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The usability of the rapid molecular test for the diagnosis of tuberculosis in a west amazonian municipality

La usabilidad de la prueba molecular rápida para el diagnóstico de tuberculosis en un municipio de la amazónica occidental

A usabilidade do teste molecular rápido para o diagnóstico da tuberculose em um município da amazônia ocidental

RESUMO
Objetivo: Descrever a usabilidade do Teste Molecular Rápido para a Tuberculose (TMR-TB) em Porto Velho, Rondônia. Método: Estudo descritivo, transversal e quantitativo, desenvolvido a partir dos registros dos doentes de tuberculose notificados entre janeiro a agosto de 2017 e que realizaram o TMR-TB. Os dados foram analisados por meio de estatística descritiva, após atender aos preceitos éticos. Resultado: Foram analisadas 2.317 amostras, solicitado principalmente pelo complexo penitenciário (33,1%), maior quantidade de resultado positivo na Atenção Terciária (27,8%), maior número de solicitações em maio (19,6%) e resultado positivo em junho (17,1%). A amostra mais analisada foi o escarro (97,6%) que representou 100% dos resultados positivos. O tempo médio entre o diagnóstico e início do tratamento foi 3,54 dias (dp=±8,32), e forma pulmonar predominante (95,7%). Conclusões: Verifica-se a necessidade de sensibilização da Atenção Primária, bem como o (re)conhecimento de quando o teste deve ser solicitado para oportunizar o início imediato do tratamento.
DESCRITORES: Tuberculose; Reação em Cadeia da Polimerase; Diagnóstico.

ABSTRACT
Objective: Describe the usability of the Rapid Molecular Test for Tuberculosis (TMR-TB) in Porto Velho, Rondônia. Method: Descriptive, cross-sectional and quantitative study, developed from the records of tuberculosis patients notified between January and August 2017 and who underwent TMR-TB. The data were analyzed using descriptive statistics, after meeting the ethical precepts. Results: 2,317 samples were analyzed, mainly requested by the penitentiary complex (33.1%), the highest number of positive results in Tertiary Care (27.8%), the highest number of requests in May (19.6%) and positive results in June (17.1%). The most analyzed sample was sputum (97.6%), which represented 100% of positive results. The average time between diagnosis and start of treatment was 3.54 days (SD = ± 8.32), and the predominant pulmonary form (95.7%). Conclusions: There is a need to raise awareness of Primary Care, and the recognition of when the test should be requested to provide an immediate start to treatment.
DESCRIPTORS: Tuberculosis; Polymerase Chain Reaction; Diagnosis.

RESUMEN
Objetivo Describir la usabilidad de la Prueba Molecular Rápida para la Tuberculosis (TMR-TB) en Porto Velho, Rondônia. Método: Estudio descriptivo, transversal y cuantitativo, desarrollado a partir de los registros de pacientes con tuberculosis notificados entre enero y agosto de 2017 sometidos a TMR-TB. Los datos fueron analizados mediante estadística descriptiva y cumplió los preceptos éticos. Resultado: Se analizaron 2.317 muestras, principalmente solicitadas por el complejo penitenciário (33,1%), mayor cantidad de resultados positivos en Atención Terciaria (27,8%), mayor número de solicitudes en mayo (19,6%) y resultados positivos en junio (17,1%). La muestra más analizada fue el esputo (97,6%), representó el 100% de los resultados positivos. El tiempo medio entre el diagnóstico y el inicio del tratamiento fue de 3,54 días (DE = ± 8,32) y la forma pulmonar predominante (95,7%). Conclusiones: Es necesario crear conciencia sobre la atención primaria, y reconocimiento de cuándo se debe solicitar la prueba para proporcionar un inicio inmediato del tratamiento.
DESCRIPTORES: Tuberculosis; Reacción en Cadena de la Polimerasa; Diagnóstico.

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INTRODUCTION

Tuberculosis (TB) is an infectious and contagious disease that spreads through the air through aerosols containing bacilli expelled by a patient and that, when inhaled by healthy people, cause tuberculosis infection and the risk of developing the disease.[1] TB is a major public health problem and, in 2018, it became the leading cause of death in the world from single-agent infectious disease. [2]

In Brazil, in the year 2018, 72.788 new cases were diagnosed, corresponding to an incidence coefficient of 34,8 cases/100 thousand inhabitants. Rondônia, presented the third largest number of new cases in the North Region of the country (582) and the capital, Porto Velho, a high incidence rate (59,5/100 thousand inhab.) And mortality (2,5/100 thousand inhab.) , in addition to being the third municipality with the highest percentage of abandonment in the country (24,6%). [3]

In this sense, conducting the search for respiratory symptoms (RS), especially bacilliferous, is one of the most efficient measures to interrupt the transmission chain and control of TB, considering that early diagnosis and immediate initiation of treatment reduces the number of bacilli transmitted by the patient. [4]

In a study that evaluated the delay in TB diagnosis, managers reported structural difficulties, lack of qualifications and an insufficient number of professionals. [5] Such aspects influenced approximately 50% of TB patients who had to seek health services four times or more in order to have an adequate diagnosis, which in most cases was performed in hospitals even due to the severity of signs and symptoms. [6]

In 2010, faced with the problem related to delay in diagnosis, a new method based on molecular biology was developed - the Rapid Molecular Test for TB (RMT-TB), in which an amplification of nucleic acids is made for the detection of Mycobacterium tuberculosis. [7] This method is able to reduce the time of diagnosis and identify the sensitivity and resistance for Rifampicin, which is one of the main first-line drugs for the treatment of TB.

In Brazil, RMT-TB was inserted as a pilot in the capitals of Manaus and Rio de Janeiro for having the highest incidence of the disease in the federation (93,8 cases/100 thousand inhab. 12 and 82 cases/100 thousand inhab, respectively).[8] By this method, an increase in the rate of bacteriological detection of TB[9] was identified, in a timely manner of two hours. The use of this test, before culture or sputum smear microscopy, should mean rapid diagnostic clarification, 7 without disregarding the importance of clinical evaluation by the health professional. The aim is to promote the timely diagnosis through the RMT-TB for new cases and to use sputum smear microscopy for re-treatments (recurrence and re-entry after abandonment) and monthly treatment control.

The evaluation of the RMT-TB is an important tool to contribute to the improvement of the diagnosis and analysis of the performance of health services, since, through this, it allows the identification of weaknesses in the offer of actions, services and care, in addition to observation of possible training needs. [10, 11]

In 2014, after its implementation, some machines were distributed by the Ministry of Health to the states, including Rondônia, which was allocated in the municipality of Porto Velho. Therefore, this study aims to describe the usability of RMT-TB for the diagnosis of the disease in Porto Velho-RO.

METHODS

This is a descriptive study, carried out in a transversal way based on a quantitative approach, developed in Porto Velho, capital of Rondônia. It is estimated that the population of the state in the year 2017 was 1.805.788 inhabitants and the municipality of 519.436 inhabitants.[12]

TB care is decentralized to Primary Health Care (PHC), which is the gateway for SRs, and must request tests and diagnostic clarification, follow up on pulmonary TB cases, perform Directly Observed Treatment (DOT), investigation of contacts and refer to other health services, if necessary.

The municipality counts on the support of specialized services, on an outpatient basis, which monitor TB/ HIV co-infected cases, an extrapulmonary clinical form associated or not with other pathologies, in addition to cases of childhood TB. At the tertiary level, TB patients who have drug resistance and hospitalization are monitored, if necessary. In addition, it has a municipal laboratory to perform the RMT-TB and sputum smear microscopy, as well as a state laboratory for sputum culture and sensitivity testing.

The result of the RMT-TB is made available in the Integrated System for the Computerization of the Hospital Environment (HOSPUB) for the unit requesting the exam within 48 hours. It is important that regardless of the result, the sputum culture exam is requested to investigate non-tuberculous mycobacteria (NTM), according to the municipal protocol.

This is a descriptive study, carried out in a transversal way based on a quantitative approach, developed in Porto Velho, capital of Rondônia. It is estimated that the population of the state in the year 2017 was 1.805.788 inhabitants and the municipality of 519.436 inhabitants.

The study population consisted of the SR who performed the RMT-TB from January 12th to August 15th, 2017, totaling 2.317 samples to be analyzed by the test. 45 samples were excluded from the data collection, 10 due to duplicate information, 20 due to the absence of a kit (May 30th, 2017), eight due to the unsatisfactory characterization of the sample, six due to an error in requesting the type of exam, considering that RMT-TB is performed for diagnosis only, and sputum smear microscopy for monthly treatment control, in addition to one for disposal in the Laboratory Environment Manager (GAL - Gerenciador de Ambiente Laboratorial) as it is material for culture.

The data were collected by the researchers, by means of a survey of the variables in the RMT-TB Register Book of the municipal laboratory, which is fed at the entrance of the samples for analysis by the professionals who work on the site and contains information about the specific record of the book, HOSPUB registration number, requesting unit, patient's name, RMT-TB result and type of sample; as well as, information in the Notifiable Diseases Information System (SINAN - Sistema de Informação de Agravos de Notificação) for the collection of data regarding the date of diagnosis, date of beginning of treatment and clinical form (Chart 1).

The closing of the monthly census, consolidated with information on the number of tests performed by the RMT-TB, was carried out every 30 days, starting between the 12th and 15th of a month and ending on the same day of the following month.

The collection was stored in a database and analyzed using descriptive statistics in TIBCO's Statistica 13.4 pro-

Chart 1. Survey of the variables of this study, according to the source of data collection.

DATA COLLECTION SOURCE	VARIABLES
RMT-TB Record Book	Health Unit requesting the RMT-TB Result of RMT-TB Sample type
SINAN*	Date of diagnosis Treatment start date Clinical form of TB

Prepared by the authors.

gram. For a better interpretation of the findings, the variable requesting unit was categorized in Penitentiary Complex, PHC (Family Health Unit and Basic Health Units of Porto Velho), secondary care (Emergency Unit, Psychosocial Care Center, Polyclinics and Center of Medical Specialties) and tertiary care (Mãe Esperança Municipal Maternity Hospital, Dr. Ary Pinheiro Base Hospital, Cosme e Damião Children's Hospital, Pronto Socorro João Paulo II State Hospital and Rondônia Tropical Medicine Center).

In addition, with regard to the results of the samples (positive, negative and error), those that were classified as positive (positive/ error, resistant and/ or sensitive to rifampicin) and negative (negative/ error and negative/ sent to culture).

This study complied with the ethical precepts provided for in Resolution 466/12 of the National Health Council, 13 through the matrix project entitled "Evaluation of the epidemiological situation of tuberculosis in the city of Porto Velho - RO" approved by the Research Ethics Committee of the Federal University of Rondônia, according to opinion 2,399,327 CEP/ NUSAU/ UNIR.

Table 1. Distribution of the quantity of samples analyzed by RMT-TB, according to the requesting unit and result, from January 12th to August 15th, 2017, Porto Velho, Rondônia, Brazil.

REQUESTING UNIT	POSITIVE RESULT		NEGATIVE RESULT		ERROR		TOTAL	
	N	%	N	%	N	%	N	%
Penitentiary Complex	52	22,2	713	34,3	1	16,7	766	33,1
Secondary Attention	52	22,2	586	28,2	-	-	638	27,5
PHC	61	26,1	481	23,2	1	16,7	543	23,4
Tertiary Attention	65	27,8	212	10,2	2	33,3	279	12,0
Other municipalities	1	0,4	20	1,0	2	33,3	23	1,0
Indigenous Health	-	-	18	0,9	-	-	18	0,8
Porto Velho Districts	2	0,9	15	0,7	-	-	17	0,7
Porto Velho - Countryside	-	-	14	0,7	-	-	14	0,6
Private Institution	-	-	6	0,3	-	-	6	0,3
Philanthropic Institution	-	-	5	0,2	-	-	5	0,2
State Laboratory	1	0,4	4	0,2	-	-	5	0,2
Street Office	-	-	2	0,1	-	-	2	0,1
Other States	-	-	1	0,1	-	-	1	0,05
Total	234	10,1	2.077	89,6	6	0,3	2.317	100

Source: RMT-TB Registration Book / Rafael Vaz e Silva Polyclinic, 2017.
Caption: PHC (Family Health Unit and Basic Health Unit of Porto Velho), Secondary Care (Emergency Care Unit, Psychosocial Care Center, Polyclinics and Medical Specialty Center), Tertiary Care (Mãe Esperança Municipal Maternity Hospital, Dr. Ary Pinheiro Base Hospital, Cosme e Damião Children's Hospital, and João Paulo II State Hospital and Emergency Room).

Table 2. Analysis of the monthly results of the RMT-TB, from January 12th to August 15th, 2017, Porto Velho, Rondônia, Brazil

MONTH	POSITIVE		NEGATIVE		ERROR		TOTAL	
	N	%	N	%	N	%	N	%
January	21	9,0	127	6,1	-	-	148	6,4
February	25	10,7	220	10,6	2	33,3	247	10,7
March	37	15,8	264	12,7	1	16,7	302	13,0
April	34	14,4	286	13,8	-	-	320	13,8
May	36	15,4	416	20,0	1	16,7	453	19,5
June	40	17,1	324	15,6	2	33,3	366	15,8
July	24	10,3	244	11,8	-	-	268	11,6
August	17	7,3	196	9,4	-	-	213	9,2
Total	234	10,1	2077	89,6	6	0,3	2.317	100

Source: RMT-TB Registration Book/ Rafael Vaz e Silva Polyclinic, 2017

RESULTS

It was found that the prison complex was the unit that most requested the RMT-TB (33,1%), followed by secondary care (27,5%), PHC (23,4%) and tertiary care (12,0%). In addition, it was observed that tertiary care (27,8%) and PHC (26,1%) were the levels of care that obtained the greatest amount of positive results (Table 1).

In addition, in May there was a greater number of requests for RMT-TB (19,6%), however in June there was a higher percentage of positive results (17,1%) (Table 2).

As for the type of material analyzed, most came from sputum samples (97,6%), but it is noteworthy that during the period studied there was an analysis of other types of samples, such as CSF (1,1%) and washed gastric and bronchial (0,5%). Regarding the sample result, it was possible to identify that all positive results (10,3%) were from sputum samples (Table 3).

It was observed that the average time between diagnosis and start of treatment was 3,54 days (sd = ± 8,32), with a minimum of 0 days and a maximum of 61 days, in which, regardless of the clinical form, most patients cases started treat-

Table 3. Analysis of the quantity and type of sample requested monthly from the RMT-TB, from January 12th to August 15th, 2017, Porto Velho, Rondônia, Brazil

MONTH	SPU		CSF		LAV		URI		ASP		BL		LYM		TOTAL	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
January	147	6,5	-	-	1	9,1	-	-	-	-	-	-	-	-	148	6,4
February	241	10,6	3	11,5	1	9,1	1	12,5	1	14,3	-	-	-	-	247	10,7
March	293	13,0	5	19,2	1	9,1	2	25,0	-	-	1	33,3	-	-	302	13,0
April	309	13,7	7	26,9	-	-	1	12,5	-	-	2	66,7	1	100	320	13,8
May	445	19,7	2	7,7	-	-	2	25,0	4	57,1	-	-	-	-	453	19,6
June	353	15,6	2	7,7	7	63,6	2	25,0	2	28,6	-	-	-	-	366	15,8
July	264	11,7	4	15,4	-	-	-	-	-	-	-	-	-	-	268	11,6
August	209	9,2	3	11,6	1	9,1		-	-	-		-		-	213	9,2
SAMPLE RESULT																
Positive	234	10,3	-	-	-	-	-	-	-	-	-	-	-	-	234	10,1
Negative	2021	89,4	26	100	11	100	8	100	7	100	3	100	1	100	2077	89,6
Error	6	0,3	-	-	-	-	-	-	-	-	-	-	-	-	6	0,3
Total	2261	97,6	26	1,1	11	0,5	8	0,35	7	0,3	3	0,1	1	0,05	2317	100

Source: RMT-TB Registration Book/ Rafael Vaz e Silva Polyclinic, 2017.
Caption: SPU: sputum; LAV: gastric and bronchial lavage; URI: urine; ASP: tracheal aspirate; BL: blood; LYM: lymph node fragment.

Table 4. Analysis of the time between the diagnosis of TB by the RMT-TB and the beginning of treatment, according to the clinical form of the disease, from January 12th to August 15th, 2017, Porto Velho, Rondônia, Brazil.

TIME FOR THE TREATMENT BEGINNING	CLINICAL FORM						TOTAL	
	PULMONARY		EXTRAPULMONARY		PULMONARY + EXTRAPULMONARY			
	N	%	N	%	N	%	N	%
0 days	106	60,2	6	100	1	50,0	113	61,4
1 to 2 days	26	14,8	-	-	1	50,0	27	14,7
3 to 7 days	14	8,0	-	-	-	-	14	7,6
8 to 14 days	16	9,1	-	-	-	-	16	8,7
15 to 30 days	11	6,2	-	-	-	-	11	6,0
> 30 days	3	1,7	-	-	-	-	3	1,6
Total	176	95,6	6	3,3	2	1,1	184	100

Source: SINAN, 2017.

ment on the same day as the diagnosis of RMT-TB and pulmonary TB predominated (95,7%) (Table 4).

DISCUSSION

In view of the results found, it was found that although the usability of RMT-TB occurred for the diagnosis of the disease, the coverage by the test was low, given the number of inhabitants of the state and the number of tests performed during the study period. At the same time, such quantitative was carried out only on one machine, which was available to the entire state, and could not be able to supply the demand. This scenario can be changed with the acquisition, in November 2017, of the new machines by the State Health Surveillance Agency (AGEVISA - Agência Estadual de Vigilância em Saúde) belonging to the State Secretariat of Health of Rondônia, installed four in the interior in municipalities that host the Health Regions and more one in the capital at the tertiary state reference service. [14]

Although the number of tests requested by the Penitentiary Complex was higher when compared to the other health units, it is well below the recommended, since Rondônia has 53 prison units, with a prison population of 7.631 individuals, even with 4.928 places. [15]

This finding reflects on the weaknesses of the low active search and tracking of TB even in the face of the increase in people deprived of their liberty (PDL), overcrowding, little air circulation in cells, high PPL turnover in detention centers, and sharing the same location between those awaiting trial with those already convicted, which makes facilities inadequate and an environment conducive to the spread of infectious diseases, 16 and consequently, increases the sus-

ceptibility to infection within the PDL, family members and employees. [17, 18] This can lead to worsening the health of this population, resistance to medications and even death.

Other challenges are the delay in identifying suspected TB cases, difficulties with PDL in relation to the initiation and continuity of treatment after diagnosis in prison units and outside of them for those who are in the semi-open regime, [19] as well as the lack of professionals to give segment to the DOT, being that in some cases, it is the prison officers themselves who carry out it.

With regard to secondary care, this finding may reflect on the functional dynamics of the institutions, which limit control actions and lead to delayed diagnosis, whether in the detection of RS and/ or delay in diagnostic confirmation, lack of knowledge and/ or awareness professionals in the face of a suspicious case, accessibility and opening hours of the PHC, [19, 20] in addition to the difficulty in the way health services organize themselves to diagnose and detect cases early. [21]

It is noted that the attention to TB in PHC is weakened, as professionals are often unaware of the number of cases in their territory and, at other times, omit their responsibility for monitoring and controlling TB actions, in face of the real needs and vulnerabilities of the enrolled population. [7, 22]

The different laboratory methods are available for detection, however, professionals need to find ways out for the timely diagnosis. RMT-TB, in this case, specifically, is an instrument for confirming cases and identifying sensitivity and resistance to rifampicin in the short term when compared to sputum smear and sputum culture, respectively.

However, how the subject understands himself to be sick should also be discussed, since the weaknesses in accessing and resolving his PHC problems contribute to delaying the diagnosis, which is often performed at other levels of care, as occurred in this study, with the highest number of positive results in Tertiary Care. This finding corroborates a study carried out in Porto Velho that identified that the diagnostic clarification has not occurred in PHC, highlighting the low resolution of the primary level and the local weaknesses for TB monitoring and control actions, among them the articulation between the health services. [23]

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The perception of the subject in the health-disease process is subjective, considering the singularities inherent to the individual, as well as their socioeconomic and cultural situation, and the environment in which they are inserted. [24] In addition, some specific symptoms, such as cough, fever and weight loss when they do not prevent the RS from exercising their daily activities, end up being neglected, affecting the immediate search for care.

PHC should be the first unit, as a gateway, to request the RMT-TB, in view of its role as coordinator of care and organizer of the Health Care Network, aiming at the promotion and prevention of health, and, when necessary, refer to another level of care.[25, 26]

Accessibility can be understood as the degree of adjustment to the characteristics of the service offer and the population, including the search process and obtaining assistance, therefore, the choice of the unit is linked to previous experiences, ease of access, guarantee of care and resolution of the health problem, in which the levels of assistance need to be prepared for these demands, in order to ensure that the points of care considered priority and sensitive to TB are resolvable. [27]

Studies address that users seek resolution in secondary and/ or tertiary care, as well as in health units outside their area of coverage, either due to the perception of their relationship with the service offer, technological density or even because of the disease's own stigma. [19, 20, 26] In this sense, the importance of training to raise awareness and assist professionals to carry out the early diagnosis of TB is emphasized, in addition to the development of health education actions with the community.

It was also observed that the highest number of requests for RMT-TB occurred in May. It is known that the North Region has a rainy and low temperature period that occurs between the end of November and the beginning of April, in which the population tends to stay longer in closed environments, facilitating the proliferation and infection by the bacillus. Therefore, it is clear that there may be a seasonality of TB for the increase in requests in the month of May in the municipality studied.

It is noteworthy that the largest number of positive cases came from sputum samples, reflecting the predominant clinical form, the pulmonary. RMT-TB is more sensitive when it comes to a sputum sample, not requiring large amounts of bacilli for this. This finding is in line with the current literature, which points out that sputum samples, when satisfactory, are easily detected by RMT-TB. [28]

The predominance of the clinical pulmonary form is justified by the fact that the bacillus grows in an oxygenated place and with great blood flow. Pulmonary TB is an important public health problem and needs methods for it to be controlled, considering its implications, [29] because it is one of the transmissible forms of the disease, requiring a timely diagnosis by means of the RMT-TB, and an immediate start of treatment, considering the advantages of analysis and results for the detection of the bacillus in the test when compared to other conventional methods of diagnosis. [9, 30]

However, it was observed that even though the majority of TB patients started drug therapy on the same day, a significant number of individuals started late. This finding is worrisome, because in addition to the implications that this delay can cause regarding the continuity of the transmission chain, it brings with it the problems related to the individual's health condition even with the early diagnosis of TB. [30]

At the same time that other factors could contribute to the delay, such as the organization of services, weaknesses in the computerization system and the search for RS. It is also worth noting the lack of adequate structure in PHC, easy physical, financial, geographic and structural access to provide an integrated and articulated Health Care Network. [26]

RMT-TB provides the result of four samples analyzed, concomitantly, confirming (or not) the case in two hours. However, the local scenario, in the period of this study, had a single machine for the analysis of requests from different levels of care in the state, which could result in a waiting list, delay in the analysis of samples and availability of results, but that would not influence the start of treatment.

CONCLUSION

The results found in this study by assessing the usability of the RMT-TB reveal its innovative character, considering the importance for the diagnosis of the disease and the benefit that this new health technology has brought to the state and the municipality in relation to the disease diagnosis and measures to control the disease, especially in view of the epidemiological situation of TB and NTMs.

In this sense, it is essential that PHC managers and professionals are made aware of the use of RMT-TB, with actions aimed at health surveillance, strategies for the co-responsibility of the population in the control of TB and reorganization of PHC to strengthen this level of attention through articulated planning between the Tuberculosis Control Program and the coordination of the Department of Primary Care.

As a limitation of this study, it is emphasized the non-computerization of the records about the requests of the RMT--TB, which could contribute to the local assessment, in real time, in the health and management units. ■

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