

# Evaluation of Investigations Suitable to Stop Treatment in Spinal Tuberculosis

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## Abstract

Spinal tuberculosis is the most common extra pulmonary manifestation of tuberculosis and accounts for half of the cases of skeletal tuberculosis and 2 % of all tuberculosis cases. The prevalence of spinal tuberculosis is widespread in an endemic country like India where many people live under poor socioeconomic demographics. It is still a major cause of morbidity and economic loss as it generally affects the productive age groups and the deformities of spinal tuberculosis can have long-lasting effects on the affected population. Detection of drug-resistant strains is another worrying factor that contributes to the reemergence of spinal tuberculosis as a major cause of concern as it can lead to prolonged treatment and failure if not properly addressed on time. There is no proper gold standard investigation to reliably detect the endpoint of treatment in spinal tuberculosis and there is a lack of consensus regarding the exact duration of antitubercular therapy. This remains a grey area even today. This review article aims to look into some of the investigations that can help determine the endpoint of treatment with a special focus on Magnetic resonance imaging (MRI) and Positron emission tomography scan (MRI PET scan).

**Keywords:** Spinal tuberculosis, MRI scan, PET scan

## Introduction

Tuberculosis is a disease widely prevalent in India where many people live under very poor socioeconomic demographics. Spinal tuberculosis is the most common extrapulmonary manifestation of tuberculosis and accounts for approximately 15% of all cases and almost half of the skeletal tuberculosis [1]. Early diagnosis and initiation of treatment of spinal tuberculosis can prevent spinal deformity and neurological deficit [2].

The current treatment modality for Spinal tuberculosis in India is as per Index TB guidelines for extrapulmonary tuberculosis [3]. The guidelines state that ATT can be started in a patient empirically with a strong suspicion of spinal tuberculosis clinically and radiologically in an endemic country like India and monitor their progress. However, it also states that whenever possible a biopsy of the lesion should be done to

confirm the diagnosis through culture, rule out other differentials and drug sensitivity testing can also be carried out in suspected cases of drug resistance. The exact clinical or radiological criteria for diagnosis of spinal tuberculosis have not been mentioned clearly and even the biopsy for culture may not yield results as spinal tuberculosis is a paucibacillary and deep seated disease. Hence, the guidelines are not well defined for the start or endpoint of treatment. Many grey areas still exist in the field of spinal tuberculosis with the onus falling on the experience and clinical judgment of the treating doctor.

The various investigation modalities include plain x rays of the spine and chest, CT scans or CT guided biopsy, MRI of the Spine and nuclear imaging. Plain radiographs are usually the first line of investigations for a clinically suspected case [4]. However, it can be normal in the early part of the disease [5]. CT Scans can be useful in defining the extent of bony destruction and supplement the findings of plain radiographs [6]. However, their use is limited except in situations where guided biopsy is required [7]. MRI is considered the modality of choice for the diagnosis of spinal tuberculosis [8]. It can detect the lesions in the early stage [9] and can detect in detail the amount of soft tissue involvement along with the spread of abscess and neural compressions leading to paraplegia [10].

Nuclear imaging can be used for differentiating between

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Table 1: Summary of included studies

Publication	Study design	Subjects	Intervention	Outcome
Dureja et al, Spine, 2014	Prospective observational study	33 patients	Role of 18F-FDG PET as an imaging biomarker for non-invasive evaluation in uncomplicated skeletal tuberculosis.	The PET Scan uptake is a useful marker for metabolic activity and hence response evaluation after treatment in spinal tuberculosis.
Fuster et al, Nuclear medicine, 2014	Prospective study	26 patients	Prospective comparison of whole body 18F-FDG PET CT and MRI of spine in diagnosis of haematogenous spondylodiscitis.	18F-FDG PET Scan can possibly be the first choice imaging procedure for diagnosing infective spondylitis and proving most useful in cases where MRI suggests infection but absent soft tissue involvement.
Bassetti et al, Skeletal Radiology, 2017	Retrospective case control study	30 Patients	Higher 18 F-FDG PET uptake in Tuberculous compared to bacterial spondylodiscitis.	Higher uptake levels in Tuberculous compared to bacterial spondylodiscitis and PET CT is useful in follow up of disease after the start of treatment.
Mittal et al, Indian journal of orthopaedics, 2019	Prospective observational study	37 patients	Evaluating healed status of spine TB by contrast MRI and PET-CT Scan.	PET-CT is more reliable than MRI scan to find the endpoint of treatment in spinal tuberculosis
Misra et al, Neuroradiology, 2020	Retrospective case study	36 patients	MRI findings in Pott's spine and correlating clinical progress with radiological findings	Radiological changes lags behind clinical improvements and there can even be worsening of radiological changes even though clinically improved.

infectious and non-infectious disease [11], measuring the metabolic rate of lesions and thus the disease activity [12]. F-18 FDG (Fluorine 18-Fluoro-2-Deoxy-D-Glucose) PET integrated with CT is useful for monitoring disease activity and treatment response [13]. Treatment includes a two months intensive phase of four drugs (Isoniazid, Rifampicin, Pyrazinamide and Ethambutol) then a continuation phase of 10-16 months with three drugs (Isoniazid, Rifampicin and Ethambutol) depending on the treatment response of the patient [14]. There is no consensus regarding the optimum treatment duration and the endpoint of treatment of spinal tuberculosis as the duration can extend beyond 18 months in many occasions [15].

### Methods

A review of literature as shown in PRISMA chart figure 1 is done to evaluate the investigations suitable for finding the endpoint of treatment in spinal tuberculosis. PubMed was searched on 8th April 2020 using the advanced search tool for MeSH terms "spinal tuberculosis" and "investigations", "magnetic resonance imaging", "positron emission tomography" yielding 661 papers. Filters were applied for inclusion of only articles written in English, full-text articles, articles involving only human subjects and articles published in the past 15 years. Then articles were screened individually for relevance to the role of MRI and PET scan in spinal tuberculosis and in finding the endpoint of treatment. Applying all these criteria, five clinical studies relevant to the topic were selected (2 prospective case series, 2 prospective observational study and 1 non-randomized retrospective case-control study) and included in our systematic review.

### Results

The first article is an observational study by Dureja et al conducted on 33 patients who had either suspicious radiological findings or histopathologically diagnosed skeletal

tuberculosis at the time of presentation [17] as shown in Table 1. Patients in the trial underwent aspiration and biopsy from the lesion to prove the diagnosis of tuberculosis. Then, they underwent a whole-body FDG PET CT Scan before the start of ATT and uptake was calculated. After the scan, all patients were put on antitubercular treatment.

Changes in uptake value in PET scan during follow up were compared from baseline. Further, change in mean uptake with clinical response indicators was measured viz. ECOG score (Eastern co-operative oncology group) and VAS pain score (visual analogue scale). On follow up, the pain score

fell significantly ( $p = 0.001$ ) at all time points and improved in ECOG score as treatment progressed. There was a significant fall in mean SUVmax (standardized uptake value) as treatment progressed and a significant correlation between fall in SUVmax and VAS score. Another significant finding was the detection of occult non-contiguous multifocal skeleton involvement during PET CT scanning which was rare in most previous studies which used mainly conventional radiography or MRI Scans for screening. It resulted in a low reporting rate of these lesions thus underestimating the actual prevalence. This showed the high sensitivity of PET CT for detecting lesions with very little radiological changes [15]. Overall, the study demonstrated changes in uptake in PET scan following treatment with ATT [20]. This showed that Standardized uptake value in PET scan is a promising marker for assessing treatment response and thus, helpful in finding the endpoint of treatment. Also, treatment non-responders can be identified early in the course of treatment thus paving the way for diagnosis of multidrug resistance.

Fuster et al demonstrated the useful applications of 18F-FDG PET CT with a possibility of it becoming the imaging procedure of choice in infective spondylodiscitis [16]. They also compared the usefulness of PET scan with MRI scan. Their study was conducted on 26 patients that came with back pain and features of spine infection. All patients were subjected to an MRI scan and Whole-body 18F FDG PET CT scan along with total leucocyte count, C-reactive protein and Erythrocyte sedimentation for analysis. The microbiological culture was done from blood or spinal puncture fluid to document infection. Higher FDG uptake in PET scan at adjacent vertebrae compared to bone marrow were considered positive results. MRI Scan of the spine was done and results were considered positive for spondylodiscitis when there was disc space narrowing, involvement of intervertebral disc, epidural enhancement along contrast enhancement. Calculations were

done for Sensitivity, Specificity, positive predictive value (PPV) and negative predictive value (NPV). Patients who had spine infection showed high FDG uptake in 15 out of 18 patients correctly.

Also, ruled out spondylodiscitis correctly in 7 out of 8 non-infected patients. On the other hand, infection was identified in 17 out of 18 patients by MRI and also helped to rule out infection in 3 out of 8 patients. So, 18F-FDG PET showed sensitivity, specificity, PPV and NPV of 83%, 88%, 94% and 75% and MRI showed 94%, 38%, 77% and 75% respectively. False positivity was found in one patient in PET CT and five for MRI. Combining PET CT and MRI showed 100% detection of infection in spondylodiscitis. This study showed that 18 F-FDG PET CT is a valuable investigation in patients with suspected spondylodiscitis and can prove most useful in cases where MRI suggests infection without noticeable soft tissue involvement. Thus, 18 F-FDG PET CT being highly specific, can be the imaging technique for diagnosing spondylodiscitis and follow up whenever possible [21].

Bassetti et al compared tuberculous and pyogenic spondylodiscitis with regards to clinical features along with FDG PET CT characteristics of both [18]. All patients underwent ultrasound or CT guided aspiration from the paravertebral collections or pathological bone tissues for histological analysis. MRI and whole-body FDG PET CT were done within 2 weeks after the start of symptoms for analysis. Any patient who had increased FDG uptake in adjacent vertebra compared to bone marrow and soft tissues uptake was taken as a positive case. The thoracolumbar spine was commonly involved in tuberculosis, which was shown by MRI. Multiple intervertebral localizations were seen in tuberculous while only one among pyogenic controls showed multiple vertebrae involvement. Also, patients with tuberculous spondylodiscitis present with focal, extraosseous paraspinal masses compared to pyogenic controls.

FDG PET CT showed different characteristics among cases and controls. Tuberculous cases showed a mean SUV value of 12.4 but pyogenic controls showed a mean of only 7. Also, SUV > 8 had a significant correlation with tuberculous spondylodiscitis compared with pyogenic. MRI showed little changes while following up during treatment and can be difficult to interpret. However, due to intense FDG uptake in active tuberculous lesions, FDG PET CT can be used for localization of active lesions or follow up of therapy by following the decrease in SUV [22].

Also, promising results were shown by PET CT in situations where MRI was unable to differentiate between infection and degeneration. This study showed promising results of FDG PET CT in diagnosis and follow up of Spinal tuberculosis which can help in finding the endpoint of treatment.

Mittal et al conducted a study on 37 patients with TB spine and

followed up for treatment response with MRI scan and PET-CT scan [15]. The patients were enrolled after diagnosing through clinico-radiological imaging, histopathology and molecular methods. They were given ATT as per Revised National TB Control Programme and followed up for response with plain radiographs and blood investigations every 2 months. Contrast MRI and PET scan was done at 9 months to check for signs of healing. Clinical improvement were considered when there was reduction of pain along with constitutional symptoms, gain of weight, healing of sinuses, absent cold abscess and reduction of Erythrocyte sedimentation rate (ESR) along with improvement in haemoglobin. Radiological healing was seen as vertebral bodies remineralisation, bony trabeculae reappearance, cortical margins sharpening and fusion of vertebrae. MRI features of healed lesion were resolution of abscess, marrow edema replacement by fat or calcification and absence of contrast enhancement. Absence of uptake in PET scan were considered healed lesion.

ATT was stopped for patients on MRI or PET scan based healing and continued for those with active disease or resolving lesion. Those with continued ATT were reevaluated at 12, 18, 24 and 30 months till healed status was seen. 28 patients achieved healed status among which 11 had both MRI and PET based healing, 6 patients had active lesions on MRI but healed on PET scan, 2 had healed lesion on MRI with active uptake on PET scan. Remaining patients had PET scan based healing due to incompatible implants for MRI scan. PET scan showed healed bone lesion for endpoint of treatment in 28/28 patients (100%) while MRI showed healed lesion in 13/25 patients (52%). They concluded by saying that PET scan can be a better measure than MRI scan to find out the endpoint of treatment in spinal tuberculosis.

Misra et al conducted a study to correlate clinical progress with MRI findings in 36 patients of Pott's spine on treatment with Anti tubercular drugs [1]. The diagnosis was clinico radiological and histology based. Patients were assigned into 4 different groups based on the timing of the repeat MRI (3rd, 6th, 9th and 12th months). MRI findings include spondylodiscitis, vertebral collapse and para vertebral soft tissues involvement. MRI changes were compared with clinical findings at the time of each MRI. During follow up, the changes seen on MRI were found lagging behind clinical improvement. The first parameter to improve was the inflammatory cord changes and then reduction of abscess. However some parameters like collapse of vertebrae or lesions in spinal cord or vertebrae showed late improvement or no improvement at all. In the 3 month group, clinical improvement was found in 8 out of 12 patients but MRI showed improvement in only 2 out of 12 patients. At 6th, 9th and 12th month groups, all patients had variable clinical improvement but MRI parameters improved in 5 out of 9 patients in 6th month group, 6 out of 9 in 9th month



group and 5 out of 6 in 12th month group. Also, deterioration of radiological findings in spite of improvement in clinical condition was seen in 14 out of 36 patients, called as paradoxical worsening. Most frequently, it was found in the 3rd month group with 6 out of 12 patients followed by 4 out of 9 in 6th month, 3 out of 9 in 9th month and 1 out of 5 at 12th month group.

A 3rd MRI was done in 16 patients which had radiological improvement in all patients but not entirely normal. Clinical improvement occurred in 66% patients in 3 months and all patients by 6 months while radiological improvement was 16% at 3 months, 55.5% at 6 months and 83.3% at 12 months. Thus, the improvement in radiological findings lags behind clinical improvements. Some of the changes in MRI can remain for a long time in fully treated cases even.

### Discussion

The endpoint of treatment in spinal tuberculosis is not clearly defined and there is lack of consensus regarding the exact duration of treatment and the gold standard investigation to find out the same.

The INDEX TB guidelines which are the standard guidelines for the treatment of extrapulmonary TB in India mentions the duration of ATT for spinal tuberculosis to be 2 months Intensive phase of 4 drugs (Isoniazid, Rifampicin, Pyrazinamide and Ethambutol) followed by a continuation phase of 10-16 months consisting of 3 drugs (Isoniazid, Rifampicin and Ethambutol) with a total duration of 18 months ATT. However, it is quite often seen that many patients does not achieve healed status even after 18 months ATT and it has to be continued much beyond 18 months. Thus, the exact duration of ATT is quite confusing even with the existing guidelines which does not mention anything beyond 18 months.

Adding to the confusion is the management protocol to be followed if any patient does not achieve healed status even after 18 months of ATT. Also, prolonged intake of ATT can have several side effects ranging from hepatotoxicity, peripheral neuropathy and vision diminution. Thus, the morbidity due to prolonged treatment and due to the disease process itself becomes profound. The onus falls on the experience and clinical judgement of the treating doctor. A refined standard protocol for treatment and follow up and to determine the endpoint of treatment is the need of the hour.

Plain x rays form an important screening tool in the management of spinal tuberculosis being available in most parts even in rural areas. However, x rays fail to detect the disease at an early stage and the early lesions are mostly missed in plain radiographs. They may not be apparent till 3-4 months and even fails to detect a tuberculous foci less than 1.5cms and also until the vertebra loses 30% of the bone mineral. Though, the sensitivity as a diagnostic modality is less, it can be used for serial

monitoring of treatment response and for any impending signs of any deformity or collapse. Signs of healing in X rays include vertebral remineralization, sharpening of bony margins and the start of fusion of the affected vertebrae.

MRI is commonly used in many centres worldwide for the diagnosis of suspected cases of spinal tuberculosis and for following up the response to treatment. MRI is considered one of the best modality for diagnosis of spinal tuberculosis which can detect the disease process in its early stage.

This can enable the start of ATT in the early stage itself which can prevent vertebral destruction and permanent deformities. This is important especially for the paediatric population which can have devastating sequelae. Signs of healing in MRI includes resolution of abscess, resolution of marrow edema and lack of contrast enhancement.

Jeon et al stated that MRI is a sensitive test and useful for monitoring response but little correlation have been found between clinical response and radiological changes [19]. There can be worsening of marrow edema and involvement of vertebra can be seen even at 14 months. MRI fails to differentiate between active and sterile lesions and also patients continue to have pain even after healing of TB. Misra et al also concluded that the improvement in radiological findings lags behind clinical improvements [1]. Some of the changes in MRI can remain for a long time in fully treated cases even.

PET scan is a newly emerging investigation modality that uses nuclear imaging techniques to check the metabolic activity of any lesion of the body. Tuberculous lesions are characterised by the presence of granulomatous inflammation with a high number of lymphocytes and macrophagic activity. These cells are characterized by high intake of glucose which is expressed as FDG avid lesions in PET scan. The uptake of glucose by macrophages and lymphocytes in tubercular granulomatous inflammation can reliably give information about the healing or healed status of the lesion.

Dureja et al showed the high sensitivity of PET CT for detecting lesions with very little radiological changes and also demonstrated changes in uptake in PET scan following treatment with ATT [17]. They concluded that PET scan can be a reliable modality for follow up of treatment response. Fuster et al also showed PET CT as highly specific and can be the imaging technique for diagnosing spondylodiscitis and follow up whenever possible [16]. Bassetti et al in their study showed intense FDG uptake in active tuberculous lesions and concluded that PET CT can be used for localization of active lesions or follow up of therapy by following the decrease in uptake values [18]. Also, promising results were shown by PET CT in situations where MRI was unable to differentiate between infection and degeneration.

Mittal et al in their study demonstrated that PET scan showed healed bone lesion for endpoint of treatment in 28/28 patients

(100%) while MRI showed healed lesion in 13/25 patients (52%). They concluded by saying that PET scan can be a better measure than MRI scan to find out the endpoint of treatment in spinal tuberculosis [15].

### Conclusion

Spinal tuberculosis is widely prevalent in an endemic country like India and is found to affect the most productive age groups which can have a profound effect on the economy. Early and correct diagnosis is important to start ATT on time and prevent the long term complications and deformities. There is no proper gold standard investigation so far that can reliably predict the endpoint of treatment and no consensus regarding the exact duration of ATT to be given. MRI finds an important place in diagnosis and follow up of treatment response but studies have

shown that the MRI changes lag behind clinical improvement and some changes even persist after cure of the disease. 18F-FDG PET CT is a promising investigation tool for diagnosis and further assessment of treatment response in spinal tuberculosis. Various studies available at present show that no other investigation modality is more sensitive, specific or accurate than the PET scan for detecting the endpoint of treatment. Hence, PET scan can be said to be the gold standard test in identifying the endpoint of treatment in spinal tuberculosis at present. Also, the duration of ATT can vary from one person to another and so there should not be a fixed duration of ATT for stopping treatment. It has to be individualized and followed up closely. A negative PET scan supplemented by MRI, x rays and blood parameters can reliably predict the endpoint of treatment.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

**Conflict of Interest:** NIL; **Source of Support:** NIL

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