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GenXpert Positivity: A Cross-Sectional Analytical Study Carried out at the Tuberculosis Screening and Treatment Centers of Haut-Uélé

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Abstract

Introduction: Tuberculosis (TB) is a major cause of morbidity and mortality worldwide. It represents a major public health problem. The objective of this study is to evaluate the role of the Xpert test in the microbiological diagnosis of TB in children in the Haut-Uélé province, eastern Democratic Republic of the Congo (DRC). **Methods:** Analytical cross-sectional study was conducted from January 1, 2019 to December 31, 2023 in the Haut-Uélé province in eastern DRC. A total of 105 children aged 0 to 15 years clinically diagnosed as TB cases were included in this study. Clinical, paraclinical and therapeutic data were collected in the following health care facilities (HCFs): Isiro General Reference Hospital (HGR), Watsa HGR and Kibali Hospital Center (CHK). These data were entered into Excel software and processed with R software version 4.4.2. **Results:** In multivariate analysis, weight (OR = 0.85; [95% CI = 0.72 - 0.98]) and being on anti-tuberculosis treatment (OR = 19.7; [95% CI = 2.25 - 442]) were significantly associated with a positive GeneXpert result. Weight loss (OR = 6.26; [95% CI = 0.93 - 150]), dyspnea (OR = 2.36; [95% CI = 0.80 - 7.15]) and neurological disorders (OR = 12.6; [95% CI = 0.74 - 576]) multiplied the risk of GeneXpert positivity in a non-significant manner. **Conclusion:** The GeneXpert test has proven its value in contributing to the diagnosis of tuberculosis in children in our setting. It was positive in most patients with a clinical picture characteristic of tuberculosis in both bivariate and multivariate analysis.

Keywords

GenXpert, Tuberculosis, Child, Predictive Factors, Haut-Uélé

1. Introduction

Tuberculosis (TB) is a major cause of morbidity and mortality worldwide and represents a major public health problem [1] [2].

Globally, 1.25 million people died from TB in 2023 (161,000 of whom also had HIV infection). TB has likely returned to being the leading cause of death from a single infectious agent, whereas coronavirus disease 2019 (COVID-19) had held that position for the previous three years. TB is also the leading cause of death among people living with HIV and a leading cause of death related to antimicrobial resistance [3].

All social categories are affected by this pathology. According to WHO estimates, 10.8 million people, including 6 million men, 3.6 million women and 1.3 million children, contracted tuberculosis worldwide in 2023. Tuberculosis is present in all countries and affects all age groups, particularly children aged 0 to 15 years. However, it is a disease that can be prevented [3].

Multidrug-resistant tuberculosis (MDR-TB) continues to cause a public health crisis and remains a threat to health security. Only about two in five people with drug-resistant tuberculosis had access to treatment in 2023 [3].

On the African continent, tuberculosis mainly affects children aged 0 to 15 years. A study conducted by Bilolo *et al.* [4] in 2024 found that Gabon is among 30 countries with a high prevalence of tuberculosis [4].

Furthermore, in Côte d'Ivoire, the study by Dembélé *et al.* [5] states that the number of TB cases in children was 1243 in 2013, representing 5.2% of new cases and 4.9% of all reported cases.

Diagnosis of tuberculosis remains a major challenge in the child due to the lack of specificity of the table clinical, biological and radiological examinations [6]. It is one of the targets of Sustainable Development Goals (SDGs) and its management is done using a multisectoral approach [2]. Childhood TB remains among the top 10 causes of infant mortality [2]. Delays in diagnosis and the rapidly evolving forms of young children are the main culprits behind this strong mortality [7]-[9]. Its diagnosis is not easy because of its low bacillary status, the difficulties of expectoration for the youngest, the low use of sample collection procedures by health care providers and the low integration of TB research activities in children [2]. For this, its diagnosis takes into account a bundle of epidemiological, clinical, and paraclinical (immunological and/or radiological) arguments, which are widely used despite their poor performance and often financially inaccessible because of the low socioeconomic level of the population [2] [10] [11].

Early detection of TB can be challenging, but GeneXpert MTB/RIF (Xpert) has improved the efficiency of the diagnostic process [12]. Currently, the test (Xpert) is a diagnostic tool that has been shown to be effective in improving the diagnostic accuracy of TB, with high sensitivity and specificity [12]. However, the accuracy of Xpert varies depending on different diagnostic specimens and sites of TB infection.

The study by Khadka *et al.* [13] conducted in Asia (Nepal) demonstrated the

diagnostic performance of Xpert, which confirmed that TB in 23.61% (85/360) of patients was declared negative by culture on NZ medium. Another study conducted by Pérez-Butragueño *et al.* [14], in Ethiopia on the impact of Xpert MTB/RIF in the diagnosis of childhood TB in rural areas, observed that almost half (49.5 % of patients diagnosed with clinical tuberculosis had obtained confirmation microbiological where culture was failing.

Despite the progress made with Xpert in the accurate diagnosis of TB in children in other countries, the situation is not the case in the DRC where the literature does not report any evaluation of this tool. In Isiro, the capital of the Haut-Uele province, in the East of the DRC, Xpert has been available for almost five years. However, local studies that have evaluated its performance as a gold standard in improving the diagnosis of childhood TB are not available to our knowledge. It is this lack of literature on this valuable tool in improving the management (PEC) of childhood TB that prompted us to conduct this study, the objective of which is to evaluate the contribution of the Xpert test in the microbiological diagnosis of childhood TB by evaluating the correlation between the characteristic clinical presentation of tuberculosis and the positivity of GeneXpert among the children in our sample.

2. Patients and Methods

2.1. Study Framework

We conducted this study in the Haut-Uélé province located in the East of the DRC. This province is one of the 26 provinces in the DRC. Its total population is 2,493,989 inhabitants, with an area of 89,683 km^2 and a density of 25.3 inhabitants per km^2. It has 13 health zones (ZS) with 13 HGR, 213 CS and 95 Hospital Centers including polyclinics and secondary hospitals. Three health care establishments (ESSs) were concerned, including HGR Isiro, HGR Watsa and Kibali Hospital Center (CHK). Their choice was justified by the fact that they are the three main ESSs of reference in this province which have a suitable technical platform including the GeneXpert device.

2.2. Sample and Sampling

We performed non-probability convenience sampling. We calculated the minimum sample size based on a cross-sectional study published in 2017 in Lubumbashi [15] which revealed a hospital prevalence of childhood TB of 8.2%. Using the Schwartz formula, we obtained a minimum sample size of 115 cases.

Inclusion criteria

The inclusion criteria for this study are:

- Be aged between 0 and 15 years old;
- Have a clinical diagnosis of tuberculosis;
- GeneXpert test;
- Have a complete medical record according to the variables of interest in our study.

Exclusion criteria

All children whose medical records did not have sufficient information related to the variables of interest in our study were excluded.

2.3. Methods

2.3.1. Type of Study

This was an analytical cross-sectional study.

2.3.2. Data Collection

Data collection was retrospective from January 1, 2019 to December 31, 2023, a period of 5 years. We used the documentary analysis technique. Socio-demographic, clinical, paraclinical and therapeutic data were collected from available medical documents (patient records, consultation register, hospitalization register, laboratory register, laboratory vouchers for examinations carried out on children aged 0 to 15 years).

2.3.3. Statistical Analysis of Data

This data was entered into a Microsoft Office 365 Excel sheet to create a database.

All statistical analyses were performed using R software version 4.4.2 (R Group Corporation, Austria, Vienna).

In bivariate analysis, we used Pearson's chi-square tests and Fisher's exact test for comparison of percentages. Comparison of means was performed using Welch's two-sample t-test.

Bivariate analysis allowed us to select the variables to be included in the initial logistic regression model. Thus, all variables with a value ≤ 0.4 were included in the initial logistic regression model. The selection of variables to be included in the final model was carried out using the backward stepwise selection method based on the Akaike information criterion (AIC). The lower the Akaike information criterion, the better the model. Thus, in the final model, the raw odds ratios and the adjusted odds ratios were calculated by the univariate and multivariate logistic regression technique respectively. Multivariate analysis allowed us to calculate the adjusted odds ratios in order to limit the effect of possible confounding variables included in the final model.

In all cases, the significance threshold was 5% (p-value < 0.05).

4. Results

The results of our study showed that the prevalence of tuberculosis was higher in female children compared to male children. A total of 105 were clinically diagnosed as TB cases and had performed GeneXpert, of which 81.0% of female patients had positive GeneXpert (p-value = 0.014). The socio-demographic data of the patients are shown in Table 1.

4.1. History, Biometrics and General Signs

Among the patient's personal histories, biometrics and general signs studied, only

Table 1. Socio-demographic data associated with GeneXpert positivity.

Characteristic	GeneXpert positive		Total N = 105[1]	p-value
	Yes N = 21[1]	No N = 84[1]		
Age (years)				
Average age	7.4 (4.6)	9.2 (3.4)	8.8 (3.7)	0.11[2]
Age groups				0.3[3]
<5	5 (23.8%)	10 (11.9%)	15 (14.3%)	
5 - 10	8 (38.1%)	32 (38.1%)	40 (38.1%)	
10 - 15	8 (38.1%)	42 (50.0%)	50 (47.6%)	
Sex				**0.014[4]**
Female	17 (81.0%)	43 (51.2%)	60 (57.1%)	
Male	4 (19.0%)	41 (48.8%)	45 (42.9%)	
Status of the child				>0.9[3]
Already followed	1 (4.8%)	4 (4.8%)	5 (4.8%)	
New patient	20 (95.2%)	80 (95.2%)	100 (95.2%)	
Origin				0.8[4]
Home	15 (71.4%)	62 (73.8%)	77 (73.3%)	
Referred	6 (28.6%)	22 (26.2%)	28 (26.7%)	

[1]Mean (SD); n (%); [2]Welch two-sample t-test; [3]Fisher's exact test; [4]Pearson chi-square test.

current antituberculosis treatment was significantly associated with GeneXpert positivity. GeneXpert detected the majority of tuberculosis cases that were already under treatment before this test was performed. Indeed, 23.8% of patients under specific treatment had a positive GeneXpert result versus 1.2% of those who had a negative GeneXpert result (p-value = 0.001). The mean weight of patients who had a positive GeneXpert result was lower than that of patients who had a negative GeneXpert result with 18.0 ± 8.2 versus 23.5 ± 7.7 kg respectively (p-value 0.010). The notion of weight loss and malnutrition not responding to nutritional rehabilitation was more observed in the group of patients who had a positive GeneXpert result compared to those whose GeneXpert result was negative with 90.5% versus 71.4% respectively (p-value = 0.040) (Table 2).

4.2. Respiratory and Extra-Respiratory Signs

The results of our study clearly show that GeneXpert was positive in most patients with a clinical picture characteristic of tuberculosis. Indeed, dyspnea and/or respiratory distress was more noted in the group of patients with positive GeneXpert compared to those with negative GeneXpert result with 52.4 vs. 23.8% respectively (p-value = 0.010). Haemoptysis was more observed in the group of patients with positive GeneXpert compared to those with negative GeneXpert result with 23.8

vs. 7.1% respectively (Table 3).

Table 2. Patient's personal histories, biometrics and general signs associated with GeneXpert positivity.

Characteristic	GeneXpert positive		Total N = 105[1]	p-value
	Yes N = 21[1]	No N = 84[1]		
Weight (kg)	18.0 (8.2)	23.5 (7.7)	22.4 (8.0)	**0.010[2]**
Follow-up for treatment				0.6[3]
Yes	2 (9.5%)	5 (6.0%)	7 (6.7%)	
No	19 (90.5%)	79 (94.0%)	98 (93.3%)	
Under anti-tuberculosis treatment				**0.001[3]**
Yes	5 (23.8%)	1 (1.2%)	6 (5.7%)	
No	16 (76.2%)	83 (98.8%)	99 (94.3%)	
Unexplained fever not responding to ATB/Antimalarials				0.2[4]
≤2 weeks	7 (33.3%)	41 (48.8%)	48 (45.7%)	
>2 weeks	14 (66.7%)	43 (51.2%)	57 (54.3%)	
Night sweats				0.5[4]
Yes	16 (76.2%)	58 (69.0%)	74 (70.5%)	
No	5 (23.8%)	26 (31.0%)	31 (29.5%)	
Weight loss and malnutrition not responding to nutritional rehabilitation				**0.040[4]**
Yes	19 (90.5%)	60 (71.4%)	79 (75.2%)	
No	2 (9.5%)	24 (28.6%)	26 (24.8%)	
Asthenia and anorexia				0.6[4]
Yes	21 (100.0%)	80 (95.2%)	101 (96.2%)	
No	0 (0.0%)	4 (4.8%)	4 (3.8%)	

[1]Mean (SD); n (%); [2]Welch two-sample t-test; [3]Fisher's exact test; [4]Pearson Chi-square test.

Table 3. Respiratory and extra-respiratory signs associated with GeneXpert positivity

Characteristic	GeneXpert positive		Total N = 105[1]	p-value
	Yes N = 21[1]	No N = 84[1]		
Persistent cough not responding to ATB				0.4[2]
Yes	20 (95.2%)	83 (98.8%)	103 (98.1%)	
No	1 (4.8%)	1 (1.2%)	2 (1.9%)	
Dyspnea and/or respiratory distress				**0.010[3]**
Yes	11 (52.4%)	20 (23.8%)	31 (29.5%)	
No	10 (47.6%)	64 (76.2%)	74 (70.5%)	

Continued

Hemoptysis				**0.041[4]**
Yes	5 (23.8%)	6 (7.1%)	11 (10.5%)	
No	16 (76.2%)	78 (92.9%)	94 (89.5%)	
Spinal deformation				>0.9[4]
Yes	0 (0.0%)	3 (3.6%)	3 (2.9%)	
No	21 (100.0%)	81 (96.4%)	102 (97.1%)	
Abdominal mass or ascites				0.14[4]
Yes	3 (14.3%)	4 (4.8%)	7 (6.7%)	
No	18 (85.7%)	80 (95.2%)	98 (93.3%)	
Bone or sinus joint swelling				0.2[4]
Yes	1 (4.8%)	0 (0.0%)	1 (1.0%)	
No	20 (95.2%)	84 (100.0%)	104 (99.0%)	
Neurological disorders				0.10[4]
Yes	2 (9.5%)	1 (1.2%)	3 (2.9%)	
No	19 (90.5%)	83 (98.8%)	102 (97.1%)	
Erythema nodosum				0.2[4]
Yes	1 (4.8%)	0 (0.0%)	1 (1.0%)	
No	20 (95.2%)	84 (100.0%)	104 (99.0%)	

[1]n (%); [2]Welch two-sample t-test; [3]Pearson chi-square test; [4]Fisher's exact test.

4.3. Multivariate Analysis of Factors Associated with GeneXpert Positivity

4.3.1. Socio-Demographic Factors and Patient History

In multivariate analysis, weight (OR = 0.85; [95% CI = 0.72 - 0.98]; p-value = 0.043) and being under anti-tuberculosis treatment (OR = 19.7; [95% CI = 2.25 - 442]; p-value = 0.016) were significantly associated with a positive GeneXpert result. Indeed, weight was found to be a protective factor (OR < 1). An increase in weight of 1 kg decreased the risk of GeneXpert positivity by 15%, conversely, a decrease in weight of 1 kg increased the risk of GeneXpert positivity by 15%. In addition to these 2 factors, in univariate analysis, female gender multiplied the probability of GeneXpert positivity 4 times compared to male gender (Table 4).

4.3.2. Clinical Factors

No factor significantly increased the odds of GeneXpert positivity. However, weight loss (OR = 6.26; [95% CI = 0.93 - 150]; p-value = 0.12); dyspnea (OR = 2.36; [95% CI = 0.80 - 7.15]; p-value = 0.12); and neurological disorders (OR = 12.6; [95% CI = 0.74 - 576]; p-value = 0.11) increased the odds of GeneXpert positivity in a non-significant manner.

In contrast, univariate logistic regression analysis shows that dyspnea (OR =

3.52; [95% CI = 1.31 - 9.68]; p-value = 0.013) significantly multiplied the risk of GeneXpert positivity (Table 5).

Table 4. Socio-demographic factors and patient history predictors of GeneXpert positivity

Characteristic	Univariate logistic regression			Multivariate logistic regression		
	OR[1]	95% CI[1]	p-value	OR[1]	95% CI[1]	p-value
Age	0.88	0.77 - 1.00	0.055	1.27	0.95 - 1.80	0.12
Weight	0.92	0.86 - 0.97	**0.008**	0.85	0.72 - 0.98	**0.043**
Sex						
Male	—	—		—	—	
Female	4.05	1.37 - 15.0	**0.019**	2.29	0.69 - 8.96	0.2
Under treatment Specific						
No	—	—		—	—	
Yes	25.9	3.86 - 515	**0.004**	19.7	2.25 - 442	**0.016**

[1]OR = odds ratio, CI = Confidence Interval.

Table 5. Clinical factors predictors of GeneXpert positivity

Characteristic	Univariate logistic regression			Multivariate logistic regression		
	OR[1]	95% CI[1]	p-value	OR[1]	95% CI[1]	p-value
Weight loss						
No	—	—		—	—	
Yes	3.80	1.00 - 25.0	0.088	6.26	0.93 - 150	0.12
Cough						
No	—	—		—	—	
Yes	0.24	0.01 - 6.27	0.3	0.03	0.00 - 1.26	0.056
Dyspnea						
No	—	—		—	—	
Yes	3.52	1.31 - 9.68	**0.013**	2.36	0.80 - 7.15	0.12
Neurological disorders						
No	—	—		—	—	
Yes	8.74	0.80 - 194	0.083	12.6	0.74 - 576	0.11

[1]OR = odds ratio, CI = Confidence Interval.

5. Discussion

We conducted this study to assess the contribution of GenXpert in the diagnosis of childhood TB. The results obtained highlight a significant association between gender and GenXpert test positivity, with a female predominance (81.0% vs. 19.0%,

p = 0.014). Similar results have been reported in Africa and other third-world countries. For example, a study conducted in the DRC by Zogbia *et al.* (2019) found that GenXpert positivity was more frequent in women, which could be attributed to greater household exposure to TB and immunological factors related to sex hormones [16]. Similarly, Kabedi *et al.* (2023) observed a similar trend in Kinshasa, where the majority of positive cases were women, suggesting a socio-cultural influence and differentiated access to care [17]. In other third-world countries, notably India and Bangladesh, studies have shown mixed results, with some confirming a higher prevalence in men, which may be related to more frequent risk behaviors in these populations [18]. These variations suggest that local factors, such as social habits, access to care, and immunological differences, influence the distribution of tuberculosis by sex.

Our study found a significant association between current anti-tuberculosis treatment (ATB) and GenXpert test positivity, with a positivity rate of 23.8% in patients on treatment compared to only 1.2% in those with a negative result (p = 0.001). Similar findings have been observed in Africa and other third-world countries. For example, a study conducted in the DRC by Ngombe *et al.* found a correlation between the administration of anti-tuberculosis treatment and the persistence of a mycobacterial load detectable by GenXpert, which could be related to emerging drug resistance or prolonged detection of non-viable bacterial DNA [13]. These observations suggest that GenXpert positivity on treatment could be influenced by factors such as therapeutic adherence, drug resistance, and persistence of non-viable bacterial genetic material, thus requiring careful interpretation of results to avoid overtreatment or delay in adapting treatment regimens.

The result of our study shows a significant correlation between lower body weight and GenXpert positivity, with a mean weight of 18.0 ± 8.2 kg in positive patients versus 23.5 ± 7.7 kg in negative patients (p = 0.010). In addition, weight loss and persistent malnutrition were more frequent in GenXpert positive patients (90.5% vs. 71.4%, p = 0.040). These results are in agreement with several studies conducted in Africa and other developing countries. For example, a study conducted in the DRC by Kabedi *et al.* (2023) showed that severe malnutrition was strongly associated with TB in children, with an impact on treatment response and mortality [17]. Similarly, a study conducted in India by Rao *et al.* (2020) highlighted an association between underweight and GenXpert test positivity, confirming that malnutrition increases susceptibility to infection and compromises treatment efficacy [19]. These findings highlight the importance of integrated nutritional management to improve treatment outcomes and reduce mortality associated with pediatric TB.

Our study results show that a higher frequency of dyspnea and/or respiratory distress (52.4% vs. 23.8%, p = 0.010) as well as haemoptysis (23.8% vs. 7.1%) was observed in GenXpert positive patients, highlighting the severe respiratory impact of TB. Similar findings have been observed in Africa and other third-world countries. For example, a study conducted in the DRC by Mukuku *et al.* (2019) showed

that severe dyspnea was a predictor of active TB, especially in children with advanced disease [20]. Similarly, a study in India by Kumar *et al.* (2020) reported that haemoptysis was significantly more frequent in patients with high bacterial load detected by GenXpert, suggesting extensive pulmonary involvement and possible cavitary TB [21]. These results confirm the utility of the GenXpert test in the clinical assessment of TB and highlight the need for early management of respiratory complications to improve the chances of survival of patients with pulmonary TB.

In multivariate analysis, our study highlighted that weight is a protective factor against GenXpert test positivity (OR = 0.85; 95% CI = 0.72 - 0.98; p = 0.043), while being on specific treatment is strongly associated with a positive result (OR = 19.7; 95% CI = 2.25 - 442; p = 0.016). In addition, female gender multiplies by 4 the probability of a positive GenXpert result compared to men in univariate analysis. These results are consistent with those reported in other studies conducted in Africa and in third-world countries. This is particularly the case of the study by Mukuku *et al.* (2019) [20].

Similarly, a study conducted in Bangladesh by Hamid Salim *et al.* (2004) demonstrated that women were more likely to have a positive GenXpert result, which could be related to biological, immune, and socio-economic differences in access to care [18]. These findings highlight the importance of nutritional management and rigorous therapeutic monitoring in TB patients to improve cure rates and reduce treatment resistance.

Our study reveals that weight loss, dyspnea and neurological disorders increase the risk of GenXpert positivity in a non-significant manner in multivariate analysis, while in univariate analysis, dyspnea is significantly associated with test positivity (OR = 3.52; 95% CI = 1.31 - 9.68; p = 0.013). These results are comparable to those reported in Africa and other third-world countries. On the other hand, the study by Singh *et al.* (2020) identified neurological disorders in TB patients, but their association with GenXpert positivity remained statistically non-significant, suggesting that other clinical factors influence their occurrence [22]. These results highlight the importance of comprehensive clinical management integrating respiratory and nutritional manifestations in TB screening.

6. Conclusion

At the end of this study, it is clear that the GeneXpert test has proven its interest in contributing to the diagnosis of tuberculosis in our environment in that it was positive in most patients with a clinical picture characteristic of tuberculosis in both bivariate and multivariate analysis. Regarding the distribution by sex, the GeneXpert was positive in most female patients compared to male patients, confirming the trend found by most studies that demonstrate a high prevalence of tuberculosis in female patients.

7. Limitations of the Study

Our study faced several limitations, including the retrospective collection of data

in order to have a sufficient sample compared to the minimum sample size according to Schwartz's formula. We also generalized the data to the entire population of our study setting, with a sample that was not quite sufficient compared to the extent of our region.

8. Perspectives

We propose to future researchers to conduct a large-scale analytical cross-sectional study in our environment involving all ESS in the region in order to obtain results that better describe the contribution of GeneXpert in the diagnosis of tuberculosis.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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