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PRESUMPTIVE TUBERCULAR EMPYEMA THORACIS SCORING SYSTEM (pTESS) IN CHILDREN .AN OBSERVATIONAL STUDY.

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Abstract

Introduction:

Global TB report 2018 reports that in India, an estimated 2.2 lakh children become ill with tuberculosis (TB) each year (22% of the global TB burden), with a slightly higher burden among males. Pulmonary TB is the most common form in children but the extra-pulmonary TB forms a larger proportion of cases than in adults. Aim & Objective: To find out the diagnostic efficacy of the Scoring system in presumptive tubercular empyema thoracis and the diagnostic accuracy of CBNAAT in the diagnosis of tubercular empyema thoracis.

Material & Method:

41 patients aged 1-14 years were enrolled after written informed consent was obtained from the patients. Children with ATT or preexisting lung disease were excluded from the study. Presumptive TB Empyema was defined based on the revised national tuberculosis program(RNTCP). The cutoff score for the scoring system was calculated and retrospectively applied to the 41 subjects and the efficacy was assessed.

Result:

pTESS had area under the curve 0.967(95% CI 0.902-1.000, p-value <0.001)Indicating a good predictive value in predicting tubercular empyema had sensitivity of 90.91% (58.72% to 99.77%) and specificity 96.67 %(82.78%- 99.2%), false positive rate 3.33%(0.08%- 17.22%), false negative rate 9.09%(23%- 41.28%) positive predictive value 90.91% (58.72%- 99.77%), negative predictive value 96.67% (82.78%- 99.92%), LR+=27.27 LR-=0.09OR-130.5, Youden Index 0.8. The sensitivity of CBNAAT in our study was 36.36% and specificity of 96.67% positive predictive value of 80%, negative predictive value of 80.56%,

Conclusion:

pTESS Scoring System can be used for diagnosis of TB Empyema.

Recommendation:

Clinical assessment by the pTESS scoring system may be used for diagnosis of TB Empyema in the pediatric age group.

Keywords: Pediatric, Empyemathoracis, Tuberculosis, pTESS, Submitted: 2023-06-30 Accepted: 2023-07-11

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1. INTRODUCTION.

Diagnosis of pulmonary tuberculosis in children can be challenging due to nonspecific symptoms, signs, and radiological changes and the difficulty of making a definitive microbiologic diagnosis[1] In childhood, the distinction between infection and disease is often difficult. The progression of infection to disease can be subtle and go unnoticed. This difficulty becomes more remarkable, often in extrapulmonary TB[2]. The added risk of complications of tubercular empyema thoracis like bronchopleural fistula necessitates the search for alternative methods for diagnosis. A diagnosis is often made presumptively based on a combination of clinical symptoms, signs, and radiological findings. However, in regions where other diseases with overlapping features (eg, HIV, systemic viral or bacterial infections, parasitic infections, and bacterial, viral, or atypical pneumonia) are also endemic, the sensitivity and specificity of these diagnostic approaches are imperfect[3] Tubercular and nontubercular empyema thoracis have a variable profile in terms of epidemiological variables, Clinical presentation and earlier presentation frequent association of broncho-pleural fistula formation requiring surgical intervention. India is predicted to account for 27% (22-33) of the total burden of pediatric tuberculosis in the 22 countries. The predicted proportion of tuberculosis burden in children for each country correlated with incidence, varying between 4% and 21%[4]. The overall estimated case detection rate was 35%-meaning 65% of active tuberculosis cases in children are missed every year by national programs [4]. Accurate diagnosis of childhood TB is difficult and often requires complex and expensive laboratory facilities. In the absence of a gold standard, the diagnosis of TB in children is nearly always presumptive[5]. Global Tuberculosis (TB) 2018 Report suggests that In India average of 2.2 lakh children become ill with TB each year (22% Of the global TB burden) with a slightly higher burden among males. Pulmonary TB is the most common form of Tuberculosis in children but extra pulmonary TB forms a larger proportion than in adults[6]

The general child survival strategies are expectedly focussed around the diseases with the highest mortality among the under-five and they include Pre-mature birth, perinatal asphyxia and injuries, Pneumonia, and Diarrhoea. (WHO & MCEE 2017)[6]. Pulmonary TB is the most common form of TB in children; however, extra-pulmonary TB (EPTB) in children forms a more significant proportion of cases than adults. Adults comprise the largest proportion of TB cases as the adulthood span is far longer than pediatric. In addition, TB control does not figure prominently as one of the child survival strategies. The child survival strategies are expectedly focused on the diseases with the highest mortality among the under five, including premature birth, perinatal asphyxia and injuries, pneumonia, and diarrhoea. Among the other causes of childhood, mortality is TB, albeit unrecognized yet important. However, the exact contribution of TB to 'Under-5 Mortality' is unknown. Many TB-related deaths are possibly reported as pneumonia due to similar respiratory symptoms, and autopsy studies from a few African nations support this contention. As a singular organism, *Mycobacterium tuberculosis (M.tb)* contributes to most death of under-five among the world's middle and lower-income countries[6]

Although the principles of diagnosis and treatment remain similar in children and adults, the differences in the type of disease and specific host characteristics bring up some challenging variations. Adults and older children more often have the infectious form of TB, which may be confirmed by testing sputum, while in general, younger children have forms of TB that show up poorly on sputum smears. Moreover, difficulties in accessing the specimen from children who swallow rather than bring out sputum add further challenges. Whereas alternative methods to collect respiratory samples are more invasive and require professional skills. Confirmation of TB and its drug sensitivity does require microbiological testing but the sophistication of diagnosis among children often makes it challenging to decentralize it to the community These challenges have led to poor coordination between child survival strate-

gies and TB control[6].

The challenges in pediatric tuberculosis include difficulty to obtain the sputum samples the possible nature of the disease and the nonspecific clinical and radiological findings. To overcome the problem of diagnosing pediatric tuberculosis combination of clinical characteristics, history of contact with adult active tuberculosis, tuberculin skin test result, and radiological findings have been evaluated, and scoring systems assigning various weightage to those variables have been developed. The lack of a gold standard for comparison of this system has limited the validity of this screen scoring system. Still, this is recommended as there is little prospect of devising a standard diagnostic method that involves culture, microscopy, PCR, or serological tests that are widely useful for children.

Thus, devising a scoring system for the diagnosis of tubercular empyema thoracis cases based on various clinical, radiological, and laboratory findings and history may facilitate earlier diagnosis and prevent complications. Thus the present study has been proposed to be undertaken.

1.1. Aim.

To evaluate the efficacy of pTESS in Children.

1.2. Objective.

To find out the Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value of a scoring system in presumptive tubercular empyema thoracis in children and the diagnostic role of CBNAAT in tubercular empyema thoracis in children and compare the scoring parameters between tubercular and nontubercular empyema group.

2. MATERIAL & METHODS.

After obtaining Clearance from the institutional ethical committee this Observational analytical Cohort Study was conducted at Veer SurendraSai Institute of Medical Sciences and Research(VIMSAR), Burla. [21 29" 58.88" N & 83 53,10.06" E]in patient Department of Paediatrics, Outpatient Department of Pulmonary Medicine, VIMSAR, BurlaFrom September 2019 to October 2021. All clinically or radiologically confirmed cases of pleural effusion between the age of 1-14 years of both genders were enrolled in the study after taking informed written consent from the patient or the legal guardian. Case proforma for each patient was filled and required data was collected from the sheet.

2.1. Sample Size.

From a study Outcome of Parapneumonic Empyema done in MKCG College, Berhampur, Orissa done in 2001-03 the prevalence of empyema thoracis is found to be 0.8%.The minimum sample size is calculated using Masta v 2 (BRTC, Vellore) taking p=0.008, absolute precision=5%, and CI=95% to be 12.

2.2. Selection criteria.

2.2.1. Inclusion Criteria.

Clinically or radiological diagnosed cases of pleural effusion aged 1-14 years with pleural fluid having one or more of the following characteristics[1]

- Frank pus on pleural aspiration,
- Bacteria present on gram staining,
- pH of pleural fluid is <7.20,d. Neutrophil in a fluid is >1,00,000/microlitre.

2.2.2. Exclusion Criteria.

- Patient already on Antitubercular therapy for active Tuberculosis.
- Patients with pre-existing lung disease,c.Any contraindication for thoracocentesis-bleeding diathesis, patient on anticoagulant therapy.

2.3. Sampling Technique.

As thiswas a hospital-based study the sampling method we used to collect the sample is simple convenient sampling.

2.4. *Study Procedure.*

A diagnostic study was to be done in the Department of Paediatrics, wherein a scoring system for the diagnosis of presumptive tubercular empyema thoracis was developed. The scoring system is based on the Modified Brazilian National Ministry of Health Scoring System for diagnosis of tuberculosis in smear-negative indigenous children and adolescents, Brazil, 2011done by Sandra Christo dos Santos, Ana Maria Campos Marques, Roselene Lopes de Oliveira, RivaldoVenancio da Cunha. The scoring system has been modified according to the Indian scenario.27 parameters have been included in the present scoring system wherein various parameters (symptoms and signs of tuberculosis, contact history of tuberculosis, serological testing, tubercular skin testing, radiological investigations, pleural fluid analysis and follow up parameters like clinical improvement and reduction in chest tube drainage)are chosen and assigned score between -5(lowest score)to +5(highest score)and. Patients aged 1-14 years who will fulfill the inclusion criteria of empyema thoracis were included as study subjects and were subjected to routine investigations and score was assigned to each patient and at the end of the study total score assigned to each patient was calculated the data will be analyzed using Dxt v 1.0 (BRTC, Vellore) and then the diagnostic efficacy of the scoring system will be tested and cutoff score for diagnosis of tubercular empyema thoracis will be established.

Based on a previous study done in MKCG, Berhampur, Odisha in 2001-2003, the minimum sample size is calculated using Masta v 2 (BRTC, Vellore) taking p=0.008, absolute precision =5%, CI=95% to be 12. Out of 60 pleural effusion patients admitted to the In-patient Department of Paediatrics, VIMSAR, Burla in the said study period, 52 patients made up the study pool as per the inclusion and exclusion criteria of the study. From this study pool,47 patient cases were selected by consecutive sampling. While recruiting the study sample, the parents/guardians were explained about the study and they were requested to sign the consent form for participation in the study. Of these,6 cases did not give consent to participate in the study, hence 41 were enrolled in the study. The confirmed cases were the cases that improved after 2 weeks of Anti Tubercular Treatment. As it is a hospital-based study so the target population was the same as the study population.

The patient was scored based on sex, weight, contact history with tuberculosis, tuberculin skin test, chest x-ray, ultrasonography of the chest, clinical course following empirical antibiotics, and antitubercular, pleural fluid analysis. Each parameter was scored on a scale from -5 to +5. The score of each patient was calculated.

Table-1 :Presumptive Tubercular Empyema Thoracis Scoring System (pTESS)(history)

Scoring Parameters	-5	-2	-1	0	+1	+2	+3	+5
1.Age in completed years					<5	>5		
2.1. Fever					<1week	1-2 weeks		>/=2weeks
2.2.Cough					<1week	1-2 weeks		>/=2weeks
2.3.Weight loss/No weight gain in last 3 months			Absent					Present
2.4.Contact history				No				YES
2.5Toxic Symptoms		yes				no		
2.6BCG Vaccination				Immunised, Scar present			Immunised, Scar absent	Not taken

Table -2: Presumptive Tubercular Empyema Thoracis Scoring System (pTESS)(clinical examination and associated findings)

2.7Nutritional Status(IAP/WHO)				Normal		Moderate malnutrition		Severe malnutrition.
2.8Immunity				Normal	Associated with HIV			Associated with HIV and HepB
2.9Clinical Improvement after 2weeks of Antibiotics	yes							NO
2.10Persistent Intercostal Drainage after 2 weeks of antibiotic	no							Yes
2.11Clinical Improvement after 2weeks of ATT	no							yes

Table 3 : **Presumptive Tubercular Empyema Thoracis Scoring System (pTESS)(investigation & supportive)**

3X-ray Chest 3.1A- Xray findings 3.2 follow-up XRAY	Change in Xray after 2weeks antibiotic			Normal			No Change in Xray after 2weeks antibiotic	Hilar lymphadenopathy/ Military pattern/ cavitation
3.3USG Chest				No pus	U/L Pus	B/L Pus		
4.1TST				Negative				Positive
4.2Differential Count				Neutrophil Predominant	Lymphocyte Predominance	L+N		
4.3Total Leucocyte Count			Decreased	Normal	Increased			
4.4Sputum/ Gastric Aspirate AFB/CBNAAT				Negative				Positive
4.5Granulomatous lesion on sampled specimen				Negative				Positive
5Pleural fluid Analysis 5.1- Differential Count 5.2 Sugar content 5.3 Protein Content 5.4 ADA 5.5 CBNAAT 5.6 Bacterial Culture	CBNAAT Negative		High Sugar, ADA Negative	Neutrophil predominance, Positive pleural pus bacterial culture	Lymphocyte predominance,ADA Positive, low protein in g/dl	Lymphocyte + neutrophil	High protein in g/dl	Negative Pleural Pus Culture, CBNAAT Positive

pTESS Score by Investigator 1was considered as a primary outcome variable.

Tuberculin Skin Test: The skin below 5–10 cm (2–4 inches) below the elbow joint, on the ventral forearm, the Forearm should be placed palm-up on a firm, well-lit surface was Cleaned with an alcohol swab. Expiry date and Tuberculin strength (2 TU of PPD RT23) was checked. A single-dose syringe with a short (1/4 to 1/2 inches) 27-gauge needle with a short bevel was loaded with 0.1 ml tuberculin. The needle was inserted slowly, beveled up, at an angle of 5–15° with the Needle bevel being visible just below skin.PPD is injected gently raising an Intra- dermal wheal of at least 6 mm in diameter. The syringe was discarded in the sharp container (as per BMW guidelines). The date and time of the test, Site, and location, Lot number of tuberculin, and Tuberculin strength were recorded. The patient was instructed to

Keep it clean and dry, and avoid putting creams/ lotions, or adhesive bandages, not getting the site wet with water is not harmful, but the site should not be wiped or scrubbed to avoid scratching the site. Ideally, the test should be read between 48 and 72 hours.

Total leucocyte count- was done in automated hematology analyser-HORIBA-ES60 by electrical impendence and photometry method.

CHEST X-ray was done in view, which is done in sitting posture. Chest X-ray was done by KONICAMINOLTA, INC with model no AeroDR533 digital X-ray machine. Exposure time,focus-film distance, and degree of exposure were standardized for each patient to obtain the best radiographic quality.

Chest ultrasonography was performed with GE LOGIQUE E9 XD clear 2.0 ultrasound machine using a 3.5-5 MHZ convex probe that allows visualization and quick survey of the pleura and lung field. A high-resolution 7.5-10 MHZ linear probe was used to provide a detailed description of any pleural and peripheral lung abnormality.

Pleural aspiration/Thoracocentesis was done in the 6th intercostal space in the midaxillary or posterior axillary line after clinical localization of pleural effusion on the respective side of the thoracic cavity. In selected cases, we used USG guidance for thoracocentesis, especially in loculated and minimal pleural effusion.

Pleural fluid analysis including gross and microscopic examination, nucleic acid amplification tests DNA PCR (CBNAAT), pleural fluid tests like microbiology (ZN and Gram's stain), biochemistry, ADA, cytology & pleural fluid AFB culture were performed.

2.5. *Data Analysis and Interpretation.*

Data collected from the study wasprocessed, and checked for internal errors, internal and external validation was done using Epi Data v4.2.0 and Data was analyzed in terms of Reciever Operating Characteristic (ROC) Curve by using SPSS v24 SOFTWARE (IBM, NEWYORK, USA) and Dxt v 1. 0 software.

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3. OBSERVATION.

Observational study of 41 patients was done in the study group. Of this, 25(60.98%) were male and 16 (39.02%) were female.17 (41.46%) were aged less than 5 years and 24 (58.54%) were aged 5-14 years. Among confirmed TB Empyema 2(18.18) were aged 1-4 years and 9 (81.82%) were aged 5-14 years.

TABLE :1 – CLINICAL FINDINGS OF THE STUDY GROUP.

Parameter		Frequency	Percentage
Fever	less than 1 week	17	41.40
	Between1-2 week	12	29.27
	More than 2 weeks	12	29.27
Cough	less than 1 week	18	43.90
	Between1-2 week	15	36.59
	More than 2 weeks	8	19.51
History of Weight loss/No weight gain in last 3 months	Present	8	19.51
	Absent	33	80.49
History of Contact with Pulmonary TB	Present	7	17.07
	Absent	34	82.93
BCG Immunisation Status, Scar Status	Immunised with scar present	28	68.29
	Immunised with scar present	11	26.83
	Not taken	2	4.88
Malnutrition	Moderate	17	41.46
	Severe	2	4.88
	No	22	53.66
Cervical Lymph Node Number, Consistency	Single	16	39.02
	Multiple, Matted	8	19.51
	Multiple, Non matted	12	29.27
	Absent	5	12.20
Associated Immunocompromised Disease	Yes, Associated with HIV	1	2.44
	No	40	97.56

Among the study population, 17 (41.46%) had fever less than1 week, 12 (29.27%) had fever between 1-2 weeks and 12 (29.27%) had fever more than 2 weeks and 18 (43.90%) had cough less than 1 week, 15 (36.59%) had cough between 1-2 weeks and 8 (19.51%) had cough for more than 2 weeks. TB Empyema,2 (18.18%)had fever between 1-2 weeks and 9 (81.82%)had fever more than 2 weeks and 1 (9.09%) had cough less than 1 week, 3 (27.27%) had cough between 1-2 weeks and 7 (63.64%) had cough more than 2 weeks. 8 (19.51%) had weight loss history, 7 (17.07%) had history of contact with Tuberculosis patient, 28(68.29%) had taken BCG Immunisation and had scar, 17 (41.46%) had moderate malnutrition , 16 (39.02%) had single lymph node, 8 (19.51%) had multiple, matted lymph node and 12(29.27%) had multiple, non-matted lymph node.

TABLE -2 INVESTIGATION FINDINGS OF THE STUDY GROUP

Associated Immunocompromised Disease	Yes, Associated with HIV	1	2.44
	No	40	97.56
Sputum/Gastric Aspirate AFB	Positive	3	7.32
	Negative	38	92.68
FNAC of Lymph Node	Positive	1	2.44
	Negative	40	97.56
Sputum/Gastric Aspirate CBNAAT	Positive	1	2.4
	Negative	40	97.6
Tuberculin Skin Test Result	Positive	10	24.39
	Negative	31	75.61
Toxic Symptoms	Present	23	56.10
	Absent	18	43.90

1(3.33%) had an association with HIV, 3(7.32%) had positive sputum/Gastric Aspirate AFB, 1(2.44%) had a positive Biopsy of lymph node, 10 (24.39%) had a positive Tuberculin Skin test. 23 (56.10%) had Toxic symptoms.

Among TB empyema 7(63.64%) had weight loss history, and 6(54.55%) had history of contact with Tuberculosis patient,2(18.18%) had taken BCG Immunisation and had scar,7(63.64%) had taken BCG Immunisation but scar was absent,2(18.18%) had not taken BCG,7(63.64%) had severe malnutrition,2(18.18%) had moderate malnutrition.and 2 had no malnutrition,6(54.55%) had multiple, matted lymphnode,3(27.27%) had multiple, nonmatted lymph node and 1(3.33%) had association with HIV, 1 (9.09%) had positive sputum/Gastric Aspirate AFB,0%) had positive Biopsy of lymph node, 7 (63.63%)had positive tuberculin test,2(18.18%) had toxic symptoms.

TABLE : 3 -Descriptive analysis of tuberculin skin test result, toxic symptoms, clinical improvement following 2weeks antibiotics, intercostal drainage following 2weeks antibiotics, clinical improvement following 2weeks ATT in the study population (n=41)

Parameter		Frequency	Percentage
Clinical Improvement Following 2Weeks Antibiotics	Yes	29	70.73
	No	12	29.27
Intercostal Drainage Following 2Weeks Antibiotics	Yes	28	68.29
	No	13	31.71
Clinical Improvement Following 2Weeks ATT	Clinical Improvement	11	26.8
	No Clinical Improvement	1	2.4
	Not taken ATT	29	70.7
Chest X ray Findings	Hilar Lymphadenopathy, Miliary Tuberculosis, Cavitation	6	14.63%
	No features of Tuberculosis	35	85.37
Improvement in Chest Xray Following 2Weeks Antibiotics	Improvement	29	70.73
	No improvement	12	29.27
Pus in USG Thorax	Unilateral Pus Collection	31	75.61
	Bilateral Pus Collection	8	19.51
	No Pus Collection	2	4.88

Among the study population, 29 (70.73%) had clinical improvement following 2 weeks antibiotics, 28 (68.29%) had persistent Intercostal

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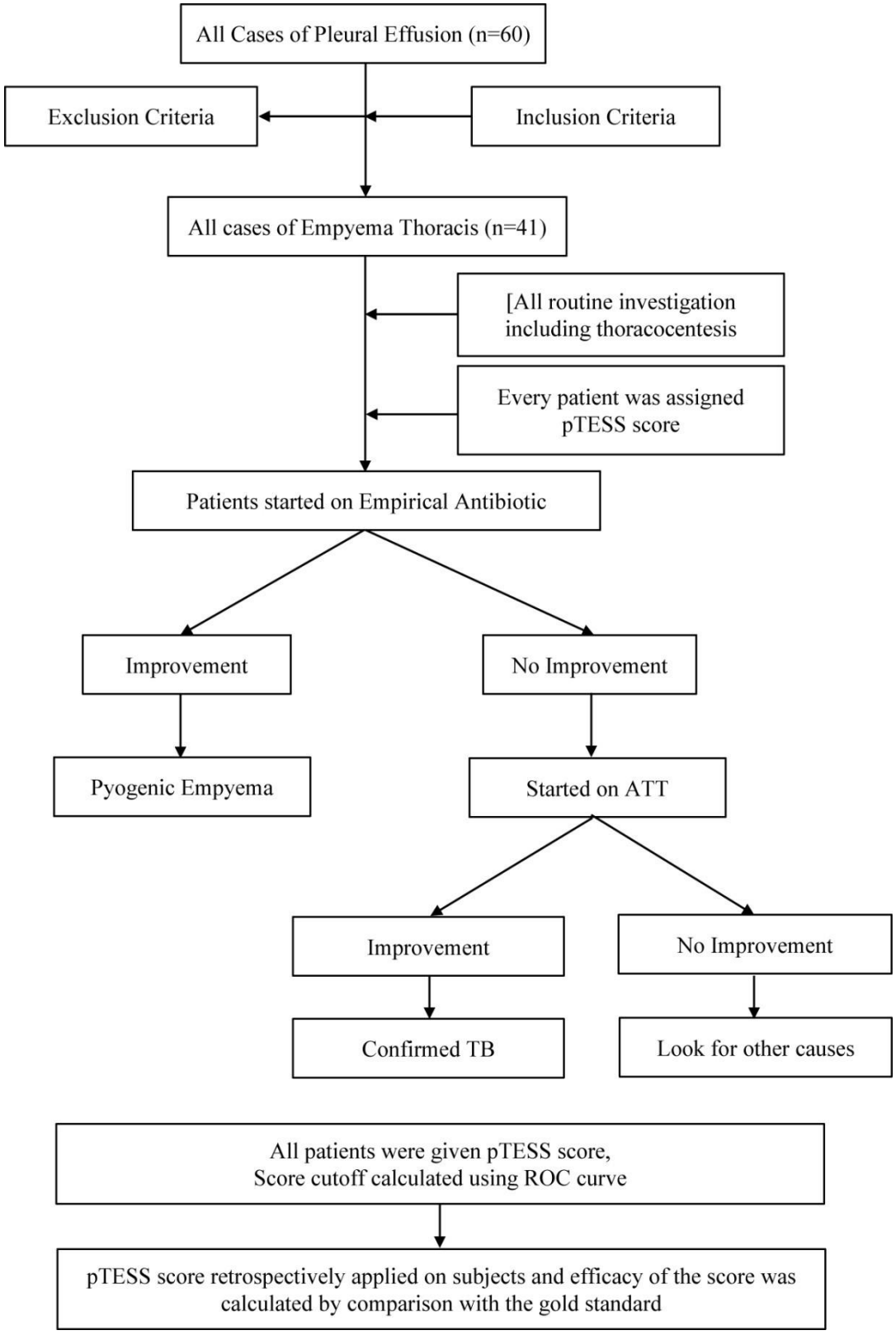

Figure 1: **Shows the study flow chart**

Drainage following 2 weeks antibiotics, 11 (26.8%) had clinical improvement after 2 weeks ATT.

Among TB Empyema,0(0%) had clinical improvement following 2 weeks antibiotics, 11(100%)had persistent Intercostal Drainage following 2 weeks antibiotics, 11 (100%) had clinical improvement after 2 weeks ATT.

Among the study population, 6 (14.63%) had chest X ray findings suggestive of tuberculosis 29 (70.73%) had improvement in chest X ray following 2 weeks antibiotics. (7.61%) had unilateral pus collection, 8 (19.51%) had Bilateral Pus collection. (Table 16& Figure 11)

Among TB empyema, 6 (54.55%) had chest X ray findings suggestive of tuberculosis 0 (0%) had improvement in chest X ray following 2 weeks antibiotics. 7(63.64%) had unilateral pus collection, 3(27.27%) had Bilateral Pus collection.

TABLE:4- Descriptive analysis of total leucocyte count, predominant cell count in differential count, pleural fluid in the study population (n=41)

Parameter		Frequency	Percentage
Total Leucocyte Count	Increased	21	51.22
	Normal	20	48.78
Predominant Cell Count in Differential Count	Neutrophil	23	56.10
	Lymphocyte	13	31.71
	Neutrophil and lymphocyte	5	12.20
Predominant Cell Count in Pleural Fluid	Neutrophil	26	63.41
	Lymphocyte	13	31.71
	Neutrophil and lymphocyte	2	4.88
Pleural Fluid Sugar in mg/dl	less than 30mg/dl	18	43.90
	more than or equal to 30mg/dl	23	56.10
Pleural Fluid Protein In g/dl	less than 4	29	70.73
	more than or equal to 4	12	29.27
Pleural Fluid ADA Result	Positive	15	36.59
	Negative	26	63.41
Pleural Fluid CBNAAT Result	Positive	5	12.20
	Negative	36	87.80
Pleural Fluid Bacterial Culture	Microorganism growth in Pleural culture	23	56.10
	No Microbial Growth in Pleural Culture	18	43.90

Among the study population, 21 (51.22%) had increased total leucocyte count and 20 (48.78%) had Normal total leucocyte count, 23 (56.10%) had Neutrophil predominance, 13 (31.71%) had Lymphocyte predominance and 5 (12.20%) had Neutrophil and Lymphocyte equal proportion.

Among TB Empyema, 5 (45.45%) had increased total leucocyte count and 6 (54.55 %) had Normal total leucocyte count, 2 (18.18%) had Neutrophil predominance, 8 (72.73%) had Lymphocyte predominance and 1 (9.00%) had Neutrophil and Lymphocyte equal proportion.

TABLE:5-Descriptive analysis of pTESS Score by Investigator 1,2 and 3 in study population (n=41)

Parameter	Mean ± SD	Minimum	Maximum
pTESS Score by Investigator 1	9.29 ± 34.78	-23.00	85.00
pTESS Score by Investigator 2	9.24 ± 35.89	-29.00	99.00
pTESS Score by Investigator 3	9.05 ± 35.84	-29.00	100.00

The mean pTESS Score by investigator 1 was 9.29 ±34.78 in the study population, minimum and maximum was -23 and 85 respectively in the study population.The mean pTESS Score by investigator 2 was 9.24±35.89 in the study population, minimum and maximum was -29 and 99 respectively in the study population.The mean pTESS Score by investigator 3 was 9.05 ±35.84 in the study population, minimum and maximum was -29 and 100 respectively in the study population.

TABLE:6- Descriptive analysis of Empyema Thoracisin the study population (n=41)

Parameter		Frequency	Percentage
Empyema Thoracis	Patients with Tuberculosis	11	26.8%
	Patients without Tuberculosis	30	73.2%

Among the study population, 11 (26.8%) were patients with Tuberculosis.

TABLE:7-Predictive validity of pTESS Score by Investigator 1 in Confirmed Tuberculosis (n=41)

Area Under the Curve	Std. Error	95% Confidence Interval of AUC		p-value
		Lower Bound	Upper Bound	
0.967	0.033	0.902	1.000	0.001

The accuracy of PTESS Score by Investigator 1for diagnosis of tubercular empyema thoracis was analysed by Receiver Operat- ing Curve(ROC),with Area under curve being 0.967(95%CI- 0.902-1.0) and the P value 0.001) indicating good predictive validity in predicting Confirmed TB Empyema.The cut off value for PTESS Score by investigator 1 came out be 30.5.

TABLE:8 -Comparison of TB and Pyogenic Empyema with pTESS Score by Investigator 1 (n=41)

Parameter		Patients with Tuberculosis (n=11)	Patients Without Tuberculosis (n=30)	Chi square	P value
Empyema thoracis	Tubercular empyema thoracis (>=30.5)	10 (90.91%)	1 (3.33%)	31.445	0.001
	Non-Tubercular empyema thoracis (<30.5)	1 (9.09%)	29 (96.67%)		

Among the patients with tuberculosis, 10 (90.91%) had tubercular empyema thoracis and among patients without tuberculosis, 1 (3.33%) had tubercular empyema thoracis. The difference in proportion of pTESS score by investigator 1 between confirmed tuberculosis was statistically significant. (P value 0.001).

TABLE:9-Predictive validity of pTESS Score by Investigator 1 in predicting Confirmed Tuberculosis (n=41)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	90.91%	58.72%	99.77%
Specificity	96.67%	82.78%	99.92%
False positive rate	3.33%	0.08%	17.22%
False negative rate	9.09%	0.23%	41.28%
Positive predictive value	90.91%	58.72%	99.77%
Negative predictive value	96.67%	82.78%	99.92%
Diagnostic accuracy	95.12%	83.47%	99.40%
Positive likelihood ratio	27.27	0.96	176.942
Negative likelihood ratio	0.09	0.03	0.61

The pTESS Score by investigator 1 had sensitivity of 90.91% (95% C. I from 58.72% to 99.77%) in predicting confirmed tuberculosis. Specificity was 96.67% (95% C. I from 82.78% to 99.92%), false positive rate was 3.33% (95% C. I from 0.08% to 17.22%), false negative rate was 9.09% (95% C. I from 0.23% to 41.28%), positive predictive value was 90.91% (95% C. I from 58.72% to 99.77%), negative predictive value was 96.67% (95% C. I from 82.78% to 99.92%), diagnostic accuracy was 95.12% (95% C. I from 83.47% to 99.40%).

TABLE:10-Comparison of Empyema Thoracis with Pleural Fluid CBNAAT Result (n=41)

Pleural Fluid CBNAAT Result	Empyema Thoracis		Chi square	P value
	Patients with Tuberculosis (n=11)	Patients Without Tuberculosis (n=30)		
Positive	4 (36.36%)	1 (3.33%)	8.201	0.004
Negative	7 (63.64%)	29 (96.67%)		

Among the patients with tuberculosis, 4 (36.36%) had positive result in pleural fluid CBNAAT and among patients without tuberculosis, 1 (3.33%) had positive result in pleural fluid CBNAAT. The difference in proportion of pleural fluid CBNAAT Result between confirmed tuberculosis was statistically significant. (P value 0.004).

TABLE:11-Predictive validity of Pleural Fluid CBNAAT Result in predicting Confirmed Tuberculosis (n=41)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	36.36%	10.93%	69.21%
Specificity	96.67%	82.78%	99.92%
False positive rate	3.33%	0.08%	17.22%
False negative rate	63.64%	30.79%	89.07%
Positive predictive value	80.00%	28.36%	99.49%
Negative predictive value	80.56%	63.98%	91.81%
Diagnostic accuracy	80.49%	65.13%	91.18%
Positive likelihood ratio	10.91	0.05	17.137
Negative likelihood ratio	0.66	0.37	1.034

The pleural fluid CBNAAT had sensitivity of 36.36% (95% C.I from 10.93% to 69.21%) in predicting TB Empyema. Specificity was 96.67% (95% C. I from 82.78% to 99.92%), false positive rate was 3.33% (95% C. I from 0.08% to 17.22%), false negative rate was 63.64% (95% C. I from 30.79% to 89.07%), positive predictive value was 80% (95% C. I from 28.36% to 99.49%), negative predictive value was 80.56% (95% C. I from 63.98% to 91.81%), diagnostic accuracy was 80.49% (95% C. I from 65.13% to 91.18%).

TABLE:12- Comparison of clinical presentations between confirmed tuberculosis (n=41)

Parameter		Empyema Thoracis		Degrees of freedom	Chi square	P value
		Patients with Tuberculosis (N=11)	Patients Without Tuberculosis (N=30)			
Age in Years	≤5years	2 (18.18%)	15 (50%)	1	3.357	0.085
	>5 Years	9 (81.82%)	15 (50%)			
Fever Duration in Week	Between1-2 Week	2 (18.18%)	10 (33.33%)	1	8.2238	0.004
	More Than 2 Weeks	9 (81.82%)	3 (10%)			
Cough Duration in Week	Less Than 1 Week	1 (9.09%)	17 (56.67%)	2	19.506	0.001
	1-2 Weeks	3 (27.27%)	12 (40%)			
	More Than 2 weeks	7 (63.64%)	1 (3.33%)			
Weight Loss History	Present	7 (63.64%)	1 (3.33%)	1	18.637	0.001
	Absent	4 (36.36%)	29 (96.67%)			
Malnutrition	Moderate Malnutrition	7 (63.64%)	10 (33.33%)	2	*	*
	Severe Malnutrition	2 (18.18%)	0 (0%)			
	No Malnutrition	2 (18.18%)	20 (66.67%)			
Tuberculin Skin Test Result	Positive	7 (63.64%)	3 (10%)	1	12.556	0.001
	Negative	4 (36.36%)	27 (90%)			
Gender of The Patient	Male	7 (63.64%)	18 (60%)	1	0.045	1.000
	Female	4 (36.36%)	12 (40%)			
Contact with Tb Patient	Present	6 (54.55%)	1 (3.33%)	1	14.910	0.001
	Absent	5 (45.45%)	29 (96.67%)			
Toxic Symptoms	Present	2 (18.18%)	21 (70%)	1	8.775	0.005
	Absent	9 (81.82%)	9 (30%)			
Lymph Node Number, Consistency	Single	2 (18.18%)	14 (46.67%)	3	*	*
	Multiple, Matted	6 (54.55%)	2 (6.67%)			
	Multiple, Non-Matted	3 (27.27%)	9 (30%)			

*No statistical test was applied- due to 0 subjects in the cells

Among the patients with tuberculosis, 1 (9.09%) had cough less than 1 week, 3 (27.27%) had cough for 1-2 weeks, 7 (63.64%) had cough more than 3 weeks. The difference in proportion of Cough duration in week was statistically significant.(p value 0.001) in this study.

TABLE:13- Comparison of clinical course between confirmed tuberculosis (n=41)

Parameter		Empyema Thoracis		Degrees of freedom	Chi square	P value
		Patients with Tuberculosis (N=11)	Patients Without Tuberculosis (N=30)			
Clinical Improvement Following 2Weeks Antibiotics	Yes	0 (0%)	29 (96.67%)	1	*	*
	No	11 (100%)	1 (3.33%)			
Intercostal Drainage Following 2Weeks Antibiotics	Yes	11 (100%)	2(6.67%)	1	*	*
	No	0 (0%)	28(93.67%)			
Clinical Improvement Following 2Weeks ATT	Clinical Improvement After 2 Weeks ATT	11 (100%)	0 (0%)	2	*	*
	No Clinical Improvement After 2 Weeks ATT	0 (0%)	1 (3.33%)			
	Not Taken ATT	0 (0%)	29 (96.67%)			
BCG Immunisation Status, Scar Status	Taken, Scar Present	2 (18.18%)	26 (86.67%)	2	*	*
	Taken, Scar Absent	7 (63.64%)	4 (13.33%)			
	Not Taken	2 (18.18%)	0 (0%)			
Associated Immunocompromised Disease	Yes, Associated with Hep B/C	0 (0%)	1 (3.33%)	1	*	*
	No	11 (100%)	29 (96.67%)			

*No statistical test was applied- due to 0 subjects in the cells

There was no statistical significance so far clinical course of the disease in the study group.

Table -14: Comparison of laboratory findings between confirmed tuberculosis

Parameter		Empyema Thoracis		Degrees of freedom	Chi square	P value
		Patients with Tuberculosis (N=11)	Patients Without Tuberculosis (N=30)			
Chest X Ray Findings	Hilar Lymphadenopathy, Miliary Tuberculosis, Cavitation	6 (54.55%)	0 (0%)	1	*	*
	No Features of Tuberculosis	5 (45.45%)	30 (100%)			
Improvement in Chest Xray Following 2Weeks Antibiotics	Improvement	0 (0%)	29 (96.67%)	1	*	*
	No Improvement	11 (100%)	1 (3.33%)			
Pus in USG thorax	Unilateral Pus Collection	7 (63.64%)	24 (80%)	2	1.296	0.523
	Bilateral Pus Collection	3 (27.27%)	5 (16.67%)			
	No Pus Collection	1 (9.09%)	1 (3.33%)			
Predominant Cell Count in Differential Count	Neutrophil	4 (36.36%)	19 (63.33%)	2	2.381	0.304
	Lymphocyte	5 (45.45%)	8 (26.67%)			
	Neutrophil and Lymphocyte	2 (18.18%)	3 (10%)			
Total Leucocyte Count	Normal	6 (54.55%)	14 (46.67%)	1	0.200	0.655
	Increased	5 (45.45%)	16 (53.33%)			
Predominant Cell Count in Pleural Fluid	Neutrophil	2 (18.18%)	24 (80%)	2	13.375	0.001
	Lymphocyte	8 (72.73%)	5 (16.67%)			
	Neutrophil and Lymphocyte	1 (9.09%)	1 (3.33%)			
Pleural Fluid Sugar in mg/dl	More than or Equal To 30Mg/Dl	0 (0%)	23 (76.67%)	1	*	*
	Less Than 30Mg/Dl	11 (100%)	7 (23.33%)			
Pleural Fluid Protein In gm/dl	≥ 4	8 (72.73%)	4 (13.33%)	1	13.715	0.001
	<4	3 (27.27%)	26 (86.67%)			
Pleural Fluid ADA Result	Positive	10 (90.91%)	5 (16.67%)	1	19.122	0.001
	Negative	1 (9.09%)	25 (83.33%)			
Pleural Fluid CBNAAT Result	Positive	4 (36.36%)	1 (3.33%)	1	8.201	0.014
	Negative	7 (63.64%)	29 (96.67%)			
Pleural Fluid Culture	Microorganism Growth	0 (0%)	23 (76.67%)	1	*	*
	No Microbal Growth	11 (100%)	7 (23.33%)			
Sputum/Gastric Aspirate AFB	Positive	1 (9.09%)	2 (6.67%)	1	0.070	1.000
	Negative	10 (90.91%)	28 (93.33%)			
Biopsy of Lymph Node	Positive	0 (0%)	1 (3.33%)	1	*	*
	Negative	11 (100%)	29 (96.67%)			

*No statistical test was applied- due to 0 subjects in the cells

The difference in the proportion of Tuberculin test results was statistically significant. (p-value 0.001)in this study. Pleural fluid differential count, high protein content, and ADA were also found to be statically significant.

4. DISCUSSION.

In the results from a previous study done in Ethiopia and other low and middle-income countries done by Satyanarayana[7]the prevalence of tuberculosis was found to be 11 to 23%. In a study done by Jose M Ramos et al [8] 45.5% were under 5 years of age and 67.2% had pulmonary TB. In the present study, 81.82% of the children in the tubercular empyema group were in the age group of 5 to 14 years whereas 50% of the children in the nontubercular group were under five years of age.

Although over 50% of the cases of tuberculosis in children might be asymptomatic, the literature shows that the combination of persistent cough for two weeks fever for more than two weeks and weight loss has diagnostic value for the disease. A study done by CinthiaPedrozoetal[9]for the establishment of the efficacy of the scoring system recommended by the Brazilian National Ministry of Health for the diagnosis of primary tuberculosis in children and adolescents regardless of their HIV status showed the statistical significance of fever, cough, and weight loss in the diagnosis of TB. Cough was the most common symptom present in 39.6% of the children in the TB group. In the present study fever for more than two weeks and cough for more than two weeks and weight loss history are statistically significant. fever for more than two weeks was the most common symptom seen in 81.82% of the children in the tubercular empyema group whereas cough for more than two weeks was the most common symptom occurring in 56.67% of the nontuberculous group. The history of weight loss was also statistically significant with p value less than 0.001.

Tuberculin skin test used in the diagnosis of tuberculosis disease and evaluation of Latent tuberculosis cases is an easily applicable reproducible and low-cost test. In a study done by Cigdemyildirimetal[10]the test positivity among the BCG unvaccinated group was 0% in five to seven years 2% in seven to 14 years and among the BCG vaccinated 0% in five to seven years and 1% in 7 to 14 years. In the present study, 63.64% population with tubercular empyema had a positive

tuberculin skin test and 10% in the nontubercular group also had a positive result. The present study concluded the tuberculin skin test result to be statistically significant.

Confirming the occurrence of tuberculosis in the household Contacts of TB, the study conducted by Kristen m little [11], a high prevalence of 3.9% of Tuberculosis was found among the household Contacts of newly diagnosed TB cases. In our present study, 54.55% of the tubercular empyema thoracic patient had a contact history of tuberculosis whereas 3.3% of the nontubercular group also had a history of TB contact, with the p-value being 0.001.

In the present study, 18.18% of the tubercular against 70% of nontubercular groups had toxic symptoms.

In a study done by HitenderGautam[12], on 140 suspected cervical lymphadenitis cases,87.14% had unilateral,81.42% had single,87.85% added matted lymph nodes and 12.86% had associated lung lesions. In the present study, 18.18% had single 54.55% had multiple matted and 27.22% had multiple non-matted lymph nodes in the tubercular group against 46.67% single 6.67% multiple mated and 30% with multiple non mated and 16.67% with no lymph nodes in the nontubercular group.

In literature, TST Contact history of TB would help in the diagnosis of TB in the paediatric group but in high endemic areas wide BCG vaccine application has indicated a high rate of false positive TB skin tests in healthy populations and also false-positive reactions due to nontuberculous mycobacterial rendering the interpretation of positive TST difficult. In a study done by Dursun Tatar et al [13] 56 to 69% positivity in TST in TB patients due to the moderate prevalence of TB and BCG vaccination. In the country of Turkey against a 24 to 77% prevalence of positive tests worldwide concluding TST is a valuable but non-specific test for the assessment of TB. In the present study 18.18%had not taken BCG vaccination 18.18% had taken BCG vaccination on this car was present and 63.64% had taken BCG but the scar was absent in the tubercular group Against 86.67% vaccinated and scar present and 13.33% vaccinated with Scar absent in the nontubercular group.

In a study done by Samantha Hearthetal [14]for assessing pulmonary involvement in extrapulmonary tuberculosis 74% had chest x-ray abnormalities. By the present study, 54.55%had chest x-ray features suggestive of tuberculosis in the tubercular empyema group.96.67% of the patient had improvement in the chest x-ray following Two weeks of empirical antibiotics in the nontubercular group against 100% of patients with persistent chest x-ray findings after two weeks of empirical antibiotics in the tubercular group.

In a study done by Samantha Hearth et al. [14], patients of extra pulmonary tuberculosis with normal chest x-ray 55%had sputum cultures performed of which 18% were smear positive.

Mestitz and Pollard (1959)[15], Reddy and Indira (1963[]16), Light et al. (1973)[17], and many others were of the view that the predominance of lymphocytes in the pleural fluid was suggestive of either tuberculosis or malignancy, the two disease which can be differentiated by pleural biopsy pleural fluid culture. In the present series, 72.73% of the patients had lymphocytic predominant in their pleural fluid and 18.18% of polymorphonuclear predominant in the tubercular group against 80% in the non tubercular group having polymorphonuclear predominant.

Glenert (1962) [18] thought that glucose contained in the pleural fluid had no relevance to etiological diagnosis. In the present work 11(100%) patients had a pleural fluid glucose content of less than 30mg% and others had values above that in the tubercular group against 76.67% had pleural fluid glucose content of less than 30mg%.

In their series, Reddy and Indira *(1963*) [16] observed that 74.73% of tubercular empyema had a pleural fluid protein of more than 4gm/dl and the rest had less than 3.0 gm% of protein. In the present study, 72.73%cases had pleural fluid protein levels of more than 4.0 gm/dl in the tubercular group against 13.33% in the non-tubercular group.

The estimation of ADA levels in pleural fluid, peritoneal fluid, and pericardial fluid has been found useful for the diagnosis of tubercular aetiol-

ogy(Chopra et al[19]. A study done by Ashutosh-NathAgarwal et al [20] with ADA cutoff 40U/L had sensitivity and specificity of 0.93%.In the present study, 90.91 % of cases had positive pleural fluid ADA more than 40U/L in the tubercular group against 16.67% in the nontubercular group.

We subjected all the pleural fluid samples to CBNAAT assay and observed in 36.3 of the cases. Positive cases were 36.36% in the tubercular group against 3.33% in the non-tubercular group. The sensitivity of CBNAAT in our study was 36.36% and specificity of 96.67% positive predictive value of 80%, negative predictive value of 80.56%, this low sensitivity can be explained by cross-contamination during the procedure which is a common problem in laboratories used in house protocol.

Reechaipichitkul et al, (2000)[21] mention a sensitivity of 50% and specificity of 61% and PCR positive in 100% of culture-positive TB effusion and only in 30-60% of the culture-negative pleural fluid. Bahador et al. (2005)[22] reported a PCR positive in 66 (84%) of 78 patients studied. Mukherjee et al [23]pleural fluid CBNAAT had a sensitivity of 72.5% and specificity of 100%.

In a study done by CinthiaPedrozo et al[9] Where they applied a scoring system for the diagnosis of TB adopted in Brazil the main scores were 24.2 for the Latent TB group,18.5 for the non-tubercular group and 45.3 for the tubercular group and 41.5 for the tubercular an HIV group. The scores were significantly higher in the TB group than in the Latent TB and non-TB groups. In addition, the TB group scores were above the cut-off value of 30 points which indicated the need to initiate ATT treatment.

In a case-control study done by M Conde[24] for the evaluation of a Diagnostic scoring system for

Pulmonary tuberculosis Found the sensitivity of the score range from 58% to 89% and the specificity from 98 to 86% with cut off of respectively,>=40 and >=30.

In a phase three validation study done by Isabella Coimbra et al[25]for assessing the diagnostic accuracy of the ASS scoring system for diagnosis of smear-negative tuberculosis in HIV-infected adults With the cut-off of 20 the sensitivity was 60.9%(52.5% to 69.4%), Specificity was 64.7% (61.9% to 67.5%), positive predictive value 16.1% (12.9%to 19.4%), negative predictive value 93.7% (92% to 95.4%) LR +=1.7 and LR-=0.6.

In the present study, pTESS Score ROC Curve gave cutoff 30.5 and pTESS had an area un- der the curve 0.967(95% CI 0.902to 1.000, p value <0.001)Indicating a good predictive value in predicting tubercular empyema had a sensitivity of 90.91% (58.72% to 99.77%) and specificity 96.67 % (82.78%to 99.2%), false positive rate 3.33% (0.08%to 17.22%), false negative rate 9.09%(23%to 41.28%) positive predictive value 90.91% (58.72%to 99.77%), negative predictive value 96.67% (82.78 %to 99.92%), LR+=27.27 LR-=0.09OR-=130.5, Youden Index 0.8.

The number of items in the scoring system was 27 with the scale reliability coefficient Cornbach's Alpha being 0.935 which means items used in the scoring system were reliable with good internal consistency.

The statistically significant variables were cough, TST, History of TB contact, BCG immunization, pleural fluid protein, and ADA.

Statistically insignificant variables were age, Gender toxic symptoms, pus in the ultrasound thorax, Differential cell count total leukocyte count.

5. LIMITATION.

There are some inherent limitations in the current study. One of them is how to define a case of TB without bacteriological confirmation in most cases using clinical and radiological improvement criteria after initiating treatment for TB. In the absence of a gold standard, the present study used improvement after ATT as the gold standard. The difficulty of obtaining metrics for bacteriological confirmation delete drug culture results in the impossibility of adopting a more expensive complex diagnostic method to justify the use of therapeutic response as a criterion for defining TB. One further limitation is related to the fact that the results encountered may be only valid for the population studied. Given the above-mentioned limi-

tations. Long-term follow-up required is required for the validity of the study. We have planned to test the reliability of the score at a community level and this is under study.

6. CONCLUSION.

The efficacy of the pTESS scoring system developed for the diagnosis of presumptive tubercular empyema thoracic patients and assess the diagnostic efficacy of pleural fluid CBNAAT in tubercular Empyema thoracic. Among children aged 1 to 14 years, a total of 41 patients admitted to the inpatient Department of Paediatrics were taken by simple convenient sampling method after satisfying the predefined inclusion and exclusion criteria. The score cut-off was 30.5 and the sensitivity of the scoring system was 90.91%and the specificity was 96.6%, the positive predictive value was 90.91%, and the negative predictive value was 96.67%. Pleural fluid CBNAAT in Tubercular Empyema Thoracis had a sensitivity of 36.36% and a specificity of 96.67%with a positive predictive value of 80% and a negative predictive value of 80.56%.

7. RECOMMENDATION.

Clinical assessment by the pTESS scoring system may be used for the diagnosis of TB Empyema in the pediatric age group.

8. ACKNOWLEDGMENT.

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9. AUTHOR'S CONTRIBUTION.

All authors were involved in research design, data analysis, and manuscript preparation and editing.

10. DISCLOSURE.

The authors report no conflicts of interest in this work.

11. FUNDING.

The study was not funded.

12. ABREVIATIONS:

ADA : Adenosine Deaminase Activity

CBNAAT: Cartridge Based Nucleic Acid Amplification Test

DR TB : Drug Resitant Tuberculosis

EPTB : Extra Pulmonary Tuberculosis

HIV : Human Immunodeficency Virus

TB : Mycobacterium Tuberculosis

MCEE : Maternal and Child Epidemology Estimation

pTESS : Presumptive tubercular empyema thoracis scoring system

RNTCP : Revised National Tuberculosis Control Programme

SAM : Severe Acute Malnutrition

TB : Tuberculosis

TLC : Total Leukocyte Count

TST : Tuberculin Skin Test

TU : Tuberculin Unit

WHO : World Health Organization

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