

Clinical and Radiological Evaluation of Healing In Tuberculosis of Spine-A Retrospective and Prospective Study.

Pranav Kothiyal¹, Gyaneshwar Tank²

¹Senior Resident, Department of Orthopaedics, L.L.R.M. Medical College, CCSU university, Meerut, U.P. India.

²Associate Professor, Department of Orthopaedics, L.L.R.M. Medical College, CCSU university, Meerut, U.P. India.

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ABSTRACT

Background: Tuberculosis of spine constitute nearly 1% of overall cases. Surgery is indicated in selected cases, and medical care is the key treatment. The duration of anti tubercular drug therapy in spine TB is controversial. **Objective:** - The purpose of this retrospective and prospective study was to see the incidence, diagnose, monitor the treatment duration and complications in patients with tuberculosis of spine. **Study Design** - From April 2013 to October 2014 one hundred and twenty one patients with TB of the spine were admitted and treated in our institution. **Methods:** The patients were carefully monitored and followed up. Those who had an indication for surgical decompression were managed accordingly. For assessment we used visual analogue scales to report the level of pain, Japanese orthopaedic association score and Nuricks grading to assess the neurological and functional improvement at initial and follow up visits. **Results:** Out of all 122 patients, 102 patients (84.4%) healed over varying period of time and 18 (14.8%) were still under treatment while the study ended. Neurological involvement was seen in 32 (26.3%) out of 122 patients at initial presentation in the form of sensory, motor or bladder bowel involvement. The duration of healing was measured from the start of ATT till it was stopped at healing and was found to be maximum in patients with involvement of the lumbar spine with a median healing of 16 months. The treatment was completed in 103 patients and ATT was stopped and the mean healing time was 14.5 months. **Conclusion:** We found that the most common involved level was at the lumbar spine and skip lesions were more common. There is no fixed criteria for the duration till which the anti-tubercular therapy has to be given. It should depend on the level and extent of spinal involvement.

Keywords: Potts spine, anti-tubercular therapy, paraplegia.

INTRODUCTION

Spinal tuberculosis is a destructive form of tuberculosis. It accounts for approximately half of all cases of musculoskeletal tuberculosis. Spinal tuberculosis is more common in children and young adults. The incidence of spinal tuberculosis is increasing in developed nations. Anti-tuberculous treatment remains the cornerstone of treatment. Surgery may be required in selected cases like patients with large abscess formation, severe kyphosis, an evolving neurological deficit, or lack of response to medical treatment but with early diagnosis and early treatment, prognosis is generally good.

The purpose of this randomized prospective and retrospective study was to diagnose and treat the cases of tuberculosis of the spine, to determine their regional distribution in the spine, to evaluate the healing by clinical and radiological features and to monitor the duration of healing and complications in patients under study.

MATERIALS AND METHODS

This study was conducted in the department of orthopedic surgery, L.L.R.M Medical College, Meerut from April 2013 to October 2014 on the patients admitted and treated in SVBP hospital.

The Inclusion criteria were All patients greater than 14 years of age with an established diagnosis of tuberculosis of the spine with the informed consent

The Exclusion criteria were Patients from which it is impossible to obtain consent and All patients

Name & Address of Corresponding Author

Dr. Pranav Kothiyal
Senior Resident,
Department of Orthopaedics,
L.L.R.M. Medical college, CCSU university, Meerut,
U.P. India.
E mail: kothiyalpranav@gmail.com

having any other associated illness or traumatic neurologic deficit or medical contraindications.

Study design

All the patients under study were subjected to detailed history taking and thorough examination. Neurological examination was done for each patient, which involved the nutritional status of the extremity, tone, power (graded according to the MRC grading), Reflexes and sensory status.

At the initial presentation a vas score was calculated along with a Japanese orthopaedic association score and the Nurick scale. The patient's clinical status was monitored by these three scoring systems in the subsequent follow ups. According to the history and examination a provisional clinical diagnosis was made for every patient. All the patients were then investigated for routine blood investigations that included complete blood counts having:-

Haemoglobin, TLC, DLC, Packed cell volume, ESR, Platelet counts, RBS, Blood urea, Serum creatinine Along with virological markers and liver function tests.

All patients were then subjected to radiographical examination that included Xrays with both the views of spine, chest X-ray and MRI of the desired spinal region with T1 and T2 weighed images. The radiological diagnosis was made on observation of demineralization of the vertebra, fuzzy para discal margin, reduction/obliteration of disc space, along with one or more of the following: destruction of end plates, wedging of the vertebra, obvious kyphotic deformity, paravertebral shadows, and anterior scalloping of vertebral body.

Retrospective patients who were under treatment already or who had finished treatment were examined again and their scores were assessed according to their previous documents and radiographs.

Treatment Regime

This involved Initial hospitalization for 4 weeks on strict bed rest restriction of activity and nursing in the supine position.

Commencement of multidrug anti-TB treatment (ATT) comprising of Rifampicin (10 mg/kg), Isoniazid (5 mg/kg) and Pyrazinamide (25 mg/kg) for all with the addition of Ethambutol (15 mg/Kg) for all adult females and adult males in the continuation phase. Streptomycin was given through intramuscular route in the dose of 750 mg/day. Pyridoxine was administered to all patients on Isoniazid at a dose of 40mg/day. Passive physiotherapy and complete paraplegia care in case of neurological involvement.

All the patients under chemotherapy were kept in observation and their clinical course was monitored.

If during their hospital stay or opd follow up the patients developed any indication for operative indication or if the patients at the initial presentation were having any indication for operative intervention itself the patients were managed accordingly with the appropriate operative management.

Pre operative evaluation and preparation

All the patients who were candidates for operative management were examined by anaesthetists and evaluated for fitness to be able to tolerate general anaesthesia. Each patient was made as fit as possible. Cardiac and respiratory status of the patients was assessed and improved as much as possible.

Intraoperative care

The method of anaesthesia was general anaesthesia and the operative technique was carried out accordingly.

Post operative Care

Nil per oral for 8 hrs postoperatively, iv fluids, iv antibiotics, im analgesics, physiotherapy of both lower limbs, check x-ray on the same or next day, suture removal on the 10th day, discharge on the 10th day if the post op period was uneventful.

Follow Up

All the cases were followed on the 1st week, 2nd month, 6th month and at 1 year or earlier if required. Serial radiographs were taken to assess the radiological healing and photographic records were taken for the final functional outcome. Patients were advised proper high protein diet, absolute bed rest and complete paraplegia care in case of neurological involvement.

The healing was assessed clinically as reduction in pain with improvement in constitutional symptoms, weight gain, improvement in daily activity, reduction in cold abscess, and healing of the sinuses; hematologically as a reduction in ESR and rise in hemoglobin.

Radiological healing was noted on serial x-rays only and the following criteria were taken as a marker for radiological healing. Re-mineralization and reappearance of bony trabeculae, Sharpening of articular and cortical margins, Bony Sclerosis in the involved vertebrae, Resolution of pre and paravertebral soft tissue shadows, Fusion of vertebral bodies.

As bony healing was evident on radiographs and the patient improved clinically the patients were made to sit, walk with support and the chemotherapy was modified according to the phase of treatment and finally stopped and the total duration taken to achieve radiological healing was noted.

On each follow up visit the Patients were asked to grade the pain as per VAS scale, a 100mm visual-analogue scale, with 0 denoting no pain and 100 denoting the worst pain that the patient could imagine. In addition to functional outcome was also seen using the Japanese Orthopaedic association score, which scored the condition of the patients, according to motor, sensory and bladder, bowel involvement ranging from a score of 0 to 17, and the nuricks grading system that categorized the patient according to their difficulty in walking from grade 0 to grade 5.

The statistical analysis in this study was carried out using SPSS 15 software for Windows program. The survival estimates were done using Kaplan meier curve. The differences between the values of the VAS score, JOA score and the Nuricks grades were done using box plot analysis and mosaic plot.

RESULTS

The age varied from 12 to 74 years with a mean age of 40 years. Most patients were from 10 - 30 years of age. The disease was more common in females (59.8%). Skip lesions were present in 10 patients (8.2%). 26.3% of the patients showed neurological involvement during the entire duration of study. The most common spinal segment to be involved was the lumbar segment with involvement in 45.1% of the patients followed by lower dorsal spine, which was involved in 37.7% of the patients. Least involvement was seen in sacrum with 3 patients of sacral tuberculosis. All the patients were managed by first line anti tubercular drugs except one patient who did not improve after first line drugs as well as operative decompression but later on improved on second line anti tubercular drugs. Four patients developed psoas abscess after initiation of treatment, which had to be incised and drained. It gradually subsided by daily dressing and instillation of streptomycin.

Surgical intervention in the form of decompression with or without stabilization was done in 17 patients (14.1%) and the rest healed conservatively. After surgical decompression and chemotherapy 15 patients out of total 17 surgically managed patients completed treatment and achieved healed status after a mean period of 14.3 months. One patient with cervical spine involvement expired after 1 week of starting chemotherapy.

The duration was found to be maximum in patients with involvement of the lumbar spine with a median healing of 16 months followed by patients with lower dorsal spine involvement in 14 months. 24 patients achieved healed status at or less than 12 months after initiation of treatment. While 7 patients took more than 18 months to heal. Out of total 102 patients (84.4%) healed after treatment, and 18 (14.8%) were still under treatment when the study concluded.

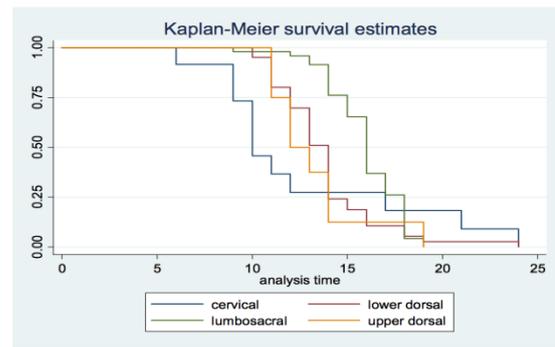


Figure 1: Time taken for healing at various sites.

From the Kaplan-meier curve, it is clearly seen that till 14 months, time taken for healing in cervical is lowest followed by upper dorsal, lower dorsal and lumbosacral, after 14 months line crossing to each other, hence no clear conclusion can be drawn, it may be because of inappropriate sample size [Figure 1].

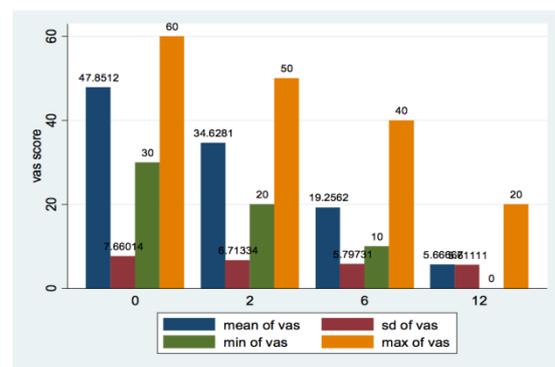


Figure 2: VAS Score.

From the graph and table we saw that the mean vas score is 47.9 ± 7.7 , 34.6 ± 6.7 , 19.3 ± 5.8 and 5.7 ± 5.6 at 0, 2, 6, 12 months respectively which is statistically significant [Figure 2].

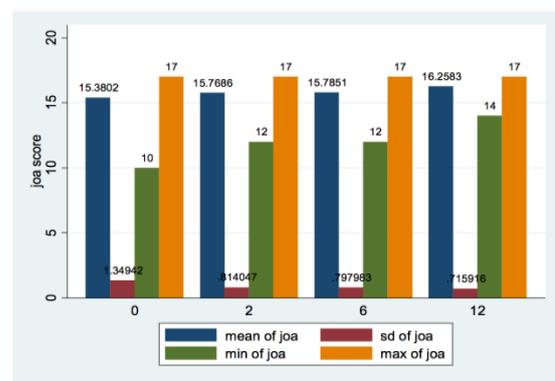


Figure 3: JOA Score.

From the graph and table, it is clear that the mean joa score was 15.4 ± 1.3 , 15.8 ± 0.8 , 15.8 ± 0.8 and 16.3 ± 0.7 at 0, 2, 6, 12 months respectively which is statistically significant [Figure 3].

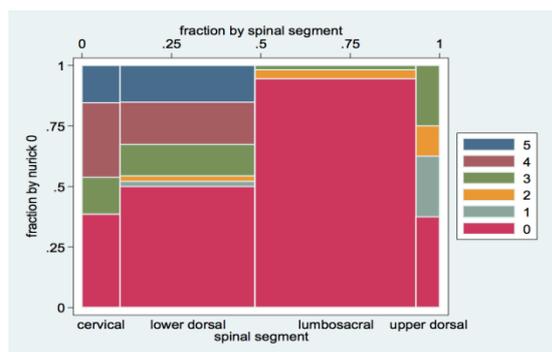


Figure 4: Nuricks Grade Analysis According To Mosaic Plot Nuricks grade distribution at 0 months (baseline).

According to the mosaic plot at the baseline 83 patients (68%) of the total had a nuricks grade of 0 9 patients (7.4%) had a nuricks grade of 5 [Figure 4]. 12 patients (9.84%) and 11 patients (9%) had a grade of 4 and 3 respectively. Maximum number of patients with nuricks grade more than or equal to 1 were in lower dorsal spine (50%). With a p value of 0.00 the data is statistically significant.

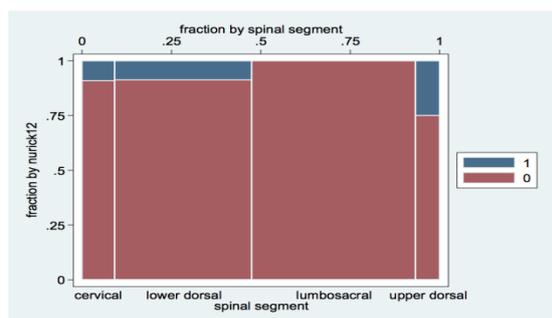


Figure 5: Distribution of nuricks grades at 12 months.

At 12 months, all the patients had a nuricks grade of either 1 or 0. 94% patients had a nuricks grade of 0 and 5.8% had a grade of 1 [Figure 5].

DISCUSSION

The present study was conducted on 122 patients both retrospective and prospective with tuberculosis of spine all of which were treated by anti tubercular treatment and surgical intervention as and when required.

The mean age in our study was 40 years with a minimum age of 12 years and the maximum being 74. Maximum number of patients that is nearly 50 percent were in the age group of 10 – 30 years showing increased incidence in the 2nd and 3rd decade of life.

In a study of 62 patients by A Akinyoola et al (2006)^[1] the mean age of the patients under study was 32 and according to another study conducted by Bhavuk Garg et al (2012)^[2] on 71 patients of spinal tuberculosis admitted to AIIMS New Delhi the mean age of presentation was 34.9 years which

is slightly less than the mean age of patients in our study but corresponds to the disease being more common in the third and fourth decade.^[1]

Out of total 73 patients (59.84%) were female and 49 patients (40.2%) were males showing the preponderance of the disease in females. Earlier studies by Sinan et al and Owolabi LF et al showed spinal tuberculosis to be more common in males with a male is to female ratio of 3:1 and 2:1 respectively but in this study Females were affected more commonly than males with a sex ratio of 0.67 this difference could be probably due to biased selection of patients without proper randomization and lesser sample size.^[3,4]

Osborn et al however showed no sex predilection.^[5] Skip lesions were present in 10 patients (8.2%) and were mostly between dorsal and lumbar spine and they were mostly having neurological involvement and took a longer duration to heal.

In a study by Pandit et al. which was a bone scan study of 40 confirmed cases of TB spine. There was, however, a 25% (10/40) incidence of *skeletal* multi-centricity reported rather than spinal multi-centricity. Of the 40 patients, 6 had vertebral skip lesions giving an incidence for noncontiguous spinal TB involvement of 15%.^[6]

A study conducted on 98 patients by Peter Polly et al identified 16 patients with skip lesions with a incidence of 16.3% and saw higher incidence of neurological involvement in noncontiguous group compared to single focus.^[7]

In maximum number of the patients the tubercular lesion was present in the lumbar spine that is 56 patients (45.1%) followed by lower dorsal spine which was involved in 46 patients (37.7%). Upper dorsal and cervical spine had been involved in 8 and 13 patients respectively. The least involvement was seen in upper region.

Studies by Sinan et al and Prateek S. Gehlot et al have shown similar results with L3 being the commonest site and lumbar spine the commonest site of involvement however this is in contrast to observations of G.R.Bajwa et al 2007 and LF Owolabi et al 2010 which showed the maximum frequency of involvement in the thoracolumbar region (45%) and thoracic region (56.7%).^[8-11]

13 patients (8.2%) had disease in the cervical spine and 3 patients (2.5%) had disease exclusively in the sacral vertebrae which roughly correlates with the findings of G.R.Bajwa et al 2007 and Elwathiq Khalid Ibrahim et al 2014 with frequency of cervical spine involvement of 6.6% and 4% respectively and no cases of sacral tuberculosis.^[10,12]

Neurological involvement was seen in 32 (26.3%) out of 122 patients at initial presentation. The maximum number of patients with neurological involvement were those having lesion in the lower dorsal spine (58%) followed by cervical spine (46%) while the least amount of neurological

deficit was seen in patients of lumbar spine involvement with only two patients having deficit. Our 122 patients had characteristic features of TB spine clinically as well as on X-rays and MRI. The histological/bacteriological/PCR proof of diagnosis was not obtained in any case.

Four patients developed psoas abscess after initiation of treatment, which had to be incised and drained. It gradually subsided by daily dressing and instillation of streptomycin.

Surgical intervention in the form of decompression with or without stabilization was done in 17 patients (14.1%) and the rest healed conservatively. The indications for operative intervention were mostly severe neurological involvement at the time of presentation or inability to improve or deterioration while under conservative treatment. After surgical decompression and chemotherapy 15 patients out of total 17 surgically managed patients completed treatment and achieved healed status after a mean period of 14.3 months.

Out of all patients 102 (84.4%) healed over varying period of time and 18 (14.8%) were still under treatment while the study ended. One patient with cervical spine involvement expired after 1 week of starting chemotherapy.

The mean vas score JOA score and Nuricks grade at initiation of treatment were 50, 15.2 and 1.12, which improved to 5.66, 16.25 and 0.06 after one year of completion of treatment.

The duration of healing was measured from the start of ATT till it was stopped at healing. The duration was found to be maximum in patients with involvement of the lumbar spine with a median healing of 16 months followed by patients with lower dorsal spine involvement in 14 months. The minimum healing time was seen in patients of cervical spine involvement with a median time of 10 months. 24 patients achieved healed status at or less than 12 months after initiation of treatment. While 7 patients took more than 18 months to heal.

The treatment was completed in 103 patients and ATT was stopped and the mean healing time was 14.5 months according to other studies Kotil *et al.* (11–15 months), Ramachandran *et al.* mean 11.2 months (range 6–18 months) and Cormican *et al.* mean 13 months (9–24 months) reported variable duration of treatment.^[13-15]

Ramachandran *et al.* retrospectively documented that patients of spinal TB on 6 months of ATT have higher relapse rate than in patient given 9 months or more of ATT.^[14]

Relapse after clinico-radiological improvement or stoppage of chemotherapy was not seen in any patient. One patient had refractory disease on 1st line ATT which healed after operative intervention and starting second line drugs after a period of 18 months.

Ramachandran *et al.* reported relapse in five out of eight patients after 6 months of chemotherapy,

while no relapse was observed after 9 months of ATT. They retrospectively documented that patients of spinal TB on 6 months of ATT have higher relapse rate than in patients given 9 months or more of ATT.^[14]

In Korea (1993), another MRC trial found that shorter duration of therapy of 6 or 9 months was equally effective as 18 months of chemotherapy. However, the end point of treatment was not defined and even after 36 months of follow up only 82% of patients had achieved favourable status.^[16]

So it can be said that with the introduction of DOTS regimen there has been consensus for the dosage of the drugs to be used, but duration is still the issue as relapses have been observed after 6 months of treatment in case of osteoarticular TB.

We saw that X-rays were found to be better as compared to MRI in evaluation of healing during follow up as MRI in the way that MRI can often be misleading with visualization of insignificant findings even after adequate period of anti-tubercular treatment has passed which do not appropriately correlate with clinical improvement.

We saw that first line anti-tubercular drugs are effective for the treatment in almost all cases and intervention by second line anti-tubercular drugs is seldom required.

Thus, we found that there are no fixed criteria for the duration till which the anti-tubercular therapy has to be given. It should depend on the level of spinal involvement with a longer duration of treatment for involvement of lumbosacral spine and a shorter duration for involvement of cervical spine, then evaluate the patients clinically, radiologically and haematologically to document healing of the lesion, and then decide whether to continue or stop the anti-tubercular therapy.

35 yr male

Potts spine 12-13 without neurological involvement [Figure 6-9]

Pre-treatment



Figure 6: 2 months post starting treatment.

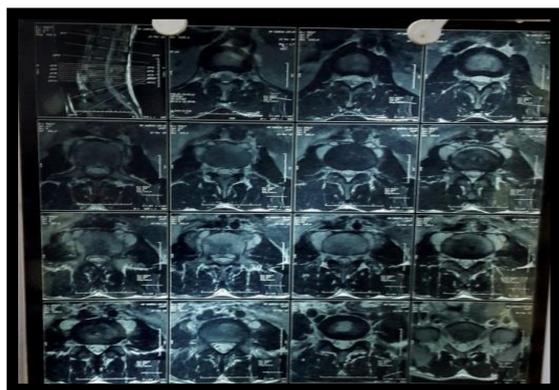


Figure 7: 6 months post starting treatment.



Figure 8: 12 months post treatment.



Figure 9: X-Ray.

CONCLUSION

We found that the most common involved level was at the lumbar spine and skip lesions were more common. There is no fixed criteria for the duration till which the anti-tubercular therapy has to be

given. It should depend on the level and extent of spinal involvement.

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