Everyone sees me, and then they know that I have this disease . . . they run away from me" (Q291); "I'm ashamed because they see me wearing a mask . . . everyone stares" (Q254).
	Isolation	"The distancing of friends" (Q18).
	Shame	"Make parents ashamed" (Q62).
	Psychological changes	"It makes us think twice if it's worth continuing with this" (Q18) "depression" (Q76); "Physical and mental exhaustion" (Q163); "It becomes a very boring life, but it takes motivation and faith to complete treatment" (Q209); "because it's too long, it's too long, it's too much time" (Q301).

Discussion

The participants' profile matches the profile of patients with tuberculosis in Portugal (DGS, 2018). All of them had undergone at least 1 month of treatment. Three important results emerged: the modality of choice is DOT by a health professional throughout the treatment. Based on the percentage of answers, there is strong evidence of the lack of patient involvement in the decisions regarding the treatment plan. This evidence may also be supported by the fact that most people undergoing treatment did not negotiate the adopted strategy nor had the opportunity to choose where to take their daily medication.

Decision-making regarding treatment may reveal a rigid, directive, and highly controlling attitude of health professionals, reducing the patient to a mere receiver of the treatment imposed. That is perhaps the nurses' way of ensuring full compliance with the prescribed medication regimen.

For some authors, adherence to treatment is a chain of responsibilities, which includes, among other aspects, the patients' behavior, the health professionals' conduct, and their decisions (Tavares et al., 2016).

In Portugal, although DOT seems effective and is the modality recommended by DGS, patients do not seem to understand and accept it (DGS, Programa Nacional

para Tuberculose, 2016). The financial burden, together with the patients' lack of participation in their treatment process, is marked by the imposed treatment modality. This modality increases patients' public exposure and reveals their condition as patients, promoting social stigma. Studies on DOT did not draw consistent conclusions as to whether its effectiveness and efficiency are higher in this modality than in other modalities (McLaren et al., 2016). Although some studies point to better outcomes when applying DOT (Yin et al., 2016), others found no convincing evidence that DOT is more effective than self-administration (Tian et al., 2014). Other authors have drawn similar conclusions, revealing that the decentralization of care and patient-centered care can improve treatment outcomes as long as they are adapted to the conditions of the local community (Zhang et al., 2016). Based on the participants' opinions, this might be a biomedical model where the characteristics of the disease are at the center of medical care to the detriment of the patient. The categories emerging from the answers to the open-ended question are associated with the patients' expectations of being an active partner in their treatment. This aspect is reflected in the dissatisfaction with the institutional guidelines about their treatment modality and the perception that people do not believe in them or involve them in the decision: "I didn't expect the nurse

to do the whole treatment” (Q76); “Why can’t I take it?” (Q94); “I consider myself responsible” (Q103); “I have not missed . . . why do I have to go to the Health Unit every day?” (Q109); “I don’t agree with having to go to the Nurse every day to take the medication” (Q163); “Why is that? Why the rule that I can’t take it at home?” (Q210). This treatment modality also aggravates the economic and financial situation of patients and families because it *forces* the patient to a prolonged absence from work and, consequently, a reduction in family income: “I need to work, the medical leave is not well-paid” (Q32); “They could let me take it myself . . . I could go to work, we need the money” (Q99), and an increase in expenses: “I have to spend a lot of money to go there” (Q199); Because of going every day to the health care center” (Q245) . . .] and time “time spent” (Q268) and, also, promotes and reinforces social stigma” “Everyone sees me and when they do, they immediately know what I have tuberculosis . . . they run away from me” (Q291); “I’m ashamed because they see me wearing a mask . . . everyone stares” (Q254). Can we state that the recognition of patients as partners in the therapeutic process and their inherent right to participation in the decisions about their disease is called into question?

From our reflection, the treatment modality seems something imposed to the detriment of patients’ active collaboration and right to participate in treatment. It also seems to be a mere mechanism to generate efficiency, which restricts people’s rights by limiting the promotion of self-care in *human beings* and not only in patients.

We may be on the edge of a conflict between two rights: the patients’ right to actively participate in their treatment and international recommendations suggesting the application of the DOT strategy for a *greater good*, that is, the public health risk.

However, when the patient is forced to go to the health care center to take the medication “I can’t understand why people are forced to go to health care centers to take medication” (Q41); “they make me go to the nurse every day to take the medications” (Q163); “we should analyze the *patient statute*, that is, the patient’s right to the confidentiality of their health information and personal privacy, which may be called into question when patients have to go every day to a health unit to take their medication and expose themselves to the general public: “they make me go to the center where everyone knows me because of my work” (Q96), “I’m ashamed because they see me wearing a mask . . . everyone stares” (Q254). The situation may aggravate the social stigma of the disease. According to Sontag (2010), the disease is like a metaphor: it consists of giving the thing a name that belongs to something else; and metaphors contribute to the stigmatizing of certain illnesses, such as tuberculosis, isolating patients from the community, which is seen, in a sentimental way, as a deteriorated identity, an incurable evil.

In this study, the same questions arose concerning the expectations associated with medication intake: “I could take it at home” (Q32), “Why the rule that I can’t take it at home?” (Q210). Bandura (1977) has defined self-efficacy expectations as one’s belief in one’s ability to successfully

perform a specific pattern of behavior: “I consider myself responsible” (Q103).

In this line of thought, the same author has defined the expectation of self-efficacy in taking medications as prescribed as the conviction in one’s ability to control the circumstances that may prevent patients from following the prescription and successfully perform such behavior (Bandura, 1977).

This finding draws attention to the importance of caregivers taking into account people’s expectations from the initial phase of the disease. Motivating and committing people to their treatment may be a protective factor for promoting full adherence to treatment.

If DOT by nurses is used as a resource to ensure full compliance with treatment, the patients’ involvement in their treatment may be an integrative and alternative strategy, considering that people with high levels of confidence in their skills approach difficult tasks as challenges to be overcome rather than as threats to be avoided (Bandura, 1977). This perspective is effective in promoting intrinsic interest and full commitment to the activities. These people impose challenging objectives upon themselves and remain strongly committed to them.

Based on the results of this study, one of the reasons for abandoning treatment was the patient’s lack of involvement, which is perceived by the patients themselves during treatment “It becomes a very boring life, but it takes motivation and faith to complete treatment” (Q209). In case of prolonged treatment, “because it’s too long, it’s too long, it’s too much time” (Q301), patients put in extra effort to motivate themselves to continue treatment, sometimes leading to psychological manifestations such as “depression” (Q76) and “Physical and mental exhaustion” (Q163).

Understanding health-protective behaviors, such as adherence to treatment, and establishing and maintaining a high level of motivation in patients undergoing treatment is an important intervention in behavioral change and adherence to treatment. These factors are essential for recovery (Bandura, 1977). Studies show that self-efficacy expectation is the main predictor of success in the performance of these behaviors, being fundamental for the intervention in the area of adherence to treatment.

Conclusion

It is important to understand the strategies and treatment modalities that health professionals are willing to explore to ensure that the patient with tuberculosis complies with the medication regimen prescribed. Understanding and meeting patients’ expectations and motivation can provide an important contribution to the development of these strategies.

The analysis of these results reveals that DOT is the modality of choice in the population under study. It is a modality decided by health professionals, focusing on compliance with the medication regimen. However, given the issues related to patients’ involvement and participation, it is important to reflect on the benefits of placing the patient at the heart of the health system, gaining a strong partner

in the treatment process to the detriment of a mere receiver of the care imposed by health professionals. Health professionals should plan their interventions taking into account the patients' values and expectations and their ability to take responsibility for their treatment process. Although there is no ideal model that can be followed by everyone and for everyone, some strategies can be personalized to ensure full adherence to treatment based on the characteristics of each patient and each health professional.

In the current context of health care organization, health professionals tend to take up a position of full guidance and responsibility for the entire care process without creating room for patients' involvement in shared decision-making. Relevant aspects were identified that could interfere with the course of treatment. These aspects are associated with the patient, the treatment strategy, the delivery of care in health services, and even the source of social stigma. It should be noted that the DOTS strategy, of which the DOT modality is part, was created in the mid-1990s. Thus, some procedures may require reassessment and a more in-depth reflection on more innovative, personalized procedures to achieve the objectives set out in the DOTS strategy.

Author contributions

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