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Validation of The Child TB LP Clinical Decision Tool For Diagnosis of Tubercular Meningitis in Children Aged 6 Months-12 Years

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Abstract

Background: 50% cases of tubercular meningitis result in death or disability. To ensure optimum outcomes it is important to diagnose it early.

Current diagnostic tests, such as CBNAAT, not available everywhere and don't offer good sensitivity. Goenka et al developed 'CHILD TB LP clinical decision tool'. It has a sensitivity 100% and specificity of 90%. In our nation, TBM is a highly prevalent ailment, and the prognosis of patients is greatly impacted by prompt diagnosis. Thus, the purpose of this study was to further assess this clinical score.

Methods: This is an observational cross sectional study. This study aims to validate the "CHILD TB LP clinical decision tool" for the diagnosis of tubercular meningitis in children between the ages of three months and twelve years, as well as to establish a correlation between the tool and radiological findings in cases of tubercular meningitis. It includes 57 people who met the inclusion criteria. After completing the evaluation and filling out a proforma, participants were divided into two groups: probable TBM (score >= 4) and no TBM (scoring <4). Participants were followed for confirming microbiologically confirmed TBM and then tool's sensitivity, specificity, PPV and NPV calculated.

Results: The "Child TB LP Clinical Decision tool" had a sensitivity of 100% and a specificity of 30.6%. Significant correlations were found between tubercular meningitis and the CSF protein, CSF CBNAAT, chest

radiography, mantoux, and computed tomography/magnetic resonance imaging.

Conclusion: The "CHILD TB LP Clinical Decision Tool" is an excellent tool for TBM screening and the commencement of anti-tubercular therapy. CT/MRI Brain can be included in the 'CHILD TB LP Clinical Decision Tool' where resources are readily accessible. Further research is required on this.

Keywords: TBM, Children, Validation, 'CHILD TB LP Clinical Decision Tool'

Introduction

Mycobacterium tuberculosis (MTB) bacilli seeding the meninges is the cause of tuberculous meningitis (TBM). Young children are disproportionately affected by TBM, a debilitating condition (1). Roughly half of the cases end in death or disability (2). There is a 36.7% chance of survival without neurological sequelae and a 53.9% chance of neurological sequelae among survivors (3). In different areas of the nation, the sickness accounts for 1-4 percent of all paediatric hospital admissions. To guarantee the best possible results, TBM must be diagnosed and treated as soon as possible. TBM causes a high death rate and lifelong impairments if it is not identified and treated in a timely manner (2,4).

Mycobacterium tuberculosis detection in cerebrospinal fluid (CSF) culture in the Lowenstein Jensen (LJ) medium is the current gold standard diagnostic test. It has a sensitivity of 29.8% and takes approximately eight weeks (5). With a reported sensitivity of 59.3%, using GeneXpert on CSF samples allows for a quicker diagnosis of TBM (6). Resource limitations is the main reason why GeneXpert is not used in many underdeveloped nations. Additional microbiological tests that can identify tuberculous meningitis include the 78.6% sensitive Acid Fast Bacilli (AFB) smear and the 66.5% sensitive Mycobacteria Growth Indicator Tube (MGIT). As AFB stain necessitates careful inspection of a smear containing a sizable amount of cerebrospinal fluid, its application is impractical in high turnover environments. GeneXpert, on the other hand, marks a substantial advancement in early diagnosis. The GeneXpert provides results in about two hours, but many instances go undiagnosed because of the low sensitivity of CSF samples (7).

Numerous authors have tried to develop scoring systems for diagnosing tuberculosis because microbiological procedures have a low yield and therapy is frequently delayed, increasing morbidity. Most of them are not specific to tubercular meningitis (6,8-10). TBM scores have been developed by a few studies, however they are intended mostly for the adult population (6,11-14). Studies including paediatric patients with suspected TBM are scarce. Because characteristics like headaches are hard to evaluate in newborns and young children, the use of adult decision tools in paediatric clinical presentations is restricted.

The "CHILD TB LP clinical decision tool" was created by Goenka et al. and is a quick clinical decision tool that is based on the most often reported and reliable indicators of paediatric TBM (4). The authors suggest utilizing a rapid clinical decision tool that incorporates predictive characteristics for the preliminary assessment of children who present to hospitals in comparable circumstances and may have a suspected central nervous system (CNS) infection. They prospectively assessed this score on a different group of kids after it was created. In order for this score to be used more broadly in the future for the early identification of TBM, Goenka et al. also recommended that it be prospectively validated in different settings with limited resources.

Given the high prevalence of tubercular meningitis (TBM) in our nation, the purpose of this study is to assess the clinical score and identify its potential utility in our system for early diagnosis of tubercular meningitis and the commencement of antitubercular treatment, thereby averting unfavourable consequences.

Methods

An observational cross sectional study was conducted over 18 months in inpatient department of Pediatrics, at a tertiary hospital in New Delhi in collaboration with microbiology department after taking ethical clearance from the institute ethical committee (S. No. IEC/VMMC/SJH/Thesis/2020 – 11/CC – 234 dated 10.12.2020).

Goenka et al. conducted a retrospective case control study across seven hospitals in KwaZulu-Natal (KZN), South Africa, in order to develop the tool. They classified children who had their CSF sent for culture as having suspected TBM. Cases were classified as children whose CSF cultures had microbiologic confirmation; at the time of the study, KZN had not yet adopted the use of CBNAAT on CSF samples. On the other hand, children with suspected tuberculosis were classified as controls if other CNS infection was isolated, or no Mtb was found in the CSF through microscopy or culture, and no anti-tuberculous medication was administered (4). The development and test groups were randomly assigned cases and controls, and univariate analysis was utilized to determine which characteristics were most predictive of TBM. A significance level of 5% was established. Then the continuous variables were dichotomized using ROC analysis to yield threshold of maximum significance and univariate and multivariate logistic regression were used to identify the most appropriate variables and the most efficient model. After that, a sample of seven cases and twenty-one controls was used to assess the tool's performance, with a sensitivity of 100% and specificity of 90%.

In our study, children aged 3months–12years with fever for >7 days and any focal neurological deficit or alteration in sensorium were included in the study, whereas those already diagnosed as TBM or on ATT or in whom alternate diagnosis is established were excluded. After informed written consent from parents or guardian, all patients underwent a thorough history and examination including a full neurological examination. A pre-designed proforma was used to record the details with special reference to the consciousness, HIV status of caregiver, illness length, lethargy, focal neurological deficit along with demographic profile, clinical presentation, underlying disease and other relevant history and examination.

Lumbar puncture with aseptic precautions was performed after ruling out raised intracranial tension. CSF samples were sent for CSF cytology, protein and sugar estimation, bacterial culture, smear for acid fast bacilli (AFB), culture on MGIT (Mycobacterial Growth Indicator Tube), CBNAAT (Cartridge Based Nucleic Acid Amplification Test).

CSF samples were sent out in four tubes: the first tube was sent for biochemical testing, the second tube was sent for cytology, the third tube was sent for regular culture, and the fourth tube was sent for additional analysis.

The CSF sample that was sent to microbiology underwent CBNAAT. After centrifuging one millilitre of CSF sample and letting it sit with the buffered solution for fifteen minutes, the sample was run through the

GeneXpert machine to search for DNA from tuberculosis bacteria.

A sterile container was used to carry the 1-2 ml collected specimen for the Mycobacterial Growth Indicator tube (MGIT) over an ice pack. This sample was either treated right away in microbiology or refrigerated till it was processed. After centrifuging, the sediment was combined with an equivalent volume of 4% NaOH to decontaminate it. After that, the sample was placed in Middlebrook 7H9 liquid medium, and its fluorescence under UV light was measured every 60 minutes. To check for tuberculosis bacteria in Acid Fast Bacilli, smears from the CSF were made, stained with Ziehl Neelsen stain, and examined under a microscope.

Goenka et al had used CSF culture to define cases as microbiologically confirmed TBM but have also mentioned that they did not have access to Xpert MTB/RIF on CSF samples. We have included CBNAAT, MGIT, AFB as microbiologically confirmed TB as we had access to these tests in our institution unlike Goenka et al.

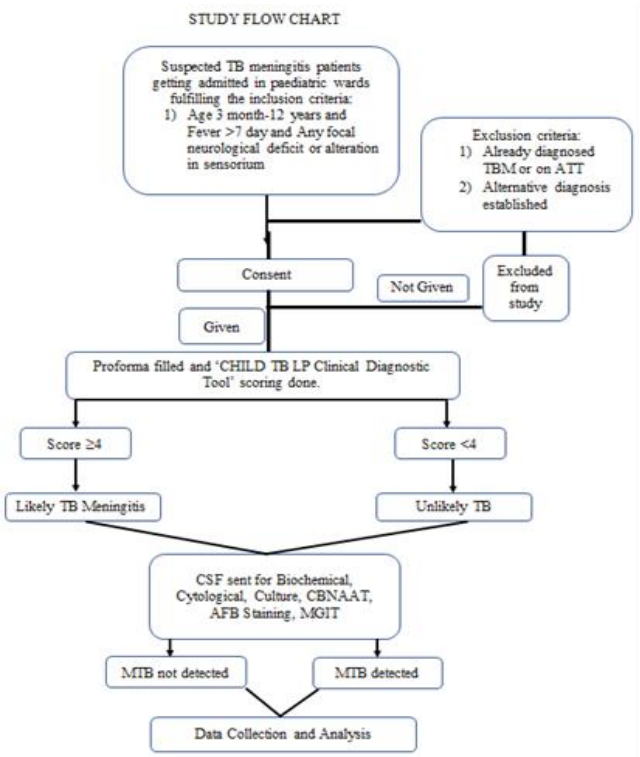
Using 'CHILD TB LP clinical decision tool' (Table 1) each patient was graded from 0-9 points and were considered as likely TBM if there were ≥4 points and <4 points were considered as unlikely TBM.

The results of these tests were collected and entered in the proforma sheet and analysed later.

The study of Goenka, et al. (4) observed that sensitivity of tool was 100%, and specificity was 90%. Taking these values as reference, the minimum required sample size with desired precision of 90%, 80% power of study and 5% level of significance is 56 patients. So total sample size taken is 56.

Statistical Methods

Categorical variables were presented in number and percentage (%) and continuous variables will be presented as mean ± SD (Standard Deviation) and median. Qualitative variables were correlated by Chi square test/Fisher's Exact test. Diagnostic test was used to calculate sensitivity, specificity, NPV (Negative Predictive Value) and PPV (Positive Predictive Value). Inter rater kappa agreement were used to find out the strength of agreement between two modalities. A p value of less than .05 was considered as significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) licensed version 21.0. The results of microbiologic investigations were correlated with 'CHILD TB LP CLINICAL DECISION TOOL' scoring to calculate the sensitivity, specificity, positive predictive value, negative predictive value of the tool to diagnose TBM.



Results

In the study, out of 57 participants, 33 (57.9%) participants were male and 24 (42.1%) participants were female. The mean age (years) was 5.87 ± 3.51. All the participants had fever duration ≥ 7 days and new neurological deficit. Fifteen (26.3%) participants had 'CHILD TB LP Clinical Decision Tool' score of <4 and 42 (73.7%) participants had score of ≥4. Three (5.3%) participants had AFB Positive and 54 (94.7%) participants had AFB negative. Four (7.0%) participants had CBNAAT positive and 53 (93.0%) participants had CBNAAT negative. Two (3.5%) participants had MGIT positive and 55 (96.5%) participants had MGIT negative. Twenty-six (45.6%) participants had mantoux positive and 31 (54.4%) participants had mantoux negative. 50 (87.7%) participants had CXR not suggestive of TB whereas 7 (12.3%) participants had CXR suggestive of TB. Twenty-seven (47.4%) participants had CT/MRI findings not suggestive of TBM whereas 23 (40.4%) participants had CT/MRI findings suggestive of TBM and 7 (12.3%) participants did not undergo CT/MRI (/Figure 1). Twenty-six (45.6%) participants were diagnosed to have TBM whereas 31 (54.4%) participants did not have TBM.

As per the present study, keeping the gold standard as microbiologically confirmed TBM, the sensitivity of the 'CHILD TB LP Clinical Decision Tool' was found to be 100% and specificity was found to be 30.6% with a PPV of 19% and NPV of 100% and a diagnostic accuracy of 40.4% (Table 2). Association between microbiologically confirmed TBM and CT/MRI is represented in Table 3 and figure 2.

Discussion

According to estimates from the World Health Organization, there were 1.2 million paediatric infections among the 10 million new cases of tuberculosis (TB) that occurred globally in 2019. India is the nation with the highest rate of tuberculosis cases worldwide, accounting for 28% of cases in children under the age of 14 (15).

The prognosis for tuberculous meningitis is dismal; many survivors experience poor quality of life and neurological sequelae even after treatment. A favourable outcome is dependent on the early initiation of treatment, which is typically postponed in our nation and many other low-resource nations for a variety of reasons. These include low diagnostic test sensitivity, the lack of a useful rapid diagnostic test for use in children, and lack of neuroimaging on a priority basis.

In our study, we had 57 participants. The mean age was 5.87 ± 3.51, which is comparable to other studies on tubercular meningitis (13,16,17). 57.9% of the participants in our study were male, and 42.1% were females, which is comparable to a study by Yaramis et al., male to female percentages of 52% and 48%, respectively. We had a slightly higher proportion of males, which could be due to preferential medical seeking attention given to male children. However, in a study by Gunes et al. in United Kingdom, they found that the percentage of males to females were 65.4% and 34.6%, which could be due to the increased predisposition of males to TBM infection (18).

Goenka et al. conducted a retrospective case-control study from 2010 to 2014 spanning seven hospitals in KwaZulu-Natal, South Africa. Using univariate analysis, they determined the characteristics most predictive of microbiologically confirmed TBM in children. A clinical decision tool was created using these factors, and its effectiveness was evaluated on a separate sample of seven cases and twenty-one controls, achieving 100%

sensitivity and 90% specificity. They came to the conclusion that the "CHILD TB LP Clinical decision tool" correctly identified TBM that was microbiologically confirmed, and they suggested that the tool be evaluated prospectively as a novel rapid diagnostic tool for the initial assessment of children who present to hospitals in comparable settings with suspected neurological infections.

With 57 children in our sample, we were able to determine that the scoring system had a 40.4% diagnostic accuracy as well as 100% sensitivity, 30.6% specificity, 19% PPV, and 100% NPV.

Since CBNAAT may provide results in two hours, it has been used in recent years to diagnose TBM. However, due to its low sensitivity of 50–60% (19), diagnosis is sometimes missed. With an NPV of 84-94%, it can't completely rule out TBM, but it is still useful in a positive scenario.

As a result, a diagnostic tool is crucial. In this instance, Goenka et al. reported that the "CHILD TB LP clinical decision tool" had a 100% sensitivity, making it effective in identifying likely cases of tuberculosis and aiding in the start of antitubercular treatment. It can also be used to rule out TBM because it has a 100% negative predictive value. It is less accurate than CBNAAT, with a diagnosis accuracy of 40.4%.

Unlike Goenka et al., we got a lower specificity which is 30.6%, compared to 90%, which could be due to i) Our study was conducted during the COVID pandemic time; patients might have had COVID earlier which could have affected certain parameters of the scoring system. ii) Patients reach our tertiary care centre after seeking treatment from various other hospitals and clinicians, and the treatment received might have affected the scoring system parameters.

According to Luo et al., the positive rate of TBM in CT examinations can reach 80%, and it can reach even higher levels in MRI examinations (20). 90.3% of TBM patients exhibited CT brain results that supported TBM, according to another study by Gunes et al. (18). In our study, we had 88.5% of patients with TBM having findings in CT/MRI brain and found a significant association between TBM and CT/MRI brain ($p<0.001$) and a high association between the two variables by Bias corrected Cramer V (0.9). Additionally, we discovered a significant association between TBM as suggested by CT/MRI and TBM that has been microbiologically validated.

The "CHILD TB LP clinical decision tool" has higher sensitivity, lower specificity, lower PPV, higher NPV, and comparable diagnostic accuracy when compared to the results of the CBNAAT.

Additionally, our study revealed that CSF Proteins, CSF CBNAAT, Mantoux, CXR, and CT/MRI brain were the variables significantly associated with TBM. Goenka et al. did not include CSF, CBNAAT, Mantoux, CXR, or CT/MRI brain as relevant variables in this study; however, these variables have been proven to be significant in other studies (2,13,16,17, 21, 22). Mantoux and CT/MRI brain are variables that are statistically significant and can be incorporated into the scoring system to increase its accuracy. These variables are taken from the list of variables that are strongly linked with microbiologically confirmed TBM. This is consistent with prior research where 80–90% of TBM patients had positive results on head CT/MRI scans, and TBM was found to be correlated with Mantoux positivity (6,16,23).

Conclusions

The "CHILD TB LP Clinical Decision Tool" is an excellent tool for detecting tuberculosis early on and starting anti-tubercular therapy, hence avoiding negative consequences from delayed diagnosis. Mantoux and computed tomography/magnetic resonance imaging of brain can be included in the 'CHILD TB LP Clinical Decision Tool' where resources are available and further research is required on this.

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Highlights

- Tubercular meningitis is a devastating disease and needs to be diagnosed early, for which Goenka et al developed a ‘CHILD TB LP clinical decision tool’ with a sensitivity of 100% and specificity of 90%.
- This study validates the ‘CHILD TB LP clinical decision tool’ as a good screening tool as it has a 100% sensitivity and 100% NPV and can help in early initiation of treatment of tubercular meningitis for better prognosis.
- This study also brings to light the role of CT/MRI brain in diagnosing TBM and its advantage in incorporating it in the decision tool.

Legend Tables and Figures

Table 1: Child TB LP Clinical Decision Tool

Child TB LP clinical decision tool	
C	Conscious, altered
H	HIV-infected caregiver
I	Illness length >7 days
L	Lethargy, chronic fatigue or reduced playfulness
D	Deficit in focal neurology which is new
T	Thrive, failure to
B	Blood/serum sodium <=132mmol/L

L	Lymphocytes (CSF) >= 10 cells x 10^6/L
P	Protein (CSF) >=0.65 g/L
Presence of each variable gives 1 point whereas absence gives 0 point	
Result	>= 4 point is likely TBM <=3 points is unlikely TBM

Table 2: Performance of 'Child TB LP clinical decision tool' for Predicting TBM

Variable	Category(s) Suggesting Outcome Present	Category(s) Suggesting Outcome Absent	Total Positives	True Positives	True Negatives	False Positives	False Negatives
TBM	Yes	No	26 (45.6%)	-	-	-	-
Score	>=4	<4	42 (73.7%)	22 (39%)	11 (19%)	20(35%)	4 (7%)

Primary Diagnostic Parameters

Variable	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
Score	84.6% (65-96)	35.5% (19-55)	52.4% (36-68)	73.3% (45-92)	57.9% (44-71)

Diagnostic Parameters for diagnosing TBM

Variable	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
Score	84.6% (65-96)	35.5% (19-55)	52.4% (36-68)	73.3% (45-92)	57.9% (44-71)
CSF AFB	11.5% (2-30)	100.0% (89-100)	100.0% (29-100)	57.4% (43-71)	59.6% (46-72)
CSF CBNAAT	15.4% (4-35)	100.0% (89-100)	100.0% (40-100)	58.5% (44-72)	61.4% (48-74)
CSF MGIT	7.7% (1-25)	100.0% (89-100)	100.0% (16-100)	56.4% (42-70)	57.9% (44-71)
CT/MRI	88.5% (70-98)	100.0% (89-100)	100.0% (85-100)	91.2% (76-98)	94.7% (85-99)
Microbiologically Confirmed TBM	30.8% (14-52)	100.0% (89-100)	100.0% (63-100)	63.3% (48-77)	68.4% (55-80)

The sensitivity and specificity of CBNAAT in our study was 15.4% and 100% respectively with a diagnostic accuracy of 61.4 % and that of all the microbiological tests combined were 30.8% and 100% respectively with the diagnostic accuracy increasing to 68.4% which is comparable to that of the 'CHILD TB LP clinical decision tool'.

Table 3: Association between Microbiologically Confirmed TBM and CT/MRI (n = 57)

CT/MRI	Microbiologically Confirmed TBM			Fisher's Exact Test	
	Yes	No	Total	$\chi2$	P Value
Not S/O TBM	0 (0.0%)	27 (55.1%)	27 (47.4%)	8.403	0.005
S/O TBM	6 (75.0%)	17 (34.7%)	23 (40.4%)		
Not Done	2 (25.0%)	5 (10.2%)	7 (12.3%)		
Total	8 (100.0%)	49 (100.0%)	57 (100.0%)		

There was a significant difference between the various groups in terms of distribution of CT/MRI ($\chi2 = 8.403$, $p = 0.005$).

Figure 1:

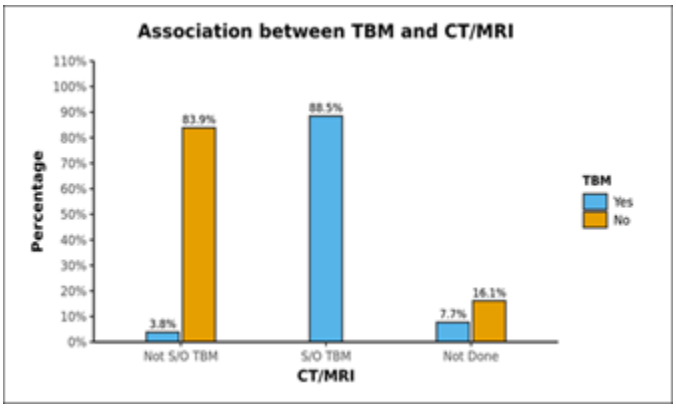

Figure 2: