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Positivity Proportion of Xpert MTB/RIF in Suspected Pediatric Pulmonary Tuberculosis Patients at Dr. Soetomo General Academic Hospital, Surabaya, Indonesia

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ABSTRACT

Introduction: The difficulty of diagnosing tuberculosis (TB) is the most significant challenge in pediatric pulmonary TB cases. More accurate and faster diagnostic tools are essential for detecting TB infections, enabling the implementation of appropriate therapy and treatment management more effectively and promptly. This study aimed to determine the proportion of positive results using the Xpert Mycobacterium tuberculosis/rifampicin (MTB/RIF) assay as a rapid molecular method in suspected pediatric pulmonary TB patients at Dr. Soetomo General Academic Hospital, Surabaya, Indonesia.

Methods: This study employed a descriptive-retrospective design, utilizing data obtained from medical records. The total number of samples included in this study was 373 samples (n=373). The data was analyzed using the International Business Machines Corporation (IBM) Statistical Package for the Social Sciences (SPSS) version 26.0 for Windows.

Results: The most commonly used specimen from pediatric TB patients in the Xpert MTB/RIF examination was sputum, accounting for 59.2%. The most common result from the Xpert MTB/RIF examination was “MTB not detected,” with a prevalence of 88.2%.

Conclusion: The most commonly used specimen for the Xpert MTB/RIF examination of pediatric pulmonary TB was sputum. The majority of results found with the Xpert MTB/RIF examination were “MTB not detected” both in sputum and gastric aspirate specimens.

Highlights:
1. This study utilized Xpert MTB/RIF result data from children using both sputum and gastric lavage specimens, which is different from previous studies that relied solely on sputum specimens.
2. “*Mycobacterium tuberculosis* not detected” was the most common result on the Xpert MTB/RIF examination in suspected pediatric TB cases.

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Introduction

Tuberculosis (TB) is the world's deadliest single-agent infectious disease, causing 1.3 million deaths in 2020.[1] The mortality rate of this disease remains the same in 2022, with a total of 1.3 million deaths, including those among people with human immunodeficiency virus (HIV).[2] In pediatric TB, the mortality rate of HIV-negative patients in 2020 was 16% and 9.8% in HIV-positive patients.[1] However, in 2022, the TB mortality rate among HIV-positive patients increased from 9.8% in 2020 to 18%.[2] The World Health Organization (WHO) estimated that there were 9.9 million (with a range of 8.9-11 million) patients infected with TB in 2020, with an incidence rate of 127 (interval: 114-140) per 100,000 population, and 11% of all cases were related to pediatric TB cases. When viewed from WHO data, the morbidity and mortality rates in children are much smaller than in adults.[1] However, in reality, childhood TB cases are more frequent in Indonesia because the high number of TB cases in Indonesia is accompanied by the number of stunting in children, with a prevalence of 21.5% in 2022-2023.[3,4] Children with stunting have a weaker immune system, making them more likely to get infected with TB.[5] The low morbidity and mortality rates of pediatric TB are likely due to the large number of undiagnosed cases, as enforcing the diagnosis of pediatric pulmonary TB presents various difficulties.[1]

The difficulty of establishing the diagnosis of TB is the biggest challenge in pediatric pulmonary TB cases. Nonspecific clinical manifestations, slow growth on culture examinations, and the difficulty of collecting high-quality specimens in the pediatric age group are key factors contributing to the difficulty in diagnosing pulmonary TB in children.[6] During the coronavirus disease (COVID-19) pandemic, enforcement of TB diagnosis became increasingly complex as the two diseases had similar clinical manifestations.[7] Therefore, the development of diagnostic tools that are faster and more accurate in detecting TB infections is crucial to ensure appropriate and timely therapy, as well as effective treatment management.[8] The WHO is developing a rapid and accurate diagnostic tool for pulmonary TB, particularly for pediatric cases. The test is called the Xpert *Mycobacterium tuberculosis*/rifampicin (MTB/RIF) rapid molecular method, which was recommended by the WHO in 2010 as a diagnostic tool to confirm TB. The results of Xpert MTB/RIF can be read in less than 2 hours after the test is performed, making it faster than bacterial culture examination with higher specificity and sensitivity.[6]

The sensitivity and specificity of the Xpert MTB/RIF using sputum as the specimen have an average sensitivity of 66% (95% CrI, 52-77%) and an average specificity of 98% with a narrow interval. On the other hand, the average sensitivity of the Xpert MTB/RIF examination using gastric aspirate specimens is 66% (95% CrI, 51-81%).[9] In another study, it is reported that the sensitivity of Xpert MTB/RIF is 72.1%, whereas bacterial culture yields a sensitivity of 44.1%.[10]

The Xpert MTB/RIF can be performed using multiple specimens. Specimens that are commonly used in pediatric pulmonary TB examination are sputum, gastric aspirate, and nasopharyngeal aspirate.[11] Sputum is more often used in Xpert MTB/RIF because it is noninvasive, easy, and quite affordable.[12] However, collecting sputum in pediatric TB patients is quite tricky. This is because the most common pediatric TB cases are of the paucibacillary type, characterized by the presence of only a few or even no MTB detectable in bacterial cultures. Additionally, only a small amount of sputum is produced in this form of TB.[13]

Other challenges that make the diagnosis of pediatric TB difficult are the clinical manifestations of pediatric pulmonary TB, which are nonspecific and difficult to differentiate from other respiratory diseases.[6] Moreover, some children infected with TB are often asymptomatic, causing active TB cases to be misdiagnosed as latent TB. Therefore, enforcement of pulmonary TB diagnosis using more accurate laboratory examinations is still needed, especially in pediatric pulmonary TB.[13]

Methods

This study employed a descriptive-retrospective model, utilizing medical records obtained from the pediatric polyclinic at Dr. Soetomo General Academic Hospital, Surabaya, Indonesia, between January 2019 and April 2023. These records were then filtered based on ICD-10 codes A15 (pulmonary TB) and A19 (milliary TB). The inclusion criteria for this study were pediatric patients with pulmonary TB at Dr. Soetomo General Academic Hospital, Surabaya, Indonesia, who had been examined using the Xpert MTB/RIF method with sputum and/or gastric aspirate specimens. This study outlined the results of the Xpert MTB/RIF examinations and the specimens used. The sampling technique in this study was total secondary data sampling, utilizing medical records. The research instruments used include secondary data retrieved from medical records and Xpert MTB/RIF logbooks of pulmonary TB patients at the pediatric polyclinic of Dr. Soetomo General Academic Hospital, Surabaya, Indonesia. The patients' data and their significant variables were then entered into Microsoft Excel 2021.[14]

Data Analysis

Data analysis in this study was conducted descriptively by examining medical records and Xpert MTB/RIF logbooks to determine the proportion of positive results obtained with the Xpert MTB/RIF examination from January 2019 to April 2023. The International Business Machines Corporation (IBM) Statistical Package for the Social Sciences (SPSS) version 26.0 for Windows was used to analyze the data.[15]

Results

The collected research data are presented in table form. Data were obtained from the medical records of pediatric patients with pulmonary TB in the pediatric polyclinic of Dr. Soetomo General Academic Hospital, Surabaya, Indonesia, from January 2019 to April 2023. It was found that the most common specimen used in the

Xpert MTB/RIF examination of patients with suspected pediatric pulmonary TB in both 2022 and 2023 was sputum, with a total of 221 samples.

The Xpert MTB/RIF examination results predominantly indicated “MTB not detected” with 329 samples (88.2%). On the other hand, “MTB detected” was only observed in 44 samples (11.2%). It was also found that most pediatric pulmonary TB patients were in the age group of 10-18 years old, with 128 samples. The highest number of “MTB detected” was also found in the 10-18 years age group, with 28 samples. Meanwhile, the highest number of “MTB not detected” cases was observed in two age groups: 0-1 years old and 10-18 years old, each with 100 samples.

Based on the specimens used, it was found that the sputum specimens showed the result of “MTB detected” and “MTB not detected” of Xpert MTB/RIF examination, more than gastric aspirate, with 31 samples of “MTB detected" from the total samples (8%) and 190 samples of “MTB not detected” from the total samples (51%).

Table 1. Clinical sample characteristics of pediatric tuberculosis patients 2019-2023

Sample	Frequency	Percentage
Sputum	221	59.2%
Gastric aspirate	152	40.8%

Source: Research data, processed

Based on Table 1, it was found that the most common specimen used in the Xpert MTB/RIF examination of patients with suspected pediatric pulmonary TB, in both 2022 and 2023, was sputum, followed by gastric aspirate.

Table 2. Xpert MTB/RIF result based on age of pediatric tuberculosis patients 2019-2023

Age (Years Old)	Xpert MTB/RIF Results		Total
	MTB Detected	MTB Not Detected	
0-1	5 (4.8%)	100 (95.2%)	105
2-4	7 (10.1%)	62 (89.9%)	69
5-9	4 (5.6%)	67 (94.4%)	71
10-18	28 (21.9%)	100 (78.1%)	128
Total	44 (11.8%)	329 (88.2%)	373

MTB: *mycobacterium tuberculosis*; RIF: rifampicin
Source: Research data, processed

Based on Table 2, it was found that the results for “MTB not detected” in pediatric pulmonary TB suspected patients were more prevalent than those for “MTB detected”. It was also found that most pediatric pulmonary TB suspected patients were in the age group of 10-18 years old. The most “MTB detected” results were also obtained in the age group of 10-18 years old, while the most “MTB not detected” results were obtained in two age groups: 0-1 years old and 10-18 years old.

Table 3. Xpert MTB/RIF result based on age and clinical specimen of pediatric tuberculosis patients 2019-2023

Age (Years Old)	Sample			
	Sputum		Gastric Aspirate	
	Detected	Not	Detected	Not
0-1	4	39	1	61
2-4	3	24	4	38
5-9	3	47	1	20
10-18	21	80	7	20
Total	31	190	13	139

MTB: *mycobacterium tuberculosis*; RIF: rifampicin
Source: Research data, processed

Based on Table 3, it was found that sputum specimens yielded more results for both “MTB detected” and “MTB not detected” using the Xpert MTB/RIF examination in patients with suspected pediatric pulmonary TB compared to gastric aspiration. It was also found that examinations using sputum and gastric aspirate specimens were primarily performed on patients in the 10-18 years old age group.

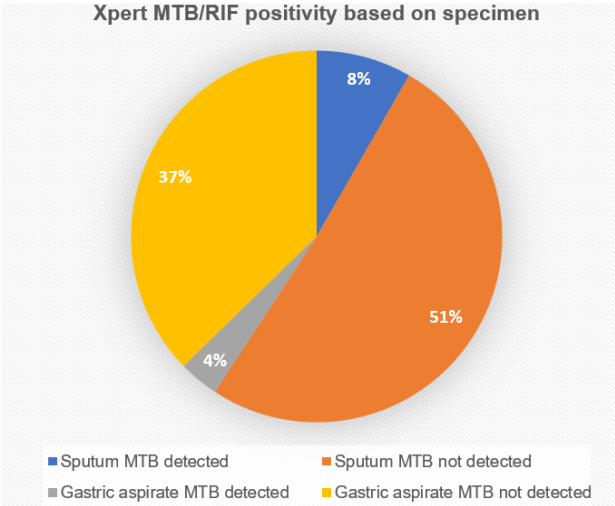

Figure 1. Xpert MTB/RIF positivity based on specimen of pediatric tuberculosis patients 2019-2023

Based on Figure 1, it was found that the “MTB detected” result in the Xpert MTB/RIF examination using sputum specimens was 8% and “MTB not detected” was 51%. On the other hand, when using gastric aspirate specimens, the “MTB detected” result was 4% and the “MTB not detected” result was 37%.

Discussion

According to Table 3 and Figure 1, the Xpert MTB/RIF examination results predominantly showed “MTB not detected” results with 329 samples (88.2%), while the “MTB detected” results were 44 samples (11.2%). This study aligns with another study conducted at Dr. Soetomo General Academic Hospital, Surabaya, Indonesia, which analyzed data from 887 pediatric pulmonary TB patients between 2016 and 2020.[16]

According to the study, 155 samples yielded positive results ("MTB detected") from the Xpert MTB/RIF examination, while 732 samples showed negative results ("MTB not detected").[16] The WHO and several studies have shown that the Xpert MTB/RIF is a tool with high sensitivity and specificity. However, this study showed that "MTB not detected" or negative results still dominated the Xpert MTB/RIF examination results. This is primarily due to the difficulties in making an accurate diagnosis of pulmonary TB using supporting tools. In children, pulmonary TB is generally paucibacillary, and sputum is rarely or not even produced, especially in children under 4 years old, making specimens difficult to collect.[17] Therefore, although Xpert MTB/RIF is accurate enough to detect MTB, if the specimens collected are not suitable, the test may show false-negative or false-positive results.[18]

According to Table 1, sputum was more widely used in Xpert MTB/RIF examination than gastric aspirate. Of the 337 samples, 221 samples (59.2%) used sputum as Xpert MTB/RIF examination specimens, and 152 samples (40.8%) used gastric aspirate. This aligns with the study conducted by Walusimbi, *et al*. (2013), who stated that most of the samples or specimens for TB examination were sputum specimens.[19] This is because sputum specimen collection is non-invasive, easy, and more affordable compared to gastric aspirate collection.[12] Therefore, gastric aspirate sampling is often used as an alternative specimen when sputum collection is not possible in pediatric patients with pulmonary TB.[20] The sensitivity and specificity of the Xpert MTB/RIF using sputum as the specimen have an average sensitivity of 66% (95% CrI, 52-77%) and an average specificity of 98% with a narrow interval. On the other hand, the average sensitivity of the Xpert MTB/RIF examination using gastric aspirate specimens is 66% (95% CrI, 51-81%).[21] It shows that sputum and gastric aspirate specimens have the same levels of sensitivity. However, the latest study conducted by WHO showed that gastric aspirates have a higher level of sensitivity at 73%, while sputum specimens have the same level of sensitivity as the latest study, which is 66%.[11] This is due to the difficulty of taking sputum specimens in children, especially those under 4 years old, because TB in this age group is predominantly paucibacillary, where sputum is rarely or not produced at all.[17]

According to Table 2 and Table 3, the highest number of samples was found in the 10-18 years old age group at 128 samples. Across all Xpert MTB/RIF examinations, both "MTB detected" and "MTB not detected" results were predominantly found in the 10-18 years old age group. This is similar to the WHO Global TB Report for 2021 and 2023, where the incidence of pulmonary TB in children aged 15-24 years was greater than that in children aged 0-4 and 5-14 years.[1,2] It also stated that adolescent and young adult males aged 15-24 years old have the highest incidence of pulmonary TB infection with an estimated number of 5.8 million cases in 2022, accounting for almost 55% of the world's total cases.[2,22] This aligns with a study conducted in boarding schools in Madura, which highlighted that children aged 15-18 years old were at a higher risk of TB infection.[23] Adolescents have a higher risk of being infected with TB, as children under 10 years old tend to develop the paucibacillary type of pulmonary TB, which is more difficult to detect and diagnose.[17] In addition, primary TB infection in adolescents follows a similar disease progression to that observed in adult infections.[24] In this type of pulmonary TB, there is increased sputum accumulation and production, resulting in more positive or "MTB detected" results from the Xpert MTB/RIF examination.[25]

In this study, more negative or "MTB not detected" results were obtained, and it was challenging to find positive or "MTB detected" results in both sputum and gastric aspirate specimens. However, in other studies, there are high positive Xpert results. In a study conducted in Southern Senegal, the positivity of Xpert MTB/RIF with sputum specimens was 33.05%.[26] Another study conducted at Dr. Soetomo General Academic Hospital, Surabaya, Indonesia, reported a sensitivity of 66.7% for Xpert MTB/RIF.[27] Both results were derived from prospective studies, whereas this study employed a retrospective design. Therefore, it is recommended that future research employ prospective studies to ensure more accurate and reliable results. Adopting a cohort study method to examine pediatric pulmonary TB patients, both before treatment and one month post-treatment, and analyzing other specimens such as stool, blood, or urine, are also recommended.[28] The study conducted in six health facilities in Tanzania found that the sensitivity and specificity of the stool Xpert MTB/RIF assay were 62.5% and 100%, respectively.[29] It also found that the sensitivity and specificity of the urine specimen for Xpert MTB/RIF examination in children were 38.8% and 97.7%, respectively, while the sensitivity and specificity of the blood specimen were 47.4% and 95.5%, respectively.[30]

Strengths and Limitations

The strength of this study lies in its relatively long observation period, spanning 5 years from 2019 to 2023, for the samples. This study was also conducted at a referral hospital recommended by the Ministry of Health of the Republic of Indonesia, ensuring that all procedures were performed in a standardized manner for laboratory diagnosis.

The limitations of this study include the lack of precise information regarding the timing of specimen collection and the absence of clear documentation in medical records indicating whether the patients had already received treatment. It was also challenging to obtain historical data from the patient's family.

Conclusion

Based on the results, sputum was more widely used than gastric aspirate to diagnose pediatric pulmonary TB with Xpert MTB/RIF examination. Most results found on Xpert MTB/RIF examination were negative results or "MTB not detected", both in sputum and gastric aspirate specimens.

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Conflict of Interest

The authors declared there is no conflict of interest.

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Ethical Clearance

This study was ethically approved by the Health Research Ethics Committee of Dr. Soetomo General Academic Hospital, Surabaya, Indonesia (No. 1122/ LOE/ 301.4.2/ XI/ 2022) on 11-11-2022.

Authors' Contributions

Designed the study and drafted the manuscript: SS, RAS, and NMM. Collected data and performed background literature review: SS. Performed statistical analysis: SS. Supervised results and discussion: NMM and RAS. All authors reviewed and approved the final version of the manuscript.

Data Availability

N/A.

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