ORIGINAL ARTICLE

THE ROLE OF IMAGE GUIDED BIOPSY IN SUSPECTED TUBERCULOSIS OF SPINE

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ABSTRACT

Introduction: India accounts for 25% of the total global TB burden, and a third of the "missing cases" that do not get diagnosed or notified. When health professional in India think of TB, they often order non-specific tests while TB can only be confirmed by microbiological tests such as sputum smear microscopy, Gene Xpert, and cultures. This study was conducted to study the role of image guided biopsy in all suspected Tuberculosis Spine cases, in terms of establishing diagnosis and to study the sensitivity and specificity of diagnostic procedures (biopsy as well as culture methods). Also, the researchers compared the available investigations results of CBNAAT, BACTEC, HPE & AFB Stain.

Methodology: The present study was conducted at the Department of Orthopaedics of our institute. It was a prospective study carried out from January 2015 to June 2016. 53 patients presented to us were suspected spinal tuberculosis on Clinico- radiological ground and were posted for bone biopsy.

Results: In our study, mean age of the patients is 42.5 ± 14.3 (Range 14-73 years). Out of 53, 34 patients (64.15 %) were male and 19 (35.85 %) were female. Patients have usually presented in early destructive stage of the disease (Type 2) (30/53). We have used USG guided aspiration (04/53), CT guided biopsy (22.64%) and in majority of cases IITV guided biopsy (37/53). 4 of 53 cases were excluded, as they were inconclusive due to inadequate sample obtained during biopsy. Diagnosis was established in 38 out of 53 patients (70.71%). Sensitivity and specificity of Z-N stain were 42.1%, and 90.9%, of HPE were 81.5% and 90.9%; of BACTEC were 89.4% and 100% respectively.

Conclusion: In the present study, it is observed that no single diagnostic modality is having a good negative predictive value. Hence, a combination of diagnostic battery is required for precise diagnosis and better results. The result of BACTEC culture and CBNAAT has detected a maximum of 38 cases. While the result of Z-N microscopy and histopathology has detected small number of cases. As culture takes long incubation time for results, the CBNAAT can be applied for rapid detection of Pott's disease.

Keywords: Tuberculosis, Spine, Image guided biopsy, BACTEC, CBNAAT.

INTRODUCTION

Tuberculosis (TB) remains a major public health concern with an estimated 8.8 million new cases and 1.3 million deaths reported in 2012 globally¹. India accounts for 25% of total global TB burden, and a third of the "missing cases" that do not get diagnosed or notified.¹

Although reliable data from India are lacking, it is expected that 15-20% of all TB is extra-pulmonary. Clinical presentations of extra-pulmonary TB (EPTB) may be diverse, leading to missed cases and delayed diagnoses. ISTC recommends that all patients, including children, who are suspected of having EPTB, should have appropriate specimens ob-

tained from the suspected sites of involvement for microbiological and histological exam. ²The ISTC emphasizes the importance of seeking microbiological and histopathological diagnosis of EPTB, and underscores the critical need for collecting appropriate samples.

The Xpert MTB/RIF assay allows for rapid detection of MTB DNA along with confirmation of rifampicin resistance using rpoB gene mutation testing. It is automated, very easy to use and produces results within 2hours. The Xpert MTB/RIF has an overall sensitivity of 88% and pooled specificity of 98%, as compared to cultureXpert MTB/RIF, when used as an initial test replacing phenotyping

drug susceptibility testing, detect 95% of rifampicinresistant TB cases with specificity of 98%.³

Thus, Xpert MTB/RIF is now considered a central test in the work-up of EPTB, and should be used along with existing tools such as microscopy, liquid cultures (which are the most sensitive technologies for MTB detection), along with histopathology (biopsy) to arrive at the final diagnosis.

When health professional in India think of TB, they often order non-specific tests such as total and differential blood counts (TC/DC), erythrocyte sedimentation rate (ESR), and chest X-ray. 4.5 While these tests can be helpful, they do not confirm tuberculosis. Abnormal X-rays, for example, do suggest TB, but other lung conditions can also produce abnormalities on radiography. So, only relying on chest X-ray can result in over-diagnosis. Tuberculosis can only be confirmed by microbiological tests such as sputum smear microscopy, GeneXpert, and cultures.

This study was conducted to study the role of image guided biopsy in all suspected Tuberculosis Spine cases, in terms of establishing diagnosis and to study the sensitivity and specificity of diagnostic procedures (biopsy as well as culture methods). Also, the researchers compared the available investigations results of CBNAAT, BACTEC, HPE & AFB Stain.

METHODOLOGY

The present study was conducted at the Department of Orthopaedics of our institute. It was a prospective study carried out from January 2015 to June 2016. All the suspected spinal tuberculosis patients on Clinico- radiological ground came to the Department of Orthopaedics in our institution, during the study period posted for bone biopsy. 53 cases presented to us during the study period were included in the study. We used clinico-radiological classification (Kumar 1988) for selection of thepatients.

Inclusion criteria: Clinico-radiologically suspected cases of tuberculosis of spine who are clinico - radiologically not responding to AKT were included in the study.

Exclusion criteria: Patient who are clinicoradiologically improving on AKT or not willing to participate in the study were exclded.

Surgical procedure: We performed Percutaneous vertebral biopsy via transpedicular route. As per our preference, we used USG guided method, wherever lesions were amenable to USG. We performed 4/53 USG guided biopsy. Rest of the cases were done



A1. USG guided 16 G needle placed in abscess cavity.

A2. Psoas abscess aspirate content in 03 sterile containers

Figure 1: USG guided biopsy with pus collected in 03 sterile containers.

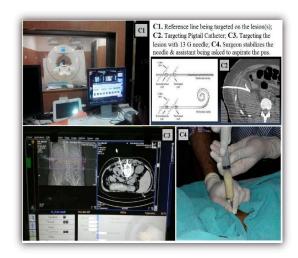


Figure 2: C1, C2, C3 & C4: CT guided biopsy procedure.

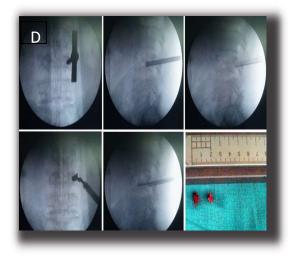


Figure 3: D1 & D2: Transpedicular biopsy (L4) (IITV Images) & obtained sample.

under image guided (28/53) or CT guide (11/53) as per the site and size of the lesion(s). Exceptionally only in 2 cases, we performed open biopsy where image guided biopsy was not successful, C5-C6 intra and paradiscal lesion and L4 medial pedicular lesion with paradiscal spread.

All suspected TB spine patients had undergone thorough clinical evaluation followed by radiological imaging as per the protocol. Imaging include x ray of local region of spine, USG-abdomen & pelvis and MRI of the regional spine with screening of whole spine for the assessment of the skiplesion. USG is preferred method whenever the lesion, especially pus is amenable to aspirate under USG guidance. Whenever lesion is intra- discal, para- discal or posterior to the dorso-lumbar fascia, image guided biopsy was done either IITV guided/CT guided. Image guided biopsy was done either transpedicular or through safe zone of kambin's triangle. Sample was collected in sterile container for Gram stain, Z – N stain, Aerobic & Anaerobic culture, Histopathology examination of biopsy material, CBNAAT and BACTEC, and was divided in 3 different samples:

- Gram stain and Z N stain, Aerobic and Anaerobic culture. (Sample1)
- Biopsy material for histopathological examination. (Sample2)
- MRTB for CBNAAT and BACTEC. (Sample3)

Post Biopsy protocol: Anti -TB treatment was started on the day of biopsy in all patients and specific treatment of non tubercular patients according to culture/sensitivity report.

RESULTS

In our study, more than 50 % of the cases (56.60%) presented in early destructive stage of the disease. In our study, we preferred to use USG guided aspiration for amenable lesions with adequate amount of pus to aspirate (preferably >10 ml). As most of the cases presented in pre or early destructive stage, we have used IITV guided biopsy in majority of our cases (69.81%). Only those cases where USG & IITV could not get the biopsy, we have used CT scan (22.64%) as last option.

In our study out of 53 patients, we found positive result in 23 patients and negative result in 14 patients rest of the 16 cases were non conclusive.

In our study out of 53 patients, we found positive result in 34 patients and negative result in 15 patients rest of the 04 cases were non conclusive.

Table 1: Clinico-Radiological Type-wise analysis of study population (n=53)

Radiological Type	No. (%)
Type 1 (Pre destructive)	14 (26.42)
Type 2 (Early destructive)	30 (56.60)
Type 3 (Mild angular kyphosis)	08 (15.09)
Type 4 (Moderate angular kyphosis)	01 (1.89)

Table 2: Modality-wise distribution of study population (n=53)

Modality	No. (%)
IITV guided	37 (69.81)
USG guided	04 (7.55)
CT guided	12 (22.64)

Table 3: Histopathological examination of study population (n=53)

HPE Result	No. (%)
Positive	32 (60.38)
Negative	17 (32.08)
Non conclusive	04 (7.55)

Table 4: Statistical Analysis for HPE

HPE	CBNAAT detection		Total
	Yes	No	
Yes	31	01	17
No	07	10	32
Total	38	11	49

P-Value < 0.000

Sensitivity = 81.5%, Specificity = 90.9%, PPV = 96.8%, NPV = 58.8%, Accuracy = 63.3%, Falsenegative = 18.42%, False-positive = 9.09%

Table 5: AFB Culture (BACTEC) analysis of study population (n=53)

AFB Culture (BACTEC)	No. (%)
Negative for TB (No)	15 (28.30)
Non Conclusive	04 (7.55)
Positive for TB (Yes)	34 (64.15)

Table 6: Statistical Analysis for BACTEC:

BACTEC	CBNAAT detection		Total
	Yes	No	
Yes	34	00	34
No	04	11	15
Total	38	11	49

P-Value = 0.000

Sensitivity = 89.4%, Specificity = 100%, PPV = 100%, NPV = 73.3%, Accuracy = 69.38%, False-negative = 10.52%, False-positive = 0%

DISCUSSION

The first large series of spine biopsies (1061) was reported by Ottolenghi in 1955 ⁶. Such early reports described various methods of blind insertion of the

needle. However, the introduction of the fluoros-copy-guided biopsy made such techniques obsolete in almost a decade.⁷

Stoker DJ et al(1985) reviewed 135 cases of percutaneous vertebral biopsy and concluded that percutaneous biopsy has a low morbidity and offers considerable advantages over open surgicalbiopsy.⁸

Renfrew DL et al (1991) did study on "CT-guided percutaneous transpedicular biopsy of the spine." and concluded that transpedicular approach be used when the location of the lesion does not allow easy access by means of the posterolateralapproach.⁹

Babu NV et al (1994) did study on "Computed tomographically guided biopsy of the spine." And concluded that Computed tomographically guided biopsy of the spine is recommended as a procedure of choice, especially in cervical and thoracic lesions. Computed tomography is superior to fluoroscopy when dealing with small, deep seated lesions especially in the cervical and thoracic regions and with lesions picked up on bone scan only, radiographs being negative. Needle biopsy under computed tomographic guidance is safe and precise. 10

Kang M et al (1999) did study on "CT-guided fine needle aspiration biopsy of spinal lesions" and concluded that CT-guided FNAB is a safe and effective technique for the evaluation of spinal lesions and is helpful in planning therapy.¹¹

Wen-Ching Hsu et al (2001) did study on "Computed Tomography-guided Percutaneous Transpedicular Biopsy of the Thoracic Spine." for 3-year period from May 1996 to May 1999, on 9 patients and concluded that CT-guided Transpedicular trephine biopsy of the thoracic spine is a safe and effective method for preoperative evaluation of various thoracic spinal disorders.¹²

Alothman A et al (2001) did analysis of 69 patients between 1985 and 1998, diagnosed as tuberculous spondylitis and concluded that both computed tomography and magnetic resonance imaging are extremely helpful for diagnosis, and tissue aspirate is a good confirmatory method.¹³

Hadjipavlou AG et al (2003) did study on "Effectiveness and pitfalls of percutaneous transpedicular biopsy of the spine" and concluded that the percutaneous transpedicular approach for biopsy is safe, efficacious, and cost-effective.¹⁴

WCG Peh et al(2006) did study on "CT-guided percutaneous biopsy of spinal lesions" and concluded that CT-guided percutaneous biopsy has a useful role in the diagnosis and the management of patients with spinal lesions.¹⁵

Dave BR et al(2009) did study on "Transpedicular percutaneous biopsy of vertebral body lesions: a se-

ries of 71 cases" showed The pathologic examinations revealed infections in 25, osteoporotic wedging in 21, metastasis in eight, plasmacytoma in three, multiple myeloma in four, nonHodgkin's lymphoma in one and round cell tumor in one patient. Diagnosis was established in 63 of 71 patients (88.7%). Remaining eight patients were reported as chronic nonspecific inflammation, and were followed up for more than 6 months. 16

Pradesh Kumar et al (2010) did study on "Percutaneous biopsy in suspected infective discitis" and concluded that Image-guided percutaneous biopsy is a safe and well-tolerated procedure that has a useful role in the diagnosis of infective discitis.¹⁷

Sadik I Shaikh et al did a study on "An analysis of clinico- radiological and histopathological correlation in tuberculosis of spine" over 5 years of period, showed One hundred sixty-six cases were histologically proved as tuberculosis and 74 proved to be nontuberculous lesions. He recommended that all vertebral lesions suspected to be of tuberculous origin not responding to empirical antituberculosis therapy should have a definitive histopathological diagnosis and radiological investigation to facilitate appropriatetreatment.¹⁸

Syed Imran Bukhari studied "Efficacy of Percutaneous Transpedicular Needle Biopsy in Vertebral Pathologies under Fluoroscopic Guidance" and positive diagnosis was obtained in 38 out of 55(69.1%) patients. The result was negative in 17(30.9%) patients. Out of 38 positive results, 28(50.9%) were of Tumor/Mets, 8(14.5%) of Infection, 2(3.6%) of Osteoporosis, and concluded that image-guided Percutaneous Transpedicular needle biopsy is 69.1% effective and safe. 19

Basu S et al (2015) did study on "percutaneous C-arm- guided wide bore needle biopsy for intraosseous spinal lesions" and concluded that percutaneous biopsy under fluoroscopic guidance by transpedicular approach is quite safe and gives high adequacy (88.4%) without significant complications associated with open and paraspinal techniques.²⁰

Joo EJ et al (2016) did retrospective cohort study of patients who received CT-guided bone biopsy at a tertiary hospital over the 13 years and concluded that results obtained by CT-guided bone biopsy contributed to prompt diagnoses of spinal infections, especially those caused by tuberculosis.²¹

Manoj Kumar et al (2014) studied the efficacy of diagnostic battery in Pott's disease. In his study, Out of 62 cases, 7 were excluded as these were turned out to be neoplastic lesions on histopathology. Amongst remaining 55 cases, the TB was diagnosed in 39 (71%) on histopathology, 37 (67.5%) on PCR, 27 (49%) on BACTEC culture and 20 (36.3%) on ZN microscopy. He concluded that the

combination of PCR and histopathology is a rapid and efficient tool for diagnosis of Pott's disease.²²

Pott's disease, accounts for 02% of all TB infections. The diagnosis of Pott's disease is principally based on classical clinical manifestations of spinal infection supplemented by modern imaging like CT and MRI. The CT and MRI in particular can detect the subtle changes in the spine, from initial changes in the intensity pattern of the vertebrae to the extreme changes like deformity of the spine including soft tissue shadow, granulation tissue and pus etc. However, various pathologies including neoplastic, non tubercular infections and other inflammatory conditions simulate with Pott's diseases on imaging.

Our study found that Dorso-Lumbar region (66.03%) being most common for suspected pott's spine. Similar results were found in several studies. ^{13,16} In these studies, we can see either Lower Dorsal or Upper Lumbar region affected the most.

Patients have usually presented in early destructive (Type 2: Early destructive (30/53), which accounts for 56.60%. Amongst the available imaging modalities, we preferred to use USG guided aspiration for amenable lesions with adequate amount of pus to aspirate (preferably >10 ml). As most of the cases presented in early destructive stage (Type II), we have used IITV guided biopsy (37/53) in majority of our cases (69.81%). Only those cases where USG & IITV could not get the biopsy, we have used CT scan guided biopsy (22.64%).

The current study excluded 04 of 53 cases, as they were inconclusive due to inadequate sample obtained during biopsy. Those all patients were offered re-biopsy but they didn't gave consent and finally lost to follow up. The remaining 49 cases, 17 (32.08%) were tested positive with ZN microscopy, 34 (64.15%) with BACTEC culture and 38 (70.71%) with CBNAAT. An earlier report by Manoj Kumar et al ²², found 36.3% positivity on ZN microscopy and 49% positivity on BACTEC culture in cases of spinal TB.

In present study, diagnosis was established in 38 out of 53 patients (70.71 %). This is similar to the results of various other studies, thus affirming the utility of diagnostic tests utilized.^{8,14,16,19}

In our study the ZN microscopy revealed lower and BACTEC culture reports revealed higher positivity in relation to the earlier published series. Our higher detection rate was because of the fact that we used the liquid culture medium BACTEC 12B medium. It is the rapid, sensitive and efficient method for the isolation of Mycobacterium in a clinical laboratory as compared to solid medium Lowenstein–Jensen. Moreover, it is established today that all the traditional tests need to have a minimum concentration of bacilli for yielding positive results as mentioned

in the introduction. Hence, if the specimens, naturally having more concentration of bacilli, like sputum and pus it may become easy to detect M. tuberculosis. Similarly, in our study the pus specimens had higher recognition of tubercular bacilli on ZN microscopy and BACTEC culture methods.

The histopathological findings are much more reliable in the diagnosis of EPTB. The study quoted the detection rate of EPTB including Pott's spine varying from 53% to 81%. The histopathological diagnosis could be reached in 62.38% (32 out of 53) of the cases which were strongly suggestive of tubercular pathology. In our series, we found 17 (32.08%) cases were negative on histology, among these negative cases, 07 (41.17%) cases were identified as tubercular on CBNAAT. In our study, 15 cases were negative on BACTEC, among these negative cases 04 (26.66%) were identified as tubercular on CBNAAT. In our study, 08 out of 53 cases had been under anti tubercular therapy for more than 03 months, in those cases 3 were non tubercular (Pyogenic), 2 cases were drug resistant tuberculosis, 1 case was sinus histiocytosis (Rosai – dorfman disease) and 2 cases were delayed responders to AKT due to immune-compromised state (HIV -TBco-infection). In an attempt to increase diagnostic precision, we performed CBNAAT, which was detected in 38/53 (71.70%) cases.

The limitation of our study is a low positive correlation of CBNAAT with histopathological findings. This can be explained up to some extent by the specimen variation as that is different specimens (such as pus, tissue) from the same subjects. Surgeons prefer to send tissue specimens for histology and pus for ZN microscopy (AFB stain), BACTEC culture and CBNAAT. In this study histology was done on tissue specimens (all 53 cases), while ZN microscopy, BACTEC culture and CBNAAT were done in pus and tissue specimens. In our diagnostic battery, all performed traditional tests were diagnosed 38/53 cases and CBNAAT was alone detected 38/53 cases. Thus, positive results of CBNAAT with the Clinico-radiological assumption it would be possible to make a decision in suspected Pott's disease to start early treatment to prevent irreversible complications.

In this study, it is observed that no single diagnostic modality is having a good negative predictive value. Hence, a combination of diagnostic battery is required for precise diagnosis and better results. The result of BACTEC culture and CBNAAT has detected a maximum of 38 cases. While the result of Z-N microscopy and histopathology has detected small number of cases. As culture takes long incubation time for results, the CBNAAT can be applied for rapid detection of Pott's disease to initiate anti-TB treatment on same day.

To conclude, for diagnosis of Pott's disease, the combined results of ZN microscopy, histopathology, BACTEC culture and CBNAAT are most appropriate. However, for rapid diagnosis CBNAAT offer a better prospect.

In all of 53 cases, we found no complications. In our study, 38/49 cases diagnosed as tubercular. In non tubercular pathologies, we found various organism like Staphylococcus Aureus (02), Salmonella Typhi (01), Escherichia Coli (01) and Pseudomonas Aeruginosa (01).

In all the vertebral biopsy we found lesion ranging from neoplasic to bacterial infection all of these were found in cases we suspected to be tubercular on basis of clinical and radiological ground. Over all vertebral biopsy was found to be contributory to the final diagnosis of spinal TB (38/53) in suspected spinal tuberculosis, as well as biopsy could prevent missed diagnosis of spinal tuberculosis in (11/53) (20.75%).

Whenever we start empirical anti TB treatment in suspected Pott's cases, we unnecessarily make burden to the patients in terms of longer duration of treatment, which further low down the immunity and that ultimately may lead to emergence of MDR or XDR cases. Although further validation with a larger sample size is recommend.

CONCLUSION

As per our observations in the present study, we can conclude that image guided transpedicular biopsy is rapid, safe, inexpensive, effective, least invasive and easy to handle procedure with calculated amount of risks involved for the patient and should be the protocol in each & every case of backache with high suspicious of TB for endemic area like India for early diagnosis and guiding appropriate treatment.

For diagnosis of suspicious TB spine, the combined results of Z-N microscopy, BACTEC culture and histopathology are most appropriate. However, for rapid diagnosis CBNAAT (Xpert MTB/RIF) offer a better prospect after Transpedicular biopsy.

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