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Corelation of clinical and radiological parameters with microbiological diagnosis in spinal tuberculosis: A cross sectional study

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Abstract
Background: Tuberculosis is the most common and deadly multisystem disease affecting the developing world. Its incidence and prevalence is on a rise in developing countries. About 10% of pulmonary tuberculosis patients present with extra-skeletal involvement of which spine is most commonly affected. It can cause neural compromise, bone destruction and spinal deformity.
Material and Methods: Our study includes 30 patients with signs and symptoms of potts spine which were evaluated further by a similar protocol of investigations in last 2 years and their demographic data, clinical, radiological and microbiological findings are reported. The clinical parameters taken into consideration were fever, cough, backache and neurological complaints and any positive findings on plain radiographs of relevant spinal region and their relative presence or absence were correlated with confirmatory diagnosis on AFB culture and gene Xpert.
Results: Fever & backache were most common complaints present in 19 (63.3%) of subjects. Neurological complaints were present in 15 (50%) of subjects followed by cough in 9 (30%) of subjects.22 subjects showed some finding suggestive of potts spine on plain radiograph.18 (60%) subjects were positive for MTB on culture from biopsy taken.23 (76.7%) subjects were having gene expert test positive while 7 (23%) subjects were having negative gene expert test. Total 7 out of 30 subjects had multi drug resistance (MDR) out of which 1 subject was HIV + ve while 6 were HIV –ve.2 subjects had already started the empirical ATT regimen from the peripheral centres.
Conclusion: Spinal tuberculosis is still prevelant in large numbers in developing countries which remains largely undetected in most of the health centres. Our study aims to find out the role of various common clinical symptoms individually as well as combined with radiological studies as screening tests in clinical detection of spinal tuberculosis and thus faster management in its direction.

Keywords: Potts spine, gene xpert, culture, fever, backache

Introduction
India has maximum burden of tuberculosis in the world [6], in 2016, there were an estimated 9.6 million incident cases of TB (range 9.1-10million) globally, equivalent to 133 cases per 100000 population [3]. The estimate in India was 2.2% for new MDR-TB cases and 15% for previously treated cases with MDR-TB [4]. Skeletal involvement occurs in approximately 10% of all patients with extra-pulmonary TB with spinal involvement being most common [1, 2, 6]. The number of cases detected are on rise [6]. Increasing use of molecular diagnostics to detect MDR-TB, their growing importance in detection of TB patients with MDR-TB and effective data surveillance are reasons for detection of MDR-TB. Drug sensitivity reporting (DST) for TB spondylitis is not routinely undertaken in resource-limited countries, generally patients are treated with a standardized or empiric regimen, without the assessment of drug susceptibility [6]. This standard of care may potentially miss drug resistance and lead to delay in diagnosis of drug resistance if any and initiation of proper treatment [6]. As there is limited availability of culture methods and gene xpert at the peripheral centres, we propose to incorporate the common clinical symptoms of spinal tuberculosis as screening tests in its early diagnostic protocol and thus, their presence or absence can indicate the chances of spinal tuberculosis in any suspect leading to early recognition and initiation of proper management including either

referral to tertiary care centre or drug therapy initiation at any nearby RNTCP centre.

We therefore propose to study the correlation of common clinical symptoms in any suspect with final diagnosis as confirmed on gold standard microbiological studies.

Methodology

Ethics approval

An observational cross-sectional study conducted at a tertiary care centre of B. J. Medical College and Sassoon Hospital, Pune and approved by the regional ethical committee. Reference no-BJGMC/IEC/PHARMAC/ D-0617100-100 dt-06/06/2017.

Objectives

1. To find out the frequency of clinical symptoms like fever, cough, backache, neurological symptoms, etc in suspected patients of spinal tuberculosis.
2. To assess the sensitivity and specificity of these symptoms individually as well as combined in early diagnosis of spinal TB with respect to its confirmation on bacteriological culture.
3. To assess the sensitivity and specificity of Gene Xpert in bacteriological diagnosis of spinal TB.
4. To assess the role of plain radiography in diagnosing spinal TB.
5. To formulate a new screening protocol for diagnosing spinal TB at peripheral centres.

Inclusion Criteria

a) All consented patients presenting to orthopaedicsopd or referred from other specialties with clinical or radiologically suspected or proven spinal tuberculosis.
b) All microbiologically proven spinal tuberculosis patients requiring surgical decompression or needle biopsy.
c) Males and females of age groups above 10 years.

Exclusion Criteria

a) Spinal tuberculosis patientsless than 10 years of age.
b) Mentally challenged patients who are not eligible to give consent.
c) Patients not willing to give consent.
d) Spinal TB patients whose obtained sample is inadequate for above mentioned tests.
e) Patients whose sample is negative for all investigations included in this study or is diagnosed with any other spinal infection.

Risk factors

Only risks involved with biopsy procedures such as excessive and persistent pain, bleeding, nerve injury, secondary infection at biopsy site, etc.

Study protocol

This was an observational cross-sectional study where new patients with suspected spinal TB were enrolled.

Study parameters

The association of different clinical symptoms like fever, cough, backache, neurological symptoms(including tingling, numbness, motor and sensory loss, bowel/bladder dysfunction, clonus, visible spinal deformity, etc) combined with radiological features (including rarefaction of the vertebral end plates, loss of disk height, osseous destruction, new-bone formation and soft-tissue abscess, multiple vertebral involvement, fusion or collapse of vertebra, etc) [1] with final diagnosis of spinal tuberculosis on microbiological culture were analyzed after collecting all data by using appropriate statistical methods. The study sample was also subjected to gene Xpert and the results were compared to culture results to assess better diagnostic method from both of them.

Study protocol and intervention

The study pertained to 30 patients encountered during a two year period from 2016 to 2018. The study was based on detailed history, general and orthopaedic examination and radiological assessment of suspected patients.

In every patient, detailed history was sought about the onset, duration and progress of symptoms followed by thorough neurological examination and radiological investigations carried out to diagnose the cause. Once the radiological diagnosis has been made out, biopsy of the lesion was done and sample/pus extracted from the lesion through one of the following methods-

1. Open biopsy
2. CT guided biopsy
3. USG guided aspiration

After the sample has been extracted, it was sent for the following investigations-

1. Gram stain and culture sensitivity
2. AFB staining and culture
3. Gene Xpert
4. Histo-pathological examination

After all of the above procedure has been completed, patient profile was updated on a printed case record form with written informed consent from patient and relatives. Consent was explained to the patient and relatives in language understood to them. (Consent form in English and Marathi languages are attached in annexures). After confirmation or exclusion of spinal TB on microbiological culture (Gold Standard) [5], presence of the above mentioned clinical symptoms were correlated with the final diagnosis. The positivity or negativity of Gene Xpert was also correlated with culture findings.

Statistics

This was an observational cross-sectional study. Graphical representations were done whenever possible. Appropriate statistical formulae and methods like Chi- square test etc were applied to the collected data at the end of the study. P-value <0.05 was considered as significant.

Results

The various parameters of the patients affected and outcomes of investigations were studied in detail and following results were obtained.

Symptoms

Bar diagram showing frequency of symptoms in potts spine patients.

Fever & backache were most common complaints & present in 19 (63.3%) of subjects. Neurological complaint were present in 15 (50%) of subjects followed by cough in 9 (30%) of subjects.

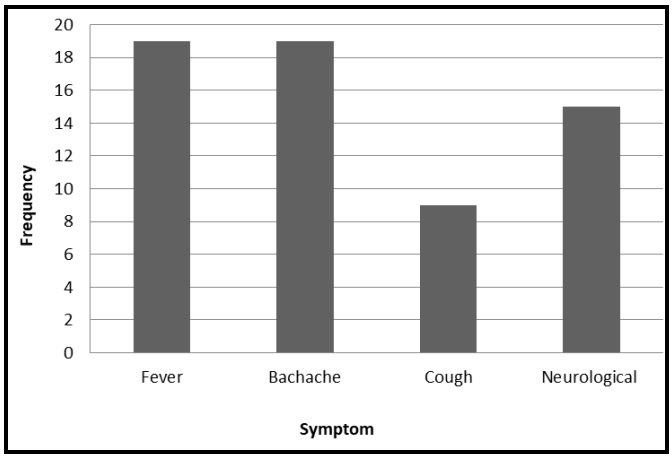


Fig 1: Symptoms among study sample

Radiology Results

22 out of 30 subjects showed one or more of the above mentioned positive radiological feature on plain radiolgraphs.

Microscopy and Culture Results

AFB was present in 16 (53%) subjects on microscopy while 18 (60%) subjects were positive for MTB on culture from biopsy taken.

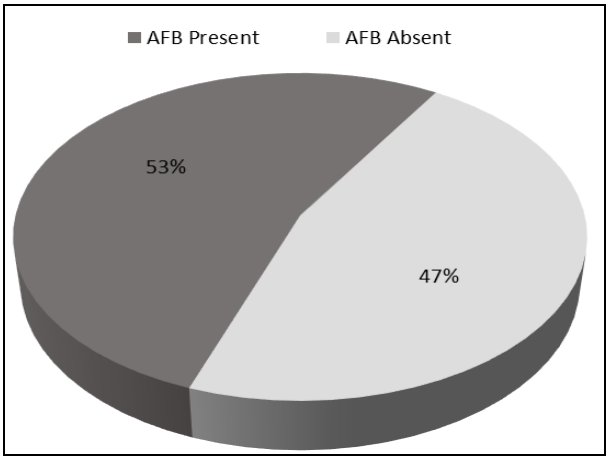


Fig 2: Microscopy

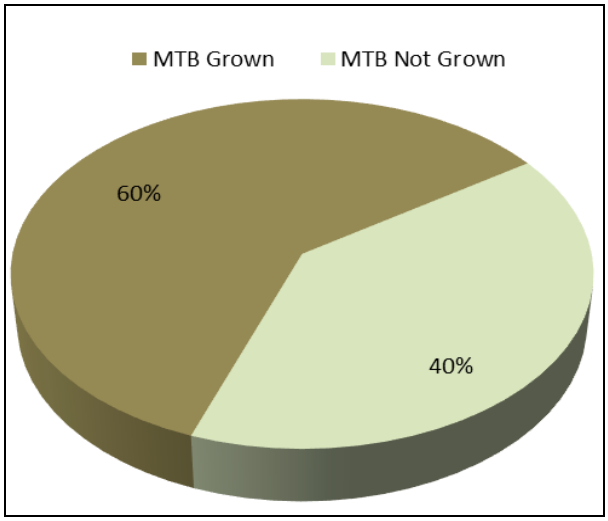


Fig 3: Culture

Gene Xpert Results

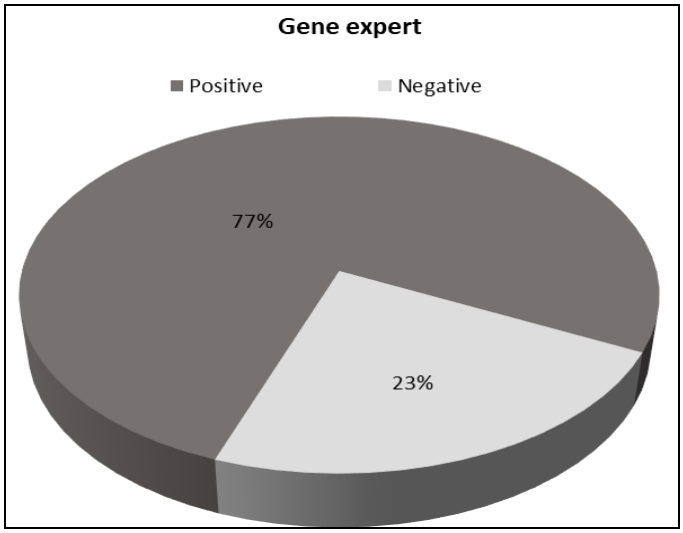


Fig 4: Pie chart showing gene expert test result among study samples

23 (76.7%) subjects were having gene expert test positive while 7 (23%) subjects were having negative gene expert test.

Discussion

Our study was unique in a way that it proves the usefulness of clinical symptoms of spinal tuberculosis for its screening and thus it can be used to predict the presence of spinal TB in peripheral centres where there is unavailability of radiological or microbiological tests and thus appropriate empirical therapy can be started on a presumptive basis.

The only radiological parameter included in our study was plain radiograph of the concerned spinal region. The other investigations such as Computed Tomography scan, Magnetic Resonance Imaging, PET scan are not included in the study due to their relative unavailability, time consuming procedure and high cost.

In our study, 18 out of 30 suspected subjects showed positive culture reports and AFB culture being considered the GOLD standard for Mycobacterium tuberculosis [5] are taken to be having spinal tuberculosis. Out of the 18 affected patients, 15 patients presented with fever and backache and rest 3 were not having these symptoms. The 12 subjects negative on culture studies were considered to be unaffected. Out of these 12 subjects, 4 subjects also presented with fever and backache. Thus fever and backache cannot be considered as diagnostic for spinal TB bt their sensitivity of 83.33% and specificity of 66.66% ensures them to be considered as useful screening signs for spinal TB. Their precision in screening spinal TB is around 79%. Cough also has a sensitivity of 70% and specificity of 83.66% but has a true positive rate of around 40%, so cannot be considered reliable in screening spinal TB. On the other side, neurological complaints mentioned before in absence of any trauma to back gives a sensitivity of 60%, specificity of 66.66% and precision of 70%. Thus, it can be considered from this study that fever and backache are the most common presenting complaints in suspects of spinal TB and can be considered for its screening more reliably than cough and neurological symptoms.

Other important parameter, the radiology was positive in 22 out of 30 subjects. Out of the 22, 18 were positive for culture

study and all 22 showed positive gene Xpert tests. Thus when compared to the gold standard culture study, radiology has a sensitivity of 100% and specificity of 67% with a precision rate of 82%. Thus radiographs alone can be considered as a very useful and productive screening test in diagnosing spinal TB.

The results obtained on combining the above parameters were amazing. On combining parameters of fever, backache and radiographs, sensitivity was 92%, specificity was 67% and precision was 80%. Thus a combination of fever + backache + radiographs can be proposed as a primary screening method in peripheral centres and TB endemic areas with a high incidence of pulmonary as well as extra-pulmonary TB thus leading to reduction in cost of investigation and early treatment initiation with anti-tubercular regimens (ATT).

Another important aspect of our study was the role of Gene Xpert in spinal TB either in addition or as a substitute to culture. Gene Xpert works on the principle of polymerase chain reaction and can detect the bacteria within 2 days as compared to culture which takes around 8 weeks for growth. In addition to time sparing factor, it has a sensitivity of 100%, specificity of 58% and precision of 78%. Though it has a high false positive rate of 41%, it can be considered as a reliable substitute to culture studies thus saving the time to treatment initiation for confirmed cases. Only disadvantage is high cost and limited availability at most of the diagnostic centres. Gene Xpert was positive in the 2 subjects who were already on ATT regimen, as gene Xpert can detect dead bacilli which culture method fails to detect. This special feature of gene Xpertmakes it more useful than culture. This is the reason behind the high false positive rate of gene Xpert as compared to culture which should be included in the false negative rate of culture. Therefore gene Xpert can be considered superior to culture in view of following reasons-

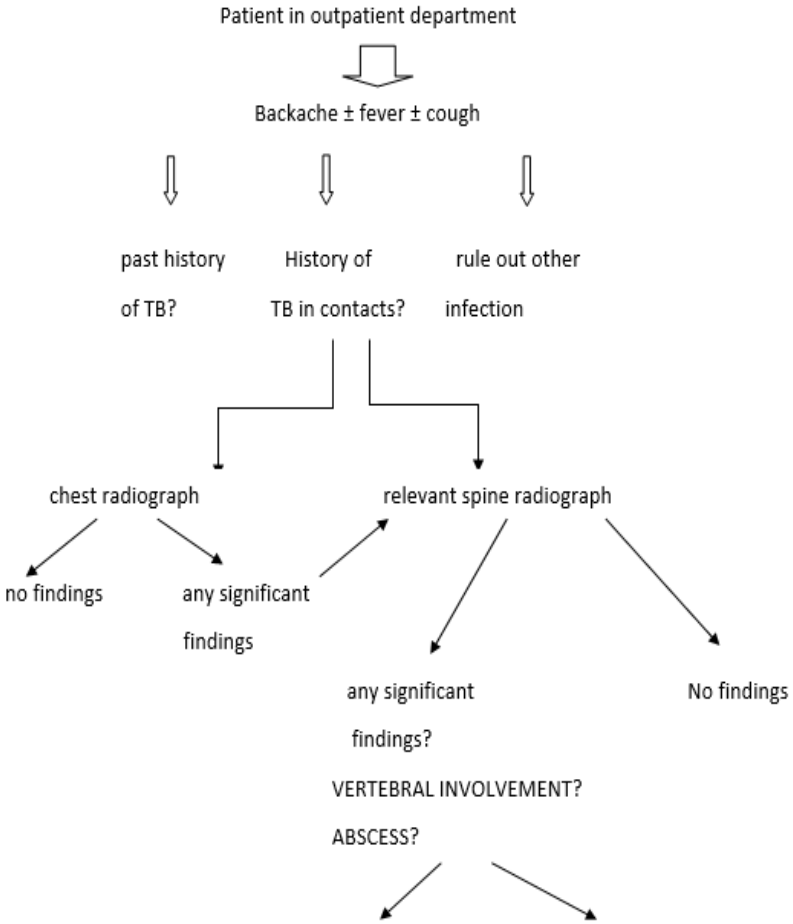
1. Rapid
2. Ability to detect dead bacilli
3. Reliable even after initiation of ATT
4. Ability to detect as few as 10–50 tubercle bacilli in various clinical samples [1]

Gene Xpert when combined with the primary screening method of fever + backache + radiography produces a sensitivity of 96%, specificity of 64% and precision of 75%. Thus it won't be incorrect to say this combination is able to diagnose 96% of suspected spinal TB patients and confirm the diagnosis based on which empirical ATT can be started.

Conclusion

Our study concludes that Gene Xpert can be reliably considered as a substitute for the time-consuming GOLD standard microbiological culture and we propose it to be used it as a FIRST-LINE investigation in the diagnosis of spinal tuberculosis. Our study also concludes that fever and backache to be considered as reliable screening symptoms of spinal TB and any patient presenting with combination of these two symptoms should be evaluated radiologically and microbiologically for spinal TB. We also propose to initiate ATT as soon as possible in patients suspected of spinal TB if they present with fever, backache and show positive radiography and spinal TB to be confirmed if positive on Gene Xpert. A suspected patient would be definitely benefitted if ATT started on the basis of our protocol instead of waiting for the final results of time consuming AFB culture.

Based on our study, an easy and important flowchart has been derived for quicker management of suspected potts spine patients visiting out patient department.



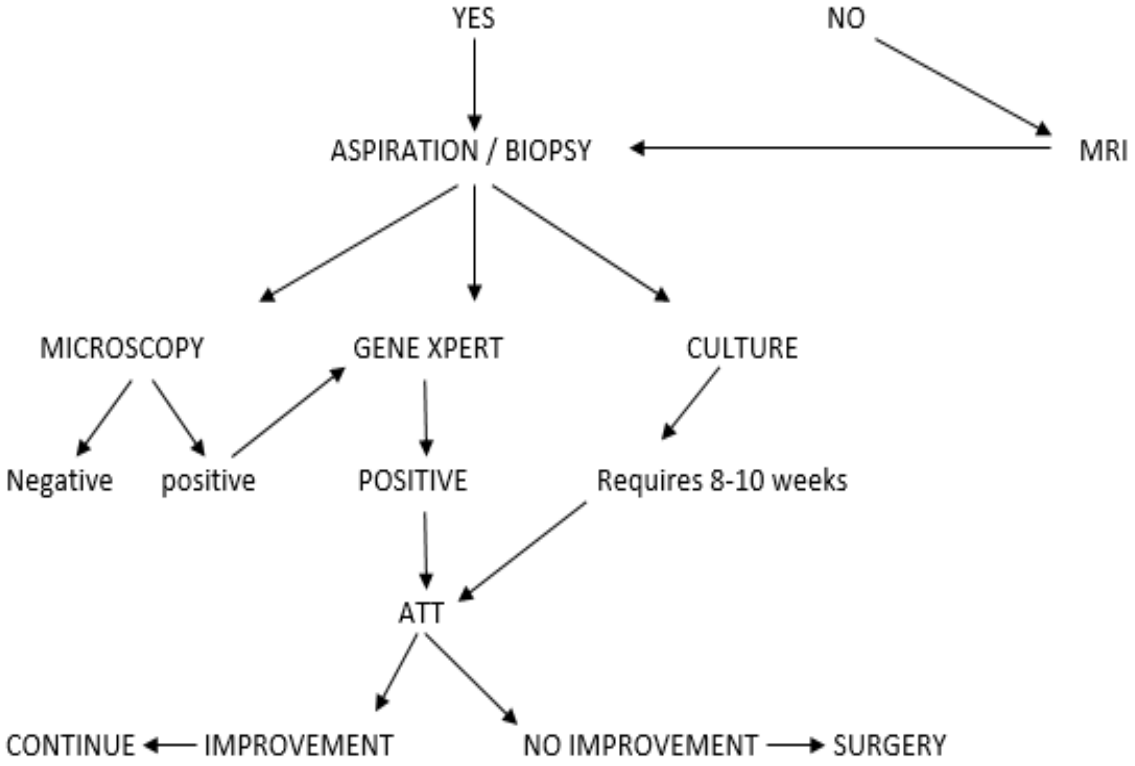


Fig 5: Flowchart for quicker management of suspected spinal tuberculosis.

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