Non-Operative Treatment of Pott's Disease with Neurologic Involvement

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ABSTRACT: Twenty-sixe patients diagnosed to have Pott's disease clinically and/or radiologically, with varying degrees of spinal cord involvement, were treated non-operatively and followed up for one month, three months, six months and one year. All of the patients who were followed up during these four evaluation periods, including those classified to have severe neurologic deficits, had significant recovery of their neurologic function (p = .005). Improvement as well as complete neurologic recovery occured as early as one month after the start of treatment. Such improvement or recovery persisted for those patients who were able to follow-up after three months, six months and one year. It is concluded that non-operative treatment is effective for Pott's disease in patients presenting with neurologic dificits.

In the Philippines, tuberculosis remains a major health problem, ranking third in terms of mortality and fifth in terms of morbidity. The Department of Health statistics reveals that tuberculosis in all forms kills 30,000 Filipinos annually. There are about 1.5 million Filipinos infected with the disease and around 300,000 are in its active stage.†

The most common and probably the most disabling form of extrapulmonary tuberculosis is skeletal tuberculosis.[1] Of the different forms of skeletal tuberculosis, tuberculosis of the spine or Pott's disease is the most common. In a study of 1,107 cases of skeletal tuberculosis by Tamesis and Pujalte,[2] 65 per cent involved the spine. At the Department of Orthopedics, Philippine General Hospital, about 10 per cent of the admissions are bone and joint tuberculosis cases, of which 60-65 per cent are spinal tuberculosis patients.[3]

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Paraplegia or even paraparesis is the most dreaded complication of Pott's disease. As early as the third century B.C., Hippocrates described spinal tuberculosis and cautioned about its seriousness in terms of paralysis and eventual death.[4]

The incidence of neurologic involvement in Pott's disease ranges from 25-39 per cent in foreign literature,[5-7] while in the Philippines, it varies from 17-44 per cent.[2,8] At the Philippine General Hospital, 39 per cent of the Pott's disease patients in a profile study showed neurologic involvement.[3]

The development of improved chemotherapeutic agents for tuberculosis as well as the more efficient implementation of public health care delivery programs has resulted in a remarkable progress in the treatment of skeletal tuberculosis during the past 30 years. However, opinions as to the best method of treating spinal tuberculosis have differed widely. At one extreme, the group of Hodgson,[6,9,10] advocated the radical operation, wherein the tuberculous abscess at the front of the spine is carefully debrided and the gap is bridged with bone grafts. They claimed excellent results in terms of clinical healing, a more rapid fusion rate and prevention of recurrences and progressive deformity.

At the other extreme, the Konstams,[5,11,12] working with limited resources and hospital beds in Nigeria, treated their spinal tuberculosis patients with antituberculous drugs, immobilized them in plaster and allowed them to walk long distances to their villages. Their results were extremely encouraging.

In an effort to resolve the controversy as to which method of treatment is the best for spinal tuberculosis, the Medical Research Working Party on Tuberculosis of the Spine conducted a series of controlled clinical trials in Korea,[13-15] Rhodesia,[16,17] South Africa,[7] and Hong Kong.[10,18] Their conclusion was for countries lacking the resources to perform the radical operation, ambulant chemotherapy is the treatment of choice.

There is therefore no argument that ambulatory or non-operative treatment is effective in the

treatment of spinal tuberculosis. The question, however, is whether non-operative treatment will also work in the presence of spinal cord involvement. So far, only Konstam's studies[5,11,12] give us an answer and in the Philippines, where the incidence of Pott's disease is quite high, no study has yet been made regarding the treatment of spinal tuberculosis with neurologic complications.

The *general objective* of this research, therefore, is to determine whether neurologic involvement in Pott's disease will recover from non-operative treatment. If there is recovery, the following *specific objectives* would be investigated: (1) to determine the extent of neurologic involvement that will recover from non-operative treatment, (2) to identify the earliest time of improvement of neurologic function from the start of treatment and (3) to establish whether lasting improvement in neurologic function occurs once full recovery is attained.

MATERIALS AND METHODS

Selection of patients

Patients seen at the Out-Patient Department or admitted to the wards of the Department of Orthopedics, UP-PGH Medical Center from January, 1980 to July, 1986 were eligible for the study if *all* of the following conditions were satisfied: (1) clinical and/or radiographic evidence of tuberculosis of any vertebral body,[3] (2) presence of neurologic deficits, (3) no previous treatment for tuberculosis elsewhere prior to consultation and (4) followed-up for at least one month. Patients were considered ineligible if *any* of the following was present: (1) active tuberculosis in a limb requiring rest in bed and (2) serious non-tuberculous disease likely to prejudice either the response to treatment or its assessment.

Variables to be measured

Patients were evaluated neurologically before the start of treatment, then one month, three months, six months and one year thereafter based on the following, parameters: (1) *motor power* (Grade 0-5), (2) *sensory loss* (expressed as %), (3) *reflexes* (0 to +4) and (4) *bladder and/or bowel dysfunction* (+ or –).

Method of assessment

Based on the above evaluation, each patient was assigned a *neurologic score* depending on the severity of his neurologic involvement. One hundred (100) is the score given to a patient with normal neurologic function. For every deficit, points were deducted from 100 in the following manner:

For every:	*Deduct (points):*
5% sensory loss	1
One grade decrease of muscle strengh	10
(+) of hyperreflexia	5
(+) of pathologic reflex	5
(+) of bladder dysfunction	10
(+) of bowel dysfunction	10

With the score a patient obtained, the severity of his neurologic deficit was classified into one of the following categories:

Neurologic score:	*Classification:*
81 – 99	Mild deficit
60 – 80	Moderate deficit
Below 60	Severe deficit

A patient is defined to have *improved* if there is an increase in his neurologic score compared to his initial (pre-treatment) score or *deteriorated* if his score decreased. He is considered to have *fully recovered* if his neurologic score reaches 100.

Study design

The design used was a historical *prospective* study, otherwise known as a *before and after* study, wherein the patients were used as their own controls. Mausner and Bahn[19] considers this type of study to possess the combined advantages of both the prospective and retrospective study designs, namely, less expense, smaller number of subjects required, lack of bias in factor and suitability for rare and chronic disease.

RESULTS AND ANALYSIS

Twenty-six patients were eligible for the study. The mean age was 24 years with 42 per cent of the patients belonging to the 0-10 age group. There was a preponderance of males over females in a ratio of 2.2.1.

The average duration of neurologic symptoms prior to the initial consultation was 3.3 months with the majority (53.8%) of the patients having symptoms between one to three months.

The most commonly affected vertebra was T9 followed by T4, T10 and L1. There were three patients with cervical spine involvement, all in the lower cervical spine.

Neurologic classification

Fifty per cent of the patients were classified to have mild neurologic deficits based on their neurologic scores while 19.2 per cent had severe neurologic deficits. These were patients who were totally unable to walk and had accompanying bladder and/or bowel dysfunction. (Figure 1)

Treatment

Less than half (46.2%) were placed in a cast while the rest were managed on anti-tuberculous medications alone. All patients received at least three chemotherapeutic agents for tuberculosis consisting of isoniazid (INH), ethambutol and rifampicin or streptomycin. The majority (77%) had rifampicin included in their regimen. (Table 1)

Follow-up

Majority of the patients (88.4%) were able to follow-up at one month. Fity per cent (50%) followed-up at three months, 31 per cent at six months and 38 per cent at one yar. Of the 23 patients who followed-up at one month, 52 per cent showed an improved neurologic status and 26 per cent fully recovered their neurologic function. At three months, all of the 13 patients who followed-

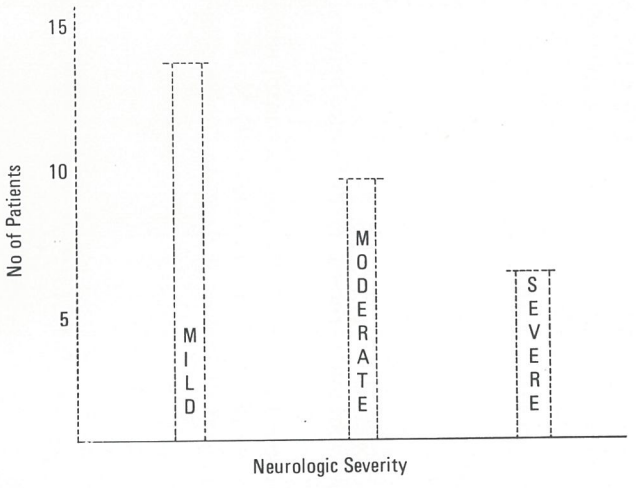

Fig. 1 Neurologic Classification.

TABLE 1
Treatment Received.

Casting	Number	Per cent
With	12	46.2
Without	14	53.8
Medications		
Rifampicin + INH + Ethambutol	10	38.5
Rifampicin + INH + Ethambutol + Streptomycin	10	38.5
INH + Ethambutol + Streptomycin	6	23.0

TABLE 2
Neurologic Scores At Consultation and Follow-up.

Patient	Initial	1 Month	3 Months	6 Months	1 Year
1	86	86	–	100	80
2	65	80	–	100	–
3	90	95	–	–	–
4	70	80	–	–	–
5	80	80	90	–	–
6	90	100	100	–	100
7	90	95	100	–	–
8	90	–	100	–	100
9	90	100	–	–	–
10	90	95	100	100	100
11	80	–	–	–	100
12	75	85	90	–	–
13	95	100	–	–	100
14	94	100	–	–	–
15	80	90	100	100	100
16	80	100	100	100	100
17	90	100	100	100	100
18	90	–	100	100	100
19	43	90	100	–	–
20	45	90	–	–	–
21	44	80	–	100	–
22	85	95	–	–	–
23	52	75	–	–	–
24	70	70	85	–	–
25	46	46	70	–	–
26	90	90	–	–	–

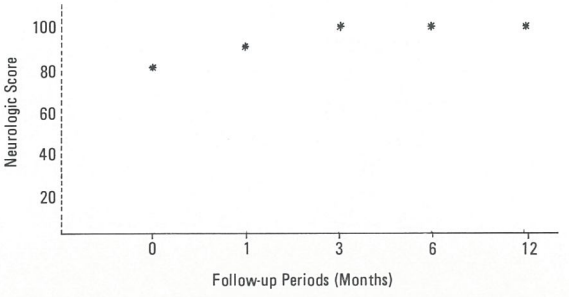

Fig 2. Median Neurologic Scores During the Initial and Follow-up Periods.

TABLE 3
Statistical Analysis of Neurologic Scores (Wilcoxon Matched-Pairs Signed-Ranks Test).

1 Month				3 Months				6 Months				1 Year			
Patient No.	d's	Rank of d	Rank w/ less freq. sign	Patient No.	d's	Rank of d	Rank w/ less freq. sign	Patient No.	d's	Rank of d	Rank w/ less freq. sign	Patient No.	d's	Rank of d	Rank w/ less freq. sign
1	0	13		1	10	4		1	14	4		1	−6	−2	2
2	15	13		2	4	4		2	35	7		2	10	5	
3	5	2.5		3	10	4		3	10	2		3	10	5	
4	10	9		4	10	4		4	20	5.5		4	10	5	
5	0			5	10	4		5	20	5.5		5	20	9	
6	10	9		6	15	8.5		6	10	2		6	5	1	
7	5	2.5		7	20	10.5		7	10	2		7	20	9	
8	10	9		8	20	10.5		8	56	8		8	20	9	
9	5	2.5		9	10	4						9	10	5	
10	10	9		10	10	4		T = 0				10	10	5	
11	5	2.5		11	57	13		T (p = .005, N = 8) = 0							
12	6	5		12	15	8.5		significant*				T = 2			
13	10	9		13	24	12						T (p = .005, N = 10) = 3			
14	20	14										significant			
15	10	9		T = 0											
16	47	18		T (p = .005, N = 13) = 10											
17	45	17		significant*											
18	36	16													
19	10	9													
20	23	15													
21	0														
22	0														
23	0														

T = 0
T (p = .005, N = 18) = 28
significant*

*H0 (null hypothesis): There is no difference between the pre-treatment and post-treatment neurologic scores of the patients.
H1 (alternative hypothesis): The post-treatment neurologic scores of the patients are higher than the pretreatment scores.
Significance level: p = .005 (one-tailed test), N = No. of pairs minus any pairs whose d is zero
Rejection region: All values of T equal to or less than the probability associated with N at p = .005

up had either improved (31%) or fully recovered (69%). During the sixth month follow-up period, 8 patients were available for evaluation. All of these patients fully recovered. Of the 10 patients who followed-up at one year, all, except one who deteriorated, had full neurologic recovery. Table 2 shows the neurologic scores of the patients during the initial consultation and subsequent follow-up periods.

Figure 2 shows the median (since an ordinal scale is being used) neurologic scores of the patients who followed-up during the four different evaluation periods.

Statistical Analysis

To test whether these observed improvements or recoveries were significant, the scores were subjected to statistical analysis, using the *Wilcoxon Matched-Paris Signed-Ranks Test.*[20] The scores obstained at one month, three months, six months and one year of follow-up were paired with the initial (pre-treatment) scores. Tables 1-3 summarizes the results of the analysis.

The neurologic scores of the patients who followed-up during each of the four evaluation periods were found to be significantly higher than their pre-treatment scores at $p = .005$.

DISCUSSION

This study has shown that significant neurologic recovery in Pott's disease can occur as early as one month with non-operative treatment, with recovery persisting for at least one year in those patients who were able to follow-up that long. Even in patients classified to have severe neurologic deficits or in those with cervical spine involvement, improvement can occur with non-operative treatment.

The causes of spinal cord involvement in Pott's disease may either be extrinsic, due to the pressure of the abscess, granulation tissue, sequestrated bone, or intrinsic, due to the involvement of the dura and meninges (pachymeningitis) and eventually the spinal cord (myelitis).[21]

It is for the above reason that some authors, particularly Hodgson, et al.,[6,9,10] advocate operative removal of the inflammatory debris (pus, necrotic bone, etc.) to adequately decompress the cord and prevent irreversible degenerative changes. Their presumption is that anti-tuberculous drugs cannot penetrate the abscess wall and cannot reach the avascular, necrotic tissue and hence cannot decompress the involved spinal cord.

However, several studies have proven that anti-tuberculous drugs given in normal doses can penetrate the walls of even thick-walled abscesses and may achieve bacteriostatic levels even in caseous tissue.[13] Furthermore, tuberculous lesions in the spine contain far fewer bacilli than are found in pulmonary disease, so it is less likely that drug-resistant bacilli will be present.[13,15] It is not therefore surprising that chemotherapy is effective in sterilizing spinal lesions.

Another reason why the proponents of the radical treatment favor operative treatment in Pott's disease is that debridement and anterior fusion of the spine results in a higher rate of healing, fewer recurrences and lesser spinal deformity.[10] However, in the Medical Research Council trial in Rhodesia,[16] wherein ambulatory treatment was compared with operative treatment (debridement with or without spinal fusion), the results were similar in the two groups at the end of five years. Hence, the long-term follow-up results show that operative treatment has no distinct advantage over ambulatory treatment, in terms of the above criteria.

It is thus clearly evident that non-operative treatment works in Pott's disease, even in those with spinal cord involvement. Konstam[5] has proven that even without operation, majority of his patients eventually recovered normal neurologic function. The same results were likewise obtained in this study.

The risk of paraplegia or the possible worsening of the neurologic condition of the patient who undergoes chemotherapeutic treatment only, is raised. This risk was recognized by the Medical Research Council so that paraplegic patients were excluded in their trials. This was not observed in our study, except in one patient, whose compliance is questionable. With the advent of more potent anti-tuberculous drugs, like rifampicin and pyrazinamide, the presumed risk of paraplegia has been lessened so a lot more physicians can become more confident in treating Pott's disease with neurologic involvement non-operatively.

The argument against non-operative treatment which may be the cause of a worsening neurologic status of the patient is the increase in the angle of kyphosis, sometimes associated with this type of treatment. This may result in an internal gibbus that could compress the cord and result in late-onset paraplegia.[21] However, in Konstam's study[5] and in the conservative trials of the Medical Research Council,[13-16] no correlation was found between the degree of angulation of the spine and the severity of the paraparesis or paraplegia. Kons-

tam[12] explains that those who developed late paraplegia may actually be having a reactivation of the disease.

What are the implications of these results? In the Philippine General Hospital, where the majority of Pott's disease patients, especially those with neurologic involvement, are treated surgically, a shift towards the non-operative form of treatment is a welcome change. Aside from being less expensive, there is the added advantage of avoiding the risks of anesthesia and surgery, and certainly lesser hospital beds and nurses are required. Patients who are able to walk can be managed on an ambulatory basis and only those with severe deficits need to be confined.

Conservative treatment is certainly an advantage in a developing country like the Philippines, which has limited financial resources. Serious diseases like tuberculosis of the spine, which run a long clinical course and require special skills in its management, create major problems for the nation's health care system. Consequently, non-operative treatment, which makes less demands on resources (like surgeons skilled in operating on the spine) and hospital beds, is highly favored in our setting. In the rural areas, where operating room facilities are lacking and hospital beds are sparse, the most practical method of treating spinal tuberculosis patients, including those with neurologic deficits, is non-operative. Even in tertiary health centers, like the Philippine General Hospital, non-operative treatment should be favored, due to the inherent risks of operating on the spine. Hodgson[6,9] himself warned that his operation is "one of magnitude and should not be undertaken lightly even where good surgical facilities exist."

There are several limitations to this study. First of all, the follow-up period was too short for most of the patients. Majority of the patients were lost to follow-up after one month so we could not determine whether those patients who recovered had persisted neurologic recovery after their last follow-up. It is possible that these patients remianed asymptomatic so they did not bother to follow-up anymore.

Secondly, the design of the study is not a controlled trial so whatever conclusions we arrive at in this study cannot be applied to all patients with Pott's disease with neurologic deficits.

Thirdly, the validity of the neurologic scoring method and classification used in this study may be put into question. Since the outcome of this study is to determine whether there is neurologic recovery or not, this recovery should be translated into measurable terms so that it could be properly analyzed. This is the reason why this classification and scoring method was conceived.

Finally, certain biases[22] have been recognized that may have been operative in this study, among which include the following. (1) popularity bias, referral filter bias and procedure selection bias in the selection of the study sample, (2) compliance bias in the exposure of the patients to the therapeutic intervention and (3) insensitive measure bias in measuring the outcome of the treatment. The first is unavoidable due to the fact that the Philippine General Hospital is a referral center for tertiary cases. The Department of Orthopedics, being part of a training institution for future spine surgeons, tends to favor operative treatment for Pott's disease cases. The second bias (compliance) cannot be fully ascertained due to the generally poor compliance rate to medications of Filipinos. However, in the presence of neurologic deficits, we presume that Pott's disease patients would be more compliant compared to their non-neurologically involved counterparts. The last bias is related to the validity of the neurologic scoring and classification used in this study. We might need to subject this measure to validity testing in future studies.

CONCLUSION

Patients in this study with neurologic involvement secondary to Pott's disease recovered normal neurologic function with non-operative treatment. Even patients classified to have severe neurologic deficits improved with non-operative treatment. Improvement as well as complete neurologic recovery occured as early as one month after initiation of treatment and, for those who followed-up after one year, the recovery of neurologic function persisted. It is concluded that non-operative treatment is effective for Pott's disease patients with neurologic deficits for this group of patients studied.

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